

Transdermal power transfer for recharging implanted drug delivery devices via the refill port

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Abstract This paper describes a system for transferring power across a transdermal needle into a smart refill port for recharging implantable drug delivery systems. The device uses a modified 26 gauge (0.46 mm outer diameter) Huber needle with multiple conductive elements designed to couple with mechanical springs in the septum of the refill port of a drug delivery device to form an electrical connection that can sustain the current required to recharge a battery during a reservoir refill session. The needle is fabricated from stainless steel coated with Parylene, and the refill port septum is made from micromachined stainless steel contact springs and polydimethylsiloxane. The device properties were characterized with dry and wet ambient conditions. The needle and port pair had an average contact resistance of less than 2Ω when mated in either environment. Electrical isolation between the system, the liquid in the needle lumen, and surrounding material has been demonstrated. The device was used to recharge a NiMH battery with currents up to 500 mA with less than 15°C of resistive heating. The system was punctured 100 times to provide preliminary information with regard to device longevity, and exhibited about 1Ω variation in contact resistance. The results suggest that this needle and refill port system can be used in an implant to enable

battery recharging. This allows for smaller batteries to be used and ultimately increases the volume efficiency of an implantable drug delivery device.

Keywords Drug delivery · Intrathecal · Power transfer · Implant · MEMS

1 Introduction

Chronic pain, at a level that causes partial or total disability, is a medical condition that afflicts an estimated 100 million people in the United States (Rainov and Heidecke 2007; Joint Committee 1999). Chronic pain arises from a variety of causes including traumatic injury, various diseases (like arthritis), surgery, or nerve damage (Phillips 2003). One treatment method for severe chronic pain or spasticity is to implant an intrathecal pump that delivers medication directly into the spinal canal (Erdine and De Andres 2006; Winkelmuller and Winkelmuller 1996; Wermeling 2005; Schug et al. 2006; Rauck et al. 2003; Deer et al. 2004). These pumps are highly effective because they have a direct path into the cerebrospinal fluid (CSF). This requires precise dosing, but it offers several benefits. It reduces drug-related side effects by decreasing the dose required to achieve a certain level of analgesia, reduces the need for oral medications, and enhances quality of life in a segment of chronic pain patients whose pain has not been controlled with more conservative therapies (Likar et al. 2006).

Implantable pain therapy pumps work by delivering medication into the CSF that is in the intrathecal space. Several companies have developed intrathecal implantable pumps (Medtronic 2008). Current pumps are generally disc shaped, 180 to 220 cc in total volume, contain a single reservoir, are implanted beneath the skin of the abdomen,

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and are typically refilled every 12–24 weeks via a subcutaneous refill port. Active devices typically use a peristaltic pump controlled by a microprocessor that can be programmed for the infusion mode (e.g. bolus, multi-step bolus, continuous, etc.) and delivery rate depending on patient needs. The battery size of these devices is typically 25–50% of total device volume because it must continuously operate for the implant lifetime (5–10 years). This research is motivated by the consideration that the overall volume efficiency of an implant, 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.

Implantable batteries can be recharged through a direct physical connection, a wireless radio frequency link, or via a wireless inductive link. While wireless power transfer is possible for very low-power applications (Boveja and Widhany 2008), DC recharge capability offers higher current levels and may be more suitable for implantable drug delivery devices (Vipul 2007). The only connection made between the external environment and the implanted drug delivery device occurs when a needle is inserted into the reservoir port during a reservoir refill session. Refill ports typically consist of an external biocompatible housing, a re-sealing silicone septum, a metal base plate that limits needle penetration, and a gap between the septum and the base plate with an exit channel through which the fluid enters the reservoir (Andrews et al. 1990; Strum et al. 1986). The refill port is typically inset within the drug pump housing in a position in which the rounded rim protrudes just above the wall of the housing (Reynaerts et al. 1996). A normal refill session begins with the puncturing of the septum using a non-coring Huber needle. The needle tip is then advanced until it presses against the base plate (The reservoir is first emptied before administering fresh drug). Medication is then driven into the device from an external syringe (Morris et al. 1992). Refills generally require 10–20 min and occur every 12–24 weeks.

Recharging the battery through an electrical coupling within the refill port may provide efficiency and convenience. It would permit implantable device designs that require significantly smaller batteries. Architectures taking advantage of this reduced battery size may be able to achieve a greater volume efficiency than traditional devices. This is particularly true for devices that have long implant lifetimes and relatively high rates of power consumption (Carmichael 2007).

