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Microneedles in Drug Delivery System

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ABSTRACT: Transdermal patches, topical creams, and hypodermic needles are the most popular ways to administer medications percutaneously. A cutting-edge transdermal delivery system has attracted significant attention lately due to its potential to disperse medications, vaccines, and biomolecules for skin-related issues, among other therapies and cosmeceuticals. Avoiding hepatic first-pass metabolism, maintaining a constant plasma concentration, safety, and compliance with oral or parenteral routes are only a few benefits of drug delivery via the skin. Typically, microneedles are between 0.1 and 1 mm long. Materials for microneedles, manufacturing processes, characterisation methods, and transdermal delivery applications are covered in this review. An improved method of drug delivery is provided by microneedle technology. Different varieties of microneedles, including coated, solid, hollow, and dissolving, are described based on the distribution method. Hollow microneedles offer a passage into the dermis, whereas solid microneedles produce micropores in the skin. In the field of drug delivery today, microneedle (MN) technology has proven to be superior. The stratum corneum (SC), the primary barrier for medication administration via the skin, is punctured by MN arrays, which are devices made up of micron-sized projections. MN technology offers the ability to increase the variety of medications available for intradermal and transdermal administration while offering localised drug delivery with low toxicity. MN technology was covered in detail with recent history in this extensive analysis. Large-scale production and adherence to regulatory requirements are necessary to develop Minnesota technology to a commercially viable level.

KEYWORDS: Microneedle technology (MN), Drug delivery, solid microneedles, Dissolving microneedles, hollow microneedles

I. INTRODUCTION

Transdermal drug delivery (TDD), a non-invasive substitute for parenteral administration, involves administering drugs via the skin to have a systemic impact. The process of transdermal absorption is a sequential one that includes penetration, which is the entry of a substance into a specific skin layer permeation, which is the entry of a substance from one layer of the skin into another, where the two layers differ structurally and functional and absorption, which is the uptake of a substance into the systemic circulation. The medication first enters the SC before entering the microcirculation of the epidermis and dermis. [1]

The transdermal route of drug delivery offers an attractive, non-invasive route of drug administration. Drugs administered through the transdermal route show high bioavailability avoiding gastrointestinal degradation and first-pass [2]

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 through it. The relatively less permeability of the layer presents many problems in designing topical formulation [3, 4].

A microneedle device is composed of an array of microneedles that can possess different properties depending on their application. For example, the length of microneedles is related to their specific function and intended application. They can range from 100 to 3000 µm, with the most common size varying from 250 to 1500 µm [5].



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Microneedles come in a variety of shapes and sizes, including solid, coated, hollow, and dissolving varieties, and can be made from silicon, metals, or biodegradable polymers. They make it possible to directly transport medications, vaccinations, proteins, peptides, and even nanoparticles into the systemic or cutaneous circulation. Improved patient compliance, avoiding hepatic first-pass metabolism, regulated release, and self-administration appropriateness are just a few of the system's many benefits. Microneedle technology is becoming increasingly popular in the pharmaceutical, vaccination, and cosmetic industries because to these advantages.

II. HISTORY

Microneedles were first mentioned in a 1998 paper by the research group headed by Mark Prausnitz at the Georgia Institute of Technology that demonstrated that microneedles could penetrate the uppermost layer (stratum corneum) of the human skin and were therefore suitable for the transdermal delivery of therapeutic agents. Subsequent research into microneedle drug delivery has explored the medical and cosmetic applications of this technology through its design. This early paper sought to explore the possibility of using microneedles in the future for vaccination. Since then researchers have studied microneedle delivery of insulin, vaccines, anti-inflammatories, and other pharmaceuticals.[6] In dermatology, microneedles are used for scarring treatment with skin rollers. As mentioned before, microneedles have also been explored for local targeted drug delivery at other drug delivery sites, such as the gastrointestinal, ocular, vascular etc., of which, ocular, vaginal and gastrointestinal have shown increasingly convincing outcomes where they serve as a more efficient, localised drug delivery system, without the drawbacks of systemic exposure/toxicity [7]. The first microneedle arrays were successfully conceived and produced in the late 1990s because to advancements in microfabrication and microelectromechanical systems (MEMS) technology. Experimental research during the early 2000s showed that microneedles could effectively and painlessly administer medications and vaccinations through the skin.

