

ToothTransformer

TT IS DIFFERENT

About US



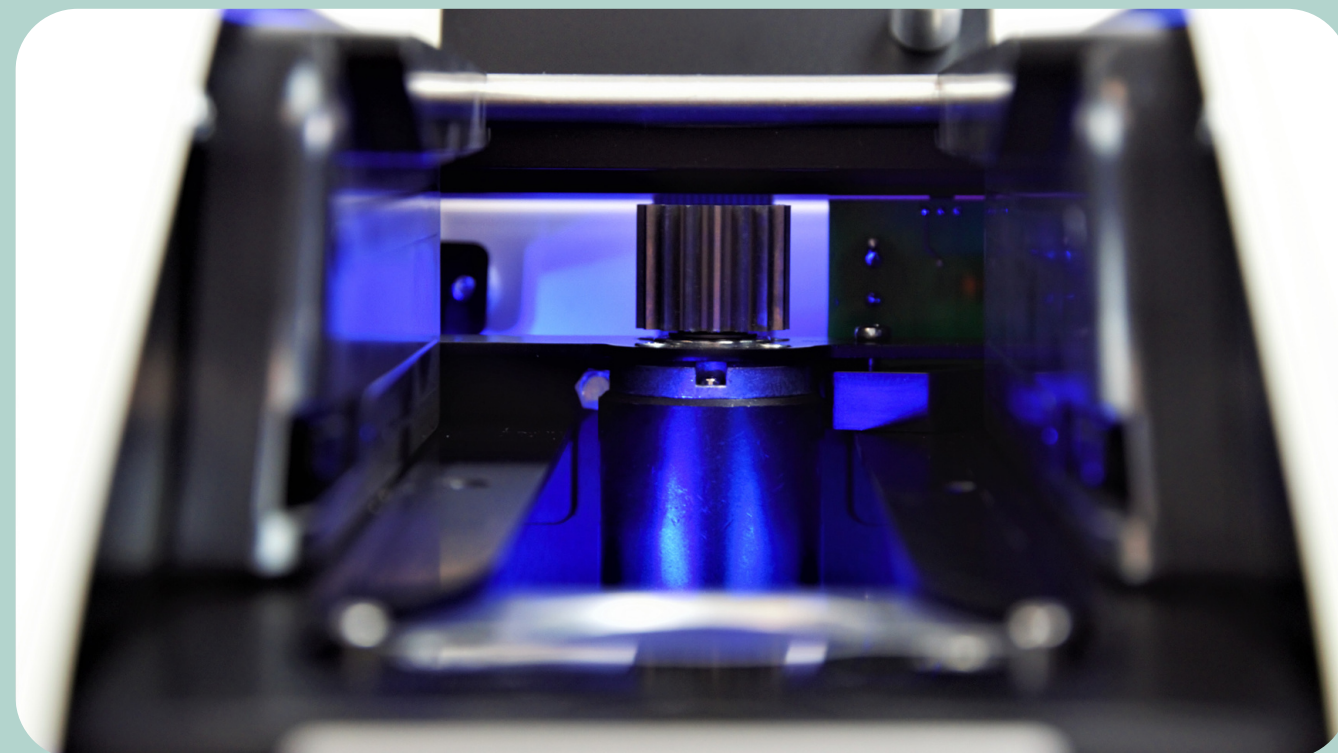
Made in Italy

Who we are

TOOTH TRANSFORMER is an innovative Italian start-up, founded in 2016 by a group of entrepreneurs and professionals in order to conceive, design and develop innovative medical devices with high technological content, in scientific collaboration with leading research centres and universities. In 2014, from an idea of the same working group, the first innovative project called "TT" for the design, implementation and clinical testing of the medical device "TT TRANSFORMER", intended for the dental sector, was launched.

The technical feasibility was analysed and deepened, biological tests were entrusted to the laboratories of the Department of Chemistry, Materials and Chemical Engineering "Giulio Natta" of the Politecnico di Milano and with the help of scanning electron microscope to maximize the effectiveness and validate the safety of the dental grafting material produced by the device. The project was completed at the beginning of 06/2018 with the issue of the CE certificate as a Class IIa medical device, necessary for marketing throughout the European Community and which allowed us to obtain a Certificate of Free Sale worldwide.

Vision & Project





Vision

The mission of Tooth Transformer is to provide dentists with an easy-to-use medical device with clear biological advantages over the grafting procedures used to date, as well as practical and economic benefits. Our slogan: preserve and innovate.

Preserve a valuable asset like the tooth to innovate surgical practice

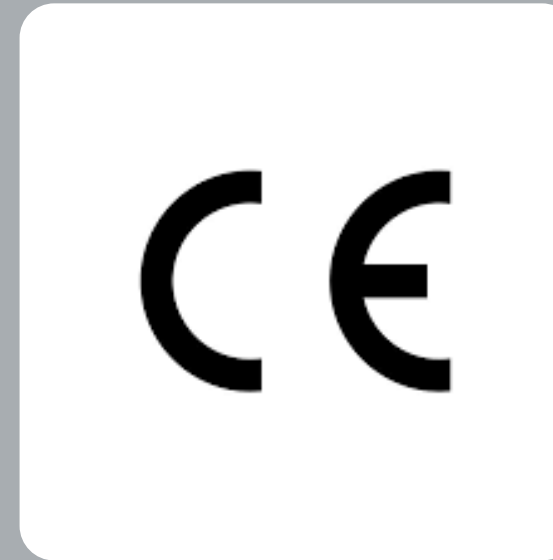
Mission

01 **SAFE**
Reduces risks of REJECTION of the dental implant.
Granulate disinfection and rinsing avoid INFECTION
No need of any INVASIVE procedure

02 **HOLISTIC**
Ecological : no unnecessary WASTE of bio-materials.
Psychological: no additional INVASIVE surgery.
Psychological: no REJECTION and pain.

03 **COOL**
INNOVATIVE approach to bone regeneration.
Classy product of Italian DESIGN.
The process is truly ECO FRIENDLY.

Certificate Timeline



2018

2021

2022



06/2018

D•CE Medical Device class IIA.

06/2021

Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

Gost-R

We started the certification in April 2021, in September we will send the devices for verification to the Russian Ministry of Health.

Product Portfolio



1) TT . Device

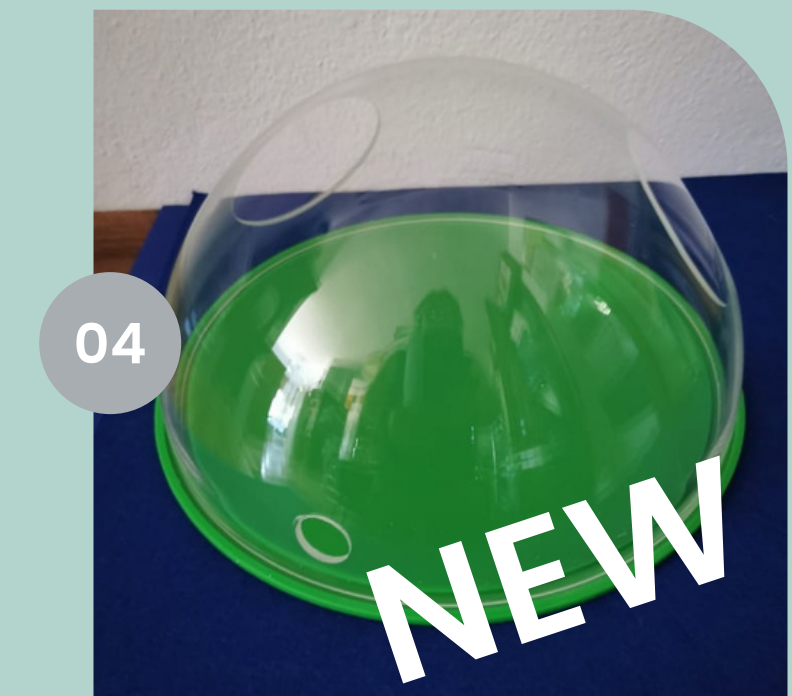
- Automatic System.
- Safety System.
- Small dimension

2) TT . Kit Single Use.

- Use for a single surgical.
- The high wettability.
- Growth factors available in the graft material.
- Max 3Gr graft material.

3) TT – Fairy (11/2019)

- Storage the Tooth.
- Identification it is guarantees.
- Dentist use this product for marketing gift.



Key Factors



01 NEXT GENERATION

Do you want to be the first in your job?
Innovation in bone regeneration
Give a second life to the tooth
The TT project is dedicated to all those dentists who want to stand out, innovate and be the first in their work

03 HEALDING CLINICAL CASE

What material would you like in your mouth, in your bone?
TT is completely natural and the graft material is produced by your organism, autologous material. Growth factors promote bone regeneration. The TT Transformer device makes a large amount of autologous growth factors available to the patient without the use of heterologous materials or invasive harvesting.

02 ECONOMIC

How much does the traditional grafting material cost?
With just one cartridge, you can produce 3 Gr of grafting material.
The grinder sterilizes up to 100 times.

04 Product line

Do you want not to lose customers, do you want new customers? Offer new products
Today, having the completeness of regenerative, synthetic, natural, autologous materials is certainly the success of the business.
TT products are a great sales tool for dental implants

Market Targeting

NUMBER OF CLINICAL CASES PER YEAR

Clinical cases in one year

Source:

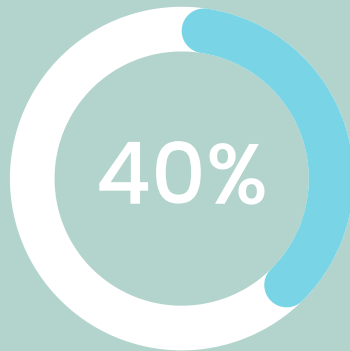
IMPLANTS SURVIVAL RATE IN REGENERATED SITES
WITH INNOVATIVE GRAFT BIOMATERIALS: 1 YEAR FOLLOW-UP

in 1 year 483 clinical cases were performed by 11 worldwide KOL
That means 44 clinical cases in each clinic



Market Targeting

What is the % of immediate implantation or delayed implantation using the autogenous tooth bonegrafting out of total implants inserted/procedures?



Source : Bibliography

Three different procedures require regenerative therapies:

- RIDGE PRESERVATION
- SOCKET PRESERVATION
- SINUS LIFT

Is important to understand ...all patient are dentulous and the dentist made a extractions

But now in our world the edentulous patients are very rare.

51.7% additional bone-augmentation procedures were required. This data is suggested from the literature(10) . In the clinics the percentage is 40%. But the percentage is greater when is necessary the socket preservations. We made the socket preservation when one of the bone walls was absent.

Following tooth extraction, the edentulous site of the alveolar process will undergo both quantitative and qualitative changes (1-2). A clinical study of bone healing after tooth extraction revealed that the average single-tooth extraction site loses 50% of its alveolar width during the 12 months after extraction (3) Thus, during healing, the bundle bone will gradually disappear, the socket will be filled with granulation tissue, provisional matrix and woven bone that eventually will be replaced with trabecular bone and marrow (4-5-6-7). Moreover, the walls of the socket will be markedly reduced both with respect to height and width (8) and the dimensional changes will be more pronounced in the buccal than in the lingual/palatal compartments of the extraction site (9).

The most common use of TT is the socket preservation because the extraction is concomitant with the regeneration. After the extraction the buccal and lingual bone walls are re-adsorbed in different ways. The pocket preservation is suggested to compensate the re-adsorption(11-12-13)

Using this therapy the volume and the aesthetic will be preserved.

