



REVIEW ARTICLE

**S3 GUIDELINES ON CERAMIC DENTAL IMPLANTS AND TITANIUM HYPERSENSITIVITY:
STATEMENTS AND RECOMMENDATIONS FOR THE WORLDWIDE IMPLANT DENTISTRY
COMMUNITY**

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Abstract

The correct choice of implant biomaterial is a key factor in the long-term success of implants. Every clinician should have a thorough knowledge of the various biomaterials used for dental implants. Today, ceramic dental implants conquer slowly their place in the dental implantology market. The products remain often controversial for many practitioners and even some scientists. At one hand, there are the early adapters and convinced users, at the other hand there are uninformed and sometimes stubborn clinicians who only accept titanium as the material for the manufacture of dental implants. Recently, the German Society for Implantology (DGI – Deutsche Gesellschaft für Implantologie) and the German Society for Dental and Oral Medicine (DGZMK – Deutsche Gesellschaft für Zahn-, Mund- und Kieferheilkunde) came with 2 scientifically substantiated guidelines: the first one on the use of dental ceramic implants; the second one on titanium hypersensitivity in implant dentistry. Both guidelines are so-called “S3” guidelines. This means that they are completely evidence- and consensus-based.

This article attempts to summarize the various dental biomaterials and it will expand the knowledge and benefits of ceramic implants. S3 guidelines are not only applicable on German implant dentistry and should therefore be spread worldwide to stop the outdated discussion on the role of ceramic implants in dental reconstruction.

Keyword: *S3 Guidelines on ceramic dental implants and titanium hypersensitivity*

Introduction

In the last decade, implants have dominated other prosthodontics treatments and have entered the mainstream of dental practice. Currently, dental implants are widely used to restore missing teeth, and long-term clinical studies have proven their clinical

reliability. The physical and chemical properties of the implant preparation materials play an important role in influencing the clinical outcome of the treatment.

The most important factor in the success of this treatment are the biomaterials that are used to

produce implants since they encounter the biological system.

Materials for implants must meet the following requirements:

- biocompatibility
- corrosion resistance
- fracture resistant

Today, various biomaterials are created, and their surfaces are modified to get better results.¹

Before selecting an implant, clinicians must have detailed knowledge of the latest implant materials, aspects of their design, and properties for a successful treatment outcome. Currently used implants are mainly made of titanium or zirconium and the design of the implant must match its physical properties.²

Titanium and Titanium alloys (Ti₆Al₄V)

Titanium is regarded as the "gold standard" for dental implant manufacturing. It can be commercially pure or alloyed. The most common titanium alloy contains 6% aluminum and 4% vanadium. The material is heat treated to improve its strength, resulting in a low-density material that is resistant to corrosion and fatigue.³

The materials used to make dental implants can be categorized according to their chemical composition or the biological reactions they elicit during implantation. From a chemical point of view, dental implants can be made from metals, ceramics, or polymers.

Some patients prefer not to have any form of metal in their bodies, moreover there is little evidence to show an allergy to titanium. But it is possible that titanium may cause hypersensitivity in some patients which may play a role in implant failure.

Allergy to titanium is rare, but it is a real possibility. Allergic reactions to titanium are associated with the presence of ions formed because of implant corrosion, which can get inside or get on the mucous membrane. The most common type of corrosion is galvanic, in which the destruction or displacement of the surface layer of titanium oxide occurs.⁴ These ions can form complexes with native proteins and act as allergens, causing hypersensitivity reactions.

Patients who have already been diagnosed with allergies to other metals will be more likely to be allergic to titanium. Titanium implants may have soft

tissue recession in some situations; in such situations, an unaesthetic display of titanium gray occurs. Bioactivation by chemical or biophysical methods increases the surface energy of the fixture and then the wettability by removing the oxidized outer layers. At present, the implant market is still clearly titanium predominates (more than 95%).

Zirconium

Zirconium is used since a shorter period, so its longevity has not yet been proven, and less is known about how it osseointegrates. Zirconium is a material that can integrate with bone in the same way as titanium, and its use eliminates patients concerns towards allergies or sensitivity. Potential benefits of choosing zirconia include zero risk of corrosion and its use eliminates the possibility of metal shining through the gums or being exposed due to gum or bone recession. Zirconium is also not thermally conductive.