The uses of microneedles have expanded over the past 20 years as they have developed into solid, coated, hollow, and dissolving varieties. [8] They are now being investigated extensively for biosensing, insulin administration, medication delivery, immunisation, and cosmetic procedures. Clinical trials have been completed for a number of microneedle-based products, and several cosmetic microneedle patches are now on the market.[9]

Concept Emergence in the 1970s

In the 1970s, the concept of puncturing the skin with microscopic needles without causing pain was initially put out. Due to the limits of microfabrication technology, the initial notions were purely theoretical.[10]

1990s: A Revolution in Technology

The design of extremely tiny, accurate needles was made feasible by developments in microfabrication and microelectronics (MEMS) technology. For transdermal delivery, researchers started experimenting with microneedles. [11]

1998: The First Useful Illustration

Mark Prausnitz and associates from Georgia Tech, USA, accomplished the first effective delivery of molecules through the skin using microneedles. This was the first time that microneedle patches were seriously studied. [12]

Preclinical Studies, 2005–2010

High patient compliance and painless drug delivery were proven by numerous animal and human trials. Applications for microneedles in insulin, vaccinations, and cosmetics are being investigated.[13]

2010s – Clinical Trials and Commercial Interest

Insulin, local anaesthetic, and vaccines (polio, measles, and influenza) have all undergone several clinical studies. Dissolving microneedles were first used by cosmetic industries for skincare and anti-aging purposes. [14]

2020s: Global Use and Commercialisation

Cosmetics, nicotine replacement, and some vaccines were among the first products to use microneedle patches. They came to light during the COVID-19 vaccine delivery research. ongoing advancements in biosensing, personalised medicine, and cancer treatment.[15]



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2023–2025 (Recent Advances)

Biosensor-equipped smart microneedles were created to monitor biomarkers and glucose in real time. Microneedle patches for the COVID-19, influenza, and insulin booster vaccines are undergoing clinical studies. Dissolving microneedle patches are being rushed to market by start-ups and pharmaceutical corporation investigation into personalised medicine using 3D-printed microneedles expanding uses in transdermal pain relief, ophthalmology, and cancer immunotherapy. [16]

III. CLASSIFICATION OF MICRONEEDLES

Microneedles are classified based on their structure, function, and material.

1 Based on drug delivery approach

❖ Solid microneedles

Structure: Solid protuberances composed of metals, polymers, or silicon.

Mechanism: The medication is not carried by them. Rather, they make tiny holes in the skin. Following that, medication formulations (such as cream, gel, or patches) are applied and allowed to diffuse via the channels that have been produced (a process known as the "poke and patch" procedure).

Uses: Vaccines (better delivery of antigens). increase the penetration of medications with poor permeability. Benefits include great mechanical strength and simple, reusable moulds. Benefits include great mechanical strength and simple, reusable moulds.[17]

❖ Coated Microneedles

Structure: A thin layer of medication is applied to the surface of solid microneedles.

Mechanism: The medication is released when the coating dissolves into the skin tissue after injection. Uses: Quick vaccination delivery (DNA, protein, inactivated viral).

little amounts of powerful medications (such as insulin and cancer vaccinations). Benefits include rapid medication release and suitability for unstable biologics.[18]

❖ Biodegradable Microneedles

Structure: The medication is incorporated in biodegradable polymers (such as hyaluronic acid, PVP, and CMC)

Mechanism: The medication is released when the microneedles are fully dissolved in the skin after insertion.

Uses: administration of insulin for diabetes. Vaccines (COVID-19 mRNA, influenza). Lidocaine MNs for pain treatment.

Advantages: Beneficial for biologics, safe (no sharp waste is left behind) [19]

❖ Hollow Microneedles

Structure: Hollow-bored needles that resemble tiny hypodermic needles.

Mechanism: The "poke and flow" method involve injecting the drug solution into the skin or tissue through a hollow conduit.

Uses: local anaesthesia (administration of lidocaine). Use in ophthalmology (eye injection of a suprachoroidal substance). Biologics and vaccines.

Benefits: Enables regulated infusion and may provide higher medication quantities than other MN types.[20]

❖ Hydrogel-forming Microneedles

Structure: Composed of crosslinked polymers that expand as interstitial fluid is absorbed. Mechanism: They don't contain any drugs themselves. Rather, they produce a hydrated route following swelling, which permits medication



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release from a drug reservoir or patch that is attached. Uses: long-term, regulated administration (e.g., insulin, hormones, pain medications). Constant observation and sampling (biosensing).

