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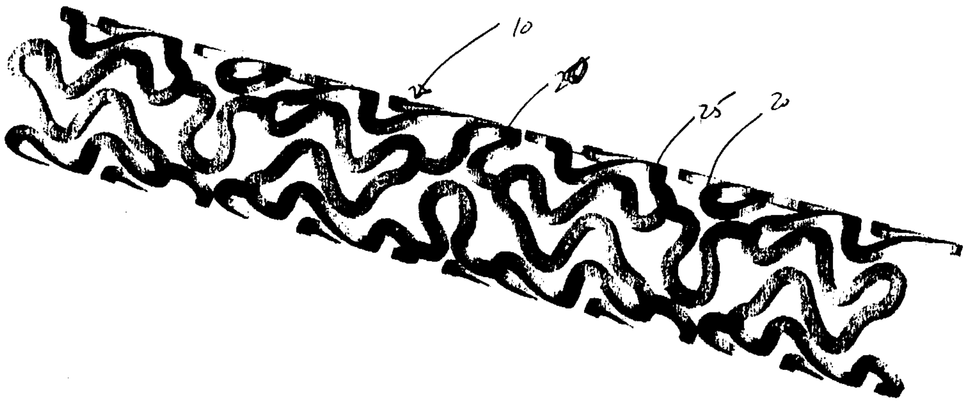
(54) **EXTENSEUR FLEXIBLE EN DIRECTION AXIALE**
(54) **AXIALLY FLEXIBLE STENT**




(57) La présente invention fait état d'un extenseur flexible dans une direction axiale. Dans une version privilégiée, l'extenseur comprend un axe longitudinal et une série de bandes longitudinales formant chacune une vague généralement continue le long d'une ligne parallèle à l'axe longitudinal. Une série de liens maintient les bandes en une structure tubulaire. Dans une autre version, chaque bande longitudinale est reliée à une bande voisine en divers endroits périodiques au moyen d'un lien périphérique court.

(57) A stent with axial flexibility, in a preferred embodiment, has a longitudinal axis and comprises a plurality of longitudinally disposed bands, wherein each band defines a generally continuous wave along a line segment parallel to the longitudinal axis. A plurality of links maintains the bands in a tubular structure. In a further embodiment of the invention, each longitudinally disposed band of the stent is connected, at a plurality of periodic locations, by a short circumferential link to an adjac6ent band.

## ABSTRACT

A stent with axial flexibility, in a preferred embodiment, has a longitudinal axis and comprises a plurality of longitudinally disposed bands, wherein each band defines a generally continuous wave along a line segment parallel to the longitudinal axis. A plurality of links maintains the bands in a tubular structure. In a further embodiment of the invention, each longitudinally disposed band of the stent is connected, at a plurality of periodic locations, by a short circumferential link to an adjac6ent band.

# AXIALLY FLEXIBLE STENT

## Cross Reference

This is a continuation-in-part of U.S. Application Serial No. 60/010,686, filed January 26, 1996, now abandoned; U.S. Application Serial No. 60/017,479, filed April 26, 1996, now abandoned; U.S. Application Serial No. 60/017,415 filed May 8, 1996; U.S. Application Serial No. 60/024,110, filed August 16, 1996 and U.S. Application Serial No. 08/770,236, filed December 20, 1996, incorporated herein by reference.

## Technical Field

The present invention relates to a stent having axial flexibility and resilience in its expanded form.

## Background Art

A stent is commonly used as a tubular structure left inside the lumen of a duct to relieve an obstruction. Commonly, stents are inserted into the lumen in a non expanded form and are then expanded autonomously (or with the aid of a second device *in situ*. A typical method of expansion occurs through the use of a catheter mounted angioplasty balloon which is inflated within the stenosed vessel or body passageway in order to shear and disrupt the obstructions associated with the wall components of the vessel and to obtain an enlarged lumen.

In the absence of a stent, restenosis may occur as a result of elastic recoil of the stenotic lesion. Although a number of stent designs have been reported, these designs have suffered from a number of limitations. These include restrictions on the dimension of the stent such as describes a stent which has rigid ends (8mm) and a flexible median part of 7-21mm. This device is formed of multiple parts and is not continuously flexible along the longitudinal axis. Other stent designs with rigid segments and flexible segments have also been described.

Other stents are described as longitudinally flexible but consist of a plurality of cylindrical elements connected by flexible members. This design has at least one important disadvantage, for example, according to this design, protruding edges occur when the stent is flexed around a curve raising the possibility of inadvertent retention of the stent on plaque deposited on arterial walls. This may cause the stent to embolize or more out of position and further cause damage to the interior lining of healthy vessels. (See Figure 1(a) below).

Thus, stents known in the art, which may be expanded by balloon angioplasty, generally compromise axial flexibility to permit expansion and provide overall structural integrity.

## Summary of the Invention

The present invention overcomes some perceived shortcomings of prior art stents by providing a stent with axial flexibility. In a preferred embodiment, the stent has a first end and a second end with an intermediate section between the two ends. The stent further has a longitudinal axis and comprises a plurality of longitudinally disposed bands, wherein each band defines a generally continuous wave along a line segment parallel to the longitudinal axis. A plurality of links maintains the bands in a tubular structure. In a further embodiment of the invention, each longitudinally disposed band of the stent is connected, at a plurality of periodic locations, by a short circumferential link to an adjacent band. The wave associated with each of the bands has approximately the same fundamental spatial frequency in the intermediate section, and the bands are so disposed that the waves associated with them are spatially aligned so as to be generally in phase with one another. The spatially aligned bands are connected, at a plurality of periodic locations, by a short circumferential link to an adjacent band.

In particular, at each one of a first group of common axial positions, there is a circumferential link between each of a first set of adjacent pairs of bands.

At each one of a second group of common axial positions, there is a circumferential link between each of a second set of adjacent rows of bands, wherein, along the longitudinal axis, a common axial position occurs alternately in the first group and in the second group, and the first and second sets are selected so that a given band is linked to a neighboring band at only one of the first and second groups of common axial positions.

In a preferred embodiment of the invention, the spatial frequency of the wave associated with each of the bands is decreased in a first end region lying proximate to the first end and in a second end region lying proximate to the second end, in comparison to the spatial frequency of the wave in the intermediate section. In a further embodiment of the invention, the spatial frequency of the bands in the first and second end regions is decreased by 20% compared with the spatial frequency of the bands in the intermediate section. The first end region may be located between the first end and a set of circumferential links lying closest to the first end and the second end region lies between the second end and a set of circumferential links lying closest to the second end. The widths of corresponding sections of the bands in these end regions, measured in a circumferential direction, are greater in the first and second end regions than in the intermediate section. Each band includes a terminus at each of the first and second ends and the adjacent pairs of bands are joined at their termini to form a closed loop.

