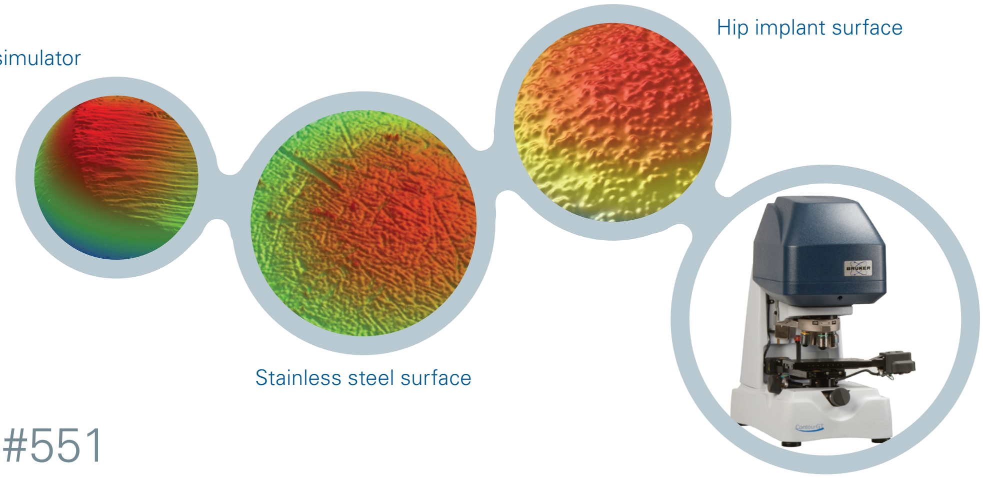

Application Note #551

3D Optical Microscopy for Orthopedic Implants

Orthopedic implants vary enormously. These variations can be in size, from tens of centimeters to millimeters; in shape, from simple spherical femoral heads to complex saddle-shaped knee prostheses; in material, from stainless steel to hydroxyapatite; and in surface finish, from super smooth for reduced friction to intricately textured to promote stability. With such a wide range of parameters, control of the critical specifications of a part can become a challenge involving many different metrology instruments suited to different tasks.

Tolerances on measured quantities are also often exceedingly small with deference to a component's functionality and longevity after successful surgical implantation. This application note discusses Bruker's 3D optical microscopy technique in both the research and development and quality control stages of orthopedic implants manufacturing. The benefits of this technique include non-contact and non-destructive characterization, an insensitivity to material type, a large dynamic range to measure very rough and very smooth surfaces, quick, accurate and repeatable areal measurements, and the capability for complete automation to measure a batch of parts and perform pass-fail summaries based on user-specified parameters.

Bruker's 3D Optical Microscopy Solution

Orthopedic parts are precision manufactured to very high specifications. Parts that have not been manufactured to correct specifications or parts that have been damaged or have defects must be identified and removed from those passing inspection. The main reason for this industry's strict adherence to part specifications is obviously patient health. Implantation of a device containing even one component that is in some way defective can have dire ramifications. Uncertainty in a component's interaction with the patient's body can prohibit the device from working as designed, or can cause future complications such as patient discomfort, the need for further treatments and surgeries, or even death.

Ultimately, manufacturers work to avoid a recall of a defective product, which incurs heavy financial burden as well as loss of integrity amongst the medical community. In addition to these critical "downstream" reasons for part inspection, failure of a part can also provide an extremely useful impact on upstream manufacturing processes. For example, parts failing due to higher than average surface roughness could be an indication of an incorrect polishing procedure. This information can be fed back to allow re-optimization of upstream tools, which in turn results in fewer bad parts being produced and less raw material waste. This is a direct example of return of investment to the manufacturer.

For all the reasons above, it is imperative that orthopedic parts are inspected in a fast, accurate, repeatable, and non destructive way. 3D optical microscopy based on white light interferometry is one of the most accurate, repeatable, and versatile methods for precision surface metrology. Instruments based on this technology successfully measure materials from research to production line environments to sub-nanometer vertical resolution in a wide range of industries, including medical, automotive, aerospace, electronics, solar, MEMS, data storage, and general manufacturing and precision machining. A 3D optical microscope has numerous advantages (discussed below) over traditional contact, stylus-based systems, which are still heavily used due to familiarity and simplicity.

