

The 2-Year Results of the QualiMed Novel Bi-Directional SFA Stent

A comparative study of safety and efficacy.

The QualiMed Self-Expanding Peripheral Vascular Stent System is a one-of-a-kind Bi-Directional stent designed to resist against the bending, torsion, and compression found in the superficial femoral artery.¹ The unique wave design provides flexibility without sacrificing radial strength and allows for minimal foreshortening. The laser-cut nitinol stent also has tantalum markers, providing excellent visibility under fluoroscopy, and it is mounted on a highly flexible delivery catheter to ensure easy and accurate delivery.

The QualiMed Bi-Directional Self-Expanding Peripheral Vascular Stent was developed to ensure resistance against torsional forces in either direction and provide a flexible and strong stent platform to treat superficial femoral artery disease.

THE Q3 REGISTRY

The Q3 Registry was designed as a prospective, multicenter, postmarket surveillance study to evaluate the effectiveness and safety of the QualiMed Bi-Directional Self-Expanding Peripheral Vascular Stent System. Between December 2014 and November 2017, 193 patients were enrolled with de novo single superficial femoral artery stenosis or occlusion across nine sites in Germany. On average, lesions were treated with 1.4 peripheral vascular stents.

The mean age of the patients was 69.7 ± 10.9 years, 69.9% were men, 37.8% of the patients had diabetes, 11.4% of patients had critical limb ischemia, and the majority had concomitant hypertension or hyperlipidemia.

The mean lesion length was 98 ± 83.9 mm. As for the lesions, 47.7% were totally occluded, 37.3% were heavily cal-

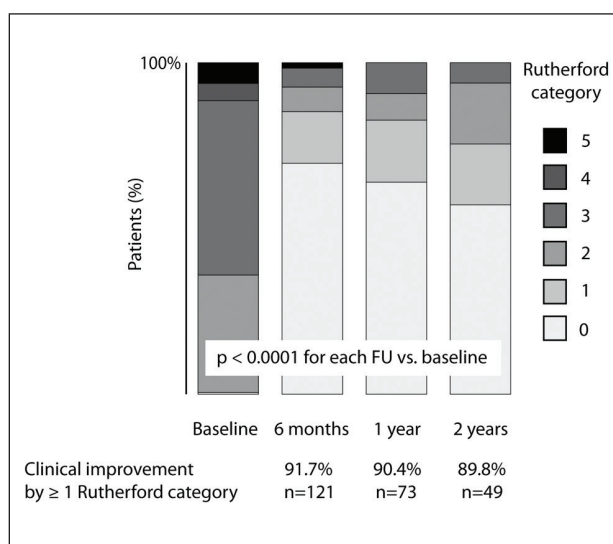


Figure 1. Clinical improvement by one or more Rutherford category was seen in 89.8% of patients at 2 years.

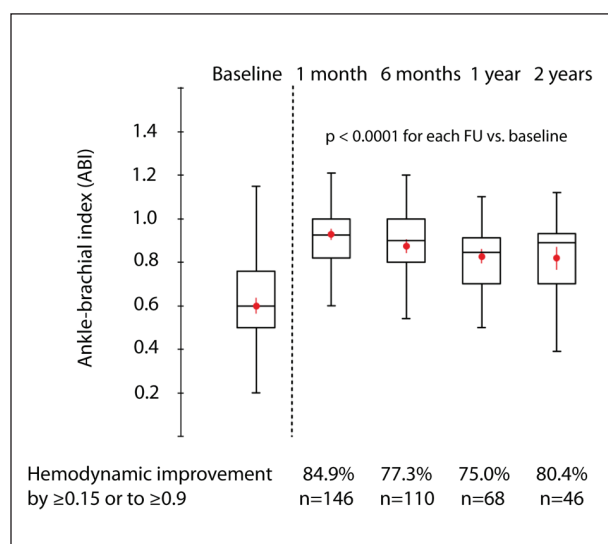


Figure 2. Hemodynamic improvement was seen in 80.4% of patients at 2 years.

