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Reductions in muscular strength three months and six months following bariatric surgery are proportional to absolute weight loss

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Abstract

Prior studies in patients following bariatric surgery have demonstrated an associated reduction in lean muscle mass concomitant with total weight loss. Less described are any changes of skeletal muscular strength following bariatric surgery and if changes in strength are proportional to total weight loss.

Purpose: To describe changes in upper and lower body strength following weight loss surgery. Methods:

Seven subjects (age (yr) = 48 ± 13 ; weight (kg) = 137.4 ± 5.4 ; BMI (kg/m^2) = 50 ± 5) who underwent laparoscopic bariatric surgery at Henry Ford Hospital (6 Roux-en-Y bypass and 1 vertical sleeve) were assessed. Within 30 days prior to surgery upper and lower body strength were assessed, respectively, by performing a one repetition max test on an isotonic chest press (CP) machine (Cybex) and a single-leg knee extension (KE) using an isokinetic dynamometer (Biodex). Strength tests were repeated three months following surgery. ANOVA tests were used to compare differences in strength between baseline, three months, and six months. Results: At three months there was a 20% weight loss ($p < 0.001$), and 25% reduction of BMI ($p < 0.001$). Overall strength was reduced at three months. The absolute decrease in strength was significant only for peak torque at $120^\circ \cdot \text{sec}^{-1}$. All other strength measures trended towards significance. However, when body weight was controlled for, relative strength for all tests were no different before and after bariatric surgery. Conclusion: This preliminary data shows reductions in absolute strength following weight loss surgery, are related to total weight loss. Future studies should examine if these changes persist beyond three months post surgery as well as if a post-operative strength-training program can minimize this impact.

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REDUCTIONS IN MUSCULAR STRENGTH THREE MONTHS AND SIX MONTHS
FOLLOWING BARIATRIC SURGERY ARE PROPORTIONAL TO ABSOLUTE
WEIGHT LOSS

By

Renee Walton

A Senior Thesis Submitted to the

Eastern Michigan University

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ABSTRACT

Reductions in Muscular Strength Three and Six Months Following Bariatric Surgery Are Proportional To Absolute Weight Loss

Prior studies in patients following bariatric surgery have demonstrated an associated reduction in lean muscle mass concomitant with total weight loss. Less described are any changes of skeletal muscular strength following bariatric surgery and if changes in strength are proportional to total weight loss. **Purpose:** To describe changes in upper and lower body strength following weight loss surgery. **Methods:** Seven subjects (age (yr) = 48 ± 13 ; weight (kg) = 137.4 ± 5.4 ; BMI (kg/m^2) = 50 ± 5) who underwent laparoscopic bariatric surgery at Henry Ford Hospital (6 Roux-en-Y bypass and 1 vertical sleeve) were assessed. Within 30 days prior to surgery upper and lower body strength were assessed, respectively, by performing a one repetition max test on an isotonic chest press (CP) machine (Cybex) and a single-leg knee extension (KE) using an isokinetic dynamometer (Biodex). Strength tests were repeated three months following surgery. ANOVA tests were used to compare differences in strength between baseline, three months, and six months. **Results:** At three months there was a 20% weight loss ($p < 0.001$), and 25% reduction of BMI ($p < 0.001$). Overall strength was reduced at three months. The absolute decrease in strength was significant only for peak torque at $120^\circ \cdot \text{sec}^{-1}$. All other strength measures trended towards significance. However, when body weight was controlled for, relative strength for all tests were no different before and after bariatric surgery. **Conclusion:** This preliminary data shows reductions in absolute strength following weight loss surgery, are related to total weight loss. Future studies should examine if these changes persist beyond three months post surgery as well as if a post-operative strength-training program can minimize this impact.

Introduction

There is an epidemic of overweight and obesity in the United States. The prevalence of excess weight is increasing rapidly across the country, and today close to 65% of the adult population is overweight or obese. Comparing the period 1976–1980 with 1999–2000 the prevalence of overweight [body mass index (BMI) $\geq 25 \text{ kg/m}^2$] has increased by 40% (from 46.0% to 64.5%) and the prevalence of obesity (BMI $\geq 30 \text{ kg/m}^2$) has risen by 110% (from 14.5% to 30.5%). There is an alarming increase in weight among the youth. More than 10% of 2- to 5-yr-olds and 15% of 6- to 19-yr-olds are overweight (BMI 95th percentile for age and gender). This represents a near doubling of over-weight children and a near-tripling of overweight adolescents over the last two decades. Whereas some segments of the population are more likely to be overweight or obese than others, people of all ages, races, ethnicities, socioeconomic levels, and geographic areas are experiencing a substantial increase in weight (Stein & Colditz, 2004).

Obesity has become an important public health problem in industrialized countries throughout the world. International data indicate that the epidemic is not isolated to the United States but is in fact a global health problem. The prevalence of obesity is rising in other developed and affluent countries and is now spreading to less affluent countries (Stein & Colditz, 2004).

The body mass index (BMI = weight (in kg)/height² [in m²]) is the primary measurement used to categorize obese patients. Excess body weight (EBW) is defined as the amount of weight that is in excess of the ideal body weight (IBW). Ideal body weight is conventionally determined by the Metropolitan Life Tables, or as a BMI of 25 kg/m^2 . In 1991, the National Institutes of Health defined morbid obesity as a BMI of $\geq 35 \text{ kg/m}^2$ and

severe, obesity-related comorbidity as a BMI of $\geq 40 \text{ kg/m}^2$ (Brethauer, Kashyap, & Schauer, 2000-2013).

Obesity is usually developed from the interactions of excessive caloric intake, eating the wrong types of foods, lack of exercise, and poor portion control. Obesity and overweight results from the interaction of many factors, including genetic, metabolic, behavioral, and environmental influences. This increase suggests that behavioral and environmental influences, rather than biological changes have contributed to the epidemic. Increased energy consumption with decreased energy expenditure, or a combination of both of these has led to a positive energy balance and a marked increase in weight in society. (Brethauer, Kashyap, & Schauer, 2000-2013) More than 60% of the population does not participate in some form of regular physical activity with about 25% being completely sedentary. Physical activity in schools has decreased or ceased due to budget cuts and economic downfall. Almost half of young Americans between the ages of twelve and twenty-one are not moderately active on a regular basis (Stein & Colditz, 2004).

Category	Body Mass Index (kg/m^2)	Over Ideal Body Weight (%)
Underweight	<18.5	
Normal	18.5-24.9	
Overweight	25.0-29.9	
Obesity (class 1)	30-34.9	>20%
Severe obesity (class 2)	35-39.9	>100%
Severe obesity (class 3)	40-49.9	
Superobesity	>50	>250%

(Brethauer, Kashyap, & Schauer, 2000-2013)

Recent evidence reporting that obesity is a major risk factor for many diseases and is associated with significant morbidity and mortality. Obesity is a chronic (long-term) disease that is increasing in frequency. More than half of American adults are overweight. Nearly one third are obese (Saber Alan: Hale & Murr, 2013). Obesity is the second leading cause of preventable deaths in the United States, after cigarette smoking, despite expenditures of over \$45 billion annually on weight loss products (Brethauer, Kashyap, & Schauer, 2000-2013). People who are obese have much higher risks of many serious health problems than nonobese people. Obesity affects every system of the body. Obesity increases the relative risk of 30 serious medical conditions including diabetes, hypertension, obstructive sleep apnea and pulmonary hypertension, heart disease, stroke, blood clots, deep venous thrombosis, and pulmonary emboli, fatty liver disease and nonalcoholic steatohepatitis, gastroesophageal reflux disease, urinary incontinence, osteoarthritis, gallstones, colon cancer, endometrial cancer, and depression (Saber Alan: Hale & Murr, 2013).

Conventional weight loss programs and medication have modest results with an average of 5-10% weight loss and poor long-term results. Bariatric surgery is currently the only modality that provides a significant, sustained weight loss for the patient who is morbidly obese, with resultant improvement in obesity-related comorbidities (Buchwald, et al., 2004). Weight loss surgery (bariatric surgery) is the only treatment of obesity resulting on average in >15% documented weight loss over ten years (Bray and Bouchard 2004).

The existing body of research discussing postoperative weight loss, fat free mass, lean muscle mass, and the problems associated with various surgical procedures are extensive. There has not been any other research that specifically correlates muscular strength and

relative strength in bariatric patients. However, there have been several studies on the impact on bone density, lean muscle mass and fat free mass.

A recent study from Zalesin et al.(2010), found that patients that lost weight the fastest appeared to have also had accelerated losses of both lean and fat mass. This study evaluated the differential rates of fat and lean tissue losses in morbidly obese patients who underwent Roux-en-Y gastric bypass surgery. Body composition was also assessed using whole-body dual energy X-ray absorptiometry (DXA) performed at two time points in the postoperative period. There were thirty-two patients in the study of which 25 were women and seven were men. During the study patients were encouraged to gradually increase aerobic physical activity after surgery and begin resistance training at six weeks postoperatively, however this did not seem to have any significant impact on the study. Only three of the 32 patients maintained or gained muscle mass during the postsurgery follow up. All three of the patients stated they had been regularly exercising and two of them were participating in resistance training. Of the other 29 patients, 52% of them had stated that they were participating in some type of endurance exercise and strength training and 86% of them had lost lean body mass (Zalesin, et al., 2010).

In another study from Buchwald et al., there was a systemic review of multiple studies. There were a total of 136 fully extracted studies, which included 91 overlapping patient populations, were included for a total of 22,094 patients. Nineteen percent of the patients were men and 72.6% of the patients were women, with a mean average age of 39 years. The objective of this study was to analyze the impact of bariatric surgery on comorbid conditions such as diabetes, hyperlipidemia, hypertension, and sleep apnea. The study also looked into the impact on healthcare economics and the impact of disease. The evidence

showed that patients who have had bariatric surgery weight loss in excess of 45 kg obtained relief from fatal comorbid diseases, an improved appearance, and an improved social and economic opportunities. A substantial majority of patients with diabetes, hypertension, hyperlipidemia, and obstructive sleep apnea experienced complete resolution or improvements in their condition (Buchwald, et al., 2004).

This study focused on two specific types of bariatric surgery, the Roux-en-Y (RNY), and the Vertical Sleeve Gastrectomy. The Roux en-Y (RNY) RNY gastric bypass surgery is considered to be the "gold standard" in gastric bypass surgeries. Formerly called roux-en-Y, gastric bypass bariatric surgery is the most commonly performed bariatric procedure. In this procedure, the stomach is separated into two sections. Six small incisions are made to allow insertion of a small scope that is connected to a video camera and the tools needed to perform the operation. The upper part is made into a very small pouch that holds one to two ounces initially. It is about the size of your thumb. This limits the amount of food that can be eaten at one time. It also provides a feeling of fullness and satisfaction with smaller portions of food. A normal stomach holds 40 to 50 ounces and is roughly the size of a person's head. The small pouch is at the bottom of the esophagus and is very resistant to stretching. The lower part of the stomach is not removed. This part of the stomach no longer receives food. Nothing enters it but it does still produce gastric juices, which aids the digestion process by eventually joining with the food in the small intestines. These two parts of the stomach are completely separated and are closed by a method of stapling and sewing to eliminate the chance of leaks. A leak is a very rare and serious condition allowing food to enter the abdominal cavity causing infection. Scar tissue eventually forms at the stapled and

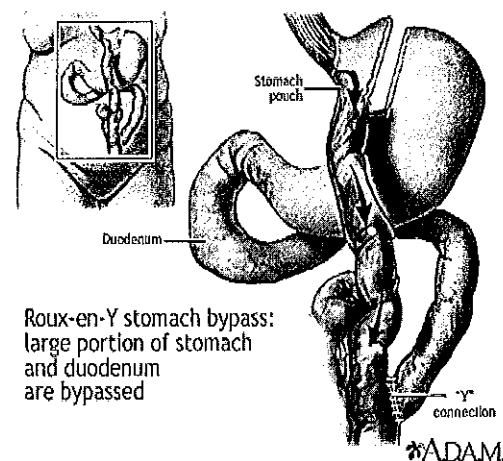
sewn area so that the pouch and stomach are permanently separated and sealed (Thompson, 2000- 2013).

