Official Title of the Study: Transmitted Light Tissue Analysis (TiLTT) (TiLLT)

Document Date: January 15, 2015

NCT Number: NCT02749201

Transmitted Light Tissue Thickness Analysis (TiLTT) (TiLLT)

The most common surgical procedure for weight loss is the sleeve gastrectomy. The laparoscopic sleeve gastrectomy (LSG) involves the linear stapling of the stomach using a stapling device [e.g. Echelon (Ethicon Somerset NJ)] fired multiple times along the length of the stomach thereby excising 80-90% of the stomach leaving the patient with a "sleeve" of stomach rather than the normal anatomical pouch. The gastric wall varies in thickness and thus there are a varied staple sizes available for this use. Staple sizes range from 2.0mm-5.0mm in height. In standard surgical practice the surgeon chooses the size of staple cartridge for each subsequent firing based on his experience and estimations about the thickness of the stomach tissue in any given region. The drawback of this technique is that it is highly inaccurate. If the surgeon's estimation is in error, the staple height chosen may be either too tall or too short leading to bleeding or leakage from between the staples or malformed/unformed staples leading to staple line failure. Any of these errors can lead to devastating complications such as hemorrhage, leak, sepsis and death. To date there is no objective way to measure the thickness of the tissue being stapled and thus staple choice relies entirely on surgeon estimation which is inherently inaccurate. We hypothesize that a light source placed in the stomach lumen will transmit light through the gastric wall. The amount of light transmitted, i.e. visible to an imaging device arrayed external to the stomach, will be directly proportionate to the thickness of the stomach. This study will take advantage of the fact that during routine procedures in the sleeve gastrectomy procedure a lighted tube is placed into the gastric lumen via the mouth. This device is called the Gastrisail and has 10 separate LED lights arrayed along its length. This allows for the measurement of transmitted light intensity through the gastric wall at 10 individual locations along the length f the stomach. In addition this study will take advantage of the fact that during standard practice in a sleeve gastrectomy a section of the stomach corresponding to the location of the lights is excised and sent for pathological evaluation. This will allow us to measure the actual thickness of the stomach at 10 points corresponding to he locations of the transmitted light intensity. For this measurement we will use a standardized and validated measurement tool/calipers. Now with two sets of numbers we plan to correlate the degree of transmitted light intensity with actual thickness measurements and thereby reach an algorithm which will allow the transmitted light intensity data alone to predict gastric wall thickness. This will provide the surgeon with an entirely non-invasive objective measure of gastric wall thickness and hopefully improve his/her choice of staple size during these surgical procedures thus improving safety.

The aim of this project is to create a noninvasive method of predicting the thickness of the gastric wall. This information can then be used to aid the surgeon in picking the correct size staple cartridge when stapling the stomach during sleeve gastrectomy surgeries.

Methods: We propose to use a standard gastric sizing bougie (plastic guide placed into the stomach at the time of stapling designed to help outline a standardized staple line) used in

common surgical practice (Gastrisail, Covidien). This bougie comes with 10 LED lights arrayed along its length. The wavelength and light intensity of these LED's is standardized. The bougie is routinely placed via the mouth, down the esophagus and into the distal stomach. the bougie will be retained in place throughout the stapling process as per standard technique. The use of the bougie is part of the standard procedure of sleeve gastrectomy and is used in 100% of all sleeve operations.

Using a standard high definition laparoscope, images of these lights within the gastric lumen will be captured. The images will then be uploaded and processed using a software package provided by ImageIQ, Inc. The software will measure the light intensity at each of the 10 LED positions on the bougie, thereby obtaining 10 individual intensity readings at 10 different sites along the length of the stomach.

There will be no measurements made on the in-vivo stomach but simply an image made of the stomach with the lighted bougie in-situ. The analysis of the light intensity from the image and data extraction will be done after the completion of the surgery using software provided by the ImageIQ corporation.

The stomach will be stapled as per standard surgical routine and the specimen side of the gastric body will be separated from the remnant stomach and removed from the abdominal cavity as per standard surgical practice. Prior to this specimen being sent to the pathology department, on the back table, a standardized, validated thickness measuring tool will be used to measure the thickness of the gastric specimen ex-vivo at the identical 10 points as light intensity imaged at the LED's.

A mathematical formula will then be created to correlate the data obtained by light transmittance through the gastric wall and the mechanical measurements of the gastric specimen we obtained using a scientific calipers. The formula will be derived as a directly proportional calculation with where $y=kx$ and k is a non-zero constant.

This predictive algorithm will allow non-invasive gastric wall thickness measurements in real-time based solely on imaged light transmittance using nothing more than a standard lighted bougie and standard laparoscope.

The study will be conducted in the operating room and will have two halves of data collection. Firstly there will be images taken intraoperatively of the lighted bougie while in proper position within the gastric lumen. Secondly there will be gastric wall thickness measurements taken of the explanted stomach specimen on a back table in the operating room prior to it being sent to the pathology department. This data collection will yield 20 measurements per patient (10 from each of these two sources). Thus each patient will be enrolled in the study only intraoperatively. Following collection of the data for all included patients (see below statistical methodology) the data from each of these sources will be analyzed and the predictive algorithm constructed.