Pain Therapy Options for the Home

A patient-based outcome review of at-home pain management devices, including the Willow Curve, Quell, and VibraCool

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This device review focuses on technologies that have emerged over the past few years which aim to benefit patients suffering from persistent pain, as well as infuse some innovation into home-based chronic pain management. The current healthcare economy and milieu in general relies on patients passively receiving clinical services, making the directionality of healthcare provision from the home to the hospital or clinic. With healthcare reform and the anticipated transition from volume- to value-based care, the clinical community will need to give greater thought to filling the post-discharge void regarding pain relief typically associated with on-site services. If reimbursement models change to reflect a greater pay-for-performance model based on outcomes, whereby providers are paid commensurate with clinical effectiveness, this trend may incentivize caregivers/providers to consider improved home-based pain management, including the judicious use of durable medical equipment (DME).

The devices featured represent just a sampling of a much larger trend that may transform healthcare delivery in the near future, including transitions from expensive inpatient settings to less costly outpatient settings, and eventually into the home. In the current complex healthcare ecosystem, having the ability to leverage the right technology for individual patients moving forward will be paramount. In addition, having access to a cohesive evidence-informed home care plan for conservative chronic pain management will be vital to total care coordination when it comes to ensuring positive outcomes. The three technologies highlighted herein are sleek, cleverly designed, and, in the authors’ view, have demonstrated medical-grade pain management at a fraction of the price.

Data Methods & Analysis: Quantifying Patient Improvement

This mixed-methods analysis utilized patient-reported outcomes and provider research with quantitative endpoints. The goal was to determine how each device worked and in which patients it worked best. The authors used a traditional odds ratio (OR) statistic to measure effect size, since ORs do not require intensive computation. In our design, the OR was simply the ratio of two probabilities: the probability of achieving the outcome of interest vs the probability of not achieving the outcome of interest. In a conventional case/control design, the subjects would be chosen based on the presence or absence of disease. In our clinical setting, the subjects were chosen based on the presence or absence of pain. Using classic OR convention, the cases and the controls represent two different groups and differ only by disease status.

When pain intensity is used as the primary endpoint, one may actually have the pain at one point in the day and not have pain in another part of the day (diurnal variation). In this modified OR format, we used the same group of patients as both the cases and the controls, taking advantage of fluctuations in pain status. By doing so, we have avoided many of the confounding factors that require statistical adjustment. However, by not implementing the same level of internal control(s) as a formal clinical trial, the data can only infer association and not causation between outcome and exposure variables.

Product Evaluation

Since the three devices reviewed do not require medical prescription, our primary outcome measure of interest was patient-reported pain intensity reduction using a 10-point visual analog scale (VAS). These three devices were presented to us at different times of the year in 2018. The Willow Curve (phototherapy) and Quell (electrostimulation) devices were tested for 8 and 11 months, respectively, while the VibraCool (vibrational) device was tested over a period of 3 months (received in October 2018). We applied a single subject design (multiple N of 1) that examined the change in pain intensity based on a single treatment session where the patient acted as his or her own control with the desired outcome of interest.
being a 3-point reduction in a 10 point (10 cm) VAS scale.

As clinicians know, it is important to be reminded that pain intensity is but one characteristic in the total pain experience of any patient and does not necessarily explain co-existing disability. The use of a pain VAS instrument as a surrogate to measure disability is not ideal as it simply measures a single dimension of the pain experience: pain intensity. However, the VAS has been shown to compare favorably to multi-item scales, showing good concurrent validity (SF-20), responsiveness, and excellent reliability. In fact, while common forms of pain intensity assessment have shown excellent test-retest reliability, the VAS has the smallest error associated with its use.

Product protocols were followed according to device instructions and verified through numerous communications.

Description & Performance of the Devices

**Product:** Willow Curve  
**Manufacturer:** Physician’s Technology, LLC (Monroe, MI)  
**Recommended for pain conditions such as:** arthralgia (joint pain), neuralgia, and myalgia  
**Cost:** $799  
**For more info:** willowcurve.com

The Willow Curve (WC, see Figure 1) is a curvilinear shaped device that fits snugly over the round contour of most joints and emits simultaneous thermal energy (heat) and photonic energy (light) within the infrared spectra, specifically the 500 to 4,000 nm wavelength range. The spectral or emission frequency pattern of WC has been identified to be in the 292 to 4,000 Hz range. This device has been developed with sophisticated technology that combines the benefits of laser, infrared, and LEDs in a therapeutic and engineering conglomerate that culminates into clinical grade pain relief.

The mechanisms of action (MOA) are those consistent with a multitude of studies already documented in the low-level laser research literature base.

The WC offers a patient-friendly treatment with an ease of use that improves patient compliance. The LED array is both visible (red lights) and sensory (heat), which helps counteract the possibility of “nocebo” effects often seen in the more silent therapies that have no visual or auditory cues. The treatment generally takes under 30 minutes and patients are put in a comfortable position for the duration. The WC performs very well with joint conditions (arthralgia) given its structural configuration, which provides a snug contoured fit around most joints and the cervical spine as well. The WC was trialed on a variety of musculoskeletal (MSK) conditions including the various arthritides (OA/RA/psoriatic/gout), joint injury (sprains/strains), post-surgical pain, and “age-related” (idiopathic) pain and stiffness.

