Stentless aortic valves. Current aspects

J. Ennker[1], A. Albert[2], I.C. Ennker[1]

[1]Mediclin Heart Institute Lahr/Baden, Lahr, Germany; [2]University of Düsseldorf, Düsseldorf, Germany

HSR Proceedings in Intensive Care and Cardiovascular Anesthesia 2012; 4(2): 77-82

ABSTRACT

The design of stentless valve prostheses is intended to achieve a more physiological flow pattern and superior hemodynamics in comparison to stented valves. First - generation stentless bioprosthesis were the Prima valve, the Freestyle valve and the Toronto stentless porcine valve. The second generation of stentless valves, as the Super stentless aortic porcine valve, need only one suture line. The Sorin Pericarbon Freedom and the Equine 3F heart Valve belong to the third generation of stentless valve pericardial bioprostheses. A stentless valve to replace a full root can be implanted by several surgical techniques: complete or modified subcoronary, root inclusion and full root. The full root technique is accompanied by the lowest incidence of patient-prothesis mismatch. Our own clinical experience reflects more than 3000 stentless valve implantations since April 1996. Randomized study trials showed a hemodynamic advantage for stentless valves, but several could not reach a significant level. Also reported was a significant advantage of stentless bioprostheses concerning transvalvular gradients, effective valve area and quicker regression of the left ventricular mass 6 months after the operation, but not at 12 months. Advantages are obvious in patients with a decreased left ventricle ejection fraction of less than 50% and in smaller implanted valve size, concomitant aortic root pathology (e.g. dissection) and aortic valve endocarditis. A survival advantage for stentless bioprostheses in comparison to stented ones has been reported by studies in the literature. Stentless valves enrich the surgical armamentarium. Time will define the place of stentless valves in the future.

Keywords: *stentless, subcoronary, full root technique.*

Presented at the 2nd Expert Forum of the Roland Hetzer International Cardiothoracic and Vascular Surgery Society, 11 February 2012, Freiburg, Germany

INTRODUCTION

During the early 1990s the concept of stentless valves came into use after homografts for aortic valve replacement were employed as the first biologic stentless prostheses. They were designed to optimize hemodynamics. For this purpose they avoided the obstructive stent and sewing cuff present in conventional stentless biological valves. The latter may increase the risk of valve prosthesis-patient mismatch, accompanied by higher transprosthetic gradients and a reduced effective orifice area, resulting in less regression of left ventricular hypertrophy and decreased survival (1, 2).

The structure of stentless valve prostheses is intended to achieve a more physiological flow pattern in comparison to stented valves. In addition to this, an improved postoperative coronary flow was reported in stentless bioprostheses in comparison to

Corresponding author:
Prof. Dr. med. Jürgen Ennker
Medical Director
Department of Cardiothoracic and Vascular Surgery
MediClin Herzzentrum Lahr/Baden
Lahr, Germany
e-mail: juergen.ennker@mediclin.de

stented bioprostheses after valve replacement for aortic stenosis (3).

Types of stentless valves *(Table 1)*
First-generation stentless bioprostheses were the Prima valve (Edwards Lifesciences LLC, Irvine, California, USA) and the Freestyle valve as well as the Toronto stentless porcine valve (St Jude Medical Inc. St. Paul, Minnisota, USA). The Medtronic freestyle aortic root bioprosthesis for example is tailored of a porcine aortic root fixated in glutaraldehyde solution under net zero difference pressure at the leaflets and treated with the anticalcification alpha-aminooleic acied agent to maintain the natural leaflet structure and reduce structural valve failure generated by calcification. Stentless valves of the second generation need only one suture line; here the tip of each commissure is fixed to the aortic wall, which leads to an advantage in the case of calcified aortic wall. An example is the Shelhigh Super stentless aortic porcine valve (Shelhigh Inc., Union, New Jersey, USA). The bovine Sorin Pericarbon Freedom and the equine 3F heart valve belong to the third generation of stentless valve pericardial bioprostheses.
The ATS 3 F aortic valve prosthesis continues to perform with satisfactory hemodynamic results, comparable to those of other pericardial valves. With minimal structural adverse events, the prosthesis demonstrates excellent intermediate intern clinical results and – today – is proving to be durable (4).
Another stentless valve is the Pericarbon Freedom stentless bioprosthesis. This valve provides excellent results concerning left ventricular mass regression, hemodynamics and early clinical outcome. A trend towards a better hemodynamic performance of the continuous suture technique was observed. However, the authors concluded that further evaluation is required (5).
New-generation sutureless stentless valves such as the Trilogy valve (6) or the 3F Enable Valve (7) are using the concept of the technique of transcatheter aortic valve implantation to anchor the valve in the aortic annulus. The authors recommend the more simple and rapid mode of implantation in comparison to that for traditional stented valves.

