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Summary

The authors, on the basis of the histological results presented in the literature have evaluated, in a clinical situation, the response to the use of a polylactic/polyglycolic filling material (FISIOGRAFT) in patients where implants were either placed following an extraction or in the presence of a dehiscence.

INTRODUCTION

The technique of guided regeneration, in agreement with the biological principals that regulate tissue regeneration, has for some time now been applied in the field of implantology for repairing bone defects. It has been demonstrated that the loss of dental elements is accompanied with the progressive resorption of alveolar bone that within two to three years often reaches levels as high as 60%.

This resorption is often exacerbated by accompanying atrophies attributed to the phenomenon of compression caused by the prosthesis. Bone defects can originate from infections, periodontal diseases or during the placement of implants which can provoke a vestibular or lingual dehiscence due to the reduced buccal-lingual dimension of the crest associated with the presence of fistulae, root fractures, endodontic

complications or from atrophies that developed after previous extractions. The surgical implant protocol foresees that in order for a treatment to be considered satisfactory it must be accompanied by the formation of dense bone (Misch classification) with a thickness of at least one millimetre on the buccal and lingual surfaces. In a situation where the quantity of bone is not considered adequate in both the horizontal and vertical planes a routine practice used in guided bone regeneration (GBR) is to apply a membrane, these membranes can either be absorbable or non-absorbable. The non-absorbable type are more frequently subjected to the phenomenon of exposure due to their greater rigidity which can traumatise the gingival mucosa limiting the blood circulation in the flap covering the membrane. There also exists a greater risk to secondary infections which will reduce the percentage of success. In addition, when this type of material is used it must eventually be removed requiring a second surgical operation. Instead, with an absorbable membrane, the main factor which must be taken into consideration is their absorption time.

Bone regeneration procedures can be performed in two ways:

- in one step - where the membrane is applied directly around the implant covering the bone defect.
- in two steps - where first, through the use of GBR, the initial quantity of bone is increased and then after a sufficient amount of time, which can vary from 6-9 months, the implants are placed.

The first type of procedure is indicated when:

1. there is a sufficient amount of bone to guarantee primary stability of the implant

2. there is a reduction in the width of the buccal-lingual bone producing a marginal dehiscence
3. there exists a scarce quantity of bone at the middle third of the implant that produces an opening exposing the implant surface.
4. in post-extraction implants with a large alveolus and/or with a thinning of the crest walls caused by progressive perio-endodontic infective processes.

The second type of procedure is indicated when:
1. there is not enough bone to provide primary stability
2. the volumetric bone defect is such that the width of the crest is equal to or less than the diameter of the implant
3. aesthetic problems due to erosion of the bone crest with insufficient coverage at the level of the marginal zone.

With both of these techniques the complication most often encountered is the tendency for the membrane to collapse onto the bone at the level of the defect preventing the formation of a space where the coagulum will form. This space is fundamental for the organisation and formation of the neoformed tissue.

This situation is even more critical when a non-absorbable membrane is utilised.

To circumvent the problems involved with bone substituting materials such as autogenous, homologous, demineralised or freeze-dried bone alternate materials such as hydroxyapatite, collagen, synthetic polymers, etc. can be utilised as space maintainers.

In more complicated cases, these materials can be combined with screws, posts or titanium grills. The artificial coagulum that is formed

from hematic colonisation inside the biomaterial stabilises the membrane and prevents it from collapsing onto the underlying plane. The osteoblastic colonisation of the stabilised coagulum that will form new bone tissue is a slow process and the use of these materials prevents the invasion of competitive cells from other tissues into this area.

On the basis of their intrinsic characteristics bone substituting materials function with three different mechanisms: osteoconduction, osteoinduction and osteogenesis.

Osteoconduction is obtained when bone is formed thanks to the growth from pre-existing bone, therefore differentiated mesenchymal bone cells must be present.

The most representative osteoconductive material is the synthetic alloplastic type which can be divided into two groups; ceramic polymers and composites. Osteoconductive materials stimulate bone growth around them and are then substituted by neoformed bone. It is principally indicated for inhibiting the premature development of fibrous tissue which develops much faster (fibrous tissue 50 microns/day, bone tissue 0,5 microns/day).

Osteoinduction induces the transformation of undifferentiated cells into osteoblasts in an area where they are not normally present due to the presence of BMP and growth factors.

