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Microneedle Drug Delivery System: Formulation, Evaluation and Application

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ABSTRACT

Transdermal drug delivery systems (TDDS) have emerged as a promising alternative to conventional routes of drug administration due to their ability to bypass first-pass metabolism, improve patient compliance, and provide controlled drug release. However, the stratum corneum acts as a major barrier, limiting the permeation of many therapeutic agents, especially hydrophilic drugs and macromolecules. Microneedle (MN) technology has gained significant attention as an innovative approach to overcome this limitation by creating microchannels in the skin, enabling efficient drug delivery with minimal invasiveness and pain. Microneedles, typically ranging from 0.2 to 1.5 mm in length, facilitate drug transport into the epidermal or dermal layers without reaching nerve endings, thereby enhancing patient acceptability. By using the polydimethylsiloxane mold PDMS the microneedle patch can be fabricated by using various polymers. Various types of microneedles, including solid, hollow, coated, dissolving, and hydrogel-forming systems, have been developed with distinct mechanisms such as “poke and patch,” “coat and poke,” “poke and release,” and “poke and flow.” These systems offer advantages such as improved bioavailability, rapid onset of action, accurate dosing, and reduced plasma concentration fluctuations.

Keyword: Microneedle, stratum corneum, control release, PDMS mold, patient compliance

1.0 INTRODUCTION

The microneedles (MNs) were first described as a novel method of drug delivery in 1998[1].Transdermal delivery has the advantages of increased local drug concentration, lower systematic exposure, no hepatic first-pass metabolism, and improved patient compliance, it is the preferred drug administration route for treating disorders that are localized within the skin . However, most therapies, especially those that are hydrophilic, cannot penetrate the stratum corneum (SC) because to its barrier function . To aid in cutaneous penetration, numerous physical tools and techniques have been developed, including microneedles (MNs), iontophoresis, sonophoresis, magnetophoresis, electroporation, and photomechanical waves.

Because they make it possible to penetrate the stratum corneum and transfer medications into the skin, microneedles—a collection of needles that are smaller than a micron—are the most efficient. Moreover, many oral drugs have low bioavailability; this issue can be addressed by using the transdermal drug delivery system , specifically for the delivery of macromolecules, peptides, and proteins that typically have low bioavailability via the oral route Microneedles, an array of micron-sized needles, are the most effective because they enable breaking the barrier of the stratum corneum for delivery of therapeutics into the skin].In addition, the needles are only 0.2–1.5 mm in length, producing minimal invasion and enabling self-administration like a patch [2].

Microneedles produce temporary passageways in the skin's outer layer, circumventing the barrier and allowing medicinal chemicals to be delivered that are not transdermal]. The microneedle has a small shaft that penetrates the stratum corneum but does not reach the nerve terminals. The characteristic features of this technology are the faster onset of action, better patient compliance, self-administration, improved permeability and efficacy. There are various type of microneedle like solid, hollow, coated, dissolving and hydrogel forming microneedle drug delivery.

Drug distribution typically uses a variety of MNs methods. In order to create pores, solid MNs must first pierce the skin. After removal, the region is covered with a transdermal patch or gel formulation to aid in distribution. As an alternative, MNs can be coated with the agent before being applied to the skin[3]. Drug-encapsulating biodegradable MNs are often designed to separate beneath the skin, allowing for controlled drug release[4]. Drugs are administered via hollow MNs in a manner akin to injection, but

with the use of physical forces like as pressure and diffusion[5]. A variety of materials, including silicon, metal, biodegradable or non-biodegradable polymers, and glass, have been used to create microneedles[6].

Microneedle have been used for different applications such as drug and vaccine delivery, cosmetic, and disease diagnostics. MN have various structural arrangements, shapes, forms, and materials. Accurate dosing and metering of microneedles is crucial for giving delicate medications like insulin and chemotherapy. Microneedle patches have comparable therapeutic efficacies to oral consumption with lower dosages due to bypassing digestion and first-pass metabolism .Microneedles have quick bloodstream uptake, making them effective for treating localized diseases with reduced medication loading compared to oral treatments. As it eliminated the pain which is involved in the hypodermic needle when administered Intravenously and so it will patient complaince self administration These microneedle reduces the fluctuation in the plasma concentration, which are applicable for the drug which has short half life drug.

