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Review Article

A Review on Microneedle Technology for Transdermal Drug Delivery

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ABSTRACT

As the transdermal delivery system has been employed extensively over the years owing to its merits over the conventional delivery systems. The microneedle technology is the latest advancement and has gained enormous attention in the transdermal delivery system by overcoming the barrier of transdermal delivery system and thus providing advantages over the conventional delivery systems. Several studies have been carried out for exploring the microneedles. This review article focuses on the materials used to constitute the Microneedles, merits and demerits of microneedles, mechanism of action of microneedles, types of microneedles, methodology for drug delivery via microneedles and applications of microneedles.

INTRODUCTION

The effectiveness of medicines relies not just on the properties of the active ingredient but also on how the drug is delivered to the body. [1] Because of this, it is important to find the best way to deliver drugs based on their specific characteristics. Oral delivery is easy and convenient since patients can take the medication themselves; however, it is difficult to use this method for biopharmaceuticals.[2] Injections provide better absorption of the drug and a faster response, but they require skilled administration and often lead to poor patient adherence. Thus, the best drug delivery method should be as

easy as oral use while also providing high absorption like injections.[3] Transdermal delivery helps the drug avoid the first-pass effect and allows for a steady release over time. However, delivering drugs through the skin is challenging because of the barrier formed by the stratum corneum.[4] Microneedles are a method used for delivering drugs through the skin. They are easy for people to use on their own and help the body absorb the drug more effectively.[3] Also, microneedles are painless and not very invasive, allowing the drug to pass directly through the stratum corneum, which is the main barrier in the skin.[5-8] The amount of drug, how fast it is released, and how well it works can all be

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controlled by how the microneedles are made and how the drug is prepared. So far, research has been done on microneedles made in different ways and from various materials, used for both drugs and beauty products.[9,7] The effectiveness and safety of microneedles have been shown through experiments on animals and in human clinical trials.[10-11]

The Microneedles

These are defined as the solid or the hollow cannula which has the approximate length of 50–900 μm & not more than 300 μm of the external diameter.[12] For the transdermal drug delivery the microneedles can be fabricated within the patch. In the biopharmaceuticals, vaccines, delivery of drugs etc, the patches containing microneedles have been evaluated. Due to the disruption of the stratum corneum by the microneedles, a quick response can be observed.[13] In 1976, though the microneedles were first proposed, until 2000s, the technology needed to make the needles of micron dimensions was not available widely.[14] The needles have been fabricated out of metals, silicon and other materials by using the low-cost mass production tools of the microelectronics industry. [15] Up to the depth of 70 to 200 μm , through the epidermis the microneedles have been designed to penetrate. The microneedles are short and thin & do not penetrate the layer of dermis with its nerves, hence a painless application is possible. [16,17] As compared with the other transdermal delivery methods, the microneedles are the more capable of enhancing the transport of drug across the skin.

The Materials Used to Constitute the Microneedles

The microneedles can be divided broadly into 03 categories: a) solid b)degradable/dissolvable and c)hollow. The selection of the material for the

constitution of a microneedle should be based on criteria such as the gentle fabrication without damage to the biomolecules which are sensitive, adequate mechanical strength for the insertion into the skin and controlled or rapid drug release as per the requirement. The microneedles had been produced by using metals, silicon and glass. The use of the polymers to constitute the microneedles has also been explored; by using plastic or the biodegradable polymers the solid microneedles have been produced.[12] The metallic microneedles are brittle, expensive and non-biodegradable. The polymer microneedles overcome the obstacles of silicon and the metal microneedles & may impart advantages like safety, low cost and mechanical strength in case of the accidental breakage of the needle in the skin.[18]

PCPP (Poly [di(carboxylatophenoxy)phosphazene]), which has a phosphorus-nitrogen structure and an organic side chain, shows strong immunoadjuvant properties. According to Andrianov and colleagues, proteins showed greater thermal stability and better resistance to harsh manufacturing conditions when they were in a solution where the protein was coated on solid microneedles with PCPP, compared to when they were in an aqueous solution. The controlled release of protein from the microneedles was achieved due to the ion-complexing ability of PCPP along with salts of multivalent ions, such as calcium chloride and spermine. [19]

