# Clinical Analysis of
# **RF Transseptal Puncture**

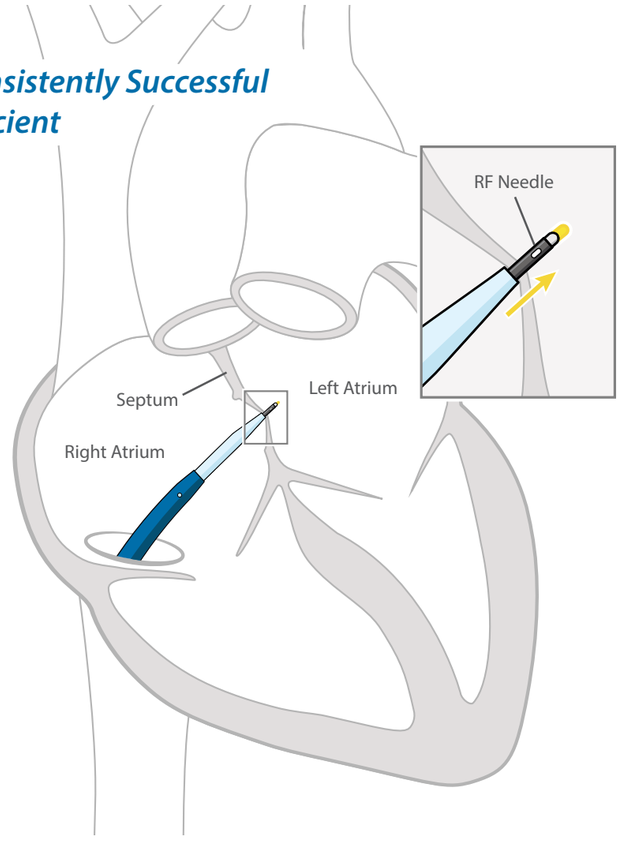
## **NRG™** Transseptal Needle

Europe

Baylis MEDICAL

*Published clinical evidence shows that*
*RF transseptal puncture using Baylis Medical technology is:*

- ***More Consistently Successful***
- ***More Efficient***
- ***Safer***




# Executive Summary

Transseptal puncture is a well-known and widely-used procedure, providing percutaneous access to the left atrium of the heart. This enables:

- treating diseases such as:
  - atrial fibrillation
  - atrial flutter

- performing common cardiac procedures such as:
  - catheter ablation
  - structural heart procedures such as transcatheter left atrial appendage occlusion and mitral valve repair

Transseptal puncture has been historically performed by pushing a sharp, "mechanical needle" across the interatrial septum. The transseptal puncture process has been associated with serious complications such as cardiac tamponade, requiring medical intervention and prolonging hospital stay. Transseptal puncture can also be time consuming and unpredictable.

To overcome these shortcomings, a radiofrequency (RF) transseptal needle was developed. The NRG™ Transseptal Needle uses a blunt-tipped electrode to deliver RF energy, allowing reliable, controlled access to the left atrium without needing to push a sharp, mechanical needle across the septum.

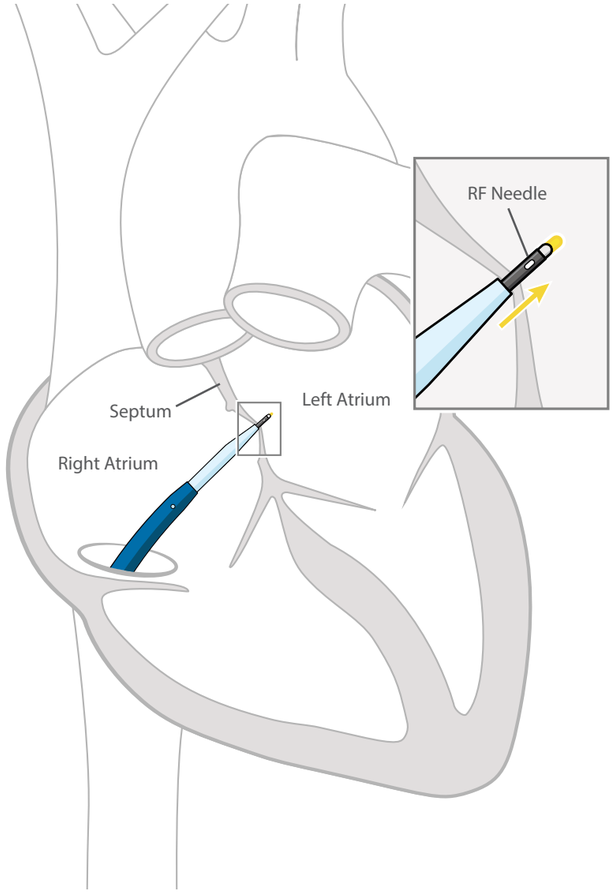
**Clinical studies have highlighted the reliability and consistency provided by Baylis Medical RF needle transseptal puncture technology by demonstrating:**

1. **Improved success with challenging anatomy**
2. **Reduced rate of failed transseptal crossings**
3. **Reduced procedure time**
4. **Reduced rate of serious complications**
5. **Reduced time of exposure to fluoroscopic radiation**
6. **Prevention of skiving/generation of visible plastic particles**

These benefits reduce burden on the hospital, patient and physician, and may be realized across all levels of physician expertise.