In a further embodiment of the invention, a stent is provided that has first and second ends with an intermediate section therebetween, the stent further having a longitudinal axis and providing axial flexibility. This stent includes a plurality of longitudinally disposed bands, wherein each band defines a generally continuous wave having a spatial frequency along a line segment parallel to the longitudinal axis, the spatial frequency of the wave associated with each of the bands being decreased in a first end region lying proximate to the first end and in a second end region lying proximate to the second end, in comparison to the spatial frequency of the wave in the intermediate section; and a plurality of links for maintaining the bands in a tubular structure. The first and second regions have been further defined as the region that lies between the first and second ends and a set of circumferential links lying closest to the first end and second end.

In a further embodiment the widths of the sectionals of the bands, measured in a circumferential direction, are greater in the first and second end regions than in the intermediate section.

In yet an additional embodiment, the stent is divided into a group of segments, and each of the segments are connected by a flexible connector. In addition, the stent segments are provided with enhanced flexibility at the flexible connectors, due to the geometrical configuration of the flexible connectors.

**Brief Description of the Drawings**

The foregoing aspects of the invention will be more readily understood by reference to the following detailed description, taken with the accompanying drawings, in which:

Figures 1(a) and 1(b) are side views of a stent having circumferentially disposed bands wherein the stent is in axially unbent and bent positions respectively, the latter showing protruding edges.

Figures 1(c) and 1(d) are side views of an axially flexible stent in accordance with the present invention wherein the stent is in unbent and bent positions respectively, the latter displaying an absence of protruding edges.

Figure 2 is a side view of a portion of the stent of Figures 1(c) and 1(d) showing the longitudinal bands, spaces, and inner radial measurements of bends in the bands being measured in inches.

Figures 3(a) and 3(b) show a portion of the stent of Figure 2 with two bands between two circumferential links (a) before expansion in the undeformed state; and (b) after expansion, in the deformed state.

Figure 4 is a view along the length of a piece of cylindrical stent (ends not shown) prior to expansion showing the exterior surface of the cylinder of the stent and the characteristic banding pattern.

Figure 5 is an isometric view of a deflection plot where the stent of Figure 2 is expanded to a larger diameter of 5mm.

Figure 6 shows a two-dimensional layout of the stent of Figure 4 to form a cylinder such that edge "A" meets edge "B", and illustrating the spring-like action provided in circumferential and longitudinal directions.

Figure 7 shows a two dimensional layout of the stent. The ends are modified such that the length ($L_A$) is about 20% shorter than length ($L_B$) and the width of the band A is greater than the width of band B.

Figure 8 shows a perspective view of a stent containing flexible connectors as described in the present invention.

Figure 9 shows a stent in which the flexible connectors are attached to stent segments, in layout form. These flexible connectors are attached in an every-other-segment pattern.

Figure 10 shows a layout view where the stent segments are connected with a flexible connector in every stent segment pattern.

## Detailed Description of Specific Embodiments

Improvements afforded by embodiments of the present invention include (a) increased flexibility in two planes of the non-expanded stent while maintaining radial strength and a high percentage open area after expansion; (b) even pressure on the expanding stent that ensures the consistent and continuous contact of expanded stent against artery wall; (c) avoidance of protruding parts during bending; (d) removal of existing restrictions on maximum of stent; and reduction of any shortening effect during expansion of the stent.

In a preferred embodiment of the invention, an expandable cylindrical stent 10 is provided having a fenestrated structure for placement in a blood vessel, duct or lumen to hold the vessel, duct or lumen open, more particularly for protecting a segment of artery from restenosis after angioplasty. The stent 10 may be expanded circumferentially and maintained in an expanded configuration, that is circumferentially rigid. The stent 10 is axially flexible and when flexed at a band, the stent 10 avoids any externally protruding component parts.

Figure 1 shows what happens to a stent 10, of a similar design to a preferred embodiment herein but utilizing instead a series of circumferentially disposed bands, when caused to bend in a manner that is likely encountered within a lumen of the body. A stent 10 with a effect analogous to a series of railroad cars on a track. As the row of railroad cars proceeds around the bend, the corner of each car proceeding around the bend after the coupling is caused to protrude from the contour of the track. Similarly, the serpentine circumferential bands have protrusions (2) above the surface of the stent 10 as the stent 10 bends.

In contrast, the novel design of the embodiment shown in Figures 1(c) and 1(d) and Figure 7 in which the bands (3) are axially flexible and are arranged along the longitudinal axis, avoids such an effect when the stent 10 is bent, so the bent bands (4) do not protrude from the profile of the curve of the stent 10. Furthermore, any flaring at the ends of the stent 10 that might occur with a stent 10 having a uniform structure is substantially eliminated by introducing a modification at the ends of the stent 10. This modification comprises decreasing the spatial frequency and increasing the width of the corresponding bands in a circumferential direction ($L_A$ and A) compared to that of the intermediate section. ($l_B$ and B).

In an embodiment of the invention,, the spatial frequency $L_A$ may be decreased 0-50% with respect to $L_B$, and the width A may be increased in the range of 0-150% with respect to B. Other modifications at the ends of the stent 10 may include increasing the thickness of the wall of the stent 10 and selective electropolishing. These modifications protect the artery and any plaque from modifications protect the artery and any plaque from abrasion that may be caused by the stent 10 ends during insertion of the stent 10. The modification also may provide increased radio-opacity at the ends of the stent 10. Hence it may be possible to more accurately locate the stent 10 once it is in place in the body.

The embodiment as shown in Figures 2 and 6 has the unique advantage of possessing effective "springs" in both circumferential and longitudinal directions shown as items (5) and (6) respectively. These springs provide the stent 10 with the flexibility necessary both to navigate vessels in the body with reduced friction and to expand at the selected site in a manner that provides the final necessary expanded dimensions without undue force while retaining structural resilience of the expanded structure.

As shown in both Figures 2, 4 and 6, each longitudinal band undulates through approximately two cycles before there is formed a circumferential link to an adjacent band. Prior to expansion, the wave W associated with each of the bands may have approximately the same fundamental spatial frequency, and the bands are so disposed that the wave W associated with them are spatially aligned, so as to be generally in phase with one another as shown in Figure 6.

The aligned bands on the longitudinal axis are connected at a plurality of periodic locations, by a short circumferential link to an adjacent band. Consider a first common axial position such as shown by the line X-X in Figures 4 and 6. Here an adjacent pair of bands is joined by circumferential link ‾. Similarly other pairs of bands are also linked at this common axial position. At a second common axial position, shown in Figure 6 by the line Y-Y, an adjacent pair of bands is joined by circumferential link 8. However, any given pair of bands that is linked at X-X is not linked at Y-Y and vice-versa. The X-X pattern of linkages repeats at the common axial position Z-Z. In general, there are thus two groups of common axial positions. In each of the axial positions of any one group are links between the same pairs of adjacent bands, and the groups alternate along the longitudinal axis of the embodiment. In this way, circumferential spring 6 and the longitudinal spring 6 are provided.

