SUMMARY OF CLINICAL DATA

TRIFECTA™ VALVE
CLINICAL INSIGHTS

Abbott

TRIFECTA AORTIC BIOPROSTHESIS ACHIEVES 8-YEAR DURABILITY WITH SURVIVAL BENEFIT

- 8-year data show a low rate of surgical explant and transcatheter valve-in-valve intervention due to SVD[1,2]
- 8-year data show improved survival with excellent freedom from valve-related mortality[1,2]
- Low rate of SVD and improved survival may be attributed to excellent hemodynamic performance and option to perform valve-in-valve intervention[5-9]

PERSPECTIVE

The Trifecta valve became commercially available in 2010 and now has two studies[1,2] demonstrating 8-year durability with a low rate of structural valve deterioration (SVD). More than 200,000 Trifecta series valves have been implanted worldwide since 2010 with many patients benefiting from an improved survival while experiencing a low rate of SVD.[1,2] A next-generation Trifecta valve (Trifecta GT) was introduced in 2016 that has additional features to enhance valve implantability and durability.[3]

KEY MESSAGES

Trifecta valve has a low rate of SVD[1,2] with improved survival at 8-years compared to historical data with a legacy stented tissue valve:

- 78.5% freedom from all-cause mortality with Trifecta compared to 65.4%[‡] with CE PERIMOUNT[1,4]
- Excellent hemodynamic performance of Trifecta valve with low rate of severe prosthesis-patient mismatch (PPM) influences survival and durability benefit[5-9]

[‡]Result at 8 years was graphically estimated from published study data.[4]

TRIFECTA LONG-TERM FOLLOW-UP (LTFU) STUDY[1]

STUDY DESIGN AND METHODS

Prospective, multicenter (N=11 in USA and Canada), non-randomized study:[10]

- Independent clinical events adjudication committee
- Kaplan-Meier survival analysis
- Competing risk analysis

PATIENT POPULATION

710 patients underwent surgical AVR with the Trifecta valve between 2007 and 2009:

- Mean age was 72.4 ± 9.3 years
- 66% male
- 58% had concomitant procedures

KEY RESULTS

Survival [Figure 1]:

- 1.5% all-cause mortality at 30-day
- 78.5% freedom from all-cause mortality at 8 years
- 99.0% freedom from valve-related mortality at 8 years

Durability [Figure 2]:

- 94.1% freedom from surgical explant due to SVD at 8 years
- 95.9% freedom from transcatheter valve-in-valve intervention due to SVD at 8 years
- 90.2% freedom from surgical explant or transcatheter valve-in-valve intervention due to SVD at 8 years

Competing Risk [Figure 3]:

- 69.5% probability of survival without requiring a surgical explant or a transcatheter valve-in-valve intervention at 8 years
- 4.9% probability of surgical explant due to SVD at 8 years

Figure 1: Trifecta LTFU Survival

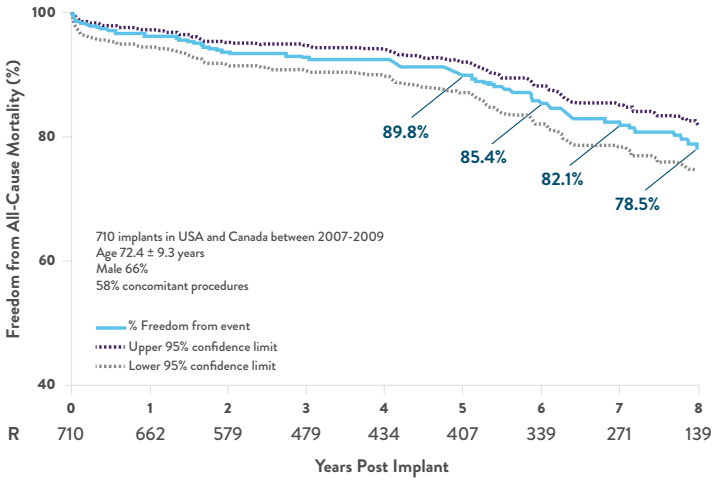
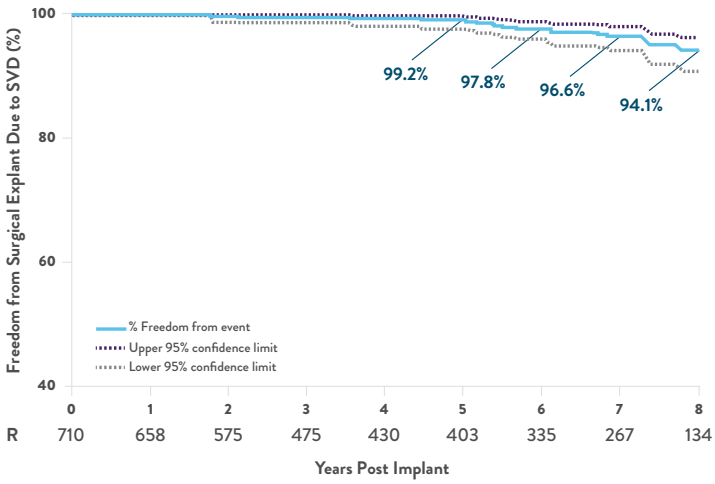


