Safety and Efficacy of Arterial Closure Devices in an Office-Based Angiosuite

Lauren E. Jones,[1] Keun Ho Yang,[2] Robert W. Feldtman,[1] Pablo V. Uceda,[1] Craig A. Ferrara,[1] Joseph M. Caruso,[1] Jasmine L. Richmond,[1] and Samuel S. Ahn,[1] Dallas, Texas and Seoul, South Korea

Introduction: We aimed to compare the safety and efficacy of 5 arterial closure devices in an outpatient endovascular surgery center.

Methods: We retrospectively reviewed all cases using femoral arterial access performed between January 2012 and December 2013. Five different arterial closure devices (AngioSeal, Perclose, StarClose, ExoSeal, and Mynx) were used by 7 endovascular surgeons. All femoral arteries were accessed with 6F sheaths under ultrasound guidance. All patients received systemic anticoagulation with sodium heparin (70 IU/kg). Sheath-shot angiograms of all arterial punctures were taken before deploying closure devices. Device failure was defined as any partial or complete failure requiring additional closure assistance. Minor complication was defined as any event that occurred because of incomplete hemostasis but did not result in hospitalization, including hematoma, hypotension, bleeding, arterial dissection, or extended recovery. Major complication was defined as any event that occurred because of incomplete hemostasis requiring inpatient management. Any device failure was identified per device and per surgeon. Device safety, efficacy, and relationships between other variables were analyzed using a binomial logistic regression. Results with P values < 0.05 were considered to be statistically significant.

Results: During the study period, there were a total of 3142 endovascular procedures, including 1976 arterial cases (62.9%). Out of 1898 femoral artery punctures, closure devices were used in 1810 (95.4%), which forms the basis of this report. Device failure occurred in 151 cases (8.34%), and minor complications occurred in 53 cases (2.93%). There were 11 hospitalizations (0.61%). AngioSeal had both the lowest device failure rate (3.5%) and minor complication rate (1.3%). Our data showed a significant difference between the respective arterial closure devices for device failure rate ($P = 0.007$) and minor complication rate ($P = 0.049$), but not for major complication rate ($P = 0.199$). No significant difference was observed between surgeons for device failure ($P = 0.798$), minor complication ($P = 0.218$), or major complication rate ($P = 0.899$).

Conclusions: With the lowest device failure and minor complication rate, AngioSeal is a consistently well-performing arterial closure device in the office surgical suite setting.

INTRODUCTION

Office-based endovascular procedures offer many advantages compared with those performed on an inpatient basis, including cost-effectiveness and convenience for both patients and physicians. These factors have influenced the move toward office-based angiosuites in the United States.[1] With the

Presentation information: This study was presented in part at the Outpatient Endovascular and Interventional Society Annual Meeting, Austin, TX, on May 16, 2014, and at the VEITH Symposium 43rd Annual Meeting, New York, NY, on November 15, 2016.

[1]*DFW Vascular Group, Dallas, TX.*

[2]*Division of Vascular Surgery, Department of Surgery, Paik Hospital, Inje University College of Medicine, Seoul, South Korea.*

Correspondence to: Samuel S. Ahn, DFW Vascular Group, 221 W Colorado Blvd, Pavilion II Suite 625, Dallas, TX 75208, USA; E-mail: ssahn100@gmail.com

Ann Vasc Surg 2018; 51: 10–17
https://doi.org/10.1016/j.avsg.2018.02.011

Manuscript received: October 10, 2017; manuscript accepted: February 19, 2018; published online: 13 April 2018

increase in frequency of office endovascular procedures, the number of arterial endovascular interventions also increased as a percentage of total procedures performed.[2] Because most complications requiring further treatment or hospitalization involve the puncture site, safe and effective control of arterial hemostasis is critical, especially in an office-based environment where support staff and emergency resources may be limited.

Different arterial closure devices have individual drawbacks stemming from their distinct structural and functional mechanisms. Nevertheless, understanding these differences is imperative to achieve optimal results. When used incorrectly, they can act as new sources of complication. Thus, every surgeon must understand their mechanisms of action, methods for use, any potential complications they may expect to encounter, and their individual effectiveness. With such a wide variety available, our aim was to evaluate and compare the safety and efficacy of these different devices among different surgeons in our office-based angiosuite.

