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Foerster

(54) **DYNAMIC TISSUE HOLDING DEVICE WITH LOW PROFILE SPRING**

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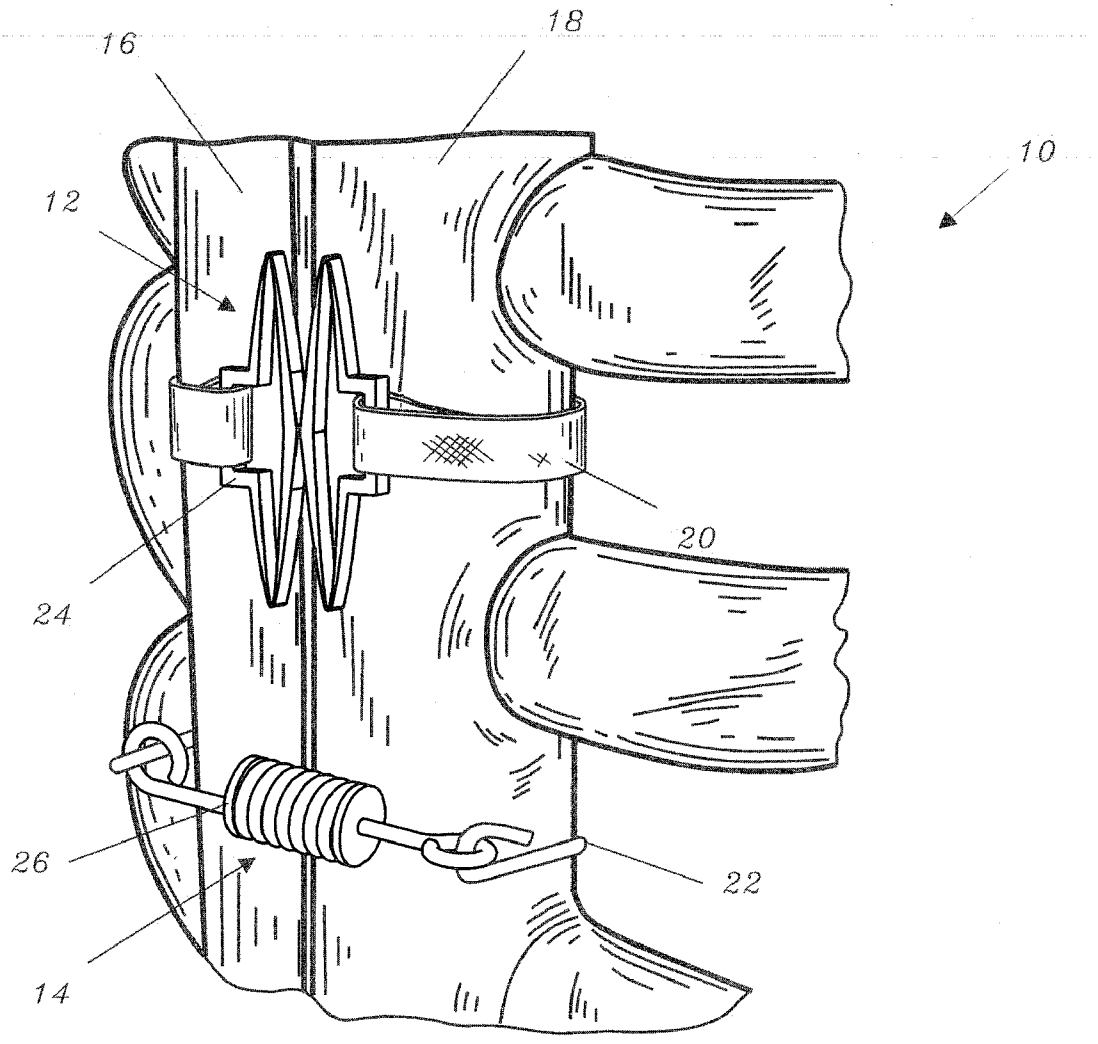
(57) **ABSTRACT**

A dynamic tissue holding device is disclosed for dynamically holding two tissue portions in contact with one another. The device comprises a biasing spring having a relatively low profile, and a band adapted for extending about the tissue portions to be held together. The band has a first end for attachment to a first attachment portion on the biasing spring and a second end for attachment to a second attachment portion on the biasing spring. The band establishes a path of tension along its length and extending linearly between the two ends of the band. Advantageously, more than one-half of the biasing spring is disposed outside of the path of tension when the dynamic tissue holding device is in place and holding the two tissue portions together.



