



# Transrectally delivered, outpatient MRI-guided laser focal therapy of prostate cancer: seven year interim results of NCT #02243033

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## INTRODUCTION AND OVERALL GOAL

In the United States alone, new prostate cancer cases for 2016 were estimated at 180,890 and deaths at 26,120[1]. Focal therapies for low risk and intermediate risk localized prostate cancer are increasingly being explored. Additionally, new treatments for patients in a salvage setting are being studied.

## SPECIFIC AIMS

Our objective is to investigate the efficacy of using MR-guided laser focal therapy for MR visible prostate cancer utilizing a transrectal approach for laser applicator placement and therapy delivery in an outpatient setting.

## RATIONALE AND BACKGROUND

Lasers have been used for soft tissue necrotization for decades[2]. A commercially available MR-guided biopsy system accommodates insertion of a 980nm laser fiber for insertion into biopsy proven cancerous lesions facilitating ablation of MR-visible tumor.

## METHODS AND MATERIALS

All MRI-guided therapy was delivered using a 1.5 Tesla Philips Achieva XR system (Philips Healthcare, Best, The Netherlands) for both image acquisition and real-time thermometry. DynaCAD and DynaLOC (Invivo, Orlando, FL, USA) software were used for image analysis and laser fiber placement planning. Laser focal therapy was delivered using a Visualase (Medtronic, Minneapolis, MN, USA) 15W, 980 nm diode laser applicator introduced transrectally using the DynaTRIM (Invivo, Orlando, FL, USA). MR imaging was used to monitor energy deposition and coagulation necrosis.

## RESULTS

Under IRB-approved, HIPAA-compliant protocol, 98 men were treated. 138 cancer foci were treated. Total procedure time was between 1.5 and four hours MRI volume of coagulation necrosis ranged from 0.6 to 38 cc (average 7.7cc). No serious adverse events or morbidity were reported. Of the 30 positive 6 mo. Biopsies, 23 were of the treatment regions, consistent with residual or recurrent cancer in 23% of biopsies performed of the treatment site at 6 mos. post therapy. We observed a 45% decrease in mean PSA at 12 months post therapy and no statistically significant change in IPSS and SHIM scores.

## DISCUSSION AND CONCLUSION

Our data indicate that outpatient, transrectally delivered MRI-guided laser focal therapy for prostate cancer is both safe and feasible. In the current climate of cost-reduction and emphasis on minimally-invasive treatment of cancer, focal treatment of prostate cancer may be an attractive option. The precision and controllability achieved under MRI-guidance may have favorable results for cost effectiveness and quality of life without eliminating the possibility of whole-gland treatment in the patient's future. We will continue to follow these men for twenty years as part of an IRB-approved clinical trial (NCT# 02243033)[3].

## REFERENCES

1. AACR Cancer Progress Report, <https://www.aacrfoundation.org/Pages/cancer-progress-report.aspx>, accessed 8/29/2017.
2. Miller JC. Brief history of laser ablation. AIP Conference Proceedings 288, 619 (1993); doi: <http://dx.doi.org/10.1063/1.44865>.
3. Phase II Laser Focal Therapy of Prostate Cancer (LITT or FLA). <https://clinicaltrials.gov/ct2/show/NCT02243033?term=02243033&rank=1>, accessed 8/29/2017.

Fig. a – PSA decline (all subjects)

