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Abstract

An external fixator element, e.g. a rod, a pin or a clamping means comprises at least one contacting surface (4). At least one of the contacting surface (4) of the element responsible to establish connection between said element and a different external fixator element is provided with a rough ablated structure (4, 5, 6). The clamping can be improved if one of the elements comprise fibres (2) having parts (5) protruding over the surface (4).

(Fig. 3)

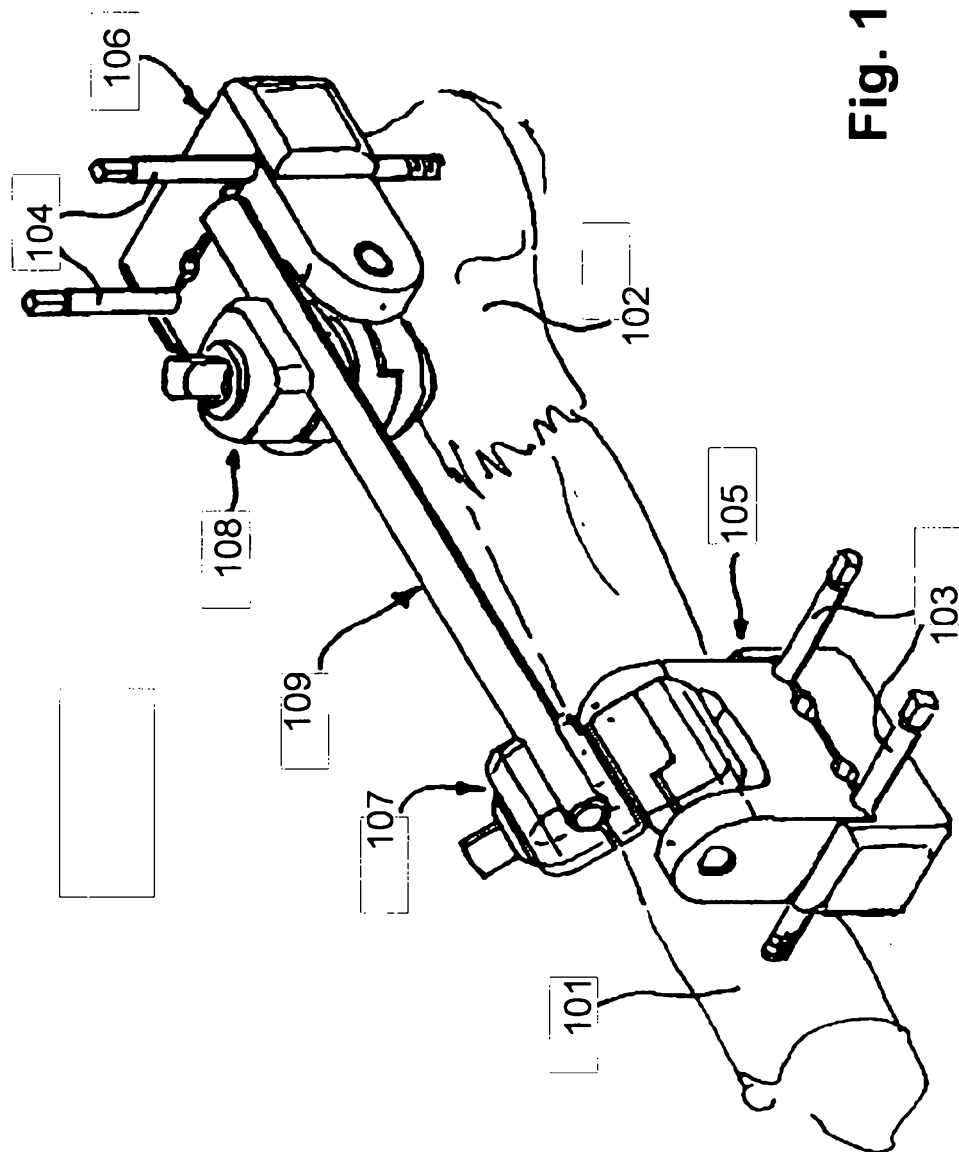


Fig. 1

External fixator elementField of the invention

The invention relates to mechanical elements that are used by external fixators and methods to manufacture such mechanical elements.

Prior Art

External fixators are well known by prior art, for example from EP 0 806 185. Such external fixators are used for stabilizing two parts of a fractured bone and holding the parts of the bone in the correct position during the healing process. Typically external fixators comprise several pins for bony attachment, rods for holding the position of the pins and clamping means for connecting the pins with the rods. These external fixator elements are usually made of steel, titanium or aluminium.

From US 6,702,814 it is known to use nuts or washers around the clamping screw to achieve a separate locking of rods or pins within a clamp.

