MicroStent—A Novel Device Designed for Treatment of BTK-CLTI: Best Practices and Outcomes for Primary Treatment or Bailout in the European HEAL Observational Study

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Abstract

Objective. To evaluate the technical aspects of the MicroStent (Micro Medical Solutions), a novel device specifically designed for the treatment of chronic limb-threatening ischemia (CLTI) below the knee (BTK) when used as primary treatment or as bailout in patients enrolled in the HEAL study, a postmarket, multicenter, European all-comers observational study. **Methods.** All consecutive patients enrolled were evaluated at follow-up visits at 30 days, 6 months, 12 months, and 24 months, including duplex ultrasound evaluation of the target lesion. Evaluation included patient demographics, target-lesion characteristics, MicroStent implantation details including primary and bailout usage, sizing, and pre- and postdilation strategies. Primary outcome measures were primary patency at 6 months and freedom from major adverse limb event (MALE) and perioperative death (POD) at 30 days. Secondary outcome measures were device and technical success, freedom from MALE and major amputation at 6, 12, and 24 months, freedom from clinically driven target-lesion revascularization (CD-TLR) at 6, 12, and 24 months, and wound healing status at 6, 12, and 24 months. **Results.** A total of 77 patients were enrolled across 9 sites in 5 European countries, representing 78 lesions and a total of 91 MicroStent devices. Patients treated had a median age of 76 years (range, 46-92). Rutherford category ranged from 3 to 6, with 9.1% category 3, 19.5% category 4, 68.8% category 5, and 2.6% category 6. Medical history included diabetes (75.3%), history of coronary artery disease (29.9%), history of peripheral intervention (45.9%), and history of amputation (21.6%). Median target-lesion length was 45 mm (range, 10-400); before treatment, 51.9% of target lesions were chronic total occlusions and 59.8% were moderate to severely calcified. MicroStents were implanted as the primary treatment in 52.2% of the target cases and as bailout options in 47.8%. Overall primary patency (regardless of relationship to the MicroStent) was 71% at 6 months. Device-related primary patency, where the MicroStent was implanted for primary treatment of the target lesion, was 96.9% at 6 months; device-related primary patency, where the MicroStent was implanted as bailout option after failed treatment of the target lesion, was 100% at 6 months. Freedom from MALE and POD (regardless of relationship to the MicroStent) was 95.9% at 30 days and 90.0% at 6 months. Device success was 98.9% and technical success was 100%. The freedom from major amputation at 30 days and 6 months were 97.3% and 94.9%, respectively. The freedom from major target-lesion reintervention at 30 days and at 6 months were 98.6% and 96.5%, respectively. **Conclusions.** Preliminary results from the HEAL study suggest that patients requiring treatment of PAD and CLTI in the lower limb, can be safely and effectively treated with the MicroStent when used as a primary treatment or bailout option after a failed treatment of the target lesion. HEAL study enrollment and follow-up is ongoing.

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Key words: bare-metal stent, below the knee, chronic limb-threatening ischemia, chronic total occlusion, clinically driven target-lesion revascularization, coronary artery disease, drug-eluting stent, major amputation, major target-lesion reintervention, percutaneous transluminal angioplasty, peripheral arterial disease, perioperative death, target-lesion revascularization

The prevalence of peripheral arterial disease (PAD) has been increasing in the developed world, with >6% of the population 65 years and older experiencing symptomatic PAD.[1] Symptoms progress in severity from mild intermittent claudication to chronic limb-threatening ischemia (CLTI), where CLTI is characterized by chronic resting leg pain, impaired wound healing, and eventually, amputation. It is estimated that CLTI has an incidence of approximately 50 to 100 per 100,000 people per year and is associated with mortality rates as high as 20% within the first 12 months after onset.[1] Within 1 year of diagnosis of CLTI, 25% of patients will require major amputation and most of the remaining patients will have nonhealed wounds.[2] CLTI patients may have disease in multiple levels and vessels, which requires multiple procedures to improve blood flow to the lower extremities.[3] It is not uncommon for a patient to have subsequent procedures over the course of several weeks and months. Endovascular techniques to treat claudication include balloon dilation (percutaneous transluminal angioplasty [PTA]), stents, and atherectomy. These techniques continue to evolve and now include covered stents, drug-eluting stents, cutting balloons, and drug-coated balloons. The technique chosen for endovascular treatment is related to lesion characteristics (eg, anatomic location, lesion length, degree of calcification) and operator experience.[4] PTA depends upon mechanical dilation of the artery and is associated with plaque fracture, intimal splitting, and localized medial dissection. Localized post-PTA dissection is a common and expected adverse outcome associated with the angioplasty mechanism. Following PTA, many physicians place metal stents to maintain luminal patency, which improves blood flow, or to bail out failed PTA due to flow-limiting dissections, acute vessel recoil, and persistent residual stenosis. Stents used in the lower leg are typically either self-expanding nickel-titanium alloy (nitinol) or balloon-expandable systems. The safety and effectiveness of stents in the vasculature is well established in both coronary and peripheral vessels above the knee.[5-9] Several studies have also evaluated the utility of stents for use in infrapopliteal lesions,[10-12] but there is still a lack of data regarding what kind of stent(s) should be used and a treatment algorithm has not been established.