# Detailed Analysis

**Contents**




# Background

**Transseptal Puncture**

Transseptal puncture is a well-known and widely-used procedure, providing percutaneous access to the left atrium of the heart. This enables:

- Treating diseases such as:
  - Atrial fibrillation
  - Atrial flutter

- Performing common cardiac procedures such as:
  - Catheter ablation
  - Structural heart procedures such as transcatheter left atrial appendage occlusion and mitral valve repair

Transseptal puncture was first described in the 1960s. Historically, a sharp, "mechanical needle" has been used to push across the interatrial septum and gain left-heart access.

**Common Challenges**

Despite its common use, the transseptal puncture process can be:
- Associated with serious complications, such as cardiac tamponade
- Unpredictable
- Time consuming

**Radiofrequency Solution**

Baylis Medical Company Inc. has developed radiofrequency (RF) transseptal needle technology.

The NRG™ Transseptal Needle uses a blunt-tipped electrode to deliver a short and highly focused RF energy pulse, allowing a reliable, controlled puncture without needing to push through the septum using a sharp, mechanical needle.

The RF technology of the NRG™ Transseptal Needle delivers benefits that reduce burden on the hospital, patient and physician.

# Benefits of RF Transseptal Puncture

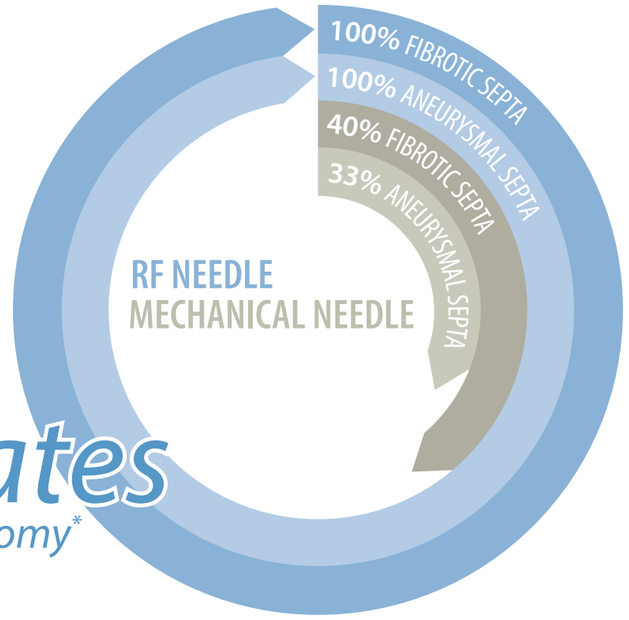
Clinical studies have highlighted the reliability and consistency provided by Baylis Medical RF needle transseptal puncture technology by demonstrating:

1. Improved success with challenging anatomy (such as thickened septum, fibrotic septum, patients who have had a previous transseptal puncture, aneurysmal septum, congenital heart disease)
2. Reduced rate of failed transseptal crossings
3. Reduced procedure time
4. Reduced rate of serious complications
5. Reduced time of exposure to fluoroscopic radiation
6. Prevention of skiving/generation of visible plastic particles

The following sections describe the evidence that supports the benefits of the RF needle in each of these categories. These benefits may be realized across all levels of physician expertise.

# 1 Improve Success With Challenging Anatomy

*Studies have shown that the RF needle is consistently successful in crossing challenging anatomy.*




## success rates
*crossing challenging anatomy**

| Study | RF Needle | Mechanical Needle |
|---|---|---|
| | Challenging Case Transseptal Results | Challenging Case Transseptal Results |
| **Fromentin et al.** | **n=119**<br>100% success in failed (crossover) cases from Mechanical Needle group (4 cases) | **n=38** - the 4 failed cases included:<br>2/4 had thick interatrial septum (patients undergoing 3rd transseptal procedure)<br>1/4 had small fossa ovalis requiring crossing through thicker portion of septum |
| **Hsu et al.** | **n=36**<br>100% success in failed (crossover) cases from Mechanical Needle group (10 cases) | **n=36**<br>4/10 failed cases were in patients who had previous transseptal puncture |
| **Jauvert et al.**** | **n=125**<br>7/7 (100%) in fibrotic (thickened) septa†<br>3/3 (100%) in aneurysmal septa<br>1/1 (100%) in small left atrium with small fossa ovalis and split septum | **n=100**<br>2/5 (40%) in fibrotic (thickened) septa<br>1/3 (33%) in aneurysmal septa |

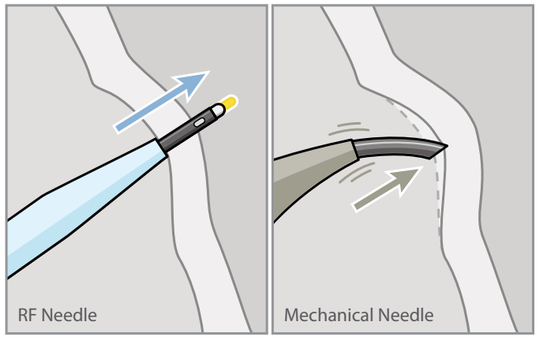
** Figure represents data from the Jauvert et al. study; details in table above and on opposite page.*

*** RF transseptal punctures were performed using a flexible RF needle: the Toronto RF Septostomy Catheter (later renamed the Toronto Transseptal Catheter) was the predecessor to the NRG™ Transseptal Needle.*

*† 2 of these 7 patients were patients in whom the mechanical needle had failed to cross previously.*

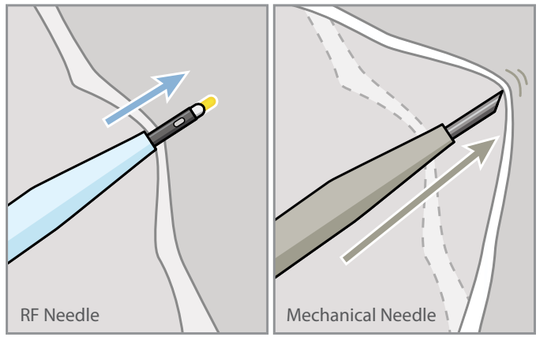


FIBROTIC (THICKENED) SEPTUM




*RF Needle crosses fibrotic (thickened) septum consistently versus mechanical needle.*

ANEURYSMAL (ELASTIC) SEPTUM




*RF Needle crosses aneurysmal (elastic) septum consistently versus mechanical needle.*

**Fromentin et al.**
Fromentin et al. conducted a prospective comparison of patients receiving RF transseptal puncture with the NRG™ Transseptal Needle (n=119) to patients undergoing transseptal puncture with a mechanical needle (n=38). The results showed that the septum was successfully crossed in all patients receiving transseptal puncture with the RF needle, whereas 4/38 patients (11%) in the mechanical needle group required crossover to the RF needle (p=0.003). Two of these patients were undergoing their third transseptal procedure and had a thickened interatrial septum, while another required transseptal puncture through a thicker portion of the septum due to the presence of a very small fossa ovalis. If crossover to the RF needle had not been possible in these cases, the physicians would have had to either try more aggressively to cross with the sharp mechanical needle, which could make the case more prone to complications, or they would have had to abort the case.

**Hsu et al.**
Hsu et al. conducted a RCT with subjects undergoing catheter ablation procedures randomized to RF transseptal puncture with the NRG™ Transseptal Needle (n=36) or a mechanical transseptal needle (n=36). The authors observed no failures to cross with the assigned needle in the RF needle group (0/36) as compared to 10/36 failures (27.8%) in the mechanical needle group (P<.001). Of these failures, 4 were in patients who had a previous transseptal puncture. The authors acknowledge the previous evidence suggesting that repeat transseptal punctures are more challenging and indicate that the RF needle may be preferred in this patient population.

**Jauvert et al.**
Jauvert et al. compared 125 consecutive patients who had transseptal puncture performed with a flexible RF needle (Toronto Catheter)** to 100 consecutive patients who had transseptal puncture performed with a mechanical needle. In the mechanical needle group, there were 3 patients with an aneurysmal septum and 5 patients with a fibrotic septum. In this subset of patients, successful transseptal puncture with the mechanical needle was only possible in 1/3 (33%) aneurysmal septa, and 2/5 (40%) fibrotic septa. This is compared to 125/125 successful transseptal punctures in the RF flexible needle group, despite an abnormal septum in 11 (8.8%) patients (7 had unusually thickened septa, 2 of which were patients in whom the mechanical needle had failed to perforate previously; 3 had aneurysmal septa; 1 patient had a small left atrium, small fossa ovalis and a split septum).

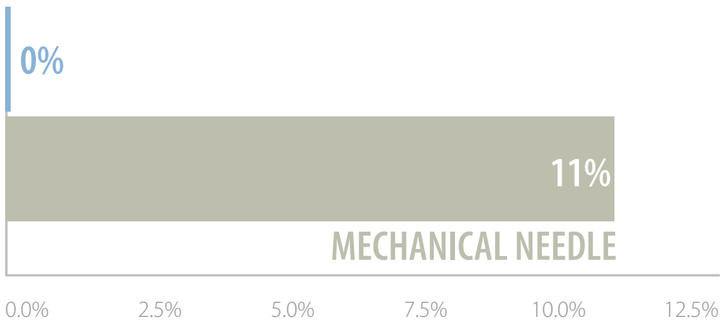
**Esch et al.**
Esch et al. conducted a retrospective chart review of 10 patients with congenital heart disease (five patients had undergone atrial switch procedures (Mustard/Senning), four had undergone Fontan operations, and one had atrial septal defect repair) who had attempts made using the NRG™ Transseptal Needle to provide transseptal access to the left heart for mapping/ablation procedures. The authors acknowledge the challenges posed to traditional mechanical needle puncture by the highly distorted anatomy in the congenital heart disease population. However, the RF needle was successful in 9/10 (90%) of these cases, including 2 which had first failed with a mechanical needle. The septal material in these cases was: atrial muscle (n=5); pericardium (n=3); and synthetic fabric (n=2). In their Methods section, the authors indicate a number of factors considered for choosing to use the RF needle rather than a mechanical needle for the initial transseptal attempt. These factors included: thick septal calcification demonstrated by fluoroscopy; thick septum at the desired puncture site; presence of a synthetic atrial patch material, large pericardial baffle, or occlusion device in the septum; and, small left atrial chamber size that made forceful tip advancement unadvisable. ■

# 2

# Reduce Rate of Failed Transseptal Crossings

*There was only 1 failure to cross the septum with the RF Needle in published comparative studies.*

## *failure rates*
*crossing the septum**




| Study | RF Needle | | Mechanical Needle | |
|---|---|---|---|---|
| | # of Transseptal Punctures | # of Failures to Cross Septum | # of Transseptal Punctures | # of Failures to Cross Septum |
| **Winkle et al.** | 575 | 1 | 975 | 12** |
| **Fromentin et al.** | 119 | 0 | 38 | 4 |
| **Hsu et al.** | 36 | 0 | 36 | 10† |
| **Jauvert et al.** | 125 | 0 | 100 | 5‡ |
| **Yoshida et al.** | 10 | 0 | 32 | 0 |

** Figure represents data from Fromentin et al. study; details in table above and on opposite page.*
*** The authors indicate that these failures in the mechanical needle group were due to inadvertent punctures of unintended structures and resulted in the termination of the procedures.*
*† The authors indicate that these failures in the mechanical needle group occurred due to concern that further forward pressure or tenting could lead to perforation of the lateral left atrial wall.*
*‡ The authors indicate that two of these cases were aborted due to an aneurysmal septum that brought the dilator too close to the left atrial roof or free wall, making the procedure too risky.*



**Winkle et al.**
Winkle et al. conducted a retrospective study comparing transseptal puncture performed with the NRG™ Transseptal Needle to that performed with a mechanical needle in patients undergoing catheter ablation of atrial fibrillation. A total of 1,167 consecutive patients who underwent 1,550 AF ablations were included in the study. Of these, 975 transseptal punctures were performed using the mechanical needle and 575 with the NRG™ Transseptal Needle. The authors found the rate of failure to cross the atrial septum was lower for the RF needle (1 of 575 [0.17%] vs. 12 of 975 [1.23%], p=.039). Further, the authors indicate that these failures in the mechanical needle group were due to inadvertent punctures of unintended structures (as shown by contrast injection staining) and resulted in the termination of these procedures without sequelae. The single patient in the RF transseptal needle group who experienced a failure to cross was due to a hypertrophic cardiomyopathy and a thick interatrial septum and also required a subsequent procedural session (the paper does not, however, provide data on overall success rates in challenging anatomies for either group).

Because the RF needle was used later in the series of patients, the authors examined their 975 mechanical needle punctures over time for evidence of improved operator performance, but found there was no trend for improved septal crossing rates (p=.794). The authors state that this suggests that the better results seen with the RF needle are probably not due to more operator experience.

In the Discussion of the paper, the authors review several differences between the mechanical needle and the RF needle that may account for the improved rate of septal crossing with the RF needle. They indicate that, after crossing with the mechanical needle, they would typically advance the needle tip a few millimeters out of the sheath to measure pressure and inject a small amount of contrast, confirming access, before advancing the larger sheath and dilator; however, in some failed crossings, contrast staining indicated that the sharp needle tip had inadvertently caused a puncture at an unintended location, leading to the decision to not proceed with the case. They contrast this with the blunt-tipped RF needle, which can inject contrast without exposing tissue to a sharp tip. Also, they indicate that RF energy may facilitate septal crossing in thicker portions of the septum or in areas scarred from previous transseptal procedures.

**Fromentin et al.**
Fromentin et al. conducted a prospective comparison of patients receiving transseptal puncture with the NRG™ Transseptal Needle (n=119) to patient undergoing transseptal puncture with a mechanical needle (n=38). The septum was successfully crossed in all patients receiving transseptal puncture with the RF needle; however, four patients (11%) in the mechanical needle group required crossover to the RF needle (p=0.003). Two of these patients were undergoing their third transseptal procedure and had a thickened interatrial septum, while another required transseptal puncture through a thicker portion of the septum due to the presence of a very small fossa ovalis. If crossover to the RF needle had not been possible in these cases, the physicians would have had to either push more aggressively to cross with the sharp mechanical needle, which could make the case more prone to complications, or they would have had to abort the case. Also, in the Fromentin et al. study, 1/38 subjects (2.6%) in the mechanical needle group experienced an interatrial septum dissection with extension to the aortic root, causing intramural hematoma. This led to the case being aborted.

**Hsu et al.**
Hsu et al. conducted a RCT of subjects undergoing catheter ablation procedures randomized to transseptal puncture with the NRG™ Transseptal Needle (n=36) or a mechanical transseptal needle (n=36). There were no failures to cross with the assigned needle in the RF needle group (0/36) as compared to 10/36 failures (27.8%) in the mechanical needle group (P<.001). The authors indicate that these 10 failures with the mechanical needle occurred due to concern that further forward pressure or tenting could lead to perforation of the lateral left atrial wall. However, all 10 patients that failed transseptal puncture with the mechanical needle had successful transseptal puncture performed after crossing over to the RF needle group. If crossover to the RF needle had not been available in these cases, the physicians would have had to either push more aggressively to cross with the sharp mechanical needle, which could make the case more prone to complications, or they would have had to abort the case.

**Jauvert et al.**
Jauvert et al. compared 125 consecutive patients who had transseptal puncture performed with a flexible RF needle (Toronto Catheter) to 100 consecutive patients who had transseptal puncture performed with a mechanical needle. In the flexible RF needle group 125/125 (100%) of subjects has successful transseptal puncture performed, as compared to 95/100 (95%) in the mechanical needle group (p=0.01). Of the 5 failures in the mechanical needle group, 2 transseptal punctures were aborted due to an aneurysmal septum that brought the dilator too close to the left atrial roof or free wall with the authors determining that transseptal puncture in these cases would be too risky. The other 3 failures in the mechanical needle group were related to a fibrotic septum, 2 of which were in patients that had previously had a transseptal puncture performed.

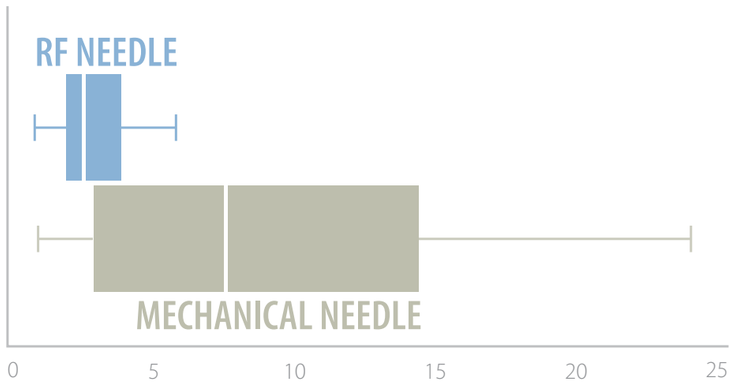
**Yoshida et al.**
Yoshida et al. conducted a retrospective study on paediatric patients (n=43) weighing less than 30kg undergoing transseptal puncture for the purpose of catheter ablation. Eight patients (n=8) in this study had the transseptal puncture performed with the NRG™ Transseptal Needle. All reported cases were successful in crossing the septum. ■

# 3

# Reduce Procedure Time

*All comparative studies that measured time showed a shorter, more predictable time for transseptal puncture with the RF needle.*

## *procedure time*
*in minutes**




| Study | RF Needle | | Mechanical Needle | |
|---|---|---|---|---|
| | # of Transseptal Punctures | Time Required for Puncture | # of Transseptal Punctures | Time Required for Puncture |
| **Winkle et al.** | 575 | 27.1 ± 10.9 minutes** | 975 | 36.4 ± 17.7 minutes** |
| **Fromentin et al.** | 119 | 7.5 ± 4.2 min† | 38 | 12.3 ± 9.3† |
| **Hsu et al.** | 36 | 2.3 min [IQR, 1.7 to 3.8 min]‡ | 36 | 7.3 min [IQR, 2.7 to 14.1 min]‡ |

** Figure represents data from Hsu et al. study; details in table above and on opposite page. Box plots show IQR of transseptal puncture procedure time, with white lines indicating median values; whiskers represent extremes within 1.5 times IQR; outliers are not shown.*

*** Time from lidocaine injection at the start of the case to time of successful septal crossing. Reported values were mean ± standard deviation.*

*† Time from initial insertion of the needle into the long sheath and when the sheath reached the left atrium (with removal of needle and dilator). Reported values were mean ± standard deviation.*

*‡ Time from pull-down of needle/dilator/sheath from the superior vena cava, until confirmation in left atrium. Reported values were median [interquartile range].*



**Winkle et al.**
In the Winkle et al. retrospective study comparing 975 transseptal punctures done with the mechanical needle and 575 done with the RF transseptal needle, the authors found that the time from lidocaine injection at the start of the case to time of successful septal crossing was shorter for the RF needle compared with the mechanical needle (27.1 ± 10.9 minutes vs. 36.4 ± 17.7 minutes, P <.0001). They attribute this shorter instrumentation time to the more expeditious transseptal puncture afforded by the RF mode of action.

**Fromentin et al.**
Fromentin et al. conducted a prospective comparison of patients receiving transseptal puncture with the NRG™ Transseptal Needle (n=119) to patient undergoing transseptal puncture with a mechanical needle (n=38). It was observed that the average transseptal time with the NRG™ Transseptal needle was shorter than that with the mechanical needle (7.5±4.2 min versus 12.3±9.3 min; p=0.005).

**Hsu et al.**
Hsu et al. conducted a RCT of subjects undergoing catheter ablation procedures randomized to transseptal puncture with the NRG™ Transseptal Needle (n=36) or a mechanical transseptal needle (n=36). A significantly shorter median transseptal time was seen in the RF needle group (2.3 minutes [IQR, 1.7 to 3.8 minutes]) as compared to the mechanical needle group (7.3 minutes [IQR, 2.7 to 14.1 minutes] (p=0.005). Further, the authors noted a greater variability in time required for transseptal puncture in the mechanical needle group, with the authors attributing this to a more uniform experience in the RF needle group. The authors' use of multivariate models found that older patient age predicted longer transseptal times, which they speculate was possibly due to more distorted cardiac anatomy or more fibrosis of the interatrial septum. ■

# 4 Reduce Rate of Serious Complications

## *no serious complications*

*attributed to the RF Needle in published comparative studies.*

### About Cardiac Tamponade

One of the serious complications associated with transseptal puncture is cardiac tamponade (also known as pericardial tamponade).

This is when blood (or other fluid) accumulates in the sac surrounding the heart (the pericardium). This puts pressure on the heart and prevents normal functioning.

Cardiac tamponade is a medical emergency. It can be fatal.

**Treatment includes:**

- Emergency pericardiocentesis (insertion of needle into pericardium and fluid aspiration)

or

- Open heart surgery (pericardial window created to cut open pericardium)

**Winkle et al.**
In the Winkle et al. retrospective study comparing 575 transseptal punctures done with the RF transseptal needle and 975 done with the mechanical needle, the authors found that there were fewer pericardial tamponades with the RF needle (0 of 575 [0.00%] vs. 9 of 975 [0.92%], p= .031). Of the 9 instances of pericardial tamponade in the mechanical needle group, one case required an open surgical procedure and 8 were managed with emergency pericardiocentesis. In the Discussion of the paper, the authors indicate that even though pericardial tamponade can be caused by steam pops during catheter ablation or excessive catheter contact force, their data indicate that the majority of pericardial tamponades occurring during AF ablation are likely related to transseptal puncture.

Because the RF needle was used later in the series of patients, the authors examined their 975 mechanical needle punctures over time for evidence of improved operator performance, but ***found that there was no trend for fewer tamponades with more operator experience (p=0.456). The authors state that this suggests that the better results seen with the RF needle are probably not due to more operator experience.*** Also, the results of the authors' multivariate analysis on the influence of gender, type of transseptal puncture needle utilized, primary physician operator, BMI, age, and LA size on the occurrence of pericardial tamponade found that ***only the use of the RF transseptal needle was associated with a reduced incidence of tamponade (p=0.04).***

In the Discussion of the paper, the authors discuss the various advantages of the RF needle that may contribute to reducing the rate of atrial perforation. These stated advantages include the fact that, after tenting of the atrial septum with a mechanical needle, the sharp needle tip must be further advanced toward the far wall of the left atrium in order to puncture the septum; whereas the RF needle uses RF energy to cross the septum without the need to push the needle forward after tenting is achieved. Instead, RF puncture allows the septum to move back towards its non-tented position, while the RF needle remains stationary. Another advantage of the RF needle stated by the authors is its blunt tip, which makes perforation unlikely if it were to contact the left atrial roof, posterior wall, or appendage after crossing the septum.

**Jauvert et al.**
Jauvert et al. compared 125 consecutive patients who had transseptal puncture performed with a flexible RF needle (Toronto Catheter ) to 100 consecutive patients who had transseptal puncture performed with a mechanical needle. In the mechanical needle group, 3 (3.0%) pericardial effusions* were observed with 2 (2.0%) of these developing into tamponade, as compared to none (0%) in the RF flexible needle group (p=0.04). The authors attribute two of these events in the mechanical needle group to overshooting following the sudden release of the septum, thereby leading to a micro puncture with bleeding worsened by anticoagulation. They attribute the third event in the mechanical needle group to the dilator sliding upward while pushing the needle.

**Fromentin et al.**
Fromentin et al. conducted a prospective comparison of patients receiving transseptal puncture with the NRG™ Transseptal Needle (n=119) to patient undergoing transseptal puncture with a mechanical needle (n=38). One tamponade occurred in the NRG™ Transseptal Needle group (0.84%), but the authors indicate that this was related to a pop observed during catheter ablation and not related to the transseptal puncture.