During gastric bypass bariatric surgery, a section of the small intestine called the jejunum is then pulled up to directly connect to the small stomach pouch. The other end of the small intestine is surgically reconnected at a point further down the small intestine. The shape of the intestine now somewhat resembles a "Y." When food is eaten, it enters the new stomach, then travels into the lower part of the intestine, bypassing the lower stomach and upper part of the intestine.

A major benefit of this rerouting is that the hormones promoting poor blood sugar control are almost immediately affected, often allowing patients to significantly reduce or eliminate their diabetes medications immediately after surgery. In addition, gastric bypass

surgery seems to diminish the appetite and promote satiety or fullness.

Because the body absorbs fewer calories and nutrients, patients are at increased risk for nutritional deficiencies. Therefore, after gastric bypass surgery, it will be important to follow a physician's guidelines for nutritional supplementation (Buchwald H, 2004).



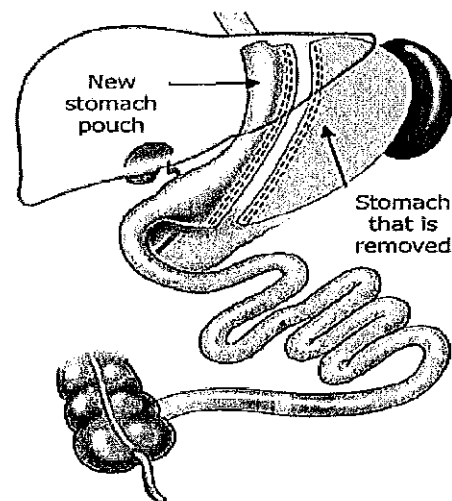
(Zieve & Rogers, 2013)

<http://www.nlm.nih.gov/medlineplus/ency/imagepages/19268.htm>

The sleeve gastrectomy, also known as a vertical sleeve gastrectomy or gastric sleeve procedure is a newer procedure in which the bariatric surgeon recreates the size and shape of the stomach, reducing how much can be eaten at one time. It is irreversible. In gastric sleeve surgery, the bariatric surgeon makes six small incisions to allow insertion of a small scope that is connected to a video camera and the tools needed to perform the operation. The surgeon then staples and divides the stomach, removing about 85 percent of it. The outer margin of the stomach is removed to restrict food intake, leaving a sleeve of stomach, roughly the size and shape of a banana, and the pylorus, the muscle that controls emptying of food from the stomach into the intestine. A sleeve gastrectomy is a purely restrictive procedure (Saber Alan: Hale & Murr, 2013).

It is important to note that the part of the stomach that is removed is responsible for secreting ghrelin, a hormone that causes feeling of hunger. As a result, patients report less hunger after the procedure. Additional benefits of gastric sleeve surgery include a minimized

risk of protein and vitamin deficiency following the surgery and a minimized risk of intestinal obstruction, as the intestines are not rerouted. The disadvantages of gastric sleeve bariatric surgery include a possibility of slow or inadequate weight loss as well as possible leaks and other complications from stapling (Shabir Bhimji, 2013).



(Laparoscopic Sleeve Gastrectomy, 2012)

<http://bariatric.surgery.ucsf.edu/conditions--procedures/laparoscopic-sleeve-gastrectomy.aspx>

According to Henry Ford Hospital, in the state of Michigan, the average three-year excess weight loss for bariatric patients is 61%. As bariatric patients are going through their weight loss, not all weight loss is fat as patients are also losing muscle. After having bariatric surgery, the body transforms into what we call a catabolic or breakdown state. This is perceived by the body as being in a starvation state and by trying to combat starvation, the body will hoard its precious fat until any other usable fuel has been burned. In general the body will prefer to use muscle as energy before consuming fat. This is why, if muscle is not regularly used (as in regular exercise), more muscle will be consumed to meet energy needs. Loss of muscle effects strength and can also impact health as it relates to bone/mineral health, fall risk, and quality of life (Shabir Bhimji, 2013).

Purpose

The purpose of this study is to describe absolute and relative changes in muscular strength at three following bariatric surgery. Absolute strength is defined as the maximum amount of force that is generated with a single effort. Often measured by performing a 1-repetition maximum (1RM) test. Relative strength is the amount of force that someone can exert in relation to his or her body size or weight. The general quantification of relative strength is the absolute muscular strength for a given exercise divided by body weight.

Methods

The subjects of this study were recruited via informational meeting following the approval of the IRB Review board of Henry Ford Hospital and the College of Health and Human Services (CHHS) Human Subjects Review Committee of Eastern Michigan

University. Subjects were recruited from the Henry Ford Bariatric surgery program prior to surgery. During enrollment, subjects were given a packet that included a letter of recruitment, confidentiality statement, consent form, Heart Smart nutrition survey, bariatric exercise questionnaire, food diary, and a synopsis of the project and protocols for each of the physiological tests they would be participating in. Exclusion Criteria included orthopedic limitations (knee/shoulder), weight greater than 450 pounds, heart failure with an ejection fraction less than 40%, and uncontrolled hypertension or diabetes. Subjects consisted of eight females and one male.

There were eight subjects who had the RNY and one subject who had the Sleeve bariatric surgery procedure. The subjects were between the ages of 39 and 64 years of age with an average and standard deviation of 51 ± 13 . All subjects were between 122 kg and 149 kg in weight with an average of 135.33 ± 3.32 (units). All subjects had a body mass index (BMI) between 44 and 52 and an average of 48.39 ± 4.36 (units). Body mass index is calculated as weight in kilograms divided by the square of the height in meters. All subjects had a mid upper arm circumference (MUAC) between 37 and 44 with an average of 40.44 ± 3.16 (units). MUAC is the circumference of the left upper arm, measured at the mid-point between the tip of the shoulder and the tip of the elbow (olecranon process and the acromion). All subjects had a block score between 7 and 17 with an average of 12.11 ± 4.57 (units). All 25 subjects participated in the physiological testing and in data collection. Within one month of surgery, subjects were assessed for both upper body and lower body strength. Testing consisted of completing a 1RM test on an isotonic chest press (CP) machine (Cybex) and a single-leg isokinetic knee extension (KE) (Biodex).

Upper body strength was measured utilizing the 1-repetition maximum test on a seated chest press. The 1RM requires a person to exert maximally on a selected weight, chosen as close as possible to the person's expected 1 RM weight. If the person cannot lift it with correct form, then a lower weight is tried after a two-minute rest interval. After the two-minute rest interval, a small additional weight is added, and the person tries again. This process is repeated until only one repetition is possible for a maximum of five tries.

Movements were performed in a seated, upright position, straddling the bench facing the machine. The hands were positioned on the handgrips slightly wider than shoulder width. The palms were facing forward, grasping the handgrip in an open, relaxed manner. Subjects were instructed to slide the hips forward until the shoulders and the hips were aligned vertically under the handgrips. During the lift, the subjects pressed the handgrips upward until the arms were near full extension,

exhaling and without arching the back. The subjects then returned the weight slowly back to the starting position. The lift was performed in a controlled manner. The subject's feet remained in contact with the floor during the entire lift.



(Chest Press, 2013)

http://www.teachpe.com/strengthening/m-chest_press.php

A single-leg isokinetic knee extension (e.g. Biodex, Cybex) was used to determine lower body strength. Isokinetic exercise is performed with a specialized apparatus that provides variable resistance so that no matter how much effort is exerted the movement is conducted at a constant speed. The Biodex System is an isolated joint isokinetic system that allows one to measure the amount of strength produced at different velocities. For this study, the speeds were set at place at 60, 120, and 180 degrees of movement per second. Isokinetic muscle loading consists of fixed speed of movement and resistance that is variable, and most importantly, totally accommodating. Because the resistance is accommodating, it allows for maximal muscle loading throughout the entire range of motion. The subject is positioned so that the body movement to be measured is isolated. The equipment is then set at different speeds and the force applied can be measured throughout the range of movement. The results were reported at different speeds so that a speed/strength/power relationship can be identified.

Statistical Analysis

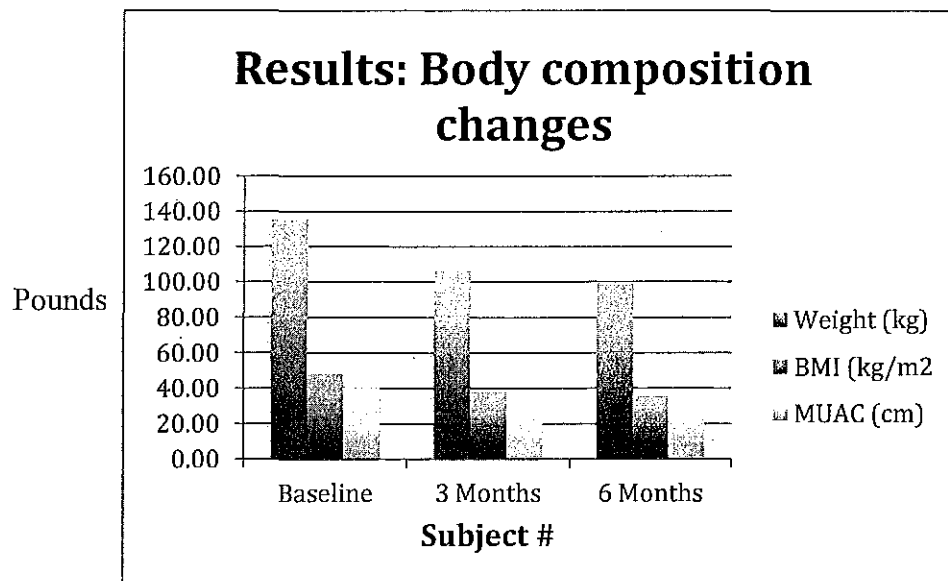
Analysis of variance (ANOVA) is a collection of statistical models used to analyze the differences between group means and their associated procedures (such as "variation" among and between groups), in which the observed variance in a particular variable partitioned into components attributable to different sources of variation. In its simplest form, ANOVA provides a statistical test of whether or not the means of several groups are all equal, and therefore generalizes t-test to more than two groups. Doing multiple two-sample t-tests would result in an increased chance of committing a type I error. For this reason, ANOVAs are useful in comparing (testing) three or more means (groups or variables) for

statistical significance (Analysis of Variance (ANOVA) , 2013). A repeated measures ANOVA test with Bonferroni pairwise comparisons were used to determine differences in strength measures between baseline, 3 months, and 6 months. (IBM Corp. Released 2012. IBM SPSS Statistics for Mac, Version 21.0. Armonk, NY).

