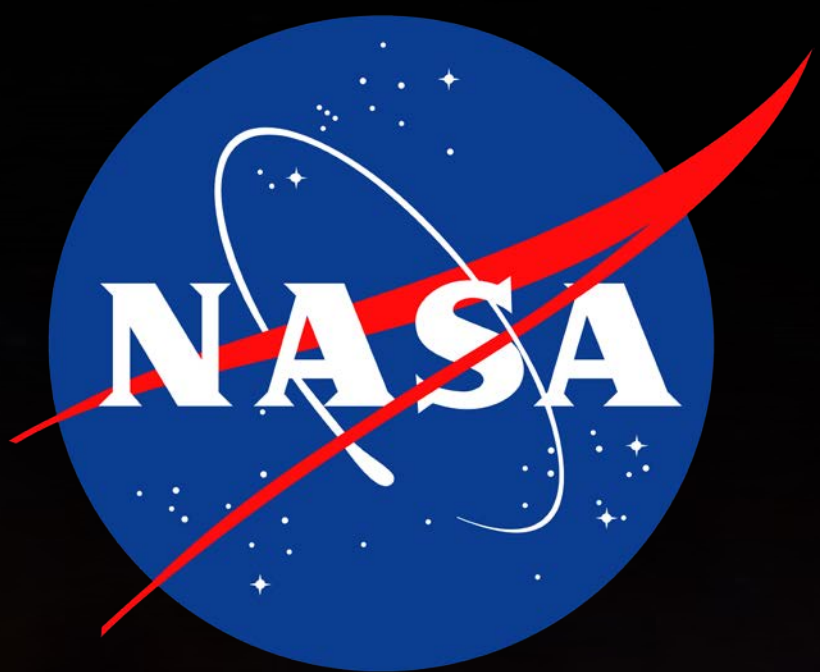


Oro-Nasal Mask versus Two-Way Non-Rebreathing Valves for Maximal Aerobic Capacity Testing in Astronauts

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Abstract

INTRODUCTION: Astronauts complete maximal aerobic capacity (VO_{2pk}) testing as part of their annual fitness assessment (AFA) as well as several times once assigned to an International Space Station mission. Historically, the 2-Way T-Shape Non-Rebreathing valve with a mouthpiece and nose clip ("*Mouthpiece*") has been used in these tests. The testing procedure was updated to use the oro-nasal mask ("*Mask*") for the AFA starting in June 2017. Astronauts who used the mask during their AFA requested it be certified to be used for all mission associated tests. Considering the criticality of the data and the schedule constraints of astronauts, it is imperative that the requested hardware change provide data with equivalent reliability and repeatability as provided by the mouthpiece. **PURPOSE:** To assess the reliability and validity of mask vs. mouthpiece by comparing submaximal and VO_{2pk} data within subjects (approximately 1 year apart). **METHODS:** Each of 17 active astronauts completed a VO_{2pk} test with the mouthpiece (first) and the mask (second) for their AFA. The VO_{2pk} test was conducted on a cycle ergometer with a metabolic cart. The nominal protocol started with a 3 minute warm-up at 50 Watts (W) and increased 25W every minute until volitional fatigue (Light: 45W start; 15W increase). The VO_{2pk} were compared between tests and the expected day-to-day variation ($\pm 5\%$) was used as the threshold for determining agreement between tests. Submaximal values were plotted and evaluated visually for deviations between mask and mouthpiece. **RESULTS:** VO_{2pk} values were more than 5% different, despite similar test times, between mouthpiece and mask in 6 of 17 comparisons, 3 of which were higher with the mask ($9.0\pm 5.9\%$) while 3 were lower ($-10.8\pm 2.0\%$) with the mask. The submaximal data did not indicate a leak in either apparatus during these tests. An Astronaut Strength & Conditioning Rehabilitation specialist confirmed that the measured differences in VO_{2pk} of these 6 astronauts was consistent with observed changes in exercise habits during the year that separated the two tests. **CONCLUSION:** After being presented with the results of this data mining effort the mask was accepted for use in all tests, accepting that, if a leak is detected without resolve, the test will be repeated (if schedule allows) and remaining tests will be completed with the mouthpiece.

