

iovera^o CLINICAL DATA SUMMARY

Retrospective total knee arthroplasty (TKA) study¹

Study overview

- Single site (Louisiana State University Health Sciences Center School of Medicine); retrospective review; N=100
- Treatment group = First 50 patients treated after iovera^o introduced
- Control group = Last 50 patients treated before iovera^o introduced

Methods

- iovera^o treatment of the infrapatellar branch of the saphenous nerve (ISN) and anterior femoral cutaneous nerve 5 days prior to TKA

Read the full study here:



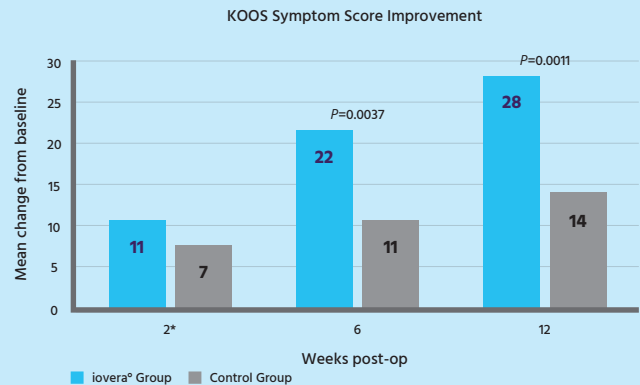
Percutaneous freezing of sensory nerves prior to total knee arthroplasty

Dasa V, Lensing G, Parsons M, Harris J, Volaufova J, Bliss R. *Knee*. 2016;23(3):523-528.

KOOS=Knee Injury and Osteoarthritis Outcome Score;
PROMIS=Patient-Reported Outcomes Measurement Information System.
*P value not reported.

Results

- The iovera^o group required 45% less opioids during the 12 weeks after surgery, based on prescription requests
- Compared with the control group, the iovera^o group demonstrated a significantly greater improvement in KOOS symptom scores at 6 weeks and 12 weeks
- The iovera^o group demonstrated within-group significant reductions in PROMIS[®] pain intensity and pain interference at 2- and 6-week follow-up, respectively ($P<0.0001$)
- The most common side effect was local bruising at the site of treatment



Prospective knee osteoarthritis (OA) study²

Study overview

- Multicenter, prospective, sham-controlled, double-blind study
- 17 sites across the United States; N=180 (randomized 2:1)
- Treatment group = 121 subjects treated with iovera^o
- Control group = 59 subjects treated with a sham tip

Methods

- Treatment of the ISN only
- Patients were followed through to 120 days

Read the full study here:

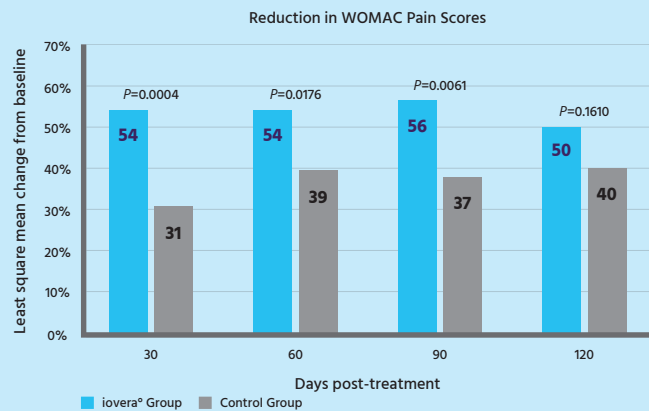


Cryoneurolysis to treat the pain and symptoms of knee osteoarthritis: a multicenter, randomized, double-blind, sham-controlled trial

Radnovich R, Scott D, Patel AT, et al. *Osteoarthritis Cartilage*. 2017;25(8):1247-1256.

Results

- The iovera^o group demonstrated a significantly greater reduction in WOMAC pain score at Days 30, 60, and 90 ($P<0.02$)
- The most common side effects were bruising, numbness, redness, tenderness upon palpation, and swelling



WOMAC=Western Ontario and McMaster Osteoarthritis Index.

