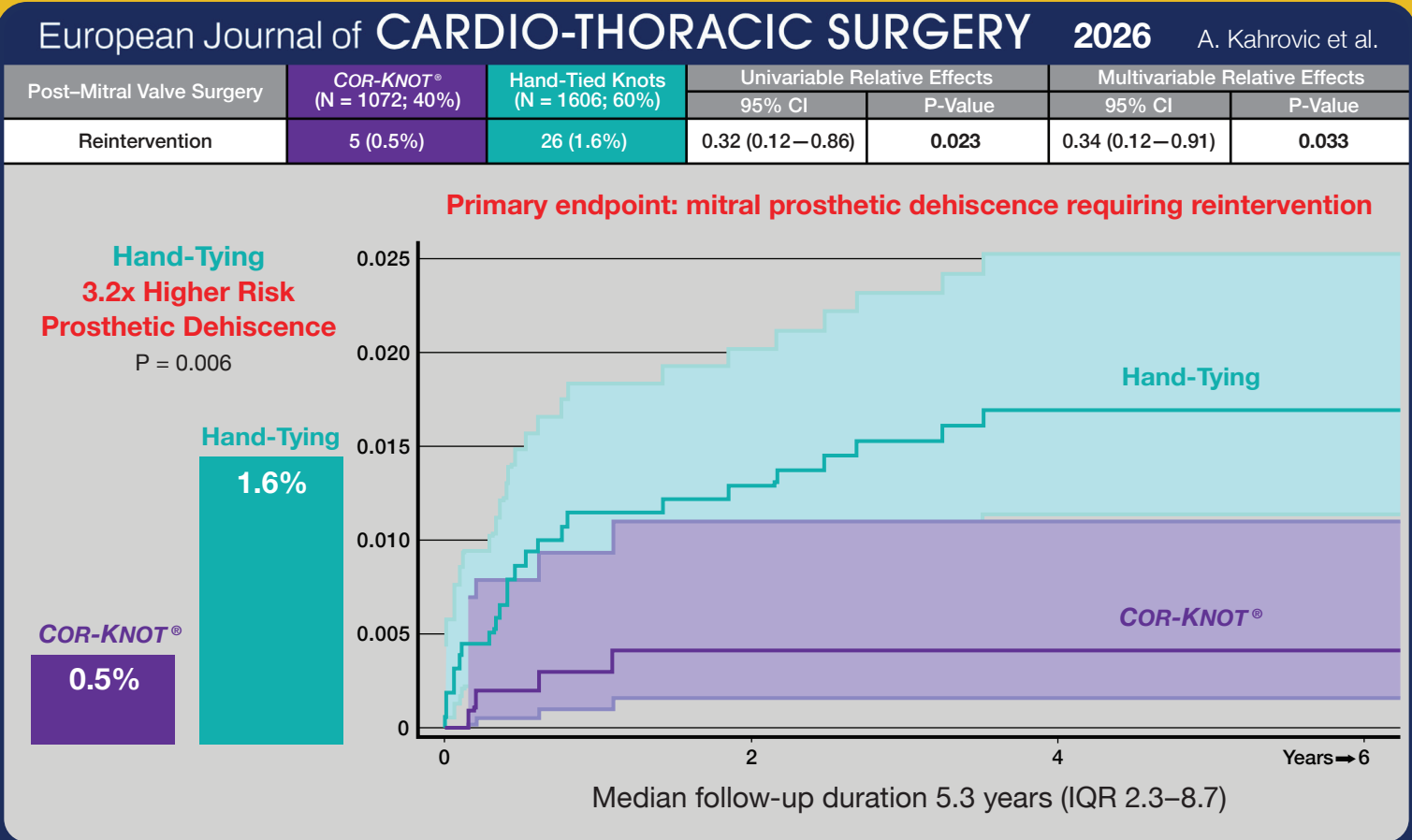
