*Bioceramics Volume 11, edited by R. Z. LeGeros and J.P. LeGeros*
*(Proceedings of the 11th International Symposium on Ceramics in Medicine)*
*New York, NY, USA, November 1998*


# IMPLANTATION OF CUBAN GRANULATED HYDROXYAPATITE "APAFILL-G™" IN PERIAPICAL BONE DEFECTS

M.C.P. Alvarez[1], R.G. Corrodeguas[2], J.A.D. Garcia-Menocal[2], I.F. Diaz[2], D.M. Arguelles[2], J R. Hernandez[1], E.A. Hernandez[1], S.A. Guttierrez[1]

[1]Clinica Estomatologica Docente de bauta Ave. 251 No. 13201, Bauta, Prov Habanna Cuba; [2]Centro de Biomateriales de la Universidad de la Habanna Ave. Unversidad s/n Cuidad Habanna 10400, Cuba

## ABSTRACT

The authors present their clinical experience implanting the Cuban granulated hydroxyapatite APAFILL-G™. Between 1990 and 1997, 708 patients, having periapical bone defects of diverse origin were treated. The follow up of cases consisted in initial and post-operatory periodical clinical and radiographic examinations over a period of one year.
The APAFILL-G™ implantation procedures were performed surgically or endodontically, depending on the nature and or characteristics of the bone defect. The results showed a treatment efficacy of 97.0%. No adverse reactions caused by the implanted material were observed during the follow-up period.
The clinical and radiographic examination showed complete bone repair after 6 months for surgically implanted cases, and 9 months for those implanted endodontically.

**KEYWORDS**: Hydroxyapatite, periapical bone defects, bone repair, endodontics, and periapical surgery

## INTRODUCTION

Hydroxyapatite ceramics are similar to bone mineral in chemical composition and crystalline structure. It has been accepted that this similarity is responsible for the biocompatibility, bioactivity, and osteoconductivity exhibited by hydroxyapatite ceramics when implanted in bone tissue. Many scientific papers concerning hydroxyapatite implantation in bone defects in animal and human subjects have been published since 1970's. The results generally point out the efficacy of hydroxyapatite as a filling material able to bond and integrate to bone tissue [1,2,3].
Odontology was the first field of application of hydroxyapatite ceramics and at present, continues to be the main consumer of hydroxyapatite products[4]. They have been successfully employed in the treatment of periodontal and periapical bone defects, and pre-prosthetic remodeling of alveolar ridge[5].
Periapical osteolytic bone lesions are quite frequent cause of attendance to Cuban dentistry services. Its origin is generally related to pulp infection processes or traumas affecting the teeth 6. APAFILL-G™ is a trademark of synthetic hydroxyapatite ceramic granules fabricated by the Centro

de Biomateriales de la Universidad de la Habana. "In vitro" tests have shown that no cytotoxic haemolytic or genotoxic activity is related to the material. Experimental implantation in dogs confirmed its biocompatibility, bioactivity and osteoconductivity.
This study presents the efficacy of APAFILL-G for treating periapical bone defects in several dental clinics in Cuba.

## METHOD AND MATERIALS

The hydroxyapatite used in this study was APAFILL-G™ (BIOMAT), a dense synthetic hydroxyapatite in the form of granules of irregular shape which fulfills the requirements of International Standardization Organization 8.
The population (who volunteered for this study) included 708 patients having periapical bone defects. They attended several public dental services in the Cuban provinces of Habana, Pinar Del Rio, Matanzas, Santi Spiritu, and Sanriago de Cuba, between 1990 and 1997. All defects were classified in the categories 0, and 1, according to the World Health Organization. Subjects were between 8 and 70 years old, without background of neither neoplasm nor uncontrolled diabetes.
The bone defects were classified into circumscribed and diffuse, according to their radiographic appearance. In circumscribed bone defects, conventional apical surgery and curettage were used. Apicoectomy debridement and sealing of the canal of the affected teeth was made when needed. APAFILL-G™ particles with a grain size between 0.1mm and 0.4mm were mixed with distilled sterile water, blood or saline, then condensed in the defect site by gentle pressure and covered with a fibrin mesh to prevent particle migration. After restoring the mucoperiosteum and the flap, the surgical incision was sutured with 3.0 silk suture or with tissue adhesive Tisuacryl® (Biomat).
Diffuse bone defects were treated by techniques of periapical reparation techniques implanting hydroxyapatite via the root canal. After a pulpectomy and careful irrigation of the root canal with calcium hydroxide solution; a paste made of calcium hydroxide solution and APAFILL-G™ (particle size lower than 0.1mm) was implanted in root canal. The root canal was temporarily scaled with Cimpat (Septodont). Irrigation, implantation and temporary sealing were repeated monthly 2 more times. Between the sixth and ninth months, the canal was permanently sealed.
The follow-up consisted of monthly clinical and radiographic exams for one year after the implantation. Three assessment categories were established by comparison to the initial clinical and radiographic exams. (1) Satisfactory: complete disappearance of radiographic and clinical initial symptom. (2) Improvement: partial disappearance of radiographic and clinical initial symptoms, or partial disappearance of radiographic, and complete disappearance of clinical ones, or vice versa. (3) Failure: clinical and radiographic symptoms similar to those initially observed. $x^2$ and t-Tests were employed to compare the frequency distribution of the three assessment categories and the efficacy, among the two treatments, surgical and endodontical.

