

Evaluation of a minimally invasive renal cooling device using heat transfer analysis and an *in vivo* porcine model

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ABSTRACT

Partial nephrectomy is the gold standard treatment for renal cell carcinoma. This procedure requires temporary occlusion of the renal artery, which can cause irreversible damage due to warm ischemia after 30 min. Open surgical procedures use crushed ice to induce a mild hypothermia of 20 °C in the kidney, which can increase allowable ischemia time up to 2.5 h. The Kidney Cooler device was developed previously by the authors to achieve renal cooling using a minimally invasive approach. In the present study an analytical model of kidney cooling *in situ* was developed using heat transfer equations to determine the effect of kidney thickness on cooling time. *In vivo* porcine testing was conducted to evaluate the cooling performance of this device and to identify opportunities for improved surgical handling. Renal temperature was measured continuously at 6 points using probes placed orthogonally to each other within the kidney. Results showed that the device can cool the core of the kidney to 20 °C in 10–20 min. Design enhancements were made based on surgeon feedback; it was determined that the addition of an insulating air layer below the device increased difficulty of positioning the device around the kidney and did not significantly enhance cooling performance. The Kidney Cooler has been shown to effectively induce mild renal hypothermia of 20 °C in an *in vivo* porcine model.

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1. Introduction

Renal cell carcinoma, or kidney cancer, affects over 58,000 people per year in the United States alone [1]. There are several treatment options, including radical nephrectomy and tumor ablation, but the gold standard for treatment of T1a (<4 cm) tumors is the partial nephrectomy [2]. In this procedure the tumor is excised while leaving the rest of the kidney intact, saving much of the organ's functionality.

During a partial nephrectomy procedure, blood flow to the kidney is occluded by clamping the renal artery to prevent excessive bleeding. This technique, however, prevents kidney tissues from receiving oxygen, a condition called warm ischemia. Permanent damage can occur to the kidney if this condition lasts for more than 30 min [3].

A mild hypothermia can mitigate the effects of warm ischemia. If the core of the kidney can be cooled to 20 °C then ischemic time can be extended up to 2.5 h [4]. In open surgery this is accomplished by packing crushed saline ice around the kidney for 10 min [3]. Upon

completion of cooling the ice can be removed with the aid of suction. In some cases, the ice is left in the body during the procedure to prevent rewarming of the kidney. This method is effective and has been adopted as standard practice by most surgeons.

Minimally invasive surgery has become an increasingly popular surgical option with advances in equipment and techniques. Studies in the literature have shown that with an experienced surgeon, minimally invasive surgery can provide equal oncologic results to open surgery but with improved patient recovery times [5]. Partial nephrectomy procedures are sometimes performed using this approach; however, there is currently no effective solution for inducing renal hypothermia with a minimally invasive approach. Thus, minimally invasive partial nephrectomies can only be performed safely in patients with small tumors in easily accessible locations.

Various strategies have previously been developed to attempt minimally invasive renal cooling, though none have been adopted for use. A cooling element inserted through an artery has been developed, but is intended for localized cooling rather than whole-organ cooling. Surface cooling devices that surround the kidney have been designed and patented that circulate a chilled liquid to act as a heat exchanger. This approach necessarily utilizes secondary equipment to recirculate and remove heat from the fluid.

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Nomenclature

Roman symbols

A	surface area, top of kidney [m^2]
c_p	specific heat capacity [$\text{J/kg}^\circ\text{C}$]
D	distance of capillary from muscle surface [m]
d	thickness
Fo	Fourier number
g	acceleration of gravity [m/s^2]
h	heat transfer coefficient [$\text{W/m}^2^\circ\text{C}$]
k	thermal conductivity [$\text{W/m}^\circ\text{C}$]
l	length [m]
l_i	characteristic length [m]
$\dot{m}$	mass flow rate [kg/s]
m	mass [kg]
NTU	number of transfer units
Nu	Nusselt number
$\dot{Q}$	heat transfer rate [W]
Q	thermal energy [J]
R	thermal resistance [$^\circ\text{C/W}$]
r	radius [m]
Ra	Rayleigh number
S	geometric shape factor [m]
t	time [s]
UA	overall heat transfer coefficient [$\text{W/}^\circ\text{C}$]
w	width [m]
x	distance [m]
z	non-dimensional distance

Greek symbols

α	thermal diffusivity [m^2/s]
β	thermal expansion coefficient of air [$1/\text{K}$]
ΔT	temperature difference from bag surface [$^\circ\text{C}$]
ϵ	effectiveness
ν	kinematic viscosity [m^2/s]
θ	non-dimensional temperature

Subscripts

air	air in body cavity
av	average
b	blood
cap	capillary in muscle
ins	insulating air layer
k	kidney
m	muscle
s	bag surface

Additionally, long tubing lengths (2 m) are required to extract sufficient thermal energy, which adds bulk to the devices. Phase change cooling has been attempted by placing ice slurry into a plastic bag that is cinched around the renal hilum [3]. This approach can achieve successful cooling but increases risk to the patient due to increased activity around the delicate renal hilum.