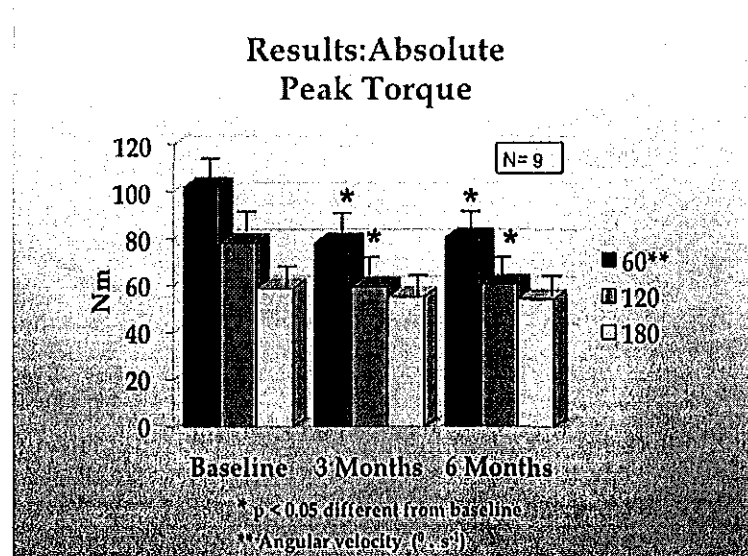
Results

According to the data collected from the exercise logs completed by the patients, the majority of the bariatric patients were sedentary. Some reported very minor aerobic or resistance training activities, but a better comparison can be found with the pre vs. post surgery muscular strength analyses included in this study. All of the subjects reported some type of planned exercise between baseline and three months post surgery. An average of 74% reported walking as their main exercise, while only 26% reported participating in resistance training >2 days per week. The raw data for each subject for absolute strength at 60, 120 and 180 degrees per second along with an average of all subjects is included in the appendices.

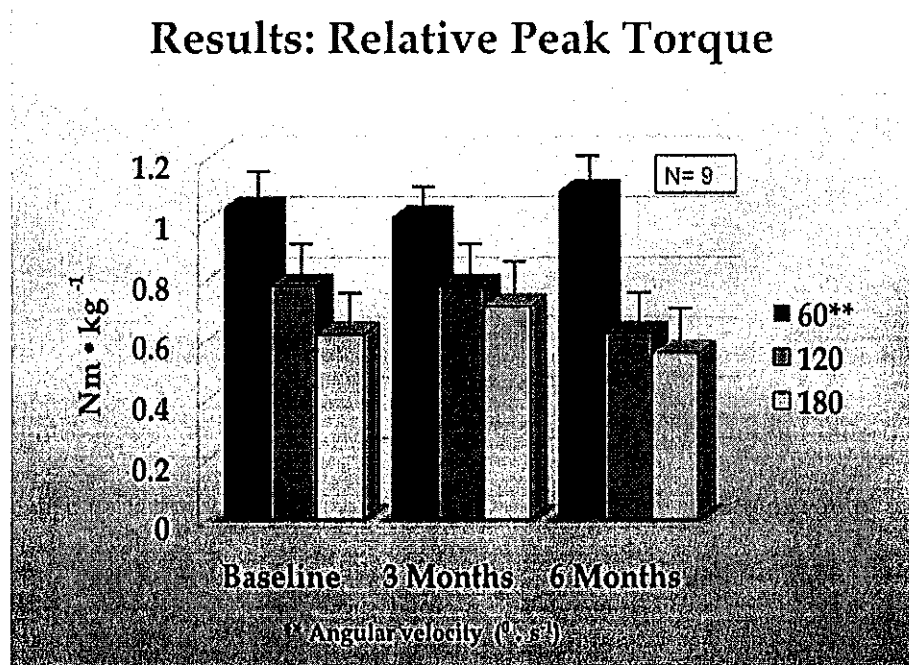
There were significant changes in body composition between baseline and three months and less significant changes between three and six months. There was a 21.04 % excess weight loss at three months and 26.1 % excess weight loss at six months. There was a 21.5 % reduction in BMI at three months and a 26.2% reduction of BMI at 6 months. There was a 14.5 % difference in MUAC at three months and a 20.5 % difference at 6 months.



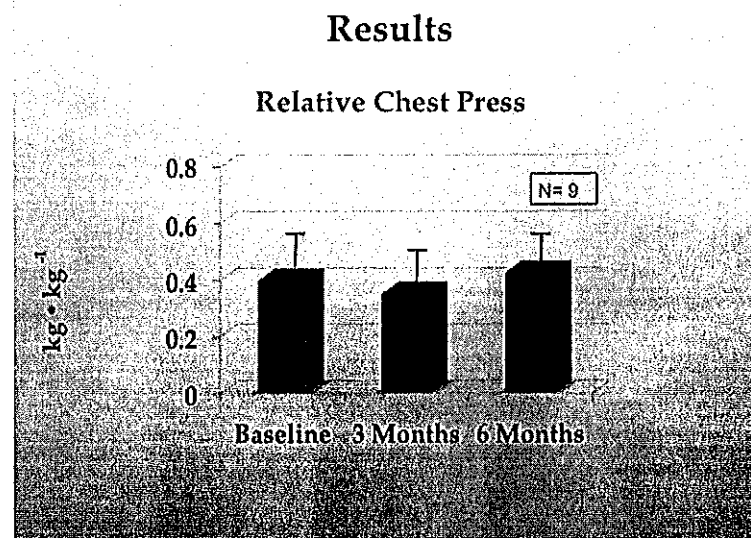
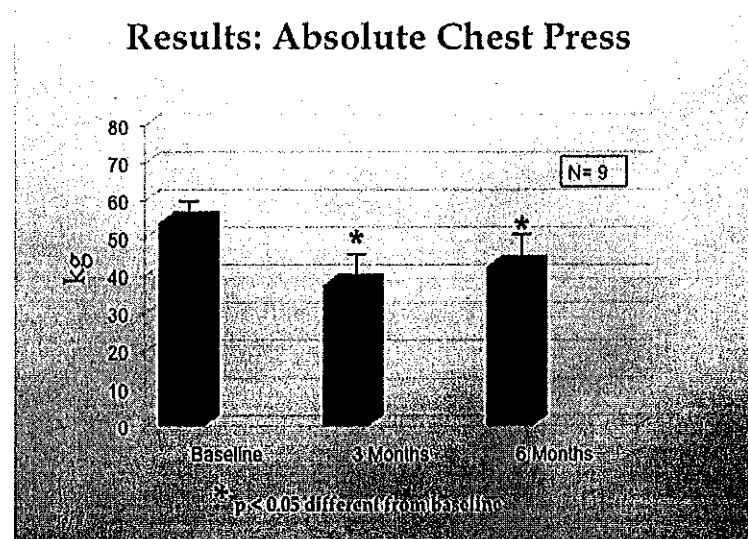
The figure below displaying absolute peak torque over time reports that overall strength of the patients was significantly reduced at three months for the speed at 60 degrees and 120 degrees per second. There was not significant difference between three and six months. Further post-hoc pairwise comparisons of absolute peak torque showed no difference between three months and six months torque.



The figure below displaying relative peak torque over time reports that, although absolute peak torque goes down from baseline to three months, at three to six months relative peak torque remains unchanged. The study reports that patients displayed a significantly higher absolute power but lower relative peak torque and power. This is indicated although the actual strength has decreased, the relative strength has not dramatically changed because the amount of weight has decreased. For example, when a person is 300 pounds and performing a chest press they are able to press 250 pounds. The person loses 100 pounds and can only press 225 pounds after the weight loss. With absolute peak torque the person was able to lift 50 pounds above their body weight, but losing the 100 pounds although the person is lifting a lighter weight at 225, the persons relative peak torque is higher than the persons absolute because their body weight is also lower so this person is actually able to lift more. Absolute in this case refers to strength where relative is the strength divided by the weight.



For the next two for the chest press tests for absolute and relative peak torque, although absolute peak torque decreases from baseline to three months, relative peak torque remains unchanged at three to six months. This study reports that patients displayed a significantly higher absolute power but lower relative peak torque and power. Further post-hoc pairwise comparisons of relative chest press results showed very little difference between three to six months. The biggest dereference was between baseline and three months.



There was no significant difference between baseline and 6 months for chest press. The increase in relative chest press at 6 months is solely driven by the fact that the patient lost weight from the surgery versus any absolute strength increases.

Discussion

This study provides a unique opportunity to look at muscular strength and how it affects bariatric patients with respect to absolute, relative peak torque, fatigue curve, BMI, MUAC, and the difference in weight (kg) at baseline, three months and six months post surgery. With the exception of relative peak torque, the results showed a big difference in each of these areas between baseline and three months with less significant change between three and six months. The relative peak torque did not report any significant changes between baseline and six months. These changes are all contributed to a drop in weight in the subjects.

Although each patient filled out questionnaires in regard to exercise, dietary intake, and nutrition, there maintains room for error in knowing whether or not the patient was accurate in their reporting of the data. It is unclear as to whether this had a negative impact on the outcome of the data.

It has been established in a study by (Zalesin, et al., 2010) that the associated changes in body composition is important because the maintenance or enhancement of lean mass is associated with augmented muscular strength and endurance. The study demonstrated that those patients who experienced the greatest rate of weight loss after bariatric surgery did so at the expense of losing relatively more lean body mass and fat tissue.

These findings contribute significantly to the research field as this is a pilot study and there are not any other studies that have been conducted specifically on the bariatric

population. As bariatric surgery becomes more prevalent it is important to understand how the changes in muscular strength affect the subjects ability to maintain their weight loss. This study will aid in helping personal trainers, exercise physiologists and other allied professionals when developing a post surgery exercise, strength and conditioning plan.

This study is a pilot study that can open the door for continued research on the relationship between lean muscle mass, metabolism, absorption, and protein intake in relationship with muscular strength. As there is not any current research on muscular strength in bariatric patients further investigation could be continued for a longer time frame to see if the changes in relative peak torque shifts after a certain period of time.

Conclusion

Bariatric surgery provides a unique opportunity to study the differences between absolute and relative strength. This preliminary data shows reductions in absolute strength following weight loss surgery are related to total weight loss. Although the patients' absolute strength decreased from baseline to six months, their relative strength did not decrease according to preliminary data. This was attenuated to the significant drop in weight. The possible long-term consequence of significant muscle loss in this population remains unclear. Strength training may attenuate the loss of lean muscle mass (LMM) and further studies are needed in this area of research.

