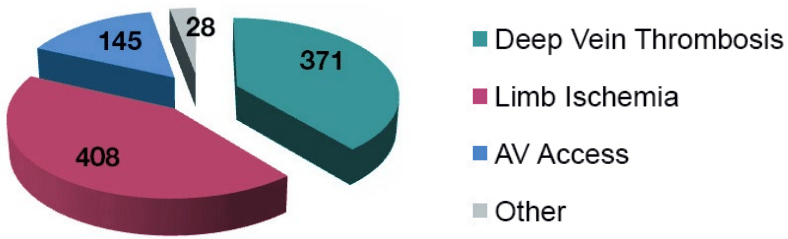
PEARL Registry Update

Overview | Venous | Arterial | AV Access

PEARL Registry Overview
(as of 10 Sep12*)

Topic	Data Support	Comments
Study Design	Prospective, non-randomized, multi-center, 2 phase registry	Phase II bringing in patient QOL and longer patient follow-up period
Objectives	• Determine efficacy of thrombus removal from baseline to final angiogram/venogram • Evaluate clinical outcomes of treated patients at defined intervals of 3, 6 & 12 mos. • Characterize treatment options used with the AngioJet® System • Characterize clinical events • Estimate rate of AngioJet Thrombectomy related adverse events	PEARL collects peripheral use of AngioJet for Identifying treatment strategies that may optimize procedural and clinical outcomes.
Patient Population	All Patients enrolled in the PEARL were treated with an AngioJet catheter at least once in the peripheral vascular system.	
Phases	**PEARL I** (N=452): Followed patients for 3 months with documentation of symptomatic improvement after rheolytic thrombectomy (with mid-length catheters). **PEARL II** (N=500): Ongoing phase following patients outcomes through 12 months after thrombectomy using any AngioJet catheter	A two-phase ongoing prospective registry of the AngioJet catheter used in the treatment of upper and lower extremity peripheral thrombus
# Enrolled Patients	**N=952** 	43% of patients treated for LI 39% of patients treated for DVT 15% of patients treated for AV Other was collection of uses outside of categories shown
# Enrolling Sites	48 enrolling sites	
What AngioJet Catheters were used in the Registry?	PEARL I: DVX® 90 cm; Xpeedior® 120 cm PEARL II: AVX® 50 cm; DVX® 90 cm; Solent® Proxi 90 cm; Solent® Omni 120 cm; Xpeedior® 120 cm; Spiroflex® 135 cm; Spiroflex® VG 135 cm; XMI® 135 cm; XVG® 140 cm	Phase II of PEARL opened collection of data to all AngioJet catheter lengths. DVX and Xpeedior have recently been discontinued offerings.
What was the Angiogram/ Venogram Occlusion Scale used in the Registry?	**Complete**: >90% occlusion **Substantial**: 50-90% occlusion **OR** <50% occlusion and >3cm in length **Partial**: <50% occlusion AND <3cm in length **Normal/Patent**: Without visible thrombus or occlusion	Baseline and final angiographic/ venographic degree of occlusions were determined by the treating physician based on the criteria shown

*Data as of 10 Sep 12. PEARL Registry enrollment completed but data collection is ongoing.

PEARL Venous Registry Update

PEARL DVT

RESULTS	DVT LOCATION	TREATMENTS	LYTIC USE	LABS & CLINICAL EVENTS

RESULTS

What are the Overall Procedural Results?

	% of Substantial Lysis
Upper	92%
Lower	95%
Overall	95%

Patients had an average of 87% (median=100%) reduction in thrombus.

Comments

A per patient extent of thrombus score was calculated for all patients using initial and final venogram information. The patient's scores were classified into 3 Grade categories similar to the Venous Registry.
Grade I = <50% lysis (reduction in thrombus)
Grade II = 50% to <100% lysis (reduction in thrombus)
Grade III = 100% lysis (reduction in thrombus)
Substantial lysis = Grades II & III
Based on these scores there was a mean reduction in vessel thrombus of 87% in all PEARL patients.

Was there a Quality of Life Improvement?†

	Follow-up (Mean)				
	Baseline N=179	**3 month N=166**	**6 month N=127**	**12 month N=97**	**p-value**
Physical Score	33.5	41.6	41.5	42.5	<0.0001
Mental Score	43.9	48.3	48.0	48.6	<0.0001

Comments

Statistically significant improvements in quality of life as measured by the physical (p<0.0001) and mental (p<0.0001) components of the SF-12v2. Baseline was compared to 3, 6 & 12 months.

What was the freedom from rethrombosis rate?

