

SUMMARY

[0009] Briefly stated, the disclosure relates to meshes, and in particular to meshes that are useful in medical applications, such as surgical and hernia meshes. The meshes of the present disclosure are particularly well suited for use in medical applications.

[0009a] In one aspect, the present disclosure refers to a partially absorbable mesh comprising: at least one bioabsorbable fiber and at least one biostable fiber; wherein the bioabsorbable fiber and the biostable fiber are combined to form a partially absorbable mesh, the partially absorbable mesh having an X-direction and a perpendicular Y-direction; wherein the partially absorbable mesh comprises pores formed by the biostable fiber, and the bioabsorbable fiber is interwoven around and reinforces the pores, and a plurality of the pores are characterized as having an average diameter; and wherein the average diameter of the pores changes by less than 25% after removal of the bioabsorbable fiber.

[0010] In one example, the present disclosure provides a partially absorbable mesh that comprises at least one bioabsorbable fiber and at least one biostable fiber. The mesh is partially absorbable in the sense that upon implantation of the mesh into a subject, the bioabsorbable fiber will degrade, or in other words, the bioabsorbable fiber will absorb into the host, leaving behind a mesh formed from the biostable fiber. The partially absorbable mesh has properties that are well suited to its initial implantation in the host, while the residual mesh formed from the biostable fiber has different properties that are well suited to a mesh that remains implanted in the host after a healing process has proceeded to a desired degree.

[0011] The bioabsorbable fiber and the biostable fiber are combined to form the partially absorbable mesh. When laid flat, the partially absorbable mesh is essentially a two-dimensional structure, having a substantial length, a substantial width, and a relatively small thickness. For convenience, the partially absorbable mesh may be described as having an X-direction and a perpendicular Y-direction, i.e., the X- and Y-

directions are perpendicular to one another. In one example, the mesh may be described as having a wale direction and a course direction, where the wale corresponds to the X-direction and the course corresponds to the Y-direction. In another example, when the mesh is prepared on a knitting machine, the resulting mesh may be described as having a machine direction and a cross-machine direction, where the machine direction corresponds to the X-direction and the cross-machine direction corresponds to the Y-direction.

[0012] The partially absorbable mesh comprises pores. After the absorbable fiber(s) absorb or are otherwise removed or dissociated from the partially absorbable mesh, the residual mass of the partially absorbable mesh comprises biostable fiber. That biostable fiber is in the form of a biostable mesh. The biostable mesh likewise comprises pores. According to the present disclosure, a pore of a mesh can be characterized by a pore size, and a plurality of pores in a mesh can be characterized by an average pore size. Methods to determine pore size, and consequently average pore size, are described herein. Thus, the partially absorbable mesh comprises pores, and a plurality of the pores are characterized as having an average diameter.

[0013] Advantageously, one example of the mesh is such that degradation of the partially bioabsorbable mesh does not significantly change the size of the pores that are present in the original mesh. For instance, the average diameter of a plurality of the pores changes by less than 25%, or less than 20%, or less than 15%, or less than 10%, or less than 5%, after removal of the bioabsorbable fiber from the partially absorbable mesh (in comparison to the original partially absorbable mesh). In other words, the biostable mesh that is a component of the partially absorbable mesh has an average pore size that is essentially the same as an average pore size of the partially absorbable mesh.

[0014] In part, this maintenance of pore size may be achieved according to the present disclosure by interweaving the bioabsorbable fiber around the pores that are formed by the biostable fiber rather than through those pores. In other words, the

bioabsorbable fiber does not cross or otherwise occlude pores formed by the biostable fiber. Instead, the bioabsorbable fiber reinforces pores that are present in a biostable mesh. Therefore, when the bioabsorbable fiber undergoes bioabsorption in a host, the tissue adjacent to the mesh does not experience a change in its interaction(s) with the pores of the mesh. This is highly desirable since tissue tends to grow into the major pores of an adjacent mesh, and if these major pores maintain a constant or near-constant size, then the growing tissue is less like to be disturbed by bioabsorption of the partially absorbable mesh. Thus, in one example, the bioabsorbable fiber is interwoven with the biostable fiber. In another example, the bioabsorbable fiber reinforces a periphery of the pores of the partially absorbable mesh.

