



## Prostate Implant New Zealand Ltd (PINZ)

### Quality Assurance **IMPROVES** Outcome

10th Advanced Meeting, Seattle, April 2007

J Matthews, D Rothwell

J Boulton, M Rice, L Dakers

Southern Cross Brightside Hospital, AUCKLAND

## Conclusions

---

- Quality Assurance
  - Ability to learn and improve technique
  - Is most useful when performed on every patient
  - Confidence in your standard of brachytherapy
  - Better outcome for patients
  - Should be routine practice

## Quality Assurance

---

“A program for the systematic monitoring and evaluation of the various aspects of a service to ensure that standards of quality are being met.”

Merriam-Webster” Medical Dictionary (2002)

## Why QA is important

---

- |  |  |
|--|--|
| <ul style="list-style-type: none"><li>• Bad implants<ul style="list-style-type: none"><li>– difficult or impossible to fix</li></ul></li><li>• A poor implant can be a disaster<ul style="list-style-type: none"><li>– Uncontrolled cancer</li><li>– Debilitating toxicity</li></ul></li></ul> | <ul style="list-style-type: none"><li>• Quality Assurance :<ol style="list-style-type: none"><li>1. Opportunity to learn and improve</li><li>2. Maximizes the chance of a good implant</li></ol></li><li>• <u>Better outcomes for patients</u></li></ul> |
|--|--|

## Optimal QA - my opinion

---

- |  |  |
|--|--|
| <ul style="list-style-type: none"><li>• From Day 1, Pt # 1<ul style="list-style-type: none"><li>➤ Most to learn</li></ul></li><li>• All cases not a sampling<ul style="list-style-type: none"><li>➤ better recognition of problems</li></ul></li></ul> | <ul style="list-style-type: none"><li>• Based on post implant dosimetry<ul style="list-style-type: none"><li>➤ Best surrogate for quality</li></ul></li><li>• Includes clinical audit<ul style="list-style-type: none"><li>➤ Dosimetry</li><li>➤ Toxicity</li><li>➤ Cancer control</li></ul></li></ul> |
|--|--|

## Implant quality - my opinion

---

- |   |  |
|---|--|
| <ul style="list-style-type: none"><li>• High quality<ul style="list-style-type: none"><li>– V100 &gt; 90%</li><li>– D90 &gt; 140 Gy</li><li>– Low rectal dose<br/>eg VR 140 Gy &lt; 1.6 - 2 cc</li><li>– Prostatic urethra<br/>120 - 150% MPD</li><li>– An appreciation of sub apical doses,<br/>(membranous urethra and penile bulb)</li></ul></li></ul> | <ul style="list-style-type: none"><li>• Adequate quality<ul style="list-style-type: none"><li>– V100 &gt; 80 %</li><li>– D90 &gt; 130 Gy</li></ul></li><li>• Poor quality<ul style="list-style-type: none"><li>– V100 &lt; 80%</li><li>– D90 &lt; 130 Gy</li><li>– High rectal dose</li><li>– High urethral dose</li><li>– High subapical dose</li></ul></li></ul> |
|---|--|

## Overview

---

- PINZ prospective QA program
- Initial technique and QA outcome
- Clinical results
- Technique refinements and validation based on QA
- Conclusions

## PINZ QA - Technical

---

- Post implant CT dosimetry (D 30) to assess implant quality on every patient from day 1
  - Prostate dosimetry V100, D90, V150, V200 from #1
  - Rectal dosimetry from # 120
  - Apical/urethral dosimetry from # 285
- “Calibration” of post implant dosimetry
- Expert review of planning and implants

## PINZ QA - Clinical

---

- All patients from Day 1
  - Acute toxicity IPSS, CTC
  - Late toxicity IPSS, RTOC/EORTC
  - PSA
- PLANNED clinical audits
- Resources
  - Time, personnel, money

## Oct 1999 - March 2007, N = 402

---

292 "low risk"

110 "intermediate risk"