MATERIALS AND METHODS

With appropriate Aspire Institutional Review Board approval, we retrospectively evaluated all endovascular cases with femoral arterial punctures performed in our angiosuites between January 2012 and December 2013. Waiver of informed consent was granted by Aspire Institutional Review Board. Procedures were performed by any of our 7 respective surgeons. We obtained patient's demographic data and risk factors that were entered prospectively using Vascunote® (VMA, Los Angeles, CA), our specialized endovascular procedure software for patient registration and coding. Patients were followed up for 30 days postoperatively. Each device failure, minor complication, and major complication requiring hospital transfer were counted and documented per device and per surgeon.

Closure Devices

We evaluated the AngioSeal VIP (St. Jude Medical, St. Paul, MN), the Perclose ProGlide (Abbott Vascular, Abbott Park, IL), the StarClose (Abbott Vascular), the Mynx Grip (Cardinal Health, Dublin, OH), and the ExoSeal (Cordis Corporation, Bridgewater, NJ).

Procedure

Most patients were selected with the intention to treat based on clinical examination and noninvasive laboratory testing. Exceptions included diagnostic cases, such as aortic arch angiograms in preparation for carotid endarterectomy or stent. After injection with lidocaine, all patients were cannulated with 21-gauge entry needles under ultrasound guidance and then accessed with 4F, 5F, or 6F sheaths. All femoral punctures were made with ultrasound guidance. Some punctures were made via stented and/or calcified femoral arteries, if needed. All procedure details, including the condition of the accessed femoral artery, introducer sheath size, indications for intervention, and patient anticoagulation status, were recorded at the time of procedure in Vascunote. Immediately after achieving access, all patients with the intention to treat were administered systemic anticoagulation with sodium heparin (70 IU/kg). Additional heparin was given as needed during procedure, according to time interval and physician preference. Heparin was not reversed.

Sheath-shot angiograms were taken of all arterial punctures just before deploying the closure device. All closure devices used in our practice are 6F. Manual compression was used in a small percentage of cases, mostly when 4F or 5F sheaths were used or the vessel was too small for a closure device (<4 mm). Device selection was primarily based on each surgeon's preference as well as the local anatomical indications determined by angiographic evidence. For example, the Mynx device was used preferentially for smaller vessels of 4–5 mm in size, and we tended to avoid using Mynx or Perclose for highly calcified or stented arteries. After successful device placement, patients were seated upright within 30–60 min and were ambulating within 1–2 hr. Additional devices were deployed to achieve hemostasis in 31 instances of Perclose primary closure device failure. In most other failure cases, only instant manual compression was applied, and at the surgeon's discretion, a FemoStop® (Radi Medical Systems Inc., Reading, MA) was applied for 30–60 min. Patients with persistent bleeding were admitted and treated as needed after achieving hemostasis.

After successful hemostasis, patients were issued oral and written instructions to be followed for the subsequent 24 hr. Immediate management for bleeding at the puncture site was explained. Most patients were eligible for discharge within 1–2 hr postoperatively, in accordance with our standardized postprocedural protocol. In cases where the surgeon anticipated the need for additional recovery time and observation, we transferred the patient to the hospital for overnight observation.

Definitions for Major Endpoints

Device Failure. Device failure was defined as any partial or complete failure of the arterial closure device in achieving complete hemostasis; the need for additional closure assistances, such as an additional closure device, manual compression, extended recovery, or FemoStop; or admission in connection with the femoral access site. Only 1 ''primary'' closure device per femoral puncture site was counted for data analysis.

Minor Complication. Minor complication was defined as any event that occurred because of incomplete hemostasis, resulting in hematoma, bleeding, hypotension, arterial dissection, or prolonged recovery not requiring inpatient management. Prolonged recovery was defined as that exceeding 2 hr. Hematoma was defined clinically as any documentation noted for this problem.

Major Complication Requiring Hospitalization. Any instance of inpatient or emergency department management related to arterial access, including hematoma, bleeding, retroperitoneal bleed, or thrombosis, was counted as a major complication requiring hospitalization regardless of length of stay.

