SR Phonares® II

Scientific Documentation

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1. Introduction

The majority of resin denture teeth are fabricated of PMMA. During the past years, composite materials have also been used in the manufacture of artificial teeth. SR Phonares II has been improved over its predecessor, SR Phonares NHC, and represents the latest generation of composite denture teeth.

1.1 History

Since time immemorial, the replacement of missing teeth has been a medical and cosmetic necessity for human kind. Denture prosthetics has undergone many development stages since the first still preserved dentures were fabricated. While 3,500 years ago, the ancient Egyptians carved false teeth out of mulberry wood and tied them to the adjacent teeth with gold wire, the Etruscans arrived at considerable skill, producing constructions made of gold and bovine teeth, which were already guided by principles used in denture prosthetics today. The first porcelain teeth were developed as early as in 1709, but their actual production in England was not undertaken until 1837. The first sets of dentures based on rubber and porcelain began to appear in 1846 [1].

With the emergence of polymer chemistry in the early 20th century, the foundation for the widespread use of removable dentures was laid.

The development of acrylates in the nineteen-thirties marks the beginnings of the industrial production of resin materials for dental applications [2]. Plexiglass, an early representative of this category of materials, was used for technical applications. Methyl methacrylate (MMA) - a small molecule – initially exhibited a polymerization shrinkage rate of approx. 21 %, which was clearly too high for use in dental restorations and denture teeth. Only after developers found a method of substantially reducing the polymerization shrinkage by adding prepolymers such as splinter polymers [3] or pearl polymers did the success story of MMA in denture prosthetics unfold. Its rise in popularity occurred almost simultaneously in Germany and the United States. First products for dental applications were launched in 1937. In 1946, barely ten years later, 98% of all dentures were manufactured using PMMA [4].

In the nineteen-fifties, Rafael Bowen developed Bis-GMA, also known as “Bowen monomer” [5; 6]. The era of dental composites commenced after a method of mixing Bis-GMA with diluting monomers and adding glass or silicate glass powders to the mixture was developed. The resulting composites showed a rather rough surface texture and unsatisfactory *in vivo* wear behaviour because of the relatively coarse filler particles.

The introduction of microfiller-containing composites solved the problems connected with a rough surface texture. Having a mean particle size of 40 nm, highly dispersed silicon dioxide appeared to be a suitable material for eliminating rough surfaces. However, the addition of amorphous silicon dioxide increased the viscosity of the material to such an extent that it was impossible to achieve an appropriate filler concentration. The isofiller technology [7] developed by Ivoclar Vivadent helped to overcome this drawback. Isofillers consist of splinter prepolymers, which are microfiller compounds in powder form. IsoCap and Isosit from Ivoclar Vivadent were the first materials to incorporate this technology. Even today, Isosit-based denture teeth (SR Orthosit PE) are among the most wear resistant teeth available on the market. As a drawback, conventional composite materials are associated with a tendency to discoloration and plaque accumulation.
The SR Phonares II material represents another step forward in the development of composite materials. The resulting denture teeth combine the highest demands of material quality and esthetics.

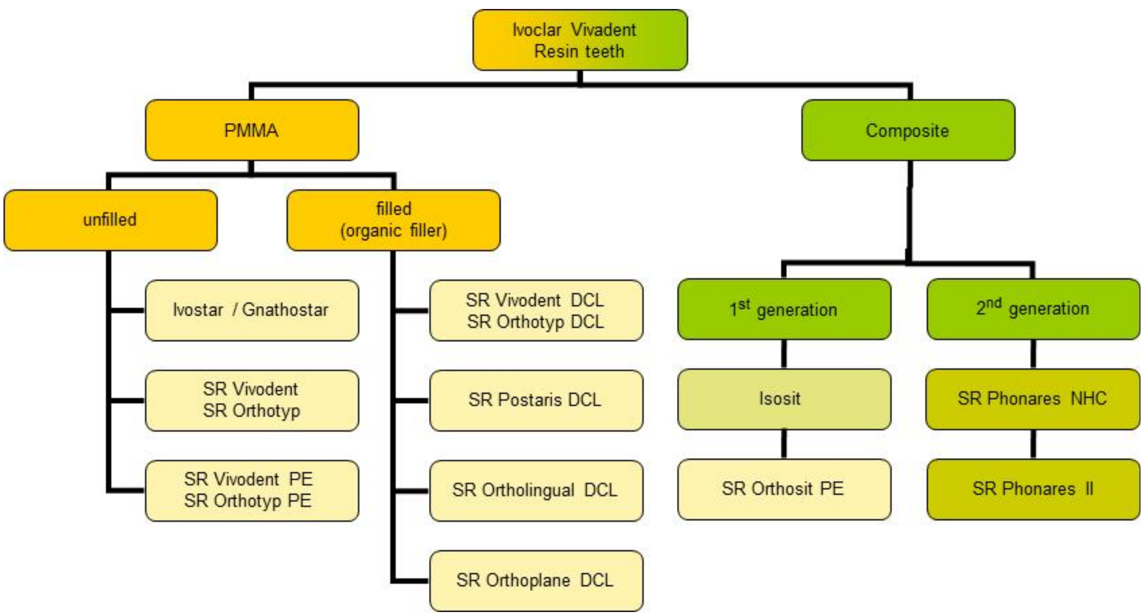
The development of dental composite materials led to extraordinarily successful results. The material grew from an inferior resin restorative into the material of choice for both esthetic restorative therapy and removable denture prosthetics. This upward trajectory was driven

forward by improvements of the material, e.g. filler technologies, development of new monomers for the matrix and new layering techniques to enhance the esthetic qualities.
The SR Phonares II tooth line combines Ivoclar Vivadent's long-standing experience in the manufacture of highly functional composites with the company's tradition in the production of highly esthetic artificial teeth.

Today, various PMMA-based materials are available for the production of denture teeth; some of these materials contain organic and/or inorganic fillers, which improve the mechanical properties of the teeth. Alongside PMMA-based denture teeth, several composite teeth are also available on the market.

The Ivoclar Vivadent range of denture teeth encompasses both resin teeth made of filled and unfilled PMMA and composite teeth. However, the majority of artificial teeth consists of conventional, unfilled PMMA – a material which has a proven clinical track record of more than 50 years.

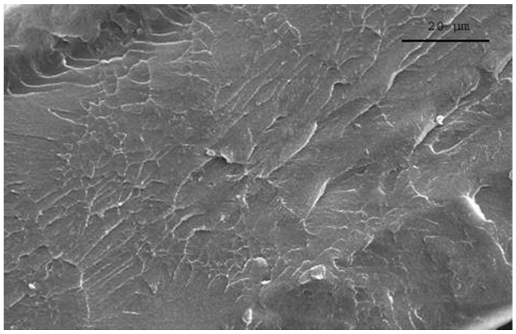
1.2 Overview of Ivoclar Vivadent resin teeth



1.3 PMMA tooth materials

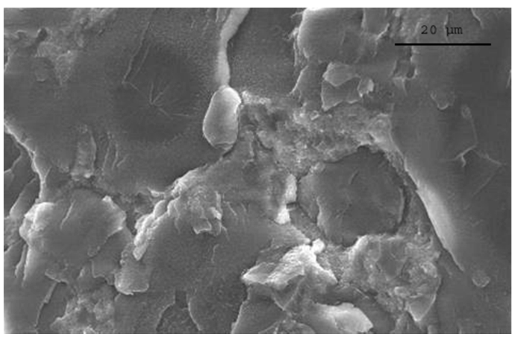
Today, various PMMA-based materials are available for the manufacture of denture teeth:

1.3.1 Conventional PMMA teeth (unfilled)



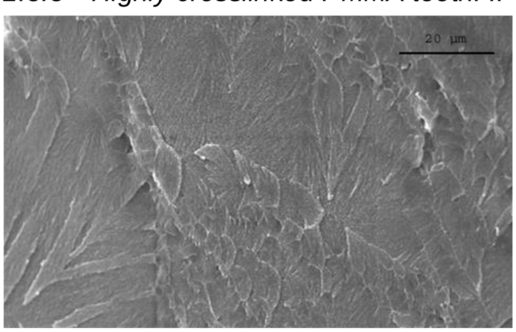
This is the classic material for the fabrication of denture teeth. In the production process, a non-crosslinked linear polymer is mixed with a monomer containing a crosslinking agent and then polymerized.
The mixture of monomer and crosslinking agent consists of a methyl methacrylate and a dimethacrylate, in most cases ethylene glycol dimethacrylate. The SR Vivodent PE and SR Orthotyp PE teeth are part of this material category.

1.3.2 PMMA teeth containing inorganic fillers



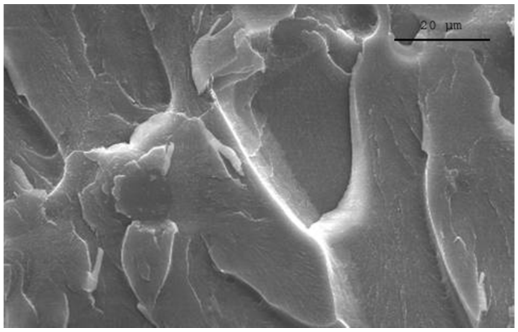
These materials are based on polymethyl methacrylates, to which inorganic fillers have been added.

1.3.3 Highly crosslinked PMMA teeth: IPN



This denture tooth material, which is known as Interpenetrating Polymer Network (IPN) material, can also be allocated to the category of PMMA materials. To produce this type of material, polymers of different chemical and physical natures penetrate each other and become interlaced with each other with the help of swelling processes.

1.3.4 Highly crosslinked PMMA teeth: DCL (organically filled)

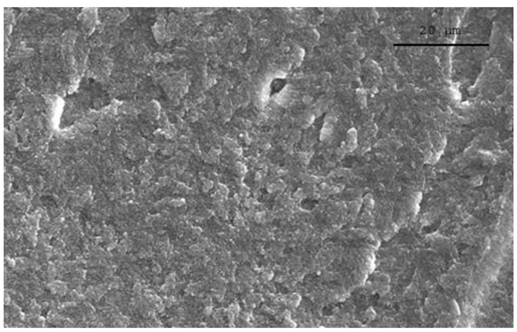


DCL is a severely modified variant of polymethyl methacrylate. The polymer filler and matrix are homogeneously crosslinked. The result is a thoroughly crosslinked material system, offering substantial advantages in terms of oral stability and wear resistance.
Representatives of this category of materials are members of the family of DCL teeth (e.g. SR Vivodent DCL, SR Orthotyp DCL).