Days after Procedure	Freedom from Rethrombosis
90 Days	94%
180 Days	86%
365 Days	81%

Comments

Freedom from rethrombosis as determined by the treating physician based on patient reports of re-intervention collected during the follow up contact.

12 month follow-up: 81% freedom from rethrombosis.

*Data as of 10 Sep 12. PEARL Registry enrollment completed but data collection is ongoing.
†PEARL II only

DVT LOCATION

Question	Data Support	Comments
What was the breakdown of Lower vs Upper Extremity?	**Lower Extremity (LE):** 89% **Upper Extremity (UE):** 11%	
Where was the location of the DVT in the LE?	**DVT Segments** / **% of Patients** Iliac Femoral Popliteal: 31% Iliac Femoral: 27% Femoral Popliteal: 24% Iliac only: 7% Femoral only: 6% Popliteal only: 2% **Unilateral:** 90%; Left=64%; Right=31% **Bilateral:** 10%	57% included Popliteal thrombus
What were the primary points of access?	**Lower Extremity:** Popliteal=83% **Upper Extremity:** Brachial= 50%	

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TREATMENTS

Question	Data Support	Comments
What AngioJet® Treatments were the patients exposed to?	Patients exposed to: AngioJet Thrombectomy without lytic use: 5% AngioJet Thrombectomy with Power Pulse (PPS): 71% AngioJet Thrombectomy with Rapid Lysis (RL): 19%	Some of the patients had both Power Pulse® and Rapid Lysis treatments.
What Adjunctive Treatments were used?	**Stents:** 32% • 79% in Iliac segments vs 16% in femoral segments **Balloons:** 75% **CDT:** 60% • CDT without PPS/RL: 9% • CDT with PPS/RL: 51%	
How many cases included IVC Filter placement?	**Pre-existing:** 24%; **During Procedure:** 23%	Majority of cases were performed without having an IVC filter placed
How long were the Procedures?	**Treatment Group*** / **Median Time in Hrs** **AngioJet Thrombectomy only (N=19)** 1.4 **+ PPS/RL (N=127)** 1.9 **+ PPS/RL + CDT (N=185)** 21.5 **+ CDT (N=31)** 40.9	Adding Power Pulse (PPS) and/or Rapid Lysis (RL) to CDT decreased the median procedure duration 44% versus Catheter Directed Thrombolysis (CDT) alone. **Overall:** 38% completed in <6 Hrs 76% completed in <24 Hrs **CDT:** 76% received CDT PRIOR to any AngioJet treatments **PPS/RL + CDT:** 92% received an AngioJet treatment PRIOR to CDT N = patients with time recorded
How many sessions did the procedure take?	**Session** / **Percentage** 1 34% 2 53% 3 11% >3 2%	**Session** = # of trips back to the interventional lab 87% cases were completed in 2 or less sessions

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LYTIC USE

Question	Data Support	Comments
What Power Pulse® Delivery specifics are being used?	**Predominate Physician Prescribed Fluid:** Activase **Predominate Dose:** 10 mg **Total Lytic given *(mean/median):*** 12.7 mg / 10 mg **Dwell Times *(mean/median):*** 35.0 minutes /25.0 minutes	**Lytics:** 99% of the PPS uses included Activase **Dose:** There were 66 different lytic: saline "recipes" used by the physicians but the 10mg: 100cc was the most predominate at 24%. **Balloon Maceration:** 39% of the PPS patients in PEARL II received balloon maceration.
Catheter Direct Lytic (CDT)	**Total Lytic Given (mean/median):** 18.7 mg /14.7 mg **Drip Times (mean/median):** 16.6 hrs / 17.0 hrs	Less lytic and shorter procedure times with either PPS or PPS + CDT use than with CDT alone.
What was the total lytic dose for patients?	See table below	The total lytic dose for treating DVT was lower when using PPS/RL (with/without CDT) versus CDT without PPS/RL. N = patients with recorded lytic doses 86% of cases utilized Power Pulse and/or Rapid Lysis.
What were the venographic results by Lytic Treatment Groups?	See table below	Amongst the 4 treatment groups there wasn't any statistically difference in baseline occlusion, final occlusion or in the change of occlusion. The difference seems to be in the treating physician's preference to treatment. N = treated vessels

Lytic Delivery Method	Mean (Median)	
	Activase Total Dose	Retavase Total Dose
PPS/RL	13.4 (10.0) (N=43)	2.0 (N=1)
PPS/RL + CDT	25.9 (24.4) (N=104)	33.0 (9.8) (N=13)
CDT	32.7 (30.7) (N=53)	25.8 (17.3) (N=3)

