A Systematic Review on the accuracy and reliability of the MedGem® / BodyGem® Indirect Calorimeter for Assessing Resting Metabolic Rate in Adults & Children

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Abstract

With the number of individuals becoming overweight or obese, healthcare professionals are in need of accurate, reliable, and convenient tools to help personalize weight loss programs. Recently, a new indirect calorimeter (i.e. MedGem / BodyGem; aka "Gem") was introduced as a convenient solution to determine resting metabolic rate (RMR) for assessment of daily energy needs. Several validation and comparison studies were conducted to determine if the Gem device is accurate and reliable. A total of 1 mechanical and 14 human studies (N=12 adult, N=2 pediatric) were performed from 2002-2006. Twelve of the human studies conducted RMR measurements in a counter-balance fashion or randomized order. All studies used similar design methodologies (i.e., morning measurements, 4-12 hour fast, abstinence from nicotine and stimulants for 2 hours, abstinence from exercise for 12-24 hours, 15-30 minute rest period prior to the initial RMR measurement). In all Douglas Bag (N=5) validation studies the Gem device was not significantly different to the DB system (mean difference: adult $\pm$ 1.53%, pediatric $\pm$ 1.15%). The intraclass reliability of the Gem ranged 0.97-0.98 and the interclass reliability of the Gem device to the DB system ranged 0.91-0.97. Though few (N=3) studies have demonstrated significantly different findings when compared to classic metabolic carts, the majority of the comparison studies (N=7) demonstrate the Gem device to be accurate and reliable when compared to classic metabolic carts. Based on these data, the Gem device appears to be a valid, reliable, and convenient indirect calorimeter for the assessment of RMR.

Introduction

The obesity epidemic is continuing to rise in the United States. Over the past four decades the average weight of a typical US adult has increased by approximately 11.4 kilograms (i.e. 25 pounds) [1]. As a result of this weight increase, over 65% of the US adult population is now classified as overweight or obese [2]. Children are also facing a similar obesity issue. Nearly 35% of the US children are classified as overweight or obese [3]. Unfortunately, the obesity epidemic will only continue to increase. It is projected by the year 2010 the percentage of obese individuals will increase 5% and normal weight individuals will decrease 4% [4] Due to the growing obesity problem, effective weight management solutions are needed to slow the problem.

Currently, most weight management programs follow industry guidelines for treating obese individuals. The major components for treating overweight and/or obese individuals involve a low calorie-low fat diet, increased physical activity, and behavior modification. An interesting component of the low calorie-low fat diet is based on a fixed calorie amount for most individuals (i.e., 1000-1200 kcal/day for women and 1200-1600 kcal/day for men) [5]. However, these low calorie diet programs are often difficult to follow and weight regain is problematic. Approximately 50-70% off individuals who attempt to lose weight will either drop out of a structured weight loss program or regain the weight [6]. Secondly, As a result of failed weight loss attempts, obesity experts believe repeated dietary interventions and weight cycling may lead to eating disorders (i.e. binge-eating, anorexia, and/or bulimia) in some individuals [7, 8]. Individuals who participate in weight management programs that are designed for the participant to chose a personal calorie level results in better program adherence and long-term weight maintenance than following a traditional low-calorie-low fat diet program [9]. Based on these factors, weight management professionals should personalize the nutrition plan to increase the possibility of program adherence and long-term weight maintenance.

Currently, most weight management professionals who attempt to personalize a diet plan use an estimation equation to determine daily energy needs. These estimations often use basic

demographic information (age, height, weight, and gender) to determine RMR. RMR accounts up to 75% of total energy expenditure (TEE) in most individuals [10]. However, many of the equations are significantly inaccurate in majority of the population [11, 12]. The most commonly used estimation equation, weight-adjusted Harris-Benedict (HB), has an error rate of 74% when compared to an actual measurement of RMR [12]. In an earlier study comparing individuals with similar demographics, the inaccuracy of the HB equation could be as high as 450 kcal/day [13]. As a result of these significant inaccuracies, the American Dietetics Association (ADA) has issued clinical guidelines for assessment of nutritional needs and recommend the use of indirect calorimetry over estimation questions for determining RMR [14, 15].

