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A Review On Biodegradable Microneedles Used In Drug Delivery

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1.Abstract:

In recent years transdermal drug delivery systems (TDDS) have gotten a lot of attention as a non-invasive and patient friendly way to administer drugs. The global TDDS market was valued at USD
5.7 billion in 2018 and is expected to reach 7.1 billion dollars by 2023 and is growing
4.5 percent each year.

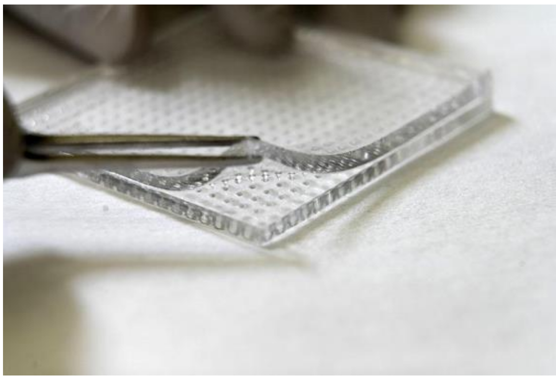
This review highlights recent progress in creating biodegradable microneedles from polysaccharide and protein-based materials. It focuses on carbohydrate polymers like cellulose and its derivatives starch, alginates, chitosan, chondroitin sulphate, xanthan gum all of which show great potential for microneedle fabrication. Overall, this review gives a broad overview of the current advancements, clinical potential, and patent landscape of biodegradable microneedle systems made from natural polymer materials.

Biodegradable microneedles are quickly becoming an exciting and commonly used option for delivering drugs through the skin in a painless and efficient way. This review explores how natural materials, especially carbohydrate-based polymers are used to create these tiny but powerful delivery systems.

2.Introduction:

The skin acts like a strong layer of protection. It mostly allows movement in one direction, from the body outward. This

natural defence system keeps most external substances out which makes it difficult for drugs to be absorbed through the skin. Because of this, delivering medications through the skin has been a challenge for a long time. In 1979, the U.S. FDA approved the first transdermal drug delivery system, Transdermal SCOP, to treat motion sickness and nausea. Since then, interest in this technology has grown a lot. The global TDDS market keeps expanding. It is expected to grow from 5.7 billion dollars in 2018 to around 7.1 billion dollars by 2023 with a compound annual growth rate of 4.5 percent, the skin is one of the most incredible organs in the human body. It acts as a protective shield and a complex biological interface. While it effectively shields against harmful external agents, it also limits the entry of helpful substances. This makes delivering drugs through the skin quite difficult.



3.History Of Microneedles:

The idea of microneedles has changed significantly over the years. Early experiments used large, basic needles. Today, we have advanced microneedle designs that are minimally invasive. The first recorded attempt to use something similar to microneedles was in 1905.A German dermatologist Dr. Ernest used motor-powered dental burs of different sizes to treat skin issues like scarring and hyperpigmentation. This helped pave the way for future developments in skin therapies.

The first documentation of microneedle use was done in 1921. It was described as injecting a needle into an egg's nucleus showing the potential for precise and localized delivery. By the 1960 scientists started exploring methods for delivering drugs directly into the stratum corneum. This marked an important shift toward targeted transdermal delivery.

The microneedle concept came in light in the 1970s. Still, it remained mostly theoretical then due to technology limitations. It wasn't until the 1990 that researchers could experimentally show microneedle-based drug delivery. This was possible because of improvements in microfabrication and biomaterial science. These breakthroughs paved the way for the modern microneedle systems we have now; they can deliver drugs, vaccines, and biomolecules safely and painlessly through the skin.

