

# Clinical and radiographic evaluation of dental implants in alveolar fissure area

*Clinical and radiographic evaluation of dental implants in alveolar fissure area*

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## Abstract

**Introduction:** The cleft lip and palate are malformations that cause important impacts not only aesthetic, auditory and phonetic, but also in the social integration of its bearer. **Objective:** To evaluate the clinical and radiographic aspects of osteointegratable implants in a region of cleft lip and palate installed in a reference center in Salvador, Bahia. **Material and method:** An observational study was carried out in which all the patients who performed osseointegrated dental implants in the area of alveolar fissure were enrolled between September 2014 and October 2016. After analyzing the records, implants were obtained that obtained secondary stability observed through bidigital locking at the time of the installation of the healing caps, as well as previous reconstruction with iliac crest graft, type of cleft, as well as complementary grafts performed in an outpatient setting and correlation of these with the success rate of the implants installed in that unit. **Result:** Fifteen implants were installed in 10 patients with different types of fissures. The clinical success rate was 80% of the implants, and radiographically, in only one case there was suspicion of failure in the new bone formation. **Conclusion:** Implants located in a region of fissure in the patients of the reference center in Salvador-Bahia presented clinically secondary stability and suggestive bone neo-formation clinically and radiographically at levels similar to those described in the literature.

**Descriptors:** Dental implants; cleft palate; biocompatible materials.

## INTRODUCTION

Among the non-syndromic malformations of the craniofacial region, the most common are the clefts with or without associated alveolar fissure; in the case of such association, is called cleft lip and palate. Labiopalatine fissures have an important impact on speech, hearing, appearance and cognition, and have a long influence on the health and social integration of the patient<sup>1,2</sup>.

In Brazil, labiopalatine fissures occur in the proportion of 1: 650 births, with an estimated 225 thousand carriers of these lesions in the country. The prevalence of craniofacial anomalies varies according to the geographic region and the ethnic group considered; it is known that the prevalence in the Northeast Region, for cleft lip and palate, is 9.72 / 10 thousand live births<sup>1</sup>.



Treatment options include orthodontic closure of the edentulous space, adaptation of conventional fixed bridges or insertion of a dental implant, reported for the first time almost 30 years ago by Verdi et al.<sup>3</sup> Due to advantages such as the preservation of adjacent teeth and the aesthetic result more favorable, the insertion of implants in patients with cleft lip and palate has become a considerable treatment, achieving results with a great functional satisfaction. And, in addition, the bone grafted in the cleft is protected from reabsorption processes when it undergoes functional loading by a dental implant<sup>2,4</sup>.

Due to the peculiarities of aesthetic-functional reconstruction in patients with cleft lip and palate, the installation of implants in the cleft region must be studied for its challenges in terms of bone and aesthetic availability. Currently, the literature about this procedure in fissured patients is scarce. The present study aims to evaluate the rates of secondary stability and the radiographic aspects suggestive of bone neoformation, which are fundamental factors in the success of implants installed in the cleft area, in addition to discussing possible factors related to the results.

## MATERIAL AND METHOD:

An observational study was performed among the patients attended at the Center for the Rehabilitation of Craniofacial Anomalies (Centrinho), located at Hospital Santo Antônio, Salvador-BA. We included all patients who had osseointegrated dental implants in alveolar fissure area, from September 2014 to October 2016. A detailed review of the charts, specifically in the implantology sector, provided epidemiological data for a descriptive analysis of the variables involved in care, such as aspects related to previous reconstruction with iliac crest graft, type of cleft, implant characteristics, as well as complementary grafts performed in the outpatient setting, also making it possible to analyze the correlation of these factors with the success rate of implants installed in this unit. This research was approved by the Human Research Ethics Committee of the Hospital Santo Antônio (Obras Sociais Irmã Dulce), under the number 1.854.465.

Patients with cleft palate or complete pre-foramen, uni or bilateral, who performed implants in the cleft region of the maxillary alveolar ridge (considered as a region of the central, lateral or superior canine incisor teeth), who had treatments of reconstruction with previous bone graft in the area of the cleft, all performed in the same health unit, without age restriction, with a minimum follow-up of six months and a maximum of eight months.

