IN VITRO DEGRADATION BEHAVIOURS OF PDO MONOFILAMENT AND ITS INTRAVASCULAR STENTS WITH BRAIDED STRUCTURE

Cong-er Wang1,2, Pei-hua Zhang1,2
1College of Textiles, Donghua University, Shanghai 201620, China
2Key Laboratory of Textile Science &Technology, Ministry of Education, China
E-mail: wangoedaily@163.com, phzh@dhu.edu.cn

Abstract:
Biodegradable intravascular stent has attracted more and more focus in recent years as an effective solution for angiostenosis. Ideal stents were expected to exhibit sufficient radial force to support the vascular wall, while suitable flexibility for the angioplasty. After vascular remodeling, stents should be degraded into small molecular and be eliminated from human body, causing no potential risk. In this paper, poly-p-dioxanone (PDO) monofilament was braided into net structure with four different braiding density, two of which exhibited sufficient radial force larger than 30 kPa, and three of which showed the bending rigidity within 11.7–88.1 N•mm. The degradation behaviors of monofilaments and stents have been observed for 16 weeks. The findings indicate that degradation first occurred in morphology region, which induced temporary increase of crystallinity, monofilament bending rigidity and stent mechanical properties. During this period, monofilament tends to be hard and brittle and lost its tensile properties. Then the crystalline region was degraded and stent mechanical properties decreased. All the results reveal that the PDO intravascular stents with braided structure were able to afford at least 10 weeks of sufficient support to the vascular wall.

Keywords:
intravascular stent, braided structure, PDO, compression strength, bending rigidity

1. Introduction
Atherosclerosis and other cardiovascular diseases have become a health hazard in recent years. Stent implanted by percutaneous coronary intervention (PCI) is an effective treatment for coronary heart disease caused by vascular stenosis and block [1]. With the method of treatment, stents were implanted to the diseased vessel segment to support the lumen [2]. Drug-eluting metal stents were mostly widely used nowadays. With antstenosis drug coated on the surface, it can be worked to healing. However, as the stent bone were made from metal, its long-term existance in vivo may have potential risk of inflammation, thrombus, and even restenosis [3]. Biodegradable stents were introduced as a ‘temporary stent’ with the advantage of biocompatibility, nontoxicity and their complete absorption after the healing process; they being the drug carriers had attracted more and more interest [4].

Materials of biodegradable stents can be divided into biodegradable metal, such as Ferro ferrite, magnesium alloy and biodegradable polymer, such as polylactic acid (PLA), polycaprolactone (PCL) and poly-p-dioxanone (PDO) [5]. The biodegradable polymers, with better biocompatibility can be modified to control its degradation velocity and get better machinability, were extensively studied [6]. PDO, authorised by FDA for clinical use, has now been applied as a surgical suture, enteric stent and esophageal stent. With the glass transition temperature below 0°C and with rich eter bond in molecular chains, PDO monofilament has great flexibility at room temperature which is suitable for stent braiding [7]. Also, it has high crystallinity and high mechanical strength. Animal experiments demonstrated that it has good biocompatibility and that it barely caused inflammation, with a full biodegradable time of 6 months [8]. Marcos [9] and Chu [10] conducted in vitro degradation experiment on PDO suture; however, there has been no long-term (>12 weeks) studies to test the in vitro degeneration properties of PDO intravascular stent.

Stent can be made from sheet, tube, wire and ribbon materials, among which tube and wire were most widely used [11]. The fabrication method mainly depends on raw material choice. Tubes were mostly produced by laser cutting, allowing a slit width of <20 μm to form a pattern. Wires can be formed into stents by coiling, braiding or knitting. Hamm et al. successfully implanted the Strecker stents with a knitting structure into the coronary arteries of 64 patients [12]. Polymers were extruded and drawn into monofilament to get a higher mechanical property, which is suitable for the wire-based fabrication to make stents [13]. The most common wire-based self-expanding stent is the Wall Stent. With its benefits of flexibility and coverage rate, Wall Stent made from PDO has been applied in the treatment of intestinal stenosis [14] and esophageal stricture [15].

