

**Development of  
microneedle technology  
for drug delivery  
in the laboratory, classroom,  
clinic and board room**



**Mark R. Prausnitz  
Georgia Institute of Technology**

# **Outline of talk**

## **In the classroom**

- pharmaceutical education at Georgia Tech

## **In the laboratory**

- design and fabrication of microneedles

## **In the clinic**

- human clinical trials

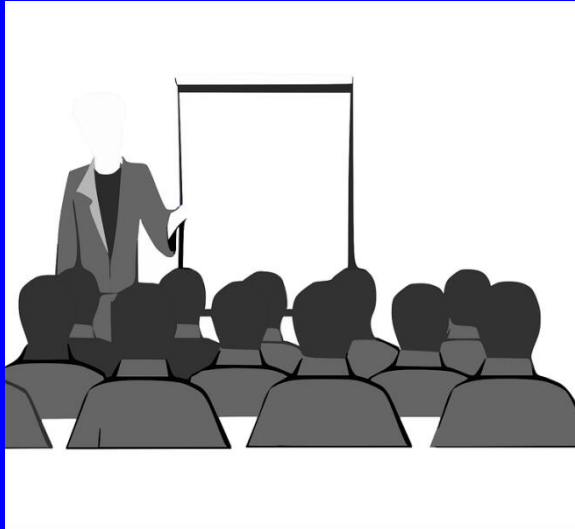
## **In the board room**

- formation of new companies

# Outline of talk

In the classroom

- pharmaceutical education at Georgia Tech



**Classes for  
undergraduates  
and graduates**



**Plant trip to  
pharmaceutical  
industry**



**Training grant  
for doctoral  
students**

# Undergraduate/Graduate Student Semester Course

## **DRUG DESIGN, DEVELOPMENT, AND DELIVERY: *An Interdisciplinary Course on Pharmaceuticals***

MARK R. PRAUSNITZ AND ANDREAS S. BOMMARIUS  
*Georgia Institute of Technology • Atlanta, GA 30332*

**F**or the past five years, Georgia Tech's School of Chemical and Biomolecular Engineering (ChBE) has offered an innovative interdisciplinary course in drug design, development, and delivery, also known as the D4 course. This course was developed due to changes in chemical engineering education over recent years, as well as needs within the pharmaceutical industry for an interdisciplinary approach to the development of novel drugs and formulations. It is offered as part of the biotechnology option track, an undeclared

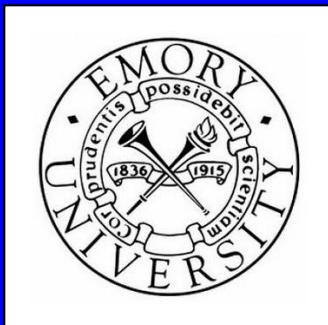
option, and undergraduates from other departments interested in pharmaceuticals. As discussed below, a balanced interdisciplinary mixture of students is assured through admissions restrictions.

This article aims to provide information on the D4 course's structure, its contents, and the instructional philosophy behind it, with the hope that this framework may be directly useful to others or might be adapted to other courses geared towards the pharmaceutical and other industries.

# Graduate Student Short Course

Pharmaceutical development: from drug lead to drug product

Georgia Tech, Mercer, Emory and Georgia State



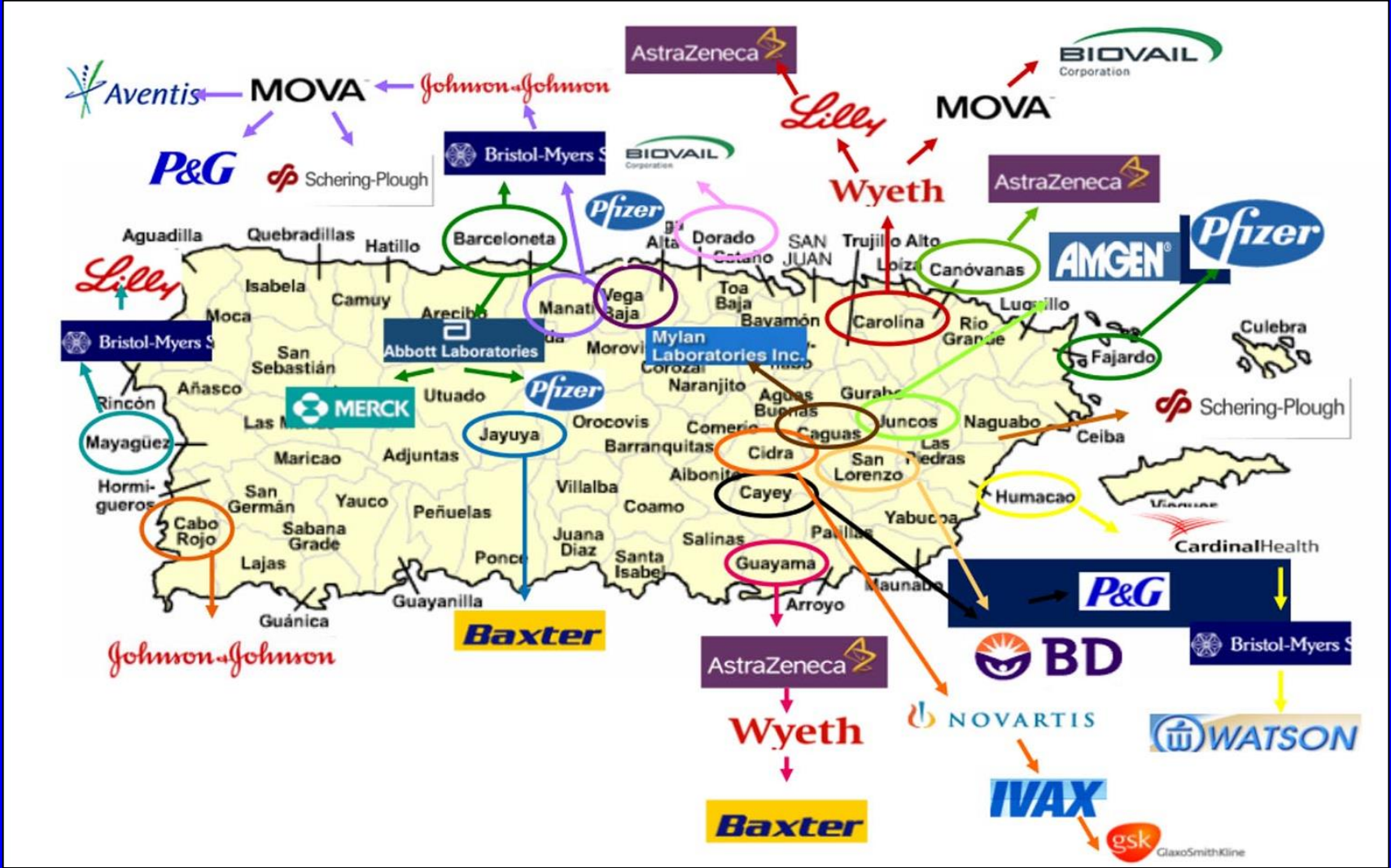
# Pharmaceutical Industry Plant Trip

Abbvie, Amgen, Bacardi, Eli Lilly, J&J, Medtronic,  
Merck, Pfizer, Wyeth



# Pharmaceutical Industry Plant Trip

## Puerto Rico



# GAANN Fellowship Program

U.S. Department of Education  
Graduate Assistance in Areas of National Need

2004 – 2013

~120 one-year fellowships to doctoral students in

BMED

CHEM

CHBE

The bottom of the slide features a banner image. On the left, the word "gaann" is written in a large, white, lowercase, sans-serif font. Below it, in a smaller, orange, uppercase font, is "U.S. DEPARTMENT OF EDUCATION". Underneath that, in a smaller, white, italicized font, is the tagline "Promoting educational excellence for all Americans". To the right of the text is a photograph of a young woman with long brown hair, wearing a red hoodie, looking through the eyepiece of a black microscope in a laboratory setting. The background shows lab equipment and shelves.

