
ceramir®

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Introduction

CERAMIR® – A BRIEF DESCRIPTION OF THE TECHNOLOGY

Development of direct[1)] and indirect[2)] dental materials is an on-going process. The major challenge – and the primary focus of all collaborative development work on direct materials – is degradation of the mechanical properties, retention and adhesion in the mouth.

The mouth is an area of constant activity – dynamic and ever-changing. The mouth is a complex environment and along with the biological microflora, we also have to consider temperature, humidity and other constraints which in certain cases (and not so seldom) make this environment one of extremes.

Acidic attack, which leads to tooth decay, is one of the most frequently encountered problems and the single biggest cause of diminished oral health. The complexity of all this places high functional demands on materials used in the mouth and makes for great difficulty in producing materials with optimal functionality in clinical situations. The development of dental materials during recent years has come a long way in creating favourable conditions to minimize these problems. But the question still remains: how best to address problems related to degradation of the mechanical properties, retention and adhesion in the mouth?

Most materials employed, function optimally when used at room temperature and in normal humidity but problems may occur in the oral cavity or when in contact with teeth.

The predictability of results when direct materials are used can be problematic. According to the literature (references supplied) the most common complication for all types of restoration is biological failures.

Bacteria that give rise to caries enter between the artificial material and the tooth and cause damage. Secondary (recurrent) caries is the most common cause for the need to redo both fillings and permanent prosthetic constructions.

A natural development

For the most part, teeth consist of collagen and hydroxyapatite, closely interwoven and with a complexity that cannot be matched without imitating nature's own way of creating material. An intact tooth functions optimally in the oral environment and has basically only one inherent weakness: its sensitivity to acidity which causes damage and leads to decay. (Damage can also take place in the periodontium causing periodontitis.)

A tooth attacked by caries can be repaired in a variety of ways. The most ideal way would be to re-establish its integrity by means of remineralising, utilizing biomimetric methods. The material used to repair a tooth should be as close to nature's own as possible, so that a harmony is created in the oral cavity by having physical and mechanical characteristics that lie close to those of the tooth itself. The development of Ceramir® is based on this basic philosophy of creating harmony in the mouth and a natural collaboration with the dental tissues by way of:

A chemical structure resembling hydroxyapatite, the ability for the tooth to be remineralised and the capability of creating natural contact zones without stress, either thermal or mechanical.

The result, Ceramir, hardens through a mechanism of dissolution and re-precipitation where phases in nanometer sizes (10–40 nm) are built and bonded to one another on site, creating a basic pH. This hardening mechanism imbues the material with a unique capability for sealing the interface to the tooth tissue and creates the conditions necessary for the building of hydroxyapatite on and in close proximity to the surface of the material. This means that the material is bioactive.

[1)] Hardens in the oral cavity [2)] Produced industrially or in the laboratory

CERAMIR® – A NEW CLASS OF DENTAL MATERIAL

Ceramir is a new class of dental material. Ceramir distinguishes itself from existing primary classes, such as resins and glass ionomers, but also from other water-based cements, such as phosphate cement.

Ceramir has the following unique characteristics:

- pH (basic pH created during hardening)
- It is stabilised in the oral environment
- Ability to create hydroxyapatite upon contact with phosphates
- It does not shrink
- Naturally nanocrystalline when hardened
- Contact with tooth tissue – nanostructural integration

Ceramir is a chemically bonded ceramic that utilizes nanotechnology, and is thus imbued with unique characteristics. The material hardens by dissolving upon reaction with water and by repeated crystallisation resulting in the formation of nanocrystalline hydrates. These hydrates consist of ions of the dissolved chemical powder and water, creating a new permanent structure once the concentration of liberated ions rises to an appropriate level. The "new material" comprises two stable hydrates: the minerals katoite and gibbsite. Katoite is a calcium-alumina-hydrate and is built as crystals, each being between 10 and 40 nanometers in size. Gibbsite is an aluminium-hydroxide and is formed first as an amorphous gel which transforms over time into crystalline gibbsite. The material attaches itself to the tooth surface by so-called nanostructural integration and therefore, by definition, belongs to the group Nano-structurally Integrating Bioceramics (NIB). The material's hardening mechanism is built on nanotechnology, which implies that it does not shrink during the consolidation process, as opposed to what happens with resin-composites. For additional comparisons between the various material classes, see the table below.