Radial force is the foremost property of stent describing the collapse resistance ability to external circumferential pressure, or the strain capacity to external force. It determined whether the stent achieved the correct deployment cling stable to the lumen wall to provide sufficient support, avoiding abrupt closure, maintain blood flowing and obtain the gain of vascular remodeling [16]. There are no general international standard
testing method and evaluation criterion currently. Rieu et al. and
Chen et al. separately tested the stent radial force by water flow
stress [17] and air flow stress [18]. These two methods enabled
the overall pressure to stents simulating the circumstance in
vascular lumen, yet complicated to operate with low accuracy.
The platform compression method expresses the radial force
indirectly and is easy to handle with close tolerance [19]. As
there is no standard value for stent radial force, the result of
Rieu [17] was used, which is higher than 30 kPa.
Bending rigidity is an important indicator to describe the
mechanical property of stents, reflecting the flexibility. Flexibility
is a complex of stiffness and pliability. The stiffness made the
delivery process easy to handle, while the pliability enabled the
deployed stent to follow vessel contour to diseased region and
reduce injury to lumen wall [20]. The generally employed testing
method was cantilever beam [21], three-point bending [22] and
four-point bending [23]. Schmidt [21] used the cantilever beam
method to test the bending rigidity of stents, and got the value
limitation of self-expanding stents between 11.7 and 88.1 N/mm².

This paper communicates the design, preparation and
mechanical properties of PDO biodegradable intravascular
stents with braided structure, and discusses the in vitro
degradation behaviors of PDO monofilament and stents. The
productive process of Wall Stent produced from one PDO
monofilament by wounding on a brass mould was first described
in detail. The long-term in vitro degradation and systematic
mechanical tests of PDO stent have not been discussed in
other paper before.

2. Experimental details

2.1 Materials

PDO monofilament (linear density 96tex, breaking strength
133 MPa, breaking elongation 48.92%) was provided by META
BIOMED CO. LTD, Korea. All chemicals were analytically pure
and used without further purification.

2.2 Monofilament behaviours during degradation

PDO monofilaments were degraded in phosphate-buffered
saline (PBS, pH 7.4), preserved in 37°C incubators (HH.CP-
T, Shanghai Sanxin, China). Scanning electronic microscope
(SEM, Hitachi, S-4800, Japan) was used to observe the
surface morphology during degradation process every 4
weeks. X-ray diffraction (XRD; D/max-2550 PC, Rigaku,
Japan) and Differential Scanning Calorimeter (DSC, Pyris-1,
Perkin Elmer) were used every 4 weeks to get the crystallinity
of monofilaments. Mass loss and tensile properties were tested
every 2 weeks after vacuum drying. Single fiber strength tester
(LLY06E, Laizhou electron instrument Co., Ltd, China) was
used to test tensile properties with the gauge length of 100 mm
and stretch speed of 250 mm/min. Fabric bending tester (KES-
FB2, KATO TEKKO CO., LTD) was used to test the bending
rigidity of monofilaments. Twenty samples were set paralysed
as shown in Figure 1, clipped to the fixture and bending to the
opposite direction separately from curvature 0 to 2.5. Sensor
attached to the fixture would got the bending rigidity of PDO
monofilament, N•mm².

Figure 1. Testing sample of PDO monofilament bending rigidity.

