Successful Implementation of Unmanned Aircraft Use for Delivery of a Human Organ for Transplantation

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Objective: To understand and overcome the challenges associated with moving life-urgent payloads using unmanned aircraft.

Background Data: Organ transportation has not been substantially innovated in the last 60 years. Unmanned aircraft systems (UAS; ie, drones) have the potential to reduce system inefficiencies and improve access to transplantation. We sought to determine if UASs could successfully be integrated into the current system of organ delivery.

Methods: A multi-disciplinary team was convened to design and build an unmanned aircraft to autonomously carry a human organ. A kidney transplant recipient was enrolled to receive a drone-shipped kidney.

Results: A uniquely designed organ drone was built. The aircraft was flown 44 times (total of 7.38 hours). Three experimental missions were then flown in Baltimore City over 2.8 miles. For mission #1, no payload was carried. In mission #2, a payload of ice, saline, and blood tubes (3.8 kg, 8.4 lbs) was flown. In mission #3, a human kidney for transplant (4.4 kg, 9.7 lbs) was successfully flown by a UAS. The organ was transplanted into a 44-year-old female with a history of hypertensive nephrosclerosis and anuria on dialysis for 8 years. Between postoperative days (POD) 1 and 4, urine increased from 1.0 L to 3.6 L. Creatinine decreased starting on POD 3, to an inpatient nadir of 6.9 mg/dL. The patient was discharged on POD 4.

Conclusions: Here, we completed the first successful delivery of a human organ using unmanned aircraft. This study brought together multidisciplinary resources to develop, build, and test the first organ drone system, through which we performed the first transplant of a drone transported kidney. These innovations could inform not just transplantation, but other areas of medicine requiring life-saving payload delivery as well.

Keywords: blood shipment, emergency, life-urgent transport, organ shipment, organ transplant, organ transportation, transplantation

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Transplantation has become the gold standard treatment for many patients with end-stage organ failure. Unfortunately, there is a woeful disparity between the number of transplantable organs and the number of patients on the waiting list.[1] Optimizing organ availability and improving transplant graft survivals are key to maximizing access to transplantation and minimizing death on the waiting list.[2,3] In this context, and with recent changes to the organ allocation system, organ transportation has become an increasingly important issue.[3,4]

Organ transportation has not undergone significant innovation within the last 60 years. At present, a complex web of couriers, commercial and charter aircraft, and organ procurement personnel are responsible for organ delivery.[5–7] This process is inefficient, time-consuming, expensive, and at times unsafe.[8] Innovated systems using unmanned aircraft systems (UAS) have the potential to decrease cold ischemia time (CIT), improve organ transplant quality, decrease costs, and increase the safety of organ transportation.[9,10]

Although a transplantable organ has never previously been moved by unmanned aircraft, we previously showed that an autonomous vertical take-off and landing (VTOL) drone could safely move a human research organ 3 miles.[10] No differences were identified in organ biopsies taken pre-and post-drone flight. We found that organs transported by VTOL drones experienced less vibration compared to commercial flight transportation. Organ temperatures also remained stable with minimal variation during the drone flight.[10] Our initial experience with VTOL drones highlighted substantial hurdles ahead of implementation of unmanned aircrafts for clinical use.[10]

Here, we sought to overcome regulatory, technical, and logistical challenges to determine if organ drone transportation might be successfully integrated into the current transplant environment. Through a multidisciplinary effort, we were able to design and build an organ drone, gain federal aviation administration (FAA) approval, organize the logistics of transfer, and to perform the first transplant of an organ transported by drone. These findings suggest that innovated technologies may be relevant in transplantation, in addition to other fields where life-saving payloads need to move efficiently from one location to another.

METHODS

Institutional Review Board Approval, Patient Enrollment, and Consent

Two institutional review boards were filed and approved, one with the Living Legacy Foundation, our organ procurement organization (OPO), and the second with the University of Maryland School of Medicine. Inclusion criteria for a drone transported kidney included a kidney donor profile index less than 85%, and viral serologies and nucleic testing negative for HCV, HBV, and HIV. The patient was consented for drone shipment over the phone at admission, before the organ recovery process began. The patient was consented a second time, in-person, with the primary investigator (PI) (J.R.S.) and the transplant research director. Patient survival, graft survival, and graft function were followed for 30 days.

