Биопротезы в хирургии пороков сердца: исторические аспекты и перспективы Путь революций

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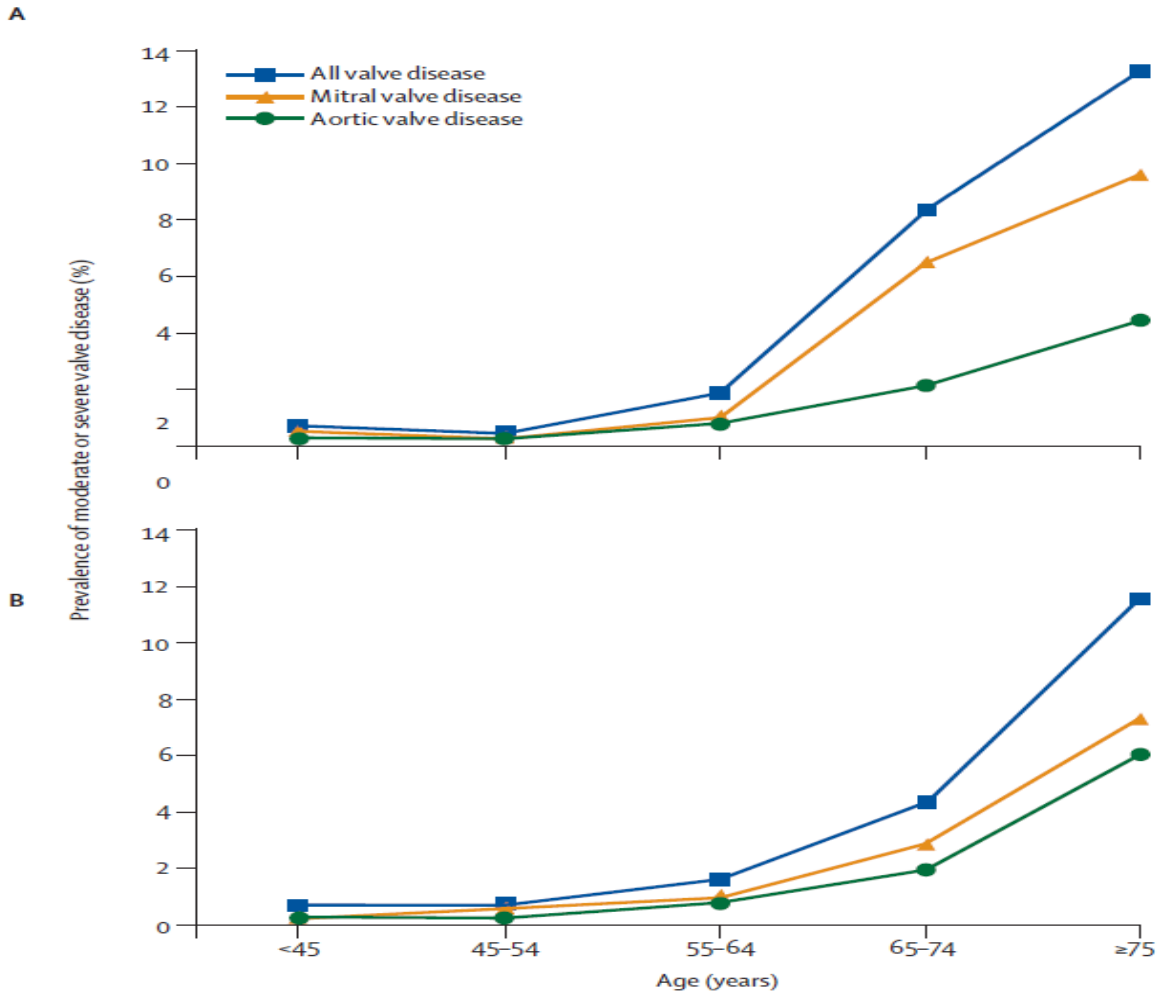
Кокорин Станислав Геннадьевич, к.м.н, ведущий научный сотрудник лаборатории кардиоваскулярного биопротезирования ФГБНУ «НИИ КПССЗ» (Кемерово)

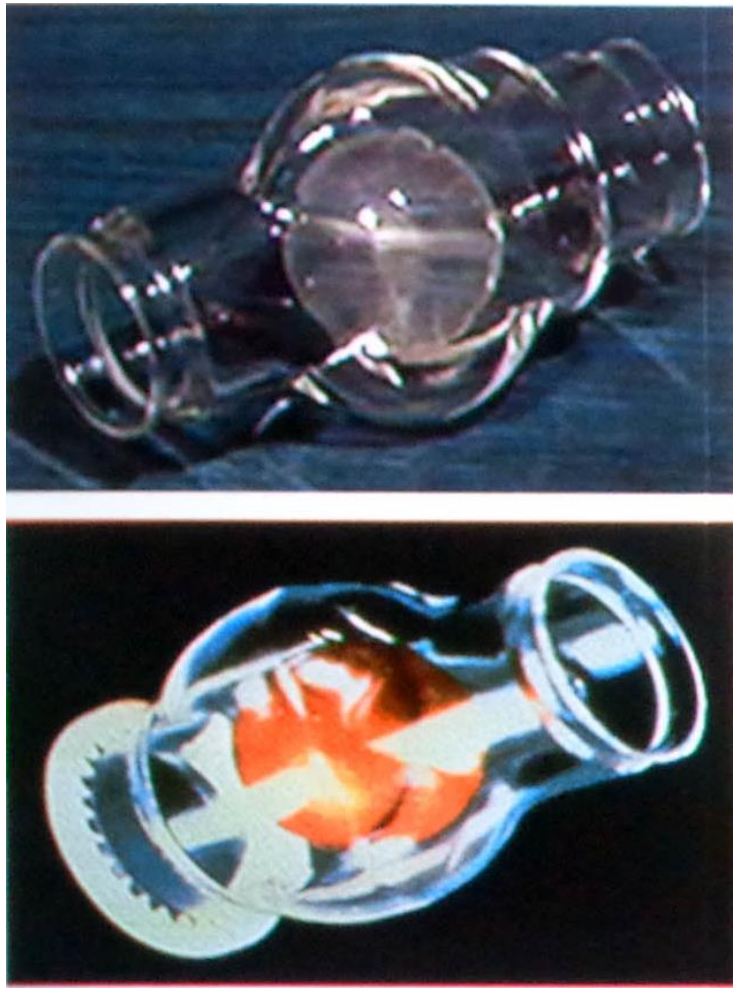
Актуальность проблемы



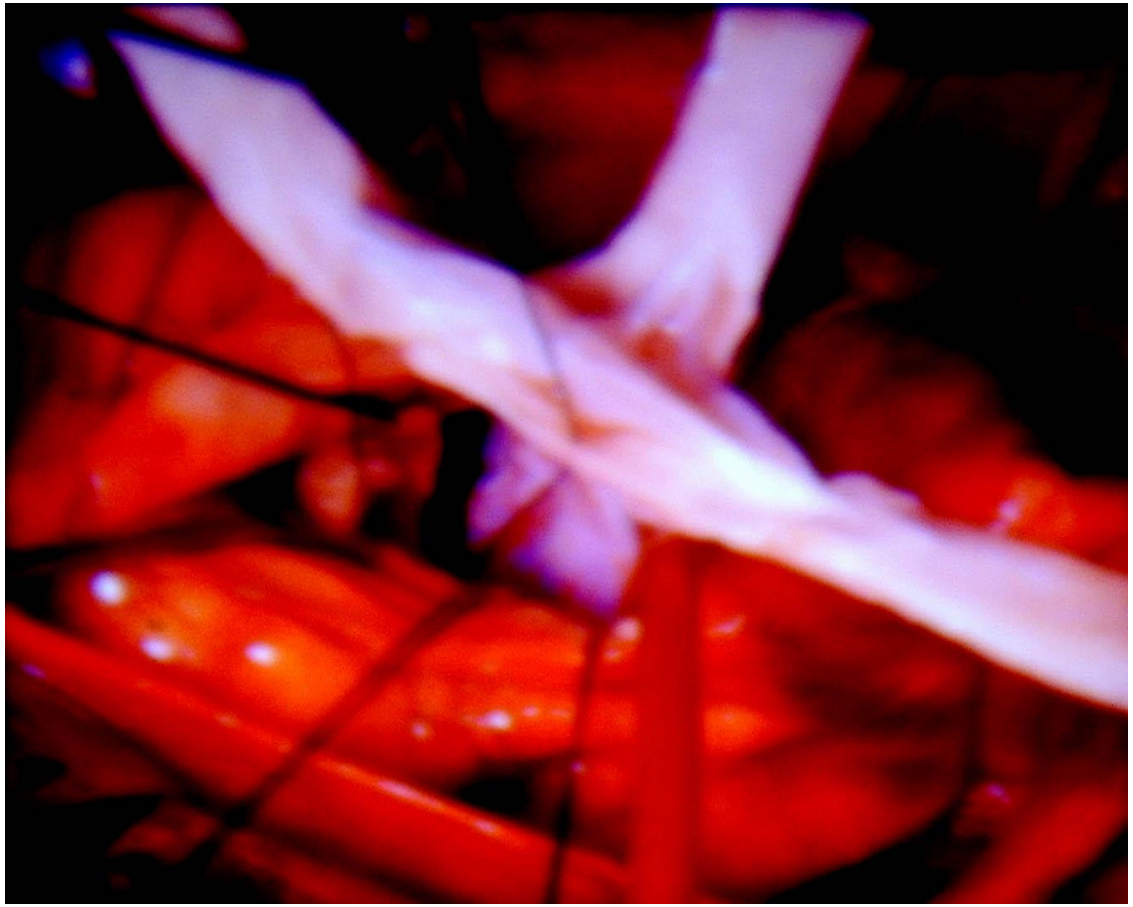
The Lancet // Vol 368 September 16, 2006

Революция 1: Первый имплантант в лечении клапанной болезни сердца

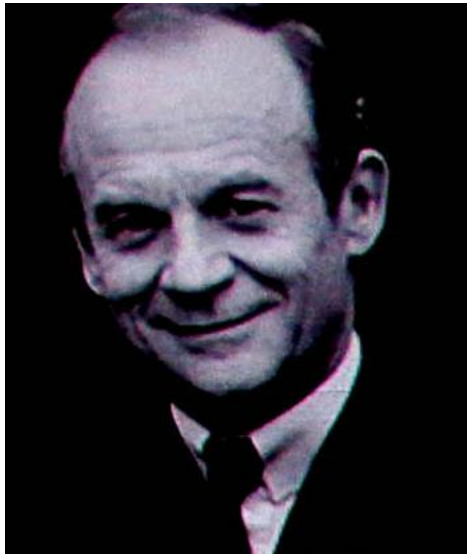
Charles Hufnagel – первый механический (шаровой) протез клапана сердца: ***Эксперимент - 1951год,***
Первая имплантация – 11 августа 1952г.
Пациент прожил 10 лет и умер от некардиальных причин

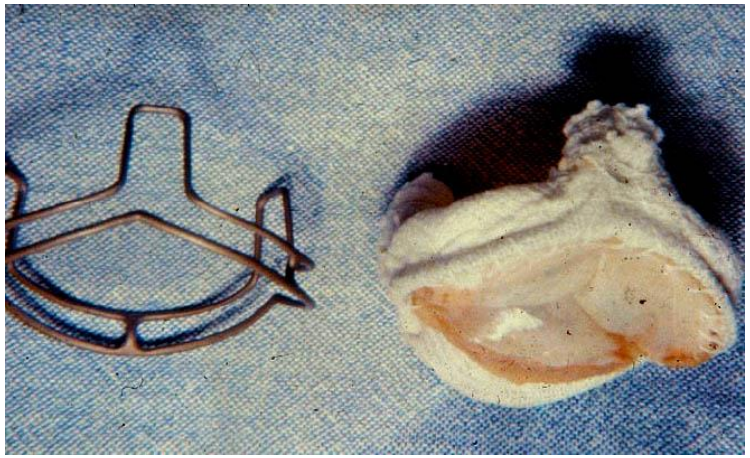


Революция 2: Первый биологический имплантант в лечении клапанной болезни сердца



Революция 3: Первый биологический протез в лечении клапанной болезни сердца – 1965-1967





Mitral and tricuspid valve replacement with frame-mounted aortic heterografts

A. Carpentier, M.D., Ph. Blondeau, M.D., B. Laurens, M.D., A. Hay, M.D., D. Laurent, M.D., and Ch. Dubost, M.D., Paris, France

The complete absence of embolic problems in the postoperative follow-up of patients with aortic valve homograft and heterograft replacement has led to much experimental work on the use of this type of valve in the mitral position. Transplantation of the mitral valve itself is possible and suturing homografts or heterografts to the mitral annulus has not presented any particular problem, but proper fixation and adjustment of the chordae tendineae is a major difficulty which may be insurmountable. Not only is it difficult to adjust the chordae to the proper length at the time of operation but early and late changes in left ventricular volume can lead to further traction or relaxation on properly adjusted chordae, which can cause late mitral incompetence.

Murray[18] and Heimbecker[10] have suggested the use of an aortic valvular orifice placed in an inverted position. In this technique the annulus of the aortic valve is sutured at the mitral annulus and the commissural strips with attached aorta are secured by stitches taken through the

obtain a competent valve in this fashion since at each systole the mitral annulus contracts and deforms the aortic annulus. Ventricular contraction probably also affects cusp function since the commissural strips are displaced with each contraction. In order to avoid some of these difficulties, Hubka[11] has suggested placing the aortic graft in an atrial position. This proved to be a much better technique and has been used in patients by Wooler and Ionescu.[12]

In our opinion, however, this technique has still several disadvantages: (1) the inferior pulmonary veins are close to the mitral annulus and interfere with proper positioning of the valve, (2) the suture on the auricular wall creates zones of traction and infolding in the auricle, particularly if the auricle is very large, (3) the high position of the functioning valve tissue creates a noncontractile cul-de-sac just above the ventricular cavity, and (4) the technique is not applicable to the tricuspid position because of the proximity of the coronary sinus

A.Carpentier 1969 г.

1. Кондиционирование: Метапериодат натрия

2. Консервация: Глутаровый альдегид

Достигнутые цели:

- **Антигенодепрессия**
- **Стерилизация**
- **Сшивка (упрочнение ткани)**

Проблемы ранних биопротезов (1969):

Biological factors affecting long-term results of valvular heterografts

Alain Carpentier, M.D. (by invitation), Guy Lemaigre, M.D. (by invitation), Ladislas Robert, M.D. (by invitation), Sophie Carpentier, M.S. (by invitation), and Charles Dubost, M.D. (by invitation), Paris, France
Sponsored by Frank Gerbode, M.D., San Francisco, Calif.

The use of biological tissue in surgery springs from a natural tendency of man to consider with affection all natural material and with suspicion any artificial substitute. This more sentimental than scientific attitude is, however, still justified at the present time in cardiac surgery because of the real advantages of valvular graft replacement, such as excellent hemodynamic function, absence of hemolysis, thrombosis, and embolism, and avoidance of postoperative anticoagulant therapy.

Heterografts in comparison with homografts provide more practical conditions for obtaining an unlimited number of samples, removed under sterile conditions, from selected donors. In addition, by the use of different animal species (lamb, pig, or calf), it is possible to obtain a great variety of sizes to supply the needs of all valvular replacement, both in adults and children. Despite these advantages, heterografts have their own disavantages, which must be emphasized to show this method of valvular replacement in its true aspect.

Having been the subject of a great deal of study in this laboratory[10, 11, 14] as well as in others,[16, 21, 26] the technical problems seem to be solved whereas the biological problems still remain relatively unknown, although they play a great part in the long-term results of such grafts.

Thus, despite continuous investigations, several questions still remained unanswered, such as: What is the host reaction to differently treated tissue? Is the effect of host cell ingrowth into the valve beneficial or harmful? What is the long-term fate of collagen and elastin? And, finally, what is the adequate method for preservation of such grafts?

Continuous analysis of data accruing from our clinical experience and from immunological and biochemical research have helped provide answers to some of these questions.

Normal and pathological evolution of grafts

Since September, 1965, the date of the first successful heterograft replacement of the aortic valve in a human,[7] we have made extensive use of this valve substitute. Some patients who died or were reoperated upon for reasons listed in Table I, made it possible to examine the graft at various time

From the Laboratoire d'Etude des greffes et prothèses valvulaires, Institut de Progenèse, Faculté de Médicine, 15, rue de l'Ecole de Médicine, Paris, France, and the Clinique de Chirurgie Cardiaque Hôpital Broussais, Paris, France.

Supported by the Délégation Générale á la Recherche Scientifique et Technique.
Read at the Forty-ninth Annual Meeting of The American Association for Thoracic Surgery, San Francisco, Calif., Mar. 31, April 1 and 2, 1969.