Techniques of implantation
A stentless valve to replace a full root can be implanted by several surgical techniques: complete or modified subcoronary, root inclusion and full root. In the case of the subcoronary technique all porcine sinuses are excised, with the exception of the noncoronary sinus in the so-called modi-

Table 1 - *Stentless bioprostheses.*

Type of prosthesis	Material
Medtronic Freestyle (Medtronic Inc., Minneapolis, Minnesota, USA)	porcine
Edwards Prima/Plus (Edwards Lifesciences LLC, Irvine, California, USA)	porcine
Toronto SPV/Root (St. Jude Medical Inc., St. Paul, Minnesota, USA)	porcine
CryoLife-O'Brien (CryoLife International Inc., Kennesaw, Georgia, USA)	porcine,
Sorin Pericarbon Freedom/Solo (Sorin Biomedica Cardio, Saluggia, Vercelli, Italy)	bovine, pericardial
Shelhigh Superstentless/Bioconduit (Shelhigh Inc., Union, New Jersey, USA)	porcine
3F Aortic Bioprosthesis (3F Therapeutics, Lake Forest, California, USA)	equine
Biocor PSB Stentless (Biocor Industria e Pesquisa Ltda, Belo Horizonte, Brazil)	porcine

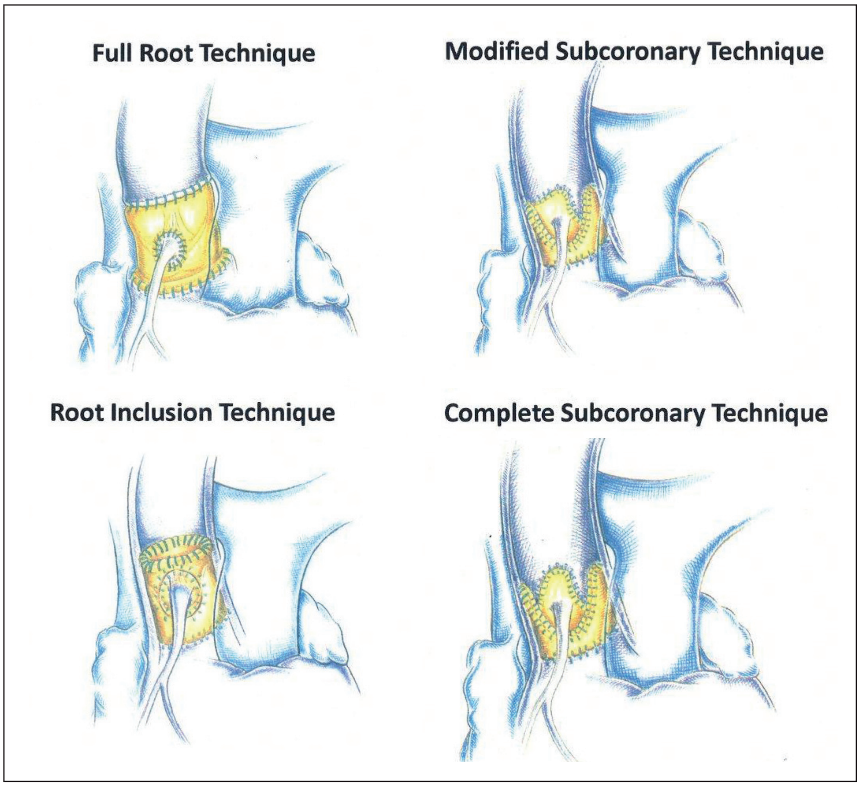

Figure 1
Techniques of implantation.

