High Precision Production Metrology for Quality Improvement in Biomedical Applications

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Abstract. *Rapid development in biomedical techniques demands the application of modern computerized measurement techniques and utilization of measuring devices with new technologies. Especially computer aided co-ordinate measuring technique can be applied to evaluate the shape of non technical structures, such as human limbs or joints with high accuracy. Measurement results create the basis for the improvement and optimization of future work in biomedical techniques and related areas. There are lots of important characteristics which describe the implant quality, desired from a successful implant. Besides defining macroscopic structure like material and shape an implant should reach defined microscopic structure such as the chemical, physical, mechanical, and topographic characteristics of the implant surface. These different characteristics describe the effect activity of the attached cells that are in close proximity to the medical implant surface.*

By using initially developed measurement techniques for engineering applications the clinicians could be able to characterise biomedical surfaces to assist in their maintenance, modification, optimisation and trauma repair. With development of robust measurement tools and best practice protocols it will be possible to quantify the appropriate metrology so that it will be possible to provide a quality assurance feedback to the clinicians to assure good practice, functional achievement and long service life of the restoration, implantation object.

Keywords: *Quality Assurance, Medical Implant, Co-Ordinate Metrology, Surface Measurement, Hip Joint, Wear Out*

1. Introduction

There exists rapid development in biomedical technique and this demands the application of modern computerized measurement technique and measuring devices. Especially computer aided co-ordinate measuring technique and 3D digitizing systems can be applied to evaluate the shape of non technical structures as there are human limbs or joints with high accuracy. The results of such measurements give for example the basis for the improvement and optimization of future work in biomedical technique.

In the last years the sophisticated 3D measurement technique has attained an important role in the industrial measurement technology. By the rapid evolution and the commitment of computer-aided coordinate measuring instruments it became possible to control the quality of the industrial products more precisely.

Increasing demand for quality and reliability on the one hand and competition with cost consciousness on the other hand are contradictory requirements in today's production engineering. This issue must be also considered from the point of view of international standards dealing with quality management and quality assurance [1, 2].

In addition to this development, an increasingly important factor, the protection of environment must be taken into consideration, too [3].

2. 3D Measurement and Analysis of Non-Technical Structures

Technical instruments can carry out accurate and reproducible movements only with the utilization of nearly exact and highly accurate predefined elements, like references and standards. Implying an analogy conclusion that human kinematics works on a common basis of exact regulations which are currently unknown. Artificial limbs, joints and their linkage would work better if we would have more accurate information about original human parts (Figure 1).

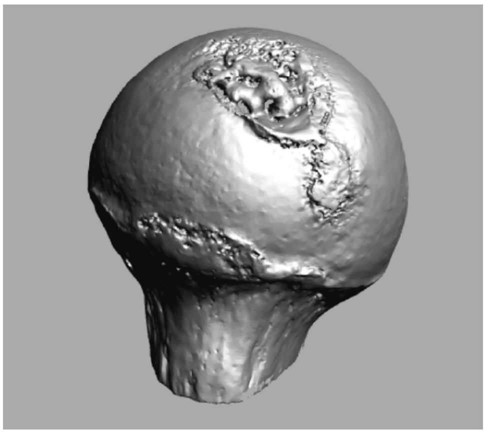

Fig. 1. Evaluation of measuring results of a human hip joint head using white light scanner.

Depending on whether macro-geometry or micro-geometry is of measurement interest in the analysis of workpieces´ surfaces, a distinction is made between form errors of different order, both in the technical literature and relevant standards (Figure 2).

It is common technical practice to collectively consider the short wave geometric deviations of the third or higher order as surface roughness characteristic on the basis of worldwide understood and internationally established parameters. As far as geometrical deviations of form and positions are concerned the increased use of co-ordinate metrology has improved common technical knowledge [4].

