Treatment of cervical precancer: Past, present, and future

Experiences with CryoPen and thermal coagulation

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Session code: 105M-T1
Track 1 – Stemming the Tide: Innovations in Prevention and Screening
Disclosure of Interest: None to disclose.
Abstract previously published: No.
Background on PATH’s work: Innovative screening tests and preventive treatment

- careHPV™ test
- OncoE6™ Cervical Test (strip test)
- Test performance in real-world conditions
- New devices for treatment

Photos (clockwise from top left): QIAGEN; PATH/Rose Slavkovsky; PATH/Patrick McKern; PATH/Jose Jeronimo

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Timeline development of CryoPen® Surgical System

- **2012**: Demonstrated of CryoPen device at PATH Seattle offices.
- **2013**: PATH carries out bench testing of CryoPen device.
- **2014**: PATH provides technical assistance for development of first prototype for low- and middle-income countries (LMIC).
- **2015**
- **2016**

CryoPen is a registered trademark of CryoPen, Inc.

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CryoPen

light blue area is the ideal temperature range for deep tissue destruction
Demonstration of CryoPen device at PATH Seattle offices.

CryoPen, Inc. delivers first prototype for LMIC to PATH for evaluation.

PATH carries out bench testing of CryoPen device.

PATH provides technical assistance for development of first prototype for LMIC.

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CryoPen: Characteristics

• **Portable**
  - Weight approx. 16 pounds (7.25 kg)

• **Requires electricity**
  - 1 hour for reaching optimal temperature

• **Price approx. US$4,000 (manufacturer)**
Timeline development of CryoPen Surgical System

2012

Demonstration of CryoPen device at PATH Seattle offices.

2013

CryoPen, Inc. delivers first prototype for LMIC to PATH for evaluation.

PATH carries out bench testing of CryoPen device.

2014

CryoPen, Inc. completes updated prototype for LMIC.

PATH provides technical assistance for development of first prototype for LMIC.

BHI receives NIH grant to complete development of unit for LMIC.

PATH is a project advisor.

2015

PATH carries out field testing in Uganda.

Need for further modifications.

2016

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CryoPen: Testing in Uganda

Photos: PATH/Jose Jeronimo
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2016
- PATH and CryoPen evaluate improved unit in Peru, March 2016.
CryoPen: Improved handheld unit

Photos: PATH/Jose Jeronimo
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- **2015**
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    - Need for further modifications.

- **2016**
  - Final version of CryoPen ready for commercialization.

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CryoPen: Current status

- FDA approved
- Ready for manufacturing and commercialization
  - Requires funding for expanding manufacturing capacity
- Price approx. $4,000 (manufacturer)
Thermal coagulator*

- Tip heated to 120° Celsius
- Requires electricity
- 40-second applications

*Formerly known as “cold-coagulator”
## Cure rates using thermal coagulator

<table>
<thead>
<tr>
<th>Authors/Location</th>
<th>Year</th>
<th>Number treated</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hussein/Scotland</td>
<td>1985</td>
<td>CIN2: 21 CIN3: 33</td>
<td>CIN2: 95% @ 4 mo.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>CIN3: 85% @ 4 mo.</td>
</tr>
<tr>
<td>Singh/Singapore</td>
<td>1988</td>
<td>CIN 2/3: 47</td>
<td>84%</td>
</tr>
<tr>
<td>Gordon &amp; Duncan/Scotland</td>
<td>1991</td>
<td>CIN 3: 1628</td>
<td>95% @ 1 yr.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>92% @ 5 yrs.</td>
</tr>
<tr>
<td>Williams/England</td>
<td>1993</td>
<td>CIN2/3: 125</td>
<td>96.5%</td>
</tr>
<tr>
<td>Zawislak/N Ireland</td>
<td>2003</td>
<td>725 (all grades CIN)</td>
<td>87%</td>
</tr>
</tbody>
</table>

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Timeline development: Liger Medical Thermocoagulator

- **2014**: Liger Medical, LLC and PATH meet to discuss the potential to develop a battery-powered thermal coagulator.
- **2015**: Liger completes first prototype of a battery-powered thermal coagulator and meets with PATH in Seattle.
- **2016**: Liger Medical develops battery-powered thermal coagulator prototype.
Expectations for the new Thermocoagulator

- Battery-powered
- Approx. 30 treatments
- Charges in approx. 5 hours
- Lights above handle to indicate treatment start and finish
- Timer
- Cost could decrease to $1,000
Liger Medical, LLC and PATH meet to discuss the potential to develop a battery-powered thermal coagulator.

2014

Liger Medical completes first prototype of a battery-powered thermal coagulator or and meets with PATH in Seattle.

2015

PATH meets with Liger Medical in Salt Lake City to further develop prototype.

Liger Medical completes development of updated prototype.

2016

Evaluations by PATH of updated prototype in Malawi, Peru, and Uganda.

Final device completed.

Liger Medical develops battery-powered thermal coagulator prototype.

Liger Medical modifies prototype based on feedback from PATH.

Liger further modifies prototype based on feedback from PATH.

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Final Thermocoagulator

- Battery-powered unit
- > 30 treatments
- Charges in approx. 5 hours
- Light and sound indicators above handle
- Timer
Final Thermocoagulator

- Electronic temperature stabilizer
- LED lights to illuminate the cervix
- Probes resistant to autoclave, CIDEX, and Chlorine
- FDA approval
- Price approx. $1,000 (manufacturer)

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Final notes

• Non-gas treatment devices are available
• Introduction expected by end of 2016
• Education of providers is required
Thank You

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worldcancercongress.org