IvoBase®

Scientific Documentation

ivoclar vivadent
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Contents

1. Introduction

1.1 Historical development of denture base materials

Up until the mid-19th century, denture bases were predominantly made from animal materials. The materials used included bovine bones and teeth of mammals, for instance ivory from elephants and walruses and hippopotamuses. From around the mid-18th century onwards, denture bases were also fabricated from porcelain and precious metals.

After Goodyear had invented the vulcanization process in 1851, rubber was used to fabricate dentures. This marked a new era in dental prosthetics, because rubber was rather easy to process and quite stable in the oral environment. However, rubber is not transparent and could be made available only in esthetically unsatisfactory colours. Hoping that more esthetic dentures could be fabricated, Perkins introduced celluloid, a product made from nitro-cellulose and camphor and similar to cellulose, in dentistry in 1870. However, as celluloid exhibited a poor oral stability and it was prone to discolouration and eventually also decomposition, it never replaced rubber as a denture base material. In addition, such dentures were not tasteless; the camphor taste was a major drawback.

After the introduction of the transparent material polymethyl methacrylate (PMMA) during the 1930s, the material was soon used in dental prosthetics. PMMA is also known as acrylic glass. This highly versatile resin material was invented by Dr Walter Bauer, who worked for Röhm & Haas. Bauer also described the fabrication of dentures from this compound. Initially, the material was supplied as polymerized, i.e. solid, plates, which were moulded to the desired shape with heat and pressure, like rubber or celluloid. In 1936, this fabrication technique was replaced by the suspension polymerization method. This technique involves the application of PMMA polymer (powder) and monomer (MMA, liquid) together with catalysts (peroxides). When mixed and after a certain dough time, these materials formed a mouldable, non-sticky substance which could be pressed to the desired shape and subsequently polymerized, initially in a vulcanization crucible and later in boiling water (heat polymerization, packing-pressing method). Kulzer company improved this procedure by optimizing the mixing ratio, patented it and launched it in dentistry under the Paladon brand name. As a result of this technique, the problem of volumetric shrinkage and shape distortion associated with the polymerization of MMA (methyl methacrylate monomer) could be drastically reduced. The first PMMA-based self-curing polymer (polymethyl methacrylate) was developed as early as in 1938. Due to the addition of tertiary aromatic amines into the monomer, the materials could be cured at room temperature (also called cold curing).

The continuous further development then ultimately led to today's PMMA denture base materials consisting of polymer powder and monomer liquid (methyl methacrylate, MMA). Most denture base resins used today are based on this MMA/PMMA system. As an amorphous polymer, PMMA is highly transparent and rather brittle, yet highly stable towards aqueous media and UV radiation. Other features of this material include biocompatibility and oral stability. Furthermore, it is tasteless, easy to repair and has a high shape stability. In addition, this material is easy to process, without requiring expensive equipment. This combination of favourable properties is most likely also the reason why other (thermoplastic) polymers, e.g. polycarbonates, polyacetals or polyamides, developed from the mid-1960s onwards for denture base fabrication were never a serious threat to the popularity of PMMA resins.

1.2 Classification of denture base materials

Depending on their chemical composition and the processing technique, denture base materials are classified into various types and classes in EN ISO 20795-1:2008. Table 1 shows the properties of different resin materials. The two most commonly used types of denture base resins are heat- and cold-curing polymers. Heat-curing polymers must be

considerably heated in order to cure, whereas the polymerization of cold-curing polymers (autopolymerizing materials) is chemically induced.

Type	Characteristics
Type 1 - Heat-curing polymers	Polymerization temperature >65°C
Type 2 - Self-curing polymers	Polymerization temperature <65°C The curing mechanism is based on a chemical reaction of the components.
Type 3 - Thermoplastic materials	Polymers which are mouldable when heated
Type 4 - Light-curing materials	Curing with UV radiation and/or visible light
Type 5 - Materials for microwave polymerization	Heat-curing systems polymerized with microwaves

Table 1: Classification and properties of denture base materials according to EN ISO 20795-1:2008

Given their chemical composition and the polymerization temperature, the IvoBase materials belong to the category of self-curing polymers.

1.3 Polymerization process

The basis for the processing of an MMA/PMMA-based denture base resin is a liquid (main component: MMA) and a resin powder (main component: PMMA). Mixing these two components induces a swelling and dissolution process that produces a dough-like, kneadable substance.

Denture base materials are polymerized in several steps. The initiator, which is brought into the mixture as a result of the dissolution process, is split into radicals either by heat (heat-curing polymer) or by the chemical reaction with the catalyst (self-curing polymer).

The initiator radical interferes with the electron system of the double bond of the monomer molecule and splits this bond. After the addition to the monomer molecule, a chain radical is formed. This chain radical, in turn, attacks another monomer molecule and links with it. This process is repeated uncountable times, until a sufficient number of monomer molecules is no longer available.

In this way, many chain molecules are created, firstly through chain growth and secondly through the combination of chain radicals. The result is a dense network of macromolecules. The solid substance created in this way forms the matrix which envelops the filler particles.

1.4 Shrinkage-compensating polymerization

The linking of monomer molecules during polymerization results in a volume loss of the material, because the individual molecules are arranged more closely to each other. However, this effect is undesirable, particularly in the case of denture base resins, the reason being that this shrinkage results in an inadequate fit. An optimum fit of the denture base is crucial for the function of the denture. Only an accurately fitting denture establishes a suction effect on the palate and allows the patient to speak and chew without problems. In addition, inaccuracies can also lead to bothersome pressure sores, which, in turn, can lead to inflammation over time. Dentures with a poor fit are furthermore conducive to accelerated jaw bone atrophy, and this may jeopardize the retention of the denture in the long term.

To counteract this phenomenon, in the 1960s, Ivoclar Vivadent developed a denture fabrication process which was revolutionary at the time: shrinkage-compensating injection

moulding. Launched 1972, Ivocap, as the system was named, was based on the injection technique. This means that the denture base dough is injected into a closed flask. An injection pressure of 17 bar is maintained in the boiling water bath during the entire polymerization. The flask was designed in such a way that a temperature gradient was achieved within the flask. As a result, the polymerization border of the denture travels from the anterior region to the injection area. The occurring polymerization shrinkage is compensated with material which is continuously pressed into the flask. Due to its simplicity and the quality of the resulting dentures, this procedure is deemed unsurpassed and has served as the technique standard for more than 30 years. With the IvoBase system, this technique has become available also for self-curing polymers [1].

1.5 The IvoBase system

The IvoBase system, which has been developed in many years of development work, combines the benefits of heat-curing polymers and those of self-curing polymers. This system requires a low initial polymerization temperature of only approx. 40°C, which means that the thermal loss is much lower than for heat-curing polymers. Due to the proven shrinkage-compensating injection moulding process that was already used for Ivocap, increases in vertical dimension during denture fabrication are virtually eliminated, and the need for subsequent grinding of the teeth to optimize the contact points is reduced. The materials feature a surface quality and fracture toughness equivalent to that of heat-curing polymers and are even superior to many other heat-curing polymers, for instance with regard to the exceptionally low residual monomer content. The high degree of monomer conversion during the standard IvoBase polymerization process results in a residual monomer content of less than 1.5%, which is very low for a self-curing polymer (limit values according to ISO 20795-1: 4.5% for self-curing polymers and 2.2% for heat-curing polymers). This content can be further reduced to below 1% by activating the RMR (residual monomer reduction) function. This function enables an additional monomer conversion by slightly prolonging the polymerization time.

