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Article *in* Transfusion · November 2016

DOI: 10.1111/trf.13900

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Timothy Amukele, Paul M. Ness, Aaron A.R. Tobian, Joan Boyd, and Jeff Street

BACKGROUND: Small civilian unmanned aerial vehicles (drones) are a novel way to transport small goods. To the best of our knowledge there are no studies examining the impact of drone transport on blood products, describing approaches to maintaining temperature control, or component physical characteristics during drone transport.

STUDY DESIGN AND METHODS: Six leukoreduced red blood cell (RBC) and six apheresis platelet (PLT) units were split using sterile techniques. The larger parent RBC and PLT units, as well as six unthawed plasma units frozen within 24 hours of collection (FP24), were placed in a cooler, attached to the drone, and flown for up to 26.5 minutes with temperature logging. Ambient temperatures during the experimental window ranged between −1 and 18°C across 2 days. The difference between the ambient and unit temperatures was approximately 20°C for PLT and FP24 units. After flight, the RBC parent units were centrifuged and visually checked for hemolysis; the PLTs were checked for changes in mean PLT volumes (MPVs), pH, and PLT count; and the frozen air bubbles on the back of the FP24 units were examined for any changes in size or shape, as evidence of thawing.

RESULTS: There was no evidence of RBC hemolysis; no significant changes in PLT count, pH, or MPVs; and no changes in the FP24 bubbles. The temperature of all units was maintained during transport and flight.

CONCLUSION: There was no adverse impact of drone transport on RBC, PLT, or FP24 units. These findings suggest that drone transportation systems are a viable option for the transportation of blood products.

Management of blood products is complex even in settings with the best resources and infrastructure. The drivers of this complexity are many, including the financial and human cost of the units, the stringent storage conditions, limited time of storage, and the unpredictable nature of the need. However, they can be broadly classified into issues of product waste via expiration, and sporadic demand. To mitigate product waste via expiration, transfusion medicine professionals adopt complex inventory management systems to use available inventory while still supporting the varied special needs of patients (i.e., antigen negative, irradiated, cytomegalovirus negative) and traumas. To respond to sporadic demand, nonconventional modes of transport such as highway patrols or helicopters are used to deliver emergency products or to move patients to hospitals with larger stocks of blood products. These management challenges are magnified in low-resource settings without strong collection, monitoring, communication, and transport infrastructure. Consequently, there is a need for a responsive transport system that can maintain the integrity (temperature, pH, and presence of hemolysis) of the blood components during transport.

Unmanned aerial vehicles, colloquially known as drones, are aircraft without an onboard human pilot. They are a potential solution to the logistic challenges outlined above because they are immune to traffic delays, have low overhead costs, and have the ability to go where there is no passable road. However, as biologic samples

ABBREVIATION: FP24 = plasma units frozen within 24 hours of collection.

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Received for publication August 8, 2016; revision received September 16, 2016; and accepted September 16, 2016.

doi:10.1111/trf.13900

TRANSFUSION 2016;00;00–00

are fragile, drones are only a viable solution if they do not adversely affect the integrity of transported samples[1-5] or product characteristics of blood components. Other transport methods such as pneumatic tubes commonly used for transportation cause damage to various types of specimens.[4,5] Thus new transport methods must be tested to determine the presence and extent of adverse effects. The forces applied on samples transported by a drone include sudden accelerations and decelerations, as well as changes in air pressure and temperature. The effects of these stresses cannot be predicted a priori. Previous work on drone transport of chemistry, hematology, and coagulation laboratory specimens[6] demonstrated that the results for drone-flown specimens were similar to those of matched controls that were not flown. However, that finding does not obviate the need for validation of blood products because their size and storage requirements are significantly different from routine testing specimens. To illustrate, the majority of laboratory samples are less than 10 mL while blood products are several hundred milliliters. In addition, red blood cells (RBCs), platelets (PLTs), and plasma units frozen within 24 hours of collection (FP24) need to be stored and transported at 1 to 6; 20 to 24; and not more than −18°C; respectively, while the majority of laboratory specimens are tolerant of a much wider range of storage temperatures.