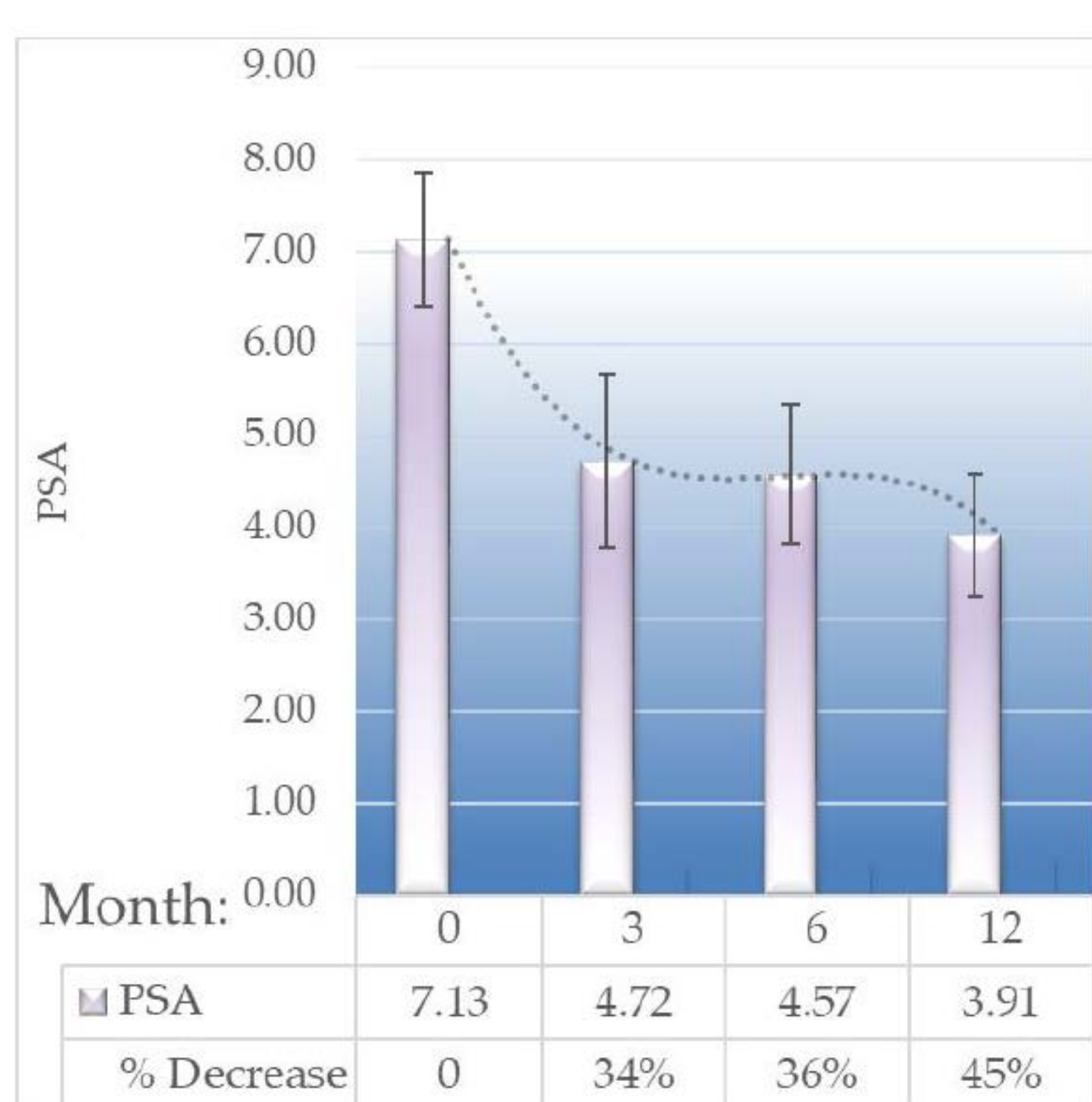


Fig. b – PSA decline (salvage)

