VITA ENAMIC®

Technical and scientific documentation

VITA shade determination | VITA shade communication | VITA shade reproduction | VITA shade control

Date of issue: 02.19

VITA – perfect match.

VITA

1. Introduction

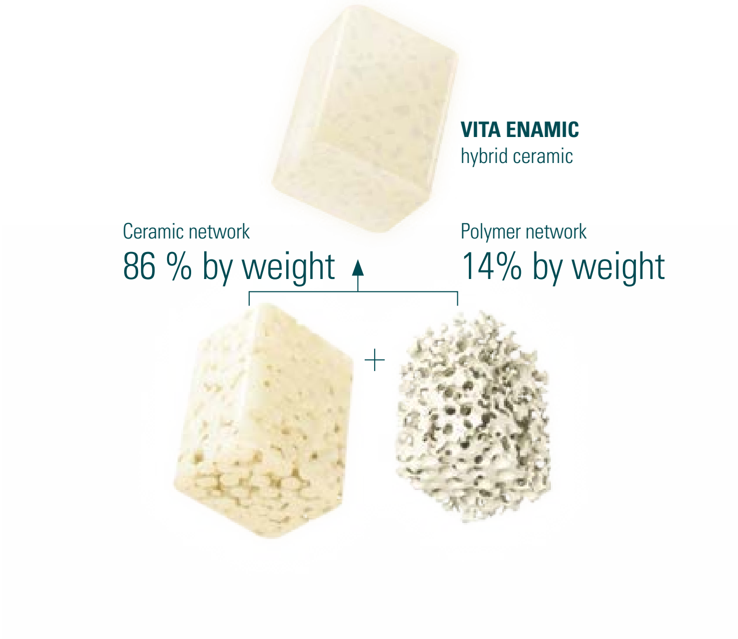
The hybrid material presented here represents a milestone in the development of CAD/CAM materials. This newly-developed hybrid material combines the positive characteristics of proven all-ceramic materials with those of the composite materials used with CAD/CAM technology.

The hybrid ceramic is comprised of a structure-sintered ceramic matrix and a reinforcing polymer network, which are fully integrated with one another. The inorganic ceramic content is 86 wt%, while the organic polymer content is 14 wt%. The combination of both of these materials provides considerable benefits for the user. For example, the tendency to brittle fracture is lower than in comparison with pure ceramics, and excellent CAD/CAM processing is also achieved.

VITA ENAMIC can be used for definitive single-tooth restorations.
The restorations are fabricated using CAD/CAM technology.

1.1 VITA ENAMIC - material composition

The hybrid material is manufactured by first infiltrating a porous ceramic base structure with a monomer mixture and then curing (polymerization) is carried out. The composition of the ceramic corresponds to that of a fine-structure feldspar ceramic enriched with aluminum oxide.

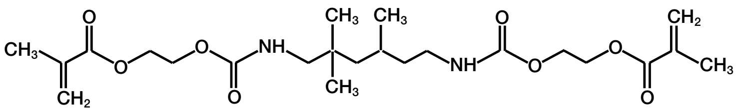


Composition of the ceramic network (86 wt% / 75 vol%)

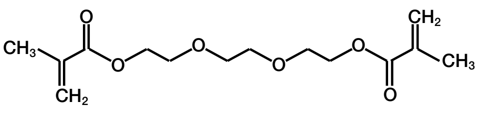
Silicon dioxide	SiO_2	58 – 63 %
Aluminum oxide	Al_2O_3	20 – 23 %
Sodium oxide	Na_2O	9 – 11 %
Potassium oxide	K_2O	4 – 6 %
Boron trioxide	B_2O_3	0,5 – 2 %
Zirconia	ZrO_2	< 1 %
Calcium oxide	CaO	< 1 %

Composition of the polymer network (14 wt% / 25 vol%)

UDMA (urethane dimethacrylate)

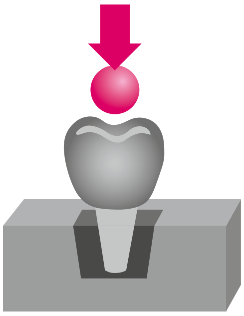


TEGDMA (triethylene glycol dimethacrylate)



1.2 Summary of the physical/mechanical properties

	VITA ENAMIC	Standard value
Static fracture load [N] (SD)	2,766 (98)	None specified
Density [g/cm³]	2.1	None specified
Flexural strength [MPa]	150 – 160	ISO 10477: ≥ 50 ISO 6872: ≥ 100
Modulus of elasticity [GPa] (SD)	30 (2)	None specified
Abrasion [µm]	In the same range as Mark II, veneering ceramics	None specified
Extension in the case of fracture [%] (SD)	0.5 (0.05)	None specified
Weibull modulus	20	None specified
Hardness [GPa]	2.5	None specified
Fracture toughness [MPa√m]	1.5	None specified
Adhesion with veneering material [MPa]	Without silane: 12 With silane: 27	ISO 10477: ≥ 5
Shear strength, cementation [MPa]	RelyX Unicem: 21, Variolink II: approx. 27, RelyX Ultimate approx. 31	None specified
Shade stability	Excellent, ΔE < 2	None specified
Machinability, edge stability	Excellent	None specified
Milling times, normal milling mode Sirona MC XL	Inlay: 7:56 min Anterior crown: 7:10 Posterior crown: 9:07 min	None specified
Milling times, fast milling mode Sirona MC XL	Inlay: 4:40 min Anterior crown: 4:19 Posterior crown: 5:13 min	None specified
Milling tool life, posterior crowns Sirona MC XL	Normal: 148 Fast: 132	None specified
Biocompatibility	Confirmed	ISO 10993
Chemical solubility [µg/cm²]	0.0	ISO 6872: ≤ 100
Water absorption [µg/mm³]	5.7	ISO 10477: ≤ 40
Solubility in water [µg/mm³]	≤ 1.2	ISO 10477: ≤ 7.5



2. Physical/mechanical properties (in vitro)

2.1 Fracture load

2.1.1 Static fracture load: crowns

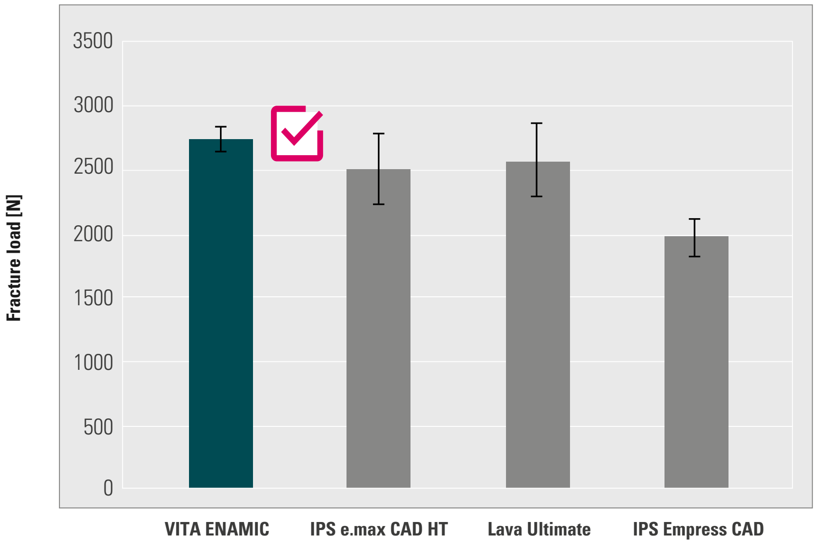
a) Materials and method

In this study, standardized, prefabricated and filled resin dies were prepared with a convergence angle of 5° and a 90 °shoulder with a width of 1 mm. The axio-occlusal and axio-gingival angles were rounded down. VITA ENAMIC, IPS e.maxCAD, Lava Ultimate and IPS Empress CAD were used to fabricate crowns with a uniform, biogeneric and fully anatomical crown geometry in Sirona's MC XL system and Multilink Automix (Ivoclar Vivadent) was used for bonding the crowns. The bonded crowns were immersed in water at room temperature for 24 hours prior to the static fracture load tests. A tin foil was used to transfer the static load with a steel ball (diameter: 4.5 mm) to the central fossa of the crown. The load that led to failure of the crown was recorded for all samples. ANOVA and Tukey tests were carried out for statistical evaluation.

b) Source

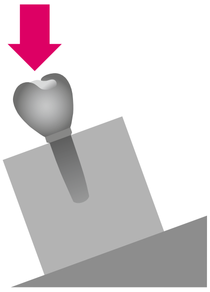
Boston University, Goldman School of Dental Medicine, Department of Restorative Dentistry/Biomaterials, Prof. Russell Giordano, report 07/13 ([1], see p. 34)

c) Result



d) Conclusion

In this test, the average static fracture load of VITA ENAMIC is 2,766 N (± 98 N), which is the highest average fracture load of the materials tested. Compared to the other materials in this test, VITA ENAMIC had the lowest standard deviation.



2.1.2 Static fracture load of implant crowns made of VITA EMAMIC IS

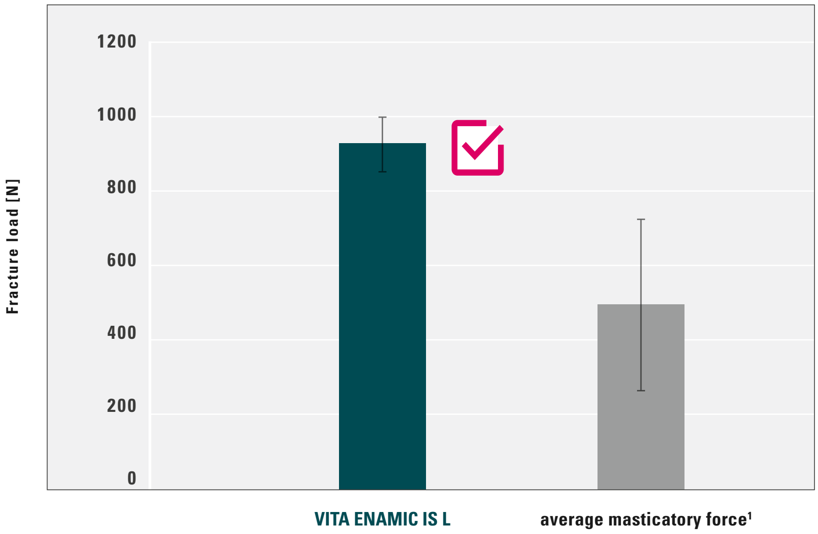
a) Materials and method

Static fracture load tests on TiBase adhesive bases (Sirona, Wals, Austria) were carried out with crowns made of VITA ENAMIC IS (IS = IMPLANT SOLUTIONS). Blanks with L-interface were used for CAM fabrication of molar crowns using SIRONA's MC XL system. The TiBase was processed in accordance with the manufacturer's instructions, conditioned and bonded to the crowns.
The implants (Bone Level Implant; Ø 4.1 mm RC, SLA 12 mm; Institut Straumann AG, Basel, Switzerland) were embedded in epoxy resin molds. The modulus of elasticity of the resin was 11 GPa (similar to the modulus of elasticity of natural cancellous bone. After the crowns were screwed to the implants, the screw channels were sealed using filling composite (Clearfil Majesty Flow; Kuraray, Tokio, Japan).
Five restoration samples ("as machined," i.e., unpolished) were exposed to static load at an inclination of 20° in a universal testing machine (Zwick Z010, Ulm, Germany) at a rate of 0.5 mm/min until fracturing occurred.

b) Source

Internal study, VITA R&D, report 10/14 ([3], see p. 34)

c) Result

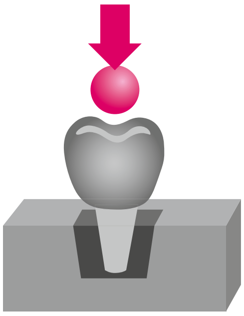


d) Conclusion

Implant-supported molar crowns made of VITA ENAMIC IS on L-TiBase adhesive bases and Straumann Bone Level implant system withstood an average load of approx. 926 N in this test. Compared to the average maximum masticatory force of approx. 490 N and maximum values of 725 N[1], the molar crowns tested reached a higher level of load capacity.

