Braiding Structure Stability and Section Treatment Evaluations of Braided Coronary Stents Made of Stainless Steel and Bio-Absorbable Polyvinyl Alcohol via a Braiding Technique

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Abstract: To simplify the manufacturing process of coronary stents, this study employs a braiding technique that uses metallic and polyvinyl alcohol (PVA) fibers to prepare the metallic and PVA coronary stents. 316L stainless steel (SS) fibers and PVA fibers are respectively made into single- and double-ply braids, during which the gear ratios of the take-up gear to the braid gear are changed to 50:50, 60:50, 70:50, 80:50, and 90:50. The braiding structure is then bonded and stabilized by using a PVA solution, after which stereomicroscope observation, scanning electron microscopic (SEM) observation, braiding angle analysis, and strut cover rate measurement are performed to test the SS and PVA coronary stents. The experimental results show that the braiding technique can prepare the SS and PVA braids with the required braiding structure. However, cutting causes the braiding structure of the SS braids to expand due to the properties of the SS fibers while the PVA braids are too soft to take the form of a hollow tube. Therefore, a PVA solution coating is applied to stabilize the structure in order to complete the preparation of the SS and PVA coronary stents. Braiding angle decreases when the tooth number on the take-up gear decreases; furthermore, the strut cover rate and fiber diameter and area have a positive correlation. This study successfully combines a braiding technique and PVA solution coating to create SS and PVA coronary stents that present a stable braiding structure after cutting.

Keywords: Braiding, Bond, Polyvinyl alcohol (PVA), Stainless steel fiber, Coronary stent

Introduction

Coronary stents are developed due to coronary artery disease (CAD) that is caused by atherosclerosis [1]. Coronary stents, i.e., bare metal stents (BMS) are developed and commonly used for CAD treatment [2], and it is hoped not to permanently use the stents inside the human’s body, thereby decreasing the possibility of restenosis caused by BMS [3-5]. Coronary stents are most commonly produced by laser engraving [6] while bioabsorbable coronary stents (BCS) are prepared by melting and extruding [7]. BSM and BCS have a complex design and require laser cutting; moreover, BMS also undergo vacuum annealing and electro polishing [7,8]. These multiple steps make the manufacturing process complex. Moreover, applying manual fabrication results in poor reproducibility and a limited yield, which also increase the production cost. To simplify the preparation process with an automatic production, a braiding technique is used for the research and design of coronary stents [9,10]. The advantages of a braiding technique include the yield of reticular, tubular braids formed by fibers and secured by the braiding angles, the ease of processing, and feasibility of combining metallic fibers and polymer fibers. During the braiding process, braiding angle is the major parameter for braiding the stents. According to the previous study conducted by Kim et al. [9], the higher the braiding gear, the greater the belling behavior and compressive properties the stents have. Braids have a wide application range in the biomedical material field, such as artificial ligaments [11,12], bone scaffold [13], and stent [9,10], all of which are products made by the combination of fibers and a braiding technique.

316L SS fiber is commonly used in the production of coronary stents [14-16]. Because stainless steel fiber has strength and flexibility, and it is suitable for use in coronary stents. Although PVA materials have been used for the preparation of stents [17,18], there are not available studies using PVA fibers to prepare the strut for the coronary stents. In this study, 316 SS fibers and PVA fibers are respectively made into reticular, tubular SS and PVA braids via the braiding technique that is programmed by this study in order to be used for a continuous process. Although SS and PVA braids can be continuously processed, the braids expand and sharp points occur on the sections after cutting. Therefore, the coating of a PVA solution is applied to obtain a stable braiding structure and reduce sharp points, thus forming the SS and PVA coronary stents.

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Experimental

Materials
316L stainless steel fiber (Yuen Neng Co., Ltd.) has a diameter of 0.12 mm. PVA fiber (Asiatic Fiber Corporation, Taiwan, R.O.C.) has a fineness of 75 denier (D)/25 f and a diameter of 0.05 mm. PVA powders (Sigma-Aldrich Co. LLC., USA) have a Mw 89,000-98,000 and are 99+% hydrolyzed.