Another highlight of the system is its user friendliness. The IvoBase Injector is a plug-and-play device. This means that only a power connection is required to operate it. A water bath is also no longer necessary for the polymerization process. Direct skin contact with the monomer is avoided since the material is supplied in predosed capsules (similar to Ivocap). The monomer is added to the polymer, and the mixture is stirred with a spatula for 20 seconds. The capsule is then inserted into the flask with a funnel in place and positioned in the IvoBase Injector. Then the device is started. All process-relevant phases, such as dough time, system aeration, pressure and heating phase, are carried out by the injector in a fully automated and coordinated process. The overall curing time is 35 minutes for the conventional IovBase Hybrid material version and 50 minutes for the impact-resistant IvoBase High Impact version. The cooling time under cold running water is 15 minutes.

Hence, using clinically proven PMMA materials, the IvoBase system enables the fully automatic fabrication of high-quality dentures from self-curing polymer. The injector is not only able to process the new IvoBase materials, but also offers programs for the proven Ivocap materials (High Impact, Clear and Elastomer).

Fig. 1: The IvoBase system comprises the IvoBase Injector (left) as well as the IvoBase Hybrid and impact-resistant IvoBase High Impact materials (middle) in predosed capsules. On the far right, the flask is shown in which the denture model is invested for polymerization.

2. Material properties

IvoBase Hybrid

Denture base material for injection moulding

Standard composition	**(in wt%)**
Powder:	
Polymethyl methacrylate	95.5
Softener (non-phthalate)	3.8
Initiator	0.6
Pigments	0.1
Liquid:	
Methyl methacrylate	95.9
Dimethacrylate (cross-linking agent)	4.0
Catalyst	0.1

Physical properties

In accordance with:

EN ISO 20795-1:2008 Dentistry – Base polymers Part 1: Denture base polymers (ISO 20795-1:2008)

		Specification Type 2 Class 1	Example values
Flexural strength	MPa	> 60	81
Flexural modulus	MPa	> 1500	2700
Residual monomer content	%	< 4.5	1.4
Water absorption	µg/mm³	≤ 32	22.8
Solubility	µg/mm³	≤ 8.0	<0.1

Other physical properties

Residual monomer content with RMR*		< 1.0	0.7

(*residual monomer reduction)

IvoBase High Impact

Denture base material for injection moulding

Standard composition	**(in wt%)**
Powder:	
Modified PMMA copolymer with increased impact toughness, PMMA copolymer, polymethyl methacrylate	97.8
Softener (non-phthalate)	1.5
Initiator	0.6
Pigments	0.1
Liquid:	
Methyl methacrylate	95.9
Dimethacrylate (cross-linking agent)	4.0
Catalyst	< 0.1

Physical properties

In accordance with:

EN ISO 20795-1:2008 Dentistry – Base polymers Part 1: Denture base polymers (ISO 20795-1:2008)

		Specification Type 2 Class 1	Example values
Flexural strength	MPa	> 60	74
Flexural modulus	MPa	> 1500	2360
Residual monomer content	%	< 4.5	1.3
Water absorption	µg/mm³	≤ 32	21.6
Solubility	µg/mm³	≤ 8.0	<0.1
Fracture toughness (K_{max})	MPa $m^{1/2}$	> 1.9	2.37
Fracture work (W_f)	J/m^2	> 900	1450

Other physical properties

Charpy impact strength (method ISO 1567:2000)	kJ/m^2	> 2.0	3.1
Residual monomer content with RMR* (*residual monomer reduction)		< 1.0	0.7

3. In vitro investigations

3.1 Mechanical properties

3.1.1 Flexural strength and flexural modulus

The flexural strength according to EN ISO 20795-1 indicates the value of the flexural tension that is present when a test specimen is loaded to the maximum. The standard for self-curing polymers states that the value must be at least 60 MPa. A value of 81 MPa was found for IvoBase Hybrid; for IvoBase High Impact, the value was 74 MPa (see Fig. 2). Thus, the materials even meet the requirements for heat-curing polymers. For such materials, the value must be at least 65 MPa. Similar things can be said about the flexural modulus indicating a material's stiffness, i.e. the resistance to elastic flexural deformation. The higher the flexural modulus, the more force is required to achieve a certain elastic deformation. For this parameter, values of more than 1500 MPa (self-curing polymers) and 2000 MPa (heat-curing polymers) are required. The value determined for IvoBase Hybrid was 2700 MPa and the value for IvoBase High Impact was 2360 MPa (see Fig. 3).

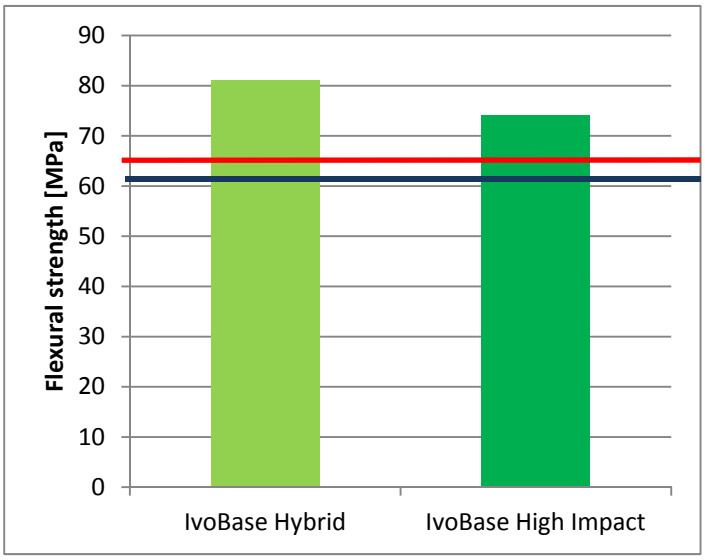

Fig. 2: Flexural strengths of IvoBase Hybrid and IvoBase High Impact. Testing according to EN ISO 20795-1. Internal measurement, Ivoclar Vivadent. The graph shows typical example values. Horizontal line: minimum requirements for heat- (red) and self-curing polymers (blue) according to the standard.

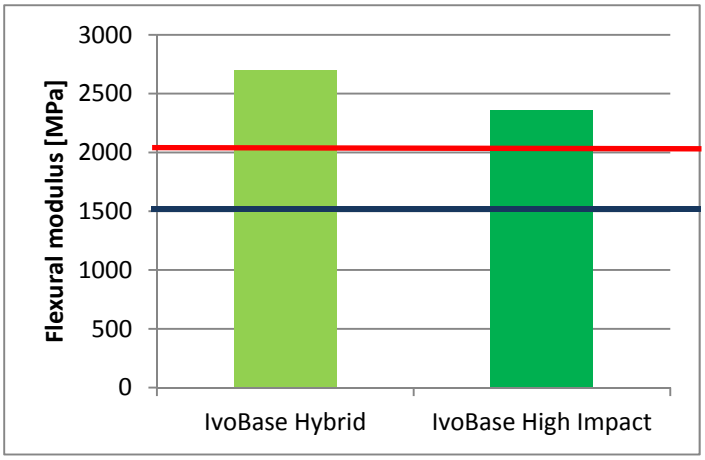

Fig. 3: Flexural modulus of IvoBase Hybrid and IvoBase High Impact. Testing according to EN ISO 20795-1. Internal measurement, Ivoclar Vivadent. The graph shows typical example values. Horizontal line: minimum requirements for heat- (red) and self-curing polymers (blue) according to the standard.

3.1.2 Fracture toughness

In clinical use, denture base materials are exposed to high mechanical loading. Therefore, a material's fracture resistance is important. Fracture toughness indicates the resistance which a material exhibits to a propagating crack. Such cracks may develop from minute flaws in a material or on its surface. Thus, when exposed to extended masticatory loading, materials with increased fracture toughness offer a higher durability than materials with a lower fracture toughness. Increased tension within the denture base material occurs particularly at the interface between the denture base resin and implants. This increases the risk of material failure. Given the increasing popularity of implant-supported dentures, impact-resistant materials are in increasingly high demand, due to their tolerance to mechanical loading.

