Perspectives on Prototyping, Part I

Has design software reached the point where it can serve as an acceptable replacement for physical prototypes in medical device manufacturing?

Steve Fidrych
Director of Molding Operations, Mack Prototype Inc.

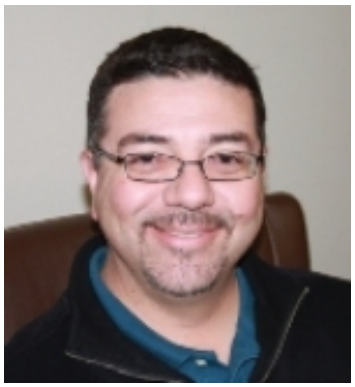
The newer, more powerful design software packages do offer medical device manufacturers more flexibility. Part and product designs can be adjusted quickly and easily, allowing engineers to address specific product development issues before building production tools. We would argue, however, that these newer programs, coupled with advances in prototyping technologies, have actually increased demand for physical prototypes.

Fused Deposition Modeling (FDM), for example, combined with today's broad array of materials that accurately mimic end-use production materials, offer design engineers the ability to prototype multiple iterations quickly and cost-effectively. And there is no substitute for a tangible, physical sample when explaining or demonstrating a new concept or design refinement to marketing, management, or medical professional personnel.

Other prototyping processes—CNC machining, urethane casting, or limited run tooling—give engineers the opportunity to broadly solicit feedback before locking in final designs for production tooling and regulatory submission. Many costly design and process modifications can be avoided by proving out conceptual solutions with physical parts produced by the appropriate prototyping process in materials that closely reflect end-use properties. So while design software is extremely beneficial to the downstream prototyping process, it cannot adequately replace the physical

part during the product development cycle.

John Vargas
Engineering Manager, Pro-Dex Inc.

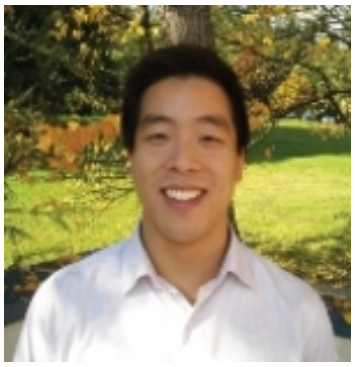


While design/analysis software has come a long way and assists in the early product development process, it does not replace physical prototypes. Engineering and manufacturing teams learn the most about a design by having physical parts that they can hold and evaluate for size/weight, ergonomics, fit, and features. This is especially true if the materials are representative of the production materials because you can begin early evaluation testing and discover potential design flaws during the prototype stage. The result is better manufacturing and assembly outcomes.

Furthermore, since rapid prototyping techniques are getting better and more affordable, the cycle time between having a design and actual parts made is significantly shortened, accelerating the entire process.

Having physical prototypes also guides higher quality conversations with the customer. Making an actual model that the customer can see, feel, and interact with helps ensure that the supplier clearly understands their customer’s requirements and can deliver the expected results.

Christopher Matsuoka
Process Engineer, Crane Aerospace & Electronics



Innovation is not always a linear process originating from a manufacturer’s research

and development and then subsequently marketed to end users. Instead, innovation may occur at any phase of a new product development.

Relying on design software exclusively limits the type of user feedback and innovation a developer is able to collect. Physical prototypes provide a greater potential for users to discover unintended uses or applications for new technology. In the medical device field, implantable pacemaker technology is now being implemented and modified for use in many neuromodulation implantable devices. The ability to proof these concepts or make such discoveries is beyond the scope of present day software design and simulation capabilities.

Medical device manufacturers must often push their design envelopes to develop smaller and lighter devices. As such, physical prototypes allow designers to verify the manufacturability of those new limits. Furthermore, they define the actual repeatability of a design and may reveal reliability concerns seen only during manufacturing. Design software effectively eliminates this variability that physical prototypes and evaluations provide.

Gabriel O. Adusei, MSc, PhD
Independent MedTech Consultant, Founder, Intl. Assoc. of MedTech Consultants

Medical device manufacturing is very dynamic and manufacturers are under pressure to reduce time to market and optimize products to higher levels of performance and reliability. These, therefore, call for optimization of all the processes involved, from design to production.

A number of products are being developed in the form of virtual prototypes, in which engineering simulation software is used to predict performance prior to constructing physical prototyping. Engineers can quickly explore the performance of thousands of design alternatives without investing the time and money required to build physical prototypes. The ability to explore a wide range of design alternatives leads to improvements in performance and design quality and the time required to bring the product to market is usually reduced substantially because virtual prototypes can be produced much faster than physical prototypes.

Software design (virtual) and physical prototypes are not competitive technologies and one cannot replace the other as they are complementary. The strengths and

advantage of one technology will address the weaknesses and limitations of the other. Industry leaders with both technologies have the ability to select the best for the task at hand

---

Damien Plisson
Solution Leader of Medical Devices, Dassault Systèmes

Significant advances have been made in virtual testing of medical devices using computer aided engineering techniques like finite element analysis and multi-physics simulation. This approach, which has been called in silico testing, provides many advantages including:

- The ability to assess device performance before hardware prototypes are available
- Easily and quickly test a wide range of configurations including populations types, environmental conditions, ages, and product variations
- Investigation of device/tissue interaction without the need for physical test protocol
- Rapid evaluation of design options
- Insight to device behavior that cannot be gained from physical tests

This approach has been proven to save significant costs, reduce time to market, and improve mitigation of in-service device failures, and yet is still immature in both adoption and FDA regulation. In fact, there are examples where the physical prototypes and clinical trials on real patients are done only for regulatory validation purposes; the actual design validation being done before in simulation. Even regulators are using simulation for their own tests on devices' short and long term reliability.