Donor Parameters and Accepted Donor Kidney

Before drone shipment, the donor kidney was perfused through a 10 mm × 35 mm cannula and pumped with a LifePort

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hypothermic pulsatile perfusion device (Serial #1514922). The pump data was analyzed using Firmware version 1.022. Total pump time was 2 hours and 49 minutes. Pump parameters at 2.5 hours on the pump reflected a systolic pressure of 29 mm Hg, diastolic pressure of 24 mm Hg, flow of 123 mL/min, resistance of 0.22, and an ice bath temperature of 1.6°C. These parameters were interpreted as excellent. The total amount of CIT (ie, recovery to impant) was 18.2 hours.

FAA Approval

Upon flight worthiness testing, an FAA certificate of authorization (COA) was obtained via Form 7711-1 on March 5, 2019. In advance of the approval, there were several FAA concerns which included minimization of risk to the public. To address this, the COA was written to allow for missions between 1:00 AM and 6:00 AM, as traffic and pedestrian activity would be low. Additional concerns surrounded the transportation of hazardous materials or "HAZMAT." However, because the viral status of transplanted tissue is comprehensively interrogated, because it comes from a single person (unlike medical waste), and because organs are transported in 3 sterile layers, the FAA concluded that organs did not qualify as HAZMAT.

Multi-disciplinary Analysis of Drone Design, Construction, and Organ Monitoring

Drones for organ transportation have not been previously built. Thus, a series of detailed meetings occurred during which mission-critical parameters were discussed with our multi-disciplinary team. The human organ monitoring apparatus for long distance travel (HOMAL) has been previously described and used to monitor payloads.[10] The HOMAL used here was nonsterile and was on the exterior portion of the payload. Data generated by the HOMAL was stored on a micro secure digital card, saved in a comma separated variable file, and pushed directly to the smartphone of transplant stakeholders via app in real time.[10]

Drone

The drone used in each of the 47 missions (the LG-1000 for "Lu's Griffin 1000"), was custom built by our laboratory. The LG-1000 is a 4-arm octocopter VTOL. Each arm holds 2 vertically mounted motors, where each motor spins in opposite directions (8 motors, 8 blades). Each rotor has a maximum speed of 10,500 revolutions per minute, but speeds vary under autonomous control. Autonomous flight software was Mission Planner (Ardupilot, open source, ardupilot.org). Energy sources were 2 Lithium Polymer batteries (6 seconds 22,000 mAh).

Logistical Planning

For experimental missions, the hospital helipad at the Shock Trauma Center was alerted. Helicopter diversion plans were developed in case of an urgent landing request during 8–10-minute drone flights. Additionally, the Baltimore City Fire Department, the Baltimore City Police, the Office of Emergency Management (OEM), and the Department of Transplantation (DOT) controlled traffic in the event of an emergency.

Organ Transplantation

The organ transplant team included 3 surgeons (J.R.S., R.N.B., and T.A.Q.). A standard right-sided kidney transplant procedure was planned. Our standard immunosuppressive induction protocol, inclusive of Alemtuzumab (30 mg intravenous $\times$ 1 dose) and solumedrol (500 mg intravenous), were used. Tacrolimus and mycophenolic acid were given for maintenance immunosuppression.

RESULTS

Drone Design

Drone characteristics identified as critical by multidisciplinary analysis included the ability to autonomously carry a payload minimum of 4.54+ kg (10+ lbs), fly 3 miles, take-off and land vertically, be fully electric, accommodate redundant piloting systems, and have a parachute. These parameters yielded a custom-designed UAS (Fig. 1). Upon flight worthiness testing, FAA COA was sought and obtained.

Test Missions 1–44

Before missions over Baltimore city, the organ drone was field-tested. The aircraft was flown 44 times (a total of 7.38 hours, mean 0.17 hours) in advance of experimental missions. Test goals and findings are summarized in Table 1. The most frequent flights were aimed at improving drone handling with and without autonomous control. There were 8 flights using payloads of different weights [(2.27 kg (5 pounds; $n = 1$), 4.54 kg (10 pounds; $n = 3$),

