TMTT Today

Your source for information on Edwards' innovations in transcatheter mitral and tricuspid therapies

Issue #8 – September 2022

New data

for the PASCAL Platform in tricuspid regurgitation (TR)

86%

TR ≤2+ at 1 year in the CLASP TR early feasibility study[1]

Also inside:

Real-world evidence from the PASTE registry: Significant clinical and echocardiographic improvements in TR with the PASCAL repair system![2]

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Dear Reader,

At Edwards Lifesciences, we strive to bring therapies to life that, in the hands of trained Heart Teams, will deliver excellent patient outcomes and redefine the possibilities for treatment.

In this issue, we discuss results from multiple TR studies. New longer-term results have recently been presented, which highlight the durability of outcomes at 1 year.[1,3] Furthermore, new data are starting to emerge from our post-market registries, as well as independent registries, showing real-world results similar to those from the safety and feasibility studies that preceded them.[2,4]

We are especially excited about the CLASP TR early feasibility study (EFS) 1-year results. In a paired analysis, 86% of patients, most of whom had severe TR at baseline, had moderate or less TR at 1 year. Furthermore, more than half of these patients had no or mild TR.[1] These Corelab-adjudicated outcomes show that the PASCAL repair system was not only able to produce excellent and safe 30-day results but, perhaps more importantly, that the reduction in TR proved durable and effective for these patients. We believe this is driven by the specific design characteristics of the PASCAL repair system, notably its Nitinol construction, and because it was designed to be gentle on the surrounding anatomy.[5,6]

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Enjoy reading!

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PASCAL Repair System in TR

One-year outcomes from the CLASP TR early feasibility study and early data from TriCLASP

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Professor Tobias Geisler is Deputy Medical Director of Medical Clinic III at the Department of Cardiology and Angiology, University Hospital Tübingen. His research interests include interventional cardiology, personalised cardiovascular medicine, platelet-mediated inflammation and thrombosis. Professor Geisler has been an Investigator in several studies of transcatheter therapies for valvular disease, including MiCLASP, TriCLASP, PASTE and TENDER.

Early data from the CLASP TR EFS (Edwards PASCAL Transcatheter Valve Repair System In Tricuspid Regurgitation Early Feasibility Study) and a compassionate use study supported the high procedural success and efficacy of the PASCAL repair system for treating patients with clinically significant TR (see *TMTT Today #6* for more information).[7-9] Here, Professor Tobias Geisler discusses the 1-year data from CLASP TR EFS and 30-day data from the post-market TriCLASP study, which provide further evidence of TR reduction and quality-of-life benefits with the PASCAL repair system in patients with symptomatic severe TR.[1,4]

We have been using the PASCAL repair system to treat TR since its introduction in May 2020[10] because we are impressed by the device's features applicable to transcatheter tricuspid valve repair (TTVr). Independent leaflet capture helps us to bridge large coaptation gaps, while the flexible Nitinol construction minimises stress on the leaflets and enables the implants to move with the leaflets throughout the cardiac cycle.[6,8] The ability to elongate the implants allows navigation within the dense chordal structures that we often encounter in the tricuspid valve.[6] In addition, the implants feature a central spacer that fills the regurgitant orifice area, and two contoured paddles that are shaped to minimise stress on the tricuspid leaflets following capture.[5,6,8]

> *'We have been using the PASCAL repair system to treat TR since its introduction because we are impressed by the device's features.'*
>
> Professor Tobias Geisler

The PASCAL repair system is comprised of the PASCAL and PASCAL Ace implants, each with distinct design features. For TTVr, we find the PASCAL Ace implant particularly suitable because of its narrower profile and longer clasps compared with the PASCAL implant.[11] These features support us in navigating the device through the complex anatomy of the tricuspid valve and in bridging large coaptation gaps.[11] Having two distinctly designed implants with different features available enables interventional cardiologists to provide a tailored approach when treating TR, taking into account patient anatomy.

Severe TR is associated with increased mortality and heart failure (HF), and prognosis is worsened further in patients with massive or torrential TR.[14] **CLASP TR EFS** – a prospective, single-arm, multicentre,

Table 1. Patient eligibility criteria for the CLASP TR EFS and TriCLASP studies.

CLASP TR EFS (NCT03745313)[12]	TriCLASP (NCT04614402)[13]
Inclusion criteria	**Inclusion criteria**
Severe functional or degenerative TR	TR grade ≥3+ (5 grade classification)
Symptomatic despite medical therapy	Patient is eligible to receive the PASCAL repair system per the current approved indications for use
Patient is appropriate for transcatheter tricuspid valve repair as determined by the local site Heart Team	Patient is a candidate for transcatheter tricuspid valve repair as determined by a Heart Team
Exclusion criteria	**Exclusion criteria**
Unsuitable anatomy	Tricuspid valve anatomic contraindications, including previous tricuspid valve replacement
Previous tricuspid valve repair or replacement	Severe aortic, mitral and/or pulmonic valve stenosis and/or regurgitation
Comorbid condition(s) that could limit the patient's ability to participate in the study (according to the investigator) including compliance with follow-up requirements, or impact the scientific integrity of the study	Concurrent medical condition with a life expectancy of <12 months, according to the investigator
	Any patient considered to be part of a vulnerable population

EFS, early feasibility study; TR, tricuspid regurgitation.

Core Lab-adjudicated study conducted in the US including 65 patients with severe (or worse) functional or degenerative TR (Table 1) – provides an early indication that patients with severe and symptomatic disease can be treated effectively using the PASCAL repair system.[1,15] This is further supported by 30-day outcomes from the TriCLASP study, a prospective, single-arm, multicentre, post-market study in Europe including 74 patients with severe (or worse) TR (Table 1).[4]

'Patients in TriCLASP had an even higher surgical risk than patients in CLASP TR EFS.'
Professor Tobias Geisler

Patients in the CLASP TR EFS were typically elderly (mean age 77 ± 9 years) with poor functional status (71% New York Heart Association [NYHA] functional class III or IV) and a Society for Thoracic Surgeons (STS) mortality score of 7.7 ± 5.5%[a]. They had prominent comorbidities (89% atrial fibrillation/flutter; 92% systemic hypertension; 43% renal insufficiency or failure) and were symptomatic despite medical therapy. At baseline, over 97%[a,b] of patients had severe or greater TR based on Core Lab analysis.[1,15] Patients in the TriCLASP study had a similar profile, with a mean age of 80 ± 6 years, poor functional status (77% NYHA functional class III or IV), an STS mortality score of 9.0 ± 6.9% and a high incidence of atrial fibrillation (96%). At baseline, 83% of patients had severe or greater TR based on Core Laboratory analysis.[4]

Successful implantation* of the PASCAL repair system was achieved in 91% of patients in CLASP TR EFS[1] and 97% of patients in TriCLASP.[4] Both procedural** (88% CLASP TR EFS; 78% TriCLASP) and clinical*** (77% CLASP TR EFS[c]; 78% TriCLASP) success were high. In CLASP TR EFS, 46% of patients received one device, 42% received two devices and 3% received three devices. A mixture of PASCAL and PASCAL Ace implants was used. Six patients had complex anatomy which prevented leaflet capture but the implants were successfully retrieved with no adverse consequences.[1] The mean number of devices implanted in TriCLASP was 1.8 ± 0.6, all of which were the PASCAL Ace implant. Notably, mean device time was shorter in TriCLASP (84 ± 49 min) than in CLASP TR EFS (147 ± 89 min[d]),[1,4] perhaps related to the clinical experience of the operators and/or reflecting the use of the smaller PASCAL Ace implant, which is easier to navigate through the dense chordae than the larger PASCAL implant. Following the procedures, the mean length of hospital stay was 3 ± 4 days[e] in CLASP TR EFS and 5 ± 4 days in TriCLASP. Almost all patients were discharged to home.[1,4,15]

'If you are a patient with severe TR, CLASP TR EFS is a very exciting feasibility study.'
Professor Tobias Geisler

[a]n=64; [b]TR severity for one patient was deemed inconclusive after Core Laboratory adjudication; [c]n=56; [d]n=58; [e]n=62.
*Implant deployed and delivery system retrieved as intended at the patient's exit from the cardiac catheterisation laboratory. **Implant success with at least one grade reduction in TR at the end of the procedure without surgical or percutaneous intervention prior to hospital discharge. ***Procedural success without major adverse events at 30 days.