Weight considerations, especially for long term patients, wearing an external fixator for extended periods of time, request a further change of material towards plastic based materials as well as the request to have X-ray transparency of the device. However it is drawback of external fixators elements of such prior art, especially when rods are made of such light weight materials, that rods may change the position relative to the clamp and therefore to other rods and pins over time due to frictional problems.

Throughout the specification reference to any prior art is not, and should not be taken as an acknowledgement or any form of

suggestion that the referenced prior art forms part of the common general knowledge in Australia.

Summary of the invention

5 The present invention provides in one preferred embodiment an element, a method and a external fixator system, contributing to the enhancement of the connection between clamps and rods and pins of an external fixator.

10 According to an embodiment of the invention there is provided a external fixator element, e.g. a rod, a pin or a clamping means comprises at least one contacting surface. At least one of the contacting surface of the element responsible to establish connection between said element and a different external fixator
15 element is provided with a rough ablated structure.

The term ablated surface comprises sand-blasting, brushing or similar procedures and especially etching.

20 The invention is based on the insight that the combination plastic material - plastic material has a low friction coefficient, wherein it is possible, according to the invention to change the low friction coefficient of plastic material when fibers parts are protruding over the surface of the plastic material. There-
25 fore an element according to a preferred embodiment comprises fibres having parts protruding over the surface, thus enhancing the roughness of the surface and improving the grip of a jaw of a clamp onto a rod.

30 Throughout the specification the term "comprising" shall be understood to have a broad meaning similar to the term "including" and will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the

exclusion of any other integer or step or group of integers or steps. This definition also applies to variations on the term "comprising" such as "comprise" and "comprises".

5 Brief description of the drawings

The drawings will be explained in greater detail by means of a description of an exemplary embodiment, with reference to the following figures:

- 10 Fig. 1 shows an example of an external fixator with different external fixator elements;
- Fig. 2 shows schematically a cross section through an external fixator element like a rod;
- Fig. 3 shows schematically a cross section through an external fixator element according to the present invention:
- 15 Fig. 4 shows a microscopic zoomed image of a surface of an element like and according to Fig. 2;
- Fig. 5 shows a microscopic zoomed image of a surface of an element like and according to Fig. 4; and
- 20 Fig. 6 shows diagrammatically the measured difference between a device according to prior art and a device according to the present invention.

Detailed description of the preferred embodiments

Figure 1 shows an example of an external fixator as an example.

25 Such an external fixator typically comprises several pins 103, 104, a rod 109 and clamping means 105, 106, 107, 108, these elements designated as external fixator elements. An external fixator is used to stabilize and to correct the direction of a fractured bone during the healing process. Typically several pins

30 103, here two, are introduced into the first part of the bone 101 and several pins 104, here two, are introduced into the second part of the bone 102. Clamping means 105, 106, 107, 108 are used to establish a mechanical connection between the pins 103,

104 and the rod 109. With the aid of the rod 109 and the clamping means 105, 106, 107, 108, the direction of the first part of the bone 101 relative to the second part of the bone 102 is adjusted.

5 Surfaces of the pins 103, 104, of rod 109 and of the clamping means 105, 106, 107, 108, which face each other upon installation of the external fixators are designated as contacting surfaces. As an example rod 109 is introduced in an opening of the
10 clamping means 107. Thereby the surface that is covered on the rod 109 by the clamping means 107 is designated as contacting surface. But also the surface that is covered by the rod 109 on the clamping means 107, in this case the surface of the opening, is also designated as contacting surface. In the external fixator as shown in figure 1, such contacting surfaces of rods have
15 typically a cylindrical shape. Clamps may have a complementary cylindrical shape or, in a cross-section view, creating a hollow triangle, providing longitudinal lines of contact between the clamp jaw and the rod or pin.

20 For the sake of simplicity pins 103, 104, rod 109 and clamping means 106, 107, 108, 109 are designated as mechanical elements further on. However, it is understood to the person skilled in the art that the term mechanical element is not limited to the
25 ones just named.

Figure 2 shows schematically a part of a cross section of a mechanical element. Reference numeral 1 designates a line being part of an untreated contacting surface of the mechanical element.
30

In this embodiment the mechanical element shown is made out of fibre-reinforced plastic. Fibres 2 are surrounded by a carrier

materiel or plastic 3.

Such a mechanical element can be manufactured by a plurality of different molding techniques e.g. and including thermoplastic and thermoset injection molding, blow molding, rotational molding, thermoforming, structural foam molding, compression molding, resin transfer molding (RTM) and others.

Such a mechanical element can be manufactured by a die-casting method. The fibres 2 are arranged randomly. It may be seen that the fibers 2 do not extend over the surface 1. This is due to the manufacturing process of such a fibre-reinforced plastic. The fibres 2 placed in the mould before casting tend to stay in a distance from the surface 1, i.e. no free fibre ends are touching or are directly aligned within the uppermost surface layer.

