

# A Retrospective Cohort Study to Evaluate the Efficacy and Safety of Minimal Arterial Access Lower-Extremity Intervention Via Peripheral Orbital Atherectomy

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**Abstract: Objectives.** The primary objective of this study was to evaluate the clinical success of peripheral orbital atherectomy procedures with transradial access. The secondary objectives of this study were to assess the acute complications of peripheral orbital atherectomy procedures via transradial access with regard to hematomas, pseudoaneurysm, radial aneurysm, asymptomatic radial artery thrombosis, retroperitoneal bleed, embolization, access-site bleed, and perforation. **Background.** More than 200 million people worldwide are diagnosed with peripheral arterial disease (PAD). The treatment of PAD is critical to prevent further complications, such as chronic limb ischemia (CLI) and amputations. Peripheral catheterizations such as angiographies, angioplasties, and atherectomies are commonly utilized in treating PAD. Peripheral atherectomies are routinely performed via transfemoral access. However, due to increased risks for complications, time to discharge, and patient satisfaction, transfemoral access can be undesirable. **Methods.** This is a retrospective, unmatched, cohort, chart review study aimed to evaluate the efficacy and safety of minimal arterial access lower-extremity intervention (MÁLEI) using peripheral orbital atherectomy in patients with mild to severe PAD. Patients included in the study had lower-extremity PAD secondary to atherosclerosis (Rutherford classification category 2-6) and underwent at least 1 transradial peripheral atherectomy. **Results.** Forty-seven patients, ages 44 to 91 years, with Rutherford classification category 2-6 who underwent a transradial peripheral atherectomy were included; 40.5% of the patients were Rutherford class 5 or class 6. All procedures (n = 47) resulted in clinical success and no complications were noted. The average procedure time was 76.6 minutes and average fluoroscopy time was 28.3 minutes. These results indicate no increased risk of access-site complication or increase in procedure or fluoroscopy time compared with standard transfemoral access. **Conclusions.** This study demonstrated that utilizing a MÁLEI transradial approach for peripheral atherectomies is a safe alternative to the transfemoral method.

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**Key Words:** transradial, peripheral arterial disease, revascularization, chronic limb ischemia

Atherosclerosis on arterial walls reduces blood flow in the coronary, cerebral, iliac, and femoral arteries, as well as in the aorta, which is responsible for coronary heart disease (CHD), ischemic stroke, and peripheral arterial disease (PAD).<sup>1</sup> PAD, more specifically, is caused by calcified plaque occlusions in the arteries of the lower extremities and affects about 20% of the elderly population.<sup>2</sup> More than 200 million people worldwide are diagnosed with PAD, resulting in substantial morbidity and healthcare costs.<sup>3</sup> PAD death rates are generally equal in men and women, and symptomatic disease does not always correlate with a higher rate of death.<sup>2</sup> Studies have demonstrated that the severity of PAD is closely associated with the risk of myocardial infarction, ischemic stroke, and death from vascular causes. Peripheral catheterizations, such as angiographies, angioplasties, and atherectomies,

are commonly utilized in treating both intermittent claudication and chronic limb ischemia (CLI).

Historically, interventions of the coronary and peripheral vessels have been performed mainly through the femoral artery. Transfemoral access (TFA) was the first and only access site when catheterization emerged and has been considered a classical approach due to ease of access.<sup>4</sup> Transradial access (TRA) is a newer approach and has historically been avoided due to concern for serious complications (eg, radial artery occlusion, spasm, perforation). TRA is usually reserved for patients with the presence of factors that limit TFA, such as obesity, heavily calcified femoral arteries, or absence of femoral pulses,<sup>5</sup> which has greatly benefited these populations as revascularization would still be limited and dangerous (or not an option) without the introduction of the

TRA site. Additionally, interventions of the coronary and peripheral vessels have been performed via TFA simply because of a lack of equipment long enough to support these procedures via the TRA. However, the use of TRA for coronary interventions has increased dramatically over the last decade, with an increase from <3% in 2007 to 36% by 2016; this number continues to rise according to the National Cardiovascular Data Registry.<sup>6</sup> This is likely due to the increasing awareness of bleeding complications and the extended length of hospital stay post revascularization with TFA procedures, which is undesirable and costly to patients.<sup>7</sup> TRA for revascularization is a novel interventional strategy for peripheral revascularization procedures and introduces the possibility of using a single access site to treat bilateral lesions in the same procedure, allowing for faster recovery, a lower risk of bleeding, and earlier discharge times post procedure.<sup>8</sup> TRA has demonstrated that it can reduce vascular access complications compared with TFA, but its effect on risk of stroke, acute kidney injury, and radiation exposure needs further study.