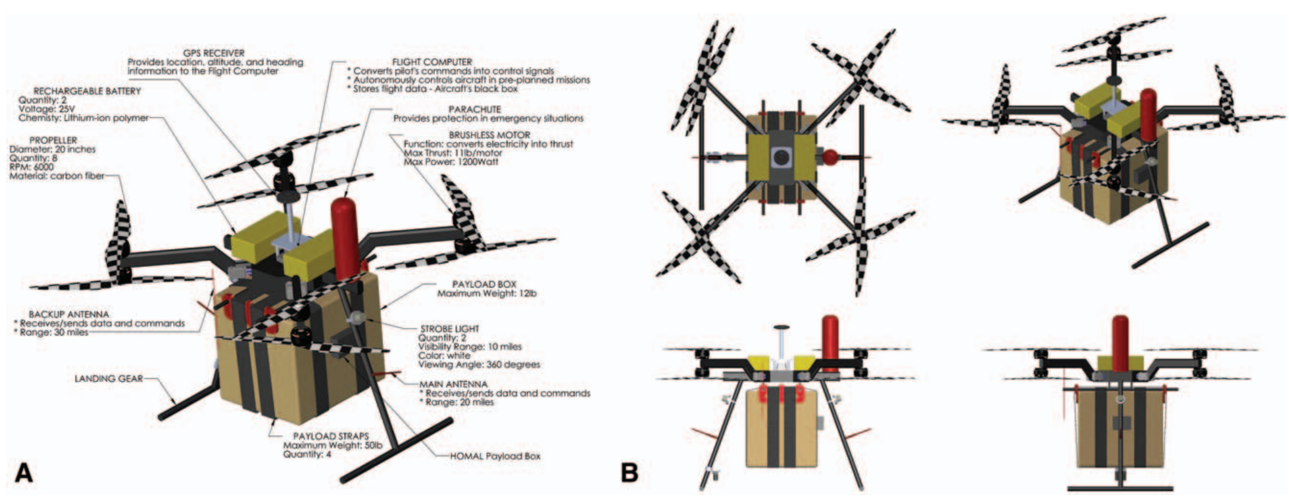

FIGURE 1. Drone used for organ shipments. (A) Drone, energy source, parachute, and payload, labeled. (B) Drone in various rotations.

TABLE 1. Summary of 44 Drone Test Flights Required for Flight Worthiness

Organ Drone Tests	n
Take-off and communications safety	3
Assessment of altitude adjustment using autonomous control	2
Autonomous control honing	6
Drone handling (pitch, roll, yaw)	14
Minimal payload and energy assessment	3
Parachute function	3
Landing operations	5
Payload (variable weights) pounds	8
Total:	44

and 5.67 kg (12.5 pounds; $n = 4$)]. Flights 14 and 39 both ended with crashes. Flight 14 was a mission focused on drone handling investigation and flight 39 was focused on an assessment of autonomous control. Both flights 14 and 39 were designed to push the device to its limits.

Experimental Missions 1–3

Before experimental flights, complete pre-flight checks (analogous to full-sized aircraft) were performed. Flight check included test director, pilots, receiving side team, BCPD, Syscom, DOT, OEM, and helipad operations. Three experimental missions were flown 2.8 miles over Baltimore City from a launch to landing site (Fig. 2). Acceleration was set at 1 m/s^2 and constant ground speed was set to 10 m/s. Energy (battery power) was contingent on speed, not vice versa.

1. Mission #1: No Payload:
   - Experimental mission 1 took place on 4/16/2019. The automated weather observing system (AWOS) reported clear weather, with wind at 8 knots and gusts to 12 knots. The ambient temperature was 8.3°C (47F). The drone flight lasted 11′10″ and operations were unremarkable. No loss of signal occurred. The aircraft was recovery safely. Battery life remaining at flight's end was 68%.
2. Mission #2: Weighted Payload (no-organ):
   - Experimental mission 2 took place on 4/16/2019, immediately after mission 1. AWOS reported the same weather. To simulate the true organ shipment, a standard United Network for Organ Sharing (UNOS) approved organ box carrying ice a 1 L saline bag and sterile blood tubes (3.8 kg, 8.4 lbs) were transported. The HOMAL device reliably recorded temperature, pressure, vibration, altitude, and geolocation. The organ box and its contents (saline, sterile blood tunes) were recovered safely. Flight duration was 10′55″ and flight operations were unremarkable. Battery life remaining was 31%.
3. Mission #3: Human organ for transplant:
   - A human kidney from a 47-year-old donor with a kidney donor profile index of 38% was identified. The donor serologies and nucleic testing were negative for HBV, HCV, and HIV. The organ was procured by our team and transferred to the OPO, per standard practice.
   - OPO personnel in addition to the PI (J.R.S.) packaged and weighed the organ in a HOMAL-outfitted, UNOS approved organ shipment box. The peri-organ temperatures dropped to <1.0°C over the course of approximately 3 minutes and remained stable at ~ 0.6°C (Fig. 3A and B). The payload

