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A review on Microneedle array for transdermal drug Delivery system

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Abstract
Although transdermal drug delivery system (TDDS) patches have been used to overcome the drawback of hypodermic needles, they also have a restricted capacity to absorb hydrophilic drugs and macromolecules such as DNA and peptides. Consequently, microscopic projections that could pierce the skin were produced, called microneedles. By avoiding contact with blood vessels and nerve fibers, microneedle array patches can reduce bleeding and pain perception by establishing a channel for medicine administration through the stratum corenum in the epidermis. Microneedles can be solid, coated, hollow, dissolving, or hydrogel, and they are made utilizing a variety of microfabrication processes.

Keywords: Application of microneedles, penetration augmentation techniques, transdermal delivery, and microneedle array

Introduction
The distribution of a medicinal material through the skin for a systemic impact is known as a transdermal drug delivery system (TDDS). Among its many benefits over oral delivery is the avoidance of the liver's first pass impact. When compared to hypodermic needles, it is painless and offers the benefit of not having the potential to spread disease that comes with reusable needles, particularly in developing nations. A transdermal medication delivery system is typically thought of as a noninvasive, self-administering, sustained release drug delivery device. Transdermal drug delivery systems are typically thought of as self-administering, noninvasive, sustained-release drug delivery methods. The epidermis, dermis, and subcutaneous fatty layer are the three layers that make up human skin. The outermost layer of skin, known as the stratum corenum, is 100-150 µm thick. Because of its composition, which keeps water out of human skin and foreign substances out, it forms a strong barrier to transdermal delivery. Another potential method for addressing the problems of enzymatic drug breakdown or inadequate absorption following oral administration is the transdermal medication delivery system. In transdermal drug delivery research, increasing the permeability of: drugs that penetrate the skin is one of the primary goals. One important metric that shows the travel length of a molecule across a specific skin thickness over time is skin permeability. The microneedle tip radius has been adjusted for better sharpness. The optimal drug permeability depends on the diameters of the microneedles used for drug delivery systems. Medicine delivery optimization aims to distribute a little amount of a medicine effectively, for as by microneedles, to prevent potential complications such as liver damage or limited absorption. Arrays that greatly affect the administration of drugs transdermally. For low-molecular-weight chemicals, several approaches have been put forth thus far to forecast skin permeability across the stratum corneum. These models for forecasting skin permeability of transdermal distribution of low-molecular-weight medicines were reviewed by Wilschut *et al*.
The permeability of the skin upon insertion and removal of microneedles is described by a theoretical *in vitro* method that was published in the literature and is represented by equation. Eleven Using macroneedles rather than microneedles, Wu *et al*.12 discovered a connection between skin permeability and the quantity of pores. Additionally, they discovered a connection between an animal's skin permeability and the molecular weight of its macromolecules.

Transdermal drug delivery systems skin

Direct application of the medication to the skin is the first step in transdermal drug delivery. Through the epidermis and dermis, the medication enters the stratum corneum. Upon reaching the dermal layer, the medication becomes accessible for absorption. This technique attempts to regulate the drug molecules' diffusion through the epidermis in order to deliver them to the bloodstream. Various methods of transdermal medication administration.

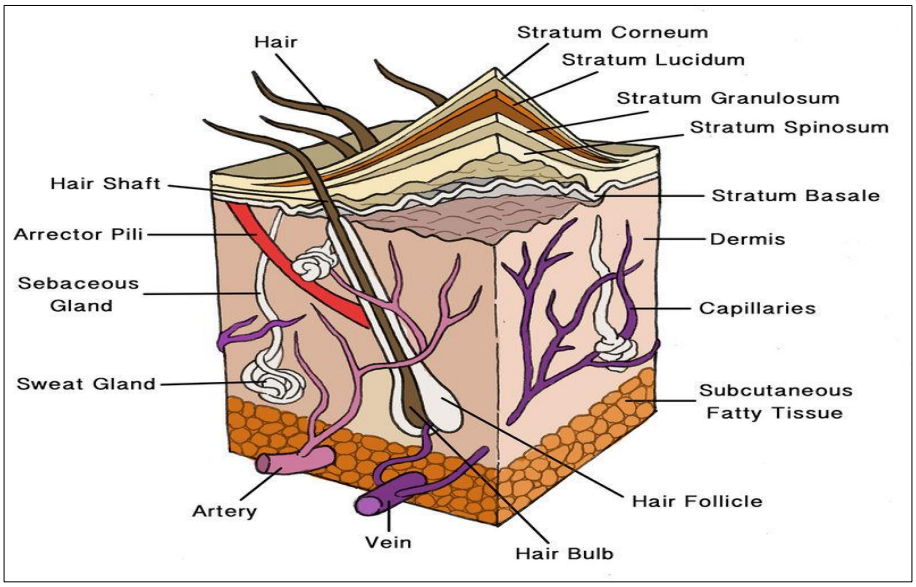


Fig 1: Structure of skin

Transdermal drug delivery (TDD) offers various benefits over conventional approaches. TDD enables controlled and sustained medication delivery to the bloodstream. The transdermal method can reduce drug side effects by keeping them from reaching important organs like the liver and kidneys. Transdermal medication administration can solve the issue of limited bioavailability of oral Transdermal drug delivery (TDD) offers various benefits over conventional approaches. TDD enables controlled and sustained medication delivery to the bloodstream. The transdermal method can reduce drug side effects by keeping them from reaching important organs like the liver and kidneys

