Transpopliteal Balloon-Assisted Excimer–Laser Atherectomy for the Treatment of Chronic Femoropopliteal Occlusions: Feasibility and Initial Results

Christopher W. Lüdtke, Fabian Scheer, Peter Kamusella, Christian Wissgott and Reimer Andresen

Institute of Diagnostic and Interventional Radiology/Neuroradiology, Westkuestenklinikum Heide, Academic Teaching Hospital of the Universities of Kiel, Luebeck and Hamburg, Heide, Germany.

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ABSTRACT

PURPOSE: Recanalization of chronic total occlusions (CTOs) of the femoropopliteal arteries depends on a successful lesion crossing with the guide wire. The aim of this retrospective study was to evaluate the safety, feasibility, and the primary results of retrograde recanalization of CTOs with balloon-assisted excimer–laser atherectomy (ELA) via a transpopliteal approach after failed antegrade attempts.

METHODS: A total number of 15 patients (10 male, 5 female) with a mean age of 68.5 years (range: 43–91 years) treated with retrograde transpopliteal ELA in the years 2009–2012 were included retrospectively. After unsuccessful antegrade recanalization attempts with conventional guide wires and catheters, patients were treated with a retrograde recanalization attempt via a transpopliteal access using an excimer laser, followed by pressure-only balloon angioplasty (POBA). The mean length of the CTOs in the femoropopliteal arteries was 17.8 ± 5.4 cm (range: 9–29 cm).

RESULTS: Technically successful recanalization was achieved in 14 of 15 patients. Provisional stenting was done in two cases. There were no major adverse events regarding the laser atherectomy or popliteal access site. One acute reocclusion was observed in the first 48 hours after intervention. The ankle-brachial Index increased from preinterventional 0.45 ± 0.07 to 0.77 ± 0.29 ($P < 0.05$) in the follow-up period (1.5 months), resulting in a primary patency of 80%.

CONCLUSION: The retrograde ELA for recanalization of chronic femoropopliteal occlusions via a popliteal access turned out to be a safe and effective procedure with promising primary results. Thus it may be an endovascular treatment option for long chronic occlusions after failed antegrade recanalization or in patients who are not suitable for surgery.

KEYWORDS: excimer laser, atherectomy, femoropopliteal occlusion, transpopliteal, retrograde, angioplasty

SUPPLEMENT: Vascular Disease

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CORRESPONDENCE: CLuedtke@wkk-hei.de

Introduction

Peripheral arterial disease (PAD) shows an increasing prevalence in the elderly. In Germany, >20% of the people above the age of 70 years are affected.[1] Today, clinical diagnostics and treatment of symptomatic PAD is a multidisciplinary challenge as PAD also serves as an important marker for systemic atherosclerosis, with increased risks for coronary heart disease and stroke.[2,3]

In >50% of the patients, the femoropopliteal arteries are affected, with often long – multiple or recurrent – stenosis or occlusions (Type C and D lesions, according to the Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease TASC[3]). The characteristic symptom of chronic lesions is intermittent claudication (Stages 1–3 according to Rutherford[4]). With progression of the disease rest pain (Stage 4) and critical limb ischemia with ulcers and gangrene (Stages 5 and 6) occur.[5] Currently, at the stage of intermittent claudication, endovascular treatment is accepted as first-line therapy.[6] An "endovascular first" strategy is also increasingly used in more severe and complicated TASC C and D lesions. In addition to the patients with multiple risk factors for surgery or expected poor surgical outcome, nowadays, a lot of patients request a minimally invasive treatment with balloons and stents. Due to these circumstances, the European Society of Cardiology has proposed an endovascular-first strategy for TASC A–C lesions.[7]

Until today, a lot of different techniques and devices for the endovascular treatment of chronic total occlusions (CTOs) in the femoropopliteal arteries have been tested and some of them have become established in daily use. Subintimal angioplasty is an often-used technique and can be facilitated by reentry devices.[8,9] Specialized catheters have also been shown to be an effective alternative for crossing CTOs.[10] The use of the excimer laser is also a safe and effective method for the crossing and debulking of femoropopliteal lesions at the same time.[11] An alternative to an antegrade crossing consists in a transpopliteal access, followed by retrograde lesion crossing (intraluminal or subintimal) and angioplasty.[12]

The aim of this retrospective study was to evaluate the technical feasibility, safety, and efficiency of excimer–laser atherectomy (ELA) via a retrograde transpopliteal access for the treatment of long CTOs of the femoropopliteal arteries. Ethics committee approval was not required by the authors' institution or national regulations, because of the retrospective nature of the study. The research was conducted in accordance with the principles of the Declaration of Helsinki.

