Robotic Prostatectomy
POTENCY AND CONTINENCE
AND THE INTRODUCTION OF HYPOTHERMIA

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University of California, Irvine Medical Center
September 20th, 2008
UCI EARLY POTENCY FINDINGS

2002-2003

(IIEF-5 22-25: <66 yrs of age)

1. Sham or No surgery
2. Bilateral Excision
3. Thermal – cautery

% potent

3 Months 9 Months 15 Months 24 Months
Gill & Ahlering Reports with Bulldog Clamps

LATERAL PEDICLE CONTROL DURING LAPAROSCOPIC RADICAL PROSTATECTOMY: REFINED TECHNIQUE

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FEASIBILITY STUDY FOR ROBOTIC RADICAL PROSTATECTOMY CAUTERY-FREE NEUROVASCULAR BUNDLE PRESERVATION

THOMAS E. AHLERING, LOUIS EICHEL, DAVID CHOU, AND DOUGLAS W. SKARECKY

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Submitted: July 24, 2004, accepted (with revisions): November 16, 2004

FIGURE 2. Laparoscopic bulldog clamps (30 mm) placed at least 1 cm from prostate (top) on VP (example shown on right VP), above rectum (bottom).
Rapid Communication

Early Potency Outcomes with Cautery-Free Neurovascular Bundle Preservation with Robotic Laparoscopic Radical Prostatectomy

THOMAS E. AHLERING, M.D., LOUIS EICHEL, M.D., and DOUGLAS SKARECKY, B.S.

ABSTRACT

Purpose: To report short-term potency outcomes with a cautery-free technique (CFT) to preserve the neurovascular bundles (NVB) during robotic laparoscopic radical prostatectomy (LRP).

Patients and Methods: All men were <66 years of age and had a Sexual Health Inventory in Men (SHIM) score of 22 to 25. They underwent unilateral or bilateral dissections. Group 1 (N = 23), the study group, had preservation of the NVB with CFT. Group 2 (N = 36) had traditional dissection using bipolar cautery. Data were collected prospectively via validated questionnaires. Potency was defined as an erection adequate for vaginal penetration.

Results: At 3 months, 10 patients (43%) in the CFT group reported potency versus just 3 (8.3%) in the bipolar-cautery group (P = 0.003). Additionally, only 2 (18%) of those having CFT reported zero penile fullness compared with 15 (68%) in the bipolar-cautery group (P = 0.01).

Conclusions: The technique of controlling the vascular pedicle of the prostate and dissecting the NVB without cautery produced significant improvement in potency outcomes at just 3 months.

Impact of Cautery versus Cautery-Free Preservation of Neurovascular Bundles on Early Return of Potency

THOMAS E. AHLERING, M.D., DOUGLAS SKARECKY, B.S., and JAMES BORIN, M.D.

ABSTRACT

Purpose: To update our short-term potency outcomes from a cautery-free (CFT) versus bipolar cautery technique to preserve the neurovascular bundles (NVB) during robotic laparoscopic radical prostatectomy (LRP).

Patients and Methods: Previously, we reported on 3-month potency outcomes in 23 men, which we now extend to 51 men. All men met three criteria: age <66 years, Sexual Health Inventory in Men (SHIM-5) score of 22 to 25, and either unilateral or bilateral NVB preservation at LRP. Group 1 (N = 31), the study group, had preservation of the NVB with CFT. Group 2 (N = 36) had traditional dissection using bipolar cautery. The average age and preoperative SHIM scores were similar for the two groups. Data were collected prospectively via validated questionnaires. Potency was defined as an erection adequate for vaginal penetration. All men were asked to estimate the fullness of erections compared with baseline (preoperative).

Results: The average age and preoperative SHIM scores were similar for both groups. The rate of potency at 3 months was 47% (22/45) in group 1 versus just 8.3% (3/36) in group 2 (P < 0.001). Additionally, only 9 of 25 CFT patients (36%) reported zero fullness compared with 15 of 22 patients (68%) in the bipolar cautery-treated group (P = 0.03).

