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Robotic-assisted simultaneous kidney-pancreas transplant without hand assistance

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20/03/2025	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/03/2025	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/03/2025	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Simultaneous pancreas-kidney transplantation (SPKT) is the best option for patients with type 1 diabetes mellitus (T1DM) and end-stage kidney disease (ESKD); however, the conventional open surgical approach is associated with a significant risk of pancreas allograft thrombosis, high morbidity, and prolonged hospital stays. Robotic-assisted SPKT (RASPKT) represents a paradigm shift in minimally invasive transplant surgery, offering the potential to reduce early post-operative complications. However, RASPKT remains technically challenging, with previous techniques requiring Gelport device hand assistance in performing vascular and bowel anastomoses. This study aims to show that this fully intra-abdominal, hands-free robotic approach to RASPKT is technically feasible and safe to perform, with excellent early clinical outcomes. However, larger studies with longer follow-ups must confirm its clinical benefit and broader applicability.

Who can participate?

Adult patients placed on the SPKT list after review by the multidisciplinary team at the participating center between September 2023 and November 2024.

What does the study involve?

Early postoperative outcomes and measures of pancreas/kidney allograft function during the first 3-12 months post-transplant were analyzed.

What are the possible benefits and risks of participating?

Robotic assistance has been a great advancement in kidney transplantation (KT), proving to be safe with excellent long-term functional outcomes. However, the application of RA to SPKT, i.e., RASPKT, has not evolved as quickly as in RAKT. The previously described techniques for RASPKT often involved the use of hand assistance through the GelPort device for performing vascular anastomosis, and bowel anastomosis is usually performed without RA. Recent advancements in robotic surgery have introduced a minimally invasive approach that offers the potential to reduce these risks, thereby potentially improving patient outcomes.

SPKT continues to be a successful surgical option carried out worldwide as a treatment of T1DM in patients who also present with end-stage kidney disease (ESKD). While SPKT has shown great outcomes, it is not without risks; complications are common and occasionally life-threatening. Among these complications, complete pancreas thrombosis is a serious one which usually leads to pancreas allograft loss. Traditionally, SPKT has been performed via open surgery, which carries significant morbidity and can lead to prolonged recovery.

Where is the study run from?
Miami Transplant Institute, Department of Surgery, University of Miami Miller School of Medicine

When is the study starting and how long is it expected to run for?
January 2012 to November 2011

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title

Robotic-assisted simultaneous kidney-pancreas transplant without hand assistance: a paradigm shift in minimally invasive transplant surgery

Study objectives

Simultaneous pancreas-kidney transplantation (SPKT) is the best option for patients with type 1 diabetes mellitus (T1DM) and end-stage kidney disease (ESKD). However, the conventional open surgical approach is associated with a significant risk of pancreas allograft thrombosis, high morbidity, and prolonged hospital stays. Robotic-assisted SPKT (RASPKT) represents a paradigm shift in minimally invasive transplant surgery, offering the potential to reduce early post-operative complications. However, RASPKT remains technically challenging, with previous techniques requiring Gelport device hand assistance in performing vascular and bowel anastomoses.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 01/07/2014, Human Subject Research Office (University of Miami, Casa Bacardi, 1531 Brescia Avenue, Coral Gables, FL 33136, United States of America; +1 305-243-3195; ltueros@med.miami.edu), ref: IRB20140129

Study design

Single-center observational retrospective cohort study

Primary study design

Observational

Study type(s)

Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied

Patients with type 1 diabetes mellitus (T1DM) and end-stage kidney disease (ESKD)

Interventions

This study was approved by the University of Miami Institutional Review Board and follows the ethical principles (as revised in 2013) of the Helsinki Declaration. All patients gave written informed consent before enrollment. The four study patients were placed on the SPK transplant list after an extensive evaluation reviewed by a multidisciplinary team; these 4 patients fulfilled the criteria set by the United Network for Organ Sharing. SPK recipients that were included in this study received a robotic-assisted SPK transplant (RASPKT).

Robotic-assisted simultaneous pancreas-kidney transplantation (RASPKT)

Intervention(s): The Surgical Procedure
Back-table preparation of the pancreas allograft
The back-table preparation of a pancreas allograft for robotic-assisted transplantation is a critical procedure that demands meticulous attention to detail to ensure optimal graft viability and function post-transplant. This process encompasses several key steps, each integral to the success of the transplantation.