The tested embodiments shown in Figure 4 were produced with thermoplastic moulding wherein the fibres were already mixed with the plastic material and brought together in the form. The portion of fibres as part of the mixture can be chosen between 20 and 70 percent by volume, preferably between 30 and 60 percent by volume, or between 40 to 50 percent by volume.

Figure 3 shows schematically a part of a cross section of a mechanical element according to an embodiment of the invention. Reference numeral 4 designates a roughened or treated contacting surface according to a method of the present invention of the mechanical elements for example of the rod 109.

In this first embodiment the material of the mechanical element is preferably fibre-reinforced plastic. Thereby the plastic is reinforced by glassfibres, carbonfibres, or aramidfibres. It is

even possible that cottonfibres are being used for that purpose. Preferably the fibres have a length between 0.1 millimeter and 2 millimeter. Even more preferably the fibres have a length between 0.25 millimeter and 1 millimeter. Preferably the fibres have a diameter between 25 micrometer and 1500 micrometer. Even more preferably the fibred have a diameter between 50 micrometer and 200 micrometer. The plastic is preferably a plastic chosen from the group of (in the case of injection moulding) polyamide, polypropylene, PEEK, polyacetal and (in the case of RTM, lamination or pultrusion, carbon epoxy pultrusion) polyester epoxide.

In this first embodiment a treated surface 4 is the result of a method according to the present invention. According to this method the untreated surface 1 will be exposed to a gas stream comprising abrasive elements. This is also designated as sand-blasting. The abrasive elements allow a steady abrasion or removal of the surface 1. Meaning that parts of the surface 1 will be removed and the treated surface 4 results. Pressurized air may be used as a gas stream. The abrasive elements are preferably chosen from the group of sand, glass beads, metal pellets, dry ice, powdered slag or powdered abrasives. However other abrasive elements that are known by the person skilled in the art may also be used. The size of the abrasive element may vary since they influence the degree of abrasion of the surface of the mechanical element. Possible sizes of abrasive elements comprise 200 micrometer to 1000 micrometer.

The degree of abrasion of the surface 1 depends on the distance between the surface 1 and the fibres 2. Thus the degree of abrasion of the first surface is reached, when some of the fibres 2 protrude from the treated surface 4. Thereby a fixed part 6 of the fibre 2 is still firmly connected to the plastic, a protruding part 5 of the fibre 2 protrudes from the surface 4.

Due to the sandblasting process, the roughness of the treated surface 4 is much higher than the roughness of the untreated surface 1, thus resulting in an enhanced friction between the contacting surfaces of the mechanical elements. Due to the protrusion of the fibres 2 the friction between the contacting surfaces of the mechanical elements is increased furthermore. Measurements have shown that friction increased over 50% if the surface 4 is rough and the fibres protrude from the surface 4 accordingly in comparison to untreated surfaces. In case the protruding parts 5 of the fibres 2 fray, the friction is enhanced additionally.

If the degree of abrasion is higher than necessary it is possible that some fibres will become detached from the plastic 3. Such fibres will be removed by the pressurized gas stream of the sand blasting process. Therefore contamination due to loose fibres is not an issue.

Depending on the material of the plastic part it is also possible that some of the abrasive elements remain as a (e.g. sand) corn 7 in the treated surface 4 with the result that the friction between the contacting surface is enhanced even more. The dimension of such embedded corns 7 depend on the abrasive materials used and can be between 250 micrometer and 500 micrometer.

Figure 4 shows the surface 1 of a mechanical element manufactured as explained in connection with figure 2 in a microscopic zoomed view. The fibre content of the specimen is rather high. The dimension of the photograph can be seen from the bar 11 showing a length of 10 micrometer. It is clearly visible that the surface is not planar but it shows a myriad of elevations. However the height of such elevations is rather small. The

height is typically in the range of several ten micrometer or can even be lower than one micrometer. There can be seen covered fibres 12. These fibres 12 are covered with a layer of the plastic material of the mixture. This layer of plastic material together with a corresponding plastic surface of a clamp shows said low friction coefficient.

Figure 5 shows a surface of the specimen figure 4 in a microscopic zoomed view after sand-blasting treatment. Of course, the photograph does not represent the identical part of the specimen but a portion which is perhaps a millimetre apart. In comparison to figure 4 it may be seen that the surface has changed dramatically. The protruding parts 5 of the fibres 6 from the schematic representations are now visible as uncovered fibres 15.

There are at least two difference. Parts of fibres oriented in the direction or plane of the surface are not longer covered by plastic material. Therefore this portion of the fibre surface having a different friction behaviour than the plastic material together with a corresponding plastic surface of a clamp shows a far higher friction coefficient. Secondly the elevations are more pronounced. Additionally there are sharp fibre ends 16 protruding out of the plane of the surface of the element.

