Suborbital Commercial Spaceflight Crewmember Medical Issues

Aerospace Medical Association Commercial Spaceflight Working Group*

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As directed by the Council of the Aerospace Medical Association, the Commercial Spaceflight Working Group has developed the following position paper concerning medical issues for commercial suborbital spaceflight crewmembers. This position paper has been approved by the AsMA Council to become a policy of the AsMA.

Keywords: acceleration, medical certification, neurovestibular dysfunction, push-pull effect, radiation, weightlessness.

THE OPERATIONAL experience for manned suborbital spaceflight (altitude greater than 100 km) is very limited, consisting of two Mercury-Redstone rocket flights in 1961, two X-15 flights in 1963, an inadvertent Soyuz launch abort in 1975, and three SpaceShipOne flights in 2004. All indications are that the sequence of acceleration-weightlessness-deceleration were well tolerated with minimal neurovestibular dysfunction. The problems that were encountered should be taken in the context of highly experimental, high performance vehicles flown in an environment that no one had ever experienced before. However, there are some indications that distraction and spatial disorientation can occur. Only further suborbital spaceflight experience will clarify whether pilot performance is affected or will be an issue. It is expected that experience in pilot performance during suborbital spaceflight will be obtained during the flight testing that will occur before spaceflight participants are carried on any of the future commercial spaceflight vehicles.

By definition, a suborbital spaceflight has to reach an altitude higher than 100 km (62 mi, 328,000 ft) above sea level. This altitude, known as the Kármán line, was chosen by the Fédération Aéronautique Internationale. The U.S. Air Force and the FAA consider an altitude of 50 miles (80.47 km, 264,000 ft) to be the altitude to qualify as spaceflight. The experience in human suborbital flight below the international standard of spaceflight (100 km altitude) is much broader (**Table I**) and should be taken into account when discussing predictions of pilot performance.

Several documents have been produced that discuss the medical standards for commercial spaceflight with regard to orbital spaceflight participants (3,6), suborbital spaceflight participants (2,4), and suborbital crewmembers (5). The content of this position paper relies heavily on information from those previous papers. In this paper we describe the flight environment during a suborbital commercial spaceflight, identify the possible medical risks, and discuss the mitigation strategies that could be used to lower those medical risks. In order to provide as much specific detail as possible, the projected flight profile of a single spacecraft and suborbital flight (SpaceShipTwo by Virgin Galactic) will be used as a baseline design reference mission. Note, however, that other suborbital flight vehicles under development will likely vary in their design and flight characteristics and, consequently, the relative severity/risk of the medical issues discussed. In addition, we have limited the discussion to critical flight crewmember (as opposed to a spaceflight participant or a non-flight crewmember) medical issues. Finally, we provide as much referenced data that currently exists to help explain any rationale. The goal is to not focus on recommendations for standards or certification, but instead to develop evidence-based, referenced evaluations and guidelines of the medical risks and ways to mitigate those risks to improve safety. Additionally, we seek to better articulate what gaps exist in the current knowledge of commercial human spaceflight issues.

Medical certification of commercial suborbital spaceflight pilots is still evolving and will continue to be better defined in the future by the FAA. A previous position paper from the Aerospace Medical Association recommended an FAA first-class airman medical certificate (5). Currently, the FAA requires that "crewmembers who have

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TABLE I. SUBORBITAL ROCKET FLIGHTS* BY VEHICLE.

Vehicle	Suborbital Altitude Trajectory	Altitude > 60,000 ft	Altitude > 50 miles	Altitude > 100 km
NF-104A	302	302	0	0
X-15 (XLR-99)	146	143	13	2
Trident II	100	98	0	0
Trident IISE	96	94	0	0
F-84G ZELMAL	28	0	0	0
X-15 (XLR-11)	28	8	0	0
SM-30 ZELL	26	0	0	0
Trident I	25	0	0	0
X-24B	24	17	0	0
X-15A2	22	21	0	0
M2-F3	22	22	0	0
HL-10	20	14	0	0
X-24A	18	9	0	0
F-100D ZEL	18	0	0	0
X-2	13	8	0	0
F-104G ZLL	13	0	0	0
SpaceShipOne	6	6	3	3
Mercury	2	2	2	2
Ba 349 Natter	1	0	0	0
Soyuz 18a	1	1	1	1
Total	911	745	19	8

* The definition of suborbital rocket flight is the criterion used by the FAA to differentiate civil aircraft subject to aircraft certification from a suborbital rocket launch subject to licensing under the Commercial Space Launch Act (49 U.S.C. Subtitle IX, chapter 701). 'Suborbital rocket' means a vehicle, rocket-propelled in whole or in part, intended for flight on a suborbital trajectory, and the thrust of which is greater than its lift for the majority of the rocket-powered portion of its ascent. The international definition (Fédération Aéronautique Internationale) of spaceflight is an altitude of 100 km, while the FAA and U.S. Air Force definition of spaceflight is an altitude of 50 mi.

a safety-critical role … possess and carry a second-class airman medical certificate." Each member of a flight crew must demonstrate the ability to "withstand the stresses of spaceflight, which may include high acceleration or deceleration, microgravity, and vibration in sufficient condition to safely carry out his or her duties so that the vehicle will not harm the public" (24). Policy and decision processes to be used for waivers and what functional tests (centrifuge, parabolic flight, altitude chamber) will be required to demonstrate that an individual can perform in the suborbital environment is still undefined by the FAA. As one of the largest potential customers, NASA may request to be consulted regarding these requirements.

