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An Initial Investigation of Unmanned Aircraft Systems (UAS) and Real-Time Organ Status Measurement for Transporting Human Organs

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ABSTRACT Organ transportation has yet to be substantially innovated. If organs could be moved by drone, instead of ill-timed commercial aircraft or expensive charter flights, lifesaving organs could be transplanted more quickly. A modified, six-rotor UAS was used to model situations relevant to organ transportation. To monitor the organ, we developed novel technologies that provided the real-time organ status using a wireless biosensor combined with an organ global positioning system. Fourteen drone organ missions were performed. Temperatures remained stable and low (2.5 °C). Pressure changes (0.37-0.86 kPa) correlated with increased altitude. Drone travel was associated with less vibration ($<$0.5 G) than was observed with fixed-wing flight ($>$2.0 G). Peak velocity was 67.6 km/h (42 m/h). Biopsies of the kidney taken prior to and after organ shipment revealed no damage resulting from drone travel. The longest flight was 3.0 miles, modeling an organ flight between two inner city hospitals. Organ transportation may be an ideal use-case for drones. With the development of faster, larger drones, long-distance drone organ shipment may result in substantially reduced cold ischemia times, subsequently improved organ quality, and thousands of lives saved.

INDEX TERMS Drone transportation, organ transplantation, transplant, transportation innovation, unmanned aircraft systems.

I. INTRODUCTION

Organ transportation has not been substantially innovated in the 60 years since the inception of organ transplantation [1] The current system for organ transportation involves a complex network of couriers and commercial aircraft [2]. Thus, the timing for organ transplants (particularly for kidneys, pancreata, and sometimes livers) is frequently contingent upon the airlines. This reliance can be quite limiting, and in many cases the accumulated time resulting from this complicated network precludes transplantation altogether [3]. An innovated system using unmanned aircraft systems (UAS), or drones, which does not rely on ill-timed commercial flights or prohibitively expensive charters would allow organs to be transplanted more quickly, improving access to transplantation [4], [5].

The topic of organ transportation optimization is particularly timely [3], [6]. Indeed, the kidney and liver allocation systems used by the United Network for Organ Sharing (UNOS) were recently changed to favor an improved immunologic match between donor and recipient, in the case of kidneys, and to improve center sharing in the case of livers. While these were smart, data-driven decisions, the new kidney allocation system (KAS) and liver redistricting policies have resulted in organs traveling longer distances [3], [7].

Travel distance for a shipped kidney has increased from 440 miles to 706 miles (60% increase in mileage). This increase in distance is associated with an increase in cold ischemia time (CIT). This is important because longer CITs are associated with poorer organ function [8], [9]. More specifically, CIT is the amount of time which accumulates between organ recovery and organ transplantation. While there are no absolute limits, surgeons strive to transplant organs as quickly as is safely possible. In general, surgeons attempt to transplant, for example, deceased donor kidneys with less than 24 hours of CIT and livers in less than about 8 hours. However, CIT is one of many donor related parameters, and decisions to use organs with shorter or longer CITs are balanced by other donor and receipted risk factors (e.g. age, medical history, surgical complexity). Like for kidney transplants, the liver allocation system was just recently changed such that centers are routinely flying 250-500 miles for these valuable organs. Data on liver CIT are forthcoming, but CITs are expected to increase [6]. Technologies which improve geographic access to organs could be of potential benefit to waitlisted organ transplant candidates.

II. METHODS

A. HOMAL

The HOMAL (Human Organ Monitoring and Quality Assurance Apparatus for Long-Distance Travel (HOMAL; patent pending) is a novel device designed to measure temperature, barometric pressure, altitude, vibration, and location via global positioning system (GPS) during transportation. These parameters were selected as they were perceived to be important during non-pressurized UAS transportation. The device was designed expressly for this project.

B. HUMAN KIDNEY

The human kidney used in this study failed to place nationally, and thus it was offered for research. Placement followed next-of-kin research consent and IRB approval. The total CIT at research allocation was 19.0 hours. The total cold ischemia prior to UAS testing (''box open'') was 63.3 hours. The kidney was shipped to our laboratory by a series of couriers and by commercial aircraft at a distance of 1060 miles. The donor was a 57 yo African-American male with a history of HTN, alcoholism, and splenectomy for trauma in the remote past. The kidney donor profile index (KDPI) was 70% and the donor was cytomegalovirus (CMV)+ as well as public health service (PHS) increased risk for social behavior. The donor was non-oliguric and was brain dead. The admission creatinine was 0.9 mg/dL, the peak creatinine was 0.9 mg/dL and the terminal creatinine was 0.5 mg/dL.

C. KIDNEY ANATOMY, BIOPSIES, AND TEMPERATURE MEASUREMENT

The kidney was 11 cm × 5 cm. A post-recovery kidney biopsy obtained prior to shipping showed 12% glomerular sclerosis. As additional CIT elapsed between allocation and testing, the kidney was re-biopsied immediately prior to drone testing. After 4.5 hours of testing (including 1 hour and 2 minutes of drone flight) the organ was biopsied a third time. The biopsies were stored in formalin and fixed in paraffin blocks. Hematoxylin and Eosin (H&E) stains were performed and the results were interpreted by a senior renal transplant pathologist at the University of Maryland.

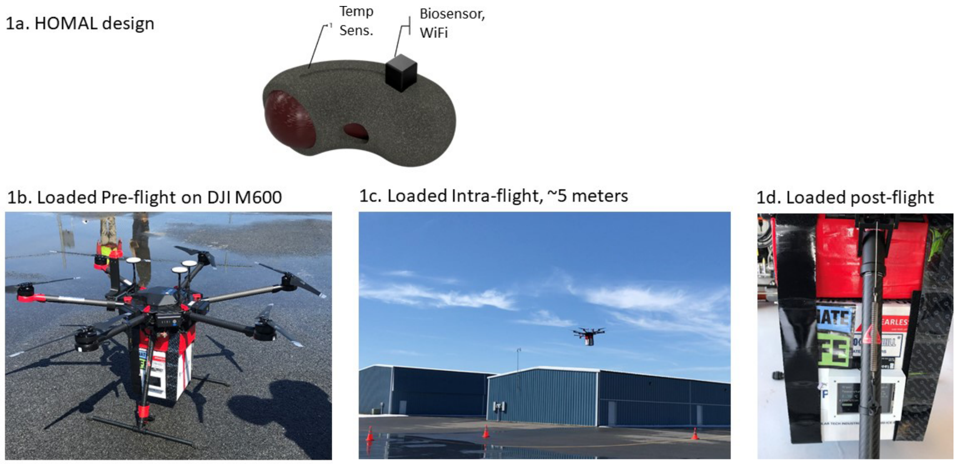
Two thermometers were utilized. The HOMAL's thermistor was silicone tipped for efficacy in conductive solution. A second digital meat thermometer (Bradshaw International, Rancho Cucamonga, CA) was used to measure the core temperature of the kidney, the ambient air, and the UW solution. The thermometer had a dual protective sheath, and a non-slip silicone head which was used to puncture the kidney. The thermometer has a manufacturer tested accuracy range of −50 degrees Celsius to 300 degrees Celsius. All temperature measurements were taken × 5, and separated by 30 seconds each. HOMAL derived pressure data were quantified in milli-bar (1 millibar = 10 kilopascals; kPa) and converted to kPa. HOMAL vibration was measured in gravitational units. Latitude and longitude were recorded by the HOMAL and were reported to the user by real-time digital mapping once downloaded from a ground-based server.

D. DRONE TYPES, TEST SITE, AND CONDITIONS

The primary drone was a DJIM600 Pro. This device contains 6 vertically oriented motors which function by battery power. Each of the 6 motors was immediately beneath each of the rotors. This is important because the payload was not in directly contact with potentially warm motors. The DJIM600 requires a warm up period of approximately 5 minutes prior to active flight. During this time the drone batteries are warmed from ambient temperature to a goal temperature of >25 .0 degrees Celsius. This particular drone can manage a payload of approximately 9.1 kg (20lbs). The drone is considered flight worthy in wind speeds of up to 32.2 km/h (20 m/h). A GoPro camera was mounted inferiorly for video data collection. The chaser drone was a DJI Inspire 1. This drone has 4 vertically oriented rotors, and an inferiorly mounted GoPro camera for video data collection. This drone is not designed to carry a payload beyond a simple camera.

The federal aviation administration (FAA) requires that a UAS not fly beyond line-of-sight. Drone pilots are specifically educated to identify the UAS at a distance. Additional regulations state that a UAS may not fly higher than 122 meters (400 feet) above structures within the area in which it is flying.

Prior to active flight a formal pre-flight Operational Readiness Review (ORR) briefing was held with all team members. To determine appropriateness of local weather patterns, we utilized the Federal Aviation Administration's (FAA) Automated Weather Observation Service (AWOS) at Saint Mary's Airport (WX AWOS-3). Each member was identified and roles were established. Safety measures were discussed. The organ donor and his family were acknowledged.



1a. HOMAL design

1b. Loaded Pre-flight on DJI M600

1c. Loaded Intra-flight, ~5 meters

1d. Loaded post-flight

FIGURE 1. **Human Organ Quality Apparatus for Long-Distance Travel (HOMAL). Fig 1a. HOMAL design, Fig 1b-d. HOMAL loaded on drone.**

The University of Maryland UAS test center is affiliated strongly with the University of Maryland, College Park, the A. James Clark, School of Engineering, the Goddard Space Center, and the National Aeronautical and Space Administration (NASA). UAS work by the University of Maryland, the Naval Air Systems Command (NAVAIR) and industries throughout Maryland is supported by federal, state and local governments, as well as industry and other sectors. All flights were performed by professional UAS pilots.

III. RESULTS

A. KIDNEY CORE TEMPERATURES WERE SLIGHTLY WARMER THAN PRESERVATION SOLUTION

The kidney was shipped in a sterile cylindrical plastic container filled with UW solution, per standard practice (**Suppl. Fig 1**). The ambient temperature was 19.6 degrees Celsius. The mean temperature of the nonsterile fluid external to the kidney was 3.3 degrees Celsius (SD 0.00). The UW solution was 0.9 degrees warmer (mean 4.2°C, SD 0.07) than the non-sterile ice water ($p<0.001$; **Suppl. table 1**). The mean kidney core temperature was 5.9 degrees Celsius (SD 0.54). Temperatures of the upper, middle, and lower poles were not different ($p>0.05$). During temperature measurements, the interior pole of the kidney was oriented up, exposing it to ambient temperatures to a greater degree than the middle or upper poles.

B. HOMAL LOADING

Five minutes of organ preparation were required in order to remove perinephric fat from the kidney. It took <10 seconds to successfully place the organ in the HOMAL and the artery, vein and ureter were unaffected by the HOMAL (**figure 1a**). HOMAL temperatures were then correlated with the UW solution in which the HOMAL was submerged. The mean temperature recorded by the HOMAL was warmer than the UW solution by 1.1 degrees Celsius. The kidney-HOMAL unit was then packaged in the Smart Cooler for transportation (**figure 1b-d**). The temperature dropped to 3.9 degrees Celsius prior to active flight. Over approximately 1 hour, the HOMAL showed a stable temperature of 2.5 degrees Celsius.

C. AMBIENT OUT-OF-DOORS MEASUREMENTS

Per the FAA AWOS, the flight time temperature was 5.0°C, wind speeds was 17-26 km/h (9-14 knots), of visibility was 16.1 km (10.0 miles).

D. UAS EXPERIMENTS

A total of 14 UAS missions were performed. Total onboard drone time was 1 hour and 2 minutes, inclusive of battery changes and flight preparation.

1) DRONE EFFECTS ON THE TRANSPLANTABLE ORGAN DURING FLIGHT

A series of take-off-and-landing (n=5) and hover (n=5) missions, designed to understand the effect of the drone flight on the organ status were performed. For take-of-and-landing missions, the drone was accelerated to 1.5 m/s to a maximum height of 61 meters (200 feet). For hover missions, the drone was accelerated 1.5 m/s to a lower altitude (30.5 meters, 100 feet) so the payload could be easily visualized with the naked eye.