1.4 Composite denture teeth

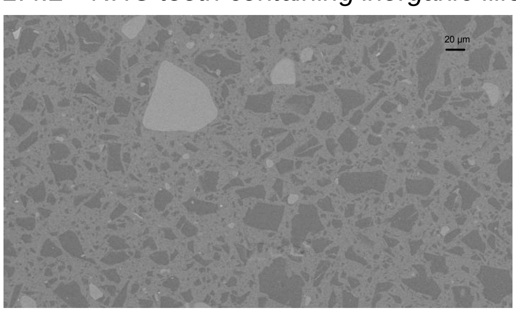
Ivoclar Vivadent uses a variety of composite materials to manufacture composite denture teeth:

1.4.1 UDMA teeth containing inorganic fillers: Isosit



In contrast to the type of materials listed in Section 1.3, the Isosit material is not based on PMMA polymers; instead it is composed of a urethane dimethacrylate-based crosslinking agent, which is reinforced with inorganic microfillers. The inorganic pyrogenic silica fillers considerably increase the hardness and rigidity of the material compared with PMMA-based materials.
This material is used for SR Orthosit teeth.

1.4.2 NHC teeth containing inorganic fillers



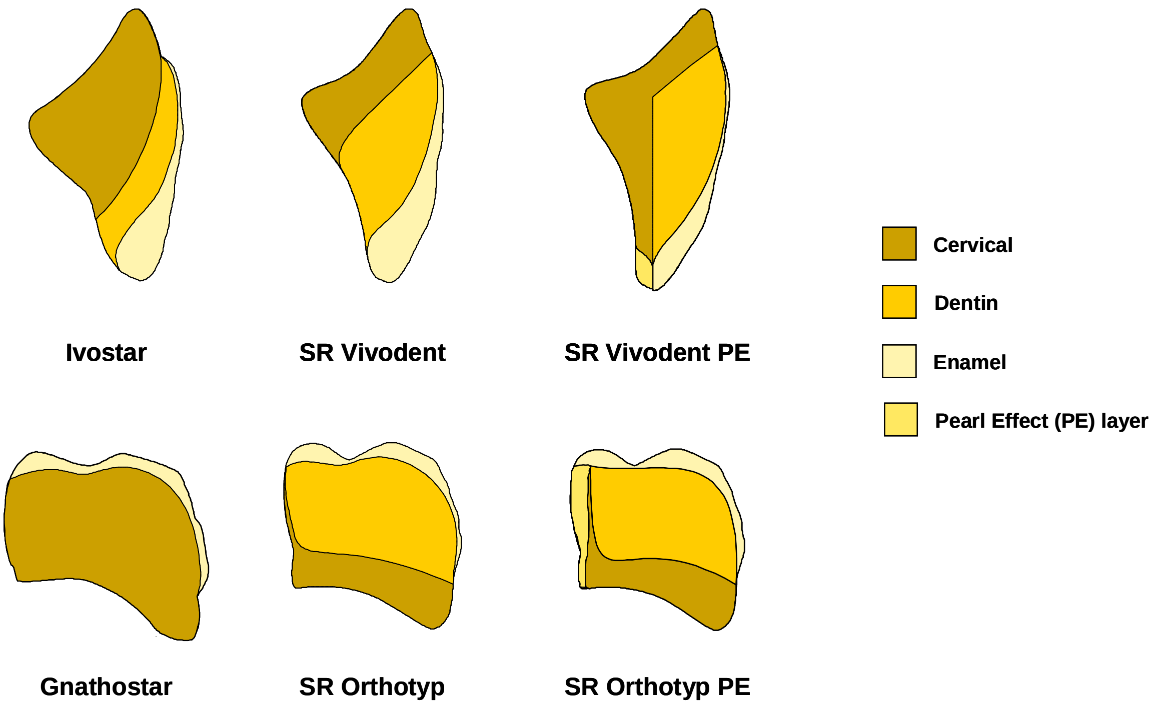
The SR Phonares NHC and SR Phonares II teeth consist of NHC material, which is a composite consisting of a urethane dimethacrylate matrix with inorganic fillers, iso-fillers (prepolymer) and PMMA clusters embedded in the structure.
Please see Section 2 for a detailed description of this material.

2. Description of material/Materials science

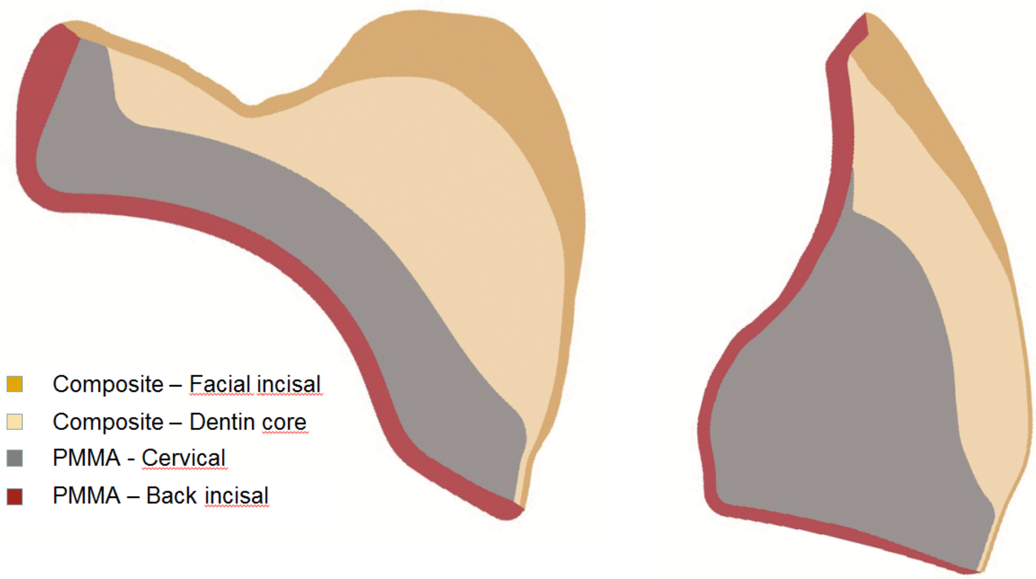
2.1 Layering schemes

The Ivoclar Vivadent range comprises resin teeth that are based on different layering schemes. The tooth lines range from posterior teeth that involve a straightforward two-layer design (e.g. Gnathostar) to highly esthetic teeth consisting of four layers (e.g. SR Vivodent PE anterior teeth or SR Phonares II).

2.1.1 Layering scheme of different Ivoclar Vivadent teeth



2.1.2 Layering scheme of SR Phonares II



The true-to-nature effect and structure of the SR Phonares II anterior and posterior teeth is achieved with four individually shaded layers. The dentin core and facial incisal consist of composite material, which imparts both high wear resistance and natural esthetics to the tooth. The back incisal and cervical layers are comprised of PMMA material to ensure an effective and stress-free bond with conventional denture base materials.

2.2 Description of material

2.2.1 NHC material

The SR Phonares II teeth consist of NHC material. This material is based on a urethane dimethacrylate matrix, which comprises various types and sizes of fillers as well as PMMA clusters.

Not only the chemical composition but also the size, shape and concentration of filler particles have a significant effect on the properties of a composite. The NHC material falls into the category of hybrid composites. The adjective "hybrid" means that this composite is a compound of different types and sizes of fillers; "hybrid" also means that the material is a combination of two types of material: composite and PMMA.

The NHC material comprises a variety of fillers: highly crosslinked inorganically filled macrofillers, highly densified inorganic microfillers and silanized nanoscale fillers based on silicon dioxide. The macrofillers are mainly responsible for the strength and colour stability of the teeth, while the microfillers enhance the material's resistance to wear.

The optical properties of these fillers are different from those of other fillers. For instance, composite pastes which contain fillers of a size smaller than 50 nm exhibit a translucent appearance, regardless of whether or not the refractive index corresponds with that of the monomer matrix. This represents a decisive advantage over conventional fillers, whose refractive index has to match that of the polymerized matrix to attain a high level of translucency. In addition, nanoscale fillers may alter the refractive index of a monomer mixture without decreasing the degree of translucency [18]. This offers additional possibilities in the development of composite teeth, which have to offer true-to-nature esthetic and translucent properties.

