Microneedle technology: From bench to clinic

Mark R. Prausnitz
Georgia Institute of Technology

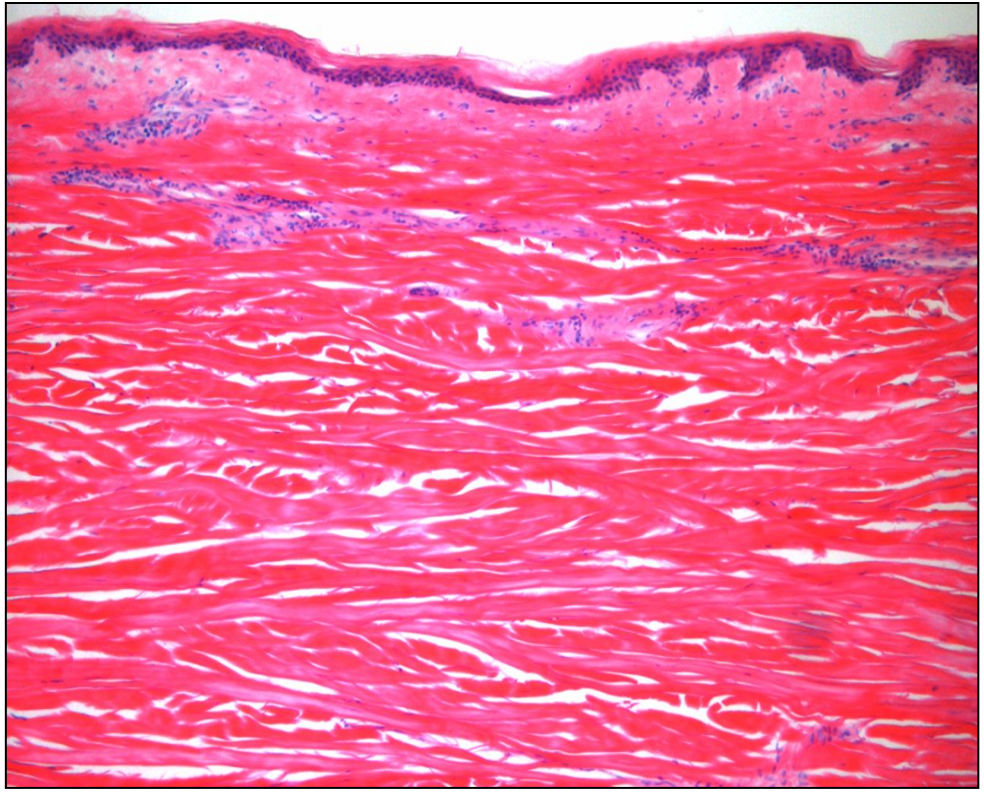
Disclosure

Mark Prausnitz is a co-founder and has a significant financial interest in

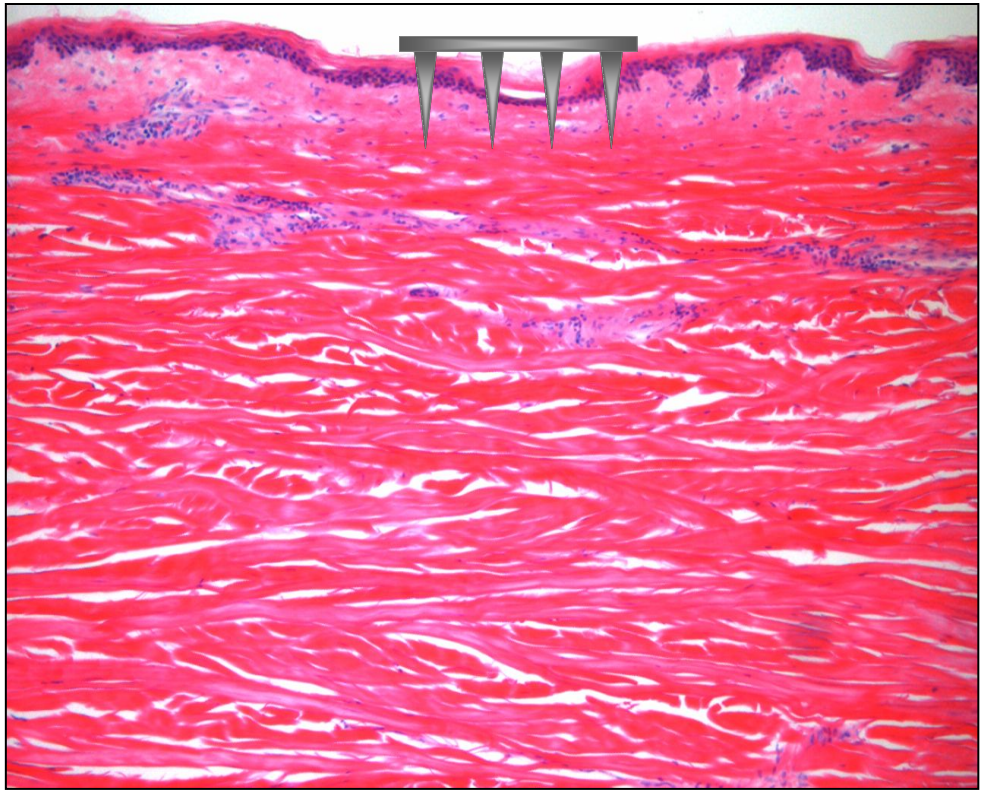
- Micron Biomedical
- Clearside Biomedical
- Microstar Biotech
- Aldena Therapeutics
- Vimela Therapeutics

This conflict of interest is managed by the Georgia Institute of Technology.

Drug delivery to skin is blocked by stratum corneum



Microneedles cross the stratum corneum barrier

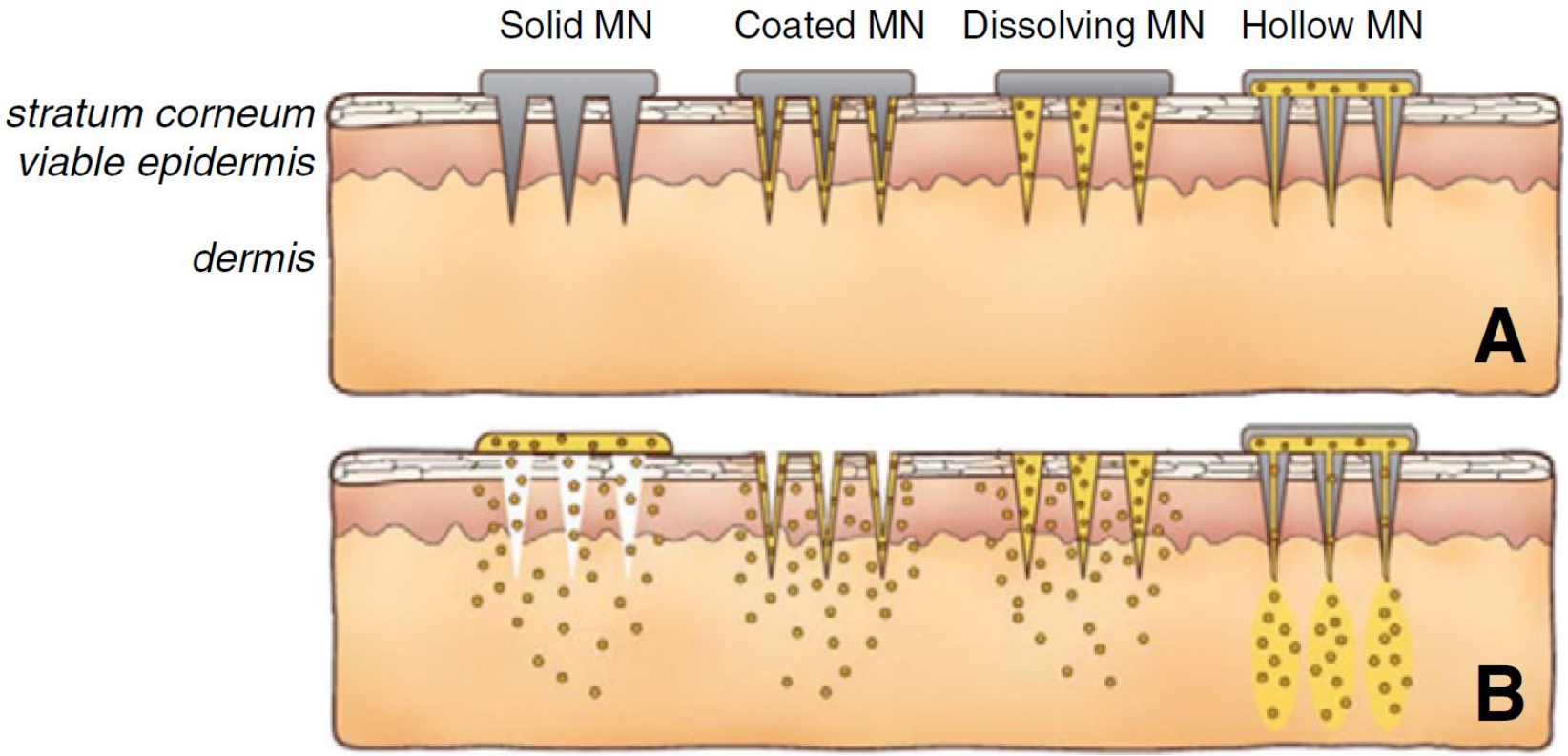


Stratum corneum

Viable epidermis

Dermis

Microneedle technology comes in various forms



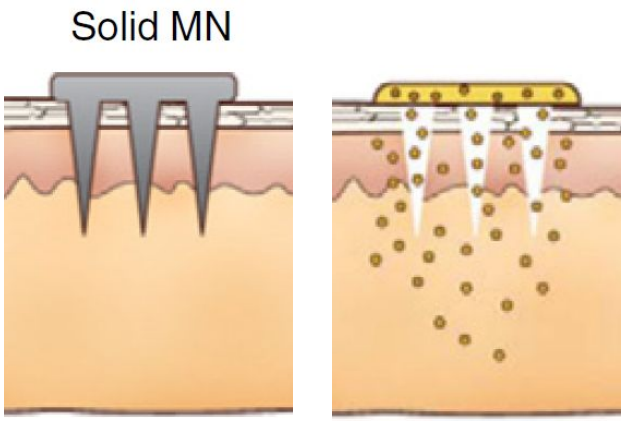
Solid microneedles to create pathways in skin

