



## Application Note #551



### Using WLI to Characterize Roughness and Wear of Orthopedic Implants

Orthopedic implants vary largely in form. 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 parameters are also often exceedingly tight with deference to a component's functionality and longevity after successful surgical implantation. This application note discusses the advantages advanced optical profilometry provides for both research and development and quality control for orthopedic implants manufacturing. In particular, the benefits of Bruker's white light interferometry (WLI) technique include non-contact and non-destructive characterization, an insensitivity to material type, a large dynamic range to measure both very rough and very smooth surfaces, quick and accurate areal measurements, and the capability for complete automation to measure a batch of parts and to perform pass-fail summaries based on user-specified parameters.

#### The Need for Surface Texture and Roughness Metrology

Orthopedic parts are precision manufactured to very high surface and volume specifications under stringent normative regulations (e.g., ISO 7206, ASTM F2033, ASTM F2068, ASTM F2791, etc.). 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 strive to avoid a recall of a defective product, which incurs heavy financial burden as well as loss of reputation among both the medical community and the general population.

In addition to these critical "downstream" reasons for part inspection, the current volume of manufacturing combined with high yield expectation has led to a strong need for in-depth integration of metrology with production processes. For example, monitoring average surface roughness could help to reveal specification deviation or an incorrect polishing process. 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 (ROI) 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. Roughness and surface roughness are main criteria for quality control (QC) in the orthopedic industry.

### Advantages of Bruker's WLI-Based Profilometry

Besides delivering the obvious benefits of non-contact profiling that are mandatory for most of the final control in orthopedic manufacturing, Bruker's WLI-based 3D optical profilers have provided the industry with unique performance advantages for roughness characterization. The basic principle behind these systems consists of illuminating the sample/part surface with white light through an interferometric objective, directly providing sub-nanometer vertical metrology capability independent from the magnification of the objective in use. This approach is also immune from surface reflectivity or color, allowing the effective measurement of shiny or dark surfaces. Finally, as with any optical microscope, WLI profiling visualizes a full field of view of a couple millimeters square at low magnification while reaching sub-micron lateral resolution at higher magnifications. Getting full areal measurement not only ensures more relevant statistical data but also reduces the chance of missing critical defective areas, as illustrated in Figure 1.

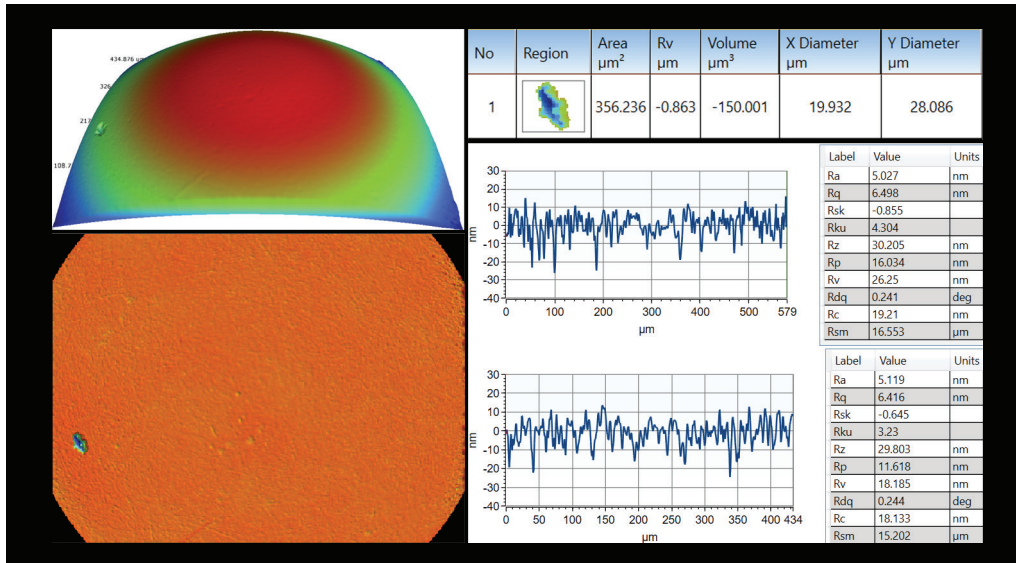


FIGURE 1.

