Scientific Documentation
1. Introduction

1.1 Core build-up – A short review

Materials such as amalgam or glass ionomer cements were formerly used for fabricating core build-ups on vital and non-vital teeth. As these materials had to be anchored primarily in a mechanical way to the remaining tooth structure, it was generally necessary to retain the core build-up by means of an endodontic post.

These therapies, however, had several disadvantages. Core build-ups made of amalgam and the use of metal endodontic posts limited the aesthetics of the restoration due to their lack of translucency. Furthermore, scientific investigations have shown that a post does not reinforce the built-up tooth (Guzy and Nicholls, 1979; Sidoli et al., 1997). On the contrary, while endodontic treatment alone hardly weakens a tooth, the preparation of the root canal for the post in which natural dentin has to be removed significantly reduces the fracture strength of a tooth (Sidoli et al., 1997). Restored teeth become weaker the more natural tooth structure is lost. Particularly MOD defects in which the marginal ridges had to be removed severely weaken the teeth (Reeh et al., 1989).

1.2 Adhesive build-ups – The state of the art

Based on such conclusions, the German Society of Dental Oral and Craniomandibular Sciences published a scientific statement in 2003 (Edelhoff et al., 2003). The following objective was formulated in the statement:

"The build-up of endodontically treated teeth should ensure reliable retention of a permanent restoration by preserving as much as possible of the healthy tooth structure."

It is specifically mentioned that thanks to the adhesive technique, build-up possibilities are available for numerous clinical situations. These possibilities should be preferred due to minimal invasive procedures as well as the minimization of the risk of a iatrogenic root perforation (Edelhoff et al., 2003).

With their scientifically consolidated statement, the experts from the GSDOM put on record that an adhesive build-up fillings or an adhesive core build-up is the procedure of choice in many clinical situations.

1.3 Objectives of the MultiCore development

The objective in the development of MultiCore was to offer a material with which dentists can efficiently fabricate build-up fillings and core build-ups with their preferred processing techniques. MultiCore is characterized by the following features:

- **Dual-curing**: MultiCore achieves excellent mechanical strength by chemical self-curing alone. By additional light polymerization, the dentist can immediately start with the preparation.

- **Two consistencies**: With the highly viscous MultiCore HB the build-up filling or core build-up can be individually shaped and modelled. MultiCore Flow in a flowable consistency allows core build-ups to be fabricated by placing the material in bulk using matrices.

The present documentation addresses the technical properties of and investigations on MultiCore.
2. Technical data

Composition

<table>
<thead>
<tr>
<th></th>
<th>MultiCore HB</th>
<th>MultiCore Flow</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Base</td>
<td>Catalyst</td>
</tr>
<tr>
<td>Dimethacrylates</td>
<td>13.5</td>
<td>13.3</td>
</tr>
<tr>
<td>Barium glass fillers, Ba-Al-fluoro-silicate glass, Highly dispersed silicon dioxide</td>
<td>75</td>
<td>75</td>
</tr>
<tr>
<td>Ytterbium trifluoride</td>
<td>11.1</td>
<td>11.1</td>
</tr>
<tr>
<td>Catalysts, stabilizers and pigments</td>
<td>0.4</td>
<td>0.6</td>
</tr>
</tbody>
</table>

Specifications are in wt %

Physical data

<table>
<thead>
<tr>
<th></th>
<th>MultiCore HB</th>
<th>MultiCore Flow</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>dual-curing</td>
<td>self-curing</td>
</tr>
<tr>
<td>Flexural strength (MPa)</td>
<td>140</td>
<td>125</td>
</tr>
<tr>
<td>Modulus of elasticity (MPa)</td>
<td>18'000</td>
<td>14'000</td>
</tr>
<tr>
<td>Compressive strength (MPa)</td>
<td>250</td>
<td>140</td>
</tr>
<tr>
<td>Vickers hardness (MPa)</td>
<td>1000</td>
<td>510</td>
</tr>
<tr>
<td>Radiopacity (% Al)</td>
<td>300</td>
<td>300</td>
</tr>
<tr>
<td>Water absorption 7 days (µg/mm³)</td>
<td>14.5</td>
<td>25</td>
</tr>
<tr>
<td>Water solubility 7 days (µg/mm³)</td>
<td>3</td>
<td>2.5</td>
</tr>
<tr>
<td>Working time at 37°C (s)</td>
<td>90-120</td>
<td>90-120</td>
</tr>
</tbody>
</table>

