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Commercial Spaceflight Participant Tolerance of Acceleration Exposure During Centrifuge-Simulated Suborbital Flight

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To whom it may concern:

Please accept the attached manuscript for consideration of publication as an original contribution in Aviation, Space, and Environmental Medicine.

Title: Commercial Spaceflight Participants Tolerance of Acceleration Exposure During Centrifuge-Simulated Suborbital Flight

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* The work herein is original and has not been publish elsewhere. It is not currently under consideration by any other journal.

* There is no financial relationship that leads to a conflict of interest. Please note that both Dr. Tizard and Dr. Vanderploeg are associated with Virgin Galactic, and the subjects within this study were potential spaceflight participants in future Virgin Galactic suborbital spaceflights. However, the authors of this manuscript received no financial or other type of benefits for

participation in this work, and the results of this study in no way influenced the selection, management or participation of any potential spaceflight participants.

* This manuscript has been read and approved by all authors and all named authors meet the criteria stated in the “Instructions for Authors Section 4” regarding qualifications for authorship.

*Statistical analysis was performed by Dr. Rebecca Blue and Dr. Jon Riccitello, who have expertise and graduate training in this area.

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Commercial Spaceflight Participant Tolerance of G-Force During Centrifuge-Simulated Suborbital Flight

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INTRODUCTION: Medical knowledge of the human body in microgravity and hypergravity is based upon studies of healthy individuals well-conditioned for such environments. Little data exist regarding the effects of spaceflight on untrained commercial passengers. We examined the responses of potential spaceflight participants (SFP) to centrifuge G-force exposure. METHODS: 77 individuals (65 males, 12 females), 22-88 years old, underwent six centrifuge runs over 48h. Day 1 consisted of two +Gz runs (peak=3.5+Gz, run 2) and two +Gx runs (peak=6.0+Gx, run 4). Day 2 consisted of two runs approximating a suborbital spaceflight profile. Data included blood pressure, electrocardiogram, and post-run questionnaires regarding motion sickness, disorientation, greyout, and other symptoms. RESULTS: Of the 77 participants, average age was 50.4±12.7yrs. Average heart rate (HR) varied by sex and direction of G-exposure (+Gz: F 150±19, M 123±27; +Gx: F 135±30, M 110±27). Age and peak HR were inversely related (HR<120bpm: 60.2±12.2yrs, HR>120: 47.1±10.9yrs). HR during peak G-exposure for the final run was associated with post-run imbalance (no imbalance: HR 126±26, imbalance: HR 145±21); no other significant hemodynamic change, sex, or age variation was associated with imbalance. Age and greyout were inversely associated; there was no association between greyout and vital sign change, sex, or G-force magnitude. Baseline/pre-trial mean arterial pressure (MAP) was not associated with any symptoms. DISCUSSION: The results suggest that most individuals with well-controlled medical conditions can withstand acceleration forces involved in launch/landing profiles of commercial spaceflight vehicles. Further investigation will help refine which conditions present significant risk during suborbital flight and beyond.

Keywords: G-force; age; neurovestibular imbalance; hypergravity; hemodynamic

Introduction*:*

The coming of the commercial age of spaceflight portends a paradigm shift concerning the medical qualifications of future spaceflight participants (SFP). The majority of the medical knowledge of the human body during spaceflight is based upon studies of remarkably healthy individuals well-trained for such flights. However, unlike career astronauts, prospective commercial SFPs will self-select based upon financial means, which is often inversely related to youth and physical fitness. With very little data regarding the effects of spaceflight on individuals with known diseases, the development of medical standards and screening of commercial SFPs is currently an area of much discussion and debate. The concern is whether spaceflight, an already hazardous endeavor, would be a greater risk for the less healthy individual [2,6,8]. It remains difficult to predict how particular disease processes will respond to the hypergravity environment during launch and landing of spacecraft, and exactly what these hazards may entail.