A feature of the expansion event is that the pattern of open space in the stent 10 of the embodiment of Figure 2 before expansion is different from the pattern of the stent 10 after expansion. In particular, in a preferred embodiment, the pattern of open space on the stent 10 before expansion is serpentine, whereas after expansion, the pattern approaches a diamond shape (3a, 3b). In embodiments of the invention, expansion may be achieved using pressure from an expanding balloon or by other mechanical means.

In the course of expansion, as shown in Figure 3, the wave W shaped bands tend to become straighter. When the bands become straighter, they become stiffer and thereby withstand relatively high radial forces. Figure 3 shows how radial expansion of the stent 10 causes the fenestra to open up into a diamond shape with maximum stress being expended on the apices of the diamond along the longitudinal axis. When finite element analyses including strain studies were performed on the stent 10, it was found that maximum strain was experienced on the bands and links and was below the maximum identified as necessary to maintain structural integrity.

The optimization of strain of the stent 10 is achieved by creating as large a turn radius as possible in the wave W associated with each band in the non-expanded stent 10. This is accomplished while preserving a sufficient number of bands and links to preserve the structural integrity of the stent 10 after expansion. In an embodiment of the invention, the strain may be less than 0.57 inches/inch for 316L stainless steel. The expansion pressure may be 1.0-7.0 atmospheres. The number of bands and the spatial frequency of the wave W on the longitudinal axis also affects the number of circumferential links. The circumferential links contribute structural integrity during application of radial force used in expansion of the stent 10 and in the maintenance of the expanded form. While not being limited to a single set of parameters, an example of a stent 10 of the invention having a longitudinal axis and providing axial flexibility of the type shown in Figure 6, may include a stent 10 having an expanded diameter of 4mm and a length of 30mm that for example may have about 8-12 rows, more particularly 10 rows and about 6-10 slots, more particularly 8 slots (a slot is shown in Figure 6 as extending between X and Z), with a wave W amplitude of about 1/4-1/10 of a slot length, more particularly 1/8 of a slot length.

The stent 10 may be fabricated from many methods. For example, the stent 10 may be fabricated from a hollow or formed stainless steel tube that may be cut out using lasers, electric discharge milling (EDM), chemical etching or other means. The stent 10 is inserted into the body and placed at the desired site in an unexpanded form. In a preferred embodiment, expansion of the stent 10 is effected in a blood vessel by means of a balloon catheter, where the final diameter of the stent 10 is a function of the diameter of the balloon catheter used.

In contrast to stents of the prior art, the stent 10 of the invention can be made at any desired length, most preferably at a nominal 30mm length that can be extended or diminished by increments, for example 1.9mm increments.

It will be appreciated that a stent 10 in accordance with the present invention may be embodied in a shape memory material, including, for example, an appropriate alloy of nickel and titanium; or stainless steel. In this embodiment after the stent 10 has been formed, it may be compressed so as to occupy a space sufficiently small as to permit its insertion in a blood vessel or other tissue by insertion means, wherein the insertion means include a suitable catheter, or flexible rod. On emerging from the catheter, the stent 10 may be configured to expand into the desired configuration where the expansion is automatic or triggered by a change in pressure, temperature or electrical stimulation.

An embodiment of the improved stent 10 has utility not only within blood vessels as described above but also in any tubular system of the body such as the bile ducts, the urinary system, the digestive tube, and the tubes of the reproductive system in both men and women.

In yet a further embodiment, there is described a stent 10 as presently disclosed containing a multiplicity of curvilinear segments 20. These curvilinear segments 20 are connected to each other via a generally perpendicular connector 25. The generally perpendicular connector 25 lies substantially in the plane perpendicular to the longitudinal axis of the stent 10. Each of the stent 10 segments as described herein is connected to an adjacent stent 10 segment. This is done using a series of flexible connectors. Importantly, the connectors themselves can be made narrower at their midpoints. This enhances the possibility of flexure at that point. Of course, it is to be realized that alternate designs of the connector to insure flexibility are possible, and contemplated by this invention.

In essence therefore, the stent 10 as described in Figure 8 is a stent 10 of considerable flexibility when compared to more rigid rectilinear stents. Nonetheless, the stent 10 of the present invention does not depart from the basic concepts set forth herein, in that it discloses a continuously curvilinear strut. This curvilinear strut is connected to other curvilinear struts via a series of "second" more flexible connectors, described above.

In any regard, it can be seen that the stent 10 of the present invention incorporates various new and useful members. One of them is the flexible connector in conjunction with a generally curvilinear stent. Another is the use of the generally larger struts at the ends of the stent 10 in order to provide for continued support at the stent 10 ends. A final aspect is the use of flexible connectors amongst stent 10 segments to provide for greater flexibility.

In all regards, however, it is to be seen that the present invention is to be determined from the attached claims and their equivalents.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A stent having first and second ends with an intermediate section therebetween, the stent further having a longitudinal axis and providing axial flexibility, comprising:

a plurality of longitudinally disposed bands, wherein each band defines a generally continuous wave having a spatial frequency along a line segment parallel to the longitudinal axis;

a plurality of links for maintaining the bands in a tubular structure, wherein the links are so disposed that any single circumferential path formed by the links is discontinuous; and

wherein the stent comprises a plurality of stent segments, each of the stent segments containing at least one generally continuous curvilinear strut, said stent segments connected by at least one flexible connector displaced between a pair of adjacent stent segments.

2. A stent according to claim 1, wherein each link is axially displaced from any circumferentially adjacent link.

3. A stent according to claim 1, wherein the wave associated with each of the bands has approximately the same fundamental spatial frequency for the intermediate section.

4. A stent according to claim 3, wherein the bands are so disposed that the waves associated with them are spatially aligned so as to be generally in phase with one another.

5. A stent according to claim 4, wherein each link is axially displaced from any circumferentially adjacent link.

6. A stent according to claim 5, wherein, at each one of a first group of common axial positions, there is a circumferential link between each of a first set of adjacent pairs of bands.

7. A stent according to claim 5, wherein, at each one of a second group of common axial positions, there is a circumferetial link between each of a second set of adjacent rows of bands, wherein, along the longitudinal axis, a common axial position occurs alternately in the first group and in the second group, and the first and second sets are selected so that a given band is linked to a neighboring band at only one of the first and second groups of common axial positions.

8. A stent according to claim 2, wherein the spatial frequency of the wave associated with each of the bands, is decreased in a first end region lying proximate to the first end and in a second end region lying proximate to the second end, in comparison to the spatial frequency of the wave in the intermediate section.

9. A stent according to claim 8, wherein the spatial frequency is decreased by about 20% compared with the spatial frequency of the wave in the intermediate section.

10. A stent according to claim 8, wherein the first end region lies between the first end and a set of circumferential links lying closest to the first end and the second end region lies between the second end and a set of circumferential links lying closest to the second end.

11. A stent according to claim 8, wherein widths of corresponding sections of the bands, measured in a circumferential direction, are greater in the first and second regions than in the intermediate section.

12. A stent according to claim 10, wherein widths of corresponding sections of the bands, measured in a circumferential direction, are greater in the first and second regions than in the intermediate section.