Treatment Group	Improved	No Change	Worsened
AngioJet w/out Lytic (N=42)	93%	2%	5%
+ PPS/RL (N=406)	92%	8%	0%
+ CDT (N=109)	90%	9%	1%
+ PPS/RL + CDT (N=789)	89%	11%	<1%

LABS & CLINICAL EVENTS

Question	Data Support				Comments
Does the AngioJet® have an effect on Hgb, K+, BUN and Creat?	**Lab Analyte**	**Pre-AngioJet Mean (median)**	**Post-AngioJet Mean (median)**	**P-value+**	**Pre-AngioJet:** within 48 hours prior to AngioJet use **Post-AngioJet:** within 48 hours post AngioJet use. Importance of pre- and post- hydration + Wilcoxon Signed Rank Test
	BUN (N=230)	16.9 (14.0)	16.5 (14.0)	0.0689	
	Crt (N=234)	1.1 (0.9)	1.2 (1.0)	0.0892	
	Hgb (N=261)	12.4 (12.4)	11.2 (11.2)	<0.0001	
	K+ (N=229)	4.1 (4.0)	4.0 (3.9)	0.0003	
What are the coag panel labs for the patients?	**Lab Analyte**	**Pre-AngioJet Mean (median)**	**Post-AngioJet Mean (median)**	**P-value+**	**Pre-AngioJet:** within 48 hours prior to AngioJet use **Post-AngioJet:** within 48 hours post AngioJet use. + Wilcoxon Signed Rank Test
	PT (N=236)	15.6 (13.7)	17.5 (14.6)	<0.0001	
	INR (N=250)	1.4 (1.1)	1.7 (1.2)	<0.0001	
	PTT (N=188)	62.1 (36.0)	72.2 (49.0)	0.0005	
What are the bleeding complications related to the interventional procedure?	**Bleeding requiring transfusions:** *2.2 %* **Hematomas at access site:** 1.3%				**Bleeding requiring Transfusions:** The AngioJet System was ruled out as a possible contributing factor in 6/8 cases.
What is the incidence of Arrhythmia occurring during the interventional procedure?	**Arrhythmia:** <1%				
What is the incidence of renal failure / insufficiency related to the interventional procedure?	**Renal Failure or insufficiency:** 1.6%				**AngioJet System related (0.5%):** 1 case of renal insufficiency (AngioJet=unknown) 1 case of acute renal failure (AngioJet=yes); diabetic with history of PE and DVT. All cases were resolved by the 3 Month Follow Up.
What is the incidence of Pulmonary Embolisms as a result of the procedure?	**Pulmonary Embolism:** <1%				There is only one case of pulmonary embolism where the interventional procedure could not be ruled out. This patient was only watched and not treated.

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Venous Registry

DEMOGRAPHICS | RESULTS

DEMOGRAPHICS

		Venous Registry (VR)*	PEARL Registry (PR)**	Comments
# of Patients		287	321	**VR** had a total of 473 pts with 186 determined to be nonevaluatable due to the venograms. **PR** had 321/371 patients with LE DVT
# of Sites		63	35	
Prior DVT		31%	39%	
Primary Treatment		CDT	AngioJet® With or Without PPS/RL	Both studies had other adjunctive treatments
Stent Placement		33%	35%	
Primary access		Popliteal	Popliteal	
Gender		Male= 48%; Female=52%	Male=57%; Female=43%	
Age *(mean)*		47.5 yrs	52.3 yrs	
Treatment Location		Iliofemoral – femoral pop	Iliofemoral – femoral pop	**PR** included all LE vessels but for the basis of venogram comparisons to the **VR** the same vessels were used.
Limbs Involved		Left=61%; Right=39%	Left=61%; Right=38%	**PR:** 1% off label use
Onset of DVT Symptoms	**Acute**	66% (≤10 Days)	67% (≤14 days)	
	Chronic	16% (>10 Days)	33% (>14 days)	
	Acute & Chronic	19%	N/A	**VR** had a 3rd group: worsening of pain &/or edema in the ≤10 days with chronic symptoms. **PR** didn't classify pts into this 3rd group.
Primary Lytic		Urokinase	TPA	

*Mewissen MW, Seabrook GR.Catheter-directed Thrombolysis for Lower Extremity Deep Venous Thrombosis: Report of a National Multicenter Registry. Radiology 1999:211:39-49 http://radiology.rsna.org/content/211/1/39.full

