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Prosthetic porous knit

Abstract

The invention relates to a prosthetic porous knit based on a monofilament of a biocompatible polymer material, the pattern followed for the knitting of said monofilament on a warp knitting machine having two guide bars B1, B2 being the following, according to the ISO 11676 standard: Bar B1: 1.2/4.5/4.3/4.5/4.3/1.0/1.2/1.0// Bar B2: 4.3/1.0/1.2/1.0/1.2/4.5/4.3/4.5// The invention further relates to a method for producing such a knit and to a hernia prosthesis comprising such a knit.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS (1) This application is a continuation of U.S. patent application Ser. No. 18/219,317 filed Jul. 7, 2023, which is a continuation of U.S. patent application Ser. No. 17/840,376 filed Jun. 14, 2022, which is a continuation of U.S. patent application Ser. No. 16/995,763 filed Aug. 17, 2020, now U.S. Pat. No. 11,359,313, which is a continuation of U.S. patent application Ser. No. 15/920,577 filed Mar. 14, 2018, now U.S. Pat. No. 10,745,835, which is a continuation application of U.S. patent application Ser. No. 14/928,082 filed Oct. 30, 2015, now U.S. Pat. No. 9,932,695, which claims benefit of and priority to European Patent Application No. 14306956 filed Dec. 5, 2014, the disclosures of each of the above-identified applications are hereby incorporated by reference in their entirety.

TECHNICAL FIELD
(1) The present invention relates to a prosthetic porous knit useful in parietal surgery, the knit having a lightweight and macroporous structure while showing good mechanical strength properties.
BACKGROUND
(2) Wall-reinforcing prostheses, for example prostheses for reinforcing the abdominal wall, are widely used in the surgical field. These prostheses are intended to treat hernias by temporarily or permanently filling a tissue defect. These prostheses are generally made of biocompatible prosthetic fabric, in particular prosthetic knits, and can have a number of shapes, for example rectangular, circular or oval, depending on the anatomical structure to which they are to be fitted.
(3) In a view of reducing the foreign material implanted into the body of a patient, it is desired to produce lightweight knits, intended to be used as wall reinforcing prostheses. In addition, for facilitating the work of the surgeon at the time he puts the prosthesis in place at the implantation site, it is further desired that the prosthetic knit show a good transparency. Moreover, the wall reinforcing prosthesis should also favor a good tissue ingrowth. In this view, it is desired that the knit used for wall reinforcing prostheses show a plurality of pores, and preferably large pores.
(4) Lightweight porous knits usable in the manufacture of wall reinforcing prostheses already exist. Nevertheless, they sometimes show poor mechanical strength. Indeed, the knit is generally pliant and soft in order to conform to the abdominal wall and flex with movement of the abdominal wall once implanted. The knit may be held in place by suturing, stapling, or tacking the knit to surrounding biological tissue. In particular, existing lightweight porous knits may show a poor resistance to fracture when they are sutured or tacked to the surrounding biological tissue.
(5) In addition, the performance of the abdominal wall hernia repair using a prosthetic knit fixed on the abdominal wall depends in part upon the shear forces experienced at the knit fixation points. These shear forces may be quite high as a result of high intra-abdominal pressure.
(6) Too high shear forces at knit fixation points, once the knit or prosthesis is implanted and has

been fixed for example by sutures at the abdominal wall, may lead to abdominal wall repair recurrences and/or generate pain for the patient. The distribution of shear forces at fixation points is important to assess the safety and the efficacy of the abdominal wall repair.

SUMMARY

(7) In particular, it would be desirable to provide a prosthesis made from a knit for which the distribution of the shear forces at fixation points is as regular as possible and for which the value of shear forces at fixation points is as low as possible, so that the prosthesis may for example be introduced at the implantation site and implanted without the surgeon having to check for a specific position of the warp or weft direction of the knit. It would further be desirable to provide a prosthesis made from a knit for which the risk of fixation pull out and/or implant failure at fixation points is reduced.

(8) In addition, if a knit is too pliant and soft, it may not resist sufficiently to the intra abdominal pressure during specific movements of the patient, for example when the patient coughs or jumps. The knit may then be prone to undesired bulging phenomenon and may not ensure sufficient reinforcement of the abdominal wall in such conditions.

(9) There is therefore a need for a porous prosthetic knit that would be capable of having a lightweight and macroporous structure while at the same time show good mechanical strength properties.