'In CLASP TR EFS, survival and freedom from heart failure hospitalisation rates were 88% and 79%, respectively, at one year.'[1]

Professor Tobias Geisler

At 1 year, survival was 88% and freedom from HF hospitalisation was 79% in CLASP TR EFS. Freedom from major adverse events was 91% at 30 days and 83% at 1 year, and only one patient had a reintervention related to the device. At 1 year, the most common major adverse events were severe bleeding* (9%), cardiovascular mortality (8%) and stroke (5%).[1] Bleeding is an unsurprising outcome for this frail and highly comorbid patient population, many of whom generally receive anticoagulants. Safety outcomes were similar in the TriCLASP study at 30 days.[4]

As with CLASP TR EFS data presented previously,[7] TR severity was significantly reduced following treatment with the PASCAL repair system (p<0.001) and the paired analysis of 36 patients showed that 86% achieved TR ≤2+ at 1 year (p<0.001; Figure 1).[1] All patients achieved at least a one-grade reduction in TR between baseline and the 1-year follow-up and 75% achieved at least a two-grade reduction. The proportion of patients with TR ≤2+ increased from 6% at baseline to 86% at 1 year (Figure 1).[1]

*Severe bleeding defined as major, extensive, life-threatening or fatal bleeding, as per the Mitral Valve Academic Research Consortium

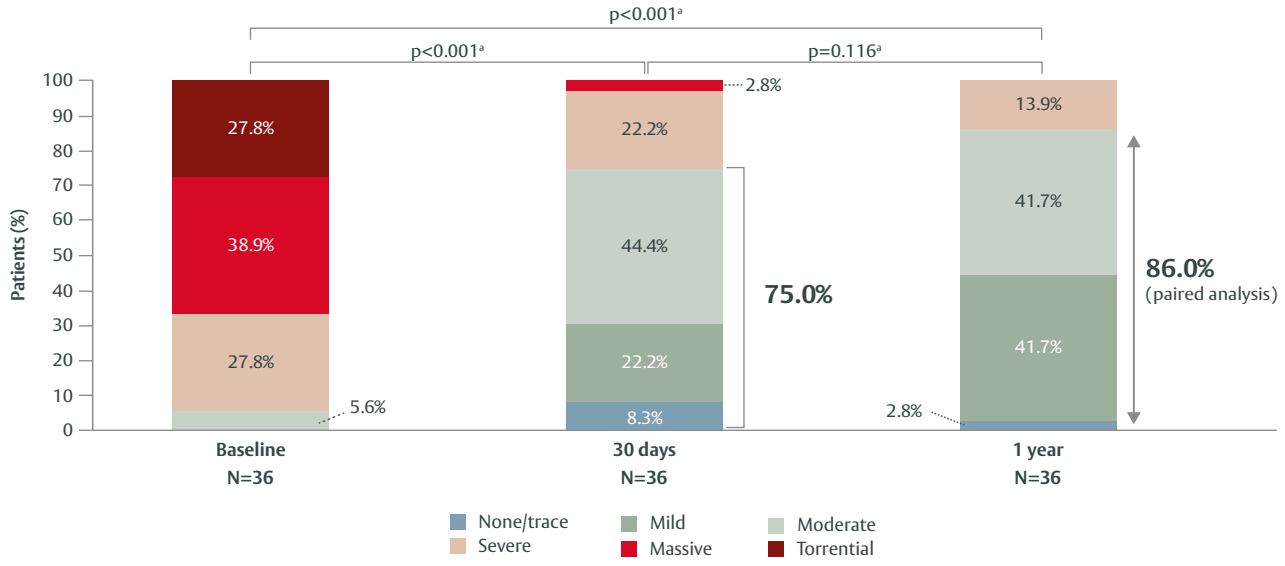

Figure 1. Post-procedural TR at 30 days and 1 year following treatment with the PASCAL repair system in patients with TR ≥2+ at baseline in the CLASP TR EFS (paired analysis shown).[1,15]

Two patients initially considered to have severe TR at baseline by transoesophageal echocardiography were reclassified as moderate TR by transthoracic echocardiography.

Percentages may not sum to 100 due to rounding.

[a]Wilcoxon signed-rank test.

EFS, early feasibility study; TR, tricuspid regurgitation.

Adapted from Hahn R. EuroPCR 2022.

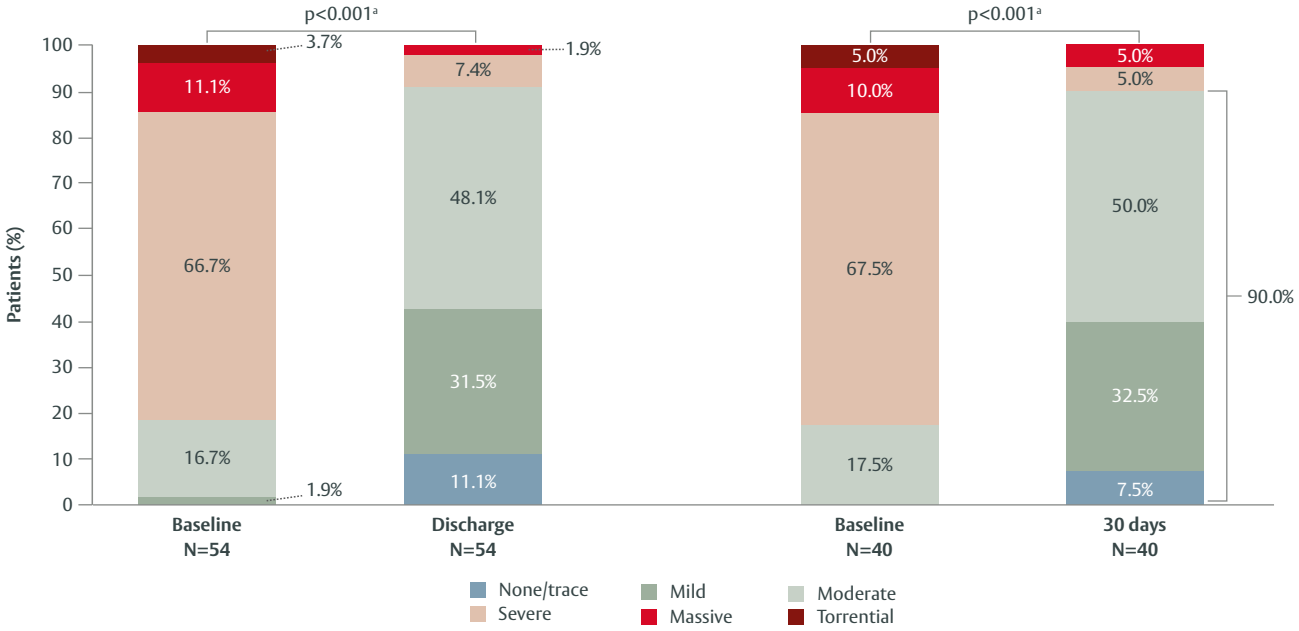

Figure 2. Post-procedural TR at discharge (N=54) and 30 days (N=40) following treatment with the PASCAL repair system in the TriCLASP post-market study (paired analysis shown).[4]

Percentages may not sum to 100 due to rounding

[a]Wilcoxon signed-rank test.

TR, tricuspid regurgitation.

Adapted from Baldus S. EuroPCR 2022.

Early outcomes from TriCLASP were consistent with the CLASP TR EFS data; 88% of patients achieved at least a one-grade reduction in TR between baseline and 30 days and 90% achieved moderate or lower TR (TR ≤2+; Figure 2).[4]

Improvements in echocardiographic outcomes were observed at the 1-year follow-up in CLASP TR EFS, providing early evidence of right ventricular (RV) remodelling (Table 2). These included significant reductions in the tricuspid annulus diameter (p<0.001) and RV end-diastolic diameter (p<0.001).[15]

Table 2. Change in echocardiographic parameters from baseline to 1 year after treatment with the PASCAL repair system in the CLASP TR EFS.[15]

Variable	Baseline	1 year	p value*
Tricuspid annulus diameter (end-diastole, apical 4Ch), cm	4.5 ± 0.8	4.0 ± 0.6	<0.001
RV end-diastolic diameter (mid) (4Ch), cm	4.0 ± 0.9	3.5 ± 0.7	<0.001
RA volume (single-plane Simpson's) (4Ch), mL	148.9 ± 81.7	130.6 ± 63.9	0.013
IVC diameter, cm	2.5 ± 0.6	2.1 ± 0.6	0.002
TR jet area (maximum), cm²	15.1 ± 5.0	6.9 ± 3.6	<0.001

Data presented are paired mean ± SD.

*p values calculated by Student's t-test.

4Ch, 4-chamber; EFS, early feasibility study; IVC, inferior vena cava; RA, right atrial; RV, right ventricular; TR, tricuspid regurgitation.

Adapted from Greenbaum A. ACC 2022.

'Both CLASP TR EFS and TriCLASP show that edge-edge therapy using the PASCAL repair system demonstrates relatively low mortality in a high-risk population, and provides convincing reduction of TR.'
Professor Tobias Geisler

These positive results were matched by sustained improvements in functional and quality-of-life outcomes in CLASP TR EFS (Figure 3). At 1 year, 92% of patients achieved NYHA functional class I or II, and there was a significant improvement in both patients' 6-minute walk distance (6MWD; p<0.014) and their Kansas City Cardiomyopathy Questionnaire (KCCQ) score (p<0.001).[1] Consistent with these data from CLASP TR EFS, the TriCLASP study also demonstrated significant improvements in NYHA functional class (p<0.001), KCCQ score (p<0.001) and 6MWD (p<0.001) between baseline and 30 days after implantation of the PASCAL Ace device.[4]

'These are very encouraging signals that need to be confirmed in a randomised study.'
Professor Tobias Geisler

Conclusion

One-year outcomes from the CLASP TR EFS show that patients with symptomatic severe TR treated with the PASCAL repair system have significant and sustained TR reduction, with improvements in clinical, functional and quality-of-life outcomes.[1,15] These benefits were observed in a selected population of comorbid patients with a high incidence of severe TR at baseline. Early outcomes from the TriCLASP post-market study are consistent with data from CLASP TR EFS and emphasise the effectiveness of the PASCAL Ace implant for the treatment of patients with severe TR.[4] Further investigation is required in randomised trials to determine treatment benefits across different patient populations. In this regard, the currently enrolling CLASP II TR study (NCT04097145) will assess the safety and effectiveness of the PASCAL repair system in patients randomised to optimal medical therapy with or without transcatheter TR repair.[16]

