MD&DI
Medical Device & Diagnostic Industry

PROTOTYPING >>

Comparing Prototype Techniques

Prototyping can improve the product development life cycle. Designers must understand different prototyping methods for mechanical and industrial design.

John Mugan

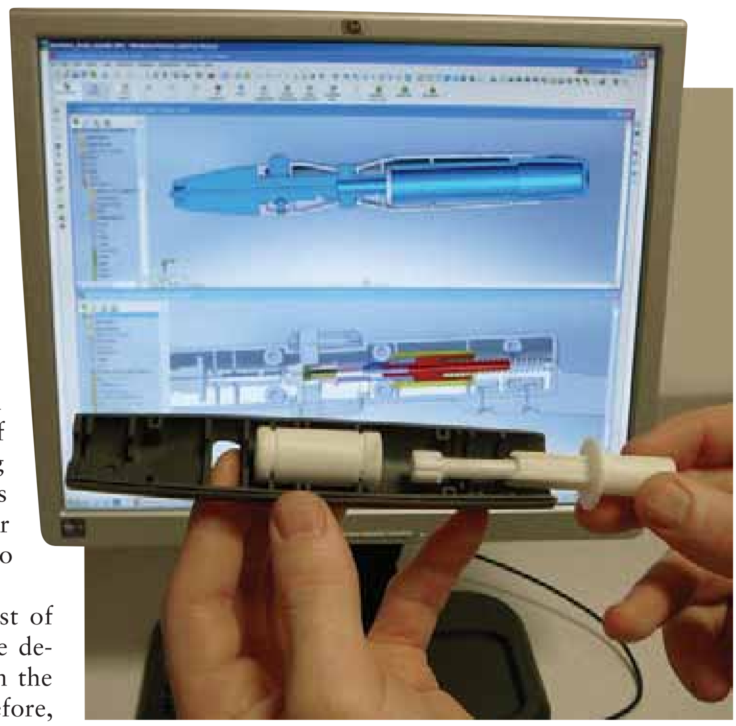
Across the medical device industry, product development is under increased pressure. An estimated 80% of a medical device manufacturer's profits come from products released within the last five years.[1] Therefore accelerated product development timelines are central to profitability. A good prototyping strategy can save OEMs significant cost and time in the design of medical devices.

Development Obstacles. The product development process has many obstacles that can impede project progress. A robust development process, design controls, planning, and effective communication between teams can minimize the risks, but the early phases of a project are fraught with uncertainty, often costing time and money. In addition, the later these obstacles are encountered in the development cycle, the greater they affect the overall project timeline and cost to market launch.

Figure 1 (see p. 86) illustrates the increasing cost of changes made to the design specification late in the development cycle. Discovering a design failure late in the development cycle would have a similar effect. Therefore, the challenge for those managing the development cycle is to capture the most complete product specification and expose design failures early in the development process. Prototyping is one of the most efficient means to crystallize a product specification and identify these failure modes.

From Problem Solving to Problem Finding. During the product development process, the more effort that is applied to problem finding early in the cycle, the less effort is necessary on problem solving later on. Prototyping enables product developers to encourage change earlier in the process. As such it leads to fewer design problems to be solved upstream and thus reduces overall time and costs.

When prototypes become available, development projects move from conceptual to physical. They help designers pose probing questions and envision likely use scenarios. This in turn creates a greater collective understanding of the design among all team stakeholders and leads to improved stakeholder feedback, thereby minimizing late-stage specification changes. Prototypes can also facilitate design improvements early in the design process.



Prototyping can shorten the product development life cycle.

Creating prototypes is one of the most efficient means of identifying device failures. The product developer should not assume anything about a project, but instead should adopt a do it, try it, fix it approach that encourages testing every aspect of a product. Even standard off-the-shelf components that reside on the periphery of a device can lead to a design failure late in the development cycle. Each prototype iteration produces new findings to improve both the features and functionality of a design.

