SUMMARY OF CLINICAL DATA

TRIFECTA™ VALVE
CLINICAL INSIGHTS

Abbott

TRIFECTA™ AORTIC BIOPROSTHESIS ACHIEVES 10-YEAR DURABILITY WITH SURVIVAL BENEFIT

- 10-year data show improved survival with excellent freedom from valve-related mortality[1,2]
- Improved survival may be attributed to excellent hemodynamic performance and the option to perform valve-in-valve (ViV) intervention[3-7]

PERSPECTIVE

The Trifecta™ valve became commercially available in 2010 and now has reached the 10-year milestone, demonstrating excellent hemodynamic performance with a low mortality rate.[1] More than 250,000 Trifecta series valves have been implanted worldwide since 2010, with many patients benefiting from an improved survival while experiencing an acceptable rate of structural valve deterioration (SVD).[1,2] A next-generation Trifecta valve (the Trifecta™ valve with Glide™ Technology (GT)) was introduced in 2016 that has additional features to enhance valve implantability and durability.[8]

KEY MESSAGES

Trifecta valve has a low rate of mortality at 10 years that is balanced by the competing risk of SVD:

- Excellent hemodynamic performance of the Trifecta valve with a low rate of severe prosthesis-patient mismatch (PPM) influences survival[3-7]
- 97.4% freedom from valve-related mortality at 10 years post-implant[1]
- 51.2% freedom from any re-intervention and all-cause mortality at 10 years post-implant, which is consistent with the rate reported for other bioprosthetic aortic valves[6,9-11]

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

STUDY DESIGN AND METHODS

Prospective, multicenter (N = 11 in the United States and Canada), non-randomized study[12]:

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

PATIENT POPULATION

710 patients underwent surgical aortic valve replacement (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 days
- 69.9% freedom from all-cause mortality at 10 years
- 97.4% freedom from valve-related mortality at 10 years

Durability (Figure 2):

- 87.3% freedom from surgical explant due to SVD at 10 years
- 75.4% freedom from surgical explant or transcatheter ViV intervention due to SVD at 10 years

Competing Risk (Figure 3):

- 51.2% probability of survival without requiring a surgical explant or a transcatheter ViV intervention at 10 years
- 9.5% probability of surgical explant due to SVD at 10 years

Figure 1: Trifecta LTFU Survival

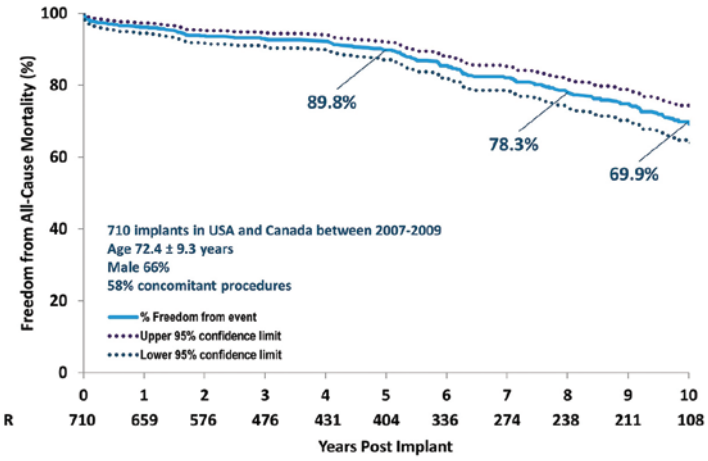
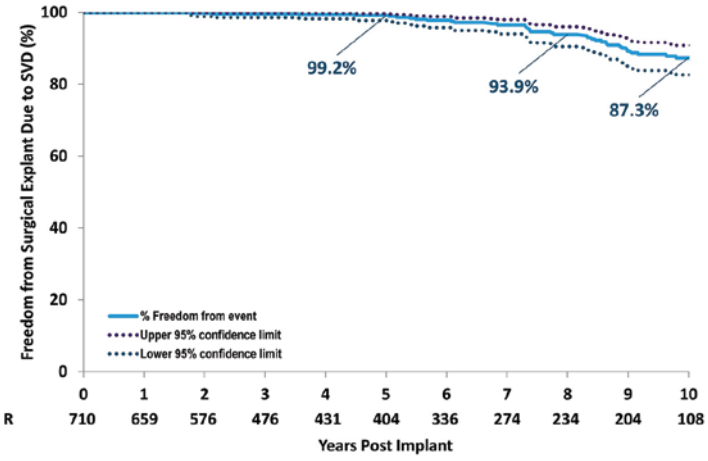