Numerous clinical studies have demonstrated a decrease in complications (eg, bleeding and access-site complications) with TRA compared with TFA in the coronary arena.<sup>4</sup> In addition, other benefits including shorter hospital stays and recovery times have been documented, creating a more advantageous route for patients and cost. Nevertheless, despite the significant positive data supporting the feasibility and enhanced safety of TRA compared with TFA for coronary revascularization procedures, the overall success rate of minimal arterial access lower-extremity intervention (MÁLEI) via TRA access for peripheral revascularization procedures, specifically for peripheral orbital atherectomy procedures, has not yet been well evaluated. A major reason for this delay was the absence of an effective atherectomy system that was long enough to enable treatment through multiple access sites while maintaining low complication rates. Cardiovascular Systems, Inc. (CSI) developed the Diamondback 360 Peripheral Orbital Atherectomy System (OAS) in response to this issue. The Diamondback 360 and Stealth 360 OAS are the only atherectomy devices that can be used for TRA due to their compatibility with 6 Fr (4 Fr and 5 Fr with Micro and Solid crowns) atherectomy catheters with shaft lengths of 145–200 cm and longer for select Solid crowns.<sup>9</sup> This OAS has the ability to sand calcified plaque while minimizing damage to the media and maintaining 360° of contact with the vessel wall. The Diamondback 360 has the additional benefit of preserving treatment options by reducing need for bailout stents in calcified anatomy.<sup>10</sup>

This study aimed to evaluate the efficacy and safety of MÁLEI through the use of peripheral orbital atherectomy in patients with mild to severe PAD in order to demonstrate that TRA (MÁLEI) is safe and efficacious for peripheral orbital atherectomies.

## Methods

**Study design and patient population.** This was a retrospective, unmatched, cohort, single-center chart review study that included 47 PAD patients who were treated via TRA with a peripheral orbital atherectomy procedure in a single institution

by one interventional cardiologist (experienced in both TRA and TFA) from July 1, 2018 through June 30, 2019. All patients seen at the Ansaarie Cardiac & Endovascular Center were reviewed and all patients meeting inclusion criteria were included in the review. The institution utilized an electronic database to identify patients who had at least one peripheral vascular atherectomy procedure through TRA access recorded from July 1, 2018 through June 30, 2019. The study cohort included patients who were 18 years of age or older with a diagnosis of lower-extremity PAD secondary to atherosclerosis (Rutherford Classification [RC] category 2–6) and no exclusion criteria were applied.

The study protocol was approved by the IntegReview institutional review board (Protocol/Reference Number: ECIR2019-01) and a waiver of informed consent was granted as patient data were reviewed and analyzed in a retrospective manner. The study was conducted in accordance with Good Clinical Practice, the United States Code of Federal Regulations, Title 21, Part 50 (21CFR50), and the study protocol.

**Procedure description.** Transradial peripheral vascular atherectomies were performed via the right or left radial artery, as clinically indicated. All radial arteries were measured via ultrasound prior to performing the procedure; if <0.26 cm, an intervention was not performed. Under ultrasound guidance, the interventional cardiologist confirmed that the TRA site was appropriate, with no proximal or distal stenosis and a vessel size within acceptable parameters. This was done by catheterization with a 4 Fr catheter into the left brachial artery and an angiography to confirm the artery was not hypoplastic or had anomalous takeoff, and that the other corresponding artery was widely patent. The radial access site was infiltrated with a 2% lidocaine solution and a 21 gauge needle was used to access the vessel using a modified Seldinger technique in the anterior wall, under ultrasound guidance. Then a 0.021" guidewire was introduced into the radial artery. A 5 Fr or a 4 Fr sheath/10 cm radial sheath was then introduced into the radial artery, activating its glide coating. At this time, a "radial cocktail" was administered, comprising 5000 units of heparin, 2.5 mg of verapamil, and 200 µg of nitroglycerin. This mixture was diluted with 20 mL of the patient's blood and then administered intra-arterially. After administration of the cocktail, an angiogram of the left upper extremity was performed using contrast. The interventional cardiologist determined the method to accomplish hemostasis post procedure by standard procedure utilized at the hospital, ie, removal of 2 mL of air starting 2 hours after sheath removal and then continuing the removal of 2 mL of air every 15 minutes until band removal. This compression is based on a new protocol that is now considered standard for deflation of the TR Band (Terumo) following coronary procedures via the radial route via protocol 1 (removal of 2 mL of air 1 hour after the sheath removal and subsequent removal of 2 mL of air every 30 minutes) or protocol 2 (removal of 4 mL of air 2 hours after sheath removal and subsequent removal of 4 mL every 15 minutes).<sup>11</sup> The technique utilized is considered the standard uniform method for closure. The radial artery was not evaluated post procedure except via