fied subcoronary technique. Root inclusion and full root technique require reimplantation of the coronary ostia (8, 9) (*Figure 1*).
Stentless valves for the subcoronary technique in patients with normal root dimensions should be neither under- or oversized. Only in the case of a planned full root technique may oversizing be justified. The size of the prosthesis can be chosen one or two valve sizes greater than the size of the aortic annulus.
Problems increasing the risk of higher mean pressure gradients postoperatively and thereby eliminating one of the advantages of stentless valves are: aortotomy too low, deviation from the virtual plane defined by the nadirs when constructing the proximal suture line, anatomical variations of the location of the coronary ostia (situated close to the annulus or commissure) and disproportion between intercommissural length of the stentless valve and the patient's annulus (as in the case of a larger noncoronary sinus of the patient). A comparison of different implantation techniques for porcine stentless bioprostheses reported better hemodynamics, functional class and freedom from regurgitation with a full root in comparison to a subcoronary implantation technique. In consequence to this, the full root technique is accompanied by the lowest incidence of patient-prosthesis mismatch (10).
The advantages of stentless valves, especially when using a full root technique, may be traded against greater technical complexity of the operation with longer cardiopulmonary bypass and cross-clamp times compared to those for stented valves. So, despite proper training and the development of routines, many surgeons are reluctant to perform the total root technique

(or stentless valve implantation at all) due to the known difficulties of this technique and the fear of bleeding and coronary complications, especially in the elderly.

Indication

Stentless valves can also be implanted for special indications, such as concomitant replacement of the ascending aorta in patients with aneurysmal enlargement of the aorta or acute and chronic dissection with low perioperative mortality and acceptable late survival in a predominantly elderly population (11).

Others used stentless valves in patients with acute aortic valve endocarditis and found a promising low rate of reinfection (12). Stentless valves were also reported to have comparable results to stented ones in octogenarians (13).

In patients with a small aortic root, stentless valves are beneficial because they generate a smaller transvalvular gradient and an enlarged orifice area. A 19 mm stentless valve implanted with a total root technique, offers a hemodynamic performance comparable to that of a 23 mm or even larger stented prosthesis (14). Thus, the excellent hemodynamic result contributes to a positive perioperative outcome and even long-term results. In consequence of the improved hemodynamics, stentless prostheses were found to be of advantage in patients with severely impaired left ventricular function (15). The decreased risk of reoperation allows the implantation in younger patients under 60 years old, if the patient so wishes.

Our own experience

Our own clinical records exceed 3000 stentless valve implantations using the Medtronic Freestyle valve in a time span starting in April 1996 (16- 18). The positive experience with this valve led to usage of over 80% for all our aortic valve procedures, while the senior surgeon did not implant a single stented valve in the last 5 years in isolated aortic valve procedures. Again, more than 80% of Freestyle valve implantations were performed using the subcoronary technique. During the last years the modified subcoronary technique was favored, as hereby - due to the preservation of the noncoronary sinus - the distance between two commissures is defined, leading to a very secure mode of implantation and diminishing the incidence of bulging or distended leaflets due to technical errors. When using the Freestyle valve as a root, the full root technique used until recently was exchanged for the root inclusion technique in patients with friable tissue and concomitant root enlargement. This technique eliminates any dislocation, especially of the right coronary ostium, which may be facilitated when freeing the ostia for reimplantation in the full root technique.

Valve in valve implantation in stentless valves

Valve-in-valve implantation for the treatment of aortic valve dysfunction has been described as an option for inoperable patients. The presence of a small bioprosthesis is associated with increased perivalvular gradients and diminished aortic valve orifice area, thus reducing the prospect of an adequate long-term postoperative outcome. The valve-in-valve implantation technique was used to overcome severe paravalvular regurgitation in Freestyle bioprostheses (19).

Rodés-Cabau J. et al. described a valve-in-valve procedure for a failed 23 mm Freestyle valve (Medtonic Inc., Minneapolis, Minnesota, USA) using a 23 mm FS Sapien valve (Edwards Lifesciences, Inc. Irvine, California, USA). They pointed out that, due to the lack of appropriate angiographic markers, the procedure was mainly guided by transesophageal echocardiography (TEE), thus demonstrating the feasibility of transcatheter aortic valve implantation (TAVI) for the treatment of structure deterioration of a stentless aortic bioprosthesis. The possibility of this technique underlines the indication for using stentless valves in patients with a small aortic root, as a valve of larger size can be implanted later in the case of pending or existing valve deterioration (20).

