An Update on the Management of Penile Prosthesis Infection

27th Annual Advances in Urology

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Faculty Disclosures

• Martin Gross, MD - Consultant Coloplast
• Paul E Perito, MD – Consultant Coloplast, Neottract and Boston Scientific
IPP Infection

- Immediate Infection
  - Majority
  - <8 weeks
  - Sepsis
  - Drainage
  - Fever

- Indolent Infection
  - Less common
  - > 8 weeks
  - Persistent pain
  - Pump fixation

Images courtesy of Ricardo Munarriz, MD
IPP Infection

• Primary implants:
  – Inherent patient factors
  – Operative technique
  – Generally occurs within 12 months
  – Late hematogenous infections rarely occur
  – S. epidermidis most common organism
  – SCI, immunosuppressed at higher risk
  – 1-3% of new IPPs

IPP Infection

• Revision/replacement implants:
  – Decreased host resistance
  – Capsule prevents antibiotic penetration
  – Scarring reduces wound healing
  – Biofilm formation
  – Diabetics at higher risk
  – 10-18% of revision/replacements

Preoperative Management

• Patient selection
  – 2002-14: 602 patients, 12 infections
  – 42% (5/12) perioperative substance abuse
  – Total rate 8% (48/602)
  – Poly-substance abusers have 892% higher rate
  – Homeless have 1170% higher rate
  – BG > 200 have 444% higher rate

Preoperative Management

• Preoperative counseling
  – Continue ASA
  – Hold or bridge warfarin and newer agents
  – Do not shave genitals
  – Understand infection risk potential

• Pretreat high-risk cases
  – S. aureus nasal testing
  – Nasal mupirocin treatment
  – Chlorhexidine scrub

Preoperative Management

• Proper glycemic control
  – Work with PCP, endocrinologist yet ?? HgA1C
  – Insulin drip per hospital protocol

• Pre-op reevaluation
  – Ensure timely antibiotic start
  – Examine penis
Intraoperative Management

Primary IPPs

• Surgeon Dependent
  – Adoption of guidelines and standards
  – Improved antibiotic selection
  – Chlorhexidine scrub
  – Contact minimization No Touch/No Air
  – Faster operative time
  – Hematoma reduction

• Device Dependent
  – Infection-retardant coatings

Intraoperative Management

Primary IPPs

• Voodoo
  – Continuity of OR team
  – Minimize OR traffic
  – Fine surgical clippers
  – Betadine urethral prep (1:10 dilution)
  – Extended hand scrub
  – Surgical drain
Intraoperative Management
Primary IPPs – Surgeon Dependent

• Adoption of guidelines and standards
  – Baseline period: 2 of 68 (2.9%) infections, 2 yr
  – Outbreak period: 6 of 11 (54.5%) infections, 5 mo
  – Checklist period: 0 of 52 (0%) infections, 2 yr

<table>
<thead>
<tr>
<th>Preoperative measures</th>
<th>Intraoperative measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Urine culture result (within 1 month prior to surgery date):</td>
<td>4. Intravenous antibiotics administered within 1 hour prior to incision (cefazolin and gentamicin; vancomycin and gentamicin for penicillin-allergic patients)</td>
</tr>
<tr>
<td>2. HgbA1c level (within 2 months of surgery date): value 9% or less (diabetic patients only):</td>
<td>5. Double glove technique for all scrubbed personnel</td>
</tr>
<tr>
<td>3. 2% Chlorhexidine whole body and groin wash for 2 nights preceding surgery</td>
<td>6. Prosthesis is to be handled only by surgeons</td>
</tr>
<tr>
<td></td>
<td>7. Five minutes chlorhexidine hand scrub for all scrubbed personnel</td>
</tr>
<tr>
<td></td>
<td>8. Ten minutes chlorhexidine genital scrub for patient followed by ChloraPrep</td>
</tr>
<tr>
<td></td>
<td>9. Antibiotic irrigation solution of 1 mg/dl rifampin and 1 mg/dl gentamicin; antibiotic soak solution of 10 mg/dl rifampin and 1 mg/dl gentamicin</td>
</tr>
<tr>
<td></td>
<td>10. Multilayered surgical closure and running skin closure (absorbable monofilament)</td>
</tr>
<tr>
<td></td>
<td>11. Minimize turnover of personnel and no room traffic after skin incision is made until wound is dressed</td>
</tr>
</tbody>
</table>

Intraoperative Management
Primary IPPs – Surgeon Dependent

• Chlorhexidine scrub

Table 2. Proportion of Patients with Surgical-Site Infection, According to Type of Infection (Intention-to-Treat Population).