**Data was as of 10 Sep 12. PEARL Registry enrollment completed but data collection is ongoing.

Venous Registry vs PEARL Registry: *Treatment of Lower Extremity DVT*

RESULTS

		Venous Registry (VR)*	PEARL Registry (PR)**	Comments
CDT Drip Times *(mean)*		48 hrs	17 hrs	Considerable less drip times in **PR** than **VR** **VR** pts were only treated by CDT. **PR** pts were treated per the physician.
Procedure Times *(median)*	**CDT (N=28)**	N/A	40.8 hrs	**Procedure Time:** Time from start of case to completion. **CDT:** 73% pts received CDT prior to any AngioJet® treatment **CDT+PPS/RL:** 91% pts received an AngioJet treatment prior to CDT. The data demonstrated that adding PPS/RL significantly decreases the procedure time.
	CDT+PPS/RL (N=167)	N/A	21.9 hrs	
	PPS/RL (N=113)	N/A	2.0 hrs	
Overall % Thrombus Removal		83%	95%	Results are based on Grades II + III • Grade II (50%-99% lysis) • Grade III (100% lysis) **PR:** There was a statistical difference in the extent of thrombus in the CDT+PPS/RL group (<0.0001) versus the other 2 groups. Even so, there wasn't a statistically significant difference in the proportion of patients who experienced lysis (p=0.8940) between the 3 groups.
By Lytic Groups: % Thrombus Removal	**CDT (N=28)**	N/A	93%	
	PPS/RL (N=113)	N/A	94%	
	CDT+PPS/RL (N=167)	N/A	96%	
Acute: % Thrombus Removal		86%	96%	Venographic results Results are based on Grades II + III • Grade II (50%-99% lysis) • Grade III (100% lysis) Refer to "Onset of DVT Symptoms" for groups
Chronic: % Thrombus Removal		68%	94%	
Acute & Chronic: % Thrombus Removal		76%	N/A	
Primary Patency		6 Mon=65% 12 Mon=60%	N/A	Determined by Duplex Ultrasound
Freedom from Rethrombosis		N/A	6 Mon= 86% 12 Mon=80%	Determined by patient reported rethrombosis events
Bleeding Complications		11% (major); 16% (minor)	5% (major & minor combined)	Bleeding Complications were calculated on all patients in each registry. **PR:** Only 1% could not rule out the AngioJet System as a possible contributing factor.

*Mewissen MW, Seabrook GR.Catheter-directed Thrombolysis for Lower Extremity Deep Venous Thrombosis: Report of a National Multicenter Registry. Radiology 1999:211:39-49 http://radiology.rsna.org/content/211/1/39.full

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CaVenT

DEMOGRAPHICS | RESULTS

DEMOGRAPHICS

		CaVenT (CT)*		PEARL Registry (PR)**	Comments
		CDT	STD		
# of Patients		90	99	321	**CT** had a total of 209 pts with 189 to be included in the ITT analysis **PR** had 321/371 patients with LE DVT
# of Sites		20		35	
Prior DVT		10%	9%	39%	PEARL with higher prior DVT rate
Primary Treatment		CDT	LMWH	AngioJet® With or Without PPS/RL	Both studies had other adjunctive treatments in the endovascular procedures.
Stent Placement		17%	N/A	35%	
Primary access		Popliteal	N/A	Popliteal	
Gender		Male=64%; Female=36%	Male=62%; Female=38%	Male=57%; Female=43%	
Age *(mean)*		53.3 yrs	50.0 yrs	52.3 yrs	
Treatment Location		CFV or iliofemoral		Iliofemoral – femoral pop	
Limbs Involved		Left=60%; Right=40%	Left=62%; Right=38%	Left=61%; Right=38%	**PR:** 1% off label use
Onset of DVT Symptoms	**Acute**	100% ≤21 days		67% (≤14 days)	
	Chronic	N/A		33% (>14 days)	
Primary Lytic		TPA	N/A	TPA	

*Enden , Haig Y. Long-term outcome after additional catheter-directed thrombolysis versus standard treatment for acute iliofemoral deep vein thrombosis (the CaVenT study): a randomised controlled trial. Lancet 2012:379:31-38