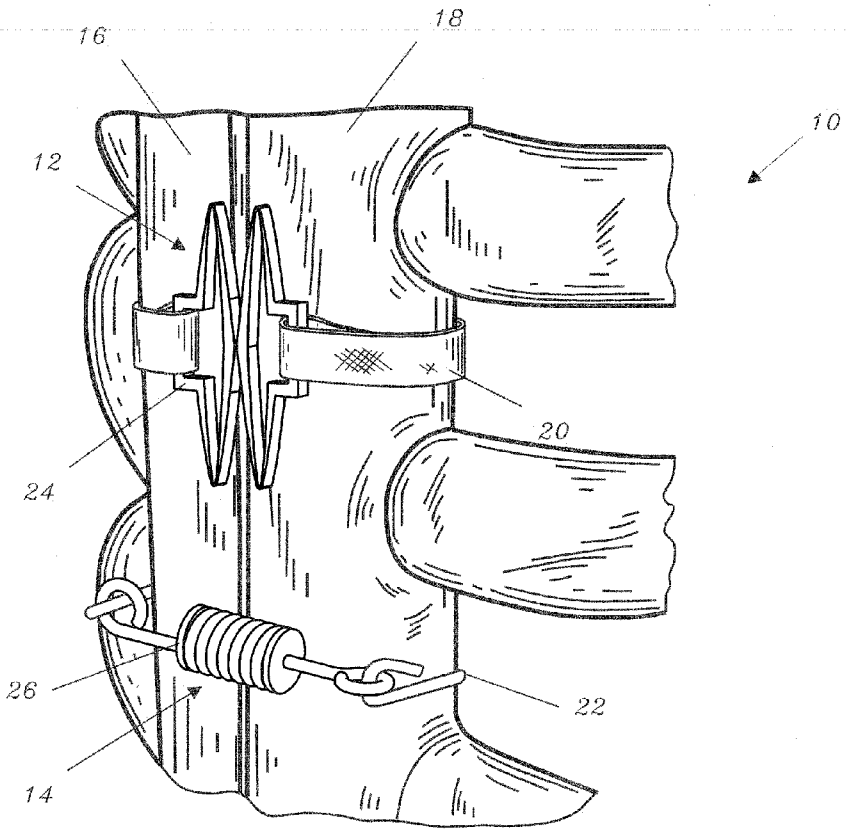


fig. 1

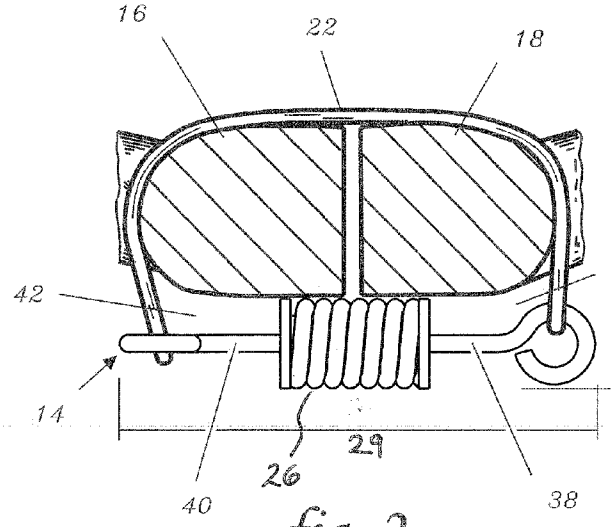


fig. 2

Prior Art