2.3 Stent preparation

Figure 2 expressed the process of biodegradable stent implanted
and interaction with vascular wall. When fat and cholesterol
accumulated to a certain extent, plaque come into being and
narrow the vascular lumen. At the same time, endothelial cells
were injured, vascular elasticity and pumping capacity receded.
Invention treatment was adopted for healing lumen narrow by
implanting a compressed stent to the diseased region with a
delivery system [Figure 2(a)]. After that, balloon dilated and
stent was deployed attaching to the lumen wall, so the vascular
was remodeled [Figure 2(b)]. The delivery system then
retreated to leave the stent in lumen, which bares the external
pressure caused by vascular elastic and movement, as well
as the internal pressure of blood flow. Therefore, stents were
expected to have sufficient radial force to support the vascular
wall during the remodelling period. Otherwise, endothelial
cells need to change nutrition and oxygen from blood flow for
proliferation, hence the porosity of stent was also necessary
to the neointimal growth [Figure 2(c)]. As a temporary stent,
after the remodeling process, the biodegradable stents were
hydrolysed into small molecules and absorbed by human body
or eliminated in vitro. Without existing in vivo permanently, the
risk of inflammation and restenosis would be effectively reduce
[Figure 2(d)].

Figure 2. Schematic of biodegradable stent placement process

With the aim of producing stent with a sufficient radial force
and bending rigidity as well as porosity, the wire-based stents
were prepared by braiding method. Using a PDO monofilament
to wound around cylindrical on a brass mould, a length set
Wall Stent was formed. Then, the stent was heat setted by
electrothermal blowing dryer (Shang Hai Yiheng Co., Ltd,
Stent with more compact structure is much more able to resist deformation and has a higher mechanical property. In this paper, four groups stents with different braiding pins were produced, five for each group.

<table>
<thead>
<tr>
<th>n</th>
<th>θ</th>
<th>d1</th>
<th>d2</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>107.19</td>
<td>2.608</td>
<td>2.306</td>
</tr>
<tr>
<td>8</td>
<td>106.21</td>
<td>1.956</td>
<td>1.814</td>
</tr>
<tr>
<td>10</td>
<td>105.61</td>
<td>1.565</td>
<td>1.473</td>
</tr>
<tr>
<td>12</td>
<td>105.19</td>
<td>1.304</td>
<td>1.240</td>
</tr>
</tbody>
</table>

As shown in Figure 2(b), the angle \( \theta \) between upward and downward helix is called braiding angle. 

\[
\theta = \alpha + \beta = \arctan\left(\frac{\pi D}{nL}\right) + \arctan\left(\frac{(n+1)\pi D}{nL}\right)
\]  

(1)

In which, \( \alpha \) is the angle between upward helix and the cylindrical mother line, \( \beta \) is the angle between downward helix and the cylindrical mother line. \( D \) is cylindrical diameter, \( L \) is the cylindrical length and \( n \) is the number of pins.

Distance between upward helix is \( d_1 \):

\[
d_1 = \frac{\pi D \cos \alpha}{n}
\]  

(2)

While distance between downward helixes is \( d_2 \):

\[
d_2 = \frac{\pi D \cos \beta}{n}
\]  

(3)

Table 1 showed the theoretical value of the braiding angle and helix distance from stents braided with four different mould. It can be seen that, the larger the pin number, the smaller the braiding angle and helix distance, as well as the porosity to make more compact stent. Stent with more compact structure is much more able to resist deformation and has a higher mechanical property. In this paper, four groups stents with different braiding pins were produced, five for each group.

2.4 Basic properties test of stent

Basic properties of stent were described with stent thickness, porosity and longitudinal shortage.

Stent thickness refers to the material thickness of stent wall, which affects not only stent mechanical property but also the cell proliferation rate and inflammation. It can be tested with micrometer.
Porosity (K) is an important parameter that expresses the blank area percentage not covered by material occupying the whole stent surface area. A certain porosity provides space for cell proliferation and the environment for gas exchange, nutrition access, and metabolite elimination. Without porous stents, intima and blood flow were blocked, which would increase the risk of thrombosis and restenosis. However, with an oversize porous, there will be not be enough area for cell proliferation, also decreased stent mechanical property. The porosity could be tested by the weight method from Equation (8).

\[ K = \left( 1 - \frac{m}{\pi D_l d_p} \right) \times 100\% \]  

In which, \( m \) is the stent weight, mg; \( D_l \) is stent inner diameter + outer diameter)/2, mm; \( L \) the stent length, mm; \( d \) stent thickness, mm; \( \rho \) the density of material, mg/mm\(^3\).

