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(54) **Titre** : TRICOT BIORESORBABLE POUR REPARATION DES HERNIES ET SA METHODE DE FABRICATION
(54) **Title**: BIORESORBABLE KNIT FOR HERNIA REPAIR AND METHOD FOR MANUFACTURING THE SAME

(57) **Abrégé/Abstract**:

The present invention relates to a bioresorbable prosthetic porous knit comprising an arrangement of yarns of bioresorbable biocompatible material defining at least two sides for said knit, said knit being provided, on one of its sides, with barbs protruding outwards from said one side, wherein each yarn of the arrangement defining said two sides is doubled. The invention further relates to a method for manufacturing such a knit.

ABSTRACT

The present invention relates to a bioresorbable prosthetic porous knit comprising an arrangement of yarns of bioresorbable biocompatible material defining at least two sides for said knit, said knit being provided, on one of its sides, with barbs protruding outwards from said one side, wherein each yarn of the arrangement defining said two sides is doubled. The invention further relates to a method for manufacturing such a knit.

Bioresorbable knit for hernia repair and method for manufacturing the same

The present invention relates to a bioresorbable prosthetic porous knit with outwardly protruding barbs on one side of said knit, showing good mechanical properties and a good elasticity in all directions, and to a method for manufacturing such a knit. The knit obtained by the method of the invention may be used in particular as a wall reinforcement prosthesis, more specifically in ventral hernia repair.

The abdominal wall in humans is composed of fat and muscles interconnected by fascias. It sometimes happens that a break in continuity occurs in the fascias, allowing part of the peritoneum to slip through and form a sac, or a hernia, containing either fat or part of the intestines. Hernias show themselves in the form of a bulge at the surface of the skin and are classed, for example, as umbilical or groin hernias or incisional hernias, depending on where they are located. In order to repair a hernia defect, surgeons often fit a textile-based prosthesis in place which replaces or strengthens the weakened anatomical tissues.

Textile-based prostheses are well known in some fields of surgery, such as abdominal wall repair. These prostheses are generally made of biocompatible prosthetic fabric conferring them a certain conformability and they may show a number of shapes, for example rectangular, circular or oval, depending on the anatomical structure to which they are to adapt. Textile-based prostheses are usually made from an arrangement of yarns, such as porous knits which comprise openings and/or pores favoring cellular growth within the knit once the prosthesis is implanted.

Some of these prostheses may be non bioresorbable or semi-bioresorbable, which means that they contain non bioresrobable parts, such as for example non-bioresorbable yarns, which are intended to remain permanently in the body of the patient.

Anyway, in some cases, it may be desirable that the prosthesis does not remain permanently in the body of the patient, for example in a view of avoiding implanting permanent foreign material in the body. In such cases, prostheses which are fully made of bioresorbable yarns are provided. Such bioresorbable prostheses are intended to disappear after they have performed their reinforcing function during the period of cellular colonization, tissue rehabilitation and tissue healing.

Nevertheless, some of the existing bioresorbable prostheses do not maintain sufficient mechanical strength during the months following the implantation. Actually, in order to realize a successful implantation, it is important that the prosthesis promotes gradual transfer of strength from the textile to the functional new tissue. For example, it would be desirable that the textile of the prosthesis carries significant strength during 5 months post implantation and for example residual strength only after 12 months. Ideally, it would be desirable that, after 5 months of implantation, a bioresorbable prosthesis shows a mechanical strength of the order of that usually shown by a non bioresorbable prosthesis at the moment it is implanted.

Indeed, ideally, the prosthesis should provide early support during the critical period of healing. According to some authors (see *Williams ZF, Hope WW. Abdominal wound closure : current perspectives. Open Access Surgery. 2015 :8 p 89-94*), healing of abdominal incisions, like any other wounds, requires three phases. The inflammatory phase lasts approximately 4 days, followed by the proliferative phase for 3 weeks. The maturation phase continues for up to a year. By the end of the proliferative phase, the fascia has only 20% of its original strength. At 6 and 20 weeks post-surgery, the fascia has only 50% and 80% of its original strength. In view of this, it can be considered that the critical period of healing lasts at least 5 months.

A prosthesis for hernia repair also needs to be anchored to the abdominal wall. It is known to anchor prostheses to the abdominal wall using surgical suture threads. Anyway, suturing may be time-consuming for the surgeon. It may also create tensions and tearing within the biological tissues. In particular, the abdominal wall is submitted to intraabdominal pressure due to activities, such as coughing, jumping, exercising, breathing, etc.. during the daily life of a person. Anchoring a prosthesis by means of suturing may prove to be painful and very unconfortable for the patient in the long term. In view of remedying to this problem, prosthetic knits provided with barbs protruding outwards from one side of the knit have been proposed. These barbs constitute hooks that are able to fix themselves either in another prosthetic fabric, belonging to the same prosthesis or not, or directly in the biological tissues, for example the abdominal wall.

The document WO01/81667 describes the production of a knit comprising barbs on one side of a knit. In this document, the knit is produced using three guide-bars of a knitting machine. Anyway, it has been observed that the knit described in this document may show limited elasticity in some directions.

As seen above, the abdominal wall is submitted to intraabdominal pressure in all directions, said stresses changing directions and intensities at all time in function of the movements and activities of the patient. The prosthesis therefore needs to be able to adapt to these movements and changes of pressure and related stresses by showing a good elasticity in all directions.

There is a need for a fully bioresorbable porous knit capable of being anchored to the abdominal wall without creating tensions, capable of efficiently reinforcing the abdominal wall at least during 5 months after implantation, while showing sufficient elasticity in all directions, preferably in the warp direction, so that the repaired abdominal wall is capable of smoothly adapting to multidirectional stresses generated by the movements of the patient in his daily life.

The applicant has found a quick and simple method of producing a bioresorbable prosthetic porous knit capable of showing, 5 months after implantation in a body, a mechanical strength of the order of that shown by a non bioresorbable knit at the moment it is implanted, said knit being capable of being anchored to the biological tissue without creating tensions, said knit further showing a good elasticity in all directions.

A first aspect of the invention is a method for manufacturing a bioresorbable prosthetic porous knit comprising an arrangement of yarns of bioresorbable biocompatible material defining at least two sides for said knit, said knit being provided, on one of its sides, with barbs protruding outwards from said one side, said process comprising the following steps:

- i) providing a warp knitting machine comprising one needle-bed comprising four guide-bars, namely guide-bar B1, guide-bar B2, guide-bar B3 and guide-bar B4,

ii) knitting on said machine yarns of bioresorbable biocompatible material as follows :

- Guide-bar B1 is unthreaded,
- Guide-bars B2 and B3 are double threaded with yarns of bioresorbable biocompatible material, the knitting patterns followed by guide-bars B2 and B3 involving at least two needles and producing said arrangement of yarns defining said two sides of said knit,
- Guide-bar B4 is threaded with a hot-melt monofilament yarn of bioresorbable biocompatible material, the knitting pattern followed by guide-bar B4 making stitches generating loops protruding outwards from said one side of said knit,

iii) heat-setting the knit obtained at ii),

- iv) forming barbs by cutting the loops via melting.

By "double threaded bar" is meant according to the present document that two yarns are present in each threaded guide of the bar.

In the present application, a "prosthetic knit" is understood as a knit intended to be implanted in the human or animal body in the form of a prosthesis or any other part designed at least in part with said knit.

Within the meaning of the present invention, « porous knit » means the characteristic whereby a knit has pores, or voids, cells, holes or orifices that are open and distributed uniformly or non-uniformly on the sides of the knit and within its thickness, and that promote cellular colonization. The pores can be present in all sorts of forms, for example spheres, channels and hexagonal shapes.

In the present application, "biocompatible" is understood as meaning that the materials having this property can be implanted in the human or animal body.

The term "bioresorbable" as used herein is defined to include biodegradable, bioabsorbable and bioresorbable materials. By bioresorbable, 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.

Another aspect of the invention is a bioresorbable prosthetic porous knit comprising an arrangement of yarns of bioresorbable biocompatible material defining at least two sides for said knit, said knit being provided, on one of its sides, with barbs protruding outwards from said one side, wherein each yarn of the arrangement defining the two sides of the knit is doubled.

By "the yarn is doubled" is meant in the present document that, during the manufacture of the knit, each threaded guide-bar contributing to the formation of the arrangement defining the two sides of the knit, namely guide-bar B2 and guide-bar B3, receives indeed two yarns instead of one yarn only usually, so that in the end, in the knit obtained, each fibrous path of the arrangement defining the two sides of the knit is formed of two yarns.

Another aspect of the invention is a bioresorbable prosthetic porous knit comprising an arrangement of yarns of bioresorbable biocompatible material defining at least two sides for said knit, said knit being provided, on one of its sides, with barbs protruding outwards from said one side, wherein each yarn of the arrangement defining the two sides of the knit is doubled, said knit further comprising, alternatively or in combination, one or several of the following features :

- the yarns of the arrangement defining the two sides of the knit may be monofilaments showing a diameter ranging from about 80 to about 140 μm, preferably showing a diameter of about 125 μm;

- the barbs may be formed from monofilaments cuts, wherein the monofilaments show a diameter ranging from about 100 to about 180 µm, preferably showing a diameter of about 150 µm;
- the bioresorbable material may be a copolymer of poly trimethylene carbonate (PTMC) and of poly-L-lactide (PLLA), for example having a composition of 80% lactide and 20% trimethylene carbonate;
- the yarns forming the knit and the barbs may be made of a copolymer of poly trimethylene carbonate (PTMC) and of poly-L-lactide (PPLA), for example having a composition of 80% lactide and 20% trimethylene carbonate; and/or the coplymer may show a molar mass Mn ranging from 100,000 to about 225,000; and/or the copolymer may show a molecular weight Mw ranging from about 100,000 g/mol to about 225,000 g/mol;
- the knit may show a gripping strength (N), measured as described in Example 1, ranging from about 60 N to about 160 N, for example from about 70 N to about 150 N,
- the knit may show a bursting strength (kPa), measured as described in Example 3, ranging from about 400 kPa to about 750 kPa, for example from about 450 kPa to about 700 kPa,
- the knit may show a tensile breaking strength (N), measured as described in Example 3, ranging from about 200 N to about 500 N, for example from about 240 N to about 380 N, in the warp direction, and ranging from about 200 N to about 400 N, for example from about 250 N to about 360 N, in the weft direction;
- the knit may show a tensile elongation under 50 N (%), measured as described in Example 3, ranging from about 20% to about 35%, for example from about 23% to about 32% in the warp direction, and ranging from about 20 % to about 45 %, for example from about 30% to about 40%, in the weft direction;
- the knit may show a tensile breaking elongation (%), measured as described in Example 3, ranging from about 40% to about 100%, for example from about 55% to about 95%, in the warp direction, and ranging from about 60% to about 110%, for example from 70% to 100%, in the weft direction;
- the knit may show a tear strength (N), measured as described in Example 3, ranging from about 30 N to about 75 N, for example from

about 35 N to about 70 N, in the warp direction, and ranging from about 25 N to about 75 N, for example from about 30 N to about 70 N, in the weft direction;

