

The Bionicare® Knee System is the most thoroughly researched, non-invasive, non-drug alternative for the treatment of osteoarthritis of the knee. The patented Bionicare device delivers an imperceptible pulsed electrical signal specifically designed for the treatment of pain and other symptoms of the osteoarthritic knee. The device may be incorporated into either the OActive® or Eagle® OA unloading knee braces to provide a synergistic benefit to the patient. The OActive and Eagle OA knee braces reduce the pressure and pain of weight bearing while the Bionicare device provides long term relief of symptoms.

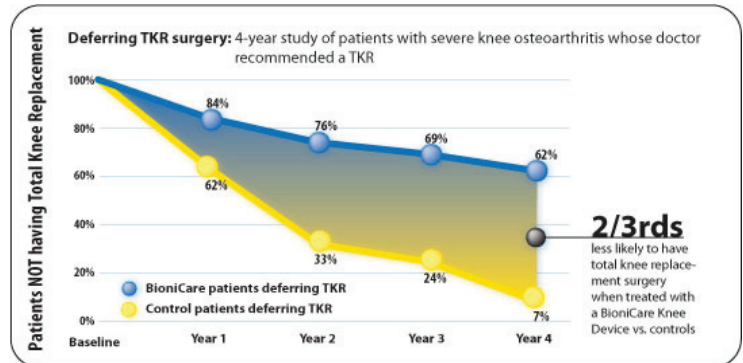
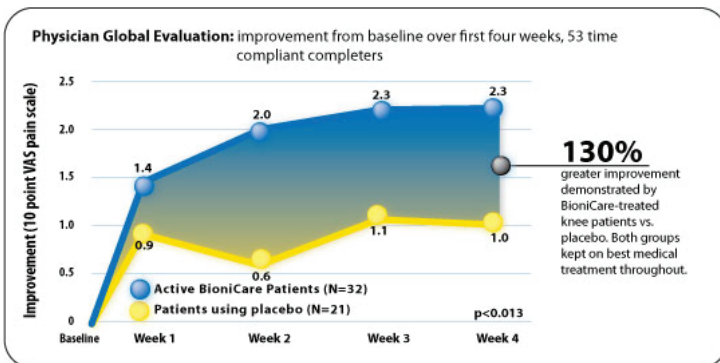
Peer-reviewed, published studies prove the effectiveness of the Bionicare Knee System



- Patients treated with Bionicare **showed a 130% greater improvement** over baseline in the Physician’s Global Evaluation
- Bionicare patients were **2/3rds less likely to have a total knee replacement**
- The effect size of the Bionicare device after 2250 hours of use was equal to the effect of a total knee replacement
- 45% of patients reduced their NSAIDs by 50% or more and 18% of patients completely discontinued their NSAIDs after using Bionicare.
- Patients treated with Bionicare had a 120% greater improvement over baseline in patient-reported pain and symptoms

In a recent, ongoing clinical study,

- Patients who wore Bionicare with a brace had 37% greater improvement in symptoms in 1/4 of the time.



REFERENCES

Mont MA, Hungerford DS et al. "Pulsed Electrical Stimulation to Defer TKA in Patients with Knee Osteoarthritis." Orthopedics. October 2006; 29(10): 887-892.

Zizic TM, Hoffman KC et al. "Treatment of Osteoarthritis of the Knee with Pulsed Electrical Stimulation." Journal of Rheumatology. 1995; 22(9): 1757-1761.

* studies were conducted with the previous Bionicare Device

For more information or to contact a VQ OrthoCare representative nearest to you, please call 800.444.1456.

INDICATIONS FOR BIONICARE

The BioniCare Knee System is indicated for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by the Physician's Global Evaluation (clinical studies).

WARNINGS

- The BioniCare Knee System must be used only as prescribed and applied only to the knee.
- Patients with demand style cardiac pacemakers should consult with their physician prior to use of this system.
- The safety of the BioniCare Knee System for use during pregnancy has not been established.
- The BioniCare Knee System is not effective for pain of central origin (including headache).
- Use only under the continued supervision of a physician.
- Keep out of reach of children.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when the BioniCare Knee Device is in use.

CONTRAINDICATIONS

- Do not use the BioniCare Knee System for any electrode placement that applies current to the carotid sinus (neck) region.
- Do not use the BioniCare Knee System for any electrode placement that causes current to flow transcranially (through the head).
- Do not use the BioniCare Knee System when pain syndromes are undiagnosed until etiology is established.

PRECAUTIONS

Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.

ADVERSE REACTIONS

Skin irritation and electrode burns are potential adverse reactions. Patients with skin irritation / reactions should be monitored.

CAUTION

Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

INDICATIONS FOR OACTIVE® AND EAGLE® OA

- Mild to severe unicompartmental knee osteoarthritis
- Medial or lateral compartment

WARNINGS

If you experience pain, swelling, sensation changes, or unusual reactions while using this product, contact VQ OrthoCare's Patient Care department at 800.452.7993 or consult a physician.



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Prescription Guidelines

The Bionicare Knee System

Rx Prescription Form and Letter of Medical Necessity

PATIENT NAME: _____ PLEASE ATTACH / FAX PATIENT FACE SHEET WITH THIS FORM FAX TO: _____
 HEIGHT: _____ WEIGHT: _____ ACCOUNT EXECUTIVE: _____
 SOCIAL SECURITY NUMBER: _____ TELEPHONE: _____

Must fill in OA / DJD DX of knee here

Must be OA / DJD DX (715.96, 715.16, 715.26, 715.36)

Please ensure that the information provided is accurate and reflects your patient's medical record.

Patient has instability due to the following diagnosis: _____ ICD-9 Code: _____

The OA diagnosis is secondary to a primary injury? Yes

Check one box to choose type of brace for your Bionicare System

Check ONLY if ordering stand-alone Night-Wrap System (no brace)

Compartment must be checked

If possible provide knee size for OActive Off the shelf with Bionicare only

Always check to ensure supplies are covered

List previous treatments and goals.

Required for brace only

Provide NPI #

Provider needs to sign and date.

Print providers name.

Severity of OA should be 4 or above.

For a custom knee brace, one of these criteria must be indicated.

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Chart notes are crucial:

- Copies of chart notes are required and must indicate that Bionicare and OA brace (if ordered) are the treatment plan for patient's osteoarthritis: —Ex: "Patient has been prescribed Bionicare and OActive brace for the treatment of knee osteoarthritis."
- Additional notes for previous treatments failed and goals of treatment are helpful.
- Diagnosis of OA/DJD needs to be clearly documented in chart.

Suggested product configuration:

- Moderate to high activity level = OActive or Eagle OA with Bionicare (Double upright Eagle OA for maximum stability/correction).
- Sedentary patient with negligible weight-bearing activity = Bionicare Night-Wrap System.
- Motivated patients should use Bionicare in brace during the day and Night-Wrap System at night to maximize hours.



The BioniCare Knee System
Prescription Form and Letter of Medical Necessity



PATIENT NAME		PLEASE ATTACH / FAX PATIENT FACE SHEET WITH THIS FORM	
		HEIGHT	WEIGHT
SOCIAL SECURITY NUMBER:		DATE OF BIRTH: (MM-DD-YYYY)	

FAX TO: _____
ACCOUNT EXECUTIVE: _____
TELEPHONE: _____
TERRITORY: _____

Please ensure that the information below is consistent with your patient's medical record.

Patient has instability due to the following diagnosis:	ICD-9 Code:
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The OA diagnosis is secondary to a primary injury? Yes

PRODUCT DESCRIPTION	
<input type="checkbox"/> OActive® Brace with BioniCare® Knee System (Single Upright Knee Brace) <input type="checkbox"/> Right Knee <input type="checkbox"/> Custom <input type="checkbox"/> Left Knee <input type="checkbox"/> Off-the-Shelf (prefabricated) <input type="checkbox"/> Bilateral	<input type="checkbox"/> Eagle® OA Brace with BioniCare® Knee System (Double Upright Knee Brace) <input type="checkbox"/> Right Knee <input type="checkbox"/> Custom only <input type="checkbox"/> Left Knee <input type="checkbox"/> Bilateral
<input type="checkbox"/> BioniCare® Night-Wrap System: <input type="checkbox"/> Right Knee <input type="checkbox"/> Left Knee <input type="checkbox"/> Bilateral	

For delivery of BioniCare treatment without a brace – complete sections 3 and 5 only.