Organ Inspection and Assessment: Upon retrieval, the pancreas allograft is maintained in a cold preservation solution, typically a University of Wisconsin (UW) solution, to preserve tissue integrity. A thorough inspection is conducted to identify any signs of injury, pancreatitis, or contamination. The anatomical integrity of the organ, including arterial and venous structures, is carefully evaluated. This assessment is crucial, as unnoticed injuries can compromise graft function and patient outcomes.

Excision of Non-Essential Tissues: The next phase involves the meticulous removal of peripancreatic fat, lymphatic tissue, and lymph nodes. This step is essential to prevent postoperative complications such as thrombosis or pancreatitis. The spleen is then detached from the pancreas, requiring careful ligation of the splenic vessels to prevent bleeding upon reperfusion. Attention is also given to preserving the integrity of the pancreatic tail to avoid potential fistula formation.

Duodenal Management: The duodenum is trimmed, typically retaining approximately 10 centimeters of the second portion. Both the distal and proximal ends of the duodenum are transected using a triple-stapling technique, and the staple lines are reinforced with interrupted 4-0 polydioxanone (PDS) sutures. This approach minimizes the risk of leakage and ensures a secure closure.

Vascular Reconstruction: A critical aspect of back-table preparation is the reconstruction of the graft's vasculature. A Y-graft is fashioned using the donor's iliac arteries. The superior mesenteric artery (SMA) and splenic artery of the pancreas are anastomosed to the limbs of the Y-graft using running 6-0 polypropylene sutures. The donor's common iliac artery is then prepared for subsequent arterial anastomosis to the recipient's vessels. Ensuring clean, atherosclerosis-free arterial sections is vital to prevent thrombosis.
Portal Vein Preparation: The portal vein is carefully dissected free from the pancreatic parenchyma, typically providing a cuff of approximately 1.5 centimeters to facilitate tension-free anastomosis. This length is generally sufficient to perform a straightforward anastomosis without twisting, thereby reducing the risk of venous thrombosis.

Final Perfusion and Leak Testing: Upon completion of the vascular reconstruction, the graft is perfused with one liter of cold UW solution mixed with 1 milliliter of methylene blue. This solution is infused by gravity through the donor's common iliac artery to avoid vascular injury. The use of methylene blue aids in identifying any vascular leaks, which are promptly addressed with additional sutures to ensure hemostasis.

Throughout the back-table preparation, maintaining the pancreas at a cold temperature is imperative to reduce metabolic activity and preserve tissue viability. The organ is typically kept in a sterile container with a cold preservation solution, ensuring it remains at the optimal temperature until implantation. This meticulous preparation is essential to minimize postoperative complications such as thrombosis and graft pancreatitis, thereby enhancing the likelihood of successful transplantation and graft function.

Patient Positioning and Preparation
The patient is positioned in the supine position with arms tucked at the sides. Aseptic preparation is performed using either chlorhexidine or povidone-iodine solution. To maintain normothermia, a warming device is utilized, and sequential compression devices are applied for deep vein thrombosis prophylaxis. The patient is placed in a 25–30° Trendelenburg position, which shifts the intestines cephalad, optimizing surgical exposure and minimizing interference with the operative field.

Abdominal Access and Port Placement

A closed pneumoperitoneum is established via Palmer's technique using a Veress needle inserted in the left upper quadrant. Once proper intraperitoneal placement is confirmed, carbon dioxide insufflation is initiated to maintain an intra-abdominal pressure of 12–15 mmHg. A Pfannenstiel incision is made to facilitate the introduction of the allografts and allow for additional instrumentation. Robotic ports are placed in a triangulated configuration for optimal instrument manoeuvrability. Specifically, four 8-mm robotic trocars are positioned above the umbilicus, approximately 8 cm apart and 15 cm from the anterior superior iliac spine (ASIS). Additionally, a 12-mm assistant laparoscopic port is placed in the lower abdomen to facilitate suction, retraction, and suturing.

Pancreas Transplantation

Following robotic system docking, the left iliac vessels are dissected to ensure adequate exposure for vascular anastomosis. The peritoneum is incised, and a retroperitoneal pocket is created behind the descending colon to accommodate the pancreas. The external iliac artery and vein are identified, dissected, and mobilized. Four bulldog clamps—two straight and two curved—are introduced into the abdomen. The external iliac vein is clamped first using two straight bulldogs. The donor pancreas is then introduced through the Pfannenstiel incision, ensuring its head-down and tail-up orientation to optimize venous and arterial drainage.

