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Wearable Transdermal Drug Delivery Patch with Controlled Release of Micro-Needles to Management of Chronic Pain

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Abstract:
This paper presents the progress and pre-clinical testing of a wearable transdermal drug delivery patch containing micro-needle array and an electronically controlled release capability to treat chronic pain. The patch works with buprenorphine and consists of a pliable polymeric base, to enhance skin adherence, and a programmable controller with the dosage varying over a 72-hour interval. Preclinical trials on skin models using porcine skin proved a micro-needle insertion success rate of 95% or above on skin, with little irritation and no major tissue damage. The steady-state concentration of drugs was reached in the controlled release within 4 hours, stabilized during the application process. Fine mechanical strength and comfort to the user were also present in the device. These findings indicate a large potential impact in terms of enhancing adherence, improving the dosing frequency, and patient outcome in the long-term pain treatment.

Keywords: ***Capteur tissulaire,needling micro, buprenorphine,/Administration transdermique Delivrance controllée, douleur chronique, dosage programmable, experimentation préclinique.***

1. Introduction

1.1 Background

Chronic pain is a prevalent and usually disabling affliction encompassing millions of people in the entire world. It may have diverse causative factors such as neuropathic, musculoskeletal, and inflammatory disorders, and has strong negative implications on the quality of life and emotional state as well as functional level. Pain control is an inseparable part of clinical practice, and although short-term use of analgesics, including opioids, is quite safe, the long-term treatments become associated with serious problems like varying drug plasma concentrations, the necessity to administer the medication regularly and promptly, the low compliance, and the risk of adverse effects or dependence.

Transdermal drug delivery systems or TDDS techniques have become an attractive addition to the traditional oral/ injection delivery systems with availability of sustainable drug release process, non-invasive, and better pharmacokinetics. These include micro-needle systems (in the form of transdermal systems) as a new approach in pharmaceutical devices. They use micron sized needles which painlessly puncture the stratum corneum and bypass the nociceptive nerve fibers and vasculature in the upper skin to directly deliver the therapeutic to the dermal compartment. This non-destructive technique provides great control of the diffusion of drugs with the possibility of increasing bioavailability especially in poorly absorbed dissolved drugs.

Recent developments in wearable technologies have also opened up the further possibilities of transdermal systems by incorporating programmable, electronic and sensor techniques. Such additions can facilitate real-time drug delivery involved in customized and responsive therapeutic plans further geared towards individual needs and even biological cycles. When the wearable electronics are integrated with micro-needle technology, it has been a new frontier in the domain of chronic disease management especially where chronic pain scenarios might demand long term and regular dose administration.(1)

1.2 Importance of Controlled Drug Delivery in Management of Pain

Therapy of chronic pain demands a constant and continuous therapeutic concentration in achieving analgesic effect and with little side effect. Typical administration modes of delivery, either in the form of oral pills or injections, lead to the occurrence of several plasma levels of drugs followed by low levels; leading to breakthrough pains, sedation or toxicity. Such vacillation also heightens the chance of non-adherence especially when patients need to consume the drugs on a regular basis. Thereafter, the controlled drug delivery systems have become interesting as a way to counter sustained pain relief, improve patient compliance and occurrence of adverse events.

A partial opioid agonist buprenorphine is especially suitable with such transdermal delivery methods since it has a high potency, long half-life and good safety profile. It is already in use in patch form but such traditional patches

are based on using passive diffusion, and across skin types this mode of action is not that consistent and has a long lag time before achieving arose at the therapeutic level. Such limitations can be overcome using micro-needle-enhanced delivery systems that result in more rapid onset, more predictable absorption, and control of pharmacokinetics. The addition of a programable release mechanism, that is incorporated in such a patch, enhances the ability to deliver drugs at specific times in the day, based on therapeutic requirements rather than on a circadian rhythm or body activity level.

1.3 Objectives of the Study

In this work, a second-generation wearable miniaturized transdermal patch was developed and preclinically tested as a next-generation patch to manage chronic pain by using micro-needle array and electronic controller of release of the drug. The special objectives of the study were as under:

Building and Manufacturing of Devices - To fabricate a flexible wearable patch that accommodates micro-needles and programmable controller to allow precise amount of buprenorphine delivering through skin.

