

# Wearable, Sustained Acoustic Medicine for Back Pain

Completed Technology Project (2014 - 2016)



## Project Introduction

1. Original project aims/objectives: Back pain due to disk-herniation and space-adaptation is a serious concern for the health and wellbeing for astronauts. Current therapeutic drugs and devices to treat space travel related back pain are either systemically and/or cognitively dangerous for mission critical activities, ineffective, and/or non-renewable. The aims of this project were to evaluate long-duration ultrasound therapy as a therapeutic option to non-invasively and non-pharmaceutically effectively treat chronic low-back pain by reducing inflammation, muscle tightness, and modulating neuronal activation at the site of pain. Specifically, the project studied the use of a Food & Drug Administration (FDA)-cleared multi-hour prescription use sustained acoustic medicine device (SAM Professional) as a solar-rechargeable therapeutic device to reduce pain, improve range of motion, and increase quality of life for patients with chronic low back pain. Additionally, the project included technology development of other ultrasonic frequencies and device form-factor that could prove useful in the space environment.

2. Key findings: The SAM Professional medical device was determined to reduce pain by approximately 2 points on the 0-10 Numeric Rating Scale for patients with moderate to severe low back pain. In 65-subjects meeting study inclusion criteria, back pain was reduced by approximately 30% from baseline when the device was applied 5 times per week over 8 weeks of treatment. Patients in the study reported improved range of motion with less pain, and improved quality of life during daily activities. Analysis of the human subjects' data demonstrated statistically significant ( $p < 0.01$ ) pain reduction for chronic back pain. The multi-hour ultrasound technology was further developed into a coin-sized form factor capable of multi-hour ultrasound delivery, and electronics/transducers were designed and tested for 1 MHz ultrasonic capability. Both clinical and technological project aims and objectives were successfully accomplished.

3. Impact of key findings on hypotheses, technology requirements, objectives and specific aims of the original proposal: The project found that multi-hour daily ultrasound therapy significantly reduced chronic back pain. This clinical study on 55-subjects provides additional clinical efficacy data on managing the symptoms of lower back pain with SAM. When combined with other studies on the SAM Professional device for back pain (approximately 120 patients in total) the therapeutic intervention is an available non-surgical/non-drug option for back pain patients. The technology is currently available on the US market for prescription use only. Additional electronic testing and validation of the devices would need to be conducted for space deployment.

4. Proposed research plan for the coming year: The project was successfully completed and no additional work is scheduled. The project team anticipates preparation of the key findings for clinical dissemination of the outcome data.



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## Anticipated Benefits

The objectives of this project were primarily focused on clinically evaluating multi-hour ultrasound therapy on chronic low back pain. The results from this study demonstrate that sustained acoustic medicine when delivered for 4 hours per day 5 days per week provides a significant pain reduction and improved quality of life for chronic pain patients. These results support clinical efficacy data and dosing to establish treatment guidelines for the SAM professional device for people of Earth. The National Space Biomedical Research Institute (NSBRI) project therefore has a direct and immediate impact on the care of chronic back pain patients on Earth. Additionally, this project was the third positive clinical trial on long-duration ultrasound therapy on back pain that confirmed device efficacy, functionality, and clinical value as a drug free non-invasive medical technology. Finally, the results of this study have supported insurance coverage and broad deployment of the technology in the US market to help alleviate the use of opioids in treating chronic pain.

## Primary U.S. Work Locations and Key Partners

Organizations Performing Work	Role	Type	Location
National Space Biomedical Research Institute(NSBRI)	Lead Organization	Industry	Houston, Texas
ZetrOZ Systems, LLC	Supporting Organization	Industry	

## Closeout Summary

Over the last funding year the project concluded engineering design and testing activities for the new ultrasound device technology, and completed clinical trial enrollment and close out for the back pain study. Additionally, the team has completed data entry and submission of outcome data for biostatistician analysis and interpretation.

## Stories

Articles in Peer-reviewed Journals  
 (<https://techport.nasa.gov/file/47163>)

## Project Website:

<https://taskbook.nasaprs.com>

## Organizational Responsibility

### Responsible Mission Directorate:

Human Exploration and Operations Mission Directorate (HEOMD)

### Lead Organization:

National Space Biomedical Research Institute (NSBRI)

### Responsible Program:

Human Research Program

## Project Management

### Program Director:

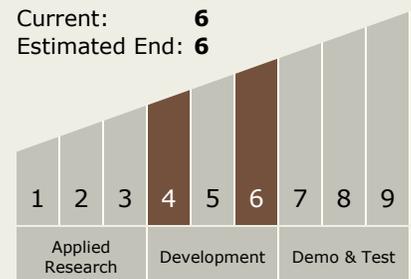
David K Baumann

### Principal Investigator:

George Lewis

## Technology Maturity (TRL)

Start: 4  
 Current: 6  
 Estimated End: 6





## Technology Areas

### Primary:

- TX06 Human Health, Life Support, and Habitation Systems
  - └ TX06.3 Human Health and Performance
    - └ TX06.3.2 Prevention and Countermeasures

## Target Destinations

The Moon, Mars