Application of Sophisticated Production Metrology and Nanometrology for Quality Control in Bio-Engineering

[1]M. Numan DURAKBASA*, [1]P. Herbert OSANNA*, [1]Ali AFJEHI-SADAT*, [2]Dayananda SAMARAWICKRAMA**, [3]Ales KRSEK***

[1]Vienna University of Technology, Austria; Department of Interchangeable Manufacturing and Industrial Metrology,
Karlsplatz 13/3113 A-1040 Wien, E-mail: aum@mail.ift.tuwien.ac.at
[2]Queen Mary University of London, UK, d.y.d.samarawickrama@qmul.ac.uk
[3]Slovak University of Technology, Bratislava, SK, Department for Production Systems, krsek@kvs.sjf.stuba.sk

Abstract *Currently biomedical procedures are skill based to a wide extent and clinicians performance in this wide field of science is considerably variable. There are no scientific methods available to the biomedical and dental clinicians for measurement and feedback of the skill-based activities although some limited rules do exist to assist them in learning their procedures. The lack of formal procedures and measurement techniques makes it extremely difficult to develop consistent procedures and results. The subject though has opportunities for broad support by metrology techniques that have been developed initially for engineering applications and will assist the clinicians in characterising biomedical surfaces to assist in their maintenance, modification, optimisation and trauma repair.*
With the development of robust measurement tools and 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.
To achieve this it is necessary to develop the techniques and protocols and to embody them in effective communication practices and to evaluate the surface components of human bodies whereas this includes teeth, gums, skin, bones, joints, endo prostheses and artificial prostheses parts.

Keywords: bio-engineering, quality assurance, quality control, production metrology, surface evaluation, co-ordinate metrology

1 Introduction

At the time being no scientific methods are available to the clinicians in biomedicine, dentistry and bioengineering for measurement and feedback of the skill-based activities although some limited rules do exist to assist them in learning their procedures. Those procedures are more or less skill based to a wide extent. So clinicians performance in this wide field of science is considerably variable. The lack of formal procedures and measurement techniques makes it extremely difficult to develop consistent procedures and results.

But the subject has many opportunities for broad support by measurement techniques that have been developed initially for engineering applications and will assist the clinicians in characterising biomedical surfaces to assist in their maintenance, modification, optimisation and trauma repair. With the development of robust measurement tools and 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.

2 The Cost of Medical Services in Europe

Currently the European budgets for medical and dental services are extremely large and growing larger continuously each year. The adult citizens of member countries of the European Union are enjoying greater longevity and this is expected to increase substantially over the current century. In addition the expectations of the populations of European nations are increasing as technology develops; and they expect, indeed demand, improved treatment and preventative medical and dental care.

If European governments are to meet their population expectations as economically as it is realistically possible, there has to be great attention paid to health care practices and the resultant quality assurance that good practice supported by scientific feedback can achieve. It is expected that through the introduction of an integrated suite of metrological procedures it will be possible to bring greater measured science to these important disciplines and its initiation timely, since over recent years, partly through the development of computing and modern electronic instrumentation, such developments are now realistically possible.

3 Opportunities for Biomedicine and Bioengineering

It is believed that through evaluating existing biomedical devices and prostheses it will be possible to determine how they perform in their functional environment. To achieve this, we need to develop or to adapt the measurement tools, the data acquisition methods and the digital processing of data that are associated with it that are appropriate to medical surfaces. From this combination of activities it is possible to evaluate many important components of the human body and their prosthetic replacements and then to discover areas where their functional performance deteriorates in service [1]. This statement is true of both biomedical and dental devices and prostheses.

Figure 1 shows as example the carried out measurement of artificial teeth for implantation in human jawbones and the measuring data respectively. Such problems can only be solved with sufficiently high accuracy using this method. The measured specimen is an artificial tooth for human teeth prosthesis. Because of the sharp bends and curvature on the surface of artificial tooth the form can be measured as a free form surfaces using a very small probe e.g. with a stylus radius of 0.3 mm.