Several values are used to express the fracture toughness: K_{max} (maximum factor of the loading intensity), fracture work W_f and the Charpy notch impact toughness test. The fracture toughness of various denture base resins was measured according to the standard's specifications (K_{max} and fracture work according to EN ISO 20795-1:2008; Charpy notch impact toughness test according to EN ISO 1567:2000 AM1).

Figures 4 to 6 show that high-impact materials exhibit considerably higher K_{max}, fracture work W_f and Charpy notch impact toughness values than conventional denture base materials. Also these minimum values stipulated in the standard are clearly exceeded by IvoBase High Impact for K_{max} (1.90 $MPam^{1/2}$) and W_f (900 J/m^2). Together with Promolux High Impact (Merz Dental), IvoBase High Impact is the most impact-resistant material. However, PalaXpress ultra (Heraeus Kulzer), an impact-resistant material according to the manufacturer's instructions, does not meet the minimum W_f value for impact-resistant denture base materials (see Fig. 6).

Impact-resistant materials have served as technology standard for heat-curing materials for a long time. So far, this feature has not been available for self-curing polymers. Thus, the IvoBase High Impact material is a first in this regard.

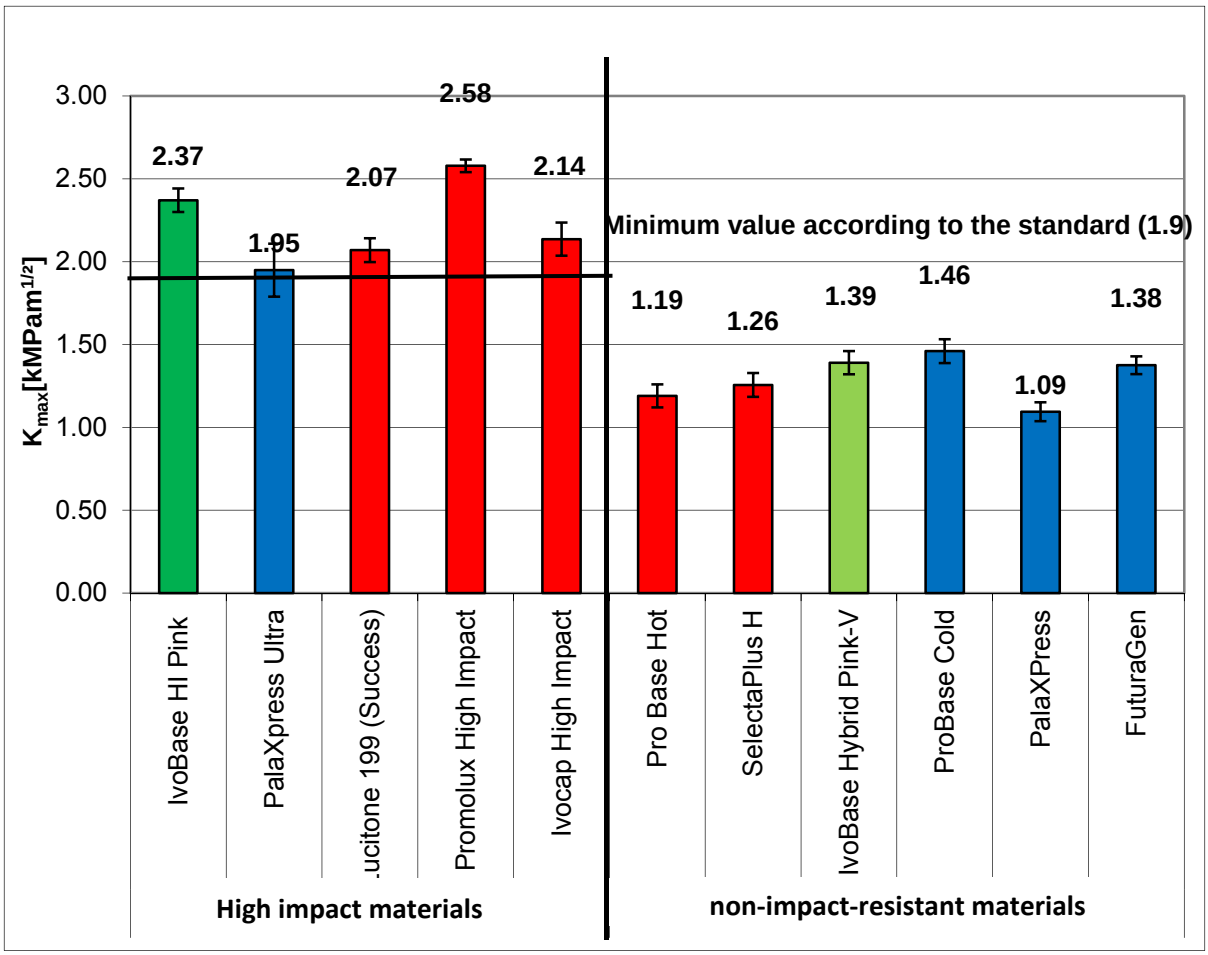

Fig. 4: Maximum factor of loading intensity (K_{max}) for various denture base materials after 1 week of water storage at 37°C. Testing according to EN ISO 20795-1. Internal measurement, Ivoclar Vivadent. Horizontal line: minimum requirements for High impact materials stipulated in the standard. Blue: self-curing polymers. Red: heat-curing polymers.