Recently, a new device for achieving renal hypothermia during minimally invasive surgery was developed by the authors utilizing a phase change cooling approach [6]. An *ex vivo* model was used for preliminary evaluation of its cooling capabilities. The present study describes the development of an analytical model of kidney heat transfer *in situ* to determine the effect of kidney thickness on cooling time. *In vivo* porcine testing of the device was conducted to evaluate cooling performance and identify opportunities for improved surgical handling.

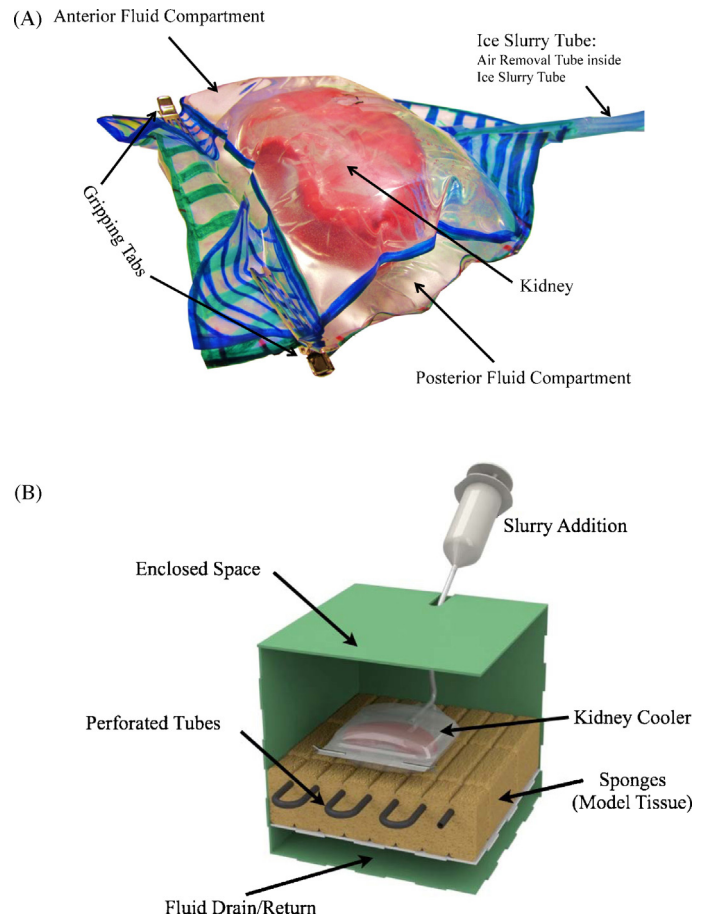


Fig. 1. (A) The Kidney Cooler device filled with fluid and wrapped around a model kidney. Ice slurry fills the anterior and posterior fluid compartments through the attached slurry tube. An embedded air removal tube allows venting while filling. Bulldog clamps (represented by clips) are placed along the gripping tabs to keep the device in position around the kidney. Color-coding of different faces improve visualization in the minimally invasive environment. (B) *Ex vivo* abdominal cavity environment to evaluate kidney cooling time. Perforated tubing is embedded within a sponge layer housed within a plexiglass container. Water is heated to 37°C and circulated through the tubing to model blood perfusion through abdominal tissue. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of the article.)

2. Methods

2.1. The Kidney Cooler

The Kidney Cooler, shown in Fig. 1(A), was previously described by the authors [6]. Briefly, it is a device that is inserted through a 15 mm trocar, surrounds the kidney with ice slurry, and is removed upon completion of cooling. Two fluid-filled compartments are in contact with the anterior and posterior surfaces of the kidney, covering nearly 100% of the organ's surface area. Ice slurry is added through a urethane tube with an embedded vent to equalize pressure. The device is made with 0.051–0.127 mm thick urethane film that can be manipulated with standard laparoscopic instruments without tearing. Tabs located at the end of the bag provide accessible gripping points that do not interfere with the renal hilum and are secured with bulldog clamps once the device is situated. Select devices were manufactured with a thin inflatable air layer on the outer posterior compartment of the device. This air layer insulates the ice slurry in the posterior compartment from heat generated by the abdomen. The added stiffness from this air layer facilitates handling by the surgeon. The design process and additional features of