Osteogenesis stimulates the formation of bone even in the absence of undifferentiated mesenchymal cells: this characteristic is a feature of the materials derived from natural bone (demineralised bone from banks, freeze-dried and autogenous bone) and are utilised in the most demanding cases where a particularly efficient osteogenesis is required in areas with insufficient growth or in situations where bone grafts are used to reconstruct large defects. These materials can be used either

alone or in combination with other osteoconductive materials. It is not an easy task to obtain these materials derived from bone due to both the risk of cross contamination as well as the need to harvest them from a donor site: iliac crest, maxilla, cranium or ascending branch of the mandible.

DISCUSSION

Amongst the various osteoconductive materials that are widely used today we find the synthetic biodegradable polymers which include, polyglycolic acid (PGA) and polylactic acid (PLA).

PLA is present in various stereo-isometric forms, the most important being poly-l-lactide or PLLA

These polymers are metabolised respectively into glycolic and lactic acid.

The PGA is degraded rapidly (about 2 months), the PLA, which is more hydrophobic, remains for a longer period of time (up to 12 months); their degradation, which takes place by enzymatic catabolism, is favoured by the presence of macrophages and neutrophils while the level of absorption is a function of the percentage ratio between the two copolymers.

Given their high degree of biocompatibility and degradation they are well tolerated by the host organism which, when used as filling materials, have been shown to demonstrate not only a mechanical action but an action favouring the regeneration of new bone tissue as well.

A material that is commercially available is a co-polymeric combination of polylactic acid and polyglycolic acid: FISIOGRAFT (GHIMAS S.p.A. Casalecchio di Reno - Bologna), which is produced in different formulations: sponge, gel and powder, has an extremely low density

which permits its complete absorption in a relatively short period of time, depending mainly upon the quantity utilised (between 4 and 8 months). The slow and progressive absorption of Fisiograft, is accompanied by an orderly and progressive re-growth of bone tissue which, in situations where implants are involved is surely one of the indispensable conditions necessary for clinical success.

These evaluations are confirmed by the studies presented in the literature (M. Piattelli, S. Pappalardo ed altri: Healing of bone defects treated with Fisiograft: a histological study in the rabbit tibia, J. D. Res. 2000) PHOTO: 1,2,3,4,5,6,7,8.

(M. Piattelli, S. Pappalardo ed altri: Healing of bone defects treated with Fisiograft: a Histological study in the rabbit tibia, J. D. Res. 2000) PHOTO: 1, 2, 3, 4, 5, 6, 7, 8.
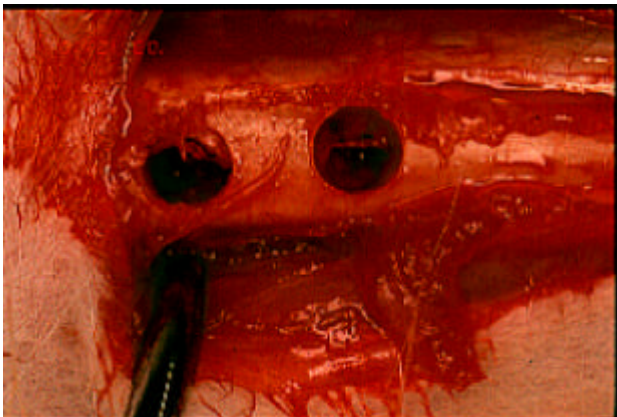
PHOTO 1
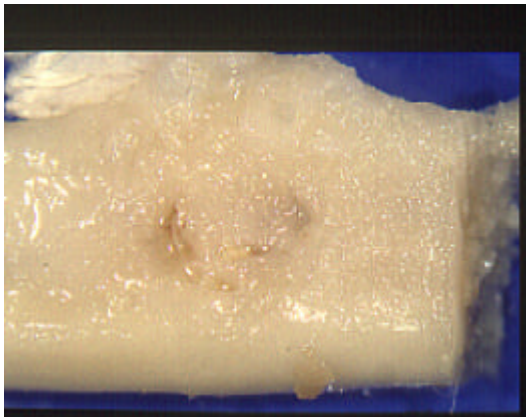Preparation of the artificial alveolus
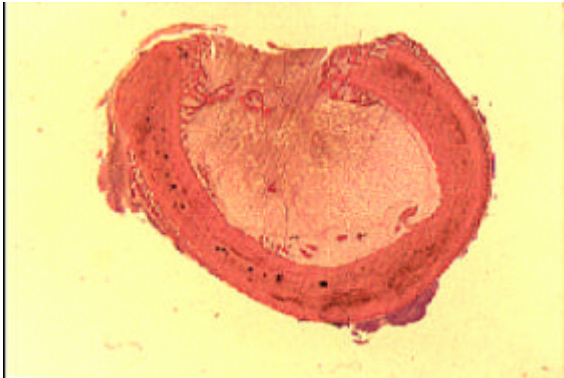

