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OrthoTec

SPRING 2010
VOL. 1 NO. 1

Providing expert insight on orthopaedic technology, development, and manufacturing

PREMIERE ISSUE

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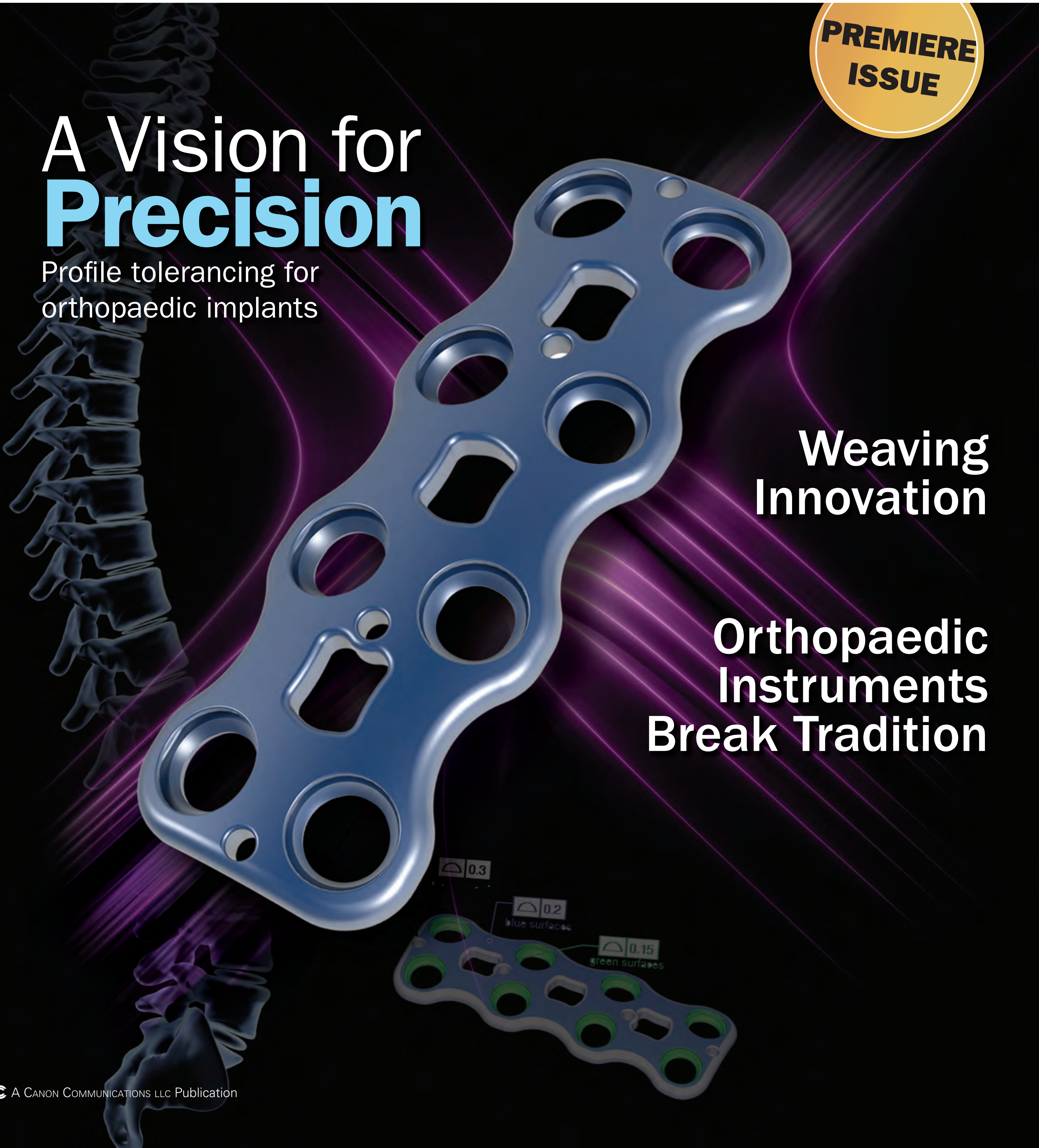
Profile tolerancing for orthopaedic implants

Weaving Innovation

Orthopaedic Instruments Break Tradition



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Speaking a Precise **Language**

Orthopaedic component manufacturers should use profile tolerancing to achieve high mechanical precision.