Transdermal medication administration can solve the issue of limited bioavailability of oral medicines, particularly macromolecules, pPassive transdermal medication delivery may not be effective for high-dose or high-molecular-weight medicines, necessitating an active penetration enhancer. BTransdermal medication administration may need unique manufacturing and patient-specific formulations, potentially leading to higher therapeutic costs TDD faces the difficulty Passive transdermal medication delivery may not be effective for high-dose or high-molecular-weight medicines, necessitating an active penetration enhancer Transdermal medication administration may need unique manufacturing and patient-specific formulations, potentially leading to higher therapeutic costs. TDD faces the difficulty of being limited to 22 strong medicines with excellent physicochemical qualities, which are not commercially viable. Being limited to 22 strong medicines with excellent physicochemical qualities, which are not commercially viable.

These include substances like nicotine, estrogen, and nitroglycerine that can pass through epidermal barriers and passively disperse in order to reach therapeutic quantitviabl. The stratum corneum, the outermost, biphasic layer of skin that is 10-20 micrometers thick and contains both hydrophilic and hydrophobic patches, is the main barrier that restricts the flow of drugs into the skin. Considerable attempts have been made to improve the medications' transdermal penetration into the stratum corneum with the aid of physical or chemical enhancers. Microneedles allow the majority of medications to be delivered via the skin by either physically enhancing the stratum corneum or physically disrupting it. Considerable attempts have been made to improve the medications' transdermal penetration into the stratum corneum with the aid of physical or chemical enhancers. Microneedles allow the majority of medications to be delivered via the skin by either physically enhancing the stratum corneum or physically disrupting it. Drugs can diffuse through the skin if they come into touch with the interstitial fluids after the stratum corneum has been penetrated. Therefore, hydrophilic medications can be delivered in this way, or as a backup mechanism, sweat glands can be used. Microneedles solve some of the main issues with transdermal delivery.

Definition

Microneedle Array of Transdermal Drug Delivery System:

In a transdermal drug delivery system, a microneedling array is a minimally invasive procedure that delivers medications directly into the skin or systemic circulation by penetrating the stratum corneum, the skin’s outermost layer, with an array of tiny needles called microneedles. These microneedles improve drug permeability without the need for oral administration or hypodermic needles, are often painIiand because little tissue harm.

Microneedle (MN) for Transdermal Drug Delivery

Active transdermal drug administration is possible with MN technology, which is meant to take the place of conventional syringe injections. By penetrating the stratum corneum, the MN array delivers the medication in a less invasive manner. Micro-sized needles, these arrays range in height from 25 to 2000 µm. Drug and vaccine delivery, cosmetics, and illness

diagnostics are just a few of the uses for MNs. This review study goes into additional detail about the many structural configurations, forms, geometries, and materials used in MN, as well as the various manufacturing techniques.

display a few modern commercial MN devices. Microneedle research constituted for 30% of the most current scholarly literature in "transdermal delivery technology," according to Donnelly *et al*. Skin physiology, physiochemical characteristics, and ambient circumstances are examples of external variables that can affect the MN drug delivery pathway. These consist of the temperature and relative humidity in the neighborhood of the application region. Excessive water and the presence of other salts can alter the osmotic gradient for transdermal drug delivery, while excessively high humidity (such as sweat) can disrupt drug release kinetics. Conversely, too sparse (low humidity) will delay the release of medications to the epidermal layers. The elution of medications via the skin can also be further delayed by excessive sweat, which might hinder the microneedle patch's ability to adhere to the skin. Likewise, extremely low or extremely high pH ranges near the skin area may cause the medicine to be less permeable into the stratus corneum and beyond. Transdermal absorption can be aided by defatting the stratus corneum, which is a barrier layer formed by the skin's excessive lipid coatings. Because warm skin increases diffusivity and dilatation of skin vessels, it can improve medication penetration. When giving delicate medications like insulin and chemotherapeutics, microneedles' dosage loading and metering accuracy are crucial. As digestion and first-pass metabolism are avoided, micronee-dle patches usually require a lower dosage to provide equivalent therapeutic efficacies than oral intake. When compared to the oral route, microneedles' pharmacokinetics demonstrate a quick bloodstream absorption that can be useful for treating localized conditions with far lesser drug loading. When it comes to carrying larger dosages than solid microneedles, hollow microneedles can act as drug reservoirs. Inkjet and spray atomization techniques can be used to coat solid microneedles composed of metal or ceramic materials with extremely accurate drug formulations. Patient profile, intended treatment plan, and medication type all have a significant impact on the amount of drug loading for microneedles. Because manufacturing and medication loading processes are controlled, MNs provide a very accurate delivery system. Drug dissolution within skin interfaces, however, may vary depending on the physiology of the skin, the surrounding environment, and the method of application to the skin's surface.

