IMO

DESCRIPCIÓN

Stent.

Objeto de la invención

La presente invención, tal y como se expresa en el enunciado de esta memoria descriptiva, se refiere a un stent que consiste en un dispositivo para dilatar los diámetros de vasos sanguíneos, uréteres, uretra, conductos biliares, árbol bronquial, aneurismas, conducto lagrimal, vías respiratorias altas y en general cualquier otro conducto tubular del cuerpo de un ser humano o animal.

Comprende en principio una estructura tubular que se introduce contraída en posición plegada y se dilata después desplegándose de forma conocida en una zona determinada de tal conducto tubular, tal como un estrechamiento del orificio corporal donde será introducido previamente a fin de conseguir que tal estrechamiento recupere su paso o diámetro normal, manteniéndose el mismo después gracias al desplegado del stent.

Así pues, el stent es una prótesis para uso animal y humano que sirve para expandir cualquier tubo o canal que precise aumentar sus diámetros, bien porque los redujo de forma natural (envejecimiento entre otros), por un daño producido en dicho tubo o simplemente porque se precisa su dilatación. En la jerga médica, a estos dispositivos se les denomina stent, término anglosajón, teniendo en general una forma de muelle, a la vez que su uso está extendido universalmente para tratar las lesiones que estrechan las arterias coronarias principalmente. Al procedimiento de dilatarlas, se denomina angioplastia percutanea.

Al emplearse en seres vivos debe ser biocompatible, es decir, asumible por el receptor sin que provoque efectos secundarios, y como se dijo, la imagen más parecida es la de un resorte muelle de un bolígrafo que se introduce torsionándolo para reducir sus diámetros y así poder pasar por la estrechez. Una vez situado en el sitio adecuado, se expande mediante el inflado de un balón o globo situado en su interior. Este pequeño tubo stent, está hecho de un hilo entrelazado en forma de malla que se deja fijo en la lesión en posición desplegada, como si fuera un andamio o armadura para evitar que de nuevo se estreche.

Esta prótesis también es aplicable a cualquier otro tubo o canal que precise dilatarse sin descartar su uso para otras dilataciones y en otros sistemas no tubulares.

Partiendo de esta premisa, el objetivo esencial de la invención consiste en conseguir dilatar un conducto disminuyendo al máximo la agresión que se produce con los actuales stents sobre la superficie interna de tal conducto al expandir o desplegar el citado stent dentro del conducto tubular correspondiente.

Antecedentes de la invención

En la actualidad, son conocidos los stents fabricados a partir de una malla de plástico, metal, tela o nuevos materiales, de manera que una vez armados o conformados, presentan una estructura tubular de pared perforada, clasificándose fundamentalmente en tres grupos.

Un primer grupo cuya estructura tubular se obtiene a partir de una malla que se dilata.

Un segundo grupo en el que el stent tiene la aplicación de liberar fármacos. Para ello, la estructura tubular del dispositivo es rebozada con una serie de sustancias que actúan sobre las paredes en contacto con la malla evitando reacciones adversas de la misma, bien sea directa con la proliferación celular, etc, o indirectas. Entre éstas, la más frecuente es la trombosis por excitación del sistema plaquetario o activación de la coagulación pero, al igual que otros stents coronarios, éste se deja permanentemente en la arteria.

Un tercer grupo se corresponde con los stents reabsorbibles, los cuales una vez colocados se van reabsorbiendo hasta desaparecer.

El desplegado o expansión del stent se realiza mediante un globo o balón desinflado ubicado dentro de la propia prótesis plegada, de manera que cuando la misma alcanza el estrechamiento donde se debe instalar, se procede al inflado del globo colocado previamente desinflado dentro del stent en posición plegada, hasta conseguir el diámetro requerido del stent desplegado que conformará un armazón que asegura el diámetro óptimo de esta zona del conducto tubular evitando que se contraiga. En una fase posterior se procede a extraer el globo desinflándolo previamente.

La dilatación con el globo y la colocación del armazón son sincrónicos, es decir, el armazón va encogido sobre el globo y al dilatar el globo se dilata y asienta el armazón por la parte interna del stent. La presión que se ejerce sobre el interior del citado stent pueden llegar hasta las 20 atmósferas y la expansión del armazón, a esa presión puede provocar el desgarro del conducto tubular del paciente.

Es decir, cuando hay una estrechez, por ejemplo de una arteria, se introduce un balón desinflado que va cubierto por un armazón a modo de malla, de manera que cuando el balón se infla se ensancha la arteria y el armazón, que-

dando luego éste estirado de forma definitiva, impidiendo la constricción de la arteria, para finalmente extraer el balón desinflado, tal y como se ha referido anteriormente.

Esta forma de dilatar a tal presión ejerce un daño sobre la estructura que se dilata produciendo desgarros, y hasta ahora no se contempla disminuir la agresividad de dicho procedimiento.

Se establece que la fabricación de los stents está hecha en cualquier material biocompatible (es decir, tolerado por los seres vivos o sin reacciones adversas), ya que las características del material dan al sistema propiedades físicas diferentes en cuanto a dureza, flexibilidad, capacidad de dilatación, entre otras.

Todos los diseños actuales de stents, se fabrican en forma de malla expansible y en la actualidad existen varias formas de entramado de las mallas pero ninguna de ellas contempla que el área de barrido que recorre el hilo de la malla durante su expansión sea el mínimo como ocurre en la invención que nos ocupa. Esto quiere decir que al expandir la malla a tanta presión el hilo tiene necesariamente que rasgar un área de la superficie en la que apoya provocando una lesión.

Por otro lado, las características y propiedades más importantes de un stent son las siguientes:

- Que sean fáciles de introducir, es decir que se puedan llevar al lugar de la lesión mediante un fácil desplazamiento a través de los conductos previos a las lesiones, definiéndose esta propiedad en la jerga médica como navegación a lo largo del conducto en el que se introduce la prótesis (stent).

- Que después del desplegado o expansión del stent, éste no se retraiga, de manera que cuanto menos se retraiga el efecto curativo será mayor.

- Que dañen lo menos posible la superficie sobre la que están en contacto. Al expandirlo se ejerce una fuerte presión sobre la superficie que se aplica y se debe tener en cuenta que el desgarro producido por el hilo de la malla es importante.

- Que se adapte al conducto lo mejor posible.

Los dos primeros puntos indicados son dados por la forma de tejer el hilo de la malla, es decir, por el entramado de la malla y el tercer punto por la sección del hilo redondo o plano, o como en este caso de la invención que nos ocupa que presenta una característica curvatura curvo-convexa. En cuanto al cuarto punto citado, en relación con la forma longitudinal y teniendo en cuenta que las arterias se van haciendo cada vez más pequeñas a modo de cuerno, la nueva configuración de la invención que nos ocupa es la que mejor se adapta.

Por otro lado también cabe señalar que desde que los stents comenzaron su andadura los beneficios obtenidos son elevados, guiándose la fabricación de los mismos por patrones económicos fundamentalmente, una loca carrera por las ventas sin que se hiciese ningún estudio serio de la geometría, anatomía, capacidad de adaptación, capacidad de integración, agresividad y eficacia, entre otros.

A las promesas de los fabricantes de los stents les siguen problemas reales, como por ejemplo que en algunos casos fue necesario extraer los stents una vez implantados, con los consiguientes daños provocados al paciente, existiendo otros casos en los que no fue posible su extracción ni retirada.

Todos los stents actuales presentan una configuración cilíndrica tanto en su posición plegada como en su posición desplegada, generando entre otros, los siguientes problemas:

- En cuanto a su forma, mientras que transversalmente el stent convencional presenta una forma circular y se adapta a la sección transversal de la arteria, longitudinalmente son cilíndricos y no se adaptan al estrechamiento progresivo de una arteria, por ejemplo.

- El hilo de la armadura de malla es tan fino que su superficie es cortante. En este caso la zona de contacto es mínima y al expandir el stent sobre la superficie interna del conducto tubular donde se instala a 20 atmósferas de presión, se provocan desgarros del tejido.

- La geometría de la malla que define la capacidad de expansión, navegabilidad y retracción. La malla de los diseños actuales tiene muchos recovecos que lesionan aún más la pared del conducto tubular. La soldadura o unión entre los distintos anillos o aros hace que al expandirse el stent se refuerce aún más produciendo un mayor daño a la superficie interna del conducto que se dilata.

- Se daña el endotelio formado por unas células que recubren el interior de todos los vasos sanguíneos.

Algunos ejemplos de stents se corresponden con las Patentes de Invención con número de publicación en España 2223096, 2144657, 2119537 y 2243274.

Descripción de la invención

Con el fin de alcanzar los objetivos y evitar los inconvenientes mencionados en los apartados anteriores, la invención propone un stent que comprende en principio una estructura tubular conformada por una pared envolvente definida por una armadura de malla y la cual delimita un primer espacio menor en una posición plegada y un segundo espacio mayor en una posición desplegada en la que tal estructura tubular se encuentra dentro de una zona debilitada de un conducto tubular de un cuerpo humano o animal, habiéndose introducido previamente tal estructura tubular en la posición plegada a lo largo del conducto tubular hasta alcanzar la zona debilitada donde se procede al desplegado mediante el inflado de un globo ubicado por dentro del propio stent en la posición plegada.

Se caracteriza porque:

- La estructura tubular comprende una configuración tronco-cónica al menos en la posición desplegada.

- La estructura tubular integra unos tramos longitudinales correspondientes con las generatrices de la citada configuración tronco-cónica, y al menos dos anillos de trayectoria circunferencial de diferente diámetro unidos a los tramos longitudinales.

- Los anillos de trayectoria circunferencial integran, en la posición plegada, unos dobleces contenidos en la superficie envolvente de la estructura tubular.

Los anillos de trayectoria circunferencial se caracterizan a su vez porque comprenden varios tramos curvados delimitados entre los puntos de cruce de los tramos longitudinales con respecto a los citados anillos de la estructura tubular, caracterizándose también porque tales tramos curvados integran sendos dobleces en la posición plegada de la estructura tubular.

Cada uno de los dobleces de los anillos de trayectoria circunferencial comprende al menos un par de pliegues envolventes mayores enfrentados, unidos por uno de sus extremos mediante un pliegue central de trayectoria curvada, mientras que los extremos libres de tales pliegues envolventes mayores se prolongan en unos pliegues menores en oposición que son continuación de unas porciones extremas de los tramos curvados conformantes de los anillos.

En una realización preferente, la estructura tubular comprende una configuración tronco-cónica también en la posición plegada.

Otra característica de la invención es que los dobleces de los anillos de la estructura tubular se estiran completamente en la posición desplegada, mientras que los tramos longitudinales mantienen en todo momento su longitud inicial.

Los tramos longitudinales y anillos de la estructura tubular integran una característica sección de configuración arqueada que se estrecha progresivamente desde una zona central hacia sus extremos laterales.

Tal sección de configuración arqueada comprende una cara interna y una cara exterior curvo-convexa que está en contacto con la superficie interna del conducto tubular en la posición desplegada de la estructura tubular del stent.

Las zonas extremas de la cara exterior curvo-convexa comprenden unas porciones terminales de curvatura reducida en cuyos extremos convergen el final de la cara interna de los anillos y tramos longitudinales de la estructura tubular.

Otra característica de la invención es que la cara interna de los tramos longitudinales y anillos de la estructura tubular comprende tal cara interna un plano curvo-cóncavo.

En otra realización tal cara interna presenta una superficie plana.

La anchura de la sección de configuración arqueada de los tramos longitudinales y anillos de la estructura tubular, es tal anchura sustancialmente mayor que el grosor de la zona central de tal configuración arqueada.

Otra característica de la invención es que los tramos longitudinales y anillos comprenden una estructura porosa que tiene una configuración fractal.

La estructura porosa del stent facilita la absorción del medicamento en estado líquido a modo de esponja, empapándose de tal medicamento líquido, con lo cual el transporte del medicamento junto con el stent resulta sumamente sencillo y práctico. Así pues, tal medicamento líquido ocupará la multitud de cavidades de tal estructura porosa.

Entre otras, las ventajas que presenta el nuevo stent son las siguientes:

- Su diseño de estructura de malla al expandirse la misma hasta alcanzar la posición desplegada del stent, recorre una menor área de barrido sobre la superficie a dilatar, lo que implica una minimización de la agresión sobre el tejido, mayor protección, reducción de la herida o desgarro.

- La forma que se le da a la estructura de malla está basada en reducir al máximo el recorrido dañino del hilo (tramos longitudinales y anillos de la estructura tubular) sobre la superficie a expandir.

A continuación para facilitar una mejor comprensión de esta memoria descriptiva y formando parte integrante de la misma se acompañan unas figuras en las que con carácter ilustrativo y no limitativo se ha representado el objeto de la invención.

Breve descripción de los dibujos

Figura 1.- Muestra una vista en perspectiva del stent en posición plegada, objeto de la invención. Presenta una característica estructura tubular de configuración tronco-cónica, cuya pared comprende también una característica malla, a partir de la cual se obtiene el stent. También se muestra un conducto tubular con un estrechamiento donde se instalará el stent.

Figura 2.- Muestra una vista en perspectiva del stent en posición desplegada, en la que ocupa un volumen sustancialmente mayor que en la posición plegada.

Figura 3a.- Muestra una vista de la malla en posición plegada, a partir de la cual se obtiene el stent de la invención.

Figura 3b.- Muestra una vista similar a la anterior, con otra realización diferente.

Figura 4.- Muestra una vista frontal del stent en posición desplegada.

Figura 5.- Muestra una vista de la característica sección que presenta un hilo, a partir del cual se fabrica la malla para conformar después el stent de la invención.

Descripción de un ejemplo de realización de la invención

Considerando la numeración adoptada en las figuras, el stent contempla la siguiente nomenclatura empleada en la descripción:

1.- Estructura tubular.

2.- Conducto tubular.

2'.- Estrechamiento.

3.- Tramos longitudinales.

4.- Anillos.

5.- Tramos curvados.

6.- Dobleces.

7.- Pliegues envolventes mayores.

8.- Pliegue central.

9.- Pliegues menores.

10.- Porciones extremas.

11.- Cara exterior curvo-convexa.

12.- Cara interna.

13.- Superficie interna.

13'.- Porciones terminales.

14.- Puntos de cruce.

Comprende una estructura tubular 1 de configuración tronco-cónica que facilita su introducción en posición plegada dentro de un conducto tubular 2 donde se vaya a instalar, facilitando también tal configuración tronco-cónica su navegabilidad a lo largo de tal conducto tubular 2 hasta alcanzar la zona concreta de colocación, tal como por ejemplo un estrechamiento 2'. Evidentemente el extremo delantero del stent que va en cabeza durante su avance por el interior del conducto tubular 2 es el extremo de menor diámetro.

No obstante, en otra realización menos ventajosa, el stent podría comprender una configuración diferente a la tronco-cónica en la posición plegada, como por ejemplo una configuración cilíndrica.

A su vez, la estructura tubular 1 del stent se conforma a partir de una armadura de malla y está conformada por varios tramos longitudinales 3 correspondientes con las generatrices de la configuración tronco-cónica y al menos dos anillos 4 de trayectoria circunferencial unidos a los citados tramos longitudinales 3. Estos son de trayectoria recta.

En una realización, la armadura de malla está formada por hilos unidos en sus puntos de cruce 14, fabricados mediante un material de nitinol compuesto por níquel y titanio al 50%, sin descartar otros materiales, como por ejemplo un acero inoxidable.

Los anillos 4 de trayectoria circunferencial comprenden varios tramos curvados 5 delimitados entre los puntos de cruce 14 de los tramos longitudinales 3 con respecto a los citados anillos 4 de la estructura tubular 1.

Al menos en la posición plegada del stent, las porciones curvadas 5 de los anillos 4 integran sendos dobleces 6, formado cada uno de ellos por al menos un par de pliegues envolventes mayores 7 enfrentados, unidos por uno de sus extremos mediante un pliegue central 8 de trayectoria curvada, mientras que los extremos libres de cada uno de tales pliegues envolventes mayores 7 se prolongan en otros pliegues menores 9 en oposición que son continuación de unas porciones extremas 10 de los tramos curvados 5 conformantes de los anillos 4 pertenecientes a la estructura tubular 1 del stent.

Una vez situado el stent en el estrechamiento 2' del conducto tubular 2 donde se desea instalar, se procede a su desplegado de forma convencional a través de un elemento inflable (globo) que será introducido previamente dentro del reducido espacio interior del stent en posición plegada. Tal elemento inflable no está representado en las figuras por no considerarse necesario.

La estructura del stent en posición desplegada adopta también una configuración tronco-cónica, con lo cual, se facilita la circulación de la corriente de fluido que avanza a lo largo del citado conducto tubular 2 donde se ha instalado, fluido que puede ser sangre u otros fluidos. Para ello, el sentido de la corriente del fluido será desde el diámetro mayor del stent hacia su diámetro menor. Esta ventaja puede ser muy beneficiosa para los pacientes a fin de conseguir una mejor solución a su problema médico.

Durante el proceso de desplegado del stent mediante el inflado del globo incorporado, los dobleces 6 de los distintos anillos se despliegan de forma controlada estirándose progresivamente hasta alcanzar el volumen o tamaño requerido del stent para recuperar así el diámetro requerido en el estrechamiento 2' del conducto tubular 2 donde se ha instalado.

En cambio, los tramos longitudinales 3 del stent en la posición desplegada mantienen la misma longitud que en la posición plegada.

Evidentemente, el tamaño mayor del stent se corresponderá con los estiramientos completos de los dobleces 6 integrados en los distintos anillos 4 de trayectoria circunferencial, siendo esta realización la preferente.

Los dobleces 6 de los anillos 4 cuando se estiran durante el desplegado barren un área sustancialmente menor que cualquier otro stent convencional, con lo cual, se minimizan al máximo los daños por rozamiento y desgarro sobre el tejido del conducto tubular 2 del paciente al expandirse el stent.

Por otro lado, la sección de los distintos anillos 4 y tramos longitudinales 3 del stent, tal como se muestra en la figura 5, presenta una estructura arqueada que integra una cara exterior 11 curvo-convexa y una cara interna 12 seleccionada entre una trayectoria curvo-cóncava como se aprecia en la citada figura 5 y una trayectoria plana.

Los tramos longitudinales 3 y anillos 4 de la estructura tubular integran una sección de configuración arqueada que se estrecha progresivamente desde una zona central hacia sus extremos laterales.

La nueva estructura del stent de la invención proporciona una buena estabilidad longitudinal y flexibilidad lateral, que se traduce en una buena navegabilidad.

Las caras exteriores curvo-convexas 11 del stent que contactan con la superficie interna 13 del conducto tubular 2 donde se ha instalado tal stent, ejercen una presión sustancialmente menor que en el caso de los stents convencionales, ya que tal presión disminuye proporcionalmente a la superficie de contacto, distribuyéndose las fuerzas en el desplegado o expansión del stent en una superficie de contacto mayor en la invención que nos ocupa con respecto a los stents convencionales en los que la superficie de contacto es muy reducida.

Las zonas extremas de las caras exteriores curvo-convexas 11 comprenden unas porciones terminales 13' con una curvatura menor que el resto de tales caras exteriores curvo-convexas 11.

Los hilos de los stents convencionales tienen un apoyo contra la cara interna del conducto tubular en una reducida superficie, y por lo tanto, al desplegarse tales stents convencionales, la fuerza expansiva provoca que la presión puntual

concentrada de tales hilos se incruste en la estructura dilatada del conducto tubular respectivo desgarrando el mismo y provocando daños de extrema gravedad en algunos casos.

Por otro lado, la configuración curvo-convexa de las caras exteriores de la estructura de malla del stent de la invención evita exponer sobre la pared una superficie cortante, que ofrece una alta resistencia y que se clava en la estructura a dilatar, como ocurre con los actuales hilos. El hilo del que está compuesta la armadura de malla del stent de la invención presenta las siguientes ventajas:

- Facilita el deslizamiento del stent disminuyendo la resistencia.
- Aumenta la superficie de contacto.
- Disminuye la agresión y erosión al expandirse el stent.
- Disminuye la presión sobre la estructura a dilatar.

Con la característica estructura geométrica que presenta el stent de la invención es posible aumentar la longitud de los anillos 4 barriendo el mínimo de área posible de la superficie interna 13 del conducto tubular 2. El stent tendrá tantos pliegues envolventes mayores 7 como se necesite para aumentar el diámetro del stent hasta alcanzar la longitud circunferencial necesaria acorde con el diámetro interior del conducto tubular 2 donde se vaya a instalar el stent.

Tanto mayor es el diámetro basal del stent menor dificultad se tendrá en el diseño, pues los distintos pliegues envolventes mayores 7 pueden ser solamente dos. El problema surge cuando el diámetro del que partimos es mínimo, como por ejemplo 0,5 mm y se debe aumentar hasta alcanzar los 3 mm acorde con la posición desplegada del stent en el interior del conducto tubular 2 correspondiente. En este caso el perímetro circunferencial del stent deberá aumentar de forma sustancial desde la posición plegada a la posición desplegada, de manera que la longitud circunferencial del stent aumentará de forma sustancial pudiéndose multiplicar por treinta veces el aumento de tal contorno circunferencial.

La longitud de los anillos 4 del stent será proporcional a los pares de pliegues envolventes mayores 7. Por lo tanto se pueden incorporar tantos pares de pliegues envolventes mayores como sean necesarios para pasar, por ejemplo, de 0,8 mm de contorno circunferencial del stent hasta los 27 mm de contorno circunferencial del stent en posición desplegada o expandida, pudiéndose aplicar así el stent de la invención a lesiones estrechísimas de conductos tubulares que hasta ahora eran inabordables.

Así pues, cada milímetro de recorrido con el stent de la invención, supone el triple de longitud circunferencial, es decir, de manera que cada par de pliegues envolventes mayores pueden multiplicar su longitud por el triple de la misma, a lo que hay que añadir la longitud del pliegue central 8 y pliegues menores 9 de los anillos.

En la actualidad los stents convencionales, tal como se ha referido anteriormente presentan una configuración cilíndrica, es decir, que tienen en sus dos extremos el mismo diámetro a diferencia del stent de la Patente de Invención que nos ocupa que presenta una configuración tronco-cónica de manera que su forma se adapta a los diámetros de aquellos conductos tubulares cuya luz se reduce a medida que se avanza por su cauce, como por ejemplo en el caso de las arterias coronarias.

Los stents actuales tienen un diámetro inicial y un diámetro final idénticos, con lo que se adapta como un guante a su dedo, lo que provoca una desigual dilatación, una desigual presión y altera así la normal anatomía del tubo arterial coronario, por ejemplo.

Así, por ejemplo, para la coronaria izquierda el diámetro se reduce 1 mm cada 2 cm con una desviación del 15% mientras que para la coronaria derecha es 1 mm cada 4 cm de longitud con una desviación del 15%.

Las arterias presentan una configuración tronco-cónica adaptándose al interior de las mismas perfectamente el stent de la invención.

Así pues, para diseñar con exactitud y precisión el stent de la invención para adaptarlo a las coronarias se deberá tener en cuenta que en el caso de la coronaria derecha la reducción del diámetro es de 1 mm cada 4 cm de longitud mientras que para la coronaria izquierda será de 1 mm cada 2 cm.

Resumiendo pues el stent de la invención presenta las siguientes ventajas:

- Al presentar una configuración tronco-cónica frente a la configuración cilíndrica de los stents convencionales, el plegado del hilo de la armadura de malla permite aumentar el área de la circunferencia por encima de los stents actuales.
- El hilo de la malla al ser asimétrico y no circular o aplanado como los hilos convencionales, tiene dos caras opuestas de gran superficie, a modo de un ala delta.

- El material del stent es conocido, siendo preferentemente el nitinol, con una característica sección estructural definida anteriormente, destacándose la cara exterior 11 curvo-convexa y fractal (objeto semigeométrico cuya estructura básica fragmentada o irregular, se repite, a diferentes escalas). Cabe señalar que fractal significa también quebrado o fracturado.

- Se disminuye al máximo la agresión que se produce con el stent de la invención con respecto a los actuales stents.

- Mayor capacidad de transporte de sustancias (geometría fractal).

- Adaptación a la anatomía cónica de la arteria.

- Se obtiene mayor capacidad de dilatación.

- El diseño de los anillos 4 dispuestos en planos transversales permite una gran expansión del stent, de manera que el área barrida es mínima, reduciéndose de esta forma el daño erosivo producido durante tal expansión.

- El diseño de los anillos 4 dispuestos en planos transversales permite una gran expansión del stent al aumentar la longitud de tales anillos 4 durante el desplegado, de manera que el área barrida es mínima, reduciéndose de esta forma el daño erosivo producido durante la deformación de los aros mientras dura la expansión o desplegado del stent.

- El hilo de la armadura de malla proporciona una mayor superficie de contacto sin un borde cortante reduciéndose la fricción y con una expansión de menor resistencia en su desplazamiento.

- La configuración geométrica del stent de la invención se adapta perfectamente a la anatomía real de las arterias coronarias con una reducción en su diámetro en torno al 25% para la coronaria derecha y en torno al 33% para la coronaria izquierda.

Los tramos longitudinales 3 y anillos 4 comprenden una estructura porosa que tiene una configuración fractal.

La estructura porosa del stent facilita la absorción del medicamento en estado líquido a modo de esponja, empapándose de tal medicamento líquido, con lo cual el transporte del medicamento junto con el stent resulta sumamente sencillo y práctico. Así pues, tal medicamento líquido ocupará la multitud de cavidades de la estructura porosa, para después liberarse dentro del cuerpo humano o animal.

REIVINDICACIONES

1. Stent, que comprende una estructura tubular conformada por una pared envolvente definida por una armadura de malla y la cual delimita un primer espacio menor en una posición plegada y un segundo espacio mayor en una posición desplegada en la que tal estructura tubular se encuentra dentro de una zona debilitada, tal como un estrechamiento, de un conducto tubular de un cuerpo humano o animal, habiéndose introducido previamente tal estructura tubular en la posición plegada a lo largo del conducto tubular hasta alcanzar la zona debilitada donde se procede al desplegado, **caracterizado** por que:

- la estructura tubular (1) comprende una configuración tronco-cónica al menos en la posición desplegada;

- la estructura tubular (1) integra unos tramos longitudinales (3) correspondientes con las generatrices de la citada configuración tronco-cónica, y al menos dos anillos (4) de trayectoria circunferencial de diferente diámetro que están unidos a los tramos longitudinales (3);

- los anillos (4) de trayectoria circunferencial integran, en la posición plegada, unos dobleces (6) contenidos en la superficie envolvente de la estructura tubular (1).