In order to produce a quick therapeutic effect, drugs can be administered directly into the bloodstream using a variety of methods, including intramuscular (IM) and intravenous (IV).However, there are several disadvantages to the parenteral drug delivery method. First of all, injection entails the painful insertion of a hypodermic needle into the skin, which reduces patient compliance. Second, the administration and management of drugs require trained personnel. Transdermal drug delivery systems (TDDS), mucosal administration, magnetically modulated drug delivery systems, nanofibers, inhalers, and nano-tubing are examples of newer, safer, and more efficient methods that have been developed to eliminate these documented disadvantages[7].

2.0 TYPES OF MICRONEEDLES

2.1 SOLID MICRONEEDLE

Solid microneedles are commonly used to create pores on the skin prior to treatment. The pointed tips of needles pierce the skin, creating micron-sized channels that allow drugs to enter the skin layers when applied as a patch this increases permeation. The medication is taken up by the capillaries, causing a systemic impact. Additionally, it can have a local effect [29]. Solid microneedles deliver drugs to epidermal layers by passive diffusion. Solid microneedles are easy to manufacture, have superior mechanical properties, and sharper tips when compared to hollow microneedles . Moreover, the solid microneedle can be fabricated from different materials such as silicon, metals, and polymer. Proteins, peptides, growth hormone, insulin, and vaccinations can all be administered using solid MNs. Additionally, they can be utilized to provide medications in semisoliddosageforms[8]. Solid MNs increase skin permeability without harming the stratum corneum. They can be used to provide proteins, peptides, and growth hormone. Compared to hollow MNs, solid MNs are simpler to create, have sharper tips, and increase skin permeability without harming the stratum corneum. They can also be utilized to provide medications in semisolid dose forms. In contrast to hollow MNs, solid MNs are easier to create, have sharper tips, and have mechanical properties.

2.2 HOLLOW MICRONEEDLE

A hollow microneedle can deliver drugs into the epidermis or dermis, making it ideal for high molecular weight molecules. Additionally, it regulates drug release over time, making it appropriate for use with liquid vaccines. Hollow microneedles can have variable release kinetics by optimizing their material formulation and production settings. Higher concentration pharmaceuticals can cause burst release, whereas matrix-loaded medications can provide steady-state release for days to weeks, depending on the application. The hollow microneedle has been successfully applied to a range of vaccines. These consist of empty cavity inside each needle of microneedle and a bore on a needle tip. These allow the movement of drug solution to be injected and which involves a mechanism of poke and flow. Hollow microneedle is made up of ceramics, metal, glass[8].

2.2.1 Limitations:

- Expensive and complex manufacturing process.
- Diminished mechanical strength in comparison to solid microneedles, particularly when silicon is used.
- Clogging caused by skin tissue during implantation.
- Poor insertion may be linked to a larger tip diameter.
- Infusion rates are limited by back pressure (10-100 l/min).

- Retraction is required after insertion in order to boost infusion rates.The necessary flow rate must be controlled (microfluidics component).[11]

2.3 COATED MICRONEEDLE

This approach uses the "coat-and-poke" procedure to deliver medicines. It is made of stainless steel and titanium. In a single step, the medication coating is placed to the MNs prior to their subcutaneous insertion. The pharmacological coating from the MNs can be absorbed by the skin. After then, the MNs are eliminated and dissolved. Only a specific quantity of medication can be applied to the tip and shaft of MNs. The thickness of the coating solution and the size of the needle have an impact on the medication dosage. The coating may enhance the MN's target selectivity and functionality. Additionally, it enhances the MN's mechanical qualities, making it more resilient and long-lasting[8].

Drugs, including proteins and peptides, can be administered minimally invasively using coated MNs. Coated MNs allow for self-administration, which eliminates the need for hospital stays, specially trained personnel, and the related expenses. The creation of biocompatible coated MNs with no adverse effects is one obstacle that needs to be overcome. The second challenge is that the costly and time-consuming production process of the coating process can occasionally make it challenging to scale up.