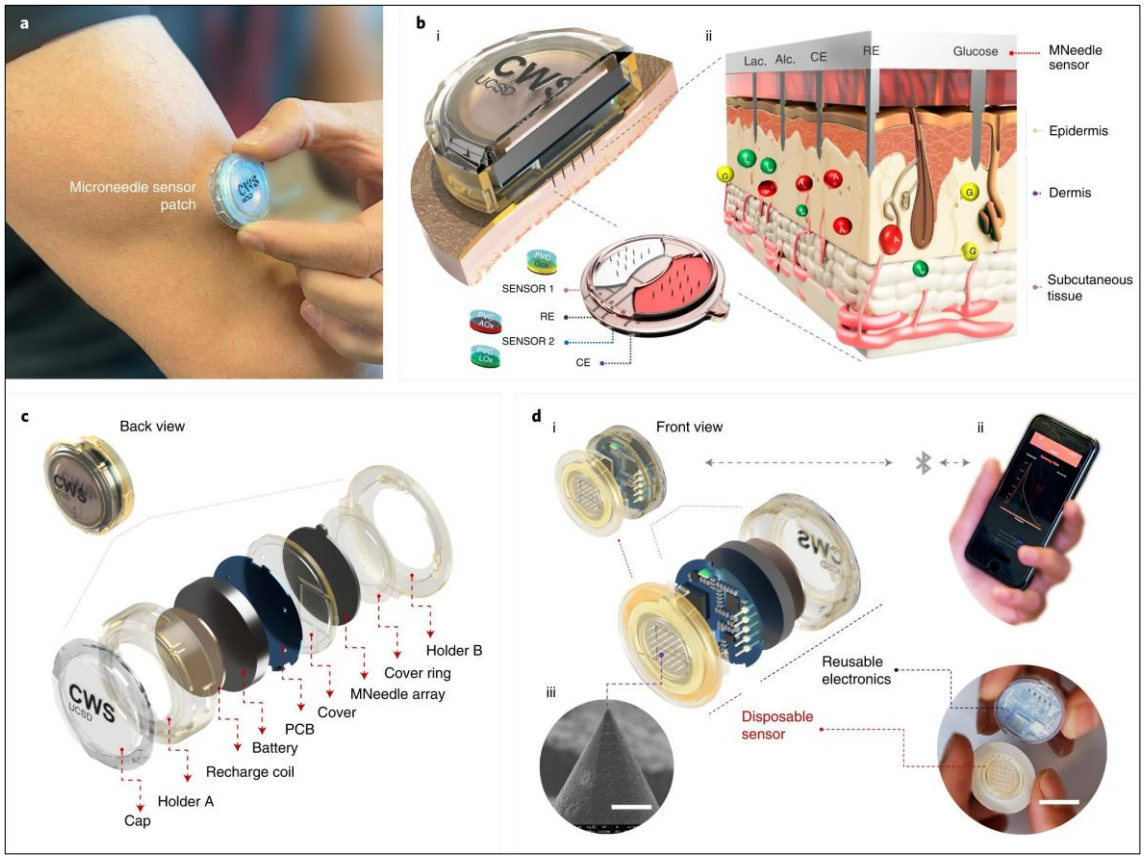


Fig 2: microneedle pathche

Material: Water-soluble and biodegradable polymers, including hyaluronic acid (HA), Polyvinylpyrrolidone (PVP), Polyvinyl Alcohol (PVA), and Carboxymethylcellulose (CMC). During the manufacturing process, the medication is integrated into the microneedle matrix. Mechanism: After being inserted, the microneedles disintegrate and release the medication in a matter of minutes to hours. There is no biohazard waste because the entire microneedle dissolves in the skin, eliminating the need to dispose of sharps.

The global market for microneedle patches is projected to reach USD 1.65 billion in 2024 and grow at a compound annual growth rate (CAGR) of around 18.8% to reach USD 10.95 billion by 2035. According to another analysis, the value is estimated at USD 1.8 billion in 2024 and is expected to expand at a 14.2% CAGR to USD 5.5 billion by

2033. Another projection places it at USD 1.2 billion in 2023 and USD 3.8 billion by 2032, with a 13.7% compound annual growth rate. In the meantime, a different forecast predicts USD 6.4 billion in 2023 and USD 10.9 billion by 2032, with a 5.4% compound annual growth rate.
Asia-Pacific Area In 2024, the Asia-Pacific microneedle drug delivery systems market brought in USD 1,153.6 million (~US 1.15 billion). From 2025 to 2030, it is expected to grow at a compound annual growth rate (CAGR) of 9%, reaching USD 1,885.8 million (~US 1.89 billion). The Skincare & Cosmetics Sector At a compound annual growth rate (CAGR) of 8.2%, the cosmetics microneedle patch market is projected to grow from its 2023 valuation of USD 446 million to USD 776 million by 2031. The market for microneedle skincare patches is projected to reach USD 704 million by 2030, with a compound annual growth rate (CAGR) of 6.9%, according to a related study.

