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Application Note

Measurement Soluions for Industry

In this issue:

The Measurement of Medical Devices using Focus Variation Metrology

Introduction

The use of Optical Metrology for industrial applications and R&D has increased dramaitically over recent years and there are varying techniques in use today.

The Focus Variation principle was first commercially developed by Alicona (now Bruker Alicona) in 2001 and is now accepted in many industries as the defacto method of verification of components within those industries.

As the technology has evolved and been developed over these years the applications that are now possible has increased. This now includes very smooth surfaces, and internal bores making the technology useful and necessary in many areas. This application note covers one of those areas.

With all measurements being fully traceable to international standards, known levels of uncertainty and highly repeatable the technique has become a "go to" technique for many users.

APPLICATION:

The Measurement of Medical Devices using Focus Variation

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Introduction

The use of Ultra High Molecular Weight Polyethylene (UHMWPE) as an acetabular liner material in full artificial joint replacements has been shown to increase longevity in medical devices. However, implant loosening and osteolysis can be attributed to submicron UHMWPE particles being generated through wear. Current research is focussing on the different formulation of UHMWPE and in vivo testing for wear assessment [1-4]

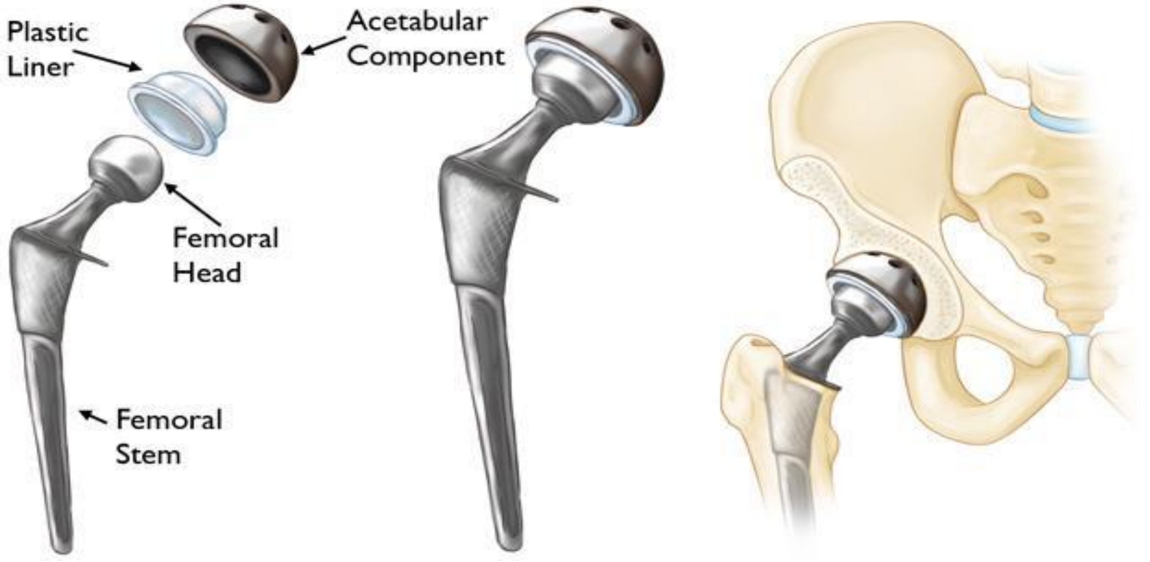


Figure 1- Diagram of a prosthetic hip (5)

The measurement of wear in UHMWPE medical devices currently relies on both gravimetric and contact methods [6]. Gravimetric measurement allows for the calculation of material weight lost between pre-wear and post-wear in vivo testing. However, gravimetric testing does not quantify specific areas of material loss or any occurrences of material displacement. Contact measurement (stylus profilometry) will acquire changes in surface topography, but risks damage to the surface through plastic deformation of UHMPE due to contact with a harder material.

UHMWPE is a semi-transparent material, and acetabular liners have a large height range and steep flank angles, resulting in difficulty of non-contact measurements. Data loss is apparent in interferometric techniques due to both steep flank angles and the absorption of light by the semi-transparent material minimising the amount of light reflected to the detector. Emerging techniques such as Computed Tomography and laser CMM can acquire topographical data without the use of a contacting stylus, however datasets are often acquired at sub-optimal resolution.

The Alicona Infinite Focus G5 can acquire high resolution datasets on UHMPE acetabular and quantitatively calculate differences in wear liner due to:

- Modular lighting which can be changed to suit the material
- The ability to measure angles of up to 89°
- A possible measurement volume of 100x100x200mm
- Areal surface characterisation based on ISO standards

The use of the Bruker Alicona InfiniteFocusG5 will allow for a step change in the surface measurement of UHMPE biomaterials, which will no longer rely on possibly damaging methods.

The lifespan of hip implants ranges from 10 – 15 years [7-8], with the reason for the failure of hip implants broken down into 3 major factors; patient, implant and surgical [9]. Of these factors, it has been noted by the national joint registry that the most common reason for failure is that of aseptic loosening [7] - a patient related factor whereby a failure of the bond between the bone and implant occurs in the absence of infection. It is the wear of UHMWPE that is currently documented as the primary reason for aseptic loosening [7]. With research finding over 100 million UHMWPE wear particles released daily into the surrounding tissue [10].

