Scientific Studies on

VarseoSmile Crown plus

Valid from
December 2020

Partners in Progress

BEGO

Scientific Studies on VarseoSmile Crown plus

VarseoSmile Crown plus is the world's first hybrid material for 3D printing of permanent single crowns, inlays, onlays and veneers.

Scientific studies by renowned universities and institutes prove the excellent material properties.

The summary of the study results includes the following aspects:

- **Breaking Load and Abrasion Resistance** (10-year Chewing Simulation)
- **Abrasion and Surface Roughness** (5-year Toothbrushing Simulation)
- **Long-term Cementation Stability, Decementation Behavior and Marginal Gap Formation** (5-year Chewing Simulation)
- **Solubility**
- **Cytotoxicity**

VarseoSmile Crown plus – Technical data

Density	ca. 1.4–1.5 g/cm³
Layer thickness	50 µm
Viscosity	2,500–6,000 mPa*s
Flexural strength	116 MPa
Flexural modulus	4.090 MPa
Water solubility	0.23 µg/mm³
Water sorption	3.6 µg/mm³

VarseoSmile Crown plus – Chemical composition

Esterification products of 4.4'-isopropylidiphenol, ethoxylated and 2-methylprop-2enoic acid. Silanized dental glass, methyl benzoylformate, diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide.
Total content of inorganic fillers (particle size 0.7 µm) is 30–50 % by mass.

BEGO
Compatibility Overview 3D Printing System Components:
https://www.bego.com/3d-printing/compatibility-overview

BEGO USA
Compatibility Overview 3D Printing System Components:
https://usa.bego.com/3d-printing/compatibility-overview

VarseoSmile Crown plus is distributed by Formlabs* as Permanent Crown.
* This symbol is a commercial designation/registered trademark of a company that is not part of the BEGO company group.

Breaking Load and Abrasion Resistance

10-year Chewing Simulation

Objective

In this study, the long-term (10-year) performance of 3D printed crowns made of VarseoSmile Crown plus was studied, with a focus on the breaking load and abrasion behaviour.

Materials and methods

3D printed crowns made of VarseoSmile Crown plus, and crowns made of the manually-layered material Sinfony* (Fa. 3M*), were tested under the same conditions for comparison purposes. Sinfony was chosen as the comparison material since it is a hybrid material that has been well-established in the market and has demonstrated the highest abrasion resistance to date in scientific studies [1]. The crowns were affixed onto milled stumps made of Trinia* (by Bicon*, modulus of elasticity of the stump material conforms to the 18.8 GPa of natural dentin), using Variolink Esthetic DC* (by Ivoclar Vivadent*).

The breaking load for both materials was determined using a series of 8 crowns in each case, measuring both before and after a simulated in-vivo 10-year masticatory load (2.4 million chewing cycles at a load of 50 N and a lateral motion of 0.7 mm with simultaneous thermocycling of 12,000 cycles of between 5 and 55 °C). Steatite, a magnesium silicate with properties similar to enamel, was used as antagonist material. Measurement of the breaking load was performed via a compression test in a universal testing machine. For this purpose, the respective test specimen was placed in the testing device and loaded with a test die (ball ø 6 mm) onto the middle of the crown, until breakage. The abrasion following the lateral motion was determined by comparing the digital 3D scans of the occlusal surfaces both before and after the chewing simulation.

Results

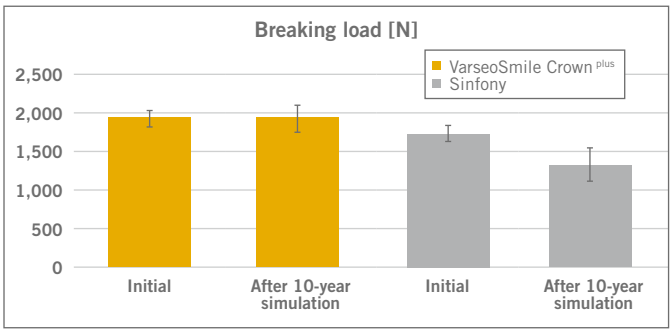
The breaking loads for the VarseoSmile Crown plus crowns exhibited an initial average value of 1,936 N before the chewing simulation. This average value did not change after the chewing simulation. Thus, no detectable material fatigue took place. With an average breaking load of 1,740 N, the comparison product Sinfony exhibited a lower maximum value before the chewing simulation, as compared to VarseoSmile Crown plus. After the simulation, this value decreased to 1,337 N due to material fatigue.

