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PRECISION-CONTROLLED CONDUIT RESTRICTION DEVICE

Abstract

The invention relates to a device for providing controlled restriction of a hollow conduit in a body. The device may include a band element having a tunnel section with a proximal opening and a distal opening. The device may further include a length of the band extending from the proximal opening. The device may further include a controller, removably connected to the distal opening, comprising an adjusting mechanism for changing a diameter of the band. The end of the band may be insertable through the proximal opening to form a loop around a hollow conduit, and the end of the band length may be advanced into the controller to permanently engage with the adjusting mechanism. After adjusting the diameter of the band, the band may be secured and the controller disconnected, leaving the band and securing means around the hollow conduit.

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Background/Summary

TECHNICAL FIELD

[0001] Generally, the invention relates to the field of vascular access and blood flow regulation, and more particularly, to a device that is designed to controllably band blood conduits, thereby facilitating stable and precise control over blood flow rates within these conduits.

BACKGROUND

[0002] Kidney failure due to chronic kidney disease or diabetes compels individuals to begin dialysis as a substitute for kidney function. A significant majority, approximately 90%, opt for hemodialysis, undergoing three sessions per week. To facilitate the required blood flow for the dialysis machinery, the preferred approach is the creation of an arterio-venous (AV) access. This access may be achieved through a natural vein or a vascular graft, both collectively referred to here as a “fistula.” Functionally, a fistula requires specific attributes, such as a blood flow of around 500 ml/min, a diameter of 5-6 mm, and the ability to sustain cannulation for dialysis access three times a week.

[0003] However, some patients experience an escalating blood flow through the fistula, which leads to ischemia and cardiac complications. In certain cases, the flow may reach 2-3+ liters/minute, a significant fraction of the cardiac output. Addressing such high flow becomes imperative to prevent issues ranging from cold extremities to high-output heart failure. Clinical methods to reduce AV fistula flow are in place, which include vessel surgeries and banding of the fistula.

[0004] Vessel surgeries generally redirect a portion of the incoming blood to the fistula through various techniques. However, these procedures lack precise control over the final flow, and come with associated challenges, morbidity, and costs. The adequacy of flow reduction usually relies on surgical judgment based on visual indicators like color and pulse return. Vascular surgical flow reduction does not significantly affect peripheral resistance.

[0005] Banding involves directly reducing the diameter of the fistula, which has the effect of increasing peripheral resistance. As a result, banding can potentially alleviate both ischemic and cardiac symptoms. Existing banding techniques include plication, MILLER banding, and applying fabric cuffs around the fistula.

[0006] Some devices have been developed to restrict the diameter of fistulas. One prior art device for restricting fistulas is described in U.S. Patent Application US20190336675-A1 (hereinafter the '675 device). The '675 device discloses an adjustable band and a disposable delivery system for banding blood conduits. The band is connected to a female connector at one end and a controlling mechanism on the other. The male connector houses a catheter that is used to draw-in the band when adjusting the band diameter. The band is secured by a lock that cinches a sleeve over the catheter.

[0007] However, the '675 device has significant limitations regarding clinical safety and convenience that render it clinically and commercially unviable. Some of these limitations are:

[0008] The '675 device requires a hard plastic component, female connector, to be attached to the end of the band. Leading this small component around a vessel requires care and skill. Further, it requires a precise orientation to attach the female connector to the male connector. This step involves manipulating small plastic parts in a surgical field, which may be awkward and difficult. Moreover, this snap-together connection is made at or near the outside surface of the vessel, which may potentially pinch the vessel when the two parts are brought together.

[0009] The device also requires a secondary securing of the snapped-together pieces, to be performed by wrapping and tying-off suture around annular grooves on the connectors. This is an extra and inconvenient procedure.

[0010] Further, the band of the device creates a pinch point on the outside of the vessel as the band is drawn into the catheter inside the male connector during band closure. The pinching is caused by having an open gap between the outer vessel wall, band, and the hard stationary faces presented by the male and female connectors. The moving band tends to compress the vessel wall against these faces, which can damage the vessel wall and lead to thrombosis.
[0011] In addition, the band has a segment that consists of a fixed piece of plastic with a fixed curvature, female connector. This creates a physical discontinuity in the band and prevents it from ever being circular. Also, the fixed end of band is bonded into a bushing, which is then bonded into female connector. As a result, the band exits the female connector at a fixed angle, which contributes to the non-circular nature of the band.
[0012] Furthermore, the device requires implanting adhesive that is used in three locations: bonding the fixed end of the band to a bushing, bonding the bushing to female connector, and bonding catheter to male connector. Implanting adhesive may pose risks of a toxic or allergic reaction.
[0013] Therefore, there is a need for an improved device for controllably banding blood conduits that overcomes these limitations and provides stable and precise blood flow control.
[0014] Thus, a heretofore unaddressed need exists in the industry to address the aforementioned deficiencies and inadequacies.