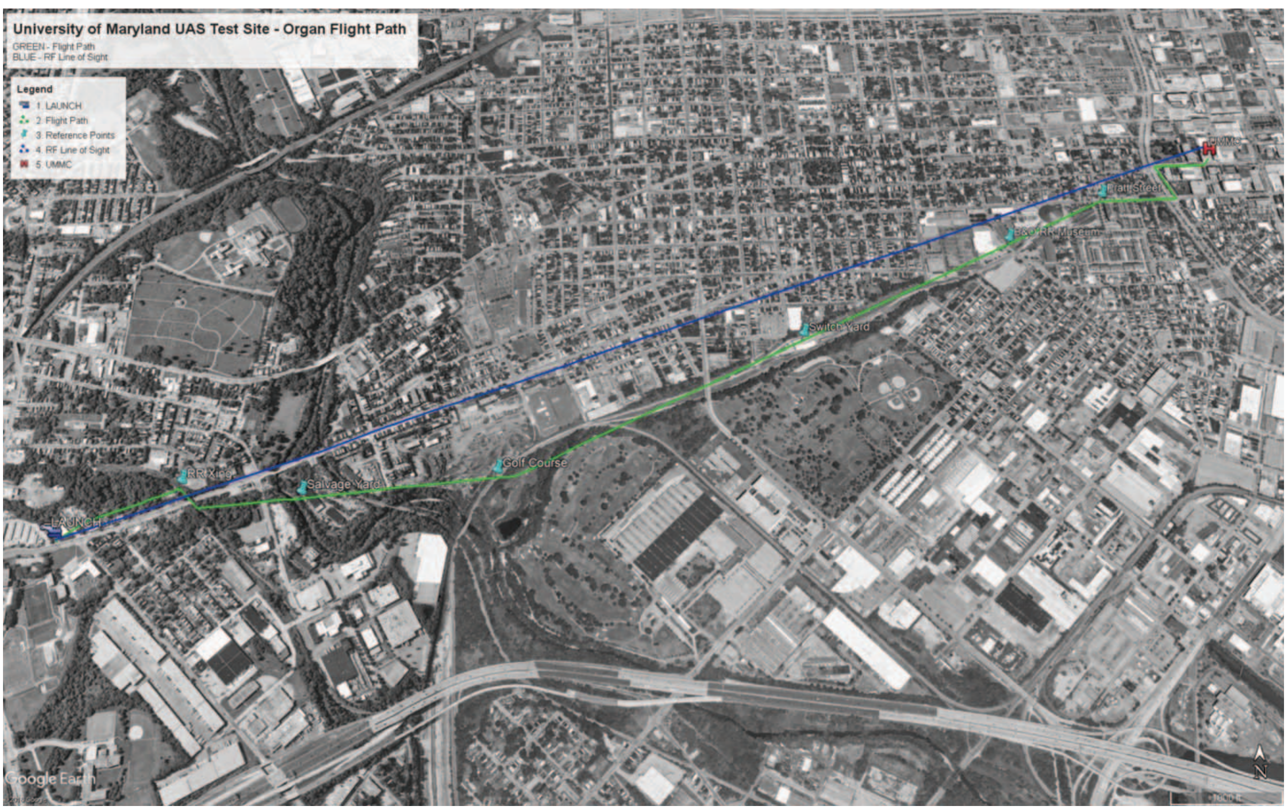

FIGURE 2. Flight path of organ drone over Baltimore City, Maryland.