2.2.2 Schematic of NHC microstructure

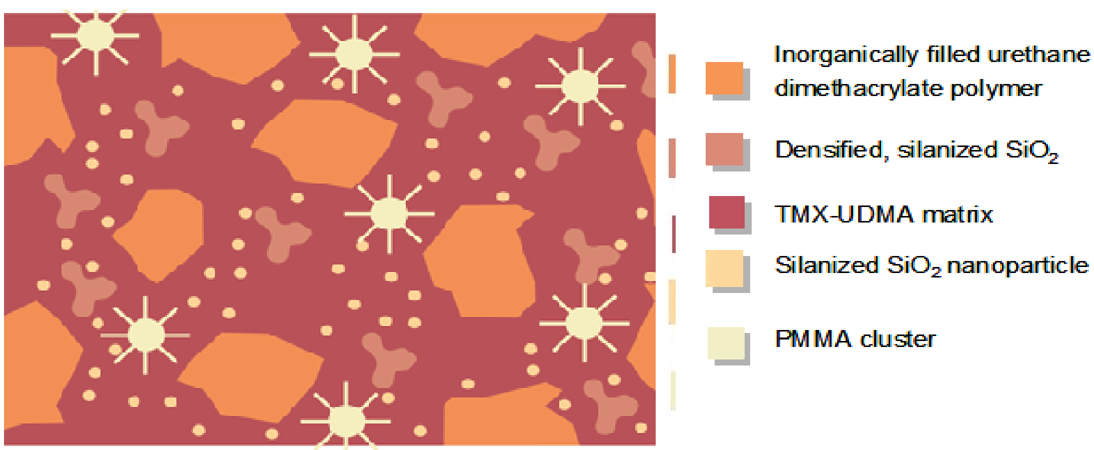


Fig. 1: Schematic of NHC microstructure

2.2.3 Microstructure of NHC material (SEM image)

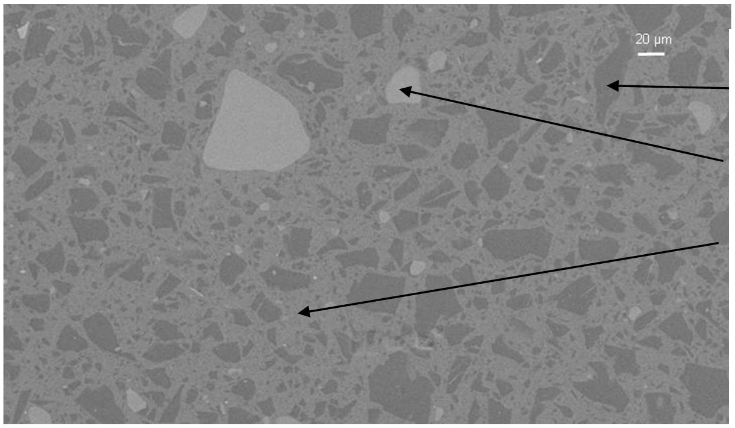


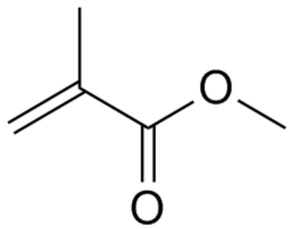
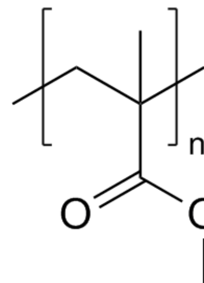
Fig. 2: SEM image of a ground and polished NHC sample

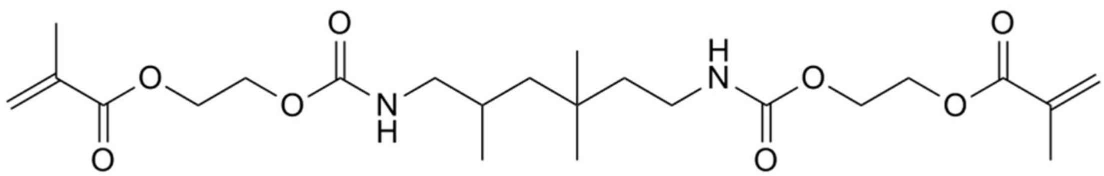
2.2.4 Description of the components of NHC

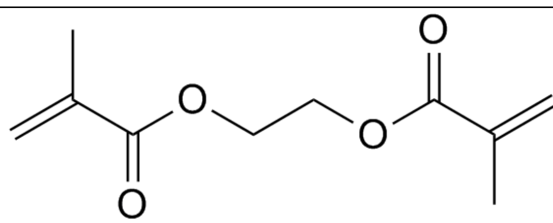
NHC component	Function	Main advantages
UDMA (urethane dimethacrylate) and other methacrylates	Matrix	The UDMA matrix is characterized by a high degree of crosslinking. The material structure is very stable and resistant to chemical attacks.
Densified, silanized SiO_2	Filler 1	This inorganic filler is utilized to strengthen the matrix and increase the material's hardness and wear resistance. It also optimizes the material's refractive index and therefore its true-to-nature shade effect and opalescence.
Silanized SiO_2 filler particle	Filler 2	These nanoscale surface-modified inorganic particles strengthen the composite structure. Because of their nanoscale nature, these particles form homogeneous contact surfaces. This also helps to preserve the opposing tooth structure.
Inorganically filled urethane dimethacrylate polymer	Filler 3 (isofiller)	These matrix-based prepolymer particles reduce the polymerization shrinkage stress.
PMMA cluster	Inclusions	These PMMA clusters are embedded in the composite structure and reduce the material's affinity for plaque accumulation and discoloration.

2.2.5 Chemical structure

The monomers utilized in the manufacture of SR Phonares II are shown below. The matrix consists mainly of UDMA, with smaller proportions of MMA and EGDMA. The polymer of MMA (PMMA) improves the properties of the composite with regard to discolouration and plaque accumulation. In addition, PMMA is the main component of the cervical and back incisal layers.

MMA: Methyl methacrylate	PMMA: Polymethyl methacrylate
	

UDMA: Urethane dimethacrylate


EGDMA: Ethylene glycol dimethacrylate


3. Technical data

SR Phonares II

Material type: Facial incisal and dentin = Nanohybrid composite (NHC)
Back incisal and cervical = Polymethyl methacrylate (PMMA)

Tooth structure: Four layers: Incisal (I), Dentin (D), Cervical (C) and Palatinal Enamel (PE) made of different methacrylate composites

Standard composition: **(in % by weight)**

	I	***D***	***C, PE***
Dimethacrylate	18.5 - 22.0	17.5 - 22.0	1.0 - 4.0
Polymethyl methacrylate	25.0 - 29.0	23.0 - 28.0	94.0 - 98.6
Highly dispersed silicon dioxide	10.0 - 12.0	9.0 - 12.0	-
Inorganically filled prepolymer	39.0 - 44.0	41.0 - 45.0	-
Pigments, depending on shade	0.1 - 0.3	0.2 - 0.8	0.1 - 0.4
Initiators and stabilizers	0.5 - 0.9	0.5 - 0.9	0.3 - 0.5

Physical properties:

ISO 22112:2005 – Dentistry, artificial teeth for dental prostheses
In accordance with ISO 10477:2004 – Polymer-based crown and bridge materials

	Test method		Specification	**I** Example values	**D** Example values	**C, PE** Example values
Flexural strength	ISO 10477	MPa	≥ 50	119	132	137
Water sorption	ISO 10477	µg/mm³	≤ 40	35	33	26
Water solubility	ISO 10477	µg/mm³	≤ 7.5	0.5	0.2	0.1
Other physical properties						
Modulus of elasticity	ISO 10477	MPa		3927	4410	3467
Ball indentation hardness	ISO 2039-1	MPa		210	223	170
Vickers hardness HV 0.5/30	internal requirement	MPa		235	258	190

4. In vitro investigations

4.1 General

The results of *in vitro* investigations cannot be taken as a direct measure of a material's clinical suitability. However, these results can provide important indications of how the product behaves under certain test conditions.

The values obtained in the process should not be used as absolutes; instead, they should be interpreted/utilized against the test configurations and conditions.

As a consequence, the wear measurements shown in the diagrams of Section 4.2 are not represented in absolute values; instead they indicate the relative wear in comparison with PMMA material.

4.2 Wear

4.2.1 The problems of interpreting in vitro wear measurements

Interpreting the outcome of wear measurements creates a great deal of difficulty because wear measurements involve complex interrelationships and numerous factors affecting the results.

The wear behaviour of a material is not only determined by its mechanical properties but is also significantly affected by other factors, e.g. surface roughness, irregularities, phases and inclusions, orientation of crystals, etc. Furthermore, the type of antagonists, experimental design and environment also play an important role.

The wear resistance of teeth is a frequent topic of publications. Widely varying test methods [8; 9] are described and used in such studies and, at times, contradictory results are measured and published [10; 11]. Heintze *et al.* [8] compared the controversial wear results of *in vitro* investigations with the results of clinical studies. The issues involved in transferring *in vitro* results to *in vivo* conditions are described and discussed in detail in this publication.

Individual methods produce different results and what is more, even the same wear measurement method may provide differing results, depending, for instance, on the type of antagonist material selected for conducting the test. Hahnel *et al.* [12] studied the wear behaviour of different tooth materials in conjunction with different antagonist materials (steatite, steel, artificial teeth) using a two-body wear method (pin on block). This study showed that the material of the antagonist had a significant effect on both the wear mechanism and loss of material. Steatite emerged as the "gold standard" to determine the wear resistance of artificial teeth in this study. Steatite enables a significantly more accurate differentiation of the wear resistance of individual denture teeth when they are tested.

The fact that individual chewing simulators fail to provide results that correlate with each other is particularly worthy of notice. This problem may be attributed to the fact that most methods can only simulate one or two of the different wear mechanisms occurring in the oral cavity at any one time. Therefore, dental materials should be tested in two or more chewing simulators to enhance the clinical relevance of the results. The results of a single wear measurement run may be misleading.

4.2.2 In vitro investigations

The following graphs illustrate the results of *in vitro* wear measurements obtained with SR Phonares II. The results are shown in comparison with different kinds of materials typically used for denture teeth. The illustrations demonstrate the relative wear in comparison with PMMA.