## RESULTS

The following table summarizes the results in the study. An efficacy of 97.3% and 96.7% was found for surgical and endodontical implantation procedures, respectively considered as the obtained rate of satisfactory. Both values had no statistical difference ($\alpha$= 0.05), and the global efficacy was 97.0%.

The $x^2$-Test showed that the frequency of the three categories, S, D, and I was the same p=0.05) for both procedures, surgical and endodontical.

**Table** Frequency distribution (absolute) of the assessment categories.

| Treatment | S | I | F | Total |
|---|---|---|---|---|
| **Surgical** | 366 | 7 | 3 | 376 |
| **Endodontical** | 321 | 6 | 5 | 332 |
| **Total** | 687 | 13 | 8 | 708 |

S: Satisfactory, I: Improvement, F: Failure

**Typical circumscribed defect, surgically treated**

Male 30 years old carrying a typical circumscribed periapical bone defect related to a cyst that affected the central and lateral upper right incisors without clinical symptoms.
A well-delimited radiolucent area that corresponded to the bone defect occupied by cystic soft tissue was observed in the initial radiograph. The radiolucent area showed radiopacity similar to normal adjacent bone but implanted granules could be stilled distinguished. The picture was similar one month after surgery, but a radiolucent well-defined border between implanted material and adjacent bone appeared. After 6-months, the radiolucent border disappeared and no difference in optical density between the implanted site and surrounding normal bone could be detected in the radiograph picture after 1-year was the same, without any sign of regression.

**Typical diffuse defect, endodontically treated**

Female, 27 years old carry a typical periapical bone defect affecting central and lateral right lower incisors. Antecedent of trauma involving the affected teeth and clinical symptoms of pain, mobility-3, and active fistula were detected.
Pain and fistula completely disappeared two months after the endodontical implantation. Physiological mobility was achieved after 6 months.
Fetidness in the conduit was completely removed in the third month. Definitive scaling was carried out 6 months after implantation. No regression of clinical symptoms was detected at 1-year clinical exam.
Radiographically, a wide radiolucent area with diffuse limits was observed, indicating destruction of periapical alveolar trabeculae. Two months after implantation, radiolucency started to gradually disappear. The initial radiolucent area became indistinguishable 6 months after implantation. Radiological examinations after 1-year showed that the initial radiolucent area exhibited normal radiopacity and no evidences of regression were observed.

## DISCUSSION

The main cause of failure in circumscribed periapical bone defects was the regression of radiolucency due the presence of false conduits originated in a previous root canal treatment, that were not detected during the surgical procedure (2 cases). Other cause of failure (1 case) was a post-operatory trauma, which caused root fracture of the affected tooth. In satisfactory, cases the initial clinical symptoms normally disappeared 1- month after the implantation. Radiographically, a demarcation line between hydroxyapatite granules and bone appeared in the 1-month radiograph and disappeared between the third and sixth month. Bleeding from the bone walls after the

implantation may cause this phenomenon[9]. The initially distinguishable granules were apparently integrated by bone, which grew from the wall of the defect after the sixth month.
The causes of failure in the endodontial treatment of diffuse bone defects could not be identified. However, the authors presume that success it is related to the absence of soft tissue in the defect. The clinical symptoms in satisfactory cases disappeared 1 month after the implantation. The radiographic aspect of the defect gradually becomes similar to the adjacent wealth bone and indistinguishable between the third and sixth month.
No signs of rejection of the implanted material were observed neither in surgical nor endodontical treatments. The high rate of success obtained in this study suggested that surgical and endodontical implantation of granule hydroxyapatite APAFILL-G™ is an effective techniques for the repair of periapical bone defects. The success of the procedures strongly depends on the proper selection and evaluation of the patient and a previous preparation technique.

## ACKNOWLEDGEMENTS

Authors acknowledge the financial support of the Cuban Ministries of Health, and Science, Technology and Environment. The work is part of the activities of the Joint Project CYTED VIII.6.

## REFERENCES

1. LeGeros RZ, LeGeros JP, In Hench LL, Wilson J, Eds. *An Introduction to Bioceramics*, Singapore: World Scientific, 1993: 139-180.
2. Shors FC Holes RE. In Hench LL, Wilson J Eds. *An Introduction to Bioceramics*, Singapore; World Scientific: 1993: 181-198.
3. LeGeros RZ *Calcium Phosphates in Oral Biology and Medicine*. Monógraphs in Oral Science, Vol. 15 Eds. Myers HM, ed., Basel; Karger, 1991: 154-171.
4. Jarcho M. Dent Clin North AM 1992: 36: 19-26.
5. LeGeros RZ. Adv. Dent Res. 1988; 2; 164-180.
6. Alvarez L Endodoncia. La Habana : Ed Revolucionaria, 1977: 421-455.
7. APAFILL-G Technical information, La Habana, Centro des Biomateriales, 1997
8. ISO/DIS 13779-96 Implants for Surgery. Ceramic materials based on Hydroxyapatite. International Organization for Standardization 1996.
9. Hara Y. in Gold St. Midda M, Mutlu S, Eds. Recent Advances in Periodontology, Vol. II, Excerpta Medicia; Amsterdam, 1991: 69-76.