**Data was as of 10 Sep 12. PEARL Registry enrollment completed but data collection is ongoing.

CaVenT vs PEARL Registry: *Treatment of Lower Extremity DVT*

RESULTS

		CaVenT (CT)		PEARL Registry (PR)*	Comments
		CDT	STD		
CDT Drip Times *(mean)*		57.6 hrs (2.4 days)	N/A	17 hrs	Considerable less drip times in **PR** than **CT** **CT** pts were treated by CDT or STD (LMWH). **PR** pts were treated per the physician.
Procedure Times *(median)*	**CDT (N=28)**	N/A		40.8 hrs	**Procedure Time:** Time from start of case to completion. **CDT:** 73% pts received CDT prior to any AJ treatment **CDT+PPS/RL:** 91% pts received an AJ treatment prior to CDT.
	CDT+PPS/RL (N=167)	N/A		21.9 hrs	
	PPS/RL (N=113)	N/A		2.0 hrs	
Overall % Thrombus Removal		89%	N/A	95%	Results are based on Grades II + III • Grade II (50%-99% lysis) • Grade III (100% lysis) **PR:** There was a statistical difference in the extent of thrombus in the CDT+PPS/RL group (<0.0001) versus the other 2 groups. Even so, there wasn't a statistically significant difference in the proportion of patients who experienced lysis (p=0.8940) between the 3 groups.
By Lytic Groups: % Thrombus Removal	**CDT (N=28)**	N/A		93%	
	PPS/RL (N=113)	N/A		94%	
	CDT+PPS/RL (N=167)	N/A		96%	
Acute: % Thrombus Removal		89%	N/A	96%	Venographic results Results are based on Grades II + III • Grade II (50%-99% lysis) • Grade III (100% lysis)
Chronic: % Thrombus Removal		N/A	N/A	94%	
Primary Patency		6 Mon = 65.9%	6 Mon = 47.4%	N/A	Determined by Duplex Ultrasound
Freedom from Rethrombosis		N/A	N/A	6 Mon= 86% 12 Mon=80%	Determined by patient reported rethrombosis events
Bleeding Complications		22% (major & minor combined)	0%	5% (major & minor combined)	Bleeding Complications were calculated on all patients in each registry. **PR:** Only 1% could not rule out the AngioJet® System as a possible contributing factor. **CT:** 22% bleeding but only 9% were considered clinically relevant.

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PEARL Arterial Registry Update

Overview | PEARL Limb Ischemia | HOME

PEARL Limb Ischemia

RESULTS	LI LOCATION	TREATMENTS	LYTIC USE	LABS	CLINICAL EVENTS

PEARL Limb Ischemia (N=408 Patients*)

RESULTS

What are the Overall Procedural Results?

	% of Substantial Lysis
Upper	100%
Lower	93%
Overall	93%

Patients had an average of 90% (median=100%) reduction in thrombus.

A per patient extent of thrombus score was calculated for all patients using initial and final angiogram information. The patient's scores were classified into 3 Grade categories.
Grade I = <50% lysis (reduction in thrombus)
Grade II = 50% to <100% lysis (reduction in thrombus)
Grade III = 100% lysis (reduction in thrombus)
Substantial lysis = Grades 2 & 3
Based on these scores there was a mean percent reduction in vessel thrombus of 90% in all PEARL patients.

The % of lysis was calculated after the completion of the interventional procedure and includes all treatments the patient received: stents, CDT, angioplasty, etc.

Was there a Quality of Life Improvement?

	Follow-up (Mean)				
	Baseline N=199	3 month N=168	6 month N=122	12 month N=68	p-value
Physical Score	30.6	39.0	38.5	35.9	<0.0001
Mental Score	45.1	48.0	48.0	48.7	0.0007

Statistically significant improvements in quality of life as measured by the physical (p<0.0001) and mental (p=0.0007) components of the SF-12v2. Baseline was compared to 3, 6 & 12 months.

The SF-12v2 is a standardized generic QOL questionnaire. A comparison group with at least one chronic condition has a mean physical score of 48.7 and mental score of 51.9.

Was there an improvement in ABIs on the treated limbs?

	Follow-up (Mean)					
	Baseline N=175	Discharge N=95	3 month N=25	6 month N=23	12 month N=22	p-value
ABI	0.36	0.83	0.79	0.76	0.81	<0.0001

N=number of sides measured.

Mean ABI at discharge was 0.83 versus 0.36 baseline. ABIs were consistently lower for patients who had a bad outcome (p=0.0034). A bad outcome was defined as an event of rethrombosis, restenosis, amputation, bypass and/or surgical intervention of the treated limb.

ABI readings:
- 1 - 1.1 = normal
- < 0.9 = presence of PAD
- < 0.26 = severe limb-threatening occlusion

What is the Limb Salvage Rate?

90%

191 had threatened limbs at baseline based on Rutherford scoring. Of these 191, 171 were not amputated, i.e. the limb was salvaged. Therefore, the limb salvage rate was 90% (171/191).

