Closure Devices

Peter F Ludman
Advanced Angioplasty 2003
Where Radials fear to tread

- Male, 46 yrs, ACS (CK to 792)
  - Diabetes
  - Morbid obesity
  - Wheel chair bound
  - Moderate LV dysfunction, LMS and RCA disease
  - Surgeons declined to operate

- Femoral access preferred
  - >160Kg - poor imaging
  - Bifurcation LMS
  - IABP
Where Radials fear to tread
Where Radials fear to tread

- Good coronary result
- Two femoral punctures sites....
## External Guide Diameter

<table>
<thead>
<tr>
<th>Device</th>
<th>6F</th>
<th>7F</th>
<th>8F</th>
<th>9F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brachytherapy</td>
<td></td>
<td></td>
<td></td>
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<td>Novoste</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Cordis</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Emboli protection devices</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>AngioGuard (Cordis)</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>PercuSurge</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
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<td>Angiojet</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Rotablation</td>
<td></td>
<td></td>
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<td>≤1.5</td>
<td>Yes</td>
<td>Yes</td>
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<td>≤1.75</td>
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<td>Yes</td>
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<td>≤2.15</td>
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<td>No</td>
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<tr>
<td>≤2.25</td>
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<td>DCA</td>
<td></td>
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<td>5</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>6</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td>7</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>X-sizer</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Femoral Haemostasis

• Potential advantages of closure devices:
  – ↓ prolonged bed rest
    • increased comfort
    • reduced cost (LOS)
  – ↓ pain and associated ‘vagal’ reactions
  – Improve use of physician / nurse time
  – ↓ complications
Closure devices

Primary Intention Clips and Sutures
- Angiolink
- Onux
- Perclose
- X-site
- Sutura

Collagen / thrombin / pads...
- Angioseal
- Vasoseal
- Duett
- Quick seal Sub Q (gel foam)
- BioIntervention
- Clo sure PAD
- Syvek
- Flo seal
- Biodisc
- Therus (Ultrasound)
Closure devices

Primary Intention
Clips and Sutures

Angiolyink
Onux

Perclose
X-site Sutura

Angioseal
Vasoseal
Duett

Collagen / thrombin / pads...

Quick seal Sub Q (gel foam)
BioIntervention
Closure PAD
Syvek
Flo seal
Biodisc
Therus (ultrasound)
Perclose
Redwood City, CA, USA

- **TechStar**
  - 7F – 1 suture

- **ProStar XL**
  - 8F and 10F – 2 sutures

- **The Closer**
  - 6F – 1 suture
  - Knot making tool
  - 3-0 braided polyester (non-absorbable)
Perclose - Closer
Perclose - Closer
Perclose - Closer
Perclose - Closer
Perclose - Closer
Angioseal
St Jude Medical, St. Paul, Minnesota, USA

- 6F and 8F devices
- Components
  - Biodegradable anchor (intra-arterial)
  - collagen plug (extra-arterial)
  - 3-0 Vycril suture (with clinch knot)
• Modifications
  – improved collagen weave pattern
  – mono-fold sheath tip
  – enhanced suture delivery and release mechanisms
  – re-designed anchor
  – anti-rotation sheath cap
  – Improved indication markings

Angioseal
Angioseal
Angioseal
Vasoseal
Datascope, Montvale, NJ, USA

- Extravascular collagen plug
  - Delivery followed by short period of manual compression
  - Vasoseal VHD
  - Vasoseal ES – 5F to 8F
1. Secure sheath position
Duett
Vascular Solutions Inc., Minneapolis, Minnesota, USA

- Collagen and thrombin
  - Intra arterial balloon during thrombin delivery
  - Seals artery and tissue tract
  - Balloon then removed
  - Delivery followed by short period of manual compression

- 5F to 9F
• Insert the Duett catheter into the artery via the existing introducer sheath.
• Inflate the balloon.
• Withdraw the Duett catheter and sheath as a unit until the balloon is positioned firmly against the inner arterial wall.
Duett

- Deliver the procoagulant directly to the puncture site through the sidearm of the introducer sheath.

- Continue procoagulant delivery until the entire tissue tract is filled.
Duett

- Deflate balloon.
- Remove the Duett catheter and introducer sheath from the patient.
- Maintain direct pressure over the puncture site for 2-5 minutes.

