SCIENTIFIC
COMPENDIUM

Scientific Compendium ceram.x® one

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1 Introduction

DENTSPLY DeTrey develops advanced technologies for superior dental materials. A breakthrough was achieved by applying **nano-ceramic technology** to develop the universal nano-ceramic restorative **ceram.x one***.

ceram.x one 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 one** offers natural aesthetics achieved by a simplified procedure, superior handling characteristics and excellent durability.

ceram.x one is available in two distinct shading systems:

ceram.x one UNIVERSAL, the single translucency system, comprises seven shades of intermediate translucency comparable to conventional composites (e.g. Spectrum®), which is optimal for fast and simple, everyday restorations of posterior or anterior teeth.

ceram.x one DENTIN & ENAMEL, the dual translucency system, offers four dentin shades with translucencies similar to natural dentin and three enamel shades which mimic natural enamel. Their design has been optimised 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 to be 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.

* 'ceram.x one' is synonymously used as the brand name for all detailed information on the chemical, physical, and clinical properties of Ceram•X materials given in the following chapters.

2.1 Traditional Composites

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

- **Micro filled composites** comprise micro fillers with an average agglomerate size (d_{50}) of $\leq$ 0.4 µm. To increase filler load, micro filled composites also contain pre-polymerised micro filled resin (Figure 1).
- To further increase filler load and mechanical strength, hybrid composites comprise solid glass fillers instead of the pre-polymerised resin particles as well as the agglomerates from micro fillers. These glass fillers are of an average particle size (d_{50}) of about 1 – 10 µm (Figure 2).
- Recent developments have led to smaller sizes of the glass filler with an average particle size (d_{50}) of about 0.4 – 1 µm resulting in the **micro-hybrid composites** (Figure 3).

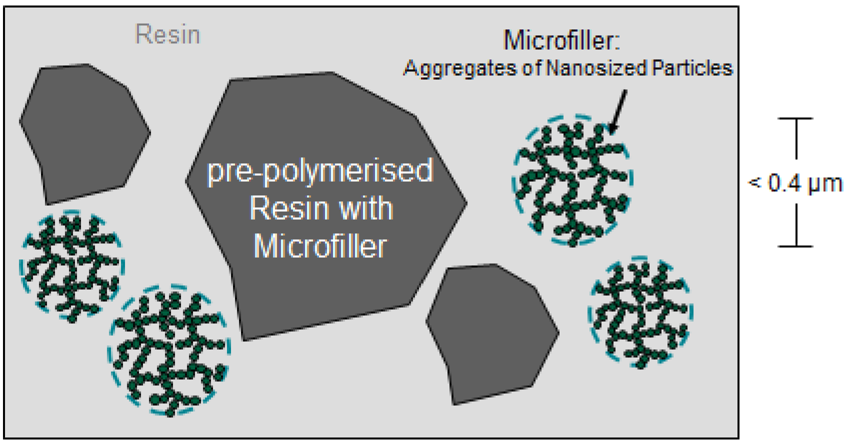


Figure 1 Schematic illustration of a micro filled composite

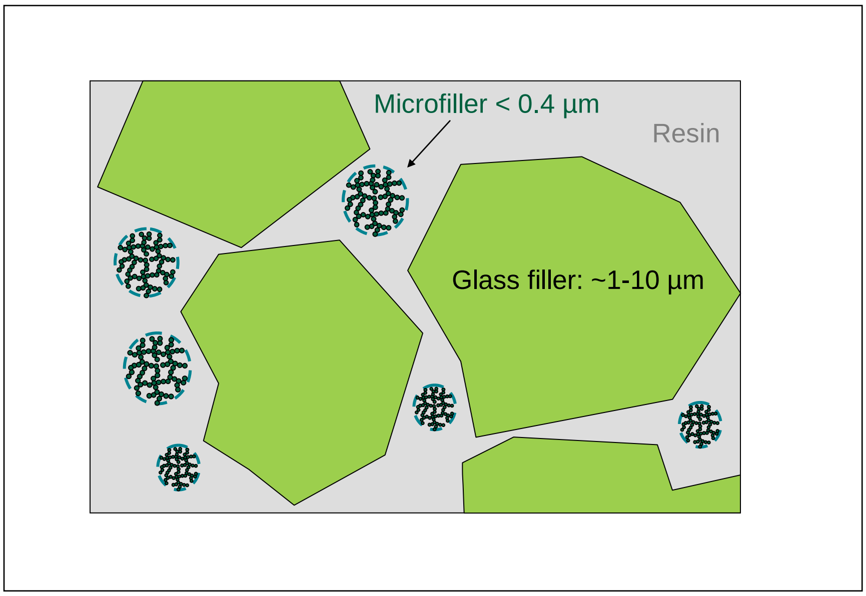


Figure 2 **Schematic illustration of a hybrid composite**

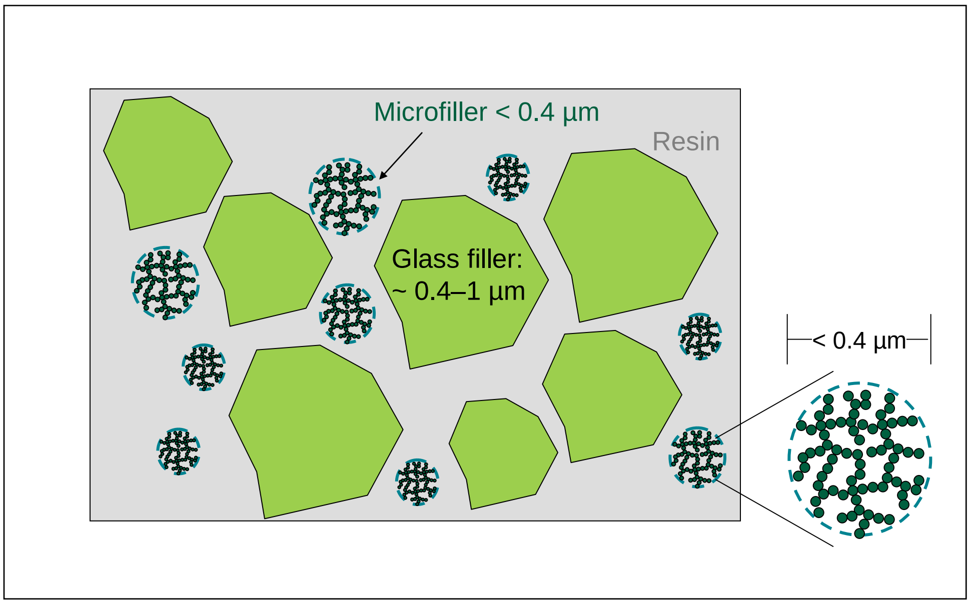


Figure 3 **Schematic illustration of a micro-hybrid composite**

In general, high filler loads increase mechanical strength and reduce polymerisation shrinkage. Larger filler particles facilitate high filler loads due to their smaller 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 thus partially off-set the desired effects.

Typically, primary particles sized ≤ 50 nm are not homogeneously dispersed but aggregate strongly to form large three-dimensional agglomerates of several 100 nm in a diameter up to ca. 0.4 µm (400 nm) (Figure 1).

The homogeneous dispersion and complete resin wetting of nano-sized filler particles is needed 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 Spectrum® bond which is reinforced with highly dispersed and non-aggregated nano-fillers.

Based on the long experience DENTSPLY gained in the field of nano-technology, ceram.x one comprises **organically modified ceramic** nano-particles and **nano-fillers** as used in Spectrum bond combined with **conventional glass fillers** of ~1 µm (Figure 4).

ceram.x one merges hybrid composite filler technology with advanced nano-technology. This results in **nano-ceramic technology**.

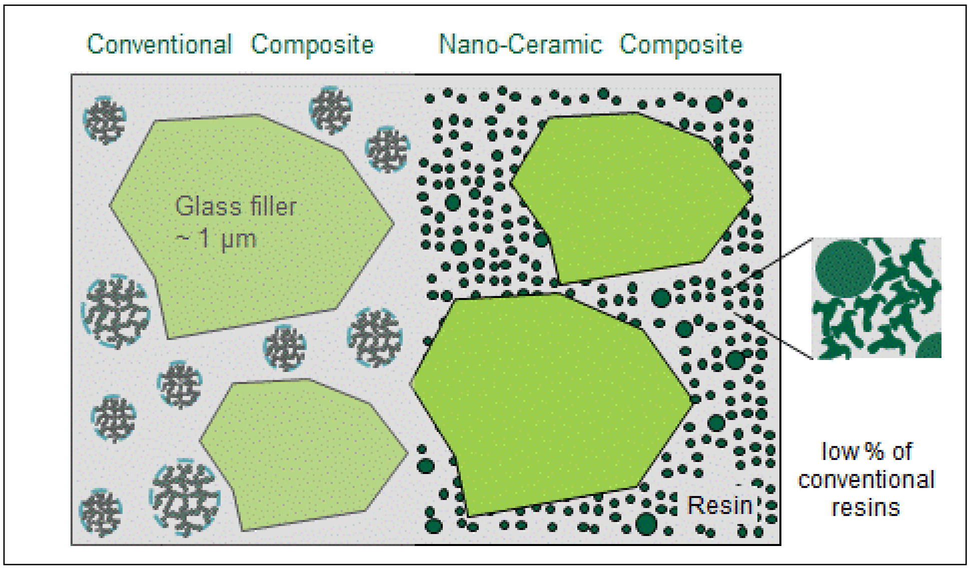


Figure 4 Schematic illustration of ceram.x one compared to conventional composite

The ceram.x one 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).