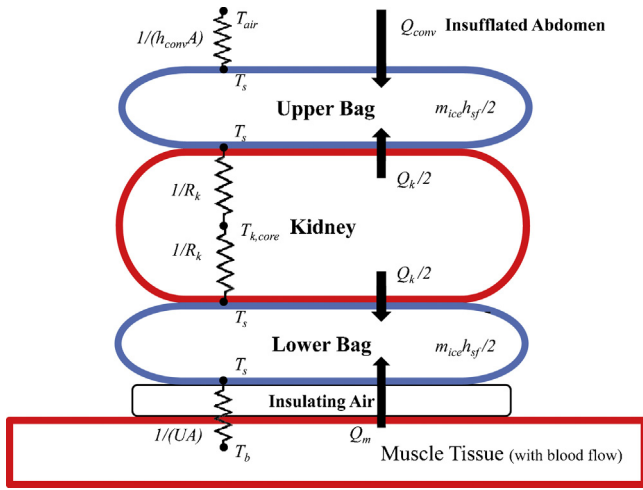


Fig. 2. Schematic diagram of heat transfer through the thickness of the kidney with losses to the environment. Arrows represent heat energy into the bag. The bag is assumed to have distinct halves, each holding half the total ice mass. The bag has constant surface temperature T_s . The insufflated abdominal cavity has constant temperature T_{air} , which is used to calculate heat transfer to the environment through natural convection (Q_{conv}). Blood in the abdominal tissues has temperature T_b ; heat transfer to the muscle tissue (Q_m) was modeled as a heat exchanger.

this device are detailed in previous work published by the authors [6].

Previous evaluation of the Kidney Cooler was performed in an *ex vivo* testing environment and is described here briefly. The setup, shown in Fig. 1(B), simulated heat generation from blood flowing through abdominal tissue and the closed environment of an insufflated abdomen. The device was situated on a bed of porous sponges through which water at 37 °C was circulated. Results showed that the device can cool porcine kidneys to a core temperature below 20 °C within 5–20 min after addition of ice slurry, depending on the kidney thickness [6].

2.2. Heat transfer analysis

To assess the scope of the problem and guide the initial design of the device, a heat transfer model was developed to approximate the cooling time and cooling energy requirements for reducing kidney temperature from the normal body temperature (37 °C) to 20 °C in a closed environment that would be found in a patient's insufflated abdomen during a laparoscopic procedure.

2.2.1. Solution for cooling time

To estimate the cooling time, the kidney was approximated as a slab of total thickness $2d$ and thermal diffusivity α , with a uniform initial temperature T_i . At zero time the top and bottom surfaces of the slab are placed in contact with a surface of constant temperature T_s , consistent with a phase change material melting/freezing. Since the top and bottom of the kidney are in contact with the device the energy has to travel through the thickness to reach the core, making this the critical dimension for cooling. A schematic diagram of the model is shown in Fig. 2. To simplify the analysis, three dimensionless numbers are used: the Fourier number, a dimensionless position; z , and a dimensionless temperature; θ .

$$\theta = \frac{T_f - T_s}{T_i - T_s} = \frac{20 - 0}{37 - 0} = 0.54 \quad (1a)$$

$$Fo = \frac{\alpha t}{d^2} \quad (1b)$$

$$z = \frac{x}{d} - 1 \quad (1c)$$

In general, the variation of temperature in a solid material where heat is transferred by conduction can be described as an infinite series [7]:

$$\theta = \sum_{n=1}^{\infty} \frac{4}{n\pi} e^{-Fo(n\pi/2)^2} \sin\left(\frac{n\pi z}{2}\right) \quad (2)$$