pulse oximeter that was connected to the patient's index finger. No patient had ischemic complication of the hand.

**Objectives and outcomes.** The *primary objective* of this study was to evaluate the clinical success of peripheral orbital atherectomy procedures with TRA access. *Clinical success* was defined as the total number of successful revascularizations with peripheral orbital atherectomy procedure using TRA without conversion to TFA. The *secondary objectives* of this study were to assess the acute complications of peripheral orbital atherectomy procedures via TRA access with regard to hematoma, pseudoaneurysm, radial aneurysm, asymptomatic radial artery thrombosis, retroperitoneal bleed, embolization, access-site bleed, and perforation. The secondary outcomes were measured as rates of acute complications post procedure.

**Data collection.** Data collected from the study cohort included demographics, weight, height, severity of PAD (RC category 2–6), date of procedure, access-site artery or arteries, location of access site(s), order of access site(s) (primary, secondary, or tertiary), and reason for additional access sites, if applicable. Data regarding the procedures were collected, including the target vessel(s) and location(s), success of the procedure(s), associated CPT codes, and any procedure-related acute complications over 30 days post procedure (hematomas [mild, moderate, or severe], retroperitoneal bleed, pseudoaneurysm, asymptomatic radial artery thrombosis, embolization, radial aneurysm, postprocedure access-site bleeds, and perforation).

**Statistical analysis.** The study utilized a convenience sample of all patients meeting study criteria; thus, no formal sample size determination was undertaken. Patient characteristics were summarized via descriptive statistics. For the primary efficacy analysis, success rate was calculated as the proportion meeting the clinical success criteria. The primary safety analysis was calculated based on the incidence of acute complications overall and individual complications that occur.

## Results

Forty-seven patients (55.3% male, 44.7% female) ages 44 to 91 years underwent at least 1 transradial peripheral atherectomy (Table 1 and Table 2). At the time of the procedure, 22 patients (46.8%) presented with RC grade 3, 6 (12.8%) with RC grade 4, 6 (12.8%) with RC grade 5, and 13 (27.7%) with RC grade 6. Over half of the patients were former smokers ( $n = 22$ ) or current smokers ( $n = 5$ ) and 46 (97.9%) had a history of hypertension at baseline. Regarding glycemic status, 23 patients (42.5%) had type 2 diabetes, 4 patients (8.5%) had type 1 diabetes, and the remaining 23 patients (42.5%) were non-diabetic at the time of their procedure (Table 2).

Evaluating the primary and secondary objectives of this study, all 47 procedures (100%) resulted in clinical success and no complications were noted. The primary access site was the radial artery in 40 procedures (85.1%) and 7 patients (14.9%) required

**Table 1. Demographics.**

Demographics	Mean	Median	Range
Age (years)	72.5 ± 10.5	72.8 (65.5-81.3)	44.9-91.3
Weight (kg)	80.6 ± 16.9	82.0 (67.0-94.0)	46.0-108.0
Height (cm)	169.6 ± 10.8	167.0 (160.0-180.0)	152.0-187.0

Data presented as mean ± standard deviation, median (interquartile range), or range (minimum-maximum).

