

**COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK
OFFICE**

Application No. : 17/213,251 Confirmation No.: 2988
Applicant : Aortic Innovations, LLC
First Named Inventor : Ali Shahriari
Filing Date : March 26, 2021
TC/A.U. : 3774
Examiner : Shipmon, Tiffany
Docket No. : 426/2/22 UTIL
Customer No. : 175373

Title of Invention: TRANSCATHETER VALVE REPAIR HAVING IMPROVED
PARAVALVULAR SEAL

Via EFS-Web

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CONTINUED EXAMINATION

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 5 of this paper.

Amendments to the Claims:

The claims are amended as follows and will replace all previous versions and listings of claims:

Listing of Claims:

Claims 1-10 (Canceled)

11. (Currently Amended) An endovascularly deployed heart valve assembly comprising:
- ~~an inner frame comprising a non-porous~~ a graft covering ~~housing a~~ for engaging prosthetic heart valve leaflets, wherein the graft covering extends around the prosthetic heart valve leaflets for providing sealing ~~thereto~~ the heart valve;
 - an outer frame formed from a metallic material and defining ~~a gridded~~ an open cell configuration and having an inflow end portion and an outflow end portion, and being secured to the graft covering ~~by stitching~~; and
 - a sealing material positioned externally to the outer frame for providing sealing between the outer frame and a patient's anatomical wall of the aorta to prevent paravalvular leaks,
- wherein the sealing material begins at the inflow end portion of the outer frame and extends over at least two rows of cells formed in the ~~gridded~~ open cell configuration of the outer frame,
- wherein the sealing material includes a plurality of non-metallic radially outwardly extending fibers that extend outwardly of the outer frame,[[;]]
- wherein the fibers are arcuate,
- wherein the fibers are in contact with the outer frame along a height of the sealing material,
- wherein the fibers are spaced-apart to define spacings in a circumferentially extending direction and an axially extending direction along the outer surface of the frame,
- wherein the spacings extend radially through a thickness of the sealing material beginning at an outermost portion of the fibers and extending to the frame,
- wherein the heart valve assembly has a radially compressed orientation and a radially expanded orientation,

wherein the sealing material is configured for being pressed against native aortic leaflets of the patient and compressing in response thereto, wherein the pressing against the native aortic leaflets forms a seal against the native valve leaflets and the frame by compression of the fibers into the spacings,

wherein the heart valve assembly is configured for being delivered endovascularly through a femoral artery of a patient.

12. (Currently Amended) The endovascularly deployed heart valve assembly of claim 11, wherein the ~~plurality of radially extending~~ fibers are collagen fibers.

13. (Currently Amended) The endovascularly deployed heart valve assembly of claim 11, wherein open cells formed in the ~~gridded~~ open cell configuration are of a same shape.

14. (Canceled)

15. (Previously Presented) The endovascularly deployed heart valve assembly of claim 11, wherein the graft covering, prosthetic leaflets, and the sealing material are radially overlapping.

16. (Currently Amended) The endovascularly deployed heart valve assembly of claim 11, further comprising a second plurality of fibers, the second plurality of fibers being spaced-radially inwardly of the plurality of ~~non-metallic radially extending~~ fibers ~~that extend outwardly of the outer frame,~~

wherein, expansion of the ~~inner frame~~ graft covering closes a gap between the ~~inner frame~~ graft covering and the second plurality of fibers to thereby create a seal therebetween.

Claims 17-19 (Canceled)

20. (Currently Amended) The endovascularly deployed heart valve assembly of claim 11, wherein the ~~radially extending~~ fibers extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly.

21. (Currently Amended) The endovascularly deployed heart valve assembly of claim 11, wherein the graft covering ~~of the inner frame~~ extends to the inflow end portion of the outer frame, wherein, stitching extending between the graft covering ~~of the inner frame~~ and through the outer frame secures the graft covering to the inflow end portion of the outer frame.

22. (Currently Amended) The valve assembly of claim 11, wherein an end of the most proximal apices of the outer frame are uncovered by sealing material and the graft covering ~~of the inner frame~~,

wherein the end of the most proximal apices of the outer frame extends more proximally than a proximal end of the sealing material.

Claims 23-25 (Canceled)

REMARKS

This is in response to the Office Action dated November 2, 2021, and the Notice of Appeal filed on April 4, 2022.

Certain rejections under 35 USC 112 were made to claim 25. Appropriate correction has been provided.

The claims primarily stand rejected under 35 USC 103(a) as being unpatentable over Spenser (USPN 7,510,575) in view of Dehdashtian (WO 2006/005015) and further in view of Ketharanathan (US Publication No. 2004/0030407).

While not used as a reference in the November 2, 2021 Office Action, Levi is of record in related matters and will be discussed as well herein for completeness.

THE AMENDED CLAIMS RECITE AN IMPROVEMENT IN SEAL STRUCTURE THAT ALLOWS FOR AN OUTER SEAL WITHOUT SIGNIFICANTLY IMPACTING CRIMP PROFILE

Applicant has amended the claims to recite that the fibers are spaced-apart to define spacings in a circumferentially extending and axially extending direction before compression of the fibers in response to radial expansion of the valve assembly.

Amended claim 11 is presented below for reference:

11. *An endovascularly deployed heart valve assembly comprising:*
~~*an inner frame comprising a non-porous*~~ *a graft covering housing a for engaging*
prosthetic heart valve leaflets, wherein the graft covering extends around the prosthetic heart
valve leaflets for providing sealing thereto the heart valve;
an outer frame formed from a metallic material and defining a gridded an open cell
configuration and having an inflow end portion and an outflow end portion, and being secured
to the graft covering by stitching; and
a sealing material positioned externally to the outer frame for providing sealing between
the outer frame and a patient's anatomical wall of the aorta to prevent paravalvular leaks,
wherein the sealing material begins at the inflow end portion of the outer frame and
extends over at least two rows of cells formed in the gridded open cell configuration of the outer
frame,
wherein the sealing material includes a plurality of non-metallic radially outwardly
extending fibers that extend outwardly of the outer frame.]]

