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PERIPHERAL AND CAROTID

First Clinical Experience With Celt ACD®: A Femoral Arterial Puncture Closure Device

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Introduction: *This prospective nonrandomized study compared the safety and efficacy of a novel arterial closure device (ACD) in common femoral artery procedures to that of the FDA submitted historical manual pressure control group, who underwent either a diagnostic angiogram (DA) or a percutaneous coronary intervention (PCI) procedure.*

Methods and Results: *A total of 55 patients were enrolled in this study of the novel ACD. Of the 55 patients, 39 were enrolled in the DA group and 16 were enrolled in the PCI group. Six patients were excluded. A device was deployed in 49 patients. Time to hemostasis (TTH), time to ambulation (TTA), device function, and device-related vascular complications were measured. In the device group, the TTH for the combined DA and PCI patients was 32 seconds (0.54 ± 0.93 minutes), significantly lower when compared with 16.0 ± 12.2 minutes ($P < 0.0001$) for the control group. Overall major vascular complication rate did not differ significantly, device group (1/49) and the historical control group (1/217). TTA in the combined PCI and DA device group was 226.4 ± 231.9 at the German site (site ambulation policy). In the Irish site, the average TTA in the PCI group was 187 minutes ($n = 8$) and 85 minutes ($n = 14$) in the DA group.*

Conclusion: *The Celt ACD® device is safe, effective, and significantly decreases the TTH compared to manual pressure and has a low vascular complications rate. The device may be effective in early ambulation and discharge of patients postcoronary intervention procedures.* (J Interven Cardiol 2013;26:417–424)

Introduction

In the past decade, a variety of arterial closure devices (ACDs) have become available to facilitate the management of access sites after percutaneous vascular interventions.[1] It was estimated that in 2007, ACDs were used to achieve hemostasis at the access site in approximately 30% of the nearly 10 million percutaneous vascular procedures performed in the United States.[2] Along with major complications related to the coronary procedure, such as coronary artery dissection, thrombus formation, and coronary artery spasm leading to acute occlusion of a coronary vessel, there are additional vascular complications related to the site of peripheral arterial access, including hematoma, bleeding, arteriovenous fistula, and pseudoaneurysm. The reported overall vascular complication rates range from 1.5% to 9%.[3–8] Up to 20% of patients who experience such complications require surgical repair.[7] After removal of the vascular introducer sheath, hemostasis is usually achieved by manual compression at the vascular access site with or without the use of adjunctive mechanical compression devices. Thereafter, prolonged bed rest is often recommended. Bed rest and compression are associated with discomfort to the patient. Arterial puncture closing devices have been developed to avoid manual compression and shorten the period of bed rest required postprocedure. Vascular complications increase the length of stay and therefore the overall cost of the procedure.

Celt ACD® Device Description. The Celt ACD® (Vasorum, Dublin, Ireland) vascular closure device was designed to provide immediate hemostasis and permanent closure of a femoral puncture site in a safe and

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effective manner. It is used to close a percutaneously created femoral artery puncture site following a diagnostic or percutaneous coronary intervention procedure, shorten the time taken to perform the closure of the puncture site, and rapidly ambulate patients with or without anticoagulation therapy. The Celt ACD® implant is made from biocompatible stainless steel and is MRI compatible. It is delivered by a single use, disposable unit through the existing sheath and closes the puncture site unlike other closure devices such as AngioSeal (St Jude Medical, St Paul, MN, USA) and Starclose (Abbott Vascular, Abbott Park, IL, USA) where a new sheath must be placed and the puncture site dilated for the closure of 5F holes. Two device sizes have been developed; one which fits a 5F vascular introducer sheath and the other a 6F vascular introducer (targeting vessels dia. >5 mm; Fig. 1). Consequently, it can be used in conjunction with $>95\%$ of diagnostic and therapeutic interventional procedures. The Celt ACD® is inserted in tubular form, through the procedure introducer sheath used by the physician which is positioned through the puncture site and is within the common femoral artery. The distal half of the implant which is deployed on the endoluminal side of the puncture has a number of laser cut longitudinal slits and a similar number of slits are also on the proximal half which is deployed on the adventitial portion of the vessel. The section of the implant between proximal and distil portion does not contain slits. When a force is applied, wings will flair outward at the distal and proximal segments of the implant in a manner independent from each other forming a sandwich closure across the vessel puncture