[0015] As noted above, in one example, the biostable fiber forms a biostable mesh, and the biostable mesh is a component of the partially absorbable mesh. Optionally, the biostable fiber forms a biostable mesh having a weight of 35-70 g/m². Within this weight range, the biostable mesh has a desirably high strength to remain as a supporting mesh within the host, however it is not so large as to cause undesirable irritation within the host. This weight range is also desirable in that bioabsorbable fiber may be added to this weight of biostable mesh without creating a mesh that is heavyweight (>140 g/m²).

[0016] The bioabsorbable fiber is preferably interwoven into the biostable mesh formed from the biostable fiber. This does not mean that the biostable mesh is necessarily formed first and the bioabsorbable fiber is added to the biostable mesh, although that is one option. However, it is also an option that the biostable mesh and the partially absorbable mesh are formed simultaneously, for example, by bringing the biostable and bioabsorbable fibers together at the same time as the partially absorbable mesh is formed. Thus, a statement that the bioabsorbable fiber is interwoven into the biostable mesh denotes a structure and not a method of making a mesh.

[0017] Likewise, the bioabsorbable fiber may be described as existing within the

partially absorbable mesh in terms of a pattern. For instance, the bioabsorbable fiber may be present in a recognized stitch pattern, such as a pillar stitch. In one example, the bioabsorbable fiber is present as a pillar stitch in the partially absorbable mesh. In another example, a pillar stitch runs through the biostable mesh, where the pillar stitch is formed from bioabsorbable fiber, so that the resulting mesh is a partially absorbable mesh. In one example, the bioabsorbable fiber in the form of a pillar stitch is interwoven with the biostable fiber.

[0018] In one example, the partially absorbable mesh is anisotropic. In other words, the value of a mesh property as measured in the X-direction is different from the value observed for that same mesh property when it is measured in the Y-direction. As an example, the elongation of the mesh (a mesh property) may be greater in the Y direction than in the X direction, when that elongation is measured under standard conditions such as 16 N/cm. Optionally, the biostable mesh that forms a component of the partially absorbable mesh is, itself, anisotropic. However, in one example, the addition of the bioabsorbable fiber induces or modifies anisotropic properties in the partially absorbable mesh that are not observed in the absence of the bioabsorbable fiber. As another example of anisotropy, in one example the mesh of the present disclosure has an elongation in the X-direction when measured at 16 N/cm, where that elongation increases by at least 50%, or by at least 60%, or by at least 70%, or by at least 80%, or by at least 90%, after removal of the bioabsorbable fiber.

[0019] The structure of the mesh may also, or alternatively, be anisotropic. For example, in one example the bioabsorbable fiber runs in the X-direction of the mesh. In another example, the bioabsorbable fiber runs in the X-direction of the mesh and does not run in the Y-direction of the mesh. In yet another example, the mesh comprises both colored and uncolored bioabsorbable fiber, where the colored bioabsorbable fiber runs in the X-direction of the mesh and does not run in the Y-direction of the mesh. Alternatively, in one example the bioabsorbable fiber runs in the Y-direction of

the mesh, while in another example, the bioabsorbable fiber runs in the Y-direction of the mesh and does not run in the X-direction of the mesh. In yet another example, the mesh comprises both colored and uncolored bioabsorbable fiber, where the colored bioabsorbable fiber runs in the Y-direction of the mesh and does not run in the X-direction of the mesh.

[0020] Having a colored thread run in one direction and not the perpendicular directions allows the surgeon to see an anisotropy in the mesh which may translate to anisotropic physical properties for the mesh. This allows the surgeon to position the mesh in a manner consistent with a preferred placement, without having to guess which direction provides which physical properties.

[0021] The biostable fiber component of the partially absorbable mesh does not degrade within the body after placement of the mesh in a patient's body. Examples of polymers that are biostable, and from which biostable fiber may be prepared, include polyolefins such as polypropylene and polyethylene. Optionally, the biostable fiber component may be replaced in whole or part with a slowly bioabsorbable fiber. A slowly bioabsorbable fiber maintains at least 90% of its physical properties for at least six months after placement in a host. Examples of slowly-absorbing bioabsorbable fibers include polylactic acid, PLLA, segmented block copolymer containing a majority of L-lactide derived units, e.g., 88% L-lactide and 12% trimethylene carbonate, and polyester such as poly(4-hydroxybuterate).