Methods

Study design. HEAL (An All-Comers Observational Study of the MicroStent Peripheral Vascular Stent System in Subjects with Peripheral Arterial Disease) is a single-arm, multicenter, observational, combined prospective and retrospective postmarket trial of all consecutive patients treated with the MicroStent device (Micro Medical Solutions). The study was approved by the local Medical Ethical Committee of all participating centers. HEAL study inclusion and exclusion criteria are minimal. Participating subjects must be ≥18 years old and willing to sign a patient informed consent form. All subjects with peripheral arterial lesions previously treated or intended to be treated with the MicroStent per the manufacturer's instructions for use (IFU) are eligible for study participation. *Exclusion criteria* are (planned) pregnancy during the study, life expectancy <1 year, known allergy to concomitant medication, contrast agents, antiplatelet, anticoagulant, or thrombolytic medications, or enrollment in another study that has not reached its primary endpoint at the time of enrollment. *Primary outcome measures* of the HEAL study include primary patency at 6 months, defined as freedom from target-lesion occlusion and clinically driven target-lesion revascularization (CD-TLR). A distinction is made between device and non-device-related primary patency. *Loss of device-related primary patency* includes only occlusions related to the MicroStent and CD-TLRs related to the MicroStent, as determined by the investigator (compliance with dual-antiplatelet therapy and inline occlusions to the target lesion are considered when determining device relatedness). *Clinically driven* is defined as reintervention due to complaints of leg pain/worsening pain, a progressing nonhealing ulcer, or new ulcer formation with or without the presence of an abnormal noninvasive test. *Other primary outcomes* are freedom from major adverse limb event (MALE) and perioperative death (POD). *Major adverse limb events* include above-ankle amputations, new bypass graft or graft revision, and/or thrombectomy/thrombolysis involving the target lesion. *Perioperative death* includes all-cause death within 30 days of the index procedure. *Secondary outcomes* include *device success*, defined as the operator's assessment of successful MicroStent deployment according to the IFU and *technical success*, defined as attainment of ≤30% residual stenosis (by visual estimate) in the treated lesion using only the study device according to the IFU (ie, including predilation/postdilation). *Other secondary outcomes* were freedom from MALE and major amputation, freedom from CD-TLR, and wound healing status measured at 6, 12, and 24 months. *Major amputation* was defined as amputation above the ankle (tibiotalar joint) in the target limb. *Freedom from CD-TLR* was defined as freedom from any revascularization procedure with involvement of the target lesion that is due to complaints of leg pain/worsening pain, a progressing nonhealing ulcer, or new ulcer formation with or without the presence of an abnormal noninvasive test. All data used in the analysis are site reported. Data were 100% source verified by the North American Science Associates (NAMSA). Statistics were independently performed by NAMSA.

Data extraction. The HEAL study data cut is dated July 8th, 2022. NAMSA prepared the validated tables and listings utilizing the July 8th, 2022 data cut. HEAL study enrollment and follow-up are ongoing. The HEAL study is registered at www.clinicaltrials.gov (NCT04110327).

Statistical analysis. Statistical analyses were conducted using SAS, version 9.4 (SAS Institute). Categorical variables are reported as counts and percentages on the available data, specified as denominator. Continuous variables are presented as mean ± standard deviation. The number of nonmissing values

(N), median, and minimum-maximum are also presented. The index procedure date corresponds to the reference date for any analysis or reported events. For the time-to-event variables (eg, primary patency), subjects with events occurring through the upper limit of the visit window were considered failures; subjects without events and having follow-up to at least the lower limit of the visit window were considered event free. The lower limits of the visit windows are 23 days, 150 days, 305 days, and 670 days for 30-day, 6-month, 12-month, and 24-month visits, respectively. The upper limits of the visit windows correspond to 37, 210, 425, and 790 days for 30-day, 6-month, 12-month, and 24-month visits, respectively. Time-to-event variables were also presented using Kaplan-Meier plots. The number of subjects at risk (N) is labeled at the bottom of each graph.