Projected Flight Profile of the Virgin Galactic "SpaceShipTwo"

According to publicly available information, SpaceShipTwo will have two pilots and up to six spaceflight participants. The cabin atmosphere will be pressurized to 8000 ft (2440 m) altitude or lower with re-circulated atmospheric air (21% O_2). The projected flight profile begins with a horizontal takeoff underneath the carrier aircraft "WhiteKnightTwo" with a flight to approximately 50,000 ft (15,240 m) where SpaceShipTwo will be launched. The boost phase will be 70 s and will have a maximum peak of 3.8 G (longest duration in $+G_x$ with a brief spike in $+G_z$). Speeds will be Mach 1 at 8 s and Mach 3 at 30 s. Maximum speed will be 2600 mph (4180 km $\cdot$ h^{-1}). The 0 G coast phase will last approximately 4 min and will reach an apogee of 361,000 ft (110 km). During the coast phase, spaceflight participants (but not the flight crewmembers) will be out of the seats and able to freely move around the 12 ft × 7.5 ft (3.7 m × 2.3 m) cabin. The deceleration phase will have a maximum peak of 6 G, but the seats will recline to convert most of the forces to $+G_x$ for the spaceflight participants. However, the flight crewmembers will experience most of the deceleration forces in the $+G_z$ axis. The wings rotate to a feather position to increase stability and drag for entry. At 80,000 ft (24,380 m), the glide phase will begin with a return to an unpowered horizontal runway landing that will occur after a glide of 25 min. Total flight duration will be 150 min. Radiation levels at high altitude would be 15 μSv $\cdot$ h^{-1} for less than 30 min. The noise environment and vibration forces to be experienced are still uncharacterized. In reality, virtually every data point (altitudes, duration of various portions of the flight, speed, peak G forces, etc.) will be in ranges of values rather than in absolutes as stated above. The information is based on estimates from the SpaceShipOne flights with extrapolation to SpaceShipTwo. Until test flights of SpaceShipTwo are much further along, the exact parameters will not be known. Other flight profiles that are used by other commercial spaceflight operators may have medical issues different than described in this paper. For example, XCOR with its Lynx spaceplane has one pilot and one spaceflight participant, both wearing pressure suits. They will make as many as four flights daily to 100 km. Boost is projected to be more controllable and the occupants will experience $+4\ G_x$ and 4 min of 0 G.

Medical Risks

Spaceflight exposes individuals to an environment that is far more hazardous than that which is experienced by personnel who fly on current airline transports. Pre-existing medical conditions can be aggravated or exacerbated by exposure to stressors such as acceleration and microgravity. Most of the medical issues for suborbital spaceflight are relatively straight forward as compared with those for orbital spaceflight. The short duration of suborbital flights eliminates any concern for most of the medical problems associated with orbital flight such as deconditioning, fluid shifts, and acclimation to weightlessness or re-acclimation upon return to Earth. There is also a large amount of experience and a large medical database concerning orbital spaceflight. It would be easy to conclude that the medical risks of suborbital spaceflight are well known and would be similar to orbital spaceflight, but less significant or less intense. However, the orbital spaceflight database is based upon medical standards for astronaut selection and certification that are very restrictive. Commercial suborbital flight crewmembers, under current regulations, will only be required to have an FAA second-class medical certification. Also, a critical aspect of suborbital spaceflight is the rapid change from the high-G acceleration launch forces to 0-G weightlessness followed quickly by the high-G deceleration of entry. These transitions could lead to both cardiovascular and neurovestibular effects that are currently unexplored. Even using a centrifuge and parabolic flight, there is no way to completely simulate these forces and this total environment preflight. Although the acceleration and deceleration forces can be simulated with centrifuge runs, the longest period of weightlessness that can be simulated with parabolic flight is only 25 s. This amount of time is not sufficient for complete neurovestibular and cardiovascular reflex changes to occur, which upon entry into a deceleration environment may impact compensatory processes. More importantly, the total environment of acceleration-weightlessness-deceleration has never been simulated (except for the brief +1.8 G to 0 G to +1.8 G experienced in parabolic flights) and is quite different from the orbital spaceflight experience. It is important to emphasize again that the operational experience of manned suborbital spaceflight is very limited. The pilot experience on suborbital flights will be very time intense and probably repetitive with some pilots flying daily. The effects of repetitive exposures to the physiological stresses of suborbital flight have never been experienced.

Acceleration

Significant medical concerns exist with the application of sustained gravitoinertial forces (Gs) to the human body as a consequence of space vehicle launch acceleration and entry deceleration. Neurovestibular, cardiovascular, and musculoskeletal problems are the primary health concerns associated with in-flight acceleration exposure, with head-to-foot ("eyeballs down" or $+G_z$) acceleration causing the most harm. However, exposure to either $+G_x$ or $+G_z$ can have an effect on pulmonary function proportional to its applied force magnitude by altering ventilation/perfusion ratios, resulting in hypoxemia, airway closure, and atelectasis. To avoid the potential for compromising cardiovascular and neurological function, acceleration forces are preferably applied in the $+G_x$ direction (eyeballs in). An individual is more tolerant of $+G_x$ acceleration, and with the heart and brain located at approximately the same level within the acceleration field there is less risk for acceleration-induced loss of consciousness (G-LOC) or impaired cognitive performance with almost loss of consciousness (A-LOC). Acceleration stress is also known to be dysrhythmogenic (can cause changes in cardiac rate, rhythm, and conduction). Higher G forces or longer exposures to acceleration could potentially increase the frequency of dysrhythmias. As long as the head, neck, and spine are stabilized before the acceleration exposure and remain so until the exposure is completed, the potential for musculoskeletal injury is markedly reduced (9).

