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DESIGN INSIGHT

Design for optimisation of drug administration

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SUMMARY
In the last few years, a new technology based on microneedles has been used for the delivery of drugs and vaccines. Microneedle patches ensure rapid, easy, and hygienic administration of drugs. This project was conceived to ensure the comfortable and safe transport as well as the sterile application of microneedles by users. Microneedles are particularly useful for diseases requiring daily medical care via distributed therapeutic treatments throughout the day. *Microneedle Reminder* is a wearable device for the wrist, containing nine ready-to-use patches.

Key Words
Health design; assistive technology; painless drug delivery; microneedle patches technology; human-centered design

INTRODUCTION

Researchers have developed an innovative technology that uses microneedle patches for transdermal administration of drugs and vaccines. Microneedle patches ensure an easy, fast, and painless distribution of medications and could also be used for cannabidiol (CBD) encapsulation to generate new epilepsy drugs. Cannabidiol, with its ability to relax and reduce muscle spasms, is well-suited for diseases such as epilepsy and other neurological disorders that cause convulsions.

The *Microneedle Reminder* project arose to investigate the possibility of designing a tool for the safe transport and use of microneedle patches. The outcome of the research, which we carried out in collaboration with experts such as neurologists and technologists, is a wearable device capable of hosting nine ready-to-use patches. This wearable device, which works through a simple rotation and application of slight pressure, enables the safe and hygienic drug delivery through microneedles.

SUMMARY

The outcome of the research is a biomedical device designed to treat diseases that require daily medical care involving therapeutics treatments distributed throughout the day. Epilepsy, arthritis, diabetes, and carpal tunnel syndrome are a few examples of diseases that could use this device.

The *Microneedle Reminder* project had several phases. In the first disciplinary phase, we identified the problem to be treated—that is, epilepsy—and the current techniques used for its drug treatment (scenario analysis). The second phase entailed sketching and 3D modelling of a device that could combine design and the new technology of microneedles. Finally, we created several prototypes with 3D printing, using different materials such as polylactic acid (PLA), thermoplastic polyurethane (TPU), and silicone, to test for quality and functionality. The final prototype of the bracelet was made out of silicone.

The *Microneedle Reminder* device facilitates the use of microneedle patches. It is designed to meet the demand for an easy, automatic, hygienic, conscious, painless, safe, and sterile application of

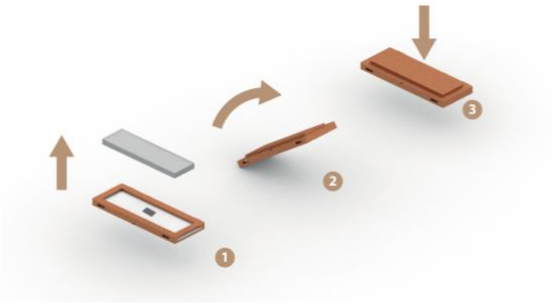
microneedles patches. It allows the administration of pharmacological substances through the derma.

Microneedle Reminder is a bracelet with a modern design (Figure 1), comprising nine pieces made of semi-flexible medical polymer material connected to each other by an elastic and transparent nylon thread, and also by flexible joints that allow the wearer to flip over each piece, so that the patch is in contact with the skin of the wrist (Figure 2).

Figure 1: *Microneedle Reminder*

The *Microneedle Reminder* bracelet consists of nine pieces made of semi-flexible medical polymer material connected to each other by elastic and flexible joints. It looks like a normal bracelet.

Figure 2: How to use *Microneedle Reminder*



How to use the patch:
1. Remove the protective cup.
2. Turn the piece toward the skin.
3. Apply a little pressure on the back of the piece to put the patch into the skin.

Each block, in the form of a parallelepiped, is composed as follows:

- It has a closed face with a side frame, forming a compartment for inserting only one microneedle patch (Figure 3).
- A protective cup safeguards the patch, preserving the sterility and ensuring the mechanical protection for the delicate and fragile microneedles (Figures 3 and 4).
- The closed face includes a part that has to be pushed for the device to operate (Figures 2 and 3).