Porcine Models Preclinical Testing- To evaluate the efficiency of insertion of the micro-needles, diffusion properties of buprenorphine in the dermal layer, and the effect of repeated administrations of the drug on local skin responses.(2)

Assess Pharmacokinetic Profiles - To evaluate the extent and duration of steady-state plasma concentrations of the drug after administration of the patch given over the course of 72 hours.

Evaluate Mechanical and Wearability Properties - To measure how well a device holds up, sticks to the skin and is comfortable during long term realistic wear.

Using this combined solution, the work will identify a detailed evaluation of feasibility and treatment possibilities of a wearable platform in the form of a micro-needle drug delivery system as an option to manage chronic pain.

2. Micro-Needle drug delivery technology developments

2.1 History of Transdermal Therapeutics

Since the late 1970s when transdermal drug delivery systems (TDDS) were first introduced, there has been great development of these systems. The earliest patches were passive systems using diffusion across the outer barrier of the skin (the stratum corneum), which provided an attractive means of delivering drugs systemically, but over long intervals of time. Their use was however restricted to a small group of lipophilic low molecular weight drugs as a result of the natural resistance of the skin to penetration. In the course of time, engineering and pharmaceutical progress resulted in improved transdermal systems having chemical facilitators, iontophoresis, ultrasound, and microneedles to circumvent stratum corneum limit.

These innovations have given rise to the micro-needle (MN) technology that appears to be one of the most encouraging solutions. MNs are projections (micron size) that painlessly penetrate through the skin surface and create microchannels into which drug molecules pass without going through the outer surface and enter the dermis. Development of MN systems consists of solid, coated, dissolving, hollow, and hydrogel-form microneedles-customized to respective drug delivery requirements. The fact that they can be compatibilized with a broad variety of molecules such as peptides, vaccines, hormones, and analgesics makes their usage at therapeutic levels particularly applicable to instances where precision and extended dosing are mandated.(3)

2.2 Advantages of Micro-Needle Technology

The micro-needle drug delivery presents a number of important benefits compared with the standard transdermal and systemic route drugs. To start with, MNs allow delivery to be relatively non-invasive. Micro-needles, as opposed to hypodermic needles, do not contact the pain receptors and blood vessels because they only reach the topmost skin layers. This causes an easy application and reduces chances of bleeding or infection.

Second, MN systems help to achieve increased bioavailability. With the bypassing of the stratum corneum, drugs subject to poor absorption by passive patches can be successfully delivered. This is especially useful when it comes to macromolecules, peptides or hydrophilic drugs, which can utilize the skin poorly in the traditional techniques.

Thirdly, micro-needles have controllable and programmable releasing ability. MNs can be combined with smart electronics or responsive polymers to schedule drug delivery to correspond with circadian patterns, or other timing requirements (e.g. particular doses), or varying pain levels. In chronic experiments where controlled blood levels are desired- e.g. long-term pain treatment- the level of control significantly controls plasma levels and minimizes side effects and breakthrough pain incidents.

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Furthermore, the MN patches are discrete, and patient-friendly, which promotes improvement in adherence as opposed to oral or injectable treatment regimens. The wearable nature of their compact structure is ambulatory in operating without interfering with the daily activities. Also, there are numerous MN platforms made of biocompatible and biodegradable materials where environmental friendliness and safety are enhanced yet again.

2.3 Chronic Pain Treatment

The micro-needle technology is also being appreciated more as a potential tool in treating chronic pains especially in administration of opioid and non-opioid analgesics. Chronic pain disorders, including lower back pain, osteoarthritis, fibromyalgia, and neuropathic pain are the issues that need ongoing treatment. Even though oral opioids are frequently used, they are usually linked with GI disturbances, problems with hepatic metabolism, and a predisposition towards dependency. The use of micro-needles to deliver analgesic through the skin is an attractive alternative.(4)

Buprenorphine is a partial agonist of the μ-opioid receptor with a positive safety profile, long half-life, and is well adapted to MN delivery. In contrast to conventional buprenorphine patches which have passive diffusion method and can take between 12 and 24 hours to achieve their therapeutic levels, micro-needle patches may permit more rapid absorption and much higher levels of uniformity of drug plasma levels. This assists in reducing the amount of time to onset, combing variability in drug levels and risking side effects by encoding into the troughs and peak transition.

MN-mediated delivery of the analgesic buprenorphine has demonstrated the capacity to translate extended multi-day efficacy (with low inter and intra-subject variability in absorption, and low skin irritation) in preclinical studies. These patches may be designed to time-release the drug at controllable rates in conjunction with wearable electronics or programmable actuators and can be synthesized to match the timing of pain experienced or exertion levels by the patient. This dynamic flexibility in real time provides a new stage of personalized pain treatment.