Also, in the Fromentin et al. study, 1/38 subjects (2.6%) in the mechanical needle group experienced an interatrial septum dissection with extension to the aortic root, causing intramural hematoma, during contrast injection. This led to the case being aborted.

**Hsu et al.**
Hsu et al. conducted a RCT with subjects undergoing catheter ablation procedures randomized to transseptal puncture with the NRG™ Transseptal Needle (n=36) or a mechanical transseptal needle (n=36). In the RF needle arm, after completion of the LA ablation procedure (3 hours after the transseptal puncture), 1 patient was found to have a pericardial effusion* detected by ICE. In the mechanical needle arm, 1 patient experienced a transient ischemic attack, with a brain MRI consistent with embolic etiology.

**Yoshida et al.**
Yoshida et al. conducted a retrospective study on paediatric patients (n=43) weighing less than 30kg undergoing transseptal puncture for the purpose of catheter ablation. Eight patients (n=8) in this study had the transseptal puncture performed with the NRG™ Transseptal Needle. No serious complications were observed in either group. ■

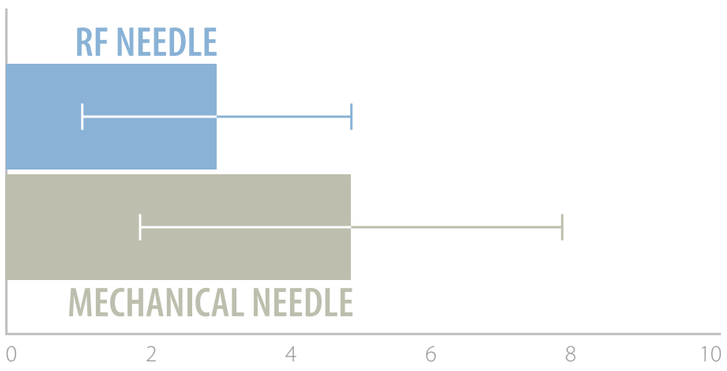
| Study | RF Needle | | | Mechanical Needle | | |
|---|---|---|---|---|---|---|
| | # of Transseptal Punctures | # of Pericardial Tamponades | # of Septum Dissections with Aortic Root Hematoma | # of Transseptal Punctures | # of Pericardial Tamponades | # of Septum Dissections with Aortic Root Hematoma |
| **Winkle et al.** | 575 | 0 | 0 | 975 | 9** | 0 |
| **Jauvert et al.** | 125 | 0 | 0 | 100 | 2† | 0 |
| **Fromentin et al.** | 119 | 1‡ | 0 | 38 | 0 | 1◊ |
| **Hsu et al.** | 36 | 0 | 0 | 36 | 0 | 0 |
| **Yoshida et al.** | 10 | 0 | 0 | 32 | 0 | 0 |

** Published clinical literature typically characterizes pericardial effusion as a minor complication.*
*** The authors state that their data indicate that the majority of pericardial tamponades occurring during AF ablation are likely related to transseptal puncture. 8 tamponades were managed with emergency pericardiocentesis; 1 required an open surgical procedure.*
*† The authors attribute these events to overshooting following the sudden release of the septum, thereby leading to a micro puncture with bleeding worsened by anticoagulation.*
*‡ The authors indicate that this was related to a pop observed during catheter ablation and not related to the transseptal puncture.*
*◊ Occurred during contrast injection and led to the case being aborted.*

# 5 Reduce Time of Exposure to Fluoroscopic Radiation

*Comparative studies showed a significantly shorter fluoroscopy time for transseptal puncture using the RF needle.*

## *fluoroscopy time*
*in minutes**




| Study | RF Needle | | Mechanical Needle | |
|---|---|---|---|---|
| | # of Transseptal Punctures | Fluoroscopy Time Required for Transseptal Puncture | # of Transseptal Punctures | Fluoroscopy Time Required for Transseptal Puncture |
| **Fromentin et al.** | 119 | 3.0 ± 1.8 min** | 38 | 4.8 ± 3.1 min** |
| **Yoshida al.** | 10 | 24.5 (18.5–32.8) min† | 32 | 30.5 (17.9–52.0) min† |

** Figure represents data from Fromentin et al. study (mean ± standard deviation); details in table above and on opposite page.*
*** Reported values were mean ± standard deviation.*
*† Reported values were median (range).*

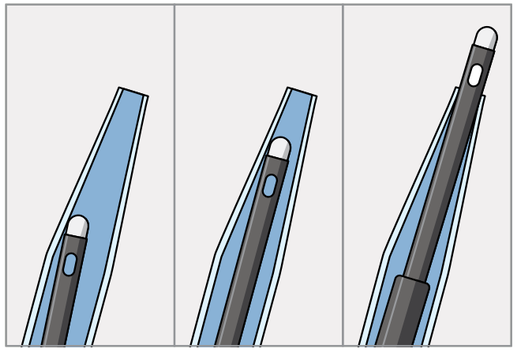
**Fromentin et al.**
Fromentin et al. conducted a prospective comparison of patients receiving transseptal puncture with the NRG™ Transseptal Needle (n=119) to patients undergoing transseptal puncture with a mechanical needle (n=38). It was observed that the total fluoroscopy time for transseptal access with the NRG™ Transseptal needle was shorter than that with the mechanical needle (3.0±1.8 min versus 4.8±3.1 min; p=0.009).