4.2.2.1 Pin on block

Two-body wear testing – Pin on block

Investigator:	M. Rosentritt, University of Regensburg, Germany
Simulation:	Regensburg chewing simulator ("pin on block" method) 120,000 cycles, 50 N, 1.2 Hz
Samples:	Samples made from denture teeth
Evaluation:	Scanning of plaster replicas using a Willytec 3D laser scanner
Antagonist:	Steatite

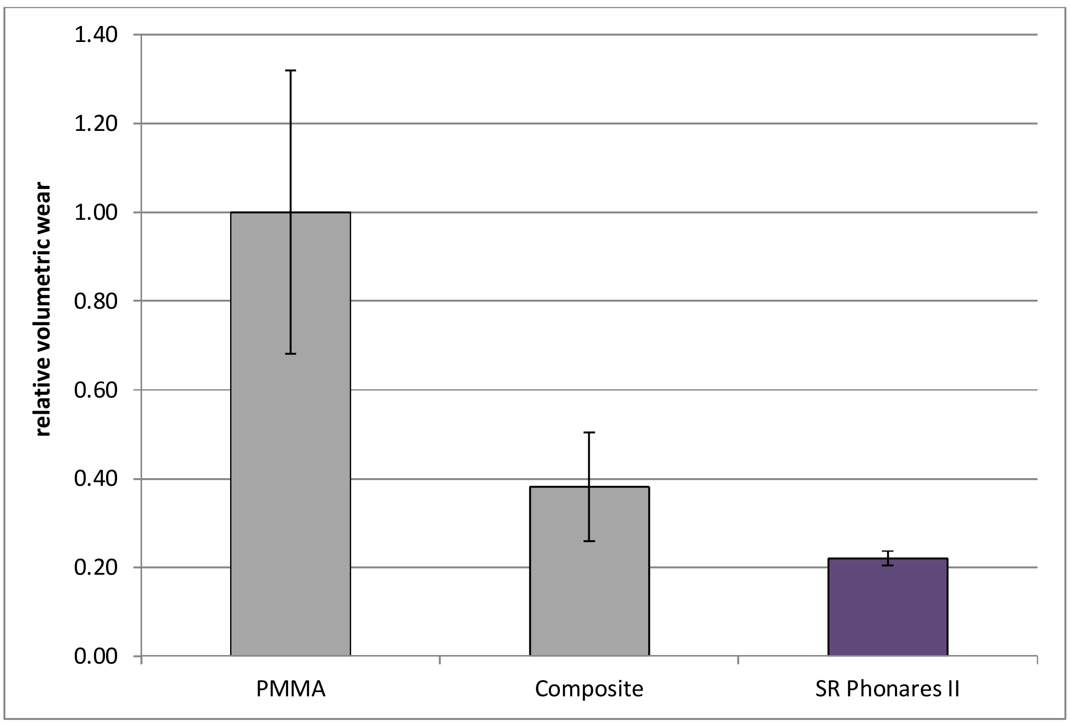


Fig. 3: "Pin on block" method: Relative wear in comparison with PMMA (Measurement: M. Rosentritt, University of Regensburg, 2011)

The wear of composite teeth is lower than that of PMMA-based teeth. SR Phonares II showed the lowest rate of wear in the "pin on block" wear test.

4.2.2.2 Leinfelder method

Three-body wear testing – Leinfelder

Investigator:	M. A. Latta, Creighton University, Nebraska, USA
Simulation:	Leinfelder chewing simulator, 80 N, 1 Hz, rotation +/-30°, 400,000 cycles, slurry (PMMA spherules)
Samples:	Samples made from denture teeth
Evaluation:	3D profilometry

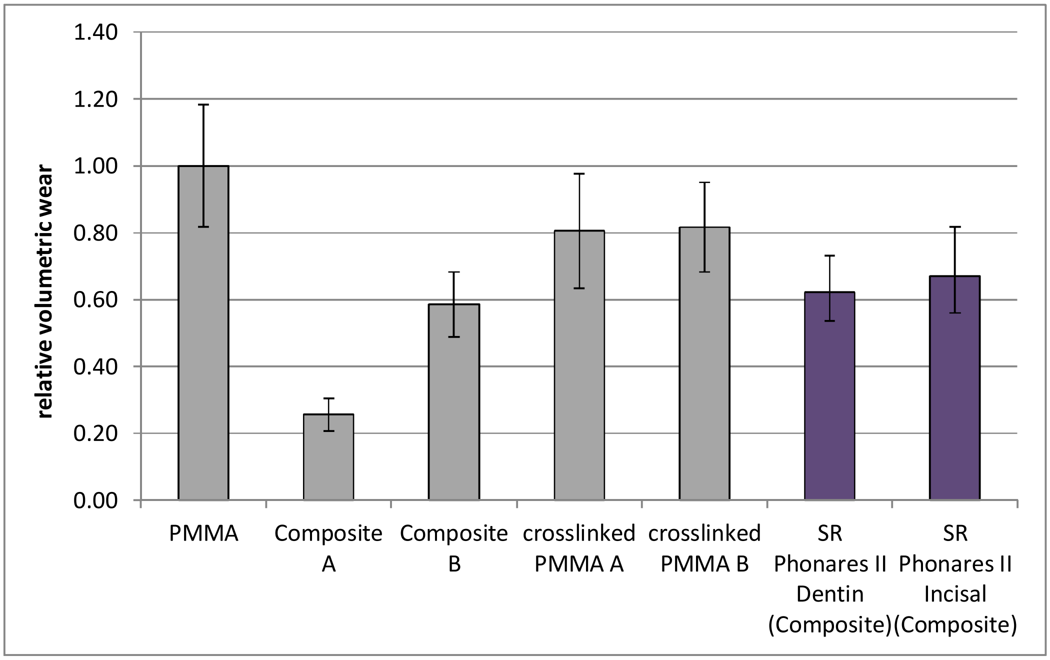


Fig. 4a: Leinfelder method: Relative volumetric wear in comparison with PMMA (Measurement: M. Latta, Creighton University Nebraska, 2011)

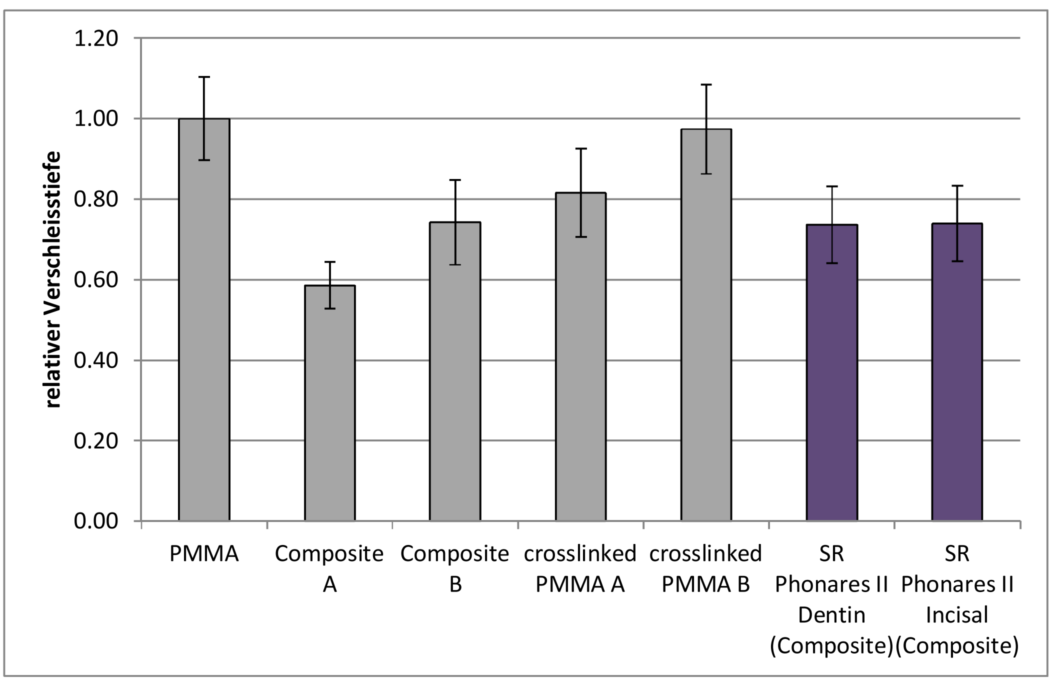


Fig. 4b: Leinfelder method: Relative vertical wear in comparison with PMMA (Measurement: M. Latta, Creighton University Nebraska, 2011)

Composite materials show the lowest wear values of all materials tested when subjected to Leinfelder three-body wear testing. The SR Phonares II materials were more resistant to wear than PMMA and crosslinked PMMA.

4.2.2.3 Willytec chewing simulator

Two-body wear testing – Willytec – Denture teeth

Investigator:	S. Heintze, Ivoclar Vivadent, R&D, Schaan, Liechtenstein
Simulation:	Willytec chewing simulator, 100,000 mastication cycles, 3 kg loading, 3 mm lateral movement, no lifting, 1.2 Hz, thermocycling (5 °C/ 55 °C)
Samples:	Prefabricated denture teeth, 8 teeth
Antagonist:	Made from prefabricated denture teeth
Evaluation:	Measuring of plaster replicas using a Willytec 3D laser scanner

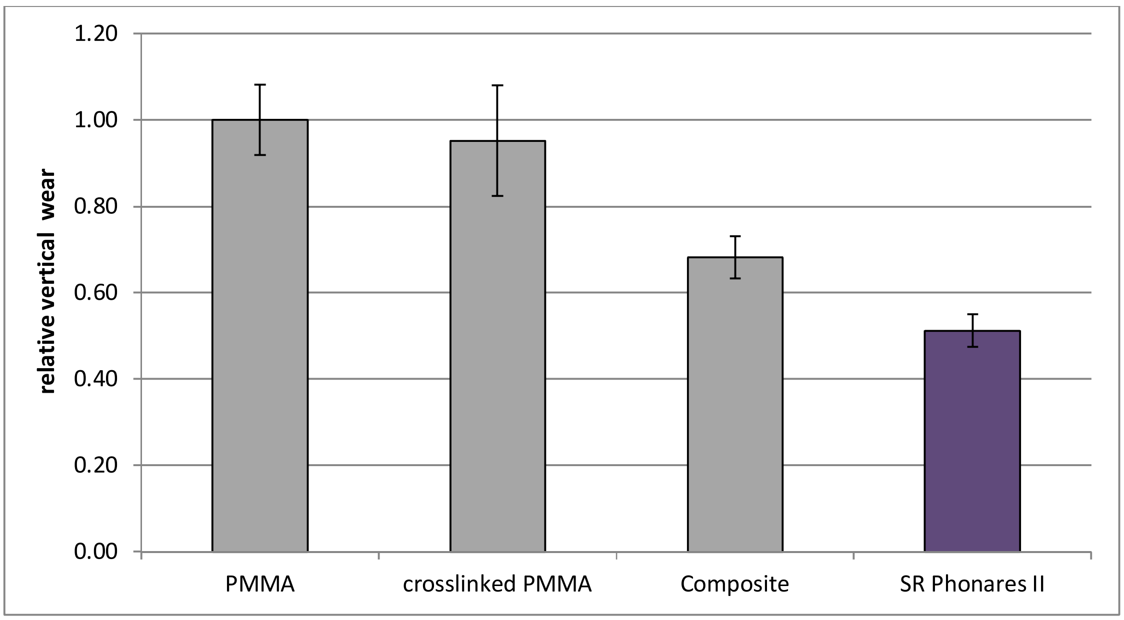


Fig. 5: Willytec method: Relative wear in comparison with PMMA (Measurement: S. Heintze, Ivoclar Vivadent, R&D, Schaan, 2009)

When subjected to testing in a chewing simulator, SR Phonares II shows very low material wear compared to the other denture teeth materials tested. If these results are combined with the antagonist wear results, SR Phonares II and the other composites tested demonstrate a significantly lower overall wear than the PMMA-based denture teeth.