Though indirect calorimetry is recommended over estimation equations, the practical use of a traditional indirect calorimetry system is limited. The cost (i.e. $30,000-50,000) and technical expertise needed to accurately operate most indirect calorimeter systems is a deterrent for assessing energy needs in a weight management program. Secondly, the time needed to assess resting metabolic rate (RMR) is approximately 30 minutes per individual [16]. Recently, a new device called MedGem® (Figure 1), 510K class II medical device, and sister device BodyGem® (Microlife USA, Dunedin, FL*) were introduced as an alternative to traditional indirect calorimetry systems for assessing RMR. The Gem is an indirect calorimeter that is a fraction of the cost (i.e. $1,800- $2,500 USD) and appears to be easier to operate by health professionals. Finally, the device requires a 5-10 minute measurement time in contrast to 15-30 minutes required by traditional indirect calorimeters [15].

The Gem is designed to be used as a stand-alone device and displays RMR in calories/day and VO_2 in milliliters/day at the conclusion of the measurement. The Gem is auto-calibrated prior to each measurement (a 5-second interval during which the flow sensors are set). The Gem is programmed to begin collecting data when the first breath is detected and continues until either a steady state or 10 minutes is reached. In this process the data collected during the first 2 minutes is not used for calculation of steady state. Sensors measure relative humidity, temperature and barometric pressure for use in internal calculations that derive RMR. Oxygen concentration in the inspired and expired airflow is measured by a proprietary fluorescent quenching sensor. The principle of operation is based on the deactivation of ruthenium in the presence of oxygen. The active and reference ruthenium cells are excited by an internal light source and fluoresce. This

* Microlife purchased the assets to MedGem and BodyGem from HealtheTech, Inc.

Figure 1. MedGem® Indirect Calorimeter.

reaction is quenched by the presence of oxygen, and the amount of quenching is proportional to the concentration of oxygen. The volume of inspired and expired air is measured using ultrasonic sensing technology. There is a transducer at each end of the flow tube that emits sound pulses. The transmission time from the sending to the receiving transducer is increased or decreased in proportion to the rate and direction of gas flow. The Gem uses standard metabolic formulas to calculate oxygen uptake. RMR is calculated from oxygen consumption and a fixed respiratory quotient (RQ) of 0.85 using a modified Weir equation [17].

The Gem device has been validated against the “gold standard”, open-circuit, Douglas Bag-based (DB), indirect calorimetry system. The DB system is referred to as the gold standard because each variable is measured independently via calibrated and traceable instrumentation. The Gem also has been compared to following systems

1. The Metabolizer (HealtheTech, Inc.; Golden, CO)
2. DeltaTrac (Datex-Ohmeda; Madison, WI)
3. Sensormedics 2900 (VIASYS Healthcare; Yorba Linda, CA)
4. Sensormedics Vmax 29N (VIASYS Healthcare; Yorba Linda, CA)

Several studies, internal and external, were conducted to determine the accuracy and reliability of the Gem device. The purpose of this white paper is to provide a comprehensive review of published and presented human studies used to evaluate the validity and reliability of the Gem device in adults and children. The varying approaches, methodologies and reference systems employed in these studies are presented along with the major findings.

Methodology

A search was conducted on PubMed using the following keywords; BodyGem and MedGem. Results from the search yielded a total of 11 published studies; 8 MedGem [18-25] and 3 BodyGem [26-28]. Next a search was conducted to determine abstract presentations for the MedGem and BodyGem device. A search was conducted at the American College of Sports Medicine's website and results indicate 2 published abstracts [29, 30]. Finally, contact was made with previous HealtheTech employees and 2 HealtheTech internal technical reports were provided for further review [31, 32].

Results

From all 14 human studies, a total of 543 adults and 159 children participated in Gem validation and comparison studies. A mixed representative number of male and females were used for the studies. The average age and BMI of the adult participant was 39.9 years (range 19-86 years) and 25.4 kg/m^2 (range 14-56.2 kg/m^2). The average age and BMI of pediatric participants was 10.8 years (range 5-17 years) and 19.9 kg/m^2 (range 13-38.4 kg/m^2).

Twelve of fourteen studies used a counterbalanced and/or randomized measurement process to eliminate measurement bias between the Gem device and reference system. Two studies first conducted the reference system measurement followed by the Gem measurement [21, 24]. All studies followed similar pre-measurement conditions by conducting RMR measurements in the morning following 1) 4-12 hour fast, 2) 2 hour abstinence from nicotine and stimulants 3) 12-24 hour abstinence from exercise or strenuous physical activity, and 4) a 15-30 minute rest period prior to the initial RMR measurement.

Gem vs. Metabolizer System

The Gem device was first validated against a system called the Metabolizer 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 was provided from a tank of calibration gas that was heated and humidified before being "expired" through the Gem device. The 'Metabolizer' simulates a range of RMR values by varying breathing frequency, tidal volume and expired gas concentration [33]. 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. The mean difference of the RMR measured by the twenty-two devices ranged less than 36 kilocalories, and the coefficient of variation averaged 1.45%. The intraclass reliability was 0.98 and interclass reliability was 0.90 [32]. Descriptive statistics of the 22 devices are presented in Table 1.

Unit #	Mean (Kcals)	StdDev	CV (%)
310	1236	9.76	0.8
333	1217	12.54	1.0
448	1330	16.33	1.2
391	1290	14.14	1.1
319	1253	9.51	0.8
276	1189	14.64	1.2
293	1250	12.91	1.0
148	1220	14.14	1.2
284	1293	11.13	0.9
367	1242	4.08	0.3
174	1233	33.86	2.7
153	1300	30.33	2.3
274	1313	28.75	2.2
220	1295	20.74	1.6
208	1215	29.50	2.4
192	1352	25.63	1.9
218	1338	16.02	1.2
311	1370	21.91	1.6
378	1250	35.78	2.9
351	1347	16.33	1.2
376	1272	11.69	0.9
223	1190	16.73	1.4
Mean	**1272.45**	**N/A**	**1.45**
StdDev	**53.80**	**N/A**	**0.68**

Table 1. Means, standard deviations and coefficient of variation (CV) across trials of BodyGem units [32].

Gem vs. Douglas Bag

The Gem device has been validated against the "gold standard" in 5 different studies (4-adult, 1-pediatric). The mean difference between the Gem device and DB system from the 4-adult studies is 1.53% (1582 kcal/day. 1572 kcal/day). Mean intraclass reliability coefficients of the Gem device is 0.98. Of the 4-published studies, three provided interclass reliability results [28, 30, 31]. Mean interclass reliability is 0.94 (range 0.91-0.97). Detailed results from all DB studies are presented in table 2.

The first Gem vs. DB study was conducted by HealtheTech [31]. Researchers at HealtheTech recruited 32 adult subjects. All subjects were tested four times each on two separate days. The overall mean oxygen uptake was 225.6 $\pm$ 53.2 ml O_2/min

(approximately 1566 kcal/day) and 234.8 ± 58.3 ml O_2/min (1621 kcal/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 interclass reliability of the internal study was 0.93 [31].

A second study was conducted by Nieman, et al. (2003). Sixty-three subjects (age 21–69 years, BMI 19.1-56.2 m/kg^2) were recruited for the study. Subjects were tested during two separate sessions within a 2-week period. The data indicated a mean RMR difference of less than 1 percent between the Gem and DB. The interclass correlation between the performance of the Gem device and the DB was 0.91. 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 intraclass reliability of the Gem device was 0.98 [28].

Two additional adult studies were conducted by Murphy, et al (2004) and Storer, et al (2004). Results from both studies were similar to previous studies and are listed in Table 2.

Nieman, et al (2005) followed-up with a second study. However, the hypothesis of the study was to determine if the Gem device is accurate and reliable in the pediatric population. Researchers recruited 59 children (N=29 males, N=30 females) ranging in age from 7 to 13 years (mean age, 11.0 ± 0.2 years) for the study. The data indicated a 1.2% difference between the DB (1460 ± 39 kcal/day) and the Gem device (1477 ± 35 kcal/day). Intraclass reliability of the Gem device was 0.94 and the interclass reliability between the DB and Gem device was 0.91.

Table 2. Comprehensive Results of Published and Non-Published Gem Validation Studies.

Adult Study	Reference System	Subjects	Age	BMI	Gem RMR	Ref RMR	Accuracy	Intraclass Reliability	Interclass Reliability
Nieman, et al (2003)	Douglas Bag	63	41	26.5	1657	1650	0.42%	0.98	0.91
Storer, et al (2004)	Douglas Bag	54	32	26.5	1494	1518	- 1.70%	0.98	NA
Murphy, et al (2004)	Douglas Bag	32	NA	NA	1525	1534	- 0.59%	0.97	0.97
HealtheTech, Inc. (2002)	Douglas Bag	32	NA	NA	1566	1621	- 3.39%	0.97	0.93
	Douglas Bag Totals	***181***	***36.65***	***26.50***	***1572***	***1587***	***- 1.53%***	***0.98***	***0.94***
Liou, et al (2006)	DeltaTrac	30	42	24	1179	1135	3.97%	0.96	0.76
St.Onge, et al (2004) [a]	DeltaTrac	15	36	31.7	1551	1558	- 0.45%	NA	0.93
Stewart, et al (2005)	DeltaTrac	50	36	25.9	1491	1486	0.34%	NA	0.94
Storer, et al (2004)	DeltaTrac	54	32	26.5	1494	1484	0.67%	0.98	NA
Hlynsky, J., et al (2005) [a]	DeltaTrac	15	35	23.1	1397	1519	- 8.01%	NA	0.60
Hlynsky, J., et al (2005) [a, b]	DeltaTrac	12	33	21.2	1243	1369	- 9.20%	NA	0.04
Alam, et al. (2005)	DeltaTrac	37	28	20.8	1390	1277	8.84%	NA	0.80
Compher, et al. (2005)	DeltaTrac	24	47	21.8	1298	1446	-10.24%	NA	NA
	DeltaTrac Totals	***237***	***41.23***	***27.86***	***1578***	***1610***	***- 2.0%***	***0.97***	***0.69***
Storer, et al. (2004)	Sensormedics Vmax 29N	54	32	26.5	1494	1451	2.96%	0.98	NA
Reeves, et al (2005) [c]	Sensormedics Vmax 29N	15	65	28.4	1351	1526	- 11.47%	NA	NA
Reeves, et al (2005)	Sensormedics Vmax 29N	15	60	26.3	1258	1371	- 8.24%	NA	NA
	Sensormedics Vmax Totals	***84***	***52***	***27.07***	***1368***	***1449***	***- 5.6%***	***0.98***	NA
Melansen, et al (2004)	***Sensormedics 2900 VH***	***41***	***40***	***26.1***	***1559***	***1530***	***1.90%***	***.90***	***0.92***

Table 2. Comprehensive Results of Published and Non-Published Gem Validation Studies (Cont.)

Pediatric Study	Reference System	Subjects	Age	BMI	Gem RMR	Ref RMR	Accuracy	Intraclass Reliability	Interclass Reliability
Nieman, et al (2005)	Douglas Bag	59	11	20.1	1477	1460	1.15%	0.94	0.91
Fields, et al (2006)	DeltaTrac	100	11	19.6	1395	1349	3.30%	0.99	NA
	Totals	***159***	***10.8***	***19.85***	***1436***	***1405***	***2.22%***	***0.97***	***0.91***

[a] Subjects were not randomized or counter balanced prior to measurement (Measurement 1: DT system, Measurement 2: Gem device)..
[b] Anorexia Nervosa patients
[c] Cancer patients

Gem vs. DeltaTrac, Ventilated Hood

The DeltaTrac (DT) ventilated hood indirect calorimeter system is one of the most utilized "classic" metabolic carts. "Classic" respiratory metabolic carts measure oxygen consumption (VO_2) and carbon dioxide production (VCO_2) and automatically calculate energy expenditure (EE), along with the respiratory quotient (RQ) [16]. The DT system has been validated in two separate studies and results indicate the DT system is accurate and reliable for assessment of EE in healthy and ventilated patients [34, 35].

A total of 8 studies (7-adult, 1-pediatric) comparing the Gem device to the DT system were conducted between 2004 and 2006. The mean difference in RMR between the Gem device (1578 kcal/day) and DT (1610 kcal/day) in the adult studies is 2% with a range between -10% to + 3%. Mean intraclass reliability of the Gem device is 0.98 and mean interclass reliability of the Gem device to the DT system is 0.69 (range 0.04 -0.94).

The first Gem vs. DT study was conducted by St. Onge, et al (2004). Researchers recruited 15 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.

The results indicated no statistically significant difference in either RMR or TEF with the two systems. Average resting energy expenditure measurements with DT and MG were significantly correlated (r = .93). There was no significant difference in average RMR between the two methods (1551.2 ± 106.9 kcal/day vs. 1557.9 ± 85.6 kcal/day, for DT and MG, respectively) [24].

Storer, et al (2004) conducted a second study comparing the Gem device to the DT system. Fifty-four adults (29 women, 24 men) aged 20 to 50 completed the study. Subjects were measured sequentially with Gem, DT, Sensormedics Vmax SMVM) system and DB. The Weir equation was used throughout with an adjustment for the urinary nitrogen based on an assumption of protein intake representing 16% total Kcal per day [29]. Mean differences in RMR between the Gem (1494 $\pm$ 252 kcal/day) and DT (1484 $\pm$ 247 kcal/day) was 0.67%. The intraclass reliability among the four instruments was 0.978 (95% CI = 0.966 to 0.986)[29].

Alam, et al (2005) conducted a third study comparing the Gem device to the DT system. A total of 37 nonpregnant, nonlactating women, aged 27.6 $\pm$ 4.5 y, BMI 20.8 $\pm$ 3.1 kg/m^2 participated in the study.

Results of the study indicated a mean oxygen consumptions measured with the Gem device were (200 $\pm$ 30 and 200 $\pm$ 26 ml/min) for session 1 and 2, respectively. Mean oxygen consumptions measured with the DT system for these sessions were (184 $\pm$ 20 and 178 $\pm$ 18 ml/min), respectively. There were no significant difference between sessions with the Gem device; however measurements with the DT were significantly different between session 1 and session 2 ($p \leq 0.05$). RMR measured by Gem was higher (mean 1390 $\pm$ Kcals/day) compared to DT measurements (1277 kcal/day and 1234 kcal/day respectively). Interclass reliability of DT and Gem device were 0.80 (p= 0.01) for session 1 and 0.75 (p=0.01) for session 2. Within-subject between-session reproducibilities were 8.2 and 4.5% for the Gem and DT, respectively (P=0.01) [25].

Compher, et al (2005) assessed whether the Gem device was accurate and reliable when compared to the DT in 24 stable home nutritional support adults.

Results of the study indicated the mean difference between two Gem measures was 0.5% with limits of agreement between 233 and -247 Kcals/day. The mean difference between the DT (1446 $\pm$ 286 kcal/day) and mean of two Gem measures (1298 $\pm$ 202 kcal/day) was -162 kcal/day, with limits of agreement between 577 and -253 Kcals/day [23]. In all, 80% of the repeated Gem device RMR measures agreed within 10%, and the mean Gem device reading agreed with the DT in 60% of cases.

Hlynsky, et al (2005) investigated if the Gem device compared to the DT system in Anorexia Nervosa (AN) patients. Researchers recruited 12 AN

subjects (32 ± 8 years; BMI 21.1 ± 6.6 kg/m^2) and 15 healthy subjects (35 ± 9 years; BMI 23.1 ± 3.4 kg/m^2). Subjects were measured with the DT, ventilated hood, and system in a supine position followed by a Gem measurement in an upright position.

Results from the study indicate the mean RMR difference was significant for both subject groups. The mean RMR for AN subjects for the DT system was (1369 ± 236 kcal/day) and for the Gem device (1243 ± 263 kcal/day) ($p \leq .05$). The mean RMR measures with the healthy subject group were significantly higher with the DT system (+ 121 ± 3.4 Kcals) ($p < .05$) [21]. Interclass reliability was 0.04 for AN subjects and 0.60 for healthy subjects.

Stewart, et al (2005) designed a unique study comparing the Gem device to the DT system. All previous studies compared separate measurements. Stewart and colleagues designed an apparatus to simultaneously compare the Gem to the DT system (Figure 2) to eliminate measurement variability [19]. Fifty subjects, (12 men and 38 women), were tested simultaneously with both the Gem device and DT.

The mean oxygen consumption and RMR did not significantly differ between the two devices, with a mean difference of 0.58 ± 15.33 ml/min ($p = 0.790$) and 4.66 ± 113.39 kcal/day ($p = 0.773$) and an absolute difference of 12.3 ± 8.99 ml/min and 86.58 ± 72.32 kcal/day, respectively. Interclass reliability of the Gem device and DT was 0.94.