2.3.1 Limitations:

- Coating formulation and technique are key to success.
- Only strong medications may be coated in a limited quantity.
- The delivery of the coated medication was crucial.
- Increased coating could make the needle less sharp.[11]

2.4 DISSOLVABLE MICRONEEDLE

Dissolvable microneedle which use the biodegradable polymer in which the drug is been incorporated. After been penetrating into the stratum corneum the polymer dissolves and release the drug rapidly. The application of dissolving microneedles involves a one-step approach since the micro-needle is not removed following application. This can be described as a ‘poke and release’ type mechanism. With lengths of only a few millimeters, dissolving MNs (DMNs) are incredibly tiny. This method entails encasing medications in MNs. The MNs disintegrate once they are placed and cannot be taken out of the skin. Dextrin, polyglycolic acid, chondroitin sulphate, and polyvinylpyrrolidone are commonly found in DMNs when selecting a dissolving MN scope, the two most crucial factors to consider are their nature. The body cannot absorb the drug if a DMN polymer dissolves and is released too quickly, kinetics, casting, air blowing, droplet-born skin irritation, laser discomfort, machining, or hot embossing. Microinjection researchers are developing molding, MNs, and ultrasonic that dissolve welding at the best performance rate of MNs of delivery is impacted by their hygroscopic problem in the natural world. A DMN cannot be absorbed by the body if it degrades too quickly. Degradation occurs if DMNs disintegrate as well[10].

2.4.1 Limitations

- Risk of skin breakage Drug stability is not supported by fabrication methods because of rigorous production circumstances.
- Drug loading capacity is limited (~1 mg on an array of 1000 microneedles).
- It is not appropriate for encasing delicate macromolecules.
- It is necessary to have a mechanism to guarantee that microneedles dissolve or remain in the skin before the base or applicator is removed (notch design).
- Careful material selection is necessary to guarantee quicker disintegration[11].

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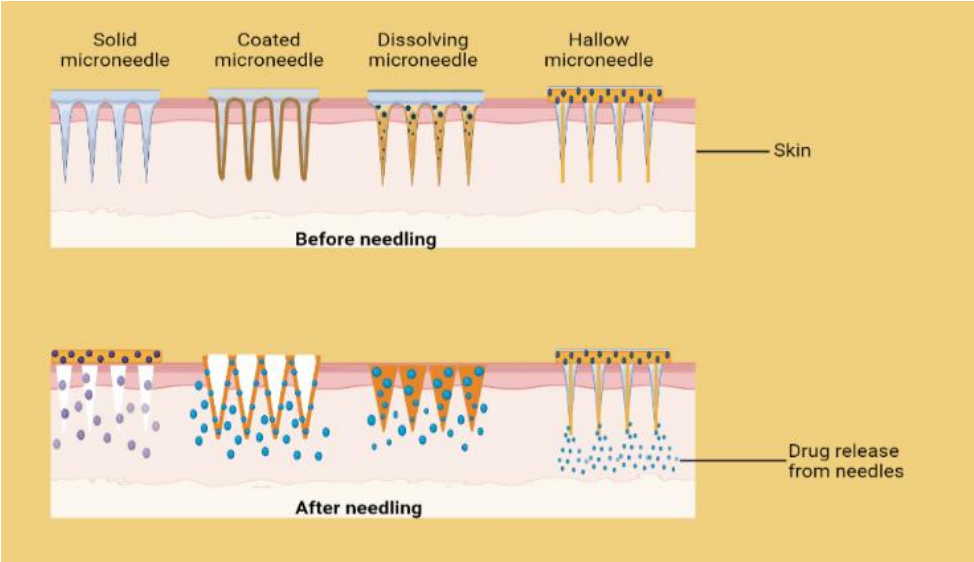

Figure 1: Types of microneedle and their mechanism.[23]

3.0 MECHANISM OF DRUG DELIVERY

The medication is administered topically using the diffusion technique. The skin is momentarily disturbed in the microneedle drug delivery device. To administer enough medication to provide the necessary therapeutic response, a microneedle device is created by arranging hundreds of microneedles in arrays on a tiny patch. It avoids the barrier layer by puncturing the stratum corneum. The medication is applied directly to the epidermis or higher dermis layer, where it enters the systemic circulation and, once it reaches the site of action, exhibits a therapeutic reaction[12].

