Advances in Bioresearch
Adv. Biores., Vol 17 (3) March 2026: 123-129
©2026 Society of Education, India
Print ISSN 0976-4585; Online ISSN 2277-1573
Journal's URL:http://www.soeagra.com/abr.html
CODEN: ABRDC3
DOI: 10.15515/abr.0976-4585.17.3.123129

Advances
in
Bioresearch

REVIEW ARTICLE

Microneedle Technology for Painless Drug Delivery

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ABSTRACT

Microneedle technology has transformed transdermal drug delivery by offering a pain-free, minimally invasive, and effective alternative to traditional injections. Micro-scale needles puncture the stratum corneum, allowing the delivery of drugs such as vaccines, insulin, and biologics, which are otherwise hard to deliver via the skin. Microneedles are categorised as solid, coated, dissolving, hollow, and hydrogel-forming types, each suited for particular drug delivery modes. Recent advances in microfabrication have facilitated inexpensive mass production, which makes microneedles a viable choice for self-administration and better patient compliance. This article discusses the types, mode of working, applications, benefits, and limitations of microneedle-based transdermal drug delivery systems. Though promising, manufacturing scalability, regulatory compliance, and patient acceptability are issues that must be tackled for it to gain broader clinical acceptance. Further research and development in this area will be key to revolutionizing painless and efficient transdermal drug delivery in the years to come.

Keywords: *microneedle, transdermal drug delivery, Painless drug administration, Vaccines, Insulin delivery, Patient compliance.*

Received 04.02.2026 Revised 23.02.2026 Accepted 21.03.2026

How to cite this article:
Dev P, Tularam B. Microneedle Technology for Painless Drug Delivery. Adv. Biores., Vol 17 (3) March 2026: 123-129.

INTRODUCTION:

Microneedle technology has ushered in a new era in drug delivery systems, providing a cutting-edge painless alternative to the conventional hypodermic needle technique. One major distinguishing factor between traditional needles and microneedles is that the latter is too small to reach the deeper stratum corneum of the skin, so patients feel virtually no pain during drug administration. This minimally invasive technique has allowed for the transdermal delivery of different therapeutic agents such as macromolecules like insulin, vaccines, and biologics, which are generally problematic to admit passively via the skin. [1,2] Learning about the domain of microneedle science, one will realize that accelerated with developments in microfabrication, arising into mass production economically and with precision. By means of microneedles for patch-like systems, scientists have created a paradigm for self-administered drug delivery, allowing continuous release of medication and reducing the requirement for intense medical supervision. Large money investment for promotion of drug bioavailability, patient adherence, and improvement of the entire spectrum of transdermal treatment options is being dredged forth by numerous pharmaceutical companies and startups. [1,3,4] This analysis covers all types of microneedle technology inclusive of classifications, mechanisms of operation, pain-free drug delivery, advantages, and disadvantages. The non-invasive, efficacious, and patient-compliant potential of microneedles provides insight into the expanding role of microneedles in medicine.[1,3,5]

TYPES OF MICRONEEDLES

Microneedles are separated into five distinct classes, each designed with a different mechanism of delivery designed to improve drug performance for transdermal administration:

1. Solid Microneedles

These microneedles work by puncturing the skin to form micro-sized openings, and the permeability of the skin to absorb the drug increases considerably after creation of these openings. Typically made of stiff materials like silicon, polymer, or metal alloys microneedles are often used in transdermal systems and dermatological therapy. [6,7,8]

2. Coated Microneedle

This type of microneedle has a thin layer of drug on the surface of the needle. After the microneedles penetrate the skin, the outer layer dissolves instantly, releasing the drug into the skin layers.[16] Coated microneedles are often used in rapid-onset therapies, including vaccinations. [9,10]

3. Dissolving Microneedles

Constructed from biocompatible and dissolving materials, these microneedles disintegrate inside the skin, and thus release the active material whilst degrading. These microneedles have single-use applications and have no concerns with the waste of needles. [11,12]

4. Hollow Microneedles

The hollow microneedles function like a small syringe, hollow channels allow for liquid drug to be injected actively into the skin and are regularly used in insulin delivery, local anaesthesia and targeted drug delivery providing exact controlled delivery of medication. [13,14]

5. Hydrogel-Forming Microneedles

Hydrogel microneedles are composed of water-absorbing polymers that swell in the presence of skin. This swelling action allows for controlled, sustained release of drugs. Hydrogel microneedles do not dissolve like dissolving microneedles; they remain intact and act as a reservoir for continuous drug delivery. Hydrogel microneedles can be of particular significance in the delivery of medications, as well as long-term medication delivery for chronic diseases. [15,16,17]

