



ED I Study

Treatment with BES for VEGF for 4 weeks

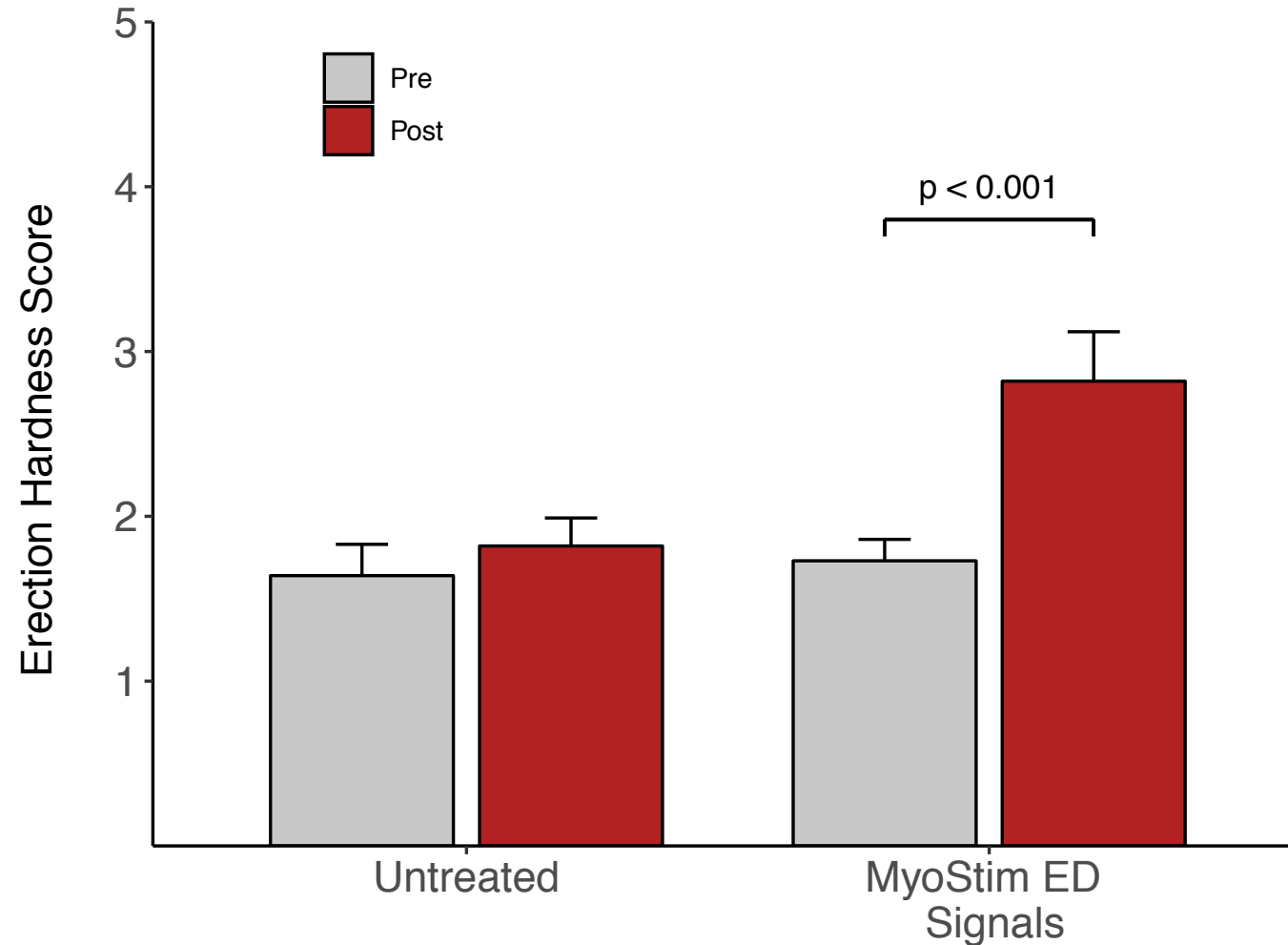
# MyoStim ED I Study

## Bioelectric Stimulation of VEGF for 4 weeks (n=20)

- Prospective, Randomized, Double-Blind, Sham-Controlled study of 20 patients
- All patients sought treatment for ED and were screened and those who met Eligibility criteria were enrolled into the study
- Patients were randomized to Control or VEGF stimulation for a total of 15 mins, 2 x's/week, for 4 weeks (8 treatments) using Neurodyne Stimulator
- The Double Blind was maintained by sham operation of the stimulator by a technician; neither the patient or investigator knew of treatment arm
- All subjects completed the full course of treatment and the questionnaires used for study end points at the beginning and end of study
- No use of PDE- Inhibitors or other ED drugs allowed in any of the studies
- No Adverse Events reported

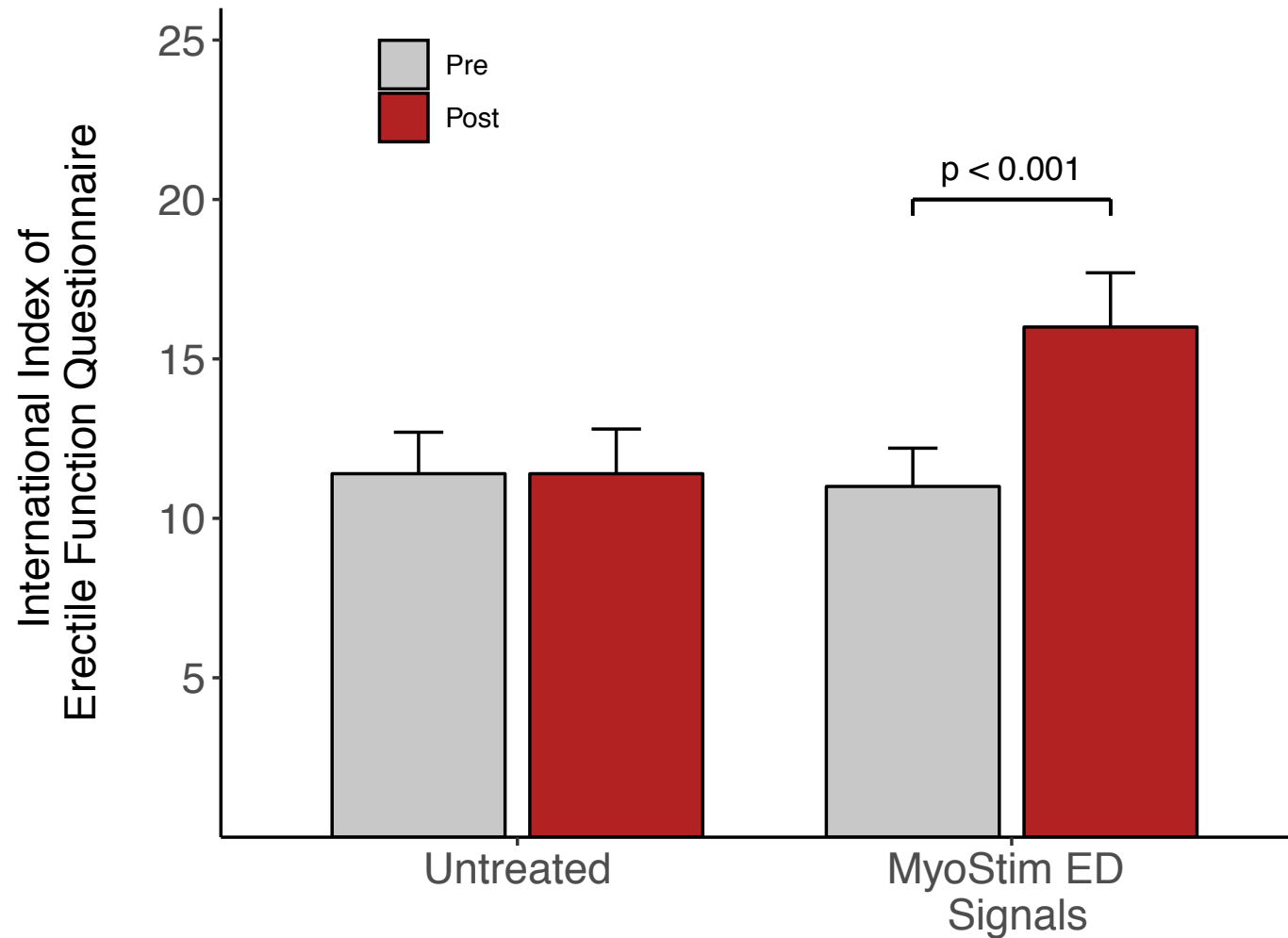
# ED | VEGF Study

## Erection Hardness Score Pre-Post Treatment



# MyoStim ED I Study of VEGF for 4 weeks

## International Erectile Function Questionnaire





# ED II Study

## Treatment with BES for 4 weeks

# ED II Study

## VEGF vs MyoStim for 4 Weeks (n=30)

- Prospective, Open Label, Double Blind, Sham Placebo-Controlled 3 Arm study of Bioelectric Stimulation for treatment of ED X 4 weeks
- Treatment involved use of Bioelectric Stimulation delivered via a 510 K approved stimulator via patch electrodes placed on the penis
- Patients were randomized to one of 3 Arms: Control, VEGF signal alone, or MyoStim Multi-Signal program (VEGF, SDF, PDGF, IGF, KLOTTHO).
- A Double Blind was maintained by the technician such that the patient and Investigator were not aware of treatment assignment.
- All patients were treated for 45 mins, 2x's/week for 4 weeks (8 sessions)
- All patients completed the full course of treatment and all questionnaires and self-assessment metrics of ED before and at end of treatment.
- No Adverse Events were reported

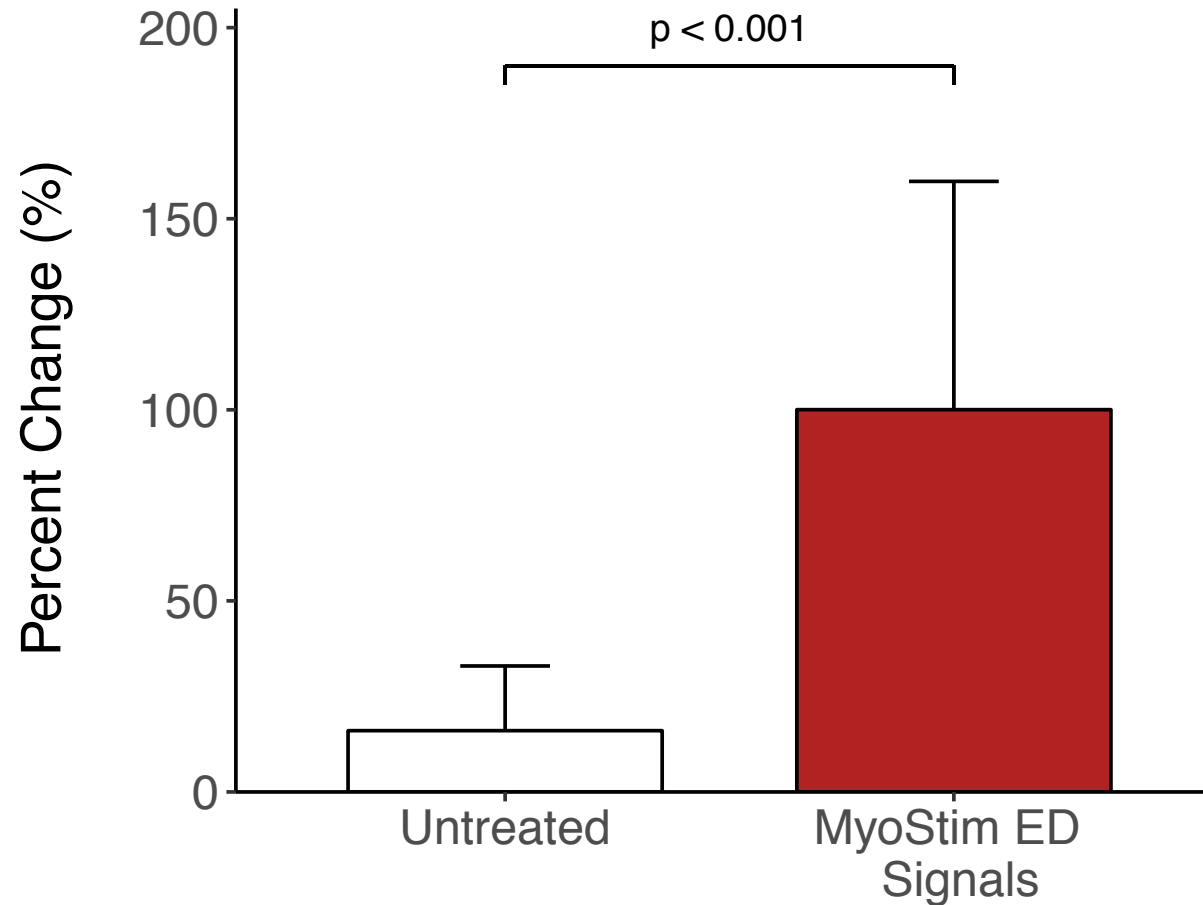
# MyoStim ED II Results

Table 1. Subject Characteristics

	Untreated (Crossover)	MyoStim ED Signals
n	10	9
Age (yr)	53 ± 9	53 ± 9
Smokers n(%)	1 (10%)	1 (11%)
Diabetics n(%)	1 (10%)	2 (22%)
Consumed Alcohol During Study n(%)	0 (0%)	0 (0%)

# MyoStim ED II Study

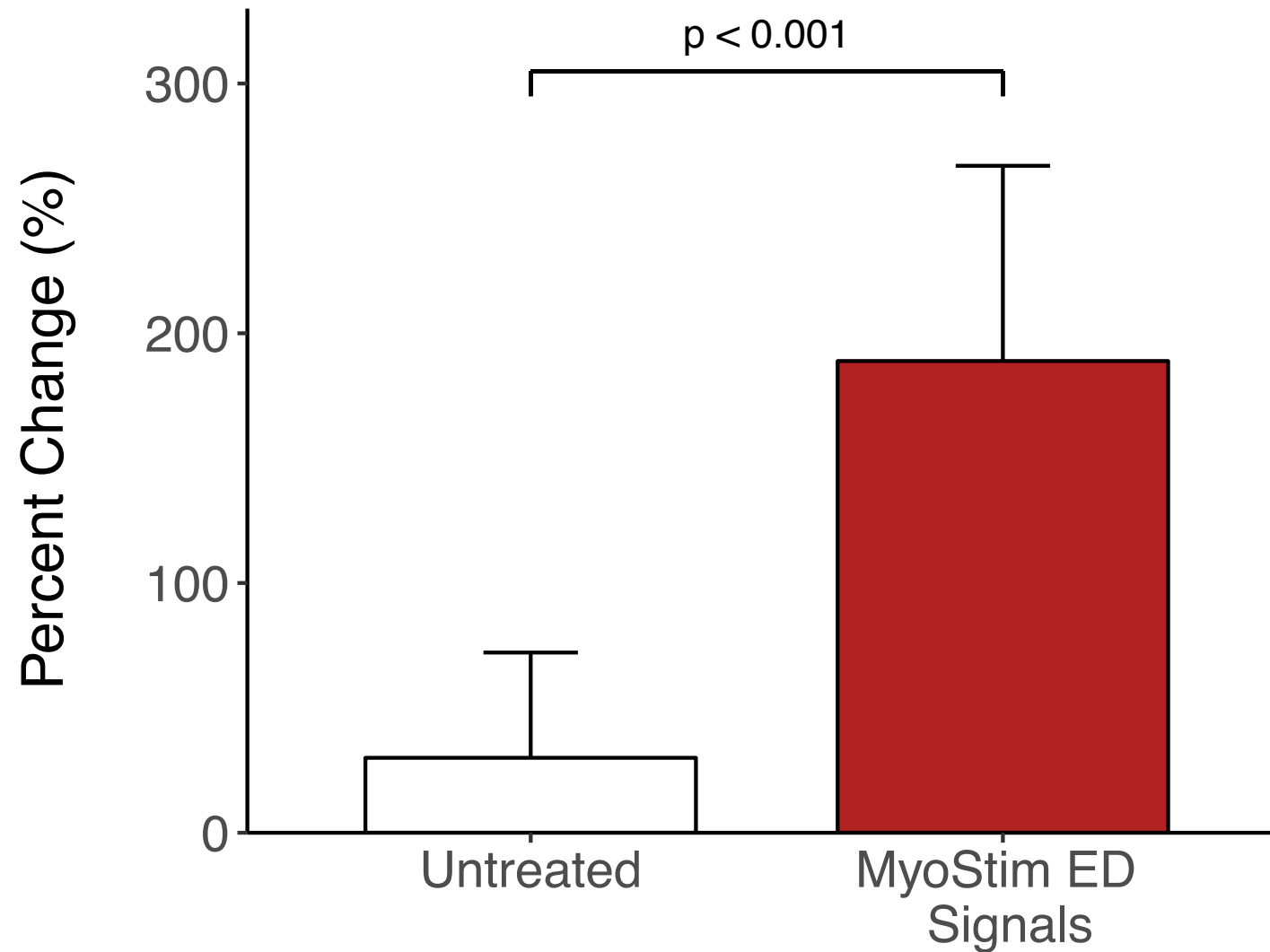
International Index of Erectile Function Questionnaire  
Combined Data of all 20 Treated with MyoStim