Drug delivery into skin

- Naltrexone
- STAR particles

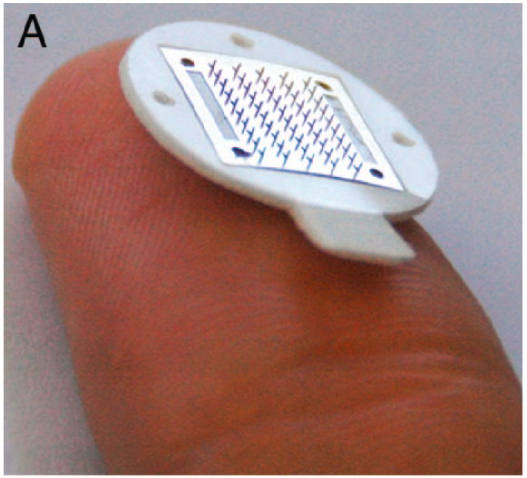
Interstitial fluid out of skin

- Novel biomarkers

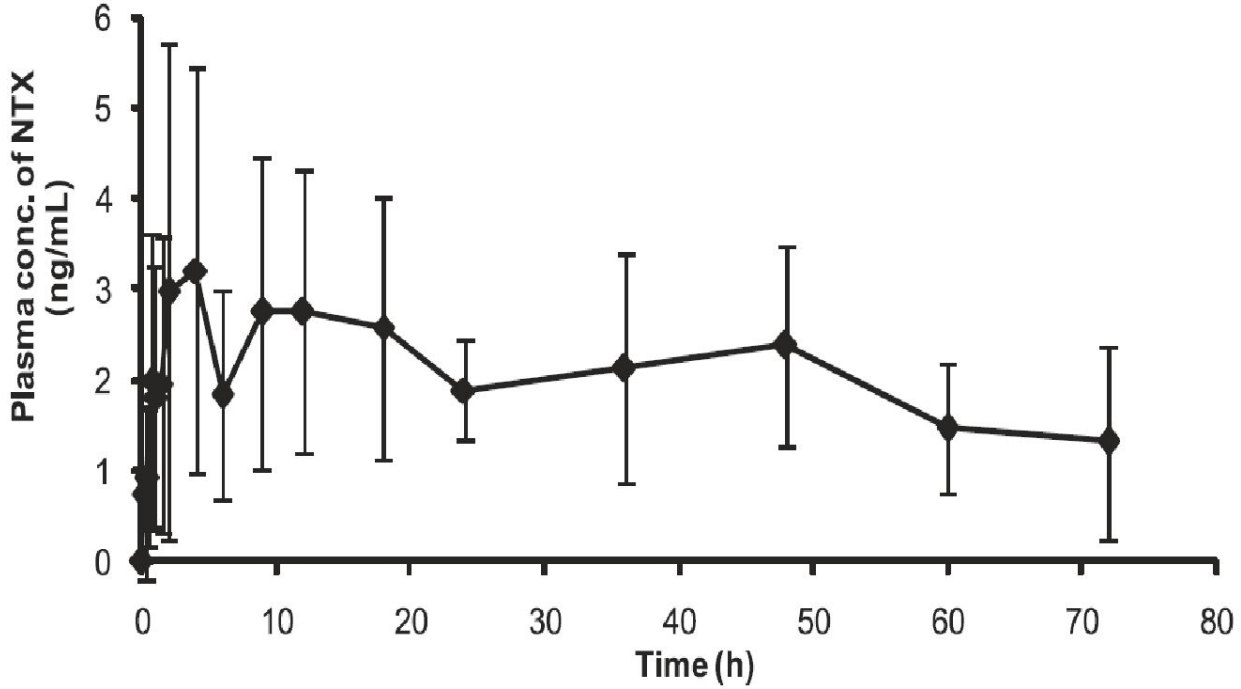


Microneedles permit transdermal delivery of a skin-impermeant medication to humans

Daniel P. Wermeling*†, Stan L. Banks‡, David A. Hudson§, Harvinder S. Gill¶, Jyoti Gupta‖, Mark R. Prausnitz¶‖, and Audra L. Stinchcomb‡



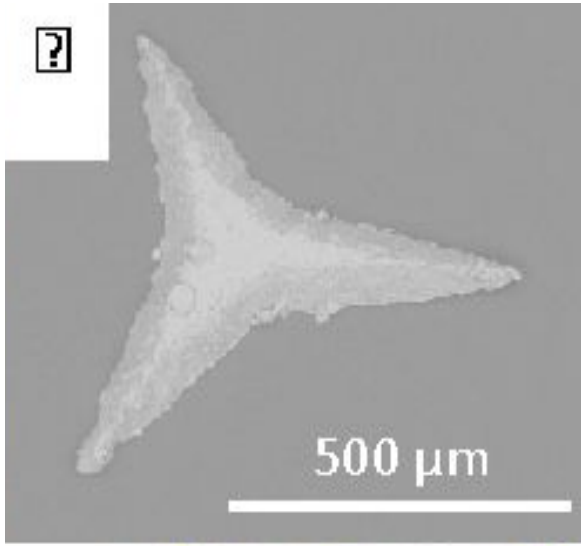
"Poke and patch"



Proceedings of the National Academy of Sciences USA ,105 (2008) 2058-2063

STAR particles for enhanced topical drug and vaccine delivery

Andrew R. Tadros[1], Andrey Romanyuk[1], Ian C. Miller[2], Andrea Santiago[2], Richard K. Noel[3], Laura O'Farrell[3], Gabriel A. Kwong[2] and Mark R. Prausnitz[1,2]



Nature Medicine, 26 (2020) 341-347

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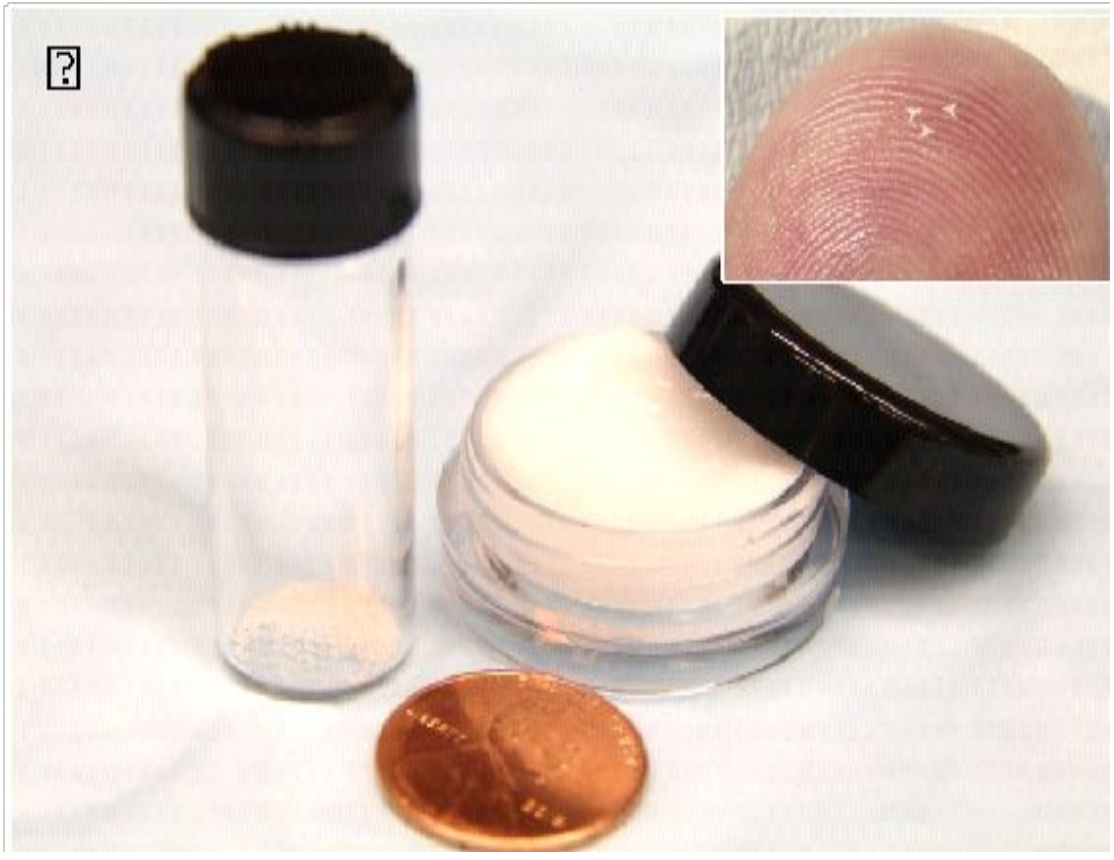

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Immediately after STAR particle application

1 day after STAR particle application

Nature Medicine, 26 (2020) 341-347

STAR particle clinical trials

- Lidocaine delivery in children (2022)

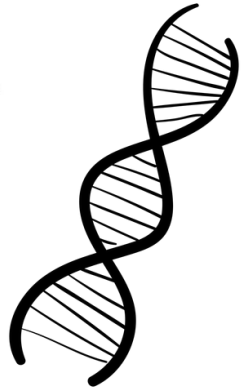
EMORY UNIVERSITY

- Cosmeceutical agents (2022)

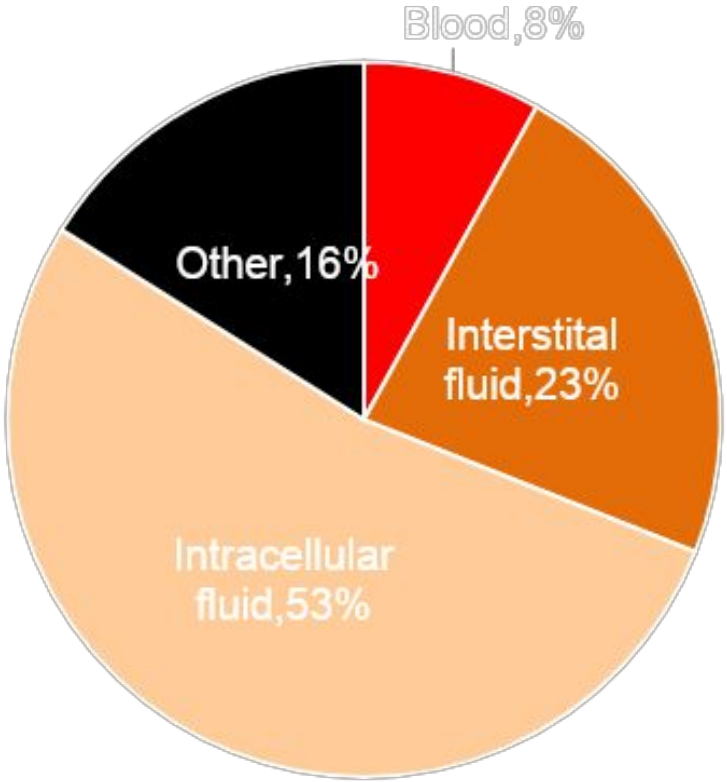
Microstar Biotech

- Nucleic acid therapies for dermatology (undisclosed)

