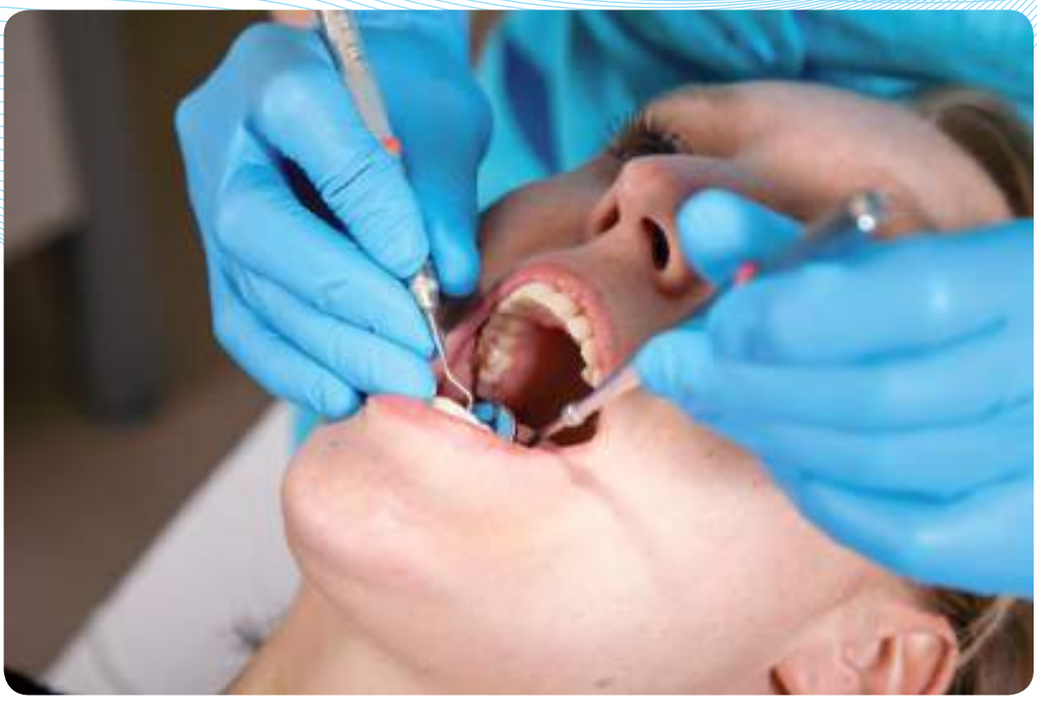
FISIOGRAFT

Totally absorbable biomaterial



It is osteoconductive

It is safe because it is SYNTHETIC

It is more biocompatible because it is totally absorbed within 3-4 months

It is easier to use because it is available in 3 forms:

SPONGE

POWDER

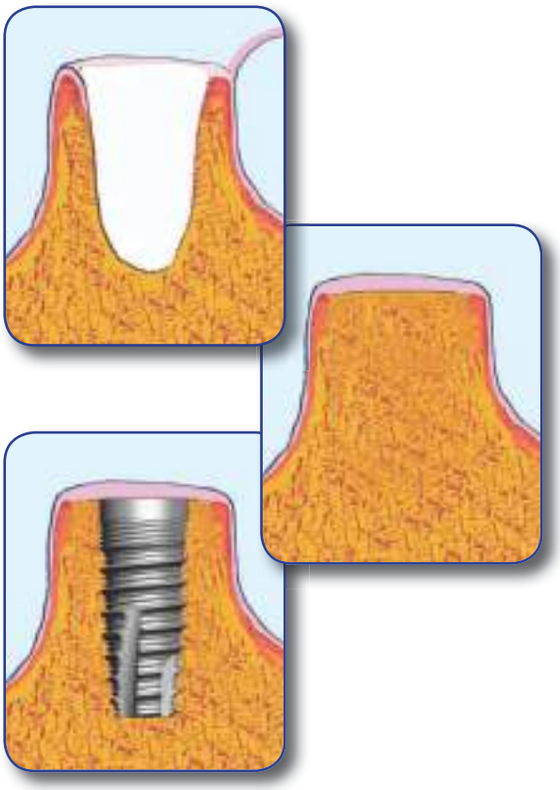
GEL

Fisiograft is easily penetrated and substituted by well mineralized trabecular bone

ENGLISH

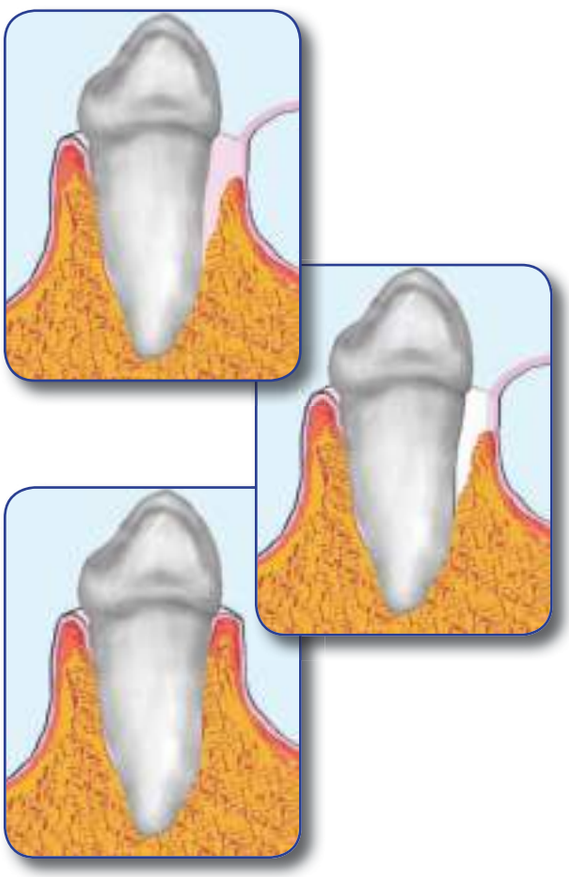
FISIOGRAFT

Post extraction sites



FISIOGRAFT **SPONGE**
when used with the **GEL** form
completely fills the post extraction site

