RESEARCH PAPER

Microneedle Patches in Transdermal Drug Delivery: Advances, Applications, and Future Perspectives

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ABSTRACT
The development of microneedle technology has transformed transdermal drug delivery from traditional needles to innovative patch-based systems. Microneedles are specifically engineered to produce tiny channels in the skin that allow the efficient delivery of therapeutics without stimulating pain receptors, making administration virtually painless. Due to their flexibility in providing a large range of uses, Microneedles can provide an effective method for delivering small molecules, biologics, and vaccines as well as overcoming the obstacles associated with gastrointestinal degradation and first-pass metabolism. Different microneedle types such as, including solid, coated, dissolving, hollow, and hydrogel-forming systems, offer unique advantages for controlled release, patient compliance, and targeted therapy. Recent advances in fabrication techniques, particularly three-dimensional (3D) printing and polymer engineering, have accelerated the translation of microneedles into clinical use. Despite challenges related to drug loading, large-scale manufacturing, and regulatory approval, microneedle patches hold immense potential as next-generation drug delivery platforms. This review highlights the evolution, applications, and future directions of microneedle technology for advancing painless, safe, and patient-friendly therapeutics.

Keywords: *Microneedles; Transdermal patches, painless drug delivery, next-generation therapeutics, controlled release.*

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1. INTRODUCTION

The use of transdermal drug delivery systems (TDDS) to deliver medication non-invasively has been popular with healthcare providers as a form of alternative therapy to orally or via injection (parenterally) delivering the medication through the skin. Microneedles are an exciting new technology in TDDS using small needles to create channels in the stratum corneum, the outermost layer of the skin, allowing drugs to penetrate through. Although oral administration remains the most convenient route for self-medication, it is often unsuitable for biopharmaceuticals because of poor absorption, enzymatic degradation, and first-pass metabolism(1). In contrast, injectable delivery ensures a rapid onset of action and excellent bioavailability but suffers from low patient compliance, the need for trained personnel, and safety concerns, such as the spread of bloodborne pathogens through needle reuse, particularly in developing countries (2,3). Other alternative routes of administration have been explored, but none have demonstrated the broad effectiveness of direct needle-based injections (4). To overcome these barriers, researchers have proposed miniaturizing needles to micron dimensions, thereby retaining their potent delivery capacity while improving patient safety and compliance (5).

Microneedles are made to be large enough to deliver a variety of drugs, including particulate formulations, but small enough to avoid pain, fear, and the need for professional administration. They create tiny channels in the skin, allowing them to bypass the stratum corneum and deliver drugs efficiently to the dermal and epidermal

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layers (6). Transdermal drug delivery systems (TDDS), including microneedle platforms, provide several benefits. These include maintaining steady drug levels, reducing gastrointestinal side effects, lowering dosing frequency, and improving patient adherence (7). Microneedles can be constructed out of numerous materials, including metals, silicon, polymers, glass and ceramics, with drugs usually coated or loaded on the microneedle tips (8).Their versatility includes different designs and types, such as solid, hollow, sharp, or flat, which are made for specific uses (9). Improvements in microneedle production methods and safe materials have broadened their clinical uses, from delivering vaccines and managing chronic diseases to cosmetic treatments (10). Microneedle systems also tackle serious public health issues, like needle phobia (trypanophobia), which affects almost 10% of adults and is especially common in teenagers (11). By lessening pain, lowering the risk of infection, and reducing complications related to administration, microneedles offer a promising new approach to drug delivery.

Microneedles (MN) are small needle arrays designed for delivering drugs and vaccines through the skin. These arrays feature tiny needle projections that usually measure between 25 and 2000 µm in height (12). Researchers have studied them as a less invasive option compared to standard hypodermic injections (13). MN are used in several fields, including drug and vaccine delivery, cosmetic applications, and disease diagnostics. They are designed in different shapes and structures, made from various materials, and produced using multiple manufacturing methods to meet specific needs. (14).