A venotomy is performed using Potts scissors, and an end-to-side anastomosis is created between the portal vein of the pancreas allograft and the external iliac vein using a continuous 6-0 Gore-Tex suture. The anastomosis is initiated at the posterior wall, followed by the anterior wall, ensuring meticulous intima-to-intima approximation and a tension-free suture line. Before completing the anastomosis, the anastomotic site is flushed to eliminate air and thrombi. A curved bulldog clamp is applied to the portal vein, and the external iliac vein clamps are released. Next, the arterial anastomosis is performed. The pancreas allograft receives arterial inflow via a Y-graft, in which the superior mesenteric artery (SMA) and splenic artery are connected to an iliac artery conduit. The common iliac artery or external iliac artery is chosen for arterial inflow. The iliac artery is clamped using straight bulldogs, and an arteriotomy is created with Potts scissors. A running 6-0 Gore-Tex suture is used to establish an end-to-side arterial anastomosis, ensuring proper alignment and avoiding redundancy. The vascular clamps are released sequentially—venous first, arterial second—to facilitate gradual reperfusion, thereby minimizing ischemia-reperfusion injury.

For enteric drainage, the donor duodenum is anastomosed to the recipient jejunum using a side-to-side, two-layered technique. The inner mucosal layer is approximated using a running 4-0 PDS suture, while the outer seromuscular layer is secured with a running 4-0 PDS suture, ensuring uniform tension and preventing leakage. The anastomosis is checked for patency, confirming adequate peristalsis and the absence of tension.

Kidney Transplantation

Following the successful implantation of the pancreas allograft, the robotic system is reoriented to the right iliac fossa for kidney transplantation. The camera is repositioned to port 3, scissors to port 4, bipolar forceps to port 1, and ProGrasp forceps to port 2. The iliac vessels are identified, and a peritoneal flap is developed to accommodate the kidney. The technique for vascular anastomosis mirrors that of the pancreas transplant, ensuring standardization and efficiency.

A venotomy is created using Potts scissors, and an end-to-side anastomosis is established between the renal vein of the allograft and the external iliac vein using a continuous 6-0 Gore-Tex suture. The posterior wall is sutured first, followed by the anterior wall, ensuring precise intima-to-intima approximation and tension-free anastomosis. Before completing the suture line, air and any clots are flushed from the anastomotic site. A curved bulldog clamp is applied to the renal vein, and the external iliac vein clamps are released.

For arterial anastomosis, the renal artery is anastomosed to the external iliac artery using a running 6-0 Gore-Tex suture. The iliac artery is clamped using straight bulldogs, and an arteriotomy is created using Potts scissors. The end-to-side anastomosis is carefully fashioned to ensure optimal alignment and blood flow dynamics. The posterior wall is sutured first, followed by the anterior wall, ensuring an intima-to-intima approximation. The vascular clamps are released sequentially - venous first, arterial second - to facilitate gradual reperfusion and minimize ischemia-reperfusion injury. Following reperfusion, ureteroneocystostomy is performed using a Lich-Gregoir extravesical approach. A 5-0 PDS running suture is used for mucosa-to-mucosa approximation, and a double-J stent is placed to ensure adequate urinary drainage. The allograft is inspected for turgor, color change, and immediate urine output.

Hemostasis and Closure
The peritoneal flap is repositioned to cover the kidney and secured to prevent adhesions. The pneumoperitoneum is released gradually to prevent hemodynamic instability. The robotic instruments are withdrawn, and the Pfannenstiel incision and port sites are closed in layers using 1 PDS for the fascia and subcutaneous layers, followed by 4-0 Monocryl for the skin.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Any surgical complications post-transplant, kidney and pancreas allograft function at 3-12 months post-transplant measured using data collected retrospectively from patient medical records at one timepoint

Key secondary outcome(s))
Operative time (min) and length of hospital stay (LOS) (days) measured using data collected retrospectively from patient medical records at one timepoint

Completion date
20/11/2024

Eligibility

Key inclusion criteria
1. Patients who gave written informed consent prior to enrollment
2. Patients placed on the SPK transplant list after an extensive evaluation reviewed by the multidisciplinary team
3. Fulfilled the criteria set by the United Network for Organ Sharing

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
4

Key exclusion criteria
SPK recipients at the participating center who received an open SPK (non-robotic assisted) transplant.

Date of first enrolment
21/09/2023

Date of final enrolment
20/11/2024

Locations

Countries of recruitment
United States of America

Study participating centre
Miami Transplant Institute, Department of Surgery, University of Miami Miller School of Medicine
Jackson Memorial Hospital, Highland Professional Building, 1801 NW 9th Avenue, 7th Floor
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Sponsor information

Organisation
Miami Transplant Institute

ROR
https://ror.org/05cpqsp49

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Gaetano Ciancio, gciancio@med.miami.edu

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes