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FABRICATION OF MICRONEEDLE PATCH FOR TRANSDERMAL DRUG DELIVERY USING 3D PRINTING TECHNOLOGY

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ABSTRACT
Transdermal drug delivery system offers an alternative system to traditional needle injection method by improving the challenges such as low drug permeation, first-pass metabolism, low complains and patient discomfort. Among TDDS, microneedle (MN) patches standout as a highly promising, non-invasive technique which contain micron sized needle that can temporarily disrupt stratum corneum layer and enable precise and enhanced drug permeation. The conventional microneedle fabrication methods like micro-molding, micro-machining are effective but often lack design specificity and flexibility. To overcome this, a simpler, cost-effective and highly customizable approach called Three-Dimensional (3D) printing technology has revolutionized for MN fabrication. The review provides a comprehensive summary of the mechanism of drug delivery via MN patch, various types of microneedles with its unique benefits. The article mainly highlights the requirements for development of MNs using additive manufacturing technology and its various type. Additionally, the review addresses the diverse application and critical challenges in MN fabrication.

KEYWORDS: Microneedle, Transdermal drug delivery, 3D printing, CAD software.

INTRODUCTION

As an alternative to the conventional needle injection method, several of non-invasive drug administration technologies have lately surfaced. Transdermal drug delivery system was a most widely investigated and most attractive routes of non-invasive drug delivery because of its improved drug permeation through skin, ease of administration, low rejection rate, and avoidance of first-pass metabolism. The barrier effect of the outermost stratum corneum layer of the skin can be resolved by delivering the drug directly into the skin tissue and passing it through the cellular and vascular tissue to reach the target tissue[1] using various TDDS, like nano-carrier topical cream, transdermal patch, and microneedle patch.[2]

Microneedle (MN) patch comprises of an array of needles in a micron size, ranging up to 2mm in height, which are arranged on a small patch.[3] It was an emerging leading technology for facilitating painless and less invasive transdermal drug delivery. Using a microneedle patch, the dose, speed of delivery, and efficacy of the drug can be regulated and monitored. The main characteristic features of this method are improving drug delivery by rapid onset of action, high drug bioavailability, delivery of drug directly into the stratum corneum, and improved permeability. It also possesses some disadvantages like limited drug dose due to the smaller size of the microneedle patch and the risk of occurrence of temporary inflammation or allergy to hypersensitive skin.[4]

A variety of microneedle fabrication methods, like micro-molding, micro-machining, lithography and droplet-air blowing, and electro drawing have been investigated in order to bring out the desired design specifications. Among these, micro-molding was found to be an efficient method in producing standardized MNs with sufficient reproducibility, but confined in terms of design customization and complexity. The growing need for a simpler, cost-effective, and more reliable, MNs mold manufacturing gave rise to additive manufacturing technology or three-dimensional (3D) printing technology.[5] 3D printing technology is a simple and rapid technique to print three-dimensional objects reasonably. 3D printed microneedle array can be designed using CAD software and fabricated using numerous 3D printing techniques such as Fused Deposition Modelling (FDM), Stereolithography (SLA), Digital Light Processing (DLP), Two-Photon Polymerization (2PP), and Selective Laser Sintering (SLS).[6] This review focuses on the mechanism of drug

delivery of microneedle patch, the type of microneedles required for microneedle design, current trends and development in the fabrication of MNs using 3d printing technology, and the challenges and limitations of this technique.

1. Mechanism Involved in Drug Delivery of Microneedle Patch

Microneedle patch consists of micron-sized needles (2mm) in an array on a tiny patch that temporarily disrupts the skin and delivers a sufficient amount of drug to have the desired therapeutic response. The needles in the patch help to pierce the outermost stratum corneum layer of skin and bypass the barrier layer. Thus, the drug is delivered directly into the epidermal or upper dermal layer of skin, which then gets absorbed into systemic circulation and then shows therapeutic response at the target site.[2]

