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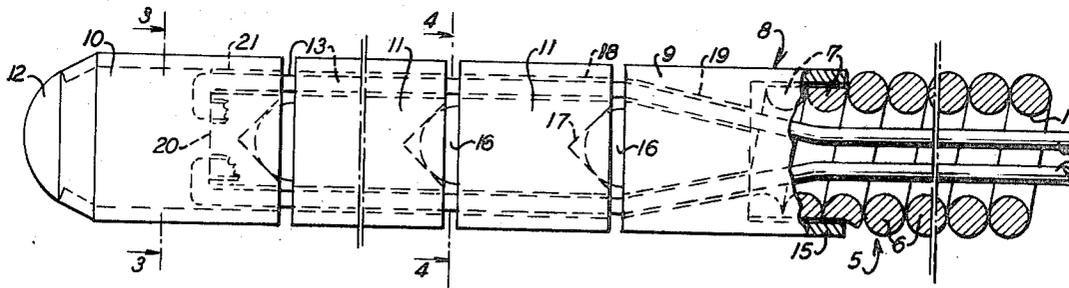
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- [54] **CONTROLLED CURVABLE TIP MEMBER**
9 Claims, 4 Drawing Figs.
 [52] U.S. Cl. **128/2.05 R,**
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ABSTRACT: A wire-controlled curvable tip for a spring guide comprising solid cylindrical links engaging each other with nonlocking ball-and-socket type of articulation and adjustable to varying degrees of curvature by means of wires, each wire passing through a series of matching tunnels lengthwise of the links, secured at one end in the most distally located link and manipulated by applying differential tension to the other ends of the respective wires at the proximal end of the spring guide.

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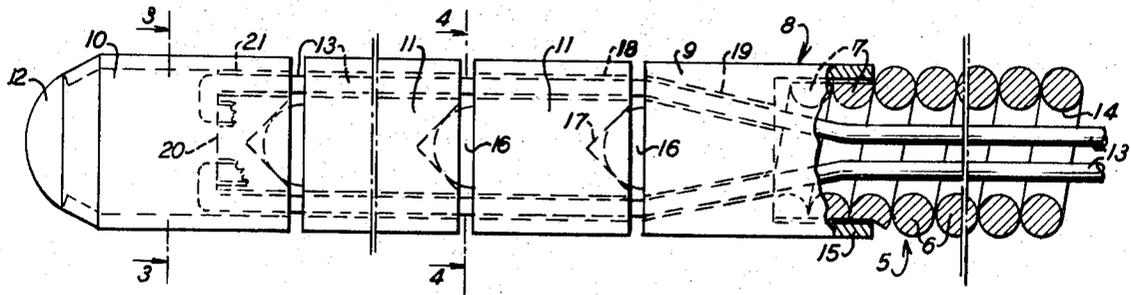