72 GI 3+4=7

4 GI 4+3=7

34 PSA >10 ≤16

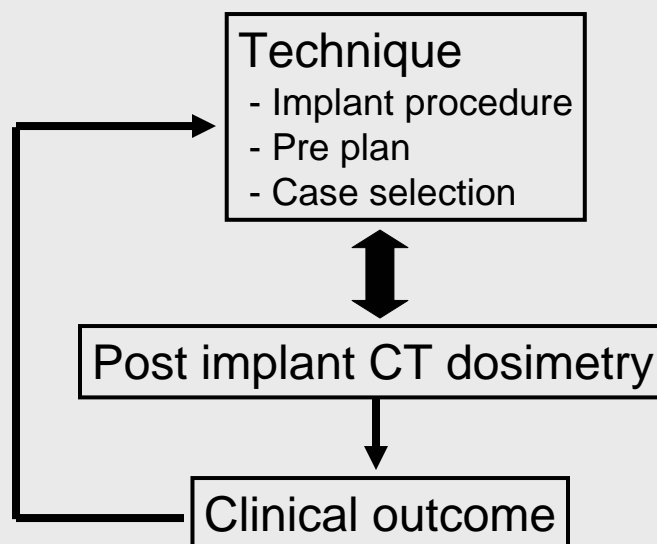
88 neoadjuvant (22%)  
hormones

	Mean	Range
Age (yrs)	61	40 - 79
Gland size (cc)	32.5	12 - 63
IPSS	5.0	0 - 22
Q max (m/s)	20	5 - 44
Av (m/s)	10.7	2.9 - 34

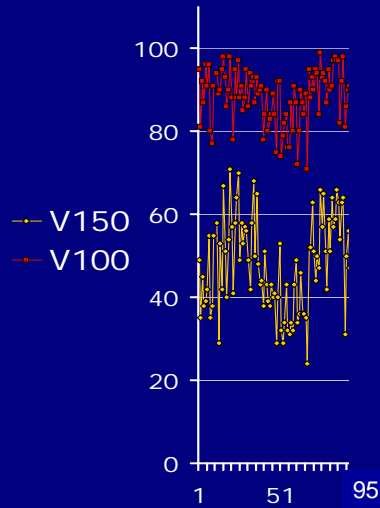
## Initial Implant Technique # 1 -285

- Pre planned
- TRUS vol study
- MMS / Variseed
- Modified peripheral loading
- Dose: 145 Gy MPD
- Preloaded needles
- Rapid Strand / loose seeds
- B&K US with mechanical probes
- Axial imaging
- Needle hub to template measurement
- One needle at a time
- Cystoscopy
- Catheter / caudal

## Technical review with Postimplant CT

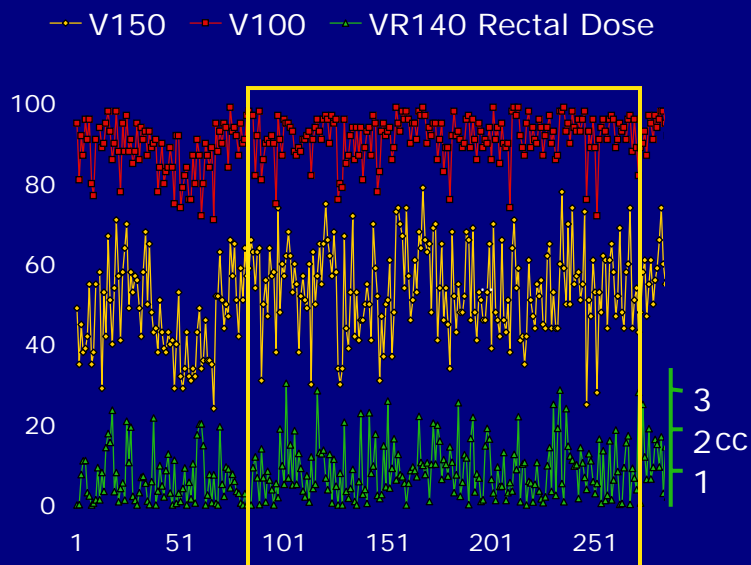


## Early dosimetry # 1 - 95



- Initial dosimetry good but
- Rising V150 and
- “unexpected” irritative urinary symptoms
- Implants cooled too much and reduced V100 and D90
- Increased activity of implants and improved dosimetry

## Intermediate dosimetry # 96 - 285



## **Intermediate experience (booklet)**

---

- Better imaging
- Less acute urinary problems
- Better V100 and D90 overall

But...