(10) A first aspect of the invention is a prosthetic porous knit based on a monofilament of a biocompatible polymer material, the pattern followed for the knitting of said monofilament on a knitting machine having two guide bars B1, B2 being the following, according to the ISO 11676 standard: Bar B1: 1.2/4.5/4.3/4.5/4.3/1.0/1.2/1.0// Bar B2: 4.3/1.0/1.2/1.0/1.2/4.5/4.3/4.5//

(11) Another aspect of the invention is a method for manufacturing the prosthetic knit above comprising the step of producing a knit with a monofilament of a biocompatible polymer material on a knitting machine having two guide bars B1, B2 according to the following pattern, according to the ISO 11676 standard: Bar B1: 1.2/4.5/4.3/4.5/4.3/1.0/1.2/1.0// Bar B2: 4.3/1.0/1.2/1.0/1.2/4.5/4.3/4.5//

(12) Guide bars B1 and B2 may be threaded **1** full 1 empty and may move symmetrically.

(13) The knitting machine may be a warp knitting machine or a raschel knitting machine.

(14) The knit of the invention is porous. In particular, the knit of the invention comprises openings or pores: these openings or pores are in particular generated by the pattern followed for the knitting of the monofilament of the knit according to the invention. The porosity of the knit of the invention confers to the knit a transparency allowing the surgeon to have a good visibility of the implantation site at the time he puts the knit or prosthesis in place.

(15) The knit of the invention is lightweight. The knit of the invention preferably shows a mass per unit area ranging from about 40 to about 70 g/m.sup.2, preferably ranging from about 40 to about 50 g/m.sup.2, and more preferably of about 44 g/m.sup.2, 45 g/m.sup.2, 46 g/m.sup.2, 47 g/m.sup.2 or 48 g/m.sup.2, measured according to ISO 3801:1977 «Determination of mass per unit length and mass per unit area», 5 specimens 1 dm.sup.2. Such a low mass per unit area allows introducing only a little quantity of foreign material in the body of the patient.

(16) The knit of the invention is made from a monofilament of biocompatible polymer material.

(17) The biocompatible polymer may be synthetic or natural. The biocompatible polymer may be biodegradable, non-biodegradable or a combination of biodegradable and non-biodegradable. The term “biodegradable” as used herein is defined to include both bioabsorbable and bioresorbable materials. By biodegradable, it is meant that the materials decompose, or lose structural integrity under body conditions (e.g., enzymatic degradation or hydrolysis) or are broken down (physically or chemically) under physiologic conditions in the body such that the degradation products are excretable or absorbable by the body.

(18) The biocompatible polymer may be selected from the group consisting of biodegradable polymers, non-biodegradable polymers, and combinations thereof.

