Appliance of Alumina (Al_2O_3) as a membrane for Guided Tissue Regeneration

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The target of this work is to demonstrate the appliance of alumina (Al_2O_3) blades as membranes for tissue isolation in Guided Tissue Regeneration (GTR). The authors have developed this material based on its high biocompatibility, widely demonstrated in literature, as well as on its mechanical properties, which betters its use. Several appliances in different fields of dentistry are indicated, such as implantology, periodontics, plastic surgery, maintenance and restoring of bone structures and so on. All different indications are based on the GTR principles. The main advantages of this new material are: therapeutic success, appliance simplicity and enhancement of GTR field.

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INTRODUCTION

On the 50's and 60's some works were published (23, 28) concerning bone regeneration. According to them, regeneration could be more predictable if the bone were isolated from the adjacent connective tissue. The biological explanation of this phenomenon (16,25,29,30,31) was later described as the GTR principle. Through the same works, it was possible to demonstrate that whenever a wound is frid from unwanted tissues, the desired cells can easily fill the original space. Nowadays, GTR is defined as a surgical procedure to separate tissues by means of a barrier which can either be natural (periosteum) ou artificial, providing regeneration instead of repair. Based on these principles, the application of GTR were extended to periodontics, seeking the correction of bone defects and the repair of the periodontal ligament. In such works, the target was to allow the bone cells and the periodontal ligament, which migrate and reproduce slowerly, to restablish natural support for the teeth, through the exclusion of connective and epitelial tissues.

Countless authors (13,14,16,25, 29,30,31) have been developing aspects of the GTR principles since the early 80's, with satisfactory results. Others (06,10,11,29,36,42) have extended its use for correction of bone defects related to implants, doubtlessly adding to the evolutions of the later. They have even applied the same principles on plastic surgery to correct local bone defects. Today, we attempt to enhance GTR application to other fields, such as correction of cleft palate and kelloid.

From the very first researches on tissue separation or isolation, there was the need of a material able to be present at the desired site, inside the organism, within the surgical wound, separating the tissues and, yet, without interfering in the regeneration process. To make it possible, it was necessary, in the first place, a biocompatible material which would also provide easy handling and shaping. Today, we are aware that the periosteum is the natural membrane or barrier used by the organism on bone regeneration with this purpose. Once there was no product specifically developed at first, Nyman et al.(29) applied for the first time in 1982 fragments of medicine filter. This filter is a medical recipient that, inside the organism, provides slow and gradual flow of the drug it carries,though it's micro-porous with diameters around 0.22 µm (11,13,29).

Later, employing teflon (politetrafluoretilen)(32), together with some adaptations, a new product reached the market: GTAM** - Gore-tex* Augmentation Material. It has flexible ends and rigid central portion, pores of approximately 0.45 µm of diameter and was first applied in 1984 by Gottlow et al.(13). This product was later succesfully applied by several authors (6,11,36,42). Comparative researches do not find differences between the results of either one. Although no work has yet been published to question the importance of the porous, we know they are unecessary as far as GTR principles are concerned. The pores have occured by chance. In Brazil (32,33), a membrane (Gengiflex****) was developed through a material based on cellulose, which has

* Millipore Filter® - Millipore SA, Type GS, France
** WL Gore & Associates, Inc., Arizona, USA
*** Gengiflex® - Biofill - Produtos Biotecnológicos S.A. - Curitiba-PR

been widely tested as synthetic skin. According to manufactor's information, " the internal part of the product is a net formed by crystaline cellulose microfibrils extruded randomly by bacterias... Both faces of the outside layers of alcalicellulose" Our aim was to solve some confomation and handeling inconviniences of these membranes and, above all, to develop a highly biocompatible material. Thus we developed a blade of alumina(Al_2O_3) (7,8,34,35,37) called Allumina** (picture 1).

Picture 1 - Alumina blade (Allumina). Made of a comercially pure aluminium core (99.33% minimum) covered by Al_2O_3 (99.48% minimum).*

MATERIAL AND METHOD

The material employed is the alumina or aluminium oxide (Al_2O_3), a ceramic material with physical and chemical biocompatibility features similiar to those of the titanium oxide (TiO_2) and the tantalum oxide (Ta_2O_5). Several caracteristics of this material are very important for its usage as a natural barrier or membrane for tissue isolation in GTR.