Preparation of SS and PVA Braids
A doubler (Shang Yang Co. Ltd., Taiwan, R.O.C.) combines two plies of 316L SS fibers or PVA fibers to form single-ply SS or PVA fibers. The double-ply or single-ply fibers are separately collected on a carrier that is fixed on a 16-spindle braid machine (Nan Hsing Machinery & Co., Ltd., Taiwan, R.O.C.) for the following braiding process. Figure 1 indicates that the braiding center is a 3-mm-diameter stainless steel bar, surrounding which the plied yarns are braided with gear ratios of the take-up gear to the braid gear of 50:50, 60:50, 70:50, 80:50, and 90:50.

Preparation of Stainless Steel Coronary Stents
PVA powders and deionized water are blended at 85 °C for 12 hours to form a 20 wt% PVA solution, which is then poured into a hollow stainless steel tube with an inner diameter of 5 mm. The stainless steel braids, which are not removed from the stainless steel bar with a diameter of 3 mm, are then inserted into the PVA solution (seen in Figure 2). This process allows the braids to be coated with PVA solution. After the PVA solution turns into a membrane, the 3-mm-diameter stainless steel bar is removed and the SS and PVA coronary stents are completed.

Tests
Braiding Angles of SS and PVA Braids and Braided Coronary Stents
SS and PVA braids and braided coronary stents made with various gear ratios are placed on the platform of a stereomicroscope (SMZ-10A, Nikon Instruments Inc., Japan), and then Image Pro Plus software (Media Cybernetics, Inc., USA) measures the braiding angle of the samples.

Tensile Strength
According to ASTM D2256, SS and PVA fibers are evaluated with tensile strength by using an Instron 5566 (Instron, USA). The distance between clamps is 250 mm, the tensile speed is 300 mm/min, the full load is 100 N, and 20 samples of each specification are tested.

Stereomicroscopic Observation
A stereomicroscope (SMZ-10A, Nikon Instruments Inc., Japan) observes the surfaces and sections of the SS and PVA braids and coronary stents, after which Motic Images Plus 2.0 software (Motic Group Co., Ltd., USA) generates the pictures.

Scanning Electron Microscope (SEM) Observation
An Ion Sputter (E-1010, Hitachi, Japan) coats the gold on the SS and PVA braids and coronary stents, after which the sections of all sample types before and after coating with gold are observed by an SEM (S3000, Hitachi, Japan).

Strut Cover Rate Measurement
The stereomicroscopic images are obtained from the section of Braiding Angles of SS and PVA Braids and Braided Coronary Stents, and they are measured for the strut cover rate by using an Image Pro Plus (Media Cybernetics, Inc., USA). The strut cover rate is calculated with the area of fibers (hereafter fiber area) and areas of SS and PVA braids and coronary stents (hereafter, tube areas) by the following equation.

\[
\text{Strut cover rate} = \left( \frac{\text{Fiber area}}{\text{Tube area}} \right) \times 100 \%
\]

Result and Discussion

Braiding Angle
Figure 3(a) shows that a decreasing tooth number of the take-up gear results in a smaller braiding angle, which is ascribed to the higher braid forming place (Figure 4). The braid forming place is higher as a result of a decreasing tooth
number of the take-up gear, which in turn decreases the braiding angle, the result of which is in line with that of the study by Lou et al. [19].

When composed of single- or double-ply fibers (cf. Figure 3(a) and (b)), the braiding angle of the PVA braids and coronary stents has a similar trend; however, the braiding angle of the SS braids and coronary stents does not exhibit any significant trend. Such results are due to the fact that the double-ply SS fibers possess a tensile strength (i.e., 29.6 N) as seen in Figure 5, which is much greater than that of the single-ply fibers, and PVA fibers. Leung et al. proved that braiding angle changes as a result of the load of the braids [20]; therefore, the use of double-ply SS fibers with a greater tensile strength in a braiding process prevents the braider from easily expanding the fibers, which in turn cause a similar braid forming place, exemplified by a barely significant trend.

### Effects of Tooth Number of Take-Up Gear on the Braiding Structure of SS and PVA Braids

Figures 6 and 7 show that regardless of the tooth number of the take-up gear, SS or PVA fibers can be made into reticular, tubular SS or PVA braids. Figures 6 and 7 demonstrate that single- or double-ply SS fibers can be fixed to form a stable structure by braiding exclusively, as indicated by yellow circles. Such a result is due to the flexibility of stainless steel fibers, which can form stable braiding angles by crossing stainless steel fibers. Figure 7 shows that stainless steel fibers are bendable and thus can be easily combined into double-ply yarns, which can be made into 2-ply stainless steel braids. However, shown in purple squares, the double-ply yarn separates in the resulting braids, this is because stainless steel fibers have smooth surfaces and the braids are not further fixed. Compared to SS fibers, both single-ply and double-ply PVA fibers are not able to form stabilized braiding angles, as indicated by yellow circles in Figures 6 and 7, which in turns results in greater variations in the diameter of the PVA braids.