The material wear was measured on the basis of the change in height profile of the crowns, and totalled 0.275 mm after simulation of the 10-year in-vivo masticatory load for the crowns made of VarseoSmile Crown plus. It is thus about 7 % lower than the material wear of 0.296 mm for the Sinfony crowns.

Conclusion

The present tests demonstrate that crowns made of VarseoSmile Crown plus achieve breaking loads that are more than two times higher than the maximum average human masticatory forces of 720 N [2], both initially as well as after a 10-year chewing simulation.

In terms of abrasion resistance, VarseoSmile Crown plus demonstrated less material loss (higher resistance to wear) after the chewing simulation than the material Sinfony.
Restorations are thus preserved for a long period of time and there is a very low risk that a crown could fracture in the patient's mouth.



Breaking loads for crowns made of VarseoSmile Crown plus (BEGO) and Sinfony (3M), before and after a 10-year chewing simulation

Source
The above information is based on a scientific study on breaking load and abrasion resistance of VarseoSmile Crown plus conducted by:
Eva Jerman, M.Sc., Marlis Eichberger, Lisa Schönhoff, B.Sc., Dr. Marcel Reymus, Prof. Dr. Dipl.-Ing. (FH) Bogna Stawarczyk, M.Sc. (2020): Fracture load and two-body wear of 3D printed and conventionally fabricated crowns: artificial aging of 10 in-vivo years, Department of Prosthetic Dentistry, University Hospital, LMU Munich, Germany

[1] Bogna Stawarczyk, Roger Egli, Malgorzata Roos, Mutlu Özcan, Christoph H.F. Hämmerle (2011): The impact of in vitro aging on the mechanical and optical properties of indirect veneering composite resin, in: Journal of Prosthetic Dentistry, Vol. 106, Nr. 6, P. 386 – 398
[2] Charles H. Gibbs, Kenneth J. Anusavice, Henry M. Young, Jack S. Jones, Josephine F. Esquivel-Upshaw (2002): Maximum clenching force of patients with moderate loss of posterior tooth support: A pilot study, in: Journal of Prosthetic Dentistry, Vol. 88, Nr. 5, P. 498 – 502

* This symbol is a commercial designation/registered trademark of a company that is not part of the BEGO company group.

Abrasion and Surface Roughness

5-year Toothbrushing Simulation

Objective

This study will test the loss of mass and the surface roughness on VarseoSmile Crown plus arising from brushing teeth with an electric toothbrush.

Material and methods

This study examined samples made of VarseoSmile Crown plus as well as samples made of Sinfony* (by 3M*) material. Here, Sinfony was chosen as the comparison material because it is a material that has proven itself in the market for many years, and is used for permanent crown restorations and cured via light.

Discs with a diameter of 15 mm and a height of 3 mm were manufactured for test purposes. In the case of VarseoSmile Crown plus this was done through 3D printing, and in the case of Sinfony it was done by filling a form and allowing it to cure on both sides with a light-curing device, in accordance with manufacturer's specifications in both cases. Next, one surface of the disc was polished.

The toothbrushing simulation was performed on the polished surfaces in a toothbrushing simulation machine. This test used the electric toothbrush Oral-B Vitality Sensitive Clean* and "elmex cavity-protection toothpaste"*. In the process, the rotational movement of the brushes was overlaid with a lateral movement of the brushes of 5 mm and a speed of 10 mm/s. The pressing force of the toothbrush on the sample was set at 1.5 N.

The toothbrushing simulation was stopped after 15:12 min (1-year simulation), 45:37 min (3-year simulation) and 76:02 min (5-year simulation). Each time, the loss of mass of the samples and the roughness of the sample surface was determined. This was performed under the assumption that the cleaning duration for the entire dentition is of 4 min per day, such that the total cleaning duration for the surface of one tooth totals a good 15 min per year.

Results

The calculated loss of mass, resulting from the toothbrushing simulation, was significantly higher for the samples made of Sinfony material than for those made of VarseoSmile Crown plus, for all three toothbrushing durations. Thus, the mean loss of mass for VarseoSmile Crown plus was 0.08 mg for the 1-year simulation, 0.32 mg for the 3-year simulation, and 0.56 mg for the 5-year simulation. In contrast, the mean loss of mass for Sinfony was almost double for all of these toothbrushing durations (1-year simulation: 0.24 mg; 3-year simulation: 0.76 mg and 5-year simulation: 0.99 mg).

