TRANSDERMAL POWER TRANSFER FOR IMPLANTED DRUG DELIVERY DEVICES USING A SMART NEEDLE AND REFILL PORT

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ABSTRACT

This paper describes a pair of micromachined components that work together for transdermal power (and data) transfer into implantable drug delivery devices. In particular, it describes a smart refill port that is electrically accessed with a mating, multi-pole, plug-in needle. These components are fabricated entirely from molded PDMS, Parylene, Kapton, and micro-electro-discharge machined stainless steel. The component pair demonstrates power transfer with low current leakage into both dry and saline ambient, and it has been used to recharge batteries with currents ranging from 10 mA up to 500 mA while temperature change is monitored.

INTRODUCTION

Motivation

Implantable drug delivery devices (IDDDs) are used to treat medical conditions, such as spasticity or chronic pain, through targeted delivery of medications like baclofen or local anesthetics. Conventional programmable IDDDs use 25-50% of the implanted device volume for a battery that is intended to last the entire duration (5-10 years) of the implant. However, in typical IDDDs [1] medication is typically refilled every 10 weeks by transdermal injection into a subcutaneous refill port (Figure 1). This research is motivated by the consideration that the overall volume efficiency of an IDDD, which is critical to its placement and usability (particularly in pediatric cases), can be improved substantially if the conventional battery is replaced with a smaller battery that is recharged. It is preferable that the recharging occurs in the same session that the drug reservoir is refilled, although not necessarily at precisely the same time [2]. While wireless power transfer is possible for very low-power applications [3], DC recharge capability [4] offers high current levels and may be more suitable for IDDDs (Fig. 2).

Power Transfer

While it is relatively easy to transfer data across most electrical connections, it is more difficult to transfer high levels of power. One problem is resistive heating in the conductors. The heat energy generated (Q) is due to the power (P) transferred through the conductor over a set amount of time (t). The power is related to the current (I) being transferred through a conductor with a particular resistance (R). The resistance is due to the resistivity of the conductor (ρ), the Length (L), and the cross sectional area (A) of the conductor. Assuming a constant material and length, the heat generated for any particular recharging current is inversely proportional to the cross sectional area of the conductor (Eqn. 1).

$$Q = Pt = (I^2R)t = (I^2\rho Lt)/A \qquad (1)$$

In order to maximize the amount of power that can be transferred across a refill port, the conductor through the needle should have the largest possible cross sectional area. The two methods of creating conductors with the largest cross sectional area are either using the needle itself, or filling the needle with a conductor (Fig. 3).

Typical refill needles used in IDDDs range in size from 22 gauge to as narrow as 28 gauge. The ratio of the inner diameter (r) to outer diameter (R) ranges from 0.55 to 0.6 across this needle range. Even in the worst case, the cross sectional area of the conductor of the two-pole needle is 1.78 times that of a filled needle. This means

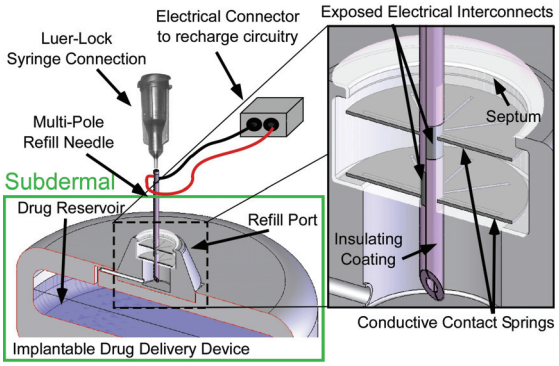


Figure 1: The system view: A two-pole needle is inserted into the refill port of a drug delivery device. Inset: A close view of the two needle halves making electrical contact with springs inside the septum.

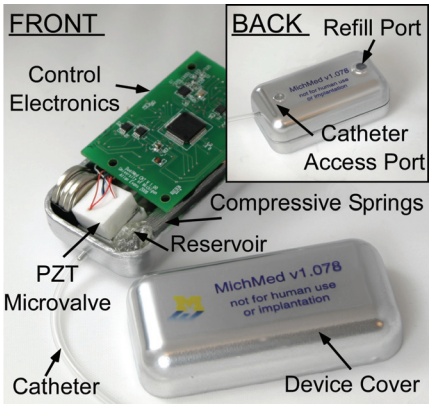


Figure 2: A photo of the front of an assembled microvalve-regulated drug delivery device with the back side refill port shown inset [8].