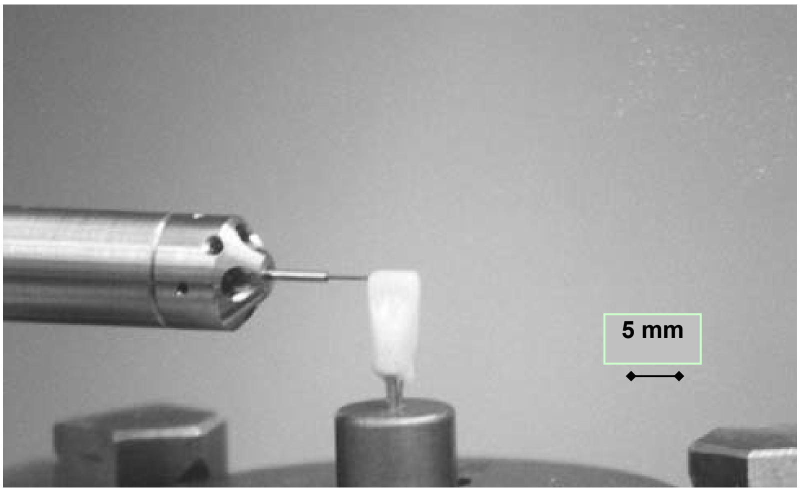

Fig. 1: Measurement of an Artificial Human Tooth

Figure 2 shows the graphic evaluation of the measured data to obtain and analyse the exact form of this complex and non-technical structure. This example illustrates that co-ordinate metrology can by used to get exact numerical information about dimensions in connection with biomechanics.

Unfortunately though, often through disease, personal abuse, either intentionally or accidentally, and at other times due to unexpected trauma, these body components fail to perform to the lifetime expectation that has been placed on them. As a consequence, intervention may be necessary by the clinicians to restore the damage caused to the human body components so that their required function can be fully, or at worst, partially restored.

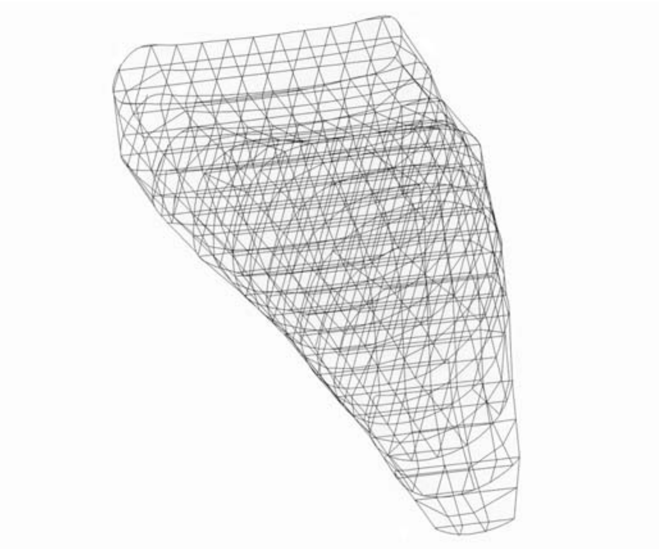

Fig. 2: Evaluation of Measuring Data of an Artificial Tooth

It is believed that by establishing effective metrology processes for restorative and prosthetic procedures, many of which are craft based at present; their underlying concepts can be understood. It is our intention that by the development of appropriate metrology, to be used to quantify these operative, restorative and prosthetic procedures, they become more robust and fulfil at least in part, the criteria applicable to precision engineering processes.

The advantage of improving the metrology of both restoration and replacement of worn and diseased body components, including those in dentistry, will benefit both the patient and European economies. It is also expected that once these metrology tools are developed, it will be appropriate to work towards the creation of international standards to formalise them in these areas of application and to broaden their application.

4 Impact on the Situation in Europe

At present there is no scientific method available to verify the quality of these preparations. They are judged to be adequate only by clinician's eye estimation. Therefore many procedures are insufficiently precisely conducted and this contributes to eventual failures of function necessitating rework, repair or replacement. This reworking is a major financial drain on the medical services in EU member states and amounts to hundreds of millions of Euros wasted each financial year.

The formalisation of quality procedures for the biomedical sciences (both in its practice and in its teaching) should assist in mitigating the cost of the increasingly comprehensive medical service expectation of the European Union's population. Quality assurance, in many industries is related to conformance to specification, which in turn is achieved through the ability to quantify, measure and to communicate the specification defined. This is also true for the science medicine.