**gaann**  
U.S. DEPARTMENT OF EDUCATION  
*Promoting educational excellence for all Americans*



# Outline of talk

## In the laboratory

- design and fabrication of microneedles

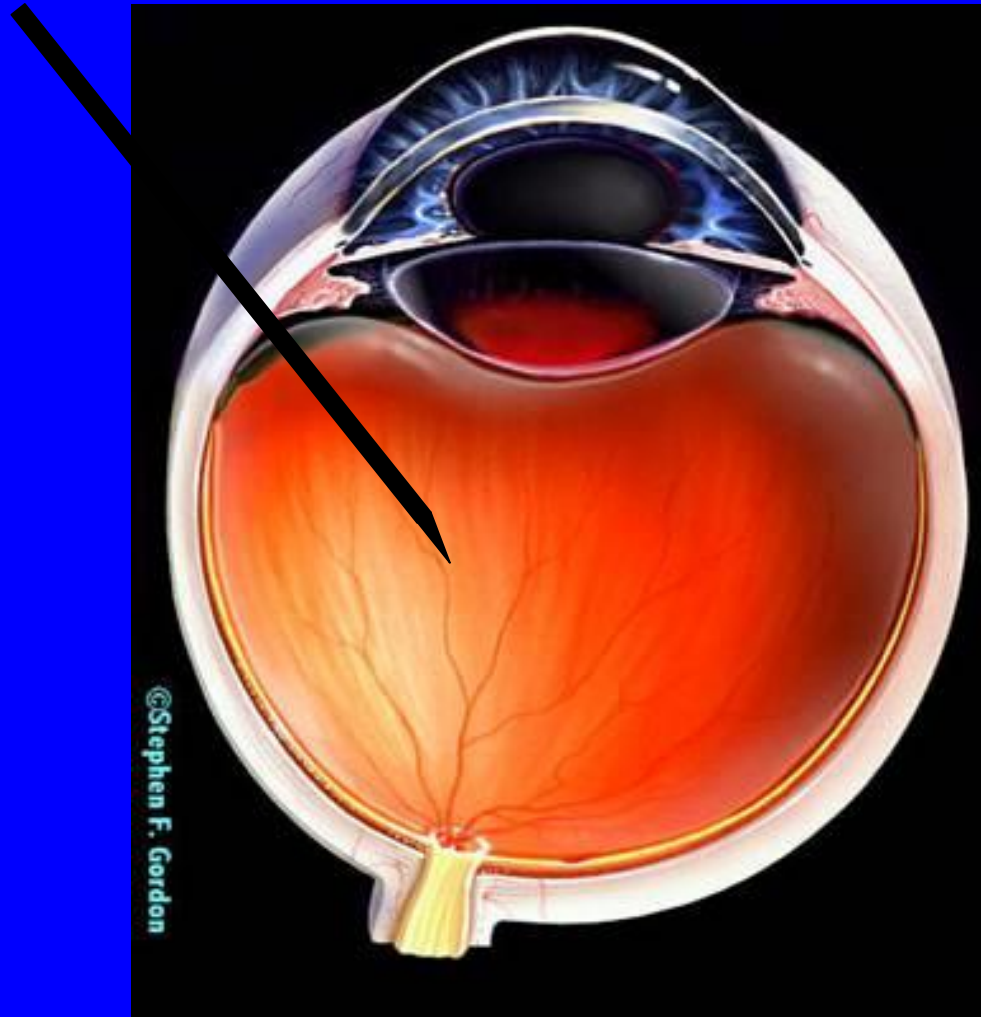


**Targeted drug delivery  
in the eye**

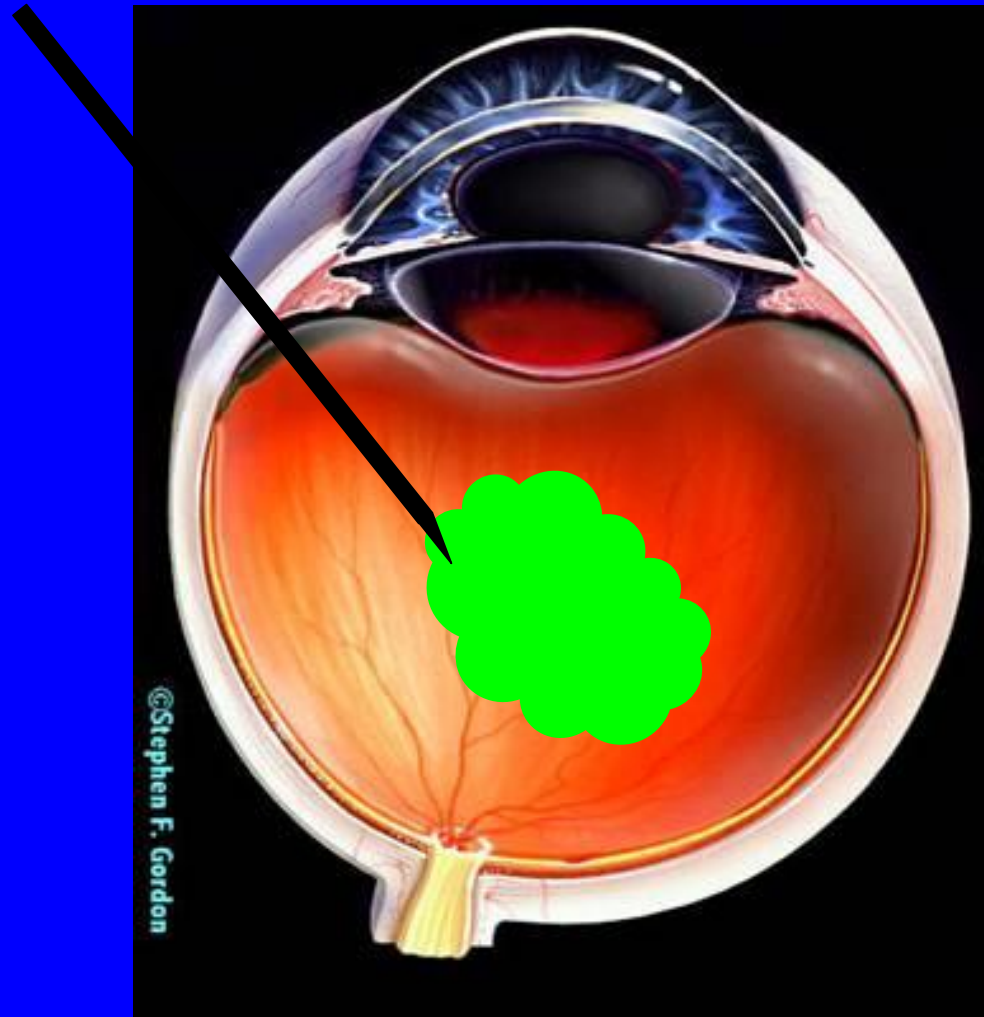


**Skin vaccination with a  
microneedle patch**

# Intravitreal injection is poorly targeted



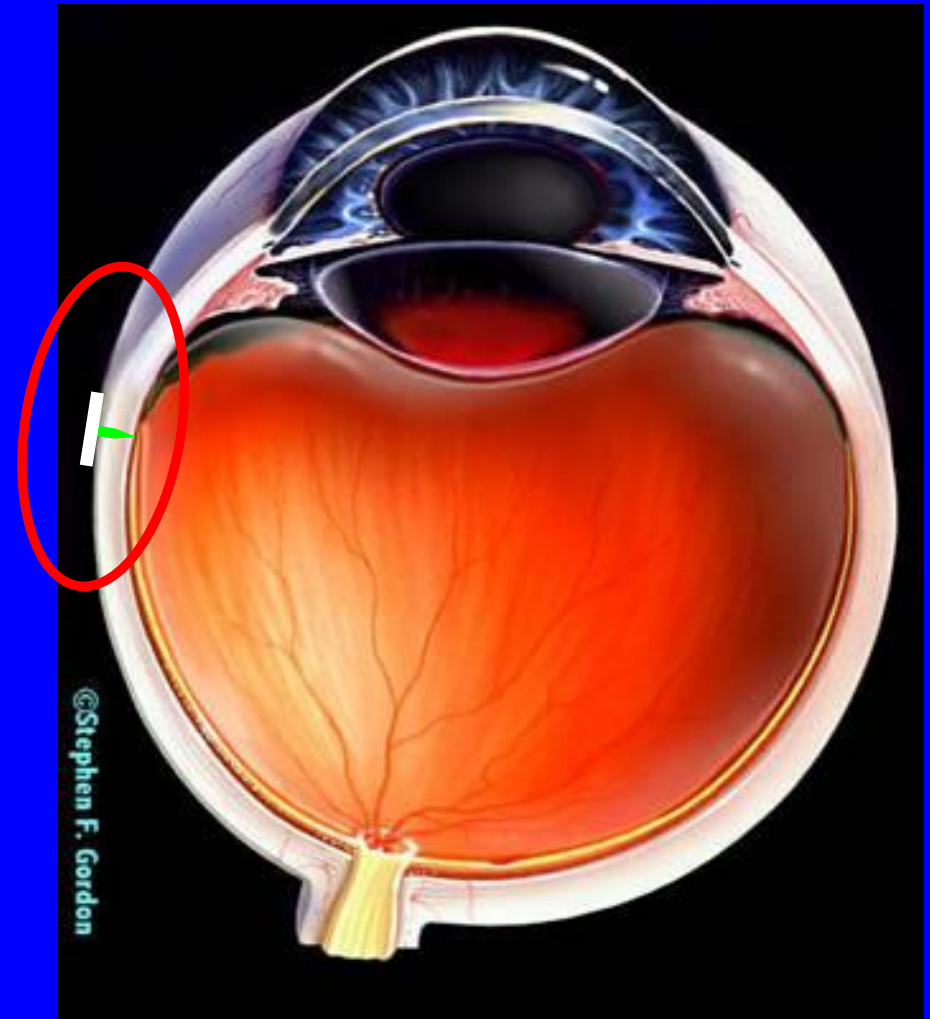
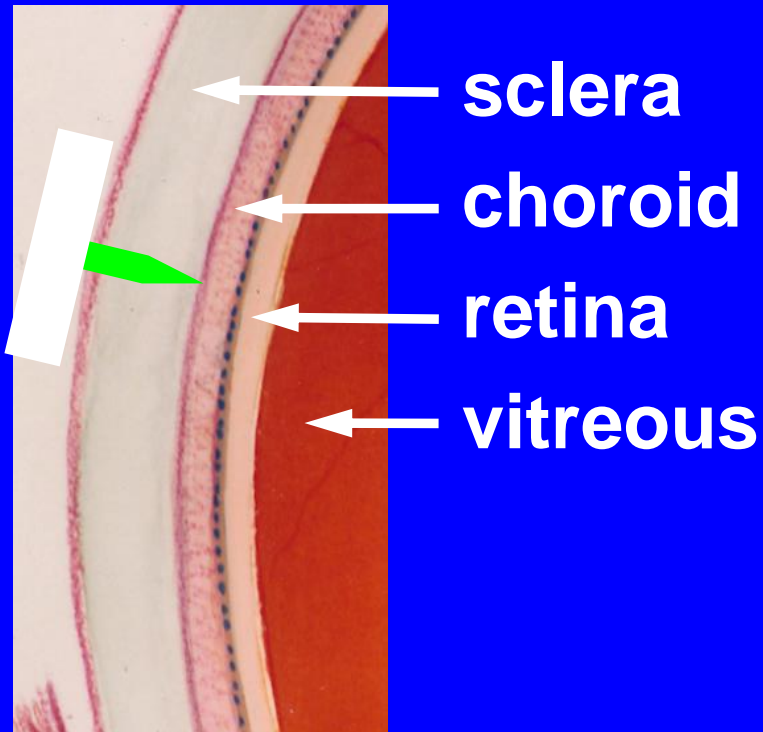
# Intravitreal injection is poorly targeted



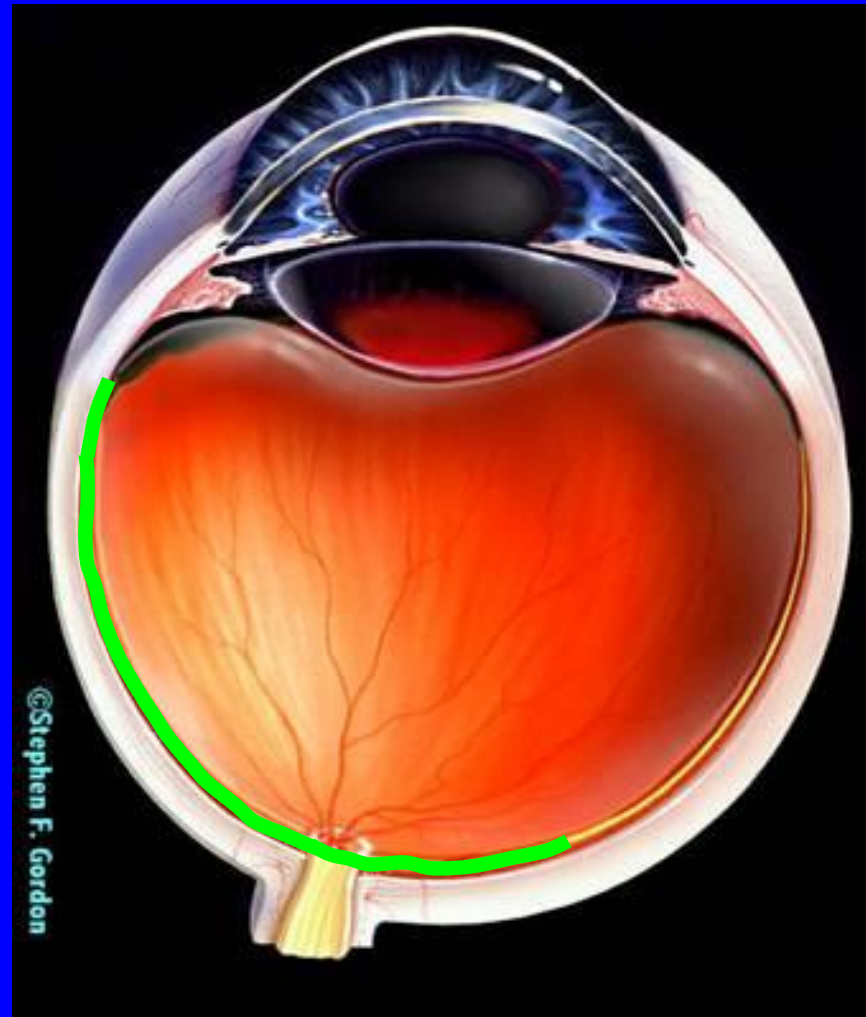
# Intravitreal injection is poorly targeted



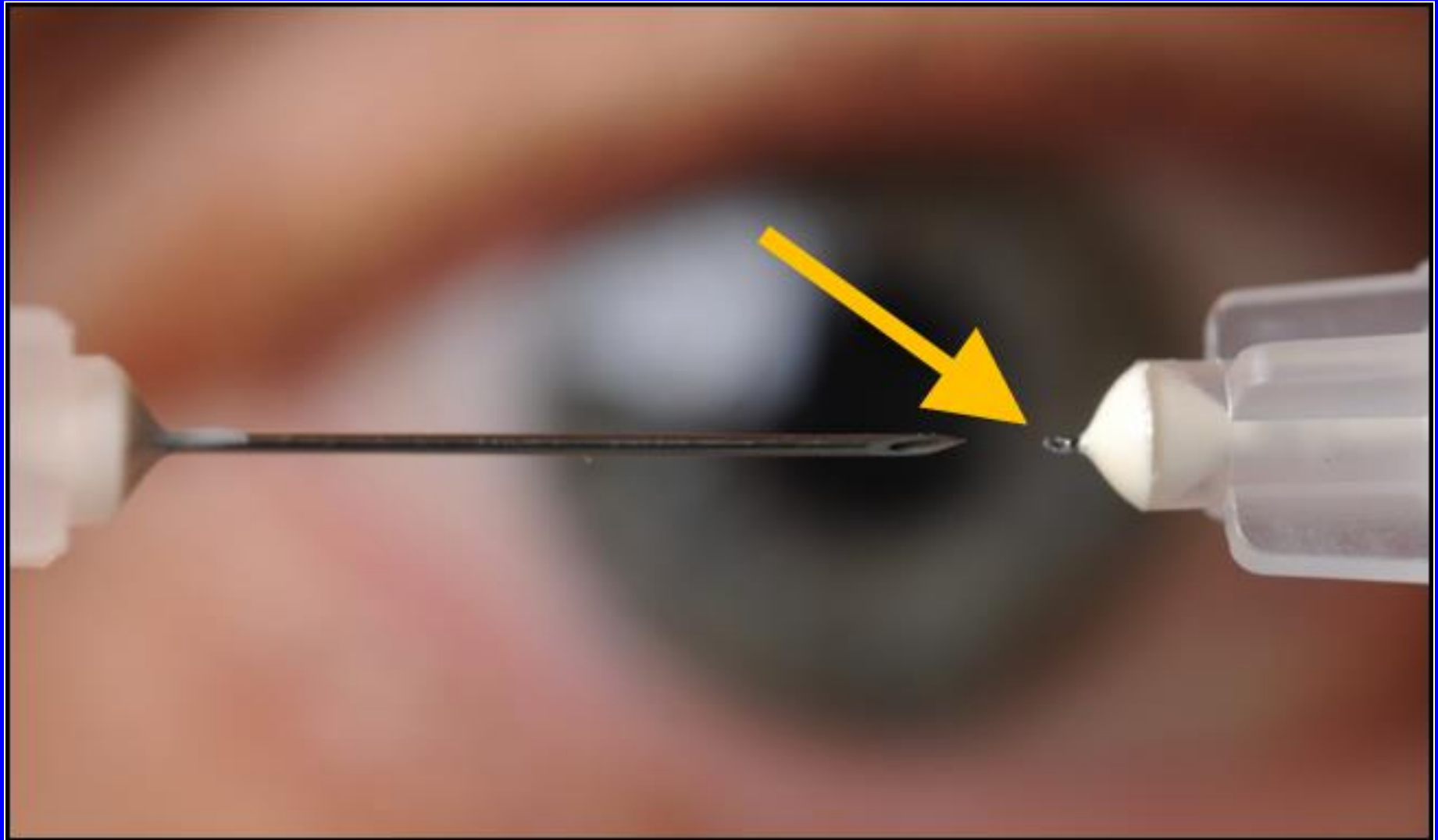
# Suprachoroidal delivery is highly targeted