SUMMARY OF INVENTION

[0015] In one embodiment, a device for providing controlled restriction of a hollow conduit (e.g., vessel) in a body is disclosed. The device may include a band element having a tunnel section with a proximal opening and a distal opening. The device may further include a length of band extending from the proximal opening. The end of the band may be connected to a controller to adjust the diameter of the band. The device may further include the controller comprising an adjusting mechanism for changing a diameter of the band element. The end of the band may be insertable through the proximal opening to form a loop around the hollow conduit, and the end of the band may be advanced into the controller to permanently engage with the adjusting mechanism.
[0016] In another embodiment, a device for providing controlled restriction of a hollow conduit (e.g., vessel) in a body is disclosed. The device may include a band element having a tunnel section with a proximal opening and a distal opening. The device may further include a length of the band extending from the proximal opening. The free end of the band may be insertable through the proximal opening to form a loop around the hollow conduit, and the end of the band may be further advanced into the controller to permanently engage with an adjusting mechanism. The device may further include periodically spaced elements on the band acting as detents when passing through the tunnel section. The device may further include an adjusting mechanism within the controller for changing the diameter of the band.
[0017] In yet another embodiment, a device for providing controlled restriction of a hollow conduit in a body is disclosed. The device may further include a band element having a tunnel section with a proximal opening and a distal opening. The device may further include a band length extending from the proximal opening. The free end of the band length may be insertable through the proximal opening to form a loop around the hollow conduit, and the end of the band length may be further advanced into the controller to permanently engage with an adjusting mechanism. After adjusting, the band may be secured in place and the controller disconnected, leaving the band and securing means implanted.
[0018] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] The present application can be best understood by reference to the following description taken in conjunction with the accompanying drawing figures, in which like parts may be referred to by like numerals.

[0020] FIG. **1** is a perspective view of a device for providing controlled restriction of a hollow conduit in a body, in accordance with an embodiment of the present disclosure.

[0021] FIG. **2** is a sectional view of the device shown in FIG. **1**, in accordance with an embodiment of the present disclosure.

[0022] FIG. **3** is a perspective view of a band element, in accordance with an embodiment of the present disclosure.

[0023] FIG. **4**A is a perspective view of the device shown in FIG. **1** in an unsecured state, in accordance with an embodiment of the present disclosure.

[0024] FIG. **4**B is a perspective view of the device shown in FIG. **1** in a secured state, in accordance with an embodiment of the present disclosure.

[0025] FIG. **5**A is a perspective view of an arrowhead end of a band length, in accordance with an embodiment of the present disclosure.

[0026] FIG. **5**B illustrates a cross-section shape of the band length for producing a saddle-shaped restriction, in accordance with an embodiment of the present disclosure.

[0027] FIG. **6**A is a perspective view of a band length passing through and extending past a tunnel section with a cut-off plane intended for disconnecting a controller, in accordance with an embodiment of the present disclosure.

[0028] FIG. **6**B is a cross-sectional view of the band length at the cut-off plane shown in FIG. **6**A, depicting the band length inside the tunnel section, in accordance with an embodiment of the present disclosure.

[0029] FIG. **7** is a side view of a band element showing the tunnel section and ramp in accordance with an embodiment.

[0030] FIG. **8** is a perspective view illustrating conformity of a ramp to an inner surface of the band length in a closed and secured state, in accordance with an embodiment of the present disclosure.

[0031] FIG. **9** is a perspective view of a receiver component illustrating the flexible arms used to capture the band end in accordance with an embodiment of the present disclosure.

[0032] FIGS. **10**A-**10**C is series of perspective views illustrating the sequence involved in the connection of the arrowhead to the receiver component, in accordance with an embodiment of the present disclosure.

[0033] FIGS. **11**A-**11**C is a series of longitudinal cross-sectional views of the device illustrating the process of a band being drawn into the controller as the band is reduced in diameter, in accordance with an embodiment of the present disclosure, in accordance with an embodiment.

[0034] FIGS. **12**A-**12**C depict a series of cross-sectional views through a controller housing, illustrating the internal channel designed to selectively constrain and permit the passage of the band, receiver component, and screw through the housing, in accordance with an embodiment of the present disclosure.

[0035] FIGS. **13**A-**13**C depict a series of perspective views of a securing means showing different stages and aspects of its functionality, in accordance with an embodiment of the present disclosure.

[0036] FIG. **14** is a flow-chart representation of a method according to the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

[0037] The following description is presented to enable a person of ordinary skill in the art to make and use the invention, and is provided in the context of particular applications and their requirements. Various modifications to the embodiments will be readily apparent to those skilled in the art, and the generic principles defined herein may be applied to other embodiments and applications without departing from the spirit and scope of the invention.

[0038] Exemplary embodiments are described with reference to the accompanying drawings. Wherever convenient, the same reference numbers are used throughout the drawings to refer to the same or like parts. While examples and features of disclosed principles are described herein, modifications, adaptations, and other implementations are possible without departing from the spirit and scope of the disclosed embodiments. It is intended that the following detailed description be considered as exemplary only, with the true scope and spirit being indicated by the following claims. Additional illustrative embodiments are listed below.