Since dimensional controls are not formalised, variability is considerable within the treatment of any practitioner and the variability between practitioners is often much greater in what are skill supported sciences.

The main requirements in implant surgery are for components used in repair and rehabilitation to be fit for purpose having long life and high reliability. Unfortunately this has not always been the case as is instanced in hip replacement components that were originally designed to have an operational life estimated at seven years and where the current requirements are for such implants to last a minimum twenty years. Much of the improvement required implies much greater precision than previously expected and much of this will require both dimensional control and surface preparation that will ultimately fall into the nano-metre range of measurement.

A well developed portfolio of research activities will assist in defining the most appropriate measurement practice that will become widely needed in future generations and will enable an unambiguous communication of the requirements for the specification of parts and their tolerances that will lead to functional reliability and the assurance of quality during and after certain clinical and dental procedures and to assist in optimising its performance in a discipline that to date is largely skill based.

Research will involve taking measurements either directly from human body components or from necessary replicas made from the human surfaces as is dictated by the clinical circumstance. Where replicas are taken they will be in accordance with established principles in this field of study.

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.

To achieve an acceptable functional performance of treated post trauma patients is another important and crucial feature. The restorative surgical or dental work must meet the lifetime needs of the patients and this will obviously depend on the typical life expectation of patients that is currently steadily increasing. It must be remembered that corrective surgery is expensive, time consuming, often disruptive and painful and places a heavy burden on the community social services.

Economic and Social Impact on the European Union

Such variation in providing surgical intervention, often due to a lack of dimensional and form control brought about by the lack of formal metrology leads to post surgical intervention performance variation. Variation is known to lead to variable success in the procedures carried out since the functional attributes of the intervention are not constant. One of the outcomes of this variation is premature failure of the surgical intervention which in turn on many occasions requires further surgical intervention. This places a heavy burden on the cost of medical services throughout the European Union as well as leading to inefficiencies in the use of medical/surgical personnel.

The resultant high costs are unacceptable and are composed of three parts:
(1) high costs of surgical intervention,
(2) high costs associated with post operative medical care provision
(3) unnecessary pain and suffering to the patient as a result of rework and "ex-plants" and re-implants.

An additional factor that has to be taken into consideration is that due to the increasing expectations of the population within the European Union for improved and extended healthcare as well as a higher quality of health care, the total cost of meeting these potentially reasonable expectations are constantly rising across whole Europe. This is further complicated by increasing life expectancy. The only way that these expectations can be met in the longer term is to achieve higher post trauma reliability, longer functional performance of the procedures that can only be achieved through improved process and quality control and micro surgical intervention.

If improved metrology was formalised in biomedical and medical services the expectation is that there would be considerable cost savings realised across the European Union and there would also be a considerable reduction in secondary repairs and "ex-plants" to yield the life expectancy required for the various treatments. As life expectancy increases the demands on the longevity of post trauma functional restoration will also increase.

The Impact on European Standards

Once this process has been accepted and has started to be used within the European Union, it is important that the formal procedures are embraced into European and later on into worldwide International Standards. Such developments need the preparation of appropriate discussion documents for circulation and dissemination prior to the relevant standards committees before taking formal action to implement the developments. The development of such discussion documents and later the development of new and improved standards is part of the directives of the European Union.

The Overriding Importance to the European Union

It is extremely important that such research is conducted on a European level since all member countries within the community are faced with a growing demand on their medical and dental services. It is also important to undertake such a programme on a European level to take advantage of the opinions of relevant persons and organisations before coming forward with far reaching proposals. For such a project to be ultimately successful there must be informative discussion between the relevant parties and there must be some influence from them on the final direction of the project.

5 Instrument Development

The current range of instrumentation has been developed, in the main, for engineering purposes. In medical and dental science there is a need for specially developed machines and equipment that have been designed to suit medical measurements and manufacture. In the short term it may be necessary initially to use conventional equipment for measurement and manufacture and therefore it is necessary to find methods to overcome the limitations imposed by them. For example most "free-form" surface measurements are made from non-geometric surfaces that predominate in medicine, othopaedics and dentistry due to the fact that human parts have developed over millions of years through evolution of the species and have developed optimal solutions to suit their function. As a consequence human parts are created "bottom-up" atom-by-atom. Engineering surfaces in contrast are created "top-down" by "whittling down" process, cutting or forging materials from a bulk form to shape them to the desired result. As a consequence of "top-down" manufacture most products are geometric in shape and waste a considerable amount of the original material in the shaping process.