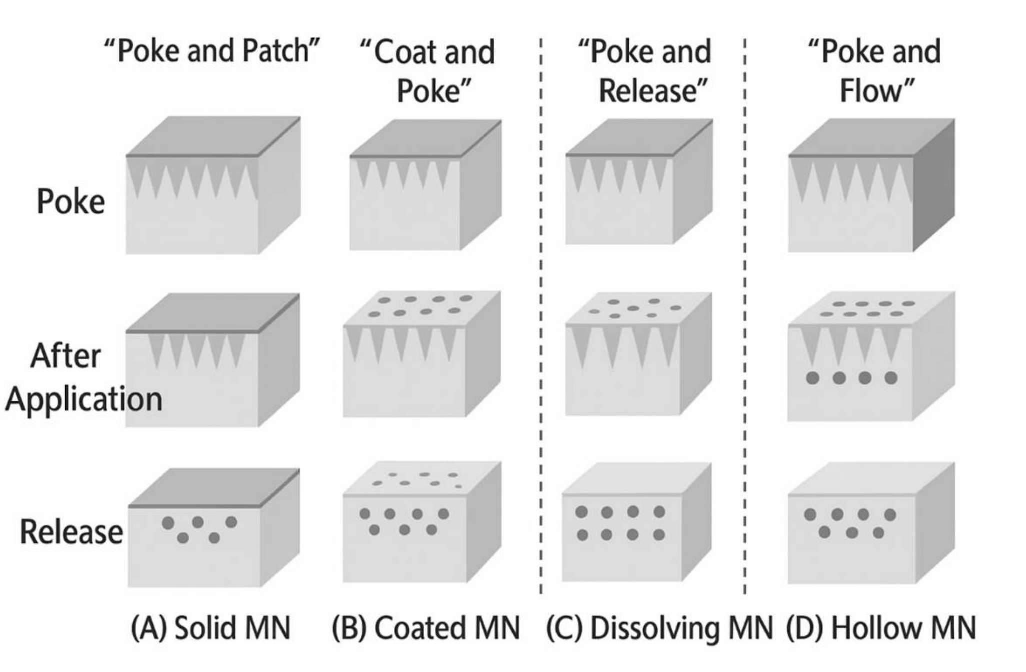

Figure 1. Illustration of drug delivery methods using different microneedle types

MECHANISM OF MICRONEEDLE-BASED DRUG DELIVERY:

Microneedles are newly designed therapeutic agents that essentially create microchannels through the skin and allow percutaneous delivery across the stratum corneum (which operates as the key skin barrier).[18,19] The MNs serve a minimally invasive role in drug delivery, ensuring that a wider range of drugs can be administered, including macromolecules that would be difficult to administer with conventional methods.[20,21]

1.Pore-Creation Mechanism (Solid Microneedles) Mechanism: Solid microneedles create microchannels by penetrating the skin, thus increasing the permeability of the skin. When they are removed, a formulation of the drug is placed on the microchannels so that the drug passes through passive diffusion into deeper skin layers.[22,23,24] Applications: promoting transdermal drug delivery and collagen induction therapy in dermatology.[25,26]

2.Surface Dissolution Mechanism (Coated Microneedles)

Mechanism: microneedles with surfaces coated with drug particles. As the coating dissolves upon insertion into the skin, a drug is thus released to the epidermis. Application: vaccination; delivery of therapeutic compounds.[27,28]

3. Polymer Degradation Mechanism (Dissolving Microneedles)

Mechanism: microneedles that dissolve are composed of biocompatible materials and have the drug encased within their matrix. When penetrated into the skin, they are dissolved in interstitial fluid and deliver the drug as a function of time.[29,30]

4.Active Infusion Mechanism (Hollow Microneedles)

Mechanism: With the presence of hollow channels, these microneedles actively deliver liquid formulations into the dermis, and the control over drug delivery is precise. Applications: Insulin injection, local anesthesia, and large-molecule drug delivery.[31,32]

5.Hydrogel Swelling Mechanism (Hydrogel Microneedles)

Mechanism: Composed of hydrophilic polymers, the microneedles swell when they absorb interstitial fluid and create a gel-like matrix that can facilitate sustained and controlled drug release.[33,34]