2. Stent, según la reivindicación 1, **caracterizado** por que:

- los anillos (4) de trayectoria circunferencial comprenden varios tramos curvados (5) delimitados entre los puntos de cruce (14) de los tramos longitudinales (3) con respecto a lo citados anillos (4) de la estructura tubular (1);

- los tramos curvados (5) integran sendos dobleces (6) en la posición plegada de la estructura tubular (1).

3. Stent, según la reivindicación 2, **caracterizado** por que:

- cada uno de los dobleces (6) de los anillos (4) de trayectoria circunferencial comprende al menos un par de pliegues envolventes mayores (7) enfrentados, unidos por uno de sus extremos mediante un pliegue central (8) de trayectoria curvada;

- los extremos libres de tales pliegues envolventes mayores (7) se prolongan en unos pliegues menores (9) en oposición que son continuación de unas porciones extremas (10) de los tramos curvados (5) conformantes de los anillos (4).

4. Stent, según una cualquiera de las reivindicaciones anteriores, **caracterizado** por que la estructura tubular (1) comprende una configuración tronco-cónica en la posición plegada.

5. Stent, según una cualquiera de las reivindicaciones anteriores, **caracterizado** por que los dobleces (6) de los anillos (4) de la estructura tubular (1) se estiran completamente en la posición desplegada, mientras que los tramos longitudinales (3) mantienen en todo momento su longitud inicial.

6. Stent, según una cualquiera de las reivindicaciones anteriores, **caracterizado** por que:

- los tramos longitudinales (3) y los anillos (4) de la estructura tubular (1) integran una sección de configuración arqueada que se estrecha progresivamente desde una zona central hacia sus extremos laterales;

- la sección de configuración arqueada comprende una cara interna (12) y una cara exterior curvo-convexa (11) que está en contacto con la superficie interna (13) del conducto tubular (2) en la posición desplegada de la estructura tubular (1) del stent;

- las zonas extremas de la cara exterior curvo-convexa (11) comprenden unas porciones terminales (13') de curvatura reducida donde convergen los extremos de la cara interna (12).

7. Stent, según la reivindicación 6, **caracterizado** por que la cara interna (12) de los tramos longitudinales (3) y anillos (4) de la estructura tubular (1), está definida tal cara interna (12) por un plano curvo-cóncavo.

8. Stent, según una cualquiera de las reivindicaciones 6 ó 7, **caracterizado** por que la anchura de la sección de configuración arqueada de los tramos longitudinales (3) y anillos (4) de la estructura tubular (1), es sustancialmente mayor que el grosor de la zona central de tal configuración arqueada.

9. Stent, según una cualquiera de las reivindicaciones anteriores, **caracterizado** por que los tramos longitudinales (3) y anillos (4) comprenden una estructura porosa.

10. Stent, según la reivindicación 9, **caracterizado** por que la estructura porosa de los tramos longitudinales (3) y anillos (4) tiene una configuración fractal.

11. Stent, según la reivindicación 1, **caracterizado** por que los tramos longitudinales (3) de la estructura tubular (1) comprenden una trayectoria recta.

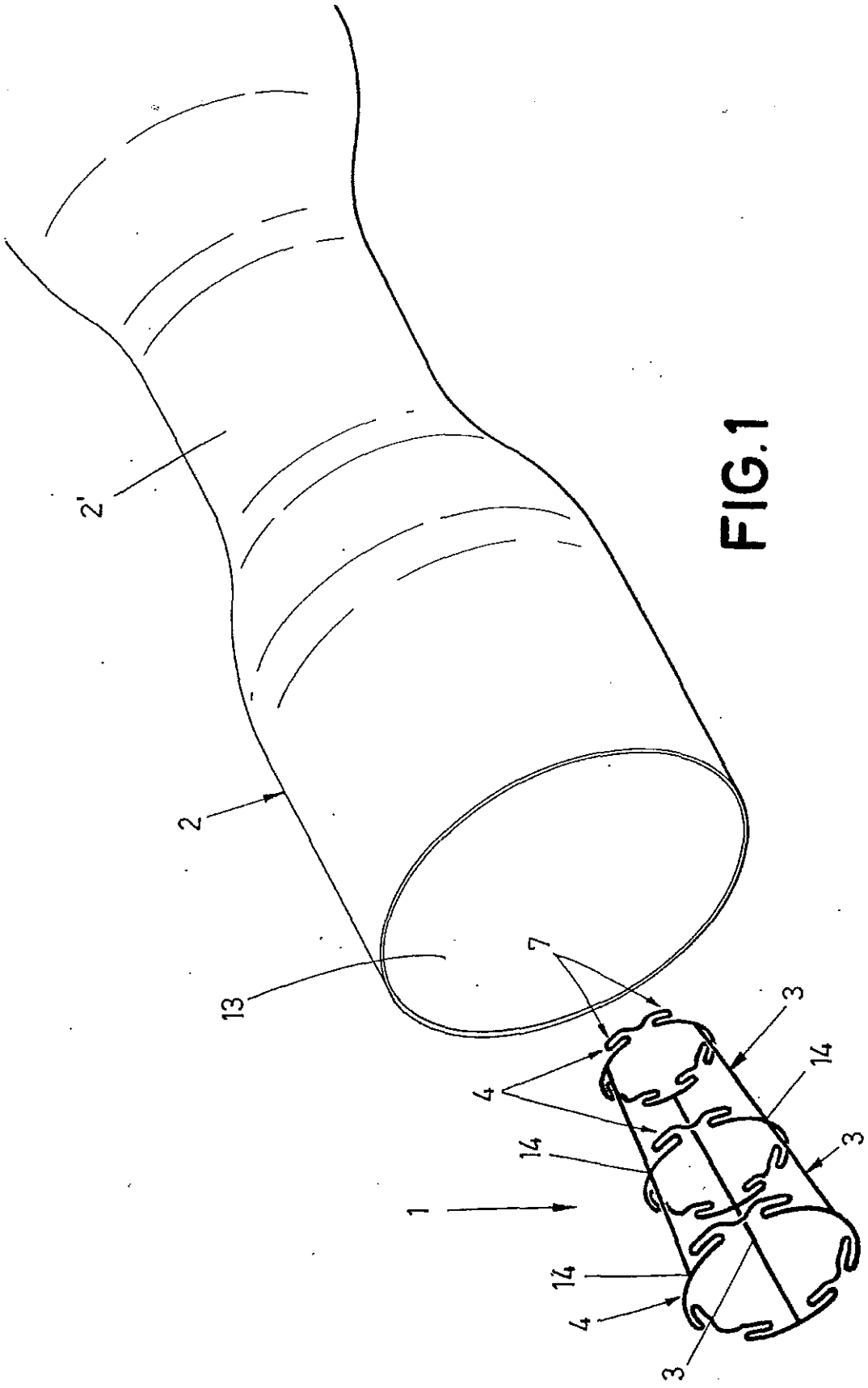


FIG.1

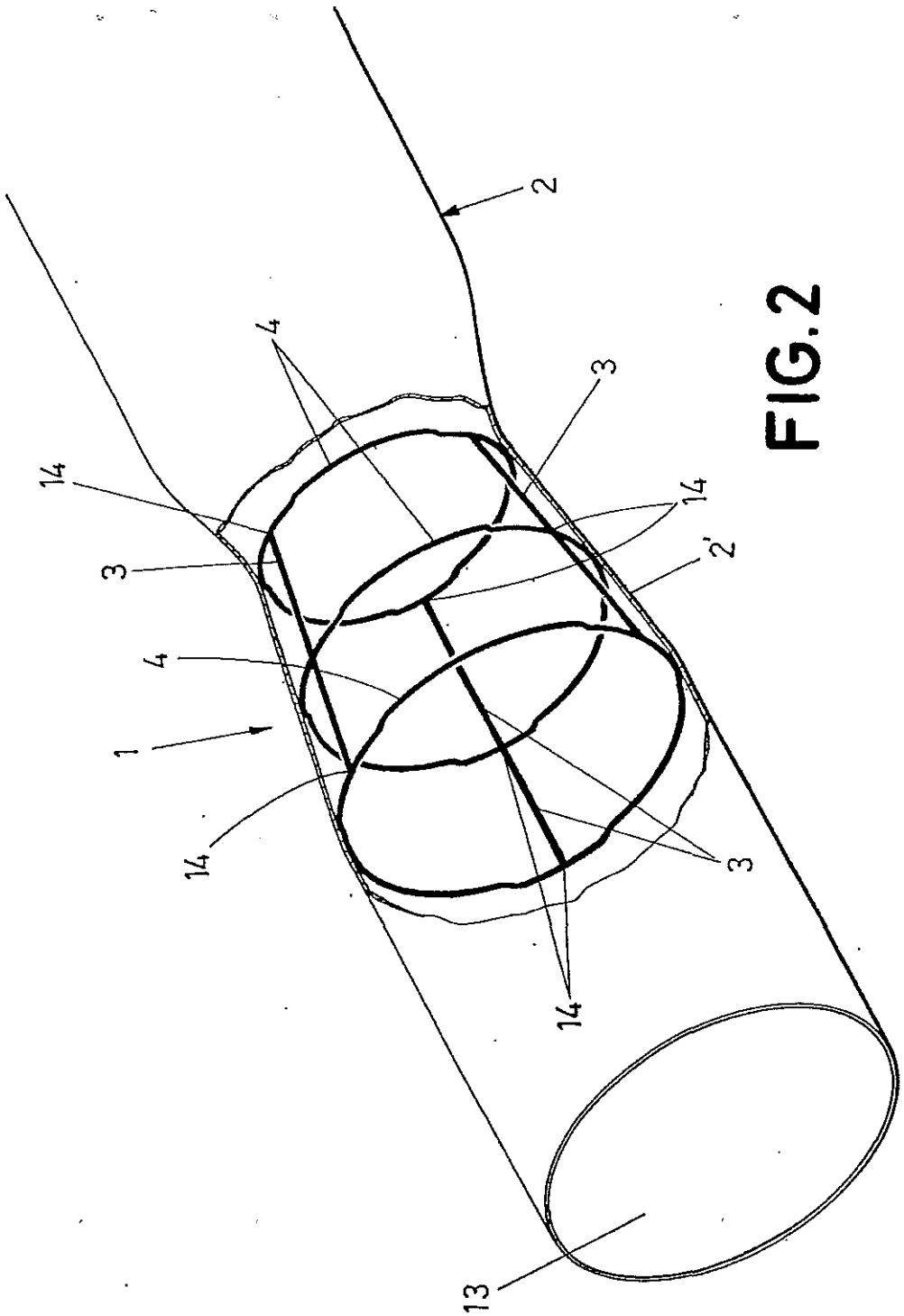


FIG.2

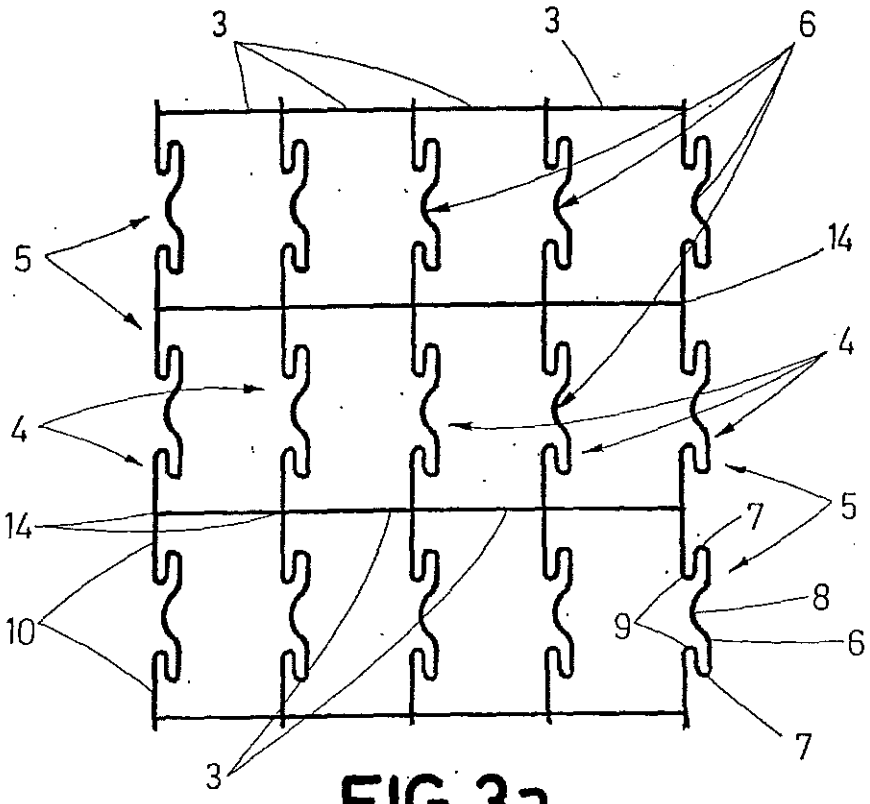


FIG.3a

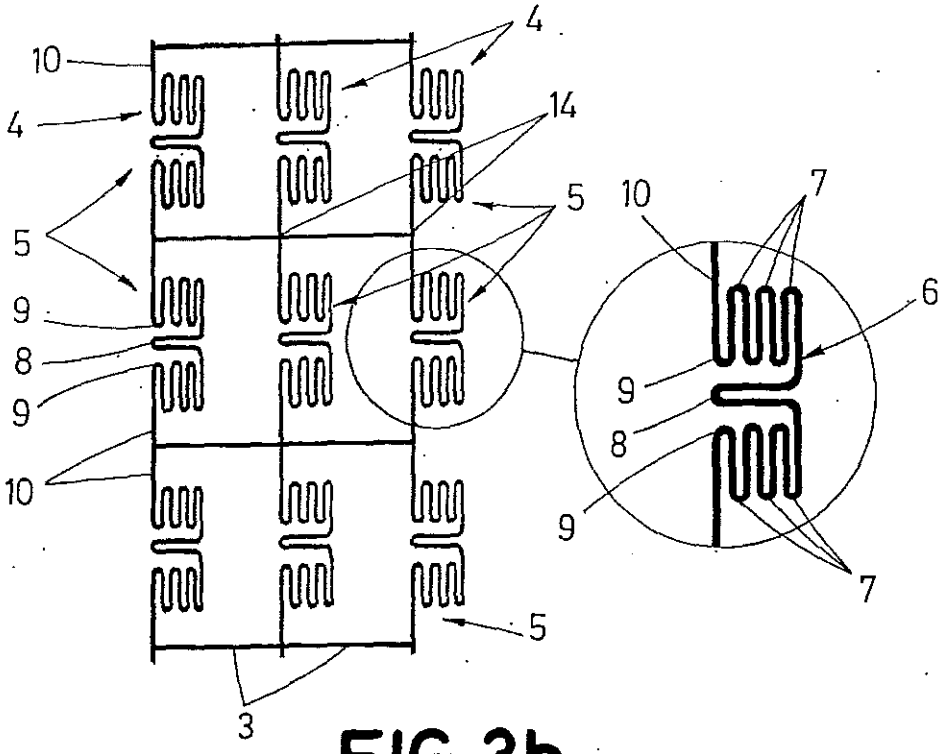


FIG.3b

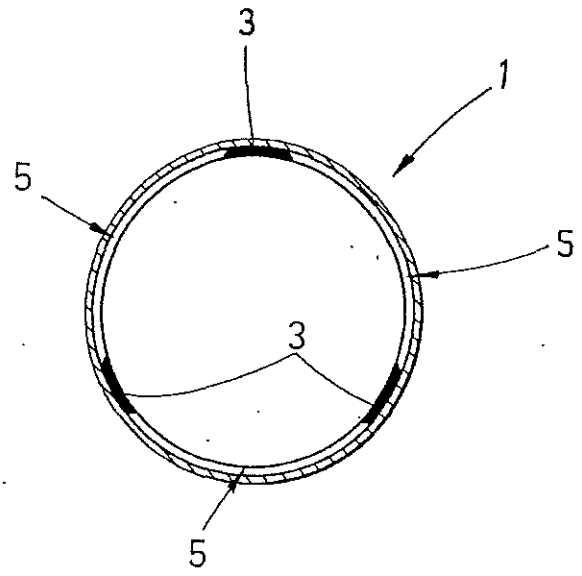


FIG.4

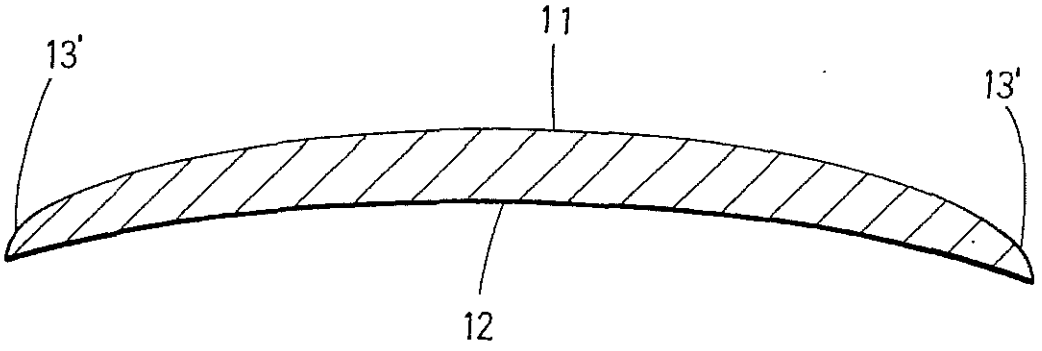


FIG.5

IM1

The Optimum expandable stent mechanical model and its application

Field and background of the invention

The invention is an expandable cardiovascular stent, which is intended for radical arterial lumen recovery matching the normal blood flow.

Modern stent implantation technology, into a coronary artery, for example, comprises the following substantial steps:

1. Positioning of the stent over a uninflated balloon of a conducting catheter.
2. Delivery of the stent to a location of a pathological formation within the coronary artery.
3. Expansion of the stent to the desired diameter through hydraulic inflation of the balloon, termination or significant moderation of a pathological formation in the coronary artery, emptying the balloon and withdrawal of the catheter from the coronary artery.
4. Functioning of the implanted stent in the coronary artery.

The first step does not show any specific difficulties for an attending physician. The second step is also rather easily performed with both short and relatively long stents, if the long ones are made of uniform short units and are interconnected by intermediate links of various construction.

During the third step, as the balloon inflates, the freely flexed stent in the artery erects and forms a linear cylinder which is dynamically extending in diameter. The balloon's load on the inward surface of the stent is so large that resistance reaction to the stent expansion, and especially to the straightening of the curved local portion of the artery, may be neglected. Only the balloon's pressure on the stent inward surface is essential in the third step, and this pressure is intended to expand the stent till its diameter reaches a required value.

Transition to step 4 is associated with the appearance of the mechanical forces of the

artery acting on the stent in radial direction, as the stent is no longer supported by the balloon. These mechanical forces tend to reduce the stent and to decrease the lumen size of the coronary artery to the pre-operational width. Said mechanical forces exert a bending influence on the stent tending to give it the curvilinear shape of a natural coronary artery curvature.

The action of the aforementioned coronary artery radial mechanical forces on the stent takes place all the way through the implantation time, changing dynamically in magnitude and direction as well as in character of its intensity distribution. These fluctuations are determined by the dynamics of arterial blood pulsation and heart muscle palpitation, constantly altering the arterial curvature.

The character of the above mentioned dynamics can typically be seen as a cyclic one with temporary changes in amplitude and period. Therefore, the optimum mechanical stent model must have the properties of dynamical compatibility with characteristics of mechanical forces and cyclic displacements of the coronary artery. These properties can be formulated as follows:

A. Maximum resistance of the stent to the coronary artery reduction.

B. Minimum resistance of the stent to the coronary artery longitudinal mechanical compliance.

The "ideal" stent model should not shrink radially while showing no resistance to the continuously changing trajectory of the artery.

The Prior Art

The articulated stent **1** (Fig. 1, 2) comprising at least two "rigid" segments **2** is known. These segments are connected by a set of cells **3**, each having an apex **4**. Upon stent **1** expansion each of the "rigid" segments **2** takes a shape of a cylindrical rhomboidal net **5**. In addition to this the stent **1** contains a flexible connector **6** which includes a set of flexible links. Each link embraces portions of each pair of

adjacent cells **3**, having a flexing flat. Upon stent **1** expansion the flexing flat remains flexed (see USA, Patent No.5,449,373, 9/1995).

The flexible connector **6** can be described either as a set of helical (spiral) hinges **7** (Fig. 1), connecting said adjacent "rigid" segments **2**, or as a group of several meshed hinges **8** (Fig. 2), each having at least one flexing flat.

The considered stent does not meet the requirements of the optimum mechanical model, first of all, because it does not have a property of maximum resistance to the coronary artery reduction. Upon stent **1** expansion, the "rigid" segments **2** form the cylindrical rhomboidal net **5**. As it is well-known, any quadrangle, including a rhomboid, loaded diagonally, is a classic example of an unsteady geometrical figure.

According to the optimum mechanical model conception, the above mentioned "rigid" segments **2** play the role of diametrical deformation compensators (CDDs), which render resistance upon stent expansion with the help of a balloon in the coronary artery. These CDDs also receive dynamical radial mechanical forces of the coronary artery after the stent **1** has achieved patency and the conducting catheter has been withdrawn.

In this construction the flexible connector **6** functions as a longitudinal deformation compensator (CLD), that is intended to counterbalance the bending forces on the stent **1** occurring together with continuous displacements of different coronary artery portions. The binding loci of the flexible connector **6** (CLD) are the apices **4** of the adjacent cells **3** of the "rigid" segments **2**. Therefore, upon stent **1** expansion, the forces are transferred, and deformation occurs to both: the "rigid" segments **2** (CDD) and the flexible connector **6** (CLD).

When the coronary artery exerts a bending force on the stent , the "rigid" segments **2** change their geometrical sizes. Since the bending forces are repeated periodically and continuously, the "rigid" segments **2** actually do not function as CDDs.

We will now consider a construction of the flexible connector **6** of the above mentioned stent, as shown in Fig. 1, 2.

Upon longitudinal deformation of the stent **1** the outward surface **9** curve radius is larger than that of the inward surface **10**. The flexible connector **6** (CLD) is intended to balance the difference in lengths of the flexing flats of the surfaces **9** and **10**. However, upon longitudinal deformation of a one-hinged stent **1** (Fig. 1), the hinge **7** does not alter its length at all, and hence does not equalize the changes in the lengths of the previously mentioned flexing flats. Therefore, the flexible connector **6** does not function as a CLD.

The flexible connector **6**, constructed as several (three) meshed hinges **8** (Fig.2), features high compensatory ability against longitudinal deformations. But as the middle hinge of the connected knot in this construction has too many degrees of freedom, its spatial orientation is uncertain. There exists a possibility that this knot would place itself in a coronary artery transversely to the blood flow. Furthermore, according to the patent formula, the flexible connector **6** comprises a set of the mentioned hinges **8**, thus providing a possibility of total occlusion of the coronary artery.

A misleading approach to the development of basic functional elements of the stent construction can be detected through the analysis of the USA, Patent No. 5.514.154, 5/1996 (Fig. 3) as well. Here, to avoid shortening of the gap between the cylindrical elements **11** upon stent expansion, the connector **12** (CLD) is made rigid. Therefore, the same cylinder **11** functions as a CDD and a CLD simultaneously, thus contradicting the very essence of the optimum mechanical model.

Summary of the invention

The purpose of the invention is creation of an optimum cardiovascular mechanical stent model featuring dynamical compatibility with coronary artery forces

characteristics and its cyclic displacements.

This aim is achieved by the fact that a series of circular bands, disposed over a common longitudinal axis, is constructed in the proposed stent mechanical model, each of these bands comprising at least one CDD and one undeformable portion of circular surface. The above mentioned CDD is positioned parallel to the above mentioned longitudinal axis of said series of the circular bands and comprises at least two rods, constructed in the lateral surface of the above mentioned circular band. Said CDD rods are conjugated by a common apex and form a v - like connection. They could also be connected either by a portion of curvilinear surface or by a rod, while their loose ends are either closed by the mentioned undeformable portion of circular surface, or are connected to the adjacent couple of CDD rods. This adjacent pair of CDD rods, that is constructed in the aforementioned lateral surface of the aforementioned circular band, can be either identical or different in shape, relative disposition and geometrical sizes to the original CDD rods.

Apart from this, the proposed mechanical stent model contains at least one CLD, that embraces the aforementioned adjacent circular bands.

Said CLD is positioned into an intermediate zone, between said adjacent circular bands perpendicularly to said longitudinal axis of the stent. The CLD comprises at least two rods that have a common apex and form a v - like connection, or are interconnected either by a portion of curvilinear surface, or by a rod, while their loose ends are closed by said undeformable portions of the circular surface of said adjacent circular bands.

In the stent construction, said CDDs and CLDs can be made either of a whole slotted tube sample or of a standard wire sample. It is preferable to make said CLDs of a biologically compatible thread of temporary activity.

In the proposed mechanical stent model said CDDs and CLDs are not

interconnected kinematically. For this reason, when bending mechanical forces are exerted on the stent, neither forces nor deformation transfer from said CLDs to said CDDs takes place. The stent outward surface generatrix curvature radius along said longitudinal axis is altered by said CLDs only. This fact provides the minimum stent resistance to the coronary artery bending mechanical forces as well as preserves the natural artery curvature, and denotes the essential claim for their dynamic compatibility.

A simultaneous diameter increment along with each circular bands' width decrement, is observed only upon stent expansion in the coronary artery with the help of a balloon. These alterations in geometrical sizes, under the stent deformation of the kind described, concern said CDDs only. As the stent is maximally expanded, each of said circular bands forms a shape, approaching that of an even undeformable closed loop, its diameter being equal to that of the coronary artery inward surface and its width approaching that of said rod of said CDD. Therefore, the stent in general provides the maximum resistance to the reduction of the coronary artery, preserves the natural arterial lumen and, consequently, the normal blood flow. This is another essential claim for their dynamic compatibility.