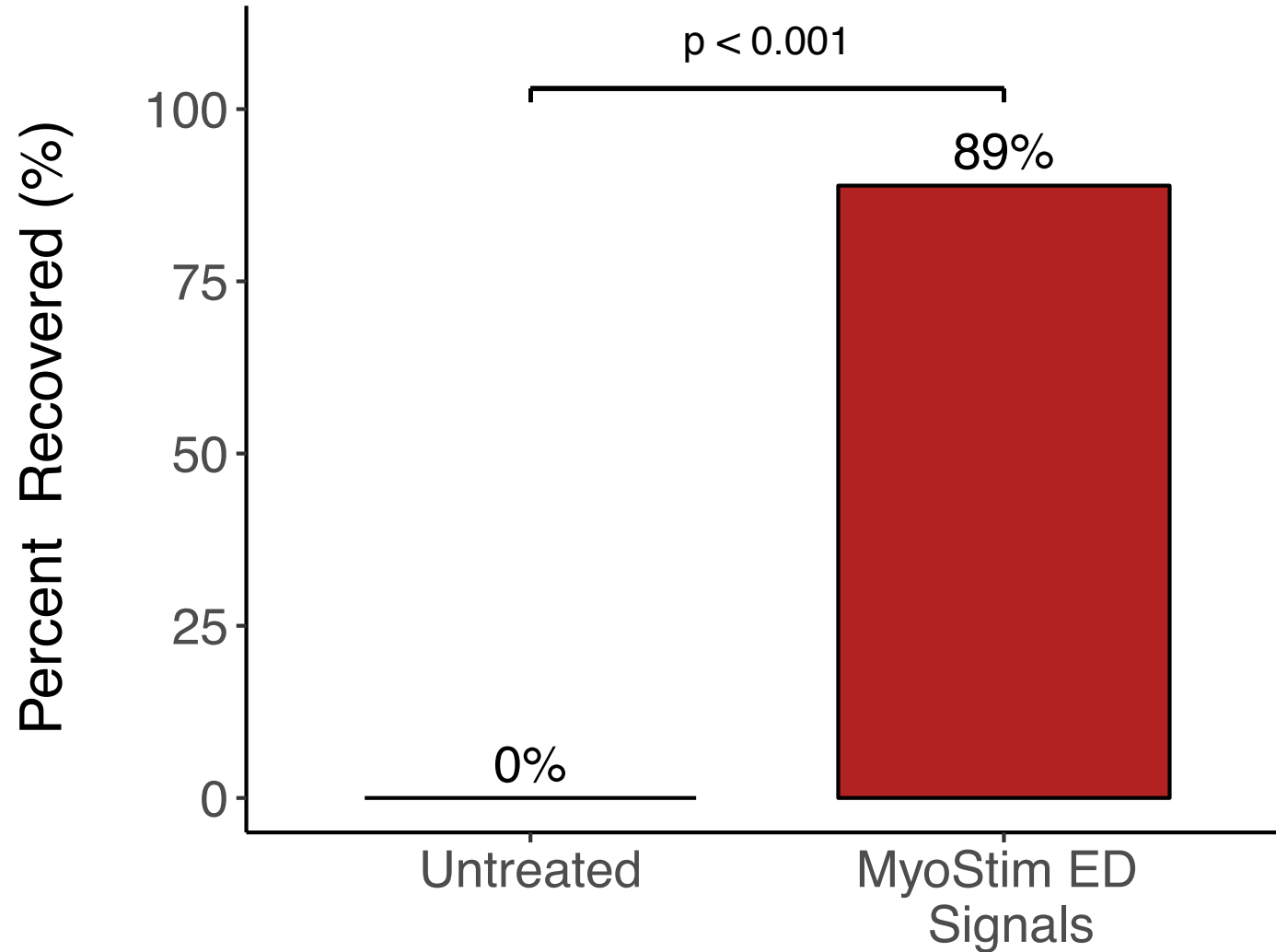
# MyoStim ED II Study

## Erection Hardness Score



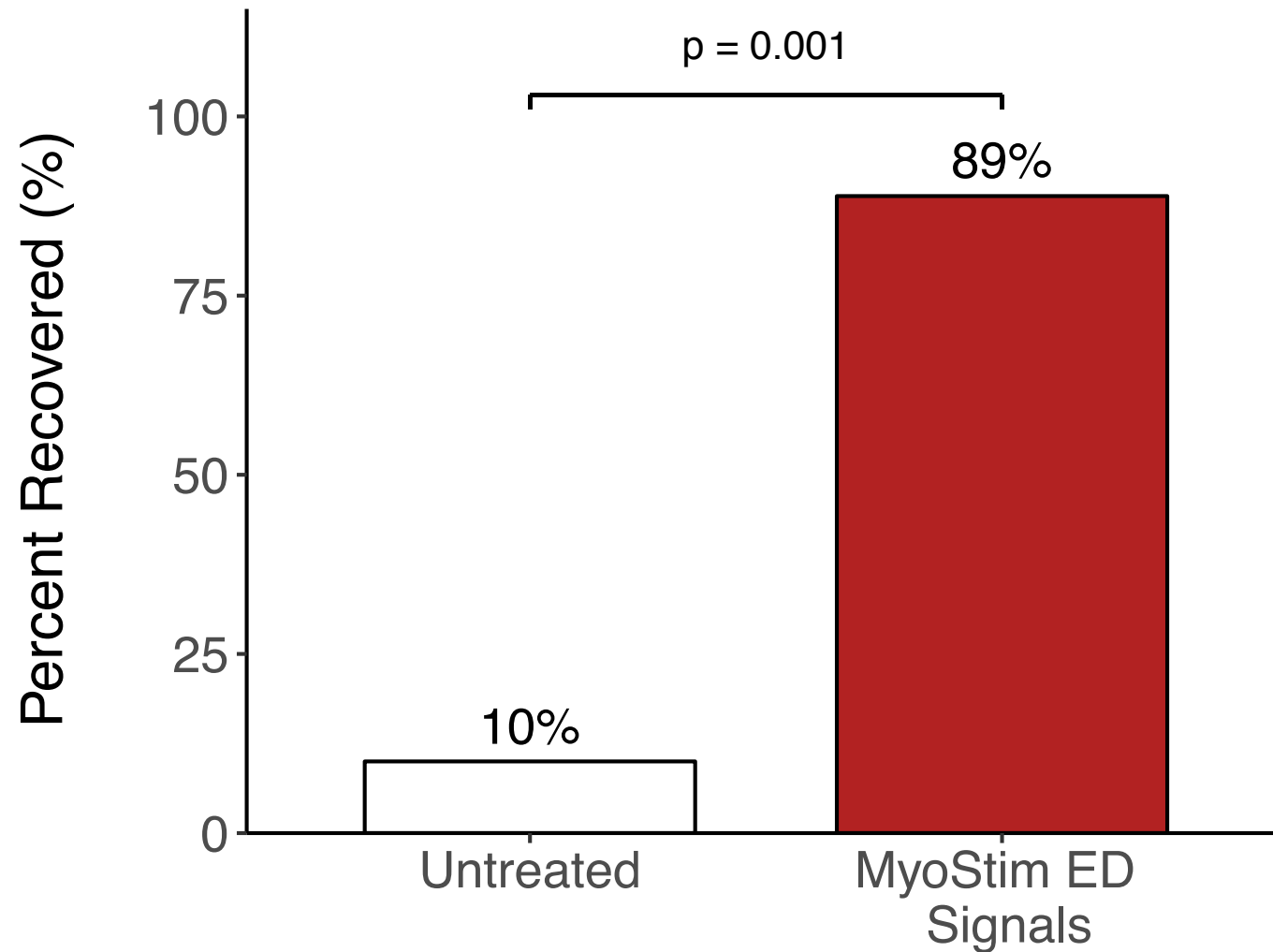
# MyoStim ED II Study

## Recovery of Penis Enlargement



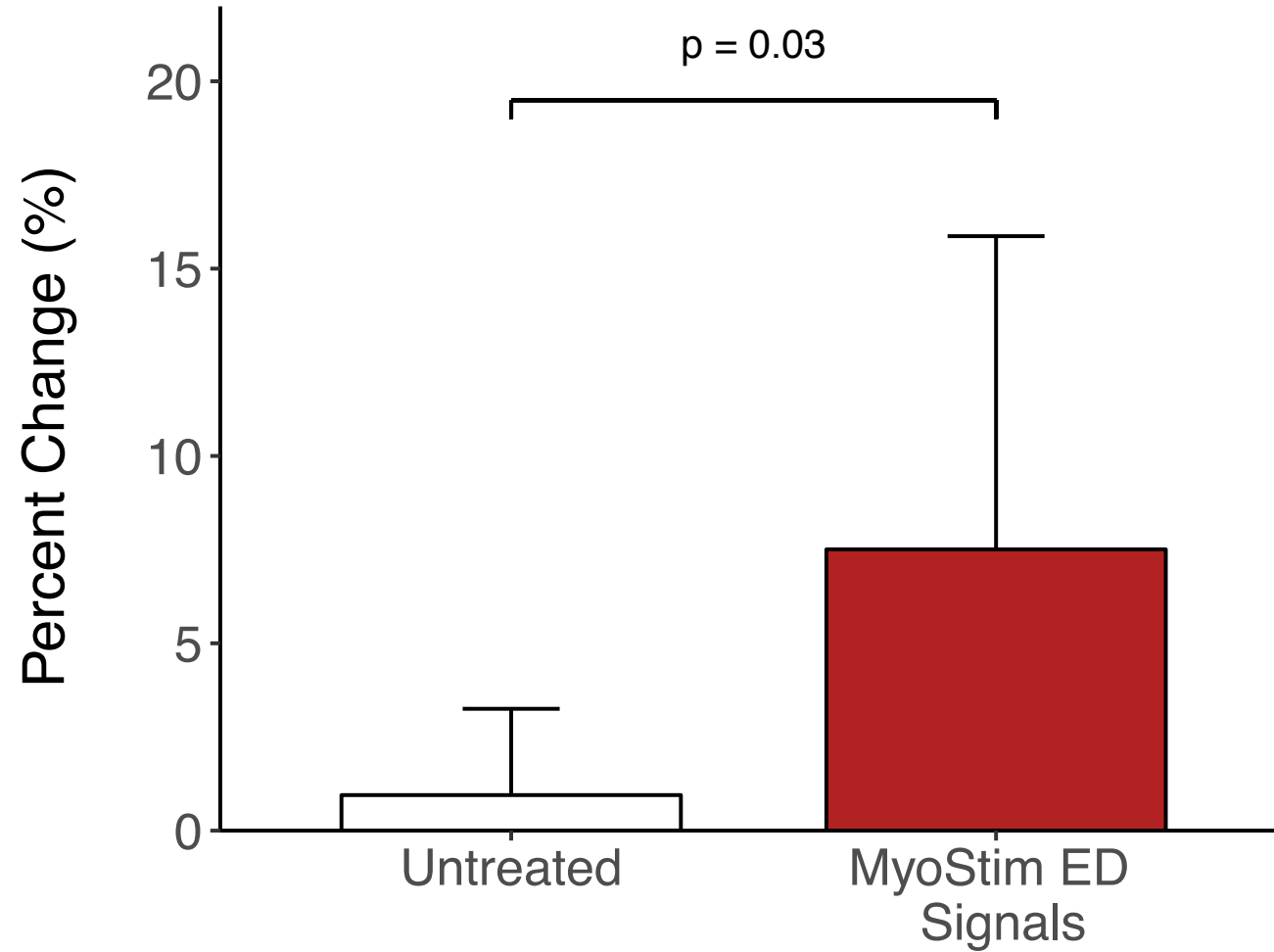
# MyoStim ED II Study

## Recovery of Morning Erection



# MyoStim ED II Study

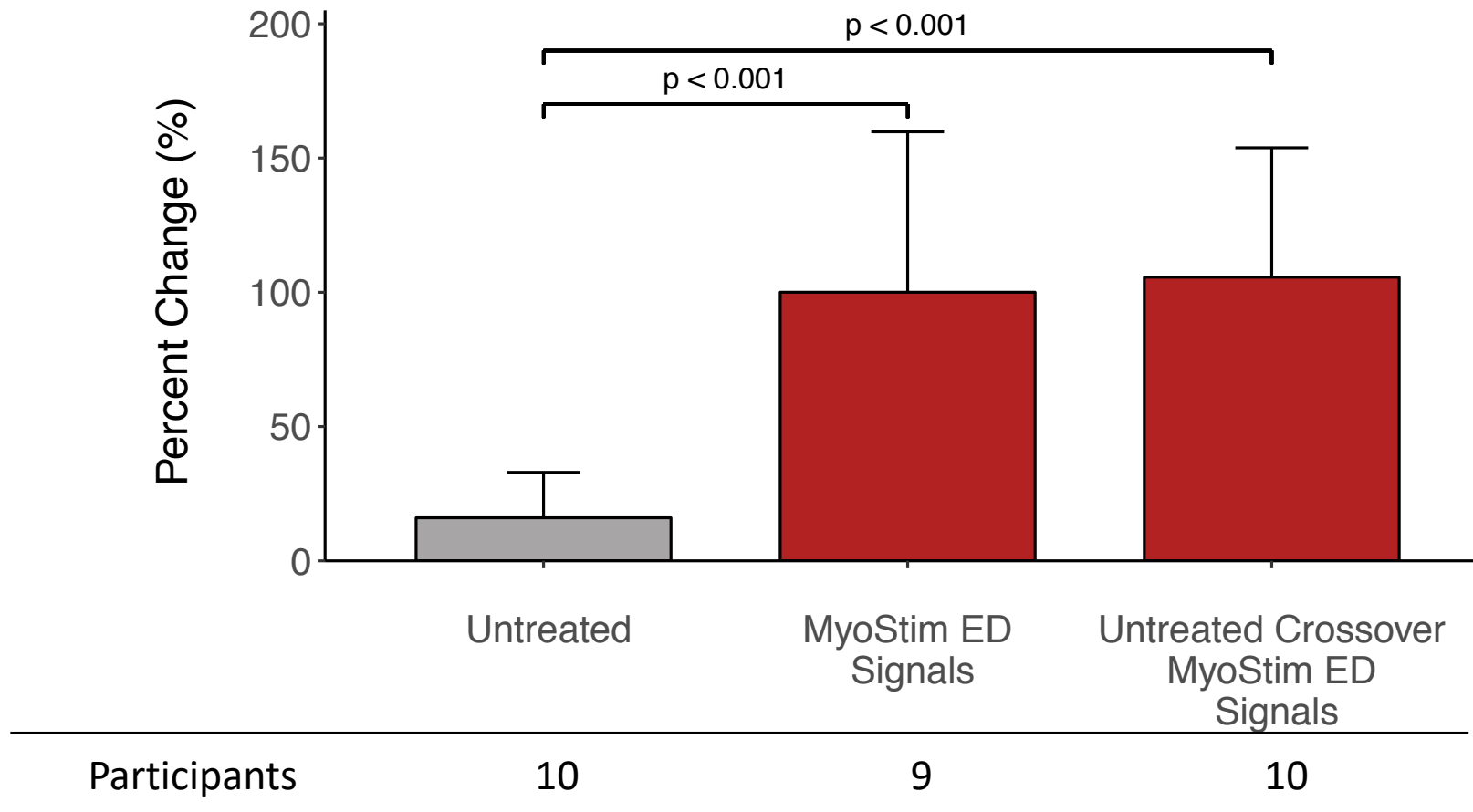
## Total Testosterone Level



# MyoStim ED II Study

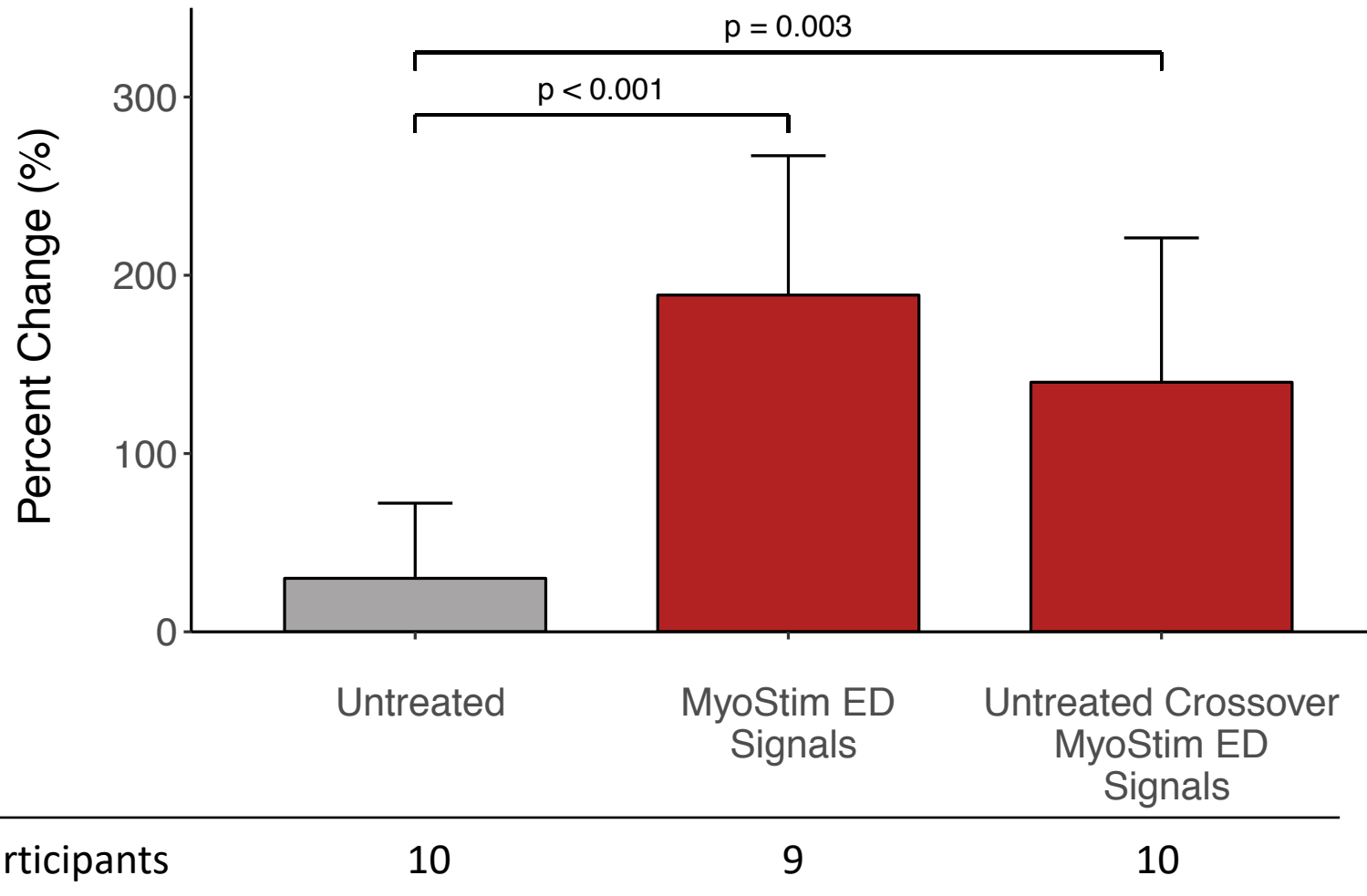
## International Index of Erectile Function Questionnaire

