Two Transformational Publications in 2024 Demonstrate

COR-KNOT® Reduces Prosthetic Valve Endocarditis[1,2]

European Journal of CARDIO-THORACIC SURGERY

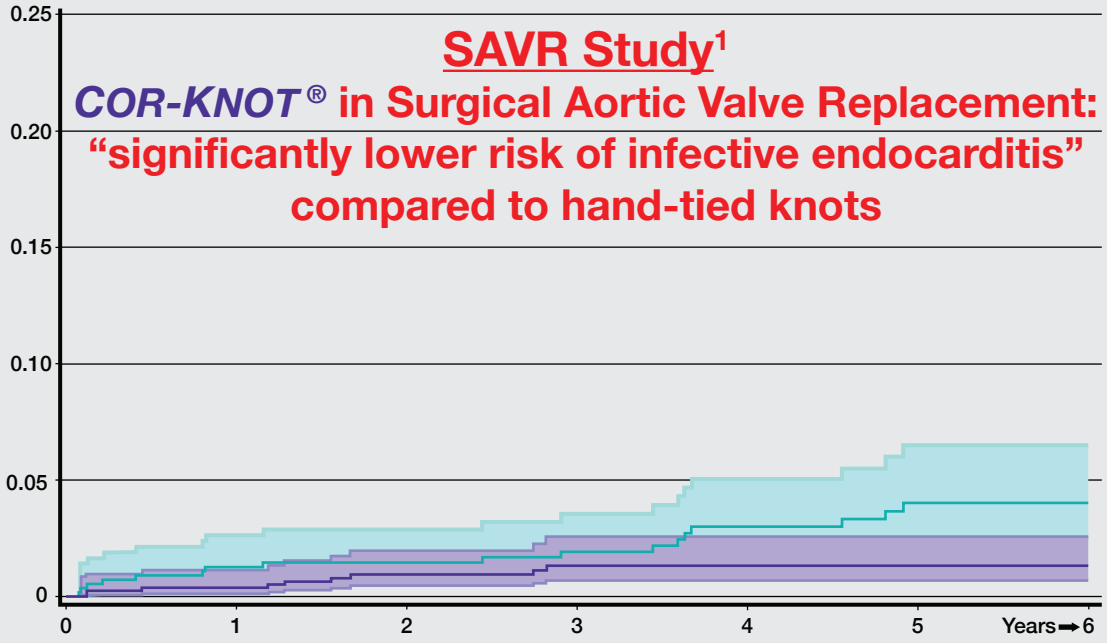
A. Kahrovic et al.

Post-SAVR	*COR-KNOT*® (N = 829; 59%)	Hand-Tied Knots (N = 576; 41%)	Univariable Relative Effects		Multivariable Relative Effects	
			95% CI	P-Value	95% CI	P-Value
Infective Endocarditis (IE)	9 (1.1%)	17 (3.0%)	0.42 (0.19—0.93)	**0.033**	0.44 (0.20—0.94)	**0.035**

Hand-Tying 2.7x Higher Post-Op IE Rate
P = 0.011

COR-KNOT®
1.1%

Hand-Tying
3.0%



SAVR Study[1]

***COR-KNOT*® in Surgical Aortic Valve Replacement: "significantly lower risk of infective endocarditis" compared to hand-tied knots**