[0022] The bioabsorbable fiber component of the partially absorbable mesh does degrade within the body after placement of the mesh in a patient's body. That degradation may begin, for example, as soon as the mesh contacts the fluid environment of the patient, and typically is well underway within two weeks of placement. In one example, the absorbable component of the mesh has completely degraded within the time period of 2-16 weeks. In another example, the absorbable component of the mesh has completely degraded within the time period of 6-12 weeks. In one example, the bioabsorbable fiber has completely dissolved after

immersion of the partially absorbable mesh for 12 weeks in a phosphate buffer at 7.4 pH and 37°C.

[0023] The following are six additional examples of the present disclosure:

1. A mesh comprising: at least one bioabsorbable fiber; at least one biostable fiber; wherein the bioabsorbable fiber and the biostable fiber are co-knit to form a structure containing pores; and size of the pores remains substantially unchanged after absorption of the bioabsorbable fiber.
2. A process for forming a biostable/bioabsorbable composite comprising: using a stitch pattern to co-knit a biostable and a bioabsorbable fiber to form a structure with pores; and bioabsorption of the bioabsorbable fiber does not substantially change a size dimension of the pores within the structure.
3. A mesh comprising: at least one bioabsorbable fiber; at least one biostable fiber; wherein the bioabsorbable fiber and the biostable fiber are co-knit to form a pattern containing pores; and the bioabsorbable fiber reinforces the periphery of the pores.
4. A mesh comprising: at least one bioabsorbable fiber; at least one biostable fiber; wherein the bioabsorbable fiber and the biostable fiber are co-knit to form an initial pattern containing pores; and wherein the pattern remains substantially unchanged after absorption of the bioabsorbable fiber.
5. A mesh comprising: at least one bioabsorbable fiber; at least one biostable fiber; wherein the bioabsorbable fiber and the biostable fiber are co-knit to form a pattern containing pores; wherein the mesh remaining after degradation of the bioabsorbable fiber exhibits decreased Y direction elongation compared to the mesh before degradation of the bioabsorbable fiber; and wherein X direction elongation increases by approximately 100%, or in another example, by greater than approximately 80%.

6. A mesh comprising: at least one bioabsorbable fiber; at least one biostable fiber; wherein the bioabsorbable fiber and the biostable fiber are co-knit to form a pattern containing pores; wherein the mesh remaining after degradation of the bioabsorbable fiber exhibits increased Y direction elongation compared to the mesh before degradation of the bioabsorbable fiber; and wherein X direction elongation increases by approximately 100%, or in another example, by greater than approximately 80%.

[0024] In addition to providing meshes, the present disclosure also provides uses for meshes, and particularly medical uses for the meshes. For example, in one example the present disclosure provides a method comprising placing a mesh according to the present disclosure in a patient, and particularly placing the mesh adjacent to tissue that would benefit from physical support. An example is a hernia, where a hernia occurs when an organ, intestine or fatty tissue squeezes through a hole or a weak spot in the surrounding muscle or connective tissue. The mesh of the present disclosure may be placed adjacent to or within the abdominal wall to reinforce a hole or weak spot in the muscle or connective tissue in order to provide a scaffold and support for healing to occur while protecting organs, intestines, or fatty tissue from passing through the abdominal wall. Examples of hernias which may be treated according to the methods of the present disclosure includes inguinal (occurs in the inner groin); femoral (occurs in the upper thigh/outer groin); incisional (occurs through an incision or scar in the abdomen), ventral (occurs in the general abdominal/ventral wall), umbilical (occurs at the belly button), and hiatal (occurs inside the abdomen, along the upper stomach/diaphragm). In one example, the mesh is placed on the tissue in need of support, where the tissue is anisotropic in terms of its elongation, and the mesh is positioned so that the direction of mesh that exhibits the greater elongation matches the direction of tissue that exhibits the greater elongation. In this way, the mesh better accommodates the movement of the tissue.

[0025] In addition to providing meshes and methods for their use, the present

disclosure also provides methods for preparing a mesh. For example, in one example biostable and bioabsorbable fiber are simultaneously used to form a mesh, where the biostable fiber forms a biostable mesh and the bioabsorbable fiber is interwoven with the biostable mesh at the same time that the biostable mesh is being formed.

Optionally, the biostable fiber is introduced to the partially bioabsorbable mesh using a pillar stitch, i.e., the bioabsorbable fiber is interwoven in the form of a pillar stitch.

