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Citation

Sandoval, E., Bhoera, R. A., Tomsic, A., Morales-Rey, I., García-Alvarez, A., Palmen, M., & Pereda, D. (2024). Learning curve of robotic mitral repair: prospective two-centre study of proficiency and clinical outcomes. *European Journal Of Cardio-Thoracic Surgery*, 66(6). doi:10.1093/ejcts/ezae426

Version: Publisher's Version

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Downloaded from: <https://hdl.handle.net/1887/4209511>

Note: To cite this publication please use the final published version (if applicable).

Cite this article as: Sandoval E, Bhoera RA, Tomšič A, Morales-Rey I, García-Álvarez A, Palmen M *et al.* Learning curve of robotic mitral repair: prospective two-centre study of proficiency and clinical outcomes. *Eur J Cardiothorac Surg* 2024; doi:10.1093/ejcts/ezae426.

Learning curve of robotic mitral repair: prospective two-centre study of proficiency and clinical outcomes

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Received 7 September 2024; received in revised form 12 November 2024; accepted 25 November 2024

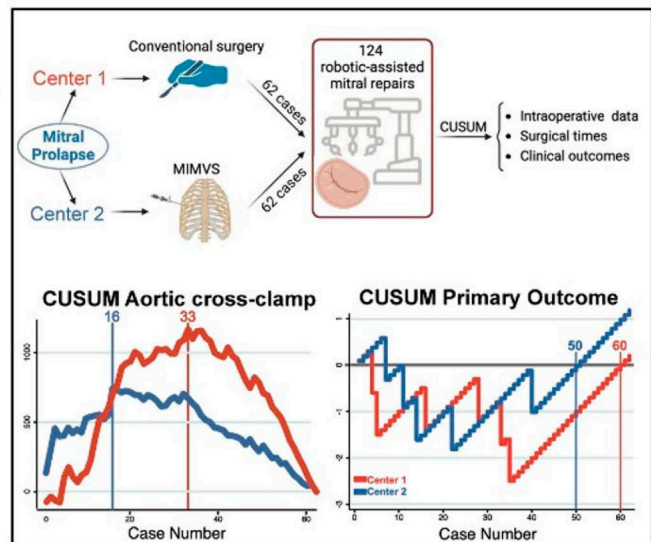
Learning curve of robotic mitral repair: prospective two-center study of proficiency and clinical outcomes

Summary

Population: First consecutive 124 robotic MV repair in 2 centres, one transitioning from MIMVS and the other from conventional surgery.

Comparison: CUSUM analyses of learning curves using clinical outcomes and surgical times.

Outcome: Successful transition to robotic surgery is feasible and safe without prior MIMVS experience, but MIMVS experience shortens the learning curve.



MV: mitral valve; MIMVS: Minimally invasive mitral valve surgery

Abstract

OBJECTIVES: Robotic-assisted mitral valve repair surgery has a steep learning curve, and it is not clear whether previous experience in minimally invasive mitral valve surgery (MIMVS) facilitates this process. We aimed to investigate the initial experience of 2 cardiac centres starting their robotic programmes, evaluating the impact of previous MIMVS experience.

METHODS: Retrospective analysis was performed for the 1st consecutive cases operated due to severe degenerative mitral valve regurgitation using the robotic surgical platform in 2 European centres, 1 transitioning from conventional surgery (centre 1) and the other from

[†]Both authors share first authorship to this work.