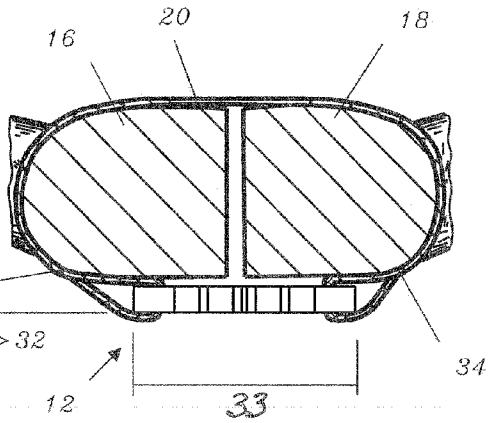


fig. 3

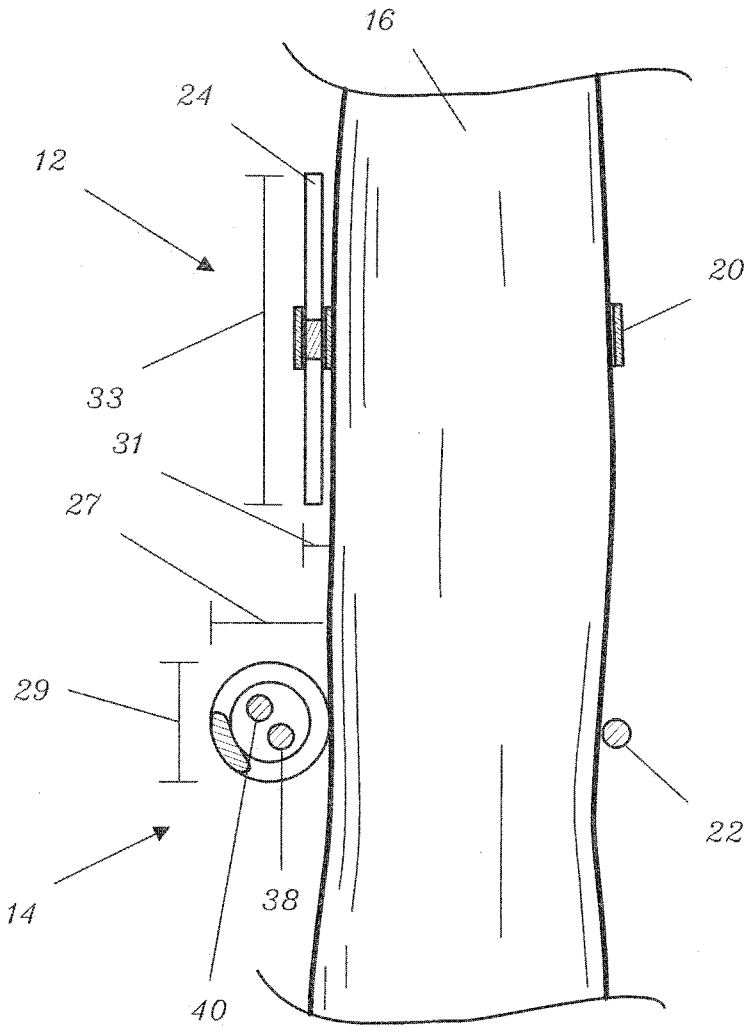
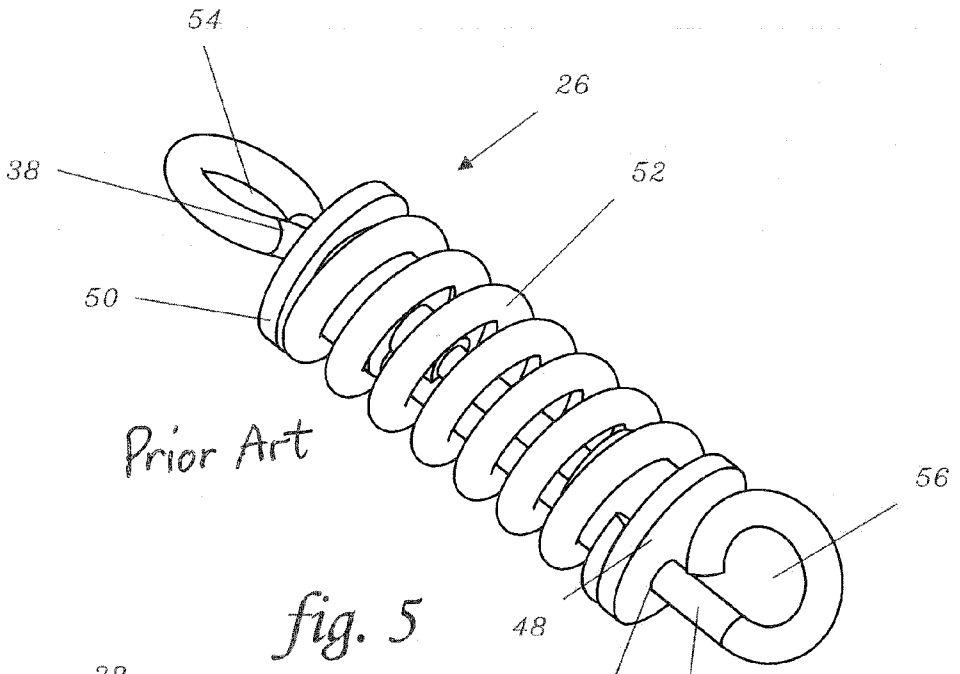