Statistical Analysis

Categorical variables were listed as count and percent when normally distributed or otherwise as median. Demographic and comorbidity information was entered by patient. No malfunctioning devices were excluded from the study. Categorical variables were subjected to χ^2 analysis for large groups and Fisher's Exact Test for small groups. A binomial logistic regression analysis was performed to analyze the relationships between the rates of device failure, surgeon, complication rate, and hospitalization rate. All analyses were performed using the statistical software R, a freeware published by the R foundation. Results with $P < 0.05$ were considered significant.

RESULTS

A total of 3142 endovascular procedures were performed at our office-based angiosuites between January 2012 and December 2013. These included 1976 (62.9%) arterial cases, with 1867 cases achieving access through one or more femoral punctures. This included 1267 cases (67.9%) involving vascular intervention with angioplasty, stenting, atherectomy, coil embolization, and/or thrombolysis and 600 cases that were purely diagnostic (32.1%). Bilateral femoral arteries were accessed in 31 patients, and 3 separate punctures were made in 1. Any of the 5 arterial closure devices were used to close 1810 of the 1898 total femoral puncture sites (95.3%) in 1220 patients, which forms the basis of this report. The femoral artery was accessed in 88 other cases, in which no closure device was deployed.

Table I. Patient demographic characteristics values reported by patient as number (%) unless otherwise indicated

Characteristic	(n = 1220)
Age, years, mean (standard deviation)	66 ± 13.26
Female	637 (52.21)
Male	583 (47.79)
Diabetes mellitus	554 (45.41)
Hypertension	998 (81.80)
Coronary artery disease	296 (24.26)

Table II. ASA classification values reported as number (%)

ASA class	(n = 1810)
I	7 (0.39)
II	129 (7.16)
III	1581 (87.74)
IV	85 (4.72)
Unavailable	8 (0.44)

Mean age was 66 ± 13.26 years (range = 17–99), and 637 patients were female (52.2%). Common comorbidities include hypertension (81.8%), diabetes (45.4%), and coronary artery disease (24.3%) (Table I). Median American Society of Anesthesiologists (ASA) physical status classification was ASA III (Table II).

In order of frequency, Mynx was used in 598 puncture sites (33.04%), Perclose in 445 (25.1%), followed by StarClose (316, 17.5%), AngioSeal (231, 12.8%), and ExoSeal (210, 11.6%). In the total cohort, there were 151 device failures (8.3%), 53 minor complications (2.9%), and 11 major complications requiring hospital transfer (0.6%) (Table III). The 53 minor complications included hematoma (31, 58.5%), extended recovery (11, 20.8%), bleeding (9, 17.0%), and hypotension (2, 3.8%). There were 11 major complications requiring inpatient management, including hematoma (7, 63.6%), bleeding (2, 18.2%), retroperitoneal bleed (2, 18.2%), and no major complications requiring emergency intervention or surgery (Table IV).

Table III. Device failure, minor complication, and major complication rates for each vascular closure device and for each surgeon values reported as number (%) for each surgeon and each device, individually and cumulatively

		N (%)								
Surgeon		Angio-Seal	ExoSeal	Mynx	Perclose	StarClose	Total	Device fail	Minor compli-cation	Major compli-cation
1	Total	215	76	18	179	3	491	28 (5.7)	7 (1.4)	3 (0.6)
	Device failure	7	3	-	18	3				
	Minor complication	2	3	-	2	-				
	Major complication	3	-	-	-	-				
2	Total	-	1	2	113	199	315	41 (13.0)	23 (7.3)	1 (0.3)
	Device failure	-	-	1	17	23				
	Minor complication	-	-	-	7	16				
	Major complication	-	-	-	-	1				
3	Total	13	19	164	75	1	272	25 (9.2)	10 (3.7)	3 (1.1)
	Device failure	1	3	12	9	-				
	Minor complication	1	2	5	2	-				
	Major complication	-	-	3	-	-				
4	Total	2	24	66	25	112	229	19 (8.3)	6 (2.6)	1 (0.4)
	Device failure	-	3	4	4	8				
	Minor complication	-	1	2	1	2				
	Major complication	-	-	-	-	1				
5	Total	1	1	49	59	-	110	13 (11.8)	1 (0.9)	2 (1.8)
	Device failure	-	1	5	7	-				
	Minor complication	-	-	1	-	-				
	Major complication	-	-	-	2	-				
6	Total	-	83	133	2	1	219	14 (6.4)	2 (0.9)	1 (0.5)
	Device failure	-	8	5	-	1				
	Minor complication	-	-	2	-	-				
	Major complication	-	-	1	-	-				
7	Total	-	6	166	2	-	174	11 (6.3)	4 (2.3)	0 (0)
	Device failure	-	1	9	1	-				
	Minor complication	-	-	4	-	-				
	Major complication	-	-	-	-	-				
Total cases	Total	231 (12.8)	210 (11.6)	598 (33.0)	455 (25.1)	316 (17.5)	1810	151 (8.3)	53 (2.9)	11 (0.6)
	Device failure	8 (3.5)	19 (9.0)	36 (6.0)	56 (12.3)	32 (10.1)				
	Minor complication	3 (1.3)	6 (2.9)	14 (2.3)	12 (2.6)	18 (5.7)				
	Major complication	3 (1.3)	0 (0)	4 (0.7)	2 (0.4)	2 (0.6)				

