INNOVATIVE RENAL COOLING DEVICE FOR USE IN MINIMALLY INVASIVE SURGERY

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ABSTRACT

Over 58,000 patients suffer from renal cell carcinoma annually in the US. Treatment for this cancer often requires surgical removal of the cancerous tissue in a partial nephrectomy procedure. In open renal surgery, the kidney is placed on ice to increase allowable ischemia time; however there is no widely accepted method for reducing kidney temperature during minimally invasive surgery. A novel device has been designed, prototyped, and evaluated to perform effective renal cooling during minimally invasive kidney surgery to reduce damage due to extended ischemia. The device is a fluid-containing bag with foldable cooling surfaces that wrap around the organ like a taco shell. It is deployed through a 12mm trocar, wrapped around the kidney and secured using bulldog clamps. The device then fills with an ice slurry and remains on the kidney for up to 20 minutes. The ice slurry is then removed from the device and the device is retracted from the body. Tests of the prototype show that the device successfully cools porcine kidneys from 37°C to 20°C in under 5 minutes.

1 Introduction

Renal cell carcinoma affects thousands of patients each year in the U.S., with over 58,000 new cases and 13,000 deaths in 2010 alone [1]. Treatment for organ-confined cancers usually requires surgery. Chemotherapy and radiation therapy are less effective, and tumor ablation is unreliable [2]. The gold standard for renal cell carcinoma has been the radical nephrectomy. This procedure involves removal of the entire kidney and the surrounding tissue. This method successfully prevents cancer from growing and metastasizing, but can cause undesirable side-effects. With only 1 kidney left, patients of radical nephrectomies have impaired renal function resulting in increased hospitalizations, increased cardiovascular events, and even an increased risk of death [2]. Recently, there has been a trend towards the partial nephrectomy, in which only a portion of the kidney is removed. This allows the patient to retain renal functionality and has a rate of cancer recurrence similar to that of radical nephrectomies. The gold standard has shifted to partial nephrectomies due to improved outcomes with decreased side-effects.

An important technical aspect of performing a partial nephrectomy is the temporary occlusion of the blood supply to the kidney, so that the highly vascular organ does not bleed excessively while the tumor is being carved out. This is achieved by placing bulldog clamps over the renal artery and vein. However, the resulting ischemia (lack of blood flow) to the kidney can have adverse consequences, particularly irreversible kidney damage which leads to decreased functionality post-operatively. This damage can begin to develop within 30 minutes of interrupting the blood flow to the kidney under normal circumstances. However, it can be avoided by inducing mild hypothermia in the kidney by cooling its core to 20°C.

Cooling is a key aspect of preforming partial nephrectomies in open surgery. In that setting, cooling is achieved by surrounding the kidney with a plastic bag filled with ice slush. This method is very effective and can achieve a kidney core temperature of 20°C in less than 10 minutes. Recently, however, there has been a trend toward minimally-invasive surgery for partial nephrectomies. This is a desirable option for many patients because of the reduced risk of infection, quicker recovery time, and
reduced scar tissue. However, minimally invasive surgery poses a significant problem for the partial nephrectomy procedure: currently there is no effective and widely adopted method for cooling the kidney in laparoscopic surgery.

This presents clinicians with two less than desirable options for a partial nephrectomy: use minimally invasive surgery and complete the procedure in less than 30 minutes, or perform open surgery to have over 2 hours of procedure time. A new device to cool kidneys laparoscopically would be key to avoiding the side effects of extended ischemia while providing the benefits of minimally invasive surgery.

2 Prior Art

There have been several attempts to induce renal hypothermia via laparoscopic techniques, all with little success. Gill et al. [3] used laparoscopic tools to place an Endocatch II bag around the kidney and synched it around the renal hilum using the bag drawstrings. They retrieved the bottom of the bag through a 12mm port and inserted ice slush into the bag. Although this technique successfully induced renal hypothermia it was difficult to perform and increased risk to the patient.