To control the manufacturing metrology through appropriate instrumentation it is necessary to develop appropriate quality assurance procedures. This is of particular importance due to the sensitivity of medical and dental science and also community legislation in terms of product specification, control and performance. Recent legislation has placed greater burdens on product manufacturers and has expected them to guarantee their products for the complete life cycle of the product.

6 Potential Impact of Surface Evaluation on Biomedicine and Bioengineering

The main requirements in implant surgery are for components used in repair and rehabilitation to be fit for purpose having long life and high reliability. Unfortunately this has not always been the case as is instanced in hip replacement components that were originally designed to have an operational life estimated at seven years and where the current requirements are for such implants to last a minimum twenty years. Much of the improvement required implies much greater precision than previously expected and much of this will require both dimensional control and surface preparation that will ultimately fall into the nano-metre range of measurement.

A well developed portfolio of research activities will assist in defining the most appropriate measurement practice that will become widely needed in future generations and will enable an unambiguous communication of the requirements for the specification of parts and their tolerances that will lead to functional reliability and the assurance of quality during and after certain clinical and dental procedures and to assist in optimising its performance in a discipline that to date is largely skill based.

Research will involve taking measurements either directly from human body components or from necessary replicas made from the human surfaces as is dictated by the clinical circumstance. Where replicas are taken they will be in accordance with established principles in this field of study.

Being a statistical or practical necessity some processes will require an extensive number of samples to achieve a scientific evaluation and may include the development of appropriate experimental design procedures. This may include the introduction where appropriate of "time series analysis" techniques to assist the interpretation of the measured results.

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.

Figure 3 shows the three-dimensional measurement of the femoral head of a human hip joint, whereas Figure 4 illustrates the CAD evaluation of the measuring data respectively.

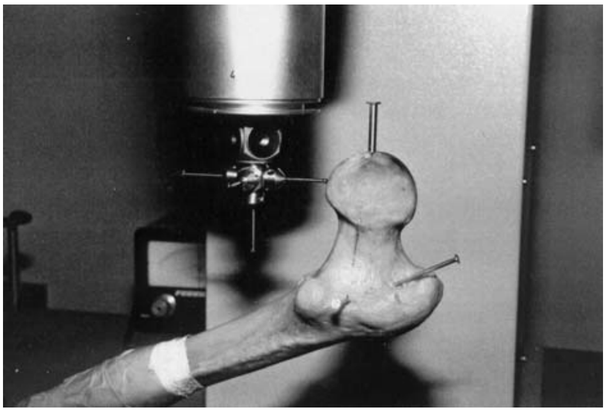

Fig. 3: Three-Dimensional Measurement of a Femoral Head of a Human Hip Joint

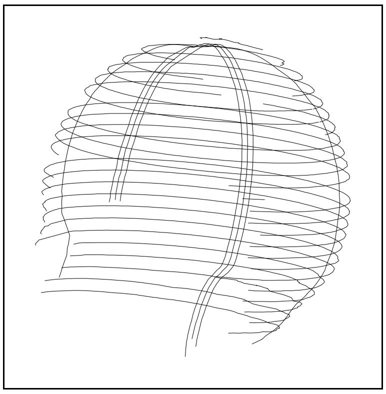

Fig. 4: Evaluation of the Measuring Data of a Human Femoral Head

To achieve an acceptable functional performance of treated post trauma patients is another important and crucial feature. The restorative surgical or dental work must meet the lifetime needs of the patients and this will obviously depend on the typical life expectation of patients that is currently steadily increasing.

7 The Current International State of the Art

This proposed research area is unusual and potentially difficult, as to date many of the analysis techniques that are proposed here will be applied to provide a functional assessment of components and surfaces in bioengineering applications. Some of these measurement processes have already been developed and exploited in other fields of science with some success. It is the intention to attempt to implement the techniques, albeit with necessary modification, to a range of bioengineering applications, in the attempt to provide a formal basis for functional bioengineering metrology.

