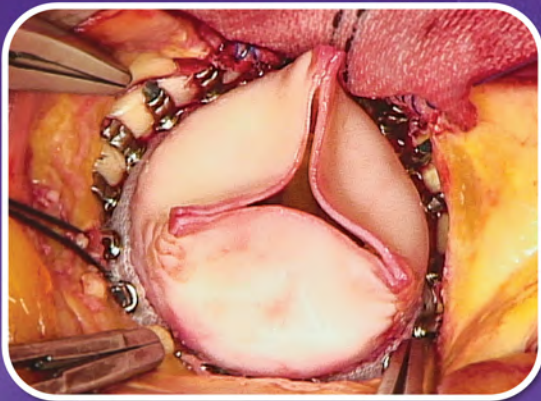


NEW

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Secure
Prosthetic
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Strong
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Aortic Valve Replacement Courtesy of Peter A. Knight, M.D.

Controlled
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Fast
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Easy



Titanium Fasteners in Open Aortic Valve Replacement Surgery: Effective and Significant Savings



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Disclosure: Dr. Peter Knight and Dr. Candice Lee receive support from LSI Solutions' donations to the University of Rochester Medical Center.

| Baseline Variable | Titanium Fasteners (n=24) | Hand-Tied Knots (n=24) | p-value ¹ |
|--------------------|---------------------------|------------------------|----------------------|
| Age, years | 73.1 ± 9.0 | 73.0 ± 6.5 | 0.985 |
| Sex | | | |
| Male | 16 (66.7%) | 16 (66.7%) | N/A |
| Female | 8 (33.3%) | 8 (33.3%) | |
| Hypertension | 17 (70.8%) | 19 (79.2%) | 0.505 |
| Smoking History | | | |
| Current Smoker | 2 (8.3%) | 1 (4.2%) | 1.000 |
| Former Smoker | 12 (50.0%) | 13 (54.2%) | |
| Never Smoker | 10 (41.7%) | 10 (41.7%) | |
| Diabetes | 7 (29.2%) | 5 (20.8%) | 0.505 |
| COPD | 5 (20.8%) | 11 (45.8%) | 0.066 |
| Renal Disease | 3 (12.5%) | 2 (8.3%) | 1.000 |
| CVA/TIA | 3 (12.5%) | 3 (12.5%) | N/A |
| NYHA Class | | | |
| I | 0 | 2 (8.3%) | |
| II | 9 (37.5%) | 10 (41.7%) | 0.254 |
| III | 9 (37.5%) | 10 (41.7%) | |
| IV | 6 (25.0%) | 2 (8.3%) | |
| LVEF (%) | 56.1 ± 15.1 | 52.2 ± 13.4 | 0.342 |
| Aortic Valve Path. | | | |
| Insufficiency (AI) | 1 (4.2%) | 2 (8.3%) | |
| Stenosis (AS) | 13 (54.1%) | 19 (79.2%) | 0.092 |
| Both AI & AS | 9 (37.5%) | 3 (12.5%) | |
| Endocarditis | 1 (4.2%) | 0 | |
| Other | 0 | 0 | |
| Concomitant | | | |
| CABG | 10 (41.7%) | 12 (50.0%) | 0.343 |
| Other | 1 (4.2%) | 3 (12.5%) | |
| None | 13 (54.1%) | 9 (37.5%) | |

OBJECTIVE To evaluate the effectiveness, time savings and cost of titanium fasteners used to secure prosthetic aortic valve suture in open cardiac surgery.

METHODS An ongoing IRB-approved prospective randomized clinical trial was conducted by a single surgeon at one institution. Open aortic valve replacement (AVR) patients were randomized to receive either conventional hand-tied knots (HT) or titanium fasteners (TF) to secure prosthetic sutures.

