

Intraoperative Donor Organ Protection in Renal Transplantation



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Kidney Protective Jacket

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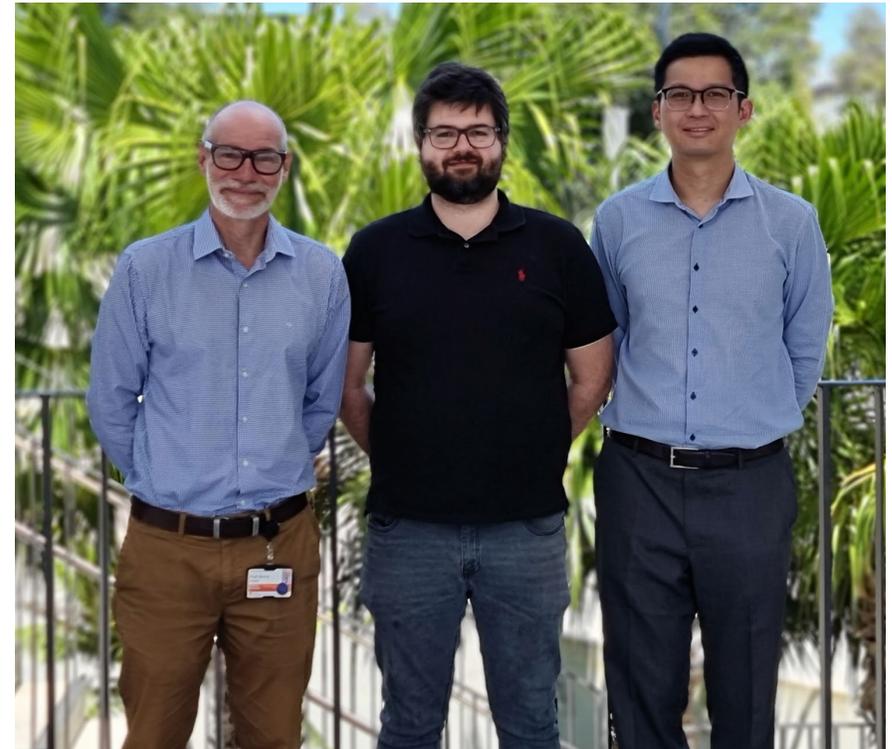
iiShield Team

A diverse a diverse, experienced, and motivated team with a strong clinical background.

- Dr Jeremy Kwarcinski (CEO, biomedical engineer)
- A/Prof Tony Pang (Executive Chair, HPB surgeon)
- Prof Henry Pleass (Director, Transplant surgeon)
- Ms Phoebe Lau (Quality and Device Engineer)
- Mr Turaab Khan (Device Engineer, PhD student)

Our Partners

New South Wales Health, NSW Government
Westmead Hospital, Sydney
The University of Sydney, Australia



Kidney Protective Jacket Summary

Problem: Every kidney transplantation surgery is a race against the clock.

Unmet need: To keep a donor organ cooler for longer or to maintain a hypothermic state during the transplant.

The impact:

Every extra minute: 5% increase in need for dialysis post-transplantation

Every extra 10-minutes: 8% increase in 5-year graft failure

Surgeons operating quickly can **lead to intraoperative surgical complications**

The Problem

There is an **unmet need** to increase available time for transplant surgery, allowing surgeons to work at their own pace, minimizing risk and complications and thermal injury.

25% of transplanted kidneys fail within 5 years.

As a result, patients often return to dialysis for treatment. This is both devastating for the organ recipient and adds significant costs to the healthcare system.



30% of transplanted kidneys experience delayed function.

After transplantation, temporary dialysis may still be required due to acute kidney injury, this further adds to the risk of cellular rejection and reduces graft survival rate.



Ischemic injury occurs regularly during transplantation.

For every 10 minutes above 59°F there is a 10% increased risk of kidney failure and a 63% increased risk of delayed function.



The Device – Kidney Protective Insulator Jacket (KPJ)

Clinicians need a device that keeps **transplant organs cooler** for longer during transplant surgery.



KidneyPJ is a single-use intraoperative organ thermal regulation device that aims to increase the available time for kidney transplantation.