Biocompatibility

It has been clearly shown in literature that titanium and aluminium high compatibilities are related to the properties of its oxide surface. As soon as these materials are obtained, a layer of oxide is formed on their surfaces. The thickness of this layer varies between 3 and 5 mm in room temperature (9,24,35,37). As ceramic compounds, these oxides have certain properties such as chemical inertia against corrosion, high dielectric constant, biomolecule adsorption capacity, low electrical potential and catalistic activity. Together, these features issue favorable conditions for biocompatibility (5,9,15). Several authors (2,9,18,21,26,39,40) have comprobated the biocompatibility of alumina in studies on bone growth, growth of epthelial tissues, such as junctional epithelium (17,26,40), implants, implanted chambers and so on. This property is no longer discussed today. Alumina, both in its policristaline and simple cristal forms, is widely used as implant material(17,18,40).

Histophily

Through clinical observation of several different types of implants, we were able to point out some typical caracteristics concerning its interaction with the tissues, which we call histophily. Such feature, related to interface biochemistry , is constant in the TiO_2 and in the Al_2O_3 and seems to be directly related to its property of adsorption of biomolecules to its surface, through chemical liasions, mainly those of Van der Waals type. This caracteristic, together with biocompatibility, seems to provide favorable conditions to cell growth (1,9,38) when in close contact with its surface. Branemark et al.(9) and several other authors (2,3,19,20,22,26,41) clearly define this situation, although without naming it.

The osseointegration process is a sure consequence of histophily. Biocompatible materials, such as stainless steel, silicon, teflon, celullose and polimetilmetacrilate are not histophilic. Therefore, they do not, or almost never, osseointegrate.

Physical properties

Allumina* blades are provided in three thicknesses: 0.030mm, 0.060mm and 0.10mm, with O temper. The small initial stiffness is due to its thickness. As they are cold deformed, both stiffness and resistence grow bigger(12,37). The large initial plasticity is one of Allumina's main advantages, since it increases its aplicability. Once it can be easily deformed, it gives the material the ability to assume any morfological condition and to maintain the desired shape permanently. The plasticity of this material reduces as it is deformed. Different thicknesses have different uses.

Texture

The surface texture of the implanted materials have several functions, depending on its size (19). Branemark(9) states that, from 100nm on, a porous surface can be mecanically advantageous to an implant, in order to spread tension. Smaller values of surface harshness may interfere in the biological interface, since the cells and the large biomolecules have the same magnitude of that of the harshness curve. Today, almost all implants present both surface aspects.

Experiments were conducted with alumina membrane, polished and texturized, and the results concerning inicial and late gengival fixing pointed out the later as the best choice (picture 2).

*Picture 2 - SEM** of alumina membrane surface. Besides the surface texture, notice the complete absence of any contaminating agent, such as dust, oil, etc. a.100x; b. 500x; c. 1000x; d. 2.000x; e. 5000x.*

* Allumina* - Itaoni Ltda. - Juiz de Fora-MG

** Our appreciation to Prof. Dr. Dircéu Spinelli - Department of material - São Carlos Engineering School-USP.

Instructions

The membrane is applied in any situation wich requires tissue isolation through GTR principles. There are three different thicknesses for difefferent needs.

Thin

It is 0.030mm thick and it is applied in any tissue isolation case. It is easily adapted over any bone, dental or implant structure, avoiding the invasion of undesired tissues. It must be carefully molded on the structure and, after achieving the correct shape, it must be pressed using an instrument or even the finger. It will, therefore, become hard and the shape will no longer be altered (picture 3).

Picture 3 - Thin alumina membrane molding all bone irregularities. This feature enhances its isolation capacity and allows greater local stability, avoiding movements that would harm the regenerative process.