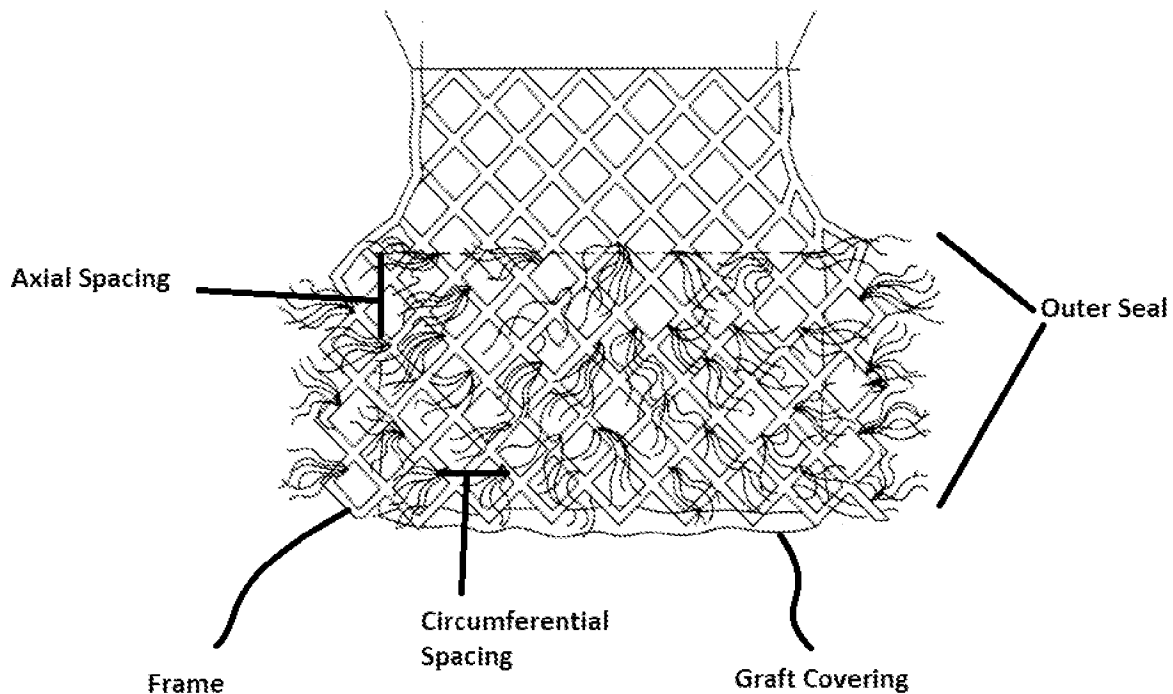
wherein the fibers are arcuate,
wherein the fibers are in contact with the outer frame along a height of the sealing material,
wherein the fibers are spaced-apart to define spacings in a circumferentially extending direction and an axially extending direction along the outer surface of the frame,
wherein the spacings extend radially through a thickness of the sealing material beginning at an outermost portion of the fibers and extending to the frame,
wherein the heart valve assembly has a radially compressed orientation and a radially expanded orientation,
wherein the sealing material is configured for being pressed against native aortic leaflets of the patient and compressing in response thereto, wherein the pressing against the native aortic leaflets forms a seal against the native valve leaflets and the frame by compression of the fibers into the spacings,
wherein the heart valve assembly is configured for being delivered endovascularly through a femoral artery of a patient.

A clean version of claim 11 is presented below:

11. An endovascularly deployed heart valve assembly comprising:
a graft covering for engaging prosthetic heart valve leaflets, wherein the graft covering extends around the prosthetic heart valve leaflets for providing sealing thereto;
an outer frame formed from a metallic material and defining an open cell configuration and having an inflow end portion and an outflow end portion, and being secured to the graft covering; and
a sealing material positioned externally to the outer frame for providing sealing between the outer frame and a patient's anatomical wall of the aorta to prevent paravalvular leaks,
wherein the sealing material begins at the inflow end portion of the outer frame and extends over at least two rows of cells formed in the open cell configuration of the outer frame,
wherein the sealing material includes a plurality of non-metallic outwardly extending fibers that extend outwardly of the outer frame,
wherein the fibers are arcuate,
wherein the fibers are in contact with the outer frame along a height of the sealing material,
wherein the fibers are spaced-apart to define spacings in a circumferentially extending direction and an axially extending direction along the outer surface of the frame,
wherein the spacings extend radially through a thickness of the sealing material beginning at an outermost portion of the fibers and extending to the frame,
wherein the heart valve assembly has a radially compressed orientation and a radially expanded orientation,
wherein the sealing material is configured for being pressed against native aortic leaflets of the patient and compressing in response thereto, wherein the pressing against the native aortic leaflets forms a seal against the native valve leaflets and the frame by compression of the fibers into the spacings,

wherein the heart valve assembly is configured for being delivered endovascularly through a femoral artery of a patient.

These features are well illustrated in annotated FIG. 20:



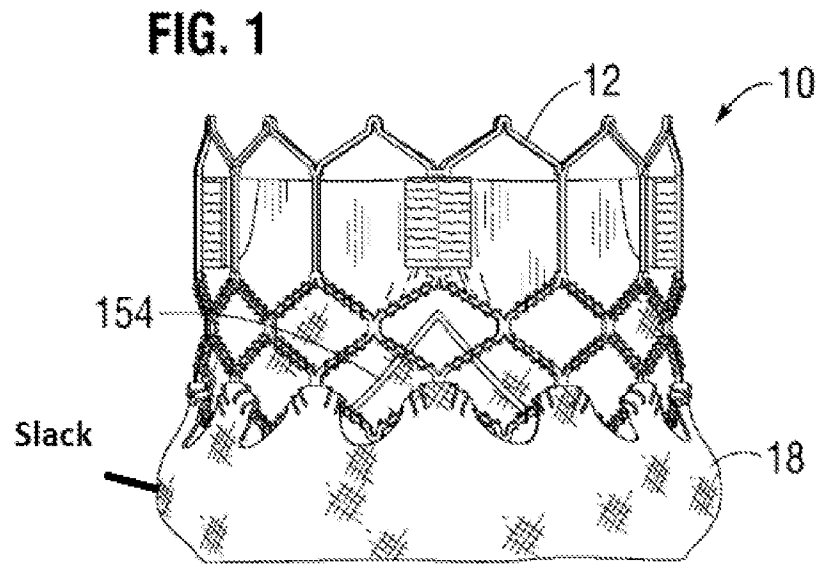
The benefit to this design is by using a lesser number of fibers than are found in, for example, a graft or sleeve¹, there is not so much fiber structure (due to the spaced-apart arrangement) that the fibers still maintain an overall small profile, which helps the device reach a crimp profile suitable for transfemoral delivery as recited by the claims. The axial and circumferential spacing between fibers allows the frame (and thus the spacing between fibers) to elongate during crimping while not experiencing bunching of the seal to maintain an overall small profile that is suitable for endovascular delivery. However, upon compression, the spacing between the fibers decreases and aids in thrombosis to then create the outer seal against the native leaflets that addresses PVL.

¹ See Dehdashtian, Levi, and NPL of Walther

Proposed seals for an outside of a transcatheter valve before Applicant's claimed invention were traditionally blood impermeable cardiovascular cloths or grafts. These grafts could have different finishes including a fibrous finish, however, this seal would have a stiff structure and design which leads to folding of the cloth in the crimping process. Due to the attachment of the graft to the stent frame, the graft impedes efficient elongation of the TAVR assembly because the outer seal cloth cannot stretch and thereby impedes effective elongation.

Because crimping the TAVR is an early procedural step of being able to deliver a low profile valve, the claimed invention of spacing within the fibers allows for elongation of the outer seal when crimping. Advantageously, the fibers and spacing provide overall low bulk and the fibers can be pressed within the spaces in between them without the folds/bunching seen with conventional cloth seals such as Bessler, Levi, and the NPL of Russell. The stretchability of the fibrous layers due to the spaces between the fibers also allows relatively uninhibited elongation of the outer metallic frame which enables a significantly reduced TAVR profile that avoids the aforementioned bunching. The crimped TAVR inside the deployment catheter is delivered to the deployment location and the formation of a seal is not critical until the TAVR is out of its delivery catheter and the seal is compressed against the native leaflets. At this critical stage, the expansion of the metallic frame presses the fibers against the native tissue and then, in operation, the compression of the fibers will form a seal. .

Various strategies have been employed to address this increase in crimp profile caused by addition of an outer seal, however, each have had their own disadvantages. Levi, for example, required retrograde blood flow for the seal to operate and slack material in the outer seal as will be further discussed herein. The slack served a dual function of capturing retrograde blood flow and allowing elongation of the frame during crimping by not restricting the frame with a tightly held outer graft.



