CHLOSITE

GHIMAS

NEW XANTHAN GEL WITH CHLORHEXIDINE COADJUVANT FOR THE TREATMENT OF PERIODONTITIS AND PERIIMPLANTITIS

For the coadjuvant non-surgical treatment of periodontitis and periimplantitis

Easy

Simple

Efficient

Safe

ENGLISH

THE PERIODONTAL DISEASE

Chronic periodontitis is the most widespread form and the easiest one to be found amongst the periodontal diseases.

Despite having the typical signs of gingivitis, which should ring an alarm, the patient often goes to the dentist when the clinical condition is already quite serious.

The disease presents alterations in the consistency of the gingival tissues and their architecture, bleeding upon brushing and sometimes even the teeth become loose. Unfortunately this last sign, which generally alarms the patient, corresponds to a very advanced stage of the disease and is the most difficult to treat.

The factor responsible for chronic periodontitis is of bacterial origin.

The prolonged presence of plaque debris at the gingival margin initiates the formation of a stable bacterial plaque that, if not removed within 24-48 hours, becomes calcified; at this point the gums first become inflamed and tend to react by either swelling or moving away from the harmful stimulus. They retract and produce an unaesthetic exposure of the tooth root, which is darker than the enamel and therefore quite evident.

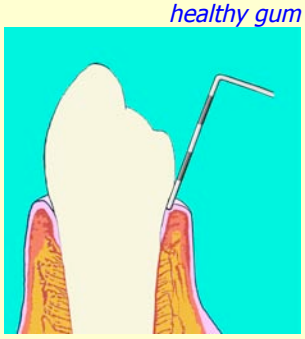
The bacteria responsible for this disease are very comfortable in this oxygen free environment between the gum line and the external surface of the tooth, where they establish themselves and **start to multiply, continually worsening the situation.**

The gingival retraction is only the most superficial manifestation of the damage that is occurring to the structures supporting the teeth; in fact, the bone, supporting the gingiva in its physiological position, may eventually undergo a progressive recession together with the resorption of bone, causing mobilization of the teeth involved.

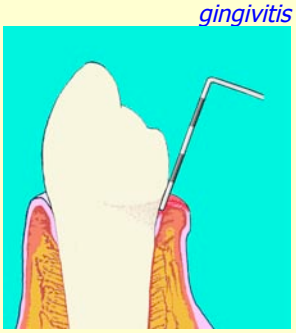
The treatment of chronic periodontitis varies according to the severity of the clinical situation and can go from the simple removal of the bacterial plaque by mechanical instrumentation, to the elevation of a muco-periosteal flap in order to perform a more thorough and radical cleaning.

Even in a situation where the loss of supporting bone is more pronounced, there is the possibility of **promoting bone regeneration** to the extent of reestablishing, even if it is only partially, a supporting structure.

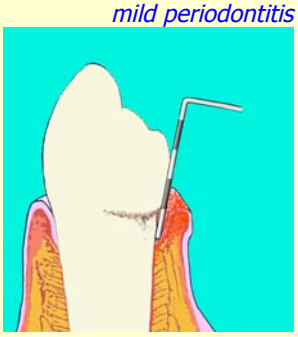
healthy gum



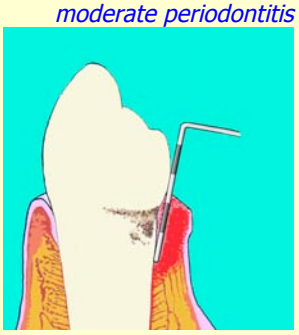
gingivitis



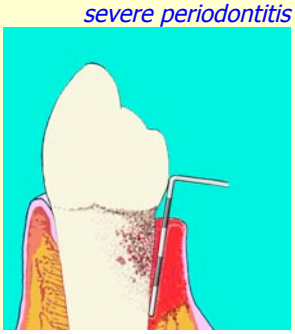
mild periodontitis



moderate periodontitis



severe periodontitis



Gingivitis is the most frequent **inflammatory lesion**, which represents the first stage of periodontal disease.