RESULTS 51 subjects (48 completed, 3 withdrawn) with no significant difference in preoperative morbidity, concomitant surgery, AVR size or number of sutures. (Table 1)

- TIME SAVINGS** (Table 2, Figure 1)
- TF use was 42% faster than HT per suture (23.0 vs 39.5 sec/suture)
 - Average aortic cross clamp time was 21.0 minutes shorter with TF (23% reduction)
 - Average CPB time was 26.0 minutes shorter with TF (23% reduction)
 - Overall operative times were 42.5 minutes shorter with TF (15% reduction)

- COST ANALYSIS** (Table 2, Figure 2)
- No significant difference between estimated total OR costs for each group (p = 0.22)
 - Higher average OR supply costs for TF, but lower average OR time costs

CLINICAL OUTCOMES No intraoperative complications occurred with use of TF. No paravalvular leaks or valve dehiscence occurred. Perioperative complications included: 3 reoperations for bleeding, 4 prolonged ventilator dependence, 1 pneumonia, 2 strokes (HT at 7 days post-op, TF at 12 days) and 1 30-day mortality (TF). Transesophageal echo in both stroke patients confirmed fully functional prosthetic valves and no thrombus.

Table 1. Patient Demographics by Method

| Variable | Titanium Fasteners (n = 24) | Hand-Tied Knots (n = 24) | p-value |
|--|-----------------------------|----------------------------|---------|
| AVR Size | 23.4 ± 2.0 | 23.4 ± 1.8 | 0.85 |
| Sutures Placed | 20.0 ± 1.7 | 20.7 ± 2.2 | 0.32 |
| Knotting Time (sec/suture) | 23.0 ± 2.9 | 39.5 ± 7.8 | < 0.001 |
| Aortic Cross-Clamp Time, AXT (min) ¹ | 69.0 IQR: 52.0 – 89.5 | 90.0 IQR: 73.5 – 113.0 | 0.01 |
| Cardiopulmonary Bypass Time, CPBT (min) ¹ | 87.5 IQR: 69.5 – 109.5 | 113.5 IQR: 91.0 – 133.0 | 0.01 |
| Total Operative Time (min) | 235.5 ± 49.8 | 278.0 ± 86.8 | 0.04 |
| OR Supply Costs | \$7,857 ± \$1,089 | \$7,034 ± \$1,124 | 0.01 |
| OR Time Costs | \$1,927 ± \$349 | \$2,230 ± \$644 | 0.05 |
| Total OR Costs ² | \$10,412 ± \$1,222 | \$9,892 ± \$1,124 | 0.22 |

Table 2. Operative Characteristics and Times for Each Method

CONCLUSIONS In this study of open AVR surgery, titanium fastener use is demonstrated as safe, effective and significantly faster than hand-tying. These data also suggest that use of this technology provides operative time savings without significantly increasing OR costs.

Table 1. ¹ Student's t-test was used to compare continuous variables. Chi-squared and Fischer's exact tests were used to compare categorical variables.

Table 2. ¹ AXT and CPBT were not normally distributed, so medians and interquartile ranges (IQR) were used for comparison between the two methods. ² Total OR Cost = OR Supply Cost + OR Time Cost + Anesthesia Cost. The anesthesia cost is a flat rate for all AVR procedures.