To apply this equation the kidney was approximated as a finite slab of a certain length (l), width (w), and thickness (d). The thickness parameter was used to calculate length and width using relationships taken from Emamian et al. [8]. The temperature profile within the kidney is estimated by taking the product of three one-dimensional slabs where each solution is of a different dimension of the finite slab. For the majority of problems the first term in the infinite series will provide an accurate solution to the Fourier number. Therefore, the infinite series is approximated to the first term ($n=1$), and after some algebraic manipulation, t as a function of θ , α , and the three characteristic lengths l_1 , l_2 and l_3 can be expressed as:

$$t = \left[\frac{2}{\pi}\right]^2 \frac{1}{\alpha} \log \left[\frac{1}{\theta} \left(\frac{4}{\pi} \right)^3 \right] \left[\frac{1}{l_1^2} + \frac{1}{l_2^2} + \frac{1}{l_3^2} \right]^{-1} \quad (3)$$

where t is the amount of time for the center of the kidney to reach 20 °C. Note that each characteristic length is equal to half that of the kidney along its three dimensions, or $l/2$, $w/2$ and $d/2$. Using this time the average temperature, T_{av} , in the entire kidney was calculated by taking a volume integral of the first term of Eq. (2) at the final time t . Using conservation of energy the amount of energy used to cool the kidney was expressed as:

$$Q_k = m_k c_{p,k} (T_i - T_{av}) \quad (4)$$

2.2.2. Heat loss to environment

The heat transfer to the environment was modeled as natural convection between the 0 °C outer surface of the device and a 28 °C atmosphere, or the approximated average temperature of the air inside the peritoneal cavity when it is insufflated. This was later confirmed by experiment. Due to the insufflation it is assumed that the top of the device does not touch any abdominal tissue. Since the top of the device faces the air in the abdomen, the convection process was modeled as natural convection on a cooled plate facing up. To calculate this value the following correlation was used [9]:

$$Ra = \frac{g\beta[\Delta T]w_k^3}{\alpha\nu} \quad (5a)$$

$$X = 13.5Ra^{-0.16} \quad (5b)$$

$$Nu = 6.5 \left[1 + 0.38 \frac{w_k}{l_k} \right] [(1+X)^{0.39} - X^{0.39}] Ra^{0.13} \quad (5c)$$

$$h_{conv} = Nu \frac{k_{air}}{w_k} \quad (5d)$$

ΔT is the temperature difference between the device and air or $T_{air} - T_s$. A is the total surface heat transfer area which is the width of the kidney multiplied by its length.

The total thermal energy lost to the air in cooling time t can be easily calculated by Eq. (6) by simply multiplying the heat transfer rate by the cooling time. This is possible as the temperatures are approximated to be constant over the entire cooling time, which is consistent with constant temperature melting:

$$Q_{conv} = h_{conv} A (T_{air} - T_s) t \quad (6)$$

2.2.3. Heat loss to muscle

The heat transfer between the device and the capillaries in the muscle tissue situated below the kidney was modeled as a heat exchanger, transferring heat between the melting slurry and the

blood flowing through the capillaries in the muscle. This situation was modeled using the $\epsilon - NTU$ method for a single stream heat exchanger [10].

$$\epsilon = (1 - e^{-NTU}) \quad (7)$$

NTU is the ratio of the total heat transfer coefficient multiplied by heat transfer area (UA) between the blood in the capillaries and the device in contact with the muscle to the heat capacity of the fluid traveling through the capillaries. Effectiveness ϵ is the ratio of the heat transfer experienced by the blood to the amount of heat transfer that would cool the blood down to 0°C , the temperature of the device in contact with the muscle. Rearranging the terms the total amount of thermal energy lost to the muscle below the kidney is expressed as:

$$Q_m = c_{p,b} \dot{m}_b \Delta T [1 - e^{-UA/c_{p,b} \dot{m}_b}] t \quad (8)$$

where ΔT in this case is the temperature difference between the device and the blood flowing through the muscle or $T_b - T_s$. The mass flow rate $\dot{m}_b$ is determined by the perfusion rate of blood through the muscle and the density of capillaries in the muscle [11].

The overall transfer coefficient UA was separated into three components: the insulation underneath the kidney, the muscle tissue, and the convection into the capillaries in the muscle. The insulation layer was filled with air, however as the air layer thickness was small compared to its length and width natural circulation was neglected. This makes the resistance through the air layer:

$$R_{ins} = \frac{d_{ins}}{k_{air} A} \quad (9)$$

The thermal resistance between the insulation and the capillaries was modeled using a shape factor, S . Each capillary was modeled as a tube of length l_{cap} , radius r_{cap} , and a distance D away from the muscle surface. The resistance in this case was modeled as:

$$R_{cap} = \frac{1}{k_m S} = \frac{\cosh^{-1}(D/r_{cap})}{2\pi k_m l_{cap}} \quad (10)$$

Convection between the capillaries and the blood flowing through them was modeled using Eq. (11). Since the diameter of capillaries and the velocity lead to laminar flow, the Nusselt number is a constant 4.364 [10] leading to a simple formulation for h_b in the form of Eq. (5d). The corresponding resistance R_b was:

$$R_b = \frac{1}{h_b 2\pi r_{cap} l_{cap}} \quad (11)$$

The thermal resistance between the fluid traveling through each capillary and the surface underneath the insulation layer was defined as the sum of R_{cap} and R_b . By considering each capillary separately and taking the sum over all capillaries directly underneath the device UA could be expressed as:

$$UA = \frac{1}{R_{ins} + [\sum (1/R_{cap} + R_b)]^{-1}} \quad (12)$$

This value substituted into Eq. (8) was used to calculate the total heat transferred into the muscle.

