



*This newsletter is published by the educational team of Bard Cancer Diagnostics under the medical leadership of Dr. Robert L. Bard. Articles posted feature current reports on cancer diagnostic studies and information about identifying cancers through recent innovations and procedures.*

## BETA TEST REPORT: AXIOBIONICS NeuroStimulator Therapy Device

*Originally published in NYCRANEWS.com / Prevention101.org and MedTech Reviews magazine*

### INTRODUCTION:

This technology review is a 2-part study combining the use of the AXIOBOINICS Wearable Therapy muscle neurostimulation system and various non-invasive hospital grade and point of care ultrasound imaging technologies.

Under the MedTech Reviews program, the main objectives include the following:

- (1) achieve an unbiased experience with the device(s) in question as an actual end user
- (2) test drive, assess, challenge and review its intended applications for reporting
- (3) generate a thorough and comprehensive review/report on all useful findings of its efficacy using both experience-based assessment and quantifiable data gathered from medical imaging/physiological scanning.



Link to this video is available at: [BardTechReviews.com](http://BardTechReviews.com)

### OVERVIEW ON THE PAIN THERAPY MARKET & CANDIDATE SELECTION PROCESS:

The American pain relief treatment industry is expansive and a vastly lucrative market. It appeals greatly to the population that is drawn to the 'promise' of restoring quality of life and physical performance through the reduction/elimination of stress and discomfort.

The varying range of pain treatment strategies on the market lends itself to a seemingly endless array of options for products, technologies, drugs and point of care therapies. Our short list of non-surgical pain relief options considered for this test included:

- NSAID/ Non-steroidal anti-inflammatory drugs
- Laser therapies
- PEMF /Pulsed Electromagnetic Field Therapy
- Topical Analgesics
- Temperature inducing devices
- Infrared Light Therapy devices
- Lidocaine Patch
- Magnetic Mattress
- TENS/Muscle Stimulator dev.
- Essential Oils
- Massage/Vibration therapy dev.
- Ultrasound therapy dev.

Source: <https://www.practicalpainmanagement.com>

Out of 25 candidates who promote non-invasive MSK therapeutic solutions for pain and injury, our producers narrowed our search to a category of WEARABLE THERAPEUTIC DEVICES. We were impressed by the real-time patient demos that highlighted a compelling BEFORE AND AFTER set of video clips presenting the efficacy of this innovation. AxioBionics was one of the main brands whose marketing website and videos stood out on our list for its wide cast of physiological issues including SPINAL CORD INJURY, DROP FOOT to GENERAL INFLAMMATION.

## BEFORE AND AFTER IMAGING: TREATMENT EFFICACY ASSESSMENT

The most sensible and logical way to identify the results of any treatment is by tracking the body's response to it. Controlled testing must show the patient's condition PRE and POST effects, where true data-finding is collecting the necessary EVIDENCE of its claims. The investigator can pull a significant amount of data from this form of validation testing: including stage-by-stage bodily response to future projections of possible side effects. Recording of any and all physiological response means the researchers are counting on the patient's reactions to communicate what it is undergoing during the testing phase. To prevent mis-reading and erroneous reports, trials tend to work with a large number of test patients (commonly 50-100) and may also employ redundancies like undergoing multiple testing protocols for a second or even third opinion. To capture the benefits of an effective BEFORE AND AFTER review, advanced ultrasound imaging and diagnostic analysis are employed to discern any and all physiological response(s) for quantifiable reporting.

## MEDICAL "DETECTIVE WORK": THE PRODUCT TEST DRIVE

User reviews about innovation is a widely useful way to support the patient community by providing valuable information about health solutions, drugs, technologies and all products for patient care. This program is produced

under a clinically-backed diagnostic platform dedicated to reviewing products assessed for and by the medical community.

Under the research team leadership and execution of Dr. Robert L. Bard, the MedTech Reviews program employs his diagnostic experience and practice-wide access to all current medical technologies. A major part of his work is research and recognition of some of all innovations before they hit the open market, and also to challenge and analyze their claims and actual effects on patients. He conducts real-world applications of prototypes, receiving validation on what's "under the hood" and even stretching the capacity of their engineering design (also known as 'battle testing') which leads to publishing a comprehensive report for both the medical and patient communities.