Levi though disadvantageously added *additional* material to their outer seal by having slack, the complete opposite of the generally preferred design parameter in TAVR design of reducing the amount of material.

As a further example, US Patent No. 8,795,357 to Yohanan allowed the outer seal to slide relative to the frame in order to keep the sealing device from significantly increasing the valve crimp profile.

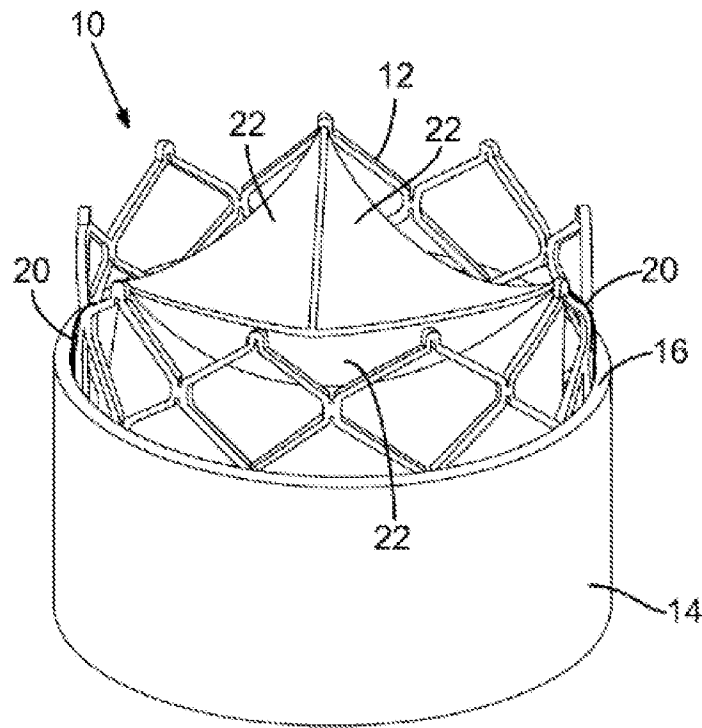


FIG. 3

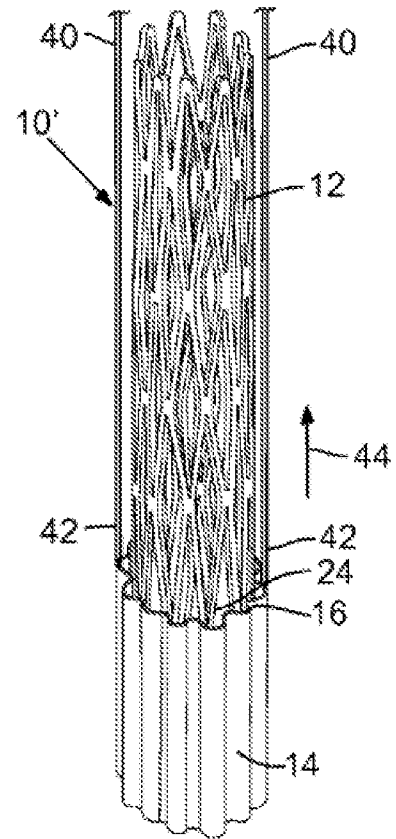


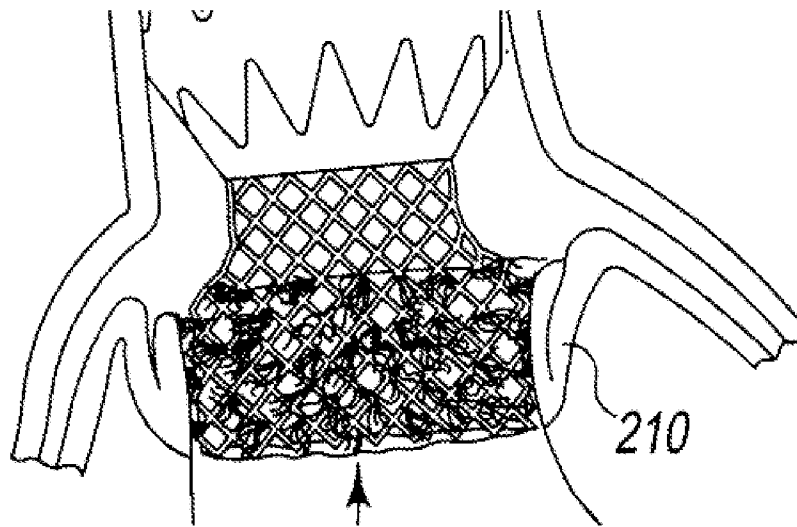
FIG. 4

Each of these solutions were aimed at the same problem, which was finding a manner in which to create an effective outer seal that did not restrict elongation of the stent during crimping and maintained a small enough crimp profile to be used transfemorally to treat the largest segment of patients in the safest manner.

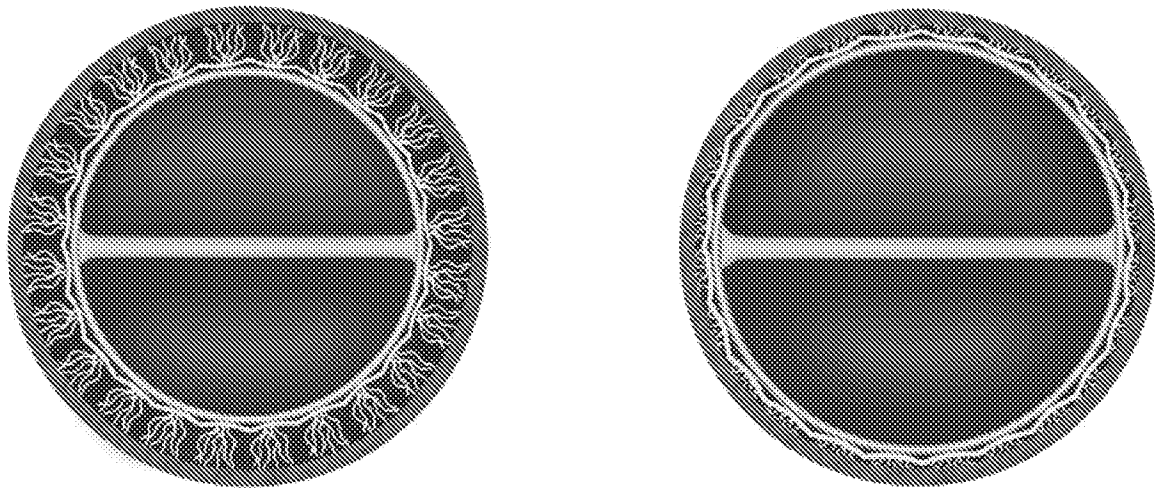
Using a seal formed of fibers with spaces between the fibers on the external surface of the stent frame as claimed and illustrated throughout the figures avoids the folding associated with traditional cloths during crimping (the fibers can be packed into the spaces in between each other in crimping) while maintaining an overall small profile. Additionally, the spaces between the

fibers allow stretchability of the fiber structure which assists the elongation of the valve assembly in crimping. Thus, this construction of the outer fiber seal helps the device reach a crimp profile suitable for transfemoral delivery as recited by the claims.