Follow-up data

Stentless aortic valves should have better durability by avoiding stress at the stent sites - theoretically. However, valve failure led to a substantial rate of reoperation in the Toronto valve (Borger) which was consequently taken off the market (21). Shorter durability compared to stented valves was also reported for the Cryolife O'Brian valve (CryoLife International Inc., Kennesaw, Georgia, USA) and the Carpentier-Edwards Perimount Valve (22), while the rate of freedom from structural valve degeneration of the Freestyle valves was 97% at 10 years (23) which was equivalent to that of stented valves. Cusp tear with resulting aortic insufficiency was the most common cause of valve failure.

The results of randomized study trials revealed controversial results concerning the superiority of stentless valves in comparison to stented valves. Most of them showed a hemodynamic advantage for stentless valves, but several could not reach a significant level. Randomized trials show a significant advantage of stentless bioprostheses concerning transvalvular gradients, effective valve area and quicker regression of the left ventricular mass 6 months after the operation, but at 12 months the results were the same. Advantages are obvious in patients with a decreased left ventricle (LV) ejection fraction of less than 50% and in smaller implanted valve size (24).

A survival advantage for stentless bioprostheses in comparison to stented ones has been reported by several studies (25) in the literature, while others did not come to the same conclusion (26).

CONCLUSION

Stentless valves enrich the surgical armamentarium for the treatment of aortic valve pathology.

They have advantages if implanted in special indications such as depressed left ventricular function, small aortic root or root disease, acute or chronic dissection or aneurysm formation.

The possibility to implant a larger valve in a given aortic diameter in comparison to traditional stented valves leads to a decreased incidence of patient-prosthesis mismatch. A longer time span has to be analyzed to evaluate if the expected advantage of longevity due to decreased stress at the leaflet level will translate into longer valve durability. In this regard a twenty year follow-up time will be available for the Medtronic Freestyle valve in two years and will give an answer at least for this stentless valve.

Time also will tell where the competition by modern technology stented valves, sutureless valves and TAVI procedures will place stentless valves in the future.

REFERENCES

1. Albert A, Florath I, Rosendahl U, et al. The late impact of surgical skills and training on the subcoronary implantation of the Freestyle Stentless Bioprosthesis. J Heart Valve Dis 2010; 19: 104-114.
2. Albert A, Florath I, Rosendahl U, et al. Effect of surgeon on transprosthetic gradients after aortic valve replacement with Freestyle stentless bioprosthesis and its consequences: A follow-up study in 587 patients. J Cardiothorac Surg 2007; 2: 40.
3. Bakhtiary F, Schiemann M, Dzemali O, et al. Stentless bioprostheses improve postoperative coronary flow more than stented prostheses after valve replacement for aortic stenosis. J Thorac Cardiovasc Surg 2006; 131: 883-8.