fig. 4



Prior Art

fig. 5

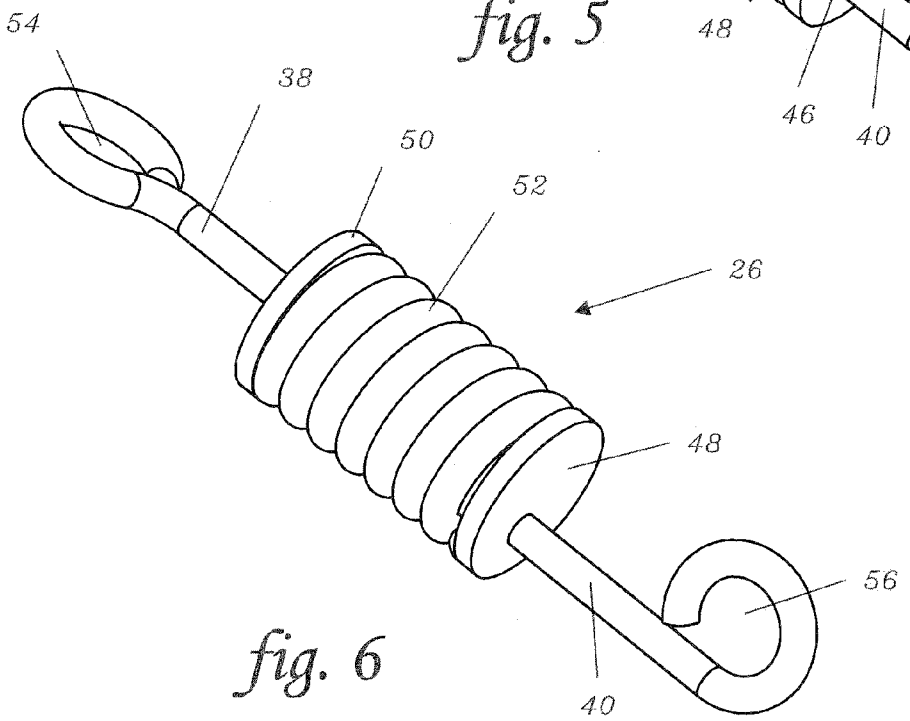


fig. 6

Prior Art

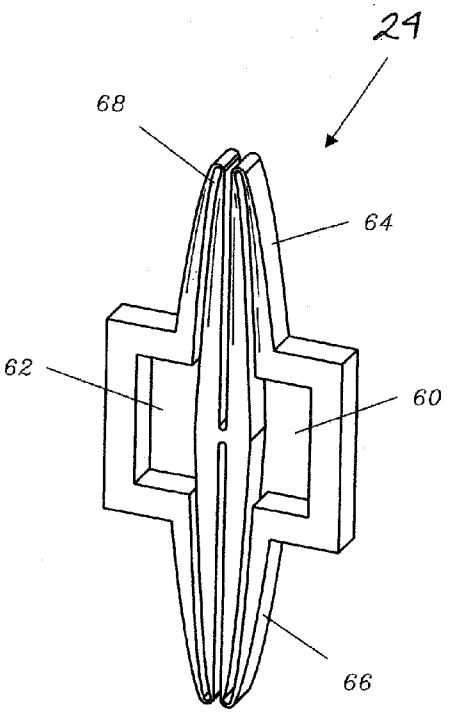


fig. 7

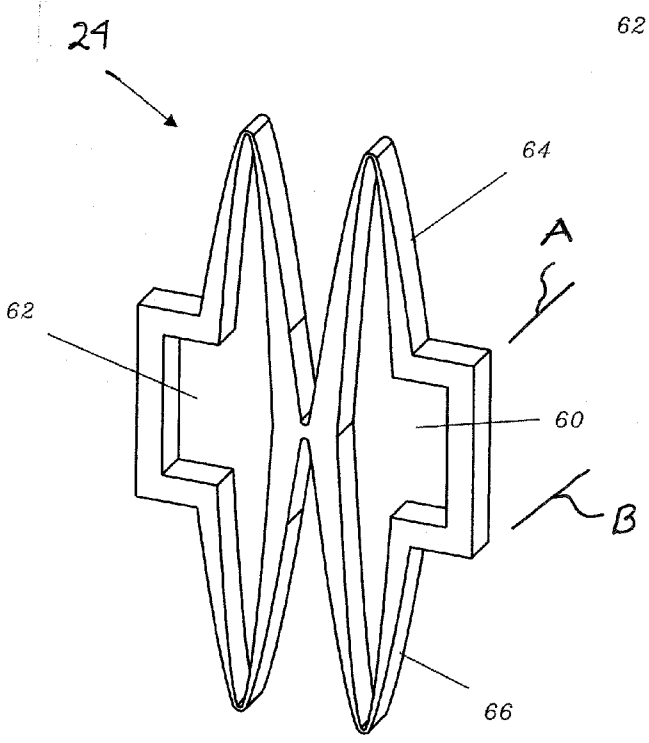


fig. 8

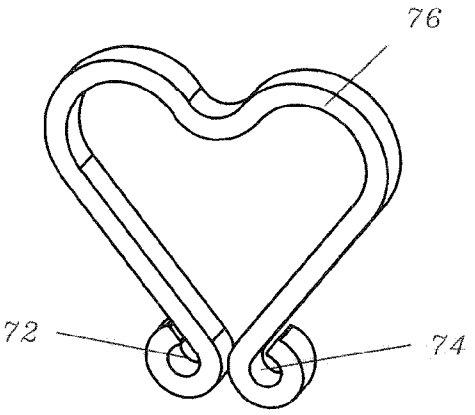


fig. 9

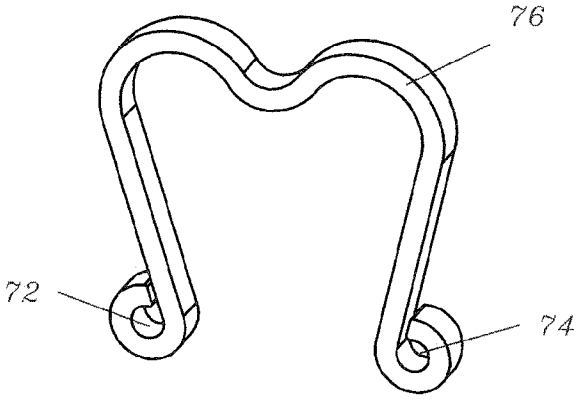


fig. 10

DYNAMIC TISSUE HOLDING DEVICE WITH LOW PROFILE SPRING

[0001] This application claims the benefit under 35 U.S.C. 119(e) of the filing date of Provisional U.S. Application Ser. No. 61/037,582, entitled Dynamic Ring Compression Device, filed on Mar. 18, 2008, and expressly incorporated herein by reference, in its entirety. This application is also related to co-pending U.S. patent application Ser. No. 12/347,821, entitled Dynamic Suture Tensioning Device and filed on Dec. 31, 2008, and to U.S. Utility Patent Application Docket Nos. A-2313, entitled Knotless Dynamic Suture Tensioning Device and Methods, and A-2396, entitled Load Shaping for Dynamic Tensioning Mechanisms and Methods, both filed on even date herewith, all of which are commonly assigned and expressly incorporated herein, by reference, in their entirety.

BACKGROUND OF THE INVENTION

[0002] The present invention is related to the general surgical repair of separated body tissues, and more particularly to internally fixating and stabilizing such body tissues, specifically bones.

[0003] In the present state of the art, there are a number of systems available to repair biological tissues separated in surgery or by injury. These products serve to approximate and stabilize the tissues so that healing may commence and provide compression in the interface to promote healing. Compression and stability are critical for proper anatomical healing of tissue. With the correct amount of compression applied to the interface of the tissue portions to be joined, signals are sent to the tissue, thus allowing the tissue to remodel in proper anatomical position. The amount of compression applied to the tissue interface needs to be appropriate to the type of tissue that is being healed.