COMPLETE SECTIONS 1-5		CUSTOM KNEE CRITERIA
1	Compartment to Unload: <input type="checkbox"/> Medial <input type="checkbox"/> Lateral <input type="checkbox"/> Neutral	<input type="checkbox"/> Deformity of the leg or knee that precludes fitting with a prefabricated orthosis <input type="checkbox"/> Disproportionate size of thigh and calf <input type="checkbox"/> Minimal muscle mass to suspend orthosis <input type="checkbox"/> Off-the-shelf failed
2	Knee Wrap Size: KNEE CIRCUMFERENCE (measured at mid-patella) <input type="checkbox"/> Small (13" - 15") <input type="checkbox"/> Medium (15" - 18") <input type="checkbox"/> Large (18" - 26")	
3	Length of Use: <input type="checkbox"/> Purchase device and supplies as needed	

STATEMENT OF MEDICAL NECESSITY					
5	The BioniCare® Knee System is being ordered as adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee, and for overall improvement of the knee.				
1. PREVIOUS TREATMENT	USING CURRENTLY	USED IN PAST	NEVER USED	FAILED TRIAL	
Acetaminophen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
NSAIDs / COX-2 Inhibitor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Exercise / Strengthening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Patient Education	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Physical / Occupational Therapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other _____					
2. Patient's instability is due to:					
Positive stress test:	<input type="checkbox"/> Varus / Valgus	<input type="checkbox"/> Anterior / Posterior Drawer			
	<input type="checkbox"/> Intrinsic instability secondary to pain in the knee	<input type="checkbox"/> Loss of cartilage and joint space producing ligament laxity			
	<input type="checkbox"/> Other cause (state) _____				
3. What is your treatment goal(s) for the use of the BioniCare Knee System? (Check all that apply)					
<input type="checkbox"/> Improvement in patient's pain	<input type="checkbox"/> Improvement in patient's function and ADL	<input type="checkbox"/> Increase performance in activities of daily living			
<input type="checkbox"/> Reduce medications	<input type="checkbox"/> Deferral of knee surgery	<input type="checkbox"/> Other _____			
4. Patient's severity of OA (pain and associated symptoms) - CIRCLE ONE:					
	MILD	MODERATE			SEVERE
	1	2	3	4	5
	6	7	8	9	10

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NPI: _____ DAW *I, the undersigned, confirm the order for the above-named patient. I also certify that the prescribed treatment is medically reasonable and necessary in reference to accepted standards of medical practice within the community for treatment of this patient's condition.*

Physician/Provider Signature: _____ Date: _____

Physician's Name (print): _____ Phone: _____



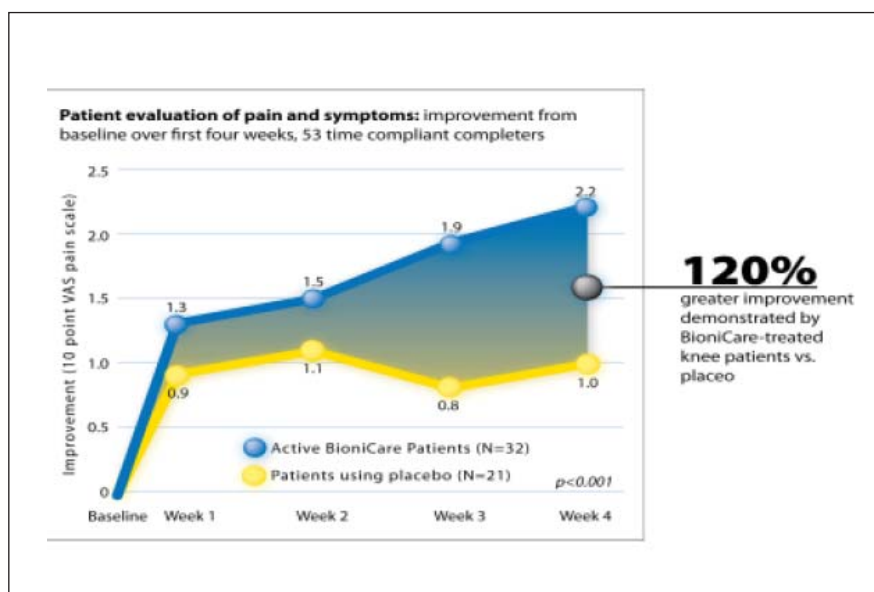
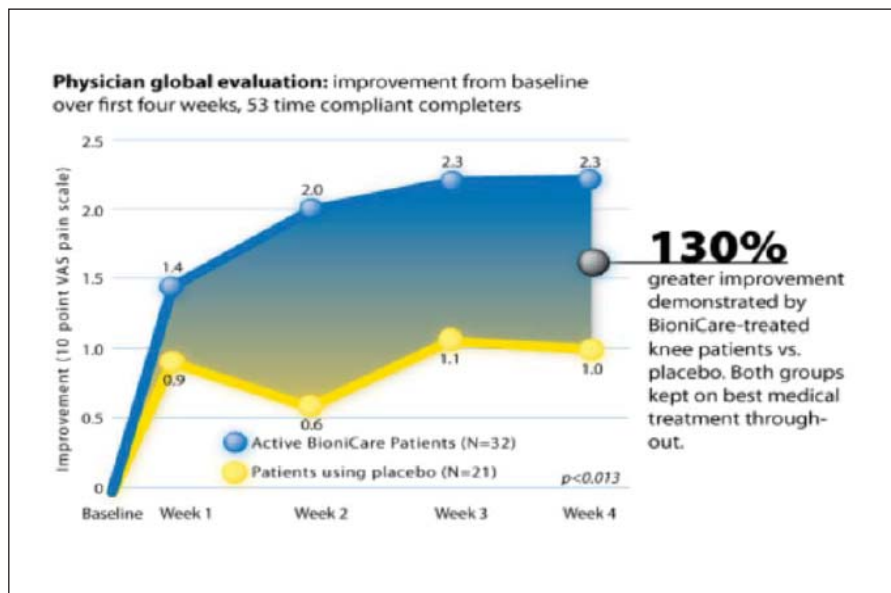
CLINICAL RESEARCH SUMMARY