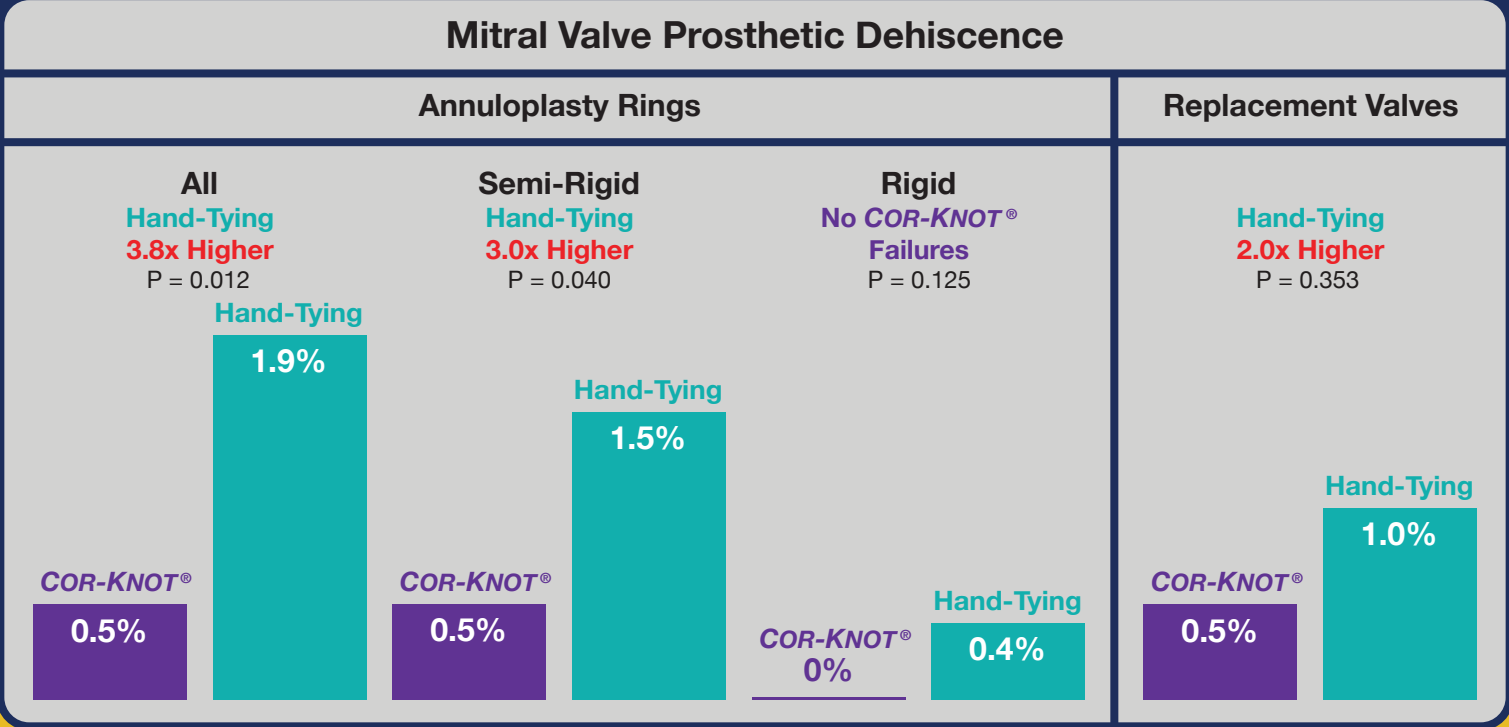