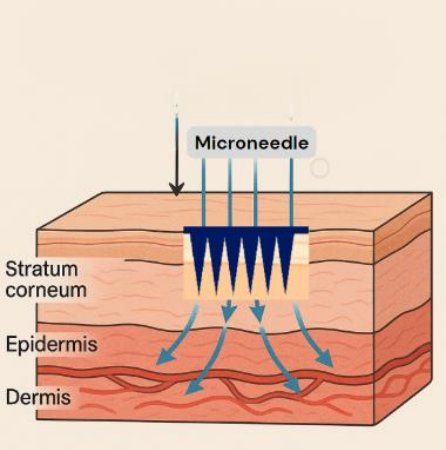


Figure 1: Mechanism of action of microneedle patch.

2. Types of Microneedles

According to the dose, onset of action, rate of drug delivery, efficacy, and patch wearing time, it is essential to choose a suitable type of microneedle for drug delivery. The common categorisations are:

2.1. *Hollow MNs*: Microneedles having a hollow core that allows drug delivery into the skin.

2.2. *Solid MNs*: The most basic kind of Microneedle comprises of needles that pierce the skin and create pores on it. Commonly used type.

2.3. *Coated solid MNs*: These microneedles have a coating that dissolves in the skin after penetration and allows drug release.

2.4. *Dissolving MNs*: It is made up of materials that dissolve in skin and allow the controlled release of a drug or other substance.[7]

2.5. *Hydrogel MNs*: Microneedles are made of a hydrogel forming matrix that does not dissolve or degrade in the skin but provides a regulated or continuous release of API.

3.1. Hollow Microneedles

Hollow MNs contain a hollow core or lumen (5-7µm wide) that enables the delivery of drug using passive diffusion or by exerting pressure using a syringe, pump, or gas. Commonly used to deliver liquid drug formulations from the reservoir through hollow MNs into certain layers of skin. Hollow MNs allow higher API content, accurate drug delivery, and ease of manufacture. The accuracy in API release can be enhanced by the consolidation of a micropump or a microfluidic chip into the array of MNs. One of the main limitations of this method is clogging of the needle tip and challenges in dry formulation delivery.[8]

3.2. Solid Microneedles

Solid microneedles are easier to manufacture and the most commonly used type. In this method, either the drug is coated on the microneedle surface or administered on the skin surface after micropores are generated by the insertion of solid microneedles. The precoated drug on MN gets dissolved after insertion into the skin[9] and permeates through the micropores by passive diffusion. This type of MN allows rapid drug delivery, ease of manufacture, and better compliance.[8]

3.3. Coated Microneedle

Coated microneedles are solid MNs coated with a drug formulation that is continuously dissolved and released into the skin after application. These MNs rapidly deliver macromolecules like peptides, vaccines, DNA, etc. Gas-jet dry coating, liquid methods including repeated immersion and dip-in coating, and spray coating are a few coating methods of MN arrays. They have a simple one-step application process. Coated MNs offer only a limited amount of drug content and limited use of potent drugs.[8,9]

3.4. Dissolving Microneedle

Dissolving microneedles are derived from the coated microneedle type. Dissolving microneedles involve the insertion of dissolving needles combined with the drug into the skin for drug dissolution. The MNs can entirely melt in the skin tissues and prevent waste leftovers during drug delivery. These types of MNs are made up of biocompatible and water-soluble materials. The main advantage of this type of MNs is inexpensive, self-administered, and rapid drug dissolution.[10]

3.5. Hydrogel Microneedles

Hydrogel forming microneedle (HFMs)technology is an attractive type of microneedle that consists of a swellable polymer. It provides sustained and controlled delivery of medicaments over a prolonged period of time, either by integrating the drug into the polymer structure during preparation or by putting the drug into a separate reservoir. Due to the inherent swelling, insolubility, and viscoelastic property, no matrix material remained on the skin after the removal of the patch. It also offers benefits like multiple drug delivery, resisting closure of pores on skin after puncture into skin, and avoiding drug deposition after MN penetration. HFMs have ability to modulate the drug delivery through the cross-linking property of MN, i.e., by increasing the crosslinking agent, the crosslinking degree can be increased while the

swelling degree can be decreased, resulting in a lower are more prolonged release of drug.[11]