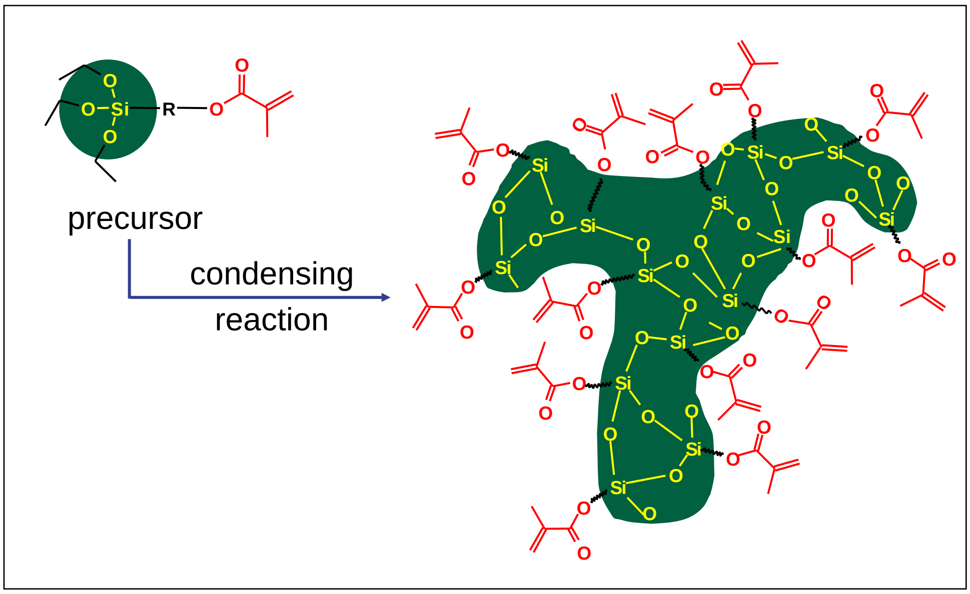


Figure 5 Processing of organically modified ceramic nano-particles

The numerous organic moieties of a nano-particle allow for polymerisation with the conventional resins of the formulation. It was therefore possible to reduce the proportion of the conventional resins to about 50%. Due to the reduced fraction of conventional resins and the high number of available double bonds per nano-particle, the monomer leakage is reduced compared to composites formulated with just conventional resins and glass fillers.

The organically modified ceramic nano-particles are made up of 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-analysis. Figure 6 shows that the backbone is highly condensed.

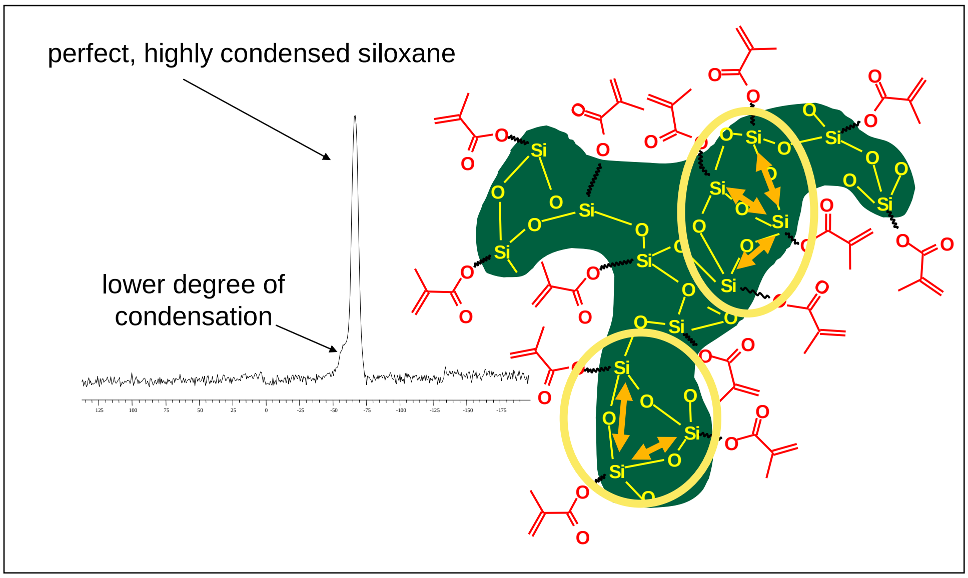


Figure 6 ^{29}**Si-NMR-analysis (Mayer, 2003)**

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 nano-fillers as used in Spectrum bond (Figure 7).

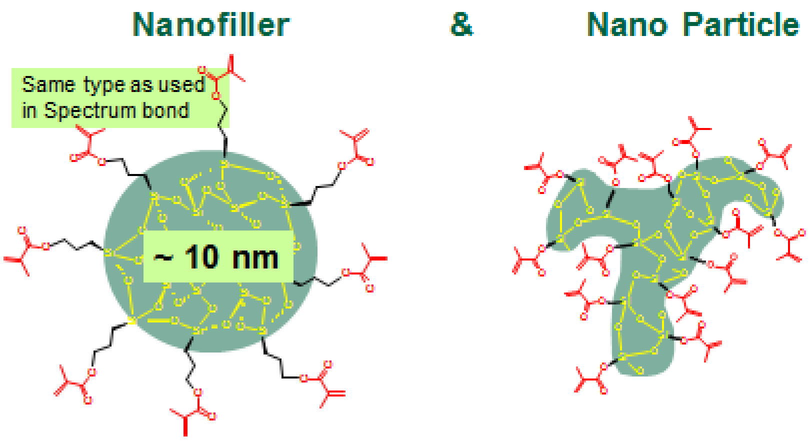
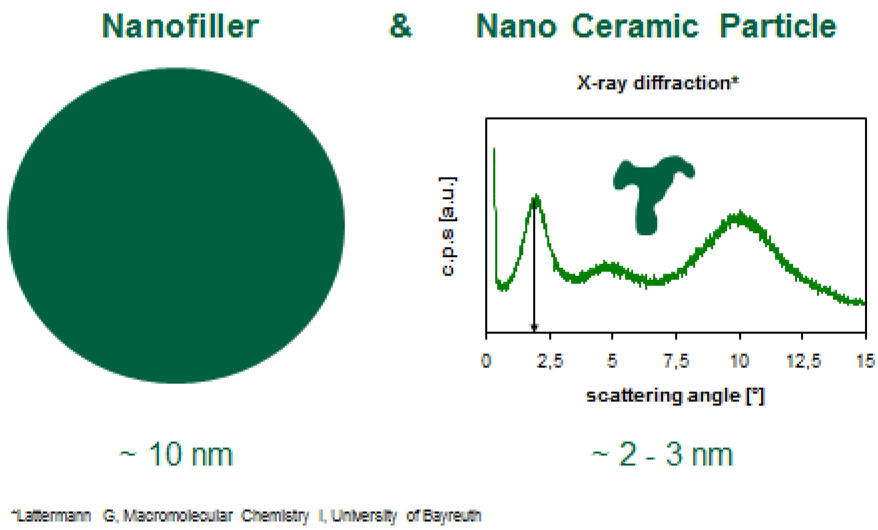


Figure 7 **Schematic structures of nano-ceramic particles and nano-fillers**

The size of the nano-ceramic particles was investigated by X-ray diffraction and was found to be ~2.3 nm (ure 8).



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

As well as being used in 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

The following chapters describe investigations performed to characterise ceram.x one in further detail and in comparison to other restoratives.

3.1 Mechanical strength

ceram.x one 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.

