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**AAO Foundation Final Report Form**  
(a/o 6/30/2020)

Type of Award, Biomedical Research Award,

Name(s) of Principal Investigator(s): Stephen Yen, Xuanyu Lu

Institution: Children's Hospital Los Angeles/ University of Southern California

Title of Project:

Predictors of Successful Alveolar Bone Graft Outcomes: a retrospective study using cone beam tomography:

Period of AAOF Support: 07-01 17 to 10-30-20

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Amount of Funding: \$30,000.00

## Summary/Abstract:

### **Evaluation of bone graft outcome in early versus late age group in complete unilateral cleft lip and palate**

#### OBJECTIVE

The purpose of this study was to compare the outcomes of alveolar bone grafting (ABG) in an early age group (7-year-old) to the traditional late age group (11-year-old) of patients with complete unilateral cleft of lip and palate.

#### METHODS

Under an IRB-approved protocol, 49 non-syndromic complete unilateral cleft lip and palate children who received alveolar bone graft between April 2018 to January 2020 at Children Hospital of Los Angeles were enrolled into this study. Two ages for bone grafting were compared. Patients in the early alveolar bone graft (E-ABG) group (21 patients, eight female 13 male) were operated at a mean age of 6.8 years (range 4.7 to 8.3) before the cleft-adjacent permanent incisor completed dental eruption. Patients from the late alveolar bone graft (L-ABG) group (28 patients, 11 female 17 male) were operated on at a mean age of 10.7 years (range 8.8 to 14.9) after the cleft-adjacent permanent incisor completed eruption and before the canine erupted. Two types of graft material were used for ABG: iliac crest bone (ICB, n=21) and bone morphogenetic protein-2 with a demineralized bone matrix (BMP2/DBM, n=28). All patients were evaluated by Cone Beam Computed Tomography (CBCT) before (average 3.4 month) and after (average 9.2 months) bone graft surgery. Based on 3-dimensional data, pre-operative cleft width, and post-graft bony bridge were analyzed and rated for thickness of the bony bridge, incisor root length, periodontal bone height on cleft-incisor and mesiodistal rotation of cleft-incisor using Dolphin Imaging software. The Bergland scale used three-dimensional CBCT to assess bone graft outcomes. A Student t-test was used for quantitative comparisons.

#### RESULT

The initial alveolar cleft width is significantly smaller in E-ABG group (n=21, mean  $5.35 \pm 1.90$  mm) compared with L-ABG group (n=28, mean  $6.58 \pm 2.03$  mm,  $p=0.035$ ). The overall Bergland scale scores were  $1.69 \pm 0.96$  (n=21) and  $2.54 \pm 1.20$  (n=29) in the E-ABG and L-ABG group, respectively ( $p=0.009$ ). The graft outcome is not associated with the type of graft materials used. The ICB group (n=28) had a mean score  $2.18 \pm 1.13$  and BMP2 group (n=21) had a mean score  $2.02 \pm 1.16$ ,  $p=0.642$ . The L-ABG group presents with a higher rate of failure (32.14%) compared with E-ABG group (14.29%). The thickness of the bony bridge in the early bone graft group ( $6.01 \pm 2.15$  mm) is 71.4% higher than the late bone graft group ( $3.5 \pm 1.8$  mm,  $p<0.0001$ ). The periodontal bone loss from cemento-enamel junction to alveolar bone was measured along the distal side of the cleft-adjacent incisor: the E-ABG group was  $6.88 \pm 2.27$  mm in contrast to  $8.84 \pm 2.87$  mm in L-ABG group ( $p=0.012$ ). The percentage of periodontal bone coverage on the root of cleft-adjacent incisors is higher in E-ABG group ( $80.85 \pm 18.61\%$ ) compared to L-ABG group ( $66.69 \pm 19.89\%$ ) ( $p=0.029$ ). There is no statistical difference in mesiodistal rotation of cleft-related incisor between the early bone graft group (mean  $33.04 \pm 21.43$  degree) and late bone graft group (mean  $39.37 \pm 18.88$  degree) ( $p>0.05$ ).

**CONCLUSION** These results suggest that, for patients with complete unilateral cleft of lip and palate, the alveolar bone graft at the early age of 7 has a better graft outcome than traditional late bone grafts. In addition, there is better periodontal bone support for the cleft-adjacent incisor

compared to the late age graft group at 11 years.

Detailed results and inferences:

Prior to this study, we showed in a pilot study described in our progress report that there was an association between negative late graft outcomes and teeth already in the cleft site below the mucosa before the bone graft was performed. This study on early vs. late bone grafting is clinically important because the study describes a possible solution for improving graft outcomes by shifting the timing of the bone grafts to an earlier age before incisor eruption. The results from this study support the use of early bone grafts when incisors are poised to erupt into the alveolar cleft site. The early graft outcomes were better than traditional late graft outcomes. This study also sets up another study on the periodontal health of teeth that are adjacent to the cleft site. Our data suggest that early bone grafting will also improve the periodontal condition of these teeth. We will continue to study what variables are an indication for successful early vs. late bone graft.

Respond to the following questions:

1. Were the original specific aims of the proposal realized? We did develop a collaboration with the University of Iowa and developed a standardization of records for future studies. However, our collaborator, Dr. Allareddy moved to the University of Illinois and Dr. MinKyeong Lee, at USC resigned from her job at Children's Hospital Los Angeles/ USC after she gave birth to her first child. The study took longer to complete under Dr. Yen and our new faculty member, Dr. Xuanyu Lu., the new co-PI. The scientific goals were realized and completed. The collaborative goals are in place. The faculty support goals were realized by transferring the support from Dr. Lee to Dr. Lu.
2. Were the results published? We just finished analyzing the data and will prepare this work for publication. We will certainly acknowledge the AAOF support for this study. We are planning to submit this work to the Cleft Palate-Craniofacial Journal. Dr. Lu will be the first author, Dr. Yen will be the senior author. We will include surgeons and a fellow who conducted the association study.
3. Have the results of this proposal been presented? We will present the results at the American Cleft Palate and Craniofacial Association and American Association of Orthodontists. In order to be eligible to present similar data at two different meetings, we will add the preliminary data to one of the abstracts to make the presentations different.
4. To what extent have you used, or how do you intend to use, AAOF funding to further your career? This grant provided research support to Dr. Lu, a new faculty member at USC. The support has helped Dr. Lu to develop his area of research as a new faculty member. He plans to continue this study and apply for NIDCR funding to determine the optimal recommendations for early bone grafting based on early CT analysis.

Accounting for Project: i.e., any leftover funds, etc.

There are no leftover funds.

We used the funds to pay for cone beam CTs, to purchase equipment and software for this study that will also be used for future studies by Dr. Lu and Dr. Yen. Some support was used to pay for part-time help to collect and organize the data for analysis.