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Comparison of radial deformability of stent posts of different aortic bioprostheses†

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Abstract

OBJECTIVES: Little is known about the stent deformability required for optimal stented heart valve bioprosthesis design. Therefore, two bioprosthetic valves with known good long-term clinical results were tested. The strain in the radial direction of the stent posts of these valves was compared with contemporary bioprosthetic valves and a native porcine aortic root.

METHODS: Medtronic Intact and Carpentier-Edwards Standard (CES), and four contemporary bioprostheses, including one self-expanding prosthesis, were tested with three sonomicrometry probes per valve fixed at commissure attachment points. The mean values from 2400 data points from three measurements of the interprobe distances were used to calculate the radius of the circle circumscribed around the three probes. Changes in the radius of the aortic root at pressures 70–90 and 120–140 mmHg (pressure during diastole and systole) and that of the stent posts at 70–90 and 0–10 mmHg (transvalvular pressure gradient during diastole and systole) were compared.

RESULTS: An increase in radius by 7.3 ± 2.6, 8.7 ± 0.0 and 3.9 ± 0.0% for the porcine aortic root, CES and Intact valves, respectively, was observed during transition from diastolic to systolic pressure and less for contemporary bioprostheses—mean 2.5 ± 0.9%, lowest 1.2 ± 0.0.

CONCLUSIONS: The results indicate that the radial deformability of bioprosthetic valve stent posts can be as low as 1.2% for xenoaortic and 3.0% for xenopericardial prostheses with no compromise of valve durability. Although these results suggest that valve stent post-deformability might not be of critical importance, a concrete answer to the question of the significance of stent deformability for valve durability can be obtained only by acquiring long-term follow-up results for valve prostheses with rigid stents.

Keywords: Heart valve • Prosthesis • Mechanical properties • Deformation • Stent

INTRODUCTION

First-generation bioprosthetic valves were made from high-pressure fixed pig aortic valve tissue or the bovine pericardium mounted on rigid supporting stents. These prostheses often experienced early failure due to leaflet rupture near the attachment points to the stent posts [1]. To solve this problem, the usage of flexible stent posts [2] that would cushion the shock loading of the leaflets at the commissural region during the onset of diastole was suggested. This concept was picked up eagerly by the medical industry, and in the 80s, there was a rapid shift to flexible stent posts. Unfortunately, there have not been any substantive studies to assess the usefulness of this feature. Theoretically, there are clear mechanical benefits of the flexible stent posts demonstrated by computer modelling [2], but it is unclear if there is any real practical gain to the durability and longevity of stented bioprostheses. This is particularly difficult to evaluate because simultaneously with flexible stent posts, other design changes of bioprosthetic valves were introduced. These include: low instead of high-pressure fixation of porcine aortic valve leaflet tissue, different tissue selection methods and others [1]. Nevertheless, there are several second-generation bioprostheses that have a follow-up close to, or even exceeding, 20 years, which include Medtronic Intact, St. Jude Biocor (predecessor of St. Jude Epic), Carpentier-Edwards Standard (CES) and others [3–6]. One can claim that their stent deformability is adequate and that it does not cause structural defects to the valve.

Although every surgeon knows by experience that modern standard bioprosthetic valves have flexible stent posts, there is no published data on their deformability. This information would be essential for developers of new traditional bioprosthetic valves

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and even more important in the blooming field of transcatheter aortic valve prostheses. To determine the minimum required deformability of valve stent posts, we did reverse engineering and studied the mechanical properties of two second-generation valve designs that have proven their durability in the long run: CES and Medtronic Intact aortic valves.

We designed an *in vitro* study to measure the radial strain of these two well-known bioprosthetic valves. Subsequently, we compared their mechanical properties with current traditional bioprostheses and with a native porcine aortic root.

MATERIALS AND METHODS

For testing of stent post deformability (radial strain of the valve framework at the level of stent posts), we used a 27-mm Medtronic Intact (Medtronic Blood Systems, Irvine, CA, USA) produced in 1988 and a Carpentier-Edwards Standard size 27-mm bioprosthesis (American Edwards Laboratories, Irvine, CA, USA) produced in 1987. Both bioprostheses were kept sealed in their original packaging at room temperature. These were compared with three contemporary standard bioprostheses with known good long-term results [6–9]: St. Jude Epic (St. Jude Medical Inc., St. Paul, MN, USA), Medtronic Hancock II (Medtronic Inc., Minneapolis, MN, USA), Sorin Soprano (Sorin S.p.A., Milan, Italy) and with an ATS 3F Enable stent prosthesis (Fig. 1) made for implantation during open surgery (ATS Medical Inc., Minneapolis, MN, USA).