Types	Material Used	Delivery Mechanism	Advantages	Disadvantages	Applications
hollow mns	Glass, silicon, metal, polymer	Drug flows through hollow core via diffusion or pressure	Accurate drug delivery, high drug volume content	Risk of clogging, manufacturing complexity	Cancer therapy, intradermal drug delivery
solid mns	Silicon, metal, stainless steel, ceramic	Create microchannel by piercing skin and drug is applied over this portion of skin	Easy to fabricate, simple design and rapid drug delivery	Low drug loading capacity	Vaccines, peptides and dermatological medicaments
coated mns	Silicon, metal	Drug is coated on the needle surface and get dissolved after insertion	Single step application, rapid onset of action	Limited drug loading capacity, risk of stability due to coating	Vaccine and protein delivery, DNA/RNA therapy
dissoliving mns	PVA, PVP, CMC, chitosan, hyaluronic acid	MN patch gets dissolved in skin and the drug embedded is released from the matrix to skin	Biodegradable, no residual, self-administration	Low mechanical strength	Insulin, vaccine, cancer therapy, cosmetic applications
hydrogel forming MNs	Crosslinking agents (PEG, PVA)	Absorb interstitial fluid and swell to release drug from patch	Sustained and controlled release, no residues	Complex formulation, slow onset of action	Suitable for diagnostic and sensing

4. DEVELOPMENT OF MICRONEEDLE PATCH USING 3D PRINTING TECHNOLOGY

In response to the demand for a microneedle manufacturing process that is inexpensive, compactible, accurate, reliable, and easily accessible, 3D printing technology was developed. It offers tremendous advantages like reduced time requirement for designing, appropriate size characteristics, design specificity, and flexibility.[12]

3D-printing technology is often known as additive manufacturing (AM) technology used to print three-dimensional objects economically using computer-aided design (CAD) software, which selectively puts materials layer-by-layer. It permits the manufacture of patient-specific dosage forms customized as per individual demand; personalized medicine.[13] Compared to the conventional method of MN manufacturing methods AM can be easily customizable, produce less wastage of materials, which helps to reduce the production cost, and allows printing using inexpensive, biocompatible printing materials. Through this method, it is able to easily fabricate more complex and arrowhead-shaped microneedles, that could be challenging to fabricate using conventional approaches.[14]

4.1. Method of Designing and Development of Microneedles Using 3D Printing Technology

The designing of 3D printed microneedles was done by creating a 3D design of MN using Computer Aided Design (CAD) software like AUTOCAD 360, which is then exported to a standard tessellation language (STL) file and uploaded to a 3D printer. The 3D printer then slices the 3D model data into consecutive 2D models by using slicing software and facilitates the fabrication of microneedles by selectively placing material layer-by-layer. After slicing, the microneedle was printed using appropriate material and then washed up to 20 minutes using Form wash and cured using Form Cure.[15]

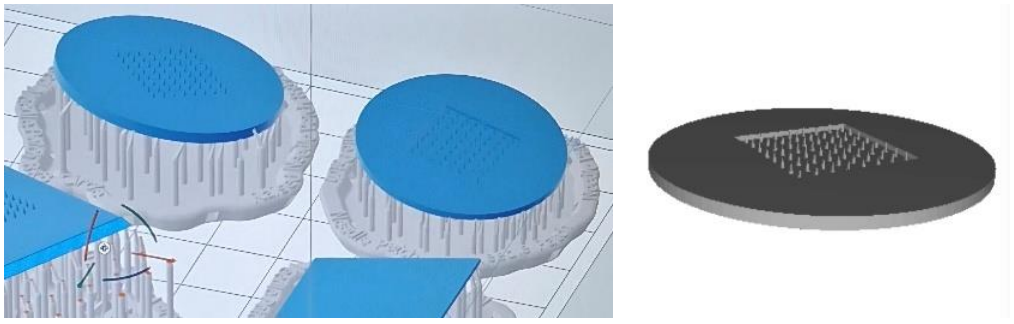


Figure 2: 3D design of microneedle patch mold.