The training of individuals in a human centrifuge can be used to prepare the SFP for the acceleration (G) forces of launch and landing, and to evaluate each participant's fitness and ability to withstand these stresses [2,5]. The initial group of Virgin Galactic future suborbital spaceflight participants, referred to as the "Founders," was trained for suborbital spaceflight utilizing the National Aerospace Training and Research (NASTAR) Center centrifuge. These participants were exposed to centrifuge-simulated G-force profiles that they might encounter during flight in the Virgin Galactic commercial spaceflight vehicle SpaceShipTwo. Here we sought to examine how these potential commercial SFPs tolerate exposure to G-force during launch and landing phases of spaceflight. We hypothesized that cardiovascular response would

be attenuated with increasing age. We further hypothesized that, despite these limitations in cardiovascular response, the Founders would largely be able to tolerate the anticipated G-forces involved in a suborbital spaceflight.

Methods*:*

This was a retrospective observational study of the subjective and objective parameters recorded during the physiologic training of the Founders at the NASTAR centrifuge. A total of 81 individuals, ranging from 22 to 88 years of age, were screened for participation in the centrifuge trials based on their self-selection as paying passengers for future Virgin Galactic suborbital spaceflights. Prior to their taking part in centrifuge activity, participants were asked to fill out a medical history questionnaire and have a physical exam form completed by their own doctor. All participants were required to provide an EKG. These documents were reviewed by Virgin Galactic and NASTAR physicians. Participants could be approved directly, be requested to undergo further tests or provide more records, or be excluded altogether depending upon their medical history. While the criteria used for these decisions were subjective, those participants with significant cardiac risk factors beyond age and sex were required to provide further information including lipid panels, hemoglobin A1c in the case of diabetes, or exercise stress testing. In rare instances other noninvasive tests such as chest radiography, pulmonary function tests or echocardiography were specifically requested. All participants signed informed consent and liability release forms before taking part in the centrifuge runs.

Approved participants underwent six centrifuge runs involving three different centrifuge profiles over a 48 hour period of time. Participants were taught the basics of anti-G straining and the

"hook" maneuver. They were advised to strain during +Gz exposure, but to use the hook maneuver only in the event of greyout symptoms. The initial exposure (Run 1) was a 2-minute +Gz (head-to-toe) centrifuge run with maximum peak of +2.15 Gz lasting 15 seconds. The second exposure (Run 2) was a 2-minute +Gz centrifuge run with maximum peak of +3.5 Gz lasting 15 seconds. The third exposure (Run 3) was a 2-minute +Gx (front-to-back force) centrifuge run with a maximum peak of 3.0 Gx lasting 15 seconds. The fourth exposure (Run 4) was a 2-minute +Gx centrifuge run with a maximum peak of +6.0 Gx lasting 15 seconds. The final two exposures were simulated spaceflight profiles using the +Gz and +Gx forces anticipated for future Virgin Galactic suborbital spaceflights. First the anticipated Virgin Galactic profile was executed at 50% intensity (Run 5) then it was repeated at full intensity (Run 6) after a short pause of less than or equal to 5 minutes. The simulated spaceflight profile involved both +Gz and +Gx components, with maximums of +6.0 Gx and +3.5 Gz in the final run. Exposure to each phase of acceleration did not exceed 2 minutes, and onset rates always remained less than 1.5 G/sec in the +Gx direction and 0.5 G/sec in the +Gz direction. The duration of time at the peaks of +Gx and +Gz was less than 5 seconds.

Audiovisual simulation was provided during each trial by the multimedia system of the centrifuge gondola to enhance the realism of the spaceflight experience. Non-prescription motion sickness medications, including dimenhydrinate or ginger, were provided if desired. In one case pre-run oral scopolamine and dextroamphetamine were administered.

Data recorded included baseline blood pressure (BP) and heart rate (HR), pre-run BP, continuous HR and EKG monitoring. Pulse oximetry was recorded by index finger probe on 16 participants.