The lack of both proper oral hygiene and complete removal of the dental plaque facilitate the inflammation of the gingiva, whose clinical signs are swelling, redness and bleeding upon probing.

Gingivitis that is properly treated is reversible, as long as it does not involve the deep periodontal tissues, the periodontal ligament and the alveolar bone.

In the case of a consolidated gingivitis, the so-called **mild periodontitis**, the gingival epithelium **looses the ability to adhere** to the enamel.

The gingival sulcus becomes deeper and is transformed into a **periodontal pocket**, which favors the colonization and growth of anaerobic Gram - bacteria, which **produce endotoxins** that are harmful to the deep periodontal tissues.

If the defense mechanisms of the organism are able to neutralize the endotoxins produced by the pathogenic microorganisms, an equilibrium is obtained.

This **condition of equilibrium** will continue up until there is a decline in the defense mechanisms or recolonization of the anaerobic bacteria produce a **new acute phase**. This worsens the periodontitis, whose clinical signs are, in addition to reddening of the tissues and bleeding upon probing, a gradual increase in the depth of the pocket due to the destruction of the periodontal ligament and the alveolar bone.

THE GINGIVAL SULCUS AND THE PERIODONTAL POCKET

The **gingival sulcus is normally about 1-mm deep** and terminates with a so-called junctional attachment, formed by the epithelial tissue positioned where the crown and the root of the tooth meet. If t**he bacterial plaque that deposits in the sulcus** is not removed, it provokes the destruction of this attachment, which defends itself by shrinking.

The gingival sulcus deepens forming a pathological condition called a **periodontal pocket**. In this site, the plaque **becomes infested with germs** that survive in the absence of oxygen and provoke damage to the supporting structures of the tooth root (periodontal ligament).

The inflammation activates cells that absorb the bone supporting the tooth root, while at the same time these anaerobic bacteria are destroying the periodontal ligament that joins the bone to the root.

The progressing periodontal disease involves the supporting structures of the root, causing their definitive loosening with the eventual loss of the tooth.

The periodontal pocket, an expression of periodontal disease, can deepen in the absence of any apparent symptoms.

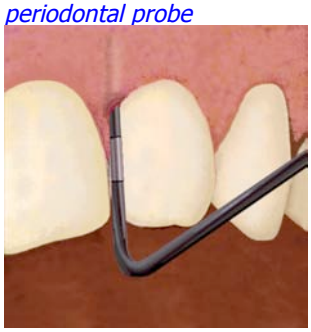
One becomes aware of having periodontal problems only when the situation, which is **already at an advanced stage**, is characterized by the **appearance of symptoms** such as **tooth loosening**, **bleeding gums**, **halitosis** and **pain**.

At this point the dentist is forced to take a radical solution, starting from the **scaling and root planning** of the tooth and root surfaces near the pocket, up to **muco-gingival periodontal surgery**.

bacterial plaque visualized with the use of plaque-revealing tablets

x-ray of a periodontal pocket

periodontal probe



periodontal probe inserted into a periodontal pocket

Scientific research has demonstrated that the control of bacterial plaque is fundamental in order to protect the health of the gingival tissues, a **scrupulous oral hygiene represents the first stage of prevention**.

To monitor periodontal diseases it is necessary to:

- **visualize the plaque** (utilizing plaque-revealing tablets)
- **determine the severity of the periodontal damage,** by **routine use of periodontal probes**, that when inserted into the gingival pocket measures its depth and also by **radiological exams**

The removal of the bacterial plaque can be accompanied at the beginning stage of the formation of the periodontal pocket, by a surgical procedure called "**scaling**" and "**root planning**" of the tooth and root surfaces near the pocket, which permit a more radical cleaning of the tooth.

... for the best result...
After inserting CHLO-SITE with the syringe it is recommended to distribute it inside the pocket using the same needle, or else by means of a small medication spatula or with a probe, preferable made from a plastic material.
If the pocket is very deep and the periodontal or periimplant damage is significant, or if doubtful that the first application is insufficient to fill the pocket, or in cases of evident bleeding on probing, it is useful to repeat another application after seven days.