In operation after implantation within the aortic valve of a patient, the fibers allow a large surface area for contact with blood and the compression of the fibers by expansion of the stent frame which then minimizes and closes the spaces between the fibers to create a seal against the native leaflets and the stent frame. This is well-illustrated in FIG. 22.



Applicant provides these additional images to show the benefit of this construction. As illustrated in the cross-sectional view, the fibers extend outwardly but maintain some spacing and gaps therebetween. Upon compression, the size of the spacing and gaps is reduced thus creating a seal.



**THE PRIOR ART OF RECORD THAT TEACHES AN OUTER SEAL TEACHES AN
OUTER SEAL THAT DOESN'T HAVE SPACING BETWEEN FIBERS**

Dehdashtian teaches a cloth that is “in the form of a sleeve.” The seal is further described as a “compressible material” that “expands after deployment at a treatment site.” (see [0145]). This is the direct opposite of Applicant’s claimed invention where the fibers are compressed upon deployment. This is due to the difference in construction of Applicant’s claimed invention, versus the cloth sleeve in Dehdashtian.

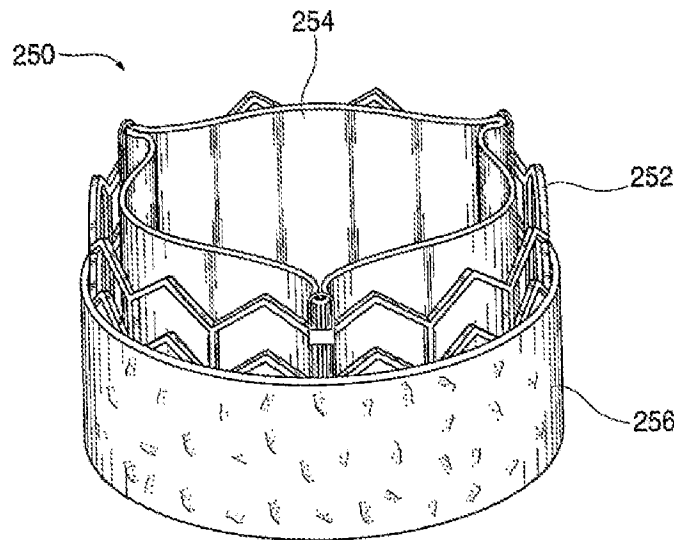
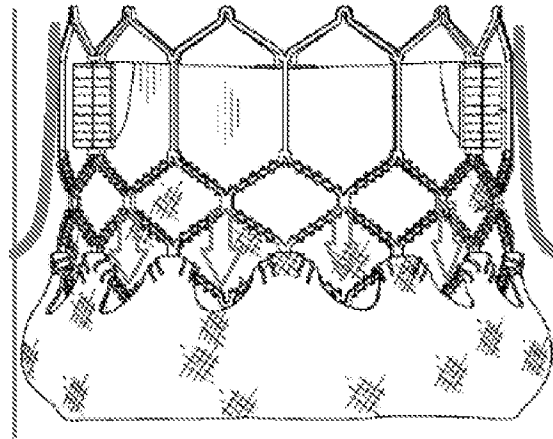


FIG. 22

In separate embodiments in Dehdashtian, a “sponge” structure is disclosed. (see for example [0142]). However, this sponge structure does not disclose spaced-apart fibers as claimed. Additionally, Dehdashtian discloses that the sleeve can be a PET material from 1.0 to 5.0 mm thick. Additionally, Dehdashtian discloses small fibers extending from the surface of the material. In other words, Dehdashtian teaches a surface from which fibers can extend, however, Applicant submits such surface would be a flat, smooth type surface generally associated with a graft covering, and not one formed from fibers with spacings therebetween. To the extent that the seal is PET, it is likely tightly woven PET as used in cardiovascular applications and not spaced-apart fibers. While all fibers have some degree of being spaced-apart, the construction from Applicant’s claimed invention clearly requires some level more spacing. Advantageously, this design allows for a construction where there is enough fiber density to form a seal upon compression.

Furthermore, Levi functions by billowing of the skirt when retrograde (i.e. downward) blood flow passes through openings formed in an upper surface of the outer skirt. The billowing of the skirt presses the outer surface of the skirt against the aortic annulus. Consider it similar to blowing up a balloon.



(Annotations provided by Applicant)

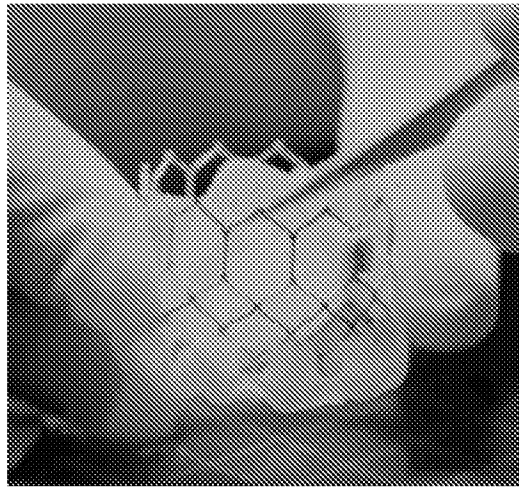
Levi requires a loosely fit outer seal to accomplish both this billowing concept and allowing slack in the outer seal for frame elongation during crimping and subsequent foreshortening during expansion (paragraph [0085] of Levi; *In another advantageous feature, the slack between the lower and upper edges of the outer skirt 18 allows the frame 12 to elongate axially during crimping without any resistance from the outer skirt and the outer skirt does not substantially affect the outer diameter of the prosthetic valve in the crimped condition*).

Levi themselves state:

Additionally and/or alternatively, due to the openings along the upper edges of the skirts, retrograde blood can flow into the openings and further open or radially expand the outer skirts with rising back pressure (e.g., diastolic pressure when implanted at the aortic position), similar to the action of a sail, to enhance the sealing of the skirts against the surrounding tissue².

An image of the commercial embodiment of Levi shows this well:

² US Patent No. 10,1279,043, which does detail a multi-level sealing member having a plurality of seals in a later filing by Levi, where the seals generally appear the same as the seal in the Levi of record. This is a subsequent filing to the Levi of record.



Thus, Levi requires that the graft seal material billows outwardly in response to the retrograde blood flow, and the seal functions similar to an inverted umbrella. If the outer seal of Levi cannot billow outwardly due to spaces in the seal limiting the “catching” of retrograde blood flow, the seal cannot function as intended. The claim amendment that the fibers have spaces thus runs counter to the operability of Levi. There is no apparent modification by the USPTO in view of Levi where Levi’s billowing outer skirt is still utilized that could meet this limitation.

Furthermore, Applicant submits that Levi must have a non-porous outer graft in order to effectively capture the retrograde blood flow to cause the billowing of the outer skirt. Continuing with the umbrella analogy, the umbrella would not be able to function with spacings (i.e. holes) in the cover. Applicant’s claim amendment that the fibers are spaced-apart simply cannot be met by Levi because Levi’s intent doesn’t include a seal in contact with the outer frame along the rows (when deployed) and Levi must use a non-porous outer seal to capture the retrograde blood flow.

Levi does disclose that the spacing between fibers on the inner graft can be increased to facilitate elongation of the skirt in the axial direction, however, Levi discloses that this density can be about 15% to 30% less than a conventional PET skirt. This reduction in spacing on the inner

graft is hardly sufficient enough to create the claimed axial and circumferential spacings recited in the claims. Furthermore, the claimed spacings are directed towards the outer seal, not the inner graft and there is no teaching of outwardly extending fibers that compress into the spacings to create a seal.