TT APPLICATION

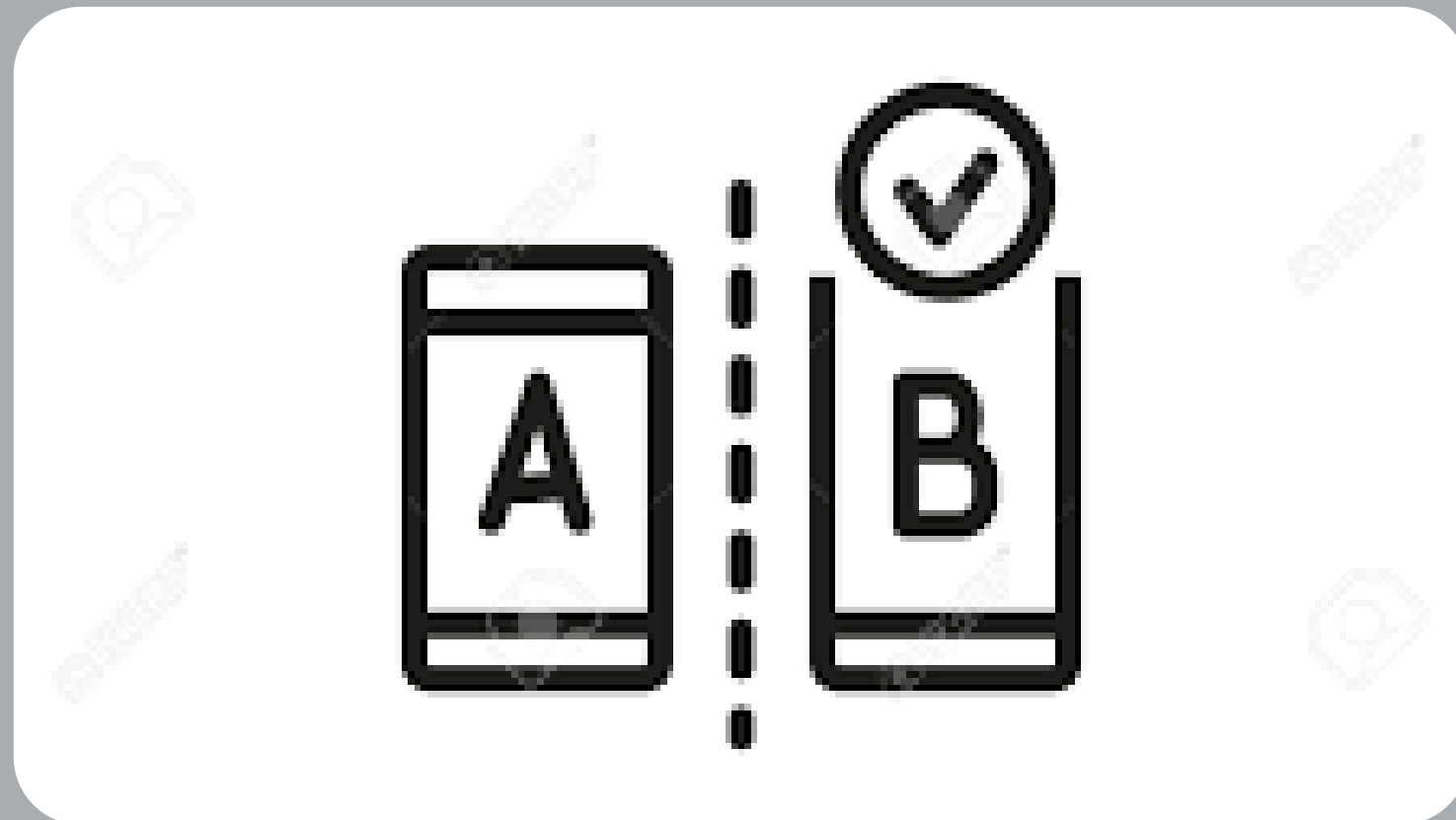
TT is use full in the majority of extractions with the aim to maintain the bone volume. We must add all cases in which we have a donor tooth (impacted tooth or deciduous tooth) and cases where-having extracted one or more teeth – it is possible to make ridge preservation or sinus lift.

1. Pietrokovski, J. & Massler, M. (1967) Alveolar ridge resorption following tooth extraction. The Journal of Prosthetic Dentistry 17: 21-27.
2. Amler, M.H. (1969) The time sequence of tissue regeneration in human extraction wounds. Oral Surgery Oral Medicine Oral Pathology 27: 309-318.
3. Schropp, L., Wenzel, A., Kostopoulos, L. & Karring, T. (2003) Bone healing and soft tissue contour changes following single-tooth extraction: a clinical and radiographic 12-month prospective study. The International Journal of Periodontics & Restorative Dentistry 2003;23: 313-323.
4. Evian, C.I., Rosenberg, E.S., Coslet, J.G. & Corn, H. (1982) The osteogenic activity of bone removed from healing extraction sockets in humans. Journal of Periodontology 53: 81-85.
5. Kuboki, Y., Hashimoto, F. & Ishibashi, K. (1988) Time-dependent changes of collagen crosslinks in the socket after tooth extraction in rabbits. Journal of Dental Research 67: 944-948
6. Cardaropoli, G., Araújo, M. & Lindhe, J. (2003) Dynamic of bone tissue formation in tooth extraction sites. An experimental study in dogs. Journal of Clinical Periodontology 30: 809-818
7. Araújo, M.G. & Lindhe, J. (2005) Dimensional ridge alterations following tooth extraction. An experimental study in the dog. Journal of Clinical Periodontology 32: 212-218
8. Araújo, M.G., Sukekava, F., Wennström, J.L. & Lindhe, J. (2006) Tissue modeling following implant placement in fresh extraction sockets. Clinical Oral Implants Research 17: 615-624.
9. Pietrokovski, J., Starinsky, R., Arensburg, B. & Kaffe, I. (2007) Morphologic characteristics of bony edentulous jaws. Journal of Prosthodontics 15: 141-147.
10. Bornstein MM, Halbritter S, Harnisch H, Weber HP, Buser D. A retrospective analysis of patients referred for implant placement to a specialty clinic: indications, surgical procedures, and early failures. Int J Oral Maxillofac Implants 2008; 23: 1109-1116.
11. Araújo MG, Wennström JL, Lindhe J. Modeling of the buccal and lingual bone walls of fresh extraction sites following implant installation. Clin. Oral Implants Res. 17, 2006; 606-614
12. Araújo MG, Sukekava F, Wennström JL, Lindhe J. Ridge alterations following implant placement in fresh extraction sockets: an experimental study in the dog. J Clin Periodontol 2005; 32: 645-652.
13. Bucco-Lingual Crestal Bone Changes After Immediate and Delayed Implant Placement Ugo Covani,* Claudia Bortolai,† Antonio Barone,‡ and Ludovico Sbordone† J Periodontol 2004;75:1605-1612.



Breakeven

Surgery, 2 Gr of material for bone regeneration



A

Using a xenografic materials
39 clinical Cases in one year
Price to 2 gr = 125€
 $39 \times 125€ = 4.875€$ Total Cost

B

Using TT Tooth Transformer
39 clinical Cases in one year
Price to 2 gr = 1 one Single Use 35€
 $39 \times 35€ = 1.265€$
1 TT Device 3.500€
TOTAL COST (Kit+TT) = 4.765€

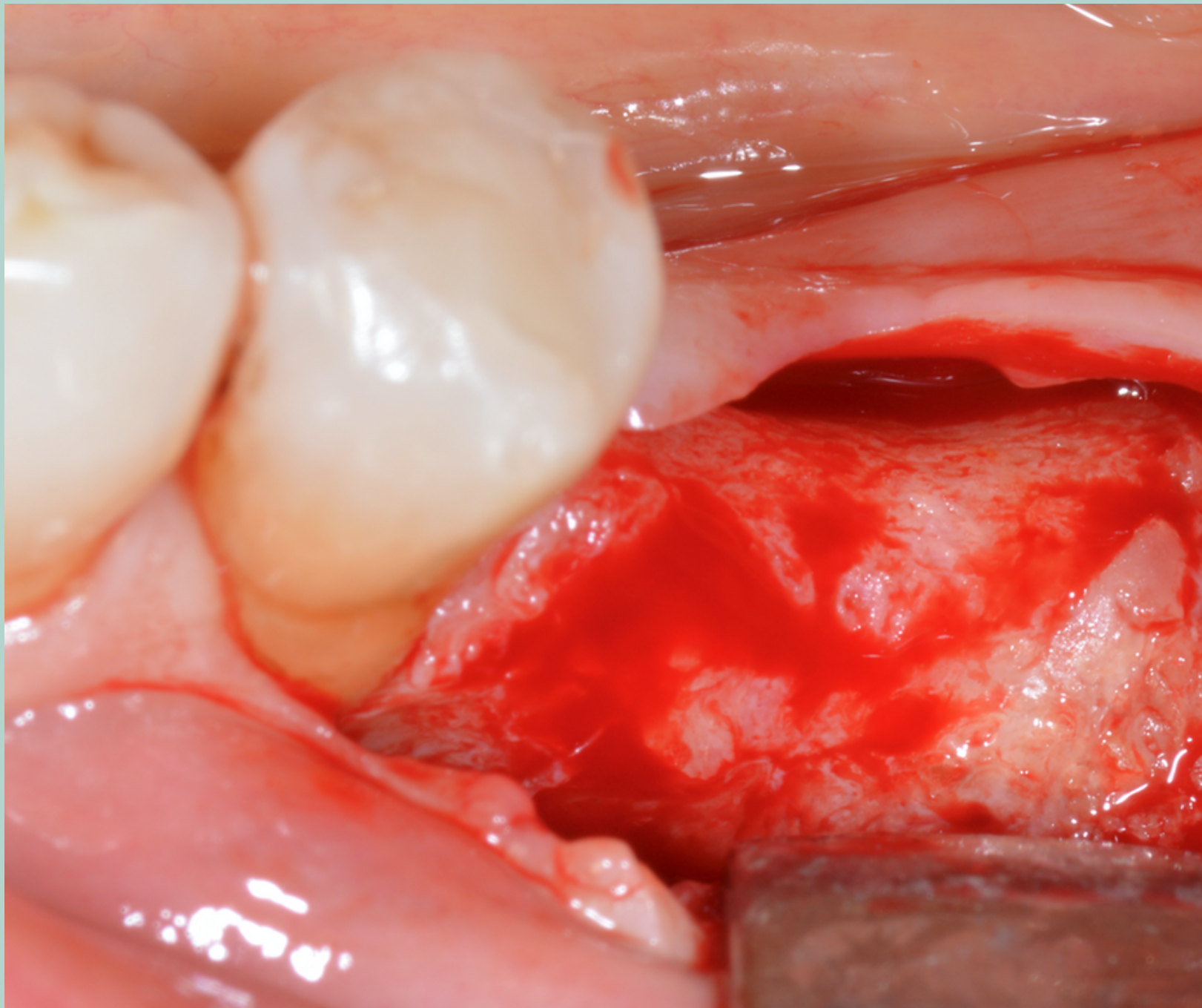
NET INCOME
After Breakeven

A (4.875€)

