



MALE
FERTILITY
AND
PEYRONIE'S
CLINIC

Efficacy of RestoreX Penile Traction Therapy in Improving Penile Length and Erectile Function Post Prostatectomy

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Disclosures

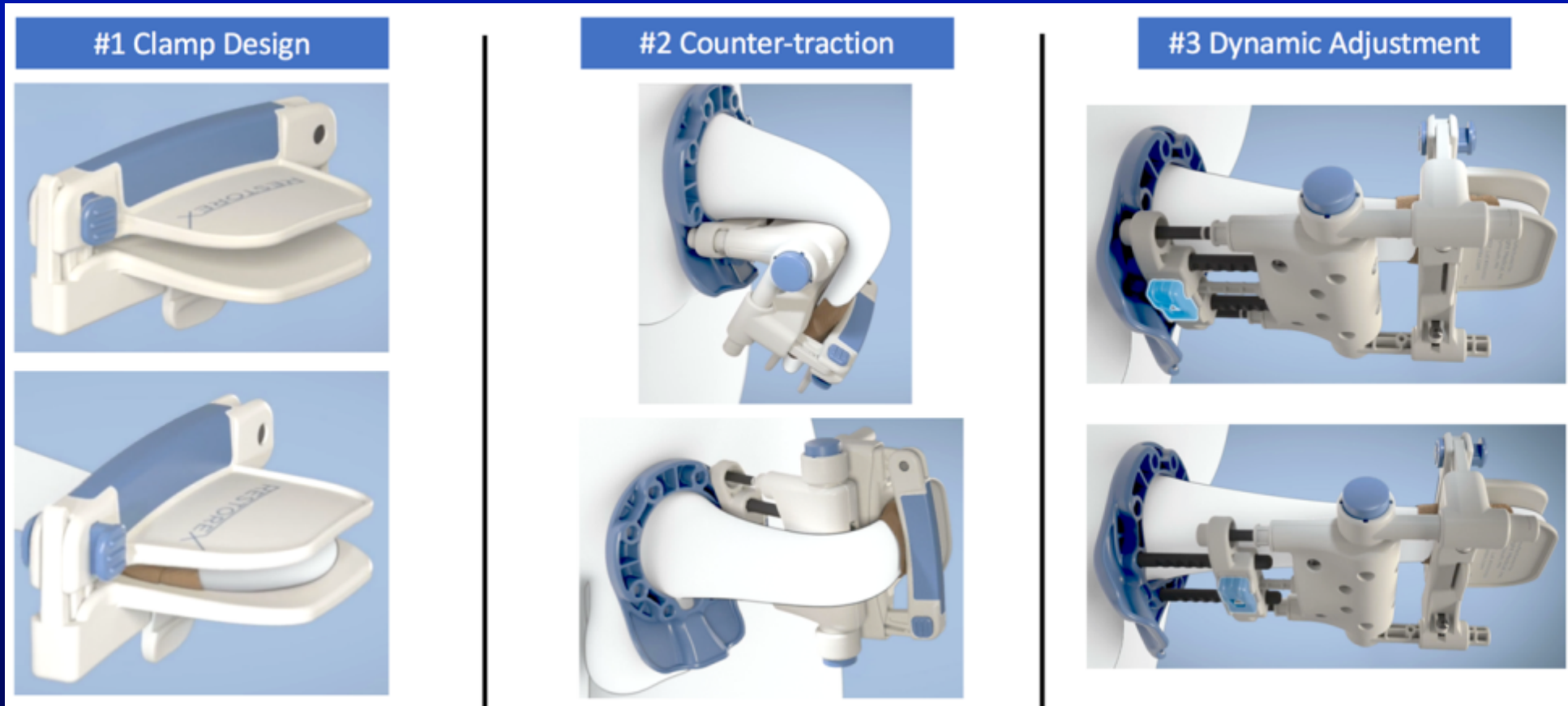
- Landon Trost – inventor of RestoreX
 - Mayo licensed to PathRight Medical
 - Provided devices free of charge
 - All other funding internal Mayo funds
- Other authors – no disclosures