### Observation of the Cutting Sections of SS and PVA Braids

Figure 8 shows that the SS braids expand on the section, which is a result of the formation method. The braids are only fixed with braiding angles. Cutting damages the braiding...
Figure 6. Stereomicroscopic images (15× with a 1-mm scale bar) of the braiding structure of the braids containing single-ply SS or PVA fibers and with a tooth number of (a) 50, (b) 60, (c) 70, (d) 80, and (e) 90 on the take-up gear. The magnification of insets is 7.5× for SS braids and 8× for PVA braids with a scale bar being 3 mm.

Figure 7. Stereomicroscopic images (15× with a 1-mm scale bar) of the braiding structure of the braids containing double-ply SS or PVA fibers and with a tooth number of (a) 50, (b) 60, (c) 70, (d) 80, and (e) 90 on the take-up gear. The magnification of insets is 7.5× for SS braids and 8× for PVA braids with the scale bar being 3 mm.
angles, the support to the braids thus disappears, and eventually the braiding structure is ruined. Figure 8 shows that cutting creates sharp points, indicated by red arrows. After the braiding structure is damaged, braiding angles fail in supporting the braid, and the braids subsequently expand and cause sharp points. Compared to single-ply SS braids, the double-ply SS braids have twice as many sharp points. The number of stainless steel fibers is double in a 2-ply stainless steel braid; therefore, there are more sharp points in 2-ply braids. By contrast, the cutting does not cause the PVA braids containing single-ply or double-ply PVA fibers to expand (viz., a swelling structure). Differing from SS fibers, PVA fibers have a lower strength and a greater softness; therefore, cutting does not cause the swelling structure of PVA braids, but inevitably leaves sharp points on the breaking end.

Effects of PVA Solution Coating on the Structure of SS and PVA Coronary Stents

Figures 9 and 10 show that PVA solution can coat constituent fibers and pores of the single-ply or double-ply SS braids to form PVA film, indicated by red rhombus. Furthermore, PVA solution can stabilize the braiding angles (indicated by yellow circles) and then the structure of stainless steel braids. PVA solution possesses good film forming ability, and as a result, the PVA solution has a good processability and thus is able to bond and stabilize the stainless steel braids to form the coronary stents.

In addition, PVA solution not only stabilizes the SS fibers, but also the PVA fibers. As seen in Figures 9 and 10, coating PVA solution provides a setting effect over the PVA fibers, and the PVA braided coronary stents are well formed due to the braiding angles that are firmly stabilized by PVA solution.

Stereomicroscopic and SEM Observations of SS and PVA Coronary Stents

Compared to Figure 8, Figures 11 and 12 show that the sections of single-ply and double-ply SS coronary stents have good stabilization, exemplified by noticeable decreases in the damages of braiding angles, fabric expansion, and inner diameter variation. The coating of PVA solution provides the braiding angles of stainless steel coronary stents with stability. Therefore, after cutting, braiding angles are still stabilized, which in turn reduces the sharp points on the sections of the SS coronary stents.

The length of coronary stents required in a common clinical practice is around 1-2 cm [21], and it is necessary to ensure a stable structure of coronary stents with this length. The single-ply and double-ply SS coronary stents shown in Figures 11 and 12 all present a stable braiding structure, indicating that PVA solution provides good stabilization to braiding angles, which allows the SS coronary stents to be cut into 1 cm long lengths.

As seen in Figure 8, PVA braids fail to have a stabilized...
Figure 9. Stereomicroscopic images (15× with a 1-mm scale bar) and insets (7.5× for SS stents and 8× PVA stents with the scale bar being 3 mm) of the coronary stents braided with single-ply SS or PVA fibers and a tooth number of (a) 50, (b) 60, (c) 70, (d) 80, and (e) 90 on the take-up gear.

Figure 10. Stereomicroscopic images (15× with a 1-mm scale bar) and insets (7.5× for SS stents and 8× PVA stents with the scale bar being 3 mm) of the coronary stents braided with double-ply SS or PVA fibers and a tooth number of (a) 50, (b) 60, (c) 70, (d) 80, and (e) 90 on the take-up gear.
Figure 11. Stereomicroscopic images of the cutting sections for SS stents (7.5×) and PVA stents (8×) made of single-ply SS or PVA fibers with a tooth number of (a) 50, (b) 60, (c) 70, (d) 80, and (e) 90 on the pick-up gear. The scale bar is 3 mm.