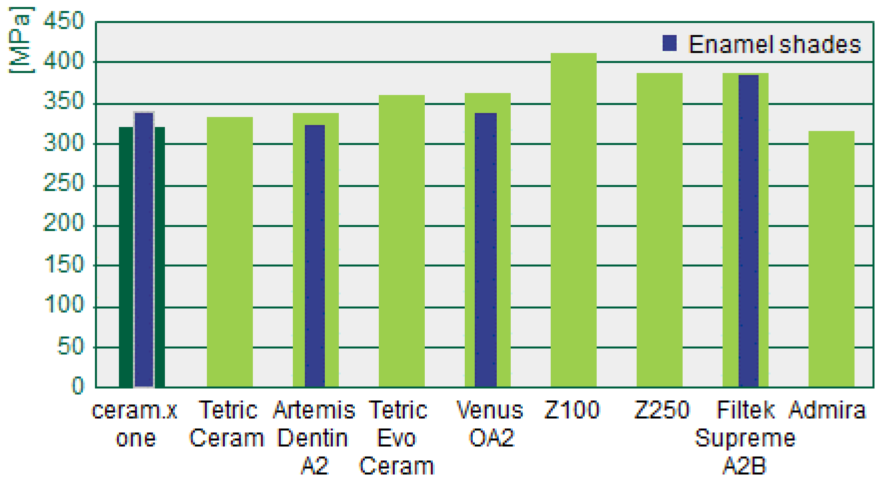


Figure 9 **Compressive Strength**

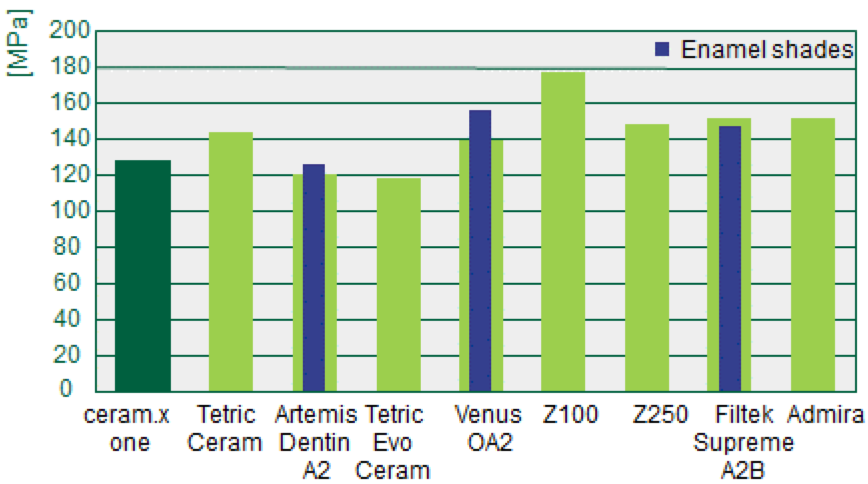


Figure 10 **Yield Strength**

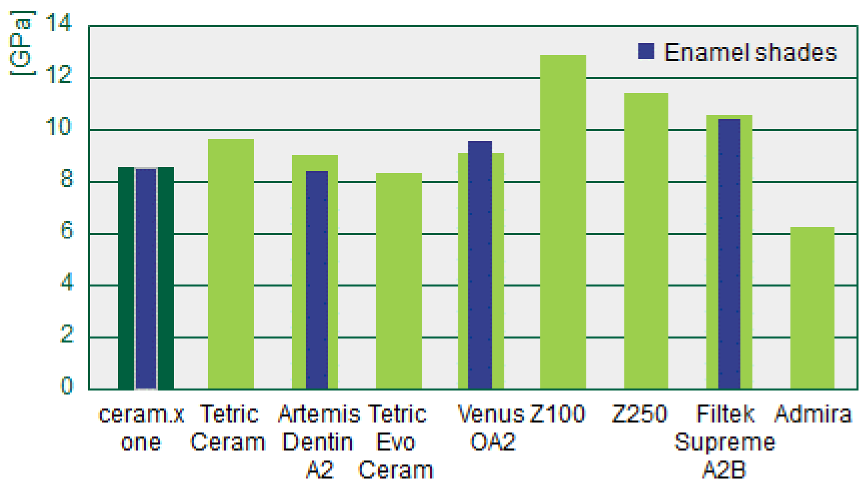


Figure 11 **Flexural Strength**

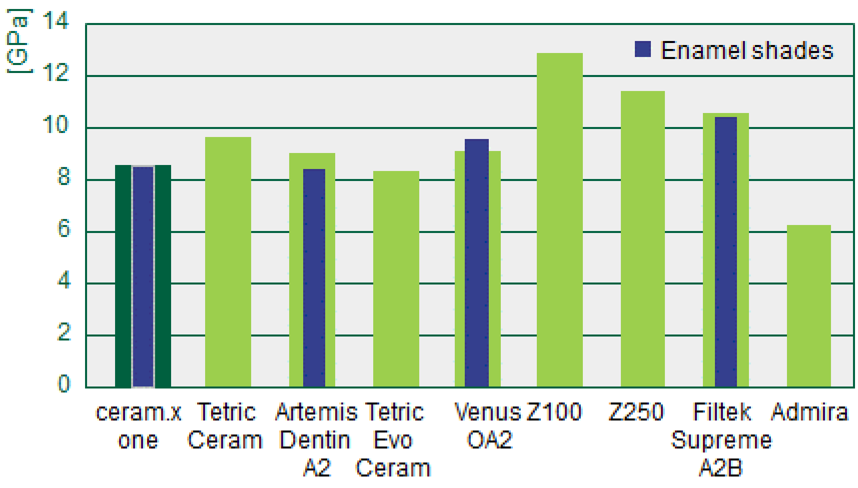


Figure 12 E-Modulus

3.1.1 Technical Data Sheet of ceram.x one versions currently available

The stipulated values represent typical findings.

Property	Unit	ISO 4049	ceram.x one		
			Universal	Dentin	Enamel
Compressive strength	MPa		350		
Flexural strength	MPa	> 80	110		
Flexural modulus	GPa		9		
Vickers hardness (VH5 / 30s)			60		
Filler[1] content (weight / volume)	%		Up to 77 wt% / up to 55 vol%		
Glass filler size (mean)	µm		1.2 – 1.6		
Shrinkage (Archimedes)	% (v/v)		2.3 [2]		
Expansion in water	% (v/v)		0.9		
Water sorption	µg/mm³	< 40	14		
Water solubility	µg/mm³	< 7.5	-0.6 [3]		
Curing time 2mm 500 mW/cm² 800 mW/cm²	s		 20	 40 30	 10
Sensitivity to ambient light (10,000 lx)	s	> 60 (8,000 lx)	125	125	170
Measured radiopacity	mm Al		2		

Table 1 Technical data sheet of ceram.x one versions currently available

Conclusions:

⇒ The mechanical properties of ceram.x one are within the range of modern restorative materials and make it suitable for direct restorations of all cavity classes

⇒ 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.

[1] Conventional and nano-filler; content varies ± 2% among the shades

[2] Internal method. 2.5 vol-% according to DIN 13907:2007

[3] Negative value due to very low solubility and remaining absorbed water

3.2 In-vitro simulations

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

3.2.1 Leinfelder Wear

The Leinfelder Wear machine allows simulation of 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 slurry of polymethylmethacrylate beads (PMMA) simulating localised wear.

Surfaces of the samples are 3D profiled before and after wear to allow determination of volume loss and maximum depth of the wear facets (Figure 13).

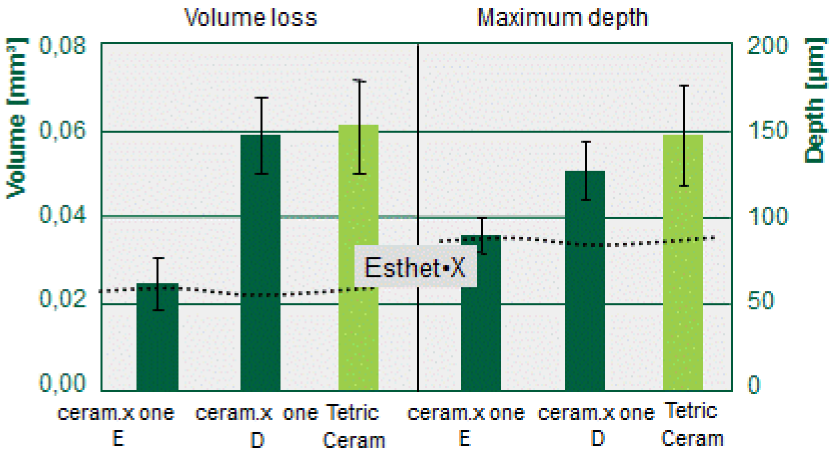


Figure 13 Leinfelder Wear: 400,000 cycles 1Hz, 80 N load, 30° rotation (Latta, 2003)

The results after a simulated wear period of ~3 years suggests that ceram.x one DENTIN (which is identical to ceram.x one UNIVERSAL aside from shading colours) compares well to the control material and that the tested ceram.x one ENAMEL shade wears significantly less compared to both and at the same level that is observed in the same test set-up performed on Esthet•X®.

Therefore it can be concluded that ceram.x one is suitable for all indications of a direct restorative in regard to wear.

3.2.2 Marginal integrity class V

Even though it depends mainly on the adhesive used, 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 fuchsine 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 using a diamond saw. Micro leakage was quantified separately for the occlusal and gingival walls of the class V cavities under an optical microscope. The extent of micro leakage (Figure 15) along the restoration was expressed in grades as listed in Table 2 and shown in Figure 14.

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

Table 2 Grading of dye penetration (Rosales, 2003)

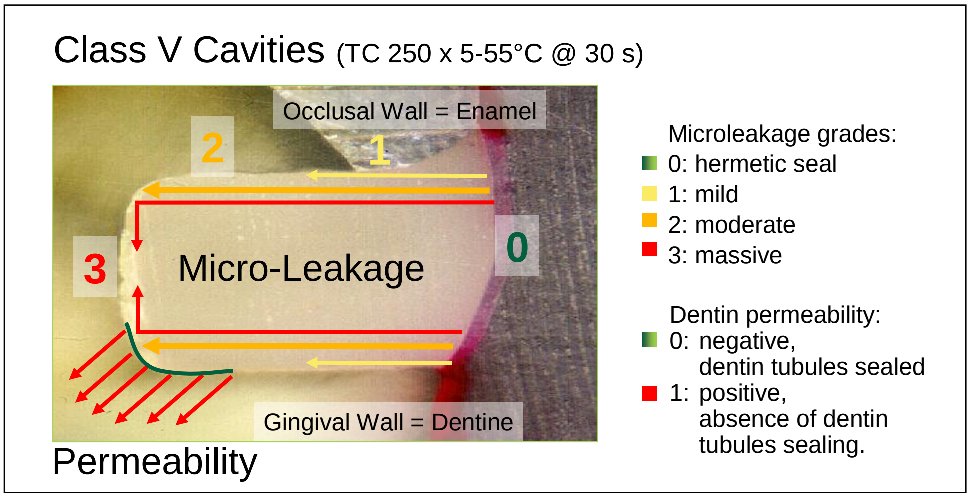


Figure 14 Legend for grades of micro leakage and dentin permeability (Rosales, 2003)

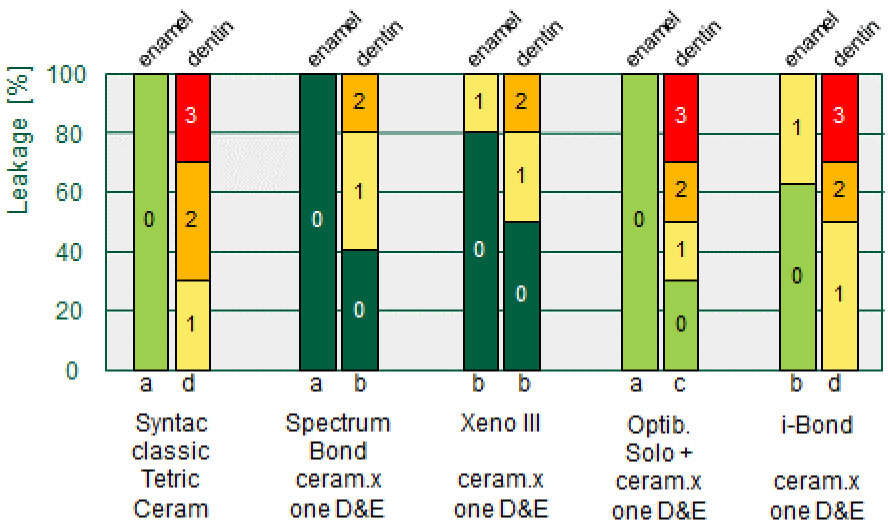


Figure 15 **Grades of micro leakage (0-3) and statistical grouping (a-d) (Rosales, 2003)**

Additional investigations with the latest restorative systems investigated the effect of prolonged thermo-cycling (TC) compared to 24 hour values.