A special test system was constructed (Fig. 2) for the testing of bioprosthetic valves at various pressures at pseudo-static conditions. To measure the radial strain of the stent posts, we used three TRX 2-mm (Sonometrics Corp., London, Ontario, Canada) probes per valve fixed at commissure attachment points. Distances between them were measured at three different pressure settings: 0–10, 70–90 and 120–140 mmHg. Mathematical analysis of the data was performed off-line with a software package for cardiovascular analysis (Sonosoft version 3.1.3., Sonometrics, London, Canada). Measurements were acquired at a frequency of 626 Hz. The mean values from 2400 data points from three measurements of the interprobe distances were used to calculate the changes in the radius of the circle circumscribed around the three piezoelectric probes. We used the formula $R = abc/4S$ in our calculations, where a, b and c are the respective interprobe distances and S, the area of the triangle formed by the three probes, which was calculated using Heron's formula ($S = \sqrt{p(p-a)(p-b)(p-c)}$, where p is half perimeter of the triangle. We compared the deformability of the bioprosthetic valves with the circumferential compliance at the level of the commissures of a fresh porcine aortic root harvested within 6-h post-mortem, where the sonomicrometry probes were fixed at the inner commissure regions.

For pair-wise comparisons of mean values, either a heteroscedastic or homoscedastic t-test was used. Statistically, different pairs were defined as having $P < 0.05$.

RESULTS

The results of the stent post deformability studies are summarized in Table 1, which also includes the corresponding data on porcine aortic root radial compliance. To evaluate the deformability of bioprostheses' stent posts, we compared the changes in the radius of the circle around the stent posts at 70–90 mmHg (transvalvular pressure gradient during diastole) and at 0–10 mmHg (transvalvular pressure gradient during systole). To assess the radial deformability of the native aortic root, we compared the respective changes in radius values at pressures of 70–90 (corresponding to pressure during diastole) and 120–140 mmHg (corresponding to pressure during systole). Deformability was defined as the relative increase of the radius during the transition from systole to diastole in percent.

Deformability of the traditional bioprostheses ranges from 1.2 ± 0.0% for the St. Jude Epic up to 8.7 ± 0.0% for CE Standard. The mean deformability in the group of traditional bioprostheses with known good long- and mid-term results is 3.9 ± 2.9%. This is very close to 3.9 ± 0.0% ($P = 0.49$), the deformability of one of the two older bioprostheses—Medtronic Intact. The deformability of all the modern bioprostheses is <3.0%, with the only exception being ATS 3F Enable with a deformability of 3.0%. The mean deformability of the older traditional bioprostheses is higher than that of the modern ones, although not reaching statistical significance, 6.3 ± 3.4 vs 2.3 ± 1.0%, respectively ($P = 0.07$). The radial deformability of the native porcine aortic root is 7.3 ± 2.6%—higher than any of the modern traditional bioprostheses.

DISCUSSION

Mechanical properties of the native aortic valve apparatus

We found the radial deformability of a native porcine aortic root to be 7.3 ± 2.6%—higher than that of any of the contemporary bioprosthesis. Still, a comparison of the deformability of bioprosthetic valve stent posts and aortic root compliance at the level of commissures is difficult and rather questionable. In principle, the radial movement of commissural regions is in the same direction—they move inwards, for both native aortic root and prostheses during transition from systole to diastole (Table 1). The problem is that this is true only when monitoring a static situation, such as in our experiment. When looking at the dynamics of the aortic root in more detail throughout the cardiac cycle, like Lansac *et al.* have done [10], one can see that aortic root dimensions at the commissural level stay the same or even increase a little at the very beginning of diastole. This coincides with a slight increase in aortic pressure at the dicrotic notch (due to the closure of the aortic valve). This is the same moment when there is a maximum stress on aortic valve leaflets [2] and, at this moment, the stent posts of bioprosthetic valves start to bend inward. This suggests that there is no stress dampening in the native aortic root via an inward motion of the commissures. From this, we can conclude that stent post deformability might not be of major importance. Yet one has to keep in mind that bioprosthetic valve tissue is less elastic than that of the native aortic leaflets [11]. Hence, they are less capable of responding to increased stress during diastole, and stent post flexibility might still be of importance for prosthetic valves, compensating for this deficit of leaflet elasticity.