Figure 6 shows a graph of a test with a rod that has a surface of non-treated plastic and with a rod that has a treated surface according to present invention. The figures shows the behaviour, if a force is applied to the connected parts, e.g. the rod is clamped using a clamp having an untreated plastic material surface. The failure 14 arrives when connected parts start to slide; with sandblasted surface much later with higher force than without sandblasting. The diagrams show the displacement of the rod against the applied force to clamp the rod. The untreated rod shows a slightly faster sliding 11 until approxi-

mately 400 Newton, when the failure 14 takes place. The treated rod can withstand a load 13 of over 800 N until the failure happens.

5 Reference is now made to figure 1. It may be seen that the position of the contacting surfaces on the rod 109 depend on the distance between the pins 103, 104. Here it is possible to designate the whole surface of the rod 109 as contacting surface. Therefore it is advantageous that whole surface of the rod 109
10 will be roughened, i.e. treated as described above. However it may also be possible that only parts of the surface of the rod 109 are treated. If that is the case said parts are preferably arranged in the end parts of the rod 109.

15 The contacting surfaces of the clamping means 107, 108 are also treated with a method as described above. Thereby the clamping means 107, 108 comprises typically two contacting surfaces. A first contacting surface is in contact with the rod 109 and a second contacting surface is in contact with the pins 103, 104.
20 Here the same applies as it does for the rod 109. Thereby it is possible that the whole contact surface or just parts of it will be treated with a method according to the present invention. It is also possible to treat both surfaces or just the first contacting surface or just the second contacting surface.

25 The method as described above may also be applied to the pins 103, 104. But due to the fact the one end of pins is introduced into the human body, said method is preferably to be applied to other free end of the pins 103, 104 in order to prevent possible
30 infections and pins are often made of steel.

It is particularly advantageous when all the contacting surfaces of all mechanical elements will be treated by the method accord-

ing to the present invention. This takes the best advantage of the method.

But it is also possible that only certain surfaces will be treated. As an example it is possible that only the surface of the rod 109 will be treated but not the contacting surface of the clamping means 107, 108. The friction here will be lowered.

In a further embodiment it is also possible that the surface 1 will be brushed, e.g. this may be done by user a fast rotating steel brush, engaging the surface of a slowly rotating rod. Such a brush can also be introduced into the cavity of a clamp brushing one or both inner clamp surfaces as it would be in the place of a rod. However, it is also possible to use non rotating brushes with longitudinal movements.

In a further embodiment it is also possible that the surface 1 will be etched away by means of an acid. The acid is applied to the surface 1 of a fibre-reinforced plastic element until the degree of removal of the surface reached the desired state an treated surface 4 results. This is the case when the fibres protrude from the surface as described above. The etching can be conducted using a strong oxidizing solution as hydrogen peroxide.

Other methods can be performed to achieve the rough ablated structure, enabling an improved grip of the external fixator element, especially when used in a set, comprising one or more clamps having treated ablated jaws clamping surfaces of rods or pins having a similar treated ablated surface.

In further not shown embodiment it is also possible that mechanical elements are made without any fibres. Here the surface

that is rougher as before will be responsible for the enhanced friction. In a preferred embodiment such mechanical elements are made out of plastics or steel or titanium. It has to be seen that the main advantage of the invention can be realized when

5 the bad friction coefficient plastic-plastic material is to be enhanced. When there are no fibres in both clamping and clamped parts, then the plastic material will deform and loose the roughness over a time of some days or weeks. Therefore a non-fiber clamp-and-rod combination can only be used over a limited

10 time frame.

List of reference numerals

	1	untreated surface
	2	fibre
5	3	plastic
	4	roughened or treated surface
	5	protruding part of fibre
	6	fixed part of fibre
	7	corn
10	10	dimension
	11	graph for the untreated element
	12	covered fibre
	13	graph for the treated element
	14	failure point
15	15	uncovered fibre
	16	fibre ends
	101	first part of a bone
	102	second part of the bone
	103	pin
20	104	pin
	105	clamping means
	106	clamping means
	107	clamping means
	108	clamping means
25	109	rod

Claims

1. External fixator element, e.g. a rod, a pin or a clamping means, wherein at least part of a contacting surface of the element responsible to establish connection between said element and a different external fixator element is provided with a rough ablated structure, wherein the element is made out of a fibre-reinforced plastic that comprises a carrier material and fibres and in that free ends of the fibres protrude from the contacting surface.
2. External fixator element according to claim 1, characterized in that the carrier material is chosen from the group of polyamide, polypropylene, PEEK, polyacetal and polyester epoxide.
3. External fixator element according to claim 1 or claim 2, characterized in that the fibres are chosen from the group of glassfibres, carbonfibres or aramidfibres.
4. External fixator element according to one of claims 1 to 3, characterized in that the ablated structure is formed by sand-blasting, brushing or etching.
5. Method to treat a grip relevant surface of an external fixator element according to any of the claims 1 to 4, characterized in that said surface is exposed to a gas stream comprising abrasive elements until free ends of the fibres protrude from the contacting surface.
6. Method according to claim 5, characterized in that the abrasive elements are chosen from the group of glass beads, metal pellets, dry ice, powdered abrasives, powdered slag or sand.

