

# Early Results of the TEECAD® System in 15 TEE Patients at the Mayo Clinic Rochester

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## SUMMARY

Visura Technologies has developed the TEECAD® System, a disposable camera that seamlessly connects to a transesophageal echocardiogram (TEE) probe to produce high-resolution, real-time direct visualization of the laryngeal/esophageal/gastric anatomy for safer intubation and a more efficient and effective TEE probe placement. In an evaluation performed at the Mayo Clinic, early results with this FDA-cleared device indicate the potential to reduce complications associated with TEE probe placement such as oropharyngeal/esophageal injuries, bleeding, perforation, and intubation failure. While useful in any cardiac diagnostic and interventional procedure requiring the use of TEE imaging, the TEECAD System may provide additional clinical benefit for high-risk patients and enable improved results for clinicians with limited TEE experience.

## BACKGROUND

Transesophageal echocardiography has become a critical adjunct for the diagnosis of cardiac pathologies<sup>1,2</sup> as well as the planning and execution of both surgical and percutaneous cardiac interventions.<sup>3</sup> This procedure, introduced in the 1970's and used by surgeons, cardiologists, and anesthesiologists, provides real-time information on hemodynamics and structural data about the heart and major vessels. Common indications for use of TEE as a diagnostic test include aortic pathology, cardiac valve dysfunction, percutaneous noncoronary cardiac interventions, infective endocarditis, atrial fibrillation or flutter, and embolism.<sup>4,5</sup> In a study of coronary artery bypass graft (CABG) procedures across 1,218 US centers, the use of TEE in CABG patients grew from 39.9% in 2011 to 62.1% in 2019.<sup>6</sup> A multinational survey of 200 institutions published in 2014 found similar results with TEE routinely used in more than 60% of CABG surgeries, as well as in over 90% of non-CABG cardiac surgeries.<sup>7</sup> Given its ability to deliver high-quality and real-time images without the need for additional x-ray exposure, the use of 3D TEE represents a significant advance in ultrasound imaging guidance<sup>8</sup> and has become a routine clinical tool in structural heart procedures and is recommended for use to guide catheter-based interventions.<sup>9,10</sup>



While TEE is considered a low-risk procedure and its benefits are well-proven, it carries the risk of adverse events related to its passage and positioning from the oral cavity to the esophagus and stomach. The TEE procedure has the potential for significant morbidity and even mortality, especially in anesthetized patients who are unable to provide feedback during probe placement and manipulation. Complications related to intraoperative TEE span from relatively minor, such as transient dysphagia and pharyngitis (0.01% - 1.8% incidence rate) to serious life-threatening injuries, including GI tract perforation and hemorrhage (<0.01%).<sup>11</sup> While the overall TEE complication rate when used in cardiac surgery has been reported between 0.2% and 1.4% in several large retrospective studies,<sup>12</sup> a recent population-based analysis of over 28,800 patients receiving surgical valve replacement found a 2.5% rate of major complications (bleeding, esophageal and/or upper respiratory tract injury).<sup>13</sup>

Major complications related to the use of TEE in structural heart procedures have been reported to range from 0.5% to 3.6% in two large retrospective studies recently published.<sup>13,14</sup> These complications included oropharyngeal or esophageal injury and gastrointestinal bleeding. In a study of 50 patients assessed via esophagogastroduodenoscopy both before and immediately after a structural heart intervention using TEE, new minor lesions (petechiae, ecchymosis) were found in 23 patients and new complex lesions (intramural hematoma, mucosal laceration) were found in 20 patients, representing an overall complication rate of 86%.<sup>15</sup> The complex lesions consisted primarily of esophageal hematomas and lacerations/abrasions. The study noted that probe placement was considered difficult in 8% of patients.

Most of the contraindications for TEE placement are related to either bleeding concerns or anatomical changes to the GI tract that would make insertion more difficult or more likely to result in a complication. Structural abnormalities associated with challenging placement of a TEE probe include extrinsic compression of the esophagus, gastritis, tortuous distal esophagus, retained food in the esophagus, gastric ulcer, esophageal erosion, esophageal stricture, esophageal fistula, esophageal atresia, hypopharyngeal diverticula, fibrosis after radiation, and hiatal hernia.<sup>12</sup> TEE probe placement failure associated with difficult probe placement has been reported to range from 0.18% to 1.9% and has been associated with pharyngeal and esophageal perforations.<sup>1,16</sup> By providing the ability to directly visualize the tissue in the path of the probe during insertion and surrounding the TEE probe during manipulation, the Visura TEECAD System allows the physician to identify these abnormalities and adjust their approach to minimize tissue trauma resulting from the TEE procedure.