Conclusions: With expanded experience, there was no change in 3-month return of sexual function (47%) compared with our initial publication. This result further supports the importance of avoiding cautery when controlling the vascular pedicle and dissecting the NVB.
THESE FINDINGS STRONGLY SUPPORT A PERIPHERAL NERVE INJURY

(IIEF-5 22-25: <66 yrs of age)

1. Sham or No surgery
2. Excisional
3. Thermal – cautery
4. Athermal

5-fold improvement

38%

18%

20%

3 Months 9 Months 15 Months 24 Months
Evaluation of Long-Term Thermal Injury Using Cautery During Nerve Sparing Robotic Prostatectomy

Thomas E. Ahlering, Louis Eichel, and Douglas Skarecky

OBJECTIVE
In our initial 125 cases, we used cautery during preservation of the neurovascular bundles (NVBs). We previously reported the short-term benefit of a cautery-free versus cautery technique. To assess long-term consequences of cautery, we report 2-year potency outcomes for these robot-assisted laparoscopic radical prostatectomies (RLP).

METHODS
Between June 2002 and February 2004, 125 consecutive patients underwent RLP by 1 surgeon. All data were entered prospectively into an electronic database. In cases 1 to 15, the vascular pedicle and nerve were dissected with monopolar cautery. In cases 16 to 125, the dissection used bipolar cautery and scissors. Preoperatively, 42 met inclusion criteria: age younger than 66 years, International Index of Erectile Function (IIEF-5) of 22 to 25 and uni (12) or bilateral (35) nerve sparing. Postoperatively all patients were encouraged to use 5-PDE inhibitors. Potency was assessed by self-administered validated questionnaires.

RESULTS
Four were excluded because of treatment intervention (3) or refusal to follow-up (1). Thirty-eight have follow-up data of 24 or more months. At 3, 9, and 15 months only 3 of 36 (8.3%), 5 of 34 (14.7%), and 16 of 37 (43.2%) were potent. However at 24+ months, 5 of 10 (50%) of unilateral and 19 of 28 bilateral nerve-sparing (68%) were potent with an average IIEF-5 of 18.4 and erectile firmness of 75% to 100% of baseline.

CONCLUSION
These findings suggest that in addition to other injury, thermal injury to the NVB is dense with very low recovery rates in the first 12 to 18 months. However, with nearly two-thirds ultimately reporting potency return, these injuries are generally not permanent and recovery approaches 75% to 100% of baseline.  UROLOGY xx: xxx, xxxx. © 2008 Elsevier Inc.
FINDINGS SUPPORT A RECOVERABLE NERVE INJURY

(IIEF-5 22-25: <66 yrs of age)

1. Sham or No surgery
2. Excisional
3. Thermal – cautery
4. Athermal
Single Institution 2 Year Patient-Reported Validated Sexual Function Outcomes After Nerve-Sparing Robot-assisted Radical Prostatectomy

Esequiel Rodriguez Jr., David S. Finley, Douglas Skarecky and Thomas E. Ahlering
Department of Urology, University of California, Irvine, CA

200 Consecutive patients (case # 151-350)

Accepted for publication J. Urol. July 2008
2-YEAR POTENCY OUTCOMES WITH AN ATERMAL TECHNIQUE.
(IIEF-5 22-25: <66 yrs of age)

1. Sham or No surgery
2. Thermal – cautery
3. Athermal
WHAT ACCOUNTED FOR PERIPHERAL NERVE INJURY

(IIEF-5 22-25: <66 yrs of age)

38% had either no injury or a Grade I nerve injury (neurapraxic) that had largely recovered within 3 months.

The remaining 62% had either a grade II (Axonotemetic) or grade III (Neurotemetic) injury.

1. Sham or No surgery
2. Excisional
3. Thermal – cautery
4. Athermal

100
90
80
70
60
50
40
30
20
10
0

3 Months 9 Months 15 Months 24 Months
Prostatic Diseases and Male Voiding Dysfunction

Prostate Weight and Early Potency in Robot-Assisted Radical Prostatectomy

Thomas E. Ahlering, Adam G. Kaplan, David S. Yee, and Douglas W. Skarecky

OBJECTIVES
Using an athermal technique for nerve preservation we noted that ~40% are potent compared with ~60% who are not at 3 months after robot-assisted laparoscopic prostatectomy (RLP). In an attempt to understand this difference, we examine factors potentially influencing potency at 3 months.

