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O'Keeffe

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# (54) INTRAVASCULAR ULTRASOUND CATHETER

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(52) **U.S. Cl.**

CPC ................. ***A61B 8/445*** (2013.01); ***A61B 8/12*** (2013.01); ***A61M 25/0051*** (2013.01); ***A61M 25/0053*** (2013.01); ***A61M 25/0054*** (2013.01); *A61M 25/0138* (2013.01)

(58) **Field of Classification Search**

USPC ......... 604/523–527, 264; 600/433–435, 585, 600/139–140, 143

See application file for complete search history.

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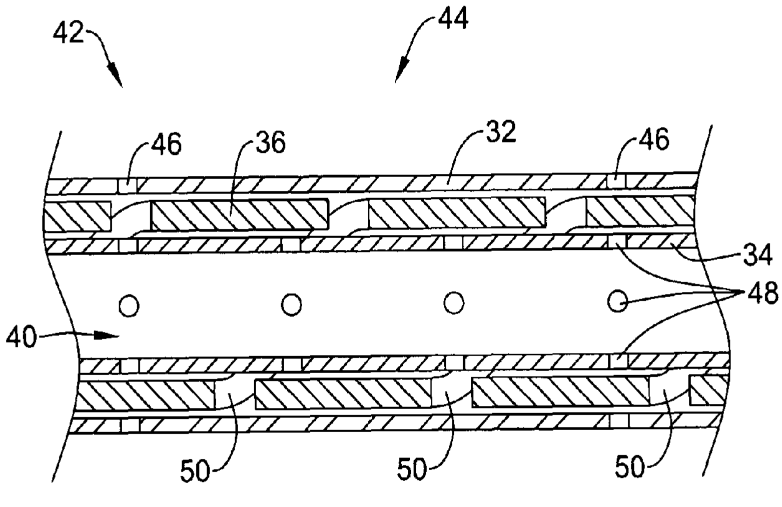
(57) **ABSTRACT**

An intravascular ultrasound catheter may include a central lumen adapted to receive a drive shaft bearing an ultrasound transducer. The intravascular ultrasound catheter may in some instances exhibit improved flexibility. The catheter can include an inner polymeric layer, an outer polymeric layer and a spiral-cut hypotube that is positioned between the inner polymeric layer and the outer polymeric layer.

**22 Claims, 13 Drawing Sheets**



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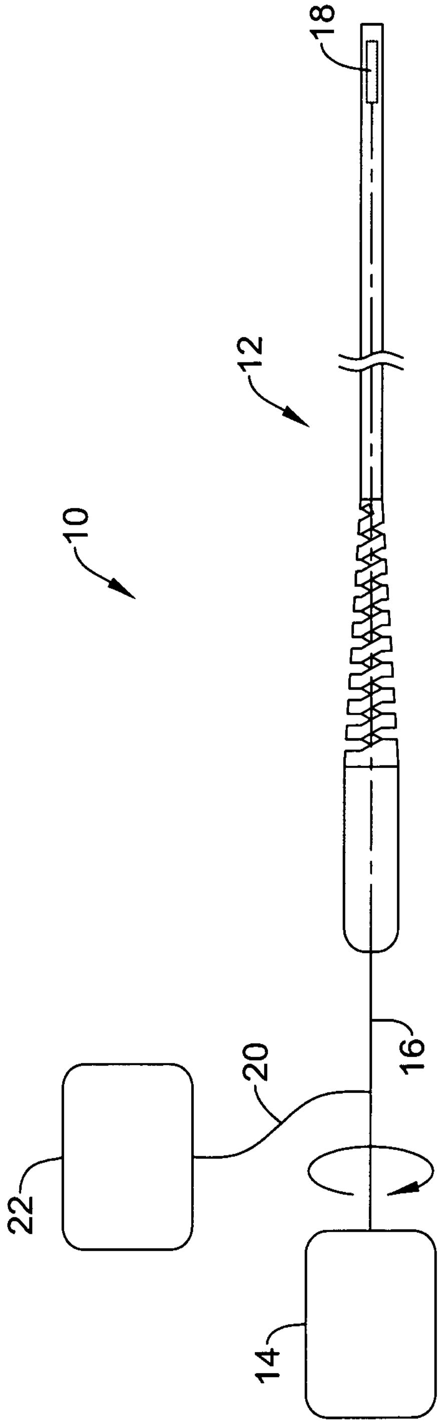