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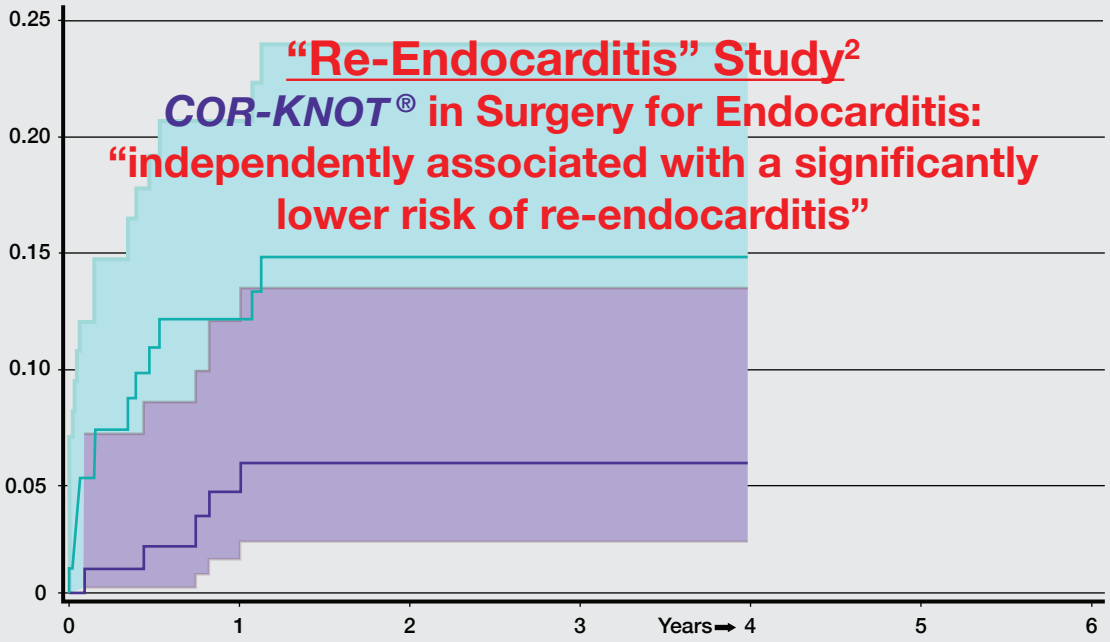
A. Kahrovic et al.

IE Patients AVR and/or MVR	*COR-KNOT*® (N = 114; 51.8%)	Hand-Tied Knots (N = 106; 48.2%)	Univariable Relative Effects		Multivariable Relative Effects	
			95% CI	P-Value	95% CI	P-Value
"Re-Endocarditis"	5 (4.4%)	13 (12.3%)	0.35 (0.12—0.96)	**0.042**	0.33 (0.11—0.99)	**0.048**

Hand-Tying 2.8x Higher Post-Op IE Rate
P = 0.042

4.4%

12.3%

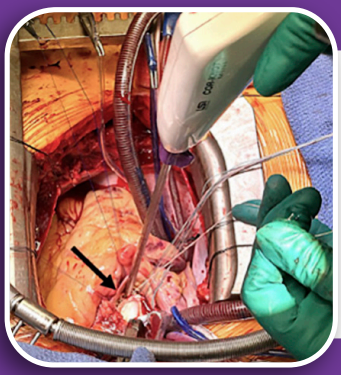


"Re-Endocarditis" Study[2]

***COR-KNOT*® in Surgery for Endocarditis: "independently associated with a significantly lower risk of re-endocarditis"**

DISCUSSION: "Surgical site contamination, including the newly implanted prosthesis, might lead to postoperative occurrence of early-onset IE"[1]

COR-KNOT®



DEVICE

"No direct hand-contact"[1]

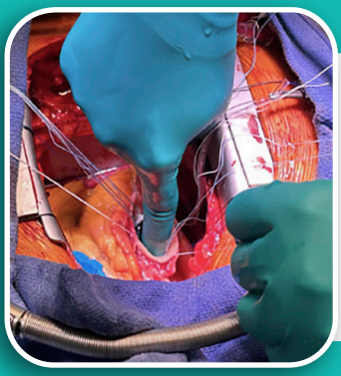
- "Potential reduction in contamination through the implementation of the no-touch principle … through a single deployment, with no direct hand-contact with the newly implanted valve prosthesis."[1]
- "Minimizing hand contact with the inflamed and infectious environment and with the … valve prosthesis might be beneficial."[2]

TITANIUM FASTENER

"Flat, uniform surface"[1]

- "The flat, uniform surface of the automated titanium fastener, crimped around the suture might be less conducive to bacterial adherence."[1]
- "We believe that the flat, smooth surface of the crimped … fastener around the suture may act as a protective sheath, thus reducing bacterial adhesion."[2]

HAND-TIED



HAND-TYING

"Over a hundred direct hand-touches"[1]