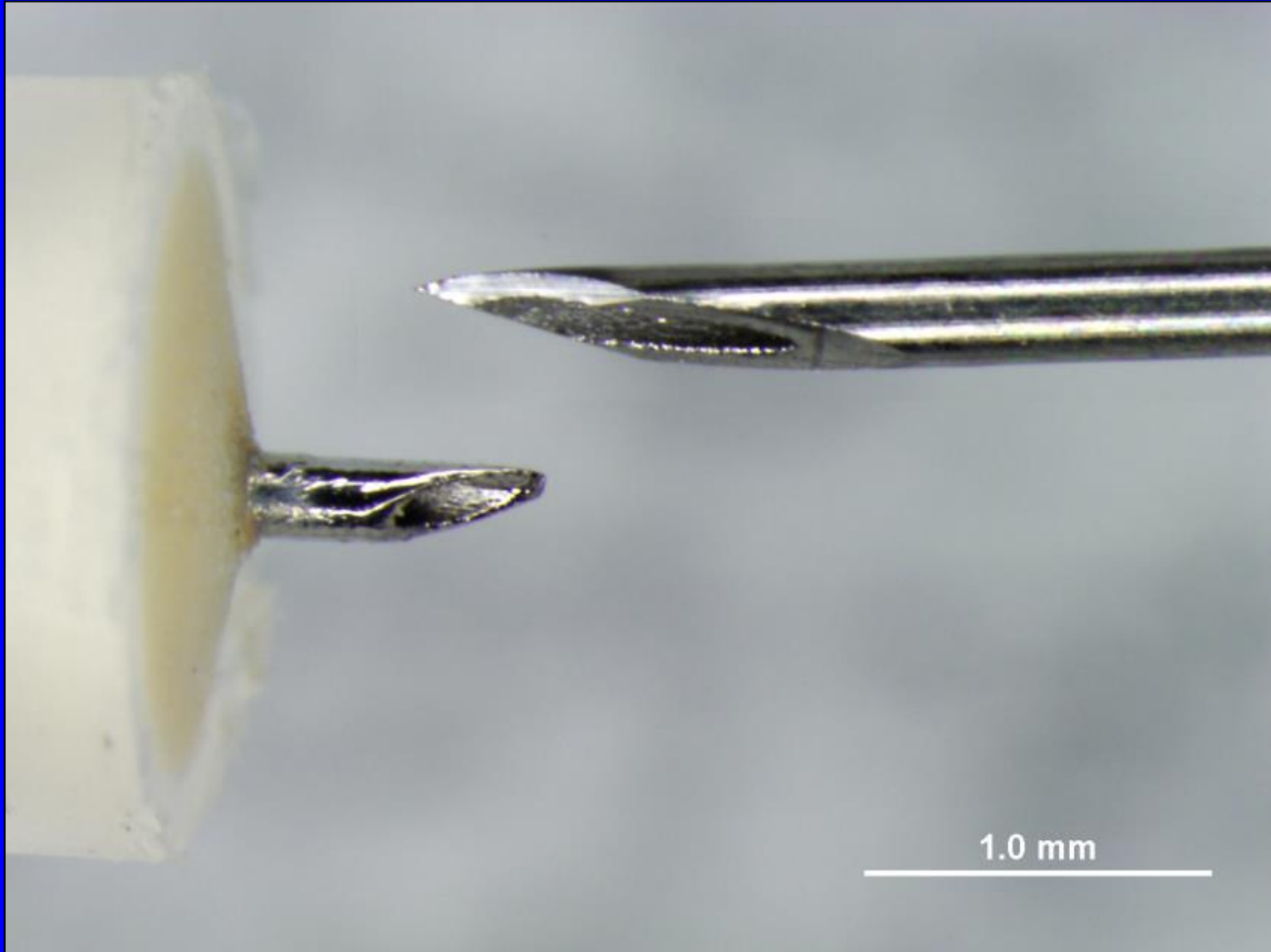
# Suprachoroidal delivery is highly targeted