- the knit may show a suture pull out strength (N), measured as described in Example 3, ranging from about 50 N to about 100 N, for example from about 60 N to about 90 N, in the warp direction, and ranging from about 40 N to about 80 N, for example from about 40 N to about 70 N, in the weft direction;
- the knit may show a Force max (N) at T0, measured as described in Example 4, ranging from about 300 N to about 600 N, for example from about 350 N to about 550 N;
- the knit may show a deflection (mm) at T0, measured as described in Example 4, ranging from about 15 mm to about 30 mm, for example from about 15 mm to about 25 mm;
- the knit may show a Force max (N) at T20ws, measured as described in Example 4, ranging from about 300 N to about 600 N, for example from about 350 N to about 550 N;
- the knit may show a deflection (mm) at T20ws, measured as described in Example 4, ranging from about 15 mm to about 30 mm, for example from about 15 mm to about 25 mm;
- the knit may show a breaking strength (N) at T0, measured as described in Example 5, ranging from about 90 N to about 250 N, for example from about 100 N to about 180 N, in the warp direction, and ranging from about 100 N to about 200 N, for example from about 130 N to about 180 N, in the weft direction;
- the knit may show an elongation under 30 N (%) at T0, measured as described in Example 5, ranging from about 15% to about 35%, for example from about 27% to about 35%, in the warp direction, and ranging from about 17% to about 45%, for example from about 25% to about 40%, in the weft direction;
- the knit may show an elongation under 50 N (%) at T0, measured as described in Example 5, ranging from about 25% to about 50%, for example from about 35% to about 50%, in the warp direction, and ranging from about 25% to about 55%, for example from about 40% to about 55%, in the weft direction;

- the knit may show a breaking elongation (%) at T0, measured as described in Example 5, ranging from about 60% to about 100%, for example from about 65% to about 95%, in the warp direction, and ranging from about 60% to about 110%, for example from about 80% to about 100%, in the weft direction;
- the knit may show a breaking strength (N) at T20ws, measured as described in Example 5, ranging from about 90 N to about 250 N, for example from about 100 N to about 180 N, in the warp direction, and ranging from about 100 N to about 200 N, for example from about 130 N to about 180 N, in the weft direction;
- the knit may show an elongation under 30 N (%) at T20ws, measured as described in Example 5, ranging from about 15% to about 35%, for example from about 27% to about 35%, in the warp direction, and ranging from about 17% to about 45%, for example from about 25% to about 40%, in the weft direction;
- the knit may show an elongation under 50 N (%) at T20ws, measured as described in Example 5, ranging from about 25% to about 50%, for example from about 35% to about 45%, in the warp direction, and ranging from about 25% to about 55%, for example from about 35% to about 55%, in the weft direction;
- the knit may show a breaking elongation (%) at T20ws, measured as described in Example 5, ranging from about 60% to about 100%, for example from about 65% to about 97%, in the warp direction, and ranging from about 60% to about 110%, for example from about 80% to about 100%, in the weft direction;
- the knit may show a breaking strength (N) at T20wd, measured as described in Example 6, ranging from about 60 N to about 150 N, for example from about 70 N to about 130 N, in the warp direction, and ranging from about 80 N to about 150 N, for example from about 100 N to about 120 N, in the weft direction.

The knit of the invention is produced on a warp knitting machine comprising one needle-bed comprising four guide-bars, namely guide-bar B1, guide-bar B2, guide-bar B3 and guide-bar B4.

The knit of the invention is produced along the warp direction of the machine by means of three guide bars out of four, the guide-bar B1 being unthreaded. Guide-bars B2, B3 and B4 operate together and repeat a knitting pattern defining the evolution of the yarns. The evolution of a yarn from one needle to another is called a course. The needles extend along the width of the machine, which corresponds to the weft direction of the knit produced. The knitting pattern corresponds to the smallest number of courses whereby the whole yarn evolution can be described. The knitting pattern therefore involves a determined number of needles, which corresponds to the total number of needles used for the yarn to complete its whole evolution.

In the method of the invention, the guide-bars B2 and B3, which form the arrangement of yarns defining the two sides of the knit, in other words the ground of the knit from which the barbs issued from guide-bar B4 will protrude, are double threaded. In other words, each threaded guide of these guide-bars is threaded with two yarns. Moreover, the yarns are made of bioresorbable material. This allows the knit obtained by the method of the invention to show, 5 months after implantation, mechanical properties of the order of that shown by a non bioresorbable knit at the moment it is implanted. Moreover, thanks to the presence of the barbs, the knit obtained by the method of the invention is capable of being anchored to the abdominal wall without the use of suturing threads, and therefore without tension. The knit obtained by the method of the invention also shows a good elasticity in all directions, allowing it to conform to the movements of the abdominal wall after implantation, without the patient feeling uncomfortable. Moreover, the barbs of the knit of the invention are also made from bioresorbable material. The knit obtained by the method of the invention is therefore fully bioresorbable and combines the benefits of both synthetic and biologic prostheses.

Guide-bar B4 is preferably single threaded. In embodiments, the knitting pattern of guide-bar B4 includes a succession of stitches and inlays. Such a knitting pattern allows having on one hand some needles producing stitches, and for example, the loops that will give rise to the barbs after melting, and on the other hand some needles not producing stitches and thereby providing enough space for receiving the two yarns coming from the double threaded guide-bars B2 and B3. In particular, the presence of inlays in the knitting pattern of guide-bar B4 facilitates the presence of two yarns in each threaded guide of bars B2 and B3. Indeed, the presence of inlays in the knitting pattern of guide-bar B4 provides needles that are not loaded with stitches and that therefore provide space for fluidly receiving the two yarns coming from bars B2 and B3. The presence of inlays in the knitting pattern of B4, combined to the presence of two yarns in each threaded guide of bars B2 and B3, allows producing a homogeneous knit.

In embodiments, the yarns threaded in guide-bars B2 and B3 are monofilaments showing a diameter ranging from about 80 µm to about 140 µm. For example, these yarns show a diameter of about 125 µm. As a result, the threaded guides of bars B2 and B3 comprise two yarns, each having a diameter of about 125 µm. As seen above, guide-bars B2 and B3 are the guide-bars that form the basis of the knit, from which the barbs issued from the loops generated by guide-bar B4 will protrude. Such embodiments, in which the two yarns threaded in the threaded guides of bars B2 and B3 show a diameter of about 125 µm, allow producing a knit that shows good mechanical strength. In particular, thanks to the presence of inlays in the knitting pattern of bar B4, the two yarns of diameter 125 µm of each threaded guide of bars B2 and B3 can be fluidly received in the needles concerned by said inlays.

In embodiments, the yarns threaded in guide-bar B4 are monofilaments showing a diameter ranging from about 100 µm to about 180 µm. For example, these yarns show a diameter of about 150 µm. Such monofilaments allow providing barbs showing a good gripping force.

In embodiments, the knitting pattern repetition unit for guide-bars B2 and B3 includes a displacement of the yarns on 5 to 9 needles along a first number of courses and a displacement of the yarns on 2 needles only along a second number of courses. For example, the first number of courses is between 4 and 6, and the second number of courses is between 2 and 4. For example, the knitting pattern repetition unit for guide-bars B2 and B3 includes a displacement of the yarns on 7 needles along 4 courses and a displacement of the yarns on 2 needles only along 2 courses. Such embodiments allow producing a knit having particularly good elongation properties, and therefore good elasticity in all directions, while showing good mechanical properties, in particular excellent tensile breaking strength and bursting strength, good tear strength and suture pull-out strength.

In embodiments, guide-bars B2 and B3 are double threaded one full, two empty, according to the following pattern according to the standard ISO 11676 (publication year 2014) :

B2 : 0-1/3-4/7-6/4-3/0-1/2-1//
B3 : 7-6/4-3/0-1/3-4/7-6/5-6//

This knitting pattern repetition unit of guide-bars B2 and B3 includes a displacement of the yarns on 7 needles along 4 courses and a displacement of the yarns on 2 needles only along 2 courses.

In such embodiments, guide-bar B4 may be threaded one full, two empty according to the following pattern according to the standard ISO 11676 (publication year 2014) :

B4 : 4-4/1-2/0-1/2-1/4-4/2-2//

Such a knitting pattern produces a succession of stitches and inlays.

With the knitting patterns as described above for B2, B3 and B4, it is possible to obtain a knit having good mechanical properties together with a good elasticity in all directions.

In other embodiments, the knitting pattern repetition unit for guide-bars B2 and B3 includes a displacement of the yarns on 4 needles. Such embodiments allow producing a knit having particularly good elasticity in all directions, while showing good mechanical properties.

For example, guide-bars B2 and B3 may be double threaded one full, two empty, according to the following pattern according to the standard ISO 11676 (publication year 2014) :

B2 : 1-0/3-4//
B3 : 3-4/1-0//

In such embodiments, guide-bar B4 may be threaded one full, two empty according to the following pattern according to the standard ISO 11676 (publication year 2014) :

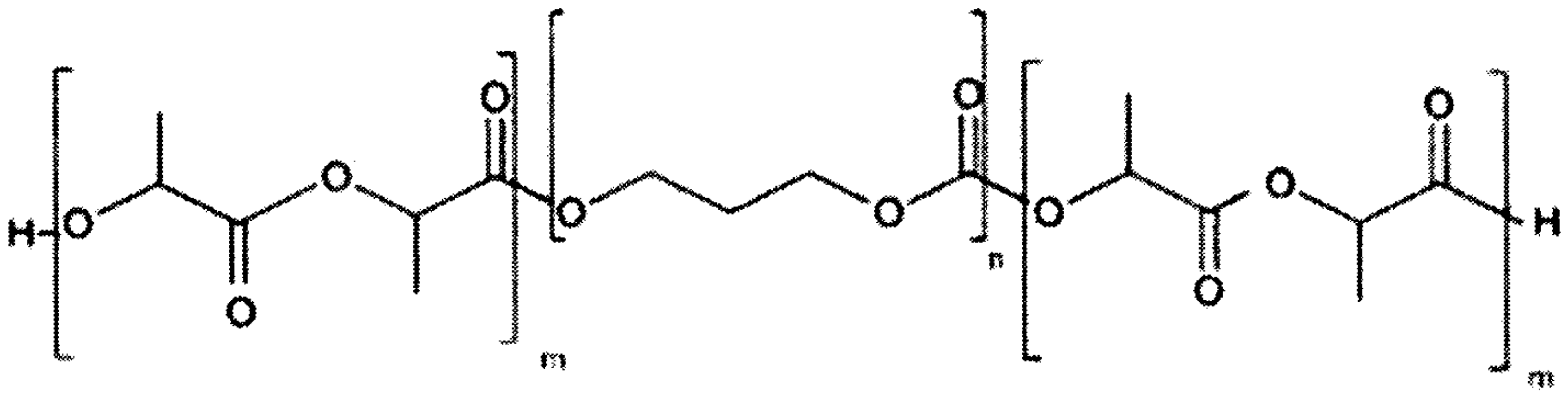
B4 : 5-5/2-3/0-0/3-2//

Such a knitting pattern produces a succession of stitches and inlays.