Crain et al. [4] tried to induce renal hypothermia in pigs using a double lumen 12 Fr catheter up the urethra. They continually flushed chilled saline through the catheter. This technique cooled the kidney to 26.1 °C, above the 20 °C expected temperature. As it did not achieve the same cooling effects as external cooling it was deemed unsatisfactory and not adopted.

Dobak, III et al. [5] patented a heating/cooling element that can be inserted into the feeding artery of an organ. This device heats or cools the organ without significantly impacting the temperature of the rest of the body. To our knowledge, this device has not been tested in minimally invasive renal surgery. However, doctors would be reluctant to adopt this technique as placing a device inside the renal artery would increase the risk of harm to the patient.

Devices to cool over the surface of a kidney have been designed and patented [6–9]. All center around containing a circulating ice slush or cooling fluid in a bag that can be inserted into the body. This creates the need for complicated systems to recirculate a cold, sterile fluid. Only two of the devices [6, 7] address surface cooling in minimally invasive surgery, but none have been studied further, placed in production, or have seen wide adoption. Unlike the above devices, which can be cumbersome to manipulate in the body, this paper presents the design of a simple, one-piece solution to the renal cooling problem that uses non-circulating two-phase fluid to induce the desired hypothermia in the kidney through its surface.

3 The Kidney Cooler

The novel Kidney Cooler is a bag that contains an ice slush mixture that wraps around a kidney. The bag can be inserted laparoscopically and be positioned around the organ to be cooled. Figures 1-2 show the prototype device and its use.

![Figure 1. The final bag prototype with relevant features labeled](image1)

![Figure 2. The final bag prototype wrapped around a model kidney and filled with fluid](image2)

The bag is made from polyethylene film and assembled with a combination of heat sealing and adhesive. The bag is designed to be rolled for its initial deployment, and pushed into the body cavity by using the fill tube. The bag is filled with air to unroll it inside the body. The air is then evacuated as the bag lays flat.
The bottom portion is then slid under the kidney as the kidney is held up by another instrument. The side tabs, marked by cross-hatches, provide an easy place for the surgeon to grab the bag without puncturing it. Then the top portion can be folded over and the tabs at the end can be clamped together with standard bulldog clamps. Once clamped, the space between the tabs allows for easy access to the renal hilum to stop blood flow. The bag is then filled with up to 470 ml of ice slush solution. Baffles in the bottom region limit fluid flow into the bottom forcing the remaining fluid to the top to completely surround the kidney as shown in Figure 2, where the clamps shown are not surgical bulldog clamps, but easier to manipulate ones used for testing purposes.

After cooling, the bag can be unclamped and manipulated by one of the tabs so fluid flows toward the tube. The pump is then reversed and most of the fluid removed. The remaining fluid can be removed by cutting a slit near the tabs. This fluid will be wrung out when the bag is pulled from the body and then gathered by suction. The bag can then be pulled through the instrument and removed. If the bag becomes lodged in the trocar, it can be easily removed by removing the trocar, simultaneously removing the bag through the incision.

The prototype bags were manufactured by hand from 0.002 inch thick low-density polyethylene film. A line heat sealer was used to construct the baffles and bag edges while the tubing was secured using 3M General Purpose Polyester Tape 8951. In future iterations, the tube will be secured with a heat sealing or ultrasonic welding process which we did not have access to for the early prototyping stages. The current bag material is LDPE which was selected for ease of manufacturing and availability. In future iterations, the bags will be made from 0.002 inch thick polyurethane film for enhanced strength and tear resistance.

3.1 Overall System

The cooling device is a component of a larger system, including a device to make ice slush, as well as pumps and hoses to move the fluid around. Figure 3 shows the overall system and how the device fits into that larger context. Our design focuses on the cooling bag part of the system since many of these components are easy to obtain off the shelf, and there is already active research into making fine surgical ice slush [10] that can be easily moved with pumps.