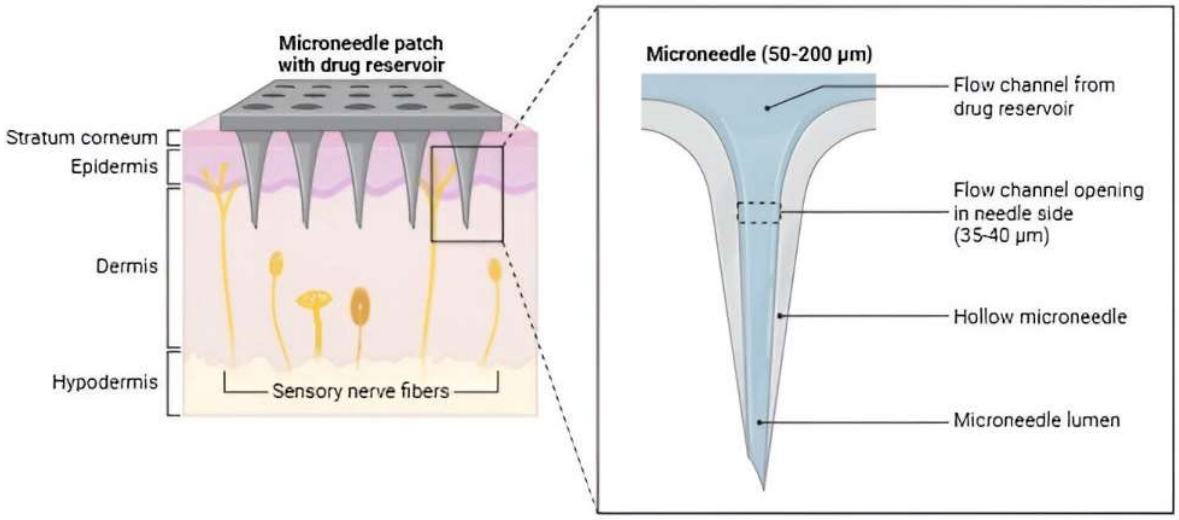

Figure1: Mechanism of Microneedle Drug Delivery (15)

Table 1: Historical evolution of microneedle technology

Year/Period	Key Development	References
Early 1900s	First reports of motor-powered dental burs used for dermatological applications (scarring, hyperpigmentation).	(16)
1960s	Concept of delivering drugs across the stratum corneum gained attention.	(17)
1970s	Formal introduction of the “microneedle” concept (first patent).	(18)
1980s	First transdermal therapeutic system approved for motion sickness.	(19)
Early 1990s	First experimental demonstrations of microneedles for drug delivery in skin.	(20)
1998	First silicon microneedles fabricated using microfabrication technologies.	(21)
2000s	Development of dissolvable microneedles enabling safer and biodegradable delivery systems.	(22)
2010s	Microneedle arrays used for skin perforation and drug delivery; first human clinical trials conducted.	(13)
2010s onward	Expansion of research into novel materials, geometries, and fabrication methods.	(23)
2020	Additive manufacturing and 3D printing proposed for microneedle fabrication.	(24)
2020s	Commercial 3D printers employed for scalable production of microneedles.	(25)

2. TYPES OF MICRONEEDLES

2.1 Solid Microneedles

Solid microneedles are mainly used to create microchannels in the skin. This enables drug delivery through a "poke-and-patch" method. They are typically made from metals or silicon and serve as skin pretreatment tools. This allows for better penetration of the applied drugs. (26,27). Their precise geometry helps puncture the stratum corneum, generating pores that facilitate drug absorption with both local and systemic effects (28,29). Research has shown that these methods effectively improve drug delivery. For example, stainless-steel microneedle arrays increased the distribution of captopril and metoprolol tartrate (15). In contrast, silicon-based microneedles significantly boosted insulin delivery both in vitro and in vivo, reducing blood glucose levels in diabetic models (30,31). However, these microneedles need FDA approval for material safety. Their use is also limited due to skin damage and uncertainty about the exact drug dose that gets absorbed (32).

2.2 Coated Microneedles

Coated microneedles have a solid core and a surface coated with a drug. When they are inserted, the drug layer dissolves, releasing the active compound into the dermal and epidermal tissues. They work well for potent drugs or vaccines that need small doses (26,14). This type has been used successfully to deliver vaccines and small molecules like pilocarpine, lidocaine, and vitamin B (33,34). Coating methods include dipping, spraying, and selective shaft coating, which provide controlled loading and stability (35). However, their limited drug-loading capacity limits their use to applications that need small doses. Still, surface modifications, such as polyelectrolyte multilayers, can broaden their use (36).