With the knitting patterns as described above for B2, B3 and B4, it is possible to obtain a knit having good mechanical properties together with a good elasticity.

Bioresorbable materials suitable for the yarns and the barbs of the knit of the present invention include polylactic acid (PLA), polyglycolic acid (PGA), oxidized cellulose, polycaprolactone (PCL), polydioxanone (PDO), trimethylene carbonate (TMC), polyvinyl alcohol (PVA), polyhydroxyalkanoates (PHAs), copolymers of these compounds and mixtures thereof.

A preferred bioresorbable biocompatible material suitable for the yarns and the barbs of the knit of the present invention is a polhydroxyalkanoate such as a copolymer of poly trimethylene carbonate (PTMC) and of poly-L-lactide (PLLA). The copolymer may have a composition of about 80 % lactide and 20% trimethylene carbonate. For example, the polymer structure is a triblock copolymer with a central bloc of poly trimethylene carbonate (PTMC) and two lateral blocks of poly-L-lactide (PLLA) as shown below under Formula (I) :



(I)

The polymer of formula (I) above may show a molar mass M_n ranging from about 100,000 to about 225,000 and a molecular weight M_w ranging from about 100,000 g/mol to about 225,000 g/mol.

In a preferred embodiment, the bioresorbable biocompatible material forming the yarns and the barbs of the knit of the invention is a triblock copolymer with a central bloc of poly trimethylene carbonate (PTMC) and two lateral blocks of poly-L-lactide (PLLA) having a composition of about 80 % lactide and 20% trimethylene carbonate, for example as described in European patent application EP 18197009.6.

The polymer may be manufactured in a dry stainless steel conical vessel reactor outfitted with two helicone-style mixing blades, under dry conditions (nitrogen gaz) by first adding trimethylene carbonate, di-functional initiator (diethylene glycol) and catalyst (Stannous octoate), which are polymerized by heating. After complete polymerization (first stage) the lactide may be added (with additional catalyst). When the reaction is complete the polymer may be extruded, pelletized and dried (to remove moisture and monomer) under heat and vacuum.

For example, the co-polymer may then be melt above the fusion temperature to be extruded through the spinneret, to produce yarns. The yarns produced may show a diameter ranging from 80 µm to 200 µm. For example, yarns of diameter 125 µm and of diameter 150 µm may be produced. The yarns are cooled in water just after their extrusion. Monofilaments are then going through a succession of oven and rolls systems to stretch them and reach their technical characteristics. Both 125 µm diameter yarns and 150 µm diameter yarns may be warped onto beams that will further be set onto the warp knitting machine.

Further to the knitting step as described above, the knit obtained is heat-set. The heat-setting step allows stabilizing the knit in width and length, in particular in the weft direction and in the warp direction. The heat-setting step may be performed at a temperature ranging from about 100°C to about 125°C, for example at about 115°C. In embodiments, the temperature at which the heat-setting step is performed is below the melting point of the hot-melt material forming the monofilament threaded in guide-bar B4, preferably at least about 10°C below said melting point. The knit may be kept under no tension, neither in the warp dircetion nor in the weft direction, during the heat-setting step.

In a further step, the loops generated by the hot-melt monofilament threaded in guide-bar B4 are cut to form the barbs. The loops are cut via melting the monofilament.

In embodiments, this step is performed by placing the side of the knit provided with the protruding loops on a cylinder that is brought to a temperature that causes the loops to melt so they are cut in two and thus form the barbs, as described in WO01/81667. This cutting generates two barbs, each of them having a head with dimensions usually greater than its stem.

The barbs obtained are particularly efficient for gripping biological tissues, such as muscles, connective tissues, etc...

The knit may then be cleaned and sterilized according to conventional sterilization methods, for example using ethylene oxide.

The knit of the invention may be used on its own or as a part of a prosthesis for wall reinforcement in parietal or visceral surgery, in particular for the treatment of hernias, preferably ventral hernias.

Another aspect of the invention is a prosthesis for the treatment of hernias, comprising at least one knit as described above. The prosthesis of the invention shows good mechanical properties, such as tensile strength, as well as good elongation properties, such as tensile elongation strength. In particular, the prosthesis of th einvention shows particularly good ball burst properties, allowing it to show a high mechanical resistance together with adequate elasticity. The prosthesis of the invention therefore ensures efficient reinforcement of the abdominal wall, with an optimal comfort for the patient, as the elasticity of the prosthesis allows it to adapt and smoothly respond to the intraabdominal pressure generated by the movements of the patient in his daily life.

The knit of the invention and the method for manufacturing said knit will be further described in details with reference to the examples below and enclosed drawings in which :

- Figure 1 is a schematic representation of the knitting pattern of Guide-bar B2 according to a first embodiment of the knit of the invention,
- Figure 2 is a schematic representation of the knitting pattern of Guide-bar B3 according to the first embodiment of the knit of the invention,
- Figure 3 is a schematic representation of the knitting pattern of Guide-bar B4 according to the first embodiment of the knit of the invention,
- Figure 4 is a schematic representation of the knitting patterns of guide-bars B2, B3 and B4 of a second embodiment of the knit of the invention,
- Figure 5 is a schematic representation of the testing machine used in the ball burst test,
- Figure 6 is a graph showing the distribution of the Force max measured for different wall abdominal samples in relation to the in vivo study described at Example 7.

EXAMPLE 1 :

A prosthetic knit according to the invention, hereinbelow referred to as Knit A, is produced on a warp knitting machine with four guide bars B1, B2, B3 and B4, as described above, where the bar B1 is in position 1 on the knitting machine, the bar B2 is in position 2, the bar B3 is in position 3, and the bar B4 is in position 4.

Guide-bar B1 is unthreaded.

Guide-bars B2 and B3 are double threaded one full, two empty, according to the following knitting pattern according to the standard ISO 11676 (publication year 2014) :

B2 : 0-1/3-4/7-6/4-3/0-1/2-1//
B3 : 7-6/4-3/0-1/3-4/7-6/5-6//

The knitting pattern of guide-bar B2 is shown on Figure 1 according to a representation well known from persons skilled in the art, where "wa" indicates the warp direction and "we" indicates the weft direction.

The knitting pattern of guide-bar B3 is shown on Figure 2 according to a representation well known from persons skilled in the art, where "wa" indicates the warp direction and "we" indicates the weft direction.

Guide-bar B4 is threaded one full, two empty, according to the following knitting pattern according to the standard ISO 11676 (publication year 2014) :

B4 : 4-4/1-2/0-1/2-1/4-4/2-2//

The knitting pattern of guide-bar B4 is shown on Figure 3 according to a representation well known from persons skilled in the art, where "wa" indicates the warp direction and "we" indicates the weft direction.

All the yarns used in manufacturing the present Knit A, namely the yarns threaded in guide-bars B2, B3 and B4, are made of a triblock copolymer with a central bloc of poly trimethylene carbonate (PTMC) and two lateral blocks of poly-L-lactide (PLLA) having a composition of about 80 % lactide and 20% trimethylene carbonate. Knit A is fully bioresorbable.

The yarns threaded in guide-bars B2 and B3 are monofilaments having a diameter of 125 µm. The yarn count is 156 dtex. Each threaded guide is threaded with two yarns.

The yarns threaded in guide-bar B4 are monofilaments having a diameter of 150 µm. The yarn count is 227 dtex. Guide-bar B4 is single threaded.

For each Figure 1-3, the graphic shows the movement of the corresponding guide-bar. The guide-bar's movement is read from bottom to top, the first knitted course being at the bottom.

The global pattern repetition size of each guide-bar is 6 courses, so that the overall pattern repetition size is 6 courses (lines named 1 to 6 in Figures 1-3).

The yarns threaded in B2 and B3 constitute the base of of the present knit, since the hot-melt monofilament yarn, intended to generate the barbs, will be regularly cut during the melting step. The knitting patterns of guide-bars B2 and B3 produce an arrangement of yarns defining the two sides of the knit.

The knitting pattern repetition unit for guide-bars B2 and B3 includes a displacement of the yarns on 7 needles along 4 courses (corresponding to the displacement referred to as A-B-C-D on Figure 1) and a displacement of the yarns on 2 needles only along 2 courses (corresponding to the displacement referred to as E-F on Figure 1).

Sequence A-B-C-D brings some strength to the knit in the weft direction, while the sequence E-F brings some performance to the knit in the warp direction.

Such a knitting pattern repetition unit allows producing a knit having particularly good elasticity in all directions, while showing good mechanical properties, in particular excellent tensile breaking strength and bursting strength, good tear strength and suture pull-out strength.

The knitting pattern followed by guide-bar B4 makes stitches generating loops protruding outwards from one side of the knit.

Once the knit is produced, it is heat-set according to a conventional method, for example at 115°C, in order to stabilize it in length and width.

After the heat-setting step, the side of the knit from which the loops produced by guide-bar B4 protrude is placed in contact with a cylinder containing a heating resistor so as to melt the loops, for example in the same manner as described in WO01/81667. The melting point of the copolymer of 80% lactide and 20% trimethylene carbonate used in the present example for forming the barbs being 172°C, the heating resistor may show a temperature of about 250-290 °C.

On melting, each loop cuts in two and gives rise to two barbs protruding outwards from said side of the knit.