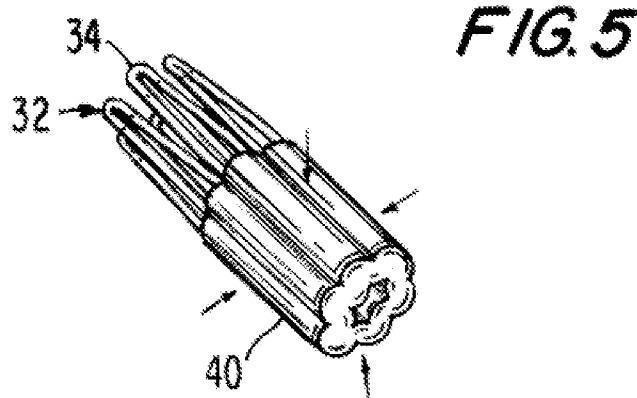
**THE COMBINATION OF LEVI-DEHDASHTIAN-RANKIN IS STILL NOT CAPABLE
OF MEETING THE CLAIMED LIMITATION OF DEPLOYED ENDOVASCULARLY
THROUGH THE FEMORAL ARTERY**

It is bedrock analysis that if the proposed combination from the USPTO is incapable of meeting the claim limitations (in this instance, endovascular deployment through the femoral artery), then the proposed combination is not proper for rejecting the claims under 35 USC 103. Catheter size is typically expressed in terms of French numbers, where each millimeter of catheter diameter equates to a 3F increase in French size. Thus, an 8.00 mm diameter catheter would be expressed as a 24F system. Spenser states that an 8.00 mm diameter catheter is the maximal for femoral access, and thus a 24F catheter would be the maximum as well.

As previously discussed, the inventors in Dehdashtian recognized a 24F catheter size at the maximal size. Levi also recognized the significance of crimp profile. Indeed, the background of Levi states:

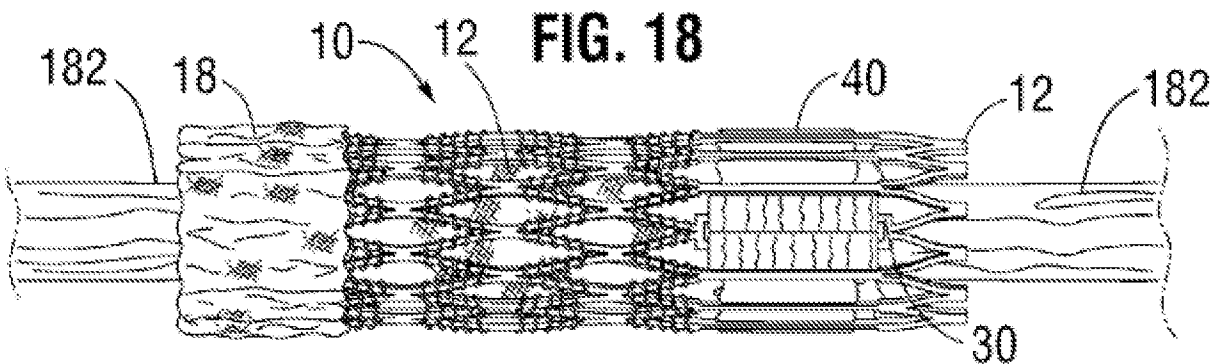
An important design parameter of a transcatheter heart valve is the diameter of the folded or crimped profile. The diameter of the crimped profile is important because it directly influences the physician's ability to advance the transcatheter heart valve through the femoral artery or vein. More particularly, a smaller profile allows for treatment of a wider population of patients, with enhanced safety.

As previously discussed, adding an outer seal to a valve structure is not trivial, and the results are not necessarily expected because of the aforementioned crimp profile concerns. Crimping of the valve necessarily creates “bunching” on the outside of the valve. This is well-illustrated in FIG. 5 of US Patent No. 5,855,601 to Bessler.



As illustrated, addition of an outer seal necessarily adds significantly to the crimp profile and may further restrict full crimping of the valve. This is even more pronounced with the proposed combination by the USPTO, where adding the outer “band” of Dehdashtian is likely to significantly add to crimped profile such that the crimped profile will exceed the “maximal size [of] 8 mm in diameter.”

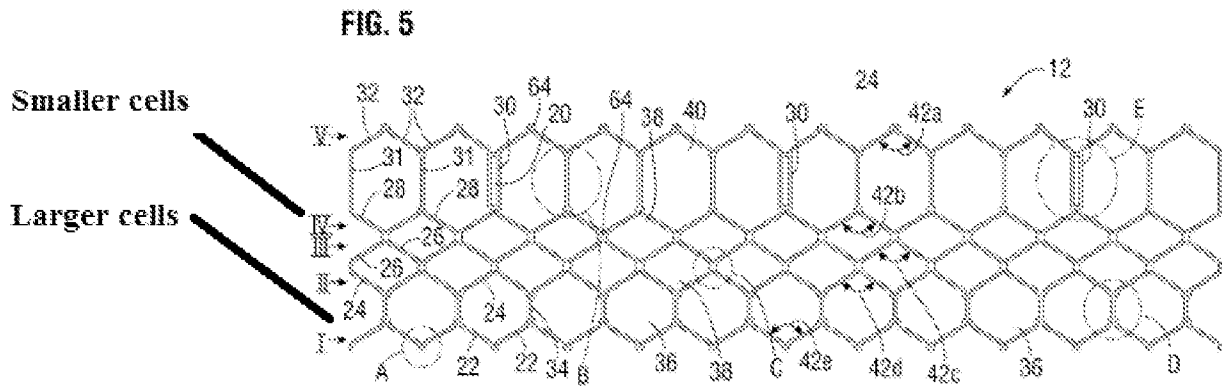
Levi understands this is an issue, as the bulging is shown in the outer seal 18 in FIG. 18 of Levi:



In order to try and reduce the overall crimp profile to accommodate for the bulging, Levi made certain design changes to accommodate the outer seal 18. Namely, Levi made the open cells or grids of the lower most row of the frame to be larger than the next row of cells, which allowed for a reduced crimp profile at the lower most row of the frame, which thus provided a reduced

crimp profile area (called “reduced diameter region 174” in Levi specification) against which the outer seal 18 could sit.

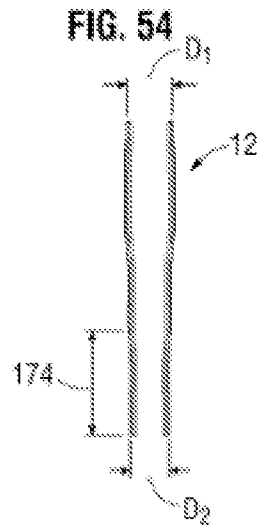
This is well illustrated in annotated FIG. 5 of Levi shown below:



And Levi discloses:

Also, as can be seen in FIG. 5, the openings 36 of the lowermost row of openings in the frame are relatively larger than the openings 38 of the two intermediate rows of openings. As shown in FIG. 54, this allows the frame, when crimped, to assume an overall tapered shape that tapers from a maximum diameter D_1 at the outflow end of the valve to a minimum diameter D_2 at the inflow end of the valve. When crimped, the frame 12 has a reduced diameter region extending along a portion of the frame adjacent the inflow end of the frame, indicated by reference number 174, that generally corresponds to the region of the frame covered by the outer skirt 18. The diameter of region 174 is reduced compared to the diameter of the upper portion of the frame (which is not covered by the outer skirt) such that the outer skirt 18 does not increase the overall crimp profile of the valve. When the valve is deployed, the frame can expand to the cylindrical shape shown in FIG. 4. In one example, the frame of a 26-mm valve, when crimped, had a diameter D_1 of 14 French at the outflow end of the valve and a diameter D_2 of 12 French at the inflow end of the valve.

