Volume 8 Issue 3 | Fall 2009

# BONEZONE

STRATEGIC SOURCING FOR THE ORTHOPAEDIC INDUSTRY

An ORTHOWORLD Publication
www.orthoworld.com

**Greg Hetland, Ph.D.**
*International Institute of GD&T*

# Mechanical Precision of Medical Components Achieved with Profile Tolerancing

Medical components are increasing in their complexity of surface geometries and decreasing feature tolerances, both of which drive the need for unprecedented precision in product design definition and identify profile tolerancing as the *key* solution for dimensioning and tolerancing practices for mechanical and electro-mechanical components and assemblies.

Conventional plus and minus tolerancing approaches result in product specifications with hundreds of individual dimensions that often fail to analyze the relationships between those dimensions. The application of profile tolerancing provides a solution that significantly improves precision measurement in manufacturing and metrology while significantly reducing costs and lead times and better conveying initial design intent.

Exhibit 1 is a solid model of a cervical plate that represents typical complex surface geometries. The features on this part represent a collection of small arc radii and are used within this article to demonstrate the tremendous value and precision of profile tolerancing.

***Exhibit 1: Solid Model of Cervical Plate with Typical Complex Surface Geometries***

**Risk to Medical Industry**
Smaller parts, tighter tolerances and more complex features make it mandatory for components and assemblies to be defined with a precision language to ensure that the functional intent of the design is met. Without utilizing this precise language, the medical industry is at a high risk of component and product failures. On the one hand, the inspection results can look good and the product still fail or in the other, the results look bad and the product can still work. In either situation, the features being examined did not address the design functionality of the component. A valid 3D analysis forms the basis for engineers to justify and validate their component's compliance. Individual feature tolerances are essential inputs to sub-assembly and full assembly analysis. The results of this analysis form the justification and traceability required by designers to ensure that components and assemblies meet their functionality and reliability requirements.

The ability of customers and suppliers to communicate in this language is the basis for meeting the terms of the contracts that bind them. Customers order component parts from suppliers with the expectation that they have trained staff to interpret and ensure compliance to the requirements, while suppliers expect their customers to communicate their requirements in a manner that facilitates manufacturing and quality assurance. Training in the higher precision language is the key for both parties.

**Implications to Technology Roadmap**
Another implication of smaller parts, tighter tolerances and more features is that manufacturing capability and measurement capability must improve at the same rate. It's common throughout industry for customers to request statistical data from suppliers and use this data to evaluate the supplier's process capability. This can take the form of capability indices such as Cpk and measurement capability such as Gage Repeatability

and Reproducibility (GR&R). One challenge with both of these methods is that they are a result of the initial design specification tolerance.

The following illustrates the effects a 6-sigma design tolerance has on manufacturing, measurement and calibration (Shown as 1-sigma values based on ratios.) using a common linear tolerance of +/- 0.05 mm (Profile of 0.1 mm).

<u>Scenario Based on Design Specification of +/- 0.05 mm</u>

- +/- 0.050 mm (.002 in) = Design specification
- +/- 0.008 mm (.000330 in) = Manufacturing requirements at 6:1 ratio (6 sigma)
- +/- 0.002 mm (.000083 in) = Metrology requirements at 4:1 ratio
- +/- 0.0005 mm (.000021 in) = Calibration requirements at 4:1 ratio

The above example highlights the critical need for all designers to aggressively ensure that drawing callouts optimally reflect functional intent, and tolerances are optimally derived based on sound 3D tolerance analysis principles. A seemingly wide open 0.050 mm design tolerance produces calibration activities with required uncertainties over 100 times greater than the initial design tolerance. What this example also highlights is the need for manufacturing and quality to provide feedback to design for optimization and potential re-distribution of tolerances on interacting features and components. If all three disciplines are not communicating effectively, the result will be increased cost and lead-time.