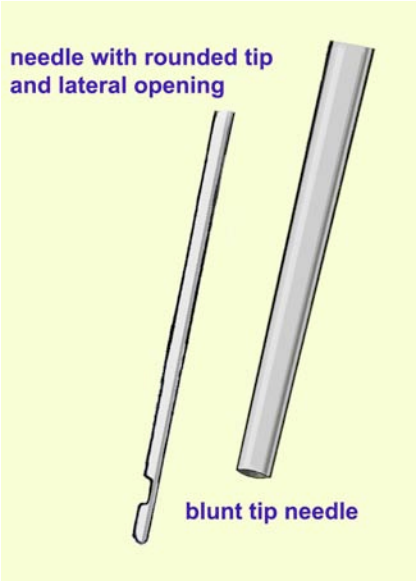
The treatment of chronic periodontitis and periimplantitis is a serious problem that the dentist is faced with today.
Amongst the products available, most of which are based upon topical **antibiotics**, **every year** we find a continuous **decline in their efficiency** due to the evolution of **antibiotic resistant strains of bacteria**.
In addition to the problem of resistance to antibiotics, which steadily increases every year, are **the cases of intolerance and allergies**, especially serious with those related to penicillin and cephalosporin (beta-lactamic antibiotics).

To resolve the problems of efficacy, antibiotic resistance by bacteria and the risk of allergies,
CHLO-SITE was born,
coadjuvant for the treatment of periodontal pockets and periimplantitis.

CHLO-SITE
- is composed of a new and innovative type of **xanthan gel**, researched and developed by Ghimas and combined with **chlorhexidine**

CHLO-SITE
- it is the only gel capable of discouraging, **for at least two weeks**, the recolonization of bacteria at the application site

CHLO-SITE
- **is easily** applied into the deepest portion of the periodontal pocket by means of **a thin needle with rounded tip** that will **not traumatize** the tissues



CHLO-SITE
- thanks to the **mucoadhesive** properties of xanthan, it stabilizes in the application site and **adheres to the mucosal tissues** of the defect

CHLO-SITE
- acts as a **sterile occluding medication** at the site of application that impedes the recolonization of **bacteria** responsible for periodontal diseases and periimplantitis

CHLO-SITE
- ***degrades spontaneously in the application site in 15-30 days and is well tolerated***

CHLO-SITE IS EASY ***CHLO-SITE*** *can be stored* ***at room temperature, it is ready for use, and it is injected*** *directly from the syringe into the pocket* ***thanks to the thin rounded tip needle.***	***CHLO-SITE IS SIMPLE*** *After mechanical removal* ***of the plaque, CHLO-SITE is applied directly into the site*** *starting from the deepest portion of the pocket, and progressing up until the gingival margin.*
CHLO-SITE IS EFFICIENT ***CHLO-SITE guarantees an occluding barrier at the application site for at least 15 days.***	***CHLO-SITE IS SAFE*** ***CHLO-SITE*** *unlike topical antibiotics,* ***does not induce bacterial resistance.***

CHLO-SITE is the coadjuvant of choice
for periodontal pathologies and periimplantitis

XANTHAN GEL

Xanthan is a **saccharidic polymer** that when combine with water forms a **three dimensional pseudo-plastic reticulum**, that is capable of **holding and maintaining in suspension various substances**, **that are then gradually released** on the basis of their physical and chemical characteristics.
The physical properties of **xanthan** render it an **optimum substrate for the formation of a stable gel** that is easily **extruded from a syringe needle**; therefore **xanthan** appears to be the **best biocompatible vehicle** for clinical applications, highly advantageous for periodontal and peri-implantar applications.

Xanthan gel undergoes a progressive process of imbibition and **is physically removed** from the application site **within 10-30 days, making a follow up visit for its removal unnecessary**.