Figure 2: Trifecta LTFU Durability



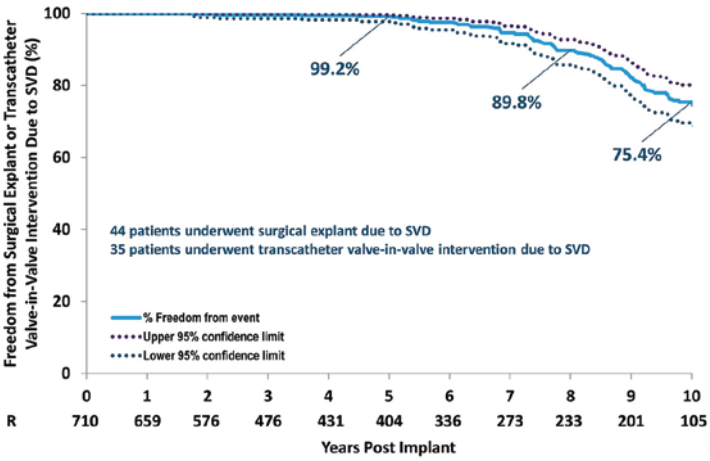
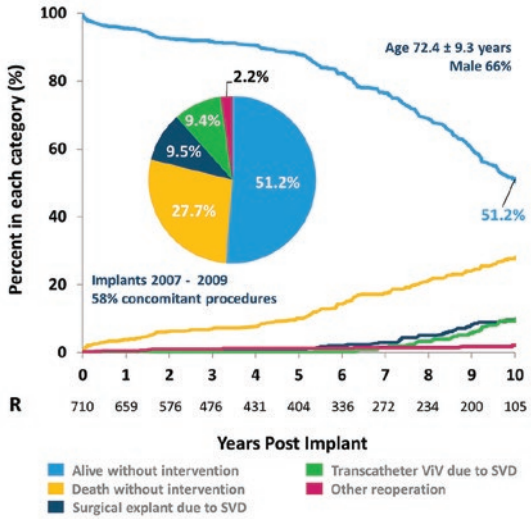
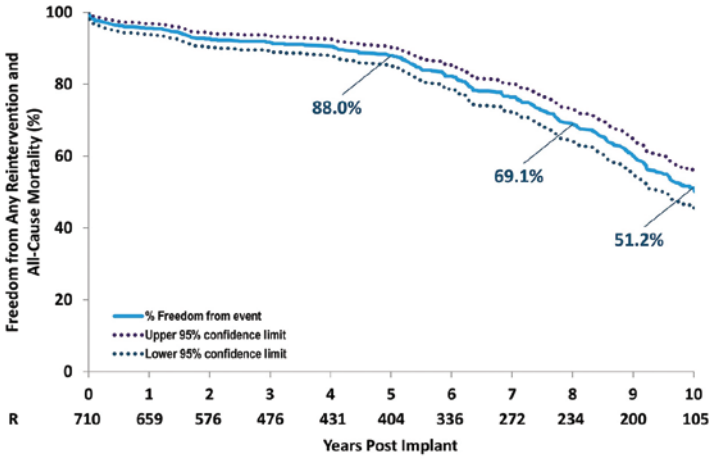


Figure 3: Trifecta LTFU Competing Risks





LEIPZIG UNIVERSITY TRIFECTA STUDY[2]

STUDY DESIGN AND METHODS

Retrospective, single-center, non-randomized study[13]:

- Kaplan-Meier survival analysis
- Competing risk analysis

PATIENT POPULATION

1,241 patients underwent surgical AVR with a Trifecta™ or Trifecta™ GT valve between 2007 and 2017:

- Mean age was 73.5 ± 6.4 years
- 54% male
- 57% had concomitant procedures
- Mean logistic EuroSCORE was 7.8 (interquartile range 4.9–15.1)

KEY RESULTS

Survival:

- 6.0% all-cause mortality at 30 days
- 78.4% freedom from all-cause mortality at 8 years

Durability (Figure 4):

- 93.3% freedom from surgical explant or transcatheter ViV intervention due to SVD at 8 years

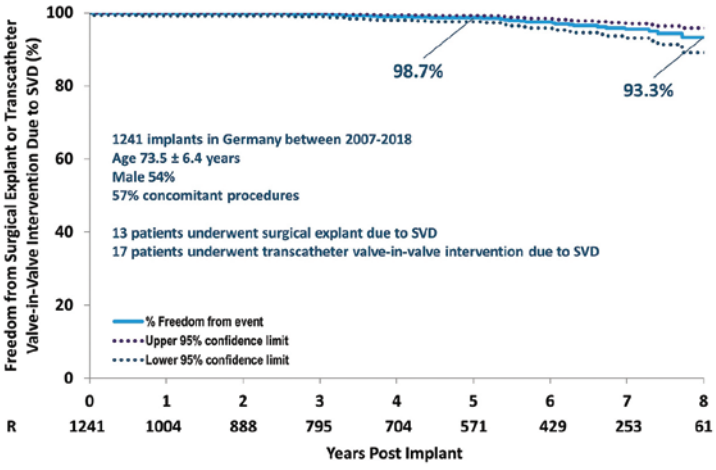
Minimally invasive AVR subgroup (N = 230):

- 98.7% freedom from surgical explant or transcatheter ViV intervention due to SVD at 8 years[14]

Competing Risk:

- 71.1% probability of survival without requiring a surgical explant or a transcatheter ViV intervention at 8 years
- 5.4% probability of surgical explant due to SVD at 8 years

Figure 4: Trifecta Leipzig Study Durability



CE PERIMOUNT‡ POST APPROVAL COHORT[9,15]

STUDY DESIGN AND METHODS

Prospective, multicenter (N = 4 in the United States), non-randomized study:

- Kaplan-Meier survival analysis
- Competing risk analysis

PATIENT POPULATION

267 patients underwent surgical AVR with the Carpentier-Edwards‡ (CE) 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 days
- 54.1% freedom from all-cause mortality at 10 years
- 90.2% freedom from valve-related mortality at 10 years

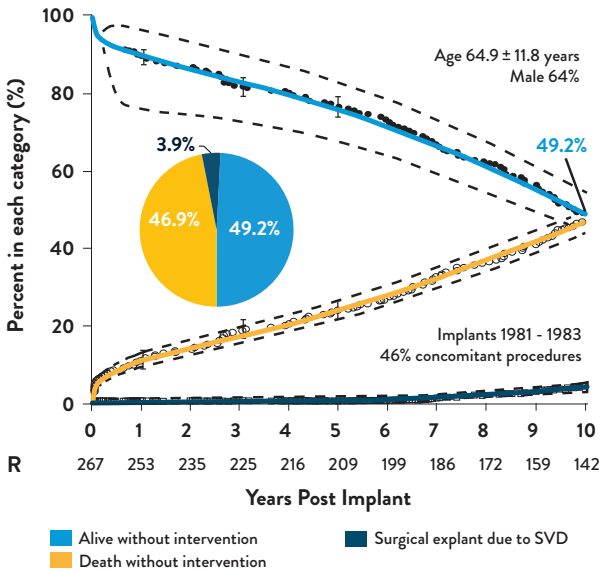
Durability:

- 93.6% freedom from surgical explant due to SVD at 10 years
- 83.8% freedom from valve dysfunction at 10 years

Competing Risk (Figure 5):

- 49.2% probability of survival without surgical explant at 10 years
- 3.9% probability of surgical explant due to SVD at 10 years

Figure 5: CE PERIMOUNT‡ Post-approval Cohort Competing Risks†



CLEVELAND CLINIC CE PERIMOUNT STUDY[6]

STUDY DESIGN AND METHODS

Retrospective, single-center, non-randomized study:

- Competing risk analysis

PATIENT POPULATION

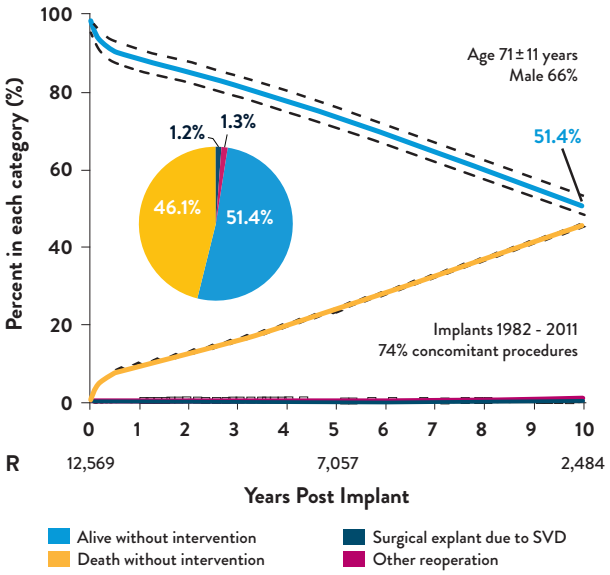
- 12,569 patients underwent surgical AVR with the CE PERIMOUNT valve (Models 2700PM and 2700) between 1982 and 2011
- Mean age was 71 ± 11 years
- 66% male
- 74% had concomitant procedures

KEY RESULTS*

Competing risk (Figure 6):

- 51.4% probability of survival without surgical explant at 10 years
- 1.2% probability of surgical explant due to SVD at 10 years