Aldena Therapeutics



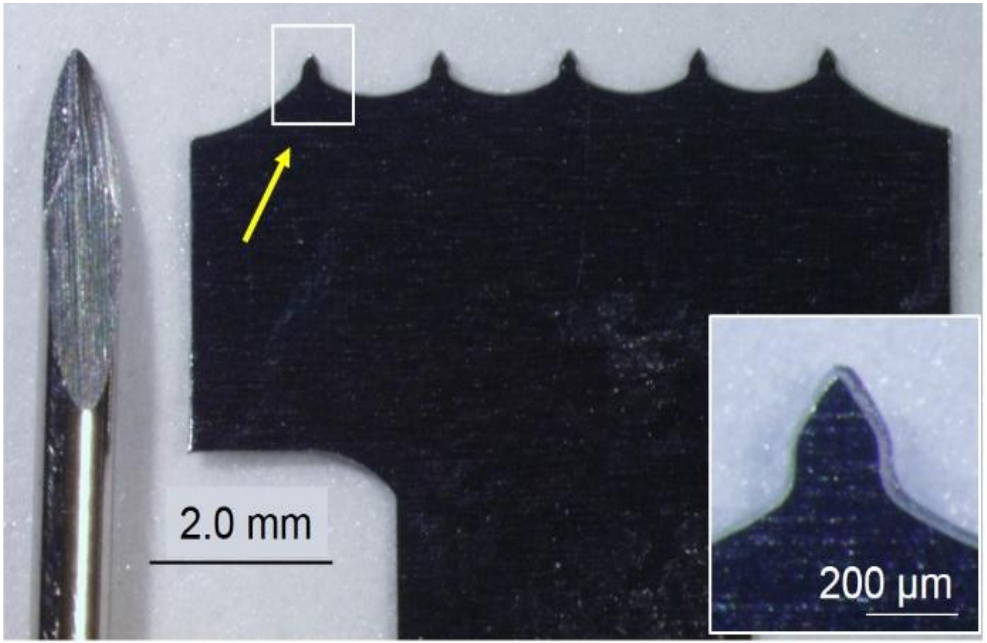
Why use blood to collect biomarkers?

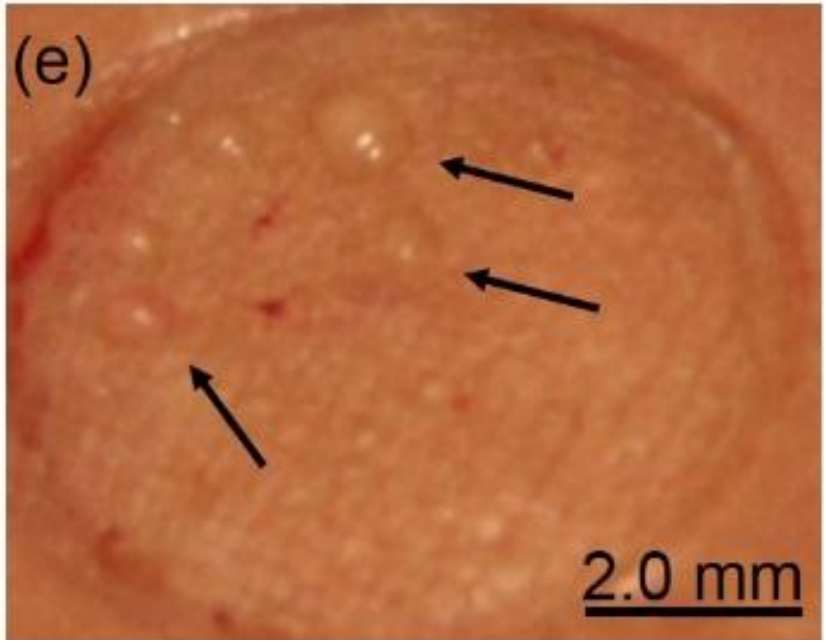


Distribution of fluids in the body

Sampling interstitial fluid from human skin using a microneedle patch

Pradnya P. Samant[1], Megan M. Niedzwiecki[2,3], Nicholas Raviele[1], Vilinh Tran[4], Juan Mena-Lapaix
Douglas I. Walker[2,3,4], Eric I. Felner[5], Dean P. Jones[4], Gary W. Miller[2,6], Mark R. Prausnitz[1]*





Science Translational Medicine, 12 (2020) eaaw0285

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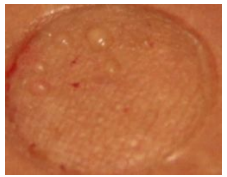
ISF



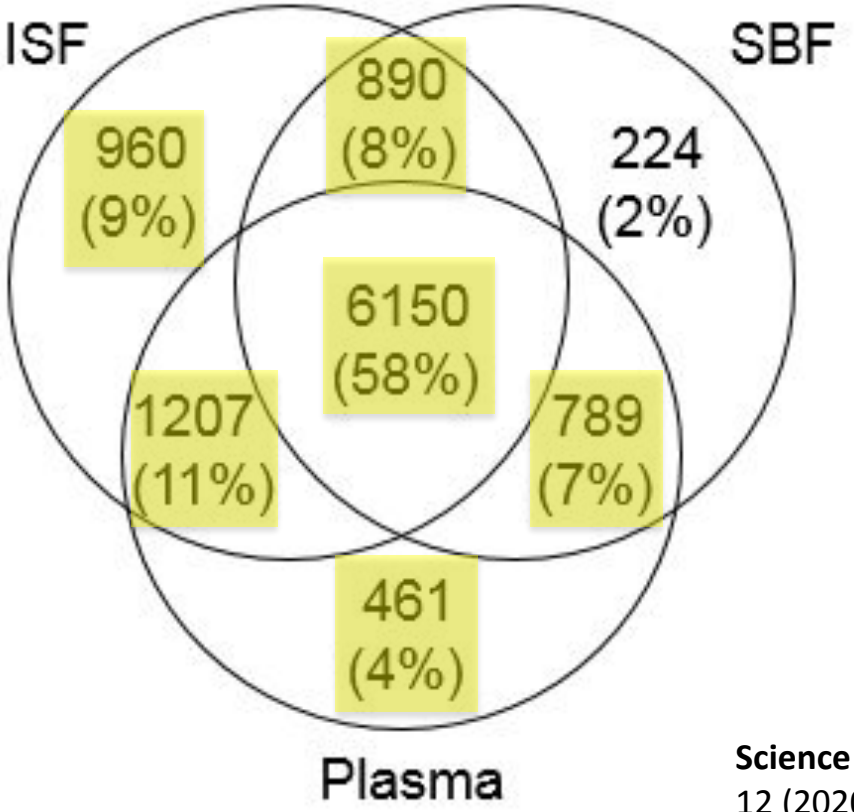
Microneedles

SBF

Suction blisters

Plasma

Venipuncture



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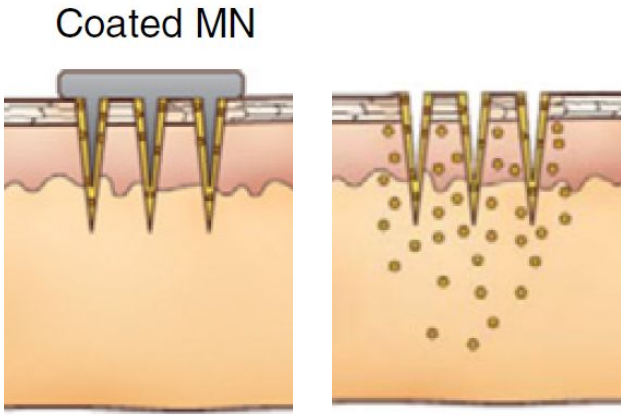
Coated microneedles for drug and vaccine delivery

Drug delivery via the skin

- Zolmitriptan
- Parathyroid hormone

Vaccine delivery to the skin

- Influenza vaccine



Clinical trials using coated microneedles

ZOSANO PHARMA

Zolmitriptan (migraine)
NDA submission

Radius®

Kindeva DRUG DELIVERY

Parathyroid hormone
Phase 3 completed

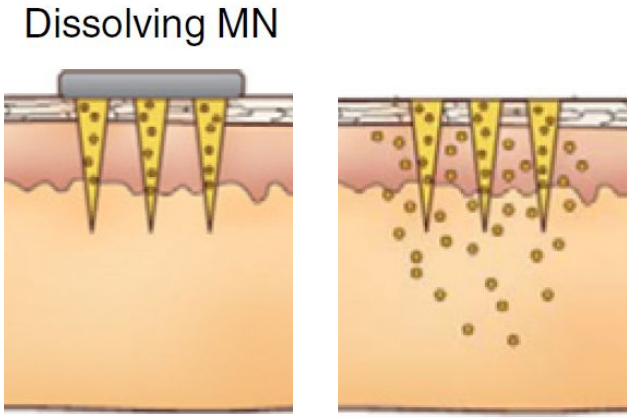
vaxxas

Influenza vaccine
Phase 1 completed

Dissolving microneedles for drug and vaccine delivery

Vaccine delivery to the skin

- Influenza vaccine
- Measles & rubella vaccine



Microneedle patch developed at Georgia Tech

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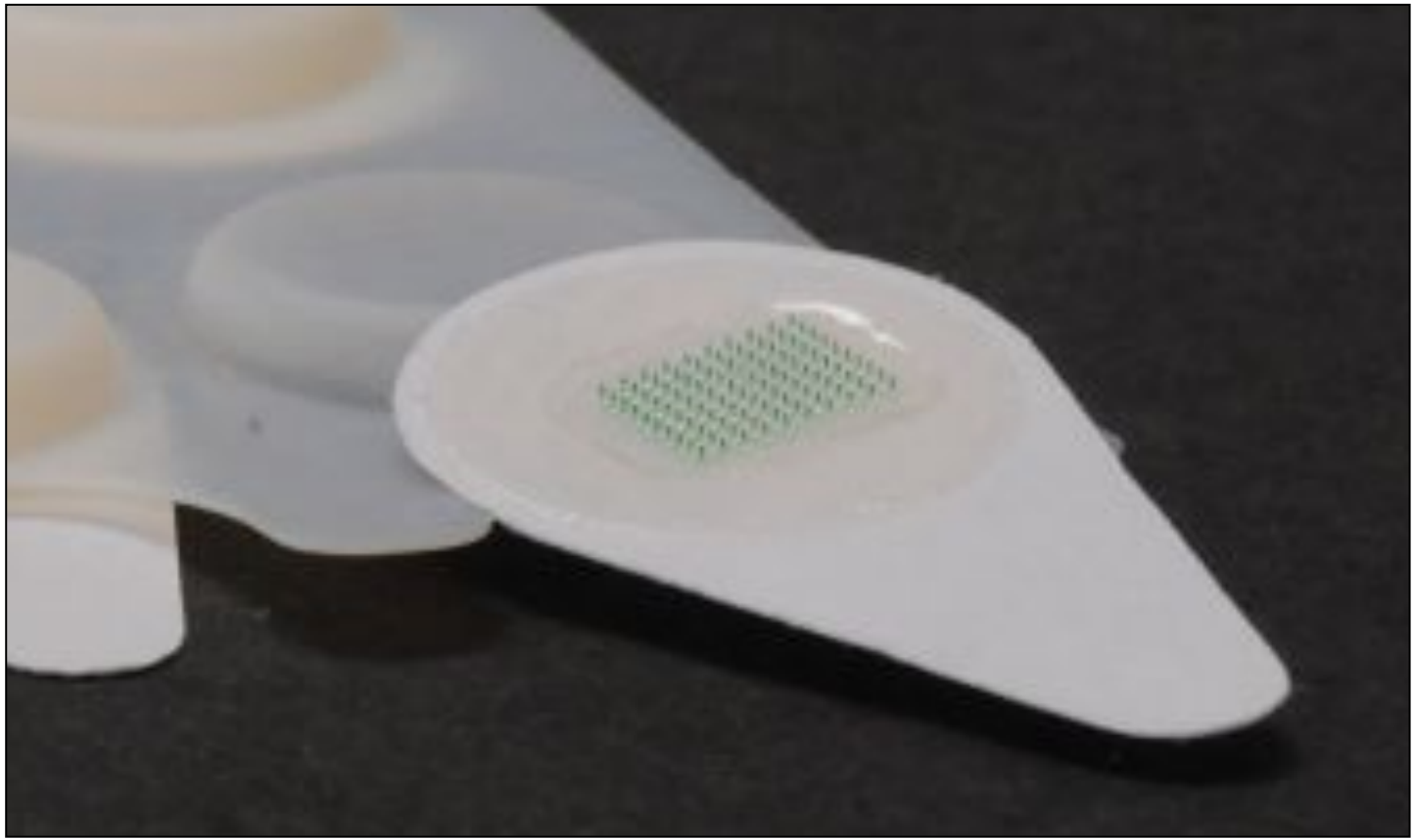