Table 2: Intraoperative and postoperative data

	Total (n = 124)	Centre 1 (n = 62)	Centre 2 (n = 62)	P-value
Cardiopulmonary bypass time (min)	180 (115–254.5)	238 (193.8–308.5)	115 (94.8–142)	<0.00001
Ischaemic time (min)	108 (80.5–153.5)	143 (114–180)	82 (67–101)	<0.00001
Total surgical time (min)	258 (225–330)	313 (251.5–386)	227.5 (200–280)	<0.00001
Type of annuloplasty (%)				
- No ring	1 (0.8)	0	1 (1.6)	0.31
- Rigid ring	68 (54.8)	62 (100)	6 (9.6)	
- Flexible ring	55 (44.4)	0	55 (88.7)	
Use of neochords (%)	102 (82.3)	60 (96.8)	42 (67.7)	<0.001
Leaflet resection (%)				
- Triangular	28 (22.6)	4 (6.4)	24 (38.7)	<0.001
- Quadrangular	0	0	0	
- Sliding plasty	1 (0.8)	0	1 (1.6)	
Concomitant AF ablation (%)	7 (5.6)	5 (8)	2 (3.2)	0.44
Second AoX (%)	10 (8)	5 (8)	5 (8)	1
Extubation in the OR (%)	63 (50.8)	29 (46.8)	34 (54.8)	0.47
Mechanical ventilation (h)	0 (0–6.5)	4 (0–7)	0 (0–6.25)	0.55
Vascular complications (%)	1 (0.8)	0	1 (1.6)	0.32
Transfusion (%)	23 (18.5)	7 (11.3)	16 (25.8)	0.04
Postoperative AF (%)	32 (25.8)	17 (27.4)	15 (24.2)	0.68
ICU stay (days)	1 (1–2)	1 (1–1)	1 (1–3)	0.03
Hospital stay (days)	5 (4–7)	6 (5–7)	4 (4–6)	<0.00001
MR at discharge (%)				
Mild or less	116 (93.5)	57 (92)	59 (95.2)	0.08
Mild–Moderate	7 (5.7)	5 (8)	2 (3.2)	
Moderate	1 (0.8)	0	1 (1.6)	

Variables expressed as median (p25–p75) or as count (%).

AF: atrial fibrillation; ICU: intensive care unit; MR: mitral regurgitation; OR: operation room.

showed that improvement in surgical times continued afterwards (Supplementary Material, Fig. S1).

Primary outcome

Regarding the primary outcome, the observed incidence was 8.9%, with no significant differences in both centres (9.7% vs. 8.0%) and mostly driven by re-exploration for bleeding (6.8% in both centres). Noteworthy, there were no cases of mortality, stroke, or valve replacement, and only 1 patient required conversion (Table 3). In the success/failure CUSUM analysis, both centres presented similar curve patterns. There was an initial learning phase with a descending curve as the outcome appeared more frequently than expected (10% expected incidence), followed by an ascending curve as its incidence reduced. Both centres then accumulated increasing positive outcomes and crossed the baseline after 60 and 50 cases, respectively (Fig. 4).

In addition, other postoperative outcomes were not different between centres, as shown in Table 2. Hospital stay was significantly shorter in centre 2 (6 vs. 4 days; $P < 0.001$) despite an initial slightly longer Intensive Care Unit stay. Mitral regurgitation at discharge was none/trace in 93.5% cases, without differences between centres.

The analysis of the primary outcome in quartiles revealed a similar evolution on both centres. The largest incidence of adverse events occurred during the 1st quartile, with a continuous decreasing thereafter (Supplementary Material, Table S1). Also, a continuous reduction of mechanical ventilation and hospital stay was also found (see Supplementary Material, Table S2). Moreover, an analysis of the primary outcome on the additional cases performed after the study period in centre 2 revealed further improvement (Supplementary Material, Fig. S1).

DISCUSSION

Our study compared the learning curves of robotic-assisted MV repair in 2 centres with vast experience in MV repair surgery that started their programmes simultaneously, following the same training but with one of them transitioning directly from conventional surgery and the other from MIMVS. After analysing the first 62 cases performed at each centre, the main findings of the present study are:

1. A robotic-assisted MV repair programme can be successfully implemented with good safety and quality standards for patients, following a standardized training pathway and coming either from a previous mastery of MT-MIMVS or directly from conventional sternotomy.
2. Performance of robotic-assisted MV repair improved progressively over time, as reflected both in surgical times and clinical outcomes.
3. Previous experience in MT-MIMVS seems to soften the learning curve of robotic-assisted MV repair and shortens the duration of the procedure (CPB, AoX and total duration).

When comparing learning curves of surgical performance from both centres, we found 2 different patterns. Centre 1 showed reduced surgical times in the initial few cases, followed then by a standard curve, reaching the proficiency phase after ~30 cases. Centre 2 displayed a standard curve from the beginning but a faster improvement over time, reaching proficiency after 16 cases and showing reduced surgical times throughout the study period.