Therefore, the proposed stent mechanical model, providing maximum resistance to the coronary artery radial forces on the one hand, and minimum resistance to its continuous alterations in spatial position on the other, is the optimum model as it features dynamical compatibility with coronary artery parameters.

Designing a given stent model, tailored to specific clinical requirements, demands calculation of the dependencies for the indicated CDDs and CLDs. Choosing technical characteristics of said stent is then predetermined by the values of the corresponding rigidity and flexibility parameters of the coronary artery.

The proposed optimum mechanical model provides the following:

- calculation of a stent diameter increment upon stent expansion in the coronary artery, the maximum stent diameter being a constant corresponding to that of the inward coronary artery surface;
- practically unalterable stent length upon its expansion in the artery;
- calculation of a stent flexibility at its stretching - compression, having the option of wide regulation of a flexibility degree;
- decrease total mass of the stent proportionally to the coronary artery diameter decrease;
- constructing the stent outward surface generatrix profile in precise correspondence to that of the inward coronary artery surface (stents with cone-like outward surface);
- production of clinical samples 4 - 80 mm in length;
- shape and size regulation of cylinder net cell cross-section, the net being formed upon stent expansion (a possibility of stent implantation into a bifurcating coronary artery);

In addition to this, the constructive features of the proposed stent allow creation of a whole theoretical concept of a cardiovascular stent design independent of the initial sample, used for this purpose (slotted tube, wire, etc.), including the "ideal" model creation. Thus, due to the feature of dynamic compatibility between the stent technical parameters and values of the coronary artery mechanical forces and movements, implantation of the stent, constructed in accordance with the proposed mechanical model, will not only increase the effectiveness of cardiological intraoperational involvement, but also optimize functioning of the stent compared to that of all known clinical analogues.

Brief description of the drawings

The invention is herein described with the help of an example and references to the accompanying drawings, wherein:

Fig. 1 - shows an articulated stent (prior art), its flexible connector being one hinge.

Fig. 2 - shows an articulated stent (prior art), its flexible connector being several meshed hinges.

Fig. 3 - shows an expandable stent with a rigid flexible connector.

Fig. 4 - shows schematically versions of stent circular band construction:

a) as a undeformable closed loop; b) as a combination of a CDD and a undeformable portion of circular surface; c) as a deformable circular surface comprising only CDDs.

Fig. 5 - shows schematically the types of CDD and CLD rod connections:

a) a v - like rod connection; b) a rod connection by a curve surface portion; c) a connection by a rod.

Fig. 6 - shows schematically a curvilinear element, a CDD used for calculation of minimum D_{min} (a) and maximum D_{max} (b) diameters dependencies:

d is the diameter of a circle inscribed into the CDD rod cross-section; $\mathbf{l}_i$ is a CDD rod length.

Fig.7 - shows schematically the stent bend along its longitudinal axis upon stretching or compression:

R_1 is the outward stent surface generatrix curvature maximum radius; R_2 is the outward stent surface generatrix curvature minimum radius; R_0 is the outward stent surface generatrix curvature neutral radius; K_1 is a segment occupied by a CDD over an arc with R_1 radius; K_2 is a segment occupied by a CDD over an arc with R_2 radius.

Fig. 8 - shows schematically a construction unit, a CLD, used for calculation of R_2 dependence.

d is a diameter of a circle inscribed into the CLD rod section; $\mathbf{l}_m$ is the CLD rod length.

Fig. 9 - shows the optimum mechanical stent model, before expansion (the stent surface evolvent is shown).

Fig. 10 - shows the same as Fig. 9, after the stent expansion.

Fig. 11 - shows the proposed optimum mechanical stent model with expansion bounded by the maximum diameter D_{max}, before expansion.

Fig. 12 - shows the same as Fig. 11, after the stent expansion.

Fig. 13 - shows the optimum mechanical stent model with expansion bounded by the maximum diameter D_{max} and a cone-like surface, before expansion (the stent surface evolvent is shown).

Fig. 14 - shows the same as Fig. 13, after the stent expansion.

Calculating dependencies for the optimum mechanical stent model

On Fig. 4 versions of a stent circular band construction are shown schematically. Fig. 4a shows a undeformable circular band constructed as an even closed loop **13**. When the expanding mechanical forces are applied, such a loop alters its geometric sizes only within the bounds of the elastic deformation of its own material. The value of such a deformation for a metal loop is rather small. For this reason, the loop **13** will restore its original sizes after its expansion.

If a circular cut is made in the undeformable even closed loop **13**, and a curvilinear element **15** is positioned into the cleave, as is shown on Fig. 4b, the curvilinear element **15** will function as a CDD upon expansion due to its bending and expanding ability.

Upon expansion, under the influence of mechanical forces, the curvilinear element **15** (CDD) promotes the circular band **14** diameter increment to a certain limited value. At the same time the degree of the circular band **14** diameter increment upon expansion is proportional to the coefficient **n** - the amount of the used curvilinear elements **15** (CDD), thus being a function of the **n** coefficient.

A circular band with maximum expanding ability is shown on Fig. 4c, the ability provided by the fact that this circular band comprises mostly CDDs (pos. **16**).

Fig. 5 shows schematically various CDD rod connections. A CDD can be

constructed as different combinations of linear or conditionally linear rods, that are merged together either by a v-like connection (Fig. 5 a), or by a curvilinear surface portion (Fig. 5 b), or by a rod (Fig. 5 c).

When all the CDDs, each comprising two rods, are compressed (Fig. 6 a), the minimum stent diameter D_{min} is bounded only by the conducting catheter uninflated balloon outward surface diameter , and can be calculated as follows:

$$D_{min} \simeq \frac{2d}{\pi} \cdot n \qquad (1)$$

where **d** is the diameter of a circle inscribed into the CDD rod section; **n** is the CDD amount in the circular band.

When all the CDDs, each comprising two rods are stretched, (Fig. 6 b), the stent maximum diameter D_{max} is calculated as follows:

$$D_{max} = \frac{\sum l_i}{\pi} \cdot n \qquad (2)$$

where l_i is the length of a CDD rod.

The maximum diameter value upon stent expansion is the most important parameter of its technical characteristics. All known clinical analogues, however, have conferred this parameter with only a recommended value, since it was not backed by constructive features and, accordingly, stent mechanical properties.

The proposed optimum mechanical stent model features diameter limitation upon expansion. The criterion of this parameter choice is the value of the coronary artery inward surface diameter D_{ca}.

For a precisely measured stent $D_{ca} \simeq D_{max}$ (3)

(where $\mathbf{D_{ca}}$ is the coronary artery inward surface diameter), because for every patient during the intraoperational involvement the coronary artery inward surface diameter is practically constant and can be measured. Therefore, the ratio $\sum l_i \cdot n/\pi$ is also a constant. Therefore, both the amount of CDDs (**n**) and rod

length (l_i) can be varied in the process of specific stent model design in accordance with clinical requirements.

The essential optimum mechanical stent model feature is the fact that upon expansion to the maximum diameter D_{max} every circular band takes a shape approaching that of a round undeformable closed loop with diameter equal to that of the coronary artery inward surface, D_{ca}, and with loop's width approaching that of a CDD rod. This allows to preserve securely the stent diameter value after expansion and decreases the stent's mass due to the more rational geometrical configuration.

The optimum stent mechanical model comprises at least two circular bands separated by an intermediate zone. Respectively, a stent with q circular bands will have (q-1) intermediate zones.

Static and dynamic function differentiation between circular bands and a construction element connecting these bands in the intermediate zone is the basis for the mechanism of dynamical compatibility between the proposed stent model mechanical characteristics and the corresponding coronary artery parameters. Since in its working position (after expansion) a circular band has exclusively a static function of keeping the size of the coronary artery lumen constant, a construction element of the intermediate zone must have a dynamic function, that is kinematic responding to spatial displacements of the coronary artery separate portions. In other words, the coronary artery bending mechanical forces influence on the stent should not be associated with forces and deformation transfer from the flexible construction element of the intermediate zone expanded to the maximum diameter D_{max} to the rigid circular band, this being the essential feature of the proposed invention.

Fig. 7 shows schematically the bend of a stent along a longitudinal axis upon stretching - compression. It can be clearly seen that upon a stent's bend, the length of a k_1 segment, occupied by a CDD on an arc of a bigger radius R_1, is larger than

that of a segment k_2, occupied by the same CDD on an arc of a lesser radius R_2. This illustrates the difference in deformation values of the compared segments of the stent diametrical cross-section. That is why the construction element of the intermediate zone is used as a CLD, featuring high compliance upon stretching - compressing.

In the optimum mechanical stent model, a construction element - CLD of the intermediate zone is made similar to CDD (see Fig. 5).

The calculation parameter of the longitudinal mechanical compliance (flexibility) of the stent with said CLDs, each comprising a couple of rods, is the stent outward surface generatrix curve minimum radius R_2 (Fig. 7, 8), for which

$$R_2 = \frac{D_{max} \cdot 2d}{\sum_{m=1}^{2} l_m - 2d} \qquad (4)$$

where $\mathbf{D_{max}}$ is the maximum diameter upon stent expansion; **d** is the diameter of the circle, inscribed into CLD rod section, l_m is a CLD length.

There are two possibilities to improve the stent flexibility, i.e. to decrease a curve radius R_2: either to decrease the numerator in the expression (4) or to increase its denominator. However, the numerator factors $\mathbf{D_{max}}$ and **d** in the expression (4) are constants. Therefore, the stent flexibility alteration parameter according to the expression (4) is the sum of CLD rods' lengths.

Being a function of this sum, the stent longitudinal mechanical compliance (flexibility) maximum value also depends on a possibility of rational positioning of the CLD rods in the intermediate zone between circular bands. For this reason, technologicity should be accounted for when designing the stent.

An additional possibility of the stent flexibility degree regulation is the amount of the CLDs and their spatial disposition in the intermediate zone. A multitude of construction modifications can be proposed here, in each specific case determined

by the corresponding clinical demands.

The curve radius R_2 absolute minimum value can be achieved if the construction element (CLD) of the intermediate zone is made of a biologically compatible thread of temporary activity.

During the stent functioning in the coronary artery, symmetric deformations in both directions take place, while the angle between the CLD rods (see Fig.5) alters periodically from 0 to 180^0. Thus, it is most reasonable to dispose these rods at the angle of about 90^0.

Specific description

Fig. 9 shows the optimum mechanical stent model according to the invention made in a whole slotted tube sample, before expansion.

A series of circular bands **17** is disposed over a common longitudinal axis. The circular band **17** comprises the alternating CDDs (pos. **19**), disposed parallel to the stent **18** longitudinal axis, as well as undeformable portions of circular surface **20**. A CDD (pos. **19**) comprises three rods **21**, conjugated in apices **22** by v-like connections. The rods **21** have different lengths and are made in the lateral surface of the circular band **17**. The loose ends of CDD rods **21** (pos. **19**) are closed by undeformable portions of circular surface **20**.

CLDs (pos. **23**) that embrace the circular bands **17** are disposed in the intermediate zone between the adjacent circular bands **17** perpendicularly to the stent **18** longitudinal axis. A CLD (pos. **23**) comprises two rods **24**, conjugated by a v-like connection at an approximately 90^0 angle in an apex **25**. The rods **24** are equal in length, and are connected by their loose ends to the portions of undeformable circular surface **20** of the adjacent circular bands **17**.

Fig. 10 shows the same stent as Fig.9, expanded to a diameter D less than its maximum diameter D_{max} according to the accepted clinical technology. It is clearly seen on Fig. 10 that only CDDs (pos. **19**) deform and alter their geometrical sizes

upon stent expansion. The CLDs (pos. **23**), joined to the corresponding circular surface **20** undeformable portions of circular bands **17**, are not sensitive to mechanical forces and deformation upon stent expansion. As all CDD (pos. **19**) rods **21** are made identical, the stent **18** preserves its cylindrical shape after expansion.

Fig. 11, 12 show the stent correspondingly before and after expansion, where the CDD (pos. **19**) rods **21** are designed in such a way, that after the stent expansion to the maximum diameter D_{max}, the circular bands **17** take a shape approaching that of a round undeformable closed loop. The outward diameter of such a loop (Fig. 12) corresponds to the coronary artery inward surface diameter D_{ca}, while the loop's width approaches that of the CDD (pos. **19**) rod **21**. Herein, after the circular bands **17** achieve the maximum diameter D_{max}, angular apices **25** of the CLD (pos. **23**) conjugated rods **24** inculcate into a wall of the coronary artery inward surface, thus promoting a better adjoining to its tissue.

The absence of kinematic connection between the CDDs (pos. **19**) of the circular bands **17** and the CLDs (pos. **23**) allows the stent **18** not to alter its length upon expansion to the maximum diameter D_{max}.

A coronary artery recovers its normal hydrodynamic properties after stent expansion. The proposed stent model implanted into the artery does not distort its natural dynamics upon heart muscle palpitations, which creates favourable conditions for the atraumatic process of the stent outward surface connection to the coronary artery tissue and for a more effective stent functioning during a long period.

The proposed stent minimum longitudinal size is determined by a sum of the corresponding longitudinal sizes of two adjacent circular bands **17** and a CLD (pos. **23**).

The proposed stent maximum longitudinal size corresponds to that of the working part of a conducting catheter balloon.

Fig. 13, 14 show a stent surface evolvent in which CDD (pos. **19**) rods' **21** lengths are consecutively decreased in a series of the disposed circular bands **17** from pos. **26** to pos. **27** of the stent **18**, before and after expansion correspondingly.

As a result of this, according to the expression (2) a stent with a cone-like outward surface is formed. Here, it is substantially important that when all the CDD (pos. **19**) rods **21** are in their undeformable, non-working position (before expansion), the stent outward surface is of a regular cylindrical shape. Only after stent **18** expansion to the maximum diameter D_{max} its outward surface takes the required cone-like shape (Fig. 14).

The proposed stent model has still another substantial feature. The diameter of a conditional stent, mounted on a uninflated balloon of a conducting catheter, can be inscribed in the diametrical sizes of a cylindrical net **28** (see Fig. 12) cell, the net **28** being formed after the stent expansion. This is achieved due to the possibility to vary the lengths of rods **21**, **24** of CDDs (pos. **19**) and CLDs (pos. **23**) respectively, which enables stent implantation into a bifurcating coronary artery.

Therefore, the proposed optimum stent mechanical model, featuring functional dynamical compatibility with the coronary artery parameters, is a breakthrough in effectiveness of coronary artery treatment, also enabling an essential increase of cardiovascular stents involvement into the most wide clinical practice.

Industrial applicability

The offered optimum stent mechanical model is a basis for design, production and application of a wide spectrum of cardiovascular samples. The model is recommended for bulk serial and massive production. A preferred mode of the optimum stent mechanical model production is described above. Still, the construction equivalent element can be improved without losing the invention advantages, formulated as follows.

What is claimed is:

The optimum stent mechanical model, comprising

1. a) A series of circular bands disposed over a common longitudinal axis, each comprising at least one diametrical deformation compensator (CDD) and one undeformable portion of circular surface; whereas said CDD is disposed parallel to said longitudinal axis of said series of circular bands and comprises at least two rods made in the lateral surface of said circular band, said rods are connected while their loose ends are closed by a undeformable portion of circular surface made in said lateral surface of said circular band;

b) at least one longitudinal deformation compensator (CLD) which embraces said adjacent circular bands; whereas said CLD is disposed in the intermediate zone between said adjacent circular bands perpendicularly to said longitudinal axis, comprising at least two rods, said rods are connected, their loose ends being closed by said undeformable portions of circular surface of said adjacent circular bands.

2. The optimum stent mechanical model as in claim **1**, wherein said circular band consists of said alternating CDD and said undeformable portions of circular surface, whereas said CDD rods are made identical in shape, relative disposition and geometrical sizes in said lateral surface of said circular band.

3. The optimum stent mechanical model as in claims **1, 2**, wherein said CDD rods are made different in shape, relative disposition and geometrical sizes in said lateral surface of said circular band.

4. The optimum stent mechanical model as in claim **1**, wherein said loose ends of said CDD rods are connected to the loose ends of said adjacent CDDs made in said lateral surface of said circular band.

5. The optimum stent mechanical model as in claims **1, 2, 3, 4**, wherein said CDDs and said CLDs are made in a whole slotted tube sample.

6. The optimum stent mechanical model as in claims **1, 2, 3, 4**, wherein said CDDs and said CLDs are made of a standard wire sample.

7. Optimum stent mechanical model as in claim **1**, wherein said CLDs are made of biologically compatible thread of temporary activity.

8. Optimum stent mechanical model as in claims **1, 2, 3, 4, 5, 6, 7** , wherein upon said stent expansion only said CDDs deform and alter their geometrical sizes,

- whereas calculation parameters of said circular band with said CDDs, each of which comprises two rods, are minimum D_{min} and maximum D_{max} diameters of said stent, calculated upon compression and stretching correspondingly of all said CDDs,calculated according to the following formulae:

$$D_{min} \approx \frac{2d}{\pi} \cdot n \qquad \text{and} \qquad D_{max} = \frac{\Sigma\, l_i}{\pi} \cdot n,$$

where **d** is a diameter of the circle inscribed into CDD rod section; **n** is the amount of CDD in a circular band; l_i is CDD rod length, and for a precisely measured stent

$$D_{max} \approx D_{ca},$$

where D_{ca} is a coronary artery inward surface diameter;

- whereas upon said stent maximum expansion, said circular band takes a shape approaching that of a round undeformable closed loop, equal in its diameter to that of said coronary artery inward surface D_{ca}, with said loop's width approaching that of said CDD rod;

- whereas the length of said rods of said CDD is decreased proportionally to said coronary artery inward surface diameter D_{ca} decrease;

- whereas a profile of said stent outward surface generatrix along said longitudinal axis is made in precise correspondence with the profile of the coronary artery inward surface, and in case of said inward coronary artery surface being conical, said stent outward surface generatrix decline magnitude along said longitudinal axis is regulated by altering the parameters l_i and **n** in the expression

$$D_{max} = \frac{\sum l_i}{\pi} \cdot n$$

9. The optimum stent mechanical model as in claims **1, 2, 3, 4, 5, 6, 7** , wherein upon said stent bending along said longitudinal axis, only said CLDs deform and alter the curve radius of said stent outward surface generatrix;

- whereas a calculation parameter of longitudinal mechanical compliance (flexibility) of said stent with said CLDs, each comprising two said rods, is a minimum curve radius R_2 of said outward surface generatrix of said stent, calculated as follows:

$$R_2 = \frac{D_{max} \cdot 2d}{2}, \quad \sum_{m=1} l_m - 2d$$

where $\mathbf{D_{max}}$ is the maximum diameter upon said stent expansion; **d** is a diameter of the circle inscribed into said CLD rod section; $\mathbf{l_m}$ is a said CLD rod length.

10. Optimum stent mechanical model as in claims **1, 2, 3, 4, 8, 9,** wherein upon said stent application to at least one of bifurcating arteries, said CDD and CLD rods' lengths are calculated in such a way that the diameter of a conditional stent, disposed over an uninflated balloon of a conducting catheter, could be inscribed into the cross-section of a cylindrical net cell, said net being formed after said stent expansion.

AMENDED CLAIMS

[received by the International Bureau on 13 June 1997 (13.06.97);
original claim 7 amended; remaining claims unchanged (1 page)]

7.Optimum stent mechanical model as in claim 1, wherein said CLDs are made of a biologically compatible tissue with a possibility of filling the said tissue with a regulated dose of medicinal preparations.

8. Optimum stent mechanical model as in claims **1, 2, 3, 4, 5, 6, 7** , wherein upon said stent expansion only said CDDs deform and alter their geometrical sizes,

- whereas calculation parameters of said circular band with said CDDs, each of which comprises two rods, are minimum D_{min} and maximum D_{max} diameters of said stent, calculated upon compression and stretching correspondingly of all said CDDs, calculated according to the following formulae:

$$D_{min} \approx \frac{2d}{\pi} \cdot n \qquad \text{and} \qquad D_{max} = \frac{\sum l_i}{\pi} \cdot n,$$

where **d** is a diameter of the circle inscribed into CDD rod section; **n** is the amount of CDD in a circular band; l_i is CDD rod length, and for a precisely measured stent

$$D_{max} \approx D_{ca},$$

where D_{ca} is a coronary artery inward surface diameter;

- whereas upon said stent maximum expansion, said circular band takes a shape approaching that of a round undeformable closed loop, equal in its diameter to that of said coronary artery inward surface D_{ca}, with said loop's width approaching that of said CDD rod;

- whereas the length of said rods of said CDD is decreased proportionally to said coronary artery inward surface diameter D_{ca} decrease;

- whereas a profile of said stent outward surface generatrix along said longitudinal axis is made in precise correspondence with the profile of the coronary artery inward surface, and in case of said inward coronary artery surface being conical, said stent outward surface generatrix decline magnitude along said longitudinal axis is regulated by altering the parameters l_i and **n** in the expression

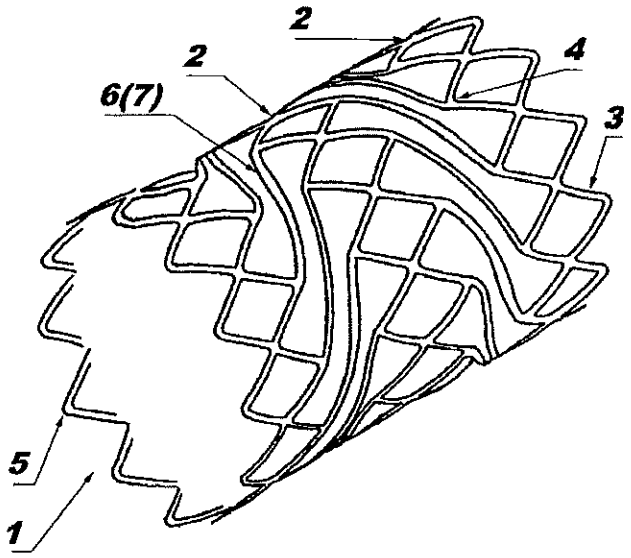


Fig.1

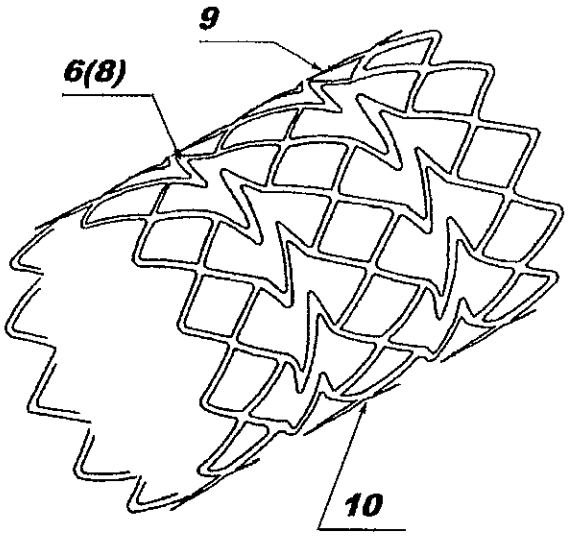


Fig.2

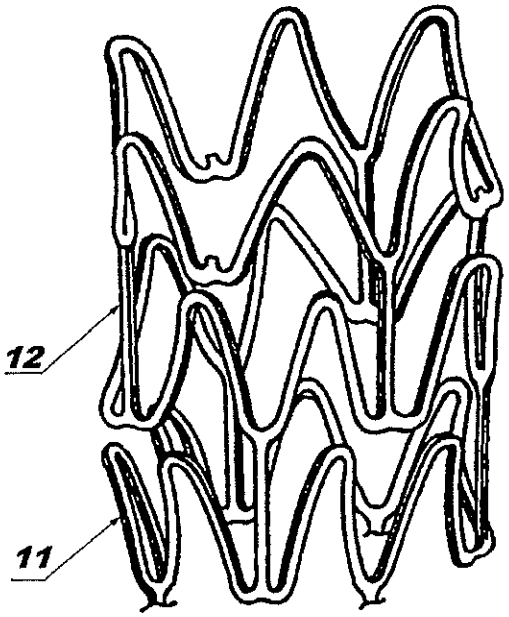


Fig.3

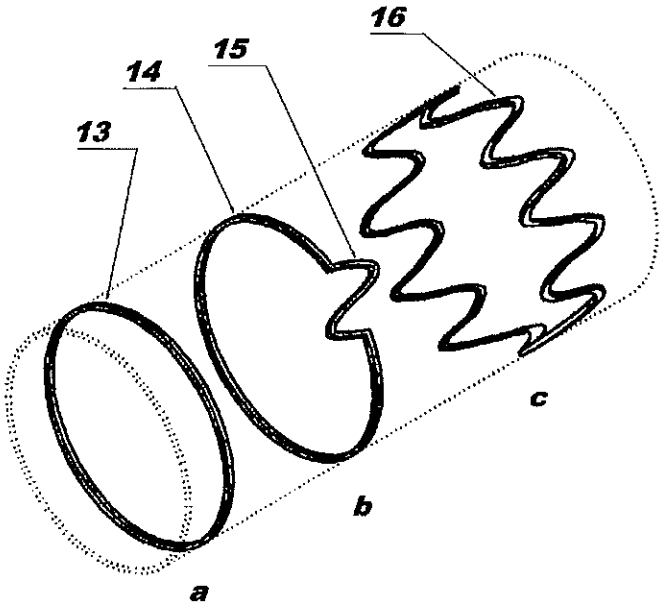


Fig.4

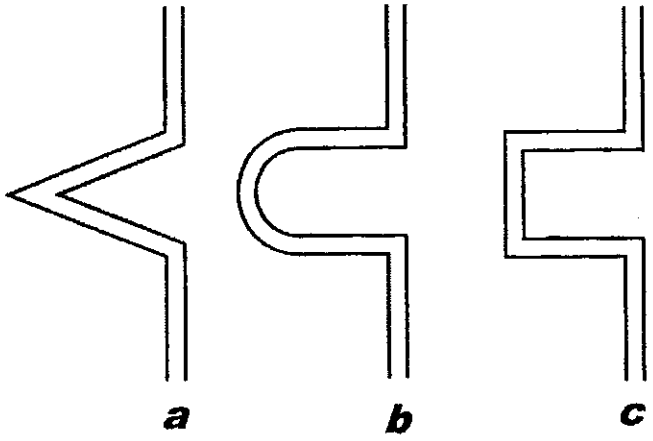
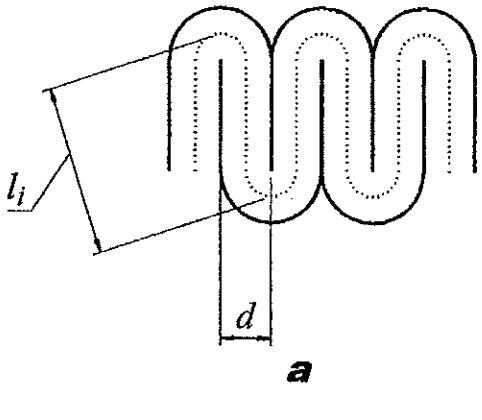