Advantages
A MN is regarded as one of the most effective methods for transdermal drug administration since medications are delivered without going through important human organs like the liver additionally, it reduces the discomfort of intravenous injections by offering a painless experience. Consequently, it is regarded as the ideal option for those with trypanophobia, or needle phobia. Because it doesn't require skilled workers, microneedle transdermal drug administration is simple to utilize. It also lowers the chance of infection spreading throughout the body. Any medicinal agent molecules cannot penetrate the stratum corneum and reach the epidermis or dermis layer because it serves as a barrier.Any medicinal agent molecules cannot penetrate the stratum corneum and reach the epidermis or dermis layer because it serves as a barrier The medicine can be painlessly delivered into the epidermis or upper dermis layer by a microneedle, which can circumvent the stratum corneum bpainles. Additionally, because the MN array is both long enough to reach the stratum corneum and short enough to avoid damaging the dermis or reaching nerve endings, it is painless.

a) Inconspicuous or Minimally Invasive because microneedles only pierce the stratum corneum, the outermost layer of skin, they do not reach pain receptors, making the procedure all but painless.
b) Enhanced Patient Adherence There is no need for hypodermic needles, which helps patients feel less anxious and afraid, especially young patients and those who are afraid of needles.
c) Improved Efficiency of Drug Delivery effectively delivers big molecules like vaccines, peptides, and proteins transdermally by avoiding the epidermal barrier, which typically prevents many medications.
d) The Ability to Self-Administrate It is as easy to apply as a patch, and patients can do it on their own at home without the assistance of medical proimmunization
e) Lower Infection Risk Unlike conventional needles, microneedles do not produce sharps waste, which reduces the risk of bloodborne infections and needlestick accidents.
f) Reduced Dosage, Increased Efficiency because it is delivered directly into the layers of the skin, less medication is required than through oral or injectable routes, which lowers costs and adverse effects.
g) Restricted and Long-Term Release can be made with prolonged release (for chronic illnesses) or fast administration (for immunizations).
h) Broad Applicability Possibility Vaccines, insulin, painkillers, cancer therapies, and cosmetic procedures (such as scar therapy and anti-aging) are all suitable.

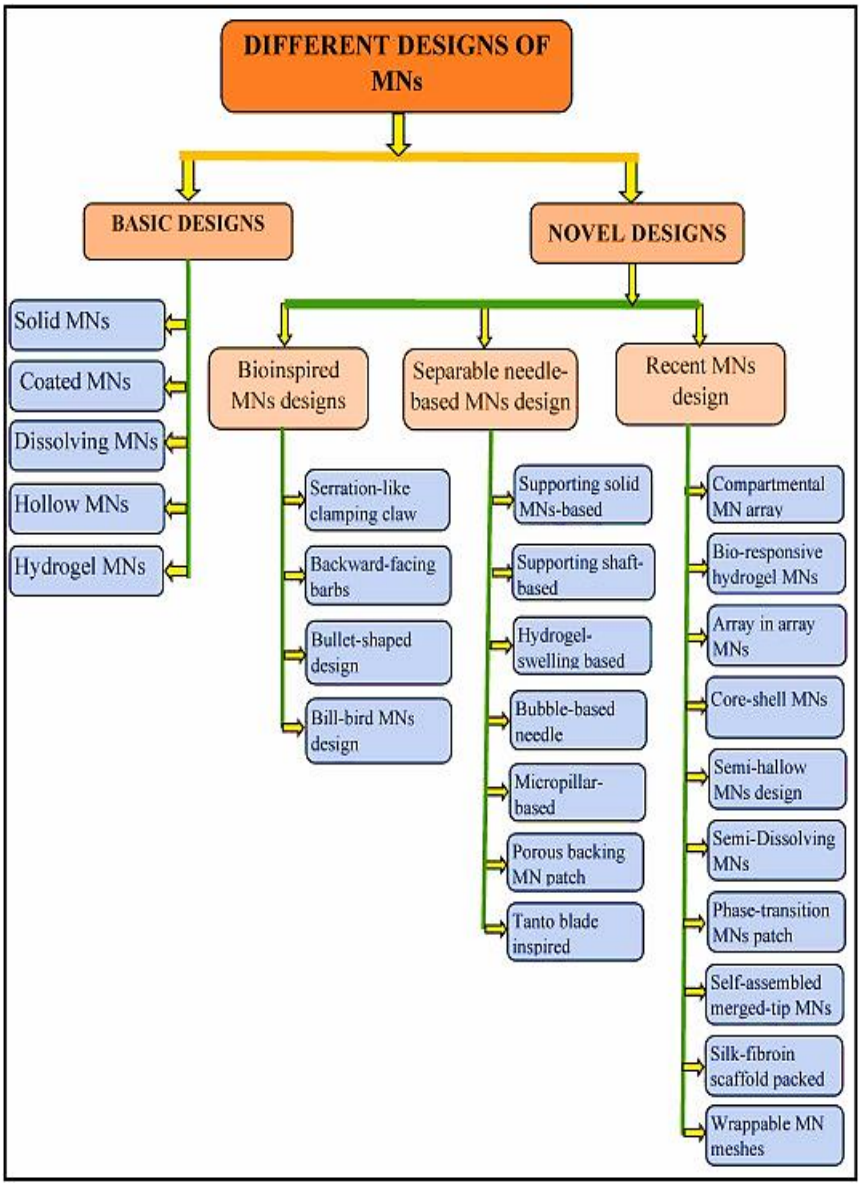
Disadvantages
Using a microneedle for transdermal drug delivery has drawbacks, including longer application times, several patches in the same location, the necessity for specialized mechanical strength, and a biocompatible substance. Rzhevskiy *et al*. claimed thatrclaimed that while taking into account the variations in the thickness of the stratum corneum and other skin layers from a variety of patient populations, MN depth design should also be carefully taken into account The MN device must be implanted orthogonal to the skin surface in order for drug administration and penetration kinetics to be effective. The medication dosage can leak, or the needles might have trouble penetrating the skin at irregular angles. Furthermore, the skin's surface may get scarred as a result of repeated microneedle treatments. The forms and conformations of needle structures may also have some limitations, which could reduce their effectiveness.

