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## Summary

In recent years, there has been a trend in dentistry towards using metal-free dental implants. For decades, implants made of titanium have been considered the “gold standard”, but can now be supplemented or even replaced by biocompatible ceramic implants. In addition to the aesthetic aspect of ceramic dentures, they also offer better tissue compatibility for patients who are allergic to individual components of titanium implants or have pre-existing conditions such as diabetes. Ceramic dental implants are made of zirconium dioxide ( $ZrO_2$ ), amongst other materials, and are highly durable and long-lasting, with improved chances of bone healing (osseointegration). Overall, this opens up new opportunities in dentistry. Ceramic is an inert (non-reactive) material that has been used for some time as a biocompatible material in orthopaedics, e.g. as hip implants. However, during the placement or use of dental implants, it might be possible that technical nanomaterials used in the ceramic composites can be released and/or nanoscale abrasion in the form of “secondary” nanoparticles can occur. This abrasion can then be either swallowed or inhaled. It is therefore essential to consider possible health risks and investigate nano-specific toxicity effects in more detail during marketing authorisation procedures. To date, no negative interactions in the human body are known, but there are only very few long-term studies on potential risks for humans and the environment.

This dossier explains the material properties of ceramic dental implants compared to conventional titanium implants. It provides an overview of the potential risks and opportunities associated with using this material in dental implantology.

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# Ceramic dental implants

## Structure, properties, and potential risks of innovative materials

### Introduction

The first evidence of dental implant use can be traced back to the Mayan culture. In a lower jawbone, ground pieces of shell were found that replaced three lost teeth. Analyses of the bone growth around these dentures confirmed that they were implanted during the individual's lifetime. As a result, they can be considered actual implants as human teeth or teeth made of ivory were previously attached to existing teeth using gold threads and were thus not implanted<sup>1</sup>. However, the era of modern implantology only began in the 1940s with Manlio Formiggini, whose spiral-shaped screws made from stainless steel enabled bone growth around the metal<sup>2</sup>. Essential insights into bone healing were gained during this phase of reconstructive surgery. The discovery of the biocompatibility of titanium surfaces by the Swedish scientist Brånemark in 1967 can be seen as another milestone. The demonstrated biological fusion of titanium foreign bodies with bone material (osseointegration) paved the way for modern dental implantology<sup>3</sup>.

Although various other materials (gold, platinum, porcelain) were also tested, pure titanium became the implant material of choice because of its high biocompatibility, excellent stability, and bone-like elasticity<sup>4</sup>.

Although described as a bioinert material, titanium can cause allergic reactions due to additives, impurities in the material, or the processing of the titanium implants, which can lead to abrasion. For example, further modification of the titanium implant surface can be achieved through oxidation, resulting in a rougher surface that can favour osseointegration on the one hand. On the other hand, this can lead to particle abrasion and subsequent allergic reactions. Cases of inflammation of the gums around the implant due to accumulated bacterial biofilms (plaque) have also been described in the literature. As a result, continuous improvements to the titanium surface or other materials are being sought to increase biocompatibility and improve the healing rate<sup>5,6</sup>.

In recent years, the demand for more aesthetics and faster treatment results in dentistry has increased, as materials such as gold or titanium often make teeth and their surroundings appear “darker”. With titanium implants, the dark colour can show through the gum tissue, which is particularly undesirable for teeth in the frontal jaw area. The sometimes stated intolerance (0.6% have a titanium allergy) has further increased interest in ceramics as a metal-free, alternative material<sup>7</sup>. The number of ceramic implants used has risen steadily since their market launch in the 1970s and today accounts for an estimated market share of 3-5%. The first generation of ceramic implants consisted of aluminium oxide ( $Al_2O_3$ ) and showed good healing in the bone (osseointegration), with further favourable properties being their white colour, good biocompatibility, and low affinity to bacterial biofilms (plaque). However, these implants were withdrawn from the market in the early 1990s because of their inferior mechanical properties compared to titanium. Consequently, much more stable and harder zirconium dioxide ceramics were used as an improvement. Since toxicity studies have also shown no mutagenic or carcinogenic effects, these ceramic implants have proven to be a promising alternative to conventional titanium implants, especially for cases with known predispositions such as allergies.