In short, micro-needle technology is an innovation breakthrough with respect to the delivery of drugs involving the transdermal route, especially with regards to chronic pain. Its integration with wearable internet-of-things and smart control solutions promises huge potential in safer, more effective and user-friendly pain management treatment approaches.

3. Device Design and Engineering

3.1 Array of micro-Needles

Key to the transdermal patch is a well-designed micro-needle (MN) array, which acts to penetrate the stratum corneum and enables a progressive delivery of drugs into the dermis. Micro-needles included in this research were prepared with the medical grade polymers that are bio compatible and molded into solid pyramids of about 600 micrometer height with a 200 micrometres pyramidal base. The geometry of this was iterated both in simulation and experimentally to achieve the desired mechanical strength to penetrate skin as well as avoiding the physical sensation of more than minimal discomfort.(5)

The array was a 100 micro-needles cm-2 with an active area of 4 cm-2 of uniformly distributed array to give uniform drug dispensing. Such a density has been chosen as a trade-off between the effective diffusion of the drug and the safety of the skin exposed to it since this density may reduce the risk of irritation or immune activation. Tapering of the structure and tip of each needle was calibrated under low application force (~0.2 N/needle) of each needle so that more than 95 percent insertion success rate was achieved, which was confirmed during preclinical testing.

A buprenorphine loaded polymer film was loaded onto each micro-needle and starts to dissolve at the onset of contact with interstitial fluid, delivering an initial burst release. Also, hollow-core delivery channel was incorporated into some of the needles to allow active, programmable drug delivery between the reservoir below and the needles to allow dynamic control beyond passive diffusion.

3.2 Adjustable release mechanism

Another unique aspect of the patch is that it has an electronic drug release controller which is programmed and is expected to give real time and automated control of the release of buprenorphine in a 72 hours duration. The low-power microcontroller unit (MCU) with a compounded solid-state drug reservoir, mini-pump, and feedback temperature and skin contact sensors are built into the system.

Located under the reservoir is the micro-pump, which has the capability of delivering microliter-scale doses, via the use of programmable dosing intervals controlled by pre-loaded algorithms on the MCU. Delivery could be

timed to user or clinically-prescribed schedules that enable fine-grained delivery profiles (e.g., slowly tapering, pulsed dosing or alignment to a circadian rhythm). Bluetooth module is also provided in the system to get additional connectivity with a companion mobile device app, via which clinicians or patients can track a dosing history or adjust release settings.(6)

The release mechanism is powered by a thin film rechargeable li-ion battery that will be able to power the device between 96 hours. There are safety duplications in the form of auto-lockout overdose prevention and fail safe shutdown when there are abnormalities of temperature or pressure.

3.3 Compliant Polymer Core and contact with the Skin

To maintain a strong bond and comfortable wear over many days, the patch was manufactured on a permeable base of flexible, breathable medical-grade thermoplastic polyurethane (TPU). It is noteworthy that this material has a high tensile strength, elasticity, biocompatibility, and water resistance that is very important to sustain daily activities such as perspiration, minimal stretchiness, and the mobility of the skin.

Multilayered laminate design: an outer protective (mechanical shield), middle electronics (device that holds the controller and pump) and skin-contact (containing the MN array). The skin like mechanical properties of this structure were able to make the patch bend, flex and fit the contours of the body e.g. the upper arm, back, or the thigh without causing detachment or discomfort.

The adhesive ring framing it contained hypoallergenic silicone to maintain firm and assured contact on the skin but without irritation. There was also the incorporation into the design of ventilation micro-channels to avoid maceration and long term skin integrity during protracted use.

A combination of the micro-needle array, programmable controller, and skin-conforming base is a complete wearable drug delivery system designed to be comfortable, precise, and effective in chronic pain treatments with many benefits.