Device description. Micro Medical Solutions received CE mark for the MicroStent Peripheral Vascular Stent System on February 13, 2017. The system is commercially available in regions of Europe. The MicroStent (**Figure 1** and **Figure 2**) is intended for permanent implantation and is comprised of a self-expanding nitinol stent preloaded into a 3.2-Fr, .014″, over-the-wire delivery system. The device is intended to improve luminal diameter in the treatment of ischemia in the lower leg with reference vessel diameters (RVDs) from 2.0 mm to 4.5 mm. The MicroStent (40-cm delivery system) and the MicroStent XL (120-cm delivery system) is manufactured by Micro Medical Solutions. The stent is formed from nitinol wires woven in a braided configuration. Upon deployment, the stent achieves its predetermined diameter and exerts a constant, gentle outward force to establish and maintain the luminal diameter. The stent wires have a radiopaque platinum core that provide improved visibility for the braided stent during deployment and subsequent follow-up. The delivery system includes a 3.2-Fr sheath catheter with a coaxial inner assembly (stent stabilizer). A proximally located rotational hemostasis valve on the sheath catheter provides hemostasis and a safety lock to prevent premature deployment of the stent as well as a means to irrigate the catheter. The stent stabilizer terminates distally through the preloaded stent and out the distal end of the sheath catheter. The distal portion of the sheath catheter contains a radiopaque marker band. A second radiopaque marker band located on the stabilizer marks the proximal portion of the self-expanding stent when it is positioned within the space between the stent stabilizer and the sheath catheter. The stent is positioned at the target site using 2 radiopaque marker bands, 1 is located distal to the stent and 1 is located proximal to the stent; and, the stent's braided structure is also radiopaque.

MicroStent implantation best practices include proper lesion characterization using standard techniques such as angiography or intravascular ultrasound. As described in the IFU, the target lesion should be predilated with 1 or more balloons (with increasing outer diameter inflation) to achieve vessel diameter equal to the diameter of the MicroStent, and with longer inflation times

FIGURE 1. The MicroStent.

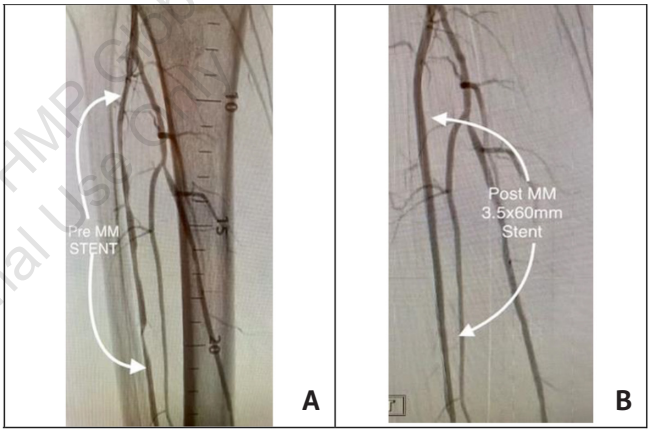
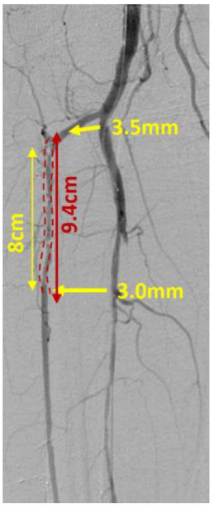


FIGURE 2. Delivery of the MicroStent is shown. (A) Pre-implantation. (B) Post implantation.

recommended (~1-2 minutes). When selecting the MicroStent size, the MicroStent:RVD ratio should match 1:1. For example, if the proximal RVD is 3.5 mm, the distal RVD is 3.0 mm and the average RVD is 3.25 mm, the 3.5-mm diameter MicroStent should be selected (**Figure 3**). For example, if treating an 80-mm lesion, the MicroStent size selected should fully cover 80 mm plus approximately 5-10 mm of healthy intima proximal and distal to the lesion per the stent dimensions table.

In order to achieve successful deployment of the MicroStent, device deployment should be slow and steady to avoid elongation and stacking, which can reduce the designed engineering properties of the MicroStent. For lesions requiring multiple MicroStents, a ~1 cm overlap is recommended. Deployment should always be distal to proximal (anatomically) such that the proximal stent (upstream) lays within the distal stent (downstream). After completion of MicroStent deployment, postdilation is strongly recommended. The labeled diameter of the balloon used should



Proximal RVD	Distal RVD	Average RVD	Length
3.5 mm	3.0 mm	3.25 mm	8 cm

→ 3.5 x 60 mm

In vivo stent dimensions.

