

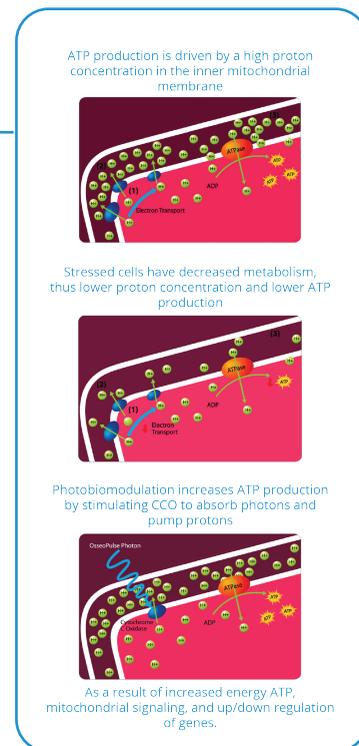
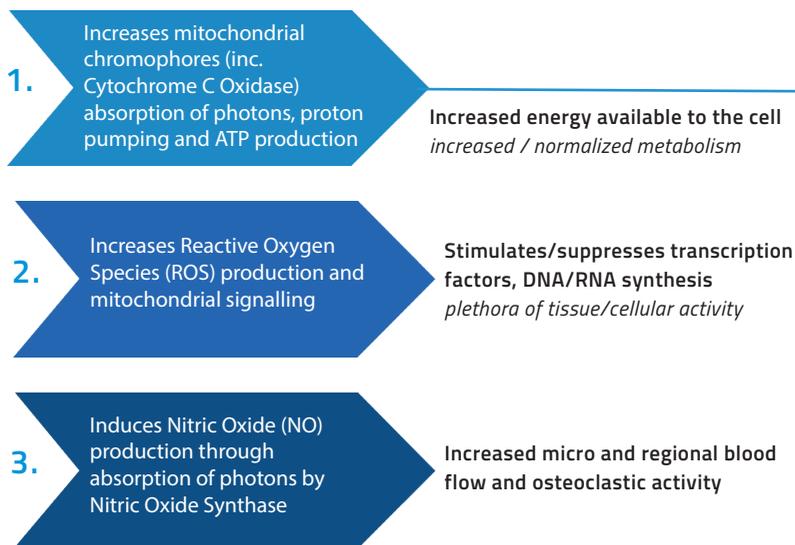
OrthoPulse® is a Class 2 medical device and has received FDA clearance, CE Mark and regulatory approval in over 40 countries. The OrthoPulse® device is intended to accelerate orthodontic movement of teeth and reduce the overall treatment time for patients. The device is designed to be used in conjunction with traditional orthodontic treatment with brackets and wires or aligners.

## The Science of Photobiomodulation

The application of therapeutic light in the near infrared wavelength (800 - 1000 nm) has been shown to produce beneficial biological effects in stressed and ischemic tissue (3000+ published peer-reviewed articles). Mitochondrial enzymes absorb these photons and increase the production of Adenosine Triphosphate (ATP, "energy"), allowing enhanced tissue metabolism.<sup>†</sup>

In 1903, Niels Ryberg Finsen won the Nobel Prize in Medicine in recognition of his contribution to the treatment of diseases with concentrated infrared and red light. Otto Warburg then went on to win the Nobel Prize in Medicine in 1931 for discovering Cytochrome c Oxidase (CCO), the terminal enzyme in the mitochondrial oxidative respiration chain. He demonstrated that the mitochondrial CCO was responsive to light stimulation.

## Photobiomodulation Mechanisms of Action



## Light Accelerated Orthodontics™

OrthoPulse® photobiomodulation enhances and accelerates bone and soft tissue remodeling leading to faster tooth movement and decreased orthodontic treatment time. Biolux Research has and continues to sponsor and support research at leading research institutions including:

- Forsyth Institute, *Harvard University affiliate*, USA
- University of Southern California, USA
- Tufts University, USA
- University of Alberta, Canada
- University of Alabama, USA
- Boston University, USA

<sup>†</sup> Hamblin M. Mechanisms and applications of the anti-inflammatory effects of photobiomodulation. *AIMS Biophys.* 2017; 4(3): 337–361.