Introduction

- A maximal aerobic capacity (VO_{2pk}) test is part of an astronaut's annual fitness assessment (AFA). Once assigned to a mission on the International Space Station (ISS), astronauts will complete several VO_{2pk} tests pre-flight, in-flight, and post-flight.
- The VO_{2pk} data is used to track fitness changes from year to year as well as during the astronaut's mission (pre-, in-, post-flight).
- The VO_{2pk} , peak heart rate (HR_{pk}), and Ventilatory Threshold (VT) are used to create pre-flight and in-flight exercise prescriptions on a cycle ergometer.
- Historically, the 2-Way T-Shape Non-Rebreathing valve with a mouthpiece and nose clip (mouthpiece) has been used in these tests. This is also the configuration that is used on the International Space Station.
- Astronauts who had experience with the oro-nasal mask (mask) requested it be certified to be used for all mission associated tests (pre-flight, in-flight, & post-flight).
- Once assigned to an ISS mission astronaut schedules have limited availability.
- It is imperative that the requested hardware change provide data with equivalent reliability and repeatability as provided by the mouthpiece since there are a limited number of sessions and an even more limited chance of a re-test.



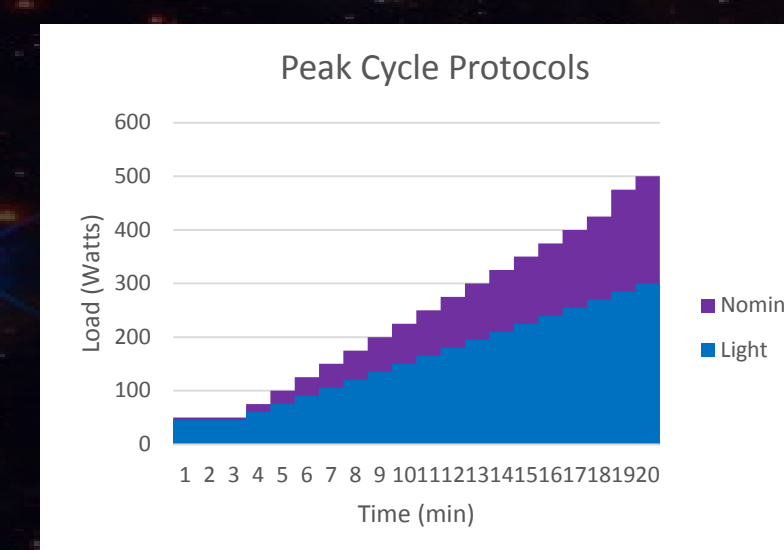
Fig. 1 (Left image) - Hans Rudolph Two-Way Non-Rebreathing Valve with Headgear and Silicone Rubber Mouthpiece (not pictured). Reusable noseclip series 9015). Fig. 2 (Right image) - Hans Rudolph Two-Way Non-Rebreathing Valve with 5 Strap Adjustable Headgear and 7450 Series Silicone V2 Oro-Nasal Mask

Purpose

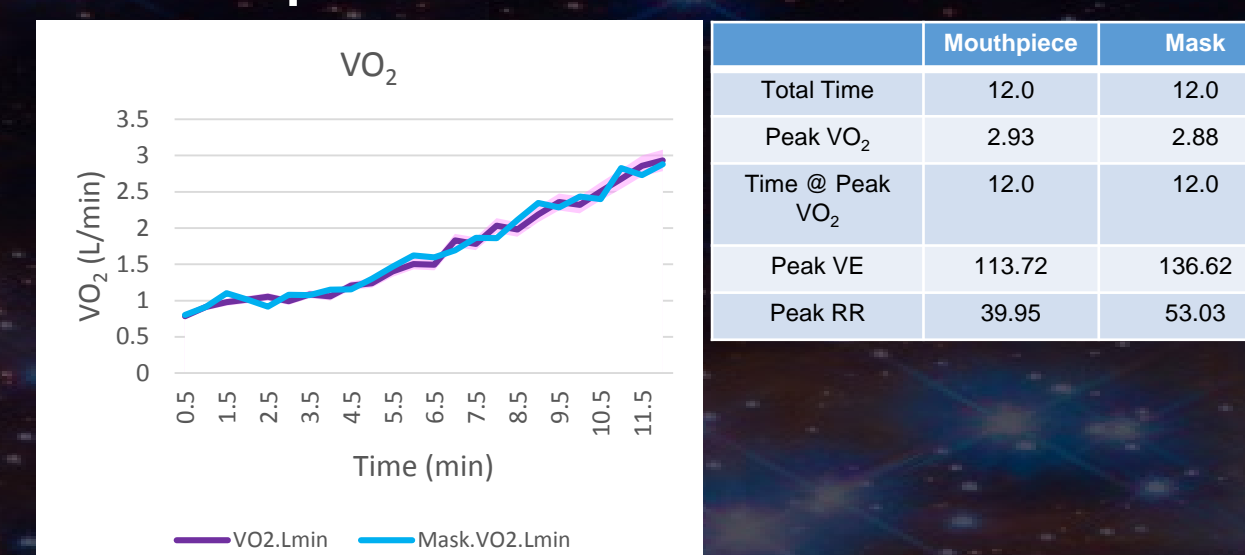
To assess the reliability and validity of mask vs. mouthpiece by comparing submaximal VO_2 and VO_{2pk} data collected on the same astronauts within 1 year.