Introduction

- 15-68% of men report penile length loss after prostatectomy
 - Associated with distress, urinary hygiene issues, difficulty with intercourse
- No data available on impact of traction on penile length post-prostatectomy
- Prior studies evaluating erectile function post-prostatectomy
 - PDE5 RCTs x 3 – no benefit for rehabilitation
 - VEDs – no study with washout - ??? Benefit

RestoreX

- RestoreX - First PTT with RCT data demonstrating improvements in penile length, curvature, and erectile function when used 30-90 minutes daily



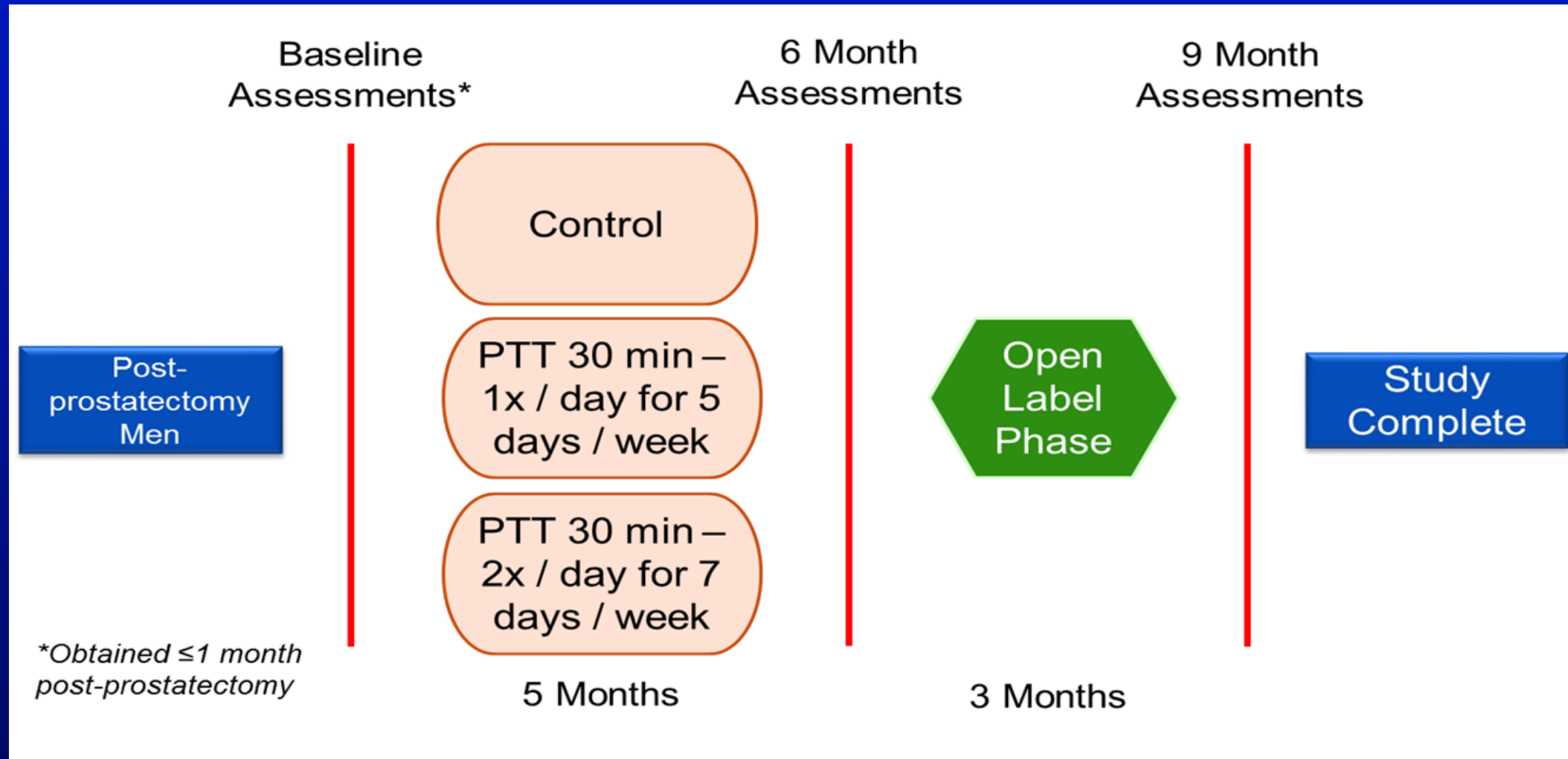
Objectives

- Compare post-prostatectomy men using RestoreX vs controls regarding:
 - Ability to maintain / increase penile length
 - Changes in erectile function
 - Overall patient tolerance and satisfaction with therapy
 - Rate and severity of adverse events

Methods

- Randomized controlled trial - RestoreX vs controls
- N = 80 men (3 groups) post robotic prostatectomy, urethral complications excluded
- Therapy initiated at 1-month post-op
- Objective measures – stretched penile length, IIEF questionnaire
- Subjective measures – non-standardized questionnaires on satisfaction, adverse events

Methods



Accrual To Date

- 80 participants accrued (26 controls, 54 PTT)
- 49 patients with 6-mo follow up (22 controls, 27 PTT)
- No de-novo penile curvature
- No major adverse events