Historically, spaceflight accelerations have been designed to be in the $+G_x$ axis, until the Shuttle entry experience, which is $+G_z$. The early Mercury, Gemini, and Apollo flights had launch accelerations of +4.5 to +6.5 G_x for 6 min and anywhere from +6 to +11 G_x during entry. The Shuttle has a maximum of +3.0 G_x during the 8.5-min launch and +1.2 G_z (briefly +2.0 G_z during turns) for 17 min during entry (12). On entry, the astronauts are in a deconditioned state due to the long-duration microgravity exposure and yet are required to maintain a high performance level in order to fly the Shuttle in for landing. For countermeasures they use fluid loading and anti-G suit protection which is mandatory for the commander and pilot.

The human response to sustained acceleration in the $+G_x$ orientation has been well known for decades. These acceleration forces are very well tolerated as the hydrostatic fluid column is very short and so cerebral perfusion is well maintained. Sustained $+G_x$ acceleration does increase the work of breathing (which is doubled at +4 G_x) and leads to some ventilation/perfusion mismatching, potentially leading to mild hypoxemia. For this reason, space vehicles are designed to keep as much of the acceleration forces in the $+G_x$ axis as possible. Early in the U.S. space program (Mercury and Gemini), astronauts received 45 h of $+G_x$ centrifuge training, with some runs going up to +18 G_x. This was later deleted as no medical or performance issues were discovered with the normal in-flight acceleration profiles experienced (+6.5 G_x for 6 min).

An individual's tolerance to $+G_z$ acceleration is dependent on the individual's anatomic (height and weight) and physiologic characteristics and the nature of the acceleration profile. Conditioning, hydration, previous and recent exposure to $+G_z$ forces, and recent centrifuge training all have the ability to influence the physiological response. The maximum $+G_z$ level, exposure duration, and the rate of onset of the $+G_z$ are all important determinants of the risk of neurological compromise, cardiac rhythm disturbances, and musculoskeletal (especially neck) injury. Rapid-onset rate (ROR) of acceleration is defined as increases greater than $0.33\ G \cdot s^{-1}$. ROR tolerance limits are approximately +1 G_z lower than gradual-onset rate (GOR) tolerances. ROR tolerances are lower because they exceed the ability of the cardiovascular system to fully respond to preserve adequate central nervous system blood flow. The cerebral hypoxia reserve time is 4–6 s (32), while the baroreceptor reflex (an increase in sympathetic tone resulting in increased heart rate, cardiac stroke volume, and total peripheral resistance) takes 6–9 s to initiate with restoration of blood pressure requiring up to 10–15 s. ROR can also result in G-LOC without any of the usual visual warning symptoms (such as tunnel vision, gray-out, or black-out). Anti-G suits increase the tolerance to $+G_z$ by approximately +1 to +1.5 G_z (9) by increasing the total peripheral resistance, shortening vascular column height, and increasing the venous return to the heart. Anti-G straining maneuvers can increase the tolerance to $+G_z$ by as much as 3 $+G_z$ by increasing intrathoracic arterial pressure, but is fatiguing and is generally used only for a relatively short period of time. Centrifuge data has allowed for the development of a model of $+G_z$ tolerance limits which incorporate $+G_z$ magnitude, duration, and rate of onset which is called the Stoll curve after the investigator who first described it in 1956 (35). Conservative relaxed, unprotected tolerance (no visual or performance dysfunction) of completely healthy humans to $+G_z$ acceleration is considered to be approximately $+3\ G_z$ (normal range 3.1 to 4.0) for rapid-onset profiles and increases to approximately $+4.5\ G_z$ (normal range 3.7 to 5.6) with gradual-onset profiles.

A pilot experiencing $-G_z$ (such as when flying an outside loop or to a lesser extent when in microgravity) will be in a state of enhanced parasympathetic tone after several seconds of exposure, which results in bradycardia, decreased cardiac contractility, and decreased total peripheral resistance. Transition to $+G_z$ can then cause a profound drop in cerebral blood pressure and may take 8–10 s to compensate. $+G_z$ tolerance is greatly decreased, resulting in a shift of the Stoll G_z tolerance curve. The Stoll curve is based on prior exposure to $+1\ G_z$ and so is an inadequate model that overestimates $+G_z$ tolerance when there is a prior exposure to a relative $-G_z$. The loss of $+G_z$ tolerance has been estimated to be about $+1.27\ G_z$, but some individuals have shown a loss at as high as $+3.9\ G_z$. This "push-pull effect" occurs often in combat engagements and has been implicated in several combat training fatalities. It has also been identified as a possible cause of 30% of G-LOC events. The key factor is in performing a series of $-G_z$ aerobatic maneuvers and thus the effect can occur in any such aerobatic flight profile. A knowledge gap exists in the complete understanding of this issue and no known countermeasures have as yet been developed (10,11). It is unclear whether a "push-pull effect" will occur in transition from microgravity to entry deceleration, but it has been described in parabolic flight (10) and concerns have been expressed that it could occur in suborbital flight (9). The push-pull effect is prolonged with increasing the duration of the prior $-G_z$ exposure (20). Normally, the $-G_z$ exposure is only several seconds in combat or aerobatic flight. In typical parabolic flight profiles, the exposure is 20–30 s. It is simply not known whether 4 min of microgravity would elicit the same response or further deterioration in the $+G_z$ tolerance. It is predicted that any effect would be transitory as the recovery period from the push-pull effect is typically less than 15 s.