On the other hand, the resulting surface roughnesses for VarseoSmile Crown plus and for Sinfony were almost equal, and for both materials they were independent of the time at which the toothbrushing simulation was stopped and the roughness measured. The mean roughness (R) ascertained for VarseoSmile Crown plus after the 1-year simulation was R_a: 0.09 µm, after the 3-year simulation R_a: 0.10 µm and after the 5-year simulation 0.11 µm. The roughness value for Sinfony after the 1-year simulation was R_a: 0.09 µm, after the 3-year simulation it was 0.10 µm and after the 5-year simulation it was 0.10 µm.

Conclusion

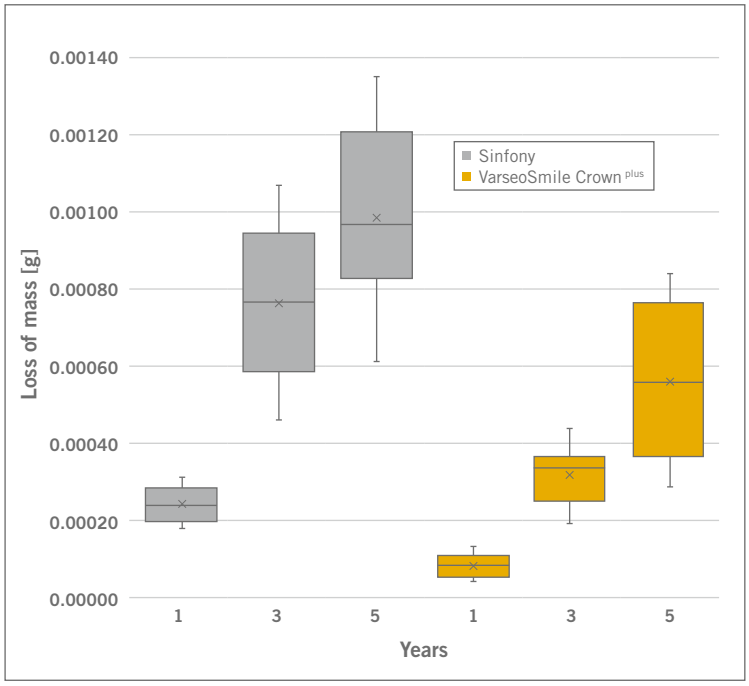
Through the toothbrushing simulation it was possible to demonstrate that crowns made of Sinfony experience significantly greater loss of mass than those made of VarseoSmile Crown plus. Restorations made of VarseoSmile Crown plus are thus preserved for a long time and the existing tooth substance is protected in the best possible manner. Moreover, the roughness values provide evidence that there is no significant increase in roughness resulting from toothbrushing duration, in the case of both materials. Since the roughness values always remained clearly below the clinically significant threshold of R_a: 0.2 µm, an increased accumulation of plaque on the surface of the tooth-restoration is not to be expected.