Materials and Methods

Patients. Fifteen (10 male, 5 female) patients, chosen from among a total number of 67 (22%) ELA-assisted interventions of the femoropopliteal arteries conducted at our department from November 2009 to December 2012 were treated via a popliteal access, and data were collected retrospectively. Mean age was 68.5 (range: 43–91) years; the other patient-related data and risk factors are given in Table 1. All patients had femoropopliteal CTOs. Preinterventional angiography showed 15 occlusions of the superficial femoral artery (SFA) and/or popliteal artery (PA), including the P1 segment, with a mean length of 17.8 ± 5.4 cm (range: 9–29 cm). According to TASC criteria, there were four type B, six type C, and five type D lesions. Inclusion criteria were a primary failed antegrade crossing attempt from an ipsilateral transfemoral (common femoral artery [CFA]) or contralateral crossover approach. In all patients, the onset of symptoms occurred more than 6 months before the primary crossing attempt. In patients with intermittent claudication, conservative medical treatment and exercise (if applied) showed no significant reduction of symptoms. Patients with acute and subacute occlusions, bypass occlusions, and untreated lesions in the ipsilateral iliac arteries were excluded from the study. The clinical stage was evaluated according to Rutherford.[4] In addition to a common clinical examination, the ankle–brachial index (ABI) was determined before intervention and in the follow-up examinations. Routine follow-up examinations were performed at 4–6 weeks after the intervention. Clinical and lesion characteristics are given in Table 2. Before the procedure, the popliteal vascular status was obtained by color-coded duplex ultrasonography in all cases. Preinterventional diagnostics also included magnetic resonance (or computed tomography) angiography and, in some cases, duplex ultrasonography of the treated limb. Complications associated with the puncture and other adverse events were evaluated clinically on the first postinterventional day and at the first follow-up visit. If puncture-related complications (eg, hematomas, fistula) were suspected, ultrasonography was conducted. Procedure-related complications were defined as bleeding/perforations needing additional treatment, arteriovenous fistula, or aneurysms.

Table 1. Risk factors.

	NUMBER	%
Diabetes mellitus	4	27
Hypertension	12	80
Smoker	8	53
HLP	4	27

Table 2. Lesion characteristics.

Occlusion length (cm, SD, range)	17.8 ± 5.4 (9–29)
Localization (in %)	
femoral	10 (67%)
femoropopliteal	5 (23%)
TASC classification[3] (in %)	
A	0 (0%)
B	4 (27%)
C	6 (40%)
D	5 (33%)
Rutherford stage[4] (in %)	
2–3	8 (53%)
4	3 (20%)
5–6	4 (27%)

Note: SD, Standard deviation.

Technique. Experienced interventional radiologists of our department performed all procedures. In all primary recanalization attempts, stiff and hydrophilic coated 0.035-inch wires (Terumo Europe©) were used with different 4F–5F catheters (eg, straight, angled), aiming to cross the lesion intraluminally. If this procedure failed, patients with mild intermittent claudication were discharged the next day and scheduled for the contemporary retrograde approach. In the other patients (Rutherford stages 4–6), the reintervention via the transpopliteal access was performed during the same hospital stay. All patients signed the informed consent.

For the retrograde transpopliteal procedure, we first punctured the contralateral CFA, with patients in the supine position, to insert a 4F pigtail catheter into the infrarenal aorta. After the sheath was fixed with sterile tapes and patches, patients were placed in the prone position. Then, an angiogram of the target limb was obtained to find a suitable puncture site in the popliteal region above the knee joint (Fig. 1A and B). The artery was then punctured under fluoroscopy with or without roadmapping function. To avoid transvenous puncture, special attention was given to the popliteal anatomy, especially the positions of the artery and the vein relative to each other.[13] Interindividual differences and abnormalities were detected with the preinterventional duplex ultrasonogram. In all cases, we used short sheaths (10 cm) up to 7F. First, we tried conventional intraluminal crossing of the lesion with a 0.035-inch stiff Terumo wire with 4F or 5F catheters (Fig. 1B). If this attempt failed, we changed to the excimer laser (CVX-300 Excimer Laser System®; Spectranetics®, USA; wavelength: 308 nm) and inserted a laser catheter suitable for the vessel