PHOTO 2
Control

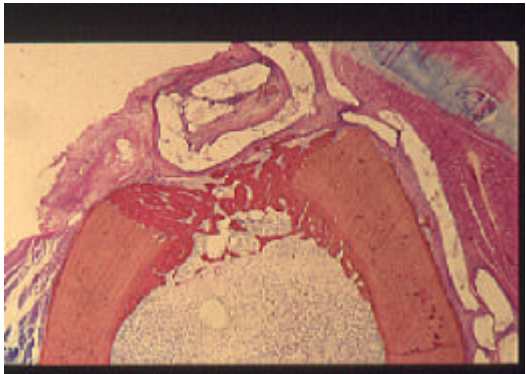PHOTO 3
Control at a later date
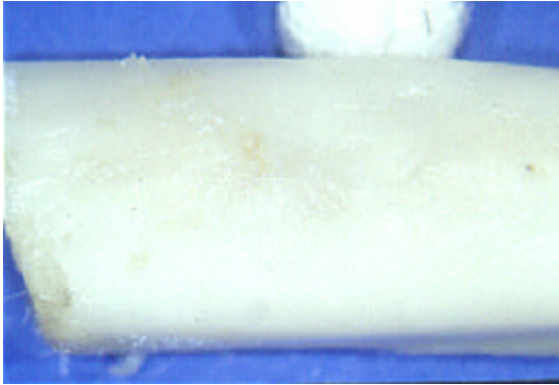

PHOTO 4
Treated with FISIOGRAFT
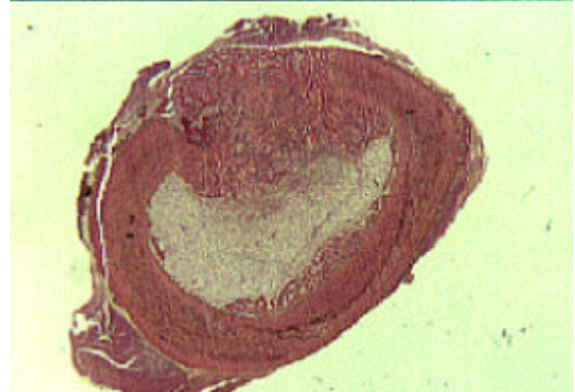
PHOTO 5
Macroscopic view

PHOTO 6
Defect treated with FISIOGRAFT. The defect has been partially filled by new bone
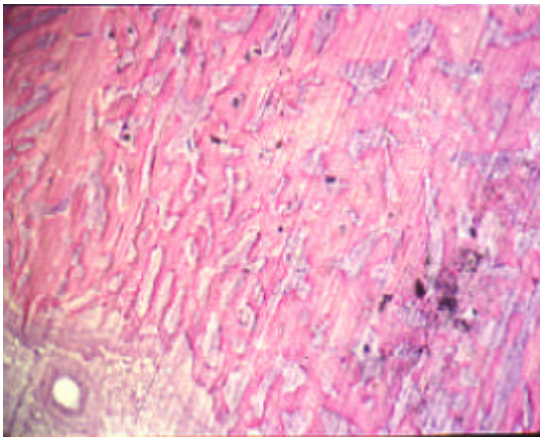

PHOTO 7
Neoformed bone is also present in the central portion of the defect
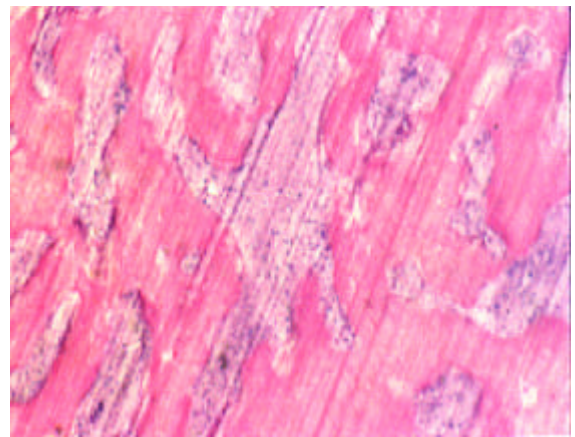

PHOTO 8
Details of the preceding photo at a higher magnification

MATERIALS AND METHODS

On the basis of these considerations we wanted to perform a clinical study involving the placement of titanium implants in post extraction sites or in thin edentulous crests in the presence of a more or less pronounced dehiscence. For this study we used TBR (Benax – Ancona) threaded titanium implants which had been sand blasted and acid etched in order to increase their surface area which is in line with the principals of osteointegration. The evaluations and measurements where made using a calibrated probe after the implants had been positioned. In the

situations where a dehiscence was present, the measurements were made starting from the head of the implant up until the deepest limit of the residual bone crest.