4.Types of Microneedles:

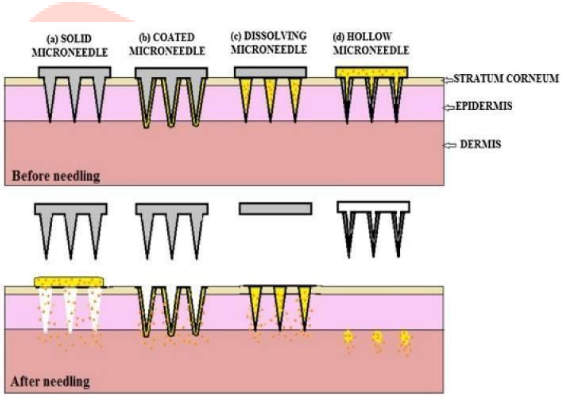
A wide range of various polymers have been used to create different types of microneedles. These include solid, coated, hollow and dissolvable designs. Each type of microneedle has its own unique features, benefits, drawbacks, and applications.

4.1. Solid Microneedles: They use a poke and patch approach to create microchannels for applying drugs later.

4.2. Coated Microneedles: In the coat and poke method, the drug is placed on the needle and dissolves upon insertion.

4.3. Dissolving Microneedles: Made from biodegradable materials these needles dissolve or disintegrate in the skin and release the drug.

4. **4.Hollow Microneedles**: These contain a liquid drug solution and inject it directly into the dermis. They work well for larger doses or molecules.



5.Materials used for Microneedles:

1.Silicon
2.Metal
3.Ceramic
4.Polymers

5. **1.Silicon:**

Silicon based materials are commonly used in medical and drug delivery applications due to their strong mechanical strength and stability against chemicals and heat. The processing technologies include laser techniques, and laser cutting. These methods are well-known and reliable. They allow for the creation of intricate silicon structures for various medical devices which include joint implants, infusion tubes, microfluidic systems, and contact lenses.

5.2. Metal:

Metals are frequently used in microneedle fabrication because of their great biocompatibility and mechanical strength. They have high fracture toughness and yield strength, which makes them stronger and less likely to break than silicon. The first metals used for microneedles were stainless steel, then titanium. Metal microneedles work well for piercing the skin, but their use may sometimes cause allergic reactions in sensitive individuals.

5.3. Ceramic:

Ceramic is used to make microneedles because they have very high chemical stability and strong compression resistance. However, ceramics usually have lower tensile strength than metals or silicon. This makes them more likely to break under stress. Other ceramics, such as calcium sulphate dihydrate and calcium phosphate dihydrate, have also been studied for microneedle production. Ceramic microneedles are usually made with the micro-Mold technique, which enables large-scale, affordable production. However, research has also shown that ceramic microneedles can break when applied manually on to the skin. This also tells us an important drawback of ceramic-based microneedles.

5. 4.Polymers:

Polymers are a flexible and promising material for making microneedles. They offer good biocompatibility, low toxicity, and are cost-effective. Although they usually have lower mechanical strength than silicon, metals, polymers are commonly used in dissolvable, hydrogel-forming, solid, coated, and hollow microneedle arrays. Biodegradable polymer microneedles have effectively delivered a range of drugs through the skin.

6.Manufacturing Methods for Microneedles:

6.1. Laser Ablation:

Laser ablation uses a light beam which removes material from the foundation. It shapes the material into microneedle arrays. This technique can work with materials at both micro and nano scales for various applications. Common laser types include Co2 lasers.

Laser ablation is fast and effective. The beam reaches the burn point in 10 to 100 nanoseconds. It is also a no contact process applying minimal heat to the substrate. This method can shape metals too. However, the heat produced at the cutting surface can change the microneedle structural and mechanical properties. This may lead to cracking or reduced fatigue resistance. Other drawbacks are high equipment costs and handling.

6. 2.Lithography:

Lithography is a method used to transfer patterns of geometric shapes in the foundation. Photolithography is the most common method because it is widely used in microelectronics. Other methods, like microelectronic and micro machining approaches often use lithography as the initial step in making microneedles.