(19) In embodiments, the biocompatible polymer material is selected from polypropylene, polyester such as polyethylene terephthalates, polyamide, silicone, polyether ether ketone (PEEK), polyarylether ether ketone (PAEK) polylactic acid (PLA), polycaprolactone (PCL), polydioxanone (PDO), trimethylene carbonate (TMC), polyvinyl alcohol (PVA), polyhydroxyalkanoate (PHA), polyglycolic acid (PGA), copolymers of these materials, and mixtures thereof.
(20) In embodiments, the biocompatible polymer material is polypropylene.
(21) In embodiments, the monofilament has a diameter of from about 0.08 mm to about 0.25 mm, preferably from about 0.10 mm to 0.15 mm, more preferably of about 0.11 mm, 0.12 mm, or 0.13 mm. Such a diameter allows obtaining a good size of the pores and maintaining the lightweight structure of the knit, while maintaining good mechanical properties. In embodiments, the monofilament has a diameter of about 0.12 mm.
(22) In embodiments, the knit comprises a plurality of pores having a diameter above 1 mm. In particular, the plurality of pores having a diameter above 1 mm defines an efficient porosity of said knit ranging from about 35% to about 70%, preferably of about 55%.
(23) By “efficient porosity” is meant according to the present application a porosity taking into account only the pores having a diameter above 1 mm, while leaving out the pores having a diameter less or equal to 1 mm. By “pores having a diameter above 1 mm” is meant the pores which have dimensions greater than 1 mm in all directions. The efficient porosity therefore corresponds to the ratio of the area of the totality of the pores having a diameter above 1 mm as defined above to the area of the totality of the knit studied. The pores having a diameter above 1 mm are measured with a profile projector such as a projector 300V from ORAMA. The “efficient porosity” and its measuring method are described in the publication “*New objective measurements to characterize the porosity of textile implants*”, T. Mühl, M. Binnebösel, U. Klinge and T. Goedderz, Journal of Biomedical Materials Research Part B: Applied Biomaterials, p. 176-183.
(24) The efficient porosity as described above is useful for characterizing the ability of the knit to favor cell colonization. Indeed, pores having a diameter above 1 mm are particularly desired for tissue ingrowth after implantation.
(25) The knitting pattern of the knit of the invention defines a plurality of pores having a diameter ranging above 1 mm. The pores may have a substantially hexagonal or circular shape.
(26) In embodiments, the knit of the invention comprises a plurality of pores having a diameter above 2 mm. Such knits with pores having a diameter above 2 mm favor cell colonization and exhibit a good transparency allowing the surgeon to have a better visibility of the surrounding tissues when he puts the knit/prosthesis in place at the implantation site.
(27) In embodiments, the knit of the invention has a tensile breaking strength in the warp direction of at least about 200 N, preferably of about 237 N. In embodiments, the knit of the invention has a tensile breaking strength in the weft direction of at least about 170 N, preferably of about 201 N. In embodiments, the knit of the invention has a bursting strength of at least about 400 kPa, preferably of about 463 kPa. In embodiments, the knit of the invention has a tear strength in the warp direction of at least about 25 N, preferably of about 30 N. In embodiments, the knit of the invention has a tear strength in the weft direction of at least about 25 N, preferably of about 37 N. In embodiments, the knit of the invention has a suture pull out strength in the warp direction of at least about 35 N, preferably of about 46 N. In embodiments, the knit of the invention has a suture pull out strength in the weft direction of at least about 38 N, preferably of about 42 N. In embodiments, the knit of the invention has a tensile strength of at least about 42 N/cm, preferably of about 47 N/cm.
(28) The tensile breaking strength (N), the bursting strength (kPa), the tear strength (N), the suture pull out strength (N) and the tensile strength (N/cm) above are measured according to the methods as indicated in the below Example of the present application.
(29) Following knitting and heat-setting, the knit can be cleaned, packaged and sterilized using conventionally known techniques. The knit of the invention can be used as provided in the package

or cut to any desired dimension once removed from the package.
(30) The knit of the invention can be implanted in extraperitoneal site either for inguinal or ventral hernia repair via open or laparoscopic approach. Fixation to the surrounding tissues can be achieved by stapling, conventional sutures or other means.
(31) The prosthetic knit of the invention shows an homogeneous distribution of shear forces at fixation points. In particular, although it is provided with a lightweight structure, the prosthetic knit of the invention shows a good resistance to fracture at fixation points compared to lightweight knits of the prior art.
(32) The knit of the invention may be used on its own as a prosthesis to be implanted into in a patient for hernia repair for example.
(33) Another aspect of the invention is a hernia prosthesis comprising a knit as described above.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
(1) The present invention will become clearer from the following description and from the attached drawings, in which:
(2) FIG. **1** is a schematic view of the knitting pattern of a knit of the invention,
(3) FIG. **2** is a front view of the knit of the invention obtained with the knitting pattern of FIG. **1**,
(4) FIG. **3** is a side view of a schematic configuration of a system for measuring the distribution of the shear forces at fixation points of a knit,
(5) FIG. **4** is an enlarged perspective view of a portion of the system of FIG. **3**.
(6) FIGS. **5** and **6** are schematic views of the form used to obtain the average distribution of shear forces at fixation points, as described in at least one embodiments herein.
(7) FIG. **7** is a schematized graph profile of the shear force distribution of a knit.
(8) FIGS. **8-10** are schematized contour profiles of Knits A, B, and C, respectively.
DETAILED DESCRIPTION
(9) With reference to FIG. **1**, is shown a graphic representing the knitting pattern of the knit of the invention, namely the following pattern according to the ISO 11676 standard: Bar B1: 1.2/4.5/4.3/4.5/4.3/1.0/1.2/1.0// Bar B2: 4.3/1.0/1.2/1.0/1.2/4.5/4.3/4.5/
(10) The overall pattern repetition size of the knit of the invention is eight courses. FIG. **1** depicts only one thread from guide bar B1 and one thread from guide bar B2 to better show the movement of the thread. The evolution of the threads at the ninth course is the same as at the first course.
(11) With reference to FIG. **2**, is shown a photograph of the knit **1** of the invention obtained with the knitting pattern as represented in FIG. **1**.
(12) The knit **1** of FIG. **2** was obtained from a monofilament of polypropylene of diameter 0.12 mm.
(13) The knitting pattern of the knit of the invention produces pores greater than about 1.0 mm in diameter. For example, the principal pores **2** of the knit **1** of FIG. **2** have an average size of 2.0×2.4 mm. Such a large size of pores is very favorable for cell colonization and confers to the knit a good transparency allowing a good visibility at the implantation site.
(14) The knit of the invention shows an homogeneous distribution of the shear forces at fixation points. The distribution of the shear forces at fixation points may be evaluated with a system for assessing shear forces distribution at fixation points of textile-based implants, such as an axisymmetrical experimental set-up as described in reference to FIGS. **3** and **4**, such a system allowing exhibiting the capability of a textile to distribute shear forces at fixation points without integrating specific geometrical considerations.
(15) Referring now to FIGS. **3** and **4**, system **10** includes a tissue model **100**, a load simulation device **200**, and an analysis system **300** for assessing characteristics of a textile-based implant **400**