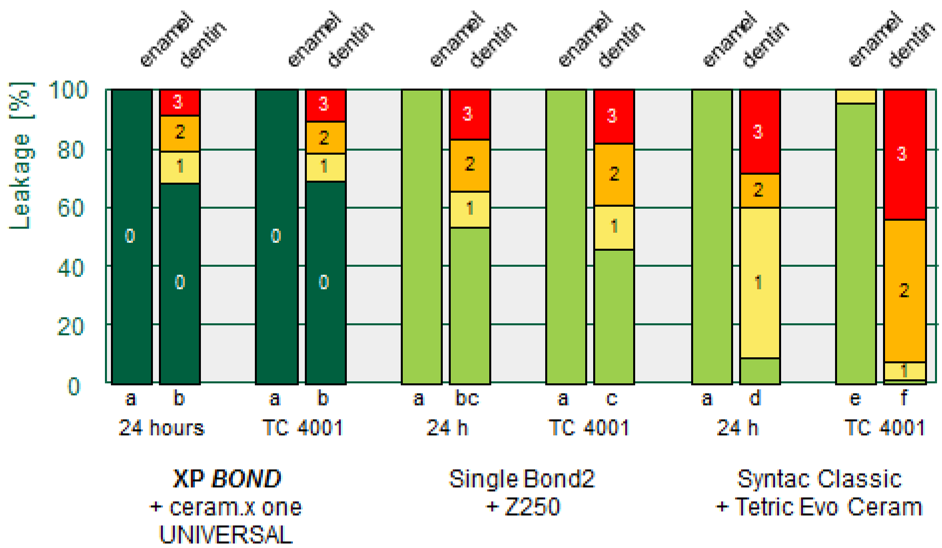


Figure 16 **Grades of micro leakage (0-3) and statistical grouping (a-f) (Rosales, 2005)**

Restorations with ceram.x one either in combination with the Etch&Rinse adhesives prime&bond one etch&rinse and Spectrum bond or the Self-Etch adhesive Xeno® III showed less marginal leakage overall compared to the control groups.

3.2.3 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 17.

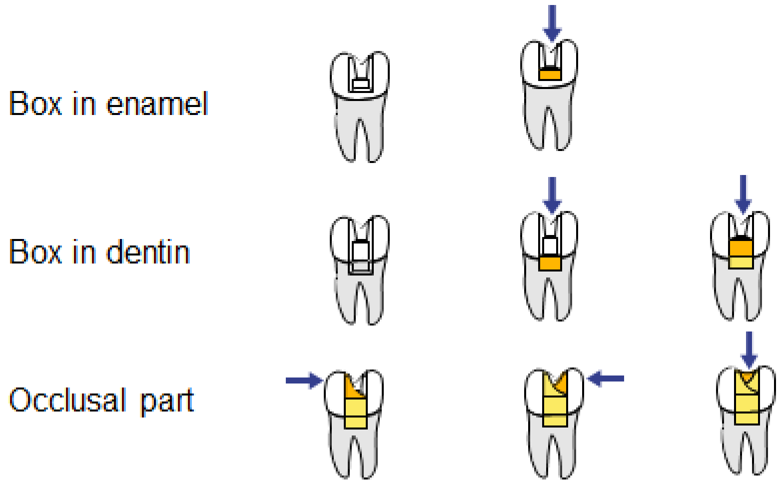


Figure 17 Incremental filling technique used for class II (Manhart, 1999)

After exerting stress the restorations with 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 with a magnification of 200x. Percentage of perfect margins, gap (>1µm), swelling, and sites that cannot be judged were recorded. Results of the present investigation and a former investigation under the same operator and the same experimental conditions are summarised in Figure 18.

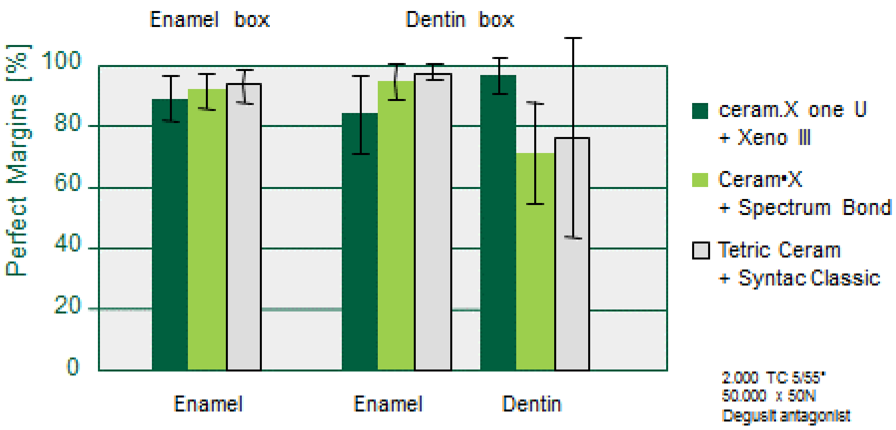


Figure 18 **Distribution of perfect margins after ageing in a chewing simulator (ceram.x one: Manhart, 2003; Tetric Ceram: Manhart, 2002)**

Micro leakage in class II restorations was tested under identical test conditions with following restorative systems: prime&bond one etch&rinse & ceram.x one UNIVERSAL (U), Syntac & Tetric EvoCeram (TEC), Single Bond2 & Z250 (SB1XT), and Optibond Solo Plus & ceram.x one UNIVERSAL (OBS+).

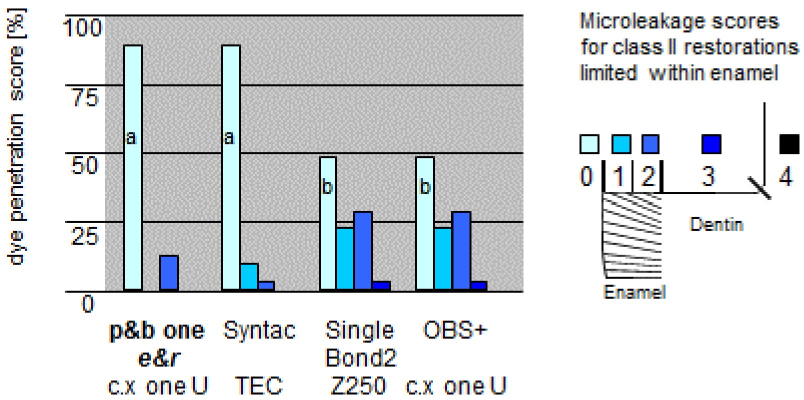


Figure 19 **Micro leakage scores in class II restorations enamel margins (Manhart 2005)**

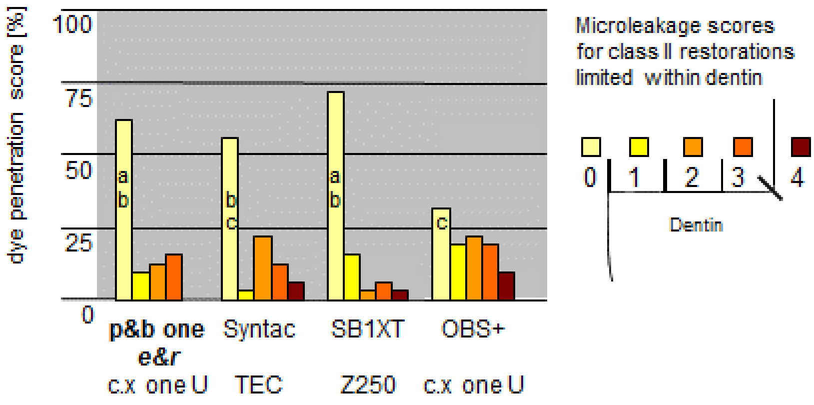


Figure 20 **Micro leakage scores in dentin margins of class II restorations (Manhart 2005)**

Conclusions

⇒ ceram.x one in combination with either prime&bond one etch&rinse, Spectrum bond or Xeno III offers marginal integrity similar to or better than the control groups

3.2.4 CEBL – Simulating re-cutting and re-bonding of composite

If different transparencies are used, the final aspect of aesthetic restorations depends, among other things, on correct layering. This is especially true at the beginning of the learning curve when using a new material and the correct thickness of layers may not be 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-Back, **E**tch, **B**ond, **L**ayer – suggests cutting back cured composite either on purpose or in cases where layering was too thick, to etch and apply a bonding before finally placing the next layer (Blank, 2003).