COR-KNOT® Reduces Mitral Prosthetic Dehiscence



“Automated Suture Securing Technology in Mitral Valve Surgery: A Strategy to Reduce Prosthetic Dehiscence?”¹

A. Kahrovic, H. Herkner, P. Werner, P. Angleitner, I. Coti, K. Osipenko, H. Lagler, A. Kocher, M. Ehrlich, D. Zimpfer, M. Andreas. *EJCTS*, January 2026. doi.org/10.1093/ejcts/ezag013



DISCUSSION: Standardized automated titanium fastener for suture securing improves the mechanical stability of mitral valve prosthetic implants

COR-KNOT®



DEVICE

AUTOMATED

- Slim, ergonomic design with 17cm or 31cm shaft length for minimally invasive and open surgical approaches
- Facilitates precise and secure automated suture fixation even with limited exposure at remote or restricted access angles



TITANIUM FASTENER

RELIABLE

- Mechanical strength, consistency, and uniformity of suture tension along the prosthetic
- Standardizes quality of suture securing, eliminating tension variability for each suture

HAND-TIED



HAND-TYING

UNPREDICTABLE

- Inherently prone to variability in suture-holding tension, and may vary with the same surgeon
- Limited exposure can impair visualization and reduce maneuverability of precise knot tying

HAND-TIED KNOT

UNRELIABLE

- Incompletely tensioned “air knots” that appear secure may inadvertently occur with hand-tying
- Inadequate mechanical tension or tissue compression at the annulus–sewing ring interface may be a nidus for dehiscence

UNSTABLE MANUAL KNOTS

Inconsistent and insufficient suture tension along the annulus-to-prosthetic contact area

CARDIAC CYCLE STRESSORS

Repetitive hemodynamic loading
LV twisting contraction / MV annular tilting

Elevated
Shear Forces

Induced
Micro-Separations

Regurgitant Jet
Tissue Erosion

OVERT
DEHISCENCE

CONCLUSIONS: Mechanical stability augmented by titanium fasteners improves long-term durability of mitral rings and valve prostheses

FASTER

CPB Saves 10 min.

166 vs. 176 P < 0.001

ACC Saves 5 min.

113 vs. 118 P < 0.001

MORE DURABLE

Early Onset
≤30 Days

No
COR-KNOT®
Failures
P = 0.067

COR-KNOT®
0%

Hand-Tying
0.3%

Late Onset
>30 Days

Hand-Tying
2.6x Higher
P = 0.030

COR-KNOT®
0.5%

Hand-Tying
1.3%

Mitral Annular Suturing

Standardized surgical techniques were employed: interrupted 2-0 mattress sutures for valve repair and pledgeted 2-0 mattress sutures for valve replacement

COR-KNOT® Surgical Reoperation Rate Is Less Than 1/5th of Hand-Tying

Of the 5 **COR-KNOT®** patients requiring reintervention for prosthetic dehiscence, 2 (40%) were successfully treated with percutaneous interventions. All 26 hand-tied knots patients required surgery (100%). The overall rate of required surgical reoperation for hand-tied patients (1.6%) was 5.3x higher than for **COR-KNOT®** patients (0.3%).

COR-KNOT® Patients Older Without Increased Risk of Stroke or Death

While **COR-KNOT®** patients were significantly older than hand-tied knots patients (median 69.6, IQR 60.1–76.3 vs. median 67.2, IQR 57.7–74.5, P < 0.001) with all other baseline characteristics comparable, there was no difference in the secondary endpoints of ischemic stroke, intracranial bleed, or all-cause mortality between the study groups.

COR-KNOT® Leaflet Perforation Never Observed

Leaflet perforation was not seen in any of the 1,072 **COR-KNOT®** patients (cumulatively well over 10,000 **COR-KNOT®** titanium fasteners).

COR-KNOT® Reduced Artificial Chordae Dehiscence

The rate of artificial chordae dehiscence was also lower among **COR-KNOT®** patients (0.0% vs 0.9%, P = 0.015).

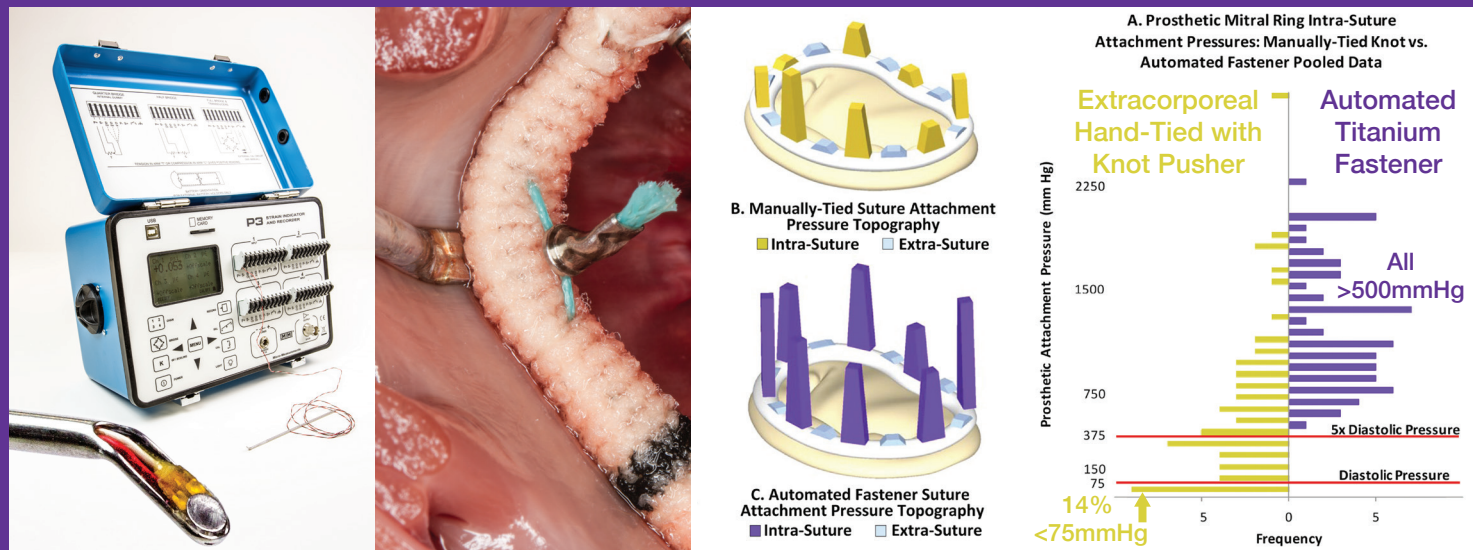
COR-KNOT® Automated Reliability Pressure Mapping

