IV, BE GONE

A REVOLUTIONARY PATCH PUMP developed by Professors Yet-Ming Chiang and Michael Cima will reduce the need for IV infusions by allowing patients to self-administer biopharmaceuticals. The intended results: better compliance, fewer hospitalizations, and lower health care costs.

An IV drip is nobody's idea of a good time.

But for millions of people being treated with today's biologically based "miracle drugs", intravenous infusions are a fact of life. "Biologics are a big part of personalized medicine," says Michael Cima, a professor of Engineering at MIT. "But compared to traditional medicines, which can be taken in tablet form, they're challenging to administer."

DON'T EAT THE PROTEINS

Manufactured from live organisms or their components, biologics can't be taken orally because the proteins in them will be digested. In a concentrated dosage, they're viscous, making a hypodermic injection painful and, in some cases, impractical. And in a more dilute form, biologics may require an IV infusion lasting several hours.

All these factors contribute to patients falling out of compliance with their drug regimes. In turn, this can lead to poor health outcomes, emergency hospitalizations, and overnight stays so patients can receive stabilizing IV infusions — all at great expense.

2ccs IS THE LIMIT

To address these challenges, device makers have created pen injectors and patch pumps that allow patients to self-administer biologics at home or work. "Unfortunately," says Cima, "most current devices are just clever miniaturizations of existing equipment, and they share a common limitation: They can't administer a dosage volume larger than 2ccs without becoming very bulky. That makes them inadequate for many therapies."

Taking a radically different approach to the challenge of self-administration, Cima and his colleague Yet-Ming Chiang created a smaller, simpler infusion pump that can deliver a dose of up to 20ccs, making it applicable to a much wider range of illnesses and medicines.

MORPHING FOR THE MILITARY

The pump evolved from DoD-funded research Chiang and Professor Steven Hall did on creating large-scale morphing structures, such as airplane wings, that can dynamically change shape to improve performance and energy efficiency. Chiang—an authority on battery technology — figured out how to harness deformation, a classic problem in battery design, to power morphing activity.

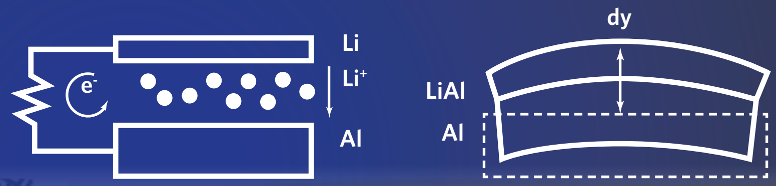
"As a battery charges and discharges, ions move back and forth between the electrodes, causing expansion and contraction," Chiang explains. "The materials being deformed have a high degree of stiffness that can generate force. My idea was to use that force to do the mechanical work of morphing." To demonstrate the concept for this device, called an electrochemical actuator, Chiang built a lab-scale model of a helicopter rotor that had lithium batteries stacked inside. These could be charged and discharged to change the rotor's shape.

KEY INNOVATORS

- YET-MING CHIANG, Kyocera Professor of Materials Science and Engineering
- MICHAEL J. CIMA, Sumitomo Electric Industries Professor of Engineering; investigator at the Koch Institute for Integrative Cancer Research.

THE BIG SQUEEZE

A schematic drawing (right) and an early prototype (below) show how an actuator generates force to squeeze medicine out of a mini-infusion bag. When the battery circuit is closed, lithium (Li) ions spontaneously interact with the aluminum (Al), causing a reaction layer (LiAl) to form on the aluminum. Because the layers have different densities, the reaction layer expands more than the aluminum, causing the aluminum plate to bend forcefully.



FROM HELICOPTERS TO HEALTH CARE

When the DoD project ended, Chiang teamed up with Cima, a longtime friend, who had experience with startups in the medical device industry. In 2006, they received a Deshpande Center grant to further develop Chiang's morphing innovation and adapt it for use in a medical device.

They soon converged on a product concept: a disposable, patch-style infusion pump—containing a single dose of medicine—that would be attached to the skin, like a Band-Aid, and worn during sleep. A built-in electrochemical actuator would not only provide the force needed to subcutaneously inject medicines but would also ensure a constant rate of administration over time. The basic pump design could be custom-tailored to treat specific illnesses using specific medicines.

FINDING THE RIGHT CHEMISTRY

"The Deshpande Center funding allowed us to take the morphing concept outlined in the DoD work and totally reinvent how it was applied," says Chiang. "Contrary to the design goal for batteries in handheld devices, where the volume change must be limited to a few percentage points at most, our goal was to maximize the displacement of the battery while delivering enough force to squeeze medicine out of a miniature infusion bag. Conventional battery chemistries just didn't meet these metrics."

The team solved this problem by designing an ingenious battery architecture and chemistry that results in a bending action, which amplifies the effect of deformation. Because the battery is the actuator, no separate power source is needed: the device is self-powered.

The infusion pump can administer a dose of up to 20ccs, making it potentially applicable to a wide range of illnesses and medicines.

PUTTING TOGETHER THE PIECES

Chiang says, "The Deshpande Center funding allowed us to develop the key innovations that make our infusion pump commercially viable. It also gave us time to put together all the pieces on the application and business side."

In 2007 Chiang and Cima formed SpringLeaf Therapeutics to commercialize the device, which is now in human clinical trials. The company expects to bring its first product to market by 2014 and anticipates licensing the technology and/or partnering with others in the future to develop applications for treating other illnesses.