a) Limited Capacity for Drug Loading This can be a problem for drugs that demand high dosages because microneedles can only transport a limited amount of substance in comparison to oral dosage forms or regular injections.
b) Limited to Specific Drugs Most appropriate for proteins, peptides, vaccines, and tiny compounds. Not recommended for medications that need to be delivered deeply into tissues or for significant volumes of fluids.
c) Manufacturing Difficulties It is more expensive and complicated to produce than traditional dosage forms since it calls for accuracy and cutting-edge technology.
d) The Fragility of Mechanical Systems If not placed or configured correctly, microneedles may shatter during application, providing a safety risk.
e) Variability in the Skin Barrier Drug absorption may be uneven depending on the type, thickness, and moisture level of the skin.
f) Danger of Infection or Skin Irritation There is still a potential of local irritation, redness, or infection at the application site, although it is far lower than with injections.
g) Low Patient Knowledge Since the technology is still relatively new, patient acceptance and education may be obstacles to its broad usage.
h) Problems with Biologic Stability Certain drug coatings or dissolvable polymers used in microneedle systems might not keep sensitive medications stable during extended storage times.

History of microneedle
1970s-1990s: Early Conceptualization 1976: Early patents referenced the concept of puncturing the skin with tiny projections to distribute drugs, but the materials and technique were not yet developed sufficiently to carry it out successfully. The possibility of developing tiny needles that may painlessly pierce the stratum corneum (outer skin layer) was demonstrated in 1998 by Mark Prausnitz and his colleagues at Georgia Institute of Technology in their

groundbreaking study on microneedles for transdermal distribution.

In the late 1990s and early 2000s, the first prototypes and research the development of microfabrication techniques, which were taken from the microelectronics sector, led to a surge in microneedle research in the late 1990s. Solid microneedles for skin preparation prior to topical formulation application were the initial designs. 2001-2003: Direct drug delivery became possible with the development of coated and dissolving microneedles.



Development for Commercial and Clinical Use (2005-2015) 2005: Microneedles for insulin and vaccine delivery were shown to be safe and tolerable in early human studies. 2010s: Drug manufacturers started investigating the use of microneedle patches for chronic illness treatments, cosmetic applications, and vaccinations. Biodegradable and polymeric microneedles have been introduced to reduce the waste from sharp objects. --- Market Growth in the Modern Era (2015-Present) Solid, coated, dissolving, hollow, and hydrogel-forming microneedles are the five primary varieties that have developed over time. The range of applications increased to include: (e.g., influenza, COVID-19 study) Vaccination Delivery of insulin in diabetes Cosmetics that brighten the skin and prevent aging Treatment for cancer and biosensing

The study explored how microfabricated microneedles can Improve drug distribution across the skin. This paper sparked substantial investigation into the microneedle domain. Microneedles are made from several materials, including glass, ceramic, metal, and polymers. In 2004, a microneedle array was used to puncture the skin for transdermal drug delivery leading to the exploration of various construction processes and materials for TDD. MNs can be solid, coated, hollow, dissolvable, and hydrogel-forming. Other production technologies include laser ablation, photolithography, and micro-injection molding. In 2005, the first reports of using a dissolvable microneedle for TDD were published.

A new era in device fabrication and opportunities for custom-built, large-volume MN manufacturing were provided by reports demonstrating the use of commercially accessible 3D printers to fabricate the MN master mold.

Type of microneedle

To create solid, coated, hollow, or dissolvable microneedles, a range of materials have been employed, including silicon,

stainless steel, sugar, and polymers. There are distinct features, benefits, drawbacks, uses, and material types for every kind of microneedle.