There are various approaches of drug delivery for various type of microneedle:

- Poke and patch
- Coat and poke
- Poke and release
- Poke and flow

4.0 Advantage:

Because medications supplied by an MN avoid important human organs including the liver, it is regarded as one of the best methods for transdermal drug administration[16]. Additionally, by offering a painless experience, it removes the discomfort related to IV injection[17]. It is therefore thought to be the greatest option for those who suffer from needle anxiety (trypanophobia). Because microneedle transdermal drug delivery applications don't require skilled staff, they are easier to employ[18]. Additionally, this lowers the chance of infection entering the body [19].

5.0 Disadvantages:

The use of a microneedle for transdermal drug delivery has drawbacks, including longer application times, the need for several patches in a given area, the need for a certain mechanical strength, and the need for a good biocompatible material[20,21]. The challenge of obtaining meaningful pharmacokinetic data via the MN patch route can affect dosing parameters and possibly cause negative side effects. According to Bariya et al., when taking into account the variations in the thickness of the stratum corneum and other skin layers from a variety of patient populations, MN depth design should also be carefully taken into account [22].

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6.0 FORMULATION METHODOLOGY

Preparation of microneedle patch using micromolding technique.

Micromolding is one of the best methods to fabricate the microneedle patch. An appropirate dissolving polymer like polyvinylalcohol, polyvinylpyrrolidine was used for fabricating dissolving microneedle patch. First, dissolve PVA with heating and then add PVP previouly dissolve in cold water and the add the drug. Now Drug polymer blend is been poured on to the Polydimethisiloxane mold. Centrifige for 1500rpm for 10 mins to get an uniform distribution and to remove air bubbles dried for 2 days and then kept in freezer for 30 minutes at 4 °C for easy separation of microneedle patch from the micro molds. The fabricated patches were peeled off from the molds using forcep, stored in butter paper in desiccators. The formulated microneedle patches were evaluated for proper formation of needles, mechanical properties, insertion capability and dissolution of needles to optimize the polymer ratio.[11]

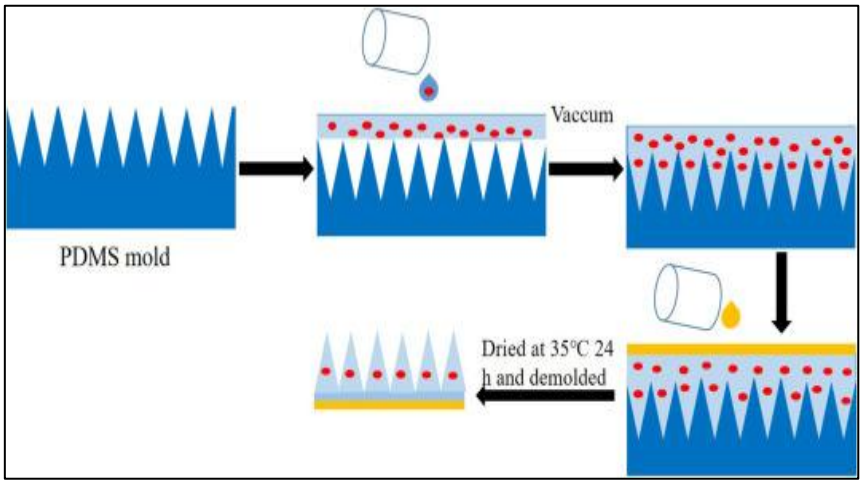

Figure 2 : Micromolding technique by using PDMS mold for formulation of microneedle patch[24]

7.0 EVALUTION PARAMETERS[11]

7.1 Physical examination

The formulated microneedle patch was evaluated for homogeneity, clarity, color, and proper formation of needle.

