Medical Support and Outcomes Of a Manned Stratospheric Balloon and Free-Fall Parachute Flight Test Program

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On October 24, 2014, the StratEx team successfully flew a manned balloon to an altitude of 41,422 m / 135,890 feet, from which the pilot was able to release and free fall safely to Earth. This accomplishment was the culmination of a multi-year program of design and testing of all the subsystems, and included thermal and vacuum chambers, airplane testing and multiple balloon flights. Exposure to such extreme environments carries with it significant risks. This paper focuses on the peculiar medical risks faced in such an endeavor, and the different approaches used to mitigate them, as well as describing the available treatment modalities were a mishap to occur.

Nomenclature

C	=	degrees Celsius
CSLAA	=	Commercial Space Launch Amendments Act, as amended in 2004
F	=	degrees Fahrenheit
G	=	force of gravity, $9.81 m/s^2$
mmHg	=	millimeters of mercury
PSA	=	Pressure Suit Assembly
psi	=	pounds per square inch
psia	=	pounds per square inch absolute
psid	=	pounds per square inch differential
rpm	=	revolutions per minute

I. Introduction

October 24, 2014, saw the culmination of the StratEx project: the successful manned flight of a pilot to 41,422 m / 135,890 feet and subsequent free fall back to Earth. The project developed the first self-contained suit specifically designed for such a flight, providing a stable thermal and pressure environment, a recovery system allowing safe descent even in case of pilot incapacitation, and consumables ensuring the flight had acceptable safety margins.

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In order to achieve this goal, the StratEx program assembled a multidisciplinary team of engineers and experts, specialists in suit design, life support systems, parachute and aerodynamics, telemetry, communications, meteorology, skydiving, and pilots, as well as search and rescue teams and medical support. This paper details the medical risks and challenges particular to the StratEx project, and how these risks were identified, mitigated, and if necessary, addressed.

II. Stratospheric Balloon Flights

Manned balloon flights trace their origins to the birth of aviation. It was in 1783 that Pilatre de Rozier first flew a manned balloon, built by the Montgolfier brothers. Since then balloons have been used for a wide range of scientific and exploration endeavors. The use of a lifting gas (most commonly hydrogen or helium) allowed balloons to reach the stratosphere at altitudes far beyond those that could be reached by contemporary aircraft. With the advent of the Jet and Space Ages in the 1940s and 50s, balloons played a key role in providing an alternate, safer access to this high altitude environment. The Lockheed U-2, still in use today, had already surpassed 20,000m/65,000 feet by 1955, and development of the A-12, precursor to the SR-71, had started in 1957. The US Air Force realized that with the higher and faster airplanes being built, the safety and recovery of the flight crew became a mounting challenge. They commissioned a series of test projects to explore this new environment. Project Manhigh (1957-58) focused on the effect of cosmic rays on aircrew. Project Excelsior (1959-60) was tasked with testing parachute systems for high altitude bailouts, and on August 16, 1960, Col. Joseph Kittinger jumped from 31,333m/102,800 feet. That record stood for almost 52 years, but not without challengers. Since 1960 there have been many attempts at parachuting from altitudes above Joseph Kittinger's record-setting height. Until the record-breaking jump by Felix Baumgartner and the Red Bull Stratos team in 2012, all of these attempts ultimately proved unsuccessful. Most of these failed attempts failed because of a lack of funding, technical problems, or other programmatic challenges. In addition, some of these attempts resulted in severe injuries and even crew fatalities.

Col Kittinger himself had two potentially fatal incidents. During his first high altitude jump, he became entangled in the stabilizer parachute and he entered a flat spin of ~ 120rpm, causing him to lose consciousness. During the ascent phase of his record-setting flight, his right glove leaked and his hand was exposed to vacuum, although without permanent injury.

Col. Piotr Dolgov was part of a Soviet effort to parachute from high altitude. On November 1, 1962, he attempted to exit from an altitude of 28,642m/93,970 feet. His visor hit the gondola and cracked, leading to a suit depressurization and his death.

Nicholas Piantanida led Strato Jump, a private, civilian effort to break Kittinger's record. On May 1, 1966, during his third stratospheric flight and at an altitude of approximately 17,374m/57,000 feet, his suit depressurized. He suffered severe hypoxia, causing a coma from which he never recovered.