In this paper, we describe a method for power transfer through a customized conductive needle designed to interface with metal spring electrodes embedded in a refill port¹ (Fig. 1). The needle adapts a current model to allow for

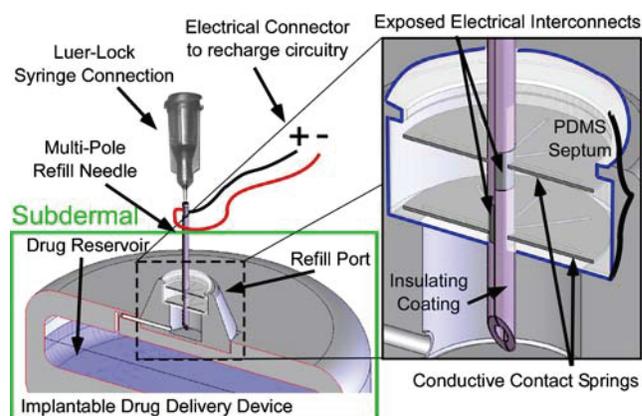


Fig. 1 The system view: A two-pole needle is inserted into the refill port of a drug delivery device. Inset: A close view of the two needle halves making electrical contact with springs inside the septum

two isolated conductive pathways. The refill port is designed with embedded metal springs to mate electrically with the modified needle. The system is designed to mate successfully regardless of the rotational orientation or insertion angle of the needle. This prevents the need for the physician to rotate or reinsert the needle to make proper contact, which may otherwise create an additional risk of infection or patient discomfort beyond that which is already experienced in the refill process (ASHP 2000). The component design and fabrication are discussed in Section 2, system results are presented in Section 3, and Section 4 contains discussion and a summary overview.

2 Component design and fabrication

The most important aspects of the design are power handling capability, isolation of the drug and tissue from electrical current, minimal tissue and drug heating, and ease of alignment between the needle and the port. In order to transfer DC power, the needle should be composed of at least two conductors, or poles, which must mate with corresponding poles in the refill port. The conductive path should also be electrically isolated. (The isolation is particularly important if the needle is being used to refill the drug reservoir at the same time the battery is being recharged. While this capability is not fundamentally required, it can improve efficiency and convenience.) Structural options for providing multiple conductive paths in a single needle include the use of multiple conductors within the lumen, the use of concentric isolated conductors, or splitting the needle longitudinally and isolating the halves. The split needle allows for simple alignment

¹ Portions of this article appear in conference abstract form in Ref (Evans et al. 2009).

because it provides access to both conductors on the exterior of the needle. Sub-section 2.1 outlines the power transfer design constraints of the needle; sub-section 2.2 outlines the design of the mating mechanism and the port for use with the multi-pole needle; sub-section 2.3 describes the assembly procedure for the needle and the refill port.

2.1 Power transfer and needle design

While it is relatively easy to transfer data across most electrical connections, it is more difficult to transfer current at levels of hundreds of milliamps as required to recharge a battery (Soria et al. 2001). One challenge is resistive heating in the conductors. For a given conductor, this requires the use of a conductive path with 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. Using the needle itself is preferable to other methods because the lumen remains unobstructed. Typical refill needles used in implantable drug delivery devices 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.

2.2 Refill port design

The refill ports of most implantable drug delivery devices are composed of a polymer septum through which the needle enters the device (Medtronic 2008). 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.

Fluid ports in conventional implants are typically accessed by non-coring Huber needles. In our design, the power transfer system mates when a multi-pole, non-coring needle punctures the polydimethylsiloxane (PDMS) 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.) Each longitudinal half of the needle is exposed at a “window” on its exterior; the window for each half is at a different point along its length. The location of metal contact springs that are embedded within the septum and the exposed windows in the insulation of the needle are designed so the windows align with the mating regions when the needle is fully inserted. This occurs upon every insertion because the tip of the needle presses against the bottom base plate of the refill port. Since two separate springs are located at different heights, rotational alignment of the needle is not necessary

to make electrical contact. This prevents the need to twist the needle upon insertion, and it also prevents mating the incorrect conductors to the springs. It should be noted that the needle and the metal springs in the septum are electrically isolated from the casing of the port, the surrounding tissue, and the drug being refilled. The metal contact springs could potentially be replaced by conductive layers that are composed of specialized polymers (Gerard et al. 2002) or conductive fibers in a weave (Tajima et al. 2002). The most important criteria for determining the structure of the mating springs are the formation of a low resistance contact and the ability to maintain functionality after repeated needle insertions.