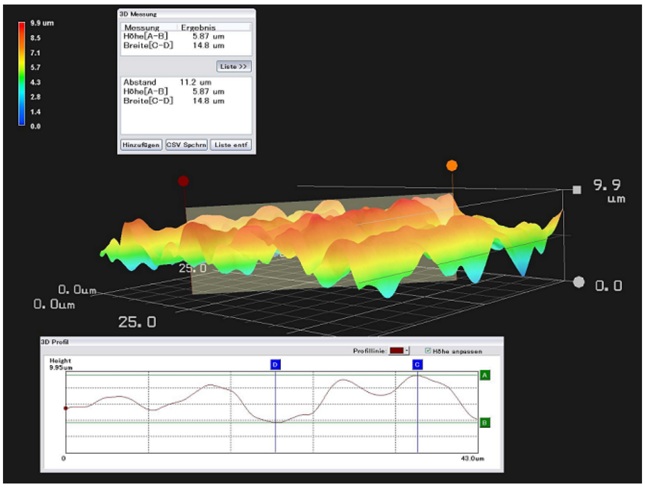

Fig. 2. 3D topographical analysis of a hip joint implant using digital microscopy system

In the case of it is necessary to choose a measuring device, this is done based on reasons of possible deviations of dimension and form measurement plan. Only with three-dimensional co-ordinate measuring machines (CMMs) it is possible to measure deviations in dimensions, forms and positions with high accuracy while using only one measuring device. Furthermore, it can be shown that accurate CMMs can be used to evaluate workpiece micro-geometry, like artificial sole modeling human foot, artificial teeth, hip joint heads, different kind of prostheses [5].

3. Coordinate Metrology for Measurement of Non-Technical Objects

Computer aided co-ordinate measuring technique can be applied to measure and evaluate with high accuracy shapes of non technical objects as human limbs or joints. Measurement results can create and widen the basis for the improvement and optimization of future work in the area of biomedical techniques. At the time being co-ordinate metrology is a very important tool for solving various problems in production metrology especially in the case of high flexibility and high accuracy are demanded.

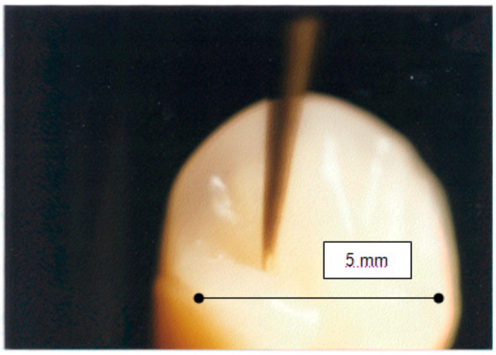

Fig. 3. Measurement of an Artificial Tooth for Implantation.

Measurement problems are handled with sufficiently high accuracy using co-ordinate metrology. The measured specimen is in figure 3 an artificial tooth from human teeth prosthesis. Due to sharp bends and curvature of the surface of artificial tooth its form can be measured as a free form surface using a very small probe, e.g. with a stylus radius of 0,04 mm.

The form of a biomedical surface can be evaluated from measured data when the form measurement is carried out by using CMM in scanning mode. CMM works here only as measuring system and digitizer. This example illustrates that co-ordinate metrology can be used to obtain exact numerical information about dimensions, forms and shapes and connections within biomechanics.

4. Data Evaluation and Applications

It is presupposed that artificial human joints must be constructed according to defined geometric kinematical regularities otherwise it would not be possible that these parts will stay in correct function during whole lifetime. They should last for decades [6, 7]. These regularities and natural motion laws are preconceived by men within technical motion systems and must be testified stepwise individually for each joint and later prosthesis.

Artificial limbs for hip joints are in general, constructed having the shape of spheres although in orthopedics literature is written that this is only an approximation [8-10]. Authors draw here the general conclusion that there exist deviations from the shape of a ball, but they do not see any further effects on the joint.

Stress distributions judgments of a hip implant are being used to study component fracture and permanent deformation, interface loosening, and remodeling process due to wearout. Stresses depend on joint loading and geometry, material properties and interface conditions, and thus are influenced by implant design, choice of materials, and fixation techniques. The importance of listed parameters can be evaluated by analytical and experimental techniques and combined.

Materials used in current total endoprotheses (TEPs) include metal alloys from such as iron, cobalt, and titanium based systems; and polymers such as polyethylene; and carbons; and ceramics. The evolution and application of these materials have established an extensive base of knowledge of short- and long-term compatibility.