3. In vivo testing

In vivo porcine testing was conducted to evaluate the cooling performance of the Kidney Cooler and identify improvements for surgeon usability. The study was performed by a surgeon who had not previously used the device and was not involved in the development of the technology. A single adult female swine was anesthetized and sedated for the duration of the study. Four testing trials were then performed in accordance with a pre-approved Institutional Review Board protocol.

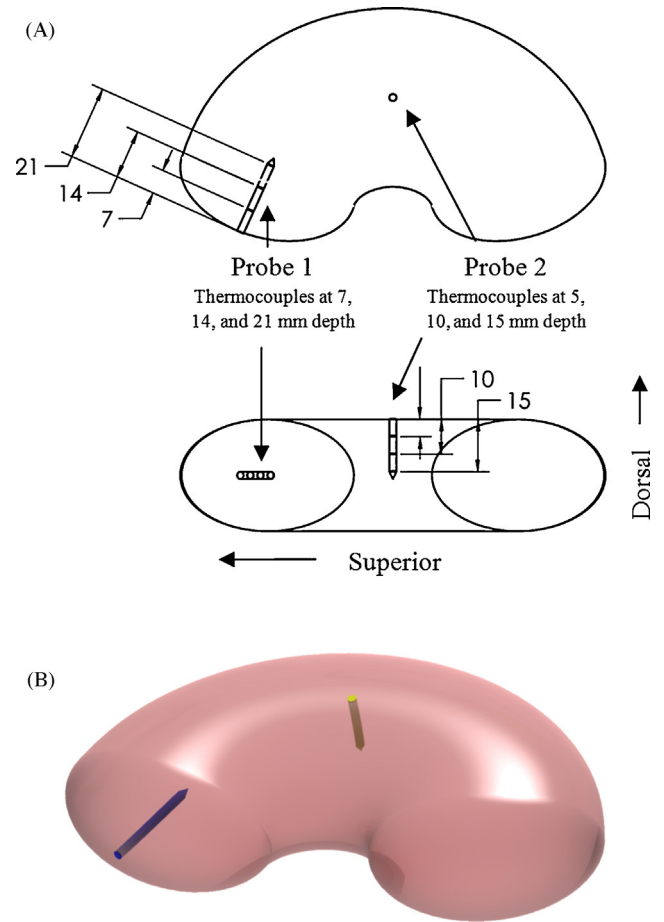


Fig. 3. (A) Diagram showing placement of thermocouple temperature probes in the sagittal and axial planes of the renal parenchyma. Each probe contains three thermocouples. Temperature gradients within the kidney during cooling can be observed through continuous monitoring of the probes. (B) Angled 3D view showing relative probe locations in a model kidney. The surgeon places the probes such that the outermost thermocouple is coincident with the outer surface of the kidney.

3.1. Temperature measurement

Temperature gradients are formed within the kidney as it is cooled from the outer surface due to the low thermal conductivity of the tissue; though the outside of the organ may be cold, the temperature can be much warmer deeper in the tissue. Measurement of kidney temperature must take into account these temperature gradients in order to accurately observe cooling of the entire organ.

Various temperature monitoring methods have been reported in the literature; Herrell et al. [12] monitored kidney temperature 1 cm deep in the parenchyma at 5 min intervals. The average thickness of a porcine kidney is on the order of 3–4 cm [8], meaning that the core temperature was not adequately measured. Sampling at 5-minute intervals does not allow for a complete representation of the cooling curve. Webster et al. [13] measured renal parenchymal temperature continuously, but at an unspecified location and depth.

A continuous, multidimensional temperature monitoring strategy was developed in order to determine the temperature at the core of the kidney as well as the temperature profile throughout the organ. Renal temperature was measured at a total of 6 locations, as shown in Fig. 3. Thermocouples were placed on the probes such that when inserted into renal tissue, temperature could be measured at the surface, core, and an intermediate depth. The two probes were placed such that the temperature profiles within orthogonal planes of the kidney (sagittal and axial) could be determined.