This “reduced diameter region” 174 is also well illustrated in FIG. 54 of Levi, where a crimped valve cross-section is shown:



As Levi discloses:

Due to the tapered shape of the frame 12 in the mounted state, even with the additional thickness of the outer skirt 18 positioned around the inflow end portion 174 of the frame 12 the overall outer diameter of the inflow end portion of the valve 10 can be about equal to, or less than, the overall outer diameter of the outflow end portion of the valve.

Levi provides significant description on this aspect, and further teaches the dimensions of diameter D1 and D2 as shown in FIG. 54:

In one example, the frame of a 26-mm valve, when crimped, had a diameter D₁ of 14 French at the outflow end of the valve and a diameter D₂ of 12 French at the inflow end of the valve.

Thus it follows that Levi, in order to accomplish a 14F crimp profile at the main portion of the frame, was able to provide a reduced diameter portion of a 12F crimp profile. In other words, the outer diameter of the outer frame as measured at D2 was about 4.67 mm and the outer diameters of the outer frame at D1, the reduced diameter portion was about 4.0 mm. Thus, an outer seal having a crimped profile that adds about 0.67 mm total thickness in the crimped profile would accomplish Levi's stated purpose of "*the outer skirt 18 does not increase the overall crimp profile of the valve.*"

Since the seal wraps around the perimeter of the outer frame, a maximum crimped seal profile would allow for a crimped profile thickness of the outer band of about 0.33 mm.

Dehdashtian discloses an outer band/sleeve with a thickness that ranges from 1 mm to 5 mm. Thus, Dehdashtian expressly teaches a thickness of the outer skirt that is greater than what Levi teaches is allowable. Dehdashtian does, however, teach the outer skirt is compressible, but provides no guidance on the compressibility of the outer skirt. Furthermore, if one were to assume that the skirt of Dehdashtian could be manufactured in thickness smaller than 1.00 mm, down to an example of 0.33 mm needed to fit within the reduced diameter region (which ignores the bunching issue), it is not clear how Dehdashtian would then provide for a “compressible material” as disclosed since compression requires some level of thickness and a 0.33 mm seal may not provide for compressibility. Dehdashtian does not appear to disclose spacing between fibers in an axial and circumferential direction that provide for the ability to reduce seal profile in the crimped orientation, yet provide sufficient surface area to effectuate sealing.

Applicant can show that the proposed combination cannot meet the claim limitations as the addition of the minimal size thickness outer band as stated in Dehdashtian of 1.00 mm would result in a crimped profile that would not fit within a catheter with a maximum outer diameter of 8.00 mm.

This is well described with reference to simple calculations.

A catheter of 4.0 mm in outer diameter as disclosed by the reduced thickness portion of Levi, necessarily has a crimped cross-area of:

$$A = \pi * (2.0 \text{ mm})^2 = 12.56 \text{ mm}^2$$

Addition of a 1.0 mm outer seal to a 25 mm valve as disclosed by Levi and Dehdashtian potentially creates an increase in cross-area of:

$$A = \pi * (13.5 \text{ mm})^2 - (12.5 \text{ mm})^2 = 81.64 \text{ mm}^2$$

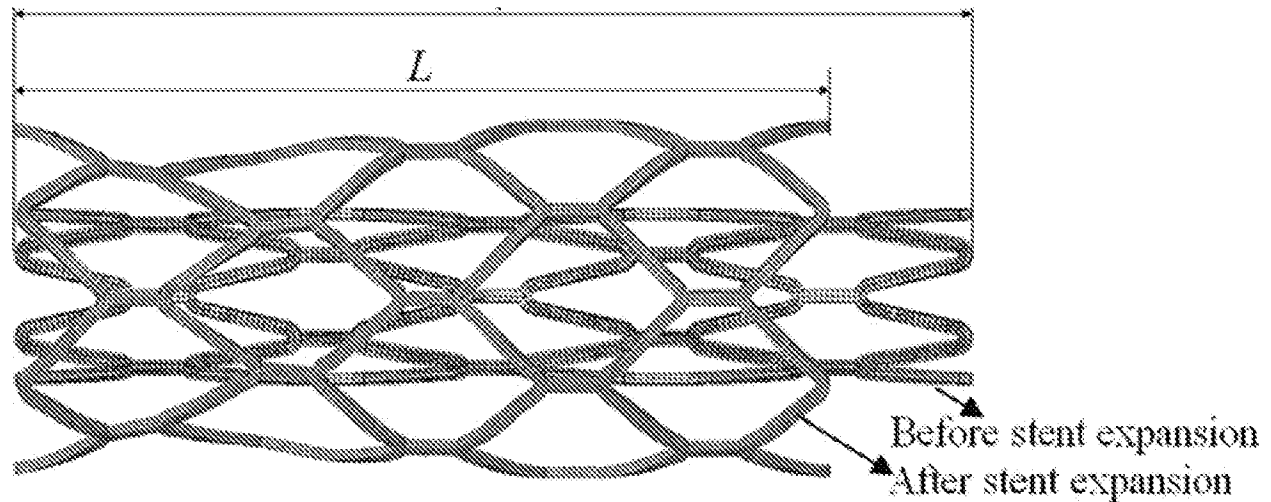
Dehdashtian does teach that the band is a “layer of compressible material 256,” so some amount of compression is expected. However, nowhere does Dehdashtian teach that the layer is compressible by over 600 percent to be able to go from a non-compressed area size of 81.64 mm² to a crimped area size of 12.56 mm².

Applicant submits that a much larger catheter would be required in order to accommodate the proposed combination by the USPTO. And the much larger catheter would not be able to meet the claim limitation of the “heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient.” Furthermore, adding bulk to the prosthetic valve would be considered undesirable to one of ordinary skill.

The band of Dehdashtian teaches that the band may take “the form of a sleeve.” Thus, it follows that Dehdashtian teaches the band is tightly held against the frame similar to a “sleeve.” This is also illustrated in the non-patent literature of Walther. Levi, however, teaches that the outer seal should not be tightly held against the frame. In fact, Levi expressly requires excess slack in the outer seal:

As can be seen in FIGS. 1, 3 and 43, the outer skirt 18 is secured to the frame 12 such that when the frame is in its expanded state, there is excess material or slack between the outer skirt's lower and upper edges 160, 162 that does not lie flat against the outer surface of the frame 12. In other words, the outer skirt is configured with excess material which causes the outer skirt to bulge outwardly as the frame foreshortens (i.e., shortens in length) during radial expansion. Accordingly, when the valve 10 is deployed within the body, the excess material of the outer skirt 18 can fill in gaps between the frame 12 and the surrounding native annulus to assist in forming a good fluid-tight seal between the valve and the native annulus. The outer skirt 18 therefore cooperates with the inner skirt 16 to avoid perivalvular leakage after implantation of the valve 10. In another advantageous feature, the slack between the lower and upper edges of the outer skirt 18 allows the frame 12 to elongate axially during crimping without any resistance from the outer skirt and the outer skirt does not substantially affect the outer diameter of the prosthetic valve in the crimped condition.