To the best of our knowledge there has been no published research examining the impact of drone transportation on blood products. These data would be needed to determine the feasibility of drone transportation for this class of biologic products, one of the three objectives of this study. The second objective is finding simple solutions for maintaining target temperatures during drone flight. Finally, such validation as presented in this work will provide a template for future experiments using other drones or in other environments.

MATERIALS AND METHODS

Study design

Six approximately 250-mL leukoreduced apheresis PLT units with ACD-A were shipped to our laboratory at 20 to 24°C and stored on a flatbed rotator at 20 to 24°C. Six approximately 350-mL leukoreduced RBC units with Adsol (AS-1) were shipped at 1 to 10°C and stored at 1 to 6°C. Six approximately 225-mL FP24 with CPD2 were shipped frozen and stored at −80°C. The ages of the PLT and RBC units were 4 and 3 days, respectively, when flown.

PLT and RBC units were split in a sterile fashion, using a sterile connecting device (TSCD, TerumoBCT). The volume of the secondary bag was approximately 30 mL for the PLT units and approximately 50 mL for the RBC units. The primary and secondary PLT and RBC units as well as the FP24 units were driven to the flight site. All the primary PLT and RBC units as well as the FP24 units were transferred into a 5-quart (4.7-L) cooler container (FlipLid 6, Coleman), attached securely to the drone, and flown for 22 ± 4.5 minutes. After takeoff, the drone orbited the flight field, within the pilot's visual range, for the duration of the test. Based on our flight speeds, this 22-minute flight was the equivalent of a 13- to 20-km distance. Each cooler had between 2 to 3 units and had a maximum weight of 1.9 kg. The temperature of the PLTs was maintained by packing with a preequilibrated thermal pack (Sonoco Thermosafe). The temperature of the RBCs was maintained by packing with half a handful of wet ice, and the temperature of the FP24 units was maintained by packing with half a handful of dry ice.

Temperatures of the blood products were monitored using a Type K thermocouple attached to a digital temperature logger (Lascar Electronics). The tip of the probe was placed in the cooler in between individual units, and the temperature logger was affixed to the outside of the cooler. The maximum ambient temperatures on the two flight days were 7 and 18°C, respectively. Minimum ambient temperatures during the experimental window were −1 and 6°C, respectively. Of note, the PLT units were flown on the morning of flight day with the lower maximum ambient temperature. Temperatures during the time of the PLT flights were around 0°C. To expand the applicability of the packing scheme described in this article, we monitored blood unit temperatures on a day with ambient temperatures of 29.5°C. Of note, this test was not performed during flight.

After the flight in the drone, all the samples (flown and stationary) were transported back to the Johns Hopkins Hospital laboratories. Pictures of the frozen air bubbles on the back of the FP24 units were taken before and after flight. All FP24 units were examined for changes in the number, size, and shape of these bubbles as an evidence of thawing. Both flown and stationary RBC units were centrifuged at 4500 × *g* for 5 minutes at 4°C and visually examined for hemolysis. PLT count, pH, and mean PLT volumes (MPVs) were measured on both the primary and secondary PLT units. pH testing was performed on a pH benchtop meter (Orion Star A211, Thermo Fisher Scientific). PLT counts and MPV were performed on a hematology analyzer (Sysmex XN-9000, Sysmex America, Inc.).

Flight protocol

The flights were conducted in compliance with Advisory Circular (AC) 91-57,[7] Model Aircraft Operating Standards, the rules in effect at time of the experiment. Briefly, samples were flown in a small multirotor aircraft ("S900" from DJI) at an altitude above ground level of 100 m. The aircraft was controlled using the manufacturer's multifrequency radio control link. A multirotor aircraft was