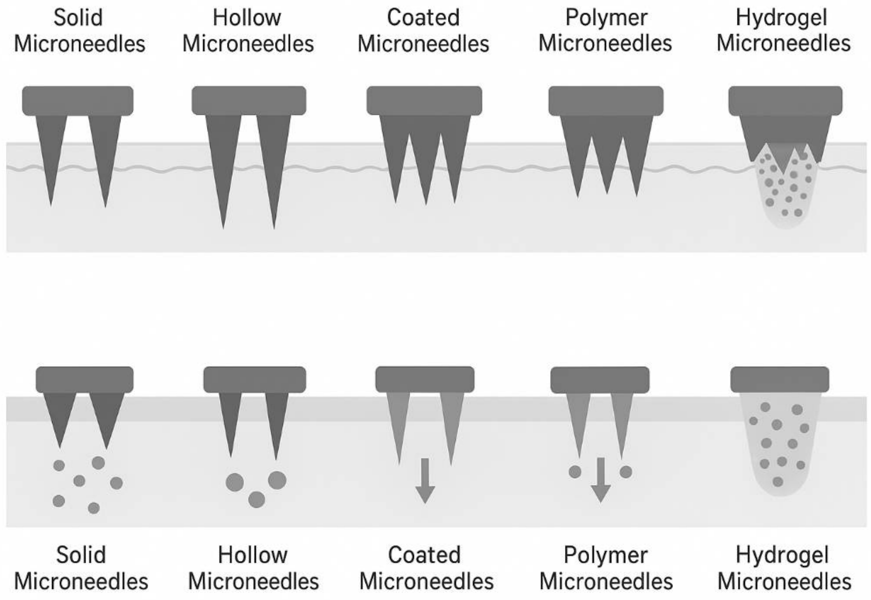

Figure 2. Overview of various microneedles

(A) A structural representation of different microneedles geometries: solid, hollow, coated (one using microneedles), dissolving polymer (these dissolve after the drug delivery), and hydrogel structures. (B) All microneedle types have variable drug delivery behavior. Solid microneedles with an increase in skin permeability are like creating microchannels. Hollow microneedles aid in the active infusion of liquid formulations into the skin. Coated microneedles deliver a medicine with a surface layer of material on the microneedle that dissolves when inserted. Biodegradable polymer microneedles trap drugs within their matrix, releasing them as the needles break down. Hydrogel microneedles, made of swellable polymers, absorb interstitial fluid to allow for controlled diffusion of therapeutic agents. [35,36]

ADVANTAGES:

Microneedle technology has many important benefits, including patient comfort. Many patients, especially children, may have needle related anxiety (needle phobia) with hypodermic needles. Microneedles reduce the fear, making patients much more willing to allow procedures like vaccinations and blood sampling.[36] Studies have found that microneedling is usually rated more favorably than standard injections in terms of discomfort, and further, they enhance the overall physiological and psychological experience.[37] While the use of microneedles has a number of provider benefits as well. Microneedles create little hazardous waste, making disposal simpler and safer than regular syringes. The components of microneedles are typically made of less material and lower-cost materials which is beneficial for reducing manufacturing costs. The ease of use also allows for simplified application with the possibility for self-application in home healthcare environments.[38,39] Microneedle systems offer new potential for healthcare expansion in home and community settings. One major disadvantage of traditional hypodermic needles is the generation of hazardous medical waste that is disposed of properly for both healthcare facilities and patients. This problem is magnified for patients who self-administer injections at home and for patients who administer injections daily or frequently, to include those who re-enter the environmental waste stream a proportion of contaminated waste. As previous literature described, unintentional use of used needles in the improper disposal of waste could affect the environment and the safety of people. [40,41] Dissolvable or hydrogel-based microneedles provide additional safety in these scenarios and offer a form of medication to be self-administered by the patient without sharp waste. Microneedle systems also eliminate the risk associated with accidental needle-stick injuries or contamination [31]. Solid and hollow microneedles still represent a potential risk because involved with microneedle systems exist the need to ensure they are disposed of correctly, and as we discussed before, this will vary from one decentralized healthcare situation to another.[8] Microneedle systems are also associated with a reduced risk of microbial contamination at the site of administration. Traditional needle injection methods create puncture wounds that can be open for up to 48 hours and might be an entry-point for pathogenic microorganisms. Conversely, microneedles only penetrate to a depth of about 10–15 µm and, do not produce lasting tissue injury, closing quickly [9,40]. This shallow penetration depth minimizes the environment for infection or acquisition of bacteria systemically. However, better understanding of whether specific pathogens can penetrate through these microchannels and how microbial invasion of the tissues mechanically works is still warranted. [12,14,41].