when fixed to the tissue model **100** and subjected to a load exerted by the load simulation device **200**. The tissue model **100** includes a base **110** having an upper surface **112** extending along a plane "P" and having a closed outer perimeter **114** that defines an opening **116** therethrough. The upper surface **112** is configured to mimic the inner surface of an abdominal wall: it is flat and horizontal. The opening **116** defined through the upper surface **112** is configured to mimic a defect in an abdominal wall and may be referred to herein as the "defect". The opening **116** has a circular shape and a uniform size and dimension through the height "H" of the base **110**. In the system of FIG. **3**, the opening **116** is an empty circle having a radius of 55 mm with a 10 mm fillet.

(16) The upper surface **112** is covered by a coating **112***a* having a coefficient of friction that mimics the frictional coefficient of an inner surface abdominal wall against a textile-based implant **400**. The coefficient of friction is about 0.3.

(17) The base **110** includes a lower planar surface **118** that is stepped down from the upper planar surface **112** at a pre-determined height "H1" and extends around the upper surface **112**.

(18) The base **110** also includes a fixation support under the form of a plurality of rods **120**, configured to secure a textile-based implant **400** thereto at two or more fixation points. The plurality of rods **120** are attached to the lower surface **118** at a predetermined distance "D1" of 20 mm from each other and a predetermined distance "D2" of 70 mm from the upper surface **112** extremity. The rods **120** are arranged in a simple circle crown fixation, centered to the opening **116**. Each rod **120** includes a first end **120***a* fixed to the lower surface **118**, an elongate body **120***b* extending from the lower surface **118** towards the upper surface **112** and defining a length "L" of 60 mm, and a second end **120***c* terminating about or above the plane "P" defined by the upper surface **112**. The elongate body **120***b* extends perpendicularly from the lower surface **118**. The rods **120** are threaded rod M3, with an equivalent radius of 2.5 mm and a Young Modulus of 110 Gpa.

(19) The rods **120** are configured for direct fixation to a portion of the textile-based implant **400** when the textile-based implant **400** is placed upon the upper surface **112** of the tissue model **100** over the opening **116** in the upper surface **112**. The tension at the fixation points in the textile-based implant **400** is minimum. Markers **122** are attached to the second end **120***c* of the rods **120** such that the markers **122** are disposed about or above the plane "P" defined by the upper surface **112**. Each marker **122** is under the form of a white circle of diameter 5 mm within a black circle of diameter of 10 mm and is localized 8 mm above the textile-based implant **400**. Markers **122** provide a visual indication of the position of the rods **120**. Markers **122** are distributed on half of the textile-based implant **400** from two warp extremities.

(20) The load simulation device **200** is positioned above the upper surface **112** of the base **110** and is configured to simulate a change in environmental loading conditions surrounding the tissue model **100** such that changes in load are generated about the tissue model **100**. The load may be referred to herein as the "intra abdominal pressure equivalent." As shown, the load simulation device **200** is a plunger **210** including a contacting surface **212** that is hemispherical (diameter 100 mm) and that is centered over the opening **116** defined through the upper surface **112**. The plunger **210** is configured to move in a direction perpendicular to the plane "P" of the upper surface **112** and exert a predetermined force, referred to hereinafter as the plunger force, against the textile-based implant **400** so that the implant **400** engages the opening **116** defined within the upper surface **112** of the tissue model **100**. The load simulation device **200** is capable of applying a quasi-static pressure (low plunger **210** descent velocity) on the textile-based implant **400** to simulate various physiological conditions. For example, the plunger force applied may be of 147 N, namely 116 mmHg, which corresponds to the intra abdominal pressure when the patient is in a standing valsalva condition. Alternatively, the plunger force applied may be of 304 N, namely 240 mmHg, which corresponds to the intra abdominal pressure when the patient jumps.

