Abstract: A surgical method and complementary apparatus for limiting the amount of food digestion. Accordingly, parts of the small intestine are used for forming alternative routes to the ingested food to decrease the interaction with digestive tissue. One or more constrictors are used to divert or stop the digested food flow in a certain length of the small intestine. The constricting mechanism for diverting ingested food into alternative routes of the digestive system, uses two blocks that can be pressed together over the small intestine, while a mechanical barrier is inserted over the main blood vessel at the site of constriction, to limit pressure over said vessels.
GASTRO-INTESTINAL OPERATIONAL PROCEDURE

TECHNICAL FIELD OF THE INVENTION

The present invention relates generally to surgical intervention in the gastro-intestinal system of a patient for the purpose of elimination and control of obesity.

BACKGROUND OF THE INVENTION

Obesity is a major health risk which concerns a substantial proportion of the western population. A common medical treatment to remedy morbid obesity is surgery, which may take several forms. In general, surgical weight loss procedures are either restrictive or malabsorptive, or a combination thereof. Restrictive procedures include constricting the stomach and/or the entrance of the esophagus, to decrease the amount of food allowed in and absorbed in the absorptive parts of the gastric system. Malabsorptive procedures for weight loss generally shorten the length of the active absorptive intestines. The parts of the digestive system that are restricted in such malabsorptive surgical procedures are the stomach and/or the small intestine. The small intestine carries out the major absorptive task of the gastro-intestinal system. The small intestines are divided into three parts, as described in Fig. 1 to which reference is now made.
Duodenum 20, is a small part of the small intestine situated at the opening of stomach 22, the duodenum receives secretions from the pancreas and liver. Jejunum 24 consisting of about 40% of the small intestine, runs between the duodenum and ileum 26. The ileum empties into large intestine 28. The native digestive system forms a single channel, in which the flow of food is unidirectional.

In US Patent applications 20030019498A1 and 20030066536A1 an implanted apparatus is disclosed for mechanically restricting the intake of food into the digestive system using external energy source from outside of the body.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic description of the gastric system showing the stomach, small intestine and connection to the large intestine;

Fig. 2 is a schematic description of a side-to-side anastomosis surgical treatment in accordance with one preferred embodiment of the invention;

Fig. 3 is a schematic description of an end-to-side anastomosis surgical treatment in accordance with another preferred embodiment of the invention;

Fig. 4 is a schematic description of an embodiment implementing two bypasses in the small intestine, one leading to a stoma.

DESCRIPTION OF THE PRESENT INVENTION
The native digestive system is a single path in which the food ingested undergoes digestion as it runs unidirectionally. The present invention provides schemes for making structural changes in the digestive system of an obese patient for the purpose of controllably limiting the amount of food absorbed by the digestive system. The structural schemes of the invention are generally described as forming a diversion of the native digestive tract by connecting two separate points along the tract, and/or implemented to limit the interaction between ingested food and the digestive system. This is achieved, generally, by limiting the amount of digesting tissue exposed to ingested food, and/or shortening the time with which the ingested food interacts with the digestive tissue.

**Bypasses and stomata**

In accordance with the present invention several alterations can be made to the native digestive system in order to limit the ingestion of food taken in by the patient and shorten by a uniquely designed bypass the effective absorptive surface and the interaction time of food with digestive tissue. A mechanical control unit is implanted in the body for constricting the aperture size of various passages, stomata or alternative pathways thereby imposing a limit to the amount of food digested in the digestive system.

In one preferred embodiment of the present invention a shunt for bypassing a substantial part of the small intestine is provided. In accordance with one preferred embodiment of the invention, the original path, leading to the large intestine, is controllably constricted as described in Fig. 2 to which reference is now made. Food entering the stomach as indicated by arrow 40 flows through
duodenum 20 and through the jejunum as indicated by arrow 42. Arrow 44 indicates a side-to-side anastomosis, whereby the side of the jejunum 24 is cut open and the opening matched to a side opening in ileum 26. Constrictor means 46 grips the intestine, disabling or restricting flow of food in the direction of arrow 48. When constrictor 46 is relaxed, food can enter in the direction of arrow 48. The actual constriction mechanism is described below.

In another preferred embodiment of the invention, a by-pass operative procedure performed, in which the sections of the small intestine are anastomosed end-to-side as described in Fig. 3 to which reference is now made. A side-cut is made in the wall of jejunum 24 at site 50 which is connected to an opening of by-pass section 52 of the small intestine. Section 52 connects to ileum 26 at site 54. In this embodiment, two constrictors 56 and 58 are disposed along the parts of the small intestine as described in the figure and discussed below.