2.3 Fabrication and assembly

The two system components requiring custom fabrication are the non-coring needle and the refill port. Two-pole Huber needles (700 μm \varnothing , 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. 2). 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 (Kim and Najafi 2005), with further insulation and sealing strength provided by inserting

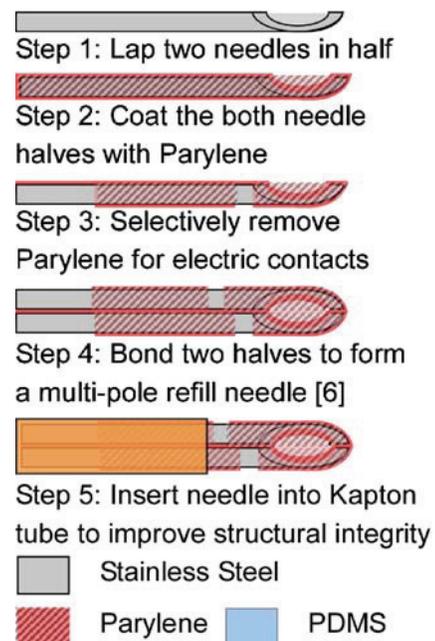


Fig. 2 The needle is fabricated from biologically compatible materials. The fabrication process creates open conduction paths or “windows” that are self-aligning once inserted into the port

the needle into a 50 μm thick Kapton tube. Stainless steel needles and Parylene are used to create the two-pole needle because they are biologically compatible materials. Additionally, the thin Parylene coating does not significantly change the inner or outer diameter of the needle.

The refill port requires a septum designed with contact springs at specific heights to allow for self-aligned mating. The electrical contact springs are fabricated from 100 μm thick stainless steel by micro-electro-discharge machining (μEDM) (Takahata and Gianchandani 2002; Richardson and Gianchandani 2008). The contact springs are 5.2 mm in diameter with four quadrants separated by 300 μm wide slots (Fig. 3). The septum is fabricated by inserting two 100 μm thick stainless steel contact springs into the septum at the positions of 4.5 and 5.5 mm above the base plate. The PDMS itself begins at 3.5 mm above the base plate and extends to 6.5 mm above the base plate. The septum is 5.88 mm in diameter and is held in place on a shelf in the refill port by compression. A fabricated needle and port are shown in Fig. 4.

The 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 rotational needle alignment. Additionally, the springs are supported by the PDMS used as the septum polymer and return to their initial positions after the needle is

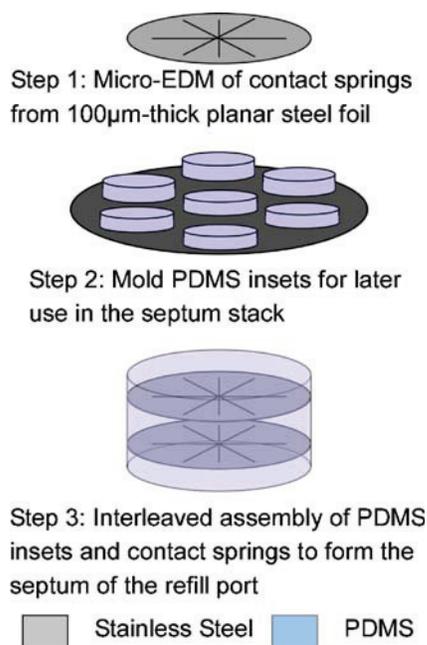


Fig. 3 The septum is fabricated from biologically compatible materials. Contact springs of various heights to contact with the openings in the needle coating to allow power transfer