In addition to high altitude jumps, there have been accidents with manned stratospheric balloons. Lt Cdr Victor Prather flew to 34,662m/113,720 feet on May 4, 1961 with Cdr. Malcom Ross to test a new pressure suit as part of the StratoLab project. Although both pilots landed safely in the ocean in their capsule, Prather drowned thereafter because his pressure suit filled with water.

III. Medical Risks and Challenges of Stratospheric Flight

As noted above, there are significant risks to high altitude balloon flights that created danger at different phases of flight:

A. Decompression Illness

Decompression illness occurs when a rapid drop in atmospheric pressure results in the release of nitrogen that was previously dissolved in body tissues. Commonly known as 'the bends' in SCUBA diving, decompression illness can also occur when ascending above 5500m/18,000 feet. The risk is mitigated by performing a 100% oxygen "prebreathe." By breathing pure oxygen prior to ascent, a steep (but safe) nitrogen diffusion gradient is established, leading to the off-gassing of dissolved nitrogen from body tissues prior to ascent. By decreasing the burden of dissolved nitrogen, the risks of decompression illness is reduced to tolerable levels. A decompression illness event ("hit") can manifest itself by a variety of symptoms, ranging anywhere from a rash or joint pain to severe neurological paralysis. In more severe cases, decompression illness requires emergent recompression in a hyperbaric chamber to be adequately treated.

B. Hypoxia

Hypoxia occurs when there is insufficient oxygen available in the bloodstream to meet the metabolic demands of the body. A 100% oxygen atmosphere and a static, face-down position minimize the risk of hypoxia. However, as the pilot ascends, the partial pressure of oxygen drops to the point that by the 12,200m/40,000ft mark, there is no longer enough partial pressure of oxygen to drive oxygen to the tissues – the oxygen entering the lungs is displaced by the water vapor and CO_2 developed from normal metabolism. To achieve appropriate oxygenation, a pressurized environment is needed to increase the partial pressure of oxygen back to appropriate physiologic levels. This is the fundamental challenge driving the need for full-pressure suits and one of the principal tasks of the StratEx suit.

C. Ebullism

At around 63,000 feet, the atmospheric pressure drops below 47mmHg (0.91 psi), the vapor pressure of water at 37 C/98.6 F (core body temperature). Exposed to this pressure, water in the body turns into gas (i.e. boils), a process known as ebullism. Above these altitudes, exposure for more than 30-60 seconds can be fatal. Very little is known about the pathophysiology and management of ebullism. Most of what is known comes mostly from dog and primate studies done thirty to sixty years ago[1,2,3] and two case studies of hypobaric chamber accidents in which humans survived[4] what has otherwise been a uniformly fatal exposure.

D. Rapid Decompression

Regardless of altitude, a sudden drop in atmospheric pressure (as may occur with a catastrophic failure of a seal or valve) could also result in a pneumothorax or gas embolism. The sudden pressure drop causes the gas inside the lungs to rapidly expand, and if the airway is closed, can result in damage to the lung tissue. The gas can tear through the lung and cause the lung to collapse (pneumothorax). Alternatively, the gas can even be forced into the vascular system, resulting in a gas embolism. This gas embolism can obstruct blood flow, leading to a drop in cardiac output and blood pressure if the obstruction is large enough, or to focal blockages in peripheral vascular beds causing infarctions, including cerebrovascular accidents (strokes) if the blockages are in the cerebrovascular system.

E. Thermal Exposure

Cold injuries are also a significant risk in high altitude flights. The air temperature drops by approximately 2 C/1,000ft gained in altitude, dropping to below -40 C/ -40 F at the tropopause (9,000-18,000m/30,000-60,000 feet). Once above the tropopause, the ambient temperature rises but the atmosphere is so thin that thermal conduction is only a small fraction of what it is at ground level. As a result, none of the heat generated by the pilot or the suit can escape, decreasing the importance of outside temperatures. In addition, at those altitudes, there is increased radiative heating from the sun, resulting in a potential heat stress. This presents a significant challenge to the suit design.

F. Acceleration-induced injury

Acceleration induced injuries and trauma are a major concern during manned flights. There are risks of trauma and injury associated with skydiving and balloon flights. However, at high altitudes the decrease in air resistance results in a significant risk of spinning. Anthropometric dummies in the 1950s Operation High Dive showed spin rates of over 200 rpm. Kittinger's jumps for Project Excelsior looked at stabilizing parachutes to prevent spin in high altitude bailouts and during the first jump Kittinger suffered a spin of 120rpm. The centrifugal forces caused by such spins force blood to the brain, leading to loss of consciousness. Indeed, Kittinger himself lost consciousness for precisely this reason. The Red Bull Stratos campaign also showed a pilot's tendency to enter "flat spins," which worsened with increasing altitude[5]. A dummy test drop during the StratEx project spun to over 160rpm, with forces >16Gs measured at the head. These forces would incapacitate, and likely cause the death of the pilot by impeding blood flow.