### Original Assigned and Cross Over MyoStim Treated (n=19)



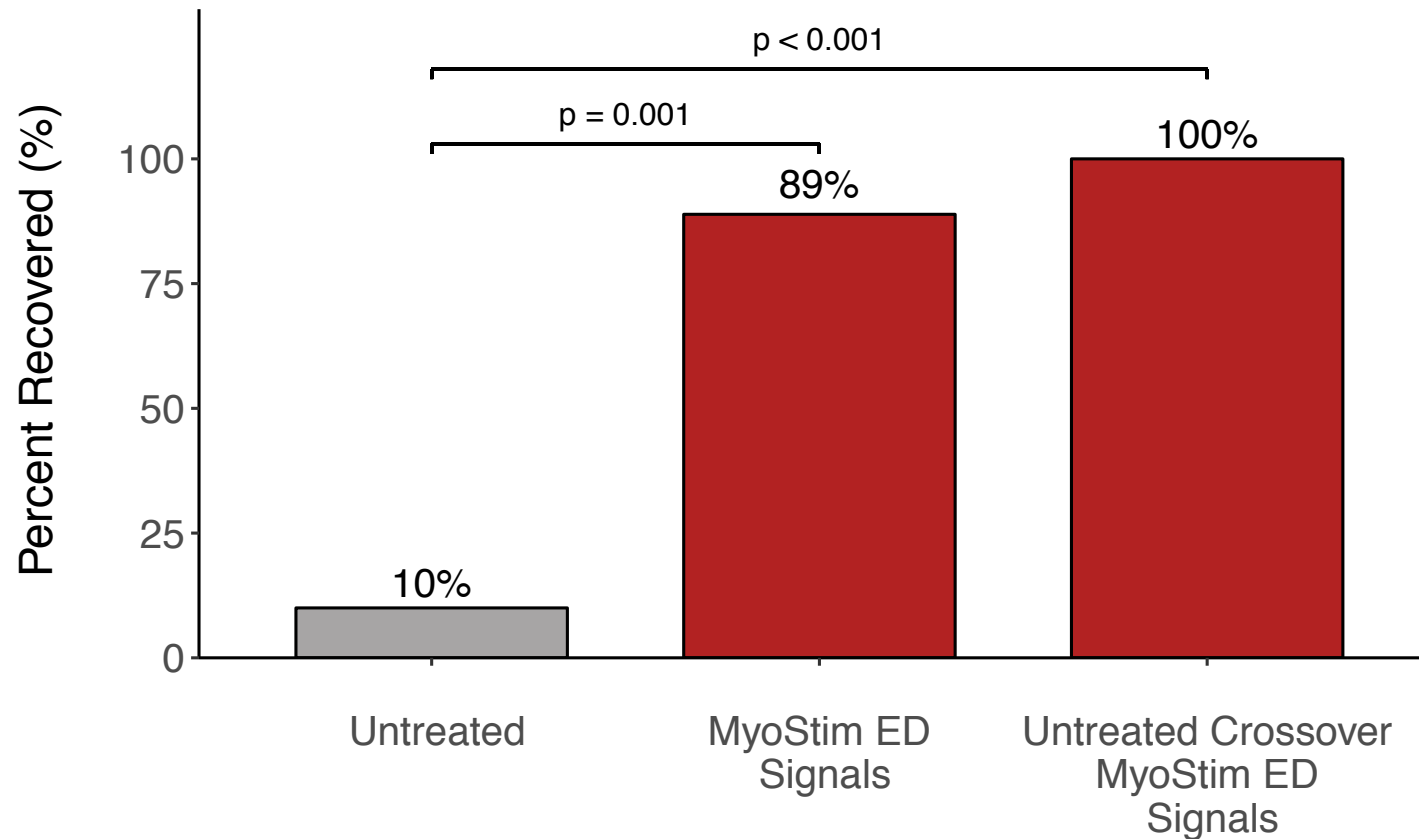
# MyoStim ED II Study

## Erection Hardness Score



# MyoStim ED II Study

## Recovery of Morning Erection



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Participants

10

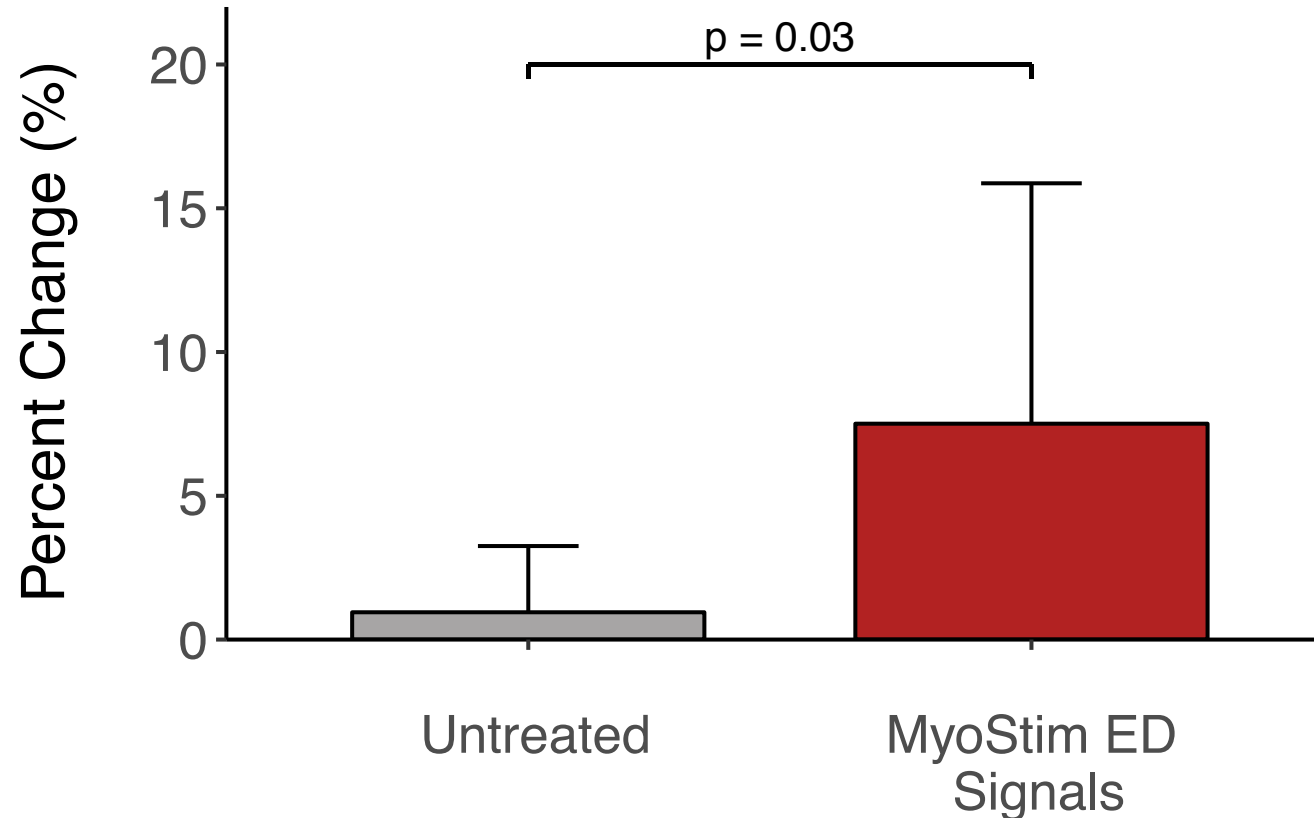
9

10

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# MyoStim ED II Study

## Total Testosterone Level



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Participants

10

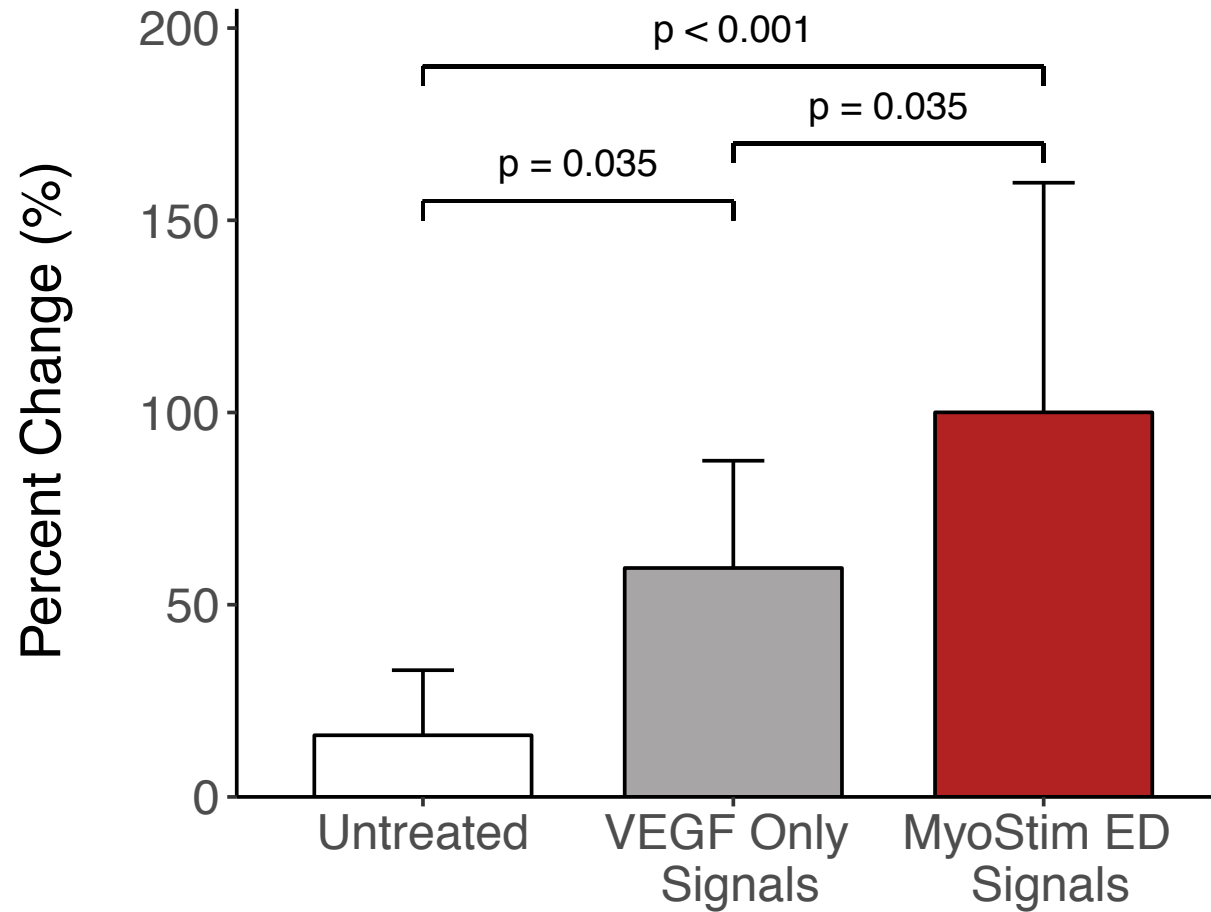
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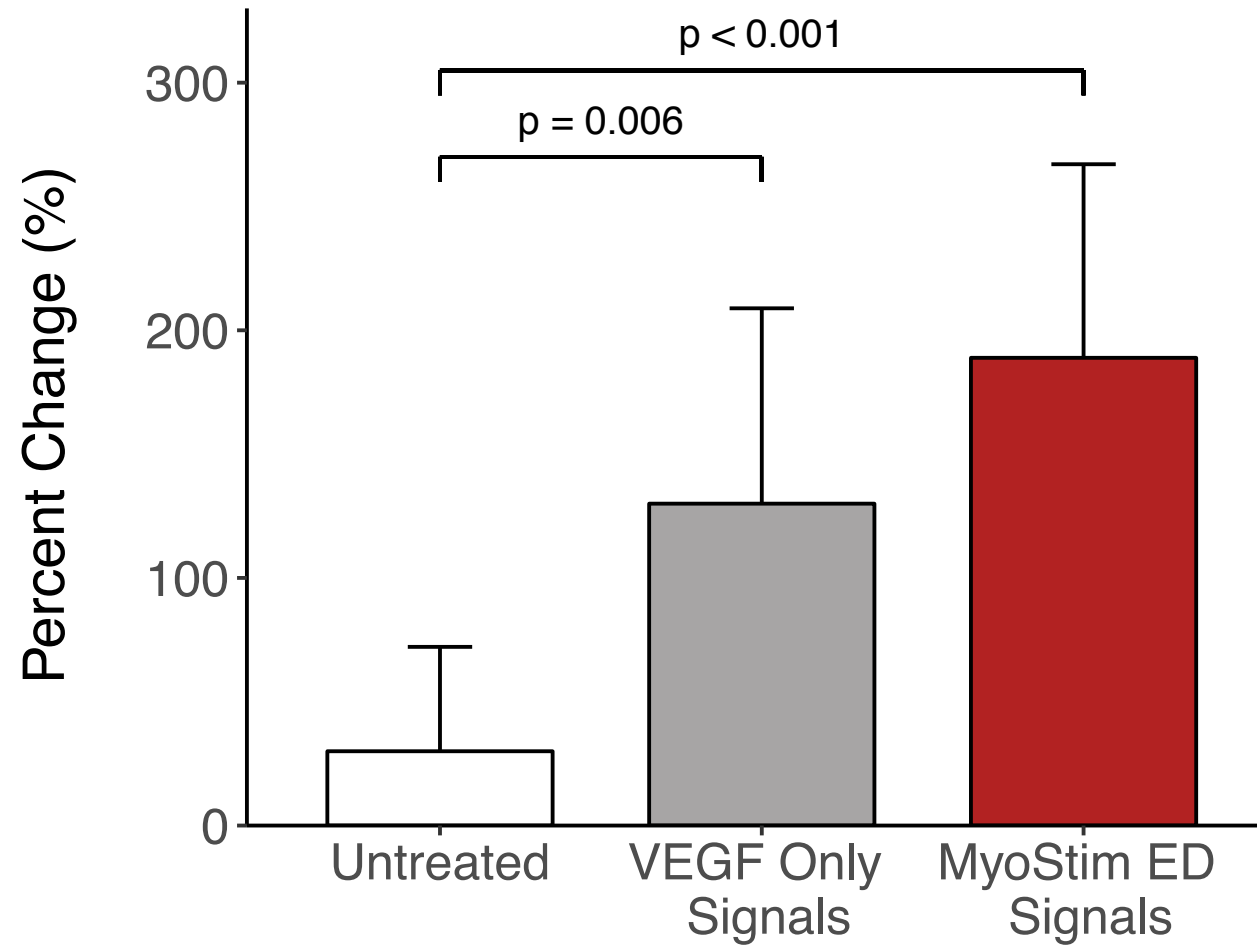
# MyoStim ED II Study

