Making Better Medical Devices with Multisensor Metrology

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Multisensor metrology is becoming a preferred quality control technology for manufacturers to develop, maintain, and improve the quality of medical devices.

Articles about multisensor measurement machines often explain the types of sensors available and what they do. In all cases, measuring sensors acquire data points from a part under test. Those data points are used in the system software to determine geographic relationships that are compared to the part design drawing. Some sensors are more efficient than others at acquiring data points from certain areas on, across, or within a part. This article describes sensors in the context of medical devices, but it goes a step further by describing what can be done with the clouds of data points acquired by any or all sensors on a multisensor measurement machine. Since the goal of any measurement is comparison to the design drawings, a 3D fit of all the data points compared to the CAD design data can actually make decision-making based on large sets of data points easier than interpreting printouts of individual measured values. Although it may seem counterintuitive, using multiple sensors to get lots of data can actually make decisions about parts and processes easier.

Specialized parts demand specialized measurement

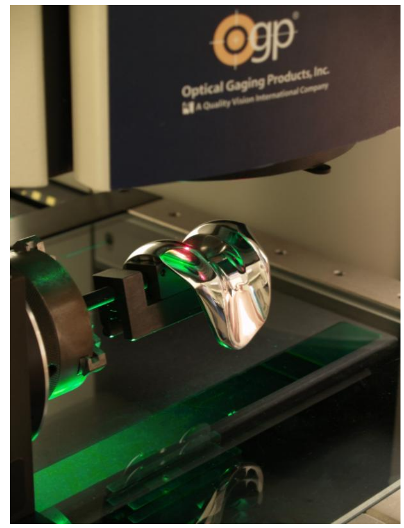
Medical devices and their component parts are usually extremely specialized in form and function. For example, they may be very small, like the parts that form middle ear prostheses for ENT applications. Regardless of size, medical device parts are also almost always fabricated to extremely tight tolerances. Measurement systems that characterize these medical device parts must be capable of high precision, often to the submicron level.

Orthopedic implants, such as prosthetic hip ball joints, or tibial and femoral knee and ankle implants, are a challenge to measure accurately. The surfaces that define their shape are higher-order curves made up of Non-Uniform Rational B-Splines (NURBS) or point coefficients. The forms they embody are often variable and organically curved, because the parts must fit with mating prosthetic parts and even mate with parts inside the human body. Their complex 3D curves make it difficult to measure all surfaces from a single direction, making it simply impossible for certain types of sensors to measure them.

Video-based measurement systems are well suited to measure prismatic parts, which by definition contain intersecting planes. Where planes intersect, there are edges, and edges are easy to measure with video. Orthopedic implants, however, are often made up of regular continuous curves (hip components) or complex contouring surfaces (knee components) — shapes that mimic the organic contours of natural body parts. These types of surfaces have few or no planes or intersecting edges. Since video sensors excel at measuring edges, video measurement of these parts would be limited to widths of outer edges illuminated from behind. Video can measure surface points, but using multiple focus points to gather enough data to support even a linear section of a contoured surface would be laborious and impractical. A touch trigger probe would have a similar limitation because each single point requires approach, trigger, and back off — possible but impractical in a manufacturing environment.

A case in point - measuring a replacement knee

A good way to verify that the organically curved profile of a replacement knee matches its design is with a laser. Laser sensors in multisensor systems work by projecting light towards a surface, collecting the reflected and/or scattered light on a dedicated sensor, and automatically calculating the distance of a measured point between the laser and the part in 3D space. Laser measurement can be accomplished for a single point, or alternately a series of data points can be gathered and calculated as the part is translated beneath the laser or the laser is moved over the part. The point spacing and sampling rate can be user-specified. Metrology software continuously calculates the distance between the laser and the part surface as the laser beam moves across the part, keeping the laser sensor within its capture range through closed-loop positioning of the multisensor system's Z-axis stage control. By keeping the laser sensor within its capture range, precise point positions can be collected quickly. Laser focus is faster and more accurate than video autofocus, and since it is non-contact, it avoids potential damage to the part surface and contamination of sterile parts.

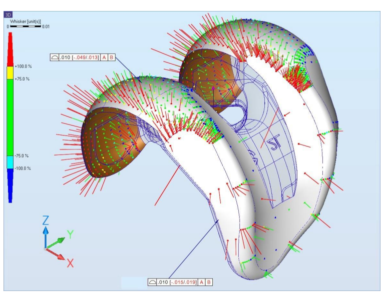


A prosthetic knee mounted to a rotary indexer being scanned by a laser sensor on a multisensor measurement machine.