[0004] When it is necessary to access the thoracic cavity for a medical procedure, for example, it is required to cut the sternum into two pieces using a rib spreader. Once the procedure is completed within the thoracic cavity, the sternum must be repaired. For such repairs, it is known to use a dynamic compression device like that shown in FIGS. **1** (device **14**) and **2**, which, for the sake of convenience and clarity, is discussed in connection with the discussion of the inventive device **12**, in the detailed description portion of the specification. Some of the drawbacks of this typical device **14**, and others which are used include:

[0005] 1. Bulky spring materials, while occupying substantial space, often do not store much energy. Some use polymer elastic bands, while other use coiled springs;

[0006] 2. Wires are sometimes used to wrap the bones into position in compression with one another. However, wires can have sharp ends that can damage adjunctive tissues. Knot stacks in suture can interfere with the natural movement of surrounding tissues; and

[0007] 3. Current banding systems that incorporate a biasing mechanism to achieve dynamic compression, like the device **14** described hereinbelow, put the biasing mechanism in line with the band or suture. This practice competes with precious space at the healing site. Suture or bands are used to approximate tissues so that they may heal. It is desirable to obtain the best purchase possible on the tissue, so that the binding mechanics offered by the suture may be utilized. The best purchase is optimized by ensuring that the suture has the greatest contact area with the tissue. If a biasing mechanism is interfering with this concept, the biasing mechanism may diminish the suture's ability to hold the tissues together.

[0008] What is needed is an improved dynamic compression system which addresses and overcomes these shortcomings in an innovative way.

SUMMARY OF THE INVENTION

[0009] The present invention solves the problems outlined above by providing a biasing system for a suture or banding system that does not adversely affect the band's ability to hold tissue together. This is done by removing most or all of the biasing mechanism from the path of the band. By placing the biasing mechanism to one or the other side of the tension path of the band, many desirable effects are realized.

[0010] The inventor has recognized that maximizing contact between the suture or band and the underlying bone or tissue is important to optimize healing. This is particularly relevant in the case of holding sternal halves together after they have been separated to access the thoracic cavity. Breathing, coughing, and any movement by the upper body impart larger forces in the repair held together by bands. Any biasing device must serve to augment or maintain the function of the bands. If this is not the case, coughing may induce stresses that concentrate on one part of the bone, causing the bands to cut into the bone. When the bands cut into the bone, the tension in the bands is released adversely, thus affecting their ability to help mend bone to bone.

[0011] More particularly, there is provided in one aspect of the invention a dynamic tissue holding device for dynamically holding two tissue portions in contact with one another. The device comprises a biasing spring having a relatively low profile, and a band adapted for extending about the tissue portions to be held together. The band has a first end for attachment to a first attachment portion on the biasing spring and a second end for attachment to a second attachment portion on the biasing spring. The band establishes a path of tension along its length and extending linearly between the two ends of the band. Advantageously, more than one-half of the biasing spring is disposed outside of the path of tension when the dynamic tissue holding device is in place and holding the two tissue portions together.

[0012] Advantageously, at least approximately four-fifths of the biasing spring is disposed outside of the path of tension. The height of the biasing spring is less than about 2 mm. In one particular embodiment, the biasing spring is formed to have a generally parabolic profile. The band preferably comprises a braided band, or, alternatively, a cable.

[0013] In one embodiment of the invention, the biasing spring comprises a first eyelet disposed in a center portion of the spring, for receiving the first end of the tensioning band, and a second eyelet disposed on an opposing side of the center portion of the spring, for receiving the second end of the tensioning band, wherein at least approximately four-fifths of the spring is disposed on either one side or the other of the first and second eyelets. More preferably, approximately two-fifths of the spring is disposed on one side of the first and second eyelets and approximately two-fifths of the spring is disposed on the other side of the first and second eyelets. The space efficiency of the biasing spring is at least about 50%, and preferably at least about 57%.

[0014] In another embodiment of the invention, the biasing spring comprises a first eyelet disposed on one edge of the spring, for receiving the first end of the tensioning band, and a second eyelet disposed on a second edge of the spring, for

receiving the second end of the tensioning band, wherein substantially all of the biasing spring is disposed to one side of said eyelets.

[0015] In another aspect of the invention, there is provided a dynamic tissue holding device for dynamically holding two tissue portions in contact with one another, which comprises a biasing spring and a band adapted for extending about the tissue portions to be held together. The band has a first end for attachment to a first attachment portion on the biasing spring and a second end for attachment to a second attachment portion on the biasing spring. A particularly advantageous feature of the invention is that the aspect ratio of the inventive device, defined as the height of the device above the tissue surface, divided by the length of the device, is less than or equal to approximately 0.50, and more preferably approximately 0.10.

[0016] The height of the biasing spring is less than about 2 mm. In one particular embodiment, the biasing spring is formed to have a generally parabolic profile. The band preferably comprises a braided band, or, alternatively, a cable.