4. Linneweber J, Heinbokel T, Christ T, et al. Clinical experience with the ATS 3F stentless aortic bioprosthesis: five years' follow up. J Heart Valve Dis 2010; 19: 772-7.
5. D'Onofrio A, Mazzucco A, Valfrè C, et al. Left ventricular remodelling, hemodynamics and early clinical outcomes after aortic valve replacement with the Pericarbon Freedom stentless bioprosthesis: results form the Italian Prospective Multicenter Trial. J Heart Valve Dis 2011; 20: 531-9.
6. Breitenbach I, Wimmer-Greinecker G, Bockeria LA, et al. Sutureless aortic valve replacement with the Trilogy aortic valve system: multicenter experience. J Thorac Cardiovasc Surg 2010; 140: 878-84.
7. Martens S, Ploss A, Sirat S, et al. Sutureless aortic valve replacement with the 3f enable aortic bioprosthesis. Ann Thorac Surg 2009; 87: 1914-17.
8. Ennker JA, Albert AA, Rosendahl UP, et al. Ten-year experience with stentless aortic valves: Full-root versus subcoronary implantation. Ann Thorac Surg 2008; 85: 445-52; discussion 452-3.
9. Kon ND, Westaby S, Amarasena N, et al. Comparison of implantation techniques using the Freestyle stentless porcine aortic valve. Ann Thorac Surg 1995; 59: 857-62.
10. Florath I, Albert A, Rosendahl U, et al. Impact of valve prosthesis-patient mismatch estimated by echocardiographic-determined effective orifice area on long-term outcome after aortic valve replacement. Am Heart J 2008; 155: 1135-42.
11. Pagni S, Slater AD, Trivedi JR, et al. Proximal thoracic aortic replacement for aneurismal disease using the freestyle stentless bioprosthesis: a 10-year experience. Ann Thorac Surg 2011; 92: 873-9.
12. Musci M, Siniawski H, Pasic M, et al. Surgical therapy in patients with active infective endocarditis: seven-year single centre experience in a subgroup of 255 patients treated with the Shelhigh stentless bioprosthesis. Eur J Cardiothorac Surg 2008; 34: 410-17.
13. Ennker J, Dalladaku F, Rosendahl U, et al. The stentless Freestyle Bioprosthesis: Impact of age over 80 years on quality of life, preoperative and mid-term outcome. J Card Surg 2006; 21: 379-85.
14. Fries R, Wendler O, Schieffer H, et al. Comparative rest and exercise hemodynamics of 23-mm stentless versus 23-mm stented aortic bioprostheses. Ann Thorac Surg 2000; 69: 817-22.
15. Gulbins H, Reichenspurner H. Which patients benefit from stentless aortic valve replacement? Ann Thorac Surg 2009; 88: 2061-8.
16. Albert A, Florath I, Rosendahl U, et al. The late impact of surgical skills and training on the subcoronary implantation of the Freestyle Stentless Bioprosthesis. J Heart Valve Dis 2010; 19: 104-14.
17. Albert A, Florath I, Rosendahl U, et al. Effect of surgeon on transprosthetic gradients after aortic valve replacement with Freestyle stentless bioprosthesis and its consequences: A follow-up study in 587 patients. J. Cardiothorac Surg 2007; 2: 40
18. Ennker JA, Albert AA, Rosendahl UP, et al. Ten-year experience with stentless aortic valves: Full-root versus subcoronary implantation. Ann Thorac Surg 2008; 85: 445-452; discussion 452-3.
19. Ng AC, van der Kley F, Delgado V, et al. Percutaneous valve-in-valve procedure for severe paravalvulär regurgitation in aortic bioprosthesis. JACC Cardiovasc Imaging 2009; 2: 522-3.
20. Rodés-Cabau J, Dumont E, Doyle D, et al. Transcatheter valve-in-valve implantation for the treatment of stentless aortic valve dysfunction. J Thorac Cardiovasc Surg 2010; 140: 246-8.
21. Borger MA, Parasongsukarn K, Armstrong S, et al. Stentless aortic valve reoperations: a surgical challenge. Ann Thorac Surg 2007; 84: 737-43.
22. Kobayashi J. Stentless aortic valve replacement: an update. Vasc Health Risk Manag. 2011; 7: 345-51.
23. Bach DS, Kon ND, Dumesnil, et al. Ten-year outcome after aortic valve replacement with the Freestyle stentless bioprosthesis. Ann Thorac Surg 2005; 80: 480-86
24. Kobayashi J. Stentless aortic valve replacement: an update. Vasc Health Risk Manag. 2011; 7: 345-51.
25. Lehmann S, Walter T, Kempfert J, et al. Stentless versus conventional xenograft aortic valve replacement: midterm results of a prospectively randomized trial. Ann Thorac Surg 2007; 84: 467-72.
26. Kobayashi J. Stentless aortic valve replacement: an update. Vasc Health Risk Manag. 2011; 7: 345-51.

Cite this article as: Ennker J, Albert A, Ennker IC. Stentless aortic valves. Current aspects. HSR Proceedings in Intensive Care and Cardiovascular Anesthesia 2012; 4 (2): 77-82

Source of Support: Nil. **Conflict of interest:** None declared.

Acknowledgements: We thank Anne Gale for carefully copy-editing the manuscript.