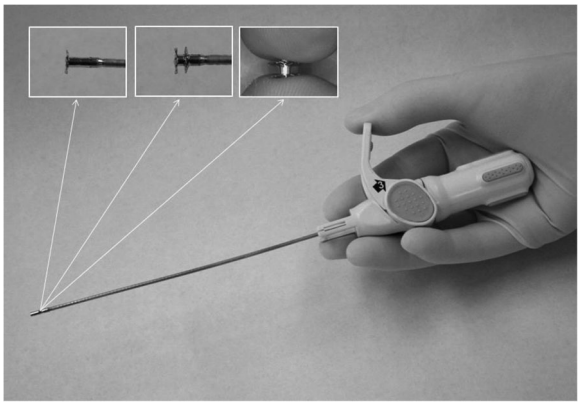

Figure 1. Celt ACD® device with implant highlighted in insets. Insets show proximal wings open, both sets of wings deployed and formed implant held between the finger tips.

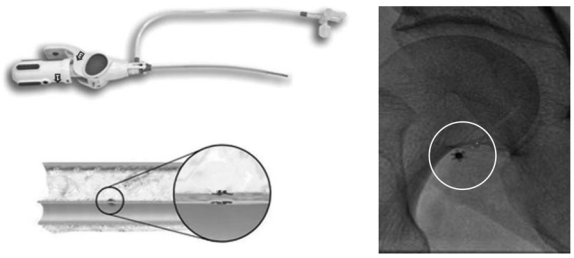

Figure 2. Celt ACD® diagram showing implant in situ in the arterial wall following deployment. Fluorography showing Celt ACD® deployed in the arterial wall postprocedure.

(Fig. 2). The Celt ACD® device achieves closure by deploying the device across luminal and extraluminal segments of the vessel wall at the puncture site. The sequence for device deployment takes approximately 60–90 seconds to complete.

Clinical Evaluation

This European study was carried out to evaluate the safety and effectiveness of the novel ACD in comparison with historical control manual pressure (MC) data as documented in FDA filing P930038 and recorded on the FDA website (www.accessdata.FDA.gov) and peer reviewed medical literature reporting results on vascular access site complications, time to hemostasis (TTH), and time to ambulation (TTA) in patients undergoing percutaneous coronary diagnostic angiography (DA), or percutaneous coronary interventional procedures (PCI) through the femoral artery. The inclusion/exclusion criteria used in this study were identical to those used in the study from which the historical control data were taken.

Study Methods. This European trial was a prospective, nonrandomized study using historical manual pressure data as a control arm. The study was conducted at 2 European Interventional Cardiology investigation sites in Germany and Ireland. Patients between 18 and 85 years of age, scheduled to undergo a diagnostic or interventional coronary procedure, via common femoral artery with a lumen diameter of >5 mm (determined by fluroscopy), using a standard 5F or 6F introducer sheath, were eligible for enrollment in the trial. The exclusion criteria included patients with a coagulopathy or platelet counts $<100 \times 10^9$ per liter, those who had received thrombolytic agents within the previous 24 hours, those with blood pressure of less

than 100 mmHg, those with a life expectancy of less than 1 year, or morbidly obese patients.