4.2.3 In vitro wear: summary of results

SR Phonares II was subjected to different wear testing methods to arrive at an accurate statement on the material's wear behaviour (see Fig. 6). Alongside SR Phonares II, several popular denture tooth materials were included in each test method.

SR Phonares II and the other composite materials included in the tests demonstrated the lowest wear in conjunction with the wear testing methods applied. The variety of methods used (Fig. 6) and the results obtained show that SR Phonares II may also offer a favourable wear resistance *in vivo*.

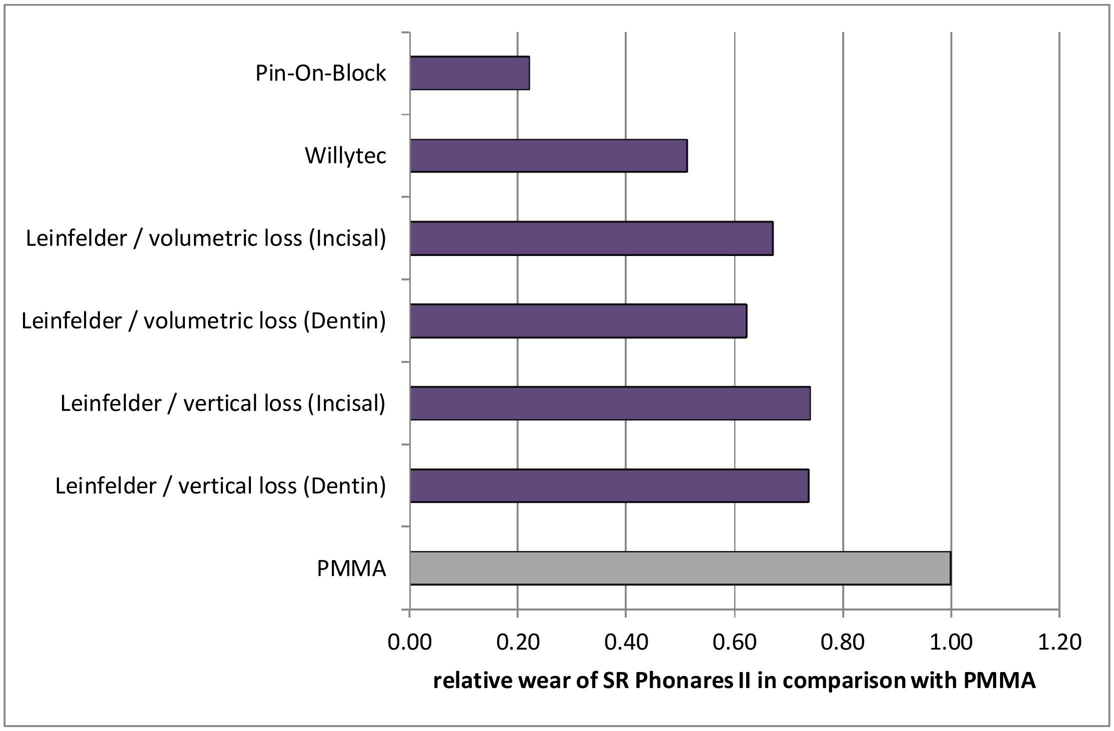


Fig. 6: Summary: Relative wear of SR Phonares II in comparison with PMMA (various methods)

4.3 Toughness

Chipping and fracture resistance constitute essential factors for the clinical durability of denture teeth because such incidents may impair the functional and esthetic properties of the denture teeth. Composite materials are more resistant to wear than PMMA but more brittle than the latter and therefore generally more susceptible to fractures. The aim is to strike a balance between wear and fracture resistance or toughness when denture teeth are developed.
Several investigations on fracture behaviour were carried out during the development of Phonares II.

4.3.1 Fracture toughness

Various values are utilized to express fracture toughness: K_{max} (maximum stress intensity factor), or W_f (fracture work). Measuring these values is not required by EN ISO 22112. As these values nonetheless provide some information on a material's characteristics, the developers at Ivoclar Vivadent decided to determine the fracture toughness of the SR Phonares II materials using a test method described in the standard for denture base materials (EN ISO 20795-1).

Investigator: K. Hagenbuch, Ivoclar Vivadent, R&D, Schaan, Liechtenstein

Method: In accordance with EN ISO 20795-1. Smaller test specimens (5 x 25 x 2.5 mm) were utilized.

Results: The fracture toughness (K_{max}) of SR Phonares II is higher than that of crosslinked PMMA (see Fig. 7). The fracture work value is comparable with that of crosslinked PMMA (see Fig. 8).

Conclusion: On the basis of the above results, it can be assumed that the clinical suitability of SR Phonares II is similar to that of the proven crosslinked PMMA material in terms of fracture behaviour.

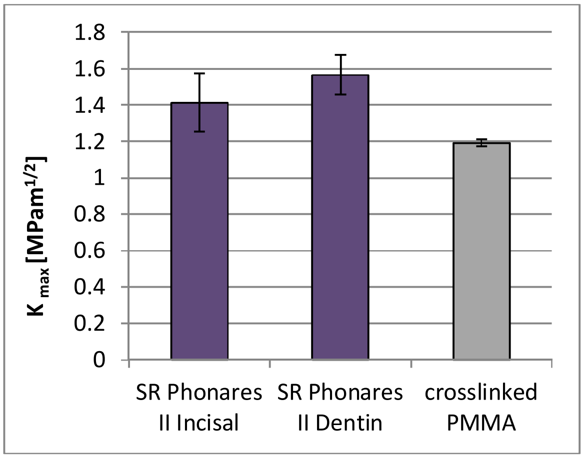


Fig. 7: Fracture toughness (K_{max}) of SR Phonares II materials in comparison with crosslinked PMMA

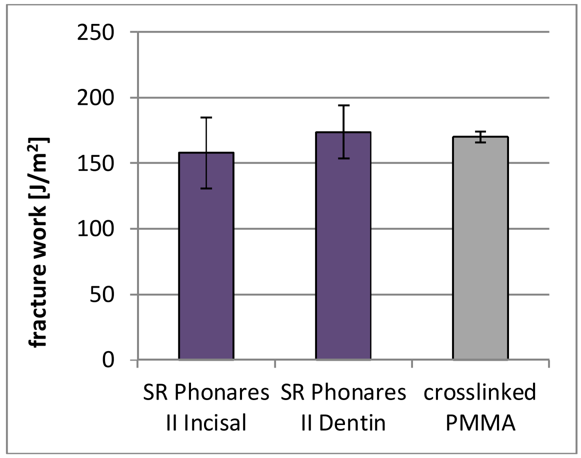


Fig. 8: Fracture work (W_f) of the SR Phonares II materials in comparison with crosslinked PMMA

4.3.2 Crack initiation

Chipping and fractures are caused by cracks in the material. For this reason, the crack initiation of various composite materials used in the manufacture of denture teeth was investigated.

Investigator: K. Hagenbuch, Ivoclar Vivadent, R&D, Schaan, Liechtenstein

Method: Test samples measuring 20 mm in diameter and 5 mm in height were loaded with a spherical metal indenter (5-mm diameter) at a speed of 5 mm/min in a universal testing machine (Zwick) (see Fig. 9a). The minimum load at which cracks were detected was recorded (see Fig. 9b).

Fig. 9a Setup for the crack initiation test

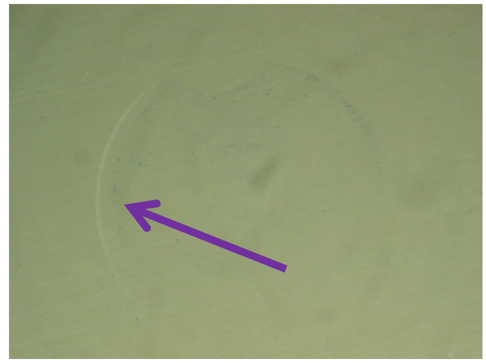


Fig. 9b Example of crack formation (see arrow)

Results: Cracks formed at 1500 N in the SR Phonares II material; other composite materials were able to withstand only half of that load or less (see Fig. 10).

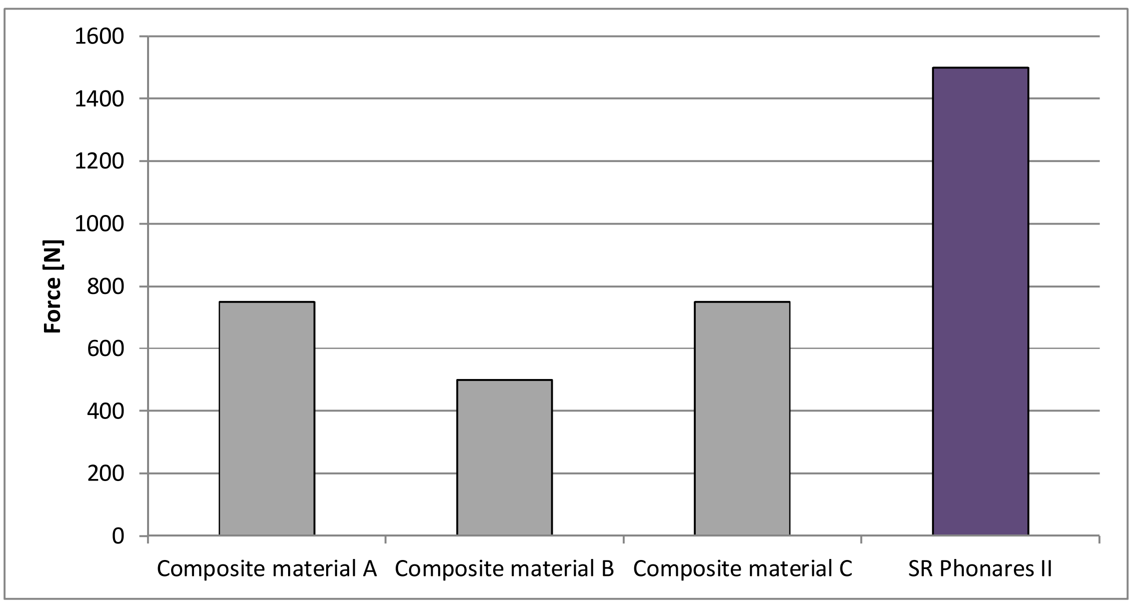


Fig. 10: Force at which first cracks began to appear in various composite materials including SR Phonares II

Conclusion: Only if exposed to very high forces does SR Phonares II show crack formation, which may cause chipping. The material is considerably more resistant to crack formation than composite materials of earlier generations.