The following properties of Knit A of the present example have been determined as follows:

- Surface density (g/m^2): measured according to ISO 3801: 1977 « Determination of mass per unit length and mass per unit area », 5 samples, 1 dm^2 disk,

- pore size (width x height) (mm): knit biggest pores width and height are measured making one measurement on 5 individual samples of dimensions 100X50 mm, with a profile projector such as a projector,

- Gripping strength (N) : the knit samples to be tested are evaluated in combination with counter-samples made of textile having hexagonal shaped pores. The knit samples are first anchored to the counter-samples thanks to their barbs as follows : counter-samples of dimensions 5 X 10 cm are prepared; knit samples of dimensions 5 X 10 cm are prepared; each counter-sample is laid on a horizontal plane, with the hexagonal shaped pores upwards; a knit sample is positioned on top of the counter-sample, with the barbs protruding downwards; the knit sample is then pressed onto the counter-sample by passing a load of 1.5 kg back and forth 5 times on the knit sample; the counter-sample and the knit sample gripped thereto are then positioned between a sliding plate and a tightening plate of dimensions 5 X 5 cm; the assembly is then mounted on a traction testing machine such as the Hounsfield model H5KS (Hounsfield, Redhill, England) provided with a fixed jaw and a mobile jaw; the counter-sample is attached to the mobile jaw and the knit sample is attached to the fixed jaw: the preload is set at 2 N; the mobile jaw is moved away from the fixed jaw at a speed of 100 mm/min; the gripping strength is the maximum shear force measured before the knit sample fails and/or slides on the counter-sample. The collected value represents the average of 5 samples.

The results are collected in **Table I** below :

Property	**Knit A**
Surface density (g/m^2)	200
Pore size (mm^2) (width x height)	1.3 x 2.3
Gripping strength (N)	112 ± 5

Table I

EXAMPLE 2 :

A prosthetic knit according to the invention, referred to herein below as Knit B, is produced on a warp knitting machine with four guide bars B1, B2, B3 and B4, as described above, where the bar B1 is in position 1 on the knitting machine, the bar B2 is in position 2, the bar B3 is in position 3, and the bar B4 is in position 4.

Guide-bar B1 is unthreaded.

Guide-bars B2 and B3 are double threaded one full, two empty, according to the following knitting pattern according to the standard ISO 11676 (publication year 2014) :

B2 : 1-0/3-4//
B3 : 3-4/1-0//

Guide-bar B4 is threaded one full, two empty, according to the following knitting pattern according to the standard ISO 11676 (publication year 2014) :

B4 : 5-5/2-3/0-0/3-2//

The knitting patterns of guide-bars B2, B3 and B4 are shown on Figure 4 according to a representation well known from persons skilled in the art, where "wa" indicates the warp direction and "we" indicates the weft direction.

All the yarns used in manufacturing the present Knit B, namely the yarns threaded in guide-bars B2, B3 and B4, are made of a triblock copolymer with a central bloc of poly trimethylene carbonate (PTMC) and two lateral blocks of poly-L-lactide (PLLA) having a composition of about 80 % lactide and 20% trimethylene carbonate. Knit B is fully bioresorbable.

The yarns threaded in guide-bars B2 and B3 are monofilaments having a diameter of 125 µm. The yarn count is 156 dtex. Each threaded guide is threaded with two yarns.

The yarns threaded in guide-bar B4 are monofilaments having a diameter of 150 µm. The yarn count is 227 dtex. Guide-bar B4 is single threaded.

The pattern repetition size of guide-bars B2 and B3 is 2 courses and the pattern repetition size of guide-bar B4 is 4 courses, so that the overall pattern repetition size is 4 courses (lines named 1' to 4' in Figure 4).

The yarns threaded in B2 and B3 constitute the base of the present knit, since the hot-melt monofilament yarn, intended to generate the barbs, will be regularly cut during the melting step. The knitting patterns of guide-bars B2 and B3 produce an arrangement of yarns defining the two sides of the knit.

The knitting pattern repetition unit for guide-bars B2 and B3 includes a displacement of the yarns on 4 needles along 2 courses.

Such a knitting pattern repetition unit allows producing a knit having particularly good elasticity in all directions, while showing good mechanical properties, in particular excellent tensile breaking strength and bursting strength, good tear strength and suture pull-out strength.

Once the knit is produced, it is heat-set according to a conventional method, for example at 115°C, in order to stabilize it in length and width.

After the heat-setting step, the side of the knit from which the loops produced by guide-bar B4 protrude is placed in contact with a cylinder containing a heating resistor so as to melt the loops, for example in the same manner as described in WO01/81667. Like in Example 1, the heating resistor may show a temperature of about 250-290 °C.

On melting, each loop cuts in two and gives rise to two barbs protruding outwards from said side of the knit.

The properties of the present knit B have been measured in the same manner and with the same methods as described in Example 1. The results are collected in the **Table II** below :

Property	**Knit B**
Surface density (g/m^2)	144
Pore size (mm^2) (width x height)	1.7 x 1.4
Gripping strength (N)	72 ± 8

Table II

EXAMPLE 3 :

In the present example, the mechanical properties of the knits of the invention of examples 1 and 2 above, namely Knit A and Knit B, have been measured according to the following methods :

- Tensile breaking strength (N), tensile elongation at break (%), tensile elongation under 50N (%): are measured according to ISO 13934-1 : 2013 *"Determination of breaking strength and elongation"*, 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),
- Bursting strength (kPa): measured according to ISO 13938-2: 1999 "Textiles – Bursting properties of fabrics – Pneumatic method for determination of bursting strength and bursting deformation", 5 samples using a Bursting strength tester, James Heal model Truburst 4,
- Suture pull out strength in the warp direction and in the weft direction measured as follows : a USP 2 suture yarn is passed through a pore of a 50X100 mm sample, at 10 mm from the edge of a small side of the sample, and is tracted away using a traction testing machine such as the Hounsfield model H5KS (Hounsfield, Redhill, England) with the following conditions : 5 samples, width 50 mm, 100 mm between the jaws, crosshead speed: 100 mm/min,
- Tear strength (N) in the warp direction and in the weft direction: measured according to superseded ISO 4674:1977 "*Determination of tear resistance of coated fabrics*" Method A2, 5 samples , width: 75 mm, Tear length ≤ 145 mm, crosshead speed: 100 mm/min,

In addition, these properties have been measured, according to the methods described above, for the following knits of the prior art :

- **Knit C** : non bioresorbable knit for hernia repair made of polyester multifilaments, commercialized under the tradename « Parietex^{TM} Hydrophilic 3 Dimensional Mesh » by the company Sofradim Production,
- **Knit D** : non bioresorbable knit for hernia repair, made of a base knit of non bioresorbable polyester monofilaments and bioresorbable

polylactic acid barbs, commercialized under the tradename « ProGrip^{TM} Self-Gripping Polyester Mesh » by the company Sofradim Production.

The knits of the present examples are tested after their manufacture, without having been submitted to any fatigue and/or degradation treatment before the tests are completed.

The results are collected in **Table III** below :

Property	**Knit A**		**Knit B**		**Knit C**		**Knit D**	
Bursting strength (kPa)	583 ± 20		672 ± 60		288 ± 15		271 ± 5	
	Warp	**Weft**	**Warp**	**Weft**	**Warp**	**Weft**	**Warp**	**Weft**
Tensile breaking strength (N)	377 ± 15	323 ± 23	243 ± 37	345 ± 6	257 ± 17	117 ± 11	129 ± 9	179 ± 10
Tensile elongation under 50 N (%)	30 ± 1	38 ± 1	28 ± 1	31 ± 2	-	-	18 ± 1	23 ± 1
Tensile breaking elongation (%)	94 ± 2	97 ± 5	58 ± 5	77 ± 5	44 ± 5	63 ± 3	-	-
Tear strength (N)	66 ± 2	65 ± 6	36 ± 1	32 ± 3	17 ± 1	17 ± 3	18 ± 1	16 ± 3
Suture pull-out strength (N)	86 ± 6	69 ± 8	61 ± 6	44 ± 6	23 ± 4	27 ± 3	35 ± 4	25 ± 4

Table III

As can be observed from the results above, the knits A and B of the invention show excellent mechanical properties, such as a bursting strength of 583 kPa for Knit A and 672 kPa for Knit B, a tensile breaking strength in the warp direction of 377 N for Knit A and 243 N for Knit B, and a tensile breaking strength in the weft direction of 323 N for Knit A and 345 N for Knit B. In the same time, Knits A and B of the invention further show good elasticity with a tensile breaking elongation of 94% in the warp direction and a tensile breaking elongation of 97% in the weft direction for

Knit A, and a tensile breaking elongation of 58% in the warp direction and a tensile breaking elongation of 77% in the weft direction for Knit B.

As a comparison, the non bioresorbable Knit C of the prior art shows a bursting strength of only 288 kPa, in other words representing only about 49% of the bursting strength of Knit A and only about 43% of the bursting strength of Knit B. The non bioresorbable Knit D of the prior art shows a bursting strength of only 271 kPa, in other words representing only about 46% of the bursting strength of Knit A and only about 40% of the bursting strength of Knit B.

As further appears from Table III above, the bioresorbable knits A and B of the invention show better mechanical properties, such as tensile breaking strength, tear strength and suture pull out strength, than the non bioresorbable Knits C and D of the prior art. The knits A and B of the invention further show better elasticity in all directions, as shown by the values measured for the tensile elongation under 50 N and the tensile breaking elongation, than the Knits C and D of the prior art.

EXAMPLE 4 :

In the present example, the ball burst properties of knits A and B of the invention of examples 1 and 2 above are compared to that of knits of the prior art.

The ball burst test method used herein is in conformity with ASTM D6797-15 "Standard Test Method for Bursting strength of Textiles – Constant-rate-of-Extension (CRE) Ball Burst Test". This ball burst test is herein described with reference to Figure 5. With reference to this figure, a square-shaped knit sample 1 of dimensions 6.5 cm X 6.5 cm of the knit to be tested is secured between the lower jaw 2 and the upper jaw 3 of a ball burst strength tester 4, by a ring clamp having a 44.45 mm inner diameter. A 25.4 mm ball probe 5 is attached to the cross head 6 of a compression testing machine such as the Hounsfield model H5KS (Hounsfield, Redhill, England) and a preload of 0.1 N is applied to the sample 1.

To complete the test, the ball probe 5 is moved downwards in the direction of the arrow F indicated on Figure 5, thereby applying a force onto the sample 1. The ball probe is moved at a rate of 305 mm/min until the sample 1 fails.