Publication	Summary
<i>Novel methodologies in regional anesthesia for knee arthroplasty.</i> Gabriel RA, et al. <i>Anesthesiology Clinics</i> . 2018.	Although a single application of ultrasound-guided percutaneous cryoneurolysis provides weeks to months of analgesia, careful selection of candidates is required. ³
<i>Ultrasound-guided percutaneous cryoneurolysis for treatment of acute pain: could cryoanalgesia replace continuous peripheral nerve blocks?</i> Ilfeld BM, et al. <i>British Journal of Anaesthesia</i> . 2017.	Concludes that “current evidence suggests that ultrasound-guided percutaneous cryoanalgesia holds enormous potential for making a dramatic leap forward in providing long-term analgesia, far surpassing typical continuous peripheral nerve blocks, with minimal risk and a lower patient burden.” ⁴
<i>Novel cryoneurolysis device for the treatment of sensory and motor peripheral nerves.</i> Ilfeld BM, et al. <i>Expert Review of Medical Devices</i> . 2016.	Concludes that “changes in the US healthcare system such as a push for the reduction of opioid use and the incorporation of Diagnostic Related Group codes, as well as recent technological advances including a handheld unit that allows for treatment of superficial nerves while protecting the skin from damage, may contribute to the resurgence of cryoneurolysis for the treatment of peripheral nerves.” ⁵
<i>Wallerian degeneration and recovery of motor nerves after multiple focused cold therapies.</i> Hsu M, et al. <i>Muscle & Nerve</i> . 2015.	There was consistent weakening of physiological function and restoration of normal function after each treatment. Low-temperature treatment of motor nerves did not result in permanent or long-term changes to nerve function or structure. ⁶
<i>Reduction in muscular motility by selective focused cold therapy: a preclinical study.</i> Hsu M, et al. <i>Journal of Neural Transmission</i> . 2014.	Application of low temperatures to peripheral motor nerves resulted in temporary denervation and loss of function of the treated rat hind limb. Low-temperature treatment on motor nerves did not result in any permanent or long-term changes to function and structure of the nerves. ⁷

Indication

The iovera[®] system is used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. It is also indicated for the relief of pain and symptoms associated with osteoarthritis of the knee for up to 90 days. The iovera[®] system is not indicated for treatment of central nervous system tissue.

The iovera[®] system’s “1x90” Smart Tip configuration (indicating one needle which is 90 mm long) can also facilitate target nerve location by conducting electrical nerve stimulation from a separate nerve stimulator.

Important Safety Information

Contraindications

The iovera[®] system is contraindicated for use in patients with the following:

- Cryoglobulinemia, paroxysmal cold hemoglobinuria, cold urticaria, Raynaud’s disease, and open and/or infected wounds at or near the treatment site

Potential Complications

As with any surgical treatment that uses needle-based therapy and local anesthesia, there is a potential for site-specific reactions, including, but not limited to:

- Ecchymosis, edema, erythema, local pain and/or tenderness, and localized dysesthesia

Proper use of the device as described in the User Guide can help reduce or prevent the following complications:

- At the treatment site(s): injury to the skin related to application of cold or heat, hyper- or hypopigmentation, and skin dimpling
- Outside the treatment site(s): loss of motor function

For more information, please visit www.iovera.com or call Customer Service at 800-442-0989

References: 1. Dasa V, Lensing G, Parsons M, Harris J, Volaufova J, Bliss R. Percutaneous freezing of sensory nerves prior to total knee arthroplasty. *Knee*. 2016;23(3):523-528. 2. Radnovich R, Scott D, Patel AT, et al. Cryoneurolysis to treat the pain and symptoms of knee osteoarthritis: a multicenter, randomized, double-blind, sham-controlled trial. *Osteoarthritis Cartilage*. 2017;25(8):1247-1256. 3. Gabriel RA, Ilfeld BM. Novel methodologies in regional anesthesia for knee arthroplasty. *Anesthesiol Clin*. 2018;36(3):387-401. 4. Ilfeld BM, Gabriel RA, Trescot AM. Ultrasound-guided percutaneous cryoneurolysis for treatment of acute pain: could cryoanalgesia replace continuous peripheral nerve blocks? *Br J Anaesth*. 2017;119(4):703-706. 5. Ilfeld BM, Preciado J, Trescot AM. Novel cryoneurolysis device for the treatment of sensory and motor peripheral nerves. *Expert Rev Med Devices*. 2016;13(8):713-725. 6. Hsu M, Stevenson FF. Wallerian degeneration and recovery of motor nerves after multiple focused cold therapies. *Muscle Nerve*. 2015;51(2):268-275. 7. Hsu M, Stevenson FF. Reduction in muscular motility by selective focused cold therapy: a preclinical study. *J Neural Transm (Vienna)*. 2014;121(1):15-20.

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