There are several potential explanations for these findings. First, centre 2 had previous experience in MT-MIMVS. As reported by other surgical specialties, previous experience in

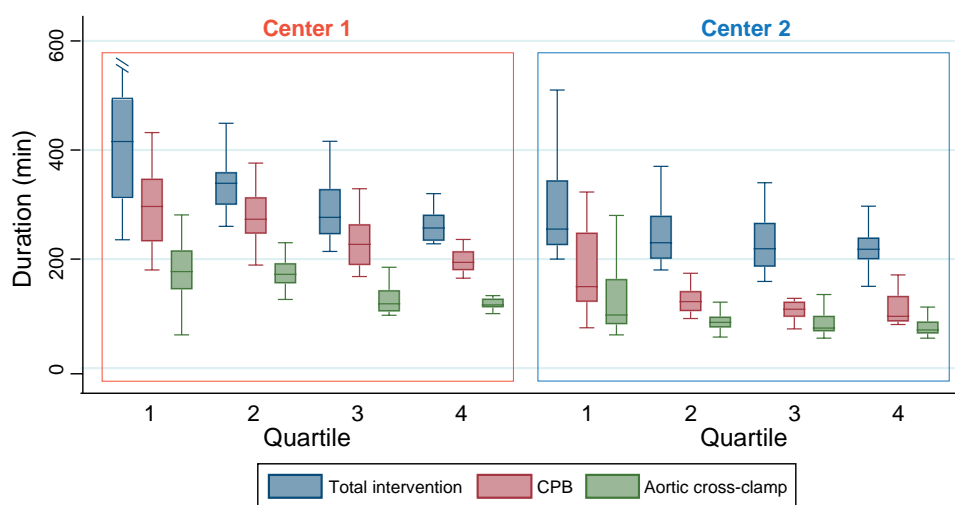


Figure 3: Evolution of all surgical times in each centre, divided by quartiles of experience, showing the continuous progressive decline in all surgical times and in its variability in both centres. CPB: cardiopulmonary bypass.

Table 3: Primary outcome

Individual subcomponents	Total (n = 124)	Centre 1 (n = 62)	Centre 2 (n = 62)	P-value
Intraoperative conversion ^a (%)	1(0.8)	1(1.6)	0	1
Failed mitral repair ^b (%)	0	0	0	1
Death (%)	0	0	0	1
Stroke (%)	0	0	0	1
Re-exploration for bleeding (%)	8(6.4)	4(6.4)	4(6.4)	1
New acute kidney injury requiring dialysis (%)	0	0	0	1
Perioperative myocardial infarction (%)	1(0.8)	0	1(1.6)	1
Low cardiac output syndrome (%)	0	0	0	1
Valve-related reoperation within the same hospital stay ^c (%)	1(0.8)	1(1.6)	0	1
Any of the above (%)	11(8.9)	6(9.7)	5(8.0)	1

^aConversion to sternotomy.

^bMitral replacement during index surgery.

^cNeed for mitral reintervention during the same admission due to recurrent or residual MR regardless of the final procedure performed (repair or replacement).

Material, Fig. S2). Furthermore, both centres used the robotic platform differently; while centre 1 used the robotic platform only for degenerative mitral cases, centre 2 performed also other procedures such as atrial septal defect closure, MV replacement, tricuspid valve repairs, CABG and others, with a total of 38 additional robotic cases performed during the inclusion period. This higher use of the robot and regularity could have also impacted the learning curve [13, 16]. However, we believe MT-MIMVS experience is the most important factor explaining the differences found, since they could be observed consistently from the very beginning in the 1st quartile, before all other factors could exert an effect.

Regarding the difference in performance observed on the very 1st cases, centre 1 performed their first 9 cases using the dual-console setup, in which both surgeon and proctor could use the robot. Centre 2 did not have this resource and only performed 2 cases with a proctor, who was giving advice without direct participation during the procedure. This dual-console strategy in the proctoring phase may explain the differences in the initial surgical cases and in our view reinforces the value of this approach.