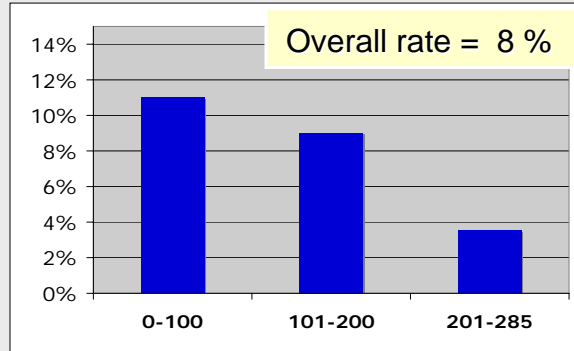
- Still significant case to case variation
- Occasional suboptimal implants
- Significant rectal dose in some patients

## **Clinical outcomes, # 1 -285**

---

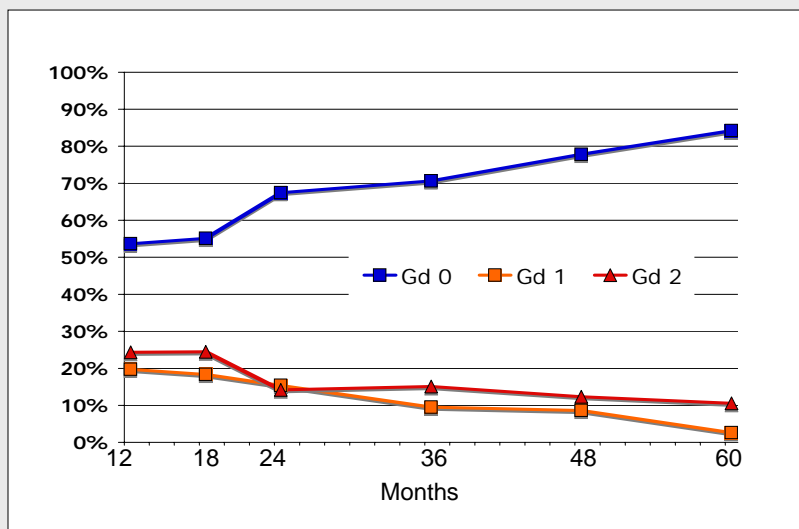
- Acute toxicity
- Late toxicity
- Biochemical RFS

## Urinary Retention n = 285

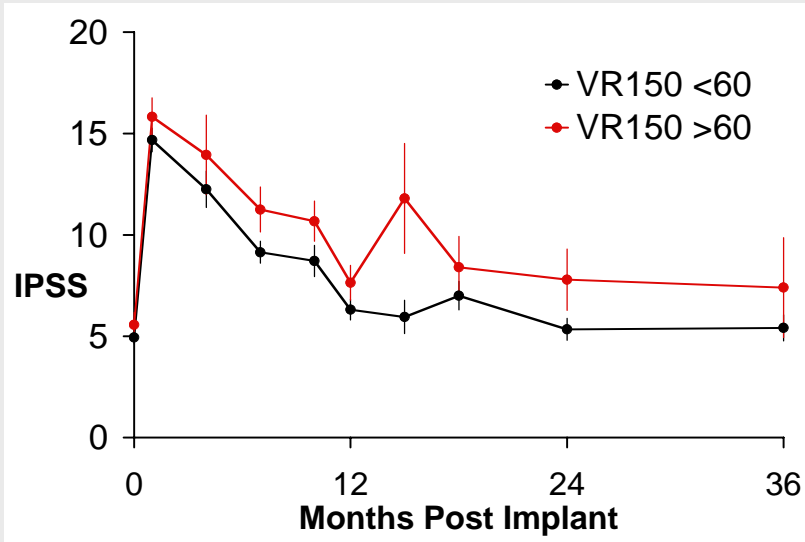


- Correlates with: IPSS / QOL scores ( $p < 0.05$ )
- Does not correlate with:
  - prostate size, flow rates, V150%, hormones

