SR Nexco Paste

Scientific Documentation

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1. Introduction

1.1 Dental Composites

Composite materials became available in dentistry in the 1960s, when Bowen introduced a Bis-GMA formulation to the market in 1962 (1). Initially, composites were employed by dentists in the anterior region where amalgam fillings were deemed unaesthetic. By the 1990s they had begun to substitute amalgam as a more universal filling material. These direct composites (applied directly into the mouth of the patient) along with innovative bonding agents, heralded a new minimally invasive era in dentistry. Direct composites however were always somewhat limited with regard to large posterior restorations due to accelerated wear and polymerisation shrinkage issues. In the 1980s therefore, the first generation of indirect composites was introduced, followed by a second generation in the 1990s.

2. Indirect / Laboratory Composites

Whereas direct composites are applied, modelled and cured by dentists intra-orally; indirect composites are designed, modelled and cured extra-orally by dental technicians. They are also referred to as lab composites. Indirect composites can be cured in units capable of delivering higher intensities of light/heat than is either possible with hand held units or would be possible intra-orally. Indirect composites can have higher filler contents and are usually cured for longer periods resulting in higher depths of cure.

2.1 A short history of lab composites

First Generation
First generation indirect composite resins were introduced in an effort to address disadvantages that could arise from the use of direct resin composites – this included technique sensitivity, anatomic form, polymerisation shrinkage, excessive wear and sub-optimal interproximal contacts (2).

Touati (3) and Mörmann (4) were the first to introduce a technique for using the first generation of lab composites. Products included SR Isosit/Ivoclar Vivadent and Visio-Gem/3M ESPE. In general the first generation of materials suffered from low flexural strength, low modulus of elasticity, discoloration and unacceptable wear and abrasion as a result of a low homogenous filler load together with a high matrix load (2).

Second Generation
Second generation indirect composites were introduced in the mid-1990s. Often termed micro-hybrids they utilize small-diameter mineral fillers of less than 1µm with the percentage/ratio of the shape, size and distribution of the fillers varying depending on the type of composite material. The higher filler content improved mechanical characteristics and the lower organic matrix content reduced polymerisation shrinkage. (5)

Indirect composites now offer not only an aesthetic alternative to ceramics for posterior teeth as inlays and onlays but also numerous other dental solutions such as anterior crowns, the veneering of metal-supported restorations and the characterisation of denture teeth and denture base materials. The mechanical properties of lab composites in comparison to ceramics are inferior, however the aim is not that indirect composites replace ceramics rather that they supplement and complement them dependent upon each individual patient situation.

2.2 Structure and composition of lab composites

As the name suggests, "composites" whether direct or indirect are composed of at least two different materials. In most cases the components are inorganic or organic fillers embedded in an organic resin matrix plus initiators, stabilizers, pigments and optical brightening agents (6). A typical lab-composite is made up of 70-80% fillers, 18-30% monomers (matrix) and 1-3% catalysts, pigments and additives. The balance between the monomers and the fillers determines the material.

Fig. 1: Components of a typical composite: monomer mixture, fillers, initiators, catalysts and pigments.

2.2.1 Fillers of dental composites

Fillers predominantly used in modern dental composite materials are; glass fillers such as barium aluminium, silicate glass or glass ceramic, silicone dioxide fillers, mixed oxide systems, radiopaque fillers such as ytterbium trifluoride and copolymers/prepolymers which are essentially pre-polymerised composite material which has been ground down into particles of e.g. 10-30 µm, to be added as filler. The fillers largely determine the mechanical properties of the material and the particle size is crucial. Composites are commonly classified according to filler type/size i.e. macrofilled, microfilled or hybrid based.

Macro-fillers refer to inorganic particles with a grain size of up to 100 µm, nowadays however milled glasses, quartzes or glass-ceramics with an average particle size of 0.5 to 40µm are used. Large filler particles permit a high filler-load, resulting in high physical stability and low polymerisation shrinkage. They are however associated with high wear, due to the dissolving away of entire particles from exposed surfaces (7). Polishing can be problematic and surfaces may become rough i.e. conducive to plaque accumulation and discoloration.

Micro-fillers refer to fillers whereby the primary grain is up to 1 µm in size (8). Highly dispersed silica is used in most cases. It is produced by means of a pyrogenic process, allowing particle sizes of 10-50 nm to be achieved. The addition of micro-fillers means increased filler surface-area which significantly increases the viscosity of the composite. Micro-filled resins therefore do not allow high filler loading if they are to keep their handling properties and tend to demonstrate reduced physical stability and higher polymerisation shrinkage. They do however demonstrate good polishability (9) and show low wear (7, 10, 11). A way around the inherent drawbacks of micro-filled composites involves the addition of prepolymer/copolymer. As these prepolymers possess properties similar to those of the polymerised matrix, they can be used to fabricate composites with similar homogenous surface morphology as that exhibited by purely micro-filled composites.

Hybrid-fillers are a combination of micro-fillers and macro-fillers. They contain various fillers of differing grain sizes ranging from 0.01 to 30 µm (8, 12).

2.2.2 Monomers of dental composites

The monomers compose the matrix of a composite material. They must be stable in the oral environment, exhibit shade stability and low polymerisation shrinkage (high molecular weight). High molecular, multi-functional (mostly bi-functional) methacrylate compounds have proven most suitable for this purpose.

Bis-GMA (bisphenol-A-diglycidyl-dimethacrylate) was synthesised and introduced in the 1960s (1) and is one of the most frequently used monomers. **UDMA** (urethane dimethacrylate and **TEGDMA** (triethylene glycol dimethacrylate) are also commonly used.

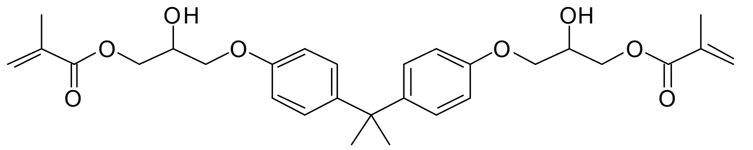
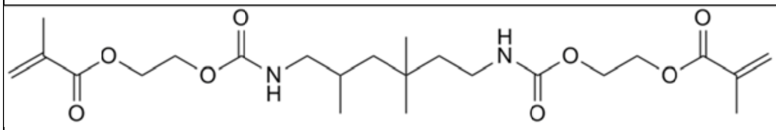
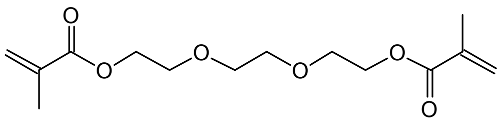
	**Bis-GMA** Bisphenol A-diglycidyl dimethacrylate
	**UDMA** Urethane dimethacrylate
	**TEGDMA** Triethylene glycol dimethacrylate

Fig. 2: Table illustrating the structural formulae for standard monomers used in dental composites

Bis-GMA used to be employed in most composite materials, as no alternative material that demonstrated a sufficiently high molecular weight and adequate reactivity to ensure thorough polymerisation was available. Bis-GMA has a relatively high viscosity and is therefore often diluted with TEGDMA which has a comparatively low viscosity in order to create a composite fit for clinical use. Both Bis-GMA and TEGDMA contain hydroxyl groups as shown in figure 2, and as a result are relatively hydrophilic. Such properties are disadvantageous as susceptibility to water absorption can lead to discoloration. Compounds belonging to the group of urethane dimethacrylates (UDMA) are also often found in dental composites. UDMA has a lower viscosity than Bis-GMA thus UDMA derivatives can be used undiluted. There is no hydroxyl side group thus composites with a UDMA matrix demonstrate lower water absorption and in turn have a lower propensity for discoloration.

2.3 Overview of current technology used with lab composites

Rather than viewing the composites by generation it is perhaps now more helpful to consider them in terms of the types of products currently available and the technology involved in their curing. Most products can be allotted to three different groups/systems. The first involves relatively basic technology hot/cold curing systems including traditional products such as the powder/liquid product SR Ivocron – a PMMA veneering material for crowns, bridges and temporary restorations; and SR Chromasit a heat/pressure cured composite. The second involves light curing only products that are flexible according to the choice of polymerisation unit. The third group refers to so-called closed systems whereby the specific composite must be cured in a specifically assigned unit that utilizes multi-level curing methods for optimal and highly coordinated results. SR Adoro restorations in combination with the Lumamat 100 for light/heat curing and tempering, belong to this third group.

System	Technology	Ivoclar Vivadent Product
Light/Heat/Pressure Curing Systems	High: One component, closed systems	SR Adoro
Light Curing ONLY Systems	Standard: One component flexible systems	**SR Nexco Paste**
Hot/Cold Curing Systems	Basic: Powder + Liquid or Paste, limited applications	SR Ivocron, SR Chromasit

Table 1: Various curing systems used with lab composites

Approximately 90% of all lab composites are light curing only which amounts to an estimated 75% share of the market for indirect composites. They are popular due to their flexibility and the fact that they are not associated with financial outlay for a specific curing unit. SR Nexco Paste has been developed to represent Ivoclar Vivadent in this standard, light-curing only group.

3. SR Nexco Paste

SR Nexco Paste is a lab-composite for framework-supported and framework-free prosthetic solutions. The paste is used for veneering restorations using the layering technique. The high content of microfillers allows the combination of exceptional aesthetics, surface-lustre, and optimal handling.

It is a solely light cured composite and is suitable for use with the most popular light-polymerisation units for laboratories. It exhibits life-like properties and exceptional layer thickness tolerance.

3.1 Indication

Composite veneering materials are versatile and simple to use. For indications such as combination dentures and/or implant retained restorations these materials are especially useful and in some cases provide the only alternative to a ceramic veneering material. In removable prosthetics, compatibility between denture teeth and lab composites is especially important, therefore SR Nexco Paste is colour-coordinated with SR Phonares II.

3.1.1 Extra-oral applications

SR Nexco Paste is indicated for the veneering of fixed denture prosthetics (framework-free and framework-supported) and removable denture prosthetics. The principle indications are listed below:

Fixed Denture Prosthetics:

Framework-based

- veneering of metal-supported restorations
- veneering of combination dentures (e.g. telescope crown veneers)
- veneering of fixed removable implant superstructures

. veneering of gingiva portions in fixed-removable implant superstructures

- veneering of CAD/CAM-fabricated metal frameworks
- masking of model cast frameworks with SR Nexco Opaquer pink

Framework-free

- inlays/onlays/veneers
- anterior crowns

Removable Denture Prosthetics:

- superficial modification and characterisation of resin teeth

3.1.2 Intra-oral applications

If minor repairs of SR Nexco Paste restorations are required, they can be carried out in the dental practice by the dentist, using either SR Nexco Paste itself or Heliomolar. SR Nexco Paste can be bonded with Heliobond. Using the same material is advantageous in terms of avoiding differences in surface hardness along the restoration, as this can lead to polishing difficulties. Repairs using SR Nexco Paste are a realistic option notably when a laboratory and practice operate together.

3.2 Structure and composition of SR Nexco Paste

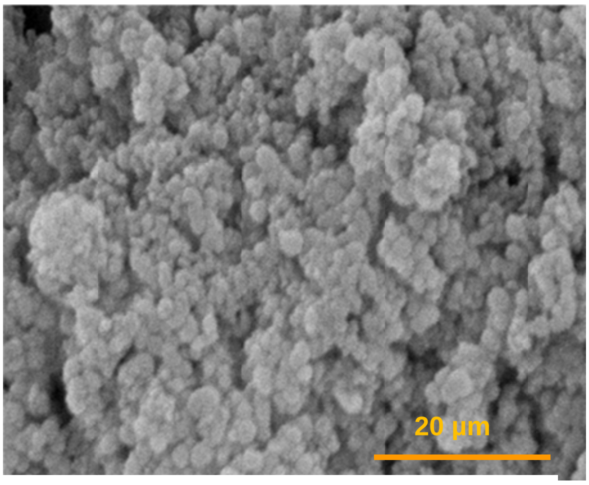
Table 2 gives an overview of the principle components of SR Nexco Paste. The fillers and monomers are discussed in more detail in the sections that follow.

