3M ESPE

All Ceramic System

technical product profile

Lava™

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1. Introduction

1.1 Overwiew

The Lava™ All-Ceramic System comprises a CAD/CAM procedure for the fabrication of all-ceramic Crowns and Bridges for anterior and posterior applications. The ceramic framework consists of zirconia supplemented by a specially designed overlay porcelain (Lava™ Ceram). The zirconia can be colored in seven different shades. The frameworks are fabricated using CAD/CAM manufacturing techniques (scanning, computer-aided design, computer-aided manufacturing) for pre-sintered zirconia blanks. The milled framework, which size has been increased to compensate for the shrinkage during sintering, is sintered in a special high-temperature furnace, thus leading to a high strength restoration with excellent fit.

Fig. 1.1: Lava™ Scan Optical 3D Scanner

Fig.1.2: Lava™ Form Computer-aided milling machine

Abb.1.3: Lava™ Therm Sintering furnace

Abb.1.4: Lava™ Frame zirconia framework

1.2 History

At all times people have tried to fabricate tooth restorations using tooth colored minerals. But only the control of the porcelain manufacturing in Europe at the beginning of the 18th century, accelerated the use of ceramics in dentistry and dental technology [1.1].
For the first time, at the end of the 18th century, the pharmacist Duchateau together with the dentist Dubois de Chemant succeeded in fabricating an all ceramic tooth restoration. At the beginning of the nineteenth century Charles Henry Land developed the porcelain jacket crown, based on a feldspathic composition, which is still used today in a slightly modified form. Fifty years later, reinforcement of the jacket crown with aluminium oxide was achieved as a result of the work of McLean and Hughes [1.2].

Further material developments, which concentrated on the inadequate fracture resistance of the ceramics, were based on increasing the crystalline content, for example leucite (Empress®), mica (Dicor®), hydroxyapatite (Cerapearl®) or glass infiltrated mixed oxides or spinells (In Ceram®) and zirconia.

Pure polycrystalline oxide ceramics have only been in clinical use for about 10 years (e.g. Procera®, see also chapter 4, Materials Science Background). For the first time they displayed a type of material that possesses sufficient stability for posterior applications, whereas pressed ceramics, such as Empress have been used successfully only for anterior crown applications for more than 10 years, however, the latter was not being used for bridges or fixed partial dentures for posterior applications. In view of the success of porcelain fused to metal for over 30 years (a minimum survival rate of 85 % after 10 years in situ is required – even for posterior bridges), any new all-ceramic system must be comparable to this standard[1,4]. Moreover, favorable conditions for a high survival rate of the all ceramic material that has been used, were also due to the adhesive bonding of Crowns and Bridges. The reason is a less critical stress situation and therefore a stabilization of relatively fracture susceptible glass ceramics by adhesive bonding. The conventional cementation, although less technically sensitive, was however, contra-indicated.

Casting (Dicor), pressing (Empress) and milling techniques (Cerec®) are all used to create morphology. The idea of using CAD/CAM techniques for the fabrication of tooth restorations originated with Duret in the 1970s. Ten years later Mörmann developed the Cerec®-system first marketed by Siemens (now Sirona), which enabled the first chairside fabrication of restorations using this technology. There has been a marked acceleration in the development of other CAD/CAM laboratory systems in recent years as a result of the rapidly increased performance of PCs and software, thus allowing the processing of high-strength polycrystalline ceramics, as e.g. zirconia.

1.3 Motivation

As a result of the requirement to provide patients with **high quality, esthetic** and **biocompatible** prosthetic dental restorations, the search for ways to fabricate all-ceramic multi-unit bridges, offering **long-term stability** also especially in posterior applications, has witnessed the limitations of glass ceramics and infiltrated ceramics.

Because of their material characteristics, frameworks based on polycrystalline ceramics are able to surmount these limitations. **Bridges for the posterior region** are also considered as an indication. It is zirconium oxide (zirconia), with its excellent **strength** and **biocompatibility** known from implant prosthetics, that makes it **the** framework material of choice. This type of framework can be **economically** fabricated by an **automated** process which supplies constant, monitored high quality and is designed to be as **flexible (in materials/indications)** as possible.

The zirconia framework also has to be the foundation of optimal esthetics **(translucency & colorability)** in combination with a perfectly matching overlay porcelain.

Due to the enormous strength and the natural esthetics of the framework, a tooth structure saving preparation as well as **traditional cementation techniques**, as used in luting porcelain fused to metal, are possible.

Biocompatibility

All-ceramic tooth restorations are considered inert with respect to oral stability and biocompatibility. The accumulation of plaque is comparable to that on the natural tooth. Due to the low thermal conductivity of the ceramic, (unlike metal-supported units), sensitivity to temperature variation is no longer expected.

Long-term stability

The main concern centers on adequate **long-term strength** under functional stress in the specified range of indications. From the clinical point of view, it is not the initial strength of the ceramic material itself that is of prime importance, but the time that the permanent restoration will last. In the case of ceramics containing glass, the type of **cementation**, adhesive bonding or conventional, is usually a decisive factor. It has a considerable effect on the stresses acting on the entire tooth preparation/restoration system.
For the clinical use of porcelains, adhesive bonding is required e.g. in the case of a **flexural strength** of around 350 MPa and a fracture toughness < 2 MPa•m1/2 (typical for glass ceramics). In the case of polycrystalline ceramic frameworks with considerably higher strength values, **conventional cementation** using glass ionomer cements may be recommended. Zinc phosphate cement is not indicated for esthetic reasons.

The lack of long-term strength (subcritical crack growth, fatigue, stress corrosion) of the glass containing ceramic systems, which are already on the market, as compared to the masticatory forces occurring in the mouth, is problematical. There is more noticeable loss of strength with glass containing systems due to the effect of oral moisture and subcritical crack growth.
To guarantee successful long-term restorations, and to allow for the material to fatigue with a prospective safety margin, an initial strength of approximately 1000 N is necessary for posterior applications,
Moreover, considering the maximal forces of 400 N in the oral anterior area and 600 N in the oral posterior area, only zirconia can guarantee the initial strength that is needed for inserting multi-unit bridges [1.5].

Conventional Working Method

Ideally, the practitioner needs a system that does not require him/her to change preparation and/or impressioning methods. The optimal system would use supragingival preparations where less tooth structure is removed, as compared with porcelain fused to metal restorations. Traditional luting, e.g. glass ionomer cements, would simplify the cementation process – and have the advantage of many years of success.

Range of indications

In modern clinical/materials scientific literature, currently available all-ceramic systems (e.g. Empress™ und In Ceram™) are seen as being suitable for crowns in anterior and some posterior applications. Anterior bridges are indicated, but posterior bridges may be suitable only as far back as the first premolar (e.g. Empress™ II). Clearly there is a need for a reliable all-ceramic system designed for use in all posterior as well as anterior situations.

Reliability

The literature describes other ceramic-specific parameters, such as **fracture toughness** and **Weibull modulus**. The Weibull modulus indicates the distribution of strength values. A high Weibull modulus (> 10) reflects a close distribution and is therefore advantageous, especially if the strength is low. However, for safety reasons a high Weibull modulus should be the goal even if there is high strength.

Accuracy of fit

Not the least consideration, a good accuracy of fit is also a determining factor for clinical success. An accuracy at the crown margin of 50 µm - 100 µm is considered ideal. A clear definition of the term ‘fit’ is important [1,6].

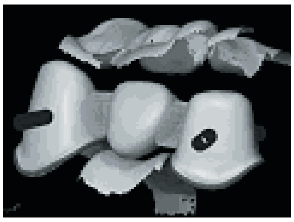
Summary

These requirements can now be achieved using precise scanning and milling technologies coupled with accurate knowledge of the zirconia ceramics.
The Lava™ crowns and bridges have been developed utilizing the accumulated knowledge of previously available materials and systems, and newly developed state-of-the-art scanning and milling expertise to provide the laboratory, dentist and patient, with the most durable and esthetic all-ceramic restorations available today.

2. Produkt-/Systembeschreibung

Working model

Scanning



Designing

Milling

Sintering

Veneering

Fig. 2.1: Process flow

The Lava™ Frame zirconium oxide frameworks are fabricated by milling centers. Each lab has the opportunity to offer its dentist CAD/CAM fabricated Lava™ restorations without any major investment and for all indications, the dentist is still able to collaborate with the laboratory that he is familiar with.

General Process Procedure (see Fig. 2.1)
After the (dental) lab has produced a sawn cut model, the milling center will digitalize the model by using the optical scanner Lava™ Scan. The restoration will then be virtually designed on the monitor using a special developed software program (CAD). The data is sent to Lava™ Form, a milling unit (CAM). The restoration is milled enlarged from a pre-sintered zirconia blank, which can be colored by choice (7 different shades) and which is then sintered to its final density in the furnace. The milling center returns the finished framework to the lab who will then veneer the framework with Lava™ Ceram and give it the final artistic finish.

Scanning with Lava™ Scan:
The unit consists of the non-contact, optical scanning System Lava™ Scan (white light triangulation), a PC with monitor and the Lava™ CAD software.

When the sawn cut model has been positioned in the scanner, the respective dies and the edentulous ridge are recorded automatically and displayed on the monitor as a three-dimensional image. In order to gain the best design, the bite registrate/occlusal record and the neighboring teeth can additionally be scanned and virtually displayed. Any unevenness and undercuts on the dies will be displayed. The CDT does not have to wax up by hand, but can do this comfortably with the Lava™ Software using a virtual wax knife. The preparation margins are automatically detected and displayed by the system, however, an individual correction on the model is also possible.

Modeling with Lava™ CAD:
At first, the software designs copings with a standardized wall thickness for crowns or abutments respectively and selects the suitable pontics from a library. Afterwards, the shape of the copings and pontics can be further individualized by using a virtual wax-knife and optimized by taking the neighboring teeth and bite registrate/occlusal record into account (Fig. 2.2 – 2.4).

Thus, the framework is designed to best support the veneer ceramic. Basal, the bridge unit is automatically fitted to the edentulous ridge taking into account the given layer thickness of the veneer ceramics. The individualized pontics can also be stored in the library for later applications. Also the positioning and the size of the cement gap as well as the cement gap enlargement are asserted by the defined basic settings, but can still be readjusted for each die. Special knowledge of the design process is not necessary. All changes will be virtually traced on the monitor. After completion, the data is then used for the calculation of the milling path.