Results are shown in Figure 21 where the positive control has composite layering without any treatment in between the layers and the test group comprises grinding with 320 grit, etching using phosphoric acid for 15 seconds, applying Spectrum bond as the adhesive and finally placing the composite. For the negative control, composite was placed on the base but not otherwise treated composite.

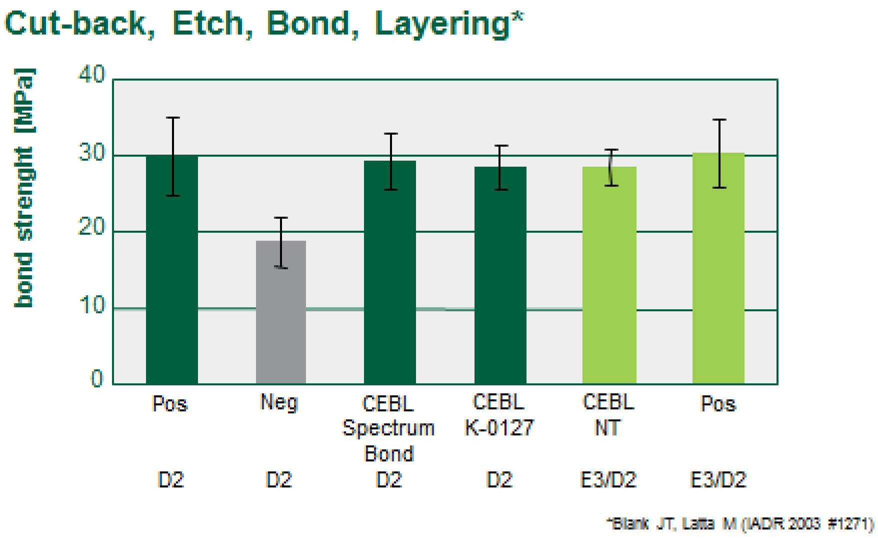


Figure 21 Bond Strength after CEBL technique (Latta, 2003)

Following identical protocols it was confirmed that prime&bond one etch&rinse also allows immediate re-bonding of ceram.x one.

Conclusions

⇒ The results suggest that immediate re-bonding of ceram.x one during the placement of a restoration does not adversely affect the bond strength between each layer.

3.3 Handling Properties

3.3.1 Working Time

ceram.x one comprises an innovative non-leachable proprietary inhibitor system (Figure 22). The working time is up to 180 sec (at 10,000 Lux) even in the case of highly translucent enamel shades. Results from measurements at 20,000 Lux simulating severe conditions being comparable to a modern operating light focused on the operating field are shown in Figure 24. This extended working time provides handling convenience. The non-leachable inhibitor molecule is polymerised into the network and does not leach out.

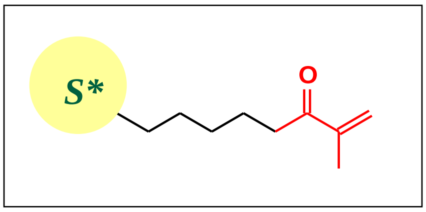


Figure 22 Schematic illustration of the new non-leachable inhibitor

The resulting working time for ceram.x one UNIVERSAL and ceram.x one DENTIN & ENAMEL is compared to a variety of restoratives in Figure 23.

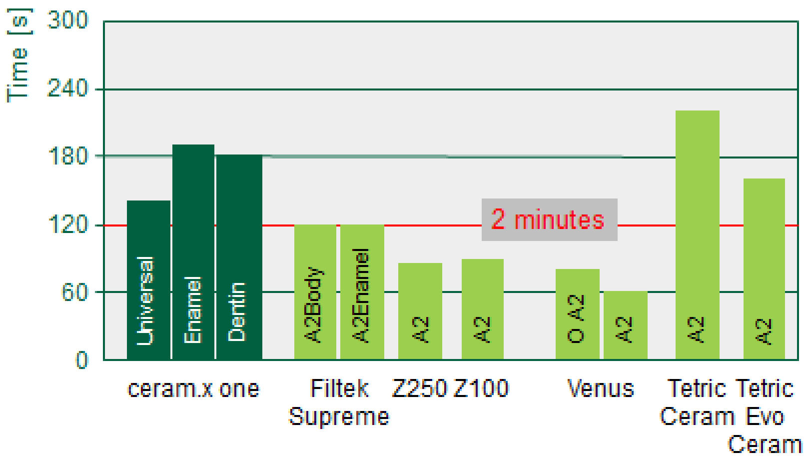


Figure 23 Working time of different restoratives and transparencies

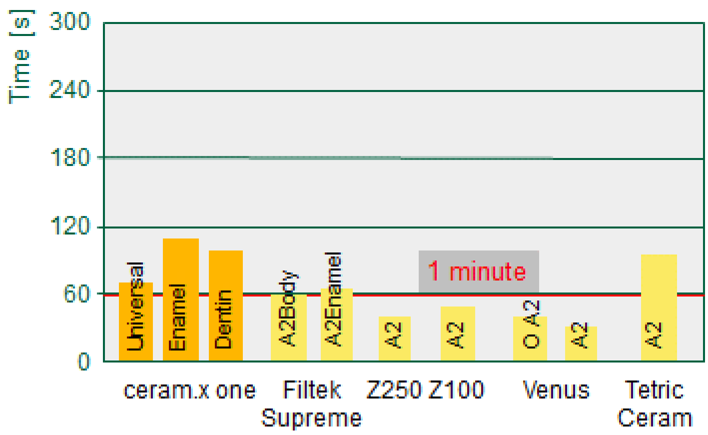


Figure 24 Working time at high light intensity (20,000 Lux)

Conclusions

⇒ ceram.x one provides more time for the practitioner to place and contour the material even under high ambient light compared to most other composites.

3.3.2 Stickiness

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

In this study a more recently published method (Al-Sharaa et al, 2003) was used to determine the stickiness of 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 then cured and measured for mean height (Figure 26) and surface area.

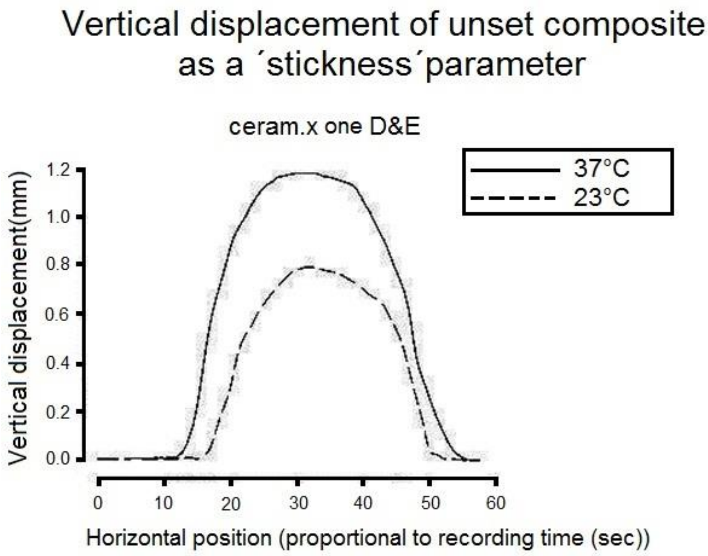


Figure 25 Plot to determine height of the resin pattern (Watts et al, 2003)

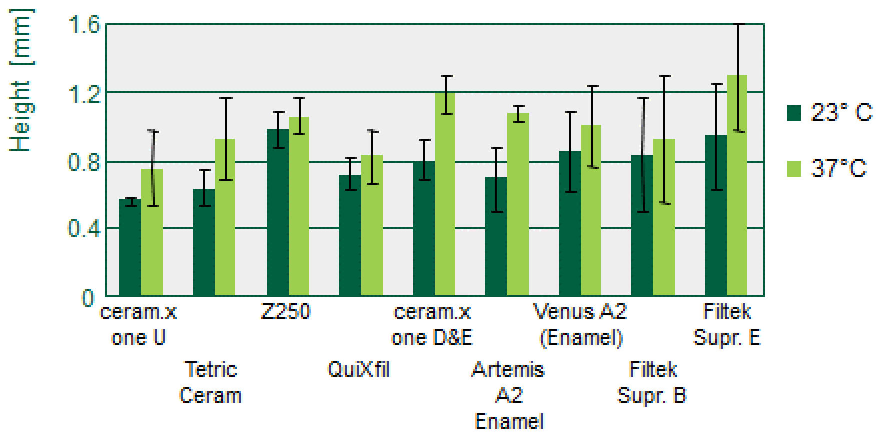


Figure 26 Stickiness to metal instruments (Watts et al, 2003)

Conclusions

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

3.4 Polishability

Superior aesthetic restorations are one of the most demanding indications for dentists. Besides matching the shade (also see chapter 4) and contour of the natural tooth, surface morphology of the final restoration is very important in achieving 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 are removed
Step 3	Fine disc 10 strokes	Prisma gloss regular 20 seconds
Step 4	Super fine disc 10 strokes	Prisma gloss extrafine 20 seconds

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

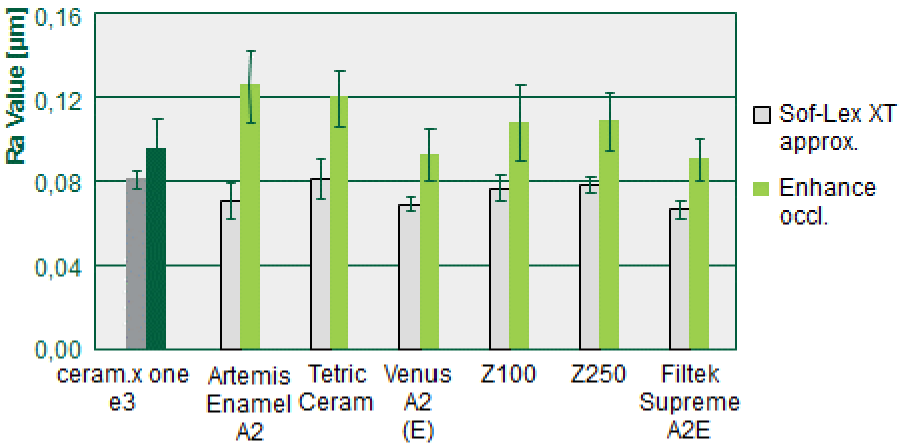


Figure 27 Surface roughness after simulated polishing procedures for approximal and occlusal surfaces (Salomon, 2003)

The influence of different one-step polishing systems on a variety of restorative materials was investigated by means of Ra values after polishing in the following study.