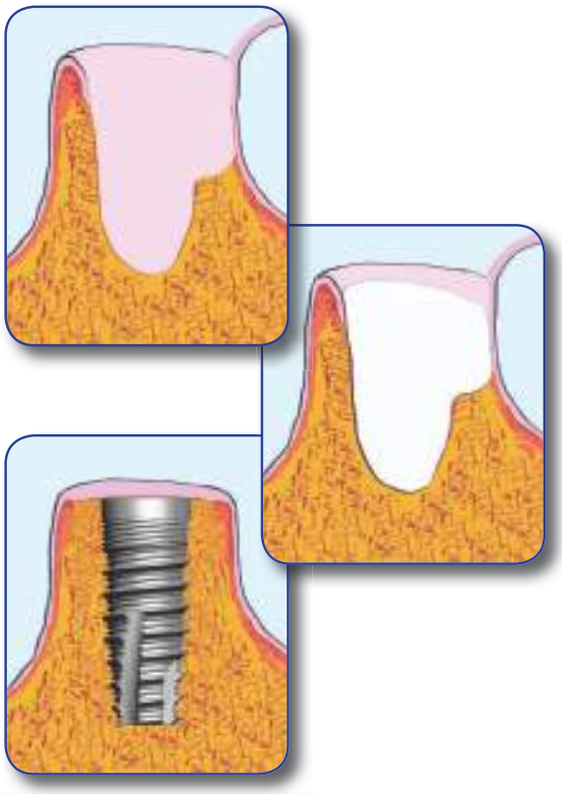
Periodontal Surgery



Fisiograft **POWDER**
when mixed together with the **GEL** form
is easy and convenient to use
even for periodontal surgeries

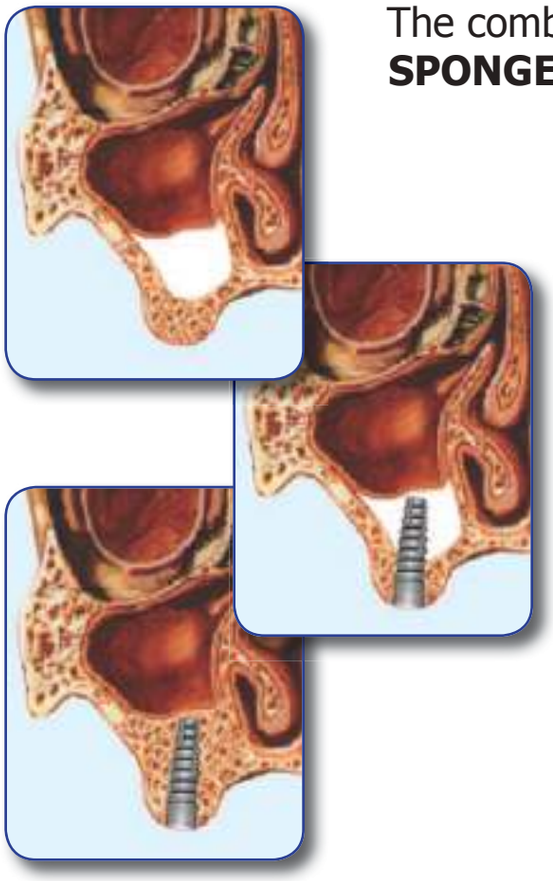
Totally Absorbable biomaterial

Bone regeneration



FISIOGRAFT **SPONGE**
when combined with the **GEL** form
fills the defect in a safe and secure way

Major maxillary sinus augmentation



The combined use of all three forms of FISIOGRAFT, **SPONGE**, **POWDER** and **GEL** guarantees the filling of large volumes without damaging Schneider's membrane

FISIOGRAFT:

characteristics — advantages

Fisiograft is a synthetic product, made from a co-polymer of polylactic acid and polyglycolic acid.

For many years, co-polymers of polylactic acid and polyglycolic acid , with different molecular weights have been used with success in orthopedics, maxillo-facial surgery, absorbable sutures, membranes etc.

*Is a **synthetic** product.*

Fisiograft is a physiological bone filler highly biocompatible and biotolerable, completely absorbed within 4 – 6 months.

Polyglycolic acid and polylactic acid are degraded in the Krebs cycle forming carbon dioxide and water as the final metabolic by-products.

- *It is **totally absorbed** within **4 – 6** months.*
- *It is completely substituted by mineralized newly formed bone.*
- *It is the only product in three forms: **Gel, Sponge** and **Powder.***
- *Consents a simplistic treatment of **all types of defects** with success, because the **Gel,** the **Sponge** and the **Powder** can be used **singularly** or **combined together**.*

Fisiograft is a space maintainer permeable to cells and osteons, and **does not produce phenomena of rejection or inflammation**.

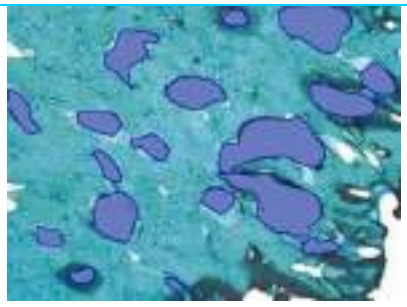
Studies made on cultures containing normal human osteoblasts with **Fisiograft** document the optimal cellular vitality and the perfect functionality of the cytoplasmatic and nuclear metabolism of the osteoblasts that grow normally on the product.

- *In some cases, **it can avoid the use of a membrane**.*
- *Being synthetic, it is absolutely **risk free** from cross contamination: BSE – HIV – HBV.*
- *Costs less than similar products that have been scientifically tested.*

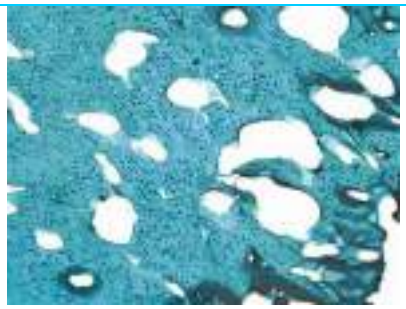
Fisiograft has osteoconductive properties because it is penetrated by and progressively and totally substituted by trabecular bone.

Studies made on cultures containing normal human osteoblasts with **Fisiograft** document the optimal cellular vitality and the perfect functionality of the cytoplasmatic and nuclear metabolism of the osteoblasts that grow normally on the product.

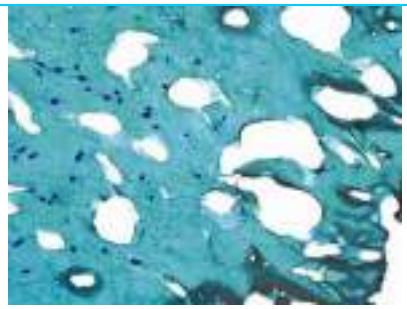
- *It is not radio-opaque. In this way the formation of new bone (radio-opaque) can be controlled radiologically at 1 – 2 – 4 or more months.*



