

[54] BILE DUCT ENDOPROTHESIS

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[57]

ABSTRACT

A bile duct endoprosthesis having a metal or plastic cannula for introduction into the bile duct and having rounded or beveled ends to aid in insertion and a radially extending portion which serves as a means for attaching a drain hose to the cannula and also as a means for insuring against longitudinal displacement of the cannula after it has been positioned within the bile duct. The cannula has two discrete end sections which are detachable joined to a push on frictional type connector that enables easier implantation of the cannula within a bile duct.

8 Claims, 5 Drawing Figures

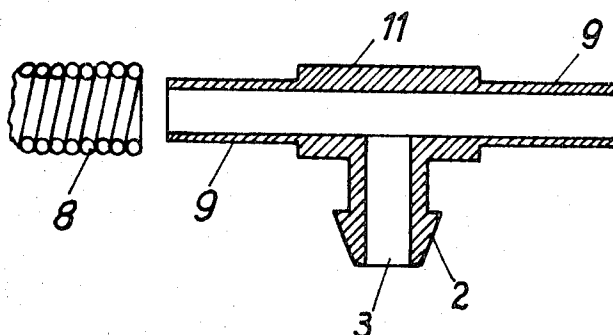


Fig. 1

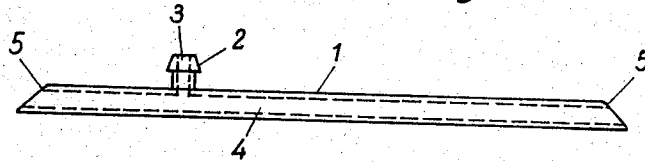


Fig. 2

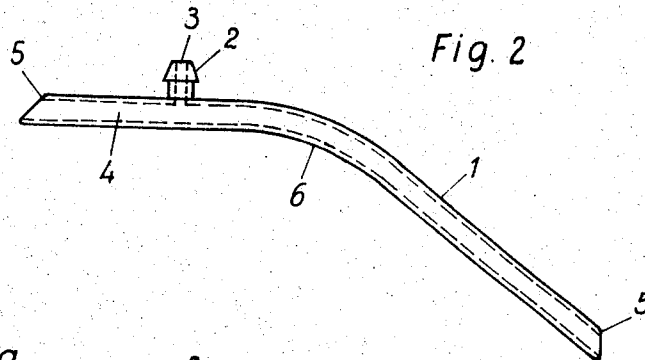


Fig. 3a

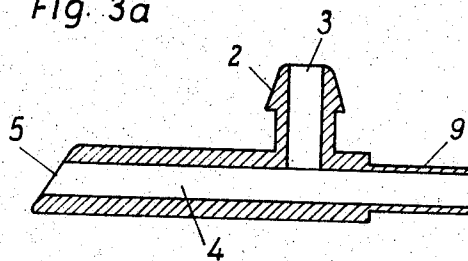


Fig. 3b

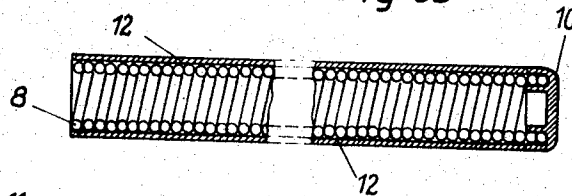
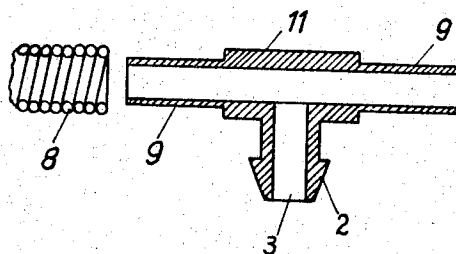


Fig. 4



BILE DUCT ENDOPROTHESIS**BACKGROUND OF THE INVENTION****1. Field of the Invention**

The present invention is directed to a bile duct endoprosthesis for restoring the biliary flux into the duodenum.

2. Description of the Prior Art

Irreparable bile duct stenoses which result in deadly bile duct congestions (cholestases) are caused by carcinoma of the pancreas, papillocarcinoma, duodenal carcinoma, antral carcinoma, carcinoma of the bile duct, carcinoma of the gall bladder, carcinoma in the hilus of the liver, retroperitoneal tumors, chronic pancreatitis, etc. When these diseases occur, the cases are rare in which short-term success is achieved by using radical by-pass anastomoses for restoring the biliary flux. However, in most cases, such irreparable methods of closing the bile ducts lead to early disturbances of the total organism resulting in death.