**Table 2. Demographics.**

Demographics	Patients (n = 47)
Sex	
Male	26 (55.3%)
Female	21 (44.7%)
Glycemic status	
Non-diabetic	23 (48.9%)
Type 1 diabetes	4 (8.5%)
Type 2 diabetes	20 (42.6%)
History of hypertension	
No	1 (2.1%)
Yes	46 (97.9%)
Smoking status	
Current	5 (10.6%)
Former	22 (46.8%)
Never	20 (42.6%)
History of CAD	
No	9 (19.1%)
Yes	38 (80.9%)
History of prior CAD procedure	
No	24 (51.1%)
Yes	23 (48.9%)
Number of prior CAD procedures	
1	15 (31.9%)
2	3 (6.4%)
3	2 (4.3%)
4	3 (6.4%)
Classification of PAD	
Severe claudication (Rutherford grade 3)	22 (46.8%)
Ischemic rest pain (Rutherford grade 4)	6 (12.8%)
Minor tissue loss (Rutherford grade 5)	6 (12.8%)
Ulceration or gangrene (Rutherford grade 6)	13 (27.7%)
Staged procedure	
No	3 (6.4%)
Yes	44 (93.6%)
Secondary access sites	
Anterior tibial	3 (6.4%)
Posterior tibial	4 (8.5%)

Data presented as count (%).

CAD = coronary artery disease; PAD = peripheral arterial disease.

an additional secondary access site (anterior tibial [ $n = 3$ ] and posterior tibial [ $n = 4$ ]) to complete revascularizations due to a non-favorable proximal cap (Table 2). More specifically, the vessels treated among the patients included in this study were

**Table 3. Arteries revascularized in all procedures.**

Revascularized Artery	Arteries (n = 69)
Common femoral artery	
Left	2 (4%)
Right	3 (6%)
Anterior tibial artery	
Left	5 (11%)
Right	1 (2%)
Superficial femoral artery	
Left	15 (32%)
Right	12 (26%)
Peroneal artery	
Left	3 (6%)
Right	3 (6%)
Common iliac artery	
Left	2 (4%)
Right	2 (4%)
Popliteal artery	
Left	7 (15%)
Right	4 (9%)
Posterior tibial artery	
Left	1 (2%)
Right	3 (6%)
External iliac artery	
Left	2 (4%)
Right	4 (9%)

Data presented as count (%).

the infrapopliteal vessels (n = 16), anterior tibial artery (n = 6), peroneal artery (n = 6), posterior tibial artery (n = 4), common femoral artery (n = 5), superficial femoral artery (n = 27), common iliac artery (n = 4), popliteal artery (n = 11), and external iliac artery (n = 6) (Table 3). There was a success rate of 100% in the case volume regardless of the difficulty of the occlusion.

**Table 4. Time outcomes for all vessels and number of vessels revascularized per procedure.**

Time Per Number Of Vessels Revascularized Per Procedure	Mean	Median	Range
<b>Total procedure time (minutes)</b>			
All revascularizations	76.6 ± 27.3	70.0 (60.0-90.0)	25.0-160.0
1 vessel revascularized	78.9 ± 32.7	70.0 (60.0-95.0)	25.0-160.0
2 vessels revascularized	70.4 ± 14.3	67.5 (60.0-85.0)	45.0-90.0
3 vessels revascularized	81.3 ± 17.5	82.5 (67.5-95.0)	60.0-100.0
<b>Total fluoroscopy time (minutes)</b>			
All revascularizations	28.3 ± 15.0	24.1 (16.8-36.4)	9.5-73.5
1 vessel revascularized	28.3 ± 15.8	23.8 (16.8-36.4)	9.5-73.5
2 vessels revascularized	23.2 ± 7.6	23.1 (16.6-25.7)	13.7-2.5
3 vessels revascularized	46.3 ± 18.4	45.6 (32.8-59.7)	24.9-68.9
<b>Time to discharge (hours)</b>			
All revascularizations	55.3 ± 98.7	6.5 (4.7-47.5)	2.8, 402.0
1 vessel revascularized	42.7 ± 76.4	5.8 (4.7-21.4)	2.8, 316.0
2 vessels revascularized	65.8 ± 131.1	9.1 (4.7-28.4)	3.6, 402.0
3 vessels revascularized	110.0 ± 120.1	85.3 (14.9-205.1)	5.4, 264.0

Data presented as mean ± standard deviation, median (interquartile range), or range (minimum-maximum).

Cases ranged from significant stenosis at the iliac level all the way to completely occluded superficial femoral arteries and to high-grade tibial lesions. The pushability and wire trackability of these TRA cases were comparable to (or slightly superior to) TFA; we hypothesize that this is because there is no “up and over” motion, indirect force is needed, and torque is usually 1:1.