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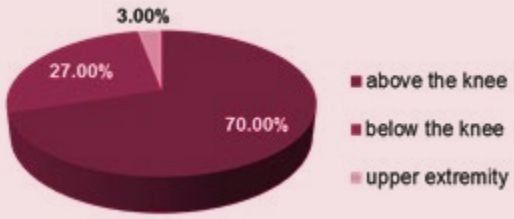
PEARL Limb Ischemia (N=408 Patients*)

LI LOCATION

Question	Data Support	Comments
What was the breakdown of Lower vs Upper Extremity Patients?	**Lower Extremity (LE):** 98% **Upper Extremity (UE):** 2%	
Where was the location of the native vessel thrombus/stenosis?	Location / % of Vessels: Iliac 17% Femoral Popliteal 53% Below the knee 27% Upper Extremity 3% **Unilateral:** 94% **Bilateral:** 6%	864 native vessels treated 
What were the angiographic results by Location?	Location / Improved / No Change / Worsened: Iliac (N=146) 78% 22% 0% Fem Pop (N=461) 88% 11% <1% BTK (N=231) 90% 9% 1% Upper (N=26) 100% 0% 0% Other (N=147) 94% 6% 0%	Other includes off label use N = treated vessels

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PEARL Limb Ischemia (N=408 Patients*)

TREATMENTS

Question	Data Support	Comments
What AngioJet® Treatments were the patients exposed to?	**Patients exposed to:** **AngioJet Thrombectomy without lytic use:** 18% **AngioJet Thrombectomy with Power Pulse:** 44% **AngioJet Thrombectomy with Rapid Lysis:** 24%	Some of the patients had both Power Pulse® and Rapid Lysis treatments.
How was the AngioJet System utilized?	**CDT cases:** 73% utilized an AJ Treatment prior to CDT **PPS cases:** 18% performed an AJ thrombectomy prior to PPS.	AngioJet Treatment = Thrombectomy, PPS or RL (Rapid Lysis) treatments
Adjunctive Treatments	**Stents:** 54% **Atherectomy:** 3% **Balloons:** 75% **CDT:** 44% • CDT without PPS/RL: 15% • CDT with PPS/RL: 29%	
How long were the arterial Procedures?	**Treatment Group* / Median Time in Hrs** **AngioJet Thrombectomy only (N=72)** 1.6 **+ PPS/RL (N=149)** 1.9 **+ PPS/RL + CDT (N=111)** 22.6 **+ CDT (N=60)** 24.4	**Overall:** 58% completed in <6 Hrs 80% completed in <24 Hrs In patients who had AngioJet and CDT: 73%: AngioJet treatment (thrombectomy or PPS/RL) first 27%: CDT first N = patients with recorded times
How many sessions did the procedure take?	**Session / Percentage** 1 56% 2 30% 3 11% >3 3%	**Session** = # of trips back to the interventional lab 86% cases were completed in 2 or less sessions

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LYTIC USE

What Power Pulse® specifics are being used?

Predominate Physician Prescribed Fluid: Activase
Predominate Activase Dose: 10 mg
Total Activase given per patient by PPS:
***(mean/median)*:** 12.2 mg / 10 mg
Dwell Times *(mean/median)*: 23.2 minutes / 20 minutes

Lytics: 80% of the PPS uses included Activase
Dose: Activase use with 10mg: 50cc Saline was the most predominate at 24% of PPS uses.

Dwell times are per PPS treatment.

Catheter Direct Lytic (CDT)

Total Lytic Given *(mean/median):* 20.4 mg /17.8 mg
Drip Times *(mean/median):* 15.3 hrs / 16.0 hrs

What was the total lytic dose for patients?

Lytic Delivery Method	Mean (Median)	
	Activase Total Dose	Retavase Total Dose
PPS/RL	10.4 (8.9) N=74	10.0 N=1
CDT	21.6 (18.5) N=41	10.2 (8.2) N=5
PPS/RL + CDT	27.3 (26.2) N=84	7.2 (4.0) N=11

222 patients had recorded total lytic doses

N = patients with recorded lytic doses

What were the thrombus score results by treatment group?

Treatment Group*	Lysis Grade			Substantial Lysis
	I	II	III	
AJ Thrombectomy only (N=75)	11%	17%	72%	89%
+ PPS/RL (N=151)	3%	11%	85%	96%
+ PPS/RL + CDT (N=117)	6%	22%	72%	94%
+ CDT (N=62)	13%	19%	68%	87%

N = patients

The patient's scores were classified into 3 Grade categories.
Grade I = <50% lysis (reduction of thrombus)
Grade II = 50% to <100% lysis (reduction of thrombus)
Grade III = 100% lysis (reduction of thrombus)

Substantial lysis = Grades II & III
Higher % of Substantial lysis were achieved in the groups with Power Pulse (PPS) / Rapid Lysis (RL).