Toothbrush simulator ZM.3.4

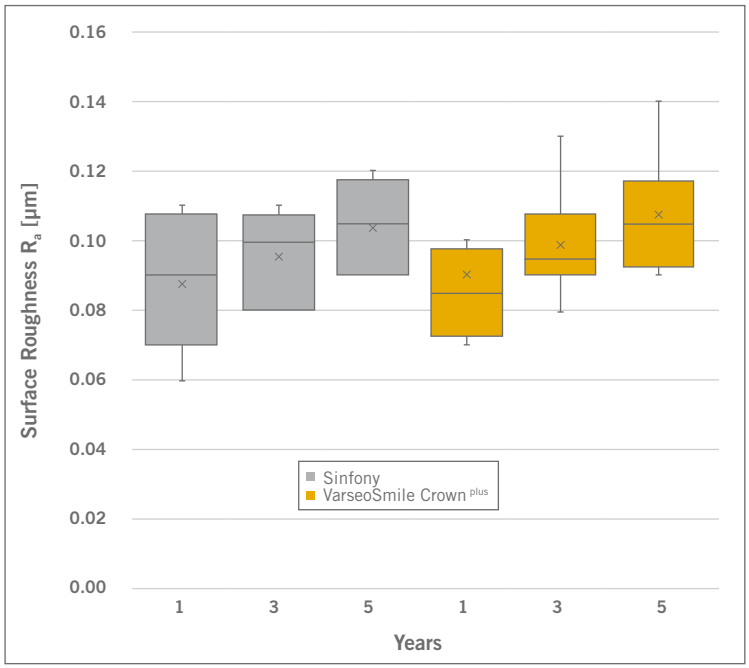
Source

The above information is based on a scientific study of the toothbrush abrasion of VarseoSmile Crown plus, conducted by:
Niclas Albrecht; SD Mechatronik GmbH, Germany

* This symbol is a commercial designation/registered trademark of a company that is not part of the BEGO company group.



Boxplot/distribution of the measured values of loss of mass



Boxplot/distribution of the measured values of surface roughness

* This symbol is a commercial designation/registered trademark of a company that is not part of the BEGO company group.

Long-term Cementation Stability, Decementation Behavior and Marginal Gap Formation

5-year Chewing Simulation

Objective

This study intends to provide information, under conditions resembling application, on

- the long-term stability of the cementation,
- the decementation behavior and
- the tendency toward microleakage (marginal gap formation)

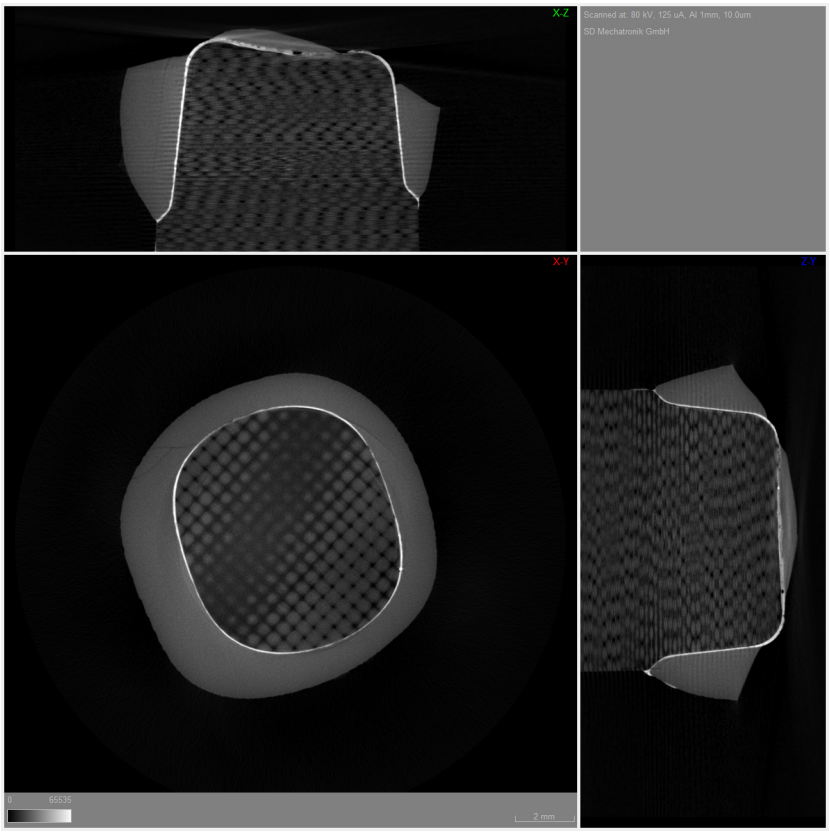
of VarseoSmile Crown plus crowns under masticatory loads.

Material and methods

The 3D printed crowns made of VarseoSmile Crown plus were cemented, i.e. adhesively affixed, to milled Trinia* stumps (by Bicon*, the elasticity modulus of the stump material of 18.8 GPa is comparable to that of natural dentin) using Variolink Esthetic DC* (by Ivoclar Vivadent*). There was no pre-treatment in which the inner surfaces were sandblasted.

This study design, based on clinical use, was subject to both a chewing simulation at 50 N load with 1.2 million chewing cycles (1.2 Hz) and 10,000 thermocycles (5 °C/55 °C) (corresponding to approx. 5 years in the mouth) and to a staircase simulation (significantly elevated requirements through gradual increase of the load force (with 50–80–120 N load), with 400,000 chewing cycles and 10,000 thermocycles (5 °C/55 °C) each time.