Labeled Stent Length	2.5 mm Stent		3.0 mm Stent		3.5 mm Stent		4.0 mm Stent		3.5 mm Stent	
	2.0 mm Vessel Diameter	2.5 mm Vessel Diameter	2.5 mm Vessel Diameter	3.0 mm Vessel Diameter	3.0 mm Vessel Diameter	3.5 mm Vessel Diameter	3.5 mm Vessel Diameter	4.0 mm Vessel Diameter	4.0 mm Vessel Diameter	4.5 mm Vessel Diameter
8 mm	11 mm	9 mm	13 mm	11 mm						
15 mm	21 mm	17 mm	23 mm	19 mm	25 mm	21 mm	27 mm	23 mm	30 mm	25 mm
25 mm	34 mm	29 mm	39 mm	33 mm	42 mm	35 mm	45 mm	37 mm	48 mm	39 mm
40 mm	55 mm	47 mm	62 mm	51 mm	67 mm	56 mm	73 mm	61 mm	79 mm	67 mm
60 mm	82 mm	70 mm	93 mm	77 mm	101 mm	85 mm	110 mm	92 mm	119 mm	100 mm

FIGURE 3. Device selection.

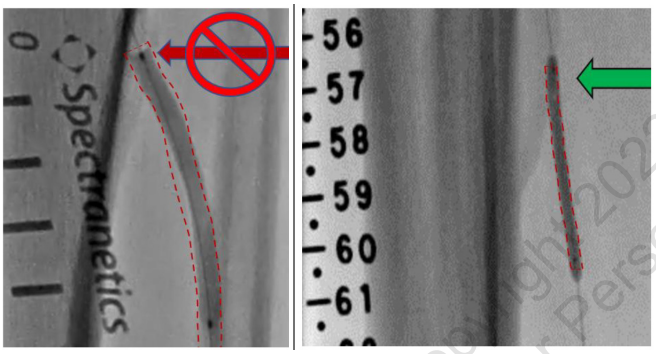


FIGURE 4. Balloon dilation. Place balloon marker band just outside of stent ends to fully dilate. The red arrow (left panel) demonstrates incorrect placement; green arrow (right panel) demonstrates correct placement.

not exceed the diameter of the MicroStent. The operator should ensure that distal and proximal ends of the stent are adequately dilated. The balloon should extend just outside of the stent end to ensure full dilation (**Figure 4**).

Postprocedural dual-antiplatelet therapy should be given per industry best practices after endovascular revascularization for lower-extremity PAD. In summary, appropriate lesion characterization, vessel preparation, MicroStent size selection, and DAPT are critical for optimal outcomes.

Results

Patient characteristics and lesion characteristics are detailed in **Table 1** and **Table 2**. A total of 77 patients were enrolled across 9 sites in 5 European countries representing 78 lesions and a total of 91 MicroStent devices. Patients treated had a median age of 76 years (range, 46-92) and 81.8% were male. The median body mass index was 25.5 kg/m^2 (range, 2.2-38.3). The Rutherford category ranged from 3 to 6. The majority of patients presented with Rutherford category 5 (68.8%) followed by Rutherford 4 (19.5%), Rutherford 3 (9.1%), and Rutherford 6 (2.6%). The majority of patients suffered from diabetes (75.3%), history of coronary artery disease (29.9%), history of peripheral intervention (45.9%), and history of amputation (21.6%). Slightly more than 39.0% were former smokers, 13.0% were current smokers, and 48.1% were nonsmokers. The median target-lesion length was 45 mm (range, 10-400 mm) and 51.9% were chronic total occlusions. The majority of lesions were located in the anterior tibial artery (38.5%), followed by tibial-peroneal trunk (28.2%), posterior tibial artery (17.9%), peroneal artery (9.0%), popliteal artery (2.6%), superficial femoral artery (1.3%), common plantar artery (1.3%), and distal popliteal artery/proximal anterior tibial artery (1.3%). Calcified lesions were found in 40.3% of patients; 19.5% of them were severely calcified. In 85.9%, de novo lesions were treated (restenotic lesions, 14.1%). The rate of adjunctive therapies used during target-lesion treatment (**Table 3**) was 14.1%, with drug-coated balloons used in 45.5% of cases, followed by specialty balloon (eg, scoring, cryotherapy) used in 45.5% of cases and drug-eluting stents used in 9.1% of cases. Out of 77 patients treated with the MicroStent, 84.4% were implanted with 1 stent, followed by 13.0% implanted with 2 stents, and 2.6% implanted with 3 stents. A total of 52.2% of MicroStents were implanted for primary treatment of the target lesion and 47.8% were implanted as bailout options after failed treatment. The majority of the reasons for bailout were flow-limiting dissection (grade C or higher) or vessel perforation (59.5%), followed by persistent residual stenosis ≥30% (21.4%), and acute vessel recoil or other negative occlusive complications (19.0%); the reason was

Table 1. Patient characteristics.