## International Index of Erectile Function Questionnaire



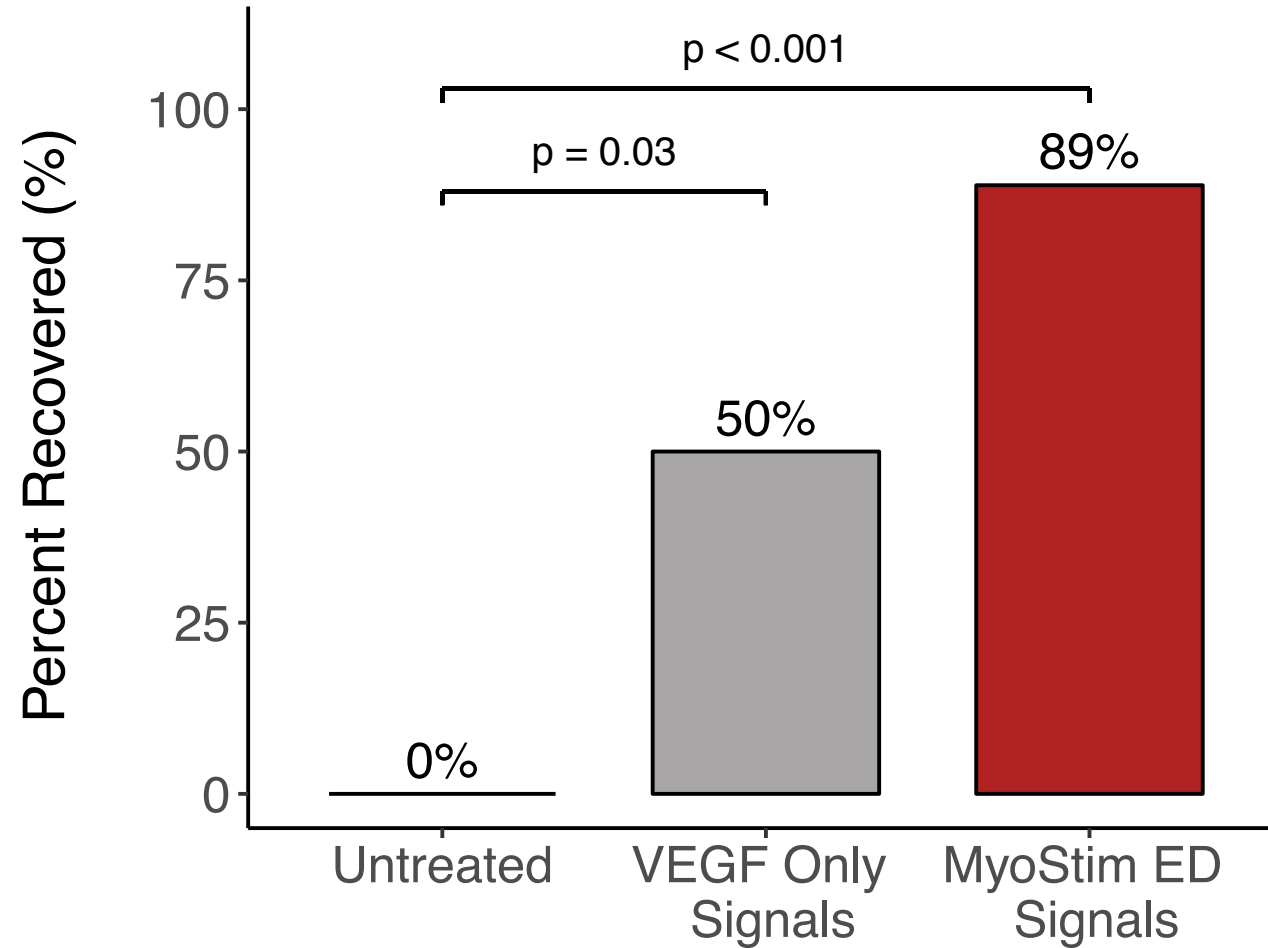
# MyoStim ED II Study

## Erection Hardness Score



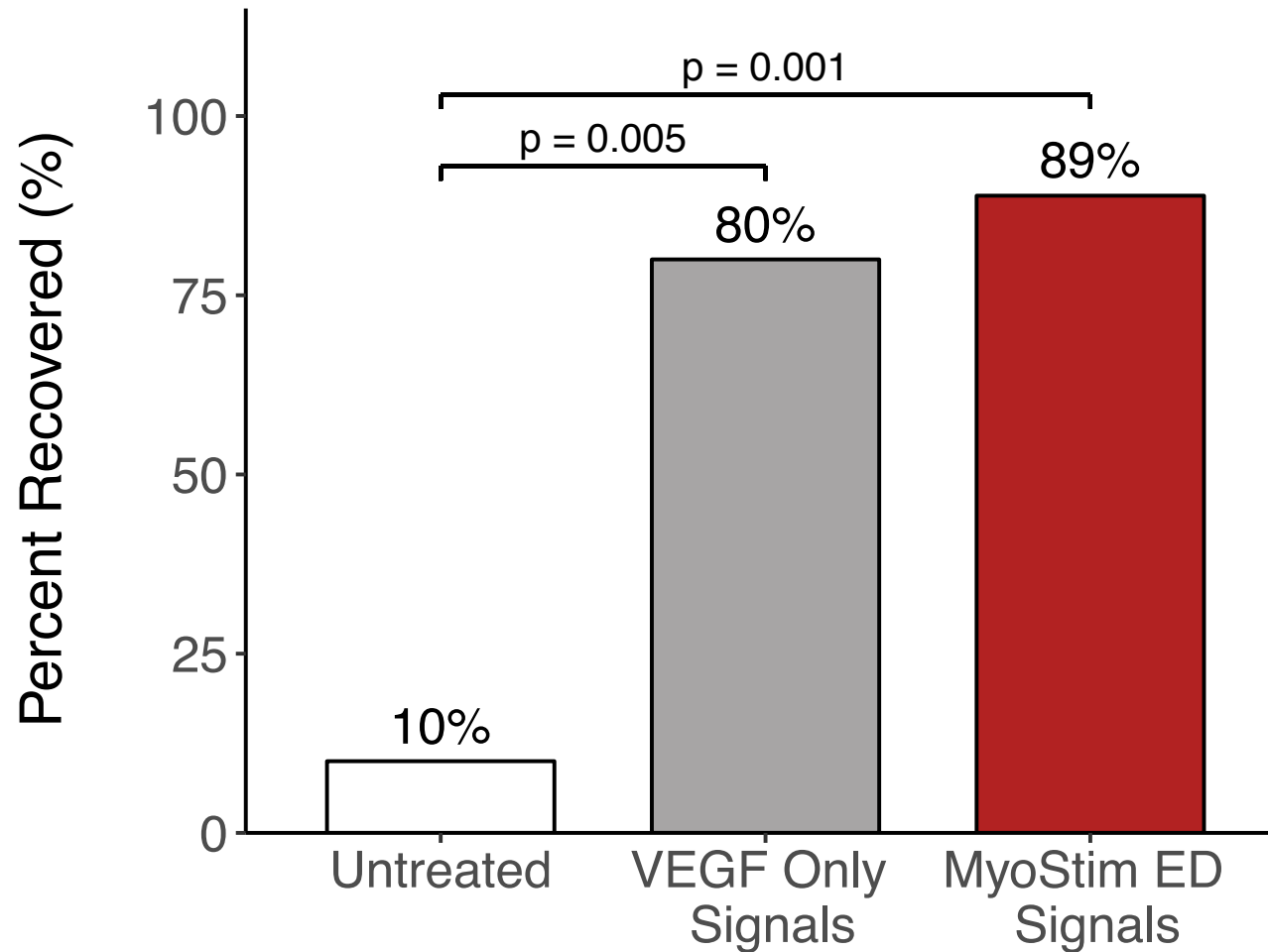
# MyoStim ED II Study

## Recovery of Penis Enlargement



# MyoStim ED II Study

## Recovery of Morning Erection



**MyoSTIM**  
bioelectric treatment of erectile dysfunction



**ED III STUDY**

**3 Month Follow Up Post**

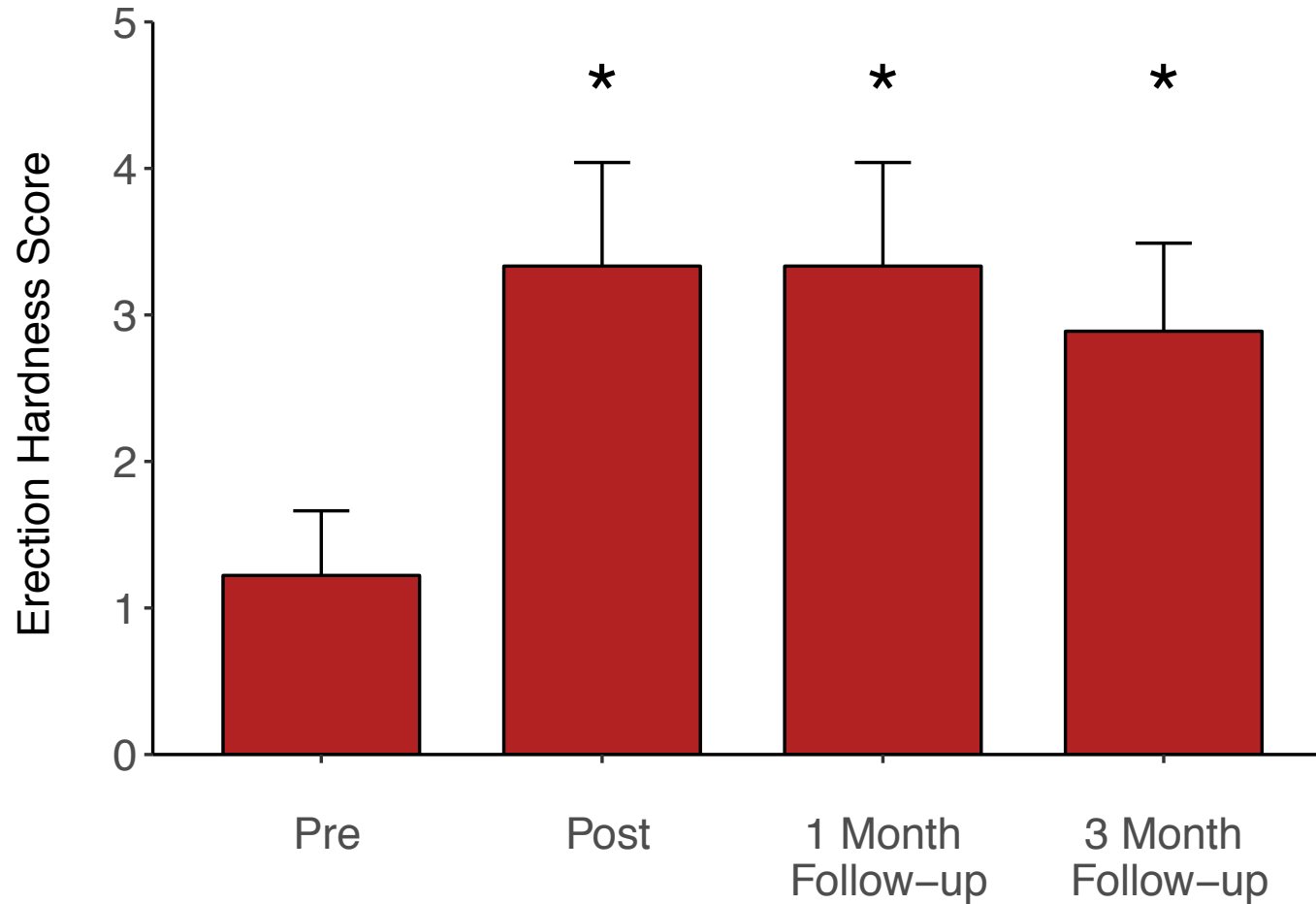
**4 weeks of Treatment**

# MyoStim ED III

## 3 month Follow Up Post Treatment of ED II Treated Patients DURABILITY (n=20)

- 20 Patients who were enrolled in the multi-signal MyoStim arm of the MyoStim ED II study, were then enrolled in the 3 month follow up study of durability of the benefit of MyoStim ED treatment
- Included All 10 Patients that completed 4 weeks of initial treatment with MyoStim ED arm of Bioelectric Stimulation, AND the 10 patients that had been initially randomized to the Control arm, and were then allowed to Cross Over to receive the 4 weeks of MyoStim multi-signal BES, were then followed for 3 months without any additional treatment.
- All patients completed the same questionnaires and self assessments of ED used during the ED II active treatment study at the completion of the 3 month follow up period to assess durability of the response to initial treatment for 4 weeks
- No adverse events were reported

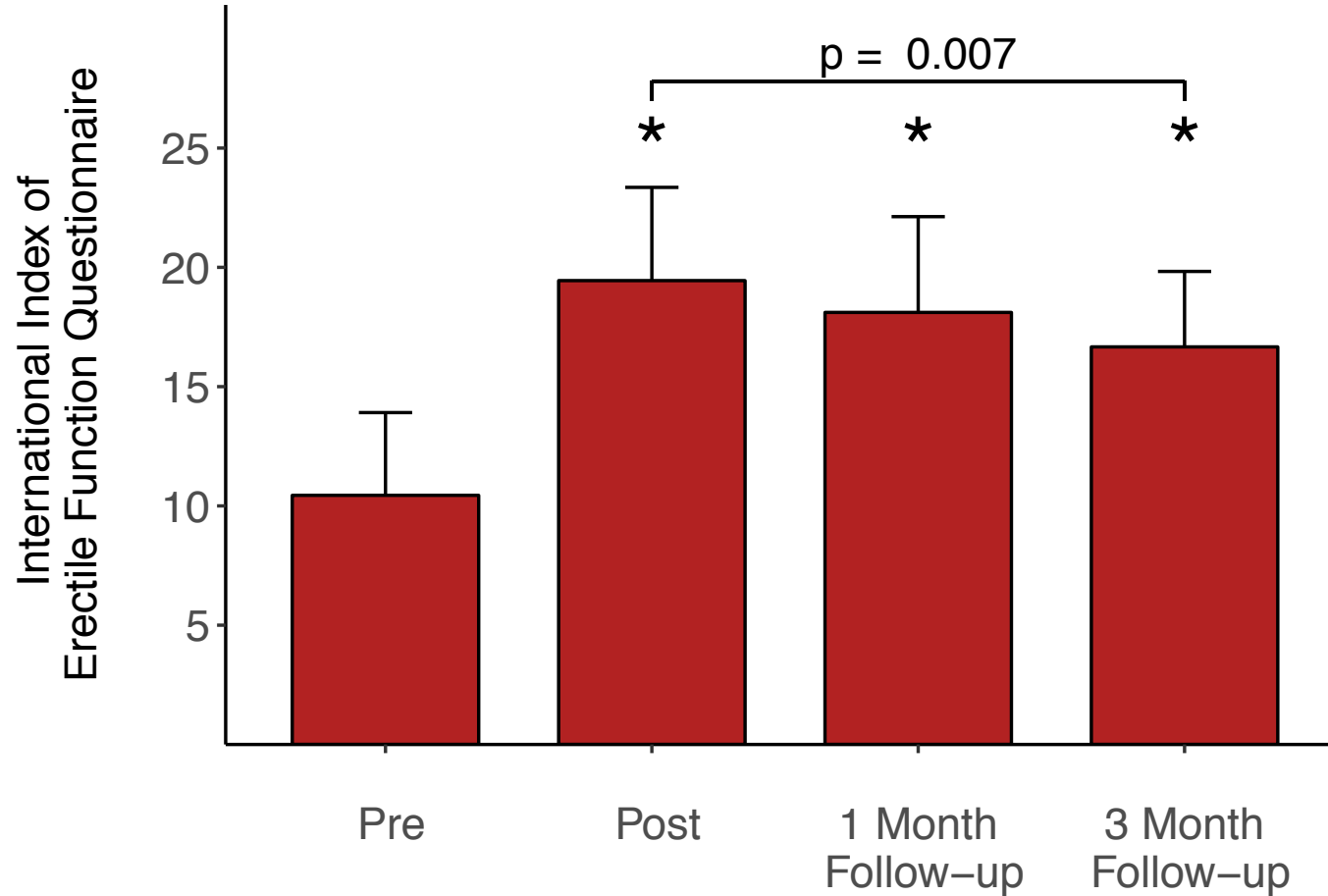
# MyoStim ED III 3 Month Follow Up Erection Hardness Score



\* Indicates significantly different than pre,  $p < 0.05$ , post hoc test with Holm method.

# MyoStim ED III 3 Month Follow Up

## International Index of Erectile Function Questionnaire

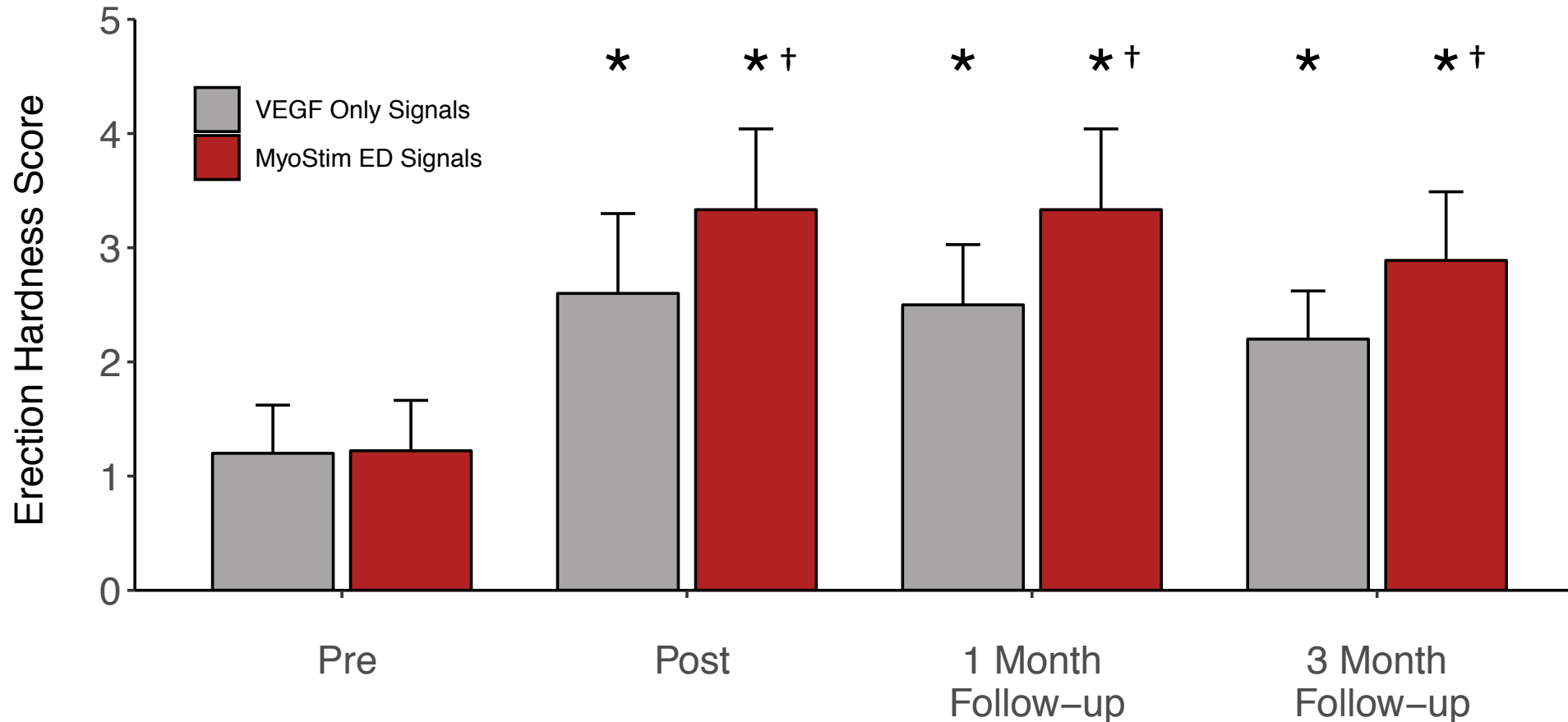


\*Indicates significantly different than pre,  $p < 0.05$ , post hoc test with Holm method.