Rapid-dissolving sugars and polysaccharides have also been studied for making dissolvable microneedles. [20] Carbohydrates have overcome many drawbacks associated with metal microneedles and enable quick drug delivery. Microneedles made from dextrin can be created without requiring specialized manufacturing tools.[21] However, challenges such as



caramelization and issues with handling molten sugar during processing are commonly encountered. Additionally, sugar-based microneedles are hygroscopic, meaning they absorb moisture from the environment. The material used should have a high Young's

modulus to ensure adequate mechanical strength.[22] Microneedles made from Gantrez AN-139, a mucoadhesive polymer, demonstrated greater resistance to compression compared to those made from poly vinyl alcohol (PVA), alginic acid, and Carbopol 971. [12]

Table 1 List of materials used for preparation of microneedles

Synthetic polymers			
Metals	Natural polymers	Non-biodegradable	Biodegradable
Mesoporous silicon [23]	Dextran, galactose, chondroitin sulfate [24] Maltose [25]	Carbopol 971 P-NF18 Polyetherimide[26]	Polycarbonate [27] Polyvinylpyrrolidone (PVP) [28]
Silicon [29]	Thermoplastic starch [30]	Polyvinyl acetate (PVA) [12]	Polylactic acid (PLA) [18]
Titanium [13]	Carboxymethylcellulose [21]	Gantrez AN-139, a copolymer of Methyl vinyl ether and maleic anhydride (PMVE/MA) [12]	Poly(lactide-co-glycolic acid) (PLGA) [18]
Stainless steel [31]	Carboxymethylcellulose [21]	Alginic acid [12]	Polyglycolic acid (PGA) [18]

MERITS OF MICRONEEDLES

- 1] Minimizing microbial entry as compared to hypodermic needles, since microneedles only penetrate the epidermis,
- 2] Enabling rapid drug delivery by pairing microneedles with an electrically controlled micropump, and
- 3] Allowing better control over the rate of drug delivery compared to methods involving the stratum corneum.
- 4] Bypassing the first-pass metabolism,
- 5] The ability to deliver large molecules,
- 6] Making administration easier,
- 7] Administering the active pharmaceutical ingredient without causing pain,
- 8] Quicker healing at the site of injection compared to hypodermic needles,

- 9] Reducing the fear associated with needles,
- 10] Enabling targeted delivery to a specific area of the skin for drug application,
- 11] Offering good tolerability with minimal long-term swelling or redness,
- 12] Potentially improving drug effectiveness which may lead to lower doses being required,

DEMERITS OF MICRONEEDLES

- 1] The tip of the microneedle may break off and remain lodged in the skin when the patch is removed,
- 2] The variation in the thickness of the stratum corneum and other skin layers among individuals, which may affect the depth of penetration,
- 3] Less precise dosing compared to hypodermic needles,
- 4] Repeated injections might cause vein collapse,



5] Compressed dermal tissue may block hollow microneedles.

6] External factors, such as skin hydration, could influence drug delivery,

7] A limited amount of drug, less than 1 mg, can be administered in a single dose, and

8] Requiring careful handling to prevent particles from bouncing off the skin surface; improper positioning may lead to drug loss or inconsistent penetration[32-34]

MECHANISM OF ACTION

The way microneedles work depends on their design. In general, microneedles work by physically breaking the skin and delivering the drug or vaccine into the epidermis, allowing it to reach the target area more efficiently. The drug is held inside the microneedles, which are then inserted into the skin, releasing the drug into the skin layers that have a rich blood supply. In some cases, the microneedles dissolve quickly, releasing the drug directly at the site where it is needed, where it can then reach the intended target.

TYPES OF MICRONEEDLES

Microneedles are typically classified based on how they are made: in-plane or out-of-plane. The other way to differentiate them is by their structure: whether they are dissolving, solid, coated, or hollow.