Newly formed bone with medullar spaces



Newly formed bone with osteocytes

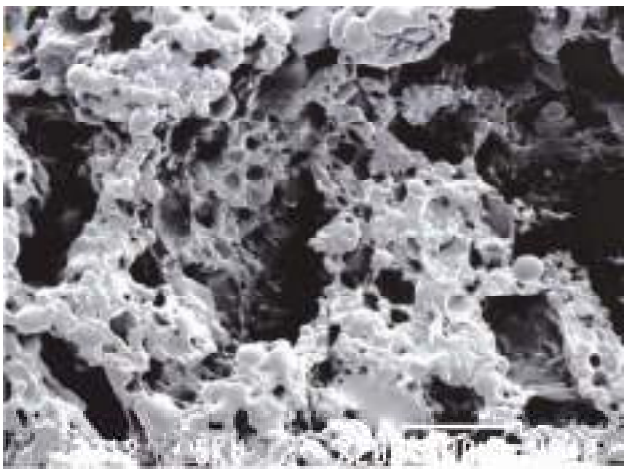


Newly formed bone with blood vessels

S.E.M. IMAGES

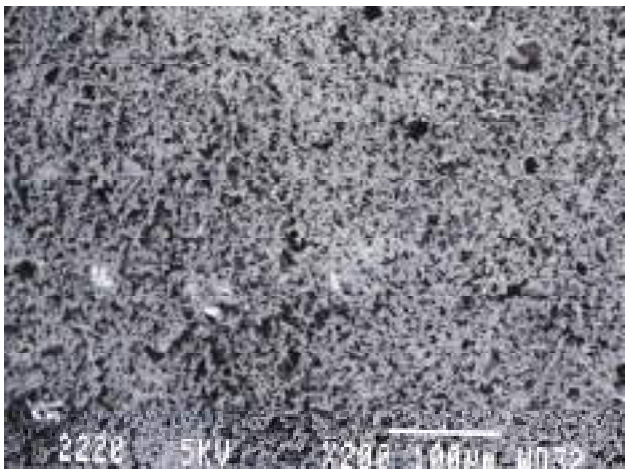
Rimondini L. U&U 2003; 1:41-3

FISIOGRAFT *Sponge*



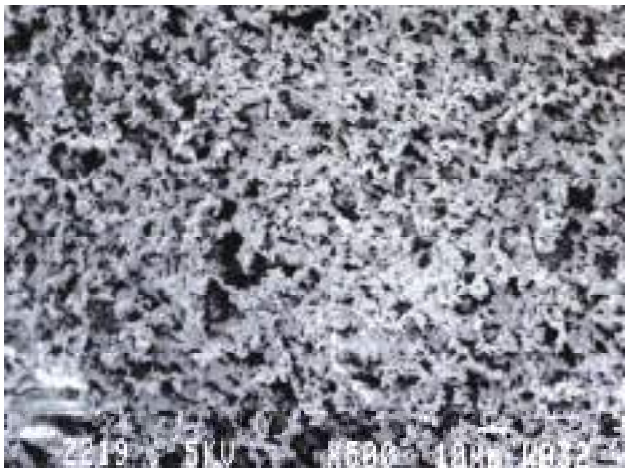
Magnification: 200X

FISIOGRAFT *Gel*



Magnification: 200X

Magnification: 500X



Magnification: 500X

FISIOGRAFT	**Composition**	
Sponge	**polylactic copolymer polyglycolic acid** . . . . . Dextran 170 mg	70 mg
Powder	**polylactic copolymer polyglycolic acid** . . . . . Dextran 357 mg	143 mg
Gel	**polylactic copolymer polyglycolic acid** . . . . . PEG 400 mg	100 mg

Fisiograft is a synthetic product…

HISTOLOGIC RESULTS

Rimondini L, Vicoli-Aldini N, Fini M, Guzzardella G., Tschon M, Giardino R.
Oral Surg. Oral Med. Oral Path. 2004 in press

A histologic study on ten white New Zealand male rabbits has assessed the effectiveness of a PLA-PGA copolymer as an osteoconductive material in critical cortical bone defects (femoral condyle).

The defects on the right sides were filled with the test material (Test sites), while the left sides were left empty as controls. Five animals were sacrificed after 30 days, the rest after 90 days.

In the defects that were left empty as controls there was absolutely no bone regeneration either after 30 days or 90 days and they remained empty (1).

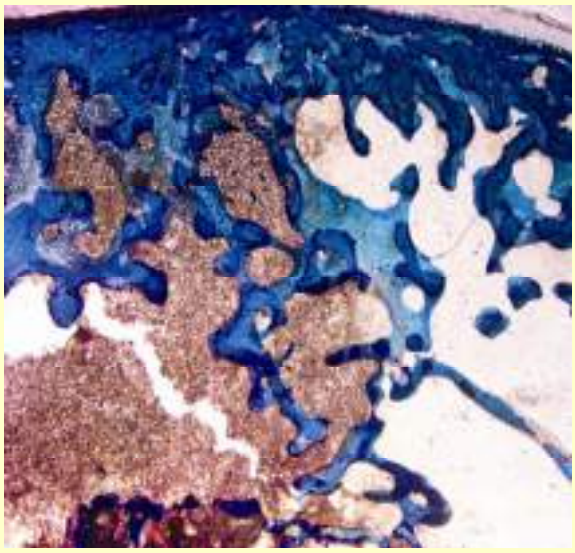
In contrast, the Test sites showed the formation of new bone inside the critical defects (2): after 30 days bone regeneration in the Test sites is very advanced (some residual particles of test material are present in the center of the defect; after 90 days the regeneration is complete; in figure 3 the new formation of bone trabeculae can be seen.

The new bone growth ranged between 11.46% and 76.82% (average $\pm$ SD = 40.63 $\pm$ 28.02%) after 30 days and between 75.98% and 95.34% (86.88 $\pm$ 9.92%) after 90 days.

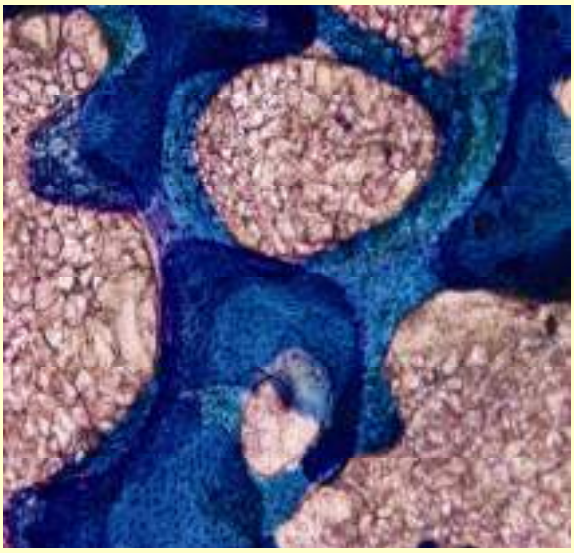
Fluorescence analysis showed new deposition of bone at both 30 days and 90 days.

No inflammatory infiltrates were ever observed.

1 Magnification: 2X



2 Magnification: 4X

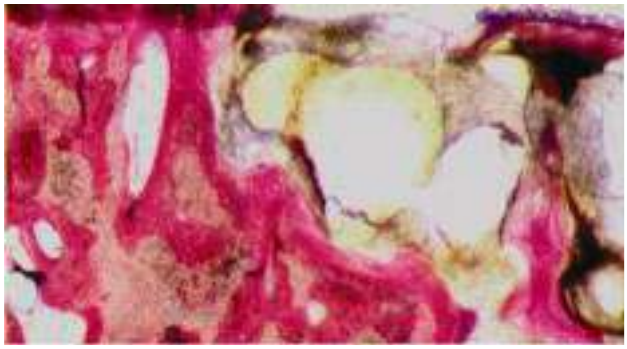


3 Magnification: 10X

… with osteoconductive properties

Orsini G, Piattelli A, Pecora G, Piattelli M, Degidi M, Iezzi G, Scarano A: Maxillary sinus augmentation with different biomaterials: a comparative histologic and histomorphometric study in man.
Best Poster Presentation Abstracts,
19th Annual Meeting of the Academy of Osseointegration. March 18-20, 2004. San Francisco, CA.

