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INTRODUCTION

- Use of a partial occluding clamp exposes the patient to possible embolization of atheromatous debris from the aorta, as well as potential aortic dissection.
- Anastomotic connectors have been developed as an enabling technology to facilitate the proximal anastomosis without the use of a partial occluding clamp.
- Connector technology promises the capability to:
 - (1) standardize the quality of the proximal anastomosis
 - (2) reduce the technical demand of the anastomosis, especially in a minimally invasive approach
 - (3) avoid aortic cross clamping
 - (4) expedite the procedure.
- Success rates for aorto-saphenous vein graft anastomosis using mechanical connectors have not been reported for long term followup. This study compares the one year outcomes of patients having beating heart surgery with either a sutured or mechanically connected proximal anastomosis.

METHODS

Connector Patients - 166 beating heart bypass cases with one or more St. Jude anastomotic connectors operated on from May to December 2001

- 162 patients (97.6%) followed by telephone, physician contact or using the national death index to determine MACE
- Mean followup of 355 ± 53 days (range 2 to 568)

Control Patients - 159 beating heart bypass cases with one or more sutured proximal vein anastomosis bypassed during prior year

- 136 patients (85.5%) followed with MACE questionnaire
- Mean followup of 664 ± 327 days (range 7 to 760)

DEMOGRAPHICS, RISK FACTORS AND OUTCOME VARIABLES

Pre-operative Risk Factor Analysis

- Analysis of 26 categorical variables including diabetes, smoking status, renal failure, peripheral vascular disease, gender, previous CABG or stent showed Connector and Control groups were comparable cohorts.
- Age, ejection fraction (EF) and Predicted Risk of Mortality (PROM) not statistically different

Analysis of Post-operative Complications

- Analysis of 21 post-operative variables including stroke, operative mortality, renal failure, perioperative MI, reoperation for bleeding, atrial fibrillation, showed no differences between groups during surgical admission.
- Post-operatively, length of stay (LOS), days in ICU or time on ventilator equal for groups

Continuous Variables (ANOVA)

	Connector	Control	p-value
Age	65.1 ± 10.9	66.8 ± 11.2	NS
PROM	0.0403 ± 0.0625	0.0477 ± 0.0556	NS
EF	51.9 ± 12.2	52.3 ± 14.7	NS
LOS	6.7 ± 5.6	7.1 ± 5.4	NS
Numb Dist Art	1.00 ± 0.45	1.25 ± 0.73	0.002
Numb Dist Vein	2.21 ± 0.88	1.86 ± 0.87	0.003
Vent Time (min)	8.2 ± 40.6	10.3 ± 61.9	NS
ICU Days	2.2 ± 3.2	2.3 ± 3.4	NS

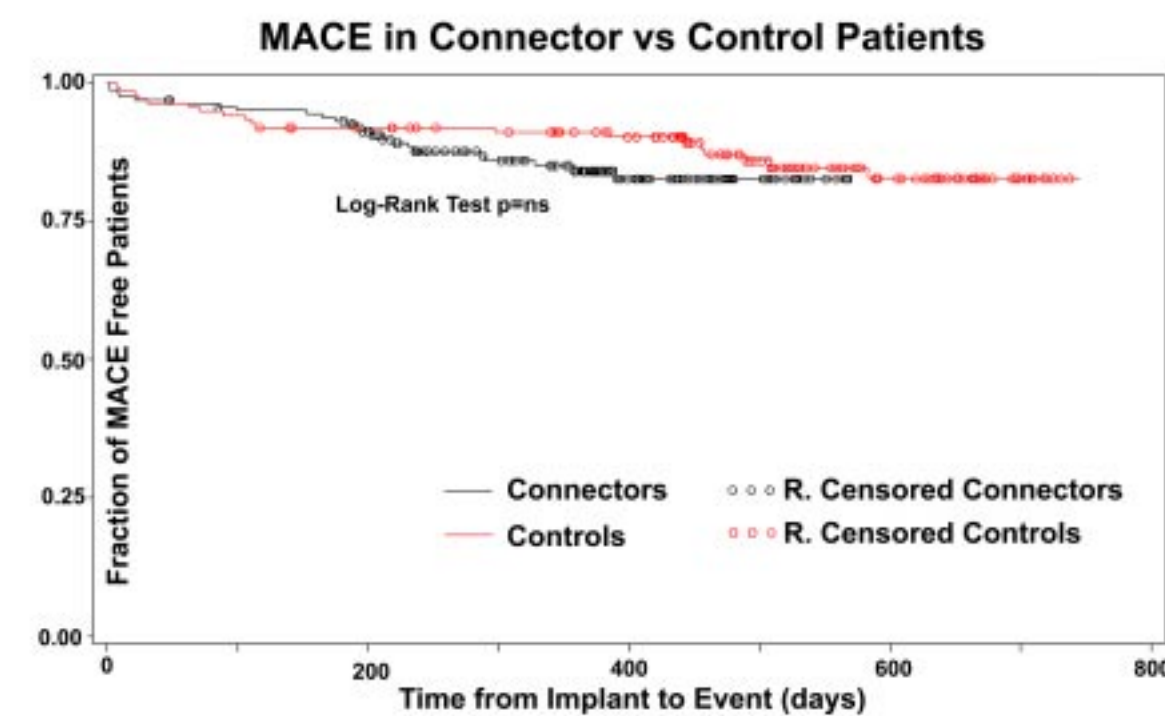
- Fewer arteries and more veins anastomosed in the connector group