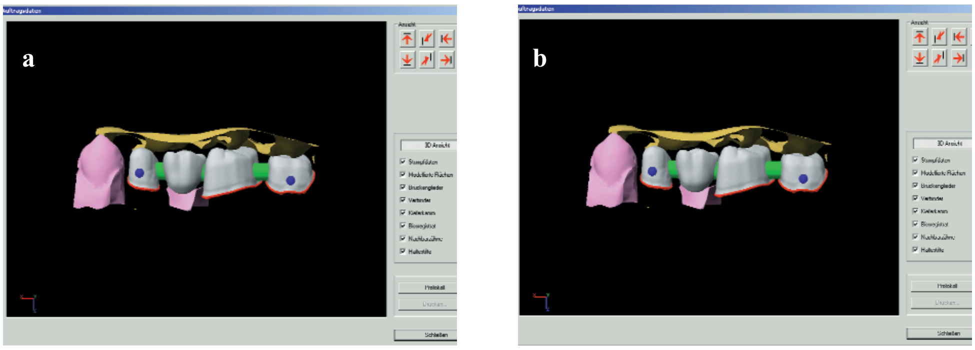


Fig. 2.2: Design of a 4-unit Lava™ Frame zirconia bridge

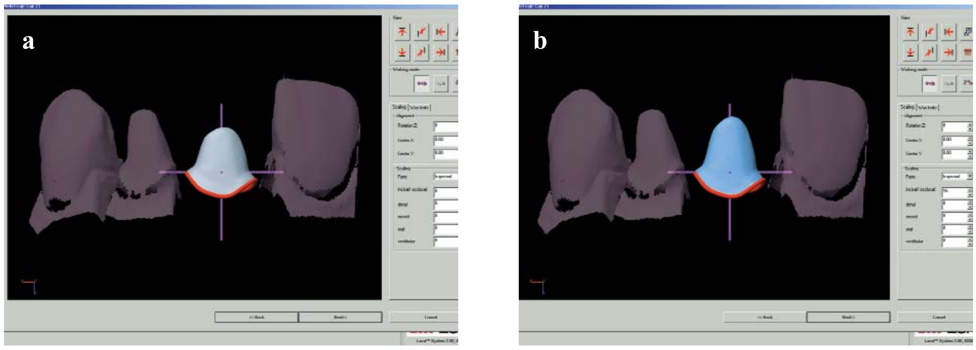


Fig. 2.3: Scaling via a virtual wax-knife

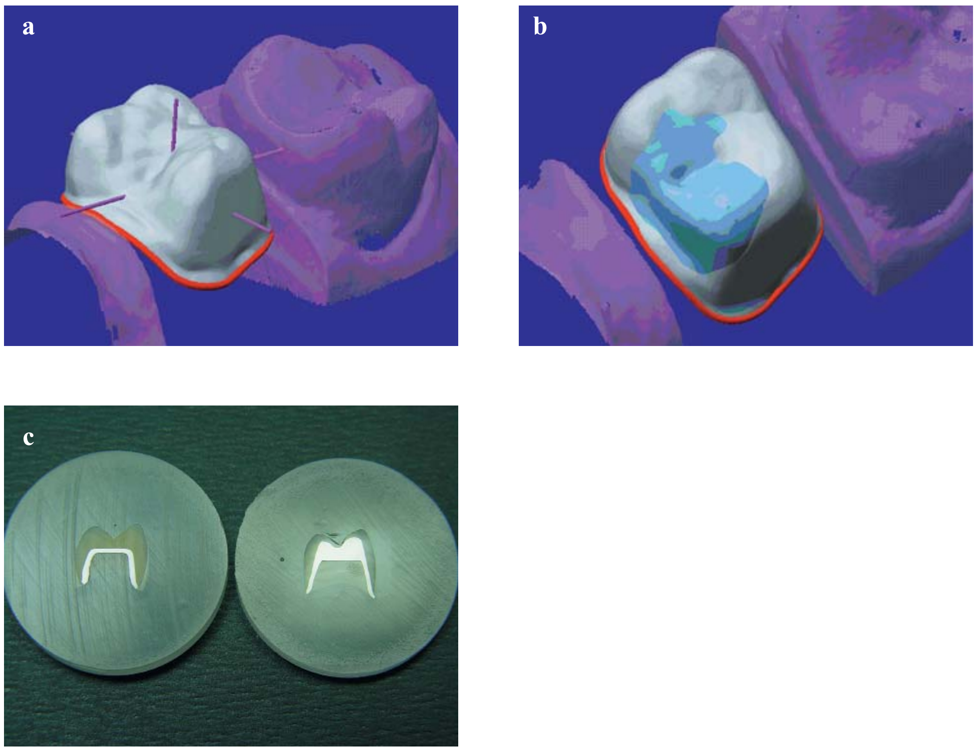


Fig. 2.4: Optimization of the tooth structure to support the veneer ceramics

Milling with Lava™ Form:
The 3D shape is milled from a pre-sintered Zirconia blank using hard metal tools. The frames are milled to a larger size according to the defined sintering parameters for the zirconia charge used, in order to compensate for the shrinkage during the sintering process. The average milling time for a 3-unit bridge is about 50 minutes. The machine has a magazine capacity of 21 blanks; new blanks can be inserted and finished frameworks removed while milling continues. Different frameworks can be milled automatically, even overnight, thanks to the automatic tool changer, thus allowing for a high throughput.

Sintering in Lava™ Therm:
Manual finishing can be carried out before sintering takes place. The coloring of the frameworks also takes place before the sintering process with respect to the prescribed veneering framework shade (7 shades, according to VITA® Classic are possible). The fully-automated, monitored sintering process then takes place with no manual handling in a special furnace, the Lava™ Therm (approx. 11 hours incl. heating and cooling phases).

Fig. 2.5: Manual finishing before sintering(a),, Coloring of Lava™ Frame zirconia framework before sintering (b)

Veneering with Lava™ Ceram:
The coefficient of thermal expansion (CTE) of the specially developed, integrated overlay porcelain has been matched closely (-0,2 ppm) to that of zirconia. The 16-shade layering system is based on the VITA Classic range. Every esthetic characterizing possibility is provided by various additional individual components. The natural translucency harmonizes very well with the translucent zirconia framework. For further information please refer to our Lava™ Ceram Layering Scheme.

Fig. 2.6: With Lava™ Ceram veneered restorations, MDT Jan Langner

Fig. 2.7: Lava™ anterior bridge framework (left); the same framework veneered after placement, CDT J.-H. Bellmann (right)

3. Clinical Aspects

3.1 Indications

Due to the outstanding mechanical and optical properties of Lava™ Frame zirconia and the Lava™ Ceram veneering ceramic it is possible to cover a wide range of crown and bridge applications for most anterior & posterior prosthetic requirements (Fig. 3.1 – 3.6).

Fig. 3.1: Lava™ anterior crowns

Fig. 3.2: Lava™ posterior crown

Fig. 3.3: 3-unit Lava™ anterior brige

Fig. 3.4: 3-unit Lava™ posterior bridged

Fig. 3.5: 4-unit Lava™ posterior bridge

Fig.3.6: 4-unit Lava™ posterior bridge inserted

3.2 Preparation

The optimal preparation is a shoulder preparation with a rounded inside angle or chamfered preparation (Fig. 3.7). In order to get an optimal scanning process, angles of ≥ 5° (horizontal) and ≥ 4° (vertical) should be adhered to.

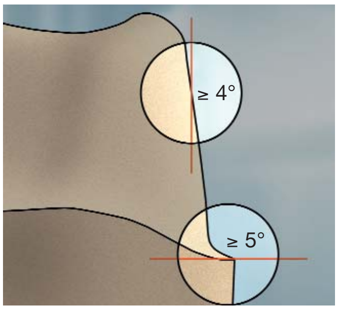


Fig. 3.7: Shoulder preparation with rounded inside angle

3.3 Cementation

The strength of Lava™ Frame zirconia is so high that adhesive cementation is not absolutely necessary. Restorations can be placed in the mouth in a conventional way by using a glass ionomer cement or by using an adhesive or self-adhesive cement. However, in the case of adhesive cements, it needs to be considered that zirconia, unlike glass ceramics, cannot be etched and therefore a silicatization/silanization (e.g. Rocatec™) for the bonding is necessary. Exemptions are self-adhesive cements (see below) which allow a direct chemical bonding with zirconia.

Conventional Cementation

In case of conventional cementation we recommend the use of glass ionomer cement, e.g. Ketac™ Cem, manufactured by 3M™ ESPE™. The use of phosphate cements fail to provide the desired esthetic results.

Fig. 3.8: Cementation of an anterior bridge with Ketac™ Cem before the removal of excess material

Self-adhesive cementation with RelyX™ Unicem

For cementation with the self-adhesive universal composite cement RelyX™ Unicem, the inside surfaces of the restoration are to be sandblasted quickly. It is however, not necessary to have a full pre-treatment with the Rocatec™ System, i.e. silicatization with Rocatec™ Soft, followed by silanization, as the special chemistry of RelyX™ Unicem bonds directly to zirconia.
For further information, please refer to the Instructions for Use of RelyX™ Unicem.

Adhesive cementation with composites

For the adhesive cementation with composite cements, the adhesive surfaces must be silicatized with Rocatec™ Soft or Cojet™ sand for 15 sec and silanized with ESPE Sil. All products are manufactured by 3M™ ESPE™. After silicatization a composite cement, e.g. RelyX™ ARC should be used without any further delay. If desired, a 'fit test' has to be done before silicatization/silanization. For details on processing, please refer to the Instructions for Use of the Rocatec™ System or Cojet™ Sand.

4. Materials Science Background

4.1 Ceramics in dentistry and its mechanical and optical properties

From a chemical perspective, a ceramic is an inorganic, non-metallic material, whose inter-atomic bonding is covalent or ionic. The material characteristics of a ceramic are determined by its basic compound composition and its structure, i.e.

1.) Of what chemical compound does a ceramic consist? (SiO_2, ZrO_2, Al_2O_3 etc.))

2.) Which atomic 3D structure, amorphous or crystalline, does a ceramic have? An amorphous structure has no long range order, whereas in a crystalline structure, every atom takes an exactly defined place within a 3D network.

All-ceramic dental materials can be very different in their chemical composition as well as in their structure and therefore demonstrate very different material properties. Veneer ceramics are feldspathic porcelains which consist almost entirely of an amorphous glass phase and therefore deliver ideal optical characteristics for the veneering. In dentistry there are three different groups of ceramics: polycrystalline ceramics, glass infiltrated ceramics and glass ceramics (see Fig. 4.1 to 4.3)

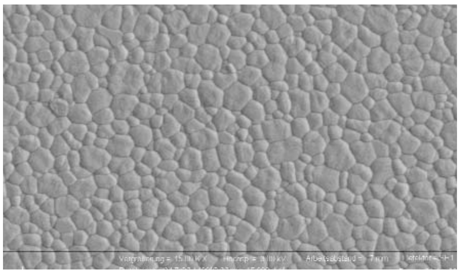


Fig. 4.1: Polycrystalline ceramic (glass-free), e.g. Lava™

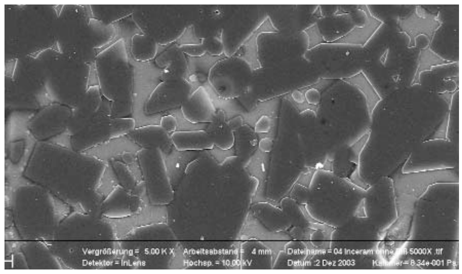


Fig. 4.2: Infiltrated ceramic (contains glass), e.g. In-Ceram™

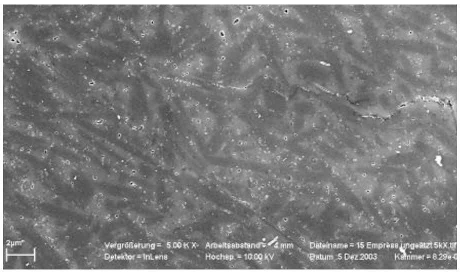


Fig. 4.3: Glass ceramic Empress® I/II (contains glass), e.g.Empress“ I/II

Glass ceramics and glass infiltrated ceramics are multi-phase materials and contain crystalline constituents (e.g. leucite crystallites in the glass ceramic Empress® II, Al_2O_3-crystals in infiltrated ceramics etc.) in addition to an amorphous glass phase.
Aluminia and zirconia are the only two polycrystalline ceramics suitable for use in dentistry as framework materials able to withstand large stresses. These materials are shown to provide both necessary esthetics (tooth color) and material properties required of a modern tooth restoration[4.1].

A dental material needs to adjust to the different influences and conditions of the oral environment. It should have high stability in order to spontaneously withstand extreme stresses and high fracture toughness in order to show the optimal tolerance level towards defects. Various examinations prove higher stability of infiltrated ceramics than of glass ceramics [4.2, 4.3, 4.4, 4.5, 4.7].
The highest stability, however, has been measured in polycrystalline ceramics [4.1, 4.2, 4.3, 4.10, 4.11., 4.12].

Next to the initial stability, especially the long-term stability is the deciding factor in the clinical success of the different systems. Therefore, the question of long-term stability which is highly dependent on subcritical crack growth and fatigue is an exceptionally important aspect in the assessment of new all-ceramic systems. An after-treatment of all-ceramic can induce micro defects [4.6], which can grow by subcritical crack growth until a critical crack length leads to fracture. The subcritical crack growth velocity is an essential parameter of ceramic material which can greatly differ from material to material. It indicates the speed at which an existing defect in the oral environment can grow subject to static and/or dynamic stress, until it results in a complete failure. The speed of crack growth also depends on the surrounding medium as well as the previously mentioned fracture toughness. H_2O in the salvia leads to so-called stress corrosion in systems containing glass (glass ceramic and infiltrated ceramic). The water (salvia) reacts with the glass causing corrosion of the latter, leading to increased crack propagation velocities and consequently to long-term strength issues. On the other hand, systems having a polycrystalline micro-structure, such as ZrO_2 or Al_2O_3 are to a greater extent glass-free and display excellent long-term stability (see next chapter; [4.1, 4.11]).