4.2. Manufacturing Methods of 3D-Printed Microneedles

4.2.1. Nozzle-based deposition system

4.2.1.1. Fused deposition modelling (FDM)

It is also referred to as the fused filament fabrication (FFF) method, which is the newest and most affordable microneedle array printing method. The FDM method relies mostly on hot-melt extrusion of thermoplastic polymer filament at the printer head. The polymer filament is concurrently being extruded and placed on the print station as the print head moves by the design in the 2D slice, and 3D structure is generated, if this procedure is repeated.[15] Thermoplastic materials can alter their shape when introduced into FDM 3D Printer and used as the starting material of this method that help to create MN arrays particular needle length, width, pitch, and density.[12] In the FDM method diverse range of thermoplastic polymers can be selected and utilized, such as polylactic acid (PLA), thermoplastic polyurethane, nylon, polyether ether ketone, and polyetherimide. The main limitation of this method is its low printing resolution and poor dimensional accuracy. This will make the surface of the microneedle array rough, and an additional post-processing step needs to be taken to smooth the surface.[15]

4.2.2. Laser-based writing system (photopolymerization technique)

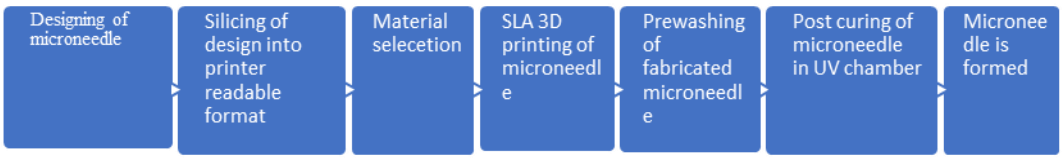
4.2.2.1. Stereolithographic method

SLA 3D printing technology is an extensively utilized 3D printing technique in the development of transdermal MNs due to its inexpensive printing cost and high printing resolution. SLA method is based on Vat photopolymerization and can selectively polymerize photosensitive polymers utilizing laser emission of projection lights. It is a liquid-based process that uses laser beam to scan photosensitive materials like resin and enables the controlled layer-by-layer solidification of the photosensitive materials. The laser tracks and draws each layer by moving along the X-Y plane and solidifies each layer.

SLA printer contains a printing platform, UV rays, and a resin tank where the desired resin is kept. Class 1 biocompatible polymer resin is used to print a cone and pyramidal geometrical microneedle patch. Based on the filling mechanism SLA process is of two types;

a) Free surface approach: The structure is printed layer-by-layer from a support platform that lies below the resin surface.
b) Constrained surface approach: The building platform is fixed above the resin bath.

The solid microneedle patches fabricated using SLA 3D printing show improved piercing capability into human skin and can withstand high force without breaking. To develop a 3D printed microneedle-mediated drug delivery system that allows in-situ control of drug administration by personalized drug therapy, SLA 3D printed hollow microneedles are combined with a diaphragmatic micropump as a microelectromechanical system. SLA 3d printer also helps to create low-cost in-lab microneedle master molds rapidly using print and fill microneedle fabrication technology.



Flow chart 1: Steps involved in SLA 3D printing of microneedle.

4.2.2.2. Digital Light Processing (DLP)

DLP is a high-resolution printing method that is capable of printing objects with a smooth surface and illuminating the entire cross-section of objects as volumetric pixels, and the complete layer is formed simultaneously. DLP printing is considerably faster than SLA printing, and the only difference between DLP from SLA 3D printing technology is in the light source used.[16]

4.2.2.3. Two-Photo Polymerization (TPP)

TPP is a one-step and rapid method that allows layer-by-layer fabrication of 3D structures based on two-photon absorption using solid, liquid or powder precursors. Using TPP, 3D microstructures with extremely high resolution can be created by focusing ultrafast laser beam like femtosecond directly on a photosensitive material after a drop of resin has been deposited on a glass substrate and this make the two-photon to absorb inside the focal zone which initiate polymerization. TPP technology can be employed for the industrial scalability and can make use of many low-cost materials like ceramics, polymers, and other photosensitive materials. The hollow microneedles containing reservoir, fabricated using TPP 3D printing method are appropriate for transdermal sampling or drug delivery. This method offers accurate and ultra-fast 3D printing of structures in submicron range with high spatial resolution.[16]

4.2.3. Powder Bed Technology

4.2.3.1. Selective laser sintering (SLS)

SLS is one of the 3D printing technologies that uses high-powered laser as a concentrated heat source to fuse small particles of thermoplastic powder into a 3D solid

structure. Sintering enables the powder particle to fuse together by heating without reaching melting point and thus form strong, cohesive solid structure with fine detailing and dimensional accuracy. SLS works by spreading a thin layer of powder evenly on the build platform and a laser selectively scans and sinter the cross-section of the 3D structure layer-by-layer based on 3D model. After each layer is sintered, a new layer of powder is spread over the previous one. The process is continued until the final structure is completed.[17]

4.2.3.2. Selective Laser Melting (SLM)

The principle used in SLM 3D printing is similar to SLS and DMLS methods, in addition SLM needs a support structure to hold the material to the build platform and the thermal stress is reduced. Usually, metal powder is usually used to form successive layers by melting it and get fused after laser scanning. They have superior mechanical property and good strength.[16]

5. APPLICATION OF 3D-PRINTED MICRONEEDLE

5.1. Immunobiological drug delivery

Usually, vaccines are administered as intramuscular or intradermal injections. But the utilization of microneedle drug delivery encourages people to take the vaccine due to its non-invasive property. The penetration time of monoclonal antibody using maltose had been decreased from 24 hours to 1 min by the use of dissolving microneedle.[18] 3D-printed microneedles have the potential to increase the drug retention in skin and to improve humoral immune response. Vaccine-coated microneedles can be easily handled and transported from one place to another without any special requirements or environmental conditions. In the future, 3D printed microneedles enable an increase in vaccination rate because of their ease of handling and self-administration property.[19]

5.2. Cancer therapy

Dissolving microneedle array with the chemotherapeutic agent doxorubicin, hyaluronic acid, and gold nanocages is used to treat superficial skin tumours. A hollow microneedle containing a large synthetic peptide can be used as a cancer vaccine that can enhance the T-cell activity against cancer. 3D-printing technologies like SLA and inkjet methods enable to coating of microneedles with cisplatin, a cancer therapy product, and allow 80-90% cisplatin delivery within 60 minutes. Tamoxifen and gemcitabine can be loaded on microneedles using the coating method and can be effectively used to treat breast cancer.[18]

5.3. Disease treatment

The therapeutic agents, like biological agents, peptides, proteins, hormones, etc, cannot be administered orally due to their first-pass metabolism. So, they can be efficiently delivered to their target tissue using the microneedle drug delivery method. Insulin microneedle array patches are developed to manage blood glucose levels in type 1 diabetic patients. The microneedle intended for transdermal drug delivery of insulin can be designed using SLA 3D printing technology and fabricated using biocompatible resin.[18]

5.4. Cosmetic application

Microneedles can effectively deliver cosmeceuticals into the skin through microchannels without reaching facial nerves. It also induces less erythema and post-inflammatory hyperpigmentation after the removal of scars with laser. A microneedle patch containing ascorbic acid and retinyl retinoate is used for the treatment of wrinkles.[18] 3D printed microneedles offer site-based drug delivery that can target skin locations such as stratum corneum, epidermis, dermis, hypodermis, and deeper tissue layers. Personalized 3D printed microneedles fabricated using digital light processing (DLP) technology can be optimized for the delivery of anti-wrinkle peptides and have great potential for the transdermal drug delivery of acetyl-hexapeptide 3 (AHP-3).