MAJOR ADVERSE CARDIAC EVENTS (MACE)

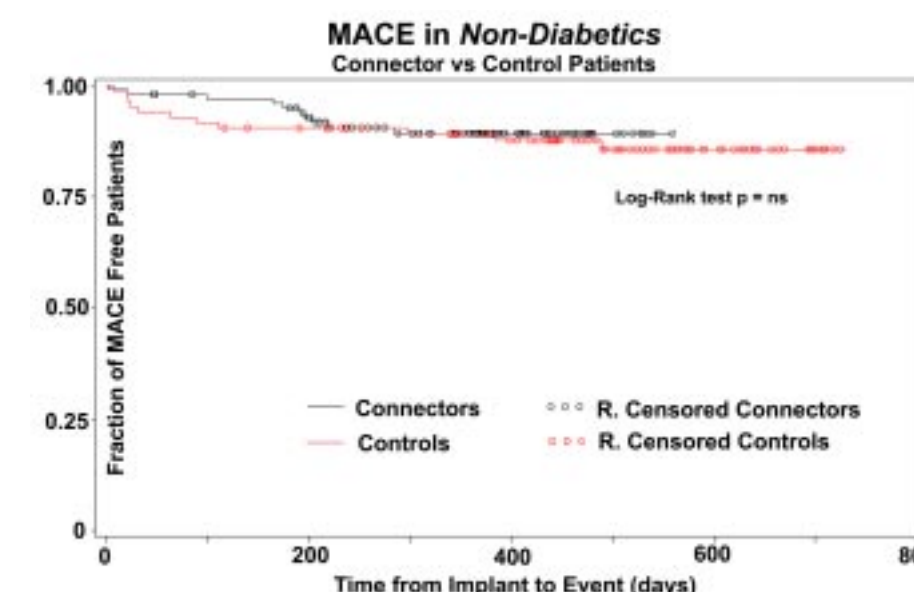
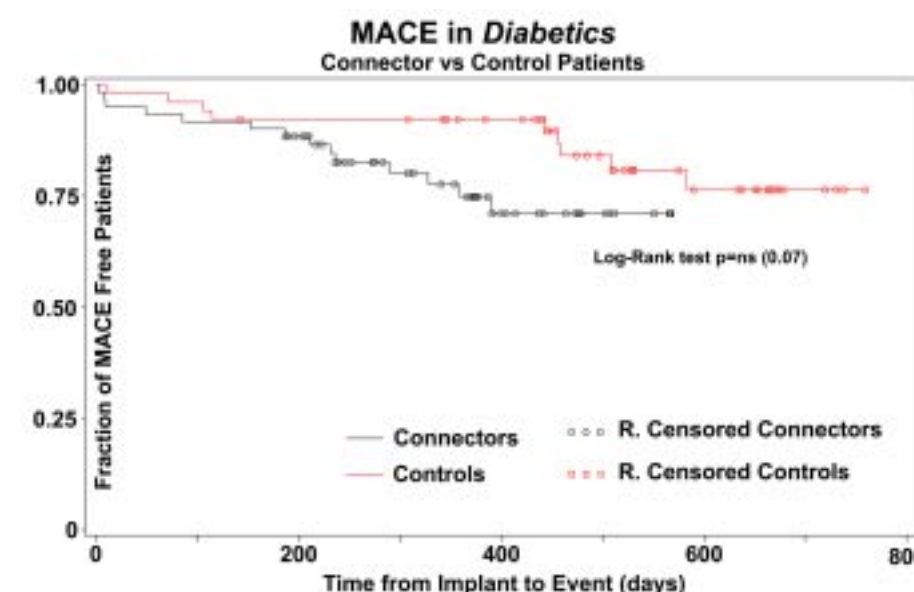
Occurrence of MACE in Connector and Control Groups as a Function of Time After Surgery