Benefits: Excellent safety, no residual polymer in the body, and appropriate for long-term release.[21]

2. Based on Material Used

❖ Silicon microneedles

Properties: brittle nature, strong, accurate microfabrication possible (MEMS technology). Benefits: Sharp tips for skin penetration, high precision. Limitations: fragile and brittle, which raises safety concerns. Applications: Early microneedle prototypes, which are currently less frequent because of safety concerns.[22]

❖ Metal Microneedles

Materials: palladium, titanium, nickel, and stainless steel. Properties: Dependable skin penetration and high mechanical strength. Benefits include strength, cost-effectiveness for large-scale manufacture, and reusability (after sterilisation). Limitations: Not biodegradable; if pieces are left behind, they could irritate skin.

Uses: Immunisation Cosmetic application (micro needling treatment) Pain relief patches[23]

❖ Polymeric Microneedles

Materials: Biodegradable or dissolving polymers such as polylactic-co-glycolic acid (PLGA), hyaluronic acid, carboxymethyl cellulose (CMC), and polyvinylpyrrolidone (PVP). Benefits include being safe (no sharp waste), biocompatible, biodegradable, and beneficial for biologics. Limitations: Not as strong mechanically as metals. Uses: Insulin and vaccine microneedle dissolution. MNs that create hydrogel for prolonged release[24]

❖ ceramic Microneedles

Calcium phosphate, calcium sulphate, and alumina were the materials used. Benefits include stability, adjustable porosity, and biocompatibility. Limitations: Fragile; may break when inserted. Applications include the delivery of medications and vaccines, particularly those with controlled release.[25]

❖ Sugar-based Microneedles

Materials: Sugars such as sucrose, maltose, and trehalose. Benefits include biocompatibility, quick dissolution, and stabilisation of delicate medications (such as proteins and vaccinations). Limitations: Humidity sensitivity and limited mechanical strength. Applications include the quick release of peptides and vaccinations.[26]

3. Based on Shape and Structures

- ❖ Blade-shaped
- ❖ Cylindrical
- ❖ Conical
- ❖ Pyramidal [27]

IV. APPLICATIONS OF MICRONEEDLES

1. Cancer Therapy

Targeted anticancer medication drug delivery increases the drug's local concentration while lowering systemic toxicity. Benefits include decreased systemic side effects and increased concentration at the tumour site. Localised administration reduces systemic toxicity by avoiding systemic circulation, particularly for powerful chemotherapeutic medicines. Increased bioavailability improved absorption through direct medication penetration into the dermis. Targeted delivery: MNs have the ability to deliver anticancer drugs to immune cells, lymph nodes, or the tumour microenvironment. Suitable for combination therapies MNs can deliver nucleic acids, medications, and vaccinations all at once.

Examples:

- Doxorubicin-loaded MNs for melanoma.
- Cisplatin MNs for skin cancers.
- Immunotherapy drugs (anti-PD-1, anti-CTLA-4) for localized cancer treatment.[28]



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2. Vaccine Delivery

efficient for administering vaccines (such as COVID-19, polio, and influenza) intradermally. Benefits include reduced dosage, painlessness, and increased patient compliance.

Benefits include, dose sparing (lower dose required), and self-administration using patches. For instance, in Phase I clinical studies, influenza vaccine patches demonstrated an immunological response that was comparable to or superior to that of traditional injections. When it comes to administering vaccines, such as those against influenza, rabies, COVID-19, anthrax, and Ebola, microneedles are especially helpful. They make self-administration possible, which could result in increased vaccination rates, particularly among marginalised groups. Furthermore, microneedle vaccinations frequently show increased stability and less reliance on cold chain storage. Compared to conventional techniques, studies have demonstrated that microneedle immunisation can elicit robust immune responses with smaller vaccination doses.