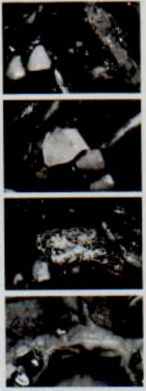
Medium

The thickness of 0.060mm gives higher resistance to the membrane. It is indicated for correction of bone defects, periodontal lesions or furcation. It can be molded according to the structure it is supposed to protect.(Picture 4)

Picture 4 - Appliance of a medium alumina membrane to protect an implant site. Notice that it is molded according the bone irregularities.

Thick

This membrane, 0.10mm thick, is applied to support the thin one, that is, to shape the area to be corrected. It should also be applied as a protection where mechanical pression could deform the thin or the medium membranes. (Picture 5)



Picture 5 - The appliance of the thick membrane (as a framework) together with the thin one (for isolation) in a case of correction of wide bone defect: a. horizontal and vertical bone loss at 13. Appliance of an osseointegrated implant at 12. b. appliance of thick membrane to shape, provide sustentation and protection to the area where correction is desired. c. sealing and isolation with thin membrane over the thick one and its surroundings. d. correction obtained six months later. Observe implant already exposed.

General Surgical Sequence

The following is the basic sequence for applying the membrane after the specific procedures of each case:

- Removal of the membrane from its package and imediate insertion in saline solution so as to prevent withering of the blood cells.
- Cutting of a portion with shape and size approximate to the site to be isolated. Generally, the membrane should be as small as possible, with no more than 3 to 5 mm around the area.
- Handling of the membrane close to the site in order to visualize the necessary fine adjustments.
- Final cuts and new proof. Up to now, the membrane shouldn't be excessively bent or wrinckled. If necessary, it could be kindly curved to acquire the desired shape. The bending and wrickling for final adjustment should only be done at the last step of the process, when it will become rigid and maintain the defined shape
- The presence of clot on the site is necessary to form the new tissue. It is important to emphasize that the clot is the natural environment and the best substract for tissue formation. All cares should be taken to assure that the entire space underneath the membrane is occupied by the clot.
- Placement of the membrane, after the formation of the clot and final molding with a round pointed instrument (such as a Willinger elevator) and the help of the surgeon fingers. On the process, the membrane will imediately become fixed over the site owing to the irregularities, isolating the area.
- Formation of the clot over the membrane and suture.

This sequence may be altered by some procedures, such as inicial appliance of the thick membrane covered by the thin one, resin fixation of the membrane, and so on.

Results

Application

Nowadays, the application field of GTR principles has been greatly widen all around the world. Through the alumina membrane (Allumina®), mainly owing to its physical caracteristics, this work could go much further. In general, the following applications can be named:

- Periodontal treatment.
- Alveolar bone ridge preservation.
- Alveolar bone ridge augmentation.
- Implant protection.
- Aesthetic corretion of bone defects.
- Corretion of furcation lesions, among others.

This membrane has been applied in different situations and the results haven always been positive.

PERIODONTAL TREATMENT - The appliance of the alumina membrane in such cases has brougth several advantages due to the possibility of achieving greater stability and resistance against muscle and food action. In picture 6, we present a case of advanced periodontal lesion of the palatine root of 26. Periodontal treatment, remotion of the palatine root and the appliance of the membrane were performed. After 21 days, the membrane was uncovered and, therefore, was removed. Three months later, the healing was quite satisfactory.

ALVEOLAR BONE AUGMENTATION - After a tooth loss on the maxila, the alveolar ridge is very likely to become narrow, just as it is common to occur bone vertical loss, making it impossible to fit an implant. At picture 7 there is a classical example of such case, in which, the placement of a Bioform Implant® * and the appliance of Allumina® allowed the implant to be placed and guided the correction of the bone defect. The first step was the introduction of the implant, which caused the vestibular blade fracture because of its particular shape. The membrane was placed such as to cover the entire area and after 21 days there was a bone matrix already formed. The membrane was then removed. Another implant was placed on a further posterior position and covered by a second membrane. After other 43 days this membrane was also removed and the results allowed implant fixation and correction of alveolar bone.