METHODS
Of 300 consecutive RLPs, we identified 139 men who met preoperative inclusion criteria: age ≤ 65 years with International Index of Erectile Function (IIEF-5) scores of 22-25. All men were instructed to take 5'-phosphodiesterease inhibitors postoperatively. All data were collected and entered prospectively into an electronic database. Sexual outcomes were obtained via self-administered validated questionnaires. We defined potency by affirmative answers to the following questions: Were erections adequate for penetration, and were they satisfactory?

RESULTS
At 3 months, 53 subjects (38%) were potent. Univariate and multivariate analysis demonstrated no effect for IIEF-5 score, body mass index, nerves spared, estimated blood loss, hypertension, diabetes, use of cholesterol-lowering agents, and lifestyle issues. Prostate weight (43.3 vs 51.4 g, P = .038) and age (55 vs 57, P = .03) were significant in univariate analysis. In multivariate analysis only prostate weight was predictive of potency (P = .04). To ascertain a possible relation between traction nerve injury and prostate weight, analysis between prostate weight groups and potency demonstrated an inverse relationship.

CONCLUSIONS
Low prostate weight was the only factor found to correlate with early return of potency. Our data also suggest that increasing prostate weight increases the risk of delay in potency recovery. UROLOGY xx: xxx, xxxx. © 2008 Elsevier Inc.
Table 1. Preoperative patient clinical and demographic data, by group