Methods

- Seventeen active astronauts (15 M; 2 F) completed a VO_{2pk} test with the mouthpiece (first) and the mask (second) for their AFA. These tests were conducted approximately one year apart.
- The VO_{2pk} tests are conducted on a cycle ergometer with a TrueOne2400 metabolic cart (ParvoMedics, Sandy, UT).
- The nominal protocol starts with a 3 minute warm-up at 50 Watts (W) and increases 25W every minute until volitional fatigue (Light: 45W start; 15W increase).

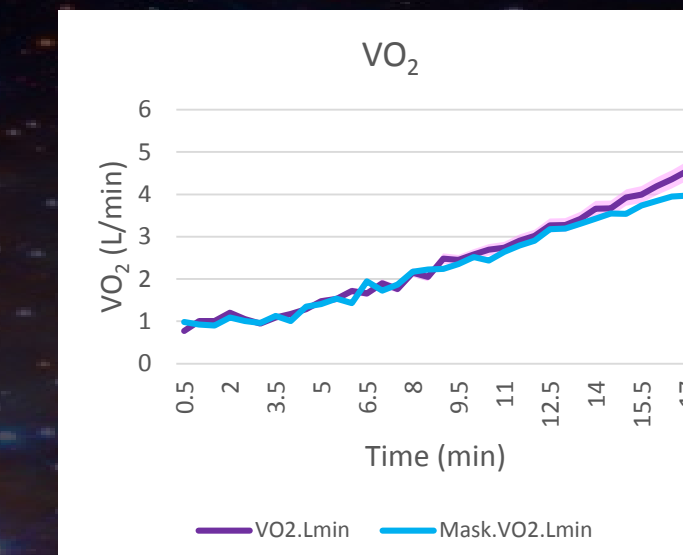


- The VO_{2pk} and submaximal values were compared between tests
- The expected day-to-day variation ($\pm 5\%$) was used as the threshold for determining agreement between tests (Noonan et al, 2000).
- Submaximal values were plotted and evaluated visually for deviations between mask and mouthpiece.



| | Mouthpiece | Mask |
|--------------------|------------|--------|
| Total Time | 12.0 | 12.0 |
| Peak VO_2 | 2.93 | 2.88 |
| Time @ Peak VO_2 | 12.0 | 12.0 |
| Peak VE | 113.72 | 136.62 |
| Peak RR | 39.95 | 53.03 |

Sample data of VO_2 agreement from a single individual. Fig. 3 (Left image) - Submaximal VO_2 data plotted every 30 seconds until test termination. The shaded area around the mouthpiece line is $\pm 5\%$ of the VO_2 at that time point. The light blue line is the mask data at the same time points. Table 1 (Right table) - Comparison table of peak information (time, VO_2 , VE, & RR) as well as the time that VO_{2pk} occurred.



| | Mouthpiece | Mask |
|--------------------|------------|--------|
| Total Time | 17.0 | 17.0 |
| Peak VO_2 | 4.55 | 3.97 |
| Time @ Peak VO_2 | 17 | 17 |
| Peak VE | 182.57 | 163.28 |
| Peak RR | 43.94 | 44.01 |

Sample data of VO_2 disagreement from a single individual. Fig. 4 (Left image) - Submaximal VO_2 data plotted every 30 seconds until test termination. The shaded area around the mouthpiece line is $\pm 5\%$ of the VO_2 at that time point. The light blue line is the mask data at the same time points. Table 2 (Right table) - Comparison table of peak information (time, VO_2 , VE, & RR) as well as the time that VO_{2pk} occurred.

Statistical Analysis

- Paired measurements of VO_2 for 17 subjects: first with mouthpiece and then with mask over a range of workloads (W).
- Model VO_2 as a function of W using mouthpiece measurements (Fig. 5). Estimate between-subject SD (σ_b) and within-subject SD (σ_w).
- Under the assumption that the mask-based method for measuring VO_2 is just as accurate as the mouthpiece method, the differences between paired measurements would have a mean of zero and a SD of $\sigma_w \sqrt{2}$ (within-subject repeatability standard deviation multiplied by the square root of 2).