Characteristics	Patients
Age (years)	
Number of patients	77
Mean ± standard deviation	74.4 ± 9.0
Median	76.0
Min-max	46.0-92.0
Sex	
Female	14/77 (18.2%)
Male	63/77 (81.8%)
Body mass index (kg/m^2)	
Number of patients	74
Mean ± standard deviation	25.9 ± 4.7
Median	25.5
Min-max	2.2-38.3
History of smoking	
Current smoker	10/77 (13.0%)
Former smoker	30/77 (39.0%)
Nonsmoker	37/77 (48.1%)
Diabetes mellitus	58/77 (75.3%)
History of coronary artery disease	23/77 (29.9%)
History of peripheral intervention	34/74 (45.9%)
History of amputation	16/74 (21.6%)
Rutherford category	
0 – asymptomatic	0/77 (0.0%)
1 – mild claudication	0/77 (0.0%)
2 – moderate claudication	0/77 (0.0%)
3 – severe claudication	7/77 (9.1%)
4 – rest pain	15/77 (19.5%)
5 – ischemic ulceration	53/77 (68.8%)
6 – frank gangrene	2/77 (2.6%)

Data presented as mean, median, min-max, or n/N (%).

Table 2. Lesions characteristics.

Characteristics	Lesions
Target-limb side (subject level)	
Left	34/77 (44.2%)
Right	43/77 (55.8%)
Target-limb vessel	
Anterior tibial	30/78 (38.5%)
Peroneal	7/78 (9.0%)
Posterior tibial	14/78 (17.9%)
Tibial-peroneal trunk	22/78 (28.2%)
Other	5/78 (6.4%)
Popliteal	2/78 (2.6%)
Superficial femoral artery	1/78 (1.3%)
Common plantar artery	1/78 (1.3%)
Distal popliteal artery/proximal anterior tibial artery	1/78 (1.3%)
Type of lesion	
De novo	85.9% (67/78)
Restenotic	14.1% (11/78)
Number of lesions treated (subject level)	
1	76/77 (98.7%)
2	1/77 (1.3%)
Target-lesion reference vessel diameter	
Number of lesions (n)	78
Mean ± standard deviation (mm)	3.2 ± 0.5
Median (mm)	3.0
Min-max (mm)	2.0-4.5
Target-lesion percent diameter stenosis	
Number of lesions (n)	77
Mean ± standard deviation (%)	92.0 ± 10.6
Median (%)	100
Min-max (%)	50.0-100.0
Target-lesion total occlusions	40/77 (51.9%)
Target-lesion length	
Number of lesions (n)	77
Mean ± standard deviation (cm)	10.0 ± 10.8
Median (cm)	4.5
Min-max (cm)	1.0-40.0
Calcification	
None	6/77 (7.8%)
Mild	25/77 (32.5%)
Moderate	31/77 (40.3%)
Severe	15/77 (19.5%)

Data presented as mean, median, min-max, or n/N (%).

not indicated in 0.2%. Predilation was performed in all patients prior to deployment of the MicroStent, while postdilation was performed in 88.9% of implanted MicroStents.

Primary outcomes included primary patency and freedom from POD and MALE. Primary patency (regardless of relationship to the MicroStent), defined as freedom from occlusion and CD-TLR, was 71% at 6 months as determined by Kaplan-Meier method (**Figure 5**). The freedom from POD and MALE (regardless of relationship to the MicroStent) was 95.9% at 30 days and 90.0% at 6 months. The

TABLE 3. Adjunctive therapies.

Therapies	Patients (n = 78)
Adjunctive therapies used during target-lesion treatment	11/78 (14.1%)
Drug-coated balloon	5/11 (45.5%)
Specialty balloon (eg, scoring, cryotherapy)	5/11 (45.5%)
Bare-metal stent	0/11 (0.0%)
Drug-eluting stent	1/11 (9.1%)
Atherectomy	1/11 (9.1%)
Thrombolysis/thrombectomy	0/11 (0.0%)
Other	0/11 (0.0%)

Data presented as n/N (%).

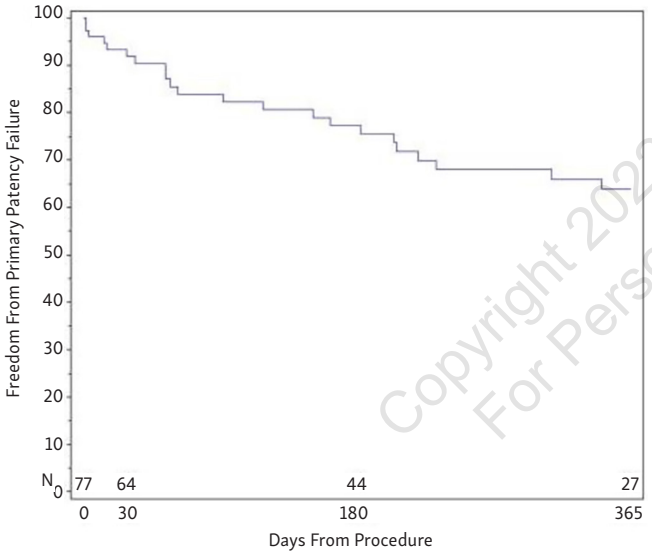


FIGURE 5. Freedom from primary patency failure (regardless of relationship to the MicroStent).

