Quality Control and Nanometrology for Micro/Nano Surface Modification of Orthopaedic/Dental Implants

P.H. Osanna, M.N. Durakbasa, K. Yaghmaei, L. Kräuter

Institut für Fertigungstechnik - Technische Universität Wien
Department for Interchangeable Manufacturing and Industrial Metrology
Vienna University of Technology, A-1040 Wien, Austria

Abstract: *Nowadays implant surfaces are created by a large variety of manufacturing processes and techniques such as: CNC turning and milling, broaching, casting, grinding, polishing, honing, electro chemical etching, welding, brazing, stamping, bending, etc. The manufacturing accuracy range and allowable tolerances for implants lie between 1 µm and 100µm.*

The most important parameters in determining the suitability of an implant are its biocompatibility, functionality, performance, and corrosion resistance. In this paper the aspects of implant surface modification methods influencing biocompatibility, corrosion resistance and mechanical property nature of implants are discussed and how these depend on geometrical dimension and size, shape, size of roughness and surface topography.

Natural bone surface contains features that are about 100 nm. The interaction of bone tissue and total hip joint and precise assessment of wear, friction and miniaturisation demand for creating of nanometer scaled implant structure, implant surfaces thin film deposition and ultra precision surface treatment require the application of state of the art of new manufacturing and measurement instrumentation and techniques. These include micro and nanofabrication of surface patterns and topographies by the use of laser machining, photolithographic techniques, and electron beam and colloidal lithographies to produce controlled structures on implant surfaces in the range of size from l0 nm to 100µm.

Keywords: Structured Surfaces, Atomic Scale Machining, Laser Machining, Nanometrology, Surface Modification, Implants, Medical Devices

1. Introduction

Nowadays implant surfaces are created by a large variety of manufacturing processes and techniques such as: CNC turning, milling, broaching, casting, grinding, polishing, honing, electro chemical etching, welding, brazing, stamping, bending, etc. The range of manufacturing accuracy and tolerances for implants lies between 1µm and 200 µm [1].

Natural bone surface contains features that are about 100 nm. The interaction of bone tissue and total hip joint and precise assessment of wear, friction and miniaturisation demand for creating of nanometer scaled implant structure, implant surfaces thin film deposition and ultra precision surface treatment require the application of state of the art of new manufacturing and measurement instrumentation and techniques. At present these developed techniques and instruments are missing in manufacturing processes in the implant industry. The scalability benefit of implant design and production from pushing the micro into nanoscale implant engineering techniques needs multidisciplinary approaches of ultra-precision engineering techniques, micro/nanoscale surface metrology, material science and medicine.

The past decades and current research and development in the area of biomaterials and medical implants show some general trends. One major trend is an increased degree of functionalisation of the implant surface, better to meet the demands of the biological host system. While the biomaterials of the past and those in current use are essentially bulk materials (metals, ceramics, polymers) or special compounds (bioglasses), possibly with some additional coating (e.g. Hydroxyapatite), at present the current research on surface modifications points toward much more complex and multifunctional surfaces for the future. Such surface modifications can be divided into three classes, one aiming toward an optimized three-dimensional physical microarchitecture of the surface (pore size distributions, "roughness", etc.), the second one focusing on the (bio) chemical properties of surface coatings and impregnations, and the third one dealing with the viscoelastic properties (or more generally the micromechanical properties) of material surfaces.

These properties are expected to affect the interfacial processes cooperatively, i.e., there are likely synergistic effects between and among them: The surface is recognized by the biological system through the combined chemical and topographic pattern of the surface, and the viscoelastic properties [1].

2. Biocompatibility

Biocompatibility consideration of metallic, polymeric and ceramic materials has led to their use as standard materials for implants and medical devices. However, increasing demands on implant materials, and the trend towards device miniaturisation due to the enhanced functionality and performance has put the spotlight on the implant surface and its properties. Implants all possess inherent morphological, chemical, and electrical surface qualities which elicit reactionary responses from the surrounding biological environment. In fact, biocompatibility can be described as multi-factorial in that simultaneous stimuli from any of these material properties can affect the host response. There are many factors which influence implant biocompatibility such as implant size, shape, material composition, surface quality and roughness.