Results

- VO_{2pk} values were more than 5% different, despite similar test times, between mouthpiece and mask in 6 of 17 comparisons (Table 3)
- 3 were higher with the mask ($9.0\pm 5.9\%$)
- 3 were lower with the mask ($-10.8\pm 2.0\%$)
- The submaximal data did not indicate a leak in either apparatus during these tests.
- A repeated-measures version of a Bland-Altman* plot of the differences vs. W with limits of agreement $\pm 1.96 \sigma_w \sqrt{2}$ is shown in Fig. 6.
- There were 447 data points in total across all 17 subjects. There are 2 data points per completed stage from the start of the test to peak.

Results con't

| Crew | Total Time | Mouthpiece | | | | Mask | | | | |
|------|------------|------------|-------------------|--------|-------|------------|------------|-------------------|--------|-------|
| | | VO_{2pk} | Time @ VO_{2pk} | VEpk | RRpk | Total Time | VO_{2pk} | Time @ VO_{2pk} | VEpk | RRpk |
| A | 12.0 | 2.93 | 12.0 | 113.72 | 39.95 | 12.0 | 2.88 | 12.0 | 136.62 | 53.03 |
| B | 15.5 | 4.25 | 15.5 | 211.5 | 59.96 | 15.0 | 4.04 | 15.0 | 168.11 | 46.09 |
| C | 14.0 | 3.68 | 14.0 | 166.75 | 44.21 | 14.0 | 3.31 | 13.5 | 142.42 | 45.67 |
| D* | 10.0 | 2.25 | 10.0 | 103.88 | 43.75 | 10.0 | 2.05 | 9.5 | 127.9 | 59.70 |
| E* | 17.0 | 4.55 | 17.0 | 182.57 | 43.94 | 17.0 | 3.97 | 17.0 | 163.28 | 44.01 |
| F* | 18.0 | 5.43 | 18.0 | 208.65 | 48.81 | 18.0 | 4.84 | 17.0 | 196.9 | 47.84 |
| G | 14.0 | 3.54 | 14.0 | 125.3 | 40.78 | 15.0 | 3.58 | 15.0 | 144.33 | 48.4 |
| H | 13.0 | 3.5 | 13.0 | 140.14 | 46.62 | 12.0 | 3.04 | 12.0 | 137.57 | 48.03 |
| I* | 15.0 | 3.79 | 15.0 | 163.04 | 63.68 | 14.5 | 3.99 | 14.5 | 173.93 | 68.85 |
| J | 14.0 | 3.55 | 14.0 | 156.3 | 49.78 | 14.0 | 3.53 | 14.0 | 146.7 | 46.54 |
| K* | 12.0 | 2.69 | 12.0 | 115.8 | 36.40 | 12.0 | 2.85 | 11.5 | 123.82 | 39.64 |
| L* | 10.0 | 1.46 | 10.0 | 81.74 | 54.33 | 10.5 | 1.69 | 10.0 | 86.29 | 58.11 |
| M | 11.0 | 2.42 | 10.5 | 117.77 | 48.16 | 11.5 | 2.47 | 11.0 | 104.22 | 38.87 |
| N | 11.0 | 2.23 | 11.0 | 102.22 | 46.25 | 10.5 | 2.28 | 10.0 | 89.04 | 39.62 |
| O | 13.5 | 3.09 | 13.0 | 130.18 | 46.76 | 14.0 | 3.28 | 14.0 | 149.87 | 52.10 |
| P | 12.0 | 2.71 | 12.0 | 126.05 | 29.54 | 12.0 | 2.82 | 11.5 | 129.15 | 31.15 |
| Q | 14.0 | 3.67 | 14.0 | 144.26 | 44.10 | 14.0 | 3.72 | 14.0 | 141.57 | 47.48 |

Table 3 - Summary of the variables compared between the mouthpiece and mask for each astronaut. The * indicates those tests where the VO_{2pk} values were more than 5% different.

- Under the assumption that the two methods (mask & mouthpiece) are equivalent, about 95% of the submaximal observations should lie between the limits of agreement. Overall, this percentage was 92.4% (413/447), with most of the discrepancies occurring at the highest workloads.
- If the data points for $0 < W \leq 300$, the percentage of agreement was 95.2% (379/398).
- Most of the extreme under-estimates of VO_2 at high workloads were seen in data from two of the subjects (Fig 3).

