

Reduced Pain Medication Consumption with Safe, Non-Drug Pain Management: Summary of 15 Case Reports

Pulsed electromagnetic field (PEMF) energy is an effective therapy for pain management.¹⁻³ The Provant® Therapy System (Regenesis Biomedical, Inc., Scottsdale, AZ) was cleared by the U.S. Food and Drug Administration (FDA) for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue. Provant treats tissue with non-thermal electromagnetic energy using 27.12 MHz pulses lasting 42 microseconds and delivered 1000 times per second. This therapeutic field is automatically monitored and regulated to ensure consistent dosing. Treatment duration is 30 minutes and is normally prescribed twice daily.

Provant is an effective alternative to opioid analgesics, which are strongly associated with negative health outcomes due to the risks of addiction and overdose. Patients suffering from chronic pain are particularly susceptible to misusing their pain medications due to a tendency to self-prescribe, which can lead to a cycle of dependence and eventually uncontrolled use of the drug.⁴⁻⁸ In addition, there are adverse effects associated with opioid pain relievers even when they are used as indicated, including depression and other mental disorders.⁹ Chronic use has also been shown to result in debilitating disorders such as physical dependency, tolerance, and for some patients, opioid-induced hyperalgesia.¹⁰⁻¹¹

As policy changes intended to curb prescription drug abuse increase, so will pressure on hospitals and practitioners to restrict the supply of opioid pain relievers.¹² Chronic pain patients will find it more difficult to access prescription pain relievers as a viable treatment option. As a result of these changes and the growing awareness of the danger posed by long-term use of opioids, it is necessary to seek out safe, non-drug pain management.

Presented here is a summary of the experiences of 15 patients treated with Provant. This case series includes patients treating lower extremities, upper extremities, and cervical and lumbar spine. These patients experienced severe postoperative pain and consumed large doses of pain medications. The patients ranged in age from 26 to 69 years (mean 47 years) and included 8 men and 7 women. Postoperative pain for all patients was refractory to common analgesic therapy. In addition to nonsteroidal anti-inflammatory drugs (NSAIDs), medications administered prior to use of Provant included hydrocodone, oxycodone, tramadol, gabapentin, methadone, baclofen, lidocaine, pregabalin, fentanyl, nortriptyline, and methocarbamol. The duration of treatment varied from patient to patient, ranging from 3½ weeks to 16 weeks. Pain levels were recorded using the 11-point numerical scale (0-10). Many of these patients had failed standard pain management therapies and had pain scores of ≥ 5 prior to treatment with Provant; 10 of 15 patients reported pain scores of at least 7.

The clinical effect of Provant was relatively uniform across all 15 patients. As seen in Table 1, reduction in average numeric pain scores ranged from a few points to 10 points with 13 of 15 patients reporting scores

of ≤ 3 ; six patients reported a pain score of zero after their therapy with Provant. Some patients experienced immediate pain reduction, but in most cases the reduction was gradual and steady over the course of several weeks. A significant reduction in pain medication consumption was reported, allowing these patients to avoid potential complications associated with pain medications. No adverse events or complications were reported in association with the use of Provant Therapy.

Lumbar and Cervical Spine

- **Lumbar Fusion:** A 44-year-old female presented with chronic uncontrolled pain (10/10) and inflammation after lumbar fusion. Her medications included methadone, gabapentin, baclofen, nortriptyline, and etodolac. Provant Therapy treatment lasted a total of 4 months and was administered twice daily. At the conclusion of the treatment period, the patient's pain score had dropped from 10/10 to 2/10 and her daily opioid use decreased, with a return to regular activity levels.
- **Lumbar Fusion and Re-operation:** A 50-year-old male presented with pain radiating down the left leg from the lower back following L4-L5 lumbar fusion for degenerative disc disease. The patient used high doses of gabapentin, Cymbalta, and oxycodone to achieve minimal pain relief. A follow-up surgery was performed to remove bone fragments, a screw, and a rod. Postoperative pain was rated at 5-6/10. Provant Therapy was started 3 days after surgery, and after 11 weeks the patient reported pain levels of 0-1/10 and 2-3/10 with activity. The daily dose of gabapentin was reduced from 600mg per day to 300mg per day, and Cymbalta and oxycodone were discontinued entirely.
- **Lumbar Fusion and Two Re-operations for Cerebral Spinal Fluid Leak:** A 57-year-old male with lumbar damage resulting from exposure to cleaning solvents (nerve toxin) and a broken back continued to experience pain following L3-L4-L5 lumbar fusion and two subsequent surgeries to treat a cerebral spinal leak. The patient was prescribed the muscle relaxant methocarbamol, as well as the pain relievers gabapentin and oxycodone. Pain following the third surgery was rated at 7/10. Provant Therapy was started 16 months after surgery and the patient reported a dramatic reduction of pain after three months. The patient's pain rating was 3/10 after using Provant Therapy and all prescribed medications were discontinued.
- **Cervical Fusion and Root Canal:** A 51-year-old female experienced severe constant pain in her right mandible and neck. Root canal and spinal fusion were performed, but the pain persisted after the procedures. The addition of Provant Therapy resulted in a decreased need for botulinum toxin (Botox) injections, and pain scores decreased from 9/10 to 4-5/10. Routine use of Provant led to a further reduction to 3/10. Provant Therapy allowed the patient to eliminate her need for narcotics and to reduce her need for other pain management modalities.

