Advanced Ceramics for Healthcare – Materials, Properties, Applications

Technical ceramics play a significant role in the field of medical technology – they are often key components in complex assemblies in this field of application. The unique properties of ceramics very often make these specific applications possible. Since the properties of ceramics differ significantly from those of metals, plastics and other materials, they are indispensable in many cases. In addition to the relatively well-known use in joint implants and dental applications, this paper will also present less well-known applications in the field of medical technology, for which the company Rauschert Heinersdorf-Pressig GmbH/DE has developed many years of expertise.

Fig. 1
Medical instruments with ceramic components

1 Areas of application – an attempt to classify them

Medical technology represents a wide field of application areas, in almost all of which ceramic materials can be used to a greater or lesser extent (Fig. 1). In this context, the term "medical device" according to the German Medical Devices Implementation Act (German: Medizinprodukte-Durchführungsgesetz, MPDG) is certainly a brief definition that clearly clarifies what the application is. The Medical Devices Implementation Act (MPDG, [1]) based on EU Regulation 2017/745 [2] has been gradually replacing the previous German Medical Devices Act (German: Medizinproduktegesetz, MPG) since May 2021.

This regulation describes what is considered to be a "medical device": "Medical device" means, in summary, an instrument, apparatus or article intended for use in humans for a medical purpose. This includes:

- Diagnosis, prevention, monitoring, prediction, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation of, or compensation for injury or disability;
- Examination, replacement or modification of anatomy or of a physiological or pathological process or condition;
- Obtaining information by the in vitro examination of samples taken from the human body (including organ, blood and tissue donations);
- Products for the regulation of conception,
- Products used for the cleaning, disinfection or sterilisation of medical devices.

Pharmaceutical products should be distinguished from this and do not fall under

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this regulation or legislation. These do not work by physical or physicochemical means like medical devices [2].

One possible way of recording applications in medical technology that goes further than the MPDG/MPG is to look at the index of goods for production statistics in Germany. Here, rarer applications in the field of medical technology are also recorded and are broken down in more detail. In 2005, a study on the situation of medical technology in Germany used this framework; a survey was carried out of possible goods that are distributed in various goods classes of the statistics [3]. The following classes of goods are identified (known applications in these areas are added in italics in brackets – no claim to completeness):

