

Clinical Study

Validation of a Novel Physical Activity Assessment Device in Morbidly Obese Females

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Assessment of physical activity in morbidly obese subjects is important especially in bariatric surgery. We examined the validity of Intelligent Device for Energy Expenditure and Activity (IDEEA) for measuring physical activity and sedentary behavior in morbidly obese women. Activity types, gait counts, and speed detected by the IDEEA monitor were compared to those reported by an observer. The IDEEA monitor detected activity types and gait counts with relatively high accuracy, although slightly lower in extremely obese women than in normal weight controls. The IDEEA monitor accurately estimated gait speeds in both groups. Since gait speed predicts energy expenditure more accurately than gait counts, it is of greater clinical relevance. Reliability of the IDEEA monitor was excellent. The IDEEA monitor is a valid instrument for measuring physical activity and sedentary behavior in extremely obese women, and therefore has potential applications in bariatric surgery both in preoperative evaluation and long-term follow-up.

1. Introduction

The Intelligent Device for Energy Expenditure and Activity (IDEEA) is a novel device for the assessment of physical activity [1, 2]. Compared to devices used commonly for the assessment of physical activity in the free living state, the IDEEA monitor has the unique capability of detecting both the type and duration of physical activity [3, 4]. Using piezo-electric sensors on the chest, thighs, and feet, the IDEEA monitor is capable of differentiating sedentary postures (e.g., sit, stand, lie, etc.) and active gaits (e.g., walk, ascend stairs, etc.) [2]. By measuring the duration of each of these types of activity, the IDEEA monitor is able to compute the energy expenditure of the subject using preprogrammed mathematical formulae. The IDEEA monitor is the first system devised that provides reliable estimates of energy expenditure in the free living state due to its unique ability to differentiate between the types of activity

[1, 2]. Therefore, the IDEEA monitor has potential clinical and research applications in the evaluation and treatment of obesity—including weight reduction surgery in the morbidly obese.

The IDEEA monitor has been validated in physical activity studies in the general population but similar studies focusing on the morbidly obese population are lacking [1, 2]. Our long-term goal is to introduce physical activity and energy expenditure assessments in the preoperative evaluation, treatment, and long term postoperative follow-up of patients undergoing bariatric surgery. The goal of the present pilot study was to evaluate the reliability and accuracy of the IDEEA monitor in the assessment of physical activity in a morbidly obese population compared to normal weight controls. Our findings indicate that the IDEEA monitor has reasonable accuracy and excellent reliability in physical activity assessment in the morbidly obese to ratify its use in further studies in this patient population.

2. Methods

This study was a pilot study supported by the University of Iowa Clinical and Translational Science Program funded by the National Institutes of Health (Pilot Grant award to Dr. I. Samuel). All protocols used in this study were approved by the University of Iowa Institutional Review Board. Written informed consent was obtained from each subject prior to commencement of the studies. All participant studies were supervised, observed, and executed by one research coordinator (S. Kwon). Using one observer for all patients was an advantage over using a different observer for different patients to maintain consistency in the data collection. On the other hand, using a set of multiple observers uniformly for all patients would have strengthened the study by limiting interobserver variations, but this was not feasible within the scope of a “Pilot Grant” study.

2.1. IDEEA Monitor. IDEEA monitors were purchased from the manufacturer (MiniSun LLC, Fresno, CA). An overview of the IDEEA system design will facilitate a better understanding of its applications. The IDEEA monitor is a portable device the size of a pager worn at the waist (Figure 1). The monitor measures 7.5 cm × 5.5 cm × 1.5 cm, and weighs 58 grams. Five sensors are taped to the body as follows: one on the front of the chest, one on the front of each thigh, and one on each sole. The five miniaturized sensors, each the size of a thumb nail, provide continuous second-by-second signals of angle, relative position, and acceleration. These signals from the sensors are sent through a thin wire (O. D. 2 mm) to an advanced microprocessor in the device that processes the incoming data and the information is saved on a Flash Memory card. The information is then downloaded onto a peripheral computer where sophisticated algorithms and software are used to analyze these signals, so as to interpret and record the type of posture changes and body motion with details such as the onset, duration, and frequency of these activities.

