

Plenary Session 2: Landscape

Microneedle Patches

Next-Generation Vaccine Delivery Technology Meeting

Geneva, Switzerland

Name: Hiromasa Okayasu

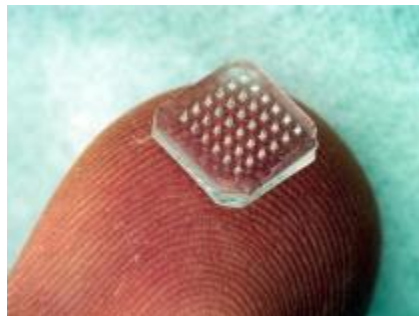
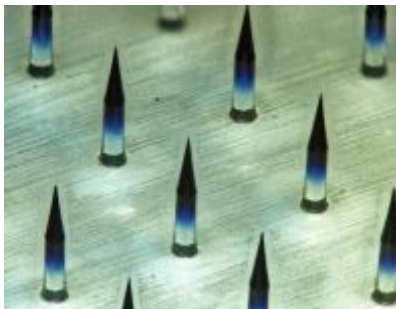
Email: okayasuhi@who.int

Date: February 18, 2014

<Intradermal Patch>: Description

Technology Description:

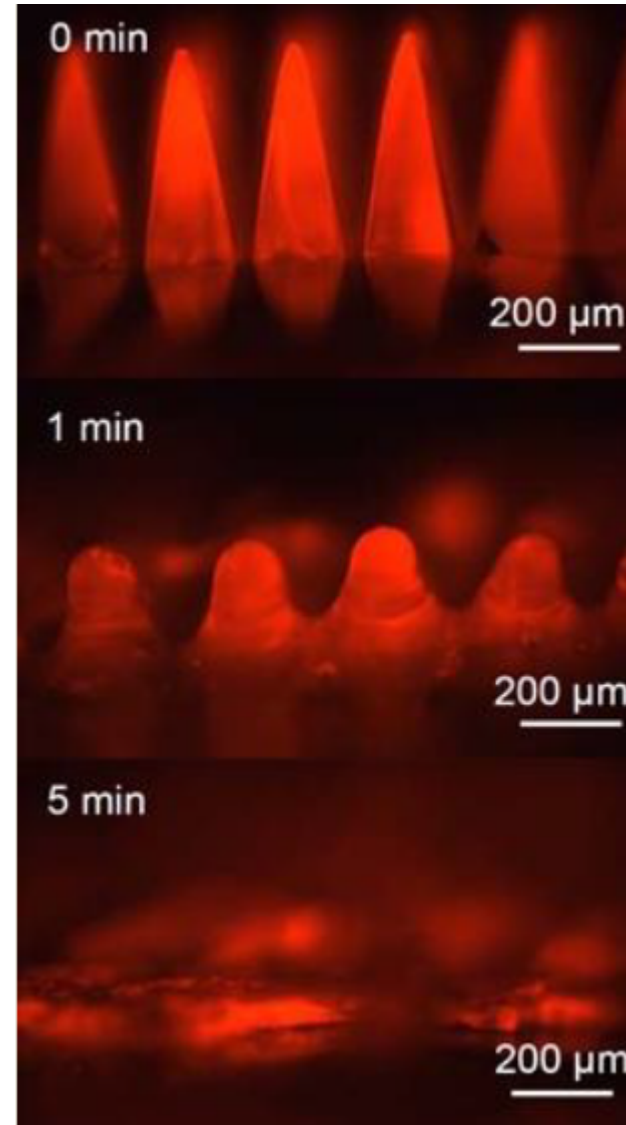
- These patches contain hundreds of microscopic needles that deliver the vaccine into the skin