Sources:
(1) Körber K, Ludwig K (1983). Maximale Kaukraft als Berechnungsfaktor zahntechnischer Konstruktionen. Dent-Labor XXXI, Issue 1/83: 55 – 60.

2.1.3 Fracture load after dynamic loading



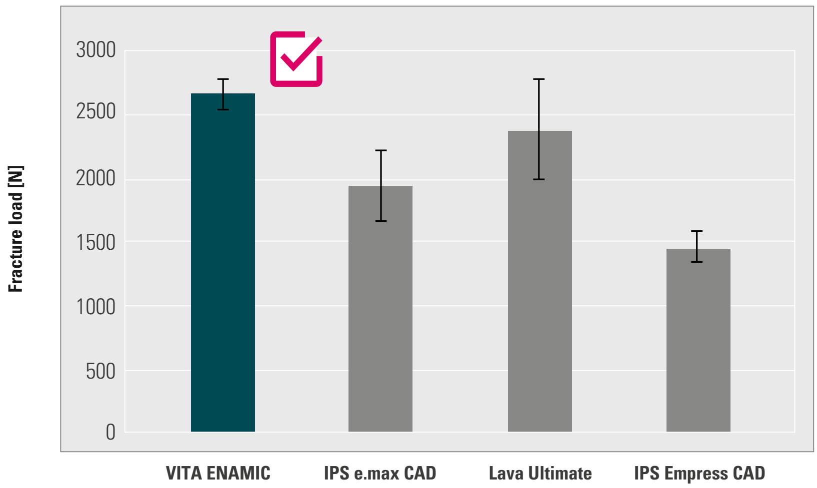
a) Materials and method

In this study, standardized, prefabricated and filled resin dies were prepared with a convergence angle of 5° and a 90 °shoulder with a width of 1 mm. The axio-occlusal and axio-gingival angles were rounded. VITA ENAMIC, IPS e.maxCAD, Lava Ultimate and IPS Empress CAD were used to fabricate crowns with a uniform, biogeneric and fully anatomical crown geometry in Sirona's MC XL system and Multilink Automix (Ivoclar Vivadent) was used for bonding the crowns. The bonded crowns were immersed in water at room temperature for 24 hours prior to the dynamic load tests. The samples that were immersed in water were subjected to cyclic loads in a specially designed continuous loading machine (pneumatic). The load was transferred to the occlusal surface (three-point contact) using a hardened steel ball (diameter: 4.5 mm) that rested on a tin foil. Initially, the samples were subjected to dynamic loading in 150,000 cycles and a maximum load of 450 N and a minimum load of 0 N at room temperature, and then subjected to static loading until fracturing occurred. ANOVA and Tukey tests were carried out for statistical evaluation.

b) Source

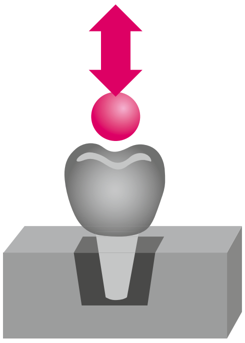
Boston University, Goldman School of Dental Medicine, Department of Restorative Dentistry/Biomaterials, Prof. Russell Giordano, report 07/13 ([1], see p. 34)

c) Result



d) Conclusion

After dynamic loading, the average fracture load of the VITA ENAMIC crowns in this test was 2,661 N (± 101 N), which is the highest average fracture load of the materials in this test. Compared to the other materials in this test, VITA ENAMIC had the lowest standard deviation.



2.1.4 Dynamic fracture load: VITA ENAMIC crowns

Chewing simulator

a) Materials and method

14 VITA ENAMIC crowns were tested in the chewing simulator. Following etching, the crowns were cemented to composite dies (modulus of elasticity approx. 18 GPa) using Variolink II, embedded in Technovit 4000 (Heraeus Kulzer) and immersed in warm water (37 °C) for 24 hours. Following accelerated aging, the crowns were subjected to a cyclic load in the chewing simulator: 198 N for 1.2 million cycles at a frequency of 1.6 Hz, with 3 mm steatite beads as the antagonist, TC 5 – 55 °C. Following the dynamic tests, static load was applied to the crowns until fracturing occurred.

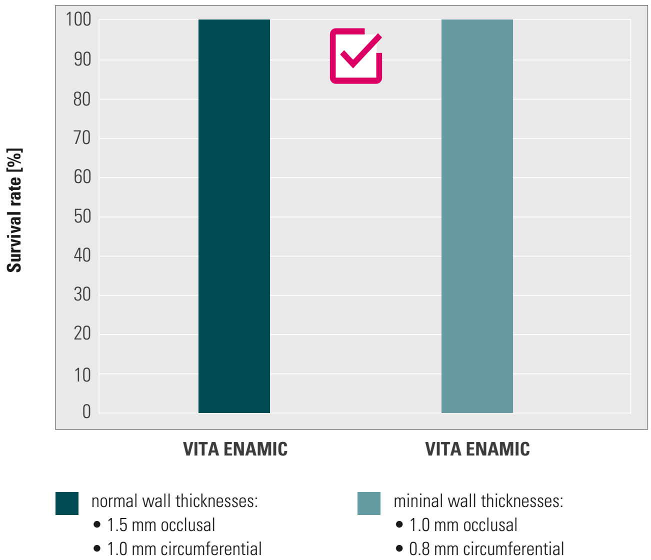
In addition to VITA ENAMIC crowns with walls of normal thickness (approx. 1.5 mm occlusal, approx. 1.0 mm circumferential), crowns with walls of reduced thickness (approx. 1.0 mm occlusal, approx. 0.8 mm circumferential) were tested in the chewing simulator.

b) Source

Freiburg University Hospital, Division of Oral and Maxillofacial Surgery, Department of Prosthodontics, Dr. Asma Bilkhair, report 12/11 ([2], see p. 34)

c) Result

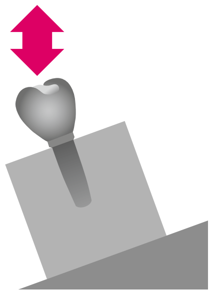
During dynamic masticatory load, none of the VITA ENAMIC crowns showed any defects.



d) Conclusion

The survival rate of VITA ENAMIC crowns with walls of normal and reduced thickness is 100%.

2.1.5 Dynamic fracture load: implant crowns made of VITA ENAMIC IS



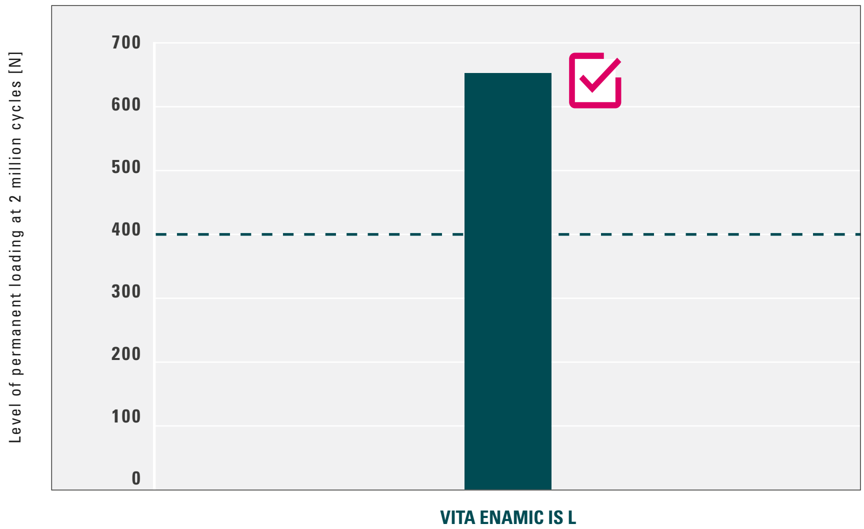
a) Materials and method

Based on the test design of the static load test, samples with implant-supported molar crowns made of VITA ENAMIC IS on L-TiBase and Straumann Bone Level implant system (Ø 4.1 mm) were fabricated using the same procedure and subjected to dynamic loads using Dynamess system (Dyna-Mess, Aachen/Stolberg, Germany). Dynamic loading was carried out at various load levels with samples immersed in distilled water (37°), amplitude of 2 Hz, inclination of 20° and a maximum number of 20 million cycles. The load was transferred to the central fossa via a spherical steel stamp (diameter: 5 mm).

b) Source

Internal study, VITA R&D, report 10/14 ([3], see p. 34)

c) Result



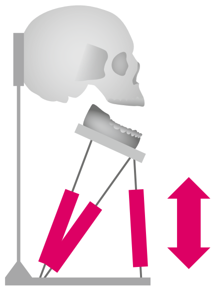
approx. level of permanent loading of ZrO_2 abutments according to literature sources [1–3]

d) Conclusion

In this test, a level of permanent loading of 648 N was achieved for implant-supported molar crowns made of VITA ENAMIC IS at 2 million cycles. Consequently, 100 % of the restorations survived dynamic loading at this level.

References for dynamic load tests indicate a level of permanent loading of approx. 400 N [1-3] for zirconia abutments on implants. However, depending on the test setup, number of cycles and type of implant, test results can vary and should only be compared to a limited extent. Due to this, the references given provide only an approximate reference value.