As a result, emphasis has been placed in the volumetric wear calculation of UHMWPE acetabular components. But importance must also be placed into the surface characterisation of the liner. This will allow for a greater understanding in the functional behaviour of the liner, giving rise to a greater insight into the varying modalities of failure. This knowledge will allow for further analysis of implant and surgical related impact factors.

Figure 2 shows the measurement taken for a worn acetabular liner; the data recorded shows a significant visual difference in acquired surface data. The measurement capabilities shown by the Bruker Alicona InfiniteFocusG5 allowed for the visual comparison between the worn and unworn surface.

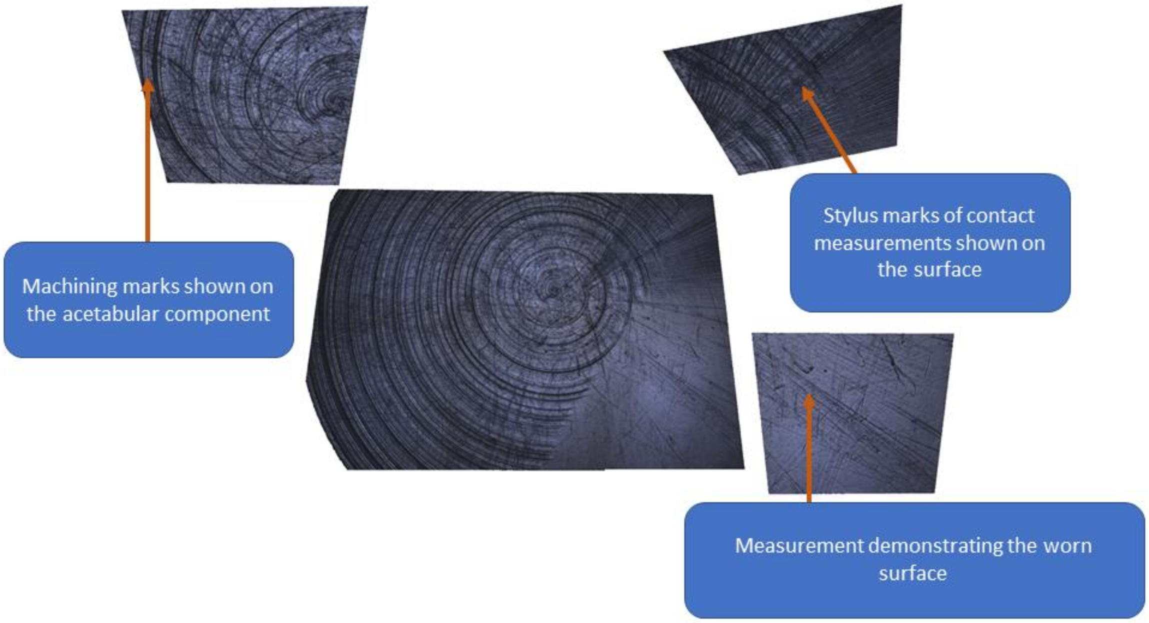


Figure 2 – Measurement of the surface of an acetabular component that has undergone artificial wear

A linear profile was initially conducted to see changes in roughness from the worn to unworn surface. As shown in figure 3 as the profile moves from the worn to unworn surface there exists an area of increased surface height. This increase in surface height is thought to be a result of ploughing – when surface material has been displaced -. This may lead to an increased wear rate as a result of this increased deviation from the reference plane.