Study End-Points. The Primary Efficacy end-points of the study were: (1) TTH, measured in minutes and was compared within a historical control of 16 ± 12 minutes. TTH was defined as the elapsed time from when the procedural sheath was removed from the artery until arterial bleeding had stopped. (2) TTA, measured in hours was defined as the time from postprocedure sheath removal until the patient was comfortable walking approximately 30 ft or 10 m. The Secondary Efficacy end-point of the study was: procedure success, defined as hemostasis achieved by the assigned method, without occurrence of a closure related serious adverse event. The Primary Safety end-point was the comparison of major vascular complication rates associated with the use of the novel ACD with FDA approved historical manual compression as documented by the FDA in the premarket approval (PMA) study P930038 and documented as 0.46% (1/217). The Secondary Safety end-points included minor vascular complications, time to device deployment, time to hospital discharge, procedure success rate and device success rate as documented in the manual compression data in PMA Number P930038.

Study Protocol and Data Collection. The device study protocol was reviewed and approved by the Ethics Committee of each participating medical institution, and all patients granted their informed consent prior to participating in the trial. An enrollment of 50 patients was planned. The enrollment period of the trial lasted 20 months. The first 25 patients were enrolled using a stainless steel delivery system which was a pre-production prototype. A plastic delivery system was subsequently developed and was used in the final 30 patients in the study. The patient clinical follow-up lasted 30/60 days. The data were collected by clinical coordinators at the clinical sites, signed off by the investigating physicians, and managed and analyzed by the Sponsor's Clinical Research Department and an independent statistian from the Department of Pharmacology and Therapeutics Trinity College, Dublin, Ireland. Detailed information regarding the catheterization procedure, including the time to deploy the closure device and removal of the procedural sheath, was recorded. A baseline duplex ultrasound examination of the target femoral artery closure site was required before and 6 weeks to 3 months after the closure procedure in a smaller cohort of patients. After the medical procedure was completed, a femoral angiogram was performed and the activated clotting time (ACT) was measured. At that point, if all the criteria for entry into the trial were satisfied, the device was used to close the femoral puncture site. After the vessel closure procedure was completed, immediate effectiveness and safety end-points were ascertained. All relevant adverse events were recorded. At the time of discharge from the hospital, or on the day the patient was judged by the investigator to be ready for discharge from the hospital, a detailed assessment of medications, pedal pulse score, interim adverse events, and secondary safety measures was performed, and the access site was closely examined for abnormalities such as ecchymosis, swelling, mass, infection, and bruit.

Follow-Up Visit. Patients were scheduled to return for a follow-up visit no earlier than 23 days and no later than 67 days after the procedure. At that time, the patient's interim medical history, clinical status, pedal pulse score, and occurrence of adverse events since hospital discharge were recorded. The access site was examined for abnormalities such as ecchymosis, swelling, mass, infection, or bruit. In addition, patients who had been selected for a baseline duplex ultrasound of the vascular access site underwent repeat ultrasound studies at the 30/60-day visit.

Procedural Anticoagulation. The anticoagulation regimens prescribed in each study subgroup before, during, and after the procedure were left to the discretion of each individual investigator. The numbers and percentages of patients treated with antiplatelet agents, oral anticoagulants, low molecular weight heparin, and intravenous heparin in each study group are shown in Table 1.

Statistical Analysis. This European study was carried out to evaluate the safety and effectiveness of the novel ACD in comparison with historical control manual pressure (MP) data as documented in FDA PMA filing P930038 and recorded on the FDA website (www.accessdata.FDA.gov) and peer reviewed medical literature reporting results on vascular access site complications, TTH and TTA in patients undergoing percutaneous coronary diagnostic angiography (DA), or PCI procedures through the femoral artery. For the effectiveness measure (TTH) descriptive analysis in terms of means, standard deviations, and 95% confidence intervals is presented. An independent Student's *t*-test was performed to compare the mean TTH between the historical controls and device group. For the safety measure (frequency and rate of major complications) descriptive analysis in terms of number