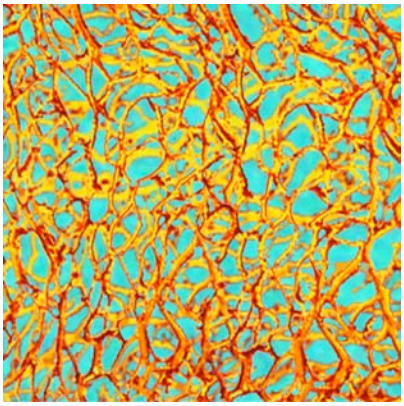
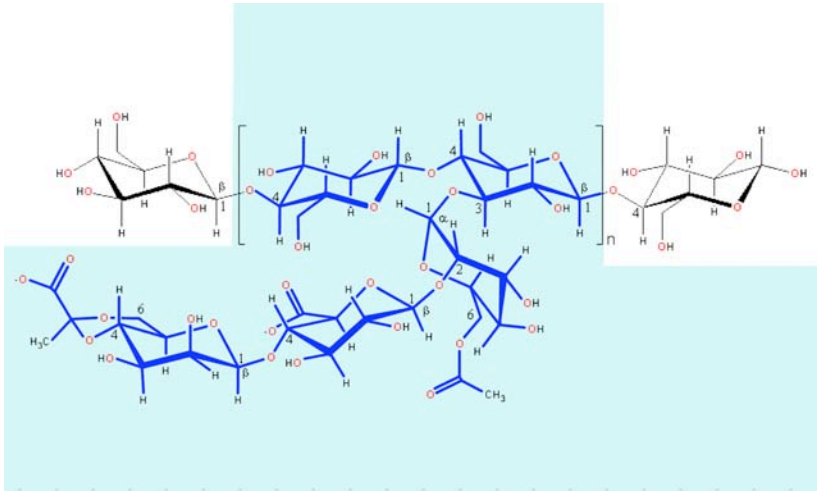


image of an entangled network of the polysaccharide xanthan.
Image size: 1.5 µm x 1.5 µm



Monomeric structure of xanthan

CHLORHEXIDINE

The accessory action of chlorhexidine is capable of not only giving CHLO-site the characteristic of maintaining the application site free from contamination but also increasing the mucoadhesiveness of the xanthan gel occluding the application site.

Chlorhexidine is present in a concentration of 1,5% of which:
0,5% is in the form of digluconate
1,0% is in the form of dihydrochloride

*Epidemiological studies have shown that **90% of the population suffers from** varying degrees of **gingival problems**. Gingivitis, when left untreated can evolve into **periodontitis** with the formation of periodontal pockets.*
The bacteria present in the pocket induce an inflammatory reaction of the bone, which consequently is reabsorbed, reducing the stability of the tooth until eventually it is lost.

CHLO-SITE is used following mechanical removal of the plaque and root levigation. CHLO-SITE is a coadjuvant for the treatment of chronic periodontitis in adults, of moderate or elevated severity and for the treatment of periimplantitis.
In addition CHLO-SITE can also be used as part of a program for periodontal treatment.

Periodontal probe inserted into the periodontal pocket

x-ray of a periodontal pocket

Periodontal pockets are formed by the action of dental plaque, which induces an inflammatory response at the level of the periodontal tissues, resulting first in the destruction of the periodontal ligament and then the alveolar bone.

The bacterial flora in the oral cavity is capable of affecting the peri-implant tissues and having a significant influence on the outcome of implant therapy.

After mechanical removal of the bacterial plaque from the pocket,

CHLO-SITE is capable of creating conditions that interfere with the recolonization of microorganisms in the pocket for at least two weeks.