13. A stent according to claim 1, wherein each band includes a terminus at each of the first and second ends and the adjacent pairs of bands are joined at their termini to form a closed loop.

14. A stent according to claim 8, wherein each band includes a terminus at each of the first and second ends

and the adjacent pairs of bands are joined at their termini to form a closed loop.

15. A stent according to claim 9, wherein the first end region lies between the first end and a set of circumferential links lying closest to the first end and the second end region lies between the second end and a set of circumferential links lying closest to the second end.

16. A stent according to claim 15, wherein widths of corresponding sections of the bands, measured in a circumferential direction, are greater in the first and second end.

17. A stent according to claim 7, wherein the spatial frequency of the wave associated with each of the bands, is decreased in a first end region lying proximate to the first end and a second end region lying proximate to the second end, in comparison to the spatial frequency of the wave in the intermediate section.

18. A stent having first and second ends with an intermediate section therebetween, the stent further having a longitudinal axis and providing axial flexibility, comprising:

a plurality of longitudinally disposed bands, wherein each band defines a generally continuous wave having a spatial frequency along a line segment parallel to the longitudinal axis; the spatial frequency of the wave associated with each of the bands being decreased in a first end region lying proximate to the first end and in a second end region lying proximate to the second end, in comparison to the spatial frequency of the wave in the intermediate section; and

a plurality of links for maintaining the bands in a tubular structure.

19. A stent according to claim 18, wherein widths of sections of the bands, measured in a circumferential direction, are greater in the first and second end regions than in the intermediate section.

20. A stent having first and second ends with an intermediate section therebetween, the stent further having a longitudinal axis and providing axial flexibility, comprising:

a plurality of longitudinally disposed bands; and

a plurality of links for maintaining the bands in a tubular structure, wherein each band is connected at a plurality of periodic locations by a circumferential link to an adjacent band, each link being axially displaced from any circumferentially adjacent link.

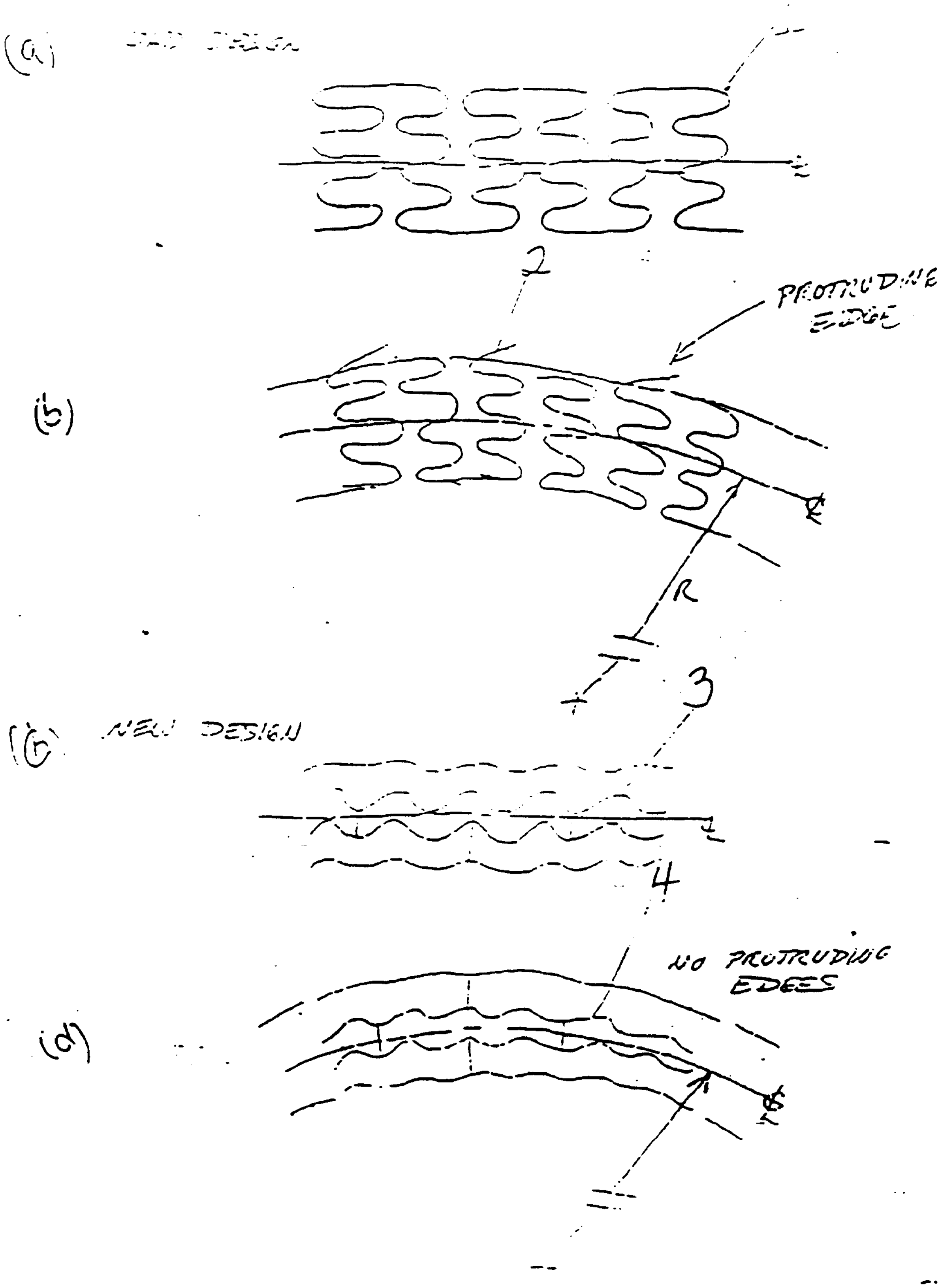

(a)
2
PROTRUDING EDGE
(b)
R
3
(c) NEW DESIGN
4
NO PROTRUDING EDGES
(d)