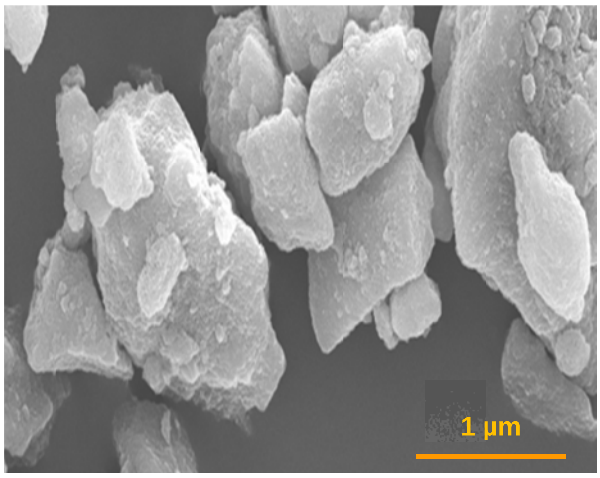
	SR Nexco Paste Dentin	SR Nexco Paste Incisal
Aromatic aliphatic UDMA + Aliphatic dimethacrylates	16.9	17.0
Highly dispersed silicon dioxide	19.8	19.8
Copolymer	62.9	62.9
Catalysts and stabilizers	0.4	0.3
Pigments	0.1 – 0.3	< 0.1

Table 2: Composition of SR Nexco Paste Dentin and Incisal - figures in weight by %

3.2.1 *SR Nexco Paste fillers*

The microfiller used for SR Nexco Paste is a highly dispersed silicon dioxide with particles in the 10 to 50 nm range and with a large surface area of up to 400m^2/g (Fig. 3). The main filling component (62.9%) is a prepolymer/copolymer which consists of pre-polymerised ground up UDMA matrix and inorganic microfiller particles (Fig. 4). This combination of microfillers plus “microfilled” prepolymer enables a very high filling ratio and excellent physical properties. As the pre-polymer is UDMA based it possesses similar characteristics to the main matrix and on polymerisation becomes completely integrated into the overall composite. The result is a homogenous composite with a high loading of inorganic microfillers.





polymer/

The use of the prepolymer allows the advantages of large filler particles to be combined with those of microfillers. This technology allows for a higher strength of composite than if only inorganic microfillers were used. However, the very high physical strength possible with inorganic macrofillers is not possible. Nevertheless, prepolymers allow the favourable properties of microfillers to be incorporated into a composite material that demonstrates a non-sticky, homogeneous consistency, low shrinkage and a durable surface gloss. SR Nexco Paste embodies these qualities.

3.2.2 SR Nexco Paste monomers

The SR Nexco Paste matrix consists of aromatic aliphatic urethane dimethacrylate and decandiol dimethacrylate/aliphatic dimethacrylate. Aliphatic refers to the carbon atoms of an organic compound being arranged in chains rather than rings. The low viscosity aliphatic dimethacrylate was developed at Ivoclar Vivadent as a viable alternative to TEGDMA for a large number of formulations; and the aromatic aliphatic urethane dimethacrylate was developed to replace Bis-GMA. In contrast to Bis-GMA and TEGDMA, these monomers do not comprise a hydroxyl group and therefore allow the development of composites that are less susceptible to water absorption and solubility. Due to their inherent disadvantages, neither SR Adoro nor SR Nexco Paste contain the monomers Bis-GMA or TEGDMA.

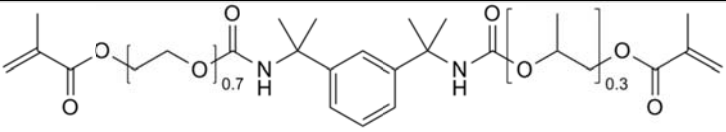
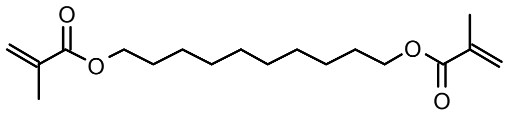
	**Urethane Dimethacrylate** Aromatic aliphatic urethane dimethacrylate
	**Aliphatic Dimethacrylate** Decandiol dimethacrylate

Fig. 5: Table illustrating the structural formulae for the monomers used in SR Nexco Paste

3.3 Components of the SR Nexco Paste system

The SR Nexco Paste system comprises a number of coordinated products, the dentin and incisal shades plus a number of coordinated accessory products:

SR Accessory Products

SR Nexco Liner is used as the basic shade on the prepared tooth in metal-free restorations, providing a reliable bond between the restoration, composite cement and prepared tooth.

SR Nexco Opaquer, available in A-D shades is used to mask the framework of metal-supported restorations. They provide excellent stability and a high masking capability even in thin layers. They also promote a reliable bond to SR Link and the veneering composites.

SR Link provides the covalent bond between the dental alloy and SR Nexco Paste (See section 3.4.1). It is a tried and tested system, and is suitable for use with alloys containing less than 90% gold, palladium or platinum, alloys with less than 50% copper or silver, base metal alloys, titanium and titanium alloys.

SR Connect is a new liquid, non-layer forming light-curing bonding agent for connecting SR Nexco Pastes to heat and cold cured PMMA materials. It can be used to carry out modifications to denture teeth such as SR Phonares II and various veneering materials such as Telio CAD and Telio Lab. It can also be used as the bonding agent for individual shade adjustments to the denture base material using gingival shades.

SR Nexco Paste Gingiva colours are coordinated with the gingiva-concept of IPS InLine, IPS d.SIGN and IPS e.max. This allows the creation of life-like artificial gingiva, notably for implant superstructures. SR Nexco Paste also offers a new intensive gingiva colour IG5 and a basic gingiva colour BG34 allowing the quick and simple modification of e.g. Ivobase dentures.

The table below shows the initial steps including the principle accessory products involved up to the initial layer of a restoration. The four principle indications are considered. Restorations are then completed according to standard dental technician layering techniques using SR Nexco Pastes, Stains and Effects. Restorations are then covered in SR Gel, polymerised and finished. Comprehensive instructions are available in the instructions for use.

Application	Inlay	Anterior crown (framework-free)	Metal-supported restoration	Modification of denture teeth
Framework	-	-	Dental alloys	Denture teeth
Surface treatment	-	-	Al_2O_3, 80-100µm, 2-3 bar	Al_2O_3,80-100µm, 2 bar
Bond	-	-	SR Link	SR Connect
Initial layer	SR Nexco Liner	SR Nexco Liner	SR Nexco Opaquer	SR Nexco Paste

Table 3: Initial steps with SR Nexco Paste system for principle indications

3.4 Bonding and cementation

The individual layers of materials must be bonded to one another and the final restoration must be aesthetically cemented to the substrate.

3.4.1 Bonding the components

Resin to resin bond

When SR Nexco Paste is applied in sequential layers e.g. when creating framework-free or framework-supported restorations a chemical bond between the individual layers of composite is possible, as atmospheric oxygen inhibits the complete polymerisation of the methacrylate resin contained within the composite matrix. As a result, a thin layer of material remains uncured on the surface. This layer is known as the inhibition layer (13, 14). The free methacrylate groups contained within this layer undergo a chemical reaction with the resin that has been applied on top of it and a covalent bond forms between the layers. This effect is exploited by building up SR Nexco Paste in increments and pre-curing each individual increment.

Metal to resin bond

When creating metal-supported restorations with SR Nexco Paste the resin must be bonded to the framework. This is achieved using SR Link. SR Link is a metal/composite bonding agent suitable for use on various frameworks i.e. alloys containing less than 90% gold, palladium or platinum, alloys containing less than 50% copper and/or silver content, non-precious alloys, titanium and titanium alloys.

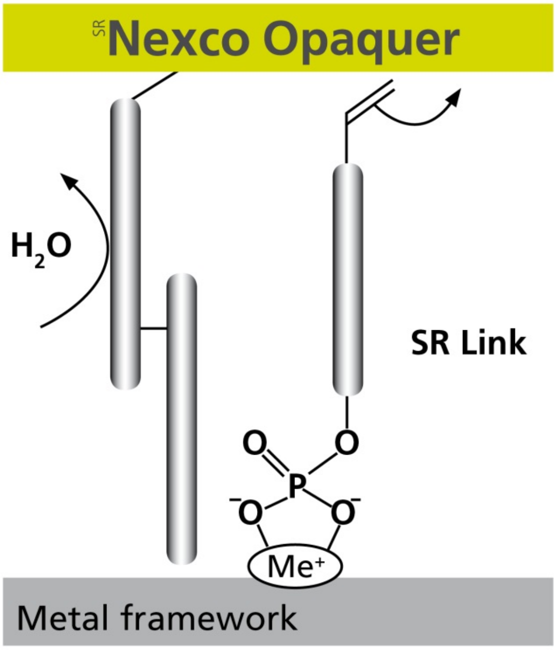


Fig. 6: Schematic diagram of the function of SR Link.

First the metal framework is blasted with aluminium oxide (100µm) at 2-3 bar pressure, depending on the type of alloy. This roughens and enlarges the surface area and also leads to localised melting processes whereby aluminium oxide particles become embedded in the metal surface (15, 16, 17). The metal oxides produced are also a prerequisite for the chemical bond (13, 14). Alloys with a precious metal content of more than 90% develop minimal bonding oxides and are therefore unsuitable. The diagram above illustrates how SR Link creates a link between the metal and the composite. The SR Link bonding system contains a phosphoric acid group coupled with a methacrylate group. The strong acid is able to establish a phosphate bond with the metal oxides at the alloy surface. The methacrylate groups react with the monomers in the SR Nexco Opaquer and thus promote the bond with SR Nexco Paste. Hydrolytic stability (insensitivity to moisture) is achieved, as SR Link comprises a monomer that contains a highly hydrophobic aliphatic carbon chain.

3.4.2 Cementing the restoration

Aesthetic cementation is essential to ensure an aesthetic end result with lab composites. Depending on the indication, SR Nexco Paste is either bonded adhesively, self-adhesively or conventionally.

Framework-free restorations must be adhesively cemented using Variolink Veneer, Variolink II or Multilink Automix. Metal supported restorations can be cemented adhesively using Multilink Automix, self-adhesively with SpeedCEM or conventionally using Vivaglass CEM.

3.5 Optical properties and aesthetics

The natural tooth consists of dentin and enamel. The outer enamel is thinner and more transparent than the dentin. The tooth shade is therefore determined largely by the dentin (18) with shade intensity increasing from the incisal edges to the cervical margins (19). Natural teeth however exhibit optical properties that go far beyond their mere shade. They exhibit both opalescence and fluorescence, and in order to create natural-appearing restorations, it is necessary that these effects be re-created.

Opalescence

Opalescence is an optical property based on the increased scattering of light of shorter wavelengths (blue light) in comparison to light of longer wavelengths (red light) by the enamel prisms within the enamel. In natural teeth, this effect gives the material a bluish appearance under reflected light (front-lighting) and an amber or orange/brown appearance under transmitted light (back-lighting) (20). Opalescence is observed to a greater degree in the incisal areas.

Fluorescence

Fluorescence is a term “derived from fluorite (fluorspar) and indicates the luminescence of materials, which, after having been illuminated with light, UV, X-rays or electron rays, emit the absorbed energy in the form of light or other radiation…..of a longer wavelength” (21). In the case of teeth, essentially invisible light (UV) is converted into visible light or luminescence.

Fluorescent compounds are distributed in natural teeth in varying intensities. Fluorescence is highest in the naturally “darker” areas of the teeth i.e. the root dentin and cervical areas, gradually decreasing towards the incisal areas. Young teeth also exhibit a higher intensity of fluorescence overall than old teeth.

Optical properties of SR Nexco Paste

The optical properties of a composite are determined by the interplay between monomer and filler particles. To ensure that a composite reaches the translucency of natural enamel the refractive indices of the fillers and matrix must be carefully coordinated with one another.

SR Nexco Pastes possess similar light properties to natural teeth, due to the inclusion of micro opal fillers. These properties enable the technician to mimic opalescence and fluorescence with relative ease. Pastes intended for cervical margins therefore exhibit high fluorescence and lower opalescence and those intended for incisal regions have lower fluorescent properties and higher opalescent features. Bright shades also exhibit a higher intensity of fluorescence than dark shades.

Figures 7 and 8, show opalescence and fluorescence in a natural human tooth. The discs on the left of the pictures are discs of SR Nexco Pastes in Margin, Dentin and Incisal shades from bottom to top. The tooth in figure 7 exhibits opalescence in transmitted light. The tooth shines with an amber-like glow due to the positioning of the light source from behind. Figure 8 shows the same tooth in ultra-violet light showing natural fluorescence. The discs of SR Nexco Pastes closely match both the varying opalescence and fluorescence of the teeth in the marginal, central and incisal sections of the tooth. From bottom to top i.e. Margin to Dental to Incisal, opalescence can be seen to increase and fluorescence to decrease.