It is known that most stents foreshorten during expansion. What this means is that the stent elongates as it becomes more narrow (i.e. crimped) and shortens as it becomes wider (i.e. expanded). This is well-illustrated with the following image:



The foreshortening of the stent can be restricted by a tightly held outer seal. Dehdashtian though was not significantly concerned with foreshortening because the rigid commissure supports of Dehdashtian restricted the degree of foreshortening. This is illustrated with annotated FIG. 22 of Dehdashtian:

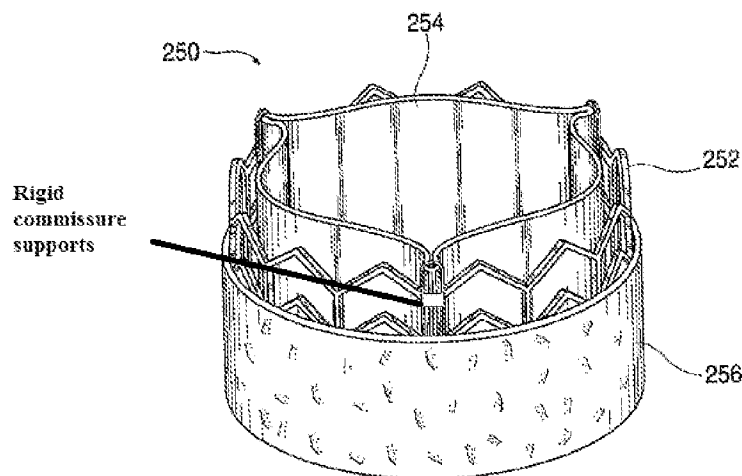


FIG. 22

However, Levi appears to undergo a significant amount of foreshortening (which helps to reduce crimp profile) and addresses the restriction of the outer seal by providing for “excess material” of the outer skirt.

If one were to stitch the seal of Dehdashtian to the outer frame of Levi at a top portion of the seal (just as shown in FIG. 1 of Levi), nowhere in the combination proposed by the USPTO is it disclosed how Levi could foreshorten without the outer seal of Dehdashtian restricting the foreshortening. If the outer seal of Dehdashtian restricts foreshortening, then the valve is not able to crimp to a fully crimped position and thus endovascular delivery through the femoral artery is unlikely if not impossible.

Applicant’s invention accomplishes this result by having the low density fiber construction where there is spacings in the axial and circumferential direction. This allows for sufficient elongation of the outer seal to allow for any foreshortening if it were to occur in Applicant’s valve design. This is well illustrated in FIG. 11 of Applicant’s application:

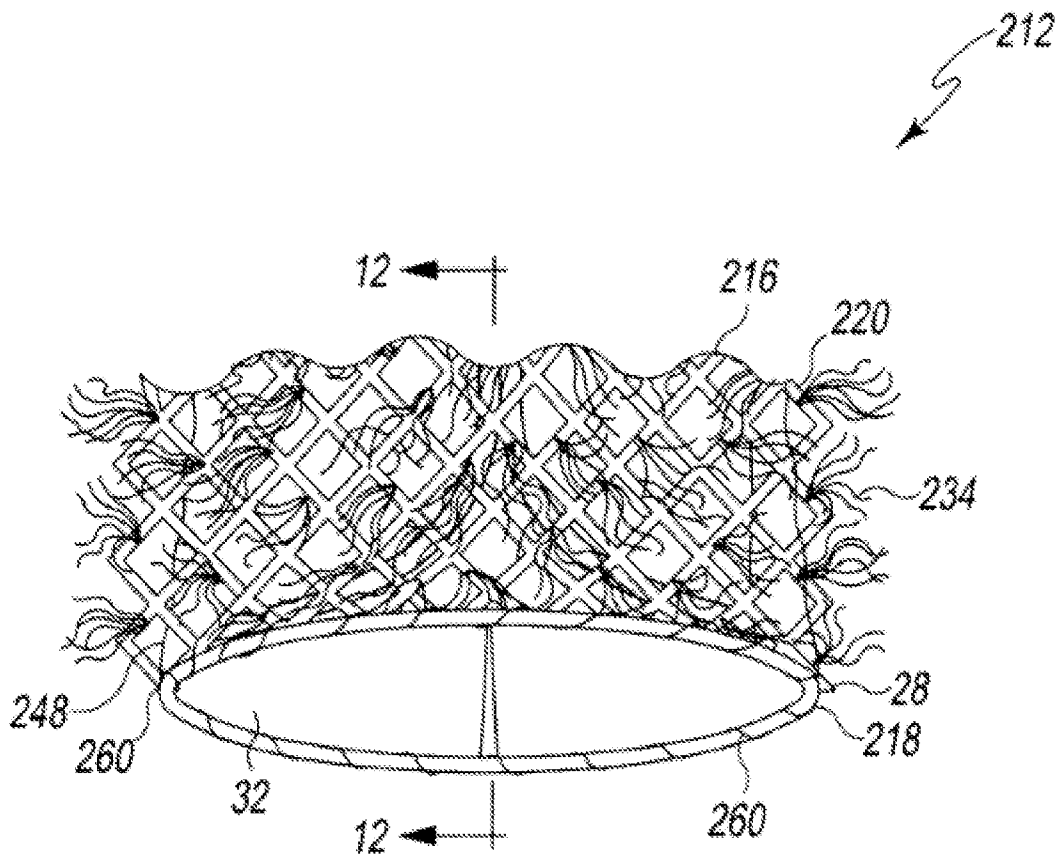


Fig. 11

There is no indication that modified Levi in view of Dehdashtian is capable of being further modified by Rankin to arrive at a device capable of delivery through the femoral artery.

The USPTO indicates in paragraph 28 that “The prior art discloses heart valves that are fully capable of collapsing.” Applicant agrees with this. However, Applicant does not agree that the proposed combined valves are capable of collapsing down to a 24F size, i.e. 8 mm, a requirement acknowledged by Dehdashtian’s coinventors in Spenser, USPN 7,510,575. The USPTO takes the position in paragraph 28 that “Additionally, it should be noted that the devices of Modified Levi et al. in view of Dehdashtian et al. can be collapsed and therefore it can be delivered through the femoral artery.”

Applicant does not agree with this characterization. As noted, the maximal size for femoral delivery appears to be a 24F catheter. As Applicant has shown previously, the uncompressed seal of Dehdashtian occupies more volume than a 24F catheter provides, and nowhere in Dehdashtian does it disclose that the seal is 600% compressible. This calculation also entirely ignores the size of the frame itself. Put simply, without a 600% compression of the Dehdashtian seal, even a fully collapsed to absolutely no thickness metallic frame would still not fit within a 24F catheter.

