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Current Projects of Isaac George, M.D.

Division of Cardiothoracic Surgery/Structural Heart & Valve Center
NewYork-Presbyterian/Columbia

Computational Modeling of Transcatheter Mitral Valve in Mitral Annular Calcium

- One of the main issues when placing a transcatheter mitral valve in calcium is that the valve may block blood flow out of the heart (left ventricular outflow tract obstruction).
- Dr. George performs very-high risk surgery on these patients and uses a transcatheter valve placed in the mitral valve to avoid having to use sutures in the calcium.
- One of the unknown issues is if they need to resect muscle in the heart to improve blood flow, called a myectomy.
- Dr. George and his team are working with engineers from Georgia Tech to model this phenomenon to help understand/predict when a myectomy is needed.
- Dr. George has included some sample flow maps, below, in actual patients he has operated on.

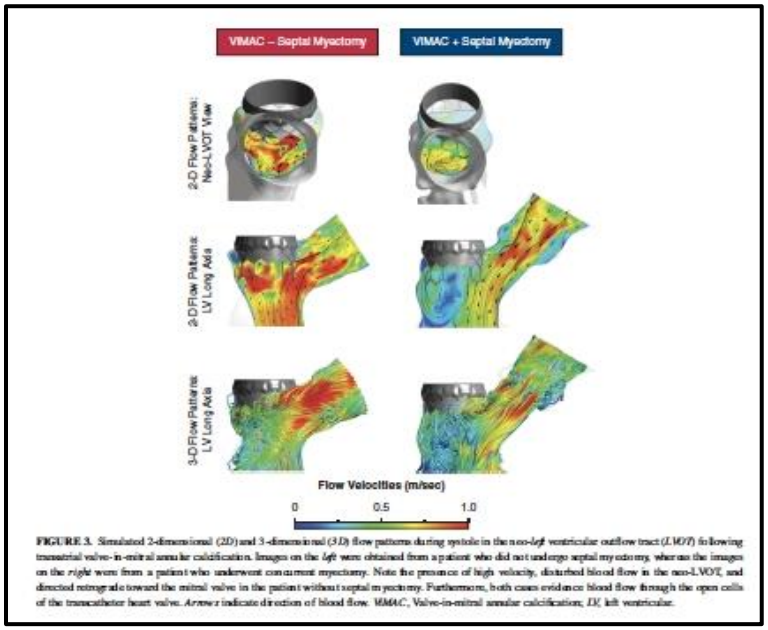

FIGURE 3. Simulated 2-dimensional (*2D*) and 3-dimensional (*3D*) flow patterns during systole in the neo-*left* ventricular outflow tract (*LVOT*) following transatrial valve-in-mitral annular calcification. Images on the *left* were obtained from a patient who did not undergo septal myectomy, whereas the images on the *right* were from a patient who underwent concurrent myectomy. Note the presence of high velocity, disturbed blood flow in the neo-LVOT, and directed retrograde toward the mitral valve in the patient without septal myectomy. Furthermore, both cases evidence blood flow through the open cells of the transcatheter heart valve. *Arrows* indicate direction of blood flow. *VIMAC*, Valve-in-mitral annular calcification; *LV*, left ventricular.

