# [Wire-frame integrity of patch-like Gore devices following atrial septal defect closure.](https://www.ncbi.nlm.nih.gov/pubmed/30680882)

Kubicki R, Fingerhut K, Uhl M, Hummel J, Höhn R, Reineker K, Fleck T, Stiller B, Grohmann J.

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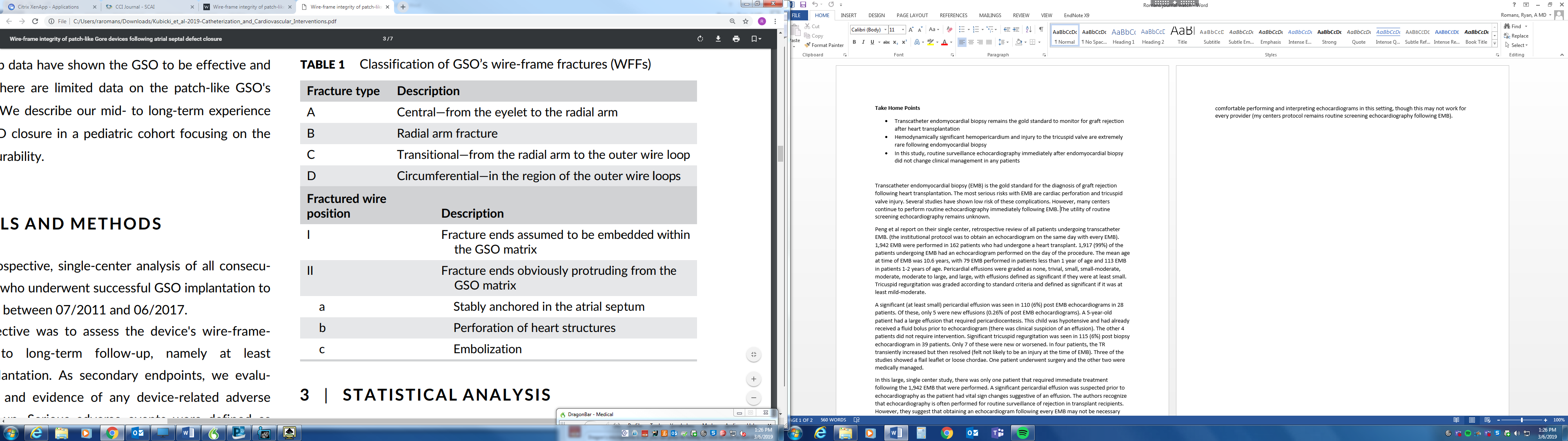
**Take Home Points**

* The Gore Cardioform Septal Occluder is safe and effective in closing secundum atrial septal defects.
* The rate of wire frame fractures is similar to the previous Gore device (Helex septal occluder) at 6.8%.
* In this small cohort, there were no clinical sequelae of wire frame fracture, though longer term follow up in a larger group are needed.



**Commentary from Dr. Ryan Romans (Kansas City), section editor of Congenital Interventional Journal Watch:** Transcatheter closure of secundum atrial septal defects (ASDs) is now first-line therapy in amenable defects. The Gore Cardioform Septal Occluder (GSO) is one of the most commonly used devices to close secundum atrial septal defects. It also has FDA approval for closure of patent foramen ovale’s. Use of this device has increased given the concerns of erosion with the Amplatzer septal occluder. These are the only two devices approved for ASD closure in the United States. The first generation device from Gore (Helex Septal Occluder, now discontinued) had a wire-frame fracture (WFF) incidence of 6-12%. The GSO features a sturdier frame design with 5 wires (instead of a single wire) and increased strength at larger diameters. This study evaluated the incidence of WFF in the GSO.

Kubicki et al describe their single center, retrospective analysis of consecutive patients who underwent successful ASD closure with a GSO over a 6 year period. Routine post-procedure EKGs and echocardiograms were also evaluated with particular attention on echocardiogram paid to residual shunts, spatial position, and alignment toward the atrial septum. A chest x-ray was performed at least one year following GSO implantation to evaluate for the presence of WFFs. The x-rays were reviewed by an interventional cardiologist and pediatric radiologist. WFFs were classified as detailed in the table below.



A total of 91 patients met inclusion criteria, with 4 patients lost to follow up. The median patient age at time of ASD closure was 5 years old (range 2-18 years) with a median weight of 20.2 kg (range 11-95). There were no serious adverse events at the time of implantation or at follow up. One patient developed new onset first degree AV block and three patients had transient supraventricular ectopy immediately after device implantation. All patients were asymptomatic at their most recent clinic visit, with a median follow up time of 42.5 months. Complete defect closure was confirmed in 96.7% of patients, with the remaining patients having only a trivial residual defect. Of the 87 patients that were seen in follow up, 80 had a chest X-ray performed, with 74/80 of adequate diagnostic quality to assess for WFF. WFF was detected in 5/74 patients (6.8%), with only types A and C seen (this may be slightly underestimated as fluoroscopy is more sensitive in detecting WFF than X-ray). No device had more than one fracture. There was no wire frame fragment embolization, device migration, clinical sequelae, or change in echocardiographic appearance (of the device or the appearance of new residual shunts). No predisposing factors (such as device size or deficient retro-aortic rim) were identified.

This small series shows that the GSO is safe and effective for ASD closure in mid-term follow up. Wire frame fractures are seen but do not affect device function or cause clinical sequelae (though this should be interpreted with caution given the small sample size). If there is any concern about the device by transthoracic echocardiography, further investigation (chest X-ray or fluoroscopy) should be pursued.