Fig. 1

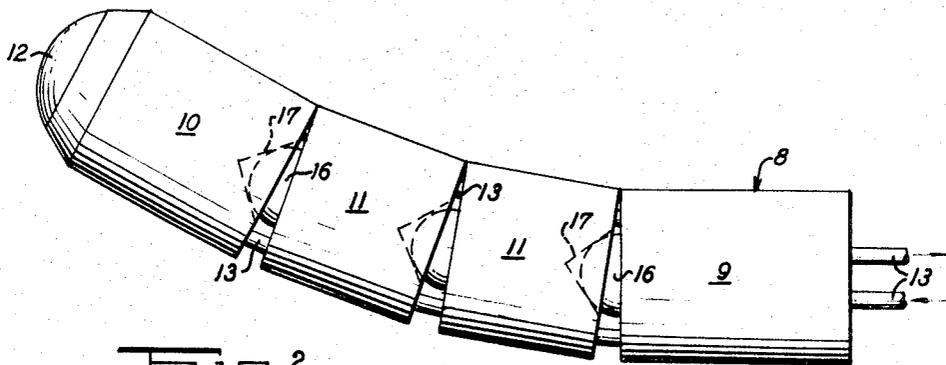


Fig. 2

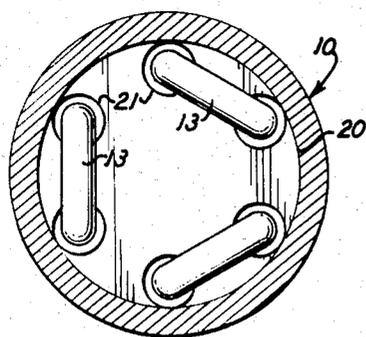


Fig. 3

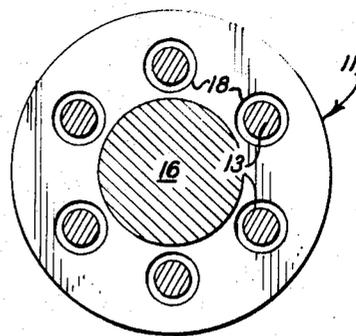


Fig. 4

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CONTROLLED CURVABLE TIP MEMBER

THE INVENTION

This invention relates to new and useful improvements in spring guides, elongated medical devices, e.g. used in vascular, intestinal, urological, etc. manipulations where the distal end within the body must be controlled from the proximal end outside the body and more particularly seeks to provide such a device that has a controlled curvable tip for easy deflection from straight line courses.

The marked advances in cardiac and vascular surgery in the past few years and other medical problems that require diagnostic study of the vascular beds and systems has led to the extensive use of cardiac or vascular catheters, particularly for retrograde aortography and angiocardiology, and less often to take blood samples, determine oxygen content, infuse medicaments, and various other uses that require the insertion of a relatively long catheter to an internal site that requires movement of the catheter into branch vessels at sharp angles relative to the feeding direction of the catheter.

The most common method for insertion of such catheters is the percutaneous technique described in 1953 by Sven Ivar Seldinger. In this procedure a local anesthesia is administered and a skin puncture made at a small angle to the vessel (e.g. femoral in the leg or brachial in the arm) with an obturator positioned within a cannula. Once the unit has been properly located in the vessel, the obturator is removed and the flexible spring guide then inserted through the cannula into the vessel for a short distance. Pressure is then applied to hold the spring guide in place while the cannula is withdrawn. The spring guide is then fed into the vessel, generally under observation by means of fluoroscope, until the desired point is reached which may require considerable manipulation if there are branched vessels or curves concerned. Thereafter the catheter is passed over the flexible spring guide and fed into the desired position and the spring guide then withdrawn from the catheter unless both are needed for cooperative manipulation purposes.

There has also been a frequent need to place elongated tubes through the nose into at least the duodenum and even further down the intestinal tract. It is fairly easy to reach the stomach but becomes difficult to pass through the pylorus because of the curvature into the duodenum. Once in the duodenum, decompression, introduction of contrast media, washing, sampling, biopsy, etc. becomes much simpler. Heretofore, flexible plastic or rubber tubes with a weighted distal end were utilized to reach the duodenum but the procedure sometimes takes several hours and sometimes cannot be accomplished at all.

There are presently available spring guides for vascular work made from stainless steel of 110 and 125 cm. lengths, each having outside diameter sizes of 0.025 (pediatric), 0.035 and 0.045 inch which are used with correspondingly shorter catheters. The guides consist of an outer case which is a closely wound stainless steel spring to form a continuous coil surrounding an inner bore which is then sealed at the distal end with a rounded tip or cap. A straight inner wire is placed within the coil bore and is either freely movable within the guide or fixed within the guide about 3 cm. short of the distal tip which is left flexible for manipulation purposes.

The spring guides are quite flexible but there is no lateral control over the distal end from the proximal end after insertion into a vessel. Thus to pass sharp curves or to go into branch vessels the surgeon must make all kinds of turning and push-pull manipulations, with the hope that by chance the distal end will finally lead into the branch vessel or around the curve as desired. Some catheters have soft curved ends which are maintained in a straight position as the catheter is fed through the vessel over the spring guide, when the catheter tip passes beyond the end of the spring guide it recovers its normal curved form and can be used to enter branch vessels, etc. This, however, has not been entirely satisfactory and presents several problems, one of which is that the surgeon must be

manipulating both the spring guide and the catheter to secure desired results. Secondly, once the spring guide is removed from the catheter tip the tip has a set curve which cannot be changed nor straightened without insertion of the guide, and perhaps most importantly, the curve is in one direction only so that rotation of elongated catheters from the proximal end is necessary.