IV. Medical Risk Mitigation and Engineering

The StratEx engineers and doctors worked together to minimize and mitigate the risks in designing the program, as well as engineering the best protocols to deal with an injury if one were to occur. This includes not just design parameters, but also flight protocols, abort criteria, field stabilization, and aeromedical transport systems.

A. Decompression Illness

Due to the extreme altitudes of the StratEx flight profiles, decompression illness posed a significant threat. In order to decrease the risk to tolerable levels, the pilot underwent oxygen prebreathe coupled with pre-flight stretching exercises. Breathing pure oxygen (or any mix that has no nitrogen in it) decreases the dissolved nitrogen burden in the tissues. Exercise, such as stretching, increases blood flow to muscles, improving nitrogen off-gassing prior to flight. From a design perspective, the suit had an operating pressure of 5.4 psid and a 100% oxygen atmosphere. This provided protection in three ways: 1) the 100% oxygen atmosphere ensured the pilot was always offgassing nitrogen, decreasing the nitrogen burden throughout all phases of flight; 2) the unusually high operating pressure of 5.4 psi (current US space suits operate at 4.3 psi, the Russian Orlan at 5.8 psi) decreased the pressure drop the pilot was exposed to, therefore decreasing the risk of decompression illness; and 3) the suit used a differential pressure, rather than an absolute pressure approach. This means that the suit was always 5.4 psi above ambient pressure, as opposed to the suit pressure tracking atmospheric pressure until it dropped to 5.4 psi (roughly the equivalent pressure at 7,620m/25,000 ft). This minimized the pilot's exposure to hypobaric conditions, again decreasing the risk of decompression. Sensors on the suit provided both pilot and mission control real time suit pressure information, allowing early detection of a possible depressurization event. A set of specific neurological tests and physical exams could be conducted as soon as the pilot landed to establish the diagnosis of decompression illness. If decompression illness were suspected, a transport plan allowing rapid evacuation to a hyperbaric facility was in place.

B. Hypoxia

The risk of hypoxia during nominal flight is addressed by the suit atmospheric environment – it provides sufficient pressure support in a 100% oxygen atmosphere to prevent hypoxia. Furthermore, the breathing gas circulation was unidirectional, with a one-way mask preventing recirculation of exhaled CO_2 into the breathing loop. Were the suit to develop a leak, it had enough oxygen flow capacity to feed a leak while having enough reserves to permit a safe return to the ground. (Further details on the suit are available in a separate paper.) The pilot also underwent hypobaric chamber training to identify his particular symptoms of hypoxia so that he would be able to recognize these symptoms in the event of a leak and act to resolve the situation prior to becoming incapacitated. In addition, were the pilot to become incapacitated, mission control would still be able to remotely trigger an emergency descent to return him to ground.

C. Ebullism

The risk of ebullism is prevented by the suit design; the suit maintains a pressure differential of 5.4 psi throughout flight and can feed a leak if one develops. In the event of a leak and depressurization, an immediate cut away and return to below 19,200m/63,000 ft would follow, minimizing exposure to extremely low pressures. If an exposure were to occur, the medical teams used a protocol developed for such a contingency[6], which included possible intubation in the field and ventilation using a high frequency oscillator to oxygenate the lungs[7] while simultaneously minimizing trauma associated with inflating and deflating injured lung tissue. The risk of ebullism was present not only on the latter two manned flights, but also during altitude chamber testing, in which the pilot was in the suit at the equivalent of over 27,000m/90,000 feet.

D. Rapid Decompression

The management of a pneumothorax would require an emergent needle thoracotomy, in which a large bore needle is inserted into the cavity between the lung and chest wall. This allows the air to escape, thus preventing a tension pneumothorax, in which the buildup of pressure in the chest cavity causes vascular collapse. A gas embolism can have devastating consequences and would require immediate transfer to a hyperbaric facility for treatment[8]; compressing the offending gas bubble can limit or even reverse the injury. As an added diagnostic modality, the medical team was equipped with a portable ultrasound unit, which would allow confirmation of pneumothorax in the field.

