PERIPHERAL VASCULAR DISEASE

Original Studies

Technique Optimization of Orbital Atherectomy in Calcified Peripheral Lesions of the Lower Extremities: The CONFIRM Series, A Prospective Multicenter Registry

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Objectives: The purpose of CONFIRM registry series was to evaluate the use of orbital atherectomy (OA) in peripheral lesions of the lower extremities, as well as optimize the technique of OA. Background: Methods of treating calcified arteries (historically a strong predictor of treatment failure) have improved significantly over the past decade and now include minimally invasive endovascular treatments, such as OA with unique versatility in modifying calcific lesions above and below-the-knee. Methods: Patients (3135) undergoing OA by more than 350 physicians at over 200 US institutions were enrolled on an “all-comers” basis, resulting in registries that provided site-reported patient demographics, ABI, Rutherford classification, co-morbidities, lesion characteristics, plaque morphology, device usage parameters, and procedural outcomes. Results: Treatment with OA reduced pre-procedural stenosis from an average of 88–35%. Final residual stenosis after adjunctive treatments, typically low-pressure percutaneous transluminal angioplasty (PTA), averaged 10%. Plaque removal was most effective for severely calcified lesions and least effective for soft plaque. Shorter spin times and smaller crown sizes significantly lowered procedural complications which included slow flow (4.4%), embolism (2.2%), and spasm (6.3%), emphasizing the importance of treatment regimens that focus on plaque modification over maximizing luminal gain. Conclusion: The OA technique optimization, which resulted in a change of device usage across the CONFIRM registry series, corresponded to a lower inci-

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INTRODUCTION

Annually, 150,000 patients in the US undergo lower extremity amputation due to advanced peripheral artery disease (PAD), a disease which affects 12–20% of Americans 60 years of age and older [1,2]. PAD incidence is likely to increase, driven by an aging population, increasing obesity and the concomitant increases in diabetes, hyperlipidemia, hypertension, and coronary artery disease, all of which are risk factors for PAD. The diffuse atherosclerotic lesions that restrict blood flow to the lower extremities in PAD often produce symptoms that range from intermittent claudication to critical limb ischemia (CLI) which is characterized as pain at rest, non-healing wounds, and gangrene [3]. PAD that results in CLI is associated with significant morbidity and mortality: within the first year of a CLI diagnosis, 25–30% of patients will die and 30% will undergo amputation [4].

In the last decade, considerable progress has been made in the treatment of PAD via percutaneous methods, however, key challenges remain. Angiography underestimates severe calcium by greater than 50% [5]. Interventions to treat calcified peripheral lesions are technically challenging and can be difficult to balloon or stent, often requiring high pressure balloon angioplasty [6]. Calcified lesions are also associated with a higher procedural complication rate (i.e., higher frequency of dissections and bail-out stent placement) that may be a negative predictor of long-term durability. Since high calcium burden and small vessel size in the peripheral vasculature remains a common occurrence, a one-size-fits-all solution continues to be elusive. Multiple percutaneous catheter-based technologies have been developed and refined to address the large clinical unmet need of PAD patients for which effective long term clinical outcomes are lacking.

The Orbital Atherectomy System (OAS) developed by Cardiovascular Systems, Inc. (CSI, St. Paul, MN) offers a versatile solution for removal of peripheral plaque as previously described [7–9]. CSI sponsored three consecutive prospective registries utilizing orbital atherectomy from October 2009 to June 2011: CONFIRM I, II, and III. These registries, which were not constrained by inclusion or exclusion criteria (medically necessary treatment per IFU was the only requirement for the study), were characterized by use of a common protocol which remained essentially unchanged throughout, affording the ability to review results discreetly as well as in aggregate. In total, 3135 procedures collected at more than 200 US institutions involving 4766 lesions are represented in the dataset, making the combined CONFIRM registries the largest and most unique resource of its type in existence.

METHODS

Registry Patients and Data Collection

The CONFIRM registry series prospectively enrolled patients on an “all comers” basis without exclusion, the only inclusion criteria being medically necessary treatment in accordance with the device’s Instructions for Use (IFU). Informed, written consent was obtained for all participants of the CONFIRM registries.