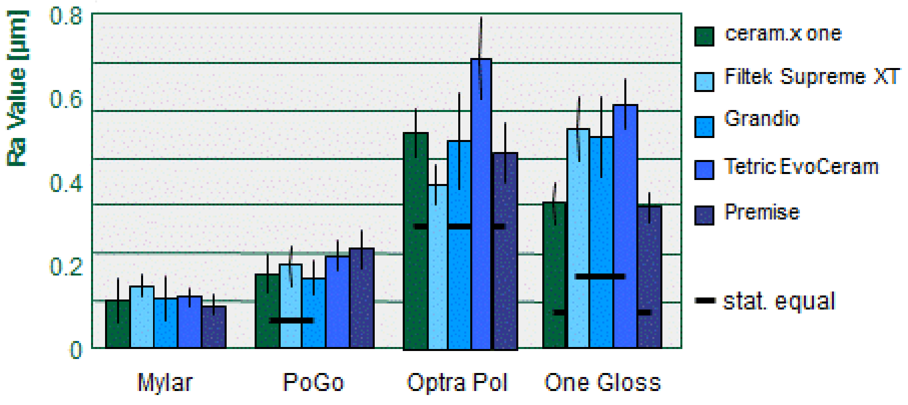


Figure 28 **Ra values of composites after polishing with different one-step polishing systems (Ergücü, 2007)**

Using PoGo resulted in significantly smooth surfaces on all composites.

ceram.x one provided smoother surfaces after polishing compared to Tetric EvoCeram with all three tested polishing systems. Overall, surface roughness was influenced by both the composite and polishing system.

Conclusions

⇒ Using the Enhance or PoGo Polishing system for ceram.x one results in very low surface roughness and high gloss.

3.5 Fluorescence

Figure 29 demonstrates that ceram.x one provides sufficient fluorescence whereas other restoratives show a lack of fluorescence. Non-fluorescent restorations exposed to black light will be prone to de-masking effects, indicating missing tooth substance.

Figure 29 Fluorescence in light of 254 nm wavelength

3.6 Radiopacity

As well as the measurement of radiopacity of ceram.x one (2 mm Al), a radiograph was taken to optically compare various restoratives (Figure 30).

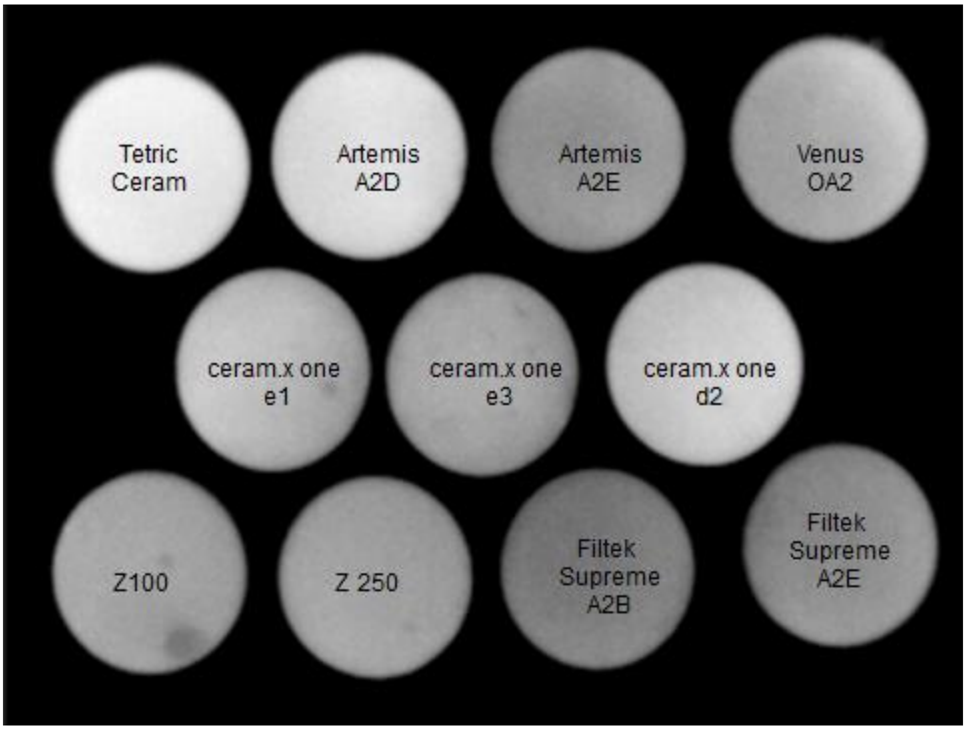


Figure 30 Radiograph of 2mm thick samples to compare radiopacity

Conclusions

⇒ ceram.x one offers a well-balanced radiopacity and can easily be detected on radiographs.

3.7 Optical Properties

ceram.x one is offered in two distinguished systems: ceram.x one UNIVERSAL as a universal single translucency system and ceram.x one DENTIN & ENAMEL as an easy to use dual translucency system to rebuild teeth naturally.

Only four dentin shades and three enamel shades of ceram.x one DENTIN & ENAMEL are sufficient to cover the whole VITA range. This is possible due to the precise tuning of chroma and opacity within these seven 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 31 opacity[4] of all ceram.x one DENTIN & ENAMEL shades are shown. The opacity of various materials that are referred to as VITA A2 is shown in Figure 32. ceram.x one UNIVERSAL falls well into the opacity of other materials available in only one translucency.

[4] Y-value black background / Y-value white background in percentage

On the other hand, it is noticeable that ceram.x one is the only double translucency system[5] from the products shown in Figure 32 that offers a difference in opacity between enamel and dentin shades which reflects the difference in opacity of human enamel to dentin.

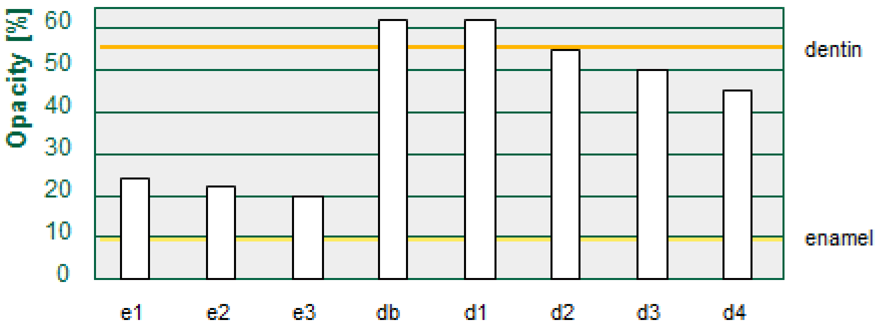


Figure 31 Opacity (Yb/Yw) of ceram.x one DENTIN & ENAMEL shades. Dentin and enamel values from Dietschi (2000)

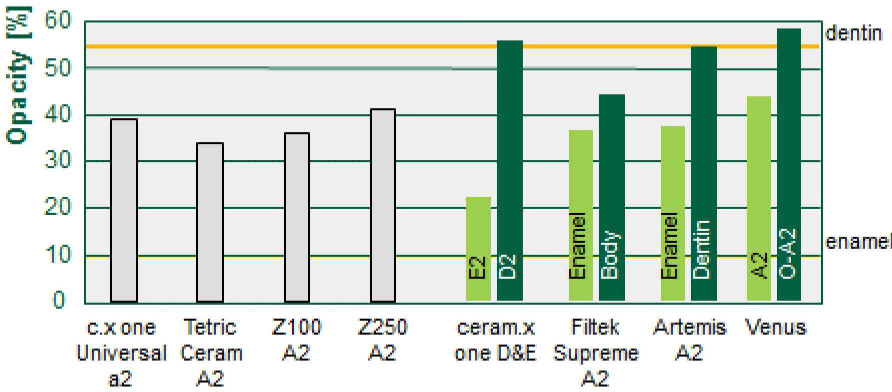


Figure 32 Opacity (Yb/Yw) of single and double translucency restorative materials. Dentin and enamel values from Dietschi (2000)

The Chroma[6] C* (which reflects the saturation of the colour) is shown in Figure 33. Note the even distribution among shades.

[5] In other systems three or more translucencies are necessary to cover this spread in opacity.