<table>
<thead>
<tr>
<th>Value</th>
<th>Impotent</th>
<th>Potent</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>56.80 (5.35)</td>
<td>54.86 (6.06)</td>
<td>.03</td>
</tr>
<tr>
<td>Body mass index</td>
<td>26.94 (3.12)</td>
<td>26.01 (3.49)</td>
<td>.13</td>
</tr>
<tr>
<td>Preoperative vital signs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temp</td>
<td>97.74 (0.74)</td>
<td>97.65 (0.65)</td>
<td>.60</td>
</tr>
<tr>
<td>Heart rate</td>
<td>73.27 (10.51)</td>
<td>71.29 (13.47)</td>
<td>.39</td>
</tr>
<tr>
<td>Respiratory rate</td>
<td>17.21 (3.12)</td>
<td>17.38 (5.60)</td>
<td>.84</td>
</tr>
<tr>
<td>Blood pressure (systolic)</td>
<td>126.69 (13.90)</td>
<td>129.56 (13.88)</td>
<td>.26</td>
</tr>
<tr>
<td>Blood pressure (diastolic)</td>
<td>80.72 (8.62)</td>
<td>82.15 (8.99)</td>
<td>.38</td>
</tr>
<tr>
<td>Lifestyle</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>69 (84%)</td>
<td>42 (87.5%)</td>
<td>.68</td>
</tr>
<tr>
<td>Spouse’s age</td>
<td>52.40 (7.21)</td>
<td>51.81 (6.15)</td>
<td>.67</td>
</tr>
<tr>
<td>Single</td>
<td>5</td>
<td>1</td>
<td>.24</td>
</tr>
<tr>
<td>Divorced</td>
<td>4</td>
<td>2</td>
<td>.45</td>
</tr>
<tr>
<td>Significant Other</td>
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<td>3</td>
<td>.11</td>
</tr>
<tr>
<td>Widowed</td>
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<td>0</td>
<td>.45</td>
</tr>
<tr>
<td>Alcohol intake</td>
<td></td>
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</tr>
<tr>
<td>Never</td>
<td>11</td>
<td>8</td>
<td>.62</td>
</tr>
<tr>
<td>&lt;1 drink/wk</td>
<td>20</td>
<td>10</td>
<td>.64</td>
</tr>
<tr>
<td>1-5 drinks/wk</td>
<td>41</td>
<td>28</td>
<td>.36</td>
</tr>
<tr>
<td>&gt;5 drinks/wk (other)</td>
<td>15 (12%)</td>
<td>2 (4%)</td>
<td>.80</td>
</tr>
<tr>
<td>Cigarette smoking</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Never</td>
<td>49</td>
<td>26</td>
<td>.54</td>
</tr>
<tr>
<td>Currently</td>
<td>5</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Quit, but smoked &gt;5 packs/y</td>
<td>28</td>
<td>19</td>
<td>.54</td>
</tr>
<tr>
<td>Medical comorbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>24 (29%)</td>
<td>17 (35%)</td>
<td>.49</td>
</tr>
<tr>
<td>Diabetes</td>
<td>3</td>
<td>0</td>
<td>.06</td>
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<tr>
<td>Coronary artery disease</td>
<td>8</td>
<td>2</td>
<td>.21</td>
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<tr>
<td>Hypercholesterolemia</td>
<td>28</td>
<td>15</td>
<td>.86</td>
</tr>
<tr>
<td>Use cholesterol lowering drugs</td>
<td>29</td>
<td>15</td>
<td>.64</td>
</tr>
<tr>
<td>Use statin</td>
<td>26</td>
<td>14</td>
<td>.76</td>
</tr>
<tr>
<td>Clinical depression</td>
<td>12</td>
<td>7</td>
<td>.99</td>
</tr>
<tr>
<td>Asthma</td>
<td>5</td>
<td>4</td>
<td>.63</td>
</tr>
<tr>
<td>Average no. of comorbidities</td>
<td>0.76 (0.91)</td>
<td>0.79 (0.82)</td>
<td>.62</td>
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<tr>
<td>Family history</td>
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<td></td>
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<tr>
<td>Stroke</td>
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<td>18</td>
<td>.70</td>
</tr>
<tr>
<td>Diabetes</td>
<td>22</td>
<td>10</td>
<td>.45</td>
</tr>
<tr>
<td>Heart disease</td>
<td>44</td>
<td>20</td>
<td>.46</td>
</tr>
<tr>
<td>Hypertension</td>
<td>44</td>
<td>20</td>
<td>.46</td>
</tr>
<tr>
<td>Cancer</td>
<td>69</td>
<td>41</td>
<td>.85</td>
</tr>
</tbody>
</table>
POTENCY AT 3 MONTHS VERSUS PROSTATE WEIGHT

% potent

0-35 36-45 46-55 56-85 >85
gms
Individual axons are encased by the myelin sheath of Schwann cells (inset) within the endoneurium (ENDO). The endoneurium is in turn encircled by a connective tissue layer, the perineurium (PERI), composed of perineural cells. Nerve fascicles are then embedded in a layer of connective tissue called the internal epineurium (Int. EPI), which is surrounded by the external epineurium (Ext. EPI).
TYPES OF PERIPHERAL NERVE INJURY
BASED ON GRADE OF INJURY

Grade 1. Myelin is injured but the nerve and sheath are intact. Injury is short-term weeks to 3 months.

Grade 2. Myelin and nerve are injured but the nerve and sheath are intact. Nerve re-growth takes 9-18 months.

Grade 3. Myelin, nerve, and sheath are injured resulting in injury that is permanent.

Courtesy of Grant, Goodkin and associates, 1943
CONCLUDING THOUGHTS

(Presented at AUA in May 2007)

• Preoperative Sexual Function and Age are the most important preoperative factors driving sexual outcomes.
• Thermal energy in proximity to the NVB appears to create a deep but recoverable nerve injury that slows return of sexual function for up to 18-24 months.
• Athermal Techniques – can avoid traction injury if the prostate is small enough relative to the pelvic confines.
• Nerve traction injuries creates a less severe injury (vs thermal) that appears to largely recover within 9-15 months.

Nerve rehabilitation logically is the NEXT FRONTIER!!!!
Therapeutic Hypothermia

- Kevin Everett fractures C4-C5. Receives hypothermia...and walks at the Super Bowl.