Participants underwent post-run questionnaires regarding the occurrence of motion sickness, spatial disorientation, greyout, or any other centrifuge-related symptoms experienced. Hemodynamic data were monitored and recorded in real time by the NASTAR medical monitor and the Virgin Galactic medical monitor. Heart rate was recorded independently by each medical monitor at predetermined times before, during, and after each centrifuge run. In the cases where pulse oximetry was measured the O_2 saturation was also recorded at predetermined times. The presence of ectopic beats and arrhythmias were noted by each medical monitor. A third independent investigator compared the two data sets and found high correlation and no significant differences between the hemodynamic values recorded by each monitor.

Data analysis followed collection, using descriptive statistics, linear regression modeling, and student t-tests. Data analysis was independent of the centrifuge trials and was approved by the University of Texas Medical Branch Institutional Review Board as a retrospective observational analysis of the data collected during the centrifuge runs.

Results*:*

Of the 81 Founders who were medically screened for centrifuge training, 77 participants (65 males, 12 females) took part in the centrifuge runs. Average age was 50.4±12.7 years. Thirty-six individuals were required to provide further medical data than the minimally required information, 21 were required to undergo stress testing or other cardiac examinations. Figure 1 shows the percentages of those with significant past medical history relevant to centrifuge exposure and spaceflight. Sixteen participants had a history of hypertension (7 of whom were taking beta-blockers), 5 with diabetes, 5 with a history of coronary artery bypass surgery or

percutaneous stenting, and 17 with hyperlipidemia. Two individuals that were not approved for training were excluded for evidence of severe peripheral vascular disease; both were identified by their primary physician before additional testing was requested by medical monitors. Of all participants required to provide additional testing and/or additional control of their medical problems, none were ultimately excluded from centrifuge exposure. One participant was limited to low intensity runs only (Run 1 and Run 3) for uncontrolled hypertension and another for an unresolved concern about coronary artery disease. Two participants were limited to only the first day of centrifuge training for significant motion sickness exacerbated by pre-existing gastroesophageal reflux disease. Four individuals only participated in Runs 5 and 6 due to their preference and availability.

The quality of data collection was very good, with rare omissions due to instrument malfunction, motion artifact, or minor technical constraints. These omissions were not considered enough to compromise the integrity of the results. There was no significant association with pre-screening requirements and any hemodynamic alteration or subjective symptoms; the 36 individuals required to provide more extensive screening had no significant alterations in their performances in comparison to those that required only minimal screening.

Hemodynamic Alterations

Average baseline HR for all participants was 69±10 beats per minute (bpm), and maximum HR for all runs was 131±26 bmp. The change in HR with Gz exposure in any run was inversely correlated with age ($p<0.001$ for all runs ΔHR from baseline). Average maximum HR varied by sex and direction of peak G exposure (Gz: F 150±19, M 123±27, $p=0.001$; Gx: F 135±30, M

110±27, P=0.006). There was an inverse relationship between age and peak HR for all runs (HR<120bpm average 60.2±12.2 years, HR>120 average 47.1±10.9 years, P<0.001). No HR greater than 180bpm was noted, and no instance of tachycardia was associated with any clinical sign or symptom. Average mean arterial pressure (MAP) was 92.2±9.3mmHg. There was a significant difference between average baseline MAP for females vs. males (F 86.9±7.1, M 93.1±9.4, p=0.04) with no significant age association for baseline or any pre-trial MAP. Baseline and pre-trial MAP was not associated with any symptoms or G-exposure intolerance.

Participants taking beta-blockers for hypertension control were noted to have significantly lower peak HRs in comparison to those not taking beta-blockers (P<0.01 for all runs); this finding was not associated with any significant incidence of symptoms or subjective complaints during any of the centrifuge runs. There was no significant difference in baseline or pre-trial MAP between participants on beta-blockers and participants not on beta-blockers.