4.3.3 Chipping resistance

Chipping of denture teeth is functionally and esthetically undesirable. Simulating the processes that may cause “chipping” involves a complexity of conditions. Using only one method is usually not sufficient to determine the chipping resistance of a material.

4.3.3.1 Chipping test

Investigator: K. Hagenbuch, Ivoclar Vivadent, R&D, Schaan, Liechtenstein

Method: Teeth were secured to metal, mounted on a universal testing machine (Zwick) and loaded at a speed of 5 mm/min (see Fig. 11). The load at which chipping occurred was measured.

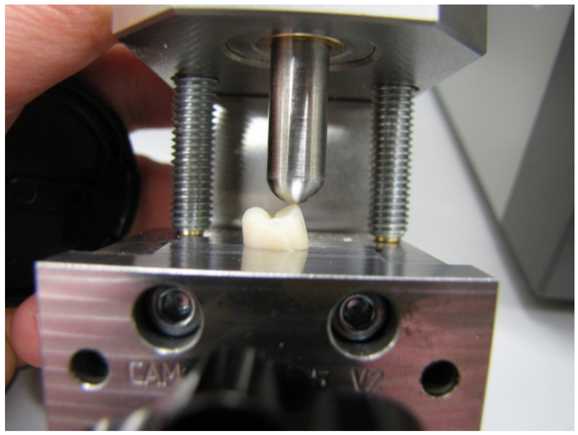


Fig. 11 Setup for chipping test

Results: Chipping only occurred at forces above 1300 N in the posterior SR Phonares II teeth and at forces above 1700 N in the anterior teeth. The reference material was only able to withstand forces lower than 500 N and 1000 N respectively (see Fig. 12).

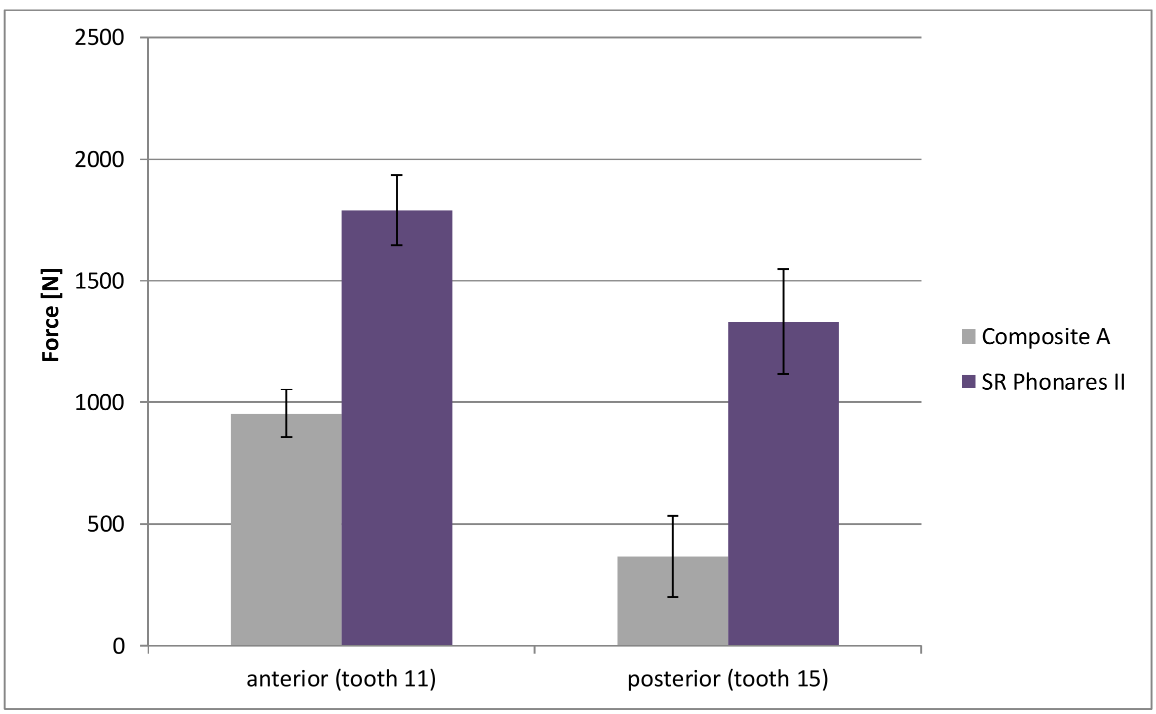


Fig. 12: Force at which chipping occurred in composite material including SR Phonares II

Conclusion: Chipping occurs in SR Phonares II only if the material is exposed to very high forces. SR Phonares II is considerably more resistant to chipping than composite materials of earlier generations.

4.3.3.2 Edge strength

Investigator: Dr N. Silikas, Prof. D.C. Watts, University of Manchester, UK

Study title: Evaluation of Edge Strength of Phonares II and Competitor Products

Method: Anterior teeth made of various tooth materials (composite, crosslinked and/or inorganically filled PMMA, interpenetrating polymer network IPN) were tested in an edge chipping machine (CK10 Engineering Systems, Nottingham, UK) using a polycrystalline diamond indenter (see Fig. 13). The mesial and distal tooth surfaces were levelled and smoothed with silicon carbide sanding paper (see Figs 14a and 14b) before the specimens were placed in the machine and loaded at a distance of 0.5 mm from the edge, using a speed of 3 mm/min. The load-to-fracture value was recorded. Three measurements were carried out and the resulting values averaged for each specimen. In addition, the fracture patterns were examined under a microscope and classified as a chip or a crack.
ANOVA and Bonferroni post-hoc tests ($p<0.05$) were used for statistical analysis.

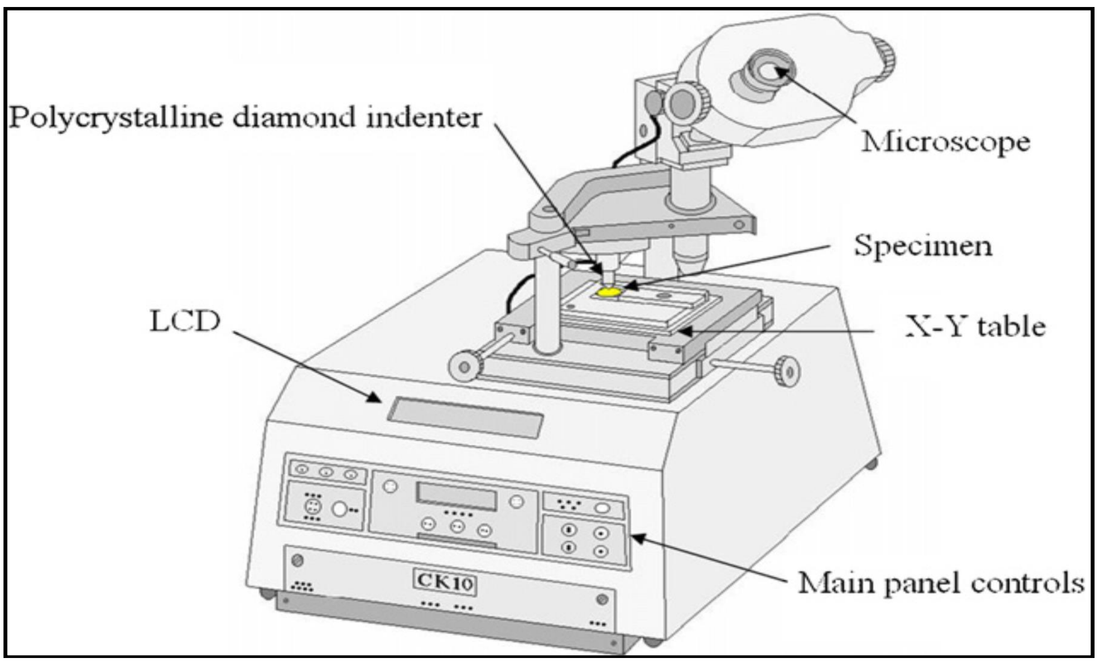


Fig. 13: Schematic of the CK10 edge chipping machine for edge strength testing

Watts DC, Issa M, Ibrahim A, Wakiaga J, Al-Samadani K, Al-Azraqi M, Silikas N. Edge strength of resin-composite margins. Dent Mater 2008;24(1):129-133.

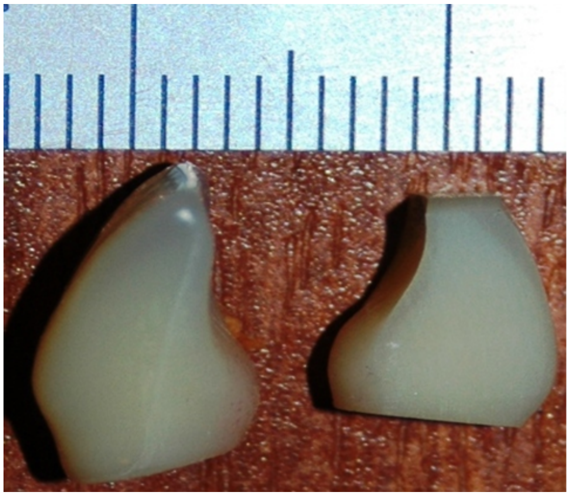


Fig.14a: The mesial and distal tooth surfaces were ground (on the left: before; on the right: after).