Stent longitudinal shortage is the length shortage of deployed stent compared with the compressed one. Stent with a high longitudinal shortage cannot cover all diseased regions after being implanted into the human body. Micrometer can be used to test the longitudinal shortage to measure the length at complete compression and deployed to inner diameter 8 mm.

**2.5 Mechanical properties of stents**

Stent mechanical properties were tested by a radial compression tester (YG061, Laizhou electron instrument co., LTD, China) to get the radial force and bending rigidity. Use the platform compression method to test the radial force, as shown in Figure 3 (a). Stent was set on the platform and being compressed by a pressure. Compress the stent to get the deformation of 50% of its outer diameter, with the pressure rate 20 mm/min, and pressure diameter 20 mm. The radial force \( P \) applied on stent at the largest deformation can be calculated by Equation 9.

\[ P = \frac{F_1}{S(1-K)} \]  

In which, \( F_1 \) is the compression strength at the largest deformation, \( S \) is the surface area of stent, while \( K \) is the porosity.

Stent bending rigidity can be measured by cantilever beam method, shown in Figure 3 (b). Stent was fixed at one end and compressed by pressure at the other end. The cantilever beam length counts from the fixed point to pressure center line. As known from cantilever beam theory, the stent bending rigidity can be calculated by Equation 10.

\[ EI = \frac{F_2B^3}{3\delta} \]  

In which, \( F_2 \) is the bending strength when stent bending to the largest deformation, \( B \) is the cantilever beam length, \( \delta \) is the bending deformation. Stent bending rigidity can be line regression calculated from the \( F-\delta \) graph. Cantilever beam length is 12 mm, largest bending deformation is 2 mm, pressure rate is 20 mm/min, and the pressure diameter is 5 mm.

During testing process, soft rubber film (thickness 0.05 mm) was used to coat the stent, in order to get more equally force and simulate the pressure status in vascular lumen. Rubber film has no effect to testing results.

**2.6 Stent behaviors during degradation**

Use phosphate-buffered saline (PBS, pH 7.4) for the in vitro degeneration of PDO stents, same process with the monofilament. Measure the stent weight, radial force and bending rigidity every 2 weeks.

**2.7 Statistical analysis**

Statistical analysis was performed using Origin (Origin lab, USA). Data results were averaged and expressed as mean ± standard deviation (SD). Statistical differences were determined by one-way ANOVA. The statistical significance was assessed by F test, significance level was \( p<0.05 \).

**3. Results and discussion**

**3.1 Monofilament behaviors during degradation**

Figure 5 were SEM micrographs of PDO monofilament during degradation process. Figure 4 (a) showed the undegraded morphology, with micropit injury got from spinning. With the degradation move on, the longitudinal groove were becoming obvious and more micropits turned up. At the 12th week, it can be seen apparently in Figure 4 (b), there were longitudinal splitting on the surface. When it went to the 16th week, shown in Figure 4 (c), sheet-like peeling occurred on the surface.

Figure 6 expressed the weight retention of PDO monofilament during degradation. During the first 8 weeks, microweight decrease occurred and only 3% loss at the 10th week. At this period, hydrolysis broke the ester bond of molecular chains and replaced it by stable ether bond. There were rarely small molecular pieces come into being to cause obvious weight
loss. At 10th week, weight dropped obviously. At this time, during the hydrolysis, more small molecular pieces separated from monofilament into solution. At the 14th week, there were visible pieces getting off the monofilament and the weight retention at 16th week was 80.42%. This result can also be demonstrated by SEM graphs, which the splitting and sheet-like peeling after 12th week caused a dramatic decrease of monofilament weight.