- The induction of hypothermia (i.e. 30-33°C or ) through artificial cooling has been used since the 1950s

- Neurological injury: post-anoxic coma following CPR resuscitation, stroke, and head injury has been reported to prevent permanent brain injury!!!

- Hypothermia to prevent the CNS, nerve, kidney and other organ injury has been widely reported in humans and animals.
Cold spinoplegia and transvertebral cooling pad reduce spinal cord injury during thoracoabdominal aortic surgery

Mitsuhiro Isaka, MD, a Hajime Kumagai, MD, a Yuji Sugawara, MD, a Kenji Okada, MD, a Kazumasa Orihashi, MD, a Megu Ohtaki, PhD, b and Taijiro Sueda, PhD, a Hiroshima, Japan

(J Vasc Surg 2006;43:1257-62.)

Group 1 – clamped with no cooling
Group 2 – ice NS only
Group 3 – ice NS + cooling pad
Group 1 – (controls) all completely paraplegic by 48 hours.

Group 2 – (ice saline only) substantial paraplegia by 48 hours.

Group 3 – (ice NS + cooling pad) no paraplegia at 48 hours.
Group I
(Tarlov score 0)

Group III
(Tarlov score 4)
Randomized Clinical Trials demonstrating neurologic outcome after cardiac arrest

![Graph showing neurologic outcomes comparison](chart.png)
Spinal Cord protection during aneurysm repair

- 70 pts underwent TAA repair with epidural cooling using continuous infusion of 4°C NS into epidural catheter vs with matched normothermic-controls.
- CSF temp reduced to avg 24 degrees C
- Neurologic deficits = 2.9% cooling vs 23% control group (p < 0.0001).

Transrectal local hypothermia

Thermodynamic Issues?

- Establish how cold we could cool the region.
- Establish when to cool i.e. before, during or after dissection of the NVB.
- Establish how long to cool?
Hypothermia Thermodynamic Findings

• The NVB was being cooled.
• And the bladder neck and external sphincter were being cooled.
RATIONALE
FOR EVALUATING CONTINENCE

• Incontinence has a major negative impact on HRQOL

• Time to continence following RP ranges from days to months with a median in our hands of about 60-70 days.

• Pad-free continence is substantially more objective to assess than 0-1 pads and potency.
f2 finds, 8/2/2008
Factors Influencing Time to Recovery of Continence

- Age
- Preoperative urinary function
- Cavernosal nerve sparing
- Prostate weight
- Urethral length
- Restoration of the posterior aspect of rhabdosphincter

Inflammatory damage
Time to Recovery of Continence of the Hypothermic Group

• Entire cohort cases # 1-668 overall.
• Entire cohort adjusted for baseline characteristics
• Learning Curve
• Technique changes i.e. Rocco (cases #593-668)
### UNIVARIATE ANALYSIS

**Baseline characteristics of Control vs Hypothermic groups**

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<th>hRLP (#666-718)</th>
<th>t-test</th>
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<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
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<tr>
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<td>61.3</td>
<td>7.4</td>
<td>59.9</td>
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<tr>
<td>AUAss</td>
<td>8.7</td>
<td>7.2</td>
<td>7.7</td>
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<tr>
<td>IIEF-5</td>
<td>19.0</td>
<td>7.5</td>
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<td>Pre-PSA</td>
<td>6.7</td>
<td>6.2</td>
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<td>BMI</td>
<td>26.9</td>
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<td>26.5</td>
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<tr>
<td>Prostate weight</td>
<td>52.0</td>
<td>21.2</td>
<td>54.4</td>
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<thead>
<tr>
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<th>Frequency</th>
<th>Percent</th>
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<td>I</td>
<td>386</td>
<td>65</td>
<td>26</td>
<td>58</td>
<td>0.236</td>
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</tr>
<tr>
<td>II</td>
<td>187</td>
<td>32</td>
<td>17</td>
<td>38</td>
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<td></td>
</tr>
<tr>
<td>III</td>
<td>17</td>
<td>3</td>
<td>2</td>
<td>4</td>
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<tr>
<td>Nerve-sparing</td>
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<tr>
<td>None</td>
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<td>0.549</td>
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<tr>
<td>Unilateral</td>
<td>159</td>
<td>27</td>
<td>13</td>
<td>28</td>
<td>0.549</td>
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<tr>
<td>Bilateral</td>
<td>396</td>
<td>67</td>
<td>34</td>
<td>72</td>
<td>0.549</td>
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Kaplan-Meier