Temperature data from all 6 thermocouples were recorded continuously throughout the trial, resulting in a high-resolution cooling curve.

3.2. Ice slurry

Ice slurry was prepared using a mixture of 55% ice water, 37% water, and 7.8% sucrose (all by weight). This solution was found experimentally to provide sufficient flow properties to pass the slurry through the tubing. A mixture containing only ice and water agglomerates and prevents transport of a homogeneous mixture [14]. Sucrose functions as a rheological additive to increase the viscosity of the mixture, thereby creating a homogeneous distribution of ice particles in the slurry. This formula was sufficient for non-survival animal testing; however, adaptations are necessary for human studies. Ice slurries with enhanced flow properties are currently being developed [15].

3.3. Surgical protocol

The following steps were used to conduct all four trials:

1. Mobilize kidney from connective tissue
2. Insert and secure temperature probes
3. Deploy Kidney Cooler through 15 mm trocar port
4. Position device around kidney and secure with bulldog clamps
5. Occlude renal artery using bulldog clamps
6. Inject ice slurry until device is filled
7. Remove ice slurry upon termination of cooling
8. Remove Kidney Cooler through trocar incision

First, a usability trial was conducted using a Kidney Cooler with an air layer; no temperature probes were placed and no ice slurry was injected. The animal was placed in a supine position with the trocar inserted through the abdominal wall directly above the right kidney. During this trial the surgeon familiarized herself with the techniques needed to position the device around the kidney. After the Kidney Cooler was successfully placed it was removed through the trocar incision.

The second trial evaluated cooling performance of a Kidney Cooler without an air layer. The right kidney was used again, with the same ports as in Trial 1. The device was removed upon completion of cooling; incisions were closed and the animal was prepared for rotation to the opposite side.

The third trial evaluated cooling performance of the device without an air layer. The animal was rotated onto the left side, with the trocar placed above the left kidney. After cooling was complete, clamps were released from the renal hilum to allow blood perfusion to warm the kidney back to 37 °C for the final testing trial.

The fourth and final trial evaluated cooling performance of a device with an air layer. An open procedure was used to place the device due to insufflation complications. The incision was closed during cooling to maintain a closed environment. The animal was euthanized immediately after the trial and the kidneys were harvested for measurement.

In humans the adrenal gland is located on the superior pole of the kidney; during partial nephrectomy procedures this region is not mobilized from the surrounding connective tissue so that adrenal tissue is not damaged. In pigs, however, the adrenal glands are located elsewhere. During the first two trials on the right kidney the superior pole was mobilized so that the surgeon was less constrained when manipulating the device for the first time. During subsequent testing on the left kidney, however, the superior pole was not mobilized from the connective tissue in order to approximate the constraints during a human procedure.

Table 1

Summary of testing conditions for *in vivo* cooling trials.

Trial #	Kidney	Air layer	Purpose	Ice slurry (g)
1	Right	Y	Usability	N/A
2	Right	N	Cooling	422
3	Left	N	Cooling	788
4	Left	Y	Cooling	426

A summary of each testing trial is shown in Table 1.

4. Results and discussion

Results of analytical heat transfer modeling and the *in vivo* testing trials are shown in Fig. 4, compared with the *ex vivo* data published in previous studies. Cooling time is reported as the length of time for all 6 thermocouples in the temperature probes to reach 20 °C; at this point it is assumed that the core of the kidney is ≤ 20 °C. In one case, a single thermocouple failed to reach the desired temperature; for this trial, cooling time was reported as the length of time to reach the lowest measured temperature.

Initial placement testing during Trial 1 revealed the device is most easily placed by first pulling the posterior half of the device under the kidney using the gripping tabs. This task can be facilitated by manipulating the anterior compartment as shown in Fig. 5. The insulation layer hindered placement of the posterior compartment due to the stiffness it added; it is preferable to have a compliant, foldable device that can be more easily manipulated in the limited confines of an insufflated abdomen. The device was successfully secured by placing bulldog clamps on the gripping tabs. However, the clamps had a tendency to slide around. Further design iterations of the device will include tabs made of a rougher, more substantial material and bulldog clamps with greater gripping force.