The AngioSeal device showed both the lowest device failure rate (3.5%) and the lowest minor complication rate (1.3%). Perclose had the highest device failure rate (12.3%), and StarClose had the highest minor complication rate (5.7%). ExoSeal had the lowest rate of major complication requiring hospitalization (0.0%), and AngioSeal had the highest rate of major complication requiring hospitalization (1.3%).

Surgeon 1 had the lowest device failure rate (5.7%), and surgeon 2 had the highest device failure rate (13.0%). Surgeon 5 had a similarly high device failure rate (11.8%) and the highest major complication rate (1.8%). Surgeon 2 had the highest minor complication rate (7.3%), and surgeons 5 and 6 had the lowest rates of minor complication (each with 0.9%). Surgeon 7 had no patient hospitalized (Table III).

Logistic regression analysis showed a significant difference between the 5 arterial closure devices for device failure ($P = 0.007$) and minor complication rate ($P = 0.049$). No significant difference was observed between surgeons for closure device failure, minor complication rate, or major complication rate (Table V).

DISCUSSION

All closure devices were initially designed to target the femoral artery,[3,4] and each has its own unique

Table IV. Minor and major complications associated with each device and for manual compression only

Complication	AngioSeal	ExoSeal	Mynx	Perclose	StarClose	Total	Manual compression
Minor complications							
Hematoma	2	3	6	7	13	31 (58.5)	1 (50.0)
Extended recovery	1	-	5	2	3	11 (20.8)	-
Bleeding	-	3	3	2	1	9 (17.0)	-
Hypotension	-	-	-	1	1	2 (3.8)	-
Arterial dissection	-	-	-	-	-	-	1 (50.0)
Total	3	6	14	12	18	53 (2.93)	2 (2.27)
Major complications requiring hospitalization							
Hematoma	3	-	2	2	-	7 (63.6)	-
Bleeding	-	-	1	-	1	2 (18.2)	-
Retroperitoneal bleed	-	-	1	-	1	2 (18.2)	1 (50.0)
Thrombosis	-	-	-	-	-	-	1 (50.0)
Total	3	-	4	2	2	11 (0.61)	2 (2.27)

Values are represented as number (%). Access site complications for group with manual compression only ($n = 88$) are shown in the last column.

Table V. Binomial logistic regression analyses

Variable	Close failure rates	Minor complication rates	Major complication rates
Surgeon	$P = 0.798$	$P = 0.218$	$P = 0.899$
Device	$P = 0.007$	$P = 0.049$	$P = 0.199$

structure and mechanism of action. The Perclose ProGlide is a suture-mediated device that evolved from the Prostar in 1994. This device has a ''foot'' which carries suture material and acts as an anchor. After ''foot'' deployment, a plunger is depressed to place needles, forming a suture loop. A pretied knot is tightened using the knot pusher to accomplish an arteriotomy closure.[3,5]

The AngioSeal VIP is a bioabsorbable collagen closure device that was approved by Food and Drug Administration (FDA) in 1996. It consists of an absorbable intraluminal anchor, a small bovine collagen plug, and an absorbable traction suture. With the combination of those 3 components, the puncture site can be ''sandwiched'' and sealed.[3,5]

The StarClose, approved in 2005, has ''wings'' and a 4-mm nitinol clip. When the ''wings'' are pulled against the arterial wall (indicating proper positioning), the clip is deployed just outside of the wall. The nitinol staple grasps the edges of the arteriotomy and draws them together to close the hole.[3,4]