Instead, in the case of post-extraction implants, starting from the head of the implant the measurements were made on the: vestibular, lingual/palatine, mesial and distal side of the alveolus, up until the maximum probing depth from the threads of the implant to the residual bone.

Twenty-one implants were inserted and in each case they all showed excellent primary stability (table 1).

When in our opinion we felt it was necessary, we resorted to the use of absorbable collagen membranes.

After 28/32 weeks following the operation we re-entered the surgical site and exposed the implant. The same techniques were repeated for the measurements and the probing.
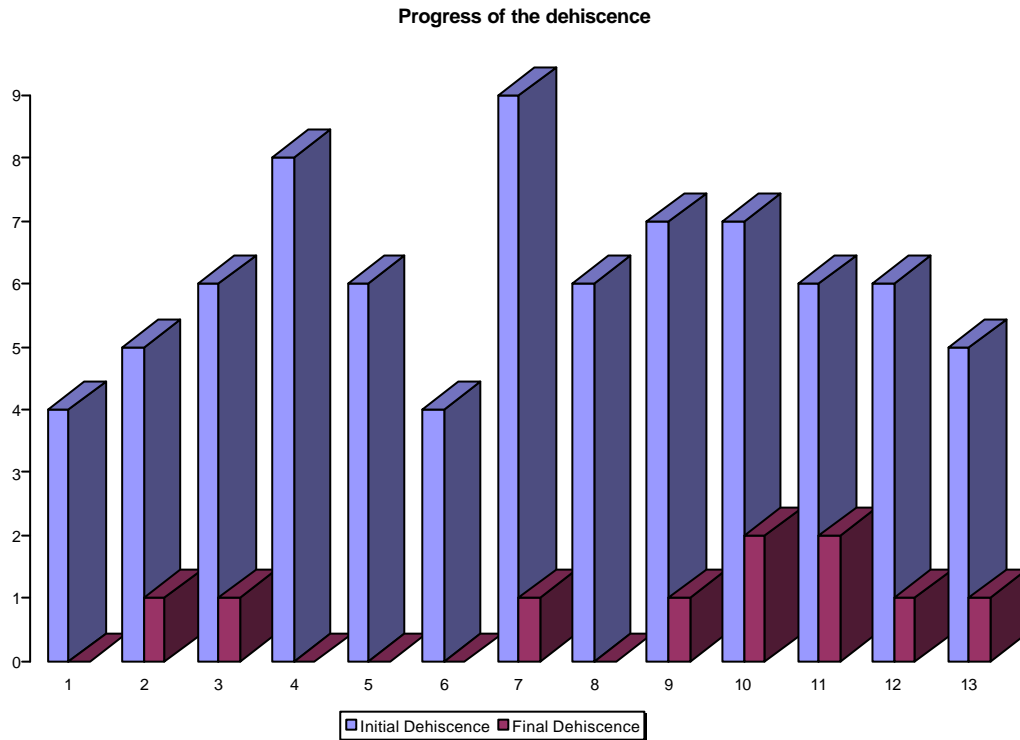
The data obtained were correlated with the initial findings and then compared.