E. Thermal Exposure

A series of thermal tests were carried out to determine the necessary insulation needed. The tests involved hanging the suit in the flight configuration in a thermal chamber cooled with liquid nitrogen to temperatures close to the tropopause. A liquid cooling garment that could circulate cold water on the ground kept the pilot cool during the ground activities. The thermal system was then switched to an on-board heating unit to provide heat during the flight. Although initially a neoprene wetsuit was used to add thermal insulation, testing showed it was not necessary. Hands and fingers were addressed separately. In order to keep the pilot's fingers warm, he was equipped with heating gloves and additional insulation layers. No thermal injuries were sustained during the flight.

F. Acceleration-induced injury

To prevent injury from a flat spin, a drogue system was developed that used a small drogue parachute attached at shoulder level. Further details on this system are available in other publications. However, were a flat spin to develop, the team developed a modified medical protocol based on previous work[9]. If a flat spin were to develop, the management would parallel that of a hemorrhagic stroke, as animal models showed that severe brain bleeds and cardiac contusions often resulted from flat spins. The first step would be to check the pilot for subconjuctival hemorrhages as they are usually the first sign and occur even with exposures that do not cause intracranial bleeding or cardiovascular compromise.

V. Medical Operations

In order to implement the full gamut of medical interventions, the medical operations team required a multidisciplinary team approach, in which the medical, engineering, suit, flight and recovery teams worked as one.

The first step in conducting operations was to conduct a detailed review of the pilot's medical history to develop a customized risk analysis and disclosure. This analysis and disclosure collected and addressed all aspects of the pilot's medical history that could be a factor in both nominal and off-nominal scenarios. This process was memorialized in an informed consent form, which discussed both general risks as well as risks particular to the pilot. Commercial human spaceflight in the United States is governed by the Commercial Space Launch Amendments Act, as amended in 2004 (CSLAA)[10]. The CSLAA requires human spaceflight operators to obtain "informed consent" for spaceflight participants before taking them into "space" (this mainly speaks to suborbital flights). This informed consent process entails informing the spaceflight participants of the risks resulting from the contemplated flight profile. Although the statute lists topics to be addressed, it does not provide a "form" nor does the list of topics include medical risks. The StratEx project provided an opportunity to test drive the informed consent process. By developing a customized list of risks and challenges, the StratEx medical team paralleled what is required of commercial human spaceflight operators while developing a first-of-its kind tailored risks assessment and disclosure. The details of this process and the resulting informed consent form will be discussed in a future paper.

Once the medical requirements were met, the most important aspect of a successful mission began: ensuring the whole team worked in unison to develop good "situational awareness." Situational awareness consists of teams staying in contact and keeping each other informed of developments in real time, while staying out of each other's way. For this to happen, each disciplinary team had to be familiar with and understand all aspects of the mission. As a result, the medical team members were not only present at testing and training events but were also embedded in non-medical teams and their operations. This resulted in a close working relationship between all personnel, which ensured that every team member had at least a basic understanding of when and how they could be of assistance. This also minimized interruptions during critical phases–a key component of situational awareness, i.e. staying out of each other's way. This went even further for the Pressure Suit Assembly (PSA) team, which was responsible for the suit and life support systems. The PSA team included and medical team and designers of the life support system, the suit, and the parachute recovery system. Every member of the PSA team was cross trained in field emergency extraction procedures. This guaranteed that no matter who arrived at the recovery site first, everyone would know the immediate necessary steps to safe the system and extract the pilot.

One major logistical challenge created by the above approach was that the medical operations team was called on an as-needed basis for various tests and flights. This meant that the medical team had to develop a deep roster of medical experts, licensed in New Mexico; all trained in recovery and extraction procedures. In order to ensure competency and currency in training, the Project Manager scheduled multiple training opportunities so all team members could rotate through all the different positions. This was challenging. An example of the challenge created was highlighted by plans for an "all jumper" recovery team. Although ultimately replaced by the use of multiple helicopters, one initial proposal was to have the extraction team, including the medical team, parachute to the landing site following the pilot in (hence the term "all jumper"). Although a valid approach, this would have required significantly more specialized training for the entire recovery team, not all of which had any experience skydiving, and an increase in the risk of injury in the field. If a similar level of medical support is needed in the future, we recommend, in place of training a deep roster for the field medical team, to instead establish a core field medical team along with a deeper roster of clinical practitioners that can substitute in for the daily clinical responsibilities of the core field team, freeing the core team to carry out their operational role when needed, while ensuring consistent medical staffing during missions.