Figure 2: Trifecta LTFU Durability



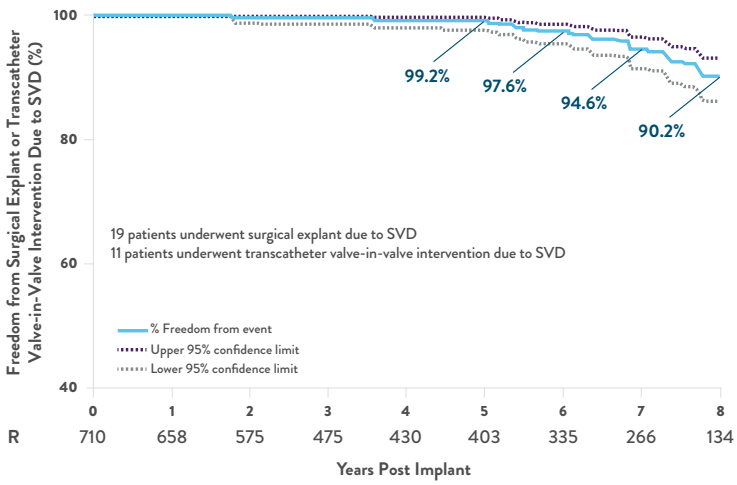
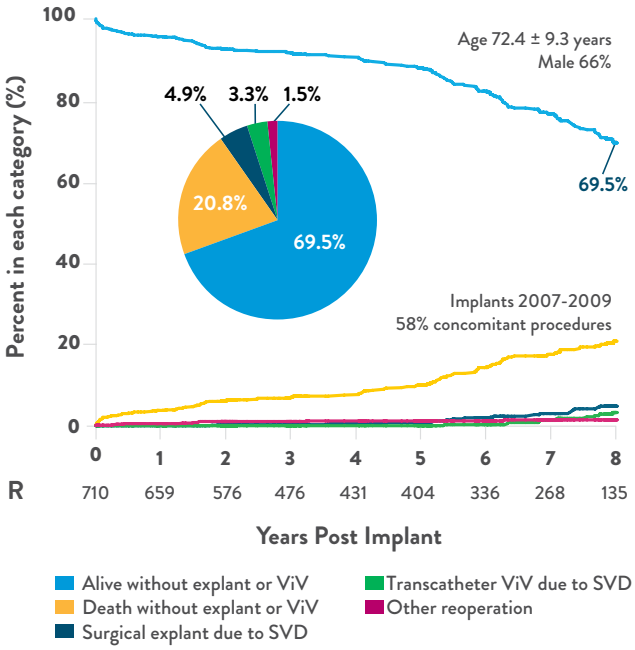


Figure 3: Trifecta LTFU Competing Risks



LEIPZIG UNIVERSITY TRIFECTA STUDY[2]

STUDY DESIGN AND METHODS

Retrospective, single center, non-randomized study[11]:

- Kaplan-Meier survival analysis

PATIENT POPULATION

1,172 patients underwent surgical AVR with a Trifecta or Trifecta GT valve between 2007 and 2017:

- Mean age was 73.4 ± 6.5 years
- 54% male
- 57% had concomitant procedures
- Logistic EuroSCORE was 13.2 ± 14.6