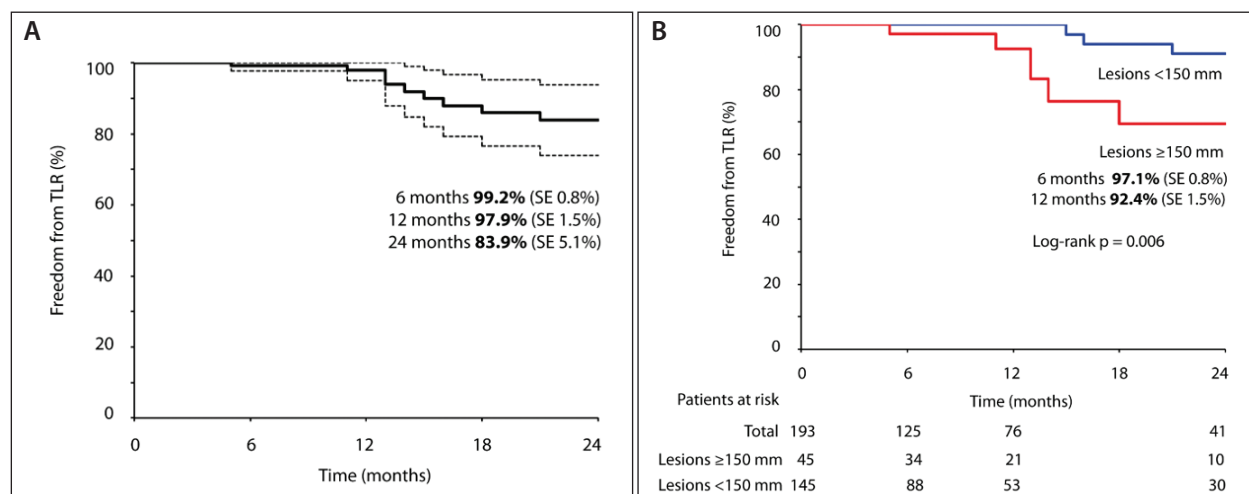


Figure 3. Freedom from target lesion recurrence (A). Duration of freedom from target lesion recurrence was less in lesions ≥ 150 mm compared to lesions < 150 mm (B).

cified, and 23.3% were long (≥ 150 mm). At the time of the analysis, 64.8%, 40.4%, and 26.4% of the patients had completed the 6-, 12-, and 24-month follow-up, respectively.

INTERIM 2-YEAR FOLLOW-UP RESULTS

Technical success (defined as successful access and completion of the procedure and $\leq 30\%$ residual stenosis) was achieved in 99% of the lesions, and acute procedural success (ie, technical success without flow-limiting dissection or major adverse events within 72 hours of the index procedure) was achieved in 96.4% of the patients. Flow-limiting dissection occurred in 2.6% of the patients.

At 2 years, clinical improvement by one or more Rutherford category was achieved in 89.8% of patients (Figure 1), and hemodynamic improvement was seen in 80.4% of patients (Figure 2). Freedom from target lesion recurrence was 99.2%, 97.9%, and 83.9% at 6, 12, and 24 months, respectively (Figure 3A). Time of freedom from target lesion recurrence was shorter in patients

with lesions ≥ 150 mm as compared to lesions < 150 mm (16.6 and 20.7 months, respectively; log rank, $P = .006$) (Figure 3B). There was no patient mortality, and no major amputations were necessary.

CONCLUSION

Interim analysis suggests a comparatively high effectiveness of the QualiMed Bi-Directional Self-Expanding Peripheral Vascular Stent for the treatment of superficial femoral artery disease, with no concerns for patient safety. ■

ClinicalTrials.gov identifier: NCT02307292

Presented at LINC 2018 by Hans Krankenberg, MD, and colleagues.

1. Cheng CP, Wilson NM, Hallett RL, et al. In vivo MR angiographic quantification of axial and twisting deformations of the superficial femoral artery resulting from maximum hip and knee flexion. *J Vasc Interv Radiol.* 2006;17:979-987.