# Hollow microneedle to target SCS

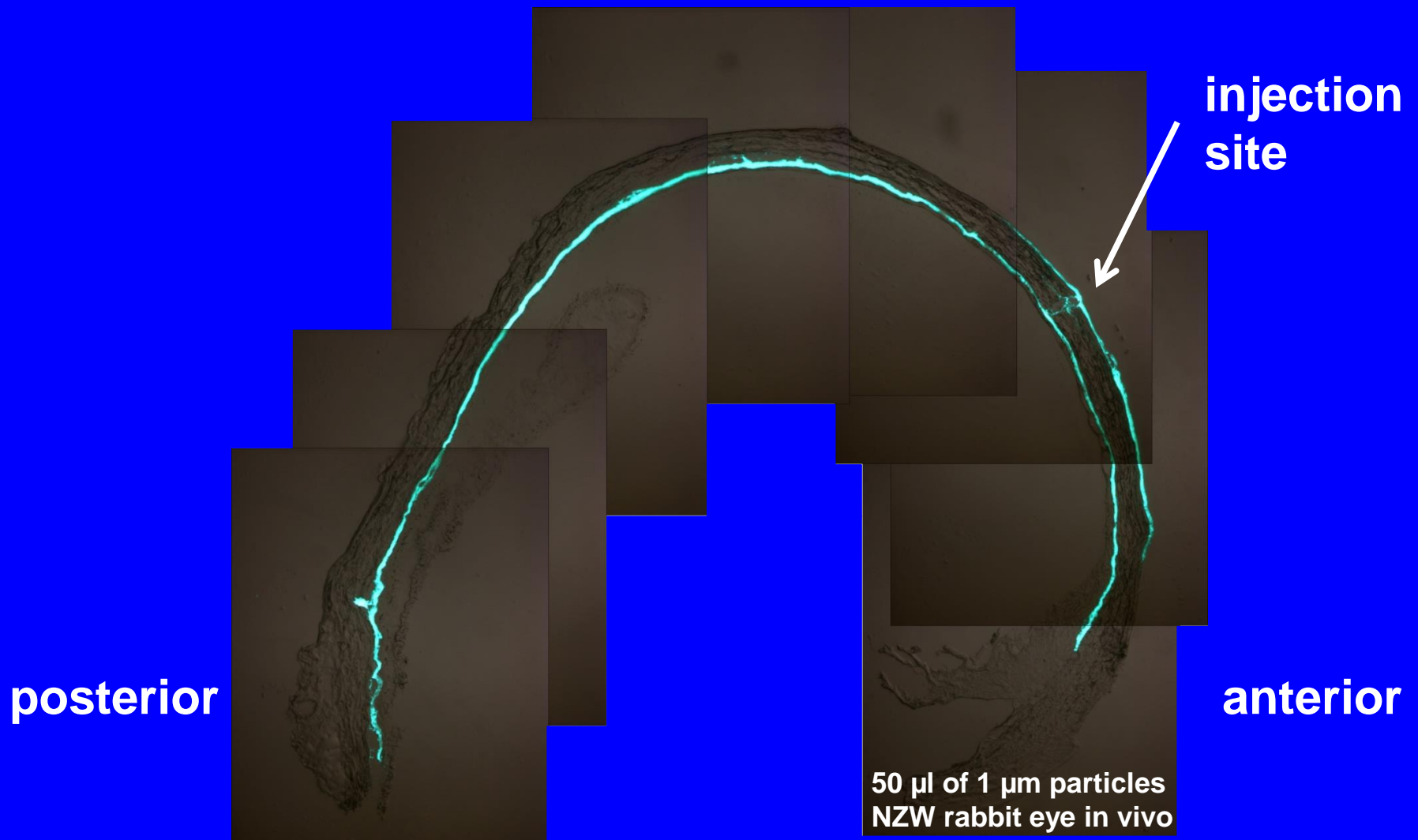


# Hollow microneedle to target SCS

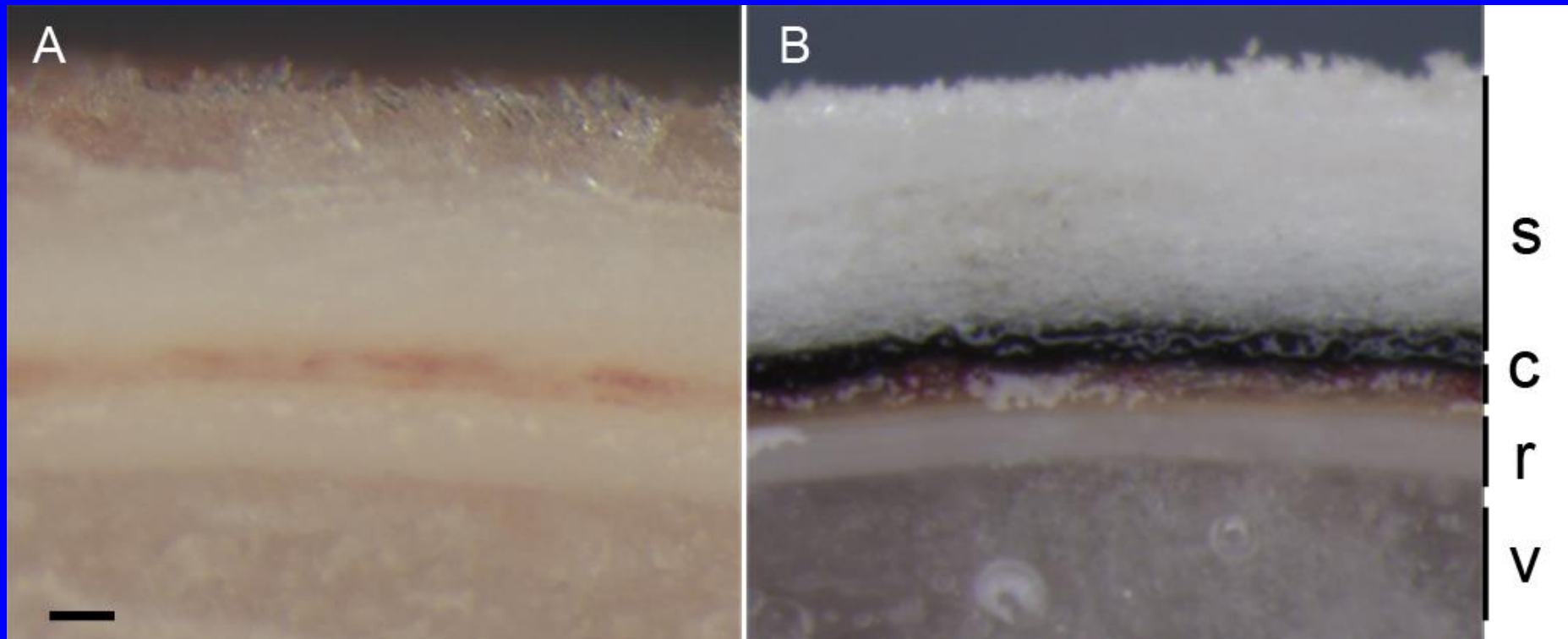




# Injection targets suprachoroidal space



# Injection targets suprachoroidal space



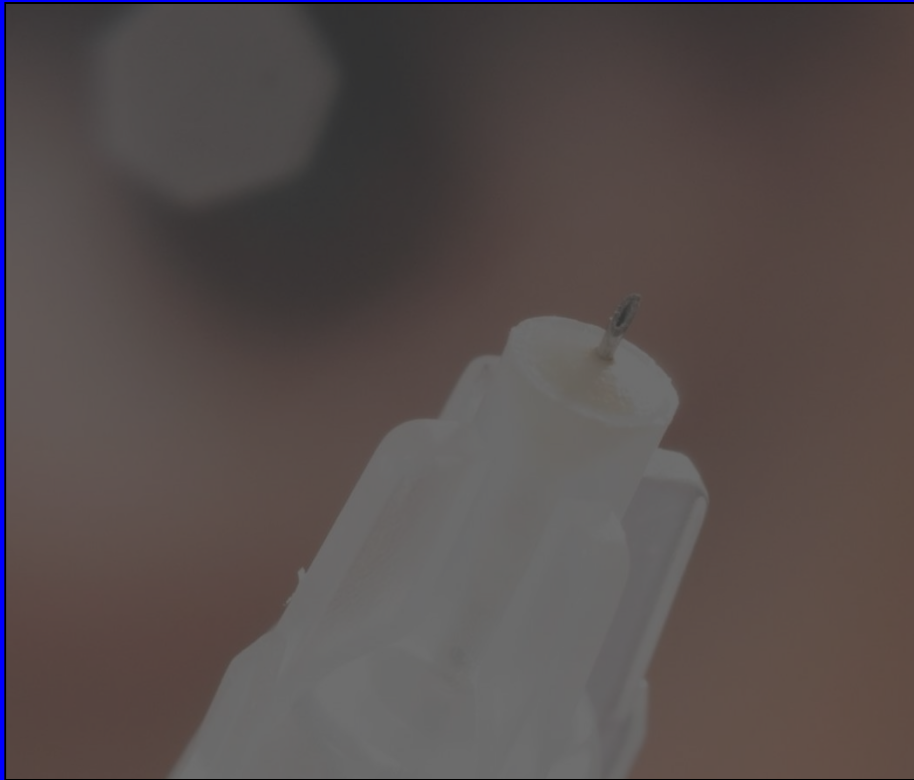
untreated

after suprachoroidal  
injection of India ink

# Outline of talk

## In the laboratory

- design and fabrication of microneedles

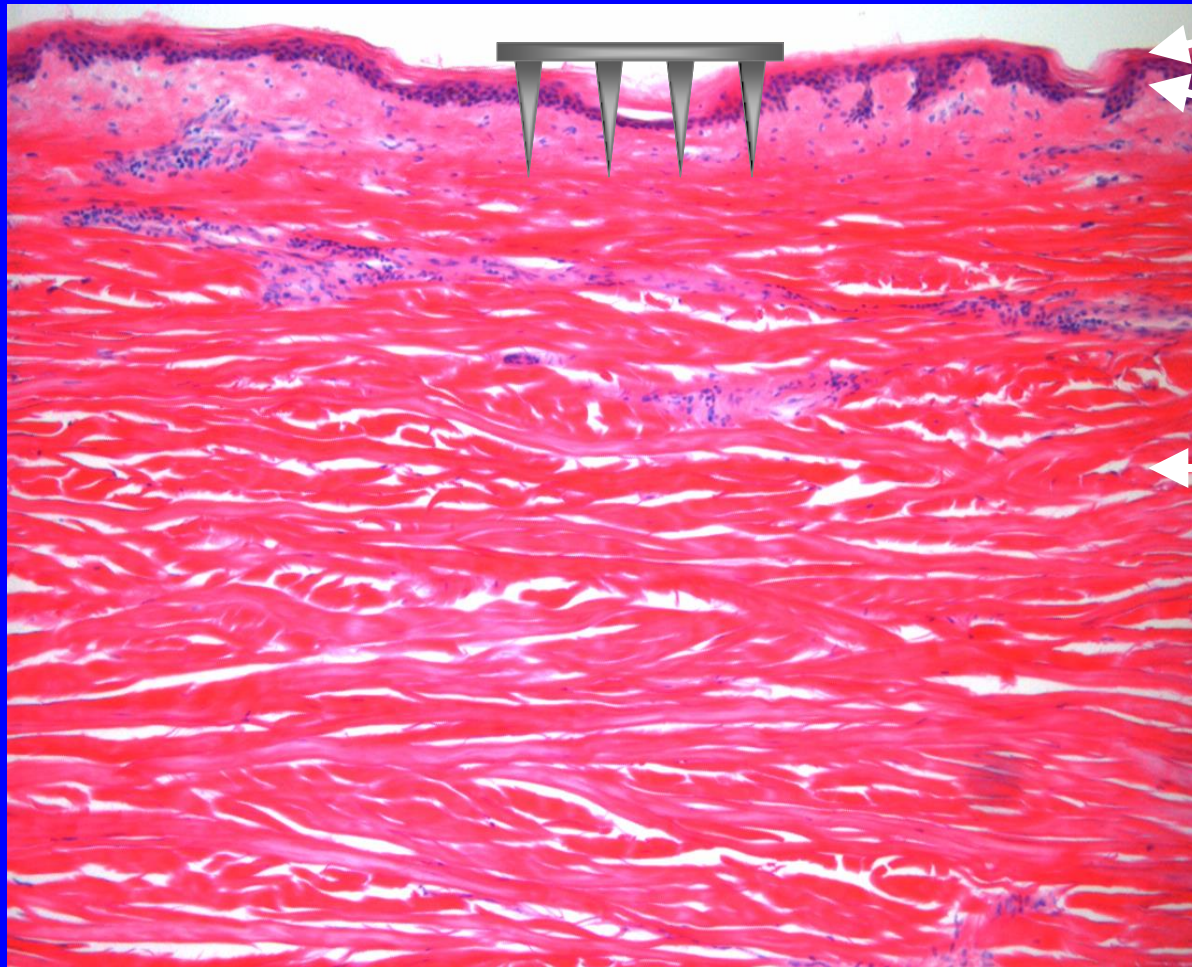


**Targeted drug delivery  
in the eye**



**Skin vaccination with a  
microneedle patch**

# Microneedle patches target vaccine delivery to the skin



Stratum corneum

Viable epidermis  
(Langerhans cells)

Dermis  
(dermal dendritic  
cells, lymphatic  
drainage)

# Vaccine delivery mechanisms using microneedles

Solid  
MN

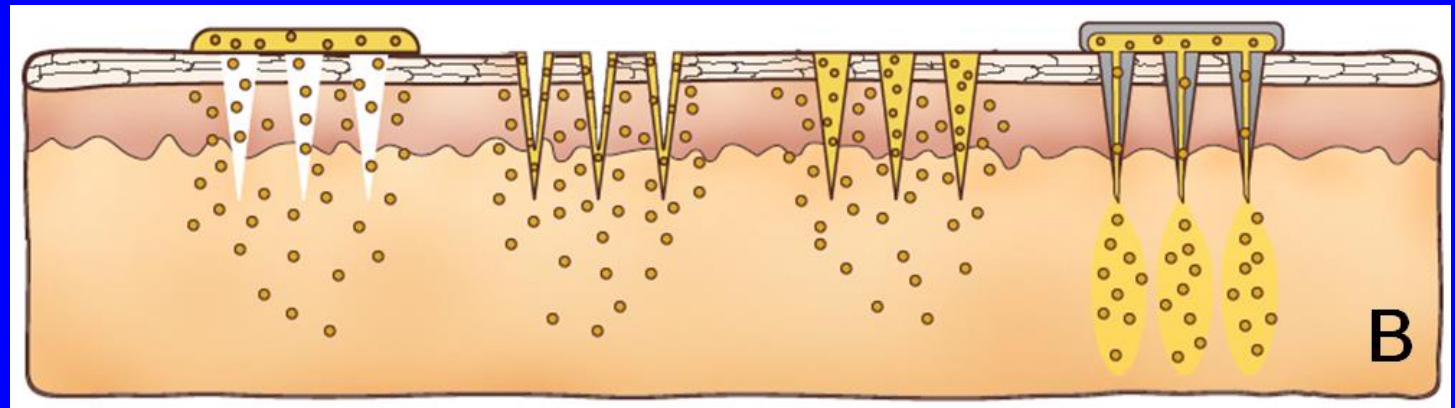
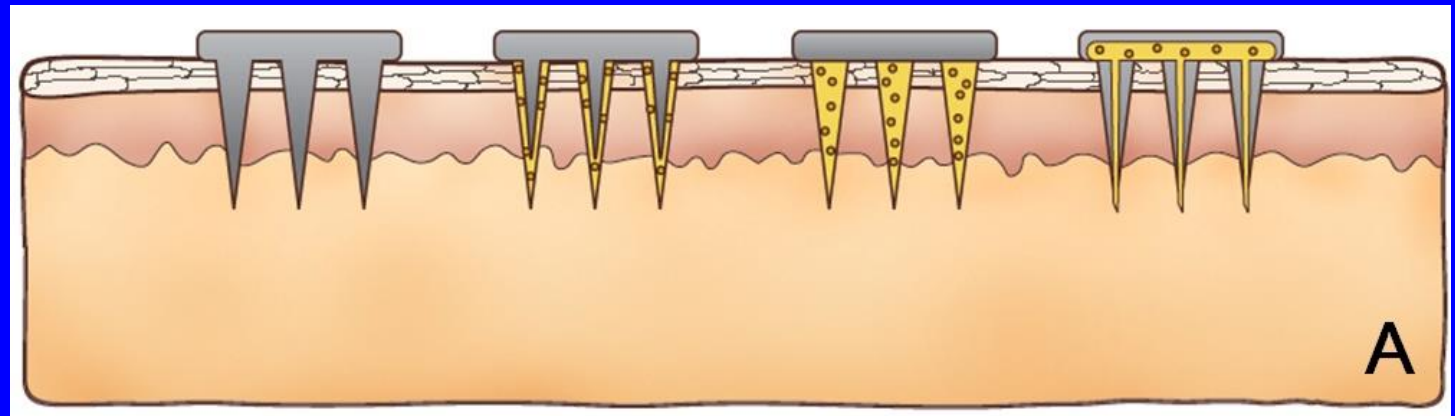
Coated  
MN