3. Corrosion of Implants

Implant Corrosion is one of the major degradation processes that might occur in vivo, and should be considered for evaluating new biomaterials and new designs of medical devices [3]. The bio-environment may be described as "aggressive and angry", and is associated with a variety of conditions. Metals and alloys, which are extensively used in medical devices, might corrode severely in this bio-environment in accordance with both thermodynamic and kinetic considerations. This degradation process is undesirable primarily because it limits the functionality and lifetime of medical devices, and secondly because it releases corrosion products that may elicit an adverse biological reaction in the host. Corrosion is a complex phenomenon that depends on geometric, metallurgical, mechanical, etc. parameters. Implant manufacturing understanding of these parameters and their synergistic effects is required in order to control implants corrosion. Fretting corrosion occurs to some extent on all load bearing orthopaedic implants.

4. Mechanical Properties

The major problem associated with the currently used implants is due to inadequate implant-tissue interface properties. The integration of load-bearing implants, such as hip and knee prosthesis and dental implants, into surrounding tissue is important [4]. Both in vivo and in vitro studies have shown that implant surface topography may affect epithelial and connective tissue behaviour. Based on these observations, a mathematical theory of ideal surface pit morphology, dimensions and densities of biomechanical significance was formulated. Another theoretical analysis concluded that if the geometric form of surface roughness is held constant, then the peak elastic stress depends on the form rather than the size of roughness. There are several in vitro studies that show how the physical, chemical and mechanical properties of implant surface can be improved. Unfortunately, they did not measure the

topography of these differently treated surfaces. It would be interesting to compare surface topographies to the above results.
Fretting of total hip and knee replacements occurs at such places as the bone-stem interface, the cement interface, and on the interfaces of modular connections between implant components. Fretting also occurs at areas of cyclic load bearing contact on metallic bone-plates and screws, such as screw-plate connections, bone-plate interfaces and screw/bone interfaces.

5. Ultra Precision Manufacturing and Nanoscale Surface Metrology for Implants

Implant surfaces are created by a large variety of manufacturing processes. Implant manufacturing has been helped in the last few years with CAD-CAM systems applying casting or machining (milling, grinding, lapping, polishing).

The indirect method for characterisation of dimensional and functional properties of engineering surfaces measures the integrity of a surface by means of micro/nano scaled surface metrology [5]. The development of surface texture, form and 3D surface characterisation methodologies, topography and roughness parameters considering wear and friction has lead the micro/nano scaled surface metrology research to become involved in characterization of implant surfaces. At the time being 3D surface measurement is already proving more and more to be an important tool in several areas of surface analysis including wear, indentation, topography, contact problems and functional behaviour of surfaces.

The measurement process leads to "control by measurement" of the manufacturing process. With the recent developments in new implant surface treatments implant surface layers are treated, or surface engineered. In new and developing technology, the implant surface features such as roughness (10nm to 100µm) are often aimed at producing the implant surface functionality which leads to enhanced implant biocompatibility and performance.

It is obvious that a full understanding between surface topography and functional performance of an implant can only be realised if a 3-dimentional approach to surface characterisation is utilised. 3D-surface measurement is a very valuable tool in implant surface analysis including wear, indentation, topography and contact problems of implants (see Figure 1).

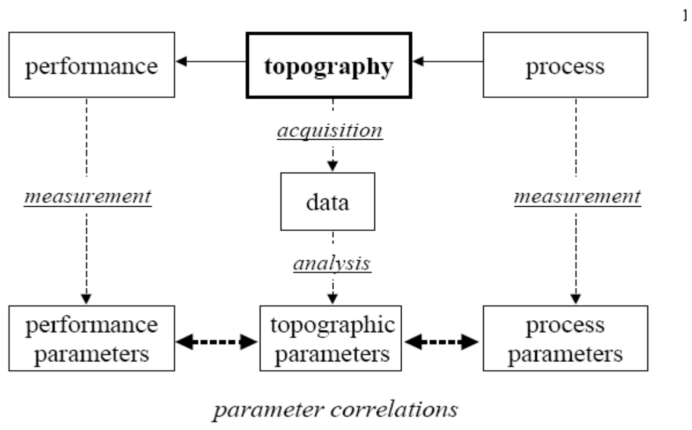

Fig. 1. Parameter correlation according to process, topography and performance.