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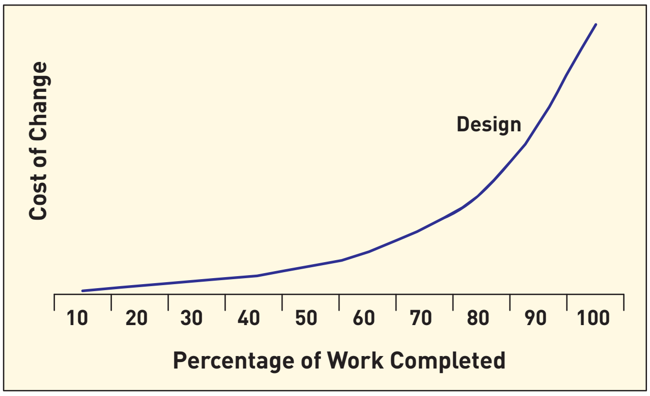


Figure 1. As the product development cycle progresses, the cost of design change increases.

Prototyping and Tooling Methods

When considering the most appropriate prototyping approach, a product designer must establish the quantity of units and level of functionality required. All prototyping methods have benefits and limitations. To outline the options, this article uses the example of a drug-delivery device.

Drug-delivery devices for minimally or less-invasive surgical treatments typically consist of a tube-based distal shaft and proximal deployment system. Both the proximal and distal sections should be prototyped and combined to gain a holistic view of the design. Prototyping for the distal shaft portion of a delivery device is easily achieved. Multiple vendors provide stock components or process capabilities for short-run prototyping. Prototyping the proximal deployment systems, which consist of mechanical components in a plastic housing, are a greater challenge.

Various options are available for prototyping and tooling the proximal deployment section, including the following:

- White models.
- 3-D printing.
- Stereolithography (SLA).
- Selective laser sintering (SLS).
- Micromachining.
- Vacuum casting.
- Metal casting (not discussed in this article).
- Prototype tooling.
- Soft tooling.
- Production tooling.

The details of the prototype depend on the stage of the development cycle. At concept stage, the prototype can simply look like the final design. For animal trials the prototype should work like the final design. At the design-freeze stage prototyping should be made like the final design. Table I presents the appropriate prototyping for different stages in the development process. All of these techniques can be developed once a CAD file of the model exists.

White Models. White models are representations of the device design. They provide a visual at an early stage. White models are generated from modeling clays or solid builds and can be completed within 24 hours. The primary function of a white model is to enable the development team to agree on the scale and look of a device.

3-D Printing. 3-D printing enables the creation of a 3-D object by layering and connecting successive cross sections of material to build a prototype model. Such printing is best suited to building one-off parts. It is a fast and inexpensive method for creating prototypes. This method produces functional, flexible parts that are also suitable for machining. However, the parts are not wholly accurate and surfaces are heavily textured.

Stereolithography. SLA produces fast, accurate prototype models using an additive fabrication process. The models satisfy form and fit requirements but are largely nonfunctional. However, new materials that allow more-functional parts with smooth surfaces in clear materials are becoming available. These options are typically not very lubricious nor are they suited to low-friction test requirements. An SLA prototype build can be achieved within 24 hours. Its strongest feature is dimensional stability.

Selective Laser Sintering. SLS is an additive rapid manufacturing technique that uses a high-power laser to fuse plastic, metal, or ceramic powders into a mass that represents a desired 3-D object. The process is suitable to prototype the strong, functional models required for physical testing. SLS prototypes are typically not as clean or dimensionally accurate as SLA prototypes, but they can be created in a greater range of materials that can also be colored. Prototypes can typically be built within 24 hours and are best suited to one-off quantities or limited builds.

Micromachining. Also known as subtractive manufacturing, this method produces extremely accurate prototypes, typically within two weeks. The prototype is machined from a block of the exact material to be used for the part in production. It enables functional and environmental testing.

Vacuum Casting. Vacuum casting is a technique in which silicone molds are created from a prototype and the mold is then used to create a number of identical parts. Vacuum casting is a fast method for developing low production quantities of a prototype. In addition, the prototypes produced by vacuum casting are of near-perfect production quality. They can be produced in various material types and durometers, including soft rubber or wax and clear polycarbonate. Color variations and surface finishes are also possible. Insert-molded components or overmolded features can even be simulated by pouring resin over a preinserted component. All parts produced by the vacuum casting are fully functional. Casting of metals can be undertaken using a similar technique.

Prototype Tooling. Although SLA, micromachining, and vacuum casting can produce functionally acceptable prototypes, the product design may still present significant tooling and production challenges. Prototype tooling is the most cost-effective method of confirming a "made like" version of the device. Suitable for simple molded parts with limited features, this technique enables production of 1000–3000 parts at a moderate piece price. Tooling costs can be amortized into the parts.