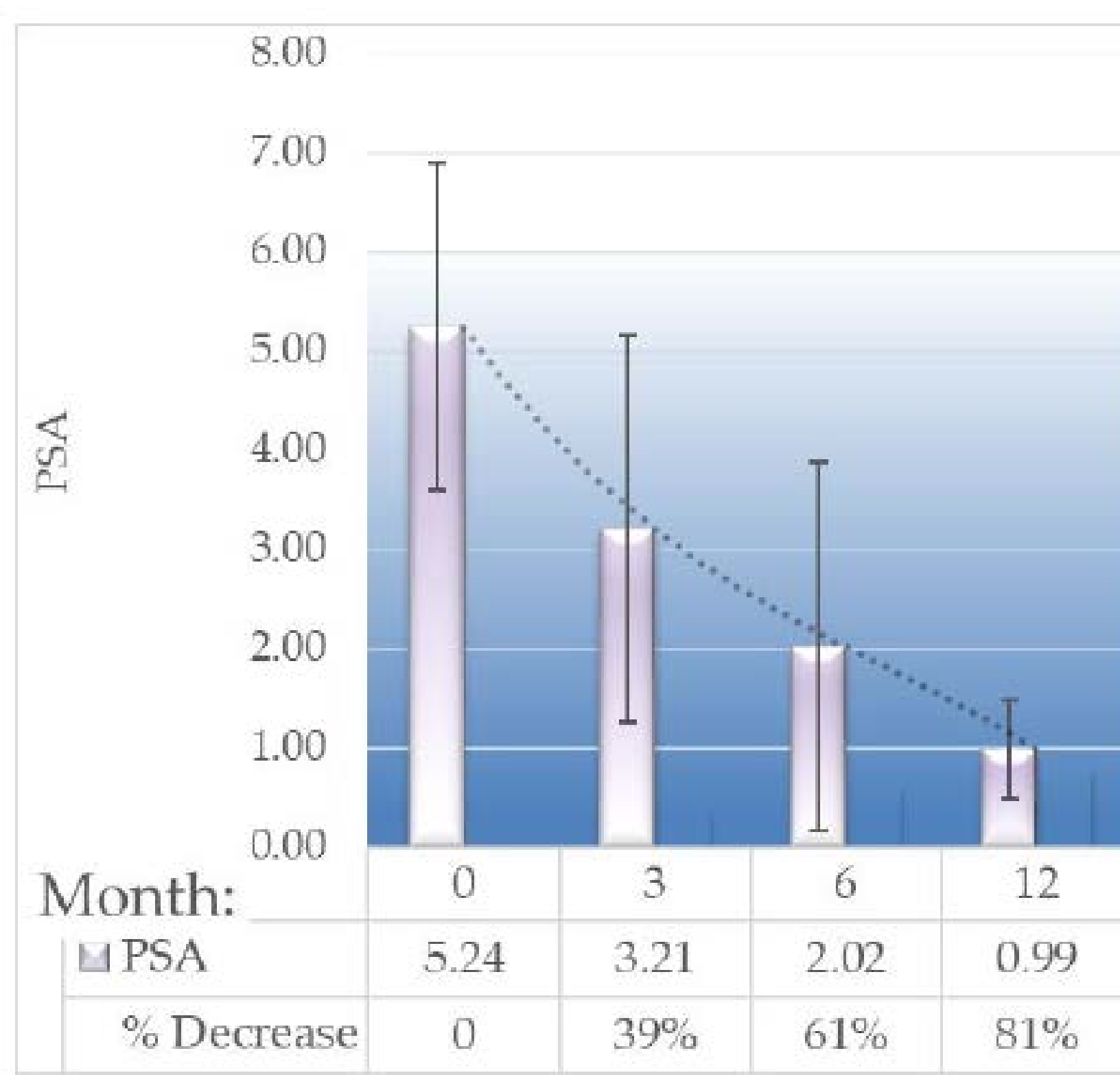


Fig. c – PSA decline (treatment naïve) Fig. d – Visualase

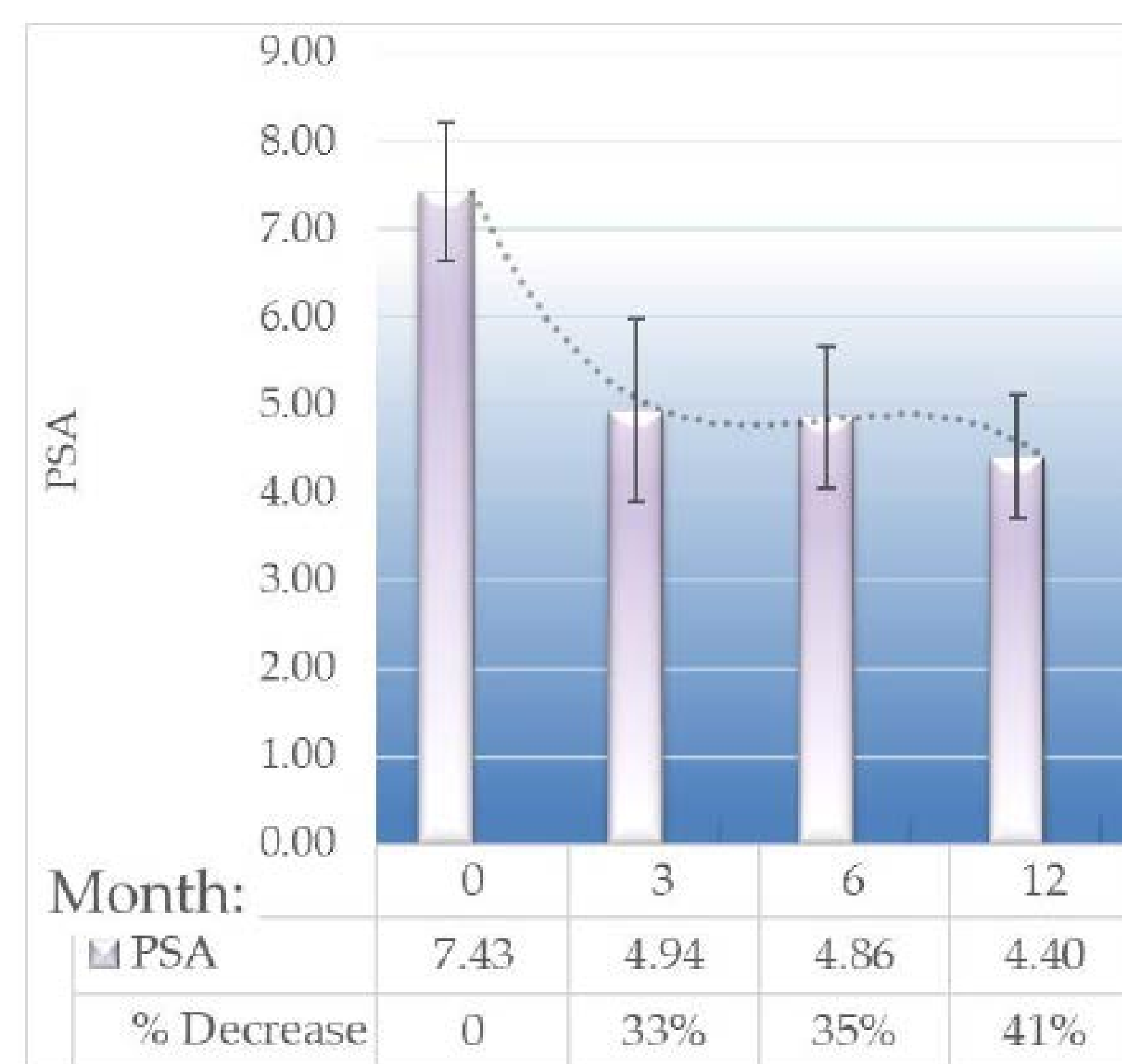


Fig. e – IPSS scores (all subjects)

The following chart shows:

- The height of the bars as the Mean value.
- The error bars as the 95% confidence interval.