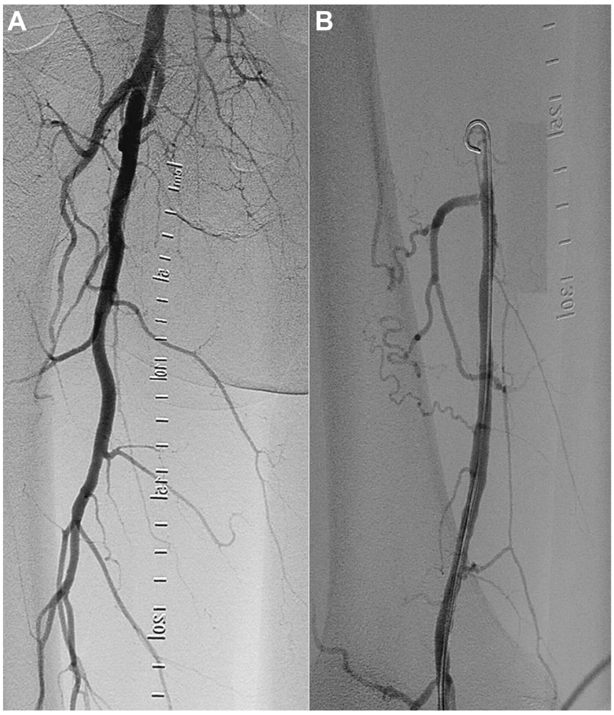

Figure 1. (**A**, **B**) Angiography of a long total occlusion of the superficial femoral artery (SFA). In (**A**), there is no stump at the origin of the SFA to enable an antegrade recanalization. Angiogram of the distal end of the occlusion after popliteal puncture is shown in (**B**).

diameter (TurboElite® 1.7–2.5 mm, Spectranetics®, USA) via a 0.018-inch wire (V18™ Control Wire, Boston Scientific™, MA, USA). At the distal cap of the occlusion, the laser catheter was then activated and slowly pushed forward, without wire guiding, under fluoroscopy for a short distance and then stopped. Then, we again probed with the wire to get an intraluminal passage. If this failed, the laser was activated again and advanced in a slow and careful motion. This procedure was repeated until the wire crossed the lesion ("step-by-step technique").[14] Irrespective of the way of lesion crossing (Fig. 2A), we then treated the whole occlusion with the laser catheter, advancing it about 1 mm/second through the lesion (Fig. 2B and C). In all cases, additional ballooning of the recanalized vessel was performed using uncoated balloon catheters with diameters of 4–7 mm and lengths up to 25 cm (Pacific/Admiral Xtreme©, Medtronic, USA; and Mustang™, Boston Scientific). In case of residual stenosis >30% or flow-limiting dissection after ballooning, we implanted self-expandable nitinol stents. For vascular closure, we used a clip-based closure device (StarClose SE® Vascular Closure System, Abbott Vascular, USA) and a bandage with mild compression for 24 hours. After turning the patient back to the prone position, we completed a final angiogram of the popliteal artery to determine any possible complication. Hemostasis of the contralateral CFA was achieved by manual compression and then compression bandage for 24 hours. We administered 5000 international units (IU) of heparin during the procedure. Afterward, all patients got full-dose intravenous heparin monitored by partial thromboplastin