Figure 1

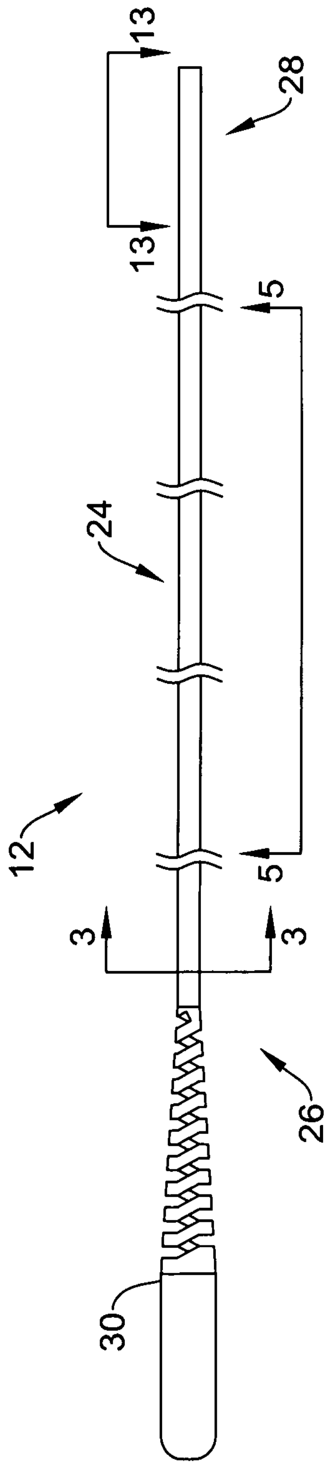



Figure 2

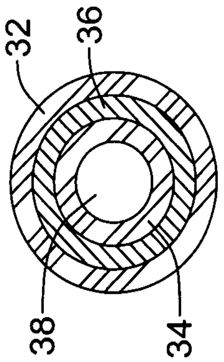



Figure 3

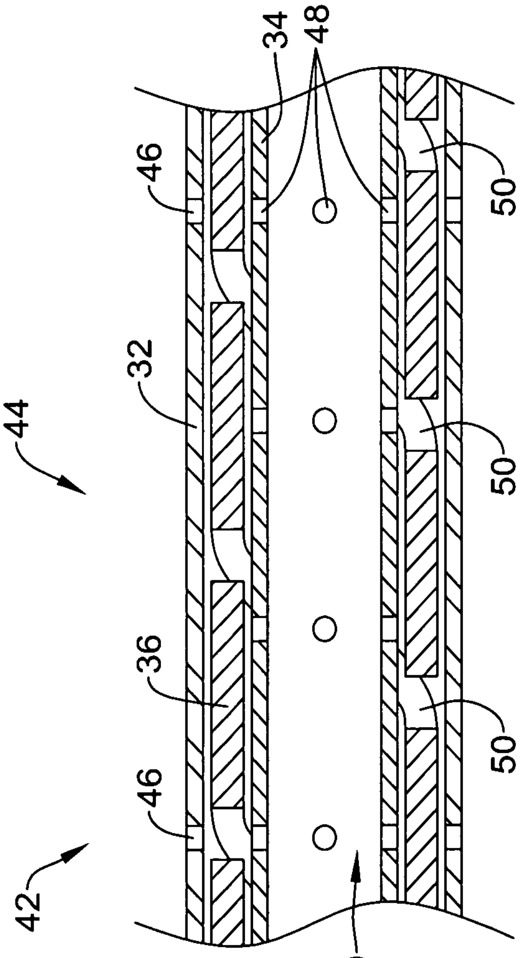



Figure 4

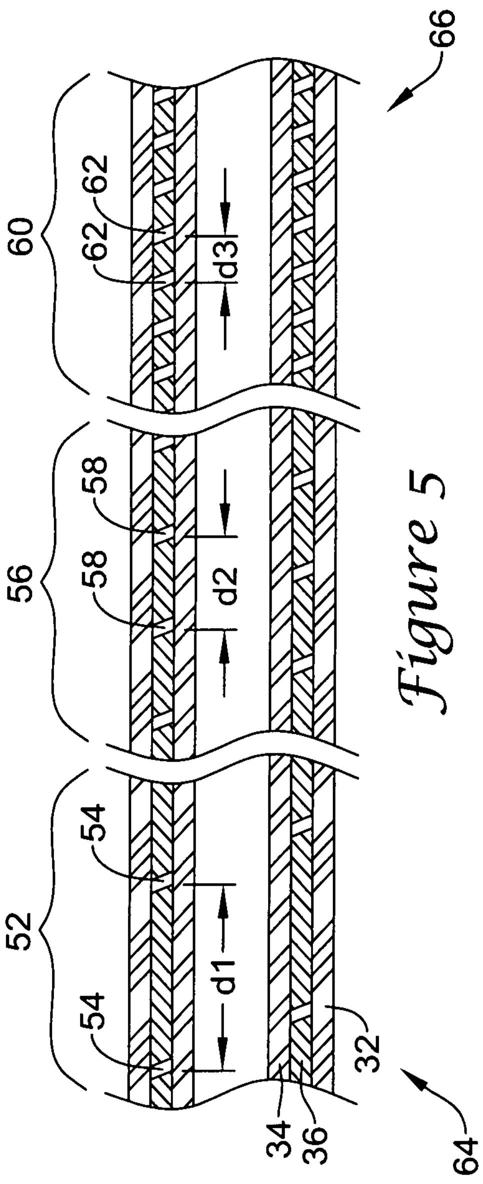



Figure 5

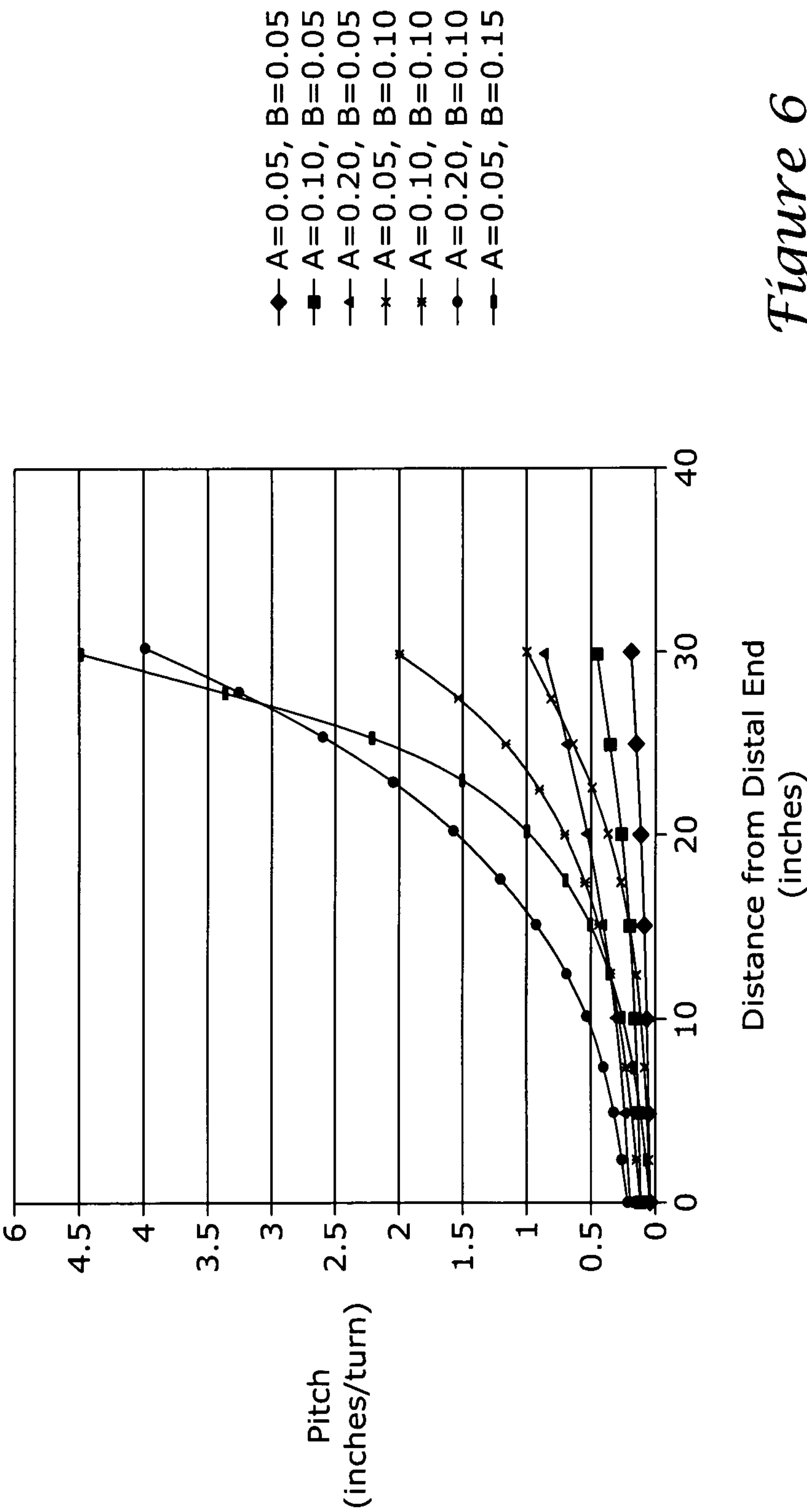

Pitch
(inches/turn)
6
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
0
10
20
30
40
Distance from Distal End
(inches)
A=0.05, B=0.05
A=0.10, B=0.05
A=0.20, B=0.05
A=0.05, B=0.10
A=0.10, B=0.10
A=0.20, B=0.10
A=0.05, B=0.15