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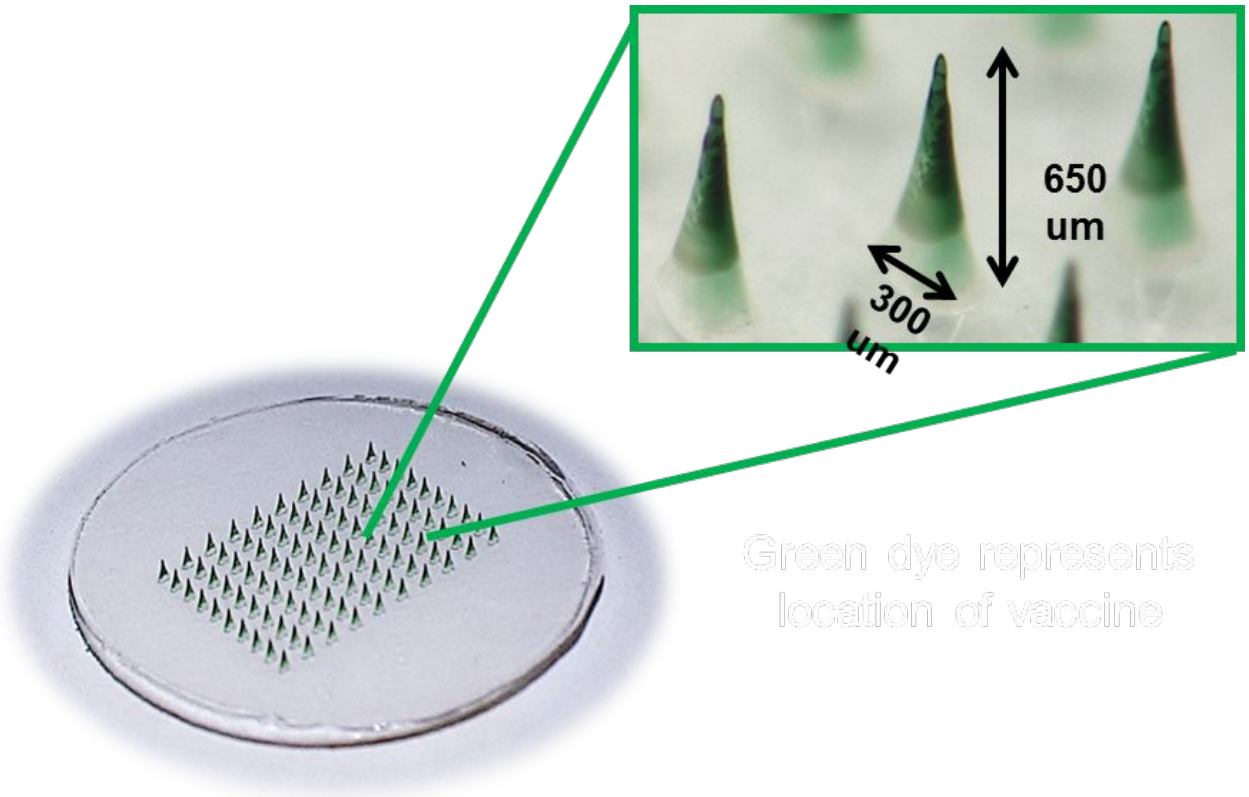
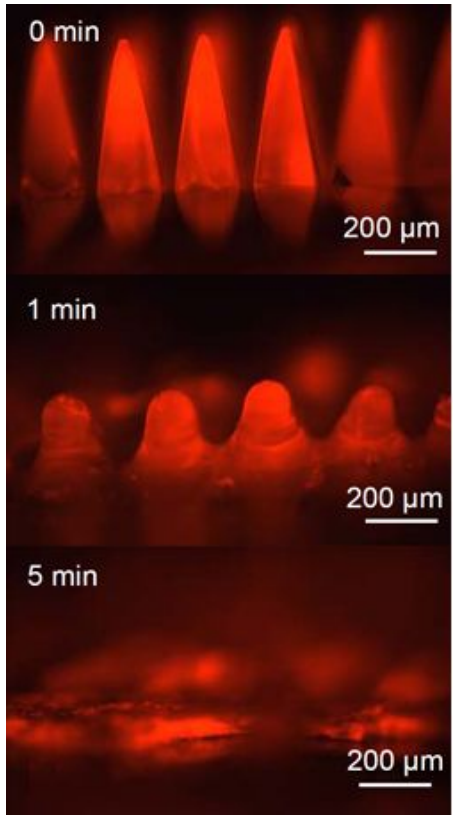
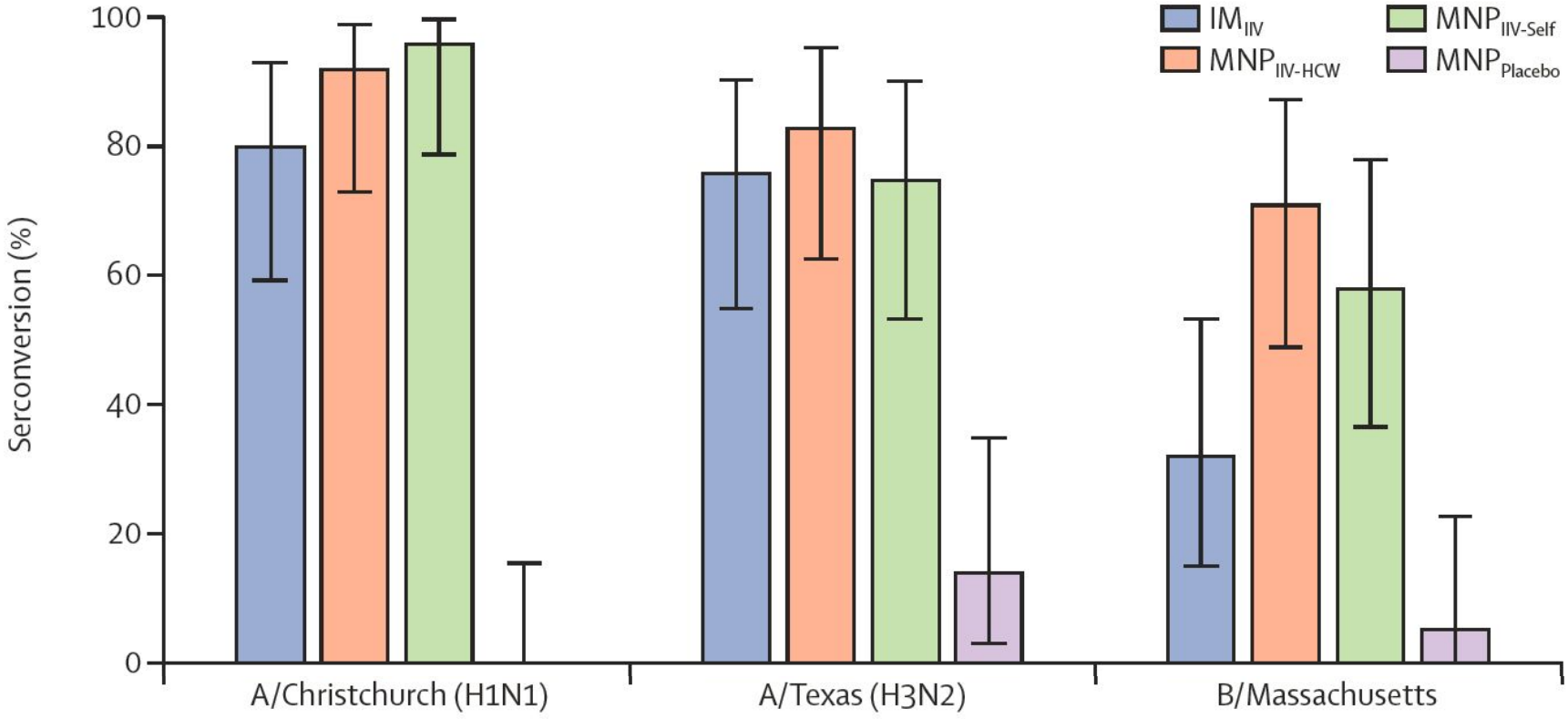




The safety, immunogenicity, and acceptability of inactivated influenza vaccine delivered by microneedle patch (TIV-MNP 2015): a randomised, partly blinded, placebo-controlled, phase 1 trial

Nadine G Rouphael, Michele Paine, Regina Mosley, Sebastien Henry, Devin V McAllister, Haripriya Kalluri, Winston Pewin, Paula M Frew, Tianwei Yu, Natalie J Thornburg, Sarah Kabbani, Lilin Lai, Elena V Vassilieva, Ioanna Skountzou, Richard W Compans, Mark J Mulligan*, Mark R Prausnitz*, for the TIV-MNP 2015 Study Group†

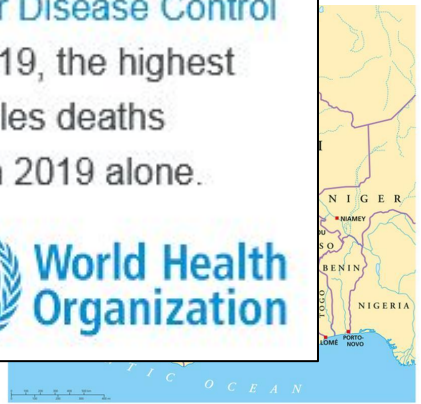
The Lancet, 390 (2017) 649-658



Worldwide measles deaths climb 50% from 2016 to 2019 claiming over 207 500 lives in 2019

Measles surged worldwide in 2019 reaching highest number of reported cases in 23 years. Highlighted in a publication by WHO and the United States Centers for Disease Control and Prevention (CDC), measles cases worldwide increased to 869 770 in 2019, the highest number reported since 1996 with increases in all WHO regions. Global measles deaths climbed nearly 50 percent since 2016, claiming an estimated 207 500 lives in 2019 alone.