For patients who have sensitivity or allergies to metals, zirconium can be a good option when used in the right clinical situation. Zirconium implant has a high biocompatibility and ability to withstand forces, and the color is close to the color of the tooth, which improves the aesthetic appearance of dental implants.⁵

One of the advantages of zirconia implants is that its white color has advantages over metal implants in narrow ridges, avoiding the "black line" for titanium dental implants in patients with gingival and bone recession.⁶ Unlike titanium, zirconia is a bioceramic. It has a higher survival rate and marginal bone loss than titanium dental implants 10 or more years after implantation.⁷ Another advantage of using zirconia is its high corrosion resistance, low infection and plaque formation.

The metal analysis showed a statistically significant advantage of zirconia implants over titanium in terms of favorable response to alveolar bone. Zirconia surfaces provide better adhesion to epithelial cells than titanium surfaces.^{8, 9} Thus, due to its ideal physical, aesthetic and biological properties, zirconia can serve as a reliable and safe material for dental implants.

Titanium-zirconium alloys with a zirconium content of 13-17% (TiZr1317) have better mechanical properties. Straumann has developed

Roxolid to meet the requirements of implant dentists and is 50% stronger than pure titanium.

Thin implants and implant components that can be subjected to high loads can be fabricated using TiZr1317 due to its better mechanical properties, provided the material exhibits the same good biocompatibility as pure titanium.¹⁰

Ceramics

With the development of biomaterials science and industrial technology, there has been renewed interest in ceramics for dental applications. Over the last 15 years, various forms of ceramic coatings have been used on dental implants. Ceramic is defined as an inorganic, non-metallic material, consisting of metal oxides, i.e., compounds of metal and oxygen.

Material	Chemical Composition
Hydroxylapatite (HA)	$\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$
Tricalcium phosphate (TCP)	$\alpha, \beta, \text{Ca}_3(\text{PO}_4)_2$
Fluorapatite (FA)	$\text{Ca}_{10}(\text{PO}_4)_6\text{F}_2$
Tetracalcium phosphate	$\text{Ca}_4\text{P}_2\text{O}_9$
Calcium pyrophosphate	$\text{Ca}_4\text{P}_2\text{O}_7$
Brushite	$\text{CaHPO}_4, \text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$
Bioglasses	$\text{SiO}_2\text{-CaO-Na}_2\text{O-P}_2\text{O}_5\text{-MgO, etc.}$
Aluminium oxide	Al_2O_3
Zirconium oxide	ZrO_2

Ceramics have been used for surgical implants due to their inert behavior and good strength and physical properties such as minimal thermal and electrical conductivity.¹¹ Some properties of ceramics, such as low ductility and brittleness, limit the use of ceramics. Ceramic dental implants represent an innovative and modern treatment option in dentistry. Looking at the actual situation in implant dentistry, 2 materials can be distinguished to produce dental implants: titanium and ceramics.^{12, 13} On titanium dental implants there are thousands of scientific peer reviewed articles; ranging from case studies to systematic reviews.^{14, 15}

The history on the use of ceramic implant materials has a complete other evolution. Sami Sandhaus was the first to use alumina as a biomaterial for screw-shaped dental implants.¹⁶ This ceramic however was

to brittle as dental implant material, causing multiple intra-bony fractures.¹⁷ These fractures are responsible for the bad name ceramic implants had for years. Almost 10 to 15 years ago, zirconia-dioxide was introduced as implant material. This material seems to have the optimal characteristics to be a successful implant material.¹⁸

Due to constant innovations, ceramic implants are experiencing a revival during the last decade. These developments offer them material properties, soft-tissue adaptations and osseointegration, comparable to those of the metal titanium. The aesthetic white color is an extra asset in thin biotype patients. Not only we see a growing demand for metal-free restorations from biologically conscious patients, also more and more practitioners start to see the advantage of full ceramic oral rehabilitations.^{19, 20}

Moreover, patients with proven (or even unproven) titanium hypersensitivity, insist more and more to be treated with complete metal-free prosthetic restorations.²¹

Due to the growing application of zirconia implants, guidelines on their use on the highest available evidence level are necessary. The German society of Implantology (DGI) developed guidelines that are of course applicable for all ceramic dental implant users worldwide.