2.3 Dissolving Microneedles

Dissolving microneedles are made from biocompatible and biodegradable polymers. They dissolve after insertion, releasing the drug inside. This makes them safe, single-use, and free of needle waste. They can release drugs quickly or over a longer period, depending on the polymer used (26,37). Researchers have examined these microneedles for vaccines and therapeutic drugs. For example, in influenza immunization, microneedle tips containing antigens in carboxymethyl cellulose and trehalose delivered the vaccine effectively (38). Polymers such as carboxymethyl cellulose, methyl cellulose, and sugars like sucrose help with stability and control disintegration (8). Although they show promise, making them requires specialized skills, and the time it takes to dissolve can differ (33,39).

2.4 Hydrogel-Forming Microneedles

Hydrogel-forming microneedles consist of swellable polymers that absorb interstitial fluids and create hydrogel matrices. This setup permits controlled, sustained drug release over time while keeping the patch intact (26). Their swelling features serve as a rate-limiting barrier, allowing for extended therapy and wound healing (40). They have several benefits. They are biocompatible, can be made in different sizes and shapes, are easy to sterilize, and can be safely removed without leaving residues in the skin.

2.5 Hollow Microneedles

Hollow microneedles are small versions of hypodermic needles with a hollow center that allows the direct delivery of liquid formulations into the skin. They can deliver larger drug volumes than other kinds of microneedles. They also allow for real-time extraction of body fluids to analyze biomarkers, such as glucose levels (41,42). They are fabricated from metals, silicon, glass, or ceramics using microfabrication techniques such as laser micromachining and photolithography (13,43). Despite their precise dosing capability, hollow microneedles are prone to challenges such as leakage, clogging, and mechanical fragility, which limit their widespread use (15,33,44).