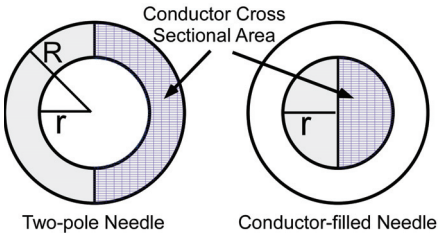


Figure 3: Two possible needle configurations. Either the needle is split (left) or it is filled with a conductor (right).

that a two-pole needle would generate about half of the heat a needle with a filled conductor would for the same recharge current. For both this reason and the retained ability to transport liquids, the transdermal power transfer system is designed to provide a mating scheme that utilizes a multi-pole needle.

Device Concept

The refill ports of most implantable drug delivery devices are composed of a polymer septum through which the needle enters the device. The polymer is relatively thick (2-5 mm), and is designed to reseal itself after the refill needle is removed from the device. Below the septum is a small open volume that is connected to the reservoir of the implant. The thickness and insulating properties of the septum make it an appealing candidate for modifications that would allow power transfer.

A two-pole needle and a power transfer refill port (Fig. 1) are designed to mate within the septum. The two-pole needle is designed so that each half is an independent conductor that is isolated from the other half, the exterior, and the interior lumen of the needle through which the drug would flow. The needle halves are exposed on the exterior at two separate locations along its length. These locations correspond to the position of two contact springs within the septum.

The ports in conventional IDDDs are typically accessed by non-coring needles that are curved at the tip (Huber needles). The system mates when a multi-pole, non-coring needle punctures the silicone septum of the refill port and is advanced until the tip of the needle reaches the metal base plate at the bottom of the port. (This metal base plate is electrically floating.) This design architecture has several advantages. The location of the springs and the exposure "windows" of the needle are designed so the windows align with the springs when the needle is fully inserted because the tip presses against the bottom of the refill port. Also, by using two separate springs located at different heights, no rotational alignment of the needle is necessary to make electrical contact. This prevents the need for medical professionals to twist the needle upon insertion, and it also prevents mating incorrect conductors to each other. This topology is also particularly safe because the springs located in the non-conductive septum and the conductors of the needle are electrically isolated from the casing of the port, the patient's body, and the drug being refilled.

DESIGN AND FABRICATION

Two-pole Needle

The two major system components are the non-coring needle and the refill port. Presently, implantable drug delivery refill ports are designed to be accessed with Huber needles ranging from 22 gauge to 28 gauge. Two-pole Huber needles (700 µm ø, 26 gauge) for use with a smart refill port are fabricated by lapping two stainless steel needles in half using an oil-based diamond slurry (Fig. 4). The needle halves are completely coated in 2.8 µm thick Parylene to electrically isolate the halves from each other and from the environment. Parylene is selectively removed from areas near the needle tip to create the contact windows that mate in the refill port and from the back of the needle to allow contact with the power source. The needle halves are then aligned and bonded [5] (Fig. 5), with further insulation and sealing strength provided by inserting the needle into a Kapton tube.

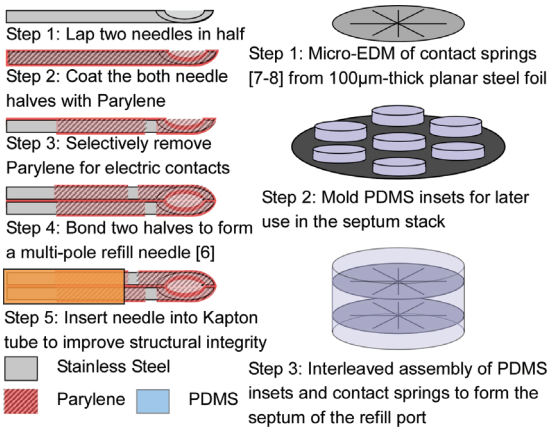


Figure 4: The needle and septum are fabricated from biologically compatible materials. The fabrication process aligns the conductive needle windows to the springs so they make contact upon insertion.

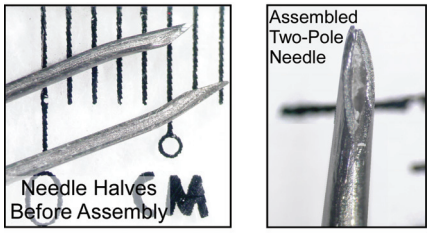


Figure 5: Photographs of 26 gauge coated needle halves before and after assembly taken on a white ruler.

Septum Springs

The refill port requires a septum designed with contact springs at specific heights. The electrical contact springs are fabricated from 100 µm thick stainless steel by micro-electro-discharge machining (µEDM) [6-7]. The contact springs are 5.2 mm in diameter with four quadrants separated by 300 µm wide slots (Fig. 6). These springs press against the needle as it is inserted. The pressure forces the needle toward the middle of the refill port, and it also improves the lead transfer conductance by maintaining pressure at the spring/needle junction. The symmetrical nature of the contact springs prevents the need for needle alignment. Additionally, the springs are supported by the septum polymer and return to their initial positions after the needle is removed. This allows for multiple recharging sessions to occur using a single port. The springs are located at specific heights within the polymer septum for needle alignment purposes.

