

Additional Information for Doctors and Patients in the United States and Hong Kong

1. Introduction

1.1 About OrthoPulse®

OrthoPulse® may accelerate orthodontic tooth movement through the use of photobiomodulation with near-infrared light. OrthoPulse® uses Light Emitting Diodes (LEDs) to produce therapeutic light in the near-infrared spectrum.

OrthoPulse® is used in conjunction with regular orthodontic appliances, such as braces or aligners, and is prescribed to you by your dentist or orthodontic professional.

WARNING: Different results may be achieved for different patients and different orthodontic appliances (e.g., aligners, brackets/wires).

1.2 Intended Use / Indications for Use

The OrthoPulse® device is intended for use during orthodontic treatment. It is used in conjunction with brackets and wires or aligners and helps facilitate minor anterior tooth movement.

OrthoPulse® is operated under prescription by your orthodontist or dentist. Your prescribing orthodontist or dentist is your best resource for information regarding your orthodontic treatment and the OrthoPulse® device. Your orthodontist or dentist should assess the fit of your orthodontic appliance (aligners or brackets and wires) at every follow up visit to ensure that your teeth are progressing at an appropriate rate, including assessments of pressure, pain, air gaps, etc., as applicable.

Please direct questions regarding your orthodontic treatment plan toward your prescribing orthodontist or dentist. Biolux Research is not authorized and unable to make representations related to patient-specific treatment and/or provide orthodontic treatment advice.

WARNING: OrthoPulse® is a single patient prescription device. OrthoPulse™ should not be used by multiple patients. Use by an individual without the proper issuance from an orthodontist may result in unintended consequences, including the possible transmission of viral and bacterial infective agents.

1.3 Contraindications for Use

- Use of osteoporosis drugs
- Use of drugs that may cause photosensitivity
- Photosensitivity
- Poor oral hygiene
- Acute oral infection or periodontal disease
- Epilepsy

A medical professional should be consulted prior to use if any of these situations are suspected.

2. Clinical Evaluations of OrthoPulse®

Clinical testing of the OrthoPulse® device with orthodontic treatment demonstrated that the device may accelerate tooth movement and may decrease treatment time. Two primary clinical studies of the intra-oral OrthoPulse® demonstrated device performance for its intended use; the device may accelerate orthodontic movement of teeth and may reduce the overall treatment time for the patient when used in conjunction with traditional orthodontic treatment with brackets and wires or aligners.

In a cross-over study where subjects served as their own control, 21 subjects (mean age 34.9 years) who used OrthoPulse® with aligners were evaluated. Eligibility criteria included requiring that the subjects have permanent dentition, mild to moderate

crowding with no labiolingually displaced teeth, Class I or Class II by 1/2 cusp or less, good oral hygiene, and be non-smoking. Subjects who were pregnant, enrolled in another study, had periodontally involved teeth, used bisphosphonates during the study or had spaces between anterior teeth were excluded. Perimeter measurement analysis was used to evaluate each patient's rate of tooth movement during baseline and OrthoPulse® periods in the mandibular arch. The degree of external apical root resorption was also investigated. Study subjects were followed from the start of orthodontic aligner treatment for 6 months. Results demonstrated statistically significant faster tooth movement compared to baseline ($p=0.024$), achieving the primary effectiveness objective of the study. There were no serious adverse events, and no root resorption, gingival recession or pathological tooth mobility reported throughout the study.

OrthoPulse® was also evaluated in conjunction with brackets and wires in a controlled study of 33 subjects (mean age 25.0 years). Matched controls (based on subjects' age, initial crowding, eligibility criteria) were retrospectively selected before any data analysis of the OrthoPulse® subjects. Eligibility criteria included requiring that the subjects have permanent dentition, mild to moderate crowding with no labiolingually displaced teeth, Class I or Class II by 1/2 cusp or less, good oral hygiene, and be non-smoking. Subjects who were pregnant, enrolled in another study, had periodontally involved teeth, used bisphosphonates during the study or had spaces between anterior teeth were excluded. There were no differences between groups in terms of gender, ethnicity, age, and initial crowding. The rate of tooth movement was measured using the change in Little's Irregularity Index measurements in both groups to evaluate OrthoPulse® use with

fixed orthodontic appliances. Root resorption was determined by use of panoramic dental X-rays collected before treatment and after 6 months of treatment. Results demonstrated that subjects treated with OrthoPulse® showed a statistically significantly faster rate of tooth movement ($p<0.001$) compared to the control group, achieving the primary effectiveness objective of the study. There were no serious adverse events, and no gingival recession or pathological tooth mobility reported throughout the study. Data demonstrated the absence of external apical root resorption with OrthoPulse® use, and that there is no device effect of accelerated tooth movement on tooth root integrity.

Several additional clinical studies were also conducted with prototype and final OrthoPulse® devices to supplement the clinical findings observed in the primary studies, and results consistently confirmed device performance for its indicated use.

Therefore, results from the clinical studies demonstrate that subjects treated with OrthoPulse® achieve statistically significantly faster rates of tooth movement than control. The amount of change in an individual's tooth movement rate during OrthoPulse® daily treatment may be dependent upon their specific biology and treatment plan. For clear aligners, only Invisalign brand aligners have been examined with daily OrthoPulse® use. Results with other brands of aligners may vary.

For further information about the clinical benefits and supporting research, visit orthopulse.com.

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