# Anticoagulation & New Generation Tissue Valve

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# Why Bioprosthetic?

- Less incidence of thrombus formation
- Anticoagulation not usually required
- Stented Bioprostheses easy to implant

# Why Not Bioprosthetic?

- A bioprosthetic valve provides its peak performance the day it is implanted
  - Tissue deteriorates over time
- Younger patients who receive bioprosthetic valves risk having another operation when the tissue valve degrades to a point where intervention is required (Structural Valve Deterioration – SVD)

# Comparison of mechanical and biological valve prosthesis

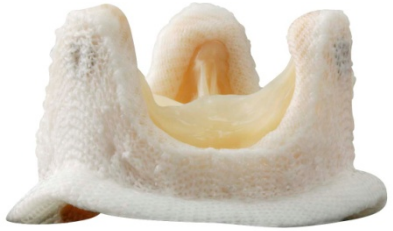
| Mechanical | Biological |
|---|---|
| Durable—valves lasting 20-30 years | Limited life span—10% of homografts and 30% of heterografts fail within 10-15 years |
| Thrombogenic—patients require lifelong anticoagulant therapy | Low thrombogenic potential—lifelong anticoagulation is not required |
| Preferred in younger patients with > 10-15 years life expectancy | Preferred in older patients with < 10-15 years life expectancy |
| Preferred in patients who require lifelong anticoagulant therapy | Preferred in those who cannot (or will not) take lifelong anticoagulant therapy |

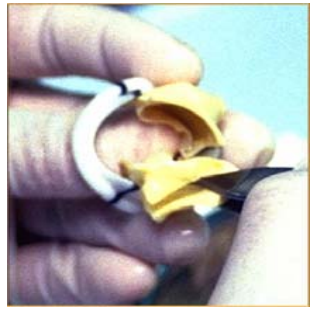
# Bioprosthetic Valve Types

- **Xenografts** – Tissue from different species
  - Porcine valve
  - Bovine pericardium
  - Composite valves
- **Homograft / Allograft** – Tissue from same species
  - Human valve – LifeNet Health
- **Autograft** – Tissue from same individual
  - Pulmonary valve to the aortic position – Ross Procedure

# Types of Tissue Valves

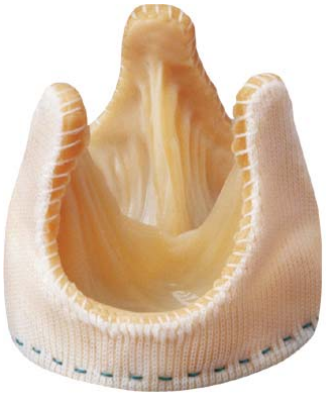
- Stented Tissue Valves
  - **Intact porcine valves**
    - Medtronic's tissue valves
      - Reduction of muscle shelf bar
    - Some Edwards' porcine tissue valves
  - **Composite porcine valves**
    - St. Jude Medical's stented tissue valves
      - Three separate leaflets – either the left or the non-coronary cusps – triple composite
  - **Pericardial valves**
    - Edwards' valves
      - Pericardial tissue

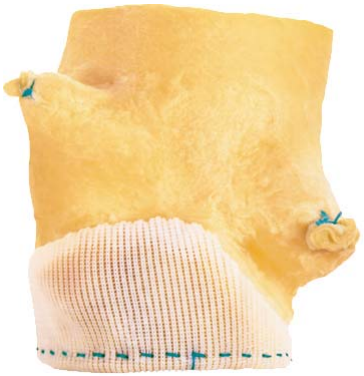




# Types of Tissue Valves

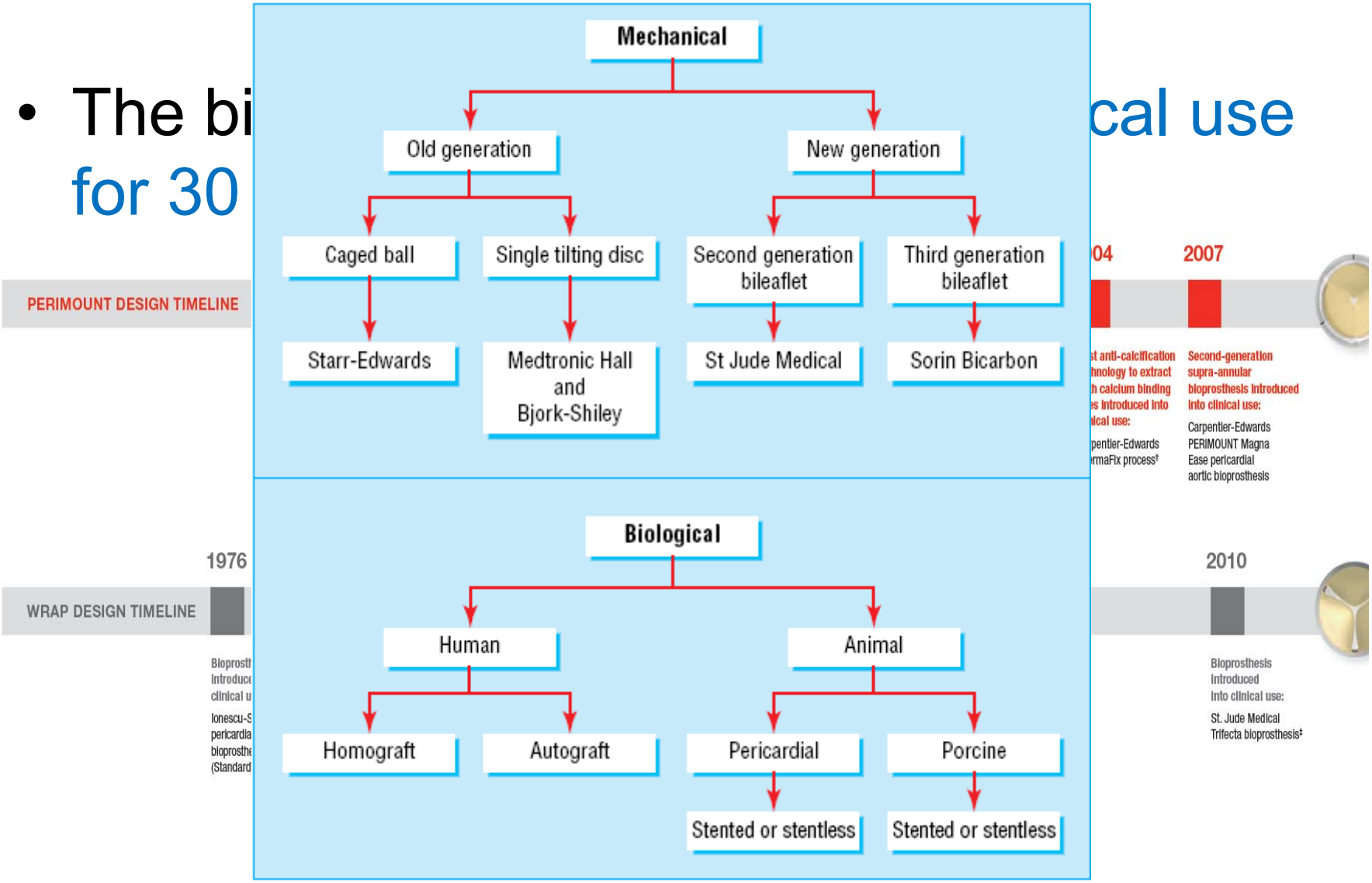
- **Stentless Tissue Valves**
  - -Subcoronary
    - Medtronic
    - St. Jude Medical
  - -Full Root
    - Edwards
    - Medtronic
    - St. Jude Medical
      - – Currently in Europe
      - – US and other geographies RELEASE CANCELED





# Evolution of tissue valves

- The bi cal use for 30



# Tissue Valve History

- Early generation tissue valves
  - Intact porcine valves
    - Septal muscle bar may reduce blood flow
  - High pressure tissue fixation
    - Flattened tissue structure
  - No anti-calcification treatments
    - May have led to early degeneration of tissue

# Tissue Valve History

- Next generation tissue valves
  - Intact porcine valves
    - Reduction of muscle shelf bar
  - Composite valves
    - Porcine tissue
      - Three separate leaflets
    - Pericardial tissue
  - Low pressure tissue fixation
    - Maintained tissue structure
  - Introduction of anti-calcification treatments
    - May prolong life of tissue valve

# Four Predictors of Bioprosthetic Performance

1. Durability
2. Hemodynamics
3. Implantability
4. Thromboresistance

# Four Predictors of Performance: Durability

1. **Durability**
   - Debatably the most important consideration
   - Current guidelines recommend bioprosthetic valve:
     - Patients ≥65 years of age for the aortic position (US)
     - Patients ≥65 years of age for the mitral position (US)
   - Stented have 20 years of reported clinical experience
   - Stentless have 10 years of reported clinical experience

# Four Predictors of Performance: Hemodynamics

## 2. Hemodynamics

- Stented tissue valves (aortic and mitral)
  - Typically inferior hemodynamics than stentless tissue valves or mechanical valves (e.g., Regent)
  - Inferiority due to bulk of design within the annulus

- Stentless tissue valves (aortic only)
  - Superior hemodynamics due to lack of stent, or bulk occluding the annulus

# Four Predictors of Performance: Implantability

## 3. Implantability

- Stented tissue valves
  - Stent provides support and ease of implantability
  - Other factors affect implantability
    - Stent material (polymer versus metal)
    - Cuff (material, thickness)
    - Post height (obstruction)

- Stentless tissue valves
  - Lack of artificial support can make implant more time-consuming
  - Takes practice, but can be mastered

# Four Predictors of Performance:Thromboresistance

## 4. Thromboresistance

- Tissue valves are naturally thromboresistant unless they degenerate
- Long-term use of anti-coagulation is not usually required
- Immediate 3 months post-op regimen currently recommends warfarin, although studies are underway to evaluate aspirin other anti-platelet drugs only

# Types of prosthetic valves and thrombogenicity

| Type of valve | Model | Thrombogenicity |
|---|---|---|
| *Mechanical* | | |
| Caged ball | Starr-Edwards | + + + + |
| Single tilting disc | Bjork-Shiley, Medtronic Hall | + + + |
| Bileaflet | St Jude Medical, Sorin Bicarbon, Carbomedics | + + |
| *Bioprosthetic* | | |
| Heterografts | Carpentier-Edwards, Tissue Med (Aspire), Hancock II | + to + + |
| Homografts | | + |

***Goldsmith et al, BMJ, 2002***

# Reasons for thromboembolism early after prosthetic valve implantation

- The pathologic sequelae of the patients' inherent to valvular disease (atrial fibrillation, dilated LA, dilated LV) may predispose to areas of stasis and thrombus formation
- Incomplete endothelial proliferation on the raw intracardiac surfaces, sewing ring and suture knots in the initial postoperative period.

# Thromboembolism with bioprosthetic valves after the first 3 months

| | Patient Years | THROM, %/yr | TE, %/yr | Reference |
|---|---|---|---|---|
| Porcine aortic valve | 3,361 | 0 | 1.5 | Glower et al[46] |
| | 2,689 | 0 | 1.9 | David et al[52] |
| | 1,673 | 0 | 2.3 | Khan et al[47] |
| Pericardial aortic valve | 2,556 | 0 | 1.8 | Banbury et al[43] |
| | 581 | 0 | 1.0 | Nakajima et al[42] |
| | 3,624 | 0 | 1.0 | Neville et al[48] |
| | 408 | 0 | 0.2 | Borowiec et al[51] |
| Porcine mitral valves | 3,128 | 0 | 1.7 | Glower et al[46] |
| | 1,168 | 0.1 | 1.5 | David et al[52] |
| | 1,781 | 0 | 2.6 | Khan et al[47] |
| Pericardial mitral valve | 969 | 0 | 0.6 | Neville et al[48] |
| Porcine aortic, mitral, or > 1 | 10,405 | 0 | 1.7 | Jamieson et al[49] |
| | 17,471 | 0 | 2.4 | Jamieson et al[45] |
| | 5,464 | 0 | 2.1 | Jamieson et al[50] |
| Pericardial aortic, mitral, or > 1 | 3,000 | 0.1 | 1.7 | Poirier et al[44] |

*THROM = valve thrombosis; TE = thromboemboli.

Long-term risk for 0.2 – 2.6%/yr

***Chest, 2001***

# High Risk of Thromboemboli Early After Bioprosthetic Cardiac Valve Replacement

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*Objectives.* We studied the rate of thromboembolism in patients undergoing bioprosthetic replacement of the aortic or mitral valve, or both, at serial intervals after operation and the effects of anticoagulant or antiplatelet treatment and risk factors.

*Background.* Thromboembolism appears to occur early after operation, but the incidence, timing and risk factors for thromboembolism and the role, timing, adequacy, effectiveness, duration and risk of anticoagulation and antiplatelet agents are uncertain.

*Methods.* The rate of thromboembolism was studied at three time intervals after operation (1 to 10, 11 to 90 and >90 days) in 816 patients who underwent bioprosthetic replacement of the aortic or mitral valve, or both, at the Mayo Clinic from January 1975 to December 1982. The effect of antithrombotic therapy (warfarin, aspirin or dipyridamole, alone or in combination) was evaluated.

*Results.* Median follow-up of surviving patients was 8.6 years. The rate of thromboembolism (%/year) decreased significantly ($p < 0.01$) at each time interval after operation (1 to 10, 11 to 90 and >90 days) for mitral valve replacement (55%, 10% and 2.4%/year, respectively) and over the first time interval for aortic valve replacement (41%, 3.6% and 1.9%/year, respectively). During the first 10 days, 52% to 70% of prothrombin time ratios were low (<1.5 × control). Patients with mitral valve replacement who received anticoagulation had a lower rate of thromboembolism for the entire follow-up period (2.5%/year with vs. 3.9%/year without anticoagulation, $p = 0.05$). Of 112 patients with a first thromboembolic episode, permanent disability occurred in 38% and death in 4%. Risk factors for emboli were lack of anticoagulation, mitral valve location, history of thromboembolism and increasing age. Only 10% of aortic, 44% of mitral and 17% of double valve recipients had anticoagulation at the time of an event. Patients with bleeding episodes (2.3%/year) were older and usually underwent anticoagulation. Blood transfusions were required in 60 of 111 patients (1.2%/year), and 13 patients (0.3%/year) died.

*Conclusions.* Thromboembolic risk was especially high for aortic and mitral valve replacement for 90 days after operation, and overall was increased with lack of anticoagulation, mitral valve location, previous thromboembolism and increasing age. Anticoagulation reduced thromboemboli and appears to be indicated in all patients as early as possible for 3 months and thereafter in those with risk factors, but needs prospective testing.

*(J Am Coll Cardiol 1995;25:1111–9)*

# High Risk of Thromboemboli Early After Bioprosthetic Cardiac Valve Replacement

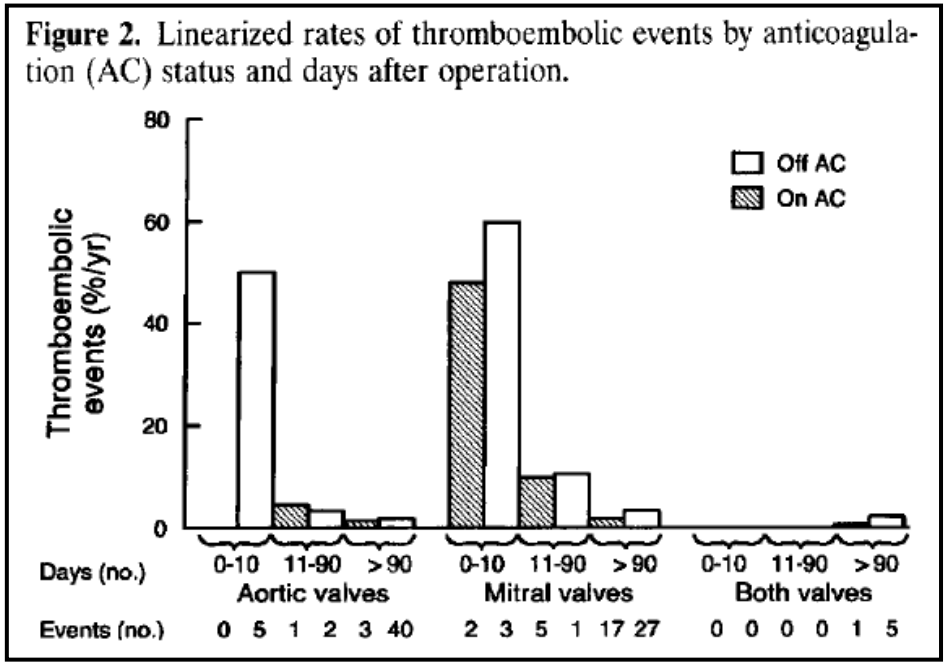
**Table 2.** Postoperative Events

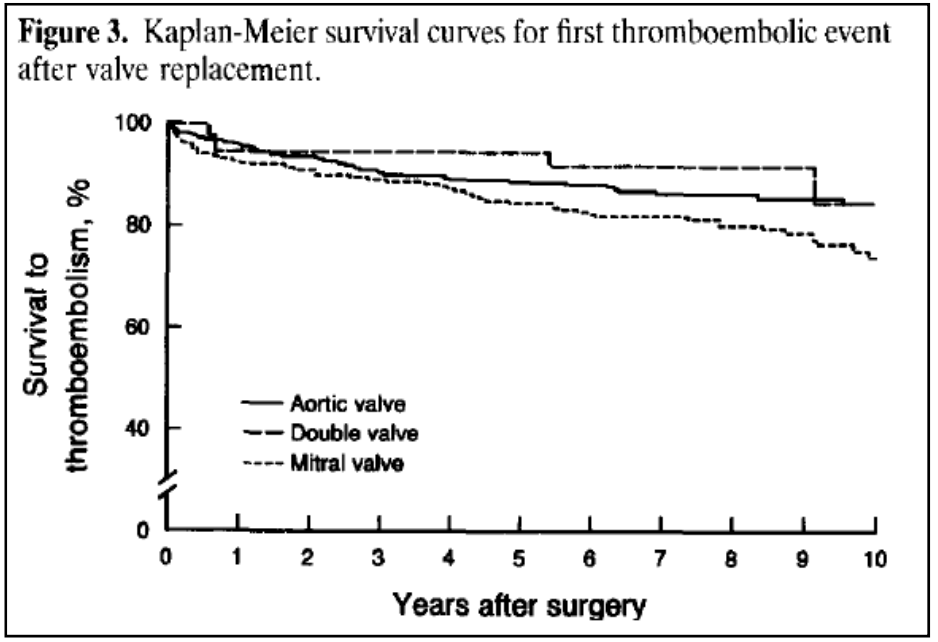
| | Valve Replacement | | |
|---|---|---|---|
| | Aortic (n = 424) | Mitral (n = 326) | Aortic and Mitral (n = 66) |
| Thromboembolism | | | |
| First | 51 (12%) | 55 (17%) | 6 (9%) |
| Second | 10 (2%) | 13 (4%) | 1 (2%) |
| Bleeding events | | | |
| First | 59 (14%) | 41 (13%) | 11 (17%) |
| Second | 13 (3%) | 6 (2%) | 2 (3%) |
| Total deaths | 184 (43%) | 165 (51%) | 36 (55%) |
| Cardiac* | 87 (21%) | 92 (28%) | 19 (29%) |
| Noncardiac | 71 (17%) | 41 (13%) | 11 (17%) |
| Operative† | 9 (2%) | 11 (3%) | 4 (6%) |
| Cerebral infarction | 5 (1%) | 4 (1%) | 1 (2%) |
| Cerebral hemorrhage | 4 (1%) | 6 (2%) | 1 (2%) |
| Systemic emboli | 2 (0.5%) | 4 (1%) | 0 |
| Hemorrhage | 6 (1%) | 6 (2%) | 0 |
| Unknown | 0 | 1 (0.2%) | 0 |
| Reoperation | 68 (16%) | 54 (17%) | 17 (26%) |

*38% arrhythmic, 17% ischemic, 43% heart failure, 2% endocarditis. †Within 30 days of operation. Data presented are number (%) of patients.

***Heras M,et al. JACC, 1995***

# High Risk of Thromboemboli Early After Bioprosthetic Cardiac Valve Replacement




| Days | <10 | 11-90 | >90 |
|---|---|---|---|
| AVR | 41%/yr | → 3.6%/yr | → 1.9%/yr |
| MVR | 55%/yr | → 10%/yr | → 2.4%/yr |

*Heras M,et al. JACC, 1995*

# Is early anticoagulation with warfarin necessary after bioprosthetic aortic valve replacement?

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**Objectives:** Freedom from anticoagulation is the principal advantage of bioprosthesis; however, the American Heart Association/American College of Cardiology and the American College of Chest Physicians guidelines recommend early anticoagulation with heparin, followed by warfarin for 3 months after bioprosthetic aortic valve replacement. We examined neurologic events within 90 days of bioprosthetic aortic valve replacement at our institution.

**Methods:** Between 1993 and 2000, 1151 patients underwent bioprosthetic aortic valve replacement with (641) or without (510) associated coronary artery bypass. By surgeon preference, 624 had early postoperative anticoagulation (AC+) and 527 did not (AC–). In the AC– group, 410 patients (78%) received antiplatelet therapy. Groups were similar with respect to gender (female, 36% AC+ vs 40% AC–, $P = .21$), hypertension (64% AC+ vs 61%, $P = .27$), and prior stroke (7.6% AC+ vs 8.5% AC–, $P = .54$). The AC+ group was slightly younger than the AC– group (median, 76 years vs 78 years, $P = .006$).

**Results:** Operative mortality was 4.1% with 43 (3.7%) cerebrovascular events within 90 days. Excluding 18 deficits apparent upon emergence from anesthesia, we found that postoperative cerebrovascular accident occurred in 2.4% of AC+ and 1.9% AC– patients. By multivariable analysis, the only predictor of operative mortality was hypertension ($P < .0001$). Postoperative cerebrovascular accident was unrelated to warfarin use ($P = .32$). The incidence of mediastinal bleeding requiring reexploration was similar (5.0% vs 7.4%), as were other bleeding complications in the first 90 days (1.1% vs 0.8%). No variables were predictive of bleeding by multivariate analysis.

**Conclusions:** Although these data do not address the role of antiplatelet agents, early anticoagulation with warfarin after bioprosthetic aortic valve replacement did not appear to protect against neurologic events.

**TABLE 4. Primary end points of stroke and bleeding**

| | All patients (n = 1151) | Anticoag + (n = 624) | Anticoag − (n = 527) |
|---|---|---|---|
| CVA | | | |
| Intraop | 18 | 9 | 9 |
| <30 days | 19 | 11 | 8 |
| 30-90 days | 6 | 5 | 1 |
| In-hospital reexploration | 74 | 32 | 42 |
| Out-of-hospital bleeding event | 11 | 7 | 4 |

*Anticoag* +, Receiving heparin and warfarin; *Anticoag* −, not receiving heparin and warfarin; *CVA*, cerebrovascular accident; *intraop*, intraoperative.

***Sundt et al, JTCS, 2005***

# Is early antithrombotic therapy necessary in patients with bioprosthetic aortic valves in normal sinus rhythm?

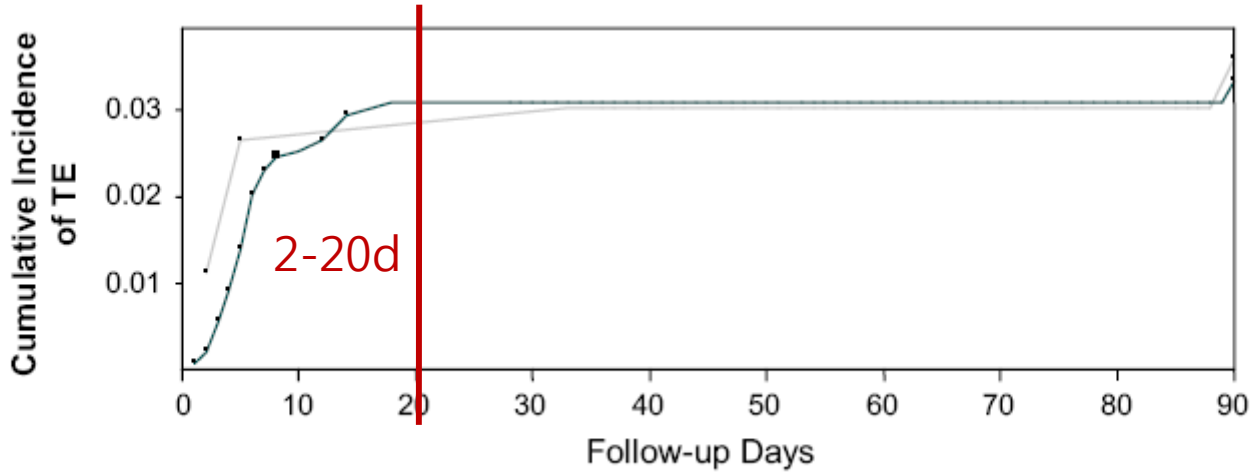


**FIGURE 2.** Cumulative incidence analysis (composite of stroke, TIA, and peripheral thromboemboli). *TE*, Thromboembolism.

**TABLE 4. Mitigation of postoperative thromboembolus in high-risk patient groups**

| | AC+ (vs AC–) | *P* value | ASA+ (vs ASA–) | *P* value |
|---|---|---|---|---|
| Age | 0.99 (0.99–1.00) | .14 | 1.005 (0.998–1.013) | .18 |
| Female gender | 0.75 (0.58–0.97) | .03 | 0.66 (0.46–0.93) | .02 |
| Height (cm) | 1.002 (0.99–1.006) | .22 | 0.99 (0.996–1.002) | .62 |
| Smoking history | 0.79 (0.61–1.03) | .08 | 1.27 (0.92–1.77) | .15 |
| NYHA III/IV | 0.73 (0.55–0.98) | .04 | 0.34 (0.10–1.07) | .06 |
| 19-mm BAV prosthesis | 0.65 (0.45–0.93) | .02 | 0.36 (0.16–0.81) | .01 |

**Conclusion:** Early anticoagulation after isolated bioprosthetic aortic valve replacement in patients in normal sinus rhythm does not seem to reduce the risk of thromboembolism except in high-risk groups. Current recommendations should be revisited, because the only patients who may benefit from anticoagulation are female, those who are highly symptomatic, and those with a small aortic prosthesis. (J Thorac Cardiovasc Surg 2010;139:1137-45)

***ElBardissi et al, JTCS, 2010***

# Antiplatelet therapy in patients receiving aortic bioprostheses: A report of clinical and instrumental safety

**Objective:** The main advantage of bioprostheses, avoidance of anticoagulant therapy, is compromised during the early postoperative period; in fact, warfarin is often administered during the first 3 postoperative months.

**Methods:** We analyzed 250 patients undergoing tissue aortic valve replacement between January 2002 and December 2005. The patients received either aspirin (group 1) or oral anticoagulation (group 2) during the first 3 mo
of these patients, we investigated the possible presence of clin
embolization by means of transcranial Doppler for microembol

| | Group 1 n = 125 (%) | Group 2 n = 125 (%) | P |
|---|---|---|---|
| Perioperative (30-d) death | 0 | 0 | |
| Major neurologic events within 30 postoperative days* | 0 | 0 | |
| Major bleeding within 30 postoperative days* | 2 (1.6%) | 2 (1.6%) | |

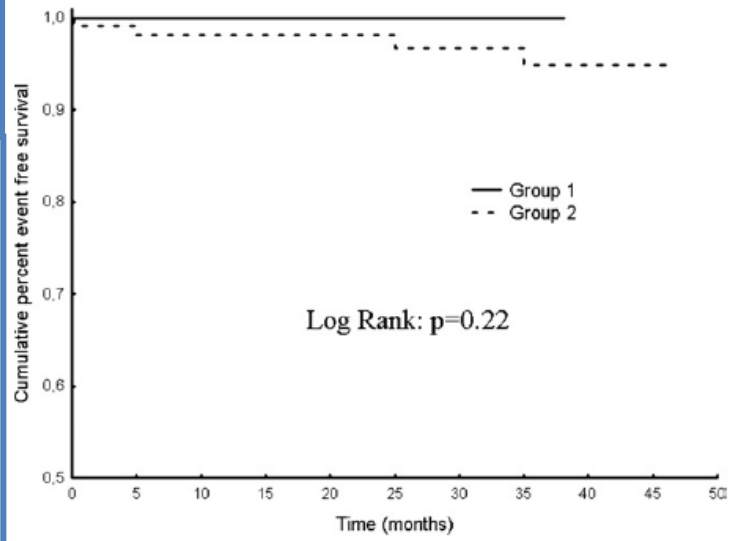


Figure 1. Stroke-free survival.

**Conclusions:** Aspirin therapy appears to be the appropriate response to both cardiac surgeons' and patients' needs in the early postoperative course after aortic valve replacement with tissue valves, demonstrating adequate antithromboembolic efficacy with no added risk for bleeding as well as ease of administration.

*di Marco et al, JTCS, 2007*

# RANDOMISED COMPARISON OF TWO INTENSITIES OF ORAL ANTICOAGULANT THERAPY AFTER TISSUE HEART VALVE REPLACEMENT

***Summary*** After tissue heart valve replacement 108 patients were randomised to standard anticoagulant control with rabbit brain thromboplastin (Dade C reagent, therapeutic range 18–24 s; international normalised ratio 2·5–40) and 102 to a less intensive regimen controlled with human brain thromboplastin (Manchester Comparative Reagent, therapeutic range 26–30 s; INR 2·0–2·25). Treatment was continued for three months, outcome measures being major or minor embolism or haemorrhage. 2 patients in each group had major embolic events and 11 in each group had minor embolic events. The 95% confidence intervals on the differences are −3·4% to 3·2% for major embolism and −9·3% to 8·2% for minor embolism. Haemorrhagic complications were significantly more frequent with standard treatment (15 patients) than with the less intensive regimen (6 patients); and of the 5 patients with major haemorrhagic complications, all were in the standard treatment group, again a significant difference. The less intensive regimen is thus no less effective and safer than standard anticoagulant therapy in patients with tissue heart valve replacement.

| — | Standard treatment | Less intensive treatment | Total |
|---|---|---|---|
| *No of patients* | 108 | 102 | 210 |
| *Age (yr)* | | | |
| Mean | 60 8 | 63·8 | 62·3 |
| Range | 28–87 | 30–81 | |
| *Sex* | | | |
| Male | 57 | 55 | 112 |
| Female | 51 | 47 | 98 |
| *Valve* | | | |
| Aortic | 58 | 59 | 117 |
| Mitral | 40 | 39 | 79 |
| Tricuspid | 1 | 0 | 1 |
| Double | 9 | 4 | 13 |
| *Rhythm* | | | |
| Sinus | 81 | 78 | 159 |
| AF | 26 | 22 | 48 |
| Other | 1 | 2 | 3 |

**Turpie et al, Lancet, 1988**

# Risk of Thromboembolism With the Aortic Carpentier-Edwards Bioprosthesis

Porcine bioprostheses provide an excellent alternative to mechanical prostheses for heart valve replacement in patients unable to comply with systemic anticoagulation and in the elderly. Long-term results of this prosthesis, however, demonstrated identical survival and parallel event-free status, albeit at a lower rate than the mechanical valves. Some discrepancy exists as to the need for and duration of systemic anticoagulation in the bioprosthesis, and some evidence exists to contraindicate anticoagulation due to a higher late mortality rate in patients with an aortic bioprosthesis. Th
having the Carpentier-Edwards
tic position as an isolated va
viewed. The overall rate of bio
was low (0.23%/patient year) an
± 2.4%; 10 year, 52.9 ± 4.9%) a
year, 67.9 ± 2.6%; 10 year, 42.4 ± 5.1%) were excellent. No

gender difference was present. A vulnerable period for neurologic events was identified by hazard function whereby the incidence of stroke was high; these were increased in the patient variables of compromised ejection fraction (0.54; $p \leq 0.003$), older age (≤73 years; $p \leq 0.02$), and preoperative atrial fibrillation or paced rhythm ($p \leq 0.01$). This pattern was similar for both transient ischemic events and strokes and rapidly decreased over the first few months of the first year and the first few years of the 12-year follow-up. These patients were not
gulated. Although, in general, patients
rosthesis in the aortic position do not
ulants, a subset of patients have been
ould receive short-term anticoagulation
o reduce the high early incidence of
s.

*(Ann Thorac Surg 1995;59:462–8)*

**Older age**
**Low LVEF**
**Preop. A-fib**
**Paced rhythm**

***Orszulak et al, ATS, 1995***

# Thromboembolic events after aortic valve replacement in elderly patients with a Carpentier-Edwards Perimount pericardial bioprosthesis


**Objectives:** Thromboembolic events after aortic valve replacement with a bioprosthesis were the most frequently occurring complications in elderly patients. Whether this was valve related or dependent on other factors needed further exploration.

**Methods:** Five hundred patients with a median age of 73 years were followed retrospectively after aortic valve replacement with a pericardial prosthesis for occurrence of thromboembolism. Of these, 348 also underwent coronary artery bypass grafting. Twenty-five factors were investigat
using univariate and multivariate analysis.

**Results:** Univariate analysis revealed 6 significant fac
($P = .0001$), preoperative cerebrovascular accident ($P$
warfarin sodium (Coumadin, DuPont Merck; $P = .0$
.023), size of valve prosthesis of 27 mm or larg
thromboembolism ($P = .040$). There was a trend to
embolism in patients without medication. With a n
remained significant: preoperative cerebrovascular
.0016), warfarin sodium (risk ratio, 3.0; $P = .0028$),
ratio, 5.6; $P = .006$), and hospital thromboembolis
Hypertension had a borderline effect. Age, sex, diab
3 other valvular factors, atrial fibrillation, and caroti
icant effect.

**Conclusions:** Some emboli seemed triggered by the valve prosthesis. A proper anticoagulant protocol but also a treatment of hypertension is important in the prevention of thromboembolism after aortic valve replacement with a bioprosthesis. We did not find a significant role of atrial fibrillation and carotid artery disease.


**TABLE 3. Simultaneous relationship between the prognostic factors and the risk of thromboembolism obtained with the Cox proportional hazards analysis**

| Factor | Risk ratio | 95% CI | *P* value |
|---|---|---|---|
| Cerebrovascular accident | 4.8 | 1.8-12.6 | .0016 |
| Warfarin sodium | 3.0 | 1.5-6.3 | .0028 |
| Hospital thromboembolism | 6.1 | 1.4-26.5 | .016 |
| Arterial hypertension | 2.7 | 0.9-7.8 | .063 |

*CI,* Confidence interval.

***Mistiaen et al, JTCS, 2004***

# Optimal antithrombotic prophylaxis for AV bioprosthesis

Guidelines for antithrombotic therapy in patients with aortic bioprosthetic valves in absence of risk factors

| Guidelines | Recommended treatment | Class of evidence | Level of evidence |
|---|---|---|---|
| ACC/AHA [17] | ASA | I | C |
| | VKA for first 3 months (INR 2–3) | IIa | C |
| ESC [18] | VKA for first 3 months (INR 2–3) | 1 | C |
| ACCP [19] | ASA | 1 | C+ |
| | VKA for first 3 months (INR 2–3) | 2 | C |
| CCS [20] | ASA | 2 | C |
| | VKA for first 3 months (INR 2-3) | 2 | C |
| BSH [21] | ASA | A | Ib |

***EJCTS, 2007***

# Flat Fibrin Thrombus Deposition on Tissue Valve After Aortic Valve Replacement

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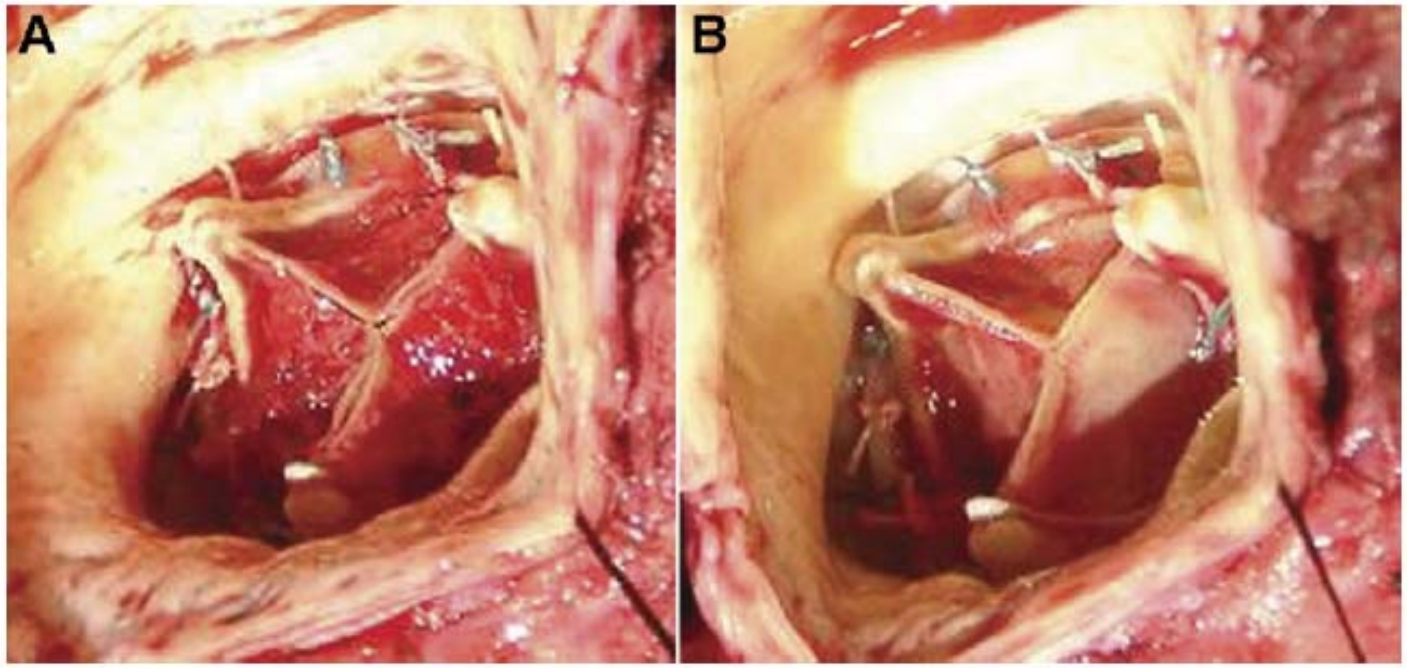


*Fig 1. (A) Flat fibrin thrombus deposition on aortic prosthetic valve. (B) After removing each thrombi, the tissue valve looked normal.*

***Ann Thorac Surg, 2010***

# Acute Myocardial Infarction due to Coronary Artery Embolism in a Patient with a Tissue Aortic Valve Replacement

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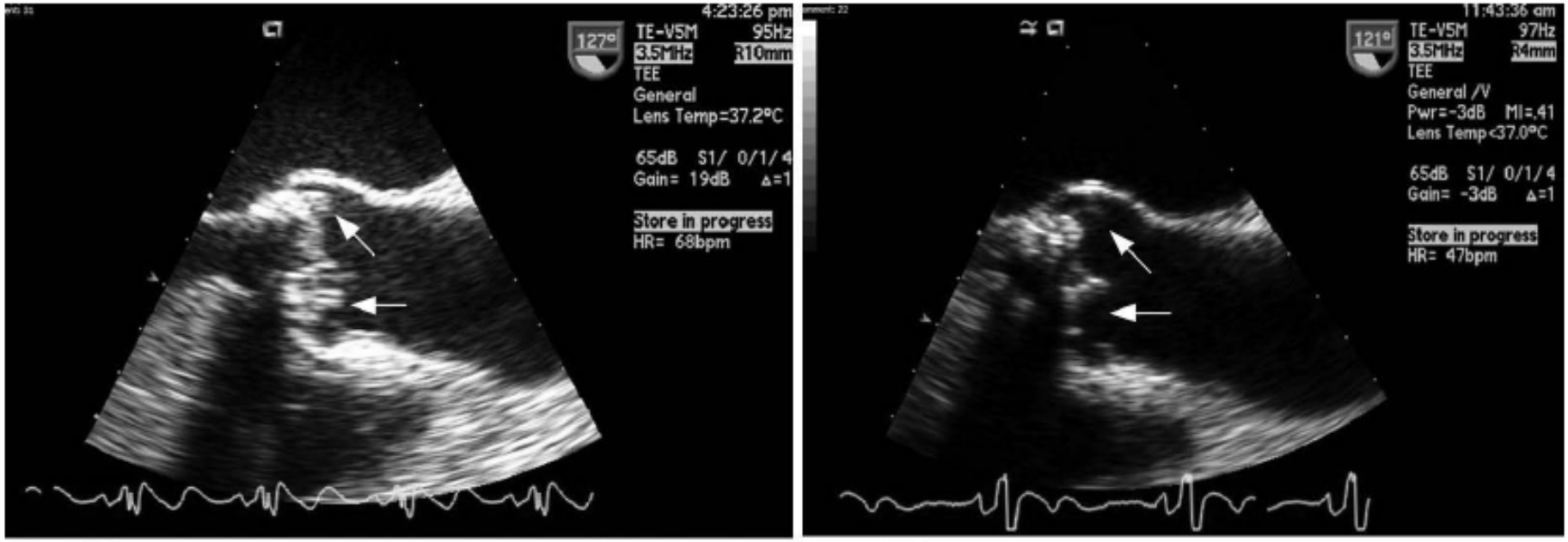



**Panel A** **Panel B**

Figure 3. Transesophageal echocardiogram from 50-year-old man demonstrating echodensities associated with the aortic valve leaflets consistent with thrombus (panel A, arrows), compared with the same view following six weeks of warfarin anticoagulation, now demonstrating near resolution of the thrombi (panel B, arrows).

***The Permanente J, 2011***

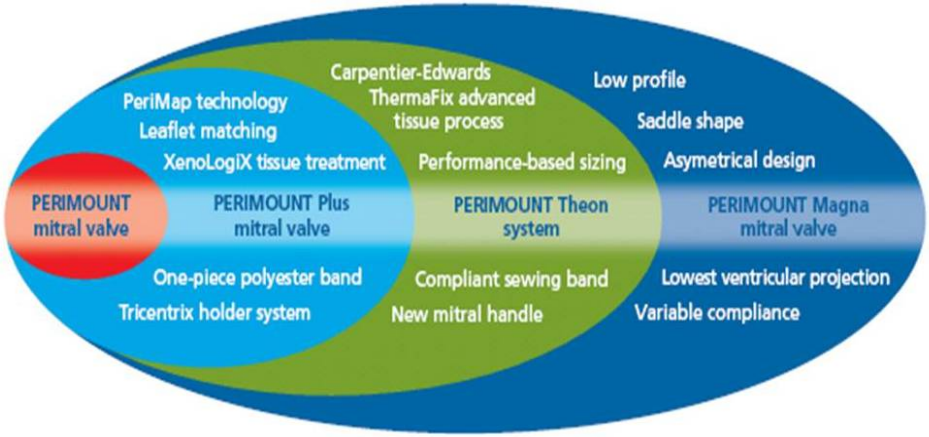
# New generation tissue valves

- Current developments in tissue valve technology includes improved methods of

  -Fixation

  -Calcification mitigation treatments

  -Stentless designs.




...to a new level of design excellence.

# Bioprosthetic Valve Durability

Durability & thromboresistance of bioprosthetic valves is influenced by tissue calcification and mechanical stress

**Mechanical Stress** + **Tissue Calcification**

**Minimized by Valve Design**

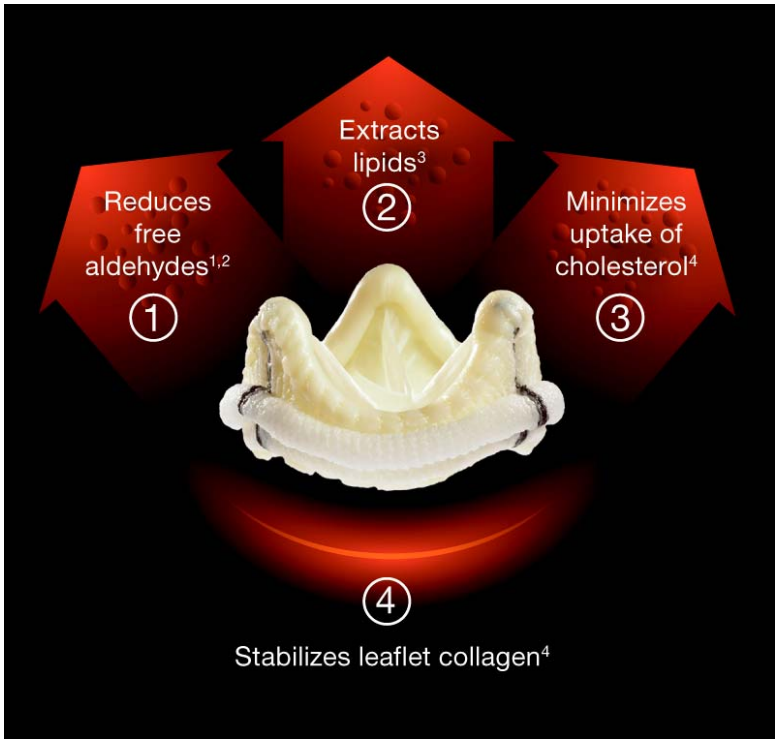
Examples: stent material, tissue attachment, fabric, sutures, etc.

**Minimized by Anticalcification Treatments**

Remember, a design that reduces mechanical stresses may play a key role in a valve's ability to resist calcification & platelet activation:
Anticalcification treatments may delay tissue calcification.

# Current Anti-Calcification Strategies

- Endcapping (aldehyde free ends)
- Removal of phospholipids (detergents)
- Blocking hydroxyapatite deposition (trivalent actions)
  - Calcium hydrozyapatite is the primary mineral of bone and teeth

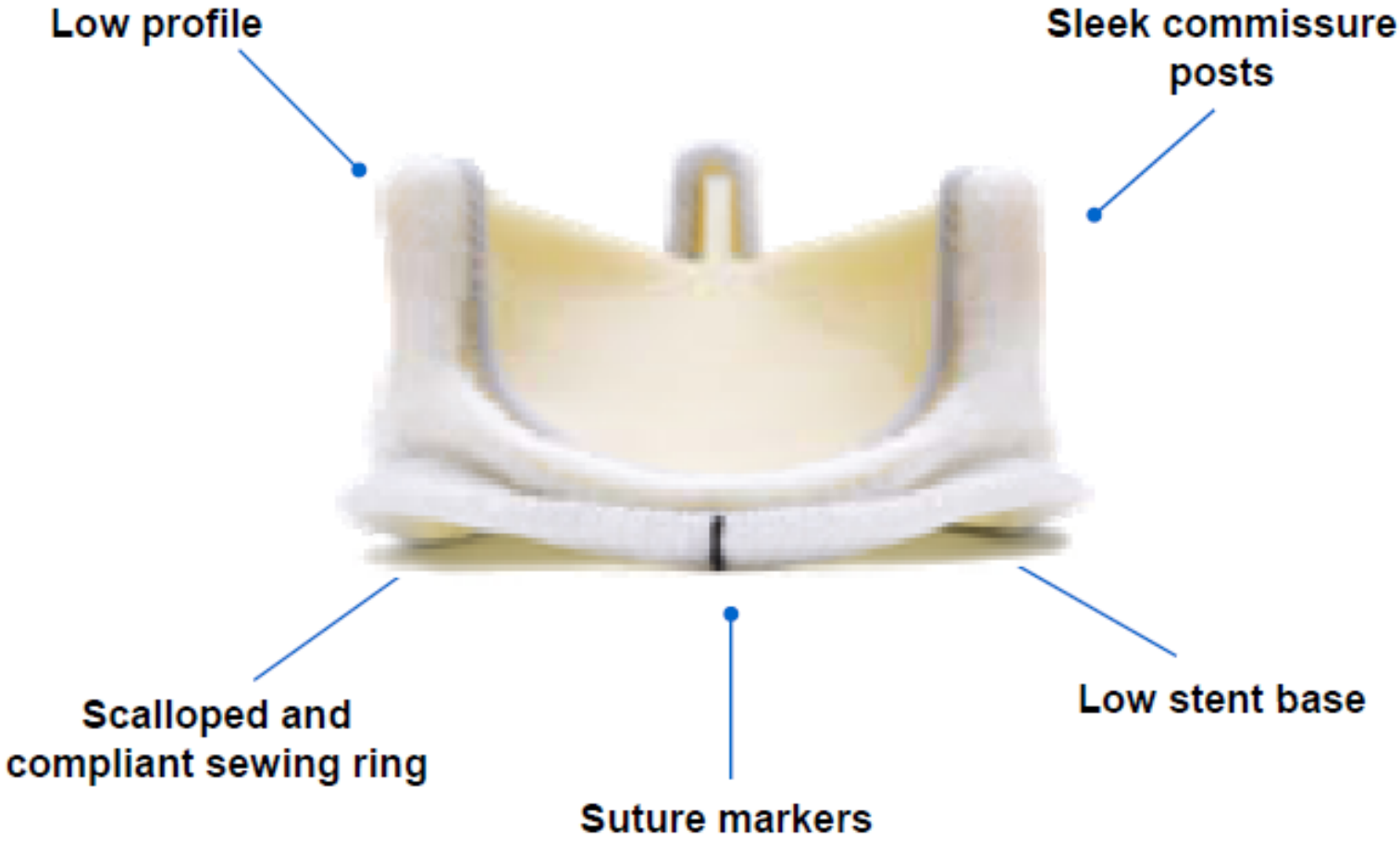


# Requirements of Anticalcification Technology

| Efficacy | Safety |
|---|---|
| ▫ Effective and sustained calcification inhibition | ▫ No adverse blood-surface interactions (hemolysis, platelet adhesion) |
| ▫ Adequate valve performance (hemodynamics, durability) | ▫ Does not enhance local or systemic inflammation |
| | ▫ Does not cause local / systemic toxicity |
| | ▫ Does not potentiate infection |

●Schoen, J. Thorac Carciovasc Surg 1992

# Changes in design of new generation tissue valves



# Competitive Overview

| ***Feature*** | ***Epic*** | ***Perimount & Magna*** | ***Hancock II*** | ***Mosaic and Ultra*** |
|---|---|---|---|---|
| ***Tissue*** | Porcine w/bovine | Pericardial | Porcine | Porcine |
| ***Design*** | Triple composite | Triple composite | Complete | Complete |
| ***Stent material*** | Acetal co-polymer | Elgiloy (metal) | Homopolymer | Homopolymer |
| ***Fixation Method*** | Low pressure (<4mmHg) | Low pressure (<4mmHg) | Low pressure (<4mmHg) | “Zero” pressure |
| ***AC Treatment*** | Linx | XenoLogiX ThermaFix | T6 | AOA |

# Summary

- Although calcification remains as the main clinical concern associated with bioprosthetic heart valve replacement, there is evidence that tissue deterioration leads to thrombosis.
- Patients with bioprosthetic valves in the mitral position as well as patients with bioprosthetic valves in the aortic position may be at risk for thromboemboli during the first 3 months after operation.

# Summary

- Due to the lack of prospective randomised trial data, the optimal antithrombotic or anticoagulation regimen in patients following bioprosthetic AVR remains unclear.

- Whilst several studies have showed equivalence between antiplatelet therapy and anticoagulation, to date, no studies have demonstrated anticoagulation leads to a reduction or increase in adverse outcomes.

# Summary

- There is no study specifically examining the safety of omitting warfarin after AVR, and therefore, guidelines remain weighted in favour of early anticoagulation.

- Although the new generation tissue valves with low blood damage and better hemodynamics have been developed, a precise antithrombotic protocol after bioprosthetic valve replacement remains to be developed.


Thank You !!!