The final adult Gem vs. DT study was conducted by Liou, et al (2006). Thirty women were recruited for the study and had a mean age of 42.0 ± 9.0 years old and a mean BMI of 24.0 ± 2.8 kg/m^2. Results of the study indicate no significant difference ($p=0.40$) between the mean Gem trials (1179 ± kcal/day) and DT system (1135 ± 136 kcal/day) when the researchers adjusted RMR for holding the Gem device.

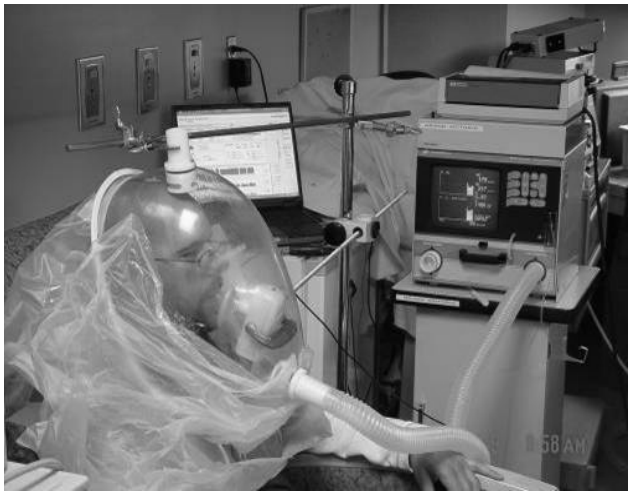

Figure 3. Photograph of a subject during simultaneous measurement with the DT & Gem (held by a C-clamp under the canopy) [19].

The interclass reliability of two Gem measurements and DT system was 0.96.The Gem measurements were conducted in an upright position and DT measurements were conducted in a supine position.

The mean Gem RMR (1452 ± 355 kcal/d) was significantly higher than DT REE (1349 ± 296 kcal/day, $p < 0.001$). Bland-Altman analysis revealed a mean bias (Gem - DT) of 104 kcal/day, with limits of agreement of -241 to + 449 kcal/day. To examine the difference in subject positioning, an independent sample of 38 subjects performed a measurement with the Gem in its normal position (sitting) and holding the Gem in a supine position. RMR by the Gem in the sitting position (1475 ± 350 kcal/day) was significantly ($p \leq 0.05$) higher than the Gem in the supine position (1419 ± 286 kcal/day) [18]. Taking into account the cost of sitting, the original Gem data was adjusted and recalculated. RMR by the Gem device (1395 ± 355 Kcals/day) was still significantly higher ($p = 0.01$) than DT (1349 ± 296 kcal/day) but within the 3-5 % allowance of repeatable measures [15].

Gem vs. Sensormedics 2900 & Vmax Systems

Melansen, et al (2004) compared the Gem device to the Sensormedics 2900 (SM2900) system. Forty-one healthy adults participated in the study. RMR was measured twice on two different mornings. Individuals were measured in a supine position with SM2900 and seated upright with the Gem device.

The initial analysis of the data indicated that RMR measured with the Gem device was about 80 Kcals/day (approximately 5 percent higher) than RMR measured with SM2900 during both trial 1 (mean difference, 85 ± 18 kJ/day, P=0.0001) and trial 2 (72 ± 19 kJ/day, P=0.0001) [27]. However, upon review of the test methodology, it was determined that the position used for testing with the Gem device was 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 holding the Gem in an upright position. It was determined that the energy cost of holding the Gem device was approximately 60 Kcals/day [27]. After accounting for the estimated energy cost of holding the Gem the device the differences between the SM2900 and Gem were no longer significant during trial 1 (1531 ± 39 vs. 1555 + 36 Kcals/day, respectively) or trial 2 (1531 ± 39 vs. 1541 + 40 kcal/day, respectively). The results indicated strong agreement in RMR measured by the Gem device or the SM2900. The intraclass reliability coefficients were above 0.90 for both the devices. Additionally, the interclass reliability of RMR measured with the Gem and the SM2900 was 0.92.

Reeves, et al. (2005) conducted another study comparing the Gem device to the SMVM system. Researchers recruited cancer patients and healthy subjects for the comparative study. Cancer patients had histological proven solid tumors. Subjects were also excluded if they had undergone surgery within

the month prior to the study, had severe endocrine abnormalities (e.g. hypothyroidism, hyperthyroidism), or were treated with high-dose steroid medications. All healthy subjects were in self-reported good health, did not have a history of cancer or severe endocrine abnormalities, had not undergone surgery within 1 month of the study, and were not treated with high-dose steroid medication [20].