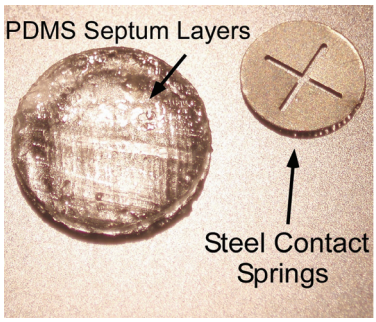


Figure 6: µEDM springs and PDMS septum layers.

Polydimethylsiloxane (PDMS; or alternatively silicone) is used as the septum material. It is shaped using circular molds of specific heights and cured for 30 min. at 70°C to form septum layers with the correct spring spacing. The PDMS and springs are stacked and inserted into the refill port (Fig. 7) to allow for electrical coupling between a needle and the implantable drug delivery device (Fig. 2).

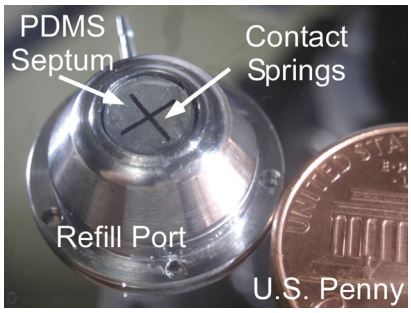


Figure 7: A photograph of an assembled refill port in which the top contact spring of the septum is clearly visible. The port is pictured here with a US Penny.

EXPERIMENTAL RESULTS

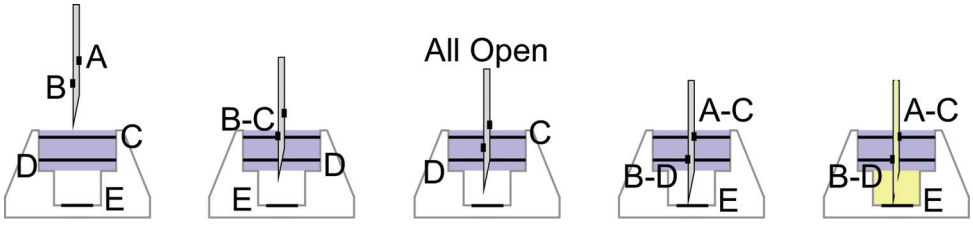
Insertion Testing

The quality of the electrical connection between the two-pole needle and the port can be evaluated by measuring the resistances between the two elements in both dry and wet environments. In mating both normal Huber needles and two-pole needles with assembled refill ports, testing can identify if electrical connections are made as expected (Fig. 8). Resistances between the two poles of the needle (A and B), the two septum springs (C and D), and the electrically floating metal base plate were measured as both types of needles were advanced into the septum. Typical resistances for a fully inserted normal needle were about 0.5 Ω from A to C and D; and 1 Ω between the A and E. The two-pole needle has slightly higher resistances from A to C and B to D (~0.7 Ω) but maintains isolation from A to B (1.6 MΩ) and from A to E (>10 MΩ). The resistance tests also confirm that the C and D are electrically insulated from each other and from the E. The slightly higher resistances attributed to the two-pole needle are likely due to the decreased cross sectional area of the needle, and the decreased contact area between the conductors of the split needle and the metallic contact springs. A number of combinations of contact points were tested during multiple insertions, and the results exhibited expected contact properties.

In order to further evaluate the performance of the mating pair, saline was introduced into the needle lumen and the port cavity. Insertion tests, similar to those above, were conducted in the wet ambient. As shown in Figure 8, resistances from A to C and B to D were low (< 2 Ω), and electrical isolation was maintained from B to C and A to E (> 2 MΩ). These results indicate that the parasitic current leakage paths are minimal. Additionally, no electrolysis was observed in either the needle or in the mated port during characterization.

Battery Recharging

Recharging batteries using the needle-port system generates resistive heating in the needle and at interface between the needle and the contact springs. Two 1.2 V NiMH AA batteries were recharged using various currents at room temperature in a dry environment. The air environment restricts the thermal conductance of heat away from the refill port as compared to a refill port located subcutaneously *in vivo*. Additionally, a lack of liquid located within or flowing through the lumen, reduces the thermal capacitance of the system and increases the temperature change of the device for any particular power transfer. Typical room temperature recharging with power transfer rates ranging from 10-500 mA demonstrate the expected temperature rises at needle-septum interface (Fig. 9) and out on the port housing (Fig. 10) of the refill port. The temperature changes at the needle septum entry point exhibit much higher swings because the PDMS is not thermally conductive, so the principal mechanism of heat dissipation occurs via conduction through the air. This is a location in the system that will experience one of the largest temperature