Figure 1 shows the basic operation of Bruker's 3D optical microscopy instrumentation. First, incident light from a high-brightness LED source is split into two beam paths, one focused on the sample for inspection, the other reflected from a mirror. Then the two beams are recombined and focused onto a CCD. The resultant display is an extremely accurate 3D contour map of the sample surface based on the different optical paths the two original beams travelled. A typical production inspection instrument will also include a laser reference signal to provide constant calibration independent of environmental variations.

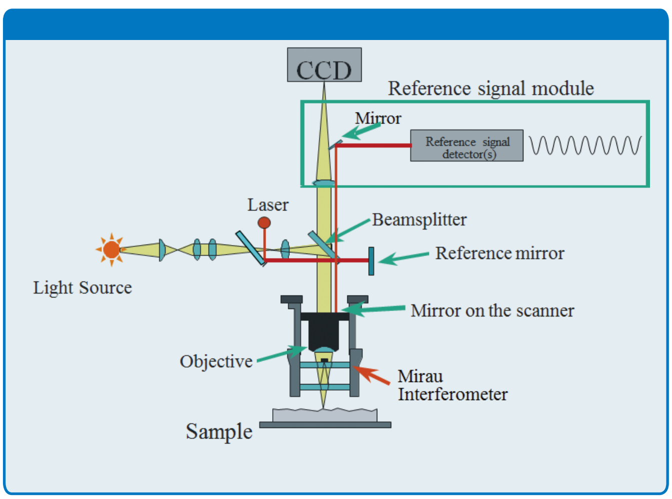

Figure 1. Schematic of a 3D microscope with a self-calibrating He-Ne laser.

3D Optical Microscopy Versus Stylus Based Techniques

Stylus profilometers have been a standard instrument for surface texture measurements in industry for decades. They are simple, robust instruments that record the vertical deflection experienced by a stylus as it is traced over a sample surface. The line trace that this produces can be used to validate surface characteristics, such as step heights, trace widths and trench depths. Also the roughness, waviness and form of that line can be reported.

Stylus profilometers suffer from a few inherent weaknesses. Since they are a contact-based technique, it is possible to damage/scratch a sample with the stylus. The stylus also acts as a mechanical filter, as a large stylus can not see fine details smaller than the stylus size on a sample surface. This in turn can lead to incorrectly reported parameters, such as an underestimated roughness. Another problem with stylus techniques is the validity of characterizing a surface based on a single line trace. To circumvent this problem, most commercial stylus profilers now have a 3D option enabling multiple line scans to be taken side by side to build up a 3D image. However, this can take a long time and is not practical for quality control of a large numbers of parts.

On the other hand, since 3D optical microscopy is a non-contact technique, there is no chance of sample damage. Furthermore, the lateral resolution is governed by the optics of the system, and at approximately 300nm, it is much higher resolving than typical stylus measurements. Vertical resolution is also improved, with a typical stylus instrument having a resolution of 100pm and a typical 3D microscope nearly an order better. Finally, the measurement technique is inherently 3D, acquiring the full array of a 480x640-pixel CCD in seconds. This would be equivalent to taking 480 parallel line scans with the stylus profilometer, which could easily take hours to complete. The provision of this rich 3D data set allows more meaningful analyses to take place that characterizes the sample surface more robustly than a single line trace. Some examples of measurements that are possible with a 3D microscope but impossible with a stylus instrument include, large step measurements, volume measurements, and defect finding within a region. For surface texture analysis, Bruker's 3D optical microscopes have the built-in capability to produce and database any of the ISO 25178 accepted areal parameters for standardized sample surface evaluation.

Quality Control – Automated Hip Cup Inspection Example

The most frequent orthopedic surgery is hip replacement. Components associated with this operation are therefore manufactured in the largest volumes. The tolerances on the components in terms of their surface finish, form, and material composition need to be strictly met. Thus, successful manufacture of hip cups requires rapid and accurate inspection.

A production floor instrument being used heavily for quality control is an entirely different situation from a research and development instrument being used in a laboratory. The