Figure 6: CE PERIMOUNT Cleveland Clinic Competing Risks†



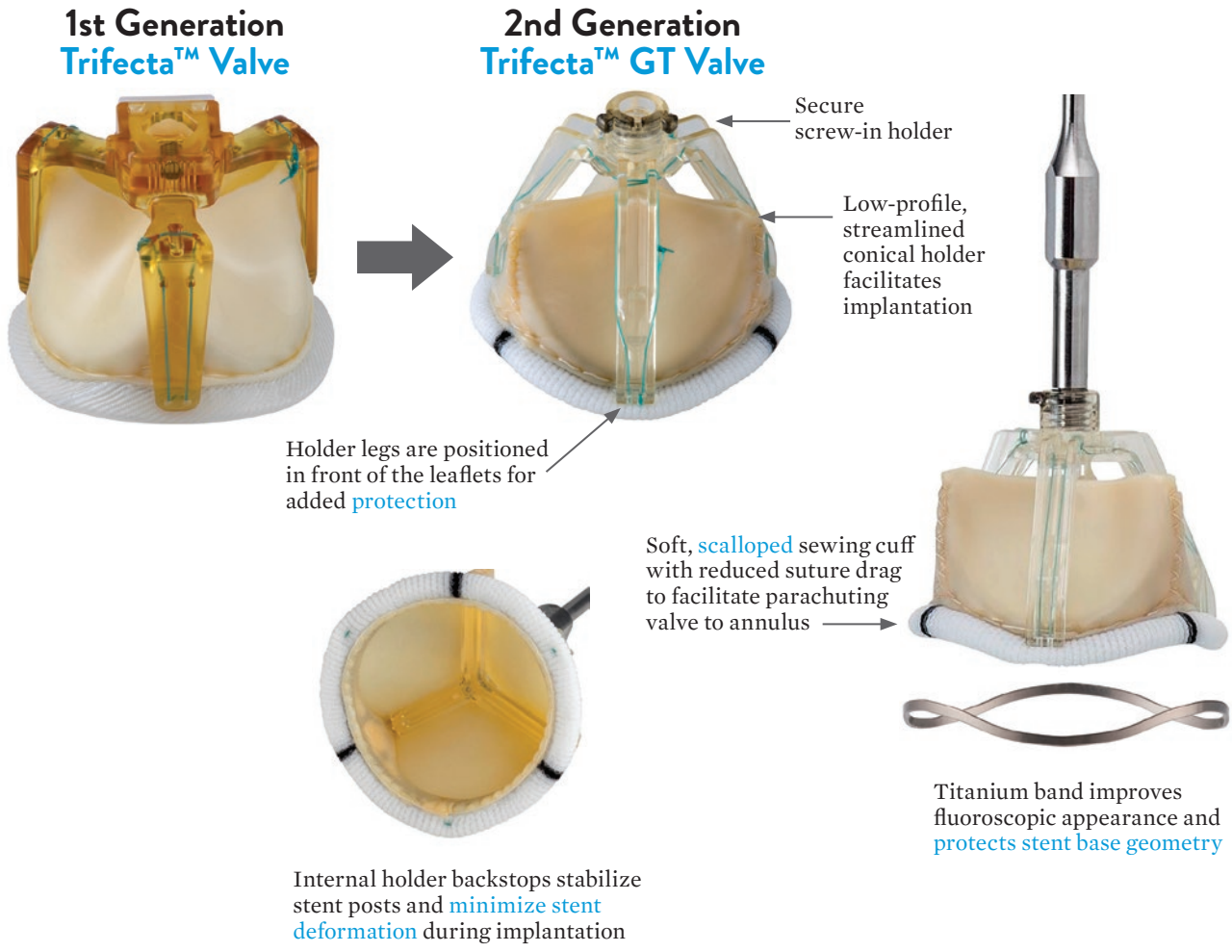
NEXT-GENERATION TRIFECTA™ VALVE

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

- A streamlined holder with legs positioned in front of the leaflets for added protection during valve insertion and knot tying
- Internal backstops within the holder to protect the stent posts from deforming during valve insertion
- A softer sewing cuff that conforms more easily to the annulus and that minimizes suture drag
- An additional titanium band that protects the stent base geometry and provides enhanced fluoroscopic visibility
- Optimized leaflet suturing process along the stent post to reduce leaflet stress
- Increased leaflet tissue tensile strength achieved by using a collagen fiber alignment technology, which ensures circumferential fiber alignment to resist fatigue-related leaflet tissue degradation

The new holder, softer sewing cuff, protective titanium band, optimal leaflet suturing pattern and 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 when combined with appropriate valve sizing and handling.[8,16] To further ease the implant procedure and improve access to the sewing cuff while suturing, a new holder is being introduced to the Trifecta GT valve in 2020. The new holder has legs with a narrower footprint to permit easier access to the sewing cuff during placement of sutures, while retaining the same protective features of the original Trifecta GT valve holder.

Figure 7: Trifecta™ Valve Enhancements



COMMENTARY

The clinical outcomes presented for the Trifecta™ valve from two independent studies[1,2] provide contemporary clinical study data at a time when transcatheter ViV intervention is available. Both studies demonstrate consistent results with a low rate of valve-related mortality. The low mortality rate may be attributed to having a valve with excellent hemodynamic performance that results in a lower rate of severe PPM, reduced heart failure related hospitalization and better left ventricular mass regression.[3-5]

Additionally, the low rate of valve-related mortality may be attributed to having the option to perform a transcatheter ViV intervention, which was not present in historical studies involving legacy bioprosthetic heart valves.[6,9,15] Therefore, when making comparisons among various studies, it is important to not only analyze the freedom from surgical explant due to SVD, but also examine the overall survival and the incidence of valve-related mortality.

CONCLUSIONS

At 10 years post-implant, the Trifecta valve demonstrates a low rate of all-cause and valve-related mortality.[1,2] The freedom from any re-intervention and all-cause mortality at 10 years post-implant was 51%, which is consistent with the rate reported for other bioprosthetic aortic valves.[6,9-11] In choosing a bioprosthetic aortic valve, the potential for SVD should be balanced against the potential hemodynamic and survival benefits of the Trifecta valve. Transcatheter ViV intervention with the Trifecta valve provides an additional option in patients with SVD. The next-generation Trifecta™ GT valve has additional features that are intended to make the valve easier to implant and potentially reduce the occurrence of nonstructural valve dysfunction and SVD over the lifetime of the valve.

*All results reported at 10 years were graphically estimated from published study data.[6,9,15]
†Figure recreated from published study.[6,9]

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