Despite the clear differences found in surgical times, we found smaller differences when analysing clinical outcomes, reinforcing

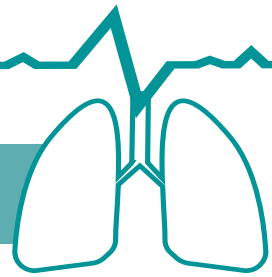
the safety of the implementation strategies on both centres. For our primary outcome, we used the same components and predicted risk of failure (10%), as previously described by the Leipzig group in their seminal studies of learning curves in MIMVS and CABG surgery [9, 10]. Using this preset parameter, centre 1 reached the 'improvement zone' after 60 cases, whereas centre 2 reached it after 50 cases, whereas in that study, 75–125 cases were usually required. In both centres, the most repeatedly observed complication was re-exploration for bleeding, with an incidence of 6.4%, which is in accordance with a previously published study [17]. Excellent results were obtained in both centres, with no cases of valve replacement and a very high successful repair rate. The additional analyses on the cases performed in centre 2 after completing this study confirm the stability of the improvement achieved both in the primary outcome and in surgical times, and even show further improvement in both areas with increasing experience.

One of the strengths of this study is that it combines data from 2 centres with vast experience in MV repair but different previous default approaches. Both centres started their robotic programmes simultaneously and followed the same training path, improving comparability. As centres had already mastered the MV repair learning curve, the current analysis is more reliably

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Real-world experience with Thopaz⁺

The Oxford University Hospitals NHS Foundation Trust experience

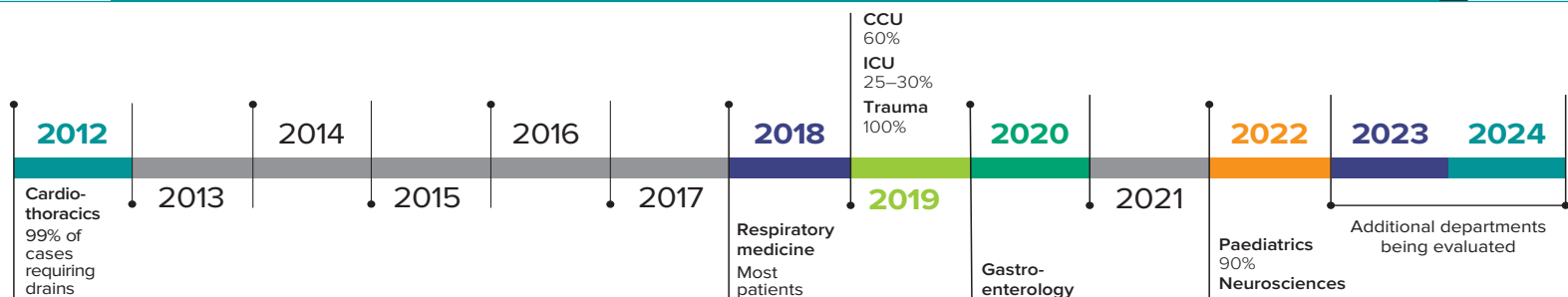


This article was funded by Medela AG

Thopaz⁺ is a portable digital chest drainage and monitoring system developed by Medela. It offers continuous objective monitoring of fluid loss and air leaks, which facilitates assessment of patients' progress, as well as standardisation of chest drainage management across different departments.¹ Clinical evidence has demonstrated that Thopaz⁺ is a useful tool in the management of patients that require chest drains and has clear clinical advantages compared with underwater seal drains.¹⁻³

Thopaz⁺ and its predecessor, Thopaz, have been used within the Cardiothoracic Department at Oxford University Hospital NHS Trust since 2012. A report on this experience contributed to [National Institute for Health and Care Excellence \(NICE\) Medical Technology Guidance 37](#).^{1,4} Use of Thopaz⁺ in Oxford has since expanded to other departments within the trust. This document summarises the experience with Thopaz⁺ based on interviews with healthcare professionals (HCPs) at Oxford University Hospital NHS Trust in February/March 2024.

Evolution of Thopaz⁺ use in Oxford: initial introduction by department and current usage*



*Percentage of cases using Thopaz⁺, where known from interviews.