*Figure 6*

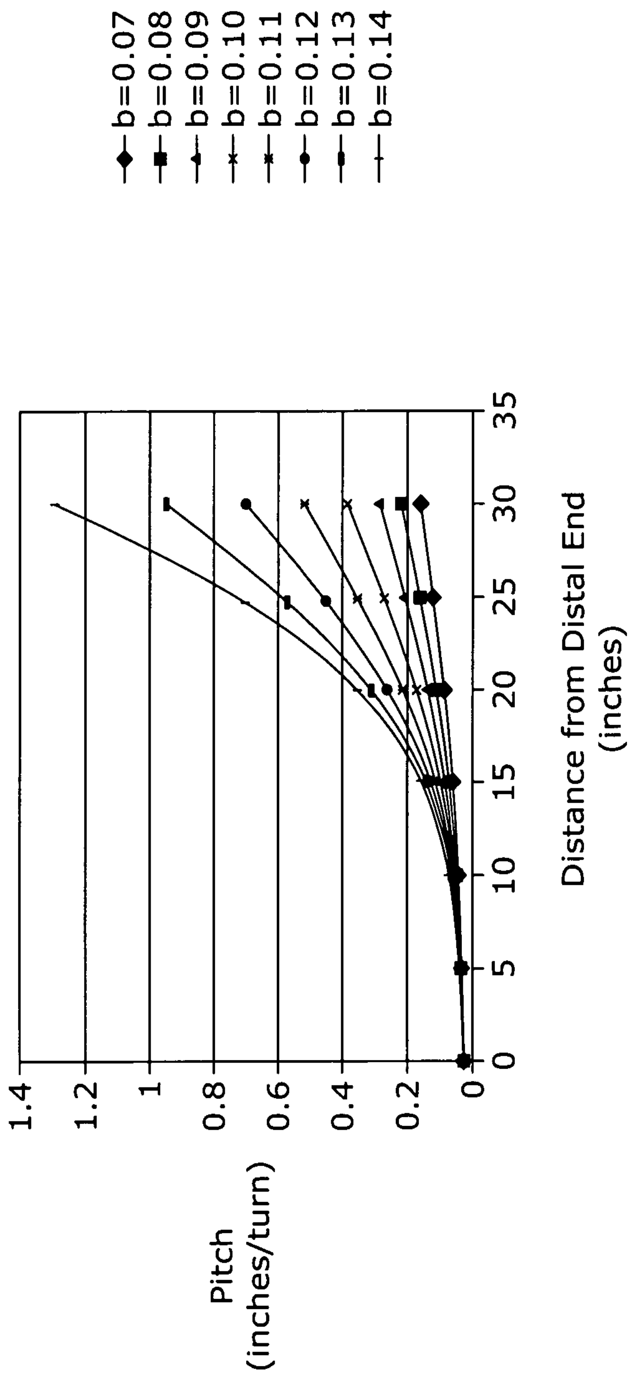
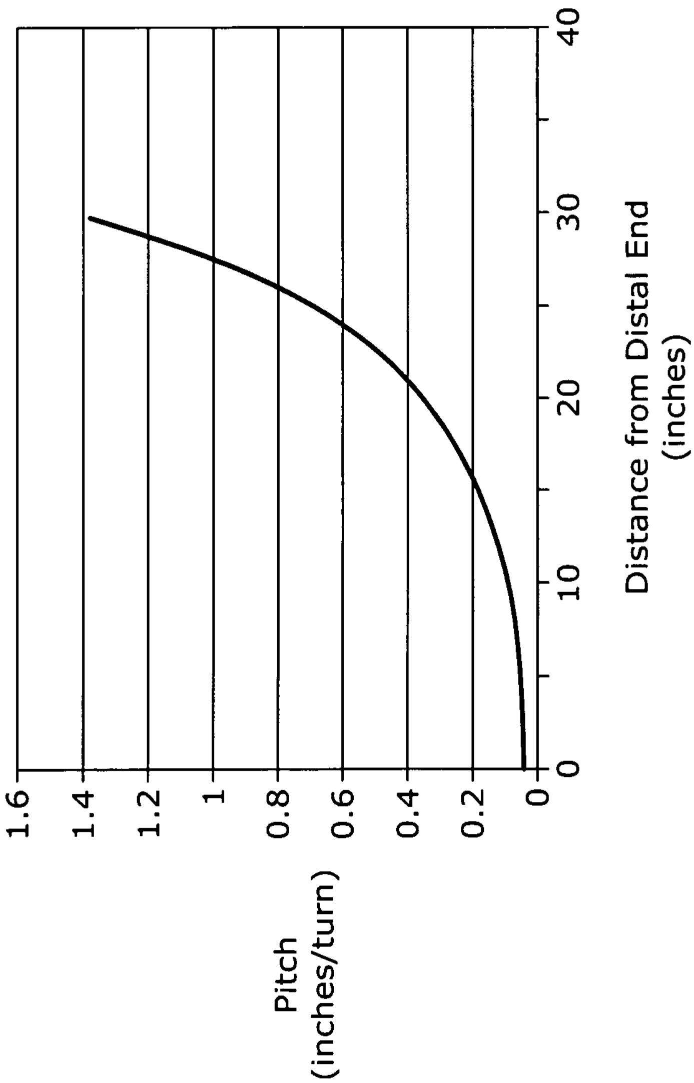
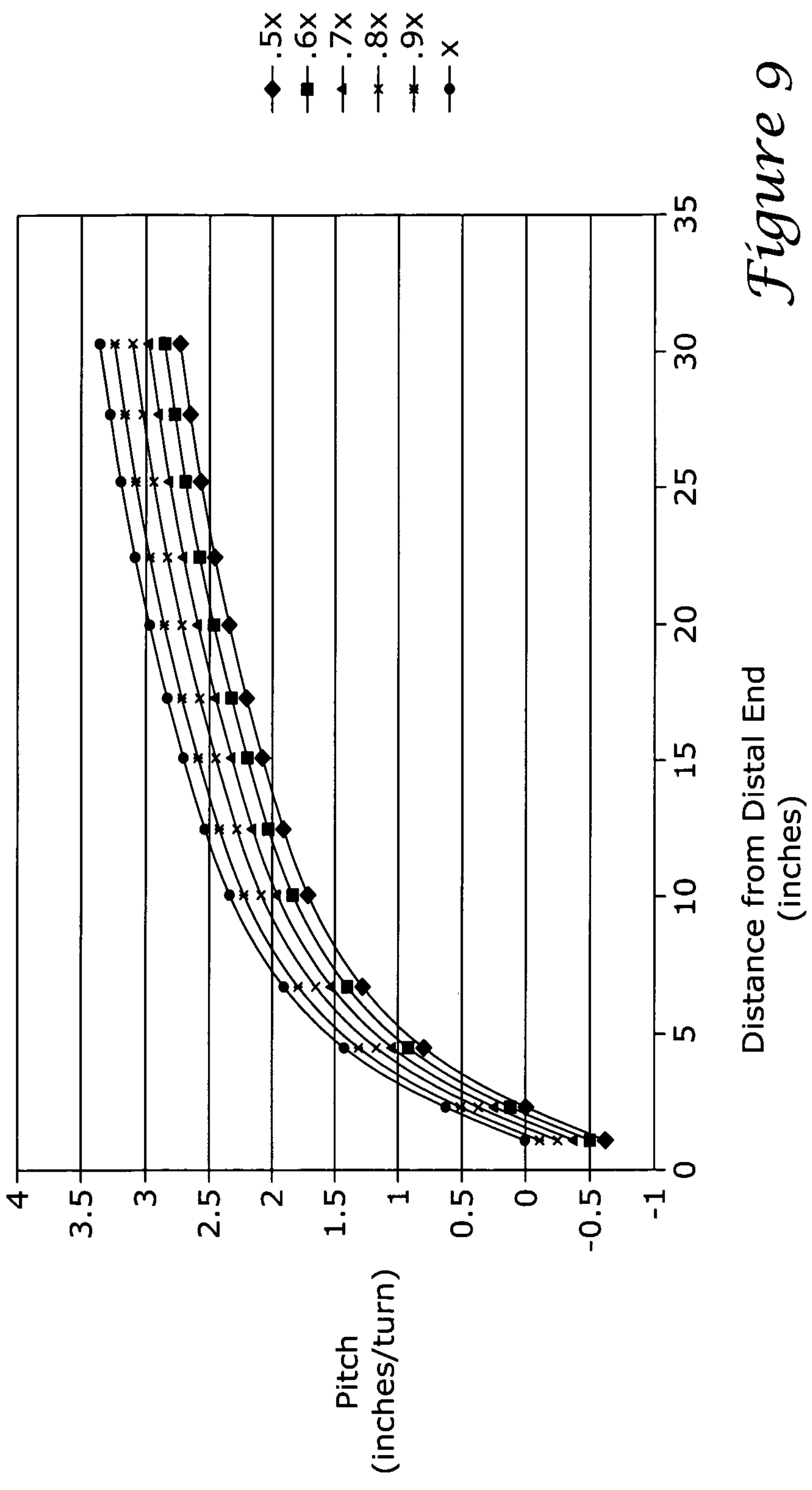

b=0.07
b=0.08
b=0.09
b=0.10
b=0.11
b=0.12
b=0.13
b=0.14
Pitch
(inches/turn)
1.4
1.2
1
0.8
0.6
0.4
0.2
0
0
5
10
15
20
25
30
35
Distance from Distal End
(inches)

*Figure 7*

*Figure 8*


Pitch
(inches/turn)
1.6
1.4
1.2
1
0.8
0.6
0.4
0.2
0
0
10
20
30
40
Distance from Distal End
(inches)



Pitch
(inches/turn)
4
3.5
3
2.5
2
1.5
1
0.5
0
-0.5
-1
0
5
10
15
20
25
30
35
Distance from Distal End
(inches)
.5x
.6x
.7x
.8x
.9x
x