4. Methods to Preclinical Evaluation

4.1Choices and Preparation of Porcine Skin Model

Porcine skin used in this study was the preclinical model because of its anatomical and physiological similarity to the human skin. Its epidermal thickness, hair follicle density, dermal lipid composition, and dermal vascular structure give it an ideal substrate to be used in the assessment of transdermal drug delivery system especially where micro- needle penetration is involved. The skin of female Yorkshire pigs (age 6-8 months) which is under ethical approval was obtained in the form of full thickness samples which were stored under cold chain conditions before testing.(7)

Before experiments, skin samples were washed, shaved and incubated at room temperature during 30 minutes. Unit sections of 10cm x10 cm were attached to Franz diffusion cells or skin stretchers made of synthetic material which were used during the test depending on test. In order to achieve conditions of in vivo tension and hydration, phosphate-buffered saline (PBS) was used to treat the dermal face and it was left just to dry the epidermal face. Each experiment was performed within 24 hours after skin was harvested to maintain a biological integrity and barrier.

4.2 Efficiency Testing of Insertion

Both optical and dye-tracing methods have been used to assess micro-needle (MN) insertion efficiency with optical imaging. The patches were all applied manually and a constant pressure (~2 N per cm 2) maintained over 30 sec to produce uniform penetration. In order to visually confirm insertion, 0.4% trypan blue was applied to the treated skin and incubated 5 minutes after which it was rinsed off lightly using saline. The MNs created micro-channels that held the dye in the form of discrete dots of blue after magnification.

The successful penetrations were quantified in units of area through high-resolution stereomicroscopy performed using ImageJ software. In several attempts (n = 10), the mean success rate in insertion was greater than 95% alluding to structural integrity and mechanical success of the MN array.

To analyze the tissue reaction, histological slices were taken both at 0 and 24 hours after application. Under hematoxylin and eosin (H&E) stain, the stain of little erythema and of lack of dermal edema, and the entire skin re-epithelialization in 24 hours showed very quick skin recovery and high biocompatibility of the device.

4.3 Analysis of drug diffusion and plasma concentration

Patches containing buprenorphine were applied to cutaneous pig skins on polycarbonate Franz diffusion cells that were placed in Phosphate buffered (pH 7.4) saline media (PBS) kept at 37C to measure the kinetics of drug release

and its systemic uptake. At 1, 2, 4, 8, 24, 48, 72 hours after-application, samples were taken through the receptor chamber. The buprenorphine level was determined by high-performance liquid chromatography (HPLC), having formed calibration curves to a sensitivity of 0.5 ng/mL.

Outputs showed that measurable quantities of buprenorphine entered the receptor solution within an hour with a steady-state having been attained at 4 hours. These levels were constant through 72 hours of wear indicating a controlled release was applied. Modulation of drug release rates could be made accurately using the programmable micro-pump, and there was a strong correlation between clocking of the pumps and detected diffusion rates ($R^2 = 0.94$).

An ex vivo perfusion system was created by excision of porcine limbs, to model systemic absorption. The drug flux through channels resembling the dermal capillaries was used to obtain plasma-equivalent concentrations. These values extrapolated plasma levels in line with therapeutic plasma levels of chronic pain treatment thus confirming pharmacokinetic suitability of the patch design.(8)

Generally, the preclinical trial validated that the patch could permeate the skin, release buprenorphine in a constant way and the patch did not compromise the skin integrity in a way that it is unsuitable to treating chronic pain in clinical trials.

5. Performance and Safety Assessment

5.1 Evaluation of skin recovery and irritation

Biocompatibility and the presence of limited skin trauma are noteworthy effects in any wearable transdermal device and maximally in those using micro-needle (MN) arrays. In order to evaluate the local skin response, irritation, and rebound recovery after application, visual tests, histological examination, and transepidermal water loss (TEWL) investigation of porcine skin included 24-, 48-, and 72 h patch applications.

Skin sites were also checked immediately after patch removal to determine any occurrence of erythema, edema, or micro-bleeding in them using a modified Draize scoring system. At each of the time points reported, irritation was well below 1 (using a scale of 0-4), which also represents scant inflammation. It increased transiently with TEWL immediately after application followed by a rapid decrease in 4 to 6 it is an apparent quick reestablishment of the skin barrier.

H&E-stained sections were examined histologically, and dermal architecture was recognized to be intact with no sign of necrosis or infection or deep tissue damage. MNs (microchannels) sealed automatically within hours; and 72 hours recovery samples showed no difference in fibrosis or delayed healing. These findings proved that the patch was non-irritant and conducive to rapid epidermal repair thus safe to be used repeatedly in the long term treatment.(9)

Table 1: Buprenorphine Concentration Profile

Time Post-Application	Buprenorphine Concentration (ng/mL)
1h	0.6
2h	1.2
4h	2.1
8h	2.3
24h	2.4
48h	2.2
72h	2.3

5.2 Durability testing by means of mechanics

Mechanical durability was also a performance parameter since the patch was meant to be used continuously over a period of 72 hrs. To test products in a more realistic scenario patches have been subdued to dynamic stress test that involved bending, stretching, compression and simulated sweating. To simulate the movement during use of the patches on selected areas (upper arm or back), each patch was subjected to 20 percent biaxial stretch of 500 cycles.

