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Research Article

Assessing the Outcome of Low-Level Laser Therapy on Bone Formation After SABG in Patients with Cleft Palate

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Abstract

To evaluate if application of Low-level laser therapy at the site of the surgical wound created during Secondary Alveolar Bone Grafting, would alter the rate of bone formation in the cleft alveolus in cleft lip and palate patients.

Keywords: Cleft Palate; SABG; LASER; Orthodontics; Pain; Bone Density

Abbreviations

SABG: Secondary Alveolar Bone Grafting; RVG: Radiovisiography; USG: Ultrasonography; CT: Computed Tomography; CBCT: Cone Beam Computed Tomography; LLLT: Low Level Laser Therapy; RME: Rapid Maxillary Expansion; BMD: Bone Mineral Density

Introduction

The goal of cleft care is to reduce the total treatment time by optimizing the outcome and benefit of each essential intervention. The secondary alveolar bone grafting procedure (SABG) is performed between the age of 9 to 11 years to coincide with dental development, most notably of the cleft side permanent canine. Secondary alveolar bone grafting using iliac crest was introduced by Boyne and Sands in 1972 [1] and is now part of the routine cleft care schedule.

The success of SABG procedure is determined by evaluating the cleft region before and after the surgical grafting procedure. Different imaging modalities including conventional radiographs [2] , Radiovisiography (RVG) [3], Ultrasonography (USG) [4], Computed tomography (CT) [5] , and Cone beam computed tomography (CBCT)[6] have been utilized to appraise the success of grafting [7]. Conventional radiography as a tool has been highlighted by the Clinical Standards Advisory Group Cleft lip and Palate audit of cleft services in the United Kingdom [8]. Presently RVG is widely used in everyday dental practice and is easily available and most importantly it has minimal radiation exposure [9]. Also measurements of density, length of root, and thickness of alveolar bone can be assessed [3] . Talaiepour., *et al.* in his study on assessment of intrabony defects showed that alveolar bone length measurements with help of RVG gives accurate results [10].

Boyne and Sands [1] claimed that the grafted bone was capable of responding physiologically to orthodontic tooth movement. Orthodontic treatment after SABG is usually started once the bone has obtained optimum density, which can take up to 6 months and contributes to the overall duration of the treatment protocol. However, there are no studies which investigates the optimal timing for the initiation of orthodontic treatment after secondary alveolar bone grafting surgery. Various studies have shown that application of low level laser accelerates tooth movement and bone support. With respect to the bone, LLLT (Low Level Laser Therapy) has been proved to modulate inflammation, accelerate cell proliferation and promote healing [11]. LLLT has a wide range of effects at the molecular, cellular, and tissue levels. Histopathological studies in animals with bone fractures and rapid maxillary expansion (RME) receiving LLLT has revealed increase in fibroblast proliferation and amount of osteoid tissue, suggesting faster ossification and increased bone mineral density (BMD).

The benefits of LLLT could be applied in cleft patients undergoing SABG. Since LLLT is non-invasive and inexpensive it was decided to investigate if LLLT could accelerate bone formation in cleft region after SABG [7]. Accelerating bone formation would promote/aid the eruption of the tooth through the graft and thus reduce overall active treatment time. The primary objective of this study

was to evaluate if application of Low-level laser therapy at the site of the surgical wound would alter the rate of bone formation in the cleft alveolus after SABG in cleft lip and palate patients.

Materials and Methods

Patients with cleft lip and palate who had visited the Department of Head and Neck, for SABG were selected for this study. The research protocol was approved by the institutional research board for ethical issues.

Inclusion criteria

- Patients with cleft lip and palate
- Age between 8-11 years.

Exclusion criteria

- Patients with any syndromes, cardiac diseases
- Repeated SABG which affected the bone density

Protocol

Since there have been no studies evaluating the effect of LLLT on bone density in cleft patients after SABG this is considered a pilot study. There were 12 patients in total. 6 were in the laser applied group which is referred to as group A. The control group had 6 patients which is referred to as Group B.