Each block hosts a single patch, which corresponds to a single dosage, established following a neurological prescription, to be applied at a specific time of the day (Figure 5). The bracelet can be worn with the microneedle patches facing outward, while the closed face of the box is placed towards the skin.

When a patch needs to be applied, the protective cup is removed, and the piece is rotated 180° towards the skin. Subsequently, the back of the piece is pressed, for a correct and uniform adherence of the patch to the wrist's skin, without touching the patch directly with dirty hands. This ensures the penetration of microneedles into the derma (second layer of the skin, after the epidermis) to the required depth for the release of the substance, preventing microneedles from being damaged (Figures 6 and 7). This automated process, facilitated by the morphology and mechanical structure of the piece and the button, guarantees a more controlled and precise application than if the microneedle patch is applied manually.

During application, when the protective cup is removed, the single part can be used with one hand without touching the patch, ensuring the operation is hygienic (Figure 8). While the initial position of the patches facing outward is not mandatory, it facilitates cup removal and allows the user to visually monitor the applications throughout the day, distinguishing patches that have already been used.

Figure 3: Elements of each piece of *Microneedle Reminder*

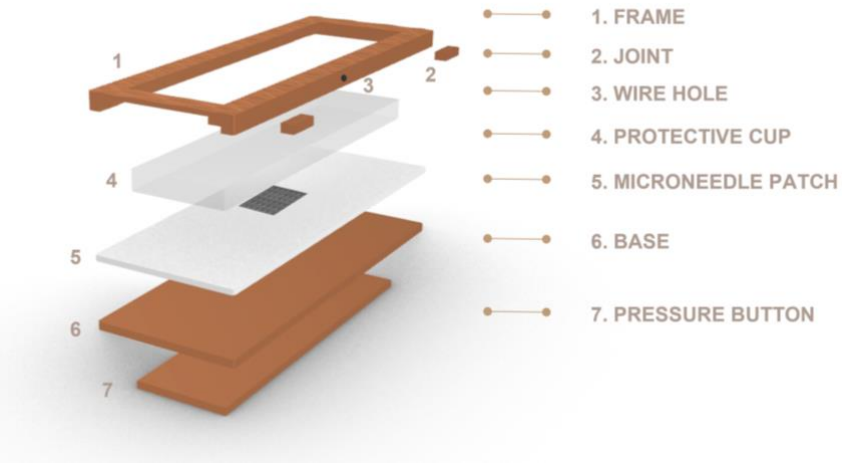


Figure 4: Patch with microneedles as part of *Microneedle Reminder*

The single patch with microneedles is inserted on the inside. The patch is isolated by a protective cup that helps to preserve the sterility and ensure its protection from external agents.

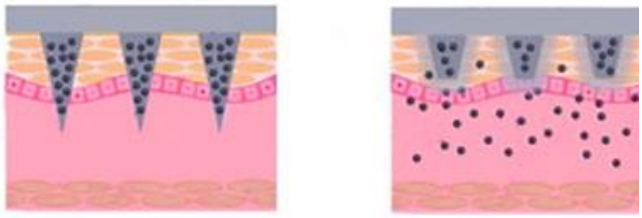
Figure 5: Single dose in *Microneedle Reminder*

Each piece contains a single patch, therefore a single dosage, depending on the prescription, to be applied at a specific time during the day.

Figure 6: *Microneedle Reminder*—microneedles penetrate the skin

Once the protective cup has been removed, the element rotates 180°. When the needles are close to the skin, the wearer only has to apply a slight pressure on the closed side. Then the needles penetrate the derma, releasing the substance.

Figure 7: *Microneedle Reminder*—how microneedles penetrate the skin



The mechanism by which microneedles deliver their substances into skin.

Figure 8: Application of *Microneedle Reminder*

During the application, the single piece can be operated by one hand, without touching the patch, to ensure the hygiene of the operation.