Dissolving  
MN

Hollow  
MN

stratum corneum  
viable epidermis

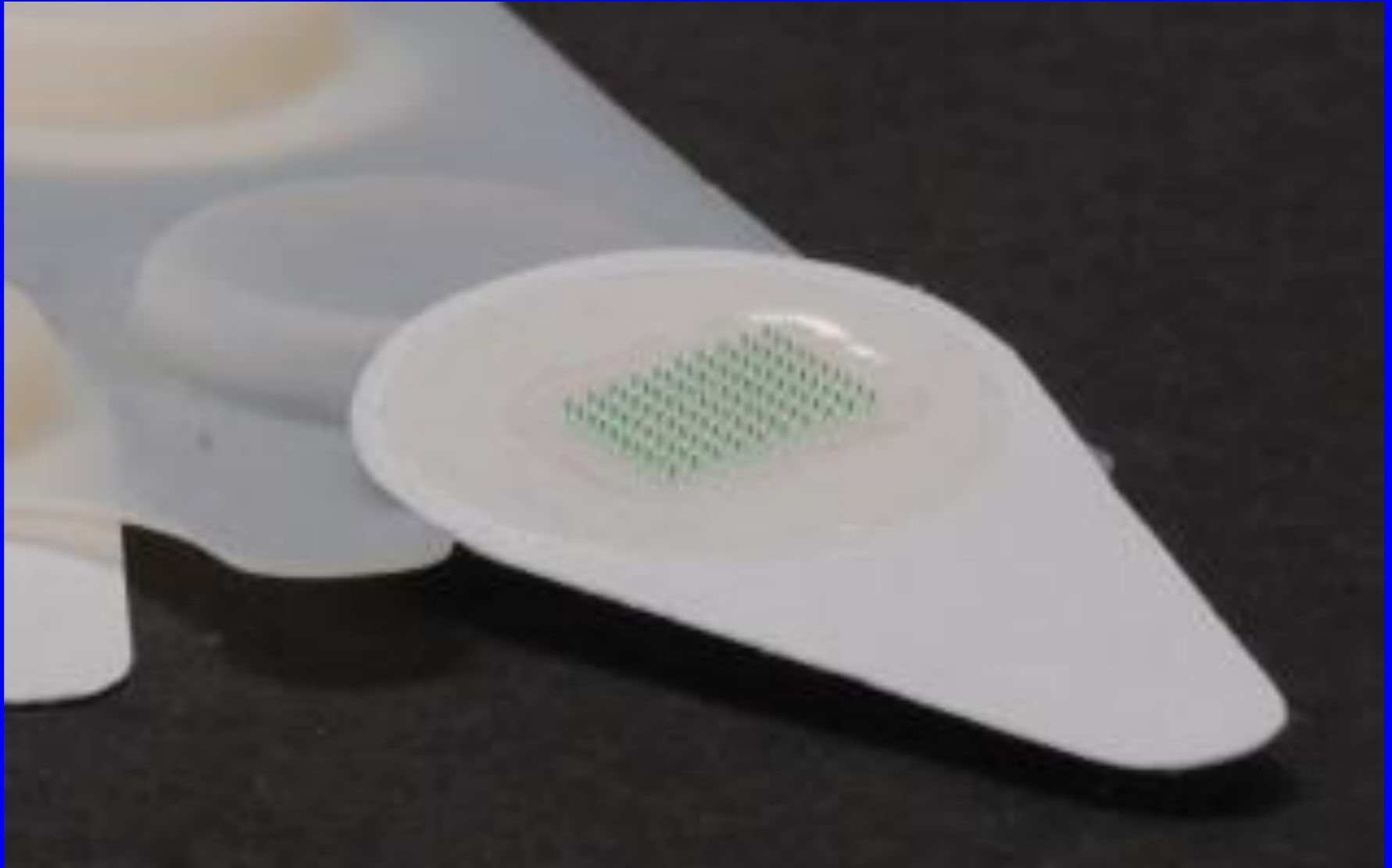
dermis



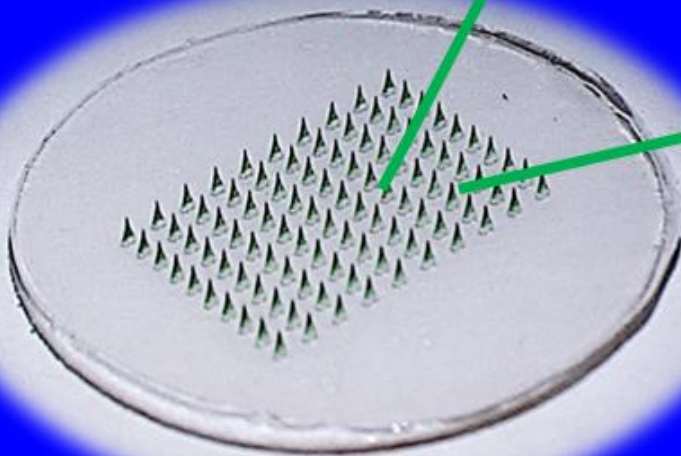
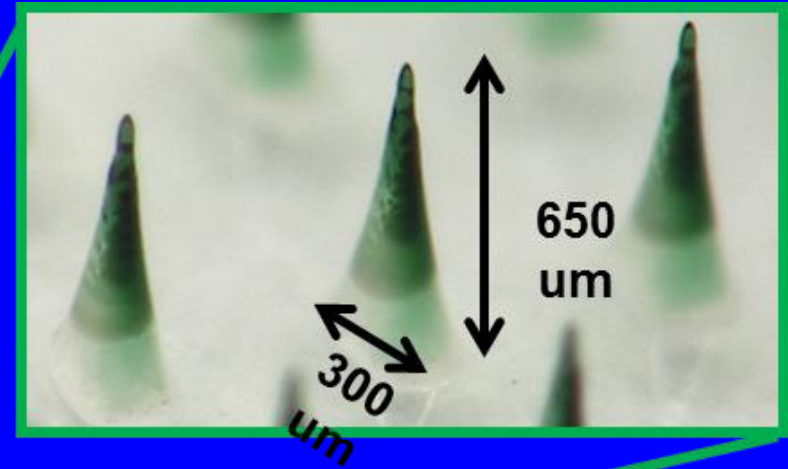
# Dissolving microneedle patches



# Dissolving microneedle patches



# Dissolving microneedle patches

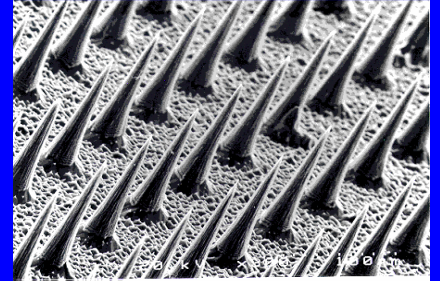


Green dye represents  
location of vaccine

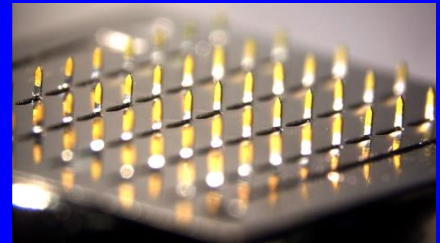


# Microneedles meet public health needs

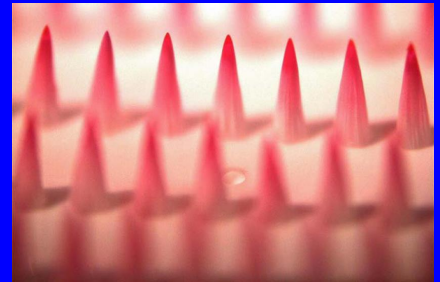
Manufacturing



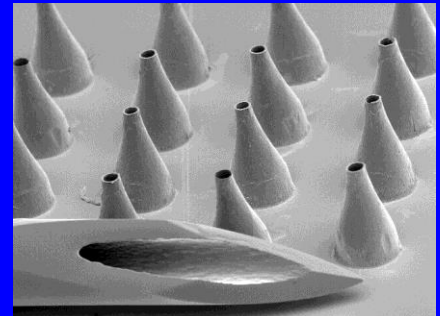
Transportation and storage



Patient administration



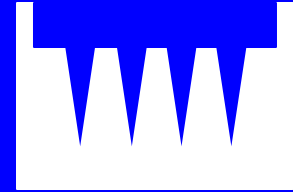
Waste disposal



# Microneedles meet public health needs

Manufacturing

**Low-cost fabrication**



Prepare  
microneedle mold

Transportation and storage

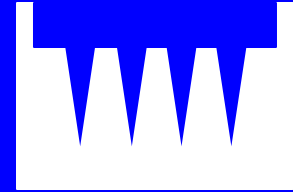
Patient administration

Waste disposal

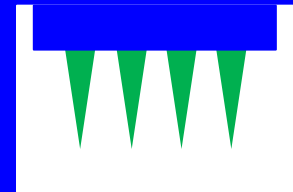
# Microneedles meet public health needs

Manufacturing

**Low-cost fabrication**



Transportation and storage



Patient administration

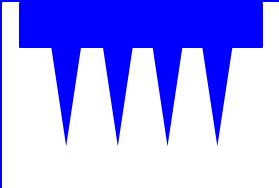
Cast antigen  
formulation into  
micromold cavities