Prior to SABG an RVG-S (Radiovisiography) of the cleft site was taken for all the patients. The RVG-S (Radiovisiography) were also taken at three weeks, one month, two months, four months and six months after SABG [3,12]. The RVG-S dynamic range is 8.6 times narrower than conventional x-ray films which made it possible to take the RVG's at these frequent intervals. The radiographic technique was standardized for all patients, allowing comparison of images from same subjects at different time points. A putty impression material was placed beneath the intraoral positioner and the patient was asked to bite on the impression material. This method helped to record the edges of lower incisors which served as a guide to standardise each radiograph [12].

This study used a Denlase diode laser emitting an invisible laser with a wavelength of 830 nm, power (P) of 100 mW, GaAlAs active medium, and 0.06 cm^2 tip diameter. The Denlase utilizes a solid-state diode as a laser energy source, and the energy is delivered to the operating area by means of a flexible fibre connecting the laser source and the hand piece. Each patient had 6 laser treatment sessions in total – this was initiated a day before surgery and continued for five days after the surgery. The protocol was to discharge patients on the fifth postoperative day but if they were discharged prior to the fifth day, they were advised to visit the clinic for further laser application. Three laser applications were performed at each treatment session (1 dose per point). The laser was operated in continuous mode for 3 minutes at each point, making a total of 9 minutes. The energy delivered per point was 18J, making a total of 54J per session.

At the region of least bone present the mid-point was marked and from the midline two points were marked on either side, i.e.: one point in the middle and two points on either side (3mm away from the mid-point) [12] (Figure 1).

Figure 1

Laser was applied intra orally with the patient in supine position as shown Figure 2. The patient was made to rinse the mouth thoroughly before application of the laser to remove any food debris if present.

Figure 2

Images were acquired with SOPIX Digital x-ray system, by the same radiology technician. The images were captured by a CMOS sensor attached to the intraoral positioner and processed by SOPRO imaging software for Windows. All images were captured in grey scale and stored in JPEG format, without any processing. The alveolar bone densities of the study and control images were the measured using Digora software in accordance with Maaitah., *et al*. [13]

The density measurement provides information about the relative pixel values using an 8-bit scale from full black (0) to full white (255) [14]. The bone density of subjects in both groups were obtained by calculating the average value measured at three different sites on the RVG using Digora software (Digora for Windows software, version 2.5; Soredex, Tuusula, Finland). The sites were selected so as to coincide as much as possible to the points of laser application. The increase in bone density is directly proportional to the amount to bone deposited [15,16].

Results

Statistical analysis

Statistical analysis was done using IBM SPSS statistics 20 windows (SPSS Inc, Chicago, USA) to test the statistical significance of the difference in the density of alveolar bone graft between the two groups at different time periods. Wilcoxon Signed Rank test was used. For all the continuous variables, the results are presented as Mean ± SD. P values less than 0.05 was considered as statistically significant. Twelve patients with cleft lip and palate in whom the treatment plan included secondary alveolar bone grafting were selected for the study based on the inclusion/ exclusion criteria. The mean bone density was assessed with the help of Digora Software on RVG's taken at intervals of three weeks, one month, two months, four months and six months. The results of the statistical analysis based on the statistical test done are summarised in table 1. Significant differences in mean bone density measurements between the two groups were noticed at 2 months ,4 months and 6 months after surgery. The greatest difference was noticed between the mean of Group A (170.52 ± 18.94) and Group B (101.19 ± 27.77) at four months.