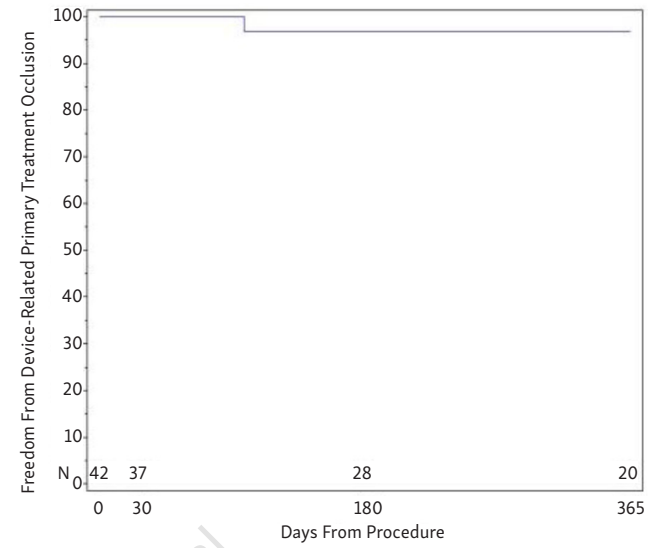


FIGURE 6. Freedom from device-related primary patency failure (where the MicroStent was implanted as bailout option after a failed treatment of the target lesion).

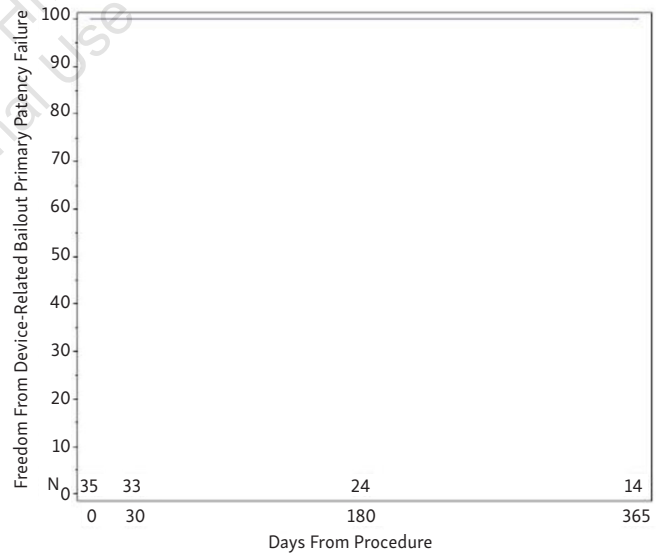


FIGURE 7. Freedom from device-related primary patency failure (when the MicroStent is implanted for primary treatment of target lesion).

rate of freedom from major amputation was 97.3% at 30 days and the rate of freedom from major target-lesion reintervention was 98.6% at 30 days. The freedom from major amputations was 94.9% at 6 months and freedom from major target-lesion reintervention was 96.5% at 6 months. The device-related primary patency, where the MicroStent was implanted for primary treatment of the target lesion, was 96.9% at 6 months and 96% at 12 months by Kaplan-Meier method (**Figure 6**). The device-related primary patency, where the MicroStent was implanted as a bailout option after a failed treatment of the target lesion, was 100% at 6 months and 100% by Kaplan-Meier method (**Figure 7**). Device-related primary patency was defined as only occlusions related to the MicroStent and only CD-TLR related to the MicroStent, as determined by the investigator (compliance with dual-antiplatelet therapy and inline occlusions to the target lesion were considered when determining device relatedness). The study outcomes included device success (98.9%) and technical success (100%). No evidence of stent fractures was noted in these patients and there were no unexpected device-related events reported.