Zirconia used in demanding environments is usually a tetragonal polycrystalline zirconia partially stabilized with yttria (Y-TZP = yttria tetragonal zirconia polycrystals) (addition of about 3mol %). This material is referred to as a transformation toughened material and it has the special property of a certain fracture inhibiting function. Tensile stresses acting at the 'crack tip' induce a transformation of the metastable tetragonal zirconia phase into the thermodynamically more favorable form. This transformation is associated with a local increase in volume, resulting in localized compressive stresses being generated at the 'crack tip', which counteract the external stresses acting on the crack tip. The result is a high initial strength and fracture toughness and, in combination with a low susceptibility to stress fatigue, an excellent life-time expectancy for zirconia frameworks.

Afterwards, restorations made from ceramic frameworks have to be esthetically veneered. Thereby the coefficients of thermal expansion (CTE) of both ceramics have to be checked against each other, especially for zirconia which shows a relatively low CTE (approx. 10 ppm). Special veneer ceramics with the same or lower CTE have been developed during the last few years. These veneer ceramics bond very well to the zirconia (see Material Characteristics Lava™ Ceram).

Various in-vitro trials confirm the enormously high fracture strength of veneered 3-unit zirconia posterior bridges [4.10]. Values greater than 2000 N have been achieved, which exceeds the maximum masticatory load by a factor of 3 - 4. With this strength, zirconia bridges demonstrate markedly better values than other all-ceramic bridges. Consequently, zirconia can now be considered a suitable framework material for multi-unit posterior bridges.
The strength values and high fracture toughness (resistance to crack propagation, K_{IC} around 5 to 10 MPa $m^{1/2}$ also enable a lower framework wall thickness than other all-ceramic systems previously available. Instead of a coping thickness of 1 mm, a Lava™ framework/coping wall thickness of 0.5 mm or 0.3 mm (anterior crowns) are considered adequate. This allows preparations requiring less aggressive tooth reduction than with most systems currently on the market. The excellent esthetics of the zirconia framework (ideal translucency and shading, see below) also enables the thickness of the veneer layer to be minimized leading to a conservative preparation technique similar to porcelain fused to metal.

4.2 Manufacturing process for Polycrystalline Oxide Ceramics

Today, polycrystalline oxide ceramics are mainly processed by applying CAD/CAM technology using industrial pre-fabricated ceramic blocks which possess a very high micro-structure quality due to a standardized manufacturing procedure.
Frames can either be fabricated by grinding already sintered blanks (e.g. DCS®, Celay®), which is both time-consuming and leads to a high mechanical wear on tools, or by processing non-sintered or pre-sintered zirconia blanks (e.g. Lava™). In the latter, restorations are milled from pre-sintered zirconia and are subsequently sintered to their full density. Thereby, the milling times are considerably shortened and the mechanical wear on the tools decreased. The restoration must, however, be milled in a larger size in order to compensate for the shrinkage during the sintering process (also see chapter 5.7 Accuracy of Fit).

4.3 Surface Finishing

The surface finishing of ceramic materials has a decisive effect on the material's flexural strength. The grinding and milling of sintered ceramics usually leads to a reduction in strength (micro defects on the surface) of the total restoration. The finishing, by grinding or milling, of sintered zirconia frameworks (either by means of the fabrication process, such as DCS, or finishing in the dental laboratory) may lead to a loss of strength compared to finishing in the green, or pre-sintered state (Lava™, 3M ESPE techniques). The finishing of sintered frameworks using grinding or milling tools is contra-indicated on the gingival side of the connector area because here enhanced tensile stress is formed.
After milling and sintering, the internal surface of the crown shows an efficient micro-retention for bonding with the cement (see chapter 3.3 Cementation). If, however, after-treatment is still necessary, fine-grained diamonds (< 40µm; [4.12]) and water cooling must be used.

5. Material Properties of Lava™ Frame & Lava™ Ceram

5.1 Overview

Zirconia has proven itself as a biocompatible material in implant dental surgery for many years. Lava™ Frame zirconia demonstrates no measurable solubility or water absorption and shows a high initial stability and excellent long term stability. Therefore, the strength of this material is maintained, even after a long period in the mouth. Lava™ Frame zirconia has no allergenic potential and is very biocompatible. Lava™ Ceram overlay porcelain has all the familiar advantages of a feldspathic overlay porcelain with respect to biocompatibility and abrasion characteristics.

Zirconia withstands many times the load level occurring in the mouth (loads measured for anterior teeth up to 400 N, posterior teeth up to 600 N, for bruxism even up to 800 N [5.1; 5.2; 5.3; 5.4; 5.5; 5.6]). Its strength is considerably higher than other all-ceramic materials. Unlike infiltrated or glass ceramics, Lava™ Frame zirconia is particularly suitable for posterior bridge frameworks and for long spans. Fig. 5.1 gives an overview of the most important external and internal examinations with regard to the mechanical and optical properties of Lava™ Frame zirconia as well as the accuracy of fit and stability of real geometries (Crowns and Bridges) which have been carried out so far.

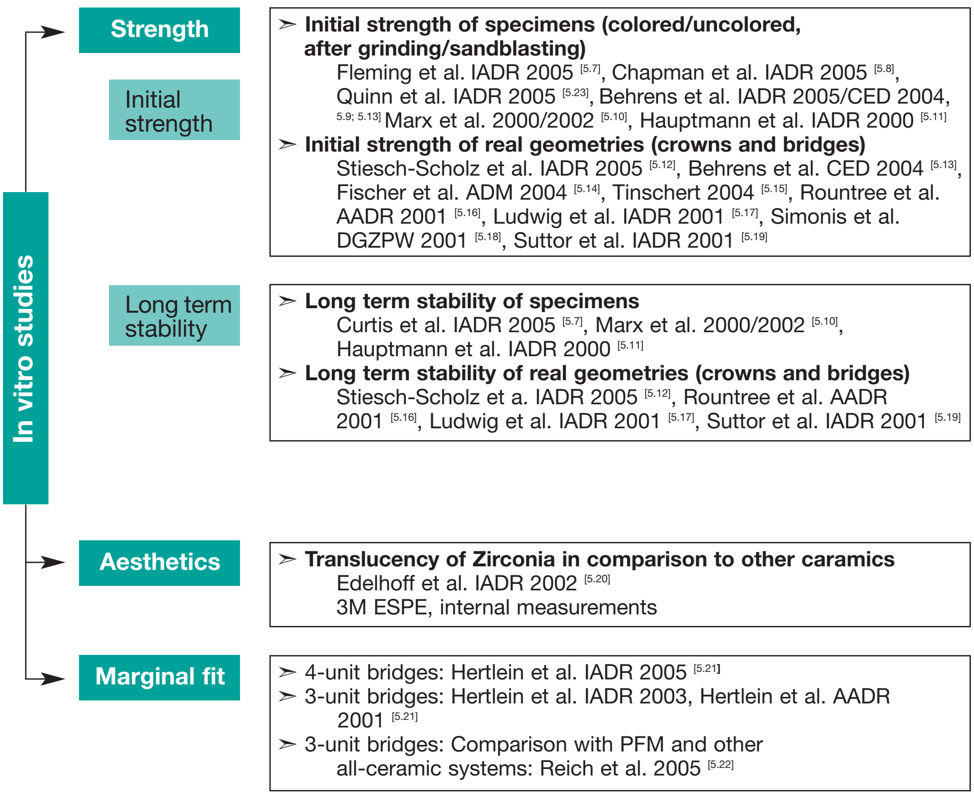


Fig. 5.1: Overview of the most important external and internal examinations with regard to the material's mechanical and optical properties as well as the accuracy of fit, which have been carried out so far.

Within the scope of the Technical Product Profile not every investigation can be explained in detail. An explanation should, however, be given about the most important mechanical and optical properties of the material. For further examinations, please refer to our brochure "Espertise & Scientific Facts Lava™ Frame Crowns and Bridges and the Compendium" All-Ceramic Material (P. Pospiech, J. Tinschert, A. Raigrodski, 3M ESPE).

5.2 Material Specifications

1. Lava™ Framework Ceramic

Density (ρ):	6.08 g/cm³
Flexural Strength (sB) (Punch Test)(#121473):	> 1100 MPa
Fracture Toughness (K_{IC}):	5-10 MPa $m^{1/2}$
(Youngs) Modulus of elasticity (E):	> 205 GPa
CTE:	10 ppm
Melting point:	2700 °C
Grain size:	0,5 µm
Vickers hardness (HV 10:	1250

2. Lava™ Ceram Overlay Porcelain

Density (ρ):	2,5 g/cm3
Flexural strength (σ_0) (3-Point):	100 MPa
Fracture toughness (K_{IC}):	1,1 MPa $m^{1/2}$
(Youngs) Modulus of elasticity (E):	80 GPa
CTE:	10 ppm
Firing temperature:	810 °C
Grain size (D50):	25 µm
Vickers hardness (HV 0,2):	530

5.3 Stability of the material

a.) Initial stability

Lava™ Frame zirconia possesses an excellent initial stability of >1100 MPa (see table 5.2). The internal test results achieved by 3M ESPE have been confirmed by test results achieved by external scientists and show that the stability of Lava™ Frame zirconia is much higher than other all-ceramic materials (Fig. 5.3 standardized data according to ISO 6872). Moreover, there was no noticeable loss of stability in the ceramic, after the material was sandblasted and grinded with fine grained diamonds (< 30 µm) (see Fig. 5.4; [4.12, 5.7, 5.25]).

Table 5.2: Flexural strengths of Lava™ Frame zirconia

Reference	Flexural Strength (MPa)	Method of examination
3M™ ESPE™	> 1100	Weibull strength, punch-test, ISO 6872
Dr. G. Fleming et al. [4.11;4.12; 5.7]	1267±161	Weibull strength, punch-test,
Prof. R. Marx/ Dr. H. Fischer [5.10]	1345	Weibull strength, flexural test DIN V ENV 843
Dr. J. Quinn et al. [5.23]	1066±131	Weibull strength 4-point flexural test

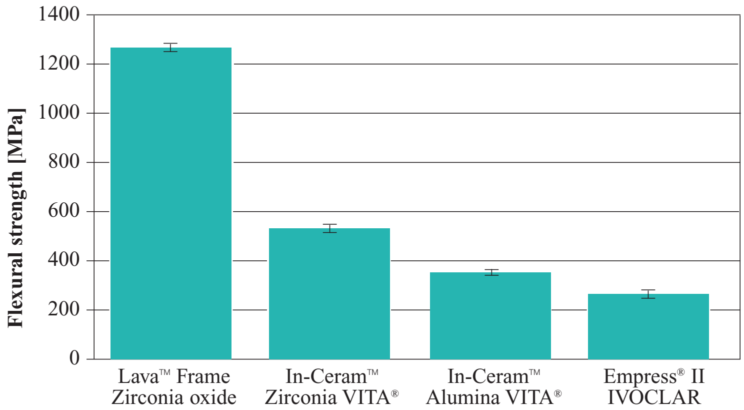


Fig.5.3: Standardized date according to ISO 6872 (dental ceramic), flexural strength of Lava™ Frame zirconia determined by the punch-test.

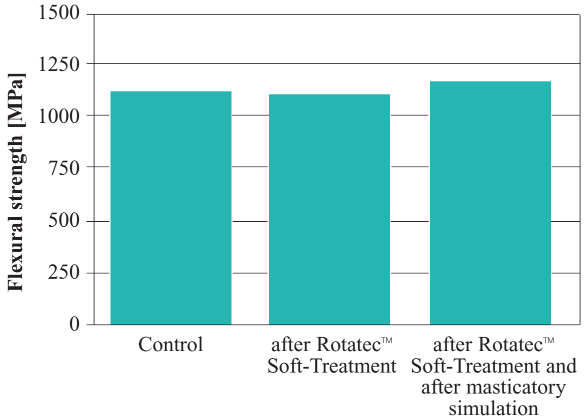


Fig. 5.4: Weibull strengths of Lava™ Frame zirconia after treatment with Rocatec™ Soft and after additional masticatory simulation (50N, 1,2 millions cycles + Thermocycling 5°/55°, 3800 cycles).

Lava™ Ceram also shows very high flexural strengths (>100 MPa) and thereby supports the initial and long-term stability of the entire restoration.