CHEST DRAINAGE PROTOCOLS

Each department has a chest drain protocol based on their use of Thopaz⁺ or underwater seal drains, and whether active suction or physio mode is needed.

MOBILISATION

Improved and earlier mobilisation is a major advantage of Thopaz⁺ in relation to complications associated with immobility.

OBJECTIVE AND CONTINUOUS MONITORING LEADS TO IMPROVED DECISION-MAKING

Continuous monitoring improves chest drain decision-making by providing objective estimates/measurement of leakage. It helps determine when air leaks are resolving (allowing for earlier drain removal and discharge planning) or when further intervention is needed (such as referral to a surgeon).

LENGTH OF STAY

Digital drainage facilitates day-case procedures by giving HCPs confidence that their patients have no persistent air leaks or fluid loss.

RESPIRATORY

70% of patients following pleural intervention and 60% undergoing thoracoscopy return home the same day.

CORONARY CARE UNIT (CCU)

Length of stay of 7 days with Thopaz⁺ compared with 10 days with underwater seal drains.

THROUGHOUT THE PATIENT JOURNEY

Thopaz⁺ can be used throughout a patient's journey, which can reduce the possibility of issues and errors, because drains can become kinked or displaced whenever a device is changed. Suction can be added to a Thopaz⁺ device set up to provide straightforward drainage simply by pressing a button to initiate suction via the device itself.

COSTS AND EFFICIENCIES

The use of the device can lead to improved operational efficiencies and cost savings, which may justify the acquisition costs. From an evidence-based practice project in the USA, a digital air leak detection device after pulmonary lobectomy led to cost savings of \$2,659 per hospital day.⁵

IMPROVED PATENT SAFETY

Thopaz⁺ is a closed system, reducing incidents, errors, mishaps, and infections. As a dry system, Thopaz⁺ prevents issues with water and device positioning. Non-medical staff can manage Thopaz⁺ if it is knocked over, with no patient impact. Thopaz⁺ has its own suction source, preventing complications with wall suction becoming displaced or unclipped.

STAFF EXPERIENCE

Precise fluid and air leak measurements including time trends, improve clinician confidence and decision-making and facilitate continuity of care. The user-friendly interface makes it easier to track air leaks and fluid output. Nursing time is saved with easy canister replacement, reduced manual monitoring, and visual and audible notifications alert HCPs of issues.

PATIENT EXPERIENCE

Patients can move around freely without nursing or healthcare assistant support. Earlier discharge reduces hospital stay. Patients can monitor their progress in terms of reducing volumes of fluid and air leaks on the display.

Summary of the real-world experience with Thopaz+

The experience of HCPs within Oxford University Hospitals NHS Foundation Trust over the past 12 years has shown that Thopaz+ has multiple benefits in the right circumstances and should be available for the vast majority of patients requiring a chest drain.

Francesco Di Chiara MD, MS THOR (Hons), FEBTS

Consultant Thoracic Surgeon Oxford University Hospitals NHS Foundation Trust



Overall, our experience at Oxford University Hospitals NHS Foundation trust has shown that Thopaz+ is an indispensable asset for HCPs, redefining standards of care and operational efficiency across multiple medical departments. We encourage all units using chest drains to consider making the move from underwater seal drains to Thopaz+ in the vast majority of patients requiring chest drainage.

Quotes from interviews with a number of healthcare professionals at Oxford University Hospital NHS Trust:



From the NHS perspective, I think it probably allows us to make earlier decisions about withdrawing chest drains and getting people out of hospital earlier.



There are a number of ways to recoup the costs: efficiencies in the system, less litigation because things don't go wrong, staff sickness due to back injuries, and length of stay if you can get patients home quicker.



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Read the full report:



The summary report has been written by HSJ Advisory on behalf of Medela AG, reflecting the views expressed in interviews with healthcare professionals. Medela AG funded the project and had input into the development of this report.

HSJ Advisory

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Turning Science into Care

Thopaz+
#1 reference for digital
drainage*



Read the evidence



*Pioneering the digital chest drainage market since 2007. Market report and data show number 1 market share as of January 2024. Thopaz/Thopaz+ being named or referred to in >100 published studies, reports, or publicly available data.