Product reviews in the medical field fosters the need to challenge developers' claims or validate their efficacy, sharing findings (let them be positive or otherwise) to benefit patient care practices across the globe. Supporting the non-invasive diagnostic and therapeutic device market also supports the expanding design/engineering trends and advancements that make up the future of medicine itself.

**TEST SERIES (Part 1)** Evaluation Date: 3/5/2021  
(4:30est) **Device 1 for review:** Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS) with reusable adhesive electrodes

Initial product info from AxioBionics:

<https://www.axiobionics.com/wp-content/uploads/MuccioTherapeutic-Effectiveness-of-AxioBionics-Wearable-Therapy-Pain-Management-System-in-Patients-with-Chronic-Lower-Back-Pain2021.pdf>



# REPORT FOR DEVICE #1 APPLICATION ON BACK INJURY / PAIN

The injury incident happened on the 27th of January where I fell on my backside. I acquired the original MRI showing the fracture. Since the injury, the pain sensation was stable (not increasing or decreasing) for over six weeks prior to inducing the AxioBionics therapeutic device. I had a 12% compression fracture of the lumbar vertebra (which is a midline structure) where the pain was most evident on the left side. The sensation rating or pain

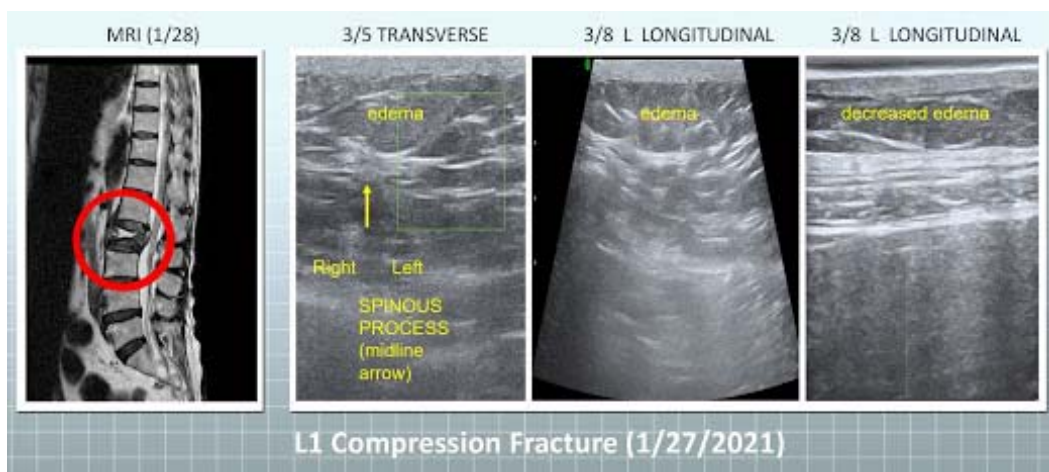


Link to this video is available at: [BardTechReviews.com](http://BardTechReviews.com)

level was consistent at 4 over 10. When I received the new AxioBionics neurostim unit on 3/4, received ample training from their tech consultant and I applied it directly on the pain on 3/5 for 20 minutes as part of my observational study. I also logged any physical reaction while maintaining the device's function setting of 4 and kept this setting throughout the review period.

As part of exploring different scanning options, I used two different ultrasound probes; the linear probe at 18 mHz and the curved probe at 14 mHz. The ultrasound transverse (which means it's from right to left across the spine) shows the arrow pointing to the spinous process, which is the high point in the back that one can feel. The edematous area (labeled in yellow) shows it more to the left of midline as per the arrow.

On 3/8, I applied the therapeutic neurostim again for another 20 minutes and then used a different probe on the left side, we still see there's EDEMA. The white line where the white Stripe above the edema is the dermis of



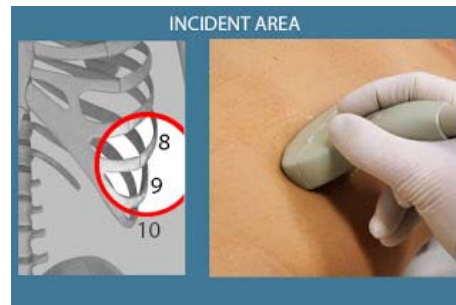
the skin which is three millimeters-note the spectacular high resolution using both probes. On 3/9, I used the neurostim for 90 minutes this time. The probe showed a definite decrease in the edema in the superficial tissues and musculature underneath (white stripe of the intact muscles on the left side).