1) Solid microneedle
2) Coated microneedle
3) Hollow microneedle
4) Disolvable microneedle

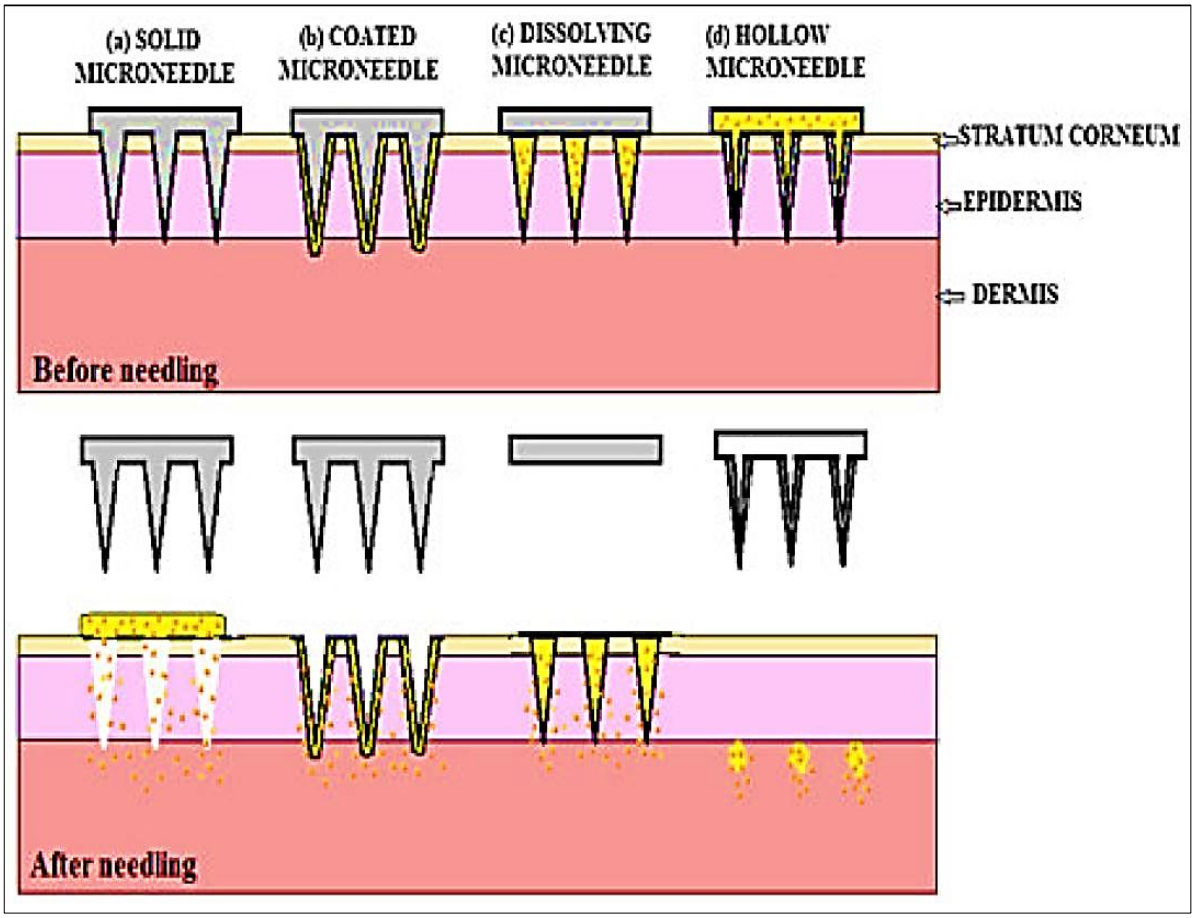


Fig 3: Type of microneedle

1. Solid microneedle

When it comes to medication delivery, immunization, or diagnostic applications, a solid microneedle is one kind of microneedle structure. Instead of having hollow channels or cavities filled with drugs, it is completely composed of a solid material (silicon, ceramic, metal, or polymer). Crucial Features Structure: Usually between 50 and 900 µm in length, these projections are solid and crisp. Material: Usually biodegradable polymers, silicon, or metals (titanium, stainless steel). Mode of Drug Delivery: Frequently applied while using the "poke and patch" or "coat and poke" method: A medication patch is applied for absorption after solid microneedles make microchannels in the skin. Coated microneedles: The medication is applied on the solid surface and dissolves once inserted Utilization of medication (for macromolecules or small molecules).preparation to improve transdermal patch penetration. Do you want me to create a transparent table that compares solid microneedles to other kinds, such as coated, hollow?

2. Coated Microneedle

Coated microneedle is a solid-type MN coated with a medication solution. The thickness of the coating layer usually determines how much of the medication it contains. The capacity to consistently apply a regulated drug layer to MNs is essential for the effective delivery of medication utilizing a coated MN. Proteins and DNA can be delivered minimally invasively using a coated MN. Although quick drug delivery to the skin is a benefit of a coated MN, additional patients could become infected by the leftover medication at the needle's tip. Lastly, the outcomes of administering the vaccine by coated MN were comparable to those of intradermal and intramuscular administration.

Composed of solid needles with a layer of medication applied on the outside. Following insertion, the medication is released when the coating dissolves in the interstitial fluid of the skin. In contrast to dissolving microneedles, needles stay intact and are extracted after insertion.