Finger probe pulse oximetry was measured on sixteen participants. No reading below 89% was obtained. Eight of these participants had a desaturation to 92% or below at least once, generally following peak Gx exposure of the run. Five of the sixteen had repetitive desaturations. Gz exposure did not result in significant changes in pulse oximetry, and no incidence of desaturation resulted in clinical symptoms.

Subjective and Observational Results

There was no significant difference in frequency of subjective complaints in patients with significant past medical history, including cardiac disease, hypertension, diabetes, and

hyperlipidemia, compared to participants without history of such diseases. As might be expected in a rotating centrifuge, nausea was common with +Gz exposure, but usually not severe. As mentioned above, two participants were unable to undergo the second day of training secondary to significant nausea and vomiting on the first day; all other cases of nausea were easily tolerable. Greyout was similarly common, but mild. In some cases, especially during the later runs, the participants would intentionally delay straining in order to experience greyout before taking corrective action, thereby artificially increasing these numbers. No participant experienced a G-induced loss of consciousness (G-LOC) event. Some participants also performed intentional head movements to induce coriolis-type sensations. No greyout occurred during +Gx-only exposure. There was an inverse association between age and incidence of greyout (no greyout: 53.2±12.6, greyout: 46.3±11.6, p=0.016); however, there was no significant association between any vital sign change (including HR, baseline or pre-trial MAP, or pulse oximetry), sex, or magnitude of G-exposure with greyout incidence. All greyout experienced was rapidly corrected by implementation of the hook maneuver or other anti-G straining maneuvers.

There were infrequent reports of palpitations (total 6 participants, 4 of which occurred during the first run), and premature atrial and ventricular contractions (PACs, PVCs), sometimes frequent, were commonly noted but did not have any clinical or operational significance (total experiencing PAC/PVC: 37 participants (48%), no significant relationship to age, sex, run, or other hemodynamic or subjective events). One participant complained of a mild back spasm during the 50% intensity flight simulation (this person subsequently completed the full intensity simulation without difficulty).

There was one complaint of chest pain in association with nausea during the final run. There were 5 complaints of mild to moderate dyspnea during +Gx exposure (participants complained of difficulty breathing against the mechanical load, though symptoms had resolved by the completion of the run). There were multiple complaints regarding sensations of vertigo. These complaints demonstrated an inverse linear correlation with progressive runs, as the majority of complaints occurred during the first or second exposures (R^2=0.92). Finally, four individuals complained of light-headedness during the final run only.

Medical monitors noted significant imbalance or unsteadiness in 26 participants (34%) following only Run 6. HR during peak G-exposure during the final run was associated with a significantly higher incidence of imbalance or "unsteadiness" following the final run (no imbalance HR 126±26, imbalance HR 145±21, p=0.002). There was no other significant hemodynamic parameter, sex, or age association with post-run imbalance.

Discussion*:*

This cohort of potential suborbital commercial SFPs successfully completed centrifuge training with little difficulty. Obtaining additional medical tests or records did not preclude anyone from participating, nor did it help predict individuals that might have difficulty with the training. There were no significant cardiac, cerebrovascular or respiratory events noted despite a wide variation in ages and underlying health conditions. While cardiovascular response was attenuated in older participants, this was not associated with any change in intolerance to G-exposure. In addition, many dysrhythmias (specifically PACs and PVCs) were noted and yet

none were malignant or resulted in clinical symptoms. There were also significant differences noted between sexes in HR and BP both at rest and in response to acceleration, but none of these differences were associated with any altered response or clinical symptoms during centrifuge exposure. Past medical history of well-controlled cardiac disease, hypertension, diabetes, and hyperlipidemia was not associated with any significant differences in hemodynamic or subjective tolerance of G-force.