The developers of the IDEEA monitor approached the complexity of daily physical activity by dividing it into four major categories [1]: (a) limb movement without locomotion; (b) five static postures (sit, stand, lean, lie, recline); (c) transitions between postures; (d) five active gaits (walk, ascend stairs, descend stairs, run, and jump). IDEEA captures movement and speed from the above described five sensor locations and translates the acceleration, movement, and angle of body parts to represent the various static postures and active gaits. In studies about the general population by Zhang et al. the data have been meticulously compared to observation of activity and measurement of energy expenditure to produce accurate predictions of time spent in different activities and of energy expended during these [1, 2].

2.2. Recruitment of Study Subjects. We recruited both morbidly obese and normal weight participants through an advertisement in the University of Iowa Hospitals and Clinics news bulletin and website. A total of 130 individuals volunteered for this study. Of these, seven volunteers were

identified as individuals suffering from morbid obesity (Body Mass Index or BMI ≥ 40 kg/m²) based on height and weight. All these seven morbidly obese volunteers were Caucasian females. In the volunteer pool, we identified seven normal weight volunteers (BMI < 25 kg/m²), who were matched with each morbidly obese participant based on age, height, gender, and race. One of the seven morbidly obese volunteers dropped out due to back pain prior to commencement of studies and was therefore excluded from the study along with the corresponding normal weight volunteer. The 12 remaining women participated and completed our studies on the validation of the IDEEA monitor; for their effort and time they received monetary incentives approved by the Institutional Review Board.

2.3. Study Protocol. Participants were asked not to have a meal two hours prior to their study visit and come with comfortable clothing and shoes for light exercise. For our device validation studies we chose two parameters for testing: (a) *accuracy* (defined as agreement between device readings and observer records), and (b) *reliability* (defined as ability of the device to detect the same posture or gait when repeated, compared to the observations of the supervising research coordinator).

To examine the accuracy of the IDEEA monitor in the measurement of physical activity *types*, five static postures (lie, sit, recline, stand, and lean) and three active gaits (walk, ascend stairs, descend stairs) were examined (Table 1). To examine the accuracy of the IDEEA monitor in the measurement of physical activity *levels*, gait count and speed were examined. Activity bout duration and sequence are detailed in Table 1. To assess the accuracy for gait count, 30 walking steps and nine steps up the stairs and nine steps down the stairs were selected to be a meaningful segment of physical activity that would represent activity in a free-living environment and to be of satisfactory duration to evaluate the accuracy of the IDEEA monitor. There were no break times between postures; whereas a 10-second period of standing still was included for the transition between active gaits.

Each study subject's height was measured and body weight was taken without shoes or heavy clothing to compute the BMI. The research coordinator placed the IDEEA monitor and sensors on each study subject, calibrated the device with the subject in the sitting position as recommended by the manufacturer, and activated the device using the IDEEA manufacturer's software [ActView Program (ActView 2), Mini Sun LLC, Fresno, CA]. Each subject wore her own shoes for the study and high heeled shoes were avoided. Each sensor was carefully positioned and then taped to the skin using Medipore hypoallergenic adhesive tape (3M; <http://www.3m.com>). Subjects were checked for comfort while walking with sensors on the soles of the feet. The posture and treadmill walking tests were conducted in an access-restricted room to avoid external interference. The room was equipped with a treadmill, hospital bed, and chairs, and the environment was controlled with respect to ambient room temperature and humidity. Each participant was studied on a separate occasion and was asked to lie down