S3 guidelines are guidelines with the highest level of systematic development. These are evidence-and consensus-based guidelines relied to systematic reviews and synopsis of evidence (Fig. 1).

S3	Evidence-and consensus-based	Representative committee, systematic review and synthesis of the evidence, structured consensus process
S2e	Evidence based	Systematic review and synthesis of the evidence
S2k	Consensus-based	Representative committee structured consensus process
S1	Recommendations by experts	Consensus reached through informal procedures

Fig. 1: S-classification guidance manual and rules

The biggest limitation concerning the safe use of ceramic dental implants is the relative lack of long-term scientific data. Whereas for 1-piece implant systems long-term data are present, for 2-piece ceramic implants the are missing (Fig. 2).²²



Fig. 2: 1-piece and 2-piece zirconia dental implants

Ceramic dental implants

The systemic literature search involved relevant clinical literature from 2008 to 2021, and the research question was designed to the PICO scheme: how to evaluate the use of ceramic implants, considering the implant survival and the success for the replacement of missing teeth at the present time.²³ Only 8 prospective clinical studies, 2 reviews and 1 meta-review could be selected for this analysis. Afterwards, a consensus conference with German medical and dental societies voted on these guidelines.

1. Material

Since 2001, zirconia dioxide (i.e., zirconia) is the ceramic material of choice to produce non-metallic dental implants. This material shows almost no aging (when environmental stresses transform the metastable tetragonal zirconia to monoclinic zirconia) anymore.²⁴ Furthermore, its bending capacity and fracture toughness are excellent for clinical application.

However, due to the continuous material improvements, products are difficult to compare so that long-term data are almost unavailable.²⁵ Moreover, every manufacturer produces implants with different material compositions, which make it even more difficult to compare study results. Another important factor is the surgical and prosthetically experience of the practitioner.²⁶

2. Plaque

Studies have shown less plaque accumulation around zirconia structures. This is caused by the lower surface roughness and surface free energy of zirconia in comparison to titanium.^{27, 26} This also seems to result in a lower incidence of peri-implant infections (mucositis-implantitis).²⁹ Soft-tissues have in general a healthier appearance around ceramic implant.

3. Osseointegration

The osseointegration of the actual generation of zirconia implants doesn't show any difference with regards to titanium implants. Especially the microroughened surfaces increase bone stability and reduce osseointegration time.^{30, 31}

4. Recommendations

Here an essential difference should be made between 1-piece and 2-piece implants. The 1-piece implants heal trans-gingival, are immediately "loaded" and demand a precise pre-operative planning. Here, high clinical success rates are demonstrated.³²

Placement of 2-piece implants, however, can be combined with bone augmentation and especially "unloaded" osseointegration. They also offer much more prosthetic rehabilitation options. However, long-term scientific data are still missing to support their overall usage.³³

5. Statements³⁴

I - Contemporary ceramic dental implants are made of zirconium-dioxide (zirconia) with a documented follow-up of up to 7-10 years.

II - Manufacturers produce implants with different compositions, making comparisons between products and over time almost impossible.

III - Osseointegration of ceramic implants reaches the same level as titanium implants. 2-piece ceramic implants seem a valid treatment option but have no long-term scientific data.

IV - Zirconia implants accumulate less plaque and seem to show less peri-implant diseases.

2-piece ceramic implants can only be recommended as an alternative therapy after detailed patient instruction. 1-piece zirconia implants are an excellent treatment option.

Titanium hypersensitivity

There are different diagnostic tests to determine titanium hypersensitivity.³⁵ The aim is to determine if patients would profit from dermatological or laboratory tests if they are suspected to intolerance or hypersensitivity towards titanium. The latter seems to play a role in the growing manifestation of peri-implantitis.³⁶

A systematic literature search was performed on this topic, including randomized controlled trials, cohort studies and cases series. The implemented PICO design studied the effect of the insertion of titanium

implants (I), on patients with and without metal allergy (P), compared to patients without dental implants or with ceramic implants (C) in terms of the development of a hypersensitivity reaction (O).