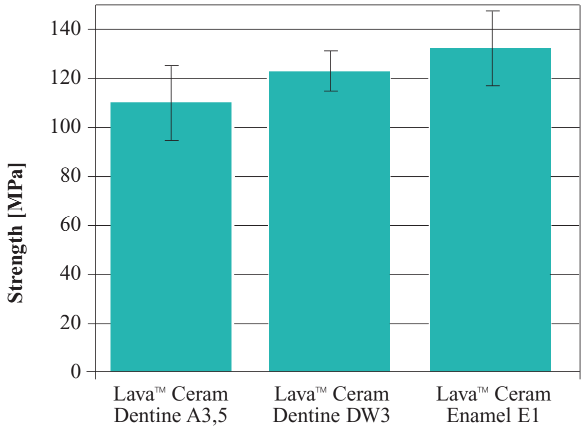


Fig. 5.5: Standardized data according to ISO 6872 (dental ceramic), flexural strength of Lava™ Ceram determined by the 3-point flexural test.

b.) Long-term stability

Table 5.6: Material specification of different dental ceramics

Ceramic	Weibull strength σ_0 [MPa]	Weibull-modulus m [-]	Fracture toughness K_{IC} [MPa√m]	crack growth parameter n [-]	crack growth parameter B [$MPa^2 sec$]
Lava™ Frame	1345	10,5	9,6	50*	-
InCeram™ Alumina	290	4,6	5	18	$6{,}0 \cdot 10^1$
Cerec (VITA® Mark II)	88	24	1,3	26	$1{,}8 \cdot 10^1$
Dicor	76	6	0,8	25	$2{,}9 \cdot 10^1$
Empress® I	89	9	1,2	25	$5{,}8 \cdot 10^1$
Empress® II	289	9	2,5	20	$2{,}3 \cdot 10^3$
HiCeram®	135	9	2,5	20	$1{,}2 \cdot 10^3$
Hydroxylapatit	114	6	0,9	17	$2{,}2 \cdot 10^2$
VITA® Omega Opaker	69	12	1,4	21	$7{,}2 \cdot 10^1$

This data was ascertained by Prof. R. Marx and Dr. H. Fischer, Aachen [4.1].

Long-term stability can be determined by calculating the life-time expectancy. The life-time of the material (see Table 5.7) can be calculated by using both the initial stability and the coefficients of the subcritical crack growth, which characterize the rate of fracture growth of a certain material (see table 5.6, parameters n and B).

Table 5.7: Long-term stability assessment of Lava™ Frame zirconia in comparison with other all-ceramic materials (boundary conditions: 60 % humidity, 22°C, static continuous loading)

	Lava Frame	Empress II	In-Ceram Alumina	VITA® Mark II
$\sigma_{2\%}$ 5 Jahre [MPa]	615	80	125	30

Source: Prof. Marx, Dr. Fischer Aachen and internal measurements

Table 5.7 has to be interpreted as follows: A Lava™ Frame zirconia specimen is tested over a period of 5 years. During this time the specimen is permanently exposed to humidity and a continuous load of 615 MPa is applied. Result: failure rate of 2 %. An Empress® II specimen fails already when a continuous load of only 80 MPa has been reached.

Long-term stabilities can also be determined by artificial ageing of the specimen. Thereby, the cyclic masticatory forces and thermal fluctuation in the oral environment are simulated after which the strength of the specimen will be determined. Dr. G. Fleming from the University of Birmingham did not notice any significant decrease in strength of Lava™ Frame zirconia, after the specimen was cyclically loaded with 80N, 500N, 700N and 800N (Table 5.8). At the same time the scattering of the strength data and consequently the reliability of the material were improved. [4.11, 5.7]. Internal measurements also show, that after treatment with Rocatec™, the strength was not altered significantly when a cycling load (1.2 millions of cycles, 50N) and thermocycling (5°/55°) were applied.

Table 5.8: Strengths of Lava™ Frame zirconia specimens after fatiguing (measured by Dr. G. Fleming, University of Birmingham) [4.11]

	Control	80N (100 000 cycles)	500N (2000 cycles)	700N (2000 cycles)	800N (2000 cycles)
Weibull strength (dry)/MPa	1267±161	1195±191	1216±136	1246±104	1259±101
Weibull strength (cyclic load in water) /MPa	1308±188	-	1216±141	1221±150	1191±127

In addition Lava™ Ceram does not show any significant loss in strength after thermocycling (Fig. 5.9).

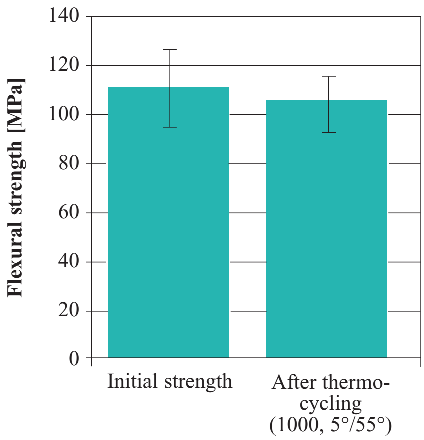


Fig. 5.9: Flexural strength of Lava™ Ceram before and after thermocycling (ISO 6872)

5.4 Strength of Real Geometries

a.) Initial strength

Fig. 5.10 shows the strength of different Lava™ indications (internal measurements carried out by 3M ESPE). Also 4-unit Lava™ bridges show a strength which is twice or three times higher than the expected maximal masticatory forces of 400 N in the anterior region and 600 N in the posterior region [5.1; 5.2; 5.3; 5.4; 5.5;]. These values for both non-veneered and veneered Lava™ restorations (3-unit and 4-unit bridges) were also confirmed by Dr. J. Tinschert from the University Aachen (Fig. 5.11).

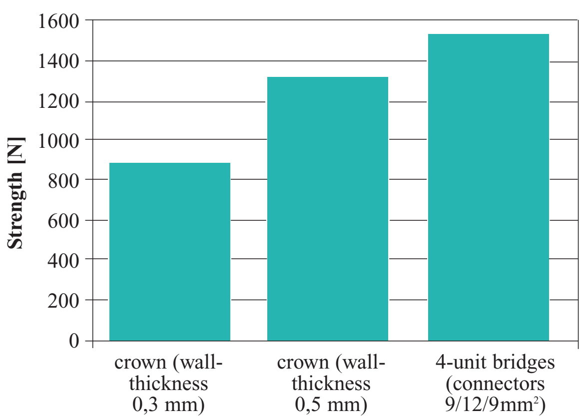


Fig. 5.10: Weibull Strength of different Lava™ Frame zirconia restorations

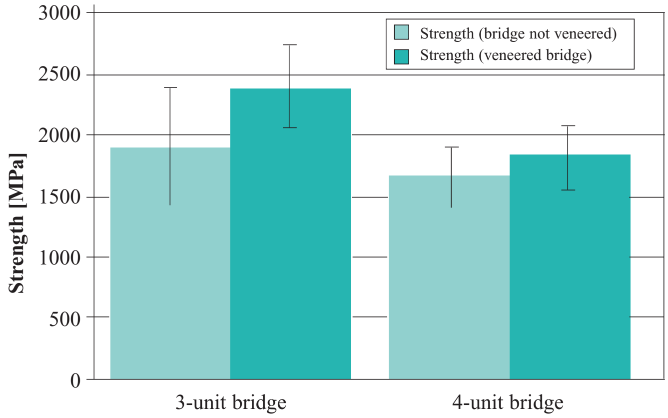


Fig. 5.11: Strength of 3- and 4-unit Lava™ Frame zirconia restorations with and without veneering with Lava™ Ceram Overlay Porcelain, measured by PD Dr. J. Tinschert, University of Aachen

b.) Long-term stabilities

Fracture strength of 3-unit posterior bridges (patient models) before and after masticatory simulation as determined by Prof. Pospiech , Dr. Nothdurft and Dr. Roundtree (University of Munich, University of Homburg) [5.16, 5.24].

The bridges were resiliently mounted after cementation with Ketac Cem (mean values of 8 bridges) and the fracture strength was measured.

a) initially after 24 h: **approx. 1800 N**
b) after 1.2 million masticatory load cycles (50N) and 10.000 thermocycles: **approx. 1450 N**

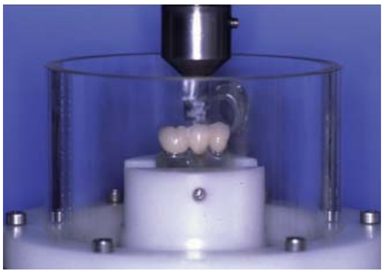


Fig. 5.12: Set-up for masticatory simulation and thermocycle

Fig. 5.13: Fracture test

The slight decrease in the values combined with exceeding the maximum masticatory loading for posterior teeth of approx. 600 N (see above) after simulating 5 years of wear suggests an excellent probability of survival.

Prof. Ludwig (University of Kiel) analyzed the fracture strength and the long-term strength of 3-unit Lava™ anterior bridges before and after masticatory simulation [5.17; 5.24].

The bridges were resiliently mounted after cementation with glass ionomer.
6 bridges (11-22) were loaded from an angle of 30° until fracture occurred.

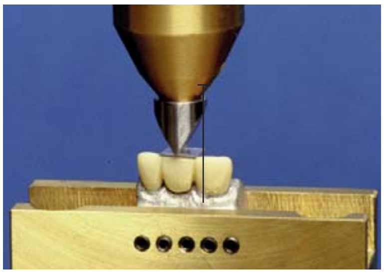


Fig. 5.14: Measurement of static fracture load

a) Initially (24h storage in water): static fracture load: **1430 N**
b) Long-term strength after masticatory simulation (1.2 million cycles – corresponding in clinical terms to approx. 5 years of wear, at 250 N, incl. thermocycling 5°/ 55°C): **no fracture**

Prof. Ludwig concluded, based upon the maximum masticatory force on the anterior teeth of 180 N, that Lava™ anterior bridges are clinically resistant to fracture in long term usage.

5.5 Abrasion

In a masticatory simulator in Erlangen (Dr. U. Lohbauer, University of Erlangen), hemispheres made from the overlay porcelains under examination were tested against bovine enamel. Lava™ Ceram was compared with Empress® II und VITA® Omega 900 (spherical) against bovine enamel (ground flat), and Lava™ Ceram itself.

The analyses were made using a scanning electron microscope (SEM) both for the spheres and the specimens, and volumetric examinations were carried out.

The value of abrasion after 200,000 Cyles with a load of 50 N and a further 1,500 cycles under thermocycle (5°C and 55°C) likewise with a load of 50 N, resulted in a mean wear of 10^{-3} mm^3 for all overlay porcelains.

Other findings:

- Differences between the individual groups cannot be established to a significant degree
- The abrasion of two ceramic surfaces in contact with each other is higher than in contact with the bovine enamel.
- The abrasion traces on the spheres are very slight and are within the same size range amongst the groups.
- Fractures which can be detected on the enamel samples on the SEM images are natural fractures in the enamel and are not attributable to the abrasion process.

The Lava™ Ceram overlay porcelain displays no fundamental differences to other commercially available products examined as far as abrasion is concerned.

5.6 Optical Properties/Esthetics

a.) Translucency of Zirconia

The translucency of the material depends not only on the material properties of the ceramic, but also on the recommended thickness of the layer, i.e. the wall thickness. Considering that zirconia requires less wall thickness due to its stability (Lava™ Frame zirconia: 0.5 mm; Empress® II: 0.8 mm), the relative translucency of Lava™ Frame zirconia and Empress II are still comparable (Fig. 5.15).