-

B (1.265€)=
4.873€

TT BONE - it is very easy

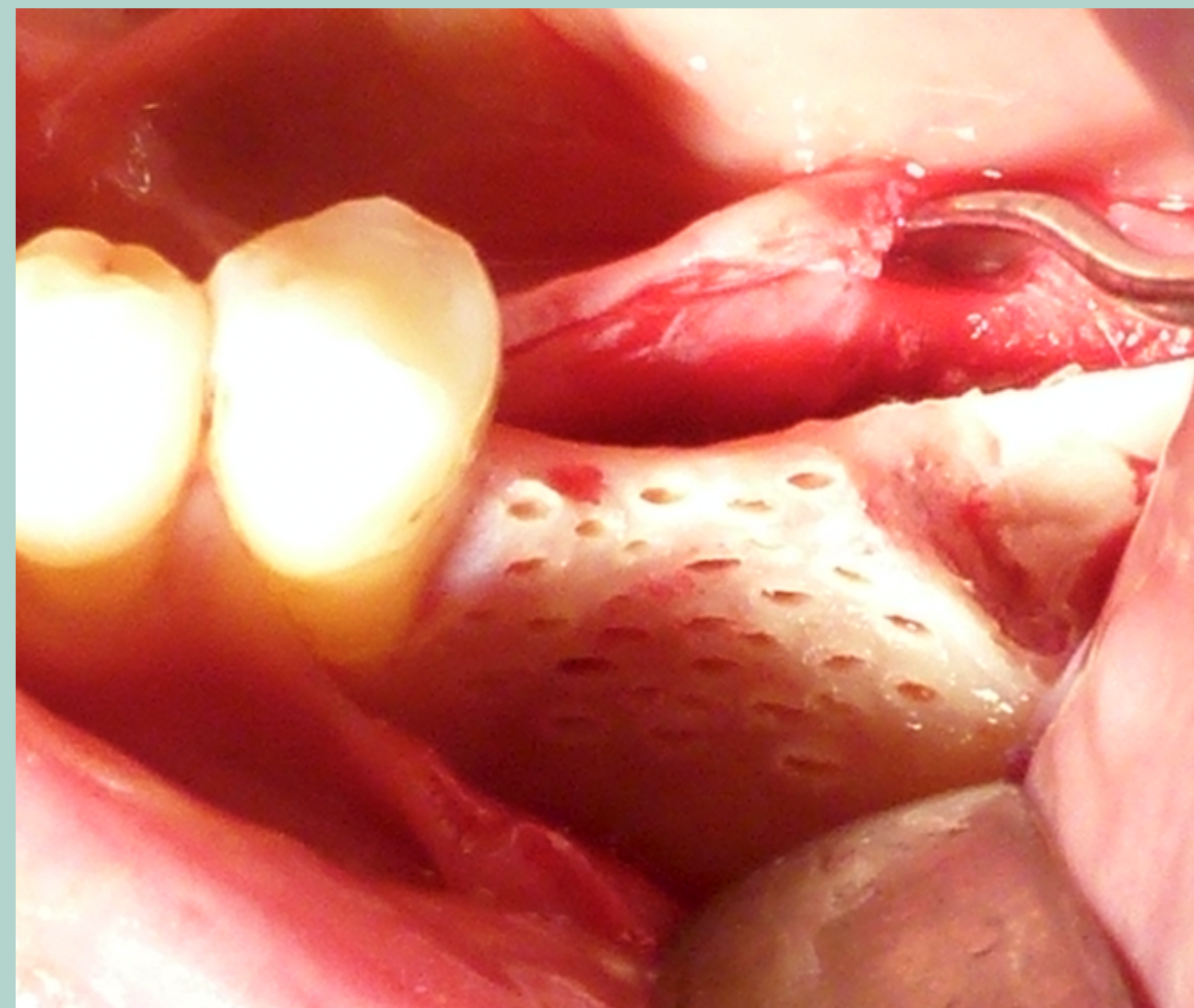


Bone made with TT procedure

How we made it?

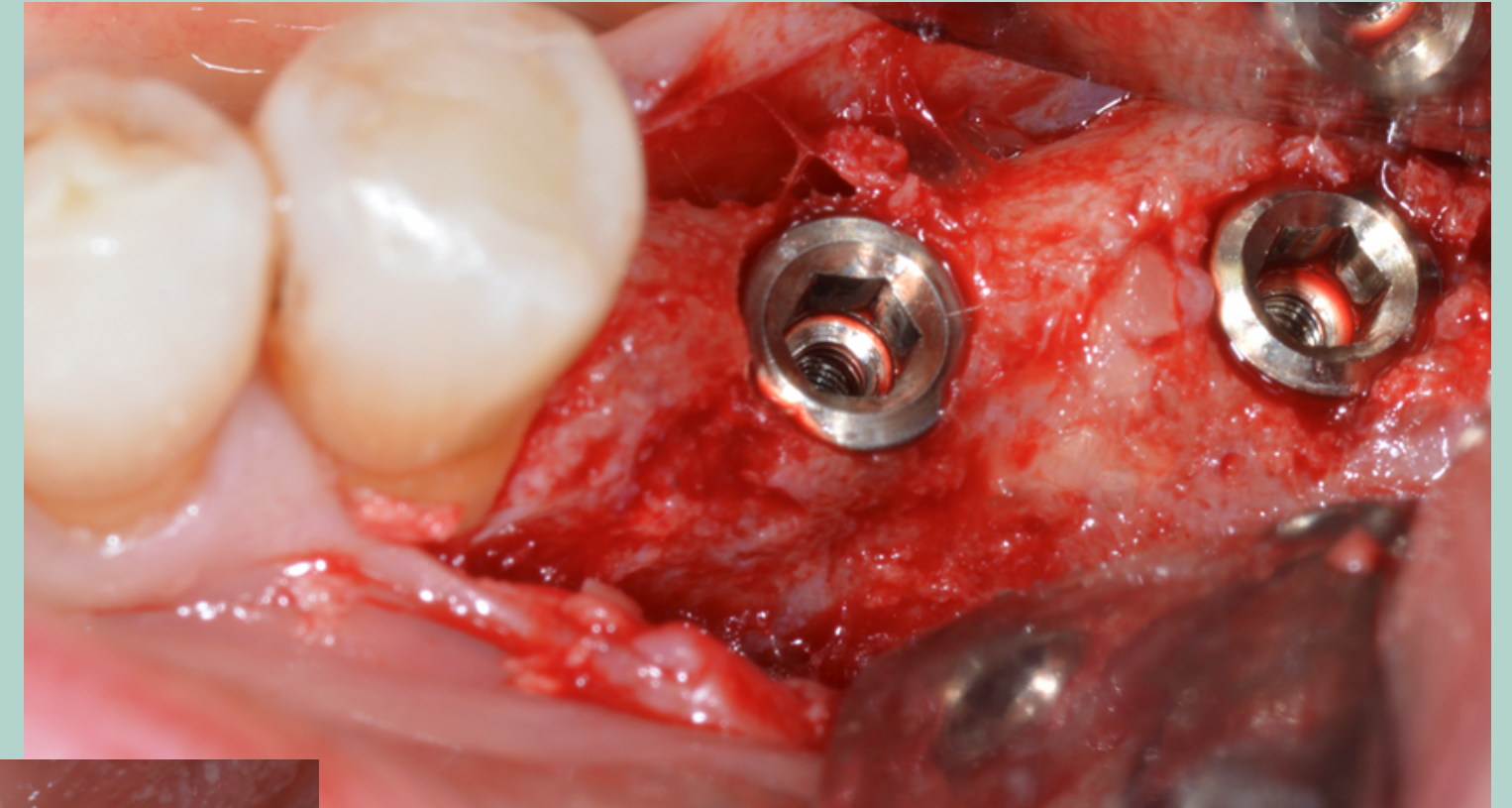
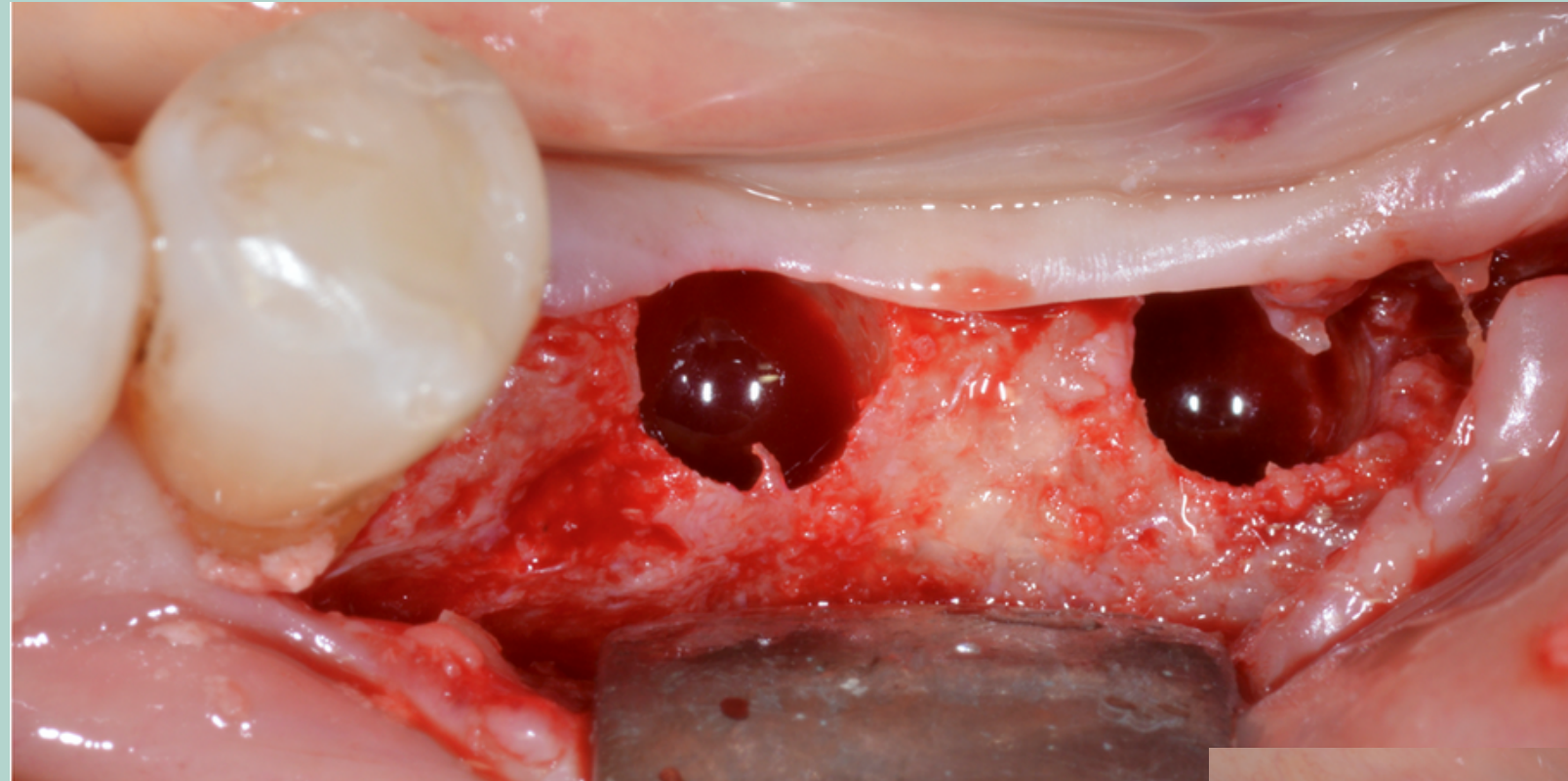
3.7 extraction, alveolar ridge preservation using Tooth Transformer with 3.7

Initial situation



How we made it?