Where a few single traces on a hip ball cannot properly identify the pit defect, areal measurement allows automatic defect detection and characterization of its severity.

These advantages, combined with the ability to automate the measurement, make this type of WLI profiler the best selection to assess the quality of roughness in the final finishing steps of polishing a hip ball with mean roughness well below 10 nm or on a carbon-reinforced PEEK hip cup. The WLI approach provides high-lateral-resolution mapping of the surface topography that complies with areal roughness standard ISO 25178 and surface finish requirements from ISO 7206-2 (see Figure 2).

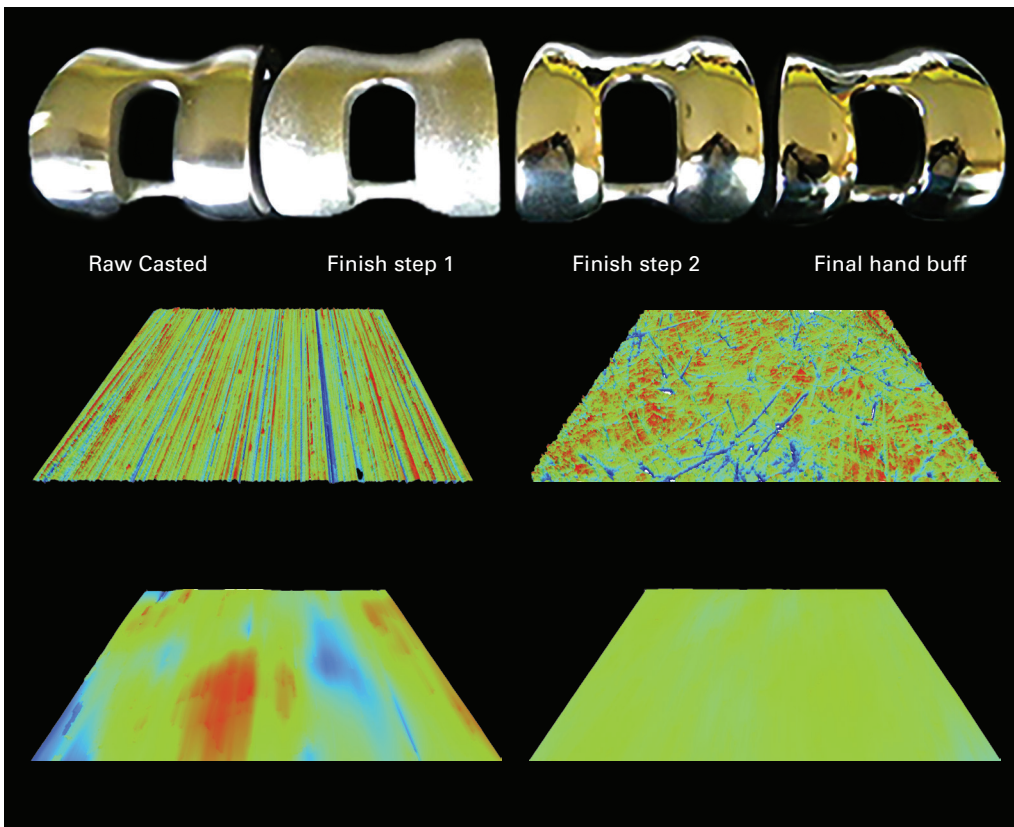


FIGURE 2.

(Top, from left to right) Raw casted, initial and final finish steps. (Bottom) Associated topographies with same vertical and horizontal scales: XY=1.6\*1.2 mm<sup>2</sup>, Z=[-2 μm; +2 μm].