[0039] Referring now to figures, FIG. **1** is a perspective view of a precision-controlled conduit restriction device **1** for providing controlled restriction of a hollow conduit in a body. FIG. **2** is a sectional view of the precision-controlled conduit restriction device **1**. FIG. **3** is a perspective view of a band element **3**. FIG. **4**A is a perspective view of the precision-controlled conduit restriction device **1** in an unsecured state. FIG. **4**B is a perspective view of the precision-controlled conduit restriction device **1** in a secured state. The following description should be read in view of FIGS. **1**-**4**B.

[0040] With reference to FIG. **1**, the precision-controlled conduit restriction device **1** may include a band element **3** and a controller **5**. The band element **3** has a tunnel section **89** with a proximal opening **33** and a distal opening **35**. The controller **5** is removably connected to the distal opening **35**. In one embodiment, the controller **5** may be a disposable controller. In another embodiment, the controller may be reusable and not disposable. The reusable controller may be designed to be sterilized between uses, and be reversibly connected to the band element **3**.

[0041] The band element **3** is depicted as a tubular structure, open at both ends, and possessing unique attributes to enable effective and secure restriction.

[0042] In various embodiments, the band element **3** is manufactured using advanced materials that meet stringent biocompatibility and safety standards. To achieve this, the band element **3** may be molded using a specialized flexible biomedical polymer such as a polyurethane or polyurethane copolymer. Furthermore, the durometer of the selected biomedical polymer generally falls within a range of about 60 A to 90 A. This durometer range generally provides an optimal balance between flexibility and structural support, allowing the length of band **25** to be readily looped around a hollow conduit and effectively changed in diameter by a controller **5**.

[0043] Further, the band **25** may be designed with a cross-sectional shape that reflects its intended functionality. The cross-sectional shape of the band **25** may be circular, rectangular, or specifically tailored to produce a desired restriction pattern. This design flexibility allows the precision-controlled conduit restriction device **1** to accommodate various clinical scenarios and patient needs, and adapting to different anatomical requirements. It should be noted that the band **25** may be of different lengths and cross-sections. For example, for AV fistula banding, the band **25** may typically be 2-10 mm wide and may have an inside diameter of 3.5-25 mm.

[0044] In other words, the band **25** used to reduce the flow of blood in an AV fistula may vary in size depending on the specific needs of the patient. The width of the band is typically between 2 and 10 mm, and the inside diameter is typically between 3.5 and 25 mm.

[0045] Additionally, the band **25** may be coated with a material to enhance either its biological or mechanical performance, or both. More particularly, the band element may be coated with a material, such as parylene to reduce friction and improve biocompatibility. This coating or covering may serve to promote friction between the band element **3** and the outer surface of the hollow conduit, effectively preventing unwanted migration or slippage.

[0046] In some embodiment, the band **25** may be treated or covered with a material to increase the sliding friction (e.g., textile fabrics) between the inside of the band and the blood conduit.

[0047] In some embodiments, the length of band (e.g., band **25**) may be covered with a textile, such as a knitted polyester, to increase the friction between the band and the vessel.

[0048] In some embodiments, the band **25** may also possess radiopaque properties, enhancing its visibility under medical imaging techniques such as X-rays or fluoroscopy. This radiopacity may

aid healthcare professionals in tracking and positioning the device during implantation and subsequent monitoring procedures. The addition of radiopacity to the band element **3** ensures enhanced visibility during medical imaging procedures, further contributing to the device's ease of implantation and monitoring.

[0049] With reference to FIG. **2**, the controller **5** may include a mechanism to adjust the diameter of the band. Receiver component **19** is bonded to screw **15**. Screw **15** is threaded through captured adjusting nut **13**. Turning adjusting nut **13** moves screw **15** linearly in and out of the controller **5**. During installation, the arrowhead **27** at the end of the band **25** is inserted through the proximal opening **33** and advanced to connect with the receiver component **19** inside the controller **5**. As a result, turning adjusting nut **13** moves the screw, receiver, and band **25** in and out of the controller **5**, thereby changing the band diameter.

[0050] The controller **5** may further include a housing **7** which may be made from a transparent material, enabling users to visualize internal components (such as, internal screw **15**). Transparent housing **7** has a diameter scale **9** and a turn indicator **11**. Turn indicator **11** shows which way to turn the adjusting nut **13** to increase or decrease the diameter of the band **25**. The scale **9** is positioned to align with a specific marker, such as the front of the screw **15**, providing an indication of the current diameter of the band **25**. The fineness of the threads on screw **15** determines the relationship between turning the screw and changing the diameter of the band **25**. For a 10-32 thread, four turns of the adjusting nut **13** changes the band diameter by 1 mm.

[0051] The controller **5** may further include an adjusting nut **13** (e.g., also referred to as a captured nut), which may be rotated to change the diameter of the band **25** by linearly moving a screw **15** that is attached to the arrowhead **27** via receiver component **19**. Changing of the diameter of the band **25** may involve drawing the band **25** into the controller **5** through the operation of the adjusting mechanism.