In one case, during the healing period the membrane became exposed, the exposure was treated with a local pharmacological therapy (chlorhexidine) and subsequently there were no further complications.
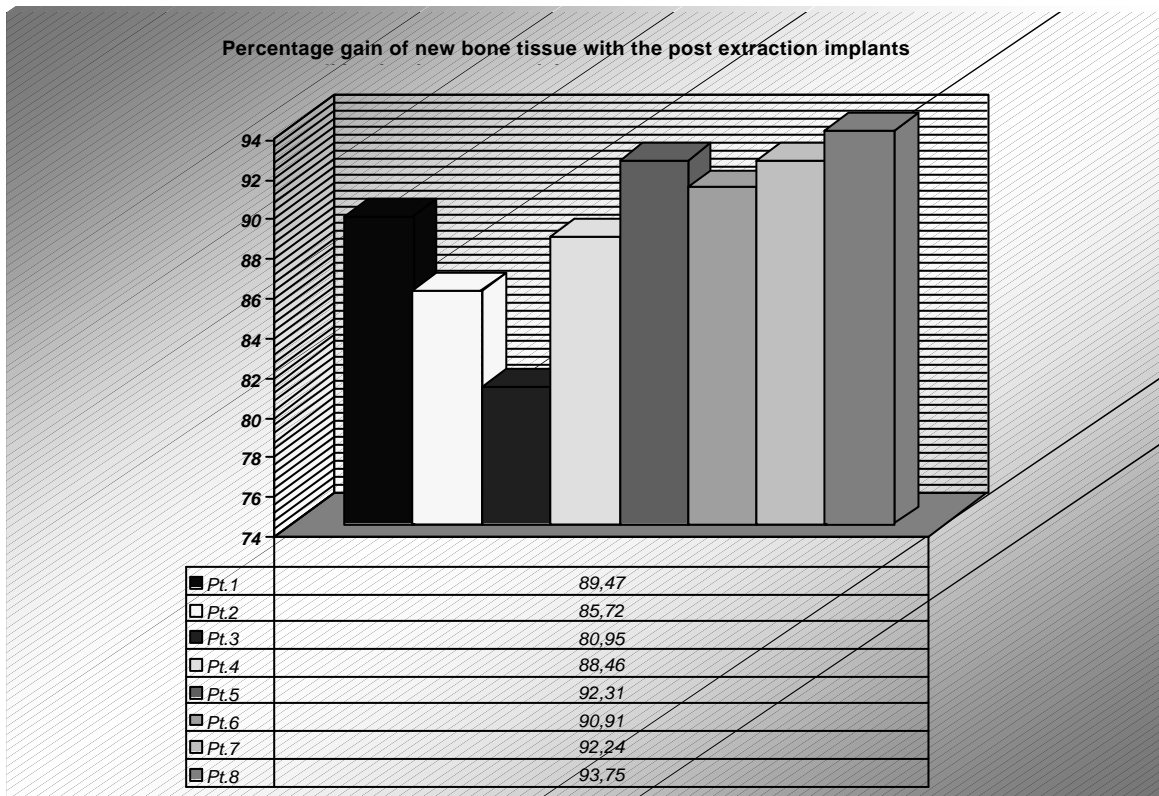
The tables illustrate the data recorded for each single implant that was inserted, information relative to the patient, the initial clinical situation (dehiscence or post-extraction implant) and the technique used. In addition they show the data regarding the gain in new bone obtained in the different situations.

Graphs 1 and 2 illustrate the results after the dehiscence were treated and the situation of the post-extraction implants with the different techniques that were used.

Graph 1

Progress of the dehiscence

Initial Dehiscence ▪Final Dehiscence

Graph 2

Percentage gain of new bone tissue with the post extraction implants

▪ Pt.1	89,47
☐ Pt.2	85,72
▪ Pt.3	80,95
☐ Pt.4	88,46
▪ Pt.5	92,31
☐ Pt.6	90,91
☐ Pt.7	92,24
▪ Pt.8	93,75

In the images (from 9 to 23) show various stages of the surgery phase performed on 3 patients involved in the study and the histological documentation.

Patient no. 1

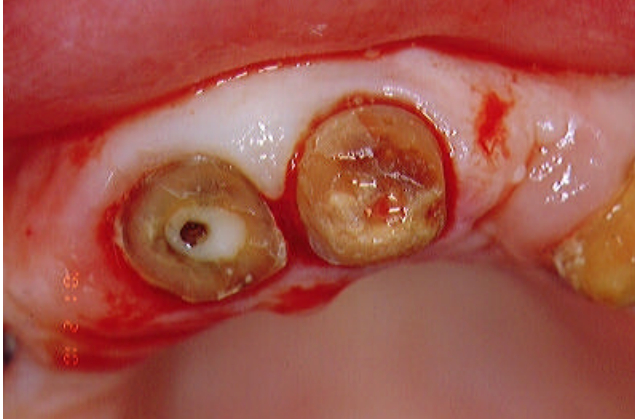Post-extraction implant

PHOTO 9
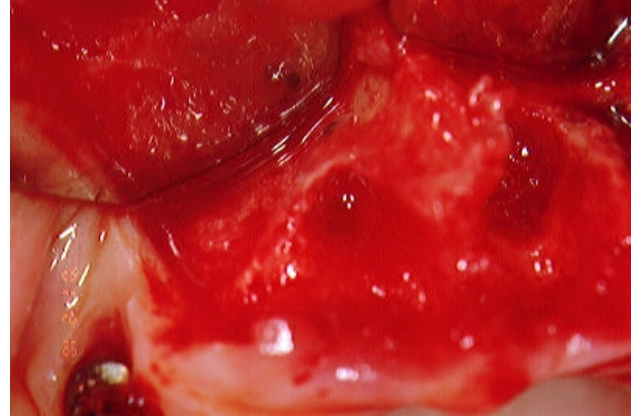The situation prior to extraction