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Appendices

Appendix A

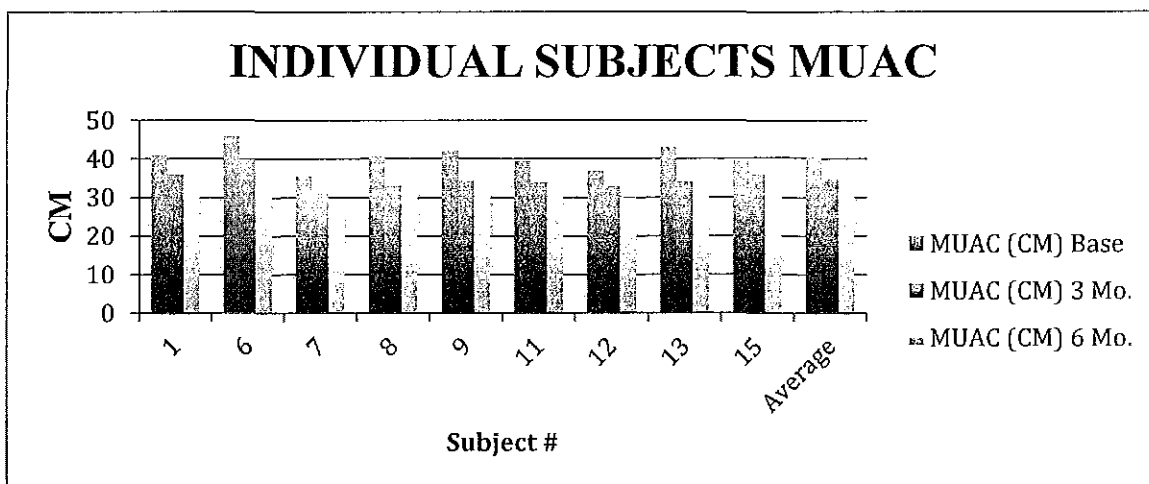
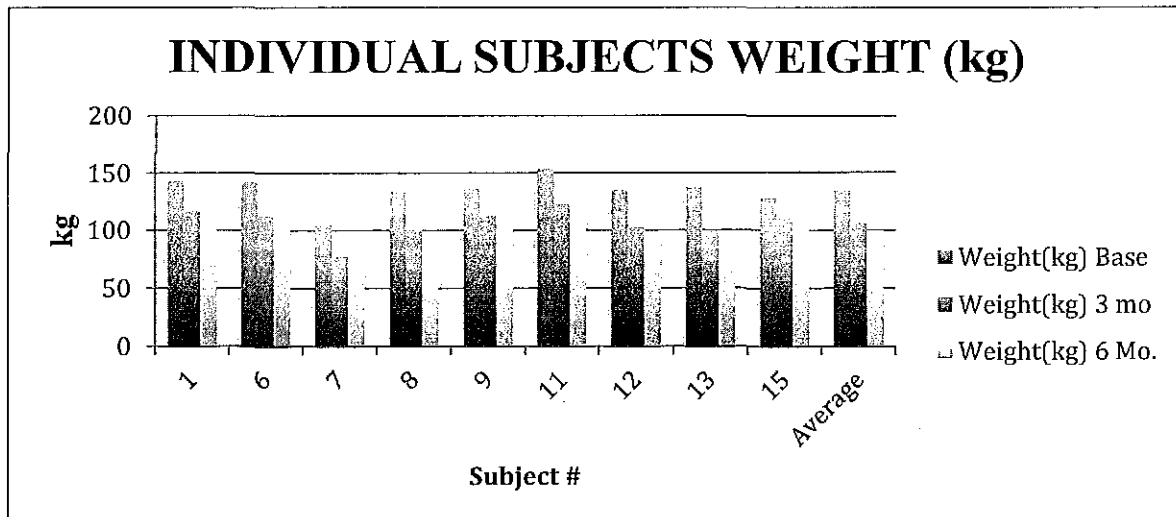
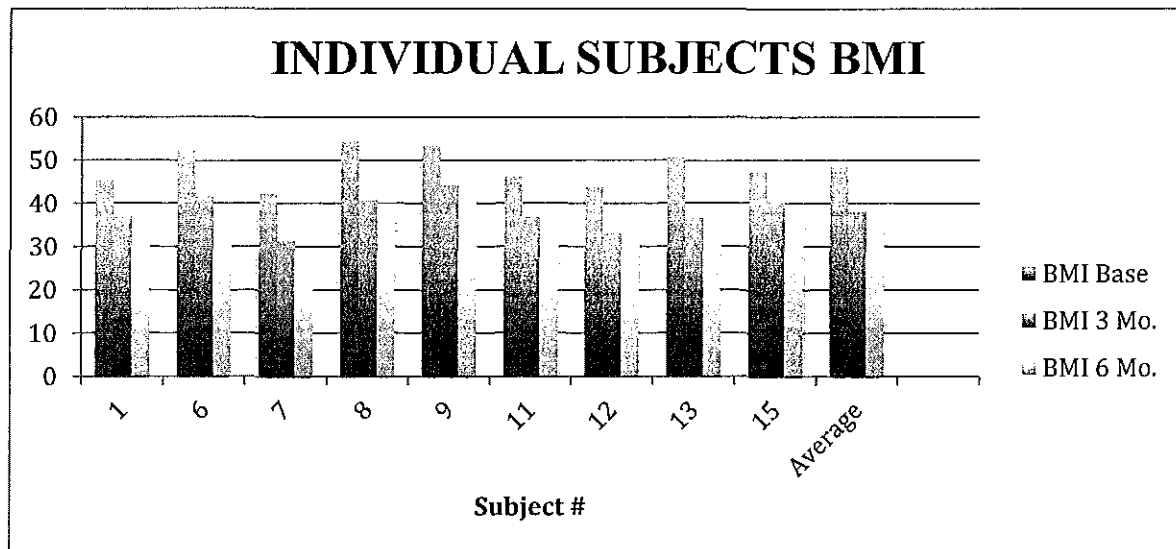
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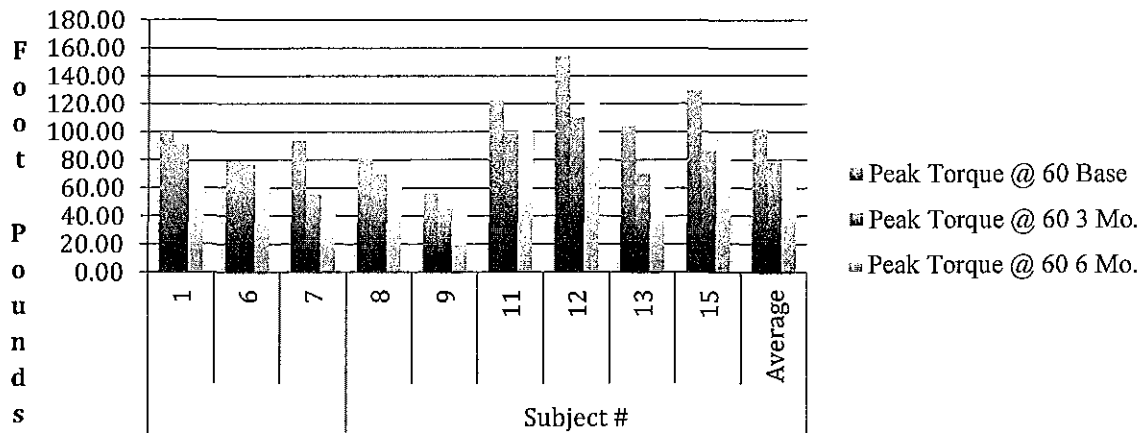
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Appendix B

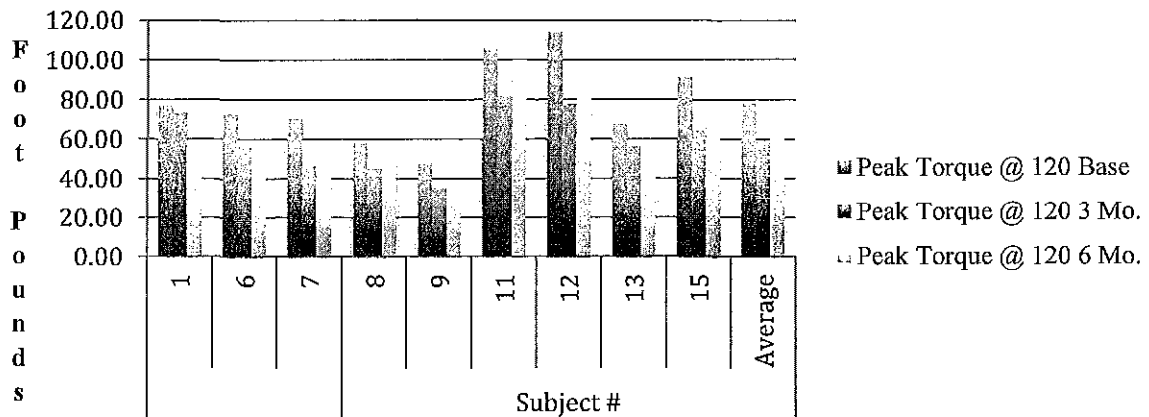
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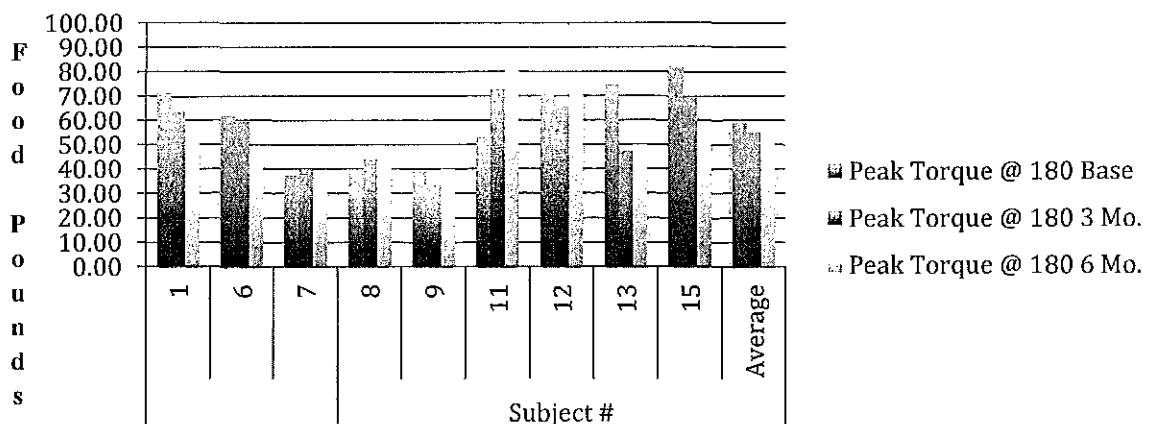
Individual Subjects Absolute Strength



