Applying Tech: Orthopedics—Part 2

How are you influencing orthopedic devices?

Daniel Steines,
SVP of R&D, ConforMIS

ConforMIS has been working since 2004, based on intellectual property that has been developed over the last ten years, to build technology platforms that let surgeons take a personalized approach to orthopedic implants. The technology uses high resolution scan data, which has become standard in medical imaging, to build customized implants and instruments that are made for an individual patient. The ability to customize the implants using patient imaging data, automated design software, and digital manufacturing methods allows for greater bone preservation, the potential for more natural kinematics, and a simpler surgical technique.

ConforMIS is the only company with a full line of knee implants built on this approach, including the iUni G2, for patients whose arthritic damage is limited to one compartment of the knee, the iDuo G2, for those suffering two compartment disease, and the iTotal CR for those in need of a total knee replacement.

It is clear that the trend toward patient-specific is revolutionizing orthopedics, with all of the major manufacturers pursuing patient-specific approaches. It is knee replacement for the 21st century.

Nick Ranly
Industry Lead—Life Sciences, Siemens PLM Software

Siemens PLM Software offers orthopedic manufacturers the tools to design, verify, manufacture, and manage implants throughout the entire product lifecycle. Quality and compliance are built into the design up-front, reducing time to market and costs.

Engineers digitally create orthopedic implants and surgical guides in NX, as well as test the implant through digital validation. The NX solution also enables machining design (CAM) so the product can be manufactured in-house through CMM programming; streamlining, and automating quality validation. Orthopedic manufacturers can then use existing product knowledge to reduce design iterations, decreasing time to market and increasing profits.

Siemens Tecnomatix solutions also predict build quality before it becomes a costly mistake. Variation analysis, a 3D representation of product geometry, tolerances, assembly processes, and tooling, can predict if problems exist well before physical prototypes or expensive tooling investments are made.

Teamcenter, Siemens PLM Software’s data management solution, tracks the entire process and ensures compliance to Title 21 CFR Part 11 and other applicable regulations. Teamcenter creates a secure platform in which design changes and project knowledge can be shared throughout the organization and with surgeons.

The result? An end-to-end solution that enables orthopedic companies to innovate with speed and confidence, reducing design and manufacturing costs, as well as increasing patient success.

Anthony Verrocchi and Rainer Walkenhorst
Technical Marketing GUR, Ticona Engineering Polymers

In the early 1960s, ultra-high molecular weight polyethylene (UHMW-PE) helped pioneer a new era of orthopedic implants for replacement hips. UHMW-PE then became a material of choice for replacement knees, shoulders, and other small joints.

This engineering thermoplastic, produced in the form of a powder, soon became the

“gold standard” for synthetic orthopedic joints or joint components that maintain high functionality over a long usage life thanks to UHMW-PE’s excellent combination of properties—biocompatibility, high abrasion resistance, impact strength, and fatigue and crack resistance.

In the 1990s, highly cross linked UHMW-PE was introduced to further increase the wear resistance of implants. UHMW-PE implants can be cross linked with modern irradiation techniques for performance improvement and/or sterilization. For the international UHMW-PE orthopedic implant community, the next step was to ask for a material that provided effective oxidation resistance. Therefore, the prevention of material degradation by *in vivo* oxidation and/or shelf aging of the implant became an important topic for research and scientific discussion.

After nearly a decade in development, UHMW-PE is set to help the surgical orthopedic implant community take another step forward. Two commercially available grades of UHMW-PE with vitamin E—GUR 1020-E and GUR1050-E—can help extend the life of orthopedic implants. One knee implant comprised of UHMW-PE with vitamin E is approved by the FDA, and several other companies with devices comprised of UHMW-PE with vitamin E are seeking FDA approval.

With the addition of a small, homogeneous amount (approximately 1,000 parts per million) of vitamin E (alpha-tocopherol) as a stabilizer, these new grades allow for effective oxidation resistance in addition to the excellent wear resistance of the latest generation of implants, which may prevent painful and costly follow-up surgeries

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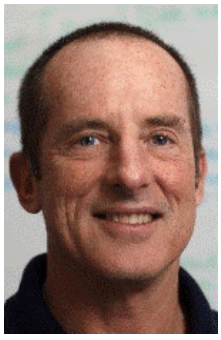
Jeff Lind
President, Compliance West USA



As cardiovascular design surpasses Medical Standard requirements, custom test equipment providers are challenged by equipment designers to build more accurate and reliable equipment, with decreasing cycle times to handle more throughput.

Because standardized tests don’t exist for many of these new designs, custom test equipment has to be based on robust engines which can be quickly modified to provide the new test package. Since the test packages are empirical, test equipment should be flexible so it can be modified after production should official test Standards become available.