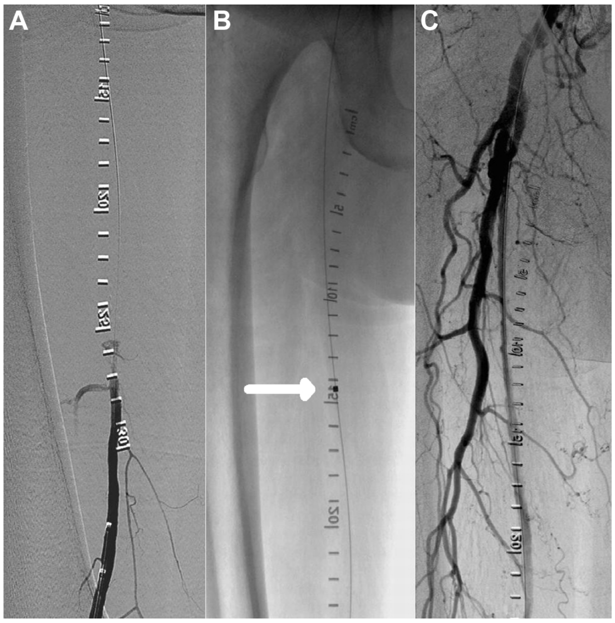

Figure 2. (**A–C**) Angiogram after successful retrograde lesion crossing via transpopliteal access is shown in (**A**). Laser catheter during recanalization (white arrow in (**B**). Recanalized lumen of the SFA after two passages of the laser catheter is shown in (**C**).

time, with a target value of 1.5–2.5 times the normal, for 48 hours. Antiplatelet therapy was administered preinterventionally with 100 mg of aspirin a day (if not applied earlier). In case of stent implantation, we additionally prescribed 75 mg of clopidogrel a day for 6 weeks, after a loading dose of 300 mg immediately after the procedure.

Technical success was defined as a total recanalization of the occlusion with <30% stenosis. Primary patency ended with the need of a reintervention in the target limb, ascertained by clinical worsening compared to baseline, significant decrease of the ankle–brachial index (ABI), or detection of restenosis or occlusion in the target lesion by diagnostic imaging.[4] The ABI is represented as mean values with standard deviations. Statistical comparison was completed with Student's t-test. P-value for significance was set at ≤ 0.05.

Results

Popliteal puncture was successful in all patients. With the assistance of the laser catheter, lesion crossing could be achieved in 14 of 15 patients. Adjunctive balloon angioplasty and provisional stenting led to satisfying postinterventional results in all patients with successful lesion crossing ($n = 14$). In one case, even the step-by-step technique failed to provide an entry into the occlusion due to heavy calcification and a hard distal cap. Subintimal crossing was suspended because there was no possibility for reentry. The patient with a Rutherford category rating of 3.0 underwent bypass surgery during a subsequent hospital stay.

In many procedures (8/14), there were almost-acceptable results after ELA, showing patent vessels with stenosis <50%

(Fig. 2C). After adjacent pressure-only balloon angioplasty of the residual stenosis, 12 of 14 patients showed satisfactory results, without flow-limiting dissections or residual stenosis >30%. Bailout stenting was needed in 2 of the 14 patients recanalized by ELA. There were no embolizations or perforations of any vessel. One acute reocclusion occurred 1 day postinterventionally and was detected in the routine duplex ultrasonogram of the popliteal artery. The patient had no rest pain but a decreased postinterventional ABI. This patient suffered from a long (26 cm) SFA occlusion with an angiographically detected (index procedure) in-stent stenosis. The reocclusion was successfully treated by rotational thrombectomy (Rotarex®, Straub Medical, Switzerland) and angioplasty with a drug-eluting balloon (IN.PACT© Pacific, Medtronic, USA). One restenosis occurred after 1 month and led to an impaired walking capacity and a reduction of the ABI from 0.64 to 0.30. Angiographically, we detected a short restenosis (3 cm) with dissection, which was successfully treated with a self-expandable stent.

The clip-based vascular closure device (StarClose SE®, Abbott Vascular, USA) was used without any difficulty in all cases. Hemostasis could be achieved within 2 minutes with mild compression to the puncture site after deployment of the clip. The angiograms obtained after closure showed no bleeding, fistulas, or narrowing of the popliteal puncture site (Fig. 3A and B).

During the hospital stay, five patients complained about mild pain in the popliteal region in the first 24 hours after intervention. After removal of the bandage, the pain decreased in all cases. There were no major hematomas in the duplex ultrasound control.

There was a significant improvement of the ABI ($P = 0.0002$) from 0.45 ± 0.07 preinterventionally to a mean value of 0.78 ± 0.25 before discharge. In the follow-up period (mean: 1.5 months), there was no significant ($P = 0.9$) decrease of the ABI (0.77 ± 0.29) in comparison to the postinterventional control (0.78 ± 0.25). This resulted in a patency rate of 80% in the short follow-up period. There were no major adverse events or deaths during follow-up. These findings are comparable to those of the antegrade ELA procedures for femoropopliteal lesions conducted within this time period at our department, with a technical success rate of >90% and a good assisted primary patency of nearly 68%. A summary of the results is provided in Table 3.