The Mynx Grip, approved in 2007, combines a polyethylene glycol sealant (hydrogel) plus a balloon catheter. The sealant is deployed outside the artery while a balloon occludes the arteriotomy site within the artery as an anchor. After the conformable sealant is deployed, the balloon is deflated and removed through the tract.[3,4]

The ExoSeal device delivers a synthetic, bioabsorbable plug to the extravascular space adjacent to the arteriotomy. The dual visual guidance, a bleed-back indicator, and an intraarterial nitinol wire loop with a visual display on the handle help the surgeon determine the proper location of plug deployment.[3–5]

The overall rate of device failure has been reported between 3.3% and 4.3%.[6,7] The failure rate was 2.1% for collagen-based devices, 6.1% for suture-based devices, and 9.5% for nitinol clip-based devices. Without exception, device failure tends to increase the risk of vascular complication compared to successful device deployment.[6]

Whether or not arterial closure devices can prevent puncture site complications remains debatable.[8–17] Arterial closure devices have not yet been definitively shown to correspond with a reduction in major complications. Various authors, however, have reported several benefits. They decrease time required to achieve hemostasis and thus allow for earlier ambulation and reduce the need for hospitalization. Furthermore, in certain populations such as anticoagulated patients, extremely obese patients, or those who have difficulty with prolonged immobilization, recent studies showed that closure devices offered obvious advantages over manual compression.[11,18–20]

We observed a similar minor complication rate and a slightly higher rate of major complication requiring hospitalization in our 88 cases with femoral access and manual compression only compared with the group with arterial closure devices used (2.27% vs. 2.93% and 2.27% vs. 0.61%, respectively) though the differences were not significant (see Table IV). This could be due to better overall vessel quality in patients with manual

compression only, of which 41% of our 88 were not administered with heparin, and nearly 20% were accessed with either a 4F or 5F sheath. In addition, procedure type (diagnostic versus interventional) was positively correlated with minor complication rate, as expected.

Advances made in the past decades led to design improvements allowing for safer use and simplified deployment, but device-related complications remain a concern. Much variation exists in reported rates of major and minor complications across devices as well as in large, randomized studies.[8,9] Chiu et al. observed no major complications and a minor complication rate of 33.7% in 31 patients with the Perclose device.[21] For StarClose, Spiliopoulos et al. reported a cumulative minor complication rate of 5.3% with 2 major complications (0.34%) in 588 patients.[22] Recent evidence showed that AngioSeal had complication rates between 0.4% and 2.5%,[5,23] whereas Fargen et al. observed no significant difference between AngioSeal and Mynx devices in a comparative study of safety with a 3% angiographic complication rate.[24] Kara et al. concluded that the ExoSeal device was associated with a higher complication rate of 3.6%,[5] whereas Boschewitz claimed the device was safe and effective even in antegrade femoral puncture with only 1 minor complication in 148 cases (0.68%).[25]

In a 2015 meta-analysis of 16,868 patients, Jiang et al. showed a reduction in rates of hematoma and combined adverse vascular events with the use of closure devices, with AngioSeal performing the best.[14] Our findings also indicated that AngioSeal had both the lowest failure rate (3.46%) and minor complication rate (1.30%). Although the device failure rate appears higher than that in some previous reports, AngioSeal, as a collagen-based device, showed efficacy and safety on par with the other devices.[6] Of note, AngioSeal may also be used without angiography. Manolis et al. showed this was possible by avoiding both low femoral puncture and entry above the inguinal ligament. This technique could benefit patients with renal disease and those with negative indications for the use of high amounts of contrast or radiation exposure.[26] We do, however, continue to use routine angiography before device selection and deployment.