After the simulation, the cemented crowns were removed from the stumps. The force required to do so was measured and the damage profile was analyzed. In addition, the marginal gaps were inspected using microcomputer tomography (µCT). The validity of the results was conclusively verified using a computer-based finite element analysis (FEA).



µCT image: No washout of adhesive in the crown margin area

* This symbol is a commercial designation/registered trademark of a company that is not part of the BEGO company group.

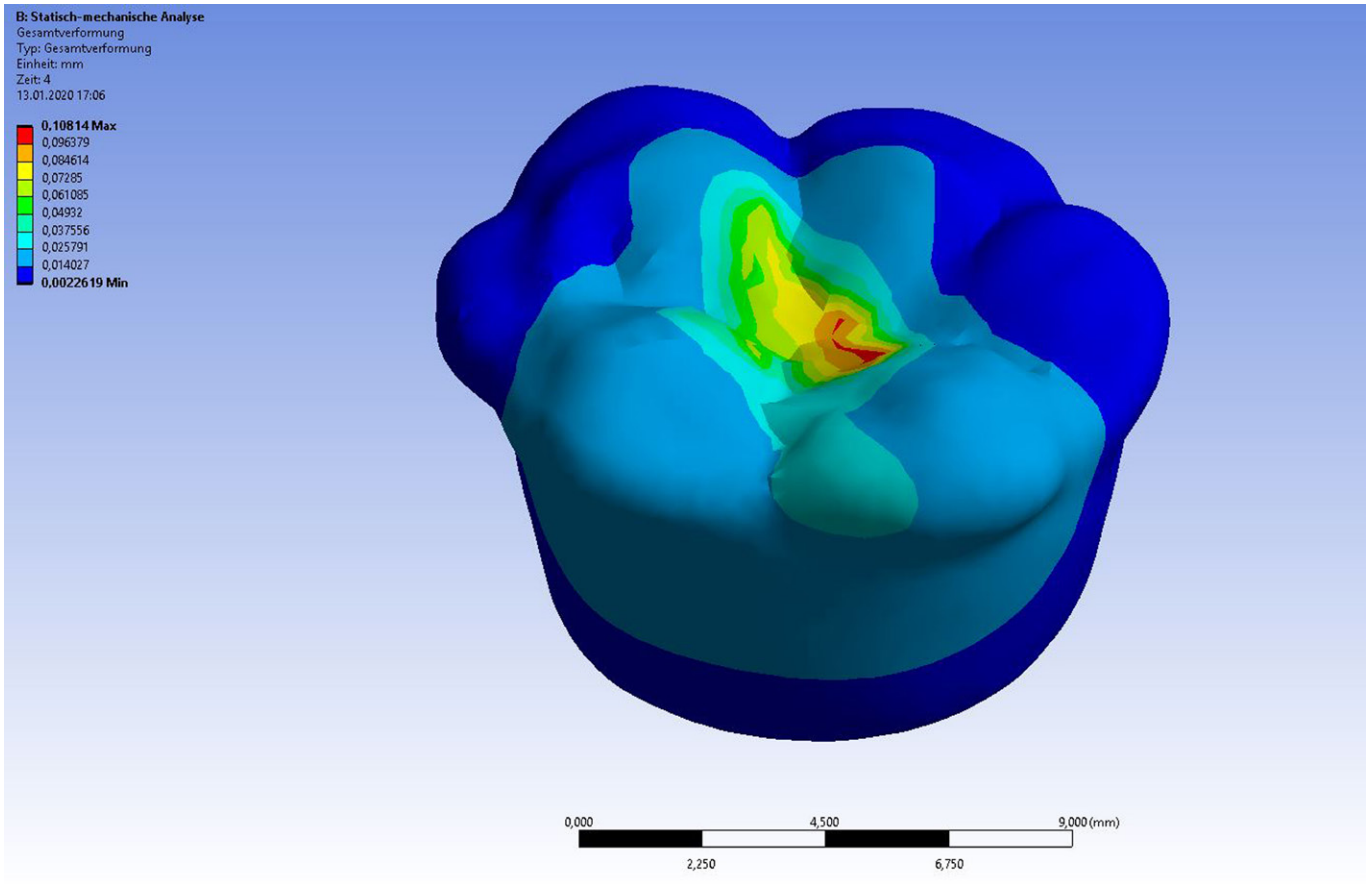
Results

The values ascertained for all BEGO VarseoSmile Crown plus crowns fell within a very high range, which speaks in favor of a long clinical retention time.

