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Barsi PC*, Mathias-Santamaria IF, Zuppardo ML, Zaniboni E, Santamaria MP, Santamaria-Júnior M

Pós Graduação - CENTRO UNIVERSITÁRIO DA FUNDAÇÃO HERMÍNIO OMETTO.

Não há conflito de interesse

The study carried out an evaluation of low-intensity electric current action in the control of pain intensity and acceleration of tooth movement during orthodontic treatment. Blind randomized controlled clinical trial, with an allocation ratio of 1: 1, with 29 adult patients, of both sexes. Patients were matched by sex, age, degree of dental crowding and divided into a control group (n: 15) and a test group (n: 14). The sequence of orthodontic treatment was followed for 3 months with monthly wire changes (.012", .014", .016" Niti wire) and weekly bioelectrical stimulation (BES) in the experimental group (10 μ A/5min). Pain perception was assessed by the Visual Analog Pain Scale (VAS) at 0h, 24h, 48h and 72h after the installation of each orthodontic wire. The amount of tooth movement was measured by comparing the results obtained using Little's irregularity index. The space gain was significantly greater in the test group compared to the control group ($p < 0.05$) after 2 and 3 months of evaluation. There was also a significant difference in the distribution of the severity of the Little Index between the control group and the test group and between the experimental times ($p < 0.05$). In the .014" wire, the pain perceived by the test group was fewer ($p < 0.05$) in the 24 hours and 48 hours in relation to the control group, as well as in the 24 hours after placing the .016" wire.

Bioelectrical stimulation (BES) has positive effects in accelerating orthodontic tooth movement and decreasing pain perception.



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Clinical Studies and Regulatory Information

The company is awaiting FDA market clearance.

Published Studies

Studies demonstrate that 60% of patients have straight teeth in 3 months, and 100% have straight teeth in 4-6 months.

Launching Stabilization Study

Based on previous laboratory research, it is expected that the study will demonstrate that precisely controlling OPG and TGFb1 protein expressions will significantly reduce relapse of teeth post-treatment compared to historical levels of 30%.

Large Multi-Center Phase II Registry Study

The company is currently recruiting investigators for this study.

Practice Costs, Revenue, and Margin

Shortened treatment time reduces the number of appointments, yet revenue remains the same – increasing gross margin to 75% per patient.

Stimulator Cost	\$200
Mouthpiece Cost	\$50
Programming Cost	Pennies
Avg Aligners Cost	\$1,250
Total	\$1,500
Avg Patient Revenue	\$6,000
Gross Margin	75%

