



Recent Advances in Microneedle - Based Transdermal Drug Delivery System

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ABSTRACT

Transdermal drug delivery systems (TDDS) offer a painless, non-invasive alternative to traditional methods, improving patient compliance and bioavailability. However, the skin's impermeability limits the range of medications that can be delivered. Microneedles, a promising technology, have been developed to overcome this barrier. This review explores recent advancements in microneedle-based TDDS, including types (solid, coated, dissolving, and hollow), materials (metals, silicon, ceramics, polymers, and silica glass), and applications (vaccines, insulin, cancer treatment, diabetes, and cosmetics). The advantages of microneedles, such as painless administration and avoidance of first-pass metabolism, are discussed, along with challenges like Parameters for MN insertion, compatibility, MN Fabrication, Safety, Regulatory Matters.

Keywords: Transdermal Drug Delivery, Microneedles, Skin Permeability, Controlled Release, Patient Compliance.

INTRODUCTION

The transdermal drug delivery system (TDDS) is a painless, non-invasive technique of medication distribution that takes priority over other classic delivery methods in this regard ¹. Transdermal medication delivery can prevent first-pass metabolism, which is the most significant disadvantage of oral administration ². Because of the impermeability of skin, topical and transdermal devices are ineffective for delivering these medicines ³. Transdermal delivery has emerged as a promising approach for individualized therapy ⁴. Biocompatible ILs were employed to produce a transdermal ionic liquid-assisted delivery system (ILDS) for the antigenic protein ovalbumin (OVA), with the Toll-like receptors (TLR) agonist, imiquimod (IMQ), as an adjuvant, employing a continuous oil phase of isopropyl myristate ⁵.

Transdermal medication delivery methods and its use in treating a variety of diseases. This review focuses on recent improvements and applications of NE with transdermal usefulness ⁶. Transdermal drug delivery is described as self-contained, discrete dose forms that, when applied to undamaged skin, release the medication into the systemic circulation at a controlled rate ⁷. Transdermal drug delivery is a highly successful method for delivering a wide range of medicines, including bioactive compounds ⁸.

To address the major issues of TDD for big therapeutic molecules, a variety of active technologies have been developed, yet the majority of these techniques have drawbacks ⁹. TDD routes that were largely non-invasive, had a low first-pass effect, and were self-administerable with few adverse effects ¹⁰. Using dissolving microneedles (MNs) to deliver insulin transdermally into the diabetic systemic circulation has a significant impact on lowering blood glucose levels and even has the same level of pharmacological efficacy as traditional subcutaneous (SC)

injection of insulin solution ¹¹. The stratum corneum's poor permeability significantly restricts transdermal medication delivery. Less than 20 medications can currently be administered through the skin, despite the fact that transdermal drug delivery has developed into a multibillion dollar industry over the last 25 years ¹². Transdermal drug delivery offers easy and painless self-administration for customized therapy ¹³.

Transdermal drug delivery systems (TDDS) have gained popularity as an effective and patient-friendly drug administration approach that provides controlled drug release through the skin ¹⁴. The transdermal drug delivery system (TDDS), a successful controlled release technology, was designed to transfer a therapeutically effective amount of medication across the skin ¹⁵. A transdermal drug delivery system (TDDS) may minimize pre-systemic metabolism and gastrointestinal degradation of these medications and enhance patient compliance, thus eliminating the issues associated with traditional medicinal formulations ¹⁶.

ADVANTAGES OF TDDS: ¹⁷⁻²¹.

1. Self-administration medicament.
2. Increase bioavailability.
3. Reduces dosing frequency.
4. Maintains consistent blood levels over an extended period.
5. Minimizes gastrointestinal side effects.
6. Easily discontinued in case of toxicity.
7. Decreases frequency of dose.
8. Reduces gastrointestinal adverse effects
9. Avoiding medication first-pass metabolism.



DISADVANTAGE OF MICRONEEDLES: ^{18,20,21.}

1. Higher cost.
2. Should not use ionic drug.
3. Limited to potent drugs for transdermal
4. Ionic medications are not appropriate for transdermal treatment.
5. Applicable solely to substances with a molecular weight below 500 Daltons
6. Some medications, like the transdermal scopolamine patch, are painful when applied behind the ear.
7. The type of patch and the environment can affect how well a patch adheres.