[6] $C^* = \sqrt{(a^{*2} + b^{*2})}$

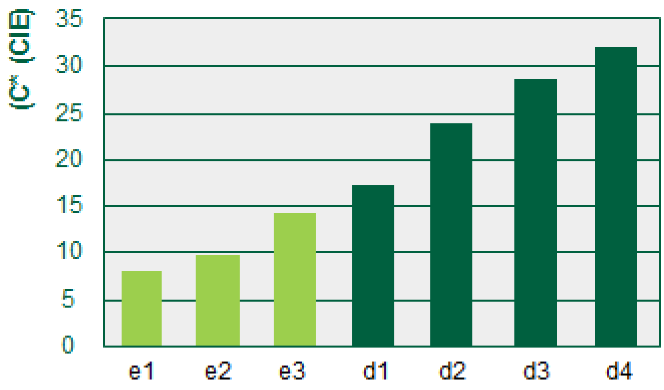


Figure 33 Chroma C* of ceram.x one

It can be seen that the ceram.x one DENTIN & ENAMEL system is systematically designed - which is reflected in the overall difference (ΔE) between the shades (Figure 34) and making it easier to learn and understand the shading concept during daily treatment in practice.

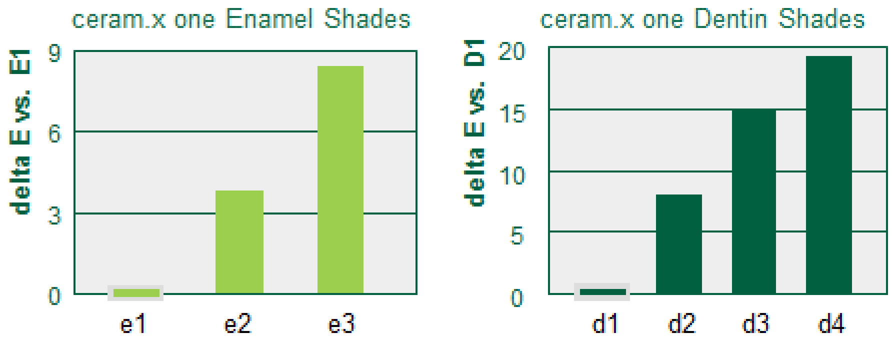


Figure 34 ΔE values for enamel and dentin shades

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 one DENTIN & ENAMEL system where shades with higher chroma have less value and opacity (Figure 35).

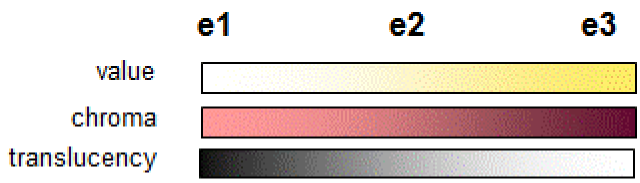


Figure 35 Schematic overview on properties influencing the final shade of a restoration

Conclusion

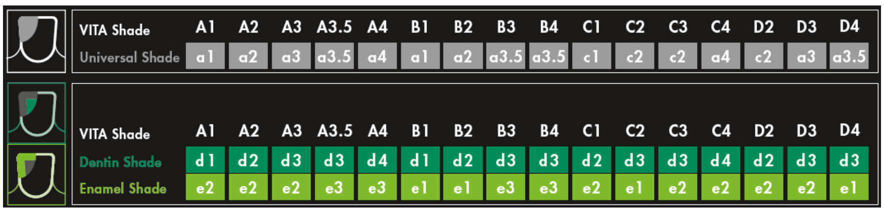
⇒ The shading concept of ceram.x one DENTIN & ENAMEL is systematically designed and reflects shade behaviour of natural dentition. Therefore, it supports the dentist in achieving aesthetical restorations.

4 The Shade System

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

With the **ceram.x one UNIVERSAL** shades a1, a2, a3, a3.5, a4, c1, and c2, ceram.x one comprises seven colours of intermediate translucency (similar to Spectrum® or Dyract® XP for example) for the complete restoration of the whole defect. The ceram.x one UNIVERSAL 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 one UNIVERSAL shades fits with several VITA shades similar in colour and lightness.

For aesthetically demanding cases, the **ceram.x one DENTIN & ENAMEL** system offers four dentin (d1 to d4) and three enamel colours (e1 to 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 one DENTIN & ENAMEL shades enable the dental professional to benefit from superior optical results. The packs come with a sticky recipe label (Figure 36), ideal for fixing onto the rear side of the VITA Shade guide, allowing the dentist to quickly refer to the specific ceram.x one shade (both UNIVERSAL and DENTIN & ENAMEL) relevant to a VITA shade.



VITA Shade	A1	A2	A3	A3.5	A4	B1	B2	B3	B4	C1	C2	C3	C4	D2	D3	D4
Universal Shade	a1	a2	a3	a3.5	a4	a1	a2	a3.5	a3.5	c1	c2	c2	a4	c2	a3	a3.5

VITA Shade	A1	A2	A3	A3.5	A4	B1	B2	B3	B4	C1	C2	C3	C4	D2	D3	D4
Dentin Shade	d1	d2	d3	d3	d4	d1	d2	d3	d3	d2	d3	d3	d4	d2	d3	d3
Enamel Shade	e2	e2	e2	e3	e3	e1	e1	e3	e3	e2	e1	e2	e2	e2	e2	e1

Figure 36 iShade label for VITA reference of ceram.x one UNIVERSAL and ceram.x one DENTIN & ENAMEL

The ceram.x one UNIVERSAL and ceram.x one DENTIN & ENAMEL systems are available separately.

5 Clinical Investigations and Handling Evaluations

In spite of the significance of in-vitro investigations, conducted both internally and externally, only clinical investigations provide final certainty concerning the efficacy of new restorative technologies. Therefore several clinical investigations on ceram.x one UNIVERSAL have been initiated in different cavity classes. Where indicated, the restorative materials have been applied in combination with an experimental formulation of prime&bond one etch&rinse, the tertiary-butanol based etch&rinse adhesive *(DENTSPLY development code: K-0127)*

5.1 4 Year Results in Class V, University of Bologna, Italy

Because adhesion still remains one of the potential weaknesses of restorative therapy, data on clinical success in class V cavities is essential. Professor Dr. G. Dondi dall'Orologio, Head of Department of Operative Dentistry at the University of Bologna, Italy, ran a longitudinal clinical investigation on the restoration of caries-free cervical lesions. 100 ceram.x one restorations have been established in 50 patients. 50 Esthet•X (DENTSPLY) restorations served as the control. The investigation was designed according to the revised guidelines of the American Dental Association (ADA) for dentin and enamel adhesive materials. Ryge criteria were applied. The 48 month results of the trial were made available and are shown in Table 4.

Criteria	ceram.x one / K-0127 [n]					Esthet•X / K-0127 [n]				
	∑	alpha	bravo	charl.	delta	∑	alpha	bravo	charl.	delta
Retention	88	86	-	-	2	44	43	-	-	1
Post-op. sensitivity (∑)	86	80	6	-	-	43	39	-	-	-
Marginal discolouration	86	80	6	-	-	43	39	-	-	-
Marginal integrity	86	80	6	-	-	43	39	-	-	-
Secondary caries	86	86	-	-	-	43	43	-	-	-
Restoration contour	86	80	6	-	-	43	39	-	-	-

Table 4 48 month results in class V (Dondi dall'Orologio, 2007)

In each group the success rate amounts to 97.7% after 4 years. The ADA Success criteria were fulfilled.

5.2 4 Year Results in Classes I / II, University of Freiburg, Germany

Being one of the major indications in restorative 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 was run at the Department of Operative Dentistry at the Albert-Ludwigs-University of Freiburg, Germany (Head: Professor Dr. E. Hellwig). Under the guidance of Main Investigator Priv.-Doz. Dr. P. Hahn, Associate Professor, 43 ceram.x one restorations and 43 controls (Tetric® Ceram/ Syntac® Classic) were placed in 43 patients. The investigation was designed according to the revised ADA guidelines for composite resin materials for posterior restorations. Ryge criteria were applied. The 48 month results on 27 patients are provided in Table 5.

Criteria	ceram.x one / K-0127 [%]					Tetric Ceram / Syntac Classic [%]				
	∑	alpha	bravo	charl.	delta	∑	alpha	bravo	charl.	delta
Retention	26	26	0	0	0	26	100	0	0	0
Post-op sensitivity	27	96.3	0	0	3.7	27	96.3	0	0	3.7
Marginal discolouration	26	80.8	19.2	0	0	26	84.6	15.4	0	0
Marginal integrity	26	88.5	11.5	0	0	26	88.5	11.5	0	0
Secondary caries	26	100	0	0	0	26	100	0	0	0
Anatomic form	26	84.6	11.5	3.8	0	26	88.5	11.5	0	0
Colour stability	26	92.3	7.7	0	0	26	92.3	7.7	0	0
Surface texture	26	100	0	0	0	26	100	0	0	0

Table 5 48 month results in class I and II (Schirrmeister, J., Hahn, P. et al, 2007)

Statistically significant differences between groups were not observed for any of the criteria. After nine months of clinical service, one ceram.x one restoration had to be removed for root canal treatment. In the same patient the Tetric Ceram restoration had to be removed before the 48 month recall. Thus, the overall success rates amount to 92.6% (ceram.x one) and 96.3 % (Tetric Ceram) after four years. The ADA Success criteria were fulfilled.

5.3 4 Year Results in Class II, University of Umeå, Sweden

Another longitudinal class I and II investigation was conducted at the Department of Operative Dentistry at the University of Umeå, Sweden, under the support of Professors Jan van Dijken and Ulla Pallesen. The investigation was designed according to the revised ADA guidelines for composite resin materials for posterior restorations. 165 ceram.x one restorations were placed in 78 patients, 92 in combination with a self-etch adhesive (Xeno III) and 73 in combination with an etch&rinse adhesive (Excite Recalls were performed at 3, 6 and 12 months, 2, 3 and 4 years.