The less known subsequent benefits enabled by Bruker optical profilers' implementation of WLI include the combination of high throughput with the ability to operate with long-working-distance objectives. The high throughput is linked to the imaging array and multiple data sets captured in a single vertical scan. Measurement cycles, including auto-focusing on the surface, can be as fast as a couple of seconds for 100% inspection. Finally, contrary to any other optical technology, these WLI profilers decouple vertical resolution from the objective magnification, leading to ultimate subnanometer vertical resolution for all objectives (see Figure 3). Bruker further enhances this unique benefit by designing super-long-working-distance (SLWD) objectives that expand capability for users to access curved hip cup surfaces or the sides of knee joints. This is even further advanced with the large swivel-head feature of the NPFLEX optical profiler.

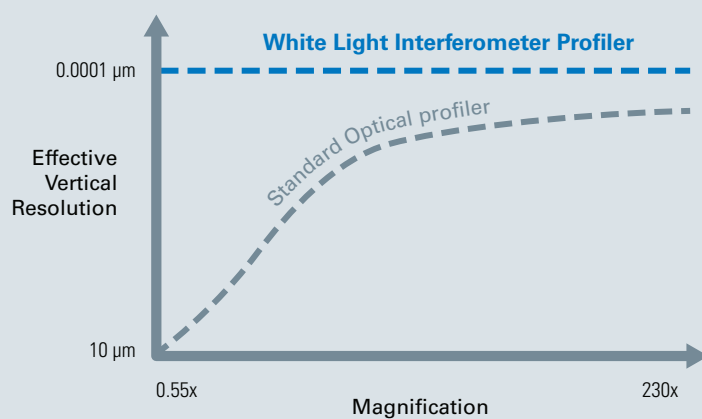


FIGURE 3.

Versatile access to complex parts without compromised vertical resolution is enabled through Bruker's unique SLWD objectives and the ±45° large swivel scan head feature of the NPFLEX WLI profiler system.



## Quality Control – Automated Hip Cup Inspection

For production floors, Bruker’s NPFLEX and ContourX WLI profilers are specifically designed to provide precise quality control of roughness with built-in vibration isolation, rigid-body for metrology stability, multiple sample-fixturing options, crash mitigation systems, and super-long-working-distance objectives to collect data from difficult-to-access areas. Optional internal laser calibration can further aid reliable metrology by ensuring self-calibration at all times and improving profiler-to-profiler matching at the same or different factory locations. The ability to flag when a profiler is out of calibration is critical for medical parts, where metrology traceability is part of quality standards.

These systems also feature a dedicated production interface that is completely separate from the standard interface. The production interface is specifically designed to allow easy programming of measurement routines, and builds off a generic production flow: operator loads part, instrument recognizes part through lot or part ID and makes pre-determined measurements, pass/fail results are reported, and prompts for next batch are displayed (see Figure 4). 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. Barcode reading can also help in setting up access control by specifying authorized operator via user-ID input. Meanwhile, the standard interface is locked by a security password, only granting access to the quality engineer to build specific recipes or run/access certain functionalities (e.g., profiler calibrations).