Vertigo induced by the rotating centrifuge was less common during the final two runs. While multiple individuals experienced sensations of tumbling or spinning vertigo in the first two runs, they were able to tolerate the final two runs without problems despite increased length and complex G-exposures in the later runs. This may suggest an extinction or training effect that improved tolerance over time. Further, it may be reasonable to expect less vertigo during actual flight as it would not include the rotational component involved with centrifuge simulation.

Neurovestibular alterations are known side effects of spaceflight, ranging from motion sickness to postural instability, and could potentially pose a risk to future commercial spaceflight participants [1,3]. Here the incidence of nausea did not seem to be affected by age, sex, or cardiovascular response to G-force. Interestingly, elevated heart rate during peak G-exposure was associated with imbalance following only the final run. The final run followed quickly after the fifth, resulting in significantly longer centrifuge exposure with minimal interruption the second day. These findings suggest that prolonged G exposure may precipitate neurovestibular disturbances. Of note, neurovestibular alterations may pose a risk to the commercial spaceflight pilot. Repetitive cycles of hypergravity – microgravity – hypergravity exposure may be a

concern in situations of multiple suborbital flights in a short period of time. Incidents of neurovestibular disturbance or motion sickness associated with such repetition may limit a pilot's ability to perform multiple suborbital trips in a short period of time. These relationships should be explored in greater detail with a larger sample size and more intense neurovestibular evaluation following centrifuge exposure.

Previously reported analysis of commercial spaceflight participant training data from the NASTAR Center, based on a smaller sample size, suggested that baseline MAP was associated with age, as was incidence of greyout, but that baseline/pre-trial MAP was unrelated to incidence of greyout [4]. These findings suggested that age was an independent risk factor for greyout symptoms. The larger database analyzed here similarly demonstrated a negative linear relationship between age and greyout incidence; however, there was no significant relationship between baseline/pre-trial MAP and age or baseline/pre-trial MAP and greyout. While this is in contrast with prior studies, our findings did support the suggested protective relationship of age and higher greyout tolerance.

The higher greyout tolerance of older participants is physiologically plausible, as age tends to lead to reduced vascular compliance. This may provide a protective effect for cerebral perfusion by resisting caudal displacement of blood volume despite the fact that baseline MAPs did not seem to vary by age. The greyout experienced by the younger participants did not lead to significant compromise, as there were no events of G-LOC or other incapacitating events. All greyout experienced was easily managed by implementation of the hook maneuver or other anti-G straining maneuvers by participants only minimally trained for such. Finally, the intentional

delay in straining in order to experience greyout artificially increased the incidence of this symptom, making results difficult to interpret.

Conclusions:

Medical screening for suborbital flight is somewhat less complicated than for extended orbital experiences. According to Federal Aviation Administration (FAA) guidelines, it is imperative that medical screening ensure that a commercial participant can tolerate the physiological stresses induced by spaceflight and still be able to evacuate the spacecraft in an emergency [2]. Furthermore, the FAA has indicated that great care should be exercised when exposing individuals with cardiovascular compromise to rapid onset of greater than 3.0 Gz sustained for over 5 seconds [2]. Despite these concerns, the relatively short duration of flight lessens the chance of an incidental medical problem occurring at an inopportune time. Definitive medical care can be obtained sooner and with less overall mission impact should an abort be necessary due to unforeseen problems during a short suborbital flight. Our results suggest that most individuals with well-controlled medical conditions are capable of withstanding the acceleration forces involved in the launch and landing profiles of commercial spaceflight vehicles, particularly as there was no relationship between the intensity of the participants' prescreening (and thus, indirectly, the concern of their physicians and/or medical monitors) and their performance during centrifuge activity. While further research and experience will help refine which medical conditions present a significant risk during suborbital flight and beyond, it seems as though most individuals with the desire to fly should, medically, be able to do so.

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Figure Caption:

Figure 1: Percentage of participants with significant past medical history (n=77).

(Abbreviations: HTN – hypertension, Hx – history of, CA – cancer, DM – diabetes mellitus, CAD – coronary artery disease)

Figures (separate file for each)
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