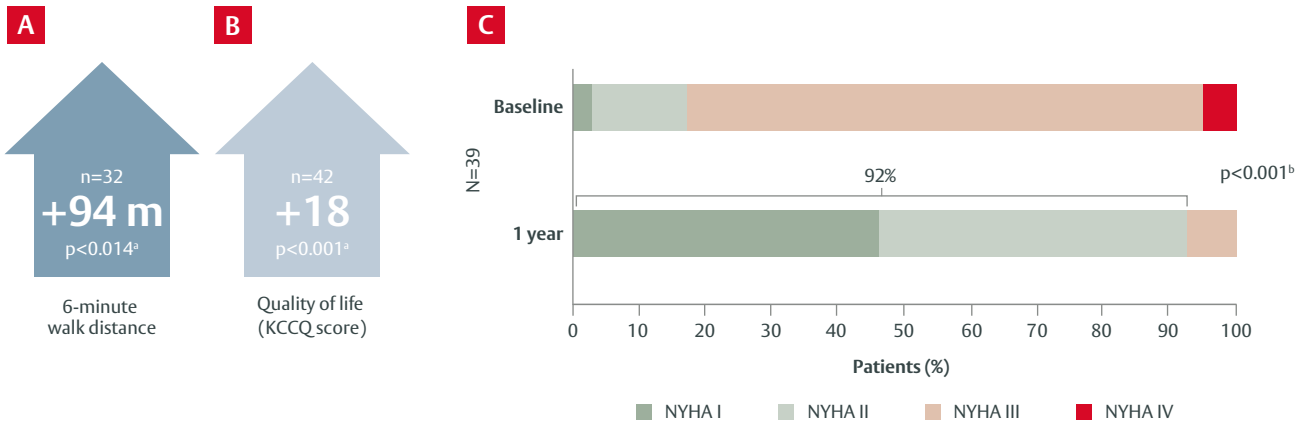

Figure 3. Change in 6-minute walk distance (A), quality of life (KCCQ score) (B) and NYHA functional class (C) from baseline to 1 year after treatment with the PASCAL repair system in the CLASP TR EFS.[1,15]

[a]Paired t-test. [b]Wilcoxon signed-rank test.

EFS, early feasibility study; KCCQ, Kansas City Cardiomyopathy Questionnaire; NYHA, New York Heart Association; TR, tricuspid regurgitation.

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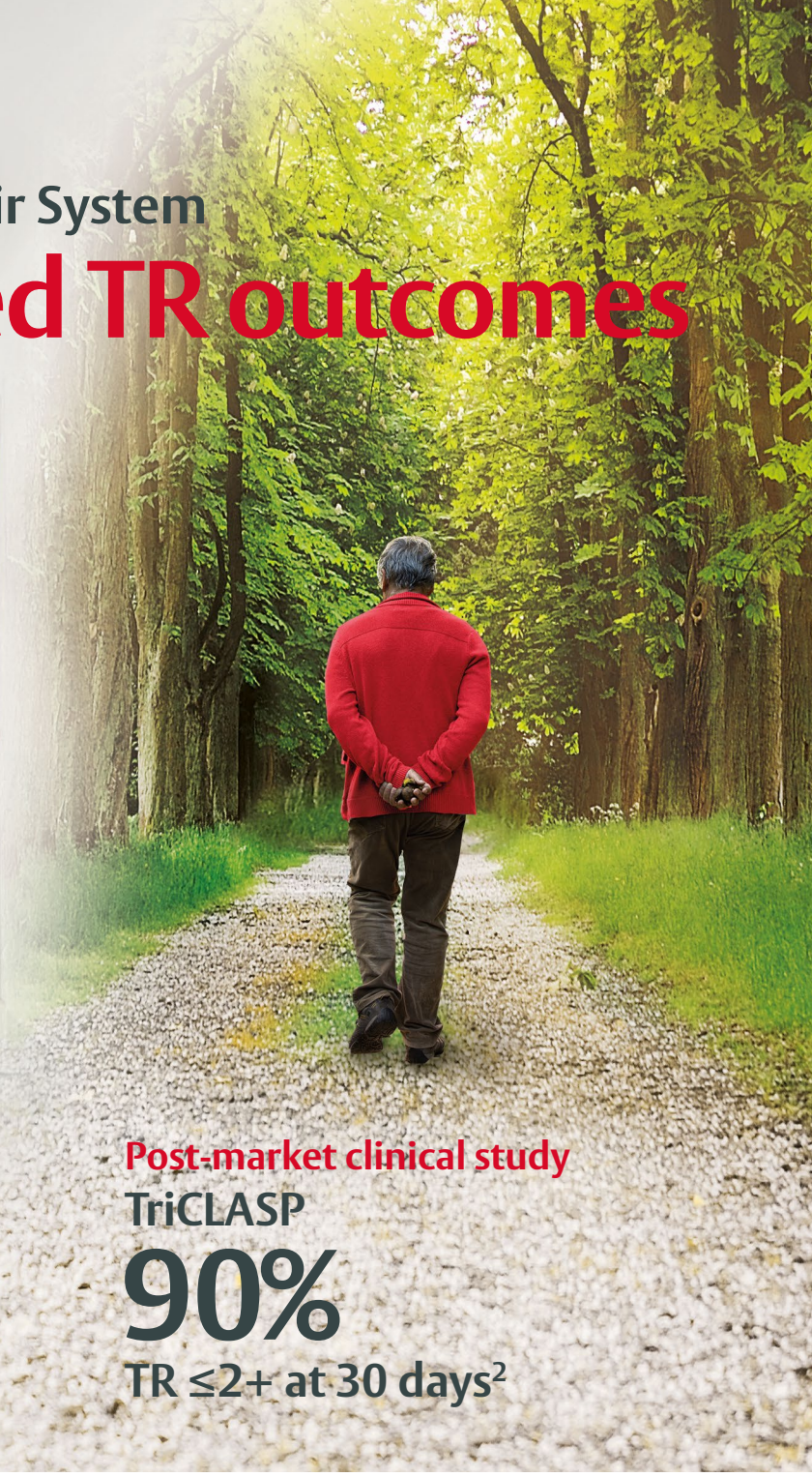

Early feasibility clinical study

CLASP TR EFS

86%

TR ≤2+ at 1 year[1]

Post-market clinical study

TriCLASP

90%

TR ≤2+ at 30 days[2]

Edwards Lifesciences strives to set new standards in the treatment of tricuspid regurgitation for the benefit of your patients.
The PASCAL transcatheter valve repair system is proving to be safe and effective, with sustained TR reduction at 1 year in the CLASP TR EFS study.

1. Hahn R. EuroPCR 2022; 2. Baldus S. EuroPCR 2022; **TR,** tricuspid regurgitation.

Left background and character: SHUTTERSTOCK.COM/TOMMASO79, SHUTTERSTOCK.COM/HALFPOINT
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PASCAL Repair System in TR

Real-world outcomes with the PASCAL Repair System in TR: The first 503 patients from the PASTE registry

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Professor Jörg Hausleiter is Professor of Medicine and the Deputy Clinic Director at LMU in Munich. He focuses on bringing new percutaneous treatments to patients with coronary and valvular diseases and has been Principal Investigator in many clinical trials, including Tric-I-HF, MiCLASP, TRILUMINATE,CLASP IID/IIF, EuroSMR, EuroTR and PASTE.

Dr med. Mirjam Wild

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Dr Mirjam Wild is a Research Fellow in the Valvular Heart Team at LMU University Hospital in Munich. She recently completed a fellowship in the Structural Heart Team at Bern University Hospital, Switzerland. Her research interests include new devices and treatment strategies for percutaneous mitral and tricuspid valve interventions, and cardiovascular imaging. Dr Wild has been involved in several registry-based clinical trials, including CHOICE-MI, TENDER and PASTE.

The PASCAL repair system – featuring the PASCAL and PASCAL Ace implants – has demonstrated impressive efficacy and safety outcomes in patients with TR, both in clinical trial and real-world settings.[1,4,7-9,15] Professor Jörg Hausleiter and Dr Mirjam Wild now describe data from the first 503 patients included in PASTE (PASCAL for Tricuspid Regurgitation – a European Registry), the largest independent investigator-initiated registry for TR to date. The data demonstrate sustained TR reduction and significant clinical improvement in patients treated with the PASCAL repair system in real-world settings.[2]

PASTE (NCT05328284) is an ongoing, retrospective, independent, investigator-initiated, observational study investigating the safety and efficacy of the PASCAL repair system in patients with TR. The registry aims to include over 1,000 consecutive patients treated with the PASCAL repair system across 18 European centres in Germany, Sweden, Switzerland and the UK.[2] Data from an early cohort of 235 patients have recently been published.[17]

In contrast to other studies in TR, including TriCLASP and bRIGHT,[13,18] PASTE provides an authentic real-world experience, with no patient selection or screening and no exclusion criteria. This is reflected in its patient baseline characteristics to date, which show an elderly population (mean age 78 ± 9 years) with a high symptom burden (89% were NYHA functional class III or IV) and surgical risk (STS-predicted risk of mortality score 8.3 ± 6.4%). The patients were also highly comorbid; 92% had atrial fibrillation, 80% had renal failure (glomerular filtration rate <60 mL/min) and 42% had coronary artery disease at baseline.[2]

'The PASTE registry provides an authentic real-world experience with a genuinely unselected patient population.'
Dr Mirjam Wild

Here, we present clinical data for the first 503 patients included in the registry. The technical success rate in these patients was high (99%), and the average number of devices implanted was 1.8 ± 0.7. The mean procedure time was 136 ± 74 minutes. Overall, 31% of patients received the PASCAL implant only, 67% received the PASCAL Ace implant only and 2% received a combination of the two. Early in the study, only the PASCAL implant was available for use. However, following its launch, the PASCAL Ace implant has become the implant of

choice for patients with TR; 93% of patients in the PASTE registry received only this device since its introduction in 2020.[2]

The PASCAL repair system demonstrated a good safety profile. A single-leaflet device attachment occurred in 2.7% of patients, and 1% had access site complications.[2]