Fig.5



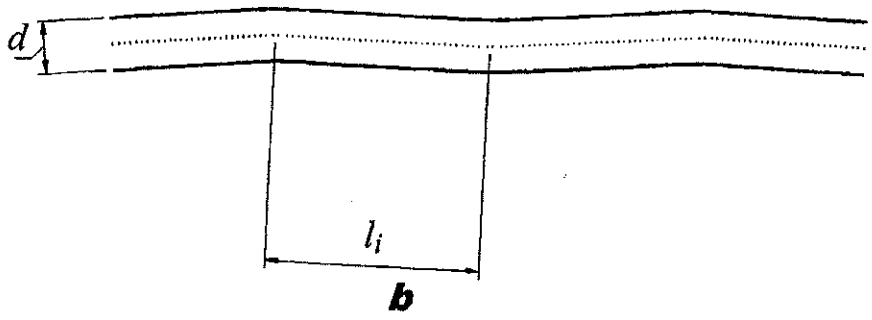


Fig.6

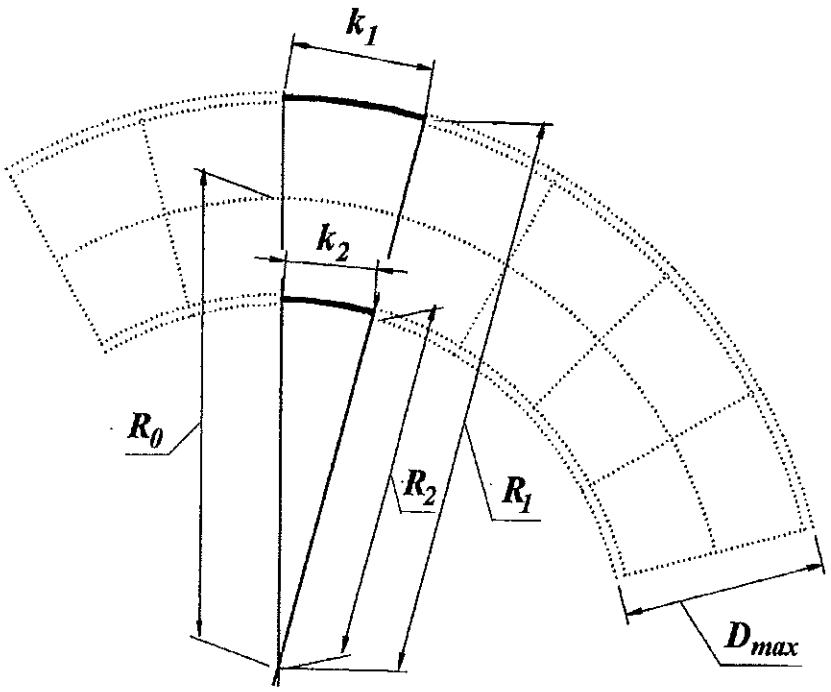


Fig.7

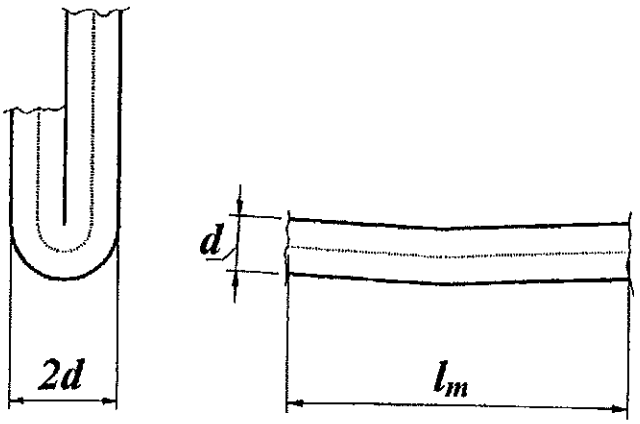


Fig.8

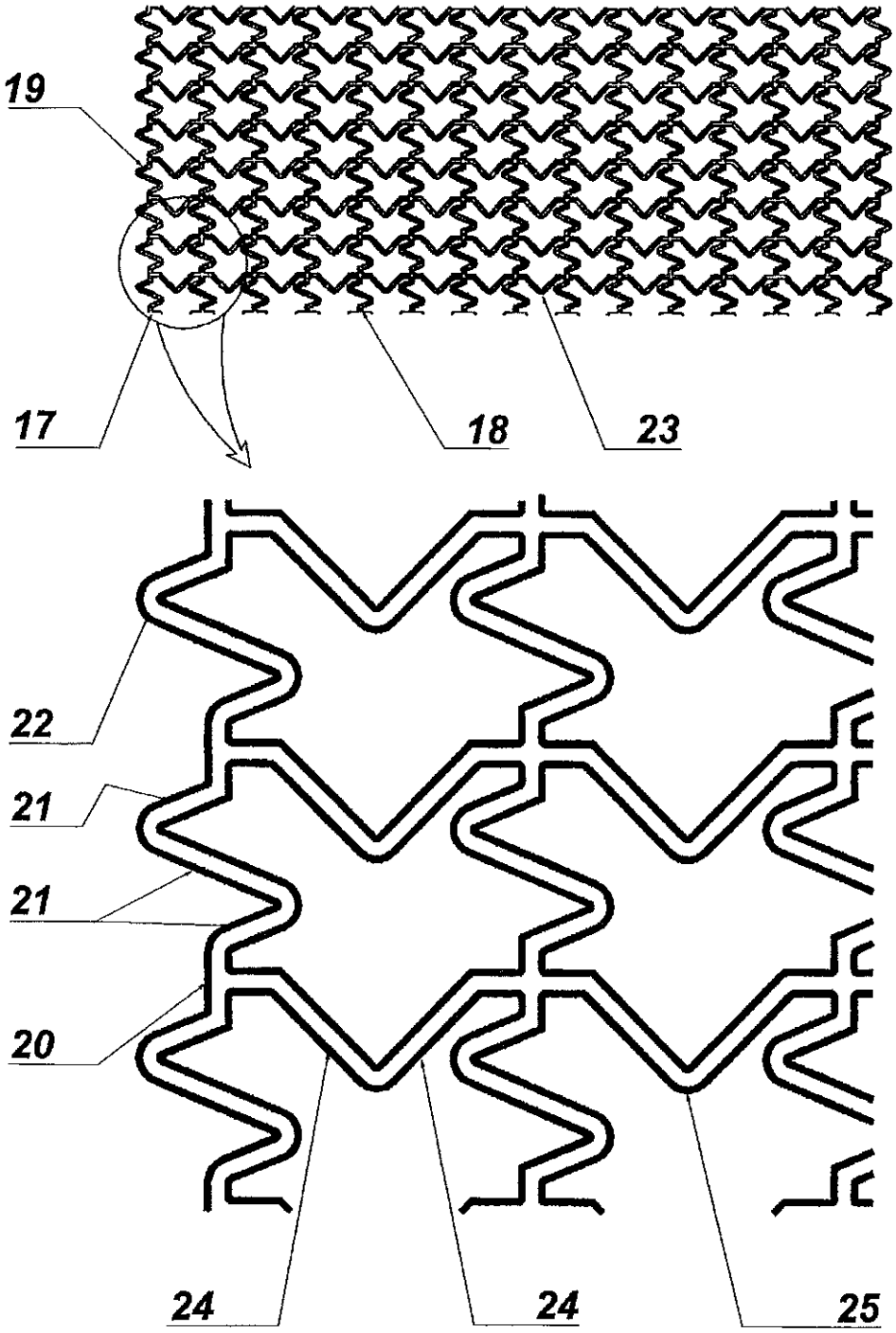


Fig.9

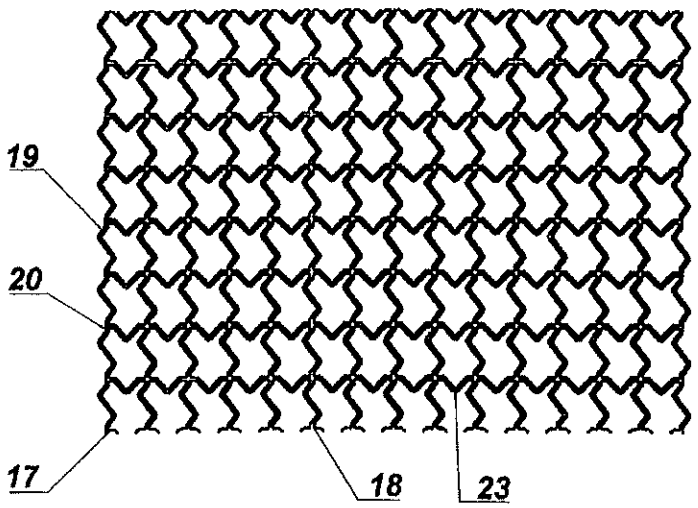


Fig.10

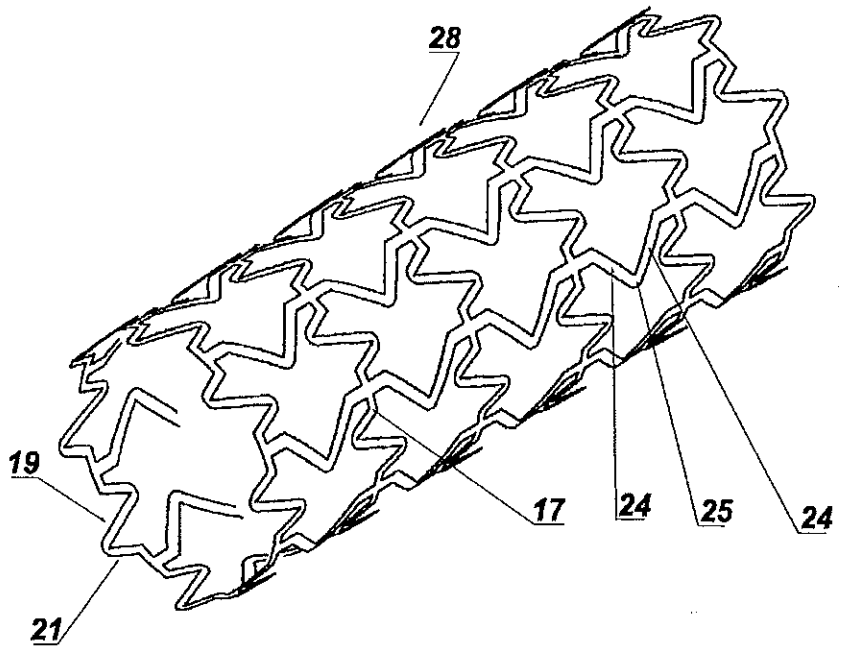


Fig.11

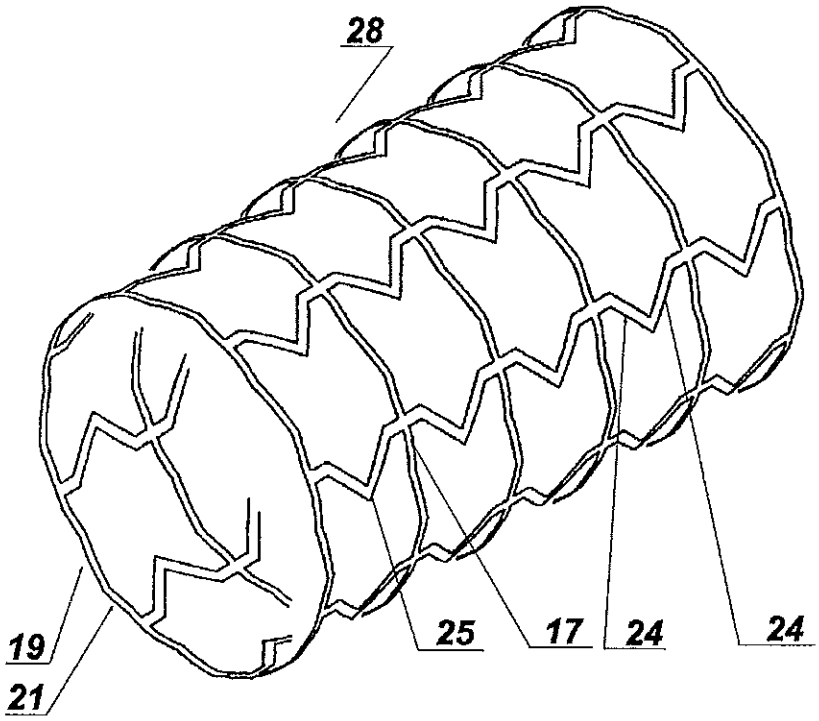


Fig.12

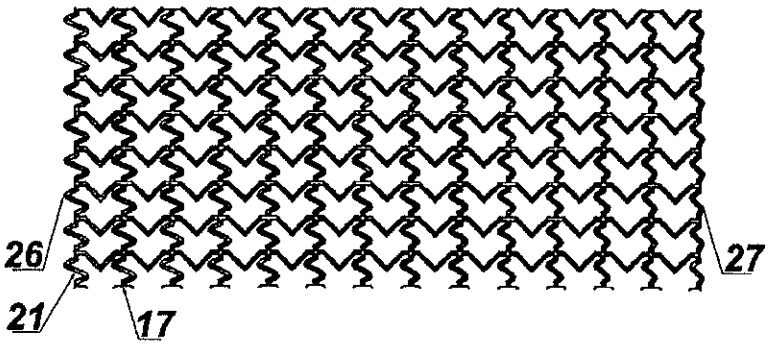


Fig.13

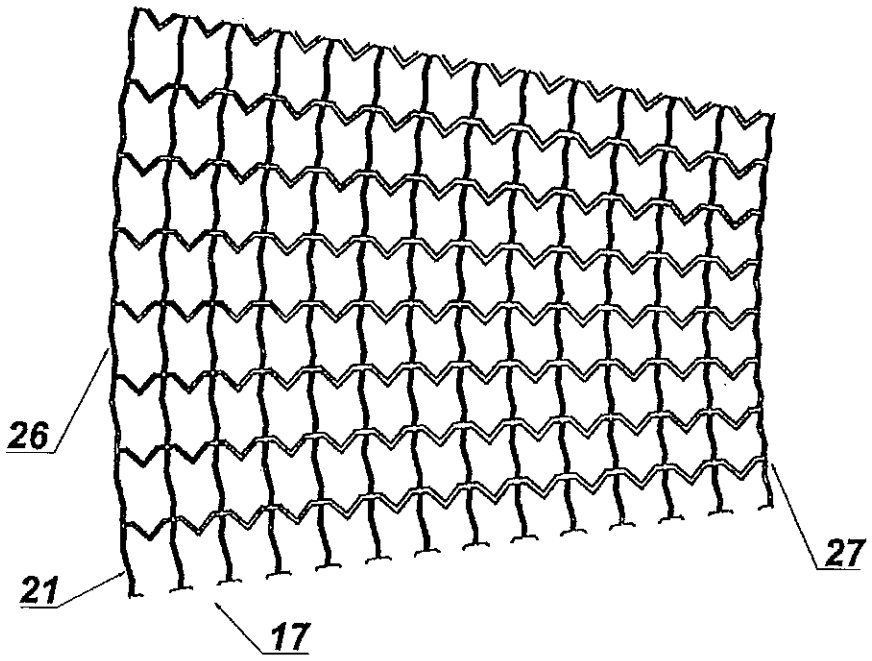


Fig.14

IM2

IMPLANTS INCLUDING FRACTAL STRUCTURES

TECHNICAL FIELD

[0001] This invention relates to implants, and more particularly to stents.

BACKGROUND

[0002] The body includes various passageways such as arteries, other blood vessels, and other body lumens. These passageways sometimes become occluded or weakened. For example, the passageways can be occluded by a tumor, restricted by plaque, or weakened by an aneurysm. When this occurs, the passageway can be reopened or reinforced, or even replaced, with a medical endoprosthesis. An endoprosthesis is typically a tubular member that is placed in a lumen in the body. Examples of endoprostheses include stents, covered stents, and stent-grafts.

[0003] Endoprostheses can be delivered inside the body by a catheter that supports the endoprosthesis in a compacted or reduced-size form as the endoprosthesis is transported to a desired site. Upon reaching the site, the endoprosthesis is expanded, for example, so that it can contact the walls of the lumen.

[0004] The expansion mechanism can include forcing the endoprosthesis to expand radially. For example, the expansion mechanism can include the catheter carrying a balloon, which carries a balloon-expandable endoprosthesis. The balloon can be inflated to deform and to fix the expanded endoprosthesis at a predetermined position in contact with the lumen wall. The balloon can then be deflated, and the catheter withdrawn.

[0005] In another delivery technique, the endoprosthesis is formed of an elastic material that can be reversibly compacted and expanded, e.g., elastically or through a material phase transition. During introduction into the body, the endoprosthesis is restrained in a compacted condition. Upon reaching the desired implantation site, the restraint is removed, for example, by retracting a restraining device such as an outer sheath, enabling the endoprosthesis to self-expand by its own internal elastic restoring force.

SUMMARY

[0006] An endoprosthesis is described that includes a member having a surface that includes a fractal structure.

[0007] A fractal structure includes a rough or fragmented geometric shape that can be subdivided in parts, each part being (at least approximately) a reduced-size copy of the rough or fragmented geometric shape. As used herein, the term "fractal structure" means a structure that includes similar structures at magnification factors of 1,000 and 10,000. In some embodiments, the fractal structure can have a surface area greater than 5 times the surface area of a smooth surface having the same dimensions. In some embodiments, the fractal structure can include a cauliflower-like structure. In some embodiments, the fractal structure can include nanopits.

[0008] In some embodiments, the member can include a bioerodable material (e.g., a bioerodable metal or a bioerodable polymer). The bioerodable metal can be magnesium, zinc, iron, or an alloy thereof. The bioerodable polymer can be polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), poly-L-lactide, poly-D-lactide, polyglycolide, poly(alpha-hydroxy acid), or combinations thereof.

[0009] In some embodiments, the member can include a non-biodegradable metal (e.g., stainless steels, platinum enhanced stainless steels, cobalt-chromium alloys, nickel titanium alloys, and combinations thereof).

[0010] In some embodiments, the surface that includes the fractal structure can be an outermost surface of the endoprosthesis. In other embodiments, the endoprosthesis can further include a second material overlying the fractal structure. For example, the second material can be a tie layer, a biocompatible coating, a drug-eluting layer, a radiopaque metal or alloy, or a combination thereof.

[0011] The endoprosthesis may be provided in the form of a stent. For example, the endoprosthesis can be a bioerodable stent including a bioerodable member having a surface having a fractal structure, where the surface includes iron or an alloy thereof.

[0012] An implant is also described that includes a bioerodable material having a surface that includes a fractal structure. For example, the implant can be in the form of a stent, a cochlear implant, a bone screw, a neuron aneurysm coil, a septal defect plug, a venous valve support structure, a pacing lead, a spinal implant support structure, a hip replacement joint, or a inter uterine implant.

[0013] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features, objects, and advantages will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

[0014] FIG. **1**. illustrates an exemplary stent.

[0015] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0016] Referring to FIG. **1**, a stent **20** can have the form of a tubular member defined by a plurality of bands **22** and a plurality of connectors **24** that extend between and connect adjacent bands. During use, bands **22** can expand from an initial, small diameter compressed state to a larger diameter to contact the stent **20** against a wall of a vessel, thereby maintaining the patency of the vessel. Connectors **24** can provide stent **20** with flexibility and conformability that allow the stent to adapt to the contours of the vessel.

[0017] The stent **20** can include a surface that has a fractal structure, as described in the Summary, above. By providing a fractal structure to the surface of a stent, the surface area of the stent can be increased. In some embodiments, the fractal structure can have a surface area greater than 5 times the surface area of a smooth surface having the same dimensions.

[0018] The fractal structure on the surface of stent **20** can include a number of fractal structures. For example, the fractal structure can include a cauliflower-like structure at magnification factors of at least 1,000 and 10,000. In some embodiments, the fractal structure can include nanopits. For example, each nanopit can include nanopit walls including smaller nanopits having a similar structure to the larger nanopit, but on a smaller scale. The fractal structure geometry can be tailored to almost any shape/structure that is desired. It can be made to match the stent geometry or it can be made not to match.

[0019] Stent **20** can, in some embodiments, include a bioerodable material (e.g., a bioerodable metal or a bioerodable polymer). A bioerodable metal can include magnesium, zinc, iron, or an alloy thereof. In some embodiments, the bioerodable material can be a metallic iron or an alloy thereof (e.g., Fe-35Mn). For example, an iron stent having an outermost surface having a fractal structure could allow for a faster erosion rate. The bioerodable material can also be a bioerodable polymer such as polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), poly-L-lactide, poly-D-lactide, polyglycolide, poly(alpha-hydroxy acid), or combinations thereof.

[0020] Stent **20** can, in some embodiments, include non-biodegradable materials, such as stainless steels, platinum enhanced stainless steels, cobalt-chromium alloys, nickel titanium alloys, or a combination thereof. In some embodiments, stent **20** can include bioerodable and non-bioerodable portions.

[0021] Stent **20** can include a uniform distribution of fractal structures. For example, an iron stent body can include a uniform distribution of fractal structures over its entire surface. In other embodiments, stent **20** can include the fractal structure on only an abdominal surface.

[0022] Stent **20** can, in some embodiments include regions of preferred erosion. For example, the stent **20** can include select bands **22** or connectors **24**, or portions thereof, that include the fractal structure, while the remaining surfaces are smooth. In other embodiments, every surface of the stent body can include the fractal structures, but select bands and/or connectors can include an outer coating to delay the erosion of those select bands and/or connectors.

[0023] Stent **20** can, in some embodiments, include a layer of a second material overlying the surface. The layer of second material can overlie at least a portion of the fractal structure. The layer of the second material can be, for example, a tie layer, a biocompatible outer coating, a radiopaque metal or alloy, and/or a drug-eluting layer. Drug eluting layers can be made of biodegradable polymer coatings such as polyesters, polyamide, polyanhidrides, polysaccharides, examples such as PLGA, PLA, Chitosan. Also biological polymers based on rproteins, peptides and amino acids are an option. Besides polymers one can use biodegradable ceramics based on phosphates. For example, a stainless steel stent surface can include a fractal structure and include a layer of a drug-eluting polymer coating over the fractal structure. The presence of the fractal structure could improve the adhesion of a drug-eluting coating to a stainless steel stent surface.

[0024] A fractal structure can be formed on a surface of a stent by a number of suitable deposition or patterning treatments, such as plasma enhanced physical vapor deposition, laser etching, and/or chemical etching. By using these processes in a way that reiterates the basic surface structure, a fractal structure can be produced. For example, in plasma-enhanced physical vapor deposition, argon ions from a plasma are accelerated in a high vacuum apparatus by an outside electrical field towards a cathode made of the coating material (e.g., Iron). Single cathode atoms (e.g., iron atoms) can then be sputtered away by the incident argon ions and be deposited on the surface of a stent. By limiting diffusion during the plasma-enhanced physical vapor deposition process, a fractal structure can be obtained.

[0025] For example, a fractal surface produced by a diffusion limited plasma-enhanced physical vapor deposition process can have a cauliflower-like appearance at a variety of magnification factors (e.g., at magnification factors between 1,000 and 10,000). An example of a fractal structure having a cauliflower-like structure at both magnification factors of 1,000 and 16,000 can be found in FIGS. 3 and 4 of Schaldach et al., Journal of Material Sciences, Materials in Medicine, 6 (1995) 844.

[0026] Chemical etching can also be used to produce a fractal structure, e.g., a fractal structure of nanopits. An example of a chemically etched fractal structure of nanopits is shown in FIG. **5**B of Yi et al., Surface Science 600, 2006, 4613.

[0027] Stents **10** can be of any desired shape and size (e.g., superficial femoral artery stents, coronary stents, aortic stents, peripheral vascular stents, gastrointestinal stents, urology stents, and neurology stents). Depending on the application, the stent can have a diameter of between, for example, 1 mm to 46 mm. In certain embodiments, a coronary stent can have an expanded diameter of from 2 mm to 6 mm. In some embodiments, a peripheral stent can have an expanded diameter of from 5 mm to 24 mm. In certain embodiments, a gastrointestinal and/or urology stent can have an expanded diameter of from 6 mm to about 30 mm. In some embodiments, a neurology stent can have an expanded diameter of from about 1 mm to about 12 mm. An abdominal aortic aneurysm (AAA) stent and a thoracic aortic aneurysm (TAA) stent can have a diameter from about 20 mm to about 46 mm.

[0028] In use, a stent can be used, e.g., delivered and expanded, using a catheter delivery system. Catheter systems are described in, for example, Wang U.S. Pat. No. 5,195,969, Hamlin U.S. Pat. No. 5,270,086, and Raeder-Devens, U.S. Pat. No. 6,726,712. Stents and stent delivery are also exemplified by the Sentinol® system, available from Boston Scientific Scimed, Maple Grove, Minn.

[0029] In some embodiments, stents can also be a part of a covered stent or a stent-graft. In other embodiments, a stent can include and/or be attached to a biocompatible, non-porous or semi-porous polymer matrix made of polytetrafluoroethylene (PTFE), expanded PTFE, polyethylene, urethane, or polypropylene.

[0030] In some embodiments, stents can also include a releasable therapeutic agent, drug, or a pharmaceutically active compound, such as described in U.S. Pat. No. 5,674,242, U.S. Ser. No. 09/895,415, filed Jul. 2, 2001, and U.S. Ser. No. 10/232,265, filed Aug. 30, 2002. The therapeutic agents, drugs, or pharmaceutically active compounds can include, for example, anti-thrombogenic agents, antioxidants, anti-inflammatory agents, anesthetic agents, anti-coagulants, and antibiotics.