<table>
<thead>
<tr>
<th>Type of Infection</th>
<th>Chlorhexidine–Alcohol (N=409)</th>
<th>Povidone–Iodine (N=440)</th>
<th>Relative Risk (95% CI)*</th>
<th>P Value†</th>
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<tbody>
<tr>
<td>Any surgical-site infection</td>
<td>39 (9.5)</td>
<td>71 (16.1)</td>
<td>0.59 (0.41–0.85)</td>
<td>0.004</td>
</tr>
<tr>
<td>Superficial incisional infection</td>
<td>17 (4.2)</td>
<td>38 (8.6)</td>
<td>0.48 (0.28–0.84)</td>
<td>0.008</td>
</tr>
<tr>
<td>Deep incisional infection</td>
<td>4 (1.0)</td>
<td>13 (3.0)</td>
<td>0.33 (0.11–1.01)</td>
<td>0.05</td>
</tr>
<tr>
<td>Organ-space infection</td>
<td>18 (4.4)</td>
<td>20 (4.5)</td>
<td>0.97 (0.52–1.80)</td>
<td>&gt;0.99</td>
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<td>Sepsis from surgical-site infection</td>
<td>11 (2.7)</td>
<td>19 (4.3)</td>
<td>0.62 (0.30–1.29)</td>
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Intraoperative Management
Primary IPPs – Surgeon Dependent

- Chlorhexidine scrub

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## Intraoperative Management

**Primary IPPs – Surgeon Dependent**

- Improved antibiotic selection

### Table: Prophylaxis for Intraoperative Management

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Organisms</th>
<th>Prophylaxis Indicated</th>
<th>Antimicrobial(s) of Choice</th>
<th>Alternative Antimicrobial(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Involving implanted prosthesis</td>
<td>GU tract and skin</td>
<td>All</td>
<td>- Aminoglycoside AND - 1st/2nd generation Cephalosporin OR Vancomycin</td>
<td>- Ampicillin/Sulbactam - Ticarcillin/Clavulanate - Pipercillin/Tazobactam</td>
</tr>
</tbody>
</table>

Current AUA antibiotic prophylaxis guidelines

http://www.auanet.org/education/aua-guidelines.cfm
Intraoperative Management
Primary IPPs – Surgeon Dependent

• Improved antibiotic selection
  – Retrospective multi-institution study, 25 centers
  – 227 cultures obtained at salvage or explant
  – 153 cultures positive

Gross MS et al. J Sex Med pending publication.
Intraoperative Management
Primary IPPs – Surgeon Dependent

• Improved antibiotic selection

<table>
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<tr>
<th>Cultured Organisms</th>
<th>Number of Cultures</th>
<th>Total %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive cultures</td>
<td>153/227</td>
<td>67%</td>
</tr>
<tr>
<td>Gram positives</td>
<td>111/153</td>
<td>73%</td>
</tr>
<tr>
<td>Gram negatives</td>
<td>60/153</td>
<td>39%</td>
</tr>
<tr>
<td>Candida</td>
<td>17/153</td>
<td>11.1%</td>
</tr>
<tr>
<td>Anaerobes</td>
<td>16/153</td>
<td>10.5%</td>
</tr>
<tr>
<td>Negative cultures</td>
<td>74/227</td>
<td>33%</td>
</tr>
</tbody>
</table>

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### Intraoperative Management