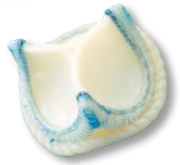
- Ранняя дегенерация
- Механические повреждения створок (несовершенство каркасов)
- Неоптимальная гемодинамика

Эволюция биопротезов

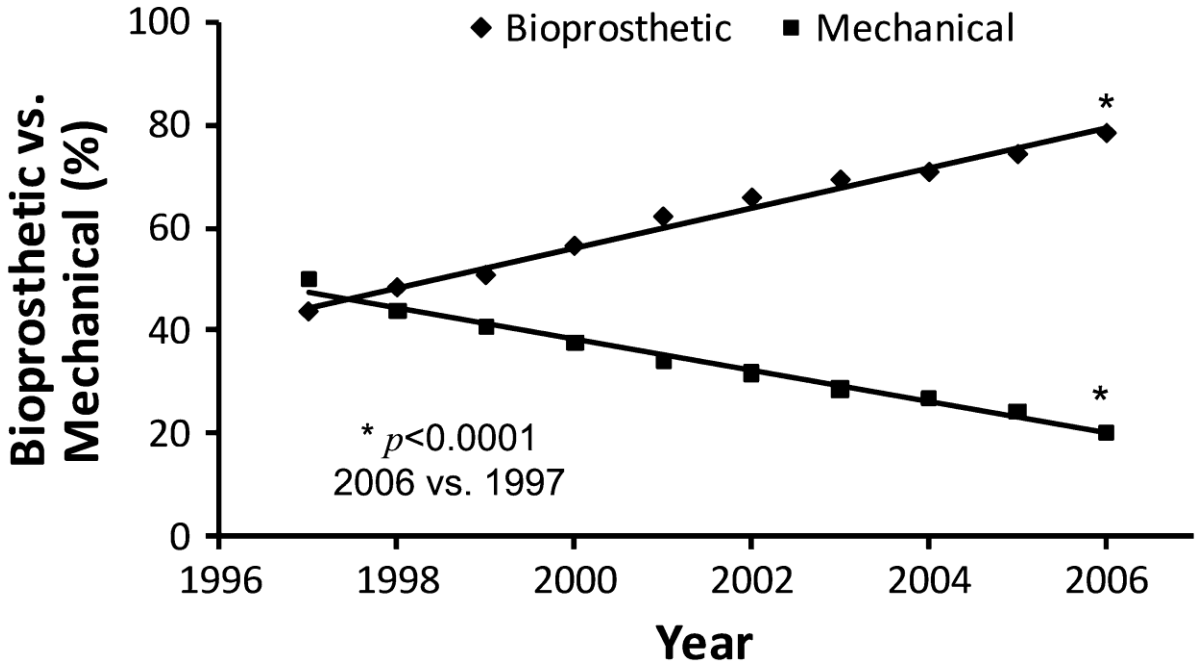
- 1965 – Первый биопротез свиной ксеноаортальный (Binet/Carpentier)
- 1971 – Перикардиальный биопротез Ionescu 
- 1975 - Перикардиальный биопротез Ionescu-Shiley 
- 1981 - Перикардиальный биопротез Mitroflow 
- 1981 - Биопротез Carpentier-Edwards 2900, 6900 
- 2002 - Перикардиальный биопротез ATS 3F 
- 2009 - Перикардиальный биопротез St.Jude TRIFECTA 

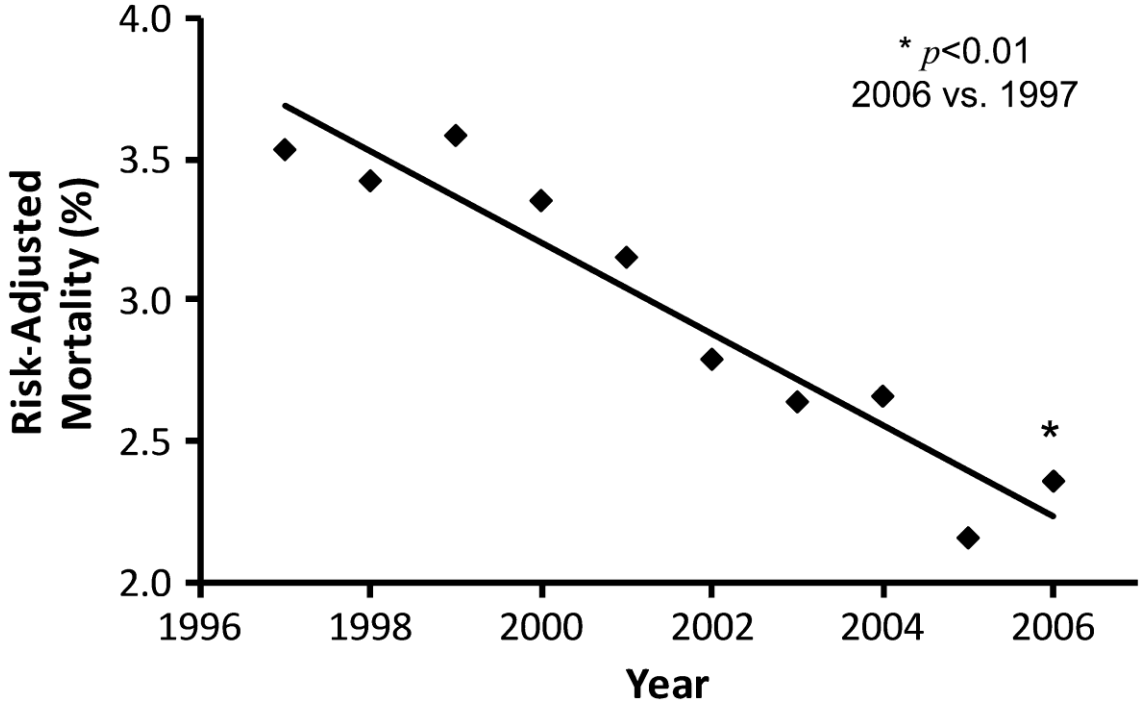
Этапы развития биопротезов ЗАО «Неокор»

- 1978г. – Первая имплантация биопротеза (тип «Ionescu»)
- 1984г. – Первая имплантация биопротеза БИОПАКС-1 (глутаровый альдегид)
- 1991г. – Первая имплантация биопротеза НЕОКОР (КемКор) (диглицидиловый эфир этиленгликоля)
- 2008г. – Первая имплантация ксеноперикардиального биопротеза ЮНИЛАЙН (диглицидиловый эфир этиленгликоля)
- 2012г. – Первая имплантация ПОЛУКАРКАСНОГО аортального ксенопериардиального биопротеза ТИАРА



Революция 4 – Первый «перекресток» и повышение безопасности

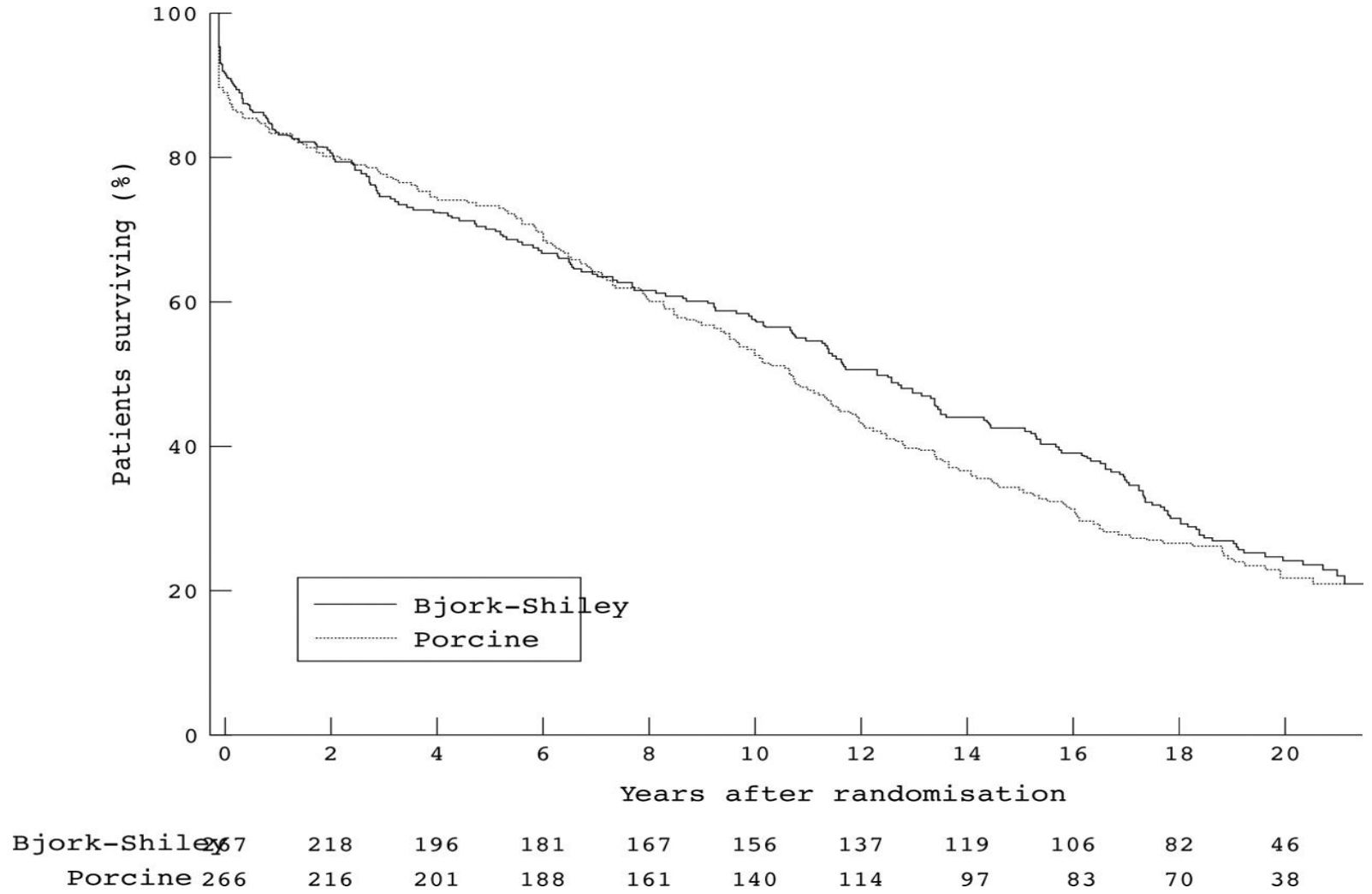




Данные STS Database

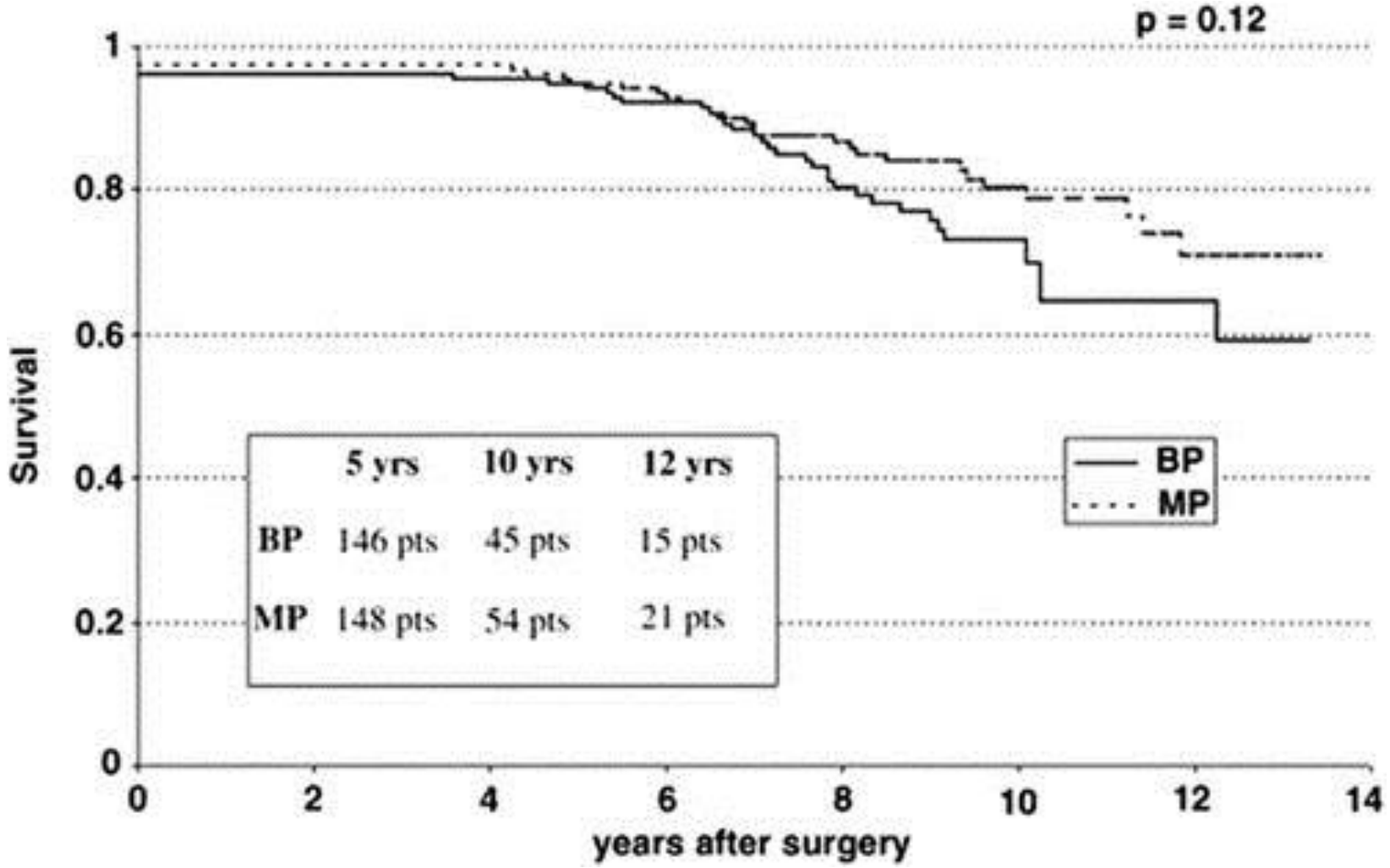
The Journal of Thoracic and Cardiovascular Surgery 2009 137, 82-90

Сравнительный анализ общей выживаемости при замещении митрального клапана механическим протезом (Bjork-Shiley) и ксеноаортальными биопротезами II поколения



