The BodyGem® is a Valid and Reliable Indirect Calorimeter for Adults & Children

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Abstract

The purpose of this white paper is to provide a comprehensive review of the studies used to evaluate the validity and reliability of the BodyGem®, (Gem) metabolic measurement device in adults and children. The varying approaches, methodologies and reference systems employed in these studies are presented along with the major findings. The Gem device has repeatedly demonstrated its ability to measure oxygen consumption (VO_2) and calculate resting metabolic rate (RMR) as accurately and reliably as reference systems.* There are no statistical or clinically relevant differences between oxygen uptake or RMR measured with MedGem and the reference systems.

The BodyGem and its companion medical device the MedGem® have been validated by HealtheTech® and by independent research institutions, including Appalachian State University, University of Colorado Health Science Center, Columbia University, University of Cincinnati Medical Center and El Camino College. The systems used for validation have included a metabolic simulator that provides highly repeatable output and classic human-based trials. In human-based tests, four different reference systems or approaches have been used for validation:

1. Open-Circuit, Douglas Bag-based, indirect calorimetry
2. Sensormedics 2900 System, Ventilated Hood
3. Delta Trac, Ventilated Hood
4. Sensormedics Vmax 29N system

In each of these situations, the Gem has produced valid and reliable measurements of oxygen consumption (VO_2) and determination of resting metabolic rate (RMR)in adults and children.

Mechanical Validation

The mechanical validation procedure was conducted internally by Jay T. Kearney, Ph.D., V.P., Clinical Affairs at HealtheTech using a proprietary metabolic simulator device developed by HealtheTech.

The 'Metabolizer' is based on a pair of motor-driven, 3-liter syringes, the first to simulate inspiration and the second to simulate expiration. The expiratory flow is provided from a tank of calibration gas that is heated and humidified before being "expired" through the Gem. The 'Metabolizer' can simulate a range of RMRs by varying breathing frequency, tidal volume and expired gas concentration. This system has been externally validated by Tom Storer, Ph.D., at El Camino College. "The device provides repeated simulated metabolic output with excellent reliability, with coefficients of variation in the order of one percent." (1)

The use of the mechanical simulation device allowed HealtheTech to specifically evaluate the technical capability of the Gem without the impact of biological variability associated with human testing. Twenty-two Gem devices were tested six times over a period of three days. Analysis of the data indicated excellent performance. The mean difference of the RMR measured by the twenty-two devices ranged less than 20 kilocalories, and the coefficient of variation (a measure of repeated performance over multiple tests) averaged 1.45 percent. The intraclass reliability alpha coefficient was .98 indicating excellent performance among the units and across the tests. The trial-to-trial correlation coefficient was $R^2 = .90$. (2)

Validation vs. Reference Systems – Human Testing

The validity and reliability of the Gem device has been repeatedly demonstrated using a variety of reference systems or approaches. The majority of these trials have been conducted by independent researchers and have been published in peer-reviewed journals, presented at professional meetings, or are currently submitted for review and publication.

a. Douglas Bag vs. Gem: Appalachian State University – Nieman

David Nieman, Ph.D., at Appalachian State University recruited 63 subjects (age 21–69 years, BMI 19.1-56.2 m/kg^2) to validate the Gem against the Douglas Bag (DB). Subjects were fasted and rested and were tested four times each for VO_2 and RMR on two separate days. During each testing session, the order of the devices was initiated randomly and continued in an alternating sequence (i.e. Gem, DB, Gem, DB). The order of devices was reversed for the second day of testing.

The DB portion of the study employed standard open-circuit indirect calorimetry using calibrated Amatek O_2 and CO_2 analyzers and a Rayfield gasometer. The DB technique is generally considered the 'gold standard' of indirect calorimetry because each of the variables is measured independently via calibrated and traceable instrumentation.