The force (N) measured at the time of failure is referred to as the "Force max", and the displacement (mm) of the sample 1 at time of failure is referred to as "Deflection". The greater the Force max, the stronger the knit sample. The greater the deflection, the more elastic the knit. A knit having a high Force max and a high deflection is therefore a resistant knit that is capable of adapting smoothly to the pressure. A prosthesis for hernia repair made from such a knit will be resistant and conformable so that it is capable of bearing the pressures the abdominal wall is submitted to on a daily basis.

In addition to the two comparative Knits C and D described in Example 3, the following knits of the prior art are also tested in the present example:

- **Knit E** : non bioresorbable knit for hernia repair made of polypropylene monofilaments, commercialized under the tradename "Optilene® Mesh LP" by the company B-Braun,
- **Knit F** : bioresorbable knit for hernia repair made of multifilaments of a copolymer of glycolide, lactide and trimethylene carbonate and of multifilaments of lactide and trimethylene carbonate, commercialized under the tradename "Tigr® Matrix" by the company Novus Scientific.

1°) Ball burst test at time T0 :

The knits A-F have been tested at time T0, without having been submitted to any fatigue and/or degradation treatment before completion of the test.

The results of the test completed at T0 are collected in **Table IV** below :

Tested Knit	Force max (N)	Deflection (mm)
Knit A	506 ± 16	25 ± 1
Knit B	367 ± 54	17 ± 1
Knit C	187 ± 13	16 ± 1
Knit D	195 ± 16	21 ± 2
Knit E	273 ± 20	22 ± 1
Knit F	463 ± 4	19 ± 0

Table IV : Force max and deflection at T0

As appears from Table IV, knits A and B of the invention show a high Force max and a high deflection at time T0. These knits are therefore particularly suitable for use as hernia repair as they are strong and adaptable.

2°) Ball burst test after 20 weeks of static degradation in vitro:

The bioresorbable knits A, B and F have further been tested after having been immersed in a static manner during 20 weeks (T20ws) in a buffer solution intended to simulate physiological fluid in a human body, in order to evaluate the behavior of the knit under such conditions. The testing is performed in accordance to the norm ISO 13781 : 1997, with the following deviations : oven precision is ± 2°C, and the buffer is changed when the pH drops below 7.2.

The knit samples are immersed in a phosphate buffer solution consisting of potassium dihydrogen phosphate and disodium hydrogen phosphate in sterile water at a concentration of 1/15 mol/L. The pH value of the buffer solution is 7.4 ± 0.1.

Samples of dimensions 7 x 7 cm are placed in a sterile 180mL polypropylene container filled with 150mL phosphate buffer solution. The containers are closed and placed into a climate chamber at 37°C in which they are maintained in a static state during 20 weeks.

After 20 weeks, each sample is removed from the solution and is directly tested for ball burst as described above.

The results of the test completed at T20ws are collected in **Table V** below :

Tested Knit	**Force max (N)**	**Deflection (mm)**
Knit A	539 ± 29	25 ± 1
Knit B	368 ± 21	16 ± 1
Knit F	143 ± 3	19 ± 1

Table V : Force max and deflection at T20ws

As appears from Table V above, the knits A and B of the invention have maintained their ball burst properties, even after having been immersed 20 weeks in the buffer solution in which they have been partially degraded. Indeed, for these two knits, the values of the Force max and of the deflection remain substantively the same at T0 and at T20ws.

As a comparison, the Force max of comparative bioresorbable Knit F has gone from 463 N to 143 N after static immersion during 20 weeks in the buffer solution, thereby losing about 69% of its initial value. As a result, the Force max of comparative Knit F at T20ws represents around 26% only of the Force max measured for inventive Knit A and around 39% only of the Force max measured for inventive Knit B.

For comparison's sake, the values of the ball burst properties of non bioresorbable comparative knits C, D and E at T0 on one hand, and of inventive knits A and B at T20ws on the other hand, are recalled in one single **Table VI** below, in order to emphasize that the knits of the invention show better ball burst properties after 20 weeks of static degradation treatment than non bioresorbable knits of the prior art which have not been submitted to any degradation treatment:

Tested Knit	Force max (N)	Deflection (mm)
Knit A (at T20ws)	539 ± 29	25 ± 1
Knit B (at T20ws)	368 ± 21	16 ± 1
Knit C (at T0)	187 ± 13	16 ± 1
Knit D (at T0)	195 ± 16	21 ± 2
Knit E (at T0)	273 ± 20	22 ± 1

Table VI : comparison of ball burst properties at T0 for non bioresorbable knits of prior art and at T20ws for bioresorbable knits of the invention

EXAMPLE 5 :

In the present example, the mechanical properties of knits A and B of the invention of examples 1 and 2 above are compared to that of comparative bioresorbable knit F of the prior art. The knits are first tested at time T0, i.e. without having been submitted to any fatigue and/or degradation treatment.

The knits A and B of the invention are also tested at time T20ws, i.e. after 20 weeks of in vitro static degradation, the static degradation protocol being identical to that described in Example 4 above.

The comparative Knit F is further tested at time T13ws, i.e. after 13 weeks of in vitro static degradation, the static degradation protocol being identical to that described in Example 4 above, except that the samples are removed from the buffer solution after 13 weeks of immersion instead of 20 weeks.

The mechanical properties of the knits are measured according to a uniaxial tensile test that has been adapted to small sizes samples as follows : tensile breaking strength (N), tensile elongation at break (%), tensile elongation under 50N (%) and tensile elongation under 30 N (%) are measured according to ISO 13934-1 : 2013 *"Determination of breaking strength and elongation"*, with the following deviations : 5 samples each direction : dimensions 25 mm X 60 mm – Length : 40 mm between the jaws, Crosshead speed : 20 mm/min, Pre-load : 0.5 N, using a traction testing machine such as a Hounsfield model H5KS.

The results are collected in the following **Table VII** and **Table VIII** :

Property	**Knit A**		**Knit B**		**Knit F**	
	Warp	**Weft**	**Warp**	**Weft**	**Warp**	**Weft**
Breaking strength (N)	165 ± 11	145 ± 5	106 ± 8	156 ± 11	175 ± 11	180 ± 9
Elongation under 30 N (%)	33 ± 2	38 ± 1	33 ± 2	31 ± 3	19 ± 1	13 ± 0
Elongation under 50 N (%)	46 ± 2	50 ± 2	43 ± 2	40 ± 3	27 ± 1	20 ± 0
Breaking elongation (%)	95 ± 6	98 ± 5	68 ± 4	80 ± 2	79 ± 7	61 ± 2

Table VII : breaking strength and elongation properties at T0

Property	**Knit A**		**Knit B**	
	Warp	**Weft**	**Warp**	**Weft**
Breaking strength (N)	164 ± 10	138 ± 5	107 ± 10	148 ± 25
Elongation under 30 N (%)	32 ± 1	38 ± 2	30 ± 3	28 ± 5
Elongation under 50 N (%)	45 ± 1	49 ± 2	42 ± 4	39 ± 5
Breaking elongation (%)	97 ± 4	98 ± 5	69 ± 2	81 ± 8

Table VIII : breaking strength and elongation properties at T20ws

As is clear from Table VII and Table VIII above, the knits A and B of the invention have maintained their breaking strength and elongation properties at a high level, even after having been submitted to a static degradation treatment during 20 weeks. Indeed, for these two knits, the values of the breaking strength, elongation under 30 N, elongation under 50 N and breaking elongation remain substantively the same at T0 and at T20ws. This means that a prosthesis for hernia repair made from inventive knits A or B will be able to remain as mechanically resistant and elastic after 20 weeks as at the time it is manufactured. Such a prosthesis will therefore be capable of resisting to and conform to the various pressures the abdominal wall of a human body is submitted to during his daily life.

For comparative Knit F, the breaking strength according to the uniaxial tensile test described above for small size samples has been measured after 13 weeks (T13ws) of static degradation, where the static degradation protocol is identical as that described above, except that tests are performed after 13 weeks immersion in the buffer solution instead of 20 weeks. The results are collected in **Table IX** below :

Property	**Knit F**	
	Warp	**Weft**
Breaking strength (N)	73 ± 9	33 ± 4

Table IX : breaking strength for Knit F at T13ws

As shown by these results, after 13 weeks of static degradation, the breaking strength of the comparative bioresorbable knit F has gone from 175 N to 73 N in the warp direction, meaning that it has lost 58% of its initial value, and from 180 N to 33 N in the weft direction, meaning that it has lost 81% of its initial value. The values measured at T13ws for comparative Knit F are inferior to that measured at T20ws for Knits A and B of the invention, despite a much lower time spent under the degradation conditions.

EXAMPLE 6 :

In the present example, the breaking strength of inventive knits A and B of examples 1 and 2 above has been measured according to the conditions of the uniaxial tensile test adapted to small size samples as described at Example 5 above, after having submitted the knits to a period of in vitro dynamic degradation of 20 weeks (T20wd) as described below.

In vitro dynamic degradation protocol :

A device equipped with several 100 N load cells, each cell having a first fixed jaw capable of grasping a first knit sample edge and a second moving jaw capable of grasping the opposite edge of the knit sample is provided. The device and the cells are immersed in a temperature controlled bath at 37°C. The bath is a phosphate buffer solution consisting of potassium dihydrogen phosphate and disodium hydrogen phosphate in sterile water at a concentration of 1/15 mol/L. The pH value of the buffer solution is 7.4 ± 0.1.

Knit samples of dimensions 60 mm X 25 mm are prepared. Each sample is attached to the jaws of one cell. The length between the jaws is 40 mm. The moving jaw is moved away and closer to the fixed jaw in accordance to a uniaxial cyclic sine wave oscillating between 6 and 8 mm displacement so as to cause a 15% to 20% deformation of the knit sample at a frequency of 1Hz. Such a fatigue treatment is supposed to approximate the anticipated mechanical loading of a knit implanted in the abdominal wall of a human body.

The samples are submitted to such a fatigue treatment during 20 weeks in a continuous manner.

The protocol described above is intended to simulate the dynamic degradation conditions to which a prosthetic knit may be submitted to once it is implanted in the body of a patient, in order to evaluate the expected behavior of the knits under such conditions.

Measure of the breaking strength :

After 20 weeks of dynamic degradation treatment above, referred to as time T20wd, each sample, maintained in wet conditions by being immersed for 1h in sterile water at 37°C, is tested for tensile breaking strength as described in Example 5.

The results are collected in **Table X** below.