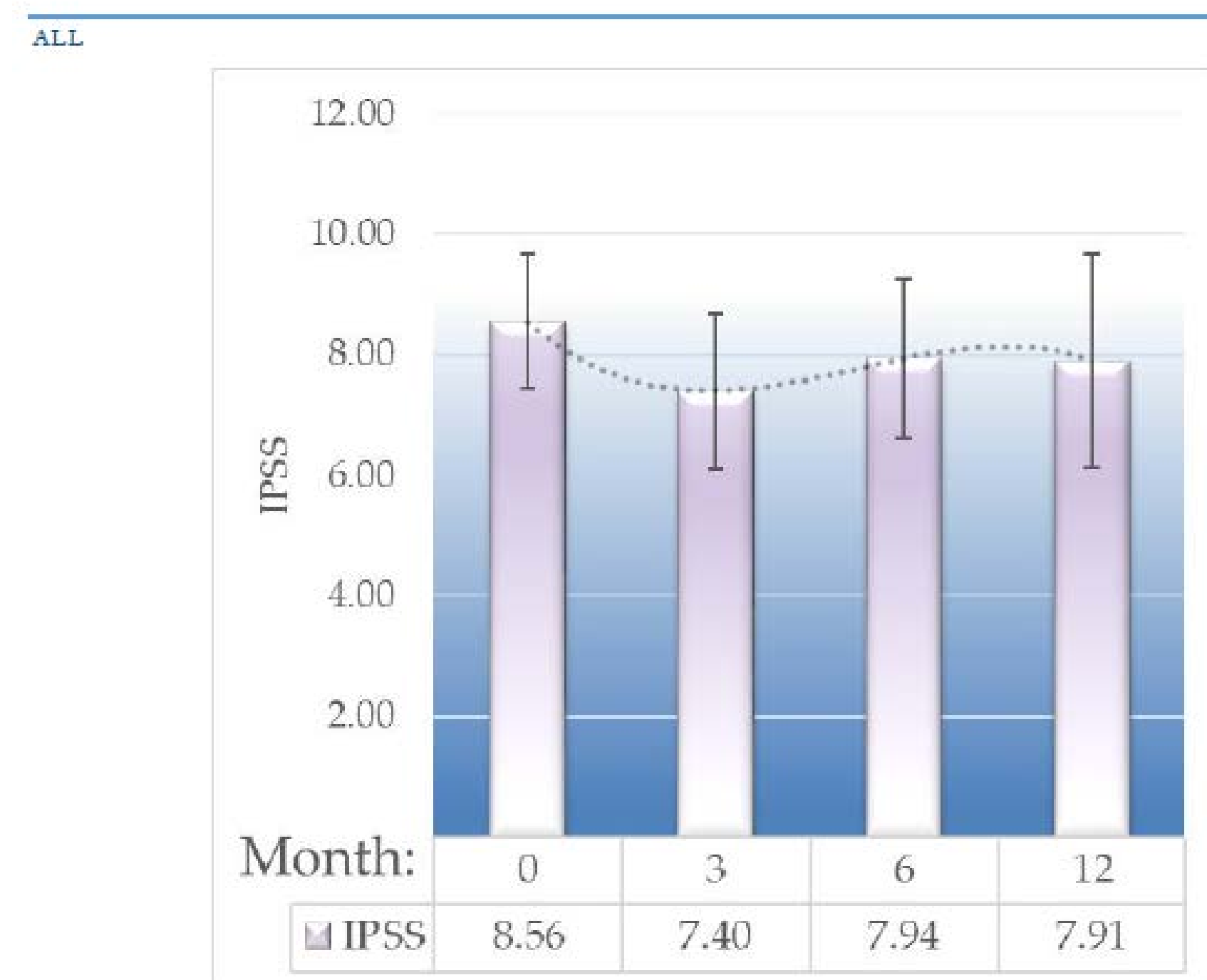


Fig. f – SHIM scores (all subjects)

The following chart shows:

- The height of the bars as the Mean value.
- The error bars as the 95% confidence interval.