GREG HETLAND, PhD

The increased complexity of surface geometries and the decreasing feature tolerances of orthopaedic components is driving the need for unprecedented precision in product design definition. Profile tolerancing is the key tool for dimensioning and tolerancing practices for components and assemblies in orthopaedics.

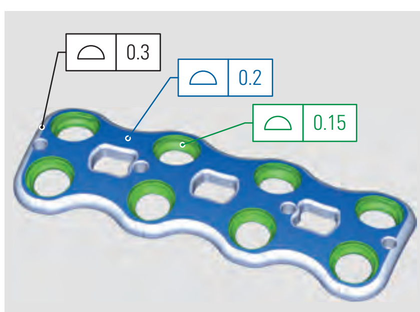
Profile tolerancing explicitly defines a uniform tolerancing boundary around the true theoretically exact dimensions. It also enables full associativity with all other geometric features defined with the same profile tolerancing methods.

Conventional plus and minus tolerancing approaches create product specifications with hundreds of individual dimensions that fail to analyze the relationship between features. The application of profile tolerancing can significantly improve precision measurement in manufacturing and metrology. It can also reduce costs and lead times and more effectively convey true design intent.

Step 1 shows 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 value and precision of profile tolerancing.

Precision Language

Smaller parts, tighter tolerances, and more-complex features make it mandatory for components and assemblies to be defined with precise language to meet functional design intent. Without using this language, the orthopaedics industry is at a high risk of component and product failures. On the one hand, the inspection results can look good but the product fails. On the other hand, the results look bad but the product works. In either situation, the way in which the features are examined does not address the component's design functionality. A valid 3-D analysis forms the basis for engineers to justify and validate their component's compliance. The individual feature tolerances are essential inputs to subassembly and full assembly analysis. The results of this analysis form the justification and traceability needed by designers to ensure that components and assemblies meet functionality and reliability requirements.



Step 1. The rectangular boxes include a symbol and a number that are defined as feature control frames. The symbol represents the profile of a surface, which is what invokes 3-D profile tolerancing. The number depicts the amount of tolerance that the designer is allowing the surface geometry to vary from its true theoretical dimension(s) specified by the CAD model.

The ability of customers and suppliers to communicate in this language is the basis for meeting the terms of binding contracts. Customers order components from suppliers with the expectation that they have trained staff to interpret and ensure compliance. Suppliers expect their customers to communicate requirements in a manner that facilitates manufacturing and quality assurance. Training in the higher-precision geometric dimensioning and tolerancing (GD&T) language is key for both parties.

Technology Roadmap Implications

Another implication of smaller parts, tighter tolerances, and more-complex features is that manufacturing and measurement capabilities must improve at the same rate. It's common for customers to request statistical data from a supplier and use these data to evaluate the supplier's process capabilities. Such data can take the form of process capability indices (Cpk) and measurement capability indices such as gauge repeatability and reproducibility (GR&R). One challenge with these methods is that they are a result of the initial design specification tolerance.

Scenario Based on Design Specification of ±0.05 mm. The following illustrates the effects that a Six Sigma design tolerance has on manufacturing, measurement, and calibration (shown as 1-σ values based on ratios) using a common linear tolerance of ± 0.05 mm (profile of 0.1 mm):

- ±0.050 mm (.002 in.)=design specification.
- ±0.008 mm (.000330 in.)= manufacturing requirements at 6:1 (Six Sigma).
- ±0.002 mm (.000083 in.)= metrology requirements at 4:1.
- ±0.0005 mm (.000021 in.)= calibration requirements at 4:1.