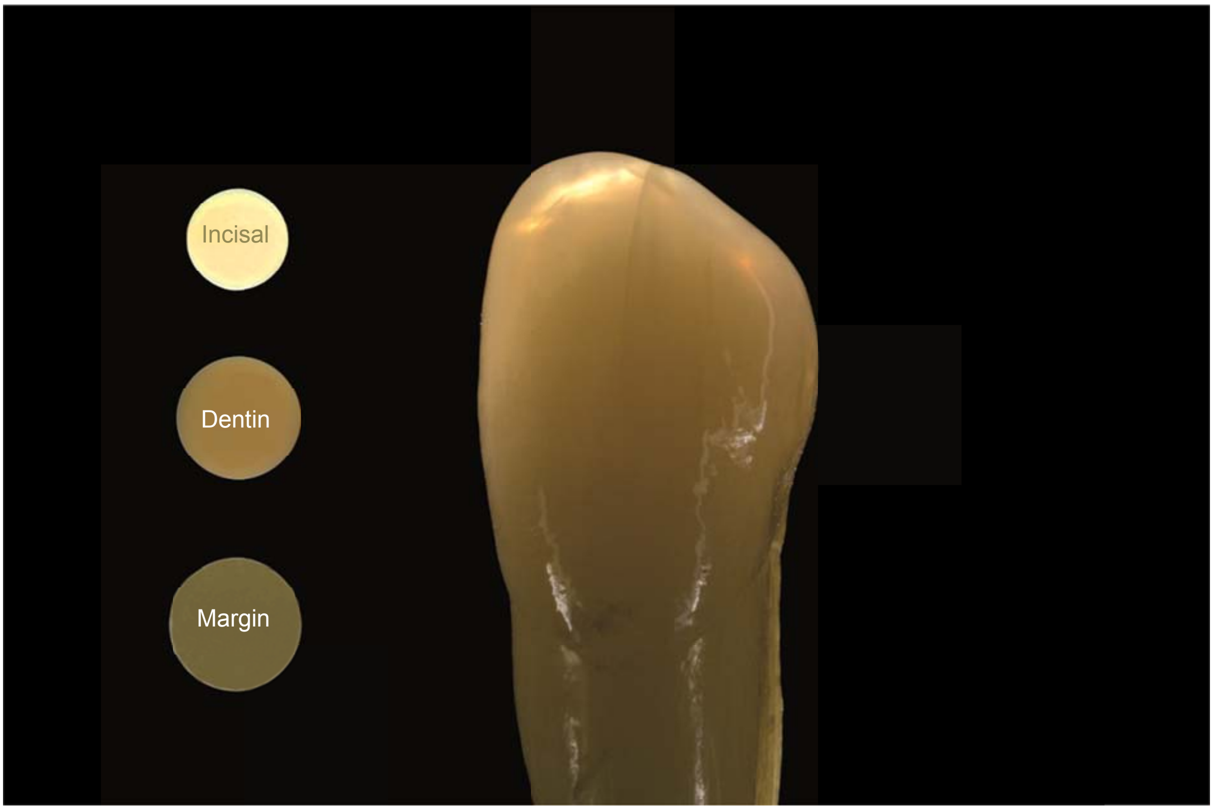


Fig. 7: Discs of SR Nexco Paste matching the opalescence of the human tooth. Picture taken in transmitted light. *Photo: V. Brosch, Essen, Germany 2012*

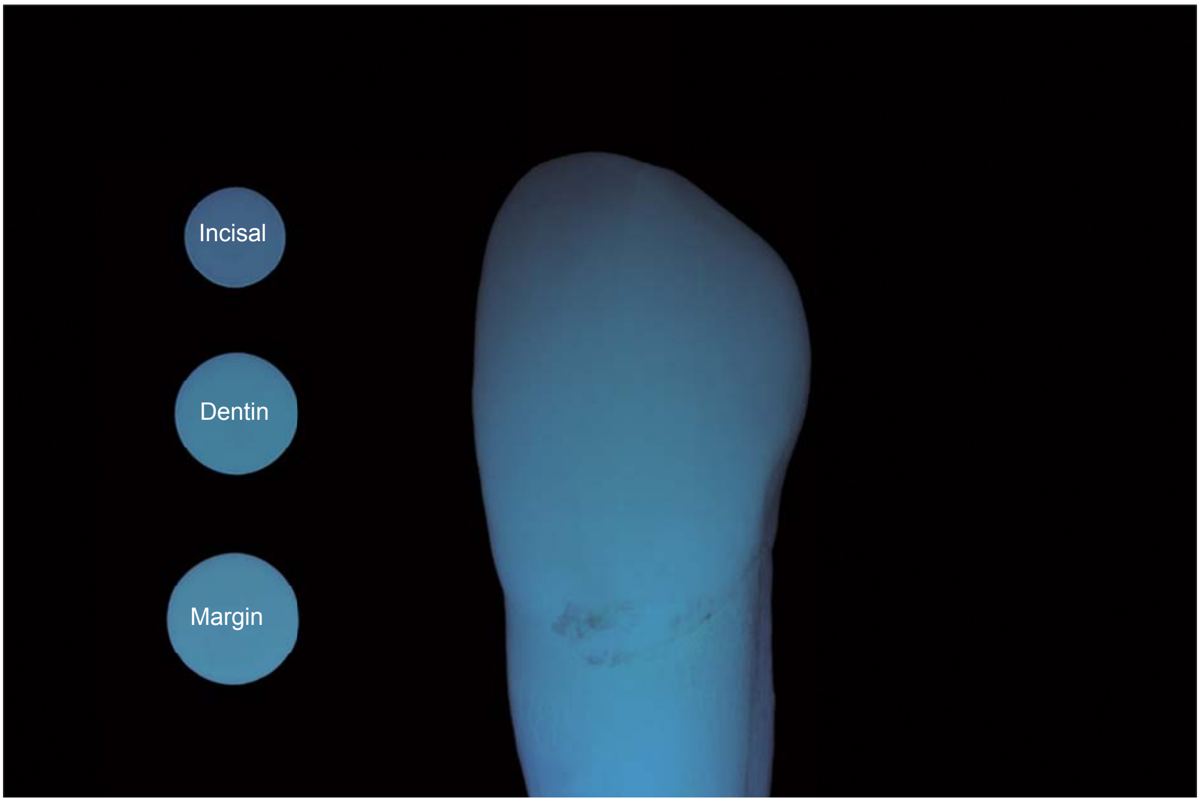


Fig. 8: Discs of SR Nexco Paste matching the fluorescence of the human tooth. Picture taken in ultra-violet light. *Photo: V. Brosch, Essen, Germany 2012*

The picture below shows the aesthetics that can be achieved with the SR Nexco Paste system. The optimised light properties of the materials enable the creation of true-to-life restorations.

Fig. 9: Tooth created with SR Nexco Paste system. Picture taken with back-lighting / transmitted light.

Picture courtesy of Hilal Kuday

3.6 Layer thickness tolerance

SR Nexco Pastes exhibit exceptional tolerance in terms of layer thickness. This means that the desired shades can be reproduced more or less irrespective of layer thickness. This offers the dental technician considerable flexibility where space is minimal. It is both time saving and means easy processing. An application of deep dentin after opaquer is also not necessary with SR Nexco Paste due to the layer thickness tolerance.

Figure 10 illustrates this phenomenon. Four discs of SR Nexco Paste Dentin in shade A3 were placed on metal bases that had been masked with opaquer. Increasing increments were applied. Within the range 0.6mm to 1.5mm, no perceptible change in shade between the test discs can be seen. This also applies to the gingival colours thus a true to nature appearance can be achieved for both fixed and removable dental restorations.

0.6 mm 0.8 mm 1.2 mm 1.5 mm

Fig. 10: SR Nexco Paste Dentin shade A3 in increasing increments illustrating colour stability with different layer thicknesses.

Layer thickness tolerance can be quantified using the CIELAB Lab Color Space model. This is a 3D colour-opponent space with an L* dimension between 0 and 100 (black to white) to depict lightness an a* dimension for colours between green and red and a b* dimension for colours between blue and yellow. The L*a*b* color space includes all perceivable colours.

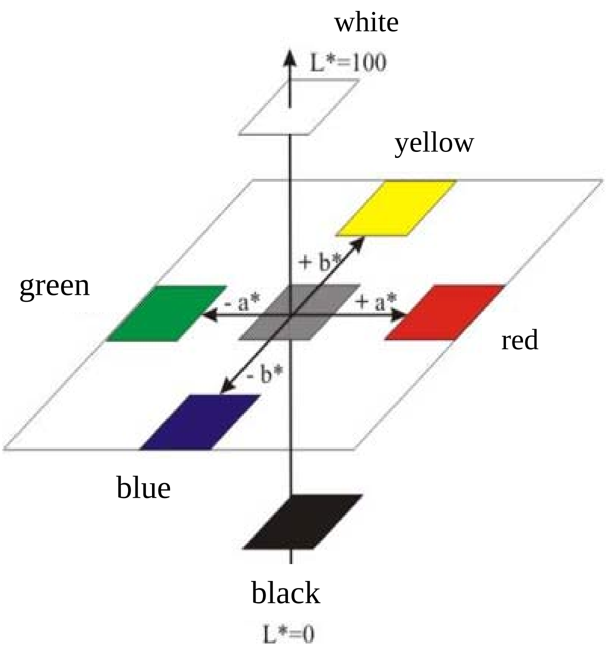


Fig. 11: CIELAB L* a* b* Color Space

The L*,a* and b* values of the colours of each of the discs were obtained using a spectrophotometer. Regardless of layer thickness, the values are notably similar for all the discs across all the values, which explains the layer thickness tolerance as perceived by the human eye. The 1.2 mm layering thickness represents a standard layer thickness.

	L*	a*	b*
A3 0.6 mm	76.47	5.19	25.12
A3 0.8 mm	76.15	5.56	25.62
A3 1.2 mm	76.17	5.73	25.52
A3 1.5 mm	76.50	5.88	25.85

Table 4: L*a*b* values for four test discs of SR Nexco Paste of varying thickness

Figure 12 shows the spectral curves of each of the discs as measured by spectrophotometer. A spectral curve shows the % of reflected colour [R], as a function of wavelength. The spectrophotometer takes measurements e.g. at 10nm increments in the visible light range of 400-700nm to create the spectral curve. At 400 nm (violet) approximately 14% of the colour is reflected and at 700 nm at the end of the curve (red) approximately 64%. It can be observed that the four curves pertaining to the discs with varying layer thickness follow each other so closely they are more or less indistinguishable from one another in the diagram.

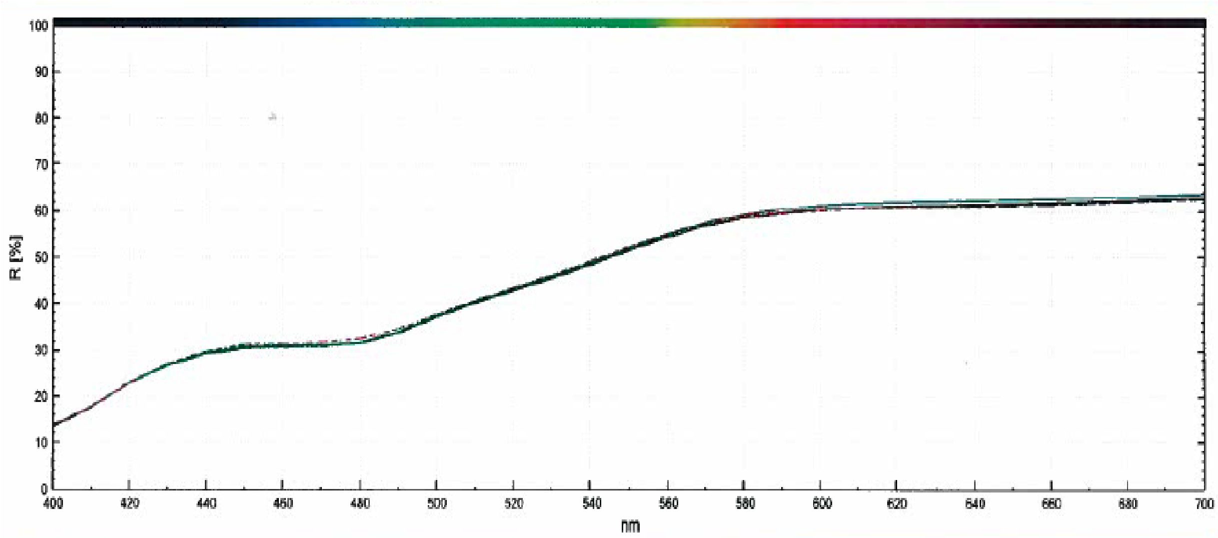


Fig. 12: Spectral curves for SR Nexco Paste, 0.6, 0.8, 1.2, and 1.5 mm discs

3.7 Equipment flexibility

SR Nexco Paste is a solely light curing composite. The product offers increased flexibility in that it can be cured in a variety of popular light-polymerisation units. SR Nexco Paste has been specifically tested for the following units: Lumamat 100, Spectramat, Labolight LV-III/GC, Solidilite V/Shofu, Visio Beta Vario/3M ESPE and HiLite/Heraeus, and the curing parameters for each are shown in the table below.

Appliance	Manufacturer	Opaquer	Dentin	Liner, Incisal, Effect, Margin	Gingiva	Stains	SR Connect	Final polymerization
Quick Lumamat 100	Ivoclar Vivadent AG	20 s Quick P2/11 min	20 s Quick	20 s Quick	20 s Quick	20 s Quick	P2/11 min	P2/11 min
Spectramat	Ivoclar Vivadent AG	5 min	5 min	2 min	5 min	2 min	2 min	5 min
Labolight LV-III	GC	5 min	2 min	2 min	5 min	2 min	3 min	5 min
Solidilite V	Shofu	3 min	1 min	1 min	3 min	1 min	3 min	5 min
Visio Beta Vario	3M	7 min no vacuum	4x 20 s Visio Alfa	4x 20 s Visio Alfa	4x 20 s Visio Alfa	4x 20 s Visio Alfa	4x 20 s Visio Alfa	4x 20 s no vacuum
HiLite	Heraeus Kulzer	180 s	90 s	90 s	90 s	90 s	90 s	180 s

Table 5: SR Nexco Paste polymerisation parameters for various light units

Comparable material quality was achieved in all of the above devices with curing times close to the companies' own materials.

