

Dose-Dependent Effects of Extracorporeal Shockwave Therapy on Post-Breast Reconstruction Fibrosis: A Follow-up Randomized Controlled Trial

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Background

- Our previous RCT¹ comparing extracorporeal shockwave therapy (ESWT) to placebo showed ESWT significantly improved pain, softness, lesion size, and sonographic features associated with post-breast reconstruction fibrosis
- Dose-response relationship between ESWT and breast fibrosis has not been established

Research Objectives

Evaluate lower- (E2) vs. higher- energy (E3) ESWT on rate and magnitude of clinical and imaging improvement

Methods

- Single-blind RCT; (N=36) adult women with clinically diagnosed fibrosis after breast surgery
- Randomization [E2 (N=30) or E3 (N=6)]
- 8 biweekly sessions delivered over 4 weeks
- Primary outcome: patient-reported softness
- Secondary outcomes: fibrosis size, pain, observer assessments, ultrasound tissue quality (homogeneity, fibrotic bands, echogenicity)

Results

- Mean age: 51.8 ± 10.9 years; Mean treatment area: 63.5 ± 41.4 mm²
- Higher-energy ESWT (E3) demonstrated significantly greater improvements in reported breast softness and size decrease; greater attenuation of the fibrotic band and improved homogeneity on ultrasound (*Figure 1*)
- Higher-energy group showed a faster reduction in fibrosis size between visits (*Figure 2*)

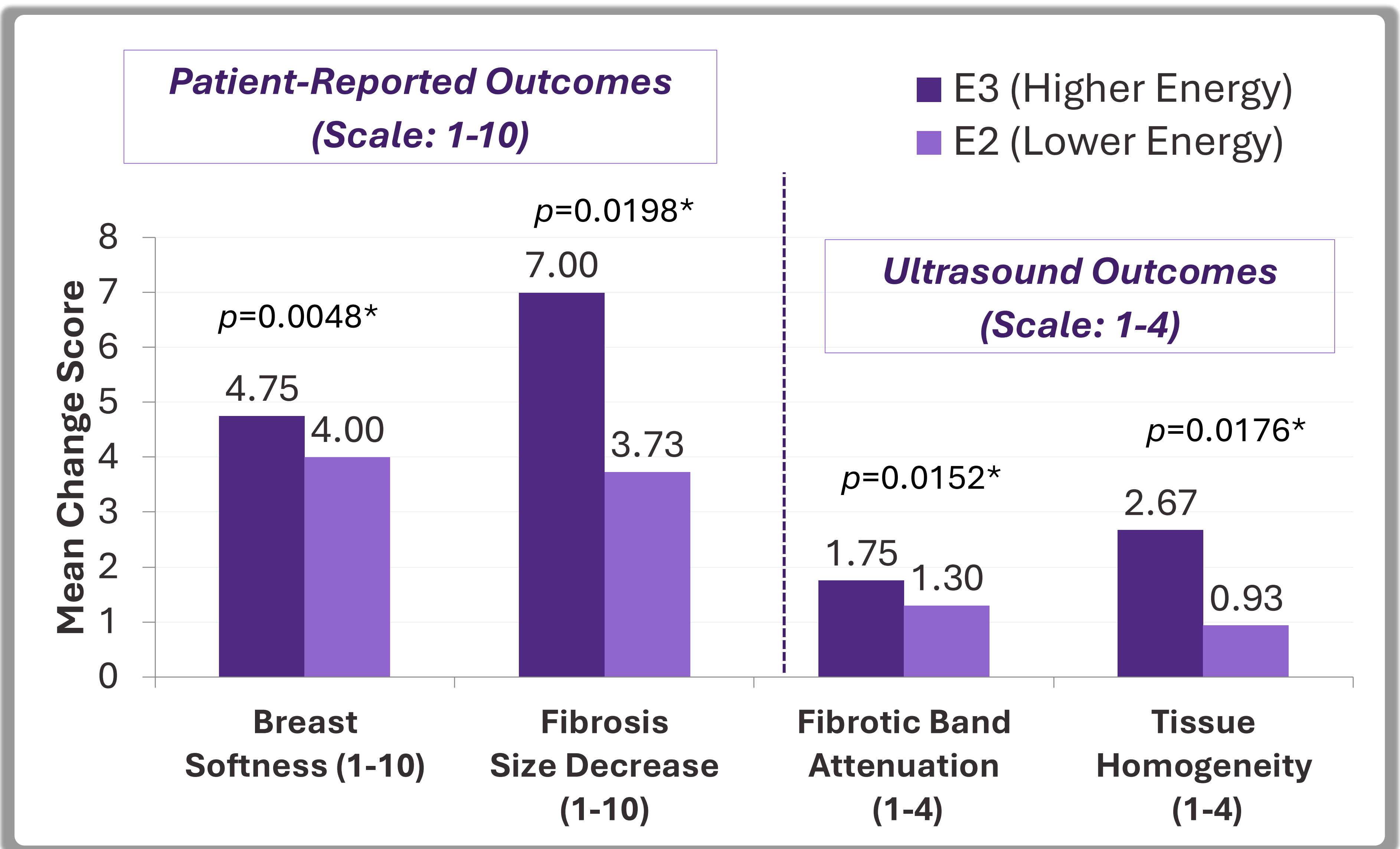


Figure 1. Mean change scores from baseline to final visit for E3 vs E2 ESWT across primary and secondary outcomes. Higher scores indicate greater improvement. Mann-Whitney U test. *indicates significant difference