After 4 months



TT BONE

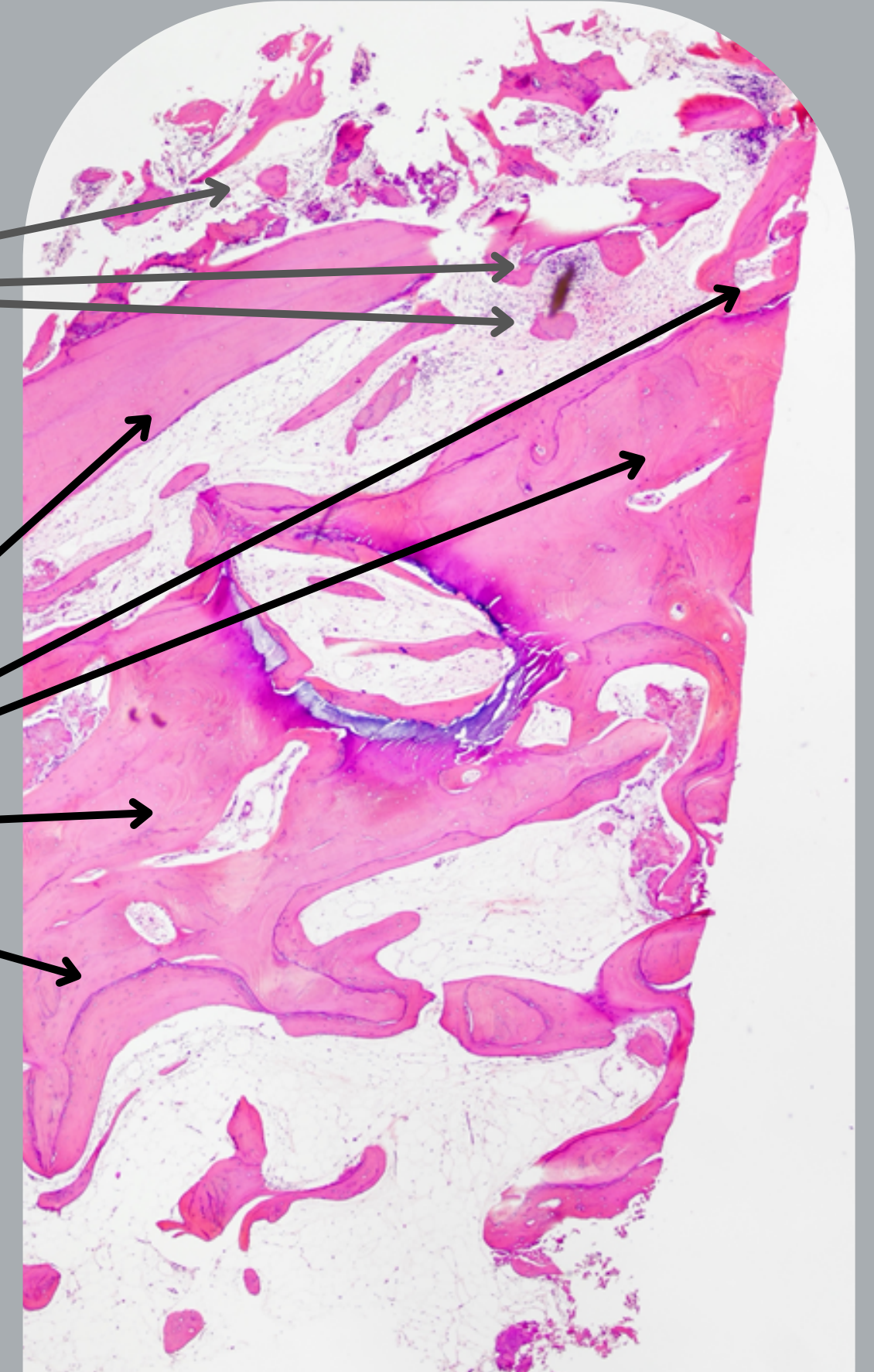
| | |
|-------------------|---------|
| TOTAL BONE VOLUME | 47,333% |
|-------------------|---------|

| | |
|----------|---------|
| NEW BONE | 41,678% |
|----------|---------|

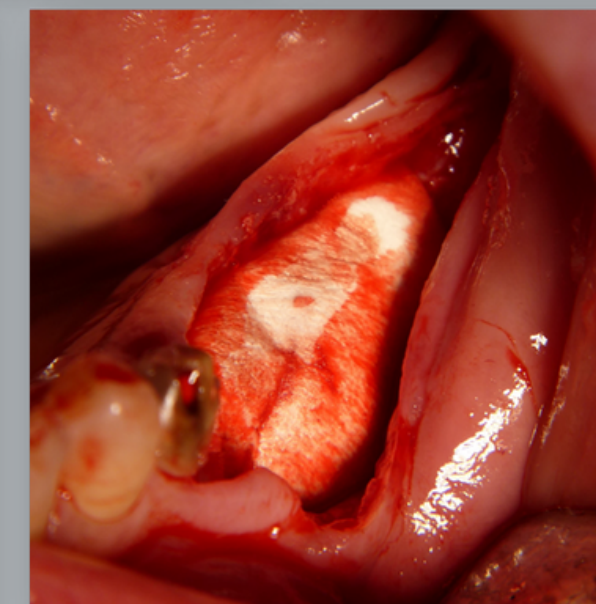
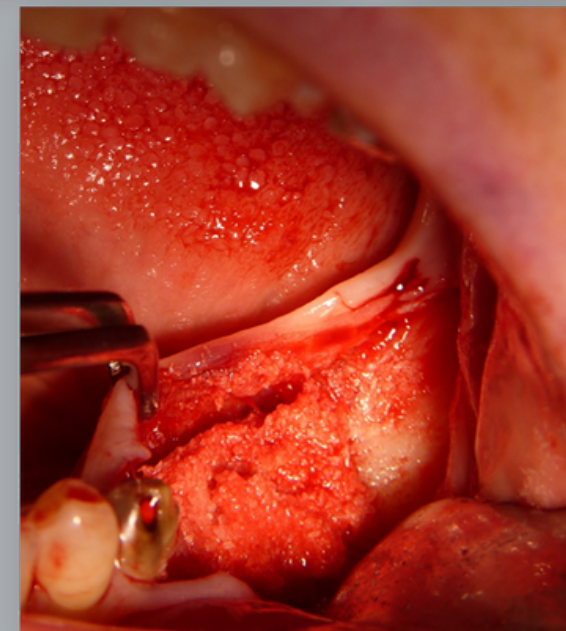
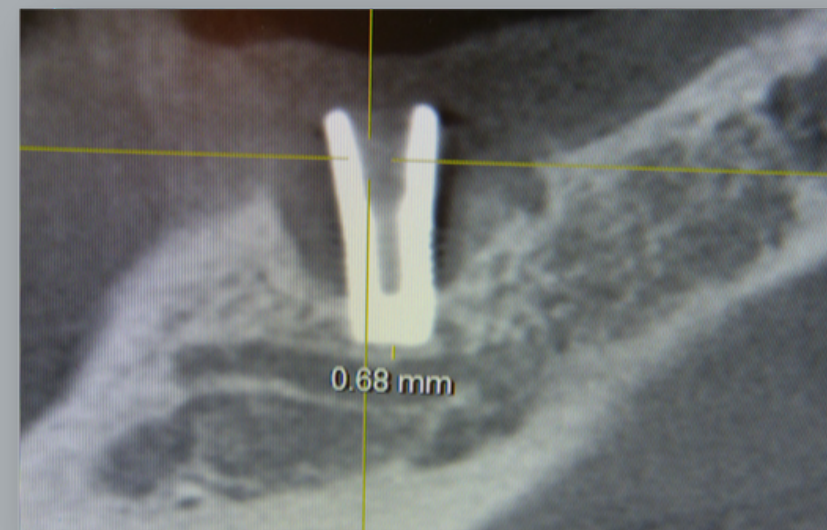
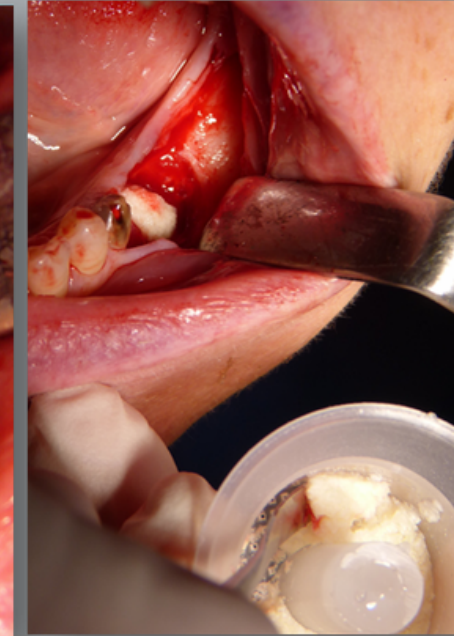
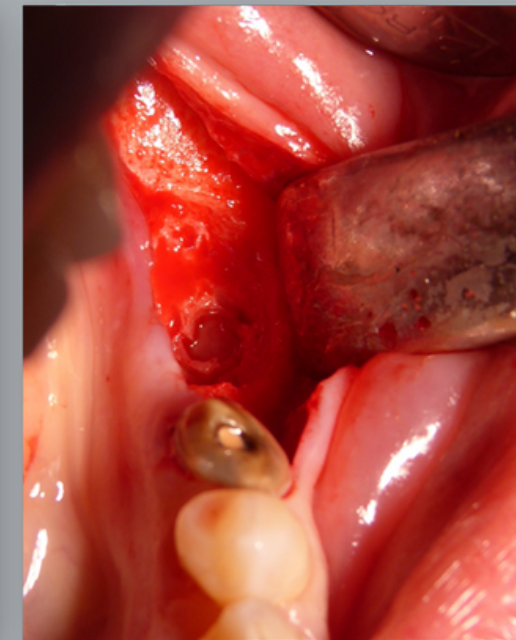
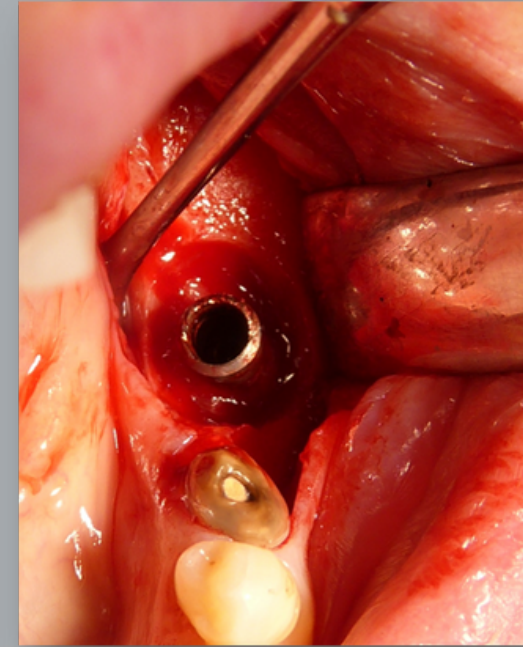
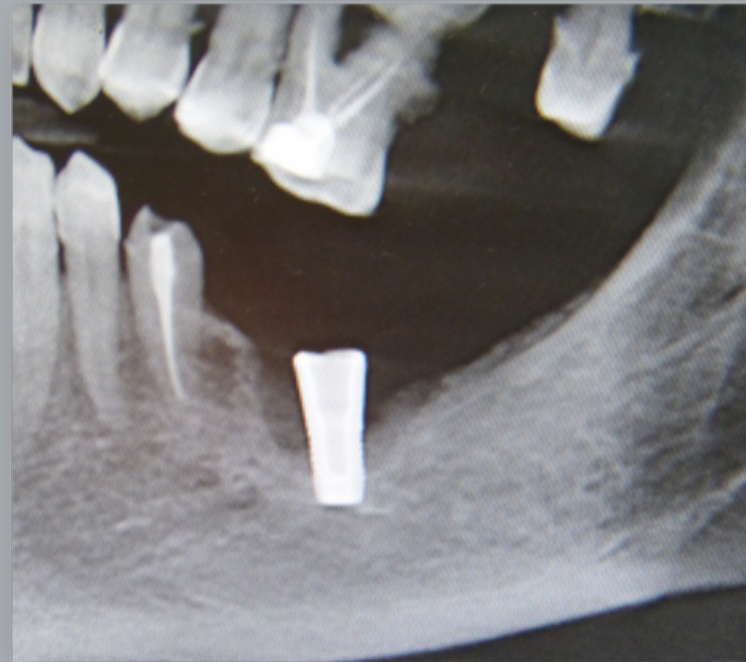
| | |
|--------------------------|--------|
| DENTIN TOOTH TRANSFORMER | 5,655% |
|--------------------------|--------|