The conservative acceleration envelope recommended by the IAA for commercial aerospace vehicles (3) should not exceed $+3\ G_z$ ($-2\ G_z$), $\pm 6\ G_x$ and $\pm 1\ G_y$. These levels, if experienced as gradual onset (increases of less than $+0.25\ G \cdot s^{-1}$), should be well tolerated by unprotected, relaxed healthy individuals. During the rocket engine boost of SpaceShipTwo, acceleration may peak as high as $+3.8\ G_x$ and there will be a brief spike up to $+3.8\ G_z$ as the space vehicle rotates to a nose high attitude. On reentry, 6 g will be imposed predominantly in the $+G_z$ axis for flight crewmembers. Because of tilt-back seating and the flight profile, most of the acceleration during entry will be in the G_x axis for spaceflight participants. Duration of these G forces is expected to be no longer than 70 s on launch and 30 s on reentry. The onset rate of the accelerative forces has not yet been defined, but is not expected to be a rapid onset rate (ROR is defined as greater than $0.33\ G \cdot s^{-1}$). There are currently no plans to utilize anti-G suits similar to the Shuttle pilots during reentry on these flights, but they could be considered for the pilots as the cost is minimal and a beneficial effect is possible. Recent centrifuge or other G-training modalities would also mitigate any difficulties in the adaptation to acceleration forces. Avoidance of any appreciable dehydration among the flight crewmembers is of key importance to avoid decrements in G-tolerance, especially given the fact that many of the proposed and planned launch sites are in hot, desert environments.

Microgravity Effects

The physiological changes resulting from exposure to microgravity depend upon the total duration of the exposure and can vary in magnitude from individual to individual. While the microgravity exposure will last only a short duration of 4 min, it is possible that inexperienced, non-adapted, or overly sensitive individuals might experience symptoms (neurovestibular or cardiovascular) associated with even short exposures to the space environment. Although no proof exists, parabolic flight experience might be a way to mitigate future suborbital flight symptoms by providing weightless experience and possibly serve to identify especially susceptible individuals. This rapid launch acceleration–weightlessness–entry deceleration profile cannot be tested or simulated in continuity. The acceleration profile segments can be simulated on the centrifuge, but the closest analogue to the 4-min weightlessness period is 25 s of parabolic flight. More importantly, the total flight profile with the rapid changes from one environment to the next cannot be reproduced. There is also only minimal operational experience with this flight profile in the Mercury-Redstone, the X-15 flights, and the recent SpaceShipOne flights.

Cardiovascular Effects

An increase in central venous pressure (CVP) is initially seen in Shuttle astronauts while they are lying on their backs in preparation for launch. This is followed by a decrease in CVP to below normal levels on first reaching microgravity (13). This is surprising as the physiological prediction would be for an increase in CVP due to the shifting of body fluids cephalad in weightlessness (14). Several explanations exist: that this is compensatory for being slightly head down during the pre-launch period; possibly due to a relative state of dehydration during the pre-launch period; a reduction in intrathoracic pressure; loss of gravitational compression of the heart; or due to a change in microgravity in the pulmonary capacitance and peripheral resistance (19). In orbital flight, cephalad fluid shifting due to the loss of the hydrostatic gradient occurs immediately and a sensation of head fullness and facial edema occurs within minutes (38). However, postflight orthostatic cardiovascular changes and urinary diuresis were not present on the early short-duration orbital Mercury flights

(22) and were only first noticed on the 9-h flight of MA-8 (Schirra) and the 34-h flight of MA-9 (Cooper). A decrease in plasma volume due to diuresis does occur, but over the next several days in orbital flight due to this cephalad fluid shift. In combination with cardiac deconditioning and blunting of the baroreflexor response, this results in increased risk of orthostatic intolerance after landing from an orbital flight.

All of these last physiological changes require time to develop in microgravity and would not be expected in suborbital flight. In addition, the SpaceShipTwo crew will not have a prolonged period of pre-launch horizontal position and should have even less shifting of fluids as compared to the Shuttle experience. The use of an anti-G suit is mandatory for the Shuttle commander and pilot on entry and is an effective countermeasure against in-flight orthostatic hypotension. Although postflight orthostatic hypotension should be minimal on suborbital flights, the risk of orthostatic hypotension during entry may be quite real. The enhanced parasympathetic tone that occurs after several seconds of exposure to $-G_z$ leads to bradycardia, diminished cardiac contractility, and peripheral vasodilatation. This response increases the risk of a fall in head-level blood pressure on re-exposure to $+G_z$. A full compensatory response can take 8–10 s with the recovery period dependent on both duration and magnitude of relative $-G_z$. Given that the period of hypoxia latency for brain cells is 4–6 s (32), the risk for $+G_z$ related symptoms is enhanced at lower than expected $+G_z$ levels. There is no data on which to assess the risk of this push-pull effect after 4–6 min of microgravity, but it may be prudent for pilots to use anti-G suits as a countermeasure during the $+6\ G_z$ entry profile.