Mechanical properties of bioprosthetic valves

Our results demonstrate that the older second-generation bioprostheses were created with more pliable stents than the modern traditional bioprostheses. Nevertheless, it must be noted

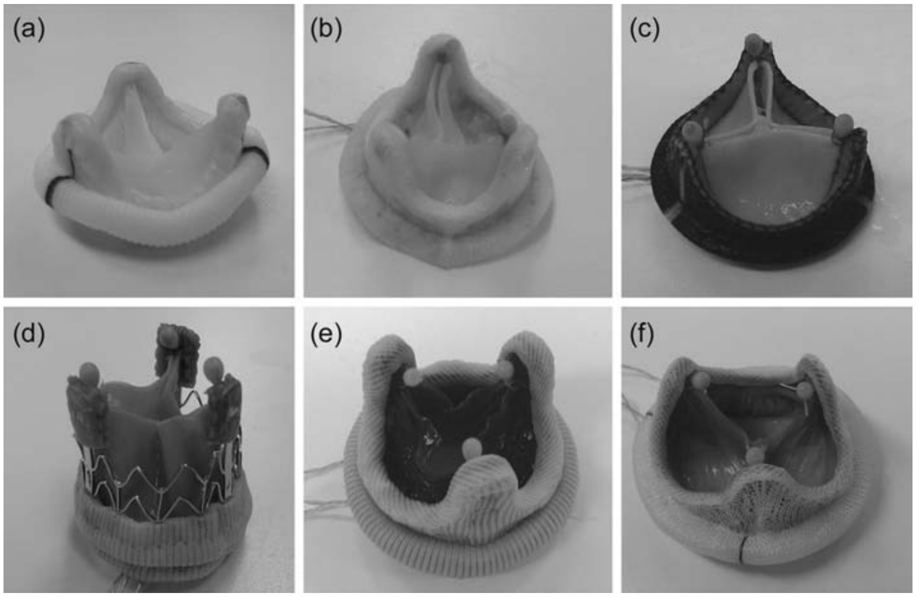

Figure 1: Photographs of bioprostheses tested: (**a**) St. Jude Epic, (**b**) Medtronic Hancock II, (**c**) Sorin Soprano, (**d**) ATS 3F Enable, (**e**) Medtronic Intact and (**f**) Carpentier-Edwards Standard.

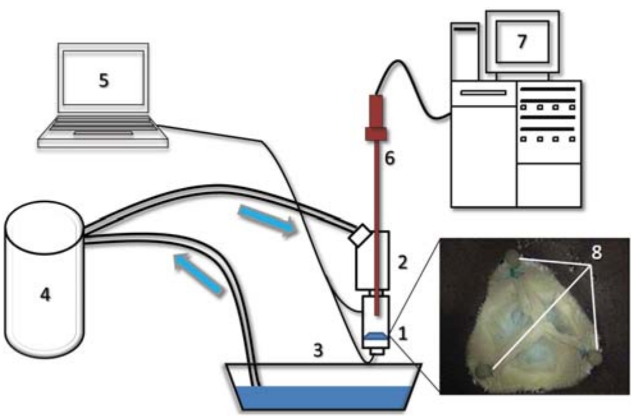

Figure 2: A schematic representation of the test set-up used in this experiment. (1) Valve-mounting chamber; (2) chamber with two ports; (3) water bath with 0.9% NaCl solution at room temperature; (4) roller pump; (5) system for real-time pressure recording; (6) endoscope; (7) endoscope 'tower'; (8) three Sonometrics probes attached at the inner sides of stent posts.

that the deformability of the two older bioprostheses differs significantly: 3.9% for Medtronic Intact and 8.7% for CE Standard (*P* <0.001). Also, the materials used as a base for stents of these two valves are different—the Medtronic valve has a stent with a polymer core, while the stent of the CE Standard valve is made of a metal alloy called Elgiloy (data from valve brochures). Nevertheless, the long-term results of both valves are equally good [3–5]. All the newer generation valves have more rigid stents when compared with the older traditional bioprosthetic valves (Table 1). Still, the long- and mid-term results of these newer valve prostheses are good [6–9]. We have also tested the ATS 3F Enable aortic valve prosthesis, which has recently become available and is used for sutureless implantation during conventional open surgery. It is made of nitinol and shares many similar design features with self-expanding transcatheter valves. Its radial deformability is 3.0 ± 0.0%, which is even more than the mean of modern standard bioprostheses. Currently, only early results of this valve are known [12, 13].