# MyoStim ED III 3 Month Follow Up

## Erection Hardness Score



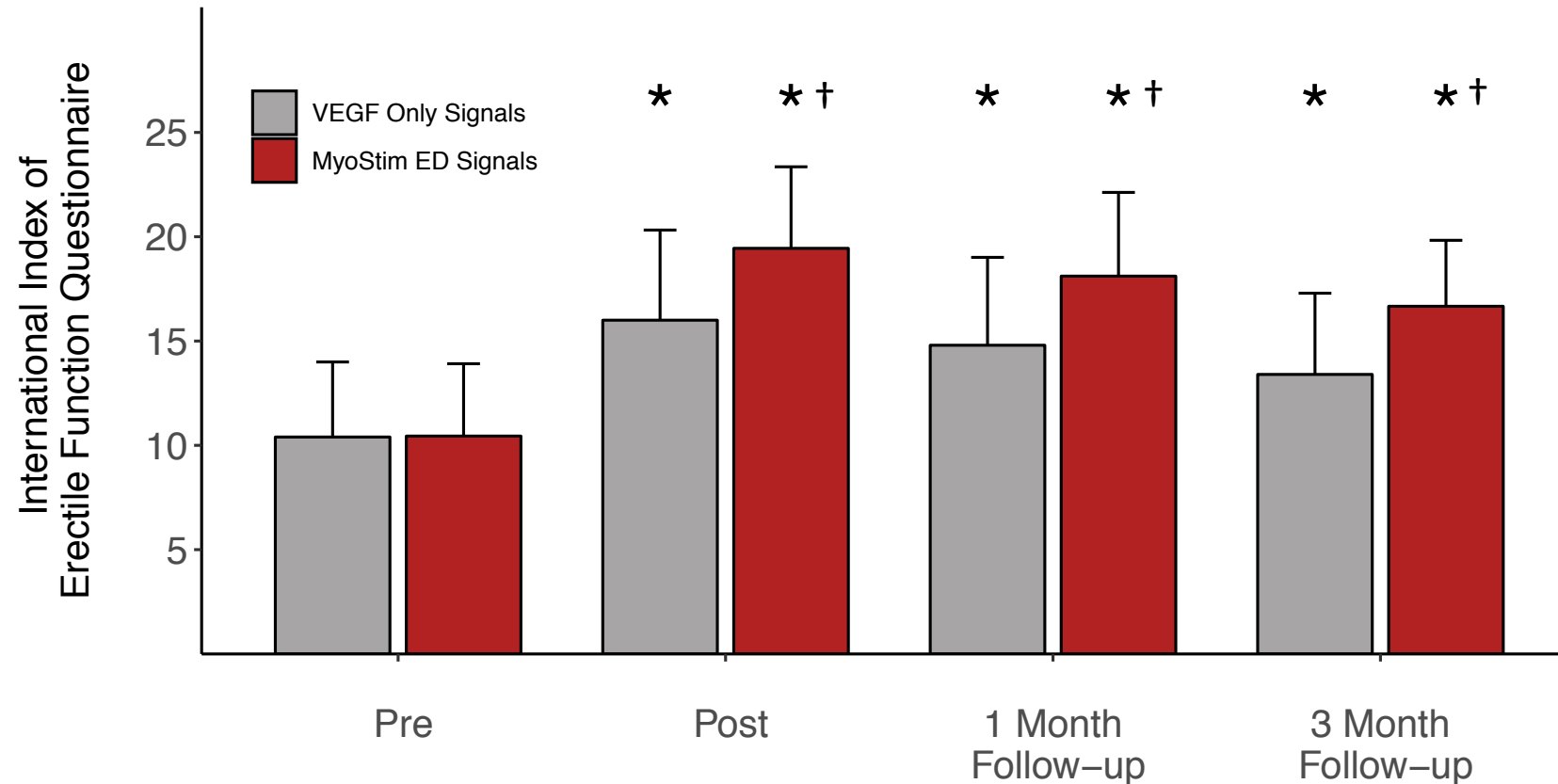
Group main effect,  $p = 0.019$ , Group by Time Interaction,  $p = 0.006$

\* Indicates significantly different than pre,  $p < 0.05$ , post hoc test with Holm method.

† Indicates group difference for respective time points,  $p < 0.05$ , two-samples T-test, not corrected.

# MyoStim ED III 3 Month Follow Up

## International Index of Erectile Function Questionnaire



Group by Time Interaction,  $p = 0.002$

Indicates significantly different than pre,  $p < 0.05$ , post hoc test with Holm method.

† Indicates group difference for respective time points,  $p < 0.05$ , two-samples T-test, not corrected.





**MyoSTIM**  
bioelectric treatment of erectile dysfunction



**ED IV REGISTRY**

**Evaluation of 8 weeks of Treatment**

**MyoStim ED Only**

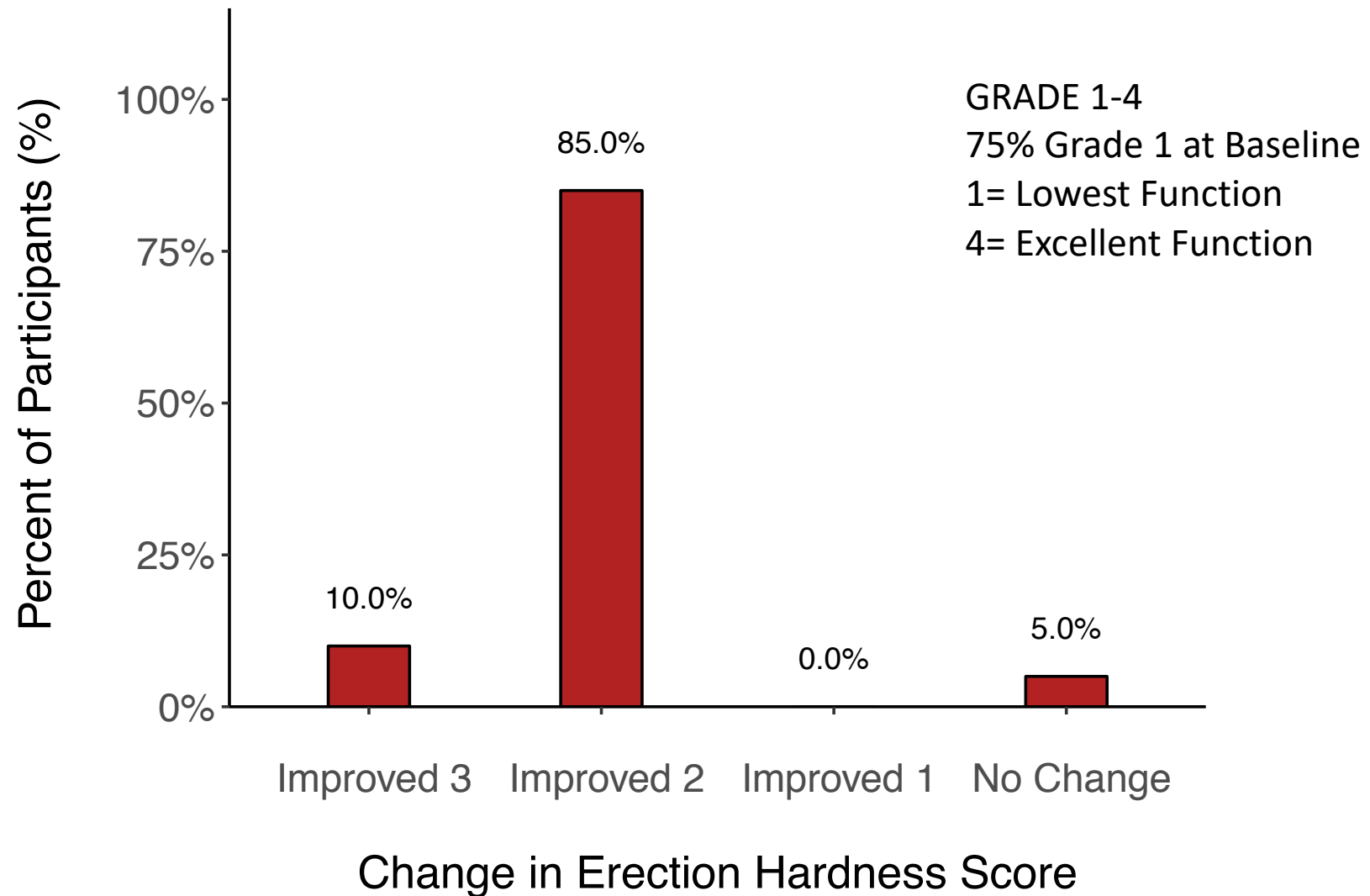
# ED IV Registry Study

## 8 weeks of MyoStim Regimen only

- Prospective, Single arm, Open-Label Registry of 20 consecutive patients treated for 8 weeks using only MyoStim BES protocol
- Treatment was use of Bioelectric Stimulation using precise signals for 5 proteins that increase blood supply, stem cell homing, induce muscle and nerve regeneration (VEGF, SDF, PDGF, IGF, Klotho) delivered via a 510K approved stimulator
- All Patients were treated for 45 minutes, 2 x/week, for 8 weeks
- All patients completed all study questionnaires and self assessment of metrics of ED both Before and After treatment
- No use of PDE-5 inhibitors or other drugs for ED for the entire study
- No Adverse Events were reported

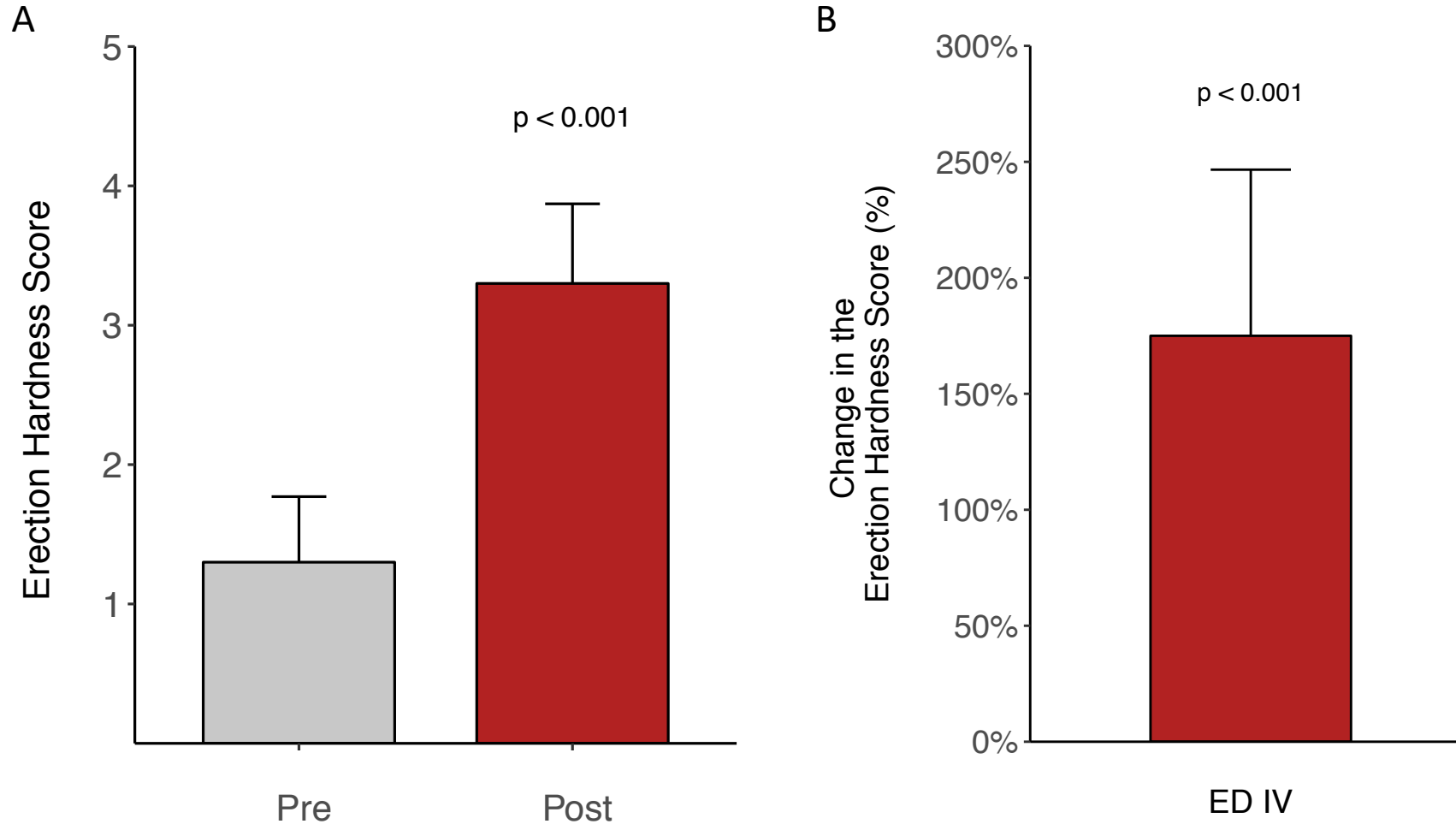
# MyoStim ED IV 8 Weeks of Treatment

## Erection Hardness Score



# MyoStim ED IV 8 weeks of Treatment

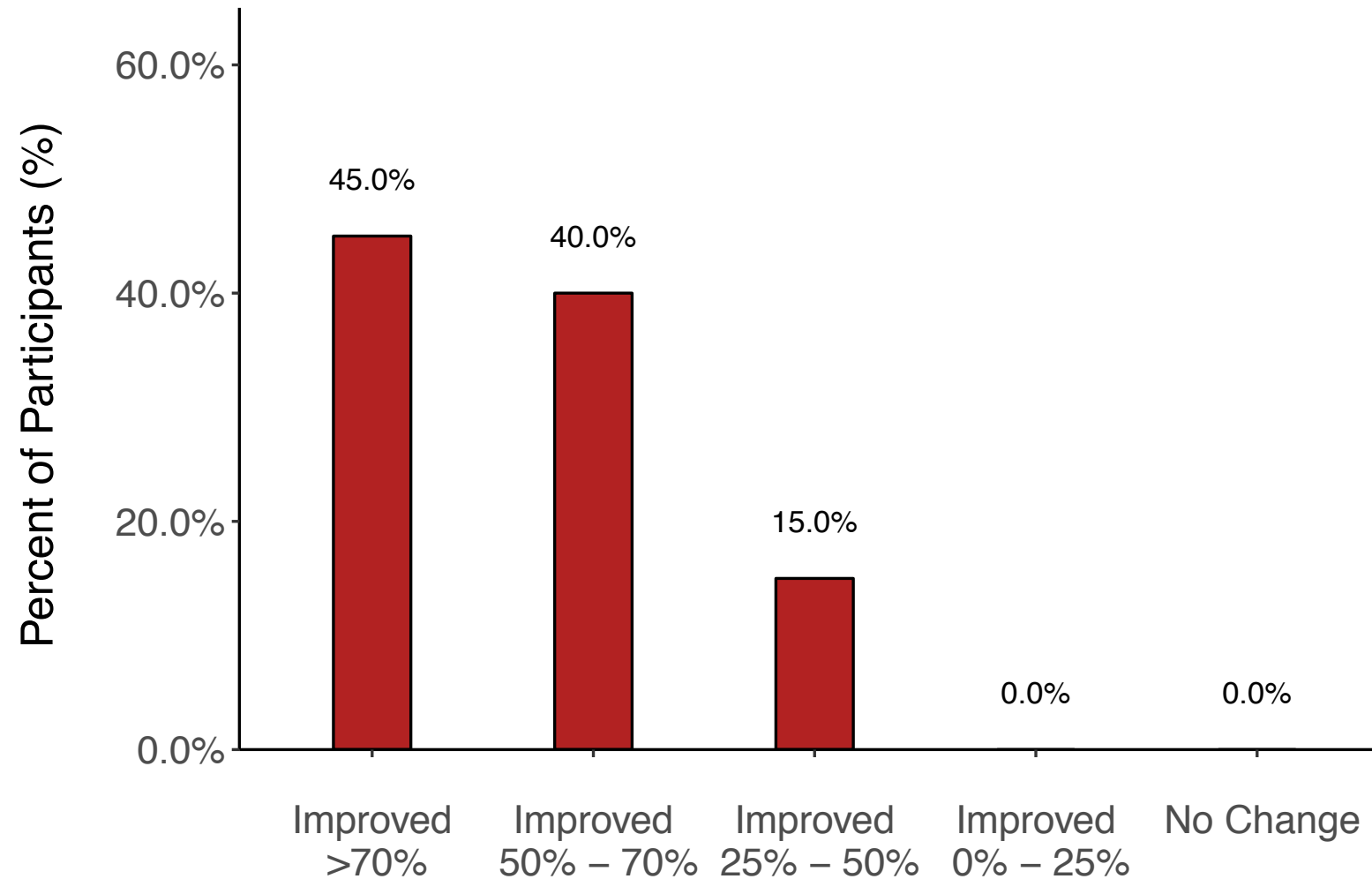
## Erection Hardness Score





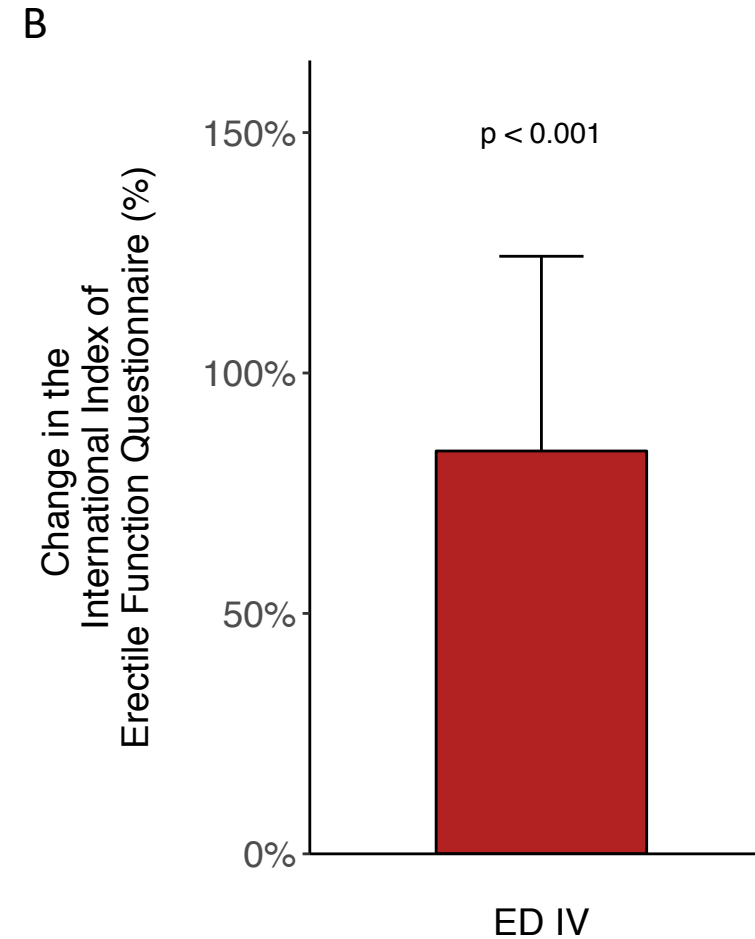
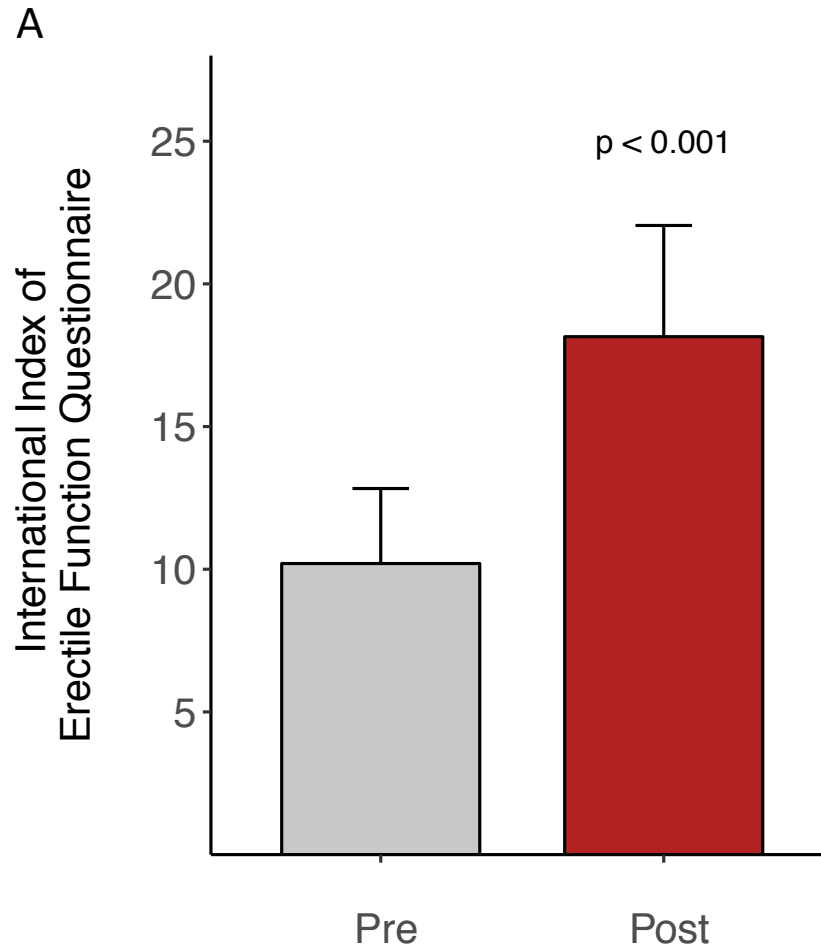
# ED IV 8 weeks of MyoStim Treatment