Temperature was predictably stable during all flights (**Suppl. figure 2a-c**). Up-and-down motion was associated with modest vibration changes of <0.5G (**figure 2a**). Vibration ranges during hover (figure 2b) were similar (**figure 2b**). We observed a mean decrease in barometric pressure of 0.69 kPa when the kidney reached maximum flight altitude (**figure 3a**). Mean pressure changes were approximately 1-half (0.37 kPa) those observed in up-and-down missions (**figure 3b**), reflecting the association between higher altitudes and lower barometric pressure.

2) MODELING DRONE ORGAN SHIPMENT AND COMPARISON WITH FIXED-WING FLIGHT

We next performed a series of distance missions (n=4), each >762 meters (2500 feet) at an altitude of 122 meters (400 feet).

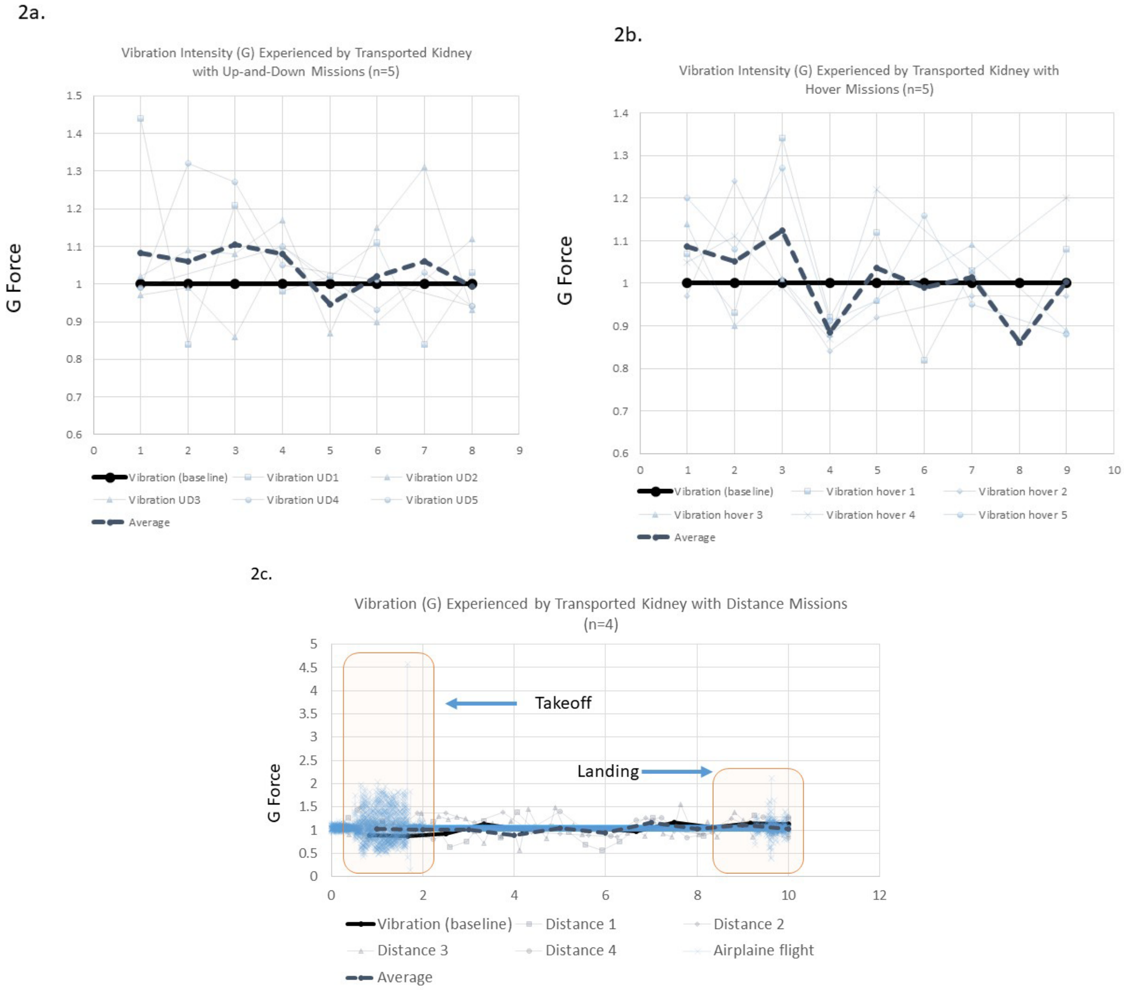