MACE

- MI
- target vessel revascularization
- cardiac mortality only



MACE IN DIABETIC AND NON-DIABETIC PATIENTS



Diabetics: 60 connector patients with 14 MACE (23.3%)

51 control patients with 9 MACE (17.6%)

p = 0.04

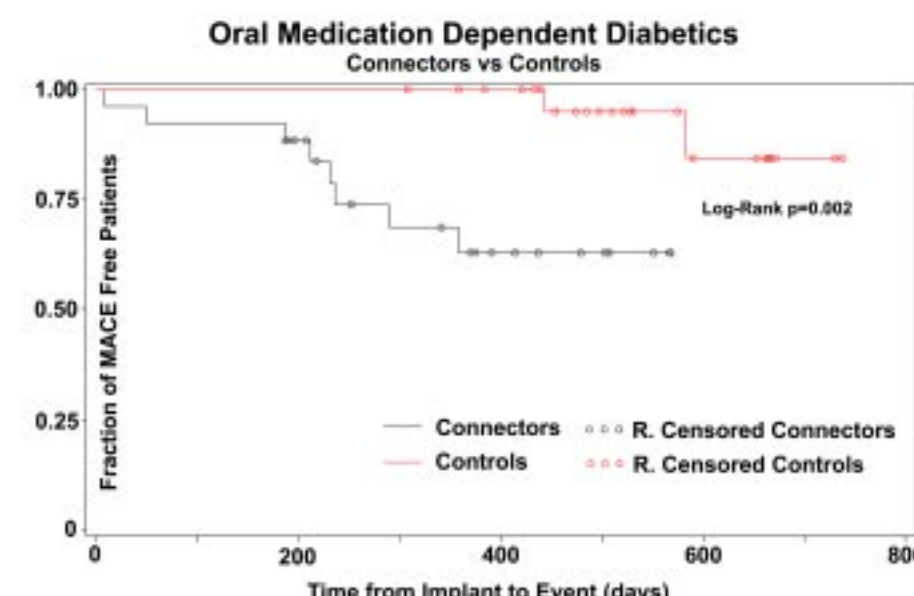
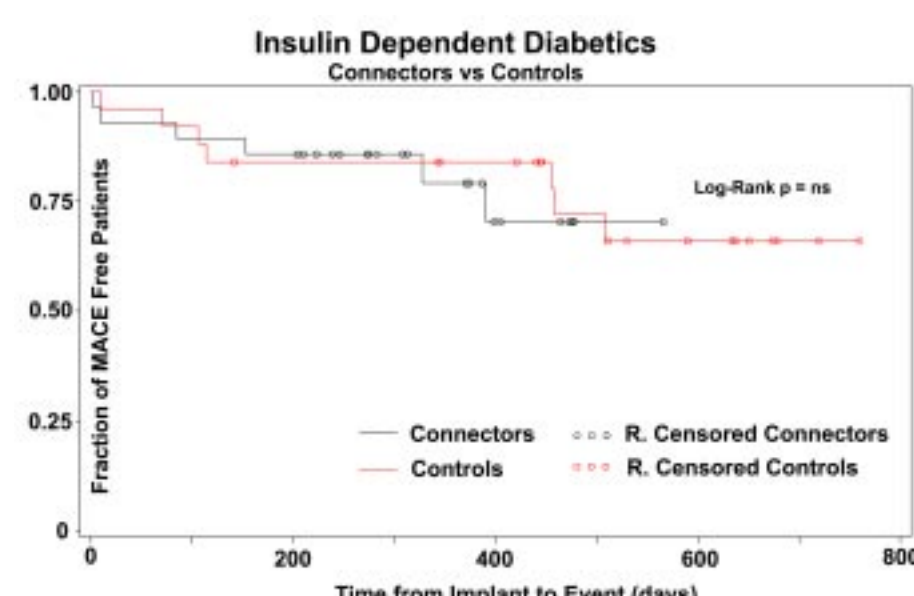
Non-Diabetics: 101 connector patients with 10 MACE (9.9%)

