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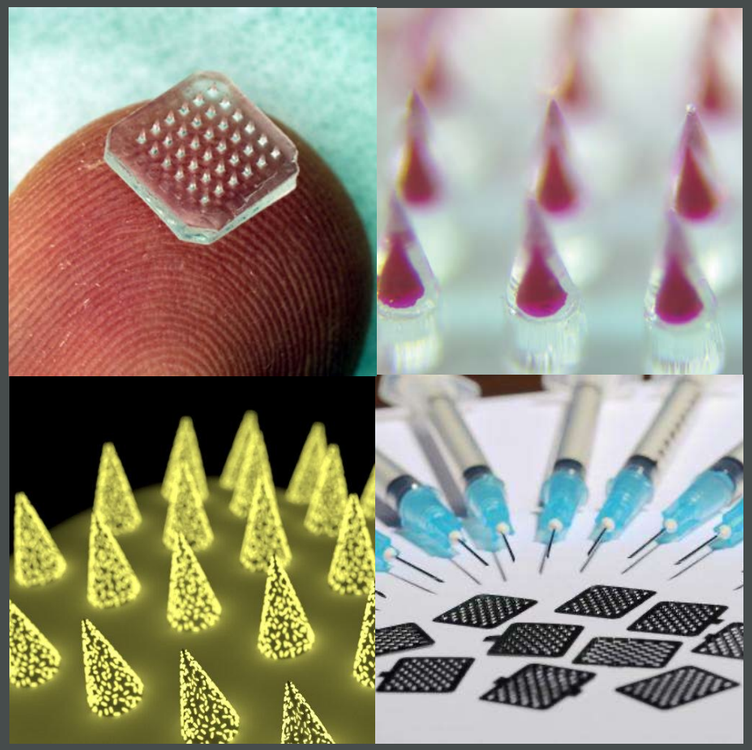

A Brief Guide to Microneedles

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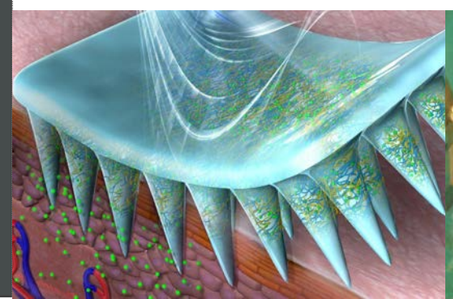

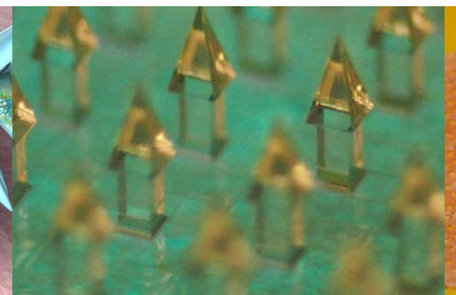

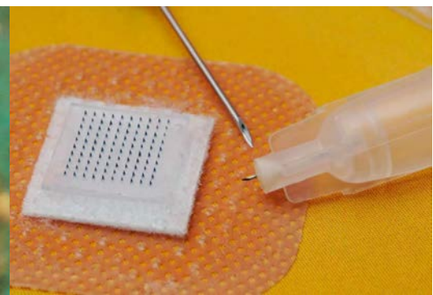

Microneedles research overview

Microneedles are minimally invasive drug delivery devices consisting of an array of micron-length needles which penetrate into the top layers of the skin. This technology was originally conceptualised in the 1970s, but fabrication was not possible until the mid-1990s when microfabrication technology became available. The first microneedles were fabricated out of silicon but since then microneedles made of metal, polymer, glass and ceramics have become available and they can be solid, hollow or dissolvable/biodegradable.

There are four main microneedle drug delivery strategies. The “coat and poke” method uses solid microneedles, coated in drug formulation, where the coated drug dissolves in the skin tissues. The “poke and patch” method uses uncoated, solid microneedles to produce microchannels in the skin, to which a drug formulation is applied. The “poke and flow” method consists of hollow microneedles which allow the delivery of medicament in a fluid form through the needle bore. The “poke and release” method consists of microneedles loaded with drug, which are left in the skin to either dissolve or degrade.

Microneedles have been studied for delivery of a range of therapeutics including vaccinations, small molecule drugs, therapeutic peptides and proteins, genes, immunotherapies, nanoparticles and cosmetics. The microneedling technique, in which microneedles are assembled on rollers, has also been used cosmetically. Microneedles overcome the major transdermal drug delivery barrier, the stratum corneum, allowing the delivery of larger molecules through the skin, compared to transdermal patches and topical formulations. Compared to hypodermic needles, microneedles cause no pain or bleeding, provide potential for self-administration and pose a lower risk of needle-stick injury and transmission of blood-borne viruses. Limitations of microneedles include solid microneedle tips potentially fracturing and remaining in the skin and thickness of skin layers and methods of application varying between patients and resulting in different therapeutic effect. These factors must be optimised.