For all procedures, the average procedure time or sedation time was 76.6 minutes (range, 25.0-160.0 minutes), average fluoroscopy time was 28.3 minutes (range, 9.5-73.5 minutes), and median time to discharge was 6.5 hours (range, 2.8-402.0 hours, including inpatient and outpatient combined) (Table 4). The average procedure time was 69.1 minutes for RC grade 3 patients, 78.3 minutes for RC grade 4 patients, 81.7 minutes for RC grade 5 patients, and 86.0 minutes for RC grade 6 patients. The mean fluoroscopy time was 20.8 minutes for RC grade 3 patients, for 34.2 minutes for RC grade 4 patients, 29.8 minutes for RC grade 5 patients, and 37.6 minutes for RC grade 6 patients. The mean time to discharge was 5.0 hours for RC grade 3 patients, 65.3 hours for RC grade 4 patients, 100.4 hours for RC grade 5 patients, and 114.9 hours for RC grade 6 patients (Table 5).

## Discussion

Patients with lower ankle brachial index values have the most severe clinical manifestations of PAD, such as CLI, and have an annual mortality of 25%.<sup>12</sup> The treatment of heavily calcified lesions in the peripheries is critical to prevent further complications, such as amputations, CLI, and/or worsening of disease.<sup>13</sup> Available literature on TRA for coronary revascularizations have proven it to be a beneficial access site in a wide variety of cases and numerous randomized controlled trials have demonstrated advantages with TRA for coronary interventions involving anticoagulation, thrombocytopenia, morbid obesity, multiple comorbidities, symptomatic heart failure, orthopedic injuries, etc.<sup>3,14</sup> In

**Table 5.** Time outcomes according to Rutherford grade.

Rutherford Grade	Grade 3-6 (n = 47)	Grade 3 (n = 22)	Grade 4 (n = 6)	Grade 5 (n = 6)	Grade 6 (n = 13)
<b>Procedure Time (minutes)</b>					
Mean	76.6 ± 27.3	69.1 ± 22.6	78.3 ± 23.2	81.7 ± 45.9	86.0 ± 25.4
Median	70.0 (60.0-90.0)	65.0 (60.0-75.0)	90.0 (60.0-90.0)	75.0 (60.0-95.0)	80.0 (70.0-90.0)
Range	25.0-160.0	40.0-140.0	40.0-100.0	25.0-160.0	55.0-140.0
<b>Fluoroscopy Time (minutes)</b>					
Mean	28.3 ± 15.0	20.8 ± 8.7	34.2 ± 11.3	29.8 ± 19.6	37.6 ± 17.5
Median	24.1 (16.8-36.4)	18.6 (14.7-25.7)	37.0 (24.9-38.1)	24.0 (16.6-31.7)	36.4 (23.7-42.5)
Range	9.5-73.5	9.5-46.9	18.1-50.5	14.8-67.9	19.1-73.5
<b>Time to Discharge (hours)</b>					
Mean	55.3 ± 98.7	5.0 ± 1.2	65.3 ± 123.1	100.4 ± 161.9	114.9 ± 102.8
Median	6.5 (4.7-47.5)	4.9 (4.4-5.8)	20.5 (5.7-24.4)	8.9 (5.3-172.3)	103.0 (28.4-150.5)
Range	2.8-402.0	2.8-7.1	4.4-316.0	4.9-402.0	5.9-342.2

Data presented as mean ± standard deviation, median (interquartile range), or range (minimum-maximum).

addition, these trials presented the TRA approach to be associated with a reduction in bleeding risk, major vascular complications, and shorter recovery times in coronary interventions, ultimately resulting in enhanced patient satisfaction.<sup>4,14-16</sup>