LIMITATIONS OF TDDS: ^{17,19.}

1. Limited skin permeability.
2. Restricted to potent drug
3. Difficulty for adhesion.
4. Ionic medicines cannot be delivered using TDDS.
5. Blood or plasma TDDS levels cannot be raised to high medication levels.
6. Drug delivery by TDDS is not pulsatile.
7. If medicine or formulation irritates the skin, TDDS cannot form.

ANATOMY AND PHYSIOLOGY OF SKIN:

The skin, the largest organ of the body.

The human skin's structure comprises three main layers: ²²

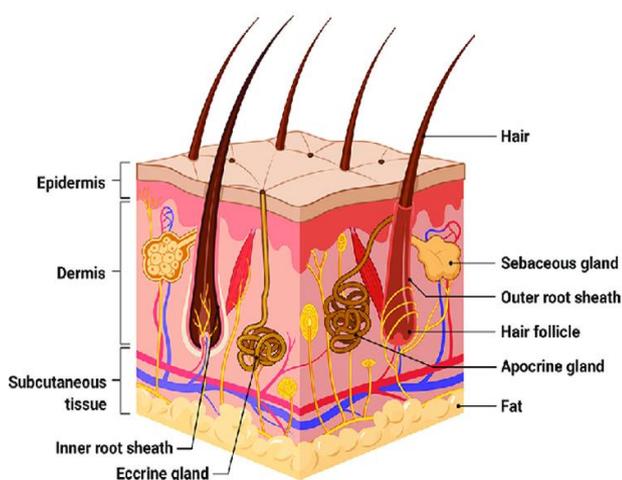
A] Epidermis, B] Dermis, C] Hypodermis

Figure 1: Structure of Human skin ²³.

A] Epidermis:

The primary cell type of the terminally developed stratified squamous epidermis is the keratinocyte ²⁴. Depending on the size of the cells and the number of cell layers, the

multilayered epidermis' thickness includes 0.8 mm on the palms and soles to 0.06 mm on the eyelids ²⁵.

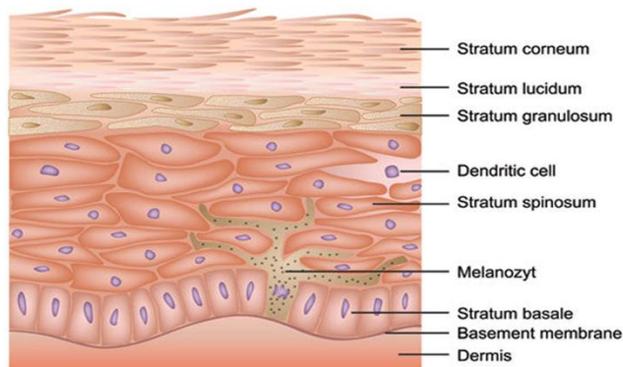


Figure 2: Structure of Epidermis ²³.

B] Dermis:

The dermis is mostly generated by mesenchymal cells that migrate from various mesodermal locations; however some cells may migrate from the dermatome and contribute to skin creation ²⁶. There are two separate regions in the dermis: the superficial papillary dermis and the deeper reticular dermis. Lineage tracing studies have indicated that the papillary and reticular dermis are produced from separate fibroblast lineages, which may explain the discrepancies in fibril architecture ²⁷. The basement membrane separates the dermis, the skin's mesenchymal component, from the epidermis ²⁸. The dermis, a layer of connective tissue composed of collagen and elastic fibers, is highly vascularized and has a well-developed network of lymphatic vessels ²⁹.