GROUP		n	Mean Density	Std. Deviation	p Value
Before surgery	A	6	73.24	10.41	0.42253
	B	6	64.99	11.55	
3 Weeks	A	6	122.13	10.91	0.63095
	B	6	113.09	24.35	
1 Month	A	6	132.63	11.74	0.10931
	B	6	119.87	21.66	
2 Months	A	6	152.80	37.51	0.02497
	B	6	117.75	15.57	
4 Months	A	6	170.52	18.94	0.00388
	B	6	101.19	27.77	
6 Months	A	6	170.92	27.99	0.01027
	B	6	119.09	22.81	

Table 1

Discussion

SABG is a well-established surgical treatment modality carried out in the transitional dentition stage before the eruption of the permanent canine. This is followed by orthodontic treatment, to align the teeth and is initiated after it is confirmed that there is enough bone formation which usually takes about 4 – 6 months.

This study proposed to evaluate if LLLT would accelerate bone formation after SABG, thus reducing the interval between the grafting and initiation of orthodontic treatment. Laser therapy is a standard therapeutic procedure approved by FDA and the lack of reports on the side effects or adverse events associated with LLLT is favourable for conducting more clinical trials. The low-power laser irradiation has its greatest effects on stimulation of bone cell resulting in cell proliferation and gene expression. Many histopathological studies have showed increased amount of osteoid tissue suggesting increased amount of bone mineral density.

The association between LLLT and bone formation have been studied previously by Saito., *et al.* [17], Trelles., *et al.* [18], Zakaria., *et al.* [19] and Theodore., *et al.* [20] showing positive correlation. Angelleti., *et al*. reported the use of laser therapy on the mid palatal anterior suture of patients aged 18-33years for every 48 hours on 3 points, with a total of 8 laser treatment sessions, accelerated bone formation [12]. This study undertaken to study the effect of LLLT on bone formation performed one laser session per day on 3 points for 6 days. In this study it was not possible to have laser sessions every 48 hours as that would have increased the time of hospitalisation. The results showed a statistically significant (p value = 0.01027) increase in bone formation at four months, similar to those reported by Angelleti., *et al.* [12].

Da Silva et al showed a greater rate of bone formation and greater volume of newly formed bone in the LASER irradiated group of

rats with 10.2 J/cm^2 proving that the laser irradiation at the grafted site stimulated osteogenesis during the initial stages of the healing process [21].

Similar results were noted in this study where a greater volume of bone formation was present in Group A (Mean Bone Density: 170.5283 ± 18.94496) compared with Group B (Mean Bone Density: 101.1994 ± 27.77150) at four months. There was an increase in bone density in both groups after surgery showing that there was bone formation in both groups. But the bone density in group A showed an increase from the second month onwards. The highest value of bone mineral density was also achieved faster i.e., at four months in Group A and this value was also statistically significantly higher (p = 0.00388) than the value obtained in Group B.

Digital radiographs were used in this study to evaluate the rapidity of bone deposition. Digora for Windows software was used to assess the changes in alveolar bone density over time. Emad., *et al*. suggested that the software of the digital radiographs can be used for managing the radiographs and analysing the images professionally [13]. Munhoz., *et al.* evaluated the accuracy of digital radiography and suggested that using digital radiography-associated software for bone density analysis offers the opportunity for clinical evaluation of bone density and minute bone density changes in the jawbone [15].

The quality of the bone formed and the rate of conversion of the grafted bone into alveolar bone is of paramount importance in the success of the orthodontic therapy following the SABG in treatment of cleft palate. These parameters also need further monitoring for longer periods of time.

Conclusion

This study was done to determine if LLLT had any positive effect on bone formation after SABG. Low level laser of wavelength 830nm, power (P) of 100 mW, GaAlAs active medium, and 0.06 cm^2 tip diameter was used in a continuous mode for 3 minutes at each point making a total of 9 minutes in each session with a total of 6 sessions.

Though the bone density was evaluated from one month, difference in bone density was evident from two months onwards. The greatest difference being showed between the groups at four months (p = 0.01027). As the sample size was small this just was done as a pilot study. It would be useful to study this in large groups and follow it for a longer period of time. This would give an insight regarding the bone density in the irradiated group even after a year and improved chances of canine eruption in the irradiated group.

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