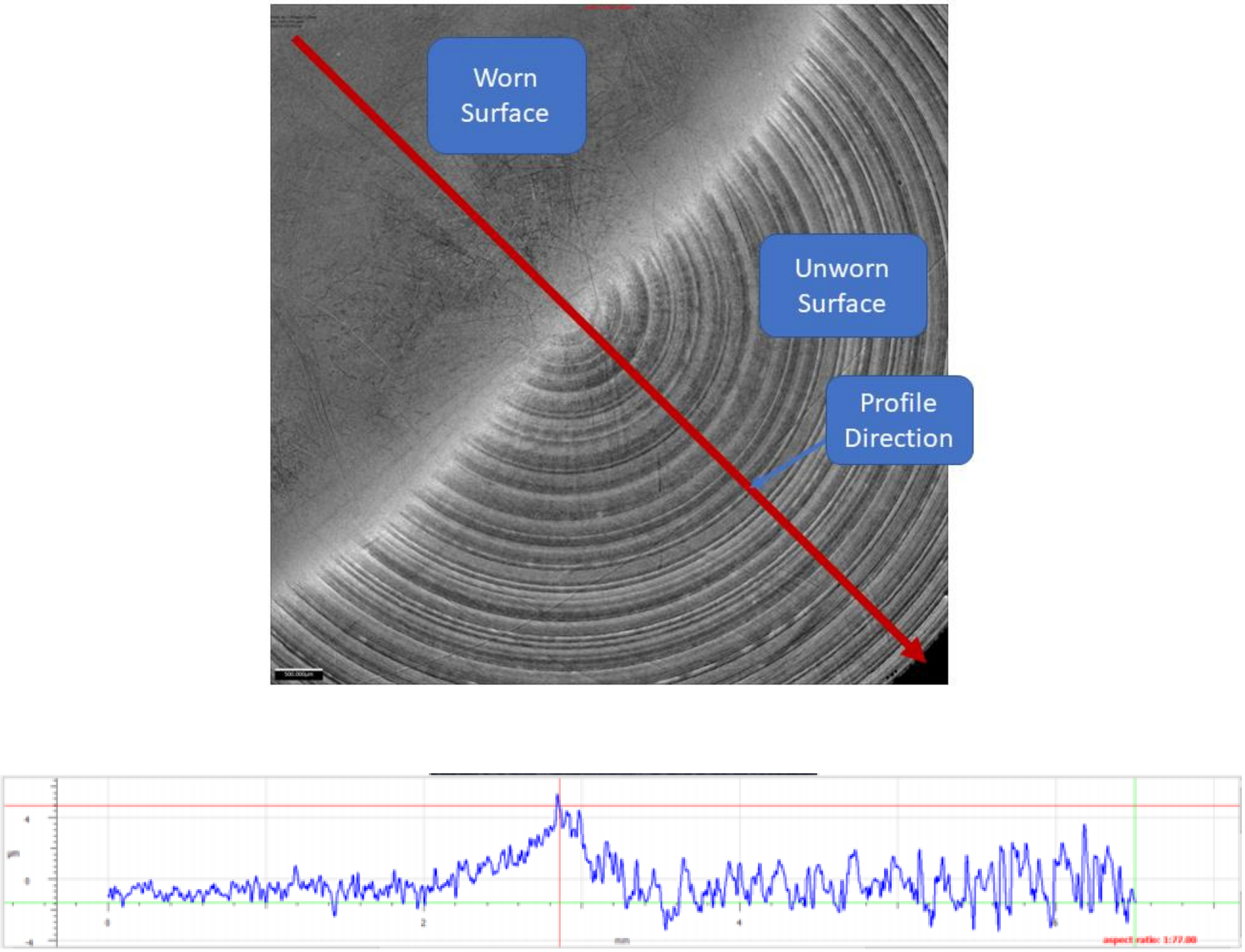
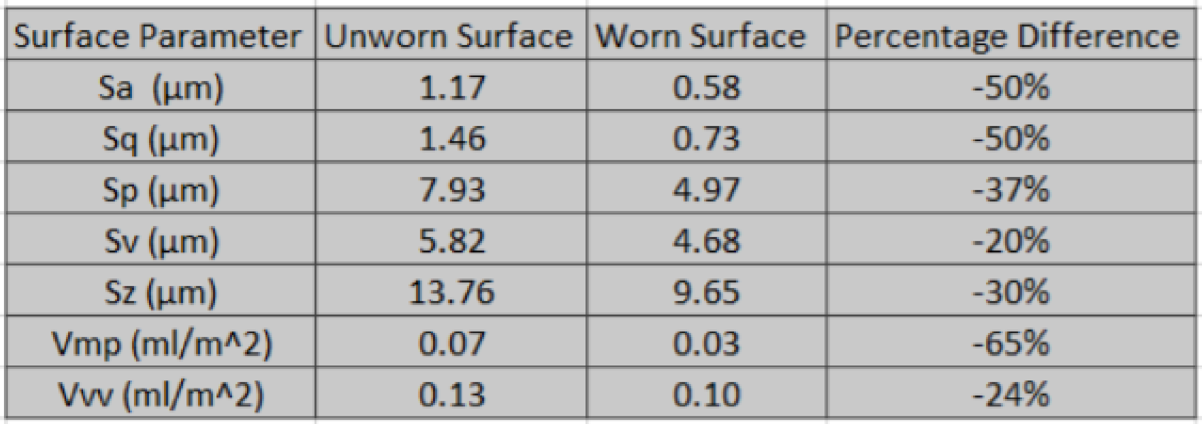


Figure 3 - Linear profile of a worn acetabular component

A comparison can also be made between the surface parameters of the worn to unworn areas of the component. The Sa value is the average height of the selected area, to calculate this, a reference plane cuts through the centre of the data set and averages the peaks and valleys. As shown (figure 4), the Sa value increases from the worn to unworn surface, which is to be expected due to decrease in maximum peak height (Sp).



Surface Parameter	Unworn Surface	Worn Surface	Percentage Difference
Sa (µm)	1.17	0.58	-50%
Sq (µm)	1.46	0.73	-50%
Sp (µm)	7.93	4.97	-37%
Sv (µm)	5.82	4.68	-20%
Sz (µm)	13.76	9.65	-30%
Vmp (ml/m^2)	0.07	0.03	-65%
Vvv (ml/m^2)	0.13	0.10	-24%

Figure 4 - Table presenting the change in surface parameters of acetabular component, pre- and post-wear.

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