Lower Extremity

- **Endoscopic Plantar Fasciotomy:** A 51-year-old female experienced continued pain after undergoing fasciotomy for an inflamed plantar fascia. At 3½ months postoperative, the patient rated her residual pain as 5/10 in intensity. Provant Therapy was used in conjunction with 9 physical therapy sessions, after which the patient self-treated at home for 4 weeks. After 4 weeks, pain levels decreased from 5/10 to 0/10 and hydrocodone was discontinued.

- **Foot and Ankle Orthopedic Surgeries Resulting in CRPS:** A 37-year-old male experienced chronic regional pain syndrome (CRPS) manifestations in his right foot and ankle for a decade after undergoing several orthopedic surgeries and neuroma excision. He achieved minimal relief through the use of NSAIDs, gabapentin, transcutaneous electrical nerve stimulation (TENS), epidural injections, and local lidocaine block. An initial 30-minute Provant Therapy session reduced pain from a baseline of 7/10 to 4/10. At 1-month follow-up, his pain score was further reduced to 3/10, and at 2 months the patient reported a daily average of 1/10.
- **Knee Arthroscopy:** A 26-year-old male initially presented with severe end-stage lateral compartment degenerative joint disease (DJD), mild medial compartment DJD, recurrent effusions, and pain at the right knee that developed over the course of the patient's career as an arena football player. His pain level after arthroscopic surgery was 8/10 and it was managed with hydrocodone taken 1-2 times daily. After 3½ weeks of Provant Therapy the patient reported a decrease in pain score from 8/10 to 0/10, and at only 1 week he discontinued his pain medications.
- **Below the Knee Amputation:** A 62-year-old male with diabetes and a non-healing foot ulcer underwent below the knee amputation. He experienced postoperative phantom pain (10/10) and edema was present over the stump. After 8 months, he began Provant Therapy which reduced pain and swelling. After 1 month of use, his pain score reduced to 5/10, and at 3 months it was 0/10. The patient was able to decrease his intake of gabapentin from 3600 mg per day to 1200 mg per day, and he was able to walk using his prosthesis.
- **Total Knee Arthroplasty:** A 66-year-old female with chronic and acute anterior knee pain and a history of osteoarthritis underwent bilateral knee arthroscopic repairs three years apart. In 2012 a total knee arthroplasty (TKA) was performed on the patient's left knee, requiring 8 weeks of post-op recovery. In 2015 the patient underwent TKA for the right knee and was treated twice daily for six weeks during the post-op period with Provant Therapy in addition to physical therapy. Two weeks after beginning Provant Therapy, the patient's pain decreased from 6-8/10 to 0/10 and her pain medications were reduced. The patient had an accelerated recovery compared to her first TKA.
- **Debrided Arterial Ulcer:** A 69-year-old female presented with non-healing post-debridement arterial ulcer in the leg. She experienced pain ranging from 5-9/10. Pain interventions included lidocaine patches, Lyrica, fentanyl patches, and hydrocodone. The patient underwent Provant Therapy twice daily for 5 weeks. The result was a pain score of 0/10 as well as the discontinuation of all pain medications except for fentanyl, which was taken for back pain.

Upper Extremity

- **Hand Degloving; Amputation Avoidance:** A 45-year-old female sustained several injuries as the result of a roll-over motor vehicle accident, including degloving of the left hand. Oxycodone, hydrocodone, and gabapentin were ineffective in managing the pain and the patient went so far as to ask her plastic surgeon to amputate the hand. In order to avoid amputation, Provant Therapy was prescribed. After 1 therapy session the patient reported an immediate reduction in pain from 10/10 to 8/10. At 2 weeks the pain level dropped by 50%, and at 4 weeks the pain, function, and sensation were completely resolved. Use of all pain medications was discontinued.
- **Shoulder Arthroscopy:** A 31-year-old male had an initial pain score of 6/10 after undergoing arthroscopic surgery in his left shoulder to treat conditions caused by injury during military deployment. After 39 days of Provant Therapy, which was offered as an adjuvant to his physical therapy plan of care, the patient's pain score dropped to 0/10. Less pain medications were consumed compared to what the physical therapist typically experiences.