[0031] In some embodiments, stents can be formed by fabricating a wire including a fractal structure, and knitting and/or weaving the wire into a tubular member. In some embodiments, medical implants other than stents include a fractal structure. Such medical implants can include cochlear implants, septal defect device plugs, AAA graph attachment stents, bone screws, Neuro aneurysm coils, venous valve support structures, heart valve support structure, placing leads, spinal implant support cages, hip replacement joints, inter uterine implants (e.g., for birth control). These medical implants can be formed of a bioerodable metal. The bioerodable metal can be magnesium, iron, zinc, or an alloy thereof. In some embodiments, the bioerodable metal can be a metal-

lic iron or alloy thereof. For example, a medical implant could include an iron portion having an outermost surface having a fractal structure.

[0032] Furthermore, polymeric stents can also include a fractal structure to accelerate the degradation.

[0033] All publications, references, applications, and patents referred to herein are incorporated by reference in their entirety.

[0034] Other embodiments are within the claims.

What is claimed is:

1. An endoprosthesis comprising a member having a surface that includes a fractal structure.

2. The endoprosthesis of claim 1, wherein the member comprises a bioerodable material.

3. The endoprosthesis of claim 1, wherein the member comprises a bioerodable metal.

4. The endoprosthesis of claim 3, wherein the bioerodable metal comprises magnesium, zinc, iron, or an alloy thereof.

5. The endoprosthesis of claim 3, wherein the member comprises iron or an alloy thereof.

6. The endoprosthesis of claim 1, wherein the member comprises a bioerodable polymer.

7. The endoprosthesis of claim 6, wherein the bioerodable polymer is selected from the group consisting of polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), poly-L-lactide, poly-D-lactide, polyglycolide, poly(alpha-hydroxy acid), and combinations thereof.

8. The endoprosthesis of claim 1, wherein the member comprises a non-biodegradable metal selected from the group consisting of stainless steels, platinum enhanced stainless steels, cobalt-chromium alloys, nickel titanium alloys, and combinations thereof.

9. The endoprosthesis of claim 1, wherein the surface is an outermost surface of the endoprosthesis.

10. The endoprosthesis of claim 1, further comprising a second material overlying the surface.

11. The endoprosthesis of claim 10, wherein the second material is selected from the group consisting of a tie layer, a biocompatible coating, a drug-eluting layer, a radiopaque metal or alloy, and combinations thereof.

12. The endoprosthesis of claim 11, wherein the second material is a drug-eluting layer.

13. The endoprosthesis of claim 1, wherein the fractal structure comprises a surface area that is greater than 5 times the surface area of a smooth surface having the same dimensions.

14. The endoprosthesis of claim 1, wherein the fractal structure comprises a cauliflower-like structure.

15. The endoprosthesis of claim 1, wherein the fractal structure comprises nanopits.

16. The endoprosthesis of claim 1, wherein the endoprosthesis is a stent.

17. An implant comprising:

a bioerodable material having a surface that includes a fractal structure.

18. The implant of claim 17, wherein the bioerodable material comprises iron or an alloy thereof.

19. The implant of claim 17, wherein the fractal structure comprises a surface area that is greater than 5 times the surface area of a smooth surface having the same dimensions.

20. The implant of claim 17, wherein the fractal structure comprises a cauliflower-like structure.

21. The implant of claim 17, wherein the fractal structure comprises nanopits.

22. The implant of claim 17, wherein the implant is selected from the group consisting of stents, cochlear implants, bone screws, neuron aneurism coils, septal defect plugs, venous valve support structures, pacing leads, spinal implant support structures, hip replacement joints, and inter uterine implants.

23. The implant of claim 17, wherein the implant is a stent.

24. A bioerodable stent comprising:

a bioerodable member that includes a surface having a fractal structure, the surface comprising iron or an alloy thereof.

25. The bioerodable stent of claim 24, wherein the fractal structure comprises a surface area that is greater than 5 times the surface area of a smooth surface having the same dimensions.

26. The bioerodable stent of claim 24, wherein the fractal structure comprises cauliflower-like structure.

27. The bioerodable stent of claim 24, wherein the fractal structure comprises nanopits.

28. The bioerodable stent of claim 24, wherein the surface is an outermost surface of the stent.

* * * * *

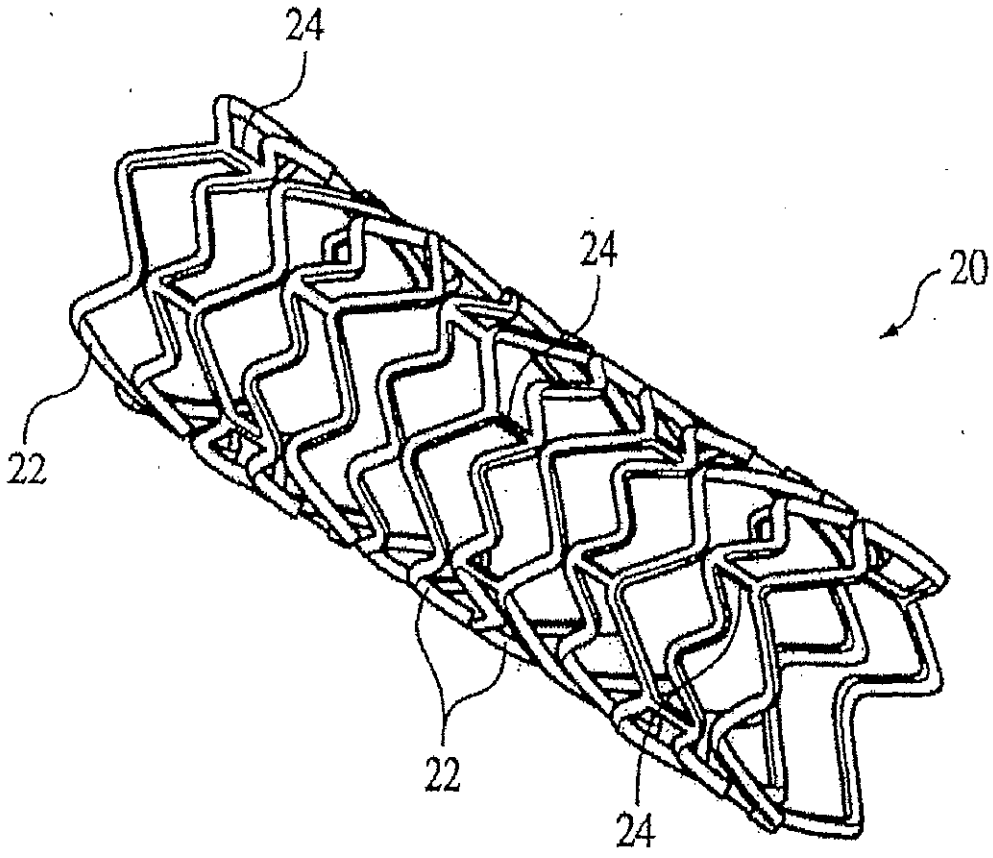


FIG. 1

IM3

LOW PRESSURE STENT

This is a continuation-in-part application of co-pending U.S. Patent Application Serial entitled "Method for Manufacturing a Stent." The contents of the application identified in this paragraph, are incorporated herein by reference.

FIELD OF THE INVENTION

In general, the present invention relates to percutaneous transluminal devices and methods which are used to treat obstructed (sclerotic) vessel lumina in humans. In particular, the present invention is an improved stent that requires low expansion pressure for deployment and improved embedding of the struts within the vessel wall.

BACKGROUND OF THE INVENTION

Cardiovascular disease is commonly accepted as being one of the most serious health risks facing our society today. Diseased and obstructed coronary arteries can restrict the flow of blood and cause tissue ischemia and necrosis. While the exact etiology of sclerotic cardiovascular disease is still in question, the treatment of narrowed coronary arteries is more defined. Surgical construction of coronary artery bypass grafts (CABG) is often the method of choice when there are several diseased segments in one or multiple arteries. Conventional open heart surgery is, of course, very invasive and traumatic for patients undergoing such treatment. In many cases, less traumatic, alternative methods are available for treating cardiovascular disease percutaneously. These alternate treatment methods generally employ various types of balloons (angioplasty) or excising devices (atherectomy) to remodel or debulk diseased vessel segments. A further alternative treatment method involves percutaneous, intraluminal installation of one or more expandable, tubular stents or prostheses in sclerotic lesions. Intraluminal endovascular prosthetic grafting is an alternative to conventional vascular surgery. Intraluminal endovascular grafting involves the percutaneous insertion into a blood vessel of a tubular prosthetic graft and its delivery via a catheter to the desired location within the vascular system. The alternative approach to percutaneous revascularization is the surgical placement of vein, artery, or other by-pass

segments from the aorta onto the coronary artery, requiring open heart surgery, and significant morbidity and mortality. Advantages of the percutaneous revascularization method over conventional vascular surgery include obviating the need for surgically exposing, removing, replacing, or by-passing the defective blood vessel, including heart-lung by-pass, opening the chest, and general anesthesia.

Stents or prostheses are known in the art as implants which function to maintain patency of a body lumen in humans and especially to such implants for use in blood vessels. They are typically formed from a cylindrical metal mesh which expand when internal pressure is applied. Alternatively, they can be formed of wire wrapped into a cylindrical shape. The present invention relates to an improved stent design which by its specifically configured struts can facilitate the deployment and embedment of the stent within a vessel and is constructed from a manufacturing process which provides a controlled and superior stress yield point and ultimate tensile characteristics.

Stents or prostheses can be used in a variety of tubular structures in the body including, but not limited to, arteries and veins, ureters, common bile ducts, and the like. Stents are used to expand a vascular lumen or to maintain its patency after angioplasty or atherectomy procedures, overlie an aortic dissecting aneurysm, tack dissections to the vessel wall, eliminate the risk of occlusion caused by flaps resulting from the intimal tears associated with primary interventional procedure, or prevent elastic recoil of the vessel.

Stents may be utilized after atherectomy, which excises plaque, cutting balloon angioplasty, which scores the arterial wall prior to dilatation, or standard balloon angioplasty to maintain acute and long-term patency of the vessel.

Stents may be utilized in by-pass grafts as well, to maintain vessel patency. Stents can also be used to reinforce collapsing structures in the respiratory, biliary, urological, and other tracts.

Further details of prior art stents can be found in U.S. Pat. No. 3,868,956 (Alfidi et. al.); U.S. Pat. No. 4,739,762 (Palmaz); U.S. Pat. No. 4,512,338 (Balko et. al.); U.S. Pat. No. 4,553,545 (Maass et. al.); U.S. Pat. No. 4,733,665 (Palmaz); U.S. Pat. No. 4,762,128 (Rosenbluth); U.S. Pat. No. 4,800,882 (Gianturco); U.S. Pat. No. 4,856,516 (Hillstead); U.S. Pat. No. 4,886,062 (Wiktor); U.S. Pat. No. 5,102,417 (Palmaz); U.S. Pat. No. 5,104,404 (Wolff); U.S. Pat. No. 5,192,307 (Wall); U.S. Pat. No. 5,195,984 (Schatz); U.S. Pat. No. 5,282,823 (Schwartz et. al.); U.S. Pat. No. 5,354,308 (Simon et. al.); U.S. Pat. No. 5,395,390 (Simon et. al), U.S. Pat. No. 5,421,955 (Lau et. al.); U.S. Pat. No. 5,443,496 (Schwartz et. al.); U.S. Pat. No. 5,449,373 (Pinchasik et. al.); U.S. Pat. No. 5,102,417 (Palmaz); U.S. Pat. No. 5,514,154 (Lau et. al); and U.S. Pat. No. 5,591,226 (Trerotola et. al.).

In general, it is an object of the present invention to provide a stent or prosthesis which can be readily expanded and embedded into an obstruction or vessel wall with low dilatation pressure thereby minimizing the trauma and damaged imparted to the vessel wall during deployment of the stent.

It is also an object of the present invention to utilize a specifically designed configuration of the outer strut surface to facilitate embedment of the stent structure into the obstruction and vessel wall with low dilatation pressure.

Another object of the present invention is to employ a manufacturing process which optimizes the stress-strain curve characteristics that achieves an increased yield strength and ultimate tensile strength when compared to the other non-wire prior art stents.

SUMMARY OF THE INVENTION

The present invention is directed to an expandable stent which is relatively flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but which is stiff and stable enough radially in an expanded condition to maintain the patency of a body lumen such as an artery when implanted therein. In addition, the struts of the present

invention have a specific trapezoidal, triangular or reduced radii configuration projecting radially outward that functions to reduce the forces necessary to penetrate the vessel wall with the stent thereby minimizing trauma or damage imparted to the wall during deployment.

The invention generally includes a plurality of radially expandable loop elements which are relatively independent in their ability to expand and to flex relative to one another. The individual radially expandable elements of the stent (cross-section of a strut) are dimensioned such that the aspect ratio of the height to width minimizes twisting or rotation during expansion. Interconnecting elements or a backbone extends between the adjacent loop elements to provide increased stability and a preferable position for each loop to prevent warping of the stent upon the expansion thereof. The resulting stent structure is a series of radially expandable loop elements which are spaced longitudinally close enough so that the obstruction, vessel wall and any small dissections located at the treatment site of a body lumen may be dilated or pressed back into position against the lumenal wall. The outward projecting strut surface converges towards the terminal end and is configured in a trapezoidal, triangular or rounded shape to facilitate embedment of the strut into the vessel wall utilizing low dilatation pressure. The individual loop elements may bend relative to adjacent loop elements without significant deformation, cumulatively providing a stent which is flexible along its length and about its longitudinal axis but is still very stiff in the radial direction in order to resist collapse.

The presently preferred structure for the expandable loop elements which form the stent of the present invention are generally a circumferential undulating or alternating loop pattern which comprises one of the radially expandable cylindrical elements. The transverse cross-section of the undulating component of the loop element preferably has an aspect ratio of about one to one (base to height) thereby minimizing any tendency of the strut to twist when expanded. The open reticulated structure of the stent allows for a large portion of the vascular wall to be exposed to blood which can improve the healing and repair of any damaged vessel lining.

The radial expansion of the expandable cylinder deforms the undulating or alternating loop pattern thereof similar to changes in a waveform which result from decreasing the waveform's amplitude and the frequency. Preferably, the undulating or alternation patterns of the individual loop structures are in phase with each other in order to yield uniform expansion and inhibit any crimping along its length. The expandable cylindrical structures of the stent are plastically deformed when expanded so that the stent will remain in the expanded condition and therefore they must be sufficiently rigid when expanded to prevent the compression of the struts and therefore partial or total collapse of the stent after deployment. The manufacturing process of the present stent invention utilizes optimized stress-strain curve characteristics to achieve, unlike other non-wire stent designs, improved mechanical properties throughout the stent. The optimized stress-strain curve increases both the yield strength and the ultimate tensile strength of the expanded stent increasing its resistance to structural failure (fracture) or stent crushing. During expansion of the stent, the radially projecting trapezoidal, triangular or reduced radii configuration of the struts outer surface will penetrate the obstruction and vessel wall. Due to the reduced area of the outer surface, the struts are able to pierce an obstruction or the vessel wall with relative easy thereby resulting in minimal trauma or damage to the vessel wall. In addition, this design feature of the present invention helps secure the expanded stent so that it does not move once it is implanted and furthermore, minimizes projections into the blood stream.

The elongated elements which interconnects adjacent radially expandable elements should have a transverse cross-section similar to the transverse dimensions of the undulating or alternation loop components of the radially expandable element. The interconnecting elements preferably are not a unitary structure but rather alternates sectionally along the length at various degrees around the circumference of the stent. In an alternate embodiment, the interconnecting element is a unitary structure which resembles a backbone connecting the expandable loop elements.

In a presently preferred embodiment of the invention, the stent is conveniently and easily formed by first heat-treating the mechanically hardened tubular member to achieve optimum stress-strain characteristics e.g. yield strength, elongation and ultimate tensile

strength. Then, the tubular member, comprising stainless steel, platinum, gold alloy, or a gold/platinum alloy, is electro-cleaned with an appropriate solution. Once the tubular member is cleansed of contaminates, the outer surface is uniformly coated with a photo-sensitive resist. Optionally, a coupling agent may be used to facilitate the bonding of the photosensitive resist to the tubular member. The coupling agent is not essential in that some tubular member compositions bond directly to the photo-sensitive resist solution without the need for a coupling agent.

This coated tubular member is then placed in an apparatus designed to rotate the tubular member while the coated tubular member is exposed to a designated pattern of ultraviolet (UV) light. The apparatus controls the exposure of the coated tubular member by utilizing a photographic film with a specified computer generated imprinted configuration, transferring the UV light in the specified pattern to the coated tubular member. The UV light activates the photosensitive resist causing the areas where UV light is present to expose (cross-link) the photo-sensitive resist. The photo-sensitive resist forms cross links where is it exposed to the UV light thus forming a pattern of hardened and cured polymer which mimics the particular stent design surrounded by uncured polymer. The film is adaptable to virtually an unlimited number of intricate stent designs. The process from the apparatus results in the tubular member having a discrete pattern of exposed photo-sensitive material with the remaining areas having unexposed photo-sensitive resist.

The exposed tubular member is immersed in a negative resist developer for a specified period of time. The developer removes the relatively soft, uncured photo-sensitive resist polymer and leaves behind the cured photo-sensitive resist which mimics the stent pattern. Thereafter, excess developer is removed from the tubular member by rinsing with an appropriate solvent. At this time, the entire tubular member is incubated for a specified period of time, allowing the remaining photo-sensitive resist polymer to fully cure and bond to the surface of the processed tubular member.

The processed tubular member is then exposed to a electrochemical etching process which removes uncovered metal from the tubular member, resulting in the final tubular

member or stent configuration. Since the tubular member has not been subjected to any process such as additional heat treatments, welding/brazing or laser cutting, the finished stent will maintain the optimized stress-strain characteristics obtained in the initial heat-treatment process.

The stent embodying features of the invention can be readily delivered to the desired lumenal location by mounting it on an expandable member of a delivery catheter, for example, a balloon or mechanical dilatation device, and passing the catheter/stent assembly through the body lumen to the site of deployment.

Other features and advantages of the present invention will become more apparent from the following detailed description of the invention. When taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view of a stent embodying features of the invention which is mounted on a delivery catheter and disposed within an arterial segment.

FIG. 2 is a plan view illustration of one frame of film with a stent configuration of the present invention imprinted on the film.

FIG. 3 is a plan view illustration of one frame of film with a stent configuration of another embodiment of the present invention imprinted on the film showing the single backbone connecting element.

FIG. 4 is a perspective view of a entire stent embodying features of the invention in an unexpanded state.

FIG. 5 is a perspective view of one stent configuration, showing the position and relationship of the loop or struts with the connecting elements.

FIG. 6A is a cross-sectional view of one configuration of the outer surface of a strut as seen along line 4-4 in Figure 4 showing a trapezoidal protruding configuration that is directed radially from the longitudinal axis of the stent.

FIG. 6B is a cross-sectional view of another configuration of the outer surface of a strut as seen along line 4-4 in Figure 4 showing a triangular protruding configuration that is directed radially from the longitudinal axis of the stent.

FIG 6C is a cross-sectional view of another configuration of the outer surface of a strut as seen along line 4-4 in Figure 4 showing a protrusion with a reduced radius that is directed radially from the longitudinal axis of the stent.

FIG. 7A is an enlarged partial view of one loop or strut of the stent of Figure 4 showing a trapezoidal protruding configuration that is directed radially from the longitudinal axis of the stent.

FIG. 7B is an enlarged partial view of one loop or strut of the stent of Figure 4 showing a triangular protruding configuration that is directed radially from the longitudinal axis of the stent.

FIG. 7C is an enlarged partial view of one loop or strut of the stent of Figure 4 showing a protrusion with a reduced radius that is directed radially from the longitudinal axis of the stent.

FIG. 8A is a cross-sectional view showing the trapezoidal configured strut scoring and penetrating an obstruction within in an arterial wall.

FIG. 8B is a cross-sectional view showing the triangular configured strut scoring and penetrating an obstruction within in an arterial wall.

FIG. 8C is a cross-sectional view showing the reduced radius configured strut scoring and penetrating an obstruction within in an arterial wall.

FIG. 9A is an elevational view, partially in section, similar to that shown in FIG. 1 wherein the stent is collapsed upon the delivery catheter within the arterial segment, and just proximal to a vascular obstruction.

FIG. 9B is an elevational view, partially in section, similar to that shown in FIG. 1 wherein the stent, in its collapsed configuration, is positioned within the vascular obstruction.

FIG. 9C is an elevational view, partially in section, similar to that shown in FIG. 1 wherein the stent is expanded within the vascular segment and embedding the specifically configured struts of the stent against and into the arterial wall.

FIG. 9D is an elevational view, partially in section, similar to that shown in FIG. 1 wherein the delivery catheter has been withdrawn and the stent is fully deployed within the vascular segment.

FIG. 10 is an illustration of a single strut or loop in both the unexpanded and expanded configurations demonstrating the amount of optimized stress-strain characteristics obtained upon deployment of prior art non-wire stents.

FIG. 11 is an illustration of a single strut or loop in both the unexpanded and expanded configurations demonstrating the amount of optimized stress-strain characteristics obtained upon deployment of the present invention stent.

FIG. 12 is an representation of the stress-strain curve showing the relative ultimate tensile of the prior art stents versus the present invention stent.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 illustrates a stent 10 incorporating features of the invention which is mounted onto a delivery catheter 11 threaded over guidewire 20. The delivery catheter 11 has an expandable portion or balloon 14 for expanding of the stent 10 within an artery 21. The delivery catheter 11 onto which the stent 10 is mounted, is essentially the same as a conventional balloon dilatation catheter for angioplasty procedures or may consist of a mechanical dilatation device. The balloon 14 may be formed of suitable materials such as polyethylene, polyethylene terephthalate (PET) or polyethylene napthalate (PEN). In order for the stent 10 to remain stationary on the balloon 14 during delivery to the site of the obstruction within the artery 21, the stent 10 is generally collapsed onto the balloon.

FIG. 2 shows a preferred stent configuration imprinted on a transparent photographic film. The drawing of the pattern is generated on a computer program, reduced and printed onto a transparent film. For example, a mechanical drawing or stress analysis program can be used to develop the computer generated printouts. The printout is then sent to a film processing facility which reduces the printout and generates a precisely dimensioned negative. As discussed in more detail below, the dimensions of the negative must be calibrated to render a specific stent design. Because of regulations concerning patent drawings which prohibits large blackened areas, an explanation of the drawings used to represent the photographic film is necessary. In FIG. 2, the open (transparent) spaces 38 which allow the UV light to pass through the film are represented as solid black lines (with white cores) which comprise a series of alternating loops 15. The alternating loop of the film 32 create the struts 50 which circumferentially comprise the expandable cylindrical elements 12 of stent 10 as shown in FIG. 5. Similarly, the linear sections 36 connecting the alternating or undulating patterns comprise the interconnecting elements 32 of stent 10 (FIG. 5). The white areas 40 of the FIG. 2 represent the exposed (black) areas of the film which will block the UV light from passing through the film and exposing the underlying areas to UV. An example of a suitable film that can be employed in the present invention is Kodak ALI-4 Accumax film made by Kodak Industries. The length 30 of stent imprint is directly

equal (1 to 1) to the circumference of present stent invention. The width 35 is equivalent to the working length of the processed stent.

FIG. 3 illustrates another embodiment of the present stent invention wherein linear section(s) 36 (which become the interconnecting elements) are disposed between alternating loops 32 (which become the radially expandable cylindrical elements) in different configurations. In FIG. 3, the resulting configuration of the stent from the imprinted film will have a single connection backbone 52. The single interconnecting element represents a backbone 52 connecting the radially expandable cylindrical elements 12 of stent 10. Not shown but contemplated in the present invention, the interconnecting elements 34 may be distributed 120 degrees around the circumference of the stent 10. Disposing three or more interconnecting elements 34 between adjacent radially expandable cylindrical elements 12 will generally give rise to the same considerations discussed above for the one and two interconnecting element designs.

FIG. 4 and 5 are representations of the preferred stent design 10 that results from the photo and etch method and the embodiment shown in FIG. 2. The stent generally comprises a plurality of radially expandable cylindrical elements 12 disposed generally coaxially and interconnected by elements 34 disposed between adjacent expandable elements. The portion of the metal covered by the photoresist that was exposed to UV illumination and changed physical properties are retained during the electrochemical process and remain intact as the struts or loops 50 of stent 10. The portions of the photoresist that were not exposed to UV illumination are removed during the development stage. The exposed metal is then chemically dissolved by employing an electrochemical process that results in the open spaces 39 in the stent 10. The structure resulting from a pattern of loops or struts 50 and open spaces 39 comprises the desired stent configuration. In keeping with the invention, and with reference to FIGS. 4 and 5, radially expandable cylindrical elements 12 are in the form of a number of loop alterations or undulations 23 of the stent resembling a serpentine pattern. FIG. 4 also illustrates the stent design in which the radially expandable cylindrical

elements 12 are in an undulating pattern but out of phase with adjacent expandable cylindrical elements.

FIG. 5 is an enlarged perspective view of the stent 10 shown in FIG. 4 with one end of the stent shown in an exploded view to illustrate in greater detail the placement of interconnecting elements 34 between adjacent radially expandable elements 12. Each pair of the interconnecting elements 34 on one side of an expandable element 12 are preferably placed to achieve maximum flexibility for a stent. In the embodiment shown in FIG. 5, stent 10 has two interconnecting elements 34 between adjacent radially expandable cylindrical elements 12 which are approximately 180 degrees apart. The next pair of interconnecting elements 13 on one side of a cylindrical element 12 are offset by ninety (90) degrees from the adjacent pair. The alternation of the interconnecting elements results in a stent which is longitudinally flexible in essentially all directions. Various configurations for the placement of interconnecting elements are possible and another example is illustrated schematically in FIG. 3. However all of the interconnecting elements of an individual stent should be secured to either the peaks or valleys of the alternating loop elements in order to prevent shortening of the stent during the expansion thereof and all of the radially facing struts will have one of the specifically designed configurations.