Waste disposal

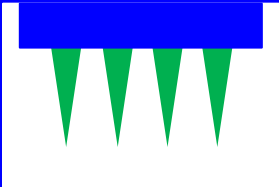
# Microneedles meet public health needs

Manufacturing

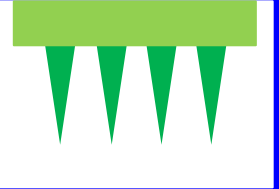
**Low-cost fabrication**



Transportation and storage



Patient administration



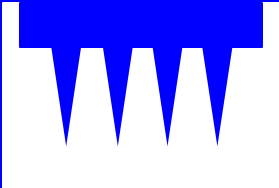
Waste disposal

**Cast matrix  
formulation onto  
micromold surface**

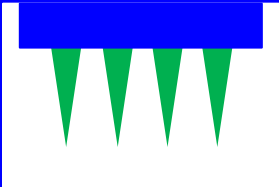
# Microneedles meet public health needs

Manufacturing

**Low-cost fabrication**



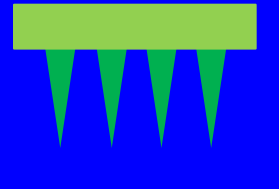
Transportation and storage



Patient administration



Waste disposal



Dry and remove  
microneedle patch

# Microneedles meet public health needs

Manufacturing  
Low-cost fabrication

Transportation and storage  
Small package size

Patient administration

Waste disposal



# Microneedles meet public health needs

## Manufacturing

Low-cost fabrication

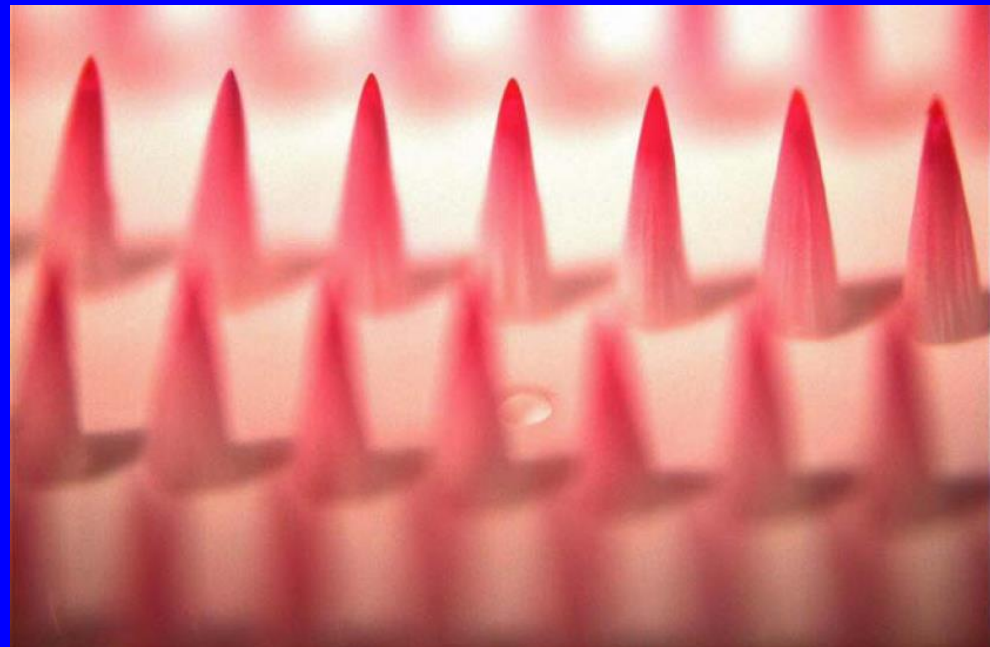
## Transportation and storage

Small package size

**Possible thermal stability**

## Patient administration

## Waste disposal



# Microneedles meet public health needs

## Manufacturing

Low-cost fabrication

## Transportation and storage

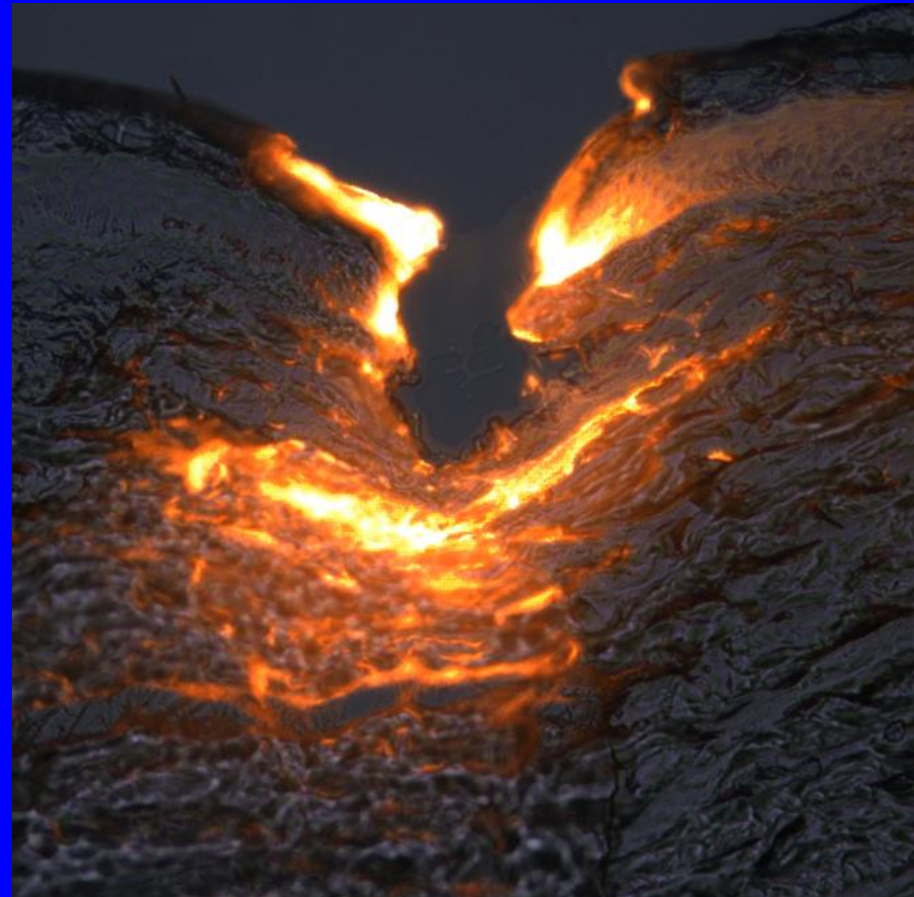
Small package size

Possible thermal stability

## Patient administration

**No reconstitution**

## Waste disposal





# Microneedles meet public health needs

## Manufacturing

Low-cost fabrication

## Transportation and storage

Small package size

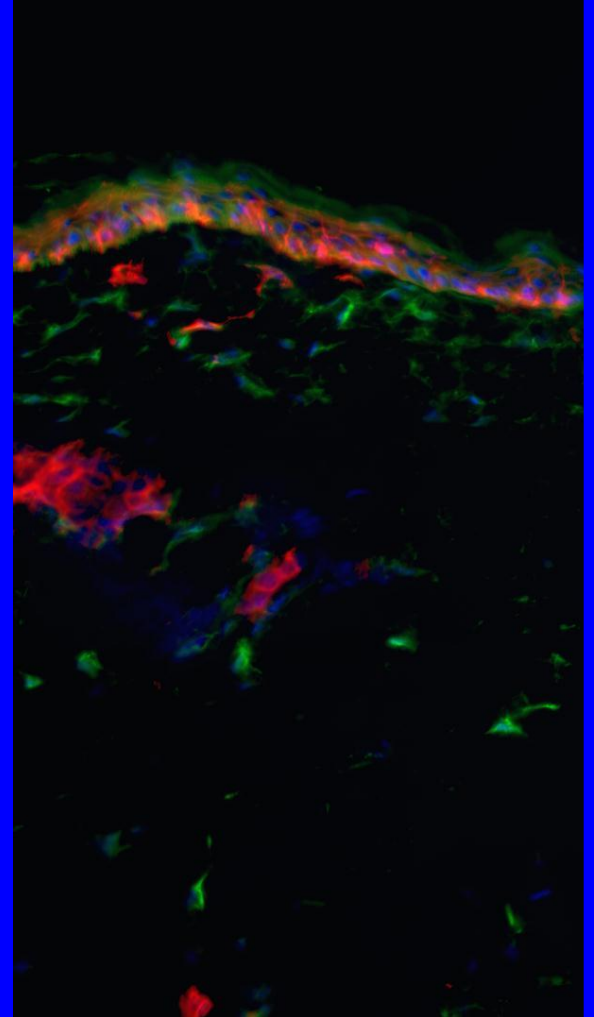
Possible thermal stability

## Patient administration

No reconstitution

**Possible reduced dose**

## Waste disposal



# Microneedles meet public health needs

## Manufacturing

Low-cost fabrication

## Transportation and storage

Small package size

Possible thermal stability

## Patient administration

No reconstitution

Possible reduced dose

**Minimally trained  
personnel**

## Waste disposal



# Microneedles meet public health needs

## Manufacturing

Low-cost fabrication

## Transportation and storage

Small package size

Possible thermal stability

## Patient administration

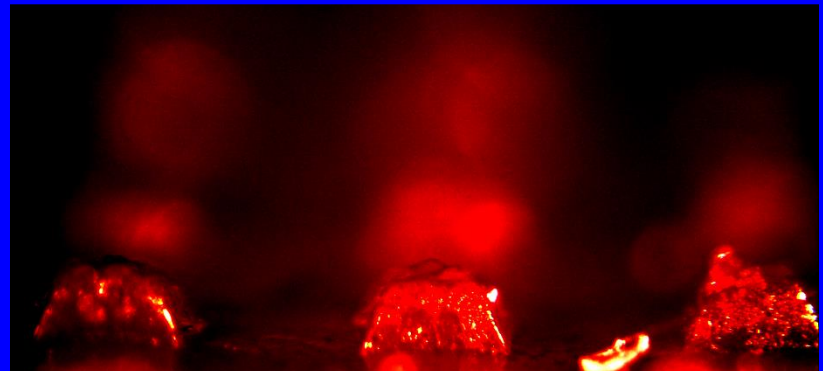
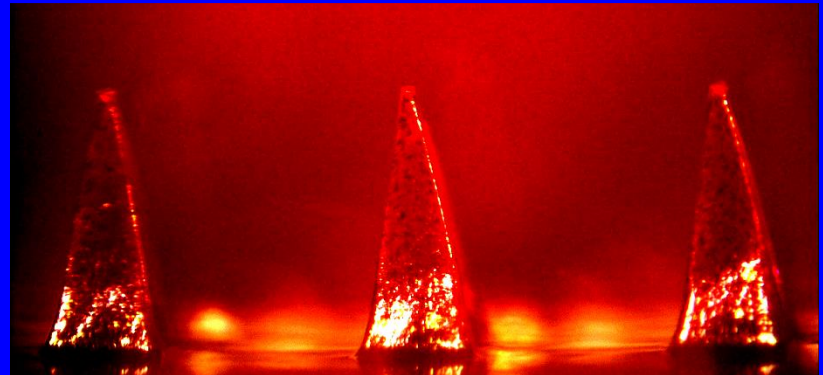
No reconstitution