In a 2014 office-based study by Jain et al., hospital transfer was required in 26 out of 6458 cases (0.4%).[1] Our data showed 11 cases requiring hospitalization from access-related complications (0.6%). Although our hospitalization rate is higher than that Jain et al. reported, the difference is not statistically significant. Furthermore, the Jain et al. cases consisted of nearly 65% arteriovenous fistula and catheter-related procedures, whereas we reported exclusively on arterial interventional cases. Considering Jain et al.'s arterial cohort, our general rate of hospitalization compares favorably (25/2260, 1.11% for Jain's report vs. 11/1810, 0.61% for the present study).[1]

We were also interested in the relationships between surgeons and devices. Each surgeon appeared to prefer certain devices over others and felt more comfortable handling those devices. Despite the reasonable assumption that each surgeon was highly experienced on their preferred devices, they showed different results for device failure rate and complication rate. Surgeon 1 and AngioSeal both had the lowest minor complication rates and device failure rates. Surgeon 1 primarily used AngioSeal, whereas other surgeons did not tend to use AngioSeal frequently.

Although it was the second most frequently used device by surgeon 1, Perclose had the highest failure rate. Surgeons 2 and 5 had similarly high device failure rates. Surgeon 2 used StarClose more frequently than Perclose, and surgeon 5 used Mynx and Perclose with almost equal frequency (Table III).

Our surgeons began using arterial closure devices from the initial opening of our office-based angiosuites in January of 2007. Although 1 joined the group in January of 2011, this surgeon had prior experience using arterial closure devices. Because of this, we assume no operator learning curve and did not include this factor in the study's design. Our data do, however, contain a cohort using the ExoSeal device, approved by the FDA in May of 2011. As a relatively new vascular device, we examined whether or not there was evidence of a learning curve by determining if outcomes improved with operator experience.

A previous study showed that as a novel device, the complication rate of ExoSeal was higher (3.6%) than that of comparator group (AngioSeal + Perclose ProGlide, 1.2%), even in a group of experienced physicians.[5] This difference could suggest that regardless of a surgeon's general experience with deployment of other closure devices, each device may have its own intrinsic risk factors that should be considered to avoid undesirable results.

According to Resnic et al., significant learning curve effects influence the safety and efficacy of a newly introduced novel vascular closure device.[27] They concluded that each attending physician required between 75 and 130 device deployments to establish proficiency and achieve the highest levels of efficacy and safety.[27] We used a total of 210 ExoSeal devices over the course of the study, and the highest number deployed by a single surgeon was 83. During the 24 months of the study

period, only 2 surgeons deployed ExoSeal over 75 times.

In support of Resnic's conclusion, our findings may suggest influence from a learning curve for ExoSeal because it was available for use only 7 months before our study period. We did observe slightly higher rates of device failure and minor complication for ExoSeal (9.0% and 2.9%, respectively) than those for other devices although the differences were not significant. Other devices did, even in the absence of an acclimation period, show higher rates of device failure and minor complication than ExoSeal (12.3% for Perclose and 5.7% for StarClose). There were no access-related hospital transfers for ExoSeal. Like other new generation devices, ExoSeal was designed for simple use and easy deployment. The ExoSeal could have fewer inherent weak points than some older devices, which may help explain the lower complication rate observed even during the operator's learning period.

In addition, close adherence to standard application protocol effectively reduced complications with ExoSeal, whereas other devices continued to present problems that were difficult to overcome even with operator experience. Perclose, for example, is susceptible to breakage when normal pressure is applied to a weak point at the junction of the sheath and the guide.[28] Such structural design flaws should be considered when choosing and using these devices.

The office-based angiosuite is an environment that should ensure procedure safety without inpatient management. According to several previous reports, arterial closure devices appear to have no definitive benefit over manual compression in preventing puncture site complications.[8–11] Clinical trials and observational studies show a wide range of results when comparing closure devices with manual compression to obtain hemostasis.[10,11,13,29] This variation may be due to noteworthy heterogeneity in the settings where the devices were used. For example, manual compression was typically performed after achieving activated clotting time reversal, whereas closure devices were applied regardless of anticoagulation status.

Compared with manual compression, use of arterial closure devices can increase the risk of some serious complications such as infection, intimal dissection, thrombosis, and distal embolization.[30] Bleeding, hematoma, and pseudoaneurysm can occur with manual compression although these minor and major complications associated with closure device use have been reported at rates ranging from 1.5% to 9.0%.[10,31] Furthermore, surgeons must consider that up to 40% of these complications may require surgical repair.[30] Manual compression should still be used to control or reduce puncture site bleeding after most instances of device failure.