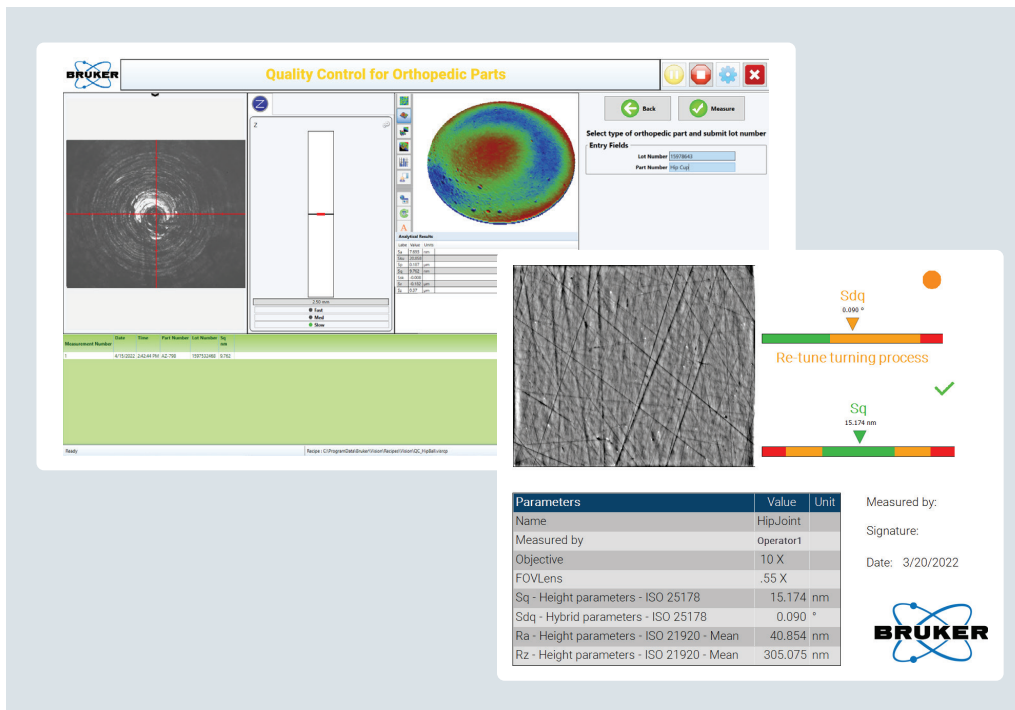


FIGURE 4.

Advanced Production Interface and an example of automatic report generation.

As an example, one could easily make a process to measure the concave surface of hip cups. Typically, the hip cup would be 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 would be scanned or entered to access the associated measurement routine. Then the instrument moves the hip cup laterally to the point of measurement, using a motorized X-Y sample stage, lowering the objective toward the hip cup until the central interior surface is in focus. This is all done without the need for user intervention. The full field-of-view topography is automatically taken and processed, typically removing a best-fit sphere from the data, and filtering is applied in accordance with areal (ISO 25178) or profile (ISO21920, ASME B46.1) roughness standards. Finally, the roughness parameter is compared to the tolerance for that part, and it is passed or failed. A full report can then be printed or automatically saved, using the part number as filename. A single measurement, from scanning the part barcode to pass/fail determination, can take less than 30 seconds. It is an efficient process that allows large volumes of parts to be measured without holding up downstream processes.

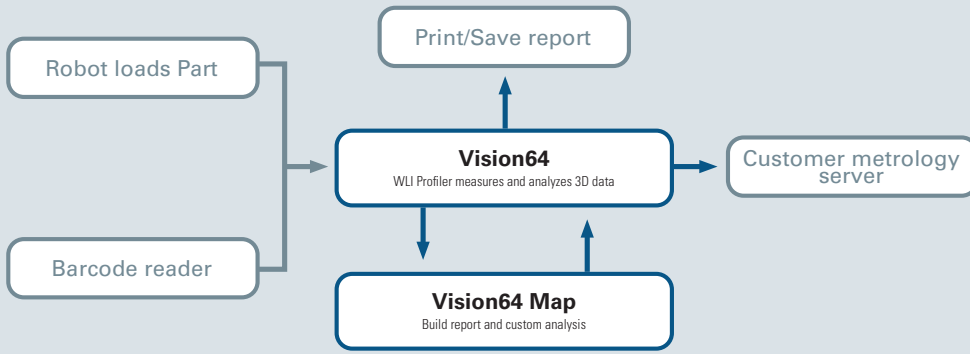


FIGURE 5.

Schematic of the integration between external devices and the Bruker measurement system.

More advanced processes can incorporate the use of a robot to load parts, as well as direct result communication to a central Statistical Process Control (SPC) server. Bruker Vision64® software already provides the necessary channels to combine with high-end automation, such as Industry 4.0, by providing TCP/IP-level commands for acquisition control by third-party software and generic Comma Separated Variable (.csv) file output for results. Comprehensive interaction channels are shown in Figure 5. Besides external interaction, Vision64 software enables recipe transfer between multiple Bruker WLI profilers, supporting export/import function for seamless spread of newly built recipes. It also sustains reproducible measurement conditions through automatic light adjustment via pre-intensity calibration, or fixture alignment, accounting for any XY position offset.