The precision language of profile tolerancing is explicitly defined in the ASME Y14.5M-1994 Standard on Dimensioning and Tolerancing, and is mathematically complemented by the ASME Y14.5.1M-1994 Standard on Mathematical Definition of Dimensioning and Tolerancing Principles. Both of these Standards form the basis for precise definition of complex surface boundaries and should be the basis for 3D tolerance analysis for designers and also 3D precision measurement analysis for physical metrologists.

**Designers' Criteria and Method of Documentation**

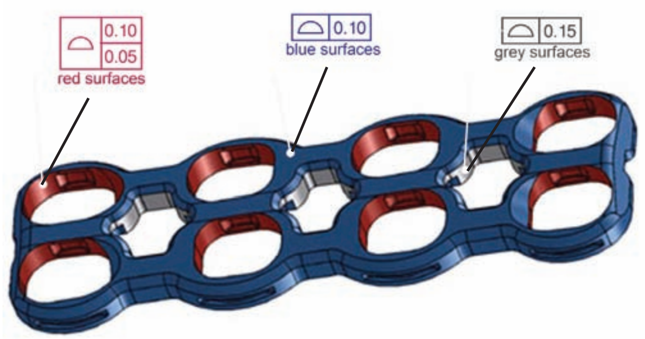
Designers' expectations dictate that all variations on the surfaces of component parts lie simultaneously within a uniform boundary. While the allowable variation of these boundaries, also known as tolerance zones, might vary from one surface or set of surfaces to another, they are all still expected to meet those requirements.

Profile tolerancing has the ability to control all aspects of the physical surface geometry, including size, form, orientation and location of any and all surfaces. Profile tolerancing also has the ability to control each of these parameters independently when required to constrain or relax the feature or set of features as necessary to optimally represent the functional intent.

Designers must specify all requirements through a precise engineering language and communicate these requirements through a mechanical drawing or electronically through the 3D CAD model and a minimally dimensioned drawing per ASME Y14.41-2003, Digital Product Definition Data Practices.

Exhibit 2 shows an engineering drawing that depicts profile tolerancing of all 3D surfaces being fully defined with three explicit profiles of surface callouts per the ASME Y14.41-2003 Standard.

***Exhibit 2: 3D Engineering Drawing Example per ASME Y14.41-2003***




*Note: Unless otherwise specified, all dimensions are basic and controlled by the CAD model.*

Once documented effectively by the designer, it is expected that manufacturing and quality engineers will be able to interpret these engineering requirements precisely to manufacture and inspect the component parts to ensure compliance with all requirements. Precision measurement science practices are used to determine how much variation is truly being used and to provide precise measurement data back to manufacturing and design for review and optimization. Lack of precise measurements will result in bad technical and business decisions, leading to negative cost, lead time impacts and product and reliability performance issues.

Ideally, this communication will be accomplished using the same optimized CAD model so additional errors are not propagated throughout manufacturing and quality. As design and manufacturing require highly confident measurement data to make technical and business decisions, it is essential that we focus attention on precision measurement and what it takes to provide precise measurement results.

**Criteria for Precision Measurement**

Precision measurement requires high confidence that the measured results reflect differences between *parts* and not differences due to errors of measurement. To accomplish this, the metrologist must ensure the following:

1. Clear definition of the specification requirements per ASME Y14.5M-1994 or applicable standard.

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a. 3D surface geometries to be defined using profile tolerancing.
b. 3D axes control to be defined using position tolerancing.

2. Qualified metrologists perform the required tasks at a sufficient level utilizing the proper measurement instruments, sensors, procedures and software. This knowledge base must start with a clear understanding of the applicable standards and be solidified with high competency in precision measurement, including in-depth knowledge on the measurement instruments, sensors, procedures, analytical software and statistical analysis methods.

3. Precise measurement instrument capable of measuring the feature.
   a. Placed in an environment conducive to the level of precision measurement required.
   b. 3D Parts require 3D measurement unless otherwise defined per engineering specifications. Anything less should be considered a rough check and does not have the ability to ensure full compliance to stated engineering requirements.