Table 1. Baseline Patient and Procedure Characteristics

	Celt ACD (n = 55)
Patient characteristics	
Age, years	65 ± 20.5 (range)
Female, n (%)	18 (32.7)
Male, n (%)	37 (67.3)
Baseline hematocrit, %	40.7 ± 5.2 (Germany only)
History: n (%) of patients	
Percutaneous coronary intervention	9 (16.4)
Coronary artery bypass graft	0 (0)
Peripheral vascular surgery or graft	5 (10.2)
Hypertension	36 (65.5)
Diabetes	14 (25.5)
Procedure characteristics	
Type of procedure, n (%) of patients	
Diagnostic	39 (70.9)
Interventional	16 (29.1)
Antithrombotic treatment, n (%) of patients	
Aspirin	41 (74.5)
Clopidogrel	27 (49.1)
Clexane (Enoxaparin)	8 (14.5)
Coumadin (Warfarin)	1 (2.0)
Heparin	28 (50.9)
Activated clotting time (seconds)	383 ± 328

and percentage of major complications is presented with 95% confidence intervals. A Fisher's exact test was performed to compare the proportion of major complications between the historical controls and device group. A relative risk (RR) comparing the complication rate in the device relative to the historical control group was calculated with 95% confidence intervals. Significance at $P < 0.05$ was assumed, and SPSS (v16.0) was used for statistical analysis.

Results

Patient demographics for the device group are summarized in Table 1. The device procedure results are summarized in Table 2. In those patients receiving the implant, hypertension was present in 65%, diabetes 25%, peripheral vascular disease 10%, and 16% had a history of a previous percutaneous coronary intervention (PCI). Of the 55 patients enrolled in the study, 49 patients received the novel implant. Of these, 33 patients (67%) underwent a diagnostic procedure and 16 patients (33%) underwent a PCI. All patients were on anti-platelet agents prior to the procedure and 16 patients in the PCI group received intraprocedure IV heparin. The average ACT in the PCI group using the data collected from 13 patients (no ACT recorded for 3 patients) was 332 ± 141 and 118 ± 30 seconds in the DA group which consisted of 29 patients. The meantime to hemostasis was 0.54 ± 0.93 minutes (range) in the device group and this was significantly lower than the 16.0 ± 12.2 minutes ($P < 0.0001$) in the historical FDA approved manual compression control group. One major complication (1.8%) occurred in patient 10 (DA) of this study as a result of the mechanical failure of the delivery system. This resulted

Table 2. Effectiveness and Safety Results Celt ACD (n = 49)

	n (%)
Safety measure to 30/60 days	
Major adverse events composite	1 (1.8)*
Access site-related bleeding requiring >30 minutes for hemostasis	1 (1.8)*
Transient access site-related nerve injury	0
Retroperitoneal bleeding	0
Ecchymosis ≥ 6 cm	0
Decreased pedal pulse	0
Death	1 (1.8) not device related
Effectiveness measures	
Time to (mean ± SD)	
Hemostasis (minutes)	0.54 ± 0.93 (n = 49); CI 95% (0.28–0.80)
Ambulation (hours) range	3.82 ± 3.83 (n = 43)**; CI 95% (157.1–295.7)
Device deployment (minutes) range	1.49 ± 1.26 (n = 43)**
Procedural success (<5 minutes hemostasis)	100%*

*This patient was excluded from the effectiveness analysis but not the safety analysis due to a technical issue with the device delivery system which was subsequently corrected.
**Six patients TTA not ambulated due to medical condition.