[0052] In some embodiments, the adjusting mechanism for changing the diameter of the band **25**, may employ a ratchet mechanism that effectively engages with periodically spaced elements on the band **25**. These periodically spaced elements along the band engage with a fixed complimentary geometry inside the tunnel section. Further, the periodically spaced elements may serve as a series of detents when the band **25** passes through the tunnel section **89**. This arrangement allows for controlled adjustments to the band element's diameter, providing precise customization of the device's restriction capabilities. With sufficiency strong detents, the need for separate securing means may not be required.

[0053] To further elaborate, the screw **15** may pass through an O-ring **23** and the adjusting nut **13**, which may be captured inside the housing **7**. The O-ring **23** may provide for the smooth rotation of the adjusting nut **13** during band closure by providing a low friction surface to the rotating adjusting nut **13**. The adjusting nut **13** may include threads that may match with the screw **15** (also referred to as a threaded rod), such that turning the adjusting nut **13** may cause linear movement of the screw **15** and the receiver component **19**, which may in turn changes the diameter of the band element **3**.

[0054] In some embodiments, anti-rotation means may be provided to the screw **15** to prevent it from spinning when the adjusting nut **13** is turned. In some embodiments, the controller **5** may include means to limit a displacement of the band element **3**.

[0055] The controller **5** may be connected to the band element **3** by inserting the end of the band element **3** into the controller **5** and advancing it until it engages with the adjusting mechanism within the controller **5**. This may cause the band element **3** to move into a fully open position.

[0056] Further, in some embodiments, the controller **5** may be disconnected from the band element **3** by cutting across a short segment of the band element **3** between the controller **5** and a securing means **17** that may be mounted on the tunnel section **89** of the band element **3**. This securing means **17** plays a vital role in maintaining the band element **3** at a desired diameter once it has been adjusted. It ensures the stability of the band diameter under normal clinical conditions.

[0057] It should be noted that the securing means **17** of the present disclosure is not necessarily intended to be an absolute lock. Rather, the securing means **17** may be designed to maintain the diameter of the band element **3** under clinical conditions, but may allow it to be released from locking state by a high-pressure balloon placed inside a blood vessel **59**. The securing means **17** may be activated by pinching its sides to close over the tunnel section **89**, compressing the band element **3** and preventing it from slipping back. The securing means **17** is also smoothly contoured with the band element **3**, without creating any sharp edges or protrusions that may damage or pinch a vessel wall.

[0058] FIG. **3** shows features of the band element **3**. The band element **3** is designed with unique properties that facilitate its interaction with both the tunnel section **89** and the controller **5**. As stated earlier, the band element **3** has a tunnel section **89** with the proximal opening **33** and the distal opening **35**. The tunnel section **89** may include a ramp **31** extending from the base of the proximal opening **33**, which conforms to the inner surface of the band **25** as it closes. The tunnel section **89** may further include a notch **37** for locating the securing means, a bonding surface **39** for connecting to the controller **5**, and a cut-off plane **41** for disconnecting the controller **5**.

[0059] The end of band **25** may be molded or shaped to form a connector, such as arrowhead **27**. The band **25** may further include a series of notches **29** across its width, which may reduce the force required to close the band **25** to smaller diameters.

[0060] FIG. **4**A illustrates how the free end of band **25** is looped around a hollow conduit, such as a blood vessel **59**. The arrowhead **27** may then be inserted into the proximal opening **33** of the tunnel section **89**. Advancing the band **25** and arrowhead **27** through the tunnel section **89** allows arrowhead **27** to connect the receiver component **19** inside the controller **5**. The band **25** is then in the fully open position as shown in FIG. **4**B.

[0061] By way of an example, consider a scenario where a user wants to use the precision-controlled conduit restriction device **1** to control the flow of blood in an arterio-venous (AV) fistula, which is a surgical connection between an artery and a vein that is used for hemodialysis. The user may first need to expose the fistula site and identify the desired location for placing the band **25** around the fistula. The user may then take the free end of the band **25**, which has an end of arrowhead shape (arrowhead **27**) and lead it around the fistula. The user may then insert the arrowhead **27** into the proximal opening **33** of the tunnel section **89**, and then advance the arrowhead **27** until it reaches and connects with the receiver component **19** inside the controller **5**. The receiver component **19** is connected to the band adjusting mechanism. The user may change the diameter of the band **25** by turning the adjusting nut **13** in the controller **5**. After adjusting the band, the band is secured by engaging a lock **17**. The controller **5** may then be disconnected from the band element **3** by cutting across line of cut-off plane **41**. This would complete the band installation, adjustment, securing, and disconnection of the controller **5**.

[0062] The band element **3** of the present invention overcomes the limitations of prior art devices by providing a number of technical advantages listed below:

[0063] In the past, users faced challenges due to use of connectors at the end of the band and rigid plastic components, leading to complications and pinching during installation. The present disclosure addresses this by providing a soft polymer band element **3** with no end connectors. This design eliminates the risks associated with implanting rigid components in the body, reducing the potential for tissue damage, vessel wall injury, and complications that were present in the prior art.