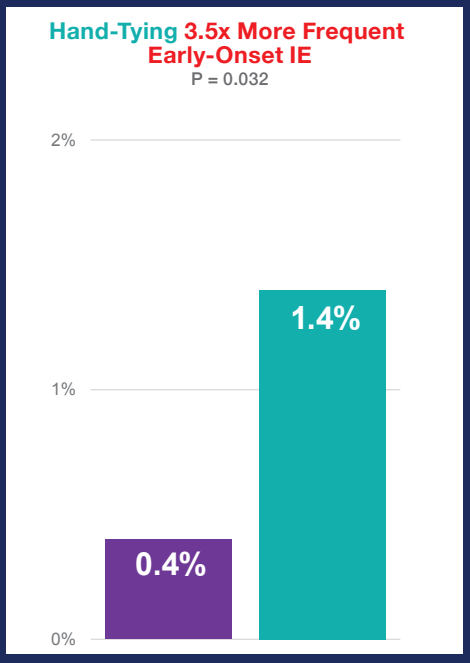
- "The hand-knot tying technique involves multiple, direct hand-touches for securing suture, resulting in over a hundred direct hand-touches on the newly implanted valve prosthesis."[1]
- "It is pertinent to note that surgical gloves might bear pathogens and subsequently, disseminate these while tying knots manually."[1]

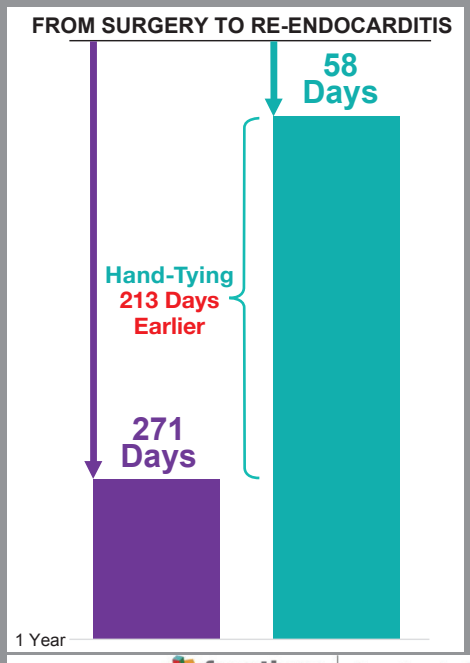
HAND-TIED KNOT

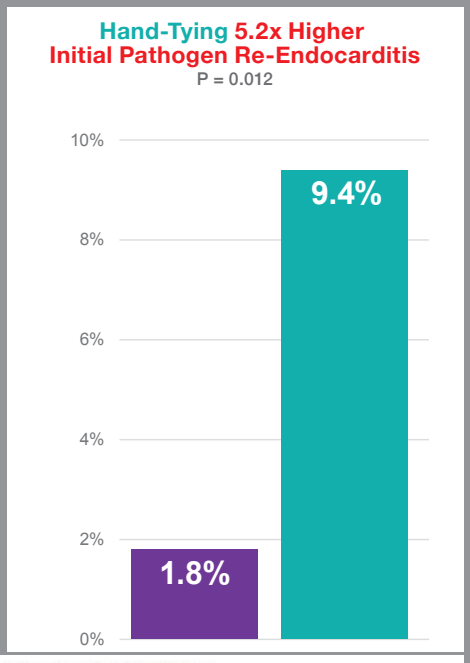
"Increased surface area for bacterial attachment"[1]

- "Irregularities in topography … in braided sutures with multiple knots, introduce numerous microenvironments where bacteria can adhere and thrive."[1]
- "Literature suggests that bacterial adherence and growth are favored on braided sutures, especially on multiple hand-tied knots, thus enhancing the formation of a biofilm."[2]

CONCLUSIONS: "Suture-securing with an automated titanium fastener device appears to be superior compared to the hand-knot tying technique"[1]







COR-KNOT® Reintervention/Reoperation Rate Reduced

In the SAVR Study, "The rate of reintervention was lower … (1.3% vs. 3.5%, P = 0.007)"[1] [2.7x lower than hand-tied] with ***COR-KNOT***®. In the Re-Endocarditis Study, "The rate of non-IE-related reoperation was significantly lower … (0.0% vs. 4.7%; P = 0.019)"[2] [none vs. nearly 5%].

