CLINICAL STUDY

Twelve-Month Results of the Nitinol Astron Stent in Iliac Artery Lesions

Mark W. Burket, MD, Marianne Brodmann, MD, Christopher Metzger, MD, Kongteng Tan, MD, and Michael R. Jaff, DO

ABSTRACT

Purpose: To evaluate the safety and efficacy of a self-expanding bare-metal nitinol stent (Astron; BIOTRONIK AG, Bülach, Switzerland) for the treatment of atherosclerotic lesions in the common and external iliac arteries. This study tested the hypothesis that the major adverse event (MAE) rate at 12 months was less than or equal to a performance goal of 15%.

Materials and Methods: In a prospective study that began in November 2011, 161 patients with symptomatic iliac lesions were treated with an Astron stent in the United States, Canada, and Austria. The primary endpoint was a composite rate of procedure- and stent-related MAEs at 12 months that included 30-day mortality, clinically indicated target lesion revascularization (TLR), and index limb amputation.

Results: The MAE rate at 12 months was 2.1% (3/146; [95% CI: 0.4% to 5.9%]; $p < 0.001$). The acute procedural success and 30-day clinical success outcomes were both 95% (153/161). The primary patency rate at 12 months was 89.8% (115/128). The comparison of baseline and 12-month Ankle Brachial Index (ABI) measurements showed a mean increase of 0.23 ± 0.19 ($p < 0.001$). The Walking Impairment Questionnaire (WIQ) PAD specific score, walking distance score, walking speed score and stair climbing score paired each showed a significant increase from baseline to 12 months ($p<0.001$).

Conclusions: The Astron stent system was shown to be safe and effective in the treatment of patients with atherosclerotic disease. The observed MAE rate met the pre-specified performance goal of 15%. The stent demonstrated a high 12-month primary patency rate and showed improvement in quality of life measures.

ABBREVIATIONS

ABI = ankle brachial index, ACT = activated clotting time, INR = international normalized ratio, MAE = major adverse event, PTA = percutaneous transluminal angioplasty, TLR = target lesion revascularization, WIQ = Walking Impairment Questionnaire

Percutaneous transluminal angioplasty (PTA) with stent placement has become the standard of care in the minimally invasive treatment of atherosclerotic occlusive disease of the iliac arteries. A meta-analysis of 2116 patients demonstrated superior primary patency for stents compared to PTA alone (1), and the American College of Cardiology/American Heart Association guidelines for the management of peripheral vascular disease gave stents a Class I indication in treating iliac artery stenosis or occlusion (2).

From the University of Toledo Medical Center (M.W.B.), 3000 Arlington Ave, Toledo, OH 43614; Clinical Division of Angiology (M.B.), Medical University Graz, Graz, Austria; Wellmont CVA Heart Institute (C.M.), Kingsport, Tennessee; Toronto General Hospital (K.T.), University of Toronto, Toronto, Ontario, Canada; and VasCore (M.R.J.), Massachusetts General Physicians Organization, Boston, Massachusetts. Received December 3, 2015; final revision received June 6, 2016; accepted June 7, 2016. **Address correspondence to** M.W.B.; E-mail: mark.burket@utoledo.edu

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The aim of this study was to evaluate the safety and effectiveness of a unique silicon carbide-coated nitinol self-expanding stent in treatment of iliac arterial disease, comparing this device to an objective performance criterion.

MATERIALS AND METHODS

Patients

Patients with lifestyle limiting claudication or rest pain with an ABI $\leq$ 0.9 were evaluated against study inclusion and exclusion criteria (Table 1). Suitable candidates provided written informed consent and underwent baseline study measurements including laboratory evaluation, six-minute walk test and angiography.

A total of 474 patients were consented, between July 2011 and September 2013. Of the 474 patients, 68 were deemed clinical screen failures and did not undergo a pre-procedure angiogram due to a failure to meet inclusion/exclusion criteria. An additional 4 patients withdrew consent prior to procedure. Another 241 patients underwent angiography but did not meet angiographic inclusion criteria. A total of 161 patients proceeded to Astron stent placement with the first implantation occurring in November 2011. Final follow-up of patients ended in September 2014.