[0064] Also in the past, the installation of the band required a snap-together connection near the vessel surface, which is cumbersome and risked vessel damage. The present invention eliminates this limitation by providing a simplified and safer installation process. The user may easily lead the arrowhead **27** of the band **25** around the blood vessel **59** and insert it into the tunnel section **89** of the band element. This moves the connection of the band end to inside the controller **5**, providing a safer and easier installation.

[0065] Also in the past, the installation of the band required a snap-together connection near the

vessel surface, which is cumbersome and risked vessel damage. The present invention eliminates this limitation by providing a simplified and safer installation process. The user may easily lead the arrowhead **27** of the band **25** around the blood vessel **59** and insert it into the tunnel section **89** of the band element. This moves the connection of the band end to inside the controller **5**, providing a safer and easier installation. The present invention effectively addresses the limitations of prior art through the following modifications: [0066] a. Molding a 1-piece soft polymer band with no hard surfaces; [0067] b. Eliminating the band end connector by molding the end of the band as a connector: [0068] c. Simplifying and improving the safety of the band installation process by using a one-way snap-in design inside the controller instead of near the vessel surface: [0069] e. Eliminating the need for secondary securing: [0070] f. Eliminating vessel pinching during band closure by using a tapered ramp that conforms to the inside surface of the band as the diameter changes: and [0071] g. Eliminating the implantation of adhesive.

[0072] Further, the securing means **17** of present invention overcomes the prior art's 675' device limitation of an absolute lock. Unlike the permanent lock of the prior art, the securing means **17** may be designed to allow the band **25** to slip past the lock and open (after having engaged the lock), in response to a pressurized balloon placed inside the blood vessel **59**. This dynamic securing mechanism ensures safety and adaptability, enhancing the clinical effectiveness of the device.

[0073] Further, in the past, the presence of a fixed rigid plastic component prevented the band from ever being round. The present invention addresses this limitation by introducing a continuously curved band element **3** that is circular over a wide diameter range. This innovative design improves the device's compatibility with different clinical scenarios. Further, the present invention eliminates the need for adhesive implantation. This design of the instant disclosure reduces the introduction of foreign materials and potential complications, enhancing patient safety.

[0074] FIG. **5**A is a perspective view of the arrowhead **27** of the band **25**, in accordance with an embodiment of the present disclosure. FIG. **5**A shows the details of the arrowhead **27** of the band **25**, which is designed to engage with the receiver component **19** inside the controller **5** as shown by longitudinal direction **6**B-**6**B. The arrowhead **27** may include an arrowhead notch **43** behind the angled front end, which may be used to receive and seat the arm ends **71** of the receiver component **19**. The taper of the arrowhead **27** may facilitate both inserting into the proximal opening **33** and the splaying-apart of the receiver arms **69**, shown in FIG. **10**.

[0075] FIG. **5**B illustrates a cross-section shape of the band **25** for producing a saddle-shaped restriction, in accordance with an embodiment of the present disclosure. FIG. **5**B shows an example of a cross-section shape **45** of the band **25** (for example, length of the band **25**), which may be used to produce a smooth saddle-shaped restriction in a hollow conduit, such as the blood vessel **59**. The cross-section shape **45** may have a curved inner surface and a flat outer surface, or other variations that achieve the same effect. In other words, the configuration shown in present FIG. **5**B is just one example, embodies the concept of creating the desired saddle-shaped restriction. However, it should be noted that other variations of the cross-section shape may achieve a similar effect.

[0076] FIG. **6**A is a perspective view of a band **25** passing through and extending past the tunnel section **89** of a band element **3**, showing cut-off plane **41** intended for disconnecting the controller **5** in longitudinal direction **6**B-**6**B, in accordance with an embodiment of the present disclosure. The cut-off plane **41** may be located in the middle of an area that does not leave any adhesive in the body when cut. This design emphasizes patient safety by preventing any residual adhesive from remaining within the body after the controller **5** is disconnected. Also shown is notch **37**, used to locate a securing means to maintain the band diameter after disconnecting the controller **5**.

[0077] FIG. **6**B is a cross-sectional view of the band **25** at the cut-off plane **41** shown in FIG. **6**A, depicting the band **25** inside the tunnel section **89**, in accordance with an embodiment of the present disclosure. FIG. **6**B shows how the tunnel section **89** surrounds band **25** at the cut-off plane **41**. The tunnel section **89** has cross-section shape **47** that reflects the cross-section shape of the band **25**, such that the band **25** may slide smoothly through the tunnel section **89**.