*Figure 9*

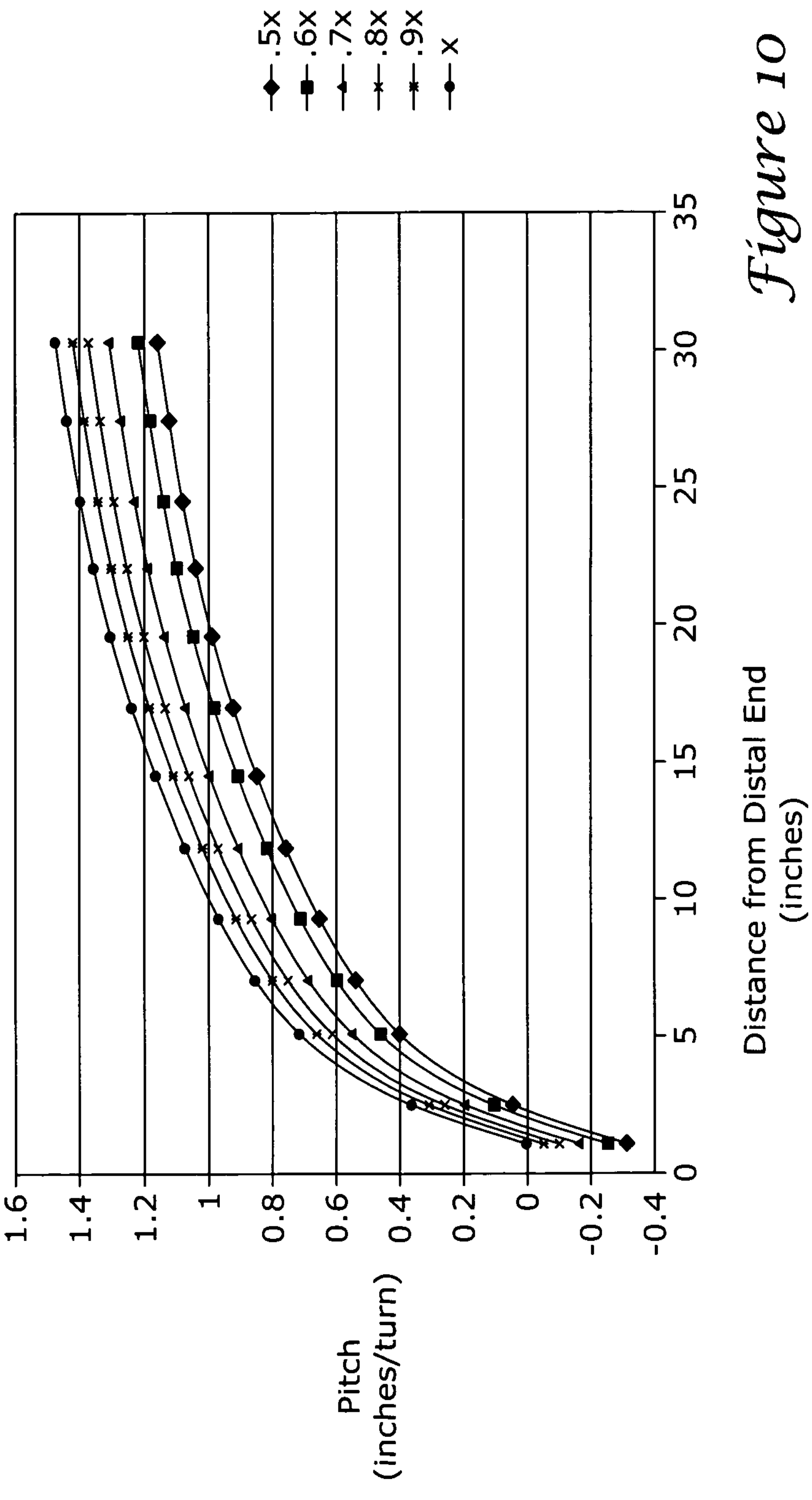

.5x
.6x
.7x
.8x
.9x
x
Pitch
(inches/turn)
1.6
1.4
1.2
1
0.8
0.6
0.4
0.2
0
-0.2
-0.4
0
5
10
15
20
25
30
35
Distance from Distal End
(inches)

Figure 10

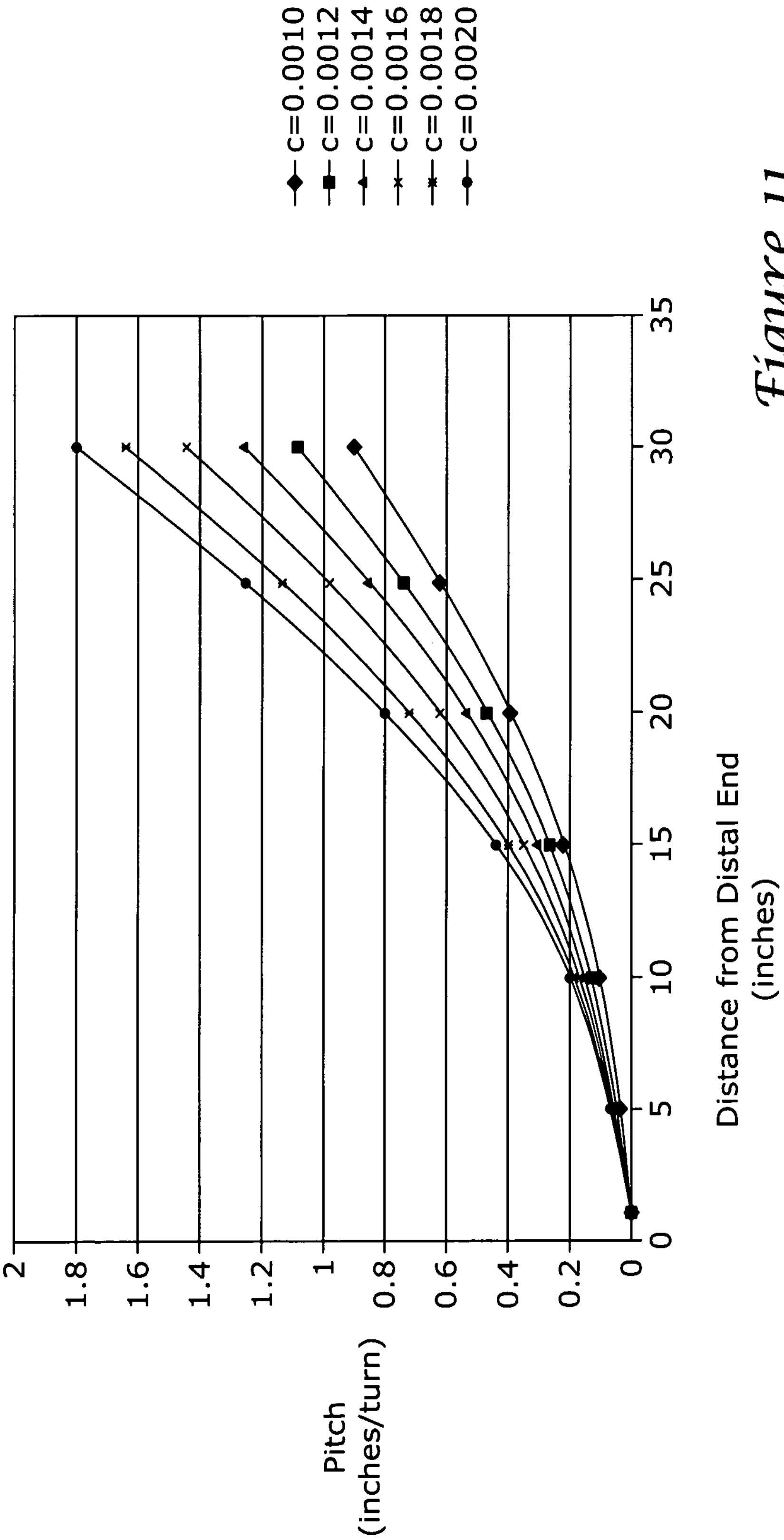

Pitch
(inches/turn)
0
0.2
0.4
0.6
0.8
1
1.2
1.4
1.6
1.8
2
0
5
10
15
20
25
30
35
Distance from Distal End
(inches)
c=0.0010
c=0.0012
c=0.0014
c=0.0016
c=0.0018
c=0.0020