Polymerisation units suitable for intermediate curing include Quick/Ivoclar Vivadent, HiLite pre/Heraeus, Visio Alfa/3M ESPE, Sublite V/Shofu and Steplight SL-I/GC.

If minor repairs of SR Nexco Paste restorations are required at the dental practice, intra-oral curing is also possible and may be carried out with e.g. Bluephase or LEDition polymerisation units.

4. Technical Data for SR Nexco Paste

Composition of main materials

	SR Nexco Paste Dentin	SR Nexco Paste Incisal
Dimethacrylates	16.9	17.0
Highly dispersed silicon dioxide	19.8	19.8
Copolymer	62.9	62.9
Catalysts and stabilizers	0.4	0.3
Pigments	0.1 – 0.3	< 0.1

Figures in weight by %

Physical properties of main materials

	SR Nexco Paste Dentin	SR Nexco Paste Incisal	Requirements EN ISO 10477
Flexural strength (MPa)	90 ± 10	90 ± 10	≥ 50
Modulus of elasticity (MPa)	6500 ± 500	6500 ± 500	-
Vickers hardness (MPa)	460 ± 5	460 ± 5	-
Water absorption (µg/mm³)	15 ± 1	15 ± 1	≤ 40
Water solubility (µg/mm³)	1 ± 0.5	1 ± 0.5	≤ 7.5
Bond to metal (MPa)*	-	18 ± 4	
Density (g/ml)	1.56	1.56	
Depth of cure (mm)	> 2	> 2**	

* *Academy Gold XH/SR Link/SR Nexco Opaquer after 10,000 thermocycles 5/55°C*

** *Except Intensive Gingiva >1 mm*

Composition of Liner, Stains and Opaquer

	SR Nexco Liner	SR Nexco Stains	SR Nexco Opaquer
Dimethacrylates	48.1	47.2	55.4
Highly dispersed silicon dioxide	1.5	29.8	5.0
Copolymer	-	21.0	-
Barium glass filler	49.5	-	-
Zirconium dioxide	-	-	37.2
Catalysts and stabilizers	0.5	0.5	≤ 2.0
Pigments	≤ 0.4	< 1.5	< 0.4

Figures in weight by %

Physical properties of Liner, Stains and Opaquer

	SR Nexco Liner	SR Nexco Stains	SR Nexco Opaquer
Flexural strength (MPa)	140 ± 10	120 ± 10	-
Modulus of elasticity (MPa)	6000 ± 500	6500 ± 500	-
Vickers hardness (MPa)	350 ± 10	405 ± 10	-
Water absorption (µg/mm³)	27.8 ± 0.9	17.2 ± 0.7	-
Water solubility (µg/mm³)	< 5	0.21 ± 0.3	-
Density (g/ml)	1.62	-	-

5. Materials Science Investigations / In Vitro

In vitro investigations form the basis for all material tests during the development phase of a dental product. Though not capable of predicting clinical success they can be useful indicators thereof and are an efficient way of comparing similar products. In the development of dental restoratives, common materials science measurements include the flexural strength of the material, the Vickers hardness, wear resistance and propensity to discoloration. The results of various tests conducted internally at Ivoclar Vivadent (R&D Schaan) are presented here. The results of three external investigations from two study centres are also presented.

EN ISO 10477 "Dentistry – Polymer based crown and bridge resins" describes the minimum normative standards placed on composite veneering materials. The standard is restricted to composites that are not exposed to occlusal loading.

5.1 Flexural strength

The flexural strength of SR Nexco Paste compared to five other composites, (SR Adoro/ Ivoclar Vivadent, Signum/Heraeus, Gradia/GC, Solidex/Shofu and Sinfony/3M ESPE) was tested according to EN ISO 10477. The dimensions of the test samples were 2 x 2 x 25 mm and all were polymerised in devices compliant with the stipulations of the respective manufacturer. The flexural strength exhibited by SR Nexco Paste was far higher than the EN ISO 10477 stipulation of 50 MPa.

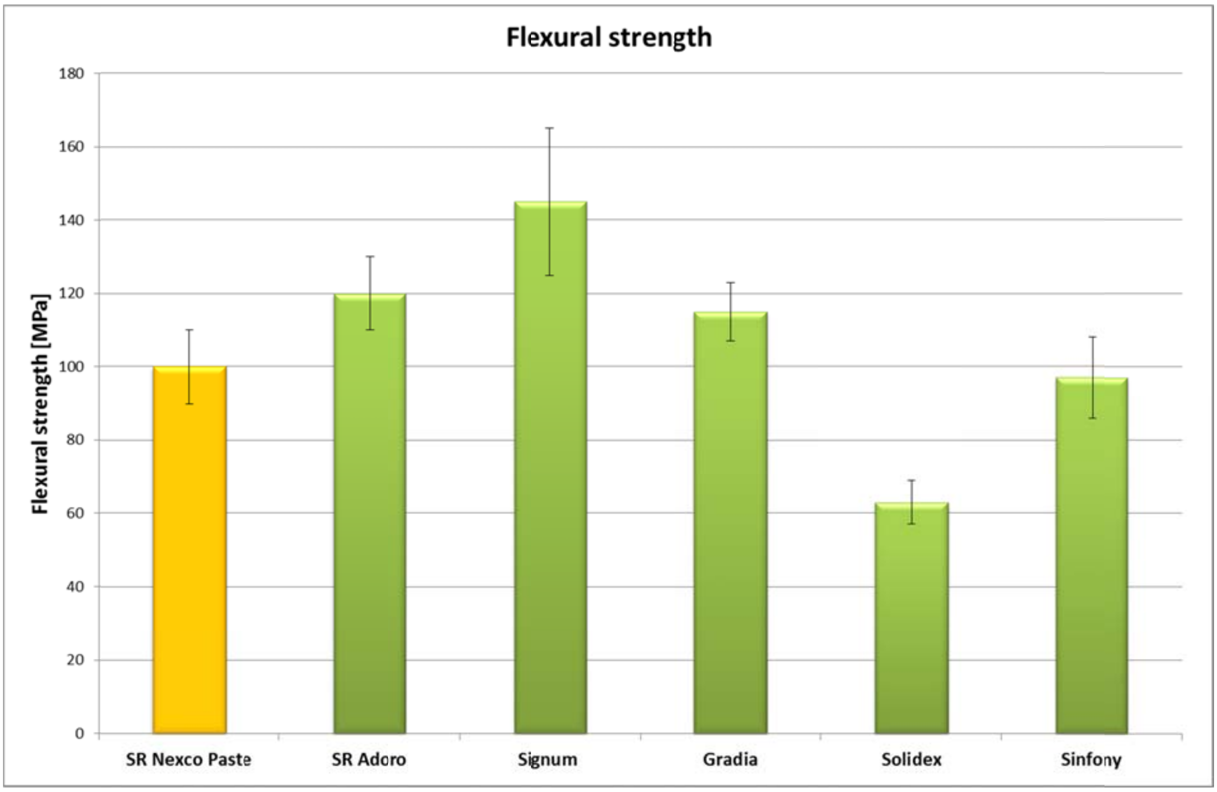


Fig. 13: Comparison of flexural strength in various lab composites (incisal materials). *R&D Ivoclar Vivadent, Schaan April 2011*

The flexural strength of both SR Nexco Paste Incisal and Dentin materials was also tested when polymerised with various popular polymerisation units. As indicated in Figure 14, there was no significant difference in the flexural strength of the materials when different polymerisation units were used.

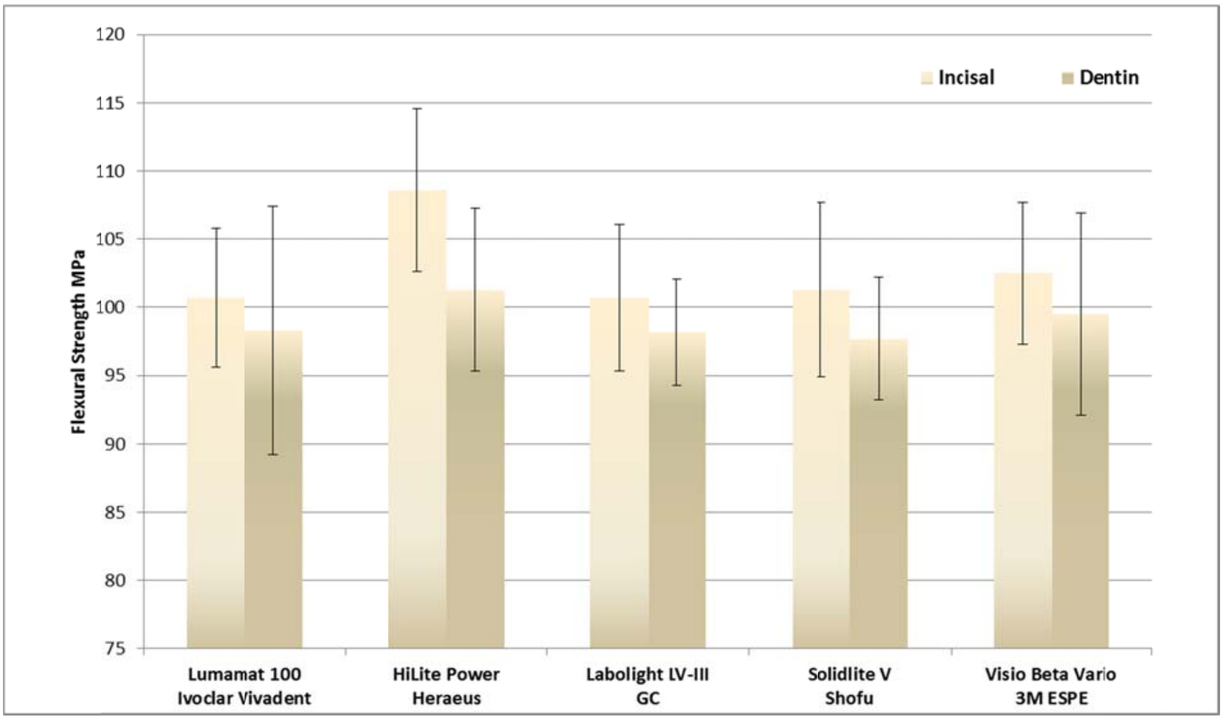


Fig. 14: Flexural strength of SR Nexco Paste Incisal and Dentin materials when polymerised with different units. *R&D Ivoclar Vivadent, Schaan, April 2011*

5.2 Vickers hardness

The Vickers hardness test method involves indenting the test material with a pyramid-shaped diamond indenter - applying a specified load for a defined period of time. Test samples (SR Nexco Paste and SR Adoro/Ivoclar Vivadent, Signum/Heraeus, Gradia/GC, Solidex/Shofu and Sinfony/3M ESPE) of incisal materials with a diameter of 10 mm and a thickness of 5 mm were used. The surface was polished to a high gloss using an aluminium oxide paste with a grain size of 0.3µm and the hardness tests were conducted in a Zwick machine at a load of 49N exerted on the composite surface for 30 seconds. Figure 15 shows the Vickers hardness for SR Nexco Paste to be in the medium range.