DSC was tested every 4 weeks, as shown in Figure 8. The tested melting point ($T_m$) and enthalpy ($\Delta H_m$) were listed in Table 2. At the first 8 weeks, there were two melting peaks at the curve, as PDO is a semicrystalline material and tend to form its own crystalline region. Then, with the degradation going on long molecular chains were broke to shorter ones, molecular distribution got closer and peaks drawn upon each other and finally join one peak at the 12th week. Though DSC testing can’t get the crystallinity directly, it can also be demonstrated that the changes of crystallinity in accordance to the XRD results, as it is in direct proportion with melting enthalpy ($\Delta H_m$), which also first grow and then drops. As errors existed among different testing method, there was a certain difference with the result of XRD.
PDO monofilament is a property to produce wire-based stent with its favourable mechanical property and flexibility as its glass transition temperature below 0°C. The tensile properties of PDO monofilament were shown in Figure 9. It decreased dramatically as soon as degradation started since hydrone got into molecular chains as soon as hydrolysis started to break ester bond and decrease the molecular weight. Then with the degradation going on, the morphology region was degraded and crystallinity increased, inducing continuous declination of tensile strength, only 13.44% of initial strength was left till the 10th week. The elongation changes were in accordance to that of breaking strength and dropped 88.08% at 10th week. Monofilament was too crispy to test at the 12th week.

Stent mechanical properties are not only determined by monofilament tensile strength but also bending rigidity. Monofilament arranged at helix status in stent, and when come under external pressure, the bending rigidity contributed more to the stent force. Figure 10 showed the monofilament bending rigidity changes during degradation. Generally speaking, the higher the crystallinity, the higher the material rigidity. The trend of monofilament rigidity changes was consistent with the results of XRD and DSC. However, the higher the crystallinity, the monofilament was easier to be a brittle failure. At the 12th week, the sample couldn’t afford the bending deformation and break off. At the 10th week, the monofilament bending rigidity increased 36.41% of initial.

### 3.2 Appearance and basic properties of stent

The appearance of stents was shown in Figure 11. It can be obviously seen from figure that the porous of stents got smaller with the increase of braiding pins. Table 3 listed the thickness, porosity and longitudinal shortage of these four groups of stents. The real tested longitudinal shortage is smaller than...
the theoretical values as the braiding angel could not be compressed to 0. However, the change rule is consistent with the theory that stent with higher braiding pins and more compact structure get less longitudinal shortage. That’s because the higher the braiding pin, there were more interlacing points to get much more friction and stable the stent structure. Also, the braiding angle $\theta$ got smaller and longitudinal deformation of rhombus unit decreased.

![Figure 11. Appearance of PDO stents of (a) 6 pins, (b) 8 pins, (c) 10 pins, (d) 12 pins.](image)

### 3.3 Mechanical properties of stents

After deployed in vascular, stent would bare the momentary pressure induced by human blood pressure and vascular elasticity and the long-term pressure during the healing process. So stents were expected to have sufficient radial force to support the vascular wall and not to slip or collapse. However, too much radial force would cause vascular injury. Though there is no Internet standard of stent radial force, the accepted value is higher than 30 kPa. Stents radial force in this research was shown in Figure 12. Stent a and b had lower force than 30 kPa, while stent c and d got the value, separately 38.46 kPa and 35.04 kPa.

![Figure 12. Radial force of PDO stents.](image)

Wall Stent is a net structure stent without a fixed cross point. Monofilament was interlaced together at the status of helix by friction force instead of bonded to form the rhombus units. When stent was compressed, the radial force was supplied by monofilament bending rigidity and friction force. When the pin number increased from 6 to 8, stent radial force significantly ($p=0.01$) increased since stents got a more tight arrangement of monofilament and more units to bare larger $F_1$. However, the radial force of stent c was a little higher than that of stent d, but not significant ($p=0.36$), since the growth of $K$ counteracted the increase of $F_1$.