*Figure 11*

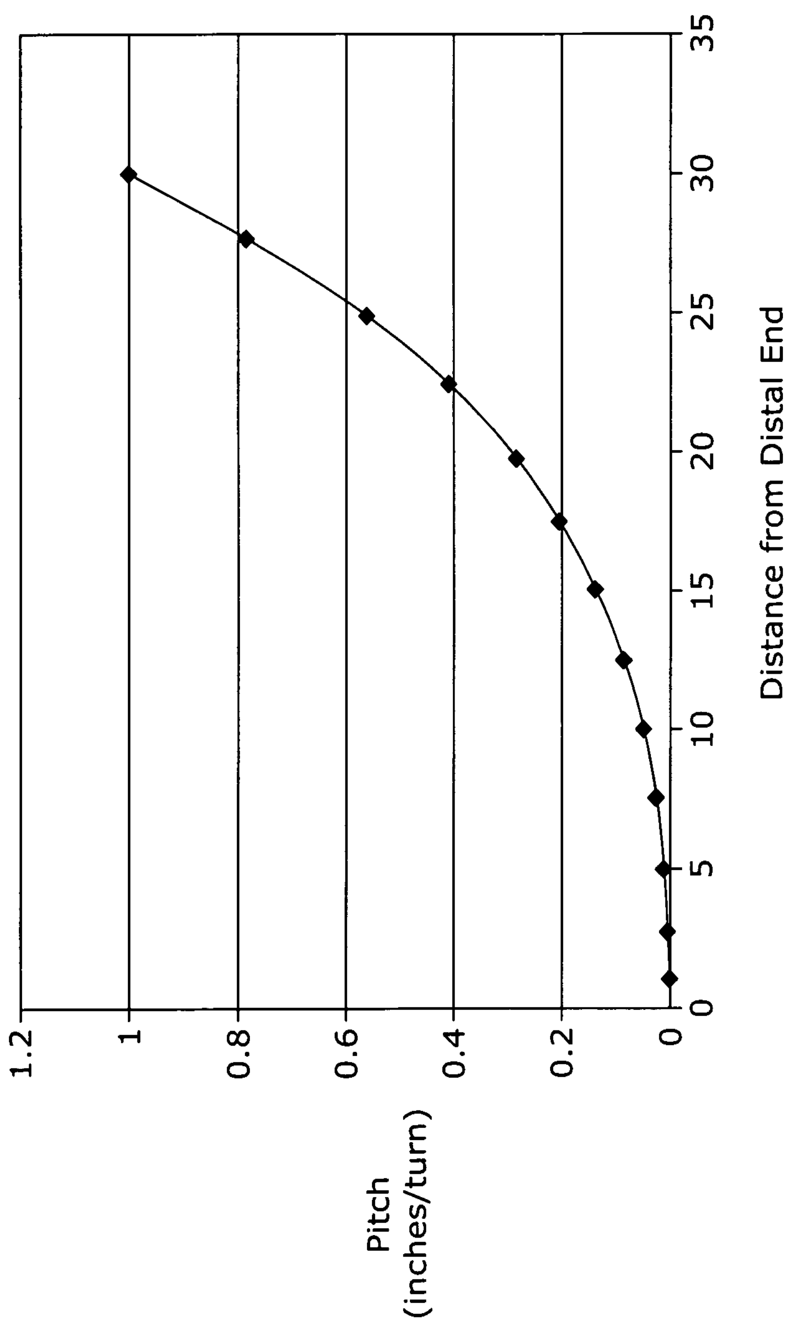

Pitch
(inches/turn)
1.2
1
0.8
0.6
0.4
0.2
0
0
5
10
15
20
25
30
35
Distance from Distal End
(inches)

*Figure 12*

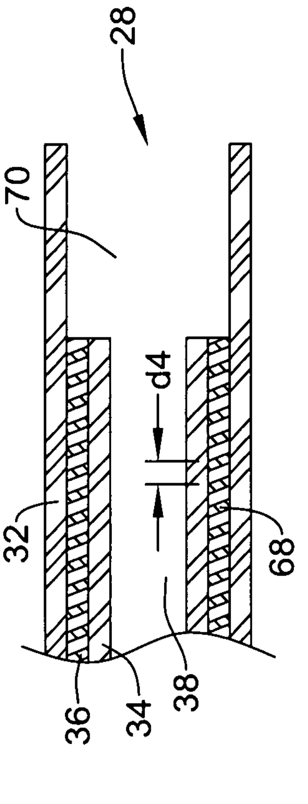



Figure 13

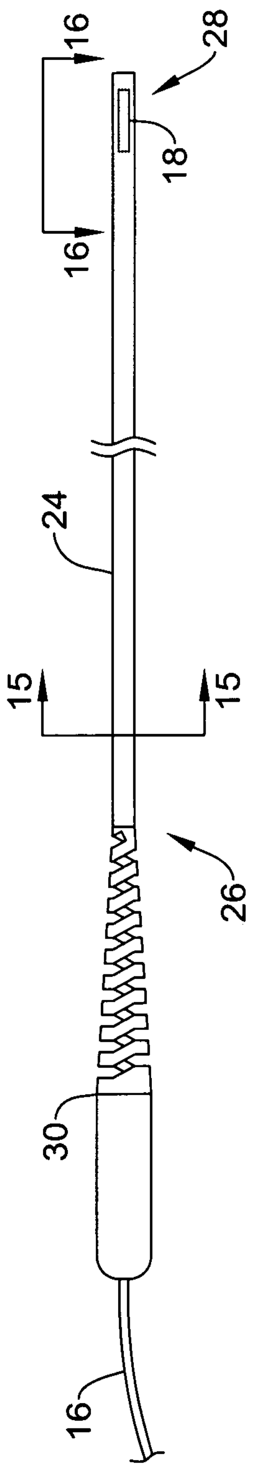



Figure 14

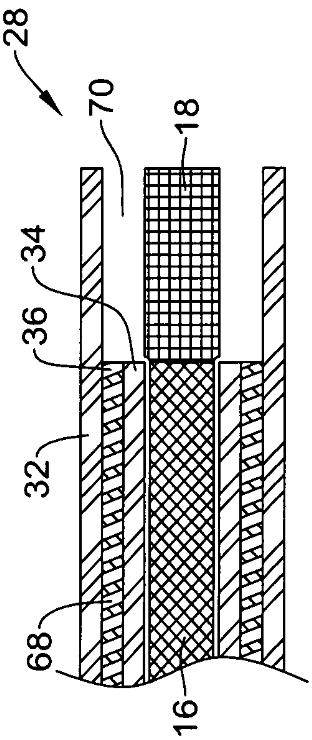



Figure 16

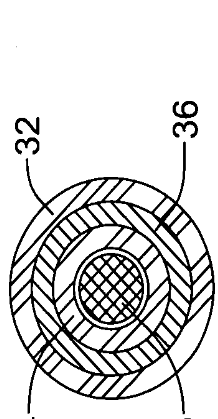



Figure 15

# INTRAVASCULAR ULTRASOUND CATHETER

## TECHNICAL FIELD

The invention relates generally to catheters and more particularly to intravascular ultrasound catheters.

## BACKGROUND

Ultrasound can be useful in a variety of medical procedures. Intravascular ultrasound, in which an ultrasound transducer is advanced into a patient's body through the patient's vasculature, has particular uses and advantages.

An ultrasound transducer can be advanced through a patient's vasculature within an ultrasound catheter. While ultrasound catheters are known, a need remains for improved ultrasound catheters. A need remains as well for ultrasound catheters exhibiting improved flexibility.

## SUMMARY

The present invention pertains to catheters such as intravascular ultrasound catheters. An intravascular ultrasound catheter may include a central lumen adapted to receive a drive shaft bearing an ultrasound transducer. The intravascular ultrasound catheter may, in some instances, exhibit improved flexibility.

Accordingly, an example embodiment of the present invention can be found in an intravascular ultrasound catheter that has a distal portion and a proximal portion. The catheter can include an inner polymeric layer, an outer polymeric layer and a spiral-cut hypotube that is positioned between the inner polymeric layer and the outer polymeric layer and that extends from the distal portion of the catheter to the proximal portion.

The spiral-cut hypotube has a pitch having a rate of change, i.e., a first derivative, that is a function of distance from a distal end of the spiral-cut hypotube. In other words, the pitch, or inches per turn, changes at a rate that depends upon relative position along the hypotube. At one point on the hypotube, the pitch can change slowly with respect to position while at a point positioned elsewhere on the hypotube, the pitch can change more rapidly with respect to position.

Another example embodiment of the present invention can be found in an intravascular ultrasound assembly that includes an intravascular ultrasound drive shaft having a distal end and an ultrasound transducer positioned near the distal end of the intravascular ultrasound drive shaft. The assembly also includes a catheter that is adapted to receive the intravascular ultrasound drive shaft.

The catheter has an inner polymeric layer that defines a lumen that is adapted to accommodate the intravascular ultrasound drive shaft. The catheter includes an outer polymeric layer and a spiral-cut hypotube that extends between the inner polymeric layer and the outer polymeric layer from a distal portion to a proximal portion of the catheter.