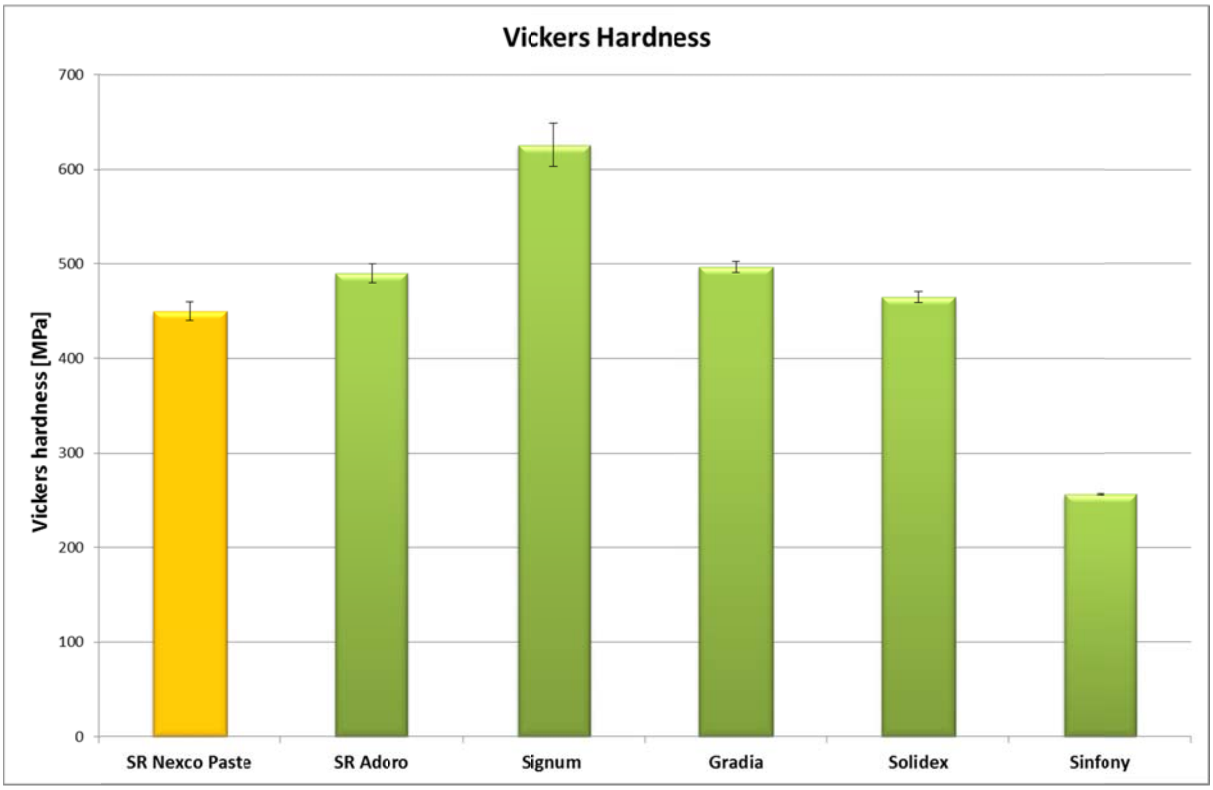


Fig. 15: Comparison of Vickers hardness in various lab composites. *R&D Ivoclar Vivadent, Schaan April 2011*

5.3 Wear resistance

Wear tests attempt to simulate the clinical wear of a material in the laboratory. Two-body wear refers to wear resulting predominantly from non-masticatory forces such as bruxism, i.e. the physiological wearing away of tooth structure due to tooth to tooth contact. Three-body wear involves an additional component i.e. an intervening slurry of abrasive particles. Three-body wear simulators attempt to mimic the oral environment whereby the slurry represents the role of food during mastication (22).

Ivoclar Vivadent measures wear using a long established two-body wear test without an abrasive medium conducted using a chewing simulator. Flat test samples are subjected to 120,000 chewing cycles in the Willytec machine with a frequency of 1.67 Hz and a load of 50 N.

Fig. 16: Willytec chewing simulator

An artificial tooth cusp made of IPS Empress ceramic material is used as the antagonist. Once the antagonist comes into contact with the test sample, it slides horizontally over the sample for 0.7mm so simulating wear. The samples are simultaneously subjected to thermocycling between 5 °C and 55 °C. The volumetric and vertical substance loss is quantified using a 3D laser scanner. If there is less than 200 µm of vertical substance loss this is considered low wear, 200-300 µm substance loss is considered medium wear and over 300 µm loss is considered high wear.

The following graph shows that both SR Nexco Paste and SR Adoro exhibit far less wear than the other lab composites tested (Signum/Heraeus, Gradia/GC, Solidex/Shofu and Sinfony/3M ESPE) and are both far below the 200 µm level designated as indicative of low wear.

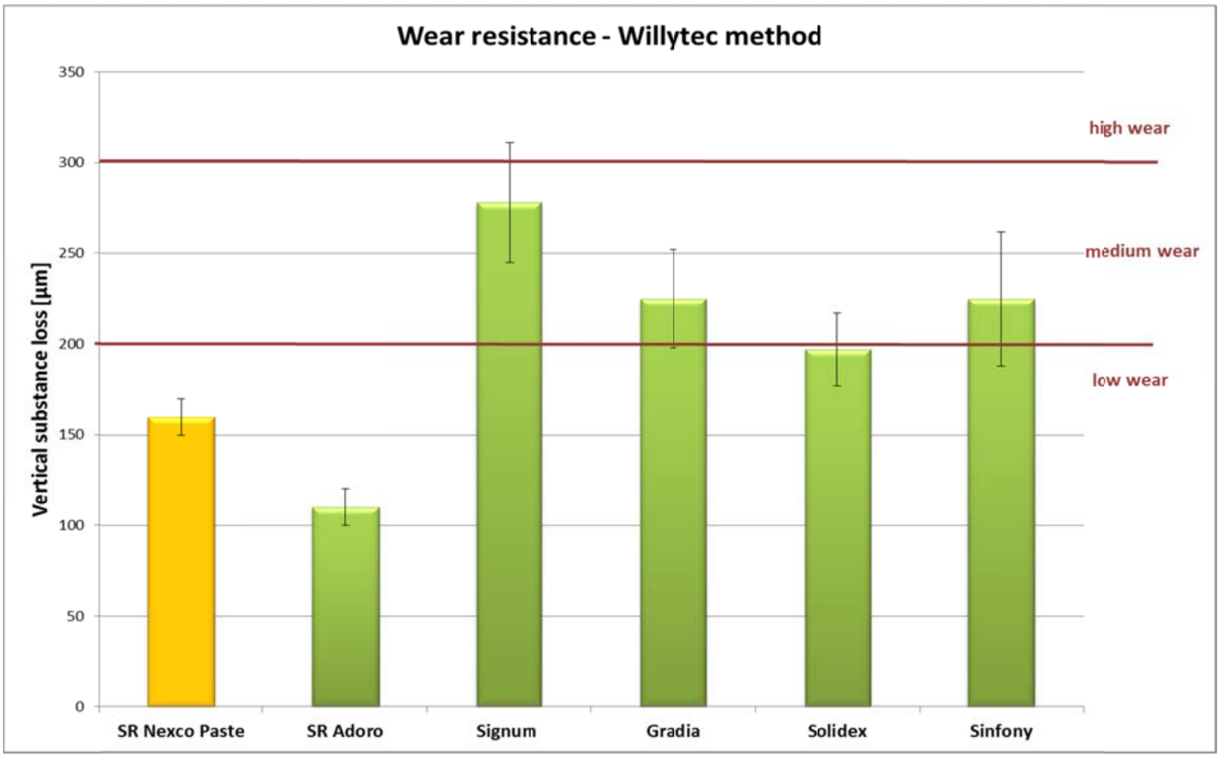


Fig. 17: Comparison of wear resistance in various lab composites. *R&D Ivoclar Vivadent, Schaan, April 2011*

M. Rosentritt. ACTA Abrasion measurements on experimental materials. University Clinic Regensburg, Germany, 2011.

Objective: To compare the wear behaviour of SR Nexco Paste samples compared to the reference material Sinfony/3M ESPE using a Willytec D wear machine developed by the Academic Center for Dentistry Amsterdam (ACTA). To establish any differences in wear/material loss of SR Nexco Paste depending on the polymerisation source.

Methods: 12 chambered sample wheels were used to hold samples of the incisal versions of all materials (see Table 6). 6 samples of each material were prepared. Wear was simulated via opposing rotations of a sample-wheel and an antagonist-wheel rotating at different speeds with a 15 N load and 15% slip. A millet-husk/rice slurry was used as the abrasive media over 50,000, 100,000, 150,000 and 200,000 cycles progressively. The slurry was changed each 50,000 cycles. The five SR Nexco Paste sample groups were cured with different polymerisation units and wear measurements were calculated after every 50,000 cycles.

Material	Polymerisation
Sinfony / 3M ESPE	Visio Beta Vario / 3M ESPE
SR Adoro / Ivoclar Vivadent	Lumamat 100 / Ivoclar Vivadent
SR Nexco Paste / Ivoclar Vivadent	Lumamat 100 / Ivoclar Vivadent
SR Nexco Paste / Ivoclar Vivadent	HiLite Power / Heraeus
SR Nexco Paste / Ivoclar Vivadent	Labolight LV–III / GC
SR Nexco Paste / Ivoclar Vivadent	Visio Beta Vario / 3M ESPE
SR Nexco Paste / Ivoclar Vivadent	Solidilite V / Shofu
Signum / Heraeus	HiLite Power / Heraeus
Gradia / GC	Labolight LV –III / GC
Solidex / Shofu	Solidilite V / Shofu

Table 6: Material groups and polymerisation unit used in 3-body wear test

Results Figure 18 depicts the average wear/material loss for the five SR Nexco Paste groups listed above as compared to Sinfony/3M ESPE. All SR Nexco Paste groups showed lower wear than the reference material Sinfony/3M ESPE. SR Nexco Paste when cured with Lumamat 100 or Labolight LV-III/GC showed the lowest wear after 200,000 cycles at approximately 99µm. The highest wear was found in the Solidex/Shofu group (not shown in diagram). The type of polymerisation unit had no significant effect on the wear results of the SR Nexco Paste groups, confirming the thorough and “uniform” curing of SR Nexco Paste regardless of the curing unit used.

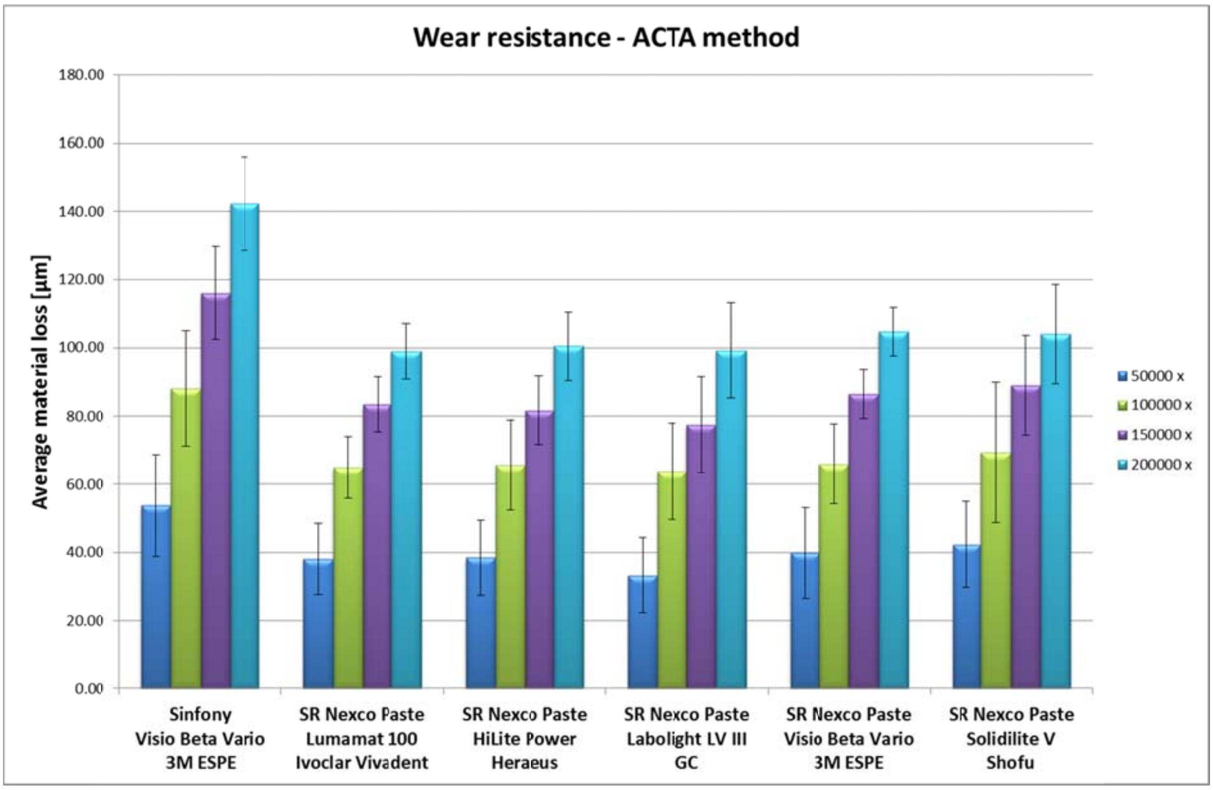


Fig. 18: Average wear/material loss after progressive wear cycles for SR Nexco Paste (various polymerisation units) compared to Sinfony/3M ESPE. *M. Rosentritt, University of Regensburg, Germany 2011*

5.4 Shear bond strength

Bond to metal alloys

Section 3.4.1 described how a bond to metal is established with SR Nexco Pastes using SR Link. Metal bond tests were carried out according to EN ISO 10477. This guideline requires composite veneering materials to achieve a bond strength of at least 5 MPa on the recommended metal alloys, and the test samples must be subjected to 5000 cycles of thermo-mechanical loading between 5 °C and 55 °C and immersed in water baths for 30 to 35 seconds. Ivoclar Vivadent however usually employs stricter requirements than the guideline requiring a minimum bond strength of 15 MPa after 10,000 thermocylces at 5 °C/55 °C.