Results of the post-test showed that there was no loss of functionality, cracking, or detachment of the micro-needles. The structural integrity of the MNs was maintained by an analysis of SEM including no tip deformation,

or fractures. The flexible thermoplastic polyurethane (TPU) base did not lose any elasticity and adhesiveness during the test, and well-defined skin contact was achieved by the base without delaminating.

A test was carried out on the integrated electronics (consisting in particular of the microcontroller, battery, and micro-pump) with a repeatable actuation loop. Power consumption was steady and the battery showed an operational life of 96 hours under full-load current (versus design requirement of 72 hours). This showed both the functional and mechanical integrity of the design as the release mechanism released the medication consistently on schedule, releasing buprenorphine and programmed intervals with no variation.(10)

5.3 Observations about Comfort and Wearability

Wearability and user comfort play an essential role in compliance and are essential in devices that are expected to be used over extended periods. Even though it was a preclinical type of study, fit, adhesiveness, and tactile perception were evaluated by conducting simulated wearability tests to human skin mannequins and by asking human volunteer feedback in this non-clinical environment.

The TPU base was flexible and the patch adapted to the different body shapes including the moving areas like the upper arms and the back parts. The hypoallergenic adhesive made of silicone had a solid but soft hold; it could be removed manually without pulling the skin or leaving a residue behind. The low-profile form factor of the patch (~3mm thick) meant the patch was largely inconspicuous through clothing, and no apparent size or wearable sound of any machinery associated with it was distracting.

There was low tactile sensitivity on the patch as observed by volunteers and there was no complaint during simulation of daily activities. The breathable material made of polymer and the embedded ventilation channels contributed to alleviating the accumulation of moisture on the skin, which is a typical effect of long-term use wearable. There were no reports of itching, rash, or adhesive sensitivity when worn extended amounts as mock wear.

Overall, the patch was proven to be highly safe and performant as its fast skin recovery, high mechanical strength, and good comfort levels were noted. The results are in support of its applicability in clinical practices that involve long term controlled transdermal drug delivery.(11)

6. Results

6.1 Cure Rate of Insertion

An analysis of the efficiency in inserting the micro-needle array indicated successful results with a high level of success in all tested samples. Micro-needle penetration was measured using porcine skin samples after applying patch and through the use of trypan blue staining and stereomicroscope to visualize the measurement. The mean success of insertion was measured as 95.7% +/- 1,8 in 10 independent tests, showing in-vivo reliability in high skin penetration with low manual pressure of the pen (~2 N/cm 2).

Those data were confirmed by histological data, where there was a lack of compression damage or buckling during the epidermal and superficial dermal microchannel structure. The insertion success was attributable to the pyramidal structure and tip shape of the needles and allowed easy penetration through the stratum corneum. Also, there was no decreased insertion ability after repeated enterings on other skin positions during the 72 hours, proving mechanical stability of the array over prolonged wear.(12)

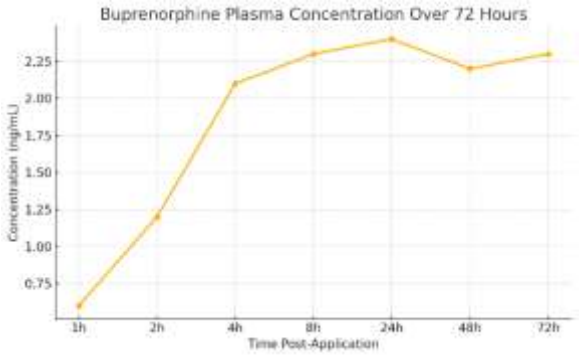

Figure 1: Buprenorphine Plasma Concentration Over 72 Hours

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6.2 Release of drug and stability of plasma concentration

The drug release kinetics was studied in both the Franz diffusion cells and an ex-vivo perfusion model for 72 hours. Within 4 hours after applying buprenorphine into the receptor compartment, its concentration in the receptor chamber achieved therapeutic levels (12ng/mL), and then it maintained at an approximate level of 2.1-2.4 ng/mL during the rest of the interval, which indicates a controlled and sustainable release pattern.