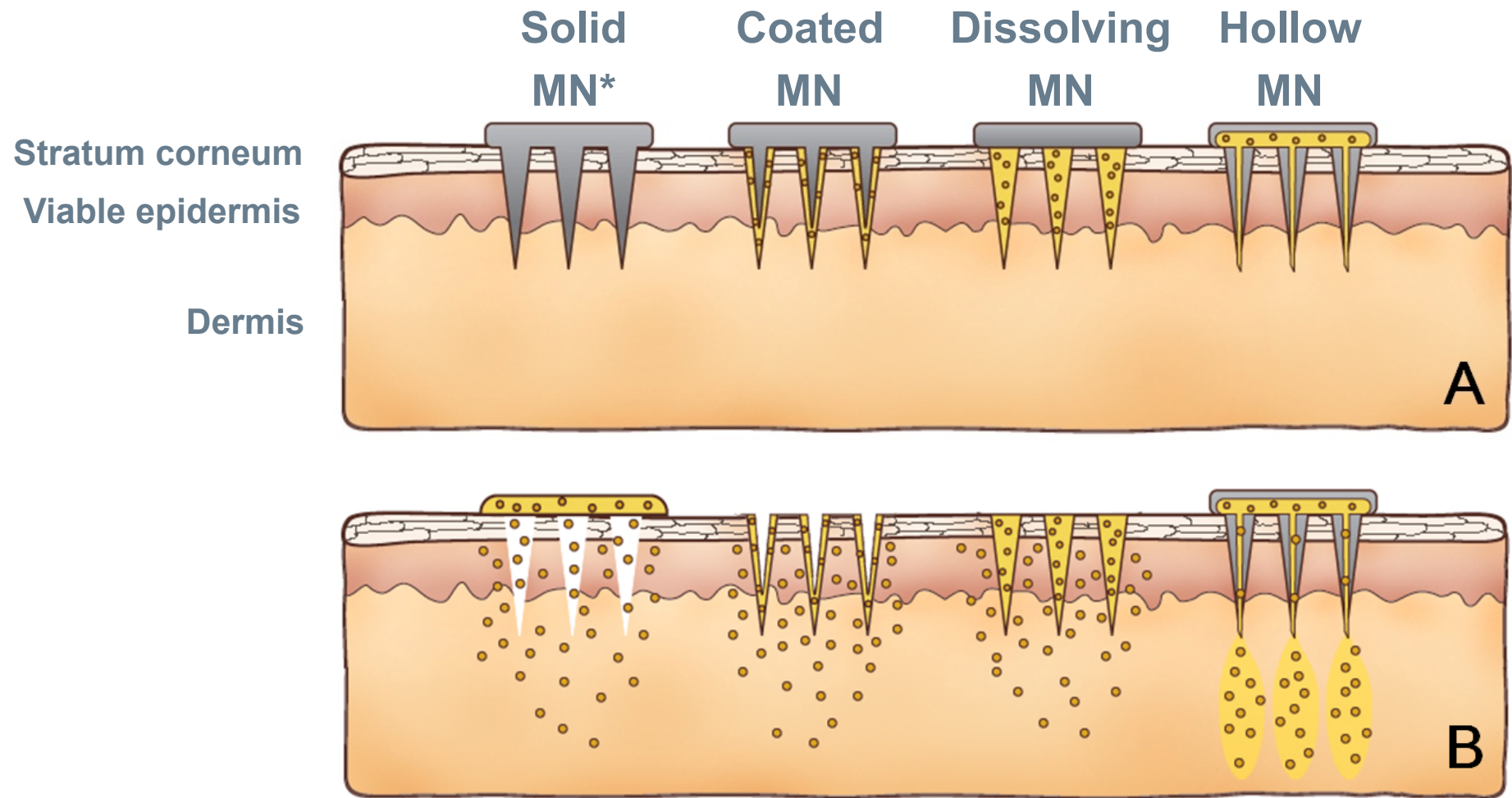
<Intradermal Patch>: Mechanism of Action

Overview:

- These patches contain hundreds of microscopic needles that deliver the vaccine into the skin with or without applicator
- The development is ongoing for different vaccines and drugs



Microneedle Designs



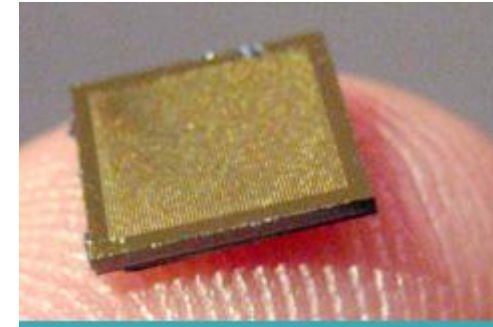
Graphic courtesy of Mark Prausnitz (Georgia Tech).