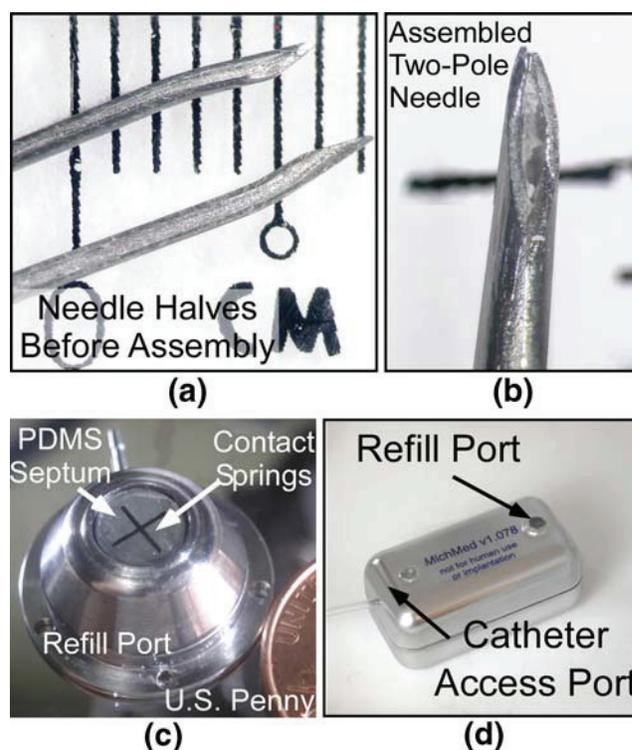


Fig. 4 (a) Photographs of 26 gauge coated needle halves before and (b) after assembly taken on a white ruler. (c) A photograph of an assembled refill port in which the top contact spring of the septum is clearly visible. The port is pictured here with a US Penny. (d) An implantable drug delivery device with the refill port and a similar catheter access port

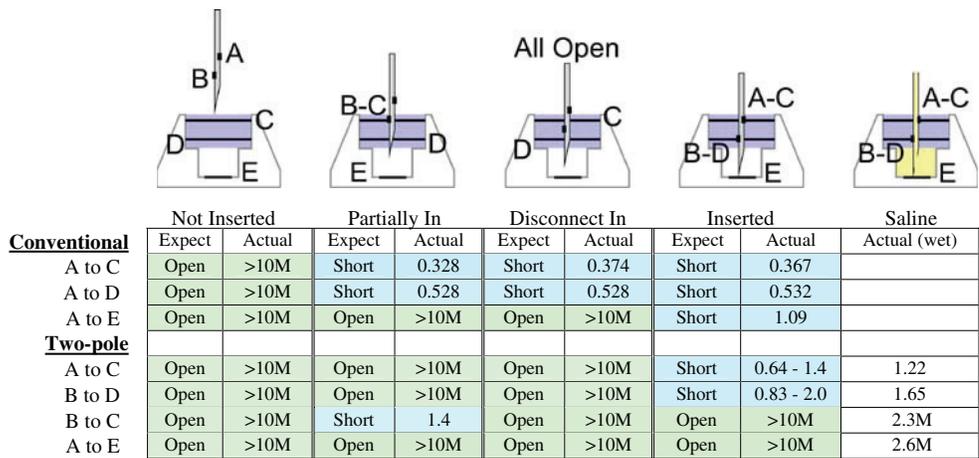
removed. This allows for multiple recharging sessions to occur using a single port.

3 Experimental results

Contact resistance, in both dry and wet ambients, can provide an indication of the integrity and power handling capability between the needle and the port. Higher transfer currents can alter the contact properties of the mating pair, and these changes can be monitored while recharging batteries. Long term viability can be determined by puncturing the septum multiple times and monitoring the transient changes in resistance and septum deformation. Proper testing allows for determination of both short term and long term properties of the mating pair.

In mating both conventional Huber needles and two-pole needles with assembled refill ports, continuity tests can identify if electrical connections are made as expected (Fig. 5). 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 (E) were measured as both types of needles were advanced into the septum. In a dry ambient, typical resistances for a fully inserted normal

Fig. 5 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)



needle were about 0.5Ω from A to C and D; and 1Ω between A and E. The two-pole needles had slightly higher resistances from A to C and B to D ($\sim 0.7 \Omega$) but maintained isolation from A to B ($1.6 M\Omega$) and from A to E (greater than $10 M\Omega$). The resistance tests also confirmed that C and D were electrically insulated from each other and from E. The slightly higher resistances attributed to the two-pole needles were 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. These tests indicated that both the modified and original needles made good electrical contact with the springs. Additionally, the isolation mechanisms of the split needle and the septum functioned as expected. This was verified in the fully inserted state because a normal needle short circuited with both springs and the base plate while the split needle functioned as expected.

Saline is often used as the carrier agent for medication. Saline can also be used to approximate the *in vivo* electrical conditions experienced by implantable devices. In a separate set of tests, saline was introduced into the needle lumen and the port cavity. The exterior of the port was also immersed in saline. Insertion tests, similar to those conducted in a dry environment, were conducted in this wet ambient. As shown in Fig. 7, resistances from A to C and B to D were low (less than 2Ω), and electrical isolation was maintained from B to C and A to E (greater than $2 M\Omega$). This suggests that the isolation techniques used in the system are effective at isolating the conductive paths from both the medication and the surrounding environment. Additionally, no electrolysis was observed in either the needle or in the mated port during characterization.