## International Index of Erectile Function Questionnaire



# ED IV 8 weeks of MyoStim Treatment

## International Index of Erectile Function Questionnaire







**MyoSTIM**  
bioelectric treatment of erectile dysfunction

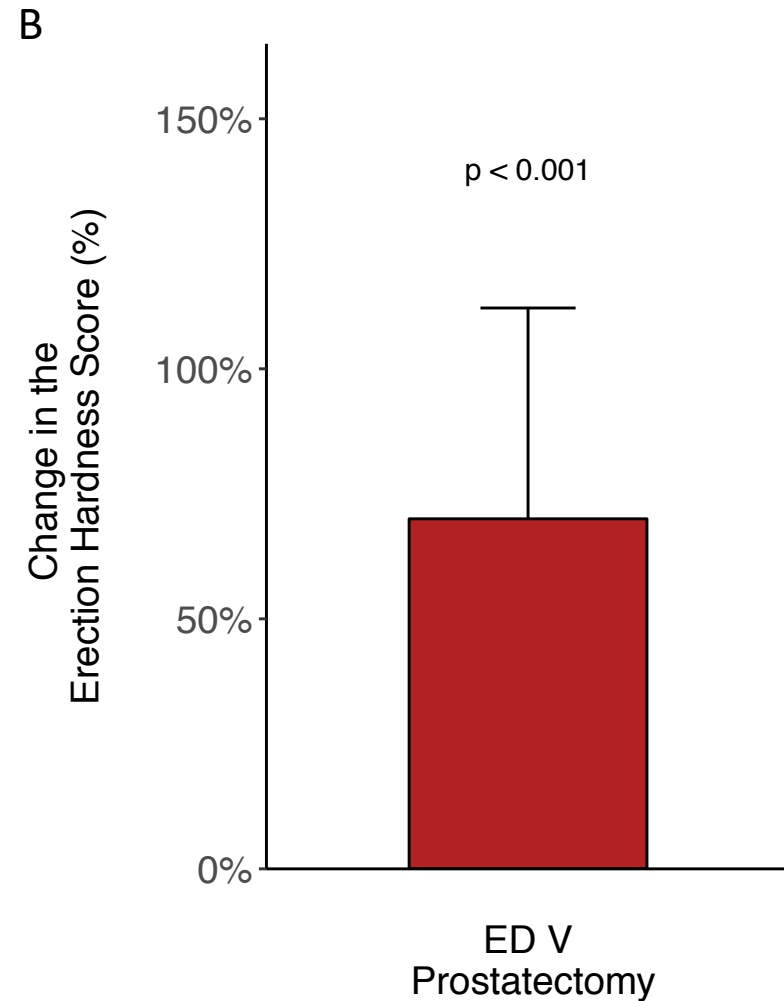
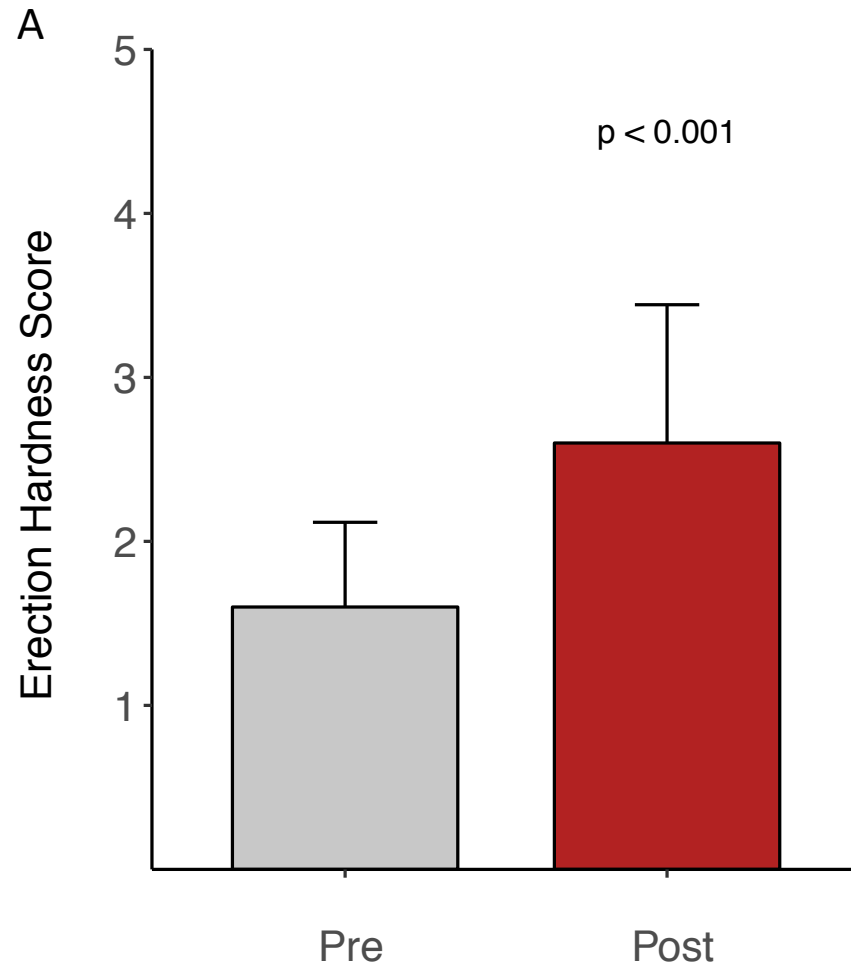


**ED V REGISTRY**  
**POST PROSTATECTOMY**  
**Treated for 8 Weeks**

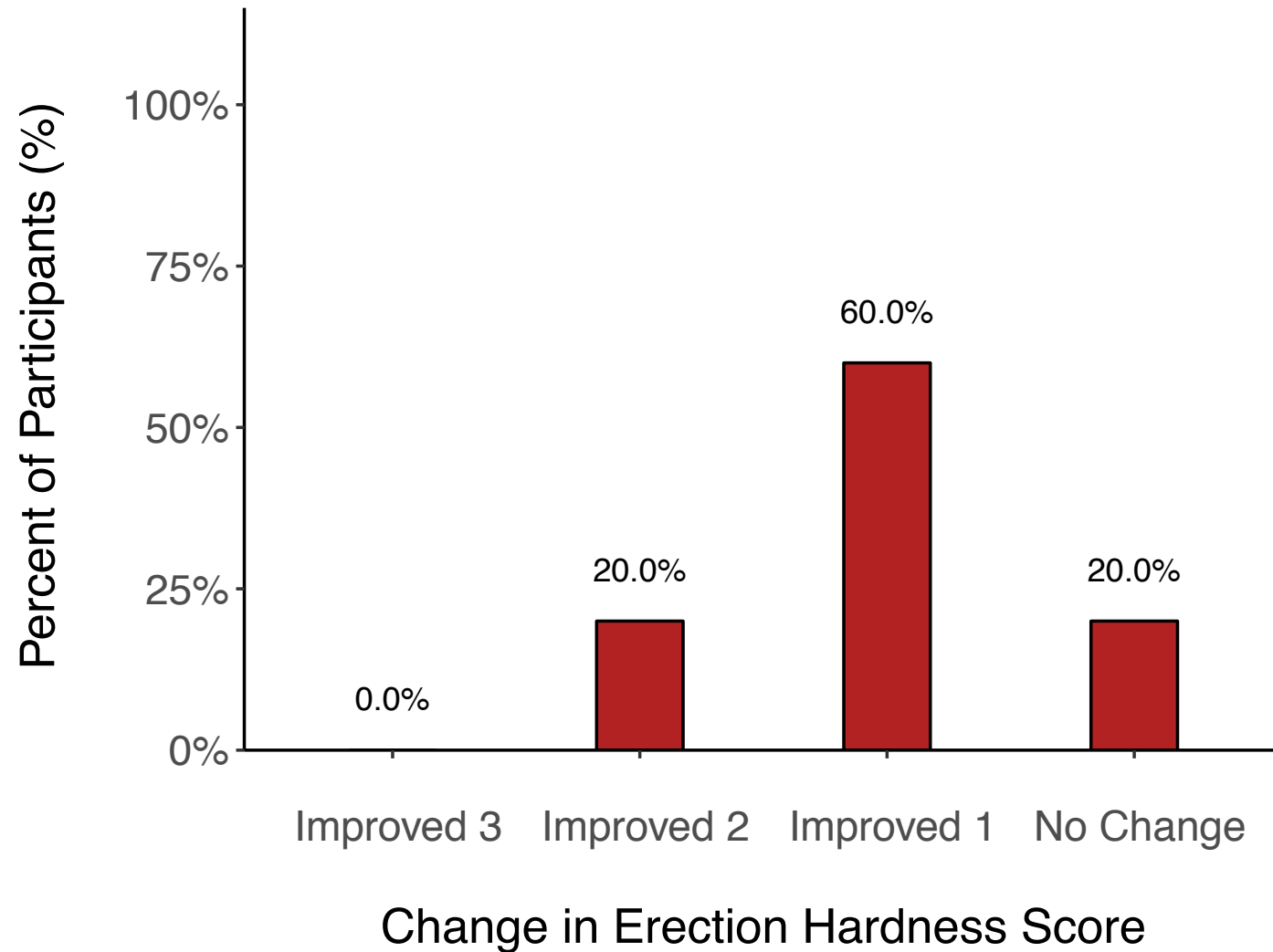
# ED V Treatment of Erectile Dysfunction POST PROSTATECTOMY REGISTRY

- Prospective, Open Label, Single Arm study of use of Bioelectric Stimulation for treatment of ED Post Prostatectomy
- All patients had undergone surgical prostatectomy and were at least 3 months post surgery
- All patients completed study End Point Questionnaires and self assessment of metrics of ED before and after treatment
- Treatment involved use of Bioelectric Stimulation delivered via a 510 K approved stimulator via patch electrodes placed on the penis
- All patients were treated for 45 mins, 2x's/week for 8 weeks using the MyoStim Multi-signal program. (VEGF, SDF< PDGF, IGF, KLOTHO)

# MyoStim ED V - Prostatectomy Patients Erection Hardness Score



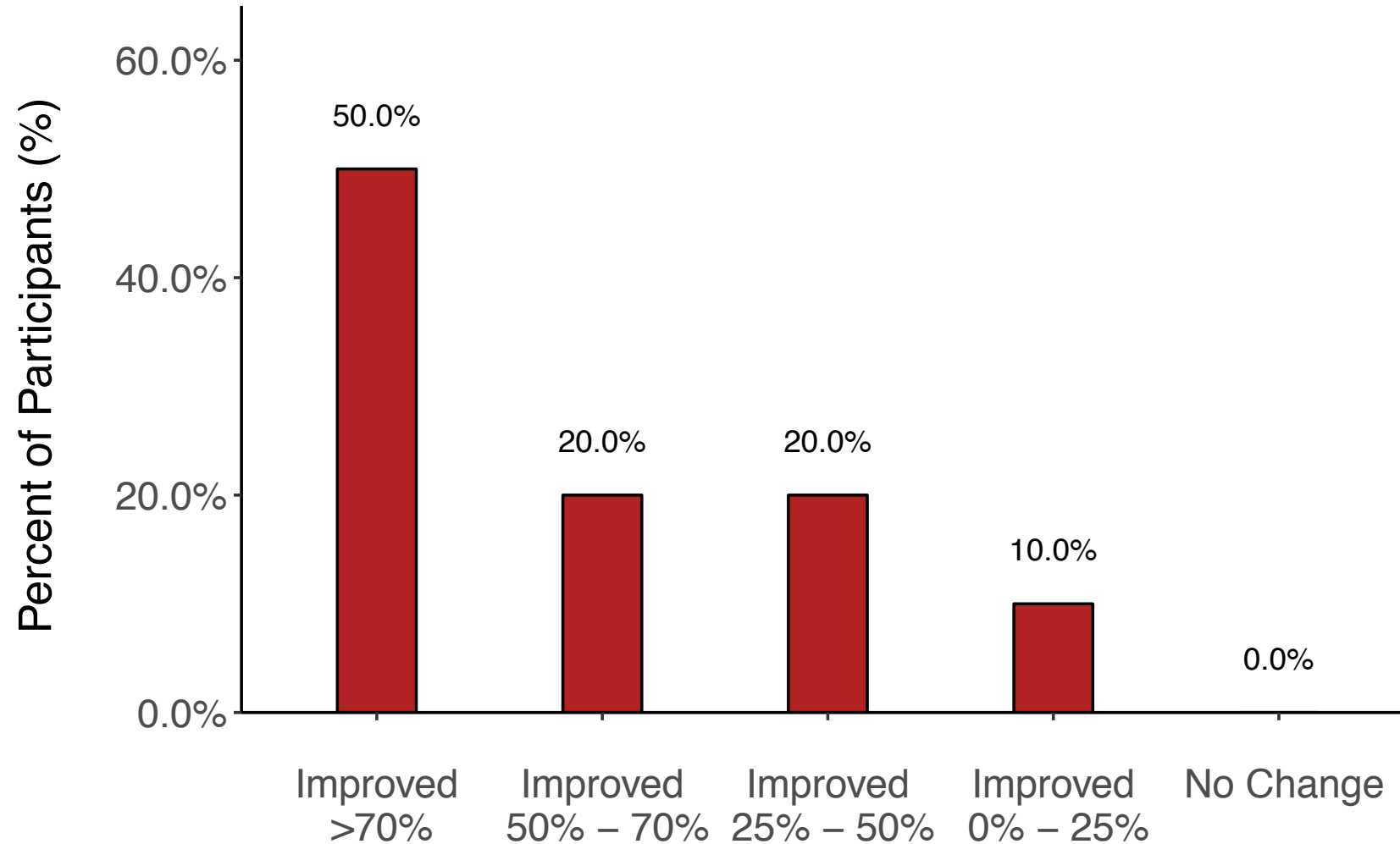
# MyoStim ED V - Prostatectomy Patients Erection Hardness Score