**Primary IPPs – Surgeon Dependent**

<table>
<thead>
<tr>
<th>Cultured Organism</th>
<th>Number of Cultures (% of 130 Positive Cultures)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Candida albicans</td>
<td>17/153 (11.1%)</td>
</tr>
<tr>
<td>Bacteroides spp.*</td>
<td>3/153 (2%)</td>
</tr>
<tr>
<td>Peptostreptococcus*</td>
<td>3/153 (2%)</td>
</tr>
<tr>
<td>Prevotella bivia*</td>
<td>3/153 (2%)</td>
</tr>
<tr>
<td>Propionibacterium*</td>
<td>3/153 (2%)</td>
</tr>
<tr>
<td>Anaerobes (unspeciated)*</td>
<td>2/153 (1.3%)</td>
</tr>
<tr>
<td>Clostridium innocuum*</td>
<td>1/153 (0.6%)</td>
</tr>
<tr>
<td>Finegoldia magna*</td>
<td>1/153 (0.6%)</td>
</tr>
<tr>
<td>Lactobacillus acidophilus*</td>
<td>1/153 (0.6%)</td>
</tr>
<tr>
<td>Peptoniphilus asaccharolyticus*</td>
<td>1/153 (0.6%)</td>
</tr>
</tbody>
</table>

Gross MS et al. J Sex Med *pending publication.*
Intraoperative Management

Primary IPPs – Surgeon Dependent


<table>
<thead>
<tr>
<th>Pt.</th>
<th>Wks. to Infection</th>
<th>Culture Results*</th>
<th>Followup (mos.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>KB</td>
<td>24</td>
<td>Staph. epidermidis</td>
<td>Well (42)</td>
</tr>
<tr>
<td>MC</td>
<td>12</td>
<td>Staph. epidermidis</td>
<td>Well (33)</td>
</tr>
<tr>
<td>MH</td>
<td>11</td>
<td>Staph. epidermidis</td>
<td>Well (28)</td>
</tr>
<tr>
<td>OP</td>
<td>224</td>
<td>No growth, obvious purulence</td>
<td>Mild pain with intercourse (25)</td>
</tr>
<tr>
<td>GR</td>
<td>3</td>
<td>No growth, obvious purulence</td>
<td>Well (21)</td>
</tr>
<tr>
<td>FF</td>
<td>6</td>
<td>Staph. epidermidis</td>
<td>Well (19)</td>
</tr>
<tr>
<td>LC</td>
<td>5</td>
<td>Staph. epidermidis</td>
<td>Well (18)</td>
</tr>
<tr>
<td>RM</td>
<td>156</td>
<td>Staph. epidermidis, <em>Candida albicans</em>, <em>Torulopsis glabrata</em></td>
<td>Well (17)†</td>
</tr>
<tr>
<td>PT</td>
<td>184</td>
<td>Staph. epidermidis, <em>Citrobacter koseri</em></td>
<td>Well (17)†</td>
</tr>
<tr>
<td>AD</td>
<td>20</td>
<td>Staph. epidermidis, <em>Bacteroides species</em></td>
<td>Well (14)</td>
</tr>
<tr>
<td>VG</td>
<td>36</td>
<td>Staph. epidermidis</td>
<td>Well (13)</td>
</tr>
<tr>
<td>PT</td>
<td>24</td>
<td>Staph. epidermidis</td>
<td>Well (9)</td>
</tr>
</tbody>
</table>

* All colony counts were greater than 10⁶.
† Subsequent salvage failure.

- Candida in 2/12 patients (17%)
- Bacteroides in 1/12 (8%)
Intraoperative Management
Primary IPPs – Surgeon Dependent

<table>
<thead>
<tr>
<th>Organism</th>
<th>% of Reports</th>
<th>Average Number of days from implantation to onset</th>
<th>Median Number of days from implantation to onset</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus Epidermidis</td>
<td>34%</td>
<td>366</td>
<td>154</td>
</tr>
<tr>
<td>Staphylococcus Aureus</td>
<td>29%</td>
<td>402</td>
<td>63</td>
</tr>
<tr>
<td><strong>Candida Albicans</strong></td>
<td><strong>11%</strong></td>
<td><strong>215</strong></td>
<td><strong>118</strong></td>
</tr>
<tr>
<td>Enterococcus</td>
<td>9%</td>
<td>NI</td>
<td>NI</td>
</tr>
<tr>
<td>Escherichia Coli</td>
<td>8%</td>
<td>764</td>
<td>389</td>
</tr>
<tr>
<td>Pseudomonas Aeruginosa</td>
<td>6%</td>
<td>106</td>
<td>63</td>
</tr>
<tr>
<td>Klebsiella Pneumonia</td>
<td>3%</td>
<td>208</td>
<td>175</td>
</tr>
</tbody>
</table>

Mentor Product Evaluation Department
Explanted devices 1992-2000
Intraoperative Management

Primary IPPs – Surgeon Dependent

• Improved antibiotic selection
  – Current recommended regimens do not cover candida and anaerobes or MRSA adequately
  – Candida and anaerobes total 22% of positive cultures at salvage and explant
  – MRSA are in 9.2% of positive cultures
  – 33% of cultures negative

Gross MS et al. J Sex Med pending publication.
Intraoperative Management
Primary IPPs – Surgeon Dependent

• Contact minimization
  – No-Touch technique
  – Reduced implant contact with skin flora, i.e. operative time
  – Infections reduced to 0.46% with infection-retardant coated IPPs

Intraoperative Management
Primary IPPs – Surgeon Dependent

• Faster operative time
  – IPP surgeon compared to private practice partners
  – Two 57 patient groups
  – Median OR time 34 mins vs 94 mins
  – No infections or complications vs 8/57 complications

Intraoperative Management

Primary IPPs – Surgeon Dependent

- Hematoma reduction
  - Mummy wrap dressing
  - 83 % decrease in infection

“To Drain or Not to Drain?”

- Place Drain in most dependant portion of scrotum.
- 10lb sandbag for 2hrs post-op
- No conclusive evidence showing retrograde migration of bacteria (Sadeghi-Nejad)
Scrotal Hematoma

4% incidence penoscrotal cases not drained. Even with drain, inflation & running closure of corpora: 1%.

THOSE THAT DRAIN SEE 75–250 CC/24 HOUR REGULARLY
Intraoperative Management
Primary IPPs – Device Dependent

• Infection-retardant coatings
  – AMS: InhibiZone® (rifampin and minocycline)
  – Coloplast: hydrophilic coating
  – Meta-analysis: IRC 0.89% vs. NC 2.32%

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Coating</th>
<th>Number</th>
<th>Infection Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMS 700®</td>
<td>InhibiZone®</td>
<td>3,158</td>
<td>0.63%</td>
</tr>
<tr>
<td>Coloplast Titan®</td>
<td>Rifampin/gentamycin</td>
<td>181</td>
<td>0.55%</td>
</tr>
<tr>
<td>Coloplast Titan®</td>
<td>Vancomycin/gentamycin</td>
<td>181</td>
<td>4.42%</td>
</tr>
<tr>
<td>Coloplast Titan®</td>
<td>Hydrophilic only</td>
<td>1,176</td>
<td>1.11%</td>
</tr>
</tbody>
</table>

Intraoperative Management
Revision and Replacement IPPs

• Revision washout
  – Multicenter retrospective study
  – 140 patients underwent antiseptic lavage during R/R with IRC implants
  – Bacitracin, betadine, hydrogen peroxide
  – 43 patients underwent R/R without lavage
  – 4/140 (2.86%) had subsequent infection
  – 5/43 (11.6%) became infected

Postoperative Management

• Postop antibiotics
• Discharge antibiotics
• Regular monitoring
Postoperative Management

• Postop antibiotics
  – IV antibiotics for 24 hours

• Discharge antibiotics
  – SMS members 94%, levofloxacin 500 mg qd
  – Non-SMS members 88%, cephalexin 500 mg qid
  – Trimethoprim-sulfamethoxazole DS bid x 1 wk

• Regular monitoring
  – 2 weeks, 6 weeks, 6 months
  – 3 month global vs adequate care