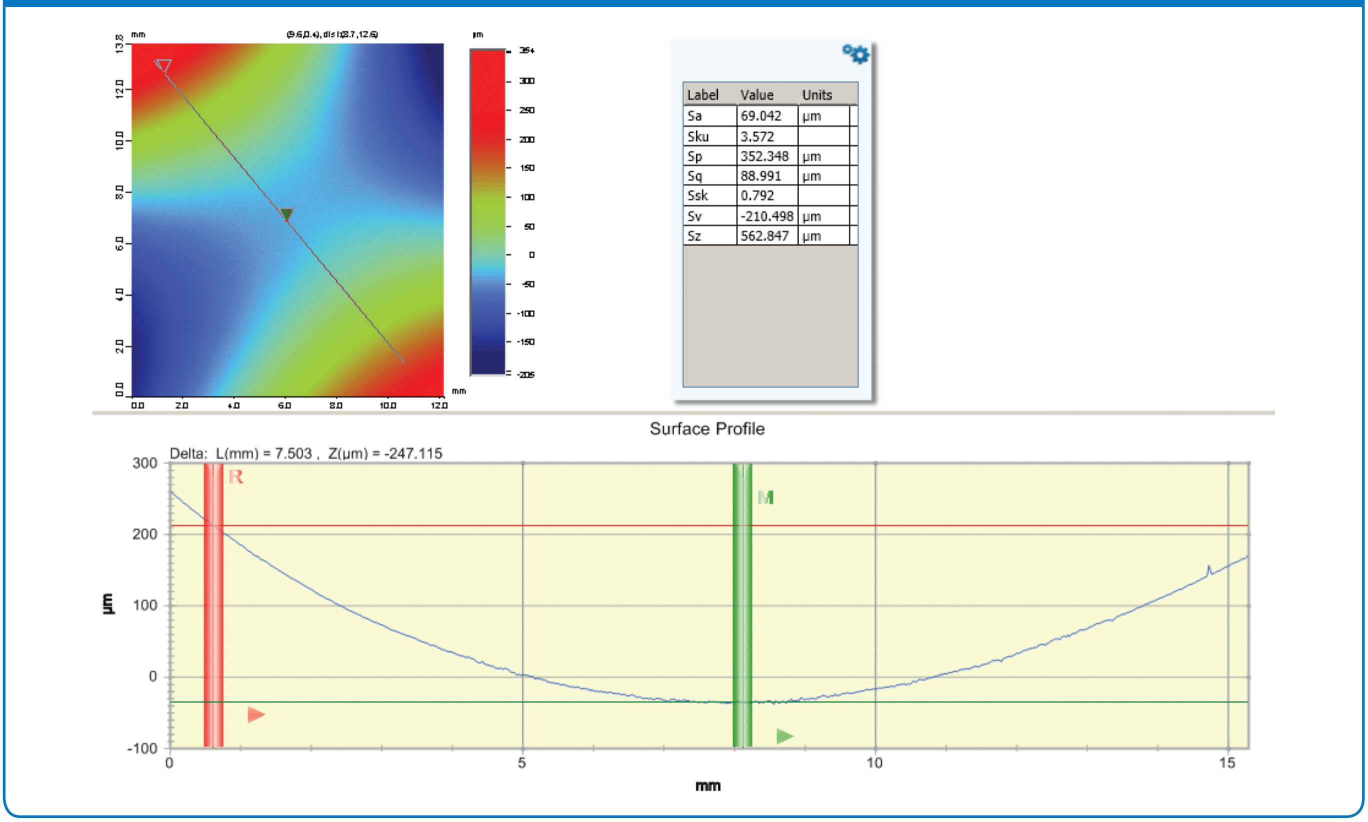

Figure 2. A 3D optical microscopy image of a representative polished surface. Below the image is a software cross section that is exemplifying a single line trace that would have been seen by a stylus profiler across the center diagonal of the image. The parameters on the right are areal roughness parameters based on the entire image dataset and compliant with ISO 25178.

latter usually has dedicated technicians that fully understand the technology and fine nuances of the software. On the shop floor, where there could be a number of different operators that will use the instrument as a black box, there must be a different approach to both instrument and software design.

In instrument design, Bruker's latest floor-standing NPFLEX™ and ContourGT® 3D optical microscopes include built-in vibration isolation, internal laser calibration, robust gantry designs to increase sample fixturing possibilities, crash mitigation systems, and ultra-long working distance objectives to collect data from difficult to access areas (i.e., inside small diameter hip cups). These systems also feature a production interface that is completely separate from the standard interface. Designed specifically to allow easy programming of measurement routines, this interface builds off of a generic production flow: operator loads part, instrument recognizes part and makes pre-determined measurements, pass fail results are reported and prompts for next batch are displayed. Minimal knowledge is required on the part of the operator and ease-of-use features, such as barcode scanning, can be easily implemented to enable keyboard-free measurements.