![Figure 13. Bending rigidity of PDO stents.](image)

Figure 13 expressed the bending rigidity of stents. It can be seen that with the growth of braiding pins, stent had more compact structure to resist significantly higher ($p=0.01$) bending force at the same deformation. Braiding pins determined the cycle number of monofilament, which would increase the resist of bending force. Stent a had lowest bending rigidity of 34.43 N·mm$^2$, and stent d the highest of 91.35 N·mm$^2$. Apart from stent d had higher value, the other three groups all within the limit of 11.7–88.1 N·mm$^2$.

<table>
<thead>
<tr>
<th>Pin number</th>
<th>Sample</th>
<th>Thickness (mm)</th>
<th>Porosity (%)</th>
<th>Theoretical value of longitudinal shortage (%)</th>
<th>Actual value of longitudinal shortage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>a</td>
<td>0.59±0.003</td>
<td>87.26±0.87</td>
<td>40.47</td>
<td>38.46±1.07</td>
</tr>
<tr>
<td>8</td>
<td>b</td>
<td>0.61±0.008</td>
<td>81.37±1.23</td>
<td>39.89</td>
<td>37.50±1.43</td>
</tr>
<tr>
<td>10</td>
<td>c</td>
<td>0.63±0.004</td>
<td>76.76±0.69</td>
<td>39.50</td>
<td>36.91±0.96</td>
</tr>
<tr>
<td>12</td>
<td>d</td>
<td>0.68±0.005</td>
<td>69.41±0.94</td>
<td>39.23</td>
<td>36.51±0.73</td>
</tr>
</tbody>
</table>

Table 3. The basic properties of PDO stents (± SD, n=5)
3.4 Stent behaviors during degradation

Figure 14 showed the morphology change of four groups of stents during degradation process. During the first 12 weeks, there were no obvious morphology changes except lighter colored. At the 14th week, few breaking points occurred on stent a and b, while stent c and d kept perfectly. At the 16th week, stent a and b were totally damaged, while stent c were partly broken and stent d still maintained integrity with few breaking points. Figure 15 showed the weight change of stents during degradation. The undegraded stents had larger weight with increase of braiding pins and significant different (p=0.03). During the first 10 weeks, there were micro loss of stent weight, all below 1%. Weight decreased since the 12th week and at the 14th week, small pieces of material apart from stent to cause obvious decline. At the 16th week, stent damaged and the weight decreased apparently. During the 16 weeks of degradation, stent a and b separately lost 17.07% and 18.06% of its initial weight, while stent c lost 15.28% and stent d the lowest 13.07%. Stent weight loss compared with that of monofilament (19.58% at 16 weeks) was slower. Because the interfacing structure of stents helps resist hydrone getting in and holding small material pieces. Stent with more compact structure lost less weight as hydrone were not easy to get into the stent structure compared with sparse ones.

Stent radial force changes during degradation were shown in Figure 16. During the first 10 weeks, in addition to some fluctuations, all other three stents were on the rising trend apart from stent a. The radial force of stent d increased apparently as the degradation started, 14.54% of growth at the second week, then fluctuated at the fourth and eighth week, increasing rapidly to 27.56% at the 10th week. Stent b and c had similar tendency, apart from fluctuation at second and eighth week, were on a rise trend and separately increased 11.14% and 11.49% at the 10th week. Stent a experienced slightly decline during the first 4 weeks of 8.69%, then increased slowly, kept lower than original value. At the 12th week, all stents showed decrease tendency, however all other three groups were higher than initial radial force except stent a. At the 14th week, radial force of all stents was lower than its initial value. At the 16th week, apart from stent d, all other groups were damaged and lost much radial force, the retention of four groups was 38.62%, 40.23%, 43.81% and 67.52%, respectively, with stent d the highest. During the whole period, differences between stent c and d were not significant, while differences among stent a, b and c were significant till the 16th week.