Medical team-specific training–for example the use of high frequency percussive ventilation—was accomplished via particular medical in service training on the equipment. However, the full StratEx team (including the pilot) was given an opportunity to familiarize itself with the techniques and equipment. This again helped raise the team's situational awareness as to the potentially necessary protocols and requirements.

The medical equipment required on scene was developed specifically for the mission. The medical team created a set of identical medical backpacks that could be easily transported on the helicopters and in the field, but would still provide full airway support and trauma stabilization as well as cover minor injuries and lacerations. For medical transport, an aero medical transport company provided a helicopter that flew in formation with the recovery helicopters.

This equipment, along with an on-site clinic at the launch site, served to deliver emergent healthcare services to the full StratEx support team. The clinic was structured to provide initial medical care and stabilization, as well as manage minor illnesses or injuries. This worked in complement with the mission goals, as it allowed minor issues to be resolved on site, minimizing support crew downtime, as well as triaged more serious injuries out to local medical services, permitting the StratEx leadership to focus on mission operations.

The clinic was geared to support a slew of risks associated with any construction/engineering program, such as trauma, pinching hazards, fractures, burns, cold injuries, eye injuries, pressurized tools and heavy machinery injuries, vehicle accidents, dehydration and falls. It also took into account additional risks associated with an operation like StratEx: hypoxia from liquid nitrogen in enclosed spaces, altitude chamber exposures, skydiving trauma, night operations, oxygen fires to name a few. The location of the launch site in Roswell, New Mexico created threats of its own such as extreme cold at night and heat during the day, as well as rattlesnakes, black widow spiders, scorpions and other wildlife.

VI. Conclusion

As a result of effective teamwork, cross training, and a continuous focus on safety and situational awareness, the StratEx team was able to fly a manned balloon to 41,422m/135,890 feet and bring the pilot safely without injury. This achievement sets an example of how operations can be carried out in a safe and effective fashion. Embedding the medical team into the rest of operations resulted in effective and cohesive contingency planning. Future spaceflight operations should strive towards developing cross-trained, interdisciplinary teams, particularly when the total number of personnel is limited, as it maximizes productivity and situational awareness, ultimately benefiting crew safety and mission success.

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References

1 Koestler AG, Reynolds HH . Rapid decompression of chimpanzees to near vacuum . J Appl Physiol 1968 ; 25 : 153 – 8

2 Cooke JP, Fife WP, Bancroft RW . Comparative cardiovascular responses of baboons and dogs to near-vacuum pressures . Aerosp Med 1969 ; 40 : 51 – 4

3 Dunn JE, Bancroft RW, Haymaker W, Foft DW . Experimental animal decompressions to less than 2 mmHg absolute (pathological effects) . Aerosp Med 1965 ; 36 : 725 – 32

4 Kolesari GL, Kindwall EP . Survival following accidental decom- pression to an altitude greater than 74,000 feet (22,555 m) . Aviat Space Environ Med 1982 ; 53 : 1211 – 4

5 Red Bull Stratos Scientific Data Review, http://www.redbullstratos.com/science/data-report/, Accessed 15 January 2015

6 Murray, D. H., Pilmanis, A. a., Blue, R. S., Pattarini, J. M., Law, J., Bayne, C. G., … Clark, J. B. (2013). Pathophysiology, Prevention, and Treatment of Ebullism. Aviation, Space, and Environmental Medicine, 84(2), 89–96. doi:10.3357/ASEM.3468.2013

7 Hall JJ, Hunt JL, Arnaldo BD, Purdue GF . Use of high frequency percussive ventilation in inhalation injuries . J Burn Care Res 2007 ; 28 : 396 – 400

8 Mirski MA, Lele AV, Fitzsimmons L, Thomas JK, Toung MD . Diagnosis and treatment of vascular air embolism . Anesthe- siology 2007 ; 106 : 164 – 77

9 Pattarini, J. M., Blue, R. S., Aikins, L. T., Law, J., Walshe, A. D., Garbino, A., … Clark, J. B. (2013). Flat Spin and Negative Gz in High-Altitude Free Fall: Pathophysiology, Prevention, and Treatment. Aviation, Space, and Environmental Medicine, 84(9), 961–970. doi:10.3357/ASEM.3648.2013

10 CSLAA, https://www.faa.gov/about/office_org/headquarters_offices/ast/media/PL108-492.pdf, Accessed 15 January 2015