Consider this process with regard to hip cups. Typically, a hip cup is placed in a fixture or mount on the instrument to make sure the part is rigidly and correctly oriented during measurement. Next the part number of that cup is scanned or entered to access the associated measurement routine. The instrument moves the hip cup laterally to the point of measurement, using a motorized X-Y sample stage, then lowers the objective toward the hip cup until the central interior surface is in focus. The 3D dataset is taken and processed, typically removing a best fit sphere from the data and applying filtering in accordance with standardized surface texture measurement. Finally the roughness parameter is compared to the tolerance for that part and is passed or failed. A single measurement from scanning the part barcode to returning the part and passing/failing takes less than 30 seconds. It is an efficient process that allows large volumes of parts to be processed without hold up for downstream processes.

Research and Development – Designing Future Orthopedic Components

As mentioned previously, shop floor and research laboratory settings imply different users, different usage, and different samples. In the research laboratory, speed and throughput is not king. Accuracy and repeatability are still imperative, but much more importance is placed upon flexibility.
In an automated measurement the sample is a known quantity having a regular shape, definite measurement

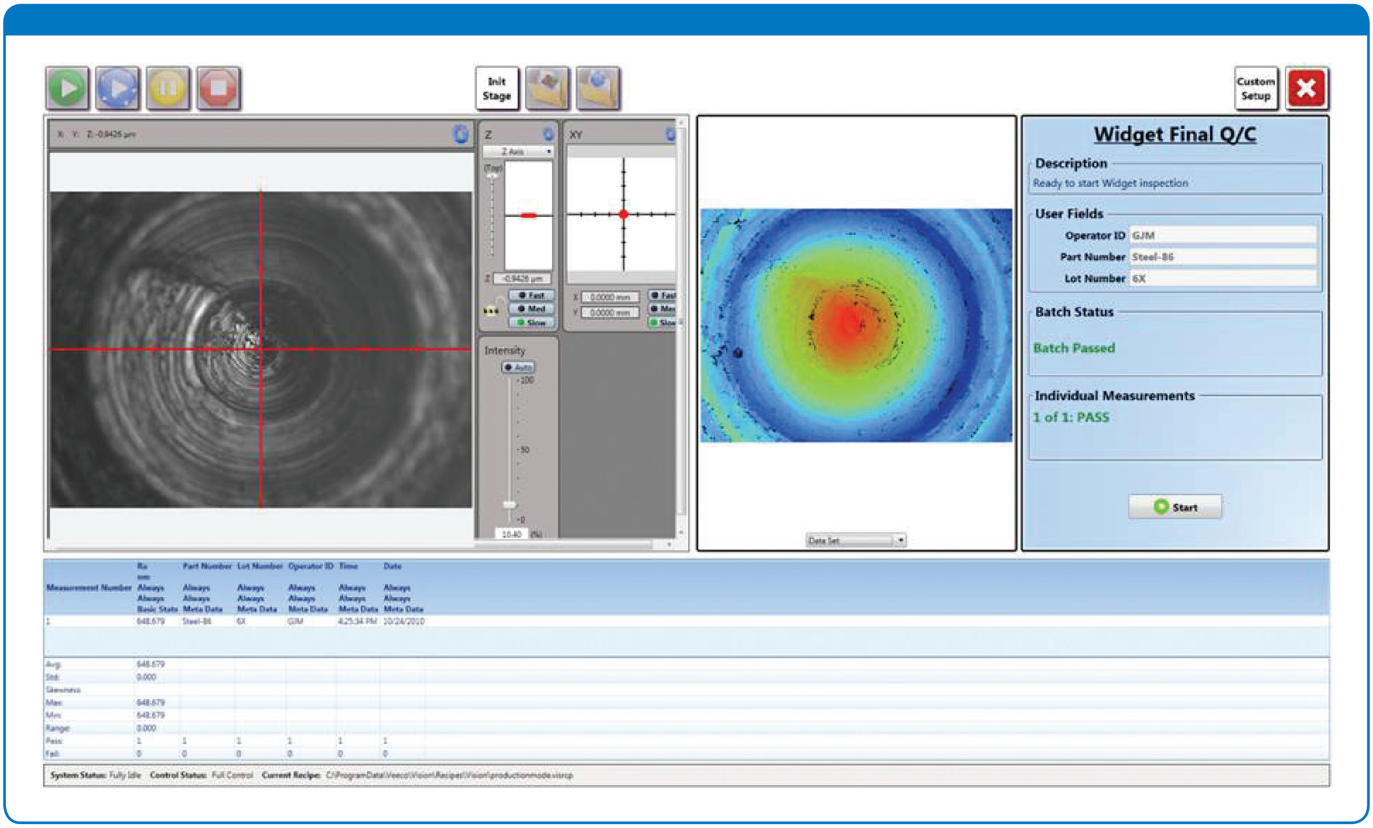

Figure 3. A screenshot of the production interface. The left side image shows the live video image from the camera. The right side shows the measured surface, as well as input fields for Operator ID, Part Number and Lot Number.