Property	Knit A		Knit B	
	Warp	Weft	Warp	Weft
Breaking strength (N)	123 ± 12	115 ± 2	75 ± 5	104 ± 5

Table X : breaking strength at T20wd

For comparison's sake, the breaking strength of comparative non bioresorbable knits C, D and E has also been measured according to the conditions of the uniaxial tensile test adapted to small size samples as described in Example 5 above, at T0, the knits being submitted to no fatigue and/or degradation treatment before completion of the test.

The values of the breaking strength of non bioresorbable knits C, D and E at T0 on one hand, and of inventive knits A and B both at T20ws and at T20wd on the other hand, are collected in one single **Table XI** below, in order to emphasize that the knits of the invention show better breaking strength properties after 20 weeks of static degradation treatment (T20ws) or after 20 weeks of dynamic degradation treatment (T20wd) than non bioresorbable knits of the prior art which have not been submitted to any degradation treatment.

Tested Knit	Breaking strength (N)	
	Warp	Weft
Knit A (at T20ws)	164 ± 10	138 ± 5
Knit A (at T20wd)	123 ± 12	115 ± 2
Knit B (at T20ws)	107 ± 10	148 ± 25
Knit B (at T20wd)	75 ± 5	104 ± 5
Knit C (at T0)	81 ± 8	51 ± 4
Knit D (at T0)	49 ± 10	79 ± 8
Knit E (at T0)	71 ± 10	33 ± 8

Table XI : comparison of breaking strength at T0 for non bioresorbable knits of prior art and at T20ws and T20wd for bioresorbable knits of the invention

EXAMPLE 7 :

In the present example, knits A and B of examples 1 and 2 above have been implanted in vivo in swines in order to evaluate the capabilities of the knits of the invention to reinforce, over time, a repaired ventral abdominal wall defect in a porcine model. The performance of knits A and B regarding ball burst properties after a certain time of implantation have been compared to that of a native abdominal wall on one hand, and to that of a wall for which the defect has been simply sutured without any reinforcement knit at all.

The protocol followed for the present study is the following one. The four following treatments, including optionally surgical repair, have been applied :

Treatment 1 : Negative Control : a disc-shaped defect of 3 cm diameter is created in the ventral abdominal wall of the animal. Surgical repair consists in simply closing the defect with absorbable suture with no use of reinforcement knit.

Treatment 2 : Positive Control : corresponds to the native abdominal wall. No defect is created. No surgical repair is performed.

Treatment 3 : Knit A : a disc-shaped defect of 3 cm diameter is created in the ventral abdominal wall of the animal in the same manner as in Treatment 1. Surgical repair consists in closing the defect with absorbable suture and reinforcing the abdominal wall with a disc-shaped sample of Knit A of Example 1 above, having a diameter of 9 cm.

Treatment 4 : Knit B : a disc-shaped defect of 3 cm is created in the ventral abdominal wall of the animal in the same manner as in Treatment 1 and Treatment 2 above. Surgical repair consists in closing the defect with absorbable suture and reinforcing the abdominal wall with a disc-shaped sample of Knit B of Example 2 above, having a diameter of 9 cm.

20 weeks after surgical repair, the animals are euthanized. Abdominal wall samples are collected as follows : each site (native wall for Treatment 2 or repaired defect sites for Treatments 1, 3 and 4), and an appropriate amount of surrounding tissue, are explanted, trimmed, wrapped in saline soaked gauze and subjected to ball burst testing according to the method described in Example 4 above in which the knit sample is replaced by the abdominal wall sample.

Figure 6 reproduces a graph showing the distribution of the Force max measured for the different Treatments above, namely the Negative Control, the Positive Control, Knit A and Knit B.

The dotted line of the graph of Figure 6 represents 80% of the value of the Force max for the native abdominal wall.

As appears from this Figure, the knits of the invention show, 20 weeks after implantation, in other words about 5 months after implantation, a Force max that is well above 80% of the Force max of the native abdominal wall.

As a result, the implanted knits of the invention still contribute to the repair of the abdominal wall at the end of the critical period of healing of at least 5 months as defined above.

CLAIMS

1. Method for manufacturing a bioresorbable prosthetic porous knit comprising an arrangement of yarns of bioresorbable biocompatible material defining at least two sides for said knit, said knit being provided, on one of its sides, with barbs protruding outwards from said one side, said process comprising the following steps:

- i) providing a warp knitting machine comprising one needle-bed comprising four guide-bars, namely guide-bar B1, guide-bar B2, guide-bar B3 and guide-bar B4,

ii) knitting on said machine yarns of bioresorbable biocompatible material as follows :

- Guide-bar B1 is unthreaded,
- Guide-bars B2 and B3 are double threaded with yarns of bioresorbable biocompatible material, the knitting patterns followed by guide-bars B2 and B3 involving at least two needles and producing said arrangement of yarns defining said two sides of said knit,
- Guide-bar B4 is threaded with a hot-melt monofilament yarn of bioresorbable biocompatible material, the knitting pattern followed by guide-bar B4 making stitches generating loops protruding outwards from said one side of said knit,

iii) heat-setting the knit obtained at ii),

iv) forming barbs by cutting the loops via melting.

2. Method according to claim 1, wherein the knitting pattern of guide-bar B4 includes a succession of stitches and inlays.

3. Method according to claim 1 or 2, wherein the yarns threaded in guide-bars B2, B3 and B4 are monofilaments showing a diameter ranging from about 80 μm to about 180 μm.

4. Method according to claim 3, wherein the yarns threaded in guide-bars B2 and B3 are monofilaments showing a diameter of about 125 μm.

5. Method according to claim 3, wherein the yarns threaded in guide-bar B4 are monofilaments showing a diameter of about 150 μm.

6. Method according to any one of claims 1 to 5, wherein the knitting pattern repetition unit for guide-bars B2 and B3 includes a displacement of the yarns on 5 to 9 needles along a first number of courses and a displacement of the yarns on 2 needles only along a second number of courses.

7. Method according to claim 6, wherein the first number of courses is between 4 and 6, and the second number of courses is between 2 and 4.

8. Method according to claim 6 or 7, wherein the knitting pattern repetition unit for guide-bars B2 and B3 includes a displacement of the yarns on 7 needles along 4 courses and a displacement of the yarns on 2 needles only along 2 courses.

9. Method according to any one of claims 1 to 5, wherein the knitting pattern repetition unit for guide-bars B2 and B3 includes a displacement of the yarns on 4 needles.

10. Method according to any one of claims 6 to 8, wherein guide-bars B2 and B3 are double threaded one full, two empty, according to the following pattern:

B2 : 0-1/3-4/7-6/4-3/0-1/2-1//
B3 : 7-6/4-3/0-1/3-4/7-6/5-6//

and guide-bar B4 is threaded one full, two empty according to the following pattern :

B4 : 4-4/1-2/0-1/2-1/4-4/2-2//

11. Method according to claim 9, wherein guide-bars B2 and B3 are double threaded one full, two empty, according to the following pattern :

B2 : 1-0/3-4//
B3 : 3-4/1-0//

and guide-bar B4 is threaded one full, two empty according to the following pattern :

B4 : 5-5/2-3/0-0/3-2//

12. Method according to any one of claims 1-11, wherein the bioresorbable biocompatible material is a copolymer of poly trimethylene carbonate (PTMC) and of poly-L-lactide (PLLA), for example having a composition of 80% lactide and 20% trimethylene carbonate.

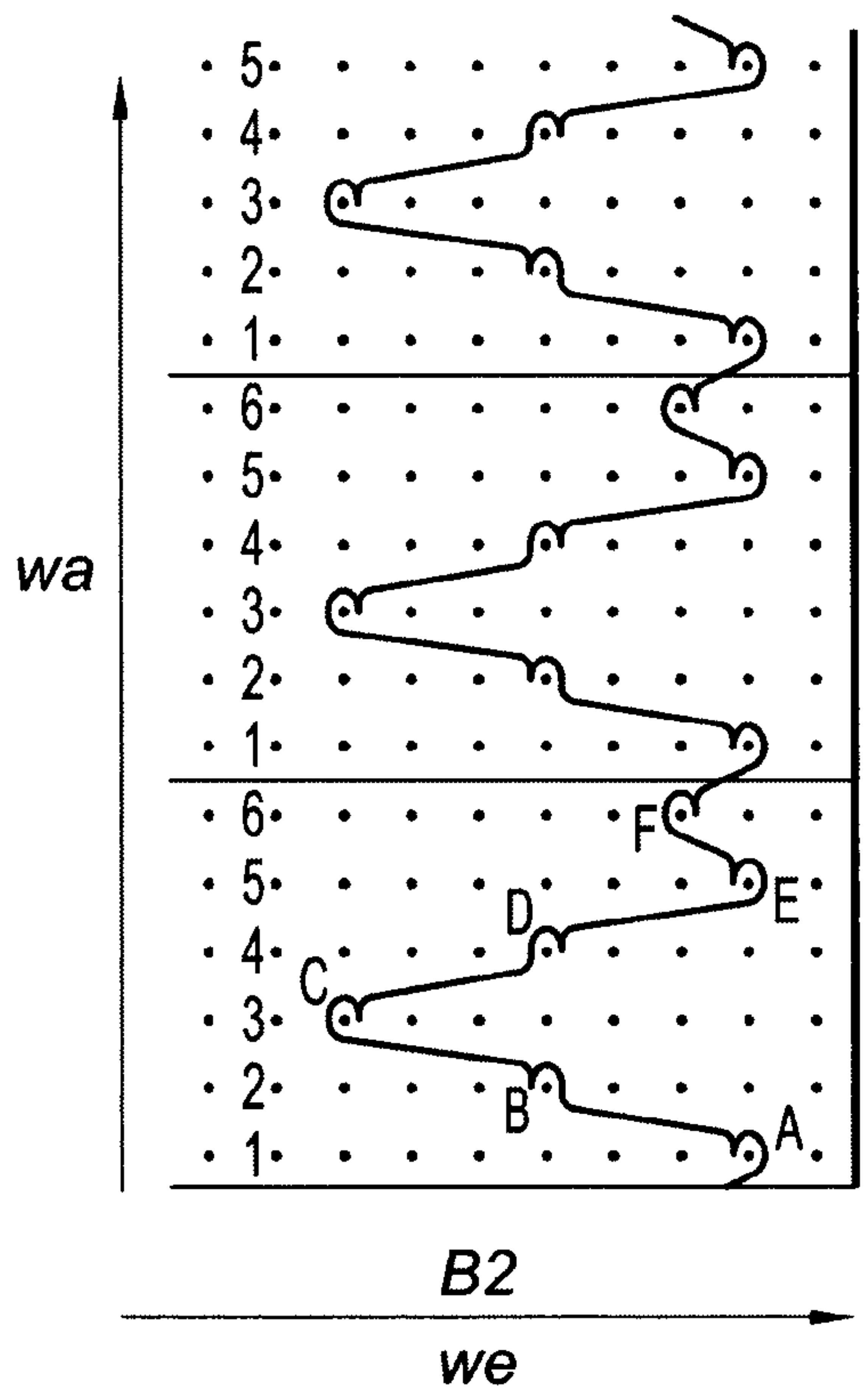
13. Bioresorbable prosthetic porous knit comprising an arrangement of yarns of bioresorbable biocompatible material defining at least two sides for said knit, said knit being provided, on one of its sides, with barbs protruding outwards from said one side, wherein each yarn of the arrangement defining the two sides of the knit is doubled.