4. Sound measurement procedure that will ensure true characterization of the feature.
   a. Holding fixture and devices as defined per the engineering specifications.
   b. Sufficient point densities to ensure positive characterization of the feature. Point densities are critical to characterizing the total manufacturing variation, and it is insufficient to take minimal points if the metrologist does not have previous knowledge of the part or process to justify a reduction in points taken on the surface.

5. Robust measurement software capable of completing the analysis per the defined standards such as ASME Y14.5M-1994 and ASME Y14.5.1M-1994 or other applicable standards. Software such as SmartProfileTM developed by Kotem Technologies that defaults to the ASME Y14.5.1 Standard. This software has been extensively tested with mathematically defined datasets for Profile and Position Tolerancing with and without datums and fully invoking the rule of simultaneity. A word of caution: The majority of coordinate measuring machines (CMM) software used in all industries currently default to using least-squares fitting algorithms, which simply means they are averaging the measured results.

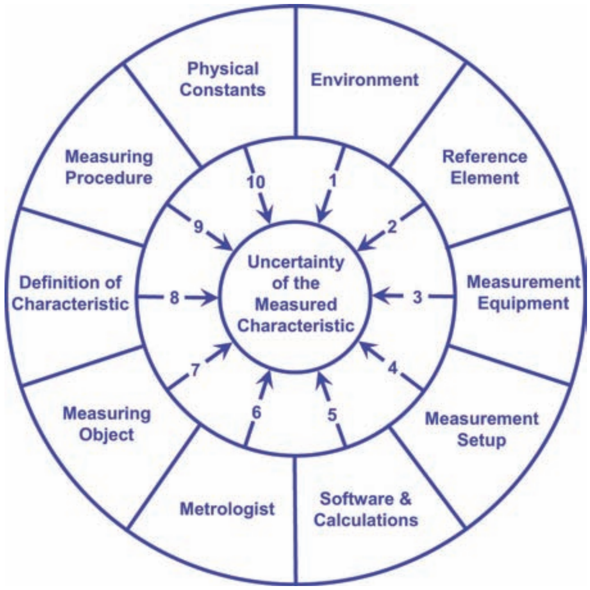
6. Proper analytical methods for evaluating the uncertainty of the measured results. ASME B89.7.3.2 technical report provides Guidelines for the Evaluation of Dimensional Measurement Uncertainty and is a simplified guide for metrologists to evaluate all the contributing factors that influence the measured result.

The above should be considered a beginning list of requirements the metrologist should consider when developing an inspection plan. For insight to inspection planning, users can reference ASME B89.7.2-1999, Dimensional Inspection Planning, which provides guidance for ensuring compliance with requirements.

**The Wheel of Uncertainty**

Many error sources must be considered by the metrologist when measuring parts. Exhibit 3 shows a wheel of uncertainty contributors which depicts categories of inherent error sources that should be a minimum consideration by the metrologist.

***Exhibit 3: Wheel of Uncertainty Contributors***




Companies using only GR&R as their basis for measurement systems analysis would be at high-risk. This limited method of analysis is not able to capture the full magnitude of measurement error and biases induced by many influencing factors. Measured results must be repeatable and reproducible. By itself this is a tremendous risk. It is very easy to have measured results that are repeatably and reproducibly incorrect as uncorrected biases are easily induced that can be many times larger than the R&R numbers initially recognized by the metrologist. Any of the items noted in the criteria of precision measurement can be influencing factors that must be evaluated individually for their level of error contribution.

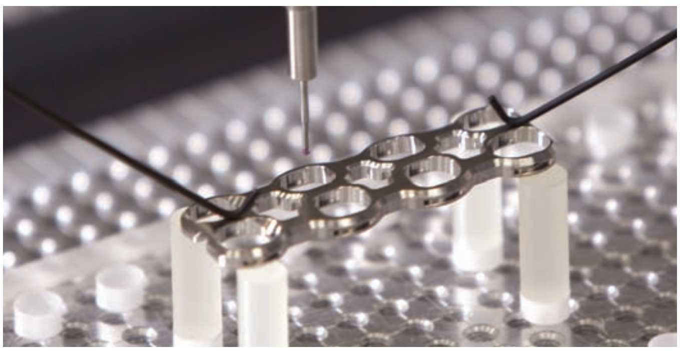
Customers and suppliers already know when this is occurring, as one of the two following situations happens: Measurement data can look good—it complies with specification requirements, but the parts do not work or fit properly. Or measurement data can look bad—it does not comply with specification requirements, but the parts actually do work.