World Health Organization



Clinical trial design for measles & rubella vaccination study

Phase 1/2, randomized, active-controlled, double-blind, double-dummy, age de-escalation trial.

Measles and rubella vaccine administered by
- microneedle patch
- subcutaneous delivery

Study groups
- 45 adults [18-40 years]
- 120 toddlers [15-18 months]
- 120 infants [9-10 months]

Local systemic adverse events, safety labs collected
Measles and rubella serum neutralizing antibodies measured
Final study visit on day 180

Micron Biomedical

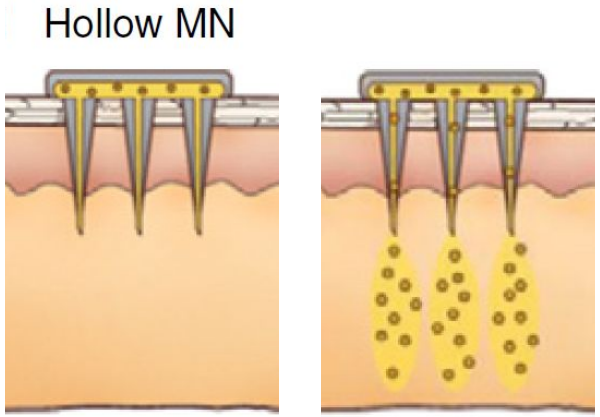
Hollow microneedles for targeted tissue delivery

Targeting the skin

- Local anesthesia
- Insulin delivery

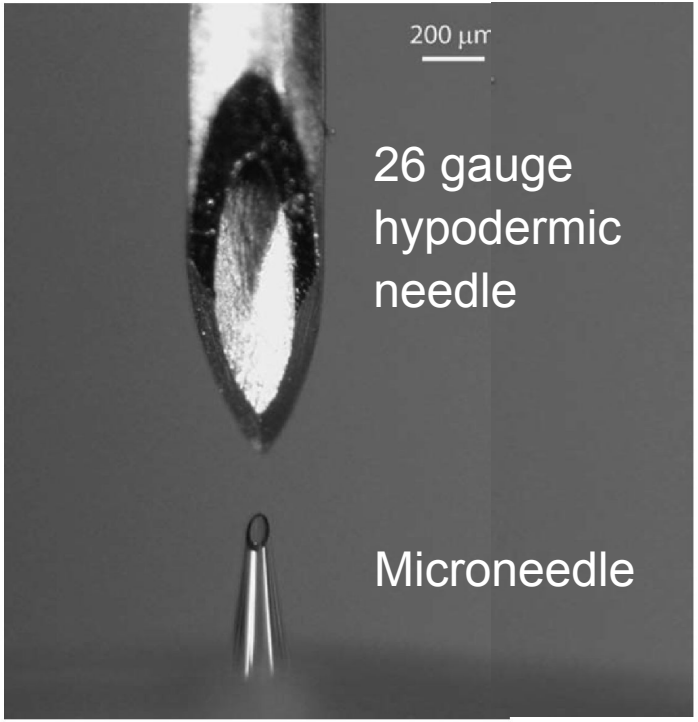
Targeting the eye

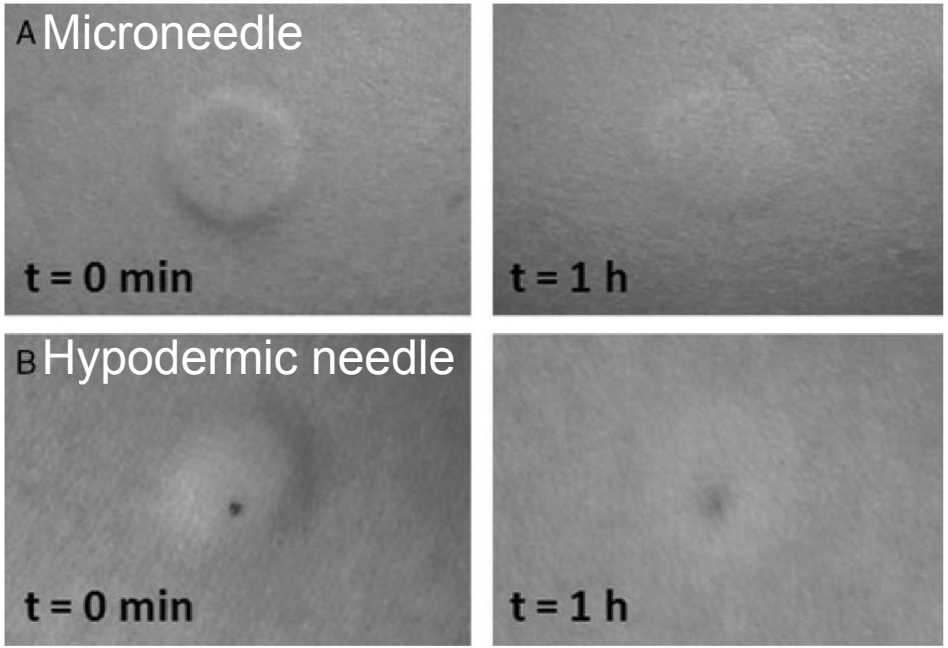
- Suprachoroidal space



Rapid Local Anesthesia in Humans Using Minimally Invasive Microneedles

Jyoti Gupta, PhD, Donald D. Denson, PhD,† ‡ Eric I. Felner, MD, MS,*§ and Mark R. Prausnitz, PhD**





Clinical Journal of Pain, 28 (2012) 129-135

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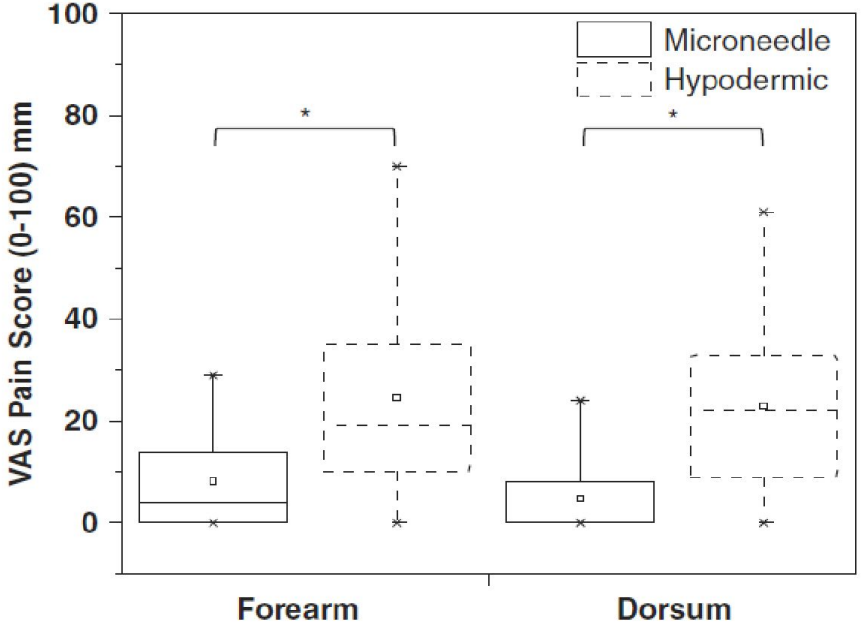
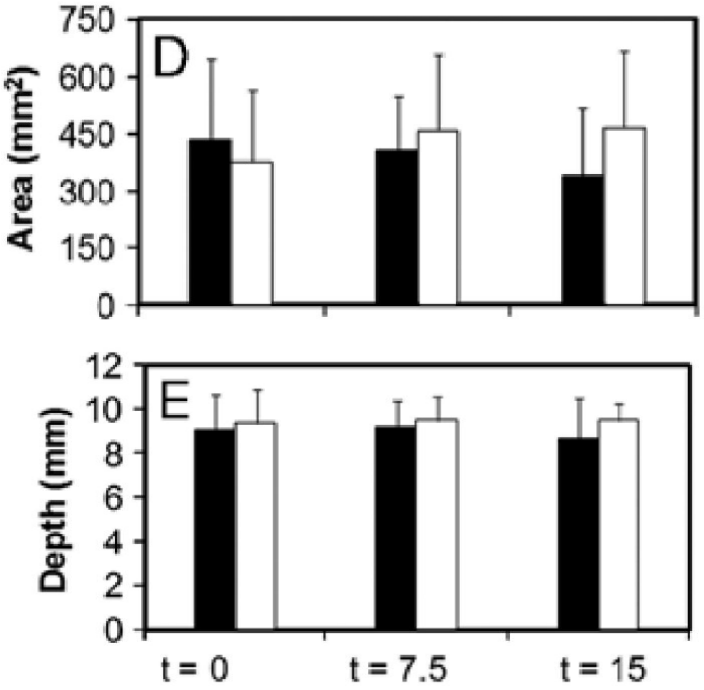
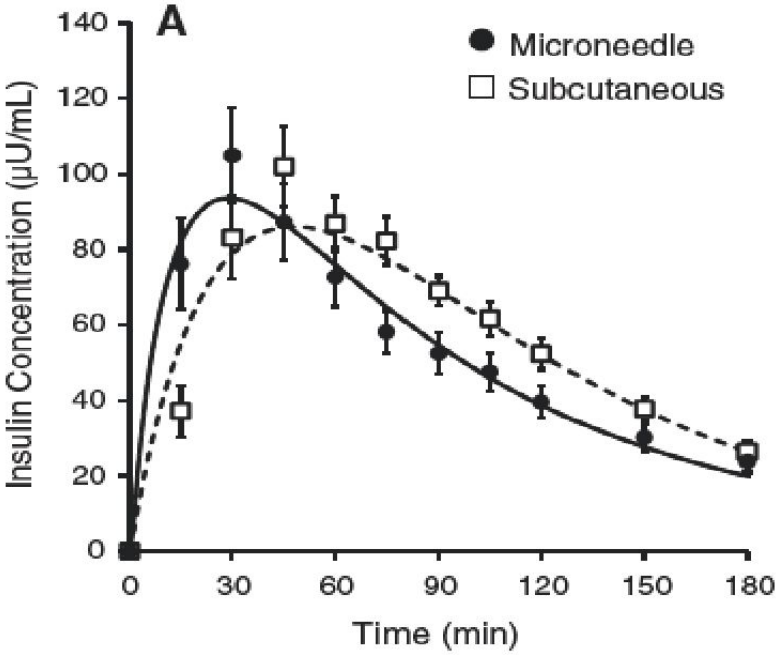