[0017] In one embodiment of the invention, the biasing spring comprises a first eyelet disposed in a center portion of the spring, for receiving the first end of the tensioning band, and a second eyelet disposed on an opposing side of the center portion of the spring, for receiving the second end of the tensioning band, wherein at least approximately four-fifths of the spring is disposed on either one side or the other of the first and second eyelets. More preferably, approximately two-fifths of the spring is disposed on one side of the first and second eyelets and approximately two-fifths of the spring is disposed on the other side of the first and second eyelets. The space efficiency of the biasing spring is at least about 50%, and preferably at least about 57%.

[0018] In another embodiment of the invention, the biasing spring comprises a first eyelet disposed on one edge of the spring, for receiving the first end of the tensioning band, and a second eyelet disposed on a second edge of the spring, for receiving the second end of the tensioning band, wherein substantially all of the biasing spring is disposed to one side of said eyelets.

[0019] The invention, together with additional features and advantages thereof, may best be understood by reference to the following description taken in conjunction with the accompanying illustrative drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. **1** is an isometric view showing a sternum having bone halves which are being held together by a device constructed in accordance with the principles of the present invention, and also by a prior art device, for comparative purposes;

[0021] FIG. **2** is a top cross-sectional view of the prior art dynamic compression device shown in FIG. **1**;

[0022] FIG. **3** is a top cross-sectional view similar to FIG. **2** of the dynamic compression device of the present invention also shown in FIG. **1**;

[0023] FIG. **4** is a cross-sectional view of the sternum shown in FIG. **1**, illustrating the respective profiles of each of the prior art device and the inventive device;

[0024] FIG. **5** is an isometric view of a coiled spring for use as a drawbar spring in the prior art device of FIG. **2**;

[0025] FIG. **6** is an isometric view similar to FIG. **5** of the prior art coiled spring in a compressed configuration;

[0026] FIG. **7** is an isometric view of the device of the present invention in a compressed configuration;

[0027] FIG. **8** is an isometric view similar to FIG. **7** of the device in an expanded configuration;

[0028] FIG. **9** is an isometric view of an alternative embodiment of the invention, in its initial relaxed state; and

[0029] FIG. **10** is an isometric view similar to FIG. **9**, illustrating the alternative embodiment is its tensioned, energy stored state.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0030] Referring now more particularly to the drawings, there is shown in FIG. **1** a sternum **10** which is comprised of two bone halves **16** and **18**. The two bone halves have been separated, as is necessary for performance of open heart surgical procedures, or other procedures requiring access to the thoracic cavity. To conclude the procedure, it is necessary to re-join the bone halves **16** and **18** and to do so in a way that will ensure proper healing.

[0031] A dynamic compression device **12**, which has been constructed in accordance with the principles of the present invention, is illustrated in a deployed orientation for holding the bone halves **16**, **18** together. Also illustrated is a typical prior art dynamic compression device **14**, also in a deployed configuration, for purposes of comparison. With reference also to FIG. **2**, the prior art device **14** uses a biasing mechanism-suture configuration, wherein the biasing mechanism comprises a drawbar spring **26** which is placed directly in line with the tension of a length of suture **22**. The biasing mechanism **26** serves to pull the bone halves **16** and **18** into each other by means of tensioning suture **22**, thus holding the sternum **10** together so that it may heal.

[0032] Now referring to FIG. **3**, as well as FIG. **1**, the inventive device **12** functions to pull the upper intercostal spaces together by means of a braided band **20** and a biasing spring **24**. The braided band **20** may alternative comprise a cable and still be well within the scope of the present invention. The entirety of the drawbar spring element **26** of device **14** can be seen to be directly in the path of the tension of suture **22**. On the other hand, in the present invention **12**, four-fifths of the flat biasing spring **24** lies outside of the tension path of the band **20**. This feature offers several significant advantages over the prior art approach.

[0033] FIGS. **2** and **3**, taken side-by-side, as well as FIG. **4**, clearly demonstrate the advantageous features of the inventive device **12**, respective to the typical prior art device **14**. FIG. **2** is a top cross-sectional view of the prior art device **14**, as situated on a patient's sternum **10**, and FIG. **3** is a similar cross-sectional view showing the inventive device **12** similarly situated on the patient's sternum. FIG. **4** is a cross-sectional view, perpendicular to the osteotomy showing bone half **16**, and extending through the sternum and devices **12** and **14** (see FIG. **1**). In this view, the profile of the inventive device **12** can be easily compared to that of the prior art device **14**. The aspect ratio may be used as a measurement of the profile. The aspect ratio of device **12** is defined as the height **31** of the device above the bony surface, divided by the length **33** of the device. In the illustrated embodiment of device **12**, its aspect ratio is approximately 1/10. Other suitable inventive devices may have aspect ratios of up to about ½ and still realize substantial benefits of the present invention. In con-

trast, the prior art drawbar spring device **14** has an aspect ratio of its height **27** divided by its length **29**, which is approximately 1.

[0034] Both of the devices **12** and **14** are constructed of a suitable known medical grade material, preferably surgical stainless steel, to thereby yield similar performance characteristics which are necessary to supply dynamic compression to sternal halves **16**, **18** so that optimum healing may occur. Sternal halves **16**, **18** also represent a typical sternal cross-section in its width of approximately 24 mm.