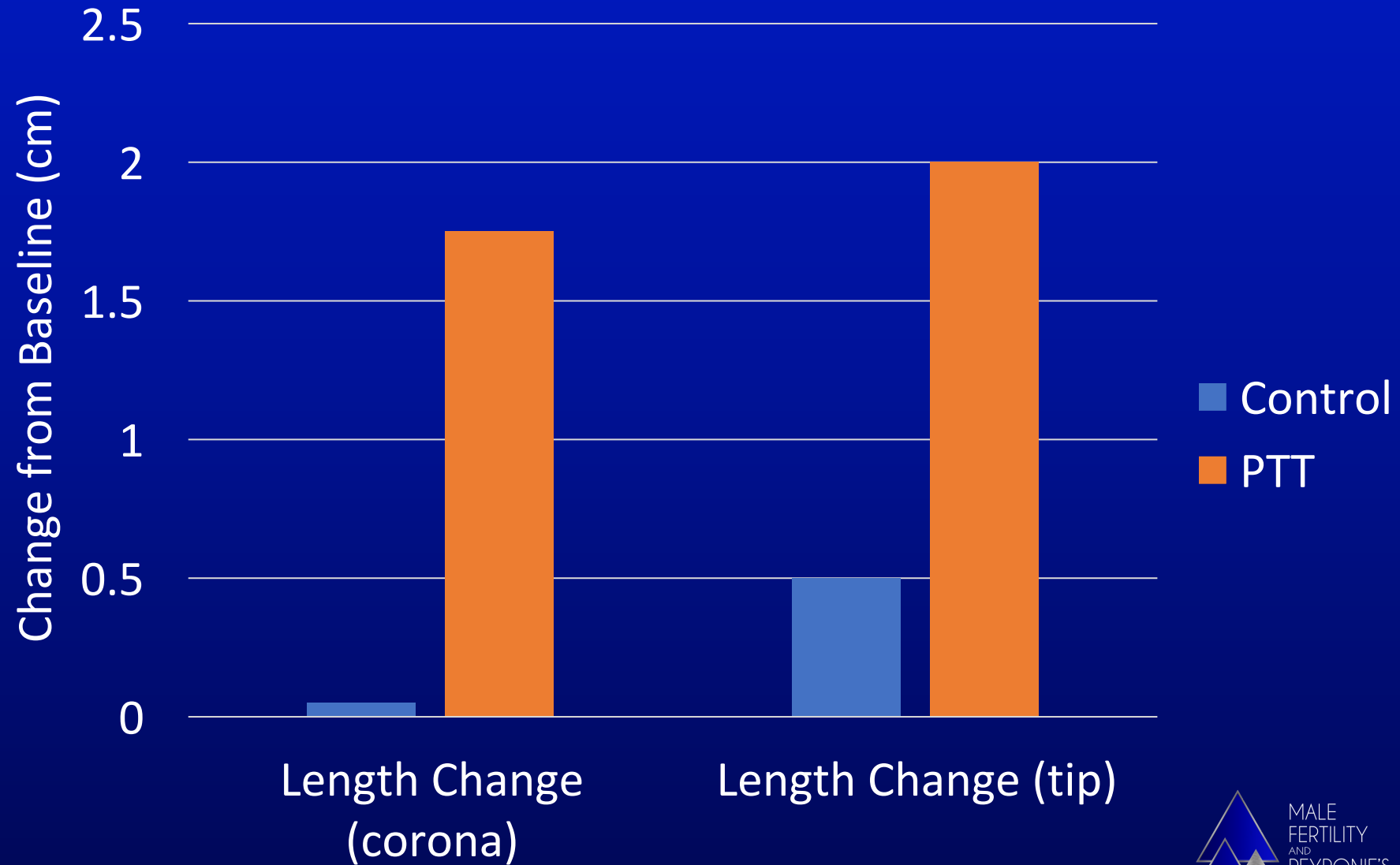
Demographics – Similar

Variable	PTT	Control	P-value
Age, mean (SD)	58.6 (6.8)	58.0 (4.5)	0.72
Months w ED, median (range)	24 (1 – 120)	31.5 (12 -240)	0.55
Pre op ED, (% yes)	47%	63%	0.21
Pre op curvature, (% yes)	17%	20%	0.72
Pre op shortening, (% yes)	13%	20%	0.45
Length lost, median (range)	1 (0.5-3)	1 (0.5 – 1.5)	0.38
IIEF-EFD score, median (range)	27 (1 - 30)	27.5 (1 – 30)	0.43
Penile length (cm), median (range)			
to corona	12.5 (9 – 17)	13 (10 – 18)	0.53
to tip	16 (12 – 19.5)	15.5 (11 – 21)	0.80

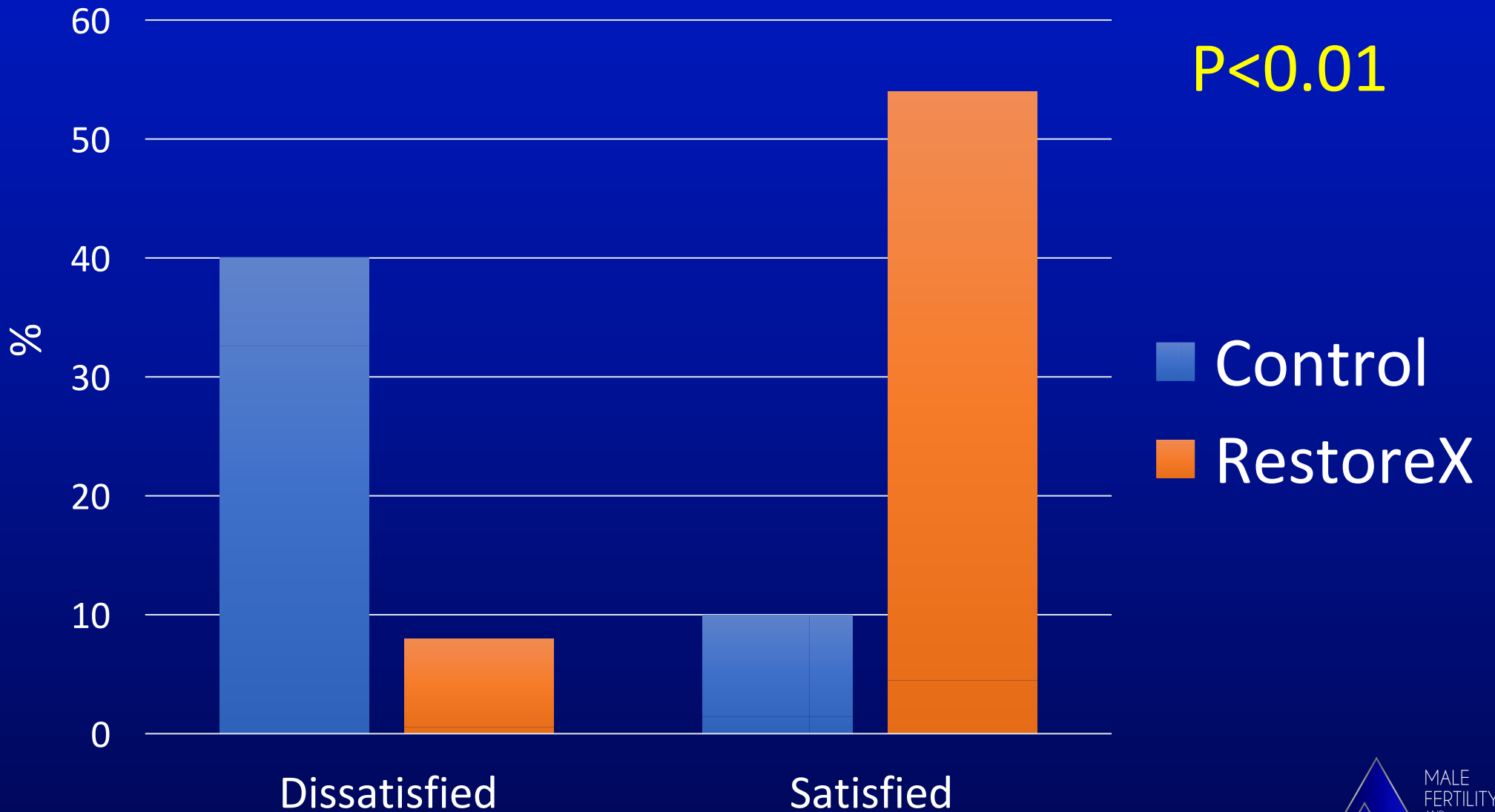
Results – Penile Length at 6 Months

Median length increase

- 1.75 cm vs 0 cm (corona)
- +2 cm vs +0.5 cm (tip)
- $P=0.01$ to <0.01

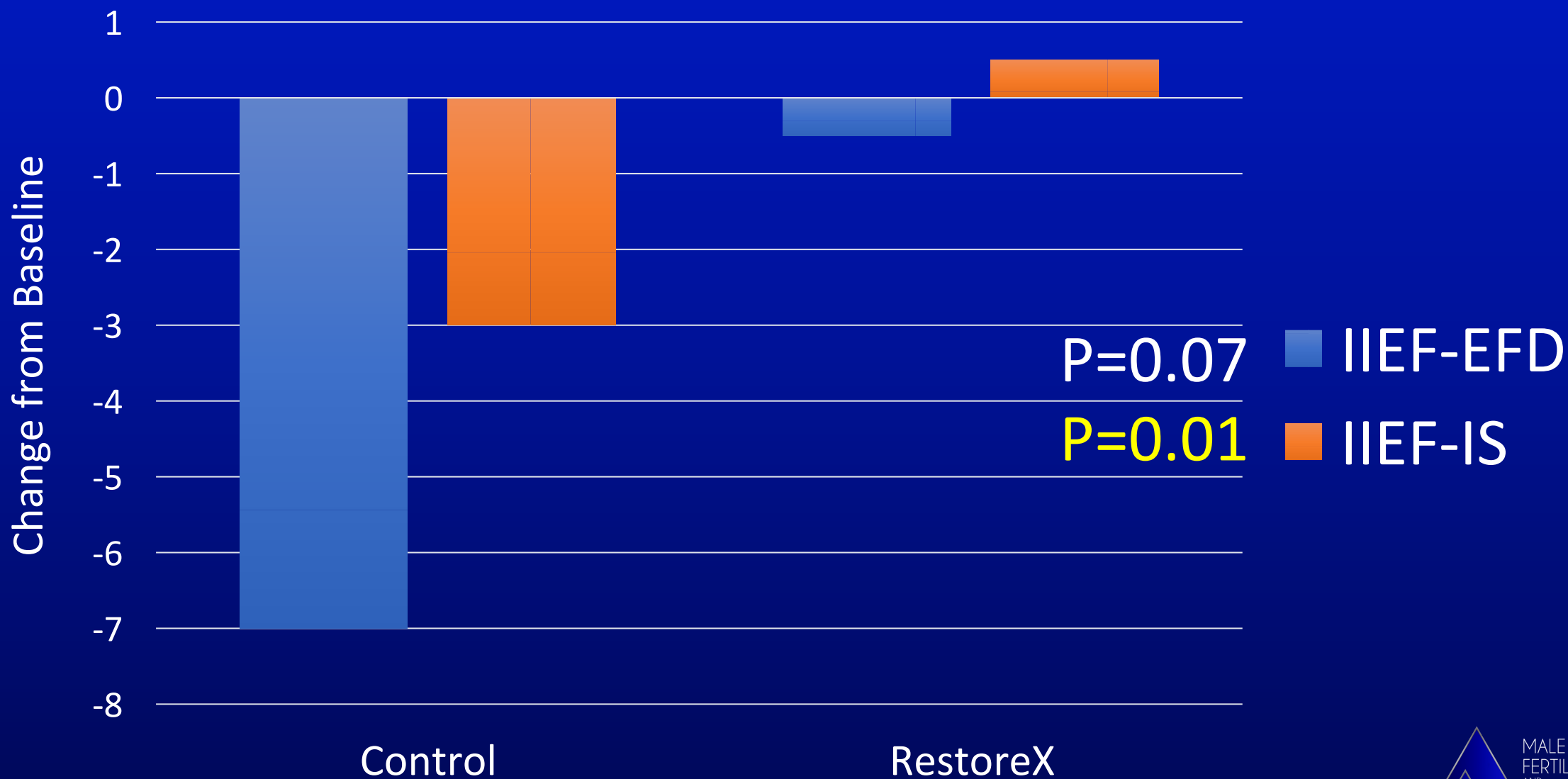