time to 0-pads Hypothermic vs. Control group

HYPO group
39 days

59 days Control cases #1-667

p=0.002
## Multivariate Analysis

**Hypothermia vs Control (# 1- 667)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>S.E.</th>
<th>p-value</th>
<th>Hazard Ratio</th>
<th>Lower</th>
<th>Upper</th>
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<tr>
<td>All controls vs.</td>
<td>0.176</td>
<td>0.036</td>
<td>1.445</td>
<td>1.024</td>
<td>2.038</td>
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<tr>
<td>Hypothermic</td>
<td></td>
<td></td>
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<tr>
<td>AUA</td>
<td>0.007</td>
<td>0.012</td>
<td>0.982</td>
<td>0.968</td>
<td>0.996</td>
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<td>IIEF-5</td>
<td>0.007</td>
<td>0.010</td>
<td>1.019</td>
<td>1.005</td>
<td>1.035</td>
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<td>AGE</td>
<td>0.007</td>
<td>0.003</td>
<td>0.979</td>
<td>0.966</td>
<td>0.993</td>
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<tr>
<td>PROSTATE WT</td>
<td>0.002</td>
<td>0.251</td>
<td>0.997</td>
<td>0.993</td>
<td>1.002</td>
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EFFECT OF LEARNING CURVE
Kaplan-Meier Cooling vs. Learning Curve
### Multivariate Analysis

**Hypothermia vs Rocco (#593-667)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>S.E.</th>
<th>p-value</th>
<th>Hazard Ratio</th>
<th>Lower</th>
<th>Upper</th>
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<tr>
<td>Hypo vs. Rocco</td>
<td>0.238</td>
<td>0.021</td>
<td>1.735</td>
<td>1.088</td>
<td>2.768</td>
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<td>AUA</td>
<td>0.019</td>
<td>0.001</td>
<td>0.940</td>
<td>0.906</td>
<td>0.975</td>
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<tr>
<td>IIEF-5</td>
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<td>0.807</td>
<td>1.005</td>
<td>0.964</td>
<td>1.049</td>
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<tr>
<td>AGE</td>
<td>0.020</td>
<td>0.325</td>
<td>0.980</td>
<td>0.943</td>
<td>1.019</td>
</tr>
<tr>
<td>PROSTATE WT</td>
<td>0.005</td>
<td>0.026</td>
<td>1.011</td>
<td>1.001</td>
<td>1.021</td>
</tr>
</tbody>
</table>
• The delay of return in continence and potency following radical prostatectomy clinically suggests a role of inflammation.

• Theoretical and basic research evidence strongly supports that hypothermia can suppress the inflammatory cascade.

• Clinical studies (cardiac, CNS, kidney, liver, joints etc.) demonstrate the potential benefit of Hypothermia in many clinical settings.

• Our continence results provide introductory evidence for proof of concept. We expect potency should also respond favorably to cooling.
We are presently enrolling patients into a RCT comparing hypothermia intraoperatively vs intraoperatively and for 1 hour in Recovery.

Clinical studies continue to examine the thermodynamics of when to cool and how cold to lower temperatures...

We are soon to start a multi-centered Randomized Clinical Trial comparing Hypothermia to No Hypothermia with time to no pads as the clinical outcome.
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• Kathy Osann, PhD
• Douglas Skarecky, BS

Disclosure

• National and International Patents have been submitted under the auspices of Univ. of California, Irvine.
• We have entered into a Licensing Agreement with Innercool Inc. (USA) to make a clinical device.
Prostate Weight vs Potency @ 3 Mos

(SHIM 22-25: <66 yrs of age)