The results of this study were presented at the 2001 North American Association for the Study of Obesity (NAASO) meeting in Quebec City (3) and at 2002 Nutrition Week Conference (4) in San Diego, CA. The manuscript was published in the May 2003 issue of the *Journal of the American Dietetic Association* (5). The data indicated a mean RMR difference of less than 1 percent between the Gem and DB. The correlation between the performance of the Gem device and the DB was r = .89. Additionally, there was no systematic effect of the difference between the Gem and the DB across metabolic rates from approximately 1,100 kilocalories to almost 2,500 kilocalories, and across subjects grouped by BMI. The test-to-test repeatability using the Gem device was consistently in the range of r = .90.

The authors concluded that the Gem, "… is an accurate and reliable device for measuring oxygen consumption and calculating RMR during repeated tests within a day, single tests on separate days, or when measurements are averaged." (5)

b. Douglas Bag vs. Gem: HealtheTech, Inc. – Kearny

In February 2002, 32 subjects were tested four times each on two separate days. Testing order and gas analysis procedures were comparable to the design and instrumentation used by Nieman. The overall mean oxygen uptake was 225.6 ml O_2/min (approximately 1,566 kcals/day) and 234 ml O_2/min (1,621 kcals/day) for the Gem and DB, respectively. This difference of 9.17 ml O_2/min is less than 4 percent of RMR and it is neither statistically nor clinically meaningful. The test-to-test R^2 in the internal study was .86, indicating a strong degree of repeatability. (6)

In May of 2003, a second internal validation was completed using identical methodology and instrumentation. The mean RMR was 1,525$\pm$43 kcals/day, and 1,534$\pm$30 kcals/day for the Gem and DB, respectively (a difference of only 8 kcals/day or 0.6%). These results were highly repeatable, with an intraclass correlation coefficient alpha = .97. (7)

c. Sensormedics 2900 VH vs. Gem: UC Health Science Center – Melanson

A second external or independent validation trial of the Gem device was completed at the Center for Human Nutrition and Department of Preventive Medicine and Biometrics, University of Colorado Health Sciences Center, with Ed Melanson, PhD as the principal investigator. A poster abstract of these data was presented at Nutrition Week in 2003 (8), and the manuscript was published in the *International Journal of Obesity* (9). In this particular trial, the validity and reliability of the Gem was compared to RMR measurements obtained from a standard metabolic cart, the Sensormedics 2900 Ventilated Hood System (SM2900). RMR was measured twice on two different mornings in 47 healthy adults. On each morning, the RMR was measured using both the metabolic cart and the Gem device. The pre-measurement protocol was the classic procedure for clinical determination of resting metabolic rate: (a) 12-hr post-prandial, (b) no strenuous exercise for 24 hours and (c) no smoking or stimulants for 2 hours. The results indicated strong agreement in RMR measured by the Gem device or the SM2900. The trial-to-trial intraclass reliability coefficients were above .90 for both the devices. Additionally, the RMR measured with the Gem and the SM2900 were highly correlated (r = .92).

The initial analysis of the data indicated that RMR measured with the Gem device was about 80 kcals (approximately 5 percent higher) than RMR measured with the Sensormedics system. However, upon review of the test methodology, it was determined that the position used for testing with the Gem device was slightly different than the position used when testing with the SM2900. The researchers subsequently tested a subgroup of 10 individuals to determine the approximate energy cost of this difference. It was determined that the cost was approximately equal to 60 kcals/day and, therefore, it was concluded that the ability to measure RMR with the Gem device and the SM2900 were comparable. To quote…"The Gem provides a valid and reliable measurement of RMR. The ease of use and low cost make the Gem a viable option for measuring RMR."(8). Additionally, the authors demonstrated that the Gem device provided a more accurate measurement of RMR in overweight and obese subjects than would be obtained using the Harris-Benedict estimation equation.