Neurovestibular Effects

Although the neurovestibular effects of prolonged microgravity are well known, these prolonged adaptive changes are not considered a significant factor since the exposure to microgravity will be less than 5 min duration for each suborbital flight. Neurovestibular dysfunction after orbital flight includes an altered ability to sense tilt and roll, defects in postural stability, impaired gaze control, and changes in sensory integration (16). These changes are dependent on the duration of weightlessness. However, there have been neurovestibular alterations observed in even short exposures to altered gravity environments in susceptible individuals. With rapidly changing gravitoinertial forces, compensatory eye movements may be inappropriate, leading to oculomotor dysfunction. Maintaining a "dual-adaptive" state by virtual reality based (see Space Motion Sickness below) or centrifuged based training has been suggested to mitigate these effects or to attempt to identify susceptible individuals (18). However, there are only anecdotal reports that it is beneficial.

That pilot performance after brief exposure to 0 G and re-adaptation back to a hyper-G environment (without the usual long period of adaptation, as in orbital flights) could be degraded is of some concern. Somatogravic illusions with spatial disorientation were reported on several of the high altitude X-15 flights. The total flight profile of rapid launch acceleration–weightlessness–entry deceleration profile with the rapid changes from one environment to the next cannot be tested in continuity. There is also only minimal operational experience with this flight profile in the Mercury-Redstone and the X-15 flights followed by the SpaceShipOne more recent flights. An additional concern is that many pilots will be flying these suborbital profiles repeatedly and maybe on a daily basis. There is no experience to indicate whether repeated and frequent suborbital profile exposures will be adaptive or cummulatively maladaptative to neurovestibular function. Obviously, more experience in suborbital flight is needed and will better define whether this is even an issue. In the initial phases of flying suborbital missions, postflight medical debriefs and data collection would be helpful until more experience has been obtained and there is more confidence that there will not be any performance medical issues. Frequent flights by the same pilot would also be another reason for close medical monitoring initially as there is absolutely no experience with frequent daily suborbital flights by the same pilot.

X-15 Neurovestibular Experience

Three X-15s were built, flying 199 test flights, with the first one flown on June 8, 1959, and the last one on October 24, 1968. Twelve test pilots flew the X-15; among them were future NASA astronauts Neil Armstrong and Joe Engle. During the X-15 program, 13 of the flights (by 8 pilots) met the U.S. Air Force spaceflight criteria by exceeding an altitude of 50 mi (80.47 km, 264,000 ft), thus qualifying the pilots for U.S. astronaut status. Of all the X-15 missions, only two flights (both piloted by Joe Walker) qualified as spaceflights per the international (Fédération Aéronautique Internationale) definition of a spaceflight by exceeding an altitude of 100 km (62.137 mi, 328,084 ft). Flight 90 on July 19, 1963, reached 105.9 km (65.8 mi, 347,440 ft) and Flight 91 on August 22, 1963, reached 107.8 km (67.0 mi, 354,200 ft). Physiological parameters were not measured on the X-15 flights, but pre- and postflight medical examinations were never reported as abnormal. The most reliable performance data possible, which is the requirement to fly the demanding X-15 aircraft, showed that a high degree of pilot performance was obtained. Importantly, pilot performance was not impaired by launch acceleration–weightlessness–entry deacceleration. The disturbing exception to this was the crash of X-15-3 on November 15, 1967, on X-15 Flight 191 which killed the pilot, Maj. Michael J. Adams. This was due to a combination of system anomalies and pilot errors, including display misinterpretation, distraction, vertigo, and loss of situational awareness. Pilot overload due to his attention being focused on troubleshooting the science payload was also a factor. The various G forces imposed on the pilot during the boost phase of the flight were very conducive to severe vertigo. Every X-15 pilot experienced this disorientation and sensed that he had over-rotated his climb angle. Mike Adams had reported severe vertigo during several of his X-15 flights during the boost phase. The accident investigation conducted after Mike Adams' fatal X-15 flight concluded that the pilot suffered severe vertigo during climb-out which caused spatial disorientation. Small heading deviations caused by a degraded flight control system were made worse by incorrect pilot inputs at an altitude of over 20 km (65,000 ft). The pilot misinterpreted a roll indication for a slide slip indication and made control inputs in the wrong direction. Most puzzling was Adams' complete lack of awareness of major heading deviations in spite of accurately functioning cockpit instrumentation. An extreme heading deviation of 90° developed which led to a hypersonic spin. Although recovery from the spin was made, a control system oscillation developed which increased in magnitude and eventually caused aerodynamic breakup of the aircraft. As a result of the accident investigation, it was recommended that all future X-15 pilots be medically screened for labyrinth (vertigo) sensitivity. It was also noted that a fixed-base simulator was adequate to prepare for flight as long as the pilot had been exposed to centrifuge simulation training (37).

Space Motion Sickness

Microgravity exposure results in space motion sickness in about 70% of astronauts flying on orbital spaceflights for the first time. It is thought to be due to a sensory conflict between visual, vestibular, and proprioceptive stimuli. Susceptibility cannot be predicted by susceptibility to ground-based motion sickness or preflight testing. Symptoms typically occur within the first 24 h. However, symptoms have been reported immediately after main engine cut off with dizziness, pallor, sweating, and severe nausea and vomiting. Vomiting can crescendo quite suddenly without any prodromal symptoms. In a multi-passenger vehicle, one passenger becoming nauseated can potentially trigger nausea in the other vehicle occupants.