[0078] FIG. **7** is a side view of the tunnel section **89** of a band element **3** showing a proximal opening **33**, in accordance with an embodiment of the present disclosure. FIG. **7** shows how the ramp **31** extends from the base of the proximal opening **33**. The ramp **31** has an upward tilt angle **53**, which may allow the ramp **31** to contact the inner surface of the band **25** at larger diameters than if the ramp **31** was parallel to the floor of the tunnel section **89**. The ramp **31** may also provide a smooth and tapered stationary element that allows the closing of band **25** to slide up the ramp **31** without pinching the vessel wall. FIG. **7** also shows notch **37** which may be used to locate a securing means, and rib **49** used to keep the securing means within notch **37**. Bonding surface **39**, is used to connect band element **3** to controller **5**.

[0079] FIG. **8** is a perspective view illustrating conformity of the ramp **31** to the inner surface of the band **25**, in accordance with an embodiment of the present disclosure. The ramp **31** is tapered and has a small, soft, radiused edge. FIG. **8** shows how the ramp **31** adapts to the inner surface of the band **25**, providing a continuously curved inside shape **65** at all diameters. The tapered ramp **31** is made of a thin, soft, and flexible material that bends to provide a smoothly continuous arc to the closing of band **25**. This dynamic adaptation may ensure a harmonious interface between the stationary ramp **31** and the movable band **25**, preventing any gap or pinch point between the band **25** and the ramp **31**, which may pinch the vessel wall and occlude the vessel. FIG. **8** further illustrates an exemplary locked band **87** after cutting across cut-off plane **41** and disconnecting the controller **5**. Also shown in FIG. **8** are rear notches **29** which increase the flexibility of band **25** at smaller diameters, allowing easier closure.

[0080] FIG. **9** is a perspective view of the receiver component **19**, which is used to connect the arrowhead **27** of the band **25** to the screw **15** inside the controller **5**. The receiver component **19** has two flexible receiver arms **69** that extend from a base **57** and have arm ends **71** that are shaped to engage with the arrowhead notch **43** in the arrowhead **27**. The receiver component **19** also has side openings **75** that accommodate the wide aspect of the arrowhead **27**. The base **57** has two side extensions or wings **73** that ride inside a channel in the housing **7**, shown in FIG. **12***b*, to provide anti-rotation means to the screw **15**. The base **57** also has a rear extension **55** that is used to bond the receiver component **19** to the end of the screw **15**.

[0081] In other words, the receiver component **19** is a two-part system that connects the arrowhead **27** of the band **25** to the screw **15** inside the controller **5**. The two flexible receiver arms **69** of the receiver component **19** fit into the arrowhead notch **43** in the arrowhead **27**, and the side openings **75** accommodate the wide part of the arrowhead **27**. The base **57** of the receiver component **19** has two side extensions, or wings **73**, that ride inside a channel in the housing **7** to prevent the screw **15** from rotating.

[0082] FIGS. **10**A-**10**C is series of perspective views illustrating a sequence involved in the connection of the arrowhead **27** to the receiver component **19**, in accordance with an embodiment of the present disclosure. FIG. **10**A shows the arrowhead **27** approaching the receiver component **19**. As the angled arrowhead **27** moves closer to the receiver component **19**, it is positioned to spread the receiver arms **69** of the receiver component **19**.

[0083] FIG. **10**B shows how the arrowhead **27** continuing its advancement, elastically spreads the receiver arms **69** of the receiver component **19**. The design of the arrowhead **27** facilitates this spreading motion by exerting outward force on the receiver arms **69**. This elastic spreading is an integral part of achieving a secure and reliable connection.

[0084] FIG. **10**C shows how, after further advancing the arrowhead **27**, the arm ends **71** (e.g., two-receiver arm ends) drop into the arrowhead notch **43**, securing the connection to band **25**. In this final stage of the sequence, the connection of the arrowhead **27** to the receiver component **19** is completed. This one-way engagement securely locks the band **25** in place, and provides a strong push/pull capability to the controller **5**. At this point, the device reaches a stable state where the band **25** is in its maximum diameter position, forming a loop around the hollow conduit. This position is also shown as FIG. **11***b*.

[0085] FIGS. **11**A-**11**C is a series of longitudinal cross-sectional views of the precision-controlled conduit restriction device **1** illustrating the process whereby band **25** is drawn into the controller **5** as the band **25** closes, in accordance with an embodiment of the present disclosure. FIG. **11**A shows the precision-controlled conduit restriction device **1** as produced, with the band **25** free to be led around a blood vessel **59**. At this stage, the precision-controlled conduit restriction device **1** is shown with the band **25** in a free state, unsecured and ready to be led around the hollow conduit, represented as a blood vessel **59**.

[0086] FIG. **11**B shows the precision-controlled conduit restriction device **1** when arrowhead **27** is first connected to the receiver component **19**. This position represents the fully-open state of the band **25**. The precision-controlled conduit restriction device **1** is in the state just after the successful connection of the arrowhead **27** to the receiver component **19**.

[0087] FIG. **11**C shows the band **25** in a reduced diameter position. The band **25** has been drawn into the controller **5** through the adjusting mechanism, and both the receiver component **19** and the screw **15** are correspondingly displaced to the right, extending the screw **15** out of the back of the controller **5**. This sequence visually captures the mechanism through which the precision-controlled conduit restriction device **1** achieves the desired level of restriction.