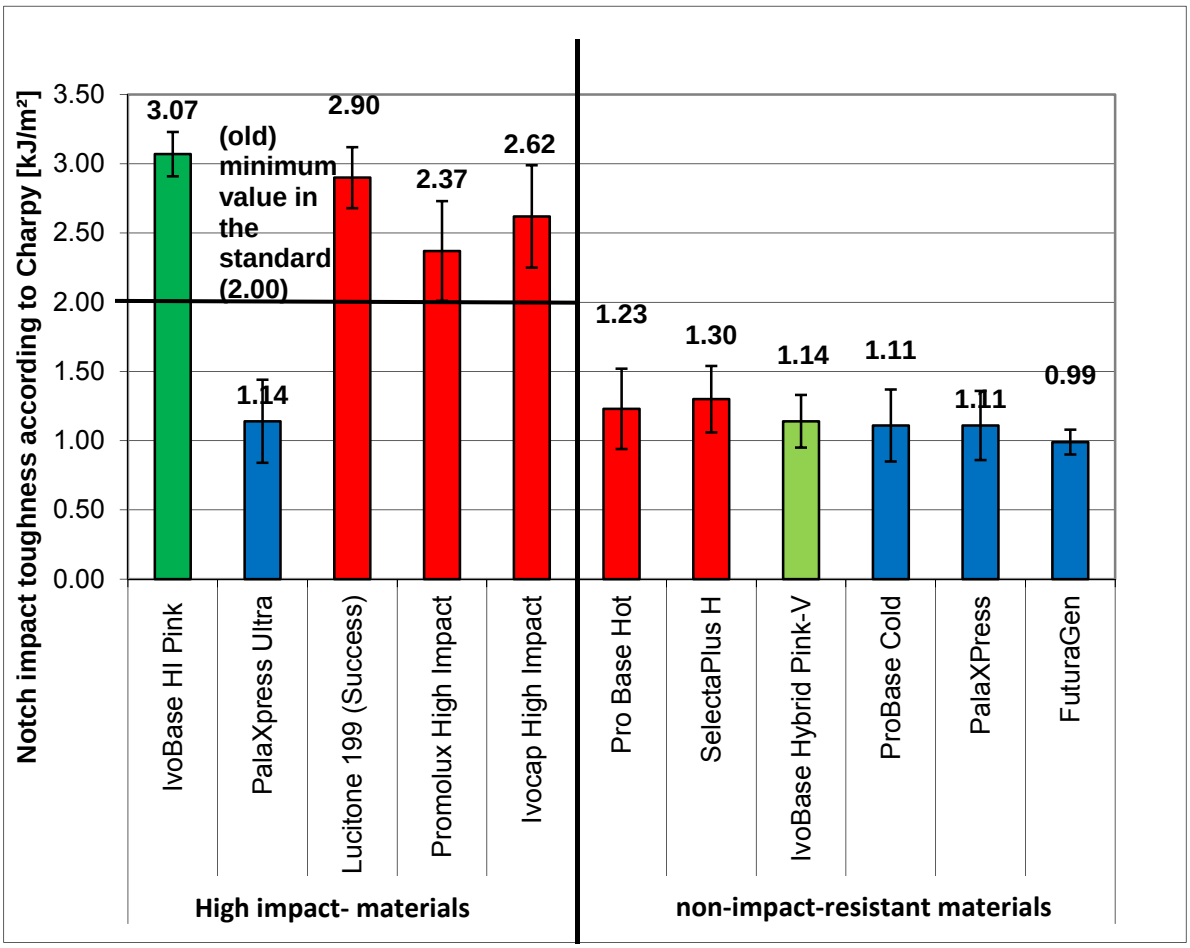

Fig. 5: Notch impact toughness according to Charpy for various denture base materials after 1 week of water storage at 37°C. Testing according to EN ISO 1567:2000. Internal measurement, Ivoclar Vivadent. Horizontal line: minimum requirements for High impact materials stipulated in the norm. Blue: self-curing polymers. Red: heat-curing polymers.

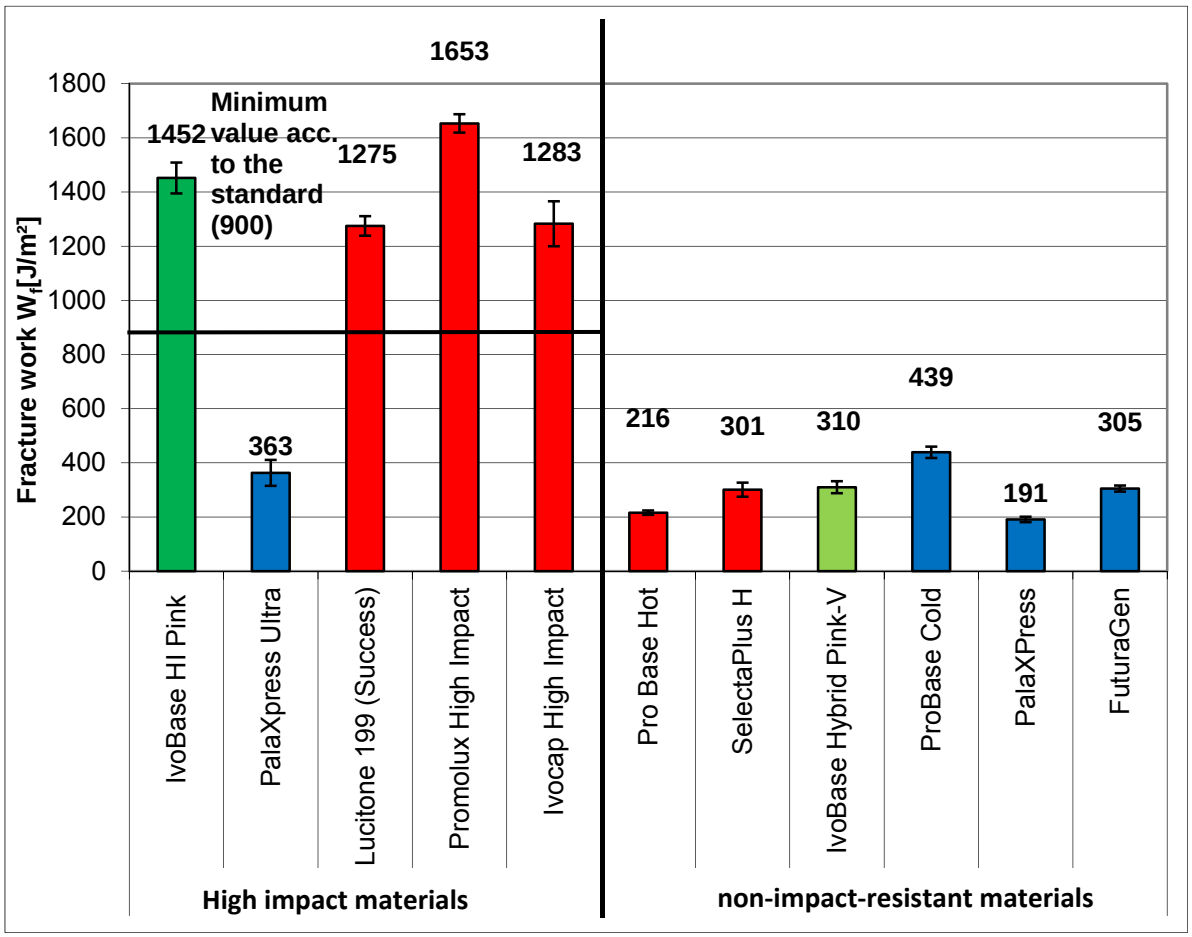

Fig. 6: Fracture work W_f for various denture base materials after 1 week of water storage at 37°C. Testing according to EN ISO 20795-1. Internal measurement, Ivoclar Vivadent. Horizontal line: minimum requirements for High impact materials stipulated in the standard. Blue: self-curing polymers. Red: heat-curing polymers.

3.2 Residual monomer content

Residual monomer may have a sensitizing effect in sensitive patients. In general, heat-curing polymers contain less monomer residue than self-curing polymers, because the higher polymerization temperatures applied for heat-curing polymers promote monomer conversion [2-5]. According to the norm, a residual MMA value of 4.5% is acceptable for self-curing polymers. For heat-curing polymers, however, this value is only 2.2%.

After polymerization, IvoBase materials contain 1.4% (Hybrid) and 1.3% monomer residue (see Fig. 8). These values are clearly below the limit value for self-curing polymers and even below the requirements stipulated for heat-curing polymers. However, there is more to it: The RMR function of the IvoBase Injector uses the fact that the polymerization time also has an influence on the residual monomer content [3]. If the RMR key is selected, the process cycle is prolonged by 10 minutes. This leads to a further MMA monomer conversion, so that eventually only 0.7% monomer residue are contained in the resin (see Fig. 8).