Solid Microneedles

Solid microneedles are a series of small projections used to create tiny holes in the stratum corneum, the outermost layer of the skin, before applying a drug.

These needles are inserted into the skin for a specified period and then removed.[35] The channels formed allow the drug to move through the skin into the viable epidermis.[36]

Coated Microneedles

Coated microneedles are similar to solid microneedles, but they have a drug coating on their surface. This coating dissolves upon insertion, releasing the drug into the skin or tissue. The amount of drug that can be delivered is limited to the amount that can be coated on the tip and shaft of the microneedles, which is usually less than 1 mg for small arrays.[18]

Dissolving Microneedles

Dissolving microneedles fully dissolve in the skin, leaving no harmful waste after use. This type of microneedles usually constitute of the water-soluble materials such as sugars and polymers that are inert and safe & after insertion will dissolve in the skin. This dissolving microneedle can be used as a skin pretreatment to escalate the permeability, for release into the skin the drugs are often encapsulated inside the microneedle [30].

The Hollow microneedles

In the center of the needle it contains the hollow bore. The hollow bore present bypasses the stratum corneum layer of the skin, when inserted into the skin, and produces the direct channel into the other lower layers of the epidermis [36]. To inject the drug solutions directly into the skin, these microneedles are mainly employed. [37], by diffusion, to carry the drug into the body [21]. The hollow microneedles enable pressure-driven flow of a liquid formulation, alike to hypodermic injection. Pressure, and consequently flow rate, can be adjusted for the rapid bolus injection, the slow infusion or the time-varying rate of delivery.



The apparent superiority of this is that for a given time, the considerably larger amount of drug can be delivered, thus opening for the applications where relatively big amounts are needed to obtain the therapeutic effect. For delivery using microneedles, the liquid formulation may simplify the use of existing injectable formulations, but misses the opportunity of the solid microneedle delivery methods to administer the dry-state drug formulations without the reconstitution to improve stability of drug and the patient benefit of the patch based delivery method. To remove the fluid from the body for analysis the hollow microneedles are also used [21].

Hydrogel forming Microneedles

Hydrogel-forming microneedles are the latest advancement in microneedle technology. They are arrays of microneedles made from a swelling material with a drug reservoir attached to the baseplate. [24,26,28,39] After insertion into the skin, the microneedles absorb interstitial fluid and expand to form continuous channels between the dermal microcirculation and an attached patch-type drug reservoir, allowing the drug to diffuse into the skin.[24,28] Initially, these microneedles act as a tool to pierce the stratum corneum. Once swollen, they function as a rate-controlling membrane. These microneedle arrays are mainly produced using synthetic polymers, such as aqueous polymer gels, which can be easily cross-linked through chemical or physical methods. [25] Once swollen, these materials should remain structurally sound and durable during handling.[28] Although hydrogel-forming microneedles are made from polymers, they have distinct characteristics compared to traditional dissolving polymer microneedles. Advantages of hydrogel-forming microneedles include the ability to be fabricated in various patch sizes and shapes, ease of sterilization, resistance to closing while in

place, and complete removal from the skin.[24] However, there is a need to explore a broader range of materials to enhance these transdermal drug delivery systems. Hydrogel-forming microneedle arrays have been used to deliver a wide variety of molecules, from small molecules to high molecular weight compounds.[24,28 19-20] Their use for minimally invasive extraction and quantification of drug substances and glucose from skin both in vitro and in vivo demonstrates their potential for patient monitoring and diagnosis. [22]

METHODOLOGY FOR DRUG DELIVERY

A variety of delivery methods have been used to utilize microneedles for transdermal drug delivery.

These include:

- i] Poke and patch
- ii] Coat and poke
- iii] Poke and release
- iv] Poke and flow

i] Poke & Patch

This technique involves inserting an array of solid microneedles into the skin and then applying a drug patch at the treated area.

