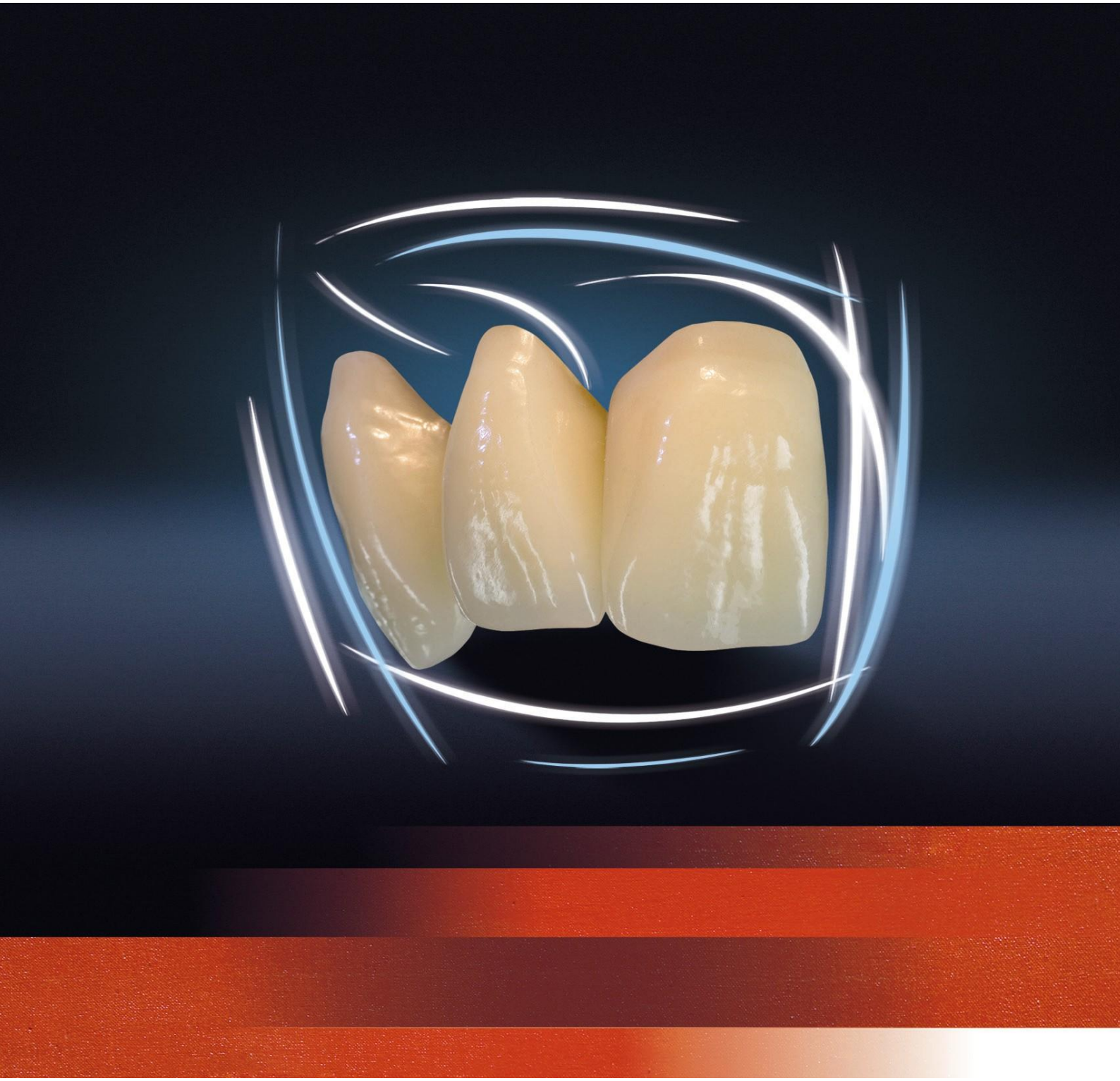
Candulor
The Swiss Art of Prosthetics

Nanoparticles in dental products



www.candulor.com

Nanoparticles in dental products

Background

At the end of October 2009 the German federal health office warned of the risk that some types of nanoparticles in food, clothing and cosmetics could adversely affect health. Because their size, nanoparticles are capable of penetrating the natural barriers of tissue, cells and organs. According to the health office this means that a hazard to human health cannot be excluded.