Fig 2

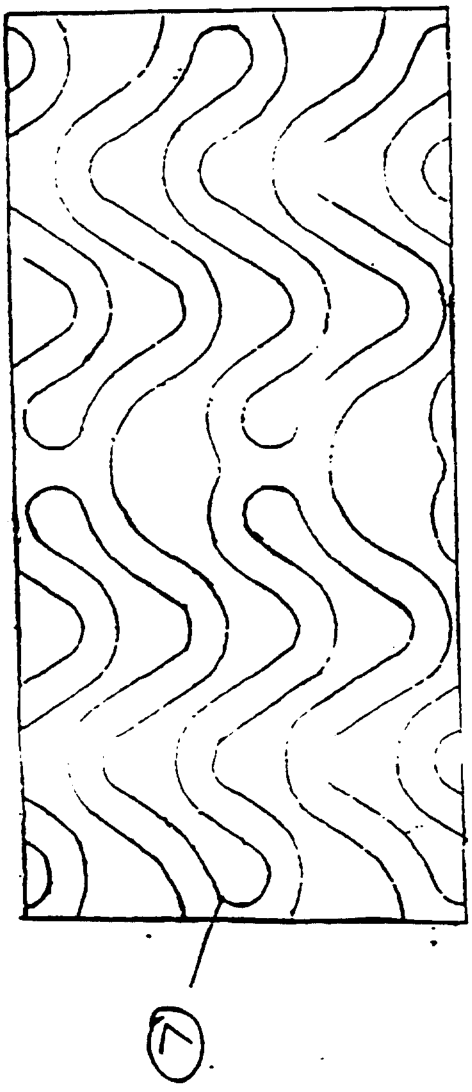
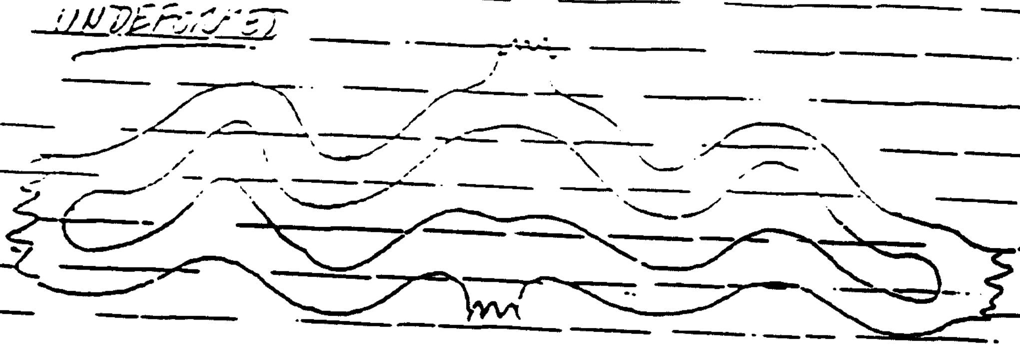



Fig 2

Fig3


(a)
UNDEFORMED

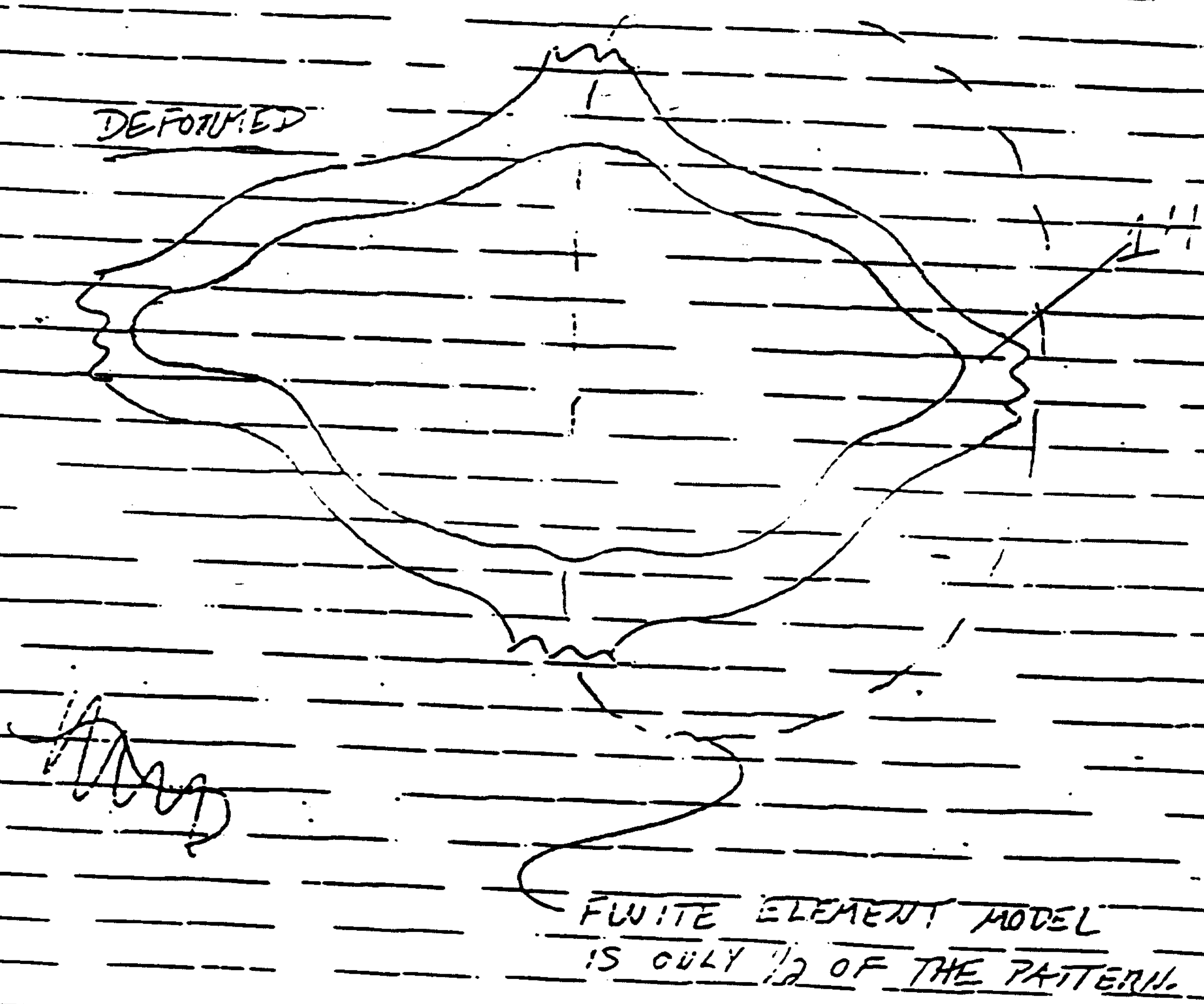

(b)
DEFORMED
FINITE ELEMENT MODEL
IS ONLY 1/2 OF THE PATTERN.