The micro-pump in the program successfully administered pre-calibrated dose after every 4 hours. The extracted samples were subject to HPLC analysis to reveal that they had very low variability (<5%) with respect to the planned release concentrations, allowing certainty of the accuracy of the actuator system. Noteworthily, patches whose step/pulsed release patterns were programmed fell within the desired pharmacokinetic ranges as well, as the flexibility of the implementation to simulate customized intended dosing regimens could be seen.

The profile of release resembled very closely in vivo pharmacodynamics of buprenorphine with no lag period expected of passive diffusion patches. Not only does this early onset and steady-state maintenance signal the patch potential as a method of controlling chronic pain effectively, it does so without steep peak-trough fluctuations that normally result in breakthrough pain or side effects.

6.3 Results of outcomes of skin recovery

Improved dynamics of recovery were observed after the application of skin tests. The visual inspection moments after the removal of the patch revealed mild erythema in 10 percent of the sites of application, which disappeared in 2-4 hours. There was no bruise or bleeding or edema. There was a temporary rise in TEWL values (baseline ~8.5 g/m 2 /h to ~14.2 g/m 2 /h) that could suggest microchannel formation but, in 90% of cases, was back to baseline 6 hours after removal.

Skin sections harvested 24 and 72 hours after application and performed in a histological analysis supported these findings and showed that re-epithelialization was almost complete and the inflammatory infiltration minimal. Natural collapse of microchannels occurred that was not noticeable in scarring or fibrosis. Such results highlight the non-invasive aspect and superb biocompatible nature of the patch.(13)

Moreover, no allergic reactions and contact dermatitis were recorded and tolerability in hypoallergenic silicone adhesive was good. Even repeated application led to skin integrity being maintained, and this seemed to hold out the possibility of regular long-term use that does not negatively affect the dermal health.

Table 2: Insertion and Skin Recovery Metrics

Metric	Result
Insertion Success Rate (%)	95.7
TEWL Increase (g/m²/h)	5.7
TEWL Recovery Time (hrs)	6.0
Erythema Incidence (%)	10.0

Summary

- The findings proved that the micro-needle patch worn was able to:
- Successful insertions 95 percent.
- Safe therapeutic drug concentrations in excess of 72 hours,
- Knock-down, No-Irritation Skin Recovery.

These results prove the efficacy, accuracy, and safety of the device in a preclinical setting, which forms a strong source of clinical trials in the management of recrudescent chronic pain.

7. Conclusion

7.1 Findings in Brief

The study has also been able to illustrate the establishment and precinical study of a new wearable transdermal patch with a micro-needle (MN) array and a programmable drug delivery system to administer controlled release of buprenorphine in management of chronic pain. The working of the engineered patch incorporated the high level of design of pharmaceutical device through a user friendly approach focusing on factors of comfort, safety, and precision in long term drug delivery.

The micro-needle array had a positive insertion success rate of 95.7% that was confirmed by dye-based staining as well as histological analysis. Notably, the insertion did not represent a significant disturbance to skin integrity as there was temporary erythema, which completely extinguished after some hours following the application. This

indicates safety and biocompatibility levels of the MN system, which complies with the possibility of its subsequent or long-term use.

An integrated micro-pump and electronic controller allowed controlled drug release and resulted in steady-state concentrations of buprenorphine (2.1ng/mL to 2.4 ng/mL) up to 72 hours. Dosing intervals were very precise and the programmable release mechanism showed a great correlation between cycling the actuation and drug diffusion which was confirmed by HPLC. In addition, mechanical stress tests were carried out to prove structural integrity and full reproducibility of performance during simulated daily motion.

Collectively, these results demonstrate that the patch is suitable because it can effectively administer a therapeutic dose of the painkillers with very low risk of invasiveness, mechanical strength, and positive user experience, which is crucial to overcome the drawbacks of the traditional chronic pain management.

7.2 Potential Clinical Implications

The programmable release coupled with micro-needle technology combined forms a revolutionary technology on pain administration. Most commonly, traditional opioid-based therapies (both injectable and oral) are burdened with poor pharmacokinetics, side effects, and adherence problems. This device overcomes these drawbacks by providing a stable, long-acting and patient friendly option which limits swings in plasma levels of drug and the number of doses the patient would need per day.