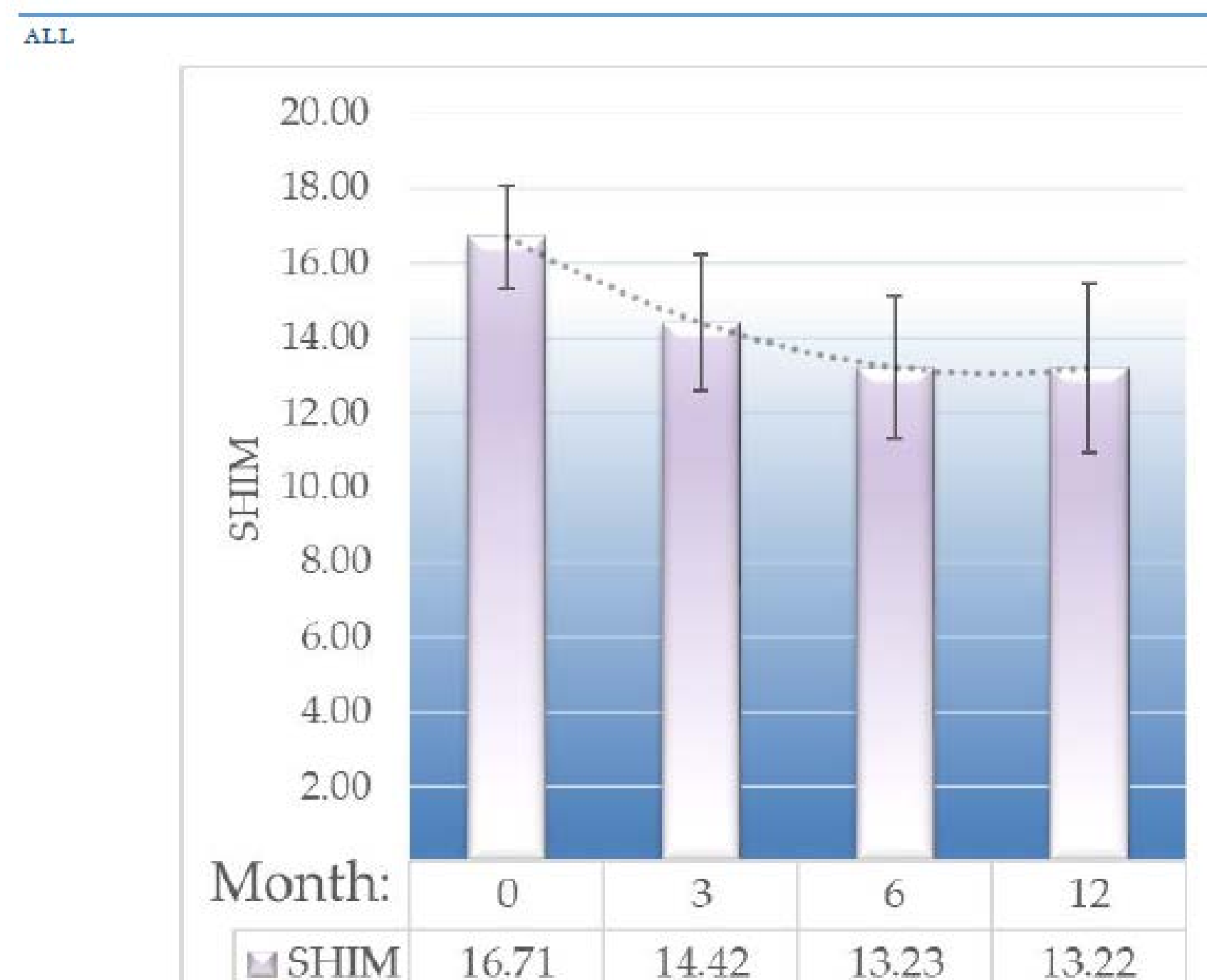


Fig. g – User interface