The pattern of FIGS. 4 and 5 can be formed of any size; a preferable size of stent 10 is between 0.035 thousandths to 0.100 thousandths in diameter when formed and in the constrained configuration. The expanded or deployed diameter of stent 10 ranges from 2.0 mm to 8.0 mm with a preferred range for coronary applications of 2.5 mm to 6.0 mm. The length of the stent 10 is virtually constant from its initial formation length to its length when expanded and ranges from 2 mm to 50 mm, with a preferred length for coronary applications of 5 mm to 20 mm.

Each radially expandable cylindrical element 12 of the stent 10 may be independently expanded. Therefore, the balloon 14 may be provided with an inflated shape other than cylindrical, e.g. tapered, to facilitate implantation of the stent 10 in a variety of body lumen shapes.

The particular pattern and how many undulations per unit of length around the circumference of the radially expandable cylindrical element 12, or the amplitude of the loops, are chosen to fill particular mechanical requirements for the stent such as expanded size and radial stiffness. The number of undulations may also be varied to accommodate placement of interconnecting elements 34 at the peaks of the undulations or along the sides of the undulations (not shown). As previously mentioned, each radially expandable cylindrical element 12 is connected by interconnecting elements 34. Undulating pattern 23 is made up of a plurality of U shaped alternating loops. Alternately, the undulating pattern could be made up of W-shaped members or Y-shaped members each having a different radius so that expansion forces are more evenly distributed over the various members.

The stent 10 serves to hold open the artery 21 after the catheter 11 is withdrawn, as illustrated by FIG. 9D. The undulating portion of the radially expandable sections 12 provide good tacking characteristics to prevent stent movement within the artery. Furthermore, the closely spaced radially expandable cylindrical elements 12 at regular intervals provide uniform support for the wall 22 of the artery 21, and consequently are well adapted to tack up and hold in place small flaps or dissections in the wall 22 of the artery 21.

The method of manufacturing the present invention results in the preferred stent design 10 having specifically configured struts 50. FIGS. 6A, 6B, and 6C illustrate, in cross-section, three exemplary stent strut designs. As demonstrated in FIG. 6A, the preferred stent design has the outer portion of the struts protruding in a trapezoidal configuration 54 which is directed radially from the longitudinal axis of the stent. The pattern of the preferred stent employs cross-section FIG. 6A in a series of U-shaped loops 50 and an alternating connecting elements 34 running along the length of the stent, thereby forming the basic scaffold of the stent design.

In an alternate embodiment the pattern of stent 10 is similar to that of FIGS. 4, 5 and 6A but differs in the outer portion of the strut comprising a triangular configuration (FIG. 6B) where the point of the triangle is directed radially from the longitudinal axis of the stent.

In an another alternate embodiment, the pattern of stent 10 is similar to that of FIGS. 4, 5 and 6A, but differs in the outer portion of the strut comprising an extended base with a reduced radius 58 (FIG. 6C) that is directed radially from the longitudinal axis of the stent.

A terminal section of the loop of stent 10 is shown in FIGS 7A, 7B, and 7C. It can be seen in the cross-sectional illustration that the strut has a trapezoidal configuration 53 in FIG 7A, a triangular configuration 55 in FIG 7B, and an outer reduced radius configuration 57 in FIG 7C. Each strut configuration can be associated with any combination of alternating loops or struts 50 and interconnecting elements 34. Furthermore, it can be seen that the aspect radio of the height to width minimizes twisting or rotation during expansion.

As shown in FIG. 8A, 8B and 8C, the specifically configured radially facing strut surfaces are designed to facilitate the embedment of the expanded stent into the arterial wall or obstruction. By providing a trapezoidal 54 (FIGS. 8A), triangular 56 (FIGS. 8B) or reduced radius 58 (FIGS. 8C) configuration embedment of the stent is relatively atraumatic because less strut area is required to penetrate the vessel wall. Expansion and eventual embedment of the present invention stent is accomplished in such a way that vascular baropressure is overcome in a controlled and relatively docile manner. Vessel trauma and damage is thereby reduced resulting in less subsequent intimal or smooth muscle proliferation. In contrast, the prior art non-wire stents present a relatively flat surface to penetrate the vessel wall therefore providing none of the advantages described above for the present stent invention.

In a preferred embodiment, the delivery of the stent 10 is accomplished in the following manner. The stent 10 is first mounted onto an inflatable balloon 14 or mechanical delivery system (not shown) on the distal extremity of the delivery catheter 11. The stent 10 is crimped or collapsed to the exterior surface of balloon 14. The stent/catheter assembly is then introduced within the patient's vasculature through a guiding catheter utilizing the conventional Seldinger technique. A guidewire 20 is disposed across the obstruction within the vascular section and the stent/catheter assembly is advanced over a guidewire 20 to the obstruction (see FIG. 9A) Then the stent/catheter assembly is advanced further until the stent

10 is positioned and centered within the obstruction 25 (see FIG. 9B). The balloon 14 of the catheter is then inflated, expanding the stent 10 against the obstruction 25 and possibly arterial wall 22, as illustrated in FIG. 9C.

As shown in FIG. 9D, the artery 21 is preferably expanded slightly by the expansion of stent 10 to provide volume for the expanded lumen. As a result of this embedment, interference of blood flow by the stent is minimized as well as to prevent further movement. The radially expandable elements 12 (or struts 50) of stent 10 which are pressed into the wall of the artery 21 will eventually be covered with endothelial cell growth which further minimizes blood flow interference.

FIG. 10 illustrates the limited amount hardening (increased tensile loop or strength) that results when the prior art non-wire stents are plastically deformed during deployment. When the prior art non-wire strut 50 is expanded, a relatively small area 62 becomes hardened when deformed and therefore less resistance to crushing or further deformation.

FIG. 11 illustrates a large amount of hardening (increased tensile strength) that results when with the present invention is plastically deformed during deployment. The amount of cross sectional area having an increased tensile strength is achieved by the present invention's representative manufacturing processes and is substantially greater than for the non-wire prior art stents. As depicted in the upper and lower comparisons, as the loop or strut 61 is expanded, the center of the loop becomes hardened. Once the center becomes hardened, the adjacent areas on both sides of this hardened center become hardened as the plastic deformation continues. Due to the manufacturing process which optimizes the stress strain characteristics, when the loop is expanded to its fullest extent, the total area of hardening is significantly greater in the present invention than the prior art non-wire stents. The larger portion of hardening 66 equates to a stent having increased resistance to crushing and further deformation. Conversely, the prior art non-wire stents have a limited portion of hardening and therefore significantly less resistance to crushing or further deformation. This characteristic is clinically important, for any tendency of a stent to become crushed during

deployment or worse yet, after deployed, could restrict blood flow or increase the potential for restenosis.

FIG. 12 illustrates the a standard stress-strain chart comparing the curves for the prior art non-wire stents with the present stent invention. As the chart demonstrates, the prior art non-wire stents have an approximate 30,000 psi yield strength at which additional stain induces plastic deformation. The present invention can produce a yield strength ranging from 35,000 to 70,000 psi. The manufacturing process can select a yield point anywhere within this range to achieve the desired result. The higher end of the range is significantly greater than the prior art non-wire stents. These properties are responsible for the present invention having increased resistance to crushing.

Furthermore, FIG. 12 also demonstrates that the prior art non-wire stents have an ultimate tensile strength of approximately 60,000 psi. Any additional strain beyond this point results in failure of the material. The present invention can produce an ultimate tensile strength ranging from 65,000 to 120,000 psi. The manufacturing process can select a ultimate tensile strength anywhere within this range to achieve the desired result. The higher end of this range is significantly stronger then the prior art non-wire stents. These properties are responsible for the present invention also having an increased resistance to crushing.

While the invention has been illustrated and described herein in terms of its use as an intravascular stent, it will be apparent to those skilled in the art that the stent can be used in other instances such as to expand prostate urethras in cases of prostate hyperplasia. Other modifications and improvements may be made without departing from the scope of the invention.

Other modifications and improvements can be made to the invention without departing from the scope thereof:

I claim:

1. A low pressure stent for implanting in a vessel comprising;

a plurality of substantially cylindrical loop elements which are independently expandable in the radial direction and which are interconnected to generally align said cylindrical loop elements in a common longitudinal axis;

one or more connecting elements for interconnecting said cylindrical loop elements; and

an outer surface on said cylindrical loop elements, said outer surface comprising a converging configuration projecting radially from said longitudinal axis prior to expansion of said stent, said converging configuration maintaining its radial projection as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter.

2. A low pressure stent as recited in claim 1, wherein said converging configuration of said outer surface of the loop element comprises a trapezoidal configuration.

3. A low pressure stent as recited in claim 1, wherein said converging configuration of said outer surface of the loop element comprises a triangular configuration.

4. A low pressure stent as recited in claim 1, wherein said converging configuration of said outer surface of the loop element comprises a reduced radii configuration.

5. A low pressure stent as recited in claim 1, wherein said loop elements include an undulating, alternating loop or serpentine pattern.

6. A low pressure stent as recited in claim 1, wherein said outer surface of said loop elements are embedded into the vascular wall of the body lumen in order to more firmly attach said stent to the vascular wall.

7. The low pressure stent as recited in claim 1, wherein said loop elements are capable of maintaining their expanded condition upon expansion thereof

8. The low pressure stent as recited in claim 1, wherein said stent is formed of a material selected from the group of materials consisting of stainless steel, platinum, gold alloy, or a gold/platinum alloy.

9. The low pressure stent as recited in claim 1, wherein said stent is formed from a single piece of tubing.

10. The low pressure stent as recited in claim 1, further comprising coating said stent with a biocompatible coating.

11. The low pressure stent as recited in claim 1, wherein said loop elements have a yield strength greater than 35,000 psi.

12. The low pressure stent as recited in claim 1, wherein said loop elements have an ultimate tensile strength greater than 65,000 psi.

13. A low pressure stent for implanting in a vessel comprising;

a plurality of substantially cylindrical loop elements which are independently expandable in the radial direction and which are interconnected to concentrically align said cylindrical loop elements in a common longitudinal axis;

one or more connecting elements for interconnecting said cylindrical loop elements, so that said stent, when expanded radially outward, retains its overall length without appreciable shortening; and

an outer surface on said loop elements, said outer surface comprising a converging configuration projecting radially from said longitudinal axis prior to expansion of said stent, said converging configuration maintaining its radial projection as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter.

14. A low pressure stent as recited in claim 13, wherein said converging configuration of said outer surface of the loop element comprises a trapezoidal configuration.

15. A low pressure stent as recited in claim 13, wherein said converging configuration of said outer surface of the loop element comprises a triangular configuration.

16. A low pressure stent as recited in claim 13, wherein said converging configuration of said outer surface of the loop element comprises a reduced radii configuration.

17. A low pressure stent as recited in claim 13, wherein said loop elements include an undulating, alternating loop or serpentine pattern.

18. A low pressure stent as recited in claim 13, wherein said outer surface of said loop elements are embedded into the vascular wall of the body lumen in order to more firmly attach said stent to the vascular wall.

19. The low pressure stent as recited in claim 13, wherein said loop elements are capable of maintaining their expanded condition upon expansion thereof.

20. The low pressure stent as recited in claim 13, wherein said stent is formed of a material selected from the group of materials consisting of stainless steel, stainless steel, platinum, gold alloy, or a gold/platinum alloy.

21. The low pressure stent as recited in claim 13, wherein said stent is formed from a single piece of tubing.

22. The low pressure stent as recited in claim 13, further comprising coating said stent with a biocompatible coating.

23. The low pressure stent as recited in claim 13, wherein said loop elements have a yield strength greater than 35,000 psi.

24. The low pressure stent as recited in claim 13, wherein said loop elements have an ultimate tensile strength greater than 65,000 psi.

25. A low pressure stent for implanting in a vessel comprising;

a plurality of substantially cylindrical loop elements which are independently expandable in the radial direction and which are interconnected to concentrically align said loop elements in a common longitudinal axis;

one or more connecting elements for interconnecting said cylindrical loop elements, so that said stent, when expanded radially outward, retains its overall length without appreciable shortening; and

said loop elements having a yield strength of at least 35,000 psi.

26. A low pressure stent for implanting in a vessel comprising;

a plurality of substantially cylindrical loop elements which are independently expandable in the radial direction and which are interconnected to concentrically align said cylindrical loop elements in a common longitudinal axis;

one or more connecting elements for interconnecting said cylindrical loop elements, so that said stent, when expanded radially outward, retains its overall length without appreciable shortening; and

said loop elements having an ultimate tensile strength of at least 65,000 psi.

27. The method of deploying a stent having a plurality of substantially cylindrical loop elements which are independently expandable in the radial direction and which are interconnected and generally aligned with said cylindrical loop elements in a common longitudinal axis, one or more connecting elements for interconnecting said loop elements, an outer surface on said loop elements, said outer surface comprising a converging configuration or reduce radius projecting radially from said longitudinal axis prior to expansion of said stent, said converging configuration or reduced radius maintaining its radial projection as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter;

providing a catheter with an expandable member on its distal end and positioning said stent coaxially on said expandable member;

positioning said expandable member with said stent at a selected implantation site within a vessel of a patient;

expanding the expandable member radially to expand said stent within a lumen of said vessel;

contracting said expandable member; and

removing said catheter from said patient.

28. A method of deploying a stent as recited in Claim 27, further comprising the step of implanting said stent within a vessel wall after the step of expanding said expandable member within said lumen of said vessel.