Treatment with the PASCAL repair system provided efficient TR reduction (Figure 4). At baseline, 92% of the 372 patients with available echo analysis had severe or worse TR (31% massive TR; 20% torrential TR). At discharge, 83% of patients achieved moderate or less TR (TR ≤2), up from only 8% at baseline. This was sustained (81% with TR ≤2) at a median follow-up of 6 months. In addition, NYHA functional class improved significantly (p<0.001; Figure 5); at follow- up, 65% of patients were in NYHA functional class I–II compared with only 11% at baseline. Patients showed a significant increase in 6MWD compared with baseline (p<0.001), and significant decreases in body weight (p<0.001) and serum N-terminal pro B-type natriuretic peptide levels (NT-proBNP; p<0.001; Figure 6). Together, these data suggest that the PASCAL repair system provides sustained TR reduction and significant clinical and echocardiographic improvements in patients who are elderly, highly symptomatic and comorbid in real-world settings.[2]

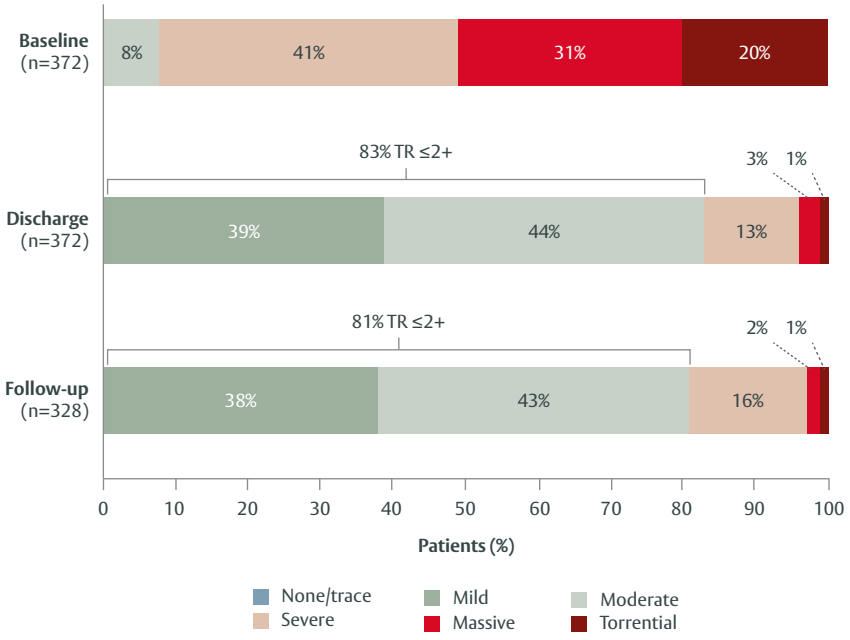


Figure 4. TR severity before and after treatment with the PASCAL repair system in the PASTE registry (median follow-up 6 months).[2]

TR, tricuspid regurgitation.

Adapted from Hausleiter J. A patient-focused transcatheter portfolio of options to treat TR. Edwards TNT, EuroPCR 2022.

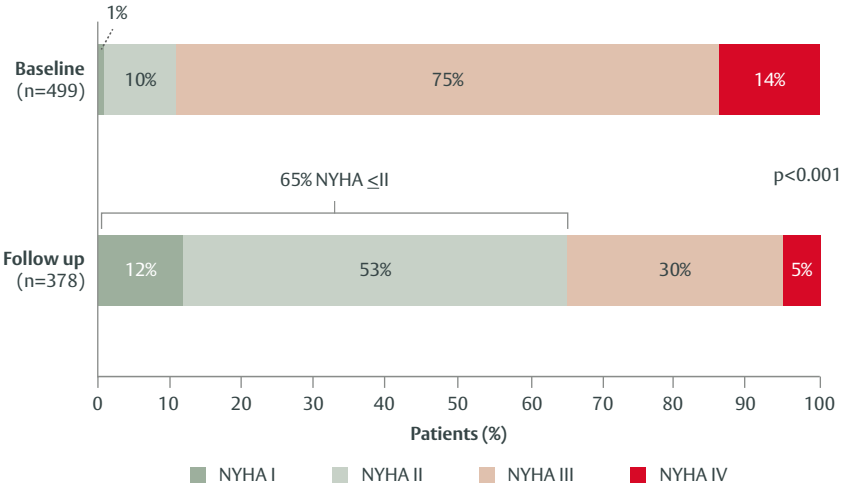


Figure 5. NYHA functional class before and after treatment with the PASCAL repair system in the PASTE registry (median follow-up 6 months).[2]

NYHA, New York Heart Assocation; TR, tricuspid regurgitation.

Adapted from Hausleiter J. A patient-focused transcatheter portfolio of options to treat TR. Edwards TNT, EuroPCR 2022.

'We saw significant improvements in patients' symptoms and functional class.'
Dr Mirjam Wild

The design of the PASCAL repair system, and in particular the PASCAL Ace implant, is beneficial for TR treatment. The implant can be elongated, easing navigation through the dense chordae of the tricuspid valve.[6] Independent grasping enables leaflets to be captured even with large coaptation gaps, and the implant's Nitinol construction provides flexibility to allow the implant to move with the cardiac cycle, thereby reducing stress on the leaflets.[5,6,8]

'The design of the PASCAL repair system is beneficial for TR treatment.'
Dr Mirjam Wild

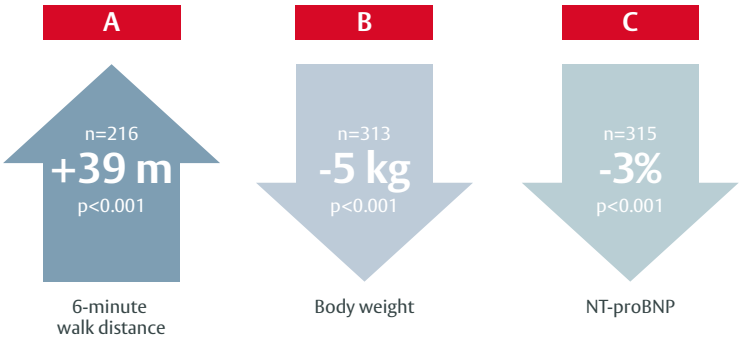


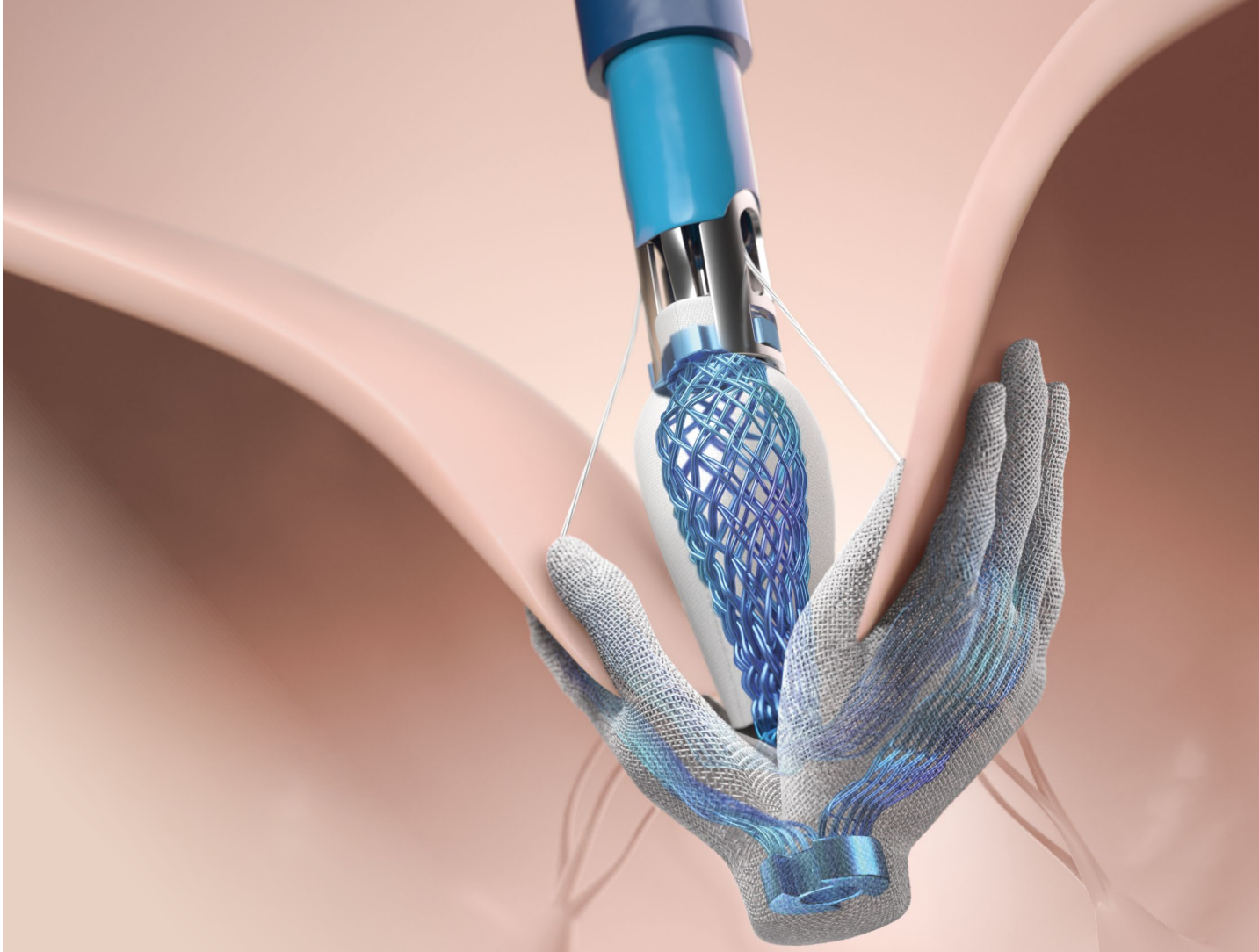
Figure 6. Change in 6-minute walk distance (A), body weight (B) and serum NT-proBNP levels (C) after treatment with the PASCAL repair system in the PASTE registry.[2]

NT-proBNP, N-terminal pro B-type natriuretic peptide.