Glass Ionomer	Resin-modified Glass Ionomer	Resin (bonded)	Self-adhesive Resin	Phosphate Cement	CERAMIR
Acidic	Acidic	Acidic/neutral	Acidic/neutral	Acidic	Basic
Polymers	Monomers	Monomers	Monomers	Non-monomer	Non-monomer
Cross-linked	Polymerised	Polymerised	Polymerised	Non-polymerised	Non-polymerised
Irritant	Allergenic	Allergenic	Allergenic	Non-allergenic	Non-allergenic
Non-shrinking	Non-shrinking	Shrinks	Shrinks	Non-shrinking	Non-shrinking
Degraded in the mouth	Degraded in the mouth	Degraded in the mouth	Degraded in the mouth	Degraded in the mouth	Stable
		Etching and bonding	Etching and bonding (in one product)		
Hydrophilic	Hydrophilic	Hydrophobic	Initially Hydrophilic / Hydrophobic	Hydrophilic	Hydrophilic
Micro-mechanical retention/Chemical bonding	Micro-mechanical retention / Chemical bonding / Adhesion	Adhesion / Micro-mechanical retention	Adhesion / Micro-mechanical retention	Micro-mechanical retention	Nanostructural integration
					Bioactive

Ceramir®
– Technological Background

TECHNOLOGICAL BACKGROUND

Biomaterials are used in the field of medicine to replace parts of living systems and to operate in close contact with living tissues. The technology associated with biomaterials have been undergoing intensive development and Sweden is a leading player in the field.

First generation biomaterials (for example, Ti, Co-Cr and polymeric compounds including high-molecular PE) are biocompatible, which means that the body accepts these materials. Areas where biomaterials have long been in use include restorative dentistry as well as hip-joint procedures.

Second generation biomaterials integrate with the body and are therefore bioactive. The result is a whole new range of treatment opportunities. Especially interesting application areas can be found in the field of dentistry, together with orthopedics and tissue regeneration.

Biocompatibility

Biocompatibility is a collective name that has been adopted to describe the properties of a material or implant in relation to the tissue's response in any specific application.

The extent of biocompatibility is dependent on the collective effect of all the characteristics, all constituent components, trace elements, contaminants and their content.

BIOCERAMICS

Recent decades have seen ceramics become an increasingly common alternative to traditional polymers as biomaterial in dentistry. Ceramics are often defined as inorganic, non-metallic material. Ceramics can be manufactured in two ways: either physically, whereby finished product compounds are sintered together at high temperature; or chemically, by means of a chemical reaction.

Many ceramics are found in their natural state and as such are classified as minerals. Apatite, the most common biologically manufactured mineral in the body and the main ingredient of all the body's hard tissue, is also found in nature. Therefore, apatite is the ideal end-product as a biomaterial.

Ceramics are natural and are notable for their extremely high chemical and thermal stability. The component elements are in their natural state and are at their lowest energy level. Because they are end-products, they contain no inherent driving force to change their state, meaning they have tremendous dimensional stability. They are also linearly elastic, meaning they undergo no permanent deformation when subjected to load. In principle, the crystalline system of a ceramic precludes the shearing of atoms from one another within its structure.

Bioceramics are found within all the classical ceramic groupings: traditional ceramics, special ceramics, glass, glass ceramics, as well as within chemically-bonded ceramics (see table next page). The use of bioceramics places high demands on material properties, not least low toxicity and high biocompatibility. The most common application of bioceramics is as implants.

Classification of ceramics into families (sub-groups), with examples of bioceramics in each group

Ceramic Classification	Bioceramic Examples
Traditional ceramics	Dental porcelain, Leucit
Special ceramics	Al-, Zr- and Ti-oxides
Glass	Bioglass
Glass ceramics	Apatite, Wollastonite
Chemically-bonded ceramics	Calcium phosphates, Calcium Sulphates, Calcium Aluminates

CHEMICALLY-BONDED CERAMICS

Most ceramic materials are formed at high temperature using a variety of sintering processes. However, by using chemical reactions – normally achieved by mixing ceramic powder and liquid – it is also possible to produce ceramic materials at lower temperatures (body temperature).