There was a difference (p=0.0003) in the mean baseline thrombus between the 4 groups. With the Thrombectomy + lytic by AJ & CDT having a greater occlusion initial score than the other groups.

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LABS

Question	Data Support				Comments
Does the AngioJet® have an effect on Hgb, K+, BUN and Creat?	**Lab Analyte**	**Pre-AngioJet Mean(median)**	**Post-AngioJet Mean (median)**	**P-value+**	**Pre-AngioJet:** within 48 hours prior to AngioJet use **Post-AngioJet:** within 48 hours post AngioJet use. Importance of pre- and post- hydration + Wilcoxon Signed Rank Test
	BUN (N=258)	19.1 (17.0)	18.8 (17.0)	0.0183	
	Crt (N=266)	1.4 (1.0)	1.4 (1.0)	0.4977	
	Hgb (N=271)	13.5 (13.2)	11.6 (11.1)	<0.0001	
	K+ (N=260)	4.1 (4.1)	4.1 (4.0)	0.0015	
What are the coag panel labs for the patients?	**Lab Analyte**	**Pre-AngioJet Mean(median)**	**Post-AngioJet Mean (median)**	**P-value+**	**Pre-AngioJet:** within 48 hours prior to AngioJet use **Post-AngioJet:** within 48 hours post AngioJet use. + Wilcoxon Signed Rank Test
	PT (N=167)	15.2 (12.9)	15.4 (13.9)	<0.0001	
	INR (N=186)	1.3 (1.1)	1.3 (1.2)	0.0012	
	PTT (N=152)	49.3 (33.0)	60.8 (47.0)	0.0004	

*Data as of 10 Sep 12. PEARL Registry enrollment completed but data collection is ongoing.

CLINICAL EVENTS

Question	Data Support	Comments
What are the bleeding complications related to the interventional procedure?	**Bleeding requiring transfusions:** 4% **Hematomas at access site:** 2% **Cerebral Vascular Accident:** <1%	**Bleeding requiring Transfusions:** The AngioJet System was ruled out as a possible contributing factor in 7/18 cases. **The AngioJet System is Isovolumetric and observing runtimes is imperative** **CVA:** 1 case attributed to the procedure but NOT AngioJet
What is the incidence of Arrhythmia occurring during the interventional procedure?	**Arrhythmia:** <1%	
What is the incidence of Pancreatitis related to the interventional procedure?	**Pancreatitis:** <1%	1 case where the AngioJet System could not be ruled out (unknown cause).
What is the incidence of renal failure / insufficiency related to the interventional procedure?	**Renal Failure or insufficiency:** 2.7%	**AngioJet related (1.5%):** 3 cases of renal insufficiency; no txm 3 cases of acute renal failure where the AJ could not be ruled out (unknown cause) • 1 death where pt had hx of prior renal insufficiency and respiratory arrest with surgeries. • 1 case physician believed was contrast induced • 1 case of prior renal insufficiency
What is the incidence of Embolization as a result of the interventional procedure?	**Distal Embolization:** <1%	2 cases; one where the AngioJet System could not be ruled out.

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PEARL AV Access Registry Update

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PEARL Hemodialysis Access

RESULTS | HA LOCATION | TREATMENTS | CLINICAL EVENTS

PEARL Hemodialysis Access (N=135 Patients*)

RESULTS

Question	Data Support	Comments
What is the Overall Procedural Success?	Overall 93% had procedural success.	**Procedure Success:** procedure completion and hospital discharge without rethrombosis or surgery. Procedural Failures included 8 cases requiring surgery and 2 cases requiring re-intervention.
What were the thrombus score results?	See table below	Patients were divided in graft vs fistula groups. Some treated vessels included native vessels besides the graft or fistula. N = treated vessels
What are the patency rates?	See table below	The Life Table Method of analysis was used to calculate patency rates.

Treatment Group	Improved	No Change	Worsened
Graft (N=111)	99%	<1%	0%
Fistula (N=59)	97%	3%	0%

98% of the treated vessels had angiographic improvement after treatment.