4 Cooling Analysis

Analysis was performed to determine which cooling fluid will be used. A phase change material solution (saline ice slush) was considered. Phase change material takes advantage of the large latent heat of fusion of water (334 kJ/kg) and a lot less fluid is therefore required. This also eliminates the requirement for circulation and allows for a greater margin of error as the available space for fluid in the body cavity greatly exceeds the volume required for cooling. The amount of required slush can be calculated with the following equation:

\[ m_{sl} h_{sl} = m_k c_p (T_i - T_f) \]  

where \( m_{sl} \) is the mass of slush solution, \( n_s \) is the fraction of solids, \( h_{sl} \) is the latent heat of fusion of saline, \( m_k \) and \( c_p \) are the mass and specific heat capacity of the kidney respectively, and \( T_i - T_f \) is the kidney temperature difference from the initial to final temperatures. During the cooling process the outer surfaces of the kidney would be far cooler than the core, down to nearly 0 °C where the surface contacts the ice slush. Equation 1 can be used to bound the amount of ice required. If it is assumed that the whole of an adult kidney (0.15 kg) [11] goes to its lowest temperature, 0 °C (\( T_i - T_f = 37 °C \)), then 151 g of 50% ice solution would be required to cool. If the whole kidney went to 20 °C, then 64 g of the same ice slush solution would be required. Using the larger amount, less than 1/4 L of slush would be required which is very feasible in this application.

Because of the temperature gradient through the organ, an estimate of the time required to cool can only be found by considering heat conduction within the kidney and its temperature profile. Closed-form solutions for the temperature profile and cooling time are available for simple geometries based on a non-dimensional temperature change \( \theta \), and non-dimensional time given by the Fourier number, \( Fo \):

\[ \theta = \frac{T_f - T_i}{T_i - T} = \frac{20 - 0}{37 - 0} = 0.54 \]  

\[ Fo = \frac{\pi^2}{\alpha T^2} \]
\[ Fo = \frac{\alpha}{l^2} \] (2b)

\( T_s \) is the applied surface temperature or ice slush temperature, \( t \) is the time, \( \alpha \) is the thermal diffusivity of the tissue, and \( l \) is the length from the surface to the kidney core. Curves relating the Fourier number to the non-dimensional temperature difference for slabs [12] are used to obtain a Fourier number for calculation of time required to cool the kidney core. The time to cool the core with a \( 0 \, ^\circ\text{C} \) surface temperature was 26 minutes for an depth of 2 cm, or half the thickness of an average kidney [13]. In reality the kidney is not a slab and has rounded features. Because of this odd shape the kidney was modeled in a 3D modeling and thermal analysis software (SolidWorks Analysis) and an assessment was made of the time and energy required to cool the core to \( 20 \, ^\circ\text{C} \), or body temperature (37 \( ^\circ\text{C} \)). The model is nominally 12 cm long, 5.1 cm wide, and 3.2 cm thick, resembling an adult kidney. The calculation was conducted using the thermal properties of water, due to the high water content in tissue. Water, however, has a slightly lower thermal conductivity than highly vascular tissue [14] so the model is a conservative baseline assumption. Modeling the kidney with its vascular architecture would not be feasible due to its complexity and would not confer much more information due to the variation in kidney size and contact area with the cooling bag. Figure 4 shows the temperature distribution inside the kidney after cooling is complete. It was found that it takes 9 mins to cool the core to \( 20 \, ^\circ\text{C} \). For this model the surface was assumed to stay at a constant \( 0 \, ^\circ\text{C} \) which represents the use of an ice slush where the temperature remains constant during the phase change.

![Figure 4. Output of finite element thermal analysis at end of cooling. Color map between blue (0 \( ^\circ\text{C} \)) and red (20 \( ^\circ\text{C} \)).](image)

Finally this analysis was verified with testing. Tests were done with porcine kidneys of similar weight to human kidneys, this time cooling them with ice slush filled bags that cover a varying amount of surface area, as well as directly submerging the kidney in an ice-slush solution for direct surface contact. Table 1 shows the results.