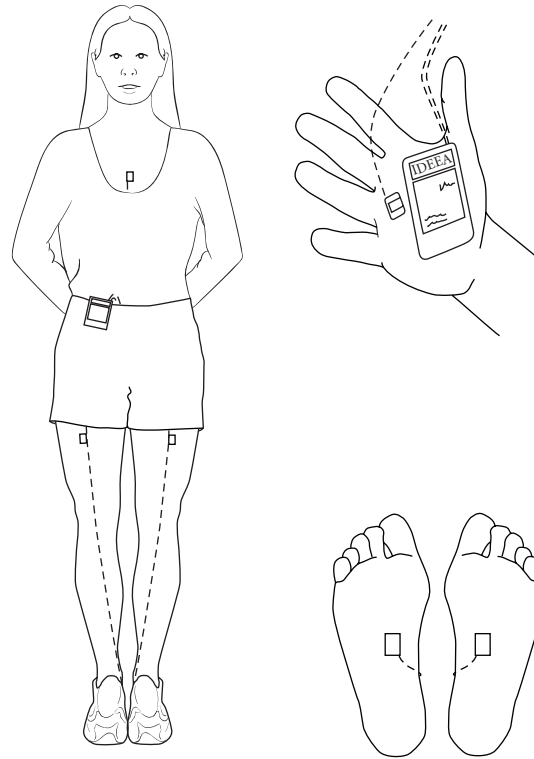


FIGURE 1: Representative diagram showing the IDEEA monitor secured to a person's waist with five sensors attached to the chest, both thighs, and the soles of both feet. The IDEEA monitor is about the size of a pager and collects data in the free-living state. Each sensor is the size of a thumb nail.

TABLE 1: Activity protocol for IDEEA monitor accuracy tests.

Sequence	Activity	Duration	Sequence	Activity	Duration/step counts
1	Lie	2 min	16	Sit	4 min
2	Sit	4 min	17	Lie	2 min
3	Recline	1 min	18	Break	5 min
4	Stand	4 min	19	Hallway walk 1	30 steps
5	Lean	1 min	20	Break (stand still)	10 sec
6	Treadmill walk 1	4 min	21	Hallway walk 2	30 steps
7	Treadmill walk 2	4 min	22	Break (stand still)	10 sec
8	Treadmill walk 3	3 min	23	Ascend stairs 1	9 steps
9	Treadmill walk 4	3 min	24	Break (stand still)	10 sec
10	Recline	1 min	25	Ascend stairs 2	9 steps
11	Stand	4 min	26	Break (stand still)	10 sec
12	Lean	1 min	27	Descend stairs 1	9 steps
13	Treadmill walk 5	4 min	28	Break (stand still)	10 sec
14	Treadmill walk 6	4 min	29	Descend stairs 2	9 steps
15	Treadmill walk 7	3 min	30	Break (stand still)	10 sec

To test the accuracy of the IDEEA monitor in the detection of postures (lie, sit, recline, stand, and lean) and active gaits (walk, ascend/descend stairs), each study participant went through a series of activities wearing the IDEEA monitor and the readings were compared to that of observations by the study coordinator.

for about 10 minutes to rest before starting the study protocol. The research coordinator fully explained the physical activity protocol and then demonstrated each of the postures followed by a second verbal explanation. The participant practiced treadmill walking and speed adjustment prior to the measurement session.

When the study protocol was commenced, each subject began in the lie posture and the observer recorded postures and concurrent time. Sitting, reclining, standing, and leaning postures were followed in the sequence described in Table 1. The subject then used the treadmill where the speed was gradually increased to 1.5 mph. Seven levels of treadmill

speed were used: 1.5, 2, 2.5, 3, 3.5, 4, and 4.5 mph, and the sequence of walking at those speeds was randomly selected. However, if a participant could not keep up with walking at a particular speed for reasons such as knee-pain, either the treadmill speed was reduced or the walking session was stopped. If the speed was too fast for a participant to walk, the participant was allowed to run. Between treadmill walking sessions (after treadmill walking at the first four different speeds), a posture test for reclining, standing, and leaning was conducted to provide rest between treadmill sessions. After the final treadmill test, one more posture test for sitting, and lying down was conducted.

After the posture and treadmill tests, a participant had a short break before the hallway walking and the ascending or descending of stairs. Each participant walked for 30 steps in the hallway followed by ascending and then descending nine steps of stairs. The hallway walk and stair protocol were repeated twice. The research coordinator observed and recorded the times of postures, activity types, treadmill speed, and gait counts throughout the protocol. The study protocol lasted about 90 minutes for each participant.

2.4. Data Analysis. SAS version 9.2 (<http://www.sas.com>; SAS Institute Inc., Cary, NC) was used for data analysis and the results were cross-checked with the R Statistical software (<http://www.r-project.org>). For analysis of physical activity types, the first and the last 10 seconds of each posture session were excluded from analysis. If the IDEEA monitor detected postures correctly during more than 90% of the time, it was regarded as detecting correctly. When the device detected less than six out of nine steps up and down stairs, it was regarded as incorrect detection of the stair activity *type*. Regarding analysis for gait counts, one case (and the corresponding control participant) whose climbing up and down activities were detected as walk by the IDEEA monitor was excluded from the stair count analysis. Means and standard deviations of the qualifying activity counts were calculated. The intraclass correlation coefficient (ICC) was used to test the reliability of gait counts by the device, and assess whether the device is more influenced by within subject variability than by between subjects variability. A mixed effect regression model was used to examine whether the device estimates walking speed accurately. This model is adequate for the speed data because we would have expected a within and a between participants' variability. The model applied has a fixed factor in speed and a random factor in participants. This model would be appropriate for an additional reason that findings would have the potential to be applied to a random population (provided an adequately sized study).

3. Results

3.1. Participant Demographics. Each morbidly obese study subject (case) was matched with a normal weight control with regard to age, height, gender, and race (Table 2). The BMI ranged between 40.8 and 56.2 kg/m² in the case group and 20.1 and 22.8 kg/m² in the control group.

3.2. Physical Activity Types. The detection accuracy of the IDEEA monitor for activity types was good (Table 3). The IDEEA monitor detected the five postures and three gaits more accurately among controls (92.7%) than among cases (82.3%), and this 10.4% difference was statistically significant (chi-square test, $P = .029$). The IDEEA monitor detected walking activity accurately in all participants, but accuracy for climbing up and down stairs was lower than for walking in both groups. In one extremely obese participant (BMI 56.23 kg/m²), the IDEEA monitor failed to detect several postures correctly by detecting "lie" or "recline" as "sit," "lean" as "stand," and "ascend/descend stairs" as "walk."

3.3. Physical Activity Levels. Results of gait count detection show that the IDEEA monitor is extremely reliable, especially for walking in both normal weight and morbidly obese individuals (Table 4). However, the accuracy of gait counts during ascent or descent of stairs was lower than during hallway walking in both groups.

3.4. Reliability. When five different postures were repeated twice (12 participants \times 5 postures = 60 pairs), 59 out of those 60 pairs were concordant. intraclass correlation (ICC) for gait counts were 0.972 among cases and 0.992 among controls.

3.5. Gait Speed Estimates. When applying the generalized linear mixed effect model, we observed that actual walking speed is well predicted by the IDEEA monitor. Approximately 95% of the variability in actual speed can be explained by the random effect model ($r^2 = 0.953$). When we further examined predictability according to the groups, the IDEEA monitor estimated walking speed accurately in both case and control groups (Figure 2, $r^2 = 0.981$ in cases, $r^2 = 0.931$ in controls). The IDEEA monitor tended to underestimate actual speed in cases but this difference was not statistically significant.

4. Discussion

We provide new evidence for the accuracy and reliability of a novel physical activity monitor, the IDEEA monitor, in detecting the type and duration of common forms of physical activity in a unique population of patients—morbidly obese females. We have compared IDEEA monitor measurements in morbidly obese females to measurements in appropriately matched controls and related the readings to that of an observer. In addition, we have also shown that the IDEEA monitor's prediction of the speed of walking compared to that measured by a treadmill is as excellent in morbidly obese females as in normal weight controls. Our findings are important because physical activity is a vital aspect of energy balance and maintenance of healthy body weight, and because physical activity assessment can contribute substantially to the diagnosis and treatment of obesity [5]. Moreover, as the IDEEA monitor is designed for use in the free living state, measurements of physical activity and computations of energy expenditure can potentially be used

TABLE 2: Participant characteristics.

Pair	Cases				Controls			
	Age (yr)	Height (m)	Weight (kg)	BMI (kg/m ²)	Age (yr)	Height (m)	Weight (kg)	BMI (kg/m ²)
1	29	1.62	108.1	41.19	31	1.61	52.0	20.06
2	32	1.65	142.3	52.27	35	1.65	60.8	22.33
3	33	1.70	117.9	40.80	32	1.68	63.5	22.50
4	46	1.65	141.0	51.79	44	1.64	61.2	22.75
5	57	1.60	111.1	43.40	55	1.59	51.0	20.17
6	58	1.68	158.7	56.23	58	1.64	60.6	22.53
Mean \pm S. D.	42.5 \pm 13.0	1.65 \pm 0.04	129.4 \pm 20.4	47.61 \pm 6.62	42.5 \pm 11.8	1.64 \pm 0.03	58.2 \pm 5.3	21.73 \pm 1.25

Each one of the six morbidly obese study participants (cases) was matched with a normal weight control with regard to age, height, gender (all females), and race (all Caucasians).