Partial cooling was observed during Trial 2, as the deepest thermocouple of the probe normal to the transverse plane of the kidney did not reach below 22.9 °C. This occurred because no ice slurry entered the posterior compartment of the bag, due to space constraints of the supine position. Successive trials avoided this problem by placing the animal on its side in a position known as left lateral decubitus. Trial 2 emphasized the importance of using the proper amount of ice slurry with the device. Complete cooling can be achieved if adequate ice slurry is delivered and is

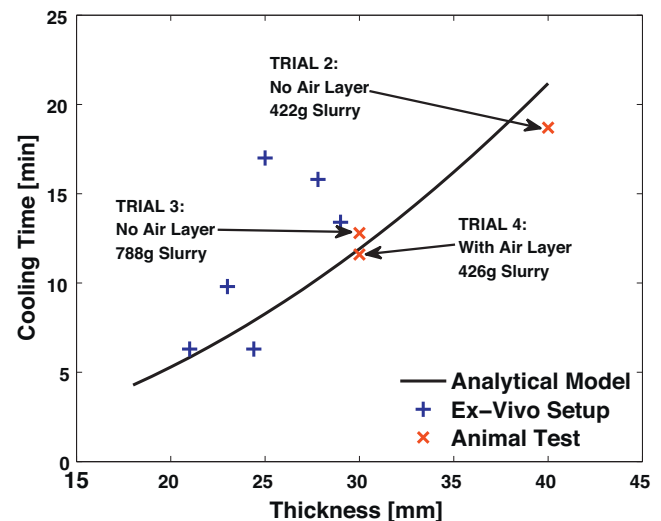


Fig. 4. Plot of kidney thickness vs cooling time. Results from *in vivo* testing are compared with the analytical heat transfer model and previously published results [6] for *ex vivo* testing. Cooling time is the timepoint at which all thermocouples have reached the target temperature of 20 °C.

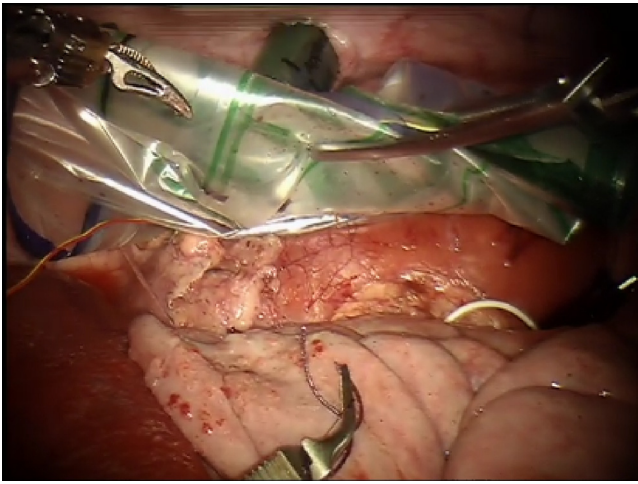


Fig. 5. Minimally invasive camera view of Kidney Cooler placement during an *in vivo* porcine trial. The device has been passed through the trocar; ice slurry has not been added. This view shows the anterior fluid compartment rolled and secured with a bulldog clamp in a non-obstructive position above the kidney. This allows unrestricted access to the posterior fluid compartment, which is then pulled underneath the kidney.

properly distributed to both compartments of the device. Design changes were subsequently made as a countermeasure to this particular failure mode; the length of the tapered urethane at the top of the device was shortened from 11.5 cm to 3 cm, and this tube was positioned so that the bottom compartment will be filled first.

Trials 3 and 4 had similar cooling times, even though Trial 4 used an air layer and Trial 3 did not, indicating that the insulation layer is not necessary for achieving sufficient cooling. Rather, it is more important to use an adequate amount of ice slurry, and have the slurry evenly distributed throughout the anterior and posterior compartments. Though this insulation layer does not affect cooling time, it has the potential to increase re-warming time if an air layer were to remain below the kidney for the duration of the surgery. Further testing is needed to explore this possibility.

Surgical conditions in Trials 3 and 4 closely approximated those of a human procedure. The Kidney Cooler device was successfully placed even with the superior pole tethered to the surrounding connective tissue. All other surgical methods were consistent with those used in human procedures, including insufflation, trocar placement, and occlusion of the renal hilum. Only one extra trocar port was needed to implement and remove all components of the Kidney Cooler device. The surgeon was able to successfully position the device without having previously practiced. The design modifications listed previously will further improve surgical handling, thereby decreasing the time required to position the device.