Figure 12. Stereomicroscopic images of the cutting sections for SS stents (7.5×) and PVA stents (8×) made of double-ply SS or PVA fibers with a tooth number of (a) 50, (b) 60, (c) 70, (d) 80, and (e) 90 on the pick-up gear. The scale bar is 3 mm.
reticular, tubular structure due to the softness of PVA fibers. Coating with PVA solution (Figures 11 and 12); however, improves such a disadvantage by stabilizing the braiding angle and then the structure of PVA braids. As a result, the reticular, tubular structure of PVA coronary stents remains stabilized even after being cutting into 1 or 2-cm sections. Figure 13(a), (b) shows that sharp points occur on the section of the stainless steel braids as a result of cutting. After cutting, stainless steel braids expand and expose the single-ply or double-ply stainless steel yarn. The presence of sharp points will injure adjacent vessels. Figure 13(c), (d) displays a decrease in the sharp points on the sections, proving that coating with PVA solution significantly reduces sharp points. The braiding structure that is fixed by the braiding angle is full of numerous spaces composed of fibers. PVA solution can saturate the braids, cover the stainless steel fibers (indicated by red circles), and then the braiding angles (indicated by yellow arrows), and finally turns into membranes, which effectively reduces the sharp points and prevents the inner diameter from greatly expanding, after the coronary stents are cut.

The amount of the sharp points of SS fibers can be reduced via coating with PVA solution; conversely, PVA braided coronary stents exhibit an optimal interfacial status on their cutting sections. Figure 14(a), (b) shows that the sharp points of the PVA braids occur as a result of the cutting, indicated by red arrows; by contrast, Figure 14(c), (d) show the presence of an optimal cutting section of the PVA coronary stents, where the PVA solution and fibers profoundly combine, indicated by red circles, and the sharp points caused by cutting are completely absent.

**Figure 13.** SEM images (50×) of (a), (b) SS braid and (c), (d) SS coronary stents. (a), (c) and (b), (d) using single-ply and double-ply SS fibers, respectively.

**Figure 15.** SEM images of take-up gear with different tooth numbers, showing the strut cover rate of single-ply SS braids and coronary stents. (a) Tooth number between 50-80, strut cover rate is between 31-35%. (b) Tooth number 90, strut cover rate is 26.45%. (c) Tooth number ranging from 50 to 90, strut cover rate is between 48-56%. (d) Double-ply SS braids and coronary stents have a greater strut cover rate, due to a greater amount of fibers and a larger strut area. The tooth number on the take-up gear changes the braiding angles but is proved insignificantly correlated with strut cover rate. Strut cover rate is positively correlated with the amount of fibers.
correlated with the area of fiber.

PVA braided coronary stents have a strut cover rate beyond 70%, which is far greater than that of SS coronary stents. Polymers are different from metallic materials; therefore, it is acceptable that PVA stents are exemplified with a greater strut cover rate than that of SS stents for their application as coronary stents [3].

Figure 14. SEM images (50×) of (a), (b) PVA braids and (c), (d) PVA coronary stents with (a), (c) and (b), (d) using single-ply and double-ply PVA fibers, respectively.

Figure 15. Strut cover rate of SS and PVA braids and coronary stents consisting of (a) single-ply and (b) double-ply fibers.
Conclusion

This study successfully creates SS and PVA coronary stents by applying a braiding process. The reticular, tubular SS and PVA braids can be yielded by changing the tooth number on the take-up gear, except for those made of double-layer SS fibers, which may cause an unstable braiding manufacture. SS fibers and PVA fibers can both form the braiding angles that subsequently stabilize the braiding structure. In addition, coating with PVA solution can further stabilize the braiding angles formed by SS fibers or PVA fibers, which in turn prevent braid expansion, decrease the sharp points, and stabilize the inner diameter. In particular, the PVA fibers and PVA solution have an optimal interfacial bonding. The use of double-ply stainless steel yarn results in a poor braiding process and a high strut cover rate. It is more appropriate to use single-ply stainless steel yarn for coronary stents. The SS and PVA coronary stents sustain good structural stability after being cut into 1 cm long lengths.

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