Data collected included demographics; ABI and Rutherford Classification; co-morbidities; lesion characteristics including length, plaque morphology and extent of stenosis pre- and post-treatment; device usage parameters; and procedural outcomes. Plaque morphology was reported by the principal interventionalist using the following criteria: severe calcium (≥75%), moderate calcium (50–75%), mild calcium (25–50%), minimal calcium (<25%), fibrotic, or soft plaque. Plaque reduction was determined angiographically by the principal interventionalist with no core lab adjudication. Procedural complications were reported by the principal interventionalist with no core lab adjudication. Slow flow was defined as sluggish flow post treatment as compared to pre-treatment. Abrupt closure/no reflow was defined as closure of the vessel, typically related to vessel recoil, intimal flap formation, or embolization. Spasm was reported as constriction of the vessel as seen on cine. Thrombus was defined as a blood clot and macro-embolization was reported if there was flow limiting debris. The CONFIRM data was analyzed to provide descriptive data about the population treated and procedural outcomes.

Device Description

All patients were treated with the OAS manufactured by CSI (St. Paul, MN). Three device iterations were evaluated over the Series. CONFIRM I evaluated the Diamondback360 exclusively (n=733 subjects; 1146 lesions);
CONFIRM II evaluated the Predator360 exclusively (n = 1127 subjects; 1734 lesions); and CONFIRM III evaluated all devices: Diamondback360°, Predator360°, and Stealth360° (n = 1275 subjects; 1886 lesions).

In contrast to other atherectomy devices, filtration is not required as the differential sanding mechanism of the device removes particles small enough to be naturally absorbed by the body via the reticuloendothelial system, otherwise known as the mononuclear phagocytic system (MPS). Crown sizes range from 1.25 to 2.25 mm, allowing for treatment of vessels throughout the lower extremities, from above-the-knee all the way to the foot. The OAS consists of a low-profile catheter with an eccentrically mounted diamond-coated crown, control handle with control knob, flexible drive shaft, and protective sheath (Figs. 1–3). The flexible drive shaft and crown travel and rotate over a guide wire, and, as the diamond-coated abrasive crown orbits at high speeds, plaque is sanded away differentially with each pass. The OAS first received FDA clearance for US market release in 2007 for treatment of occlusive arterial atherosclerotic disease, and to date, more than 70,000 patients have been treated with the various product iterations.

Statistical Methods

Data regarding patient characteristics are reported as frequency counts and percentages. Percentages are computed using available data only, with missing values excluded from analyses. Means and standard deviations are reported for quantitative measurements, whereas minimum and maximum values are reported to indicate data ranges. Relationships between various patient or lesion characteristics and patient outcomes were analyzed by a chi-squared test (for categorical measurements) or ANOVA (for quantitative measurements). Rarely observed data categories were combined (e.g., pre-treatment stenosis percentages of less than 70% were collapsed into a single category of stenosis ≤70%) as necessary to allow sufficient counts in cells for valid Chi-square analysis. P-values < 0.05 are considered statistically significant.

RESULTS

Overall Results: Patient and Lesion Characteristics

Patients in the CONFIRM registries had a profile typical of the PAD population. They tended to be male (60%), mean age of 71.5 ± 10.5 years (range 24–99), previous or current smokers (73%) with high occurrence of co-morbidities: hypertension (92%), hyperlipidemia (81%), coronary artery disease (66%), diabetes
The 3135 patients had 4766 treated lesions (averaging 1.5 ± 0.8 treated lesions per patient). Mean lesion length was 72.3 ± 71.9 mm, with a range of 1.0–600.0 mm. Eighty-one percent of treated lesions were scored by the principal interventionalists as having either severe (43.6%) or moderate (37.5%) calcification. Stenosis among patients at presentation for treatment was profound, averaging 88% ± 12%. Overall plaque burden was reduced by more than 50% as indicated by angiogram (visually estimated by physician) following athrectomy. Final residual average stenosis was 10% +/-11% with adjunctive treatments, typically low-pressure PTA. Lesion compliance, measured as maximum balloon inflation pressure, averaged 5.7 ± 2.9 atm; inflation time averaged 143 sec. Forty-six percent of lesions were located above the knee, 36% below the knee, and 16% in the popliteal artery, with approximately 20% of patients presenting with multi-vessel disease (Table I).