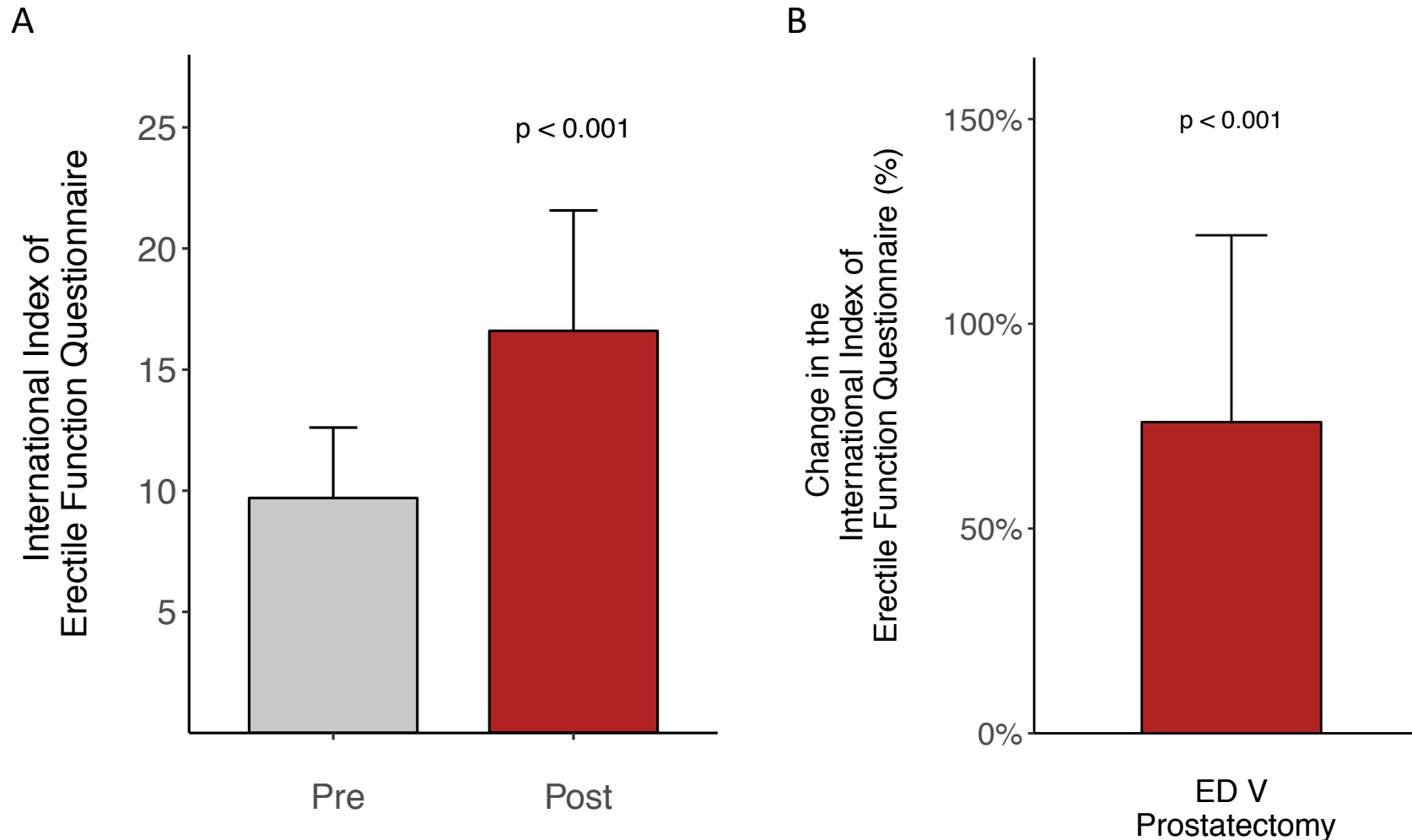
# MyoStim ED V - Prostatectomy Patients

## International Index of Erectile Function Questionnaire



# MyoStim ED V - Prostatectomy Patients

## International Index of Erectile Function Questionnaire









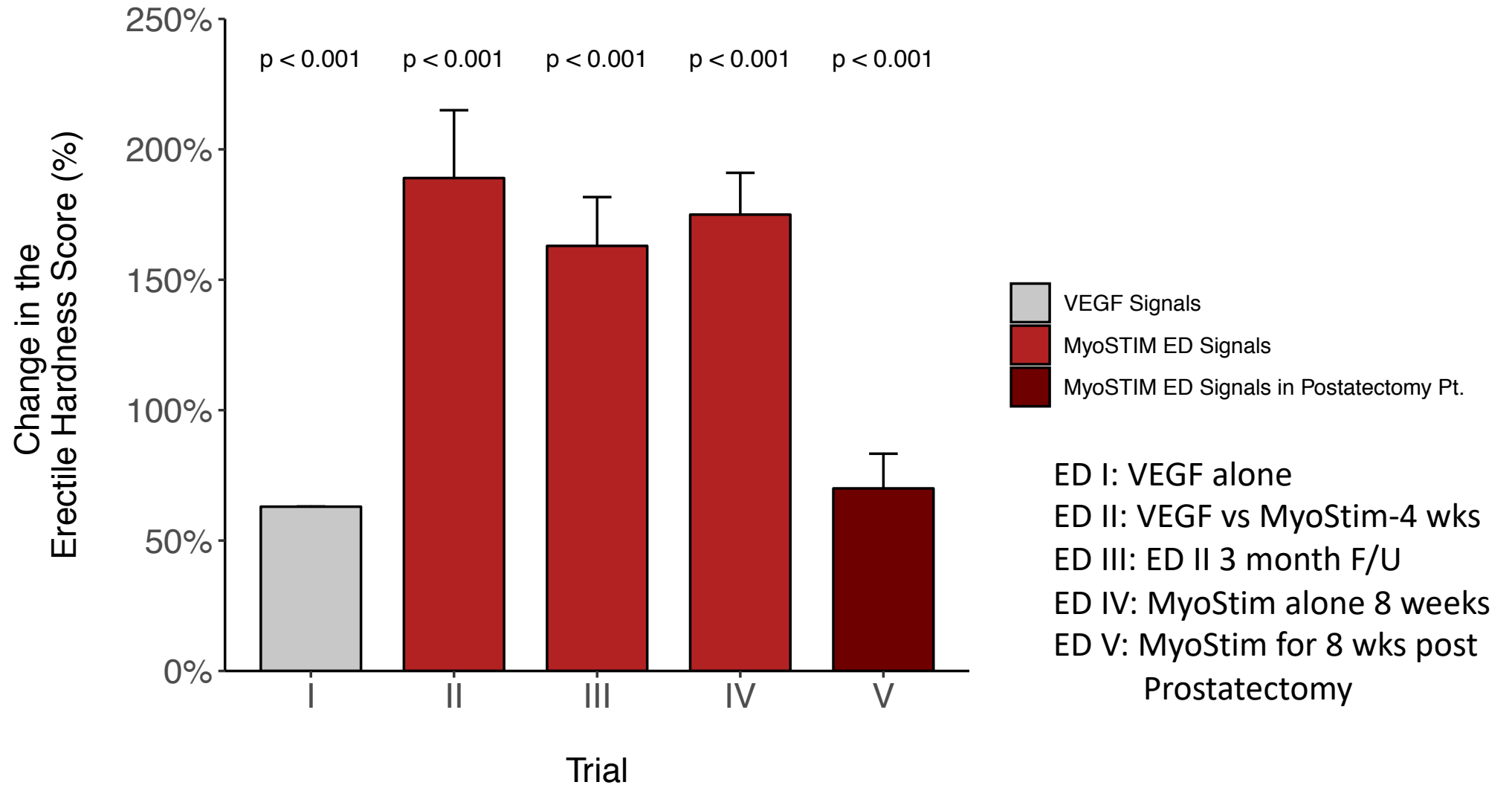
## Summary of the 5 Trials

# SUMMARY OF ED STUDIES

- Number of trials completed:
- 3 Prospective Randomized Trials and 2 Registry studies
- Total number enrolled: 81, plus another 21 coming from So Africa
- In a second site for the ED IV Registry of MyoStim alone for 8 weeks
- Significant-up to 90-200% improvement in metrics for ED
- Durability demonstrated
- 8 weeks was not significantly better than 4 weeks of treatment
- NO ADVERSE EVENTS reported
- No additional studies planned

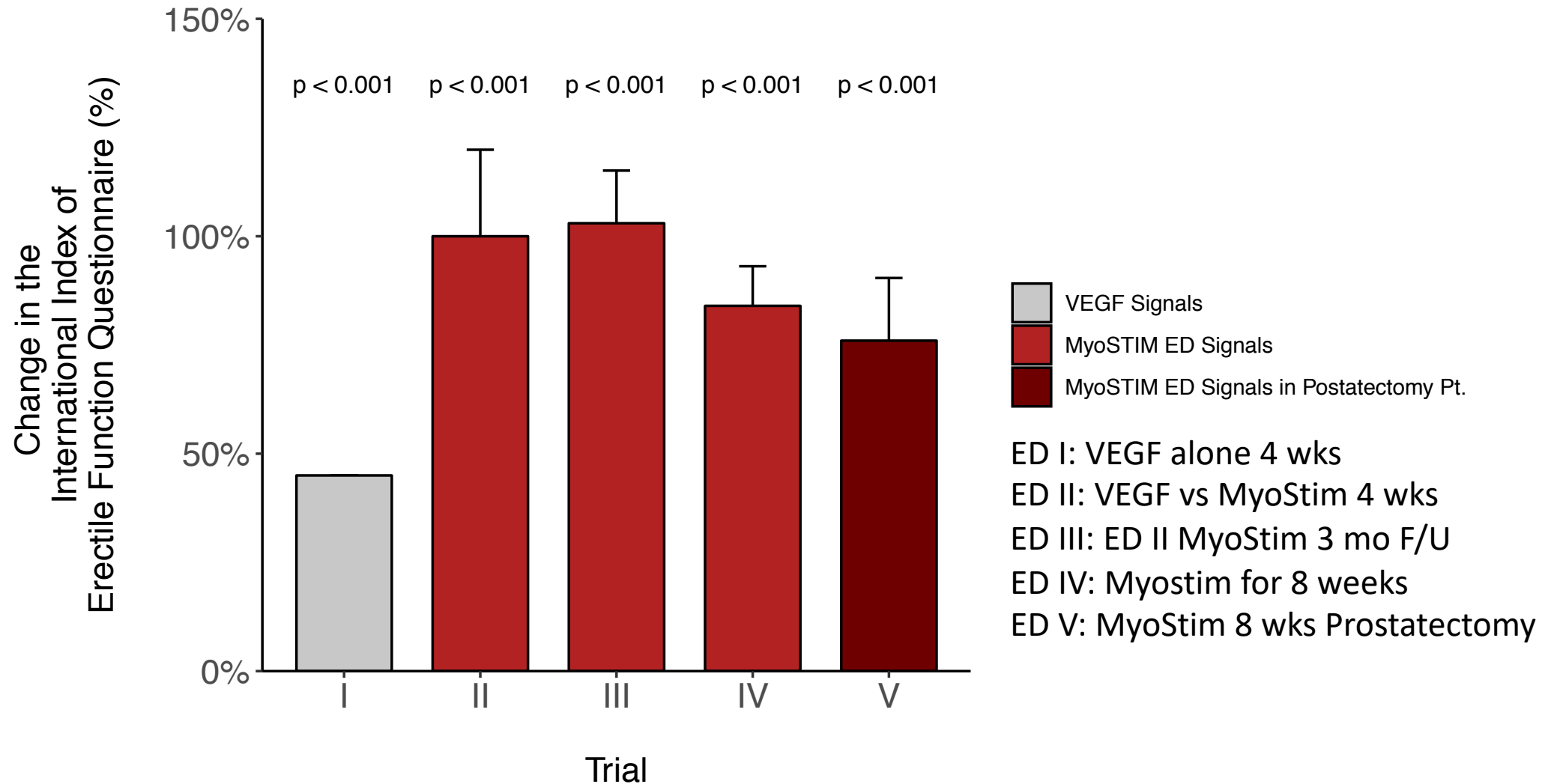
# MyoStim ED

## Erection Hardness Score



# MyoStim ED

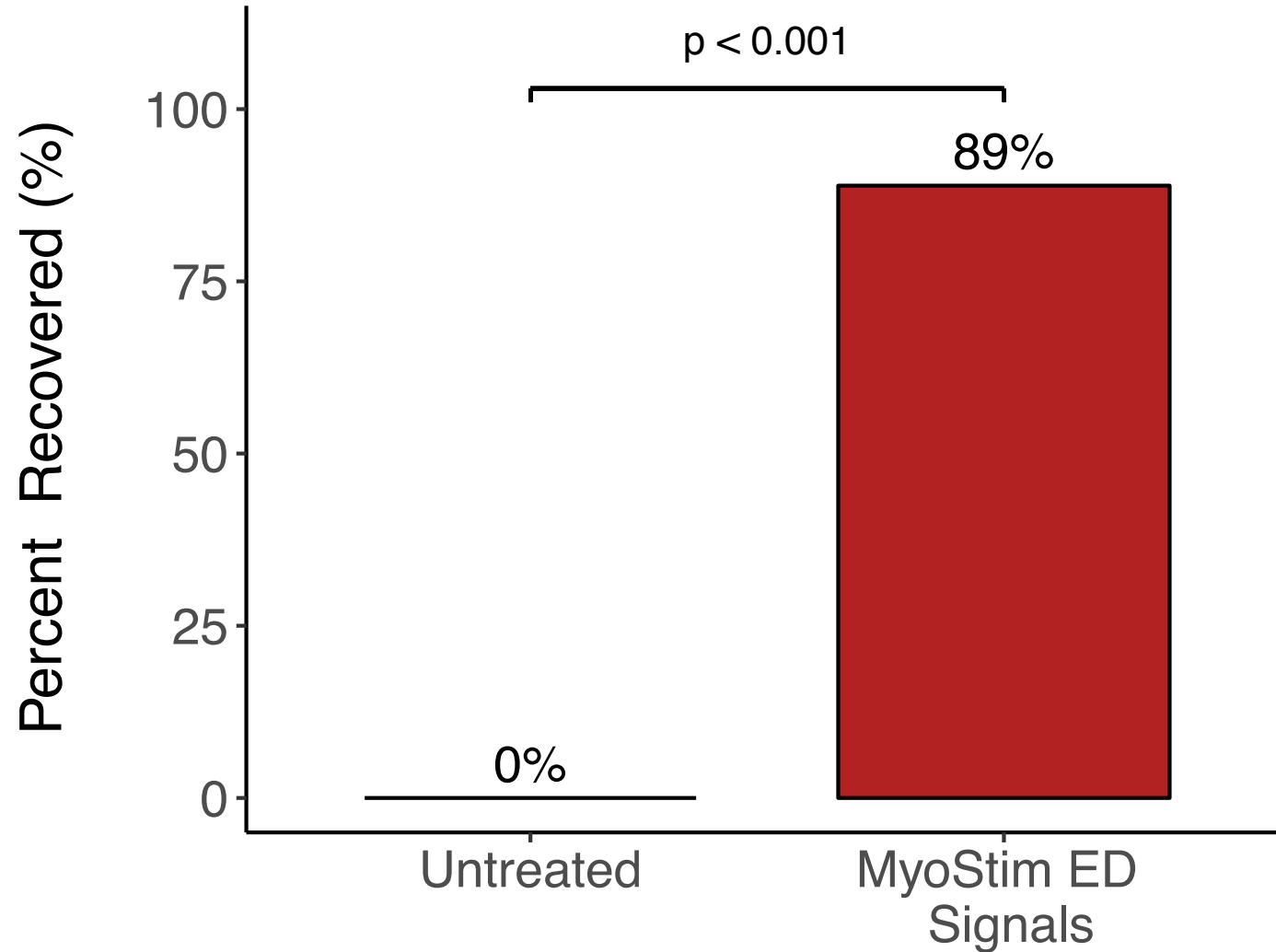
## International Index of Erectile Function Questionnaire





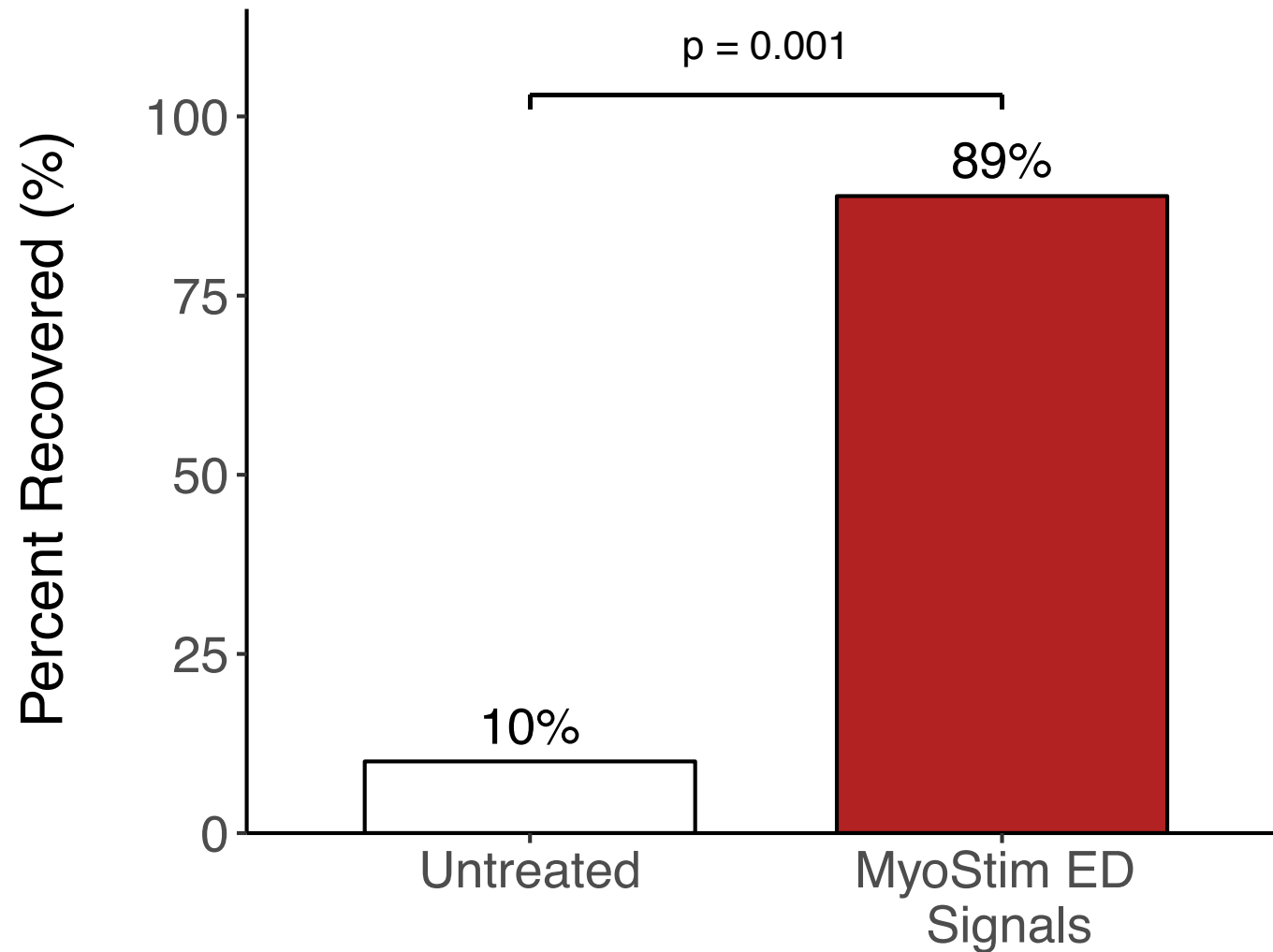
# MyoStim ED II Study

## Recovery of Penis Enlargement



# MyoStim ED II Study

## Recovery of Morning Erection



BACK UP SLIDES

# MyoStim ED I Study of VEGF for 4 weeks

## Patient Demographics

**Table 1** Characteristics of the sample

Variable	Total sample	IG ( <i>n</i> = 11)	CG ( <i>n</i> = 11)	<i>p</i>
Age	58.5 ± 5.3	58.6 ± 5.3	58.4 ± 5.8	.940
Race				.534
White	19 (86.3)	10 (90.9)	9 (81.8)	
Black	3 (13.7)	1 (9.1)	2 (18.1)	
Scholarship	5 (4–8)	5 (4–8)	5 (4–8)	1.0
Smoker	12 (54.5)	5 (45.4)	7 (63.6)	.392
Alcoholic	5 (22.7)	3 (27.2)	2 (18.1)	.611