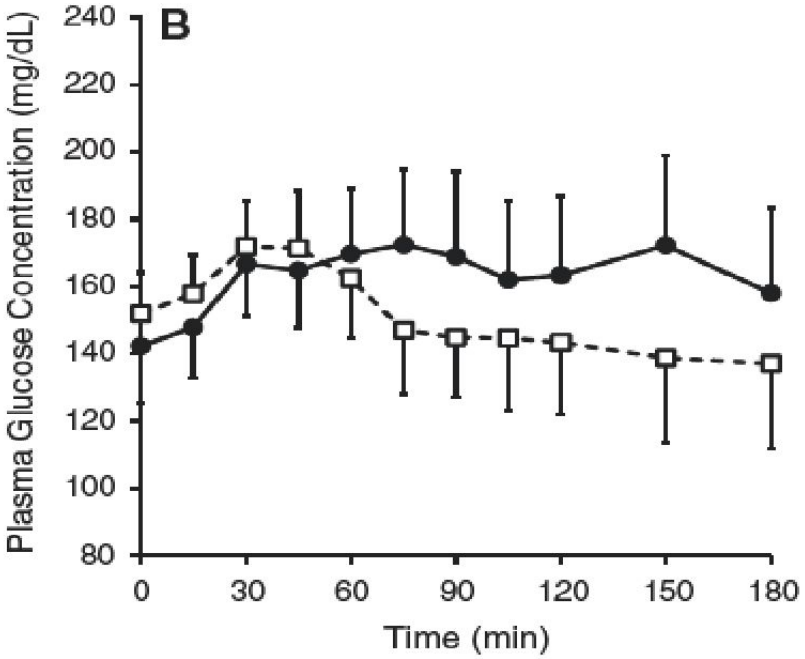


Clinical Journal of Pain, 28 (2012) 129-135

Faster pharmacokinetics and increased patient acceptance of intradermal insulin delivery using a single hollow microneedle in children and adolescents with type 1 diabetes

James J Norman[a,b], Milton R Brown[a], Nicholas A Raviele[a], Mark R Prausnitz[b] and Eric I Felner[a,b]





Pediatric Diabetes, 14 (2013) 459-465

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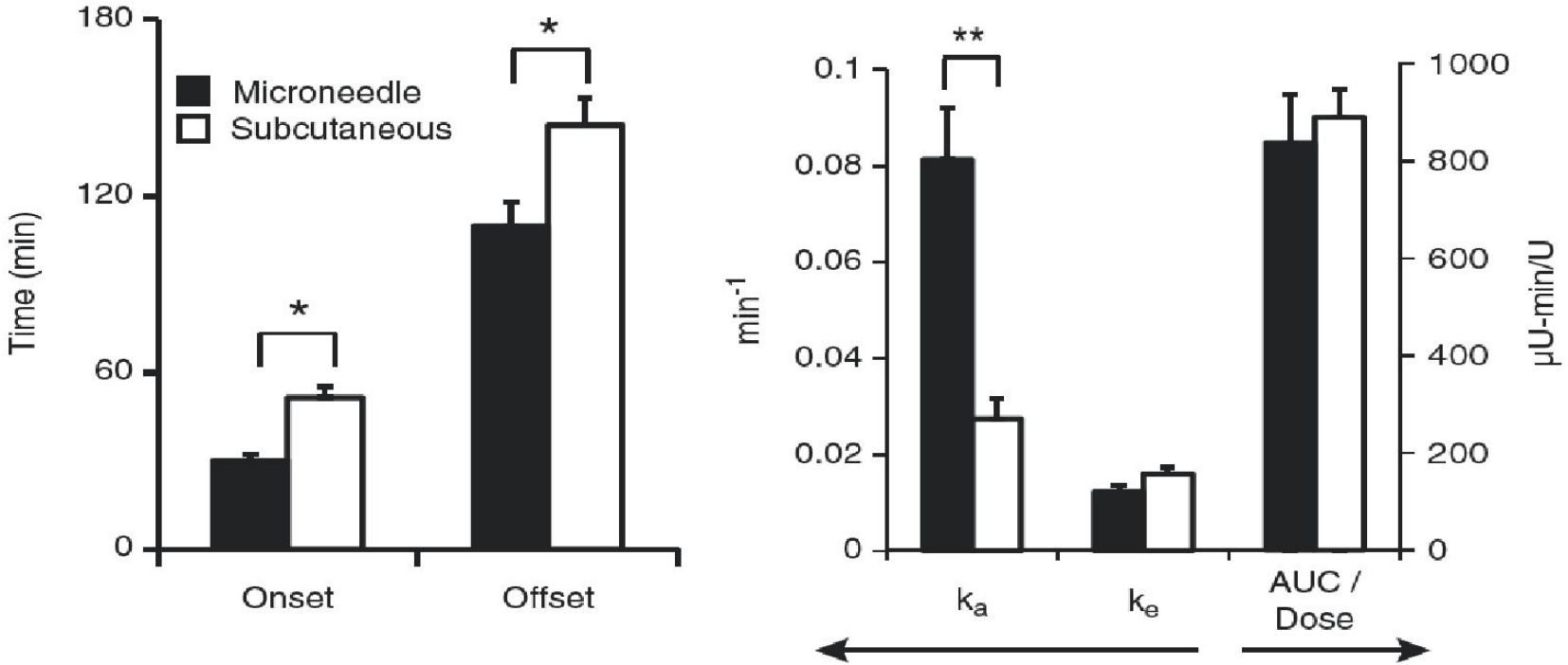
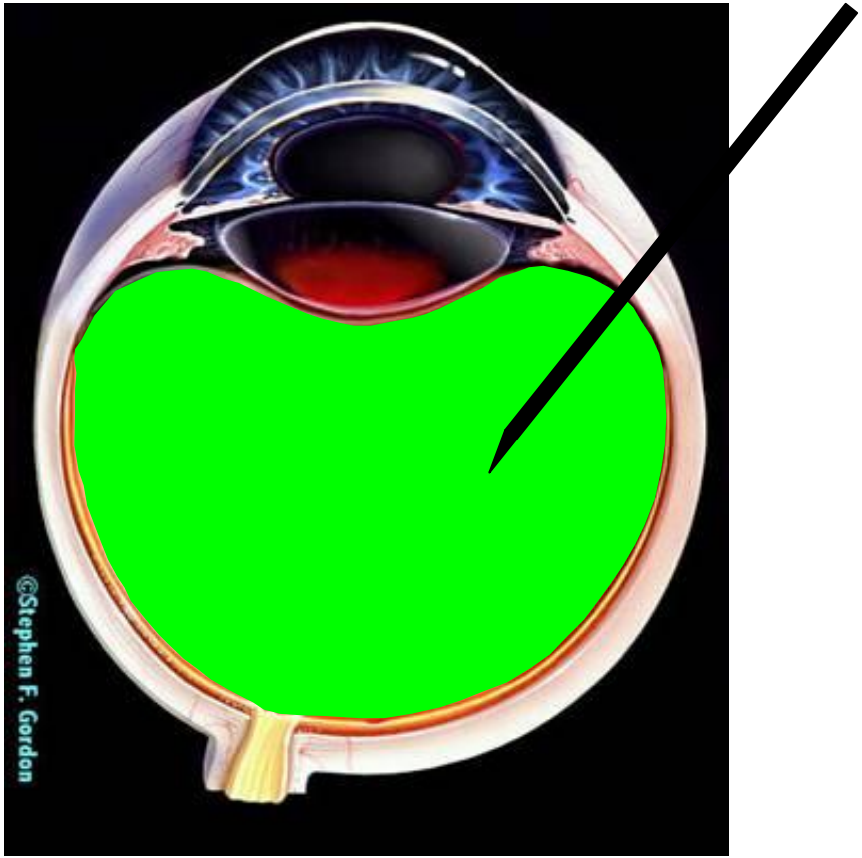