14. Bioresorbable prosthetic knit according to claim 13, wherein the yarns of the arrangement defining the two sides of the knit are monofilaments

showing a diameter ranging from about 80 to about 140 µm, preferably showing a diameter of about 125 µm.

15. Bioresorbable prosthetic knit according to claim 13 or 14, wherein the barbs are formed from monofilaments cuts, wherein the monofilaments show a diameter ranging from about 100 to about 180 µm, preferably show a diameter of about 150 µm.

16. Bioresorbable prosthetic knit according to any one of claims 13 to 15, wherein the yarns forming the knit and the barbs are made of a copolymer of poly trimethylene carbonate (PTMC) and of poly-L-lactide (PPLA), for example having a composition of 80% lactide and 20% trimethylene carbonate.


5
4
3
2
1
6
5
4
3
2
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F
E
D
C
B
A
wa
B2
we

Fig. 1

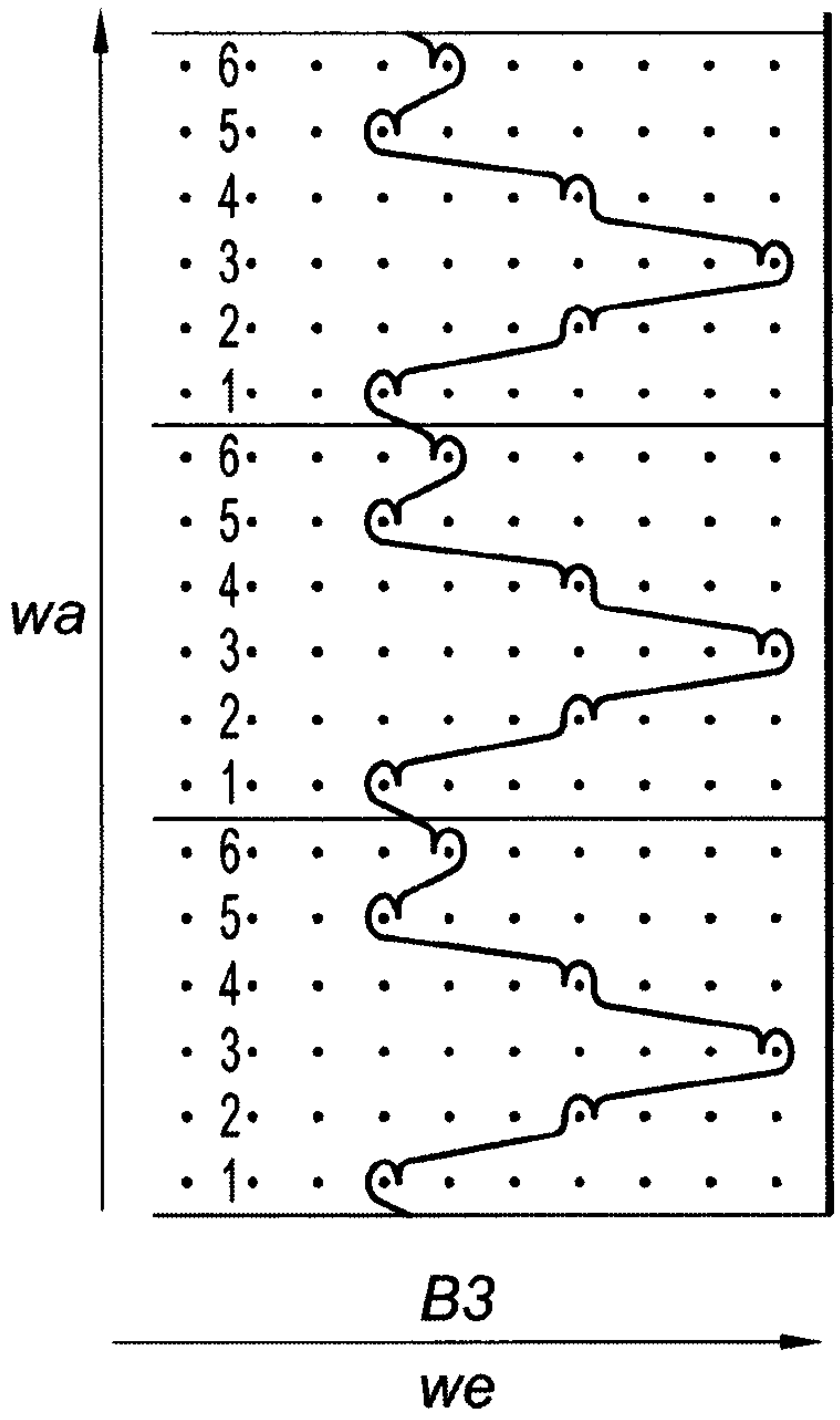
6
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Fig. 2