Therefore, it is an object of this invention to provide a spring guide, the straight distal end of which can be manipulated from the proximal end that is outside the patient to make it useful for intestinal studies and more useful for vascular studies.

It is a further object of this invention to have a spring guide which has a spinelike tip at the distal end which may be manipulated in arc or curved condition by means of wires that lead through the bore of the spring guide to the distal end where the spinelike tip is positioned.

It is also an object of this invention to provide a spring guide that can be curved in any direction from outside the patient while it is being fed through vessels or may be curved after the catheter is placed thereover and thus cause the catheter to curve.

I have found that a conventional spring guide may be used to carry a single or preferably a series of fine wires from the proximal end to the distal end, which wires then pass from the guide bore through the walls of a series of pivotal links that extend beyond the coil tip, to be anchored in the most distal link. With this arrangement, if one wire is pulled at the proximal end, it will cause curving of the pivotal links at the distal end.

With the above and other objects and features in view, the nature of which will be more apparent, the invention will be more fully understood by reference to the drawings, the accompanying detailed description and the appended claims.

In the drawings:

FIG. 1 is a longitudinal cross section taken through a spring guide constructed in accordance with this invention with the tip in straight position;

FIG. 2 is a perspective view of the tip when in a curved condition;

FIG. 3 is a transverse section taken along line 3—3 of FIG. 1; and

FIG. 4 is a transverse cross section taken along line 4—4 of FIG. 1.

This invention as illustrated shows a spring guide having a curvable tip controlled through a series of three double wires or six single wires, the number of which could obviously be anything from one single wire to as many as could be carried within the bore of the spring guide coils.

A conventional spring guide 5 is shown in FIG. 1 made up of continuous contiguous coils 6 which in this instance have the distal coils 7 machined slightly for close fitting of the tip shown generally at 8 that includes a proximal link 9, a distal link 10 and a plurality of intermediate links 11. Securely fixed to the distal link 10 is a rounded cap 12 which prevents entry of blood into the unit and also serves as a blunt leading edge that will not pierce or irritate the vessels when being fed into position.

A series of fine wires 13 (preferably 0.002 inch diameter with a range of 0.001 to 0.004 inch) pass through the inner bore 14 of the spring guide coil portion extending freely out the proximal end for manipulation manually or by handles developed for that purpose.

At the distal end of the coils it will be noted that proximal link 9 is provided with a recess 15 which fits over the distal coil 7 and is secured thereto by welding or other means. Each link proximal to distal link 10 is provided with a spherical extension 16 on the distal end thereof which serves as a pivot bearing for the link distal thereto and rests within the cavity 17 provided in the proximal end of each link distal to proximal link 9. Each intermediate link 11 is provided with a series of radially spaced tunnels 18 that extend longitudinally through the body thereof parallel to the longitudinal axis. The proximal link 9 is provided with a corresponding set of tunnels 19,

except that these are at an angle in order to extend from recess 15 to the distal end where they must meet tunnel 18 of the first intermediate link. Distal link 10 has also been provided with a recess 20 at its distal end and associated tunnels 21 which are parallel to the outer surface and extend from the proximal end into the recess 20. Each wire strand 13 emerges from distal coils 7 and passes into an associated tunnel 19 within the proximal link 9 and then into a series of tunnels 18 in the intermediate links 11 and then into an associated tunnel 21 in the distal link 10. On emerging from tunnel 21 the wire is immediately reversed as shown best in FIG. 3 and goes into another of the tunnels 18, then back through proximal tunnels 19 and finally back into the bore of the coil portions and then extends to and beyond the proximal end of the coil portion.

It will be appreciated that there is no attachment or securing of the various links to one another, except through the wires 13 which thus permits each one to pivot relative to the contiguous links. However, it is necessary that the cap be secured to the distal link 10 and preferable that the proximal link 9 be secured to the distal coil 7.

With this construction, by applying tension to one of the strands 13 at the proximal end of the spring guide or to several of the wires as long as they are on the same side of the tip, one may bend the tip through as much as 180° with little difficulty, depending somewhat of course on how many intermediate links 11 are provided. For example, with 16 intermediate links covering about three-fourths inch, one can easily curve the tip through 180° with a radius of three-sixteenths inch.