[0035] The width of the sternum **10** ends up being a critical dimension in the procedure. The width of an adult sternum may range from 18 to 80 mm, but the tissue may not be dissected to access its entire width. While dissection may be done to accommodate larger devices, such trauma to tissue should be avoided. Thus, the figures show a sternal width of approximately 24 mm as this is the common dissected width used to accommodate the saw used for the initial osteomety.

[0036] At 24 mm in sternal width, the prior art device **14** is too large to function correctly. The suture **22** is unable to wrap around the bone appropriately, causing gaps **42** and **44**. The gaps **42** and **44** cause the suture **22** to pull the device **14** directly into the sternal halves **16** and **18**. This causes a rise in suture tension to realize the same compression between sternal halves **16** and **18**, should gaps **42** and **44** not be present. The tension is such, in the system of device **14**, that it is likely that arms **38** and **40** of the device will bend to the point of affecting the returning function of the spring **26**. The net effect is that the device **14** cannot supply the same compression between the sternal halves **16** and **18** as is the case with the inventive device **12**, even though the springs **26** and **24**, respectively, have substantially the same spring constants and are fabricated of the same material. The width **29** of the prior art device **14** is twice the width **33** of the inventive device **12**. The inventive device **12** also shows smaller gaps, with the band **20** lying on the bone surfaces **34**, **36**, enabling the band **20** to hold tension on both sides of the bone.

[0037] The dermal layer on top of the sternum is rather thin. Even when a surgeon employs only twisted wire to repair the sternum, some patients can feel that wire under their skin. Consequently, the profile of a closure device can have cosmetic as well as practical concerns. The dermal layer over the sternum on an average adult female is 5 to 10 mm thick. The prior art device **14** has a height **27** of approximately 5.3 mm (FIG. **4**). This is sufficiently thick to be rather clearly seen in some adults. As noted above, the device **14** presents a much higher profile off the sternum **10** (the difference in profile between the two devices being shown as reference numeral **32**) than does the inventive device **12**, which has only a height **31** (FIG. **4**) of about 1.8 mm off the sternum. Moreover, because the profile of the inventive device **12** is spread out over a large surface area, resulting in a much more favorable aspect ratio, it will not be easily seen when viewing the patient from the outside.

[0038] FIGS. **5** and **6** illustrate the drawbar **26** of the prior art device **14** in greater detail. FIG. **5** illustrates the coiled spring **52** in its initial, untensioned configuration. An eyelet **54** is connected to the arm **38**, which moves freely through an end cap **50** and is solidly attached to an end cap **48**. And eyelet **56** is connected to the arm **40**, which moves freely through the end cap **48** and is solidly attached to the end cap **50**. The spring **52** is trapped between the end caps **50** and **48**. As the eyelets **54** and **56** are drawn apart, as is needed to tension the suture, end caps **50** and **48** are drawn together, thus compressing the spring **52** and causing the spring **52** to store energy as shown in FIG. **6**.

[0039] FIG. **1** clearly shows the width requirement for the device on the top surface of the sternum, and FIGS. **2** and **4** show the deficiencies of the drawbar spring design. FIG. **5** illustrates how the drawbar spring is inherently a poor design. As can be seen in FIG. **5**, the eyelets **54** and **56** are necessarily placed outside of the ends of spring end caps **48** and **50**. It is because of the way that the drawbar design is assembled that this must be so. Eyelets **54** and **56** are then pulled farther apart to fully compress the spring **52**.

[0040] The space efficiency of the device **12** is an important design criteria. A smaller, more efficient spring enables the device **12** to be used in more scenarios with less trauma to the patient. A material is capable of storing energy based on its volume. How that energy is stored and released is based on the length of the material and its cross-section. Both devices **12** and **14** have been designed to have equivalent performance both in energy stored and in the delivery of the energy. However, the respective space efficiencies of the springs of each device are far different. The space efficiency of the spring is defined as the total space it occupies divided by the space or volume the spring material actually physically occupies. In the case of the prior art device **14**, the spring wire is 0.040 in. in diameter, and makes 7.5 revolutions. The spring itself is 0.210 in. in diameter and is 0.475 in. long. Thus, the space efficiency of the device **14** is the volume of the spring wire divided by the volume occupied by the spring, which equals 32%. Note that the end caps **50** and **48**, and the arms **38** and **40** are left out of this calculation because they do not store energy. There is also some design space beneath the spring, between the bone and the spring that is not used and could be used by other designs. With this space included, the space efficiency of the device **14** drops to 28%.

[0041] The inventive device **12** more than doubles this space efficiency at 57%, by following a few innovative precepts. As can be seen in FIG. **7**, the inventive device more closely spaces the eyelets **60** and **62**, thereby eliminating the dead space in the width of the design. The spring cross-section is rectangular, thus eliminating the wasted space brought on by a wire. The spring starts in its most compacted state, widthwise, so that spaces between the spring elements do not contribute to the width of the device.

[0042] Advantageously, the spring **24** as shown particularly in FIGS. **7** and **8** is fabricated from a flat sheet of material. Grooves **68** are made as small as possible, using the smallest cutter possible. A presently preferred cutting method is by a Wire Electrical Discharge Machine (wire EDM), because it can accurately cut the parabolic profile of the springs which is necessary for an optimum spring performance. However, alternative cutting approaches may utilize laser, plasma cutters, band saws, water jets, photo etching, etc., wherein the cutting process enables a high density of biasing elements, and wherein the cutting process achieves such a high density by cutting the left side of one element and the right side of another element using the same cut. Cutting these slots using just one pass of the machine also shortens machining time, which lowers the cost of the device.