## Late urinary toxicity, n = 285



## V150 by IPSS (P=0.001)



## Late Grade 3 Urinary Toxicity

Urethral stricture	12 / 285 (12 m + FU)	4.2%
TURP	1	<1%
Retention $\geq$ 6 m	5 / 306 (6 m + FU)	1.6%
<b>Total</b>	<b>18</b>	<b>~7 %</b>

(Gelblum1999)

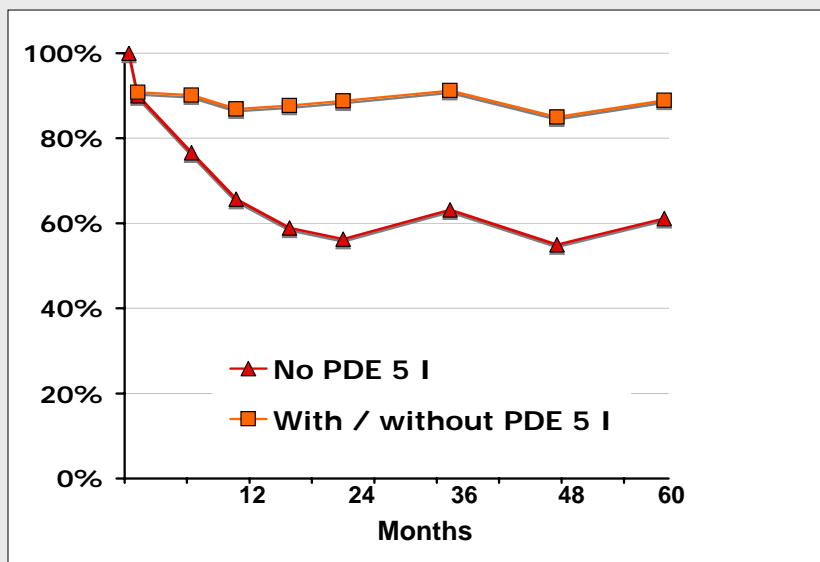
## Late Bowel Toxicity n = 168

### Serious toxicity rare

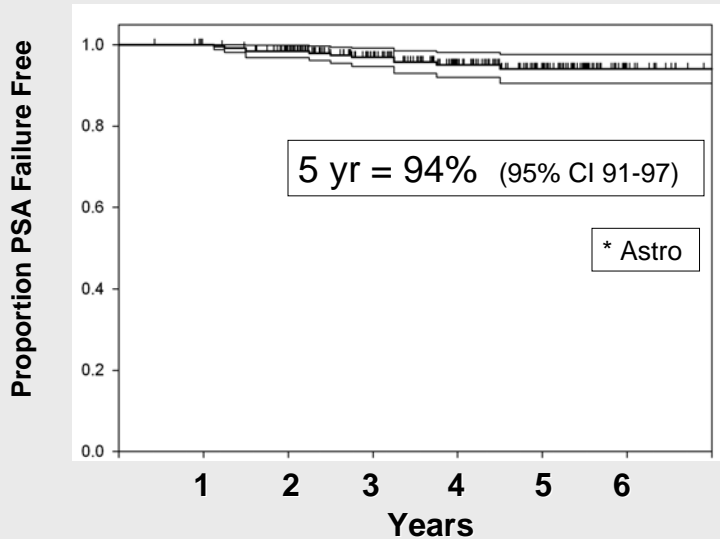
- 5% Gd 2 at 5 years
  - usually mild, transient bleeding
  - No APC or formalin
- <1% (1pt) Gd 3 (ulceration)
  - Resolved
- Risk related to rectal dose
  - HR 2 - 5 when > Snyder's "cut points"



## Potency (no neoadjuvant AD) n = 130



## Freedom from PSA Failure\* n = 260 (2+ yr)



## Next level Quality Goals

- High cure rate → Adequate prostate dose

And..