Tissue track also Rx
Early trial data

• Complications with devices
  – Less forgiving of poor puncture location
  – Most require large arterial diameter (i.e. CFA)
  – More sensitive to PVD and vessel calcification
Puncture site

- Optimal
- A-V fistula
- Pseudoaneurysm
- Thrombosis
- Vessel laceration

- Retroperitoneal haemorrhage

- External Iliac
- Profunda femoris
- Superficial femoral
Profunda femoris pseudoaneurysm

Kumar S, Bury RW, Roberts DH, Heart 2002;88:215
Femoral Artery Anatomy

Schnyder G Cathet and Cardiovasc Int 2001;53:289

• 200 patients for coronary angiography
  – 60% male
  – Mean age 64 yrs
  – 30% diabetes

• 18% with >25% CFA stenosis
Puncture location

Schnyder G Cathet and Cardiovasc Int 2001;53:289

% where puncture will be above bifurcation

<table>
<thead>
<tr>
<th>Level</th>
<th>Number of Patients</th>
</tr>
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<tbody>
<tr>
<td>I</td>
<td>111</td>
</tr>
<tr>
<td>II</td>
<td>44</td>
</tr>
<tr>
<td>III</td>
<td>34</td>
</tr>
<tr>
<td>IV</td>
<td>8</td>
</tr>
<tr>
<td>V</td>
<td>3</td>
</tr>
</tbody>
</table>

54.5%  81.5%  94.5%  98.5%
Published Data

- Evolving PCI techniques
  - Sheath sizes
  - Anti-thrombotic regimens

- Evolving closure equipment
  - mechanical differences
  - modifications to deployment methods

- Trials
  - small patient numbers
  - few randomised
  - important differences in data presented
  - Variable length FU
  - learning curve variably incorporated
Recent trials

- **Ellis SG et al**
  - The SEAL trial
  - AHJ 2002;143:612-9

- **Carey D et al.**
  - Complications of Femoral artery closure devices
  - Cathet and Cardiovasc Int 2001;52:3-7

- **Cura FA et al**
  - Safety of Femoral Closure Devices after PCI in the era of GP IIb/IIIa platelet blockade
  - Am J Cardiol 2000;86:780-782

- **Applegate RJ**
  - Vascular closure devices in patients treated with anticoagulation and IIb/IIIa receptor inhibitors during percutaneous revascularization
  - JACC 2002;40:78-83
SEAL

- Randomised (ratio 3:5)
  - Duett v manual compression
  - FA angio in all
  - 30/7 post discharge FU

- Ambulation
  - No antithrombotics
    - 5F – 6F 1-2 hrs
    - 7F – 8F 2-4 hrs
  - With Heparin during procedure
    - 5F – 6F 3-4 hrs
    - 7F 4-5 hrs
    - 8F 5-6 hrs
    - 9F 6-7 hrs

Ellis SG, AHJ 2002;143:612-9
SEAL

Ellis AHJ 2002;143:612-9

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**Duett**

- Total: n=392
- PCI: n=266
- GP inhib: n=94

**Manual**

- Total: n=238
- PCI: n=155
- GP inhib: n=58
<table>
<thead>
<tr>
<th></th>
<th>Duett</th>
<th>Manual</th>
</tr>
</thead>
<tbody>
<tr>
<td>8F sheath or larger</td>
<td>48%</td>
<td>59%</td>
</tr>
<tr>
<td>GP IIb/IIIa blockers</td>
<td>24%</td>
<td>24.5%</td>
</tr>
<tr>
<td>Time to haemostasis</td>
<td>14 min</td>
<td>195 min</td>
</tr>
<tr>
<td>Time to ambulation</td>
<td>338 min</td>
<td>705 min</td>
</tr>
</tbody>
</table>

Ellis AHJ 2002;143:612-9
P=NS for all

With GP IIb/IIIa blocker

Duett
Manual
• 0.5% distal limb ischaemia (Duett)
Power calculations

- Assume
  - Major complication rate 3%
  - Interested in a change to 1.5%
    - 85% chance of detecting change
    - 5% level of statistical significance
    - \( n = 4000 \) (2000 in each arm)
  - Pseudoaneurysm rate 0.3%
  - change to 0.15%
    - \( n >> 10,000 \) in each arm
Vasoseal / Angioseal / Techstar

- Registry - prospective data collection
- 4 “eras”

<table>
<thead>
<tr>
<th></th>
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<th></th>
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</thead>
<tbody>
<tr>
<td>Control</td>
<td>n=1019</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vasoseal</td>
<td>n=937</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angioseal</td>
<td>n=742</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Techstar</td>
<td>n=1001</td>
<td></td>
<td></td>
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<td></td>
</tr>
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</table>

