Obesity and Orthopedic Conditions: Evaluating the Bariatric Surgery Option

A review of available literature

This white paper has been prepared by Ethicon US, LLC, and has not been subject to peer review.

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES
Bariatric surgery is used in the treatment of qualifying obese adult patients for significant long-term weight loss. Individual results following bariatric surgery may vary. Bariatric surgery may be appropriate for some patients and not for others, depending on their specific weight, age, and medical history. Patients and doctors should review all available information on non-surgical and surgical options in order to make an informed treatment decision.

ETHICON manufactures and markets general surgical instruments used in bariatric surgery. The potential benefits discussed are associated with the patient's weight loss and other metabolic effects following bariatric surgery, not with the use of the instruments. ETHICON is offering this information in good faith as an overview to published literature in this area and a starting point for further research. It is not intended to constitute medical advice or recommendations.
Obesity and Orthopedic Conditions: Evaluating the Bariatric Surgery Option

Introduction
Obesity, a chronic disease of substantial public health concern in the United States, is now being classified as an epidemic. More than one third of the American adult population, 75 million adults, is classified as having obesity, with 15 million people classified as having severe obesity (a body mass index (BMI) of \( \geq 40 \text{ kg/m}^2 \)). Often, individuals living with obesity suffer from obesity-related health conditions such as type 2 diabetes (T2DM), hypertension, hyperlipidemia, sleep apnea and arthritis. There are over 40 known obesity-related conditions. This is particularly problematic because when BMI increases so does the prevalence of obesity-related conditions. As a result, patients with severe obesity often experience diminished quality of life and increased mortality.

The Link between Obesity and Orthopedic Conditions
A strong relationship exists between increasing weight and the presence of orthopedic conditions such as premature lower extremity degenerative joint diseases, chronic low back pain, disc herniation, spinal disorders, gout and osteoarthritis. According to the CDC, 22.6% of overweight and 31.2% of Americans with obesity had doctor-diagnosed arthritis, compared with 15.9% of Americans with a normal BMI. Osteoarthritis is one of the leading causes of pain and disability, affecting more than 37% of adults over the age of 60. In women, a separate study showed 4 times greater likelihood in developing knee osteoarthritis in obese individuals compared with those who were normal weight.
Guh and colleagues performed a systematic review and meta-analysis of 89 studies for 20 comorbidities, finding a statistically significant relationship between being overweight (BMI of 25-30 kg/m²) or having obesity (BMI ≥30 kg/m²) and osteoarthritis and chronic back pain. In the same meta-analysis, the relationship between weight status and prevalence of osteoarthritis was determined by gender, with men showing a higher risk ratio for obesity. In women, a separate study showed a 4 times greater likelihood in developing knee osteoarthritis in individuals with obesity compared with those with normal weight. Additionally, overall physical function may be impaired by excess body weight. In individuals with severe obesity with a BMI of greater than 40 kg/m², substantial impairment of postural sway has been shown, suggesting biomechanical constraints due to the increased body weight which may result in less coordination and less balance recovery.\textsuperscript{13}

The relationship between obesity and orthopedic conditions is multifaceted. For one, excess body weight has obvious effects on weight-bearing joints. It is also suggested that adipose tissue may impact the development of osteoarthritis. In a review by Sowers and Karvonen-Gutierrez on the relationship between obesity and knee osteoarthritis, the authors move beyond an outdated "wear-and-tear" theory of increased mechanical loading as reason for the progression of knee osteoarthritis, instead, focus is placed on the numerous biochemical changes that degrade cartilage as a result of increased adipose tissue.\textsuperscript{10} Leptin (detected in high amounts in obese individuals) has been found in the synovial fluid and plasma of patients with osteoarthritis and has been shown to be pro-inflammatory and catabolic in cartilage metabolism. In addition to leptin, other adipocytokines, such as resistin and adiponectin, are released from adipose tissue and also modulate the inflammatory process surrounding osteoarthritis and compound damage to the joint.\textsuperscript{10} Furthermore, obesity promotes a disordered state of glucose and lipid metabolism, which may include the formation of glycation end products, these have been associated with alterations in collagen stiffness, mechanical properties of the extracellular matrix, and proteoglycan synthesis which may result in cartilage degradation.\textsuperscript{10}

**The Bariatric Surgery Treatment Option for Weight Loss**

Traditional approaches to weight loss, including changes in diet and physical activity, are important for a healthy lifestyle. However, a landmark Swedish study found that on average, a 200-pound patient fighting obesity with diet and exercise alone would only be able to achieve a sustained weight loss of 4 pounds over 20 years.\textsuperscript{29} Weight loss resulting from behavioral interventions generally leads to a "starvation response."\textsuperscript{79} The body seeks to defend its body weight by increasing appetite while lowering the metabolism limiting weight loss and promoting weight regain.\textsuperscript{59}