### *Surgical Protocols*

After clinical and radiographic assessment (Figure 1) of the alveolar ridge, in the cleft region, with adequate prosthetic space for dental rehabilitation, all patients were submitted to the surgical procedure under local anesthesia, in an outpatient setting, with intraoperative and extra preoperative antisepsis - oral with 0.12% chlorhexidine. An intra-sulcular incision was carried out on the

adjacent teeth and in the edentulous alveolar ridge, using a periosteal detachment to lift the flap in envelope.

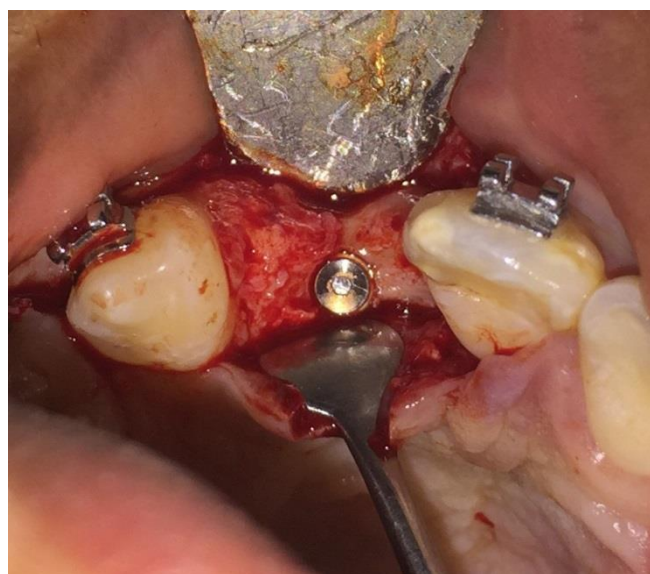
After the remaining bone was evaluated in height and thickness, the local was prepared, under constant irrigation, with the specific drill sequence, and the implant of height, diameter and platform more suitable for each case was installed (Figure 2).

Fifteen implants of the Bionnovation brand were installed in a cleft area in a total of 10 patients and 06 implants inserted in a full pre-foramen cleft area. In the transforamot-type fissure, 09 implants were installed. There were 12 implants in the upper lateral incisor region, 02, in the upper central incisor region and 01 in the upper canine region.

Bone graft of bovine origin, lyophilized and granular (Figure 3) was added for better bone volume or covering of exposed threads. Three complementary on lay grafts were performed in the form of autogenous block in a total of 02 patients, all fixed with screws of the 1.5mm system, and with bovine granular lyophilized bovine bone graft of the brand Bionnovation. In these sites, the average time between



**Figure 1.** Preoperative panoramic radiograph representing one of the cases of dental implant to be installed in the area of the right alveolar fissure, previously reconstructed with autogenous bone graft of the iliac crest. Source: Centrinho Pictures.



**Figure 2.** Example of an implant installed in a cleft region for prosthetic rehabilitation of the unit 12. Source: Centrinho Pictures.

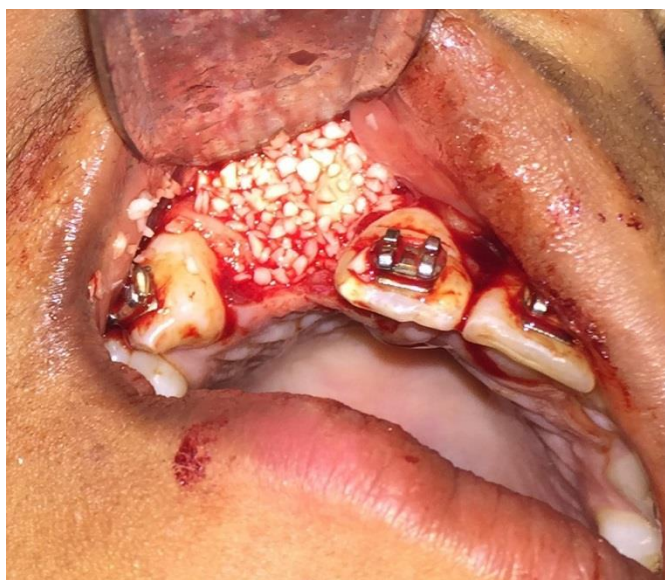
reconstruction of the fissure with iliac crest graft until insertion of the complementary graft was 106.6 months; of the on lay graft, for implant installation, the mean time was 8.7 months. The surgical wound was sutured without tension with 5-0 nylon thread.