“Comparison of Strength, Consistency, and Speed of COR-KNOT® versus Manually Hand-Tied Knots in an Ex Vivo Minimally Invasive Model”²

C. Lee, J. Sauer, H. Gorea, A. Martellaro, P. Knight. *Innovations*, March/April 2014.

Objective: “A novel miniature pressure transducer system was developed to quantify pressures between sutured prosthetic rings and underlying cardiac tissue.”

Discussion: “Mitral valve annuloplasty ring sutures secured with **COR-KNOT®** were, on average, twice as strong, significantly more consistent, and more than five times quicker to apply than manually hand-tied knots.”

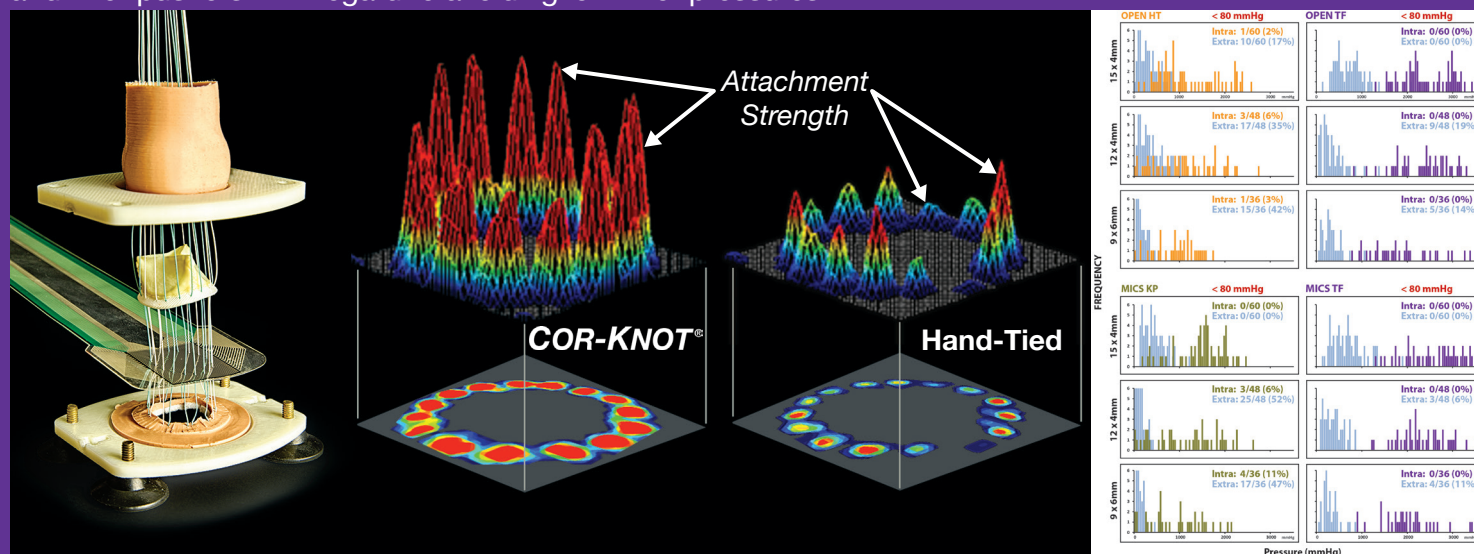


“Prosthetic Aortic Valve Fixation Study: 48 Replacement Valves Analyzed Using Digital Pressure Mapping”³

C. Lee, J. Wong, R. Ross, D. Liu, K. Khabbaz, A. Martellaro, H. Gorea, J. Sauer, P. Knight. *Innovations*, September/October 2016.