Discussion

The HEAL study is an ongoing, multicenter, postmarket European trial. It includes patients in a real-world setting who had stenting of the lower limb with CE-marked, commercially available sizes of the MicroStent for treatment of severe claudication or CLTI. This manuscript reports on the technical aspects of the MicroStent device and includes case examples and a limited interim dataset of patients with primary and secondary outcomes at 6 months. So far, the HEAL study cohort consists of a true representation of patients encountered in the everyday CLTI practice. Patients have significant comorbidities (including coronary artery disease, diabetes, history of peripheral intervention, history of amputation, history of cigarette smoking), heavily calcified lesions, and a high rate of chronic total occlusions. Importantly, the vast majority of this patient population are real CLTI patients (71.4% were Rutherford Category ≥5 at baseline, with 70% nonhealing ulcers and 20% rest pain patients. Only a small minority are severe claudicants. Unlike other vascular stent procedures, CLTI patients may have multilevel disease and vessels that require multiple procedures to improve blood flow to the lower extremities.[13] Revascularization remains the cornerstone of therapy for CLTI and is recommended by the professional guidelines.[14] To date, plain old balloon angioplasty (POBA) is still an important treatment method in CLTI. However, POBA is limited by the occurrence of recoil and severe flow-limiting dissections.[15-17] Stenting—more specifically, the use of drug-eluting balloon-expandable stents—is feasible in short lesions, but is limited by the need to use multiple stents to achieve full lesion coverage and dissection repair. Thus, there is the need for other treatment options, such as longer devices that do not restrict vessel-wall compliance and flexibility, as much as the traditional balloon-expandable devices do. The MicroStent design minimizes chronic outward force, maximizes radial resistive force (crush resistance), and is highly flexible, allowing for conformity in tortuous anatomy and minimizing flow disturbances. The ability to implant 1 or more overlapping MicroStents allows the treatment of small to very long lesions. In addition, there is evolving value of the utilization of lower compatibility profile devices. With its 3-Fr profile, the MicroStent is the only available stent to date that meets the definition of "micro delivery device." This provides operators a significant advantage and an edge to lead the ongoing struggle in treating CLTI. Current results show that the MicroStent is a safe and feasible treatment option for challenging BTK disease. Of interest, the 6-month results also indicate that there is minimal difference in outcomes when the MicroStent is implanted for primary treatment or is used in a bailout setting. In addition, there are 2 approaches observed when the MicroStent is implanted for bailout. The first approach entails a partial coverage of the lesion (only in areas of dissection/perforation, acute vessel recoil, or persistent residual stenosis of ≥30%); the other approach is full coverage of the entire lesion. A subanalysis of these 2 approaches is planned once additional patients have been enrolled and more follow-up data are available. The HEAL study is a first-of-its-kind study that utilizes a nitinol stent specifically developed for lower-limb treatment. For patients currently undergoing endovascular intervention in Europe, there is no other approved nitinol stent that is specifically designed for the lower limb. The goal of the HEAL study is to continue enrollment and collect long-term follow-up data to conduct further analyses and to keep looking at real-world MicroStent outcomes as well as potential comparisons with other treatment modalities. To demonstrate daily practice, 2 case examples are provided (1 bailout [**Figure 8**] and 1 primary treatment [**Figure 9**]). Both cases show excellent results through 24 months.

Bailout case example. The patient is an 87-year-old male with a body mass index of 27.78 kg/m^2. Medical history included type

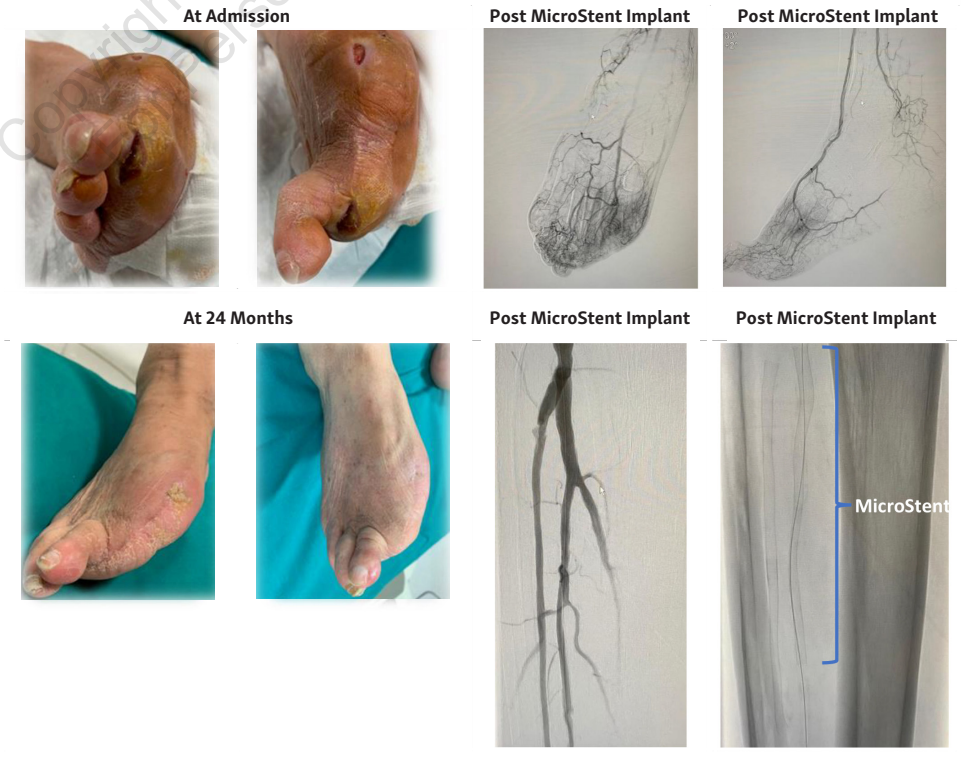


FIGURE 8. Bailout case example.