The developments in "free-form" metrology have successfully been applied in medicine and dentistry, but to date only modest developments have occurred, although clearly improved measuring techniques and data processing are developing continuously. Essentially computer aided co-ordinate measuring techniques can and are being applied to evaluate the shape of non-technical structures such as those found in bio-engineering. Preliminary work has been conducted on human joints, limbs and teeth and it has been shown that this data acquisition can be done with reasonable accuracy. One of the problems associated with free form measurement is that the current range of modern instruments associated with measurements and surface assessment have been designed for application to engineering surfaces which have either regular form or at least partially mathematical forms. Human surfaces are significantly different since they have evolved through evolution to be optimally functionally efficient and are not as a consequence geometrically formed. To overcome these problems human surfaces have often to be divided into several sections for data logging and afterwards, usually before analysis, the surface segments have to be "stitched" together to provide a contiguous surface. Such "stitching" has to be done with great care to ensure the fidelity of the assembled data. A limitation to the more effective exploitation of the use of free form analysis is the current data acquisition system that has been designed to assess conventional engineering surfaces.

Currently, the systems most frequently used for data acquisition in biomedical metrology are co-ordinate measuring machines, which are often too large for the purpose and have data acquisition resolution considerably inferior to that found in the parallel subject, surface topography evaluation.

Free form surfaces are mathematically unlike geometric elements, such as spheres, cylinders and cones and as a consequence there is much more difficulty in creating algorithms that lend themselves to easy solution. The data collection and manipulation may be more likened to that found in CAD analysis. As the mechanical transport systems are refined data fidelity improves and it is believed that in time the resolution of free form surface data would mirror what is regularly achieved in surface topography.

It is believed that some of the techniques for mathematical approximation and the supporting interpolation methods that are currently applied to vehicle body parts will translate effectively and efficiently to the biomedical area.

There is currently recognition in bioengineering, dentistry and orthopaedics that effective metrological descriptions need to be evolved, evaluated and implemented if better control and improved quality are to be achieved. The scientific work in this research area can be designed in that direction so it will contribute to this objective.

8 The Scope of Measurement Opportunities

1. Three-dimensional free-form measurement of medical, orthopaedic and dental components [1, 2].

2. Development of measurement strategy for medical components from data obtained from point 1 mentioned above.

3. Develop functional assessment rules for the evaluation of medical surfaces.

4. Development of an efficient basis for experimental methods to be applied to measurements in bio-medicine.

5. Error uncertainty analysis in the analysis of free form surfaces.

6. Three-dimensional representation of tooth surfaces (see Figure 2) can give the basis for quality assurance of tooth preparations and restorations and also the production of artificial teeth. By developing the process of objective feedback of dental restoration through metrology it is possible to identify the areas of sites of bacterial accumulation at the rough margin [3, 4].

7. The quality control of tooth preparation and restoration by ensuring high quality restorative dentistry with high accuracy and repeatability. To achieve this it is necessary to have a quantitative method that supports the appropriate tolerances to express the size and shape of the tooth modification necessary to achieve the desired restoration. It is important in the training of future dentists that the basis of original measurements and subsequent machining is formalised and understood.

8. Objective feedback of dental restoration through metrology is the process of taking replicas and it is possible to collect data from the inverted object and to restore the information to the correct form. From the inverted images it is possible to produce visualisation plots of the restorative process to enable student's work to be evaluated in a more fundamental way that is currently possible by in-situ evaluation of the restorative work.

9. Identification of sites of bacterial accumulation at the rough margin that have sufficient volume to enable harmful bacterial accumulation [4]. It is important that corrective action can be made to the gum/tooth interface to minimise or eliminate the gum disease. In the past such sites have been viewed and recognised through the subjective judgement of the dentist, although more recently some digital techniques have been developed to assist identification. A method of providing a formal basis for an objective assessment of the condition is to produce dental replicas of the sites under consideration and to assess these using a CMM and appropriate software.

10. Assessment of tooth wear to develop an understanding of the nature and extent of wear. To investigate tooth wear further, it is necessary to analyse the three-dimensional surface topography of teeth using appropriate analysis software. Wear measurements may be made by taking high dimensional fidelity replicas where the tooth topography can be assessed at specific time intervals through the wear cycle.