- Least toxicity → Avoid excessive dose
  - Urinary                      Prostatic urethra  
   Membranous urethra
  - Rectal                         Rectum
  - Erectile                        Penile bulb

## QA Audit of Suboptimal Implants

---

### 1) Seeds too low

- 1) Base dose low
- 2) Apex / subapical dose high
- 3) Rectal dose high

“Triple trouble”

- Seeds too posterior
  - Rectal dose high

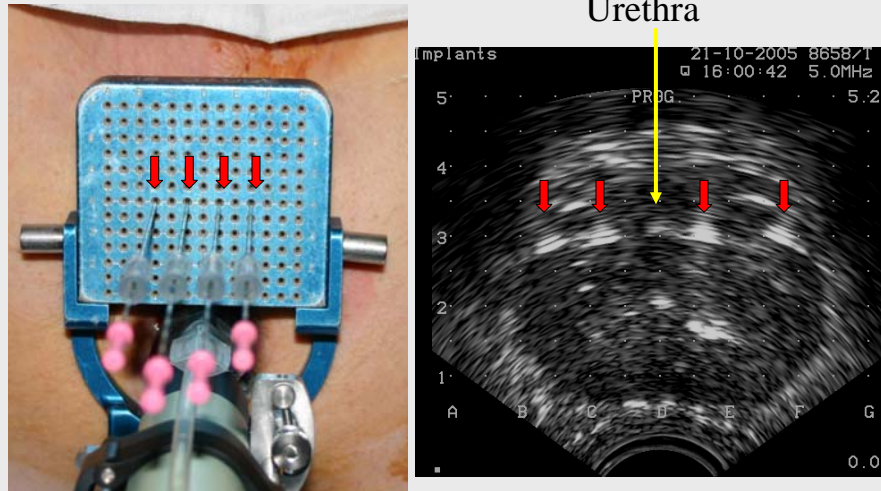
- Seeds too high
  - Apex / subapical dose low
  - Bladder base dose high

## Review of technique - May 2005

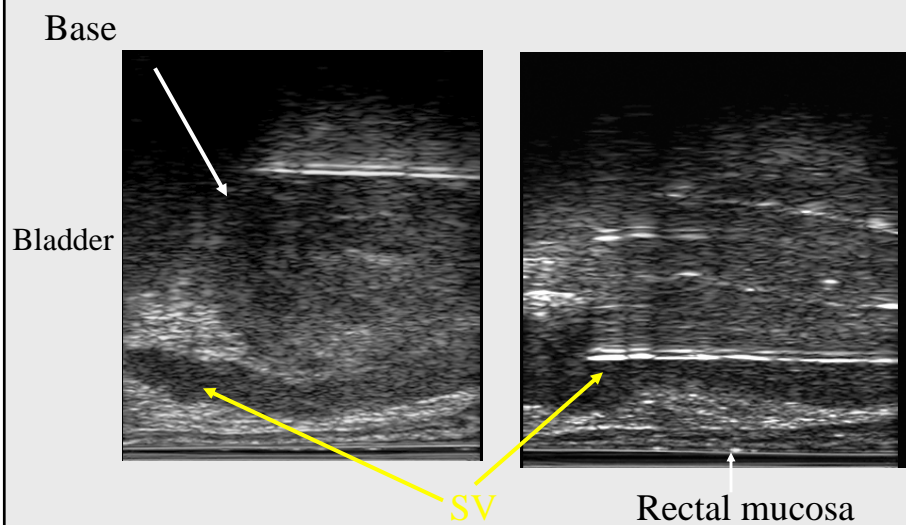
---

- Advice from SPI / Pro Qura
- Insertion of all needles in the row
- Electronic probe with excellent sagittal imaging
- “Image guided” not “grid” and “measurement” guided implant