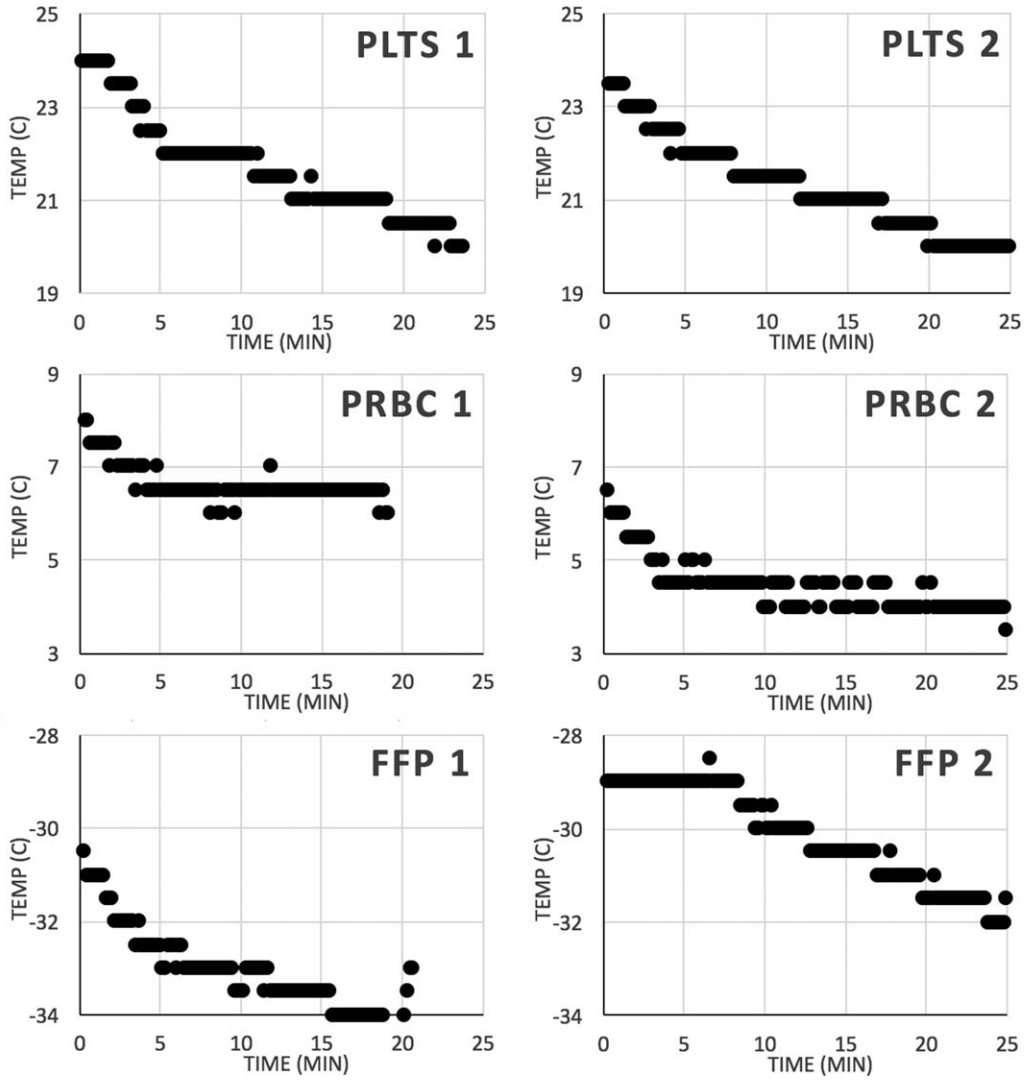

Fig. 1. Temperature charts of PLT, RBC, and FP24 units during individual flights.

selected over other aircraft types, such as helicopter or fixed wing, because it has the capability to take off and land vertically and is mechanically simple and inexpensive. Among other precautions, the test was conducted away from populated areas, the aircraft was under the control of a ground-based pilot, and the aircraft's altitude was less than the FAA-mandated 120-m (400-ft) limit.

RESULTS

Figure 1 shows graphs of the temperature of the blood products during flight. For all units there was a decrease in temperature of between 1.5 and 4°C during the course of the flight. The cause of the decrease in temperature was probably the ambient temperature in the case of the PLT units and the wet and dry ice in the case of the RBC and FP24 units, respectively. In addition, there was an up to 2°C difference between individual flights for both the RBC and the FP24 units. This small difference in temperatures is likely due to the differences in the amounts of wet and dry ice placed in the cooler.