d. Delta Trac vs. Gem: Columbia University – Heymsfield

Steven Heymsfield, Ph.D., used fifteen healthy subjects to investigate RMR and the thermic effect of food (TEF) following a 600 kcal liquid breakfast meal. RMR and TEF were measured at rest and for 7 hours post-prandial using a Delta Trac metabolic cart (DT) and the Gem device. The results indicated no statistically significant difference in either RMR or TEF with the two systems. Average daily energy expenditure measurements with DT and MG were significantly correlated (r = .93). There was no difference in average RMR between the two methods (1551.2 ± 106.9 kcal/d vs. 1557.9 ± 85.6 kcal/d, for DT and MG, respectively). The researchers concluded that: "A novel hand-held energy expenditure measuring device can accurately track post-prandial energy expenditure relative to a commonly used indirect calorimetry system and could therefore be used in clinical settings and large-scale trials to asses RMR and TEF."(10-12)

e. Delta Trac vs. Gem: University of Cincinnati Medical Center– Stewart

Stewart, Branson and Goody designed a unique system that allowed the Gem device to be supported inside the ventilation canopy of a Delta Trac calorimeter (DT). This system allowed RMR to be measured simultaneously using the Gem and the DT. Twelve men and 38 women completed the testing, which was done under standard clinical conditions for measurement of RMR. The measured VO_2 and RMR values using the two systems were highly correlated and virtually identical: difference in VO_2 = 0.58ml O_2 and difference in RMR = 5 kcals/day. The authors concluded that, "The results of this study indicate that the [Gem] device can be used to accurately measure RMR and oxygen consumption in capacities where a traditional metabolic cart would not be practical or cost-effective …" (13,14)

f. Multisystem Validation vs. Gem: El Camino College – Storer

Tom Storer, Ph.D., at El Camino College has recently completed a comprehensive validation trial that compared the ability of the Gem device, Delta Trac metabolic cart (DT), Sensormedics Vmax29N metabolic cart (Vmax), and Douglas Bag based indirect calorimetry (DB) to measure RMR. Forty-two subjects reported to the laboratory after an overnight fast, no exercise, and abstention from smoking or stimulants and completed a RMR test using each of the 4 systems. Device order was randomized. The mean difference in RMR between the BodyGem and DT, Vmax, and DB systems were 10, 42, and 24 kcals/day, respectively. The intraclass correlation coefficient among the 4 devices was alpha = .98. Bland-Altman plots revealed that the distribution of differences among the measurement systems was very comparable and there was no trend across the range of metabolic rates. (15)

h. Douglas Bag vs. Gem in Children: Appalachian State University – Nieman

Nieman and colleagues recruited 59 children (59 children (N=29 males, N=30 females) ranging in age from 7 to 13 years (mean age, 11.0±0.2 years). Subjects followed the same protocol as outlined in the previous studies conducted by Nieman (3-4). Results of the study were presented in a poster session at the 2004 NAASO conference in Las Vegas, NV. (16) The manuscript was published in the 2005 Volume 15 issue of the *International Journal of Sports Nutrition and Exercise Metabolism*. (17) The data indicated a 1.2% difference between the DB (1460 + 39 kcals/day) and Gem device (1477 + 35 kcals/day) in RMR and DB being highly correlated (r=.909). Test to test reliability correlation coefficients for oxygen consumption for the Gem device were r=0.94, and for the Douglas bag method, r=0.95. The authors concluded that "the Gem device is a reliable and valid system that is quick and convenient for measuring oxygen consumption and RMR in children". (16-17)

Conclusion

In conclusion, the Gem device has been tested in two mechanical trials and eight different human studies employing each of the methodologies typically used clinically or in research settings. In each case, the results have demonstrated that the Gem device accurately and reliably measures oxygen consumption and RMR, Additionally; there is no statistically significant or clinically meaningful difference between RMR measurement utilizing the Gem device and the alternative systems in adults or children. Individuals interested in obtaining more information or discussing specific studies used to support the conclusions presented above are encouraged to directly contact one of the members of the Clinical Affairs Department at Microlife USA, Inc. A tabular summary of these validation trials is presented in Table 1 below.