Due to the topography assessment of implant surfaces:
- Optical microscopy,
- Scanning electron microscopy (SEM) and
- Atomic force microscopy (AFM)

are applicable for metrology.

6. Structure at the Bone-Implant-Interface

Natural bone surface contains features that are about 100 nm across. If the surface of an artificial bone implant were left smooth, the body would try to reject it. Because of that smooth surface is likely to cause production of a fibrous tissue covering the surface of the implant. This layer reduces the bone-implant contact, which may result in loosening of the implant and further inflammation [6]. It was demonstrated that by creating nano-sized features on the surface of the hip or knee prosthesis one could reduce the chances of rejection as well as to stimulate the production of osteoblasts. The osteoblasts are the cells responsible for the growth of the bone matrix and are found on the advancing surface of the developing bone.

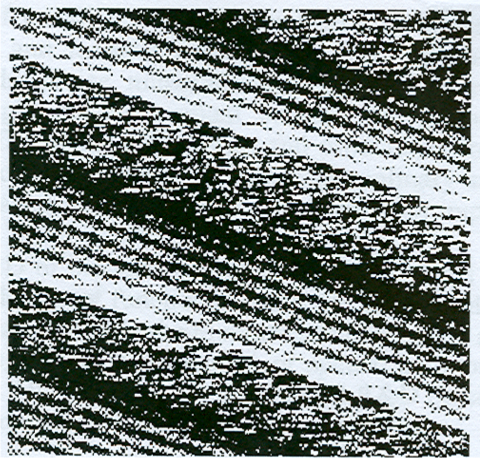

Fig. 2. Laser machined surface

In the last few years, there has been a recent development in the functional significance of surface finish. This is the use of periodic pattern on the surface to enhance a specific use. Structured surfaces are surfaces with a deterministic pattern of usually high aspect ratio, geometric features designed to give a specific function [7,8]. In general structured surfaces are made using conventional processes like cutting with single point diamond turning. Some other ways of making structured surfaces are:

- Moving/removal material (machining, burnishing),
- etching (plating, evaporation),
- replication (hot embossing, casting),
- material modification (Laser texturing) (see Figure 2),
- solidification of liquids),
- photolithographic techniques, and
- electron beam lithographies are attractive ways of making structured surfaces.

Using these techniques enables structures to be imparted on many different and difficult materials.

These techniques for structuring of implant surfaces have made surface structure with pore diameters up to 10 nm to 100µm possible. This permits the development of defined, reproducible and economical surface topographies which reduce wear and friction and will contribute to corrosion resistance and improving biocompatibility, functionality and performance of implants.

7. Biocompatible Coatings

Developing thin film technology for different industrial applications including machining and bio-medicals industries with regard of enhanced orthopaedic implant performance is one of the fastest-growing areas in the field of biomaterials and many developments are anticipated over the next decade.

Biocompatible coating deposited on implants facilitates implant fixation and bone ingrowths. Modifying of implant surfaces by ion implantation or physical vapour deposition exhibit superior hardness and wear resistance. Such technology will also be applicable to the rapidly expanding field of dental implantology where osseo-integration depends on the surface roughness of implants.

Coating is applied to orthopaedic components and other medical devices for a variety of reasons. Porous metal and ceramic coatings deposited on implants facilitate implant fixation and bone ingrowth [9]. Implant surfaces modified by ion implantation or physical vapour deposition exhibit superior hardness and wear resistance. Polymeric coating formulations are used to enhance biocompatibility and biostability, thromboresistance, antimicrobial action, dielectric strength, and lubricity; make medical devices used within the body more visible to ultrasound.