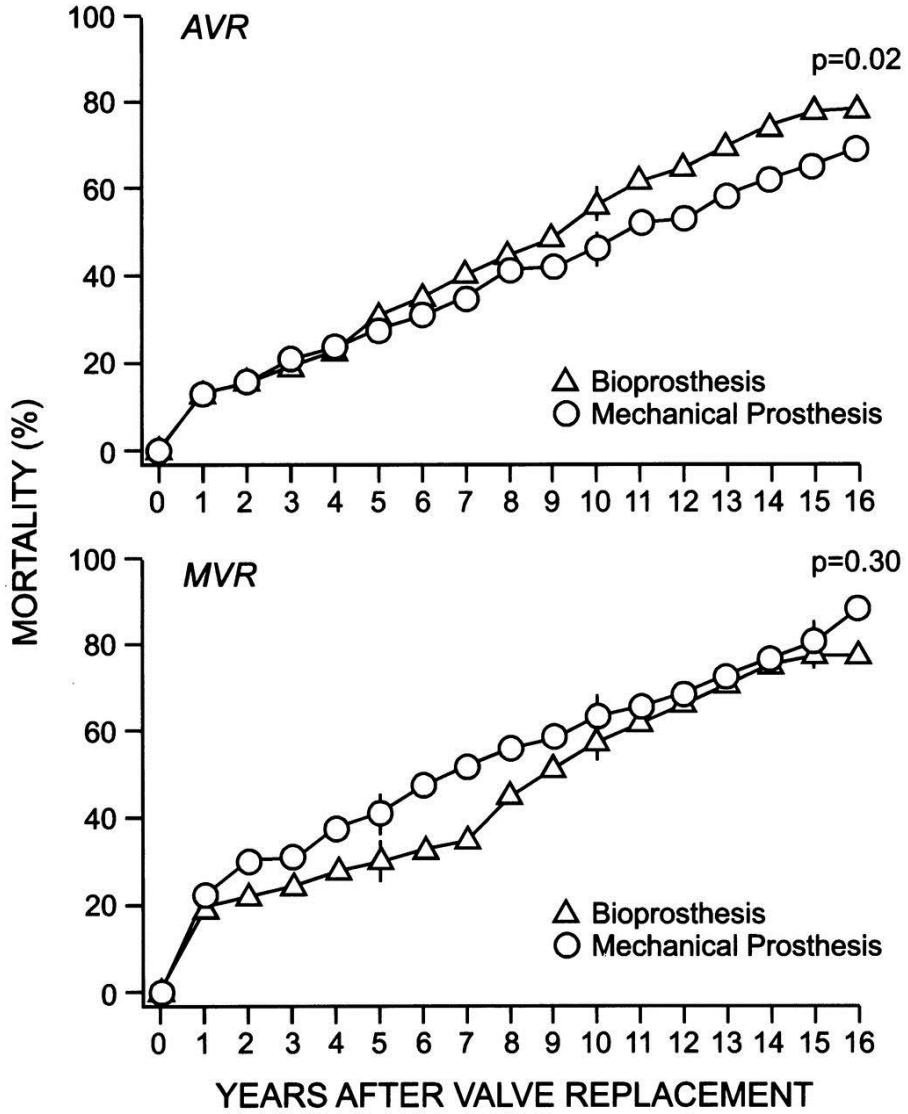
H Oxenham et al. Heart 2003;89:715-721

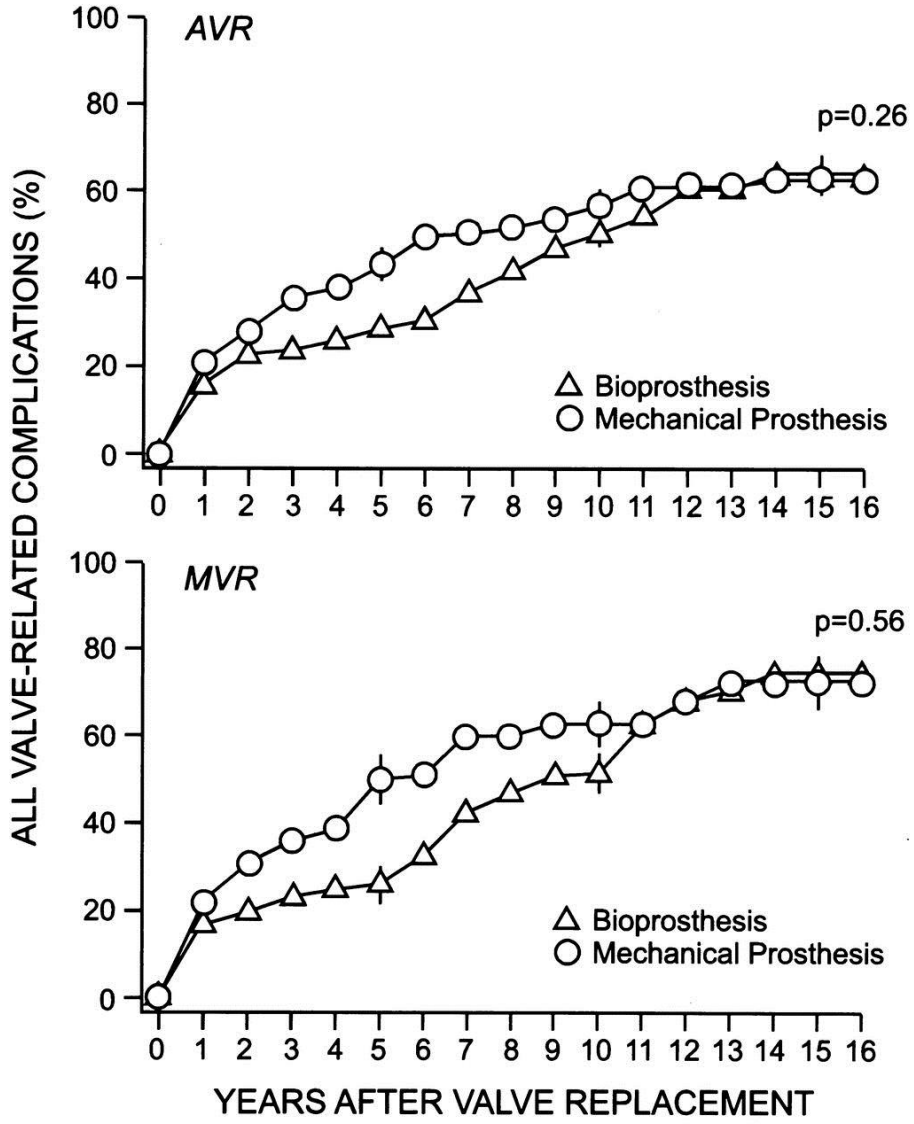
Сравнительный анализ общей выживаемости при замещении аортального клапана механическими и биологическими протезами



Rakesh M. Suri. Circulation. Selection of Aortic Valve Prostheses: Contemporary Reappraisal of Mechanical Versus Biologic Valve Substitutes, Volume: 128, Issue: 12, Pages: 1372-1380

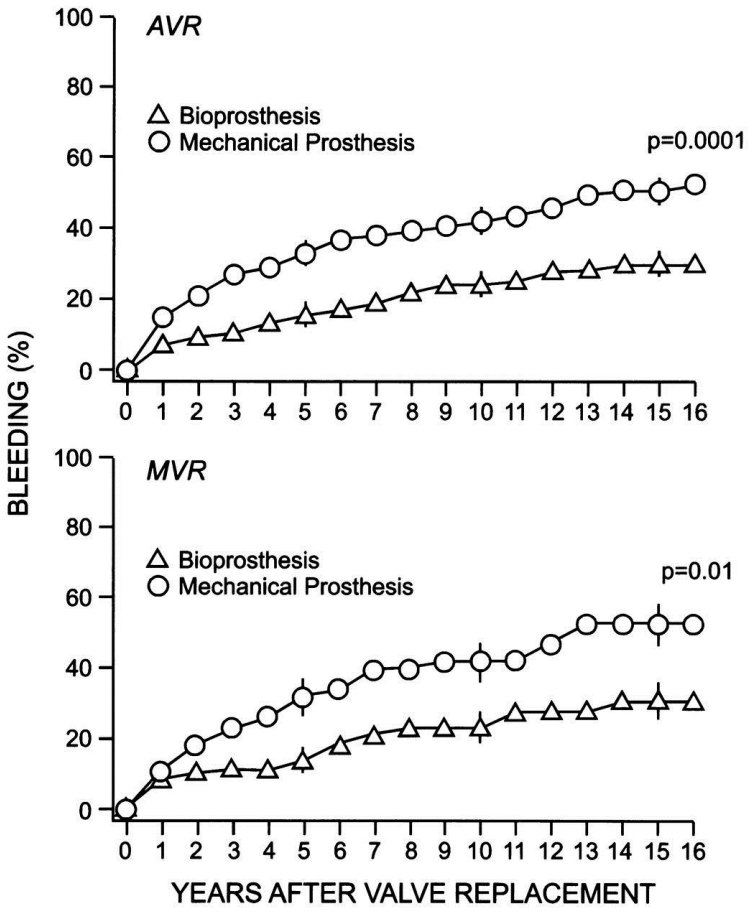
Сравнительный анализ отдаленных результатов имплантации механических и биологических протезов

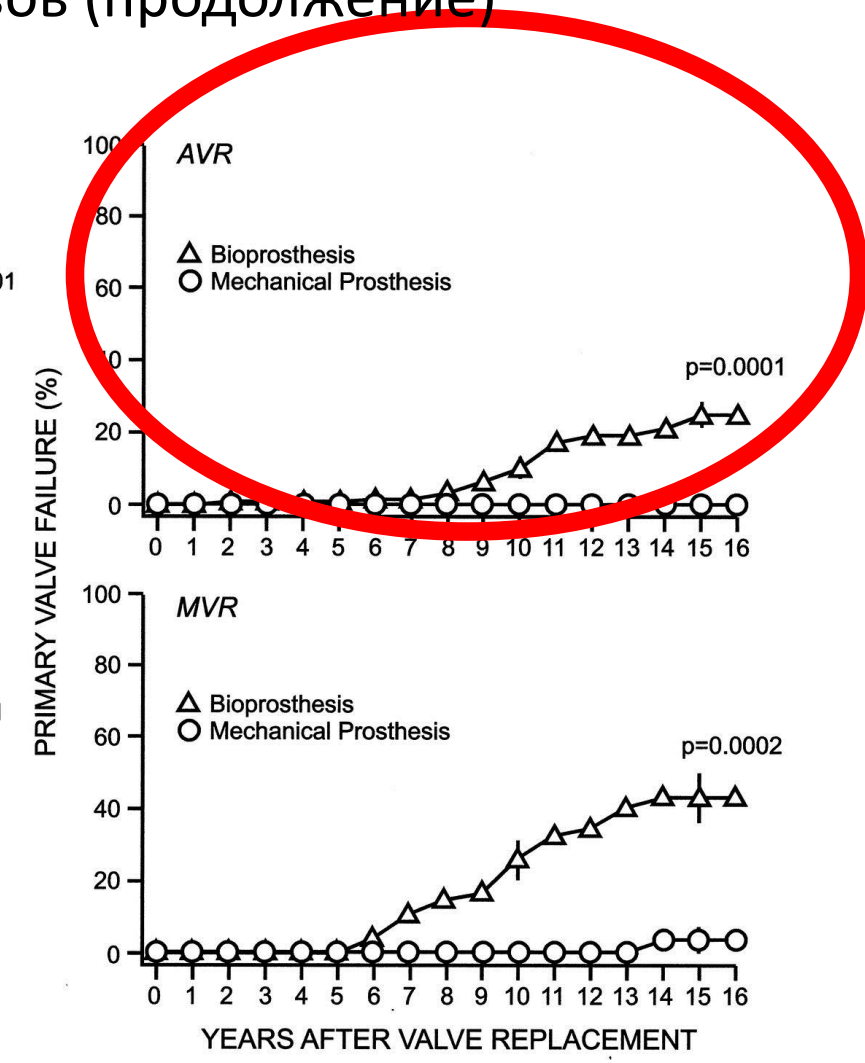


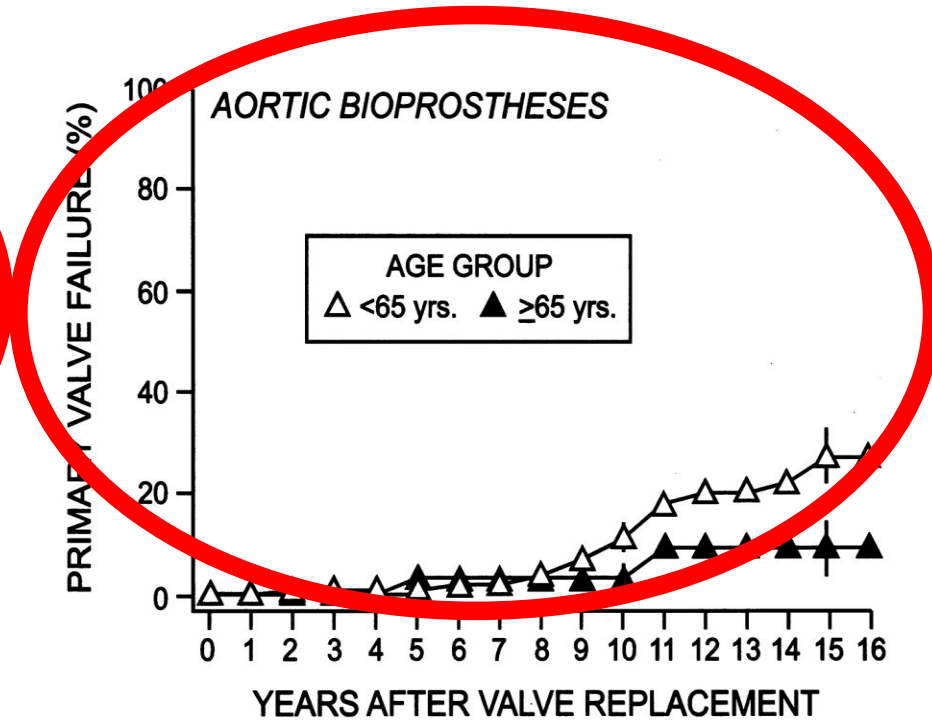


Hammermeister et al. JACC 2000;36:1152-1158

Сравнительный анализ отдаленных результатов имплантации механических и биологических протезов (продолжение)

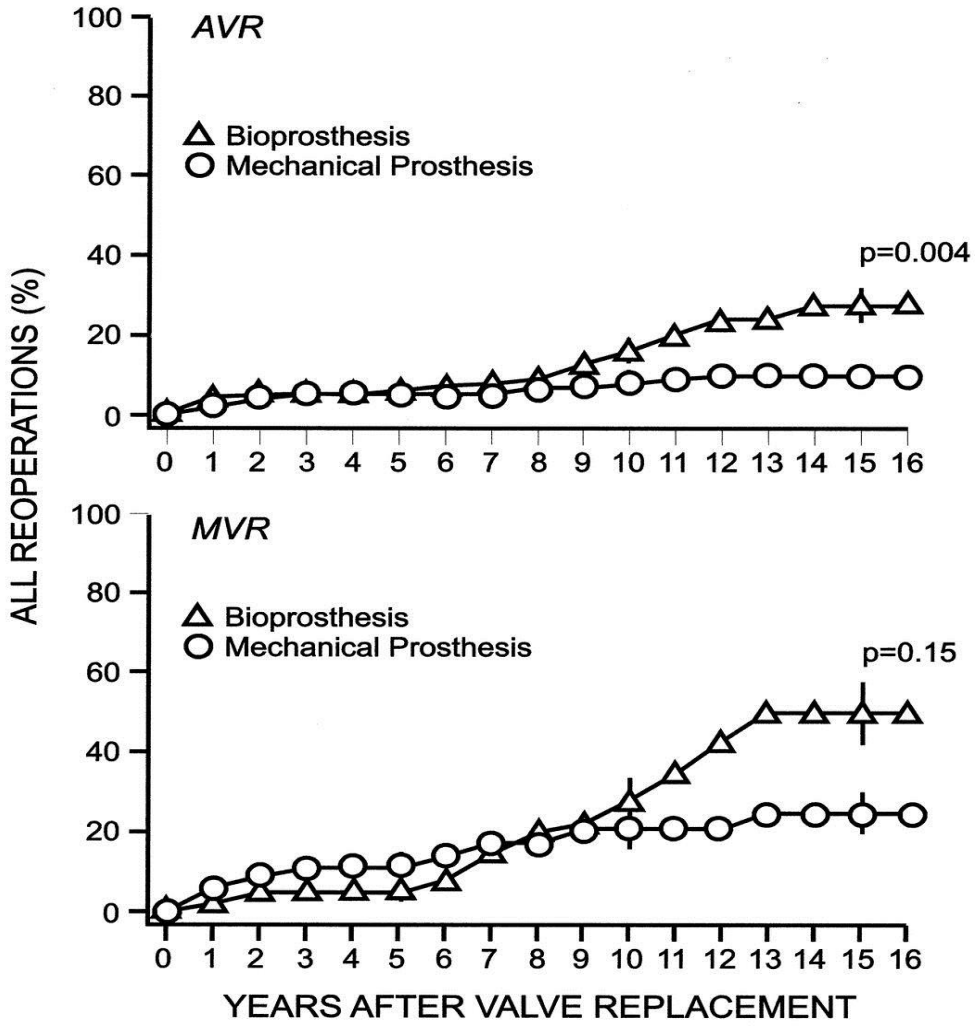






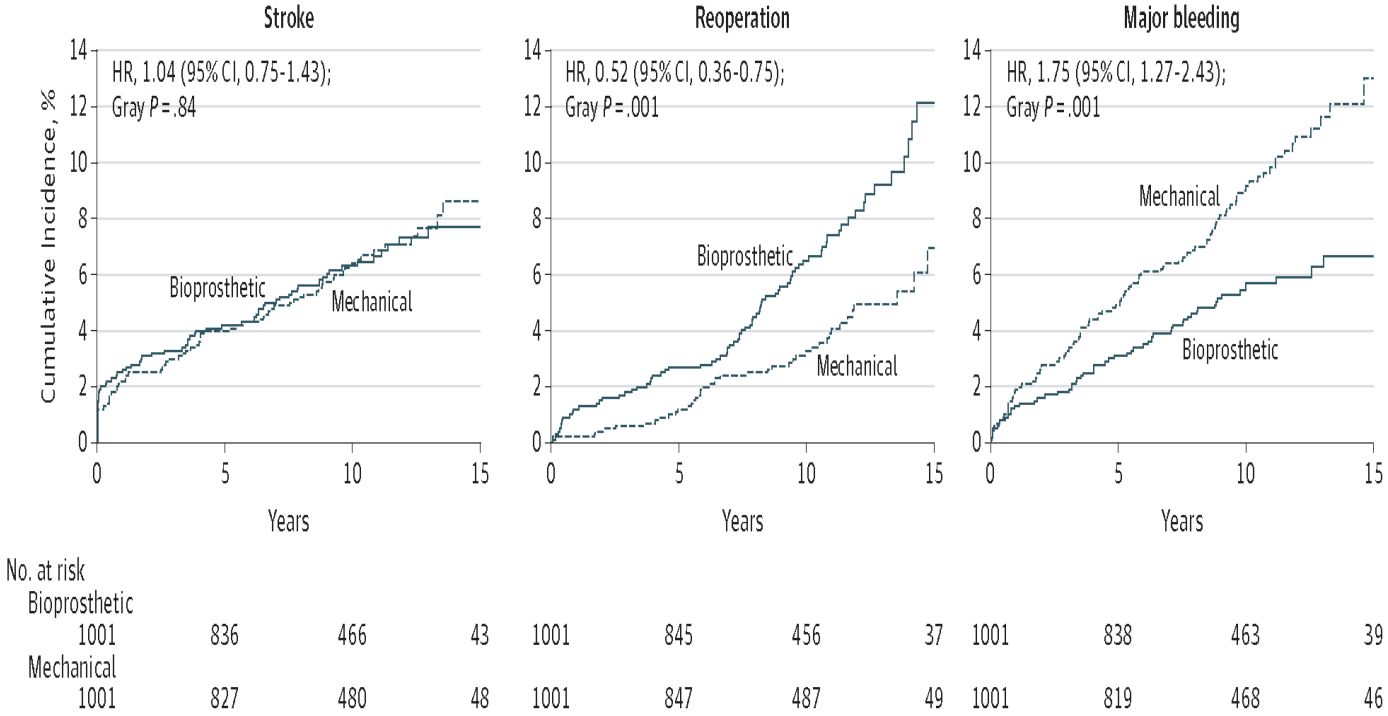
Hammermeister et al. JACC 2000;36:1152-1158

Сравнительный анализ отдаленных результатов имплантации механических и биологических протезов (продолжение)



Hammermeister et al. JACC 2000;36:1152-1158

PSM данные:



Survival and Long-term Outcomes Following Bioprosthetic vs Mechanical Aortic Valve Replacement in Patients Aged 50 to 69 Years
JAMA. 2014;312(13):1323-1329.

Выбор типа протеза клапана в 2006г.

ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology

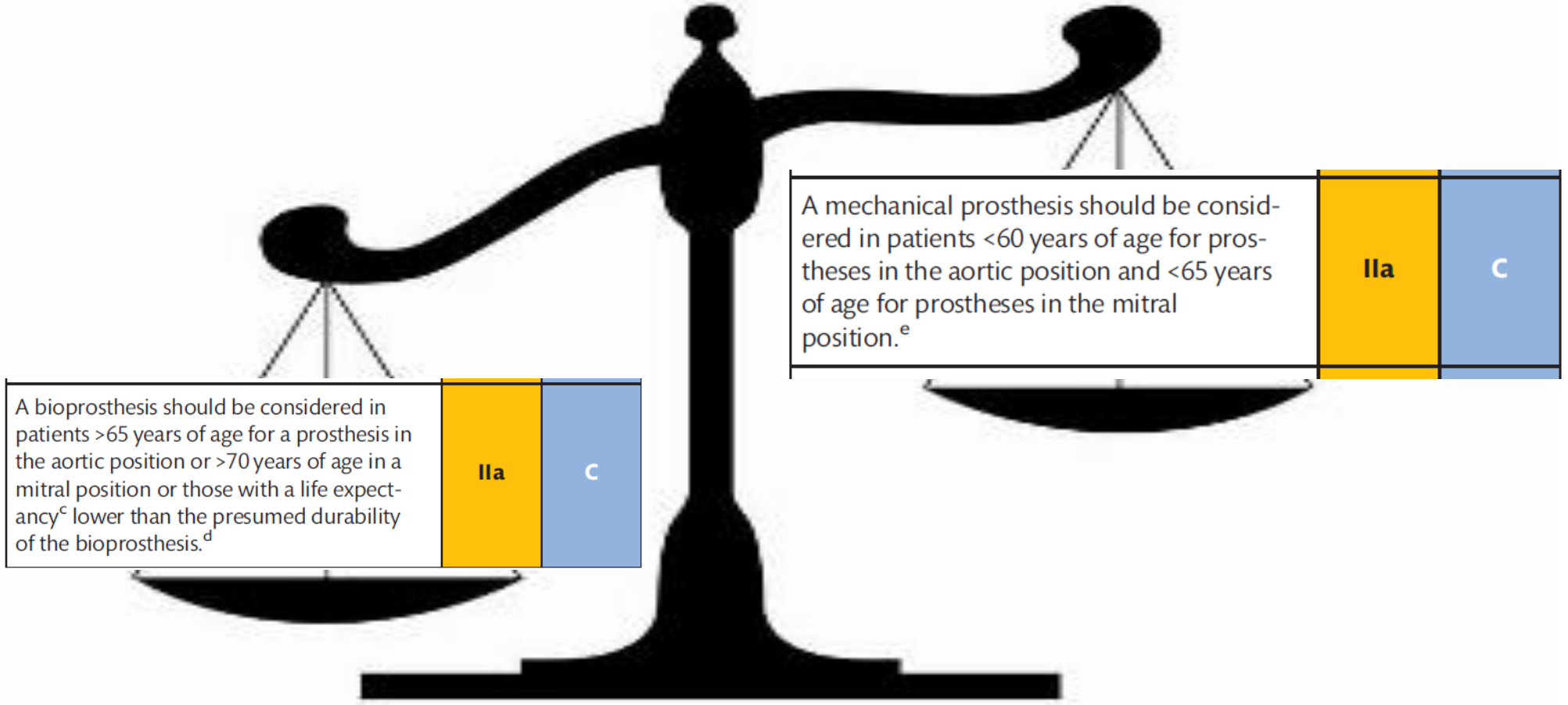
Class IIa

A bioprosthesis is reasonable for AVR in patients aged 65 years or older without risk factors for thromboembolism.
(Level of Evidence: C)

A bioprosthesis is reasonable for MV replacement in patients 65 years of age or older. ***(Level of Evidence: C)***

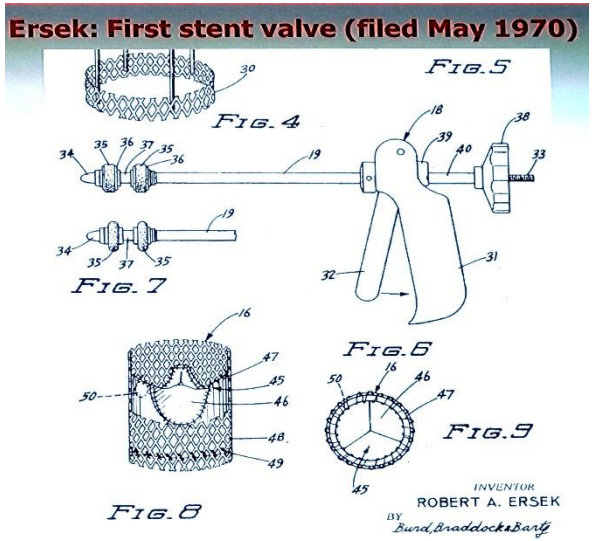
Выбор типа протеза

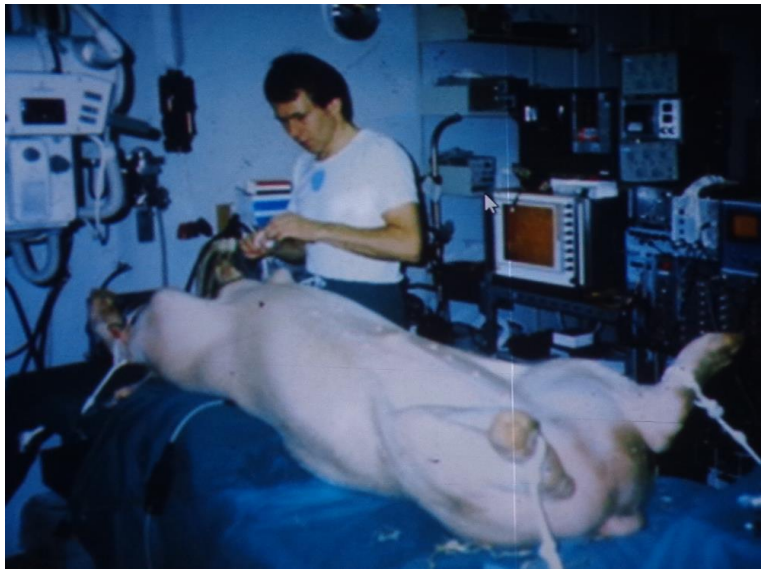
2017 ESC/EACTS Guidelines for the management of valvular heart disease
The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)



60-65 лет для аортальной позиции и 65-70 лет для митральной позиции – это СЕРАЯ зона?

Революция 5: Первый дизайн (1970г.) и имплантация транскатетерных биопротезов в эксперименте (1992г.)





European Heart Journal (1992) **13,** 704–708

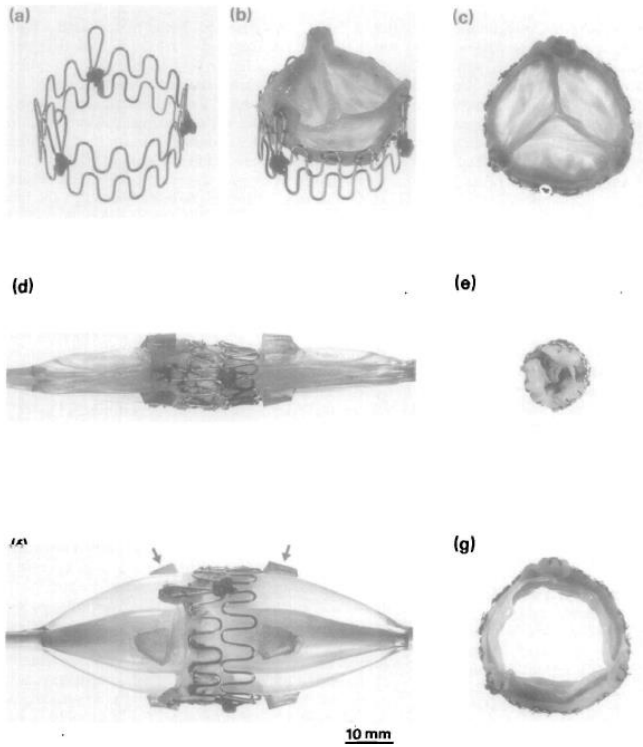
Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs

H. R. ANDERSEN*, L. L. KNUDSEN* AND J. M. HASENKAM†

*Departments of *Cardiology, †Thoracic and Cardiovascular Surgery, and the Institute of Experimental Clinical Research, Skejby University Hospital, Aarhus, Denmark*

KEY WORDS: Expandable stent–valve, transluminal implantation, prosthetic heart valve, pigs.

A new artificial aortic valve prosthesis was developed for implantation by the transluminal catheter technique without thoracotomy or extracorporal circulation. The new heart valve was prepared by mounting a porcine aortic valve into an expandable stent. Before implantation, the stent–valve was mounted on a balloon catheter and compressed around the deflated balloon. The stent–valve mounted balloon catheter was then advanced retrogradely to the ascending aorta or the aortic root in anaesthetized pigs. Implantation was performed by balloon inflation which expanded the stent–valve to a diameter exceeding the internal diameter of the vessel — thus ensuring a stable fixation against the vessel wall. A total of nine implantations were performed in seven 70 kg closed chest pigs. Sub- and supracoronary implantation was performed in two and three pigs, respectively, while implantation in both positions was done in two. Angiographic and haemodynamic evaluation after implantation revealed no significant stenosis (≤ 16 mmHg) in any of the nine valves and trivial regurgitation in only two. Complications were associated with restriction of the coronary blood flow in three animals. This preliminary study indicates that artificial aortic valves can be implanted in closed chest animals by transluminal catheter technique.

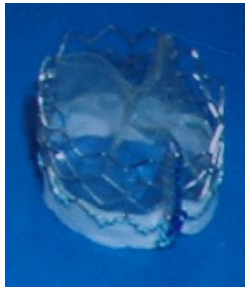
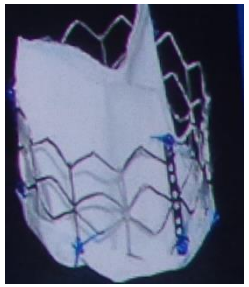


Революция 5 (продолжение)
1999г. – Создание стартапа PVT (Percutaneous Valve Technologies)

S.Rowe A.Cribier S.Rabinovich M.Leon

Прототипы:



Финальное изделие:


Революция 6 : Первая имплантация в клинике! (2000г.)

Early report

Percutaneous replacement of pulmonary valve in a right-ventricle to pulmonary-artery prosthetic conduit with valve dysfunction

Philipp Bonhoeffer, Younes Boudjemline, Zakhia Saliba, Jacques Merckx, Yacine Aggoun, Damien Bonnet, Philippe Acar, Jérôme Le Bidois, Daniel Sidi, Jean Kachaner

Summary

Background Valved conduits from the right ventricle to the pulmonary artery are frequently used in paediatric cardiac surgery. However, stenosis and insufficiency of the conduit usually occur in the follow-up and lead to reoperations. Conduit stenting can delay surgical replacement, but it aggravates pulmonary insufficiency. We developed an innovative system for percutaneous stent implantation combined with valve replacement.

Methods A 12-year-old boy with stenosis and insufficiency of a prosthetic conduit from the right ventricle to the pulmonary artery underwent percutaneous implantation of a bovine jugular valve in the conduit.

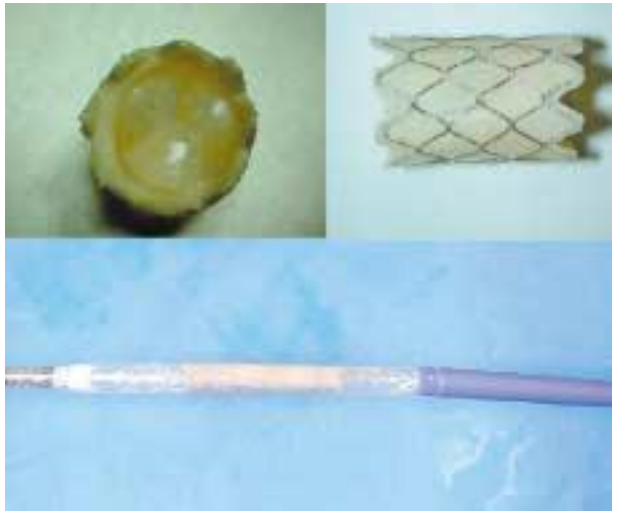
Introduction

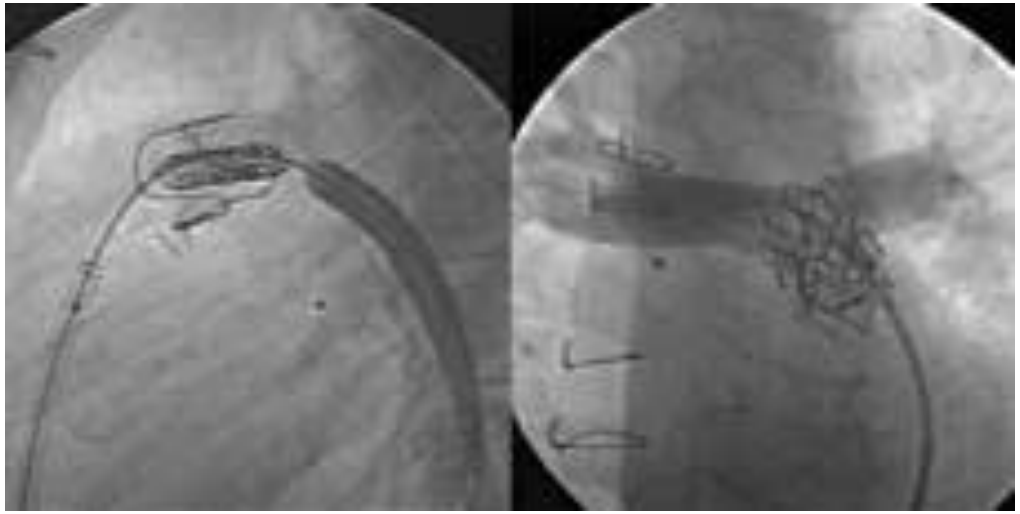
The treatment of congenital heart disease has become increasingly interventional as the armamentarium of tools grows. The most important advancements in interventional cardiology are the development of devices for closure of septal defects, and stents with or without covering.[1]

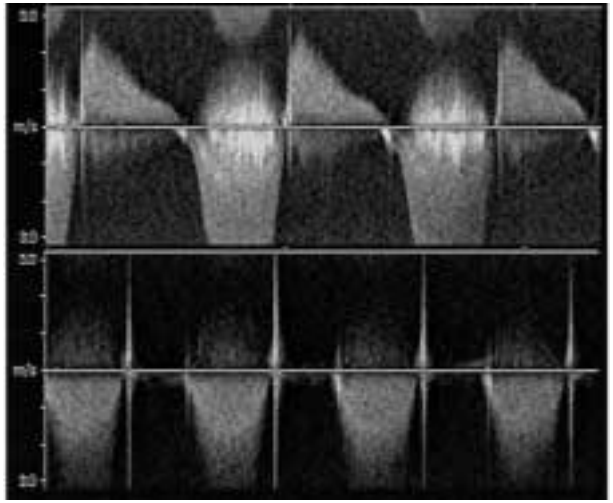
The development of extracardiac conduits for the establishment of right-ventricular to pulmonary-artery continuity has been one of the major advances in paediatric cardiac surgery. Conduits have permitted repair of previously uncorrectable congenital heart defects, and facilitated the treatment of other complex diseases. The prosthetic conduits are either valveless,[2] or use xenograft,[3-8] pericardial,[9] or homograft valves.[10-12]

Ph.Bonhoeffer – ПЕРВАЯ в мире транскатетерная имплантация клапана (*Париж, Франция*)

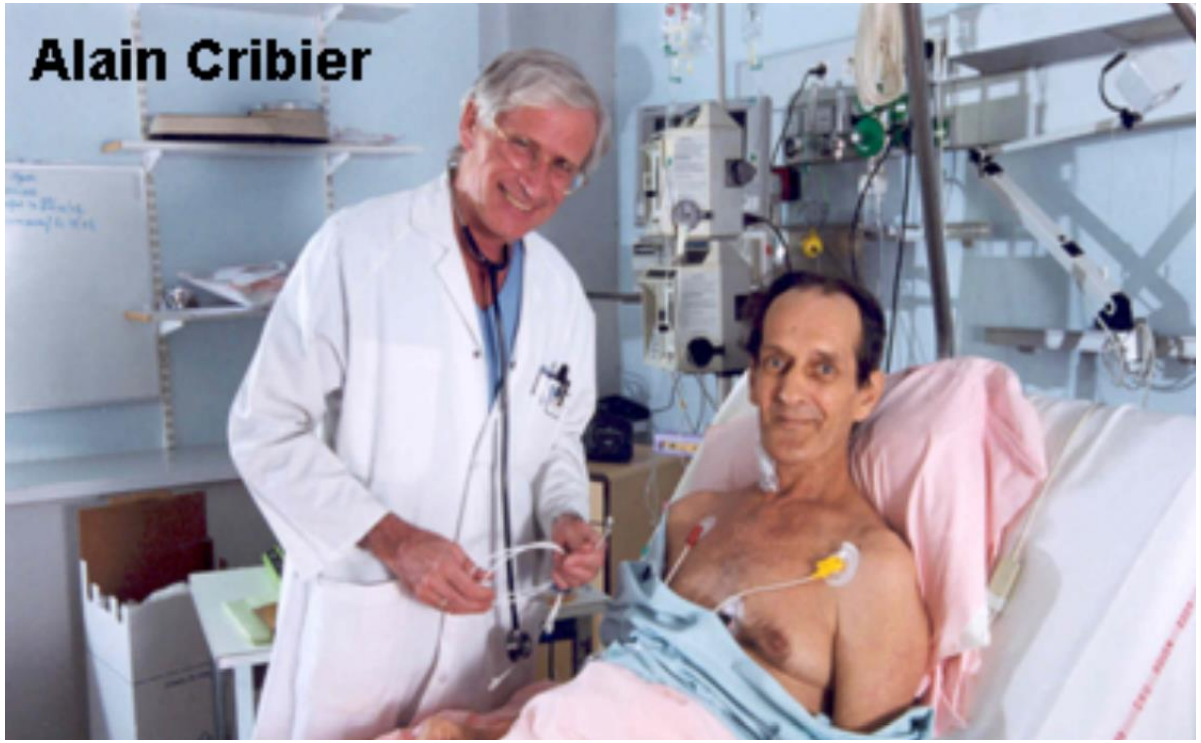
(THE LANCET • Vol 356 • October 21, 2000)



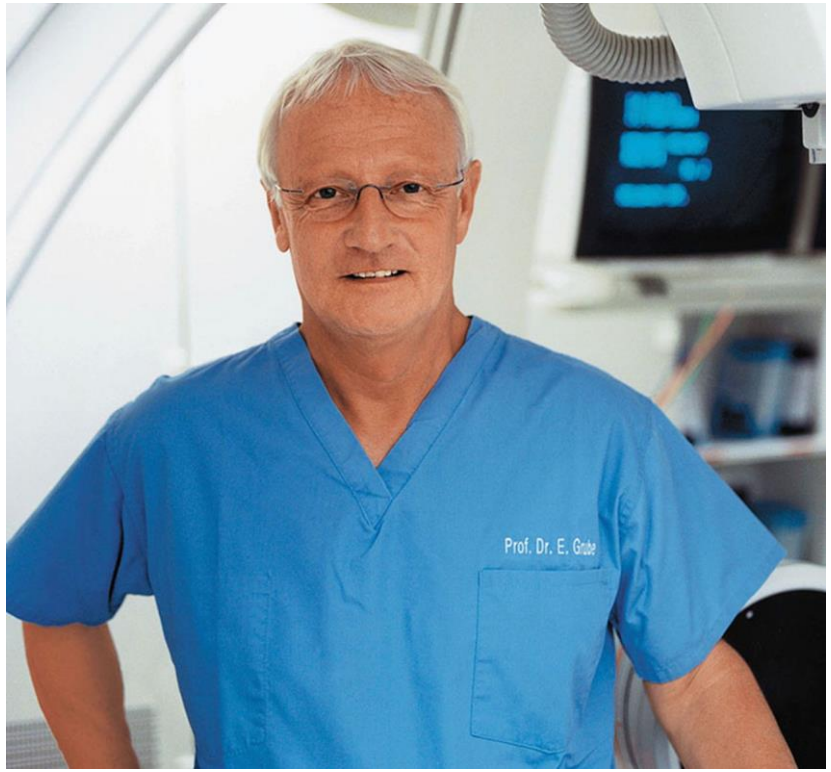




Революция 6 (продолжение): Первые транскатетерные имплантации в клинике аортальных клапанов РАЗЛИЧНОГО дизайна

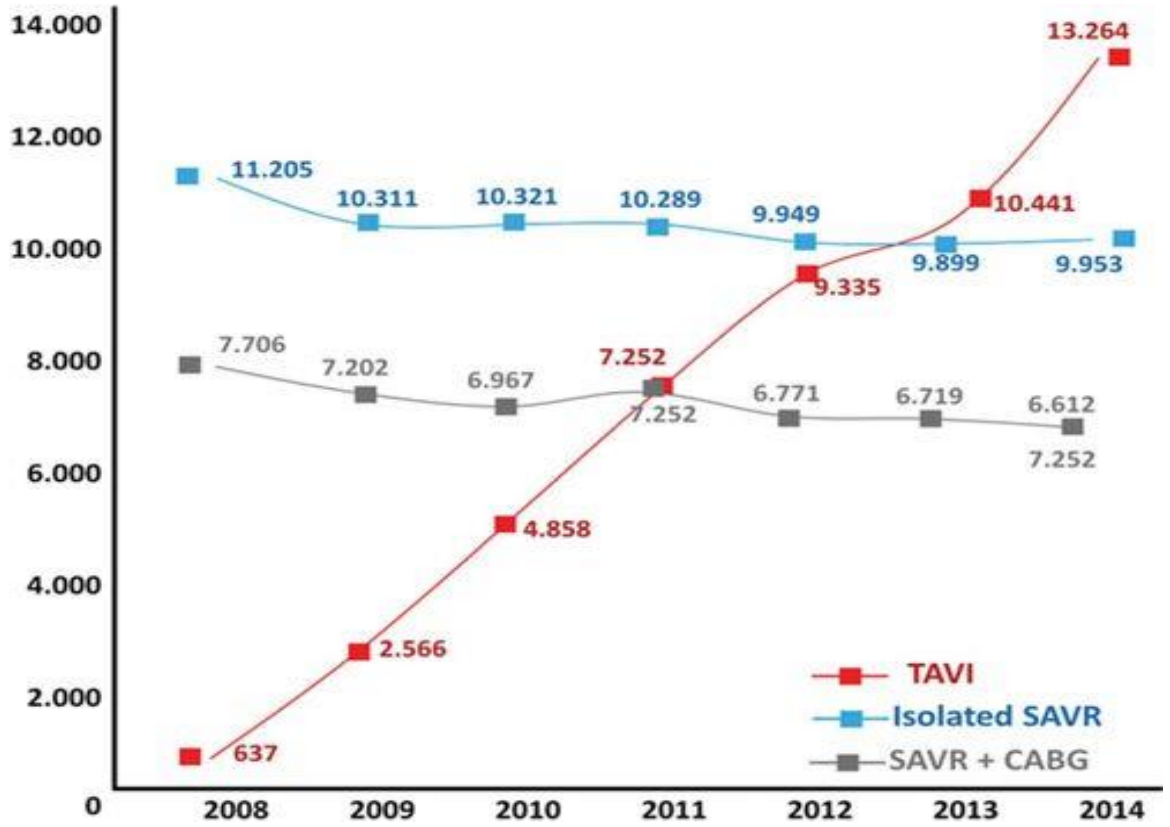


A.Cribier 16 апреля 2002г. – ПЕРВАЯ чрезкожная имплантация биопротеза клапана сердца человеку (SAPIEN) (Руан, Франция)



E.Grube (2004г.) – первая чрезкожная имплантация саморасширяющегося клапана сердца человеку (CORE Valve) (Зигбург, Германия)

Революция 7: второй «перекрест» и расширение показаний



По данным Европейского регистра EACTS

RESEARCH ARTICLE Open Access

Comparison 30-day clinical complications between transfemoral versus transapical aortic valve replacement for aortic stenosis: a meta-analysis review

Xuebiao Li†, Minjian Kong†, Daming Jiang and Aiqiang Dong*

Abstract

Background: Since 2002, transapical aortic valve replacement has been developed as a clinical pathway for transcatheter aortic valve implantation (TAVI). However the appropriate role of TA in the AS population versus TF remains unclear. We performed a meta-analysis to assess if TF has any benefit in reduction of 30-day clinical complications in AS.

Methods: We conducted a comprehensive search on pub-med and web of knowledge from 2002 through September 2012 using following terms: aortic stenosis, aortic valve replacement, transcatheter aortic valve implantation, TAVI, trans-artery, transfemoral, trans-apical. Studies in the original research or review articles were also considered. Included studies must meet the preconditioned criterias. Two investigators independently browsed the studies by title and abstract, finally making decision according to full-text. Disagreements were discussed in group.

Results: A total of 20 studies met inclusion criteria's and were included in the analysis (including 4267 patients in TF group, 2242 in TA group). No random clinical trial, one was a retrospective study, others were prospective trials. Our meta-analysis found that TF had the low incidence of 30-day mortality compared with TA procedure (7.5% versus 11.3%). The incidence of stroke at ≤ 30 days was relatively low (3.8% in TF versus 4.0% in TA). Although the incidence of post-operative heart block was high (8.5% versus 7.5%), but no differences were indicated [1.06,95% CI(0.85,1.33)].

Conclusions: The result of our meta-analysis suggested that TF may have a low risk for 30-day mortality against TA procedure. No difference was found in the incidence of post-operative stroke and heart block.

Keywords: Transcatheter aortic valve implantation, Transfemoral, Transapical, Aortic stenosis, Meta-analysis

19 из 20 исследований показали существенно более высокие основные риски трансапикальной имплантации по сравнению с трансфеморальной

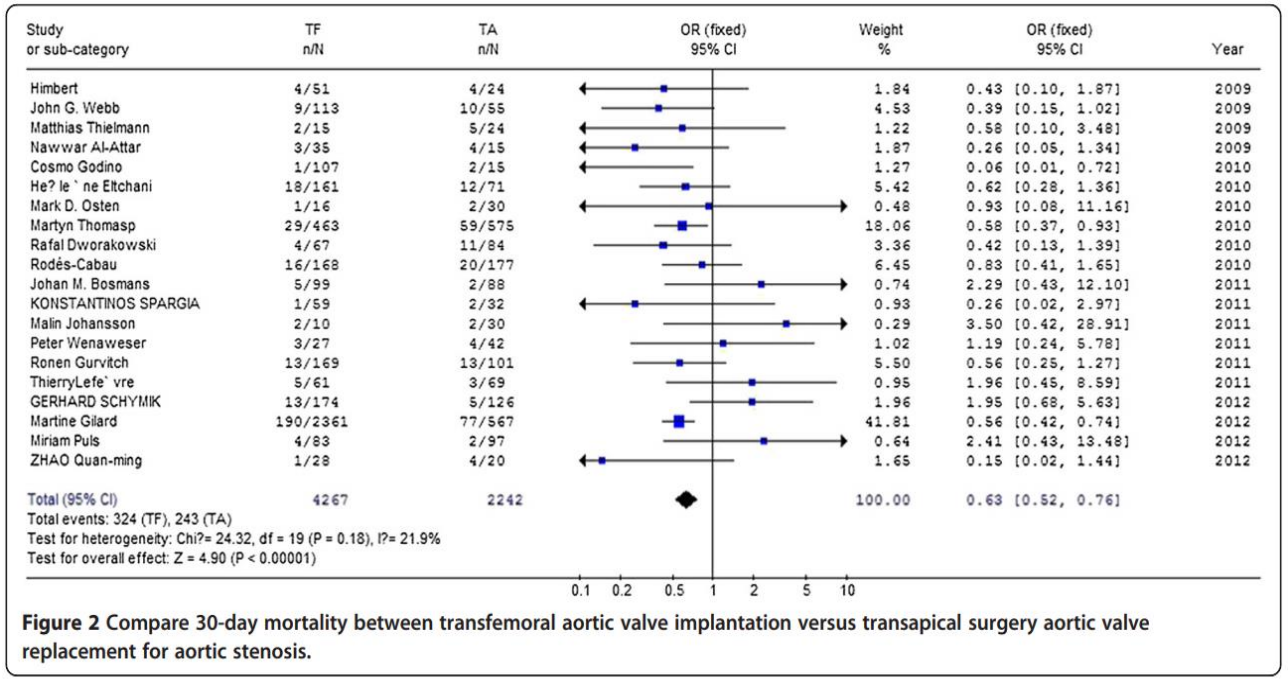


Figure 2 Compare 30-day mortality between transfemoral aortic valve implantation versus transapical surgery aortic valve replacement for aortic stenosis.

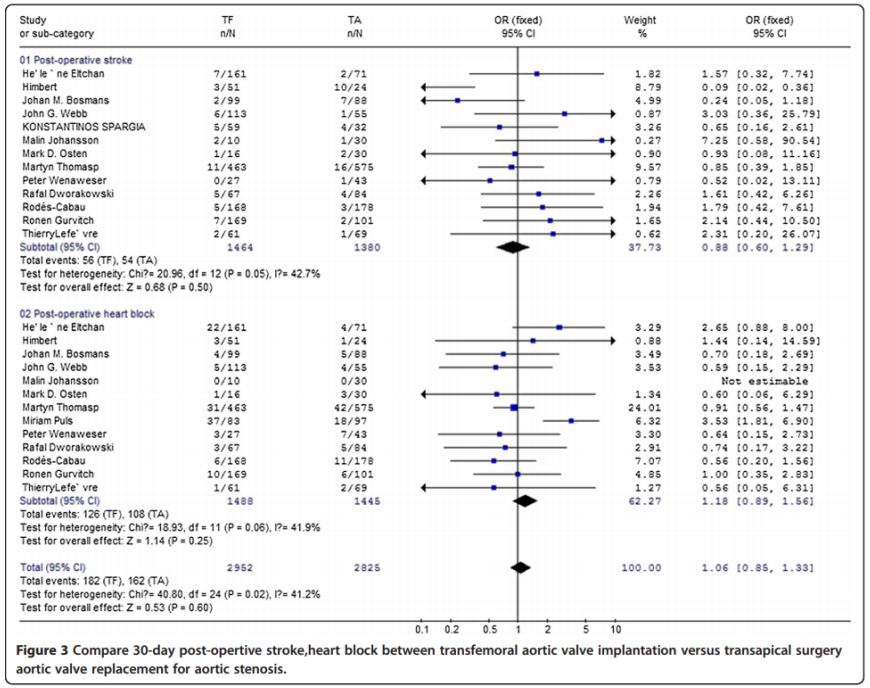
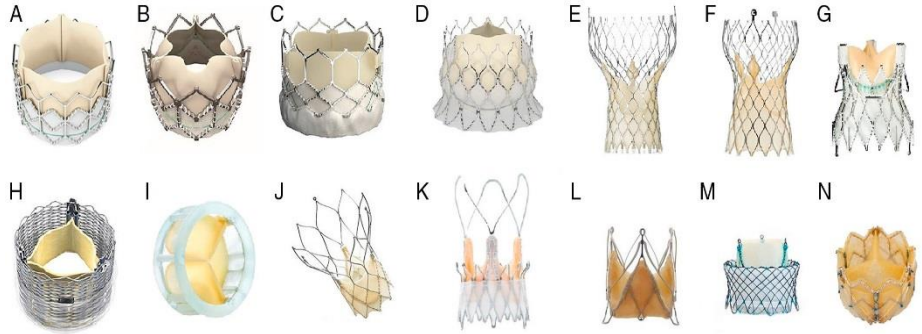


Figure 3 Compare 30-day post-opertive stroke,heart block between transfemoral aortic valve implantation versus transapical surgery aortic valve replacement for aortic stenosis.

На пути к доминированию

Перспективные модели транскатетерных митральных биопротезов

Современные и перспективные модели транскатетерных аортальных биопротезов



A) Edwards SAPIEN; B) Edwards SAPIEN XT; C) Edwards SAPIEN 3; D) Edwards Centera; E) Medtronic Core Valve; F) Medtronic Core Valve Evolut R; G) Medtronic Engager; H) Boston Lotus; I) Direct Flow medical; J) St. Jude Portico; K) Symetis Acurate; L) Jena Valve; M) Heart Leaflet Technologies; N) Colibri Heart Valve

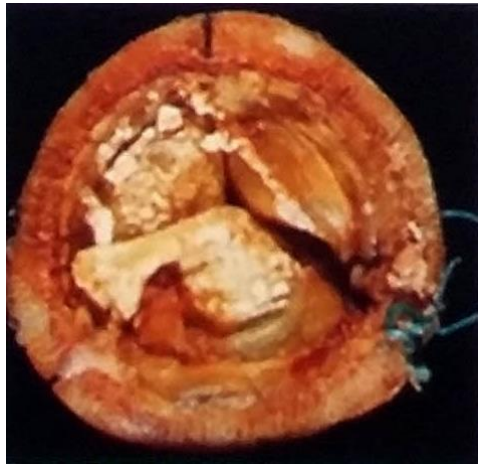
ОСНОВНЫЕ ТИПЫ ДИСФУНКЦИИ БИОПРОТЕЗОВ

Разрывы створок

Паннус

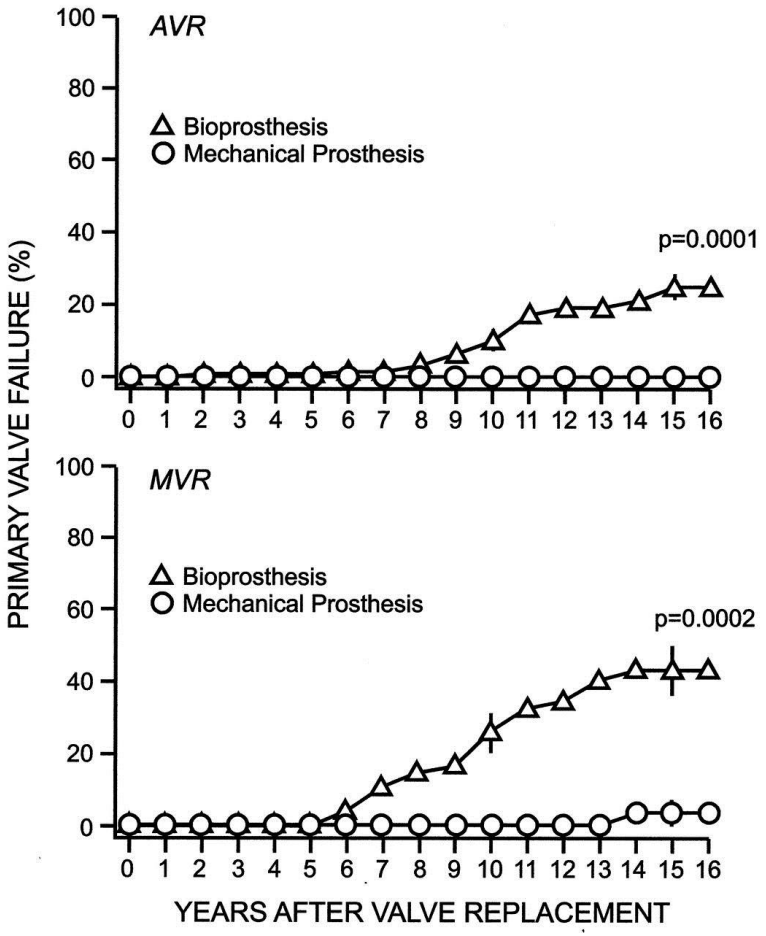
Тромбоз

Кальциноз



Эндокардит

Риск повторных операций при дисфункциях биопротеза повышен



Hammermeister et al. JACC 2000;36:1152-1158

Clinical Investigation

Reoperation for Prosthetic Heart Valve Dysfunction

19 Years' Experience

Zahi Masri, MD
Roland Girardet, MD
Abdulla Attum, MD
Ronald Barbie, MD
Isam Yared, MD
Allan Lansing, MD, PhD

Between September 1968 and October 1987, 152 patients (66 males and 86 females; age range, 15 to 79 years) underwent 1 or more reoperations (total, 179) for prosthetic valve dysfunction at our hospital. In this report, we present material and statistics reflecting our experience with the last reoperation in these 152 patients. The procedures involved the mitral valve in 93 patients, the aortic valve in 38 patients, double valves (aortic and mitral) in 19, and the tricuspid valve in 2. Sixty-five patients were operated on for mechanical valve dysfunction, and 87 for tissue valve dysfunction.

The modes of valve dysfunction that indicated surgery were primary valve failure (85 patients), valvular thrombosis and valve-related thromboembolic episodes (27 patients), paravalvular leak (25 patients), prosthetic valve endocarditis (14 patients), and hemolysis (1 patient). Three patients were in New York Heart Association functional Class II, 77 were in Class III, and 61 were in Class IV; the remaining 11 cases were emergencies. The 30-day operative mortality was 14.5%, the 5-year survival was 75%, and the 10-year survival was 63%. The preoperative functional class and the mode of valve dysfunction significantly influenced both early and late mortality. ***(Texas Heart Institute Journal 1990;17: 106-11)***

Исследование RECORD (2014)

European Journal of Cardio-Thoracic Surgery (2014) 1–12
doi:10.1093/ejcts/ezu116

ORIGINAL ARTICLE

ADULT CARDIAC

Mid-term results of aortic valve surgery in redo scenarios in the current practice: results from the multicentre European RECORD (REdo Cardiac Operation Research Database) initiative†

Francesco Onorati[a,*], Fausto Biancari[b], Marisa De Feo[c], Giovanni Mariscalco[d], Antonio Messina[e], Giuseppe Santarpino[f], Francesco Santini[g], Cesare Beghi[d], Giannantonio Nappi[c], Giovanni Troise[e], Theodor Fischlein[f], Giancarlo Passerone[g], Juni Heikkinen[b] and Giuseppe Faggian[a]

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[e] Cardiac Surgery Unit, Poliambulanza Foundation Hospital, Brescia, Italy
[f] Department of Cardiac Surgery, Klinikum Nürnberg, Nuremberg, Germany
[g] Division of Cardiac Surgery, IRCCS San Martino University Hospital, Genoa, Italy

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Received 11 September 2013; received in revised form 10 February 2014; accepted 18 February 2014

Abstract

OBJECTIVES: Although commonly reported as single-centre experiences, redo aortic valve replacement (RAVR) has overall acceptable results. Nevertheless, trans-catheter aortic valve replacement has recently questioned the efficacy of RAVR.

METHODS: Early-to-mid-term results and determinants of mortality in 711 cases of RAVR from seven European institutions were assessed in the entire population and in selected high-risk subgroups [elderly >75 years, urgent/emergent procedures, preoperative New York Heart Association (NYHA) functional Class IV and endocarditis].

RESULTS: Hospital mortality was 5.1%, major re-entry cardiovascular complications (MRCVCs) 4.9%, low cardiac output syndrome (LCOS) 15.3%, stroke 6.6%, acute respiratory failure (ARF) 10.6%, acute renal insufficiency (ARI) 19.3% and need for continuous renal replacement therapy (CRRT) 7.2%, transfusions 66.9% and for permanent pacemaker (PMK) 12.7%. Mid-term survival, freedom from acute heart failure (AHF), reinterventions, stroke and thrombo-embolisms were 77.2 ± 2.7, 84.4 ± 2.6, 97.2 ± 0.8, 97.2 ± 0.9 and 96.3 ± 1.2%, respectively; 87.5% of patients were in NYHA functional Class I–II. Preoperative left ventricular ejection fraction of <30% [odds ratio (OR) 8.7, 95% confidence interval (CI) 2.1–35.6], MRCVCs (OR 20.9, 95% CI 5.6–78.3), cardiopulmonary bypass time (OR 1.1, 95% CI 1.0–1.1), perioperative LCOS (OR 17.2, 95% CI 5.1–57.4) and ARI (OR 5.1, 95% CI 1.5–18.1) predicted hospital death. Endocarditis (OR 7.5, 95% CI 2.9–19.1), preoperative NYHA functional Class IV (OR 4.7, 95% CI 1.0–24.0), combined RAVR + mitral surgery (OR 5.1, 95% CI 1.5–17.3) and AHF at follow-up (OR 2.8, 95% CI 1.3–6.0) predicted late death at the Cox proportional hazard regression model. Elderly >75 years had similar hospital mortality ($P = 0.06$) and major morbidity, except for a higher need for PMK ($P = 0.03$), as well as comparable mid-term survival ($P = 0.89$), freedom from AHF ($P = 0.81$), reinterventions ($P = 0.63$), stroke ($P = 0.21$) and thrombo-embolisms ($P = 0.09$). Urgent/emergent indication resulted in higher hospital death, LCOS, transfusions, MRCVCs, intra-aortic balloon pumping (IABP), stroke, prolonged (>48 h) ventilation, pneumonia, ARI, CRRT, lower mid-term survival and freedom from AHF ($P \leq 0.03$). Preoperative NYHA functional Class IV correlated with higher LCOS, IABP, prolonged ventilation, pneumonia, ARF, ARI, CRRT and MRCVCs and lower mid-term survival, freedom from AHF, reinterventions and stroke ($P \leq 0.02$). Endocarditis demonstrated higher hospital mortality, MRCVCs, LCOS, IABP, stroke, ARF, prolonged intubation, pneumonia, ARI, CRRT, transfusions and PMK and lower mid-term survival and freedom from AHF and reinterventions ($P \leq 0.04$).

CONCLUSIONS: RAVR achieves overall satisfactory results. Baseline risk factors and perioperative complications strongly affect outcomes and mandate improvements in perioperative management. New emerging strategies might be considered in selected high-risk cases.

Keywords: Redo • Aortic valve replacement • Endocarditis • Prosthetic endocarditis • Emergent cardiac surgery

Многоцентровое исследование повторных операций при дисфункции протеза в аортальной позиции (711 пациентов, средний логистический EuroSCORE 10%)

- **Госпитальная летальность 5,1%**
- **ОНМК – 6,6%**
- **Острая почечная недостаточность 19,3% (диализ 7,3%)**
- **Имплантация ЭКС 12,7%**
- **Рестернотомии (кровотечение) – 7%**

За 20 лет госпитальная летальность снизилась в 3 (!) раза, но частота осложнений все еще высока

Первая серия «Клапан-В-Клапан» (1989г.)

Retention of bioprosthetic valve annulus in mitral prosthetic replacement

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Abstract. Mitral valve prosthetic replacement carries high mortality rates by modern standards, and mitral bioprostheses are particularly prone to degeneration. Bioprosthetic replacement may be technically difficult when there is calcification of the tissue ingrowth, strut incorporation, or valve-to-annulus size mismatch at the primary operation. A "valve-in-valve" technique is described where the mechanical prosthesis is implanted in the bioprosthetic annulus in order to avoid such difficulties. The results in the first eight patients are presented, showing post-operative Doppler-derived transvalvar mean gradients between 3.9 mm Hg and 7.5 mm Hg, and estimated valve areas between 1.9 cm^2 and 3.5 cm^2. All patients are alive at between 20 and 30 months (mean 23.6 months) after operation, they are without serious post-operative morbidity and are in functional class I or II (NYHA classification). [Eur J Cardio-thorac Surg (1993) 7:511–513]

Key words: Mitral valve – Mitral prosthetic replacement

Революция 8: Первая транскатетерная имплантация «Клапан-В-Клапан» (2007 год)

Catheterization and Cardiovascular Interventions 70:760–764 (2007)

Case Report

Percutaneous Aortic Valve Replacement for Severe Aortic Regurgitation in Degenerated Bioprosthesis: The First Valve in Valve Procedure Using the Corevalve Revalving System

Peter Wenaweser, MD, Lutz Buellesfeld, MD, Ulrich Gerckens, MD, and Eberhard Grube* MD, FACC

Percutaneous valve replacement for severe aortic stenosis has shown to be an alternative treatment option for non-surgical candidates. We report on the first successful valve in valve procedure in an 80-year-old patient with a severe regurgitation of a degenerated aortic bioprosthesis using the Corevalve Revalving system.

Key words: aortic regurgitation; percutaneous; valve replacement; bioprosthesis

INTRODUCTION

Percutaneous aortic valve replacement (AVR) has emerged as alternative, palliative therapy of severe, symptomatic valvular aortic stenosis [1–3]. After the first animal studies on transluminal implantation of artificial heart valves [4,5], a percutaneous valve implantation in pulmonary [6] and aortic position in humans [7] was successfully performed in 2002. After these milestones of interventional cardiology, a great enthusiasm for this approach has caught the interventional community of cardiologists, encouraged by the recent reports of favorable, procedural outcomes in patients with severe aortic stenosis treated with the CoreValve and the Edwards-Cribier prosthesis [1,3]. The use of these devices has been limited to patients with aortic stenosis combined with a high perioperative risk as well as contraindications for surgical valve replacement. As demonstrated by Bonhoeffer et al., a percutaneous valve insertion in pulmonary position for graft insufficiency is feasible [6].

We report on the first valve in valve procedure for treatment of severely insufficient bioprosthesis in aortic three-vessel disease, and several cardiovascular risk factors (arterial hypertension, dyslipidemia, peripheral artery disease) presented severely dyspnoic with a NYHA IV status to our emergency room. Furthermore, he complained of angina pectoris (Canadian Cardiovascular Society Classification grade 3) since several weeks and was primarily evaluated with a transthoracic echocardiography. A severe central, aortic regurgitation of the bioprosthesis (Mitroflow, 23 mm) with moderately reduced systolic left ventricular function (LVEF 46%) was diagnosed. Presumably, the biological prosthesis was severely degenerated in the follow-up period of an endocarditis the patient suffered 5 years prior. An embolic cerebrovascular insult and a complete atrio-ventricular block that had been treated with the implantation of a permanent pacemaker had complicated this infection.