(21) The analysis system **300** includes a digital image acquisition and processing component **310** including two cameras **312** for recording the position of the markers **122** in a 3D coordinate system and digital image correlation software **314**, namely Vic 3D™ from the company Correlated

Solutions for calculating the displacement vector of each of the markers **122** resulting from bending of the rods **120** in response to the loads exerted on the textile-based implant **400** by the load simulation device **200**. The analysis system **300** records the plunger displacement **210**. The analysis system **300** also includes a mathematical software component **320** that is utilized to calculate the shear force vector at each fixation point where a marker **122** exists using the displacement vector component in the plane "P" of the markers **122** and the continuum mechanics theory applied to the rods **120**. Accordingly, each shear force vector is a function of the "intra abdominal pressure equivalent." The mathematical software component **320** may include any numerical software package, such as, for example, MATLAB® from the company Matchworks.

(22) An indication on the bulging of the textile-based implant **400** through the opening **116** may be given by the assessment of the plunger penetration through the opening **116**.

(23) In an exemplary method of use, a textile-based implant **400**, such as a prosthetic knit, is placed on the upper surface **112** of the base **110** of the tissue model **100** such that the implant **400** lies along the plane "P" defined by the upper surface **112**. The implant **400** is centered placed about the opening **116** in the upper surface **112** and, as should be understood by a person of ordinary skill in the art, the orientation of the fibers of the implant **400** is controlled with respect to the upper surface **112**. The textile-based implant **400** is then directly fixed to the plurality of fixation rods **120**. A plurality of markers **122** are then affixed to a portion of the fixation rods **120** such that the markers **122** extend between the two warp extremities of the implant **400**.

(24) With the implant **400** fixed to the tissue model **100**, the analysis system **300** is activated such that the cameras **312** capture the position of the markers **122** in a 3D coordinate system. The acquisition of the position/positional changes of the markers **122** via the cameras **312** is synchronized with the activation of the load simulation device **200** as the forces applied to the implant **400** by the load simulation device **200** is transferred to the rods **120** at the fixation points and results in bending of the rods **120**. Accordingly, any movement of the rods **120** results in movement of the markers **122** which is recorded by the cameras **312** and used in determining the shear force vector at each fixation point as described above.

(25) As will appear from the Example below, the system of FIGS. **3** and **4** allows evaluating the properties of prosthetic knits regarding the distribution of shear forces at fixation points, bulging phenomenon and fracture at fixation points.

(26) The advantages of the knit of the invention will appear more clearly in the Example below.

Example

(27) Two lightweight knits of the prior art (Knits A and B) and a knit of the invention (knit C) have been produced as described below.

(28) Knit A:

(29) knit A is a knit of the prior art as described in WO2011/042811, namely obtained by knitting a monofilament of polyethylene terephthalate of diameter 0.08 mm on a warp knitting machine having two guide bars B1, B2, according to the following pattern, according to the ISO 11676 standard: Bar B1: 1.0/1.2/1.0/2.3/2.1/2.3/4.5/4.3/4.5/3.2/3.4/3.2// Bar B2: 4.5/4.3/4.5/3.2/3.4/3.2/1.0/1.2/1.0/2.3/2.1/2.3//

(30) Guide bars B1 and B2 are threaded **1** full 1 empty and move symmetrically.

(31) Knit B:

(32) knit B is a knit of the prior art as described in U.S. Pat. No. 6,408,656, namely obtained by knitting a monofilament of polypropylene of diameter 0.10 mm on a warp knitting machine having two guide bars B1, B2, according to the following pattern, according to the ISO 11676 standard: Bar B1: 5.4/4.3/2.1/0.1/1.2/3.4// Bar B2: 0.1/1.2/3.4/5.4/4.3/2.1//

(33) Guide bars B1 and B2 are threaded **1** full 1 empty and move symmetrically.