PHOTO 10
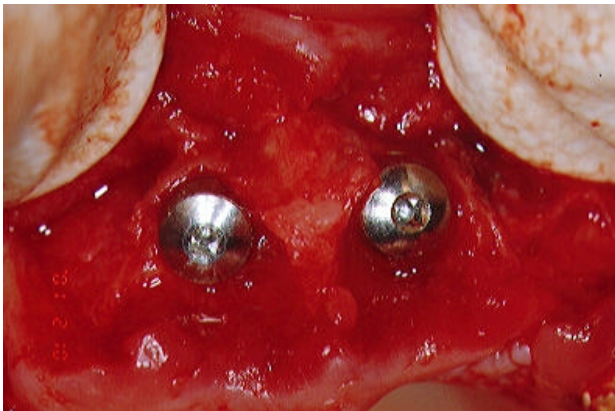The alveolus after the tooth has been extracted

PHOTO 11
Impianti posizionati con stabilità primaria but lacking bone around them due to the greater diameter of the post-extraction alveolus

PHOTO 12
Filling of the defect with FISIOGRAFT powder.

Patient no. 2

PHOTO 13
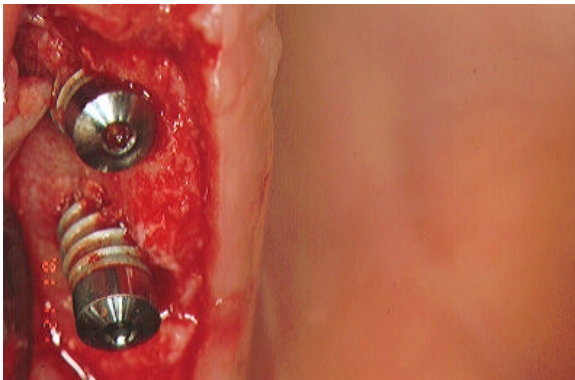Implant positioned in a dehiscence. The bone defect and the incomplete covering of the implant threads can be clearly seen.
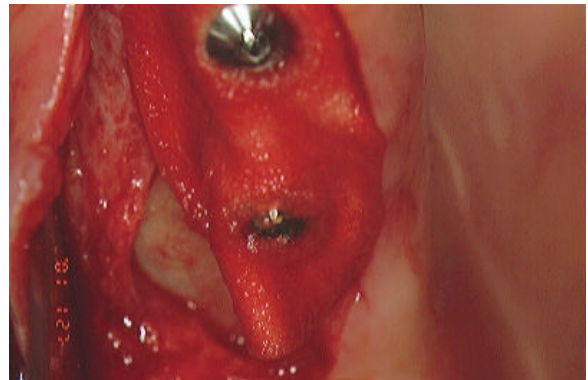

PHOTO 14
Membrane in position over the implants
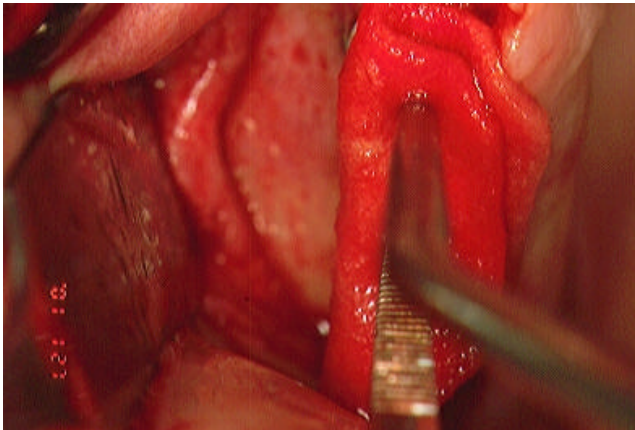
PHOTO 15
Overturning the membrane. The bone defect can clearly be seen.
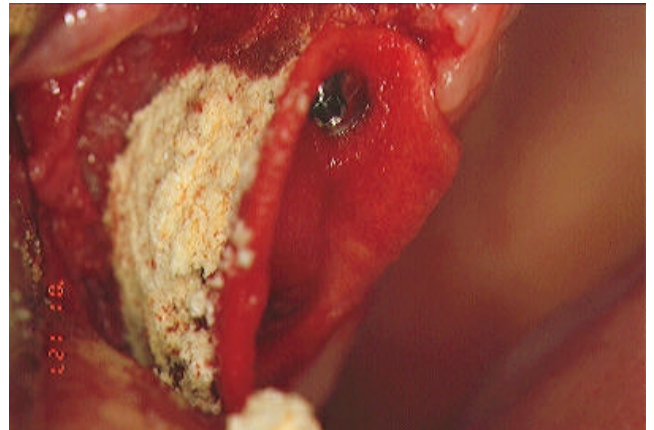
PHOTO 16
Filling the bone defect with FISIOGRAFT powder.

