Applying Tech: Orthopedics

How Are You Influencing Orthopedic Technology?

Dr. Greg Hetland: President, International Institute of GD&T

Miniaturization of medical components and significant reduction in feature tolerances make it mandatory for components and assemblies to be defined with precision GD&T and profile tolerancing to ensure functional intent of the design is truly met. The most critical component of a successful GD&T program is the engagement of competent, well-trained staff in engineering, manufacturing, and quality. Only in this way can OEMs and suppliers meet their future needs and reap the benefits of a commitment to profile tolerancing.

I have developed a unified approach to bridge the gap between design, manufacturing, and metrology. The bottom-line goal is to build upon the concept of proper design intent to improve your cost of business through greater efficiency in engineering, manufacturing, and improved quality.

The International Institute of GD&T offers fundamental to advanced training in the principals, applications, and analysis of GD&T per the ASME Y14.5 Standard. From in-house training and consulting to seminars in locations around the world, the Institute is bringing the precise language of GD&T and profile tolerancing to the medical device industry. Our job is to deliver accurate, exclusive, and expedient training that can be specifically tailored to meet the needs of your organization.

Peter Broer: President, Lumitex MD Inc.

Visualization and access traditionally have been primary obstacles to safe minimally-invasive orthopedic surgery. Recently, a variety of surgical tools and techniques have improved access. Improving visualization remains a primary goal to help enable access and safety, especially in small-incision hip and spinal applications.

Lumitex Medical Devices (MD) Inc. applies a unique, patented fiber-optic technology to bring cool, shadow-less light into minimally invasive, small-incision cavities. The Ortho-Light is a low-profile flexible strip designed to adhere to most retractors, connect with standard OR light sources, and flood the surgical cavity with light to promote better visualization.

Surgical tool innovations can help lessen barriers and promote safe navigation. They can help make small incision and minimally invasive approaches more visible and, therefore, safer by presenting the anatomy more clearly. The Ortho-Light represents a significant contribution to this effort, minimizing time and blood loss, and lessening the risk that poor visualization inevitably causes.

Jim Sterz: Quality Manager, Lowell Inc.

Lowell Inc., a precision machining company, is among the leaders in an approach called profile tolerancing. One of the challenges facing precision manufacturers and their medical device manufacturing partners is the increasing feature complexity of their products. These complex geometries can result in long inspection and

verification times and put even the most sophisticated measurement equipment and processes to the test.

Lowell has moved from 2D linear or ± tolerancing to 3D or profile tolerancing to inspect and verify these features. When profile tolerancing is applied correctly, manufacturing and inspection functions are provided with unambiguously defined tolerancing that is manufacturable and measurable. Customers can see cost and lead time reductions with parts that consistently meet the design intent. Components will function properly, eliminating costly rework, redesign, and missed market opportunities. We've invested in training from Dr. Greg Hetland at the International Institute of GD&T, sub-micron level measurement equipment (including a climate controlled environment for our Leitz PMM), and SmartProfile software from Kotem Technologies to implement profile tolerancing to reduce inspection time, improve accuracy, and reduce measurement error.

Glenn Kennedy: Channel Sales Manager, Roland DGA Corp.

As the worlds of engineering and orthopedic surgery continue to merge, Roland DGA is providing 3D input/output devices to capture complex anatomical geometry and create patient-by-patient custom formed components in a wide range of materials including FDA approved plastics.

Problem/Solution Example 1 (scan to manufacture): Doctors are able to scan a patient using MRI and CAT scans. This data can then be converted to a format which is compatible with 3D engineering design software. The 3D data is used to create geometry for a patient-specific surgical cutting template.

Workflow: MRI/CAT scans performed on a patient produce scan data to be entered into software, such as 3D Doctor or Mimics, and then converted to polygon mesh data (.stl). The STL file is imported into SolidWorks and used as reference geometry to build a patient-specific surgical cutting guide. This 3D geometry is used to drive a Roland MDX-540 mill to rapid manufacture the custom component from FDA approved plastic resin.

Example 2: Rocky Mountain Tissue bank uses Roland MDX mills to create spinal implants from human cadaver and bovine bone. Workflow: They design 3D geometry in CAD software and then use that geometry to rapid manufacture implants on the Roland MDX-540.

Example 3: Northwestern University R&D department uses a Roland LPX scanner to digitize the intricate surface details of cadaver knee joints to help develop better replacement parts. 3D laser scanning with a Roland LPX machine captures thousands of points on the opposing surfaces and the complex curves found on organic objects. This data is then used in 3D design and analysis software to help develop new surgical implants and joint replacement parts.

Robert Lynch: VP, R&D, Tecomet Inc.

Tecomet is a metallurgical technology company that has pushed the limits of orthopedic implant manufacturing since its early days, as part of Thermo Electron almost 40 years ago. As the first to forge titanium, cobalt chrome, and zirconium for orthopedic applications to improve the strength and grain structure of metals, Tecomet has been the recognized leader in forging hip, knee, and shoulder implants. Tecomet's advanced understanding of material flow, tool design, and superior process controls, allow forging of near net shapes that optimize product performance specifications, while reducing raw material waste and the cost of subsequent machining operations. Besides forging and extensive precision multi-axis CNC and EDM machining, Tecomet also possesses expertise in the area of photochemical etching. This technology produces burr-free, stress-free precision products that are commonly used for oral maxillofacial reconstruction, such as custom cranial plates and titanium trauma meshes. Tecomet's etching process has also been refined to create surface texturing capabilities that improve primary fixation and bone in-growth performance for a wide variety of orthopedic, spinal, and dental implants. Overall, Tecomet has a wealth of knowledge and experience in the orthopedic implant market with its broad range of metallurgical technologies that enable their customers to overcome ever more extreme product challenges.

Gabriel O. Adusei, MSc, Ph.D.: Founder, International Association of Medical Technology Consultants

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Recent developments in biomedical research are advancing the technologies of generation and growth of patient-specific new active tissues to treat a variety of diseases, including spinal cord injuries among a number of other impairments and conditions. These emergent technologies combined with others, such as developments in advanced smart medical biosynthetic and synthetic nano-materials, are being employed in the dental and orthopedic biomaterials research and development.

The challenges and consequences for the medical community, industry, and governments in the growing regulatory environment cannot be overemphasized. In addition to safety and efficacy required for regulatory approvals, government health institutions are also interested in the proof of effectiveness and outcome benefits that, from the industry's standpoint, are increasingly important for market adoption of new medical technologies. The regulatory requirements of new technologies, such as advanced therapy medicinal products that are in combination with devices, are complex and not straightforward.

It is against the backdrop of such regulatory affairs gray areas and a number of industrial needs that International Association of Medical Technology Consultants with its "Consult" accreditation scheme aspires to raise the standard of consultancy services to enhance the speedy development of emerging new medical technologies from bench-top to bedside and beyond.