**Yoshida et al.**
Yoshida et al. conducted a retrospective study on paediatric patients (n=43) weighing less than 30kg undergoing transseptal puncture for the purpose of catheter ablation. Eight patients (n=8) in this study had the transseptal puncture performed with the NRG™ Transseptal Needle. The results demonstrated that the RF transseptal group showed a significantly lower fluoroscopy time compared to the mechanical needle group (24.5 [18.5–32.8] min versus 30.5 [17.9–52.0] min; p=0.036). In their conclusions, the authors indicate that they consider the use of RF needles as one method of increasing the safety of transseptal puncture in children. ■

# 6 Prevent Skiving/Generation of Visible Plastic Particles

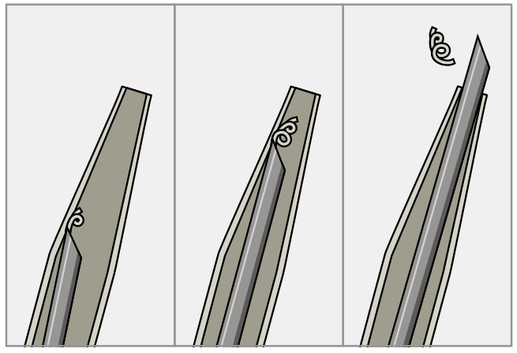
*Testing has demonstrated that the RF needle does not generate visible plastic particles as it is advanced through the sheath and dilator.*

RF NEEDLE



*RF Needle does not generate visible plastic particles as it is advanced through the sheath and dilator.*

MECHANICAL NEEDLE



*Mechanical Needle generates visible plastic particles as it is advanced through the sheath and dilator. Plastic particle illustrated above is to scale with a 2 mm long coil.*

| Study | RF Needle | Mechanical Needle |
|---|---|---|
| | Percentage of Tests That Found Visible Plastic Particles* | Percentage of Tests That Found Visible Plastic Particles* |
| **Hsu et al.**** | 0% | 33% |
| **Feld et al.†** | 0% | 100% |

** Study results are not necessarily indicative of clinical performance.*

*** Preprocedural ex vivo testing. Transseptal needles were placed through dilator and sheath, then removed and the dilator and sheath were flushed with heparinized saline to check for grossly visible plastic particles.*

*† In vitro study simulating transseptal catheterizations. Any particles generated from advancement of the transseptal needles through the sheath and dilator were collected and analyzed.*



**Hsu et al.**
Hsu et al. conducted a RCT of subjects undergoing catheter ablation procedures randomized to transseptal puncture with the NRG™ Transseptal Needle (n=36) or a mechanical transseptal needle (n=36). They conducted preprocedural ex vivo testing of both needle groups that involved placing the transseptal needle through the dilator and sheath, then removing the needle and flushing the dilator and sheath with heparinized saline to check for grossly visible plastic particles. Plastic particles were grossly visible in 0 (0%) of RF needle cases and 12 (33.3%) of mechanical needle cases (P<0.001). The authors provide an example of one of these particles which, in its coiled configuration, measures approximately 2mm x 3mm in size.

**Feld et al.**
Feld et al. conducted an in vitro study simulating transseptal catheterizations performed using mechanical needles and the NRG™ Transseptal Needle. Any particles generated from advancement of the transseptal needles through the sheath and dilator were collected and analyzed. A light microscope was used to identify particles in the visible range (50µm to 4mm), and particles in the sub-visible range (10µm to 50µm) were counted using a light obscuration method. The results demonstrated that all simulated procedures using the mechanical transseptal needles generated visible particles, whereas the RF transseptal needle generated no visible particles. The visible particles generated by the mechanical needles measured up to 6 mm in length (uncoiled) and over 0.3 mm in width. All needles tested generated sub-visible particles, but one mechanical needle type generated a significantly greater number than all other needles tested (p<0.01). The authors indicate that the results of this testing confirm the generation of particles which they suggest could potentially lead to embolism. ■

# Conclusion

The radiofrequency (RF) puncture technology offered by the Baylis Medical NRG™ Transseptal Needle allows access to the left atrium in a reliable and consistent manner.

This is supported by published clinical evidence showing that RF transseptal puncture using Baylis Medical technology is:

**More Consistently Successful**
Improves success with challenging anatomy
Reduces failure to cross septum

**More Efficient**
Enables shorter and more predictable procedure time

**Safer**
Reduces serious complications
Reduces time of exposure to fluoroscopic radiation

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