- **X-ray and radiotherapy equipment:** computer tomographs (*bearings, pump components, valves, high-voltage insulators, tubes for generating X-rays*), other X-ray equipment (*see above*), X-ray tubes (*tube housings, high-voltage insulators*), alpha, beta, gamma ray equipment for diagnosis and therapy (*see above*);
- **Other electrodiagnostic equipment and systems:** magnetic resonance equipment, scintigraphy equipment, ultrasound diagnostic equipment (*piezoceramics for ultrasound generation*), electrocardiographs, endoscopes (*lens holders*);
- **Therapy system:** ultraviolet and infrared therapy equipment (*long-term and temperature-resistant insulators on the UV/IR lamps, suitable lamp holders*), ultrasound therapy equipment (*piezoceramics for ultrasound generation*), dialysis equipment (*insulators for flow meters, sensors for air bubble detection*), mechanotherapy equipment (*bearings*), therapeutic gas equipment (*pressure sensors, porous ceramics for gas sensors*), respiratory equipment (*same as therapeutic gas equipment*), anaesthesia equipment *(same as therapeutic gas equipment),* transfusion and infusion equipment (*same as therapeutic gas e quipment*);
- **Surgical devices and systems:** scissors, forceps and other surgical instruments (*insulating pieces, ceramic axes and ceramic coating spacers/insulating layers*), surgical catgut and suture material, sterile adhesives, laminaria pins, needles, syringes, catheters and cannulae;
- **Implants and prostheses:** artificial joints (*hip, knee, finger joint implants, intervertebral disc implants*) eye prostheses, other artificial body parts and organs, vascular supports (*stents*), pacemakers (*insulating, hermetically sealed feedthroughs*), hearing aid implants;
- **Orthopaedic aids, appliances, devices and vehicles for physically handicapped persons:** splints, bandages, orthoses, walking aids, wheel (driving) chairs;
- **Audiological devices and systems:** hearing aids, hearing glasses and accessories for hearing aids (not hearing implants);
- **Ophthalmological devices and systems:** ophthalmological diagnostic and measuring devices, ophthalmological laser devices, opticians' workshop devices, visual aids (contact lenses, glasses);
- **Dental materials, devices and systems:** dental cement (*bone substitutes*), dental fillers, dental wax, dental impression compounds, dental prostheses (*dental implants, root posts, abutments*), modelling equipment, drills (*ceramic drills*), polishing equipment, suction devices, forceps, mouth mirrors and other dental instruments (not dental chairs) (*ultrasonic generators for tooth cleaning/tooth scaling*);
- **Diagnostics and reagents:** In-vivo and in-vitro diagnostics, contrast media for diagnostic procedures (no diagnostic equipment unless associated with the reagent);
- **Dressing materials:** plasters, dressing material made of gauze, cellulose, cotton wool, non-woven fabric, whether or not covered with medicinal substances, first-aid kits;
- **Textiles and products made of rubber for medical use:** Wadding and spun bonded textile materials for medical purposes, surgical gloves, condoms and other products of soft rubber for medical purposes;
- **Special equipment for clinics and medical practices:** dental chairs, examination and treatment tables and chairs for X-ray apparatus, operating tables, beds, stretchers for medical and surgical use;
- **Other medical equipment and devices:** e.g. sterilising equipment (*valves, pump components*), blood pressure monitors, heart rate monitors, suction pumps, generators (*electrical insulators*), plaster scissors, suction bells, pulse meters, medical robots, defibrillators, foreign body detectors, percussion hammers, equipped medical cases;
- **Services:** Installation, maintenance and repair of medical equipment and instruments.

It should be emphasised once again that the above classification according to classes of goods is independent of the definition of medical devices according to EU Regulation 2017/745 [2] or the laws based on it, as it serves other purposes. The intention of this selection is to get as complete as possible an overview of the industry, so that no application is left out, as the further version of the definition of medical device under [3] shows. In addition to the direct applications of ceramic materials, other more or less indirect applications can also be identified (selection of examples):

- Cutting ceramics for the manufacture of surgical instruments, components for X-ray and radiotherapy equipment etc. by turning, milling, drilling etc.;
- Dip moulds made of glazed porcelain for the manufacture of surgical gloves;
- Ceramic thread guides made of aluminium oxide, zirconia and mixtures of these two materials for the manufacturing of plasters, gauze dressings, surgical suture material, etc.

There are other, similar indirect applications of ceramics in medical technology, but for the sake of clarity they will not be discussed in this article.

Also less familiar in their use are the numerous ceramic-based components in microelectronics (capacitors, integrated circuits, resistors, etc.). These are installed in more or less large numbers in every electronic control system, without which, as is well known, only a few applications can work nowadays. This technical paper does not go into any further detail about these either.

2 Properties of ceramic materials

Compared to metals and plastics, ceramic materials have some outstanding properties that set them apart from other material groups (Fig. 2) [4].