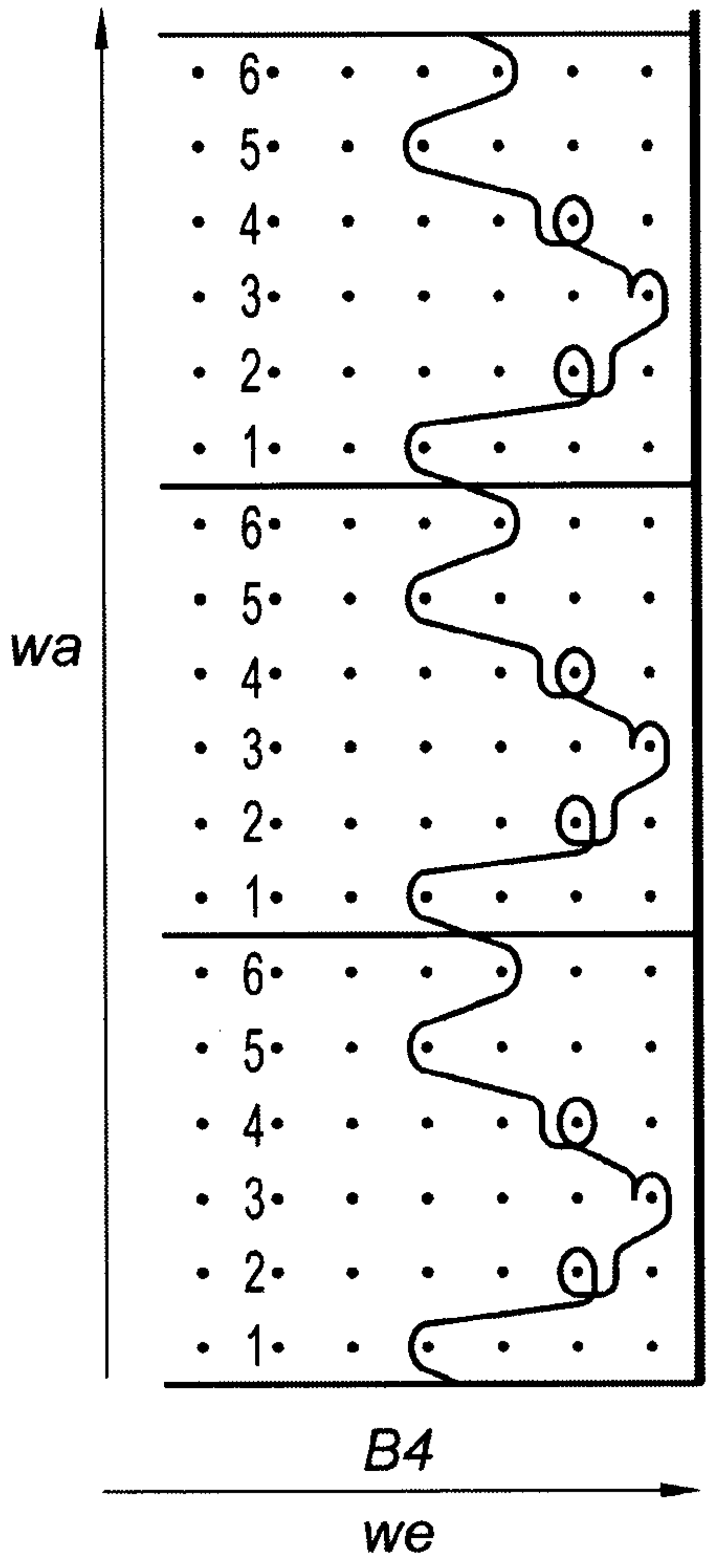

Fig. 3

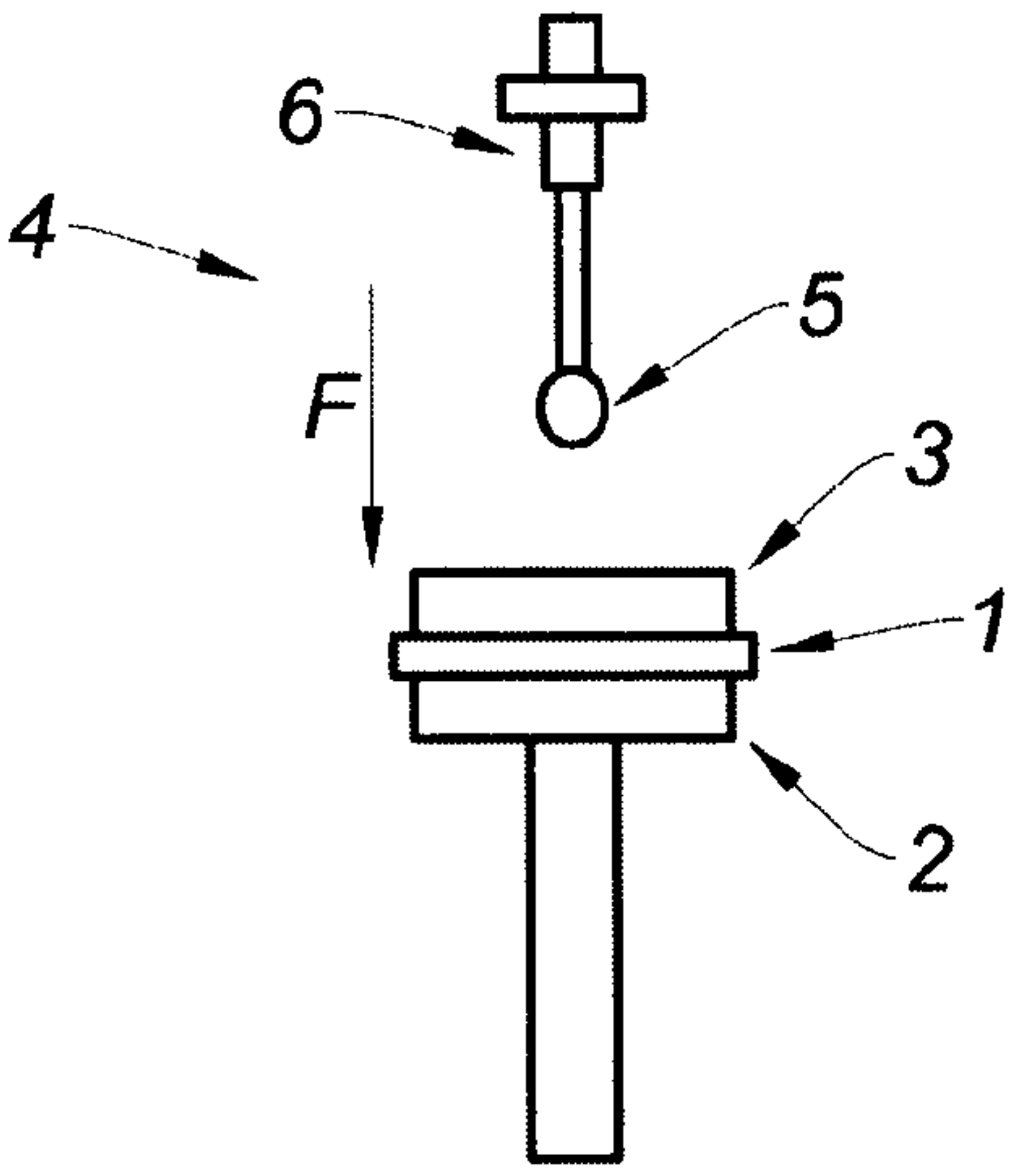

Fig. 5

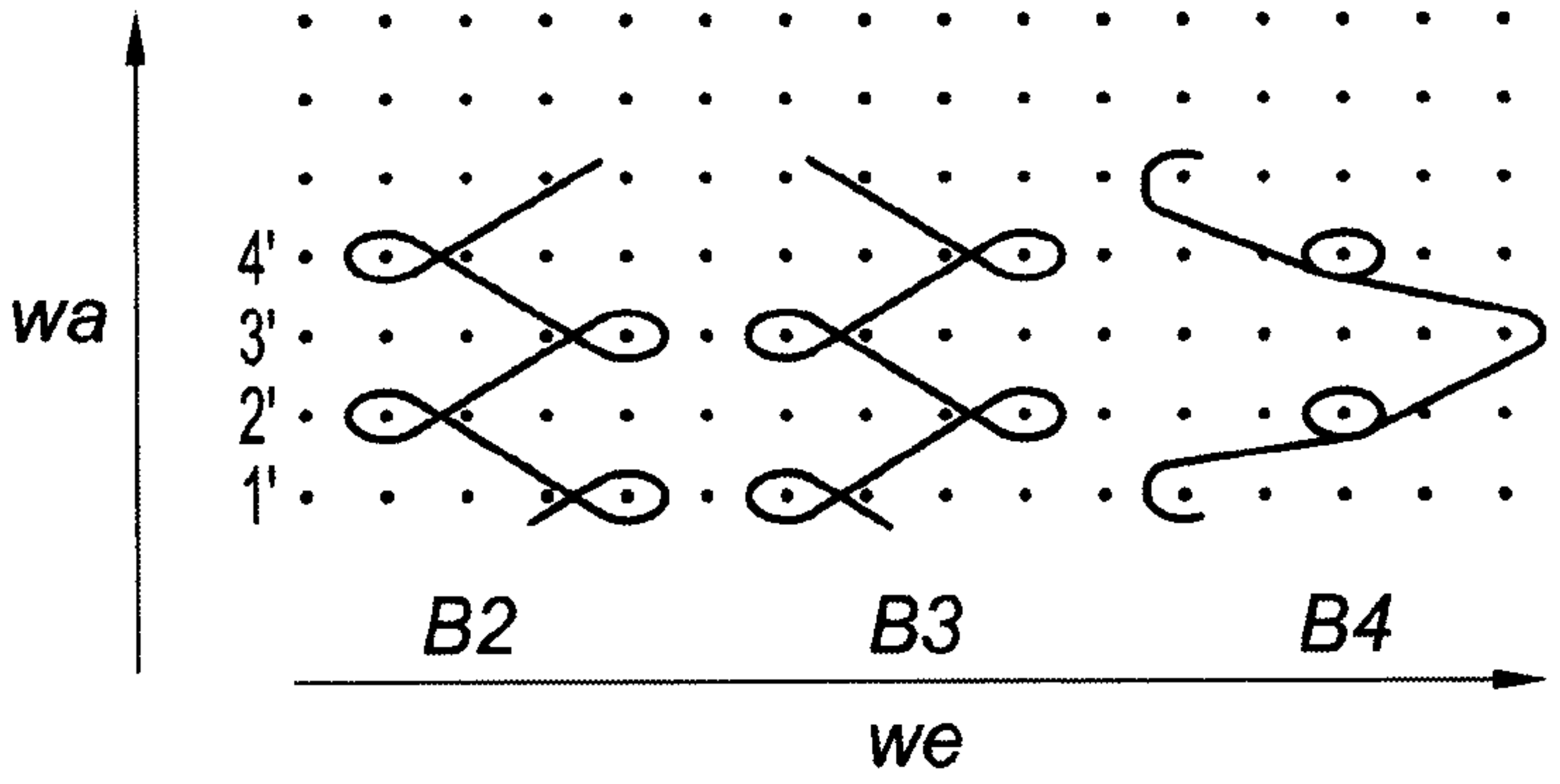

Fig. 4

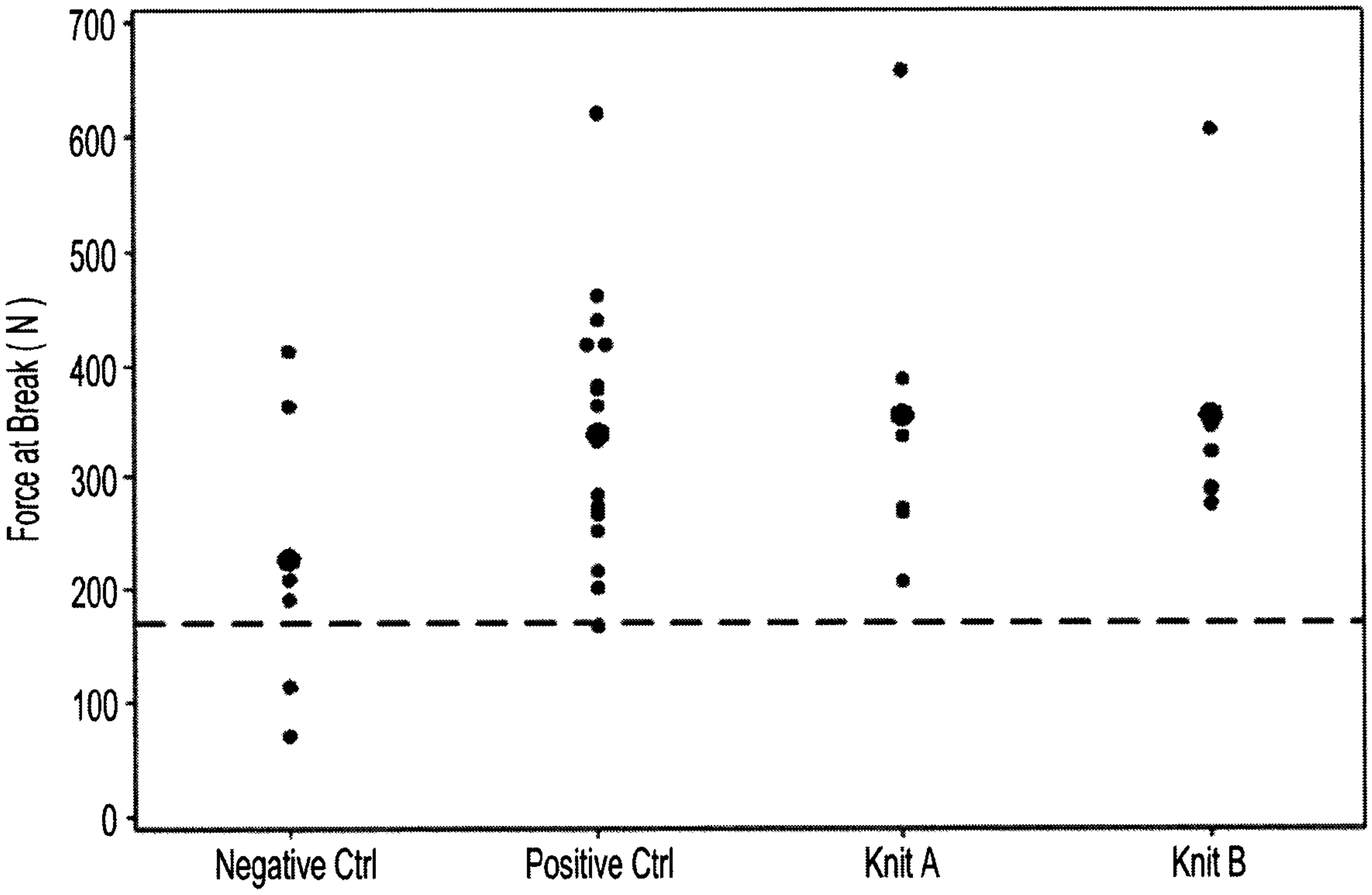
Force at Break (N)
700
600
500
400
300
200
100
0
Negative Ctrl
Positive Ctrl
Knit A
Knit B

Fig. 6