in the deployment of the implant (formed normally) intra-arterially. The implant was retrieved under radiological control. The sheath puncture site was inspected and closed by the vascular surgeon with no follow-up complications. The delivery system was modified for all subsequent patients and no further delivery system issues occurred. One minor complication (1.8%) was documented in the study. This was the result of a hematoma occurring in a PCI patient but did not result in the delayed discharge or in any further complications for the patient. Comparison of the major and minor complication rates between the Celt ACD® group and the historical manual compression group shows there is no statistical difference. The documented major and minor complication rates in the historical FDA approved manual compression group are 0.46% and 10%, respectively. Procedural success rate (defined as hemostasis in <5 minutes) was 100% in the Celt ACD® group. Device success rate was 98% (1 failure [2%] of delivery system) and this is defined as the number of devices that functioned as per expected — correctly indicating the location of the arterial wall and correctly deploying the implant to effect hemostasis. A total of 55 patients were recruited into the study and of these, 49 patients are included in the analysis. Of the 6 patients excluded from the analysis, 1 (patient 10) was a result of the failure of the delivery system as described above. A second patient (patient 8a) had the implant correctly deployed in the arterial wall but this was inadvertently pulled out by the investigator prior to release of the implant from the delivery system. This resulted in the implant being deposited in the subcutaneous tissue. Manual pressure was applied using a Femstop device for 1 hour and the patient was ambulated after 4 hours 55 minutes. A clinical decision was made by the investigator to leave the implant in the subcutaneous tissue as is common practice with metallic clips such as those used for varicose vein surgery. The patient had no postprocedure complications and was well on follow-up ultrasound at 2 months. Of the other 4 patients excluded from the TTH analysis, 3 (patients 1B, 3A + 6B) did not receive implant due to a highly calcified femoral artery which is exclusion criteria and the fourth patient (patient 12) had severe peri-sheath bleeding prior to deployment of the implant. This patient developed a hematoma postdischarge and has been documented as a minor complication in the study. The hematoma resolved over a few days and the patient was well on 1 month postprocedure ultrasound. TTA in the combined PCI and DA device group was 226.4 ± 231.9 minutes as a result of policy at the German site not to ambulate for 4 hours postprocedure. In the Irish site, the average TTA in the PCI group was 187 minutes (n = 8) and 85 minutes (n = 14) in the DA group across both sites; in the 31 diagnostic patients TTA was 179.3 ± 89.7 minutes and in the 12 PCI patients 361.67 ± 392.4 minutes. The exclusion of the 6 patients from TTA analysis was as a result of other medical conditions which did not allow them to be considered for the ambulation analysis.

Duplex Ultrasound Results. At the German clinical investigation site, preprocedural duplex ultrasound of the target femoral artery was obtained in 11/22 patients (50%). Immediately postprocedure an ultrasound was obtained in 18/22 (82%) patients and at the 30-day follow-up, ultrasounds were obtained in 17/22 patients (77%). At the Irish site, where the protocol specified ultrasound at the 60-day follow-up, 20/33 (61%) patients had a ultrasound performed. In patients undergoing ultrasound examination of the groin, the duplex ultrasound studies were technically satisfactory in 100% of patients (no turbulent flow or stenosis noted) at both clinical investigation sites. Furthermore no pseudoaneurysms, arteriovenous fistula, or hematoma was observed at either the 30- or 60-day follow-up ultrasounds examination. Patients who did not have follow-up 30 or 60 days ultrasounds were unable to travel to the hospital due to long distance from home. Sample ultrasounds are shown in Figures 3–5.

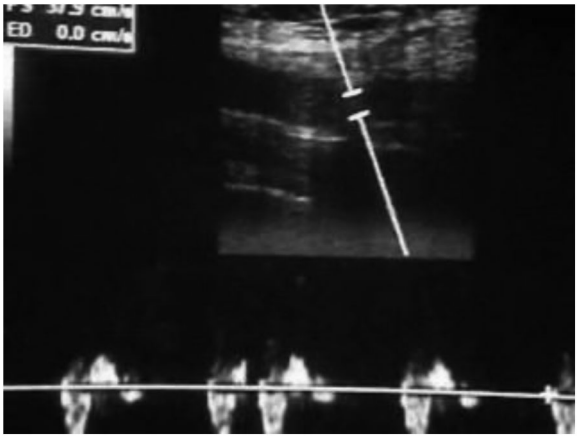

Figure 3. Ultrasound showing normal Doppler signal and normal vessel lumen size above, below, and at the site of implantation. Position of implant indicated by the yellow circle.