'The PASCAL repair system enables very efficient TR reduction in a real-world setting.'
Dr Mirjam Wild

Conclusion

The partial outcome data from the first 503 patients in the PASTE registry provide further support for the safety and efficacy of the PASCAL repair system, particularly the PASCAL Ace implant, in treating patients with TR in a real-world setting. Despite the elderly, highly symptomatic and comorbid population, the PASCAL repair system provided sustained TR reduction and significant clinical and echocardiographic improvements.[2] Longer follow-up data will now be required to determine the safety and durability of the PASCAL repair system in patients with TR. In addition, prospective randomised studies are now underway to compare leaflet repair plus medical therapy *versus* medical therapy alone as treatments for TR.[16]



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Cardioband Tricuspid System in treating TR

One-year outcomes from the Cardioband tricuspid system early feasibility study

Professor Dr med. Roman Pfister

Heart Center of the University Hospital of Cologne, Germany

Professor Roman Pfister is Deputy Head of the Department of Internal Medicine III at the Heart Center of the University Hospital of Cologne and leads the Heart Failure and Transplantation Programme and the Interventional AV-Valve Treatment Programme.

The Cardioband tricuspid valve reconstruction system is a novel treatment for functional TR, which increases tricuspid valve function by reducing or reconstructing the annulus.[19] A growing evidence base, including clinical and real-world studies, supports the efficacy and feasibility of the Cardioband tricuspid system in patients with moderate (or worse) symptomatic TR.[20-23] Here, Professor Roman Pfister presents 1-year outcomes from the Cardioband Tricuspid Valve Reconstruction System Early Feasibility Study (Cardioband tricuspid system EFS; NCT03382457). The study shows significant and sustained reductions in TR severity, alongside clinical and quality of life improvements, in a population of patients with predominantly torrential baseline TR.[3]

Patients with severe isolated TR typically have high perioperative risk and limited treatment options.[21] In 90% of cases, TR occurs due to dilation of the tricuspid annulus.[20] Annuloplasty is the most common treatment for TR, and surgical ring annuloplasty can outperform suture techniques with regard to long-term valve durability.[24,25] The Cardioband tricuspid system is a transcatheter alternative to surgical annuloplasty rings that can be positioned precisely during implantation to accommodate a patient's anatomy and allow real-time adjustment to confirm procedural results.[21]

Cardioband tricuspid system EFS is a multicentre, prospective, single-arm, early feasibility study investigating outcomes following implantation of the Cardioband tricuspid system in 37 patients with symptomatic, chronic and functional TR.

Study patients were elderly (age 78 ± 7.5 years), with poor functional status (65% of patients with NYHA functional class III–IV) and severe or worse TR (19% massive TR; 60% torrential TR) based on Core Lab assessment. They also presented significant comorbidities, including atrial flutter/fibrillation (97%), pulmonary hypertension (73%), hypertension (70%), renal disease (38%) and chronic anaemia (35%). Many patients (38%) had received a prior valve intervention or surgery or had a pacemaker fitted (30%).[3]

Early published data from Cardioband tricuspid system EFS showed high procedural feasibility with no 30-day mortality.[20] The 1-year follow-up data confirm and build upon these findings, showing that device success with the Cardioband tricuspid system is high, with patients being discharged from hospital within a median of 2 days post-procedure (Table 3).[3]

Table 3. Procedural outcomes following treatment with the Cardioband tricuspid system.[3]

Procedural outcomes	N=37
Device success rate*, %	92
Length of stay in hospital, median days (range)	2 (1–30)
Procedure time**, min (range)	189 (93–448)[a]

[a]n=34.

*Device deployed and delivery system retrieved as intended before exiting the cardiac catheterisation lab. **Implant delivery system insertion to removal.

Adapted from Gray W. EuroPCR 2020.

The Cardioband tricuspid system demonstrated good efficacy in this elderly, highly comorbid patient population. After 1 year, all-cause mortality and HF rehospitalisation rates were low (13.5% and 10.8%, respectively; Figure 7).

Bleeding was the most frequent complication and was severe* in 22% of patients at 30 days and 35% of patients at 1 year. Major access site and vascular complications requiring intervention occurred in 8.1% of patients at both the 30-day and 1-year follow-ups.[3]

'73% of patients had moderate or less TR at 1-year follow-up; this was very impressive.'
Professor Roman Pfister

*Severe bleeding defined as major, extensive, life-threatening or fatal bleeding, as per Mitral Valve Academic Research Consortium

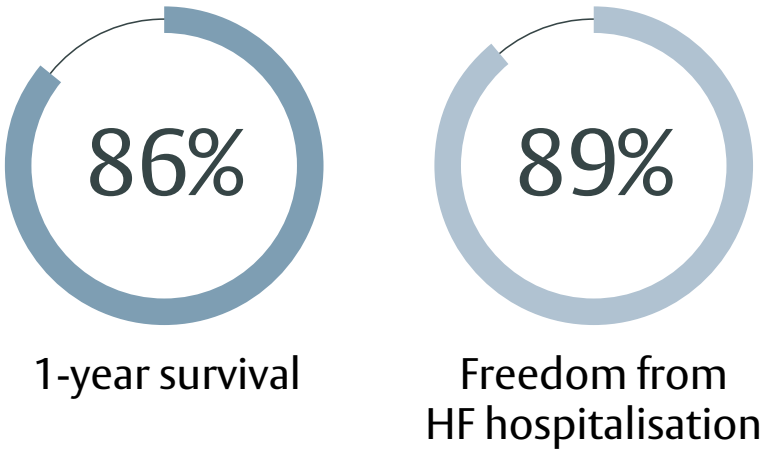

Figure 7. Survival and freedom from HF hospitalisation at 1 year following implantation of the Cardioband tricuspid system.[3]

HF, heart failure.

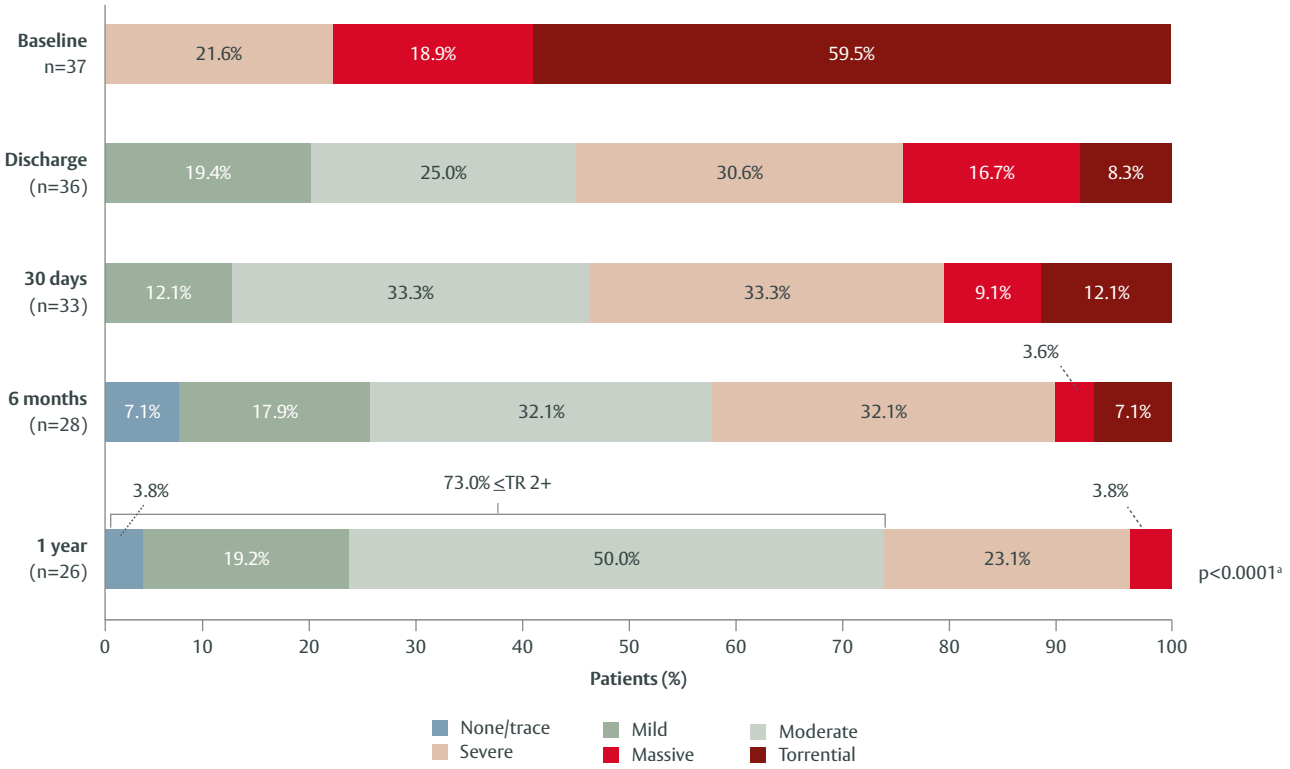

Figure 8. Change in TR following treatment with the Cardioband tricuspid system in patients with TR ≥3+ at baseline.[3]

Percentages may not sum to 100 due to rounding.

[a]Wilcoxon signed-rank test for TR grade at baseline and discharge, and baseline and 1 year.

TR, tricuspid regurgitation.

Adapted from Gray W. EuroPCR 2020.