The drug can move through the skin by diffusion, or through iontophoresis if an electric field is applied.[40] This method was also used to collect interstitial fluid for non-invasive glucose level measurement.[41]

ii] Coat & Poke

In this method, the microneedles are first coated with the drug and then inserted into the skin to release it through dissolution. The entire dose of



the drug is applied directly onto the needle. [42] A variation of this method is the dip and scrape approach, where the microneedles are dipped into a drug solution and then scraped across the skin surface, leaving the drug in the micro-abrasions created by the needles.[43] However, only a limited amount of drug can be coated on the microneedles—approximately 1 mg—and extensive optimization is needed to achieve a uniform coating in this ‘coat and poke’ method.

iii] Poke and Release

This method involves releasing an encapsulated drug into the skin from microneedles made from polymers and polysaccharides that slowly dissolve or degrade after insertion. The advantage of the ‘poke and release’ approach is that drug release can be controlled based on specific requirements, using a range of available polymers and polysaccharides.[30]

iv]Poke & Flow

In this method, the skin is first pierced using external pressure, and then the drug is allowed to flow through hollow microneedles from a reservoir in the patch.[44]

APPLICATIONS

The microneedles had been explored for several applications & are extended to numerous fields. Owing to the advantage of piercing in the manner of minimally invasive apart from being the alternative to the hypodermic therapy which is conventional, they have also been employed for intracellular, ocular and systemic delivery. To deliver the high molecular weight compounds like peptides and proteins, immunobiologicals like antibodies, vaccines, etc. the microneedles can be used [45], By the poke and flow method the large amount of drug can be administered. Moreover,

the pressure-driven delivery adds the possibility to precisely steer the flow rate and to obtain the extra controlled delivery. To deliver the drugs either systemically or at the restricted site [local action], all of the above mentioned approaches can be employed. The bioactive agents or the bio macromolecules like heparin, albumin, growth hormones, insulin, [46]. In the field of cosmetics the microneedles have also gained prominent attention & various cosmeceuticals have been used for the treatment of pigmentation, skin toning, acne, and wrinkles as well as scars.[45]

In Cosmeceuticals

Strong interest in microneedle technology has been shown by the cosmeceutical industry. Many cosmetic products are now being adapted for use with microneedles, which offer non-surgical and non-ablative treatment options for various skin conditions, such as aging (including wrinkles and loose skin), scarring (like acne and surgical scars), photo damage, hyperpigmentation (such as age or brown spots), and hair loss (alopecia). This method promotes the skin's natural repair process without causing lasting damage to the outer layer of the skin. Microneedles are mainly used in cosmetic applications for treating skin imperfections and delivering active cosmetic ingredients. [47-48] Products like Derma rollers® and stamps are marketed for treating skin issues and enhancing appearance. MTS Dermaroller®[49] is a cosmetic tool that features needles capable of penetrating the skin up to a depth of 0.2–0.3 mm. It has 200 very fine stainless-steel needles that create micro-channels in the epidermis. Clinical studies from various countries have demonstrated that therapeutic serums can be absorbed up to 1000 times more effectively when applied using the MTS Dermaroller®. A dissolving microneedle patch made with hyaluronic acid has been developed for intradermal delivery of ascorbic



acid and retinyl retinoate. When tested on human volunteers,[50] this patch improved the appearance of the skin in terms of roughness and wrinkles. Enhanced local delivery of eflornithine,[51] used to reduce facial hair growth, was observed both in vitro and in vivo when microneedles were used before applying the eflornithine cream. Microneedle technology can also be applied to treat different types of scars through dermabrasion.[52-56] Dermabrasion involves using microneedles to pierce the skin multiple times, encouraging collagen production. Significant improvement was seen in the treatment of patients with dermal scars (striae distensae) using a disc microneedle therapy.[53] However, similar to acne treatments, this method may involve limitations such as skin bleeding and discomfort. Aesthetic improvements were reported in patients with acne scars, with a reduction in scar severity observed in all subjects treated with Dermaroller®.[57] Similar results were also found for the treatment of atrophic facial scars using Dermarollers®.[58] An alternative approach to using Dermarollers® for acne scar treatment is the fractional radio frequency microneedle system. This new device was recently introduced for facial rejuvenation. It works by creating radiofrequency-induced thermal zones, which damage the reticular dermis and lead to skin thickening. Clinical trials have shown that this technique is effective for treating acne scars, as it reduced scar severity in more than 80% of volunteers.[59]

The Immunobiologicals

Due to the limitations of traditional vaccination methods, such as needle phobia and the discomfort caused by inserting a needle into the skin, recent research has focused on developing needle-free vaccination techniques.