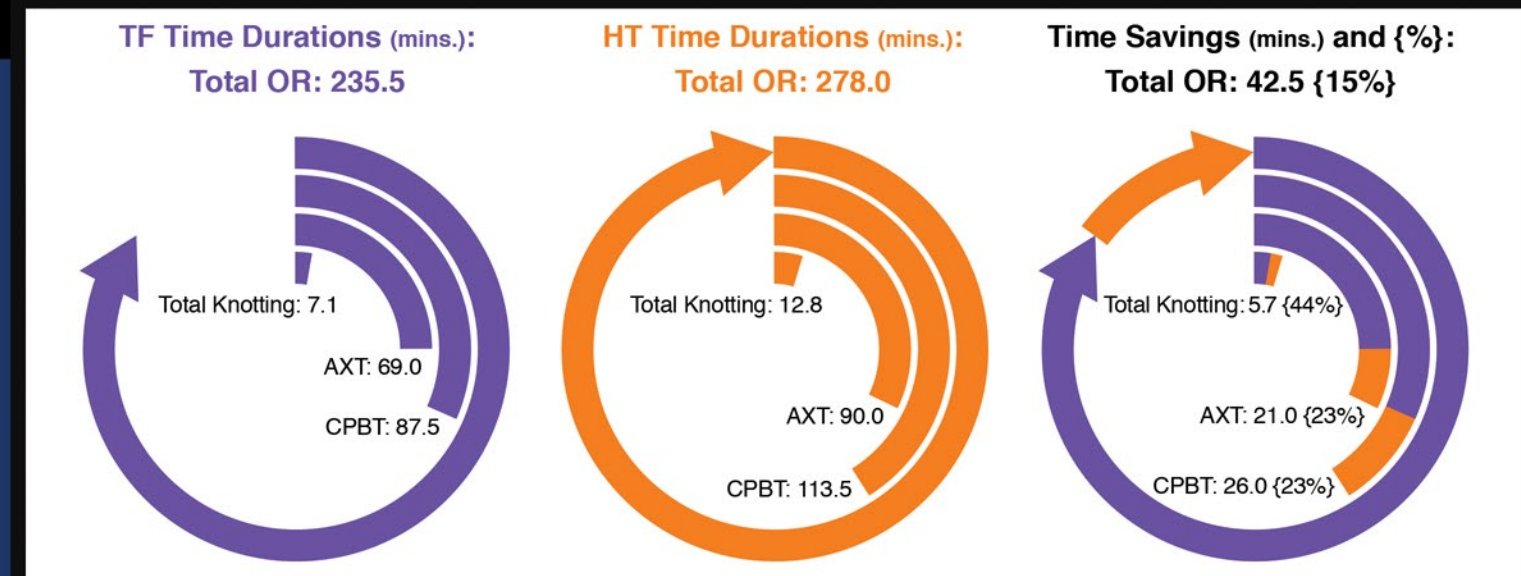


Figure 1. Difference in Operative Times Between AVR Procedures Using TF Versus HT