The importance of stent deformability for the field of transcatheter valves

The field of transcatheter heart valves is evolving rapidly [14]. New prostheses enter the market with stents made from various materials. Many of these stents give a subjective impression of being very rigid. Correspondingly, some concerns arise about the longevity of these prostheses, which could face problems similar to the first generation of bioprostheses. Thus, the question of a minimal required deformability for a valve stent is becoming even more important. This question is not so critical from a technical point of view when designing new traditional stented bioprostheses. Nonetheless, the use of flexible material for the stent posts is still a challenge, because of difficulties in correctly adjusting the size of the valve leaflets to avoid tissue surplus after inward motion of commissure regions. Flexible polymer materials can cause several other problems, for instance, there is a risk of stent material deformation with time, stent asymmetry etc. [1]. The situation is even more complex when designing new heart valves for transcatheter delivery, because only the radial force of their stents keeps them fixed in position at the level of the aortic annulus. Thus, rigid stents with high radial force are preferred. Unfortunately, we did not have the opportunity to test the deformability of any of the true transcatheter valves currently on the market or in clinical trials. Hence, the discussion regarding the possible longevity issues should be considered only as strictly theoretical reasoning with an unproven assumption about transcatheter valve stent rigidity. The long-term results of these prostheses might finally give an answer, whether stent deformability is of any clinical significance. This will only be possible, if data on their stent deformability is shared by their producing companies.

Table 1: Changes of radius at various tested pressure levels (*R*-radius, mean value ± standard deviation)

Transvalvular pressure gradient (mmHg)	*R* at the level of commissures (mm)			Increase of *R* (%) from diastole to systole
	0–10 (systole)	70–90 (diastole)	120–140	
Edwards CES (1987)	7.99 ± 0.00	7.35 ± 0.01	7.20 ± 0.02	8.71 ± 0.02
Medtronic Intact (1988)	7.24 ± 0.02	6.97 ± 0.01	6.85 ± 0.02	3.87 ± 0.02
Medtronic Hancock II	10.24 ± 0.03	9.96 ± 0.03	9.78 ± 0.01	2.82 ± 0.03
Sorin Soprano	10.37 ± 0.01	10.07 ± 0.04	9.95 ± 0.03	2.99 ± 0.02
St. Jude Epic	8.76 ± 0.00	8.66 ± 0.02	8.65 ± 0.02	1.18 ± 0.01
ATS 3F Enable	11.66 ± 0.03	11.32 ± 0.01	11.13 ± 0.02	3.00 ± 0.03
Transvalvular pressure gradient (mmHg)	0–10	70–90 (diastole)	120–140 (systole)	
Native aortic root	11.64 ± 1.73	14.38 ± 3.17	15.37 ± 3.01	7.30 ± 2.57

Minimum stent deformability required

There are bioprostheses including the tested St. Jude Epic showing only 1.2% deformability with good long-term clinical results [6]. In addition, this is a prosthesis that has never been reported to suffer from commissural dehiscence even in the mitral position, despite its rigid stent [15]. Meanwhile, CES, Medtronic Intact and Hancock II, all have been previously reported to suffer the rare cases of commissural dehiscence [16–18]. This fact further supports the assumption that most likely stent post flexibility is not a critical issue for bioprosthetic valve longevity. The poor results of the first-generation bioprostheses must be explained by other differences in prosthesis design. One of the most important flaws might have been the combined use of rigid stents and high-pressure fixed, stiffer valve leaflets [19]. Keeping this in mind, and considering the hypothesis, that there is no direct kinetic involvement of the commissural region of the native aortic root in dampening the stress on valve leaflets, we could cautiously claim that stent post deformability is a non-critical factor. Based on our results, stent post deformability of 1.2% is sufficient to warrant bioprosthetic valve durability at least for some xenoaortic bioprostheses (i.e. the St. Jude Epic). This value certainly might be different for xenopericardial prostheses, because their material properties are different. From our tested prostheses, only the Sorin Soprano is xenopericardial, with a measured deformability of 3.0%.

Study limitations

It has to be noted that only a single valve per bioprosthesis type has been tested, albeit several times, due to limited availability. This precludes the evaluation of material deformability among the various copies of a specific prosthesis model.

Due to the pseudo-static nature of our test, the actual maximum inward deformation values of stent posts, which most likely appear at the very onset of diastole, might have been missed.

The radius calculated here does not strictly fit the dimensions of the actual porcine aortic root, but only the circle circumscribed around the three sonomicrometry probes. It is well known that the aortic root at the level of the sinuses of Valsalva and the sinotubular junction corresponds more to an epitrochoid with $R = 3r$ [20, 21] than to a circle.

CONCLUSIONS

The older bioprostheses were made with more deformable stents when compared with modern bioprostheses.

According to our data, the radial deformability of bioprosthetic valve stent posts can be as low as 1.2 and 3.0% for some of the xenoaortic and xenopericardial prostheses, with no compromise of valve durability.

Although our results suggest that valve stent post deformability might not be of critical importance, a concrete answer to the question of the significance of stent deformability for valve durability can be obtained only by acquiring the long-term follow-up results for valve prostheses with rigid stents.

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Conflict of interest: none declared.

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