Sources:
(1) Gehrke et al.; Zirconium implant abutments: fracture strength and influence of cyclic loading on retaining-screw loosening; Quintessence Int. 2006 Jan; 37(1):19-26.
(2) Mitsias et al.; Reliability and fatigue damage modes of zirconia and titanium abutments; Int J Prosthodont. 2010 Jan-Feb; 23(1):56-9.
(3) Jiménez-Melendo et al.; Mechanical behavior of single-layer ceramized zirconia abutments for dental implant prosthetic rehabilitation; J Clin Exp Dent. 2014 Dec 1;6(5):e485-90



2.2 Absorption of occlusal forces of restorative materials

a) Materials and methods

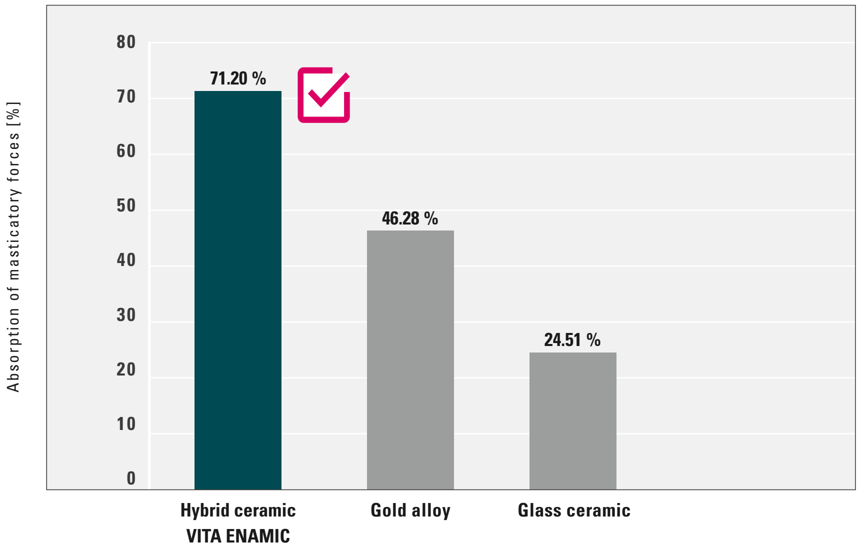
Monolithic crowns made of materials, such as zirconia, glass ceramic, gold alloy and the VITA ENAMIC hybrid ceramic were fabricated for various test series. To simulate the transfer of forces to the periimplant bone, the crowns were placed on a sterilized implant abutment (pin) in the chewing simulator/robot, which was fixed on a platform equipped with sensors. The fixed crowns (three crowns of each type of material were tested) were subjectd to dynamic loading by means of chewing simulation (100 cycles). The forces transferred to the simulated, periimplant bone within the scope of dynamic loading, were recorded and evaluated statistically. The chart of results below shows specific types of materials.

b) Source

Source: University of Genoa, Department for fixed and implant-prosthetic restorations, Dr. Maria Menini et al., Genoa, Italy, report 01/15 ([8], see p. 35)

c) Result

Absorption of masticatory forces compared to zirconia (ZrO_2)



Material class	Modulus of elasticity [GPa]	Force transmission (N)	Absorption of forces (%) compared to ZrO_2
Zirconia	210 GPa	641.8 N (SD 6.8)	
Glass ceramic	96 GPa	484.5 N (SD 5.5)	-24.51 %
Gold alloy	77 GPa	344.8 N (SD 5.7)	-46.28 %
VITA ENAMIC hybrid ceramic	30 GPa	184.9 N (SD 3.9)	-71.20 %

d) Conclusion

The values of force transmission to the simulated periimplant bone determined in this test setup show that a relatively elastic material, such as the hybrid ceramic, can reduce or absorb about 70 percent of the force, compared to the comparatively stiff zirconia. In addition, compared to glass ceramic and gold, VITA ENAMIC also reveals a higher capacity of absorption of simulated masticatory forces.

2.3 Distribution of forces

a) Materials and method

In this test, force-displacement diagrams were determined for various restorative materials (VITA YZ, IPS e.max CAD, VITABLOCS Mark II, VITA ENAMIC). In this case, indentations were made in the samples of different materials using a sphere; in other words, a load was applied while maintaining the defined force of 100 N (newtons) for 20 seconds, before the load was removed.

b) Source

Internal study, VITA R&D, report 11/13 ([3], see p. 34)

c) Result

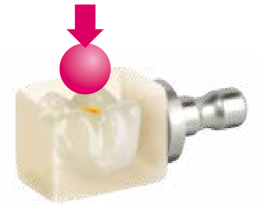


Fig. 1a Traditional silicate ceramic

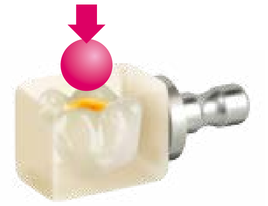


Fig. 1b VITA ENAMIC hybrid ceramic

Force-path diagram

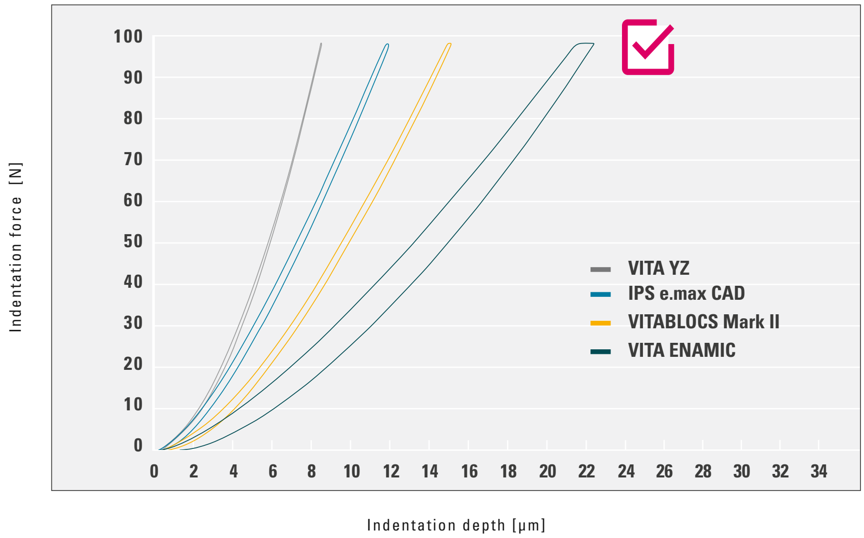
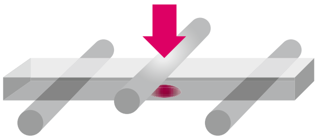


Fig. 1 a – b) Exemplary schematic illustration of specific and extensive distribution of forces across a contact surface.

d) Conclusion

The lower the modulus of elasticity (i.e., more elastic material), the deeper the sphere will penetrate. This provides for better distribution of forces so there is no excessive load in individual areas, which may lead to the development of cracks. The following benefits can be expected from the results: in the case of a relatively elastic material, such as the VITA ENAMIC hybrid ceramic (modulus of elasticity: approx. 30 GPa), the occlusal force applied during mastication is distributed across a wider contact surface area, reducing the intensity of loading/stress.



2.4 Damage tolerance

a) Materials and method

In this study, load tests were carried out following previous damage to the material. The influence of the damage caused by the antagonist cusp during mastication was simulated. For this purpose, test specimens (bending bars) made of silicate and hybrid ceramics (diameter: 1 mm) were damaged using a tungsten carbide sphere (load of 500 newtons) as part of a first step, and in a second step, a load was applied to the test specimens as part of 3-point flexural strength testing, until the material failed. The fractured surfaces were subsequently analyzed using a light microscope.

b) Source

Internal study, VITA R&D, report 11/13 ([3], see p. 34)

c) Result

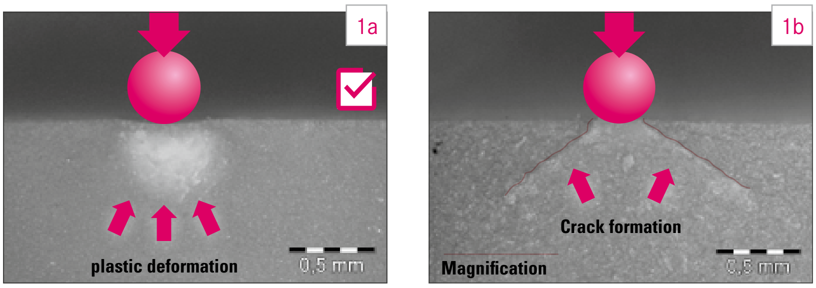


Fig. 1a) VITA ENAMIC hybrid ceramic – cross section of the fractured surface following prior damage using a tungsten carbide sphere. The whitish area reveals the plastic deformation with a visible indentation on the surface caused by the sphere.

Fig 1b) Traditional silicate ceramic - cross section of the fractured surface following prior damage using a tungsten carbide sphere

d) Conclusion

This test setup examines the industry-accepted damage tolerance of dental materials. Two typical types of damage could be determined in light microscopic analyses: due to the dual-network structure and the comparatively high elasticity, VITA ENAMIC exhibits plastic deformation following the application of force and accordingly, a certain tolerance for damage (Fig.1a). A relatively brittle and stiff material, such as traditional silicate ceramic, reveals cracks, known as cone cracks, following prior damage and loading (Fig. 1b).

2.5 Modulus of elasticity

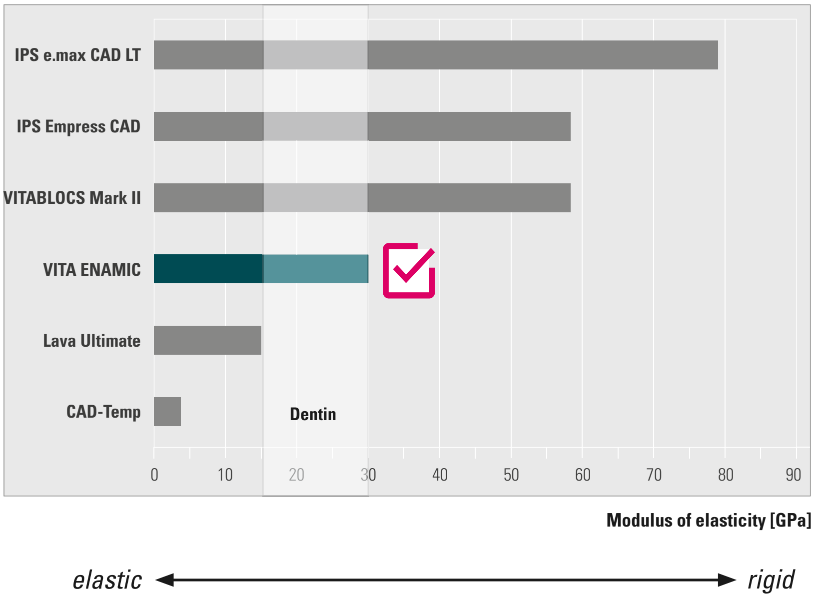
a) Materials and method

The modulus of elasticity was determined based on the stress-strain curves of the measurements of flexural strength.

b) Source

Internal study, VITA R&D, report 03/12 ([3], see p. 34)

c) Result



d) Conclusion

With an elasticity of 30 GPa, VITA ENAMIC is in the same range as human dentin.