The current invasive evaluation revealed patent bypass grafts without significant disease, a significant

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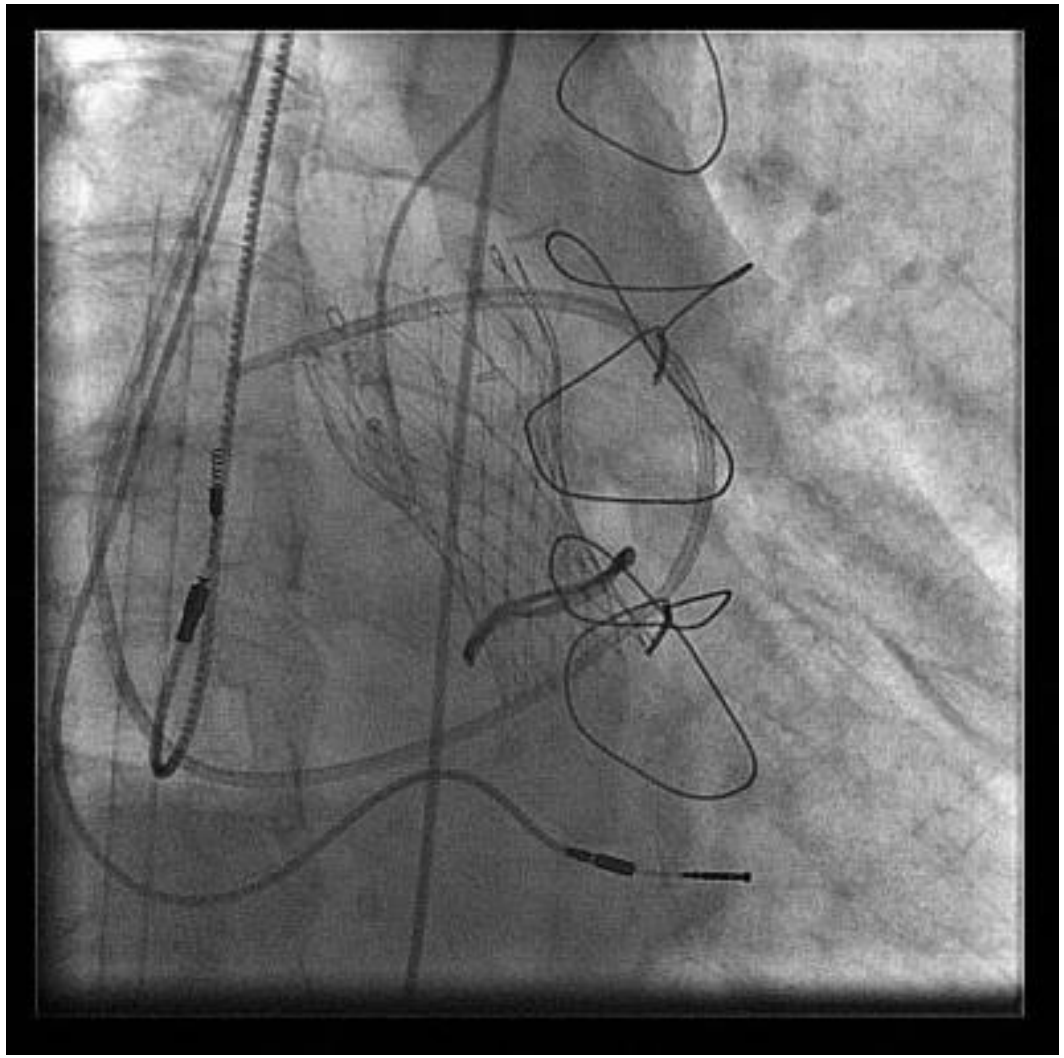
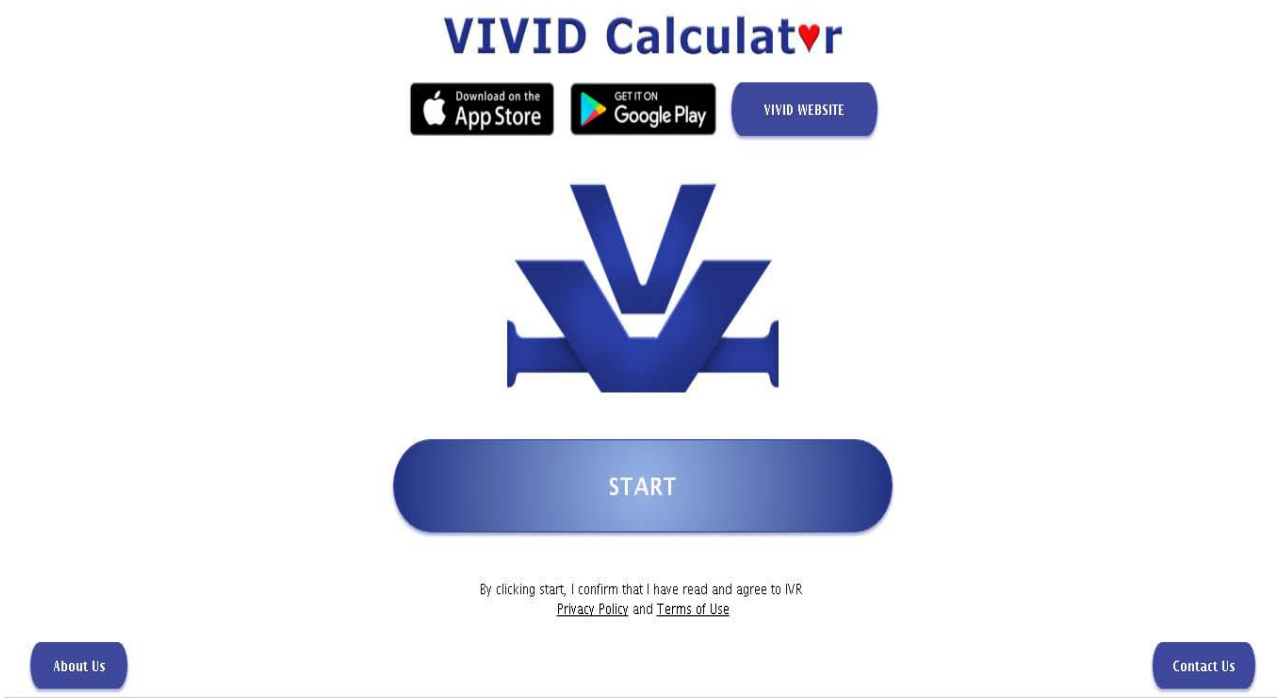
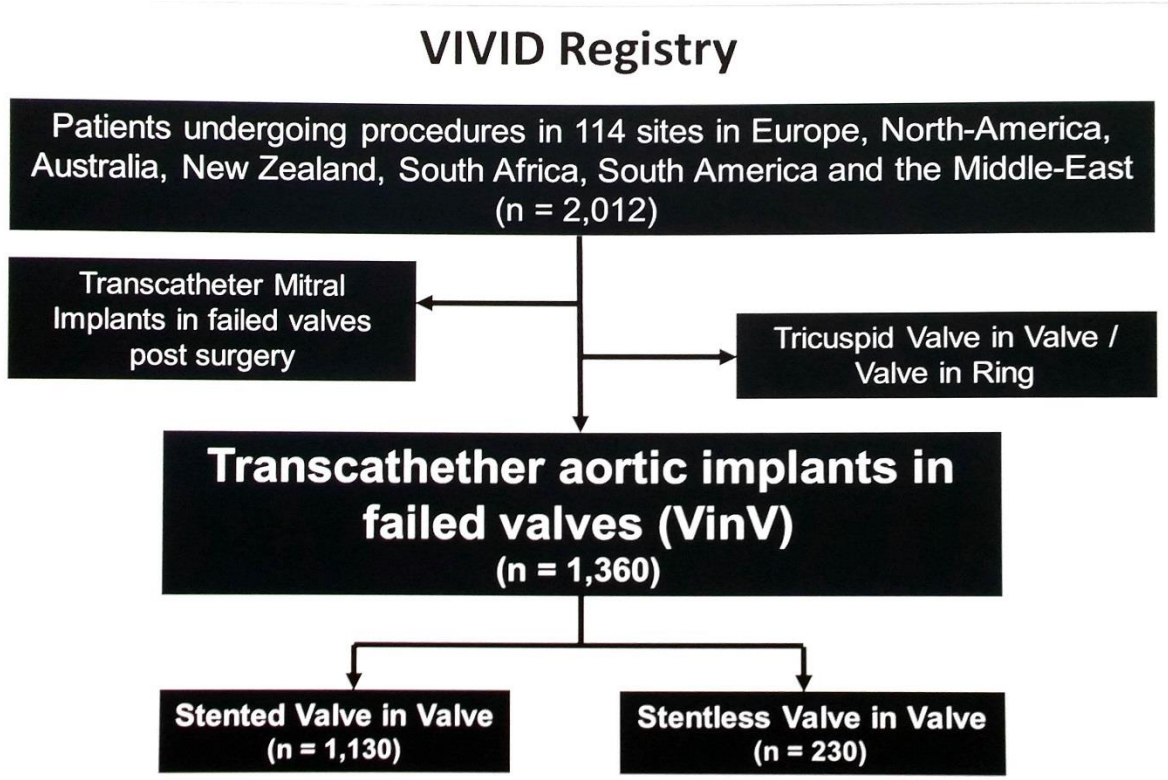
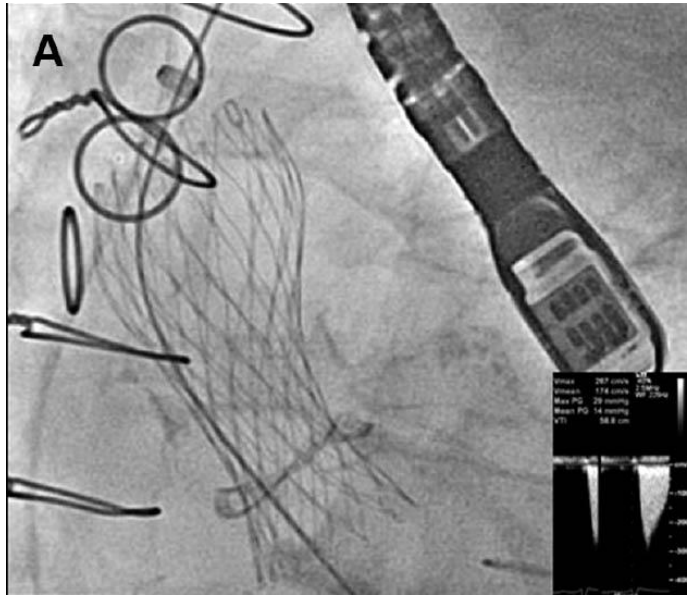


Мировой регистр транскатетерных имплантаций «Клапан-В-Клапан»



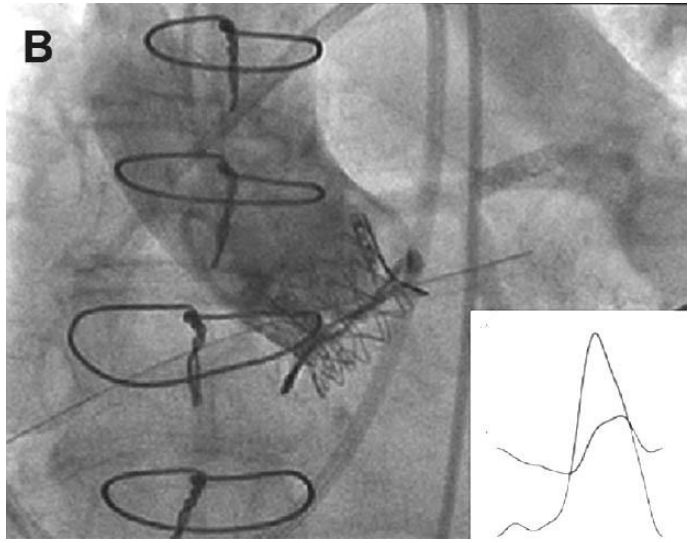


Процедура Valve-In-Valve дисфункции биопротеза в аортальной позиции (ДИЗАЙН ИМЕЕТ ЗНАЧЕНИЕ) (взято из Dvir et al., 2012)



A – имплантация 26 мм Core Valve в клапан Mitroflow с посадочным диаметром 19 мм и внутренним 15,4мм

ПОСТПРОЦЕДУРНЫЙ ГРАДИЕНТ **29/14mm Hg**

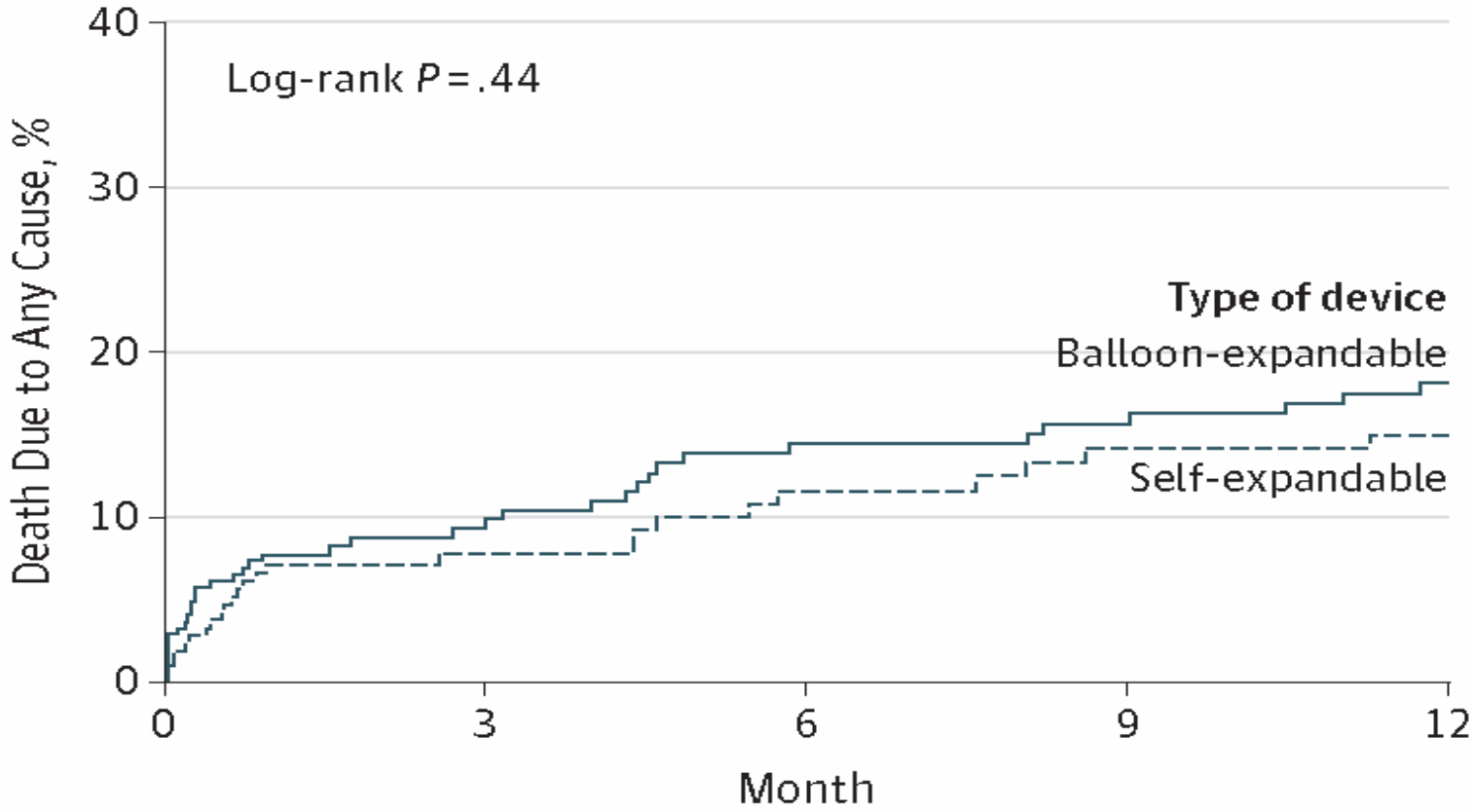


B – имплантация 23 мм Edwards Sapien в клапан Mitroflow с посадочным диаметром 21мм и внутренним 17мм

ПОСТПРОЦЕДУРНЫЙ ГРАДИЕНТ **88/58mm Hg**

Процедура Valve-In-Valve дисфункции биопротеза в аортальной позиции (ДИЗАЙН ИМЕЕТ ЗНАЧЕНИЕ?)

C Device used during valve-in-valve implantation

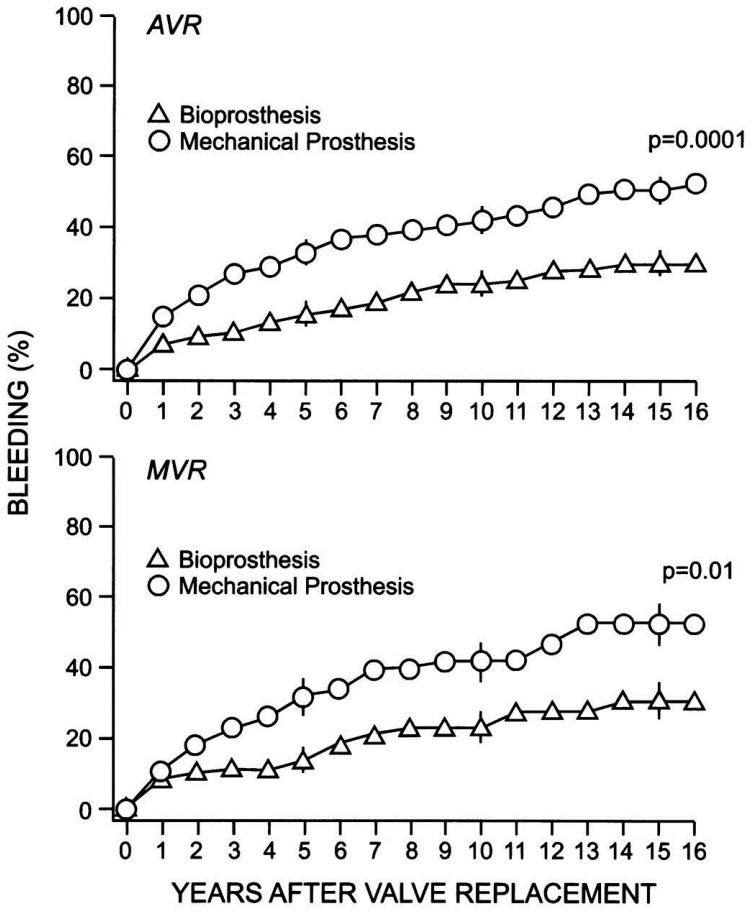


No. at risk by type of device					
Balloon-expandable	246	163	146	136	130
Self-expandable	213	126	112	101	98

JAMA. 2014;312(2):162-170.

Процедура Valve-In-Ring

Новые возможности для улучшения результатов биопротезирования



Hammermeister et al. JACC 2000;36:1152-1158

Management of atrial fibrillation in patients with VHD

Recommendations	Class[a]	Level[b]
Anticoagulation		
NOACs should be considered as an alternative to VKAs in patients with aortic stenosis, aortic regurgitation and mitral regurgitation presenting with atrial fibrillation [38–41].	IIa	B
NOACs should be considered as an alternative to VKAs after the third month of implantation in patients who have atrial fibrillation associated with a surgical or transcatheter aortic valve bioprosthesis.	IIa	C
The use of NOACs is not recommended in patients with atrial fibrillation and moderate to severe mitral stenosis.	III	C
NOACS are contraindicated in patients with a mechanical valve [45].	III	B
Surgical interventions		
Surgical ablation of atrial fibrillation should be considered in patients with symptomatic atrial fibrillation who undergo valve surgery [37].	IIa	A
Surgical ablation of atrial fibrillation may be considered in patients with asymptomatic atrial fibrillation who undergo valve surgery, if feasible, with minimal risk.	IIb	C
Surgical excision or external clipping of the LA appendage may be considered in patients undergoing valve surgery [46].	IIb	B

LA: left atrial; NOAC: non-vitamin K antagonist oral anticoagulant; VHD: valvular heart disease; VKA: vitamin K antagonist.
[a]Class of recommendation.
[b]Level of evidence.

2017 ESC/EACTS Guidelines for the management of valvular heart disease
The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

ПРОФИЛАКТИЧЕСКАЯ АНТИТРОМБОТИЧЕСКАЯ ТЕРАПИЯ У ПАЦИЕНТОВ С БИОПРОТЕЗАМИ

2017 ESC/EACTS Guidelines for the management of valvular heart disease
The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Bioprostheses		
Oral anticoagulation is recommended lifelong for patients with surgical or transcatheter implanted bioprostheses who have other indications for anticoagulation.[c]	I	C
Oral anticoagulation using a VKA should be considered for the first 3 months after surgical implantation of a mitral or tricuspid bioprosthesis.	IIa	C
Oral anticoagulation using a VKA should be considered for the first 3 months after surgical mitral or tricuspid valve repair.	IIa	C
Low-dose aspirin (75–100 mg/day) should be considered for the first 3 months after surgical implantation of an aortic bioprosthesis or valve-sparing aortic surgery.	IIa	C
Dual antiplatelet therapy should be considered for the first 3–6 months after TAVI, followed by lifelong single antiplatelet therapy in patients who do not need oral anticoagulation for other reasons.	IIa	C
Single antiplatelet therapy may be considered after TAVI in the case of high bleeding risk.	IIb	C
Oral anticoagulation may be considered for the first 3 months after surgical implantation of an aortic bioprosthesis.	IIb	C

ACS: acute coronary syndrome; CAD: coronary artery disease; INR: international normalized ratio; LMWH: low-molecular-weight heparin; LV: left ventricular; PCI: percutaneous coronary intervention; NOAC: non-vitamin K antagonist oral anticoagulant; TAVI: transcatheter aortic valve implantation; UFH: unfractionated heparin; VKA: vitamin K antagonist.
[b]Class of recommendation.
[c]Level of evidence.
[f]Atrial fibrillation, venous thromboembolism, hypercoagulable state or, with a lesser degree of evidence, severely impaired LV dysfunction (ejection fraction <35%).

Итоговые данные

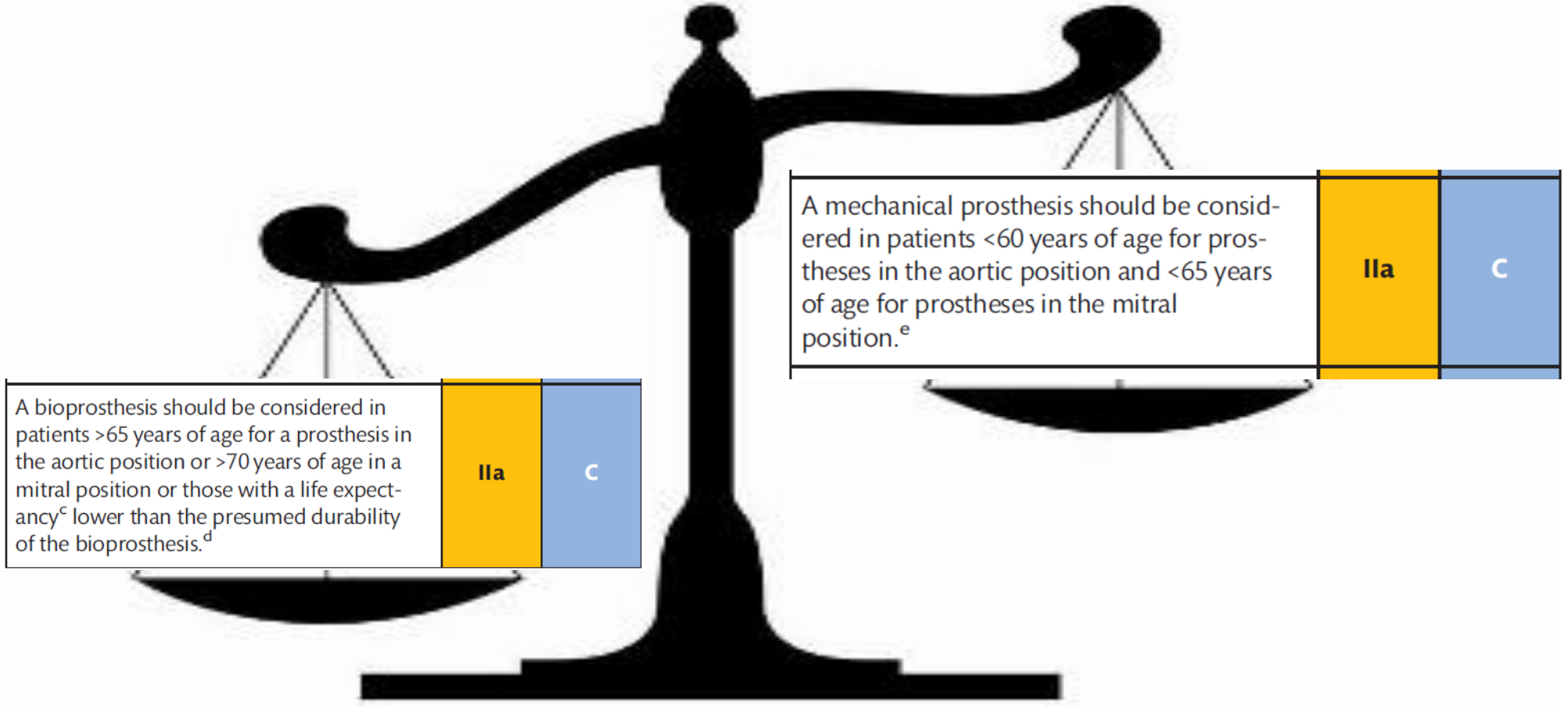
- Повышение долговечности
- Малая травматичность имплантации
- Меньшее количество осложнений в сроки наблюдения
- Возможность малоинвазивных реопераций
- Свобода от кровотечений
- Независимость от определения МНО

Результат

Смена парадигмы биопроте-зирования!!!

Выбор типа протеза

2017 ESC/EACTS Guidelines for the management of valvular heart disease
The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

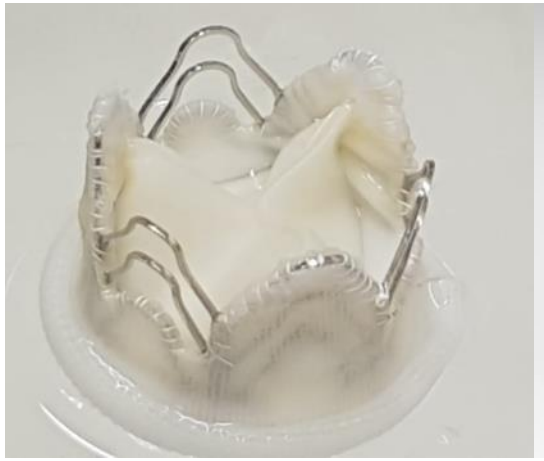


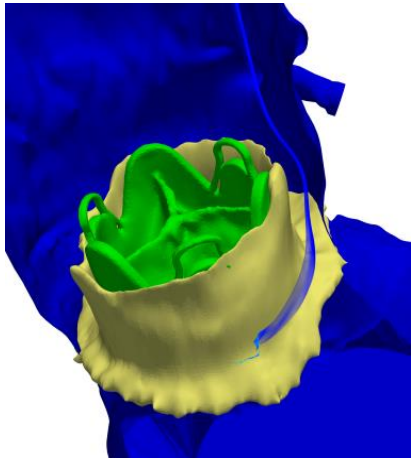
60-65 лет для аортальной позиции и 65-70 лет для митральной позиции – это СЕРАЯ зона?

НЕТ. ЭТО ЗОНА ПРИМЕНЕНИЯ СОВРЕМЕННЫХ БИОПРОТЕЗОВ!

Инновационные проекты

Система хирургического репротезирования клапанов сердца на основе баллоно-расширяемого метода имплантации





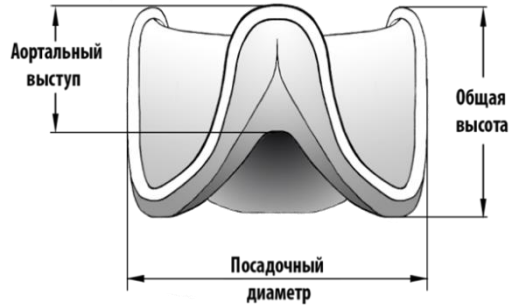
До имплантации

S = 2,66 см2
ΔP макс = 9,6
ΔP ср = 5,0
v ср = 1,04

ПОСЛЕ имплантации

S = 2,20 см2
ΔP макс = 12,5
ΔP ср = 6,3
v ср = 1,20

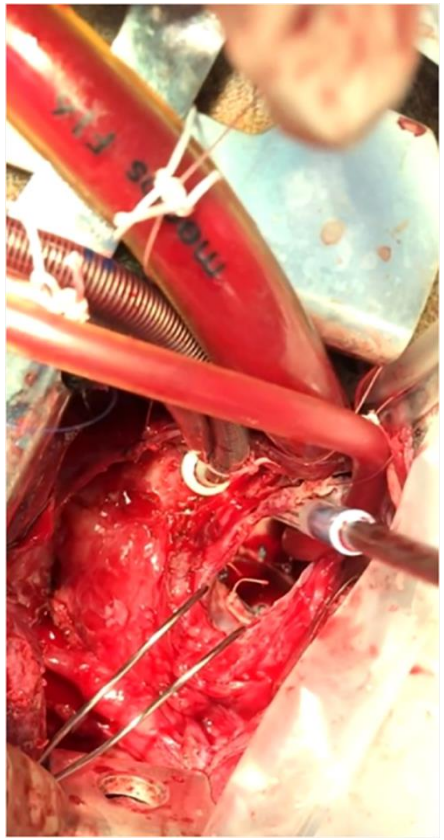
Полукаркасный биопротез «ТИАРА» - уникален по своим свойствам: сочетает простоту имплантации каркасных биопротезов и гемодинамику бескаркасных



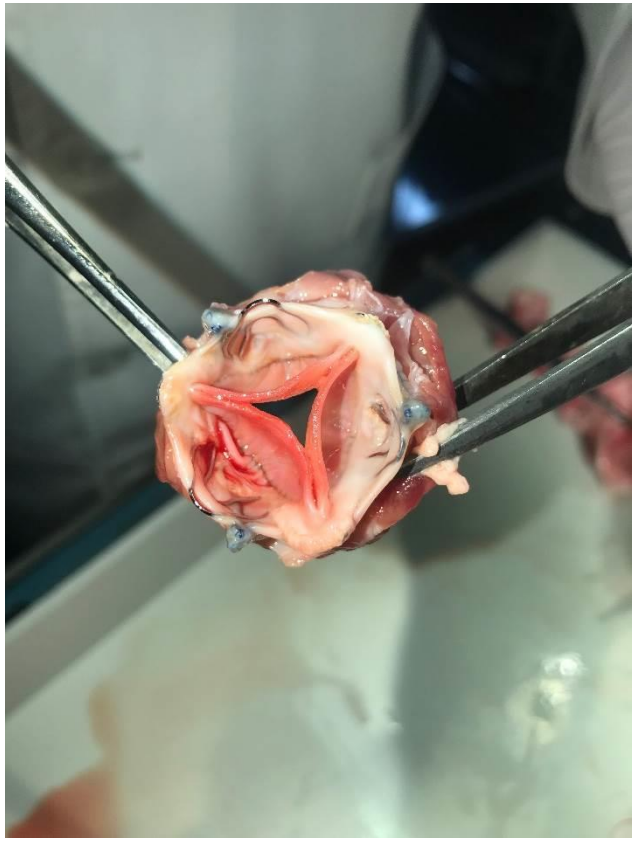
REF	d, mm	h, mm	h_1, mm
TA19	19	16,6	10,1
TA21	21	17,8	10,1
TA23	23	19,0	10,1
TA25	25	20,2	10,1

НИИ КПССЗ: баллонрасширяемый биопротез для процедур «Клапан-В-Клапан»

Эксперимент на крупных животных

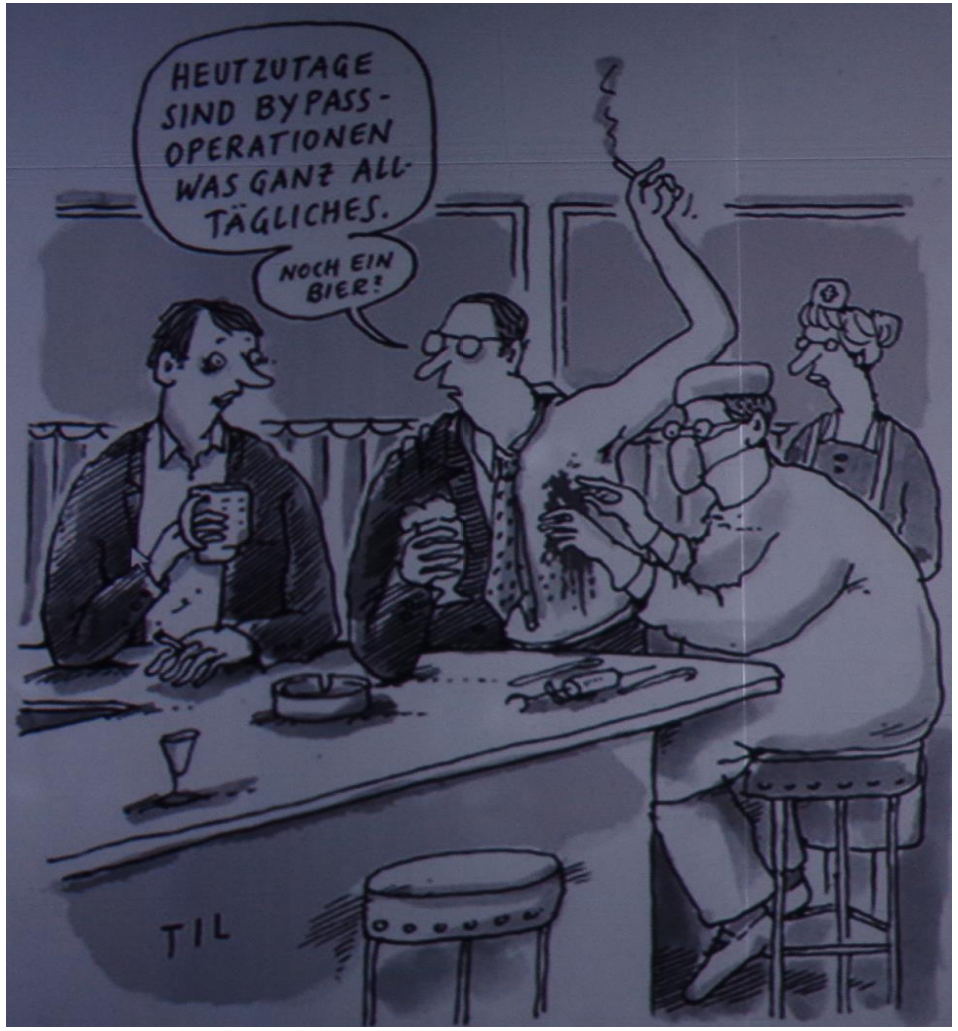


В ходе имплантации



При выведении из эксперимента

Будущее биопротезирования



- Снижение инвазивности
- Снятие возрастных ограничений
- Повышение долговечности биопротезов
- Улучшение тромборезистентности
- Повышение устойчивости к инфекции


Благодарю за внимание