### Research and Development — Designing Future Orthopedic Components

As mentioned previously, shop floor and research laboratory settings imply different users, usages, and samples. For example, speed and throughput is not as key a requirement in the research laboratory. Regardless of settings, utmost accuracy and repeatability are still imperative, with an added importance placed upon flexibility.

In an automated measurement, the sample is a known quantity having a regular shape, definite measurement locations, and known material composition. In the research laboratory, novel materials may be tested based on a 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, the testing 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/to long-term rigidity in the body.

For these types of evaluation, Bruker's benchtop ContourX optical profilers and standard software interface provide all the researcher needs. One of the major benefits of the latest generation of ContourX WLI profiler 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, or even highly transmissive. External illumination, together with advanced live-signal processing also brings unique capability for a researcher to overlay high-resolution topography with all-in-focus intensity images to further investigate cross-correlation between reflectivity and potential defects, or simply to create better visibility of represented data. The same setup helps navigation through samples, revealing slopes and underlying details while using the same interferometric objective.

Bruker also provides an easy-to-use interface (VisionXpress™) that provides users comprehensive and flexible control over the optical profiler (see Figure 6). This is important in R&D environments where researchers must deal with a wide range of characterization techniques. Finally, Bruker’s unique Universal Scanning Interferometric (USI) mode ensures that the system, irrespective of the sample/part surface or operator experience, automatically adapts and selects the best algorithm to ensure accurate results.

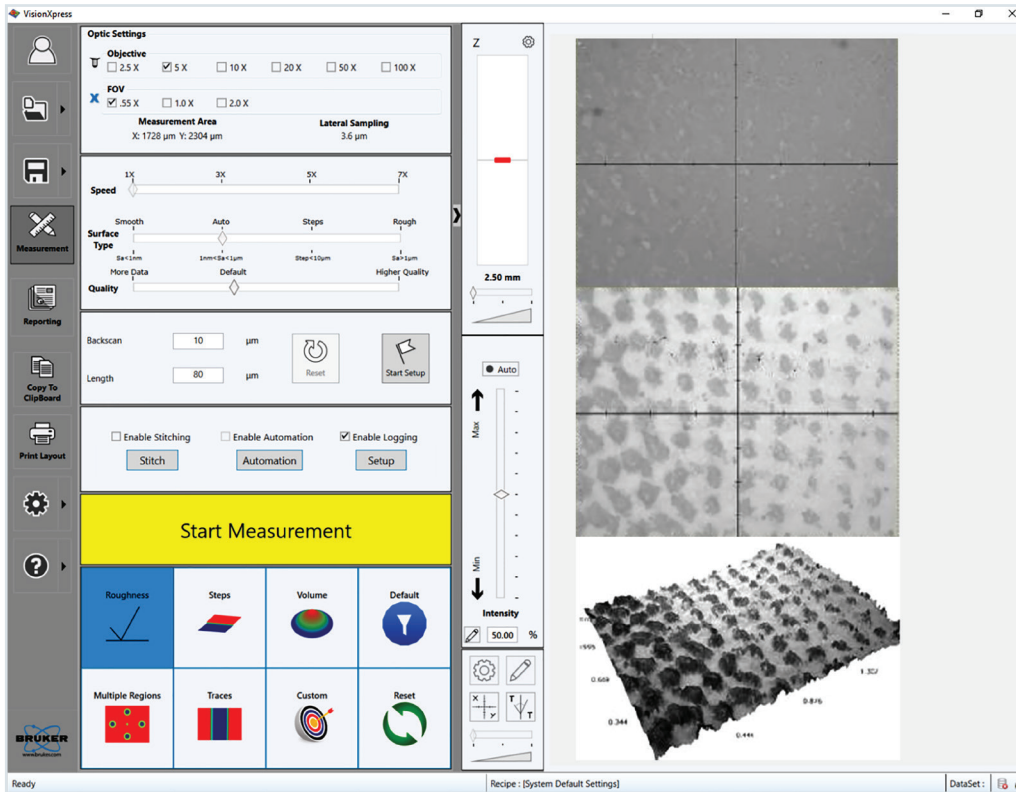


FIGURE 6.