In accordance with ISO 4049 – Polymer-based filling, restorative and luting materials
3. Materials science investigations on MultiCore

3.1 Vickers hardness

The materials were processed according to the instructions of the manufacturer. All the materials were tested using both the self-curing as well as the dual-curing method. The samples were stored in the dry box for 24 hours at 37°C. Subsequently, the Vickers hardness was measured in compliance with EN ISO 4049. For this purpose, the sample was subjected to a specified load by a pyramid indenter for a defined period of time. The two diagonals of the indentation left in the surface of the material after removal were measured and the hardness calculated.

Investigation: R&D, Ivoclar Vivadent, Schaan

3.2 Flexural strength

The materials were processed according to the manufacturer’s instructions using the self- and dual-curing methods. For dual-curing purposes, the material was additionally polymerized with a Heliolux light for 40 s with a light intensity of 500 mW/cm². After 24 hours, the flexural strength was measured by means of a Zwick universal testing machine in compliance with EN ISO 4049.

Investigation: R&D, Ivoclar Vivadent, Schaan
3.3 **Flexural modulus**

The materials were processed according to the instructions of the manufacturer using the self-curing as well as the dual-curing method. After 24 h, the flexural modulus was measured with a Zwick universal testing machine in compliance with EN ISO 4049.

Investigation: R&D, Ivoclar Vivadent, Schaan

3.4 **The curing of MultiCore as function of time**

When processing a self- or dual-curing composite material for core build-ups, the time needed for curing plays a decisive role. The material has to set sufficiently in order to be processed with rotating instruments. Therefore, the Vickers hardness of MultiCore HB and MultiCore Flow was measured as a function of time both for self-curing as well as for dual-curing applications with light.

If curing is additionally initiated by light, MultiCore Flow and MultiCore HB can be processed without delay. What is noteworthy is that both materials achieve the same Vickers hardness after 24 hours of self-curing as they do if they are additionally light-cured.

Investigation: R&D, Ivoclar Vivadent, Schaan
3.5 **Tolerance of MultiCore HB towards hand-mixing**

The mixing ratio of the base and catalyst paste may vary for all hand-mixed self-curing or dual-curing materials, as the quantity of the material used depends on the operator’s visual judgement. Therefore, the material has to cure reliably while offering manageable working times even if slight deviations of the mixing ratio occur. MultiCore HB was tested with these properties in mind.

<table>
<thead>
<tr>
<th>Mixing ratio (Base : Catalyst)</th>
<th>2 : 1</th>
<th>1 : 1</th>
<th>1 : 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working time (s)</td>
<td>120 – 150</td>
<td>120 – 132</td>
<td>120 – 126</td>
</tr>
<tr>
<td>Flexural strength self-curing (MPa)</td>
<td>117 ± 6</td>
<td>122 ± 7</td>
<td>123 ± 10</td>
</tr>
<tr>
<td>Flexural strength dual-curing (MPa)</td>
<td>141 ± 7</td>
<td>143 ± 7</td>
<td></td>
</tr>
<tr>
<td>Flexural modulus self-curing (MPa)</td>
<td>12,400 ± 1,200</td>
<td>15,100 ± 600</td>
<td>13,400 ± 1,500</td>
</tr>
<tr>
<td>Flexural modulus dual-curing (MPa)</td>
<td>18,100 ± 900</td>
<td>16,700 ± 800</td>
<td></td>
</tr>
</tbody>
</table>

Investigation: R&D, Ivoclar Vivadent, Schaan

Result: The data show that large deviations from the stipulated mixing ratio of 1:1 neither significantly influence the working time nor the physical strength of MultiCore HB.