LESSONS LEARNED

There is a notable global absence of wearable devices—especially for the wrist—designed for the safe transport and storage of microneedle patches, and which preserve the user's health, prevent damage, and protect the patches from bacteria and humidity. Historically, microneedle technology is used mostly in the cosmetic field, against the imperfection of skin wrinkles. In this instance, patches are sold in a package.

Researchers and medical device designers have overlooked the enormous potential to use microneedle technology in the medical field.[1] However, in recent years, microneedle technology has also been applied to the administration of drugs and vaccines (such as COVID-19), to achieve easier, faster, and painless distribution of substances.

Microneedle patches contain hundreds of microscopic needles, which, once applied, dissolve into the derma. This administration method speeds up drug action and allows for prolonged release of the medicinal substance. Microneedle technology also offers advantages such as preventing gastrointestinal side effects associated with oral drugs, and eliminating the pain caused by injections or other invasive administration methods.

CBD, a non-psychoactive compound found in hemp, is one promising substance for encapsulation in microneedles. Unlike THC, CBD is increasingly recognised for its diverse therapeutic benefits, including anti-inflammatory, antioxidant, anxiolytic, anticonvulsant, antiemetic, antipsychotic etc.[2] Recent neuroscience studies and experiments have demonstrated the effectiveness of CBD on neurological diseases such as epilepsy.[3] Cannabidiol has the ability to interact with receptors of the nervous system at the central and peripheral level. Many epilepsy patients do not respond adequately to traditionally prescribed antiepileptic drugs and need other treatment options to improve their quality of life. Numerous scientific studies have shown CBD's anticonvulsant properties. Cannabidiol appears to modulate the excitatory-inhibitory ratio to counteract hippocampus activity, a brain region involved in seizures.[4]

Currently, CBD is administered in the form of crystals or oils, each with distinct characteristics. Within the CBD crystals all the plant materials contained in the hemp plants, such as oils, waxes and chlorophyll, are removed. The removal of all the other components of the plant leaves a fine white powder that contains 99 per cent pure CBD.

CBD oil can be delivered through different methods (inhalation, ingestion, transdermal). Users begin to feel the effects within 15 or 30 minutes, and the duration can range from 2 to 12 hours. Several factors must be considered when looking for the perfect CBD dosage, including the patient's sex, height, body weight, age, method of consumption (oil, powder, capsules), experience with CBD, medical condition, the type and severity of the medical problem, and metabolism.[5]

Following the research on CBD, researchers expressed a desire to develop a new method to administer CBD for the treatment of epilepsy that is fast, effective, and painless. This desire led to the technological innovation of microneedles, which ensure a gradual but faster release compared to transdermal patches because microneedles penetrate beyond the dermis to the epidermis. CBD is directly encapsulated in the microneedles during their fabrication and the choice of the polymer determines the release time of the product. Highly vascularised areas such as the wrists are the most suitable areas for administering this type of patch. A square centimetre of the patch (256 needles) contains 3 micrograms of material, which is not just active ingredient. The needles are usually 600 microns high, with the patch adaptable to any shape and size.[6]

This research has revealed the enormous potential of the use of patches with microneedles, an innovative technology undergoing continuous experimentation. It has also revealed the countless beneficial effects of CBD, a substance often underestimated or whose use is excluded due to prejudice. Collaboration with doctors and engineers provided interesting reflection points. The designer's role is to respond precisely to contemporary needs by collaborating with other scientific figures with the aim of improving the quality of life.

DESIGN INSIGHT

The aim of this research was to offer a viable alternative to existing therapies on the global market, using the latest technological and scientific innovations. These innovations demonstrated that the administration of drugs for different types of diseases, even those of a more common entity, can be both fast and painless, without compromising the effectiveness of the prescribed treatments.

The developed product aims mainly to facilitate the patient's life with a comfortable, practical, and easily usable device that assists the user in daily self-care. This tool also helps in monitoring the dosage to be taken, serving as a visual reminder, while ensuring maximum patient privacy.

Users can take their medicines anywhere and anytime without attracting attention. The kit has been protected with a utility patent in Italy.

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CONFLICTS OF INTEREST

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