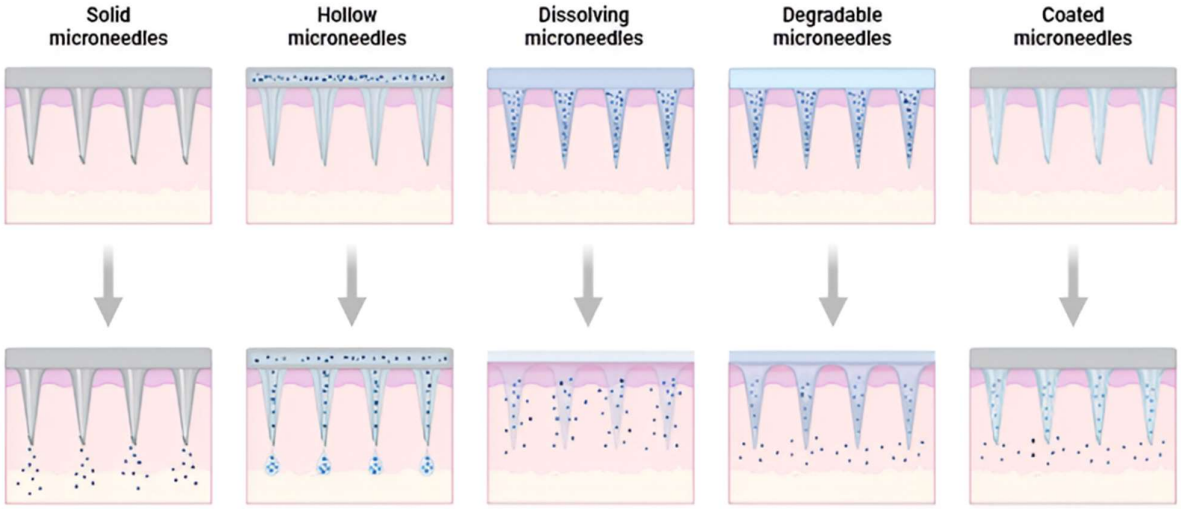

Figure2: Types of microneedles

Table 2: Types of microneedles

Type of Microneedle	Material Used	Mechanism of Action	Advantages	Limitations	Applications	References
Solid Microneedles	Metals (stainless steel), silicon, polymers	Create microchannels in skin ("poke and patch"), drug applied later diffuses through pores	Simple design, enhances permeation, reusable in research	Two-step process, uncertain dose delivery, may damage skin	Pretreatment for drug patches, insulin delivery, antihypertensives	(27,28,30)
Coated Microneedles	Solid microneedles coated with drug layer	Drug coating dissolves rapidly after insertion	Suitable for potent drugs in low doses, rapid action, useful for vaccines	Limited drug load, penetration may reduce due to coating thickness	Vaccines, small molecules (e.g., pilocarpine, lidocaine, vit. B)	(14, 34,36)
Dissolving Microneedles	Biodegradable & water-soluble polymers, methyl cellulose, sugars)	Needle dissolves in skin fluids, releasing drug	Single-use, safe, avoids needle disposal, tunable release	Technical expertise required, dissolution time varies	Vaccines (influenza), therapeutic peptides/proteins, insulin	(37,38,33,8)
Hydrogel-Forming Microneedles	Hydrophilic swellable polymers	Absorb interstitial fluid, swell to form hydrogel matrix → controlled drug diffusion	Sustained release, biocompatible, easy sterilization, intact removal	More complex fabrication	Prolonged drug therapy, wound healing	(26, 40)
Hollow Microneedles	Metals, silicon, glass, ceramics	Hollow bore allows direct liquid injection into dermis	Allows large volume delivery, precise dosing, useful for fluid extraction	Expensive fabrication, clogging, fragility, risk of breakage	Vaccines, biomarker sampling (e.g., glucose monitoring)	(41,42,45,13)

3. MICRONEEDLE FABRICATION MATERIALS

The primary advantage of microneedles (MNs) is their ability to penetrate the skin without breakage or deformation. To address the challenges associated with MN fabrication, factors such as the choice of material, manufacturing techniques, and structural design have been evaluated extensively. Different types of MNs have been created using a variety of materials. For example, there are silicon-based MNs, metal-based MNs, ceramic-based MNs, polymer-based MNs, and carbohydrate-based MNs as can be found in Table 3 (46, 47). Biocompatible materials have also been integrated into MN devices across multiple fields (drug delivery, tissue engineering, and biomedical implant industries) (48, 49).

Table 3: Materials used for microneedles

Material	Key properties	Advantages	Disadvantages	Applications	References
Silicon	Brittle, non-biodegradable	Well established, microfabrication	Time consuming, Expensive	Diagnostic, Biosenser	(50)
Metals (stainless steel, nikel, titanium)	High mechanical strength	Good skin penetration	Non-biodegradable	Insulin delivery	(51,52)
Polymers (PLA, PGA,	Good biodegradability, biocompatibility,	Shows better toughness	Exhibits lower strength than metal, ceramics	Dissolving microneedles, drug patches	(53)

PLGA)					
Ceramic (calcium)	chemical resistance, compressive strength, and long-term stability	Stable	Costly	Dissolving Microneedles	(54,55)
Carbohydrates (maltose,sucrose)	Biocompatible, dissolves fast	Cheap and safe for the human health	Degrade at high temperature	Dissolving microneedles	(51,56)

4. ADVANTAGES OF MICRONEEDLE

1. Microneedles (MNs) are recognized as an advanced strategy for transdermal drug delivery, as they enable therapeutic agents to circumvent hepatic first-pass metabolism, thereby enhancing systemic bioavailability (57).
2. These delivery systems minimize the discomfort associated with conventional intravenous injections, providing a painless and patient-friendly alternative (58).
3. Microneedles are designed to pass the stratum corneum barrier so that drugs can be easily delivered to the epidermis (upper layer of skin) or upper dermis without causing pain (59).
4. Microneedles have sufficient length to penetrate the stratum corneum but not long enough to reach the lower dermis or stimulate nerve endings, thus allowing for painless drug delivery (60).
5. Microneedle drug delivery does not need trained staff, making it easy for patients to use on their own (61).

5. CHALLENGES AND LIMITATIONS

1. **Mechanical Strength and Breakage Risk:** Microneedles fabricated from polymers, sugars, or biodegradable materials may exhibit insufficient mechanical strength, leading to bending or breakage during insertion. Detached fragments remaining in the skin can pose safety concerns (62,36).
2. **Drug Loading Capacity:** The limited surface area and volume of microneedles restrict the quantity of drug that can be incorporated, making them unsuitable for molecules that require high doses (63).
3. **Drug Stability Issues:** Biological therapeutics, such as proteins, peptides, and vaccines, may lose their structural integrity during microneedle fabrication or storage. Additionally, they are highly sensitive to environmental factors, such as temperature, moisture, and sterilization methods (64,13).
4. **Insertion Variability:** The efficiency of microneedle insertion is influenced by skin thickness, elasticity, and force of application. Inconsistent penetration may result in incomplete or variable drug delivery (60,62).
5. **Patient-Related Limitations:** Skin conditions, including eczema, psoriasis, scarring, or excessive hair growth, may hinder penetration. Furthermore, despite being minimally invasive, some patients may still experience pain, irritation, or discomfort (60,36).