KEY RESULTS

Survival:

- 2.8% all-cause mortality at 30-day
- 77.0% freedom from all-cause mortality at 8 years

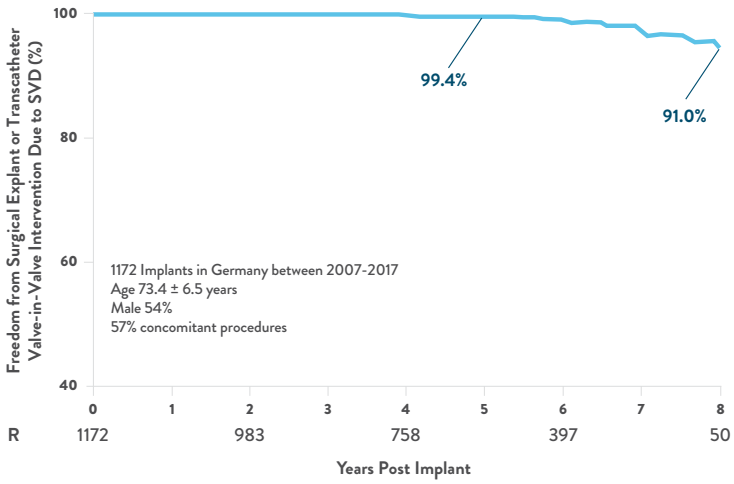
Durability [Figure 4]:

- 91.0% freedom from surgical explant or transcatheter valve-in-valve intervention due to SVD at 8 years

Minimally Invasive AVR Subgroup (N=230):

- 98.7% freedom from surgical explant or transcatheter valve-in-valve intervention due to SVD at 8 years[12]

Figure 4: Trifecta Leipzig Study Durability



CE PERIMOUNT POST APPROVAL COHORT[4,13]

STUDY DESIGN AND METHODS

Prospective, multi-center (N=4 in USA), non-randomized study:

- Kaplan-Meier survival analysis
- Competing risk analysis

PATIENT POPULATION

267 patients underwent surgical AVR with the Carpentier-Edwards PERIMOUNT valve (Model 2700) between September 1981 and December 1983:

- Mean age was 64.9 ± 11.8 years
- 64% male
- 46% had concomitant procedures

KEY RESULTS*

Survival:

- 4.9% all-cause mortality at 30-day
- 65.4% freedom from all-cause mortality at 8 years
- 92.3% freedom from valve-related mortality at 8 years

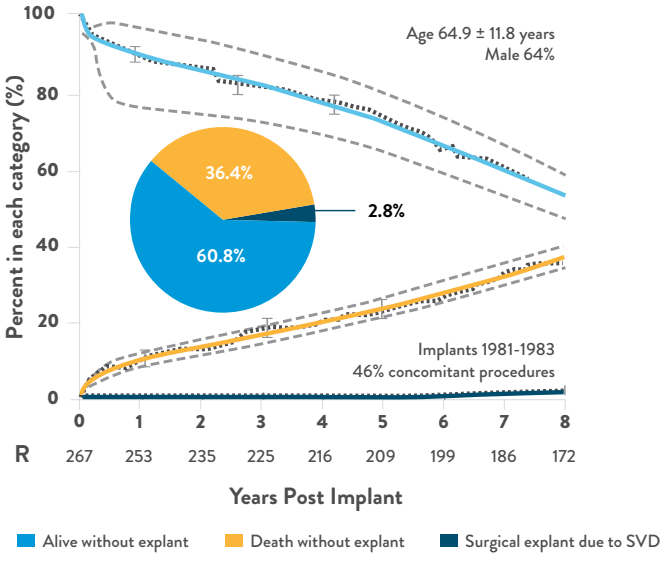
Durability:

- 97.3% freedom from surgical explant due to SVD at 8 years
- 91.9% freedom from valve dysfunction at 8 years

Competing Risk [Figure 5]:

- 60.8% probability of survival without surgical explant at 8 years
- 2.8% probability of surgical explant due to SVD at 8 years

Figure 5: CE Perimount Post-Approval Study Competing Risks[+]



CLEVELAND CLINIC CE PERIMOUNT STUDY[8]

STUDY DESIGN AND METHODS

Retrospective, single center, non-randomized study:

- Competing risk analysis

PATIENT POPULATION

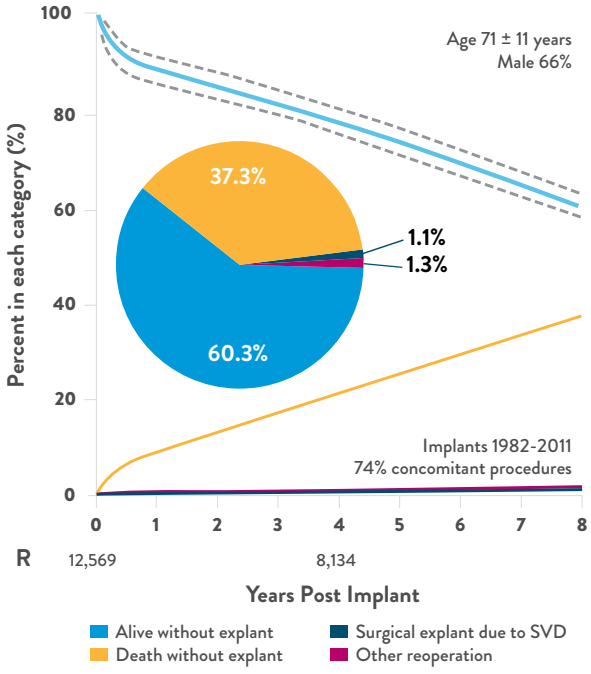
- 12,569 patients underwent surgical AVR with the Carpentier-Edwards PERIMOUNT valve (Model 2700PM and 2700) between 1982 and 2011
- Mean age was 71 ± 11 years
- 66% male
- 74% had concomitant procedures

KEY RESULTS*

Competing Risk [Figure 6]:

- 60.3% probability of survival without surgical explant at 8 years
- 1.1% probability of surgical explant due to SVD at 8 years

Figure 6: CE Perimount Cleveland Clinic Competing Risks[†]



*All results reported at 8-years were graphically estimated from published study data.[4, 8, 13]

†Figure recreated from published study.[4, 8, 13]