Zizic TM, Hoffman KC, Holt PA, Hungerford DS, O'Dell JR, Jacobs MA, Lewis CG, Deal CL, Caldwell JR, Cholewczynski JG, et al. The treatment of osteoarthritis of the knee with pulsed electrical stimulation. J Rheumatol. 1995 Sep;22(9):1757-61.

OBJECTIVE: The safety and effectiveness of pulsed electrical stimulation was evaluated for the treatment of osteoarthritis (OA) of the knee.

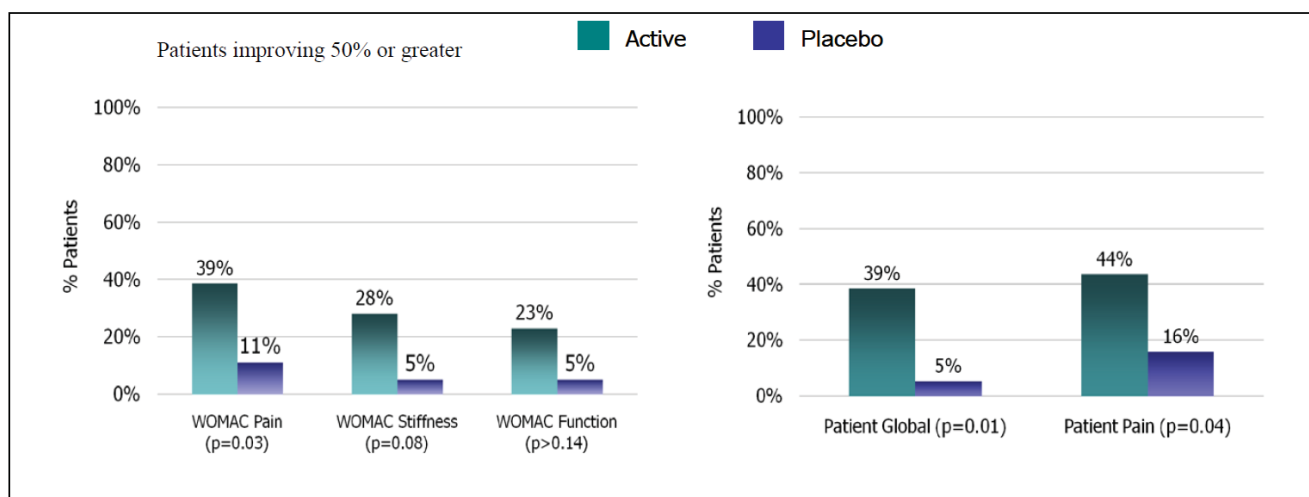
METHODS: A multicenter, double blind, randomized, placebo controlled trial that enrolled 78 patients with OA of the knee incorporated 3 primary efficacy variables of patients' pain, patients' function, and physician global evaluation of patients' condition, and 6 secondary variables that included duration of morning stiffness, range of motion, knee tenderness, joint swelling, joint circumference, and walking time. Measurements were recorded at baseline and during the 4 week treatment period.