After a minimum period of six months and maximum of eight, after the installation of the implant, the digital panoramic radiography in standardized image clinic. Through the evaluation of x-ray, it was verified the formation of bone around the implant threads and absence of radiolucent range throughout the bone/implant interface (Figure 4). Clinically, the presence or absence of pain, and fistula and/or secretion, which carried out the procedure for reopening to heal installation.

In cases in which the implant was noticed when the transmucosal fixation, it was removed and the mucosa was sutured, being considered in the study as a clinical failure.

### Data collection procedure

Data from patient records were collected in a fill-in form and then tabulated on a computer. This research instrument covers information on the age of



**Figure 3.** Alveolar bone graft complementary with biomaterial. (granulated lyophilized bovine bone). Source: Centrinho Pictures.



**Figure 4.** Panoramic radiograph of one of the cases, in which the signs suggestive of new bone formation were evaluated. Source: Centrinho Pictures.

performing the reconstruction of the fissure with iliac crest bone graft (primary, secondary or tertiary) and the time to implant installation; genre; type of cleft; dental unit rehabilitated; need, type and timing of complementary grafts for the implant; success of the implant (established by the digital locking in reopening to place the healing cap): complications of the procedures, as well as radiographic signs of bone neo-formation. Implants that presented some complication that resulted in the necessity of their removal before or at the time of reopening, as well as those that presented mobility during the installation of the healing caps, were considered as failures.

### Data analysis

The data analysis was performed in a descriptive manner by the distribution of all study variables, by relative frequency and absolute values. The related factors were investigated through the evaluation of association between the studied variables and the success rate of implants performed.

## RESULT

Fifteen implants of the Bionnovation brand in a total of 10 patients, with 04 of male gender and 06 of female gender, and the age of these patients ranged from 17 to 31 years. The time between the reconstructions of the fissure with autogenous iliac crest graft until implant installation ranged from 47 to 166 months, with a mean of 88.8 months. Ten (66.6%) external Hexagon implants were installed, with dimensions between 2.9 and 3.75 mm (in diameter) and between 8.5 and 11.5 mm (in height); 05 (33.3%) Cone Morse type implants with dimensions of 3.5 mm in diameter and height ranging between 10 mm and 13 mm. The use of the biomaterial graft in isolation occurred only at the moment of implant installation, and was performed in 08 cases (Table 1).

The previous reconstruction of the fissure with autogenous iliac crest graft was performed in all patients before implanting, as a treatment protocol for the Center of Craniofacial Anomalies of the Hospital Santo Antônio. No patient underwent bone reconstruction of the fissure up to 1 year of age (primary reconstruction); in 7 patients, secondary reconstruction was performed, being 05 of the secondary-secondary type (8 to 12 years) and 02 of the late secondary type (after permanent canine eruption and before adulthood); in three patients, tertiary type, in adulthood. There was complication with a need for re-attachment and a new graft for reconstruction in 01 patient, with a left transforamen fissure, due to the infection of the grafted bone.

Radiographic signs suggestive of bone neo-formation were observed in 14 (93.3%) of the implants. However, secondary locking was observed in 12 (80%) of the total implants. Mobility was observed and removal of 3 (20%) implants was performed promptly, with no failure occurring in the same patient. (Table 2).