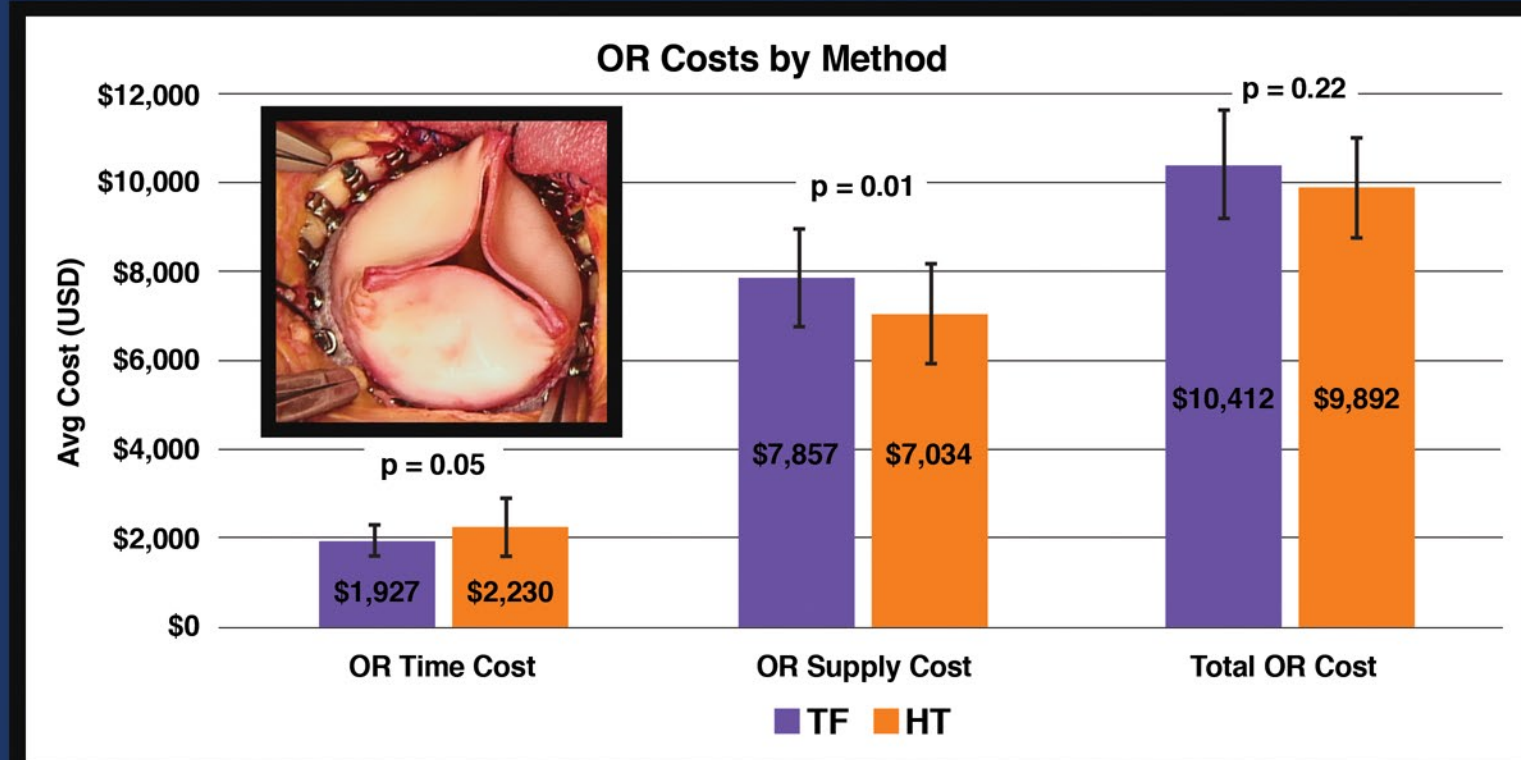
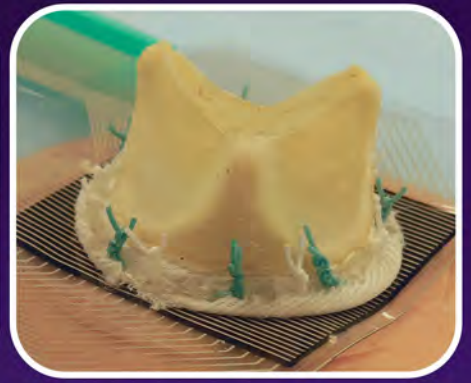
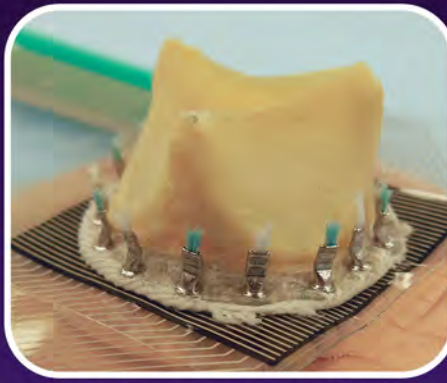


Figure 2. Comparison of Average OR Costs by Method of Securing Suture. Error Bars Represent Standard Deviation