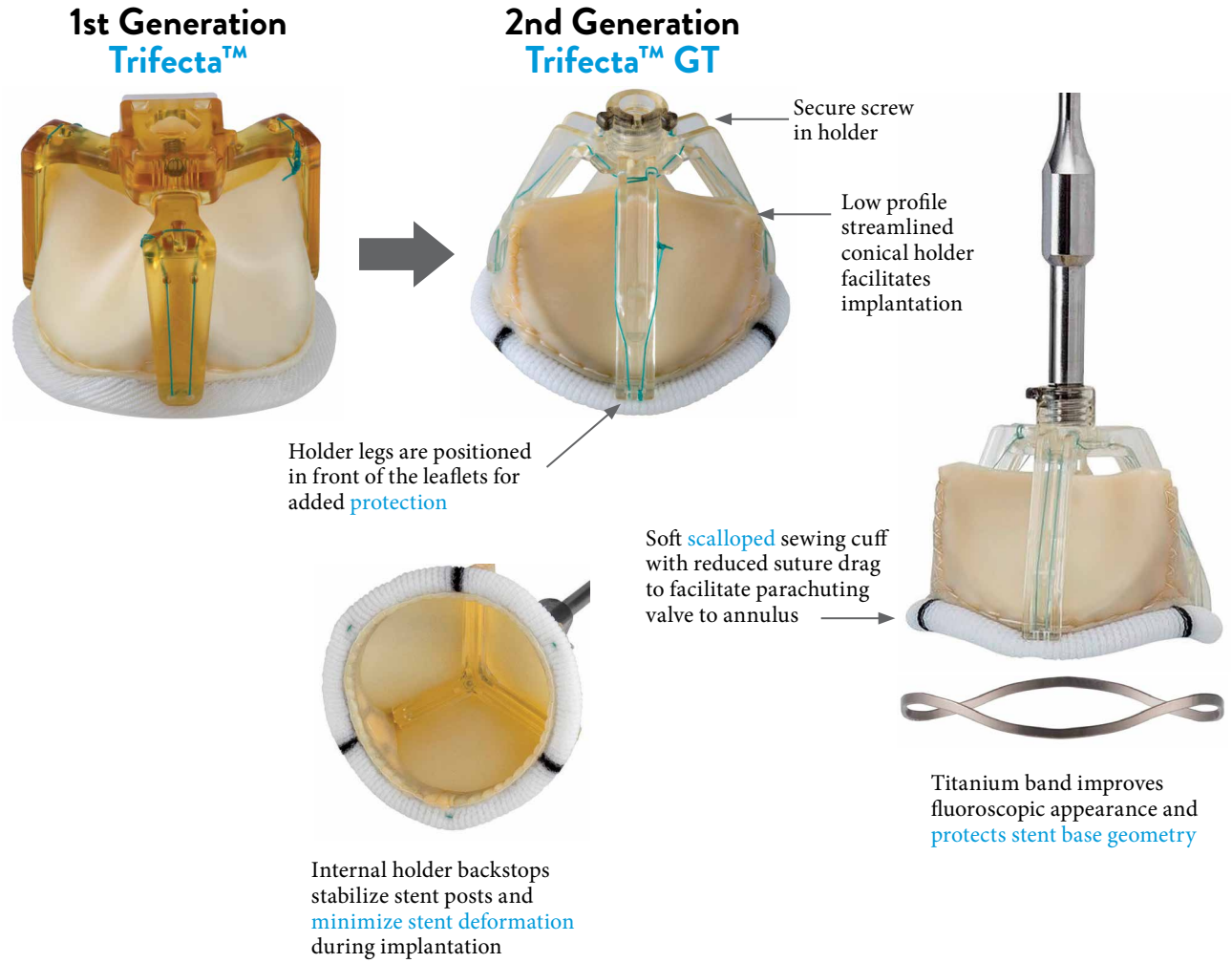
NEXT-GENERATION TRIFECTA VALVE

To ease the implant procedure and provide added protection to the stent and leaflets, a next-generation Trifecta™ valve with Glide Technology (Trifecta™ GT) was introduced into commercial use in 2016. The Trifecta GT has the following new features [Figure 7]:

- A new streamlined conical holder
- A softer sewing cuff that conforms more easily to the annulus and minimizes suture drag
- An additional titanium band around the base that provides enhanced fluoroscopic visibility and protects the stent base geometry
- A narrower leaflet suturing pattern that optimally reduces leaflet stress along the posts
- A collagen fiber alignment technology that ensures circumferential fiber alignment to maximally resist fatigue related leaflet tissue degradation

The new holder, softer sewing cuff, protective titanium band, optimal leaflet suturing pattern, and the collagen fiber alignment technology are intended to minimize the occurrence of implant-related valve failure and as a result, enhance the durability of the valve.[3,14]

Figure 7: Trifecta Valve Enhancements



COMMENTARY

The 8-year clinical outcomes presented for the Trifecta valve from two independent studies[1, 2] provide contemporary clinical study data at a time when transcatheter valve-in-valve intervention is available. Both studies demonstrate consistent results with excellent survival through 8-years of follow-up and a low rate of valve-related mortality. The improved survival may be attributed to having a valve with excellent hemodynamic performance that results in a lower rate of severe prosthesis-patient mismatch (PPM), reduced heart failure-related hospitalization, and better left ventricular mass regression.[5-7]

Additionally, the low rate of valve-related mortality may be attributed to having the option to perform a transcatheter valve-in-valve intervention which was not present in historical studies, involving legacy bioprosthetic heart valves.[4,8] Therefore, when making comparisons among various studies it is important to analyze not only the freedom from surgical explant due to SVD but also to examine the overall survival and the incidence of valve-related mortality.

CONCLUSIONS

At 8-years post-implant the Trifecta valve offers a low rate of SVD with improved survival and a low rate of valve-related mortality.[1, 2] In the absence of contemporary long-term follow-up data on newer generations of bioprosthetic heart valves, comparisons to historical studies with legacy valves are challenging. Transcatheter valve-in-valve intervention with the Trifecta valve provides an additional option in patients with SVD who are at high or prohibitive risk for a traditional surgical aortic valve explant and replacement procedure. The next generation Trifecta GT valve has additional features that are intended to make the valve easier to implant and result in improved long-term durability.

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