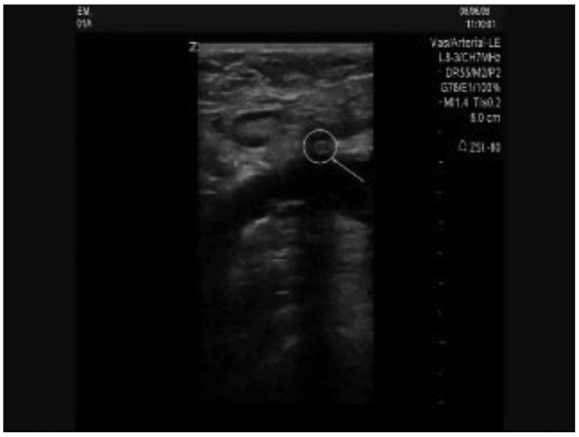

Figure 4. Ultrasound showing normal vessel lumen with implant located in the vessel wall, indicated with yellow circle.

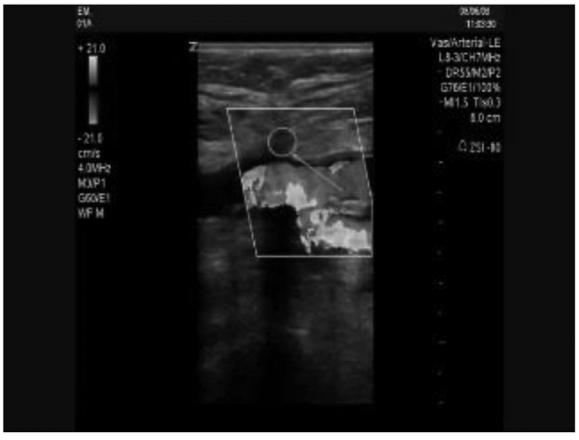

Figure 5. Ultrasound image showing the implant (shown inside yellow circle) located in the common femoral artery above the bifurcation of the superficial and profunda femoris.

Discussion

Several investigators in the field of cardiology have studied the safety of manual compression and early ambulation after transfemoral catheterization.[1,2] However, manual compression is time-consuming and requires prolonged patient bed rest, particularly in patients who have undergone a PCI.[9] It has been shown by several authors that ACDs can contribute to patient comfort, reduce the time to achieve hemostasis, reduce the TTA and contribute to an early discharge.[4,9,10,11] ACDs can also be helpful in hypertensive patients, patients taking anticoagulants, and patients who are unable to lie flat for prolonged periods of time.[12] We report here the first-in-man use of the Celt ACD® in a European clinical trial in which the implant was deployed in 49 patients at 2 European centers. Patients having a diagnostic cardiac angiogram represented 67% (33/49) of the cohort and 33% (16/49) of patients underwent a PCI. In this study, the device proved to be safe and effective when compared to manual pressure. Only 1 major complication was experienced which was a result of a design issue with the delivery system and not with the implant itself. Furthermore only 1 minor complication was experienced, and this was a hematoma which did not prolong the patients stay in hospital. Thirty-one of the 49 patients (63%) in the device group exhibited immediate hemostasis with all other patients exhibiting complete hemostasis in less than 1 minute even in presence of a high average ACT of 332 ± 141 seconds in the PCI group. Several clinical studies including our historical control group (FDA PMA filing P930038) for hemostasis in manually controlled patients showed that hemostasis is obtained at approximately 16 minutes in diagnostic patients following manual compression and at approximately 25 minutes in PCI patients who generally receive large amounts of intravenous Heparin during the coronary procedure (FDA-PMA No: P 9300 38).[13–15] The reported incidents in the literature of major and minor complications after manual compression on the femoral artery puncture site have ranged from 1.5% to 9% (FDA-PMA No: P 9300 38).[3,14] The lower range of this reported incidence is in keeping with the results observed in the device group of 1 major and 1 minor complication (1.8%). Indeed, if this delivery system failure had not occurred, no major complication would have been observed. Ambulation in the device group was 3.7 hours. This TTA is high due to a 4-hour restriction in ambulation at the German site. However, several of the final 10 patients recruited at the Dublin site were ambulated almost immediately as the clinicians had confidence in the immediate sealing capability of this novel ACD. Currently, there is no perfect closure device and existing devices have significant limitations. Disadvantages of closure devices have included the potential for serious complications such as vessel dissection, occlusion, and distal embolization.[13,15] According to Eidt et al.[8] the most common major device-related complication is thromboembolic occlusion of the femoral artery at the puncture site, with Koreny et al.[13] reporting an incidence of 0–2% in a meta-analysis of complications reported in the literature following use of ACDs. In this study, there were no incidents of thromboembolic

