FUNCTIONALIZED SYNTHETIC SURGICAL MESH

CROSS-REFERENCE TO RELATED APPLICATION

[001] The present application claims the benefit of U.S. Provisional Application No. 63/282,570, filed November 23, 2021, the entire contents of which is incorporated by reference herein.

FIELD

[002] The present Specification relates to the production and use of surgical mesh materials.

BACKGROUND

[003] Surgical mesh is a medical device that supports damaged tissue, such as around a hernia, as it heals. Surgeons place the mesh across the area surrounding the hernia, attaching it with stitches, staples or glue. Pores in the mesh allow tissue to grow into the device. Surgical mesh is used in nine out of ten hernia surgeries annually in the U.S.

[004] Several forms of surgical mesh are currently in use; patches are designed to go over or under the weakened or damaged tissue; plugs fit inside a hole in the tissue; and sheets can be custom cut and fitted for the patient's specific condition.

[005] While effective, current mesh designs do not provide optimum performance, particularly in terms of cell in-growth and tissue adherence. Therefore, improved systems, devices, and methods are desirable.

SUMMARY

[006] The instant disclosure provides a novel class of fully synthetic biodegradable surgical meshes. Disclosed examples promote cell in-growth on the superficial mesh surface in contact with tissue in a competitive manner as compared to current biologic meshes, and display minimal tissue adherence on the surface in contact with the viscera.

[007] Disclosed examples employ surface charges and specific charge patterning methods to create a scaffold with an architecture engineered for cell in-growth and the

ability to provide the stability and strength needed for hernia meshes, as well as for controlled biodegradation.

[007a] In one aspect, the present disclosure provides a biodegradable synthetic surgical mesh comprising a polymeric material, wherein the surface of said mesh is functionalized with a zwitterionic functional group comprising at least one of a polybetaine, sulfobetaine methacrylate (SBMA), carboxybetaine methacrylate (CBMA), or a polyampholyte.

[008] The present disclosure comprises scaffold surface coatings, for example comprising surface species immobilized by, for example, chemical or physical bonding. In examples, the surface species can comprise antimicrobials.

[009] The present disclosure also comprises methods of making the disclosed surgical mesh materials.

[010] The present disclosure also comprises methods of use of the disclosed surgical mesh materials.

[011] The present disclosure also comprises kits comprising the disclosed surgical mesh materials.

[011a] In another aspect, the present disclosure provides a kit for use in performing a surgical procedure, comprising the synthetic surgical mesh as described herein.

DETAILED DESCRIPTION

[012] Disclosed surgical mesh embodiments comprise synthetic surgical meshes with improved cell in-growth potential, minimal visceral tissue adherence, and biodegradation, thus improving patient outcomes. As fully synthetic devices, disclosed embodiments are distinguished by manufacturing processes and functionalization. For example, while current synthetic meshes are manufactured using a weave pattern of polymeric material(s), disclosed embodiments can comprise a uniform, non-woven polymeric material. Further, while current synthetic meshes employ multiple materials for specific functions, the instant disclosure provides polymeric materials functionalized with synthetic moieties to achieve specific treatment goals.

[013] Definitions:

[014] “Administration,” or “to administer” means the step of giving (*i.e*. administering) a medical device, material or agent to a subject. The materials disclosed herein can be administered via a number of appropriate routes, but are typically employed in connection with a surgical procedure.

[015] “Patient” means a human or non-human subject receiving medical or veterinary care.

[016] “Therapeutically effective amount” means the level, amount or concentration of an agent, material, or composition needed to achieve a treatment goal.