OSSERVATORIO SIFO DISPOSITIVI MEDICI

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I**nfluence of sex on outcomes of stenting versus endarterectomy: a subgroup analysis of the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST).**

Howard VJ, Lutsep HL, Mackey A, Demaerschalk BM, Sam AD 2nd, Gonzales NR, Sheffet AJ, Voeks JH, Meschia JF, Brott TG; CREST investigators.

BACKGROUND: In the randomised Carotid Revascularization Endarterectomy versus Stenting Trial (CREST), the primary endpoint did not differ between carotid artery stenting and carotid endarterectomy in patients with symptomatic and asymptomatic stenosis. A prespecified secondary aim was to examine differences by sex.
METHODS: Patients who were asymptomatic or had had a stroke or transient ischaemic attack within 180 days before random allocation were enrolled in CREST at 117 clinical centres in the USA and Canada. The primary outcome was the composite of stroke, myocardial infarction, or death during the periprocedural period or ipsilateral stroke within 4 years. We used standard survival methods including Kaplan-Meier survival curves and sex-by-treatment interaction term to assess the relation between patient factors and risk of reaching the primary outcome. Analyses were by intention to treat. CREST is registered with ClinicalTrials.gov, NCT00004732.
FINDINGS: Between Dec 21, 2000, and July 18, 2008, 2502 patients were randomly assigned to carotid endarterectomy (n=1240) or carotid artery stenting (n=1262), 872 (34.9%) of whom were women. Rates of the primary endpoint for carotid artery stenting compared with carotid endarterectomy were 6.2% versus 6.8% in men (hazard ratio [HR] 0.99, 95% CI 0.66-1.46) and 8.9% versus 6.7% in women (1.35, 0.82-2.23). There was no significant interaction in the primary endpoint between sexes (interaction p=0.34). Periprocedural events occurred in 35 (4.3%) of 807 men assigned to carotid artery stenting compared with 40 (4.9%) of 823 assigned to carotid endarterectomy (HR 0.90, 95% CI 0.57-1.41) and 31 (6.8%) of 455 women assigned to carotid artery stenting compared with 16 (3.8%) of 417 assigned to carotid endarterectomy (1.84, 1.01-3.37; interaction p=0.064).
INTERPRETATION: Periprocedural risk of events seems to be higher in women who have carotid artery stenting

than those who have carotid endarterectomy whereas there is little difference in men. Additional data are needed to confirm whether this differential risk should be taken into account in decisions for treatment of carotid disease in women. FUNDING: National Institute of Neurological Disorders and Stroke and Abbott Vascular Solutions (formerly Guidant).	
Acta Orthop. 2011 Jun;82(3):308-14. **Excessive distal migration of fiber-mesh coated femoral stems.** Baad-Hansen T, Kold S, Olsen N, Christensen F, Søballe K. BACKGROUND: The surface texture, localization, and magnitude of the surface material applied to the femoral stem can facilitate bone ingrowth and influence the survival of total hip arthroplasties. Clinical and radiographic studies have shown superior bone ingrowth in proximally porous-coated stems with a diaphyseal grit-blasted surface in comparison to a smooth diaphyseal surface. Surface textures-especially porous surface material-have been suggested to have a sealing effect against migration of polyethylene debris along the implant-bone interface and to reduce the inflammatory response, leading to a prolonged implant survival. PATIENTS AND METHODS: Between 2004 and 2006, we conducted a randomized, controlled trial (RCT) involving 50 patients with non-inflammatory arthritis. They received either a distally tapered, extended coated stem or a straight, proximally coated stem. During surgery, tantalum markers were inserted into the greater and lesser trochanter. Implant migration was evaluated at 3, 12, and 24 months postoperatively by radiostereometric analysis. The primary endpoint was stem migration 2 years after surgery. RESULTS: All femoral components in both groups showed pronounced distal translation, with the highest rate of translation occurring between 0 and 3 months. After 2 years, the mean distal translation was 2.67 (95% CI: -3.93 to -1.42) mm for the tapered, extended coated stem and 1.80 (-2.45 to -1.15) mm for the straight, proximally coated stem. Half of the tapered, extended coated stems and two-thirds of the straight, proximally coated stems had migrated more than 1 mm. No difference between the 2 stems could be seen with regard to translation or rotation at any time point. After 2 years, 2 hips have been reoperated due to mechanical loosening of the stem. INTERPRETATION: An excessive amount of migration of both stem types was seen 2 years postoperatively. It is of vital importance to follow this patient cohort since radiostereometric analysis is known to be predictive of late implant failure, especially in this study where pronounced early migration was observed. We recommend longer follow-up of both stem types.	**Valeria Fadda**
J Thorac Cardiovasc Surg. 2011 Jun;141(6):1449-54 **St Jude Medical Epic porcine bioprosthesis: results of the regulatory evaluation.** Jamieson WR, Lewis CT, Sakwa MP, Cooley DA, Kshettry VR, Jones KW, David TE, Sullivan JA, Fradet GJ, Bach	**Valeria Fadda**

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BACKGROUND: The St Jude Medical Epic heart valve (St Jude Medical, Inc, St Paul, Minn) is a tricomposite glutaraldehyde-preserved porcine bioprosthesis. The St Jude Medical Biocor porcine bioprosthesis is the precursor valve to the St Jude Medical Epic valve. The Epic valve is identical to the Biocor valve except that it is treated with Linx AC ethanol-based calcium mitigation therapy. METHODS: The St Jude Medical Epic valve was implanted in 761 patients (mean age 73.9 ± 9.2 years) between 2003 and 2006 in the US Food and Drug Administration regulatory study in 22 investigational centers. The position distribution was 557 aortic valve replacements, 175 mitral valve replacements, and 29 double valve replacements. Concomitant coronary artery bypass grafting was performed in 50.8% of patients undergoing aortic valve replacement and 36.6% of those undergoing mitral valve replacement. RESULTS: The early mortality was 3.6% in aortic and 2.3% in mitral valve replacement. The follow-up was 1675.5 patient-years with a mean of 2.2 ± 1.2 years/patient. Late mortality was 5.2%/patient-year in aortic and 6.6%/patient-year in mitral valve replacement. The late major thromboembolism rate was 0.98%/patient-year for aortic and 2.6%/patient-year for mitral valve replacement. There were 19 reoperations, including 2 for structural valve eterioration, 1 for thrombosis, 9 for nonstructural dysfunction, and 7 for prosthetic valve endocarditis. The actuarial freedom from reoperation owing to structural valve deterioration for aortic valve replacement at 4 years for age 60 years or less was 93.3% ± 6.4%; for ages 61 to 70 years, 98.1% ± 1.9%; and for older than 70 years, 100% ($P = .0006$ > 70 vs ≤ 60 years). There were no events of tructural deterioration with mitral valve replacement. The actuarial freedom from major thromboembolism for all patients at 4 years was 93.6% ± 1.0%. The 2 cases of structural valve deterioration occurred in aortic valves that became perforated without calcification causing aortic regurgitation. CONCLUSIONS: The performance of the St Jude Medical Epic porcine bioprosthesis is satisfactory at 4 years for both aortic and mitral valve replacement. This study establishes the early clinical performance including durability of this porcine bioprosthesis.