Importance of Microneedles?

Microneedle technology is a field with significant applications, which continues to expand. This technology allows for increased delivery of therapeutics to the skin, thus circumventing some of the problems associated with the transdermal route of delivery amongst others. Additionally, the incorporation of microneedles in wearable sensors allows for the increased monitoring of physiological signals and key analytes in certain medical conditions.

Since their conception microneedles have been shown to successfully deliver several therapeutics to skin for both local and systemic effects. A key focus of microneedle technology is vaccination. Vaccine delivery using microneedles can have a substantial impact due to several benefits including simplified distribution, reduced pain and, therefore, improved patient compliance. There is even the potential for mass immunisation programmes where patients could self-vaccinate due to the ease of microneedle application. Even amidst the current pandemic, researchers have focused on using microneedles to deliver a potential COVID-19 vaccine.

New microneedle designs have been developed over the years, which have led to new applications. In addition to vaccination, microneedles offer a minimally invasive means of monitoring physiological signals and key analytes. Continuous glucose monitoring represents one of the largest areas of microneedle sensors. With the increasing worldwide prevalence of diabetes, controlling glycaemia remains key in the management of the condition. Hollow microneedles have been utilised to sample dermal fluids. Incorporation into a wearable device could address the need of the diabetic community as microneedles could eliminate multiple daily fingerprick tests and provide patients with real-time glucose readings allowing them to closely track blood sugar levels and trends. Wearable microneedle devices could also be employed in the field of physiological signal monitoring whereby patients could be monitored remotely in the community.

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Current research in Microneedles at Cardiff University and how this could impact industry?

We are collaborating with companies and academic partners on various microneedle-based projects to support innovation in industry.

We are studying the performance and use of microneedles in the cosmetics, sensing and diagnostics fields, using the expertise and facilities available at our institution. This includes the use of an ex vivo human skin model, optical coherence tomography and microscopy, histology and 3D printing as well as reviewing the literature.

The research being conducted is supporting industry by aiding the companies' growth through providing data for publications, informing the development of their technologies, and informing current and future projects. This work, in turn, ensures they remain market leaders and simultaneously contributes to advances in the microneedles field.

Application of research into Microneedles?

Following the fabrication of the first microneedle device in the 90s, microneedle technology has made significant progress in revolutionising the field of transdermal drug delivery. As an emerging device, microneedles offer a multitude of advantages and have been utilised in delivering a plethora of therapeutics to the skin. A number of microneedle-based products have been approved for both medical and cosmetic purposes for instance the Soluvia® and Dermaroller®. Most recently, the FDA received a new drug application for Zosano Pharma's Qtrypta, which could have a significant impact in the treatment of debilitating migraines. Over the next decade, it is expected that an increasing number of microneedle-based devices will enter into clinical trials and subsequently the market. In light of the current COVID-19 pandemic, microneedles could have a substantial impact with respect to mass immunisation. Due to their ease of application and lack of pain, microneedle-based devices could be used to rapidly vaccinate a population against a disease. For instance, products such as Soluvia® are currently approved to vaccinate against influenza.

Microneedles, whilst initially developed to overcome challenges associated with conventional transdermal delivery methods, can be applied to other research fields. There has been an increasing interest in the use of microneedles as transdermal sensors. Microneedles have the ability to access interstitial fluid within the skin which can be used to monitor key analytes. In addition to electrochemical sensing, to date microneedle-based electrodes have been used to capture important physiological signals, for instance the electrical activity of the brain, heart and muscle. Whilst the field of microneedle sensors faces many challenges, the next decade could see many researchers addressing these unmet requirements. Wearable sensors for health monitoring is a continually expanding field. Given the success of devices such as Fitbit®, microneedle sensors will likely be utilised in future on-body monitoring devices.

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Summary

Microneedles are novel, minimally invasive devices consisting of an array of micron-sized needles. They pierce through the main drug delivery barrier allowing access to underlying skin layers, optimising transdermal drug delivery, in a pain-free and bleeding-free manner. Microneedles have been studied and used for the delivery of a range of therapies, with vaccine delivery being one of the most widely researched applications. This is particularly relevant in light of the current pandemic, with a recent publication on the delivery of a potential microneedle COVID-19 vaccine making headlines.

In addition to drug delivery, microneedles have been widely studied in a number of other research areas, including the cosmetic and health monitoring sectors. In our institution, we are researching some of these applications and are supporting Welsh and Irish SMEs to achieve their current and future goals.

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