(34) Knit C:

(35) is a knit of the invention obtained with the knitting pattern of FIG. **1**, by knitting a monofilament of polypropylene of diameter 0.12 mm knitted on a warp knitting machine having

two guide bars B1, B2, the pattern followed being the following, according to the ISO 11676 standard: Bar B1: 1.2/4.5/4.3/4.5/4.3/1.0/1.2/1.0// Bar B2: 4.3/1.0/1.2/1.0/1.2/4.5/4.3/4.5//

(36) Guide bars B1 and B2 are threaded **1** full 1 empty and move symmetrically.

(37) The following properties of knits A, Band C have been determined as follows: Mass per unit area (g/m.sup.2): measured according to ISO 3801:1977 «Determination of mass per unit length and mass per unit area», 5 specimens 1 dm.sup.2. pore size (width×height) (mm): knit biggest pores are measured making one measurement on 10 individual samples with a profile projector such as a projector 300V from ORAMA, Bursting strength (kPa): measured according to ISO 13938-2:1999 "Textiles—Bursting properties of textiles-Pneumatic method for determining the bursting strength and bursting deformation", 5 samples Tensile strength (N/cm) is measured through a plunger test with a traction testing machine such as the Hounsfield model H5KS (Hounsfield, Redhill, England)., crosshead speed: 50 mm/min, 5 samples: the burst pressure can be determined using a circular mesh sample with a radius of R.sub.m=56.4 mm and with a test area of 100 cm.sup.2 clamped at the outward boarder (modified DIN 54307 superseded standard). Then, the mesh is loaded with a spherical stamp of a radius R.sub.s=50 mm, velocity v=50 mm/min until rupture occurs. Based on the measured forces and the resulting stretch, the tensile strength (N/cm) can be calculated; Tear strength (N) in the warp direction and in the weft direction: measured according to ISO 4674:1977 *"Textiles covered with rubber or plastic—Determination of the tear strength*" Method A2, 5 samples, width: 75 mm, Tear length≤145 mm, crosshead speed: 100 mm/min, Thickness: is measured according to ISO 9073-2:1997 *"Textiles—test methods for nonwovens—Part* 2*: Determination of thickness"*, 10 samples, 100×50 mm, Tensile breaking strength and elongation at break: is measured according to ISO 13934-1:2013 *"Textiles—Tensile properties of fabrics—Part* 1*: Determination of maximum force and elongation at maximum force using the strip method'*, 5 samples, width: 50 mm, Length: 200 mm between the jaws, Crosshead speed: 100 mm/min, Pre-load: 0.5 N, using a traction testing machine such as the Hounsfield model H5KS (Hounsfield, Redhill, England); Effective porosity: pores having a diameter above 1 mm are measured with a profile projector such as a projector 300V from ORAMA, 1 sample of 100×50 mm; Suture pull out strength in the warp direction and in the weft direction measured according to NF S94-801:2007 "Reinforcement implants introduced by the vaginal route for the treatment of stress urinary incontinence and/or of prolapse of the pelvic organs-pre-clinical trials and clinical trials"—§ 5.3.3 5 specimens 50×100 mm, USP 2 suture yarn, crosshead speed: 100 mm/min, using a traction testing machine such as the Hounsfield model H5KS (Hounsfield, Redhill, England).

(38) The results are collected in the following tables:

(39) TABLE-US-00001 TABLE I mechanical properties Knit A Knit B KnitC Warp Weft Warp Weft Warp Weft Tensile breaking strength (N) 175 ± 12 129 ± 2 187 ± 16 149 ± 10 237 ± 6 201 ± 6 Elongation under 50N (%) 54 ± 0 50 ± 6 43 ± 1 59 ± 1 38 ± 1 46 ± 0 Bursting strength (kPa) 280 ± 19 361 ± 38 463 ± 19 Tear strength (N) 22 ± 1 23 ± 2 23 ± 2 22 ± 3 30 ± 1 37 ± 5 Suture pull out strength (N) 32 ± 4 36 ± 1 33 ± 1 33 ± 2 46 ± 5 42 ± 3 Tensile strength (N/cm) 24 ± 1 40 ± 1 47 ± 1

(40) TABLE-US-00002 TABLE II mass per unit area and porosity Knit A Knit B Knit C Mass per unit area (g/cm.sup.2) 45 36 46 Thickness (mm) 0.4 0.4 0.6 Pore size (mm) 1.5 × 1.5 1.6 × 1.4 2.0 × 2.4 (width × height) Efficient porosity (%) 53 35 55

(41) With reference to Table I above, the knit of the invention (Knit C) shows improved mechanical properties in comparison with the knits of the prior art (Knits A and B). In particular, the knit of the invention shows a higher tensile breaking strength both in warp and weft directions than Knits A and B. The knit of the invention shows a higher bursting strength than Knits A and B. The knit of the invention shows a higher tear strength both in warp and weft directions than Knits A and B.