Furthermore, no part of the embodiment of FIG. 22 of Dehdashtian teaches the limitations of “deployed endovascularly through a femoral artery of the patient.” The USPTO seems to acknowledge this. It is just as likely that Dehdashtian offers a surgically deployed valve due to the large profile, or a mitral valve, where the access pathways are much larger. The reason for this is simple; Dehdashtian discloses that the outer cloth is 1.0 mm thick as a minimum. As Applicant has previously shown in the December 14 remarks, addition of a 1.0 mm thick cloth before compression on a 25 mm valve would add 81.64 mm² to the valve profile before compression of the cloth. As shown, this increase in area is, in fact, larger than a 24F catheter by itself, without even allowing for space for the stent frame and prosthetic leaflets. Such a combination would require a 600% compression of the outer seal profile of Dehdashtian to accommodate a 24F size. (See arguments of December 14). Applicant submits that it is just not possible to deploy Dehdashtian endovascularly through the femoral artery. Dehdashtian was generally reduced to practice in the already provided NPL of Walther-Dehdashtian, and Walther-Dehdashtian managed only a 33F catheter size, which the prior art indicates is incapable of TF delivery.

If one were to assume a construction of the Levi outer graft, with fibers extending therefrom as the USPTO has proposed in the Office Action mailed April 19, 2022 in co-pending application no. 16/941,117, this construction would still not arrive at the claimed invention because Levi must have a non-porous outer seal to function to capture the retrograde blood flow. Levi would thus not have fibers with spacings in a circumferentially extending and axially extending direction.

Similarly, the combination proffered by the USPTO of Spenser in view of Dehdashtian suffers from the same crimp profile that has just been discussed. The outer seal of Dehdashtian

at its smallest thickness is too large without compression to fit within an 8F catheter, and this entirely ignores the thickness of the frame itself. Dehdashtian does teach that the band is a “layer of compressible material 256,” so some amount of compression is expected. However, nowhere does Dehdashtian teach this much compression.

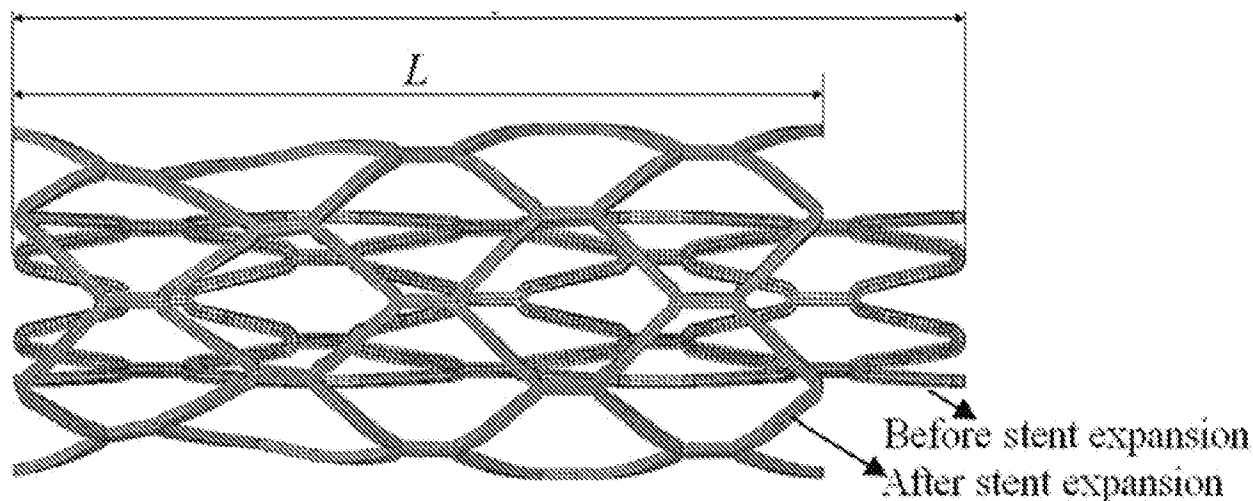
Applicant submits that a much larger catheter would be required in order to accommodate the proposed combination by the USPTO. And the much larger catheter would not be able to meet the claim limitation of the “heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient.”

**THE CLAIM AMENDMENTS AND LIMITATIONS COOPERATIVELY FORM A
TAVR WITH A LOW CRIMP PROFILE AND HIGH SURFACE AREA FOR SEALING**

The claim amendments of the fibers are spaced-apart to define spacings in a circumferentially extending direction and an axially extending direction AND in wherein the heart valve assembly is configured for being delivered endovascularly through a femoral artery of the patient are not just random limitations within a claim. In fact, the fibers being spaced-apart provides for an outer seal of low enough bulk density to allow compression of the frame to be able to treat transfemorally. As already discussed, this generally requires a 24 F crimp profile. And the use of fibers provides sufficient surface area to cause thrombosis of the blood to create a seal.

**ONE WOULD NOT LOOK TO MODIFY THE PRIOR ART OF RECORD TO
INCLUDE THE CLAIM LIMITATIONS ADDED HEREIN**

It is known that most stents foreshorten during expansion. What this means is that the stent elongates as it becomes more narrow (i.e. crimped) and shortens as it becomes wider (i.e. expanded). This is well-illustrated with the following image:



The foreshortening of the stent can be restricted by a tightly held outer seal. Dehdashtian though was not significantly concerned with foreshortening because the rigid commissure supports of Dehdashtian restricted the degree of foreshortening. This is illustrated with annotated FIG. 22 of Dehdashtian:

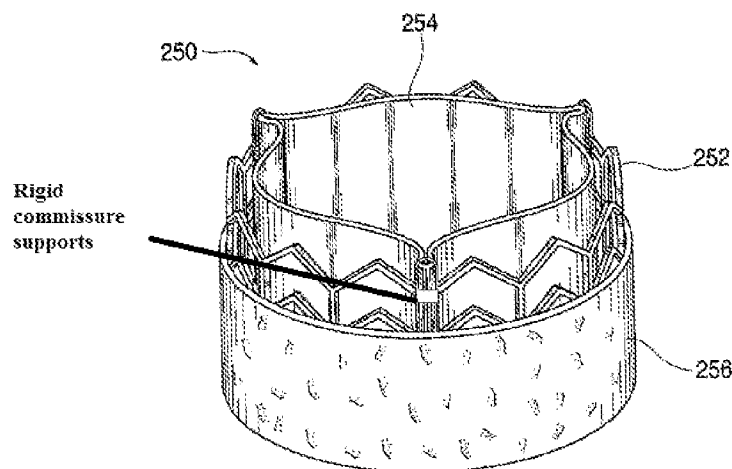


FIG. 22

Thus, to the extent that a seal structure even existed in the prior art that would meet the claim limitations of circumferentially extending rows of fibers that are spaced-apart from adjacent rows, Dehdashtian would not have necessarily looked to that type of construction for an outer seal since one of the advantages of the claimed outer seal is the ability for the outer seal to elongate axially, a characteristic that is largely not of concern with a valve frame having rigid

Appl. No: 17/213,251
Docket No: 426/2/22 UTIL
Amdt. dated: May 17, 2022

commissure supports. Additionally, Walther and Spenser utilize a similar frame structure with rigid commissure supports.

And finally, Levi, as discussed previously, needs a non-porous outer seal in order to function as intended, and the spaced-apart claimed arrangement would change the mode of operation of Levi.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any otherwise unpaid fees associated with the filing of this correspondence to Deposit Account No. **50-6191**.

Respectfully submitted,

Date: May 17, 2022

/Justin R. Nifong/
Justin R. Nifong
Reg. No. 59,389

NK Patent Law
4917 Waters Edge Drive, Suite 275
Raleigh, NC 27606
Telephone: (919) 348-2194
Facsimile: (919) 882-8195

Customer No. 175373