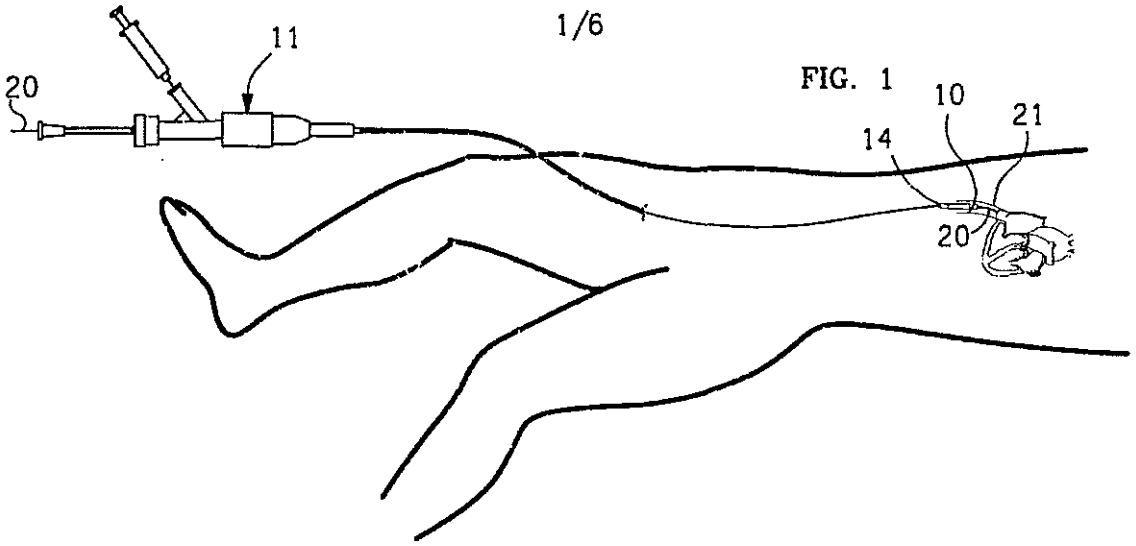


FIG. 1

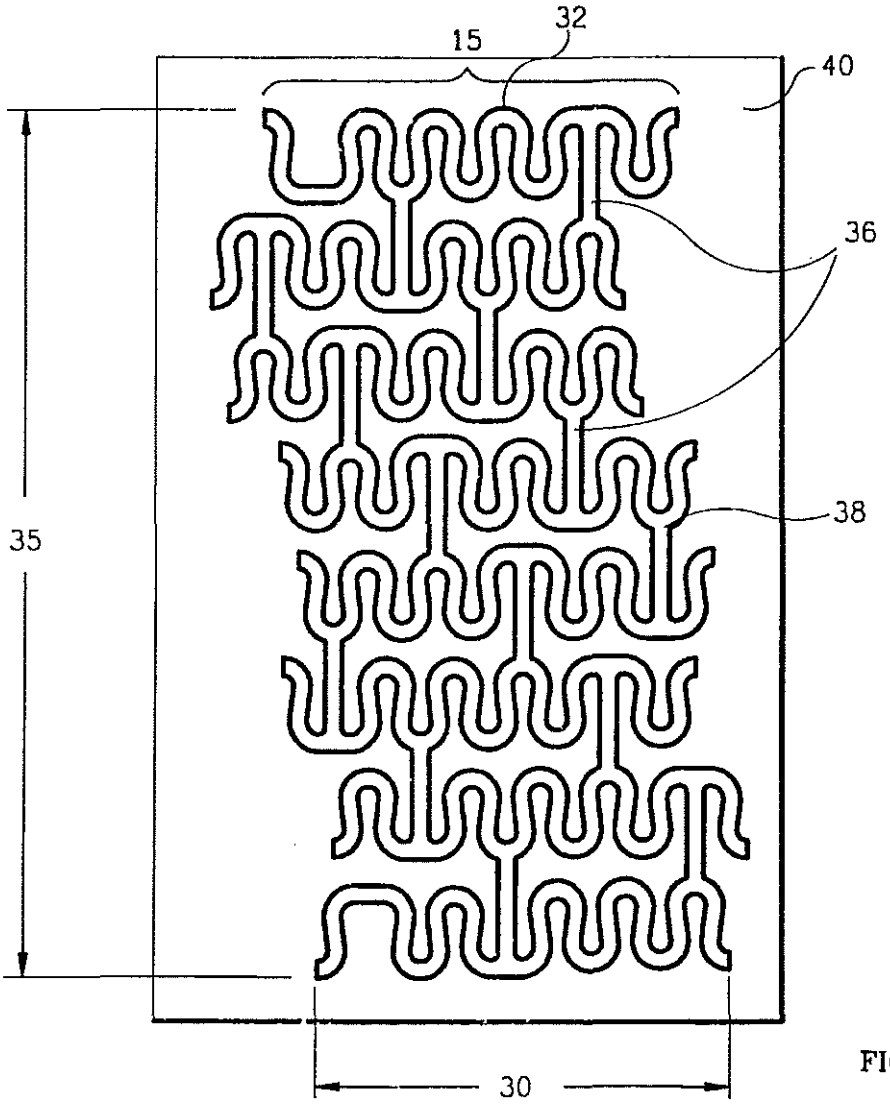


FIG. 2

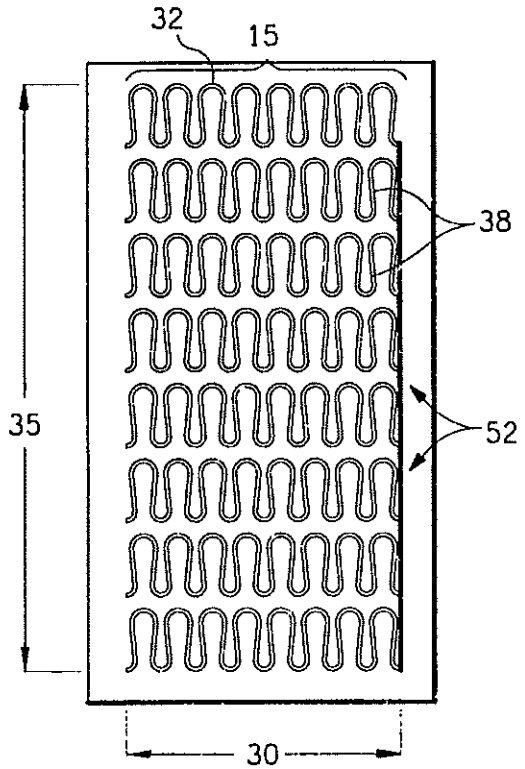


FIG. 3

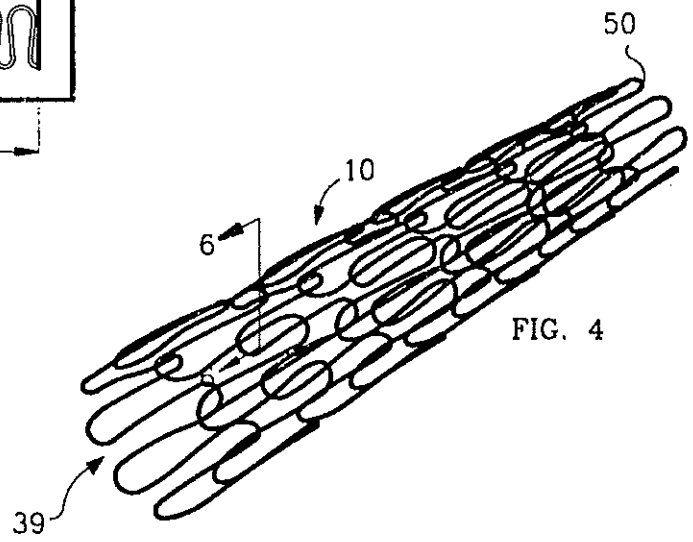


FIG. 4

FIG. 5

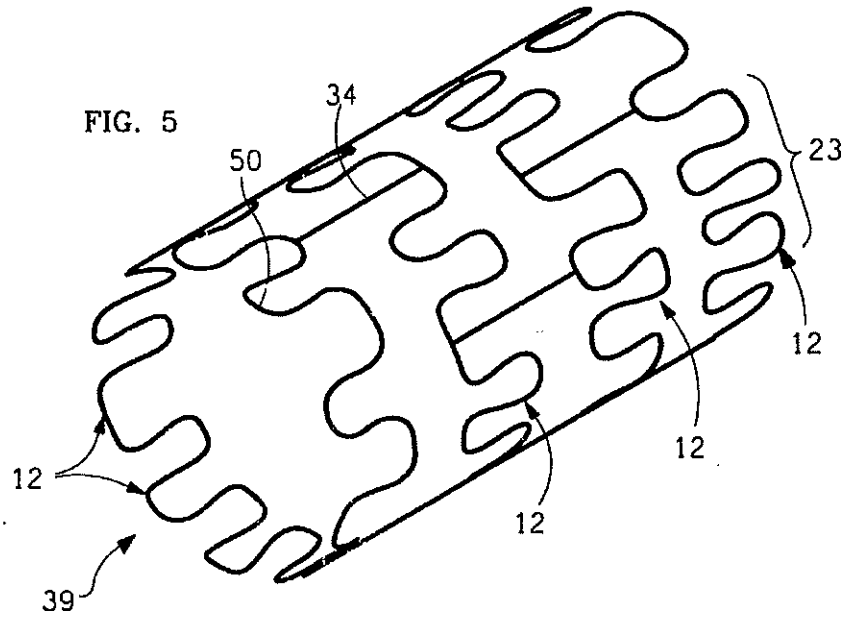


FIG. 6A

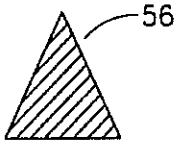


FIG. 6B

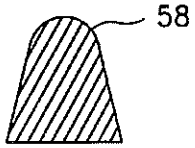


FIG. 6C

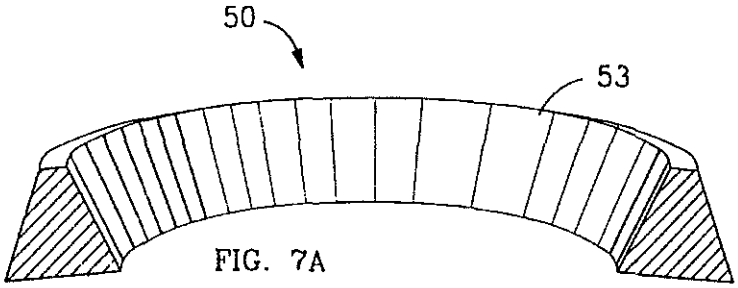


FIG. 7A

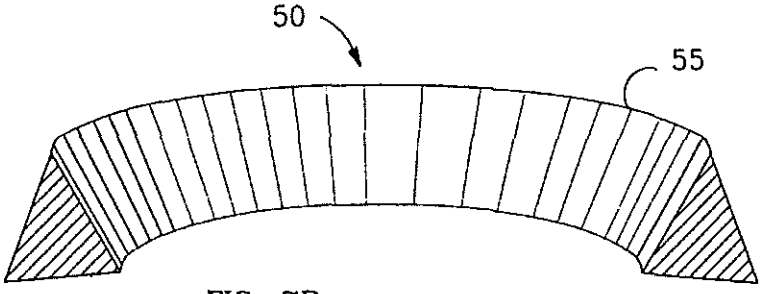


FIG. 7B

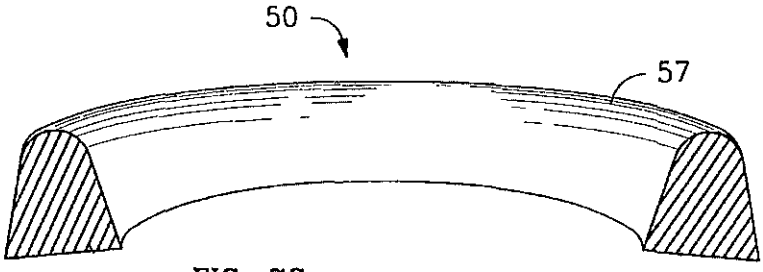


FIG. 7C

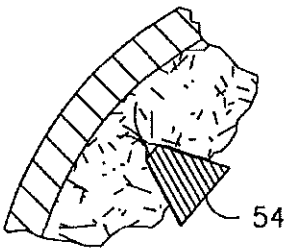


FIG. 8A

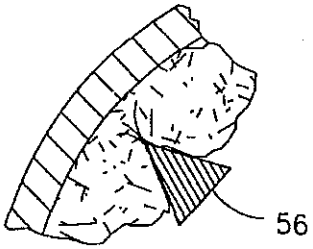


FIG. 8B

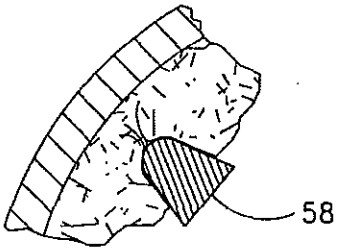


FIG. 8C

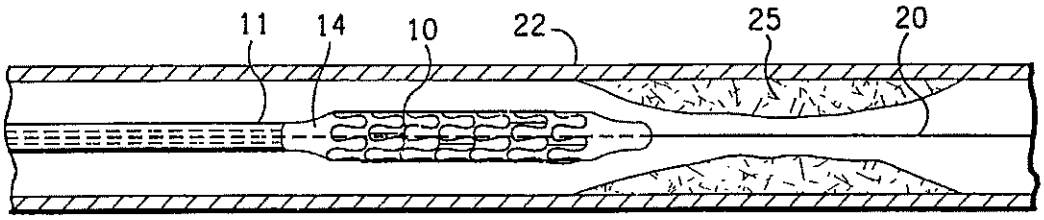


FIG. 9A

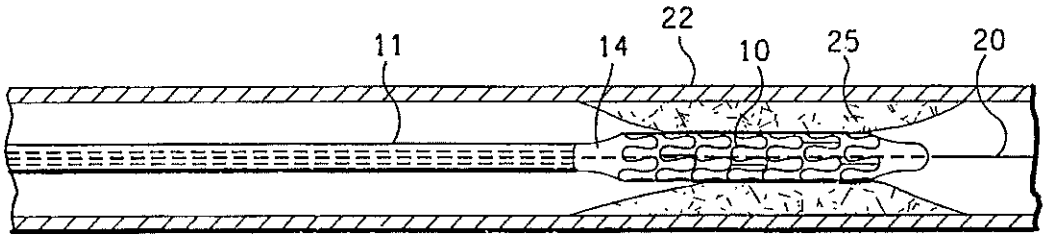


FIG. 9B

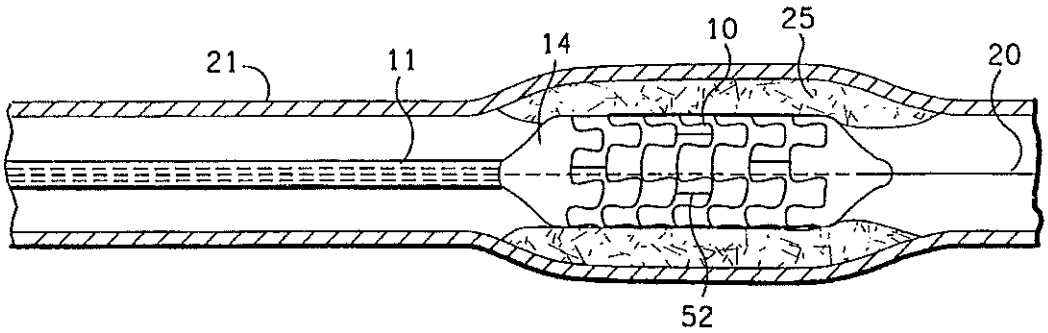


FIG. 9C

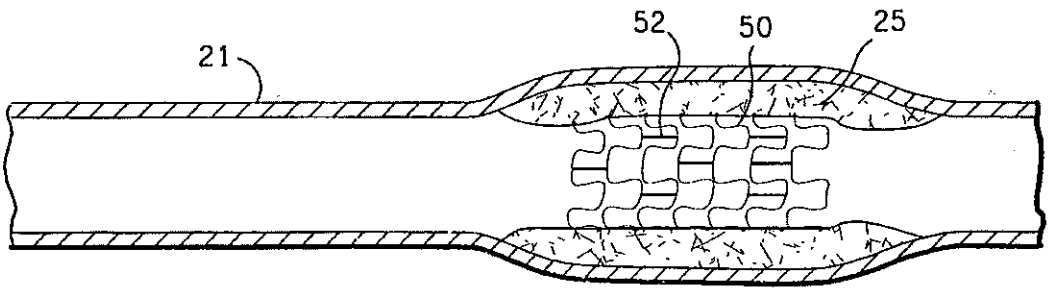


FIG. 9D

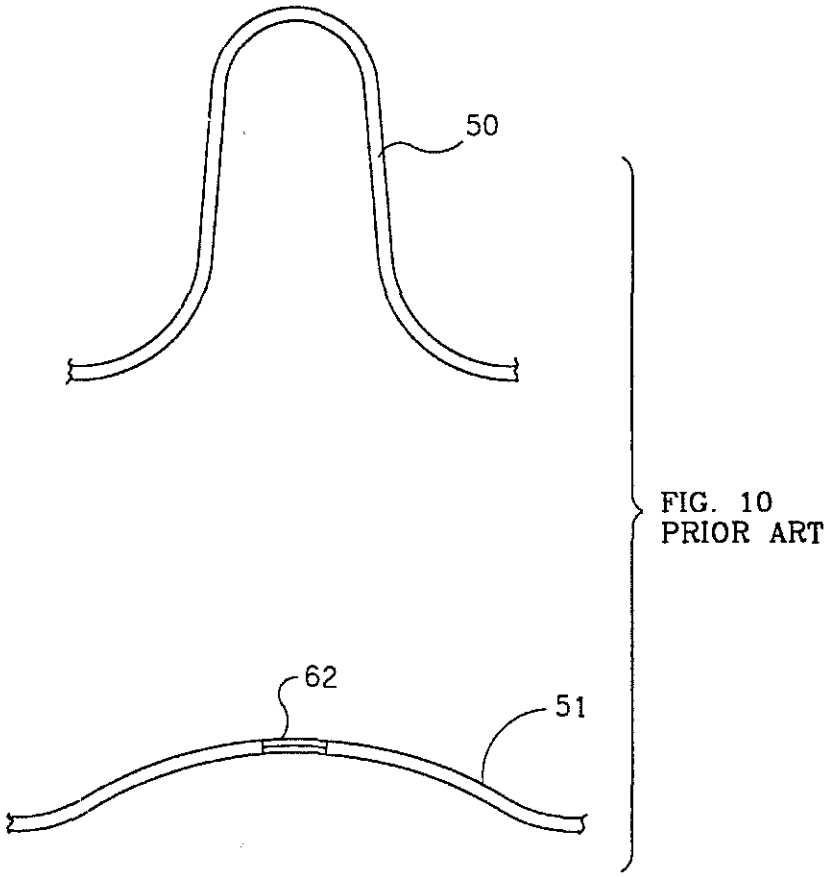


FIG. 10
PRIOR ART

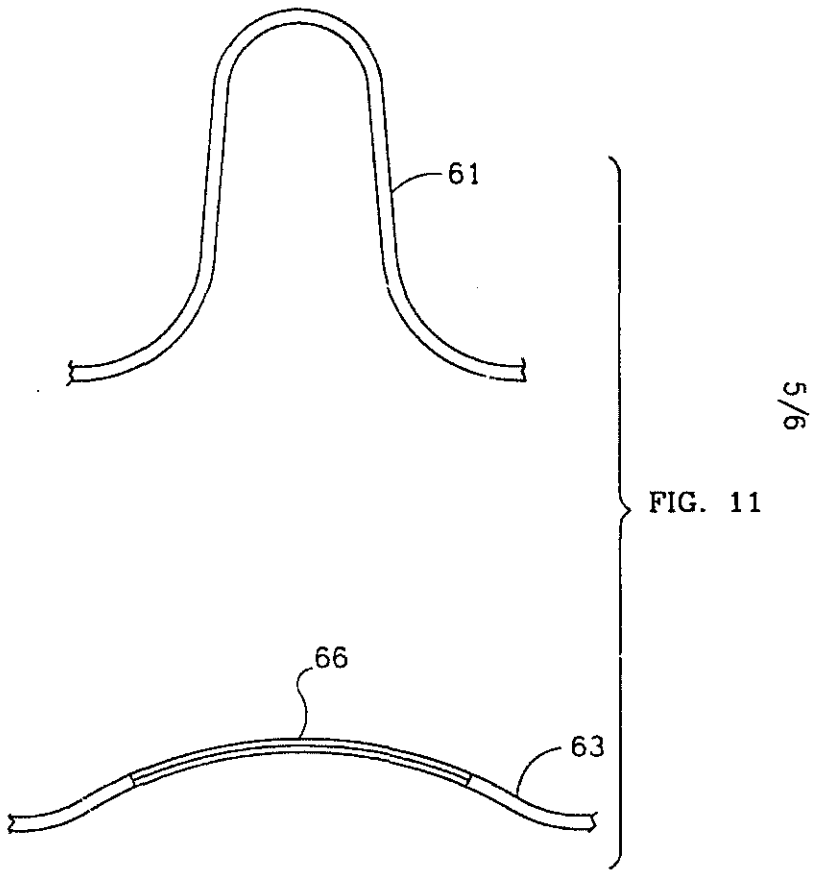
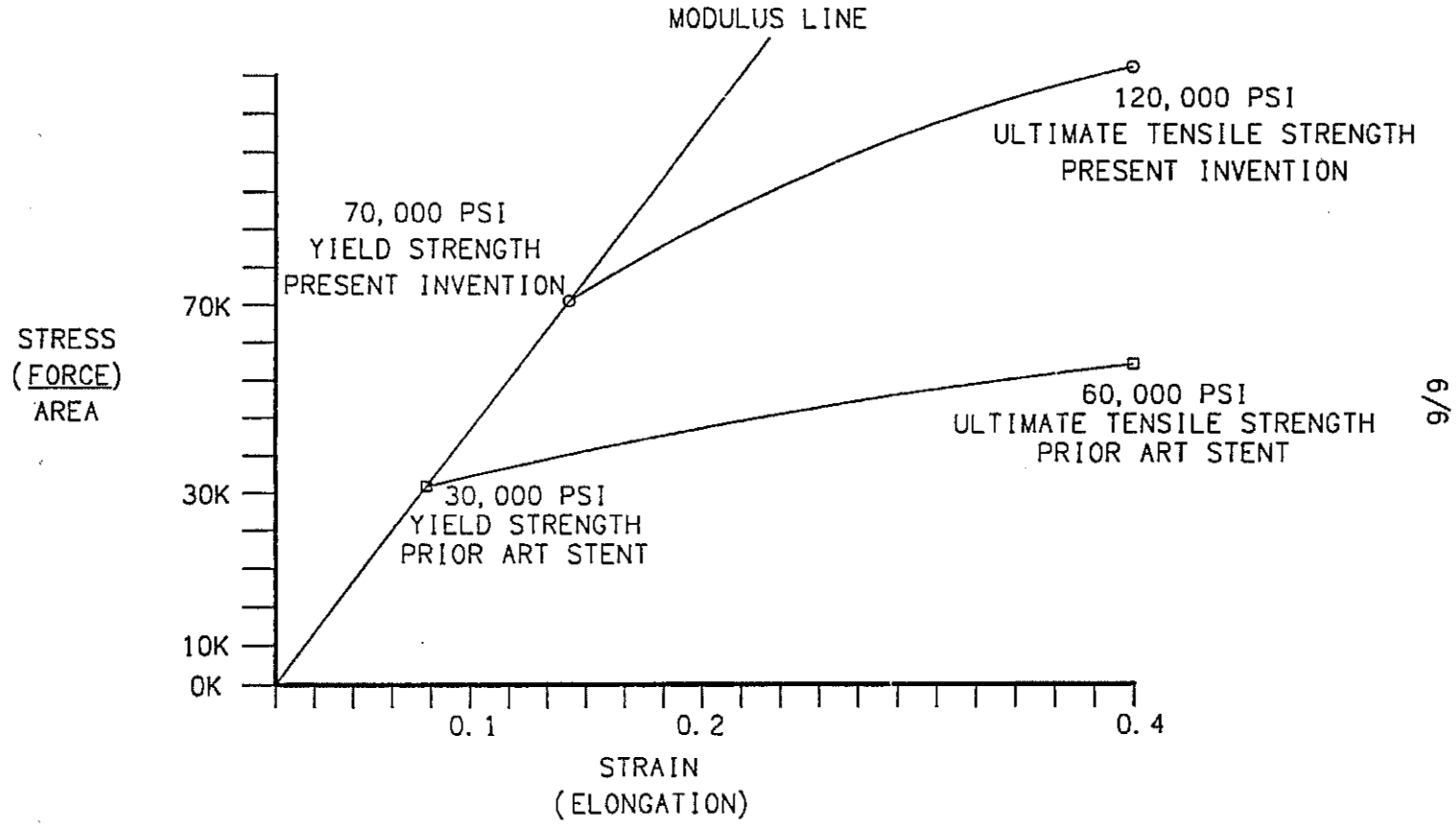


FIG. 11



▫ PRIOR ART NON-WIRE STENTS
○ PRESENT INVENTION

FIG. 12

IM4

TAPERED SELF-EXPANDING STENT

BACKGROUND OF THE INVENTION

The present invention relates to expandable endoprosthesis devices, generally known as stents, which are designed for implantation in a patient's body lumen, such as blood vessels, to maintain the patency thereof. These devices are particularly useful in the treatment and repair of blood vessels after a stenosis has been compressed by percutaneous transluminal coronary angioplasty (PTCA), percutaneous transluminal angioplasty (PTA), or removed by atherectomy or other means.

Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Ideally, implantation of such stents is accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen at the stenosis, and expanding the stent to an expanded state by inflation of the balloon within the stent. The stent can then be left in place by deflating the balloon and removing the catheter.

A bifurcated stenosis typically can occur in the carotid or coronary arteries at the carina between adjoining arterial branches and around the ostia of the adjoining arterial branches. Employment of a stent for repair of vessels that are diseased at a bifurcation requires that the stent must, without compromising blood flow, overlay the entire circumference of the ostium to a diseased portion and extend to a point within and beyond the diseased portion. Particularly at a bifurcation, lesions may form along the side walls of the blood vessel and at the carina of the bifurcation, not only contributing to stenosis of a main branch and side branch of the bifurcation, but also interfering with the normal rheology of flow at the bifurcation to create eddy currents that can contribute to formation of thrombosis.

A conventional stent might be placed so that a portion of the stent extends into the pathway of blood flow to a side branch of the bifurcation or extend so far as to

completely cover the path of blood flow in a side branch. The conventional stent might alternatively be placed proximal to, but not entirely overlaying the circumference of the ostium to the diseased portion. Such placement of the conventional stent results in a bifurcation that is not completely repaired. Also, where the stent does not overlay the entire circumference of the ostium to the diseased portion, the stent fails to completely repair the bifurcated vessel.

In a conventional method for treating bifurcated vessels, the side-branch vessel is first stented so that the stent protrudes into the main vessel. A dilatation is then performed in the main vessel to open and stretch the stent struts extending across the lumen from the side-branch vessel. Thereafter, the main-vessel stent is implanted so that its proximal end overlaps with the side-branch vessel. However, the structure of the deployed stent must be recrossed with a wire by trial and error.

In another prior art procedure, known as "kissing" stents, a stent is implanted in the main vessel with a side-branch stent partially extending into the main vessel creating a double-barreled lumen of the two stents in the main vessel proximal to the bifurcation. Another prior art approach includes a so-called "trouser legs and seat" approach, which includes implanting three stents, one stent in the side-branch vessel, a second stent in a distal portion of the main vessel, and a third stent, or a proximal stent, in the main vessel just proximal to the bifurcation.

In addition to problems encountered in treating disease involving bifurcations for vessel origins, difficulty is also encountered in treating disease confined to a vessel segment but extending very close to a distal branch point or bifurcation which is not diseased and does not require treatment. In such circumstances, very precise placement of a stent covering the distal segment, but not extending into the ostium of the distal side-branch, may be difficult or impossible.

It is important for stents to be sized correctly for the vessel into which they are implanted. In some situations, like the carotid artery, it is desirable to place a single stent from the common carotid artery to the internal carotid artery. The diameter is

about 2 to 3 mm smaller in the internal carotid artery, so it is difficult to size a stent appropriately for both vessels. A stent that is designed for a large diameter vessel is not optimal for a small diameter vessel, and vice versa.

To address the deployment problems at a bifurcation and to address the stent sizing problems, the present invention is directed to a tapered stent. With such a tapered stent, the diameter of the stent varies along the length of the stent.

Some tapered stent designs are known in the art. For example, PCT Publication No. WO98/53759, entitled "Carotid Stent," by Jay S. Yadav discloses a stent for cardiovascular application wherein a substantially cylindrical tubular member tapers from its proximal end to its distal end. This type of tapered stent is intended for stenting the common carotid bifurcation or the proximal internal carotid artery.

PCT Publication No. WO98/34668, entitled "Non-Foreshortening Intraluminal Prosthesis" by Gary S. Roubin et al. discloses an intraluminal prosthesis provided with a plurality of annular elements. The stent may be provided with varying flexibility along its length and/or circumference, and may include segments that have different diameters. The differing diameters may be accomplished by providing the stent in a tapered or a stepped configuration.

Other tapered stents include U.S. Patent No. 5,222,964 to Cooper, disclosing a tapered stent made of resilient material for interconnecting portions of a Fallopian tube after a resection procedure. U.S. Patent No. 5,180,392 to Skeie et al. discloses a prosthesis for use in joining hollow organ parts or systems wherein the prosthesis may have tapered outer ends. U.S. Patent No. 4,441,215 to Kaster discloses a vascular graft of a synthetic material including a tubular member having a braided inner layer and a compliant outer covering layer. This synthetic vascular graft can have an increasing or decreasing taper.

Another tapered stent is known as the "Flamingo Wallstent." The Flamingo Wallstent is intended for esophageal malignant strictures. It is partially covered at the ends to protect against tissue injury, and inside to prevent food impaction and tumor

growth. A major drawback for the Flamingo Wallstent design is its inability to be accurately placed due to unpredictable foreshortening after deployment.

There is, however, still a need for an improved tapered stent for deployment in, for example, the common carotid bifurcation or the proximal internal carotid artery. These areas are the most common sites for cerebrovascular atherosclerotic disease.

SUMMARY OF THE INVENTION

To address the aforementioned problems, the present invention is directed to a stent having a taper along its length and having varying radial strength as a function of the diameter of the stent and spacing between the struts. In a preferred embodiment, the present invention is directed to a longitudinally flexible stent for implanting in a body lumen and expandable from a contracted condition to an expanded condition, comprising a plurality of adjacent cylindrical elements, each cylindrical element having a circumference extending around a longitudinal axis and being substantially independently expandable in the radial direction, wherein the plurality of adjacent cylindrical elements are arranged in alignment along the longitudinal stent axis, and wherein a plurality of cylindrical elements include sequentially increasing diameters to create a tapered profile, with each cylindrical element formed from struts arranged in a serpentine wave pattern; and a plurality of interconnecting members extending between the adjacent cylindrical elements and connecting the adjacent cylindrical elements to one another; wherein the struts and interconnecting members at the tapered profile increase in length along the longitudinal stent axis.

Such a tapered stent with smaller diameters as well as larger diameters has several benefits. A stent having a smaller diameter can have greater radial strength, better coverage of the vessel wall, and less foreshortening than is achievable with a stent having larger diameters. Obtaining these optimized features is especially important for the carotid application in which the internal carotid artery has the most

significant disease, but the common carotid artery diameter dictates many of the design requirements of the stent.

As mentioned earlier, carotid stent procedures frequently involve the treatment of a diseased artery where plaque extends across the bifurcation between the common and internal carotid arteries. Selection of an appropriate stent diameter becomes precarious because the internal carotid artery tends to be smaller than the parent common carotid artery. The stent selected must be large enough to treat the common carotid artery, but using a stent sized to the common carotid artery can require implantation of a stent much larger than the nominal diameter of the internal carotid artery. This stent diameter mismatch and concomitant oversizing could lead to vessel injury and poor clinical results.

In the present invention, each end of the stent has preferably been designed specifically for the appropriate diameter range. That is, when deployed, the smaller diameter end of the stent supports the diseased portion of the internal carotid artery while the larger diameter end of the tapered stent supports the large diameter of the common carotid artery.

The present invention can be made from a shape-memory metallic alloy such as Nitinol or superelastic Nitinol to create a self-expanding stent. Alternatively, the present invention stent can be balloon expanded. With a balloon expandable stent, the shape of the balloon can be used to control the final shape of the stent. For example, a balloon with more than one diameter can be used to expand a stent having two final diameters. Separate balloons can also be used to post dilate the stent with a step in its diameter.

The present invention tapered stent presents a logical solution for carotid stenting across the bifurcation. The varying stent diameter accomplishes at least two goals: it allows adequate treatment of a lesion in both the common and internal carotid while maintaining a suitable stent-to-artery ratio for each vessel.

Other features and advantages of the present invention will become more apparent from the following detailed description of the invention, when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a side elevational view depicting the present invention stent and a deployment system as the stent is carried through a vessel.

FIG. 2 is a top plan view of a handle of the deployment system.

FIG. 3 is a cross-sectional view of the present invention tapered stent after deployment at the bifurcation between the common and internal carotid arteries.

FIG. 4 is a perspective view of a preferred embodiment of the present invention tapered stent in its expanded mode.

FIG. 5 is a plan view of a flattened strut pattern of the present invention tapered stent in its unexpanded mode.

FIG. 6 is a plan view of a flattened strut pattern of an alternative embodiment tapered stent in its unexpanded mode.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is directed to a tapered stent with a strut pattern that changes the spacing between struts to achieve various design objectives. While the present invention is described in detail as applied to the carotid artery of a patient,

those skilled in the art will appreciate that the present invention can also be used in other body lumens as well.

FIG. 1 is a side elevational view and partial sectional view of self-expanding stent 10 of the present invention as carried inside stent delivery system 12. Stent delivery system 12 includes elongated catheter body 14 for delivering and deploying stent 10 which is shown in the compressed or unexpanded state. As seen in FIG. 1, elongated catheter body 14 is positioned within artery 16 or similar type vessel.

Stent delivery system 12 further includes housing assembly 18 attached to proximal end 20 of delivery catheter 14. Housing assembly 18 is used to manually deploy compressed stent 10 mounted at distal end 22 of delivery catheter 14. Delivery catheter 14 further includes inner tubular member 24 that extends within outer tubular member 26 in a coaxial arrangement.

Outer tubular member 26 has a proximal end attached to pull-back handle 28 that is designed to move along the longitudinal axis of delivery catheter 14 while supported by base 30 of housing assembly 18. When pull-back handle 28 is translated in the proximal direction, outer tubular member 26 is likewise translated in the proximal direction exposing compressed stent 10. Because base 30 of housing assembly 18 remains stationary, inner tubular member 24 also remains stationary during the stent deployment.

Applying tensile force to the shaft of outer tubular member 26 during stent deployment creates an equal and opposite compressive force on inner tubular member 24. Inner tubular member 24 possesses sufficient column strength to prevent buckling or deformation during deployment.

Distal end 32 of inner tubular member 24 has stent holder 34 upon which compressed stent 10 is mounted. Tip assembly 36 having a preferably tapered profile is positioned at distal end 22 of delivery catheter 14 to help cross any areas of occlusions in the diseased artery. Tip assembly 36 is made from a small segment of preferably stainless steel hypotube that has internally tapered wound coil 38 welded to

the distal end of tip assembly 36. An optional radiopaque tungsten element 40 is placed at the distal end of tip assembly 36. An opening at the distal end of tip assembly 36 permits guidewire 42 to advance therethrough thereby allowing delivery catheter 14 to track into the diseased artery.

Other aspects of the delivery system are disclosed in co-pending patent application serial no. 09/313,780, filed May 17, 1999, entitled "Self-Expanding Stent with Enhanced Delivery Precision and Stent Delivery System," whose entire contents are hereby incorporated by reference. Although this delivery system is used in conjunction with the present invention self-expanding stent, other types of delivery systems are contemplated. For example, the present invention stent may be made of stainless steel or tantalum for example, and may be deployed on a balloon catheter delivery system and balloon expanded at the delivery site. Such balloon delivery systems are well known in the art. FIG. 3 provides a cross-sectional view of the present invention as deployed in bifurcation 44 between common carotid artery 46 and internal carotid artery 48. It is clear that selection of an appropriate stent diameter becomes important because internal carotid artery 48 tends to be smaller than the parent common carotid artery 46. Furthermore, the denser strut pattern, described below, giving greater hoop strength of stent 10 is important at this particular location to support diseased regions 50.

As seen in FIG. 3, outer tubular member 26 has been withdrawn in the proximal direction exposing stent 10 which self-expands. This is accomplished by fabricating stent 10 from a highly resilient alloy such as superelastic Nitinol or other spring-like materials known in the art.

FIGS. 4 and 5 show expanded and contracted states of stent 10, respectively. As seen in these figures, the preferred embodiment of the present invention stent 10 is constructed from a plurality of nested cylindrical elements 52 arranged coaxially along a common longitudinal stent axis to assume a tubular form. Adjacent cylindrical elements 52 are joined at predetermined circumferential locations by interconnecting

members 54 so that each cylindrical element 52 is independently expandable. In the preferred embodiment shown in FIGS. 4 and 5, interconnecting members 54 are aligned axially.

As best seen in FIG. 4, each cylindrical element 52 has a generally serpentine wave strut pattern constructed from repeating patterns of upright and inverted V's 56. Connecting upright and inverted V's 56 are strut arms 58. Each strut arm 58 is generally straight but may include shoulder 60. Optional shoulder 60 is included in strut arm 58 in order to squeeze the stent to a smaller profile in the delivery system. In other words, inclusion of shoulders 60 in strut arms 58 permits tighter packing of the struts of the stent. This leads to better coverage of the vessel wall. Conversely, if strut arms 58 were straight, the vessel coverage by the stent struts is diminished.

Each cylindrical element 52 has a longitudinal dimension or length as measured from peak 84 of one inverted V to valley 86 of the next upright V. Cylindrical elements 52 are described as nested to mean that those lengths of adjacent cylindrical elements 52 overlap each other. Thus, peaks 84 of inverted V's 56 of one cylindrical element 52 lie within the open areas of peaks 84 of inverted V's 56 of adjacent cylindrical elements 52. In a similar fashion, valleys 86 of upright V's 56 of one cylindrical element 52 lie within the open areas of valleys 86 of upright V's of an adjacent cylindrical element 52. This preferred strut arrangement could be described as a loose herringbone pattern.