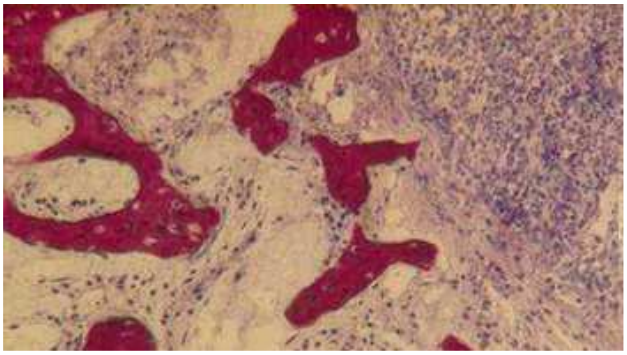
HISTOLOGIC RESULTS



Autologous Bone

Neoformed Bone	Medullary spaces	Residual material
42%	**40%**	**18%**

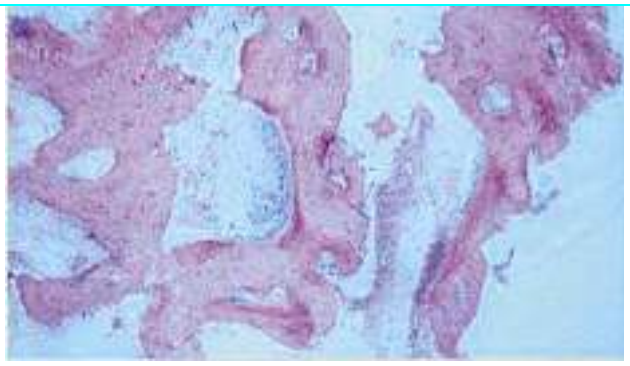
All the particles of autologous bone are surrounded by neoformed bone.
The autologous bone undergoes a very slow process of absorption.



Fisiograft

Neoformed Bone	Medullary spaces	Residual material
43%	**56%**	**1%**

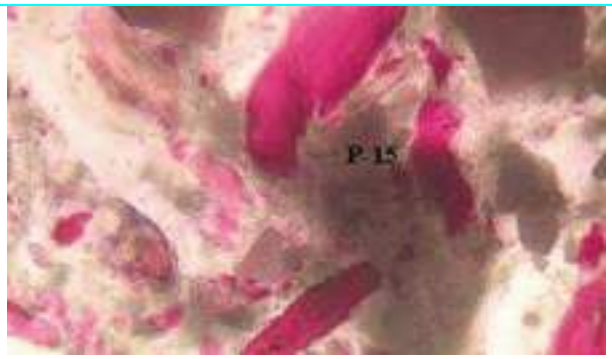
The biopsies show mature cortical bone tissue with signs of remodelling in the apical spaces, while in the central portion, bone which is more trabecular, is present.



DFDBA

Neoformed Bone	Medullary spaces	Residual material
29%	**37%**	**34%**

In some areas the trabeculae of the neoformed bone have an appearance of mature osteonic lamellar bone while in other areas there is seen non-lamellar dystrophic mineralized tissue with the presence of large lacunae.
In some areas around the particles of the DFDBA it is possible to observe an inflammatory infiltrate.



Pep-GenP15

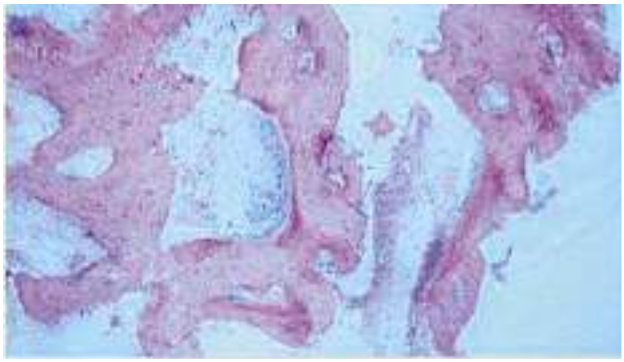
Neoformed Bone	Medullary spaces	Residual material
40%	**37%**	**23%**

A large majority of the particles do not show signs of absorption and are completely surrounded by mature bone.
The bone appears to be in direct contact with the particles of the biomaterial, without any spaces between the material and the bone.

Orsini G, Piattelli A, Pecora G, Piattelli M, Degidi M, Iezzi G, Scarano A. AAO San Francisco 2004: P-120

The histological results confirm the characteristic of **Fisiograft as an "ideal space maintainer".**
The results show Fisiograft to be the most absorbable biomaterial"

HISTOLOGIC RESULTS



Biocoral

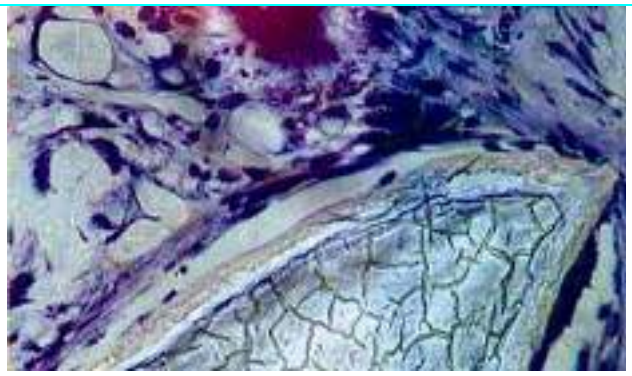
Neoformed Bone	Medullary spaces	Residual material
42%	**40%**	**18%**

The particles of BioCoral are surrounded by neoformed bone tissue. At the interface between the Biocoral and the neoformed bone spaces that are optically empty are observed.
In some zones on the surface of the granules of Biocoral areas of resorption were found.

Calcium Sulfate

Neoformed Bone	Medullary spaces	Residual material
48%	**39%**	**13%**

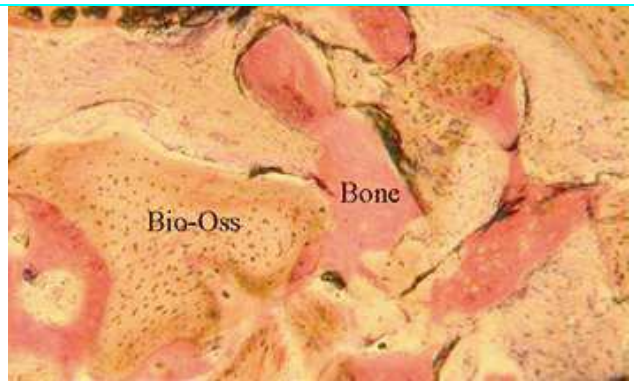
The biopsies highlight large lacunae in the neoformed bone tissue. In some fields small residual amounts of calcium sulfate, dark grey in color, surrounded by bone or phagocytic cells can be observed.