The Benefits

2x greater working time for transplant procedures.

2x

Protection of kidney from heating up during transplant procedure.



More time leads to less stress. Facilitates operation and reduces operative errors.



Kidney Protective Insulator Jacket aims to provide a surgical environment which fosters improved short and long-term transplant outcomes.



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Kidney Protective Insulation Key Features Explained

Single-use thermal regulation device that thermally insulates and provides hypothermic impact to the cold donor kidney during surgery

Temperature Regulation

- Internal space for hypothermic processing
- Internal texture for thermal regulation

Surgical Design Usability

- Anatomical design to be fitted for average adult kidney
- Low profile does not impede surgery
- Can be used in open procedure or robotic procedure
- Flaps for anatomical placement permitting guidance (manipulate and manoeuvre kidney)
- Unobstructed removal following anastomosis



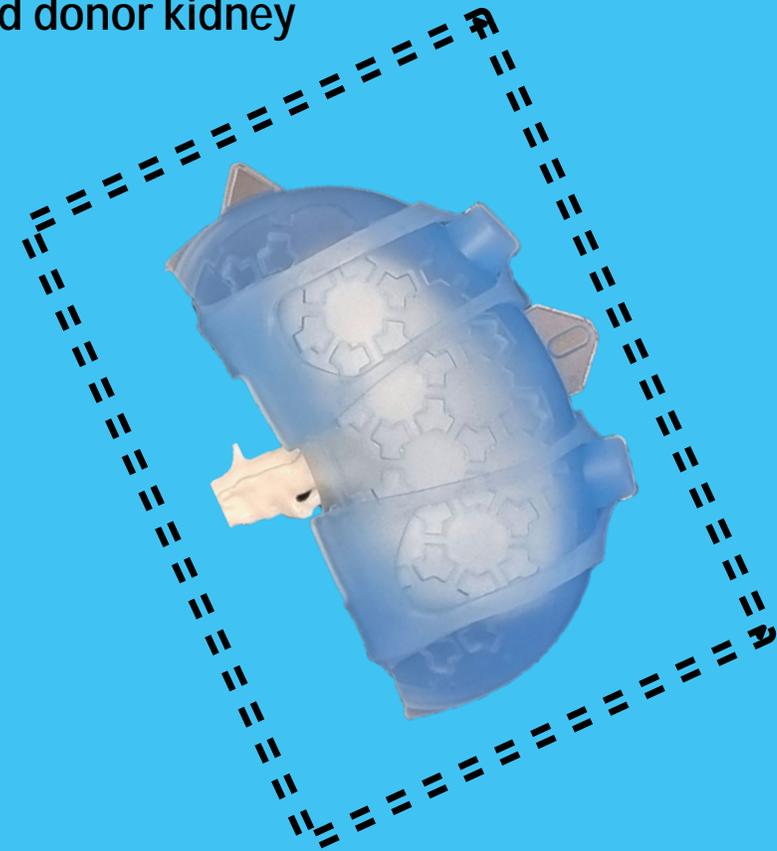
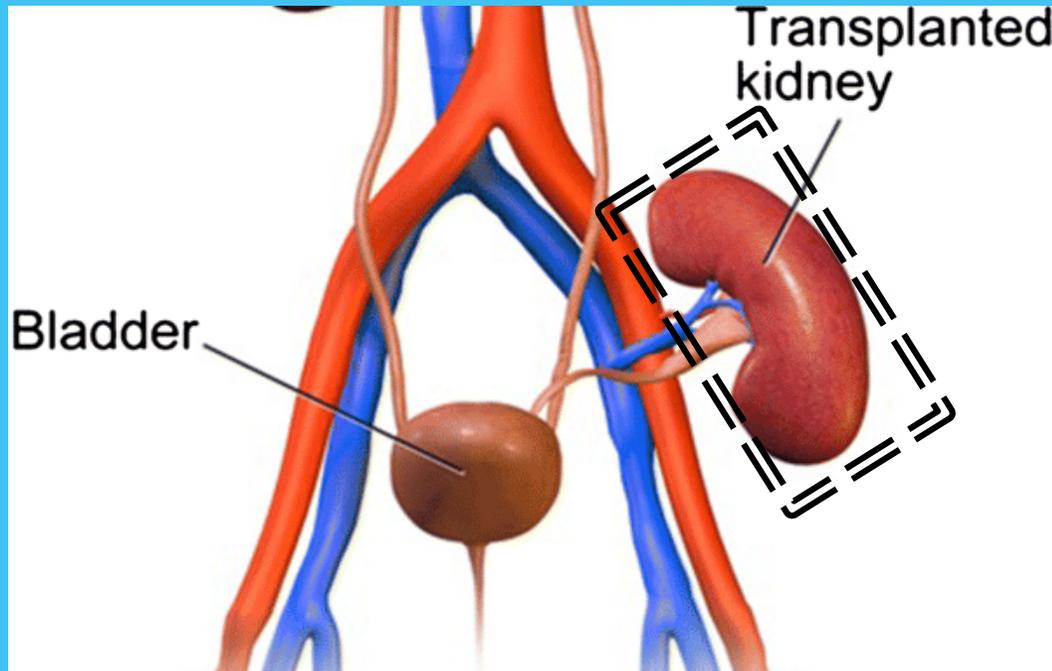
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Kidney Protective Jacket