## Insertion of all needles in a row

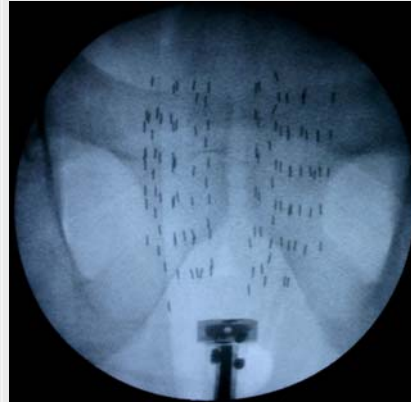


## Benefits of sagittal imaging

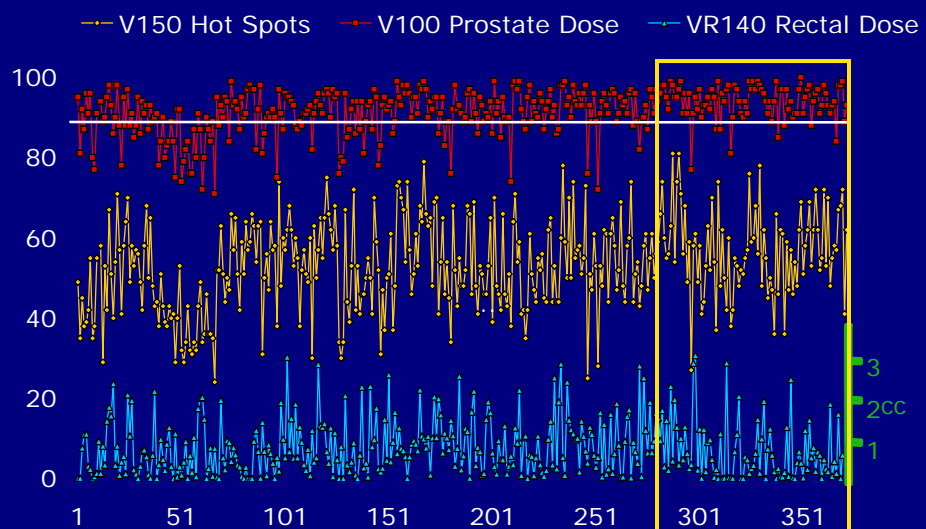


## Early Clinical outcome

- More uniform implants
- No / minimal haematuria
  - No cystoscopy
  - No IDC
  - No caudal anaesthesia
- Fewer immediate urinary symptoms



## Post change dosimetry #286 - 400



## Improvements in dose and coverage

Mean	# 1 - 95 "learning"	# 96 - 285 "pre change"	# 286 - 400 "post change"	P - value
V100	88.5	91.9	94.2	<0.0001
D90	99.7	105.5	111.2	<0.0001

## Reduction in rectal dose, VR140 Gy

VR 140 Gy	# 96 - 285 "pre change"	# 286 - 402 "post change"	p - value
Mean	0.91	0.65	0.01
% pts > 1.6cc	16.5%	9%	0.04
% pts > 2 cc	8.9%	4.9%	ns

## Bowel Toxicity 2/3 Free Survival

Prognostic Factor	HR	P value
VR80 Gy > 4.0 cc	5.0	0.028
VR100 Gy >3.0 cc	2.4	0.229
VR120 Gy >2.5 cc	2.2	0.294
VR140 Gy >2.0 cc	4.6	0.063
VR160 Gy >1.3 cc	4.5	0.068
Any elevation	4.6	0.038

†Significance assessed Wald tests and fitting Cox proportional hazards model

## Reduction in dose below apex

	Mean % MPD		p - value
	# 96 - 285 "pre change"	# 286 - 400 "post change"	
Apex	117	118	ns
Apex + 0.5 cm	93	89	ns
Apex + 1 cm	68	63	ns

	% of patients		p - value
Apex + 1 cm < 80 % MPD	93	98	0.05

## Dosimetry of strictures

---

	% MPD		P - value
	No Stricture	Stricture	
Apex	117	134	0.002
Apex + 0.5 cm	92	113	0.0003
Apex + 1 cm	66	86	0.0003

## Summary of our QA Program

---

- Improved dosimetry
  - Higher V100, D90
  - Reduced rectal dose
  - Reduced subapical dose
- Expected outcomes
  - Improved cure rates
  - Reduced toxicity
    - Fewer strictures
    - Less proctitis
    - Less impotence

## Conclusions

---

- Quality Assurance
  - Ability to learn and improve technique
  - Is most useful when performed on every patient
  - Confidence in your standard of brachytherapy
  - Better outcome for patients
  - Should be routine practice