5.5. Wound healing

Acrylate-loaded microneedles possess a promising effect for the treatment of wounds and reduction of skin infections. Also, the microneedle array filled with drug-eluting hydrogel helps in the delivery of vascular endothelial growth factor (VEGF), which promotes the epithelialization in wounds. 3D printing microneedle mold fabrication technique provides support for building high drug loading complex structures and more microneedles with wound healing property.[19]

5.6. Biosensing and diagnostic applications

3D printed microneedle arrays have been identified as a promising candidate for fabricating biosensing setups, which can be utilized in point-of-care biosensing applications, when the target molecules and biomarkers are readily collected using microneedle arrays. Microneedle-based biosensors can provide an invasive and convenient sampling approach. For glucose monitoring, microneedle-based biosensors have been developed. Microneedles which having the capability to draw interstitial fluids containing biomarkers are used to analyse and detect various diseases and tumours in humans. Metal-coated and dissolving microneedles can be used for gene therapy and the delivery of low and high-molecular-weight agents.[19]

6. CHALLENGES IN THE FABRICATION OF MICRONEEDLE

6.1. Parameters affecting microneedle insertion

The insertion and penetration nature of microneedles on skin depends upon various parameters like geometry, tip and base diameter, sharpness, length, etc. The geometric structure of microneedles affects the mechanical strength and penetration of microneedles. The microneedles having sharp edges of triangular and square shape have superior insertion capacity compared to hexagonal

microneedles. The sharpness of the tips of the microneedles can control the skin puncture force.

6.2. Loading capability and dose accuracy

Loading Capability: The coating type microneedle only contains 1mg of medicine, and the passive diffusion nature of nature of drug across the skin makes it difficult to deliver high dosages.

Dosage accuracy: It is difficult to control and monitor the drug delivery of solid microneedles.

6.3. Biocompatibility, biodegradability, and stability

Dissolving microneedles should be prepared using biodegradable polymers. Because they have to be degraded and removed from the body safely. The evaluation of the biocompatibility of the microneedle using various tests is necessary to ensure its safety in clinical use. The stability of microneedles can be assessed to ensure their degradability and fragile nature of microneedle. They are usually stored at different temperatures like -25^{0}C, 4^{0}C, 20^{0}C, 40^{0}C and 60^{0}C.

6.4. Sterilization of the microneedle patch

Sterilization is one of the main challenges in the formulation of microneedle patches because sterilization can affect the morphology, physicochemical, and mechanical properties of microneedle patches. The most commonly used sterilization methods, like moist heat, gamma or microwave radiation, and ethylene oxide, may adversely affect the microneedle patch if it contains sensitive ingredients like biomolecules, vaccine peptides, etc. Solid microneedles can be directly sterilized using the dry heat sterilization method, the moist heat sterilization or by gamma radiation method. Ethylene oxide and electron beam sterilization methods are effective but less destructive sterilization methods.

6.5. Skin irritation and recovery

Depending upon the size, properties, and type of therapeutic agent, the skin may produce mild or temporary erythema due to the immunogenic nature of skin. Therefore, the drug should be evaluated for all its safety assessments like, skin irritation, sensation, and immune response, in animals before a human clinical trial.[20]

CONCLUSION

The integration of microneedle technology with 3D printing represents a significant breakthrough in non-invasive transdermal drug delivery. The barrier effect of skin can be effectively overcome using microneedle patch, which offers painless and efficient delivery of wide spectrum of therapeutic agents such as vaccine, insulin, cosmetic compound and anti-cancerous drugs. It is possible to design and fabricate customized microneedle with required geometry and precision using 3D printing technologies, including FDM, SLA, DLP, TPP and SLS leading to personalization of medicine. These innovative drug delivery methods enhance patient compliance, drug delivery, bioavailability and have rapid onset of action comparing to conventional drug administration techniques. Despite microneedle patch have impressive advancement, they still confront numerous critical challenges like drug loading capability, dose precision, biocompatibility, sterilization et.al. As 3D printing technology continues to advance, all these challenges will be addressed in future. While, 3D technology offers minimum development cost and less material wastage it can be widely use in microneedle fabrication and paving way for a new era of patient-centric, highly effective, efficient and globally accessible drug delivery system.

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