RESULTS: Patients treated with the active devices showed significantly greater improvement than the placebo group for all primary efficacy variables in comparisons of mean change from baseline to the end of treatment ($p < 0.05$). Improvement of $>$ or $=$ 50% from baseline was demonstrated in at least one primary efficacy variable in 50% of the active device group, in 2 variables in 32%, and in all 3 variables in 24%. In the placebo group improvement of $>$ or $=$ 50% occurred in 36% for one, 6% for 2, and 6% for 3 variables. Mean morning stiffness decreased 20 min in the active device group and increased 2 min in the placebo group ($p < 0.05$). No statistically significant differences were observed for tenderness, swelling, or walking time. **CONCLUSION:** The improvements in clinical measures for pain and function found in this study suggest that pulsed electrical stimulation is effective for treating OA of the knee. Studies for long term effects are warranted.



Garland D, Holt P, Harrington JT, Caldwell J, Zizic T, Cholewczynski J. A 3-month, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of a highly optimized, capacitively coupled, pulsed electrical stimulator in patients with osteoarthritis of the knee. *Osteoarthritis Cartilage*. 2007 Jun;15(6):630-7.

OBJECTIVE: To investigate the efficacy and safety of a capacitively coupled, pulsed electrical stimulation device in treating knee osteoarthritis (OA). **DESIGN:** Fifty-eight outpatients with moderate to severe OA of the knee entered a 3-month, double-blind, placebo-controlled trial, using either an active or placebo device at home for 6 to 14 h/day. Outcome measures included a patient global evaluation, a patient report of knee pain severity, and the Western Ontario and McMaster Universities (WOMAC) questionnaire. **RESULTS:** Active treatment provided superior outcomes between baseline and 3-month follow-up measurements: 50.6% greater improvement than placebo in patient global (P=0.03), 31.2% in patient pain (P=0.04), 25.1% in WOMAC stiffness (P=0.03), 29.5% in WOMAC function (P=0.01), 19.9% in WOMAC pain (P=0.11), and 27% in total WOMAC (P=0.01). The percent of patients who improved by more than 50% was 38.5 active vs 5.3 placebo in patient global (P=0.01), 43.6 vs 15.8 in patient pain (P=0.04), 38.5 vs 10.5 in WOMAC pain (P=0.03), 28.2 vs 5.3 in WOMAC stiffness (P=0.08), 23.1 vs 5.3 in WOMAC function (P=0.14), and 23.1 vs 5.3 in total WOMAC (P=0.14). Twenty-one percent of placebo and 18% of actively treated patients developed a transient rash at the electrode sites. No other adverse device effects were reported. **CONCLUSION:** A highly optimized, capacitively coupled, pulsed electrical stimulus device significantly improved symptoms and function in knee OA without causing any serious side effects.



Mont MA, Hungerford DS, Caldwell JR, Ragland PS, Hoffman KC, He YD, Jones LC, Zizic TM. Pulsed electrical stimulation to defer TKA in patients with knee osteoarthritis. *Orthopedics*. 2006 Oct;29(10):887-92.

TKA deferral –severe OA patients

Year	TKA deferral	
	BioniCare (103)	Control (42)
1	84%	62%
2	76%	33%
3	69%	24%
4	62%	7%

BioniCare-treated patients 8 times more likely to defer surgery after 4 years!