7.2 Uniformity of weight

By weighing each formulated patch separately and comparing its weight to the average weight of the prepared patches, the microneedle patches were exposed to mass fluctuation. An analytical balance that had been calibrated was used to measure the patch weight. For every formulation, the calculation was done in triplicate.

7.3 Surface PH

The surface pH of the microneedle patches was measured using a calibrated pH meter. In a test tube, 1 mL of distilled water and microneedle patch was kept at room temperature (25 ± 2°C) for 2 h. The water from the test tube was decanted and the wet patch was used for surface pH analysis. The pH electrode was placed at three different places at the swollen part of the patch for calculating the average pH.

7.4 Percent moisture content

The prepared microneedle patches were weighed individually and kept in desiccators containing fused calcium chloride at room temperature for the duration of 24 hours. After 24 hours, the films were re-weighed and the percentage moisture content was determined by the given formula:

$$\% \text{ moisture content} = (\text{Initial weight of patch/Final weight}) \times 100$$

7.5 Percent moisture uptake

The prepared microneedle patches were weighed individually and kept in desiccators containing buffer solution at room temperature for the duration of 24 hours. After 24 hours, the films were re-weighed and the percentage moisture content was determined by the given formula:

% moisture uptake = (Initial weight of patch/Final weight) ×100

7.6 Mechanical properties

The mechanical strength of microneedle patches against static forces was measured by placing different weights over the patches. The microneedle patches were placed on a solid platform needle upward, onto which weights of 50 g, 500 g, and 1000 g were placed gently on the top of each patch, respectively. After 5 min, the weights were removed, and morphological changes were evaluated.

7.7 In-Vitro permeation studies

A Franz diffusion cell with a 15 ml receptor chamber was used for the in vitro drug permeation investigation. The microneedle patch was placed between the donor and receptor chambers of the Parafilm M®. Phosphate buffer saline pH 7.4 was added to the receptor chamber, and the solution was agitated with a magnetic stirrer at 37 °C±0.5 °C. At intervals of 15, 30, 60, 120, 240, 360, and 480 minutes, a 5 ml sample was taken out of the receptor chamber and replaced right away with new phosphate buffer saline pH 7.4. Using a UV spectrophotometer (Shimadzu 1700) set to 280 nm, the drug concentration in the removed samples was determined.

7.8 Drug content test

The optimized microneedle patch (OPBTMN) was placed in a beaker with 50 ml of phosphate buffer saline pH 7.4 and stirred for 1 h to dissolve the microneedle patch. The resultant solution was appropriately diluted with phosphate buffer saline pH 7.4 and analyzed on UV-spectrophotometer (Shimadzu 1700) at 280 nm. The percentage of drug amount was calculated as per the formula mentioned below.

$$\%\ \text{Drug amount} = \frac{(\text{Estimated amount of drug})}{(\text{Total amount drug loaded})}$$

7.9.Invivo animal study

The study may employ hairless rats. The animal must be put to sleep using an appropriate method. Trans-epidermal water loss (TEWL), which is evaluated both before and after microneedling, is one of the factors taken into account. This parameter is measured with a Delfin Vapometer.[15]

8.0 APPLICATIONS

8.1 Cosmetics:

The use of microneedles in cosmetics is becoming more and more popular, particularly for treating scars and imperfections on the skin. The microneedle method was used in an attempt to provide various cosmetic active substances, such as ascorbic acid, eflornithine, and retinyl retinoate. Melanin was added to phosphatidylcholine liposomes (also known as nanoliposomes), which demonstrated improved lipid solubility. Various application of microneedle are been used for anti aging, skin rejuvenation, atropic scar ends, hypertrophic burn scar, tropic facial scar, vagaries, skin lesion a hyaluronic acid-based dissolvable MN patch for the intradermal delivery of ascorbic acid and retinyl retinoate for anti-aging. To reduce facial hirsutism a drug delivery of efloritine is been used[16].