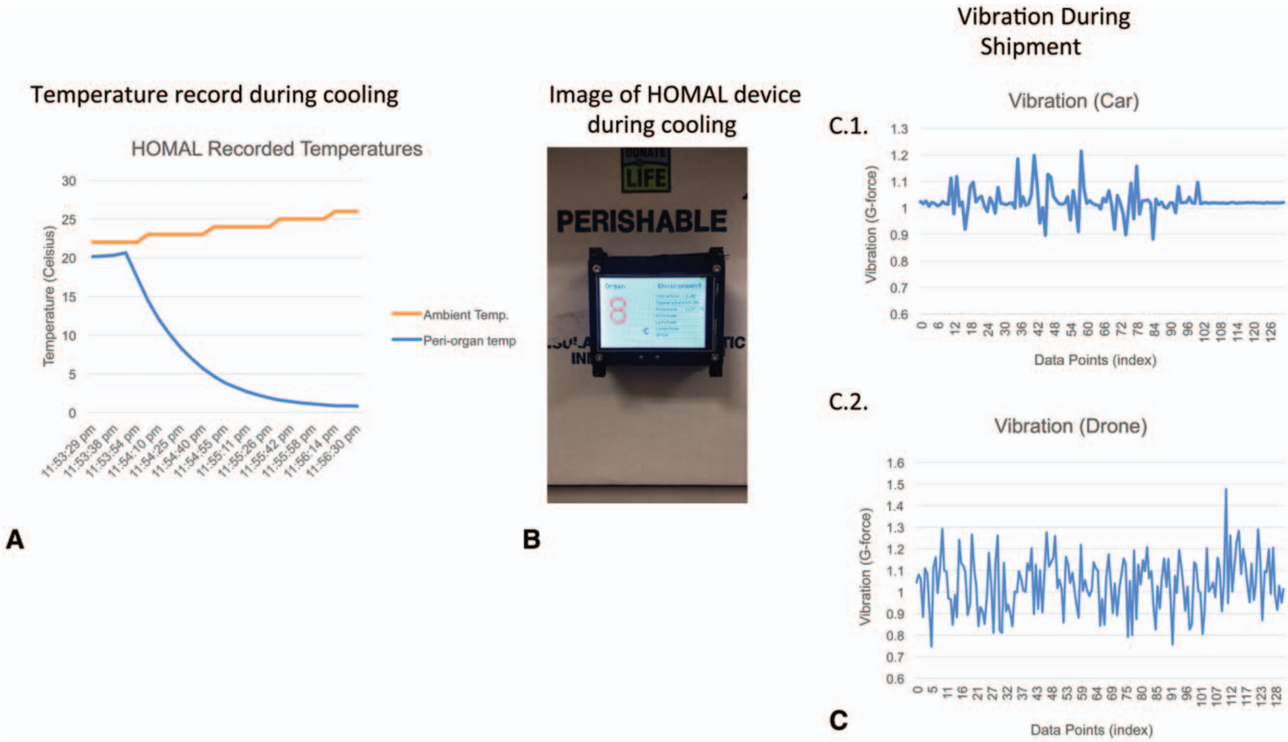

FIGURE 3. HOMAL generated data during drone experimental drone shipments. (A) Temperature depression with time, upon organ packaging in HOMAL mounted organ box. (B) Photo of HOMAL device on organ box during temperature reduction after human organ was loaded. (C.1) Vibration data taken from organ shipment in car, en-route to launch site. Upon arrival at test site, vibration scores decrease to near 0. (C.2) Vibration data during drone flight. Drone flight vibration was no different than by car. For (C.1.) and (C.2.) trips were of different durations (drone flight was longer than car drive). To this end, results were normalized to reflect an equal number of data points. HOMAL indicates human organ monitoring apparatus for long distance travel.

weighed (4.4 kg, 9.7 lbs) and was transferred by car to the launch site, proximate to the OPO facility. There were no differences in vibration when we compared car transport with drone flight ($P = 0.2$, Fig. 3C.1 and C.2).

- Mission 3 took place on 4/19/2019. AWOS reported clear weather, with wind at 10 knots and gusts to 14 knots. The ambient temperature was 19.4°C (67F). A moment of silence was held for the donor and donor family. Flight duration was 9′52″ and flight operations were nominal. Battery life remaining was 29%. The organ was then taken into the hospital for preparation for organ transplantation.

Biopsy

Before drone flight and after arrival, the organ was biopsied to determine if drone flight had a negative impact on histology compared to the biopsy taken before flight (Fig. 4). Patchy acute tubular necrosis was seen in both biopsy samples, and organ quality appeared no different when the 2 biopsies were compared by a senior pathologist (C.B.D.).