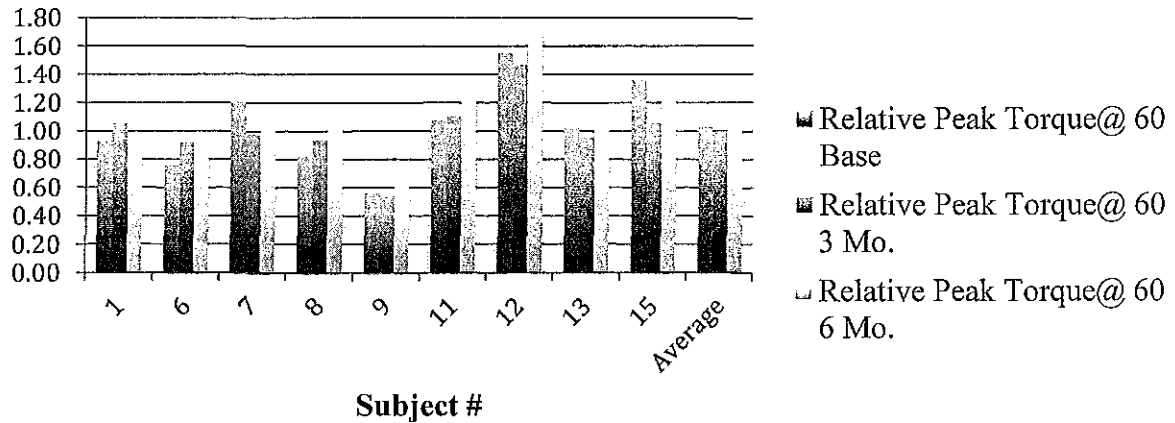
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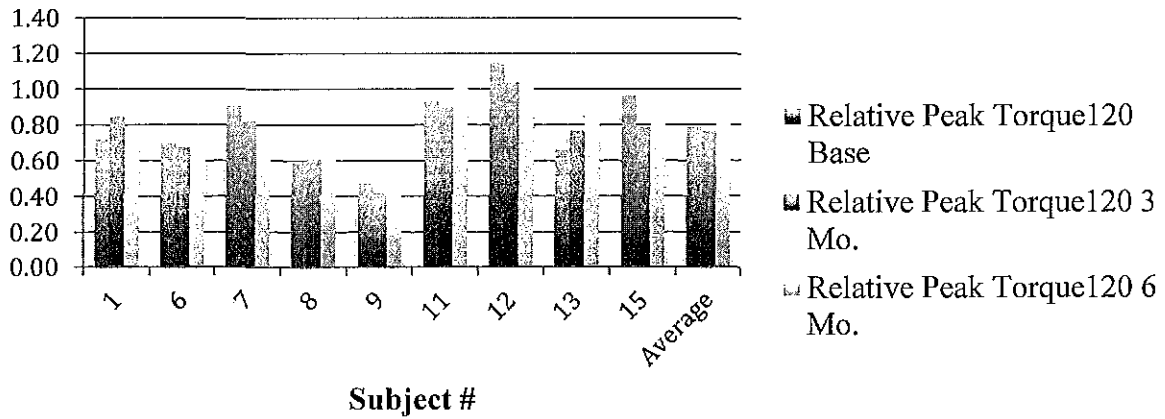
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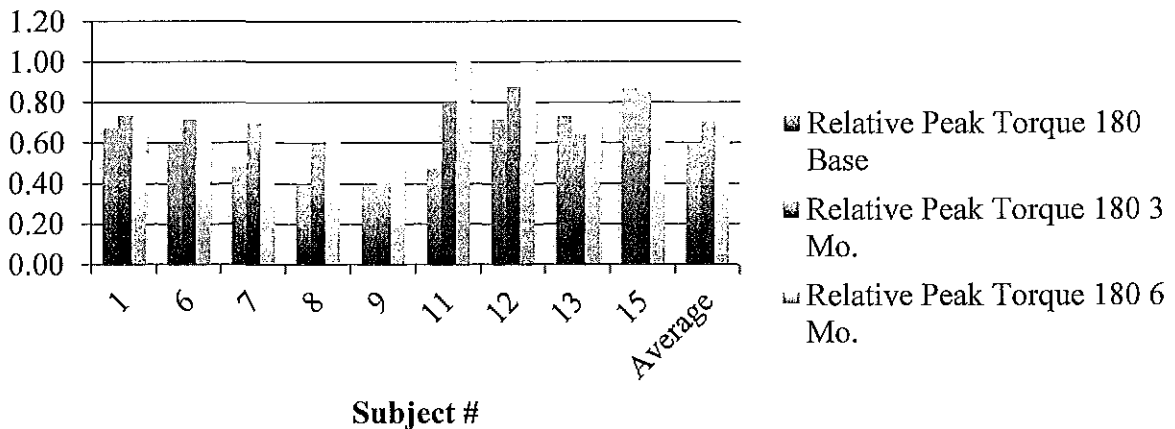
INDIVIDUAL SUBJECTS RELATIVE PEAK TORQUE

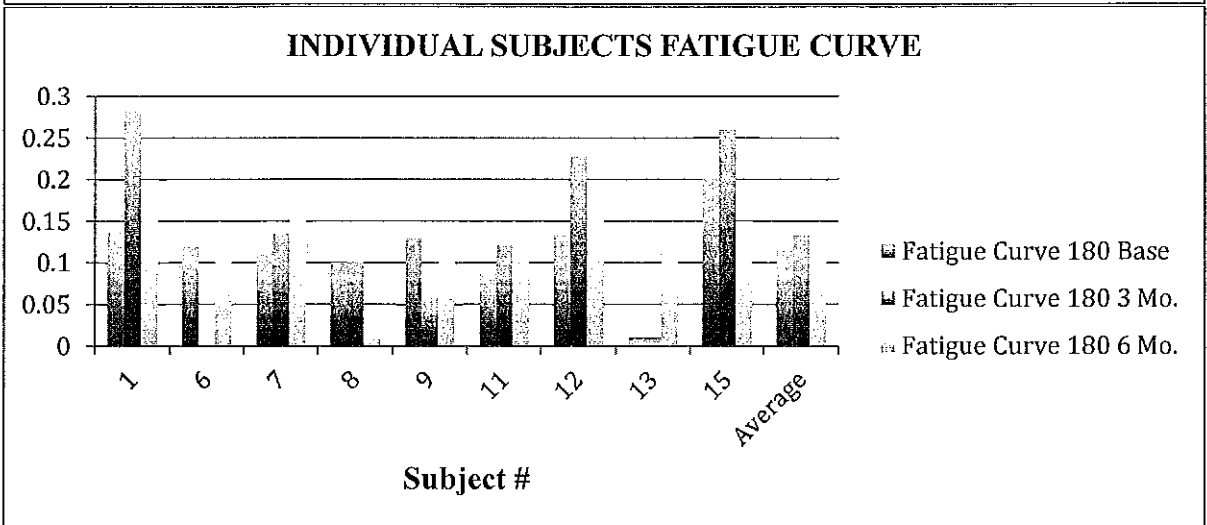
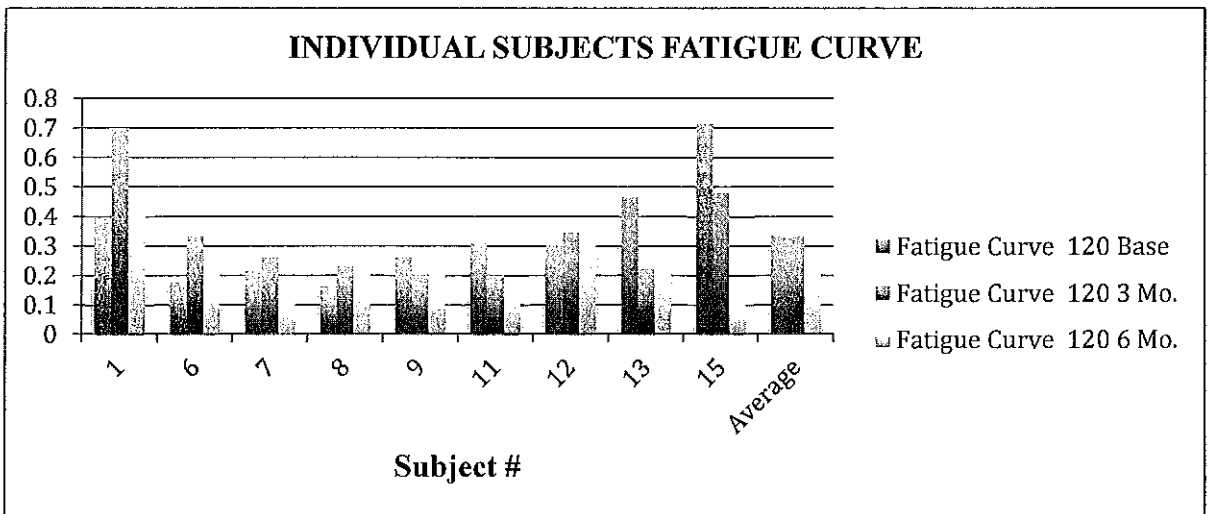
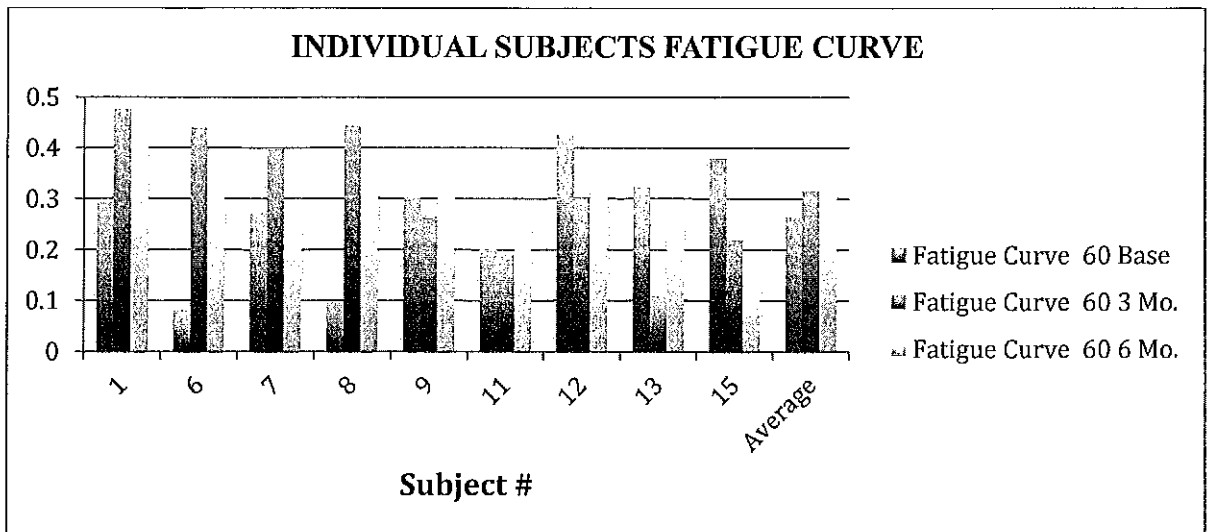


INDIVIDUAL SUBJECTS RELATIVE PEAK TORQUE



INDIVIDUAL SUBJECTS RELATIVE PEAK TORQUE





HFHS Bariatric Exercise Study

We would like to invite you to assist us with our effort to better understand bariatric surgery outcomes and how the surgery relates to any possible changes in muscular strength.



➤ **PURPOSE:**

Describe changes in muscular strength pre-surgery, and at three and six months following bariatric surgery. In addition, we propose to examine the relationship between strength and several potential co-variants.

➤ **WHO CAN PARTICIPATE:**

Any bariatric patient within the Henry Ford Health System (i.e. Detroit, West Bloomfield, Macomb, Warren, and Wyandotte).^{*} While we anticipate that most will be eligible, there are some exclusion criteria.

➤ **COMPENSATION:**

For the study you will be compensated by receiving a one month free membership to our PREVENT program.



