Docket #: S20-382

Nonsurgical Split Orthodontic Airway Plates (S-OAP) for infants

This invention is an intraoral palate expanding plate with an expansion screw for both cleft palate and restricted airways that can be produced by 3-D printing and CT scans.

Worldwide, about 1 in 700 babies is born with a cleft palate and about 1 in 8000 babies is born with restricted airway such that they are not able to breath or take milk. These issues are typically treated surgically, but the issues have a higher incidence rate in developing nations where the patients can't afford surgery and there are few doctors with the requisite experience. Palate plates can also be used for treatment (like a more robust retainer) to help guide the growth of the developing palate, lower jaw, and tongue, which minimizes the need for surgery. However, such a treatment requires significant effort and skill from the orthodontist to develop these plates repeatedly to accommodate the facial growth of infants since the plate needs to be worn for several months to complete the treatment. This procedure requires obtaining new oral imprints and adjusting the plates under wake nasopharyngoscopy periodically.

The invention addresses these needs with the split palatal plate system using simple expansion screw design that can enlarge the plate precisely and quickly without repeating intraoral imprints and plate adjustments. The invention further enables fabrication of a serious of custom palatal plates to accomodate the baby's facial growth via pre-treatment intraoral scan, face CT scans, and/or face MRI scans, utilizing 3D printing technology. 3D printing technology with automatic detection of size and dimensions of the pharyngeal component will be able to eliminate the need of the expansion screw because a series of plates can be printed in gradually larger sizes. This way, this treatment can reach infants in remote locations with no easy access to the treatment.

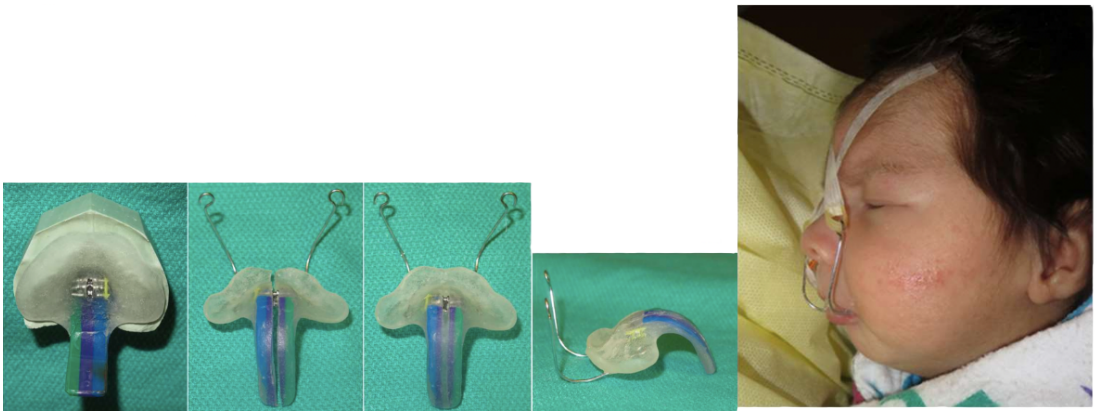


Figure description - example of how a Split Orthodontic Airway Plate (S-OAP) can be enlarged when the plate needs to get bigger to accommodate the baby's facial growth. the OAP is split in half, the expansion screw is turned a few times to enlarge the palatal plate, then the gap is filled up using splint acrylic. The plate is thoroughly polished to prevent any oral irritation prior to inserting inside the baby's mouth and throat. When another enlargement is needed in a few weeks, this split and seal process is repeated. A profile view of baby patient wearing the device is shown.

Image Credit-inventor

Stage of Development

- Clinical Trials
- Clinical research on face CT analysis of Robin babies to identify average length and angulation of the intrapharyngeal component of the S-OAP to serve as the first trial plate with 3D printing technology.
- Clinical research on growth of the maxillary arch of infants with cleft palate or Robin Sequence

Applications

- **Infants with cleft palate, Robin sequence, glossoptosis, obstructive sleep apnea, and airway obstruction**
- **Newborn patients** with small jaw and glossoptosis who require mandibular distraction osteogenesis surgery or tracheostomy surgery due to their obstructive apnea and feeding difficulties

Advantages

- **Customized fabrication providing absolute comfort** to babies while wearing the plate
- **Can be adjusted** to accommodate babies' facial growth over 3-6 months of wearing device without re-imprinting and re-adjusting, which are extremely time-consuming and uncomfortable to babies. Currently, a new device needs to be re-made to accommodate facial growth
- **Can potentially avoid surgery**
- **Easy fabrication**
- **Low cost and easy to create** – can be applicable to developing countries

Publications

- HyeRan Choo, Rohit K. Khosla, Kara D. Meister, Derrick C. Wan, Hung-Fu C. Lin, Robert Feczko, Karl Bruckman, Elena Hopkins, Mai Thy Truong, and Hermann P. Lorenz. "Nonsurgical Orthodontic Airway Plate Treatment for Newborns With Robin Sequence." *The Cleft Palate-Craniofacial Journal* (2021): 10556656211007689.
- Darren B. Abbas, Christopher Lavin, Evan J. Fahy, HyeRan Choo, Mai Thy Truong, Karl C. Bruckman, Rohit K. Khosla, H. Peter Lorenz, Arash Momeni, and Derrick C. Wan (2021) "A Systematic Review of Mandibular Distraction Osteogenesis vs. Orthodontic Airway Plate for Airway Obstruction Treatment in Pierre Robin Sequence". Cleft Palate Craniofac J. (In Press. Accepted 3/17/2021) Manuscript # CPCJ-21-0011.R1.

Patents

- Published Application: WO2022126002
- Published Application: 20230310198

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