84 control patients with 12 MACE (14.3%)

Statistics Diabetic: connector vs control p = ns

Non-Diabetic: connector vs control p = ns

Control: Diabetic vs Non-Diabetic p = ns



- MACE in Insulin dependent connector patients is not statistically different from Non-Diabetic controls

LOGISTIC ANALYSIS

- Analysis for pre-operative factors that might be predictive for a MACE event in connector patients.
 - gender
 - diabetes
 - smoking
 - renal failure
 - CVA
 - connector size
 - previous stent or CABG
 - left main disease greater than 50%
- Only significant predictor was diabetes (p = 0.04) with an odds ratio of 2.6 (95% CI: 1.1, 6.6).

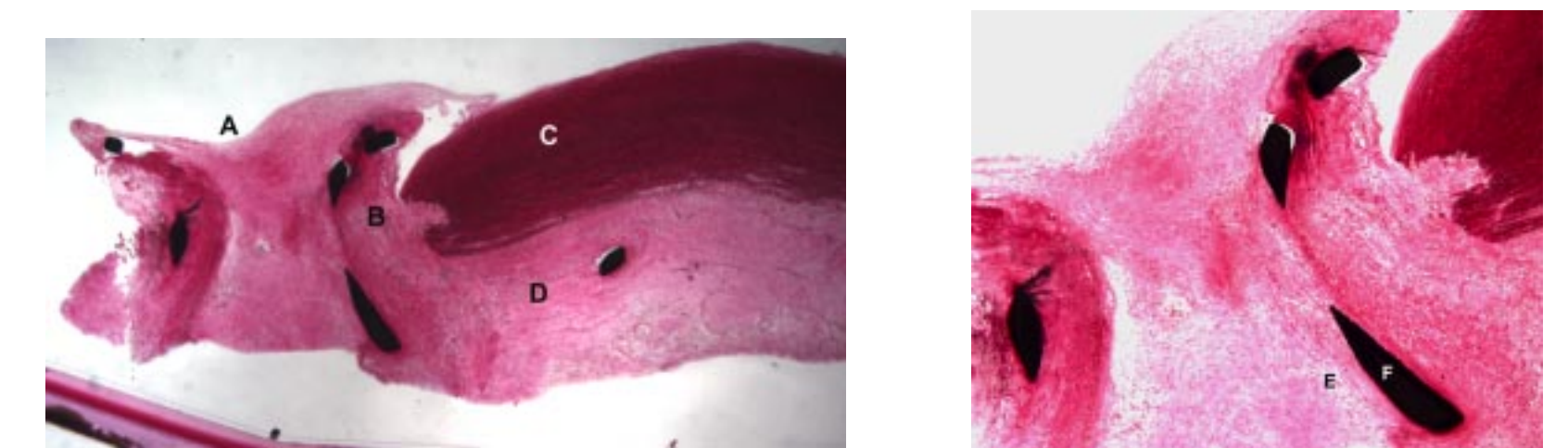
LEARNING CURVE

Connector Patients with Occlusions by Month of Bypass Surgery

Month	Total # Cases	# Patients with Occlusions	Percent
May	5	0	0
June	18	5	27.8
July	25	4	16.0
August	26	7	26.9
September	29	5	17.2
October	21	3	14.3
November	20	3	15.0
December	18	3	16.7

- No strong evidence of learning curve effect

HISTOLOGY (OCCLUSION)



A- Fibrous tissue occlusion in vein graft

B- Vein wall

C- Aorta intima

D- Aorta adventitia

E- Necrosis area in vein wall

F- Metal strut of connector

- Histology of connector retrieved from transplant patient (1 specimen)

CONCLUSIONS

- Increased incidence of early MACE in connector patients
- Subgroup analysis of MACE shows that connectors used in patients who are
 - Non-Diabetics are same as Controls
 - Insulin Dependent Diabetics are same as Controls
 - Oral Medication Dependent Diabetics are associated with increased MACE
- Distribution of occlusion provides no evidence of learning curve.