**Precision Measurement Technology**

Measurement technology has advanced significantly over time. In today's environment, CMMs are commonly used to measure parts and have the ability to generate a 3D high-density point cloud. Single sensor and multi-sensor CMMs use sensors such as tactile, vision, laser, white light and other technologies to optimally capture the measured point arrays and characterize physical variations induced by the broad spectrum of manufacturing processes such as machining, stamping, castings or injection molding.

Exhibit 4 shows the cervical plate machined from the drawing shown in Exhibit 2 and measured with an enhanced accuracy Leitz CMM using a small tactile probe with low probing forces, and analyzed using SmartProfile software. The part is held in a manner with low clamping force that ensures that it does not distort or move during the probing process.

*Exhibit 4: Tactile Probing of Cervical Plate*

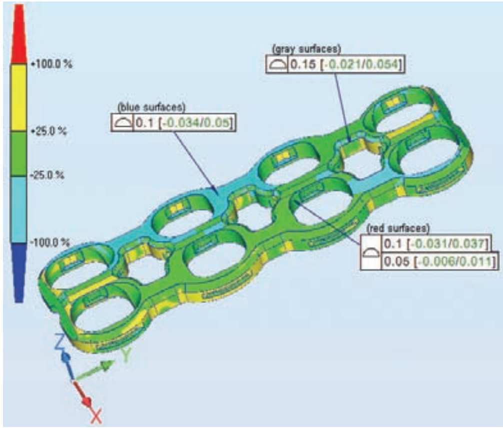


**An Example of Profile Tolerancing**

Historically, metrologists have found measurement of profile tolerancing too complex due to CMM software limitations. Today, profile tolerancing is considered one of the simplest ways to analyze complex surface geometries as long as the users have the applicable software.

Exhibit 5 shows the graphical output of profile tolerancing using SmartProfile software. The color coded surface profiles are shown as a topographical map. This quickly communicates compliance or non-compliance to the specified tolerance. The software integrates a bar graph showing the deviations so users can quickly analyze the true magnitude of variation on each of the surfaces with user-programmable allocations indicating percentage of tolerance used.

*Exhibit 5: Graphical Output of Profile Tolerancing Showing Actual Deviations*




Surfaces or values out of tolerance are shown and highlighted in red or blue. Further, two additional values are shown in the feature control frames that were not in the original drawing shown in Exhibit 2. The first value indicates the worst case deviation in the minus material direction. The second value indicates the deviation in the plus material direction. These values are what the metrologists and engineers use to determine compliance vs. non-compliance as well as inputs into any level of statistical analysis.

Exhibit 6 on the following page provides additional information that is tremendously valuable to manufacturing and engineering functions. It graphically represents absolute deviations showing the total range of results. This level of information allows manufacturing engineers to immediately see root-cause effects resulting from the manufacturing process and provides indications on how to optimize the process and achieve better results. If the manufacturing engineers cannot see the variation, then optimization is much more difficult. The SmartProfile viewer can also be used by machinists, inspectors, managers, customers and suppliers to communicate the results of the profile inspection.

The profile analysis results as well as detailed information and statistics can be printed as a hard copy document or saved as a PDF file. This allows any individuals who are accustomed to mechanical drawings to easily understand and analyze these graphical reports. Previous methods using verbal or numerical communication are much more difficult, less graphical and unclear.

