Assessment of morbidity following insertion of fixed preoperative orthopedic appliance in infants with complete cleft lip and palate

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Objective. To examine physiologic and behavioral indicators of pain within the first 24 hours following insertion of the fixed presurgical orthopedic appliance (FPOA) under general anesthesia in infants with unilateral and bilateral complete cleft lip and palate.

Methods. The study sample included 109 infants who had either a dentomaxillary appliance (DMA) or an elastomeric chain premaxillary retraction (ECPR) appliance. Vital signs and FLACC (Face, Legs, Activity, Cry, Consolability) scores were used to measure the outcomes.

Results. There was an initial postoperative increase in the median heart rate. Heart rate returned to the median baseline level by 8 hours. The median systolic blood pressure increased postoperatively and remained elevated throughout the time of evaluation. The median respiratory rate remained below that at baseline throughout the study period. The highest mean change in FLACC measurements was observed approximately 2 hours postoperatively. By 3 hours postoperatively, the scores decreased.

Conclusions. Although there was a large individual variability, the FLACC scores became reduced after 3 hours following surgical insertion of the DMA and the ECPR appliance. (Oral Surg Oral Med Oral Pathol Oral Radiol 2015;119:278-284)

Clefts of the lip, alveolus, and palate are the most common congenital anomalies of the craniofacial skeleton. The incidence of cleft lip and palate (CLP) is 0.664 per 1000 births.[1] In the United States, the incidence of CLP has been reported to be about 1 in 600 births.[2] According to the U.S. Centers for Disease Control and Prevention, about 2650 babies are born in the United States with cleft palate, and 4440 babies are born with cleft lip with or without cleft palate each year.[2,3] Treatment objectives for patients with CLP include restoration of normal function and esthetics. Several treatment modalities are in use for treating CLP before lip repair, and these include using nasoalveolar molding appliances, facial taping, passive appliances, and fixed Latham-type dentomaxillary appliances.[4-7] The goal of preoperative infant orthopedic therapy (PSOT) is to improve the position and/or shape of the cleft maxillary alveolar ridges before lip repair. Although alveolar segments are the primary target, overlying soft tissues are also affected, resulting in the closer proximity of the lip segments and, to a lesser extent, the base of the nose. The efficacy of PSOT has been widely debated, and evidence so far has been mixed.[8] Proponents of PSOT claim that significantly better outcomes could be achieved from a surgical perspective when the initial deformity is mild, or reduced to a more minimal state, rather than severe. Studies originating from the Eurocleft and Dutchcleft data have shown that the benefits realized from PSOT are short term at best and that there are no long term benefits.[9-11]

PSOT can be accomplished by using a fixed presurgical orthopedic appliance (FPOA) by means of a stainless steel pin–retained, Latham-type appliance over the maxillary processes.[5,12] Very few craniofacial centres across the world use FPOA in infant orthopedic treatment. The general perception is that FPOA is associated with increased morbidity and associated complications resulting from the use of general anesthesia. However, the outcomes associated with FPOA treatment are predictable.

Statement of Clinical Relevance

Preoperative orthopedic therapy in infants with unilateral and bilateral complete cleft lip and palate can be accomplished with dentomaxillary and elastomeric chain premaxillary retraction (ECPR) appliances without causing excessive levels of pain.

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The FPOA has been the PSOT of choice at the Boston Children's Hospital for over 20 years. There is a paucity of published studies documenting the physiologic or behavioral indicators of pain in infants who have had PSOT with FPOA. The objective of the present study is to examine the physiologic and behavioral indicators of pain within the first 24 hours following insertion of the FPOA under general anesthesia in infants with unilateral and bilateral complete cleft lip and palate.

MATERIALS AND METHODS

Study design and institutional review board approval

The present study is a retrospective analysis of hospital discharge data from a single-cleft treatment centre. The patients were infants who underwent PSOT with FPOA at the Boston Children's Hospital between January 2005 and June 2012. Before the study was started, approval was obtained from the Committee on Clinical Investigation of the Boston Children's Hospital.