As best seen in FIG. 4, the lengths of interconnecting members 54 and strut arms 58 increase from first end 64 toward second end 62. Looking at it another way, the strut pattern under this configuration becomes more dense toward first end 64 due to the shorter struts. Taper 82, however, is not created by the varying strut arm lengths 58. Rather, the strut arm lengths 58 is enabled by the taper. The tapering 82 is dictated by the expansion process, that is, the shape of the expansion mandrel when the stent is fabricated. Again, the tapered profile is best seen in the expanded mode of FIG. 4.

Of course, by imparting the length and angle of taper 82 as well as its location on the expansion mandrel, the shape and profiles of the individual strut arms 58 and interconnecting members 54 are likewise formed. In the embodiment shown in FIG. 4, taper 82 is positioned at a center portion of stent 10. Naturally, taper 82 can be relocated as needed along the length of stent 10.

Taper 82 may be continuous or discrete, and include changes in shape or dimension, with small flares, or tapers only at the ends of the stent. For instance, some types of tapers contemplated in the present invention tapered stent 10 include a step taper as seen in the expanded state of stent 10 in FIG. 4. That is, stent 10 has first end 64 with cylindrical elements 52 at that end having a small constant diameter; second end 62 with cylindrical elements 52 at that end having a large constant diameter; and center section 82 with sequentially changing diameters in cylindrical elements 52 along the longitudinal stent axis to achieve the step taper. Of course, the length and location of center section 82 containing the taper can be changed as necessary to accommodate the specific anatomy of the patient.

The present invention in an alternative embodiment (not shown) further contemplates straight conical tapers; that is, the stent has an angled profile from one end to the opposite end. The shape of the taper in the step diameter change can be varied from straight to parabolic to other shapes as well.

Many physical parameters of the present invention stent can be changed to achieve specific engineering objectives. For example, the density of the strut pattern can be adjusted as needed by varying the lengths of strut arms 58 and interconnecting members 54 to affect the amount of open areas. The included angles of the peaks and valleys of inverted and upright V's 56 can be changed to affect strut density. Increasing the number of inverted and upright V's 56 in a given cylindrical element 52 can also increase strut density. Furthermore, the degree of nesting can be adjusted by only changing the lengths of interconnecting members 54. Shortening interconnecting members 54, for example, would result in a more tightly packed or nested strut

pattern. Changing the phase of inverted and upright V's 56 in one cylindrical element 52 to the next can also affect the amount of open space in stent 10, its flexibility, vessel coverage, etc.

Adding or decreasing the number of interconnecting members 54 joining adjacent cylindrical elements 52, positioning them at specific locations around the circumference, and aligning them in a row such as that shown in FIGS. 4 and 5 are all different methods of affecting the stent's hoop strength, foreshortening, flexibility, recoil, and other engineering characteristics. The length of stent 10 can be varied by increasing or decreasing strut arm lengths 58 and interconnecting member lengths 54, by using more or fewer cylindrical elements 52, and by changing the included angles of the inverted and upright V's 56.

In general, the present invention stent is preferably fabricated through manufacturing processes known in the art appropriate for pseudoelastic Nitinol. Other stent materials known in the art, such as stainless steel, are contemplated but not explicitly described here.

First, in the preferred process, the stent strut pattern is laser cut out of a tube stock of pseudoelastic Nitinol. Second, any scale on the surface of the material is removed by bead blast or acid wash.

Third, because the stent is made from Nitinol, it is expanded on an expansion mandrel and heat set. The heat set imparts the shape memory to the alloy, and preferably occurs at approximately 500 to 550 degrees Celsius. After heat set, the stent is quenched in water. Both the heat set and quenching help control the transformation temperature between martensite and austenite of the Nitinol material. Furthermore, the expansion and heat set cycle is performed in stages, sometimes up to five steps, to avoid damaging the stent. The last one or two steps are performed on tapered mandrels to impart the tapered profile. The stent has inherent resilience, which conforms the stent profile to the profile of the tapered mandrels at each stage.

Fourth, the Nitinol stent is electropolished. Preferably, the electropolish solution is a methanol based, acidic mixture. Specifically, the mixture consists of 465 ml absolution methanol, 37.5 mil sulfuric acid (>96.5 percent), and 12.5 ml hydrocloric acid (saturated), which combined produces approximately 500 ml of solution.

The stent is placed in an electropolish fixture preferably constructed from four round, Nitinol wires acting as anodes to hold the stent. The four anode wires are placed around the circumference of the stent, parallel to the stent's longitudinal axis. There is a center cathode made of a platinum rod. The cathode is located at the center of the four anode wires and extends through the center of the stent, parallel and coextensive with its longitudinal axis. The negatively charged center cathode is used to complete the circuit in the solution to polish the inside diameter of the stent.

A curved sheath cathode made of platinum mesh is located parallel to the longitudinal stent axis and partially surrounding the Nitinol wires. The curved sheath cathode is used to complete the circuit in the solution to polish the outside diameter of the stent. The curved sheath is placed just below the four holding anodes, wherein the distance between the sheath and the stent is determined by the size of the part needed to be polished. The fixture and stent positioned thereon are immersed in the solution described above and an electrical current is applied to the circuit.

Fifth, after electropolish, the stent diameter is reduced for fitment with a delivery system. Sixth, the stent is loaded in a delivery system. The end result is a stent with varying diameter along its length as illustrated in FIGS. 4 and 5.

A tapered stent such as in the present invention presents a logical solution for carotid stenting across the bifurcation. The varying stent diameter allows adequate treatment of a lesion in both the common and internal carotid arteries, while maintaining a suitable stent-to-artery ratio for each vessel.

A tapered stent can be applied to other parts of the vascular system where a bifurcation is present such as the coronary arteries and relevant areas where peripheral

vascular disease may exist. Tapered stent diameters, lengths, flexibility, radiopacity, and radial hoop strength are all features that would be optimized depending on the expected application of the present invention stent.

FIG. 6 provides a flattened, plan view strut pattern of an alternative embodiment stent 66. Stent 66 is preferably constructed from a plurality of cylindrical elements 68 arranged along a common, longitudinal stent axis to assume a tubular form. Each cylindrical element has decreasing lengths from first end 70 to second end 72 of stent 66, similar to the embodiment depicted in FIGS. 4 and 5.

In FIG. 6, each cylindrical element 68 is formed from struts arranged in a repeating serpentine wave patterns. Interconnecting members 74 join adjacent cylindrical elements 68. In this exemplary embodiment, the serpentine wave pattern is made from alternating U's and W's joined by straight strut arms 80. Each interconnecting member 74 joins W's 78 to U's 77.

Formation of the taper at any portion along the length of stent 66 can be achieved through processing steps described above. FIG. 6 does not show the taper because stent 66 is in the unexpanded state.

The shorter cylindrical elements 68 near second end 72 improve the radial strength and also increase vessel coverage. Opposite second end 72 has longer straight strut arms 80 to allow expansion to larger diameters although the radial force and vessel coverage are reduced.

Clearly, there are other parameters that could also be varied to optimize performance at each end. For example, the stent struts could be varied in width or thickness. The material processing conditions could be varied to impart different engineering characteristics. The number of repeating patterns that form the serpentine wave pattern around the circumference of cylindrical element 68 could be changed. The number of cylindrical elements 68 and the number of interconnecting elements 74 may be varied to change flexibility and other typical design parameters.

While the present invention has been illustrated and described in terms of its use as carotid stents, it will be apparent to those skilled in the art that the present invention stent can be used in other instances in all lumens in the body. Since the present invention stent has the novel feature of self-expansion to a large diameter while retaining its structural integrity, it is particularly well suited for implantation in almost any vessel where such devices are used. This feature, coupled with limited longitudinal foreshortening of the stent when it is radially expanded, provide a highly desirable support member for all vessels in the body. Other modifications and improvements may be made without departing from the scope of the present invention.

CLAIMS

WHAT IS CLAIMED IS:

1. A longitudinally flexible stent for implanting in a body lumen and expandable from a contracted state to an expanded state, comprising:

a plurality of adjacent cylindrical elements, each cylindrical element having a circumference extending around a longitudinal stent axis and being substantially independently expandable in the radial direction, wherein each cylindrical element is formed from struts arranged in a serpentine wave pattern;

wherein the plurality of adjacent cylindrical elements are arranged in alignment along the longitudinal stent axis, and wherein a plurality of cylindrical elements include sequentially increasing diameters to create a tapered profile;

a plurality of interconnecting members extending between the adjacent cylindrical elements and connecting the adjacent cylindrical elements to one another; and

wherein at least one of the plurality of struts and interconnecting members at the tapered profile increase in length along the longitudinal stent axis.

2. The longitudinally flexible stent of claim 1, wherein the stent includes a pseudoelastic alloy material.

3. The longitudinally flexible stent of claim 1, wherein the stent includes a shape memory alloy material.

4. The longitudinally flexible stent of claim 1, wherein the plurality of interconnecting members are aligned end to end.

5. The longitudinally flexible stent of claim 1, wherein the serpentine wave pattern of a cylindrical element further comprises a repeating strut pattern of upright V's and inverted V's.

6. The longitudinally flexible stent of claim 5, wherein the strut pattern of upright V's and inverted V's of one cylindrical element is in phase with the strut pattern of V's and inverted V's of an adjacent cylindrical element.

7. The longitudinally flexible stent of claim 6, wherein the strut pattern of upright V's and inverted V's of one cylindrical element nest into the upright V's and inverted V's of the adjacent cylindrical element.

8. The longitudinally flexible stent of claim 1, wherein the serpentine wave pattern of a cylindrical element further comprises a repeating strut pattern of U's connected to W's.

9. The longitudinally flexible stent of claim 8, wherein the serpentine wave pattern of a cylindrical element is out of phase with the serpentine wave pattern of an adjacent cylindrical element.

10. A longitudinally flexible stent for implanting in a body lumen and expandable from a contracted state to an expanded state, comprising:

a plurality of adjacent cylindrical elements, each cylindrical element having a circumference extending around a longitudinal stent axis and being substantially independently expandable in the radial direction, wherein the plurality of adjacent cylindrical elements are arranged in alignment along the longitudinal stent axis and define a first end, a second and, and a center section;

wherein the center section is tapered when expanded such that the first end includes a small diameter and the second end includes a large diameter;

each cylindrical element formed from struts arranged in a serpentine wave pattern;

a plurality of interconnecting members extending between the adjacent cylindrical elements and connecting the adjacent cylindrical elements to one another; and

wherein in the expanded state of the stent, a distance between adjacent cylindrical elements increases from the first end to the second end.

11. The longitudinally flexible stent of claim 10, wherein the plurality of interconnecting members are aligned end to end.

12. The longitudinally flexible stent of claim 10, wherein the serpentine wave pattern of a cylindrical element further comprises a repeating strut pattern of upright V's and inverted V's with each upright V and inverted V including a shoulder.

13. The longitudinally flexible stent of claim 10, wherein the serpentine wave pattern of a cylindrical element further comprises a repeating strut pattern of U's connected to W's.

14. The longitudinally flexible stent of claim 10, wherein the stent includes a nickel-titanium alloy.

15. A method for providing a longitudinally flexible stent for implanting in a body lumen and expandable from a contracted state to an expanded state, the method comprising the steps of:

providing a plurality of adjacent cylindrical elements, wherein each cylindrical element has a circumference extending around a longitudinal stent axis and is substantially independently expandable in the radial direction;

arranging the plurality of adjacent cylindrical elements in alignment along the longitudinal stent axis to define a first end, a second end, and a center section;

providing a tapered profile in the center section when expanded by providing small diameter cylindrical elements in the first end and gradually increasing the diameters toward the second end;

forming a serpentine wave pattern in each cylindrical element;

providing a plurality of interconnecting members extending between the adjacent cylindrical elements;

connecting the adjacent cylindrical elements to one another using the interconnecting members; and

wherein when the stent is in the expanded state, a distance between adjacent cylindrical elements increases from the first end toward the second end.

16. The method of claim 15, wherein the step of forming the serpentine wave pattern further comprises forming a repeating strut pattern of upright V's and inverted V's.

17. The method of claim 16, wherein the step of forming the serpentine wave pattern further comprises nesting the upright V's and inverted V's of one cylindrical element with an adjacent cylindrical element by arranging the serpentine patterns in phase and shortening the interconnecting members.

18. The method of claim 15, wherein the step of forming the serpentine wave pattern further comprises forming a repeating strut pattern of U's connected to W's.

19. The method of claim 15, wherein the step of providing a plurality of adjacent cylindrical elements includes forming the cylindrical elements from shape memory alloy material.

20. The method of claim 15, wherein the step of providing a plurality of adjacent cylindrical elements includes forming the cylindrical elements from a pseudoelastic alloy material.

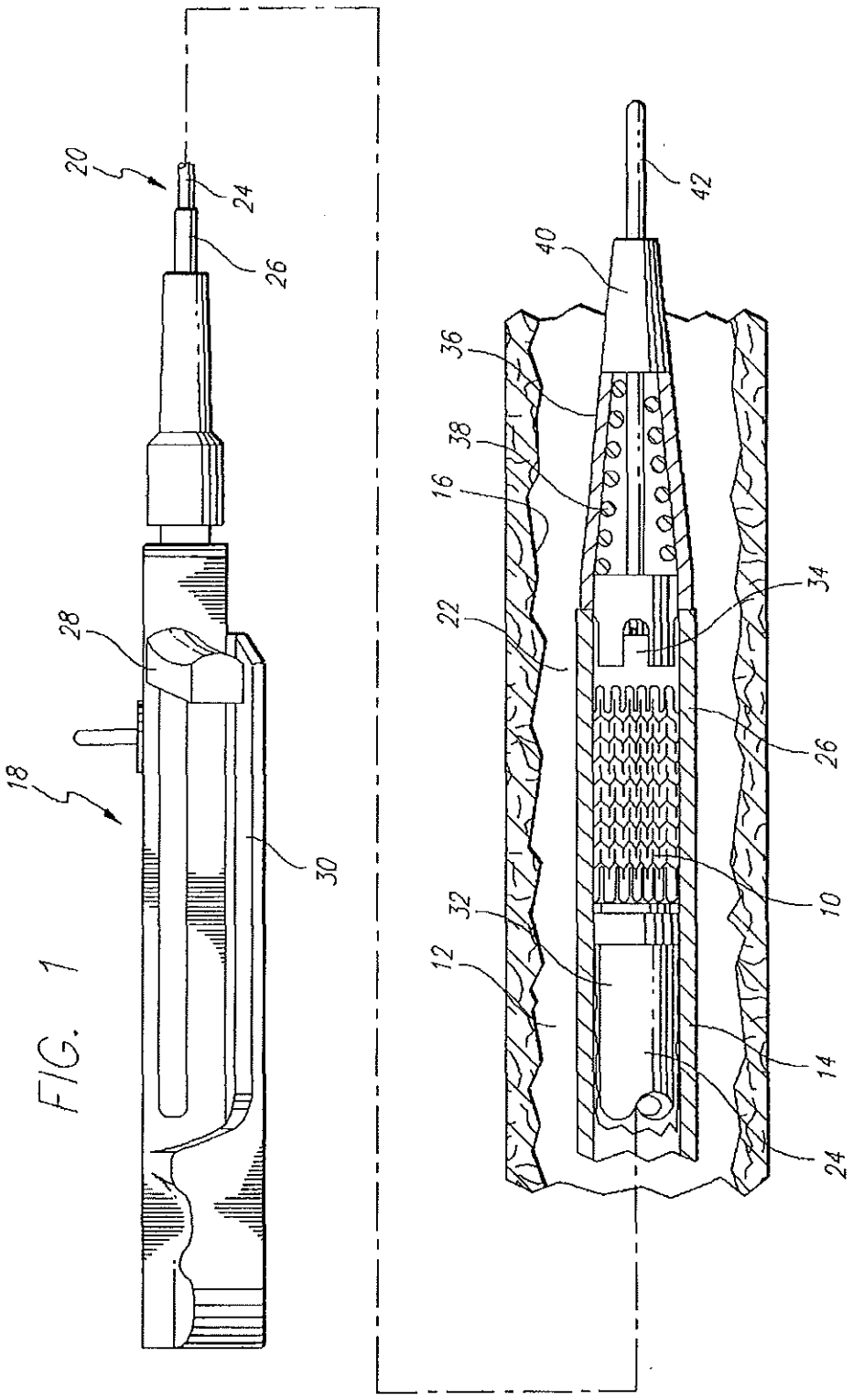
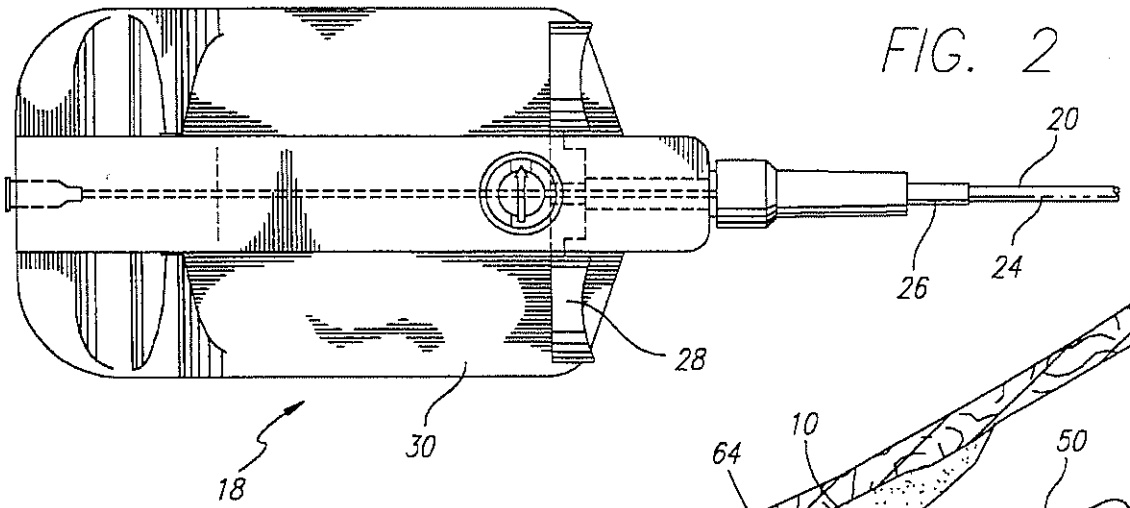


FIG. 1

FIG. 2



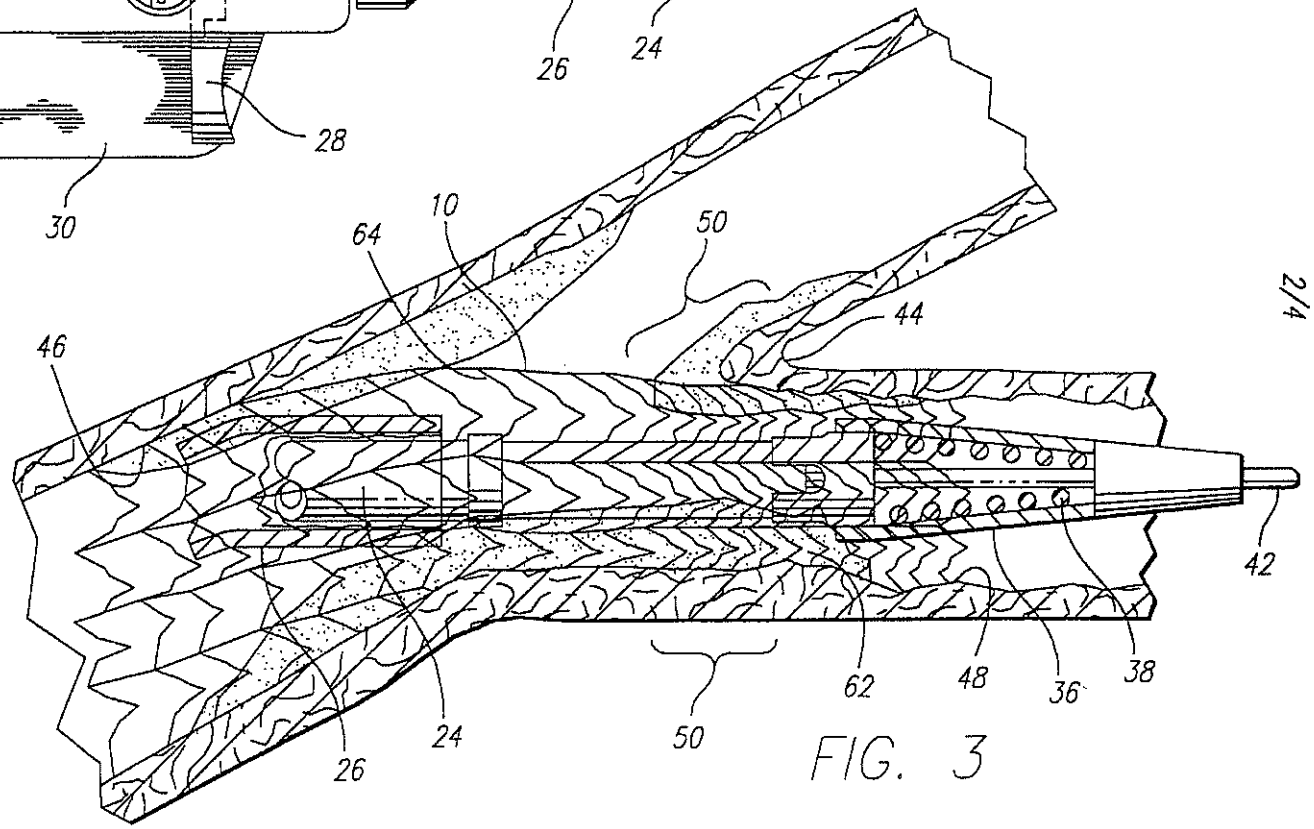


FIG. 3

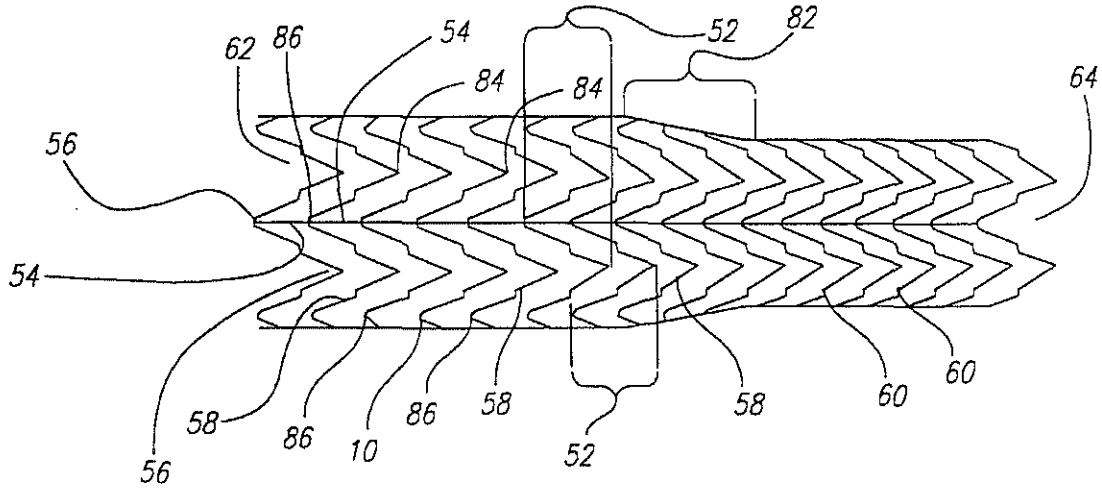

62
86
54
52
82
84
84
64
56
54
58
86
10
86
58
52
58
60
60
56

FIG. 4

FIG. 5

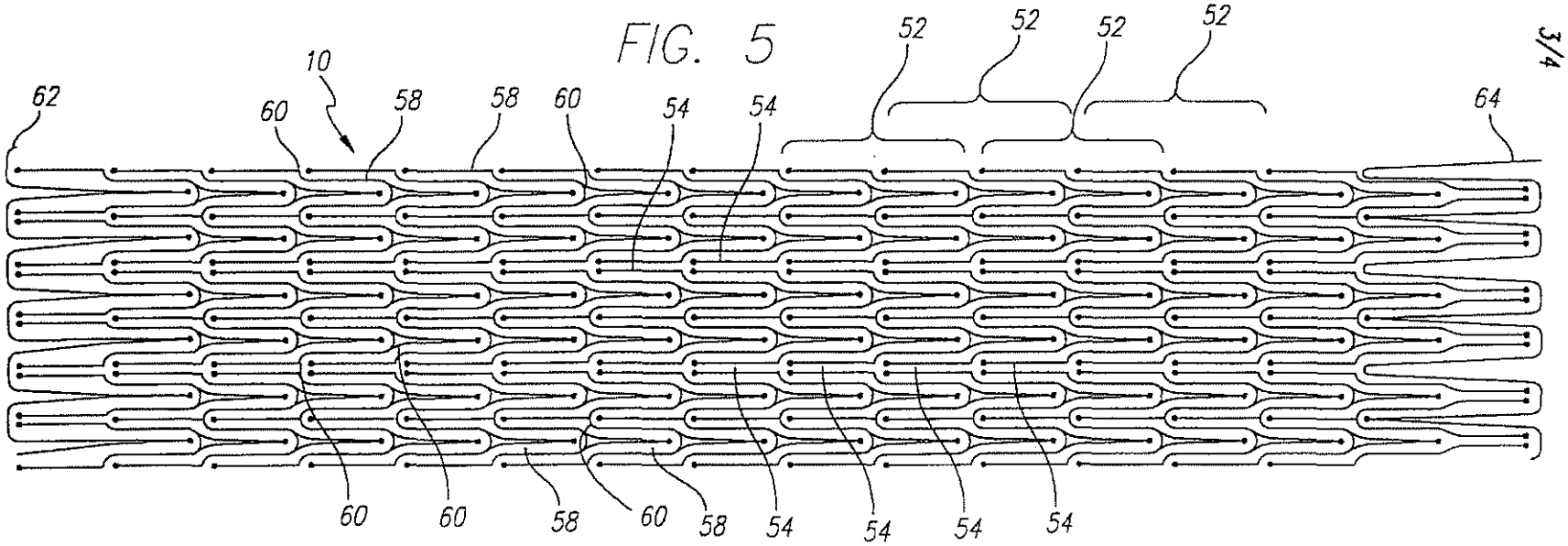

52
52
52
52
10
62
60
58
58
60
54
54
64
60
60
58
60
58
54
54
54
54

FIG. 6