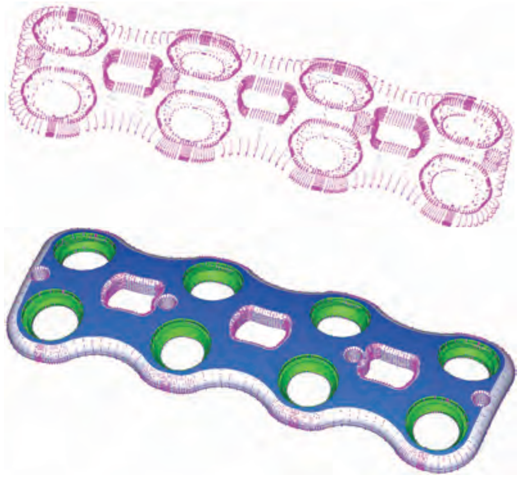
This example highlights the critical need for designers to aggressively ensure that drawing callouts optimally reflect functional intent and that tolerances are optimally derived based on sound 3D tolerance analysis principles. A seemingly wide-open 0.050-mm design tolerance produces calibration activities with required uncertainties more than 100 times greater than the initial design tolerance.

Documentation Criteria and Method

Designer expectations dictate that all variations on the component surfaces fall 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 expected to meet those requirements.

The precision language of profile tolerancing is explicitly defined in the American Society of Mechanical Engineers (ASME) standard Y14.5M–1994 on dimensioning and tolerancing.[1] It is mathematically complemented by the ASME Y14.5.1M–1994 standard.[2] These standards form the basis for the precise definition of complex surface boundaries and should be the basis for 3-D tolerance analysis for designers as well as for 3-D precision measurement analysis for physical metrologists.

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



Step 2. **The top image is a measured point array. Each point is used when calculating the profile.**

Step 3. **The bottom image is a measured point array combined with the software to analyze results.**

Designers must specify all requirements through a precise engineering language and communicate these requirements through a mechanical drawing, or electronically through the 3-D CAD model and a minimally dimensioned drawing per ASME Y14.41–2003 standard on digital product definition data practices.[3] Step 1 shows an engineering drawing example that depicts profile tolerancing of all 3-D surfaces being fully defined with three explicit profiles of a surface callout per ASME Y14.41–2003.

Once the designer effectively documents the specification requirements, manufacturing and quality engineers are expected to precisely interpret these engineering requirements to manufacture and inspect the parts to ensure full compliance. Precision measurement practices determine the level of variation and provide precise data to manufacturing and design for review and optimization. Ideally, this communication can be accomplished using the same optimized CAD model to ensure that additional errors are not propagated throughout manufacturing and quality. An optimized tolerance model results in smooth transitions between individual neighboring features.

Because design and manufacturing require highly accurate measurement data to make technical and business decisions, it is essential to focus attention on precision measurement and the steps involved to provide precise results. Precision lost on the product specification and measurement side must be compensated by using more accurate machine tools that reduce variation. This method can be much more expensive than teaching engineers the importance of GD&T and measurement uncertainty.

Precision measurement requires high confidence that the measured results reflect differences between parts and not differences due to errors of measurement. To accomplish this task, see the sidebar "Criteria for Precision Measurement" on p. 10. It provides a beginner's list of the requirements that a metrologist should consider when developing an inspection plan. Users can also reference ASME B89.7.2–1999 for guidance on complying with requirements.[4]

The Wheel of Uncertainty

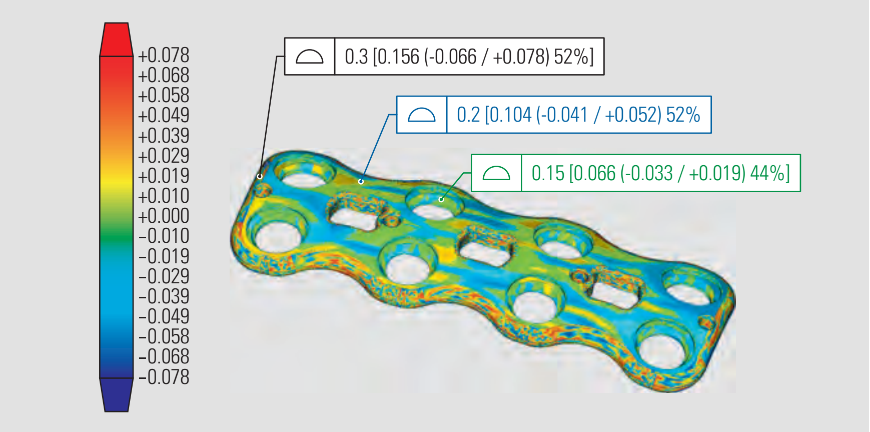
When measuring parts, a metrologist should take into account several error sources. Figure 1 shows a wheel of uncertainty contributors with categories of inherent error sources that should be a minimum consideration by a metrologist.