DENTIN

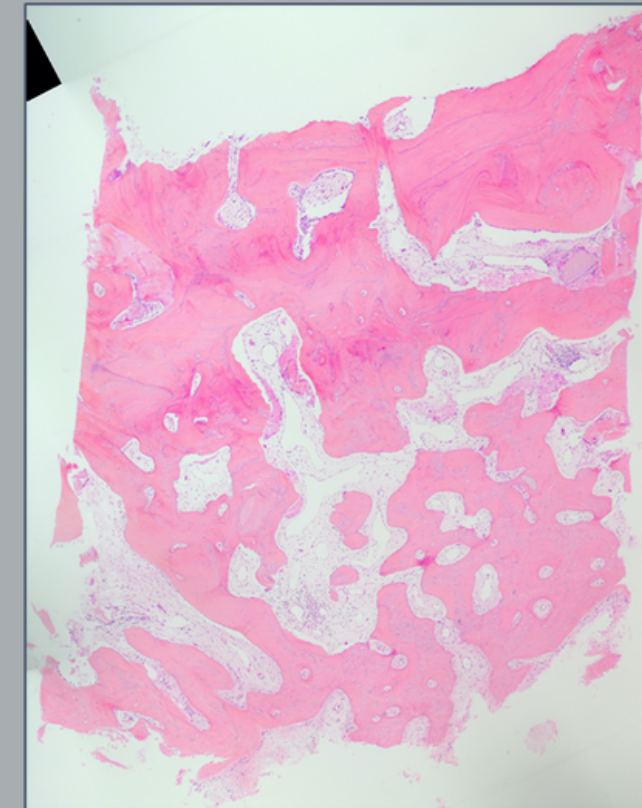
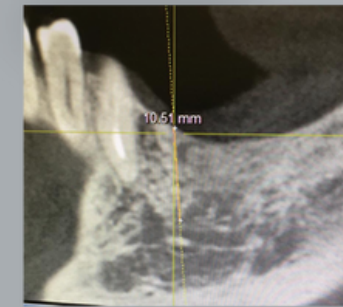
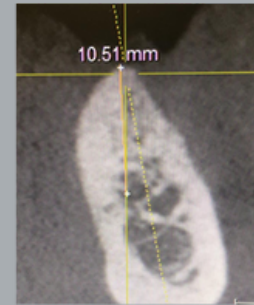
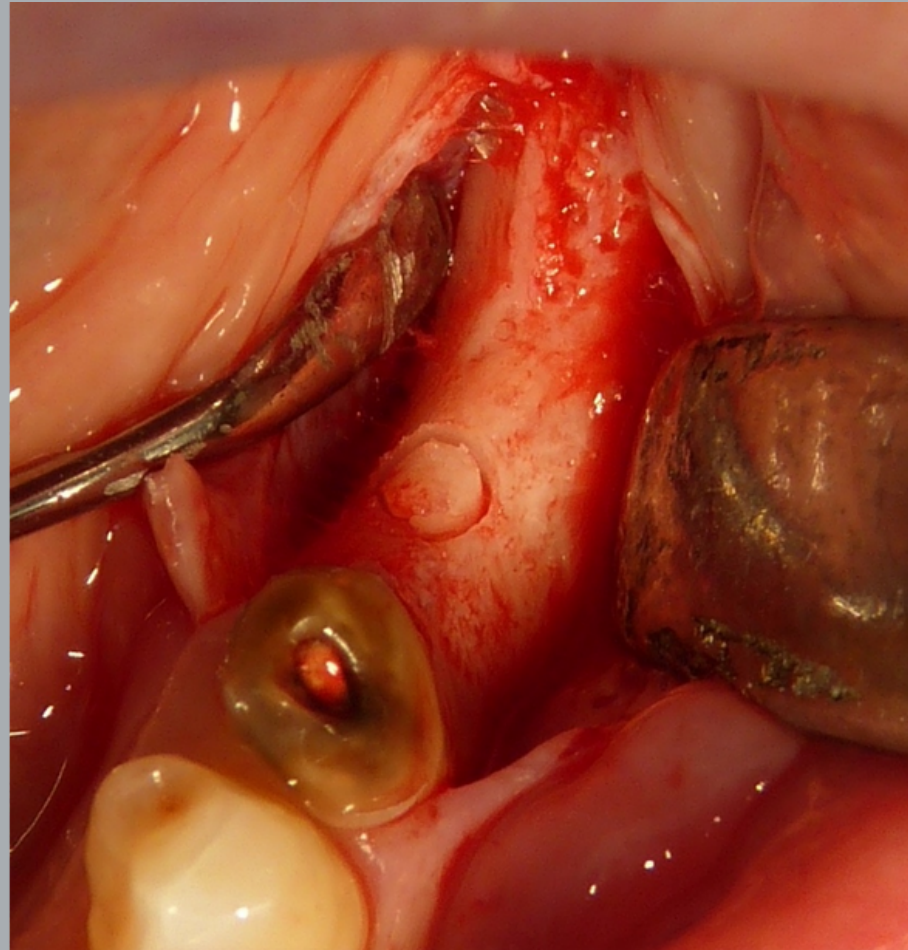
Bone



EASYTT BONE



EASY31 M Follow up

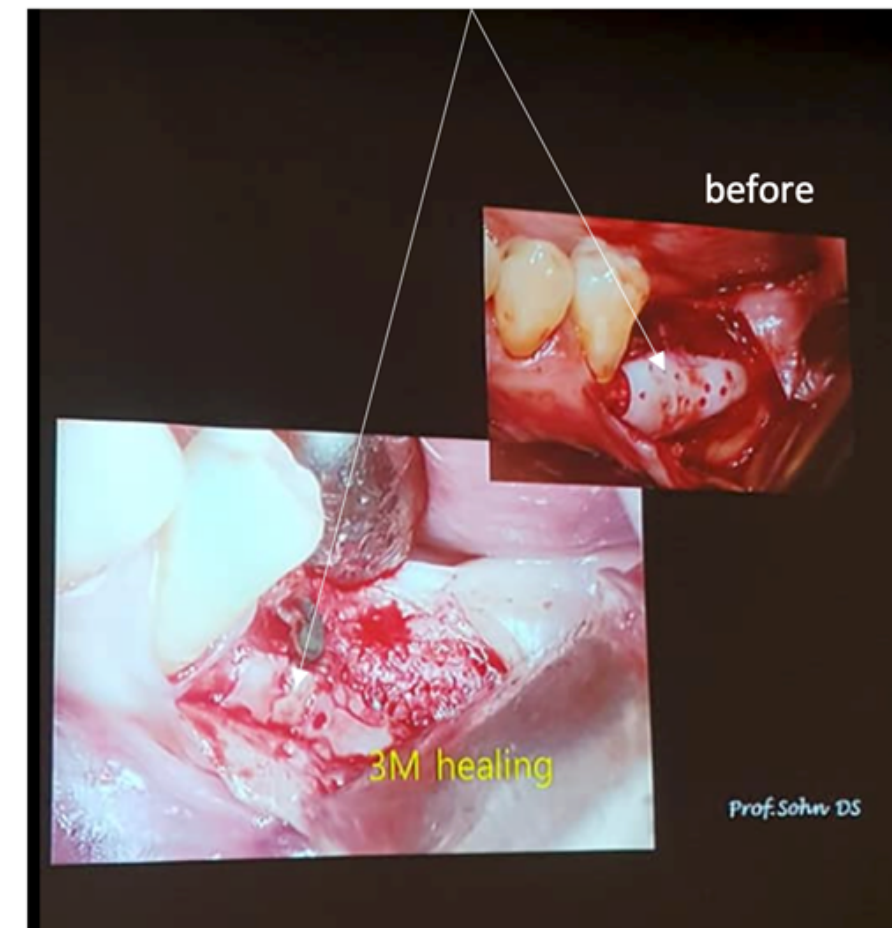


| | |
|-------------------|---------|
| New bone | 63,431% |
| Tooth transformer | 0,162% |

And what happen using other systems?

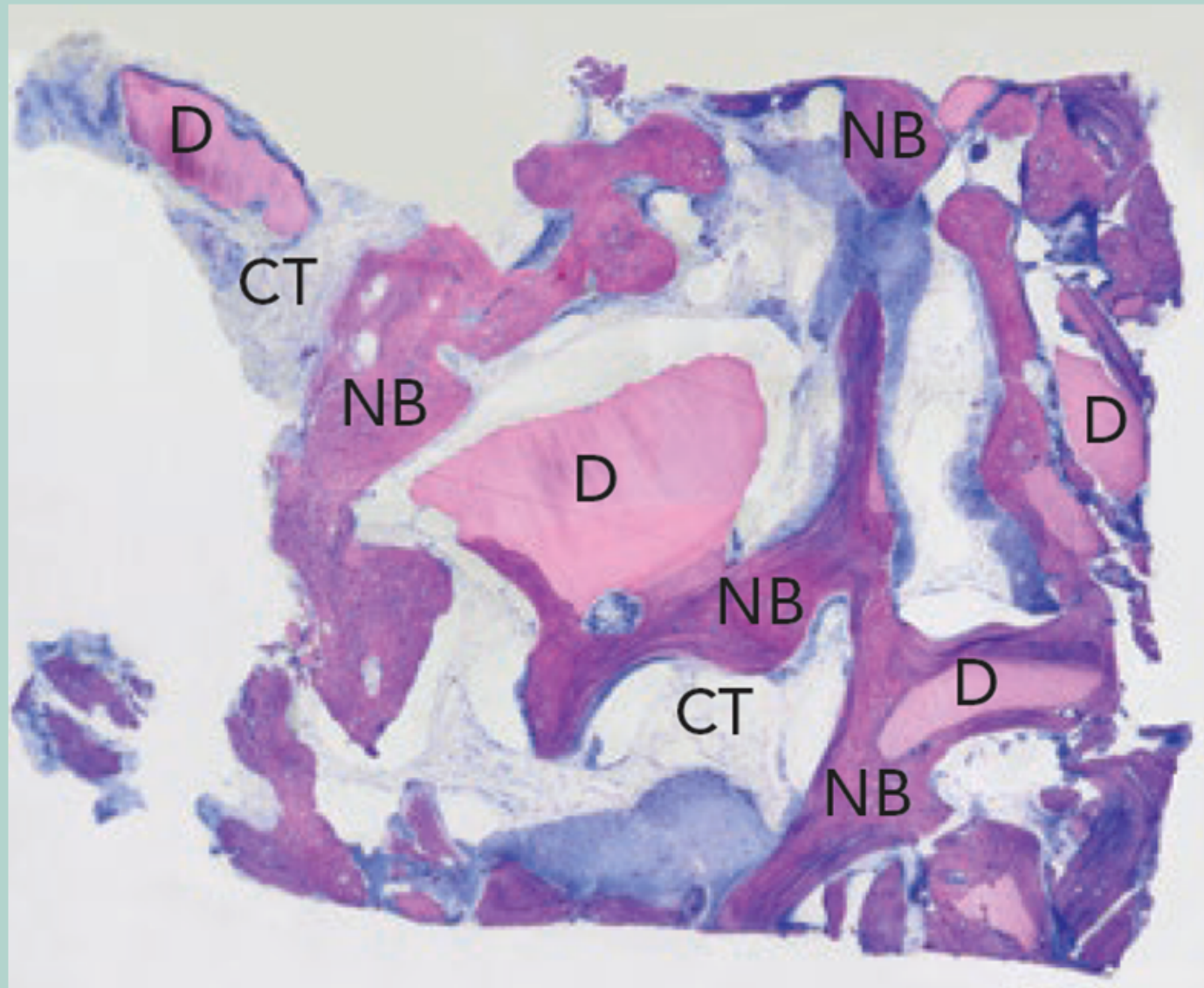
SUSE OF THE TOOTH like A BLOCK. The idea is interesting but to make the results they need to remove all proteins . Using very aggressive acid.