(42) The knit of the invention (Knit C) shows an improved suture pull out strength both in warp and weft directions compared to the knits of the prior art (knits A and B). The knit of the invention shows a higher tensile strength both in warp and weft directions than Knits A and B.

(43) With reference to Table II above, the knit of the invention further shows an improved efficient porosity compared to Knits A and B.
(44) In addition, the system described at FIGS. **3** and **4** has been utilized to assess the following properties of knits A, B and C under various simulated physiological conditions. For proceeding to these measures, the textile-based implant **400** of FIGS. **3** and **4** is replaced by the knit sample, either Knit A, B or C, to be evaluated.
(45) The following properties have been evaluated: 1°) The shear forces distribution profile at fixation points of the knit: for each plunger force, namely 147 N respectively 304 N, the marker displacement as described above is transformed into the shear force at each fixation point where markers exist from the initial fixation position, using the mechanical continuum theory applied to the rods implemented in the software MATLAB® from the company Matchworks. The shear force vector is recorded. The Max and min vector norm values are recorded. The average distribution of shear forces at fixation points may be obtained under the form as shown in each of FIGS. **5** and **6**, with reference to the following plunger forces, respectively:
(46) Plunger force: 147 N Plunger force: 304 N
(47) The shear forces distribution may be schematized by the graphic profile shown in FIG. **7**.
(48) An Average force Min-Max (N) is determined: on the example of the profile above, the Average force Min-Max (N) at a plunger force of 147 N is 3.8-8 and the Average force Min-Max (N) at a plunger force of 304 N is 7.1-13.5.
(49) For a knit, when the range of the value of the Average force Min-Max is low, the risks of failure of the knit are decreased. The knit and therefore the abdominal wall repair will be more efficient.
(50) In addition, the more the profile of the shear forces is close to a semi-circle or a semi-ellipse, the more regularly the shear forces are distributed. The risks of tensions in a specific direction are therefore decreased. In addition, the forces being of similar values in all directions, the knit may be implanted without having to check for a specific position of the warp or weft direction of the knit. The knit, or the prosthesis made from the knit, will also be more comfortable for the patient. 2°) The bulging indication: corresponds to the distance in mm of penetration of the plunger **210** as described in FIGS. **3** and **4**, from an initial position in which its contacting surface **212** is tangent to the sample knit to a final position obtained after application of the plunger force.
(51) A too high bulging indication, like for example above 50 mm at a plunger force of 304 N or for example above 45 mm at a plunger force of 147 N, may mean that the knit/prosthesis may be two soft for ensuring its reinforcement function of the abdominal wall, and/or may generate discomfort and/or aesthetics disturbance. 3°) The rupture of knit at fixation: the number of ruptures at fixation points is recorded.
(52) The results are collected in the following table:
(53) The contour profile of Knits A, B, and C are shown in FIGS. **8**-**10**, respectively.
(54) TABLE-US-00003 TABLE III assessment of shear forces Average number of Average fracture at bulging fixation Plunger indication Average force Knit points force (N) (mm) Min-Max (N) Knit A 2 147 48 3.9-4.8 304 58.7 6.5-8.6 Knit B 2 147 44.6 2.2-5.7 304 54.5 4.5-11.2 Knit C 0 147 40.2 3.6-8 304 48.3 7.1-13.5
(55) As appears from the table above, the knit of the invention (Knit C) shows a regular contour profile very close to a semi-circle. The shear forces are therefore regularly distributed. The knit of the invention may therefore be introduced at the implantation site and implanted without the surgeon having to check previously for a specific positioning of the warp or weft direction of the knit.
(56) In addition, the number of fracture at fixation points is 0 for the knit of the invention, whereas it is 2 for the knits of the prior art (knits A and B). The knit of the invention is therefore more reliable once sutured or tacked to the surrounding biological tissues than the knits of the prior art.
(57) Regarding the bulging indication, the knit of the invention (knit C) shows a better bulging

indication at both plunger forces than the knits of the prior art. The knit of the invention will therefore ensure its reinforcement function of the abdominal wall and will be more efficient than the knits of the prior art in physiological conditions such as jumping or coughing.