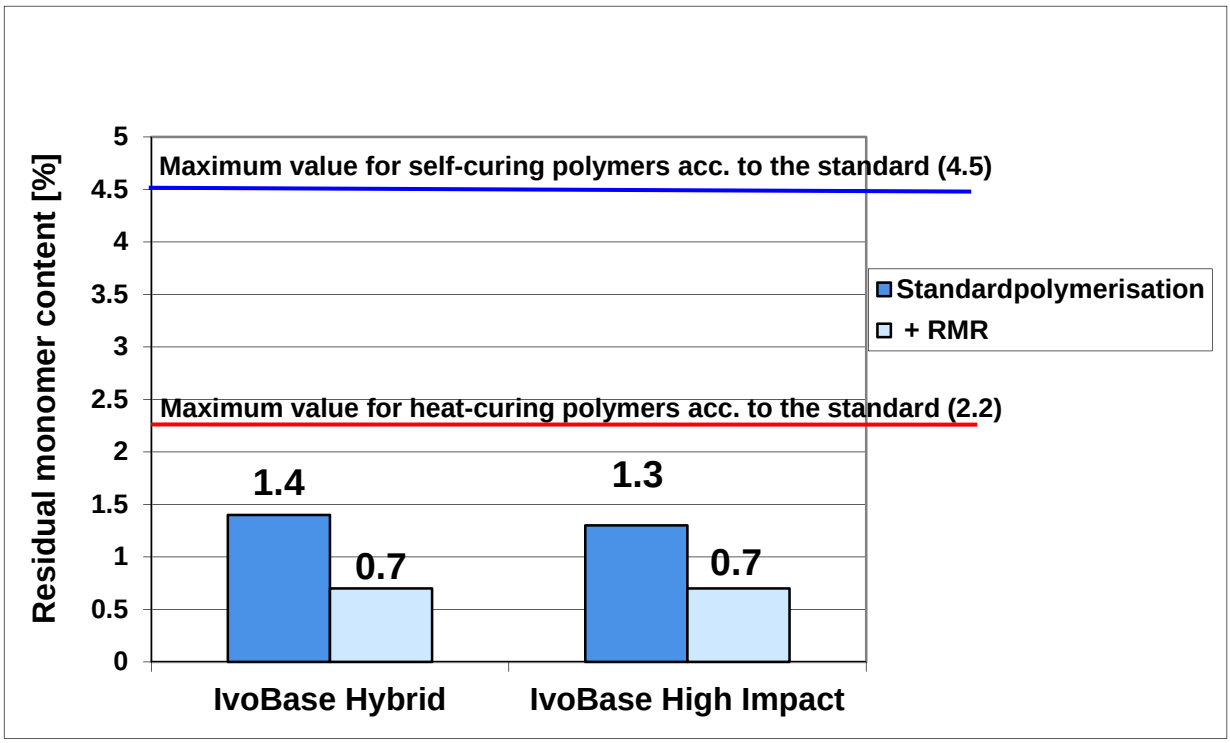

Fig. 7: Residual monomer content (MMA) of IvoBase Hybrid and IvoBase High Impact after standard polymerization (dark blue) and with activated RMR (residual monomer reduction) function (light blue). Testing according to EN ISO 20795-1. Internal measurement, Ivoclar Vivadent. The graph shows typical example values. Horizontal line: minimum requirements for heat- (red) and self-curing polymers (blue) according to the standard.

3.3 Bond to teeth

A sound bond between the denture teeth and the resin denture base is an important aspect that influences a denture's quality. The bond between IvoBase materials and popular denture teeth was investigated in the development department at Ivoclar Vivadent in accordance with the norm ISO 22112. Only cohesive fractures occurred in all test series (see Figures 8a and b). This means that the tooth did not debond at the interface between the tooth and the denture base but the fracture went through the tooth or the denture base material. This advantageous fracture behaviour was even observed when the teeth were not conditioned as indicated by the manufacturer (sandblasting, wetting with monomer).

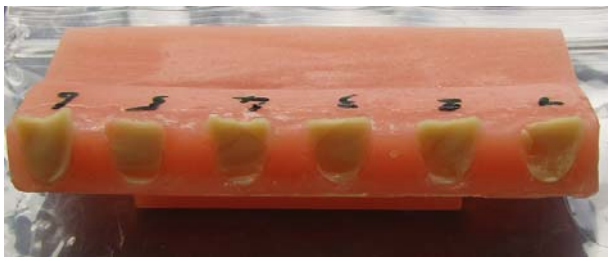

Fig. 8a: Bond of SR Vivdent DCL teeth with IvoBase Hybrid. Testing according to EN ISO 22112. Internal measurement, Ivoclar Vivadent.

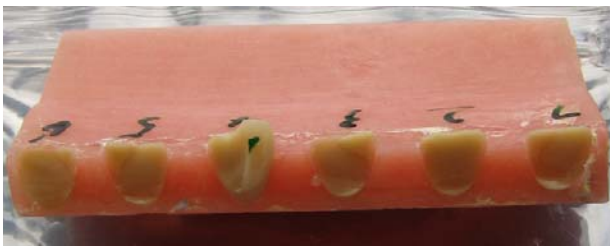

Fig. 8b: Bond of SR Vivdent DCL teeth with IvoBase High Impact. Testing according to EN ISO 22112. Internal measurement, Ivoclar Vivadent.

In an additional investigation conducted together with the University of Bordeaux (Prof. C. Bertrand), the tooth bond of various denture base materials was compared. The following materials were used: IvoBase Hybrid, IvoBase High Impact and ProBase Hot (heat-curing polymer) from Ivoclar Vivadent as well as Perform from Coltène Whaledent (heat-curing polymer). For each material, 5 templates with 6 anterior teeth (SR Vivodent PE, Ivoclar Vivadent) were fabricated. The teeth were subjected to tensile stress of 4 mm/min in an INSTRON machine.

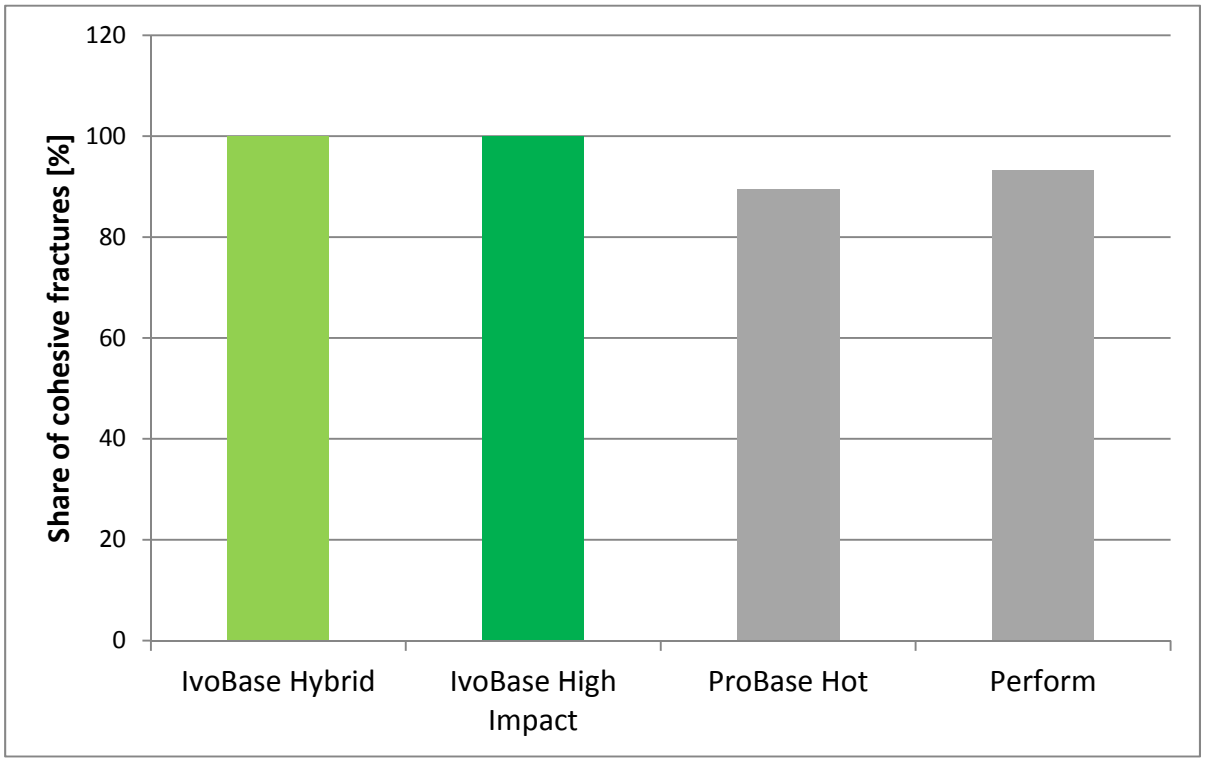

Fig. 9: Bond of SR Vivodent PE teeth with various denture base materials (IvoBase Hybrid, IvoBase High Impact, ProBase Hot and Perform). Testing according to EN ISO 22112. Measurement made at the University of Bordeaux, Prof. Bertrand.

Only cohesive fractures were observed for IvoBase Hybrid and High Impact. With a cohesive fracture share of 90% and 93%, respectively, ProBase Hot and Perform showed a poorer performance (see Fig. 9).