Carey D, Cathet and Cardiovasc Int 2001;52:3-7
Interventional Closures

Use of IIb/IIIa Inhibitors

Carey D, Cathet and Cardiovasc Int 2001;52:3-7
Vasoseal / Angioseal / Techstar

Infection

Carey D, Cathet and Cardiovasc Int 2001;52:3-7
Vasoseal / Angioseal / Techstar

Carey D, Cathet and Cardiovasc Int 2001;52:3-7

Acute Femoral Closure

<table>
<thead>
<tr>
<th></th>
<th>Manual</th>
<th>Vasoseal</th>
<th>Angioseal</th>
<th>Techstar</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>0</td>
<td>0.1</td>
<td>0.5</td>
<td>0.2</td>
</tr>
<tr>
<td>n</td>
<td>0</td>
<td>0.1</td>
<td>0.5</td>
<td>0.2</td>
</tr>
</tbody>
</table>
Closure after PCI with GP IIb/IIIa inhibitors

- **Perclose** (n=408) / **Angio-seal** (n=411) / **Manual** (n=2,099)
  - FA angio all patients
  - Antibiotics
    - diabetics
    - immunocompromised
    - very obese
    - prolonged procedure
  - Registry - Closure method up to the operator

- **GP IIb/IIIa inhibitor**
  - 59% of patients (ACT target 200 to 250)
  - 98% abciximab

Cura FA Am J Cardiol 2000;86:780-782
Closure after PCI with GP IIb/IIIa inhibitors

Immediate Haemostasis

Cura FA Am J Cardiol 2000;86:780-782
### Table 3: Femoral Complications in the Whole Study Population

<table>
<thead>
<tr>
<th>Variables</th>
<th>Manual Compression (n = 2,099)</th>
<th>Angio-Seal (n = 411)</th>
<th>Perclose (n = 408)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematoma ≥5 cm</td>
<td>1.4%</td>
<td>1.5%</td>
<td>1.0%</td>
<td>0.80</td>
</tr>
<tr>
<td>Arteriovenous fistula</td>
<td>0.7%</td>
<td>0%</td>
<td>0.2%</td>
<td>0.13</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>0.9%</td>
<td>0.5%</td>
<td>0.7%</td>
<td>0.29</td>
</tr>
<tr>
<td>Vein thrombosis</td>
<td>0.1%</td>
<td>0%</td>
<td>0.2%</td>
<td>0.63</td>
</tr>
<tr>
<td>Retroperitoneal hemorrhage</td>
<td>0.1%</td>
<td>1.0%</td>
<td>0.8%</td>
<td>0.01</td>
</tr>
<tr>
<td>Access site-related blood transfusion</td>
<td>0.8%</td>
<td>1.2%</td>
<td>1.7%</td>
<td>0.16</td>
</tr>
<tr>
<td>Vascular occlusion</td>
<td>0.3%</td>
<td>0.2%</td>
<td>0%</td>
<td>0.49</td>
</tr>
<tr>
<td>Access-site infection</td>
<td>0%</td>
<td>0%</td>
<td>0.5%</td>
<td>0.02</td>
</tr>
<tr>
<td>Vascular surgery</td>
<td>0.4%</td>
<td>0.2%</td>
<td>1.0%</td>
<td>0.25</td>
</tr>
<tr>
<td>All complications</td>
<td>3.1%</td>
<td>2.9%</td>
<td>3.2%</td>
<td>0.96</td>
</tr>
</tbody>
</table>
Closure after PCI with GP IIb/IIIa inhibitors

Retroperitoneal Haematoma

Cura FA Am J Cardiol 2000;86:780-782
Closure after PCI with GP IIb/IIIa inhibitors

All femoral complications

Cura FA Am J Cardiol 2000;86:780-782

![Bar chart showing femoral complications percentage with and without GP IIb/IIIa inhibitors.](chart.png)
Recent large clinical experience

- 4,525 consecutive patients
- All PCI with abciximab (ACT 200 to 250)
- Intention to device close all
- FA angio in all
  - no closure
  - if puncture below bifurcation
  - if extensive calcification
  - if CFA < 5 mm diameter
- Manual (n=1,824)/ Angioseal (n=524)/ Perclose (n=2,177)
  - Choice of device by interventionalist
  - buddy wire in last 399 angioseals
  - 1% epinephrine to tissue tract