p<0.0001

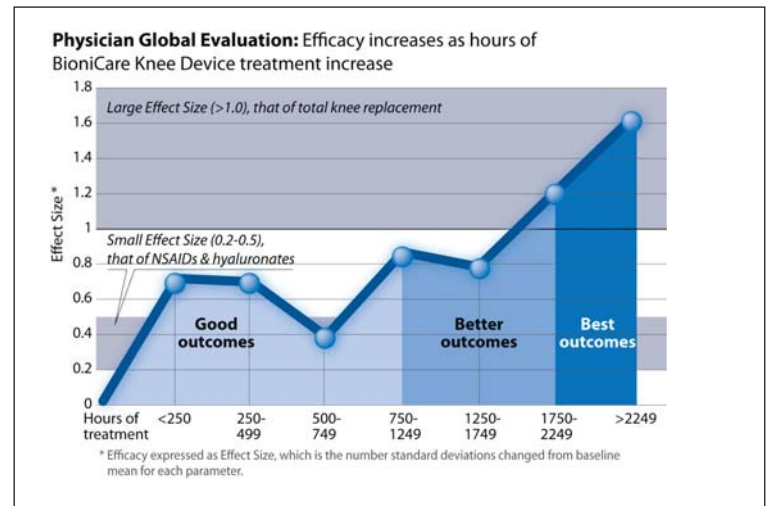
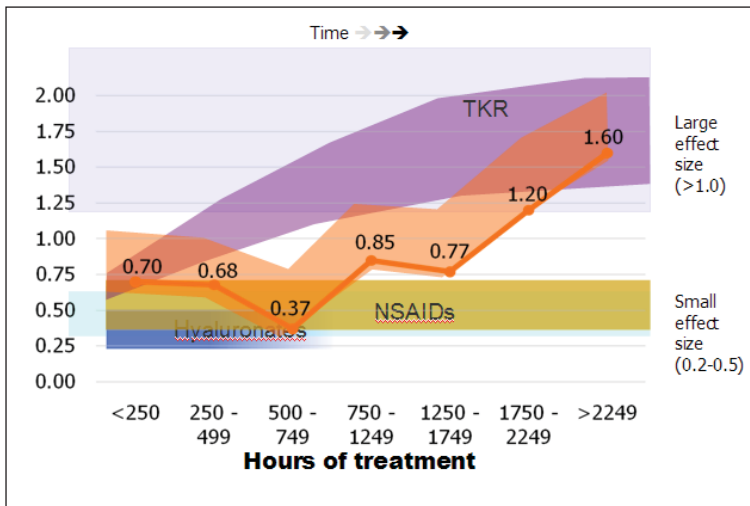
TKA deferral – all patients

Year	TKA deferral	
	BioniCare (157)	Control (101)
1	83%	67%
2	75%	51%
3	65%	46%
4	60%	35%

p<0.001

Farr J, Mont MA, Garland D, Caldwell JR, Zizic TM. Pulsed electrical stimulation in patients with osteoarthritis of the knee: follow up in 288 patients who had failed non-operative therapy. *Surg Technol Int.* 2006;15:227-33.

BACKGROUND: Optimized pulsed electrical stimulation (PES) regulates chondrocyte genes, enhances production of cartilage matrix materials, and inhibits production of matrix catabolic factors. **METHODS:** This prospective, cohort study examined the use of a PES device in treatment of knee osteoarthritis (OA) in patients who had failed non-operative therapy. Primary outcome measures were patient and physician global evaluation, and patient assessment of knee pain. **RESULTS:** This study included 288 (95 men, 193 women) patients who used the device from 16 to more than 600 days (mean: 889 hours). Improvement in all efficacy variables ($p < 0.001$) occurred. A dose-response relationship between effect size and hours of usage was observed as cumulative time increased to more than 750 hours. Improvement in patient or physician global occurred in 59.0% of patients who used it less than 750 hours, and for 73.0% of those who used it more than 750 hours. An economic analysis of a sub-group of patients showed that 45.3% reduced nonsteroidal anti-inflammatory drug (NSAID) use by 50.0% or more. **CONCLUSIONS:** A highly optimized PES device successfully attenuated knee OA symptoms in patients who had failed non-surgical therapy. Less than 250 hours of therapy provided relief, but improvement increased in a dose-response manner after 750 hours of cumulative use.



Lippiello L, Chakkalakal D, Connolly JF. Pulsing direct current-induced repair of articular cartilage in rabbit osteochondral defects. *J Orthop Res.* 1990 Mar;8(2):266-75.

Osteochondral defects in the distal femoral condyles of rabbits exposed to a pulsing direct current exhibits an enhanced quality of repair. The signal, with a peak value of 2 microA repeating at 100 Hz, imposed an electric field in the tissue of 20-60 mV/cm². Maximum efficacy was seen with a shorter period of exposure (40 vs. 160 h) initiated 48 h after surgery for 4 h/day. Repair tissue originated primarily from metaplasia of subchondral elements although hyperplasia of pre-existing chondrocytes at the margins of the defect could be detected. Defects in treated joints contained Safranin O staining material that was histologically similar to a disorganized hyaline cartilage. Central areas of the defects in control animals contained Safranin O-negative material that generally extruded over the surface as a pannus. The edges of nontreated defects also had characteristics of cartilaginous healing, stressing the importance of using serial sectioning techniques in this model of cartilage repair.



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