TABLE 3: The accuracy of activity type detection by the IDEEA monitor.

	Sit	Lie	Stand	Recline	Lean	Walk	Ascend stairs	Descend stairs	Total
Case	12/12	10/12	12/12	8/12	8/12	12/12	9/12	8/12	82.3%
Control	12/12	12/12	12/12	10/12	12/12	12/12	10/12	9/12	92.7%
Total	100%	91.6%	100%	75.0%	83.3%	100%	79.2%	70.8%	87.5%

This table presents the number of correct detections by the IDEEA monitor over the number of total trials ($n = 6$ cases and 6 controls). The 10.4% difference in accuracy in controls versus cases (92.7% versus 82.3%) was statistically significant (chi-square test, $P = .029$).

TABLE 4: Reliability of the IDEEA monitor for gait counts in walking on a flat and ascending or descending stairs.

	30 steps walking ($N = 24$)	Ascend 9 stairs ($N = 20$)	Descend 9 stairs down ($N = 20$)
Case	28.17 \pm 2.37	6.30 \pm 1.16	5.90 \pm 1.52
Control	29.42 \pm 1.56	7.40 \pm 0.84	6.50 \pm 1.18
Total	28.79 \pm 2.06	6.85 \pm 1.14	6.20 \pm 1.36

For walking count analysis, 24 data points from 2 walking tests in each of 12 participants were used. For stair count analysis, 20 data points from two stair tests in each of 5 cases and 5 controls were used.

in the preoperative evaluation, postoperative monitoring, and long-term follow-up of bariatric surgery patients.

Previous validation studies of the IDEEA monitor have been performed in the general population [1, 2] and in special groups such as the elderly [6] or those with cerebral palsy [7]. Our study is unique in that we have targeted the morbidly obese population as the focus of our investigation. A particularly innovative aspect of our work is the emphasis on both sedentary and gait activity measurements. Our recruitment process and the careful selection of well matched normal weight controls are additional strengths of our study. The absence of morbidly obese males in our cases was a result of the pattern of volunteering rather than any selection bias on the part of the investigators. Therefore, our study evolved into a focused validation of the monitor in the female gender only. As obesity is a much more common problem in females than in males [8–12], our focus on the morbidly obese female is an appropriate direction to take in the context of women's health. In summary, our focus on multiple components of

physical activity in a typically neglected population is a distinctive strength of our study.

The IDEEA monitor has shown remarkable reliability with 98% concordance for all five postures studied and 97%–99% intraclass correlation for all three gaits studied. However, the detection accuracy of the IDEEA monitor at 92.7% in the *normal* weight group in the present study compares less favorably than the 98%–99% accuracy obtained by Zhang et al. in their studies in a similar population [1]. Additionally, the 10.4% diminution of detection accuracy of the IDEEA monitor in our case group of morbidly obese females compared to our control group of normal weight females was statistically significant. The lower accuracy for detecting postures in morbidly obese women than in normal-weight women could be explained by detection error from the chest sensor related to differences in chest contour in this patient population. Lower accuracy of detecting gait activities in morbidly obese women than in normal weight women may be due to their walking patterns characterized by slower movements, shorter strides, and limited thigh movements. It is also possible that some of our shortcomings may be related to our relative inexperience with the use of this new device when compared to Zhang et al. who were pioneers in the validation and use of the IDEEA monitor [1, 2].