AVR SUTURE SECURITY

Thin Film Pressure Mapping



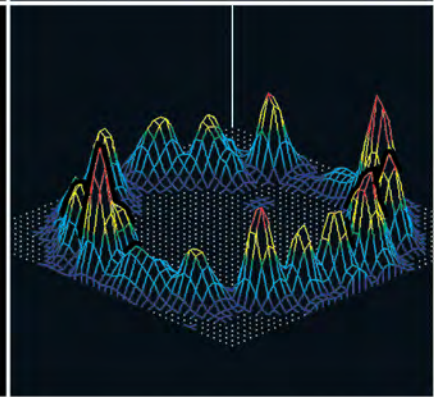
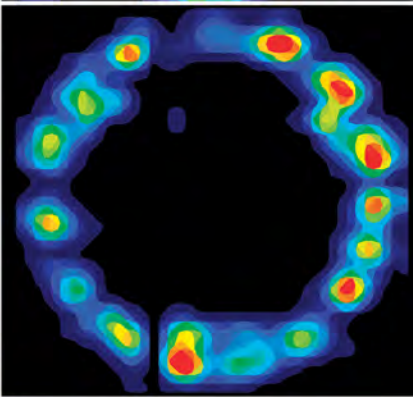
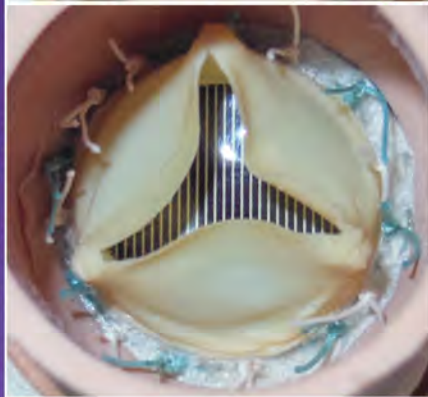
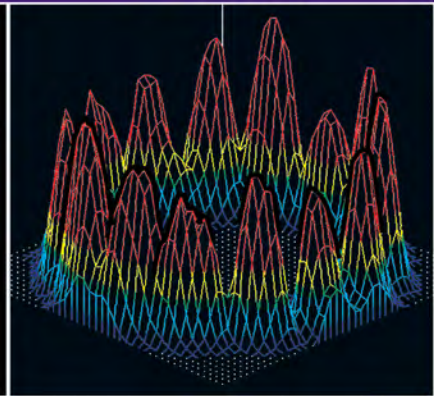
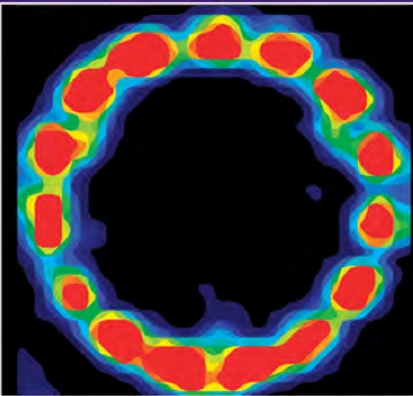
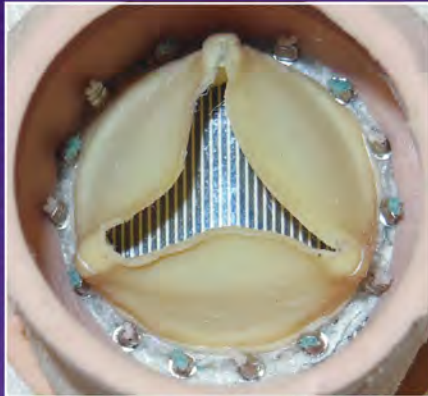
COR-KNOT MINI™ and Hand-Tied Models: Aortic Root Removed

Study Model

2-D Map

3-D Profile

OPEN AVR Model
COR-KNOT MINI™
Hand-Tied



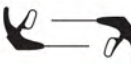


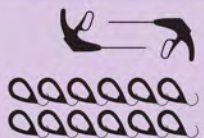
1875

mm Hg

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| | REORDER | PRODUCT | DESCRIPTION |
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|  x 12 | REF 030950 | COR-KNOT® QUICK LOAD® SINGLES | Box of 12 SINGLES (1 FASTENER per Pouch) |
|  x 12 | REF 030902 | COR-KNOT® QUICK LOAD® 6-POUCH | Box of 12 Pouches (6 FASTENERS per Pouch) |
|  x 6 | REF 031450 | COR-KNOT MINI™ COMBO KIT | Box of 6 Kits (2 Devices & 12 FASTENERS per Kit) |

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