Bioglass

Neoformed Bone	Medullary spaces	Residual material
40%	**43%**	**17%**

The particles of Bioglass are surrounded by neoformed bone and when the bone-bioglass interface is observed under high magnification it does not show any optically empty spaces and in some areas it is impossible to distinguish the Bioglas particle from the surrounding bone.



Bio-Oss

Neoformed Bone	Medullary spaces	Residual material
39%	**34%**	**27%**

Most of the biomaterial appears surrounded by neoformed bone, in particular the most peripheral areas, while, in the central zone, inside the lacunae cells with morphological characteristics different from those of osteocytes.
Bio-Oss shows a very low level of absorption.

Orsini G, Piattelli A, Pecora G, Piattelli M, Degidi M, Iezzi G, Scarano A. AAO San Francisco 2004: P-120

Fisiograft is the most absorbable biomaterial

In a recent study published in "Implantologia Orale", titled "Biomaterials utilized in bone regeneration: histological results", parameters that were taken into consideration were the quantity of mineralized bone, the amount of medullar spaces and the quantity of residual material, once bone regeneration has been accomplished, 6-8 months after the grafting of different space-mantainers.

The data, in the following table, indicate that all the biomaterials used produced newly formed bone, but **Fisiograft** proved to be the most resorbable biomaterial.

This study was presented in **a Poster** at the Congress of the American Academy of Osseointegration, which took place in March 2004 in San Francisco, and **won 1st prize**.

The histological results confirm **Fisiograft** as an "**ideal space maintainer**".

Its progressive centripetal erosion,
up until its complete degradation, permit, in fact, the regeneration of bone tissue without interfering with the physiological repair processes.

	newly formed bone	*medullar spaces*	*residual material*
BIOCORAL	42%	40%	18%
BIO-OSS	39%	34%	27%
BIOGLASS	40%	43%	17%
DFDBA	29%	37%	34%
FISIOGRAFT	**43%**	**56%**	**1%**
HYDROXYAPATITE	41%	30%	31%
AUTOLOGOUS BONE	42%	40%	18%
PEP-GEN P-15	40%	37%	23%
CALCIUM SULPHATE	48%	39%	13%

Piattelli A. Implantologia-Orale. 2003; 4: 77-80

FISIOGRAFT: applications

Fisiograft has been show to possess an elevated manageability in periodontal and implantological applications.
The different forms **Gel, Sponge** and **Powder** permit choosing, case by case, the type which adapts best to assure a surer filling with newly formed bone.
The three forms, used singularly or in combination with each other, guarantees easier placement and consequently an easier integration with the tissues; resulting in a rapid absorption and a more complete colonization.
Fisiograft is the ideal space maintainer even when an absorbable membrane must be used, because it will prevent it from collapsing.

Fisiograft is completely absorbed

INSTRUCTIONS FOR USE

The method of use of the three types of **Fisiograft** requires procedures that are analogous and can be summarized as follows:

- **How to prepare the site**

The receiving site must be rendered perfectly clean, cleared of all contaminant material, such as tartar, granulation tissue, very thin portions of bone, which if not adequately vascularized can become necrotic: therefore, the use of curettes, low speed drills and if necessary bone rongeurs of an appropriate size for obtaining the best possible preparation of the receiving site. The bone cavity, at the end of the treatment, must have sufficiently thick borders and without any irregularities; any eventual roots that are present must be completely decontaminated and polished: to accomplish this, etching Gel may be used on the root, for example, a highly concentrated solution of citric acid. Usually, especially if there is little bleeding at the site, at the end of the cleaning with the bur, cruentation of the cavity walls permits a greater presence of marrow blood, rich with osteoblast cells.

Examples of application

1

Preparation of the site

2

*Application of **Fisiograft Powder***

3

*Successive application of **Fisiograft Gel***

4

Suturing the site

Lenharo A. Internal Data Ghimas 2001

Fisiograft consents a simplistic treatment…

- **How to fill the site**

A general rule is to completely fill the site up to the coronal border of the cavity. **Fisiograft** is available in three different forms – **Sponge**, **Powder** and **Gel** – that can be used in the various cases separately or in combination to optimize the filling.

The **Sponge** type is usually cut – by means of a scissor or sterile scalpel – into fragments with a dimension appropriate for the receiving site. The technique is to apply small pieces, a little at a time, that are lightly packed using a cylindrical or ball shaped compactor, until it is completely filled.

From the moment the **Sponge** type is bathed with liquid, such as blood, it becomes much more malleable, losing its initial rigid consistency. Before compacting it, it is important to wait until it is completely hydrated which is accomplished in general thanks to the presence of blood. In cases where there is a scarcity of blood at in the receiving site the **Sponge** type should be wet with a few drops of sterile saline solution.

The **Powder** type is applied into the receiving site with a spatula or with a bone chisel. Wetting the **Powder** with blood transforms it into a cohesive mixture, which is able to spontaneously remain localized at the receiving site.

Examples of application

1

Preparation of the site

2

*Application of **Fisiograft Sponge***

3

*Adapting the **Sponge** to the site*

4

Suturing the site

Lenharo A. Internal Data Ghimas 2001

… of all types of defects with success

Since it is not possible, do to the characteristic of the form, to compact it, the **Powder** type is used in simple cavities, without irregularities and of a reduced dimension.

The **Powder** type can also be mixed with the **Gel** type to obtain a denser mixture and to make it easier to place it into the receiving site.

The **Gel** type is supplied in a syringe from which the product can be applied directly into the receiving site.

Like the **Sponge** type, it is a good rule, above all in deep and complex defects, to divide the filling into several steps.

After each increment the **Gel** type, while absorbing blood, becomes more compact and if necessary this compactness can be increased by mixing it with the **Powder** type: in this way an optimal compacting of **Fisiograft** can be obtained more efficiently and simpler.

- **How the filled site should be covered**

The covering of the site, after it has been filled with **Fisiograft**, depends strictly on the type of operation that was performed and on the choice of the surgeon.

The possibilities can be summed up as follows:

a) Uncovered sites:

the material is exposed to the oral environment and only the sutures that are placed above it keep it in place.