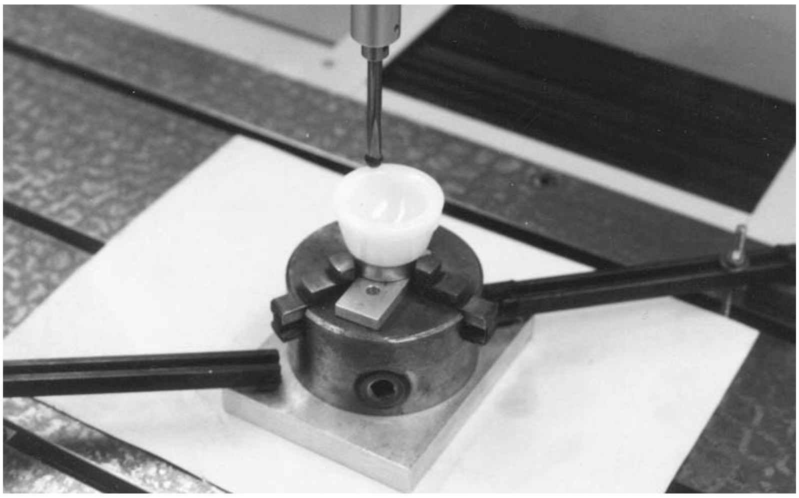

Fig. 5: Measurement of a Polyethylene Hip Prosthesis by Using Co-ordinate Metrology

11. The analysis of hip joints is an important aspect in ensuring that prosthesis has been manufactured in a way that yields long life and functional reliability. The life of a replacement hip joint is most usually related to the micro-topography of the joint whilst the overall form of the joint itself can also affect wear of the joint and its functional reliability. Free-form surface analysis of the prosthesis can be used to identify major geometric errors and wear of the implants that will lead to joint pain and ultimately failure in service. In Figures 5 and 6 the measurement and evaluation of a socket joint of an explanted and worn out human hip prosthesis is shown as practical example.

12. Measurement problems to be solved go directly into the direction of nanometrology. As example Figure 7 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 an atomic force 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.

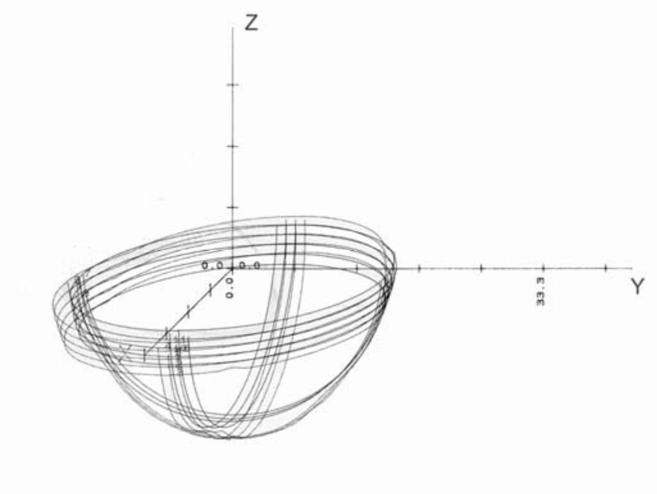

Fig. 6: Comparison of Nominal Data and Measuring Data of a Socket Joint of an Explanted and Worn out Hip Prosthesis.