Results from the study indicated the mean bias (Gem vs. SMVM) was 10% and limits of agreement (± 2 standard deviations) were -42 to 21% for cancer patients; mean bias -5% with limits of -45 to 35% for healthy subjects. Less than half of the cancer patients (n = 7, 46.7%) and only a third (n = 5, 33.3%) of healthy subjects had measured RMR by Gem within clinically acceptable limits of SMVM. Measured RQ By SMVM was considerably lower for both cancer patients (0.71) and healthy subjects (0.72) compared to the assumed RQ of 0.85 with the Gem device [20].

Discussion

Due to the obesity problem, accurate and reliable tools are needed for appropriate energy assessment to personalize an individual's nutritional plan. Previously, indirect calorimetry was unavailable and/or impracticable for assessment of energy needs for personalized weight management plans. Now, technology is available to easily assess energy needs for individuals with weight management goals. Due to the recent established guidelines for determining energy needs [14], simple and affordable indirect calorimeters are needed for clinicians. The Gem device provides a simple and affordable solution compared to the DB system and classic metabolic carts.

In all, the Gem device has been validated against the "gold standard" in 5 studies. Results from these studies suggest the Gem device to be accurate and reliable for assessment of resting oxygen consumption and resting metabolic rate in adults and children [22, 28-31].

The Gem device has been compared to 4 different indirect calorimetry systems in 11 studies. Four of these studies suggest the Gem device is not accurate as the referenced system [20, 21, 23, 25] and the remaining 7 studies suggest the Gem device to be accurate and reliable as compared to the referenced system [18, 19, 24, 26, 27, 29, 30].

After reviewing the study design for each study, it was observed that the common design included 1) morning measurements, 2) overnight or 4-12 hour fast, 3) abstinence from nicotine and stimulants for 2 hours, 4) abstinence from exercise for 12-24 hours, 5) 15-30 minute rest period prior to the initial RMR measurement, and 6) reference system measurements were conducted in a supine position compared to a seated position with the Gem device. Melanson, et al (2004) indicated the seated position while holding the Gem device results in an approximate 60 kcal/day increase in RMR when compared to the supine position. Fields, et al (2006) also indicated the seated position holding the device results in approximately 55-60 kcal/day increase in RMR when compared to holding the Gem device in a semi-recumbent position. These results confirm an earlier study indicating sitting upright results in a 70 Kcal/day increase in RMR versus a supine position [36].

Compher, et al (2005), Alam et al (2005), and Hlynsky, et al. (2005), had subjects in either a supine position or semi-recumbent position for the reference system measurement compared to a seated upright position holding the Gem device. Reeves, et al (2005) did not indicate if subjects were in a seated, semi-recumbent, or supine position for the reference system measurement. If adjusting for the caloric demands of holding the Gem device in a seated position (i.e., 60 Kcals/day), the data from Alam, et al (2005) may not have been significantly different (i.e. adjusted mean Gem RMR: 1330 Kcals/day vs. 1277 Kcals/day).Though the results would indicate a 4% difference, the allowable critical value difference for repeated measures is 3-5% [15]. Therefore, the Gem device may be as accurate and reliable (r=0.80) when compared to the DT system in this study.

The results from Compher, et al (2005) would widen the mean RMR difference between the Gem and reference system. As a result of this adjustment, the Gem device is not as accurate when compared to the reference system. However, researchers did indicate the Gem device readings have adequate reproducibility and acceptability for patients [23].

St.Onge, et al (2004) and Hlynsky, et al (2005) first measured all subjects with the DT system followed by the Gem device. This method did not result in a significant difference in RMR between the Gem and DT system in the study conducted by St.Onge, et al (2004). However in the study conducted by Hlynsky, et al (2005) all Gem RMR measurements were substantially lower across both subject groups when compared to the DT system [25]. Even if the adjustment of 60 kcal/day were made for each Gem measurement, the mean difference would widen. The study conducted by St.Onge, et al (2004) had similar subject positioning and therefore no adjustment of RMR positioning was needed.