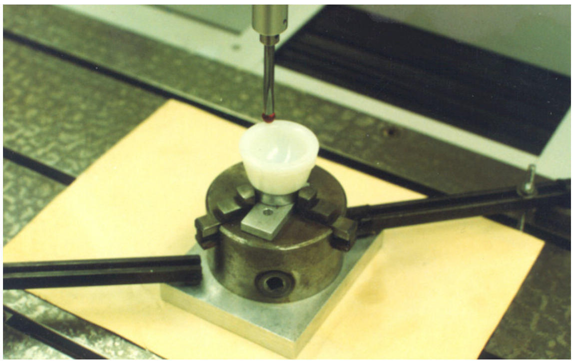

Fig. 4. Measurement process on polyethylene prosthesis using a CMM in scanning mode

The selection of materials depends upon physical, geometrical, mechanical, and chemical properties related to compatibility. Various form properties measurement of wornout prostheses, material friction on these objects and the wearout itself provide us with information and knowledge to establish complete series of quantitative correlations applicable later within clinical practice.

Figure 4 shows how a polyethylene prosthesis form can be measured when the form measurement is carried out by using CMM in the scanning mode. CMM only works as the measuring system and digitizer. The evaluation is done by transferring data to an evaluation computer and using evaluating program for calculation and optimization.

Comparison of nominal data and measured data of socket joint for implanted and worn out prostheses are a good example of application. The calculation for both the socket joint of implanted and worn out prosthesis will be carried out by using the best fit criteria.

The numerical evaluation of measured data and comparison with the nominal geometry of the socket joint form allows for measurement analysis and creates the basis for the improvement of the implementation of ball and socket joints (Figure 5).

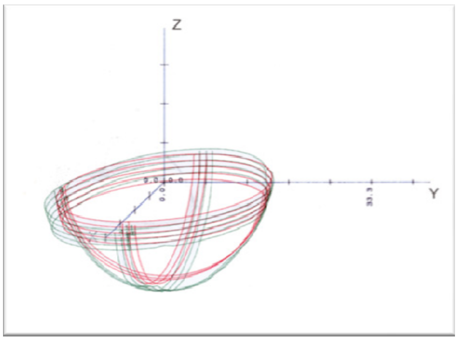

Fig. 5. Comparison of nominal data and measuring data of socket joint of implanted and worn out prostheses.

To achieve acceptable functional performance it has been shown in bio-implants that the surface quality and its adherence to form is the major feature. In hip joints for example poor surface topography has been responsible for most of the early failures in service. In addition product cleanliness is an important issue and the research project will maintain the practices that are defined and essential to ensure that infections to patients do not result from any aspect of measurement of part creation that is undertaken. As example Figure 6 shows the measurement results taken from the surface of an endo prosthesis for the femoral head of a human hip joint. The used measuring instrument is a digital microscope and the results show clearly a scratch that occurred during production of this endo prosthesis that may cause problems with the biocompatibility when already implanted.

Stress analyses can add to an understanding of the complex structure by quantifying and interrelating parameters and natural phenomena. Moreover, finite element methods can be used to predict on a relative basis the mechanical performance of different devices.

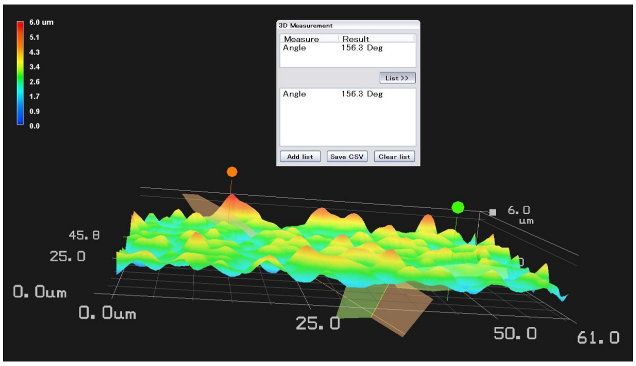

Fig. 6. Measurement taken from the surface of an endo prosthesis for the femoral head of a human hip joint CoCrMo

Finally, stress analyses can provide guidelines to assess consequences of design choices and surgical compromises. For instance, the relative contribution of parameters such as cement layer thickness, stem stiffness, stem length, and stem cross-sectional shape have been established and quantified.

5. Conclusions

In the paper is described an extensive measurement of non technical objects, here implants of various kinds, especially hip joints as well as dental implants carried out using the co-ordinate metrology with tactile probing methodology and non-contact approach using laser scanner for feature measurement.

This can create the standard method for a great variety of different and especially complex tasks for workpiece measurement. Results of various measurement and measurement evaluation can help to start, develop and enhance basis for the improvement and optimization of biomedical techniques for the future.

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