## ORTHOPULSE® EVIDENCE

### Clinical Research

#### Fixed Appliances

- No clinically significant root resorption<sup>1,2,3</sup>
- 54% reduction in time to achieve anterior alignment
- 46% increase in rate of space closure in adults<sup>4</sup>
- 73% reduction of peak pain compared to sham-controls<sup>5</sup>
- Two-fold faster rate of tooth movement during alignment<sup>3,6</sup>

#### Aligners

- 63% reduction in the average time per aligner during OrthoPulse® treatment as compared to conventionally recommended aligner wear time<sup>7</sup>
- No measurable root resorption in 6 months<sup>7</sup>

#### Case Reports

- OrthoPulse® use allowed for faster aligner change rates compared to conventional protocol<sup>8</sup>
- Two long-distance patients, unable to attend frequent and regular appointments, achieved excellent results at a reduced overall treatment time when using OrthoPulse®<sup>9</sup>
- A patient using OrthoPulse® changed aligners every 3 days throughout treatment and achieved successful results<sup>10</sup>

### Cellular Research

- Increased gene expression in human cells<sup>11</sup>
- Increased proliferation of gingival fibroblasts and endothelial cells<sup>12</sup>
- Increased proliferation and mineralization of human osteoblasts<sup>13</sup>

### Animal Research

- 3.3-fold faster rate of tooth movement<sup>14</sup>
- 80% less root resorption<sup>15</sup>
- Increased mature bone in expanded sutures<sup>16</sup>
- Lower failure rate of immediately loaded temporary anchorage devices (TADs)<sup>17</sup>
- Increased mandibular growth stimulation<sup>18</sup>
- Less relapse following photobiomodulation during active tooth movement phase<sup>19</sup>

<sup>1</sup> Nimeri et al. The effect of photobiomodulation on root resorption during orthodontic treatment. *Clin Cosmet Investig Dent* 6:1-8.

<sup>2</sup> Shaughnessy et al. Intraoral photobiomodulation-induced orthodontic tooth alignment: a preliminary study. *BMC Oral Health*, 2016. 16:3.

<sup>3</sup> Al Okla N, Bader DM, Makki L. Effect of photobiomodulation on maxillary decrowding and root resorption: A randomized clinical trial. *APOS Trends Orthod* 2018;8:86-91.

<sup>4</sup> Samara et al. Velocity of orthodontic active space closure with and without photobiomodulation therapy: a single-center, cluster randomized clinical trial. *Laser Dent Sci* (2018) 2:109-118.

<sup>5</sup> Al-Okla N, Ferguson D et al. Pain perception of photobiomodulation treated and sham-controlled patients undergoing orthodontic treatment: ARCT. *Data on file*.

<sup>6</sup> Kau CH, et al. Photobiomodulation accelerates orthodontic alignment in the early phase of treatment. *Prog Orthod*. 2013 Sep 19;14:30.

<sup>7</sup> Dickerson, T. A randomized controlled crossover trial on the effect of OrthoPulse® on the rate of orthodontic tooth movement during alignment with Invisalign® aligners. *Data on file*.

<sup>8</sup> Dickerson, T. Invisalign with Photobiomodulation: Optimizing Tooth Movement and Treatment Efficacy with a Novel Self-Assessment Algorithm. *J Clin Orthod*, 51(3):157-165.

<sup>9</sup> Shaughnessy, T. Long distance orthodontic treatment with adjunctive light therapy. *J Clin Orthod*, 2015. 12:757-69.

<sup>10</sup> Ojima, K, Dan C, Kumagai Y, Schupp W. Invisalign Treatment Accelerated by Photobiomodulation. *J Clin Orthod*. 2016;50(5):309-17.

<sup>11</sup> Guo et al. Visible red and infrared light alters gene expression in human marrow stromal fibroblast cells. *Orthod Craniofac Res*. 2015 Apr; 18(0 1): 50-61.

<sup>12</sup> Iscan et al. Photobiostimulation of gingival fibroblast and vascular endothelial cell proliferation. Presented Turkish Society of Orthodontics, 2014 Ankara, Turkey.

<sup>13</sup> Le et al. Human Osteoblast Response to Low-Level Laser Treatment. Presented at IADR 2015 General Session. Boston, MA. March 14, 2015.

<sup>14</sup> Chiari S et al. Photobiomodulation-Induced Orthodontic Tooth Movement. *Data on file*.

<sup>15</sup> Ekizer A et al. Effect of LED-mediated-photobiomodulation therapy on orthodontic tooth movement and root resorption in rats. *Lasers Med Sci*. 2015 Feb;30(2):779-85

<sup>16</sup> Ekizer A et al. LED photobiomodulation: effect on bone formation in orthopedically expanded suture in rats-early bone changes. *Lasers Med Sci*. 2013 Sep;28(5):1263-70

<sup>17</sup> Uysal T et al. Resonance frequency analysis of orthodontic miniscrews subjected to light-emitting diode photobiomodulation therapy. *Eur J Orthod*, 2012 Feb; 34(1):44-51.

<sup>18</sup> El-Bialy T. et al. The effect of light-emitting diode and laser on mandibular growth in rats. *Angle Orthod*. 2015 Mar;85(2):233-8. doi: 10.2319/030914-170.1.

<sup>19</sup> Kantarci A, Pamuk F. Photobiomodulation and orthodontic relapse. Forsythe Institute, Cambridge, MA. *Data on file*.

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