6. APPLICATIONS OF MICRONEEDLE TECHNOLOGY

Microneedles have become useful tools for drug delivery across various therapeutic areas.

1. **Vaccination:** They allow for efficient vaccine administration. This leads to a stronger immune response and less vaccine needed, along with formulations that do not require refrigeration. These factors make microneedles ideal for resource-limited settings.
2. **Chronic Disease Management:** For diseases like diabetes and hormone deficiencies, microneedles offer a painless way to deliver drugs in a controlled and sustained manner. This approach improves patient compliance.
3. **Pain Management:** Delivering pain relievers directly with microneedles lowers systemic side effects. This method is particularly beneficial for patients with chronic pain conditions such as arthritis and neuropathy.
4. **Cosmetic Applications:** Microneedles are popular in skincare. They help agents like hyaluronic acid and peptides penetrate the skin better and promote collagen production for skin rejuvenation (65).
5. **Gene Therapy:** Microneedles provide a non-viral, low-immunogenic way to deliver DNA, RNA, and siRNA. This method shows promise for treating genetic disorders (66).
6. **Cancer Therapy & Immunotherapy:** Microneedles enhance the delivery of anticancer drugs and vaccines through the skin. This approach reduces pain and hazardous waste compared to traditional. They also enhance immune-based cancer therapies by efficiently delivering antigens and immunostimulants to antigen-presenting cells, thereby inducing strong systemic antitumor responses (67-70, 24).
7. **Diabetes Management:** Multiple preclinical studies have demonstrated the effectiveness of microneedle patches for insulin delivery. Both dissolving and polymer-based microneedles provide rapid absorption, high bioavailability, and glucose-responsive release, showing therapeutic outcomes comparable to subcutaneous injections (71-81).

7. FUTURE DIRECTIONS IN MICRONEEDLE TECHNOLOGY

1. **Smart Microneedles**: Microneedles integrated with biosensors enable minimally invasive monitoring of biomarkers (e.g., glucose, lactate, cytokines), moving toward closed-loop "sense–analyze–respond" systems for precision dosing. Stimuli-responsive MNs triggered by pH, enzymes, ROS, temperature, or external cues (light, magnetic fields, and ultrasound) allow on-demand release. Advances in printable materials and additive manufacturing support bio-inspired geometries for reliable insertion and efficient sampling (82,83,84).
2. **Personalized Therapy**: Patient-specific factors, such as skin thickness, hydration, and biomechanics, necessitate customized MN designs (height, tip shape, and density). ISF-based pharmacokinetic feedback enables adaptive dosing in diabetes, oncology, autoimmune disorders, and pain management. Clinical trials should be stratified by skin phenotype, activity level, and adherence metrics to validate personalization strategies (84).
3. **Integration with Digital Health**: Future MN patches will connect with wearables and smartphones for real-time analytics, clinician dashboard, and telemedicine. Embedded edge AI supports local data processing and dosing decisions while preserving privacy. Flexible substrates, energy-efficient electronics, and interoperable data standards are key to multi-day wearability and regulatory compliance (83).
4. **Cross-Cutting Challenges**: Key barriers include large-scale clinical validation, insertion robustness across diverse skin types, long-term biosensor stability, good manufacturing practice (GMP) for electronics-integrated patches, cybersecurity, and clear regulatory frameworks for combination products (83).

CONCLUSION

On the basis of research from our group (84, 85, 86, 87, 88, 89), we can conclude that Microneedles are an extremely viable approach to providing transdermal (through the skin) drug delivery with next results. They provide a pain-free method of administering drugs and allowing the patient to use them with greater ease (higher patient compliance). Additionally, they can deliver many different types of medication through skin including vaccines, biologics or small molecules. Advances in fabrication and materials have expanded their clinical potential; however, challenges such as drug-loading limitations, stability issues, large-scale manufacturing, and regulatory approval remain. Future innovations in smart microneedles, personalized therapy, and digital integration are expected to overcome these barriers, establishing microneedles as a safe, effective, and patient-friendly alternative to conventional injection.

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