Profile analysis software such as SmartProfile makes complex profile analysis simpler with icon driven navigation and many customizable features. The software imports many common format CAD models such as STEP, IGES or DXF. The CAD features are selected and the tolerances are simply entered by the user directly from the drawing. The program is saved and can be used again, eliminating the need to recreate it. The measured points originally saved by the metrologist are imported from

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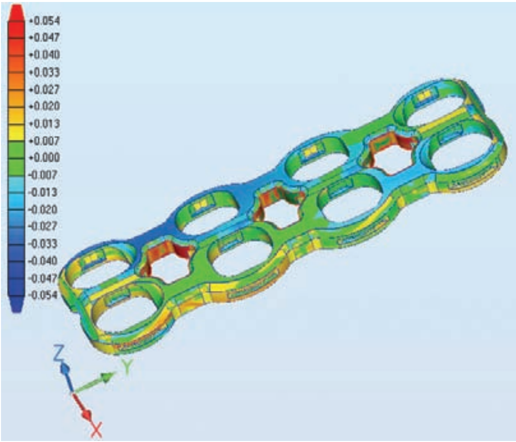
***Exhibit 6: Graphical Output of Profile Tolerancing Showing Absolute Deviations***




their CMM program, a quick alignment is done and the points are evaluated. The profile analysis software performs an optimum fit analysis of the measured points to the CAD model by translating and rotating the measured points until optimum fit is achieved.

SmartProfile accepts 2D and 3D point clouds x/y or x/y/z points from any CMM, which can turn any CMM into a simple point collector. The metrologist can spend much less time worrying about how they will set up their datum reference frame and do the analysis one step at a time within their program, focusing their attention on how to collect a low uncertainty point cloud.

SmartProfile also solves the software validation effort on every metrology software package. Many companies are not capable of analyzing results to the ASME Y14.5.1 Math Standard. This allows validation to a single software that can be used no matter what CMM they have. Supplier Engineers, Development Engineers and others can simply request the measured point array from the metrologist and analyze the results in minutes rather than rely on confusing inspection reports.

**Conclusion**

Miniaturization of medical components and significant reduction in feature tolerances make it mandatory for components and assemblies to be defined with profile tolerancing to ensure that functional intent of the design is truly met. This precision language supported by optimum manufacturing equipment, precision measurement system, capable analytical software and competent individuals within all disciplines will allow customers and suppliers to meet future needs.

**A Customer and Supplier Partnership in Profile Tolerancing**

A commitment to profile tolerancing is a true partnership between an OEM customer and its supplier. Here are some tips on how you can be sure both parties are committed to profile tolerancing.

- Are designers precisely defining complex surface geometries using profile tolerancing?
- Have both parties invested in the high end physical metrology instruments and supporting precision measurement tools needed to measure complex geometries with low measurement uncertainty?
- Have they acquired capable profile analysis software to analyze the complex surface profiles simultaneously?
- Has there been fundamental to advanced training in profile and position tolerancing per the ASME Y14.5 Standard?

Only by customers and suppliers partnering and investing in and committing to profile tolerancing can both experience its full benefits.

The author wishes to thank Lowell, a precision manufacturer of orthopaedic implants, and Productivity Quality Inc. of Minneapolis, Minnesota for ccertain components, graphics and test data used within this article.

*Dr. Hetland has 30+ years experience in the Medical, Aerospace, Defense and Commercial industries with extensive expertise in the mechanical & precision engineering fields as an engineer, consultant, educator and author. He has extensive technical society affiliation and is recognized worldwide as chairman & member of U.S. committees as well as U.S. representative on international standards development in the areas of dimensional tolerancing, physical metrology, statistical tolerancing and uncertainty analysis with emphasis in the sub-micrometer regime.*

Dr. Greg Hetland, President
International Institute of Geometric Dimensioning & Tolerancing
12159 Quail Ave Lane N., Stillwater, MN 55082
651-275-8952 (phone)
www.iigdt.com

Lowell, Inc.
9425 83rd Avenue North
Minneapolis, MN 55445
763-425-3355 (phone)
www.lowellinc.com

Productivity Quality, Inc
15150 25th Avenue North Suite 200
Plymouth MN 55447
800-772-0620 (phone)
www.productivityquality.com