staple lines and anastomoses (gastro-entero; entero-entero). The most frequent postoperative complications after bariatric surgery are bleeding, leaks, and stenosis of the anastomosis.

[005] Therefore, improved systems, devices, and methods are desirable.

SUMMARY

[006] The instant disclosure provides a novel class of surgical staple line reinforcement systems, devices, and methods. Disclosed examples provide increased adherence, hemostatic, and sealing properties as compared to current technology. In examples, a biocompatible matrix or substrate material, for example a collagen matrix material such as non-crosslinked bovine pericardium, is modified prior to use, for example by the addition of a self-expanding polymer such as NHS-PEG (N-hydroxylsuccinimide functionalized polyethylene glycol) coating, to provide increased adherence, hemostatic, and sealing properties that current commercially-available products lack. This NHS-PEG enhancement is an improvement over known glue-applied buttress materials.

[007] Disclosed examples comprise covalent bonding among the biocompatible matrix, the self-expanding polymer, and tissue surface, resulting from adding a surface coating of, for example, NHS-PEG on to a collagen matrix, and hemostatic properties are achieved by an increased compression along the staple line and collagen matrix buttress resulting from the swelling of the self-expanding polymer. During use, the NHS-PEG forms a hydrogel layer that bonds with the biocompatible matrix, the tissue, and also self-crosslinks, increasing adherence to a treatment area to prevent slippage or misplacement.

[008] Sealing properties are improved by the increased adherence and compression resulting from the combination of self-expanding polymer and the collagen matrix along the staple line. The combination of these properties advances the utility of staple line buttresses when used on tissue, specifically friable or diseased tissue (*e.g.*, emphysematous lung parenchyma, cirrhotic liver parenchyma, inflamed or denuded bowel, etc.). As no existing staple line reinforcement technology has the disclosed attributes, this is a significant and novel improvement for the repair of soft tissue deficiencies using surgical staplers when staple line reinforcement is needed.

[009] Disclosed examples comprise a biocompatible matrix, for example a collagen matrix coated with a self-expanding polymer, for example NHS-PEG.

[010] Disclosed examples comprise a self-expanding polymer, for example NHS-PEG, covalently bonded to a biocompatible matrix, for example a collagen matrix.

[011] Disclosed examples comprise a staple line reinforcement material comprising a biocompatible matrix, for example a collagen matrix, and a self-expanding polymer, for example NHS-PEG.

[012] Disclosed examples comprise methods of producing a biocompatible matrix, for example a collagen matrix, coated with a self-expanding polymer, for example NHS-PEG.

[013] Disclosed examples comprise methods of use for the surgical repair of soft tissue deficiencies using surgical staplers when staple line reinforcement is advantageous.

[014] Examples can comprise use with linear or circular staple lines, or combinations thereof. Disclosed examples comprise methods of use for the surgical repair of soft tissue deficiencies such as abdominal and thoracic wall repair, muscle flap reinforcement and repair of hernias. Disclosed examples can improve surgical outcomes such as blood loss, need for transfusion(s), complications, and surgical revision, reducing hospital stay duration.

[015] In examples, upon application, body fluids dissolve the NHS-PEG coating. Then, four-arm NHS-PEG reacts with NH_2 groups of tissue proteins. Covalent amide bonds are formed, cross-linking the PEG and the tissue proteins. During the reaction, NHS molecules are released (*see* FIG. 1).

[015a] In one aspect, the present disclosure provides a method for treating a surgical staple line comprising applying to the line a resorbable sponge coated with a self-expanding polymer.

[015b] In another aspect, the present disclosure provides a device for treating a surgical staple line, said device comprising a resorbable sponge and a self-expanding polymer.

[015c] In another aspect, the present disclosure provides a kit for use in treatment of surgical staple lines, comprising;

a resorbable sponge coated with a self-expanding polymer; and

at least one administration device, buffer solution, syringe, tube, catheter, forceps, scissors, sterilizing pad or lotion.

[015d] In another aspect, the present disclosure provides a method of manufacturing a device for treating a surgical staple line, said device comprising a biocompatible matrix and a self-expanding polymer; said method comprising:

a) providing a biocompatible matrix comprising a resorbable sponge in dried form;

b) providing a self-expanding polymer material in an aqueous solution with a pH of lower than 5, or a water free organic solvent based solution based on ethanol, acetone, or methylenechloride;

c) contacting the matrix with the self-expanding polymer solution; and

d) drying the material.

[015e] In another aspect, the present disclosure provides a method of manufacturing a device for treating a surgical staple line, said device comprising a biocompatible matrix and a self-expanding polymer; said method comprising:

a) providing a matrix of a resorbable sponge in dried form;

b) providing one self-expanding polymer material in the form of dry powder

c) fixing the self-expanding polymer material on the matrix.

BRIEF DESCRIPTION OF THE DRAWING

[016] FIG. 1 shows a schematic demonstrating the action of a disclosed embodiment.

CLAIMS

1. A method for treating a surgical staple line comprising applying to the line a resorbable sponge coated with a self-expanding polymer.

2. The method of claim 1, wherein said resorbable sponge comprises collagen.

3. The method of claim 2, wherein said self-expanding polymer comprises PEG.

4. The method of claim 3, wherein said PEG comprises NHS-PEG.

5. The method of claim 1, wherein said surgical line is associated with a bariatric procedure.

6. The method of claim 1, wherein said surgical line is associated with a gastric procedure.

7. The method of claim 1, wherein said surgical line is associated with a lung procedure.

8. The method of claim 1, wherein said surgical line is associated with a bowel procedure.

9. The method of claim 8, wherein said bowel procedure comprises a small bowel procedure.

10. A device for treating a surgical staple line, said device comprising a resorbable sponge and a self-expanding polymer.

11. The device of claim 10, wherein said resorbable sponge comprises collagen.

12. The device of claim 10, wherein said self-expanding polymer comprises PEG.

13. The device of claim 12, wherein said PEG comprises NHS-PEG.

14. The device of claim 10, further comprising a pressure-sensitive adhesive.

15. A kit for use in treatment of surgical staple lines, comprising;

a resorbable sponge coated with a self-expanding polymer; and

at least one administration device, buffer solution, syringe, tube, catheter, forceps, scissors, sterilizing pad or lotion.

16. The kit of claim 15, wherein said resorbable sponge comprises collagen.

17. The kit of claim 15, wherein said self-expanding polymer comprises PEG.

18. The kit of claim 16, wherein said self-expanding polymer comprises NHS-PEG.

19. A method of manufacturing a device for treating a surgical staple line, said device comprising a biocompatible matrix and a self-expanding polymer; said method comprising:

a) providing a biocompatible matrix comprising a resorbable sponge in dried form;

b) providing a self-expanding polymer material in an aqueous solution with a pH of lower than 5, or a water free organic solvent based solution based on ethanol, acetone, or methylenechloride;

c) contacting the matrix with the self-expanding polymer solution; and

d) drying the material.

20. A method of manufacturing a device for treating a surgical staple line, said device comprising a biocompatible matrix and a self-expanding polymer; said method comprising:

a) providing a matrix of a resorbable sponge in dried form;

b) providing one self-expanding polymer material in the form of dry powder
c) fixing the self-expanding polymer material on the matrix.