Chemically-bonded ceramics are those which are built using chemical reactions at "low" temperatures and these ceramics are attractive for a variety of reasons:

- They are injectable
- Hardening takes place in the body
- Minimal negative effect on the system that the material is interacting with
- Dimensionally stable
- Avoidance of temperature gradients (thermal stress)

These properties clearly indicate great potential in the use of chemically-bonded ceramics as biomaterials.

Chemically-bonded ceramics can be classified into five main groups with separate characteristics (see table below).

Each of these groups are currently in use as bioceramics in a variety of application areas, primarily in the form of injectable pastes. Making use of pastes based on these ceramic systems opens up opportunities for the application of ceramics in areas hitherto addressed primarily with polymeric materials. All five systems have their own specific characteristics and benefits and are therefore adaptable to varying types of applications.

Chemically-bonded ceramics can be classified into five main groups

Group / name	Calcium content systems	Typical phases achieved
Silicates	$CaO\text{-}SiO_2$	Amorphous CSH, Tobermorite, etc
Aluminates	$CaO\text{-}Al_2O_3$	Katoite and Gibbsite
Sulphates	$CaSO_4$	Gypsum, $CaSO_4 2H_2O$
Phosphates	$CaO\text{-}P_2O_5$	Apatites and other Ca-phosphates
Carbonates	$CaO\text{-}CO_2$	Calcite, Aragonite

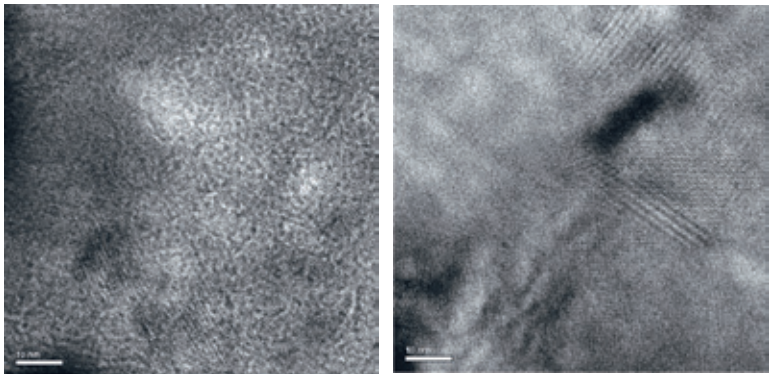
UNIQUE PROPERTIES

The calcium aluminate system has a number of inherent characteristics that make it more appropriate than other chemically-bonded ceramics for use in dentistry. For example:

1. One important property is that the calcium aluminates system has a high turnover of water during the hardening process, which means that a lot of water is bonded within the material as it hardens. This large volume of bonded water makes for great strength – many times greater than for normal calcium phosphates. In addition, the high water turnover results in greater variability of its viscosity and composition, making it possible to use calcium aluminates in a broader spectrum of applications.
2. Another positive characteristic is that the system has a rapid hardening. This is a quintessential prerequisite for dental materials.
3. Moreover, the system shows excellent biocompatibility and a unique capacity to create hydroxyapatite in phosphate containing solutions.
4. Important from a clinical view is the antibacterial features of the calcium aluminate system and the fact that these features do not have any negative impact on the material's biocompatibility and bioactivity.
5. Finally and crucial for dental applications; the calcium aluminate system must be stored at 37°C and 100% humidity i.e. mouth environment, in order to reach optimal performance. It means that in the oral environment all physical properties including retention will be optimized instead of degraded over time.

NIB-TECHNOLOGY – THE BASE FOR CERAMIR

Ceramir utilizes nanotechnology, and consequently has some unique properties. The material consolidates through its reaction with water, first dissolving and then re-crystallizing as nanocrystalline hydrates. As it dissolves, the material wets the tooth and then as the nanocrystals begin to form, they precipitate on the wall of the tooth, on filler particles and on any pre-existing crystals. Therefore its adhesion to the tooth takes the same form as the material's own infrastructure. These general mechanisms are built on surface energy and mechanical interlocking at the nano-level. The whole is called, nanostructural integration. Bioceramics, which attach themselves to their surroundings in this way, are known as Nanostructurally Integrating Bioceramics (NIB).