Fig3

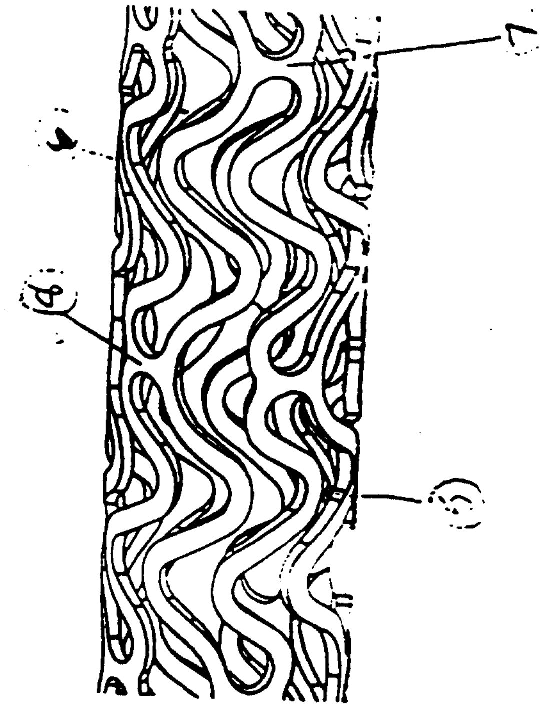


Fig 4

Fig 4

Fig 5

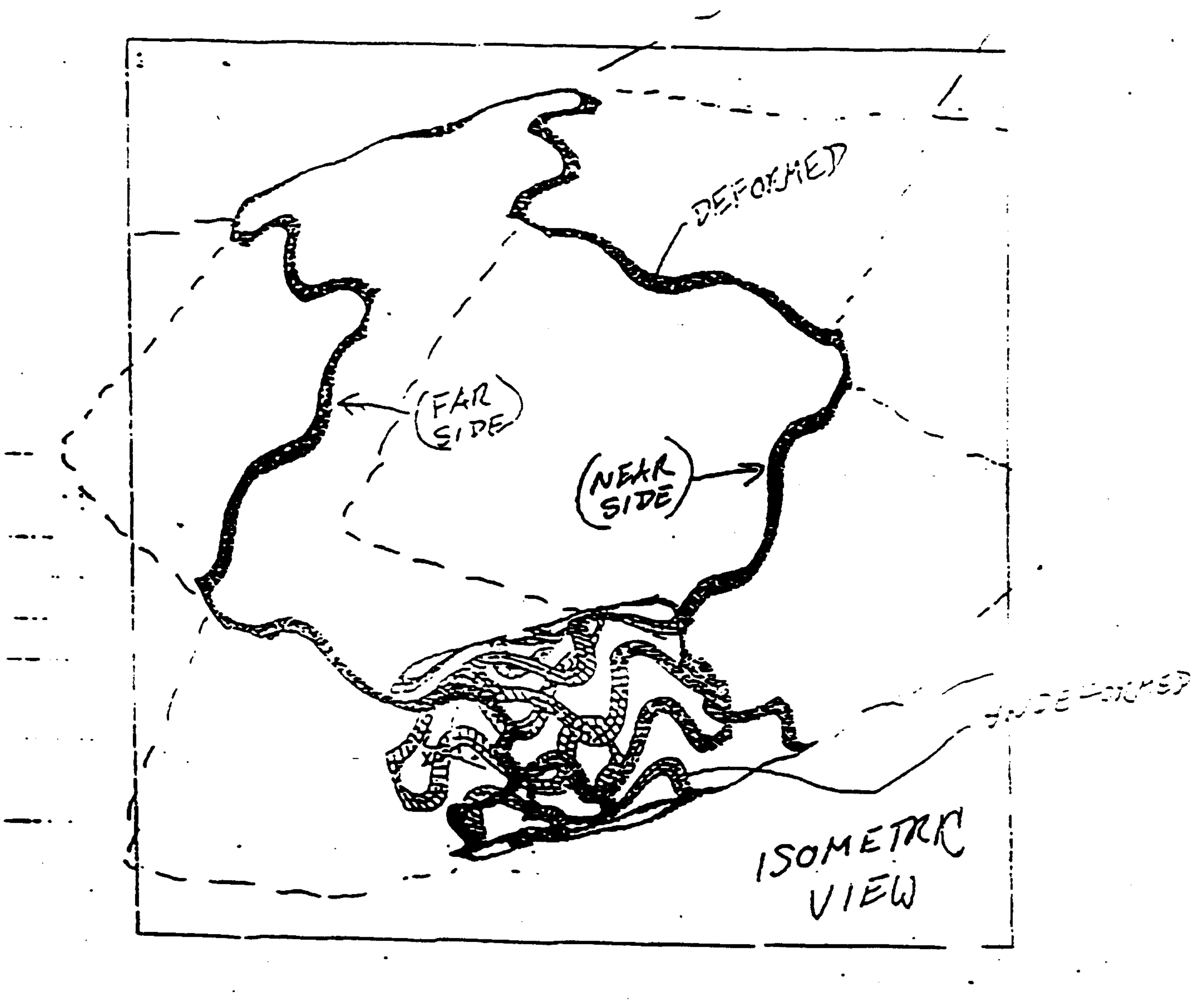