PHOTO 17
Repositioning of the membrane that is supported by the underlying FISIOGRAFT.

Patient no. 3

Post-extraction implant.
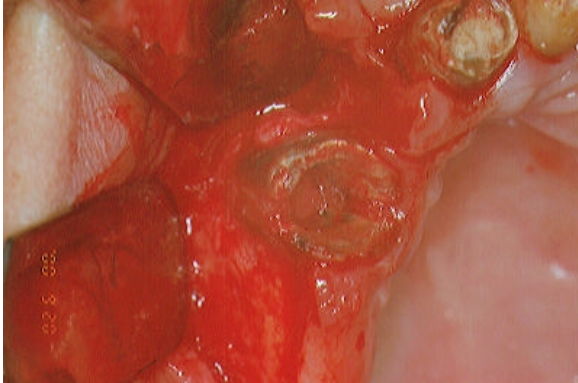
PHOTO 18
Situation prior to extraction of the canine tooth.
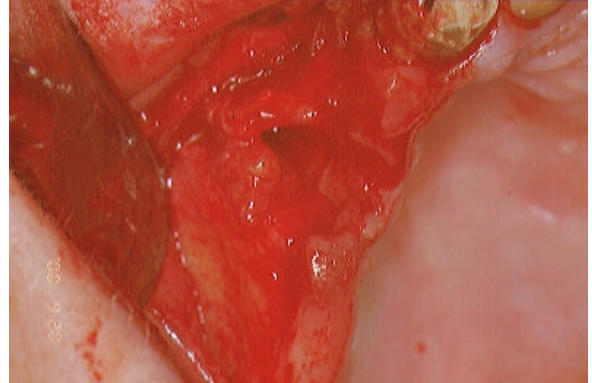
PHOTO 19
The alveolus after the extraction
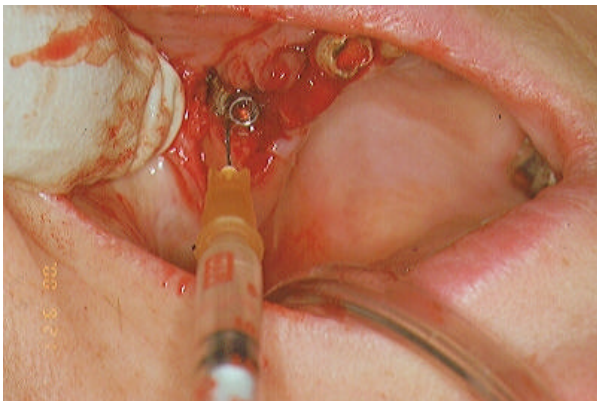
PHOTO 20
Implant in position and filling of the alveolar defect with FISIOGRAFT Gel
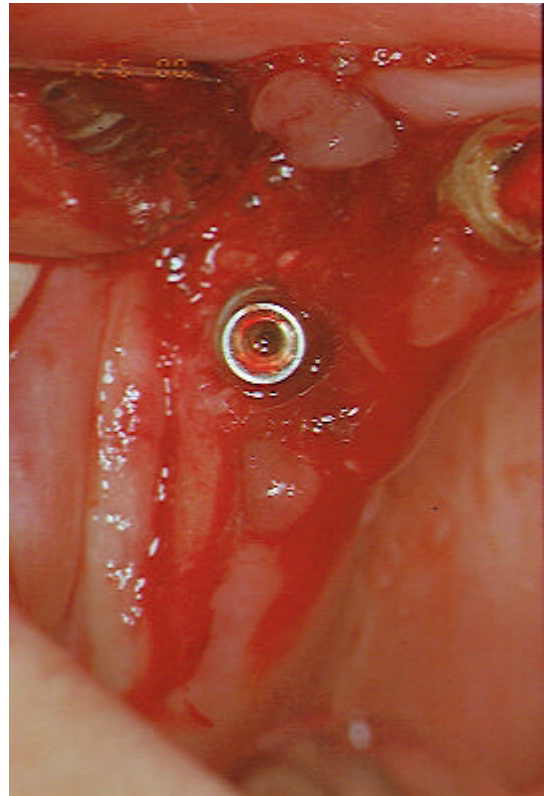
PHOTO 21
Subsequent phase.
Defect filled with Fisiograft Gel.
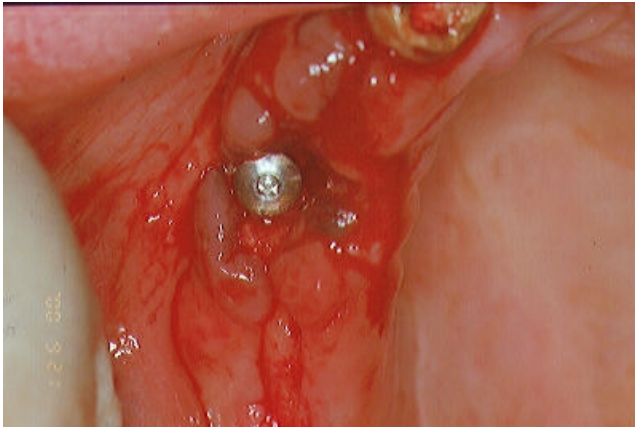
PHOTO 22
Insertion of the healing abutment on to the implant