### Procedural and Outcome Data

Run time with the OAS averaged 116 ± 74 sec. Number of devices and adjunctive treatments were 1.1 ± 0.3 and 1.2 ± 0.5, respectively. The most common adjunctive therapy used following orbital sanding was balloon angioplasty in 73.3% of the lesions. The second most frequently used adjunctive therapy was stenting, used for 5.7% of the lesions. Stents were placed for the following reasons: planned decision to place the stent prior to or during the procedure but was not related to a suboptimal result (>30% residual stenosis or a procedural event); stent placed due to suboptimal result (>30% residual stenosis); stent placed due to complication. Complication rates were low, the most common being dissection (11.3%), spasm (6.3%), and slow flow (4.4%), with low incidence of embolism (2.2%), vessel closure (1.5%), thrombus (1.2%), and perforation (0.7%). Procedural events are summarized in Table II. There were no patient predictors of procedural events.

### Patient Predictors of Calcification

Presence of co-morbidities including diabetes, CAD, renal disease, hypertension, and hyperlipidemia, were statistically greater in patients presenting with moderate and severe calcification compared to other types (mild/minimal calcium or fibrotic/soft) (Table III). Gender, ankle brachial index (ABI), and smoking status were found to be similar across plaque types.

### Plaque Reduction and Modification by Morphology

Plaque removal was highest in severely calcified lesions (54%) and lowest for soft plaque (41%). Overall, plaque removal decreased with decreasing calcium burden. Plaque removal was similar for fibrotic and minimally calcified plaque (Table IV).

### Cross Series Device Usage and Plaque Removal

Device usage and plaque removal and modification varied across the three CONFIRM Series. The OAS spin times were significantly longer in CONFIRM I compared to CONFIRM II and III (P < 0.001), with no difference between latter studies (Fig. 4). Smaller crowns were increasingly used in CONFIRM II and III compared to CONFIRM I (Fig. 5). These differences...
corresponded with significantly lower procedural events, including slow flow, vessel closure, and spasm, in the latter studies compared to CONFIRM I (Fig. 6) and higher post-procedural stenosis across the Series (32, 34, and 39% for CONFIRM I, II, and III, respectively). Overall plaque removal diminished across the Series (Fig. 7).

**Results Comparison by Lesion Location: ATK versus BTK versus POP**

Subjects with below-the-knee (BTK) lesions had a higher mean Rutherford classification and incidence of diabetes, whereas the mean lesion length was intermediate to above-the-knee (ATK) and popliteal (POP) lesions. In regards to the BTK lesions, the pre-procedural

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**Table III. Patient Predictors of Plaque Morphology for the CONFIRM Series**

| Characteristics   | Severe/moderate calcification | Mild/minimal calcification | Fibrotic/soft       |
|-------------------|-------------------------------|---------------------------|---------------------|
|                   | N    | Mean ± SD or N (%) | N    | Mean ± SD or N (%) | N    | Mean ± SD or N (%) |
| Age               | 3694 | 71.6 ± 10.4       | 569  | 72.2 ± 11.3       | 191  | 68.9 ± 11.1        |
| Diabetes          | 3812 | 2375 (62)        | 586  | 276 (47)         | 200  | 111 (56)           |
| Coronary artery disease | 3788 | 2640 (70)      | 586  | 346 (59)       | 199  | 85 (43)            |
| Renal disease     | 3803 | 1518 (40)        | 577  | 156 (27)        | 200  | 55 (28)            |
| Hypertension      | 3835 | 3570 (93)        | 586  | 517 (88)        | 201  | 178 (89)           |
| Hyperlipidemia    | 3805 | 3167 (83)        | 585  | 450 (77)        | 201  | 155 (77)           |
| Mean Rutherford   | 3785 | 3.68 ± 1.27      | 579  | 3.36 ± 1.29     | 197  | 3.28 ± 1.12        |