“Customized digital thin film pressure transducers were sutured between aortic annulus models and 21-mm bioprosthetic valves.” Real-time pressure measurements: 12/144 (8.3%) hand-tied knots fell to <80mmHg vs. 0/288 (0%) **COR-KNOT®** fasteners ($P < 0.001$).

Clinical Perspective: “**COR-KNOT®** fasteners were found to be more effective than both manual hand tying and knot pushers with regard to avoiding low knot pressures.”



COR-KNOT[®] Reduces Paravalvular Leak Rate by >5x

Additional PVL peer-review adjudicated references

Minimally Invasive Mitral Valve Surgery⁴

COR-KNOT[®] Patients: MVR = 119; MVR = 14

≥1 Year

Paravalvular Leak
Dehiscence

0%

Thrombus
Hemolysis

0%

Fastener Failure
Adverse Outcomes

0%

Open & MICS AVR⁵

COR-KNOT[®] = 153 Hand-Tied = 882

>2 Years

1.1%

6.5%

PVL
Relative Risk:
Hand-Tying
5.7x
Higher

P = 0.04

Single-Center Heart Valve Surgery⁶

COR-KNOT[®] = 100 Hand-Tied = 100

30 Days

0%

6%

PVL
Relative Risk:
Hand-Tying
>6x
Higher

P = 0.029

Minimally Invasive AVR⁷

COR-KNOT[®] = 75 Hand-Tied = 44

30 Days

1.4%

32.4%

PVL
Relative Risk:
Hand-Tying
23.1x
Higher

P < 0.001

Partial vs. Full Sternotomy AVR⁸

COR-KNOT[®] = 331 Hand-Tied = 321

Mean: 2.1 Days

0.6%

3.4%

PVL
Relative Risk:
Hand-Tying
5.7x
Higher

P = 0.013

MICS AVR with COR-KNOT[®] vs. TAVR⁹

COR-KNOT[®] = 476 TAVR = 679

30 Days

0%

5.9%

PVL
Relative Risk:
TAVR
5.9x
Higher

P = 0.001



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"In mitral valve surgery, the annuloplasty ring and valve replacement prosthesis are traditionally anchored using hand-tied sutures. However, the tension of these sutures is dependent on the surgeon's manual technique, introducing variability in suture-holding strength and annular compression. Such inconsistency may lead to uneven mechanical stress distribution along the sewing ring-annulus interface, facilitating the development or progressive enlargement of micro-paravalvular leaks under persistent elevated flow pressure, and ultimately increasing the risk of prosthetic dehiscence over time."



Dr. med. univ. Amila Kahrovic, Ph.D.
Cardiac Surgery Resident, Vienna, Austria
Ph.D. Celebration, 23 June 2025

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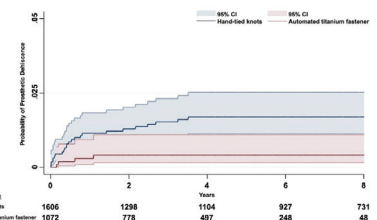
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Results – Primary Study Endpoint - Prosthetic dehiscence

Variables	sHR	95% CI	p-value
Automated titanium fastener	0.34	0.13 – 0.92	0.034
Functional mitral valve disease	1.58	0.76 – 3.28	0.222
Previous mitral valve surgery	2.83	0.81 – 9.86	0.103
Minimally-invasive surgery	0.74	0.27 – 2.03	0.560
Extensive annular calcification	4.91	0.54 – 44.99	0.159
Annular decalcification	0.91	0.12 – 7.00	0.928
Mitral valve repair with annuloplasty ring	2.40	0.86 – 6.70	0.096

a) Effects calculated as sHR based on a multivariable proportional competing risk regression model.



Research Limitations "This study is a retrospective, single-centre analysis ... may not be fully generalizable to other centres ... residual and unmeasured confounding cannot be fully ruled out. Detailed information on suture placement technique (everting vs non-everting) for mitral valve replacement was not available ... Prosthetic dehiscence may occur due to the fragility of the tissue or technical aspects of the procedure itself, such as superficial suture placement."

Citations 2–9

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