Design improvements, along with efforts to optimize use, appear to effectively reduce device-related complications.[8,32] Arterial closure devices offer the clear benefit of achieving more rapid hemostasis than manual compression, making early ambulation possible without inpatient management.[7–9,11] Thus, the use of closure devices may be advantageous, particularly in the office setting.

If device malfunction is excluded, patient local anatomical variation, along with surgeon's experience level and device selection, may help to explain these different device-related complications. With proper technique and patient selection, the complication rate can be reduced to <2% and may especially benefit high-risk patients.[33] Although we had 64 total complications (3.54%), none required surgical repair.

Although much evidence exists concerning each device, we were unable to find any previous report comparing specific devices along with operator effect. Our data did not reveal a significant difference between our 7 surgeons for device failure, complication rate, or hospitalization rate. Although the number of complications and hospitalizations were low enough to potentially cause type II statistical error, we believe these results support previous findings that AngioSeal has low failure and complication rates, suggesting it is safe and effective for achieving hemostasis after vascular intervention.[14,34,35]

CONCLUSION

These data suggest that there is a significant difference between arterial closure devices for closure device failure although possibly subject to type II statistical error. AngioSeal had the best results in our experience, but this could be, in part, due to surgeon proficiency. Although our results are not conclusive, AngioSeal is our preferred choice with the lowest device failure rate and minor complication rate and is a consistently well-performing arterial closure device in the office surgical suite setting.

The authors thank Dr. Kenneth R. Kollmeyer and Dr. Karen L. McQuade for their data contributions and Kaitlyn E. Egan for her assistance with data collection. This study was funded in part by the California Vascular Research Foundation.

REFERENCES

1. Jain K, Munn J, Rummel MC, et al. Office-based endovascular suite is safe for most procedures. J Vasc Surg 2014;59:186–91.