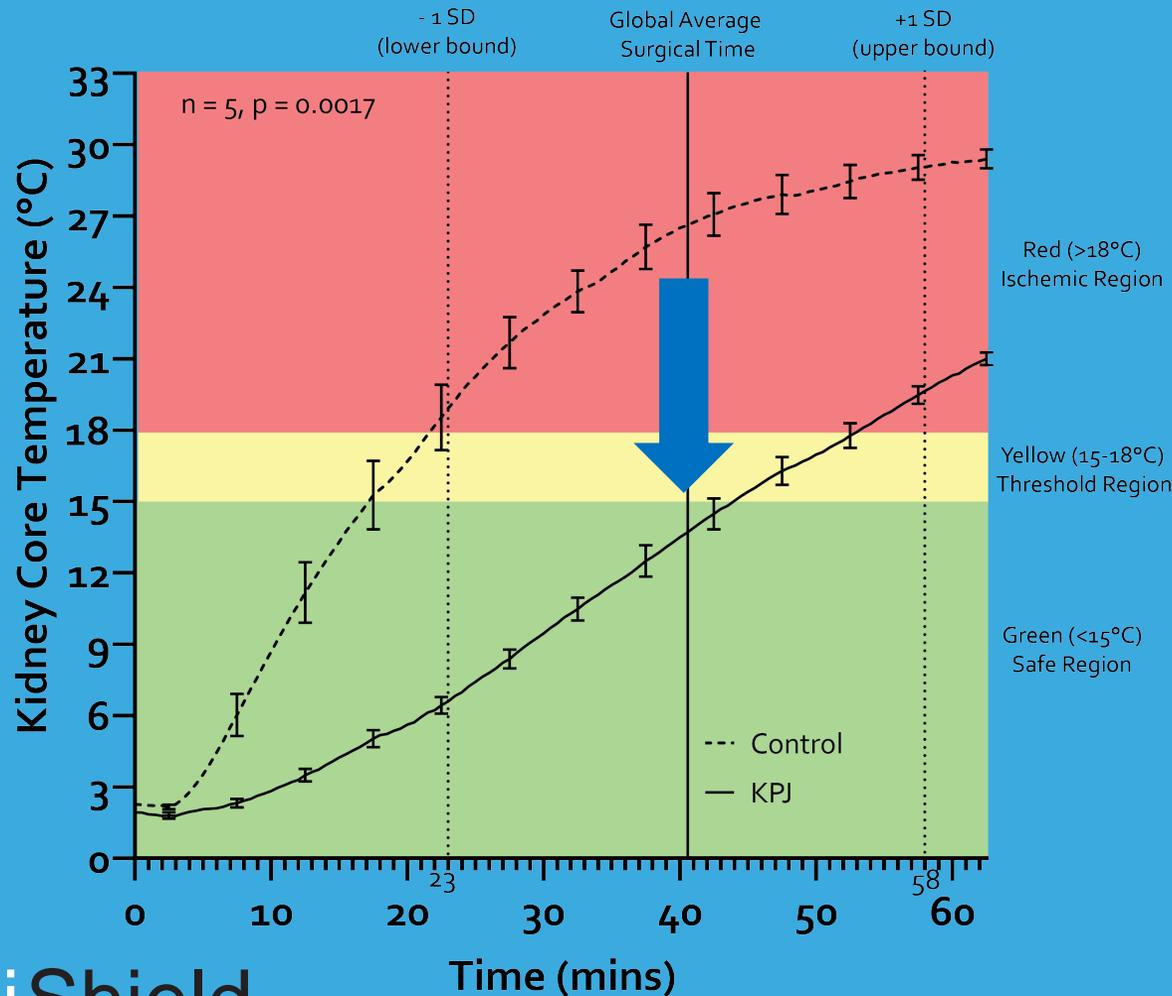
Intraoperative regulation pouch that thermally insulates/maintains hypothermia for the cold donor kidney



