MANUFACTURING ENGINEERING

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Filling in the BLANKS

Rapid adds new dimensions to the space between prototyping and manufacturing.

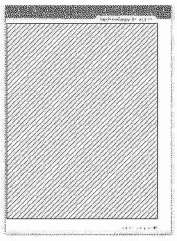
The process now known by many simply as rapid has evolved a long way from its origins as rapid prototyping. It has stretched well into the manufacturing space. The materials it uses now include sophisticated metals as well as more plastic material. The evolution into the realm of manufacturing promises to expand at an accelerating pace.

That doesn't mean, however, that there is not space to be explored between that promising future and that primitive past.

Ivivi Technologies (Montvale, NJ) is one of the explorers of that space. It develops noninvasive electrotherapies for a wide range of medical applications. Its devices are used to treat pain and swelling by stimulating the patient's anti-inflammatory responses. In addition, Ivivi is working on devices for a broad spectrum of other applications, including cardiac, neurological, and orthopedic. Other medical devices are being developed to handle sports

Ivivi Technologies found that Objet's Eden350 3-D printer could quickly create precise devices ready to accept electronic components for speedy delivery to clinical trial participants.

James D. Sawyer
Yearbook Editor



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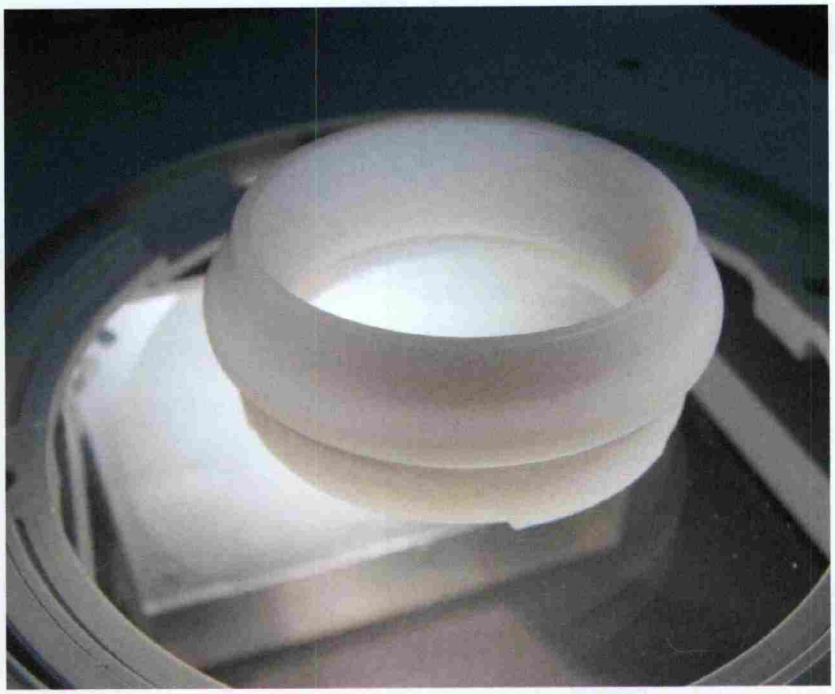
injuries, nonhealing wounds such as diabetic ulcers, and other health conditions.

As a result, Ivivi is in need of continuous production of small quantities of production-intent devices to be used in clinical trials. Before turning to rapid technology, each trial could not take place until many months had passed and many dollars had been spent on planning, development, and production.



Improved Petri dish was developed for use in advanced diabetes research.

"We were relying on outside resources and, often, it was taking months to create just one very expensive and extremely delicate prototype, which of course would have to be modified at least a few times to get the final product right for the trial," says Andre' A. DiMino, Ivivi's vice chairman of the board and co-chief executive officer. "We needed a faster system that would let us do the engineering, development, and production of clinical trial-ready devices in-house."

After investigating a number of systems from a variety of companies, Ivivi settled on the Objet Geometries Ltd. Eden350. The company's rationale was that it could quickly create precise devices ready to accept electronic components for speedy delivery to clinical trial participants. Other benefits include the light weight of the printed objects, and their smooth finish and durability.

Ivivi saw a positive return on its investment in the rapid technology in less than a year.

"We've cut an average of five to six weeks off the clinical trial device production process," DiMino says. In addition, Ivivi is able to develop new prototypes more quickly, allowing product changes to be accomplished literally overnight in some cases. Furthermore, the company now has its own means to design and manufacture custom jigs, fixtures, and other production tools for finishing clinical trial devices, and it can do so in a rapid cost-effective manner. Previously this work was contracted out.

Also, and perhaps just as important, Ivivi's ability to modify devices in order to meet business and patient needs in one day's time has strengthened its relationships with key distribution partners.

Biorep Technologies Inc. (Miami, FL) is another developer of original equipment medical devices. It is affiliated with another Miami enterprise, the Diabetes Research Institute (DRI). Biorep focuses primarily on devices aimed at finding a cure for diabetes. In order to make progress toward this goal as rapidly as possible, it strives to offer islet isolation equipment at a reasonable price to give access to the technology it develops to as many research centers as possible.