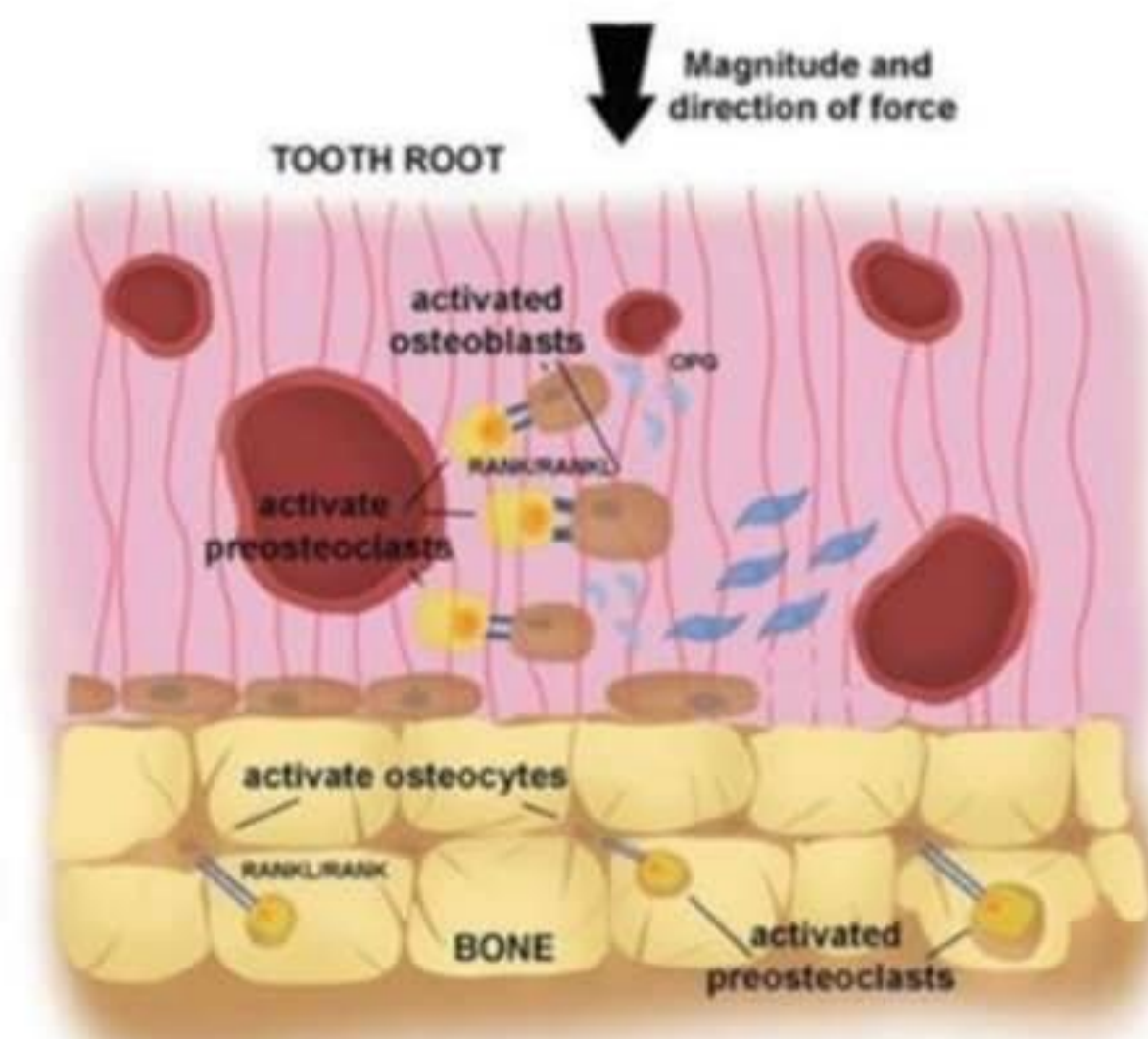


Straighten Teeth in 4–6 Months Instead of 18–24

OrthodontiCell Summary

- OrthodontiCell utilizes patented bioelectric stimulation technology to precisely control the release of RANKL, which accelerates bone demineralization and facilitates rapid tooth movement. Patients can complete treatment in 4 to 6 months instead of 18 to 24+ months.
- Once teeth are in the aligned position, precise control of OPG and TGFb1 proteins stabilize teeth – virtually eliminating relapse.
- The patented OrthodontiCell mouthpiece works over aligners or braces. Treatment takes only 20 minutes twice a week, and patients report 70% less treatment discomfort.

OrthodontiCell is the only system with precise biologic control of RANKL, VEGF and SDF1 to accelerate bone demineralization and tooth movement while OPG and TGFb1 accelerate stabilization after alignment to fundamentally eliminate relapse.



Patents

We believe OrthodontiCell has the strongest patent estate of any company for tooth movement acceleration and stabilization. Over 13 patent claims are issued, pending, licensed, or optioned to control RANKL, VEGF, SDF1, OPG, and TGFb1 protein expressions.

Management Team

John Marchetto, DMD,
President and Co-Inventor

Howard J. Leonhardt, Co-Inventor,
Executive Chairman, and CEO.

Leslie Miller, M.D., Chief Medical Officer,
Cardiologist

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Brian Hardy,
Director of Marketing

Lynn Hammerschmidt, M.A.,
Chief Marketing Advisor



1 Kent Court
Mission Viejo, CA 92694
Phone: 424 291-2133
<https://orthodonticell.com/>

"OrthodontiCell substantially shortens the time it takes to treat patients. There are other products on the market, but they do not provide biologic control of the release of essential cells and proteins to speed up the process of bone demineralization to facilitate tooth movement, so they fall short of being dependable and effective. After treatment, we can stabilize teeth in the straightened position – virtually eliminating relapse – something no other company can claim."

John Marchetto, DMD
President & Co-Inventor

Three Stimulator Options

In-Clinic



Current product configuration – FDA 510K market-cleared benchtop stimulator for improving blood circulation and pain reduction. Signals delivered via comfortable mouthpiece.



Portable **Need better Photo or use generic below**



Handheld home-use stimulator runs the signaling program with simple push button activation. Uses same comfortable mouthpiece.

Micro-Mini



In development – elegant third generation Micro-Mini stimulator is embedded into the mouthpiece, no other equipment required.