On the other hand, even 82.3% detection accuracy in morbidly obese females and 92.7% detection accuracy in normal weight females may be of clinical importance in view of the paucity of monitors available that can monitor the type and duration of physical activity in the free living state. In this regard we must emphasize that detection accuracy of sit, stand, and walk were 100% in cases and in controls in our study and these three physical activity

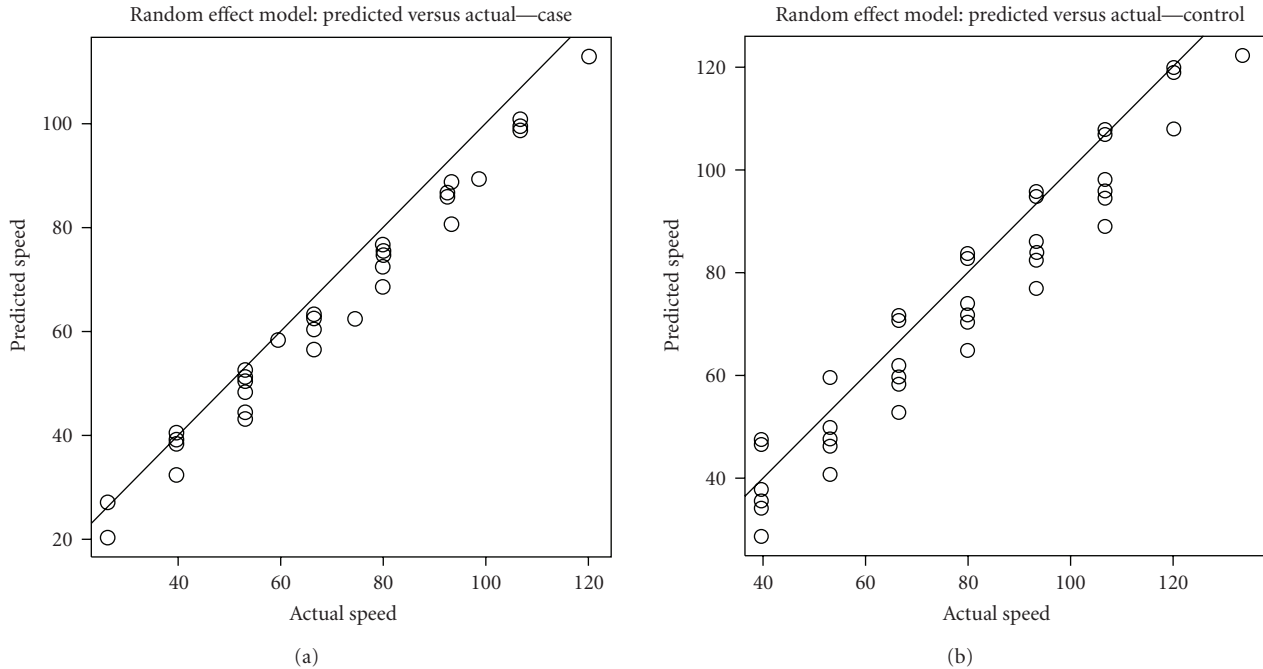


FIGURE 2: Mixed effect models for predicted speed by the IDEEA monitor are shown in cases (a) and in controls (b). The graphs show how the IDEEA monitor readings of speed during walking predict the actual speed measured by a treadmill (meters/min). The 45 degree line on the figure is where all the predicted dots should be in a perfect world. The IDEEA monitor does as well as the treadmill in measuring walking speed with greater than 95% correlation. Although we observe a tendency for the IDEEA monitor to underestimate speed in morbidly obese cases, this difference is not statistically significant.

types are the most important for our clinical purposes as morbidly obese females tend to not use stairs very often (or run or jump) and the difference in energy expenditure between sedentary postures such as lie, recline, and sit would be of minimal clinical consequence. Therefore, by taking into perspective that the IDEEA monitor shows excellent detection accuracy of sit, stand, and walk, in both normal weight females and morbidly obese females—in parallel with remarkable reliability and excellent measurement of speed—we can be reassured that the IDEEA monitor is a valuable new tool in physical activity assessment in the obese. In spite of our small study numbers, we believe that our results are an encouraging outcome of this initial exploratory study and justify the launching of bigger studies to further investigate the use of the IDEEA monitor in the evaluation and treatment of morbid obesity.

Morbid obesity is widely prevalent, is increasing in incidence, and is associated with life-threatening comorbidities [8, 10, 13–16]. As a consequence, an increasing number of patients are resorting to weight reduction surgery in the recent years [8, 13, 17–20]. Our understanding of energy expenditure in bariatric surgery patients is limited as suitable methods to measure physical activity in the free-living state are lacking. The IDEEA monitor is a new digital device that not only measures physical activity in the free living state but also computes energy expenditure by using the physical activity data it captures and applying the data to established mathematical formulae [1, 2]. The IDEEA monitor is noninvasive, convenient, and versatile.