# MyoStim ED I VEGF Study

## Results of Two Primary End Points

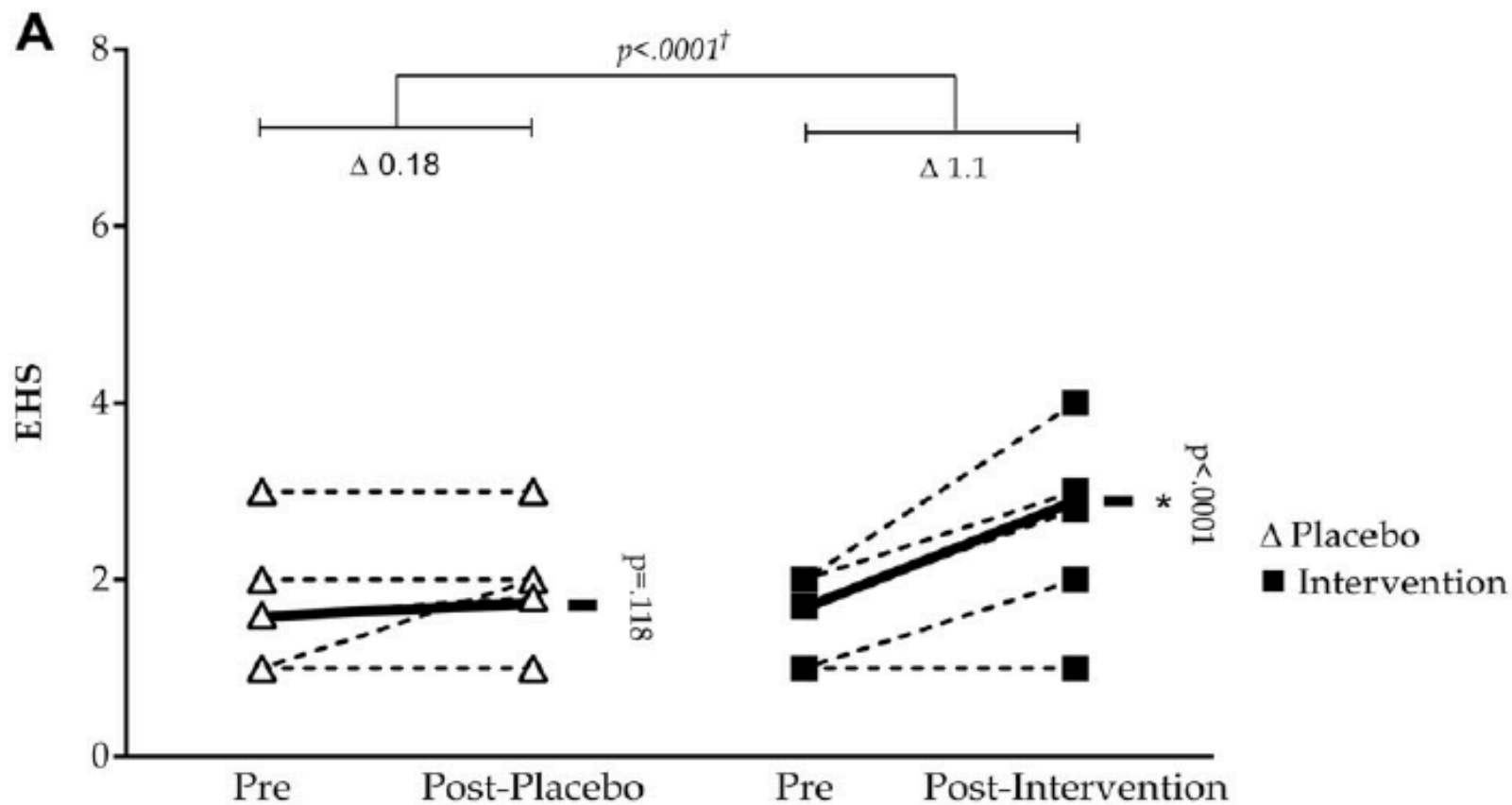
**Table 2** Comparison between groups and intra groups regarding EHS and IIEF-5 questionnaire

Variable	Placebo			Intervention		
	Pre	Post	Diff	Pre	Post	Diff
EHS	1.64 ± 0.19	1.82 ± 0.17	.18	1.73 ± 0.13	2.82 ± 0.3*	1.1 <sup>†</sup>
IIEF-5	11.4 ± 1.3	11.4 ± 1.4	0	11 ± 1.2	16 ± 1.7*	5 <sup>†</sup>

Value are Mean ± SEM

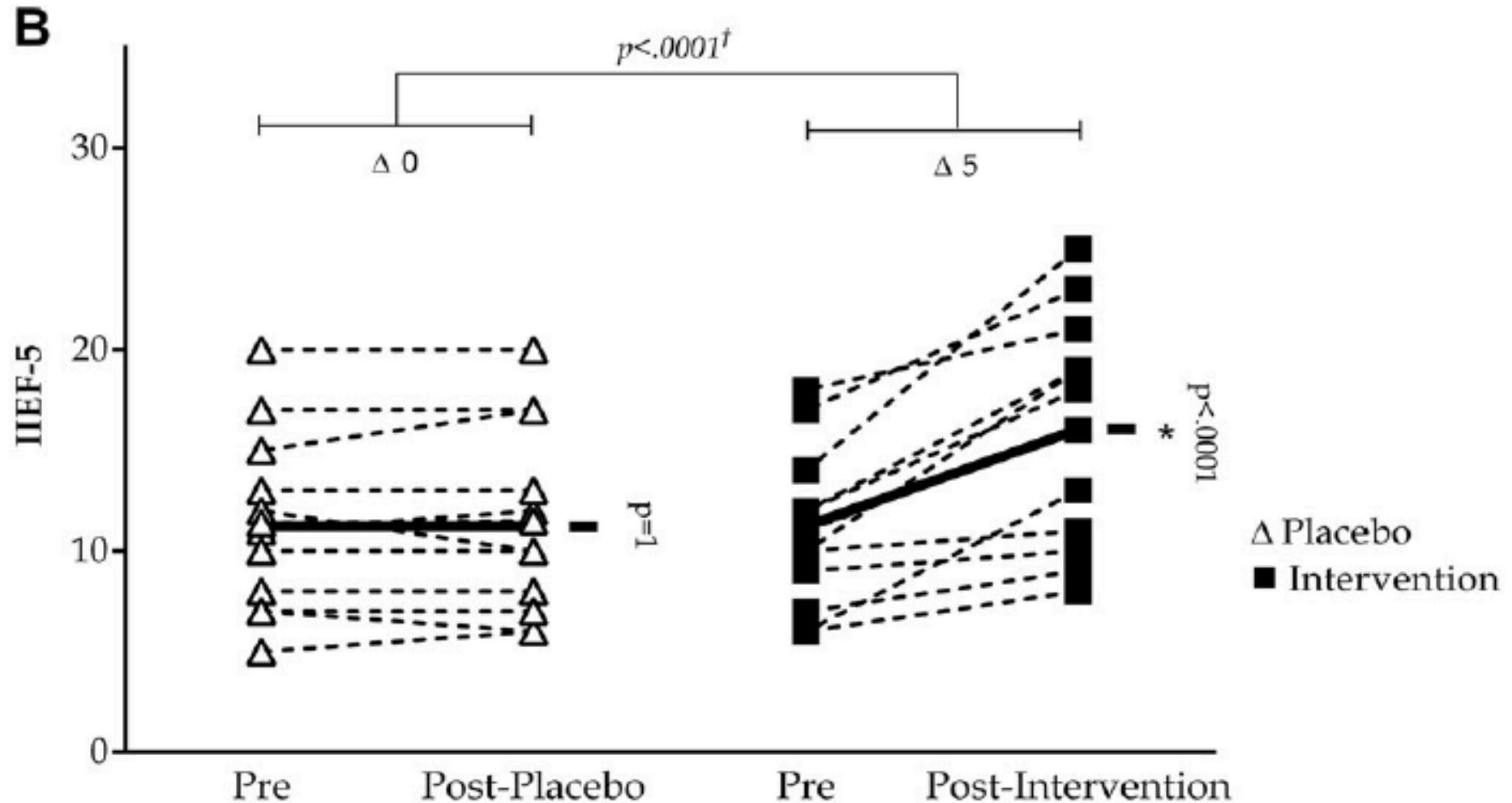
# ED | VEGF Study

## Erection Hardness Score Pre-Post Treatment

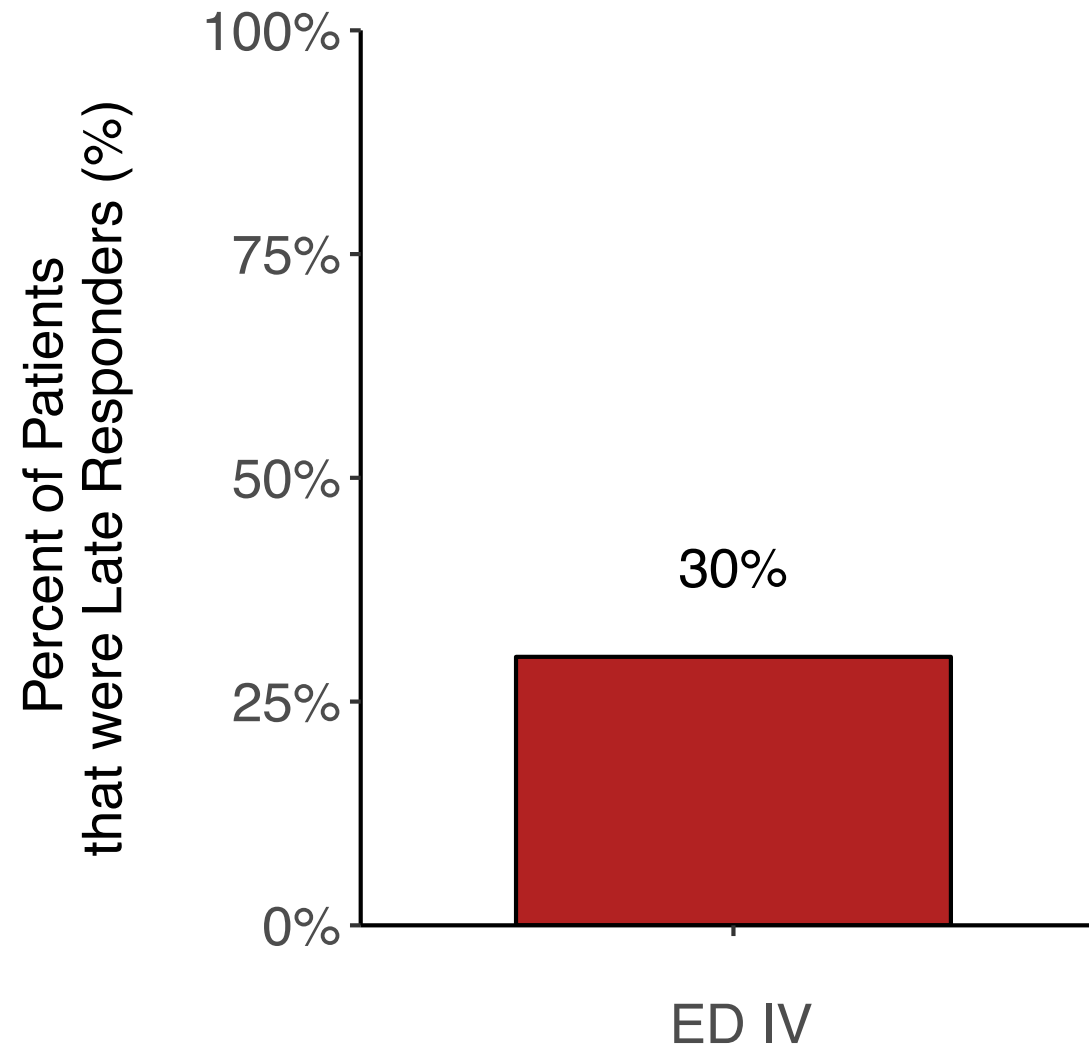


# MyoStim ED I Study of VEGF for 4 weeks

## International Erection Function Questionnaire

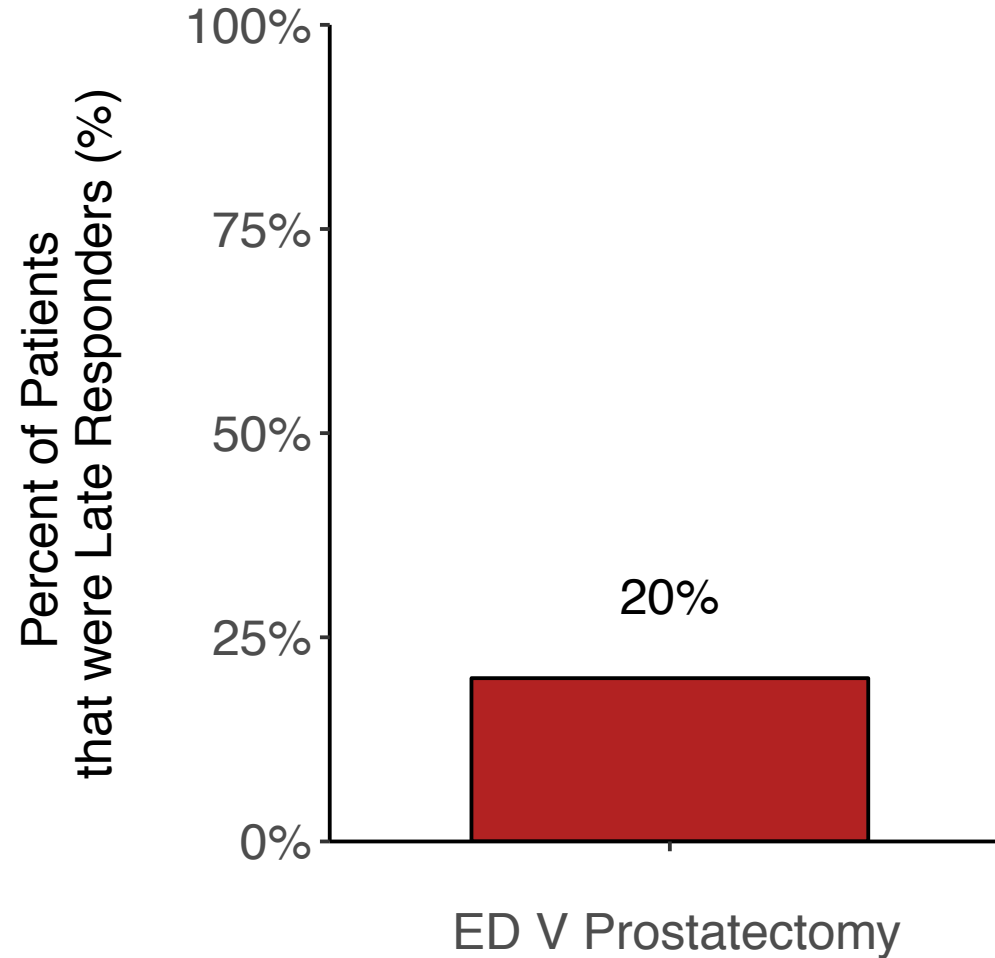


# MyoStim ED IV Late Responders



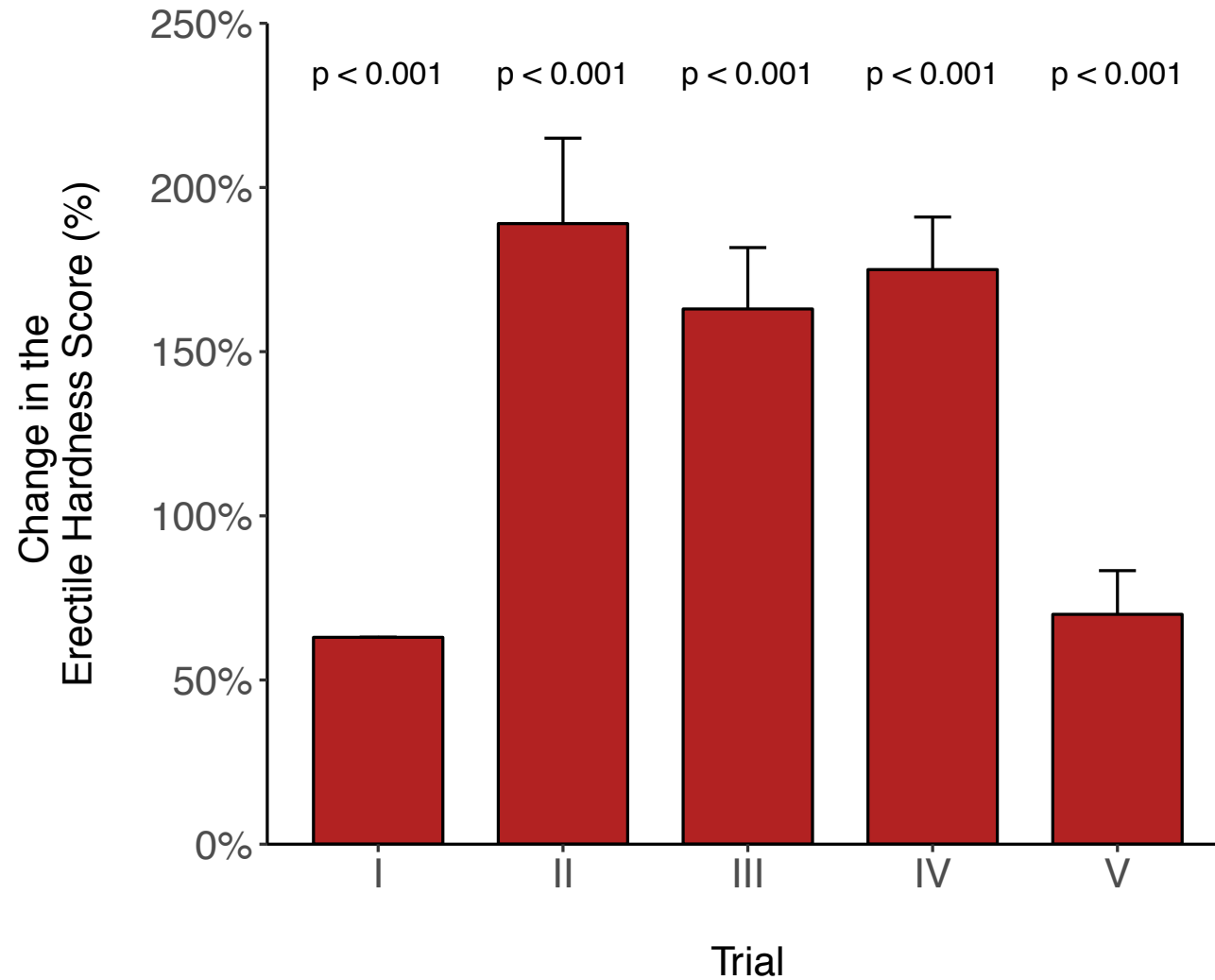


# MyoStim ED V - Prostatectomy Patients Late Responders



# MyoStim ED

## Erection Hardness Score



# MyoStim ED

## International Index of Erectile Function Questionnaire