The shear bond strength values are calculated by fabricating metal discs which are conditioned by blasting them with aluminium oxide (100 µm in diameter) at 2-3 bar pressure depending on the alloy concerned. The discs are then coated with SR Link, SR Nexco Opaquer is applied in two layers and polymerised. A cylinder of SR Nexco Paste is then bonded to the disc and test samples are polymerised and tempered in the Lumamat 100. Samples were subjected to thermocycling before testing.

Figure 19 shows the shear bond strength values of SR Nexco Paste test samples bonded with SR Link to a selection of suitable alloys from Ivoclar Vivadent, varying from Co/Cr, Ni/Cr and Ag/Pd to high gold alloys. The alloys were prepared according to the respective instructions for use.

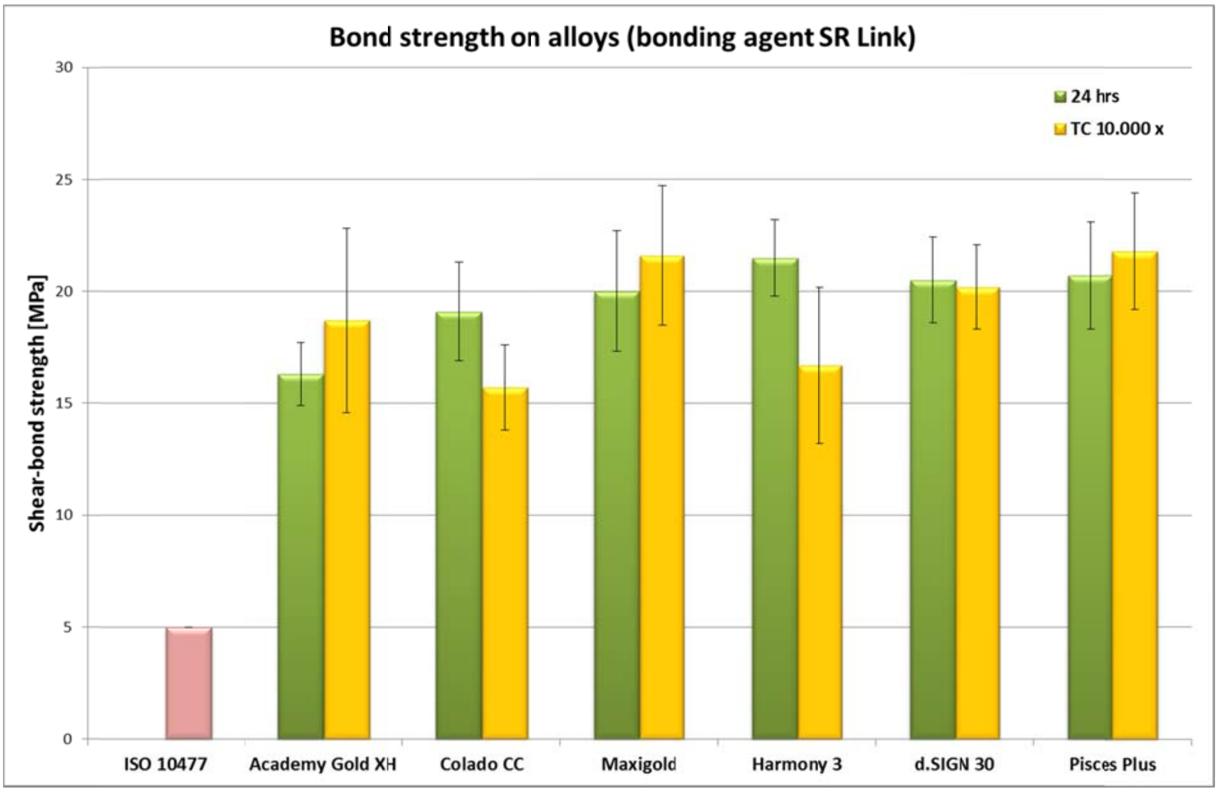


Fig. 19: Shear bond strength of SR Nexco Paste to metal alloys, bonded with SR Link. *R&D Ivoclar Vivadent, Schaan, April 2011*

The metal bond strength values indicate that SR Link mediates an excellent bond between the metal alloys in question and SR Nexco Paste. All values are at least 10 MPa beyond the level stipulated by EN ISO 10477. The values are shown after 24 hours at 37°C in distilled water and after 10,000 thermocycles between 5 °C and 55 °C. In all cases the break occurred between the metal and the opaquer.

Fig. 20 shows the excellent bond strengths achieved on nickel chromium alloy, independent of the polymerisation unit used.

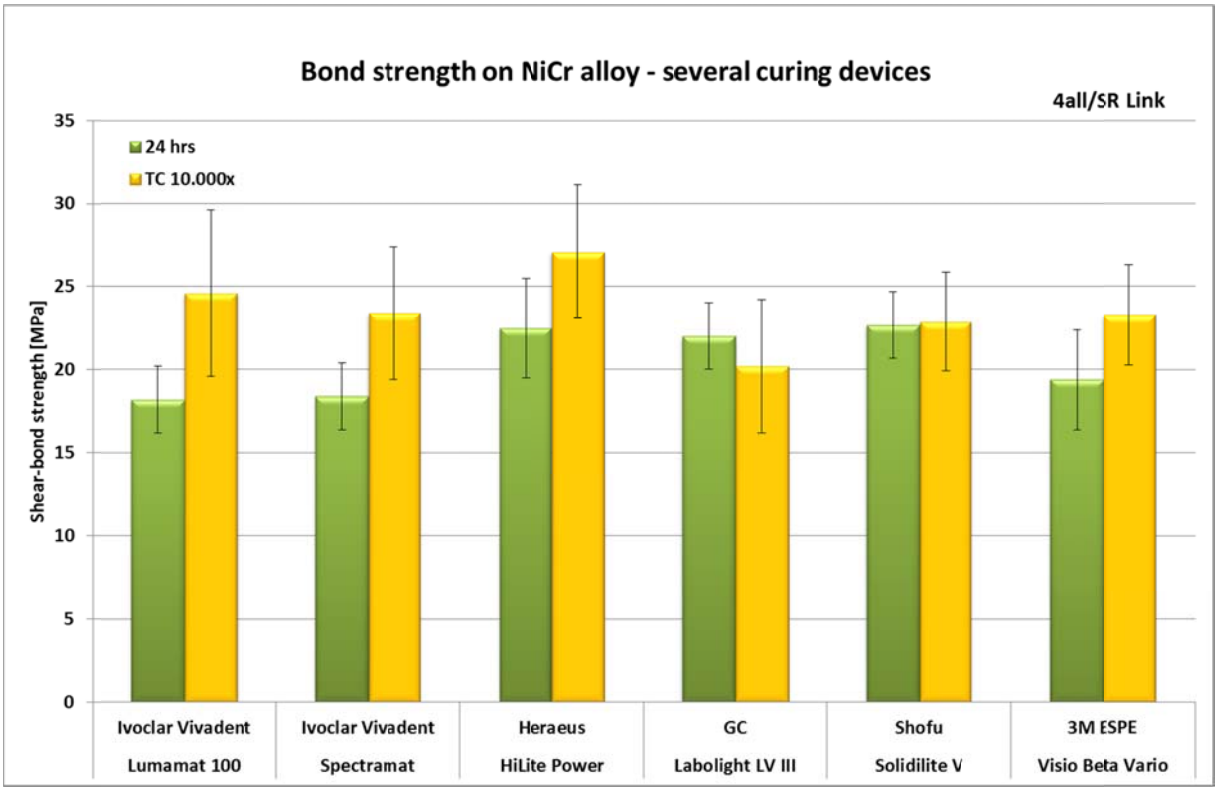


Fig. 20: Shear bond strength of SR Nexco Paste to nickel-chromium alloy using varying polymerisation units. *R&D Ivoclar Vivadent, Schaan, November 2011*

Bond to PMMA / resin denture materials

SR Connect is a light cured non-layer forming conditioner used for bonding SR Nexco Paste to dental structures such as PMMA, denture base materials and resin denture teeth.

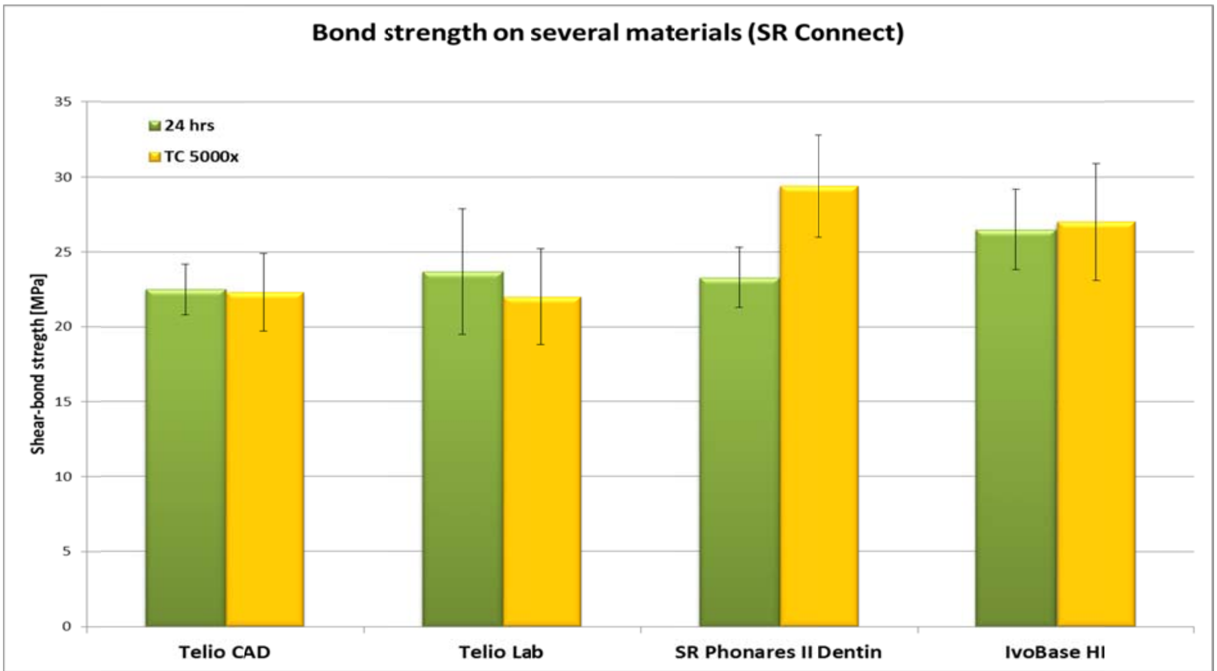


Fig. 21: Shear bond strength of SR Nexco Paste to various dental materials using SR Connect. *R&D Ivoclar Vivadent, Schaan, April 2012*

Figure 21 shows the excellent bond strength values achieved on various dental materials using the bonding agent SR Connect after 24 hours at 37°C in distilled water and after 5,000 thermocycles.

Cementation bond

Framework-free restorations must be adhesively cemented using Variolink Veneer, Variolink II or Multilink Automix. Metal supported restorations can be cemented adhesively using Multilink Automix, self-adhesively with SpeedCEM or conventionally using Vivaglass CEM. Figure 22 shows the shear bond strength values achieved with various bonding agents and cements in combination. These investigations test the bond between the various bonding agents/cements and SR Nexco Paste only, they do not involve the bond to the tooth/dental structure.

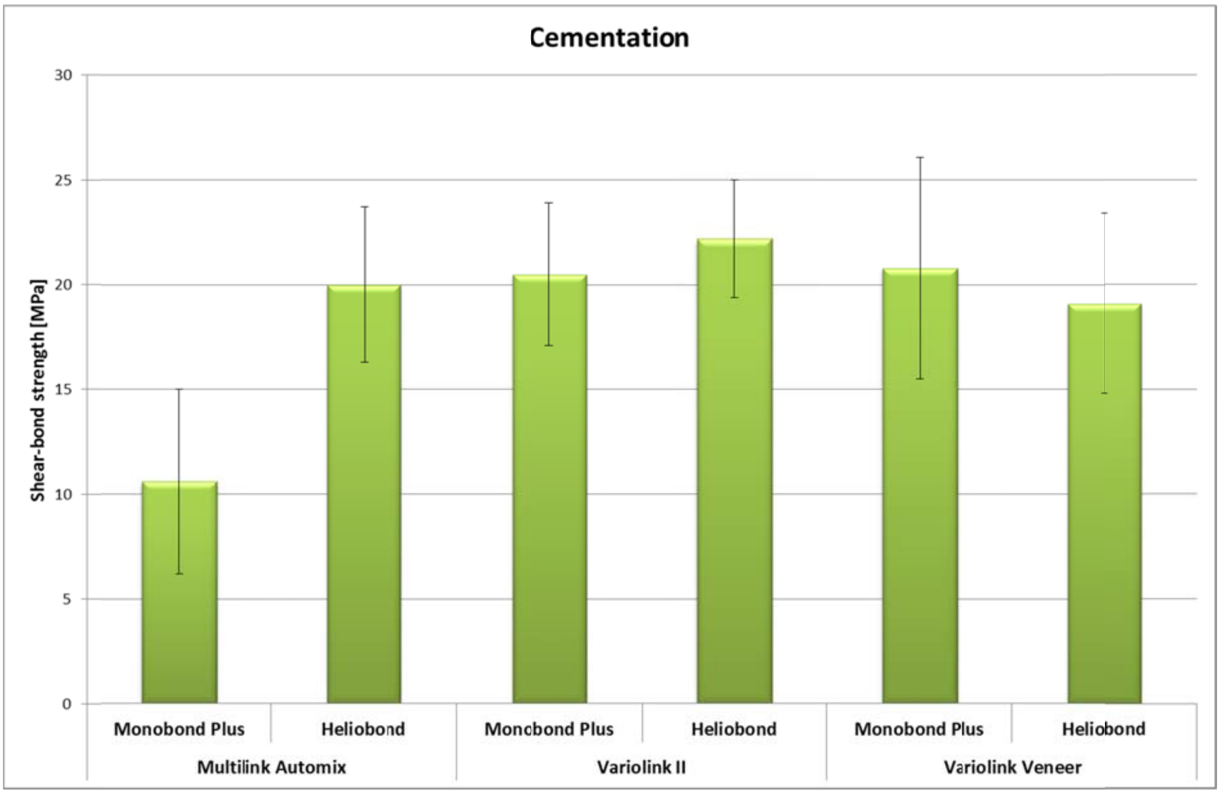


Fig. 22: Shear bond strengths of SR Nexco Paste cemented with various bonding agents and cements. *R&D Ivoclar Vivadent, Schaan, May 2011*

5.5 Material discoloration

Food and drink can cause discoloration in both natural and artificial teeth. Usually it is superficial and can be removed with professional tooth cleaning however the propensity to discoloration of composite materials in comparison to ceramics remains a hot topic. Discoloration tests are typically carried out in the laboratory via storing test samples of dental materials in various staining solutions.