Continuous multi-dimensional temperature monitoring was shown to be an effective approach for determining kidney core temperature. Minimal bleeding was observed during insertion of the two temperature probes. Measurements from each of the trials are shown in Fig. 6. Temperature begins to decrease around time $t=1$ min, after slurry has been added to the device. After this time point, temperature in both probes begin to decrease; as expected, the surface thermocouples reached the target temperature much faster than the deepest thermocouples, with the outer surface reaching the cooling temperature twice as fast as the core. Around time $t=10$ min temperature in the outermost thermocouples begins to increase. At this point the cooling energy of the ice slurry has been depleted, and the tissue begins to warm. However, the temperature of the deepest thermocouples continues to decrease. This information about the temperature distribution

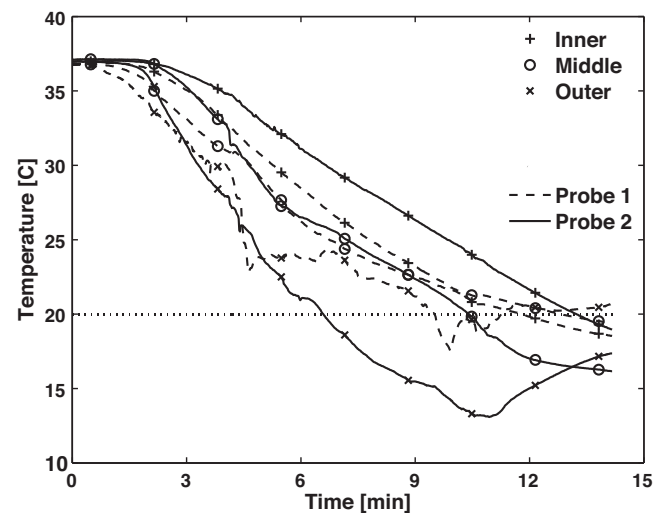


Fig. 6. Internal kidney temperatures for Trial 3 of the *in vivo* porcine testing. The thermal gradient within the kidney during cooling is evident; the outer thermocouples are fastest to reach the target temperature of 20°C, while the inner thermocouples are the slowest due to the low thermal conductivity of the kidney tissue.

within the organ could not have been observed without use of the multi-dimensional temperature monitoring strategy.

Kidney thickness is the critical dimension used in the analytical model; length and width were calculated from thickness based on correlations taken from Emamian et al. [8]. However, the shape of the kidney is complex and variable. In certain cases, two kidneys of the same thickness may have different cooling times because of differing mass, volume, or other geometric parameters. This is observed in the *ex vivo* results for 25 mm kidney thickness. Future iterations of the analytical model could include these other parameters to improve accuracy.

Analytical modeling of heat transfer *in situ* was accurate within 3 min of measured results from *in vivo* testing. With further validation, the model has potential to be a tool for preoperative planning. Survival studies cannot utilize the temperature monitoring method presented here because of traumatic damage to the kidney tissue. For these cases, non-invasive measuring techniques such as MRI can be used to measure a patient's kidney size. An analytical model can then be used to provide an estimate for cooling time based on the patient's individual kidney morphology. This method could function as a surgical planning tool to augment noninvasive MRI temperature monitoring techniques [16].

5. Conclusion

The Kidney Cooler device was developed as a method for renal cooling in minimally invasive surgery, allowing surgeons to extend procedure time without the risks associated with warm ischemia. An analytical model of the kidney cooler *in situ* was developed to predict cooling time given kidney thickness. *In vivo* porcine testing was conducted to evaluate cooling performance and identify opportunities for design improvements. This work led to several important conclusions:

- The Kidney Cooler can reduce core temperature of the kidney to less than 20°C in 10–20 min in a live animal, showing strong potential for human surgical use.
- The analytical model shows promise as a tool for predicting kidney cooling time.

- Temperature monitoring into the depth of the organ is crucial for ascertaining the cooling time for such a device as the organ core can take over twice as long to cool as the exterior of the organ.

Minimally invasive renal cooling will increase the number of potential candidates for laparoscopic or robotic partial nephrectomy. These surgical approaches are recognized as having many benefits, including reduced blood loss, shorter hospitalization time, and shorter recovery time [5,17]. Previously, only patients with small tumors in easily accessible locations were candidates for minimally invasive partial nephrectomy. Extended surgery time will allow surgeons to operate on more complex tumors using a minimally invasive approach.

The Kidney Cooler design has been enhanced based on surgeon feedback from the *in vivo* porcine testing. Further work is underway to prepare the device for human trials testing and FDA approval.

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Competing interests

The authors do not have any disclosures relating to employment, consultancies, stock ownership, honoraria, paid expert testimony, or grants. Authors have a patent pending on the technology (United States of America Patent Application No. 13/347,178).

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Ethical approval

Not required.

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