One potential limitation on the current levels that can be sustained during a recharging operation is imposed by the parasitic resistive heating of the implantable device, medication, and surrounding tissue. In order to determine the resistive heating in the needle and at the interface between the needle and the contact springs, the change in

temperature was monitored as batteries were recharged. Two 1.2 V NiMH AA batteries were recharged using various current levels 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* or in an aqueous medium. Additionally, a lack of liquid located within, or flowing through, the lumen reduces the thermal capacitance of the system and increases the heating of the device for any particular power transfer rate. Typical room temperature recharging with power transfer rates ranging from 10–500 mA demonstrated the expected temperature rises at needle-septum interface (Fig. 6) and on the port housing (Fig. 7) of the refill port. The temperature changes at the needle septum entry point exhibited much higher variations because the PDMS septum is not thermally conductive. This is a location in the system that will experience one of the largest temperature increases. The battery voltage was monitored (Fig. 8) along with temperature for varying current to confirm the batteries were recharging at rates relative to the transfer current. Typical starting voltages ranged from 1.1 V to 1.4 V. No measureable heating

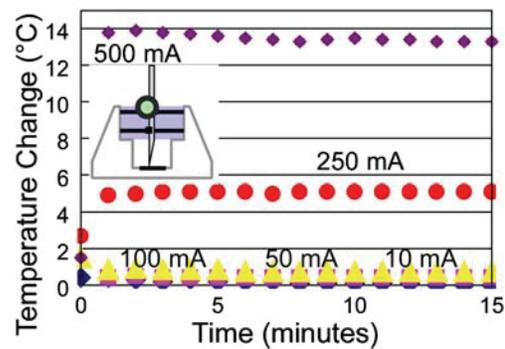


Fig. 6 Temperature change at the septum entry point over time for recharging currents from 10–500 mA. The circle in the inset denotes the temperature sampling location. The test was conducted in an air ambient environment with a baseline temperature of 22.4°C

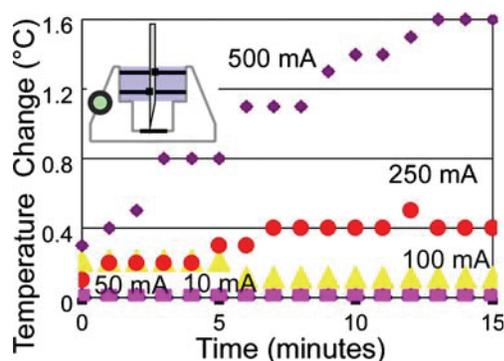


Fig. 7 The temperature change of the exterior of the port housing for battery charging currents ranging from 10–500 mA. The temperature increase has resolution of 0.1°C and was conducted in ambient air with a temperature of 22.4°C. The circle in the inset denotes the temperature sampling location

was observed for charging currents of 100 mA or less. At higher current levels (above about 500 mA), modest heating occurred: temperature increases were less than 15°C at the septum and 2°C at the casing. Overall, these results indicate that this type of port is suitable for rapidly recharging a small battery in an implantable drug delivery device.

In addition to forming good electrical connections and limiting heat generation during battery recharging, this type of power transfer system needs to be reliable over many refill sessions. This is particularly true for mechanical springs because of potential plastic deformation. Typically refill sessions occur once every 6–8 weeks, and device lifetimes range from 5–8 years (Grabow et al. 2001). Assuming the device is refilled every 6 weeks for 8 years, the refill port could be punctured as many as 70 times. Puncturing the septum many times acts as an approximate simulation of the effect of accumulated refills on the springs, silicone, and device connectivity.

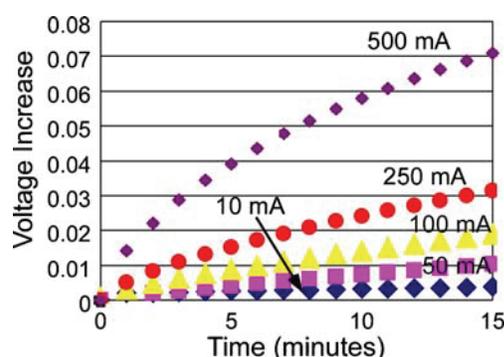


Fig. 8 The voltage increase of a NiMH 1.2 V AA battery as it is being recharged across a refill port with various charging currents. Typical starting voltages range from 1.1 V to 1.4 V. Charging profiles match expected values, and demonstrate power transmission with acceptable heating rates for a smart needle and port to be used in implantable drug delivery devices