*MN: microneedle.

< Intradermal Patch >: Nanopatch (Vaxxas)

Description:

- Nanopatch™ (Vaxxas) consists of an array of thousands of vaccine-coated microprojections that perforate into the outer layers of the skin when applied with an applicator device



Status:

- Pre-clinical work is ongoing with several vaccines, including IPV
- Mouse studies indicated the potential for dose-sparing (e.g. 100-fold reduction has been achieved in the mouse model when delivering flu vaccine)



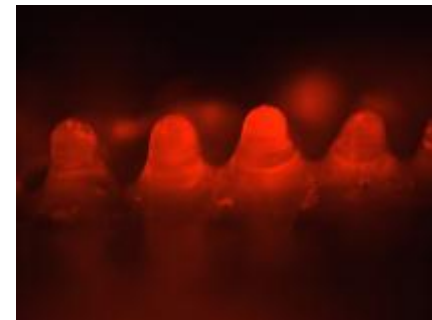
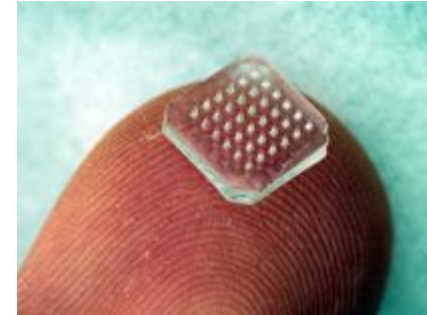
< Intradermal Patch >: Microneedle Patch (Georgia Institute of Technology)

Description:

- A patch containing 100 dissolving microneedles
- Microneedles dissolve in the skin in 3-5 minutes

Status:

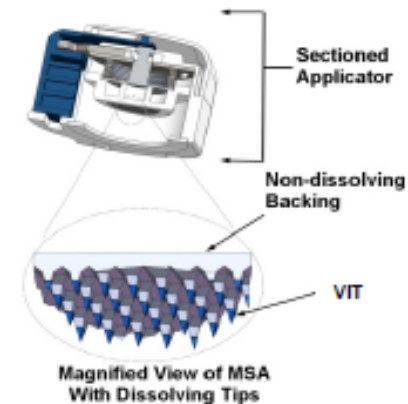
- Pre-clinical work is ongoing with several vaccines, including IPV
- Animal studies (including mice and primates) demonstrated immunogenicity and safety for different vaccines



< Intradermal Patch >: MicroCor® (Corium)

Description:

- MicroCor® integrates the active drug ingredients and vaccines directly into arrays of biodegradable microstructures (called “microneedles”)
- The array is also integrated with applicator device



Status:

- Pre-clinical work is ongoing with several vaccines, including IPV
- Phase 2 development is ongoing with PTH



< Intradermal Patch >: Benefits and Challenges

Benefits:

- Ease of Administration (no trained health worker needed)
- Less cold chain requirements
- Less wastage disposal requirements
- (Possibly) Dose sparing

Challenges:

- No immunogenicity demonstrated in human (for vaccine)
- Regulatory pathway needs to be established
- Scale-up of production capacity needed
- Some devices needs optimization for commercialization

< Intradermal Patch >: Opportunities and Way Forward

Global Public Health Challenge:

- Devices are needed to enable house-to-house vaccination campaign (e.g. outbreak response, catch-up immunization)
- Current, needle and syringe option is not suitable due to requirements for trained health workers and cold-chain equipment's

Technology Availability:

- Production of GMP material is ongoing with several vaccines (e.g. IPV, Flu)
- Clinical trials will confirm the feasibility of this technology in human conducted in 2-3 years
- The significant investment (20M USD+) required to scale-up the production capacity before moving to Phase III and commercial production