Change from baseline to 1 year

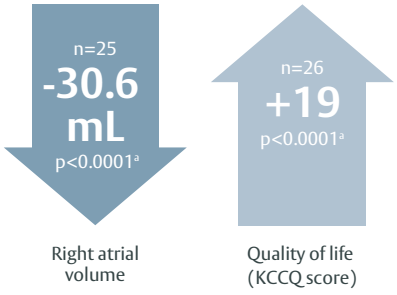

Figure 9. Change in right atrial volume and quality of life (KCCQ score) from baseline to 1 year after treatment with the Cardioband tricuspid system.[3]

[a]Paired t-test.

KCCQ, Kansas City Cardiomyopathy Questionnaire.

'Annular dilatation is the key driver of TR. The data show that sustained annular reduction was achieved at the one-year follow-up.'
Professor Roman Pfister

Patients who received treatment with the Cardioband tricuspid system demonstrated a significant and sustained decrease in TR grade up to 1 year, with 73% achieving moderate or less TR based on Core Lab assessment (Figure 8). All patients improved TR by at least one grade and 73% improved TR by at least two grades. Tricuspid valve annular diameter was significantly reduced (by 21%) after 1 year.[3]

In addition to reductions in TR grade, echocardiographic, clinical and quality of life outcomes significantly improved after 1 year. Right atrial volume was reduced by over 30 mL (Figure 9), and patients' functional status improved significantly, with 92% achieving NYHA functional class I–II after 1 year (Figure 10). Patients' quality of life also improved significantly during this period based on the KCCQ score ($p<0.0001$; Figure 9).[3]

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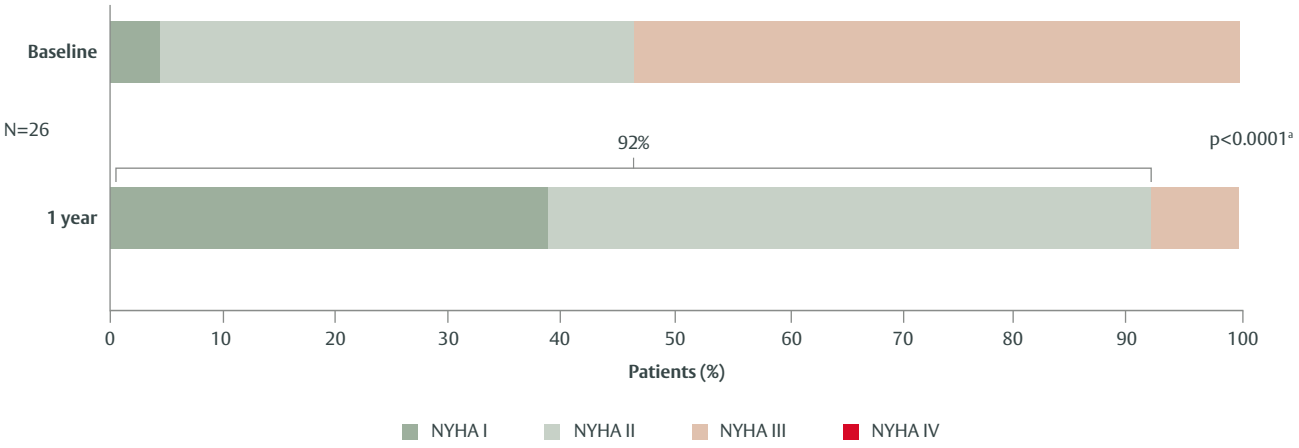

Figure 10. NYHA functional class before and 1 year after treatment with the Cardioband tricuspid system.[3]

[a]Wilcoxon signed-rank test.
NYHA, New York Heart Association.

The 1-year outcomes from Cardioband tricuspid system EFS are consistent with data from the TriBAND and TRI-REPAIR studies, which showed annular reduction, reduced TR severity and functional and quality of life improvements following treatment with the Cardioband tricuspid system.[22,23]

'Annuloplasty is an effective treatment even for patients with torrential TR and a large coaptation gap.'
Professor Roman Pfister

Case study

Professor Pfister described the case of a 78-year-old female patient who presented with progressive HF symptoms and preserved ejection fraction, permanent atrial fibrillation and a recent history of right heart decompensation. The patient had torrential functional TR (Figure 11) and poor functional status (NYHA class III). Due to her frailty and comorbidities, the Heart Team chose a catheter-based treatment option, and direct annuloplasty was selected based on a 50-mm dilatation of the RV annulus. The patient was treated with the Cardioband tricuspid system and the procedure was completed without complications. Following the procedure, her septolateral diameter was reduced from 47 mm to 33 mm and TR was reduced from torrential (5+) to moderate (2+). At 30 days post-procedure, there was a sustained improvement in the patient's TR, and her RV annulus was reduced to 41 mm. At 6 months post-procedure, the patient had good functional status (NYHA class I). This case highlights the benefits of using the Cardioband tricuspid system on TR and clinical outcomes in an elderly patient with torrential TR and significant comorbidities.

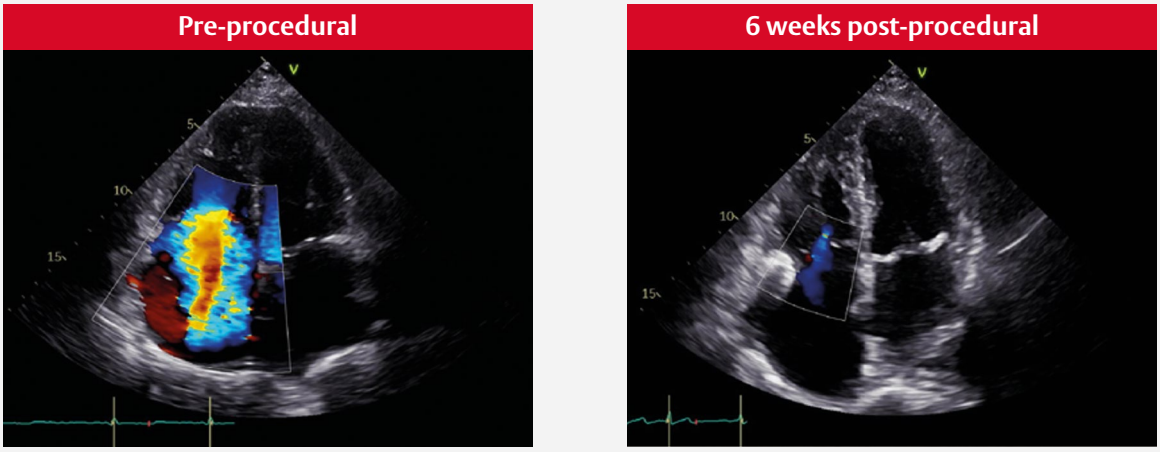

Figure 11. Case study showing a reduction in TR in a patient following implantation of the Cardioband tricuspid system.

Image courtesy of Professor Roman Pfister.

Annuloplasty using the Cardioband tricuspid system, tricuspid valve repair and tricuspid valve replacement are all transcatheter techniques with the potential to treat patients with severe TR, currently and in the future.[6,8,9,26] Cardioband tricuspid system EFS suggests that patients with severe-to-torrential TR and a large annular diameter may be particularly good candidates for annular reduction using the Cardioband tricuspid system.[19,20] However, additional data will be required from randomised trials to clarify how these different techniques are suited to specific patient and disease characteristics.

Conclusion

The 1-year outcomes from Cardioband tricuspid system EFS further support the feasibility of the Cardioband tricuspid system as an effective and durable treatment for patients with severe TR, including elderly patients with significant comorbidities.[3]

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PASCAL implant selection

Optimal treatment for patients with mitral regurgitation: A case-based discussion

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The PASCAL repair system is designed for predictable capture, positioning and release in patients with mitral regurgitation (MR). Two different implants are available: the PASCAL implant and the PASCAL Ace implant. Here, Professor Tobias Geisler explains the design differences between the two implants, and Professor Philip Raake, Dr Sam Dawkins and Dr Dabit Arzamendi illustrate their perspectives on selecting the most suitable implant using case studies.[27]

Two implants, broad coverage

The PASCAL repair system received its CE Mark for the treatment of MR in February 2019.[28] As of 2020, two implant designs are available: the PASCAL implant and the PASCAL Ace implant.[29] While the PASCAL implant has a broad spacer between the two paddles to reduce tension on the leaflets, the PASCAL ACE implant has a narrower spacer, designed to improve ease of subvalvular navigation through the chordae (Figure 12). The paddles of the PASCAL Ace implant closely follow the centre line and can close to nearly parallel, whereas the PASCAL implant paddles meet at the distal end and gradually recede proximally. The clasp and paddle widths on the PASCAL Ace implant are notably smaller than on the PASCAL implant. These differences in design enable coverage of a broad range of pathologies – recommendations are listed in Table 4.[27]