One challenge therefore appears to be to design biocompatible coatings that can resist both the chemical and mechanical environments, which are often poorly defined for both orthopaedic and dental applications, without degrading the very property that is required in the advance material. Hydroxyapatite (HA), is the material for biologically compatible coatings on metal substrates.

8. Further Development and Future Research

8.1 Basic Research:

- Nano scaled surface metrology.
- Micro/Nanotribology and material characterization.
- Development of new parameters and tolerances for micro and nanoscale surfaces.
- Characterization of ultraprecise manufactured implant surfaces and devices.
- New approaches to a comprehensive Quality assurance for implants.
- Biomaterials: Biocompatibility test methods, standards.
- Medical Informatics: Image analysis and reconstruction, knowledge based systems.
- System Analysis: Modelling, Computer aided simulation, functional analysis.
- Collection of all received data in a database.
- Biomechanics.

8.2 Applied Research:

- Application of new measurement instrumentation and methods for implant production.
- Application of PVD, CVD, Hydroxyapatite porous coatings in implant manufacturing.
- Application of nanoscale surface modification techniques in the implant production process.
- Micro/nanotribology assessment and material testing for implants.
- Approaches to development of new measurement instruments.

9. Synopsis and Concluding Remarks

This needs the integration of nanometrology in implant manufacturing processes for precise manufacturing and biocompatibility of implants. The novel nanoscale surface metrology philosophy introducing the new attempt of industrial nanometrology in implant science and technology will lead to industrial breakthrough in manufacturing and measurement of orthopaedic and dental implants and devices, and to point out specific points of special interest [2]:

- Ultra-precision machining of orthopaedic and dental implants and devices.
- Application of nano scaled surface metrology in the implant production process and characterization of ultra-precise manufactured implant surfaces and devices.
- Application of new measurement instrumentation and methods for implant production.
- Development of new parameters and tolerances for micro and nanoscale implant surfaces due to the development of standards at the nanometer level.

The other related activities to the objectives are:

- Investigation of implant size, shape, roughness influencing biocompatibility.
- Investigation of implant size, shape, roughness influencing corrosion resistance.
- Improving the implant-tissue interface properties for load-bearing implants through nano-scale 3D surface topography.
- Determining of the implant mechanical properties (elasticity modules, Poisson's ratio, and stress), plastic deformation, density, adhesion, friction, and tribological behaviour.
- Tribology of hard bearing surfaces in hip prosthesis
- Surface modification of implants due to enhanced tribological performance through reducing the wear of artificial joints.
- Biocompatibility testing on metallic, ceramic polymer implants.
- Measurement methods, standards for the scientific understanding at the interface between the materials and biological sciences.
- Work towards providing traceable nanometrology resources and development of standards at the nanometer level.

References

[1] Kasemo, B., Gold, J.: Implant Surfaces and Interface Processes. Adv. Dent. Res. 1999, June 13, 8/20.

[2] Yaghmaei, K.: Direct and Indirect Methods for Micro/NanoCharacterisation of Dimensional and Functional Properties of Engineering Surfaces. P.H.D. Dissertation, Thesis, 2005.

[3] Eliaz, N., Mudali, U.K.: Biomaterials Corrosion Reviews. Special Issue Vol. 21, 2003, N.2-3.

[4] Kapanen, A.: Biocompatibility of Orthopaedic Implants on Bone Forming Cells. ISBN 951-42-6606-4.

[5] Stout, K.J.., Blunt L.: Application of 3-D Topography to Bio-Engineering, 6th International Conf. on Metrology and Properties of Engineering Surfaces. 1994, Birmingham, UK.

[6] Salata, O.V.: Applications of Nanoparticles in Biology and Medicine. Journal of Nanobiotechnology,2004, 2:3 doi:10.1186/1477-3155-2-3.

[7] Whitehouse, D.J. : Handbook of Surface and Nanometrology. 2000.

[8] Toenshoff, J., Von Alvensieben, H.K., Temme T., Willrnann G.: Review of Laser Micro Structuring. Proc. 1st Conference of Euspen. 1999, Bremen, Germany.

[9] Handbook of Materials for Medical Devices. ASM International, Materials Park, Ohio, USA.