Bariatric surgery helps to reset the body’s ability to effectively manage weight by altering the complex relationship the body has with food and its metabolism.\textsuperscript{20} New research indicates that with procedures that alter the stomach or intestine, surgery has metabolic and hormonal impacts that enable the body to regulate itself down to a lower set point for body fat.\textsuperscript{20} Following bariatric procedures such as sleeve gastrectomy and gastric bypass, the digestive tract is altered in a way that decreases appetite due to modification of gastrointestinal (GI) hormone levels including ghrelin, glucagon-like peptide-1, peptide YY, cholecystokinin, amylin, leptin, insulin, and adiponectin.\textsuperscript{21} Many patients experience a decrease in hunger, increased satiety, and even healthier food preferences.\textsuperscript{22}

Bariatric surgery is the most effective long-term treatment option for qualifying patients with obesity.\textsuperscript{22} It has been shown to improve associated conditions through weight loss, or in some cases such as T2DM, through metabolic processes that can complement or replace the need for other treatments.\textsuperscript{23} According to the America Heart Association Scientific Statement from 2011, “it is clear that obesity surgery today offers the only effective long-term treatment option for the severely obese patient.”\textsuperscript{22} Bariatric surgery has been shown to provide the greatest amount of excess weight loss with greater than 45% one year post surgery compared to 10% or less for lifestyle and pharmacological treatments.\textsuperscript{24-26}

Obesity-related health conditions have been resolved in up to 80% of patients.\textsuperscript{27} Approximately 179,000 bariatric procedures were performed in 2013 in the US.\textsuperscript{28}

![A comparison of weight loss between obesity treatment options](image-url)

Percent average weight loss = % of total body weight lost as a result of treatment

Percent excess weight loss = % of body weight in excess of the ideal body weight that is lost as a result of treatment.
Orthopedic Condition Improvements Associated with Weight Loss Following Bariatric Surgery

For individuals with severe obesity, who are at increased risk for developing osteoarthritis, bariatric surgery provides a compelling treatment option. In most patients, bariatric surgery produces excess weight loss of +25% at 5 years. A weight loss of only 11 pounds can reduce the odds for developing knee osteoarthritis by 50% among women.

Patients who have experienced weight loss after bariatric surgery have demonstrated reduced likelihood of developing osteoarthritis or diminished symptoms of osteoarthritis. Gastric bypass and sleeve gastrectomy procedures have shown promising results: the use of gastric bypass reduced the average participants’ BMI from 51 to 39 kg/m² by a 9-month follow-up, with 91% of patients experiencing a resolution of arthropathy by 21 months. In this same study, the number of medications per day per patient decreased from 9 to 4. After undergoing a sleeve gastrectomy procedure to reduce BMI by an average of 9.2 kg/m² at 1 year, 76% of patients with arthritis experienced joint pain resolution after 6 months, with all patients experiencing joint pain resolution at 1 year after surgery.

Chronic pain can have devastating consequences on quality of life. Weight loss may offer an effective means for reducing pain, and bariatric surgery provides the most effective means for reducing weight in the severely obese patient. After gastric banding, the resulting weight loss was 44kg at 22.5 months, and 89% of patients (n=105) experienced relief of pain in one or more joints after surgery. Furthermore, after the procedure the prevalence of back pain, knee pain, and ankle pain decreased by 82%, 76%, and 94%, respectively. In addition to the improvement in pain, weight loss has also been shown to improve postural stability and sway during walking.

Further studies are currently underway to determine if post-operative joint replacement stability outcomes are better if bariatric surgery is performed before joint replacement surgery or after. In a recent article appearing in the Journal of Bone and Joint Surgery, a new computer model-based evaluation “supports bariatric surgery in morbidly obese patients with end-stage osteoarthritis (loss of cartilage and joint pain, caused by aging and use) prior to TKR.” Outcomes were evaluated comparing a total knee replacement without prior weight loss and 2 years after bariatric surgery in patients with morbid obesity. The results were “We know that bariatric surgery can be an effective treatment for morbid obesity, reducing a patient’s excess weight. In addition, the surgery also reduces the burden of co-morbidities, like diabetes and high blood pressure, and may extend a patient’s life span.” If joint replacement is necessary, many orthopedic surgeons prefer to perform bariatric surgery before a joint replacement because the reduced weight, as a result of bariatric surgery, may lead to shorter anesthesia times, shorter operative times, and shorter tourniquet times.