locations, and known material composition. In the research laboratory, novel materials may be tested based on some property that makes them better performing than current implant materials. The type of testing could also be more complicated than simple roughness inspection. For example, it could determine how the part wears over time, which could involve testing a newly made part, applying some accelerated aging process to it, then remeasuring and quantifying the difference. Another example could be qualifying a particular machining or texturing process that imparts structure to the implant surface to give it advantageous anchoring and long term rigidity in the body.

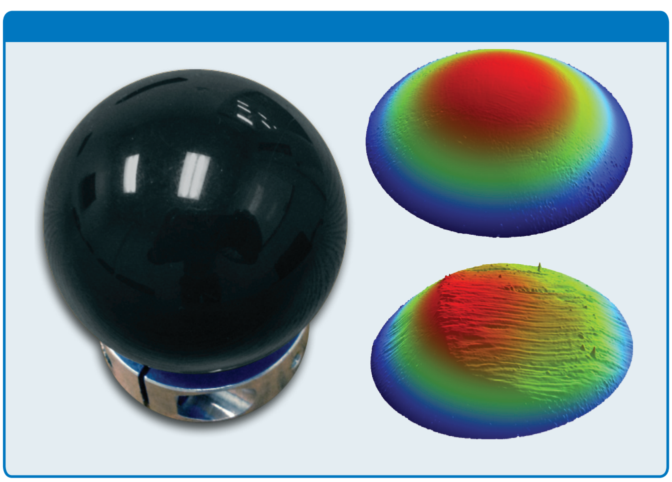

Figure 4. A triptic showing a PEEK (PolyEtherEtherKetone) sphere (left), the surface before wear testing (top right), and the surface after wear testing (bottom right). The images can be analyzed for volume of material lost, among other parameters.

For these types of evaluation, bench top ContourGT 3D optical microscopes and standard software interface provide all the researcher needs. One of the major benefits of the latest generation of ContourGT 3D optical microscopes is that the combination of high-brightness LEDs for the light source and high numerical aperture interferometric objectives makes obtaining data from various materials simple and straightforward, whether they be smooth and reflective, rough and non reflective, and even highly transmissive.

Returning to our hip cup example, but from a research and development viewpoint, hip implants are particularly prone to wearing mechanisms. Each implant assembly has a shell-like structure with femoral head in intimate contact with a liner, which in turn is in contact with an acetabular cup. It is known that various combinations of plastics, metals, and ceramics in contact can produce friction and debris, and that debris can cause inflammation of the tissue surrounding the implant. The wear and resulting inflammation can lead to osteolysis (bone destruction), pseudotumors, and even loud frictional squeaking due to ceramic-on-ceramic "stripe wear" patterns in limited cases. In all these cases, careful characterization of the wear and wear rate for the materials involved is critical to improving the long term performance and stability of these products. This type of information is readily attained using 3D optical microscopy. Figure 4 shows a sphere made of PEEK (PolyEtherEtherKetone), a thermoplastic with chemical resistance and mechanical properties that has led to its adoption as an advanced biomaterial in medical implantations. Here we show how we can measure the surface before and after wear testing to gain valuable insight into how it would perform as part of a working device.

Conclusion

Bruker's NPFLEX and ContourGT 3D optical microscopes provide versatile, rapid, non-contact characterization of surface finish and tribology in a wide array of applications for both the research laboratory and the production floor. The accurate and repeatable measurements this technology provides ideally suit the stringent needs of the orthopedics industry. The 3D datasets produced are often quicker to obtain than a single line trace from a contact stylus profilometer, and they contain much more valid data for surface characterization. The specific automation case presented demonstrates the capability of 3D optical microscopy to deliver simple, high-throughput, reproducible inspection of hip cups. The research-based case study demonstrates a highly accurate wear metrology solution tailored to the medical implant industry. In summary, 3D optical microscopy provides an excellent metrology solution for the full life cycle of orthopedic implants, from design, through manufacture to simulated wearing and aging of the product.

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