

# The Influence of Age on Longevity of a Stentless Bioprosthesis Valve

A. MALIK<sup>1</sup>, L. FARHAT<sup>2</sup>, A. MAKKINEJAD<sup>2</sup>, E. NORTON<sup>3</sup>, M. SAREINI<sup>4</sup>, E. PIERRE<sup>2</sup>, X. WU<sup>2</sup>, J. HAFT<sup>2</sup>, M. ROMANO<sup>2</sup>, R. PRAGER<sup>2</sup>, K. KIM<sup>2</sup>, H. PATEL<sup>2</sup>, F. PAGANI<sup>2</sup>, G. DEEB<sup>2</sup>, and B. YANG<sup>2</sup>

<sup>1</sup> University of Michigan Medical School, Ann Arbor, Michigan, USA  
<sup>2</sup> Michigan Medicine, Ann Arbor, Michigan, USA  
<sup>3</sup> Creighton University School of Medicine, Omaha, Nebraska, USA  
<sup>4</sup> Wayne State University School of Medicine, Detroit, Michigan, USA

## Background

- Stentless bioprosthetic valves serve as effective and durable option for Aortic Valve Replacement (AVR).
- Provide excellent hemodynamic performance<sup>1</sup>
- Do not require anticoagulation
- Favourable clinical outcomes in terms of mortality, reoperation, and valve deterioration<sup>2</sup>
- Freestyle stentless bioprosthetic valve
  - Stentless porcine aortic root
  - Prepared using a proprietary low or 0 pressure fixation process and a-amino oleic acid leaflet anticalcification treatment
- Implanted as either subcoronary, root inclusion or modified inclusion, or total root replacement
- 10 year durability described as freedom from reoperation due to structural valve deterioration is above 95%<sup>3</sup>

## Objectives

The longevity of stentless valve in younger patients (20-60 years old) is not well known. Our aim is to compare the durability of the stentless bioprosthetic valve in different age groups. We hypothesized that younger age has an adverse effect on longevity of the stentless bioprosthesis.

## Methods

### Patient Selection

- Between 1992-2015 patients undergoing primary aortic valve replacement or aortic root replacement with Freestyle stentless bioprosthetic valve (n=1947).
- Indication for replacement due to aortic stenosis, aortic insufficiency, aortic dissection, or root aneurysm. Patients with endocarditis were excluded.
- Stentless valve implantation as subcoronary(12), modified inclusion or root inclusion(1812), or total root replacement(60).

### Data Collection

- Data obtained from Society of Thoracic Surgery from University of Michigan Cardiac Surgery Warehouse to determine pre-, intra-, and post-operative characteristics.
- Demographics, medical records, and operative reports were reviewed to supplement data collection.
- Survival data obtained from National Death Index through December 2015, questionnaire response, and medical record review.
- Questionnaire(letters and phone calls) evaluating outcomes and subsequent aortic re-operations through December 2015.

## Results

**Table 1: Demographics**

Variables	Stentless Bioprosthetic Valve Replacement (n=1947)
Patient Age (years)	
20-30	28 (1.4)
31-40	90 (4.6)
41-50	204 (10.5)
51-60	353 (18.1)
61-70	574 (29.5)
71-80	537 (27.6)
>80	161 (8.3)
Gender (female)	606 (31.1)

Age listed as age at time of operation. Data presented as n (%) for categorical data.

**Table 2: Intraoperative Outcomes**

Variables	Stentless Bioprosthetic Valve Replacement (n=1947)
Indication for Operation	
Aortic Insufficiency	393 (20.2)
Aortic Stenosis	1168 (60.0)
Aortic Root Aneurysm	227 (11.7)
Aortic Dissection	101 (5.1)
Unknown	58 (3.0)
CPB Time (minutes)	181 (149, 223)
Clamp Time (minutes)	144 (117, 179)
Blood Transfusion, PRBC (units)	2 (1, 4)
Implant Size (mm)	26 (25, 27)
Technique of Freestyle	
Modified Inclusion	1812 (93.0)
Total Root	60 (3.1)
Subcoronary	12 (0.6)

Data presented as median (25 %, 75 %) for continuous data and n (%) for categorical data. Abbreviations: CPB, cardiopulmonary bypass; PRBC, packed red blood cells.

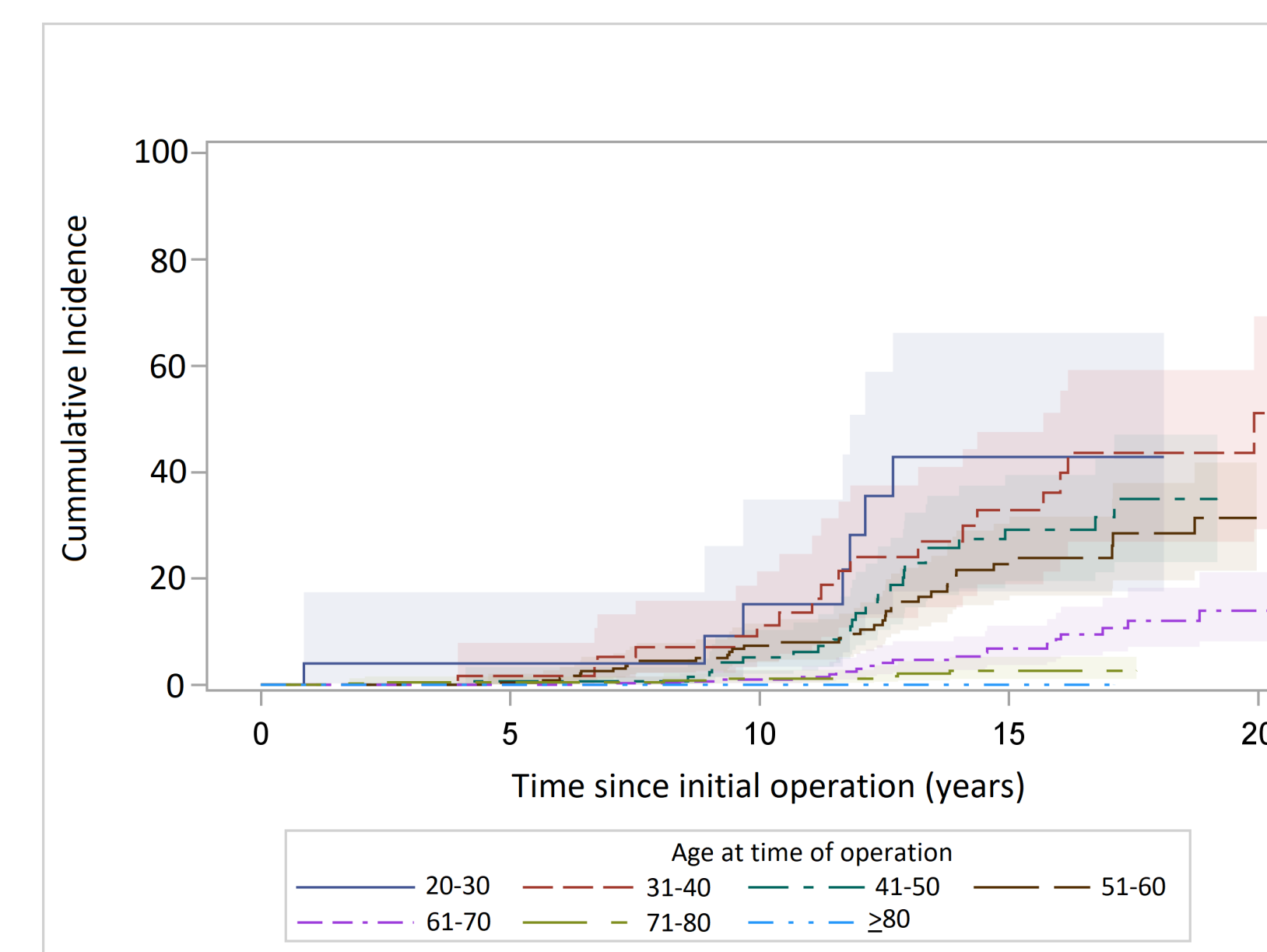
**Table 3: Postoperative Outcomes**

Variables	Stentless Bioprosthetic Valve Replacement (n=1947)
Hours to Extubation	10.6 (5.0, 18.8)
30-day Mortality	51 (2.6)
In Hospital Mortality	65 (3.3)
Reoperation for Bleeding/Tamponade	77 (4.0)
MI	8 (0.4)
CVA	40 (2.0)
Atrial Fibrillation	718 (36.8)
Complete Heartblock or Pacemaker	81 (4.2)
Post-op Creatinine (mg/dL)	1.1 (0.9, 1.4)
New Onset Renal Failure	64 (3.3)

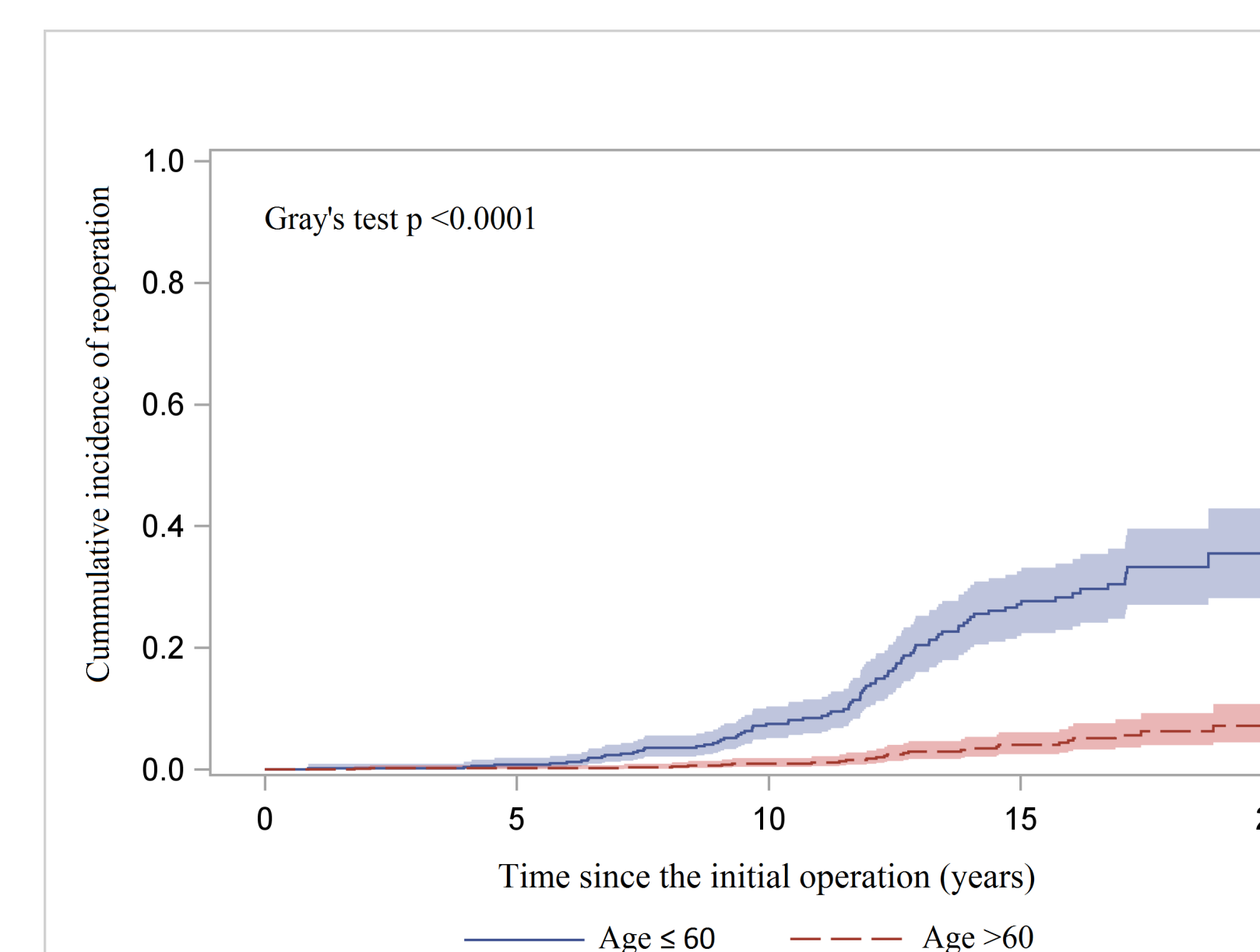
Data presented as median (25 %, 75 %) for continuous data and n (%) for categorical data. Abbreviations: CVA, cerebral vascular accident; MI, myocardial infarction.

**Figure 1: Cumulative Incidence of Reoperation for AVR after Stentless Bioprosthesis Aortic Valve Replacement**

A. Organized by Age Decade



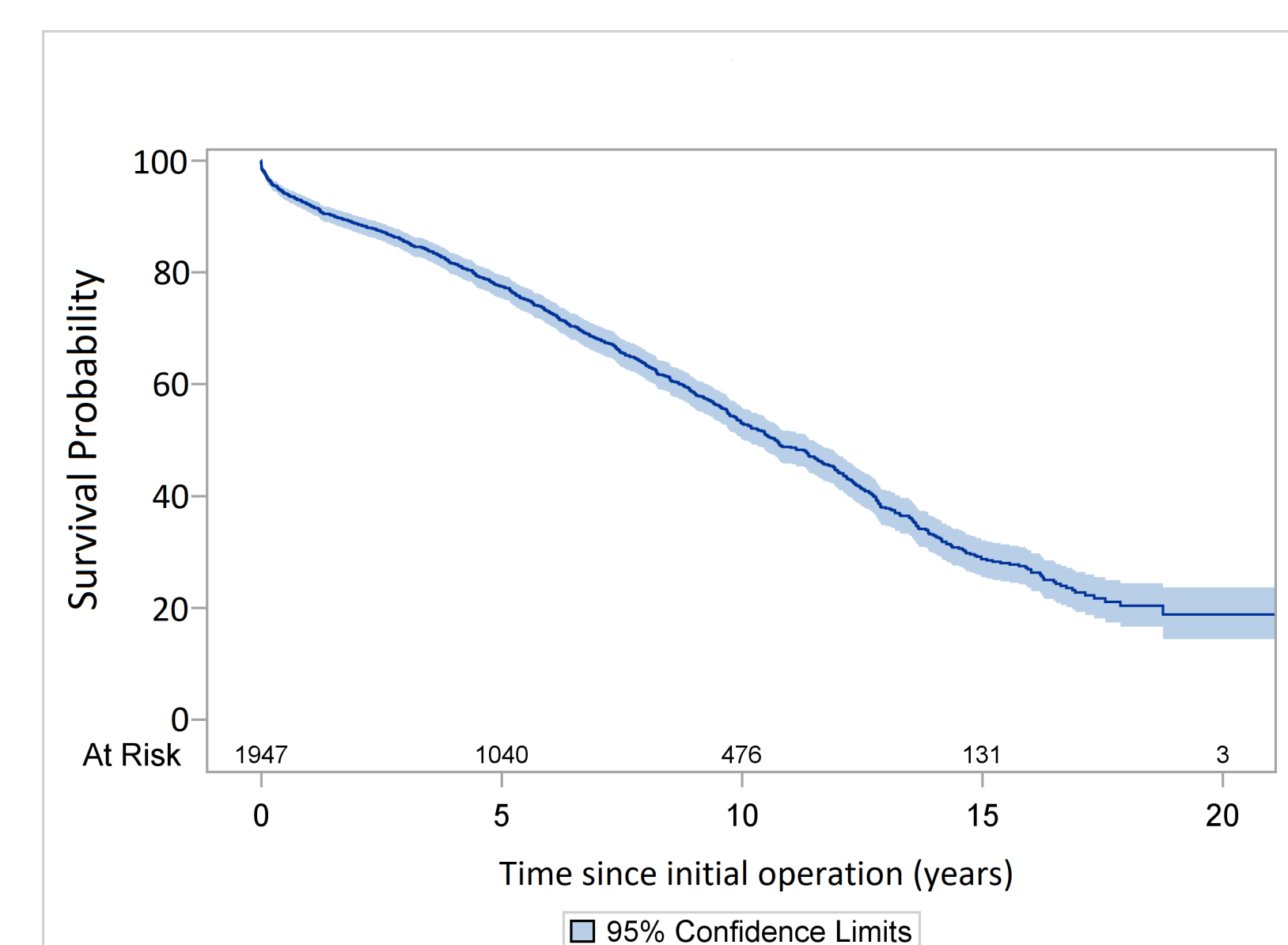
B. Age ≤ 60 vs Age > 60



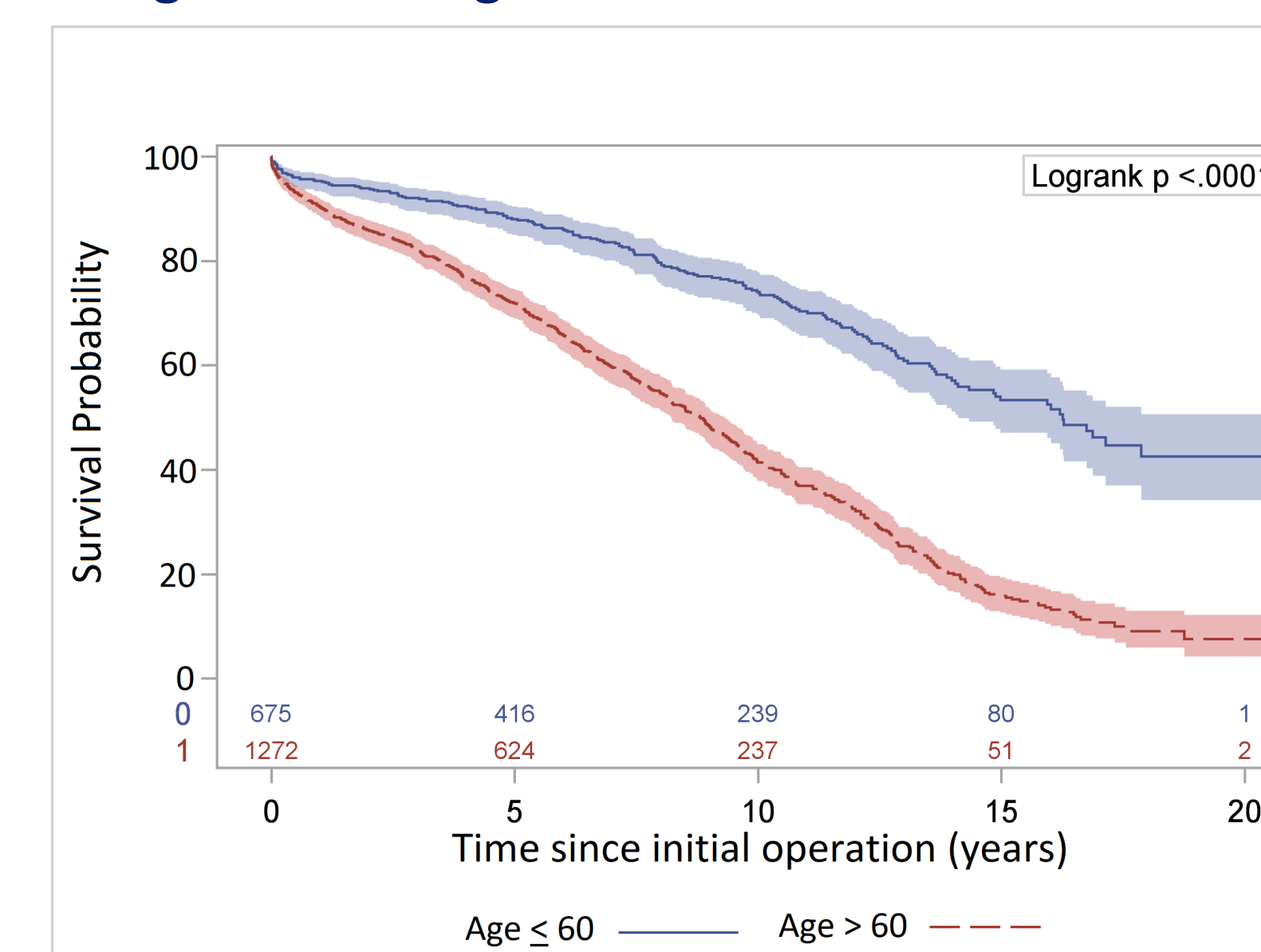
After adjusting death as competing risk, among the patients <60 old, there was no significant difference in reoperation risk by age cohort (20-30 vs. 31-40 vs. 41-50 vs. 51-60). Among patients >60 years old, the risk of reoperation significantly decreased in the older cohort (61-70 vs. >70) (Figure 1, A). The accumulated incidence of reoperation was significantly higher in patients < 60 years old (n=675) compared to patients older than 60 (n=1272) at 10 and 15 years. (7.8% vs. 1.1% and 27.7% vs 4.4%, respectively, p < 0.0001) (Figure 1, B).

**Figure 2: Long-term survival probability of patients with AVR with Stentless Bioprosthesis.**

A. Whole Cohort



B. Age ≤ 60 vs Age > 60



Kaplan-Meier analysis of survival probability of patients after stentless bioprosthetic aortic valve replacement. The 10- and 15-year survival in the whole cohort was 53% and 29% (Figure 2, A).

The 10- and 15- year survival of patients ≤ 60 years old was greater than patients >60 (74% vs. 41% and 53% vs 15%, respectively, p<0.0001) (Figure 2, B).

## Conclusions

- The hazard ratio of reoperation for ≤ 60 to > 60 years was 5.1 (95% CI 3.3, 8.0), P < 0 .001.
- The stentless aortic root bioprosthesis provides satisfactory durability as a conduit for aortic valve/root replacement for patients who prefer a bioprosthesis.
- However, the stentless bioprosthesis valve should be judiciously considered for patients younger than 60 years due to increased incidence of reoperation for structural valve deterioration.

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## Contact Information

Primary Contact: Dr. Bo Yang, MD, PhD

Affiliation: Michigan Medicine

Email: boya@med.umich.edu

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## Disclosures

Dr. Deeb is a consultant for Medtronic.

Dr. Patel is a consultant for WL Gore, Medtronic, and

Terumo.