Non-invasive Interactive Neurostimulation (InterX®) as an adjunct in pain control for patients following Total Knee and Total Hip Arthroplasty: a Randomized Placebo Controlled Trial

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Introduction:
Total knee arthroplasty (TKA) and total hip arthroplasty (THA) are painful procedures that have seen the postoperative implementation of a number of strategies to advance patient comfort and early mobilization. The aim of postoperative analgesia is to make patients as comfortable as possible with the lowest possible morbidity from analgesic modalities, such as cardiopulmonary or central nervous system depression. Thus, the development and study of a non-opioid, non-invasive means of delivering a targeted, verified pain management for the purpose of improved patient comfort and potential cost-savings relating to better patient outcomes with some suggesting that the next major development in THA technology will be a pain relief innovation. It has previously been demonstrated that a 25% reduction in opioid consumption can lead to as much as a 40% reduction in clinically meaningful events/side effects.

The InterX is a non-invasive interactive neurostimulation device manufactured by Neuro Resource Group, Plano, Texas, USA. It is an advancement of neurostimulation technology which provides a more precise and more targeted laminar to optimize the therapeutic parameters and significantly improve the physiological and clinical benefits. The interactive, impedance sensitive waveform allows for the delivery of stimulation through small, closely spaced electrodes to optimize treatment points at an amplitude 4-5 times higher than other transcutaneous devices and without the risk of painful muscle contraction. These characteristics provide a powerful and consistent pain-relieving effect and have even been shown to reduce inflammation, a mechanism not generally associated with transcutaneous electrical stimulation. InterX technology has demonstrated significant clinical efficacy in two published trials of Level One Therapeutic evidence.

This randomized, placebo controlled, prospective study was designed to research the technology on total joint replacement patients, a population which has previously proven difficult to treat with neurostimulation due to poor efficacy and risk factors.

Hypothesis:
In this study it is hypothesized that active InterX Therapy as added to a usual in-patient rehabilitative care of post-operative hip and knee replacement will:

Primary:
Reduce pain severity on a 0-10 scale when compared to sham therapy or reduce pain medication when compared to sham therapy over time

Secondary:
Reduce length of time required to achieve discharge goals when compared to sham therapy over time

Study Population
87 consecutive patients presenting for admission to the Presbyterian Rehabilitation Unit following hip or knee primary joint replacement and meet the entry criteria will be eligible. Patients were randomized to be treated with the InterX device or to the placebo group which used a sham device. All patients gave informed consent and the protocol received formal approval from the institutional review board. Participants were randomized using a stock randomization schedule.

Inclusion Criteria:
40 years of age or older
Postoperative primary hip or knee replacement at Presbyterian Hospital of Dallas.
Willing to abide by protocol and treatment schedule
Able and willing to give informed consent

Exclusion Criteria:
Implants, intra-cranial, or patient inapplicable with electrical stimulation
History of epilepsy or seizure
Pregnancy
Medical conditions that delay active physical therapy upon admission
Bilateral joint replacements
Revisions and/or traumatic joints

Method:
The groups received InterX treatments 2 times per day starting 72 hours after surgery. Treatment with the device was approximately 20 minutes per session. Patients were instructed the patients that they may or may not experience the stimulation. Therapists were trained to respond in the same manner whether or not the stimulation was felt or the patients remained blinded. Part of the use of the device involves scanning for points of low impedance around the surgical site as these represent optimal treatment points for neurostimulation. This procedure was also followed with the sham device. Data on pain medication was documented daily. Parenteral morphine equivalent (PME) conversion was performed by the pharmacist.

Parenteral Morphine Equivalents (PME) conversion:
The IV conversion will be: Morphine IV 10mg = Hydromorphone 1.5mg IV = Fentanyl 0.1mg IV

Transdermal fentanyl (note the equivalence is based on a 24 hour amount): Morphine IV 22mg per 24 hours = 25mcg/hr fentanyl patch

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Conclusions:
The effects of InterX’s treatment on TKA and THA patients is statistically significant and also has clear clinical and financial implications. The cost in patient rehabilitation ranges from $600.00 to $1,000.00 per day, so the cost savings for early discharge on this study population offer significant potential. This study alone demonstrates a potential saving of in-patient costs of between $25,200 and $42,000. The case for inclusion of InterX is furthered by the fact that the manufacturer has recently developed a patient-administered version of the technology which does not require the continual attendance of a therapist and can be self-administered for both low to high level pain.

References:
5. Zhao S.Z., PhD, MD, et al. Non-invasive Interactive Neurostimulation (InterX®) as an adjunct in pain control for patients following Total Knee and Total Hip Arthroplasty: a Randomized Placebo Controlled Trial
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Fig. 1

InterX Significantly Reduces Medication Requirements (PME)

Fig. 2

InterX Significantly Reduces Days in Rehab

Fig. 3

Knee Surgery Daily Medication Intake

Fig. 4

Days in Rehab

Knee Arthroplasty Patients

This was against a backdrop of pain scores which remained around 4/10 for the duration of the in-patient stay in both groups. This demonstrates the clear ability to significantly reduce pain scores with the InterX device by offering an average reduction of 34% in pain scores compared to the placebo group. We used analysis of variance (ANOVA) that adjusted for differences in BMI. There was significant treatment effect on total pain medication intake (p<0.050) in the InterX Group. The estimated means were 85.0mg vs 95.0mg (Control vs InterX) for hips and 104.6mg vs 74.0mg (Fig.1) (Control vs InterX) for knees.

We also looked at the effect of therapy on number of days in the rehab unit. Considering all patients and using the non-parametric Mann-Whitney test, InterX patients spent significantly fewer days in rehab, p<0.01 (Fig.2)