In most instances, the user may not be able to fixture the knee replacement to assure a direct line of sight between all its critical surfaces and the laser sensor. In those cases, mounting the replacement in a rotary indexer may provide a solution, as well as an opportunity to speed measurement throughput by eliminating multiple positional fixtures while cutting down on manual part handling. Typically a datum is established from surfaces on the back of the knee with a touch probe. Then, the rotary indexer rotates the knee replacement to present its desired surface to the laser sensor for measurement. Since the opposite side of the measured surfaces defines the datum, it is imperative that the metrology system be equipped with fully 3D-capable metrology software that rotates the coordinate system when the indexer rotates. In this way, every data point captured by the laser can be tracked in 3D space by the metrology software, regardless of the rotary indexer position.

A different method of measuring the complex contours of a prosthetic knee implant is with a multisensor system equipped with a Renishaw® SP25 scanning touch probe. Like the laser, the user specifies start and end points for the scan on the knee replacement, but in this case, the probe tip maintains constant contact with the implant surface as the system moves it along the part surface acquiring data points as it goes. Unlike touch trigger probes that must approach the surface, trigger, then back off, the SP25 scanning probe maintains constant contact. As with a laser, the data point density and scan rate are user-definable. The multisensor system must be configured for the SP25, and also must be equipped with 3D-capable metrology software to track the data points in XYZ space.

There are other ways to measure a knee replacement that is fixtured in a rotary indexer. As mentioned above, a linear laser or contact probe scan can be performed across the rotary-fixtured knee's top surface. Since such a line scan represents a section across the 3D part, that section may be measurable as an edge using a video sensor. By rotating the knee 90°, that "section" becomes a distinct edge when the part is illuminated from behind. This technique requires a good metrology lens system that has a long working distance and limited influence from the knee's steep surfaces. Since the "section" is larger than an optical field of view, functions such as "Edge Trace" are good for this application where the system automatically follows the edge over multiple fields, acquiring points at each position.



A GD&T analysis of a point cloud of data from multiple laser scans of a prosthetic knee showing deviations from the CAD model.

When mounted in a rotary indexer, the knee's entire surface can also be measured by rotating it incrementally, a few degrees at a time, and performing multiple linear scans (or edge traces). With tight point sampling density, the collection of all the points from these multiple scans will yield point clouds of data. These point clouds can be imported into 3D-capable fitting software, which, by knowing the center of rotation, can show how all the part data coincide with the CAD model of the part. Some fitting software even has the capacity to perform a GD&T analysis of the point cloud data satisfying simultaneous requirements, and showing graphically any deviations from the design file. Not only can this information be used for acceptance testing of each part, the manufacturing engineer can use the information to make changes to manufacturing processes to enhance accuracy and/or efficiency for subsequent parts.

GD&T analysis of point cloud data could potentially support a critical conclusion that would not be immediately obvious otherwise. For example, point cloud data may show that two perpendicular linear laser scans are within spec, but GD&T analysis of the both of those scans taken as a whole, may show the entire part to be out of tolerance.

A custom video solution

At the other end of the spectrum of medical devices, seemingly simple plastic syringe bodies require numerous dimensional measurements. Sometimes a custom solution is the best way to measure batches of medical device parts like this. As a minimum, the length and outside diameter of each of the tubular syringes is measured. This could easily be accomplished by fixturing a syringe horizontally on the stage of a multisensor system, backlighting it, and using a video sensor to measure the edges that define its outer diameter and length to determine the distance between those edges. (See Fig. 1) The syringe bodies could be measured one at a time as shown here, but could be more efficiently measured if mounted in a multi-part fixture, better supporting production volumes and lowering the cost per syringe.

The above solution works for the outer cylinder, but for these parts, diameters are important too. Video measurement of these perpendicular diameters cannot be gathered while the syringe body is in a horizontal position. The user could re-mount the syringes vertically in a separate fixture, but that would add parts, labor costs, and time to the process. It would also be possible to mount each syringe, one at a time, on a rotary indexer. That way, the length and outside diameter can be measured with the syringe body in one position, then rotated 90° so its important diameters can be imaged and measured. (See Fig. 2) This would automate the measurement process, but again it is not efficient. Each syringe body must be loaded and unloaded, and measured one at a time, and indexer rotation takes time, too.