3.3 Accuracy of fit

Same as the proven Ivocap process, the IvoBase Injector applies shrinkage-compensating polymerization. Under high pressure (15 bar), monomer/polymer mixture is continually supplied during the injection process. Volumetric loss caused by the polymerization is therefore compensated. In addition, the thermal loss is clearly reduced due to the low initial polymerization temperature for self-curing polymers (approx. 40°C as opposed to approx. 80°C for heat-curing polymers). These two processing properties combined allow accurately fitting dentures to be fabricated.

An individually fabricated denture must exhibit a high accuracy of fit, as it is pressed on the mucous membrane during swallowing, chewing and speaking. Inaccurately fitting dentures may lead to bothersome pressure sores, which might become inflamed. Furthermore, inaccurately fitting dentures accelerate the bone resorption in edentulous jaws, and this, in turn, leads to poorer retention of the denture.

In an investigation carried out at the University of Kiel, the accuracy of fit of denture base materials resulting from volumetric shrinkage was analysed [6]. A trapeziform pattern made

from an Invar alloy showing a very low volumetric change with varying temperatures was used as a model. Thus, the exothermic reaction occurring during the setting of the plaster did not result in an undesired dimensional change of the test geometry. The test specimens were fabricated with various injection systems (IvoBase/IV, Ivocap/IV, Palajet/Heraeus, Futurajet/Schütz and Success/Dentsply) and the respective resin materials (IvoBase Hybrid/IV, IvoBase High Impact/IV, Ivocap High Impact/IV, PalaXPress/Heraeus, FuturaGen/Schütz, Lucitone 199/Dentsply). After 1-day and 30-day water storage at 37°C, the volume of the test specimen was determined by means of the buoyancy-flotation method and compared with the original model. Fig. 6 shows the volumetric shrinkage in per cent of various materials. PalaXPress, FuturaGen and Lucitone 199 exhibited a shrinkage of 4.8 to 6.9 vol%. The values found for test specimens fabricated using shrinkage-compensating processes (IvoBase and Ivocap) were much lower. Ivocap showed a volumetric loss of 3.2%. The two IvoBase materials shrank by only 1.1% and 1.4%. Due to the absorption of water, the values after 30-day water storage are somewhat lower for all materials. The trend, however, is the same (see Fig. 7).

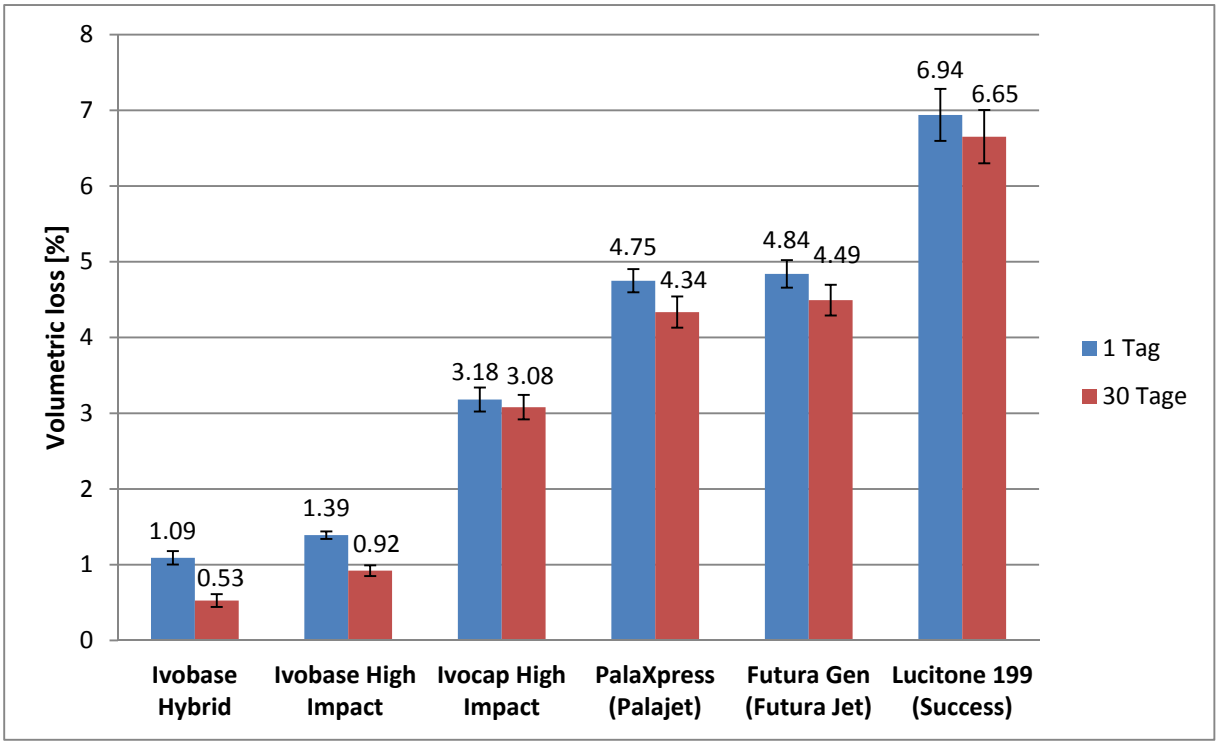

Fig. 10: Volumetric loss in per cent of various denture base resins. After polymerization, the test specimens were stored in water at 37°C for 1 (blue) or 30 days (red). Measurement by the University of Kiel [6].

The higher the polymerization shrinkage, the higher the deformation of the denture upon divestment resulting from internal tensions. It can thus be assumed that IvoBase dentures exhibit a higher accuracy of fit than dentures made using non-shrinkage-compensating systems.

3.4 Surface quality

3.4.1 Basal gloss

Smooth and shiny surfaces on a denture are not only esthetic, but also an important prerequisite in terms of denture hygiene. Smooth surfaces are less prone to colonization with harmful microorganisms [7], which might cause inflammation (stomatitis) and bad breath.
Dentures made with IvoBase material exhibit a very smooth surface which shows a good vacuum retention and which can be easily cleaned already after divestment (see Fig. 11).