Examples of application

1

Preparation of the site

2

*Application of **Fisiograft Gel***

3

*Adapting the **Gel** to the site*

4

Suturing the site

Lenharo A. Internal Data Ghimas 2001

Fisiograft in some cases avoids…

In any event it is advised NOT to pull the sutures tight, eventually leaving part of the **Fisiograft** uncovered because the product cannot be attacked by bacteria, if the patient performs a correct and frequent oral hygiene with a 0,2% Chlorhexidine mouthwash.

b) Site covered with a flap:

in this case the muco-gengival flaps are positioned directly above the graft until primary closure is obtained. This procedure might require some periostal releasing incisions.

c) Site covered with a membrane:

in this case the membrane is interposed between the **Fisiograft** and the flap, which must have primary closure (see the following paragraph), a membrane that provides a separation between the graft area (and therefore undergoing regeneration) and the epithelial and surrounding connective tissue, according to the principals of guided tissue regeneration (GTR). For this purpose non absorbable membranes can be used, however they must be removed within a predetermined period of time, or else absorbable ones that do not require surgical removal. This last type, absorbable, appear highly preferable because they do not require a second surgical operation for removal of the membrane itself; its use is favored and this is made possible thanks to the efficiency of **Fisiograft** which defends and maintains the space under the membrane, it prevents a possible collapse of the absorbable type of membrane.

Examples of application

1

Preparation of the site

2

*Application of **Fisiograft Sponge***

3

*Successive application of **Fisiograft Gel***

4

Suturing the site

Lenharo A. Internal Data Ghimas 2001

… the use of a membrane

- **How to perform a more correct post-operative recovery**

After surgery, the patient must be informed of the possible appearance of swelling and varying degrees of pain, in general dependent upon the severity and magnitude of the surgical procedure.

Medications are limited in general to the use of a 0,20% chlorhexidine based mouthwash for the first week and then followed by a 0,12% concentration, used three times per day at the surgical site, instead of daily brushings, that are absolutely prohibited for the first 7/10 days.

The use of analgesics and anti-inflammatory agents is foreseen only if necessary, while an antibiotic therapy should not be routinely prescribed, except in cases when a membrane is used or the surgeon thinks it will be useful.

The sutures are removed after 7-10 days and then the patient can start using a soft bristled toothbrush.

Periodic controls of the regeneration are at the discretion of the surgeon, however radiological controls are recommended at 6-8 months, the time considered necessary and sufficient for a complete regeneration and a successive follow-up of the patient should also be made at 12 and 18 months.

Examples of application

1

Two fenestrations and a dehisced defect are present on the implants

2

Bone graft in excess is positioned in recipient site

3

***Fisiograft Gel** is positioned to cover the bone graft*

4

24 weeks post-op. at re-entry. The original bone defects appear filled with new regenerated bone

Rocchietta I, Pilloni A, Rasperini G, Simion M. AAO San Francisco 2004: P-118

Fisiograft is not radio-opaque. In this way…

FISIOGRAFT Gel in Surgery

Grassi R. Internal Data Ghimas 2003

Fracture of the mesial root of 47

Clinical aspect shows extensive bone absorption (1), which calls for the extraction of the mesial root (2). **Fisiograft Gel** is inserted into the post extraction site. When reopened after three months, the clinical aspect shows evidence of good bone formation, suitable for inserting a fixture (3).

Clinical aspect after application of the prosthesis (4).

In figures 5-8 the radiographic evolution of the case can be appreciated:

- initial situation of the fracture of the mesial root of 47 (5),
- Radiograph after the **Fisiograft Gel** has been positioned (6),
- Photograph at 3 months that shows the complete filling of the site with newly formed bone (7),
- Positioning of an implant 3,25 mm in diameter and 10 mm in length (8).

5

6

7

8

… the formation of new bone (radio-opaque) can be controlled radiologically

FISIOGRAFT Gel in Surgery

Rimondini L. Internal Data Ghimas 2002

Root fracture
after endodontic treatment of 14

Clinical and radiological aspect of the vertical root fracture (1 and 2).

The compromised element is extracted after exposing it with a small flap.

Fisiograft Gel is inserted in the alveolus and then sutured (3).

Radiological controls are made at 3 and 6 months after the extraction (4 e 5).

The site is reopened after 6 months for insertion of the fixture. The bone at the post-extraction site has healed with good bone regeneration on both the buccal and lingual sides (6).

At re-entry, before inserting the implant, the bone at the post-extraction site appears to have regenerated correctly and without defects, even in the presence of a saddle in the intermediate portion do to the significant initial loss of bone (7).

1

2

3

4

5

6

7

FISIOGRAFT Sponge in Surgery

Rimondini L. Internal Data Ghimas 2002

Radiological aspect of the vertical root fracture in 14 after endodontic treatment (1).

When the flap is opened, one notes the vertical fracture of the root of 14 and the lack of the external cortical bone (2).

The root is extracted and **Fisiograft Sponge** is inserted into the defect (3).

Aspect of the soft tissues two months after the extraction (4).

Aspect of the site after the flap has been reflected for inserting the implants (5 and 6).

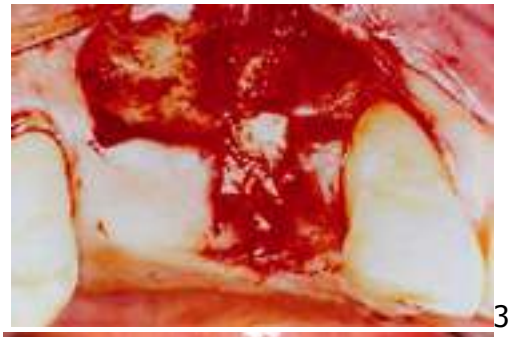
Photo of the sutured flap and the radiograph taken after the implants were inserted (7 and 8).

The bone at the post extraction site has healed with good bone regeneration, even if not completely at the palatine side.

We want to emphasize, that the time from when the biomaterial was used and the implants were inserted was only two months.


1


2


3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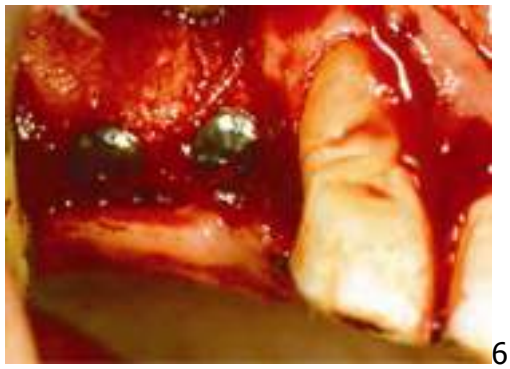
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FISIOGRAFT Gel + Sponge in Surgery

Stancari F, Zanni B, Bernardi F, Calandriello M, Salvatorelli G. Quintessenz (De) 2000; 51

Post-extraction site at 24 treated without the use of a membrane

In a situation that was particularly compromised, it was decided to extract the tooth and insert **Fisiograft** into the alveolus in order to obtain the formation of well mineralized bone.
Once the site is prepared, which presented without the vestibular wall (1),
Fisiograft Gel and **Sponge** were positioned (2) and then covered with a muco-gingival flap.
Radiographic controls taken when the material was implanted and then after 3 and 6 months show the progressively increasing opacity of the site (3, 4 and 5).
After six months a muco-gingival flap is made that permitted visualization of the new bone tissue (6), utilized for inserting an implant.
The tissue sample that was removed underwent a histological exam and electron microscopy (7 and 8), appears to be constituted of well mineralized lamellar bone with the characteristics of alveolar bone.