3.6 **Dentin bonding of MultiCore**

The bond of MultiCore to dentin was tested with Syntac, AdheSE and Excite. First, the adhesive was applied to dentin according to the Instructions for Use and light cured in all cases. Subsequently, MultiCore was either light cured (DC) or self-cured (SC) if Syntac or AdheSE were used. In contract, a dual-curing composite has to be light cured if Excite is used (see Instructions for Use). The following figure shows the shear bond strength on bovine dentin, which was measured in compliance with ISO/TS 11405

[Shear bond strength graph]

Investigation: R&D, Ivoclar Vivadent, Schaan
3.7 **Filler particles of MultiCore**

The development of core build-up composites implies other priorities than those for the development of restoratives. Composites for Class I and II fillings should primarily feature minimum wear. However, for composites for the anterior region, aesthetics and polishability and the surface lustre in particular are decisive properties. Minimum wear and good polishability are achieved with microfillers. These features, however, are irrelevant for core build-up materials. The focus here is set on high strength and good handling properties. For this purpose, especially the viscosity has to be accurately adjusted.

MultiCore HB is highly viscous and can be conveniently modelled and shaped. Nevertheless, the material should allow hand-mixing. MultiCore Flow has to feature a low viscosity so that the material can be dispensed from the double-barrel cartridge and the mixing tip. However, it should not be too flowable to prevent the material from flowing away from the application field.

The mixing properties, physical strength, viscosity and the handling characteristics depend to a large extent on the filler particles used. The following figures show the fillers of MultiCore.

Samples made with MultiCore were polished and examined under the scanning electron microscope (SEM). The bright white particles are ytterbium trifluoride, which is responsible for the radiopacity of the material. Therefore, ytterbium trifluoride reflects most of the electrons under the SEM and thus appears white. The polymer matrix and silicon dioxide fillers are dark. Fillers of barium glass and Ba-Al-fluorosilicate glass appear grey. They have diameters of up to several micrometers. Big filler particles result in high physical strength and allow high filler contents to be achieved.

Images: R&D, Ivoclar Vivadent, Schaan
4. Biocompatibility of MultiCore

4.1 Composition of MultiCore

MultiCore HB and MultiCore Flow are composed of dimethacrylates and fillers. The monomer matrix consists of Bis-GMA, urethane dimethacrylate and triethylene glycol dimethacrylate. The inorganic fillers are barium glass, Ba-Al-fluorosilicate glass, silicon dioxide and ytterbium trifluoride. The present documentation first deals with the toxicity of the fillers and then addresses that of the monomers.

4.2 Toxicity of fillers

Glass and silicon dioxide fillers are considered to be chemically inert. During the polymerization process, the fillers are additionally embedded in a resin matrix. Therefore, these fillers do not pose a toxicological risk. According to the materials safety data sheet, the LD_{50}-value for the acute oral toxicity of silicon dioxide in rats is greater than 10,000 mg/kg [1]. The toxicity of the ytterbium trifluoride filler, which is responsible for the excellent radiopacity of Ivoclar Vivadent composites, was tested in rats. At the maximum dose of 5000 mg/kg tested, none of the rats died and no pathologic organ changes were observed in any rat [2]. A test also revealed that ytterbium trifluoride shows no radioactivity beyond natural background [3].

This information shows that the filler particles used in MultiCore per se pose no toxicological risk. Therefore, the toxic properties of composite materials are essentially determined by their monomer matrix.

4.3 Toxicity of dimethacrylates used in MultiCore

Cytotoxicity data

<table>
<thead>
<tr>
<th>Compound</th>
<th>XTT_{50}</th>
<th>Cell line</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urethane dimethacrylate</td>
<td>600 µg/ml</td>
<td>L929</td>
<td>4</td>
</tr>
<tr>
<td>Bis-GMA</td>
<td>25 µg/ml</td>
<td>L929</td>
<td>4</td>
</tr>
<tr>
<td>Triethylene glycol dimethacrylate</td>
<td>25 µg/ml</td>
<td>L929</td>
<td>4</td>
</tr>
</tbody>
</table>

