CERAMIC MATERIALS

History

Since 1970, ceramic materials (at that time Alumina, AI_2O_3) helped to realise some important advances in medical technology. In the Orthopaedic, this material is used as femoral ball heads (hard-soft coupling) and as acetabular liners (hard-hard coupling). Since then, improvements in the manufacturing such as grain size reduction, pore-free ceramic microstructure thanks to HIP compaction treatments, combined with high precision machining allowed to drastically reduce the risk of device fracture. Excellent biocompatibility, high wear resistance and absence of metal ions - consequently no metallosis- are of great advantage fort the patient. Recently, the development of high-tech composite ceramics with even higher mechanical strength, such as ATZ (Alumina Toughened Zirconia) or ZTA (Zirconia



FIGURE 1 : Example of hard-hard pairing in Alumina

Toughened Alumina), allows them to be used also in other articulations such as knee components or as thinner components for hip resurfacing.

These new materials, summarized under the term « Bioceramics », have opened new pathways for implantology in orthopaedics.

Glossary

Ceramics: Inorganic, non-metallic materials.

High-Tech Bioceramics: Ceramic materials with high purity, high strength, excellent biocompatibility and excellent wear resistance.

Production

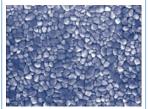
- Composition and properties according to ISO, ASTM and other international or national standards.
- Raw material in form of high purity powder.
- Compaction by pressing (isostatic cold pressing, CIP).
- Sintering at high temperatures.
- Additional heat treatment to eliminate remaining pores by HIP process (hot isostatic post-compaction).
- Machining in the dense, sintered/hipped state, in various process steps...
- Precision grinding, lapping and polishing to obtain closest tolerances in shape, dimensional and surface quality.
- Quality control corresponding to highest international standards.
- Materials registered as Master files and corresponding national and international registrations.

Materials

- Various kind of bioceramics are used in orthopaedics:
- Alumina, Al₂O₃, 99.9% pure, strength 600 MPa. Color ivory. Material with the longest experience in orthopaedics, since 1970.
- Zirconia TZP or TZP-A (with addition of Al_2O_3): 95%ZrO₂, 5% Y_2O_3 , strength 1300 MPa. Color pearly.
- ZTA: Zirconia Toughened Alumina : 80% Alumina, 20% ZrO₂-TZP, additives Cr_2O_3 , Sr_2O_3 , strength 1000 MPa. Colour pink.
- ATZ: Alumina Toughened Zirconia: 80% ZrO₂-TZP, 20% Alumina, strength.



Alumina



Zirconia TZP

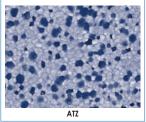


FIGURE 2 : Microstructures

2000 MPa. Colour white.

The average load capacity for femoral ball heads or acetabular liners has to be greater than 46kN, as defined by the standards. No single fracture load below 20kN is allowed.

Technical data:

Ceramic properties, as compared to metals (Titanium, CoCr), are:

- equally strong,
- higher stiffness,
- no deformation possible,
- more inert: chemically and biologically,
- wear rates much lower
 (→ No metal ion release),
- less forgiving to local stress (→ sensitive to

contaminants such as bone splinters, cement particles, blood drops...). Particular attention has to be made during implantation.

Preferred articulation for groups of:

- Ceramic on Ceramic (hard-hard): young, active to very active patients.
- Ceramic on PE, Highcross-PE (hard-soft): medium to high activity, middle aged patients.

Limited application for:

Obese, high weight patients (BMI > 35).

Avoid activities/sports with risk of choc onto the articulation.

Market share

Amongst all Total Hip Prostheses implanted in Europe: 39% with Me (femoral head)-PE (acetabular liner) coupling, 31% Ce-PE, 21% Ce-Ce and 8% Me-Me.

Use of Ceramics in THR (Total Hip)

Depending on region:

- high in central Europe (up to 50% of ball heads and 30% acetabular liners),
- low in USA (about 15%).

Use of Ceramics in TKR (Total Knee)

Very low (to date only as femoral component).

Summary

There are hard-hard (Ceramic-Ceramic) and hard-soft (Ceramic-PE) couplings.

There is a tendency toward hard-hard.

The composite ceramics, like ZTA or ATZ, provide better mechanical resistance than pure Alumina and thus reduce the risk of in-vivo fracture.

Today, the main use of ceramics in Orthopaedics is principally for THA. New applications in the knee arthroplasty or hip resurfacing and even spinal implants are in development.

Partner

Founded in 1978, Metoxit AG is a medium-sized Swiss company specialised in the manufacture and processing of high-performance ceramic products (oxide ceramics) that are usually developed and produced according to customer specifications.

The high range of vertical integration gives customers the assurance of having with Metoxit a competent partner in finding an answer to their requirements.

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