Patients

The inclusion criteria for this study were infants who, due to the severity of their unilateral or bilateral CLP deformity, required PSOT with FPOA between January 2005 and June 2012 and subject ages under 12 months at the time of insertion. All infants who were hospitalized 2 or more weeks before insertion of the FPOA and those with a confirmed or suspected diagnosis of a syndrome at the time of FPOA placement were excluded from this study. Patients with unilateral (UCCLP) and those with bilateral cleft lip or palate (BCCLP) were both included. Infants with UCCLP had a pin-retained dentomaxillary appliance (DMA), whereas those with BCCLP had an elastomeric chain premaxillary retraction (ECPR) appliance. The final sample comprised 109 healthy infants (75 males, 34 females). The group was further divided into those who had ECPR appliances (20 males, 7 females) and those who had treatment with the DMA (55 males, 27 females).

Treatment protocol

Appliance protocol. At the Boston Children's Hospital, the Latham-Millard protocol is followed for treating patients with UCCLP and BCCLP. Initial maxillary arch impressions were obtained from infants with UCCLP, who were at least 2 weeks of age. The DMA (Figure 1) and the ECPR appliance (Figure 2) are custom fabricated in a laboratory and surgically inserted under general anesthesia. In the present study, the age at insertion of the DMAs for the study cohort ranged from 9.9 weeks to 13.7 weeks, and the age at insertion of ECPR appliances ranged from 12.4 weeks to 18 weeks of age. Both the DMA and the ECPR appliance are retained by four stainless steel pins that are approximately 18 mm in length. The ECPR appliance also includes a transvomer pin, with elastomeric chains running posteriorly from this pin to retract the premaxilla. Following surgical placement of the appliance (either DMA or ECPR appliance), the patient is typically hospitalized overnight and discharged the following day after ensuring that the infant is feeding well and voiding normally and that there are no issues with the appliance. The patient

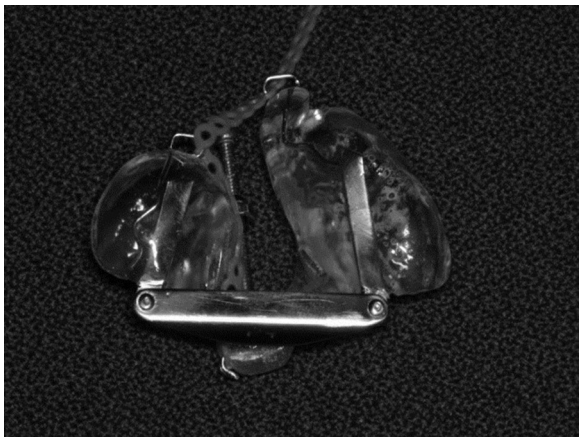

Fig. 1. Dentomaxillary appliance (DMA).

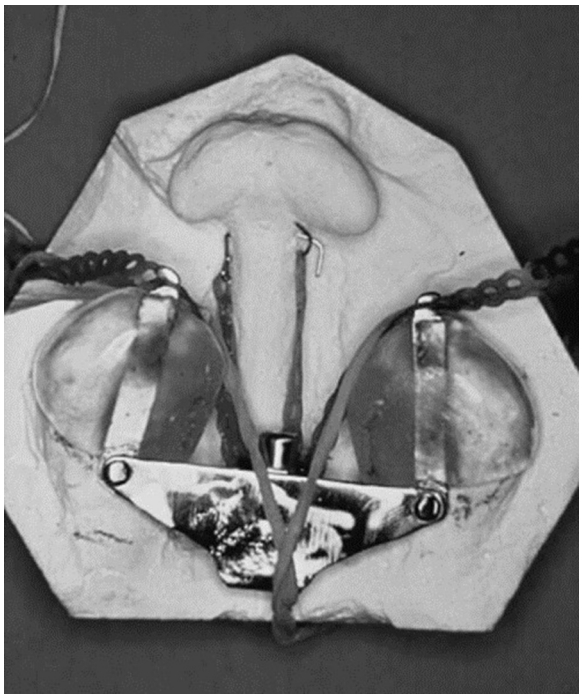

Fig. 2. Elastic chain premaxillary retraction (ECPR) appliance.