Fig 5

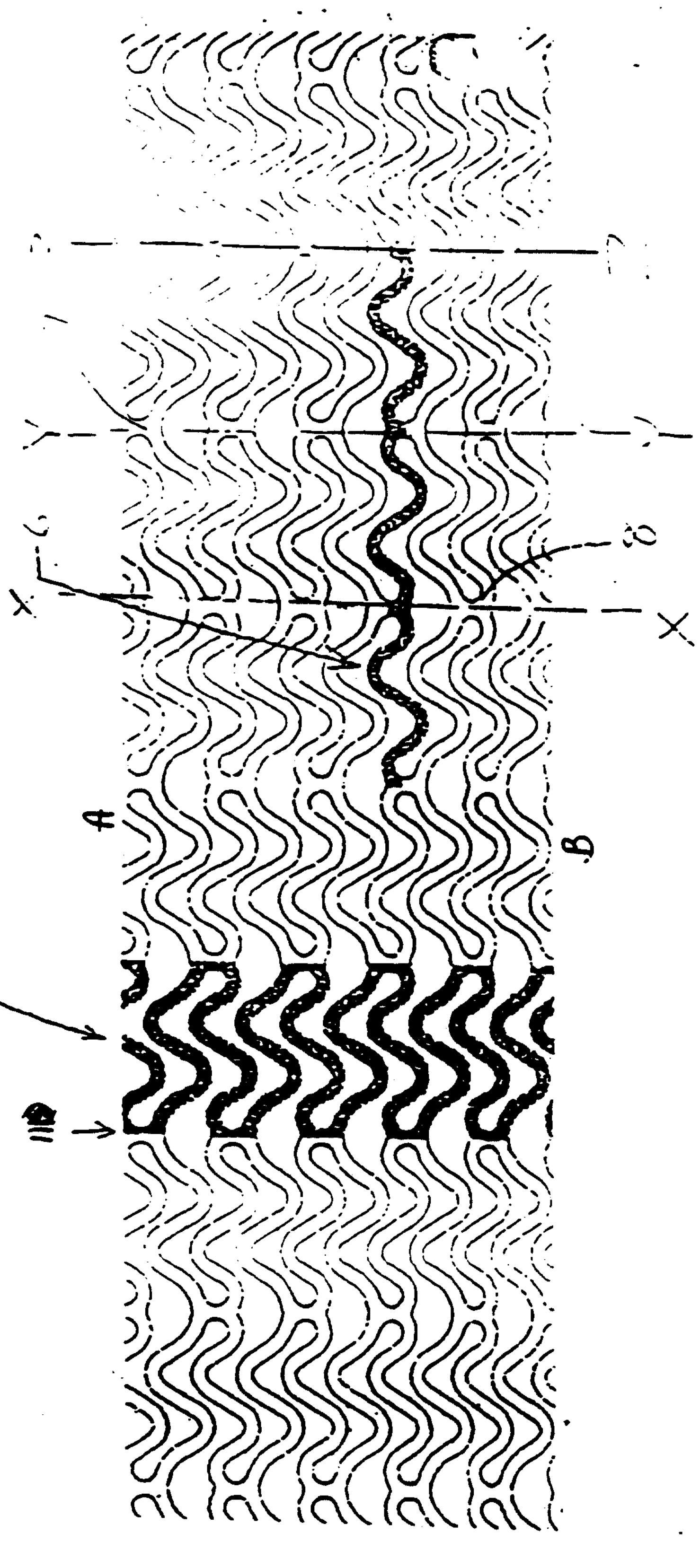
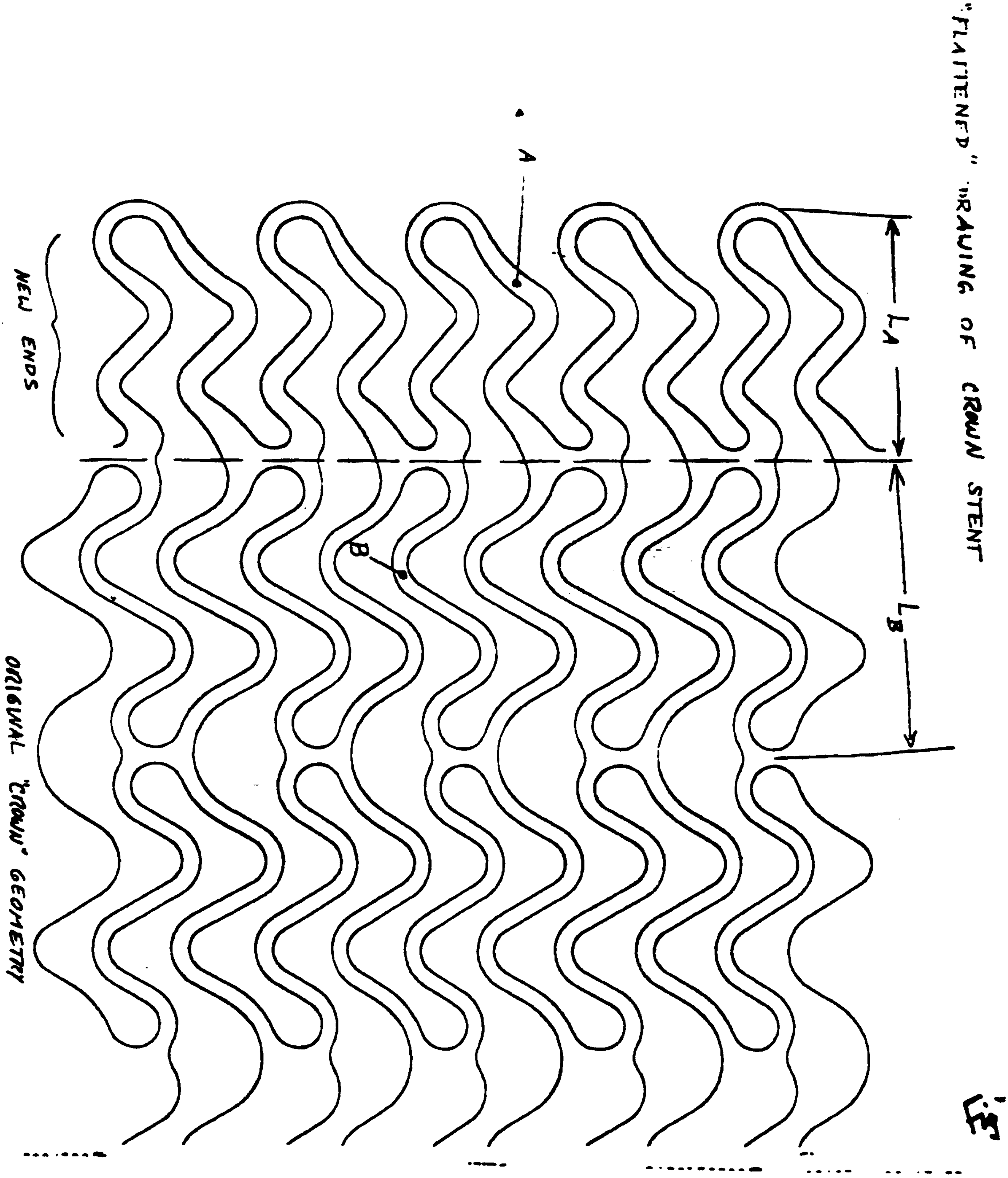