The demonstration is this image.
After 3 months healing the tooth is again visible and is not readsorble like our granulate. This indicate the tooth is not enter in the bone methabolism



Histologies from Kometa-bio

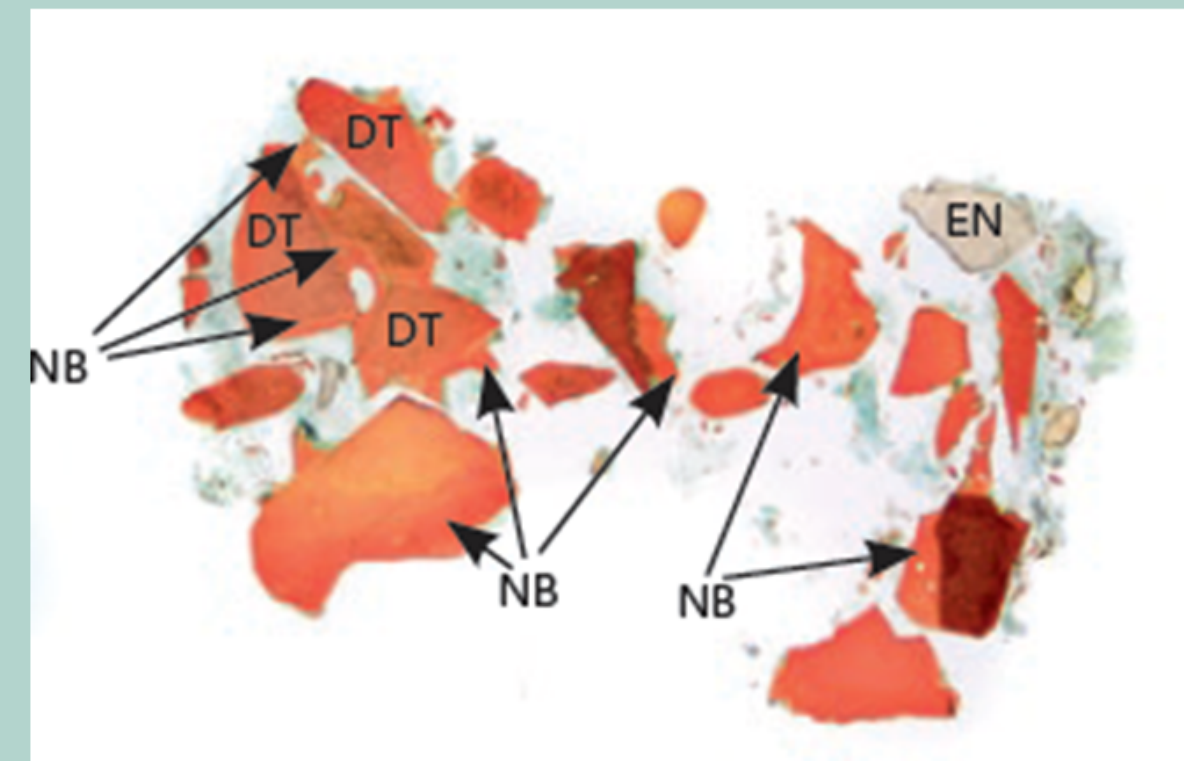
6 mesi, the granules are still presents..why?



Healing dynamics following alveolar ridge preservation with autologous tooth structure
Z.Mazor, R Horowitz, H Prasad, G Kotsakis
Int J perio restorative dent 2019;39:697-702

All these articles analyzed only 4 walls defect...

After 3 months the new bone is a small quantity...



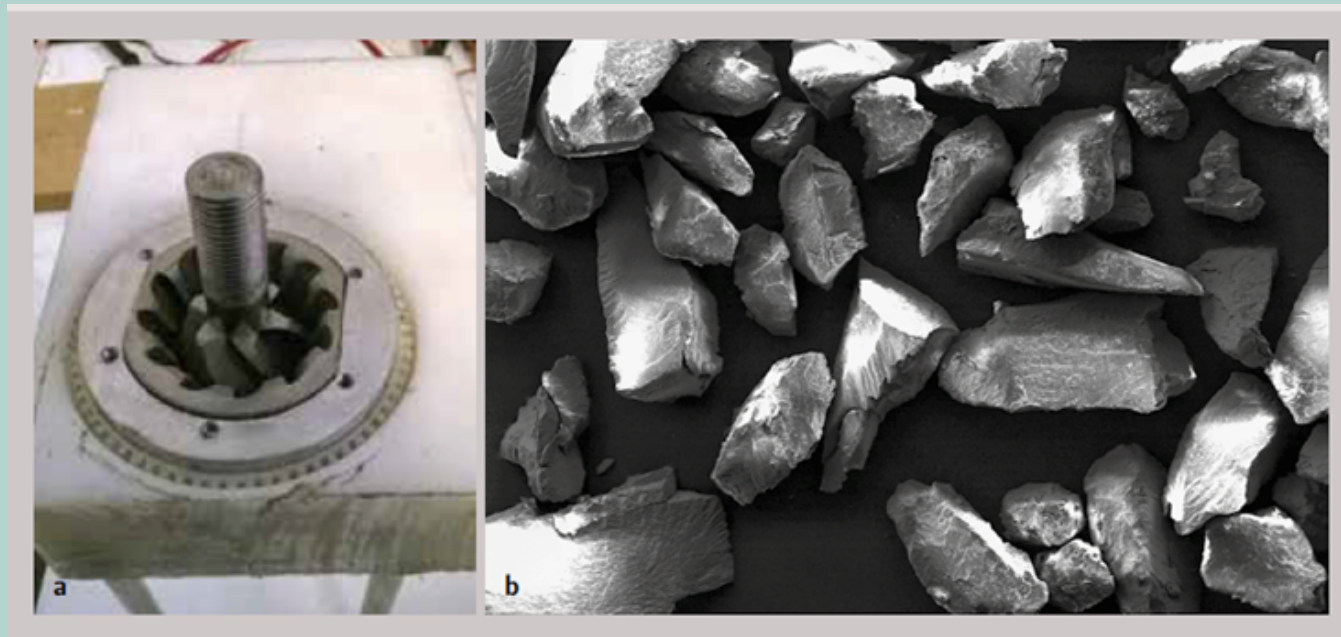
New bone formation using an extracted tooth as a biomaterial: a case report with histologic evidence

D.Cardaropoli , M Nevins, P Schupbach Int J perio restorative dent 2019;157-163

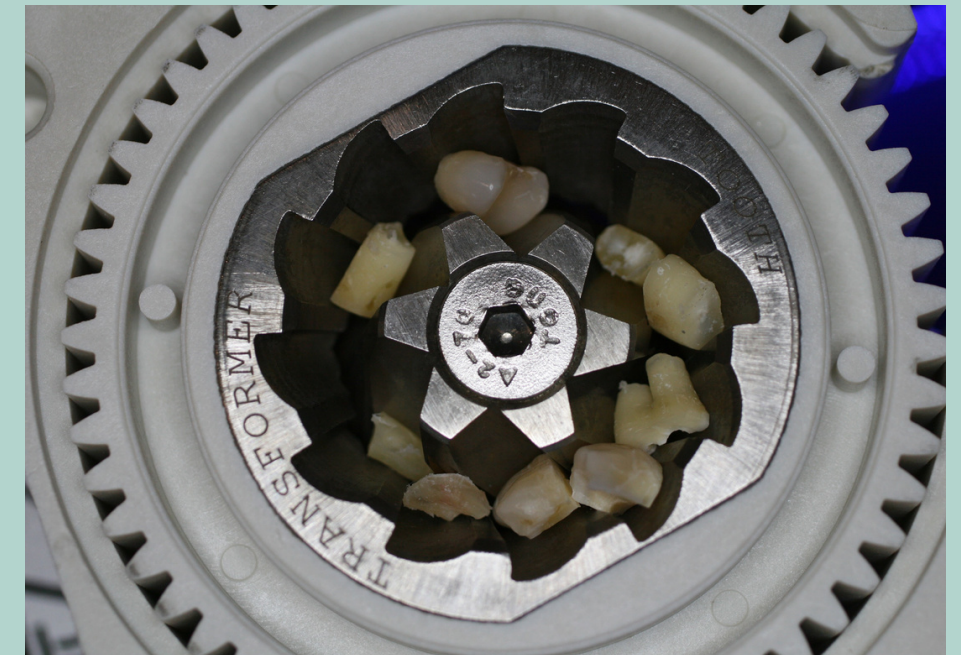
GRINDING



High-speed grinding results in granules of different sizes and with dissimilar shapes .

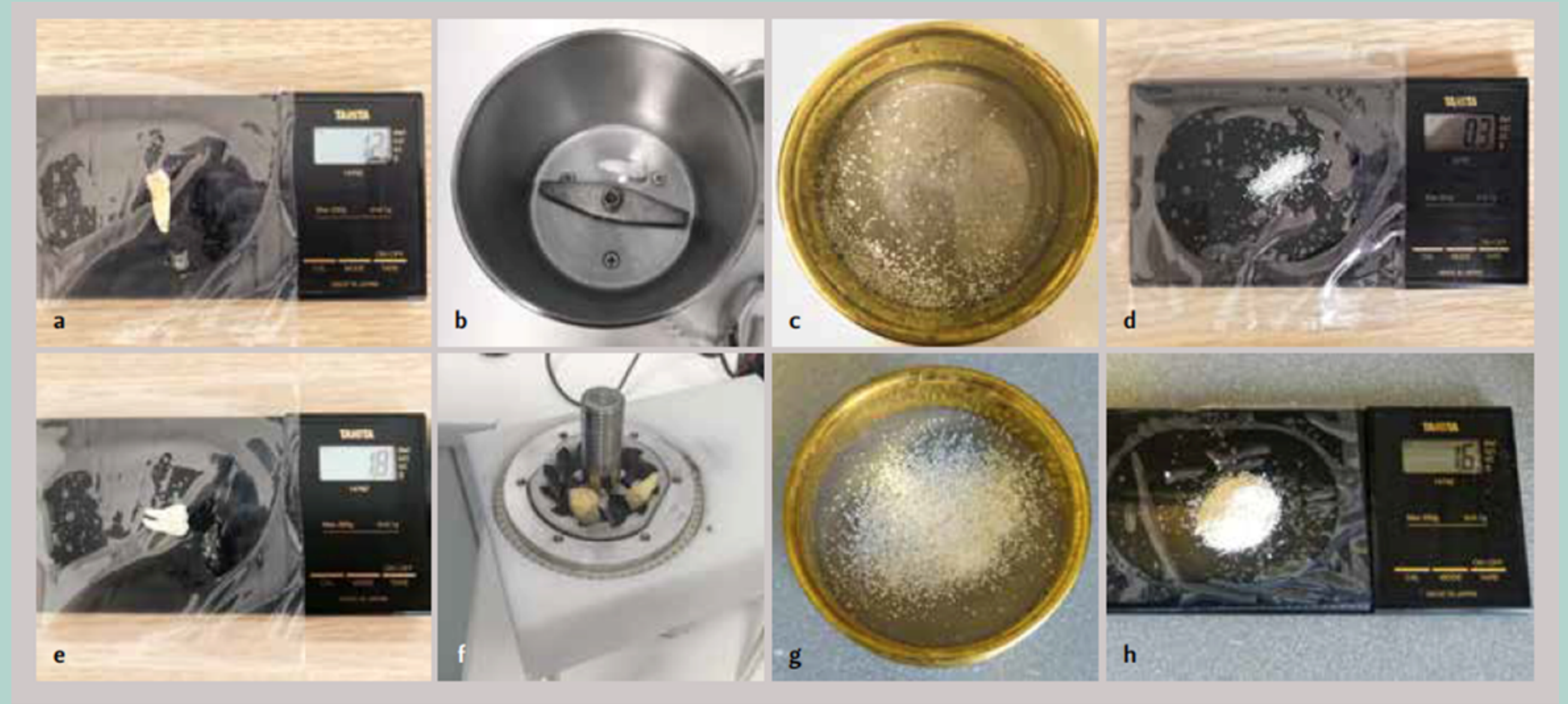


Low speed grinding results in similar granules of size and shape .