Pediatric Diabetes, 14 (2013) 459-465

Steroid delivery to treat macular edema needs better targeting



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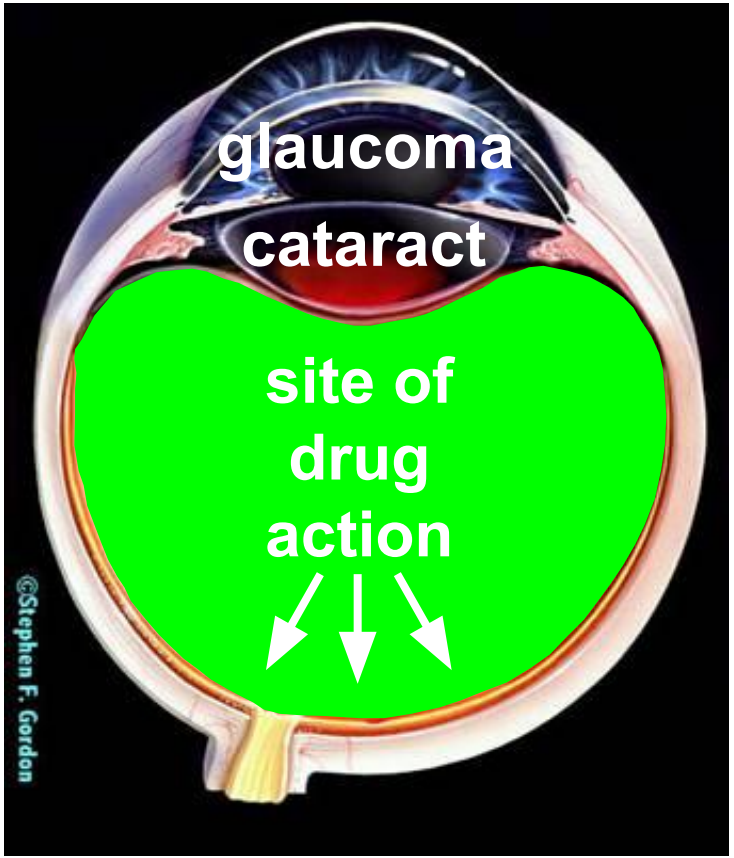
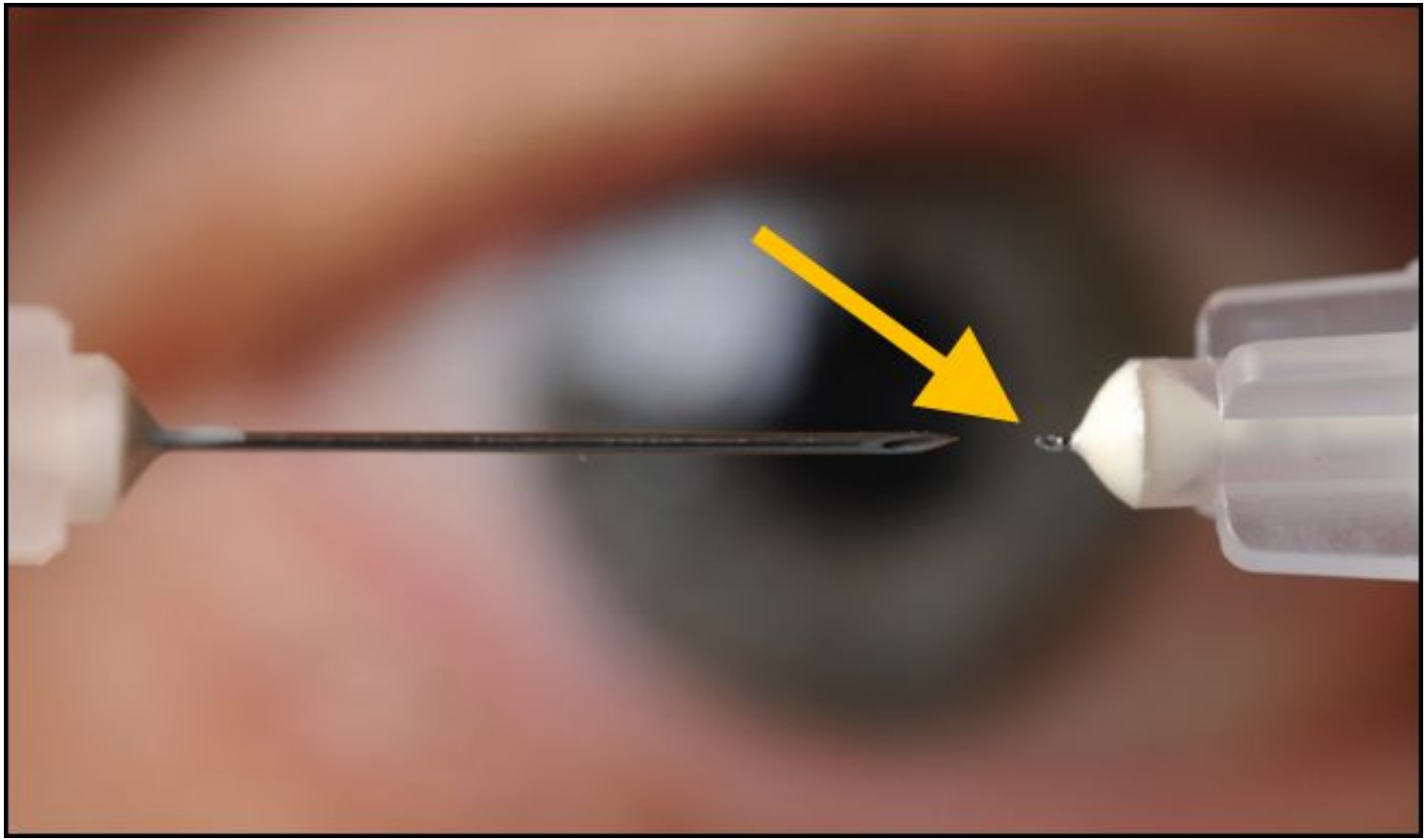


vs.

Hollow microneedle to target the suprachoroidal space



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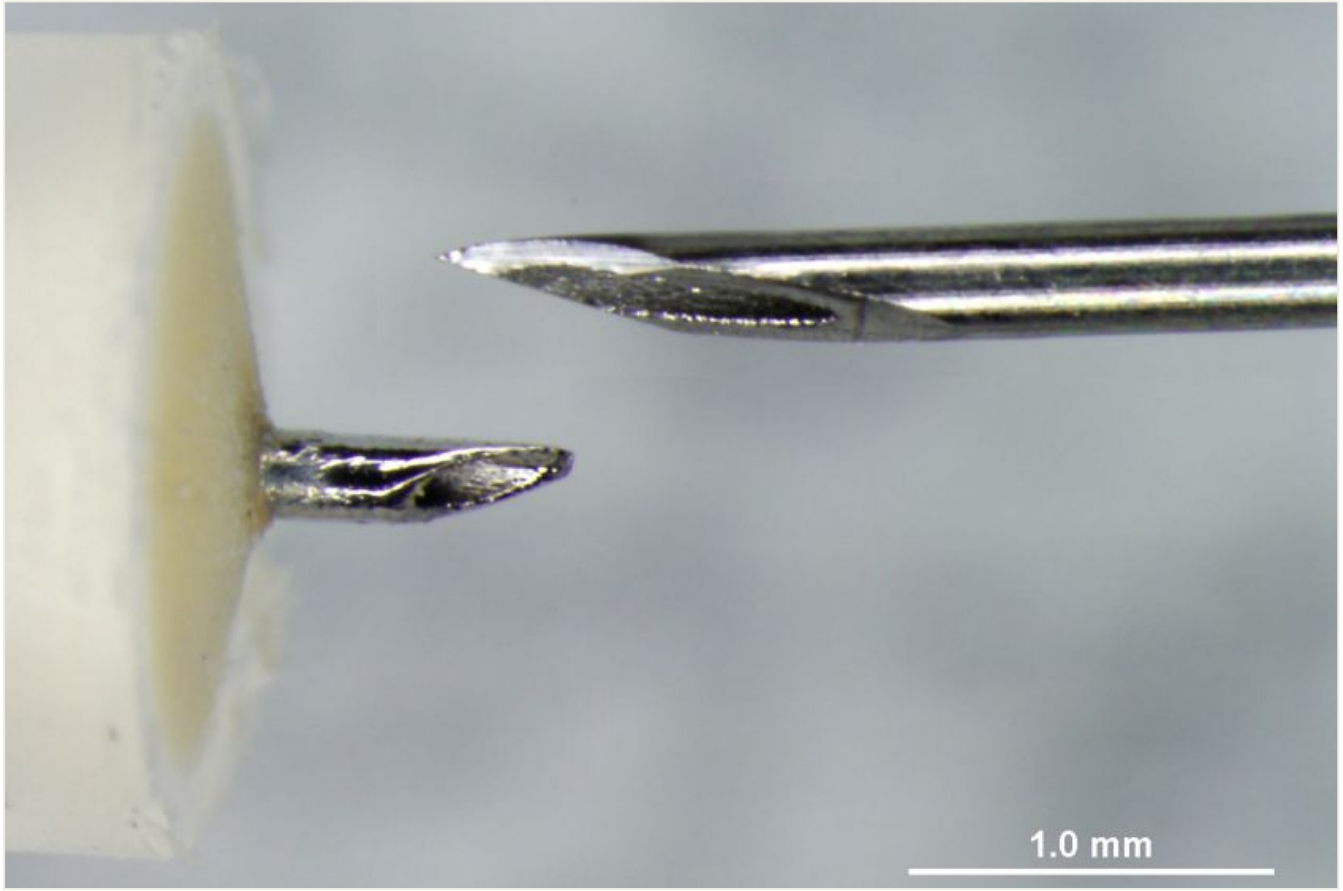
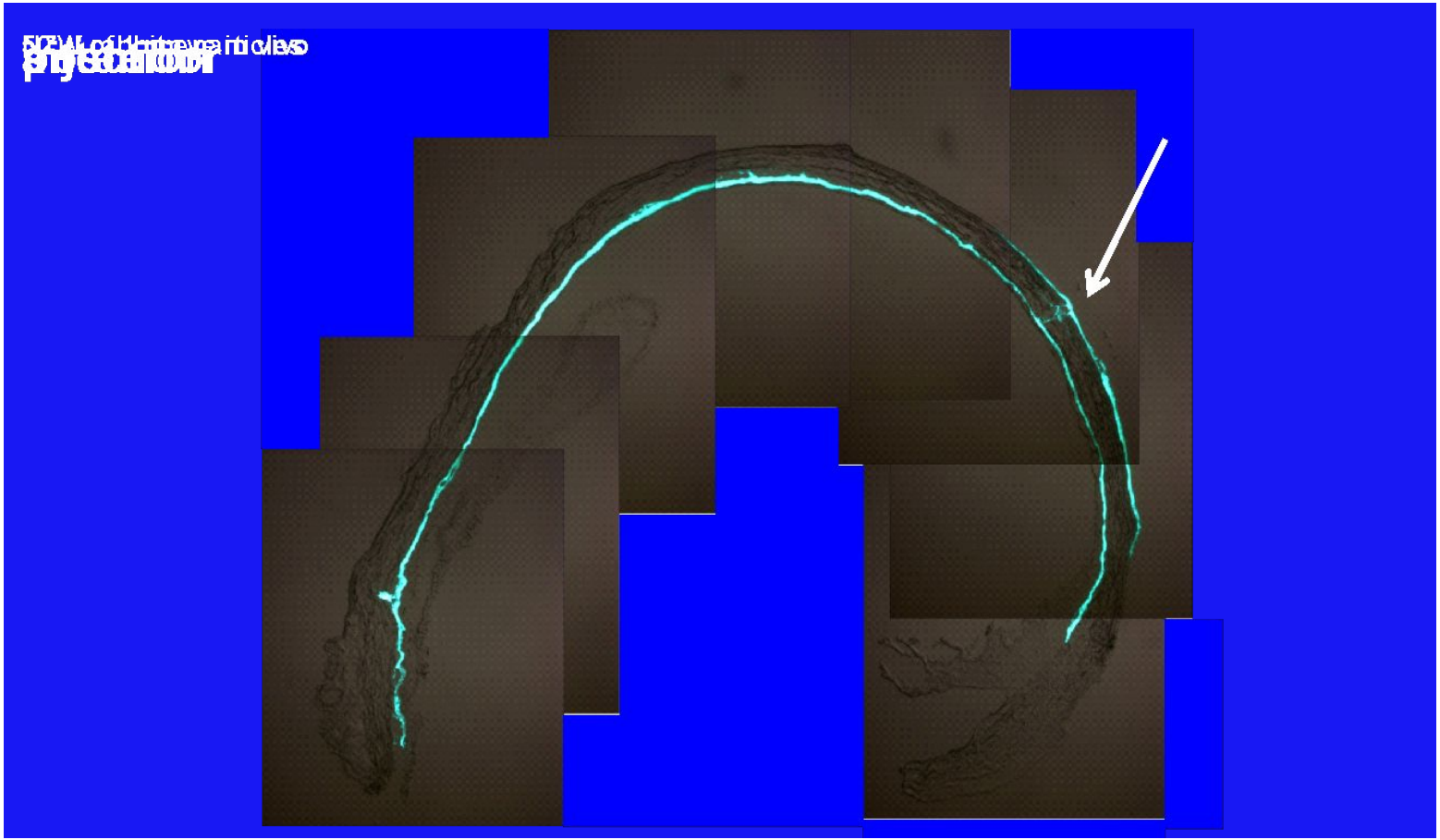