## Properties and compatibility of currently used ceramic dental implants

### Material properties

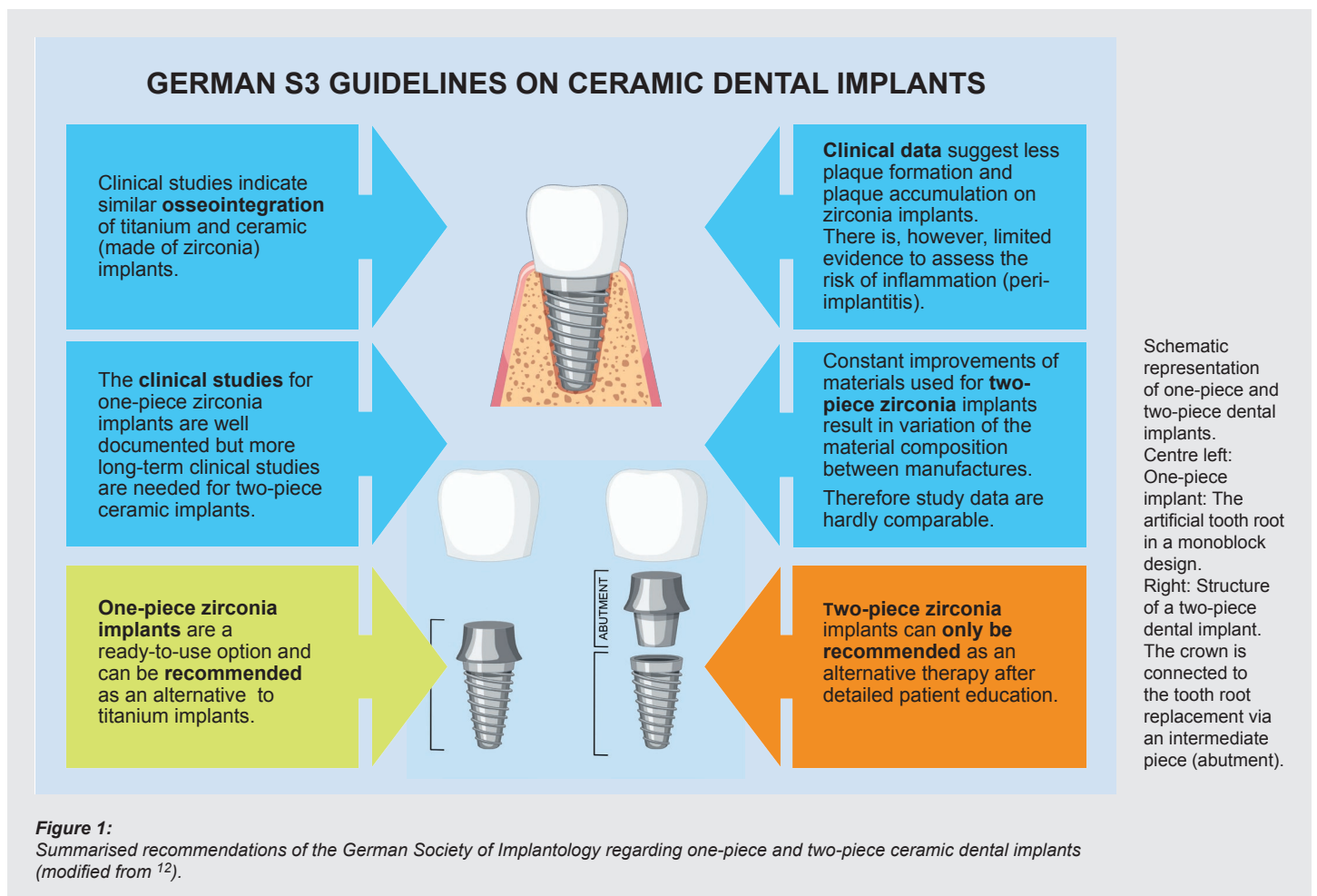
Glass-ceramics (cerium-reinforced bioglass), and aluminium-reinforced glass-ceramics in particular, exhibit excellent physical and mechanical properties, including low heat transfer and high corrosion resistance. Tetragonal zirconium polycrystals, additionally stabilised with yttrium oxide ( $Y_2O_3$ ), are currently the most commonly used ceramic material. These implants have very high strength and durability, thus making them highly resistant to fractures. The high flexural strength can be improved or modified by using an additive, e.g. aluminium oxide ( $Al_2O_3$ )<sup>8</sup>.

### Osseointegration

Osseointegration describes the firm integration of the denture into the jawbone as a result of the bone's self-healing process. Bone-forming cells (osteoblasts) form a solid connection between the jawbone and the implant surface. The requirements for successful osseointegration include precisely fitting implants made of high-quality material with osteoblast-friendly surfaces, sterile and temperature-neutral drilling into the bone, sufficient primary stability, and immobilisation of the implant. Adequate blood circulation and the absence of infections are also essential. If these parameters are met, an unencumbered healing phase can be achieved within 3-6 months. Consequently, osseointegration is the decisive factor for healing and thus successful and long-term implant restoration.

### Inflammations

Infections (peri-implantitis) caused by bacterial plaque can occur in the gums and periodontium around the implant, often caused by, amongst other things, poor oral hygiene. At an advanced stage of this inflammation, degradation of bone mass and gum tissue can occur, resulting in the loosening and potential loss of the implant. Ceramic implants appear to be less susceptible to the adhesion of bacterial biofilms (plaque), whilst inflammations are reported more frequently with titanium implants<sup>7</sup>. Zhou *et al.*<sup>9</sup> also describe a slow release of titanium particles from the implant into the surrounding tissue and bone, which can lead to an increased local titanium concentration or even accumulation in distant tissues by transport via the bloodstream. This, combined with the hypoallergenicity of the ceramic materials, suggests better biocompatibility for ceramic dentures.