The TEECAD System guiding a TEE probe through the esophagus.



## Mayo Clinic Evaluation Results

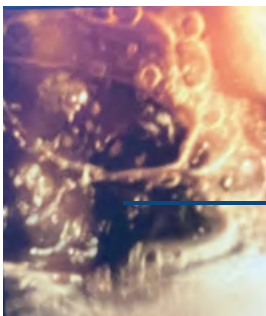
The TEECAD System was accepted by the Mayo Foundation for Medical Education and Research (MFMER) for evaluation within the Mayo Clinic hospital system. Device use within this program is consistent with appropriate standard of care and evaluations are performed with Institutional Review Board approval when required.

The TEECAD System was used on 15 patients undergoing TEE procedures for cardiac assessment between February 2022 and January 2023. Patient age ranged from the mid-30's to the mid-80's with a variety of clinical presentations including stroke, valvular disease, atrial fibrillation, patent foramen ovale (PFO), and post left atrial appendage occlusion (post-LAAO) device placement evaluation. The TEE procedures were carried out either in the intensive care unit or in the cardiac catheterization lab. All cases were performed using the TEECAD camera attached to a Philips TEE probe. All intubation times from insertion into the oral cavity until correct probe placement were measured at two minutes or less, with most under one minute. First pass success was achieved in 14 of the 15 cases. The presence of the TEECAD camera and cable created no image artifact in any of the cases even when left in place during TEE imaging after intubation. No adverse events or complications were seen in the 15 cases. Physicians noted that the TEECAD System was effective in all cases in aiding faster probe placement when compared to conventional TEE procedures where there is no direct, real-time visualization. Physicians also commented that the simple system set-up made TEECAD easy to use and integrate into their TEE procedures.

# CASE EXAMPLES

**Case 1:** An 82-year-old male presented for TEE with primary mitral regurgitation and comorbidities including atrial fibrillation/flutter and evaluation of atrial fibrillation and mitral regurgitation. The patient had undergone prior TEE procedures and angiography, both focused on only the heart. The physician noted that the patient was difficult to intubate and concluded he was an especially good candidate for use of the TEECAD System due in part to the patient's age and frailty. Intubation was successful on the first attempt and took two minutes with the physician estimating that the procedure would have taken approximately twice as long without visualization from the TEECAD System. Image clarity was rated as excellent, and it was noted that the removal of the TEECAD camera during the TEE procedure caused no change to the echocardiogram. The patient experienced no adverse events.

**Case 2:** An 80-year-old female presented for TEE with primary mitral valve regurgitation, tricuspid regurgitation, and aortic valve stenosis, along with smoking as a comorbidity. She had previously undergone TEE and had received quadruple coronary artery bypass graft and two stents. The physician noted that the patient was difficult to intubate due to a narrow throat. Intubation was successful on the first attempt and took two minutes, which the physician felt would have been longer without using the TEECAD System. As with **Case 1**, image clarity was rated as excellent. The probe moved out of position during the TEE procedure, likely due to patient movement, but with no impact on the echo image. The physician noted that the recommended removal of the TEECAD camera once the TEE probe was properly positioned may reduce the risk of inadvertent probe movement. There were no adverse events.



Screen shot from **Case 2**.  
Note the opening of the  
esophagus can be seen.

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**Case 3:** The last patient in the evaluation series was a 50 year old female presented for TEE to assess the functionality of the mitral valve. The procedure was performed by a cardiology fellow. Following advancement of the TEE probe fixed with the TEECAD camera, the esophagus was seen using slight anteflexion. The probe was then advanced into the esophagus, which was tighter than usual and required careful maneuvering. It was noted that use of the TEECAD System allowed the fellow to safely proceed through the esophagus restriction, when he otherwise would have completely removed the TEE probe and started over, thus avoiding increased risk of injury to the patient and adding valuable time to the procedure. The physician concluded that the TEECAD System enabled an efficient and effective TEE probe advancement to the lower esophagus on the first pass, and as a result, the TEE study was performed without difficulty, complications, or escalation of care.

Physician identifying  
esophageal opening.



## CONCLUSION

The results of the Mayo Clinic evaluation indicated that real-time direct visualization of TEE probe placement may play an important role in reducing complications such as oropharyngeal/esophageal injuries, bleeding, perforation, and intubation failure. First pass intubation failure is a common issue that may be substantially reduced with the TEECAD device. Use of TEECAD was effective in reducing the potential time needed for accurate probe placement and promoting first pass intubation success with no adverse events. It may also help reduce the cost-of-care for TEE as additional staff do not need to be called in to support intubations. TEECAD shows promise as a novel but essential device for cardiology TEE intubation.

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