Table 1 shows the pH, PLT counts, and MPVs of matched primary and secondary PLT units. The results from the primary and secondary units were similar and did not show a significant change exceeding small variations inherent in the individual assays.[8] The laboratory coefficients of variation for PLTs and MPV in the respective ranges were 2.5 and 4%, respectively.

Figure 2 shows a picture of the bubbles in an individual FP24 unit before and after flight. There was no apparent change in the size or shape of these bubbles. In general, any thawing would lead to coalescing of the bubbles. Figure 3 shows temperature charts of the blood products compared to ambient temperatures between 29 and 30°C. The RBC units did not exceed the target temperature range of 1 to 6°C while stored in the cooler for up to 60 minutes.

Figure 4 shows the interface of the plasma and cellular components of the primary and secondary RBC units after centrifugation. Visual inspection of RBC units showed that there was no evidence of hemolysis in either the primary or the secondary unit.

DISCUSSION

The goals of the current work were threefold: evaluate the stability of blood products transported by small drones, provide a template for future similar work, and examine options for maintaining target blood product temperatures in flight. Our results demonstrate that there was no adverse impact to RBC, PLT, and FP24 units flown in a drone for up to 26.5 minutes (https://vimeo.com/160783688). In particular, there was no detectable RBC or PLT lysis or PLT clumping. Our results also demonstrate that the target temperatures of all the products were maintained even when ambient temperatures were more than 20°C from their target storage temperatures (Figs. 1 and 3).

At the inception of this work, there was no precedent for packaging blood products for drone transport. We considered environmental variables that might be relevant for this mode of transportation including temperature, atmospheric pressure, and acceleration. Changes in temperature and atmospheric pressure with altitude are small (0.6°C/100 m and 0.012 atm/100 m) for the environment in which the aircraft were operating.[9] Therefore, we reasoned that no specific measures would be needed to stabilize temperature or pressure when ambient conditions were not extreme. Previous work on drone transport of laboratory specimens[6] involved packaging designed to meet IATA guidelines for the packaging of potentially infectious liquid biologic materials (REF 6.1).[10] In that study, each sample was enclosed by three layers of packaging and enough STP absorbent material (SAF-T-PAK; http://www.saftpak.com/STPPack/) to absorb twice the full volume of all the samples in the payload. Contrary to laboratory samples designated for testing, blood products for the purpose of transfusion are not subject to the stringent packaging regulations indicated for IATA-defined infectious substances.[11] Thus, our approach for packaging was to approximate methods used for automobile transportation of blood products while minimizing the amount of passive temperature buffers (ice, thermal packs, etc.), as drones are exquisitely sensitive to weight. We adopted a cooler used for in-hospital transportation of blood products and monitored it to determine its ability to maintain the unit temperature in ambient conditions. The cooler was able to maintain the internal temperature of the unit despite two challenges: the approximately 20°C difference between the unit and ambient temperatures for the PLT and FP24 units and the poor seal necessitated by the temperature probe.

In previous experiments we utilized a fixed-wing (i.e., traditional airplane) style drone that is launched by a hand toss and lands by sliding on its belly.[6] However, we

TABLE 1. The pH, PLT counts, and MPVs of matched primary (flown) and secondary (not flown) PLT units*

	Primary (postflight)			Secondary (not flown)		
Sample ID	pH	PLT count	MPV	pH	PLT count	MPV
1	6.92	942	9.9	6.93	964	9.8
2	6.96	924	9.5	6.90	951	9.8
3	6.71	1266	10.2	6.64	1282	10.2
4	6.41	1361	11.5	6.41	1346	11.5
5	6.85	1356	9.8	6.84	1361	9.9
6	6.66	1359	10.5	6.63	1372	10.6

*The primary units were flown in the drone.