**ENDING STATEMENT:** There is a different relationship between swollen tissue and the pain sensation. They often related temporally, but the compression of the pain fibers come from edematous pressure on the nerves.

And if the nerves are relieved sufficiently, even though there's minimal healing or decrease in the tissue, the pain level may decrease significantly locally. After one week of repeated therapeutic application of the neurostim, the pain has been completely eliminated (0/10). The big takeaway from this experiment is the potential future where patients have their own therapeutic neurostim devices AND their own portable scanners to track their pain and injury. This allows them to know how to go forward.

## REPORT FOR DEVICE #2 APPLICATION ON RIB FRACTURE PAIN

**DAY ZERO:** Initial injury from the incident - Inflammation & Fracture  
Patient 1 has experienced injury induced pain from a minor fall, causing direct impact to his left 8th & 9th rib, resulting in rib fracture impacting with a blunt furniture protrusion. Within 1 hour of the incident, the patient was scanned in the area of impact to identify the level of muscular injury.



From the patient, the pain level was verbally noted at 8/10. Soon after, the patient applied ice to the injured area. 24 hours later, the patient proceeded to use the NeuroStim Therapy device for 20 minutes each day for 5 sessions (at a level setting of 1) within a span of 10 days. This is used alongside other therapeutic solutions administered by the

patient's Physical Therapist, including Cold Laser therapy & Pool therapy. Throughout the 10 days, the patient continued to feel the same pain level, feeling "very little or no remarkable reduction in pain" or any quantifiable reduction in the inflammation (from scans).



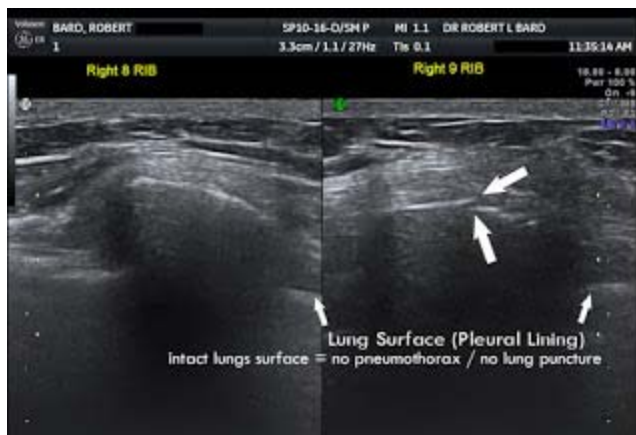
**EXCERPT FROM RADIOLOGY REPORT:** The ultrasound verifies that there's no hematoma around the lit rib and that there was no evidence of puncture of the lung that is no pneumothorax and no hematoma in the lung.

SCAN 2: FIG 8-1 (Image-L) Scan of the right 8th rib area.

Note the black area from the bottom goes all the way up to the curved rib outline. So this is a normal rib outline.

Because the ribs are curved structures, x-rays may miss many rib fractures. (Image-R) On the right side of the ninth rib, two arrows are indicating the impact and fracture area. The top arrow points to the elevated part of the spiral fracture or "green stick" fracture (something that happens with long bones, like legs and femurs). The space

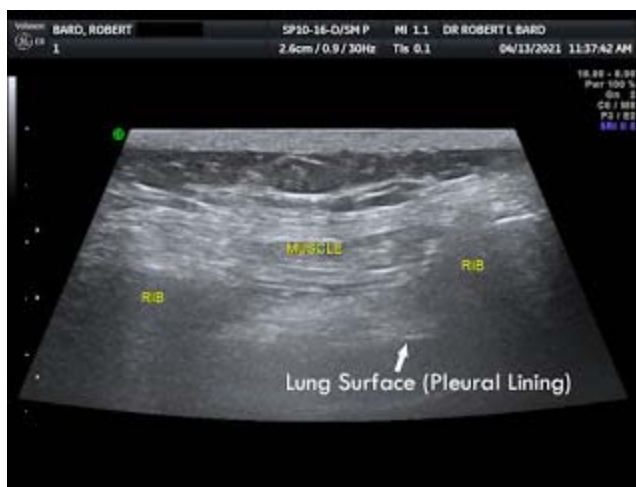
between the top arrow and the bottom arrow shows the displacement of the fracture, which is over the point of maximum pain to correlate. This may not always show up on an x-ray or an MRI. It would show up on a pet CT scan, which is impractical in rib fractures.