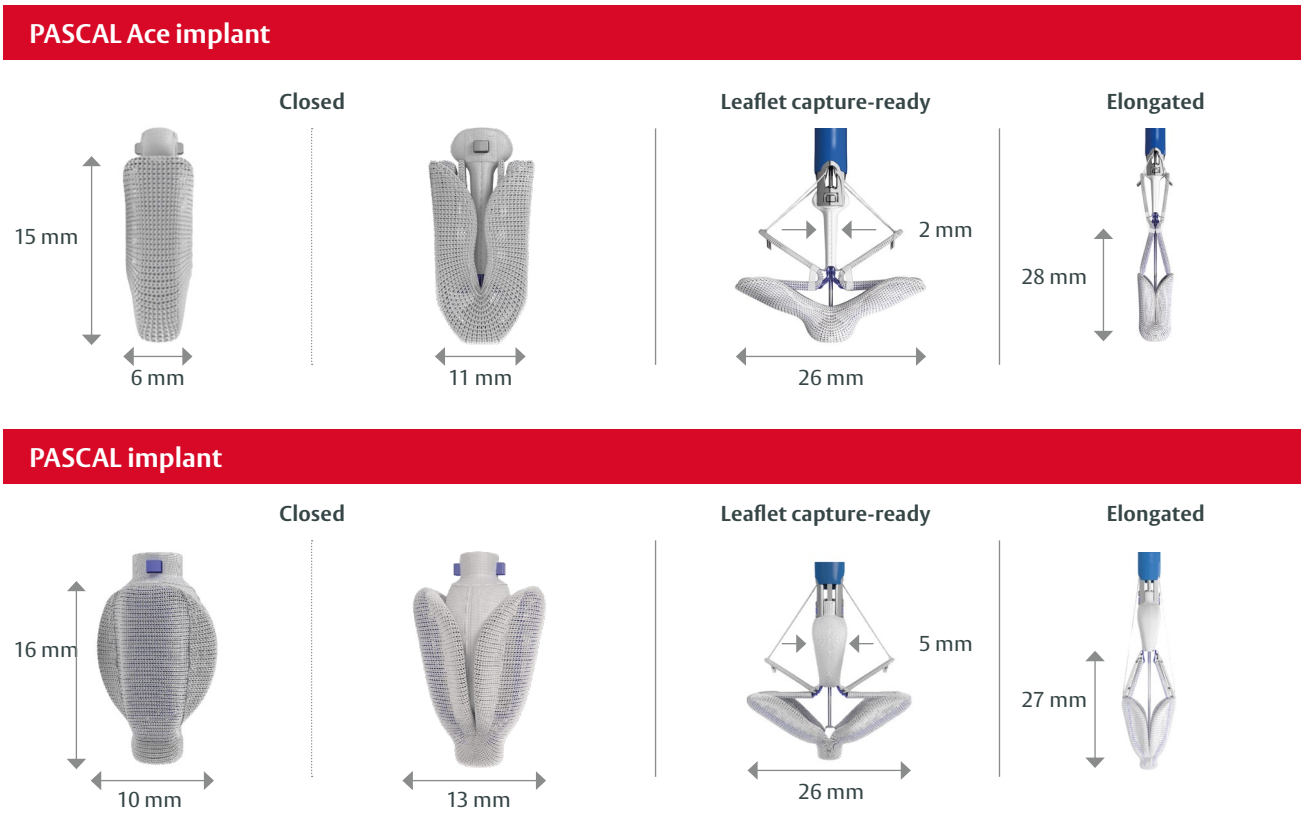

Figure 12. Dimensions of the PASCAL Ace and PASCAL implants.[27]

Table 4. Suggested guide* for implant selection for mitral regurgitation with the PASCAL repair system.[27]

PASCAL implant recommended	PASCAL Ace implant recommended	Where consensus is needed
Restricted/shorter leaflet	Commissural jet	Calcification near the grasping zone
Functional MR	Dense chordae	Large flail gap
	Longer leaflet	Extensive prolapse
	Degenerative MR	Mitral valve area <4 cm^2
		Severe tethering
		Clefts

Adapted from Geisler T *et al*. A patient-focused transcatheter portfolio of options to treat TR. Edwards TNT, EuroPCR 2022.
*Expert opinions, advice and all other information expressed represent contributors' views and not necessarily those of Edwards Lifesciences.
MR, mitral regurgitation.

The following case studies describe the implant selection process for patients with a variety of pathologies.

Case study 1
Patient with a large flail gap

Case study 2
Patient with a short, restricted leaflet

Case study 3
Patient with calcification near the grasping zone

Case study 4
Patient with a small mitral valve area

Professor Dr med. Philip Raake
Department of Cardiology, University Hospital Augsburg, Germany

Case study 1

Professor Philip Raake is Director of Cardiology at University Hospital Augsburg. He has authored and co-authored several papers on HF, focusing on basic molecular mechanisms, gene therapy and clinical aspects of advanced disease.

Patient with a large flail gap[27]

Click on each image to watch the video

Professor Raake describes the case of an 84-year-old woman who was referred to University Clinic Heidelberg with MR grade 3+ with a flail leaflet in the P1/P2 segments.

'The patient was symptomatic, in NYHA functional class III, with a left ventricular ejection fraction of 52%. Right heart catheterisation was performed before the implant procedure, revealing elevated systolic pulmonary artery pressure (65 mmHg) and elevated V-wave (33 mmHg). As the patient was in poor physical condition, the Heart Team decided upon an interventional procedure. A large flail was evident on transoesophageal echocardiogram, along with a calcified annulus with calcified chords, which might have been the source of the flail leaflet and prolapse (Figure 13). As is common in degenerative MR, an eccentric jet extended towards the aortic valve (Figure 13).'

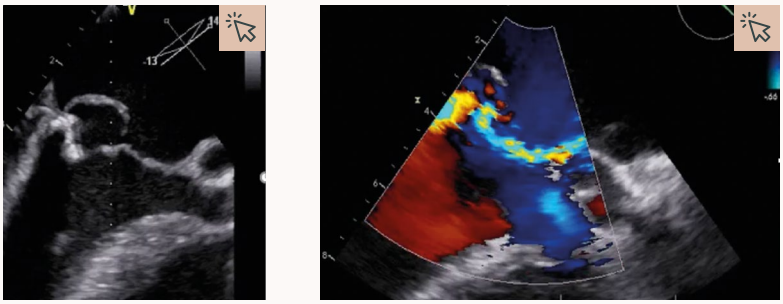

Figure 13. Baseline transoesophageal echocardiograms showing the flail leaflet (left) and eccentric jet (right).[27]

Adapted from Geisler T *et al*. A patient-focused transcatheter portfolio of options to treat TR. Edwards TNT, EuroPCR 2022.

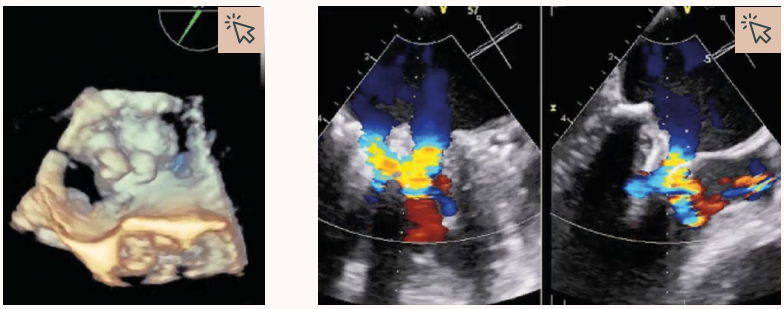

Figure 14. Two PASCAL Ace implants placed in a V-shaped position (left), leading to a good final result by echocardiogram (right).[27]

Adapted from Geisler T *et al*. A patient-focused transcatheter portfolio of options to treat TR. Edwards TNT, EuroPCR 2022.

'A PASCAL Ace implant was selected because of its longer clasps and tighter control of the valve, which is advantageous in flail anatomy. The strategy was to directly grasp the flail. While the first grasping attempt was too lateral, a more medial grasp was successful. However, the result was suboptimal, so a second PASCAL Ace implant was placed directly lateral in the flail position. The resulting V-shaped arrangement of devices gave a good result for the patient (MR 0–1+; Figure 14).'

> When choosing PASCAL for degenerative MR, I prefer the PASCAL Ace implant.
>
> **Professor Philip Raake**

Dr Sam Dawkins
John Radcliffe Hospital, Oxford, UK

Case study 2

Dr Sam Dawkins is a consultant cardiologist at John Radcliffe Hospital in Oxford. He specialises in general cardiology, interventional cardiology and structural intervention, including transcatheter edge-to-edge repair.

Patient with a short, restricted leaflet[27]

Click on each image to watch the video

Dr Dawkins describes the case of a 65-year-old man who presented to the referring hospital with breathlessness, reporting chest pain 3 weeks previously.

'The patient was found to have severe three-vessel coronary artery disease and severe MR with severe left ventricular (LV) impairment. Cardiac magnetic resonance imaging showed a full thickness lateral infarction. In the process of being transferred for Heart Team review, he deteriorated, requiring inotropic support and an intra-aortic balloon pump. Baseline transthoracic echocardiogram (TTE) revealed that both leaflets were tethered and being drawn into the ventricle, leading to a posteriorly directed jet of severe MR (Figure 15).'

'By this point, the patient required renal replacement therapy. Combined with cardiogenic shock and severe LV impairment, this put the patient at prohibitive risk for surgery. The Heart Team decided to treat the MR with transcatheter edge-to-edge repair (TEER), followed by percutaneous revascularisation later.'

'Baseline transoesophageal echocardiogram (TOE) confirmed the findings of the TTE: a short, tethered posterior leaflet and a severe jet of MR, confirmed with pulmonary vein flow reversal (Figure 15).

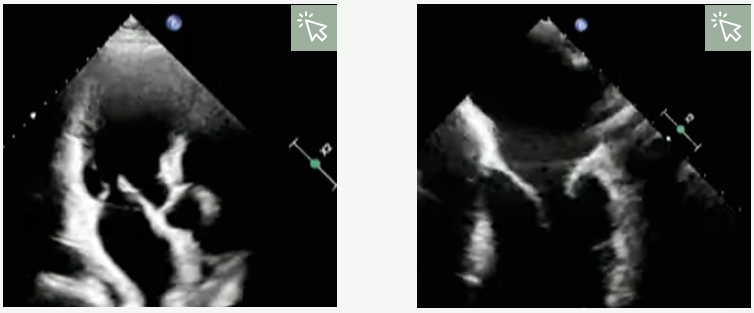

Figure 15. Baseline transthoracic (left) and transoesophageal (right) echocardiograms, displaying tethered leaflets.[27]

Adapted from Geisler T *et al*. A patient-focused transcatheter portfolio of options to treat TR. Edwards TNT, EuroPCR 2022.