Figure 3. (**A**, **B**) Result after balloon angioplasty **A** and **B**. There were no flow-limiting dissections or residual stenosis in the final angiogram of the SFA. Additional stenting was not needed.

Discussion

Bypass surgery is a well-established treatment for infrainguinal chronic occlusions and is considered to be the standard of therapy so far.[15] Endovascular therapies have to be compared with those results, especially the long-term outcome (patency and amputation-free survival). Despite only moderate success rates for the endovascular treatment of CTOs in earlier studies,[16] there is an increasing use of this technique in daily practice particularly because of a lower morbidity and mortality compared to surgery.[7,17]

Indications for the popliteal access are SFA occlusions with no stump or involvement of the CFA. Furthermore, it can be considered in obese patients or patients who underwent surgical procedures in the groin earlier. With a crossover access via the contralateral CFA, one may be faced with challenging aortal configurations (stent prosthesis, surgical reconstruction). Compared to the crossover access, antegrade femoral or retrograde popliteal approaches offer more antegrade push and better steering of the wire during recanalization. Compared to retrograde pedal access methods developed in the past few years for the treatment of popliteal and femoral lesions, the popliteal access allows a greater sheath size and ensures a short way to the beginning of the occlusion. First mentioned by Tonnesen et al.[12], the retrograde popliteal access is a safe and helpful alternative in the repertoire of endovascular approaches. The possible complications are comparable to those in the CFA when considering the specific anatomy of the popliteal region.[13] With fluoroscopy or ultrasound guidance, popliteal puncture is straightforward and safe.[18,19] Many of the reported complications are related to the application of vascular closure devices.[18,20] In compliance with our own experiences, Noory et al.[18] showed a safe and effective closure with the StarClose SE® (Abbott Vascular, USA). A possible

Table 3. Results.

Successful recanalization (in %)	14 (93%)
Patency during follow-up (in %)	12 (86%)
ABI ± SD (*P*-Value)	
preinterventional	0.45 ± 0.07
postinterventional	0.78 ± 0.25 (<0.05)
follow-up	0.77 ± 0.29 (0.9)

Note: $P \leq 0.05$.
Abbreviations: ABI, Ankle–brachial index; SD, Standard deviation.

disadvantage of the described popliteal access may be the need to turn the patient in the prone position. In our experience, we found no exceeding time consumption or discomfort even in obese patients, especially when thinking about the efforts in terms of material, men, and time, which are out in, in general, in the treatment of challenging CTOs. The disadvantage of only one access site to work with at one time led to the development of different techniques for retrograde access to the femoropopliteal arteries. Acceptably feasible and safe alternatives are the direct puncture of the distal SFA[21] and puncturing the PA in the supine position of the patient.[22] In these techniques, the way to the artery is much longer than the same in the popliteal region and more tissues might be affected.

With our technique, we have the option to treat possible complications or proceed with the procedure from antegrade over the femoral (contralateral) access even when the popliteal access has already been removed. Because of the time consumed in snaring the wire and turning the patient back in the supine position to proceed via the crossover access, we proposed to carry out the definite treatment via popliteal access as an alternative.

In the treatment of femoropopliteal lesions, the results of the antegrade and retrograde techniques are comparable, with no differences when considering freedom of target-lesion revascularization.[23] The popliteal approach was more often used for occlusions than for stenosis in these patients. Sangiorgi et al.[24] report technical success rates of nearly 96% in long TASC C and D lesions and propose the transpopliteal access as a safe and effective alternative when antegrade recanalization attempts have failed.

The major challenge when facing femoropopliteal CTOs is, first of all, the lesion crossing. There are different techniques for lesion crossing, such as subintimal angioplasty. Since the first descriptions[8] and regardless of controversial discussions, the application of subintimal angioplasty is widespread, and the technique and results have become advanced. A promising low reintervention rate of 25% (mean value after 8 months) in a relatively large collection has been reported.[25] Furthermore, there is the retrograde subintimal angioplasty, which showed a good procedural success (98%) with low complication rates.[26] A relatively high stent rate of about 71% and a restenosis rate of about 55% after 12 months reflect the complexity of those lesions. Reentry devices have been developed to facilitate subintimal angioplasty. Today, the use is widespread with good success rates.[9,27] Yet, even moderate calcifications of the vessel walls at the desired reentry site may result in a failure of the devices.[28] The Frontrunner® XP (Cordis Corporation, USA) is a specifically developed CTO catheter for intraluminal wire crossing and shows technical success rates comparable to those of the reentry devices (about 65%) with high stent rates.[10] A limitation of this device is also a high calcium burden. Another alternative for the treatment of femoropopliteal CTOs consists in rotational thrombectomy if lesion crossing is successful.[29]

The ELA technique achieves a debulking of the atherosclerotic plaques by photochemical, photomechanical, and photothermal effects at the tip of the catheter. High rates of recanalization even in long symptomatic SFA occlusions could be achieved in large earlier trials.[30] In patients with critical limb ischemia, who were not good candidates for surgical procedures/bypass, ELA showed a promising low amputation rate after 6 months.[31] In our own experience, in the treatment of long TASC C and D lesions, ELA showed good technical success rates with low complication rates.[11] The long-term results are good in light of the complexity of the lesions but depend on a conscientious follow-up care. The use of ELA enables recanalization of CTOs without subintimal lesion crossing.[32]

Combination of the transpopliteal access with ELA provides a high recanalization rate in femoropopliteal occlusions for which conventional crossing attempts failed. An advantage of the retrograde approach might consist in an easier entry into the occlusion because of a softer distal cap. However, in most of our cases, only the use of ELA enabled the passage of wire by using the step-by-step technique. In addition to the help in lesion crossing, the excimer laser accomplishes an effective debulking of the atherosclerotic material and thus prepares the vessel for an effective angioplasty.[32] In this manner, the need for bailout stenting could potentially be reduced.

Limitations of this study are the retrospective design with only few patients and the lack of a control group with the use of angioplasty alone for comparison. So far, there are no long-term results available for this technique.

Summary

In summary, lesion crossing and recanalization of CTOs in the femoropopliteal arteries remains challenging for endovascular specialists. Endovascular procedures have to be compared with the well-established surgical options with acceptable long term-results. In the course of an increasingly practiced endovascular-first strategy, ELA showed promising results in the treatment of TASC C and D lesions. Vascular specialists of all kind are increasingly confronted with patients who are expected to have a bad outcome after surgery due to their comorbidities. Today, there are even more patients who insist on endovascular therapies because of the less-invasive manner of treatment. For such patients, the technique of retrograde transpopliteal ELA proved to be an efficient and safe procedure in a small cohort. Clinical results have to be further evaluated and compared with well-established surgical options, but transpopliteal ELA might be another "tool in the box" for doctors in the treatment of complex femoropopliteal occlusions.

The benefit of laser angioplasty in the treatment of long chronic occlusions lies in the support available for wire crossing and debulking. At least in our evaluation, ELA facilitates the subsequent balloon angioplasty and results in a promisingly low stent rate. The use of this debulking technique in combination with drug-eluting balloons and stents may be another advancement in the area of endovascular therapies of femoropopliteal CTOs and will be further investigated in the future.

Author Contributions

Conceived and designed the experiments: CWL. Analyzed the data: CWL. Wrote the first draft of the manuscript: CWL. Contributed to the writing of the manuscript: CWL, FS, CW. Jointly developed the structure and arguments for the paper: CWL, FS, CW. Agree with manuscript results and conclusions: CWL, FS, PK, CW, RA. Made critical revisions and approved final version: CWL, FS, PK, CW, RA. All authors reviewed and approved the final manuscript.

Disclosures and Ethics

As a requirement of publication, the authors have provided to the publisher signed confirmation of compliance with legal and ethical obligations, including but not limited to the following: authorship and contributorship, conflicts of interest, privacy and confidentiality, and (where applicable) protection of human and animal research subjects. The authors have read and confirmed their agreement with the authorship and conflict of interest criteria of the International Committee of Medical Journal Editors. The authors have also confirmed that this article is unique and not under consideration or published in any other publication, and that they have permission from rights holders to reproduce any copyrighted material. All disclosures have been made in this section. The external blind peer reviewers report no conflicts of interest.

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