7. Method to treat a grip relevant surface of an external fixator element according to any of the claims 1 to 4, characterized in that said surface is etched until free ends of the fibres protrude from the contacting surface.

8. External fixator set comprising at least two elements according to one of claims 1 to 4, comprising two rods and/or pins and at least one clamping means, wherein the clamping means is responsible to establish connection between the two rods and/or pin, wherein at least one of the contacting surfaces of the rod and/or of the pin and/or of the clamping means is provided with a rough ablated structure, characterized in that said at least one of the contacting surfaces is made out of a fibre-reinforced plastic that comprises a carrier material and fibres and in that free ends of the fibres protrude from the contacting surface.

9. External fixator element, , e.g. a rod, a pin or a clamping means substantially as hereinbefore described with reference to the accompanying drawings.

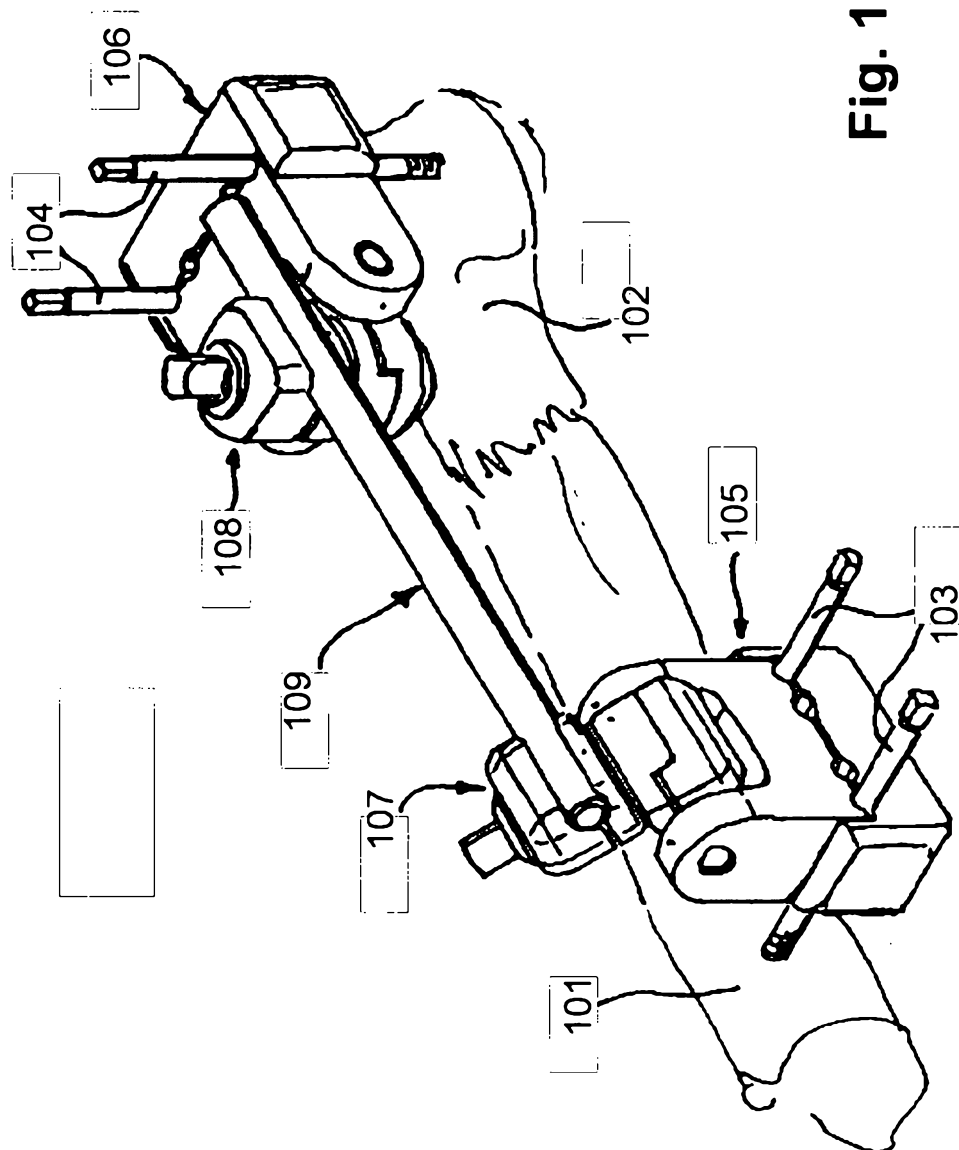


Fig. 1

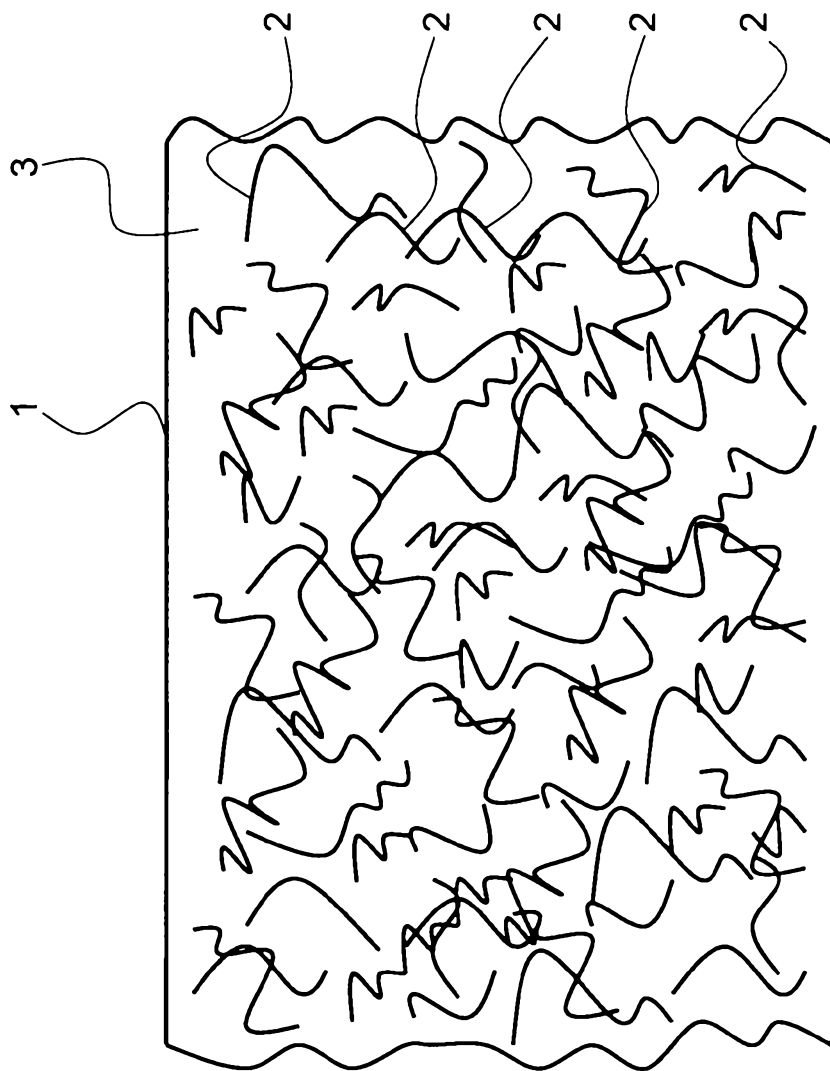


Fig. 2

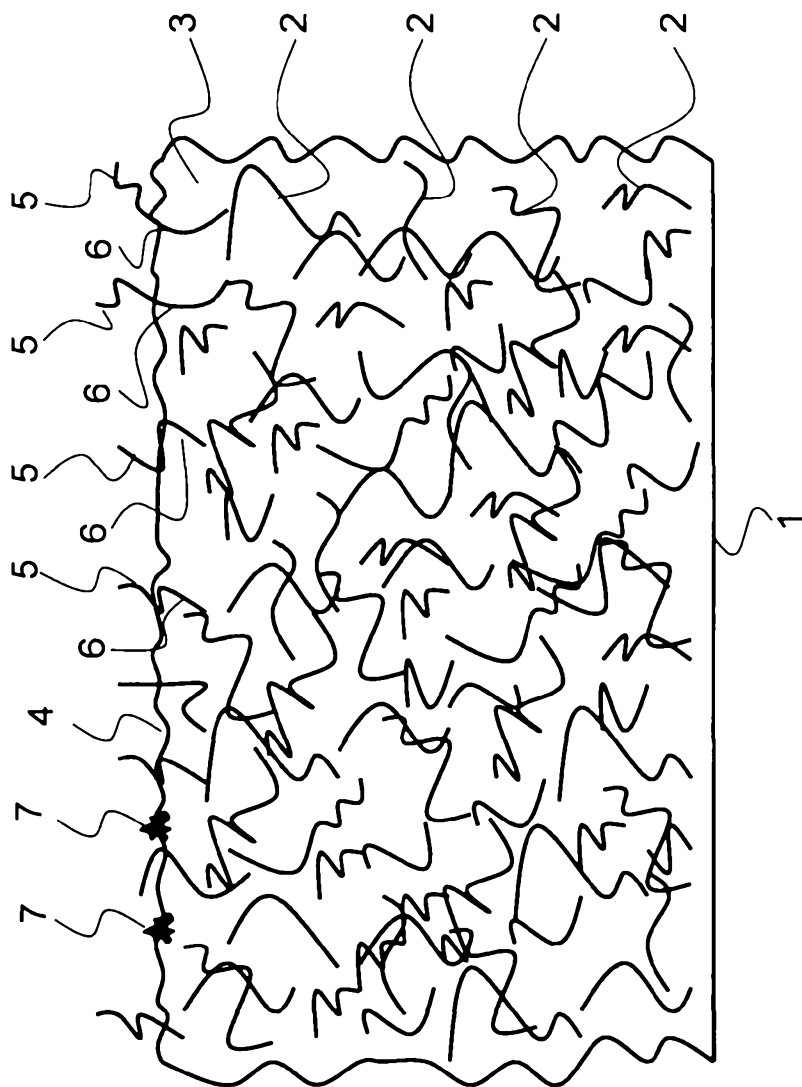


Fig. 3

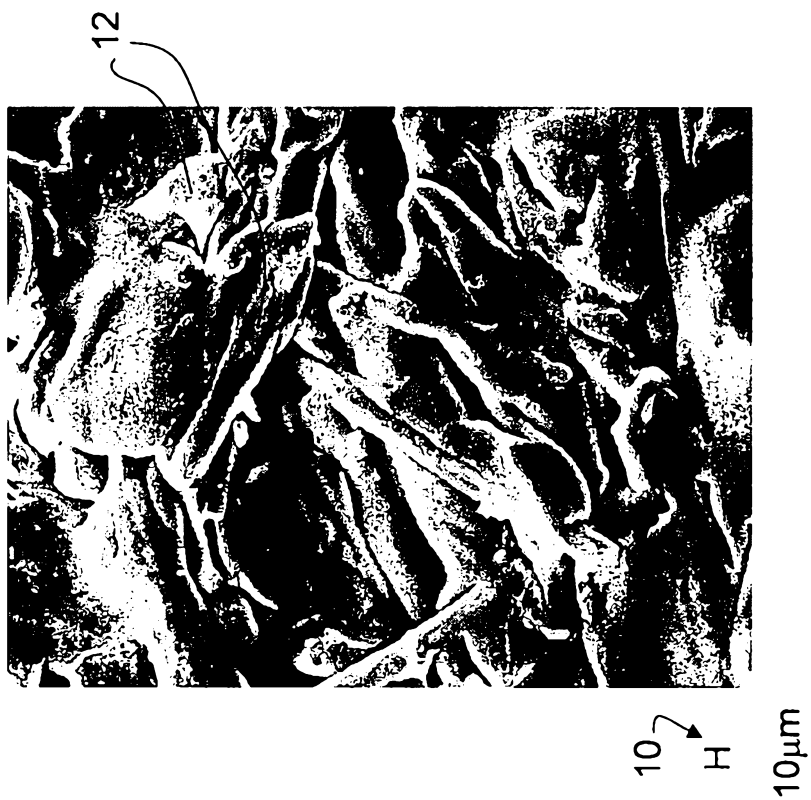


Fig. 4

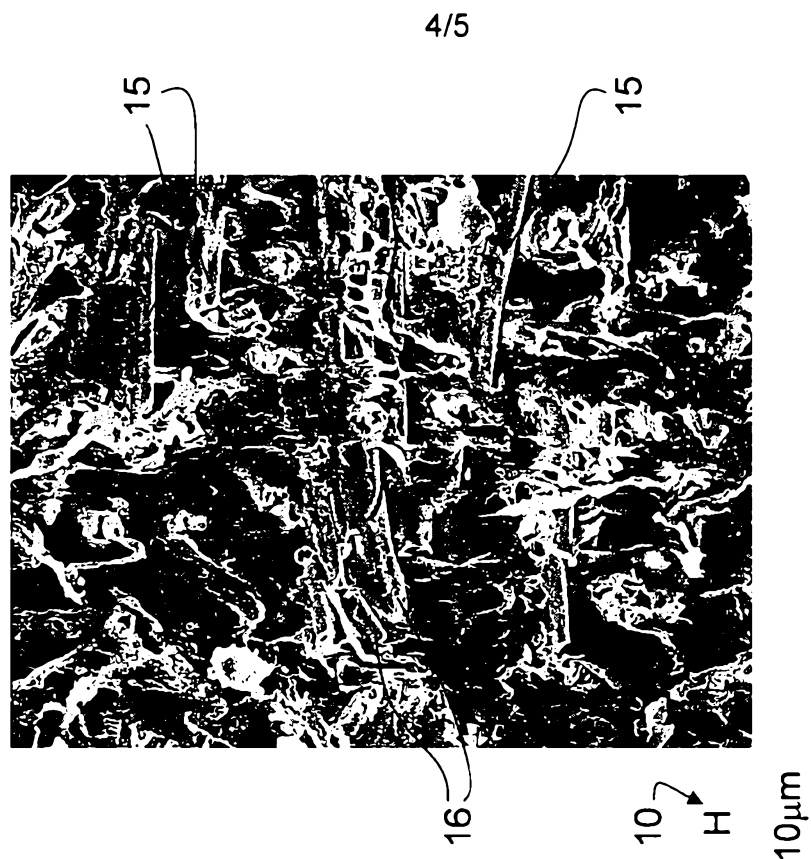


Fig. 5

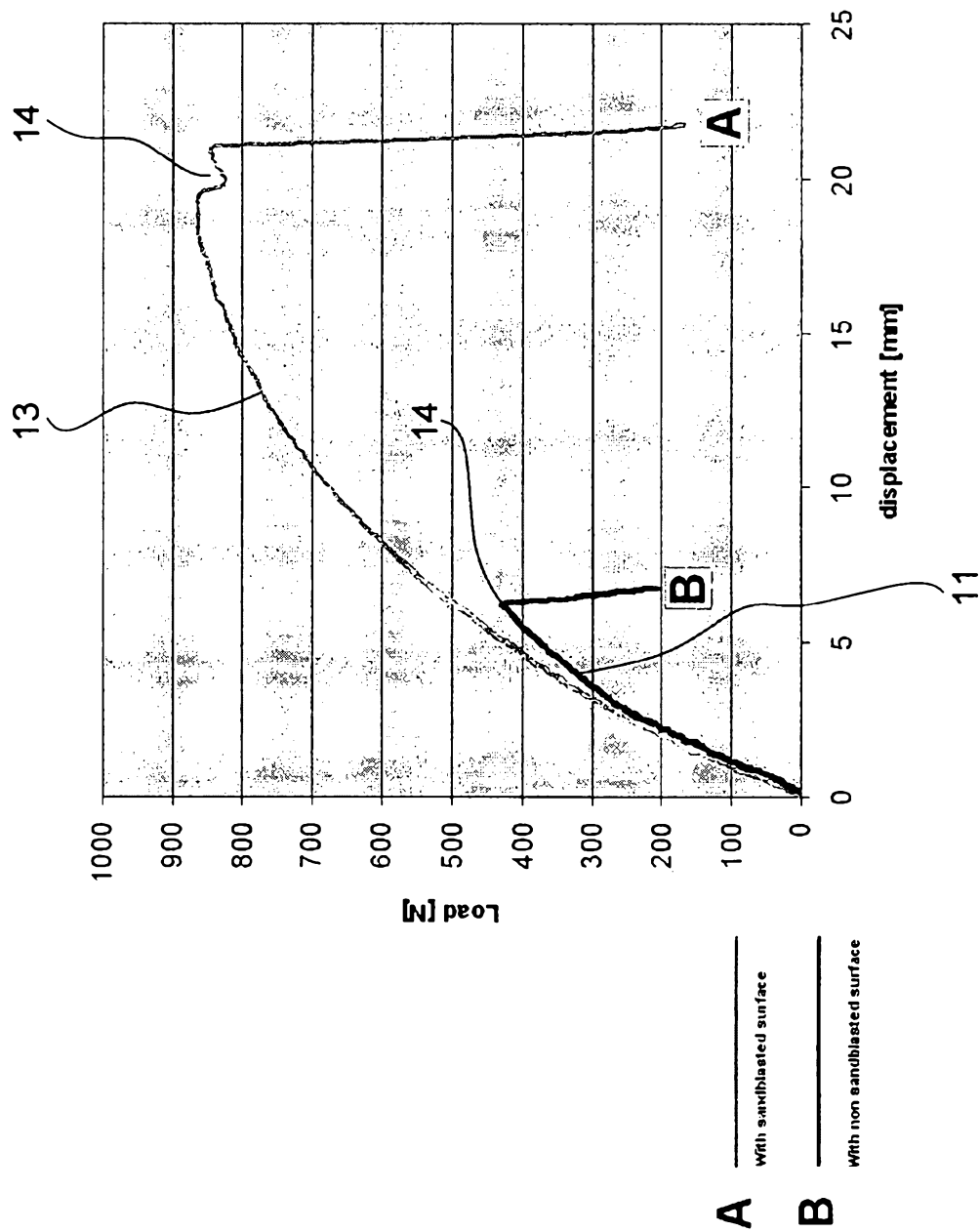


Fig. 6