[0026] This Brief Summary has been provided to introduce certain concepts in a simplified form that are further described in detail below in the Detailed Description. Except where otherwise expressly stated, this Brief Summary is not intended to identify key or essential features of the claimed subject matter, nor is it intended to limit the scope of the claimed subject matter.

[0027] The details of one or more embodiments are set forth in the description below. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments. Thus, any of the various embodiments described herein can be combined to provide further embodiments. Aspects of the embodiments can be modified, if necessary to employ concepts of the various patents, applications and publications as identified herein to provide yet further embodiments. Other features, objects and advantages will be apparent from the description, the drawings, and the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] The construction designed to carry out the disclosure will hereinafter be described, together with other features thereof. The disclosure will be more readily understood from a reading of the following specification and by reference to the accompanying drawings forming a part thereof, wherein an example of the disclosure is shown and wherein:

[0029] Figure 1 shows a feature of a prior art mesh construct where one fiber type occludes pores formed from a different fiber type.

[0030] Figure 2 shows a feature of a mesh construct pursuant to the current disclosure where one fiber type reinforces pores formed from a different fiber type.

[0031] Figures 3A, 3B and 3C shows the same exemplary sample of a mesh of the present disclosure, where Figure 3A focuses on the pores of the mesh; Figure 3B focuses on how to determine pore size of a mesh; and Figure 3C focuses on an exemplary placement of bioabsorbable fiber within the mesh.

[0032] Figure 4 shows a diagram depicting present day mesh hernioplasty.

CLAIMS

What is claimed is:

1. A partially absorbable mesh comprising:
at least one bioabsorbable fiber and at least one biostable fiber;
wherein the bioabsorbable fiber and the biostable fiber are combined to form a partially absorbable mesh, the partially absorbable mesh having an X-direction and a perpendicular Y-direction;
wherein the partially absorbable mesh comprises pores formed by the biostable fiber, and the bioabsorbable fiber is interwoven around and reinforces the pores, and a plurality of the pores are characterized as having an average diameter;
and
wherein the average diameter of the pores changes by less than 5% after removal of the bioabsorbable fiber.
2. The mesh of claim 1 wherein the bioabsorbable fiber is interwoven with the biostable fiber.
3. The mesh of claim 1 wherein the bioabsorbable fiber reinforces a periphery of the pores.
4. The mesh of claim 1 wherein the biostable fiber forms a biostable mesh, and the biostable mesh is a component of the partially absorbable mesh.
5. The mesh of claim 1 wherein the biostable fiber forms a biostable mesh having a weight of 35-70 g/m², and the biostable mesh is a component of the partially absorbable mesh.
6. The mesh of claim 1 wherein the bioabsorbable fiber is interwoven into a biostable mesh formed from the biostable fiber, where the bioabsorbable fiber is interwoven via a pillar stitch.
7. The mesh of claim 1 which is anisotropic.
8. The mesh of claim 1 wherein the bioabsorbable fiber induces an increased degree of anisotropy in the partially absorbable mesh compared to an

anisotropy of the biostable mesh component of the partially absorbable mesh.

9. The mesh of claim 1 having a greater elongation in the Y-direction than in the X-direction when measured at 16 N/cm.
10. The mesh of claim 1 having an elongation in the X-direction when measured at 16 N/cm, the elongation increasing by at least 50% after removal of the bioabsorbable fiber.
11. The mesh of claim 1 wherein the bioabsorbable fiber runs in the X-direction of the mesh.
12. The mesh of claim 1 wherein the bioabsorbable fiber runs in the X-direction of the mesh and does not run in the Y-direction of the mesh.
13. The mesh of claim 1 comprising both colored and uncolored bioabsorbable fiber, where the colored bioabsorbable fiber runs in the X-direction of the mesh and does not run in the Y-direction of the mesh.
14. The mesh of claim 1 wherein the biostable fiber is prepared from a polymer selected from the group consisting of polyethylene, polyethylene terephthalate, and polypropylene.
15. The mesh of claim 1 wherein the bioabsorbable fiber has completely dissolved after immersion of the partially absorbable mesh after 12 weeks in a phosphate buffer at 7.4 pH and 37°C.
16. The mesh of claim 1 which is sterile.
17. The mesh of claim 1 which is packaged in a foil pouch.