As did Ivivi, Biorep originally used a machine shop for prototyping. On occasion, when it needed to evaluate the design of small parts, it would turn to a service bureau to prototype them. As the company's equipment became more compact and sophisticated, however, its design team, led by Engineering Director Felipe Echeverri and R&D Engineer Andres Bernal, found that the volume of small part prototypes had reached a point where it made sense to bring rapid prototyping in-house.

"When we outsourced 3-D printed models," Echeverri says, "they were often more expensive than the cost to machine them in-house, and it wasn't much faster. We knew we could really accelerate our design productivity if we had the ability to print a part overnight, in our office."

Biorep knew doing things in-house could lower the cost and increase the speed of rapid prototyping. There were other considerations, too. "Most often," says Echeverri, "we use rapid prototyping to prove concepts and check fit, form, and function before committing to tooling for injection molding, so accuracy was really important. But we also estimated that we would produce about twice as many prototypes if we had in-house capabilities, and we have a small team, so ease of use and reliability were also crucial." The Objet Eden250 that Biorep chose has, says Echeverri, helped

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his team produce better designs and has accelerated the time to market for new products.

A Biorep product called the silicone membrane Petri dish illustrates the advantages of taking rapid in-house.

A standard plastic Petri dish allows oxygen in only from the top. DRI scientists theorized that if oxygen could reach the cells in a Petri dish from both the top and the bottom, the cells used to produce insulin would be more viable because they could breathe better.

"Silicone is permeable to oxygen," says Echeverri, so Biorep looked to develop a Petri dish that used a silicone membrane. "DRI scientists developed a proprietary silicone blend," he adds, "that enhances oxygen permeability." Biorep's job was to devise a means to hold the membrane that would provide the form and function of a traditional dish.

After coming up with an initial design, Biorep's team experimented with a number of different ways to ensure manufacturability and proper assembly. The final membrane design is just 300 µm thick. Their prototyping not only assured the manufacturability of the dish, be also its ability to be mass produced. The prototypes that came out of that effort were used to apply for a National Institutes of Health grant to help fund continued development of the product.

"CAD drawings just aren't as effective," says Echeverri, "when you are presenting a completely new type of design."

"Our ability to produce prototypes in-house is absolutely critical," he adds. "First, we are able to design parts without regard for the limitations of machining, which really frees our thinking. When we have a new idea we can design, print, and test it right away. And second, because we are able to produce a lot of prototypes very quickly at low cost, we do a lot of testing. That helps us find and fix problems very early on that really could hurt a project if we didn't find them until later."

From drawing board to the beginning of field tests in a number of labs took half a year. "Six months is an incredibly short time to get a medical device into field testing," Echeverri says. "Our ability to produce rapid prototypes in-house cut development time in half."

DRI scientists report that the results of the early field tests are promising. The cells are healthier and produce more insulin, which is crucial for advancing diabetes research.

We needed a faster system that would **let us do the engineering, development and production** of clinical trial-ready devices in-house.

Instrumentation and minimally invasive devices are among the innovations Orchid Design develops using rapid prototyping.

A good outcome arose from Orchid Design's use of rapid prototyping, too.

Designers and engineers at the Shelton, CT, division of Orchid Orthopedic Solutions (Holt, MI) work with medical professionals to design, prototype, and test new orthopedic solutions. "It involves very high-precision work," says Brian McLaughlin, Orchid Design's business development manager, "and of course it's all subject to FDA approval. There's no room for error."

Despite this close scrutiny, Orchid Design found that the rapid prototyping it did in-house on a 3-D printer resulted in better quality and manufacturability of design compared with traditional methods. And, more strikingly for the bottom lines of Orchid Design and its customers, by using rapid prototyping the company could produce high-resolution models up to 20× faster than before.

For example, McLaughlin says, a physician came to Orchid Design on a Thursday and described his idea for a new spinal device that he wanted to explore quickly. Orchid's designer spent the next two days developing CAD drawings. On Monday a 3-D prototype was produced. The designer reviewed it with the physician the next day. Wednesday was spent refining the design using this feedback, and this was printed on Thursday. The physician brought that prototype to a meeting with potential investors on Friday. Impressed with the device, the investors provided funding.

While eight days might not be typical, explains McLaughlin, it does demonstrate the value of a high-quality working prototype. "The physician told us," he says, "that having a physical working prototype was definitely a factor in being able to land funding so quickly."

Another advantage for Orchid Design is that it is generating more repeat business from satisfied customers.

"Rapid prototyping and the subsequent design enhancements it facilitates really help showcase our expertise not just in design," McLaughlin says, "but also in manufacturability. And our customers remember that when it comes time to transfer the product into manufacturing. It gives them a really high degree of comfort about working with Orchid for the entire process, not just the design."