9 Conclusions

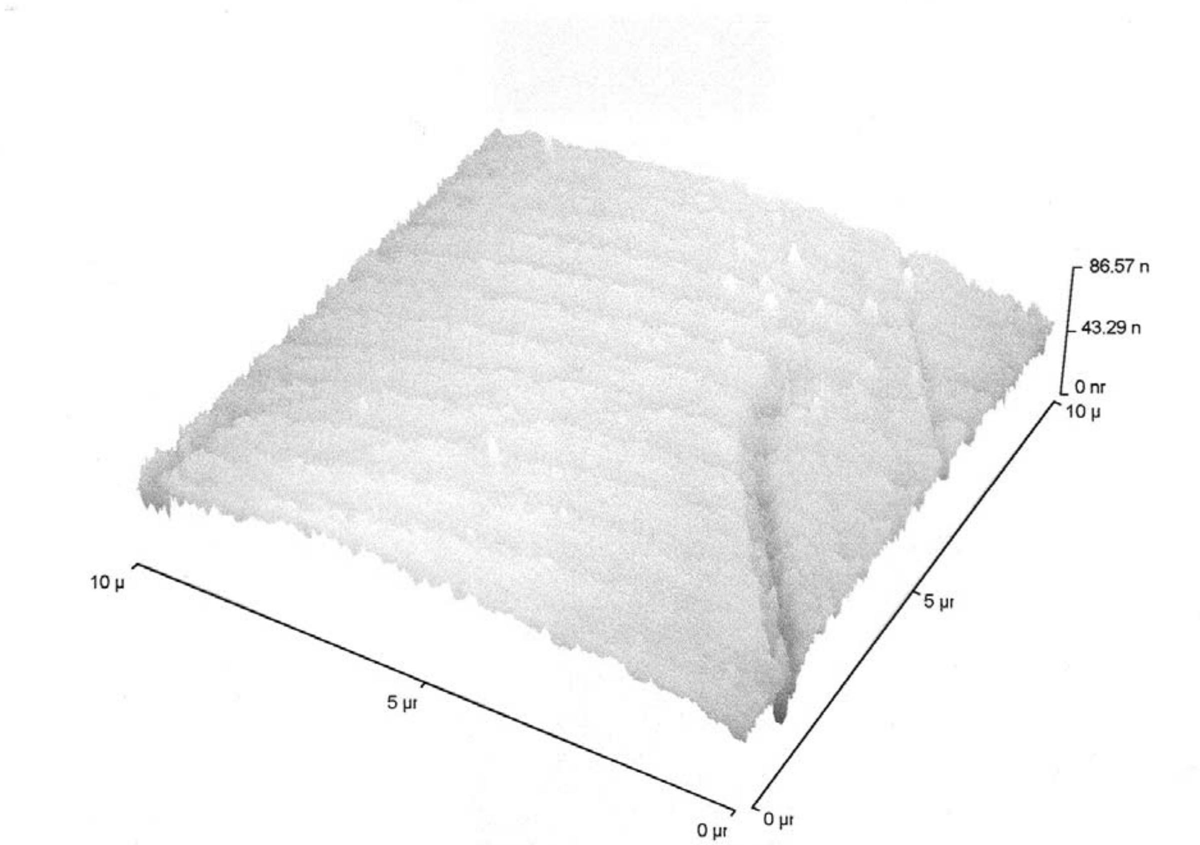

Fig. 7: Measurement taken from the surface of an endo prosthesis for the femoral head of a human hip joint

The presented overview about the research area Surface Assessment in the fields of biomedicine and bioengineering demonstrates clearly the great importance of this development. It is fully in line with the general ideas of production metrology, nanometrology and engineering of technical surfaces.

As technology increases and the techniques for healthcare improve the expectations of the society of the European Union could be realised in this important area at a realistic cost that would not place a prohibitive burden on the European Union's healthcare budget.

References

[1] Osanna, P.H., Rezaie, K., Durakbasa, N.M., Heiss, C.P.: *Form Measurements - A Bridge Between Production Metrology and Biomechanics.* Int. J. Mach. Tools Manufact. Vol. 35 (1995), No. 2, pp.165-168.

[2] Zou, L., D.Y.D. Samarawickrama, V. Jovanovski, J.C. Shelton: *Measurements of Sequential Impressions of Acetabula Cups From a Total Hip Joint Replacement Using a Non-contact Measurement System.* International Journal of Machine Tools & Manufacture, Vol. 41 (2001), pp. 2023-2030.

[3] Zou, L.: *An Optical Measurement System to Measure Free Form Surfaces.* Ph.D. Thesis, University of London, 2002.

[4] Wieczorowski, M., Cellary, A., Matthews-Brzozowska, T.: *Profilometry Studies on Enamel Surface Roughness of Human Teeth.* Rosen, B.-G., Thomas, T. R. (Editors): 9th International Conference on Metrology and Properties of Engineering Surfaces. Halmstad University, S, 2004, ISBN 91-631-5455-2, 165-172.