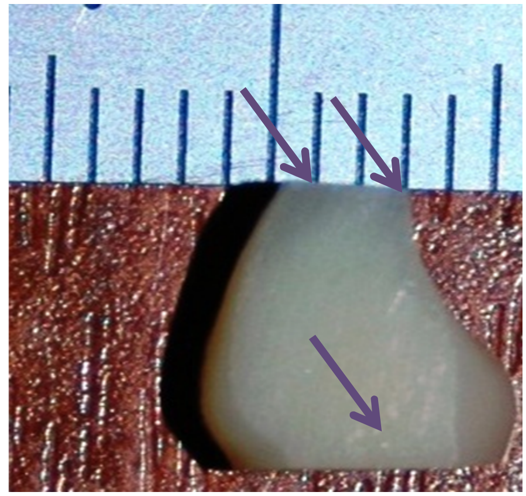


Fig. 14 b: Three measurements were carried out at different locations (arrow) on each specimen.

Result: SR Phonares II was able to withstand a load of up to 300 N before chipping occurred. The edge strength of other materials such as PMMA (crosslinked, inorganically filled or interpenetrating polymer network IPN) was statistically significantly lower than that of Phonares II (see Fig. 15).

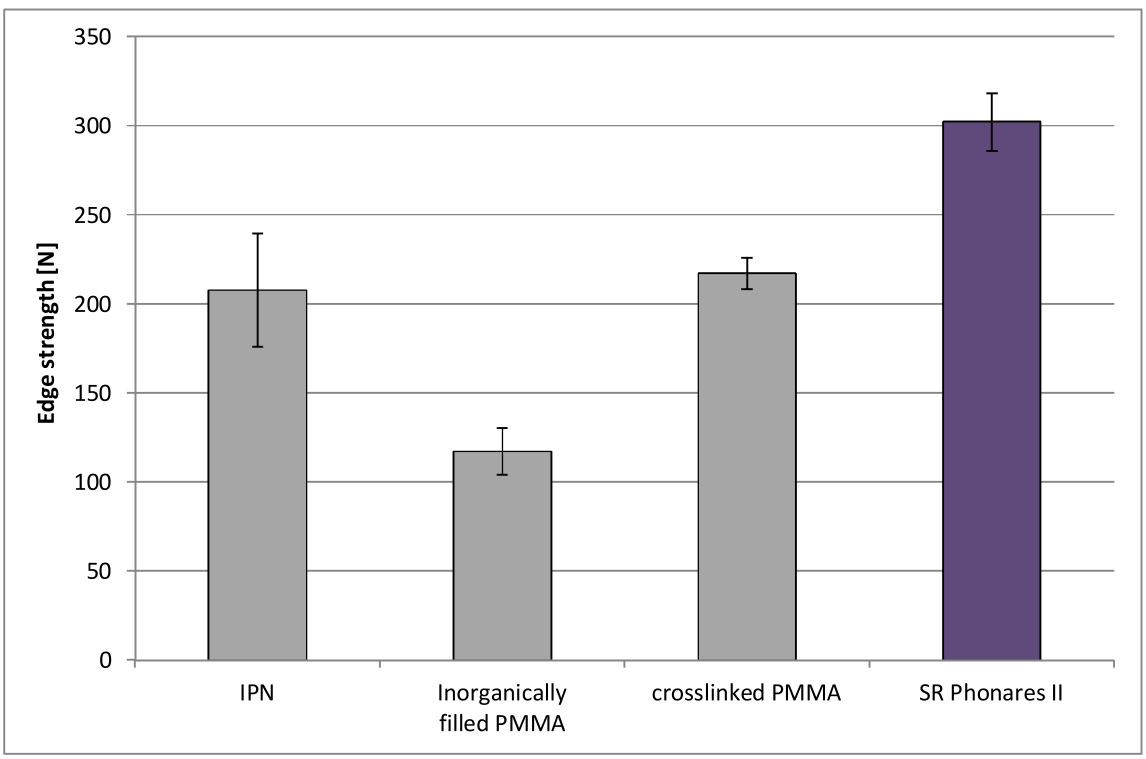


Fig. 15: Edge strength of various types of denture teeth. Measurement by: D. Watts, University of Manchester, 2011.

4.3.3.3 Compressive strength

Investigator: Dr C. Muñoz, University of Buffalo, New York, USA

Study title: Fracture Strength of Denture Teeth (Compressive)

Method: A range of teeth (SR Phonares II; teeth made of composite materials of earlier generations and teeth made of highly crosslinked PMMA) were loaded at a speed of 1 mm/min until fracture occurred. The base of the teeth was embedded in resin. The incisal surfaces of the anterior teeth were ground to be able to apply the force to a level surface (see Fig. 16). Premolars were loaded with an indenter that was touching the two cusps without touching the bottom of the occlusal surface. The molars were loaded with a spherical indenter so that 3 cusps were involved. Ten teeth were tested for each group.

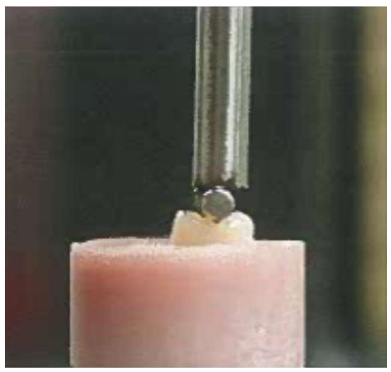


Fig. 16. Setup for compressive strength testing

Results: It is in the nature of premolars and molars that they withstand higher forces than anterior teeth. A comparison of various materials has shown that SR Phonares II anterior teeth tend to be able to bear considerably higher forces than the anterior teeth of other test groups. The load-to-fracture values measured in the SR Phonares II premolars and molars were significantly higher than those measured for the teeth made of composite material of an earlier generation. By and large, SR Phonares II lies in the range of teeth made of highly crosslinked PMMA (see Fig. 17).

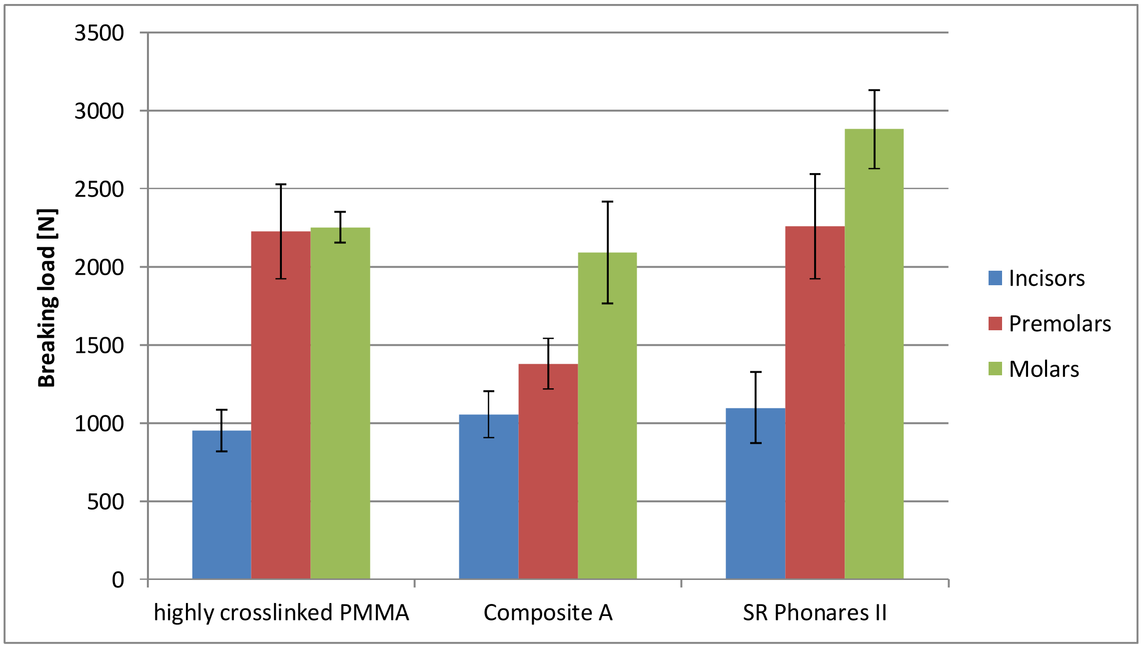


Fig. 17. Fracture load of various denture teeth

4.3.3.1 Shear strength

Investigator: Dr C. Muñoz, University of Buffalo, New York, USA

Study title: Fracture Strength of Denture Teeth (Shear)

Method: Teeth (SR Phonares II; teeth made of a composite of an earlier generation and teeth made of highly crosslinked PMMA) were loaded at a speed of 1 mm/min until they fractured. The premolars were loaded at an angle of 70° to the longitudinal axis of the tooth (see Fig. 18). The indenter was placed on the lingual surface at a distance of 2 mm from the incisal edge. The base of the teeth was embedded in resin. Ten teeth were tested for each test group.

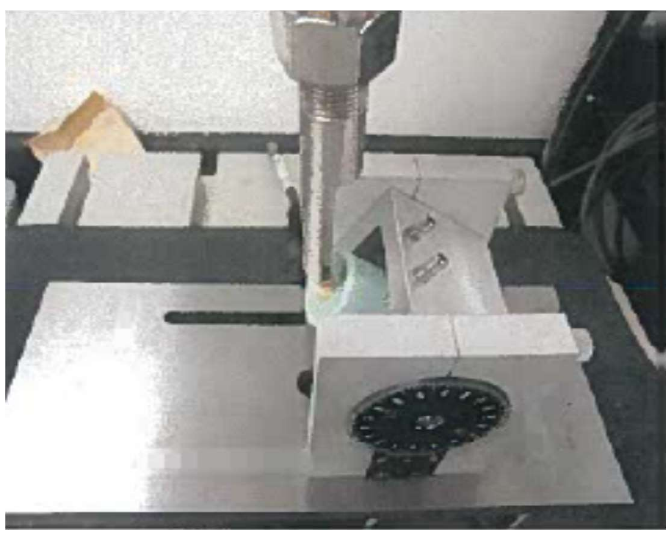


Fig. 18. Setup for shear strength testing

Results: Statistically, the fracture load of the denture teeth tested did not differ significantly in a comparison of several materials (see Fig. 19).