Summary of results at <u>48 months</u> based on 162 restorations (91 Xeno III/ceram.x one and 71 Excite/ceram.x one)

General observations

The handling characteristics of the self-etching primer and the nano-filler resin composite restorative material were estimated as good and easy to adapt to.

Postoperative sensitivity was reported for six teeth between 1-3 weeks after baseline, three Xeno III/ceram.x one restorations during biting forces and three Excite/ceram.x one restorations during biting forces or cold stimuli.

4 year results

Eleven failed restorations (6.8%) were observed during the follow up, seven Xeno III/ceram.x one (7.7%; three premolar and four molar teeth) and four Excite/ceram.x one (5.6%; four molar teeth), resulting in non-significant different annual failure rates of 1.9% for the Xeno III group and 1.4% for the Excite group.

Reasons and year of failure for the Xeno III group were: fracture (1yr, 2yr, 3yr, 4yr, 4yr), cusp fracture (3yr), and caries (3yr). Reasons and year of failure for the Excite group were fracture (2yr, 3yr), caries and fracture (3yr) and endodontic reason (2yr).

Small chip fractures were observed in three restorations, which were treated by polishing.

A significant decrease in colour match was observed between baseline and four years. The colour changes observed were within the acceptable score range and no significant differences were seen between the bonding groups.

Slight marginal discoloration was observed in both groups in twenty percent of the restorations.

The surface characteristics of the nano-hybrid resin composite showed no clinical change from smooth characteristics at baseline to the four year smooth characteristics observed.

In the overall intra-individual comparisons between the etch & rinse and the self etching technique, no significant differences were observed at the recalls.

Frequencies of the scores for the evaluated variables:

1. **Anatomical form:**
   Xeno III / ceram.x one: 85.6% A, 8.9% B, 5.5% C
   Excite / ceram.x one: 90.0% A, 5.7% B, 4.3% C
2. **Marginal integrity:**
   Xeno III / ceram.x one: 93.4% A, 1.1% B, 2.2% C, 3.3% D
   Excite / ceram.x one: 94.3% A, 2.9% B, 1.4% C, 1.4% D
3. **Colour match:**
   Xeno III / ceram.x one: 84.9% A, 15.1% B
   Excite / ceram.x one: 91.0% A, 9.0% B
4. **Marginal discolouration:**
   Xeno III / ceram.x one: 80.3% A, 19.7% B
   Excite / ceram.x one: 79.1% A, 20.9% B
5. **Surface roughness:**
   Xeno III / ceram.x one: 100% A
   Excite / ceram.x one: 100% A
6. **Secondary caries:**
   1 Xeno III and 2 Excite restorations showed secondary caries.

Conclusion by the Investigator at 4 years

"The nano-hybrid resin composite restorations evaluated showed, also taking into account of their rather extensive sizes, a good clinical performance with a 1.7% annual failure frequency during the four year follow up. The main reason for failure was partial material fracture. The restorations placed with the one-step self-etching adhesive system showed comparable good clinical effectiveness compared to the ones placed with the etch & rinse adhesive system."

Criteria	Alpha ratings at 4 year recall	
	Xeno III DENTSPLY	Excite Vivadent
Marginal discolouration	80.3%	79.1%
Marginal integrity	93.4%	94.3%
Secondary caries	98.1% (91 / 92)	97.2% (70 / 72)
Annual failure rate	1.9%	1.4%

Table 6 Results after four years in class II (Dijken JV)

Summary by the sponsor on the performance of ceram.x one based on the reports up to 48 months after placement

Over the four year observation period of this University of Umea clinical study, occlusal stress bearing posterior ceram.x one restorations showed a very good clinical performance in combination with both conventional etch & rise adhesives and the self-etching adhesive Xeno III. The main investigator of the study, Professor Jan van Dijken especially recognised the excellent gloss retention of the restorative.

Conclusion

⇒ Based on the results of the clinical studies, it can be concluded that ceram.x one nano-ceramic restorative is safe and efficient when used for its intended purposes.

5.4 Handling Evaluation

Handling properties of ceram.x one were rated by 21 dental practitioners. Stickiness, consistency, sculptability, polishability, marginal adaptability and processing time were rated in comparison to the standard restorative product currently used in the respective practices. For all those criteria, a clear majority of practitioners rated ceram.x one equal or better than the standard. The results are provided in Figure 37. The overall rating of handling properties is shown in Figure 38.

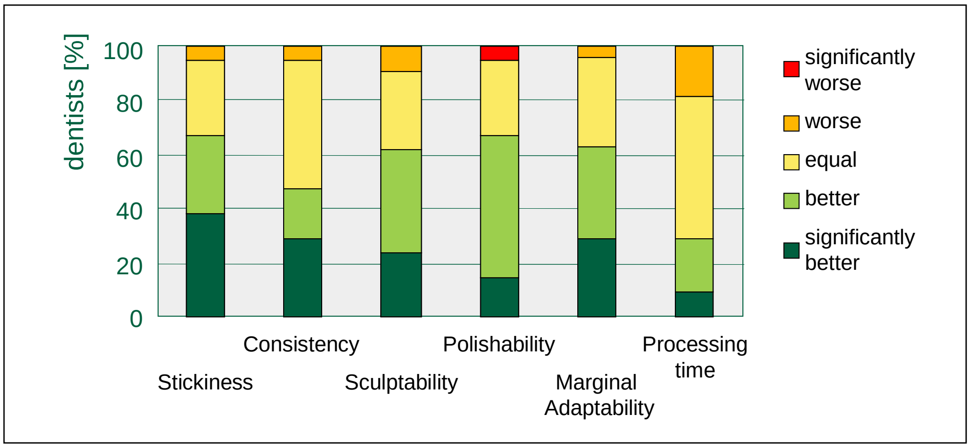


Figure 37 Rating of ceram.x one handling properties compared to standard restorative product

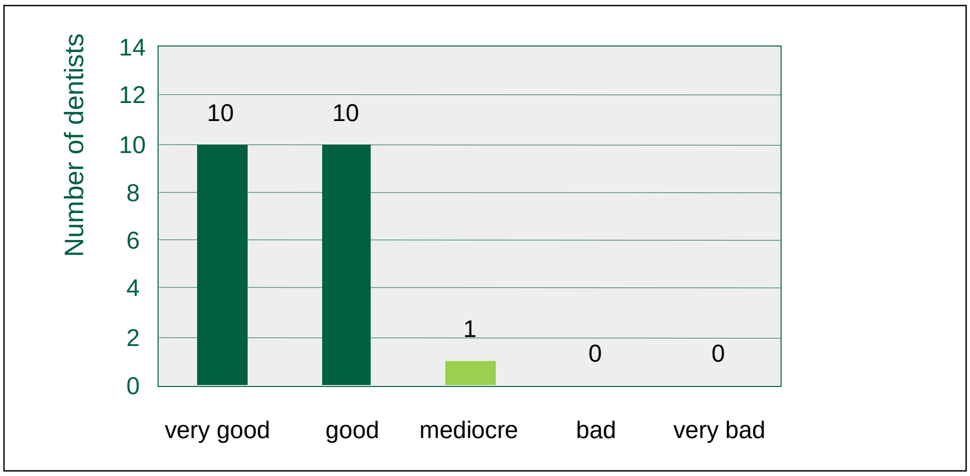


Figure 38 Overall rating of handling properties

In the same context as 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. In the results, ceram.x one was rated equal or superior to the reference materials Z100 and Tetric Ceram.

Conclusion

⇒ From both handling evaluations it can be concluded that the material demonstrates very good handling properties. Ceram.x one convinced the practitioners working with the material.

6 Instructions for Use

The up-to-date version can be found in all European languages on www.dentsply.eu.

7 References

Al-Sharaa KA, Watts DC (2003) Stickiness prior to setting of some light cured resin-composites. Dental Materials 19, 182-187

Blank JT, Latta M (2003). Bond Strength of Composite to Composite Simulating clinical layering. Dent Res 82 (Spec Iss B) #1271.

Craig RG (Ed.) (1997). Restorative dental materials 10, Mosby Publishing Co, St. Louis, MO.

Dietschi D (2000). Exploring the layering concepts for anterior teeth. In: Roulet JF, Degrange M (Editors). Adhesion. The silent revolution in dentistry. 235-251 (Quintessence)

Dondi dall'Orologio G (2007). Report to DENTSPLY DeTrey GmbH.

Ergücü Z, Türkün LS (2007). Surface roughness of novel resin composites polished by one-step systems. Operative Dentistry, 32, 185-192.

Hahn P (2003). Report to DENTSPLY DeTrey GmbH.

Lattermann G (2003). Report to DENTSPLY DeTrey GmbH.

Latta M (2003). Report to DENTSPLY DeTrey GmbH.

Manhart J, Hollwich B, Mehl A, Kunzelmann K-H, Hickel R (1999). Randqualität von Ormocer- und Kompositfüllungen in Klasse-II-Kavitäten nach künstlicher Alterung. Dtsch Zahnärztl Z; 54:89-95

Manhart J (2002). Report to DENTSPLY DeTrey GmbH.

Manhart J (2003). Report to DENTSPLY DeTrey GmbH.

Manhart J (2005). Final Report 14.1105. Data on file.

Mayer HA (2003). Report to DENTSPLY DeTrey GmbH.

Rosales JI (2003). Report to DENTSPLY DeTrey GmbH.

Rosales J (2005). Final Report 14.1101. Data on file.

Salomon JP (2003). Report to DENTSPLY DeTrey GmbH.

Schaller HG (2003). Report to DENTSPLY DeTrey GmbH.

Watts DC (2003). Report to DENTSPLY DeTrey GmbH.

8 List of Figures and Tables

Figures

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