Perspectives on Manufacturing Technologies, Part II

The capabilities of manufacturers are growing to enable the fabrication of components that are extremely tiny, very complex, and incredibly intricate. These advances are leading to medical devices that could not have been developed just a few years ago. With this in mind, this months Perspectives asked about how these capabilities would impact future devices.

How will new(er) manufacturing technologies impact the design and/or capabilities of upcoming medical devices?

Jim Hunter
R&D Engineer, Putnam Plastics

Clinicians at the vanguard demand the impossible; delivery of total therapeutic effect with zero side effects. Contract manufacturing specialists, like PolyMedex Discovery Group, are delivering on those demands. Minimally invasive devices, such as those used in NOTES and Single-Port surgical techniques, depend on advanced technologies to treat the most remote anatomies with minimal negative impact to the patient. Customized drug eluding polymers enable medical devices to directly mitigate pain and inherently resist infection. New polymer filtration technologies result in ultra-pure materials that facilitate precision extruded components with smoother and thinner walls.

Combining this technology with super strong and lightweight polymers allow devices to reach deeper into the anatomy while ultra-soft, thin-walled extrusions allow for greater articulation through tortuous paths. Advanced software-driven

process controls result in tighter dimensional tolerances that empower device designers to pack more therapeutic punch into ever smaller spaces. New component finishing and assembly technologies allow complex miniature extrusions to be incorporated into new devices, densely packed with therapeutic technologies. Rapid prototyping capabilities reduce development timetables, putting new devices in the hands of clinicians faster. With these advanced manufacturing technologies, unreachable disease becomes reachable, previously devastating side effects disappear, and clinicians deliver on the impossible.

David A. Cabral
President, Five Star Manufacturing Inc.

Breakthroughs in the development of cutting tools greatly impact the designs, material choices, and capabilities of medical devices. The tooling industry has put significant focus on reducing machining cycles through the development of new material grades of cutters and inserts. The result is less machine downtime due to extended tool life, increases in speeds and feeds, surface finish improvements, and reductions in non-value-added operations.

Today, competitiveness is the elimination of waste and shorter lead times to customers. Machine cycle time is a large percentage of total time to manufacture medical devices; by decreasing cycle times, on-time delivery becomes an achievable goal. With the introduction of specialty cutters, Five Star Manufacturing is experiencing increased utilization of carbon fiber in the product mix. The use of this material allows for lighter weight devices that reduce surgeon fatigue, while retaining the strength of the more commonly used materials. One very favorable attribute of this carbon fiber is radiolucency and the value it brings during surgery. Unlike metals, the ability to allow x-rays to pass through without shadow eliminates the need for the surgical setup to be disassembled to allow the surgeon to view his site. If a modification is necessary, as in orthopedic surgery, the instruments must be reassembled in the site before continuation. With the use of radiolucent

materials, the x-ray can be performed and immediate steps taken to realign the patient.

With the technological advances to machine tools, these, and many other difficult to machine materials, can be successfully incorporated into a design.

John Slamin
Vice President, Knee Implant Engineering, ConforMIS

Throughout the last decade, a host of technologies have been developed in the direct digital manufacturing area that have helped companies like ConforMIS offer novel medical device technologies.

The traditional method in orthopedics manufacturing has been to invest in production runs scaled to create medium to large inventories of stock. One of the large orthopedic manufacturers, for example, will invest more than $150 million each year to create surgical instruments with an average depreciation period of three to five years.

Through manufacturing redesign, ConforMIS has been able to employ rapid prototyping technologies, such as Fused Deposition Modeling or Laser Sintering (e.g., SLS or DMLS), that are ideally suited for cost-effective small run production of implants and instruments. This has enabled us to offer an entirely patient-specific approach to knee resurfacing. With lower inventory carrying costs and the opportunity to introduce rapid product iterations without replacing field inventory, these new manufacturing technologies deliver a competitive advantage.

Kenneth Holt
Applications Lab Manager, Herrmann Ultrasonics

Herrmann Ultrasonics welders have long been used to effect the joining of two plastic parts without solvents, glues, or fasteners. Recent developments in these machines' interfaces, software, and machine form make them uniquely suited to the modern cleanroom, highly regulated production, and precise manufacturing. These are all incorporated in the Medialog system offered by Herrmann for these demanding applications.

The FDA System component is an integrated program that provides time stamped audit trails and individual access authorization, at five levels of security, to limit changes to critical welding parameters.

The BarcodeScan Dialog software/hardware is an innovation allowing product scanning and data archiving with the barcode attached to the data. This system can be programmed to use a specific weld set-up for a group or type of parts (e.g., color, enhancing traceability of production).

Calibration of critical system parameters of force, down-speed, amplitude, and distance measurement is accomplished via on-board software using traceable standards, and documentation can be output via PDF files.

The advanced pneumatic system has a five micron filter and provides capability to exhaust air directly into the ventilation system. This unit's white color, smooth finish, and stainless side panels suit the cleanroom environment by allowing easy cleaning and low particulates.

Christopher M. Alibozek
Engineering Manager, Technical Services, GW Plastics Inc.

Some manufacturers are beginning to realize its benefits. However, a scientific molding (SM) approach will become absolutely necessary to achieve the ever-increasing quality and validation requirements of upcoming medical devices made from engineered plastics. Parts must be designed for high volume manufacturability with zero defects. At the same time, tool design and construction must also meet increasingly tighter tolerances and faster cycle times. The materials used and the processing parameters must be carefully derived to mold a consistent, repeatable product, cycle after cycle. SM ensures that the four key processing variables–plastic temperature, plastic flow rate, plastic pressure, and cooling rate and time–are addressed as part of the tool validation process.

At GW Plastics, we utilize our GW/SM tool validation process to establish optimized molding parameters for every tool we run. Various tests, such as short shot analysis, viscosity vs. flow rate curves, gate freeze, balance of fill analysis, pressure loss, and part weight studies, allow us to achieve the most repeatable molding process regardless of final manufacturing location. Then, once in production, if an unacceptable variation is detected, continuous process monitoring data collected will help isolate the problem, allowing for a quicker, more scientific, data-based correction to be made.

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