The above summary of the present invention is not intended to describe each disclosed embodiment or every implementation of the present invention. The Figures, Detailed Description and Examples which follow more particularly exemplify these embodiments.

## BRIEF DESCRIPTION OF THE DRAWINGS

The invention may be more completely understood in consideration of the following detailed description of vari-



ous embodiments of the invention in connection with the accompanying drawings, in which:

FIG. **1** is a schematic illustration of an intravascular ultrasound assembly in accordance with an embodiment of the invention;

FIG. **2** is a schematic illustration of an intravascular ultrasound catheter in accordance with an embodiment of the invention;

FIG. **3** is a cross-section taken along line **3-3** of FIG. **2**;

FIG. **4** is a diagrammatic longitudinal cross-section representing a particular embodiment of a portion of the intravascular ultrasound catheter of FIG. **2**;

FIG. **5** is a longitudinal cross-section taken along line **5-5** of FIG. **2**;

FIG. **6** is a graphical representation illustrating examples of exponentially decaying pitch in accordance with an embodiment of the invention;

FIG. **7** is a graphical representation illustrating examples of exponentially decaying pitch in accordance with an embodiment of the invention;

FIG. **8** is a graphical representation illustrating an exponentially decaying pitch in accordance with an embodiment of the invention;

FIG. **9** is a graphical representation illustrating examples of logarithmic decaying pitch;

FIG. **10** is a graphical representation illustrating examples of base **10** logarithmic decaying pitch;

FIG. **11** is a graphical representation illustrating examples of second power decaying pitch in accordance with an embodiment of the invention;

FIG. **12** is a graphical representation illustrating an example of third power decaying pitch in accordance with an embodiment of the invention;

FIG. **13** is a longitudinal cross-section taken at the distal end of FIG. **2**;

FIG. **14** is a schematic illustration of the intravascular ultrasound catheter of FIG. **2**, shown including a drive shaft positioned within the catheter;

FIG. **15** is a cross-section taken along line **15-15** of FIG. **14**; and

FIG. **16** is a longitudinal cross-section taken at the distal end of FIG. **14**.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention.

## DETAILED DESCRIPTION

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

All numeric values are herein assumed to be modified by the term "about", whether or not explicitly indicated. The term "about" generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value, i.e., having the same function or result. In many instances, the term "about" may include numbers that are rounded to the nearest significant figure.

As used in this specification and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the content clearly dictates otherwise. As used in this specification and in the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

The following description should be read with reference to the drawings, in which like elements in different drawings are numbered in like fashion. The drawings, which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention. Although examples of construction, dimensions, and materials are illustrated for the various elements, those skilled in the art will recognize that many of the examples provided have suitable alternatives that may be utilized.

FIG. **1** illustrates an intravascular ultrasound assembly **10** in accordance with an embodiment of the invention. The intravascular ultrasound assembly **10** includes an intravascular ultrasound catheter **12**. A motor **14** rotates a drive shaft **16** that extends through the intravascular ultrasound catheter **12**. An ultrasound transducer **18** is positioned at the distal end of the intravascular ultrasound catheter **12**. The drive shaft **16** can include one or more wires **20** for carrying a signal from the ultrasound transducer **18** to a monitor **22**.

Several of these components can include elements known in the art. For example, the motor **14** can be any suitable electrically driven motor having an appropriate speed and load rating. The drive shaft **16** can be formed from any suitable material or materials. The ultrasound transducer **18** may be any suitable transducer crystal made from any suitable material such as a barium titanate, a lead zirconate titanate, a lead metaniobate, and others. The monitor **22** can simply be a display unit such as a cathode ray tube or an LCD display. In some instances, the monitor **22** can represent a computer system including data processing systems as well as a display unit.

The intravascular ultrasound catheter **12** can be discussed in greater detail with respect to FIG. **2**. In the illustrated embodiment, the intravascular ultrasound catheter **12** includes an elongate shaft **24** that has a proximal end **26** and a distal end **28**. A hub and strain relief assembly **30** can be connected to or disposed about the proximal end **26** of the elongate shaft **24**. The hub and strain relief assembly **30** can be of conventional design and can be attached using conventional techniques. The intravascular ultrasound catheter **12** can be sized in accordance with its intended use. The catheter **12** can have a length that is in the range of about 50 to about 200 centimeters and can have a diameter that is in the range of about 1.7 F (French), but can be as large as about 12 F for certain applications.

FIG. **3** is a cross-sectional view of the elongate shaft **24**, taken along line **3-3** of FIG. **2**, and illustrates a portion of elongate shaft **24**. In particular, elongate shaft **24** includes an outer polymer layer **32**, and inner polymer layer **34**, and an intermediate metallic layer **36**. In some embodiments, the intermediate metallic layer **36** can be a hypotube. A lumen **38** is defined by the inner polymer layer **34** and extends through the elongate shaft **24**. The lumen **38** can in, some instances, be adapted to accommodate an intravascular ultrasound drive shaft **16** (as illustrated in FIG. **1**). In particular, the lumen **38** may provide a smooth, low-friction surface for the drive shaft **16**.

In some embodiments, the inner polymer layer **34** can be formed of or include a coating of a material having a suitably low coefficient of friction. Examples of suitable materials include polytetrafluoroethylene (PTFE), better known as TEFLON®. The inner polymer layer **34** can be dimensioned to define a lumen **38** having an appropriate inner diameter to accommodate its intended use. In some embodiments, the inner polymer layer **34** can define a lumen **38** having a diameter of about 0.020 inches and can have a wall thickness of about 0.001 inches.

The outer polymer layer **32** can be formed from any suitable polymer that will provide the desired strength, flexibility or other desired characteristics. Polymers with low durometer or hardness can provide increased flexibility, while polymers with high durometer or hardness can provide increased stiffness. In some embodiments, the polymer material used is a thermoplastic polymer material. Some examples of some suitable materials include polyurethane, elastomeric polyamides, block polyamide/ethers (such as PEBAX®), silicones, and co-polymers. The outer polymer layer **32** can be a single polymer, multiple longitudinal sections or layers, or a blend of polymers. By employing careful selection of materials and processing techniques, thermoplastic, solvent soluble, and thermosetting variants of these materials can be employed to achieve the desired results.

While not expressly illustrated, it is contemplated that the elongate shaft **24** may include several different sections that can vary in flexibility. In some instances, for example, the inner polymer layer **34** and perhaps the intermediate metallic layer **36** may extend continuously at least substantially the entire length of the elongate shaft **12**. The outer polymer layer **32**, however, may have several sections formed of differing polymers to provide additional flexibility. For example, the outer polymer layer **32** may include (not illustrated) a proximal section, a middle section and a distal section. The distal section may be formed of a polymer having a lower durometer than that of the middle section, which may itself be formed of a polymer having a lower durometer than that of the proximal section.

In particular embodiments, a thermoplastic polymer such as a co-polyester thermoplastic elastomer, for example, that available commercially under the ARNITEL® name, can be used. The outer polymer layer **32** can have an inner diameter that is about equal to the outer diameter of the inner polymer layer **34**. The outer layer **32** can have an inner diameter that is slightly greater than the outer diameter of the inner polymer layer **34** to accommodate the thickness of the intermediate metallic layer **36**. In some embodiments, the outer polymer layer **32** of the shaft can have an inner diameter in the range of about 0.025 inches to about 0.100 inches and an outer diameter in the range of about 0.028 inches to about 0.150 inches.

The outer polymer layer **32** may in, some instances, provide a compressive force to the intermediate metallic layer **36** in order to help retain a desired tubular shape for the intermediate metallic layer **36**. In some cases, the outer polymer layer **32** may have a compression fit over the intermediate metallic layer **36**. In some instances, the outer polymer layer **32** may have an interference fit or a slip fit with the intermediate metallic layer **36**.

In some instances, it may be useful to be able to provide fluid from an interior of the catheter **12** to the exterior of the catheter **12**. FIG. **4** is a diagrammatic partial cross-section of a portion of the catheter **12** illustrating optional features. This particular cross-section may represent a cross-section through any particular section of the catheter **12** and will be referenced as catheter section **44**. FIG. **4** illustrates an embodiment in which fluid may pass from an interior **40** of catheter section **44** to an exterior **42** of catheter section **44**. In some instances, it may be useful to, for example, hydrate an exterior portion of the catheter **12** prior to or during use. Alternatively, it may be useful to provide fluid from an interior of the catheter **12** to surround the intermediate metallic layer and the inner surface of the outer polymer layer.