Warm Ischemia is Largely Unaddressed Issue in Kidney Transplantation

- Innovations have been limited in the kidney transplant surgical suite in years past.
 - There is currently no effective and commercially available medical device that seeks to intraoperatively reduce warm ischemia experience by the kidney during transplantation.
- Simple one-of-a-kind solution to hospital (compared to organ preservation machines)
 - No change in way operation is performed, unobtrusive.
 - Kidney Protective Jacket can be used with organ preservation machines or without
 - Surveyed surgeons recognize unmet solution to thermal injury and report high interest in device
 - No complications have been reported.
- Potential Outcomes
 - Decreased rate of Delayed Graft Function (DGF) which requires postoperative hemodialysis
 - Decreased rate of graft failure

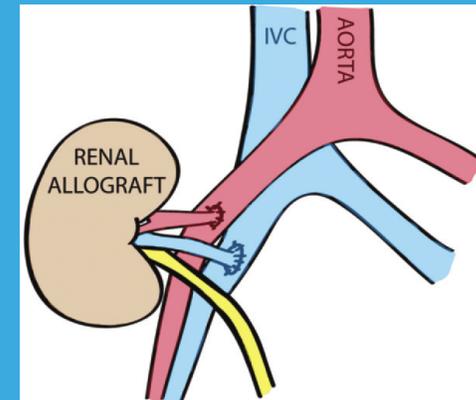
Impact on Kidneys



The average surgeon takes 41 minutes to reconnect the blood vessels to the donated kidney.

41 minutes

Device to provide 48% reduction in core organ temperature



Potential Clinical Impacts and Future Directions

- Estimating Clinical Impact:

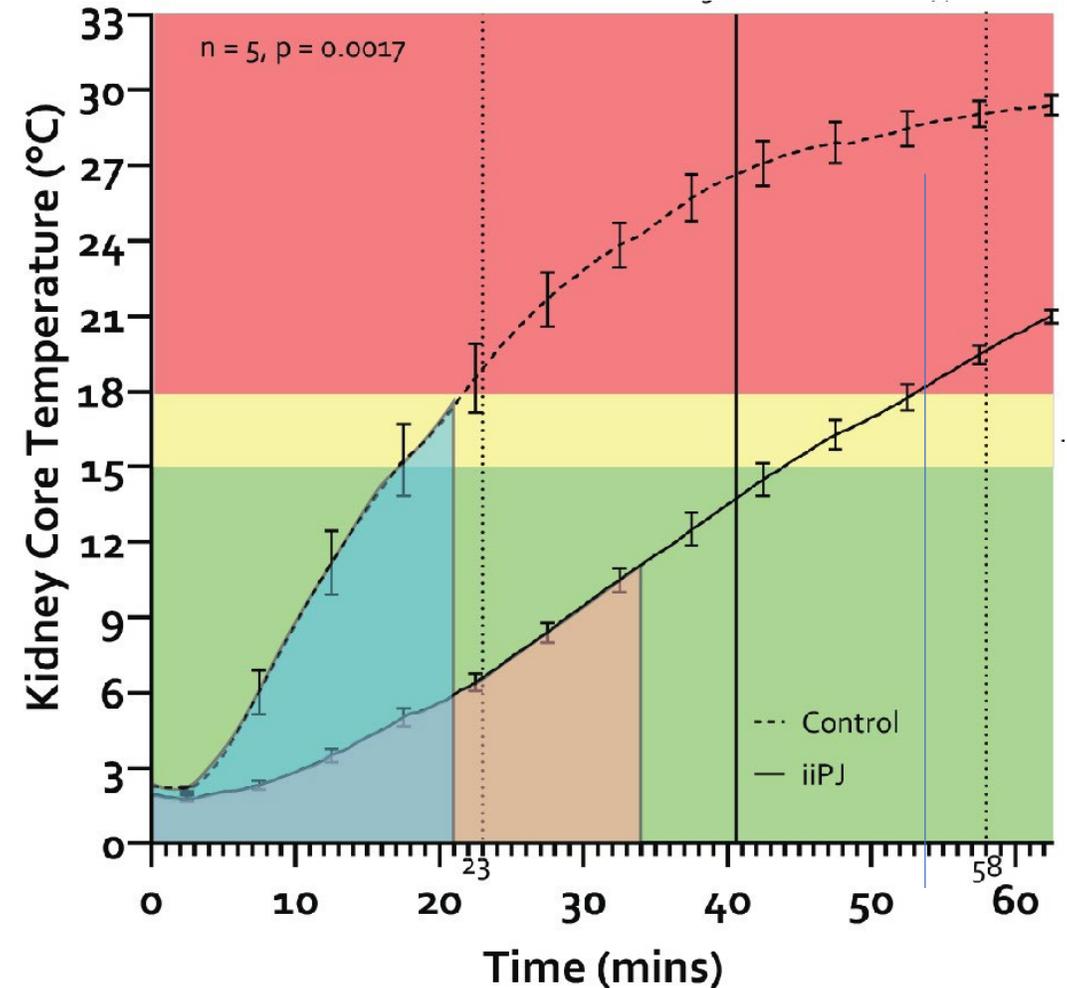
- Area under the curve as thermal energy transfer
- Assuming:
 - Thermal energy transfer = injury
 - Effect of thermal energy transfer does not vary with temperature
- **34 minutes with KPJ = 21 minutes without KPJ**
 - i.e., equivalent to 13 minutes ↓ anastomosis time
 - DGF (for DCD kidneys): 31% -> 19%
 - 5-year graft failure: HR 0.87
 - Alternatively, **34 without KPJ = 54 min with KPJ**

- Future Directions:

- Perfusion Experiments (scheduled Oct 2023)
- First in human (Phase I) trial (Early 2024)
- Pivotal RCT (Phase III) (post-market)

- Adverse Events:

No complications/sequela/adverse events reported in the use of the Kidney Protective Jacket.



Kidney Transplants in the US

Estimated U.S. Average (Year 2020)

	Total Estimated Transplants	Under 65 - Estimated Transplants	65 and Over - Estimated Transplants
Kidney	21,963	17,131	4,832
Kidney - Heart	238	192	46
Kidney - Pancreas	900	895	5
Liver - Kidney	807	613	194

Reference: Milliman Research Report. 2020 U.S. organ and tissue transplants: cost estimates, discussion, and emerging issues. January 2020 Accessed from <https://www.milliman.com/-/media/milliman/pdfs/articles/2020-us-organ-tissue-transplants.ashx>

Medical Record Documentation for Kidney Protective Jacket

- The application and removal of the device will be documented in the operative report as a back table/bench preparatory procedure. Back bench preparatory procedures are routinely integrated into the surgical reports in organ transplants.
- The device must be removed. Thus, increasing the probability that surgeons will document detailed use of this device to alleviate any concern that the device may be left inside the patient.
- Documentation in the operative report may reference Kidney Protective Jacket (KPJ) or Kidney Protective Insulation Jacket.

Additional key terms may include:

- *Thermal Insulating Jacket
- *Kidney Protective Insulator Jacket
- *Intraoperative Regulation Pouch
- *Donor Organ Protective Thermal Insulation

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