Table 1. Summary of Validation Trials

Reference System	Measured RMR Reference vs. Gem	Delta %	Reliability
Mechanical simulation[2]	1,263 to 1,283	+1.5%	r = .95
Douglas bags[3-5]	1,657 vs. 1,650	- 0.4%	r = > .90
Douglas bags[6]	1,566 vs. 1,621	- 3.4%	r = .93
Douglas bags[7]	1,534 vs. 1,525	- 0.6%	r = .97
Douglas bags[15]	1,518 vs. 1,494	- 1.67%	r = >.90
Douglas Bag [16-17]	1,460 vs. 1,477	+ 1.2%	r = .91
Sensormedics 2900 VH [8]	1,530 vs. 1,559	+ 1.2%	r = > .90
Delta Trac VH[10-12]	1,551 vs. 1,558	+ 0.4%	r = .93
Delta Trac VH [13-14]	1,486 vs. 1,491	+ 0.3%	r = .94
Delta Trac VH [15]	1,484 vs. 1,494	+ 0.4%	r = > .90
Vmax 29N [15]	1,451 vs. 1,494	+ 2.9%	r = > .90

References:

1. HealtheTech Technical Report #1 – Validation of the Metabolic Simulator, “Metabolizer.”
2. HealtheTech Technical Report #2 – Comparison of the BodyGem to a Mechanical Simulation Device.
3. Nieman DC, Trone G, Austin M. “Validation of a New Handheld Device for Measuring Resting Metabolic Rate” NAASO abstract – Quebec City, Canada October 2001.
4. Nieman DC, Trone G, Austin M. “Validation of a New Handheld Device for Measuring Resting Metabolic Rate” Nutrition Week, San Diego, CA. Feb. 2002.
5. Nieman, David C., Trone, Greg A. and Austin, Melanie D.,”A new handheld device for measuring resting metabolic rate and oxygen consumption.” Journal American Dietetic Association 2003:103 (May), 588-593.
6. HealtheTech Technical Report #4 - MedGem vs. Douglas Bag Validation, February, 2002.
7. Murphy, O.F. and Kearney, J.T. “Validation of the MedGem device for measuring resting metabolic rate”. Abstract May 2004 ACSM Conference, Indianapolis, IN.
8. Melanson, Edward L. et al, “Validation of the BodyGem Hand-Held Indirect Calorimeter.” Nutrition Week, 2003, San Antonio, TX. Nutrition Week; Program Guide and Abstracts, p.102.
9. Melanson, E.L. et al., Validation of the BodyGem hand-held calorimeter. International Journal of Obesity 2004: 28, 1479-1484.
10. St-Onge, Marie-Pierre et al. “Energy Expenditure Measured with a Novel Hand-Held Device is Similar to Calorimetry Equipment.” 2003, Obesity Research, Spring, 2004.
11. St-Onge, Marie-Pierre et al. “Energy Expenditure Measured with a Novel Hand-Held Device is Similar to Calorimetry Equipment.” Presented at the Canadian Society of Clinical Nutrition, Vancouver, and Feb. 2003.
12. St-Onge, Marie-Pierre, et al., “Energy Expenditure Measured with a Novel Hand-Held Device Is Similar to That Using Traditional Indirect Calorimetry Equipment”, Presented at NAASO, Oct 11-15 Ft. Lauderdale, FL; Obesity Research 11 (Sept.) A60, Supplement, 2003.
13. Stewart, C., Branson, R., Goody, C.M., “A Comparison of Two Systems for Measuring Energy Expenditure”. Abstract Jan 2005 ASPEN conference, Orlando, Florida.
14. Stewart, C., Branson, R., Goody, C.M., “Comparison of Two Systems of Measuring Energy Expenditure.” Journal of Parenteral and Enteral Nutrition 2005:29 (May/June), 212-217.
15. Storer, T.W., et al. “Validation of the MedGem Device for Measurement of Resting Metabolic Rate”, Abstract May 2004 ACSM Conference, Indianapolis, IN.
16. Nieman, DC, et al. **“**Validation of a new handheld device for measuring resting metabolic rate and oxygen consumption in children.” Presented at the North American Association for the Study of Obesity 2004 Annual Meeting, Las Vegas, Nevada, November 15-17, 2004.
17. Nieman, DC, et al. Validation of a new handheld device for measuring resting metabolic rate and oxygen consumption in children. International Journal of Sports Nutrition and Exercise Metabolism 2005: 15, 186-194