



Cryo On-Line Database (COLD) Registry

John Eberts, Endocare, Inc

AA wholly-owned subsidiary of HealthTronics, Inc

COLD Registry Overview

- Online Retrospective Database sponsored by Endocare, Inc
- Controlled by independent Board of Directors
 - Principal Investigator: Eric Klein, Cleveland Clinic
- Data housed at Watermark Research Partners
 - In process of moving to Cleveland Clinic
- Largest Cryoablation Dataset in Existence
- 17 Peer reviewed publications
 - 5 AUA Abstracts in 2018

Limitations & Lessons Learned

- Sites enter own data
 - Heterogeneous dataset
 - Follow-up data hard to acquire: Esp. long term
- Teams go to large sites intermittently
- Investigators retire or move or die
- Some fields reliable (PSA, fistula); others not (IIEF; biopsy details)
- Version 2.0 in Development
 - Name courtesy of Jim Hu, MD

COLD Registry Data Distribution

Total Number of patients
7835

Primary
whole
4257

Salvage
Whole
969

Primary
Focal
1065

Salvage
Focal
111

Repeat
79

Unknown
1354

Focal Therapy

Procedure Type

Please select procedure type

Full Gland Partial



Targeted Focal Therapy

Very limited destruction of prostate tissue isolated to the area of known tumor. Requires detailed prostate mapping biopsy.



Nerve Sparing (Bilateral)

Destruction of all prostatic tissue excepting the posterior lateral on both sides of the prostate.



Nerve Sparing (Unilateral Left)

Destruction of all prostatic tissue excepting the posterior lateral on one side of the prostate.



Nerve Sparing (Unilateral Right)

Destruction of all prostatic tissue excepting the posterior lateral on one side of the prostate.



Anterior 3/4 Ablation (Right)

Hemi-ablation of the prostate PLUS anterior contralateral region.



Anterior 3/4 Ablation (Left)

Hemi-ablation of the prostate PLUS anterior contralateral region.



Posterior 3/4 Ablation (Right)

Hemi-ablation of the prostate PLUS posterior contralateral region.



Posterior 3/4 Ablation (Left)

Hemi-ablation of the prostate PLUS posterior contralateral region.



Hemi-Ablation (Left)

Destruction of all prostate tissue within a lateralized hemisphere.



Hemi-Ablation (Right)

Destruction of all prostate tissue within a lateralized hemisphere.



Zonal Ablation (Left)

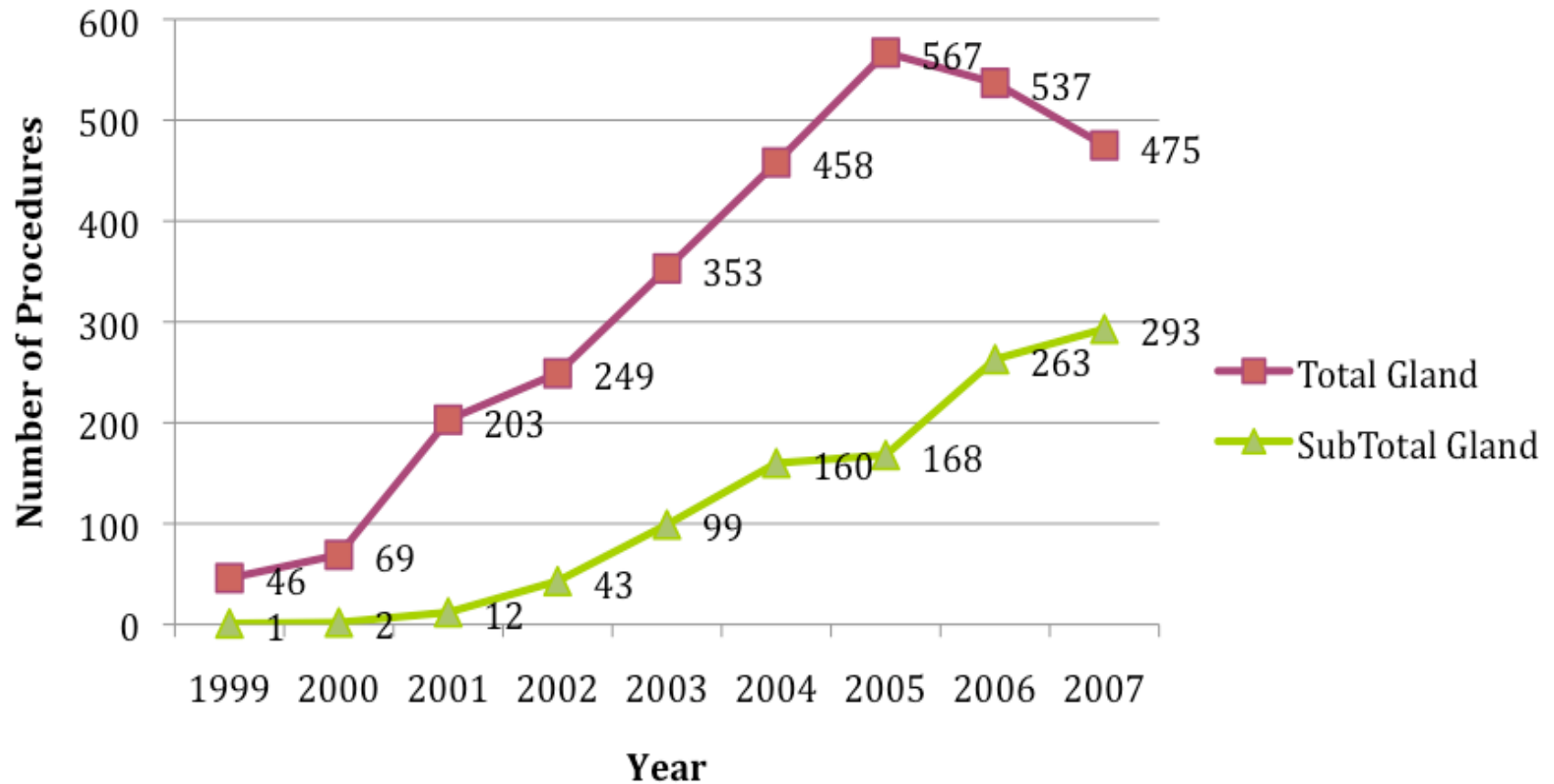
Destruction of sector (anterior or posterior Sextant) containing cancer after extended prostate biopsy using spatial targeting device.