occlusion of the femoral artery at the puncture site observed, though the study may not be powered to detect this level of complication. The ultrasound study carried out in 76% (37/49) of patients in the study confirmed at 30 or 60 days the excellent results seen clinically immediately postimplantation. The device has several potential advantageous features over currently available ACDs which may offer clinical advantages for the patient and will be the subject of future clinical trials. These include:

1. A shorter TTH than reported for any other ACD and a statistically significant shorter TTH than the manual control group.
2. The lack of necessity to exchange the procedure sheath prior to implantation of the Celt ACD® unlike the Angio-Seal™ (St Jude Medical) and Starclose™ (Abbott Vascular) devices.
3. The ability to clearly see the implant under fluoroscopy which may be advantageous for arterial re-entry for subsequent vascular procedures.
4. The small size of the implant which may facilitate use of the device at vessel bifurcations and in antigrade punctures of the superficial femoral artery and in women with peripheral vascular disease who tend to have small calibre vessels.
5. The lack of any biological tissue which is known to provoke inflammation and groin redness and may be a nidus for infection.
6. The ability to carry out a restick procedure for reentry of the same-side femoral artery immediately should it be clinically necessitated. This immediate reentry ability is currently contraindicated with the Angio-Seal™ device for a period of 90 days, with the other femoral artery being used in the intervening period.

Potential clinical disadvantages include:

1. Loss of the implant in the femoral artery necessitating radiological retrieval.
2. Disruption of the intimal surface of the artery, though in this study it was not observed clinically or in the ultrasound study.
3. Implant is pulled out of the artery into the surrounding tissue; any resulting damage to the artery is mitigated as the wings are designed to bend forward when force is applied.

In the current European study, the patients reported excellent comfort though this was not formally assessed and the data collected anecdotally. It is anticipated that a pain score study will be carried out in the future. An excellent level of comfort for the patient is anticipated since the implant is delivered locally on both sides of the femoral puncture and is not introduced at skin level thus avoiding painful compression of branches of the femoral nerve on top of the femoral artery.

Study Limitations. As mandated by the protocol, patients with femoral arterial disease and moderate calcifications at the site of sheath insertion or whose femoral artery was cannulated within the prior 30 days were excluded from the trial. The study reports the first-in-man results of a device which is now CE marked. However, there are limitations posed by its limited size, strict exclusion criteria, and historic control. Several postmarketing studies are underway or planned and an FDA approved study is currently recruiting, in a 207 patient multicenter randomized 2:1 control trial in PCI patients only.

Conclusions

Celt ACD® is effective in decreasing mean TTH as it showed a significant decrease in the TTH in comparison to manual pressure. Celt ACD® is comparable with manual pressure in terms of major and minor complications and shows normal ultrasound images of the test arterial implantation site at 30- or 60-day follow-up scan. It is thus a safe and effective device, which will be of significant benefit to patients. Further studies will be required in the postmarketing phase to demonstrate the many potential clinical advantages that the Celt ACD® may offer patients in comparison with currently available ACDs.

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