## Structure of the ceramic implants

Originally, ceramic dental implants were manufactured and inserted as one-piece designs (monoblock design). These one-piece implants consist of a section inserted into the jaw, acting as a type of artificial dental root, and a section to which a prosthetic restoration, such as a crown, is attached. However, one-piece ceramic implants can encounter problems during the healing phase, especially when they protrude through the mucosa (transgingivally or through the gums), which can negatively affect osseointegration and thus delay the healing process<sup>10</sup>. In recent years, however, there has been a trend towards using two-piece ceramic dental implants (hybrid concept). With this design, the implant and the denture are connected via an abutment, a flexible screw-in part that protrudes through the gums. The abutment serves as an attachment and fastening element, acting as a supporting pillar for the stability of the denture<sup>11</sup>. Depending on the application and requirements, a ceramic abutment is also customised to the patient's individual needs with high precision in the dental laboratory, along with the dental crown. This customisation allows for better results, particularly in aesthetically important areas. A potential disadvantage of two-piece implants is the need for a second operation. Other possible issues with two-part implants include (1) potential bacterial colonisation between the implant and the abutment, (2) breakage or loosening of the abutment screw connection, and (3) higher material costs and the resulting higher expenses.

Although there are already numerous case studies with long observation periods showing comparable results between one-piece ceramic dental implants and titanium implants, data for two-piece implant restorations are still lacking. As a result, the German Society of Implantology (DGI) currently only recommends one-piece ceramic implants<sup>12</sup>.

## Clinical studies

Many studies in recent years have shown success rates of new-generation zirconium dioxide implants that are comparable to those of standard titanium implants<sup>13</sup>. However, it is still pointed out that there are no long-term studies to rule out possible long-term effects. Whilst advantages in osseointegration and soft tissue acceptance of one-piece ceramic dental implants compared to titanium implants have been described<sup>7</sup>, there are also critical voices, especially in the USA, that continue to view titanium as the first choice,

despite the recognised advantages of ceramic implants<sup>14</sup>. This preference is because of positive experiences with titanium implants, which have been in use for decades. In addition to the lack of long-term studies, ceramic implants are more expensive, and there is a lack of training in the implantation and restoration of the new material.

Whilst the recently published long-term studies on one-piece ceramic dental implants are increasingly able to refute these counterarguments, similar studies for newly marketed two-piece ceramic implants have yet to be conducted. Short-term clinical studies currently show no difference between the two ceramic implant designs, with both strategies showing good results<sup>11</sup>. Good contact between the bone and implant as well as the rotational force required to remove an implant again are additional key parameters for evaluating the applicability of new implant materials. Animal experiments have found no significant differences between ceramic and titanium implants<sup>13</sup>.

The DGI now considers one-piece ceramic implants an equivalent alternative to titanium implants and evaluates the constant improvement of materials for two-piece implants as positive. However, long-term studies for two-piece ceramic implants are still lacking, as these materials are constantly being developed and improved. Consequently, ceramic alternatives are only considered after a detailed patient consultation, during which all the advantages and disadvantages should first be explained and weighed up<sup>12</sup>.

## Possible risks of material abrasion

Animal studies show that titanium implants cause abrasion in the microparticle and nanoparticle range, which can lead to inflammatory processes and reduced healing success<sup>9</sup>. Particulate abrasion is also possible with ceramic materials, as described in chewing simulation studies. However, more detailed investigations are still needed to estimate the quantity of abraded material and to characterise and evaluate the released particles. For a risk assessment of innovative composite materials, it is necessary to investigate release mechanisms (such as drilling, grinding, teeth grinding, etc.) and possible toxic effects of the abraded particles. Furthermore, making such studies available to the public would also be important.

## Conclusion

Titanium dentures have established themselves as the "gold standard" in dental implantology because of decades of experience, long-term functionality, and compatibility. However, allergies and inflammation, which exert a continuous stimulus on the immune system, have been repeatedly described in the literature. The greyish, dark implant material shining through the gum tissue, especially in aesthetically important tooth areas, has also been viewed negatively. This has led to an increased demand for compatible implants made of innovative ceramics. As a result of the continuous development of ceramic implants, zirconium dioxide-based implants have become the centre of interest. The material properties of ceramics, such as fracture resistance, are now similar to those of titanium. There is no observable difference in load-bearing capacity, stability, and flexural strength between ceramic and titanium implants. Ceramic implants exhibit good osseointegration and less adhesion of bacterial biofilms (plaque), resulting in reduced frequency of inflammation and less plaque formation. To date, no adverse effects such as inflammation triggered by unintentional abrasion or substance release from the composite materials have been observed with ceramic implants. In fact, the good biological integration of ceramic implants promotes better blood circulation in the gum tissue. However, one of the most important arguments in favour of ceramic dentures remains the pure white colour of the artificial tooth root, which ensures that the implant cannot be distinguished from a natural tooth, even if the gums recede. Whilst one-piece zirconium dioxide ceramic implants are now recognised as an equivalent material and considered an alternative to titanium, there are no studies evaluating the long-term success of two-piece ceramic implants. As these reversible screw-retained implant systems significantly extend the range of prosthetic applications, their recommended use is only a matter of time.

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## MASTHEAD

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