Examples:

- Influenza vaccine delivered via MN patches.
- Polio, measles, and rabies experimental MN vaccines.
- COVID-19 microneedle patch vaccines under trials. [29]

3. Insulin Delivery in Diabetes

Insulin is injected directly into the skin via dissolving or hollow microneedles. prevents uncomfortable injections and offers a regulated and continuous release. Microneedles make it easier to administer insulin for the treatment of diabetes. By releasing insulin in reaction to glucose concentration, glucose-responsive microneedle patches can control blood sugar levels and may provide a more painless and regulated method of managing diabetes than conventional injections. Frontiers says that closed-loop systems that combine insulin delivery and glucose detection are also being investigated. [30]

4. Cosmetic Applications

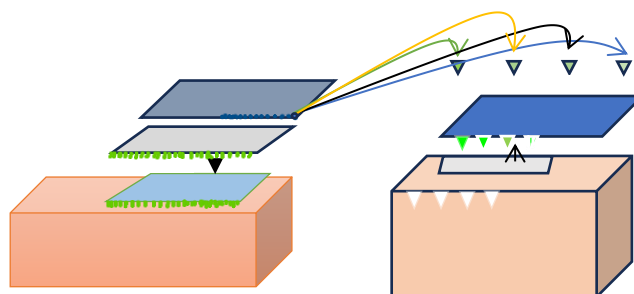
helps supply vitamins, peptides, and hyaluronic acid for anti-aging, skin-brightening, and scar reduction. Popular in cosmetic dermatology already are used in the cosmetic industry to provide whitening agents, peptides, vitamin C, and hyaluronic acid. For instance, hyaluronic acid MN patches are popular in Korea for skincare products that fight ageing.[31]

5. Gene Therapy / Nucleic Acid Delivery

A promising tool for gene therapy, microneedles provide a patient-friendly, less intrusive method of delivering genetic material such as DNA, mRNA, and siRNA. They offer a number of benefits and get around the drawbacks of conventional delivery techniques. Bypassing the skin barrier: Microneedles pierce the stratum corneum, the skin's outermost layer, forming microchannels that let genetic material into the underlying cells, including the immune-rich epidermis and dermis. Improved delivery and bioavailability:. [32]

6. Transdermal Delivery of Small Molecules

increases the permeability of the skin for medications such as analgesics, hormones, and nicotine avoids the first-pass metabolism of the liver. By making tiny passageways through the stratum corneum, the skin's protective outer layer, microneedles enable the effective delivery of medications, vaccinations, and other substances including proteins and DNA. This technique works particularly well for administering medications that would often have trouble getting past the epidermal barrier, such insulin and vaccinations, which are big molecules and macromolecules. [33]





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7. Pain Management

For localised pain relief, apply microneedle patches containing analgesics (such as lidocaine or ketoprofen). Lidocaine and bupivacaine are examples of local anaesthetics that typically require slow-onset injections or gels. Benefit: Easy administration and quick onset. For instance, in just two minutes, lidocaine-coated MNs produced fast cutaneous anaesthesia. [34]

8. Ophthalmic Drug Delivery

Drugs for diseases including macular degeneration and glaucoma are administered into the eye using hollow microneedles. Because the eye has several protective layers, including the cornea, conjunctiva, blood-retinal barrier, and tear film, delivering medications to the eye is one of the most difficult tasks in pharmacy. Eye drops, ointments, and systemic medications are examples of conventional techniques that frequently have low bioavailability (<5%).[35]

9. Suprachoroidal Drug Delivery

Drugs are injected using hollow microneedles into the suprachoroidal space (SCS), which is the area between the choroid and sclera. Uses: administration of corticosteroids for uveitis, such as triamcinolone acetonide. Anti-VEGF medications for diabetic macular oedema and age-related macular degeneration (AMD).[36]

10. Diagnostics & Monitoring (Future Scope)

As a painless substitute for finger pricks, microneedles can draw interstitial fluid for the monitoring of biomarkers or glucose. The process of drawing blood is intrusive. Interstitial fluid (ISF) can be extracted by MNs for the purpose of biomarker analysis. Because hydrogel-forming MNs swell in the skin and absorb ISF, it is possible to monitor the amounts of drugs, lactate, or glucose. For instance, MN sensors are used to continuously monitor blood sugar levels in diabetic patients. [37]

V. SUMMARY

Transdermal drug delivery methods, such as hypodermic needles, topical creams, and patches, have limitations like pain, low patient compliance, and poor bioavailability due to the skin's barrier function, mainly the stratum corneum. Microneedle (MN) technology has emerged as a promising, minimally invasive alternative for delivering drugs, vaccines, and biomolecules while bypassing first-pass metabolism and improving patient comfort. Microneedles, typically 0.1–1 mm in length, create microchannels in the skin to enhance drug penetration. They were first introduced in 1998 by Mark Prausnitz's research group and have since been explored for applications in vaccination, insulin delivery, dermatology, ocular therapy, and other localized treatments.

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