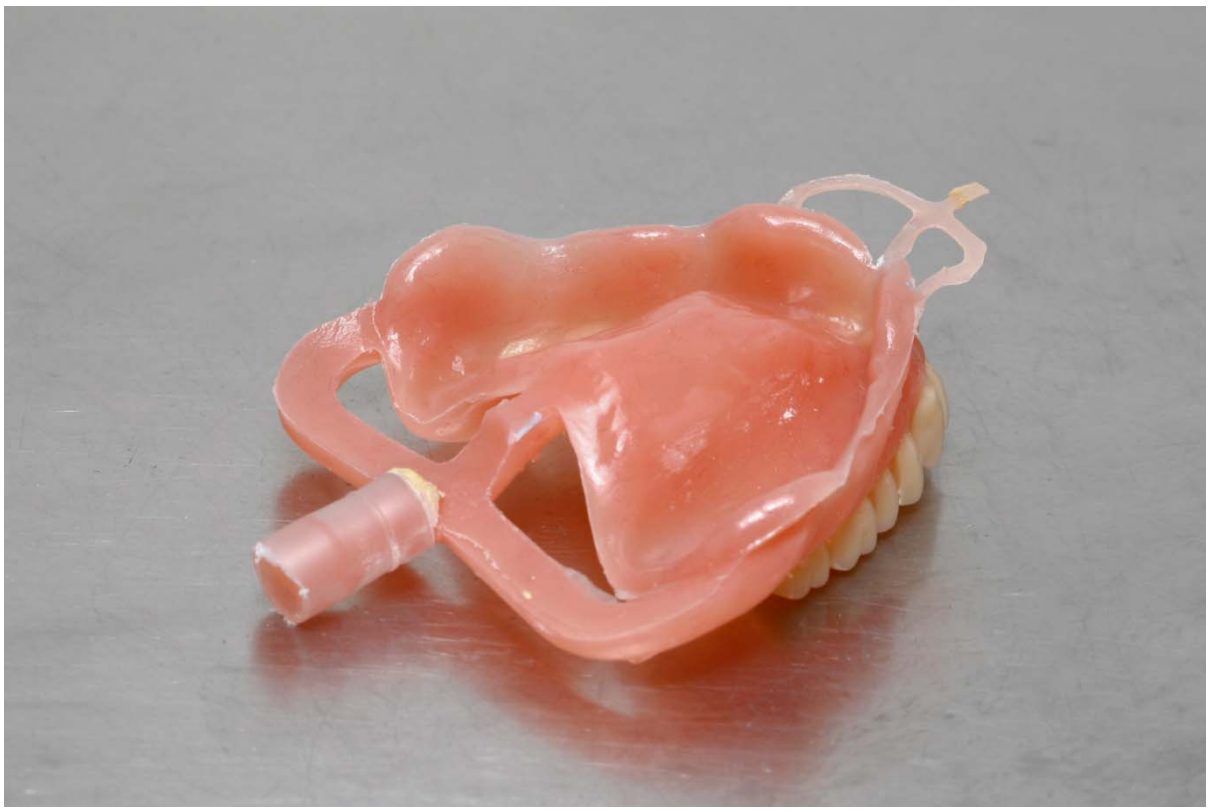

Fig. 11: Basal gloss of a denture fabricated with the IvoBase system

3.4.2 Colonization with microorganisms

An investigation carried out by Carlos Muñoz-Viveros (University of Buffalo, New York) illustrates the surface quality of IvoBase materials. In this study, 8 test specimens (10 x 10 x 3 mm) each were fabricated from various denture base resins.

- IvoBase Hybrid (Ivoclar Vivadent)
- Ivocap (Ivoclar Vivadent)
- ProBase Cold (Ivoclar Vivadent)
- Lucitone 199 Compression (Dentsply)
- Lucitone 199 Success (Dentsply)

The test specimens were polished with a pumice suspension and a felt cone, cleaned with ultrasound and stored in water for 24 hours. Half of the test specimens were stored in human saliva for 30 minutes. All test specimens were incubated with *C. albicans* for 30 minutes at 37°C. The number of *C. albicans* cells that attached to the surface was determined under a light microscope for 10 fields of view. The ANOVA and Tukey or Mann-Whitney tests were used for the statistical analysis; a level of significance of 0.05 was defined.

The lowest *C. albicans* counts in both series (with and without saliva) were found for IvoBase Hybrid (see Figs. 12 to 14). The results for IvoBase and Ivocap (as well as Lucitone 199 Success in the series without saliva storage) did not differ statistically. However, significant differences were found between Lucitone Compression, ProBase Cold, Lucitone Success (with saliva) and IvoBase Hybrid. When we compare saliva-coated and non-saliva coated specimens, it becomes obvious that saliva-coated specimens show higher colonization counts. This is not surprising, as the saliva coating promotes the attachment of cells. The test series with saliva coating is clinically more relevant, because dentures always come into contact with saliva when they are used.

Thus, there are clear differences in the degree to which *C. albicans* attaches to different denture base materials. The IvoBase material is colonized by microorganisms to a much lesser extent than other resins. Therefore, the material supports denture hygiene.

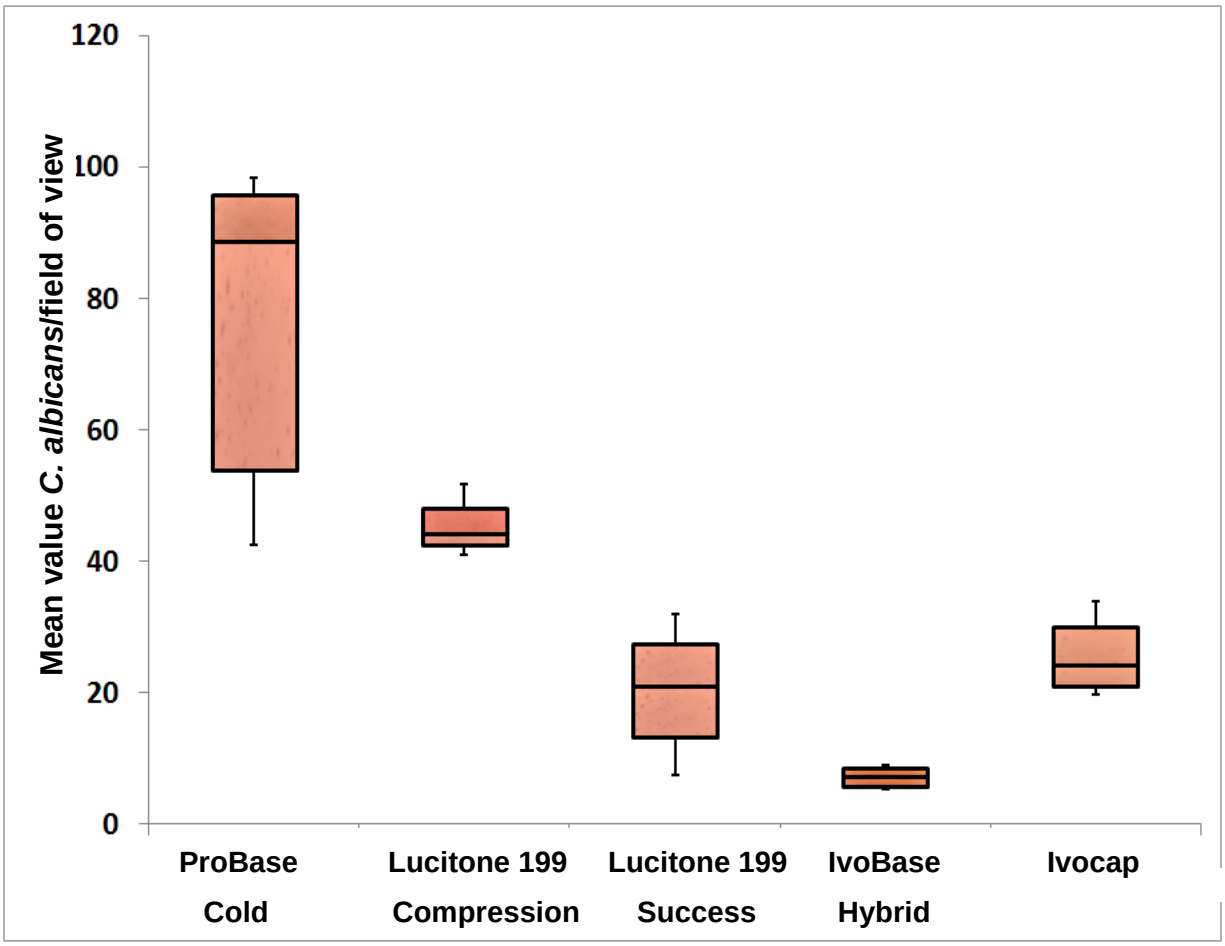

Fig. 12: *C. albicans* colonization on denture base resins after 30-minute incubation without prior storage of the specimens in saliva