## EXPANDED SCAN REPORTS OF POST-THERAPY (FROM DAY 10)

FIG 8-2: The two structures, each labelled "RIB" are the intercostal ribs (eighth and the ninth). What do you see labeled muscle in between is the intercostal muscle that connects and moves through the cage. This is important, especially in patients who have had COVID and had been on ventilators because this muscle atrophies. So we have a way of measuring the contraction of the muscle where the atrophy of the muscle for physical therapy resuscitation.

The transducer (ultrasound probe) is placed between the normal rib and the fractured rib to review/show the muscle structure that is intact. In other words, there's no hematoma in the muscle. Plus one can see the muscle contracting and expanding with respiration normally or abnormally.

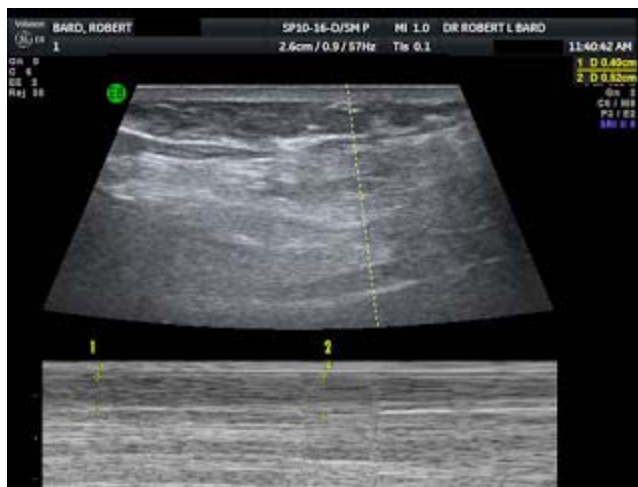


The therapy device was not expected to heal the bone fracture- which normally takes eight to 10 weeks. However, the pain itself has gone to zero - attributing to the daily therapies from the PT, but mostly to the advanced neurostim device on the final day where the stimulation has allowed better breathing function because the pain is no longer a factor. The therapy device (at its final setting of 9) appeared to have addressed the inflammation, stimulating the muscle to contract more efficiently as the pain has been reduced to a completely tolerable level.

As the patient is no longer feeling pain, the scan reflects this by showing that the fibers of the normalized muscle next to the fractured rib shows no more inflammation, and appears intact without any evidence of hematoma or

muscle rupture. Looking back at Scan Zero, (the first scan of the injury), our images revealed that the muscle fibers are separated by hemorrhagic fluid, which are now no longer present in the intact muscle bundles in the post-treatment rib and muscle scan.

FIG 8-5 Motion mode (a setting on an ultrasound probe) is used to analyze the heart and is also used on the rib cage and lung. This demonstration which goes from the left, is measured at 0.4 centimeter and it expands on the right at a 0.5 centimeter excursion. We see that the lung respiratory muscular function is approaching normal around the fractured rib. There would be no change in the distance because of spasm and guarding. Also note that the bottom of the picture on the right is a line about one quarter from the bottom that looks different from the left side. This is the pleural surface, which indicates there is no pneumothorax or other injury to the pleura or lung surface.



**END POINT:** 10 days after the incident, the patient elected to apply the neurostim treatment device on the area of injury- this time increasing the application time to 90 minutes at a setting of 9. To his surprise, the pain level dropped to a significant 1/10 (from 8/10) immediate after use. Applied pressure on the area by pressing on it also marked a significant improvement, showing little or no pain. 1 Week later, the patient continues to feel 0 (NO) pain from the previously injured area. No irritation to breathing. Mobility is fully restored.