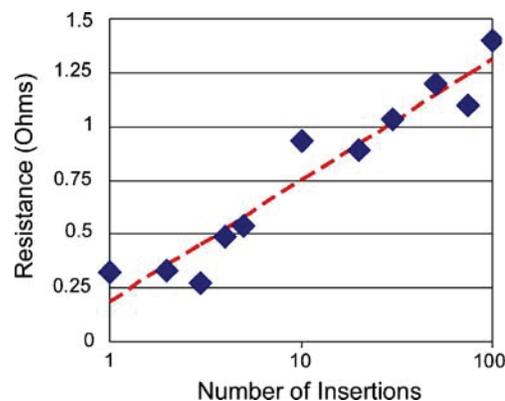


Fig. 9 The resistance of the needle and spring contact resistance across many insertions with a logarithmic fit. The resistance varies from 0.27–1.4 Ω over 100 punctures. The logarithmic nature of the resistance indicates that the principal changes to the connection occur early in the life cycle of the refill port

Puncture tests were conducted in an air environment using a refill port and a standard Huber needle. A refill port was punctured one hundred times, and both the resistance and images of the septum were captured. The resistance measurements (Fig. 9) varied over 0.27–1.4 Ω and exhibited a roughly logarithmic increase with the number of needle insertions. The image data (Fig. 10) clearly displays the plastic deformation that occurs to the septum

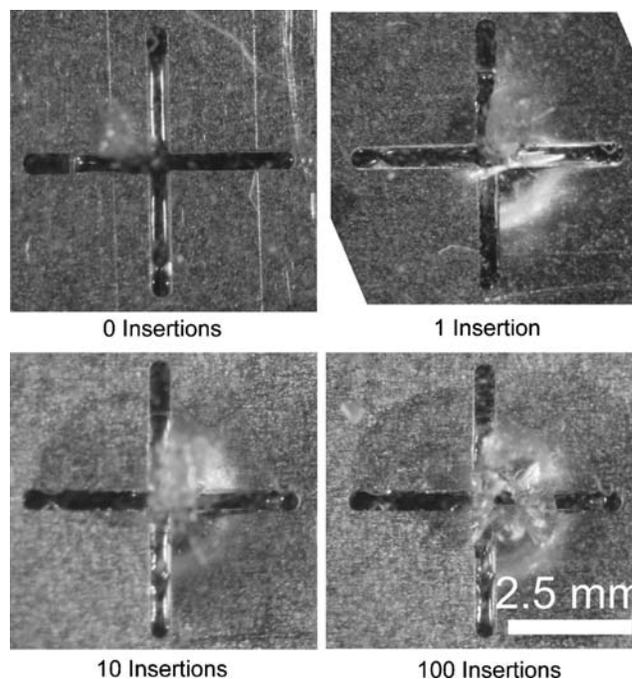


Fig. 10 Photographs of the needle septum after a set number of punctures taken under a microscope. The photographs reveal that almost all of the spring deformation occurs during the first needle insertion, and subsequent punctures cause minimal mechanical alteration to the port

springs during the initial insertions. Additional punctures caused no apparent changes to the springs, and only slightly altered the PDMS. The image analysis indicates that plastic deformation in the springs and additional mechanical failures in the septum are only likely to manifest themselves during the first few insertions. This logarithmic resistance tendency agrees with the image analysis and further suggests that changes to the mechanical properties of the system occur early in the lifecycle of the device. The long term tendency to approach a stable operating point, in addition to acceptable electrical and thermal performance from the complete system, indicates that it could be used to recharge batteries in an implantable drug delivery device.

4 Conclusions

This effort explored a method for transferring electrical power across the needle through the refill port of an implantable drug delivery device. The method is intended for current levels up to 500 mA and voltage levels up to 3.3 V, as needed to rapidly charge batteries. The approach utilizes a longitudinally split, two pole Huber needle and a mating port with spring-loaded connections. The refill port springs self-align with the needle and make ohmic contact when the needle is fully inserted without additional alignment. The electrical contact and insulation perform well in both wet and dry ambients. The mechanical properties of the refill port remain functional for repeated needle insertions. The modest increases in temperature for even the highest current levels indicate that this recharging mechanism is promising. The possibility of recharging the battery of an implantable drug delivery device during a drug refill session could result in an implantable drug delivery device size reduction of up to 40%. With more sophisticated needle and port designs, high speed parallel data transfer may also be possible.

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