Name: _____ Date: _____

Heart Smart® Nutrition Survey

These questions are to find out how often you eat each of these food items. Look carefully at the choices at the top of each column. Notice that some of the choices are per month, and others are per week. When answering, think about your eating habits over the past month. About how often do you eat each of these foods? Please put an "X" in the appropriate box.

Meats and Snacks	Less than 1 time a month	2-3 times a month	1-2 times a week	3-4 times a week	5 or more times a week
Hamburgers, ground beef, meat burritos, tacos					
Beef or pork, such as steaks, roasts, ribs or in sandwiches					
Fried Chicken					
Hot Dogs or Polish or Italian sausage					
Cold Cuts, lunch meats, ham (not low-fat)					
Bacon or breakfast sausage					
Salad dressings, mayonnaise (not low-fat)					
Margarine, butter or mayonnaise on bread or Potatoes					
Margarine, butter or oil in cooking					
Eggs (not egg beaters or just egg whites)					
Pizza					
Cheese, cheese spread (not low-fat)					
Whole Milk (not skim, ½%, or 2%)					
French fries, fried potatoes					
Corn chips, potato chips, popcorn, crackers					
Doughnuts, pastries, cake, cookies (not low-fat)					
Ice cream (not sherbet or non-fat)					



Bariatric Exercise Questionnaire

Over the past month, other than your regular job, how many days per week do you participate in planned exercise like walking, biking or swimming? _____ days/week

If you do participate in planned exercise, how many minutes might you spend each time you engage in planned exercise? _____ minutes

Does your planned exercise include walking? Yes ☐ No ☐

If yes to walking.....How many walking sessions per week? _____

How many miles walked per session? _____ miles

Average duration per session? _____ Minutes?

What is your usual pace of walking? (circle one)

Casual or
Strolling
(<2 mph)

Average or
Normal
(2 to 3 mph)

Fairly
Brisk
(3 to 4 mph)

Brisk or
Striding
(≥ 4 mph)

What type of activity (if different from walking) did you spend the most time doing during the past month? (choose one)

<input type="checkbox"/> Aerobic Dance _____ min.	<input type="checkbox"/> Horseshoes _____ min.	<input type="checkbox"/> Skating (ice/roller) _____ min.
<input type="checkbox"/> Backpacking _____ min.	<input type="checkbox"/> Jogging/running _____ min.	<input type="checkbox"/> Snow skiing _____ min.
<input type="checkbox"/> Badminton _____ min.	<input type="checkbox"/> Jump roping _____ min.	<input type="checkbox"/> Snorkeling _____ min.
<input type="checkbox"/> Basketball _____ min.	<input type="checkbox"/> Lacrosse _____ min.	<input type="checkbox"/> Snow shoeing _____ min.
<input type="checkbox"/> Baseball _____ min.	<input type="checkbox"/> Life Circuit weights _____ min.	<input type="checkbox"/> Softball _____ min.
<input type="checkbox"/> Bicycling _____ min.	<input type="checkbox"/> Martial Arts _____ min.	<input type="checkbox"/> Spinning/cycling _____ min.
<input type="checkbox"/> Bowling _____ min.	<input type="checkbox"/> Miniature golf _____ min.	<input type="checkbox"/> Stairmaster _____ min.
<input type="checkbox"/> Calisthenics _____ min.	<input type="checkbox"/> Nautilus _____ min.	<input type="checkbox"/> Step aerobics _____ min.
<input type="checkbox"/> Canoe/Kayaking _____ min.	<input type="checkbox"/> Nordic Track _____ min.	<input type="checkbox"/> Stretching exercises _____ min.
<input type="checkbox"/> Cardio glide _____ min.	<input type="checkbox"/> Pilates _____ min.	<input type="checkbox"/> Swimming (laps) _____ min.
<input type="checkbox"/> Cross trainer _____ min.	<input type="checkbox"/> Ping pong _____ min.	<input type="checkbox"/> Tai Chi _____ min.
<input type="checkbox"/> Dancing _____ min.	<input type="checkbox"/> Play with kid (active) _____ min.	<input type="checkbox"/> Tennis/platform tennis _____ min.
<input type="checkbox"/> Fishing _____ min.	<input type="checkbox"/> Punching bag _____ min.	<input type="checkbox"/> Ultimate frisbee _____ min.
<input type="checkbox"/> Football _____ min.	<input type="checkbox"/> Racquetball _____ min.	<input type="checkbox"/> Volleyball _____ min.
<input type="checkbox"/> Frisbee _____ min.	<input type="checkbox"/> Rafting _____ min.	<input type="checkbox"/> Water jogging/aerobics _____ min.
<input type="checkbox"/> Gardening _____ min.	<input type="checkbox"/> Rock climbing _____ min.	<input type="checkbox"/> Water skiing _____ min.
<input type="checkbox"/> Golf _____ min.	<input type="checkbox"/> Rollerblading _____ min.	<input type="checkbox"/> Weight lifting _____ min.
<input type="checkbox"/> Handball _____ min.	<input type="checkbox"/> Rowing _____ min.	<input type="checkbox"/> Wrestling _____ min.
<input type="checkbox"/> Hiking _____ min.	<input type="checkbox"/> Sailing or paddle boat _____ min.	<input type="checkbox"/> Yoga _____ min.
<input type="checkbox"/> Hockey _____ min.	<input type="checkbox"/> Scuba diving _____ min.	<input type="checkbox"/> Other _____ min.
<input type="checkbox"/> Horseback riding _____ min.	<input type="checkbox"/> Shuffleboard _____ min.	<input type="checkbox"/> Other _____ min.
<input type="checkbox"/> Hunting _____ min.	<input type="checkbox"/> Soccer _____ min.	<input type="checkbox"/> Other _____ min.



Henry Ford Weight Management Program

FOOD DIARY

In order for this to be most useful for the dietitian working with you please pay attention to the following:

1. **EVERYTHING** you eat or drink is important to note. Even the smallest item should be written on this sheet, including dressing, condiments and drink additions, like cream and sugar. Even write down if you took a bite of something to see how it tastes; or had a snack from 7-11 or a free sample at the Supermarket; or a hot dog at the hardware store or K-Mart.
2. Be as specific as you can. Include brand names or restaurant if applicable.
3. Preparation: Include how the food was prepared. If cooked was it baked, broiled, fried, etc.?
4. Amount Consumed: Although you don't need to measure how much you are eating, do the best you can to show how much you are eating. Example: 3 cookies, a baseball size portion of rice, or a piece of meat the size of a deck of cards.
5. Associated Activity: Identify what you are doing while eating, like watching TV, reading or working at a computer, or simply eating at mealtime.
6. Mood: Identify how you feel when you eating. Are you happy, sad, angry, depressed, non-emotional, etc.
7. Hunger Rating: Using a scale from 1 (not hungry) to 5 (very hungry), describe how hungry you feel.
8. **REMEMBER**: Document the items you eat, not the foods you think the dietitian wants you to eat.
9. **Look at the examples below to help you complete your food diary.**
10. **Choose 3 days to write down what you eat.** It is usually best to do this on either Thursday, Friday, Saturday; OR Sunday, Monday, Tuesday.

Time	Food Item And Preparation	Amount Consumed	Where Are You Eating	Associated Activity	Mood	Hunger Rating
7:00	Orange juice	1 cup	Kitchen	Eating breakfast	tired	3
7:00	Cheerios cereal	1 ½ cups	Kitchen	Eating breakfast	Tired	3
10:15	Popcorn	Small bag	Theater	Watching a movie with the kids	Frustrated	2
12:30	Ham and Cheese sandwich from 7-11	1	In car	Driving	Hurried	4
12:30	Coke Big Gulp	44 oz.	In car	Driving	Hurried	4
12:30	Dorito's	Small bag	In car	Driving	Hurried	4
4:00	Ball Park hot dog on a bun-grilled	1	At hardware store	Shopping	Happy	3
4:30	Chocolate shake from McDonald's	Medium	At home with kids	Watching TV with kids	Bored	2



Henry Ford Weight Management Program

FOOD DIARY

Name: _____

Date: _____

MRN: _____

Time	Food Item And Preparation	Amount Consumed	Where Are You Eating	Associated Activity	Mood	Hunger Rating

Muscular Strength Data Sheet

Preventive Cardiology
Henry Ford Heart & Vascular Institute
Henry Ford Hospital

Subject Number:				Date:		Time of day:	
Name:				MRN:			
Age	DOB		Wt: Ht:		MUAC (cm): Thigh Circ (cm):		Gender M / F
Medications: <input type="checkbox"/> yes <input type="checkbox"/> No Time taken:							
BP:				Test: Baseline 3 Month 6 Month			
HR:							
NuStep Warm Up				Settings: Seat: Arms:			
Stage	Watts	Time	Comments				
Rest	---						
Isokinetic Test			Settings: Seat ht: Front/back:		Seat back:	Leg:	Lateral:
Peak Torque	% Fatigue	Time	Speed	RPE	Comments		
			60				
			120				
			180				
1. Rep Max/Chest Press			****Two minute rest time between attempts**** (warm-up not included)				
			Settings: Seat:		Arms:		
Attempts	Pounds	RPE	Comments				
Warm up							
1							
2							
3							
4							
5							
Do you participate in resistance/weight training?							
If yes how often? 0-1 days/wk 2-3 days/wk 4 or more days/wk							
How would you describe your program: Upper body only Lower body only Total body Alternating total							
How many repetitions? Less than 7 8 to 11 12 to 15 more than 15							
How many sets? One Two Three Four More than four							

HENRY FORD HEALTH SYSTEM INSTITUTIONAL REVIEW BOARD

Continuation/Final report form

The IRB is responsible for the continuing review of research to ensure that the rights and welfare of human participants are being protected. This application for renewal of approval or final report must be submitted to the Research Administration (IRB) Office by the published deadline date at least one month prior to the expiration date to guard against lapse in IRB approval.

EXPIRED RESEARCH: *If you have not responded in time to renew the protocol before it lapses, the protocol is considered expired. Any research activity conducted under an expired protocol is in violation of federal regulations, and could jeopardize the Health System's privilege to conduct human research. The federal regulations allow no "window" after the expiration of the approval period. It is important that your protocol be renewed on time. If your approval expires and you wish to continue your research, the protocol may have to undergo IRB review again as a new protocol. Timely renewal avoids approval lapses.*

The IRB must determine from the information provided on this form whether or not this study should be approved to continue. *Per Federal regulations, "continuing review of research must be substantive and meaningful."* Insufficient information may result in a delay in approving continuation of your project. If this study is part of a multi-center project, provide data on HFHS subjects separately from national data but include both when available.