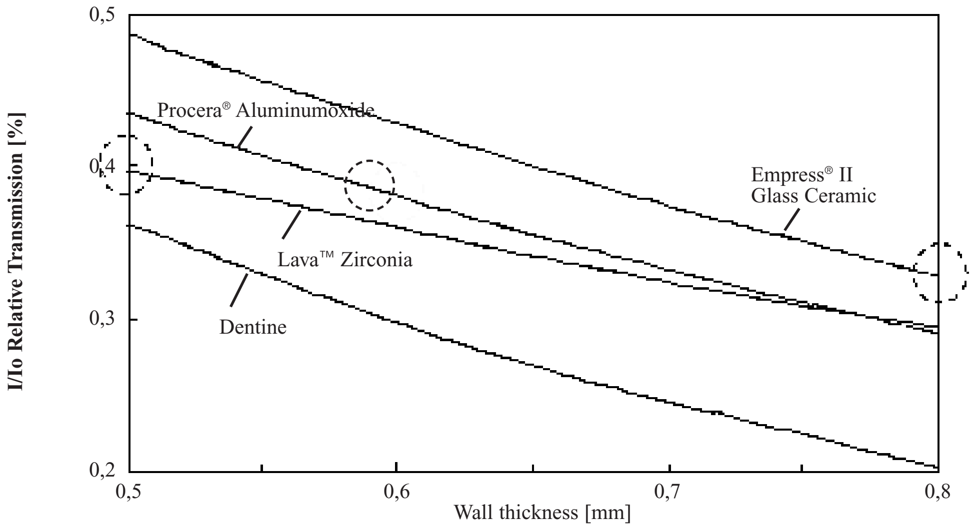
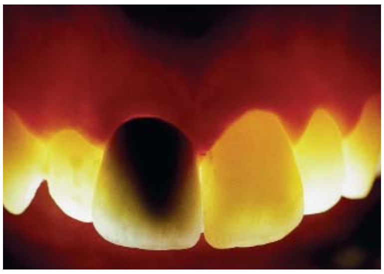


Fig. 5.15: Comparison of translucency as a function of wall (coping) thickness

With a wall thickness of 0.3 mm , as used for Lava™ anterior bridges, the transluceny of Lava™ Frame zirconia can be improved even further. (Fig. 5.16).



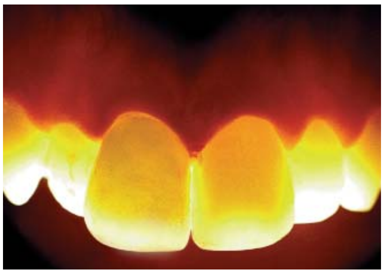


Fig. 5.16: Comparison of the translucency of a metal-ceramic (PMF) crown (a) and a Lava™ Crown (b) with a 0.3 mm layering thickness (11). PD Dr. D. Edelhoff, und MDT V. Weber, Aachen

b.) Esthetics

With the classic color scheme of 16 colors, all tooth shades can be easily reproduced. Special effect components and stains lead to a natural esthetic.

The Lava™ Ceram overlay porcelain components are optimal, matching the range of shades which can be applied to the framework made from Lava™ Frame zirconia. This results in a harmonic color appearance and blends naturally into the oral environment (see also Lava™ Layering Scheme).

The ideal translucency results from the material properties and the low wall thickness of the sintered zirconia. No light-absorbent opaquer or opaque dentine layers are necessary for the build-up of Lava™ all-ceramic restorations.

Moreover, the relatively thin framework permits optimal modeling even in difficult situations. An appropriate selection of unique modifiers complete the Lava™ Ceram set.

The framework can be colored in 7 shades in the VITA® Classic color scheme and is therefore ideal for a natural looking build-up (Fig. 5.17).

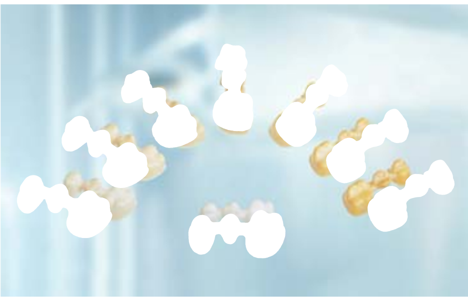


Fig. 5.17: 7 different colored frameworks (first bridge not colored)

Fig. 5.18: Lava™ anterior bridge from 11 to 13, MDT J-H. Bellmann

Fig. 5.19: Anterior crown with Lava™ zirconia with a wall thickness of 0.3 mm (11, 12) and veneer.

5.7 Accuracy of Fit

Lava™ Crowns and Bridges have an excellent accuracy of fit. The Lava™ Form milling unit operates on a high and reproducible accuracy level, as well as the scanning device Lava™ Scan.

In the Lava™ procedure the crown or bridge framework is milled from a so-called 'greenbody' (called blank). This blank is made from presintered zirconia and is therefore considerably softer than dense and fully sintered material. Milling is thus performed quickly, accurately and economically before the extreme strength is achieved during the final sintering. The material shrinks linear by 20% during the final sintering. In order to compensate for this sintering shrinkage, the frames are milled in an enlarged scale corresponding to the sintering parameters defined for this zirconia batch. An excellent fit is achieved due to the high accuracy and the exactly defined sintering parameters.

Control of this procedure provides one of the fundamental innovations of the Lava™ technique. Specific 3M™ ESPE™ know-how and sophisticated production processes for the presintered blanks ensure accuracy of fit.

Studies of marginal fit measurements for 3- and 4-unit Lava™ bridges produced values of less than 40 µm or less than 70 µm for MO (marginal opening, see below) and AMO (absolute marginal opening, see below) (Table 5.21, [5.21]). Furthermore, Dr. S. Reich, University of Erlangen, was able to show that there is no significant difference between the AMO-values for 3-unit Lava™ restorations and metal-ceramic restorations[5.22].

Table 5.21: MO and AMO values for different Lava™ bridges (K = abutment, B = bridge unit)

Values in µm	KKKK	KKBK	KBK
MO	31±23	29±26	25±10
AMO	68±37	67±35	59±21

Fig. 5.22: Light-optical microscope exposure: cross-section of 4 splinted crowns in the posterior region

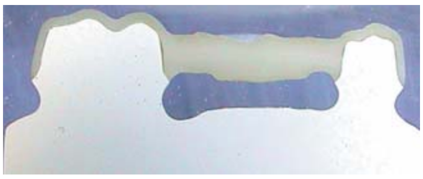


Fig. 5.23: Light-optical microscope exposure: cross-section of a 3-unit posterior-bridge from 35 - 37

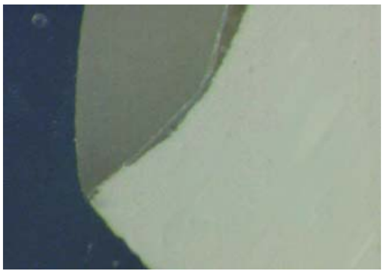


Abb. 5.24: Detail enlargement 37 buccal

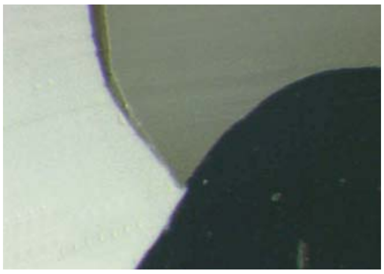


Abb. 5.25: Detail enlargement 37 mesial

MO (marginal opening) can be interpreted as the distance between the framework and the abutment close to the crown margin. AMO (absolute marginal opening) also includes possible contouring work above and below and measures the distance between the end of the crown margin and the preparation margin[5.26].

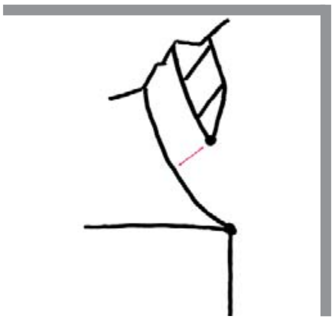


Fig. 5.26: MO with underextension

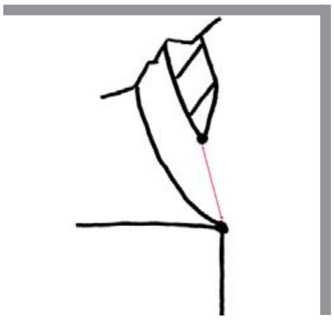


Fig. 5.27: AMO with underextension

5.8 Biocompatibility

Another remarkable feature of zirconia, in addition to its extraordinary strength, is its very high level of biocompatibility. For this reason it has already been in use for more than a decade as a material for surgical implants. The zirconia utilized, and likewise the overlay porcelain, manifests no measurable solubility or allergy potential and produces no irritation of the tissue.

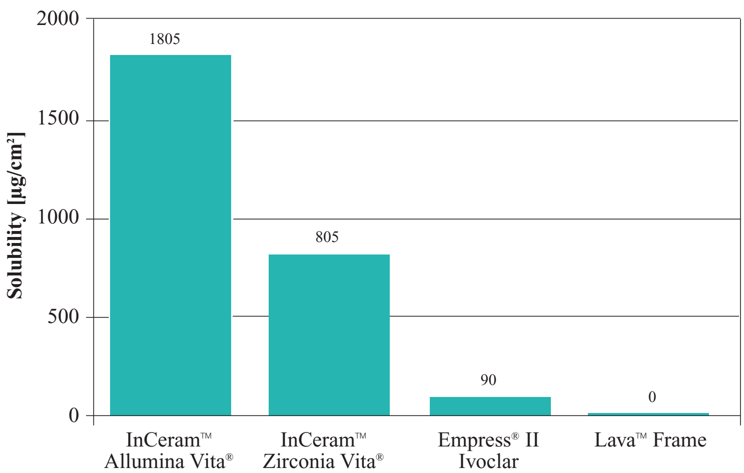


Fig. 5.28: Chemical solubility of zirconia used for Lava™ Frame: The unmeasurable solubility shows the high biocompatibility of the zirconia (Lava™ Frame).

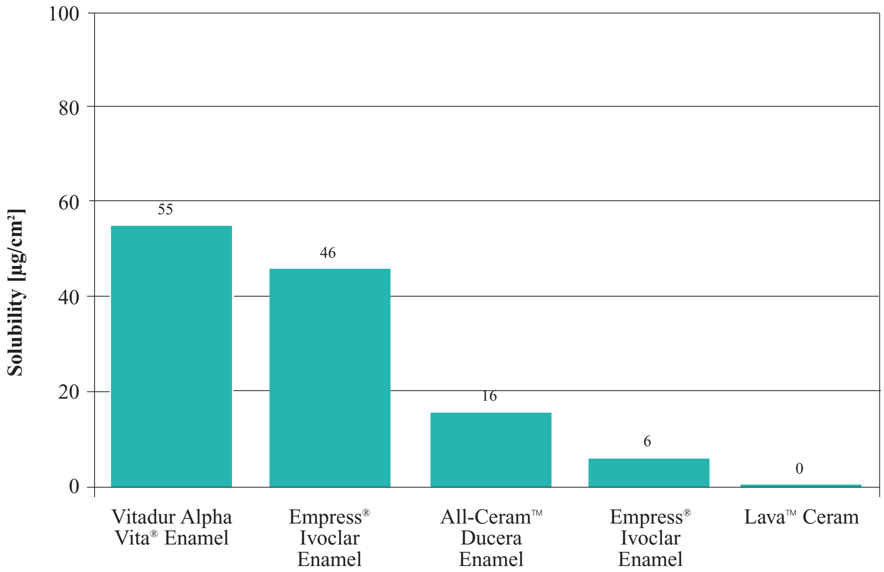


Fig. 5.29: Chemical solubility of the overlay porcelain Lava™ Ceram. Like for the framework ceramic the solubility cannot be measured. This shows its high biocompatibility.

The considerably lower thermal conductivity in comparison to metals provides comfort for the patient. Moreover, the material does not contribute to galvanic processes in situ.

6. Clinical Results

Since its launch in 2002, the Lava™ System has established itself in the market as one of the leading all-ceramic systems and looks back to a successful 5-years clinical experience.

Several clinical studies in different countries [Figure 6.1] confirm an excellent clinical performance of Lava™ restorations [6.1; 6.2; 6.3]. The longest running Lava™ study so far is conducted by Prof. Peter Pospiech, University of Homburg/Saar according to EN 540 (ISO 14 155) since summer 2000. In this survey, 34 patients fitted with 38 3-unit posterior bridges are being monitored for a period of 5 years [6.1; 6.2]. The study is already running for 4,5 years and until today there was no fracture of a restoration, no allergic reaction and no negative influence on the neighboring gingiva [6.1; 6.2]. These results are confirmed by the clinical studies of Prof. A. Raigrodski (University of Washington, Seattle) and Prof. G. Chiche (Louisiana State University, New Orleans), who are also testing 3-unit Lava™ posterior bridges [6.3]. Figure 6.1. gives a overview of studies started with Lava™ restorations.