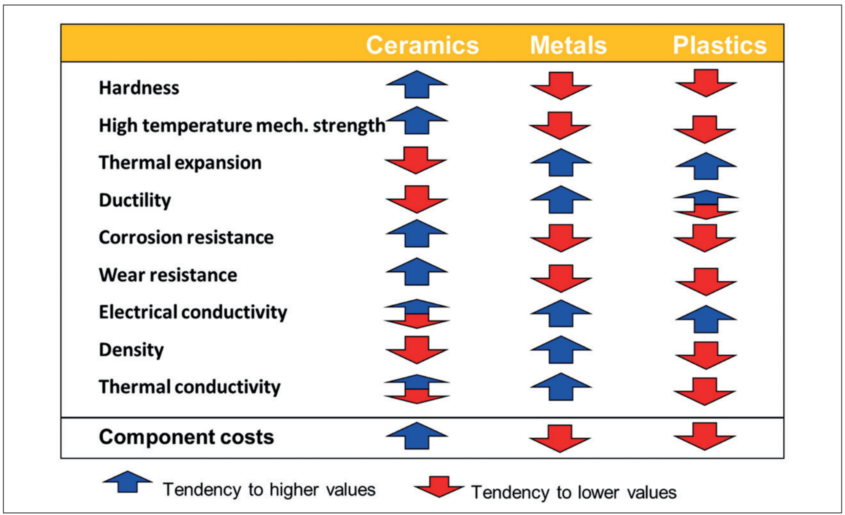

Fig. 2
Comparison of typical properties of ceramics compared to metals and plastics [4]

It is therefore clear which load cases in concrete applications virtually challenge the use of ceramics:

- Whenever stiff and hard components are required, ceramics can be used, ceramics are not ductile, permanent deformations are impossible;
- If temperatures of more than approx. 400 °C occur in the application – even for a short time – ceramics must be used; even temperatures of more than 1000 °C are easily tolerated by most ceramic materials;
- If the components are used in corrosive environments, this is where ceramics come into their own with their excellent corrosion resistance;
- the wear resistance of ceramic materials is outstanding, resulting from a combination of hardness, strength, low ductility, good high-temperature resistance and good corrosion resistance. Many abrasives are therefore based on ceramic materials (corundum → Al_2O_3, carborundum → SiC). Because of these properties, many fired ceramics can only be machined using diamond tools;
- Ceramics can save weight compared to metals - but plastics still have a lower density than ceramics. The use of ceramics can also be a possible approach in applications where the aim is to reduce mass inertia;
- Typically, ceramics are known as electrical insulators, but with some ceramic materials it is also possible to set specific electrical conductivities. New approaches to solutions can certainly be derived from this idea;
- Depending on the requirements, ceramic materials are available with high or low thermal conductivity. By adjusting porosity, the thermal conductivity can be reduced even further than in dense, solid material.

Of course, the economic efficiency of using ceramic components should not be ignored. If the pure component costs are considered, ceramics do not perform particularly well, but if the overall service life is considered, the use of ceramics can certainly be economically justified: Ceramic components often have a significantly longer service life than the same components made of other materials - keywords: corrosion resistance, hardness, wear resistance etc.

If, however, metals or plastics cannot be used at all because their properties do not meet the requirements (e.g.: temperature in the application, strength/stiffness requirements, requirements on corrosion resistance), only ceramic materials can be considered as an alternative solution. If metals or plastics also meet the requirements, they are the most economical solution in almost all cases; ceramics are - when used correctly - the problem solvers for demanding applications.

3 Materials and properties

Depending on the area of application, different materials or material groups are used. Ceramic materials are often divided into groups according to their chemical and mineralogical composition. However, this classification does not cover all ceramic materials commonly used in medical technology.

3.1 Overview

Generally speaking, medical ceramic materials are usually divided into three groups:

- Silicate ceramics [5]: They are the oldest of all ceramics and are originally derived from natural raw materials such as clays/kaolins, feldspars, soapstone and other natural raw materials. What they all have in common is that the mineral phases of the raw materials all contain silicate groups. In addition to classical applications in the field of tableware, sanitary ceramics, tiles/roof tiles, etc., technical ceramics have also emerged from this group, which essentially consist of the ceramic materials porcelain steatite, cordierite and mullite.
- Oxide ceramics [6]: These are materials consisting predominantly of single-phase metal oxides. They are based almost exclusively on synthetic raw materials. The most important representatives of this group are aluminium oxide (alumina) and zirconium oxide (zirconia) as well as their mixtures. Other oxide ceramics are not considered here.
- Non-oxide ceramics [7]: Only synthetic raw materials are used for the production of these materials. This group includes carbides and nitrides, as well as borides, silicides and fluorides. The most important representatives are silicon carbide and silicon nitride; the other members of this material group are not discussed here.