Fig. 23: Discoloration Test

Discoloration tests were carried out on SR Nexco Paste and the incisal/enamel materials of four competitor products using the commonly used stains, safranine red T (red food colouring) and coffee extract. Distilled water was also used for comparison. Test samples of the dental materials were rubbed down first with 1000-grit and then 4000-grit abrasive paper and polished with a 0.3 µm aluminium oxide paste. Thus all samples were polished to a high gloss at the outset. The polished samples were either left untreated or subjected to a 16 hour boiling test in distilled water, a 0.1% safranine red T solution or coffee in a reflux condenser. (Fig. 23). A photographic image of the resulting disc discoloration was taken, and can be seen in table 7.

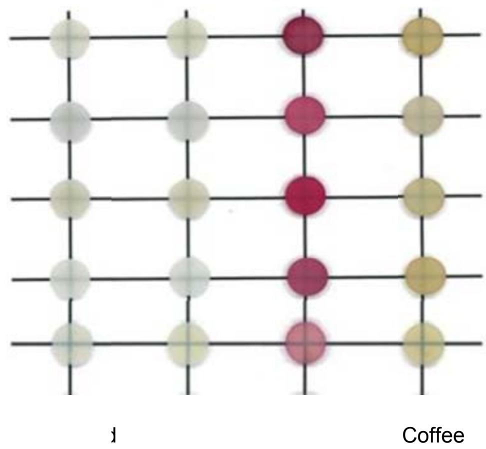
Material	Polymerisation Unit	Discoloration Results
Sinfony	**Visio Beta Vario (3M ESPE)**	
Solidex	**Solidilite V (Shofu)**	
Gradia	**Labolight LV-III (GC)**	
Signum	**HiLite Power (Heraeus)**	
SR Nexco Paste	**Lumamat 100 (Ivoclar Vivadent)**	

Table 7: Discoloration of SR Nexco Paste compared to competitor products, polymerised with own manufacturer units. *R&D Ivoclar Vivadent, Schaan, April 2011*

It can quite visibly be seen that the SR Nexco Paste discs (bottom row) show less discoloration (remain most transparent) from the staining solutions than the competitor products.

Discoloration tests were also carried out with SR Nexco Paste Incisal and Dentin materials when polymerised with various polymerisation units. As shown in table 8, no visible difference could be discerned between discs of either Incisal or Dentin SR Nexco Paste when polymerised with different units.

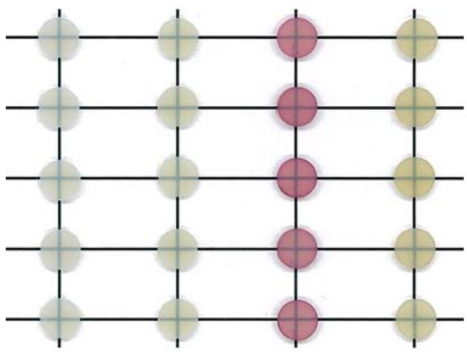
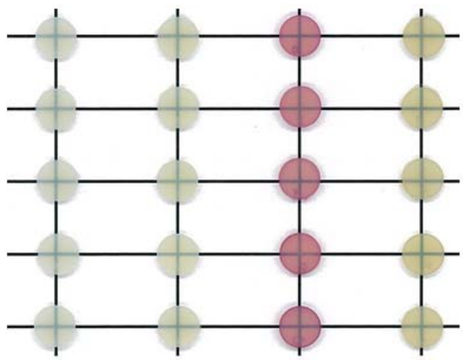
Polymerisation Unit	**Discoloration Results**	
	SR Nexco Paste Incisal	**SR Nexco Paste Dentin**
Visio Beta Vario **Solidilite V** **Labolight LV-III** **Lumamat 100** **HiLite Power**	 Untreated Distilled water Safranine T Coffee	 Untreated Distilled water Safranine T Coffee

Table 8: Discoloration of SR Nexco Paste Incisal and Dentin when cured with various manufacturers' polymerisation units. *R&D Ivoclar Vivadent, Schaan, April 2011*

A. Shinya. In vitro study of wear (gloss) and in vitro study of discoloration in SR Nexco Paste and other veneering composites. Nippon Dental University, Tokyo, Japan 2012.

External discoloration tests were also carried out by Shinya in Japan using SR Nexco Paste, SR Adoro, ten further veneering composites from predominantly Japanese companies (Gradia/GC, New Prossimo/GC, Estenia/Kuraray, Epricord/Kuraray, Ceramage/Shofu, Solidex/Shofu, Twiny/Yamakin, Luna-Wing/Yamakin, Signum Ceramis/Heraeus, Signum Sirius/Heraeus) plus IPS e.max Press as a control.

Thirty specimens of each product were prepared and stored for 5 weeks in either distilled water (as a control), red wine, coffee, tea or a cola-type beverage. Six specimens were used per staining liquid. Specimens were 16mmx16mmx1mm and polishing was not performed. Discoloration (change in colour: ΔE) was measured using a dental chromameter Minolta CR 200 Colorimeter using the l*a*b* colour values. Figure 24 compares the resulting colour change experienced by SR Nexco Paste plus 5 other veneering composites, after 5 weeks' immersion in the staining liquids.

SR Nexco Paste exhibited low colour change across all the staining liquids. Red wine had the highest staining potential. As expected, IPS e.max Press as the control (not shown in the diagram) exhibited the lowest average colour change of E = 0.6. Of the veneering composites however, SR Nexco Paste had the lowest average colour change across all staining fluids at E = 2.5 whilst Ceramage exhibited the highest average colour change at E = 10.3.

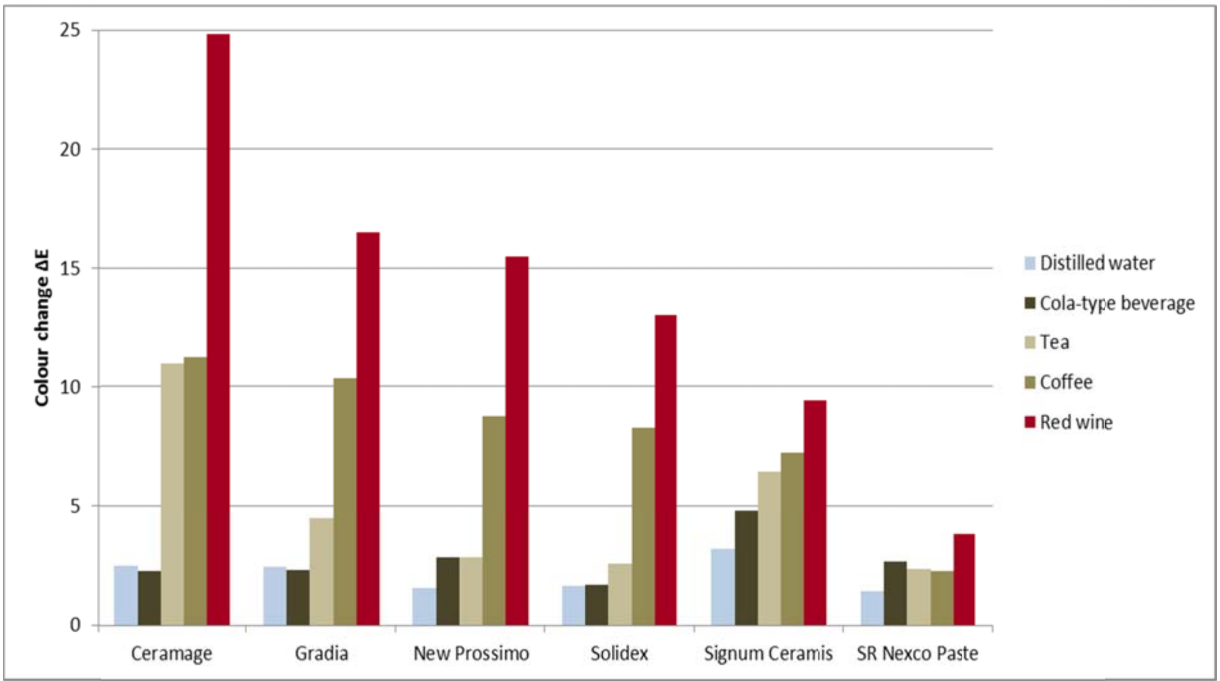


Fig. 24: Discoloration of SR Nexco Paste and other veneering composites. Colour change after 5 weeks in various staining liquids. *A. Shinya, Nippon Dental University, Tokyo, Japan 2012*

5.6 Gloss stability

Gloss is an optical property that refers to the ability of a material's surface to reflect light. In gloss measurements, the amount of incident light that is reflected by a material at a certain angle (e.g. 60°) is recorded. Black glass which achieves 94.2 gloss units is usually used as a reference. (23)

Aesthetic restorative materials should show tooth-like lustre and gloss after polishing and ideally should maintain this appearance over a considerable period of time. It is common however for restorative materials to lose their lustre over time. The in vitro data on loss of gloss after simulated tooth brushing are comparable to clinical data to a certain extent. (24) Heintze et al estimate that an hour of simulated brushing is roughly equivalent to 21 months in vivo. (23)

The gloss stability of SR Nexco Paste and five competitor lab composites were compared over time in a one hour tooth-brushing simulation investigation. Discs of each material were prepared according to manufacturers' instructions and polymerised using the respective manufacturers' polymerisation lamp. An initial polishing with 4000 grit abrasive paper and a polishing-liquid (0.05 µm) was carried out and gloss values of the materials measured. Subsequently, the specimen discs were brushed with Colgate Total toothpaste using a contact pressure of 250 g, and surface gloss (angle 60°) was measured at 15 minute intervals. Figure 25 shows the decrease in lustre of the lab composites over the course of 1 hour. The SR Nexco Paste test discs exhibited a statistically significant higher gloss stability than the other products and after 15 minutes lustre remained relatively stable. The product Signum/Heraeus exhibited the lowest gloss stability (ANOVA, post hoc Tukey B, $p<0.05$). There was no significant difference between Ceramage/Shofu, Sinfony/3M ESPE and Gradia/GC ($p>0.05$). It is important to note that SR Nexco Paste maintained its lustre of more than 70 gloss units (gloss index) after exposure to simulated tooth-brushing. Beyond 70 gloss units the human eye cannot distinguish between high and very high lustre i.e. a material that achieves 70 gloss units does not look any less shiny to the naked eye than a material that achieves 90 gloss units.