DIRECTIONS FOR FORM COMPLETION:

1. Use this form for all continuation or final reports. Tab through the form, entering your information in the spaces provided.
2. E-mail this completed form and consent form/s (if still recruiting subjects) to: research_admin@hfhs.org
You must follow these directions:
 - The e-mail subject line must be in the following format (with underscore):
 - a. Indicate 'IRB continuation' or 'IRB final'
 - b. PI last name
 - c. HFHS IRB #
 - d. Indicate 'expedited' or 'full'
 - e. **Example:** 'IRB continuation_Jones_123_full' or 'IRB final_Jones_123_expedited'
 - Attach the continuation/final report form saved with a title of: PI last name and IRB number (i.e. 'jones_123'). Note use an underscore between the items.
 - *If applicable:* attach the consent saved with PI last name, IRB number and 'ICF' (i.e. 'jones_123_ICF') as the title. If there is more than one consent form, differentiate them by number (ICF_1, ICF_2, ICF_3, etc.) or other obvious way (ICF_main study, ICF_genetic_substudy) (use an underscore between the items).
3. Your forms will be returned to you by e-mail. You may print them for your records as you will **not** be receiving copies through interdepartmental mail. As always, should you need a copy, the IRB maintains paper files for every study.

All IRB forms are available on our website (<http://henry.hfhs.org/body.cfm?id=7764>).



Institutional Review Board

Continuation/Final Report

All submissions must be sent electronically to: research_admin@hfhs.org
Investigators are responsible for utilizing the most current versions of IRB forms and the IRB has the authority to refuse out of date forms.

Please Indicate: ☒ Continuation ☐ Final Report

SECTION 1 INVESTIGATOR INFORMATION

Principal Investigator (PI): **Dennis John Kerrigan**

Department (select from the drop downs): **Internal Medicine** Division: **Cardiology**

Entire Project Title (no acronyms): **Short-Term Muscular Strength Changes in Patients Following Weight Loss Surgery. A Pilot Study**

IRB #: 7301 Current IRB Approval Period: 2/11/2012 – 2/11/13

Location to send correspondence (required): **WCFCAM**

Contact Person: **Dennis Kerrigan** Contact phone #: **313-972-4077** Contact e-mail: **dkerrig1@hfhs.org**

Current source of funding: **Internal** Is this study currently NIH funded? ☒ No ☐ Yes (grant #)

If yes, was it originally submitted as such? ☒ No (if no, submit copy of grant) ☐ Yes

Current budget period (if federally funded): – Title of NIH grant (if different):

THE REST OF THIS PAGE IS FOR IRB USE ONLY

Type of IRB Review:

- ☒ Full Board
☐ Expedited (all expedited continuation & final reports are reviewed as informational items at fully convened IRB meetings)

Result of IRB Review:

- ☒ Continuation Approved
☐ Approval Withheld (see reason below)
☐ Final Report Approved (Closure #)

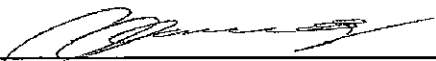
APPROVAL STAMP

APPROVAL PERIOD

Feb 12, 2013 – Feb 11, 2014

INSTITUTIONAL REVIEW BOARD

The HFHS IRB has read & reviewed this protocol & finds this research is appropriate in design and meets the requirements of the Federal Guidelines, 45 CFR Part 46 and 21 CFR Part 50.


Chairperson or designee - Henry Ford Health System IRB

Date: **2/12/13**

Abstentions:

Comments:

Action required:

SECTION 2 UPDATE OF PROJECT ACTIVITY

Please provide a brief yet concise protocol summary. Include the purpose, objective, study design, treatment, and procedures. If your approval period has lapsed, please provide the IRB of how you will prevent this from occurring in the future and whether or not information was obtained from patients enrolled during the lapse.

Purpose: The purpose of this proposed study is to describe changes in muscular strength and body fat at three and six months following bariatric surgery.

Study Design: All subjects are recruited from the Henry Ford Hospital Bariatric Programs (i.e. Detroit, West Bloomfield). Enrollment criteria will include those patients: who have received clearance from their surgeon, adult's ≥ 18 years of age, weight max of 450 lbs, and are free of orthopedic, metabolic, or cardiovascular limitations to exercise. At baseline (T1) (i.e. 1 month before surgery), three months post-surgery (T2), and six months post-surgery (T3), subjects will visit the William Clay Ford Center for Athletic Medicine to undergo strength testing assessments. Testing will include a mild intensity 10 minute warm-up on a recumbent stepper (i.e. NuStep) followed by a familiarization test on both the isokinetic dynamometer (ID) (Biodex, Shirley, New York) and an isotonic chest-press (ICP) resistance machine (Cybex). The isokinetic test will measure relative peak torque (Torque/body mass) at three different speeds as a measure of leg strength. Subjects will be asked to perform 15 consecutive maximal leg extensions on the ID using their dominant leg with five minute rest periods between each speed. Following the ID upperbody strength will be assessed using a seated chest press machine. This will be done using the one-repetition maximal test, which simply measures how much weight an individual can push (elbows fully extended) a single time.

To determine the relationship between muscular strength and body composition, we will measure changes to lean and fat mass on a subset of patients using the Bod Pod.

Statistics: A paired-t test will be used to compare changes in relative strength between the three time periods (T1, T2, T3). Associations between relative peak torque and potential co-variants will be determined using the Pearson-correlation-coefficient. Alpha level will be set at 0.05.

Current status of study: (Please place a checkmark adjacent to each relevant statement.)

- ☐ No subjects have been enrolled. If not, please explain why and a plan to increase enrollment:
- ☒ Research is active (please check appropriate box below)
- ☒ Research is still open to enrollment
- ☐ Research is permanently closed to subject enrollment, but study remains active for HFHS subjects receiving study treatment.
- ☐ Research remains active for long-term follow-up of HFHS subjects and/or data analysis.
- ☐ Research remains active for data analysis only or for long-term follow-up of HFHS subjects without any type of intervention/treatment. This continuation will be reviewed through the expedited process.
- ☐ Requesting termination. If so, please explain (i.e., final report, research and data analysis complete, study never initiated, sponsor request):
- ☐ Other:

SECTION 3 ENROLLMENT UPDATE

- What is the currently approved number of subjects to be enrolled?:
HFHS: 40 Multicenter (if applicable):
- Number of subjects enrolled to date (not including screen failures) at:
HFHS: 21 Multicenter (if applicable):
- If your number enrolled to date exceeds your targeted accrual goal, please explain and provide the new number of subjects approved (you must have had IRB and/or sponsor approval to enroll more than targeted):
 - If yes, did you obtain IRB approval?
☐ No (submit a planned change form with a request to increase the number of subjects)
☐ Yes

b. If yes, did you obtain sponsor approval? ☐ No, not required ☐ Yes

4. Number of subjects enrolled since last IRB review:

HFHS:9 Multicenter (if applicable):

5. For studies that involve chart/medical record review, number of records reviewed: 21

6. Estimated date of enrollment completion (if complete indicate date of completion): 1/26/14

7. Cumulative HFH accrual by race/ethnic group since study initiation (this satisfies Federal requirements assuring equitable distribution of study subjects):

	Caucasian	African Amer	Hispanic	Asian	Other	TOTALS:
Male	4					4
Female	14	3				17
TOTALS:	18	3				

8. Is there an equitable distribution of ethnic and gender groups? ☒ No ☐ Yes

If no, provide justification for the inequity. **The majority of patients who elect to have bariatric surgery are female.**

9. If this study has a low accrual rate to date, please explain why the accrual rate is not what was anticipated (indicate obstacles encountered in enrolling patients):

SECTION 4 PROCEDURAL CHANGES

Have any procedural changes in the protocol been implemented since the study was last approved? ☐ No ☒ Yes

Yes, if so provide a concise narrative summary explaining the reasons for the change:

Procedural/Planned Change (list all versions separately, using attached additional pages as necessary)	Date of IRB Approval	Concise Narrative Summary
Protocol amendment	4-24-12	Addition of Bod Pod test to measure body fat.
Revised Informed Consent*	4-24-12	Addition of Bod Pod test to measure body fat.
Advertisement		
Investigator Brochure		
Sponsor notifications		
Data Safety Monitoring Report		
Other: please specify		

* Note: No consent form revisions can be made in conjunction with this report. Consent revisions must be submitted separately on a Planned Changes form.

Has any new information become available since the last IRB annual review that was disclosed to enrolled subjects? ☐ No ☐ Yes, if so please provide a concise narrative summary explaining the reason(s):

Source of Information	Date of IRB Approval	Concise Narrative Summary
Patient Letter		
Revised Informed Consent		
Addendum to consent form		
Verbal Communication		
Other: please specify		

SECTION 5 SUBJECT WITHDRAWALS

Has any HFHS subject been withdrawn (i.e., patient does not fulfill the requirements of the protocol?) for any reason after signing a consent form? ☒ Yes ☐ No

If yes, please indicate the reason for withdrawal and the total number of withdrawn patients:

- 1 Screen failure _____ Physician discretion _____ Treatment toxicity _____
 _____ Patient request _____ Death _____ Disease Progression _____
 2 Patient non-compliance _____ Patient's medical status _____ Other (specify): _____

Please provide additional information if appropriate:

SECTION 6 SUMMARY OF RESULTS TO DATE

1. If this is a HFHS PI initiated study, are there any pertinent preliminary results available associated with the study? ☒ No ☐ Not a PI initiated study ☐ Yes (please attach to this report).
2. Has this study been audited in the past year by external auditors, not including routine monitoring (i.e. sponsor, FDA)? If so, please submit a copy of the report with this continuation/final report. ☐ Yes ☒ No
3. Please provide a list of clinically significant protocol deviations in the last year, as determined by the investigator, and subject complaints and the processes put in place to prevent their recurrence.
4. Please describe the means whereby the results of the research are going to be disseminated. **Peer-reviewed journals, scientific meetings.**
5. Clinical Trial Registration: Has the study been registered with ClinicalTrials.gov? The PI is responsible for determining that registration requirements are met. Normally, the clinical trial will be registered by the sponsor, lead site (in multi-center studies) or Institute funding the research (in NIH sponsored trials). Refer to the FAQ section of the IRB website for more details. ☐ Yes ☒ No If no, please explain: Small pilot study.

SECTION 7 ADVERSE EVENT REPORTING

Since the last review, have there been any unanticipated problems or serious adverse events encountered in **HFHS subjects** that meet the HFHS IRB criteria for Adverse/unexpected events? (If yes, document in summary table below) ☐ Yes ☒ No

Since the last review, have you received and reviewed one or more reports of adverse drug reactions or other adverse events **from the Sponsor** that meet the HFHS IRB criteria for Adverse/unexpected events? (If yes, document in summary table below) ☐ Yes ☒ No

Number of events by body system				
Body system	# HFHS patients in previous year	# non- HFHS patients in previous year	Total # events (HFHS & non-HFHS) in the previous year (add column 1 & 2)	Total # events (HFHS & non-HFHS) since study start
Allergy/Immunology				
Cardiovascular				
Dermatological				
EENT				
Endocrine/metab				
GI				
Hepatic				
Hematological				

Infection				
Malignancy (1° or 2°)				
Musculoskeletal				
Neurological				
Pain				
Pulmonary				
Renal/GU				
Other				

**ALL OF THE ABOVE REPORTS MUST BE SUBMITTED TO
THE IRB PRIOR TO THIS CONTINUATION/FINAL REPORT.
IF THEY HAVE NOT, PLEASE SUBMIT IMMEDIATELY.**

SECTION 8 PRIVACY

1. Where are the names of research subjects kept? **On a password protected HFHS drive**
2. Where are signed original consent forms kept? **In a lock file cabinet**
3. What provisions do you have in place to ensure confidentiality of data? **Once all data collection is complete all HIPAA patient identifiers will be removed and the database will be closed. All paper documents will be discarded in a HIPAA compliant process**

SECTION 9 CONFLICT OF INTEREST

Principal Investigator: Do you, any member of your family, or any person affiliated with the project have any financial interest, financial relationship, or administrative affiliation with any entity that is providing funds or which has rights to intellectual property resulting from this study?