Note:
There are a wide range of references concerning the modulus of elasticity of human dentin in literature.

Sources:
Kinney JH, Balooch M, Marshall GW, Marshall SJ. A micromechanics model of the elastic properties of human dentin. Archives of Oral Biology 1999; 44:813-822.
Kinney JH, Marshall SJ, Marshall GW. The mechanical properties of human dentin: a critical review and re-evaluation of the dental literature. Critical Reviews in Oral Biology & Medicine 2003; 14:13-29

2.6 Abrasion

2.6.1 Two-body abrasive wear

2.6.1.1 Results: University of Zurich

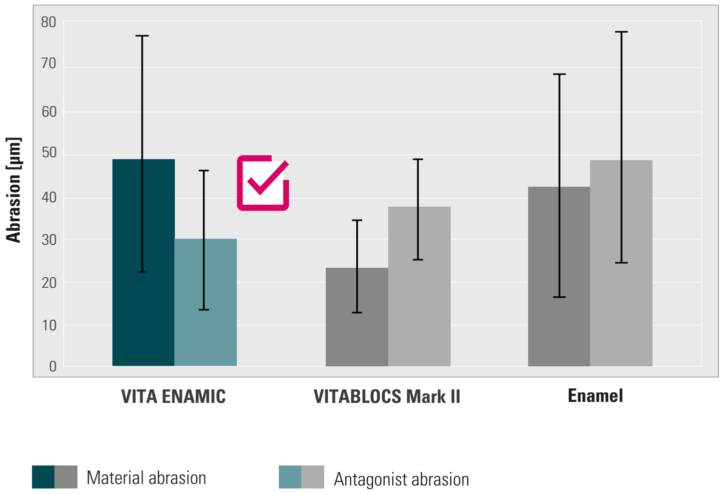
a) Materials and method

Zurich chewing simulator, 1.2 million cycles, 1.7 Hz, load 49 N, 6,000 thermal cycles, natural enamel as the antagonist

b) Source

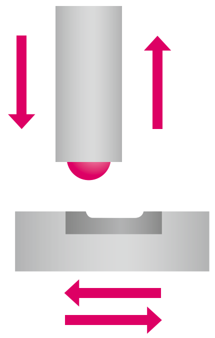
University of Zurich, Center of Dental and Oral Medicine, Clinic for Preventive Dentistry, Periodontology and Cariology, Dept. of Computer-Aided Restorative Dentistry, Prof. W.H. Mörmann, report 04/13 ([4], see p. 34)

c) Result



d) Conclusion

The abrasion level of VITA ENAMIC is 49 µm. The level of abrasion to the antagonist enamel caused by VITA ENAMIC is 30.2 µm. VITABLOCS Mark II causes a slightly higher level of abrasion to the antagonist of 38.1 µm. As a control group, the abrasion of enamel to enamel was measured in the study. The goal with VITA ENAMIC was to further improve on the antagonist-friendly properties of VITABLOCS Mark II without abandoning the ceramic behavior of the material.



2.6.1.2 Results: University of Regensburg

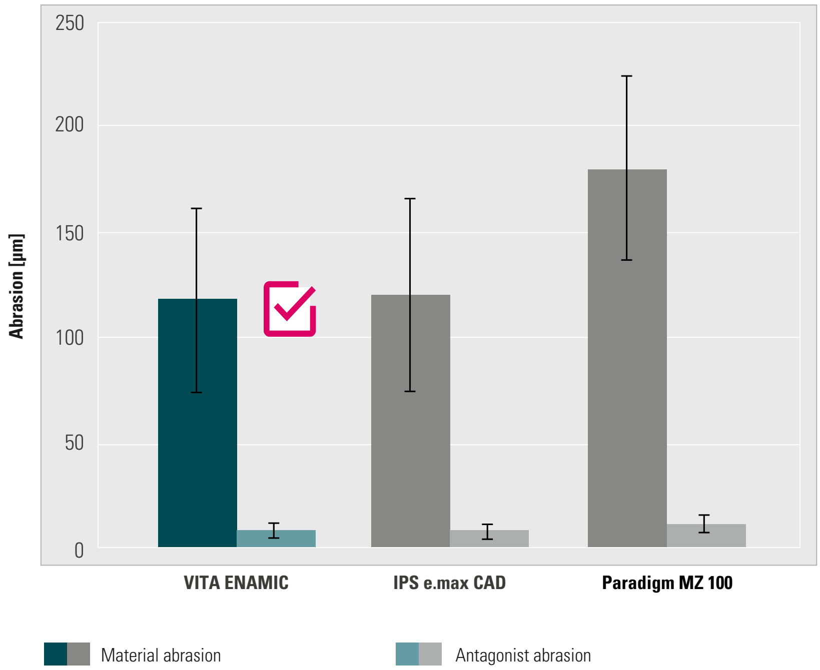
a) Materials and method

– Pin-on-block wear test design in chewing simulator
– Steatite beads as the antagonist
– 50 N load force
– 1.2 x 10^5 cycles, 1.6 Hz
– 600 thermal cycles, 5 – 55 °C
– Evaluation: measurement of substance loss

b) Source

University of Regensburg, Faculty of Medicine, Polyclinic for Dental Prosthetics, Prof. Martin Rosentritt, report 05/11 ([5], see p. 34)

c) Result



d) Conclusion

With an abrasion level of approx. 120 µm, VITA ENAMIC is in the same range as ceramic. In this test, the composite material Paradigm MZ 100 demonstrates a significantly higher level of abrasion of approx. 185 µm.

2.6.2 Three-body abrasive wear

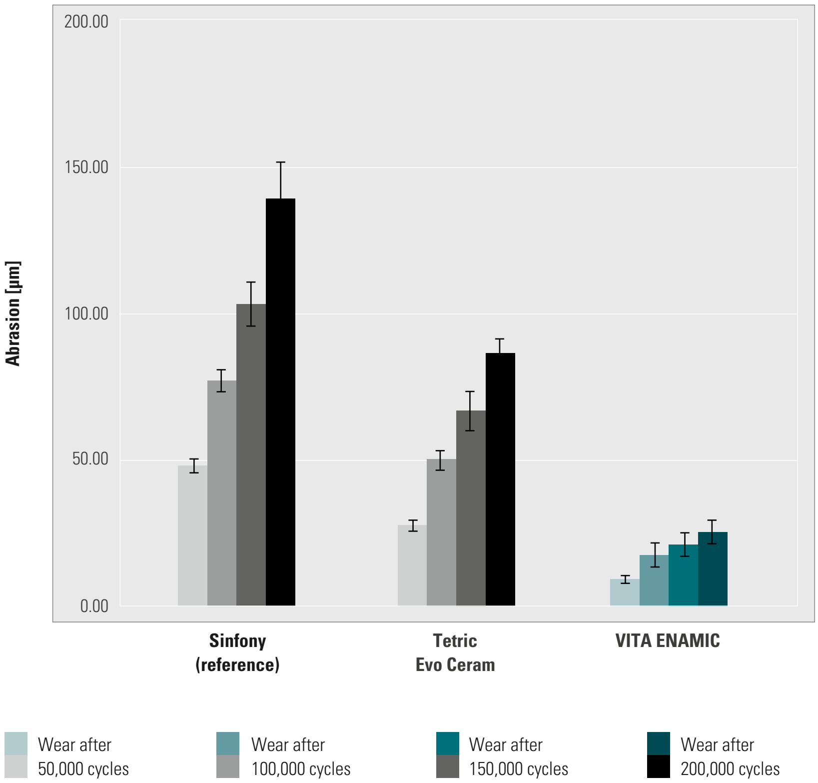
a) Materials and method

3-body abrasion testing in accordance with the ACTA (Academisch Centrum Tandheelkunde Amsterdam)

b) Source

University of Regensburg, Faculty of Medicine, Polyclinic for Dental Prosthetics, Prof. Martin Rosentritt, report 03/11 ([6], see p. 34)

c) Result



d) Conclusion

The level of wear increases for all three materials as the number of cycles increases. Comparatively speaking, the highest level of wear resistance was measured for VITA ENAMIC.

2.6.3 Toothbrush abrasion

a) Materials and methods

Five high-gloss polished samples, each with a surface of 2.5 cm² made of the CAD/CAM materials VITA ENAMIC (VITA Zahnfabrik), VITABLOCS Mark II (VITA Zahnfabrik), SHOFU Block HC (SHOFU), Lava Ultimate (3M ESPE) and Cerasmart (GC) were brushed mechanically for 32 hours with abrasive toothpaste (Depurdent, Dr. Wild & Co. AG) under a defined load (Fuchs Clips Depot interchangeable heads, medium Interbros GmbH). Then loss of weight (XS104, Mettler Toledo) and surface roughness (Hommel-Etamic T8000 RC, JENOPTIK) were measured. Additionally, SEM pictures (EVO MA 10, ZEISS) of the sample surfaces were taken following toothbrush wear.

b) Source

Internal study, VITA R&D, report 03/16 ([3], see p. 34)

c) Result

Loss of weight and surface roughness following toothbrush abrasion test.

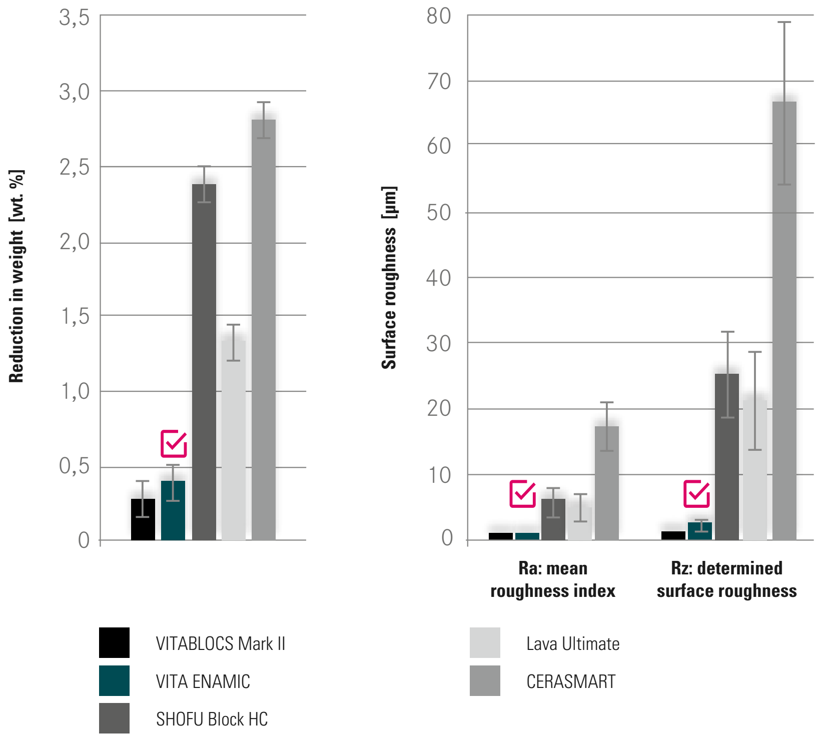


Fig. 1 Averages for weight loss and surface roughness after toothbrush abrasion on the basis of five samples per material. The lower the parameters Ra and Rz, the smoother the surface.