According to the American Association of Orthopedic Surgeons “if you need total knee or total hip replacement surgery—and your weight is significantly higher than it should be—your doctor may advise you to lose weight before your procedure.” Furthermore, they note that “patients with obesity are more likely to have certain diseases and health conditions that increase the risks of surgery. These include:

- Cardiovascular disease, including high blood pressure
- Type 2 diabetes
- Obstructive sleep apnea, and
- Metabolic syndrome—a group of health conditions that increase your risk for developing cardiovascular disease and type 2 diabetes

Bariatric surgery has been shown to be effective to reduce weight, provide a 45% to 68% improvement or resolution of T2DM, a 42% to 62% resolution of hypertension and a 45% to 76% resolution of sleep apnea.
**Cost Effectiveness of Bariatric Surgery**

Following bariatric surgery, patients may have substantially lower costs associated with reduced medications and a reduced interaction with all levels of the healthcare system as their obesity-related conditions improve. The cost of surgery may begin to be recouped within the first four years, and related cost savings for antidiabetic, antihypertensive and dyslipidemia agents may continue through six years. According to the American Journal of Managed Care (AJMC), a peer-reviewed journal on health outcomes research, health insurers recover their costs for bariatric surgery in about two years for laparoscopic surgery and in about four years for open surgery. The analysis covered six months of pre-surgical evaluation and care, the surgery itself, and up to five years of post-surgical care. Bariatric surgery appears to be a clinically effective and cost-effective intervention for moderately to severely obese people compared with non-surgical interventions.

**Bariatric Surgery Risks**

All surgeries have risks, such as adverse reactions to medications, problems with anesthesia, problems breathing, bleeding, blood clots, inadvertent injury to nearby organs and blood vessels, even death. According to outcomes data from Bariatric Surgery Centers of Excellence, bariatric surgery has an overall mortality of about 0.1%, which is less than cholecystectomy (0.7%) and hip replacement (0.93%). The success of bariatric surgery is highly correlated with the experience of both the surgeon and the health center.

The overall likelihood of bariatric surgery major complications is 4.3%. The risk for serious complications depends on the type of bariatric surgery, the patient’s medical condition, and age, as well as the surgeon’s and anesthesiologist’s experience. General risks associated with bariatric surgery include a failure to lose weight, nutritional or vitamin deficiencies, inflammation of the gallbladder, gallstones, dilated pouch, dysphagia, GERD, incisional hernia, malnutrition, and weight regain. Bariatric surgery may also cause changes to the autonomic nervous system, specifically to the processes that regulate energy balance and metabolic function. While these changes may help to sustain a lower weight set point, they also could induce changes to circulating bile acids, distribution of bacteria in the gut microbiota, and altered vagal and sympathetic neural activity.

Each type of bariatric surgery is associated with its own risks. Risks related to gastric bypass may include nutrient deficiency, anastomotic stenosis, leak or fistula, marginal ulcer/gastritis and stenosis, bowel injury or obstruction, nausea/vomiting, internal/incisional hernia, and pouch dilation. Sleeve gastrectomy may be associated with gastric leak, intra-abdominal abscess, pulmonary embolism, delayed gastric emptying, splenic injury, stenure, and late choledocholithiasis. Gastric banding risks can include gastric perforation, port rotation or leak, band or port-site infection, band obstruction, malposition, nausea/vomiting, and band erosion.

**Identifying a Candidate for Bariatric Surgery**

Bariatric Surgery can be considered for weight reduction in patients that are 18 years of older with a BMI of >40 or ≥35 with an obesity related condition. Bariatric surgery is a viable alternative when diet exercise and other behavioral interventions are not effective. Bariatric surgery has been shown to produce +25% excess weight loss at 5 years.

Achieving weight loss through bariatric surgery may be suitable for reducing orthopedic risk in patients with low back pain, or a BMI or other health conditions (such as out of control diabetes), prior to proceeding with joint reconstruction.

Since bariatric surgery is a life changing event it is important to ensure patients are well informed, motivated and cognizant of the operative risk. It is also important to advise patients on the need for long term follow up. Clinical evidence suggests that the overall risks of severe obesity often outweigh the risks for bariatric surgery. Bariatric surgery results may vary and surgery may or may not be appropriate for particular patients depending on their specific age, weight and medical history. Patients and doctors should review all available medical information on surgical and non-surgical options in order to make an informed decision.

**How to Refer Patients**

After discussing a patient’s candidacy for surgery, a specific referral to a bariatric surgeon can be made. It is important to emphasize behavioral and psychological readiness for the procedure, discuss the benefits and possible complications,
manage post-operative expectations, as well as emphasize the long term responsibilities, such as the need to continue diet and exercise post bariatric surgery. Recommend that the patient check with their current health insurance plan to determine specific requirements for surgery or worth with their bariatric surgeon’s office to do so. Proactively provide them with the necessary documentation that will be required for their surgical consultation. These documents may include weight loss attempts, medical records, and a pre-surgery health evaluation.

Additional Resources

Online resources are available at ethicon.com/obesity, or ASMB.com for those healthcare professionals interested in learning more about bariatric surgery or realize.com for patients who are interested in attending a local informational bariatric surgery seminar or finding a surgeon.

Patients can receive more information and answers to common questions about obesity and bariatric surgery by calling Ethicon’s Obesity Patient Hotline at 1 (855) 273-2549.

References

37. EES analysis of data from US Clinical Trial PMA 070009.