[0043] FIG. **8** illustrates the spring **24** in its expanded state, storing all of the energy needed to force the tissues under the suture in compression throughout the healing cycle. Preferably, approximately ⅘ of the spring is disposed above the

eyelets at **64** and below the eyelets at **66**. This enables the width of the device to be as small as possible.

[0044] FIGS. **9** and **10** illustrate another embodiment of the present invention, wherein the entire spring element **76** is paced to one side of suture eyelets **72** and **74**. FIG. **9** shows the spring element in its initial relaxed state, and FIG. **10** shows the embodiment in its tensioned, energy stored state.

[0045] While the inventive concept is disclosed as being particularly adapted for use in repairing the sternum after a thoracic cavity procedure, it is, of course, applicable to a great many other procedures requiring repair of bodily tissue, particularly bone.

[0046] Accordingly, although exemplary embodiments of the invention have been shown and described, it is to be understood that all the terms used herein are descriptive rather than limiting, and that many changes, modifications, and substitutions may be made by one having ordinary skill in the art without departing from the spirit and scope of the invention, which is to be limited only in accordance with the following claims.

1. A dynamic tissue holding device for dynamically holding two tissue portions in contact with one another, the device comprising:

a biasing spring having a relatively low profile and comprising a substantially flat material; and

a band adapted for extending about the tissue portions to be held together, the band having a first end attached to a first attachment portion on the biasing spring and the band extending in a direction from the first end away from the spring, and a second end attached to a second attachment portion on the biasing spring and the band extending in a direction from the second end away from the spring;

the band establishing a path of tension along its length and extending linearly between the two ends of the band, in a configuration so that the band and the spring together form a loop, with the spring forming a part of the length of the loop;

said biasing spring comprising a first eyelet disposed in a center portion of the spring, for receiving the first end of the tensioning band, and a second eyelet disposed on an opposing side of the center portion of the spring, for receiving the second end of the tensioning band, wherein at least approximately four-fifths of the spring is disposed on either one side or the other of the first and second eyelets;

wherein more than one-half of the biasing spring is disposed outside of said path of tension when the dynamic tissue holding device is in place and holding the two tissue portions together.

2. The dynamic tissue holding device as recited in claim **1**, wherein at least approximately four-fifths of the biasing spring is disposed outside of said path of tension.

3. The dynamic tissue holding device as recited in claim **1**, wherein the height of said biasing spring is less than 2 mm.

4. The dynamic tissue holding device as recited in claim **1**, wherein the biasing spring is formed to have a generally parabolic profile.

5. The dynamic tissue holding device as recited in claim **1**, wherein the band comprises a braided band.

6. The dynamic tissue holding device as recited in claim **1**, wherein the band comprises a cable.

7. (canceled)

8. The dynamic tissue holding device as recited in claim **1**, wherein approximately two-fifths of the spring is disposed on one side of the first and second eyelets and approximately two-fifths of the spring is disposed on the other side of the first and second eyelets.

9. The dynamic tissue holding device as recited in claim **1**, wherein the space efficiency of the biasing spring is at least or about 50%.

10. The dynamic tissue holding device as recited in claim **1**, wherein the space efficiency of the biasing spring is at least or about 57%.

11. (canceled)

12. The dynamic tissue holding device as recited in claim **1**, wherein the aspect ratio of the device is less than or equal to approximately 0.50.

13. The dynamic tissue holding device as recited in claim **12**, wherein the aspect ratio of the device is approximately 0.10.

14. A dynamic tissue holding device for dynamically holding two tissue portions in contact with one another, the device comprising:

a biasing spring comprised of a substantially flat material; and

a band adapted for extending about the tissue portions to be held together, the band having a first end attached to a first attachment portion on the biasing spring and the band extending in a direction from the first end away from the spring, and a second end attached to a second attachment portion on the biasing spring and the band extending in a direction from the second end away from the spring;

the band establishing a path of tension along its length and extending linearly between the two ends of the band, in a configuration so that the band and the spring together form a loop, with the spring forming a part of the length of the loop;

wherein said biasing spring comprises a first eyelet disposed in a center portion of the spring, for receiving the first end of the tensioning band, and a second eyelet disposed on an opposing side of the center portion of the spring, for receiving the second end of the tensioning band, wherein at least approximately four-fifths of the spring is disposed on either one side or the other of the first and second eyelets;

and further wherein the aspect ratio of the device is less than or equal to approximately 0.50.

15. The dynamic tissue holding device as recited in claim **14**, wherein the aspect ratio of the device is approximately 0.10.

16. The dynamic tissue holding device as recited in claim **14**, wherein the biasing spring is formed to have a generally parabolic profile.

17. The dynamic tissue holding device as recited in claim **14**, wherein the height of said biasing spring is less than about 2 mm.

18. (canceled)

19. The dynamic tissue holding device as recited in Claim **14**, wherein approximately two-fifths of the spring is disposed on one side of the first and second eyelets and approximately two-fifths of the spring is disposed on the other side of the first and second eyelets.

20. The dynamic tissue holding device as recited in claim **14**, wherein the space efficiency of the biasing spring is at least about 50%.

21. (canceled)

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