[0088] In FIGS. **12**A-**12**C, the focus shifts to the internal workings of the precision-controlled conduit restriction device **1**, specifically the housing **7**. FIGS. **12**A-**12**C depict a series of cross-sectional views through the housing **7**, as defined in FIG. **11**A-**11**C. Internal channel wall **61** is shaped to constrain and permit the passage of the band **25**, receiver component **19**, and screw **15** through the housing **7**, in accordance with an embodiment of the present disclosure. The internal channel wall **61** allows the passage of these components without interfering with their movement or function. FIG. **12**A shows how the screw **15** is constrained by internal channel wall **61**. FIG. **12**B shows how receiver component **19** is constrained by the internal channel wall **61**. The wings **73** of the receiver component **19** are constrained by the internal channel wall **61**, thereby providing anti-rotation means to the screw **15**. Internal channel wall **61** orients receiver component **19** ensuring its proper alignment to connect to arrowhead **27**. FIG. **12**C illustrates how band **25** is constrained by internal channel wall **61**. FIG. **12** serves to highlight the dynamic functionality of the internal channel wall **61** in facilitating the smooth and effective operation of the controlled restriction mechanism.

[0089] FIGS. **13**A-**13**C depict a series of perspective views of a securing means **17** showcasing different stages and aspects of its functionality, in accordance with an embodiment of the present disclosure. FIG. **13**A shows the securing means **17** in the open or unlocked position mounted in the notch **37** and retained by the rib **49**. The primary purpose of the securing means **17** is to compress the tunnel section **89** over the band **25**, thereby preventing movement of the band **25**.

[0090] FIG. **13**B provides a closer look at the securing means **17** in the open position. This view shows the securing means **17** in an open position, with arrows **77** indicating the location for pinching the sides of the securing means **17** to close or lock. The positioning of arrows **77** indicates the specific locations where pressure can be applied to pinch the sides of the securing means **17** together. This action is what eventually enables the securing means **17** to transition from an open to a locked state **63**, effectively securing the band **25** in place.

[0091] FIG. **13**C shows the securing means **17** (for example, a securing means lock) in a closed or locked state **63**. In this state, the securing means **17** compresses the tunnel section **89** over the band thereby preventing movement of the band. The securing means **17** may be designed to allow the band **25** to slip past lock **17** in response to a high pressure intraluminal balloon inserted inside the blood vessel **59**.

[0092] In one embodiment, the securing means **17**, implemented as a click-together design, may be placed around the tunnel section of band element **3** to compress the tunnel section over the band **25**. The degree of compression may be precisely controlled by the shape of the inside curve of the locking mechanism.

[0093] Fabrication of the securing means **17** may be performed using electrical discharge machining (EDM), utilizing materials such as 0.062″ thick titanium sheet. The two-dimensional and digital nature of the securing means is instrumental in achieving its intricate design. The degree of tunnel compression may be finely controlled by altering the inside shape of the securing means, which is conveniently performed in a two-dimensional CAD environment, then translated into a cutting path.
[0094] In another preferred embodiment, the band element **3** may incorporate a strategically designed weak point that allows the band to break or stretch open in response to an angioplasty balloon.
[0095] The securing (e.g., lock) of the band element **3** may be achieved through various design means, all of which yield a similar clinical outcome, ensuring controlled and secure band engagement.
[0096] FIG. **14** is a flow-chart representation of a method according to the present invention. The method is based upon having a length of band, wherein one end is attached to a hollow section. The hollow section is designed to allow passage of the band. One end of the hollow section is designed for insertion of the band end, and the other is removably attached to a mechanism capable of controllably moving the band through the tunnel.
[0097] In block **90**, the free end of a band is led around a blood conduit. The band may be shaped to facilitate this process.
[0098] In block **92**, the end of the band is inserted into the hollow section attached to the opposite end of the band. The band then forms a loop around the blood conduit.
[0099] In block **94**, the band is advanced through the hollow section to connect to a detachable mechanism, connected to the opposite end of the tunnel section, capable of varying the diameter of the band loop around the blood conduit.
[0100] In block **96**, the band adjusting means of the mechanism is employed to change the diameter of the band.
[0101] In block **98**, after adjustment, the band diameter is secured by activating securing means to prevent the band from opening under normal clinical conditions.
[0102] In block **100**, after securing the band diameter, the adjusting mechanism is detached from the tunnel section, leaving the secured band around the blood conduit.
[0103] As will be appreciated by those skilled in the art, the techniques described in the various embodiments discussed above are not routine, or conventional or well understood in the art. The techniques discussed above may provide several advantages over the prior art for controlling the flow of fluid in the hollow conduit, such as the blood vessel **59**. Some of the advantages are as follows: the precision-controlled conduit restriction device **1** of the present invention is easy to install and adjust, without requiring any complex or delicate manipulation of small parts in a surgical field. Further, the precision-controlled conduit restriction device **1** is safe, without using any hard or sharp components that could damage or pinch the vessel wall. Further, the precision-controlled conduit restriction device **1** does not require any secondary securing of the band element **3**. Furthermore, the precision-controlled conduit restriction device **1** is versatile and adaptable, without having any fixed or rigid elements that prevent the band element **3** from being circular or conforming to the vessel shape.
[0104] In light of the above-mentioned advantages and the technical advancements provided by the disclosed method and system, the claimed steps as discussed above are not routine, conventional, or well understood in the art, as the claimed steps enable solutions to the existing problems in conventional technologies. Further, the claimed steps clearly bring an improvement in the functioning of the precision-controlled conduit restriction device **1** itself as the claimed steps provide a technical solution to a technical problem.
[0105] The foregoing description of various embodiments of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention

to the precise embodiments disclosed. Numerous modifications or variations are possible in light of the above teachings. The embodiments discussed were chosen and described to provide illustrative examples of the principles of this invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated.

[0106] While various embodiments have been described above, it should be understood that they have been presented by way of example only, and not limitation. Thus, the breadth and scope of the present disclosure should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the following claims and their equivalents.

Claims

1. A device for providing controlled restriction of a hollow conduit in a body, the device comprising: a band element having a tunnel section with a proximal opening and a distal opening, a length of band extending from the proximal opening, a controller removably attached to the distal opening, comprising a mechanism for adjusting a diameter of the band, wherein an end of the band is insertable through the proximal opening to form a loop around the hollow conduit, and wherein the band is advanced into the controller to permanently engage with the mechanism for adjusting the diameter of the band, a securing means to fix the band diameter after adjustment, and a means to disconnect the controller from the band element after securing, leaving the band and the securing means around the hollow conduit.

2. The device of claim 1, wherein the controller is disconnected by cutting a short segment of the band element between the controller and the securing means lock so as to leave the band element secured around the hollow conduit.

3. The device of claim 1, wherein the band element is coated with a material, such as parylene to reduce its sliding friction or stiction.

4. The device of claim 1, wherein the band element is radiopaque.

5. The device of claim 1, wherein the band has a circular cross section, a rectangular cross section, or is shaped to provide a specifically-shaped restriction.

6. The device of claim 1, wherein the band is partially covered with a material, such as a textile to provide friction between the band and an outside surface of the hollow conduit to prevent band migration.

7. The device of claim 1, wherein the mechanism for adjusting the diameter of the band comprises a captured nut that linearly moves a threaded rod connected to the end of the band thereby drawing the band into the controller.

8. The device of claim 1, wherein the securing means is a lock that compresses the tunnel over a section of band to produce a controlled resistance to band movement which maintains the diameter of the band under normal clinical conditions, and allows the band element to open from its secured state in response to a pressurized balloon placed inside the hollow conduit.

9. The device of claim 1, wherein the controller further comprises an indicator for displaying the diameter of the band.

10. The device of claim 1, wherein the band element is molded using a biomedical polymer with a durometer from about 60 A to 90 A.

11. A device for providing controlled restriction of a hollow conduit in a body, the device comprising: a band element having a tunnel section with a proximal opening and a distal opening, a length of band extending from the proximal opening, a controller removably attached to the distal opening, comprising a mechanism for adjusting a diameter of the band, wherein an end of the band is insertable through the proximal opening to form a loop around the hollow conduit, and wherein the band is advanced into the controller to permanently engage with the adjusting mechanism, a securing means located inside the tunnel section to secure the diameter of the band, and a means to

disconnect the controller from the band element, leaving the band and securing means around the hollow conduit.

12. The device of claim 11, wherein the band is secured using a detent-type mechanism within the tunnel section, wherein periodically spaced elements along the band engage with a fixed complimentary geometry inside the tunnel section.

13. The device of claim 11, wherein the band element is secured by creating a friction-fit between the band element and the tunnel section, and wherein the controller is a disposable or a reusable controller.

14. The device of claim 11, wherein the securing means is a lock that compresses tunnel over a section of band to produce a controlled resistance to band movement that maintains the diameter of the band under normal clinical conditions, and allows the band to open from its secured state in response to a pressurized balloon placed inside the hollow conduit.

15. The device of claim 14, wherein wherein the controller is disconnected from the band element by cutting a short segment of the band element between the controller and the securing means so as to leave the band element secured around the hollow conduit.

16. A method to controllably reduce a flow in a blood conduit, the method comprising the Steps of: leading an end of a band around a blood conduit; inserting the end of the band into a hollow section connected to an opposite end of the band so as to form a loop around the blood conduit; advancing the band through the hollow section to connect to a mechanism detachably connected to the opposite side of the hollow section, said mechanism being capable of controllably drawing the band in and out of the hollow section so as to vary a size of the loop; adjusting a diameter of the band using an adjusting mechanism; securing the band; and detaching the mechanism from the hollow section so as to leave a secured band in place around the blood conduit.