These include liquid jet injectors, powder injectors, thermal ablation, and microneedles. These methods aim to deliver immunobiologicals through subcutaneous, intramuscular, or intradermal routes to prevent infectious diseases. Microneedles have several advantages over other methods, including the absence of pain, the ability for self-administration, and rapid vaccine delivery.[45-46] The use of microneedles enables vaccines to pass through the stratum corneum and trigger a clinical immune response. In the case of dissolving microneedles, controlled and complete penetration is a critical factor to consider. These microneedles can deliver small doses, typically less than several milligrams, of various substances such as peptides, proteins, vaccines, hormones, and organic compounds. A wide range of studies have been conducted and reported on vaccine delivery using microneedles, including human IgG[60], tetanus toxoid[61], DNA vaccine[43], influenza vaccine[62], hepatitis B vaccine[63], human papilloma virus vaccine[64], west nile virus vaccine[65], chikungunya virus vaccine[65], herpes simplex virus vaccine[66-67], Bacillus Calmette Guérin vaccine[68], ovalbumin[69], live attenuated chimeric JE vaccine (ChimeriVax)-JE/flavivirus vaccine[70], diphtheria vaccine[71], malaria vaccine[71], and combination and recombinant protein vaccines for anthrax, botulism, plague, and staphylococcal toxic shock.[72]

The Phlebotomy

Phlebotomy is the process of drawing blood samples for the analysis of specific components in order to help diagnose diseases. Blood can typically be collected from capillaries by gently pricking the skin or from veins using evacuated tubes, depending on how much blood is needed for testing. These methods can have certain drawbacks, such as excessive bleeding, infection,



scarring, fainting, or feeling light headed. Some individuals may avoid giving blood due to the fear of needles and the discomfort that comes with the procedure. In such cases, using painless blood sampling techniques with microneedles can be a much better alternative to traditional hypodermic needles.[73-74] Microneedles placed at a depth of 500 to 2000 micrometers in the dermis layer under the skin can be used to collect precise amounts of body fluids and blood samples from capillaries. In addition to making the process painless, microneedles also require much smaller blood samples, up to 200 nanoliters. However, it is crucial that the microneedle reaches the correct depth, so careful attention must be given to the design, material choice, and size of the microneedle to ensure it can penetrate effectively without breaking. Painless hollow microneedle-based microsampling can be used instead of traditional methods for measuring glucose levels, especially in individuals with diabetes who need to monitor their blood sugar regularly.[75] Microneedles can also be used to monitor the levels of therapeutic drugs in the body.[76] A jagged-shaped, hollow in-plane silicon microneedle, which resembles the proboscis of a mosquito, has been developed for collecting blood for testing.[77] Arrays of 350-micrometer-long, hollow, out-of-plane microneedles have also been demonstrated for the in-situ extraction of biological fluids through capillary action.[78]

Bioactive [Biopharmaceuticals]

Bioactive macromolecules, such as insulin, heparin, and growth hormones, face challenges in being administered orally due to proteolytic degradation and limited absorption. As a result, most commercially available biopharmaceuticals are given through the parenteral route. However, there is a need for a non-invasive alternative.