This technique enables precise patterning of photoresist creating microneedles with accurate shapes and smooth vertical sidewalls. Lithography works with many materials, including glass, metals, ceramics, and plastics, making it useful for different applications. However, it requires specialized facilities, such as cleanrooms, takes longer to produce, and adds significantly to costs, making up roughly 30 to 35 percent of integrated circuit manufacturing expenses.

6.3. Micro Moulding:

Micro moulding is a process that makes a copy of an original Mold by casting it with a mix of a polymer and an activated pharmaceutical ingredient. This method is cost-effective and commonly used for producing microneedles especially from polymer materials.

PDMS (polydimethylsiloxane) is often used in micro-moulding because it is affordable, easy to handle, has low surface energy and maintains thermal stability. However, micro-moulding has some drawbacks, such as difficulty in controlling needle depth, drug loading capacity, and the mechanical properties of the polymer.

6.4. Injection Moulding:

Injection moulding is a common method for making microneedles, especially for large-scale production. In this process molten polymer is injected into a carefully designed Mold creating the microneedle array. The hot embossing technique often works with injection moulding to improve the accuracy and surface quality of the needles.

Several studies show how effective this method can be. Lhernould. created a 4 × 4 hollow polymer microneedle array using polycarbonate. This array withstood high insertion forces and could be reused many times without becoming dull Samoura.[17] moulded polymeric microneedles that successfully penetrated fresh chicken leg and beef liver extracting about 0.04 micro-L of liquid from the tissues.

Benefits of injection moulding include high reproducibility, scalability, and low cost, which make it ideal for mass production. It can work with various polymer materials such as PLA, PC, and PMMA. However, it can be difficult to precisely control needle dimensions, tip sharpness, and uniform drug loading. Also, the initial cost of making Molds can be high but the efficiency of large-scale production balances this out.

6.5. Additive Manufacturing:

In 2019 Johnson created the first microneedle template using a 3D printer. This achievement marked an important step in microneedle research. Following this Krieger established a twostep print and fill method. In this method the microneedle Mold is printed first and then filled with a polymer or drug loaded material to form the final MN structure. Other studies have also used stereolithography (SLA) and digital light processing (DLP) technologies to make high resolution MN patches. These techniques allow for precise control over tip sharpness and structural strength.

7.Applications of Biodegradable Microneedles:

1.Vaccine delivery

2.Disease diagnosis

3.Cosmetic applications

4.Biocompatibility of MN’s

7.1. Vaccine Delivery:

Dissolvable microneedles (MNs) are some of the most commonly used microneedles for vaccine delivery. They were created to replace traditional hypodermic needles. These microneedles offer a painless, safe, and easy option for vaccination. Unlike regular needles, dissolvable MNs are made from materials that are safe for the body and break down after use. This feature eliminates hazardous waste and reduces the risk of needle-stick injuries. These microneedles are strong and can be made in large quantities. They work well for mass immunization programs, especially in areas with limited resources where cold storage and trained staff are hard to find. Over the years, dissolvable MNs have been tested for delivering vaccines against malaria, diphtheria, influenza, hepatitis B, HIV, and polio.

7.2. Disease Diagnosis:

Traditionally diagnosing diseases and monitoring treatment effectiveness depend on bioassays that test body fluids like blood or interstitial fluid.[2] These methods assess a person's health, but they can be painful and require specialized equipmentand trained healthcare professionals. This makes frequent testing inconvenient and uncomfortable for patients.

In contrast microneedle technology provides a painless and user-friendly option for bioassays. Microneedles gently penetrate the skin surface to collect or analyse small amounts of body fluid without discomfort. This method simplifies disease monitoring and could lead to easy, at-home health testing and real-time diagnostics.

Hollow microneedles (MNs) have shown great potential in the diagnosis and monitoring of various diseases, including cancer, diabetes, and Alzheimer's disease . By allowing the extraction or delivery of fluids through tiny, precise channels, they enable minimally invasive sampling and real-time analysis.