GRINDING

The low speed grinder guarantee a greater amount of tooth and the size of the granulate are more constant, thus ensuring a better performance of regeneration.



High speed grinding: (a) mini digital scale to measure the initial weight of the tooth; (b) the same tooth in the high-speed grinder; (c) metal sieve to select the granules of the desired size; (d) weight of the dental granulate after being sieved. Low speed grinder: (e) mini digital scale to measure the initial weight of the tooth; (f) the same tooth in the low-speed grinder; (g) metal sieve to select the granules of the desired size; (h) weight of the dental granulate after sieving.

Liquid

We analyze all these solutions mixing them each other

| Demineralization | Detoxification | Rinsing |
|---|--|--|
| <ul style="list-style-type: none"> • Ethanol • HCl • EDTA • Nitric acid • Sodium hydroxide • Calcium chloride • Lactic acid • FDNB • Calcium hydroxide • Phosphoric acid • Hexamethyldisilazan • Liquid nitrogen • Sulfuric acid | <ul style="list-style-type: none"> • Hydrogen peroxide • Peracetic acid • Ethanol • Ethyl alcohol • Phenol • Ethyl ether • Ethylene oxide • Temperature • β-propiolactone • Chloroform • Methanol • Isopropanol • Gamma rays • Gentamicin | <ul style="list-style-type: none"> Sodium chloride Distilled water |

Liquid

Values of minerals expressed on the analyzed granules with and without treatment.

The native bone has a mineral ratio between Calcium and Ca/P phosphorus = 1.67.

A ratio very similar to the natural human bone indicates that the use does not alter the natural chemistry of the bone. It can be seen that only few procedures allow to keep the ratio in the proximity of the natural values.

Obviously if the ratio is totally different the behavior of the receiving bone will be different.

| | | P% | Ca% | Ca/P ratio (Control 1.67) |
|----------------------------|-----------------------------------|----------------------------------|---------------|---------------------------|
| Untreated dentine | | 8.59 ± 1.33 | 16.56 ± 3.73 | 1.92 |
| Untreated Deciduous Enamel | Reference values | 8.54 ± 1.62 | 12.94 ± 3.06 | 1.51 |
| Xenograft (Bio-Oss) | | 11.04 ± 0.82 | 20.25 ± 3.16 | 1.83 |
| | | 8.62 ± 0.20 | 12.45 ± 0.41 | 1.44 |
| 0.001 M HCl | | 3% H ₂ O ₂ | 8.56 ± 0.54 | 13.23 ± 1.68 |
| 0.001 M HCl | 10% H ₂ O ₂ | 10.39 ± 0.66 | 27.29 ± 27.29 | 2.62 |
| 0.001 M HCl | 36% H ₂ O ₂ | 8.11 ± 0.56 | 12.10 ± 1.40 | 1.49 |
| 0.01 M HCl | 3% H ₂ O ₂ | 8.02 ± 0.33 | 12.84 ± 1.00 | 1.60 |
| 0.01 M HCl | 10% H ₂ O ₂ | 8.16 ± 1.79 | 18.18 ± 4.76 | 2.23 |
| 0.01 M HCl | 36% H ₂ O ₂ | 7.75 ± 1.56 | 11.56 ± 3.03 | 1.49 |
| 0.1 M HCl | 3% H ₂ O ₂ | 7.14 ± 3.08 | 14.28 ± 4.31 | 2.00 |
| 0.1 M HCl | 10% H ₂ O ₂ | 5.04 ± 0.60 | 8.59 ± 1.37 | 1.70 |
| 0.1 M HCl | 36% H ₂ O ₂ | 2.34 ± 0.59 | 3.56 ± 1.08 | 1.52 |
| 0.6% HCl | 3% H ₂ O ₂ | -0.23 ± 0.21 | 0.30 ± 0.15 | -1.30 |
| 0.6% HCl | 10% H ₂ O ₂ | 0.52 ± 0.12 | 0.39 ± 0.12 | 0.75 |
| 0.6% HCl | 36% H ₂ O ₂ | -0.27 ± 0.07 | 0.14 ± 0.05 | -0.51 |
| EDTA 17% | | 5.48 ± 2.91 | 13.39 ± 7.37 | 2.44 |
| EDTA 10% | | 8.37 ± 0.39 | 21.55 ± 0.45 | 2.57 |
| Alcol etilico 70% | | 9.29 ± 1.64 | 25.88 ± 1.99 | 2.78 |
| Alcol etilico 62% | | 10.03 ± 2.17 | 27.45 ± 5.70 | 2.73 |
| EDTA 17% | H ₂ O ₂ 10% | 9.44 ± 1.63 | 25.47 ± 2.75 | 2.69 |
| EDTA 10% | H ₂ O ₂ 10% | 8.50 ± 1.43 | 22.50 ± 4.46 | 2.64 |
| Ethyl alcohol 70% | H ₂ O ₂ 10% | 11.18 ± 3.27 | 27.97 ± 5.88 | 2.50 |
| Ethyl alcohol 62% | H ₂ O ₂ 10% | 11.74 ± 1.42 | 30.61 ± 2.72 | 2.60 |
| Ethyl alcohol 70% | EDTA 17% | 10.44 ± 0.8 | 28.33 ± 0.92 | 2.70 |
| Ethyl alcohol 62% | EDTA 10% | 8.59 ± 1.8 | 23.17 ± 3.92 | 2.69 |

In aqua green color: solution that at the end of the tests was considered as more effective in maintaining proteins and detoxifying.

Surface

Upon careful evaluation of the surface of the granules subjected to different treatments, two things were evident:

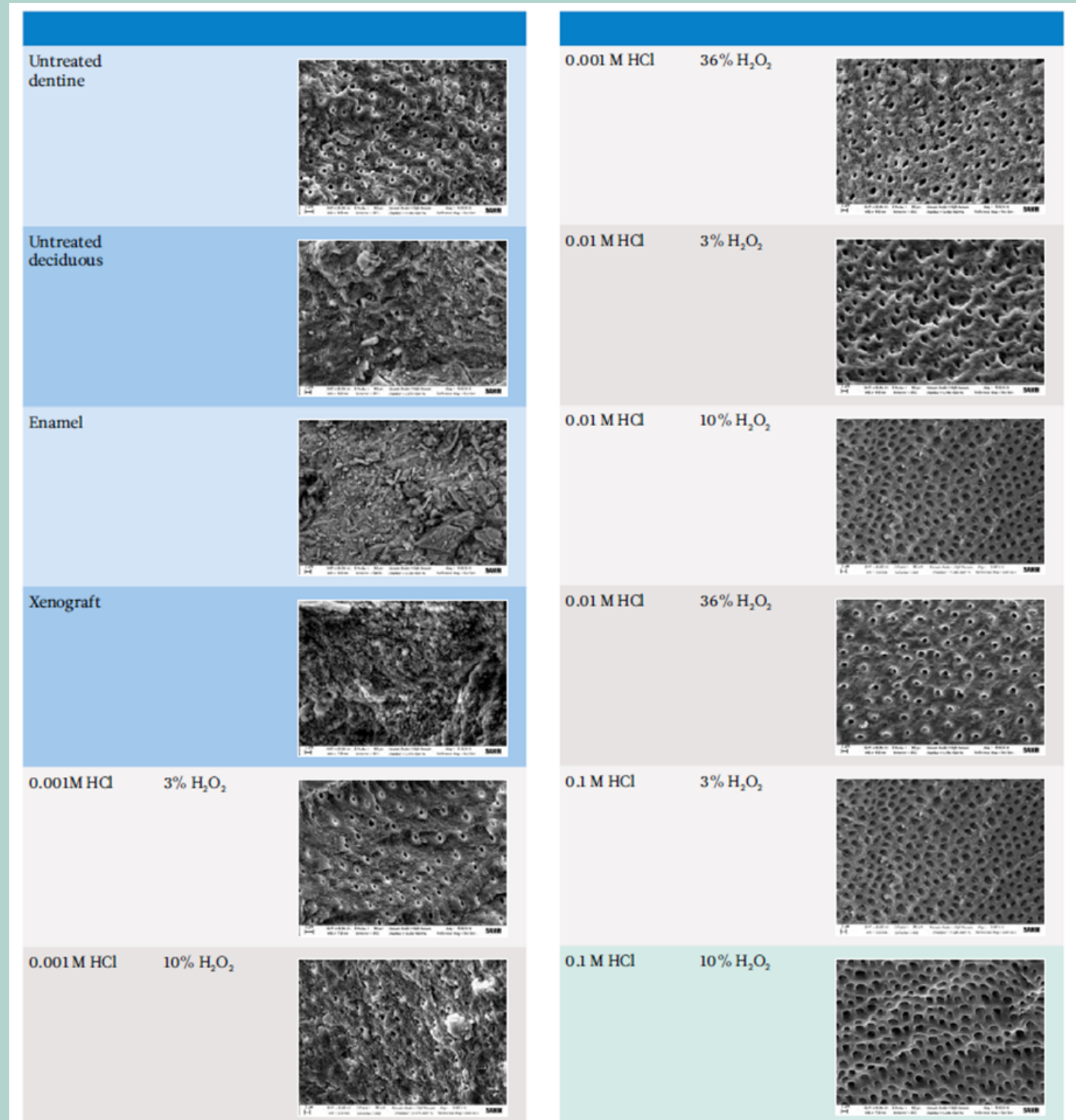
- the surfaces may appear clean or with residues of various origins;
- the shape and size of the dentina tubules varies.

One of the focal aspects of this surface variation is the increase in wettability, with an increase in the hydrophilicity of the surface.

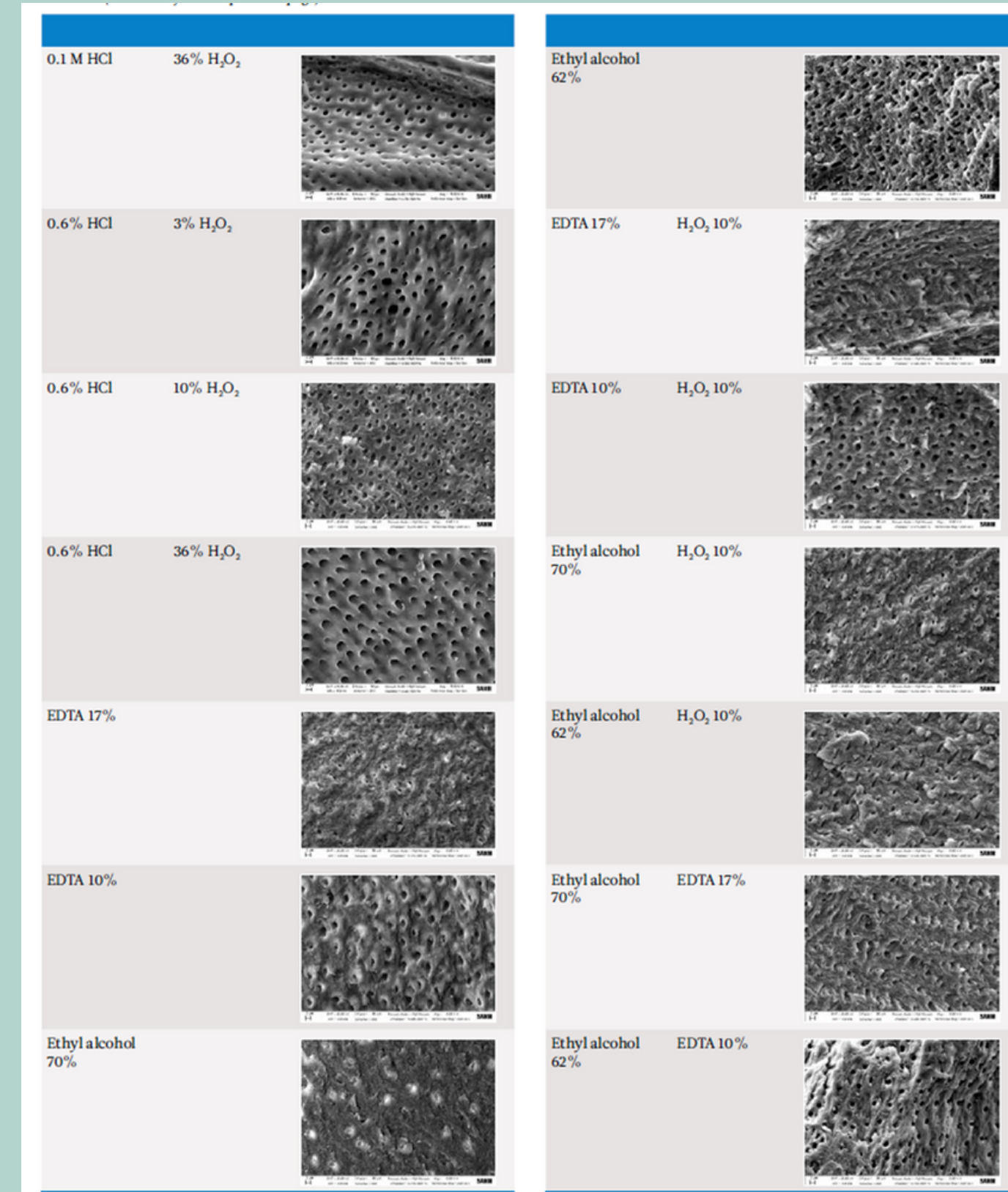
The hydrophilic surfaces demonstrated an increase in osteoblast maturation, an increase in the production of local factors and a mineralization compared to the hydrophobic surfaces.

