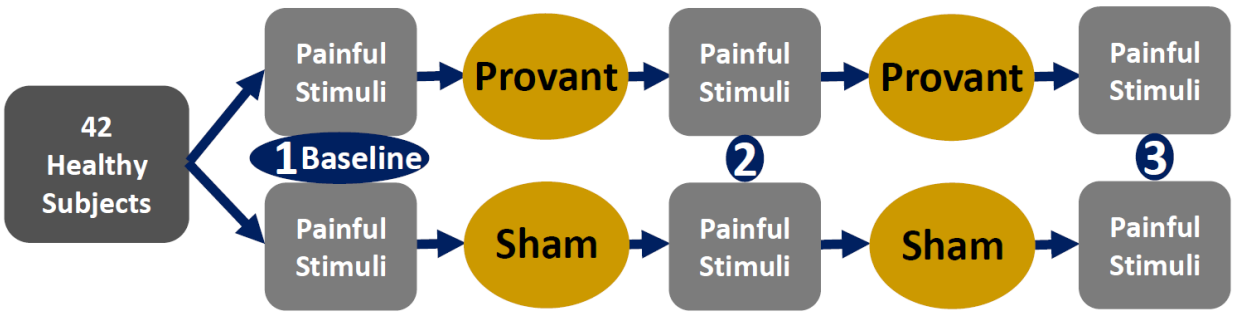
Randomized Controlled Trial with Statistical Significance

Subjects treated with Provant® Therapy have an improvement in tolerance to induced ischemic pain, distinguishing active Provant Therapy from placebo effect.

- Controlled pain trials use well-known, well-vetted, stimuli to evaluate the analgesic effect of interventions for managing clinical pain.
- This methodology allows for delineation of the complicating influence of emotion and cognition (nonspecific placebo effects) from sensory perception (specific effects).
- Reported here is a study on 42 healthy subjects. Subjects were randomized to active treatment or sham.
- A standard blood pressure cuff was applied to the non-dominant forearm and inflated at a steadily increasing rate until the subject was unwilling to withstand any further increase in pressure (pain tolerance) and testing was stopped.
- Assessments of pain score and pressure tolerance were performed at baseline and after either active Provant Therapy or sham; two 30-minute treatments.



SUMMARY
Blood Pressure Cuff Controlled Stimuli Pain Trial

- 42 healthy subject controlled pain stimuli trial.
- Blood pressure cuff induced pain.
- Pain scores and pressure tolerance were assessed at baseline, and after active or sham treatments.
- Randomized to active Provant (n=25) or sham (n=17).
- Active Provant was associated with an improvement in tolerance to induced ischemic pain.

Results of the Controlled Pain Stimuli Trial: Statistically Significant

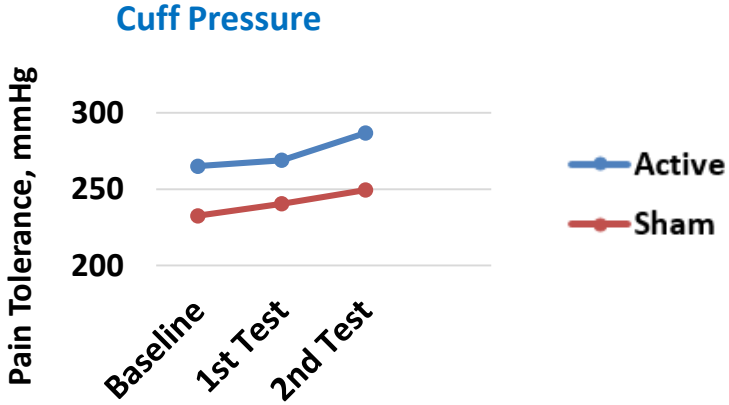
Cuff Pressure

Test of pain threshold and tolerance

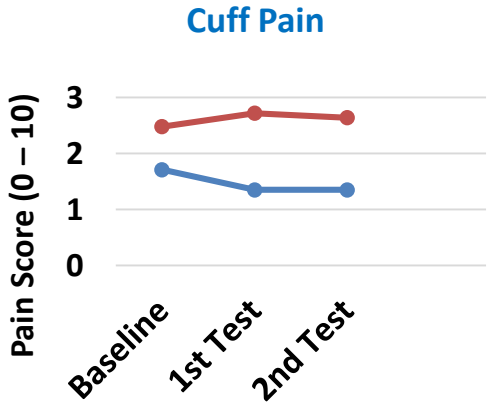
Standard blood pressure cuff was applied to the non-dominant forearm and inflated at a steadily increasing rate until the subject was unwilling to withstand any further increase in pressure (pain tolerance), and testing was stopped.

Results: In this controlled stimuli pain trial, Provant Therapy was associated with a statistically significant improvement in tolerance to induced ischemic pain vs. sham. Cuff Pressure was significant at p=0.0150 and Cuff Pain at p=0.0263. No adverse events were reported.

Discussion: The results are clinically meaningful and indicate Provant has a real effect. This prospective, randomized controlled trial demonstrated that a clear and distinct effect of Provant Therapy can be distinguished from placebo. These blood pressure cuff ischemic pain findings are part of a broader study of controlled pain which assessed four other stimuli. The ischemic pain outcomes were the most significant. Consistent with results reported using Controlled Pain Stimuli to evaluate other energy-based therapies, there was no significance seen when Provant Therapy was used in healthy subjects where no ischemia or other pathological environment was induced by the stimuli. Additional controlled pain studies will be performed.



p=0.0150



p=0.0263

The Provant System is indicated for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue. Provant received FDA clearance in 1997, 2010, and 2013. These findings have not been reviewed by FDA. Prior to use, please see the Provant Instruction Manual for more information on indications, contraindications, precautions, warnings and operator's instructions. Regenesis, Provant, Energy Starburst logo, and the color yellow as applied to the Provant Therapy System are registered trademarks of Regenesis Biomedical, Inc., Scottsdale AZ.
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Provant® Therapy System

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