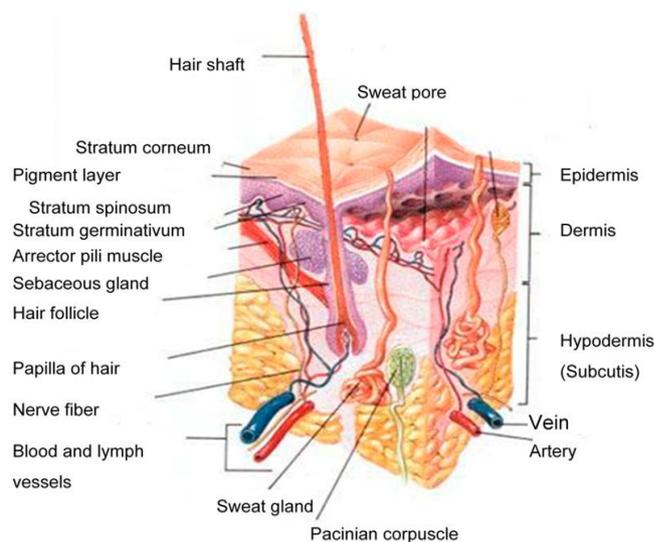


Figure 3: Structure of Dermis ³⁰.

C] Hypodermis:

The dermis and epidermis are supported by the hypodermis, or subcutaneous fat tissue. It acts as a place to store fat. This layer offers mechanical protection, nutritional support, and temperature regulation. It may have sensory pressure organs and transports the skin's main blood vessels and nerves ¹⁷. It supports the dermis and epidermis. It is used as a fat storage space. This layer

supports nutrition, helps regulate body temperature, and offers mechanical protection. major lipophilia in blood ³¹.



Figure 4: The Structure of Hypodermis ¹⁸.

FUNCTION OF SKIN: ³²

1. Prevents the loss of moisture, helping to maintain skin hydration.
2. Reduces the harmful effects of UV radiation from the sun.
3. Functions as an immune organ, capable of detecting and responding to infections.
4. Plays a role in the production of vitamin D when exposed to sunlight.

MICRONEEDLES:

The microneedle structure mostly determines the needle's qualities. Because of the microneedles modest size, the fluid enclosed in the channel has a low volume ³³. Microneedles are micron-scale needles ranging from 25 to 2500 μm in length, 20 to 250 μm in width, and 1 to 25 μm tip diameter ³⁴. Most biotherapeutics and vaccinations are administered by a hypodermic needle ³⁵. Microneedles (MNs) have emerged as a promising physical penetration-enhancement technology, with substantial research conducted over the last few decades for a variety of uses, including medicinal, diagnostic, cosmetic, and immunological ³⁶. Microneedles (MNs) are a minimally invasive alternative to standard injections with potential advantages over existing needleless technologies ³⁹.

TYPE OF MICRONEEDLES:

1) Solid microneedles:

Solid microneedles can be made as skin preparation to create big pores for medication delivery. Topical formulations (ointment, gel, and lotion) used to treat skin can enter the dermis through the pores once they have formed. They can then be dispersed throughout the body through systemic circulation ⁴⁰. Solid microneedles are frequently applied as a pretreatment to the skin. To create micron-sized pores on the skin's surface, they are first put into the skin and then taken out ⁴¹.

2) Coated microneedles:

Coated microneedles are made by first preparing solid or hydrogel microneedles, then coating them with a medication solution or dispersion. When the coated microneedle system is inserted into the skin in order to create coated microneedles, solid or hydrogel microneedles must first be prepared. The coating dissolves a few minutes

after application and the exposed microneedles are then extracted from the skin ⁴².

3) Dissolving microneedles:

Fast-dissolving MNs are made from biodegradable hydrophilic polymers with medicines incorporated inside. Polymers commonly utilized include polyvinylpyrrolidone, polyglycolic acid, polylactic acid, poly(vinyl alcohol), a few polysaccharides, and so on ⁴³. Dissolving microneedles, which use biocompatible and lipophilic polymers as primary matrix materials, were developed to solve biohazard and sharp waste residual issues connected with the silicon and metal used in the manufacture of solid and coated microneedles ⁴⁴.

4) Hollow microneedles:

Hollow MNs use materials that are similar to solid MNs. However, each needle contains an additional microscopic microchannel. In other words, this device is a form of syringe that contains tiny arrays of needles rather than a single hypodermic needle ⁴³. The process of hydrogel-based MN drug delivery is the same as dissolvable MN insert into the skin, release the pharmaceuticals, and there is no need to discard the needle ³⁴. used for injecting liquid drug Formulations through the MN bores into the skin ⁴⁵.