Organ Transplant Outcome

The transplant recipient was a 44-year-old female with a history of hypertensive nephrosclerosis and anuria on dialysis for 8 years. Her body mass index was 36 kg/m^2. The patient's preoperative labs revealed a creatinine of 8–12 mg/dL. Her admission potassium was 4.5 mmol/L. Her ejection fraction on recent echocardiogram was 70% and a stress test was negative.

The patient underwent an uneventful transplant of a left donor kidney to the right iliac fossa. There was minimal atherosclerotic disease. The renal vein was anastomosed to the right external iliac vein, and the renal artery to the right external iliac artery. Urine was managed with ureteroneocystostomy. Postoperative mean arterial pressures were maintained above 75 mm Hg, per protocol. Her urine output increased each day during the postoperative period, reaching a peak of 3.6 L in the 24 hours preceding POD4 (Fig. 5). The creatinine decreased starting on POD 3, to an inpatient nadir of 6.9 mg/dL. She was immediately started on tacrolimus and her level was 1.3 ng/mL on day of discharge. The patient has been followed closely in the transitional care clinic and transplant surgery outpatient clinic. The recipient was followed for 30 days, at which point her creatine was 2.36 mg/dL.

DISCUSSION

Organ transportation has become a hot topic amongst transplant providers and the UNOS in the last several years.[5,6,11,12] Indeed, as allocation systems change, there is an increasing need for more efficient organ travel.[6,12] Furthermore, when the time from explant to implant is increased, transplant organ function decreases.[5,13] In addition to quality, a faster, data-rich transport process could simplify transplant scheduling, reduce operations costs, improve recovery team safety, and yield more transplantable organs.[6,14]

Drone organ delivery in transplantation is appealing for several reasons. First, at present, many organs (particularly kidneys)

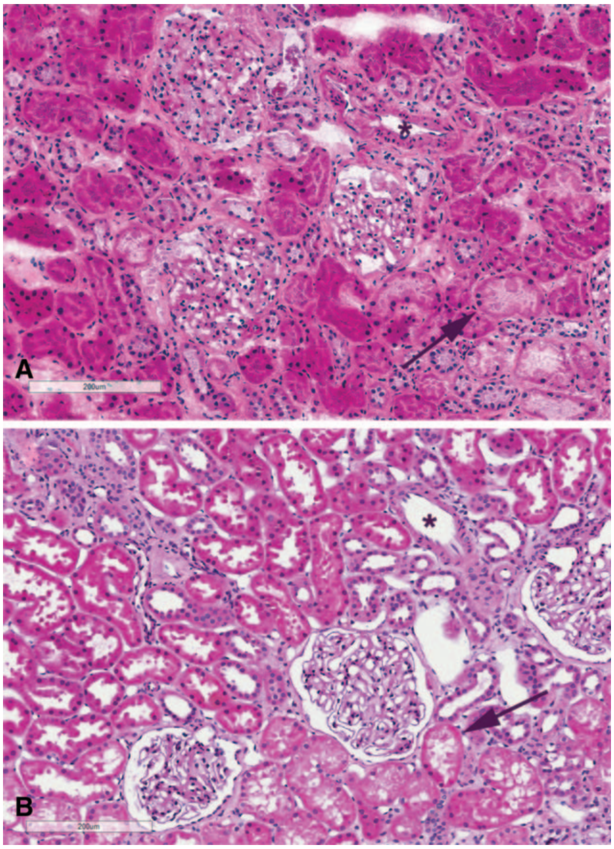

FIGURE 4. Biopsy of the drone transported kidney before and after transport. (A) Frozen section of baseline wedge biopsy (7 microns thick), before drone transportation. There is patchy acute tubular necrosis (arrow). (B) Permanent paraffin-embedded section of preimplantation wedge biopsy (4 microns thick), shows similar degree of acute tubular necrosis (arrow). Arteries in each section are marked with an asterisk.

are shipped by commercial aircraft. However, there are rarely flights that accommodate the time-sensitive nature of human organs. Accordingly, many organs sit on the tarmac awaiting ill-timed flights. As such, the average CIT for a kidney in the United States is 17.9 hours, despite an average travel distance of about 267.2 miles.[3] In Europe, this number is slightly higher, at 21 hours. Furthermore, in the USA, both travel distance and CIT have increased after recent changes to the kidney allocation system. Similar changes are also happening for liver and thoracic organs.[3,6,14] The alternative to commercial carriers is to charter an airplane or helicopter, but this comes at significant financial cost.

