INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

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Review Article

Micro Needle Drug Delivery Systems

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ARTICLE INFO

Published: 11 Sept 2026
Keywords:
Transdermal Drug Delivery, Microneedles, Stratum Corneum, Physical Drug Delivery Techniques, Microneedle Fabrication.
DOI:
10.5281/zenodo.22705616

ABSTRACT

Transdermal drug delivery (TDD) provides an attractive and alternative drug delivery when compared to oral and other drug delivery as the former route offers several advantages like avoiding pre-systemic first pass metabolism of administered drugs, patient compliance, and avoiding gastric irritation. However, stratum corneum (SC), the upper most layer of skin, limits the permeation of number of drugs because of its barrier property. To breach or bypass this barrier, two approaches namely: chemical and physical are generally used. Physical approaches seem to be better as it does not involve the use of chemicals in the formulations, which could interact, with other component of formulations and more importantly may cause reversible damage to the skin. Microneedle technique is one of the most advanced physical techniques, which can easily by-pass, the SC and allow the drug to reach viable epidermis directly. The needles used in microneedle techniques are in hundreds of micron length range and when applied on skin generally produce little or no pain. The objective of this review is mainly focused on types of microneedles, various materials and fabrication techniques used in the preparation of microneedles. Furthermore, various techniques used in the application of microneedles and mechanism of action are described. In addition, this review also describes commercial products, patents on microneedle technology and recent works carried out on microneedles research and safety aspects of microneedles.

INTRODUCTION

Hypodermic needles and topical creams are most commonly used when it comes to delivery of the drug through the skin. Needles are less accepted by patients due to pain associated with them and topical creams show less bioavailability. Skin serves as the major barrier for delivering drug through the topical route. Skin is made up of three main layers- the outermost stratum corneum, middle epidermis and the thickest of all, dermis. The stratum corneum layer behaves like a major barrier as it allows only certain molecules like lipophilic and low molecular weight drugs to pass

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

through it. The relatively less permeability of the layer presents many problems in designing topical formulation [1,2]. Various topical or transdermal delivery systems have been investigated for improving drug permeation through the skin like nanocarrier loaded topical creams, transdermal patches, and microneedles [3.41. The microneedles (MNS) have been studied by various researchers for delivering drug through the transdermal route and for overcoming the limitations of the conventional approaches. Microneedle device consists of needles of micron size, which are arranged on a small patch. Considering the problems of the hypodermic needle and the transdermal patch, microneedle drug delivery system was developed and is thought to be the hybrid of both. The major problem associated with transdermal technology is that many of the drugs are not able to cross the skin at the required rate necessary for the therapeutic action.

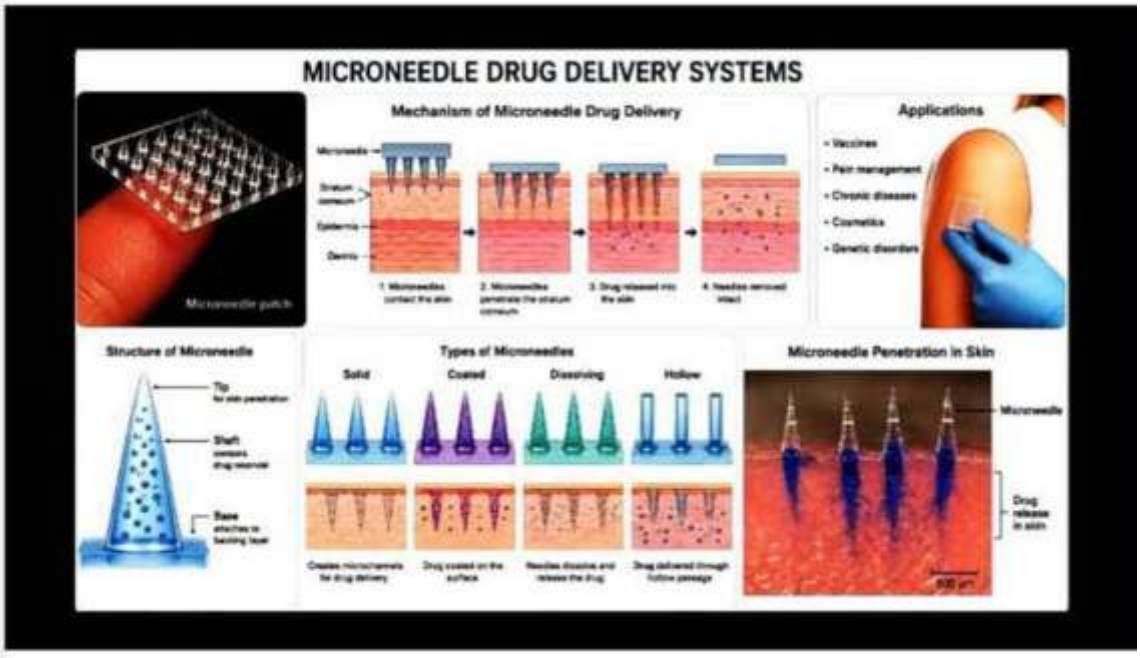
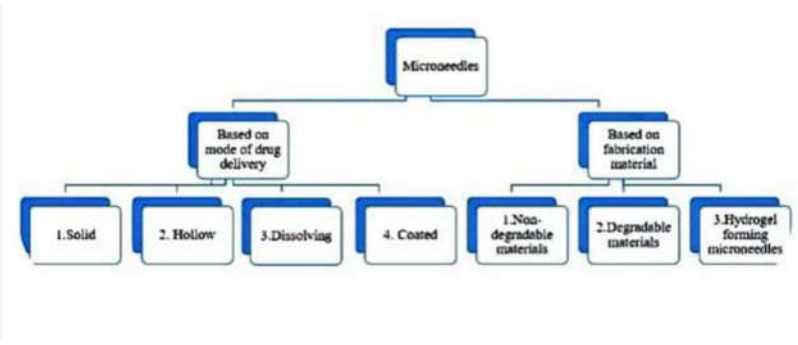


Table 1. Comparison between topical cream, transdermal patch, hypodermic needle, and microneedle drug delivery systems.

Parameter	Topical cream	Transdermal patch	Hypodermic needle
Description	Emulsion/emulgel cream/ointments	Adhesive patch to be placed on the skin	Fine, hollow tube having a sharp tip with small opening at end
Onset of action	Slow	Slow	Faster
Pain	Painless	Painless	Painful
Bioavailability	Poor	Insufficient	Sufficient
Patient compliance	Less	Better	Less
Self-administration	Possible	Possible	Not possible
Mechanism of drug delivery	Permeation through skin pores	Drug has to cross stratum corneum barrier, thus poor diffusion of large molecules	Drug placed directly in the dermis

2. CLASSIFICATION OF Micro Needle Drug Delivery Systems



2.1 Based on mode of drug delivery:

There are four types of microneedles: Solid, hollow, dissolving and coated microneedles.

2.1.1 Solids microneedles:

Since solid microneedles are introduced and removed to create pores on the skin's surface that are micro in size, they can be utilized in the skin pre-treatments They function by creating micro channels using the "poke and patch" method. These micro channels increase the permeability of the medication by permitting diffusion straight into the dermal layer from a formulation. An experiments on rat skin has demonstrated that when placed under occlusive conditions such as occlusive tape, the micro pores created by the microneedles persisted for at least 72 hours following microneedle therapy. Without applying occlusive tape, the micro pores quickly closed. It was found that the solid MN-created micro channels healed quickly in just 2 hours, without causing secondary infection. The "scrape and patch"

2.1.2 Hollow microneedles:

The microneedles are a tiny version of the traditional hypodermic needle systems. A pressure-driven liquid formulation flow is used to administer drugs. This method can deliver significant dosages into the dermal layer. It is challenging to construct hollow microneedles because of their fragility and structure. The hollow microneedle work on the principle of 'puncture & flow'. Davis et al (2005) created a series of hollow metal microneedles for one such study. In diabetic rats, the administration of insulin using these microneedles was investigated. The study found that the pharmacodynamics profiles of hollow microneedles are similar to those of a conventional hypodermic injection.

2.1.3 Dissolving microneedles:

These types of microneedles are governed by "poke & release" principle. Compared to other microneedles, they are simple to use and manufacture, which is why they have attracted a lot of interest recently. The biodegradable elements used to make manufacture, these microneedles offer an advantage over convenient. Microarrays made of dissolving hyaluronic acid were created by Liu et al. When used as cumulative microneedle the array, penetrated amount of dextran rose by an astonishing 610 times with minimal lag drug penetration time. Researchers are looking into using dissolving microneedles to deliver vaccines via the skin. It has been demonstrated that carboxy methyl cellulose and hyaluronan microneedle totally

disintegrate in rat skin, 5minutes after applications, releasing the IgG payload specific to the antigen.

2.1.4 Coated microneedles:

Coated microneedles are those that operate on the "coat and poke" principle. These microneedles are made out of a solid covered in microneedle foundation medication solutions or dispersions. Numerous for coating most used because it studies have been investigated microneedles. Dip coating is the technique, but it is challenging requires exact control to ensure.

Advantages

1. Painless or minimally painful — Microneedles are very small and generally cause little discomfort.
2. Improved drug absorption — They bypass the stratum corneum, which is the main barrier to skin penetration.
3. Avoids first-pass metabolism - Drugs delivered through the skin can bypass gastrointestinal degradation and hepatic first-pass metabolism.
4. Controlled drug delivery — Can provide sustained or controlled release of drugs.
5. Improved patient compliance.More convenient and acceptable than conventional injections for many patients.
6. Reduced risk of infection - Particularly with dissolving microneedles, which leave no sharp needle behind.
7. Suitable for sensitive drugs -Can be useful for peptides, proteins, vaccines, and other biologics that may have poor oral bioavailability.
8. Self-administration is possible - Some microneedle patches can potentially be applied by patients themselves.

Disadvantages

1. High manufacturing cost - Fabrication requires specialized equipment and technology.
2. Limited drug loading — The small size of microneedles restricts the amount of drug that can be incorporated.
3. Skin irritation — Redness, swelling, itching, or inflammation may occur.
4. Variable skin penetration — Delivery can differ depending on skin thickness, hydration, and application force.
5. Mechanical problems — Microneedles may bend or break during application.
6. Stability problems — Some drugs, especially proteins and peptides, may be-S unstable during formulation and storage.
7. Difficult scale-up — Large-scale, reproducible manufacturing can be challenging.
8. Limited suitability for some drugs — Very large doses or certain drug molecules may not be suitable for microneedle delivery.
9. Regulatory challenges — Combination products involving the microneedle device and drug can require extensive evaluation.

Microneedle Drug Delivery Systems -

Uses Microneedle drug delivery systems are tiny needles, usually 25-2000 pm in length, that penetrate the outer skin layer (stratum corneum) to deliver drugs with minimal pain.

Major uses

1. **Transdermal drug delivery**

Deliver drugs through the skin directly into systemic circulation.

Useful for drugs that have poor oral bioavailability.

2. **Vaccination**

Used to deliver vaccines such as influenza and other vaccines.

Can target immune cells present in the skin.

3. **Insulin delivery**

Microneedles can provide minimally invasive delivery of insulin and other peptides.

4. **Delivery of proteins and peptides**

Useful for biological drugs that are degraded in the gastrointestinal tract. Examples include peptides, proteins, and some hormones.

5. **Cancer therapy**

Can be used for localized delivery of anticancer drugs and immunotherapeutic agents.

6. Pain management

Used for controlled delivery of analgesic drugs through the skin.

7. Dermatological applications

Delivery of drugs for acne, psoriasis, infections, and other skin disorders.

8. Cosmetic applications

Used to enhance delivery of compounds such as hyaluronic acid, peptides, and vitamins into the skin.

9. Controlled and sustained drug release

Specially designed dissolving or coated microneedles can release drugs gradually over time

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HOW TO CITE: Thota Srinivas, Palavalasa Deepika, Pamarthi Yasaswini Devi, Mailapalli Maranatha Stuthi, Dr. B. Thangabalan, Micro Needle Drug Delivery Systems, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 9, 1299-1304. https://doi.org/10.5281/zenodo.22705616