Consultation with the toolmaker is advisable as the device design progresses to ensure that the final part is mold friendly and that the additional costs (e.g., sliding cores) are minimized if not eliminated. This method is ideal for

PART OPTIONS	LOOKS LIKE	WORKS LIKE	MADE LIKE
White models	X		
3-D printing		X	
SLA and SLS	X		
Micromachining	X	X	
Vacuum casting	X	X	
Prototype tooling	X	X	X
Soft tooling	X	X	X
Production tooling	X	X	X

Table I. Prototyping and tooling options at various stages of the development process.

good laboratory practice (GLP; e.g., animal trials) or even batch-release clinical trials.

Soft Tooling. Soft tooling is a means to produce a low-cost tool suitable for low-quantity production. Metal injection molds are manufactured from an aluminum or pretoughened steel and do not require advanced production supports such as water cooling or ejection systems. Soft tooling is of lower quality than full production tooling and has a limited ability to accommodate any modifications. But it is sufficient to support manufacturing requirements for the regulatory approval process.

Full Production Tooling. Once the design is frozen and confidence in the product design is high, full hardened production tooling is developed. This tooling produces molded parts with high degrees of tolerance in quantities from thousands to millions.

Prototyping Costs

Table II summarizes prototyping options. This table also shows the typical cost per prototype for two sample devices used in orthopedic surgery. Design A is a feature-rich, complex device. Design B is a more standard device design.

Tooling costs are dependent on the level of detail in the part (the greater the detail, the higher the tooling cost). For example, soft tooling costs for an outer skin of a handheld deployment system could double if the designer integrates complicated internal features to accommodate subassemblies and components. When developing a budget for prototypes, it is advisable to match the prototyping approach to the quantities of prototypes required. As a general guideline, white models, 3-D printing, SLS, SLA, and micromachining are best suited to unit quantities of less than 10. Vacuum casting is better for quantities of 10–50, and prototype tooling is best for quantities up to 3000. Soft and hard tooling is best suited to quantities in excess of 100,000.

The table also demonstrates the relatively low cost of vacuum casting and prototype tooling, which can typically support product development through GLP, first-in-man trials, and, in some cases, full clinical trials. One thing to keep in mind, however, is that these two approaches also have longer lead times than most methods. The methodologies are best suited to product designs in advanced stages of development, when speed becomes a lower priority than achieving physical detail.

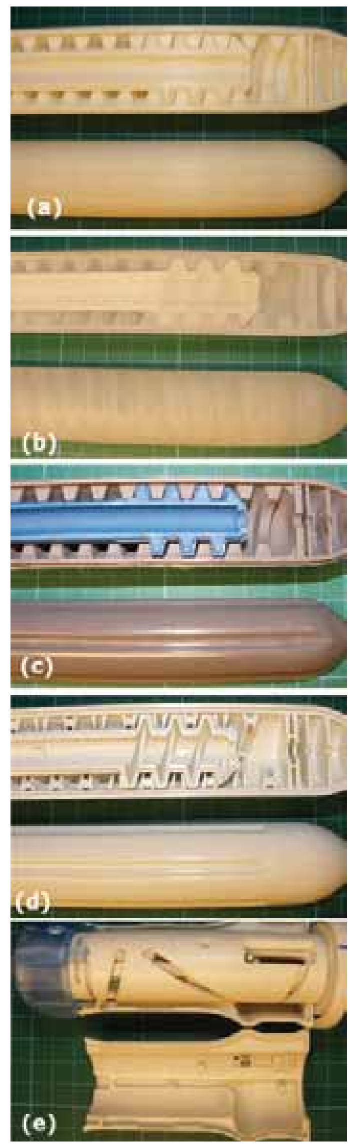
For most OEMs, the cost of acquiring the equipment to prototype in-house is prohibitive. Only the largest device OEMs with extensive product pipelines can justify purchasing specialized prototyping equipment. For example, the cost of acquiring an SLA suite exceeds $110,000 and requires a full-time skilled technician to maintain and operate the equipment. Micromachining and soft tooling capabilities demand a dedicated and fully staffed tool room with specialized process equipment and software. It is typical for early-stage companies to work with external partners in each of the prototyping areas or coordinate all prototyping projects through a contract design partner.

Prototyping in Action

The best way to demonstrate how designers use prototyping is to look at real examples.

Example 1. A complex Class IIb device was in development with a large and diverse group of stakeholders providing design input. These groups included physicians who were providing ergonomic input, a marketing team to provide styling input, an R&D team seeking to meet mechanical requirements and optimize the design for manufacturing and an industrial design team who offered anthropometric data.

Design inputs and requests from stakeholders often conflicted and had the potential to derail development. Prototyping helped the team incorporate the feedback of all groups, resolve conflicting requirements, and progress the device design. Early-stage prototypes included white models to provide the physicians, marketing, and industrial design team with a look-and-feel perspective of the outer skin. Two iterations of these early prototypes were sufficient to achieve design consensus from the groups. Then the industrial design team sought to verify functionality, which demanded proto-



Prototype part manufactured using (a) 3-D printing, (b) SLA, (c) silicone molding, and (d) prototype tooling. As a rule, the longer the processing time the better the surface finish. Some prototyping techniques allow for (e) greater detail.

PROTOTYPING AND TOOLING METHOD	LEAD TIME	DESIGN A COST PER UNIT [a]	DESIGN B COST PER UNIT [a]	TYPICAL QUANTITIES	MERITS OF METHOD	LIMITATIONS OF METHOD
White modeling	24 hours	\$1000	\$1000	1 set	Appreciation of scale	No functionality
3-D printing	24 hours	\$350	\$300	1–3	Partially functional and machinable	Not accurate
SLA and SLS	1 week	\$2000	\$2000	1–3	Very accurate	Rigid
Micromachining	2 weeks	\$2000	\$2400	1–3	Exact material	Restricted by machining techniques
Vacuum casting	3 weeks	\$300[b]	\$160[b]	1–100	Fully functional, for ≤30 pieces	Short mold life
Prototype tooling	6 weeks	\$10–\$15[b]	\$5[b]	50–3000	Fully functional, for ≤30 pieces	Tooling restrictions
Soft tooling	6 weeks	\$10[b]	\$5[b]	500–10,000	Full detail, functional	Expensive
Production tooling	12 weeks	\$8[b]	\$3[b]	5000–1 million	Full detail, functional, low piece price	Expensive

[a] Costs calculated at time of print, indicative for sample design specified.
[b] Tooling costs not included.

Table II. Prototyping and tooling examples of lead time, costs, merits, and limitations for selected designs. Design A is a device with 11 components. Design B is a device design with seven components.

typing of component part detail that was dimensionally and functionally representative. This was achieved through a combination of SLA and micromachined parts. Because the device had a complicated mechanism, four design iterations were developed to achieve a final functional design. Vacuum casting satisfied the needs of GLP and initial first-in-man studies.

The design process moved from concept to first-in-man in six months. As the design progressed through trials, it saw a number of design iterations. Prototyping proved key to managing design inputs while also keeping the project to agreed-upon timelines and within budget, ultimately resulting in a device that was successful in large clinical trials.

Example 2. A young venture-backed company was developing a Class III implantable device. It was imperative that the firm meet key milestones to secure further investment. The company had focused all of its resources on the implantable element of the device and had failed to develop an adequate deployment system. The OEM did not have the resources or time to develop the system. However, without that system, the company knew it would fail to meet its milestone. Within 72 hours, a rudimentary deployment mechanism progressed from sketch to CAD model to a 3-D printed prototype device. Despite its limited functionality, this single prototype iteration enabled the company to secure further investment. The prototype was even retained for first-in-man trials.

Conclusion

Prototypes hold the key to a fully functional design at design freeze. It is a tool that allows an inclusive critical review by all the stakeholders. However, it is critical to select the right method for the product and number of units needed. Because an infinite number of devices can be made available before tooling, prototyping helps lock down the specification early and identify failure before the cost of change becomes exorbitant. Prototypes enable the product designer to find failures early in the development cycle and minimize design creep later on, thereby leading to a better overall design within a shorter time frame.

Reference

1. *Forecast for the Medical Device Outsourcing Market: Growth and Consolidation*, [online] (Frost & Sullivan, 2006 [cited 24 November 2008]); available from Internet: www.frost.com/prod/servlet/market-insight-top.pag?docid=59785202. ■