PHOTO 23
Sutures.
In this case a membrane was not used.

CONCLUSIONS

The results we obtained indicate that FISIOGRAFT was shown to have, from a clinical point of view, a high degree of osteoconductive capabilities favouring the regeneration of bone tissue.

The granulometric characteristics of the material provide an adequate support for the stabilisation of the coagulum favouring an optimum regeneration of the bone tissue.

The positive clinical results are also confirmed by the histological tests, where the material showed a high level of biocompatibility correlated to its total absorption without producing any negative side affects.

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Table 1

PATIENTS TREATED WITH IMPLANTS AND GBR					
FEMALE	7	IMPLANTS INSTALLED	14	AVERAGE AGE	45.28
MALE	4	IMPLANTS INSTALLED	7	AVERAGE AGE	54.75
TOTAL	11	TOTAL IMPLANTS	21	TOTAL AVERAGE AGE	48.73

Table 2

Patient	Sex	Age	Clinical situation	Technique performed		Iª probing dehiscence		IIª probing dehiscence		IIIª probing dehiscence				Sum of the probings		GAIN IN NEW BONE TISSUE (%)
			Implant with dehiscence	FISIOGRAFT	FISIOGRAFT + MEMBRANE	Initial	Final	Initial	Final	Initial	Final			Initial	Final	
AP	F	48	2	X		6	1	5	1					11	2	*81.82%*

2 implants with dehiscence with an 81,82% gain in new bone tissue (using FISIOGRAFT)

BC	F	41	2	X	X	4	0	5	1					9	1	*88.89%*
FF	F	45	2	X	X	6	0	4	0					10	0	*100%*
IA	F	59	2	X	X	7	2	6	2					13	4	*69.23%*
PT	M	63	2	X	X	6	1	8	0					14	1	*92.83%*
AU	M	59	3	X	X	9	1	6	0	7	1			22	2	*90.91%*

11 implants with dehiscence with an 88.37 ± 11.49% gain in new bone tissue (using FISIOGRAFT + MEMBRANE)

Patient	Sex	Age	Clinical situation	Technique performed		Mesial probe		Distal probe		Vestibular probe		Lingual probe		Sum of the probings		GAIN IN NEW BONE TISSUE (%)
			Post-extraction implant	FISIOGRAFT	FISIOGRAFT + MEMBRANE	Initial	Final	Initial	Final	Initial	Final	Initial	Final	Initial	Final	
FM	F	37	1	X		5	0	4	1	3	0	7	1	19	2	*89.47%*
FF	F	45	1	X		6	0	5	1	7	2	3	1	21	4	*80.95%*
FC	F	51	1	X		6	1	6	0	9	2	5	0	26	2	*92.31%*
DG	M	66	1	X		3	0	5	0	7	2	6	1	21	3	*85.72%*
PG	M	31	1	X		7	1	8	1	6	1	5	0	26	3	*88.46%*

5 post-extraction implants with an 87.38 ± 4.30% gain in new bone tissue (using FISIOGRAFT)

LA	F	36	1	X	X	7	0	3	0	8	1	4	1	22	2	*90.91%*
FF	F	45	1	X	X	6	0	5	1	7	0	3	0	21	1	*95.24%*
FF	F	45	1	X	X	4	0	5	0	6	1	2	0	16	1	*93.75%*

3 post-extraction implants with a 93.30 ± 2.20% gain in new bone tissue (using FISIOGRAFT + MEMBRANE)