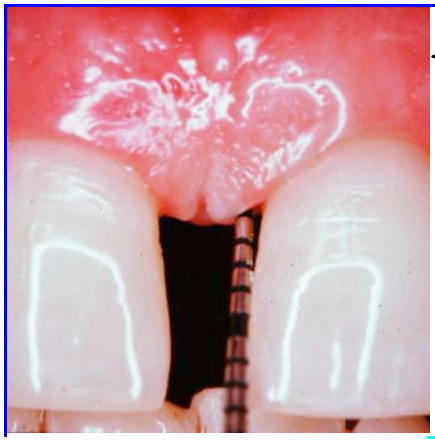
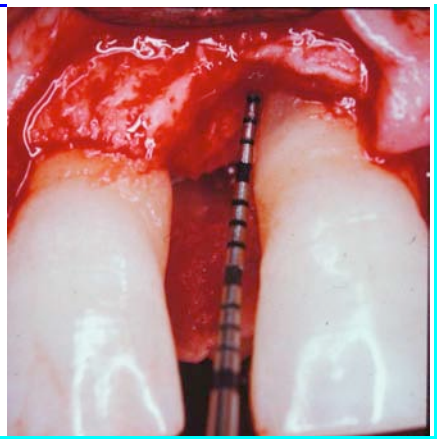
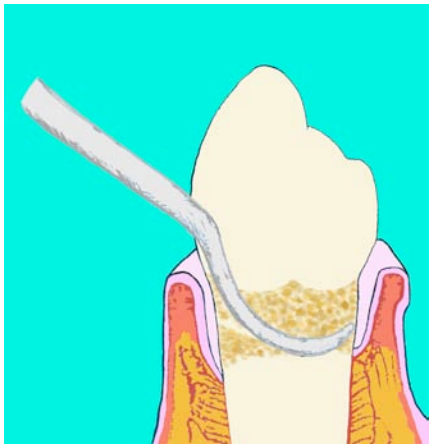


Photo of a periodontal pocket

The same periodontal pocket after surgery: the destruction of the periodontal ligament and the alveolar bone is evident



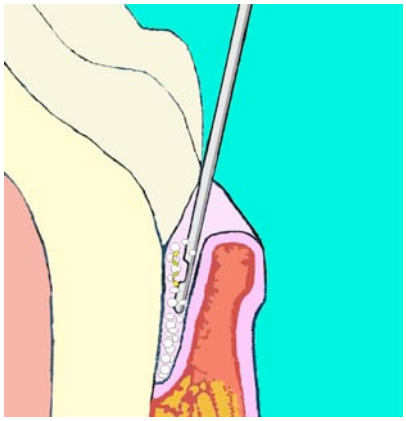
INSTRUCTION FOR USE



Mechanical removal of the plaque and root levigation

Wash and then dry the site with paper points

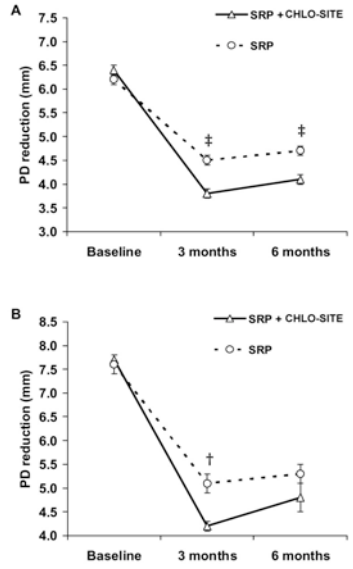
CHLO-SITE is applied directly from the syringe into each pocket requiring treatment; the gel is first injected into the deepest part of the pocket up to the gingival margin.



The needle supplied in the package has a blunt tip with lateral opening.
This facilitates the application of the product and avoids traumatizing and damaging the tissues involved in the disease process.

One syringe of CHLO-SITE is sufficient to treat several periodontal pockets.

PD at baseline and 3 and 6 months



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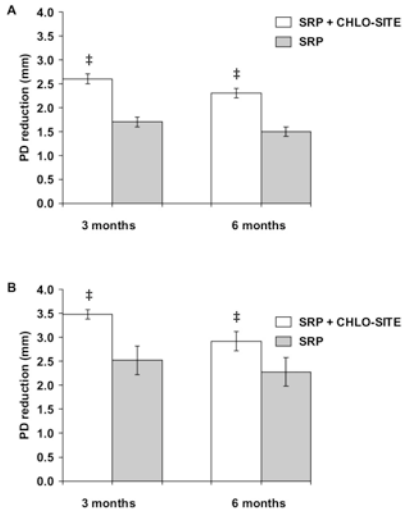
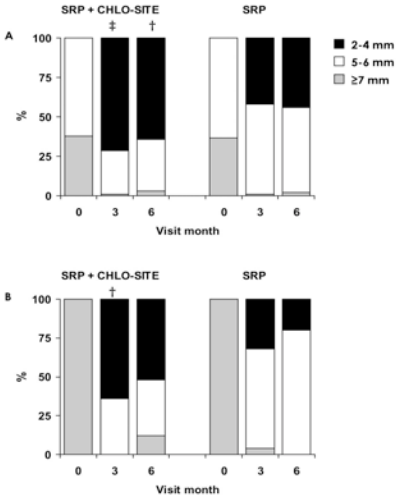
Mean PD reduction (mm) at 3 and 6 months from the baseline scores