Injection targets the suprachoroidal space



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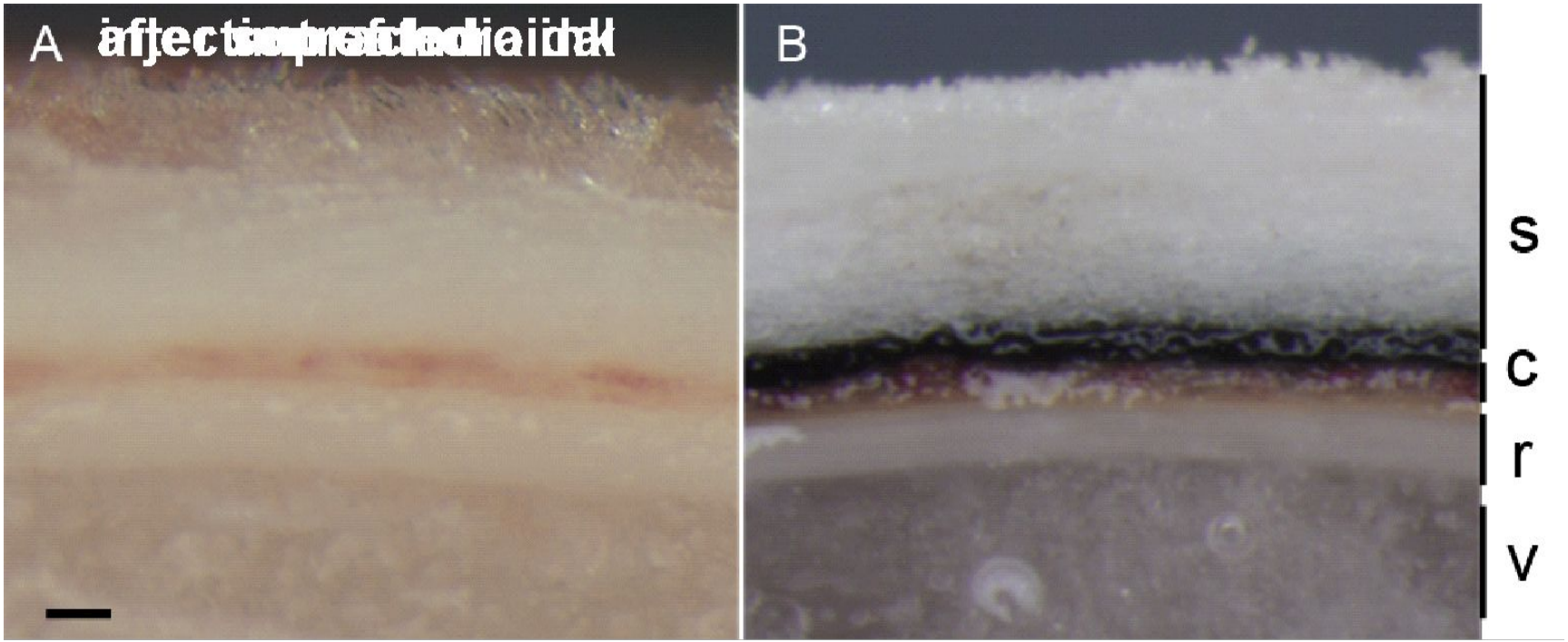


Untreated tissue

After suprachoroidal injection of India ink

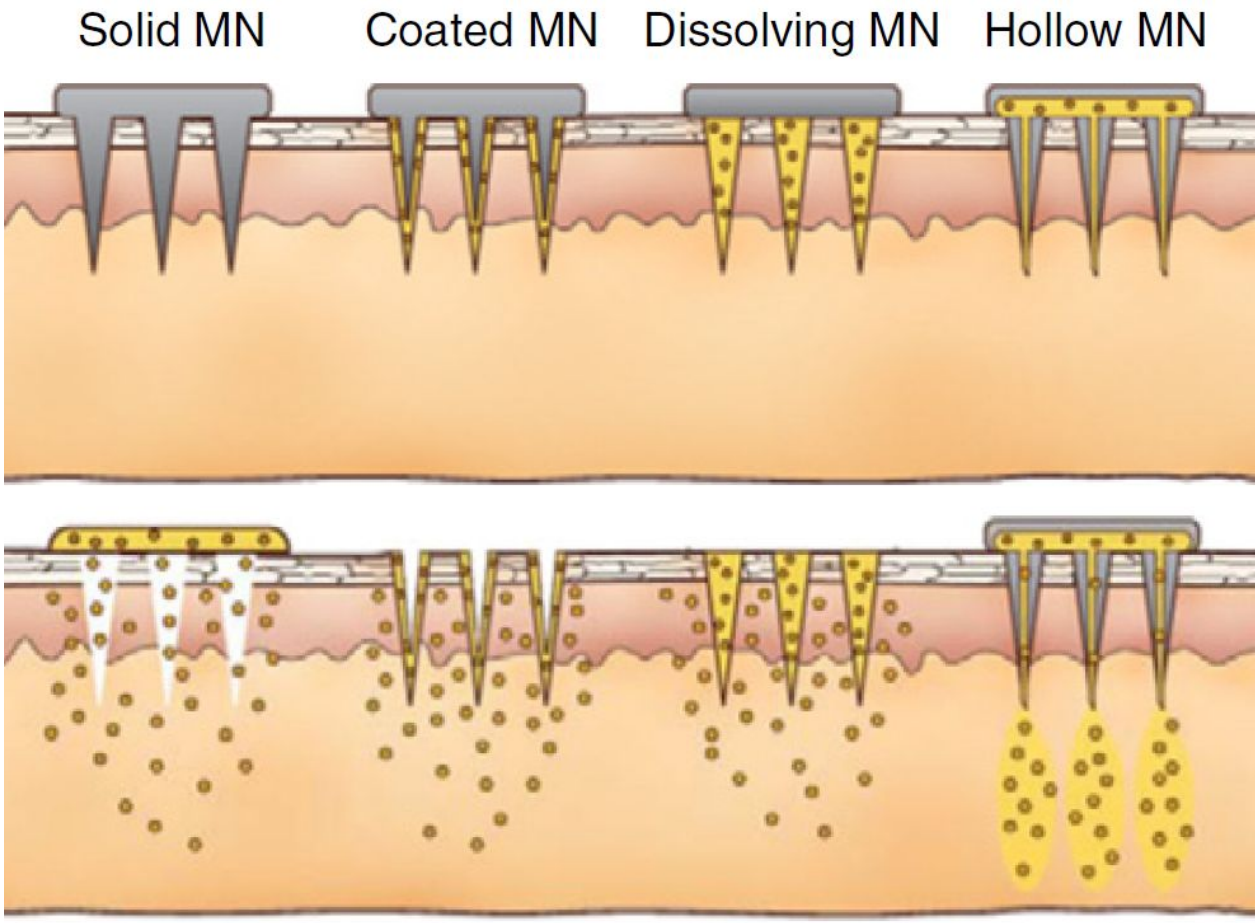
XIPERE®
(triamcinolone acetonide injectable suspension) 40 mg/mL

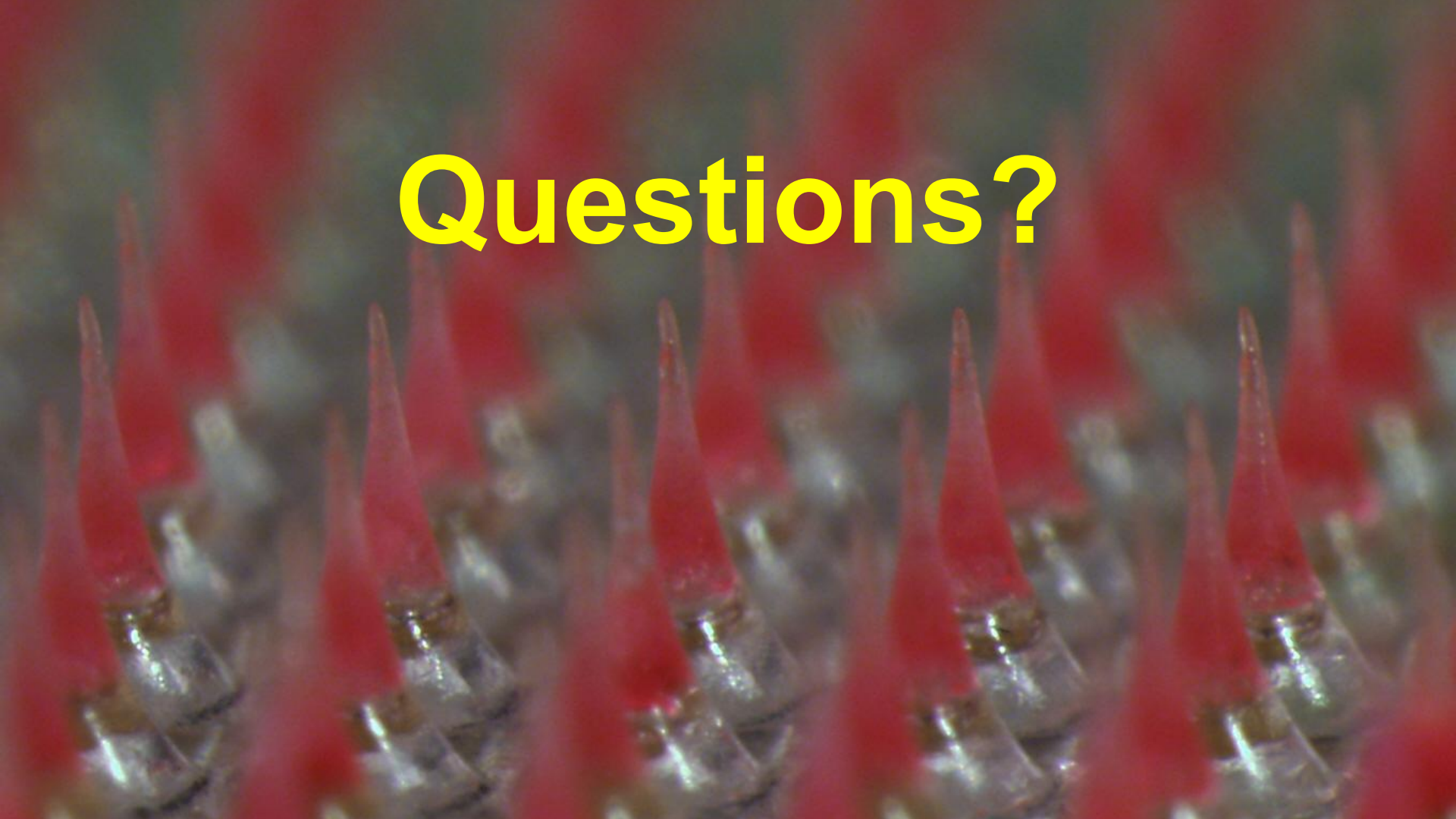
- Treatment of macular edema
- FDA approved in 2021
- Product launched in 2022

CLEARSIDE BIOMEDICAL

BAUSCH Health

Summary




Questions?