Macromolecules

Microneedle arrays have been shown to improve the transport of both low and high molecular weight compounds across dermatomed human skin.[79] Importantly, the length of the microneedles and the depth of penetration into the skin do not affect the transport of either type of compound. The dissolving microneedles made from the water-soluble polysaccharides have been developed to achieve both rapid and controlled release of these molecules,[80,81] on the administration of the biopharmaceuticals using microneedles the research includes the delivery of low molecular weight insulin [82], heparin [81], L-Carnitine [83], calcein, bovine serum albumin [84], desmopressin [85], recombinant human growth hormone [86], albumin [87], calcein [88], erythropoietin [89], oligonucleotides [90], porphyrin precursor 5-aminolevulinic acid (ALA) [91], salmon calcitonin [92], daniplestim [93], leuprolide acetate [94], parathyroid hormone [95], and human growth hormone.[96]

Diagnosis

Microneedles can also be used in the field of diagnosis. Hollow microneedles, along with quantum dots, aid in medical diagnosis. Quantum dots are nano-sized crystals that emit light. The multiphoton microscopy technique can quickly detect cancers or other health issues.[97] Recent studies focus on creating magnetic nanoparticles combined with magnetic microneedle tips, which safely collect biomarkers that signal early-stage osteoarthritis in joints like the knees and hips.[98] Research has also led to the development of two types of sensing devices based on hybrid microneedle arrays for both diagnostic and therapeutic purposes. These hybrid microneedles have a porous structure and can hold various biological molecules, acting as bioprobes or drug carriers. The first device is an electrochemical sensor where microneedles contain enzymes in



their structure. These enzymes interact with glucose, and through a redox reaction mediated by ferrocene, they generate a current that is proportional to the glucose level. The second device is a therapeutic tool that allows for controlled drug release using optical methods. In this device, a porous silicon membrane with a Bragg's mirror is used, and the wavelength of its reflection is related to the drug's concentration in the microneedle.[99] Microneedle sensors have also been created at the end of an endoscope using poly caprolactone (PCL) microneedles coated with poly (3,4-ethylenedioxythiophene) (PEDOT), with hemin molecules on their surface. These sensors are used for endomicroscopic imaging and biosensing of colon cancer through real-time electrical detection of nitric oxide.[100] Microneedles have also been developed as sensors for detecting hydrogen peroxide, lactate, dissolved oxygen, and glutamate.[101-103] They have also been used as bioelectrical interfaces, particularly for neural recording and stimulation,[104-112] as well as for electrocardiography (ECG) [113] and electroencephalography (EEG) measurements. [114-115]

Drugs

It is important for a drug molecule to have the right physical and chemical characteristics to pass through the skin. The ability of a drug to move through the skin and how quickly it does so depends on its physicochemical properties, such as the balance between water and fat solubility, solubility in different substances, and molecular size. Challenges in delivering drugs through the skin can be addressed using microneedles. Microneedles improve the absorption of drugs and can avoid the need for chemical substances that help the drug penetrate the skin, which might cause irritation. Microneedles can also lower the risk of side effects and problems that come with

taking medication orally or through injection. Drugs that can be delivered using microneedles include L-Ascorbic acid [116], riboflavin [18], galanthamine [117], aspirin [118], docetaxel [119], pilocarpine [120], methotrexate [121], prochlorperazine edisylate [122], lidocaine hydrochloride [123], ropinirole hydrochloride [124], ketoprofen [125], naltrexone with diclofenac sodium [126], phenylephrine [127], naltrexone [128], mannitol [129], and glycerol [130].

CONCLUSION

Several studies on microneedles show that they are effective and promising for transdermal drug delivery. Their importance has grown because they offer safety, convenience, and painlessness, which are major advantages over traditional delivery methods. Microneedles have proven to be a good solution for getting around the barrier created by the stratum corneum, allowing more drugs and molecules to be delivered through the skin. A lot of research has been done to improve microneedles and explore their many uses. In addition to transporting a wide range of drug molecules, including those that are difficult to pass through the skin, large molecules, and biopharmaceuticals, microneedles are also used in blood sampling, diagnosis, and cosmetic treatments. When combined with delivery systems like vesicles, nanoparticles, or microparticles, microneedles can provide controlled release of drugs. Using microneedles with micro pumps allows for accurate drug delivery, while loading them into pockets or grooves enables a larger dose to be delivered. Therefore, it is clear that microneedles are more efficient than hypodermic needles and other traditional delivery systems.



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