**Table IV. Reduction in Plaque Burden by Morphology for the CONFIRM Series**

| Plaque morphology | N    | Mean | SD   | P    |
|-------------------|------|------|------|------|
| Severe calcium     | 1966 | 54%  | 21%  | <0.001|
| Moderate calcium   | 1690 | 52%  | 20%  |      |
| Mild calcium       | 430  | 50%  | 21%  |      |
| Minimal calcium    | 121  | 45%  | 20%  |      |
| Fibrotic           | 167  | 45%  | 20%  |      |
| Soft               | 30   | 41%  | 22%  |      |
percent stenosis was higher while post-procedural percent stenosis was lower. The rate of spasms and perforations were higher than other locations, while the overall dissections (all types) and emboli were significantly reduced BTK. Compared to other lesion locations the ATK lesions were less frequently associated with renal disease and coronary artery disease (CAD). For ATK lesions, the mean Rutherford classification was lower, ABI was less compromised, and maximum balloon inflation pressure was higher compared to other lesion locations. In accordance with larger ATK vessel size, spasm occurred less often, average spin time was increased, and larger crown sizes were more frequently selected. Popliteal lesions had similar rates of dissection (all types), perforation, and embolism compared to ATK lesions (Table V).

**DISCUSSION**

The CONFIRM registry series demonstrated the unique ability of orbital atherectomy to preferentially remove calcium over soft plaque. Among available endovascular treatments, including atherectomy, most products fail to address the complicating factor of calcification which is commonly associated with adverse procedural events (e.g., dissection rates as high as 74% following angioplasty) [6]. The rate of dissection for the

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**TABLE V. Data Summary by Lesion Location for the CONFIRM Series**

| Summary by subject | ATK | BTK | POP | P-value | A vs B | A vs P | B vs P |
|--------------------|-----|-----|-----|---------|--------|--------|--------|
| Male (%)           | 59  | 62  | 56  | 0.32    | 0.40   | 0.06   |
| Age (years)        | 71.0±10.2 | 72.5±10.6 | 72.5±10.8 | <0.001 | <0.001 | 0.99   |
| Diabetes (%)       | 54  | 68  | 60  | <0.001 | 0.003  | <0.001 |
| CAD (%)            | 65  | 70  | 67  | 0.005  | 0.36   | 0.18   |
| Renal disease (%)  | 33  | 41  | 40  | <0.001 | <0.001 | 0.72   |
| Hypertension       | 92  | 92  | 92  | 0.47   | 0.62   | 0.92   |
| Hyperlipidemia     | 82  | 80  | 82  | 0.11   | 0.88   | 0.26   |
| Past/current smoker (%) | 81  | 70  | 75  | <0.001 | 0.001  | 0.03   |
| Mean Rutherford    | 3.4±1.2 | 3.9±1.3 | 3.7±1.2 | <0.001 | <0.001 | <0.001 |
| ABI                | 0.63±0.29 | 0.59±0.24 | 0.59±0.25 | 0.05   | 0.19   | 0.8    |

| Lesion characteristics | ATK (n=2213) | BTK (n=1708) | POP (n=786) | P-value | A vs B | A vs P | B vs P |
|------------------------|--------------|--------------|--------------|---------|--------|--------|--------|
| Moderate/severe Ca²⁺ (%) | 82           | 84           | 83           | 0.24    | 0.42   | 0.92   |
| Mean lesion length (mm) | 77.1±77.3    | 74.3±72.0    | 53.6±47.8    | 0.24    | <0.001 | <0.001 |
| % Stenosis (Pre-)      | 87±12        | 90±12        | 87±13        | <0.001  | 0.43   | <0.001 |
| % Stenosis (Post-)     | 37±19        | 33±20        | 36±19        | <0.001  | 0.29   | <0.001 |
| % Stenosis (Final)     | 11±11        | 10±11        | 11±11        | <0.001  | 0.61   | 0.04   |
| Max. balloon pressure (atm) | 5.8±3.0    | 5.5±2.8      | 5.5±2.9      | <0.001  | 0.04   | 0.55   |