Companies using GR&R as the basis for measurement systems analysis are at high risk, because this limited analysis method cannot capture the full magnitude of measurement error and biases. Measured results must be repeatable and reproducible; however, results can be a tremendous risk by itself. It is easy to have measured results that are repeatably and reproducibly incorrect. Uncorrected biases are easily induced and can be many times larger than the GR&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 individually evaluated for their level of error contribution.

Precision Measurement Technology

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

Measurement technology has significantly advanced. CMMs are commonly used to measure parts and generate 3-D high-density point clouds. Single-sensor and multisensor CMMs use tactile, vision, laser, white light, and other sensor technologies to optimally capture the measured point arrays and characterize physical variations induced by the broad spectrum of manufacturing processes such as machining, stamping, casting, or injecting molding.



Step 4. **In this graphical output of profile tolerancing, the color-coded surfaces are displayed as a topographical map. The bar graph shows absolute point deviations.**

Step 2 represents a set of measured points commonly referred to as a measured point cloud or measured point array. Each of these measured points can be extracted from a CMM and have an associated x, y, and z value, which are used in the profile calculations. CMM programmers can extract the x, y, and z points from any of their contact or noncontact CMMs. The number of points measured by a metrologist can contribute to uncertainty, so the higher the point density, the better the confidence will be in the measured results.

The CAD model image in Step 3 shows the measured point array is integrated into the SmartProfile software, which is then used to analyze results. The software allows for integration of the point array in multiple formats.

Step 4 shows the graphical output of profile tolerancing. The color-coded surface profiles are shown as a topographical map and communicate

Criteria for Precision Measurement

- Establish a clear definition of the specification requirements per ASME Y14.5M-1994 or an applicable standard. Define 3-D surface geometries using profile tolerancing. Define 3-D axes control with position tolerancing.
- Qualified metrologists perform required tasks at a sufficient level using 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 tool knowledge.
- Use a precise measurement instrument that can measure the feature and place it in an environment conducive to the level of precision measurement required.
- Use a sound measurement procedure that will ensure true characterization of the feature. Hold fixture and devices as defined per the engineering specifications. Sufficient point densities 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.
- Use robust measurement software that completes the analysis per the defined standards such as ASME Y14.5M-1994 and ASME Y14.5.1M-1994. Software such as SmartProfile defaults to the ASME Y14.5.1 standard. It has been extensively tested with mathematically defined data sets for profile and position tolerancing, with and without data, and fully invoking the rule of simultaneity. A word of caution: the majority of CMM software used in all industries currently default to using least-squares fitting algorithms, which simply means they are averaging the measured results.
- Use proper analytical methods for evaluating the uncertainty of the measured results. The ASME B89.7.3.2-2007 technical report provides guidelines for evaluating dimensional measurement uncertainty. It is a simplified guide for metrologists to evaluate the contributing factors that influence the measured result.

compliance or noncompliance to the specified tolerance. The software integrates a bar graph showing absolute point deviations, so users can quickly analyze the true magnitude of variation on each of the surfaces in the plus and minus material directions.

Surfaces or values out of tolerance can clearly be seen in the expanded feature control frames by the additional information shown in brackets in Step 4. The first value in brackets is directly compared with the specification requirement, which is the first indication of compliance or noncompliance. If the value is less than the specification requirement, it is in compliance. The second and third values shown in parentheses within the brackets indicate the worst-case deviation in the minus and plus material directions. The fourth value in the brackets indicates the percentage of the specification tolerance used, which is valuable to manufacturing and quality because it is a quick indicator of how effectively the process is operating.

The graphical information in Step 4 is tremendously valuable to manufacturing and engineering functions, because it allows them to immediately see root-cause effects resulting from the manufacturing process. It also provides indications on how to optimize the process to achieve better results. When manufacturing engineers cannot see the variation, optimization is much more difficult.

