

# Jawz Endomyocardial Biopsy Forceps from Argon Medical: A Review of Safety and Efficacy Based on Literature Review and Bench Model Comparison With the Cordis Bioptome

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## Introduction

Endomyocardial biopsy (EMB) is a critical tool for the diagnosis and management of cardiac diseases, as well as to gauge allograft rejection post heart transplant.<sup>1</sup> Traditional EMB techniques can be difficult, time-consuming without adequate image guidance, and may carry a risk of complications or inconclusive diagnosis attributed to crush artifact or inadequate specimen yield.<sup>2</sup>

The Jawz Endomyocardial Biopsy Forceps from Argon Medical is a device designed to simplify the EMB procedure by optimizing excisional removal of myocardium. This paper will review the safety and efficacy of the Jawz biopsy forceps, including data from cited studies and bench top model comparison to the Cordis bioptome (Cordis Medical, Miami Lakes, FL, USA)

## Objectives

The objective for this study is to analyze the safety and efficacy data surrounding the Jawz endomyocardial bioptome device in peer reviewed literature and compare it to the performance of other endomyocardial bioptome devices currently available for utilization in percutaneous endomyocardial biopsy.

To date there is no specific data quantifying the safety and performance of the Jawz bioptome device via meta-analysis, and as such we hope to be able to conclude safety and general efficacy in-situ use.

We also plan to utilize bench top testing via comparative, head-to-head sampling with the Cordis endomyocardial biopsy forceps to evaluate performance parameters with regards to specimen yield and specimen quality, as both bioptomes are commonly used for performance of image-guided percutaneous endomyocardial biopsy procedures.



## Methodology

This study was determined to be exempt from need for IRB approval since it is a retrospective literature review based on published peer reviewed literature and a comparative bench top performance analysis without utilization of human biological tissue.

A public literature search was performed utilizing biomedical literature databases, specifically Embase [www.embase.com](http://www.embase.com) and PubMed [pubmed.ncbi.nlm.nih.gov](http://pubmed.ncbi.nlm.nih.gov)

Key research terminology entered into the database search engines include the words; endomyocardial biopsy, Jawz, forceps, and bioptome. Utilization of those keywords yielded thirty-three different peer-reviewed submissions. These submissions were reviewed for specific inclusion of safety, and efficacy data, as well as specific citation of the use of the Jawz endomyocardial biopsy forceps which yielded five specific studies that offered all the parameters we were looking for.

For bench top testing, a bovine heart was obtained without preservation. Cannulation of the right atrium was performed with placement of an acrylic conduit to allow passage of the selected bioptomes. A 5.5 French by 50 cm Cordis Bipal and a 5 French by 50 cm Argon Medical Jawz bioptome were selected due to comparable harvest capacity. Each device was advanced into independent sections of the bovine heart utilizing ultrasound guidance via a Butterfly IQ Ultrasound system (Capsa Healthcare). Ten specimens were obtained from different portions of the interventricular septum. The specimens were stained and placed on slides and evaluated under lighted microscopy to look at overall volume, adequacy, and crush artifact or fragmentation.



Fig. 1 Bovine Bench Model

## Results in Literature

In consideration of safety and efficacy, the Jawz Endomyocardial Biopsy Forceps has been demonstrated to be safe in multiple journal articles. In a study by Hahn et al., the Jawz biopsy forceps were utilized in 108 patients. The results showed that the Jawz forceps had a significantly high rate of safety with no reported SAE and efficacy with satisfactory specimens obtained in all cases reported. A similar study by Paul et al. found similar results, with a low overall complication rate and no mortality in a 482-patient sampling. In Daly et al., a total of 2,665 EMB cases were performed in 744 pediatric heart transplant recipients (median age, 12 years [interquartile range, 4.8, 16.7]; 54% male). AEs occurred in 88 cases (3.3%), of which 28 (1.1%) were HSAEs. AEs attributable to EMB .10 (1.2%) resulted in a coronary-related AE. There were no myocardial perforations or deaths. EMB yielded sufficient tissue for diagnosis in 99% of cases. Longer time since heart transplant was the most significant predictor of a non-diagnostic biopsy sample ( $p < 0.001$ ). This study demonstrated high yield and specimen quality with low rates of complications in a pediatric biopsy population utilizing the Jawz endomyocardial biopsy

## Bench Model Results

Under ultrasound guidance, ten specimens were obtained with the Argon bioptome, and the Cordis bioptome. On measurement for volume, the Cordis bioptome averaged a 2.39mm<sup>3</sup> tissue specimen compared to a 2.44 mm<sup>3</sup> specimen for the Argon bioptome. Under backlight microscopy, both bioptomes demonstrated sufficient myocardial tissue yield to be deemed diagnostic. It is noted however that the specimens obtained using the Cordis bioptome demonstrated crush artifact and architectural compression on the borders of the specimen in 4 out of 10 of the obtained specimens. Crush artifact was demonstrated in 1 out of 10 specimens obtained utilizing the Jawz biopsy forceps.

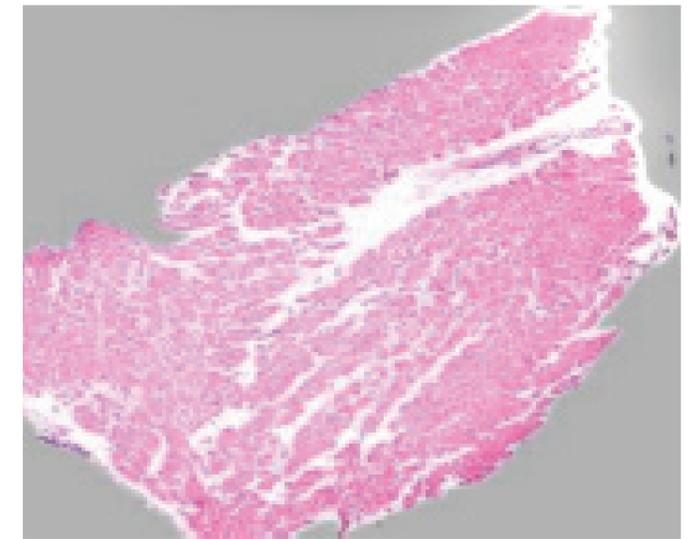


Fig. 1 Bovine Bench Model

## Conclusions

In meta-analysis of peer reviewed, published literature, the Jawz endomyocardial biopsy forceps demonstrated a high degree of safety and efficacy with regards to specimen quality and ability to make a conclusive diagnosis based on samples obtained in a study population of 3,255 EMB procedures.

Bench testing in comparative, side by side sampling between the Jawz 5 French x 50 cm bioptome, and the Cordis 5.5 French x 50 cm bioptome, demonstrated more tissue volume with less crush artifact in the specimens obtained using the Jawz device compared to the Cordis bioptome, though both devices produced tissue deemed satisfactory to make a diagnosis.

## Citations

1. Antoni Bayés-Genís, Alberto Aimo, Josep Lupón, Biopsia endomiocárdica en la miocarditis. Necesidad de una correcta caracterización tisular para mantenerla viva, Revista Española de Cardiología, Volume 75, Issue 11, 2022
2. Hahn, et al (2020). Endomyocardial Biopsy Characterization of Heart Failure With Preserved Ejection Fraction and Prevalence of Cardiac Amyloidosis. JACC. Heart failure, 8(9), 712-724. <https://doi.org/10.1016/j.jchf.2020.04.007>
3. Paul et al, Safety of Endomyocardial Biopsy in Patients With Arrhythmogenic Right Ventricular Cardiomyopathy: A Study Analyzing 161 Diagnostic Procedures, JACC: Cardiovascular Interventions, Volume 4, Issue 10, 2011
4. Daly et al, The Journal of Heart and Lung

Transplantation,  
Volume 31, Issue 4, 2012.

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