8.2 Delivery of insulin via microneedle patch:

The subcutaneous approach is recommended for medications like insulin or different immunotherapy treatments, although discomfort, inconsistent pharmacokinetics, and low absorption are significant problems. Concerns about dosage repeatability and local effects are frequently raised by alternative administration methods, such as nasal or inhalational delivery. Lastly, because there are only a few drugs available—many of which are employed in the dermatological field—topical routes are restricted. This pathway is mostly restricted by the pharmacologic agent's capacity to permeate through the stratum corneum, the skin's outermost layer[14].

Microneedles are long enough to penetrate the epidermis and the outermost stratum corneum, but not deep enough to activate the dermal nociceptive nerve endings . Additionally, their narrower, shorter shapes help minimize pain. Furthermore, MNs may direct the delivery of drugs to the dermis, a layer with abundant lymphatic and vascular perfusion. Additionally, this layer has distinct pharmacokinetic and pharmacodynamic characteristics, which are presently being studied for systemic applications[14].

Drug distribution typically uses a variety of MNs methods. In order to create pores, solid MNs must first pierce the skin. After removal, the region is covered with a transdermal patch or gel formulation to aid in distribution. An alternative is to coat MNs with the chemical before applying them to the skin. Drug-encapsulating biodegradable MNs are often designed to separate within the skin, allowing for controlled drug release. Drugs are administered via hollow MNs in a manner akin to injection, but with the application of physical factors such as pressure and diffusion.

Insulin is a peptide hormone that is used to treat elevated blood sugar. It was discovered that administering insulin by microneedle reduced blood glucose levels more effectively (Martano et al., 2004.Insulin administered via manufactured solid microneedles lowers blood glucose levels to 29% of the starting level at 5 hours, confirming the enhanced permeability of insulin to the skin in diabetic mice [9].

Microneedles were combined with pancreatic β-cell capsules, which sense blood glucose levels and secrete insulin. However, the patch was found to be ineffective, so a microneedle matrix containing synthetic glucose signal amplifiers (GSAs) was created. This matrix consisted of nanovesicles that contained the enzymes glucose oxidase, α-amylase, and glucoamylase. These amplifiers displayed the β-cell capsules' insulin secretion[9].

8.3 In the treatment of pain:

Numerous strategies have been put out to create quick and painless intradermal medication delivery for anti-inflammatory and pain control treatments. Zhan et al. created lidocaine-loaded dissolvable microneedles that produced statistically significant anaesthetic efficacy. When applied to hairless rats, Tas et al.'s dissolvable polyvinylpyrrolidone microneedles loaded with dihydroergotamine mesylate demonstrated relative bioavailability and plasma levels that were not statistically significantly different from a subcutaneous injection. Xie et al.'s dissolvable microneedles loaded with a selective antagonist of calcitonin gene related peptide, a neuropeptide involved in the perception of neuropathic pain. The team demonstrated increases in rats' pain thresholds in response to mechanical and thermal stimulation using a number of neuropathic pain models.[9] Polydimethylsiloxane molds were used to create polymeric microneedles filled with meloxicam. About 100% of the medication was released in 60 minutes, according to the in-vitro permeation experiments. Improved transdermal flow of 1.60 µg/cm2/hr was noted, and the drug deposition was found to be 63.37%. In comparison to the free medication solution, the penetration increased 2.58 times[15].

8.4 Anti-cancer therapy:

Since cancer is still one of the principal causes of morbidity and death in the world, sophisticated medication delivery methods that maximize therapeutic efficacy while reducing systemic toxicity must be developed. Chemotherapy, radiation, and surgery are examples of conventional cancer treatments that are frequently linked to serious side effects, low patient compliance, and non-specific medication distribution. Microneedle (MN) technology has shown promise in this regard as a minimally invasive transdermal delivery method for the treatment of cancer. Tamoxifen and gemcitabine can be delivered through microneedles for the treatment of breast cancer. Basal cell carcinoma is treated with a topical lotion that contains 5-fluorouracil. Applying the lotion to skin treated with solid microneedles increased the permeability of 5-fluorouracil by up to 4.5 times[9].