Outside of these three traditional ceramic groups, there is the group of calcium phosphates or, in particular, hydroxyapatites, which are important in medical technology, serve as bone replacement material and are very similar to bone. After implantation in the body, they slowly degrades and is replaced by natural bone material.

Another application of ceramics in medical technology is ceramic coatings. Various processes are used here:

- APS: Atmospheric plasma spraying;
- HVOF: High-Velocity-Oxygen-Fuel spraying;
- CVD: Chemical Vapor Deposition;

• PVD: Physical Vapor Depostion;
• Other methods.

The APS and HVOF processes can be used to apply thicker ceramic layers in the range of 50–250 µm, while PVD and CVD can be used to apply thin layers in the range of a few nanometres to micrometres.
In the following, the individual material groups silicate ceramics, oxide ceramics, non-oxide ceramics and ceramic coatings will be discussed more in detail.

3.1.1 Silicate ceramics

The group of silicate ceramic materials was standardised very early – for the first time in 1940 – for electrotechnical applications in the then DIN 40685. The DIN EN 60672/IEC 672/VDE 0335 based on this is the current standard [8].
From the electrotechnical insulating material group, steatite materials, and more rarely cordierite, mullite and aluminium oxide materials, are used in medical technology, but not in areas that require biocompatibility. Presumably, most of these materials would also be biocompatible, it is just that they have not yet been tested for this requirement due to a lack of demand. Strictly speaking, the aluminium oxide materials of these standards belong to the group of oxide ceramics, but are considered here comparatively with the silicate ceramics, especially since they are listed in the standard for electrical insulation materials. [8].
Typical applications are electrical and/or thermal insulation inside devices and assemblies. Fig. 3 shows the cross bending strengths of various material groups, usually combining several individual materials of a group. The span indicates the minimum strengths of the individual materials according to DIN EN 60672.
For electrical insulation materials, the dielectric strength (Fig. 4) and the thermal conductivity (Fig. 5) are of particular interest. The range of thermal conductivity values in particular is very wide, so it is usually possible to find a suitable material for every application.

3.1.2 Oxide ceramics

The most important representative of oxide ceramics is aluminium oxide. Even if "conventional" aluminium oxides do not show top values in mechanical properties, they play a very important role because they are characterised by an excellent cost/benefit ratio. This is due to the "relatively" low-cost raw materials (the element Al is the third most abundant element in the earth's crust after O and Si); the necessary raw materials for many aluminium oxide materials can be extracted from the aluminium metal ore (bauxite) and a simple sintering processes in air [9]. However, by using highly pure and very fine-grained, synthetically produced raw materials, it is possible to develop high-quality materials that are used, for example, as joint implants.
Compared to silicate ceramics, aluminium oxide stands out due to its high hardness and mechanical strength (Fig. 6), high melting point (2050 °C) and good corrosion resistance; however, the dielectric strength of aluminium oxide is matched by many silicate ceramics [9], and in some cases even surpassed. In addition to the above-mentioned applications as insulators, aluminium oxide materials are also often