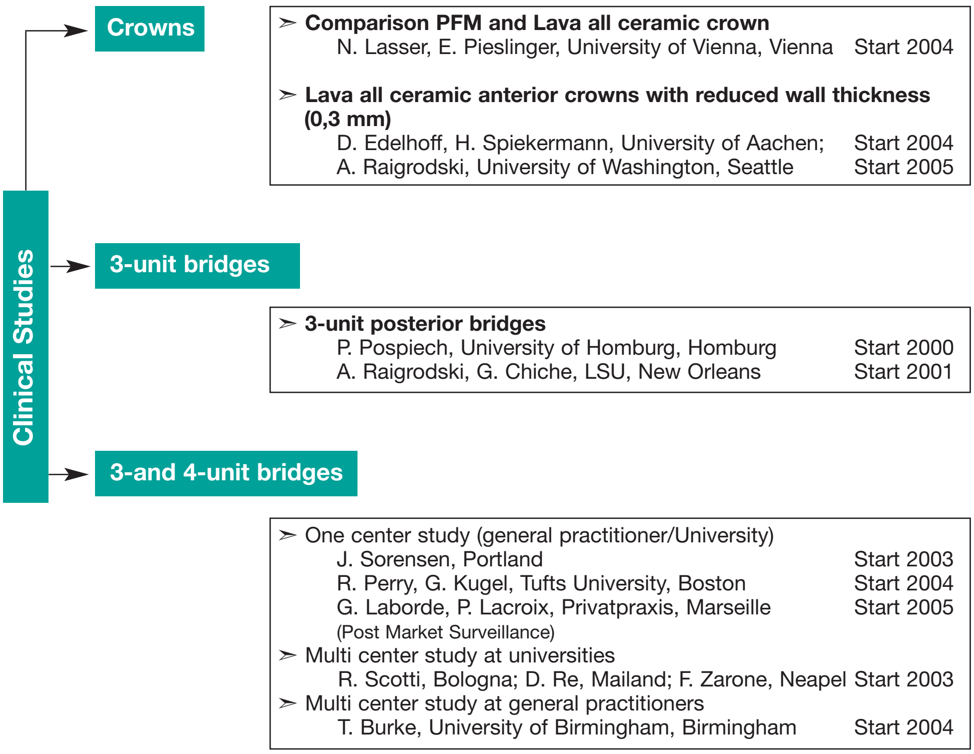


Fig. 6.1: Overview of clinical studies with Lava™ Crowns and Bridges

Fig. 6.2: 3-unit posterior bridge 25 to 27 (Source: G. Neuendorff, Filderstadt)

7. Instructions for Use

7.1 The Framework Ceramic

Lava Frame

Zirconia Crown/Bridge Mill Blanks

Product Description

Lava™ Frame Zirconia mill blanks are used for the fabrication of frameworks for all-ceramic restorations. The frameworks are designed at the Lava Scan™ computer, which then calculates the milling data. The blanks are processed in the CNC milling unit Lava™ Form. After milling, the frameworks are dyed with one of the 7 Lava Frame Shade dyeing liquids as required to achieve the desired tooth color, then sintered. The dyed frameworks are sintered using the specialized program of the Lava™ Therm sintering furnace. All of the Lava products are manufactured by or for 3M ESPE.

☞ Instructions for Use should not be discarded for the duration of the product use. For details on all mentioned products, please refer to the respective Instructions for Use.

Areas of Application

Fabrication of all-ceramic frameworks for the anterior and posterior teeth, taking into consideration the prescribed coping wall thicknesses and connector cross-sections, see "Framework Design":

- Single crowns
- Up to 4-unit bridges
- Blockings
- Cantilever bridges with incisor or premolar as final bridge unit (cantilever bridges have not been approved for patients with bruxism)

Perfectly fitting restorations can be manufactured only in compliance with the preparation guidelines, see Lava Scan operating instructions.

Model Preparation

- A light plaster (white, beige, light gray, light blue, ISO 6873, Type 4) without polymer additions must be used for model preparation. The model must not have any silicon oil residue (e. g., from doublication or bite registration).
- All segments of the saw cut model have to be removable and secured against rotation (double pin or block pin).
- The model base should have a smooth bottom.We recommend the use of the universal model holder to fix the models in the scanner.
- The die must have a sharp undercut underneath the preparation margin; the preparation margin must not be marked, and the die must not be varnished or hardened.
- Block out defects and undercuts (as necessary, after consultation with the dentist) with a light wax.
- Reflecting areas on the die are detrimental for the scanning procedure; if necessary, dull these areas with a suitable scan spray (e. g., Scan Spray from the company Dentaco).
- If there are blockings, the interdental space between the margins must be a minimum of 1 mm.

- Caution: In cases of distinct bifurcation, there may, in rare cases, be insufficient detection, inherent to the system, of the preparation margin. We recommend blocking out these areas as a preventive measure and using a diamond tool to fit the framework afterwards.

Framework Design

The coping wall thicknesses and connector cross-sections are decisive for the strength of the later restoration. Perfect milling results depend, among other factors, on the correct positioning of the holding pins and the ideal milling direction.
The design of the frameworks, the positioning of the holding pins, and the alignment in the mill blank are done after digitalization at the Lava Scan computer.

- When entering data into the Lava Scan computer, please observe the design guidelines described in the Lava Scan Operating Instructions.
- Generally speaking, the coping wall thickness must not be less than 0.5 mm.
  There are the following exceptions:
  – Anterior copings ≥ 0.3 mm, but not in cases of bruxism.
  – Abutment tooth coping to the cantilever bridge unit for posterior teeth ≥ 0.7 mm.
  – Abutment tooth coping to the cantilever bridge unit for anterior teeth ≥ 0.6 mm.
- Connector cross-sections must not be less than shown below.

– Anterior tooth:	Bridge unit – bridge unit	7 mm^2
	Die – bridge unit	7 mm^2
	Die – die	7 mm^2
	Die – cantilever bridge unit	8 mm^2
– Posterior tooth:	Bridge unit – bridge unit	12 mm^2
	Die – bridge unit	9 mm^2
	Die – die	9 mm^2
	Die – cantilever bridge unit	12 mm^2

- For anterior copings with a wall thickness of less than 0.5 mm, the holding pins should be positioned at the height of the tooth equator or higher. Otherwise, the coping margins may be damaged during removal.

Caution: Failure to observe the prescribed minimum wall thickness or connector cross-section may cause fracture of the later restoration. In extreme cases, the patient may swallow or even breathe in parts, resulting in risks to his/her health. Surgical intervention may be required under certain circumstances. In general, the risk of fracture is greater for cantilever bridges. Users are themselves responsible for the use of Lava Frame only for the approved indications, for observing the prescribed minimum wall thicknesses and connector crosssections, and for the correct positioning of the holding pins.

Preparation of the Milling Unit

- Use only burrs of type 4 (rough milling), 5 (finishing), and 6 (fine-finishing) for milling frameworks in the CNC milling unit Lava Form; see also the Lava Form operating instructions.
- Prior to processing Lava Frame frameworks, clean the milling chamber of the Lava Form milling unit and make sure that no oil remains on or is fed to the cutting spindle and that all metal or plastic dust is removed.

Processing After Milling

- Caution, ceramic dust: Aspirate all dust and air with a fine dust filter commonly used in the dental lab. Use protective goggles in all framework processing work.
- In order to prevent contamination, the blank must not be exposed to water or any other liquids, fats (hand lotion) or oils during processing.

Removal of the Milled Framework from the Holding Device

We recommend the use of a turbine handpiece to remove the framework due to the lower degree of vibration as compared to other handpieces! If no turbine is available, fine cross-cut tungsten carbide cutters can also be used - rotary speed ≤ 20,000 rpm!

- First, notch all holding pins on their top as close as possible to the crown from the occlusal side and then carefully extend the notches from the opposite side to separate the framework.
  - Use as little pressure as possible in removing the framework and let it gently slip into the hand or onto a soft pad!

Finishing of the Blank Surface

Compared to finishing already sintered frameworks, shape correction and surface smoothing of the green body (pre-sintered framework) is not only simpler but also a more reliable procedure. Grinding sintered frameworks may cause damage invisible to the naked eye. For this reason, corners, edges, joints of the holding pins, and all other uneven surfaces should be smoothed prior to sintering so that it is necessary only to fit the framework once it has been sintered.
Caution: The presence of notches and sharp edges or damage on the bottom side of the interdental connectors may substantially reduce the stability of the sintered framework. These surfaces should be smoothed in the green state!

- Use Universal Polishers from Brasseler (Type Komet # 9557) for finishing only - rotary speed 10,000-20,000 rpm!
- First finish the holding pin joints, then all of the edges outside of the crown margin.
- When finishing the outer contour in the vicinity of the crown margin, make sure that the crown margin is not damaged.

Cleaning of the Framework

To ensure even coloring, the framework must be clean, free of oils and completely dry prior to dyeing!

- Touch the framework only with clean, non-oily hands.
- Use a soft brush, e. g., Tanaka brush for layered ceramic, size 6, to clean thoroughly the entire framework, including the interior surfaces of the coping, from milling dust.

Dyeing of the Framework

Preparation of the Dyeing Liquid/Dyeing Process

- Select the size of the immersion container according to the framework. The container must be large enough to allow easy insertion and removal of the framework without the risk of jamming. The immersion container must be dry, clean, and free of any residual dyeing liquid to ensure that the desired color results are obtained.
- Select the suitable Lava Frame Shade dyeing liquid for the desired tooth color:

Lava Frame Shade Dyeing liquid	FS 1	FS 2	FS 3	FS 4	FS 5	FS 6	FS 7
Coordinates with VITA Classic colors	A1 B1	B2 C1	A2 A3	A3,5 A4	B3 B4	C2 C3 C4	D2 D3 D4

- Shake the dyeing liquid well before use!
- Pour only enough of the dyeing liquid into the immersion container to cover the frame work completely during the dyeing process.
- Reseal the bottle immediately after use so that the concentration of the dyeing liquid does not change.

Dyeing Process

- Use plastic forceps to place the framework into the immersion container; the framework must be completely covered by the dyeing liquid.
- Carefully rock the immersion container to allow any air bubbles trapped inside a coping to escape.
- Leave the framework in the dyeing liquid for 2 minutes, then use plastic forceps to remove it. Dye each framework only once!
- Remove the excess dyeing liquid from the coping and from around the interdental connectors, e. g., using a cotton swab or an absorbent paper towel, to ensure even coloring. Make sure that no lint from the paper towel remains on the framework.
- Then place the framework on a sintering carrier (see Positioning for Sintering) and place it in the cold (room temperature) sintering furnace within 2 hours. The drying process for the framework begins when the sintering program see Sintering) is launched.
- The dyeing liquid can be used for up to 24 hours if it is covered immediately after use and stored in a cool, dry place. Failure to observe the above precautions may have the following effects on the framework:
  – Discoloration
  – Changes in sintering behaviour, e.g. distortion due to sintering
  – Reduction in durability
- Dilute used dyeing liquid with large quantities of water and pour down the drain.

Notes

The dyeing liquids may cause irritation if they come into direct contact with skin and eyes.

- Wear suitable protective gloves and goggles.
- Do not swallow the dyeing liquid.

Sintering of the Framework

Positioning for Sintering
The framework shrinks by about 20-25% (linear) during sintering. This shrinking movement is only possible if the sintering wires and pegs are loosely attached in the sintering carrier and the honeycomb sintering carrier is not deformed; this should be checked every 2 weeks. Check the sintering carrier for acceptability for the sintering of bridges by laying it on both sides on a flat surface.
The framework must be secured so that it cannot tip over and be freely suspended during sintering, without touching the neighboring frameworks or the sintering carrier, so that it does not become deformed.

- Place the sintering wires and pegs on the sintering carrier so that they can follow the shrinking movements of the framework.
- Place no more than one sintering wire or peg in each honeycomb opening of the sintering carrier.
  Caution: The sintering wires and pegs must be placed in the honeycomb so that they are not under tension; this will ensure that they are free to move.
- Use 1 to a maximum of 4 pegs for each framework, see below.
- Position the bridges perpendicularly to the direction of insertion into the furnace.

Positioning of Copings for Sintering

Framework type	Number of sintering support
Front tooth	1
Premolar	2 – 3
Molar	3 – 4

Positioning of Two Blocked Crowns for Sintering

Framework type	Number of sintering supports per coping
Front tooth	1
Premolar	2
Molar	2 – 3

Position of Anterior Tooth Frameworks with Three or More Units for Sintering:

- Position anterior tooth frameworks on one peg for each outer coping.
  - Position the pegs in a slight V-shape without allowing them to touch the coping walls.
  - The bridge framework must hang freely without touching the sintering carrier. If this is not possible, use sintering wire.