FIGURE 2. **Vibration changes in G-force as measured by the HOMAL. 2a-b show vibration changes during drone transportation for up-and-down and for hover missions, respectively; Figure 2c compares fixed wing aircraft induced vibration (light blue data points, n>13,000) with drone induced vibration (gray scale).**

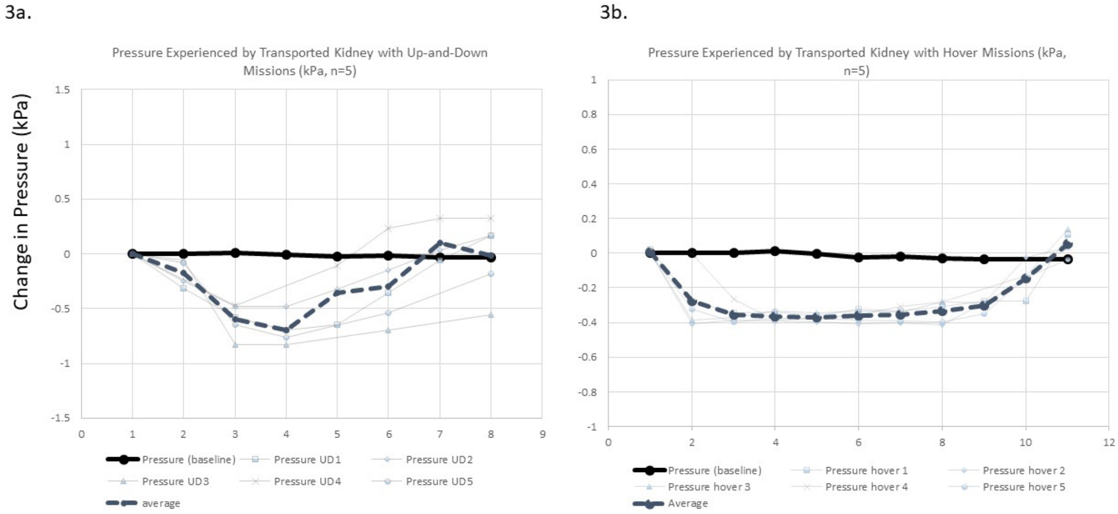


FIGURE 3. **Pressure changes in kPa as measured by the HOMAL. 3a shows kPa changes for Up-and-down missions. 3b shows kPA changes for hover missions.**

These missions were modeled for the potential shipment of donor organs between inner city hospitals.

The maximum speeds were 38 m/h, 30 m/h, 41 m/h, and 42 m/h for missions 1-4, respectively. Differences in drone speed were driven by wind. The maximum travel distance was at the limit of line-of-site, (mission 3), during which the kidney was transported outbound 2415 meters (7924 feet, 1.50 miles), for a total of 4830 meters (15,848 feet, 3.0 miles).