Hollow glass microneedles have been used to measure glucose levels. This method is a less painful option compared to traditional finger prick tests. O'Mahony. also developed a microneedle-based system to improve the quality of electrocardiography (ECG) signals.[2] This shows its potential for continuous health monitoring. In another study researchers created enzyme functionalized microneedles to detect alcohol levels in artificial interstitial fluid.

7.3. Cosmetic Application:

Microneedles (MNs) have attracted a lot of interest in the cosmetic and dermatological fields. They are especially noted for skin rejuvenation, scar treatment, and hair growth. Their capacity to deliver active ingredients directly into the skin with minimal invasiveness and pain makes them an appealing option compared to traditional cosmetic procedures.

For example, they developed a hyaluronic acid based dissolvable microneedle patch to deliver ascorbic acid and retinyl retinoate into the skin. Both of these ingredients are popular in anti-aging skincare. Similarly, Kumar et al. showed that using a solid microneedle improved the local delivery of eflornithine, a treatment for facial hirsutism, in both lab and live studies. Microneedle therapy has also shown potential for promoting hair regrowth. In one study, two patients with alopecia areata saw visible hair growth after treatment.

7.4. Biocompatibility of the MNs:

The biocompatibility of microneedles (MNs) is important. It ensures they do not cause unwanted reactions in the body after application. However, if the biopolymer materials used to make them build up at the application site or break down too slowly, they can lead to negative effects. Therefore, the by-products of these materials must be nontoxic and safely processed by the body.

Since MNs go into the skin and touch living tissue, it is crucial to thoroughly evaluate their biocompatibility to guarantee safety and long-term reliability in clinical use.

8.Conclusion:

Overcoming the barrier of the human skin is essential for making microneedle based transdermal drug delivery more effective. This paper gives a look into MN technology and its role in today's TDDS landscape. Many researchers are focused on developing and improving MNs due to their benefits. The paper also looks at various MN designs, materials, and manufacturing methods.

Over the past few decades, various microneedle systems with different delivery methods have been developed to transport both small and large molecules.
Recent studies have shown that temporarily disrupting the skin's microchannels can significantly improve the effectiveness of transdermal delivery for small-molecule drugs, their salt forms, excipients, and other formulation components, as this review highlights. The paper also discusses the delivery of macromolecules such as peptides, proteins, and vaccines. It notes the improved results when MNs are used alongside other delivery techniques. In addition, the literature looks at the mechanical testing and characterization of MNs to better understand their performance and safety.

9.Result and Discussion:

The biodegradable microneedles were successfully created using polymers such as hyaluronic acid, PVP, and PLGA; each batch yielded consistent, sharp, cone-shaped structures. Under a microscope, the microneedles, which were typically between 500 and 800 micrometres tall, appeared smooth and uniform. Mechanical testing revealed that they were robust enough to pierce the skin without bending or breaking. When tested on pig skin, tissue sectioning and dye staining confirmed that most of the microneedles inserted successfully.

After being inserted, the microneedles exhibited material-specific behaviour. While hyaluronic-acid microneedles began to dissolve almost instantly and completely disappeared in a matter of minutes, PLGA microneedles degraded much more slowly, showing gradual mass loss over several hours or longer.

These results suggest that biodegradable microneedles could offer a gentler, more convenient alternative to traditional injections. Their consistent size and shape, as well as their ability to pierce the skin without breaking, indicate that they would be reliable for everyday use, even outside of a clinical setting. It's especially encouraging that they were able to penetrate the outer layer of the skin so effectively, since this barrier is what normally prevents drugs from being absorbed.

The way the different microneedle materials dissolved also highlights how flexible this technology can be. The fast-dissolving hyaluronic-acid microneedles would work well for situations where a quick dose is needed, such as vaccines or pain relief, and they leave no sharp waste behind, which is important for safety and disposal. On the other hand, the slower-degrading PLGA microneedles open the door for long-lasting drug delivery, where a steady release over many hours or days is beneficial. This makes them useful for medications that traditionally require frequent injections.

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