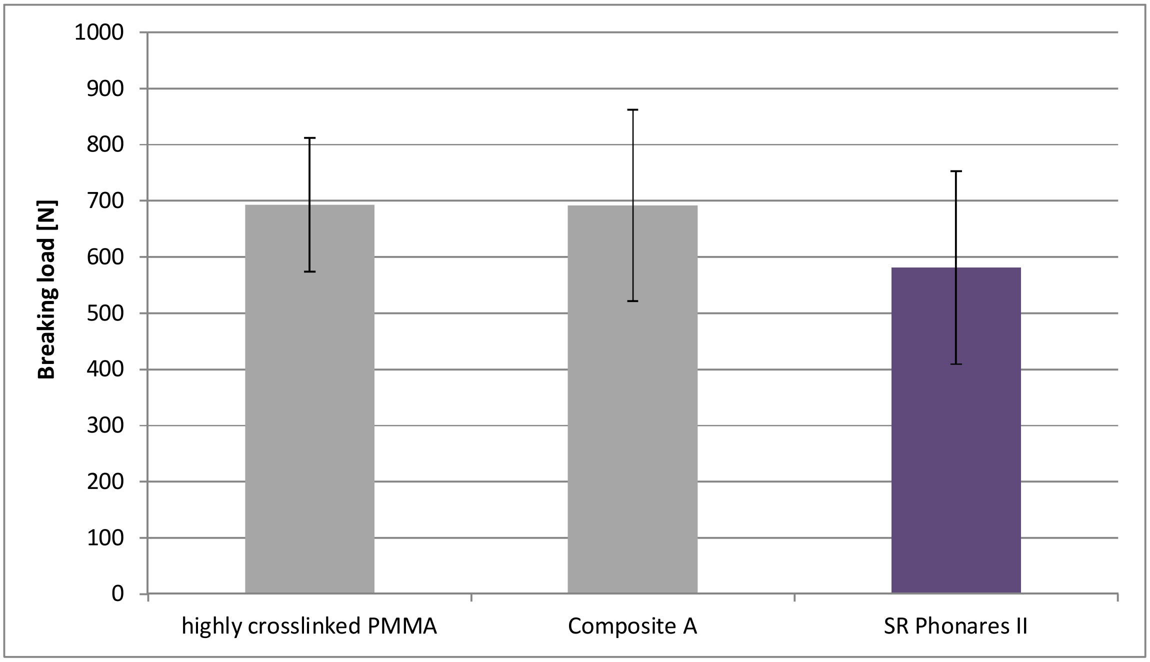


Fig. 19. Fracture load of anterior denture teeth made of different materials in a shear strength test

4.4 Colour stability

Food and beverages may cause discolouration in both natural and artificial teeth. The tendency to discolouration of a material can partly be simulated in the laboratory by storing test specimens in coloured dye solutions.

The image below shows a number of specimens made of different types of materials. The teeth were boiled in coffee or 0.1% Safranine T under reflux for 16 hours.

It has to be taken into account that the initial shade was not identical in the test samples.

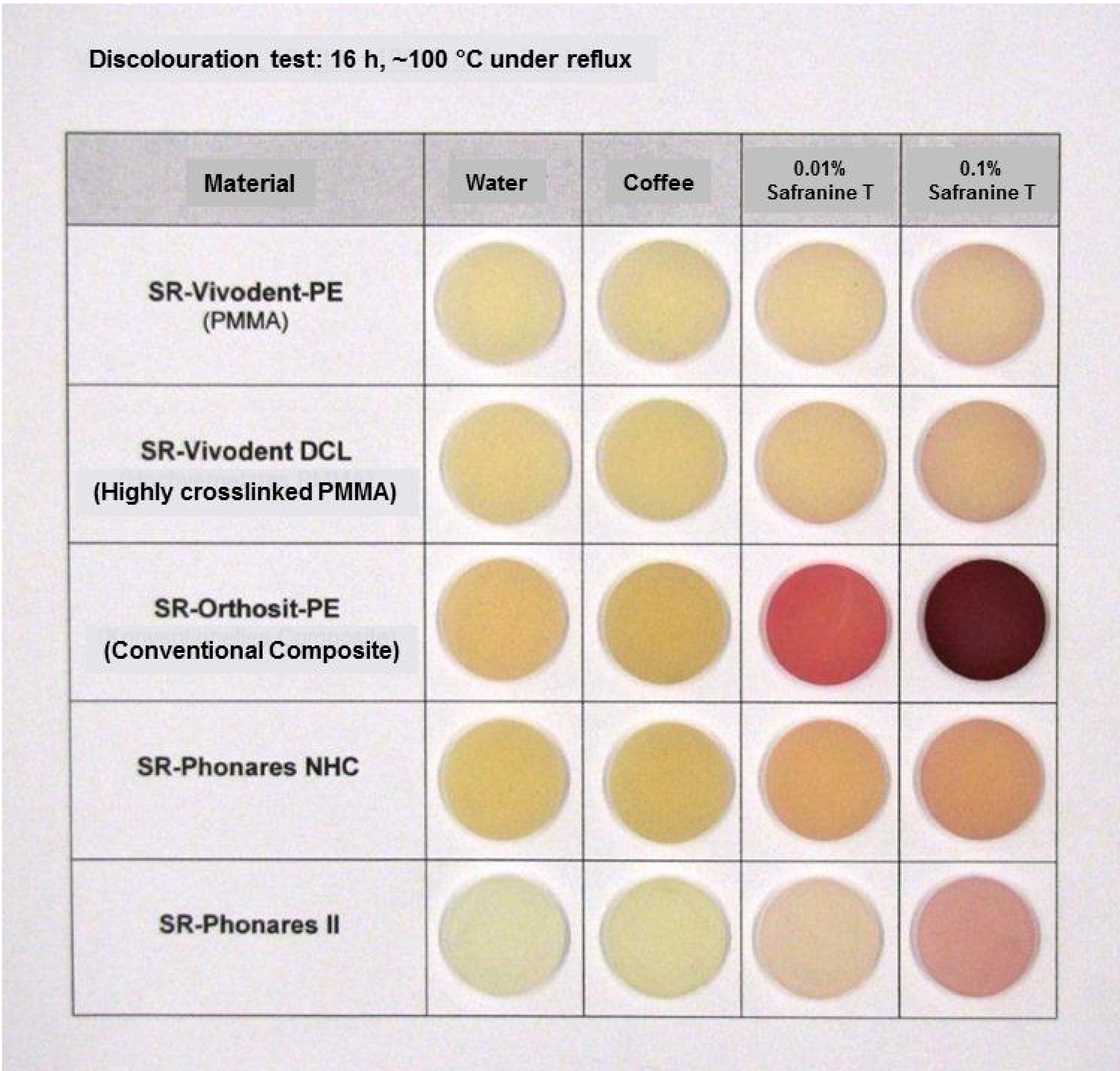


Fig. 15: Results of discolouration test: denture tooth materials after having been stored in various dye solutions (16 hours, under reflux) (Measurement: Ivoclar Vivadent, R&D, Schaan, 2012)

Generally, composite teeth are more prone to discolouration than PMMA teeth. SR Phonares II consists of a material whose resistance to discolouration is significantly increased over that of both conventional composites and the predecessor material.

5. Clinical investigations

5.1 Ernst-Moritz-Arndt-Universität Greifswald, Germany

Investigators: Prof. Dr R. Biffar, OA Dr Th. Klinke

Study title: *Clinical evaluation of SR Phonares II*

Objective/
Experimental design: Twenty-seven patients received dentures in September 2011. These dentures included 26 complete upper dentures, 16 complete lower dentures and 1 partial lower denture. The dentures were set up according to the TiF principles (Merz Dental) to achieve a canine guided, bilaterally supported occlusion. Recalls will be carried out at regular intervals to assess the durability (cracks, chipping), tendency to plaque accumulation, colour stability and patient satisfaction.

Results: Follow-up data up to 6 months are available. No negative results have been observed so far.

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

Investigators: Dr Ronny Watzke, Dr Frank Zimmerling

Study title: *Clinical behaviour of SR Phonares II*

Objective/
Experimental design: Forty-three dentures were inserted in 22 patients. These dentures included 26 complete dentures set up according to the BPS method and 17 combined dentures, whose esthetic and static aspects were designed individually to meet the specific requirements of the patient and to achieve an ideal antagonist situation in the opposing dentulous jaw. The durability (cracks, chipping), tendency to plaque accumulation, colour stability and wear will be rated at regular recalls.

Results: No negative findings have been reported in the observation period that has been running for 6 months so far.

6. Biocompatibility

6.1 Introduction

The raw materials polymerize to a solid material during the production process of the denture teeth. The biocompatible properties of the solid materials are different from those of the raw materials. The denture teeth consist of an insoluble polymer which is not accessible to the organism and can be regarded as inert. Only substances that may dissolve from the material could pose a risk of exposure to the patient. For this reason, the eluates were subjected to a range of biocompatibility tests.

6.2 Cytotoxicity

The toxicity of the NHC material was determined by means of an XTT cytotoxicity assay according to ISO 10993. Using cell culture media, the samples were subjected to extraction tests and the resulting eluates were examined. The extracts from SR Phonares II revealed no cytotoxic potential [13].

6.3 Irritation

The irritation potential of SR Phonares NHC, the predecessor product of SR Phonares II, was tested according to ISO 10993-12 in an *in vitro* test using a skin model (Episkin). SR Phonares NHC, which is chemically very similar to SR Phonares II, proved to be non-irritating in this test [14].

6.4 Genotoxicity

The NHC material was subjected to an Ames test (Salmonella typhimurium and Escherichia coli reverse mutation assay) according to ISO 10993-12 to assess the mutagenic potential. SR Phonares II revealed no mutagenic potential in this test [15].

6.5 Conclusions

On the basis of the data available to date and the present standard of knowledge, it can be stated that SR Phonares II is biocompatible. If the material is used correctly, it poses no health hazards to patients, dental technicians and dentists.

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