To eliminate the within-subject variability from repeated measures and different measurement positioning, Stewart, et al (2005) assessed the accuracy of the Gem device to the DT system during simultaneous measurements. The mean difference for RMR was 4.66 ± 113.39 kcal/day. When all variables (i.e., repeatable measurements and subject positioning) can be controlled, the Gem device appears to be as accurate and reliable.

The large differences between the Gem device and reference system in the Compher, et al (2005) and Reeves, et al (2005) studies may be the result of three factors; 1) undetected air-leaks by the Gem device, 2) reference system and/or Gem device inaccuracies, and/or 3) a fixed RQ of 0.85.

In contrast to a reference system using a ventilated hood, the Gem device uses a disposable mouthpiece (Figure 3) and a disposable noseclip similar to the mouthpiece of a snorkel. The Gem device provides an error code (Err 01) when the Gem device detects an air leak [37]. To remedy the error, the clinician should (1) make sure the subject's mouth is sealed completely around the mouthpiece, (2) ensure that the noseclip is across the subject's nose, eliminating any air passing through the nostrils, and (3) breathing is done through the mouth. However, the device may not always detect an air-leak if the subject is able to provide enough air-flow for the sensors to measure the amount of oxygen during respiration. In these instances, the device will determine RMR from the low air flow and the measurement will be lower due to the low air-flow. Due to the design of the Gem device, clinicians are unable to determine if an air-leak may have occurred. However, the manufacture does provide a software program called MedGem® / BodyGem® Analyzer that enables a clinician to monitor real-time breath-by-breath data. The Analyzer software may be used to monitor potential air-leaks by evaluating real-time breath-by-breath data.

Another possible reason for the RMR discrepancies between the Gem device and reference system is one or both devices were out of calibration. Compher et al (2005) acknowledged this possibility due to the age of the oxygen sensor in the DT system (i.e. 15 + years) versus the oxygen sensor in the Gem device being only a few years old. All reference systems (i.e. DT, SM2900, SMVM) have been validated in previous studies with the DB system. The Gem device also has been validated against the DB system. So, the technology of each reference system and Gem device has demonstrated accuracy and reliability when compared to the "gold standard." However, the Gem devices and reference systems used in the DT, SM2900, and SMVM studies were not the same devices used in the previous validation studies. Therefore, it is possible that the Gem device and/or the reference system were not in calibration resulting in a significant difference between RMR measurements.

Finally, it has been suggested that the Gem's fixed RQ of 0.85 may result in a significant difference when compared to using the actual RQ [20, 21]. However, An RQ of 0.85 is generally considered or expected to indicate appropriate energy provision in a patient on a mixed-fuel regimen [38]. As noted by Holdy (2004) "within the RQ range of 0.70 to 1.0 assuming a fixed RQ of 0.85, measuring only VO^2 may result up to a $\pm$ 4% error rate." Secondly, if an RQ is below 0.70 and above 1.0 the measurement may be invalid due protocol violations or inaccuracy in the gas

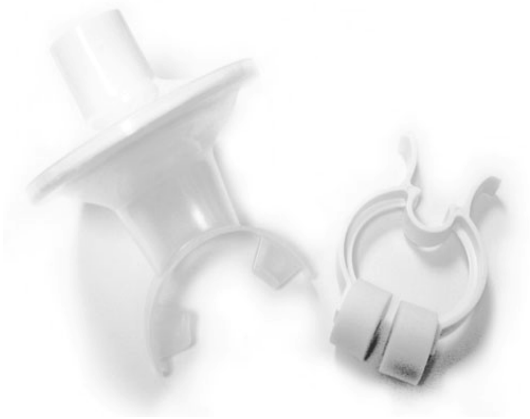

Figure 4. Photograph of a disposable mouthpiece and noseclip.

measurements [15]. Therefore, using a fixed RQ of 0.85 should not result in a significant difference when determining RMR in most individuals.

In conclusion, the Gem device has been tested in 1 mechanical and 14 different human studies employing each of the methodologies typically used in clinical or research settings. When comparable methodologies are used for validating or comparing the Gem device to a referenced indirect calorimeter, the Gem device appears to be accurate and reliable for determining RMR. Based on this comprehensive review, the Gem device may provide clinicians and researchers a viable solution for an accurate assessment of energy needs for developing nutritional plans for most adults and children.

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