Possible reduced dose

Minimally trained personnel

## Waste disposal

**Difficult or  
impossible reuse**



# Microneedles meet public health needs

## Manufacturing

Low-cost fabrication

## Transportation and storage

Small package size

Possible thermal stability

## Patient administration

No reconstitution

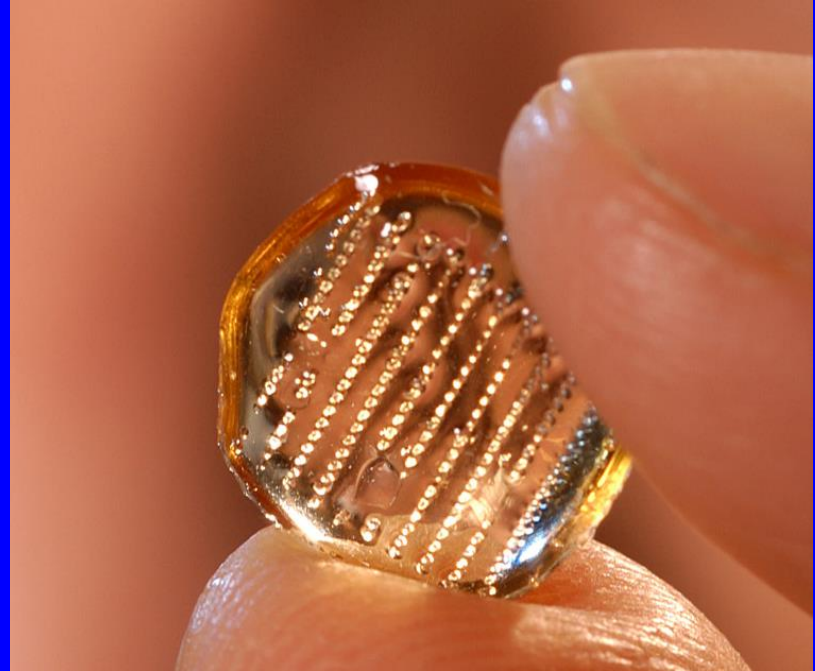
Possible reduced dose

Minimally trained personnel

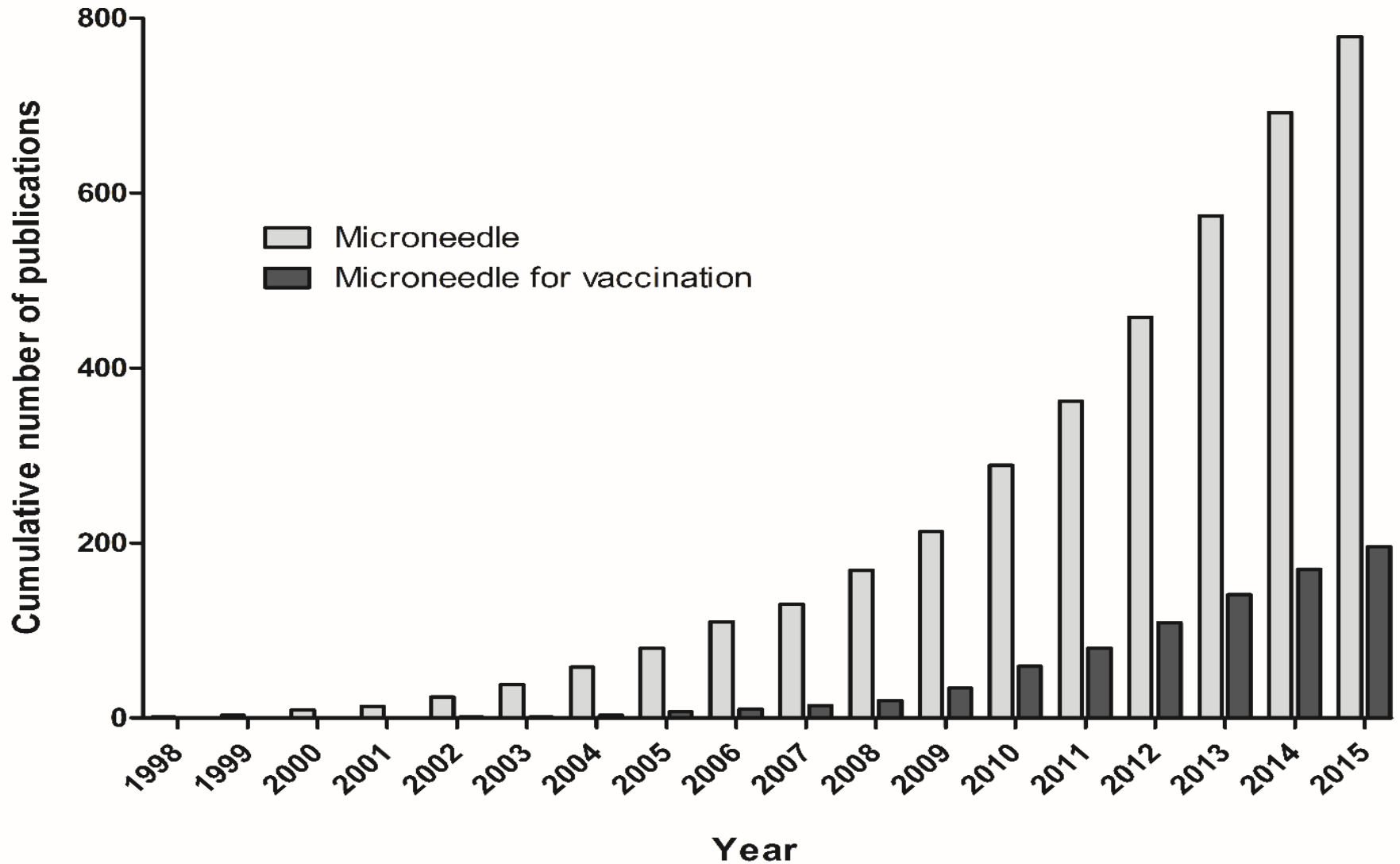
## Waste disposal

Difficult or impossible reuse

**Reduced or no disposal volume**

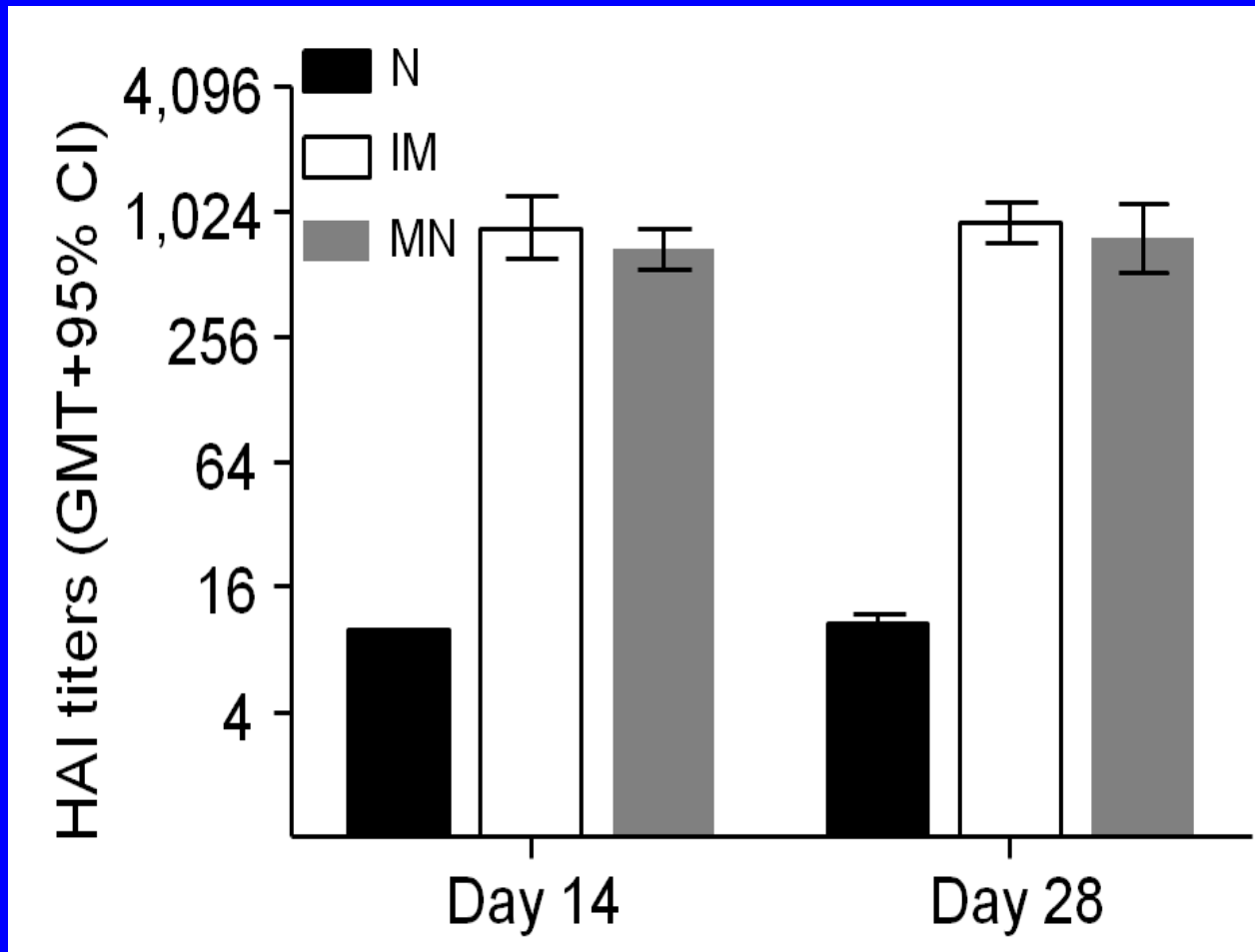


# Microneedle research is increasing



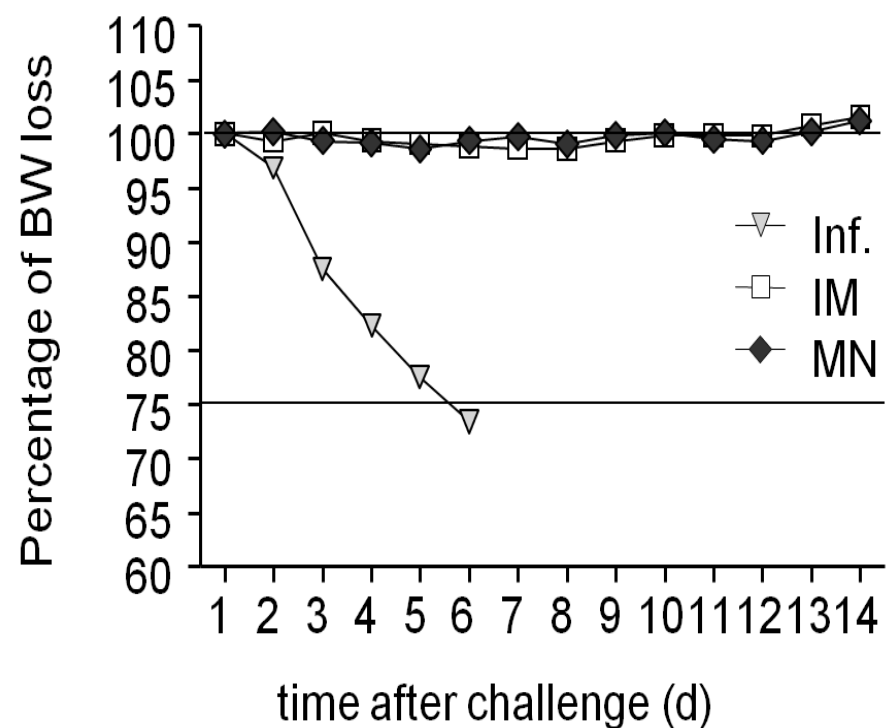
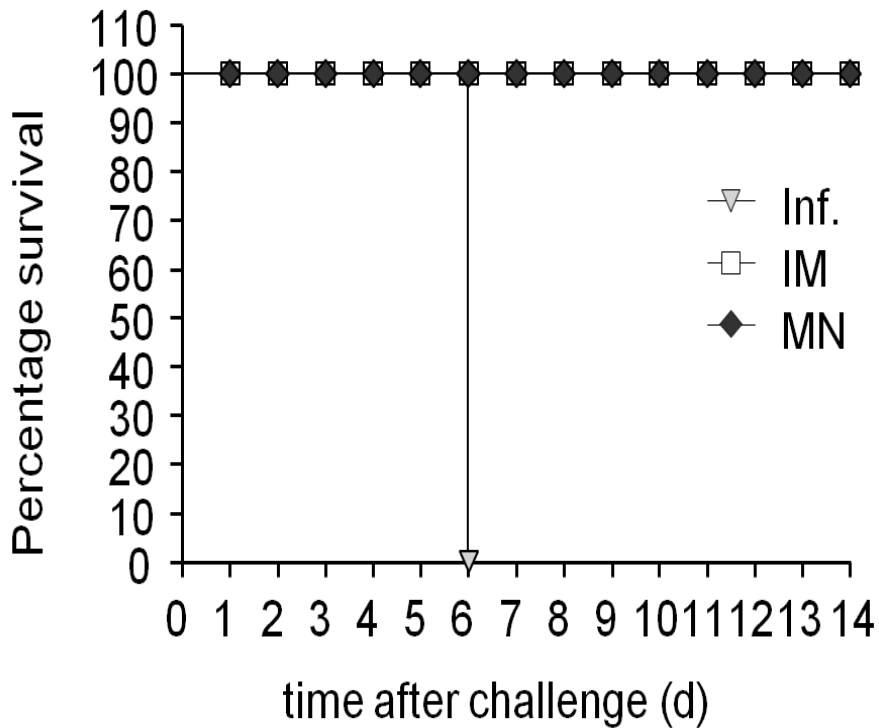
# Influenza vaccination