A total of 161 patients received the Astron stent at 30 sites (27 United States, 2 Canada, 1 Austria). The overall follow-up compliance rate was 97.2% and the cumulative follow-up duration was 154.5 patient-years with mean follow-up of 0.96 years/patient. A total of 145 patients completed the 12-month study visit. The remaining subjects either missed the 12-month visit (n=6), withdrew consent (n=5) or died prior to the 12-month interval (n=5). The mean age of the evaluable patients was 63.6 years with the majority being male (65.2%). Patient risk factors included hyperlipidemia (77.6%), hypertension (72.7%) and patients that were current smokers (48.4%) (Table 2).

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria
Lifestyle limiting claudication or rest pain with ankle brachial index (ABI) $\leq$ 0.9
De novo, restenotic or occluded lesions in the common or external iliac artery
Target lesions $\leq$ 140 mm in length if de novo or restenotic, or $\leq$ 50 mm if occluded
Target vessel reference diameter of 6 to 9 mm by visual estimate
Angiographic evidence of $\geq$ 70% stenosis or occlusion (operator visual assessment)
Exclusion Criteria
Previously stented lesions in target vessel
Target lesion treatment within the previous 6 months
Life expectancy of less than one year
Prior peripheral vascular bypass surgery involving the target limb
Coronary or non-target limb bypass surgery within the previous 30 days
Percutaneous interventional procedure within 30 days of the index procedure
Other arterial lesions in the target limb requiring treatment
Perforation or aneurysm following pre-dilation of the target lesion
Excessively calcified or tortuous target lesion
Major or minor tissue loss in the target limb*
Stroke or transient ischemic attack within the previous six months
Unresolved bleeding disorder (INR $\geq$ 1.6) at the time of the index procedure
Contraindication to anti-platelet or anticoagulant therapy
Hypersensitivity to nickel or amorphous silicon carbide
Renal failure (serum creatinine $>$ 2.5mg/dL)

ABI = ankle brachial index; INR = international normalized ratio.
*Minor tissue loss defined as non-healing ulcer or focal gangrene with diffuse pedal ischemia; major tissue loss defined as tissue loss extending above transmetatarsal level where functional foot is no longer salvageable

Study Design

Following the baseline evaluation, patients were required to have specific laboratory measurements that included creatinine, complete blood count and international normalized ratio (INR). Patients proceeded to the index procedure within 45 days if laboratory exclusion criteria were not met. Anti-platelet therapy was administered prior to and during the index procedure. Aspirin was given pre-procedure with a dosage of 80-325 mg if

Table 2. Baseline Demographics and Clinical Characteristics

Variable	Data
Evaluable patients, n	161
Mean age (y) $\pm$ SD	63.6 $\pm$ 10.1
Male gender, n (%)	105 (65.2)
Diabetes, n (%)	32 (19.9)
Hypertension, n (%)	117 (72.7)
Hyperlipidemia, n (%)	125 (77.6)
Current smoker, n (%)	78 (48.4)
Congestive heart failure, n (%)	11 (6.8)
Ischemic heart disease, n (%)	69 (42.9)
Renal insufficiency, n (%)	11 (6.8)

Note–Results are expressed as the number (percentage) of patients with the characteristic unless otherwise noted.
Criteria for subjects with hypertension and/or hyperlipidemia required treatment with prescription medication. Congestive heart failure was defined as subjects with a left ventricular ejection fraction $<$ 40% or a heart failure diagnosis. Ischemic heart disease history was defined as prior myocardial infarction, angina pectoris, percutaneous or surgical coronary revascularization, positive exercise test or concomitant anti-anginal pharmacologic therapy. Renal insufficiency denoted subjects with a serum creatinine $\geq$ 1.5 mg/dL based on their last measurement prior to baseline.