COR-KNOT® Fewer Paravalvular Leaks

Noted in the SAVR Study, "The occurrence of the paravalvular leak might be attributed to the undesirable loose hand-tied knots or 'air-knots.' In the present analysis, the rate of reoperation due to the paravalvular leak was lower in the automated titanium fastener group; however, the significance level has not been reached (0.4% vs. 1.0%, P = 0.116)"[1] [2.5x lower than hand-tied]. In the Re-Endocarditis Study, "The causes of non-IE-related reoperation in the hand-tied knots group were major paravalvular leak (2.7%)."[2]

COR-KNOT® Leaflet Perforation Never Observed

From the SAVR Study: "The cases of leaflet perforation attributed to automated titanium fastener have been reported in a few case reports … Noteworthy, in the present study involving 829 patients in the automated titanium fastener group, no such complication was documented."[1]

COR-KNOT® No Increase in Risk of Stroke

In the SAVR Study, ***COR-KNOT***® was "not associated with an increased risk of stroke (adjusted sub-hazard ratio 0.82, 95% confidence interval 0.47–1.45, P = 0.504)."[1] In the Re-Endocarditis Study, ***COR-KNOT***® was "not associated with an increased risk of stroke (adjusted HR 0.54, 95% CI 0.27–1.08, P = 0.082)."[2]

COR-KNOT® REFERENCES: SAVR Study[1]: Preventive Role for IE? Re-Endocarditis Study[2]: For Prosthesis Fixation in IE

European Journal of
CARDIO-THORACIC SURGERY

1. Automated Titanium Fastener for Surgical Aortic Valve Replacement—Preventive Role for Infective Endocarditis? Amila Kahrovic, Harald Herkner, Philipp Angleitner, Paul Werner, Alfred Kocher, Marek Ehrlich, Dominik Wiedemann, Guenther Laufer, Paul Simon, and Martin Andreas. *Eur J Cardiothorac Surg* 2024. doi: 10.1093/ejcts/ezae236

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2. Automated Titanium Fastener vs. Hand-Tied Knots for Prosthesis Fixation in Infective Endocarditis. Amila Kahrovic, Philipp Angleitner, Harald Herkner, Paul Werner, Thomas Poschner, Leila Alajbegovic, Alfred Kocher, Marek Ehrlich, Günther Laufer, and Martin Andreas. *Front. Cardiovasc. Med.* 2024. doi: 10.3389/fcvm.2024.1363336

Research Limitations Single-center retrospective studies. Suture-securing technique was surgeon-dependent. Only patients with a definite diagnosis of IE (following Duke criteria and current guidelines) were included in analysis. Information regarding minor paravalvular leak as the possible predisposition for IE was not available for analysis. Current literature on this topic is limited.

Automated titanium fastener for surgical aortic valve replacement - preventive role for infective endocarditis?

Amila Kahrovic[1]; Harald Herkner[2]; Philipp Angleitner[1]; Paul Werner[1]; Alfred Kocher[1]; Marek Ehrlich[1]; Dominik Wiedemann[1]; Guenther Laufer[1]; Paul Simon[1]; Martin Andreas[1]
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Study Objectives

During surgical aortic valve replacement (SAVR), the sutures can be secured with an automated titanium fastener device (Cor-Knot Device, LSI Solutions, United States) or with a hand-knot tying technique. Data on long-term clinical outcomes considering the suture-securing techniques used in SAVR are still lacking.

Figure 1: Suture-securing techniques during SAVR (automated titanium fastener vs. hand-tied knots)

Patients and Methods

A total of 1405 patients who underwent SAVR between January 2016 and December 2022 were included.

The exclusion criteria were surgery of mitral, tricuspid, or pulmonary valve in combination with SAVR, Bentall procedure, replacement of ascending aorta, previous cardiac surgery, and infective endocarditis (IE) at baseline. The occurrence of IE during follow-up was set as the primary study endpoint. As secondary study endpoints, stroke, all-cause mortality, and a composite outcome of either IE, stroke, or all-cause mortality were assessed.