Position of Posterior Tooth Frameworks with Three or More Units for Sintering:

- Position posterior tooth frameworks on two sintering wires in the area of the outer connectors.
- If the center of gravity is in an awkward position, the bridge may tip over from the sintering wires. In this case, use sintering wires or a combination of wires and pegs instead. Position the pegs in the coping wall area near the bridge units without touching the coping wall.
- Generally position bridges with the occlusal side up.

Sintering

For information on the operation of the sintering furnace, please refer to the Operating Instructions of the Lava Therm unit.

- Once the Start button is pressed, the sintering program starts up automatically and heats the furnace after the 3.5 hours drying period to 1,500°C/2,732°F. The sintering including the drying time is approximately 11 hours. The furnace is automatically unlocked once the temperature drops below 250°C/452°F during the cooling phase of the furnace.
  - **Caution when opening furnace door: Burn hazard!**
  - If the temperature is above 250°C/452°F, do not force the furnace door open since the resulting extreme drop in temperature may destroy the furnace and the frameworks!
- Use tongs or another suitable tool to remove the sintering tray from the furnace. Place the sintering tray on a refractory surface and allow the frameworks to cool down slowly on the sintering tray.

Finishing the Sintered Framework

- Finish sintered frameworks using a turbine at 30,000 to 120,000 rpm or with a fast-running handpiece at up to 30,000 rpm. The use of any water cooling which is available can always be recommended, but is not necessary for selective adjustments.
- Use only fine-grain diamonds with grain sizes between fine 30 µ (red) and extra-fine 15 µ (yellow). Whether the diamonds are bonded galvanically or ceramically is of importance only for the endurance of the diamond cutter.
- To avoid overheating the framework, apply only light pressure and smooth a particular place for only a short time.
- If there is cervical smoothing, whether intentionally or accidentally, on a connector, the position must be polished again. Diamond-equipped rubber polishers, discs or cones, are suitable for this, coarse = blue, medium = pink, fine = gray (high polish).
- Check the wall thickness of the framework before veneering. The values must not be below the minimum, see Framework Design.

Veneering

- Use Lava™ Ceram veneer ceramic for veneering; it has been especially developed for this Zirconia framework material. Please comply with the Instructions for Use of Lava Ceram when processing.

Temporary Cementation

- Clean the Lava Frame restoration thoroughly.
- If you are planning to use a composite cement to cement the restoration permanently, a eugenol-free luting cement (e. g., RelyX™ Temp NE, manufactured by 3M ESPE) must be used for the temporary cementation.
  - Residuals of products containing eugenol inhibit the setting of composite cement during the permanent cementation process!
- If you are planning to use a conventional cement to seat the restoration permanently, you may use eugenol-free temporary luting cements or such containing eugenol (e. g., RelyX Temp NE or RelyX™ Temp E, manufactured by 3M ESPE).

Permanent Cementation

- Thoroughly clean the restoration and blast the interior surfaces of the crowns with aluminum oxide ≤ 40 µm.
- Please see the appropriate instructions for use for detailed information about the products mentioned below.

Conventional Cementation

- Use a conventional glass ionomer cement, e. g., Ketac™ Cem, manufactured by 3M ESPE, for the cementation. The use of phosphate cements will not lead to the desired esthetic results.

Adhesive Cementation

Lava Frame frameworks are so strong that adhesive cementation does not offer any additional mechanical advantages in comparison with conventional cementation. Lava Frame frameworks cannot be etched or silanized by direct application of a silane coupling agent.

Adhesive cementation with RelyX™ Unicem, manufactured by 3M ESPE:

- Thoroughly clean the Lava Frame restoration and blast the interior surfaces of the crown with aluminum oxide ≤ 40 µm.
- Please follow the instructions for use for the self-adhesive universal composite cement when processing RelyX Unicem.
- Stronger adhesion is achieved by adhesive cementation with silicatization, followed by silanization with the Rocatec process. The procedure is described in the chapter "Adhesive Cementation with Composites."

Adhesive Cementation with Composites:

- If the restoration is to be tried in, it must be done before the silicatization/silanization.
- For adhesive cementation with composite cements, the adhesive surfaces must be silicatized for 15 seconds with Rocatec™ Soft or CoJet™ Sand and silanized with ESPE™ Sil.
  - See the instructions for use for Rocatec™ System or CoJet Sand for details about processing.
- Place the restoration in the mouth with a composite cement, e. g., RelyX Unicem or RelyX ARC, as soon as possible after silanization.

All of the products mentioned in this chapter are manufactured by 3M ESPE.

Removal of a Seated Lava Restoration

- Use conventional rotating tools and adequate water cooling to introduce a slit and lift the restoration and/or common office instruments as an aid to pull off the restoration.

Error	Cause	Solution
Coping breaks during removal from the holding structure.	Holding pin was separated too far from the object.	Separate closer to the object to reduce vibrations.
	Handpiece wobbles.	Check the handpiece. Use a turbine, if available.
	Cutter is blunt.	Use a new cutter.
Framework does not fit.	Erroneous positioning of crowns and bridges during sintering.	Ensure proper positioning during sintering as described under "Positioning for Sintering".
	Die was not placed correctly on the model.	Prior to scanning, check the proper position of the die on the model.
	The preparation guidelines were not observed.	Contact dentist/customer, rework model as necessary.
	Inadequate model preparation.	Observe the model in the guidelines Lava Scan operating instructions. Rework the framework as necessary and contact the customer, or do the work again..
	Not all of the data for the die surface was captured during scanning (causing gaps in the data)	Use Scan Spray before scanning. Depending on the scale, rework the framework or create a new one.
Contamination on the coping surface.	The dyeing liquid was used too often and is contaminated.	Do not use the dyeing liquid for more than 24 hours!
Whitish spots apparent on the coping surface.	Milling dust was not removed.	Carefully remove all milling dust prior to dyeing.

Incompatibilities
In susceptible individuals sensitization to the described products cannot be excluded. Use of the respective product should be discontinued and the respective product completely removed, if allergic reactions are observed.

Storage and Shelf-Life
Store Lava Frame Shade dyeing liquid at 15-25°C/58-77°F.
Avoid direct exposure to sunlight.
Do not use after the expiration date.

Customer Information
No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Warranty
3M ESPE warrants this product will be free from defects in material and manufacture.
3M ESPE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

Limitation of Liability
Except where prohibited by law, 3M ESPE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Date of the information December 2004

7.2 The Overlay Porcelain

Lava Ceram

Overlay porcelain for Lava Frame zirconia frameworks

Product Description

Lava Ceram overlay porcelain and Lava Frame mill blanks, both manufactured for or by 3M ESPE respectively, are both components of the Lava All Ceramic System for fabrication of all-ceramic restorations. These overlay porcelains and mill blanks are specially designed to be used in combination and cannot be combined with other overlay porcelains.
Lava Ceram overlay porcelains are available in 16 VITA colors; the color range consists of the following components: 7 shoulder ceramic porcelains, 16 framework modifiers, 16 dentine porcelains, 10 Magic intensive shades, 4 enamel porcelains, 2 enamel effect porcelains, 4 transparent-opal porcelains, 1 transparent-clear porcelain, 10 stains, 1 glaze, and the corresponding mixing liquids.

Instructions for Use should not be discarded for the duration of product use.

Veneering of Lava Frame zirconia framework

Preparation

Preparation of the Framework

- After dyeing and sintering, clean the framework in an ultrasonic bath or by briefly using a steam cleaner.
  The framework must be absolutely clean and free of grease!

Color Selection

Combination Table for VITA Classic Colors

VITA Classic Colors	A1	A2	A3	A3,5	A4	B1	B2	B3	B4	C1	C2	C3	C4	D2	D3	D4
7 Shoulder-materials	SH1	SH3	SH3	SH4	SH4	SH1	SH2	SH5	SH5	SH2	SH6	SH6	SH6	SH7	SH7	SH7
16 Framework modifiers	MO A1	MO A2	MO A3	MO A3,5	MO A4	MO B1	MO B2	MO B3	MO B4	MO C1	MO C2	MO C3	MO C4	MO D2	MO D3	MO D4
16 Framework modifiers	D A1	D A2	D A3	D A3,5	D A4	D B1	D B2	D B3	D B4	D C1	D C2	D C3	D C4	D D2	D D3	D D4
4 Incisal materials	E2	E2	E3	E3	E4	E1	E1	E3	E3	E4	E3	E3	E4	E4	E3	E3

Color Table

Shoulder-materials:	SH 1 – SH 7	**Framework modifiers:**	MO A1 – MO D4	**Dentine materials:**	D A1 – D D4
Incisal-materials:	E 1 – E 4	**Enamel effect-materials:**	E 5 Polar E 6 Sun	**Transparent-Opal materials:**	T 1 neutral T 2 yellow T 3 blue T 4 grey
Magic Intensive-materials:	I 1 Ocean blue I 2 Atlantis I 3 Chestnut I 4 Havanna I 5 Orange I 6 Khaki I 7 Vanilla I 8 Honey I 9 Gingiva I 10 Violet	**Extrinsic colors:**	S 1 Ocean blue S 2 Atlantis S 3 Chestnut S 4 Havanna S 5 Orange S 6 Khaki S 7 Vanilla S 8 Honey S 9 Gingiva S 10 Violet	**Glaze material:** **Transpa-Clear:**	G CL

- Keep on hand appropriate porcelains that match the color of the teeth.

Veneer Production

Mixing

Folgende Anmischflüssigkeiten stehen zur Verfügung:
The following mixing liquids are available:

- – Modeling liquid
- – Shoulder ceramics liquid
- – Stain/Glaze liquid
- Mix the ceramic powders and the appropriate liquid with a glass or agate mixing spatula until a creamy consistency is attained. The mixing ratio is 2.5 g powder to 1 g liquid.

Layering of Shoulder Porcelain

A ceramic shoulder is to be baked to the framework, if the cervical area of the framework was reduced for the purpose of shoulder porcelain baking or if the preparation edge was inadvertently damaged.

- Select the appropriate color to match the color of the tooth and mix with shoulder ceramics liquid.
- Insulate the plaster model with a commercial insulating liquid –plaster against ceramics.
- Place the framework on the model.
- Apply the shoulder porcelain to the framework and shape down to the preparation edge of the die, then blot the liquid off.
- Remove the framework from the model and fire the shoulder as described under "Baking procedure".
- Compensate any shrinking during the sintering process by another step of shoulder porcelain baking. Then continue the processing by applying framework modifier.

Application of Framework Modifier

The framework modifier is what gives the framework its basic color.

- Mix the framework modifier with modeling liquid.
- Apply a thin coat (0.1-0.2 mm) to the entire surface to be veneered.
- For adequate wetting, vibrate well and then blot off the liquid in order to prevent air inclusion and bubble formation.
- As an option, a thin layer of Magic intensive shade can either be applied as such to the framework using a wet brush or, alternatively, after mixing with framework modifier.
- The framework modifier should be fired separately – using the same procedure as for "Initial dentine and enamel baking" – or the dentine layer should be directly applied onto the framework modifier.

Layering of Dentine/Enamel Porcelain

- Mix the dentine, enamel, and "transpa" porcelain with modeling liquid and build up the restoration.
- To adapt the procedure to the individual needs of the patient, you may wish to mix-in some Magic intensive shades into the dentine, enamel or transpa porcelain and apply a layer of these mixtures in particular locations.
  – The Magic shades are very intense so that the materials should be used in small amounts only.
- Working with bridges, separate the teeth all the way down to the framework prior to initial baking, using a flexible instrument.
- Initial baking should be done in accordance with the baking table; please refer to "Baking procedure".
  – After baking there is no need to roughen or blast the surface of the ceramic.
- Shape corrections, if any, can be done with fine-grained diamonds at low pressure.
  – Never damage the framework when separating the veneer ceramic interproximally!

- Complete modeling the restoration with dentine or enamel porcelain.
- Close interdental spaces and separate again, if required.
  – After baking there is no need to roughen or blast the surface of the ceramic.
- Correction baking must be done in accordance with the baking table; please refer to "Baking procedure".

Finishing

Caution! Ceramic dust is a health hazard! Use a common suction device for laboratory use with fine dust filter while processing ceramic materials.