Salvage and Explant

- Infection historically treated with explant and time, followed by reimplant
- Explant appropriate in:
  - Sepsis
  - Necrosis
  - Inability to tolerate surgery
  - Patient preference
Carrion Cast

• Injection of synthetic high purity calcium sulfate into the corpora
• SHPCaSO₄ infused with abx
• Alternative to simple explant
• Later reimplant feasible and easier.
• Long-term data pending

Mulcahy Salvage

- Revolutionized infection management
- 82% infection-free rate
- Minimizes loss of penile size and fibrosis
- Decreases sexual inactivity
- Avoids difficult reimplantation

APPENDIX 1: SALVAGE PROTOCOL
Remove all prosthetic parts and foreign material
Irrigate wound with 7 antiseptic solutions
Change gowns, gloves, surgical drapes and instruments
Insert new prosthesis
Close wounds with no drains or catheters
Oral antibiotics for 1 month

APPENDIX 2: ANTISEPTIC IRRIGATING SOLUTIONS
Antibiotics (kanamycin—bacitracin)
Half strength hydrogen peroxide
Half strength povidone iodine
Pressure irrigation (water pic) with 1 gm. vancomycin and 80 gm. gentamicin in the 5 l. irrigating solution
Half strength betadine
Half strength hydrogen peroxide
Antibiotics (kanamycin—bacitracin)

Mulcahy Salvage

- Uncommon use in practice
- Estimated 17.3% salvage rate nationwide
- More common in academic centers, younger patients
- Suggests an easier, safer alternative is needed
- Very few studies since original paper

Malleable Implant Salvage Technique

• Retrospective multi-institution study

<table>
<thead>
<tr>
<th></th>
<th>Time</th>
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<tbody>
<tr>
<td>Mean Age</td>
<td>63.9 years (26-79)</td>
</tr>
<tr>
<td>Time to Salvage</td>
<td>5.3 months (2-124)</td>
</tr>
<tr>
<td>Surgical Time</td>
<td>148 minutes (47-209)</td>
</tr>
</tbody>
</table>

# Malleable Implant Salvage Technique

<table>
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<tr>
<th>Surgical History</th>
<th>N</th>
<th>Salvage Rate %</th>
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<tbody>
<tr>
<td>First Time IPP</td>
<td>42</td>
<td>90% (38/42)</td>
</tr>
<tr>
<td>Previous IPP Surgeries (Mean 2.6, Range 1-9)</td>
<td>16</td>
<td>100% (16/16)</td>
</tr>
<tr>
<td>Total</td>
<td>58</td>
<td>93% (54/58)</td>
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Malleable Implant Salvage Technique

• Improved infection-free rate with malleable vs. IPP Mulcahy salvage (93% vs. 82%)

• Feasible to convert malleable to IPP (31%)

• Many patients elect to keep malleable

Salvage Protocol

• 1) Obtain cultures before antibiotic administration
• 2) Antibiotic and antifungal coverage
  – Vancomycin, Piperacillin-tazobactam, and Fluconazole
• 3) Salvage procedure with IPP (82%) vs. MPP (93%)
  – Follow Mulcahy protocol
  – Soak malleable in Vancomycin, Piperacillin-tazobactam and Amphotericin B if hydrophillic coating
• 4) Continue this regimen until cultures return
  – Tailor antibiotics if appropriate
  – If cultures negative, then 1 month of Trimethoprim-sulfamethoxazole and Amoxicillin-clavulanic acid

Gross MS et al. J Sex Med pending publication.
• Balen AK et al. Active poly-substance abuse concurrent with surgery as a possible newly-identified infection risk factor in IPP placement based on a retrospective analysis of health and socioeconomic factors. J Sex Med; accepted.
• Gross MS et al. A Review of Microorganisms Isolated at Salvage or Explant of IPPs: Are We Covering the Correct Bugs. AUA 2015 Abstract Podium Presentation PD26-02.
• Eid JF et al. Coated implants and "no touch" surgical technique decreases risk of infection in inflatable penile prosthesis implantation to 0.46%. Urology. 2012; 79:1310-5.