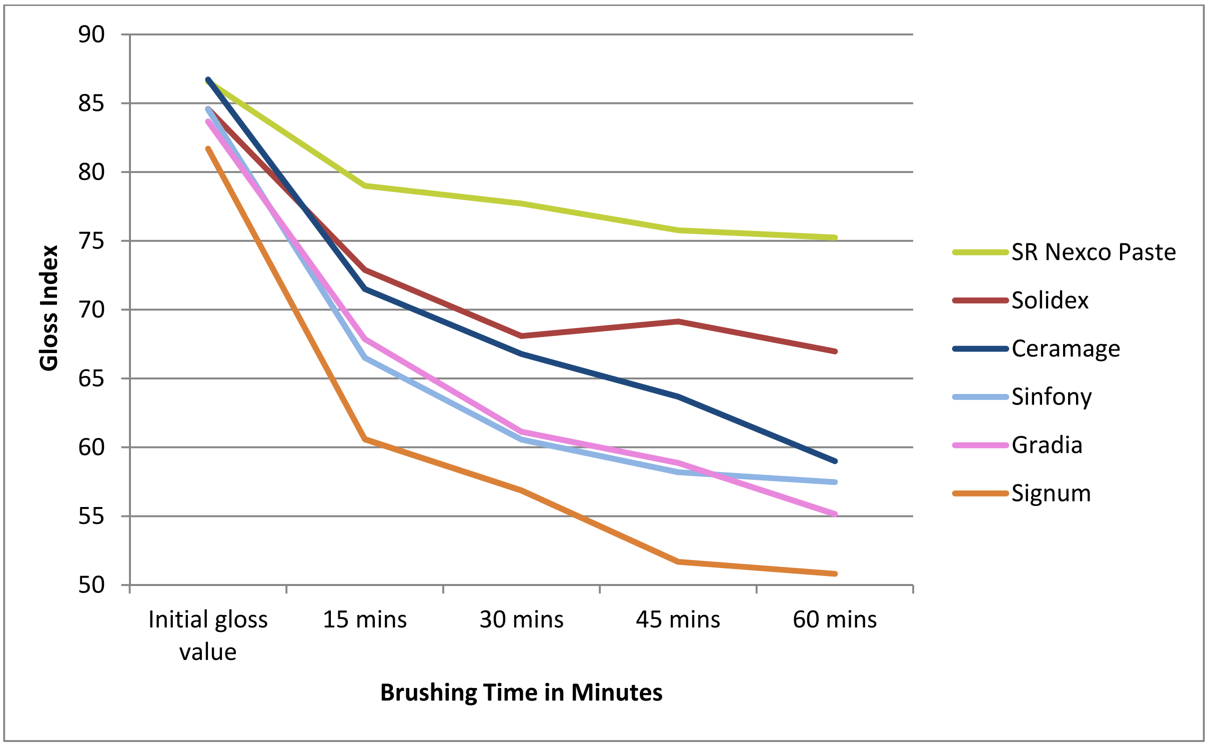


Fig. 25: Gloss stability tests on SR Nexco Paste and other lab composites over 1 hour of tooth brushing simulation. *Pre-clinic R&D Ivoclar Vivadent, Schaan, November 2011*

A. Shinya. In vitro study of wear (gloss) and in vitro study of discoloration in SR Nexco Paste and other veneering composites. Nippon Dental University, Tokyo, Japan 2012.

External gloss stability tests were also carried out at the Nippon Dental University in Tokyo. Shinya conducted tooth-brushing simulation tests over 50,000 tooth-brushing cycles. The same materials as used in the discoloration tests were used (section 6.5), that is 12 different veneering composites including SR Nexco Paste. 15 specimens (20mmx10mmx1.5mm) of each product were prepared and brushed in a Nippon Mecc Abrasion machine using a slurry liquid of 1:1 brushing paste and water, over 50,000 cycles at a load of 200g. Gloss was measured using a VG 2000 gloss meter from Nippon Denshoku using reflected light, at an angle of 60°.

Similarly to figure 25, the results showed higher gloss stability for SR Nexco Paste. The initial gloss values for the composites were similar after polishing and ranged from 81.9 to 88.8% with SR Nexco Paste at 85.5%. From 15,000 cycles onwards SR Nexco Paste had the highest gloss index values i.e. it withstood brushing most successfully.

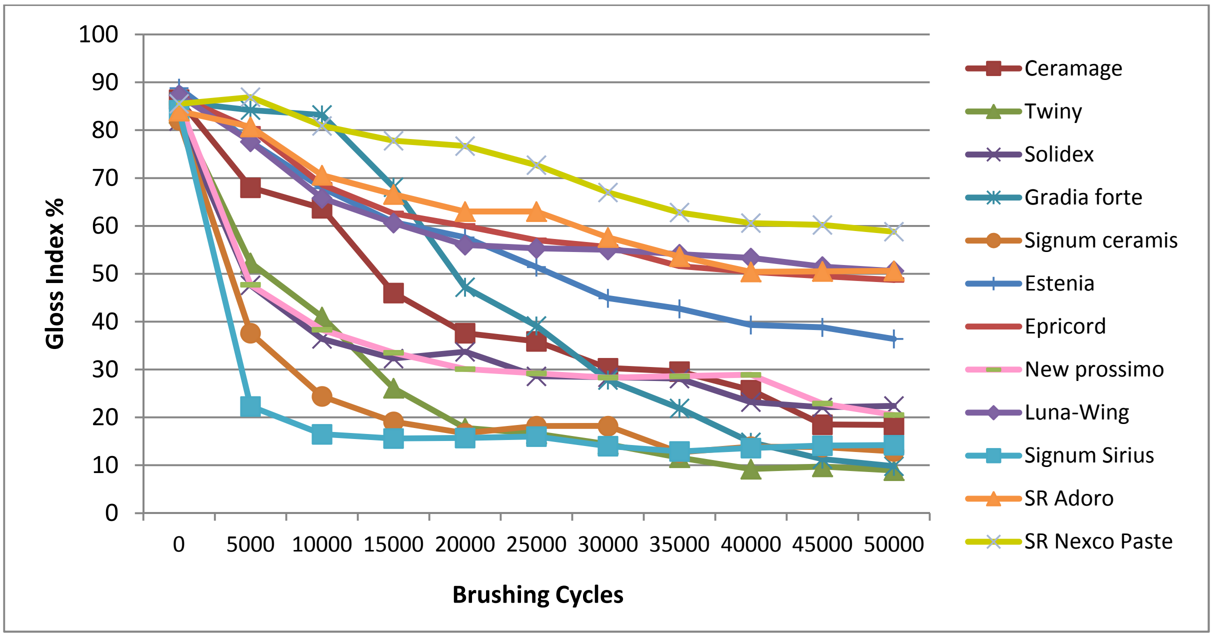


Fig. 26: Gloss stability tests on SR Nexco Paste and other lab composites over 50,000 simulated tooth-brushing cycles. *A. Shinya, Nippon Dental University, Tokyo, Japan 2012*

5.7 Conclusion

SR Nexco Paste is an innovative new lab-composite with good mechanical properties, independent of curing device used. It has outstanding bond strength, widely independent of bonding agent; it exhibits low wear, excellent opalescence and fluorescence and good gloss stability.

6. Clinical Investigations / In Vivo

SR Nexco Paste differs from SR Adoro in terms of the extra light initiators employed to facilitate the sole use of light polymerisation units. In other respects the two products are very similar. SR Adoro has been used successfully on the market since 2004 and several clinical studies have been conducted. For this reason just one clinical study is due to run with SR Nexco Paste. The study will commence in autumn 2012.

Study Centre: Dr A. Shinya, Nippon Dental University, School of Life Dentistry at Tokyo Department of Crown and Bridge, Tokyo, Japan.

Study Objective: 30 patients will be recruited for a 2 year study. Each patient will receive a crown or bridge for the anterior region as this indication is covered by Japanese Health Insurance. The restorations will be SR Nexco Paste veneered and will be cemented using Multilink Automix. Gloss and surface texture of restorations will be evaluated at 6, 12 and 24 months. The exact study methodology is still under discussion but will involve the evaluation of wear, discoloration, gloss, marginal gaps, fracture or chipping, secondary caries and retention.

7. Biocompatibility

SR Nexco Paste is a light curing polymer-based lab-composite. It has been developed on the basis of SR Adoro, a light/heat curing polymer-based lab-composite. SR Nexco Paste utilises the same fillers and monomers as SR Adoro. The additional initiators and stabilisers employed are industry standard and have also been used in other Ivoclar Vivadent products.

7.1 Composition of SR Nexco Paste components

All SR Nexco Paste masses consist of a mixture of dimethacrylates and filler particles. The following table gives an overview of which monomers and filler types are included in the particular masses.

Monomer	**Dentin**	**Enamel**	**Liner**	**Stains**	**Opaquer**
Aromatic aliphatic urethane dimethacrylate	X	X	X	X	X
Decandiol dimethecrylate	X	X	X	X	X
Other dimethacrylates	X	X	X	X	-
Filler	**Dentin**	**Enamel**	**Liner**	**Stains**	**Opaquer**
Zirconium oxide	-	-	-	-	X
Barium glass	-	-	X	-	-
Silicon dioxide	X	X	X	X	X
Copolymer	X	X	-	X	-

Table 9: Monomers and fillers contained in the various materials of the SR Nexco Paste system

7.2 Toxicity of cured SR Nexco Paste

Cytotoxicity
An in vitro cytotoxicity assay was carried out on extracts of cured test specimens by an independent test facility. No cytotoxic effects were observed following incubation with an extract of SR Nexco Paste up to the highest tested concentration (i.e. 100% = undiluted extract). Due to the lack of cytotoxicity, an XTT_{50} value could not be calculated. It can therefore be stated that under the experimental conditions reported in this study, extracts of the test item SR Nexco Paste do not have a cytotoxic potential (25).

7.3 Toxicity of filler particles in SR Nexco Paste

Inorganic fillers such as glass, silicon dioxide and zirconium oxide, can be considered chemically inert, and as they are also enclosed within a polymerised matrix, they pose no toxicological risk. SR Nexco Pastes and Stains also contain copolymer, a pre-polymerised organic filler.

The acute oral toxicity of a pre-polymerised filler similar to that used in SR Nexco Paste (and SR Adoro) was tested in rats. At the maximum dose of 5000 mg/kg, no rats died within the observation period of 15 days and no macroscopic organ changes were observed (26). LD 50 is the amount of a material given all at once, which causes the death of 50% of a group of test animals. Expressed per kg of body weight, the higher the LD 50 the lower the toxicity. The LD 50 value for highly dispersed silicon dioxide given in the material safety datasheet is greater than 10,000 mg/kg (27), thus the filler particles used in SR Nexco Paste pose no toxicological risk *per se*.

7.4 Toxicity of dimethacrylates used in SR Nexco Paste

Acute oral toxicity data is available for UDMA and Decandiol dimethacrylate, both exhibit high LD_{50} values of over 5000 mg/kg and are therefore not acutely toxic upon oral intake:

Chemical	LD 50	Species	Reference
UDMA	>5000 mg/kg	Rat	(28)
Decandiol dimethacrylate	>5000 mg/kg	Rat	(29)

To date, there have also been no reports of oral toxicity relating to SR Adoro which contains the same monomers and fillers.

Cytotoxicity data is also available for the following monomers of SR Nexco Paste

Chemical	XTT,IC,TC_{50}	Cell line	Reference
Aromatic aliphatic UDMA	85 µg/ml	L929	(30)
UDMA	600 µg/ml	L929	(31)
Decandiol dimethacrylate	>600 µg/ml	L929	(32)
Aliphatic dimethacrylate	58 µg/ml	L929	(33)

The decandiol dimethacrylate and UDMA are of comparably low cytotoxicity, while the aromatic aliphatic UDMA and the aliphatic dimethacrylate possess a higher cytotoxic potential. Both however are considerably less toxic than the monomer Bis-GMA (20 µg/ml) (31). To date there are no adverse toxic effects known related to Bis-GMA a frequently used monomer in dental materials.

7.5 Genotoxicity

Mutagenicity testing is an accepted tool to evaluate the potential risk for genotoxicity of chemical substance or medical devices. The most established mutagenicity test is the bacterial reverse mutation test or Ames test with strains of Salmonella typhimurium and Escherichia coli. An Ames test was carried out at an independent testing facility whereby SR Nexco Paste was found to be non-mutagenic. That is it did not induce gene mutations by base pair changes or frame shifts in the genome of the strains used. (34)

7.6 Irritation and Sensitisation

Like all dental composite materials SR Nexco Paste contains dimethacrylates. Such materials may have an irritating effect and initiate a sensitisation to methacrylates, which can lead to allergic contact dermatitis. The occurrence of such reactions can be minimised by clean working conditions and avoiding any contact of unpolymerised material with the skin. (35, 36) Commonly employed gloves made of latex or vinyl do not provide effective protection against sensitisation. Allergic reactions are extremely rare in patients but are increasingly observed in dental personnel who handle uncured composite materials on a daily basis (37).

As undiluted extracts of SR Nexco Paste did not show any cytotoxicity (25), it can be assumed that the risk of the product causing mucosal irritation is extremely low. SR Nexco Paste contains proven ingredients that have been used in similar products such as SR Adoro. Clinical trials with SR Adoro have been conducted and no mucosal irritation has been reported to date.

7.7 Conclusion

The toxicological evaluation of SR Nexco Paste shows that according to current knowledge, SR Nexco Paste provides the same level of safety as other composite materials currently used in dentistry. SR Nexco Paste is similar in composition to SR Adoro. Clinical experience with SR Adoro dates back to 2004 and no undesired effects relating to biocompatibility issues have been reported to date. According to current knowledge, if used as indicated, SR Nexco Paste poses no risk for the patient, user or third party, and the benefits of the product exceed any residual risk.

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