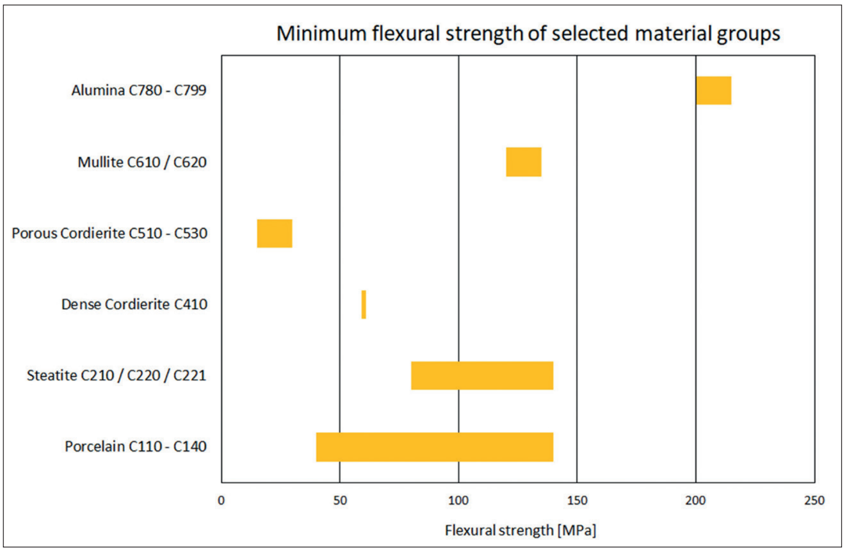

Fig. 3
Minimum flexural strengths according to DIN EN 60672 [8] for selected material groups of ceramic insulation materials

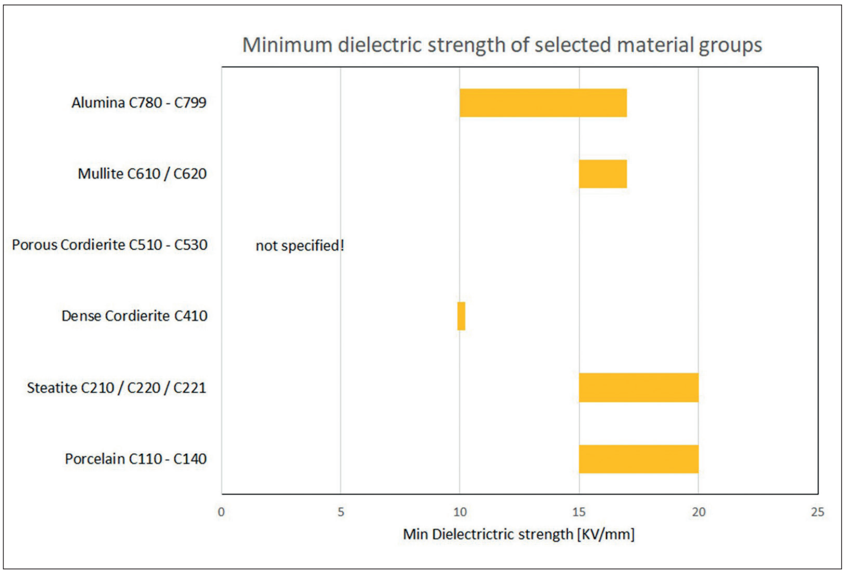

Fig. 4
Minimum dielectric strength according to DIN EN 60672 [8] for selected material groups of ceramic insulation materials

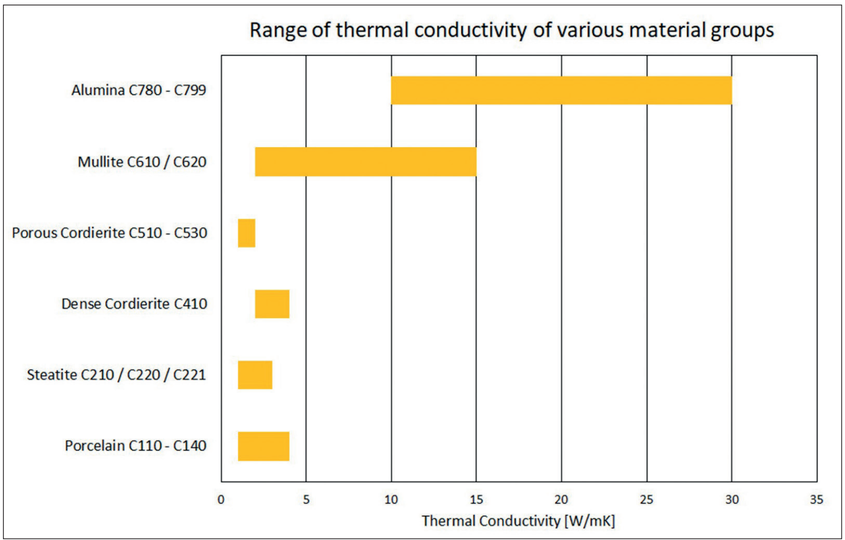

Fig. 5
Range of thermal conductivities according to DIN EN 60672 [8] for selected material groups of ceramic insulation materials

used in metallised versions and soldered to metal components, such as X-ray tubes, vacuum-tight feedthroughs, etc. Alumina products are also used as insulation materials for the production of feedthroughs in pacemakers and implanted defibrillators. Occasionally, they are also used in endoscopic instruments, if very high mechanical loads can be avoided.