Distribution of the PD at baseline and 3 and 6 months



when applied after scaling and root planning is a winner for the treatment and clinical control of chronic periodontitis

This multicenter randomized study investigated the effects of a xanthan-based chlorhexidine gel (CHLO-SITE) when used as an adjunct to scaling and root planing (SRP) in the treatment of chronic periodontitis (Paolantonio et Al. J Periodontol 2009;80:1479-1492).

The SRP + CHLO-SITE treatment groups showed greater improvements when compared to the SRP group alone for both PD and CAL at both 3 and 6 months (p<0.001). The differences in PD reduction between the treatments were 0.87 mm and 0.83 mm at 3 and 6 months, respectively (p<0.001); for CAL, these were 0.94 mm and 0.90 mm, respectively (p<0.001). Similar results were obtained when the subgroup of pockets ≥7 mm was considered.

The percentage of sites positive for BOP was similar between the treatments at each time point.

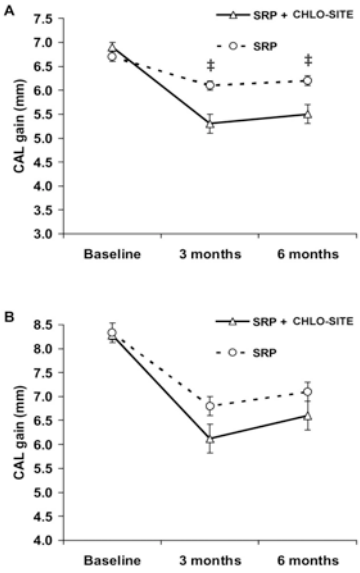
For the comparison between treatment groups, no differences were seen in the TBCs and GCF ALP activity at baseline and 6 months; However in the the SRP + CHLO-SITE treatment group at 3 months (p = 0.018 and p = 0.045, respectively). Moreover, greater reductions in the percentages of sites positive for periodontopathic bacteria strains were generally seen for the SRP + CHLO-SITE group with respect to SRP alone.

A - All (n = 98)
B ≥ 7 mm (n = 25) pockets for each time point (±SEM).
All of the pairwise comparisons between time points within each treatment (not shown) were statistically significant (p = 0.000).
Statistical significance of the differences between the groups at each time point: † p < 0.01, ‡ p < 0.001.

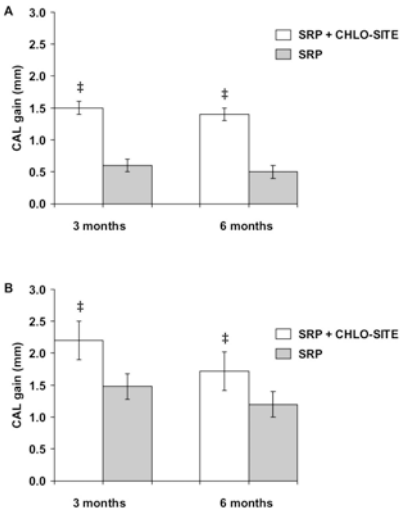
allows the dentist to safely manage periodontal disease when patients are checked every 3-4 months.