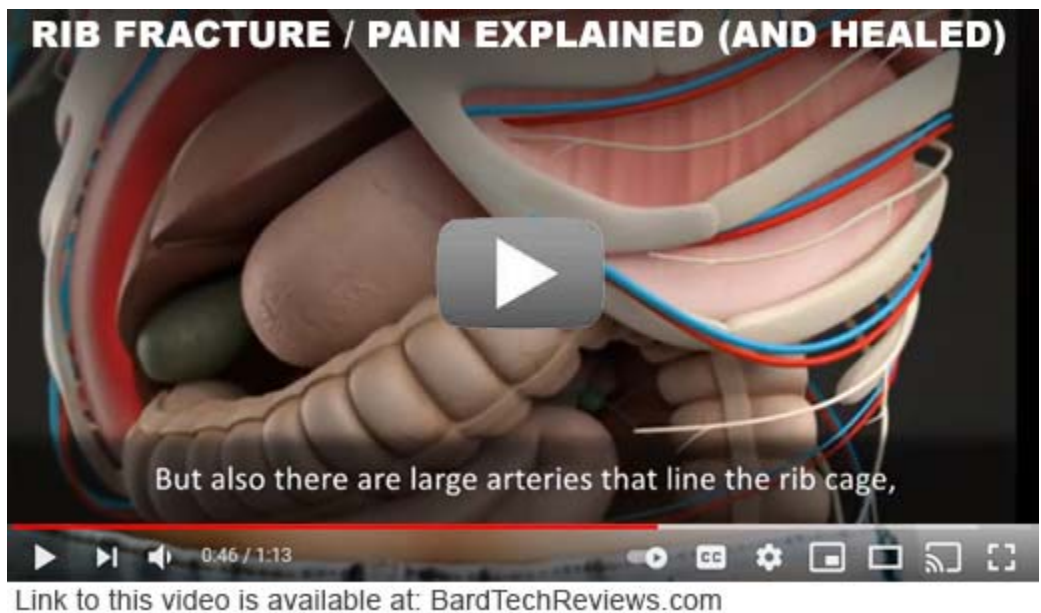


Complete patient experience log: Daily tracking since incident (click thumbnail to enlarge) Post Incident Afterthoughts: When you break a bone like a rib, even though the fracture is painful, it's more the fracture site that elicits the changes in the pain nerve fibers. Bone itself has no nerves, however, the tissues and ligaments around a fracture site are what's recording the pain. After this acute injury from a sharp object on the rib, I noticed that pain on direct pressure was a 6/10. However, when I bent down to pick up something, I couldn't bend down straight because the pain was at a level eight, and I had to adjust any bending to shift the pain away from the rib and the muscles that connect the rib to the pelvis, which are inter-connected. So they put pressure on the damaged tissues.

The most important thing with a chest wall injury and the fractured rib is to make sure that the surface of the lung is not broken producing a PNEUMOTHORAX which is life-threatening. Then also there are large arteries that line the rib cage- the intercostal artery that stretches between the intercostal muscle which can be a source of great bleeding.

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**VIDEO SUMMARY CLIP:**



*Audio recording of Dr. Bard describing a clinical analysis of the rib injury from actual ultrasound scans of the injured area + observational readings from actual (personal) assessment of his healing process.*



## PATIENT NOTES FOR RIB INJURY

4/3	Injury Incident	<ul style="list-style-type: none"> <li>- pain bending 8/10</li> <li>- video shows hemorrhage into intercostal muscle and fracture site</li> <li>- Pain on direct pressure 6/10</li> </ul>
	Applied Ice / no pain meds	
4/4	Neurostim Therapy (20 minutes) Level setting 1	Pain level : 8/10 (no positive response)
4/6	Neurostim Therapy (20 minutes) Level setting 1	Pain level : 8/10 (no positive response)
4/8	Neurostim Therapy (20 minutes) Level setting 2	Pain level : 8/10 (no positive response)
4/9	Applied Cold Laser therapy @ PT 1 Session/ 10 mins.	Pain level : 8/10 (no positive response)
4/10	Neurostim Therapy (20 minutes) Level setting 2	Pain level : Stayed at 7/10
4/12	Pool Therapy 1 hour session	<p>Pain level : 7/10</p> <ul style="list-style-type: none"> <li>- Minimal reduction in pain</li> </ul> <p>This form of therapy is a standard physical therapy. It provides some effect because the body is relatively weightless, so you take the pressure off the muscles around the rib cage. So I did notice a slight change after a one hour session of weightlessness and weight reduced the pool therapy.</p>
4/13	Neurostim Therapy (90 min) Level setting 9	<p>Pain level : 1/10 after 90 minutes of stimulation</p> <ul style="list-style-type: none"> <li>- No pain while bending</li> <li>- Mild pain on direct pressure (1-2/10)</li> </ul> <p>FINAL EFFECT FINDINGS: After various sessions with the Neurostim, I elected to raise the setting to #9 for 1.5 hours. I realized soon after that the pain level was 1/10- with some direct contact with the area of the root pain. The next day there was no pain whatsoever while bending. Pain only occurs at 1/10 if I pressed hard on the fracture site.</p>

Confirmed by: Dr. Robert L. Bard, chief examiner/radiologist