Time Interval	% Maintained Patency	
	Graft	Fistula
3 Month Follow Up	58.4%	75.0%
6 Month Follow Up	31.1%	54.5%

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PEARL Hemodialysis Access (N=135 Patients*)

HA LOCATION

Question	Data Support	Comments
What was the % of grafts vs fistulas cases?	**Grafts:** 65% **Fistulas:** 35%	
What was the location of the thrombus/ stenosis?	**Left Upper Extremity:** 66% **Right Upper Extremity:** 33% **Left Lower Extremity:** 1% **Right Lower Extremity:** 0%	

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PEARL Hemodialysis Access (N=135 Patients*)

TREATMENTS

Question	Data Support	Comments
Which AngioJet® Catheters were used?	**Catheter** / **Percentage**: DVX® 45%; AVX® 29%; Xpeedior® 15%; Solent® Proxi 8%; Other 2%; Solent® Omni <1%	The majority of the PEARL patients were enrolled prior to the launch of the Solent family of AngioJet peripheral catheters.
What AngioJet Treatments were the patients exposed to?	**Patients exposed to:** **AngioJet Thrombectomy without lytic use:** 91% **AngioJet Thrombectomy with Power Pulse®:** 13% **AngioJet Thrombectomy with Rapid Lysis:** 2%	Some of the patients had multiple AngioJet treatments with/ without lytics. The *AngioJet Thrombectomy without lytic use* was the only AngioJet Treatment in 84% of the patients.
Adjunctive Treatments	**Stents:** 42% **Balloons:** 87% **Other Thrombectomy/Embolectomy:** 24% **CDT:** <1%	**Other Thrombectomy/Embolectomy:** Most used the Fogarty balloon for occlusion and then pull the thrombus to the AngioJet.
How long were the declot Procedures?	**Treatment Group*** / **Median Time in Hrs**: **AngioJet Thrombectomy Only (N=114)** 1.3; **+ PPS/RL (N=20)** 1.4; **+ CDT (N=1)** 14.0	**Overall:** 99% completed in <2 Hrs N = patients with recorded times

*Data as of 10 Sep 12. PEARL Registry enrollment completed but data collection is ongoing.

CLINICAL EVENTS

Question	Data Support	Comments
What are the bleeding complications related to the interventional procedure?	**Bleeding requiring transfusions:** <1% **Hematoma at the access site:** <1%	None related to the AngioJet® System
What are other complications related to the interventional procedure?	**Dissection of Treated Vessel:** <1% **Arrhythmia:** <1% **Contrast Reaction:** <1%	AngioJet System related (0.7%) • 1 case of arrhythmia (AngioJet=Yes) no treatment required.

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The PEARL Registry is a Bayer HealthCare sponsored study.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

AngioJet® Thrombectomy Systems

General Indications/Contraindications AngioJet System peripheral indications include: breaking up and removing thrombus from infra-inguinal peripheral arteries, upper and lower extremity peripheral arteries, upper extremity peripheral veins, ileofemoral , infra-iliac and lower extremity veins, A-V access conduits, and for use with the AngioJet Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system. AngioJet System coronary indications include: removing thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions prior to balloon angioplasty or stent placement. Do not use in patients: who are contraindicated for intracoronary or endovascular procedures, who cannot tolerate contrast media, and in whom the lesion cannot be accessed with the wire guide.

General Warnings and Precautions The System has not been evaluated for treatment of pulmonary embolism in the US and some other countries or for use in the carotid or cerebral vasculature. Some AngioJet devices have not been evaluated for use in coronary vasculature. Operation of the catheter may cause embolization of some thrombus and/or thrombotic particulate debris. Cardiac arrhythmias may occur and cardiac rhythm should be monitored during catheter use and appropriate management employed, if needed. Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. Operation of the System causes transient hemolysis. Large thrombus burdens may result in significant hemoglobinemia which should be monitored. Consider hydration, as appropriate. Before coronary AngioJet treatment, verify the presence of thrombus because routine use of AngioJet in every STEMI patient, without proper selection for thrombus, has been associated with increased mortality risk. Do not use the system in the coronary vasculature without placing a temporary pacing catheter to support the patient through hemodynamically significant arrhythmias which may occur.

Potential Adverse Events Potential adverse events (in alphabetical order) which may be associated with use of the system are similar to those associated with other interventional procedures and include but are not limited to the following: abrupt closure of treated vessel, acute myocardial infarction, acute renal failure, arrhythmias (including VF and VT), bleeding from access site, death, dissection, embolization (proximal or distal), emergent CABG, hematoma, hemolysis, hemorrhage requiring transfusion, hypotension/hypertension, infection at access site, myocardial ischemia, pain, pancreatitis, perforation, pseudoaneurysm, reactions to contrast medium, stroke/CVA, thrombosis/occlusion, total occlusion of treated vessel, vascular aneurysm, vascular spasm, vessel wall or valve damage.

Indications, operating specifications and availability may vary by country. Check with local product representation and country-specific *Information For Use* for your country.

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