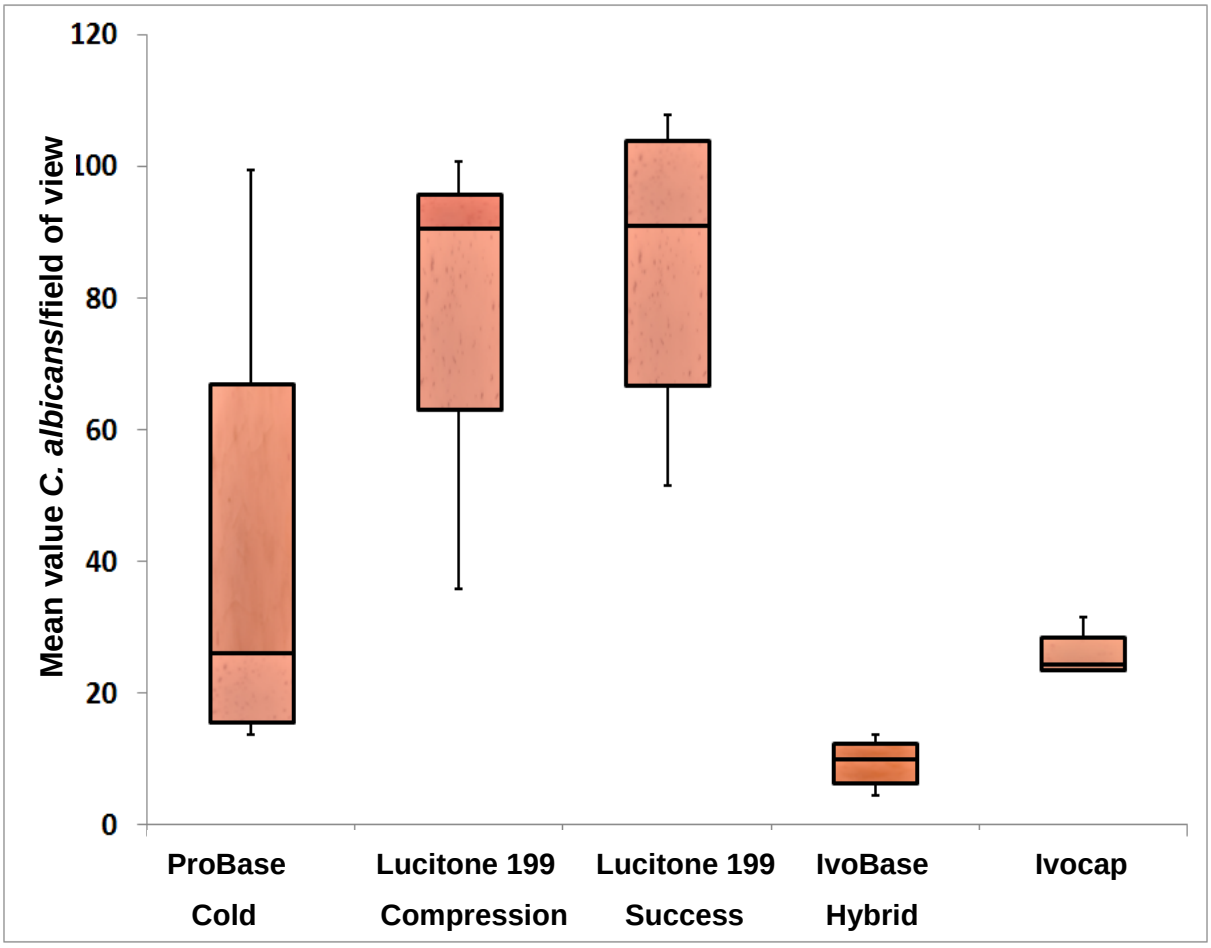

Fig. 13: *C. albicans* colonization on denture base resins after 30-minute incubation with prior storage of the specimens in saliva

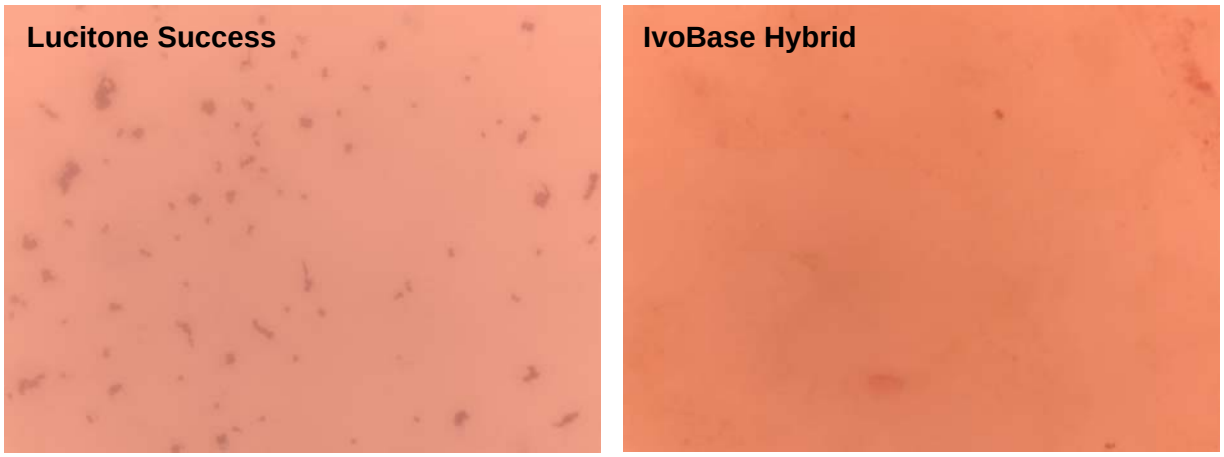

Fig. 14: *C. albicans* colonization on Lucitone Success and IvoBase Hybrid after 30-minute incubation with prior storage of the specimens in saliva. Considerably more cells had attached to Lucitone Success than to IvoBase Hybrid.

4. Clinical studies

4.1 Ivoclar Vivadent AG, R&D Clinic, Schaan, Liechtenstein

Test physicians:	Dr Ronny Watzke, Dr Frank Zimmerling
Title of the study:	*Clinical performance of IvoBase materials*
Objective/study design:	A total of 23 dentures were fabricated. Twelve dentures were made of IvoBase High Impact (11 complete maxillary dentures, 1 complete mandibular denture) and 11 dentures were made of IvoBase Hybrid (complete mandibular dentures). The parameters surface gloss, inherent discolouration, plaque accumulation, fracture, marginal adaptation, marginal discolouration, status of the mucosa covered by the denture base material and patient satisfaction are evaluated.
Results:	No negative events were reported in the observation time of up to 6 months.

5. Biocompatibility

5.1 Cytotoxicity

Cytotoxicity tests were conducted on cells of the mouse cell line L929 with extracts of IvoBase Hybrid and IvoBase High Impact. The extracts did not reveal any cytotoxic effect [8; 9].

5.2 Genotoxicity

The AMES reversion mutation test was conducted on bacterial cells with extracts of IvoBase Hybrid and IvoBase High Impact. The extracts did not show any mutagenic effects [10; 11].

5.3 Irritation

An in vitro irritation test ("EpiSkin™") was conducted with extracts of IvoBase High Impact. The material did not have an irritating effect on skin cells [12]. Since the chemical composition of IvoBase Hybrid is very similar, the results are also applicable to this material.

5.4 Sensitization

It is known that contact with MMA may result in sensitization. Dental technicians are affected by this in particular, as they often come into contact with MMA during the fabrication of dentures. An epidemiologic study found an allergy to (meth)acrylates in 31 patients. Fourteen of these patients were working in a dental profession [13]. Similar results were found in a study conducted in Poland: Of a total of 1619 dermatitis patients, 9 were allergic to acrylates. Of these 9 individuals, 4 were dental technicians [14]. Customary laboratory gloves provide only insufficient protection against MMA. The delivery of IvoBase in predosed capsules is therefore particularly user friendly, because any skin contact with the material is eliminated.

Given the IvoBase materials' very low monomer residue content (see chapter 3.2) of less than 1.5% (regular polymerization) or 0.7% (polymerization with RMR function), the allergy risk for the patient is eliminated to a large extent.

5.5 Subchronic toxicity

A risk for subchronic toxicity might be present if a product releases soluble compounds. To assess this risk, the water solubility of the IvoBase materials was determined according to ISO 20795-1. The maximum water solubility was 0.2–0.3 µg/mm^3. This low value is an indicator that IvoBase does not pose a health risk due to subchronic toxicity.

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