SUMMARY OF THE PRESENT INVENTION

The present invention makes it possible to eliminate irreparable bile duct stenoses and thus to prolong or save the lives of patients. For this purpose, the invention provides a bile duct endoprosthesis for restoring the bile flux into the duodenum, characterized by a metal or plastic cannula which can be introduced into the bile duct. The cannula has rounded ends and at least one radial extension for protection against longitudinal displacements.

After the bile duct has been opened on one side of the stenosis and after the stenosis has been dilated with a bougie on both sides, the cannula can be introduced into the bile duct and thus, a safe and unhindered bile flux is made possible. The radial extension prevents displacements and thus prevents the prosthesis from sliding out of the bile duct.

To facilitate the introduction of the cannula, not only are its ends rounded off, but also according to a further development of the invention, there is provided a beveling at least at one end, i.e., the cannula is not cut off straight, but beveled, and hence tapers.

A further development of the invention additionally provides that the cannula is subdivided into two sections. Both sections can then be introduced separately during the operation, and hence, they can be introduced easier. Afterwards, they can be joined, preferably by means of a detachable push-on connection.

In a further development, the invention proposes that the cannula is shaped according to the normal curvature of the bile duct or, at least is shaped so for a part of its length. For this purpose, one of its sections can be rendered flexible so that the prosthesis can automatically adapt itself to the natural curvature of the bile duct. According to a further development of the invention, the flexible section consists of a tightly wound coil spring, one end of which is attachable to a part of the other section having a reduced diameter while the other end of the coil spring carries a toroidal end ring. Likewise, both sections can consist of such coil springs each having a toroidal end ring and being attachable to a short connecting piece of a reduced diameter on both sides and having the radial extension.

The flexible section, especially one formed as coil spring, can be slightly loose when curved. Therefore, a further development of the invention provides that the

flexible section is covered with a thin-walled plastic hose. The hose must consist of a material compatible with body tissue, for example, silicone rubber.

An important development of the invention is characterized in that the radial extension is formed as a nipple having a perforation which is in communication with the interior of the cannula. Then, the nipple not only prevents longitudinal displacements of the endoprosthesis, but simultaneously serves as a means for attachment with a hose to temporarily drain the bile to the outside and to administer irrigations.

DESCRIPTION OF THE DRAWINGS

A better understanding of the present invention will be achieved upon reference to the accompanying drawings in which several preferred embodiments are illustrated and in which:

FIG. 1 is a side elevational view of a bile duct endoprosthesis of the present invention in the form of a straight cannula;

FIG. 2 is a view similar to FIG. 1 but illustrating a bile duct endoprosthesis of the present invention in the form of a bent cannula;

FIGS. 3a and 3b are side elevational views of other preferred prosthesis of the present invention; and

FIG. 4 illustrates the connecting piece of a prosthesis upon which two flexible sections according to FIG. 3b can be attached.

DESCRIPTION OF SEVERAL PREFERRED EMBODIMENTS

A bile duct endoprosthesis of the present invention is illustrated in FIG. 1 as comprising a rigid cannula 1 made of material that can be implanted in a bile duct of the human body, i.e., metal or plastic. At about one-third of its length, a perforated nipple 2 is mounted on the cannula 1 and has a perforation 3 which is in communication with the internal boring 4 of the cannula 1. A hose (not shown) can be pushed on to the nipple 2, and utilized to drain temporarily the bile to the outside and to administer irrigations. Simultaneously, the nipple 2 together with the connected hose forms a radial extension which protects the cannula from longitudinal displacements.

At the ends of the cannula 1, there are bevels 5 which facilitate the insertion into the bile duct. Roundness of the outer surfaces prevents injuries.

FIG. 2 illustrates another preferred embodiment of the present invention which differs from the prosthesis according to FIG. 1 in that the cannula 1 is bent at 6 for adapting itself to the natural form of the bile duct.