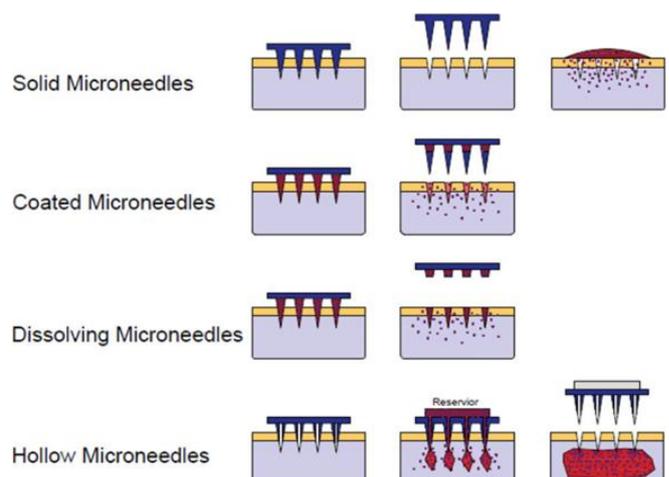


Figure 5: Type of microneedles ⁴⁶

ADVANTAGES OF MICRONEEDLES:

1. The active ingredient in the medication is administered painlessly.
2. Local administration allows for the avoidance of first-pass metabolism
3. The injection site heals more quickly than with a hypodermic needle ⁴⁷.

DISADVANTAGE OF MICRONEEDLES:

1. The MN application may require good mechanical strength, extended application time, and several patches.
2. The chances to develop immunological skin reactions such as skin irritation, redness, pain, swelling ⁴⁸.

3. Needles that are used only once are easily disposed of could affect delivery.
4. Repetitive injection may collapse the veins.
5. The tip of the microneedle may break off and remain within the skin on removal of the patch ⁴⁹.

FIBRILLATION OF MICRONEEDLES ⁵⁰.

1. A digital scheme of the specified design is generated using CAD software, and the measurements are refined using printer specifications.
2. The scheme is converted into a Standard Tessellation Language format, sent to a computer that operates the 3D printer, and the size and orientation of the printing are chosen.
3. The object is printed

MATERIALS USE IN MICRONEEDLES:

1. Metal:

Metals have been used in the pharmaceutical industry for several decades. Typical examples include hypodermic needles made of stainless steel and implants and prosthesis made of titanium. Metallic components are widely used in transdermal medicine administration systems due to their mechanical strength and durability. Metallic materials can be used to produce robust and novel microneedles ²⁰.

2. Silicon:

Silicon has strong mechanical strength and is a flexible material, allowing MN arrays to be manufactured in a variety of forms and sizes. Solid-uncoated, solid-coated, and hollow MN arrays were reported to be made from silicon ⁴⁹.

3. Ceramic:

Alumina and calcium sulfate dihydrate ceramics have been used to fabricate solid and hollow MN arrays. Scaling up production of ceramic MN arrays at low cost was doable and successful, however ceramic MN arrays are fragile. Alumina is a biocompatible yet brittle substance (Bystrova and Lutge) that is not suitable for large-scale manufacture ⁴⁹.

4. Polymers:

suited for manufacturing solid polymer needles by injection moulding. Polymer micromolds for solid needles. Polymer micromolds were made using a variety of ways. One method involved creating polydimethylsiloxane (PDMS) micromolds from silicon or polymer masters. A mold was created by covering a fabrication of polymer microneedles. Polymer microneedles were created by melting polyglycolic acid ⁵¹.

5. Silica glass:

8 mm thick onto the master, vacuuming to eliminate any trapped air bubbles, curing at 90°C for 1 hour, cooling, and

gently peeling off the mold (which left the master intact for future usage). These molds were used to make solid microneedles from glass ⁵¹.

MICRONEEDLES DESIGN:

This indicates that the fabrication process uses a bi-mask technique to achieve a dependable side port design and to be able to place the tip on top of a cylindrical needle base instead of directly on the wafer surface ⁵². The fabrication process uses a bi-mask technique, which creates two levels of etching masks (Mask A and Mask B) before the actual etching process, in order to realize a dependable side port design and to be able to place the tip on top of a cylindrical needle base rather than directly on the wafer surface ³⁴.