In another embodiment of the present invention, an ileal stoma is provided surgically such that a patient is able to empty at least a part of the digestive track's contents into an external container. A mechanically controlled constrictor manages the dimensions of the aperture, hence the amount of excluded contents. Furthermore, as described in Fig. 4, reference to which is now made, two bypasses can be applied to the same patient. The small intestine's main branch 70, carries food along the small intestine to the large intestine, whereas bypass 72 directs food to the colon. Secondary bypass 74 connects bypass 72 with a stoma clearing food in the form of bowl content out of the body. In such case two constrictors are employed. Constrictor 82 constricts the small
intestine's passage, whereas constrictor 84 constricts the other branch, leading to the stoma and/or to the colon.

**The constrictors and constriction control**

The side-to-side anastomosis as described in Fig. 2, to which reference is again made, employs constrictor 46, gripping the intestine past the anastomosis. When the constrictor is activated, i.e. its grip over the intestine is strengthened, ceasing or diminishing flow in the direction of arrow 48. Food can flow in the direction of arrow 50. When the constrictor is relaxed, food can flow in the direction of arrow 48 again. The end-to-side anastomosis as described in Fig. 3 to which reference is again made, lends itself to a double restriction control. Food flow in the direction of arrow 24 can be arrested by the activation of two constrictors, constrictor 58 arresting flow in the direction of the original intestine as indicated by arrow 48. Through the anastomosis, constrictor 56 can arrest the flow in the direction of by-pass section 52.

A constrictor of the invention is made typically in the form of two parallel linear blocks substantially embracing an organ. Such a constrictor is capable of clenching the digestive organ, thereby blocking its lumen, by drawing the two parallel blocks together. Activating the constrictor is achieved typically by will of the treated patient. Thus, when a patient wishes to cease or diminish the absorptive action of the intestine, the constrictor activation is triggered by signaling. The signaling mechanism is exogenic (external) and can be chosen from any remotely activating physical field. Typical signaling media are electromagnetic fields or magnetic fields, but mechanical force may be used for
signaling as well. A receiver of a signal is connected to the actuator of the constrictor. The receiver receives a signal from a transmitter employed by the user/patient. Actual activation of the constrictor is achieved by electrical motor, or a pneumatic actuator. Another possibility is the construction of an artificial constrictor made from an endogenic muscle tissue. The energy for actuating the constrictor may be obtained externally or endogenically. Thus, electromagnetic or electric energy or magnetic energy may be supplied by an external source to activate the constrictor. Alternatively, energy may be supplied by piercing the skin to provide electric contact. If the source of energy is endogenic, an implanted battery may be used. The external energy is applied only to trigger the actuation of the constrictor. In some embodiments of the invention the control over the constrictors is external, such that an external trigger activates or relaxes the constrictor. Another restriction method is that of an internal balloon that inflates inside the lumen of the intestine in order to congest the lumen. In such a case a liquid or gas is to be driven into the balloon by a pump thereby causing it to inflate.

In cases in which the restrictor is made of endogenous muscle tissue, the activation is effected by a specially designed electronic muscle pacer, such as used today for anal sphincter control, or for activation and maintenance of denervated striated muscles.

Tissue protection appliances

To control the risk of damage to the small intestines, permanent pressure sensors and continuous oxymetry of bowel tissue can be carried out at the site of actual constriction to detect excessive pressure or tissue oxygen deficiency. If a
significant decrease is detected, constriction is automatically ceased, relaxing the tissue of the intestines. Limiting the constriction may additionally be affected by predetermining the minimal mechanical space allowed between the blocks making up the constrictor. Such regulation is typically brought about by placing a mechanical barrier around the main blood vessels feeding and draining the site of constriction. Accordingly, a device should be secured to the inner abdominal wall, enhancing control and reducing the risk of bowl rotation and secondary damage.

Stomach distension

In another embodiment of the invention, sensors are attached to the stomach that sense the tension exerted on the walls of the stomach. A change in the volume of the stomach correlates with the tension exerted on the walls of the stomach. Accordingly, a control over the digestive system is imposed so as to automatically counterbalance to amount of food taken in. The control is exerted by the action of one or more of the constrictors operative in connection with the digestive system as described above.
CLAIMS

1. A method for limiting the amount of food digestion, whereby parts of the small intestine are used for forming alternative routes to the ingested food to decrease the interaction with digestive tissue, wherein at least one constrictor is used to at least divert the digested food into bypasses of a certain length of the small intestine.

2. A constricting mechanism for diverting ingested food into alternative routes of the digestive system, wherein two blocks are pressed together over the small intestine, and a mechanical barrier is inserted over the main blood vessel at the site of constriction, to limit pressure over said vessels.

3. A method for limiting the amount of food digestion, whereby sensors attached to the stomach for sensing the change in the volume of said stomach subsequently to control the constriction applied to the digestive system.