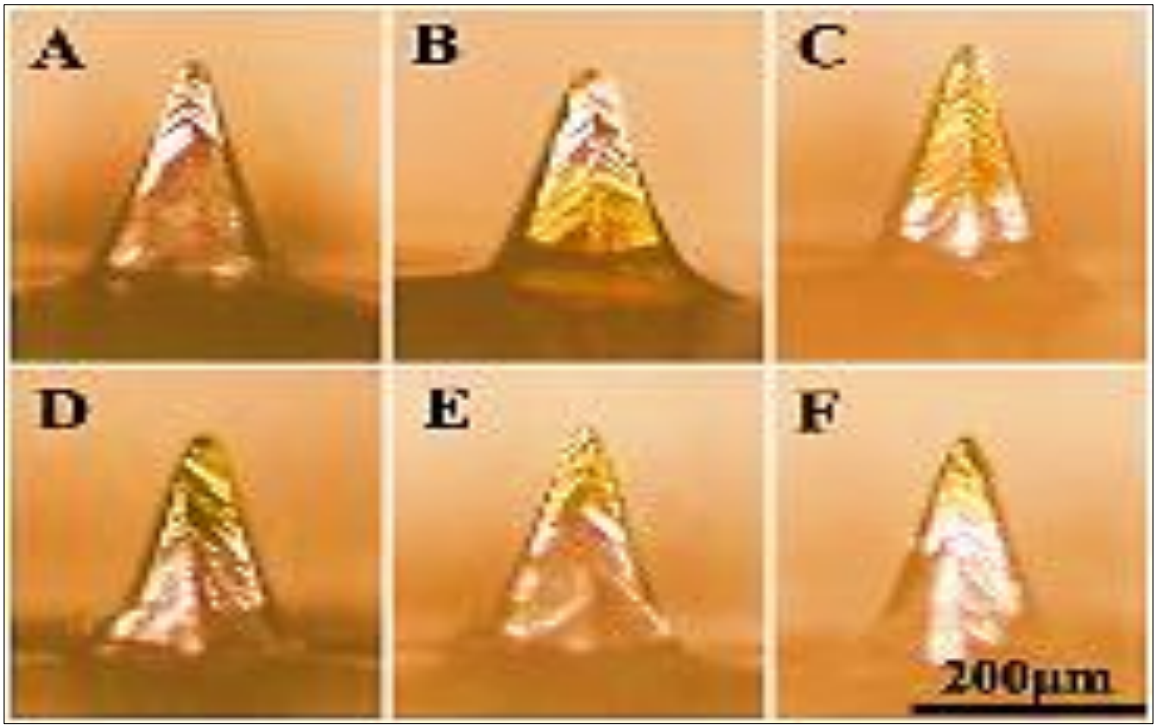


Fig 4: coated microneedle

There aren't enough thorough studies, nevertheless, looking at coating techniques and their range of applications. The objective of this work was to determine the range of molecules and particles that may be coated onto microneedles and to create a straightforward, adaptable, and regulated microneedle coating procedure for creating consistent coatings on microneedles. Microneedles were initially made from stainless steel sheets in the form of arrays or single microneedles. A GRAS coating formulation and a new micron-scale dip-coating technique were developed to consistently provide homogeneous coatings on single microneedles as well as arrays of microneedles. This method was used to coat substances such as plasmid DNA, vitamin B, calcein, and bovine serum albumin. Additionally, modified vaccinia virus and 1-20 micrometer-diameter microparticles were coated. Coatings may be made to disintegrate in pig cadaver skin in 20 seconds and applied only to the needle shafts. The microneedle coatings were transported into the skin and did not wash off after insertion, according to histological analysis. The microneedle coatings were transported into the skin and did not wash off after insertion, according to histological analysis. A straightforward, adaptable, and manageable technique for coating microneedles with proteins, DNA, viruses, and microparticles for quick skin administration is presented in this study's conclusion.

3. Hollow microneedle

Drug fluid is injected or kept in a hollow, empty core or chamber that makes up the hollow microneedle design. A larger dose or volume of medication solution may be handled by the hollow microneedle in comparison to the solid microneedle. Additionally, a hollow microneedle can transport the medicine into the living dermis or epidermis, which is appropriate for drugs with a high molecular weight. Furthermore, it regulates drug release over time, which qualifies it for use with vaccine formulations that are liquid. In contrast to solid microneedles, which mainly use the osmotic gradient to elute pharmaceuticals, hollow microneedles are an active drug delivery device that creates a channel for drug diffusion into the dermis using a non-pressurized drug reservoir.

To enable adjustable release kinetics, hollow microneedle production settings and material formulation can be used. While matrix-loaded pharmaceuticals can allow for a steady-state drug release that lasts for days to weeks, depending on the application goal, higher concentration medications may produce burst release drug profiles. Hollow microneedles, like hypodermic needles, can be made to allow for pressure and flow rate adjustment. For a time-varying delivery rate, delayed infusion, or quick release, process variables such the microneedle aspect ratio (height to base diameter ratio) can be adjusted. A range of vaccines and inoculations have been effectively administered using hollow microneedles over time.