One meta-analysis of 2068 patients showed a 73% reduction in major bleeds with TRA compared with TFA ( $P < .05$ ) in endovascular procedures.<sup>5,15</sup> In addition, the study demonstrated early ambulation post revascularization and a decrease in hospital stay by 0.4 days with TRA compared with TFA.<sup>15</sup> A prospective registry study with 13,499 consecutive cases compared the safety and efficacy of TRA vs TFA for percutaneous coronary interventions from 2000 to 2006. The registry compared 3198 TFA cases with 3198 TRA cases and demonstrated fewer access complications (1.5% in TFA vs 0.6% in TRA;  $P < .001$ ) as well as shorter length of hospital stay for TRA patients.<sup>17</sup> Brueck et al studied 512 patients and demonstrated a decrease in access-site vascular complications, such as pseudoaneurysm, hematomas, decreased hemoglobin levels, and arteriovenous fistulas, with TRA compared with TFA for cardiovascular procedures (0.59% vs 3.71%, respectively;  $P < .001$ ).<sup>16,18</sup>

While the benefits of TRA are well defined for coronary interventions, there is a lack of literature supporting its use for peripheral interventions and there are concerns for increased risk of access-site complications, such as radial artery occlusion.<sup>4,6</sup> In addition, although vascular specialists, including interventional cardiologists, are aware of the potential benefits of utilizing TRA for peripheral interventions, many still use the TFA approach due to personal preference, a fear of complications, and/or limitations of equipment at their institutions. Data from our study imply that the suggested risk of access-site complications (ie, radial artery occlusion, spasm, or perforation) may be exaggerated and the clinical success of peripheral orbital atherectomy procedures with TRA is similar to success rates with TFA. Regarding the risk of radial artery occlusion, all TRA procedures in our study used an intraoperative radial cocktail that included nitroglycerin, which has been associated with a lower incidence of radial artery occlusion.<sup>6</sup> Most subjects were discharged within 8 hours of completion, with some staying

longer due to discharge nurse availability. However, others were retained in the hospital due to numerous comorbidities not associated with their PAD, which affected the overall discharge time in this review. No subject was retained for >24 hours specifically due to TRA and/or TRA procedure.

In this study, TRA is considered the first-line approach and TFA is reserved as a last resort at the interventional cardiologist's institution, providing the rationale for choosing TRA over TFA to perform the peripheral orbital atherectomy. Often, vascular specialists reserve the use of the radial artery for a narrowly defined patient population based on height, weight, and estimated radial artery size. However, the demographics (weight, height, body mass index, and age) of the patients in our study demonstrated a wide variety of patients and do not demonstrate a restricted patient population. It should be noted that the institution used in our study had the Terumo R2P sheaths and CSI peripheral OAS available; the interventional cardiologist was therefore not limited by equipment and was able to perform the peripheral orbital atherectomies on a variety of patients.

One positive outcome from our study was the similarity in procedure times for the TRA peripheral orbital atherectomies compared with TFA results in the literature.<sup>9,15,17,18</sup> Historical literature and some smaller studies documented that while the TRA approach was safe, effective, and reduced the risk of complications, it created longer procedure times and fluoroscopy times, which increased radiation exposure.<sup>17,18</sup> A study conducted by Hung et al was also able to illustrate comparable success and complication rates regardless of the access site (TRA vs TFA), but the fluoroscopy time was longer in the TRA group than in the TFA group (27.3 minutes vs 20.4 minutes, respectively;  $P = .03$ ).<sup>14</sup> However, our study illustrated similar fluoroscopy times with TRA compared with published TFA fluoroscopy times.<sup>19</sup> In addition, our data showed similar procedure times and time to discharge with MÀLEI compared with the standard TFA approach for peripheral orbital atherectomies. Furthermore, using secondary access sites with TRA allows multilevel vessel interventions without accessing the femoral artery within the same amount of time. These

results demonstrate that for patients with severe PAD (RC grade 3–6), utilizing a MáLEI-transradial approach for peripheral orbital atherectomies is a safe alternative to the TFA method.

**Study limitations.** The procedures included in the present study comprised the interventional cardiologist's initial TRA patients for peripheral orbital atherectomies; due to the steep learning curve associated with the access site, the procedure times and fluoroscopy times may be an inaccurate representation when compared with an interventional cardiologist who is experienced performing peripheral interventions via TRA. It is believed that the procedure times and fluoroscopy times continue to improve with experience performing the procedure via TRA. Another limitation to this study is that patients from both inpatient and outpatient settings were included in the analysis, which could affect the outcome times due to other comorbidities present at the time of the procedure.

