Georgia Institute of Technology
Research News

Contact: John Toon (404-894-6986)
E-mail: (john.toon@edi.gatech.edu)
or Jane Sanders (404-894-2214)

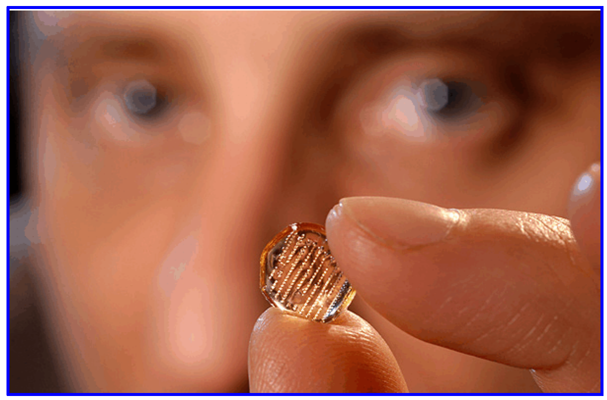
For Immediate Release
November 17, 2003

MICRONEEDLES: REPORT DESCRIBES PROGRESS IN DEVELOPING NEW TECHNOLOGY FOR PAINLESS DRUG AND VACCINE DELIVERY

A paper published in the November 17 online issue of the journal *Proceedings of the National Academy of Sciences* describes progress in the development of microneedle arrays for delivering drugs and vaccines through the skin – without causing pain.

The paper describes research at the Georgia Institute of Technology on fabricating hollow and solid microneedles in a variety of sizes and shapes from metals, biodegradable polymers, silicon and glass. It also reports on testing with cadaver skin and animals that demonstrates the ability of the micron-scale needles to deliver proteins, nanoparticles, and both small and large molecules through the skin.

"We've opened up the potential use of microneedles for delivering a broad range of therapeutics," said Mark Prausnitz, a professor in Georgia Tech's School of Chemical and Biomolecular Engineering and principal investigator for the project. "Fabricating both hollow and solid microneedles in a variety of shapes, sizes and materials allows us to deliver large molecules with significant therapeutic interest such as insulin, proteins produced by the biotechnology industry, and nanoparticles that could encapsulate a drug or demonstrate the ability to deliver a virus for vaccinations."



Researcher Mark Prausnitz holds an array of polymer microneedles that are 1,000 microns tall.

Georgia Tech's development of microneedles began in the late 1990s with microfabrication of solid needles made from silicon, using microlithography and etching technologies originally developed for the microelectronics industry. The researchers produced arrays of up to 400 needles designed to punch holes in the outer layer of skin to increase its permeability to small molecules applied with patches.

That work has broadened to include both solid and hollow microneedles in a broad range of shapes with feature sizes from one to 1,000 microns. Prausnitz and his research team have fabricated microneedle arrays from metal and

Georgia Tech Research News & Publications Office
75 Fifth Street, N.W., Suite 100
Atlanta, Georgia 30308 USA
Web: gtresearchnews.gatech.edu
Phone: 404-894-6986
Fax: 404-894-4545

polymer materials that have sufficient strength to reliably penetrate the skin without breakage.

Moving beyond the original – and complex – microelectronics-based fabrication techniques, the researchers have developed multiple manufacturing processes suitable for the mass production of microneedles from inexpensive metal and polymer materials. By making molds of their silicon needles, for instance, the research team has produced arrays of identical metal or polymer microneedles using a modified form of injection molding that can readily be adapted to industrial mass production.

Molds were also made without the need for creating silicon needles to use as masters. Metal microneedles were produced through electrodeposition onto laser-drilled polymer molds, while glass microneedle masters were fabricated using conventional drawn-glass micropipette techniques.

The broad range of sizes, shapes and materials will permit production of microneedle arrays customized for the type and volume of drug to be delivered, the time period of use, and most importantly, minimizing pain.

"There are trade offs between getting needles to go into the skin easily, getting drugs to deliver easily and making needles that don't hurt," Prausnitz said. "Not every application will need a different needle, but there will probably be classes of applications that will benefit from different needle designs."

Among the potential applications are:

• Arrays of hollow needles could be used to continuously carry drugs into the body using simple diffusion or a pump system;

• Hollow microneedles could be used to remove fluid from the body for analysis – such as blood glucose measurements – and to then supply microliter volumes of insulin or other drug as required;

• Microneedles may prove useful for immunization programs in developing countries, or for the mass vaccination or administration of antidotes in bioterrorism incidents because they could be applied by persons with minimal medical training, and

• Very small microneedles could provide highly targeted drug administration to individual cells.

Microneedles are expected to be less painful than conventional hypodermic needles because they are too small to significantly stimulate nerve endings, Prausnitz said. Small-scale studies so far have confirmed that expectation, and additional pain studies are planned. The safety and effectiveness of microneedles must still be proven in humans before they can receive Food & Drug Administration approval for clinical use.

Before microneedles find widespread use, the researchers must perfect the techniques for optimally inserting them into the skin, and complete the integration of microneedles into a full drug delivery system. The need to minimize variability in needle insertion is being addressed in part by development of an applicator device that would be part of the delivery system.

Several companies are pursuing development of microneedles, including some that are conducting clinical trials. BioValve, a Massachusetts company, has licensed the Georgia Tech microneedle technology.

"There is an aggressive movement toward bringing microneedles to the market," Prausnitz said. "We've shown that microneedles can serve as a hybrid drug delivery system, combining the advantages of conventional needles – which deliver drugs easily – with transdermal patches that are more patient-friendly. I expect that within the next five years, a microneedle device will become available for clinical use."

Beyond Prausnitz, the research team includes Devin McAllister, Ping Wang, Shawn Davis, Jung-Hwan Park, Paul Canatella and Mark Allen. The research has been sponsored by the National Institutes of Health (NIH), the National Science Foundation (NSF), the American Diabetes Association and the Defense Advanced Research Projects Agency (DARPA).

# # #

Technical Contact: Mark Prausnitz (404-894-5135); E-mail: (mark.prausnitz@che.gatech.edu)

URL for Web:
gtresearchnews.gatech.edu/newsrelease/needlespnas.htm