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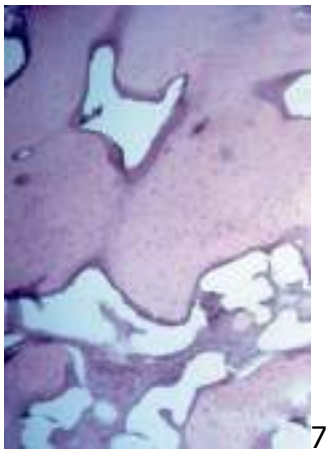
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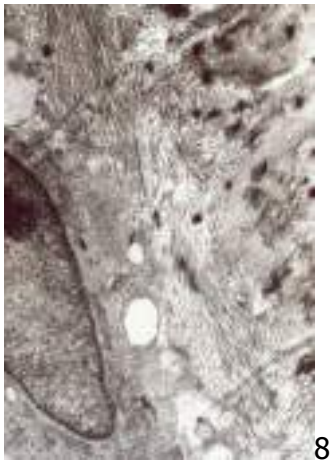
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FISIOGRAFT Sponge in post-extraction sites

Serino G, Biancu S, Iezzi G, Piattelli A. Clinical-Oral-Impl-Res. 2003; 14

The controlled study published in Clinical-Oral-Impl-Res. 2003; 14: 651-8, entitled: *"Ridge preservation following tooth extraction using a polylactide and polyglycolide sponge as space filler: a clinical and histological study in man"* (Serino, Biancu, Iezzi, Piattelli), showed that the use of **Fisiograft Sponge,** in 36 cases evaluated at six months, when inserted in post-extraction alveoli (26 alveoli test in 24 patients versus 13 alveoli controls in 12 patients), can prevent resorption of the alveolar crest with respect to the control alveoli.
In particular, the application of **Fisiograft Sponge** in the alveolus with the buccal wall completely or partially destroyed by dental pathologies, favored the reconstruction of the buccal bone at the level of the mesial and distal portion of the alveolus itself.
The material did not induce any complications during the healing phases, similar to what was observed in the control alveolus.

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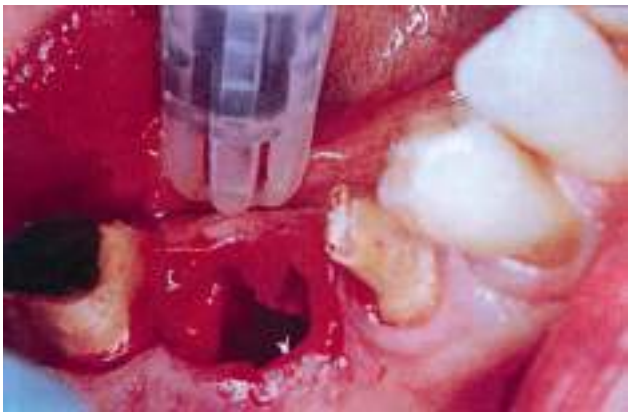

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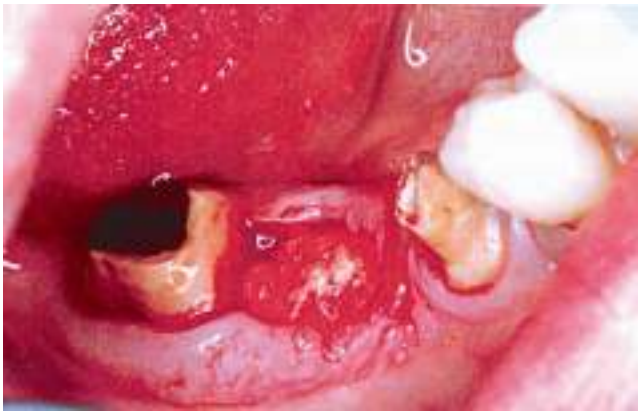


The series of photos so in one case the alveolus after the extraction (1), **Fisiograft Sponge** positioned in the alveolus (2) view after suturing without attempting to cover the material (3).

In another case **Fisiograft Sponge** positioned in alveoli 12-21-23, while alveoli 11 and 22 are left as controls (4), the site is sutured (5), healing at one week (6) and at two weeks (7).

Note how the gingival tissues heal similarly in the alveolus where **Fisiograft Sponge** was implanted and that of the control site.

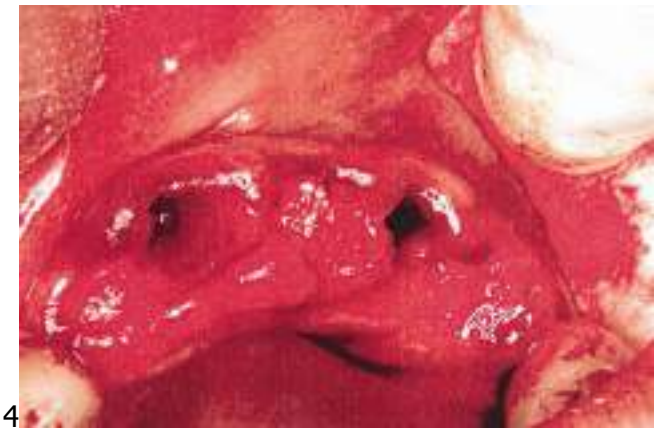
At the moment of surgical re-entry, the new bone formed in the test alveoli resulted similar in form and consistency to the bone in the surrounding area and there were no traces of the implanted material.

In addition, in the test alveoli, the insertion of the endosseous implants was performed without difficulty, obtaining primary stability also in those alveoli when at the moment of the extraction of the teeth, the buccal wall was partially or completely destroyed.

Fisiograft, when inserted in post-extraction alveoli, reduces the resorption of the alveolar crest

FISIOGRAFT Sponge in post-extraction sites

Serino G, Biancu S, Iezzi G, Piattelli A. Clinical-Oral-Impl-Res. 2003; 14



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The histological result confirmed the clinical results, showing that:

- the cortical bone appears mature in the apical portion of the biopsy
- the trabecular bone is mature in the middle and coronal portion of the biopsy
- no inflammatory tissues are present
- no traces of the implanted material were found
- there was no evidence of any soft tissue growth in the coronal portion of the biopsy that inhibited the bone regeneration process.

Here are the histologic analyses of two biopsies taken from two Test alveoli (8 and 9) and one from a control alveolus (10). Observe the compactness of the bone from the Test alveolus.