With the process of degradation went on, the crystallinity of PDO monofilament firstly increase then decline and the turning point at the 10th week. The bending rigidity of...
monofilament also showed increase trend till the crispy broke at the 12th week. Stent radial force experienced increase at the first 10 weeks induced by the increasing bending rigidity of monofilament. Stent with a more compact structure was more affected by monofilament bending rigidity as it is more dense helix arrangement. That explained the most obvious radial force increase of stent d with the highest braiding number. After the 10th week, monofilament got weak points and easily broke, so the stent radial force decreased. At the 14th week, visible pieces broke from stent and breaking points occurred, the radial force of stents sharply decreased. With the most compact structure, some breaking points would not affect the structural integrity, so stent d kept most perfectly the highest radial force at the 16th week.

Figure 16. Radial force of PDO stents during degradation. Data were mean ±SD, n=5.

Figure 16 showed the changes of stent bending rigidity during degradation. All stents showed a drop at the first four weeks with stent a at the most loss of 35.34% and stent d at the least loss of 14.11%, while stent b and c lost 17.36% and 14.59% separately. During production process, PDO monofilament were wounded and twisted to cause internal stress. At the first 4 weeks, the internal stress disappeared by stress relaxation to make stents more flexible and easy to deformed at bending force. At the 6th week, stent bending rigidity started to went up except stent c at the 8th week, and all stents higher than initial value except stent a 3.61% lower. Then the stent bending rigidity declined and at the 12th week, some stents occurred break points and the testing result were not significant different. At the 14th week, stent bending rigidity decreased sharply and the rigidity retention rate were separately 32.67%, 21.42%, 40.23% and 36.51%. Apart from stent d, all stents were damaged seriously during testing process. At the 16th week, the retention of stent d was 16.01% of initial value. Other three groups of stents were too broken to be tested.

The degradation behavior of stent bending rigidity was similar to that of radial force, increase firstly and then declined. Although the bending rigidity has some difference by the stress relaxation to cause the decrease of first 4 weeks. Stent mechanical behaviour was determined mainly by monofilament rigidity. During degradation, the monofilament rigidity increased with the growth of crystallinity, which would cause the increase of stent radial force and bending rigidity. With the degradation went on, the crystalline region was degraded and the monofilament subject was collapse to cause the stent damage and sharply damping of mechanical property. Stent d with the most compact structure had more stable status to get highest mechanical property retention.

4. Conclusion

In the present work, biodegradable Wall Stents made from PDO monofilaments have been successfully produced with the method of mould wounding. PDO monofilaments and stents were in vitro degraded for 16 weeks. The following conclusions were established through this study:

1. Undegraded monofilament was smooth with spinning injury. Splitting and peeling occurred after 12 weeks of degradation, and obvious mass loss.

2. X-ray and DSC results showed that the crystallinity of PDO first increased during first 8 weeks and then decreased, which proved that the degradation first occurred in morphology region and then the crystalline region.

3. Monofilament tensile property failed rapidly during 10 weeks degradation while the bending rigidity increased. Monofilament tends to become hard and fragile and lost its mechanical property.

4. Stent with higher pin number had lower porosity and longitudinal shortage.

5. Stent with higher pin number had a rose and fell tendency of radial force and an increase tendency of bending rigidity.

6. Stent d maintained integrity structure after 16 weeks degradation and least mass loss.

7. Stent radial force first increased in first 10 weeks of
degradation and then decreased, with stent d decreased the least.

8. Stent bending rigidity experience a fell and rose period during the first 8 weeks with the turning point at the 4th week, and then decreased till it cannot be measured, with stent d decreased the least.

Therefore, it can draw a conclusion that PDO Wall Stent was able to supply effective support to vascular wall for at least 10 weeks.

Funding

This work was supported by Financial support provided by the Government of P. R. China, 111 project, “Biomedical Textile Materials and Technology” (project number B07024).

References