| Procedural complications by lesion | ATK (n=2213) | BTK (n=1708) | POP (n=786) | P-value | A vs B | A vs P | B vs P |
|-----------------------------------|--------------|--------------|--------------|---------|--------|--------|--------|
| Dissections: all types (%)        | 14           | 7            | 12           | <0.001  | 0.13   | <0.001 |
| Perforation (%)                   | 0.4          | 1.2          | 0.5          | <0.001  | 0.005  | 0.09   |
| Slow flow (%)                     | 3.1          | 5.7          | 5.3          | <0.001  | 0.005  | 0.69   |
| Closure (%)                       | 1.4          | 1.6          | 1.3          | 0.54    | 0.79   | 0.49   |
| Spasm (%)                         | 3.5          | 9.8          | 6.7          | <0.001  | <0.001 | 0.01   |
| Embolism (%)                      | 3.2          | 1.0          | 2.4          | <0.001  | 0.55   | 0.02   |
| Thrombus (%)                      | 1.1          | 1.2          | 1.7          | 0.94    | 0.28   | 0.33   |

| Device usage | Run time (seconds) | 123±77 | 109±70 | 113±72 | <0.001 | 0.004 | 0.12 |
|--------------|--------------------|--------|--------|--------|---------|--------|-------|
| Smallest crown sizes used (%)     | 20                 | 85     | 36     | <0.001 | <0.001 | <0.001 |
| Largest crown sizes used (%)      | 66                 | 5      | 43     | <0.001 | <0.001 | <0.001 |

Abbreviations: CAD, coronary artery disease; ATK, above the knee; BTK, below the knee; POP, popliteal
CONFIRM series was 11.3% overall, reporting all dissection types (flow-limiting and non-flow-limiting); however, flow-limiting dissections were as low as 1.8% (CONFIRM III). It is noteworthy that dissections observed in CONFIRM III were associated with angioplasty in the majority of cases (63%). Low rates of embolism (2.2%) were observed in the CONFIRM series (all registries combined) when compared to other atherectomy treatments currently available, some of which have reported clinically significant macroembolization as high as 90% [10]. In such cases, dedicated capture devices, or filters are required; however other treatments may prohibit their use altogether [11,12]. This is an important consideration for physicians in selecting treatments for small distal vessels since the recommended vessel diameter of the embolic protection device is typically recommended between 3–6 mm, and the device must be placed at least 80–110 mm distal to the lesion being treated [13]. In the CONFIRM registry, use of the 1.25 mm crown (max. vessel diameter ~1.8 mm) was used in 21% of the total cases, increasing in use across the CONFIRM series. The maximum mean balloon inflation pressure across the CONFIRM series ranged from 5.5 to 5.8 atm, indicative of the vessel compliance change after atherectomy. These results were similar to the CALCIUM 360 study which provided initial compelling data in favor of orbital atherectomy, with statistically significant differences in procedure related adverse events compared to angioplasty alone [11].

In the CONFIRM registry series, a change in device usage across the studies was evidenced by shorter spin times and selection of smaller crowns in CONFIRM II and III compared to CONFIRM I. This technique optimization corresponded to lower incidence of procedural events including slow flow, vessel closure, and spasm.

**LIMITATIONS**

There are several limitations of this study, the primary being no core lab adjudication of the angiographic data since the appearance and outcomes were determined by the operator and therefore subject to bias. In addition, no long term clinical data were collected and there was no standardized procedural technique across the CONFIRM series. This study was not intended to be a definitive randomized clinical trial comparing OA to any other treatment strategy.

**CONCLUSIONS**

A change in device usage across the CONFIRM registry series corresponded to a lower incidence of adverse events (slow flow, vessel closure, and spasm) irrespective of calcium burden or co-morbidities. A change in device usage across the studies was evidenced by shorter spin times and selection of smaller crowns in CONFIRM II and III compared to CONFIRM I. These changes reflect a growing realization, among interventionalists, that maximizing luminal gain through maximal plaque removal has not translated to optimal long term clinical outcomes for PAD patients, as demonstrated by the high frequency of restenosis resulting from barotrauma and neointimal formation [14]. Therefore, as indicated by the CONFIRM series results, vessel compliance change rather than luminal gain should be the goal of atherectomy.

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