☐ Yes ☒ No If yes, please explain.

IF THIS IS A FINAL REPORT, DO NOT COMPLETE THE REST OF THIS FORM

SECTION 10 PERSONNEL UPDATE (Continuation reports only)

List Key Personnel:

	Name	Title	Dept/Division
1	Carlin, Arthur	Co-PI	Gen. Surgery/Bariatrics
2	Genaw, Jefferey	Co-PI	Gen. Surgery/Bariatrics
3	Szymanski, Wanda	RN/BSN/CBN	Gen. Surgery/Bariatrics
4	Walton, Renee	Research Assistant	Int. Med/ Cardiology
5	Rashid, Lewis	Research Assistant	Gen. Surgery/Bariatrics
6			
7			
8			

Have there been changes to Key Personnel since last approved?

- ☒ No
☐ Yes (provide letters of commitment) and explain changes.

SECTION 11 CURRENT RISK/BENEFIT ASSESSMENT (Continuation reports only)

Have you become aware of any change in the risk/benefit assessment that would affect a patient's willingness to continue participation in the study? ☐ Yes ☒ No If yes, please explain:

SECTION 12 CONSENT SUBMISSION (Continuation reports only)

For **continuation** reports, the consent form will be stamped with an approval period that matches the approval of this continuation report. **No consent forms should be greater than one year old.**

Is a copy of the current unstamped consent document being submitted with this application?

☒ Yes . Is it the most recently approved version with the 'approval stamp' box left blank?

☒ Yes

☐ No

☐ No/Not applicable, if so please identify reason:

☐ Written consent not required (waived originally)


☐ Study closed to subject enrollment

☐ Other (please explain):

SECTION 13 PRINCIPAL INVESTIGATOR'S ASSURANCE

By submitting this application with my name on it I am bound by these obligations:

- This application for continuing/final review is complete and accurate
- The research will be performed under the direction of the Principal Investigator by trained and qualified personnel
- Informed consent and HIPAA authorization from subjects or their legally authorized representative will be obtained and documented prior to any research activities using the current IRB approved informed consent
- Serious, unexpected adverse events or unanticipated problems will be reported to the IRB, as well as any information that may affect the safe conduct of the research
- The IRB will be informed of any proposed changes in the research or informed consent before changes are implemented, and no changes will occur without prior IRB approval
- **A continuing/final review application will be submitted to the IRB before the deadline at intervals determined by the IRB, but not less than once per year, to avoid expiration of IRB approval**
- A final report will be submitted to the IRB when all research activities have ended
- All Co-investigators, coordinators, staff, and students involved in this research will be informed of their obligations in meeting the above commitments
- Comply with all policies and procedures of Henry Ford Health System Institutional Review Board, as well as with all applicable federal and state regulations and guidelines and Good Clinical Practice guidelines

	<p>CONSENT TO PARTICIPATE IN A RESEARCH STUDY</p> <p>(HFH IRB form rev: 02/2009)</p>	<p>DATE:</p> <p>MRN:</p> <p>NAME:</p>
<p>APPROVAL PERIOD</p> <p>Feb 12, 2013 – Feb 11, 2014</p> <p>INSTITUTIONAL REVIEW BOARD</p>	<p>PROJECT TITLE:</p> <p>Short-Term Muscular Strength Changes in Patients Following Weight Loss Surgery. A Pilot Study</p>	

Dennis J. Kerrigan, PhD.
6525 Second Ave.
Detroit, MI 48202
313-972-1919

1. WHY IS THIS RESEARCH BEING DONE?

You have been asked to take part in a research study because you plan to have bariatric surgery. The purpose of this study is to describe changes in muscular strength within the first six months following weight loss surgery. Because muscle loss can occur along with weight loss, this study will help us determine how much strength (if any) is lost relative to your weight loss and other factors (e.g. exercise, diet, age, etc.) after surgery and if future studies should look at ways to improve this.


There will be approximately 40 people in this research study at Henry Ford Health System (HFHS).

2. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you participate in this study, you will be tested 3 separate times for muscle strength and stamina. You will also be asked to complete two exercise surveys; two nutrition surveys and we will measure the circumference of your upper arm and thigh.

Your participation in this study will last a total of 7 months. As part of this study, you will have 3 visits to the William Clay Ford Center for Athletic Medicine to perform the assessments listed below. The first visit will be done prior to surgery, the second visit is 3 months post surgery and the last will occur at 6 months post surgery.

During this study you will not be asked to perform any special exercises or training. With regards to that we suggest you follow the recommendations given to you by the Henry Ford Bariatric Team.

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Extra and not experimental:

- Diet and fitness questionnaires.** You will be asked to complete 4 questionnaires regarding eating and exercise habits.
- Limb circumference measurements.** Using a standard tape measure we will measure the circumference of your upper arm and thigh as an indirect way of determining muscle mass.
- A leg muscle strength and endurance test.** This standard leg extension test will determine how much you can lift one time and also how strong your muscles remain over a short time period using a machine specific for rehabilitation or research purposes. You will be asked to give a maximal effort.
- An upper-body muscle strength test.** This standard chest, arms, and shoulder machine will determine how much you can lift one time using a standard exercise machine that can be found at a fitness center.
- Vital signs.** This will include a standard seated blood pressure and heart rate similar to what is taken in your doctor's office.

Extra and experimental:

-Body composition test.

On three additional days (before surgery, 3 months, and six months) you will be asked to take a test using a Bod Pod, which measures the amount of fat tissue and lean tissue in your body.


The Bod Pod is an egg-shaped device which measures your body fat through changes in air pressure. You will be asked to wear specially fit swim wear and cap (this will be provided) and sit still in a chamber while a minimum of two tests are performed. Each test requires 50 seconds.

1) Are you willing to go to West Bloomfield Hospital for additional visits to perform the Bod Pod test listed under extra and experimental?

Yes, I am willing to return to the lab to perform this test; patient initials _____

No thanks; patient initials _____



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3. WHAT ARE THE RISKS OF THE STUDY?

You should tell the person obtaining your consent about any other medical research studies you are involved in right now.

It is not expected that you will have any complications or discomforts from being in this study.

While you are in the study, you are at risk for the following side effects:

- Likely
 - Minor muscle soreness
 - Tiredness following exercise, especially after the first several sessions
 - Mild shortness of breath during exercise
- Less Likely
 - Severe fatigue
 - Moderate to severe shortness of breath
 - Blisters
 - Aggravation of orthopedic (muscle, joint, or bone)
 - Fainting
 - Abnormal blood pressure response
 - Disorders of heart beat (too fast or slow or not effective)
- Rare but serious
 - Heart attack or other heart complication
 - Death

There may be additional risks or discomforts that are not known at this time.

There may be risks to you or to your unborn child if you are pregnant now or become pregnant within the time period of this study. Exercise alone is not typically harmful to the mother or the unborn child. However, the risk to the mother and unborn child are not known in those who are 3 or 6 months post bariatric surgery who also perform exercise. These risks may include abnormal development of the unborn child. Also, there could be risks to you or your unborn child that the investigators cannot predict. Because of this, you cannot be in this study if you are pregnant, breast feeding a child, or trying to become pregnant. You must use effective birth control measures including condoms and birth control pills (only if advised by your doctor).



**CONSENT TO
PARTICIPATE IN A
RESEARCH STUDY**

(HFH IRB form rev: 02/2009)

DATE:

MRN:

NAME:

APPROVAL PERIOD

Feb 12, 2013 – Feb 11, 2014

INSTITUTIONAL REVIEW BOARD

PROJECT TITLE:

Short-Term Muscular Strength Changes in Patients Following Weight Loss Surgery. A Pilot Study

4. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

You may not be helped by participating in this study. However, others may be helped by what is learned from this research.

5. WHAT OTHER OPTIONS ARE THERE?

You do not have to participate in this study. Your other choices may include:

- Participating in regular exercise and muscular strengthening without enrolling in this study.

Talk to your doctor about your choices before you decide if you will take part in this study.

6. WHAT ABOUT CONFIDENTIALITY?

By signing this consent form, you agree that we may collect, use and release your personal and health information for the purpose of this research study.

We may collect and use:


- Your existing medical records.
- New health information created during this study.

We may release this information to the following people:

- The Principal Investigator and his/her associates who work on, or oversee the research activities.
- Government officials who oversee research (Food and Drug Administration).
- Other researchers at other institutions participating in the research.

Once your information has been released according to this consent form, it could be released again and may no longer be protected by federal privacy regulations.

This consent form, test results, medical reports and other information about you from this study may be placed into your medical record. Generally, you are allowed to look at your medical record. During the research study, you will be allowed to look at your research study information that is not in your medical record.

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HFHS or others may publish the results of this study. No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This consent to use and release your personal and health information will expire at the end of this research study.

You do not have to sign this consent to release your medical information and may cancel it at any time. If you decide not to sign this consent or cancel your consent, you cannot participate in this study. If you notify us that you wish to stop participating in this study, we may continue to use and release the information that has already been collected. To cancel your consent, send a written and dated notice to the principal investigator at the address listed on the first page of this form.

7. WHAT IF I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study. You are not giving up any of your legal rights by signing this consent form.


8. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Dr. Dennis Kerrigan or his/her staff member has explained this research study and has offered to answer any questions. If you have questions about the study procedures you may contact Dr. Kerrigan at 313-972-1919. To report an injury or medical situation, please contact Dr. Dennis Kerrigan at 313-972-1919. In the case of an emergency please call 911. Medical treatment is available to you in case of an injury.

If you have questions about your rights as a research subject you may contact the Henry Ford Health System IRB Coordinator at (313) 916-2024. The IRB is a group of people who review the research to protect your rights.

9. DO I HAVE TO PARTICIPATE IN THIS STUDY?

No, your participation in this research study is voluntary. If you decide to participate, you can stop at any time. If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. There will be no penalties or loss of benefits to which you would otherwise be entitled if you choose not to participate or if you choose to stop

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your participation once you have started. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study.

10. WHO ELSE CAN STOP MY PARTICIPATION?


The Principal Investigator, sponsor or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

11. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any additional costs to you if you participate in this study.

12. WILL I BE PAID TO PARTICIPATE?

No, there will not be any compensation to participate in this study. However, you will be offered a free monthly membership into the Henry Ford PREVENT exercise program or a free personal training session at a Henry Ford facility. The free month of PREVENT and free personal training will be offered regardless if you decide to decline completion of the study following the first test. Additionally, we will provide you with feedback regarding your results in this study and our recommendations for exercise.

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13. CONSENT

You have read this consent form or it has been read to you. You understand what you are being asked to do. Your questions have been answered. Any technical terms you did not understand have been explained to you. You agree to be in this study. You will be given a copy of this consent form.

Signature of Subject

Date

Time

Print Name of Subject

Witness to Signature

Date

Time

Print Name of Person Obtaining Consent