TESTS AND CONTROLS

Controls play an important role in the validation of processes, process change and risk management analysis.

Among others, metallurgical, biomechanical, chemical tests can be conducted.

A selection is shown below as seen critical to the surgeon :

- cleanliness of implant (residuals, contamination...),
- scanning Electron Microscopy (materials, failure analysis...),
- dynamic testing of implant (endurance, dynamic load, fatigue...).

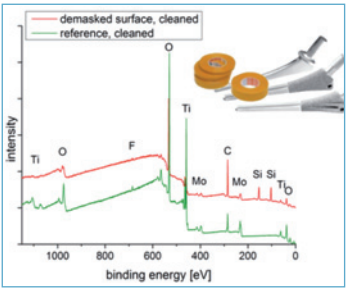
Cleanliness of Implants

The topic "Cleanliness of Implants" involves organic, inorganic, microbiological and particulate residuals on surfaces. These contaminations might be present on implant surfaces after final cleaning and sterilization. A team at the RMS Foundation has been working on this issue for several years.

Typical detection methods are a) gas chromatography or infrared spectroscopy for organic substances, b) x-ray photoelectron spectroscopy (XPS) or inductively coupled plasma (ICP) for inorganic compounds, c) bioburden and endotoxin analysis for microbial residuals and d) gravimetric investigations as well as scanning electron microscopy (SEM) for particulate contaminations (ASTM F2847, Reporting and Assessment of Residues on Single Use Implants). Cytotoxicity and general cell studies are performed to determine the limits of the residuals for validation purposes.

Example

A study contained the detection of residuals of the adhesive on titanium-molybdenum samples by XPS. Adhesive tapes are utilized to mask specific areas of the surface during blasting or electrochemical treatments. After the removal of the adhesive tapes and even after a subsequent cleaning procedure, high silicon and carbon concentrations were detected on the demasked areas. On the reference areas, there were only minor amounts of organic residuals and traces of fluorides (see XPS spectra below).



Scanning Electron Microscopy (SEM)

In the material research and testing, the SEM is a multipurpose and indispensable instrument for the analysis and depiction of surfaces and structures. The field of application of the electron microscope begins where the classic light microscope reaches the limits of the resolution or of the depth of focus. In the RMS Foundation a modern SEM with an EDX analysis unit (Energy Dispersive spectroscopy by X-rays) is available for customer mandates. It is specifically used for surface examinations and is capable to identify the elements from beryllium to uranium contained in the sample surface.

Device

Zeiss EVO MA25 with a secondary and backscattered electron detector, EDX analysis with INCA Energy 350 and x-Max 50 Detector.

Options

- Materials: polymers, metals, ceramics, and minerals.
- Enlargement: 5 to 30,000 x.

- Documentation of Topographies, impurities, and inclusions.
- Analyses of fracture surfaces, Phase identifications.
- Lateral EDX resolution: about 1µm2 depending on the sample composition.
- Quantitative analyses: Detection limits: ≈ 0.2 – 0.5%
- EDX Mapping: pictures of the elemental distribution.
- EDX Line scans: concentration profile along a grid line.

Examples

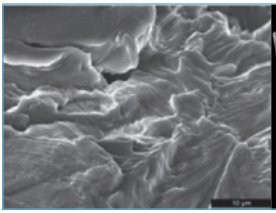


FIGURE 1: Documentation of a fracture surface with fatigue characteristics

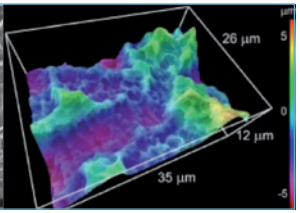


FIGURE 2: Three dimensional reconstruction of the surface topography for the calculation of the roughness parameters

Dynamic testing of hip prosthesis stems

Hip prosthesis stems (in general made of Fe-based, CoCr-based or Ti-based alloys) have to be tested dynamically for their fatigue strength according to ISO 7206. Depending on the location of risk, the performance of the middle stem or the neck portion is investigated by dynamic loading the head of the prosthesis with a compression load between 300 and 2'300 N for up to 5 or 10 million cycles. The way of embedding and fixation of the implant on the testing machine, including the angles of inclination in the frontal and sagittal planes, are exactly defined. Testing can be done in a dry state or in a medium, which limits the applied frequency range (usually between 5 – 15 Hz, maximum 30 Hz). The testing requirements are fulfilled in case that 6 stem samples survive 5 million cycles each without failure. These dynamic tests are normally performed on uniaxial, hydraulic, servo-hydraulic or pneumatic, force or displacement controlled testing devices with storage of all relevant parameters and automatic stop in case of failure of the hip stem.

Normative references

- ISO 7206: Implants for surgery – Partial and total hip joint prostheses - Part 4: Determination of endurance properties and performance of stemmed femoral components. Part 6: Determination of endurance properties of head and neck region of stemmed femoral components.

Examples

FIGURE 3: Uniaxial servohydraulic test system with «Schenk» hydraulic cylinder and «Inova EU3000» digital control

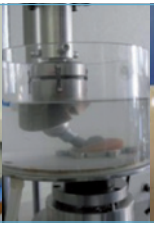


FIGURE 4: ISO 7206 test setup

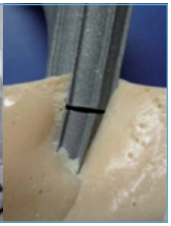


FIGURE 5: Broken specimen

Partner

The RMS Foundation is a research institute and service laboratory. The main focus of the Foundation's activities centres on projects and orders in the fields of biomechanics, biocompatibility of materials and methods, material technology, innovative manufacturing processes, and performance tests of implant systems for the treatment of skeletal lesions.

Its object is to engage in a continual process of development and a constant search for innovative solutions, in order to improve standards in medical devices and surgical techniques.

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