AESTHETIC CORRECTION - The narrowing of the alveolar bone ridge due to tooth loss results in irregularities which cause aesthetic harm. This is true mainly when there are remaining elements. If these teeth are anterior, the alteration on the arch curve is not likely to be solved by the use of a fixed work. At picture 8 we can see a classical example, solved with the help of an alumina membrane which guided the tissue regeneration, restablishing the shape of the ridge.

IMPLANT PROTECTION - Protection to the implant is provided by alumina membrane in two ways: buccal lingual deffect (due to alveolar bone ridge narrowing) and/or occlusal deffect (due to bone thickness or even irregularities of the alveolar ridge). The appliance of the membrane is positive mainly in the cases where a perfect adaptation of the implant to the bone is not easily achieved, because it prevents invagination of soft tissues as well as allows bone regeneration (picture 9).

DISCUSSION AND CONCLUSION

The clinical results obtained through the membrane confirms once more its biocompatibility features, which were present in works by Weinstein *et al.* (39), Kawahara & Hirabayashi (17,18), Branemark *et al.* (9), Mckinney *et al.* (26), Yamagami *et al.* (40), among others. Its physical properties help and easy the application procedures for tissue isolation. Through the clinical results obtained, we have been able to realize the countless possibilities yet to be explored.

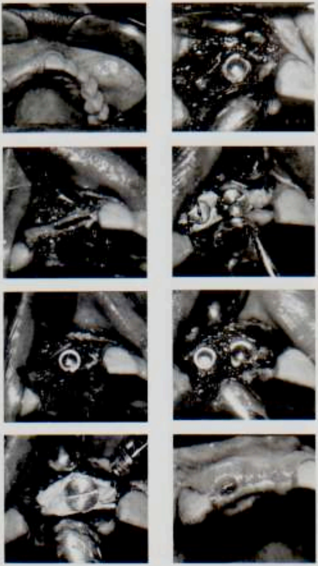
Although we haven't yet been able to test the tissue quality, other authors (11) have histologicaly studied it and have detected bone and periodontal ligament growth (13).

Based on these results, we can conclude that:

- The GTR is a procedure which applies biological principles to provide means to overcome barries that, up to now, have hinder the solution of many problems.
- The alumina membrane has physical and chemical properties that increase and easy such procedures.
- No clinical procedure based on alumina has brougth negative results; on the contrary, its use has simplified membrane appliance and accelerated the results.

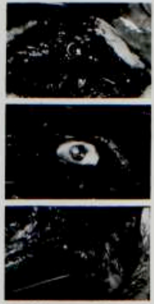
Picture 6 - Appliance of membrane to heal chronical and extensive periodontal lesion of the palatine root of 26. a. View of palatine root of 26 being cut and the bone loss around it; b. bone cavity after the remotion of the root and inflamatory tissue; c. clot being formed and alumina membrane covering the site; d. after 90 days the healing, to the best of our knowledge, was better than if the membrane had not been applied.

* Maxmar*



Picture 7. Bone thickness augmentation at the alveolar ridge. a: narrow alveolar bone, due to tooth loss; b: insufficient thickness (2.5 mm) for implant placement; preparation of the site, preserving buccal and lingual bony blades; c: placement of a 4mm diameter implant, fracturing the vestibular wall; d: 21 day re-entry - notice that the membrane is attached to the implant by the protection screw; e: tissue formed underneath the membrane and around the implant - here another implant (5 mm) was inserted distally to the first one; f: after 45 day re-entry the membrane was removed; g: the two implants; h: before the later re-entry; compare the bone thickness with that of "a".

Picture 8. Aesthetic correction of bone defects: a: flat anterior curve and narrow alveolar bone; b: membrane to be shaped; c: membrane placement and final shaping; d: aspect and shape of the tissue developed underneath the titanium membrane; e: final aspect of alveolar bone.



Picture 9 - Implant protection: a. Biofarm® horizontal implants for osseointegration: a portion of the site remains exposed; b. placement of the membrane to cover and protect the implant. The protection screw was used to fix the membrane; c. after 8 months, during osseointegration waiting period: notice the tissue formed underneath the alumina membrane.

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