

FACT vs. HYPE:

You make the call



To Whom It May Concern:

A recent morphological study by Dr. Jagdish Butany and colleagues, "Modes of Failure in Explanted Mitroflow Valves" published in the *Annals of Thoracic Surgery* may be interpreted or presented to you in a negative way, even though the results for the Mitroflow valve are very positive. During a 10-year observation of "over 600 valves" Dr. Butany and his fellow investigators studied 12 explants. However, all 12 explants cannot be classified as SVD. Five of them (Table 2: "Summary of Histologic Findings of Excised Mitroflow Valves," p.1623) were infected with endocarditis, and two of them were listed as "unknown." (p.1621)¹ With respect to SVD, the disposition of the five endocarditis cases is defined in the STS Guidelines as follows:

"Structural valve deterioration includes dysfunction or deterioration involving the operated valve (exclusive of infection or thrombosis), as determined by reoperation, autopsy, or clinical investigation." (p.1490)²

Thus, these five must also be excluded along with the two unknowns for a total of seven non-SVD histologic findings. This leaves only five valve-related explants out of 600 patients. The data represents a phenomenal multi-center SVD occurrence of 0.8% over a 10-year period.

There is no dispute that there were structural valve failures evident for five of the explanted Mitroflow valves. Indeed, the types of failures described are typical of pericardial bioprosthetic valves.^{3,4} All but one of the torn valves was calcified, and one was also infected with endocarditis. Dr. Butany himself seems uncertain about the existence of primary tears (i.e. tears unrelated to calcification): "In this series, 42% (n = 5) of our valves had cusp tears, in which all except 1 was associated with calcification at the tear edges. At explantation, it is difficult to surmise if calcification preceded or followed the tears." (p.1625)

The proven long-term structural and hemodynamic performance of the Sorin Mitroflow® Aortic Pericardial Heart Valve has been well-established.^{5,6} Contrary to the conclusion provided by the authors, the evidence presented by Butany et al. is further proof of the exceptional durability of the Mitroflow bioprostheses.

Sincerely,

Sorin Group

References

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www.sorin.com

Sorin Group USA, Inc.
14401 W 65th Way
Arvada, CO 80004
United States of America

T: 800-289-5759
F: 877-657-3605



HEART VALVES

SORIN GROUP USA, INC.
14401 W. 65TH WAY, ARVADA, CO 80004
UNITED STATES OF AMERICA
TEL. 800.289.5759 FAX 877.657.3605
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