Compared to existing methods, the IDEEA monitor has superior technological capabilities as it has the ability to detect the type, duration, frequency, and intensity of physical activity. Diet and exercise compliance are paramount for successful weight loss after bariatric surgery. By measuring physical activity, estimating energy expenditure, and recording changes in body weight, we can calculate energy intake and thus establish new methods to evaluate adherence to preoperative recommendations. This information will be especially useful in counseling patients during their education prior to bariatric surgery and in their long term postoperative follow up. The development of quantitative methods for assessment of energy expenditure and energy intake, in lieu of qualitative self-reports routinely used, will constitute a significant advance in the field.

Accurate monitors to quantify details of physical activity or estimate energy expenditure under free-living conditions are lacking [3, 21]. Doubly Labeled Water (DLW) is an alternative for energy expenditure estimations but is expensive and does not detect details of physical activity [22]. Pedometers measure step count and speed but are not sensitive to stride length and do not differentiate sedentary postures [4]. The large-scale integrated motor activity monitor (LSI) uses a mercury switch sensitive to tilt but readings correlate poorly with estimated energy expenditure levels during walking and running [23]. Accelerometers that use piezoelectric or piezoresistive rods to sense 3-dimensional accelerations make it possible to quantify duration, frequency, and intensity of motion, but have the

short-fall of not detecting the type of activity [24]. For example, sensor output could be higher while driving a car than while climbing stairs. We selected the IDEEA monitor for our studies as none of the other existing devices [25–29] matches the accuracy and versatility of the IDEEA monitor.

Given the escalating epidemic of obesity in all ages, we have identified an important area of clinical emphasis—assuring that measurement of physical activity is valid in persons who are morbidly obese. An important aspect of our study is the emphasis on both sedentary and gait activity measurements. Qualitative assessment of physical activity is important as the type of physical activity has a bearing on long-term energy balance. Conventional emphasis has been on activities that involve vigorous exertion such as short periods of strenuous exercise (e.g., running, athletic sports, swimming, intense work-outs, weight lifting). However, it is now apparent that the cumulative effect of routine daily activities involving moderate levels of activity is comparable to the effect of strenuous exercise on energy expenditure [25, 30]. Nonexercise Physical Activity (NEPA) and Nonexercise Activity Thermogenesis (NEAT) are some phrases coined to describe the postural and movement changes characteristic of the routines of daily life as opposed to strenuous exercise. NEPA assessment places emphasis on occupation-related activity, routine daily tasks, and common recreational activities. Therefore, NEPA is more relevant to the morbidly obese population that is unaccustomed to conventional forms of vigorous exercise. The IDEEA device provides qualitative analysis of the postures and movements of the routines of daily life and also provides quantitative assessment of these individual daily activities. Despite limitations of our study design such as small sample size and female participants only, this is the first study that demonstrates the validity of the IDEEA monitor for measuring physical activity and sedentary levels among *morbidly obese* individuals. An accurate measure of both activity and nonactivity are needed to determine the relative importance of diet and sedentary behavior on the incidence and persistence of obesity. Further validation studies in the morbidly obese with larger study samples are needed and should be stratified according to BMI. Additional studies should evaluate the practicality of using the device in a daily setting. Furthermore, future studies should use a team of more than one observer to overcome interobserver variation or perform digital video recordings of each physical activity session that can be viewed by a team of observers for later detailed analysis.

In summary, we have shown that the IDEEA monitor can be used with reasonable accuracy and excellent reliability for assessment of physical activity in the morbidly obese population. These preliminary findings suggest that the IDEEA monitor may be used as a clinically meaningful instrument for measuring physical activity and sedentary behavior in the morbidly obese. For future studies, there are potential applications for the use of the IDEEA monitor in the preoperative evaluation and postoperative counseling of bariatric surgery patients.

Abbreviations

IDEEA	Intelligent device for energy expenditure and activity
BMI	Body mass index
ICC	intra-class correlation coefficient
NEPA	Nonexercise physical activity
NEAT	Nonexercise activity thermogenesis

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