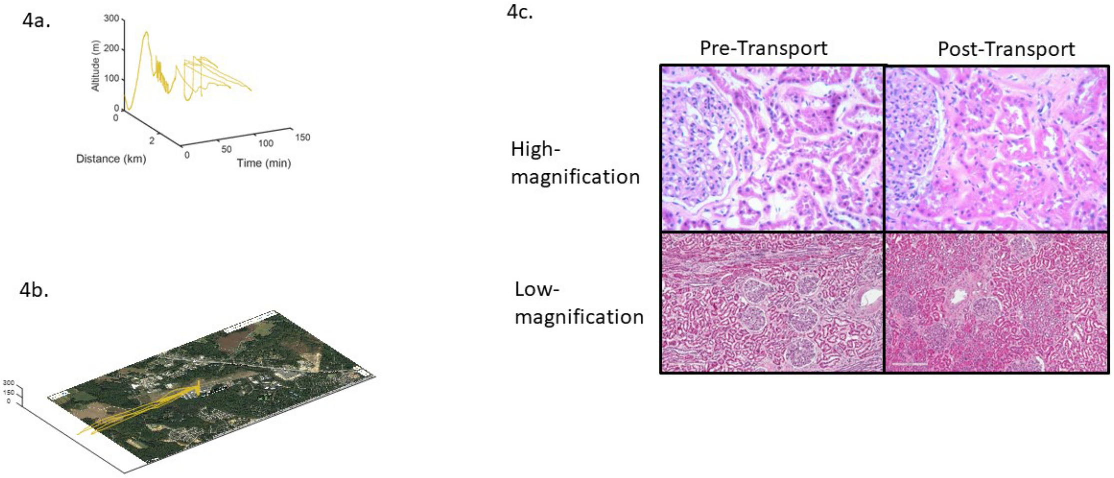


FIGURE 4. **a-b. GPS location of drone transported organ changes as recorded by the HOMAL. 4c shows H&E staining of drone transported kidney prior to and after transportation. There were no structural changes to the kidney which resulted from extrinsic forces secondary to drone transportation (i.e. injury from temperature, vibration, or pressure changes).**

Standard fixed wing flight on a dual engine turboprop King Air was used as a control for organ drone transportation. Airplanes have pressurized cabins, unlike drones. Thus, the primary comparison between standard flight and drone technology is vibration. The flight lasted 28 minutes. Fixed wing flight was associated with changes in vibration of >2.0 G (**figure 2c**). We observed significantly more vibration during takeoff and landing with a fixed wing aircraft than with drone transportation difference in the vibration intensity or pressure with air travel when compared to drone travel. Once airborne, little vibration was experienced by the kidney. Distance was recorded and mapped real-time by the HOMAL. A tracing of the drone payload tracking in 3-dimensional space is presented in **figure 4a and 4b**.

E. DRONE EFFECTS ON THE KIDNEY ARCHITECTURE

Vibration and pressure changes can injure fragile human tissues. Biopsies were taken prior to and immediately after drone flights. Drone flight did not affect biopsy results (**figure 4c**). Prior to and after drone flight, H&E staining revealed unchanged biopsies. There were equivalent degrees of glomerular sclerosis (11-12%), cortical scarring, and hyalinosis.

IV. DISCUSSION

There remains a woeful disparity between the number of recipients on the organ transplant waiting list and the total number of transplantable organs [10]. Indeed, this problem has fueled interest in organ regeneration, 3D organ printing, and xenotransplantation, however these technologies are many years away from clinical implementation. In this report, we performed an initial investigation of drone based organ transportation as potential pathway towards expanding the donor organ pool [11], [12].

Drone organ transportation has the potential to decrease CITs thus widening the donor organ pool and access to transplantation. Because organ quality is higher when CIT is low [13], and because higher quality organs result in more life-years for the recipient, lower CITs resulting from UAS transport could add life-years to transplant recipients [14]. Patients who receive a higher quality transplant are less likely to require a re-transplant, allowing another patient on the waiting list to undergo transplantation. Also, if organs could travel more efficiently, surgeons would be more likely to accept organs, particularly those considered marginal. Lastly, if the OPOs around the United States had the ability to move organs more quickly, they may entertain the use of many donors who are not currently considered candidates.

How many organs could be added to the system if drone organ transportation were adopted remains unclear. The mean rate of discarded kidneys in the United States is approximately 20%. Indeed, many of these kidneys may have been usable were CIT expedited. Based on a value of 20% and a transplant volume of 13,501 deceased donor kidneys in 2016, as many as 2,700 kidneys may have been available for transplantation were CIT minimized [10]. Accordingly, a recent study showed that for 5,000 randomly selected, declined kidney offers, patients were more likely to be alive, had offers been accepted versus declined [15]. These data suggest that if tools such as the HOMAL and perhaps drone transportation were capable of shifting the balance of information in favor of transplantation, more patients could be transplanted with currently available resources [15].