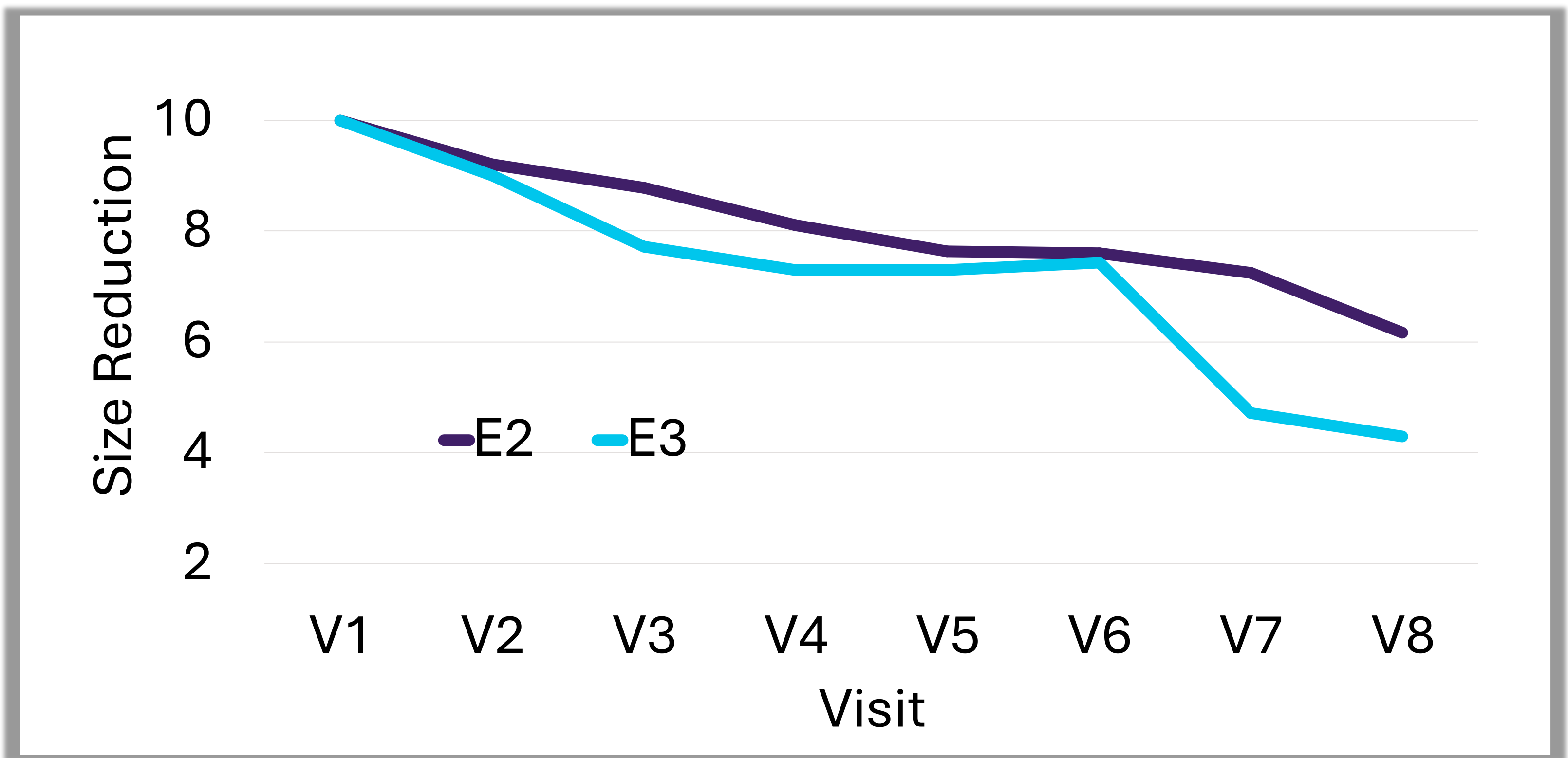


Figure 2. Mean patient-reported fibrosis size change over treatment visits (V1-V8). Both groups demonstrated progressive reduction, with E3 achieving greater overall reduction by V8. [10: No change; 1: complete reduction]

Limitations

- Statistical power is limited by small E3 sample size
- Potential response bias due to single-blind study design

Conclusion

- Our results suggest a dose-dependent response to ESWT for treating post-breast reconstruction fibrosis.
- Future research should optimize ESWT treatment protocols for clinical use and further investigate clinical significance