Prophylactic use of anti-motion sickness medications might be considered for spaceflight participants, but would adversely impair pilot performance. Space Shuttle flight crewmembers (commander, pilot, flight engineer) are not allowed to take prophylactic medications for space motion sickness (31). The risk of nausea in reduced gravity is significantly abated if provocative motions, especially of the head, are avoided. Head movements generate conflicts between the semicircular canals and the otoliths. Pitch head movements are the most provocative (15). Intense concentration on task performance is attenuating. Parabolic flight adaptation and experience in high performance jet aircraft do not appear to be protective. In the Russian space program, vestibular training using Coriolis accelerations (rotating chair) is still used. However, it does not duplicate the sensory conflicts found in space motion sickness and there is no evidence that it has decreased the incidence. Space motion sickness might be reduced by preflight adaptation training in an attempt to make pilots "dual-adapted." One study has found a 33% decrease in the incidence of space motion sickness with this technique (23). Some examples of the training aids used in this effort to duplicate sensory conflict such as occurs in microgravity are the device for orientation and motion environment (DOME), which is a spherical virtual reality simulator, and the tilt-translation device (TTD).

During suborbital flights, the risk will be reduced if flight crewmembers remain tightly strapped into their seats during the flight and limit head movements. However, suborbital flights may result in a novel manifestation of motion sickness, analogous to that sometimes experienced during parabolic flight. This phenomenon is well known and most people adapt to this after several exposures to parabolic flight.

Postflight Medical Problems

The most likely postflight medical issues to be expected involve the nervous system and sensory organs (including motion sickness, vestibular disturbances, vertigo, and postural instability), and post-landing orthostatic intolerance. As all of these problems are very dependent on the duration of time spent in weightlessness, it is predicted that they will not be issues for suborbital flight unless in-flight motion sickness has occurred. Medical debriefs postflight are highly recommended, not only for collection of critical medical data, but also for the resolution and follow-up of any health issues resulting from spaceflight.

Entry Motion Sickness

Entry motion sickness can occur on return from an orbital spaceflight and can be severe following long-duration missions. It is less frequent and less severe on shorter-duration Shuttle flights. It is a concern because it would adversely affect the ability of a pilot to control a complex vehicle during entry and landing. It could also impair the ability of any crewmember to perform an emergency egress after landing (31). We anticipate that entry motion sickness will not likely be a significant issue on very short-duration suborbital spaceflights.

Emergency Egress Capability

The major risks to the health and safety of passengers and crew are launch and landing accidents, and emergency egress capability from a survivable accident will be an important consideration. It is an operational assumption that crewmembers will be capable of performing an emergency evacuation without assistance. Between 5 and 15% of Shuttle astronauts were judged to be too impaired post-landing to perform an unaided egress (18). This was due to a combination of entry motion sickness, postflight neurological dysfunction, and postflight orthostatic intolerance. However, since all of these problems are dependent on the duration of weightlessness, they should not occur as frequently following suborbital flights, unless persistent motion sickness were to be present in any given crewmember. It is recommended that emergency egress training be performed as this would be a mitigating factor in maintaining performance even if an individual were symptomatic.

Environment Medical Issues

Spacecraft Cabin Environment

Cabin temperature and humidity will vary depending on the vehicle design. In most orbital spaceflight vehicles, the cabin temperature is typically 21-26°C (70-79°F) with a relative humidity of 30-40%. Inappropriate control or a malfunction of the cabin heating, air circulation, and/or cooling systems could result in an uncomfortable cabin environment that might affect cognitive and psychomotor performance. Space motion sickness is known to be exacerbated by over-heating. Cabin pressure also may vary depending upon the design of the space vehicle. In current orbital spaceflight vehicles, the cabin pressure is maintained at a sea level pressure of 14.7 psi (101 kPa), unless it is decreased for a specific reason such as EVA prebreathing. This allows for essentially a shirt-sleeve environment. Airline transport aircraft are designed to maintain a cabin altitude below 8000 ft (2400 m) while flying at their operational altitude. Ear and sinus blocks are possible with rapid changes in cabin pressure. Suborbital space vehicles will operate at such high altitudes that there is a potential risk for an in-flight decompression (rapid or explosive) to very low or even absent atmospheric pressures. Such an exposure could result in hypoxia or even death (due to either hypoxia or ebullism) among the occupants.

Pressure suit use could be chosen by individual commercial spaceflight operators as an additional safety option for mitigation of the risk of cabin depressurization hazard. There are disadvantages to the use of a pressure suit, including weight, expense, thermal loading, and decreased pilot performance. It is noted that a pressure suit was not used on the SpaceShipOne flights. However, without a pressure suit the crew is absolutely reliant on cabin integrity being maintained since there is no redundancy and depressurization would be catastrophic. Historically, there have been two periods where a pressure suit was not required for orbital flights. In the Soviet space program, the Voskhod and the early Soyuz flights cosmonauts did not wear pressure suits due to extreme weight and volume limitations. This was changed after three cosmonauts died on Soyuz 11, which was described as a space craft malfunction causing depressurization, but in reality was also a program failure to provide pressure suits as backup. In the U.S. program, the pre-Challenger Shuttle flights did not have the Launch and Entry Suit (LES), which was not developed until after a recommendation from the Challenger Accident Investigation Board. Physiologic training using an altitude chamber should be utilized to mitigate the hazards of a partial depressurization event as it results in better recognition with a more rapid response to hypoxia and depressurization.