Applegate RJ JACC 2002;40:78-83
Recent large clinical experience

Applegate RJ JACC 2002;40:78-83

**Table 1. Patient Characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Manual (n = 1,824)</th>
<th>Angioseal (n = 524)</th>
<th>Perclose (n = 2,177)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>64 ± 12</td>
<td>62 ± 12*</td>
<td>62 ± 12*</td>
</tr>
<tr>
<td><strong>Gender (M/F)</strong></td>
<td>63%/37%</td>
<td>66%/34%</td>
<td>71%/29%*†</td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td>51%</td>
<td>62%*</td>
<td>61%*</td>
</tr>
<tr>
<td><strong>Diabetes mellitus</strong></td>
<td>20%</td>
<td>25%*</td>
<td>25%*</td>
</tr>
<tr>
<td><strong>Smoking history</strong></td>
<td>43%</td>
<td>55%*</td>
<td>52%*†</td>
</tr>
<tr>
<td><strong>Hypercholesterolemia</strong></td>
<td>41%</td>
<td>53%*</td>
<td>56%*</td>
</tr>
<tr>
<td><strong>Vascular disease</strong></td>
<td>10%</td>
<td>4%*</td>
<td>7%*</td>
</tr>
<tr>
<td><strong>History of CABG</strong></td>
<td>15%</td>
<td>9%*</td>
<td>16%†</td>
</tr>
<tr>
<td><strong>Angina class IV</strong></td>
<td>65%</td>
<td>78%*</td>
<td>78%*</td>
</tr>
<tr>
<td><strong>Acute MI</strong></td>
<td>14%</td>
<td>9%*</td>
<td>7%*</td>
</tr>
<tr>
<td><strong>Cardiogenic shock</strong></td>
<td>1%</td>
<td>0%*</td>
<td>0%*</td>
</tr>
</tbody>
</table>

*p < 0.05 vs. manual. †p < 0.05 vs. Angioseal.
CABG = coronary artery bypass grafting; MI = myocardial infarction.
Recent large clinical experience

Applegate RJ JACC 2002;40:78-83

<table>
<thead>
<tr>
<th></th>
<th>Manual</th>
<th>Angioseal</th>
<th>Perclose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closure success</td>
<td>96.5%</td>
<td>97.1%</td>
<td>93.9%</td>
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<tr>
<td>Failure / Femostop</td>
<td>3.5%</td>
<td>2.9%</td>
<td>6.1%</td>
</tr>
</tbody>
</table>

\[ P < 0.05 \]
Recent large clinical experience
Recent large clinical experience

Applegate RJ JACC 2002;40:78-83

All Outcomes

p=ns

Manual (n=1,824)
Device (n=2,553)

Minor
Major
Both

Any Complications
Outcomes excluding lab failed device closure

Recent large clinical experience

Applegate RJ JACC 2002;40:78-83
Summary

- Devices work
- Satisfying to use
- Fiddle
- Device specific issues
New complications

- Skin tract ooze
- Failed closure
- Device Infection
- Arterial obstruction
Lessons learned

- **Device specific issues**
  - Learning curve
  - Biamino G, University Leipzig – Techstar/Prostar

- **Infection**
  - Presentation often delayed for 3 to 4 days
  - Careful aseptic technique
  - Re-glove etc.
  - Antibiotics?

- **Femoral puncture location**
  - FA angiography should be routine
The End
Re-puncture

- Perclose
  - Immediate
- Angioseal
  - Immediate
- Vasoseal
- Duetta
Femoral Access

• Guide catheter size
  – Distal embolus protection devices
    • PercuSurge Guardwire: 8 F
    • Angioguard (Cordis): 8F (lumen 7F 0.081)
    • Angiojet (Possis): 6F and 7F
  – Rotablation
  – DCA
  – TEC
  – Bifurcations with kissing balloons
Perclose
Redwood City, CA, USA

TechStar: 7F 1 suture,
ProStar XL: 8F and 10 F - 2 sutures
The Closer 6F: 1 suture

3-0 braided polyester (non-absorbable)
Vasoseal ES
### TABLE II. Complications for Each Device

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Vasoseal</th>
<th>Angioseal</th>
<th>Techstar</th>
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</thead>
<tbody>
<tr>
<td><strong>Number</strong></td>
<td>1,019</td>
<td>937</td>
<td>742</td>
<td>1,001</td>
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<tr>
<td><strong>Surgical repair</strong></td>
<td>3</td>
<td>6</td>
<td>7</td>
<td>2</td>
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<tr>
<td><strong>Acute occlusion</strong></td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>1</td>
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<tr>
<td><strong>Transfusions</strong></td>
<td>2</td>
<td>0</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td><strong>Readmission</strong></td>
<td>0</td>
<td>5</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td><strong>Infections</strong></td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>

| Total                   | 5 (0.5%)| 14 (1.5%)| 19 (2.6%)| 8 (0.8%) |
| **P value**             | 0.02a   | 0.0002a  | NSa       |

*aCompared to manual compression.*
Summarise some of the data

• Carey 2001
  – for progressive development of things

• Cura for good fairly current and gp2b3a

• Applgate
  – good current practice real world
  – Dangas prob not helpful

• SEAL for duett (and randomised), chamberlain? For vasoseal, and shrake - show poor conflicting data