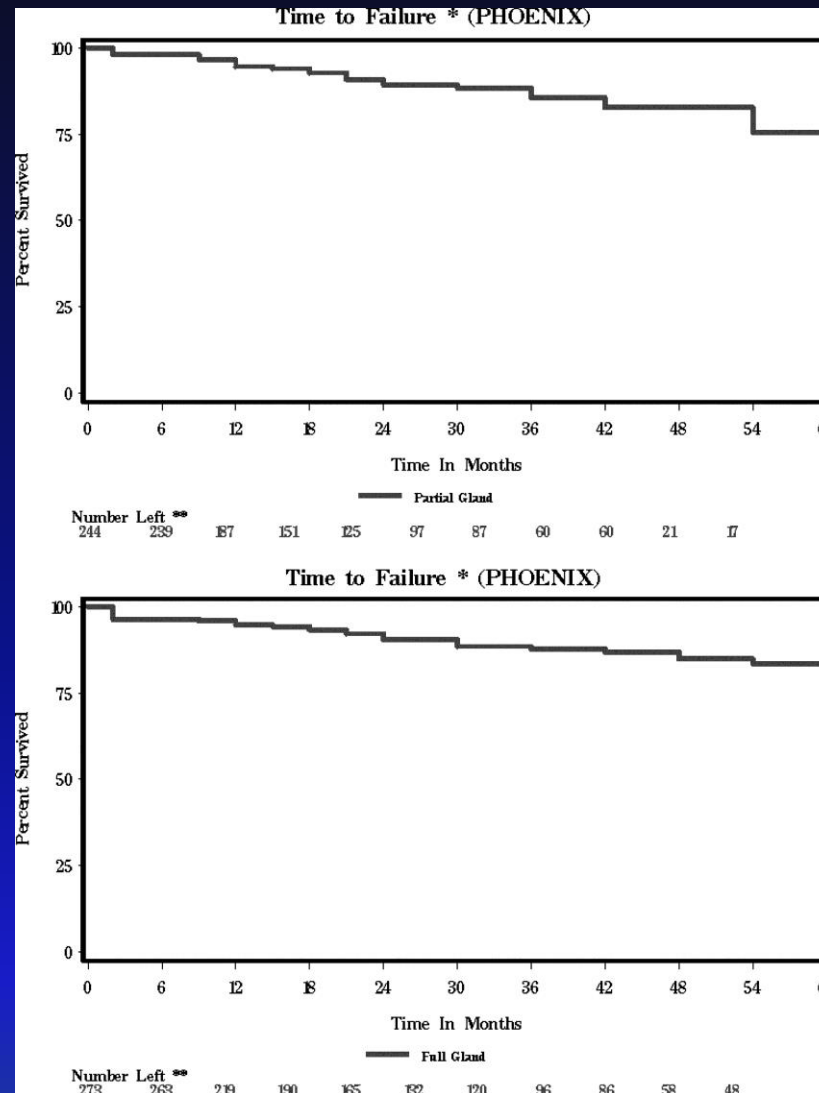
Zonal Ablation (Right)

Destruction of sector (anterior or posterior Sextant) containing cancer after extended prostate biopsy using spatial targeting device.

Focal Therapy Growth in US: Ready or Not



bDFS Whole Gland vs Focal



Morbidity

Incontinence

Focal (507)	8 (1.6)
Whole gland (2099)	65 (3.1)
Salvage (299)	33 (12.3)

New onset erectile dysfunction

Focal (291)	122 (41.9)
Whole gland (639)	432 (67.6)
Salvage (60)	36 (60.0)

Rectourethral fistula

Focal (1160)	1 (0.1)
Whole gland (4099)	18 (0.4)
Salvage (594)	9 (1.5)

Urinary retention (> 30 days)

Focal (518)	6 (1.2)
Whole gland (2177)	34 (1.6)
Salvage (282)	12 (4.3)

COLD Registry Version 2.0 Plan

- Transfer active data to Cleveland Clinic
 - End of June
- Utilize Redcap Software
- Update data from most active sites
- Strategically add sites
- Continually follow up with sites
- Export Focal data to SPARED

COLD Registry Ver 2.0 Patients

Total Number of Patients
~6000

Urology
Assc of
N Texas
(RBT)
1100

MD
Anderson
(Ward)
600

Prostate
Inst of
America
(Bahn)
500

Atlantic
Urology
(Dineen)
450

Cleveland
Clinic
(Levy)
400

Virginia
Urology
(Given)
400

Additional
Sites
TBD

Key Takeaways

- COLD Registry covers large cohort
- Focal cryoablation likely to reduce morbidity
- COLD Registry Ver 2.0
 - Better access to data
 - Better data
- Limitations will continue to be inherent in registries