II diabetes, hypertension, cardiac disease (amyloidosis), acute limb ischemia, BHP, chronic renal failure, and limb neurovasculopathy. Prior target-limb reinterventions included: (1) PTA and bare-metal stenting of the popliteal; and (2) PTA of the anterior tibial artery (middle) and previous amputations of 2 digits. The patient was classified as Rutherford V at admission with 0-vessel runoff and a 4-cm right-limb tibial-peroneal trunk/peroneal lesion, which was 100% occluded with moderate calcification. The patient was implanted with a 3.5-mm x 60-mm MicroStent as a bailout due to dissection post angioplasty. At 12-month and 24-month follow-up, the patient was classified as Rutherford 0. At the 24-month duplex ultrasound, the MicroStent was patent, no stent fractures were visible by x-ray, and the patient had biphasic flow of 60 cm/s. No target-lesion reinterventions have occurred.

Primary case example. The patient is a 59-year-old male with a body mass index of 27 kg/m^2 and type II diabetes. He was a former smoker with history of atrial fibrillation, dyslipidemia, and peripheral arterial disease. He was classified as Rutherford V at admission. At the time of the index procedure, the popliteal artery was treated with PTA; nontarget lesions (tibial-peroneal trunk, posterior tibial, lateral plantar) were also treated with PTA. The 4-cm target lesion in the right proximal anterior tibial artery was 80% occluded (moderate calcification) and implanted with a 3.0-mm x 60-mm MicroStent as a primary treatment. At final angiography, there was 10% residual stenosis. The patient had a preplanned amputation of the right third digit prior to the 30-day follow-up. At 6-month, 12-month, and 24-month follow-up visits, the patient was Rutherford 0. At the 24-month follow-up visit, the MicroStent was patent by duplex ultrasound, no stent fractures were seen by x-ray, and the patient had biphasic flow of 60 cm/s. No target-lesion reinterventions have occurred.

Study limitations. Study limitations include the absence of a comparison group of patients treated contemporaneously with similar disease severity.

Conclusion

Preliminary results from the HEAL study suggest that patients requiring treatment of peripheral artery disease and CLTI in the lower limb can be safely and effectively treated with the MicroStent when used as a primary treatment or bailout option after a failed treatment.

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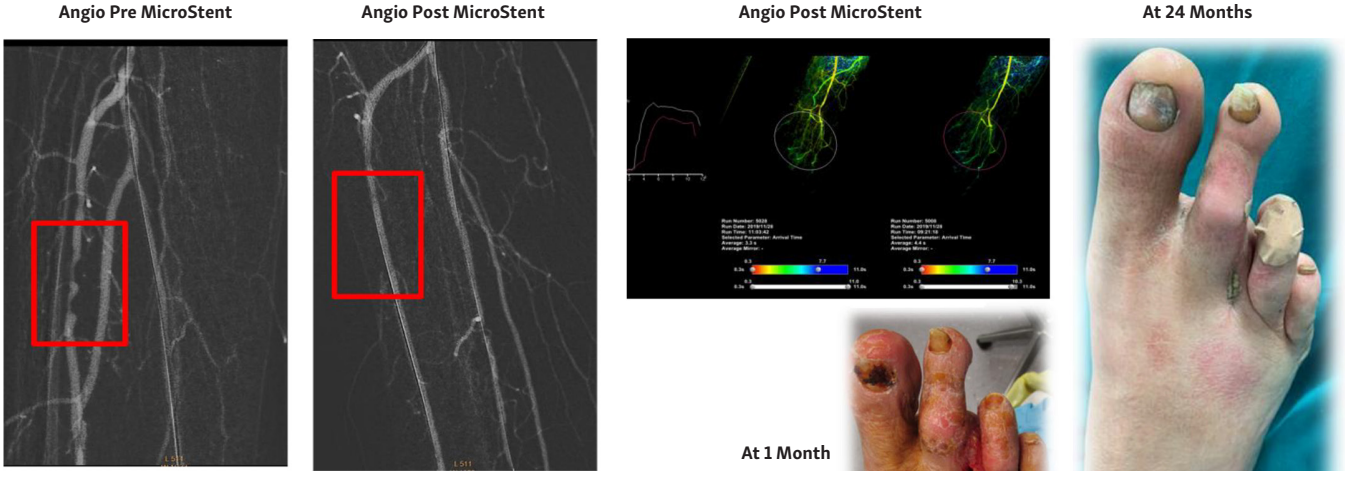

FIGURE 9. Primary case example.

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