Chest, Abdomen, Face

- **Chest Surgery:** A 53-year-old male experienced chronic chest pain for 30 years after undergoing surgery for a gunshot wound. Pain was managed with 90mg of methadone daily. Provant Therapy was administered twice daily for 3 months after which the patient's pain score decreased from 10/10 to 7/10 and his methadone dose decreased to 75mg daily. He was able to resume his supervisory construction job.
- **Cesarean Section of Nerve Damage:** A 27-year-old female experienced ilioinguinal nerve damage as a result a cesarean section. The pain radiated from her inner thigh to the location of the incision, and she experienced allodynia when she wore clothing. The patient rated her pain at 10/10 despite intervention, which included hydrocodone every 6 hours and gabapentin 3 times a day. Hypersensitivity increased during the first treatments with Provant Therapy, but after a few days the pain dropped from 10/10 to 4/10 and allodynia decreased. Eventually she obtained complete relief for periods of 6 to 8 hours after Provant Therapy and pain reduced to 2/10 with clothes on. Pain medication was eventually discontinued, and the patient was able to return to work and care for her family.
- **Lateral Canthus Reconstruction:** A 55-year-old female with a history of 7 oculoplastic bilateral lateral canthus reconstruction surgeries presented with chronic, non-healing canthal ulcers. Postoperative pain was 7/10 with spikes reaching 10/10. The patient started on Provant Therapy and experienced an immediate 2-point reduction in her pain score. Over the course of 6 weeks, the patient's pain score remained lowered, and she was able to discontinue the use of Percocet with only ibuprofen and warm compresses needed for pain management.

Table 1. Summary of Pain Score Reductions and Pain Medication Reductions

Etiology of Pain and Edema	Pain Before Provant	Pain After Provant	Pain Medication Prior to Provant Treatment	Pain Medication After Provant Treatment	Provant Treatment Length
Lumbar and Cervical Spine					
Lumbar fusion	10/10	2/10	12 months of methadone, gabapentin, baclofen, nortriptyline, etodolac	Methadone (less than prescribed, increased time between refills)	16 weeks
Lumbar fusion and re-operation	5-6/10	0-1/10	4 months of gabapentin 600 mg daily, oxycodone	Gabapentin 300 mg daily	11 weeks
Lumbar fusion and two re-operations for cerebral spinal fluid leak	7/10	3/10	16 months of oxycodone, gabapentin, methocarbamol	Pain medications discontinued	3 months
Cervical fusion and root canal	7-8/10	3/10	2 years of oxycodone, Botox injections	Cyclobenzaprine, lidocaine patches, naproxen, fewer Botox injections	Continues to treat regularly
Lower Extremity					
Endoscopic plantar fasciotomy	5/10	0/10	3½ months of hydrocodone 10 mg	Hydrocodone discontinued	4 weeks
Foot and ankle orthopedic surgeries resulting in chronic regional pain syndrome	7/10	1/10	10 years of NSAIDs, gabapentin, TENS, epidural injections, local lidocaine block	Not Specified	2 months
Knee arthroscopy	8/10	0/10	5 days of hydrocodone 10 mg twice daily	Hydrocodone discontinued	3½ weeks
Below the knee amputation	10/10	0/10	8 months of gabapentin 3600 mg daily	Gabapentin 1200 mg daily	3 months
Total knee arthroplasty	6-8/10	0/10	In hospital PCA pump	No pain meds except with physical therapy	6 weeks
Debrided arterial ulcer	5-9/10	0/10	>1 year of lidocaine patches, Lyrica, fentanyl patches, hydrocodone	Fentanyl patch for back pain	16 weeks
Upper Extremity					
Hand degloving; amputation avoidance	10/10	0/10	7 weeks of oxycodone, hydrocodone, gabapentin	Pain medications discontinued	4 weeks
Shoulder arthroscopy	6/10	2/10	4 days of 4 Percocet daily	1 Percocet daily, tramadol, ibuprofen as needed	8 weeks
Chest, Abdomen, Face					
Chest surgery	10/10	7/10	>1 year of methadone 90 mg daily, tramadol, nortriptyline	Methadone 75 mg daily	12 weeks
C-section with nerve damage	10/10	2/10	Several weeks of hydrocodone every 6 hours, gabapentin 600 mg three times daily	Hydrocodone discontinued, gabapentin 600 mg daily	7 months
Lateral canthus reconstruction	7/10	4-5/10	Several-year use of Percocet as needed	Ibuprofen as needed	6 weeks

In summary, treatment with Provant in these 15 patients resulted in important decreases in pain with a resulting decrease in required pain medications. These results demonstrate the utility of Provant Therapy in the treatment of acute to chronic postoperative pain.

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