<table>
<thead>
<tr>
<th>Experiment</th>
<th>Surface Area Covered</th>
<th>Cooling Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single ice bag on bottom</td>
<td>40%</td>
<td>20 min</td>
</tr>
<tr>
<td>Ice bag on bottom and top</td>
<td>80-90%</td>
<td>8 min</td>
</tr>
<tr>
<td>Submerged in ice slush solution</td>
<td>100%</td>
<td>6 min</td>
</tr>
</tbody>
</table>

This test clearly shows that at least both the top and bottom of the kidney must be covered with the device in order to achieve cooling in the target time.

Porcine kidneys for testing were chosen to be the same size or larger than human kidneys for accurate comparison. Pig kidneys used were nominally 0.18 kg, 12 cm long and 6.6 cm wide.

Analysis was done on circulating cold liquid close to the organ. For this calculation the flow rates required for cooling using a forced liquid would be too high, varying from 5.5 g/sec at the beginning of the process when the kidney surface is warm (20 \( ^\circ\text{C} \)) to 81 g/sec when the surface gets colder (5 \( ^\circ\text{C} \)) to maintain enough cooling power to complete the process in the required time. This process would produce high pressures that could rupture the bag and damage the organ surface.

5 Design Process

5.1 Design Space Exploration and Strategy Selection

In assessing the scope of the problem and meeting with clinicians the following list of functional requirements for the device was obtained:

1. Must not increase risk to patient.
2. Cool kidney core to 20 \( ^\circ\text{C} \)
3. Cool in less than 20 minutes.
4. Useable in minimally invasive surgery - \( \leq 12 \) mm port size
5. Provides access to surgical site after cooling
6. No freezing damage or heating of surrounding tissue.

The end product must conform to these requirements and meet them better than any other possible design or existing device.

The chosen design cools the kidney from the outer surface, similar to what is currently done in open surgery [2]. We selected this approach in the course of considering an expansive space of possible solutions, which could be divided into the following categories based on what route cooling was delivered: Cooling of blood as it flows into the organ, cooling from the interior of the organ using fluid passed into the ureter, or cooling...
on the outer surface of the organ. The first method was quickly discounted as the blood vessels were too small to cool the blood adequately though the surface of the vessel. Thermal analysis of the convection process of cooling the blood through the vessel wall would require a heat transfer coefficient several orders of magnitude over what can be achieved. This is primarily due to the small heat transfer area available on the renal artery (8 mm in diameter) and small temperature gradient due to the fact that the vessel wall cannot be brought below 0 °C without tissue damage. Furthermore, cutting the vessel would increase risk to the patient, including the possibility of a fatal embolism. The second method was discounted after a simple experiment on a porcine kidney which still had its renal hilum intact showed that there was insufficient fluid volume in the renal hilum and renal papilla to deliver enough cooling power even if a high latent heat ice slush was used. These barriers pointed to surface cooling as the best strategy.

The selected strategy was to use a phase change fluid contained in a flexible bag that would cool the organ from the outer surface. This “indirect contact” cooling method offers several advantages, including harnessing of latent heat to cool at constant temperature, while preventing leaks and making it easy to introduce and remove fluid. Other means of cooling have fluid touching the kidney (direct contact). Cooling with the fluid in direct contact with the organ offers simplicity and a smaller amount material in the body. A single layer of plastic over the organ would be required to prevent fluid from coming in contact with nearby temperature sensitive tissue, such as the duodenum. Despite its apparent advantages, this method was attempted with kidneys in laparoscopic surgery with limited success [3], with a great deal of risk arising from sealing the bag around the renal hilum, and then cutting it free at the end of cooling. Leak containment was also a serious issue, and these two problems kept this method from being adopted by physicians. This increased risk to the patient and the fact that indirect contact cooling scored better on the functional requirements compared to direct contact cooling led us to select indirect cooling.

### 5.2 Prototype Design Process

The design of the cooling bag can be divided up into modules that correspond to the operation of the device:

- **Deployment of the device through a trocar.**
- **Positioning of device over kidney.**
- **Fluid filling and cooling.**
- **Fluid removal.**
- **Device removal through the trocar.**

Each module of the device was tested separately and combined into a final device at the end.