If an organ drone could travel 350 miles per hour, an organ in Los Angeles could arrive in Baltimore (2645 miles) in 7.5 hours. Were an organ in New York, it could arrive in Baltimore (192 miles) in 33 minutes. For comparison, the national average CIT is 16-18 hours, including local and national sharing practices [14]–[16] Difficult-to-reach areas of the country, such as southern Florida have markedly longer average CITs. In some regions CITs routinely exceed 30 hours for kidneys [14].

The benefits of the DJI M600 are that, in addition to VTOL capabilities, it can carry an organ payload, whereas most drones cannot. We accelerated the drone to a maximum speed of 67.6 km/h (42 m/h). However, in the context of transplantation, drones would frequently need to travel much faster. The maximum distance traveled by a drone in this report was 3.0 miles. This distance was chosen as it models the distance between hospitals in cities such as Baltimore. While this is a modest distance, it suggests inner city drone organ transportation may be a good first-step for implementing UAS technologies. Ideally, a transplant drone would need the range and speed (480-800 km/hr, or 300-500 m/h) of a jet airplane. Further, drones would need to be large enough to carry the organ payload. Some current drone technologies allow for speeds of >100 m/h, however many of these are too small to safely carry a transplantable organ [17]. The ideal organ drone would also have VTOL capability allowing flor hospital-to-hospital, versus airport-to-airport travel. These advanced UAS technologies are in their infancy, but multiple groups are working to improve size and speed.

Extrinsic forces such as temperature, pressure, and vibration were measured at the level of the organ on day when weather was clear. However, challenging weather conditions which currently confront fixed wing aircraft (wind, rain, fog, etc.) would also be expected to affect drone organ travel. To this end, a more detailed understanding of how extrinsic forces affect both the drone an organ should be undertaken in advance of drone organ implementation.

Organ drone use would require new technologies be developed. For example, at present, organs are "accompanied" by a courier, pilot, or organ team. In the unmanned setting, organs would, perhaps, need to be "assigned" to a drone. Additionally, because drones will move from one location to another, the number of drones required and locations at which these drones will need to be housed will need to be optimized, in order to benefit from the improvement in organ transportation efficiency [18].

While the use of medical oriented drones has been suggested, little commercial activity has resulted. Drone use has been stifled for several reasons including unsatisfactory technologies and federal regulations. One notable regulation, for example, limits drone travel distance to line-of-sight. For this reason, it would be a challenge to move organs beyond only a short distance, such as hospitals in close proximity. However, while current restrictions on drone use persist, there has been significant federal dialogue to suggest UAS regulations may change in favor of civilian drone use [19]. UAS applications to transportation issues have been proposed in literature but at the moment the lack of a clear and shared regulation is a drawback and obstacle to the implementation. Additionally, a related regulatory hurdle is that of integration with preexisting aircraft operations and airspace. If drone regulations were to change, organ and potentially blood transportation might represent ideal initial use-cases [20], [21]. Further, success with transplantation could open up the possibility of additional, future UAS applications.

UNOS recently updated the KAS to allow for a better recipient-donor immunologic match. This has been a saving grace for patients who are a difficult match, through no fault of their own. After the KAS was updated, sharing organs nationally became more common. Indeed, whereas only 20% of kidneys were shared prior to the update, now more than 33% of organs are shared between organ procurement organizations (OPOs) [22]. As a result of sharing, the mean CIT has risen such that more than 22% of kidneys are now transplanted after more than 24 hours. This is important because 24 hours is the accepted "upper limit" for CIT. This increase in CIT has contributed to a problem called delayed graft function (DGF), wherein a kidney may not work immediately after transplantation. Although treatable, DGF is incredibly expensive and may lead to poor long term kidney survival. With the improvement in organ sharing on the KAS, the rate of DGF among kidney recipients has increased from 25 to 31% [6], [23]. More efficient methods for moving organs could reverse these trends, and very likely lead to improvement in CIT and DGF to pre-KAS levels.

Minimization of CIT through the use of UAS organ transportation may improve the availability of transplantable organs. Beyond solid organs, drone transportation of blood products has been suggested as well [20]. UAS organ transportation is a potentially appealing opportunity in the field of medicine.

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