**Table 1.** Implant Surgeries

No.	Patient	Unit	Age	Time after fissure reconstruction	Additional grafts	Implant Specifications
1	AEVJ	11	23	73	Biomaterial (lyophilized bovine bone, medium granulation), at the moment of Implant.	Cone Morse 3.5 × 10.0 mm
2	HSS	12	18	59	Biomaterial (lyophilized bovine bone, medium granulation) + Titanium screen, at the moment of implantation.	Cone Morse 3.5 × 13.0 mm
3	MSS	22	25	62	No.	External Hexagon 3.75 / 4.10 × 8.50 mm
4	MFG	22	22	126	Autogenous - Onlay mandibular branch block + Biomaterial (lyophilized bovine bone, medium granulation), nine months before implantation.	Cone Morse 3.5 × 10.0 mm
5	MFG	12	22	126	Autogenous - Onlay mandibular branch block + Biomaterial (lyophilized bovine bone, granulation mean), nine months before implantation.	Cone Morse 3.5 × 10.0 mm
6	LPS	12	17	92	Autogenous - Bundle of mandible onlay + Biomaterial (lyophilized bovine bone, medium granulation), nine months before implantation.	Cone Morse 3.5 × 11.5 mm.
7	MMSS	23	31	23	Biomaterial (lyophilized bovine bone, medium granulation), at the moment of Implant.	Hexagon, External, 75 / 4,10 × 8,5 mm Note: Central incisor bridge a canine, three prosthetic units.
8	MMSS	21	31	23	Biomaterial (lyophilized bovine bone, medium granulation) + Titanium screen, at the moment of implantation.	External Hexagon, 75 / 4,10 × 8,5 mm Note: Central incisor bridge to canine, three prosthetic units.
9	MSB	12	30	50	No	External Hexagon 3.75 / 4.10 × 11.5 mm
10	MGS	12	17	47	No	External Hexagon 2.9 × 10.0 mm
11	SSGS	12	24	162	Biomaterial (lyophilized bovine bone, medium granulation), at the moment of Implant.	External Hexagon 2.9 × 10.0 mm
12	SSGS	22	24	162	Biomaterial (lyophilized bovine bone, medium granulation) + Titanium screen, at the moment of implantation.	External Hexagon 2.9 × 10.0 mm
13	SSGS	22	24	166	Biomaterial (lyophilized bovine bone, medium granulation), at the moment of Implant.	External Hexagon 2.9 × 10.0 mm Note: second attempt after six months of removal.
14	SSP	12	18	92	Biomaterial (lyophilized bovine bone, medium granulation), at the moment of implantation.	External Hexagon 3.75 / 4.10 × 11.5 mm
15	SSP	22	18	92	Biomaterial (lyophilized bovine bone, fine granulation), at the moment of Implant.	External Hexagon 3.75 / 4.10 × 11.5 mm

## DISCUSSION

Labiopalatine fissures affect patients in a male and female gender ratio of 3: 2, respectively, and three-quarters of the affected patients have unilateral clefts<sup>5</sup>. In the present study, a sample with more female patients was obtained, in a ratio of 3: 2, inverse to the literature data, with a predominance of unilateral fissures.

Fissured patients are also affected by alterations in the dental arches, among the most common is anodontia in the cleft region. According to the study by Tereza et al.<sup>6</sup>, the upper lateral incisor was the tooth most affected by dental agenesis (81.3%), which was also reported by Suzuki, Takahama<sup>7</sup> and by Vanzin, Yamazaki<sup>8</sup>. However, the study by Oliveira et al.<sup>9</sup> reported a very low occurrence of hypodontia in subjects with complete cleft lip and palate. In the present study, the vast majority (80%)

**Table 2.** Postoperative evaluation of implants

No.	Patient	Complications until reopening	Radiography of control	Secondary Stability in reopening
1	AEVJ	No	Signs suggestive of new bone formation.	Yes
2	HSS	Exposure of the screen to the palate without infection.	Signs suggestive of new bone formation.	Yes
3	MSS	No	Signs suggestive of new bone formation.	Yes
4	MFG	No	Signs suggestive of new bone formation.	Yes
5	MFG	No	Signs suggestive of new bone formation.	Yes
6	LPS	No	Signs suggestive of new bone formation.	Yes
7	MMSS	No	Signs suggestive of new bone formation.	Yes
8	MMSS	No	Signs suggestive of new bone formation.	Yes
9	MSB	No	Signs suggestive of new bone formation.	No, implant removed.
10	MGS	No	Signs suggestive of new bone formation.	Yes
11	SSGS	No	Signs suggestive of new bone formation.	Yes
12	SSGS	Suture dehiscence and implant exposure on the seventh day of Postoperative	Signs suggestive of new bone formation.	No, implant removed.
13	SSGS	No	Signs suggestive of new bone formation.	Yes
14	SSP	No	Signs suggestive of new bone formation.	Yes
15	SSP	No	Discrete radiolucent band around the implant.	No, implant removed.

of the teeth rehabilitated by implant was the upper lateral incisor. Although there was a rehabilitation of 02 (13.3%) central incisors and 01 (6.6%) canine, these teeth were lost, that is, they were not absent due to anodontia, as in most lateral incisors in fissures. The respective regions of these teeth were included in our study, because it was an area adjacent to the fissure itself, and that the rehabilitation had the same peculiarities as a lateral incisor.

The long-term efficacy of implant-supported prostheses was also clearly demonstrated in several studies, with high success rates<sup>10</sup>. The success criteria of the implant have been much debated. The parameters for evaluation of clinical success are the functional capacity and the absence of pain, foreign body sensation or dysesthesia, and implant mobility, as well as the health of the periimplant mucous membrane. Patient satisfaction is also a criterion of success considered by some authors<sup>11</sup>. Buser et al.<sup>12</sup> added, as an imaginary criterion, the absence of a radiolucent zone around the implant. In this study, we considered as clinical success the implants that showed absence of persistent pain and signs of infection, or other complications that led to implant removal until the moment of reopening for transmucosal installation, where the screw should be without mobility. The radiographic success was evaluated as absence of radiolucent band around the surface of the implant.

Härtel et al.<sup>13</sup> described local risks for implant failure, such as: unfavorable position; Insufficient implant length; simultaneous implant to the bone graft; implant a lot

late after graft; scar tissue from previous surgeries in the fissure, and non-observed primary locking implants, which may lead to bone loss from grafts in the alveolar fissure region or from the implant itself. In this study, three failures were observed in the reopening for the installation of the healing caps, which refers to a 20% failure rate of the procedure.

Considering that primary stability plays a key role in the success of bone neo-formation, implant length, diameter, surface texture and thread configuration are indicated as the main factors to obtain this stability. It is observed that these factors also positively influence healing, promoting favorable cellular responses, when ideal. It is important to note that the implant design is fundamental for its stability in a low density bone<sup>14</sup>, which is usually found in the grafted cleft regions.

The selection of diameter and implant length is made according to bone availability at the recipient site<sup>10</sup>. Regarding the insertion of implants in the alveolar fissure area, the influence of these measures has not yet been sufficiently investigated<sup>15</sup>; however, Borgnat et al.<sup>16</sup> have stated that implant length is an important criterion for success and, according to these authors, many studies agree that implants should be at least 10 mm long. Clinical studies show that even implants with diameters of less than 3.0 mm provide sufficient primary stability in cases with limited bone volume<sup>17,18</sup>. In the present study, the implants varied in size

between 2.9 and 3.75 mm in diameter, with an average of 3.4 mm, and, in height, ranged from 8.5 to 13.0 mm. The data showed that implants with measures were used within what is recommended for good stability in areas of fissure. Of the three implants that failed, two had measures of  $3.75 \times 11.5$  mm and one with  $2.9 \times 10.0$  mm.

Cone Morse type implant implants have presented advantages, mainly in the unit rehabilitation of aesthetic areas. In the study by Mangano et al.<sup>19</sup>, with a five-year follow-up, in which 288 Cone Morse implants were installed in 60 non-fissured patients, a success rate of 98.6% and an average bone loss of 0.7 mm were observed around the implants, which shows results conventional implants. All of the Cone Morse implants of this study (05 implants) obtained secondary blockage found and signs suggestive of new bone formation observed radiographically.