Special software makes complex profile analysis much simpler than ever before. The procedure required to achieve these results is as follows:

1. Import a translated CAD file such as STEP, IGES, and DXF.
2. Select the CAD features and apply the GD&T as displayed on the engineering drawing as shown in Step 1. If the engineering drawing has been optimized using profile tolerancing, the process will only take a couple of minutes.
3. Import the measured points from any CMM, as shown in Step 2.
4. Roughly align the measured points to the CAD geometry as seen in Step 3. The metrologist can do the analysis one step at a time within the program, focusing attention on how to collect a low-uncertainty point cloud.

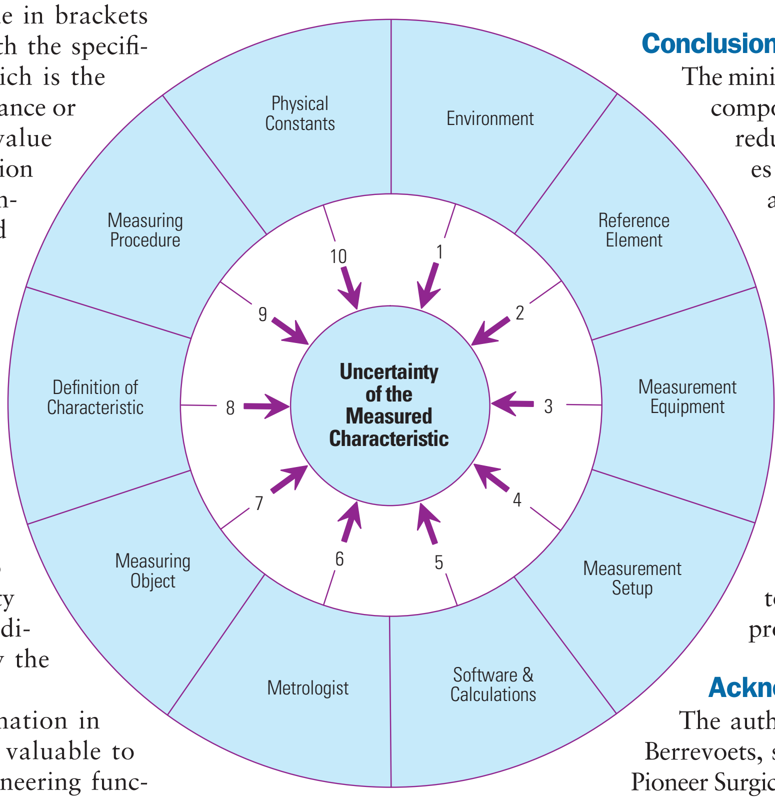


Figure 1. Metrologists must consider a variety of inherent error sources when measuring parts.

5. Click the evaluate icon to complete the analysis, as seen in Step 4. Software such as SmartProfile performs an optimization fit (not least-squares fit) analysis of the measured points to the CAD model by translating and rotating the measured points until the optimum fit is achieved.

SmartProfile software solves the software validation effort on every metrology software package, because it allows customers and suppliers to validate a single software that can be used for analysis per ASME Y14.5.1, regardless of what CMM they have. Supplier engineers, development engineers, and others can request the measured point array from a metrologist and analyze the results in minutes rather than rely on confusing inspection reports. The software also ensures evaluation uniformity within the whole manufacturing process regardless of how and on what measuring device the raw data were collected.

Conclusion

The miniaturization of orthopaedic components and the significant reduction in feature tolerances require components and assemblies to be defined with profile tolerancing to achieve functional design intent. This precise language, supported by optimal manufacturing equipment, a precision measurement system, capable analytical software, and competent individuals within all disciplines, will allow customers and suppliers to met future orthopaedic product needs.

Acknowledgments

The author wishes to thank Greg Berrevoets, senior project engineer at Pioneer Surgical Technology (Marquette, MI), Lowell Inc. (Minneapolis, MN), and Productivity Quality Inc. (Plymouth, MN) for providing certain graphics, images, and test data used within this article.

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