	Not Inserted		Partially In		Disconnect In		Inserted		Saline
Normal Needle	Expected	Actual	Expected	Actual	Expected	Actual	Expected	Actual	Actual (wet)
A to C	Open	>10M	Short	0.328	Short	0.374	Short	0.367	
A to D	Open	>10M	Short	0.528	Short	0.528	Short	0.532	
A to E	Open	>10M	Open	>10M	Open	>10M	Short	1.09	
Two-pole needle									
A to C	Open	>10M	Open	>10M	Open	>10M	Short	0.64 - 1.43	1.22
B to D	Open	>10M	Open	>10M	Open	>10M	Short	0.83 - 2.05	1.65
B to C	Open	>10M	Short	1.4	Open	>10M	Open	>10M	2.3M
A to E	Open	>10M	Open	>10M	Open	>10M	Open	>10M	2.6M

*Figure 8: Stages of insertion with resistances color coded to expected states for normal and split needles both dry and completely filled with saline after insertion. (*All resistances are in Ω)*

increases for a specific recharging current. The battery voltage was monitored (Fig. 11) along with temperature for varying current to confirm the batteries were recharging at relative rates. No measureable heating was observed for currents of 100 mA or less. The battery voltage increases coupled with the low heating levels at higher currents, like 500 mA, (< 15°C septum and < 2°C casing) represent power transfer rates necessary to fully recharge a battery used in an implantable drug delivery device during the reservoir refill session.

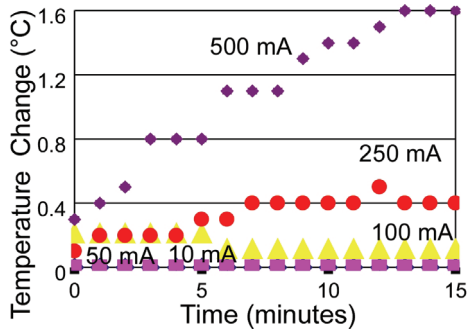


Figure 9: Temperature change at the septum entry point over time for recharging currents from 10-500 mA. The test was conducted in an air ambient environment with a baseline temperature of 22.4 °C.

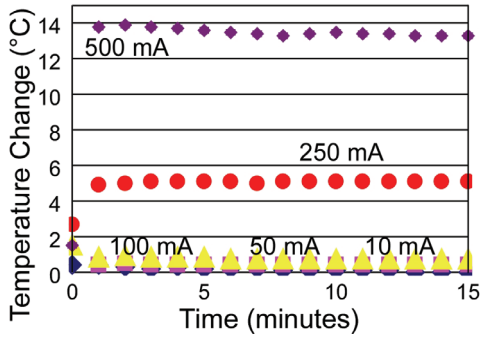


Figure 10: The temperature change of the exterior of the port housing for battery charging currents ranging from 10-500 mA. The temperature increase has resolution of 0.1°C and was conducted in ambient air with a temperature of 22.4 °C.

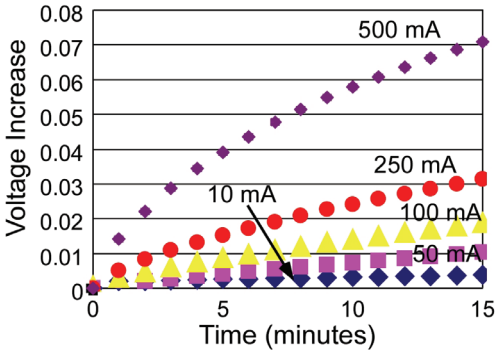


Figure 11: The voltage increase of a NiMH 1.2V AA battery as it is being recharged across a refill port with various charging currents. Charging profiles match expected values, and demonstrate power transmission with acceptable heating rates for a smart needle and port to be used in IDDDs.

CONCLUSIONS

A mechanism for transferring power across the needle through the refill port of an IDDD has been explored to maximize the power transfer rate. A two-pole needle was fabricated from bio-compatible components, and a refill port was designed with stainless steel contact springs to mate with the needle upon insertion.

During the various stages of needle insertion, the two-pole needle exhibited expected resistive characteristics with little current leakage when filled with saline. The refill port springs self-aligned with the needle and made ohmic contact when the needle was fully inserted without additional alignment. NiMH batteries were recharged using power transfer across a refill port mated with a two-pole needle. Recharging currents ranging from 10 – 500 mA were transferred for typical refill times of 15 minutes while changes in temperature were measured at various points of the system. The relatively low increases in temperature for even the highest current levels indicate that this topology can be used in implants. This allows for IDDDs to be made smaller because they will not need batteries designed to power the device for 5 - 10 years, but they will be able to use batteries that power the device for 26 weeks. With more sophisticated needle and port designs, high speed parallel data transfer may also be possible. The reduced communication circuitry and battery sizes could result in a total IDDD size reduction of up to 40%.

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