Although more sensitive controls are possible with the six wires as shown (i.e. three wires each reversed as shown in FIG. 3 which also secures the distal link 10 and other links to the coils, it is possible, of course, to have any number of wires which may run only to the distal tip without being brought back, but which then would have to be secured to the distal link. If there are two or more wires, when increased tension is applied to one or more, the opposed wire or wires (as seen in a cross section such as FIG. 4) must be released since the opposed wires must become longer (see bottom wire 13 of FIG. 2) while the pulled wires become shorter (see top wire 13 of FIG. 2). Thus two wires radially spaced 180° would provide curvature in opposite directions but only one plane, whereas three or more wires increase the third-dimensional aspect of the curvature.

The sizes, of course, must all be in relation to that conventionally used for spring guides which are restricted, particularly when being used in blood vessels. Stainless steel has conventionally been the choice for spring guide coils and the wires that run through the bores thereof and I have respected those choices as my preference in this instance. It has been found, however, that the links are easier formed from brass, but in any event, materials do not constitute a particular feature of this invention as long as the particular material can be machined into the shape shown and is compatible with the human tissues.

It will be obvious, of course, that there are various ways of utilizing this item in practice. The spring guide per se may be manipulated to run the end into branch arteries or around curves in the various vessels. In addition, the spring guide may be put in straight and then covered by the catheter and then the tip curved with the catheter thereon, which will of course also curve the catheter, so that the manipulation is done with the combined spring guide and catheter. If it is desired to pass two curves or branches with one operation, the spring guide alone can, of course, be passed around a first branch or curve

and the tip straightened, as the curve will now be held by the blood vessel itself and the tip will then be ready for further manipulation through the control wires to move into a second branch. Once again, this may be done with the spring guide alone or in conjunction with the catheter covering same.

Various changes, modifications and ramifications will of course be obvious to those skilled in the art and are considered to be within the scope of the appended claims hereto.

I claim:

1. A tubular spring guide having a curvable tip comprising a plurality of solid cylindrical links positioned along the longitudinal axis of said tip, successive links being adjacent and centrally pivotally engaging each other, a plurality of tunnels extending longitudinally and off center through each said link, a continuous wire extending freely through each said tunnel and secured to the most distally located of said links, the most proximally located of said links being adjacent the distal end of said spring guide, and each said wire extending through and to the proximal end of said spring guide whereby said tip can be controllably curved by selective tensioning of said wires.

2. The spring guide of claim 1 wherein said most proximally located link is provided with a recess that fits over and is secured to said distal end of said guide.

3. A spring guide according to claim 1 in which the tunnels through the most proximally located link lie at acute angles from the axis of said link, the distal end of each said angled tunnel being disposed opposite the proximal end of a tunnel through an adjacent link, and the proximal end of each said angled tunnel being closer to the axis and communicating with the bore of the tubular spring guide.

4. A spring guide according to claim 1 in which an individual control wire extending freely distally through an aligned set of tunnels is turned 180° in the most distally located link to return proximally through another aligned set of tunnels.

5. The spring guide of claim 4 wherein said links are each provided with six tunnels and there are three continuous control wires having six free ends available at said proximal spring guide end.

6. The spring guide of claim 4 wherein said distal link is provided with a blunt rounded cap secured beyond said tunnels and wires.

7. The spring guide of claim 4 wherein said distal link has a recess at its distal end within which said distal link tunnels terminate and said wires turn laterally to reverse their directions.

8. In a spring guide formed from a continuously coiled wire, the improvement including a curvable tip positioned adjacent and longitudinally beyond the distal end of said guide, and a plurality of control wires extending from said tip through the bore and beyond the proximal end of said spring guide, said tip comprising a plurality of longitudinally positioned solid cylindrical links, successive links being adjacent and centrally pivotally engaging each other, a plurality of tunnels extending longitudinally and off center through each said link, the tunnels in each link being in alignment with the tunnels in each adjacent link, said control wires extending freely through each said tunnel and each being secured to the most distal of said links whereby said tip can be controllably curved from said proximal end of said spring guide by selective tensioning of said wires.

9. The spring guide of claim 8 wherein said pivotal engagement means are ball-and-socket elements at the joining surfaces of said adjacent link pairs.

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