## Conclusion

The use of MáLEI via TRA for peripheral orbital atherectomies in the patients within this study demonstrated high clinical success without access-site complications. We use the term “MaLEI” because we do not want to limit it to the radial artery only, as the ulnar artery is also utilized. These findings are similar to those of coronary revascularizations and indicate that the radial artery is an appropriate choice for peripheral orbital atherectomies and likely a preferred choice for patients. Additionally, if the proximal cap was feasible, then a TRA displays a non-inferior advantage for these patients and if TFA complications are added then the TRA route becomes the more advantageous option. With the availability of longer and lower-profile devices, demonstrated clinical success, observed minimal risks, and improved patient satisfaction, the radial artery should not be reserved as an alternative option; rather, TRA should be the initial choice in a wide population.

## REFERENCES

- Ouriel K. Peripheral arterial disease. *Lancet*. 2001;358:1257–1264.
- Hankey GJ, Norman PE, Eikelboom J. Medical treatment of peripheral arterial disease. *JAMA*. 2006;295:469–584.
- Fanaroff AC, Rao SV, Swaminathan R. Radial access for peripheral interventions. *Interv Cardiol Clin*. 2020;9:53–61.
- Anjum I, Khan MA, Aadil M, Faraz A, Farooqui M, Hashmi A. Transradial vs transfemoral approach in cardiac catheterization: a literature review. *Cureus*. 2017;9:e1309.
- Kumar AJ, Jones LE, Kollmeyer KR, et al. Radial artery access for peripheral endovascular procedures. *J Vasc Surg*. 2017;66:820–825.
- Som S, Patel AK, Sethi V, et al. Barriers for transradial coronary angiography and interventions in 2016. *Cardiovasc Revasc Med*. 2017;18:221–225.
- Rao SV, Turi ZG, Wong SC, Brener SJ, Stone GW. Radial versus femoral access. *J Am Coll Cardiol*. 2013;62:S11–S20.
- Staniloae C, Kurian D, Coppola J. Transradial bilateral iliac stenting. *J Invasive Cardiol*. 2006;18:E256–E257.
- Staniloae C, Korabathina R, Coppola J. Transradial access for peripheral vascular interventions. *Catheter Cardiovasc Interv*. 2013;81:1194–1203.
- CSI. Diamondback 360 Peripheral Orbital Atherectomy System. Available at <https://csi360.com/products/diamondback-360-peripheral-orbital-atherectomy-system/>. Accessed June 11, 2021.
- Riyami HA, Riyami AA, Nadar SK. Comparison between two protocols for deflation of the TR band following coronary procedures via the radial route. *J Saudi Heart Assoc*. 2020;32:52–56.
- Hiatt WR. Medical treatment of peripheral arterial disease and claudication. *N Engl J Med*. 2001;344:1608–1621.
- Mohan S, Flahive J, Arous E, et al. Peripheral atherectomy practice patterns in the United States from the Vascular Quality Initiative. *J Vasc Surg*. 2018;68:1806–1816.
- Hung ML, Lee W, McWilliams JP, Padia SA, Ding P, Stephen KT. A reality check in transradial access: a single-centre comparison of transradial and transfemoral access for abdominal and peripheral intervention. *Eur Radiol*. 2018;29:68–74.
- Jolly SS, Shoaib A, Hamon M, Yusuf S, Mehta SR. Radial versus femoral access for coronary angiography or intervention and the impact on major bleeding and ischemic events: a systematic review and meta-analysis of randomized trials. *Am Heart J*. 2009;157:132–140.
- Kanei Y, Kwan T, Nakra NC, et al. Transradial cardiac catheterization: a review of access site complications. *Catheter Cardiovasc Interv*. 2011;78:840–846.
- Eichhöfer J, Horlick E, Ivanov J, et al. Decreased complication rates using the transradial compared to the transfemoral approach in percutaneous coronary intervention in the era of routine stenting and glycoprotein platelet IIb/IIIa inhibitor use: a large single-center experience. *Am Heart J*. 2008;156:864–870.
- Brueck M, Bandorski D, Kramer W, Wieczorek M, Höltingen R, Tillmanns H. A randomized comparison of transradial versus transfemoral approach for coronary angiography and angioplasty. *JACC Cardiovasc Interv*. 2009;2:1047–1054.
- Korabathina R, Yadav SS, Coppola JT, Staniloae CS. Transradial approach to lower extremity interventions. *Vasc Health Risk Manag*. 2010;6:503–509.

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