- On average, the force of withdrawal without conducting a chewing simulation was approx. 800 N, and after a chewing simulation it was approx. 1000 N. These high values were determined after the chewing simulation at 50 N and after the staircase chewing simulation, demonstrating that the forces of withdrawal themselves fell within a high range and even increased with the duration of wear. From a clinical perspective, the application of such high forces could result in extraction of the tooth due to failure of the adhesive bond.
- The examined crowns displayed a resistance to fracture that was greater than the physiological masticatory forces.
- A decementation was not detected throughout the entire test sequence.
- Neither a lifting of the crown margins or washout of the luting composite from the marginal gap could be observed. The µCT showed that the marginal gap did not increase, the bonding area was not damaged, and the crowns did not shift due to mechanical load, in any of the tested cases.
- The FEA analysis demonstrated that no clinically relevant tensions or deformations were detectable or to be expected in the crown margin area, for crowns made of VarseoSmile Crown plus. This result promises a stable, durable margin closure.

Conclusion

The present studies provide evidence that 3D printed crowns made of VarseoSmile Crown plus do not exhibit a tendency toward decementation, i.e. a loss of composite material or marginal gap formation, when using commercially available, dual-curing luting composites (e.g. Variolink Esthetic DC).



FEA analysis with visualization of the very minor deformation load in the crown margin area

Source

The above information is based on a scientific study of the decementation behavior of VarseoSmile Crown plus, conducted by:
Prof. Dr. Jan-Frederik Güth, ZT Josef Schweiger, M.Sc., Dipl. Ing. Dr. Kurt-Jürgen Erdelt; Polyclinic for Dental Prosthetics, Medical Center of the University of Munich, Germany

* This symbol is a commercial designation/registered trademark of a company that is not part of the BEGO company group.

Solubility

Objective

In this study, the solubility of 3D printed restorations made of VarseoSmile Crown plus were tested, since the dimensions, color, and in very unfavorable circumstances even the mechanical properties of composite restorations may be affected by the extraction (= leaching) of components.

Solubility is of great importance in the evaluation of biocompatibility. When substances formed from processes of dissolution with saliva are released into the oral cavity, undesired biological reactions (allergic or toxic) may be triggered. The extent of such reactions depends on the type and quantity of the released substances, amongst other things.

Material and methods

The solubility of composites is determined through extraction tests. To this end, test specimens made of VarseoSmile Crown plus, which were manufactured under serial conditions, were stored in a solvent for one and three days. Different polar solvents (water and ethanol) were used in order to simulate various saliva compositions.

The eluates (= solutions) obtained in this manner were analyzed via gas chromatography - mass spectrometry (GC-MS) for composite constituents that entered the solution. GC-MS is an analysis method with extremely low detection limits for organic substances.

Results

For VarseoSmile Crown plus, the tests yielded no evidence of constituents having entered the solution, regardless of solvent used. Thus, there is only an exceedingly low risk of undesired biological reactions.

Conclusion

Under the study conditions selected, VarseoSmile Crown plus yielded no substances in the detectable area. Therefore, the risk of conceivable risk to patients, e.g. through allergies, can be classified as exceedingly low.

Source

The above information is based on a scientific study of the solubility of VarseoSmile Crown plus, conducted by:
International Advising Centre for the Compatibility of Dental Materials (BZVZ) of the Ludwig-Maximilians-Universität München, Germany

* This symbol is a commercial designation/registered trademark of a company that is not part of the BEGO company group.

Cytotoxicity

Objective

The objective of the study was the testing of cytotoxicity (= cell toxicity) of 3D printed restorations made of VarseoSmile Crown plus in accordance with DIN EN ISO 10993-5, which is fundamentally intended for the determination of the biocompatibility of materials.