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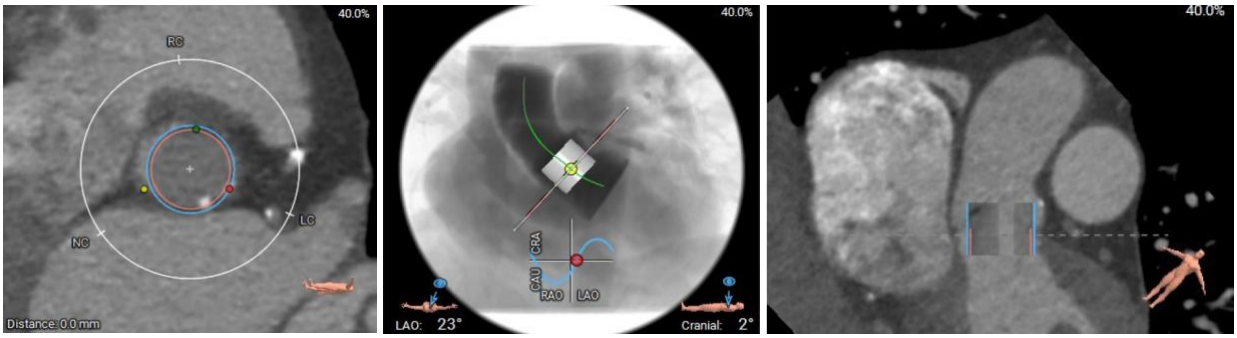
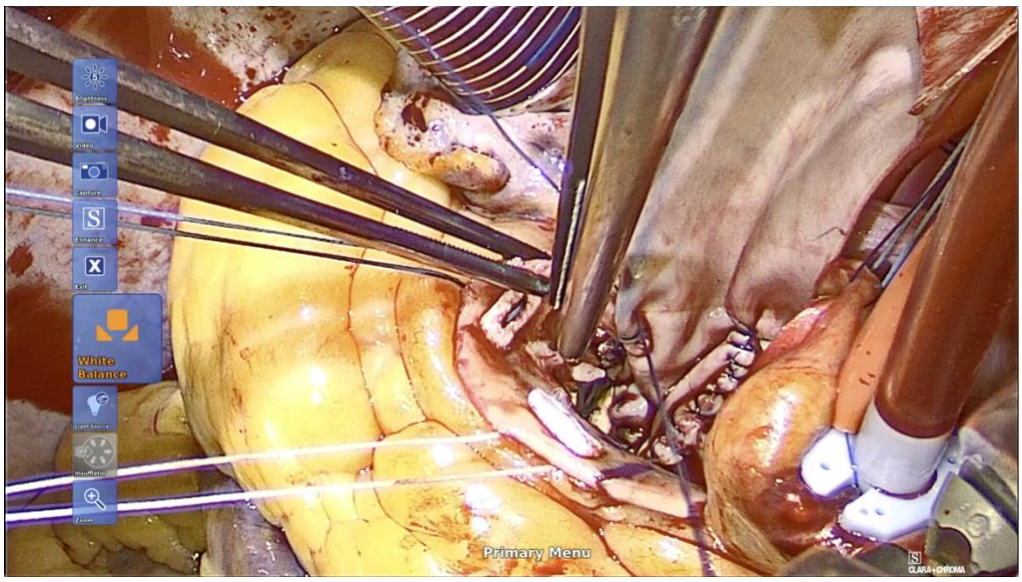
Computational Modeling in Aortic Root Enlargement: Flow Modeling, Optimal Patch, Valve in Valve

- Aortic Root Enlargement is an increasingly common procedure to enlarge the aortic annulus during aortic valve surgery, using a patch. This procedure can be complex and there are numerous scientific questions to be answered in the field. Dr. George has undertaken a comprehensive approach to the space, working with a biomedical engineer from Wooster Polytechnic Institute and Georgia Tech.
- These projects include 1) modeling flow patterns after aortic root enlargement, 2) developing an algorithm to choose the optimal patch size based on a given individual anatomy, and 3) determining if patients will be candidates for transcatheter aortic valve-in-valve after root enlargement.





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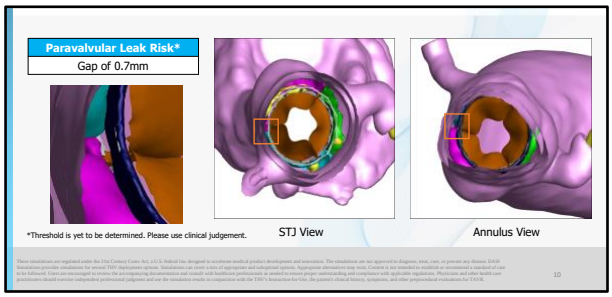
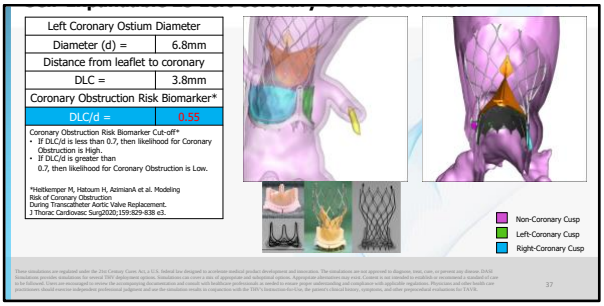
Computational Modeling of Hemodynamics after TAVR Valve-in-Valve

- TAVR has become the common valve procedure in the world, and many patients return for repeat TAVR. Dr. George has been working with the same set of engineers to understand the optimal sequence to perform TAVR and then repeat TAVR (TAVR Valve-in-valve). Using computer modeling, he is creating an algorithm for physicians to use to select the optimal devices based on individual anatomy.



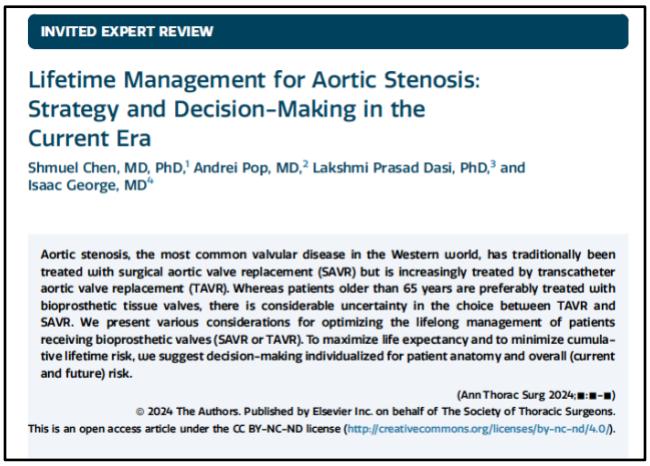


Standardization and Guidelines for Surgery using Structural Heart Principles

- Dr. George and his team are creating a set of guidelines for surgeons to help them make decisions regarding valve disease in the new era of structural heart (with TAVR, valve in valve, TMVR, and TTVR).
- It has become an obstacle for surgeons who are not directly doing these procedures, and Dr. George felt it would be worthwhile for community health-based surgeons to have a document that helps them plan their operations that will facilitate structural catheter-based procedures in the future.
- For example, there are techniques which a patient's surgeon can perform during their first operation, which would make procedures such as these easier to perform.

Lifetime Management of Aortic Valve Disease

- This is critical in the management of aortic valve disease, as Dr. George and his team offer both transcatheter and open surgical therapies, including valve-in-valve treatments they can perform in both surgical and Transcatheter Aortic Valve Replacement (TAVR) valves.
- What has not been fully understood is how to plan out a lifetime of procedures using these adjacent technologies so that the cumulative risk over a lifetime is optimized.
- The team is working on a project to illustrate some guiding principles for physicians to understand the implications of decision making, and to aid in what valve fits what patient.
- Presently this is a critical piece to examine further, as early decisions fundamentally affect what happens later in life.
- This important paper by Dr. George has received a large amount of press, and has become a well-known document for decision making in aortic valve surgery. Similar papers are underway. Dr. George is uniquely positioned to help clarify and characterize these issues, given his expertise in both cardiac surgery (surgical valve) and cardiology (transcatheter valve).



INVITED EXPERT REVIEW

Lifetime Management for Aortic Stenosis: Strategy and Decision-Making in the Current Era

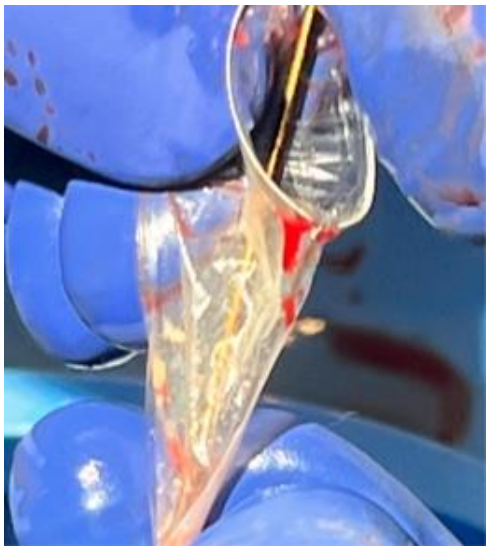
Shmuel Chen, MD, PhD,[1] Andrei Pop, MD,[2] Lakshmi Prasad Dasi, PhD,[3] and Isaac George, MD[4]

Aortic stenosis, the most common valvular disease in the Western world, has traditionally been treated with surgical aortic valve replacement (SAVR) but is increasingly treated by transcatheter aortic valve replacement (TAVR). Whereas patients older than 65 years are preferably treated with bioprosthetic tissue valves, there is considerable uncertainty in the choice between TAVR and SAVR. We present various considerations for optimizing the lifelong management of patients receiving bioprosthetic valves (SAVR or TAVR). To maximize life expectancy and to minimize cumulative lifetime risk, we suggest decision-making individualized for patient anatomy and overall (current and future) risk.

(Ann Thorac Surg 2024;■:■-■)

Cerebral Protection Filters

- Dr. George and his team are leading projects in this area including exploring a cerebral filter during cardiac surgery.
- A small filter gets inserted in the artery of a patient's arm but is placed under X-ray to collect any debris that goes from the arteries to the patient's head and in doing so, it is felt to reduce the risk of stroke.
- This filter is typically used in TAVR, however Dr. George and his team are the first to use this method in cardiac surgery.
- They are expanding this use in a randomized clinical trial that has been submitted to the NIH, as well as in a trial that will characterize the material that is collected from pathology and biochemical analysis.
- This is intended for patients undergoing high risk surgery who are also at high risk for stroke.
- The picture below illustrates small particles of calcium that were captured in the filter in one of Dr. George's cases. Remarkably, this patient did not experience a stroke.



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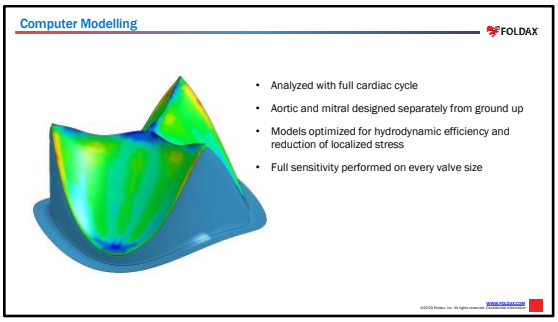
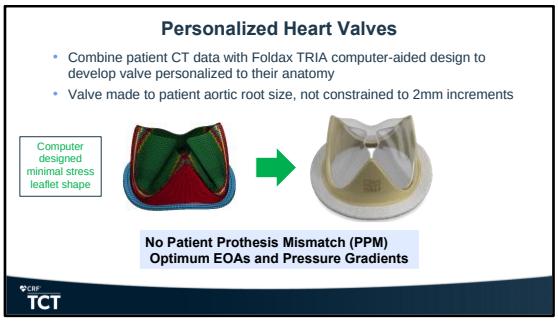
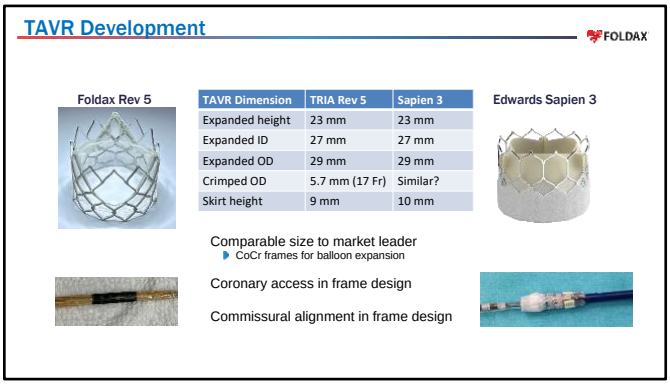
Design and Use of a New Polymeric Heart Valve

- Polymer valves have been attempted to be used for over 30 years with no success. Dr. George is the principal investigator of a global, multicenter study investigating the use of a new polymer valve in a surgical mitral valve.
- The valve, made by Foldax (Salt Lake City, UT) has been created using a siloxane polyurethane derivative, has the potential for extended durability compared to animal tissue valves. Dr. George has been working with Foldax for many years helping develop both a surgical and transcatheter valve.
- The 1 year study results will be presented by Dr. George this year (2025) as a late-breaking study at the main valve conference in the USA. This innovation could revolutionize how we treat patients with valve disease. ***Imagine placing one valve for a lifetime in a patient!***

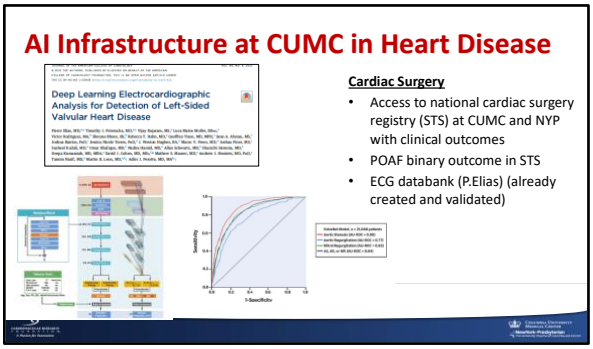


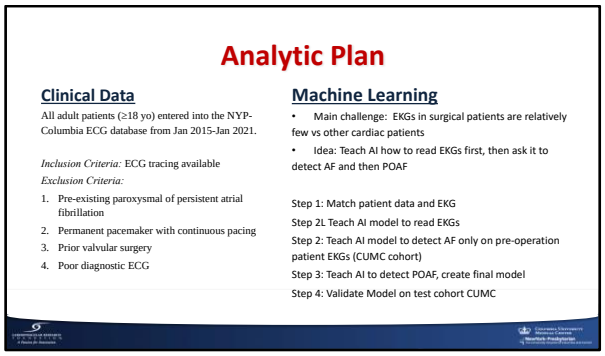




Detection of Post-Operative Atrial Fibrillation After Cardiac Surgery using an Artificial Intelligence ECG Algorithm

- Atrial fibrillation (POAF) affects up to 40% of patients after cardiac surgery, increasing both complications and hospital cost.
- Dr. George leads a research group composed of statisticians, clinicians and computer scientists to study the use machine learning to predict POAF using ECG.
- The group is developing an AI model based on thousands of pre and post-cardiac surgery patients at CUMC using ECG and clinical variables that can predict which patients will develop POAF. This information leverages both a machine learning model that is created here, as well as a large body of clinical data.



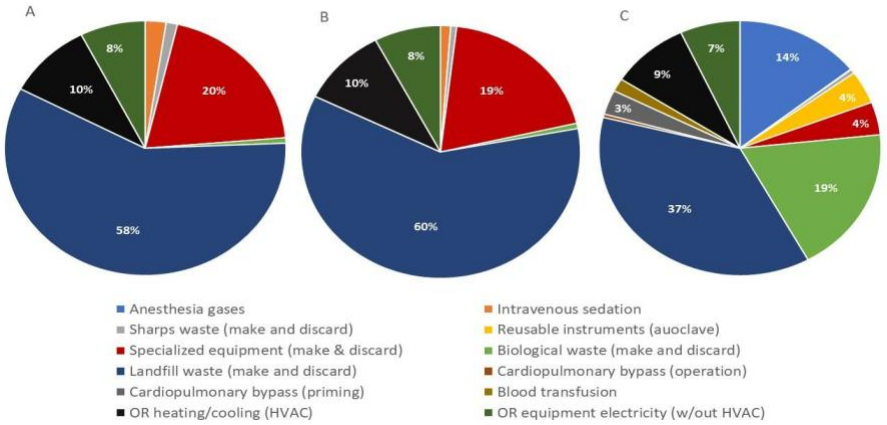


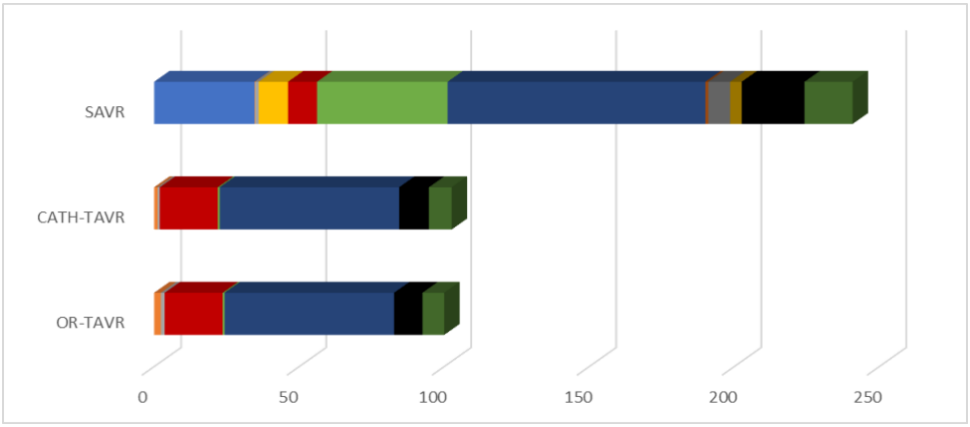
Additional Ongoing Projects

- Dr. George and his team are working on a cutting-edge project using a strategy to minimize and use no contrast dye for the planning as well as full procedure for TAVR.
    - Their research show this algorithm of steps reduces acute kidney injury without affecting clinical outcomes in patients receiving TAVR.
    - As patients get older, the rates of acute kidney injury can be very high, so better techniques to avoid renal problems are warranted.

- Dr. George and his team have an ongoing project looking at the environmental footprint of TAVR vs. open surgery.
    - Over 50 lbs. of waste are created with each surgical case, while less anesthesia and surgical resources are used with TAVR procedures.
    - Dr. George is working with the global experts in carbon foot-printing (including Dr. Christoph Meinrenken at Columbia University's Climate School) to perform this analysis, which could have implications on how medicine is practiced, particularly given the current state of the environmental climate and the ongoing changes it is facing.
    - This study could have a large impact on how use materials in procedures, with the hope of significantly reducing excess medical waste.
    - This paper is pending publication.

Figure 1. Chart comparing intraoperative emissions contributions for (A) OR TAVR, (B) CATH-TAVR , and (C) SAVR. Total intraoperative emissions associated with OR-TAVR, CATH-TAVR and SAVR as measured in kgCo2e.





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