HAI response after H1N1 whole inactivated influenza virus vaccination in mice



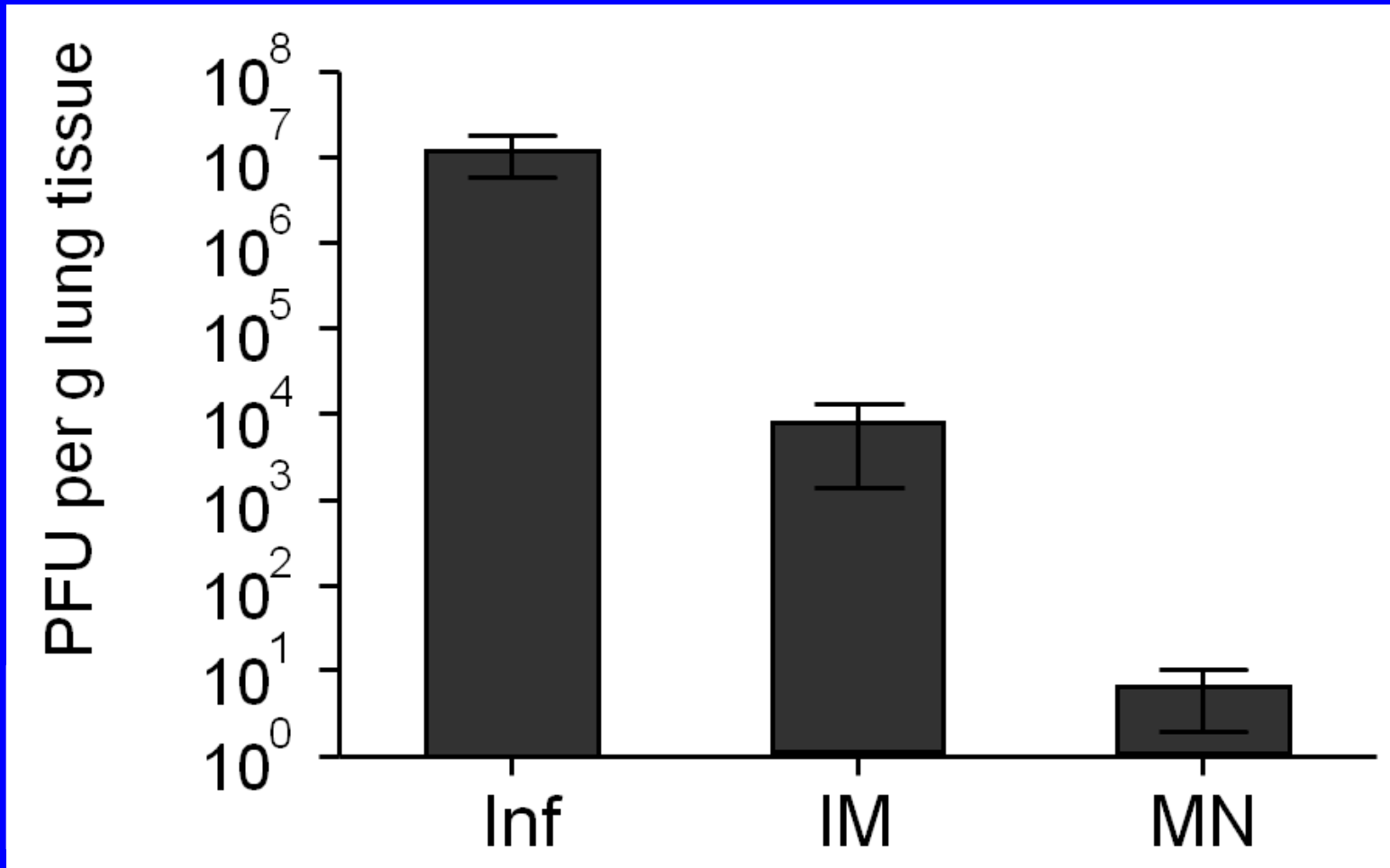
# Influenza vaccination

Protection after H1N1 whole inactivated influenza virus vaccination in mice



# Influenza vaccination

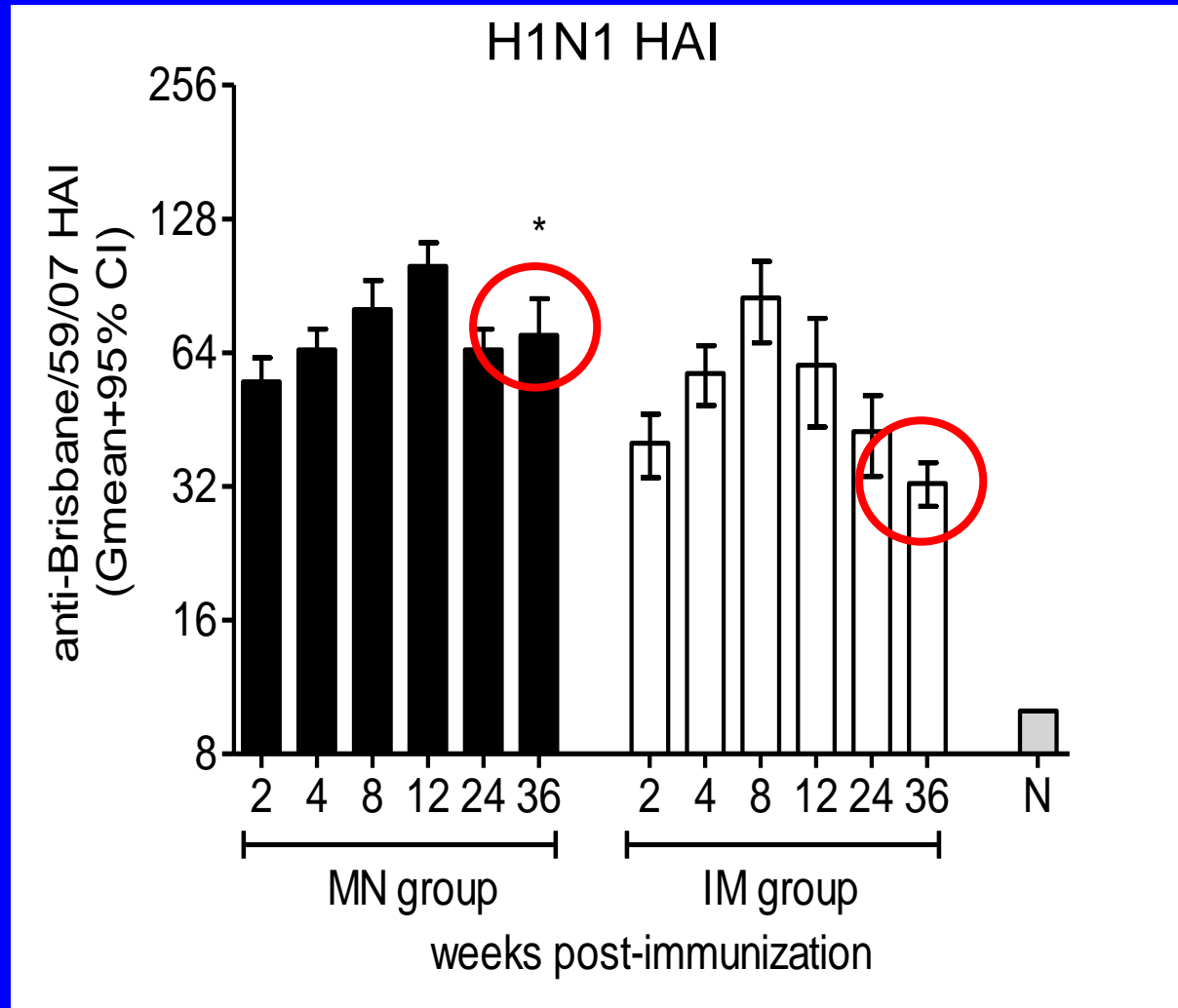
Virus clearance from lung after H1N1 whole inactivated influenza virus vaccination in mice





# Influenza vaccination

HAI response after H1N1 influenza subunit vaccination in mice



# Outline of talk

In the clinic

- human clinical trials



**Human factors  
(on-going)**

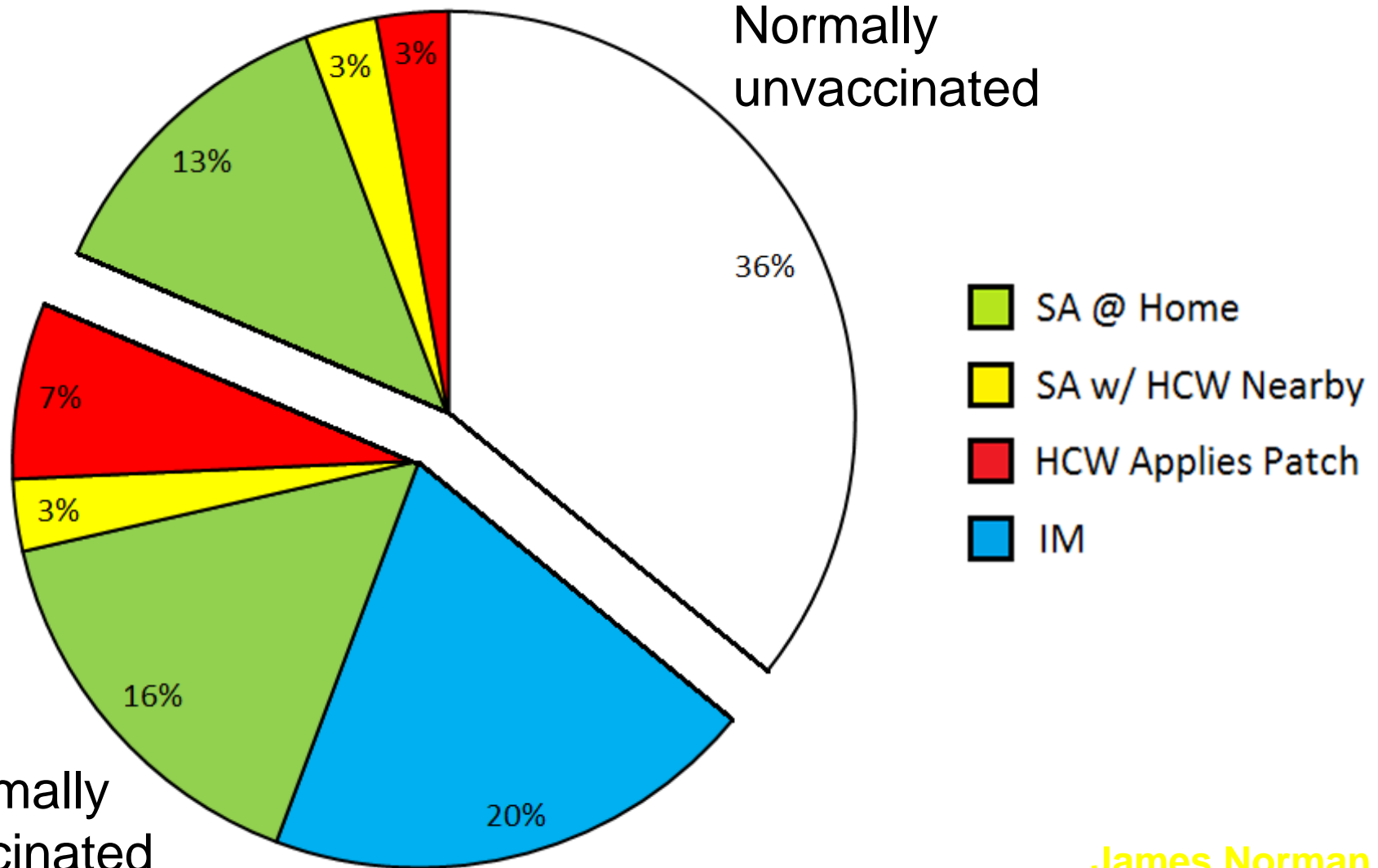


**Influenza  
vaccination  
(2015-2016)**



**Polio  
vaccination  
(2017-2018)**

# Acceptability of influenza vaccination using a microneedle patch



**Inactivated polio vaccination  
clinical trial to begin in 2017**



**POLIO** | **GLOBAL  
ERADICATION  
INITIATIVE**

The logo features the word "POLIO" in large, bold, orange letters on the left. A vertical orange line separates it from the words "GLOBAL", "ERADICATION", and "INITIATIVE" on the right, which are stacked vertically in bold, blue letters.

# Outline of talk

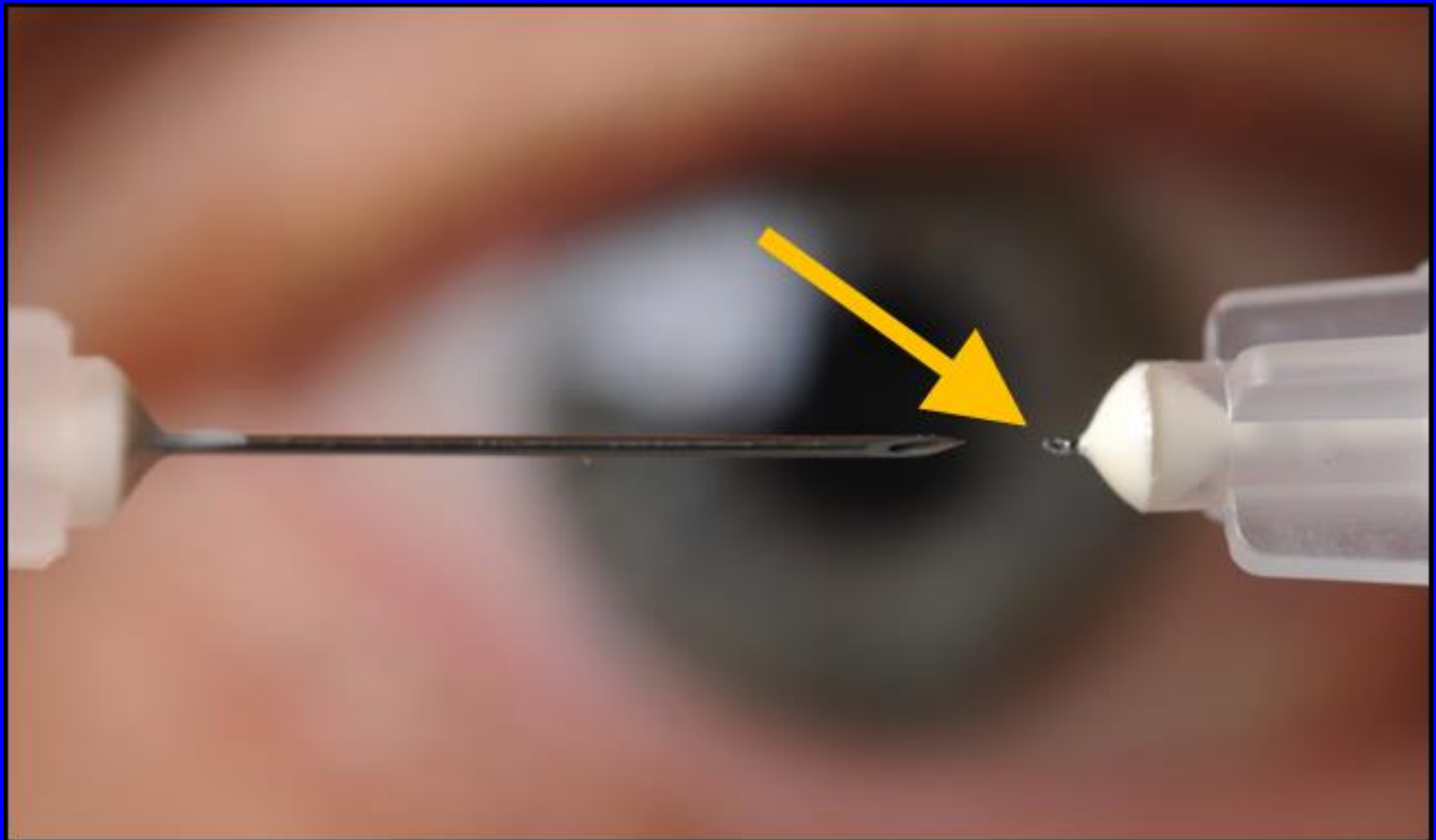
In the board room

- formation of new companies

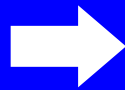


Mark Prausnitz is a co-founder and has a significant financial interest in Clearside Biomedical and Micron Biomedical.

# Clearside Biomedical



# Clearside Biomedical

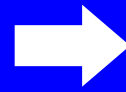


# Micron Biomedical





# Micron Biomedical



# Summary of talk

## In the classroom

- pharmaceutical education at Georgia Tech

## In the laboratory

- design and fabrication of microneedles

## In the clinic

- human clinical trials

## In the board room

- formation of new companies

# Questions?