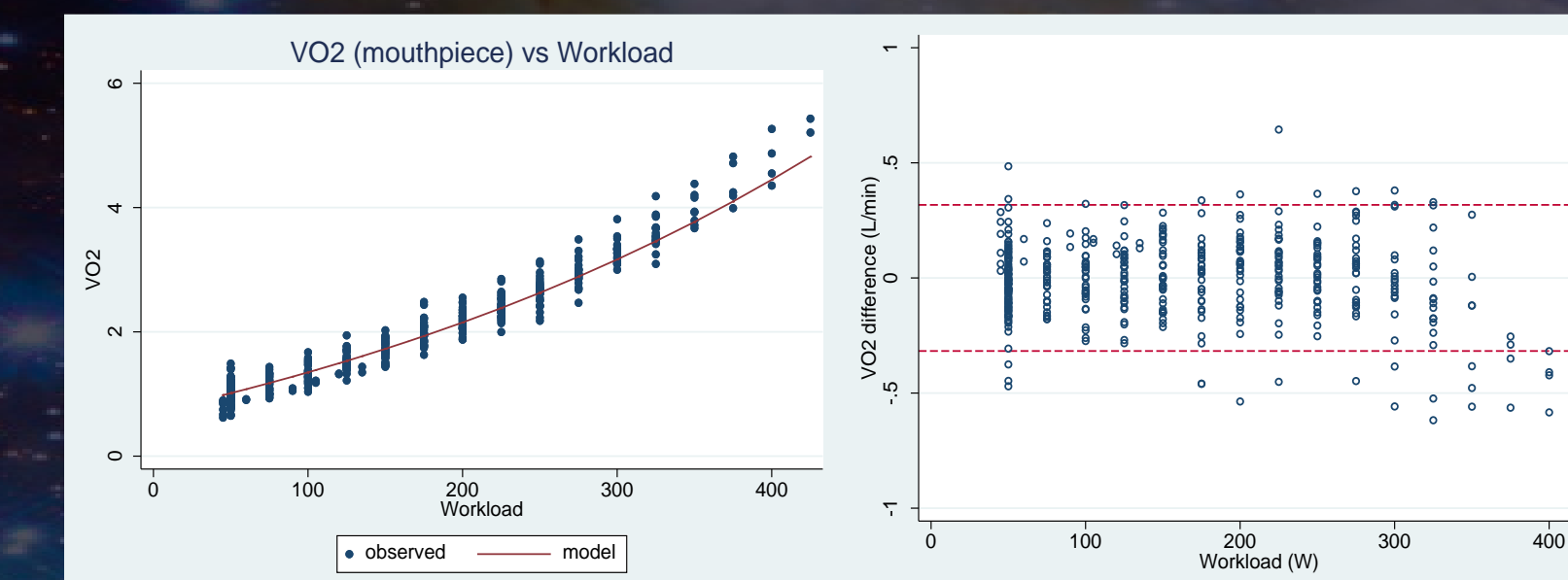


Fig. 5 (Left image) - VO_2 modeled as a function of workload (W). Fig. 6 (Right image) - A repeated-measure Bland Altman plot of the differences of the two VO_2 measures within the limits of agreement (dashed red lines). Data outside the limits of agreement are generally above 300W and from 2 astronauts.

Conclusions

- The mask showed agreement with the mouthpiece at the lower loads ($< 300W$), with discrepancies at the higher workloads ($> 300W$).
- An Astronaut Strength & Conditioning Rehabilitation specialist confirmed that the measured differences in VO_{2pk} of the 6 astronauts was consistent with observed changes in exercise habits during the year that separated the two tests. In one case, the time was 30 seconds less during the mask test.
- The results of this data mining effort were presented to the Medical Operations Group (MOG), which is a group of doctors from all over Johnson Space Center who decided on items pertaining to crew health.
- The mask was accepted for use in all tests. If a leak is detected without resolve, the test will be repeated (if schedule allows) and remaining tests will be completed with the mouthpiece.
- The mask will be checked for leaks prior to test start. The astronaut will seal the open of the mask and blow out forcefully as if at max exercise. Leaks typically occur at the bridge of the nose and at the chin.
- Real-time during the test, tidal volume (V_t) will be monitored for a decrease below the highest value that does not recover in the following minute.
- Astronauts complete a pre-flight training session on the in-flight hardware as well as four pre-flight tests. Astronauts will be trained during these sessions on proper fitting of the mask and headgear as well as how to leak check and detect.

Conclusions

- Noonan V, Dean E. Submaximal exercise testing: clinical application and interpretation. Physical Therapy 2000; 80(8): 782-807.