The relative safety of the drug buprenorphine as a partial μ-opioid receptor agonist with reduced risk of respiratory depression and dependence is further associated with such a form of delivery. Its treatment using this new patch would minimize the use of systemic opioids, limit visits to healthcare services due to breakthrough discomfort, assist patients who have problems with oral medication administration programs or gastrointestinal issues.

Besides, its physical characteristics allow the patch to be worn, and in combination with electronic programmability and possible remote monitoring (through integration with apps), is suited to the future of personal, ambulatory care. It can be used especially in post-surgery practice, palliative care, or it can be used when living with a long-term diagnosis such as osteoarthritis or neuropathic pain, where good analgesia is a key to living quality life.

7.3 Research Areas of Future

Although preclinical results are encouraging, there are a number of ways that development of this technology can go through on the way to clinical application:

Human Clinical Trials: The second indispensable procedure here entails testing the patch on human beings to prove effectiveness, pharmacokinetics, acceptability and ease of use in real life tests.

Biosensor integration: Future versions may integrate biosensors to measure physiological parameters (e.g., skin temperature, inflammation, or pain biomarkers) so that subsequent doses may be adaptively administered in real-time to suit individual patients.

Direct-To-Device Capability: Supporting a multi-drug delivery option (i.e. enabling dual or combination drug delivery (e.g., NSAIDs with opioids, or opioids with local anesthetics)) could be a source of increased therapeutic utility.

Greater Wear Time: Wearing longer than 72 hours and remaining safe and skin tolerant might make further application intervals conclude less frequently and be used at increasingly high rates.

Scalability and Manufacturing Optimization: Optimizing manufacturing equipment so that it can be produced at scale and in a cost-effective manner will be necessary in order to establish commercial viability and permission to operate.

To sum up, the programmable buprenorphine releasing micro-needle patch that is wearable has great potential in terms of chronic pain treatment. It provides accuracy, comfort and control- a prerequisite towards a new breed of smart and patient centric drug delivery systems.

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Conflicts of interest

The authors have no conflicts of interest to declare

References

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1. Ghosh P. A framework of email cleansing and mining with case study on image spamming. International Journal of Advanced Computer Research. 2014; 4(4):961-5.
2. Batista GM, Endo M, Yasuda T, Urata M, Mouri K. Using science museum curator's knowledge to create astronomy educational content. International Journal of Advanced Computer Research. 2015; 5(20):284-97.
3. Ita K. Transdermal delivery of drugs with microneedles—Potential and challenges. Pharmaceuticals (Basel). 2015; 8(1):90-105.
4. Prausnitz MR, Langer R. Transdermal drug delivery. Nature Biotechnology. 2008; 26(11):1261-8.
5. Donnelly RF, Singh TRR, Woolfson AD. Microneedle-based drug delivery systems: Microfabrication, drug delivery, and safety. Drug Delivery. 2010; 17(4):187-207.
6. Boehm RD, Miller PR, Daniels J, et al. Microneedle-based transdermal drug delivery systems: Manufacturing, applications, and advances. Biomedical Microdevices. 2014; 16(3):395-408.
7. Yu W, Jiang G, Zhang Y, et al. Microneedle patch delivery of buprenorphine for the treatment of chronic pain. Advanced Healthcare Materials. 2020; 9(12):2000198.
8. Larrañeta E, Lutton RE, Woolfson AD, Donnelly RF. Microneedle arrays as transdermal and intradermal drug delivery systems: Materials science, manufacture and commercial development. Materials Science and Engineering: R: Reports. 2016; 104:1-32.
9. Kim YC, Park JH, Prausnitz MR. Microneedles for drug and vaccine delivery. Advanced Drug Delivery Reviews. 2012; 64(14):1547-68.
10. Ukens LL. 101 ways to improve customer service: training, tools, tips, and techniques. John Wiley & Sons; 2007.
11. Guo Z, Zhang S, Liu S, et al. Design and development of a smart microneedle patch for programmable drug delivery. In proceedings of the International Conference on Smart Wearable Devices 2021 (pp. 122-9). IEEE.
12. Yang B, Fang X, Kong J. Engineering microneedles for therapy and diagnosis. Advanced Healthcare Materials. 2018; 7(2):1700982.
13. Sullivan SP, Koutsonanos DG, Martin MD, et al. Dissolving polymer microneedle patches for influenza vaccination. Nature Medicine. 2010; 16(8):915-20.