Due to limitations in infrastructure and costing for the use of computed tomography, patients in this study did not have access to this resource; therefore, the verification of the bone volume obtained before and after implantation in the reconstruction of the fissure is restricted to clinical evaluation, periapical and panoramic radiographs.

It was reported through computed tomography analysis that there was a total mean volume loss of 43.1%, approximately 1 year after the secondary repair of the alveolar fissure with iliac crest bone graft<sup>20</sup>. Feichtinger et al.<sup>21</sup> reported that the average bone loss in the first year after surgery, before the eruption of the permanent canine, reaches 49.5%. This resorption may compromise implants that do not receive additional grafting.

Among the cases of this study, complementary grafting prior to implantation was considered necessary in three sites (20% of cases) of two patients, aged 17 and 22 years, who received a block of autogenous bone of the mandibular branch.

Landes et al.<sup>4</sup> have cited that cleft area implant is a reliable treatment option with high long-term success rates. The functional aspects are comparable to those of non-fissured patients. One of the doubts in the clinical practice of this procedure would be related to the bone quality of the receptor bed for a good primary and secondary stability of the installed implants, since it is a grafted area; however, Verdi et al.<sup>3</sup>, postulate that the success rate of implants in grafted sites is close to that of implants placed in ungrafted sites, provided there is bone with quality and quantity. Matsui et al.<sup>10</sup> detected marginal bone losses of  $2.30 \pm 2.06$  mm in implants without additional graft and  $2.62 \pm 1.79$  mm in implants with additional autogenous graft. According to Tamimi et al.<sup>22</sup>, implants placed in grafted bone revealed similar bone-level changes when compared to implants inserted in ungrafted regions.

This series of cases showed a clinically proven secondary locking rate in 80% of the cases analyzed, suggesting that the long-term success rate of these implants will be close to those of other clinical studies. Although this work presented a success rate slightly lower than the other researches on implant in areas of fissure, it is a series presentation of cases. Thus, we suggest analyzes with more samples and longer follow-up, so that it is possible to evaluate with statistical significance not only the success rate in general, but other factors related to the good conduct of these cases.

Buser et al.<sup>12</sup> cite that the imaging criterion for success evaluation is the absence of a radiolucent zone around the implant. This suggests the formation of fibrous tissue rather than bone<sup>16</sup>. Only one implant of the 15 evaluated, in the present study, presented a radiolucent zone around the entire surface. These implant also failed clinically, moving with mobility at the time of reopening, and was promptly removed. However, two other implants also failed in the process of bone neo-formation and this radiographic signal was not observed. According to Agostini<sup>23</sup>, when there is an adjacent soft tissue layer, it should be wide enough to overcome the limitations imposed by the resolution of the radiographic system; otherwise it will not be displayed. Anatomical structures surrounding the implant, projected on the same part of the film, may hide this fibrous tissue interface. It is possible that this occurred in the cases of this study, since the implants are installed in areas of cleft, grafted bone and low density.

Although panoramic radiography was the standard for the evaluation of this study, the authors acknowledge that the ideal tests for this evaluation are periapical radiographic examination and computed tomography, due to the greater detail to evaluate the signs suggestive of bone neo-formation with precision.

Currently there are insufficient data and few clinical trials with well-defined information on this topic. As for the study of patients with fissure, the requirements of evidence-based medicine are difficult to meet. One reason for such difficulty is the incidence of this condition, with a rate of 1: 500 to 1: 700 live births<sup>16</sup>.

## FINAL REMARKS

Implants installed in the cleft region of patients at the Center for Craniofacial Anomalies of the Hospital Santo Antônio (Centrinho) have a high success rate, with clinical success verified through secondary stability and suggestive bone neo-formation, both clinically and radiographically, at levels similar to those described in literature.

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## CONFLICTS OF INTEREST

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The authors declare that there are no conflicts of interest.

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