Biolox forte® (Ceramtec Ltd) and Bionite® (Mathys Ltd) are examples of materials used for joint replacement.

In addition to alumina, which has a history of more than 100 years in ceramic manufacturing, the first reports about toughening of zirconia materials by phase changes were published in 1965. A publication in 1975 made these materials and their high mechanical strengths known to a wider public [10]. Partially stabilised zirconia materials derive their high strength from a partial stabilisation of the high-temperature phase. Two variants can be distinguished:

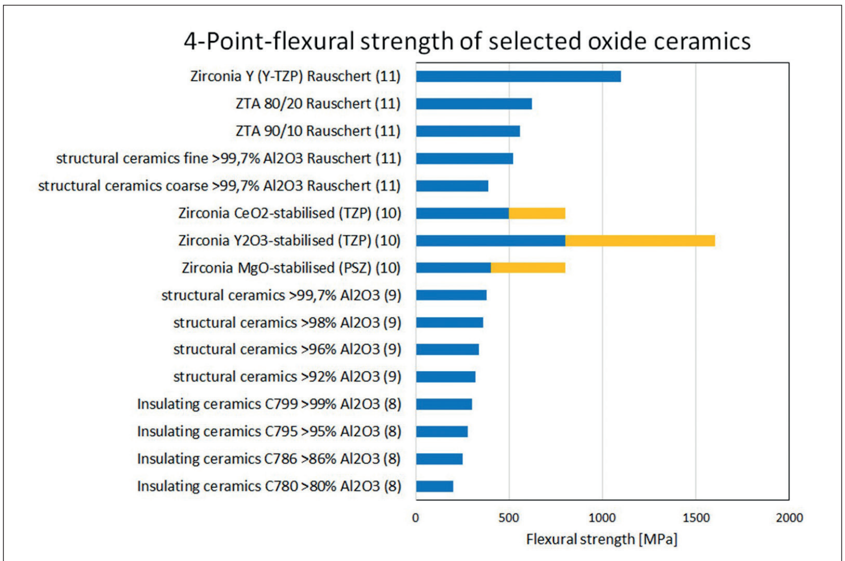

Fig. 6
4-point flexural strength of selected oxide ceramics according to DIN EN 60672 [8] and other sources [9–11].The yellow bars show the variantion in flexural strength mentioned in [10]

- In the Partially Stabilised Zirconia (PSZ) types, CaO or MgO is added and subjected to a special heat treatment that creates tetragonal precipitates within the crystal that is cubically stabilised by CaO or MgO. Importantly, only a portion of the crystals are stabilised by the addition.
- In another approach, by adding Y_2O_3 or more rarely CeO_2, part of the crystals are stabilised in the tetragonal phase up to room temperature. These materials are called TZP (Tetragonal Zirconia Polycrystal). Compared to PSZ types, they achieve even higher strengths, whereby the CeO2-stabilised types stand out in particular due to their high fracture toughness (Fig. 6) [11].

For zirconia materials, please note:

- Fused zirconia raw materials must not be used for medical applications, as they may contain excessive radioactive impurities. Chemically precipitated zirconia raw materials, however, comply with the limits for medical applications;
- In the case of Y-TZP, the tetragonal phase can destabilise under the influence of moisture at temperatures between 65–500 °C, resulting in a loss of strength. This can be counteracted by adding a small amount of Al_2O_3. Most currently available zirconia materials already have this dopant.