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MINIMALLY INVASIVE TECHNIQUE TO OBTAIN A MAJOR LIFT OF THE MAXILLARY SINUS FLOOR AIMED AT INSERTING ENDO-OSSEOUS IMPLANTS

Bucci Sabattini V, Salvatorelli G. 1999

ADVANTAGES

In line with the evolution of general surgical procedures a technique for a major lift of the maxillary sinus floor aimed at inserting endo-osseous implants was clinically proven.

This technique, presents the advantages of:

- **lowest invasiveness**
- **reducing the risk** of lacerating Shneider's membrane
- **reducing the time** to perform the procedure
- **minimizing the stress** and suffering of the patient
- good predictability of the dimensions of the lift that can be obtained highest simplicity in performing the technique.

MATERIALS

The material indicated for the execution of this mini-invasive procedure for the major lifting of the maxillary sinus is **Fisiograft type gel**.
This plastic form, when injected directly into the sinus cavity, exerts a hydraulic pressure on the membrane and raises it in a totally atraumatic manner.
This method **reduces the risk of lacerating the sinus membran**e to an absolute minimum,
a risk normally present in other procedures that is associated with the maneuver of raising the membrane with metallic instruments.
The gel, even when used by itself, **stabilizes the membrane** after it has been raised because as soon as it comes into contact with the blood, the PEG, which is hydro-thermo-labile, is removed and assumes an appearance and consistency of a soft porous plaster.
This constitutes an ideal matrix for stabilizing the coagulum originating from periosteal bone which will evolve into bone.

METHOD

The minimal invasive technique for raising the floor of the maxillary sinus is indicated when the height of the residual bone crest is insufficient for insertion of implants (1).

A horizontal and vertical CT scan is performed to define the anatomy of the sinus and to evaluate the increase in the bone volume that is desired using the new sinus lift technique.

After performing a standard nerve block, a small crestal incision and a full width stripping is performed exposing the summit of the bone crest in correspondence to the floor of the sinus where the lift is desired (2).


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A vertical CT scan defines the anatomy of the sinus and is also utilized for measuring the residual bone crest (3).
The horizontal CT scan of the maxillary sinus should be made at intervals of 2 mm for evaluating the desirable increase in the bone volume (4).
If for technical reasons it is not possible to perform a CT scan, a cranial radiograph, using the Waters projection and an x-ray of the paranasal sinuses taken from several different projections, can be used to determine within a reasonably good degree of accuracy, the volume of the maxillary sinus, providing information about the proper quantity of gel to inject. This will avoid using either too much or too little material.

In order to determine the quantity of material to be injected into the sinus, it is possible to calculate the partial volume of the sinus by using the formula for calculating the volume of a truncated pyramid (7).

Using specially designed burs one or more openings are made, depending upon the number of implants that are to be positioned immediately (6).

When the implants are to be placed at a future date a single opening will suffice. Once the opening has been made, the Valsalva maneuver must be performed to control the integrity of the membrane.
After doing this, utilizing the openings which have a diameter of 4 mm, the gel is injected directly into the sinus using a continuous but delicate pressure (7).

In a completely atraumatic way the gel raises the internal membrane of the sinus and stabilizes it, maintaining a space in which an osteoid coagulum can organize and evolve.

The diameter of the openings in the crest must be 4 mm for the following reasons:

- in these cases the crest is normally flattened,
- for prosthetic rehabilitation implants with a diameter≥4 mm are normally used,
- this opening will adapt perfectly to the tip of the syringe containing the gel. This avoids dispersion of the force applied to the syringe, permitting the best possible results for the lifting of the sinus floor.


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In addition, to obtain a better and more immediate stability to the implant, after the membrane has been elevated **Fisiograft type Gel**, it is possible to add **Fisiograft type Sponge**, making sure to reduce the sponge into fragments of an appropriate dimension (filling sinus with a "sandwich" technique).

In conjunction with the sinus lift **it is possible to immediately insert the implants** when there is sufficient bone to ensure primary stability of the implants (8). When this is not the case, it is possible to insert the implants approximately 4-6 months after the Fisiograft was placed and the lift has been obtained.

Four to six months following the surgery the vertical and horizontal CT scan or a radiograph (11) permit an optimal evaluation of the dimensions and the characteristics of the maxillary sinus lift that was obtained.

In a situation where the lift of the sinus floor is performed, when there is insufficient residual bone to immediately place the implants, four months after the surgery, before placing the implant(s), a biopsy can be taken at the site.

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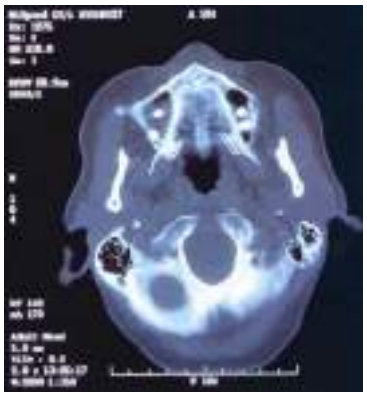

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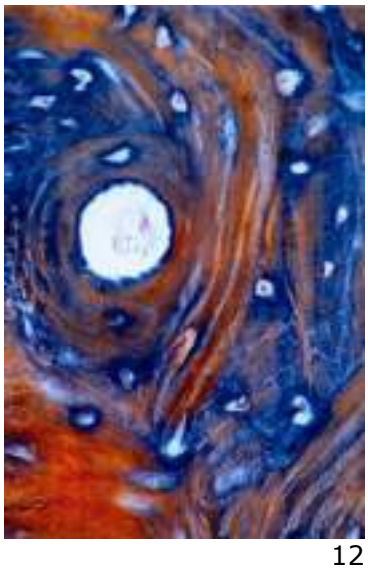
Histological results (12 - 13)

Histological exam was made four months following the procedure on the core sample that was obtained in the area where the bone was regenerated. The sections appear to be composed of laminar bone tissue in which numerous osteons, characterized by large numbers of concentric lamellae surrounding the Haversian canals are visible.

The presence of interstitial lamellae, residuals of proceeding generations of osteons, indicate healing of the bone tissue which has taken place. The osteons appear well cellularized by osteocytes present in the bone lamellae.

There are no signs of inflammatory reactions and there are no remaining traces of the Fisiograft material that was implanted.

This demonstrates that from the time Fisiograft was implanted to when the biopsy was taken, the material had been completely absorbed and was substituted by newly formed bone.



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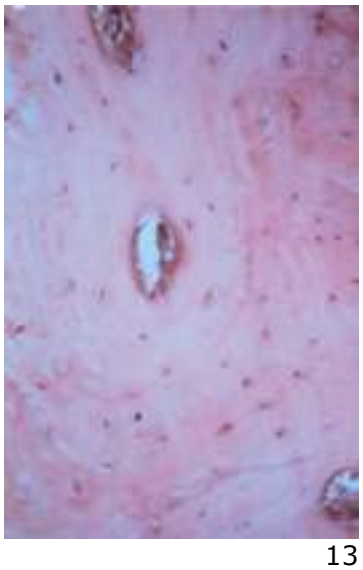

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