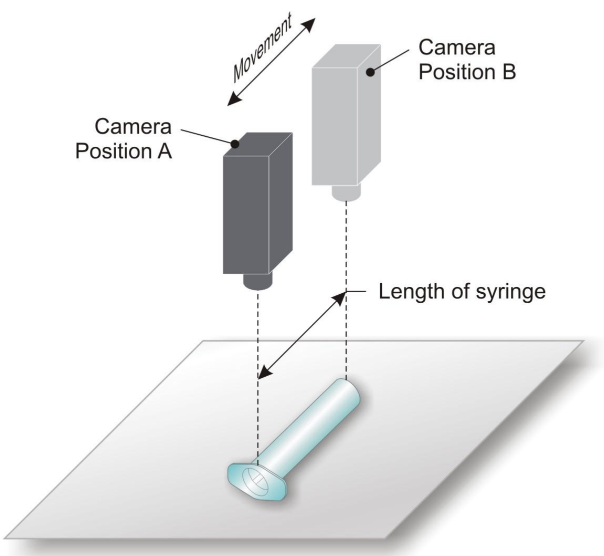


Fig. 1: Video measurement of the OD and length of a plastic syringe body.

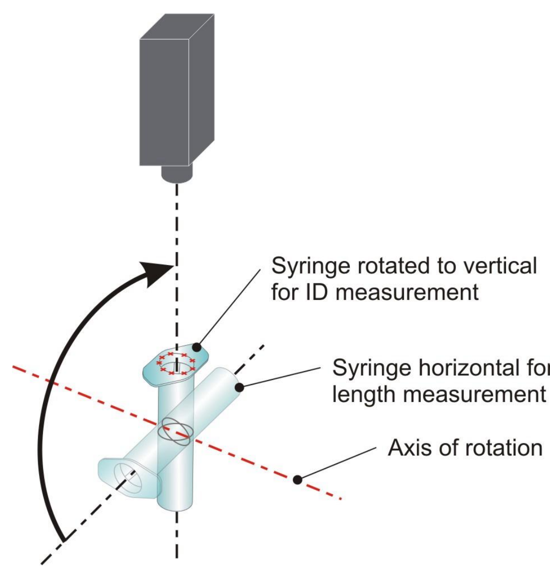
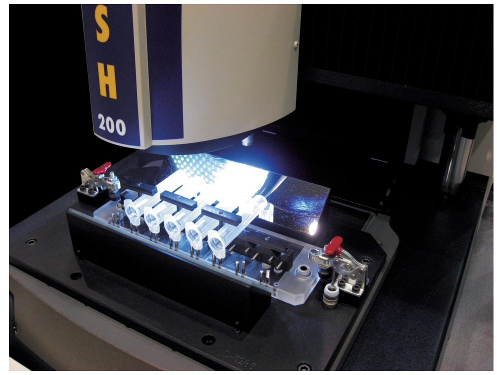


Fig. 2: Video measurement of the diameters of a plastic syringe when rotated 90°.

A specially designed multi-part fixture solves this measurement problem. With syringes mounted horizontally relative to the video optics (in the system's XY plane), a 45° mirror could allow direct imaging and measurement of the diameters with the part in a fixed position. By fixturing a number of syringe bodies side by side, the video optics can perform all the measurements with quick XY position moves and autofocus. A part routine created for one syringe can easily be copied and reused for all others to speed throughput, and since video measurement is non-contact, potential part deformation of the soft plastic syringe bodies will not be a problem.

This custom video measurement technique will only work if the video sensor optics have a long enough working distance to focus on the part after reflecting the imaging path. As an optical technique, this type of fixture can work with a TTL laser measurement sensor. Like the optics, the TTL laser would require a long working distance, as well as minimal beam triangulation. Some through-the-lens laser systems, particularly the TeleStar® TTL lasers from Optical Gaging Products (OGP®, Rochester, NY), fulfill those requirements.



A multi-part fixture with fold mirror for measuring all the dimensions of several plastic syringe bodies in a single setup.

The name of the game

Medical device manufacturers are required to have documented, controlled manufacturing processes that include the inspection equipment used for quality control and monitoring. Multisensor measurement systems are capable of verifying many of the important dimensions of medical devices quickly, accurately, and with minimal part handling — this article has presented only two examples of the myriad of medical devices currently measured by multisensor systems. Verifying that manufactured parts meet design specifications is the name of the game. The final outcome affects the health of medical device manufacturers' balance sheets — and ultimately, the health of the patient.