As discussed above, catheter section **44** includes an outer polymer layer **32**, an inner polymer layer **34** and an intermediate metallic layer **36**, much as discussed with respect to FIGS. **1-3**. In FIG. **4**, however, catheter section **44** includes one or more apertures **46** provided within the outer polymer layer **32** and one or more apertures **48** provided within the inner polymer layer **34**. It can be seen that the apertures **46** and the apertures **48** may be aligned with spiral-cuts or kerfs **50** which can be machined within the intermediate metallic layer **36**. Consequently, fluid may pass from the interior **40**, through apertures **48**, into kerfs **50**, and through apertures **46**. In an alternative embodiment, the apertures **46** can be omitted which would allow fluid to flow into the area including the intermediate metallic layer.

FIG. **5** is a longitudinal cross-section taken along line **5-5** of FIG. **2**. FIG. **5** shows that, as with respect to FIG. **3**, the elongate shaft **24** includes the outer polymer layer **32**, the inner polymer layer **34** and the intermediate metallic layer **36**. In some instances, the intermediate metallic layer **36** may include or be formed from a metal hypotube that has been spirally cut for flexibility. The elongate shaft **24** can include a first portion **52** having (as illustrated) two spiral-cuts **54**. The first portion **52** corresponds to a (relatively) proximal portion **64**. In the first portion **52**, it can be seen that adjacent spiral-cuts **54** are spaced a distance d**1** apart.

The elongate shaft **24** includes a second portion **56** having (as illustrated) four spiral-cuts **58** as an example and corresponds to an intermediate portion. It can be seen that adjacent spiral-cuts **58** are spaced a distance d**2** apart, and that d**2** is less than d**1**. The elongate shaft **24** also includes a third portion **60** having (as illustrated) seven spiral-cuts **62** as an example. It can be seen that adjacent spiral-cuts **62** are spaced a distance d**3** apart, and that d**3** is less than d**2**. The third portion **60** corresponds to a (relatively) distal portion **66**. The number of cuts and distance apart can, however, be varied within the scope of the present invention.

In some embodiments, the pitch, or the spacing between adjacent turnings or windings, may decrease considerably when moving from the proximal end **26** of the elongate shaft **24** to the distal end **28** of the elongate shaft **24**. In some embodiments, the intermediate metallic layer **36** may be spiral-cut from the proximal end **26** to the distal end **28**. In some instances, the intermediate metallic layer **36** may be spiral-cut from a position distal of the proximal end **26** to the distal end **28**. In particular, the intermediate metallic layer **36** may be spiral-cut from about a midpoint of the elongate shaft **24** to the distal end **28**, although other points along the shaft may be selected.

In some instances, the intermediate metallic layer **36** may be spiral-cut such that adjacent windings or kerfs are very close together near the distal end **28** of the elongate shaft and are substantially less close together as distance from the distal end **28** increases. To illustrate, adjacent windings or kerfs may be spaced apart from 0.005 to about 0.25 inches at the distal end **28** while being spaced about 0.2 to about 1.0 inches at an opposite, more proximal, end of the spiral cutting. As noted above, the spiral-cutting need not extend all the way to the proximal end **26** of the elongate shaft **24**.

By cutting the intermediate metallic layer **36** in this fashion, the intravascular ultrasound catheter **12** may have a flexibility that is much greater near the distal end **28** than at positions proximal to the distal end **28**. The intermediate metallic layer **36** may be cut in any suitable fashion. In a particular embodiment, the intermediate metallic layer **36** is spiral-cut by a computer-guided laser.

In particular embodiments, the pitch may be given by an equation defining the pitch in terms of a distance to the distal end **28** of the elongate shaft **24**. The pitch may have a rate of change, or first derivative in calculus terms, that is itself a function of relative position. As a result, the rate at which the pitch changes will itself vary as one moves from the proximal end **26** to the distal end **28**.

In some instances, the pitch may decrease exponentially when moving toward the distal end **28**. In some embodiments, the pitch may be given by the formula $y=A^{(Bx)}+C$, where y is the pitch, x is the distance from the distal end of the elongate shaft **24**, A is in a range of about 5 to about 100, B is in a range of about 0.01 to about 1, and C is in a range of about 0 to about 25.

FIG. **6** illustrates several possible exponential pitches in which A varies from 0.05 to 0.20, B varies from 0.05 to 0.10, and C is set equal to zero. It can be seen that the pitch, or inches per turn, increases rapidly in moving from the distal end to the proximal end of the intermediate metallic layer **36**.

FIG. **7** illustrates several additional possible exponential pitches in which A is set equal to 0.0192, B varies from 0.07 to 0.14, and C is set equal to zero. FIG. **8** illustrates a particular exponential pitch in which A is set equal to 0.0192, B is set equal to 0.1425, and C is set equal to zero. It can be seen that the pitch, or inches per turn, increases rapidly in moving from the distal end to the proximal end of the intermediate metallic layer **36**.

In some embodiments, the pitch may decrease logarithmically when moving toward the distal end **28**. In some embodiments, the pitch may be given by the formula $y=A+B \ln Cx$, where y is the pitch, x is the distance from the distal end of the elongate shaft **24**, A is in a range of about 0 to about 25, B is in a range of about 0.5 to about 25, and C is in a range of about 0.5 to about 100. FIG. **9** illustrates several possible logarithmic pitches in which A is set equal to zero, B is set equal to 1, and C varies from 0.5 to 1.0. It can be seen that the pitch, or inches per turn, increases rapidly in moving from the distal end to the proximal end of the intermediate metallic layer **36**.

In some embodiments, the pitch may be given by the formula $y=A+B \log Cx$, where y is the pitch, x is the distance from the distal end of the elongate shaft **24**, A is in a range of about 0 to about 100, B is in a range of about 20 to about 200, and C is in a range of about 0.01 to about 100. FIG. **10** illustrates several possible logarithmic pitches in which A is set equal to zero, B is set equal to 1, and C varies from 0.5 to 1.0. It can be seen that the pitch, or inches per turn, increases rapidly in moving from the distal end to the proximal end of the intermediate metallic layer **36**.

In some instances, the pitch may be a second power pitch, a third power pitch or a fourth power pitch, and may be given by the formula $y=Ax^2+Bx+C$, where y is the pitch, x is the distance from the distal end of the elongate shaft **24**, A is in the range of about 0.001 to about 0.5, B is in the range of about 0 to about 0.001, C is in the range of about 0 to about 100.

FIG. **11** illustrates several possible pitches in which A and B are set equal to zero, C varies from 0.001 to 0.002, and D and E are each set equal to zero. FIG. **12** illustrates a possible pitch in which A, C, D and E are each set equal to zero and B is set equal to $3.7\times10^{-5}$. In each case, it can be seen that the pitch, or inches per turn, increases rapidly in moving from the distal end to the proximal end of the intermediate metallic layer **36**.

One of skill will recognize that a number of other equations may also be used to determine pitch as a function of distance from a distal end. In each of the illustrative but non-limiting examples provided herein it should be noted that the pitch is a function of distance from the distal end. Moreover, in each of these examples, the rate at which the pitch changes, or the first derivative of the pitch, is also a function of relative position.

Returning now to FIG. **2**, it can be seen that FIG. **13** is a longitudinal cross-section taken near the distal end **28** of the elongate shaft **24**. In FIG. **13**, it can be seen that the intermediate metallic layer **36** includes a relatively larger number of spiral cuts **68** that are spaced apart a distance d**4**. In comparing FIG. **13** to FIG. **4**, it can be seen that in FIG. **13** (representing the distal end of the elongate shaft **24**), the spiral cuts **68** are much more numerous and are much closer together than anywhere else along the elongate shaft **24**. As discussed above, a larger number of closely-spaced spiral cuts near the distal end **28** provides improved flexibility at the distal end **28**.