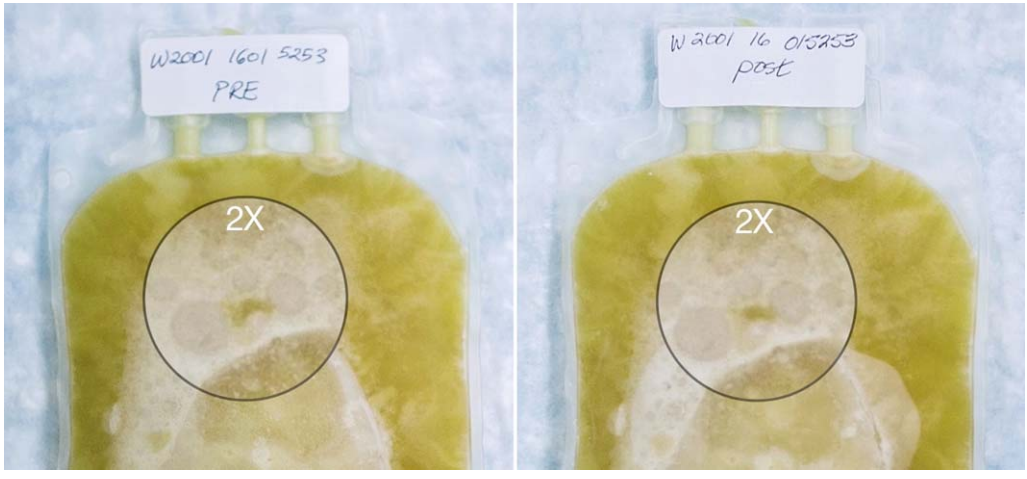

Fig. 2. Primary (left) and secondary (right) RBC units after centrifugation showing the plasma and cellular components of the primary and secondary RBC units. The primary units were flown in the drone while the secondary units were not flown. [Color figure can be viewed at wileyonlinelibrary.com]

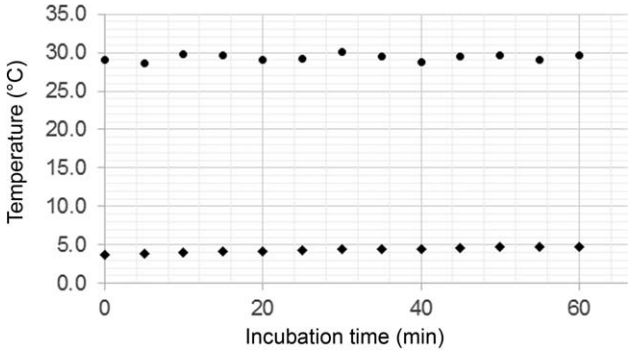

Fig. 3. Temperature charts of the blood products compared to ambient temperatures. The blood units were placed in a cooler for 60 minutes on a day with an ambient temperature of 29.5°C. (◆) Unit temperature; (●) ambient temperature.

anticipated that given the larger mass of blood products, acceleration might be a significant environmental factor so we used a multirotor drone that undergoes significantly less acceleration and deceleration in takeoff and landing. In addition, because multirotors can launch and land vertically, their use allows products to be dispatched closer to the blood bank and received closer to the patient. Their disadvantage however is that they are significantly range limited relative to plane-type drones and so may not be able to transport blood products over large distances. To illustrate, the flight speed of small civilian drones vary by up to a log, depending on the size, type (plane versus multirotor), and technologic endowment (engine, rotors, etc.) of the vehicle. The drone used in this experiment was a multirotor and has lower maximal speeds and higher energy consumption than a comparable plane drone. In addition, because of the cyclical flight path, it did not maximize its speed and flew between 10 and 15 m/sec. The flight time of less than 26.5 minutes was a limitation of the payload weight and battery capacity.

To the best of our knowledge, this is the first report of the impact of drone transportation on blood products. The results of the current study demonstrate the feasibility of using drones as a responsive system for the transport of blood products. However, there are other factors to consider including regulations, cost, and safety. A full discussion of these issues is beyond the scope of this work, but we will attempt to address them briefly here.