To increase the mechanical strength, zirconia materials can also be hot-isostatically pressed (known as the HIP process). Due to their high strength, zirconia materials are used for:

- Implants (less frequently as joint replacements, frequently in the dental field, also in the visual field);
- Components for endoscopic instruments with very high requirements in mechanical strength.

It should be pointed out that zirconia ceramics are significantly more expensive than many aluminium oxide materials due to the high raw material costs caused by the complex chemical preparation. However, high-purity and sinter-active, extremely fine-grained aluminium oxide raw materials achieve comparable raw material prices to high-quality zirconia raw materials.

Based on alumina and zirconia ceramics as described above, mixtures of both materials have been established:

• ZTA: Zirconia Toughened Alumina;
• AZT: Alumina Toughened Zirconia.

ZTA materials can be an alternative to partially stabilised zirconia materials. They close the gap between alumina and zirconia materials in terms of strength (Fig. 6) and are closer to the cheaper alumina products than to the more costly zirconia products in terms of raw material costs. Strength and fracture toughness can be adapted by varying the zirconia additive and the grain size in the sintered state. Detailed explanations can be found in [11].

In the field of medical technology, in addition to joint replacement implants (ZTA type), additionally platelet-reinforced: Biolox forte® (Ceramtec AG), CeraSurf-p® (Coorstek Medical) and ATZ type: Ceramys® (Mathys AG).

Applications in bi- and mono-polar endoscopic instruments for HF surgery are also known more frequently.

3.1.3 Non-oxide ceramics

The most common non-oxide ceramics include silicon nitride materials, silicon carbide materials and, to a lesser extent, aluminium nitride materials. The latter impresses with its very high thermal conductivity (140–180 W/mK), but is not used as a construction material, but often as an electrically insulating heat sink in electronic and electrical applications. Silicon carbide is characterised by its high hardness (most SiC production goes into abrasive applications under the name Carborundum), high temperature resistance and chemical resistance.

Therefore, it is also used as a material in pumps and valves or as a kiln furniture for sintering ceramics. All non-oxide ceramics have in common that they cannot be sintered in an air atmosphere and require inert gas or even gas pressure gas furnaces up to hot isostatic presses. Such complex sintering equipment as well as the raw material costs are reflected in the costs of these components. Silicon nitride materials are usually densely sintered with the addition of 3–5 mass-% additives. Due to its needle-shaped crystallites, which are interlocked with each other in the sintered state, a high strength and fracture toughness are achieved – similar to zirconia materials. In contrast to zirconia materials, however, no razor-sharp edges or even cutting edges are possible due to the much coarser microstructure.

The thermal conductivity of silicon nitride is ten times higher than zirconia and thus comparable to aluminium oxide. However, silicon nitride materials are grey to black, zirconia materials (if not coloured or hipped) are white or yellowish. Applications for silicon nitride materials in medical technology are occasionally implants (so-called “cages” as spinal disc replacements in spinal surgery, especially in the USA) and for components in endoscopic instruments (especially because of the grey colour and the good resistance to sterilisation).

4 Ceramic coatings

Ceramic coatings applied as thicker layers by Atmospheric Plasma Spraying (APS) or High-Velocity-Oxygen-Fuel spraying (HVOF) are based on aluminium oxide or mixtures of aluminium oxide and titanium oxide, depending on the application. Additions of titanium oxide increase the toughness of the coatings and colour them darker to black. Coatings based on zirconia are used for thermal insulation and chromium oxide coatings have the best wear resistance.

Well-known applications in medical technology are:

- Electrically-insulated rolling bearings for special applications;
- Spacers and insulating layers for endoscopic instruments used in HF surgery. Special masking techniques can be used to create point-shaped or flat geometries in a defined layer thickness.

5 Summary

Ceramic materials are used in many ways in medical technology due to their unique properties. Not only the eye-catching and popular implants (for example: dental and joint replacements) are of importance, but ceramic materials are also indispensable in many other applications: For insulation in endoscopic instruments of HF surgery, in X-ray tubes, feedthroughs and insulators as well as many other – often less obvious – areas of application.

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