The cabin atmosphere composition (O_2 and CO_2) will also need to be controlled within safe levels, realizing that cabin designs may vary and may incorporate either an open or a closed loop system. Fire detection, prevention, and suppression will be integrated into the vehicle design and could limit the maximum O_2 concentration. A redundant backup O_2 supply will probably be available. In the design for cabin air circulation, CO_2 accumulation near the heads of seated crew and passengers must be avoided so as not to affect performance.

Ionizing Radiation

Ionizing radiation consists of subatomic particles that can interact with biological tissues and cause genetic damage, possibly leading to cellular death or dangerous mutations. The sources of ionizing radiation in space are galactic cosmic radiation, solar radiation, solar flares, and the trapped radiation from the Van Allen belts. Galactic cosmic radiation is omnidirectional and originates outside of the solar system. It consists of hydrogen nuclei protons (87%), helium nuclei alpha particles (12%), and high energy heavy nuclei such as iron and lithium (1%). Solar cosmic radiation is a proton-electron plasma which is ejected from the surface of the sun at very high velocities and varies in magnitude according to the sun's 11-yr activity cycle. Solar flares are magnetic disturbances on the sun's surface generating electromagnetic radiation and high-energy protons that result in solar particle events (SPEs). The Van Allen belts contain trapped protons, heavy ions, and electrons. These magnetically trapped high-energy particles can also produce significant levels of radiation. Protection from cosmic radiation for the Earth's inhabitants is provided by three variables: the sun's magnetic field and solar wind (solar cycle dependent); the Earth's magnetic field (latitude dependant); and, most importantly, the Earth's atmosphere (altitude dependant). There is a rapid increase in the radiation dose as the altitude increases due to reduced atmospheric shielding.

The applicable radiation dose standard for radiation-exposed workers is 20 mSv/yr (averaged over 5 yr). Exposure to 20 mSv/yr over a work life of 40 yr results in an excess lifetime fatal cancer risk of 3.2%. Concerns have been expressed over increased rates of breast cancer, thyroid cancer, leukemia, and cataract formation in people exposed to even low doses of ionizing radiation. However, no studies (8) have shown a statistical increase in any of these diseases at the limits described above for occupationally exposed workers (20 mSv/yr). NASA astronauts have established monthly, 1-yr, and career exposure limits based upon a maximum of 3% excess lifetime cancer mortality (26). These limits are recommended by the National Council on Radiation Protection or NCRP (27). The recommended maximum limits were decreased further on the more recent 2000 NCRP report (28). These are individually adjusted, since those of younger age and female gender are at an increased risk. The 10-yr career effective dose limits are 0.4-3.0 Sv depending upon gender and age (39). Planned exposures to radiation (such as during an EVA or passage through the South Atlantic Anomaly) are kept as low as reasonably achievable (ALARA principle). Orbital spaceflight results in an extremely variable radiation dose exposure which is dependent on orbital altitude and solar activity and ranges from 0.01 to 0.1 Sv/mo.

Radiation levels at an altitude of 350,000 ft would be similar to high altitude Concorde flights (there is the minimal additional protective effect of the atmosphere above 60,000 ft) and, therefore, should be less than 15 microSv/h (7,8) for a total duration of less than 30 min. The occupational exposure limit recommended by the International Commission on Radiological Protection (ICRP) for commercial aircrews such as on the Concorde supersonic transport is 20 mSv per year, averaged over 5 yr with a maximum in any 1 yr of 50 mSv (29,30). This is in contrast to the ICRP recommendation for the general public to be less than 1 mSv/yr. Professional aircrews are considered to be occupationally exposed and employers have a duty of care to conform with the ICRP recommendation, even if their particular national authority does not have appropriate regulations.

For the most part, there is no concern regarding the acute effects of ionizing radiation because of the short duration of the flight and the fact that launch can be controlled depending upon atmospheric conditions. However, all flight crewmembers should be required to wear personal dosimeters to track their accumulated dose for each mission, as do radiation workers and medical imaging personnel, to ensure compliance with OSHA standards. Radiation exposure during pregnancy could have significant adverse effects on the developing fetus and should be avoided. The U.S. NCRP recommends that the total radiation dose received by a pregnant woman not exceed 5 mSv during the entire pregnancy, while the ICRP recommends the total dose during pregnancy not exceed 1 mSv. Over 100 suborbital flights would still result in exposure below this level.

Noise

The intense combustion and powerful thrust required to launch a vehicle into a suborbital spaceflight generates a large amount of noise which is transmitted through the whole vehicle. As a spacecraft is an enclosed space, the noise is reflected multiple times off the walls, floor, and ceiling. These noise levels are of short duration but can be quite intense. The physiological effects of extreme acute noise (unprotected) is reduced visual acuity, vertigo, nausea, disorientation, ear pain, headache, temporary hearing threshold shift, and degradation in pilot performance. Loud noise can also interfere with normal speech, making it difficult to understand verbal communication and affecting team interaction. Noise is a distraction and can increase the number of errors in any given task, but especially in tasks requiring multiple information sources, information processing, and vigilance (17,33). Noise levels in the crew compartment during a Shuttle launch reach close to 120 dB. Some of the space vehicles being proposed will generate loud noise levels for brief periods, although the exact decibel level is not currently known. NASA had set a goal of a noise level of less than 105 dB for the Constellation Program (21,34). Auditory protection will be required during suborbital spaceflight launch by the crew (by helmet or headset) to prevent sensorineural hearing loss (permanent threshold shift) and to facilitate communication. Hearing standards for pilots should be congruent with the current FAA hearing medical standards for all classes (audiometric speech discrimination test: unaided discrimination of pure tones with thresholds in the worse ear no worse than 35 dB at 500 Hz, 50 dB at 1000 Hz, 50 dB at 2000 Hz, and 60 dB at 3000 Hz, conversational voice test).