8.5 Skin disease:

Skin conditions include vitiligo, psoriasis, atopic dermatitis, acne, fungal infections, and skin malignancies are major global health burdens. Because of the stratum corneum's barrier function, conventional topical treatments frequently have inadequate skin penetration, and systemic treatments may have unfavourable side effects. Targeted, minimally invasive, and effective medication delivery devices are therefore desperately needed. Microneedle (MN) technology has become a potential transdermal platform for the treatment of a number of dermatological conditions[16].

8.6MELASEMA

Melasma is a disorder characterized by symmetric hyperpigmentation that can be caused by a variety of factors, including exposure to ultraviolet light or hormone imbalance. An examination of the histology of melasma reveals larger melanocytes as well as enhanced skin pigmentation. The use of hydroquinone or corticosteroid or corticosteroid creams is part of the traditional therapy for formelasma melasma, although it has limitations and weak TD penetration.

PVP was used to create polymeric MNs, and PVP methacrylic and methacrylic acid were loaded with tranexamic acid. In tests for acute toxicity, it was discovered that the manufactured MNs were both biocompatible and nontoxic. The full release of MNs in the skin was noticed within seven hours. A simulated assessment of the diffusion coefficient interstitial in interstitial fluid was used to observe the effectiveness of drug administration[16].

8.7 Scar:

The microneedle has been used for in the treatment of scars like Atopic acne vulgaris scar MN and a 15% trichloroacetic acid peel were part of the combined treatment. MN alone or in combination with MN 35% glycolic acid peels improves skin texture, scarring, and post-inflammatory hyperpigmentation. MN has also been used to treat hypertrophic surgical scars by enhancing topical drug delivery to the dermis. Collagen production is encouraged by topical application of vitamins A and C combination[16].

8.8 VACCINE MICRONEEDLE PATCH

One typical kind of MN used to administer vaccines is a dissolvable MN. The hypodermic injection needles that were normally used to give immunizations were replaced by the dissolvable MNs. The dissolvable MNs are durable, scalable, biocompatible, and do not produce biohazardous waste, in contrast to other types of MN]. Vaccines against malaria, diphtheria , influenza hepatitis B HIV], and polio were administered using dissolvable MNs. The anthrax recombinant protective antigen vaccine has been administered to rabbits via hollow MNs rather than a standard injection . In a mouse model, a hollow microneedle was assessed for plaque vaccination]. When compared to intramuscular injection, a human clinical trial utilizing hollow microneedles for influenza immunization demonstrated comparable immune system outcomes. encoded hepatitis C virus protein in a microneedle-coated DNA vaccination . In mice, the microneedle was successfully primed for certain cytotoxic T lymphocytes (CTLs). Additionally, a coated microneedle with influenza viral antigen was used to vaccinate mice. A study administered the Bacillus Calmette-Guérin (BCG) vaccine with a coated MN in order to strengthen the pigs' immune systems in a straightforward, safe, and compliant manner[13].

9.0 Conclusion

Microneedle technology represents a transformative advancement in transdermal drug delivery, effectively overcoming the limitations imposed by the stratum corneum while maintaining a minimally invasive and patient-friendly approach. The diversity in microneedle types and drug delivery mechanisms allows for flexible design tailored to specific therapeutic needs, ranging from small molecules to complex biologics such as proteins, peptides, and vaccines. The use of biodegradable polymers and advanced fabrication techniques has further enhanced the safety, efficiency, and scalability of microneedle systems. Additionally, their ability to provide controlled drug release, improved bioavailability, and reduced systemic side effects makes them highly advantageous compared to traditional oral and parenteral routes. Despite these benefits, challenges such as large-scale manufacturing, cost-effectiveness, long-term stability, and regulatory considerations still need to be addressed. Continued research and technological advancements are expected to overcome these barriers and expand the clinical applicability of microneedles. In conclusion, microneedle-based drug delivery systems hold immense potential in revolutionizing modern therapeutics by offering a safe, effective, and patient-compliant alternative for the delivery of a wide range of drugs across various medical and cosmetic applications.

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