As of May 2015, more than 4 million drones had been shipped worldwide.[12] However, only 57 of the 174 United Nations–recognized countries in the world have publically available drone regulations[13] and many of these regulations are outright bans rather than a list of criteria for the safe and legal use of drones. In the United States, there is a tiered regulatory approach to drones, with broad restrictions covering all drone use and exemptions granted for specific-use cases (https://www.faa.gov/uas/). Our study was performed in keeping with the FAA rules in effect at the time of testing: the drone was under the control of a ground-based pilot and flew within the pilot's visual range, at an altitude of less than 100 m and away from populated areas. Since drone transport of blood products will likely only be clinically useful beyond the line of sight, it is encouraging that since August 29, 2016, there are new FAA rules in effect that can accommodate beyond the line of sight flight profiles for specific FAA-certified aircraft and flight plans.

Costs for drones vary by several logs depending on the grade (military versus civilian) and technologic endowment (flight controller, sense-and-avoid ability, etc.) of the vehicle. The drone system (airframe, flight controller, etc.) used for this study is an off-the-shelf system with significant customization. Its total cost was less than $3000. The adequacy of each drone system will depend on many factors including the requirements of the mission (distance, payload), regulations, ease of use, and so forth. For example, our particular vehicle was outfitted with a parachute that would automatically deploy in the case of a system failure. This capability is of critical importance to assure that blood products are not wasted in cases of transport failure.

Manned air traffic is very safe. In the United States in 2015, commercial air carriers had 0.1 fatalities per 100 million passengers on board and general aviation (i.e., mostly small personal aircraft) had 1.03 fatal accidents per 100,000 flight hours.[14] Currently no one can answer the question "How safe are drones?" because the analogous data for drones are unavailable. Relevant groups such as the FAA are still in the process of determining the requirements for their safe operation. In the absence of these clear requirements, the most instructive approach to the question of drone safety is to examine the three main components of safety for manned air traffic: the aircraft, the operator or pilot, and the operations. We will examine each of these components briefly for current manned aircraft compared to drones.

Manned aircraft are certified in the design phase, and each individual aircraft is registered and regularly inspected. Second, operators of manned aircraft such as pilots and maintenance technicians are trained and licensed to FAA standards. In addition, their skill, health, and knowledge are regularly verified. Finally, aviation operations account for routes, weather conditions, backup airports, and fuel reserves among other factors. By contrast, there are no clear requirements for any of these components with respect to drones. However, it is likely that as the use of commercial drones increases, requirements by regulatory bodies will mirror those of manned aircraft. For example, the FAA just recently proposed a new licensing procedure adapted to drone pilots.[15] Also while drones do not require the same operational infrastructure that manned aircraft do, the FAA has confined

Fig. 4. Picture of the bubbles in an individual FP24 unit before and after a drone flight. Changes in the number, size, and shape of these bubbles are used as an evidence of possible thawing. [Color figure can be viewed at wileyonlinelibrary.com]

drone operations to 400 feet of altitude within the pilot's visual range to address operational issues in the short term. Nevertheless, drones are not an inherently less safe option. They can have certain safety features that are unique and not present in manned aircraft, such as "sense-and-avoid" technology.[16,17]

The specific products in this initial study of drone transportation of blood products were selected to reflect major medically relevant blood products: RBCs, PLTs, and FP24. However, it did not address the full range of products, physiologic tests, or functional assays that are clinically relevant. Other limitations include a lack of flying the drone in warmer temperatures as well as a lack of physiologic testing of PLTs. We attempted to address the first limitation by monitoring RBC units held in the same cooler used for the drone experiments on a day when ambient temperatures were between 29 and 30°C. Although the RBC units did not exceed the target temperature range of 1 to 6°C while stored in the cooler at rest for up to 60 minutes (Fig. 3), this test did not have the added challenge of flight as it was not performed during flight.

Drones have the potential to revolutionize the transport of blood components, increasing access in geographically challenging regions and decreasing the logistic complexity of conventional blood banking. It is clear that local regulations, cost structures, and logistic challenges will determine the adoption of this technology going forward. In addition, full adoption of drone transport of blood products will require similar studies for other types of products, drones, and environmental conditions. Nevertheless, this article addresses basic questions about the viability of drone transport of blood components and presents a template for similar work in the future.

CONFLICT OF INTEREST

The authors have disclosed no conflicts of interest.

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