SEM images of the surfaces after toothbrush wear

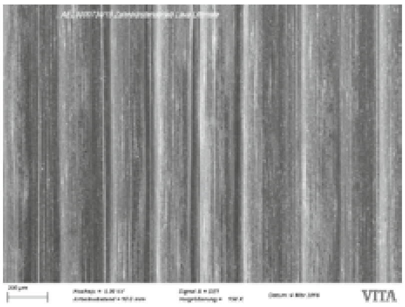


Fig.2a Lava Ultimate

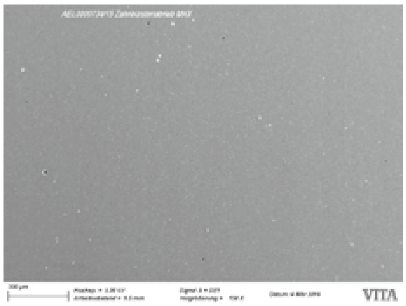


Fig.2d VITABLOCS Mark II

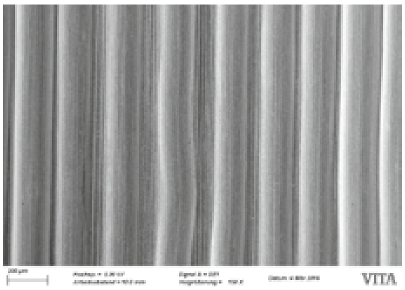


Fig.2b CERASMART

Fig.2e VITA ENAMIC

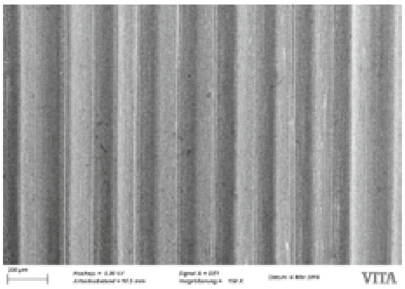


Fig.2c SHOFU Block HC

Fig. 2a-2e SEM images of material samples after toothbrush wear, 150-fold magnification

d) Conclusion

In this test, the dual-network structure of VITA ENAMIC demonstrated resistance to abrasion that was clearly superior to that of the composites examined. The abrasion behavior for VITA ENAMIC determined in the test is very similar to that of the proven VITABLOCS feldspar ceramics and allows us to expect sufficiently abrasion-resistant restorations.

2.7 Reliability/Weibull modulus

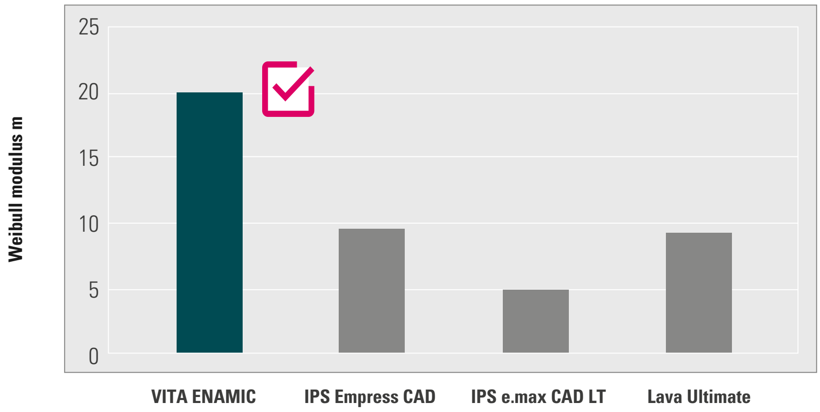
a) Materials and method

The Weibull modulus was determined based on the strength values of bending bars. "Using a theory developed by Weibull, which is based on the concept of failure of the weakest link, the strength distribution of ceramic materials can be described effectively in mathematical terms. [...] If the distribution parameters are known, a clear correlation can be drawn between the load and the probability of a fracture[1]"; in other words, a high Weibull modulus indicates consistent material quality. Together with the high load capacity values, this is an indicator of the reliability of a material.

b) Source

Internal study, VITA R&D, report 07/12 ([3], see p. 34)

c) Result



d) Conclusion

Of the materials measured in this test, VITA ENAMIC offered the greatest reliability. A Weibull modulus of 20 was achieved. When evaluating the Weibull modulus, the flexural strength (in-house measurements of VITA R&D: VITA ENAMIC: 153.82 MPa [SD 7.56 MPa], Lava Ultimate: 188.42 MPa [SD 22.29 MPa], IPS Empress CAD: 157.82 MPa [SD 17.33 MPa], IPS e.max CAD LT: 344.05 MPa [SD 64.5 MPa]) should always also be taken into account.

References:
(1) Brevier Technische Keramik, Verband der Keramischen Industrie e.V., 2003

2.8 Vickers hardness

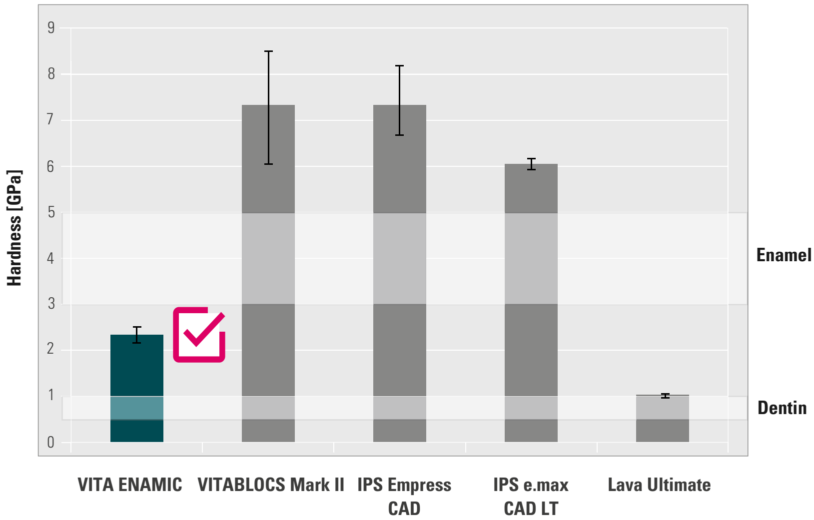
a) Materials and method

The materials embedded in epoxy (VITA ENAMIC, VITABLOCS Mark II, IPS Empress CAD, IPS e.max CAD LT and Lava Ultimate) were polished to a high-luster finish. The polished specimens were clamped into position in the hardness tester. In each case, five indent impressions were made for each material with a load of 30 N. Once the maximum load (30 N) had been reached, this was maintained for 20 seconds before release. Hardness in GPa was calculated by measuring the diagonals of the indent. The bars in the diagram correspond to the average values obtained, based on five measurements in each case.

b) Source

Internal study, VITA R&D, report 03/12 ([3], see p. 34)

c) Result



d) Conclusion

The level of hardness of VITA ENAMIC is approx. 2.5 GPa and is between that of dentin (0.6 – 0.92 GPa; [1], [2]) and enamel (3 - 5.3 GPa; [3], [4]). The hardness levels of the three ceramics (VITABLOCS Mark II, IPS Empress CAD and IPS e.max CAD) are significantly higher than that of enamel. With a hardness level of approx. 1 GPa, Lava Ultimate is in the same range as dentin.

Sources:

(1) Lawn BR, Lee JJ-W. Analysis of fracture and deformation modes in teeth subjected to occlusal loading.Acta Biomater, 2009; 5:2213-2221.

(2) Mahoney E, Holt A, Swain MV, Kilpatrick N. The hardness and modulus of elasticity of primary molar teeth: an ultra-micro-indentation study. J Dent, 2000; 28:589-594.

(3) He LH, Swain MV. Nanoindentation derived stress-strain properties of dental materials. Dent Mater, 2007; 23:814-821.

(4) Park S, Quinn JB, Romberg E, Arola D. On the brittleness of enamel and selected dental materials. Dent Mater, 2008; 24:1477-1485.

2.9 Etchability of the material

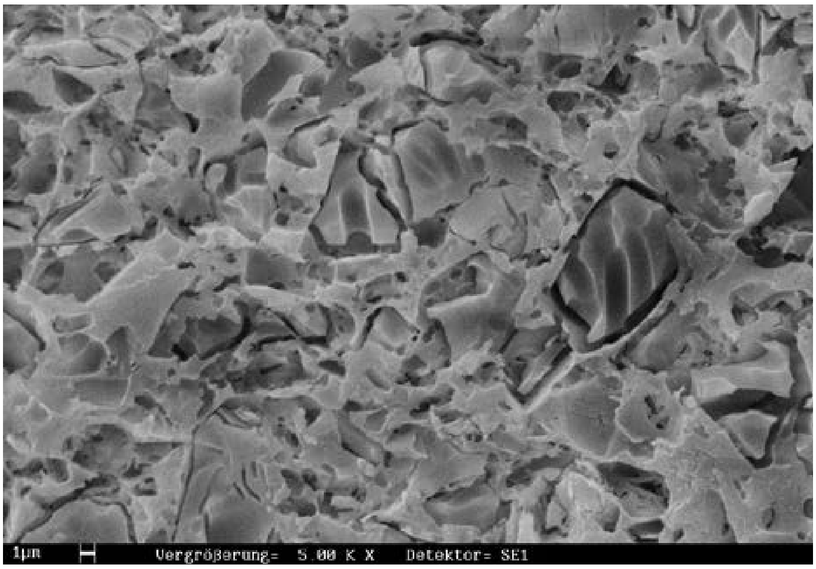
a) Materials and method

Polished VITA ENAMIC samples were etched for 60 seconds using VITA CERAMICS ETCH (5% hydrofluoric acid gel).
SEM images were then taken of the etched surface.

b) Source

Internal study, VITA R&D, report 03/12 ([3], see p. 34)

c) Result



VITA ENAMIC, 5,000 x magnification, source: VITA R&D

The etching pattern is clearly recognizable. The light grey areas represent the polymer network structure; the dark grey areas show the ceramic network structure. Etching caused the surface of the ceramic to separate.

d) Conclusion

As a result of etching, a good retentive etching pattern can be generated, since only the ceramic network structure is separated and the polymer structure and its large surface remain intact. Unlike with composites, the etched areas are clearly recognizable on the restoration.