Another preferred form of the endoprosthesis of the present invention is depicted in FIGS. 3a and 3b as comprising rigid section 7 and a flexible section 8. The rigid section 7 is formed of a metal cannula 14 and has a nipple 2 and a bevel 5 similar to that of the embodiments of FIGS. 1 and 2. At the end opposite to the bevel 5, there is disposed a connecting piece 9 of reduced diameter on which the flexible section 8 can be pushed so that clamping and tightening is effected. The flexible section 8 includes a tightly wound elastic metal wire forming an initially tensioned toroidal coil spring with the individual turns being close to each other. A toroidal end ring 10 preferably made of metal is pushed on the free end of the flexible section 8 and fastened

there. The roundness of the ring **10** facilitates insertion of the section **8** into the bile duct.

When a better sealing in the curved state is desired or required, a thin-walled hose **12** made of silicone rubber is installed to fit tightly over the coil spring. For a better understanding, the wall thickness of the hose **12** depicted in FIG. **3b** has been exaggerated.

Depending upon the prevailing conditions, it may be advantageous to utilize two flexible sections **8** like the one shown in FIG. **3b**. In that case, a center piece **11**, as shown in FIG. **4**, serves as a push-on frictional type connector. In conformity with the example according to FIG. **3a**, the center piece **11** is provided with a radial extension in the form of a nipple **2**. Connecting pieces **9** are provided on both ends for attaching the flexible sections **8**.

In order to adapt the endoprosthesis to the respective size and the course of the bile ducts and to the forms of stenosis, it is advantageous to keep available endoprostheses or their parts of different lengths, sizes, and curvatures, as well as those which are rigid and those which are flexible. The length of the complete prosthesis is normally situated in a range between 4 and 7 cm.

For the introduction of the prosthesis into the bile duct, the latter is opened above the stenosis. If the stenosis extends over the total bile duct, an attempt has to be made to obtain a passageway at one spot. The part of the stenosed bile duct is dilated by a bougie until a part of the endoprosthesis can be easily introduced and can then be pushed into the small intestine through the spot dilated by the bougie. The other part of the endoprosthesis is introduced into the bile ducts in the direction of the liver. The sections are then snapped together. For gripping both sections, a special pliers fitted to the form of the cannula **1** can be used. A hose is pushed onto the nipple **2** of the endoprosthesis and conducted through the skin to the outside. This hose makes it possible to drain initially the bile and to administer irrigations during the first weeks. The hose can be drawn off after two or three months. The surrounding tissue closes the small opening within a few days.

When the stenosis is located towards the liver, the same applies correspondingly, except that the stenosis must be dilated by a bougie in the direction of the liver.

Although I have disclosed several embodiments of the present invention, it is apparent that many changes and modifications can be made without departing from

the spirit of the invention as expressed by the scope of the appended claims.

I claim:

1. A bile duct endoprosthesis for restoring the biliary flux into the duodenum, comprising a cannula of a size which can be introduced into the bile duct, said cannula being made of material suitable for implantation in a bile duct and having rounded free ends and at least one radial extension for protection against longitudinal displacements, the cannula comprising two discrete end sections and a discrete push-on frictional type connector detachably connecting said end sections together.

2. A bile duct endoprosthesis according to claim 1, characterized in that the cannula is beveled, at least at one free end.

3. A bile duct endoprosthesis according to claim 1, characterized in that the cannula is shaped according to the normal curvature of the bile duct and is shaped so for at least part of its length.

4. A bile duct endoprosthesis according to claim 1, characterized in that at least one of the end sections is formed to be flexible.

5. A bile duct endoprosthesis according to claim 4, characterized in that the flexible end section is covered by a thin-walled plastic hose.

6. A bile duct endoprosthesis according to claim 4 characterized in that the flexible end section comprises a tightly wound coil spring, said connector having a reduced diameter portion and one end of said flexible end section being disposed over said reduced diameter portion of said connector and a torroidal end ring carried by the opposite end of said flexible end section.

7. A bile duct endoprosthesis according to claim 4 and in which each of the end sections comprises tightly wound coil springs each of which carries a torroidal end ring at one end, said connector comprising a short connecting piece having reduced diameter opposite end portions, said end section having ends opposite said end rings fitting over said end portions, said radial extension comprising said connecting piece having a radially extending drain attachment means.

8. A bile duct endoprosthesis according to claim 1, characterized in that the radial extension is formed as a nipple having a perforation which is in communication with the interior of the cannula.

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