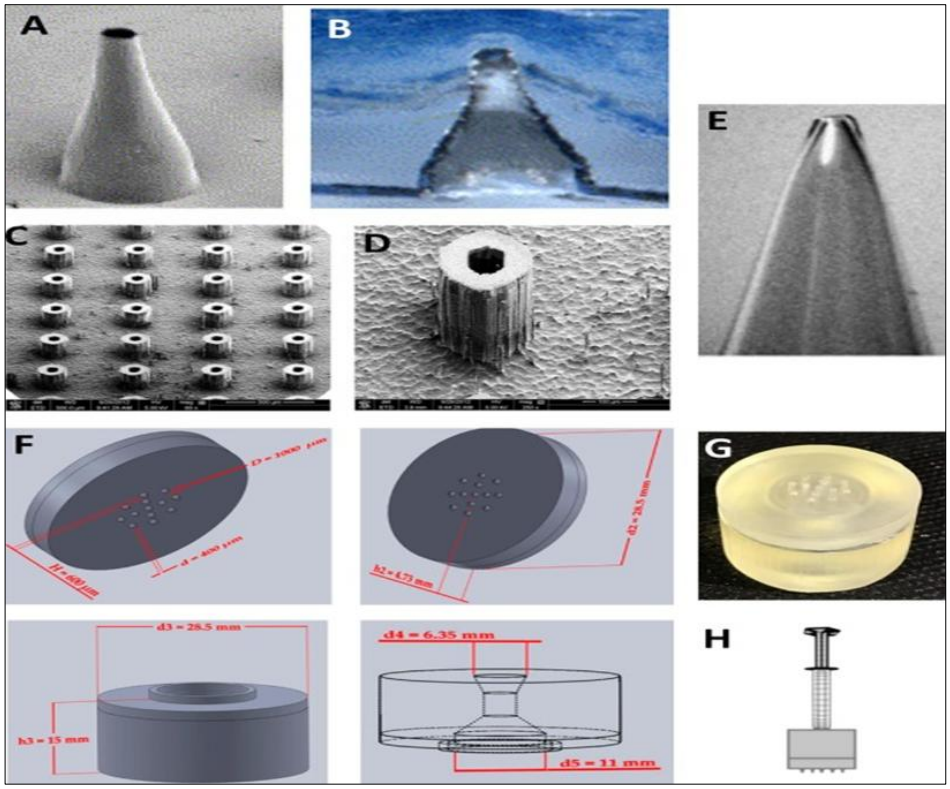


Fig 5: Hollow-microneedle nevertheless, this kind of microneedle was given less attention than the solid and hollow varieties

Nevertheless, this kind of microneedle was given less attention than the solid and hollow varieties polymer mold (200 µm tall) with straight-walled metal microneedles. (B) A tapered, beveled glass microneedle tip (900 µm in length) created using a traditional micropipette puller. (C) A tapered, 500 µm-tall metal microneedle from an electrodeposition-made 37-needle array onto a polymeric mold. (D) Side by side with the tip of a 26-gauge hypodermic needle is an array of tapered metal microneedles, each 500 µm in height [74]. Copyrighted from Devin V. McAllister *et al.*'s 2003 National Academy of Sciences publication, Microfabricated Needles for Transdermal Delivery of Macrophages and Nanoparticles: Fabrication Techniques and Transport Studies.

4. Dissolving microneedle

The dissolvable MN approach, first introduced in 2005 has shown promise due to its unique properties. These qualities include fast release of macromolecules and a one-step medication application for easier administration. The use of dissolvable MNs after "poke-and-release" is considered superior to other procedures. The dissolvable MN tip can be loaded quickly using a two-step casting procedure. When the dissolvable MN is inserted into the skin, the drug-loaded needle tip dissolves, allowing for easy release and diffusion. Dissolvables are best made with water-soluble materials. Material: Water-soluble and biodegradable polymers, including hyaluronic acid (HA), Polyvinylpyrrolidone (PVP), Polyvinyl Alcohol (PVA), and Carboxymethylcellulose (CMC). During the manufacturing process, the medication is integrated into the microneedle matrix. Mechanism: After being inserted, the microneedles disintegrate and release the medication in a matter of minutes to hours. There is no biohazard waste because the entire microneedle dissolves in the skin, eliminating the need to dispose of sharps.

Summary

Microneedle arrays (MNAs) are a rapidly advancing technology that offer a minimally invasive solution for the transdermal delivery of drugs, vaccines, and other therapeutic agents. These arrays consist of an array of micrometer-sized needles that are small enough to penetrate the outer layer of the skin (the stratum corneum) without reaching the deeper layers, thus avoiding nerve endings and reducing pain.

Conclusion

Microneedle arrays (MNAs) represent a transformative advancement in the field of transdermal drug delivery, offering a promising alternative to conventional injection-based methods. With their ability to painlessly penetrate the skin barrier, MNAs enable more efficient and targeted delivery of therapeutic agents, including vaccines, small molecules, and biologics. The technology's versatility in drug delivery, diagnostics, and even personalized medicine positions it as a key player in the future of healthcare.

However, despite their potential, the widespread adoption of MNAs faces challenges such as production scalability, skin type variability, and regulatory approval. The ongoing development of biodegradable and multifunctional microneedles is likely to address many of these hurdles, enhancing the practicality and sustainability of the technology.

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