Recommendations³⁷

I - Predictive epicutaneous test (ECT) for titanium hypersensitivity

An epicutaneous test is used in case of suspicion of allergy to substances that encounter the skin. Test material is placed in small chambers directly on the skin and is left untouched for 48 hours. The test is read after 72 hours, and the area is not washed until the test has been read.

This test should not be used for titanium hypersensitivity because contact sensitization shows a different pathophysiology compared to allergy.³⁸

II - Predictive ECT for titanium hypersensitivity in patients with anamnestic allergic symptoms

For the same reasons, this test should not be used in patients with a history of appropriate former diseases.³⁹

III - ECT in patients with clinical symptoms and suspected titanium hypersensitivity

This test should also not be performed in patients with suspected clinical intolerance.⁴⁰

IV - Predictive lymphocyte transformation test (LLT) for titanium

The lymphocyte transformation test (LTT) measures the proliferation of T cells to a drug in vitro - from which one concludes to a previous in vivo reaction due to a sensitization. This test should not be used for this purpose since titanium intolerance is not considered as classical allergic reaction.⁴¹

V - Predictive LLT for titanium in patients with anamnestic allergic symptoms

Also, for this indication, this specific test is not applicable.⁴²

VI - LTT in patients with clinical symptoms and suspected titanium hypersensitivity

LTT should not be used in patients with suspected clinical intolerance to titanium.⁴³

VII – Suprastructures

Not only implants can cause allergic reactions, also the suprastructures can. The composition of different alloys, impurities and adhesives can be at the origin of the allergic reaction. ECT and LLT can be used to test allergic contact dermatitis of the oral mucosa to these components. These tests can be done in vitro.⁴⁴

VIII - Treatment alternatives

For patients, suspected with titanium intolerance, zirconia implants are the most evident alternative.⁴⁵ The first set of guidelines described the optimal use of these ceramic implants in implant dentistry. The incidence of titanium allergy has a prevalence of 0.6%.⁴⁶ Allergy to titanium in the medical literature is described in the form of urticaria, itching of the skin or mucous membranes, atopic dermatitis.⁴⁷ Although this is a rather low occurrence, the general allergy for metals is increasing to 10-15% worldwide.⁴⁸

Since titanium implants are sometimes made of grade 5 titanium, aluminium and vanadium are included. Allergic reactions to vanadium and aluminium are common. To avoid this problem, the use of zirconium-dioxide implants can be considered.⁴⁹ Allergy to zirconia has not been documented yet.

Conclusion

Although these guidelines were issued by the German Society for Implantology, they are applicable for all patients and practitioners worldwide who are faced with these specific problems. S3 guidelines are not only applicable on German implant dentistry and should therefore be spread worldwide to stop the outdated discussion on the role of ceramic implants in dental reconstruction.

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S3 ՈՒՂԵՑՈՒՅՑ ԿԵՐԱՄԻԿԱԿԱՆ ԻՄՊԼԱՆՏՆԵՐԻ ԵՎ ՏԻՏԱՆԻ ԳԵՐԶԳԱՅՈՒՆՈՒԹՅԱՆ ՎԵՐԱԲԵՐՅԱԼ ՀԱՅՏԱՐԱՐՈՒԹՅՈՒՆՆԵՐ ԵՎ ԱՌԱՋԱՐԿՈՒԹՅՈՒՆՆԵՐ ԻՄՊԼԱՆՏՆԵՐԻ ՀԱՄԱՇԽԱՐՀԱՅԻՆ ՀԱՄԱՅՆՔԻ ՀԱՄԱՐ

Քուրդ. Ս.Լ. Բոլեն ¹, Գազիկ Հակոբյան ²

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- ² Պրոֆեսոր, Երևանի Ս. Հերացու անվ պետական բժշկական համալսարանի բերանի խոռոչի և դիմաձնոտային վիրաբուժության ամբիոնի վարիչ, Հայաստան