Early reports suggest that UAS payload delivery may be less expensive than alternatives.[15,16] However, a comparison with traditional flight is presumptive because there UAS payload delivery networks are not yet operational. At present, charter helicopter flights are approximately $15,000 and jets may exceed $40,000 for an individual trip. Because a large portion of charter cost is related to fixed costs, such as the purchase price of the aircraft, UAS travel is anticipated to be significantly less expensive on a per flight basis.[15] Beyond fixed costs, fuel consumption and carbon footprints for UAS are expected to be less substantial than for charter flights.[17]

All organs have a shelf life. For example, each hour of kidney CIT is associated with a hazard ratio for graft failure of 1.013.[13] There is an 8% increased risk of graft failure for an organ transplanted at 12 hours versus 6 hours.[13] This difference jumps to 40% at 30 hours.[13] Because many organs are declined each year on the basis of high CIT, CIT obstructs access to transplantation. For kidneys alone, the University of Maryland declines >200 organs per year because of prolonged CIT.[1] Attempts to dramatically minimize CIT, potentially through drones transportation, may have the potential to improve transplant quality and access to more organs.[9]

If VTOL drones could travel even 100 mph, which is considerably slower than a commercial aircraft, the average kidney could be transported in less than 3 hours. Adding in time required for the recovery, packaging, and reperfusion (surgery) of the organ, drone transportation has the potential to reduce CIT as much as 70%. Because organs that are transplanted more quickly have a better long-term survival, innovated systems of organ transportation would thus translate to increased life-years after transplantation and reduced costs of organ failures and medical management including dialysis.[7,13,18,19] Although the drone used in the present

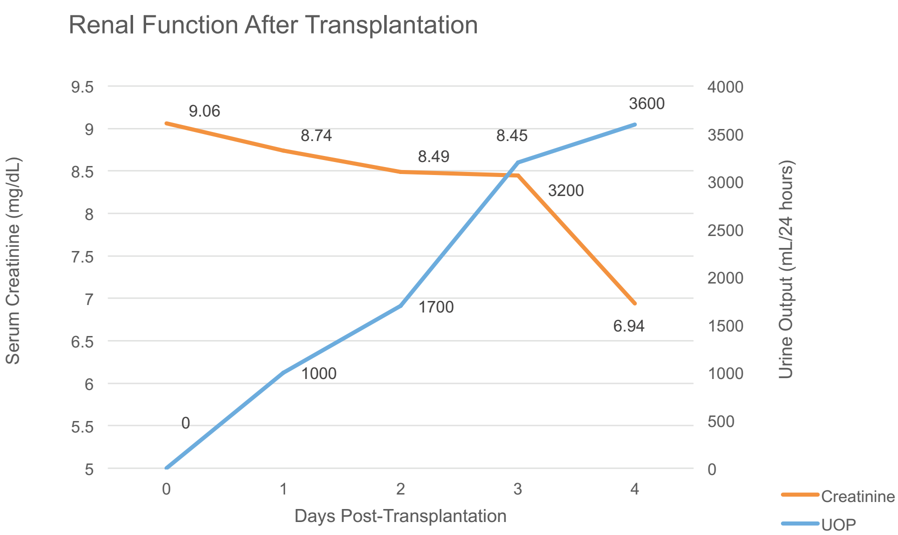

FIGURE 5. Clinical course of the transplant recipient during inpatient hospital stay. The patient was discharged on POD 4. POD indicates postoperative days.

study was small and slow, bigger and faster drones are in active development and fully autonomous devices substantially faster than 100 mph are likely to be available in the coming years.[20]

Implementation of UAS technologies for organ, blood, or medication delivery should be implementation cautiously. Although UAS could benefit both urban and rural communities, it strikes the authors that shorter, low-speed missions in sparsely populated areas may be a good way to begin implementation.

Although long-distance, high-speed transports are likely 5–10 years away, there are maybe near-term benefits to UAS with current technologies. Even at slower speeds, the ability to avoid traffic and congestion in urban areas could reduce shipment times and delays. Further, even over short distances, the simplification of transport in a helipad-to-helipad fashion, may reduce the operations time and costs required to move blood and organs.