Three overarching concepts were considered under the subset of indirect contact cooling, all pertaining to the design of the bag containing the fluid:

<table>
<thead>
<tr>
<th>Concept</th>
<th>Description</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Glove</strong></td>
<td>A tight fitting inner bag with fluid containing outer bag</td>
<td>- Simple design</td>
<td>- Requires tight fit over kidney</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Stays put during cooling</td>
<td>- May be difficult to manipulate in body</td>
</tr>
<tr>
<td><strong>Clamshell</strong></td>
<td>Bag placed under kidney and which folds over the top of kidney when filled</td>
<td>- Self aligning for cooling on top surface</td>
<td>- More material through trocar</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Requires minimal manipulation by surgeon</td>
<td>- Increased manufacturing complexity</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Harder to remove through trocar</td>
</tr>
<tr>
<td><strong>Sandwich</strong></td>
<td>Two fluid filled bags placed underneath and on top of kidney</td>
<td>- Very simple design</td>
<td>- Top bag can easily slip off</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Hard to keep in place during cooling</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Requires two entry ports</td>
</tr>
</tbody>
</table>

The best design is the “glove”, due to its simplicity, and ease of removal, while still covering the required surface area of the kidney. This was determined by evaluating the performance of each concept with respect to each other on the performance of the functional requirements.

After testing and meeting with our clinician advisor the design changed to be simpler and easier to manipulate in the body. Instead of a tight-fitting glove the bag resembled more of a “Taco shell” with a hose extending from one end. The opposing side contained flaps that could be clipped to the bottom side of the bag and still allow access to the renal hilum to close off blood flow before cooling starts. A mock-up of this revision is shown in Figure 5.

As each module was engineered it became clear that most difficult one would be the removal through the trocar. However, a backup method should this fail would be to remove the trocar and extract the bag through an enlarged incision, as is done when a large piece of tissue is extracted. This is not always optimal since some pieces of excised tissue are sometimes small enough to be removed through the trocar. Thus, the goal is to remove the cooling bag through the trocar.

The following table shows the space of designs considered to address the challenges of each module leading to the final device.
<table>
<thead>
<tr>
<th>Module</th>
<th>Designs (Selected)</th>
<th>Reason Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deployment through trocar</td>
<td>Spring loaded</td>
<td>Air puff</td>
</tr>
<tr>
<td></td>
<td>Bag starts rolled up, manually unroll</td>
<td>Small amount of ice slush</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Trapped air does not block fluid flow</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- No springs to puncture bag or tissue</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Aids manipulation by adding stiffness</td>
</tr>
<tr>
<td>Positioning device over kidney</td>
<td>Tight fitting glove with rough inner surface</td>
<td>Stiff steel spring around front opening, can be pulled tight around organ</td>
</tr>
<tr>
<td></td>
<td>Flexible bag with tube to one side that is folded over kidney and attached to itself with magnets or velcro or clamps</td>
<td>&quot;Taco shell&quot; with tube filling from top of body. Ends of each side clamped together</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Uses available surgical clamps</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Provides adequate coverage and stiffness for surgeon to manipulate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Works with space constraints in body</td>
</tr>
<tr>
<td>Fluid filling and cooling</td>
<td>Flexible bag filled from one end</td>
<td>Flexible bag filled from multiple points by a tube with many holes cut into it</td>
</tr>
<tr>
<td></td>
<td>Taco shell filled from top with baffles to force fluid onto top of kidney</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Top filling avoids fluid blockage from kinks in bag that form when it is folded</td>
</tr>
<tr>
<td>Fluid removal</td>
<td>Pump reversal</td>
<td>Cut bag, drain into body cavity, suction</td>
</tr>
<tr>
<td></td>
<td>Hold bag upright in body - gravity assist with pump reversal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Avoids loose bag material from blocking flow when suction is reversed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Can be combined with &quot;cut and suction&quot; method to remove fluid that remains</td>
</tr>
<tr>
<td>Device removal through trocar</td>
<td>Collapsible cone exits from instrument to guide bag back into instruments</td>
<td>Pull by string running parallel to tube</td>
</tr>
<tr>
<td></td>
<td>Cut bag in half and pull by 2 separate strings</td>
<td>Shape bag such that it is guided back into trocar without snags, pull with tube</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Avoids complexity of additional instrument component</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Avoids risk of needing to cut bag in body</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- No strings, reduces complexity makes manufacturing easier</td>
</tr>
</tbody>
</table>
6 Testing