In conclusion, the combined use of SRP and CHLO-SITE gel resulted in a clinically significant improvement in PD reduction and CAL gain with respect to only SRP.
These results were concomitant with the significantly greater effects that the Xan-CHX gel treatment exerted on the subgingival microbial flora and on the GCF ALP activity, when compared to SRP alone.
These results are confirmed by both chemical and biological analyses, with evidence up to 3 months after treatment, whether you consider all pocket depths, or whether you consider only the pockets with a depth > 7 mm.
This data, in addition to scientifically confirming the clinical efficacy of CHLO-SITE, permits us to say that finally periodontal disease can be safely managed by the dentist if the patient is checked every 3-4 months by supragingival professional hygiene and periodontal visits (with probing of the pockets SRP + CHLO-SITE treatment for pockets with a depth greater than 4 mm).

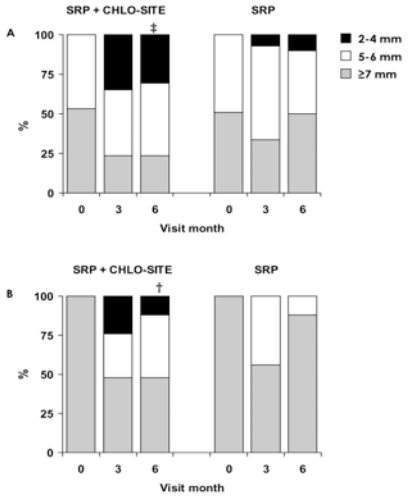
CAL at baseline and 3 and 6 months



Mean CAL reduction (mm) at 3 and 6 months from the baseline scores



Distribution of the CAL at baseline and 3 and 6 months



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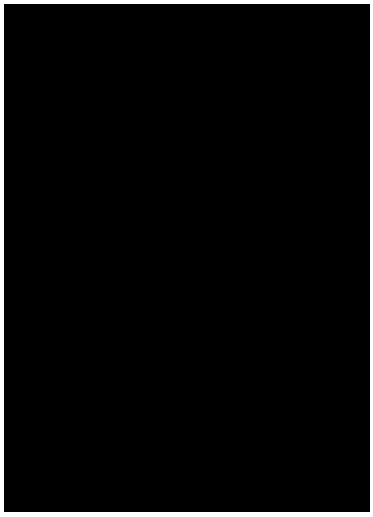
Statistical significance of the differences between the groups at each time point: † p < 0.01, ‡ p < 0.001.

How do implants "survive" in patients with periodontal disease?



The work published in the number 2 issue of the new RIS Journal - "Survival of dental implants in patients with or without a history of periodontal disease: a pragmatic multicenter retrospective cohort study with a follow-up study of 1,727 patients after 5 years" - is the largest cohort study ever performed up until now that aims to understand whether patients with a history of moderate or severe periodontal disease have a higher risk of implant failure than patients who do not \ from periodontal disease.

The results of this study should be interpreted with a critical view in light of its limitations: it is a retrospective study based on data coming from clinical records and not necessarily from specific patient recalls.

In its favor is **the high number of patients** (1,727), **a respectable follow-up** (5 years for all patients), and a **statistical technique** that takes into consideration the fact that many implants are in the same patient therefore they are subject to the same environmental conditions.
Complicating matters is the fact that the patients had very different initial characteristics: patients with a history of periodontal disease are older and receive a greater number of implants than patients without periodontal disease. Looking at the number of implant failures in absolute terms one gets the impression, in part supported by other studies, that patients with a history of periodontal disease have a greater number of implant failures.
Instead, statistical data that takes into consideration the fact that patients with a history of periodontal disease, in any case, have received on the average more implants, **one arrives at the surprising conclusion that there are no statistically significant differences.**
This means that patients with a history of periodontal disease lose less implants than was commonly thought, provided of course, that they receive adequate periodontal treatments.
If it is true that these results will be reconfirmed by subsequent studies with a longer follow-up (10 years or more), **it is also true that it does not appear justified to avoid implant-supported prosthetic rehabilitation in patients with a history of periodontal disease, provided that these patients agree to undergo regularly scheduled check-ups.**

Prof. Mark Edwards - Scientific Director of RIS

The proper use of CHLO-SITE allows all periodontopathic patients, when they are adequately kept under control, to be rehabilitated with implant-supported prostheses with the same prosthetic implant success as healthy subjects.

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