Fig 6


"FLATTENED" DRAWING OF CROWN STENT
A
$L_A$
$L_B$
B
NEW ENDS
ORIGINAL "CROWN" GEOMETRY

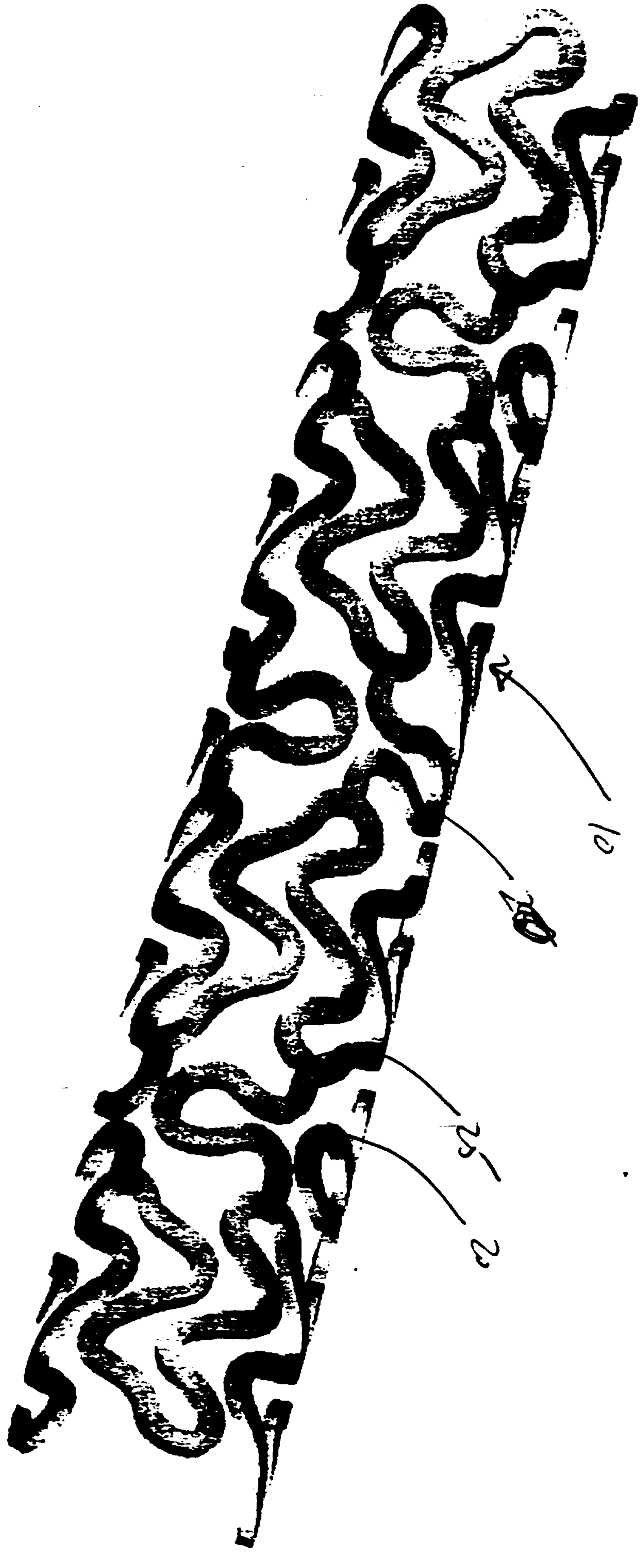


Fig 8

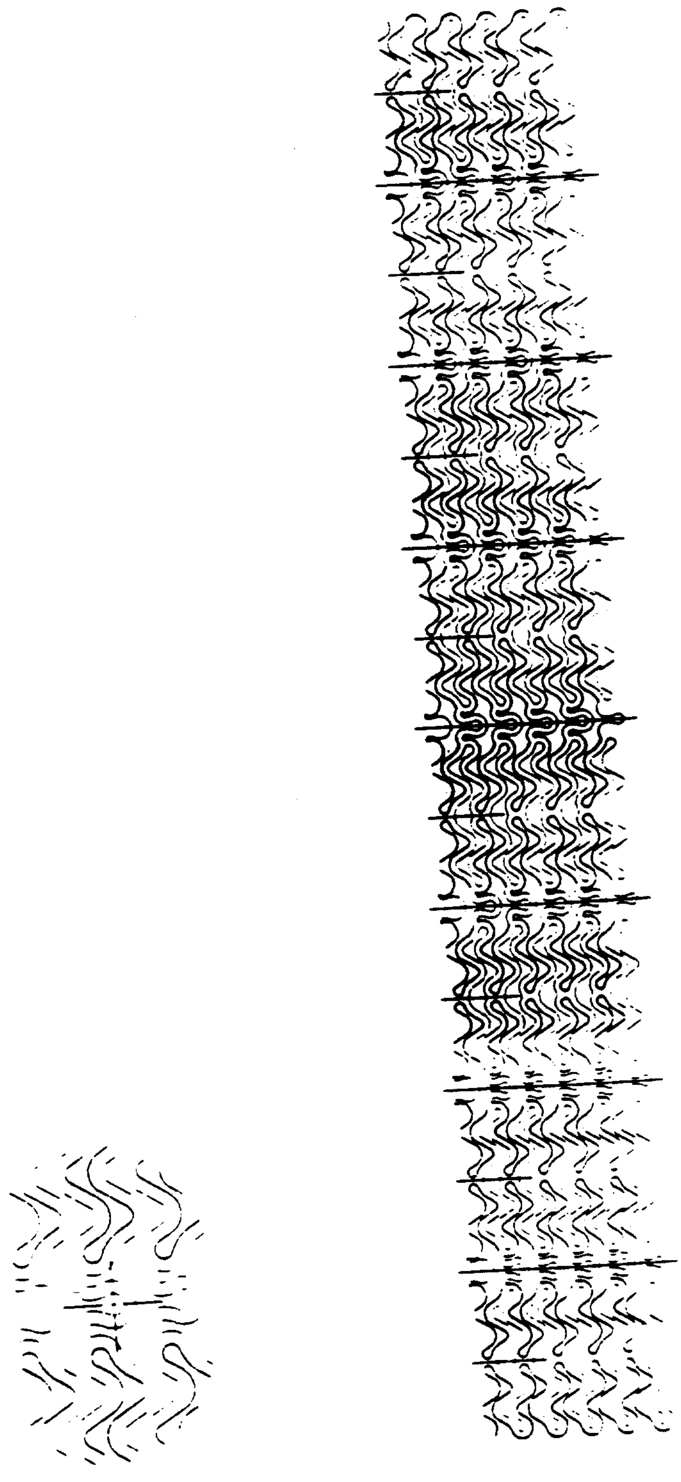
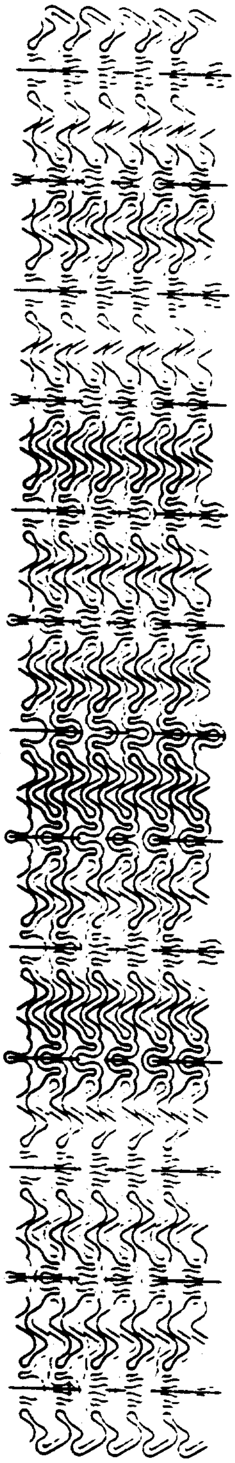


Fig 9



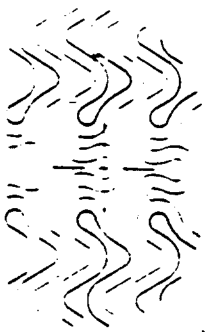
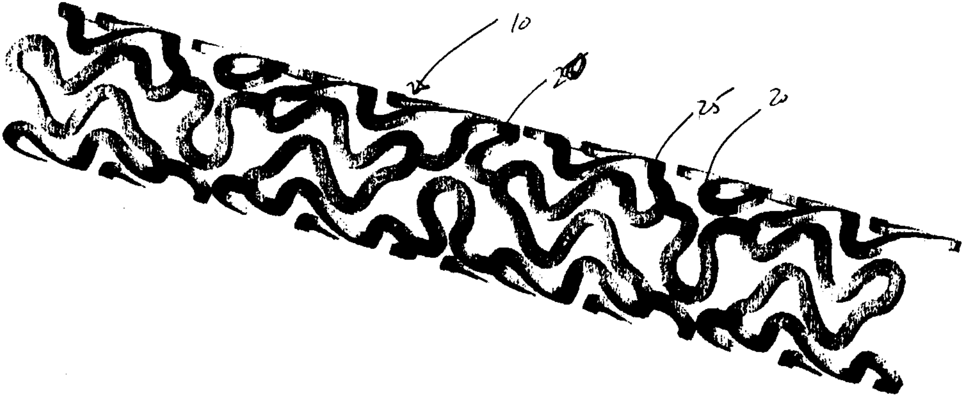


Fig 10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20