Results

Table 1: Baseline characteristics

Variables	Automated titanium fastener, N = 829 (59%)	Hand-tied knots, N = 576 (41%)	P-value
Age (years) (25th–75th interval)	70.5 (62.4–76.2)	72.1 (64.1–77.5)	**0.007**
Female (%)	271 (32.7)	211 (36.6)	0.126
Body mass index (kg/m²) (25th–75th interval)	28.0 (25.3–31.7)	27.5 (24.8–30.9)	**0.034**
EuroSCORE II, 25th–75th interval	1.8 (1.1–3.4)	2.1 (1.1–3.6)	0.054
NYHA class III–IV, n (%)	300 (36.2)	230 (39.9)	0.155
Hypertension, n (%)	726 (87.6)	489 (84.9)	0.149
Atrial fibrillation, n (%)	136 (16.4)	96 (16.7)	0.897
Paroxysmal	102 (12.3)	69 (12.0)	0.855
Persistent	34 (4.1)	27 (4.7)	0.596
Previous pacemaker implantation, n (%)	25 (3.0)	19 (3.3)	0.765
Diabetes mellitus, n (%)	232 (28.0)	160 (27.8)	0.932
Peripheral vascular disease, n (%)	84 (10.1)	46 (8.0)	0.172
Cerebrovascular disease, n (%)	161 (19.4)	93 (16.1)	0.117
History of stroke, n (%)	42 (5.1)	24 (4.2)	0.433
Dialysis, n (%)	6 (0.7)	8 (1.4)	0.217

Bold indicates statistical significance ($P < 0.05$).
EuroSCORE II: European System for Cardiac Operative Risk Evaluation II; NYHA: New York Heart Association.

Table 2: Operative characteristics

Variables	Automated titanium fastener, N = 576	Hand-tied knots, N = 576 (41%)	P-value
Era, n (%)			**<0.001**
2016–2019	426 (51.5)	437 (75.9)	
2020–2022	403 (48.6)	139 (24.1)	
Access, n (%)			
Full-sternotomy	393 (47.4)	344 (59.7)	**<0.001**
Hemi-sternotomy	305 (36.8)	181 (31.4)	**0.037**
Thoracotomy	131 (15.8)	51 (8.9)	**<0.001**
Aortic valve replacement, n (%)			0.830
Mechanical prosthesis	101 (12.2)	68 (11.8)	
Biological prosthesis	728 (87.8)	508 (88.2)	
Concomitant procedures, n (%)			
CABG	263 (31.7)	236 (41.0)	**<0.001**
Aortic reduction plasty	81 (9.8)	62 (10.8)	0.545
Aortic root enlargement	27 (3.3)	24 (4.2)	0.370
Septal myectomy	46 (5.5)	34 (5.9)	0.778
Atrial fibrillation surgery	46 (5.5)	36 (6.3)	0.581
Left atrial appendage resection	58 (7.0)	54 (9.4)	0.105
CPB time (min), 25th–75th interval	116 (95–148)	115 (92–149)	0.134

Bold indicates statistical significance ($P < 0.05$).
CABG: Coronary artery bypass grafting; CPB: cardiopulmonary bypass.

Table 3: Study endpoints

	Automated titanium fastener, N = 829 (59%)	Hand-tied knots, N = 576 (41%)	Univariable relative effects 95% CI	Univariable relative effects P-value	Multivariable relative effects 95% CI	Multivariable relative effects P-value
Infective endocarditis[a]	9 (1.1)	17 (3.0)	0.42 (0.19–0.93)	**0.033**	0.44 (0.20–0.94)	**0.035**
Stroke[a]	27 (3.3)	24 (4.2)	0.84 (0.48–1.45)	0.524	0.82 (0.47–1.45)	0.504
All-cause mortality[b]	86 (10.4)	100 (17.4)	0.76 (0.57–1.01)	0.063	0.81 (0.60–1.09)	0.169
Composite outcome[b]	109 (13.1)	124 (21.5)	0.74 (0.57–0.96)	**0.024**	0.82 (0.63–1.07)	0.152

Bold indicates statistical significance ($P < 0.05$).
[a]Effects calculated as sHR based on multivariable proportional competing risk regression model.
[b]Effects calculated as HR based on multivariable Cox proportional hazards regression model.
CI: confidence interval; HR: hazard ratio; sHR: sub-hazard ratio.

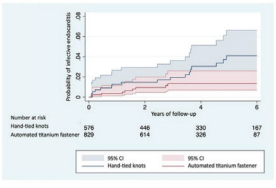

Figure 2: Kaplan–Meier cumulative event curves show the probability of IE between the automated titanium fastener group versus hand-tied knots group. CI: confidence interval; IE: infective endocarditis.

Conclusions

Suture-securing with an automated titanium fastener device appears to be superior compared to the hand-knot tying technique in terms of lower risk of IE.

Avoiding direct hand-contact on the valve prosthesis by implementing the 'no-touch principle' with an automated titanium fastener device in valve surgery might be beneficial.

Also, the importance of suture characteristics for potential bacterial adherence should not be underestimated.

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