Vibration

Vibration is oscillatory motion in a dynamic system (such as the human body) and is characterized by frequency, amplitude, resonance, direction, spectrum, and duration. Most aerospace vibration exposures remain well below injury levels. The vibration associated with launch and aerodynamic loading of a space vehicle, however, can be significantly greater than standard aircraft operations. Minimal tolerance occurs between the frequencies of 4 and 8 Hz (due to whole body resonance). Symptoms commonly elicited to vibrations include general discomfort, fatigue, headache, and back pain. Cardiopulmonary response to vibration in the 2–12 Hz range is similar to aerobic exercise. Manual tracking errors increase in the 2–16 Hz range, causing impaired psychomotor coordination. Compensatory eye movement is a physical response to vibration and affects visual performance. Blurred vision may occur at high frequencies. Transient vibrational loads of greater than 0.5 G for less than 1 min, especially at critical frequencies or in the G_z axis, sudden onset of vibrational experiences, and cumulative vibration loads of longer duration can interfere with the ability of the pilot to visually track displays, maintain situational awareness, and could interfere with pilot performance (34). This was a transient problem on Mercury-Redstone 3. Vibration was also noted on the in-cabin videos of several of the SpaceShipOne flights during both ascent and entry. SpaceShipOne Flight 16P experienced significant thrust oscillations at 5–10 Hz towards the end of the two-phase flow portion of the boost which produced an impressive amount of vibration with the pilot's head being slammed against his headrest for several seconds as seen on the in-cabin video.

Standards for whole body vibration are published by the American National Standards Institute (1) and the International Standards Organization (25) and are based upon frequency, amplitude, and duration. These do not address the more complex issue of pilot performance. Mitigation strategies for reducing vibration would be to aggressively decrease vibration in the design of the vehicle, isolate the pilot by seat design, and the use of a helmet to isolate the head, which has been shown to improve display reading performance and vibration tolerance (36).

Conclusion

Many gaps in knowledge remain concerning the medical issues discussed in this paper. The effects from acceleration, cardiovascular and neurovestibular microgravity effects, space motion sickness, ionizing radiation, noise, vibration, spacecraft environment, and post-landing performance are unlikely to be obstructions or impediments to the flight crew of commercial suborbital spaceflights that are similar to the anticipated flight profile of Virgin Galactic's SpaceShipTwo. Flight profiles other than SpaceShipTwo will probably be similar, but may have different medical issues. However, without an evidence base on which to draw, it is prudent to incorporate a vigilant observation process to expand our knowledge base, fill in the gaps in knowledge, and adjust flight crew training and medical standards as necessary.

We propose the following recommendations for operationally critical flight crewmembers participating in suborbital spaceflight:

- An FAA first-class medical certificate using the same age-based schedule as is required for ATP pilots. An FAA first-class medical certification [as recommended by the AsMA position paper (5) instead of the current FAA requirement for an FAA second-class certification] differs from a second-class only in that it requires an EKG and has to be renewed every 6 mo instead of 12 mo over the age of 40.
- Pre-flight medical evaluation. This would be beneficial in the very early developmental flights to reduce risk and liability if any unpredicted medical issues occur.
- Post-flight medical debrief with data collection, especially in the early stages of suborbital spaceflight experience.
- An independent data repository of medical findings. Establishing such a repository would enable analysis of findings and periodic reevaluation of medical standards with recommendations for changes to respond to medical issues that may be discovered.
- Periodic reevaluation of the current medical standards during the early stages of developmental flights to respond to any medical issues that may be discovered.
- Passive ionizing radiation dosimeters worn by each flight crewmember.
- Auditory protection in the helmet or headset for all crewmembers.
- Emergency egress training for all crewmembers.
- Physiologic training (altitude chamber) to ensure flight crew recognition of signs and symptoms associated with decompression, including hypoxic changes.
- Recent centrifuge or other G training. Such training may be beneficial if there are significant ($> +3$) G_z acceleration forces during the flight and the flight crewmembers have not had adequate $+G_z$ training in other environments.
- Anti-G suit use on flights until more experience has been obtained. There will be significant ($> +3$) G_z acceleration forces in the flight profile and deterioration of $+G_z$ tolerance may occur due to the "push-pull effect" after several minutes of 0 G. There are no data concerning $+G_z$ tolerance following 4 min of 0 G.
- Parabolic flight training. This may be beneficial as it provides some experience to the acceleration-weightlessness-deceleration environment, although no studies have shown that it contributes to establishing a "dual adaptive" state. Some personnel have experienced motion sickness with the initial exposure to parabolic flight, but develop tolerance with adaptation to the changing gravitational fields.
- Pressure suit use for commercial spaceflight operators. These could be adopted for some operators as they would be beneficial in the case of failure of the pressurized vehicle. Without a pressure suit, the crew is absolutely reliant on cabin integrity being maintained since there is no redundancy and depressurization would be catastrophic.
- Further investigation on the effects on pilot performance from the rapid changes in the acceleration–microgravity–entry deceleration flight profile. This flight profile cannot be simulated or trained for and there is little operational experience. Of special concern is the impact on an individual involved with repetitive flights. Current data suggest that this may be well tolerated, but only actual flight experience will show whether this is true.

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