- Finish with fine-grain diamonds at low pressure.
- Make sure to separate only the veneering ceramics with the diamond discs without affecting the framework!
  – **The framework must not be damaged interdentally as this may give rise to fractures in the future!**
- Fine-shape the surface with rotating instruments.
  Either:
  Mix stains with stain/glaze liquid and apply special color effects.
  Or:
  Mix glaze with stain/glaze liquid and apply in a very thin layer.
  Or:
  Glaze bake without stain or glaze.
  Subsequently, glaze bake in accordance with the baking table; please refer to "Baking procedure".

Firing Procedure

	Start temp.	Drying time	t ↗ under vacuum	t ↗ without vacuum	Final temp.	Hold time under vacuum	Hold time without vacuum
1. Shoulder material firing	450°C	4 min	45°C/min	./.	840°C	1 min	./.
2. Shoulder material firing	450°C	4 min	45°C/min	./.	830°C	1 min	./.
Initial dentine- and enamel porcelain baking	450°C	6 min	45°C/min	./.	810°C	1 min	./.
Second dentine- and enamel porcelain baking (correction bake)	450°C	6 min	45°C/min	./.	800°C	1 min	./.
Glaze baking with glaze or stain	480°C	2 min	./.	45°C/min	790°C	./.	1 min
Glaze baking without glaze or stain	480°C	2 min	./.	45°C/min	820°C	./.	./.

Intraoral Veneer Repair

Veneers of cemented restorations can be repaired with the Cojet™ system, manufactured by 3M ESPE, and a filling composite.

- For further details, please refer to the Instructions for Use of the Cojet™ system.

Prevention of Processing Errors

Bubble Formation in the Veneer

Bubble formation may be caused by the usual factors, such as contaminants unintentionaly introduced into the porcelain. But it can also be due to inappropriate application of the framework modifier, i.e. the framework modifier did not sufficiently wet the framework and air became trapped between the modifier and the framework.

- To provide for adequate wetting, vibrate well and then blot the liquid off.

Incompatibilities

In susceptible individuals, sensitization to the product cannot be excluded. Use of the product should be discontinued and the product completely removed, if allergic reactions are observed.

Storage and Stability

Do not store the liquids above 25°C/77°F.

Customer Information

For questions or comments in U.S.A. or Canada please call toll-free 1-800-634-2249.
No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Date of the information: 03/02

8. Questions and Answers

How comprehensive is the clinical experience with the Lava™ Crowns and Bridges
Beginning with its introduction the Lava™ System has established as one of the leading All-Ceramic Systems and looks back to a successful 5-year clinical experience. Clinical studies show a very good long term stability, no fractures of the framework, no allergic reactions as well as no negative influence on the neighboring gingiva (see chapter 6. clinical results).

What distinguishes Lava™ from the other all ceramic systems and what is its composition.
Lava™ is based on a framework made from zirconia (Lava™ Frame) and a feldspathic overlay porcelain (Lava™ Ceram), which has been specially designed to meet the requirements of the framework. The zirconia ceramic is a tetragonal polycrystalline zirconia partially stabilized with Yttria (admixture of approx. 3mol-%) (Y-TZP = Yttria Tetragonal Zirconia Polycristals), which extremely qualifies them for restorations in the anterior and posterior region. Compared to other zirconia ceramics the Lava™ zirconia frameworks can be dyed before sintering.

How does the accuracy of fit compare with typical porcelain fused to metal?
Literature indicates a theoretically required accuracy of fit of 50 - 100 µm for crowns & bridges. Investigations show an excellent accuracy of fit below the required standard values for 4-unit Lava™ bridges and 4 splinted Lava™ crowns (see chapter 5.7). Furthermore, Dr. S. Reich of the University of Erlangen was able to show, that there is no significant difference of the AMO-values for 3-unit Lava™ bridges and porcelain fused to metal restorations [5.22].

Is Lava™ really sufficiently strong for posterior bridges?
Posterior applications are possible for the first time with zirconia frameworks because their strengths exceed the maximum load (600 N) several times. Internal and external investigations confirm that 3-unit bridges after artificial ageing (simulation of 5 years carrying time) in the mastication simulator (1.2 million cycles) with simultaneous thermocycling (10.000 x 5°-55°C) have a strength of 1.450 N to 1.200 N for 3- or 4-unit bridges, respectively.

How aesthetic are the results with Lava™? Is zirconia white(-opaque)?
The Lava™ zirconia framework is ideally translucent due to its high density (no residual porosity) and homogeneity - and due to the dyeability of the Lava™ restorations no longer white-(opaque), as we know it from the past or other technical/medical applications. There is the option of coloring the zirconia framework in 7 VITA Classic shades. Highly aesthetic restorations are possible in combination with the veneering System which matches with this basic coloring.
The framework wall thickness of 0.5 or 0.3 mm, which is possible due to the high strength of zirconia, supports the excellent translucency and provides ample opportunity for aesthetic layering with the overlay porcelain.

What are the preparation requirements for a successful long-term restoration?
In principle, many of the requirements for a porcelain fused to metal restoration can be applied to the Lava™ All-Ceramic System. Fabrication of a Lava™ restoration requires a preparation having a circumferential chamfer or shoulder. The preparation angle should be 4° or greater. The inside angle of the shoulder preparation must have a rounded contour. The preparation for the Lava™ all ceramic restoration can be done with removal of less tooth structure thanks to the framework's thin wall thickness of only 0.5/0.3 mm. Supragingival preparations are possible due to Lava™'s excellent fit characteristics and optical properties.

Why don't Lava™ restorations have to be luted using adhesive? Which cement is recommended?

Permanent cementation

The strength of Lava™ Frame frameworks is so high that adhesive cementation provides no additional advantages with respect to strength! The material can neither be etched nor directly silanized with silane coupling agent.

Conventional cementation

For cementing use conventional glass ionomer cements, e.g. Ketac™ Cem manufactured by 3M ESPE. The use of phosphate cements fail to provide the desired aesthetic results.

Self-adhesive Cementation with RelyX™ Unicem

For the cementation with the new self-adhesive universal composite cement RelyX™ Unicem the inner surfaces of the restoration should be briefly sandblasted. A complete pretreatment with the Rocatec™ System, i.e. silicatization with Rocatec™ Plus/Soft with following silanization, is not necessary as RelyX™ Unicem directly bonds to the zirconia ceramic due to its special chemistry. You will find further information in the Instructions for Use for RelyX™ Unicem.

Adhesive Cementation with Composites

For the adhesive cementation with composite cements, the adhesive surfaces must be silicatized with Rocatec™ Soft or Cojet™ Sand for 15 sec and silanized with ESPE Sil. All products are manufactured by 3M™ ESPE™. Soon thereafter, place in the mouth with a composite cement, e.g. RelyX™ ARC. If desired, a fit test has to be done before silicatization/silanization. For details on processing, please refer to the Instructions for Use of the Rocatec™ System or Cojet™ Sand.

Glass ceramics are frequently luted with adhesive bonding, to enhance aesthetics and increase the strength of the entire tooth/restoration system. This no longer applies with polycrystalline oxide ceramics (Lava™). This method of cementation will not result in any further increase in strength. There are also no aesthetic disadvantages if using a glass ionomer (e.g. Ketac™ Cem) for the cementation of Lava™.

9. Summary

With the Lava™ System 3M™ ESPE™ presents the new, innovative CAD/CAM technology for all-ceramic Crowns and Bridges on a zirconia base.

Due to the remarkable strength, stability and esthetics of zirconia, Lava™ Crowns and Bridges are indicated for the anterior as well as for the posterior region. Excellent fit is guaranteed by a perfectly coordinated system.

A tooth structure friendly preparation can be achieved, and cementation can be carried out according to proven conventional techniques. In order to combine the advantages of an adhesive cementation with the simple handling of a conventional cementation, the new self-adhesive cement RelyX™ Unicem can be used for an easy-handling.

The esthetics and biocompatibility of Lava™ restorations represents the optimum in All-Ceramic Systems. Colorable frameworks of ideal translucency and thin veneer ceramic layer ensure a natural appearance due to the wide scope of esthetic

The milling of zirconia frameworks in the pre-sintered state prevents damage of the micro-structure of the material, and ensures an excellent long-term perspective for Lava™ restorations.

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11. Technical Data

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Lava™ Frame Framework Ceramic

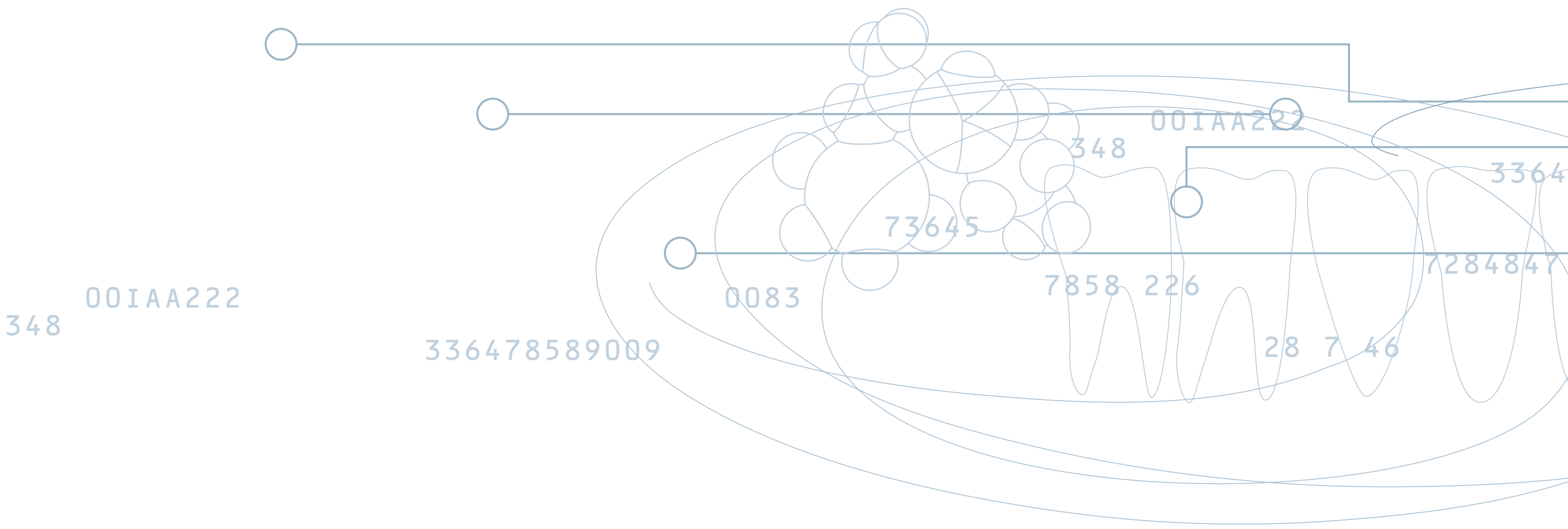
Flexural strength (Punch Test) (ISO 6872)	> 1100 MPa
Weibull strength (σ_0) (3-Punkt)	1345 MPa
Stress resistance (2% / 5 Jahre)	615 MPa
(Youngs) Modulus of elasticity (E)	> 205 GPa
Weibull-modulus (m)	10.5
Crack growth parameter (n)	50
Fracture toughness (K_{IC})	5-10 MPa $m^{1/2}$
CTE	10 ppm
Vickers hardness (HV 10)	1250
Melting point	2700 ºC
Grain size	0.5 µm
Density (ρ)	6.08 g/cm^3
Solubility (ISO 6872)	0 $\mu g/cm^2$

Lava™ Ceram Overlay Porcelain

Flexural strength (3-Punkt) (ISO 6872)	100 MPa
Youngs) Modulus of elasticity (E)	80 GPa
Fracture toughness (K_{IC})	1,1 MPa $m^{1/2}$
CTE	10 ppm
Vickers hardness (HV 0,2)	530
Firing temperature	810 ºC
Grain size (D_{50})	25 µm
Density (ρ)	2,5 g/cm^3
Solubility (ISO 6872)	0 $\mu g/cm^2$
Wear / abrasion	state-of-the-art

Lava™ clinically relevant real geometry

Fracture strength 3-unit **posterior** bridge a) initial	approx. 1800 N
b) after mastication simulation and thermocycle	approx. 1450 N
Fracture strength 3-unit **anterior** bridge a) initial	approx. 1430 N
b) long term strength at 250 N (above masticatory force)	no fracture



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