Acute oral toxicity data

<table>
<thead>
<tr>
<th>Compound</th>
<th>LD_{50}</th>
<th>Species</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urethane dimethacrylate</td>
<td>&gt; 5000 mg/kg</td>
<td>Rats</td>
<td>5</td>
</tr>
<tr>
<td>Bis-GMA</td>
<td>&gt; 5000 mg/kg</td>
<td>Rats</td>
<td>5</td>
</tr>
<tr>
<td>Triethylene glycol dimethacrylate</td>
<td>10,837 mg/kg</td>
<td>Rats</td>
<td>5</td>
</tr>
</tbody>
</table>

Evaluation of toxicological data on the MultiCore monomer:

Cytotoxicity data of all dimethacrylates used in MultiCore materials is available. The high LD_{50}-value of Bis-GMA and triethylene glycol dimethacrylate demonstrates that these dimethacrylates do not exhibit relevant oral toxicity. These results are confirmed by clinical experience with dental composite materials of more than 20 years.

The catalysts, stabilizers and pigments employed in the base and catalyst pastes of MultiCore have already been employed in other dental materials for many years without problems. Hence, it can be assumed that they do not pose an unknown toxicological risk for the patient.
4.4 Mutagenicity data of dimethacrylates used in MultiCore

Ames test

<table>
<thead>
<tr>
<th></th>
<th>Result w/o S9</th>
<th>Test conc.</th>
<th>Result w S9</th>
<th>Test conc.</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urethane dimethacrylate</td>
<td>neg.</td>
<td>5000 µg/plate</td>
<td>neg.</td>
<td>5000 µg/plate</td>
<td>6</td>
</tr>
<tr>
<td>Bis-GMA</td>
<td>neg.</td>
<td>5000 µg/plate</td>
<td>neg.</td>
<td>5000 µg/plate</td>
<td>6</td>
</tr>
<tr>
<td>Triethylene glycol dimethacrylate</td>
<td>neg.</td>
<td>5000 µg/plate</td>
<td>neg.</td>
<td>5000 µg/plate</td>
<td>6</td>
</tr>
</tbody>
</table>

To assess the carcinogenic risk of a medical device, mutagenicity tests are carried out, as cellular mutation is the initial step in the development of cancer. Today, such tests are carried out *in vitro* with bacterial or cell cultures. The advantage of *in vitro* tests is that they are usually more sensitive than *in vivo* carcinogenicity studies. A disadvantage of *in vitro* tests with cell cultures is that they may not show up components which only become mutagenic after they have been metabolized in tissues such as the liver. To simulate such 'metabolic activation' components are incubated with extracts of liver tissues (S9 mix). Under such conditions, metabolic products are formed, which also can occur *in vivo* upon exposure to the test material. Therefore, mutagenicity results are presented without metabolic (w/o S9) and with metabolic activation (w S9) in the table above. The most commonly employed test for mutagenicity is the *Salmonella typhimurium* reverse mutation test (Ames test).

4.5 Irritation and sensitization

Like all dental composite materials MultiCore contains dimethacrylates. Such materials may have an irritating effect on predisposed persons and may cause sensitization to methacrylates. This can lead to allergic contact dermatitis. These reactions can be minimized by clean working conditions and avoiding contact of the unpolymerized material with the skin. Commonly employed gloves, e.g. latex or vinyl gloves, do not provide effective protection against sensitization to methacrylates. Allergic reactions are extremely rare in patients but are increasingly observed in dental personnel, who handles uncured composite materials on a daily basis [7, 8].

4.6 Conclusions

The toxicological evaluation shows that according to the current knowledge MultiCore

- is no more toxic than dental composite materials in general.
- is not mutagenic.
- contains methacrylates. Therefore, the material can lead to sensitization towards methacrylates. This risk which is intrinsic to all methacrylate-based dental materials is particularly important for dental technicians who handle uncured material.

In summary, the information currently available shows that MultiCore provides the same level of safety as other composite materials presently used in dentistry with respect to toxicity, mutagenicity, irritation and sensitization.
4.7 Literature on toxicology


5. References and publications


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Issued: February 2004