Candulor addressed this problem in relation to dental products years ago. At the time the terms "nano" and "nano-optimized" were commonly used to describe advanced and innovative new dental materials. This was the case for some composites with optimized properties (abrasion resistance, optical properties) where the inclusion of nanoparticles (such as NFC NanoFilledComposite) was heavily advertised.

Position

Primary particles in the nano range (<100 nm) have been used in dental composites for many years. The amorphous silicon dioxides used in this context are identical to approved food additives and the ground glass particles are comparable. The composition and structure give no reason to expect any hazard.

The nanoparticles are generally in an agglomerated form, silanized and bonded in an acrylic matrix. The curing process of the composite in the mouth firmly embeds the particles in the acrylic, they are no longer mobile and cannot detach from the composite. In principle this applies to all curable and cured dental materials.

For the patient

In clinical use only very minor traces of abrasion have been observed in composites (or ceramics) after years in place. The conclusion is that the possible quantitative absorption of nanoparticles resulting from the abrasion of filling materials is absolutely negligible in comparison to the amounts absorbed from food and tooth paste.

For dental staff

Grinding dust is generated during the preparation of composites in the mouth (or the laboratory). Microscopic examination has demonstrated that the grinding dust has a very similar appearance for all composites, regardless of whether or not they contain nanoparticles. This shows that the preparation of composite fillings does not release relevant amounts of primary filling bodies into the environment and the major part of the grinding dust is not even in the nanorange.

For dental technicians

In some cases nanoparticles are used as primary particles in ceramics (e.g. zirconium oxide) or also in investment compounds. However, these materials are sintered or fired and then the primary particles are no longer present in particulate form. The critical point is only the creation of dust that could penetrate the lungs as a result of milling and grinding ceramics and investment compounds. This has nothing to with nanoparticles but it is a matter of safe working practices in the laboratory.

Safety measures

The already low risk is further minimized with the current standard safety standards such as working with water spray, the use of face masks, extraction systems and rubber dams.

Conclusion

In the current state of knowledge nanoparticles in our composites and dental materials do not pose a hazard for patients nor, when correctly processed, for dental staff.

Biocompatibility of denture teeth of NFC material

Introduction, exposure and composition

NFC teeth are artificial denture teeth for use in removable dentures. The teeth are manufactured from three compounds: incisal edge, dentine and neck. The incisal edge and dentine are made of a new material, while the neck is made from the classic PMMA material and is identical to the neck compound of TCR teeth.

During manufacture the monomers are polymerized to form thoroughly cured teeth, which generally remain completely inert. Patients and dental technicians do not come into contact with the uncured dental mass.

Patients are exposed to oral ingestion of material abraded from the teeth and also to constituents dissolved from the teeth. The dental technician and the dentist are also exposed to the grinding dust.

Composition (% by weight)	**Incisal edge and dentine**
Methyl methacrylate	32
Aliphatic dimethacrylate	10
Inorganic filler silanized silicon dioxide	38
UDMA/PMMA filler	20
Pigments, depending on shade	0.1
Initiators and stabilizers	0.4

Cytotoxicity

The toxicity of the NFC material was tested with a cytotox test (MTT). Sample bodies of NFC were extracted with nutrient solution and the extracts were tested. Cytotoxicity could not be detected [1].

Genotoxicity

The NFC material was tested for genotoxicity in an AMES test (extraction with saline and DMSO). No indication of genotoxicity could be found [2].

Sensitization

It is known that methacrylates can have a sensitizing effect. Because the teeth are delivered already polymerized, the exposure of the patient is restricted to constituents that could be mobile. The manufacturing technology means that the proportion of mobile constituents is negligible.

Irritation and local tissue intolerance

There is no evidence that polymers based on methacrylate have an irritating effect on the oral mucosa.

Conclusion

The above data indicate that denture teeth of NFC material do not pose an increased risk for patients or users when the materials are used as intended.

Sources

[1] RCC: Cytotoxicity assay in vitro: Evaluation of materials for medical devices (XTT-test) with Condyloform II – NFC. Study Report 2005

[2] RCC: Salmonella typhimurium and Escherichia coli reverse mutation assay with Condyloform II - NFC two extracts of 0.9% saline and DMSO. Study Report 2005

October 30, 2009

Scientific Service

Candulor AG

Antonio Ferilli