DISADVANTAGES

One challenge with microneedle-based delivery systems is ensuring drugs are administered correctly and completely. Coated and hollow microneedles provide the most risk of not providing the full dose if applied improperly or if the microneedle is damaged during application. Incomplete doses would mean the drug will remain on the skin's surface (where it won't be effective), or leakage occurs, and both outcomes do not contribute to developing therapeutic effectiveness.[9,32] This indicates the importance of proper training and technique by healthcare providers applying microneedle arrays to ensure consistent skin contact, the proper angle for skin insertion, and correct application pressure to maximize drug delivery efficiency and not develop suboptimal outcomes.[12] Another concern surrounding microneedle systems is the possibility of breakage during application, particularly if the microneedle array is poorly designed or improper application occurs. [33] Since microneedles are considerably thinner and less resilient than other injection needles. While match sticks are capable of piercing a hole in an object, there is a small feasible risk of broken needle fragments becoming detached and remaining embedded within the skin. This is more concerning when the materials are not biodegradable such as titanium as these have no capacity to be absorbed by the body and at worst may cause localized tissue reaction or irritation.[9] In addition, although the risk of infection is usually a smaller concern for microneedles than conventional injections, there is very little research on microneedles as a delivery system. [34] Many variables in the microneedle design process still need to be developed; for example, mechanical properties such as strength and ductility of the microneedles, safety/biocompatibility of the chosen microneedle material, and making sure the drug is stable in the microneedle delivery mechanism. It's worth mentioning that one of the main challenges to getting microneedle technology into clinical practice is the low drug loading capacity relative to possible ranges of therapeutic agents. [11,13,35]

MARKETED MICRONEEDLE-BASED PRODUCTS: The availability of multiple microneedle systems commercially available, or in clinical development and testing, has proven the clinical acceptability and patient tolerability with microneedle products, although microneedles are a recent technology. MicronJet™ (NanoPass Technologies): a hollow microneedle device approved for delivery intradermally; currently being evaluated for vaccine development and diagnostics. Qtrypta™ (Zosano Pharma): a dissolving microneedle patch system employed for the delivery of zolmitriptan to treat migraines; pending FDA approval. Soluvia® (Sanofi Pasteur): an intradermal delivery system of an influenza vaccine via a hollow microneedle syringe approved in Europe. AdminPen® (3M Drug Delivery Systems): A microneedle applicator solid device used as skin pretreatment to enhance transdermal delivery. These market examples of microneedle systems demonstrate the advancement that microneedle technology is gaining in coming into widespread healthcare, facilitate improved patient comfort, improved ease of administration, and improved bioavailability.

SUMMARY:

The reviewed literature highlights the improvement of microneedle technology as a painless, efficient, and minimally invasive method for drug delivery. Several different forms of microneedles such as solid, coated, dissolving, hollow and hydrogel-forming microneedles have also been devised, each having their unique characteristics and functionality. Figure 1 compares structure between the different types of microneedles and their interaction with skin layers. The research has shown that dissolving and hydrogel microneedles can provide safer options by getting rid of sharp waste and controlling drug delivery. This is particularly useful and beneficial for vaccines and peptides, where delivery may require continuous release or rapid release. Physiochemical processes of drug delivery between solid, coated, dissolving, and hollow microneedles are shown in Figure 2. Solid microneedles are typically used in a "poke and patch" method and hollow microneedles are used in a "poke and flow" method. Both these methods are continuously being developed in preclinical and clinical studies. Coated microneedles show quick deliverable properties, whereas dissolving microneedles have been in the most recent research for biological compatibility, as well as, ease of manufacture with polymers such as PVP, CMC, and hyaluronic acid. The medical literature demonstrates that microneedles enhance drug distribution effectiveness and decrease patient pain and boost user participation compared to conventional injection methods. According to Donnelly et al.(2012) dissolving microneedles achieved drug delivery of 80% in 1 hour with minimal tissue damage. Although microneedles offer benefits their application faces several obstacles. The limitations of microneedles include restricted drug storage capability together with potential insertion failures and problems with maintaining consistent mechanical strength. Microneedle products continue to face unresolved regulatory challenges during their approval process. Current advancements show that integrating brief and extended wearable electronic devices with intelligent patches might represent an emerging direction for future healthcare systems. These technological systems will enable feedback-regulated delivery approaches to manage chronic illnesses. The effectiveness of microneedles serves as an accurate and painless technique to deliver drugs through the skin. The ongoing research with microneedles will increase their applications for personalized healthcare solutions as well as dermatological treatments and vaccine delivery.

CONCLUSION

Microneedle technology is seen as the most advanced method in transdermal drug delivery as it is a painless, minimally invasive, and more effective method of drug administration than traditional injections. Microfabricated microdevices penetrate the stratum corneum allowing for scalable delivery of a diverse array of therapeutic agents such as vaccines, insulin, and biologics. The development of many forms of microneedles such as solid, coated, dissolving, hollow, and hydrogel-forming will yield customizable drug administration strategies. These new strategies will enhance bioavailability as well as patient compliance and therapeutic efficacy. As microneedling technologies became more standardized and cost-efficient within the microfabrication techniques it made microneedle-based platforms commercializable and tremendously scalable. Although microneedling has many advantages it still faces many hurdles including but not limited to consistent reproducible manufacturing techniques, regulatory approval, and patient acceptance. Continued research and clinical trials will be vital to developing microneedling to be incorporated into more healthcare practices as a breakthrough in the potential for pain-free drug delivery and transdermal therapeutics.

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