Satisfaction with Penile Length

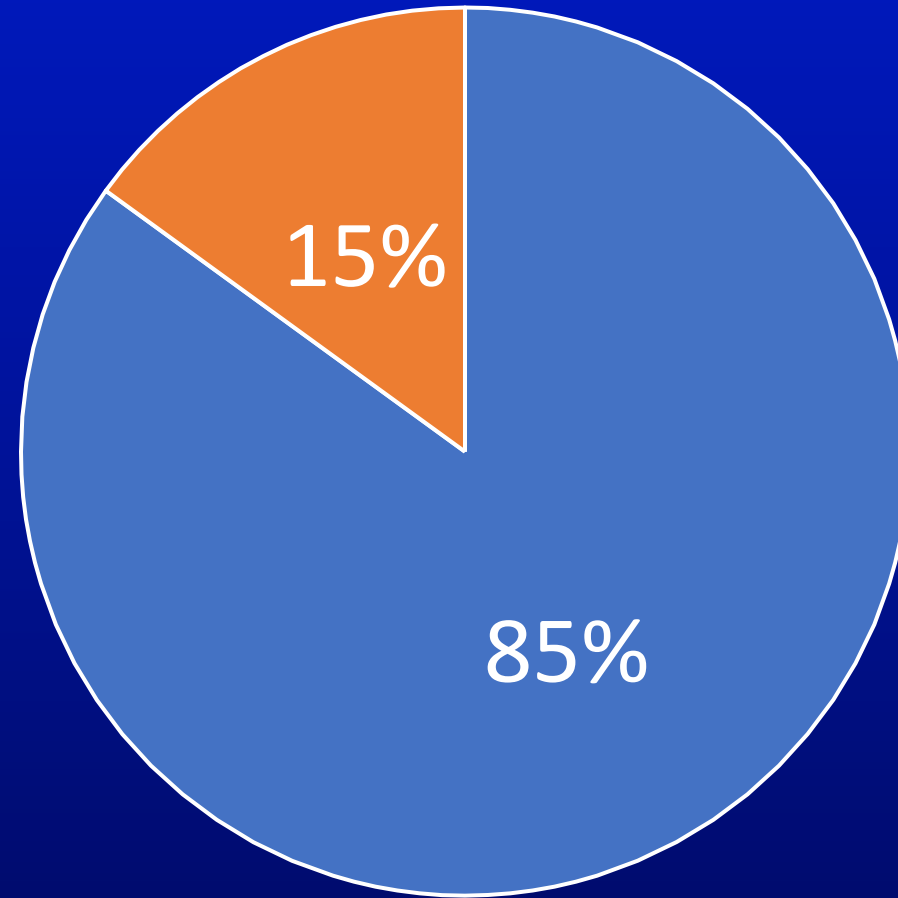


Overall
Satisfaction
with Device
8/10

Results – Erectile Function at 6 Months

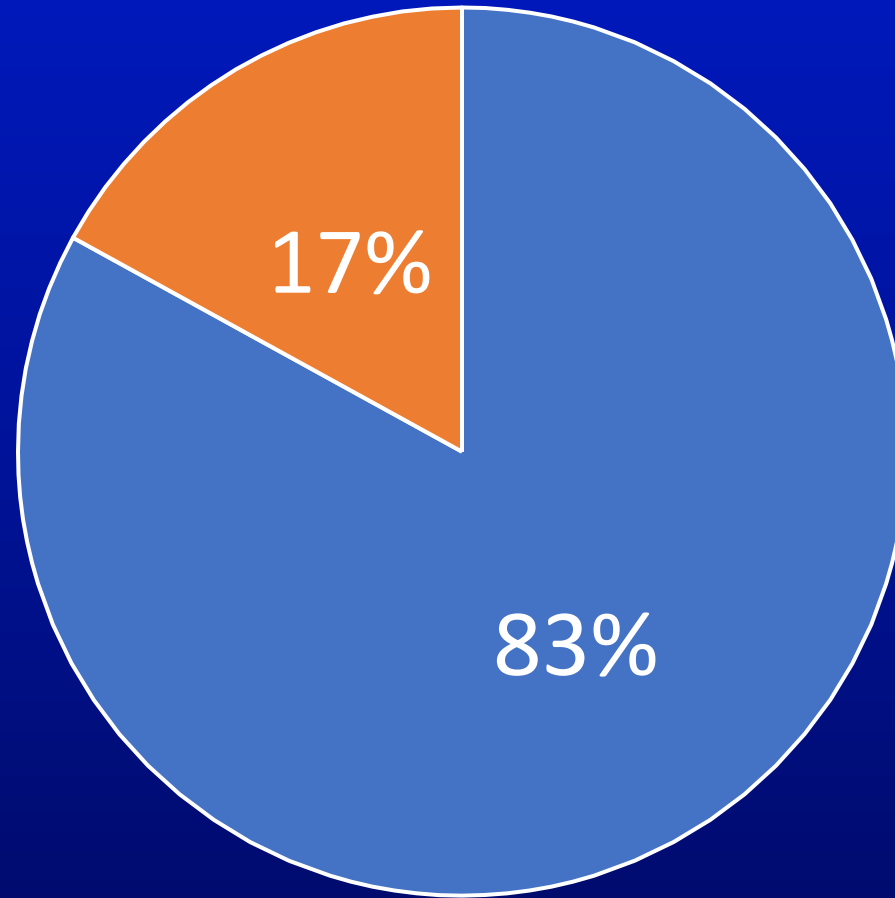


Would You Choose to Use the Device Again?



■ Yes ■ Unsure ■ No

Was the Therapy Meaningful / Worthwhile?



■ Yes ■ No

Conclusions

- Following prostatectomy, treatment with RestoreX 30-60 min/day results in:
 - Increased penile length
 - Greater satisfaction with penile length
 - Improved satisfaction with intercourse
- Non-significant findings requiring further study
 - Greater preservation of erectile function ($p=0.07$)?

Thank you