Evidently, the maturation of osteoblasts is influenced by microtomography

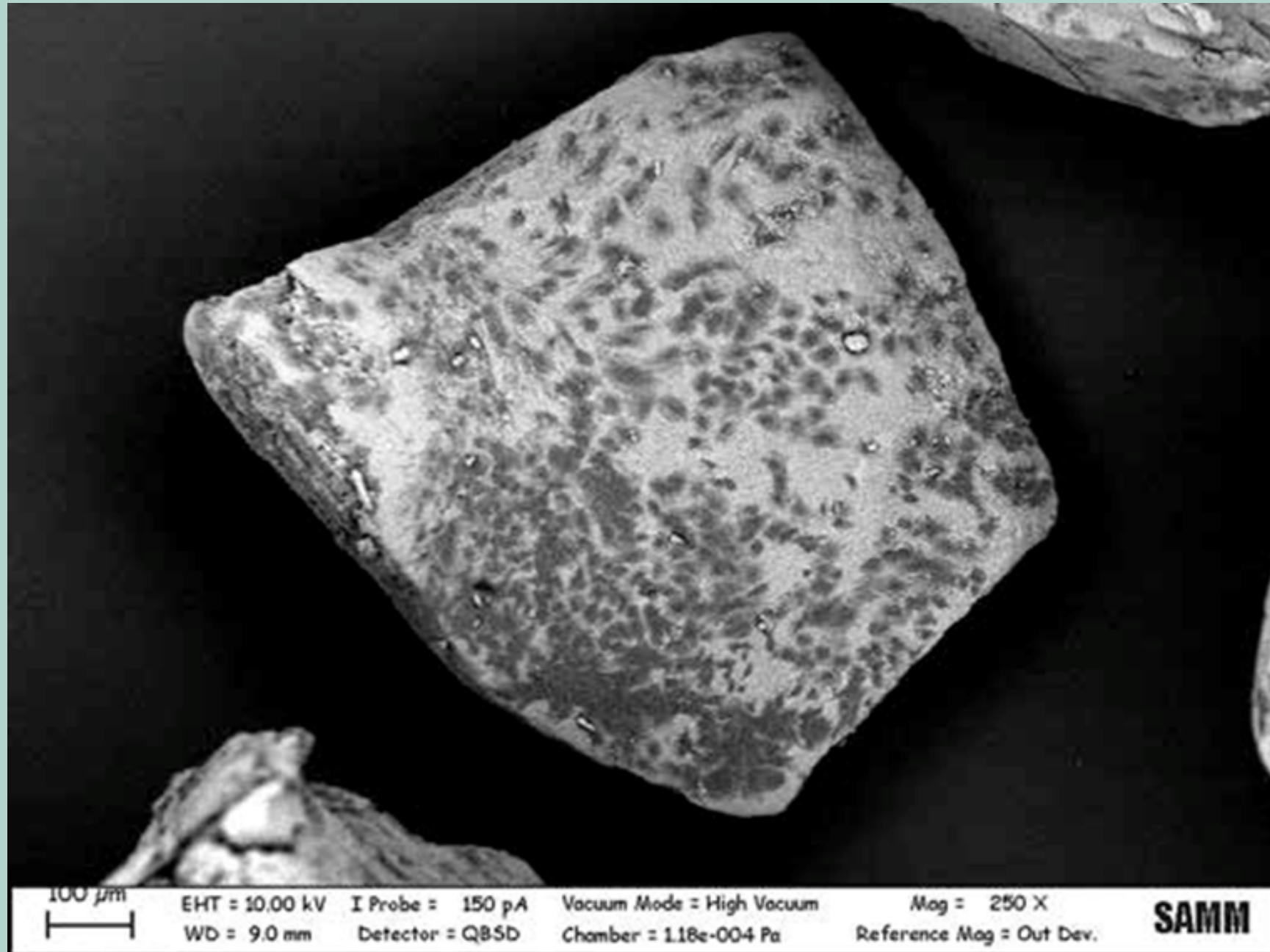
So we analyzed the dentin surface after each treatment



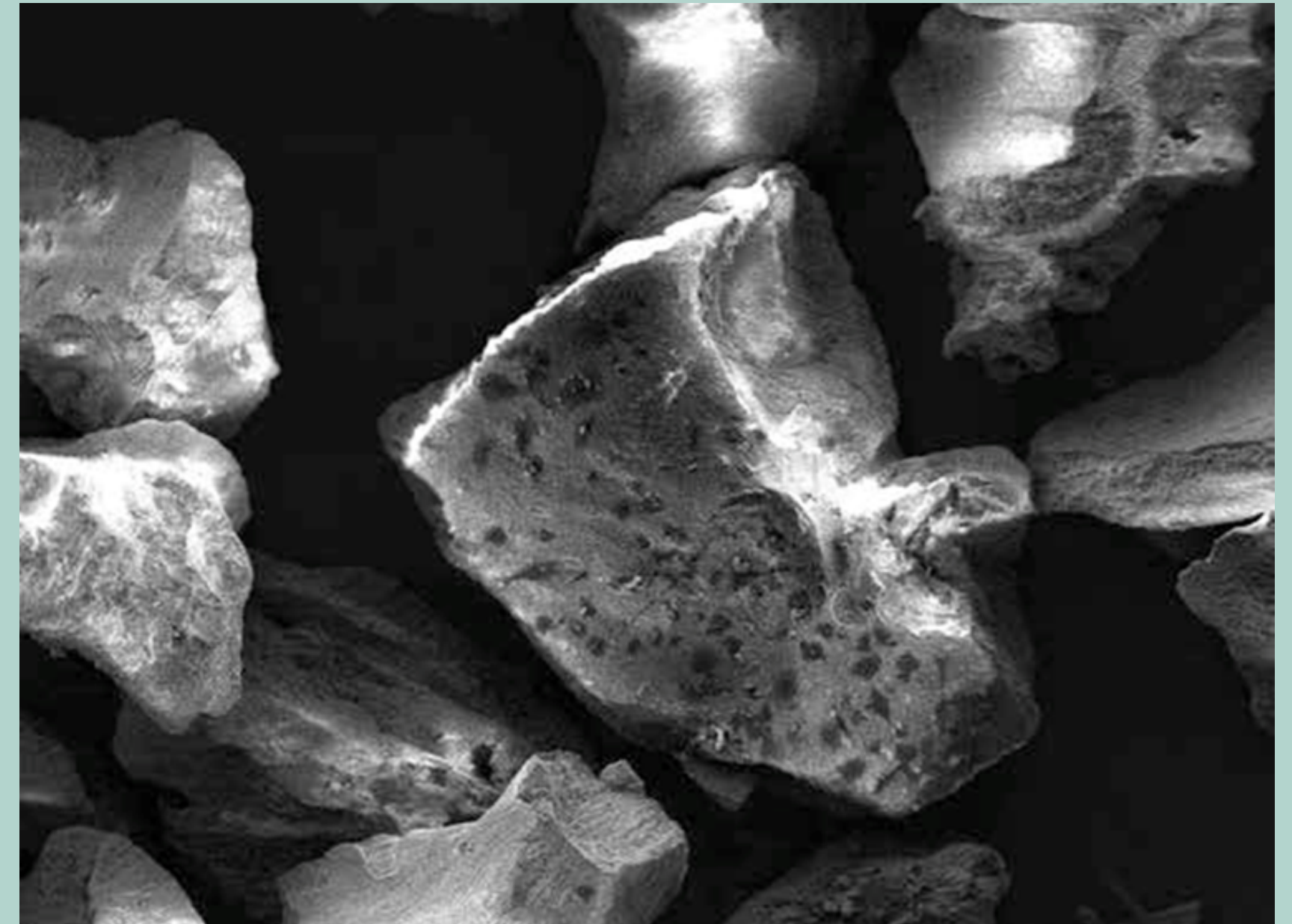
In aqua green color: solution that at the end of the tests was considered to be more effective in maintaining proteins and detoxifying.



Osteoblasts Cells on the surface after the TT treatment



Osteoblasts Cells on the surface without the TT treatment



Dentin treatment procedure chosen after the tests carried out.

The treatment chosen after the analyzes carried out so far was: grinding by a low speed system; demineralization and detoxification with concentrations of HCl 0.1 M and H₂O₂ 10%.

These are the lowest concentrations that allow either to maintain the maximum of proteins or modifying the tooth surface in a way to promote cell adhesion, as seen Above

An interesting aspect of these data is the Ca and P ratio.

In fact, the native bone has a mineral ratio $Ca/P = 1.67.44$

A ratio very similar to the natural human bone one indicates that its use will not alter the natural chemical structure of the tissue.

Pre-treatment dentin has a Ca/P ratio = 1.92. After the treatment, it appears to have a Ca/P ratio = 1.70, so the demineralization chosen leads to a result very similar to human bone. On the other hand, the xenograft material tested as a control has a Ca/P ratio = 1.44 that seems a more different value.

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Pre-treatment dentin has a Ca/P ratio = 1.92. After the treatment, it appears to have a Ca/P ratio = 1.70, so the demineralization chosen leads to a result very similar to human bone. On the other hand, the xenograft material tested as a control has a Ca/P ratio = 1.44 that seems a more different value. It should be noted that only some tests are able to maintain Ca/P ratio values similar to bone, while most display very distant values.

The ELISA test was also carried out to assess whether, after demineralization by HCl and detoxification by H₂O₂, there were variations in the values of collagen and BMP-2 present (! 5.18). It is interesting to note how the addition of H₂O₂ caused differences in the presence of BMP-2 and collagen compared to the evaluations of HCl alone.

SAFETY TT CE MEDICAL DEVICE IIa



In the electrical CE the CE symbol is without numbers.

In the medical CE, the CE symbol is followed by 4 numbers that indicate the body that certified the device by testing it following all the regulations Others only electrical CE.



MANUAL VS AUTOMATIC



MANUAL

ERRORS MAY OCCUR IN THE PROCEDURE.
ANY ERROR AFFECTS THE QUALITY OF
THE PREPARATION

AUTOMATIC


THE PROCEDURE IS ALWAYS THE SAME
AND THE RESULT COMPLIES WITH THE
CERTIFIED QUALITY STANDARDS


Thank You

N. Tesla

The progressive development of man is vitally dependent on invention.



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