In FIG. **13**, it can be seen that the outer polymer layer **32** extends to the distal end **28** while the inner polymer layer **34** and the intermediate metallic layer **36** both stop at a position that is proximal to the distal end **28**. This permits the lumen **38** to widen into a transducer volume **70**. As previously discussed, the lumen **38** may accommodate an ultrasound drive shaft. The transducer volume **70** may be sized to accommodate an ultrasound transducer, as illustrated in FIGS. **14-16**.

FIG. **14** is a schematic view of the intravascular ultrasound catheter **12** in which drive shaft **16** has been inserted through the lumen **38** such that the ultrasound transducer **18** (seen in phantom in FIG. **14**) is positioned near the distal end **28**. FIG. **15** is a cross-sectional view taken along line **15-15** of FIG. **14** showing the drive shaft **16** positioned within the lumen **38** while FIG. **16** is a longitudinal cross-section taken at the distal end of FIG. **14** illustrating placement of the transducer **18** within the transducer volume **70**.

In some embodiments, part or all of the catheter **12** may include a lubricious coating. Lubricious coatings can improve steerability and improve lesion crossing capability. Examples of suitable lubricious polymers include hydrophilic polymers such as polyarylene oxides, polyvinylpyrolidones, polyvinylalcohols, hydroxy alkyl cellulosics, algins, saccharides, caprolactones, and the like, and mixtures and combinations thereof. Hydrophilic polymers can be blended among themselves or with formulated amounts of water insoluble compounds (including some polymers) to yield coatings with suitable lubricity, bonding and solubility. In some embodiments, a distal portion of the catheter can be coated with a hydrophilic polymer, while the more proximal portions can be coated with a fluoropolymer.

The invention should not be considered limited to the particular examples described above, but rather should be understood to cover all aspects of the invention as set out in the attached claims. Various modifications, equivalent processes, as well as numerous structures to which the invention can be applicable will be readily apparent to those of skill in the art upon review of the instant specification.

What I claim is:

**1**. An intravascular ultrasound catheter having a distal portion and a proximal portion, the catheter comprising:

an inner polymeric layer, the inner polymeric layer having a plurality of apertures formed therein;

an outer polymeric layer; and

a spiral-cut hypotube, the spiral-cut hypotube positioned between the inner polymeric layer and the outer polymeric layer and extending from the distal portion to the proximal portion of the catheter, the spiral-cut hypotube having a distal end;

wherein the spiral-cut hypotube has a pitch having a rate of change that is dependent upon a distance from the distal end of the hypotube.

**2**. The intravascular ultrasound catheter of claim **1**, wherein the pitch is determined by a formula having a first derivative that is a function of the distance from the distal end of the hypotube.

**3**. The intravascular ultrasound catheter of claim **1**, wherein the spiral-cut hypotube has an exponential pitch.

**4**. The intravascular ultrasound catheter of claim **1**, wherein the spiral-cut hypotube has a pitch given by the formula $y=A^{(Bx)}+C$, where y is the pitch, x is the distance from the distal end of the hypotube, A is in a range of about 5 to about 100, B is in a range of about 0.01 to about 1, and C is in a range of about 0 to about 25.

**5**. The intravascular ultrasound catheter of claim **1**, wherein the spiral-cut hypotube has a logarithmic pitch.

**6**. The intravascular ultrasound catheter of claim **1**, wherein the spiral-cut hypotube has a pitch given by the formula $y=A+B \ln Cx$, where y is the pitch, x is the distance from the distal end of the hypotube, A is in a range of about 0 to about 25, B is in a range of about 0.5 to about 25, and C is in a range of about 0.5 to about 100.

**7**. The intravascular ultrasound catheter of claim **1**, wherein the spiral-cut hypotube has a pitch given by the formula $y=A+B \log Cx$, where y is the pitch, x is the distance from the distal end of the hypotube, A is in a range of about 0 to about 100, B is in a range of about 25 to about 200, and C is in a range of about 0.01 to about 100.

**8**. The intravascular ultrasound catheter of claim **1**, wherein the spiral-cut hypotube has a second power pitch.

**9**. The intravascular ultrasound catheter of claim **1**, wherein the spiral-cut hypotube has a pitch given by the formula $y=Ax^2+Bx+C$, where y is the pitch, x is the distance from the distal end of the hypotube, A is in the range of about 0.001 to about 5, B is in the range of about 0 to about 0.001, C is in the range of about 0 to about 100.

**10**. The intravascular ultrasound catheter of claim **1**, wherein the inner polymeric layer defines a lumen adapted to accommodate an intravascular ultrasound drive shaft and transducer.

**11**. The intravascular ultrasound catheter of claim **1**, wherein at least one of the outer polymeric layer and the inner polymeric layer extends distally from the distal end of the spiral-cut hypotube.

**12**. An intravascular ultrasound catheter having a distal portion and a proximal portion, the catheter comprising:

an inner polymeric layer;

an outer polymeric layer;

a spiral-cut hypotube, the spiral-cut hypotube positioned between the inner polymeric layer and the outer polymeric layer and extending from the distal portion to the proximal portion of the catheter, the spiral-cut hypotube having a distal end;

wherein the spiral-cut hypotube has a pitch having a rate of change that is dependent upon a distance from the distal end of the hypotube; and

wherein the spiral-cut hypotube comprises a machined kerf, and the inner polymeric layer comprises a plurality of apertures in fluid communication with the machined kerf.

**13**. The intravascular ultrasound catheter of claim **12**, wherein the outer polymeric layer comprises a plurality of apertures in fluid communication with the machined kerf.

**14**. An intravascular ultrasound assembly, comprising:

an intravascular ultrasound drive shaft having a distal end;

an ultrasound transducer positioned near the distal end of the drive shaft; and

a catheter adapted to receive the ultrasound drive shaft, the catheter comprising:

an inner polymeric layer, the inner polymeric layer defining a lumen adapted to accommodate the intravascular ultrasound drive shaft;

an outer polymeric layer; and

a spiral-cut hypotube positioned between the inner polymeric layer and the outer polymeric layer and extending from a distal portion to a proximal portion of the catheter, the spiral-cut hypotube having a distal end.

**15**. The intravascular ultrasound assembly of claim **14**, wherein at least one of the outer polymeric layer and the inner polymeric layer extends distally from the distal end of the spiral-cut hypotube.

**16**. The intravascular ultrasound assembly of claim **14**, wherein the spiral-cut hypotube has a pitch defining distance between adjacent turnings.

**17**. The intravascular ultrasound assembly of claim **16**, wherein the pitch varies as a function of distance from the distal end of the spiral-cut hypotube.

**18**. The intravascular ultrasound assembly of claim **16**, wherein the pitch has a rate of change that is a function of distance from the distal end of the spiral-cut hypotube.

**19**. The intravascular ultrasound assembly of claim **16**, wherein the spiral-cut hypotube has an exponential pitch given by the formula $y=A^{(Bx)}+C$, where y is the pitch, x is a distance from the distal end of the hypotube, A is in a range of about 5 to about 100, B is in a range of about 0.01 to about 1, and C is in a range of about 0 to about 25.

**20**. The intravascular ultrasound assembly of claim **16**, wherein the spiral-cut hypotube has a logarithmic pitch given by the formula $y=A+B \ln Cx$, where y is the pitch, x is a distance from the distal end of the hypotube, A is in a range of about 0 to about 25, B is in a range of about 0.5 to about 25, and C is in a range of about 0.5 to about 100.

**21**. The intravascular ultrasound assembly of claim **16**, wherein the spiral-cut hypotube has a logarithmic pitch given by the formula $y=A+B \log Cx$, where y is the pitch, x is a distance from the distal end of the hypotube, A is in a range of about 0 to about 100, B is in a range of about 25 to about 200, and C is in a range of about 0.01 to about 100.

**22**. The intravascular ultrasound assembly of claim **16**, wherein the spiral-cut hypotube has a pitch given by the formula $y=Ax^2+Bx+C$, where y is the pitch, x is a distance from the distal end of the hypotube, A is in the range of about 0.001 to about 5, B is in the range of about 0 to about 0.001, C is in the range of about 0 to about 100.

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摘要(译)

血管内超声导管可以包括适于接收驱动轴轴承的超声换能器的中心腔。血管内超声导管可以在一些情况下显示出改进的柔韧性。该导管可包括聚合物内层，一个外聚合物层和位于所述聚合物内层和外层的聚合物层之间的螺旋切割海波管。