Claims

1. A prosthetic lightweight porous knit for hernia repair comprising a monofilament of a biocompatible polymer, wherein the knit comprises a mass per unit area ranging from about 40 to about 70 g/m.sup.2, an efficient porosity ranging from about 30% to about 70%, and an average bulging indication of less than 50 mm at a plunger force of 304 N or less than 45 mm at a plunger force of 147 N.
2. The prosthetic lightweight porous knit of claim 1, wherein the knit comprises a pattern followed for knitting of the monofilament on a knitting machine having a first guide bar B1 and a second guide bar B2 according to ISO 11676 standard, wherein the pattern of the first guide bar B1 is 1.2/4.5/4.3/4.5/4.3/1.0/1.2/1.0// and the pattern of the second guide bar B2 is 4.3/1.0/1.2/1.0/1.2/4.5/4.3/4.5//.
3. The prosthetic lightweight porous knit of claim 1, wherein the biocompatible polymer is selected from a group consisting of polypropylene, polyethylene terephthalate, polyamide, silicone, polyether ether ketone (PEEK), polyarylether ether ketone (PAEK), polylactic acid (PLA), polycaprolactone (PCL), polydioxanone (PDO), trimethylene carbonate (TMC), polyvinyl alcohol (PVA), polyhydroxyalkanoate (PHA), polyglycolic acid (PGA), copolymers of these biocompatible polymer materials, and mixtures thereof.
4. The prosthetic lightweight porous knit of claim 1, wherein the biocompatible polymer is polypropylene.
5. The prosthetic lightweight porous knit of claim 1, wherein a diameter of the monofilament is from about 0.10 mm to about 0.15 mm.
6. The prosthetic lightweight porous knit of claim 1, wherein a diameter of the monofilament is about 0.12 mm.
7. The prosthetic lightweight porous knit of claim 1, wherein the knit comprises a plurality of pores, each pore having a diameter above 2 mm.
8. The prosthetic lightweight porous knit of claim 1, wherein the efficient porosity of the knit is about 55%.
9. The prosthetic lightweight porous knit of claim 1, wherein the mass per unit area of the knit ranges from about 44 g/m.sup.2 to about 48 g/m.sup.2.
10. The prosthetic lightweight porous knit of claim 1, wherein the knit comprises a plurality of pores, each pore having a substantially hexagonal or circular shape.
11. A prosthetic lightweight porous knit for hernia repair comprising a monofilament of a biocompatible polymer, wherein the knit comprises a mass per unit area ranging from about 40 to about 70 g/m.sup.2, a plurality of pores having a diameter above 2 mm, and an average bulging indication of less than 50 mm at a plunger force of 304 N or less than 45 mm at a plunger force of 147 N.
12. The prosthetic lightweight porous knit of claim 11, wherein the knit comprises a pattern followed for knitting of the monofilament on a knitting machine having a first guide bar B1 and a second guide bar B2 according to ISO 11676 standard, wherein the pattern of the first guide bar B1 is 1.2/4.5/4.3/4.5/4.3/1.0/1.2/1.0// and the pattern of the second guide bar B2 is 4.3/1.0/1.2/1.0/1.2/4.5/4.3/4.5//.
13. The prosthetic lightweight porous knit of claim 11, wherein the biocompatible polymer is selected from a group consisting of polypropylene, polyethylene terephthalate, polyamide, silicone, polyether ether ketone (PEEK), polyarylether ether ketone (PAEK), polylactic acid (PLA), polycaprolactone (PCL), polydioxanone (PDO), trimethylene carbonate (TMC), polyvinyl alcohol

(PVA), polyhydroxyalkanoate (PHA), polyglycolic acid (PGA), copolymers of these biocompatible polymer materials, and mixtures thereof.

14. The prosthetic lightweight porous knit of claim 11, wherein the biocompatible polymer is polypropylene.

15. The prosthetic lightweight porous knit of claim 11, wherein a diameter of the monofilament is from about 0.10 mm to about 0.15 mm.

16. The prosthetic lightweight porous knit of claim 11, wherein a diameter of the monofilament is about 0.12 mm.

17. The prosthetic lightweight porous knit of claim 11, wherein the knit comprises an efficient porosity of about 55%.

18. The prosthetic lightweight porous knit of claim 11, wherein the mass per unit area of the knit ranges from about 44 g/m.sup.2 to about 48 g/m.sup.2.

19. The prosthetic lightweight porous knit of claim 11, wherein each pore of the plurality of pores has a substantially hexagonal or circular shape.