2. Jain KM, Munn J, Rummel M, et al. Future of vascular surgery is in the office. J Vasc Surg 2010;51:509–14.
3. Schwartz BG, Burstein S, Economides C, et al. Review of vascular devices. J Invasive Cardiol 2010;22:599.
4. Krishnasamy VP, Hagar MJ, Scher DJ, et al. Vascular closure devices: technical tips, complications, and management. Tech Vasc Interv Radiol 2015;18:100–12.
5. Kara K, Mahabadi AA, Rothe H, et al. Safety and effectiveness of a novel vascular closure device: a prospective study of the ExoSeal compared to the Angio-Seal and ProGlide. J Endovasc Ther 2014;21:822–8.
6. Vidi VD, Matheny ME, Govindarajulu US. Vascular closure device failure in contemporary practice. J Am Coll Cardiol Intv 2012;5:837–44.
7. Cox T, Blair L, Huntington C, et al. Systematic review of randomized Controlled trials comparing manual compression to vascular closure devices for diagnostic and Therapeutic arterial procedures. Surg Technol Int 2015;27:32–44.
8. Schulz-Schüpke S, Helde S, Gewalt S, et al. Comparison of vascular closure devices vs manual compression after femoral artery puncture: the ISAR-CLOSURE randomized clinical trial. JAMA 2014;312:1981–7.
9. Wong SC, Bachinsky W, Cambier P, et al. A randomized comparison of a novel bioabsorbable vascular closure device versus manual compression in the achievement of hemostasis after percutaneous femoral procedures: the ECLIPSE (Ensure's Vascular Closure Device Speeds Hemostasis Trial). JACC Cardiovasc Interv 2009;2:785–93.
10. Koreny M, Riedmüller E, Nikfardjam M, et al. Arterial puncture closing devices compared with standard manual compression after cardiac catheterization: systematic review and meta-analysis. JAMA 2004;291:350–7.
11. Nikolsky E, Mehran R, Halkin A, et al. Vascular complications associated with arteriotomy closure devices in patients undergoing percutaneous coronary procedures: a meta-analysis. J Am Coll Cardiol 2004;44:1200–9.
12. Fokkema TM, Minnee RC, Kock GA, et al. Comparison of a collagen plug arterial closure device with manual compression after endovascular interventions for peripheral artery disease. J Vasc Surg 2016;64:104–8.
13. Wimmer NJ, Secemsky EA, Mauri L, et al. Effectiveness of arterial closure devices for preventing complications with percutaneous coronary intervention. JACC Cardiovasc Interv 2016;9:e003464.
14. Jiang J, Zou J, Ma H, et al. Network meta-analysis of randomized trials on the safety of vascular closure devices for femoral arterial puncture site haemostasis. Sci Rep 2015;5.
15. Robertson L, Andras A, Colgan F, et al. Vascular closure devices for femoral arterial puncture site haemostasis. Cochrane Database Syst Rev 2016;CD009541.
16. Yeni H, Axel M, Örnek A, et al. Clinical and Subclinical femoral vascular complications after deployment of two different vascular closure devices or manual compression in the setting of coronary intervention. Int J Med Sci 2016;13:255.
17. Dauerman LH. Rewriting the history of vascular closure devices. EuroIntervention 2014;10:175–7.
18. Turi ZG. An evidence-based approach to femoral arterial access and closure. Rev Cardiovasc Med 2008;9:7–18.
19. Hon LQ, Ganeshan A, Thomas SM, et al. Vascular closure devices: a comparative overview. Curr Probl Diagn Radiol 2009;38:33–43.
20. Theodos G, Raymond C, Becker MC, et al. Arteriotomy closure device safety after percutaneous coronary intervention in the direct thrombin inhibitor era: a comparative study. Catheter Cardiovasc Interv 2013;81:294–300.
21. Chiu AH, Vander Wal R, Tee K, et al. Comparison of arterial closure devices in antegrade and retrograde punctures. J Endovasc Ther 2008;15:315–21.
22. Spiliopoulos S, Katsanos K, Karnabatidis D, et al. Safety and efficacy of the StarClose vascular closure device in more than 1000 consecutive peripheral angioplasty procedures. J Endovasc Ther 2011;18:435–43.
23. Lupattelli T, Tannouri F, Garaci FG, et al. Efficacy and safety of antegrade common femoral artery access closure using the Angio-Seal device; experience with 1889 interventions for critical limb ischemia in diabetic patients. J Endovasc Ther 2010;17:366–75.
24. Fargen KM, Velat GJ, Lawson MF, et al. Occurrence of angiographic femoral artery complications after vascular closure with Mynx and AngioSeal. J Neurointerv Surg 2013;5:161–4.
25. Boschewitz JM, Pieper CC, Andersson M, et al. Efficacy and time-to-hemostasis of antegrade femoral access closure using the ExoSeal vascular closure device: a retrospective single-center study. Eur J Vasc Endovasc Surg 2014;48:585–91.
26. Manolis AS, Georgiopoulos G, Stalikas D, et al. Simplified swift and safe vascular closure device deployment without a local arteriogram: single center experience in 2074 consecutive patients. Indian Heart J 2016;68:529–38.
27. Resnic FS, Wang TY, Arora N, et al. Quantifying the learning curve in the use of a novel vascular closure device: an analysis of the NCDR (National Cardiovascular Data Registry) CathPCI registry. JACC Cardiovasc Interv 2012;5:82–9.
28. Kang K, Ferraro R, Petrella R, et al. Perclose Closure Device breakage and embolization during deployment followed by retrieval with snare. Indian Heart J 2015;67:S36–8.
29. Aggarwal K, Murtaza M. Vascular closure device complications: the case is not closed yet. J Invasive Cardiol 2004;16:251.
30. Bechara CF, Annambhotla S, Lin PH. Access site management with vascular closure devices for percutaneous transarterial procedures. J Vasc Surg 2010;52:1682–96.
31. Dauerman HL, Applegate RJ, Cohen DJ. Vascular closure devices: the second decade. J Am Coll Cardiol 2007;50:1617–26.
32. Applegate RJ, Sacrinty M, Kutcher MA, et al. Vascular complications with newer generations of Angio-Seal vascular closure devices. J Interv Cardiol 2006;19:67–74.
33. Bersin RM. Avoiding access site and closure complications. Endovascular Today 2015;2.
34. Lucatelli P, Fanelli F, Cannavale A, et al. Angioseal VIP® vs. Starclose SE® closure devices: a comparative analysis in non-cardiological procedures. J Cardiovasc Surg 2013;58:80–6.
35. Pieper CC, Thomas D, Nadal J, et al. Patient Satisfaction after femoral arterial access site closure using the ExoSeal® vascular closure device compared to manual compression: a prospective intra-individual comparative study. Cardiovasc Intervent Radiol 2016;39:21–7.