Our experience with the WC device was quite rewarding, in that we were not expecting such strong treatment effects. We continue to use the WC as part of our daily clinical treatments for chronic pain patients.

**Product:** Quell  
**Manufacturer:** NeuroMetrix, Inc. (Waltham, MA)  
**Recommended for pain conditions such as:** systemic pain such as fibromyalgia, polymyalgia, generalized age-related stiffness, muscle strain, cramping, and spinal pain  
**Cost:** $299  
**For more info:** quellrelief.com

This technology is an electricity-based, TENS-like wearable unit cleared by FDA as a Class II (safety standard) medical device (see Figure 2). It is worn mid-calf regardless of pain location or condition and acts as a peripheral nerve stimulator whose mechanism of action (MOA) invokes the widely accepted spinal gating theory, along with stimulation-induced release of endogenous opiates as the primary mechanism. This device may be worn during sleep and/or activity since it is firmly secured to the stimulation site with a strap. Quell is well described by Gozani (2015).

Another nice feature of the Quell is that its battery life lasts for 4 to 7 days and only takes a few hours to charge. The actual output power in this unit is quite high at 100 V x 100 mA, with the user able to adjust these settings when needed. The waveform is described by the manufacturer as a symmetric biphasic 60 to 100 Hz changing frequency pattern, which is very important in preventing accommodation. In fact, waveform is often understated and underappreciated; it has been the authors’ experience that electrostimulation devices
that lack this characteristic often have limited analgesic effects and usage due to central nervous system (CNS) adaptations.

Quell’s technology allows for the device to calibrate to the individual with optimal stimulation patterns, which is an impressive feat and consistent with today’s Smart technology. The Quell also comes with an app that can capture and store patient data, serving to increase patient compliance through engagement and insight.

We issued the unit to patients for 3 to 4 weeks at a time where they agreed to use the unit for 2 to 3 sessions per day at 60 minutes or more if needed. Quell was trialed on mostly neuropathic and myopathic conditions, and due to the nature of the trial parameters, it took considerably longer to capture data. The Quell database (observation points) is not as extensive as the other two technologies, but despite less empirical data, Quell performed admirably overall and became a favorite among patients.

Editor’s Note: NeuroMetrix recently released Quell 2.0, an updated version that includes an option for shorter 15-minute sessions, coaching features, and new machine learning algorithms that take into account different characteristics tailored to the user. According to the manufacturer, Quell 2.0 is 50% smaller and 20% more powerful than its predecessor.

The VibraCool (see Figure 3) provides an intervention that is a combination of ice and vibration, oscillating at 150 Hz and small enough to fit most anywhere on the body. VibraCool is a focal vibration device that is strapped on the body where needed. It provides a 10-minute continuous treatment to most any peripheral joint (we have even tested the device on painful sacroiliac joints). The vibratory frequency utilized targeted pain-specific receptors (mechanoreceptors) and nerve pathways that might further activate the spinal gating mechanism(s). Vibration (whole and/or focal) is being used therapeutically to reduce muscle atrophy, improve joint active range of motion (AROM), and reduce joint pain.

The authors found the VibraCool device to be a valuable adjunct to our clinical treatments, especially for very difficult-to-treat enthesopathic conditions that in many cases are unresponsive or recalcitrant to other forms of energy or manual therapies. These observations were consistent with the inherent predilection that vibration energy might have on ligamentous, capsular, and musculotendinous structures based on the high concentration of mechanoreceptors found in collagen-based tissue. Patients showed both high compliance and tolerance for using the VibraCool device; chronic pain patients who had some hypersensitivity to general tactile stimulation did fine with the unit.

Our younger sports medicine patients (knees, ankles, and shoulders) responded exceptionally well to this form of treatment, but it was difficult to discern whether this was related to a more youthful neurophysiological response, stimulation preferences, psychological factors, or some other variables introduced and influencing the treatment dynamic. There certainly was a tendency for younger patients to prefer being treated while they were exercising (dynamic treatment)
versus older patients who seemed to prefer a more passive treatment post-exercise.

**Summary**
The three technologies described are unique from each other and represent divergent technologies with convergent goals. They are a good example of how many different ways one may achieve cost-effective pain control at home. When used on a regular basis, these devices have demonstrated that they can modulate both acute and chronic pain and could make excellent home pain management options. Pain practitioners may want to consider adopting these devices for clinical use as well, or at least so that patient trials may be conducted in-office to determine response and whether a medical order for the device is warranted.

Since this investigation was not set up as a comparative effectiveness trial, we will report the global modified OR for the combined devices (Quell, Willow Curve, and VibraCool). The OR for the pooled data is 2.25 with a 95% CI (1.34 - 3.77) and a z statistic (3.077), all at a significance level ($P = 0.0021$). Our data suggest that these diverse devices are effective at ameliorating pain intensity and are proof that there are many ways to peel the proverbial onion.

**References**

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