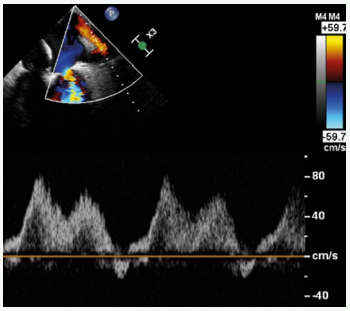

Figure 16. Haemodynamic results after closure of the first PASCAL implant.[27]

Geisler T *et al*. A patient-focused transcatheter portfolio of options to treat TR. Edwards TNT, EuroPCR 2022. Reproduced with permission.

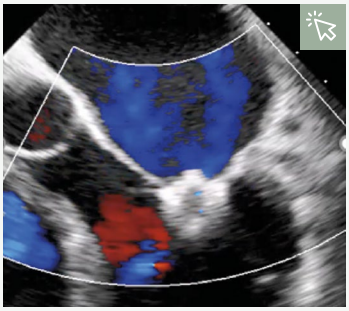

Figure 17. Final result on transoesophageal echocardiogram after placement of the PASCAL and PASCAL Ace implants.[27]

Adapted from Geisler T *et al*. A patient-focused transcatheter portfolio of options to treat TR. Edwards TNT, EuroPCR 2022.

I almost always use the PASCAL implant in this type of pathology, placed in the middle of the A2/P2 segments, as the spacer is designed to reduce the tension on the leaflets to give a more predictable result and a lower gradient.'

'After implantation, TOE showed a residual jet on both sides of the implant, with a mean pressure gradient of 4 mmHg (Figure 16). My usual practice would be to open the implant, move it medially then place

Continued

another implant on the lateral side. In this case, however, the haemodynamic result was excellent; the patient went from pulmonary vein flow reversal to normal pulmonary vein flow, with systemic blood pressure increasing by 25 mmHg. As such, the implant was left in its existing position and a PASCAL Ace implant was positioned parallel to the PASCAL implant on the medial side in an attempt to reduce the medial jet. The final result was a mean gradient of 3 mmHg, minimal residual MR (Figure 17) and normal pulmonary vein flow. The intra-aortic balloon pump was removed at the end of the procedure and the patient was weaned off inotropic support over 3 days.'

Case study 2

> 'The PASCAL implant spacer is designed to reduce the tension on the leaflets to give a more predictable result and lower gradient.'
>
> **Dr Sam Dawkins**

Dr Dabit Arzamendi
Department of Cardiology, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain

Case study 3

Dr Dabit Arzamendi in an interventional cardiologist at Hospital de la Santa Creu i Sant Pau in Barcelona. His specialisms include percutaneous aortic, mitral and tricuspid valve treatments, intracardiac septal defect repair and complex coronary interventions.

Patient with calcification near the grasping zone[27]

Click on each image to watch the video

Dr Arzamendi describes the case of an 84-year-old man with a prior history of coronary artery bypass grafting (CABG) and untreated functional MR (FMR). The patient's FMR deteriorated over time, and the patient was symptomatic despite optimal medical therapy, thus he was referred for TEER.

'We selected a PASCAL implant, as we usually do for FMR. However, while we were able to clasp the leaflets, the device wouldn't close fully because of a small calcium node on the posterior leaflet, visible in the TOE (Figure 18). We tried repositioning the implant to avoid the calcification but were unable to fix the MR. We decided to switch to the PASCAL Ace implant to try to clasp more tissue, and the result was perfect after a single attempt (Figure 19). We learned that if you need more closing strength, you would prefer to choose the PASCAL Ace implant.'

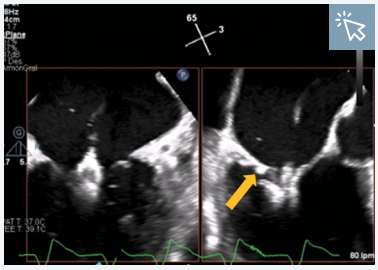

Figure 18. Screening transoesophageal echocardiogram, with the location of the calcium node indicated.[27]

Adapted from Geisler T *et al*. A patient-focused transcatheter portfolio of options to treat TR. Edwards TNT, EuroPCR 2022.

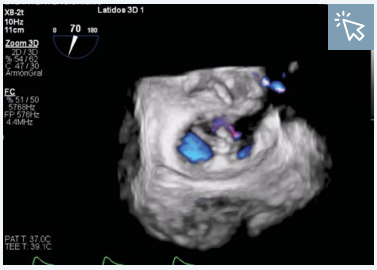

Figure 19. Final result in three-dimensional echocardiography.[27]

Adapted from Geisler T *et al*. A patient-focused transcatheter portfolio of options to treat TR. Edwards TNT, EuroPCR 2022.

> 'We learned that if you need more closing strength, you would prefer to choose the PASCAL Ace implant.'
>
> **Dr Dabit Arzamendi**

Dr Dabit Arzamendi
Department of Cardiology, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain

Case study 4

Patient with a small mitral valve area[27]

Click on each image to watch the video

Dr Arzamendi also described the case of a 61-year-old woman who underwent a heart transplant 10 years previously but had been admitted with HF symptoms 2 months previously. The patient had severe FMR and was symptomatic with shortness of breath.

'After discussion with her HF team, we decided to try to fix the MR and hopefully avoid a second heart transplant.'

'The leaflets looked good quality on TOE but appeared rigid on the 3D image (Figure 20). The baseline mean gradient was 3 mmHg and the mitral valve area was 3.8 cm^2. We assumed the PASCAL Ace implant could achieve a good result without increasing the gradient. We made several attempts at positioning the implant but always clasped too much tissue, and our best result was a gradient of 9 mmHg. We wanted a better result, so we switched to the PASCAL implant. We clasped just the tips of the leaflets in a more ventricular position for the implant during leaflet capture (Figure 21), allowing the PASCAL implant spacer to fill the gap and leading to an optimal result with a final gradient of 4 mmHg (Figure 22).'

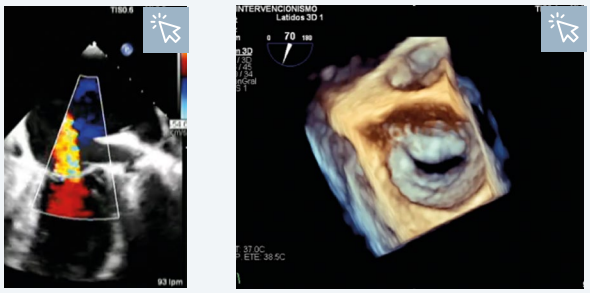

Figure 20. Baseline transoesophageal echocardiograms showing central MR and good quality leaflets.[27]

Adapted from Geisler T *et al*. A patient-focused transcatheter portfolio of options to treat TR. Edwards TNT, EuroPCR 2022.
MR, mitral regurgitation.

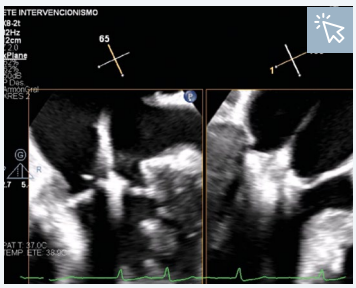

Figure 21. Intraprocedural transoesophageal echocardiogram showing low (ventricular) clasping of the PASCAL implant.[27]

Adapted from Geisler T *et al*. A patient-focused transcatheter portfolio of options to treat TR. Edwards TNT, EuroPCR 2022.

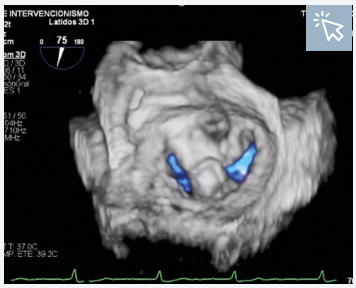

Figure 22. Final result on three-dimensional echocardiogram.[27]

Adapted from Geisler T *et al*. A patient-focused transcatheter portfolio of options to treat TR. Edwards TNT, EuroPCR 2022.

> My experience with these implants is that I can predict the results before I release the device... and I can optimise the positioning for the best result without observing any damage of the leaflets.
>
> **Dr Dabit Arzamendi**

Conclusion

These cases demonstrate the versatility of the PASCAL and PASCAL Ace implants in a wide variety of patients with MR with distinct anatomies. The design differences enable interventional cardiologists to optimise procedures to their needs and to those of their patients.

Conclusion

The PASCAL repair system is an effective treatment option for patients with MR and TR.[6,8,9,29,30] In the MR setting, design differences between the PASCAL and PASCAL Ace implants enable cardiologists to optimise procedures based on individual patients' needs. In the TR setting, the PASCAL Ace implant is becoming the implant of choice on account of its smaller size, enhanced manoeuvrability and relevant safety within the tricuspid valve.[2,5] One-year outcomes from CLASP TR EFS alongside data from the PASTE registry and TriCLASP post-market study have expanded the evidence base supporting the use of the PASCAL repair system in patients with severe TR.[1,2,4] Together, these studies demonstrated significant reductions in TR severity and improvements in patients' functional class and quality of life. Further investigations are now underway in the CLASP II TR randomised trial to determine whether transcatheter TR repair using the PASCAL repair system with optimal medical therapy improves outcomes compared with optimal medical therapy alone.[16]

Sustained TR reduction and improvements in patients' functional class and quality of life are also achievable using the Cardioband tricuspid system, as demonstrated by the 1-year outcomes from Cardioband tricuspid system EFS.[3] Together, these complementary technologies will enable a patient-tailored approach to the treatment of TR in the future.

Ask your questions...

We can be reached at TMTT-Today@edwards.com to answer your questions about the portfolio of therapies for transcatheter mitral and tricuspid valve therapies.

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