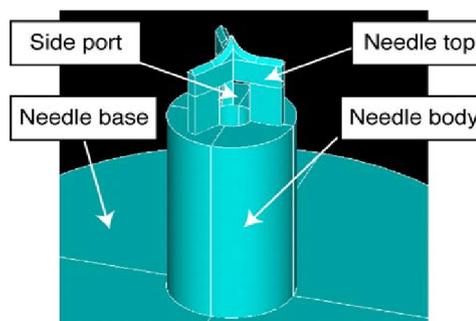


Figure 6: Structure of the microneedle array ⁵².

APPLICATION OF MICRONEEDLE:

1. Vaccines delivery:

A dissolvable MN is a popular form of MN used for vaccine administration. The dissolvable MNs were meant to replace hypodermic injection needles, which are commonly used to give vaccines. Unlike other types of MN, dissolvable MNs are biocompatible, robust, scalable, and do not generate biohazardous waste ⁵³.

2. Insulin delivery:

Hypodermic subcutaneous insulin injections are commonly used in modern medicine to control type 1 diabetes and, in certain situations, type 2. While this procedure has proven effective, many patients find injections uncomfortable and inconvenient, forcing research into other delivery systems ⁴⁹.

3. Cancer delivery:

Biodegradable Microneedle Patch in a B16 melanoma model in mice, a biodegradable microneedle patch that administered hyaluronate-antigenic peptide (cytotoxic T-cell epitope) as a preventative cancer immunotherapy exhibited a significant inhibition of tumor growth ⁴⁷.

4. Diabetes delivery:

Diabetes is a chronic disease, and diabetes-related complications impact approximately 425 million people around the globe. The current diabetic treatment relies on many daily injections of exogenous insulin to keep blood glucose levels stable. However, repeated insulin injections can lead to long-term problems and poor compliance, and

insulin overdose can result in severe shock or even death²⁰.

5. Cosmetic delivery:

Microneedle patches have been shown to successfully deliver chemotherapeutic medicines, increasing pharmaceutical penetration and decreasing systemic side effects. Microneedle patches have sparked a lot of interest in dermatology. They are commonly used to give targeted medication for pigmentation and acne disorders, as well as antiaging and skin rejuvenation therapies⁵⁴.

CHALLENGES OF MICRONEEDLES:⁴⁹

The manufacturing of microneedles with accurate geometry, constant drug loading, and mechanical toughness is technically challenging. Ensuring repeatability and tip sharpness in high-volume manufacturing remains a continuous challenge⁴⁹. Promoting the transfer of microneedle technology from the research lab to relevant sectors is a promising but demanding endeavor for the near future⁵⁵.

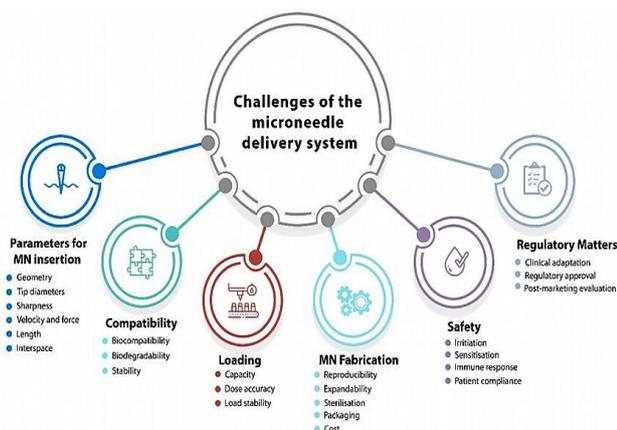


Figure 7: Challenges of microneedle-based delivery system⁴³.

CONCLUSION

Microneedle-based transdermal drug delivery systems hold great promise for revolutionizing the administration of medications. By bypassing the skin's natural barrier, microneedles enable the delivery of a wider range of therapeutics, improving treatment outcomes and patient experiences. While challenges remain, ongoing research and advancements in materials and manufacturing techniques are addressing these limitations. As the technology continues to evolve, microneedles are likely to play a significant role in shaping the future of transdermal drug delivery, offering a convenient, painless, and effective alternative to traditional methods.

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