In addition to CIT reduction and cost savings, organ drones may help alleviate resource shortage for airplanes and pilots.[4] In the newly planned, organ allocation systems for liver and thoracic organs, there will be a more pressing need for time-sensitive transport. This is because, unlike kidneys (and to a lesser degree, pancreas), livers, hearts, and lungs tolerate shorter CITs.[21,22] It is anticipated that in the new allocation systems (depending on the OPO) rates of organ exports will increase significantly (>50% in some cases), requiring costly resources including pilots and airplanes, neither of which are currently available.[4]

Unfortunately, organ recovery has been called the ‘‘riskiest job in medicine.’’[23] Indeed, in 2007, 6 members of a University of Michigan organ recovery team died during a lung recovery.[8,23,24] The University of Michigan story represents the worst-case scenario for traditional flight. In contrast, the worst-case scenario for a failed UAS organ shipment would involve loss of the smaller, lighter UAS and it's organ payload from a lower altitude (400–1000 feet, likely) and with limited fuel on board. Although loss of life is possible with a UAS crash, this risk needs to be contrasted with the obvious risks to passengers and others when full-scale airplane or helicopter is lost.

Culturally, the norm in transplant surgery has been to ‘‘recover your own organs.’’ That is, the implanting surgeon also recovers them. This practice is particularly relevant in liver, lung, and cardiac transplantation. However, if this paradigm were to shift, a surgeon separate from the implant surgeon could recover the organs. Those organs could be moved by unmanned aircraft, on demand, and travel directly from hospital-to-hospital, minimizing risk to medical staff and minimizing CIT on the organs. Although drones themselves improve safety only partially, the combination of UAS technologies with innovations in organ procurement practices could have a more substantial effect. By putting fewer people in the air, the proposed UAS system would mitigate some of the risk to transplant teams and recovery pilots.

To the knowledge of the authors, this was the first FAA-approved drone-organ payload transported in the United States or internationally, the first case of any drone-payload flown over a city (in class ‘‘Bravo’’ airspace), the first drone shipment of medical supplies (saline, blood tubes), the first drone-shipment of human organ for the purposes of transplantation, and the first transplant of a human kidney transported by drone. To assimilate these innovative transportation technologies into the current, complex web of couriers required for organ shipment requires the input of OPOs, surgeons, OR personnel, drone engineers, drone pilots, and communications and operations personnel. Beyond these individuals, strong relationships with the OEM, the Baltimore City Fire Department, the Baltimore City Police, and DOT were all required to minimize potential human risk associated with organ shipment and prepare for the unexpected.

The resource-intense approach used in this investigation would not be sustainable for large-scale organ drone use internationally. In the USA, regulatory issues, technical hurdles, and potential human impact all need to be addressed. Firstly, our flights were flown under an FAA COA for the purposes of research. A more appropriate regulatory framework would be required for large scale organ drone use. Secondly, technical hurdles still exist. For example, while moderate energy was required during experiment 1 (68% power remaining), experiments 2 and 3 landed with about 30% remaining energy. This highlights the shortcomings of eVTOL, or electronic VTOL drones. To move further and faster, gas-powered engines would be required, necessitating larger and heavier drones, and these characteristics affect FAA approval. In addition, to more completely understand the ramifications of a drone delivery system, a thorough analysis of the potential medical and human impact of drone organ shipment (eg, how many life-years can be added to the system? etc) is needed. A number of these issues are being actively addressed in the PI's laboratory.

There are potential benefits of unmanned aircraft which go beyond transplantation. Several of these applications, such as drone transportation of automated external defibrillators and blood distribution in Africa have been implemented.[25,26] Indeed, emergency services in post-disaster zones, the need to rapidly move fragile or time-sensitive tissues, implants, or assays, in addition time-sensitive drugs such as opioid antidotes are all possible.[25,27,28] Furthermore, shipment of rare blood types in both civilian and military environments may be yet another life-saving use for these technologies.[29,30]

In this report, we describe the first transplant of a human organ transported by drone. To do so, significant modifications to the current transport system were successfully implemented. The drone technologies demonstrated to be reliable, and the organ drone landed, was unharmed, and subsequently had excellent function after transplantation. Although these technologies are still in their infancy, unmanned flight represents an appealing alternative to traditional flight in the changing landscape of transplantation.

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