2.10 Adhesive bond

2.10.1 Adhesive bond of RelyX Unicem/Variolink II to (hybrid)ceramics

a) Materials and methods

From the materials mentioned below, test pairs were prepared, each comprising one plate (10 mm x 10 mm x 3 mm) with a central conical six-bore hole and a cone preparation (6 conicity). Depending on the CAD/CAM material used, the crowns and plates were subjected to the treatment processes given below after ultrasonic cleaning:

– Etched for 60 sec with VITA CERAMICS ETCH (5% hydrofluoric acid gel)
– Silanizing in accordance with the manufacturer's instructions (either with VITASIL, VITA or Monobond Plus, Ivoclar Vivadent)

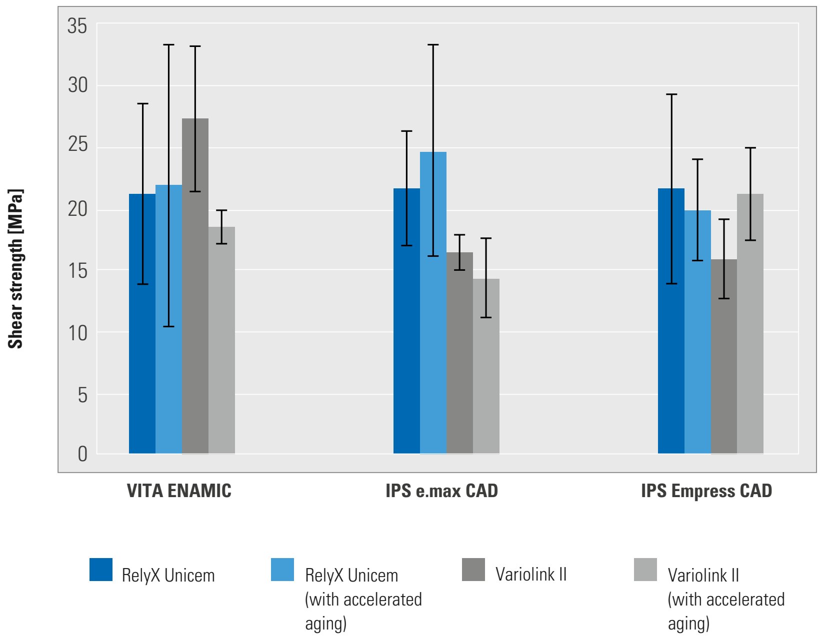
After pretreatment, the samples were bonded with the bonding composites RelyX Unicem (3M, Seefeld, Germany) and Variolink II (Ivoclar Vivadent, Schaan, Lichtenstein) in accordance with the manufacturer's instructions (under a load of 2 kg). In addition, some of the samples were immersed in water (temperature: 37 °C) for 2 weeks.

Determination of compressive shear strength:
Each average value (see diagram) is based on five test specimens (n=5). Once the test specimens had been bonded, they were tested using a universal testing machine. This involved applying a stamp to the cone preparation with a feed rate of 0.5 mm/min until ejection.

b) Source

Internal study, VITA R&D, report 05/10 ([3], see p. 34)

c) Result



d) Conclusion

When measuring the bond strength of the bonding composites mentioned above to the hybrid ceramic VITA ENAMIC and to traditional CAD/CAM ceramics (IPS e.max CAD, IPS Empress CAD), comparable measurement values were obtained for both material groups. On average, the compressive shear strength measured ranged from approx. 15 to 25 MPa.

2.10.2 Adhesive bond of Variolink Esthetic to hybrid ceramics and composites

a) Materials and methods

From the materials mentioned below, test pairs were prepared, each comprising one plate (10 mm x 10 mm x 3 mm) with a central conical 6- bore hole and a cone preparation (6 conicity). Depending on the CAD/CAM material used, the crowns and plates were subjected to the treatment processes given below after ultrasonic cleaning:

Material	Surface conditioning	Bonding agent
VITA ENAMIC	Etching with 5% hydrofluoric acid for 60 s	Monobond Plus
CERASMART	Etching with 5% hydrofluoric acid for 60 s	Monobond Plus
	Sandblasting with 50 µm Al_2O_3 at 1.5 bar	Monobond Plus
SHOFU Block HC	Sandblasting with 50 µm Al_2O_3 at 2.5 bar	Monobond Plus
BRILLIANT Crios	Sandblasting with 50 µm Al_2O_3 at 1.5 bar	One Coat 7 Universal

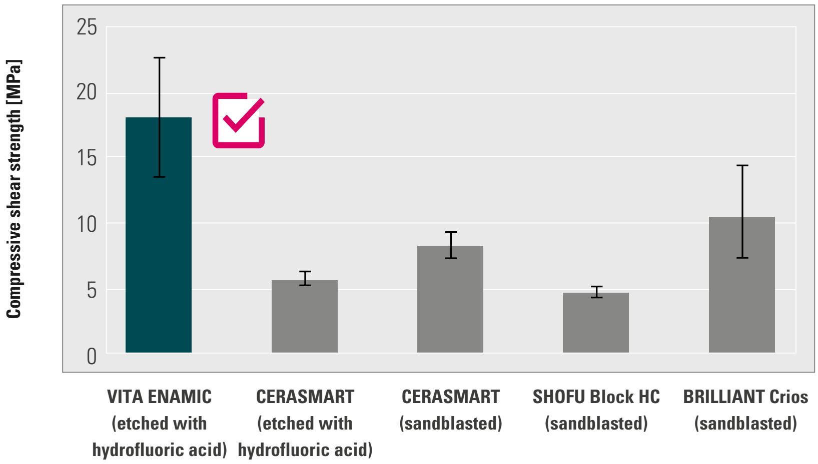
After pretreatment, the samples were bonded with the bonding composite Variolink Esthetic (Ivoclar Vivadent, Schaan, Lichtenstein), in accordance with the manufacturer's instructions (under a load of 2 kg).

Determination of compressive shear strength:
Each average value (see diagram) is based on five test specimens (n=5). Once the test specimens had been bonded, they were tested using a universal testing machine. This involved applying a stamp to the cone preparation with a feed rate of 0.5 mm/ min until ejection.

b) Source

Internal study, VITA R&D, report 10/17 ([3], see p. 34)

c) Result



d) Conclusion

In this test series, clearly higher bond strength values of the bonding composite mentioned above to VITA ENAMIC hybrid ceramic was measured than to the CAD/ CAM composites tested (CERASMART, SHOFU Block HC, BRILLIANT Crios). The solid bond with VITA ENAMIC can be attributed, among other things, to the good preconditioning properties of the ceramic network (86 % by weight) of the hybrid ceramic using etching with hydrofluoric acid (HF: Hydrofluoric acid). The preconditioning of CERASMART using hydrofluoric acid, which was indicated according to the manufacturer, did not show a positive effect on the calculated bond strength values.

2.10.3 Adhesive bond of RelyX Ultimate to VITA ENAMIC and Lava Ultimate

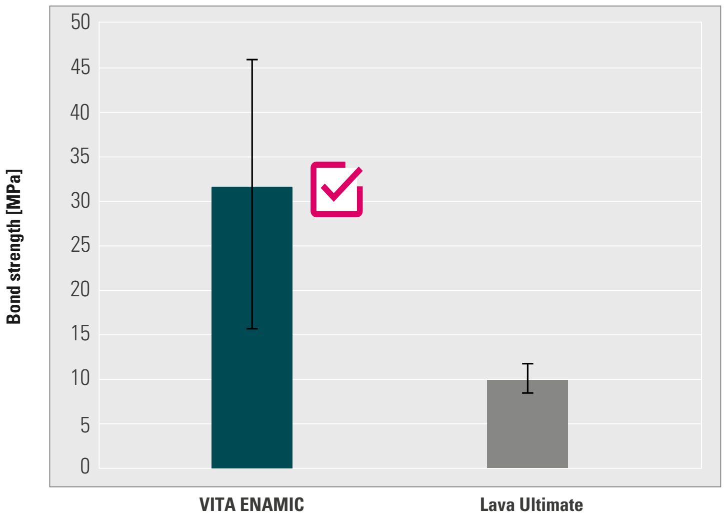
a) Materials and methods

Plates were sawed out of VITA ENAMIC and Lava Ultimate blanks.
To ensure an identical initial surface structure, all plates were ground using SiC paper (grit size 320). The prepared VITA ENAMIC plates were etched for 60 sec. (VITA Ceramics Etch). The plates made from Lava Ultimate were sandblasted in accordance with the manufacturer's instructions (50 µm Al_2O_3, 2 bar).
Following etching or sandblasting, Scotchbond (3M ESPE) was applied to the plates for 20 seconds, in accordance with the manufacturer's instructions. Then cylinders made of RelyX Ultimate were polymerized on the plates, sheared according to DIN EN ISO 10477 and the bond strength was determined. Single factor variance analysis was used for the statistical evaluation.

b) Source

Internal study, VITA R&D, report 09/13 ([3], see p. 34)

c) Result



d) Conclusion

Within the scope of this test setup, bonding of RelyX Ultimate to VITA ENAMIC can be considered very good (31.32 MPa (± 14.5 MPa)), since mainly cohesive fractures (fractures within the material) were determined for VITA ENAMIC This also explains the higher degree of variation compared to Lava Ultimate.
The bond strength of RelyX Ultimate on Lava Ultimate is 9.92 MPa (± 1.89 MPa). Primarily, adhesive fractures within the bonding zone were found.

2.11 Discoloration tests

a) Materials and method

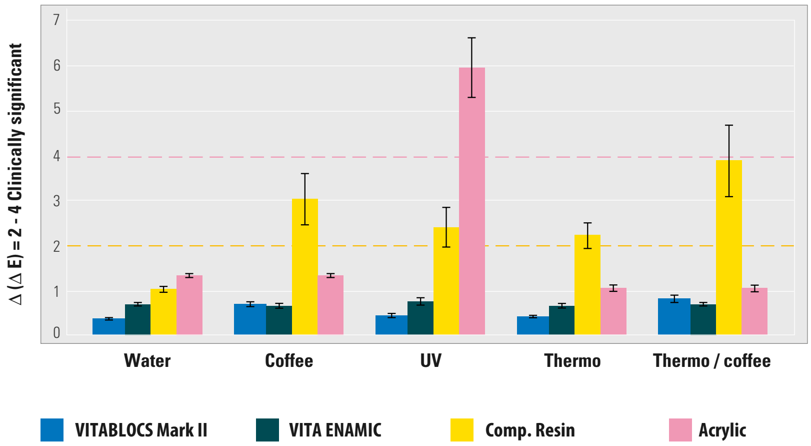
The samples (n = 40) were prepared in accordance with the manufacturer's instructions (Herculute XRV and DENTSPLY Bridge Resin) or cut out of blocks (VITABLOCS Mark II, VITA ENAMIC; Bühler Isomet saw). After polishing (Bühler Ecomet, final with 1µm diamond paste), the series of samples were immersed in coffee or distilled water and subjected to thermocycling (2,500 cycles, 5 °C - 55 °C). One series was also subjected to accelerated aging in coffee (15 days, 37 °C) after thermocycling. Another group was exposed to UV radiation for 15 days (ADA specification No. 80). The CIE L*a*b*-color coordinates before and after treatment were determined using a spectrophotometer (Color I5, X-rite), and the delta E values to determine the overall color deviation were calculated.

b) Source

Boston University, Goldman School of Dental Medicine, Department of Restorative Dentistry/Biomaterials, Prof. Russell Giordano, report 11/10 ([7], see p. 34)

c) Result

Color stability



d) Conclusion

No significant differences in color could be observed for VITABLOCS Mark II and VITA ENAMIC for different types of treatment (ANOVA and Scheffe's test). Significant changes in color were determined for the composite and the acrylic resin, in particular, following UV radiation and after thermocycling, in combination with immersion in coffee (accelerated aging).

2.12 Machinability

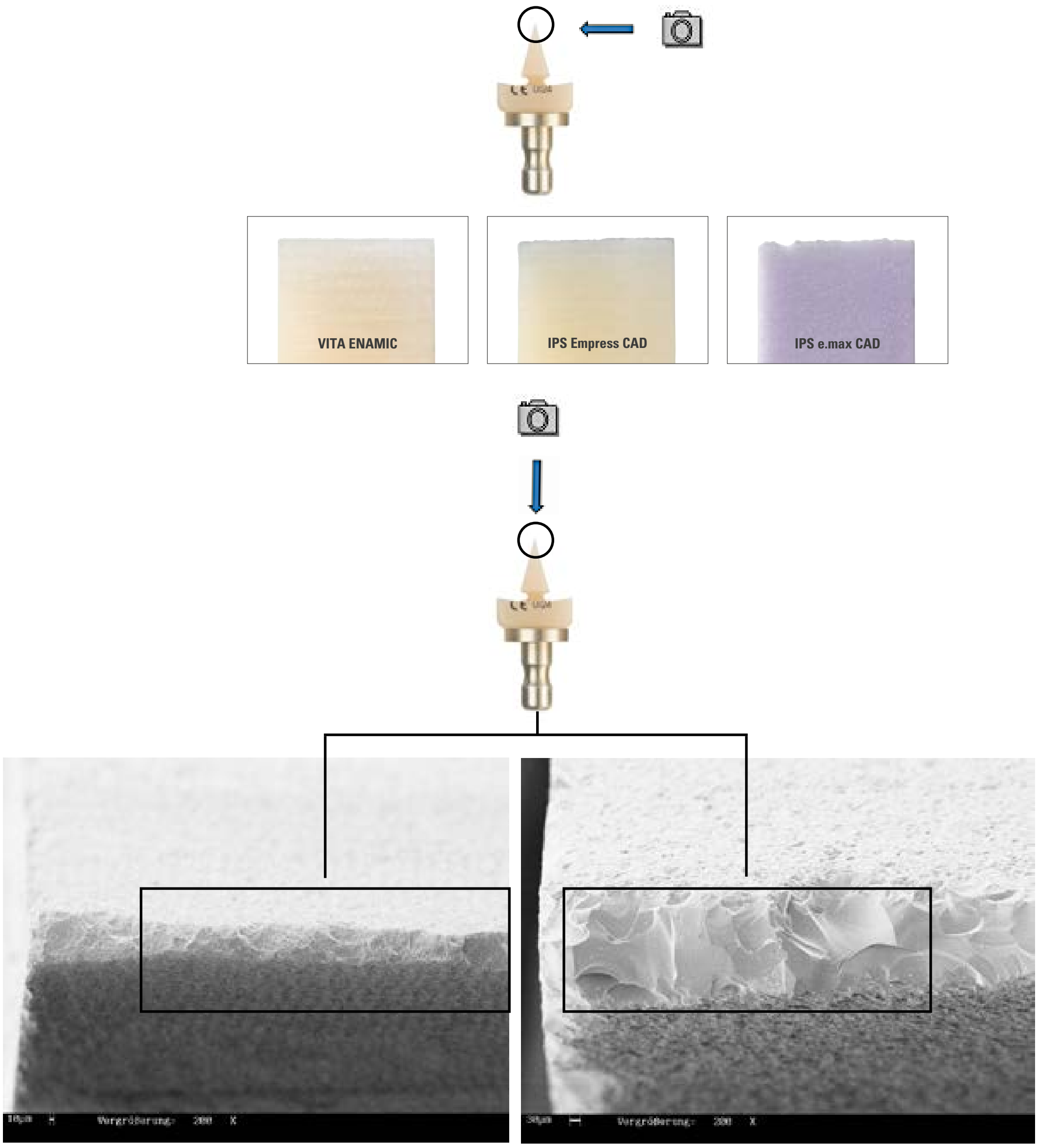
a) Materials and method

Using the Sirona MC XL milling system, 30° wedges were milled from various materials in normal milling mode.

b) Source

Internal study, VITA R&D, report 05/10 ([3], see p. 34)

c) Result



VITA ENAMIC, 200 x magnification, source: VITA R&D

IPS e.max CAD, 200 x magnification, source: VITA R&D

d) Conclusion

VITA ENAMIC demonstrates marginal accuracy that is significantly more precise than that of conventional CAD/CAM ceramic restorative materials with fewer irregularities.

2.13 Edge stability

a) Materials and method

Using the Sirona MC XL milling system, non-prep veneers were milled in normal milling mode from various materials with a wall thickness of approx. 0.2 mm. The manufacturer has not approved the use of IPS Empress CAD and IPS e.max CAD for a wall thickness of approx. 0.2 mm. Additionally, using the Sirona MC XL milling system, inlays were milled from various materials in normal milling mode (see SEM pictures).

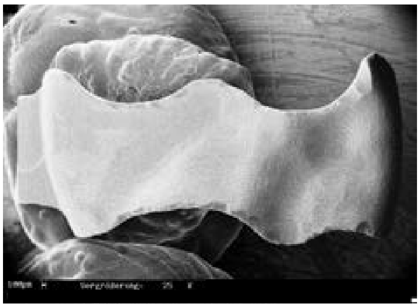
b) Source

Internal study, VITA R&D, report 10/11 ([3], see p. 34)

c) Result

VITA ENAMIC IPS Empress CAD IPS e.max CAD

VITA ENAMIC, 25 x magnification, source: VITA R&D



IPS Empress CAD, 25 x magnification, source: VITA R&D

d) Conclusion

The exact edge stability of VITA ENAMIC is demonstrated by the non-prep veneers. The geometry in this case, with a wall thickness of approx. 0.2 mm, could only be fully milled using VITA ENAMIC. The milled inlay illustrates the high edge quality of VITA ENAMIC, which provides for extremely precise milling results.

2.14 Milling times

a) Materials and method

The milling times for three types of restorations (inlay, anterior crown and posterior crown) were determined using four different CAD/CAM materials (VITA ENAMIC, VITABLOCS Mark II, both from VITA Zahnfabrik, IPS e.max CAD from Ivoclar Vivadent and Lava Ultimate from 3M ESPE). The tests were performed using the Sirona MC XL milling system. Five units were milled for each material and type of restoration. The milling times were taken from the log files.

b) Source

Internal study, VITA R&D, report 05/12 ([3], see p. 34)

c) Result

Milling times (min:sec) for the VITA ENAMIC, Mark II, IPS e.max CAD and Lava Ultimate materials. The times correspond to the average value determined on the basis of five measurements.

VITA ENAMIC	**Normal**	**7:56**	**7:10**	**9:07**
	Fast	**4:40**	**4:19**	**5:13**
VITABLOCS Mark II	Normal	10:27	10:35	13:29
	Fast	6:24	7:03	9:26
IPS e.max CAD	Normal	12:17	12:36	14:58
	Fast	10:00	8:11	12:14
Lava Ultimate	Normal	10:39	10:10	11:55
	Fast	7:27	6:27	8:24

d) Conclusion

Compared to VITABLOCS Mark II, Lava Ultimate and IPS e.max CAD, VITA ENAMIC restorations can be milled more quickly.

2.15 Service life of the milling tools

a) Materials and method

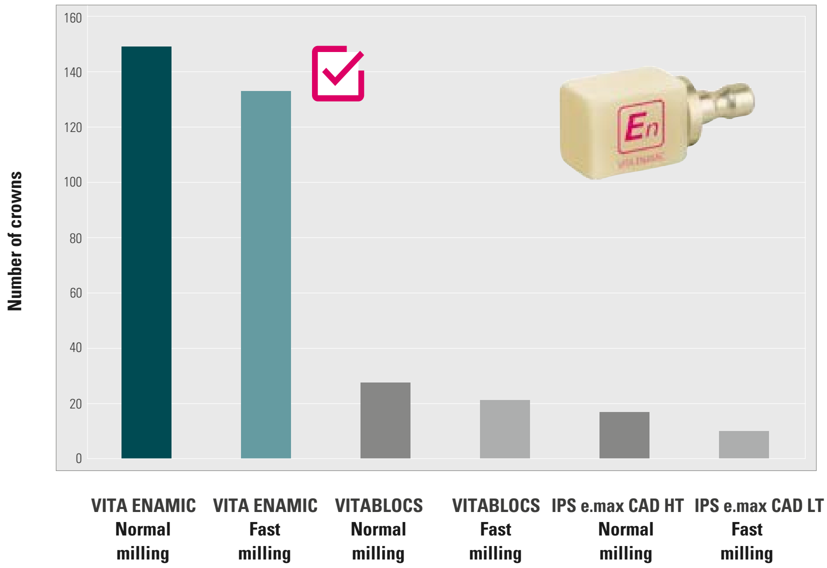
Using the Sirona MC XL milling system, one pair of milling tools in each case was used to grind as many molar crowns as possible from a variety of CAD/CAM materials in normal milling mode and in fast milling mode. The lives of the milling tools indicate the results of a series of measurements.

b) Source

Internal study, VITA R&D, report 03/10 ([3], see p. 34)

c) Result

Number of molar crowns milled with a milling pair (Sirona MC XL Software 3.8x)



d) Conclusion

VITA ENAMIC can be milled more cost-effectively than any other tooth-colored ceramic block material. The milling time for VITA ENAMIC restorations is by far the shortest in the test described (see 2.14) and also results in a long milling tool life of approx. 148 or 132 milled crowns.

2.16 Polishing results

VITA ENAMIC can be easily polished to a high-luster finish when dry (extra-orally) and when wet (intra-orally), using the polishing instruments available from VITA. This was confirmed during the acceptance phase.

2.17 Biocompatibility

Tests regarding biocompatibility were carried out by North American Science Associates Inc. (NAMSA). VITA ENAMIC was deemed biocompatible. Report 02/13

2.18 Solubility in acid, absorption of water, solubility in water

a) Materials and method
Testing in accordance with DIN EN ISO 6872 and DIN EN ISO 10477

b) Source
Internal study, VITA R&D, report 07/11 ([3], see p. 34)

c) Result
No chemical solubility in accordance with ISO 6872. Absorption of water (5.7 µg/mm^3) and solubility in water (< 1.2 µg/mm^3) are within the reference values specified by ISO 10477.

d) Conclusion
The properties of VITA ENAMIC are intermediate between those of ceramics and composites.

3. In-vivo studies

3.1 Clinical study, Freiburg University Hospital, Division of Oral and Maxillofacial Surgery, Department of Prosthodontics, Prof. Dr. Petra Gierthmühlen (née Güß): VITA ENAMIC crowns

Start date of study: November 2011
Number of restorations fitted: 71

3.2 Clinical study, Freiburg University Hospital, Division of Oral and Maxillofacial Surgery, Department of Prosthodontics, Prof. Dr. Petra Gierthmühlen (née Güß): VITA ENAMIC inlays, onlays, partial crowns, table tops

Start date of study: November 2011
Number of restorations fitted: 100

3.3 Pilot tests of VITA Zahnfabrik: VITA ENAMIC crowns, implant crowns, partial crowns, inlays, onlays, veneers

Various users in a practice setting
Number of restorations fitted: approx. 594
As of: December 2012

3.4 . Clinical observational studies: VITA ENAMIC crowns on implants

a) Materials and method

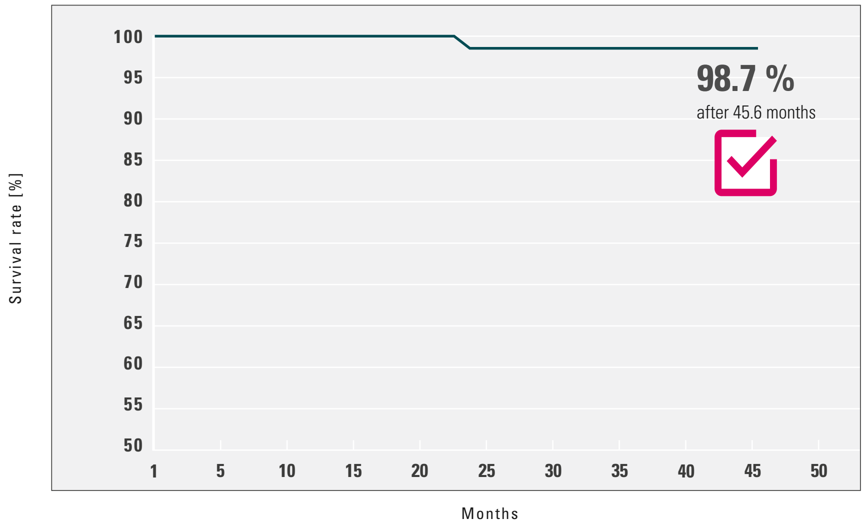
As part of a multicenter clinical observational study that included 11 dentists from Germany, Austria and Switzerland, 38 patients with indications for one or several implants in the upper and/or lower jaw, were randomly selected. The criteria for the selection of patients was based on the recommendations of DGI (German Association for Implantology) for single tooth implants. There were no restrictions or recommendations with regard to the implant systems used, and the surgical and clinical procedure could also be selected freely. A total of 60 implant crowns were inserted and observed for the purposes of the study. The patients were reexamined 14 days after seating the prosthetic restoration and every six months thereafter. The minimum observation period was six months (first recall). To determine the survival rate, debonding of the crown and partial or full fracturing (chipping) of the crown body was considered to be loss criteria.

b) Source

VITA Application Technology and Product Management in cooperation with dental pilot users, report 11/14 ([9], see p. 35)

c) Result

Survival rate of VITA ENAMIC implant-supported crowns



d) Conclusion

Within the scope of a multicenter clinical observational study over a maximum period of four years, a survival rate of 98.7 percent was determined for VITA ENAMIC crowns on implants. The average wearing period of the implant crowns examined was 23.1 months (as of: 11/14) when the report was prepared. The results of the study demonstrate comparable or higher survival rates[1-3] for VITA ENAMIC implant crowns than for alternative materials.

Sources:

(1) De Boever AL, Keersmaekers K, Vanmaele G, Kerschbaum T, Theuniers G, De Boever JA. Prosthetic complications in fixed endosseous implant-borne reconstructions after an observations period of at least 40 months. J Oral Rehabil. 2006 Nov;33(11):833-9.

(2) Thoma DS, Brandenberg F, Fehmer V, Büchi DL, Hämmerle CH, Sailer I. Randomized Controlled Clinical Trial of All-Ceramic Single Tooth Implant Reconstructions Using Modified Zirconia Abutments: Radiographic and Prosthetic Results at 1 Year of Loading. Clin Implant Dent Relat Res. 2015 Apr 15.

(3) Rinke S, Lange K, Roediger M, Gersdorff N. Risk factors for technical and biological complications with zirconia single crowns. Clin Oral Investig. 2015 Feb 7.

4. Publications

Publications on VITA ENAMIC:

Al-Harbi A, Ardu S, Bortolotto T, Krejci I.
Stain intensity of CAD/CAM Materials versus direct composites.
IADR 2012 Poster Abstract, Iguaçu Falls, Brazil

Coldea A, Swain MV, Thiel N.
Mechanical properties of polymer-infiltrated-ceramic-network materials.
Dent Mater. 2013 Apr; 29(4):419-426

Coldea A, Swain MV, Thiel N.
In-vitro strength degradation of dental ceramics and novel
PICN material by sharp indentation.
J Mech Behav Biomed Mater 2013 Oct;26(10):34-42.

He LH, Swain M.
A novel polymer infiltrated ceramic dental material.
Dent Mater. 2011 Jun;27(6):527-34. Epub 2011 Mar 2.

He LH, Purton D, Swain M.
A novel polymer infiltrated ceramic for dental simulation.
J Mater Sci Mater Med. 2011 Jul;22(7):1639-43. Epub 2011 May 26.

Mörmann W, Stawarczyk B, Ender A, Sener B, Attin T, Mehl A.
Wear characteristics of current aesthetic dental restorative CAD/CAM materials:
Two-body wear, gloss retention, roughness and Martens hardness.
J Mech Behav Biomed Mater 2013 Apr; 20(4):113-125

5. Appendix

5.1 Bibliography

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   Development of Novel All-Ceramic Restorations and Wear, Strength, and Fatigue of Restorative Materials
   Research Report, Period 09/2012 – 06/2013 to VITA Zahnfabrik, July 22, 2013
   Principal Investigator: Russell Giordano, D.M.D., D.M.Sc., Director of Biomaterials Boston University, Goldman School of Graduate Dentistry, Department of Biomaterials, Boston MA, USA

2. Bilkhair A.
   Fatigue behavior and damage modes of a monolithic CAD/CAM hybrid ceramic (VITA ENAMIC) material compared to CAD/CAM all-ceramic posterior crown restorations. Dissertation.
   Freiburg University Hospital, Division of Oral and Maxillofacial Surgery, Department of Prosthodontics, Germany, 2014.

3. Internal studies, VITA R&D:
   VITA Zahnfabrik H. Rauter GmbH & Co. KG
   Ressort Forschung und Entwicklung
   Spitalgasse 3
   79713 Bad Säckingen, Germany
   Dr. Enno Bojemüller, Leiter Festkörperanalytik VITA F&E, VITA Zahnfabrik, Bad Säckingen
   Dr.-Ing. Andrea Coldea, Materialentwicklung F&E, Bad Säckingen
   Dipl.-Min. Berit Müller, Projektleiterin VITA F&E, VITA Zahnfabrik, Bad Säckingen
   Prof. Dr. Dr. Jens Fischer, Ressortleiter F&E, Bad Säckingen
   As of : 07.16

4. Mörmann, W; Stawarczyk, B; Ender, A; Sener, B; Attin, T; Mehl, A.:
   Wear characteristics of current aesthetic dental restorative CAD/CAM materials: Two-body wear, gloss retention, roughness and Martens hardness.
   J Mech Behav Biomed Mater 2013 Apr; 20(4):113-125

5. Rosentritt M.
   Pin-on-block wear test of different dental materials.
   Report Number: 133. Author: Priv.-Doz. Dr.-Ing. Martin Rosentritt,
   Head of Research Division, University Clinic, Regensburg, Polyclinic for Dental Prosthetics, Regensburg, Germany

6. Rosentritt M.
   Untersuchung zum 3-Medienverschleiß verschiedener Polymer-/Keramikwerkstoffe.
   Report Number: 130. Author: Priv.-Doz. Dr.-Ing. Martin Rosentritt,
   Head of Research Division, University Clinic, Regensburg, Polyclinic for Dental Prosthetics, Regensburg, Germany

7. Giordano R.
   Wear and color stability testing. Research Report to VITA Zahnfabrik,
   Principal Investigator: Russell Giordano, D.M.D., D.M.Sc., Director of Biomaterials, Boston University, Goldman School of Graduate Dentistry, Department of Biomaterials, Boston MA, USA

1. Menini M.
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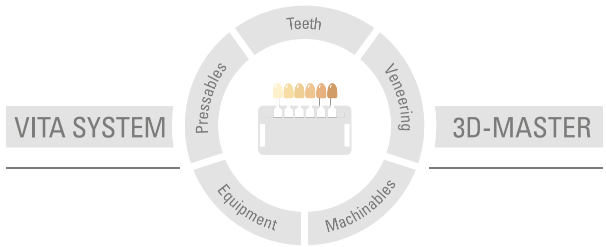
   Research report to VITA Zahnfabrik, Author: Dr. Maria Menini, Department for
   fixed and implant-prosthetic restorations, University of Genoa, Italy, 2015.

2. VITA Anwendungstechnik und Produktmanagement:
   VITA Zahnfabrik H. Rauter GmbH & Co. KG
   Ressort Vertrieb
   Spitalgasse 3, 79713 Bad Säckingen, Germany
   Claus Pukropp, Leiter Technisches Marketing, Bad Säckingen
   Andreas Buchheimer, Leiter Anwendungstechnik, Bad Säckingen
   Date of issue: 11/14

With the unique VITA SYSTEM 3D-MASTER, all natural tooth shades can be systematically determined and perfectly reproduced.



Please note: Our products must be used in accordance with the instructions for use. We accept no liability for any damage resulting from incorrect handling or usage. The user is furthermore obliged to check the product before use with regard to its suitability for the intended area of applications. We cannot accept any liability if the product is used in conjunction with materials and equipment from other manufacturers that are not compatible or not authorized for use with our product and this results in damage. The VITA Modulbox is not necessarily a component of the product. Date of issue of this information: 02.19

After the publication of this information for use any previous versions become obsolete. The current version can be found at www.vita-zahnfabrik.com

VITA Zahnfabrik has been certified and the following products bear the CE mark CE 0124 :

VITA ENAMIC®

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VITA

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