Ամփոփում

Իմպլանտի կենսանյութի ճիշտ ընտրությունը իմպլանտների երկարաժամկետ հաջողության հիմնական գործոնն է: Յուրաքանչյուր բժիշկ պետք է ծանոթ լինի ստոմատոլոգիական իմպլանտների համար օգտագործվող տարբեր կենսանյութերին: Այսօր ստոմատոլոգիական կերամիկական իմպլանտներն աստիճանաբար իրենց տեղն են գրավում ստոմատոլոգիական իմպլանտոլոգիայի շուկայում: Արտադրանքը հաճախ հակասական է մնում շատ բժիշկների և նույնիսկ որոշ գիտնականների համար: Մի կողմից կան վաղ աղապատերներ և հավատարիմ օգտագործողներ, մյուս կողմից՝ անգրագետ և երբեմն համառ բժիշկներ, ովքեր ընդունում են միայն տիտանը՝ որպես ստոմատոլոգիական իմպլանտներ պատրաստելու նյութ: Վերջերս Ստոմատոլոգիական Իմպլանտոլոգիայի Գերմանական Միությունը (DGI-Deutsche Gesellschaft für Implantologie) և Ստոմատոլոգիական և Բերանի Խոռոչի Բժշկության

Գերմանական Միությունը (DGZMK - Deutsche Gesellschaft für Zahn-, Mund- und Kieferheilkunde) մշակել են ստոմատոլոգիական կերամիկական իմպլանտների օգտագործման առաջին ապացույցների վրա հիմնված ուղեցույցներ: Երկրորդը ուղեցույցը վերաբերում են իմպլանտոլոգիայում տիտանի նկատմամբ գերզգայունությանը: Երկու ուղեցույցները վերաբերում են այսպես կոչված «S3» առաջարկություններին: Սա նշանակում է, որ դրանք ամբողջությամբ հիմնված են ապացույցների և կոնսենսուսի վրա:

Այս հոդվածը փորձում է ամփոփել ստոմատոլոգիական տարբեր կենսանյութերը և կրնդային կերամիկական իմպլանտների գիտելիքներն ու առավելությունները: S3-ի առաջարկությունները կիրառելի են ոչ միայն Գերմանական Ստոմատոլոգիական Իմպլանտոլոգիայի համար և հետևաբար, պետք է տարածվեն ամբողջ աշխարհում՝ դադարեցնելու ստոմատոլոգիական իմպլանտոլոգիայում կերամիկական իմպլանտների դերի մասին հնացած քննարկումը:

РУКОВОДСТВО S3 ПО КЕРАМИЧЕСКИМ ЗУБНЫМ ИМПЛАНТАТАМ И ГИПЕРЧУВСТВИТЕЛЬНОСТИ К ТИТАНУ: ЗАЯВЛЕНИЯ И РЕКОМЕНДАЦИИ ДЛЯ МИРОВОГО СООБЩЕСТВА ИМПЛАНТОЛОГОВ

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Абстракт

Правильный выбор биоматериала имплантата является ключевым фактором долгосрочного успеха имплантатов. Каждый клиницист должен хорошо знать различные биоматериалы, используемые для зубных имплантатов. Сегодня керамические зубные имплантаты постепенно завоевывают свое место на рынке дентальной имплантологии. Продукты часто остаются спорными для многих практиков и даже некоторых ученых. С одной стороны, есть ранние адаптеры и убежденные пользователи, с другой стороны, есть неосведомленные, а иногда и упрямые клиницисты, которые принимают только титан в качестве материала для изготовления зубных имплантатов.

Недавно Немецкое общество имплантологии (DGI-Deutsche Gesellschaft für Implantologie) и Немецкое общество стоматологической и оральной медицины (DGZMK-Deutsche Gesellschaft für Zahn-, Mund- und Kieferheilkunde) разработали 2 научно обоснованных руководства: первое-по использованию зубных керамических имплантатов; второй по гиперчувствительности к титану в имплантологии. Оба руководства относятся к так называемым рекомендациям «S3». Это означает, что они полностью основаны на фактических данных и консенсусе.

В этой статье делается попытка обобщить различные стоматологические биоматериалы, и она расширит знания и преимущества керамических имплантатов. Рекомендации S3 применимы не только к немецкой имплантационной стоматологии, и поэтому их следует распространить по всему миру, чтобы остановить устаревшее обсуждение роли керамических имплантатов в стоматологической практике.