Material and methods

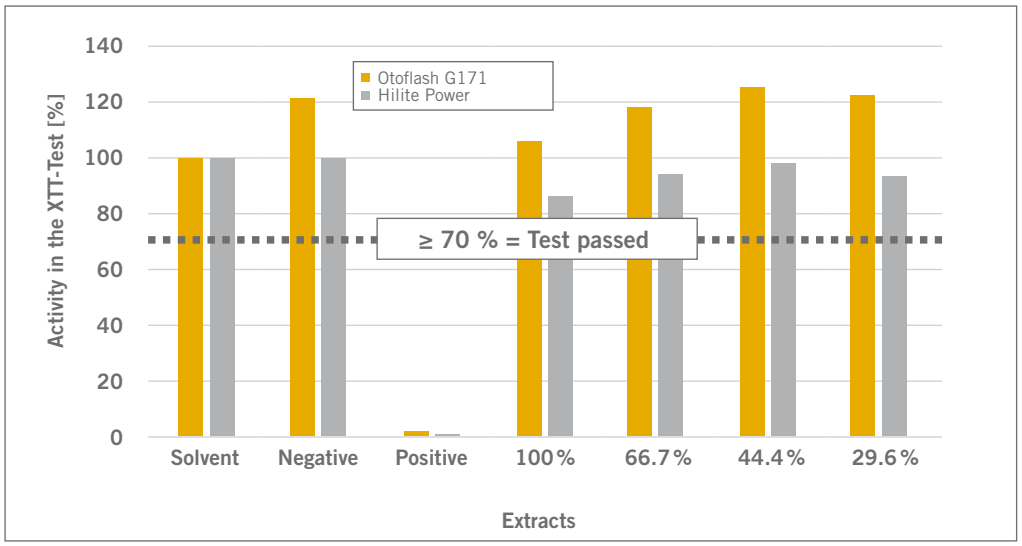
For this test, extracts of the pertinent samples, which were produced as per manufacturer specifications, were compared with the pure dissolver (solvent) and with positive and negative control samples.
To prepare the extracts, the test specimens were extracted in a solvent for 24 hours. These extractswere then diluted to obtain four different concentrations (100 % (undiluted), 66.7 %, 44.4 %, 29.6 %).
In order to ensure the validity of the test, the pure solvent (without contact to the test specimens) as well as one negative (polypropylene) and one positive sample (latex) were also tested. The pure solvent was used as reference. For the negative probe, a substance that in accordance with DIN EN ISO 10993-5 demonstrates no evidence of cytotoxicity was used. In contrast to this, a cytotoxic material was used for the positive probe.
The extracts of the control samples and the different extract concentrations of the test specimens were added to cell cultures and after 68 h to 72 h the cell activity, which is determined through enzymatic reactions, was measured. The activity of mitochondrial dehydrogenases (an enzyme) was measured as a gage of cell activity. Certain “markers”, i.e. substances that react to certain enzymes and form colored complexes, were used for detection purposes. Cell activity was determined through color intensity and the XTT method (XTT = sodium-3‘-[-(1-phenylamino carbonyl)-3,4-tetrazolium]-to(4-methoxy-6-nitro)benzenesulfonic acid hydrate) was applied as standard. With cell activity falling below 70 %, the test is considered as not passed. The closer the cell activity is to that of the solvent control, the better.

Results

The results of VarseoSmile Crown plus in the XTT test yielded, for all tested concentrations, including for the undiluted extract (100 %), cell activities (determined through mitochondrial dehydrogenase activity) that were markedly higher than 70 %. Thus, the test is considered as passed.

Conclusion

VarseoSmile Crown plus showed no cytotoxic properties in the XTT test. Thus, the results of the extraction measurement are confirmed. VarseoSmile Crown plus therefore constitutes a very well tolerated material.



Mitochondrial dehydrogenase activity of VarseoSmile Crown plus and of the dissolver (solvent), negative and positive samples in the XTT test, results for test specimens that were polymerized with either the Otoflash G171 or Hilite Power light-curing devices

Source

The above information is based on a scientific study of the cytotoxicity of VarseoSmile Crown plus, conducted by:
Eurofins BioPharma Product Testing Munich GmbH, Germany

* This symbol is a commercial designation/registered trademark of a company that is not part of the BEGO company group.

www.bego.com

BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
Wilhelm-Herbst-Str. 1 · 28359 Bremen, Germany
Tel. +49 421 2028-0 · Fax +49 421 2028-100
E-mail info@bego.com · www.bego.com

Always want to have a look at all BEGO news?
Sign up for our newsletter here: www.bego.com/newsletter

The products and services shown may not be available in all countries.

REF 81022/00 · JuR · © 2020 by BEGO · 20201203