(Left) The VisionXpress interface enables a fast learning curve and flexibility of analysis. (Right, from top to bottom) Live image without external ring illumination; with external ring illumination; and the final 3D representation with an overlay of the all-in-focus intensity image.

Applying these benefits to our hip cup example, but from an R&D viewpoint, one could investigate the wearing mechanisms to which these implants are particularly prone. Each hip cup implant assembly has a shell-like structure with the 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 in limited cases, loud frictional squeaking due to ceramic-on-ceramic “stripe wear” patterns. 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 Bruker’s 3D optical profilometers.

Figure 7 shows a sphere made of PEEK (PolyEtherEtherKetone), a thermoplastic with chemical resistance and mechanical properties that have led to its adoption as an advanced biomaterial in medical implantations. Using WLI and Bruker's profilometer technology it is easy to perform before and after wear testing to gain valuable insights into how this material would perform as part of a working device.

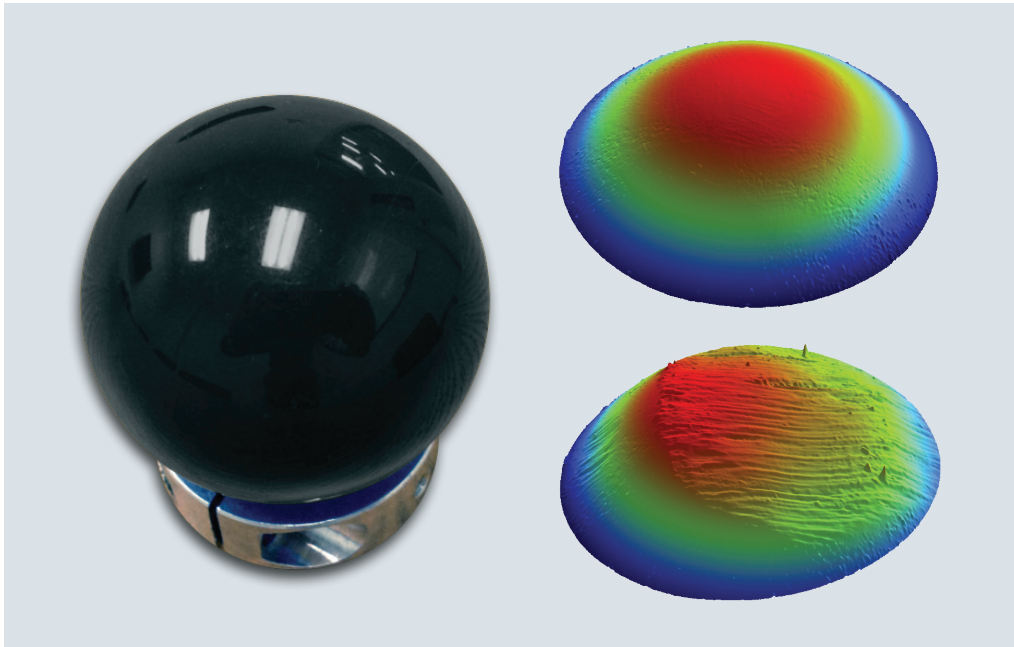


FIGURE 7.

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.

## Conclusion

Bruker's NPFLEX and ContourX WLI optical profilers 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 are well suited for 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 statistically significant data for surface characterization. The specific automation discussed demonstrates the capability of these 3D optical profilers to deliver simple, high-throughput, reproducible inspection of hip cups. The research-based example demonstrates a highly accurate wear metrology solution tailored to the medical implant industry. In summary, Bruker's 3D WLI-based optical profilometry provides an excellent metrology solution for the full life cycle of orthopedic implants, from design through manufacture to simulated wearing and aging of products.

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