The final device was tested to evaluate the performance of each module. A cooling test was conducted on porcine kidneys. All temperatures were read using K-type thermocouples connected to an Omega HH147U USB-enabled temperature reader. The testing setup is shown in Figure 6. A kidney weighing 0.19 kg was heated to 37 °C and then placed in the device. The device was situated over a bag of warm water at 27-31 °C to simulate heat generation from surrounding tissues. Ice slush was then injected into the device. Figure 7 shows the cooling curves for the surface temperature and internal temperature of the kidney. A core temperature of 20 °C was achieved in 4.85 minutes. Ice slush still remained in the device even after the target temperature was reached; the amount of ice slush needed to fully inflate the Kidney Cooler is much larger than the minimum amount needed to cool the kidney, resulting in a large factor of safety for cooling, approximately 3 times the largest amount of ice slush calculated during the analysis. The remaining fluid was removed by reversing the direction of the pump.

Multiple cooling tests were not made due to time constraints, therefore variability of cooling time could not be determined. As part of ongoing work, more rigorous testing for a final prototype of this device will be conducted. Multiple tests will be done to determine variability in cooling time and the mass of ice slush required, which may arise from different bag placements or variances in contact area because of different kidney shapes.

Insertion and removal modules were tested in the Simulation and Skills Lab at Beth Israel Deaconess Medical Center in Boston, MA. The bag was rolled into a cylinder along its long axis and placed within a steel sheath having an outer diameter of 12mm. This sheath was then placed through a 12mm trocar. Once positioned, the device was successfully pushed through the sheath and inserted into the testing cavity. The steel sheath was then taken out of the trocar. Figure 8 shows the view of the bag through a laparoscopic camera once deployed. Removal of the bag was achieved by pulling it back through the trocar. In order to prevent jamming the bag was twisted from the outside while being held taut by a grasper inside the testing cavity.

If the bag becomes stuck in the trocar it can be easily removed by removing the trocar and pulling the bag through the incision. This is common practice for removing large tumors and excised tissues that cannot fit through the trocar.
The prototype was also tested for ease of positioning and manipulation. A to-scale kidney in a simple model of the abdomen shown in Figure 9 was designed to constrain the kidney in the way it would be in the body. When used by an experienced surgeon the bag can be manipulated around the kidney in about 90 seconds.

Filling and removal is easily accomplished by a reversible pump that can handle ice slush. Such pumps are readily available. During the course of testing it was found that the bag must be mostly evacuated as air bubbles prevent fluid filling and adequate coverage of the kidney.

7 Conclusions

Testing results indicate that the device can successfully cool an adult human kidney to 20 °C in less than 20 minutes using indirect contact surface cooling. The device can be successfully deployed through a 12mm trocar, positioned around the kidney using laparoscopic instruments, and removed to allow access to the surgical site. The device can enhance current partial nephrectomy surgeries by extending procedure time up to 2 hours and reducing complications arising from warm ischemia.

The next step is to refine the design and investigate more robust methods for prototype manufacturing. Initial feedback indicated that color differentiation for the clamping tabs and top and bottom of the cooler would be very helpful. High-precision plastic sealing technologies will allow us to produce a device with smaller, stronger seals and improve features such as the baffles and tube insertion joint. With new fabrication technologies available to us, we will also investigate the addition of other features, such as a layer of thermal resistance on the underside of the bag. Manipulation of the bag will be tested by additional clinicians in a more realistic laparoscopic simulator, including the use of actual bulldog clamps. Additional cooling tests on porcine kidneys will be done with the new prototype to assess variability in cooling time. The new prototypes could then be tested in animal trials to assess in situ performance of the device.

8 Acknowledgements

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