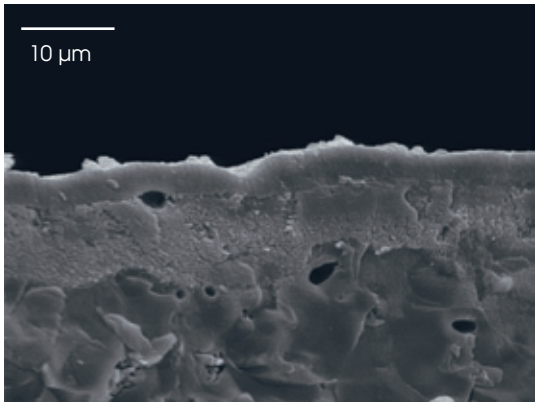


The illustrations above depict the nanostructure created by hydrated Ceramir with high-resolution transmission electron microscopy, HRTEM, with image enlargement of up to around 1,000,000 times. The illustration on the left shows a general structure, while that on the right makes visible the layout of the atoms in the hydrates.

BIOLOGICAL PRINCIPLES

Ceramir is a bioceramic technology of Doxa, a world-leader in the field of bio-active ceramic development. By the use of biological principles the ceramics build apatite when in contact with phosphate solutions, such as saliva or body fluid and once implanted in the body, bone integrates with Ceramir. This has been demonstrated in several microscopic studies. Its capacity for building apatite contributes to the material's sealing properties and also means that Ceramir has an excellent biocompatibility profile.

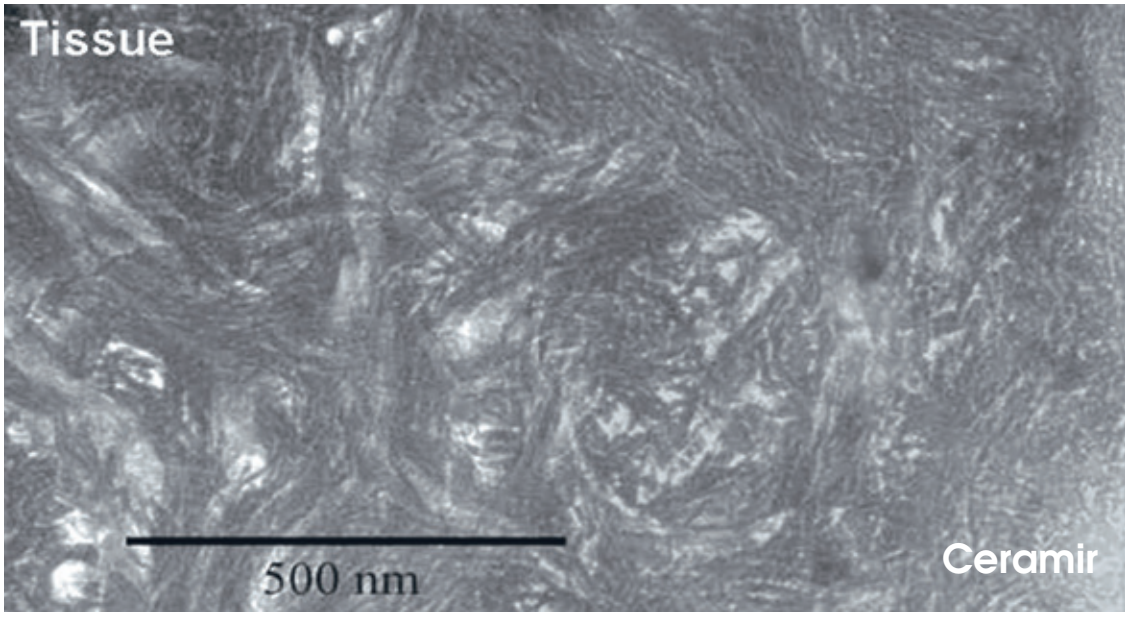
Describing the advantages of using a treatment based on biological principles is best done by using the definition of bio-mimetics, "Use nature as the source of solution to the problem". Treatments based on biological principles are in general more "forgiving", meaning they will be easier to perform and less technique sensitive. In addition both the immediate and long-term results will be more predictable. Thus, instead of using technologies and materials that fight biological principles, use a technology that is actually driven by the natural chemistry of the human body – Ceramir.



The photograph illustrates how Ceramir creates apatite on the tooth surface, when in contact with phosphate solution

pH, bioactivity and apatite formation

At a neutral pH, which is the natural state in the body, the tooth hard tissue is stable and in equilibrium with the phosphate and calcium ion levels in the saliva. If the pH drops, as it does e.g. when acid producing bacteria are present or when you drink acidic beverages, the balance is off-set and the enamel and



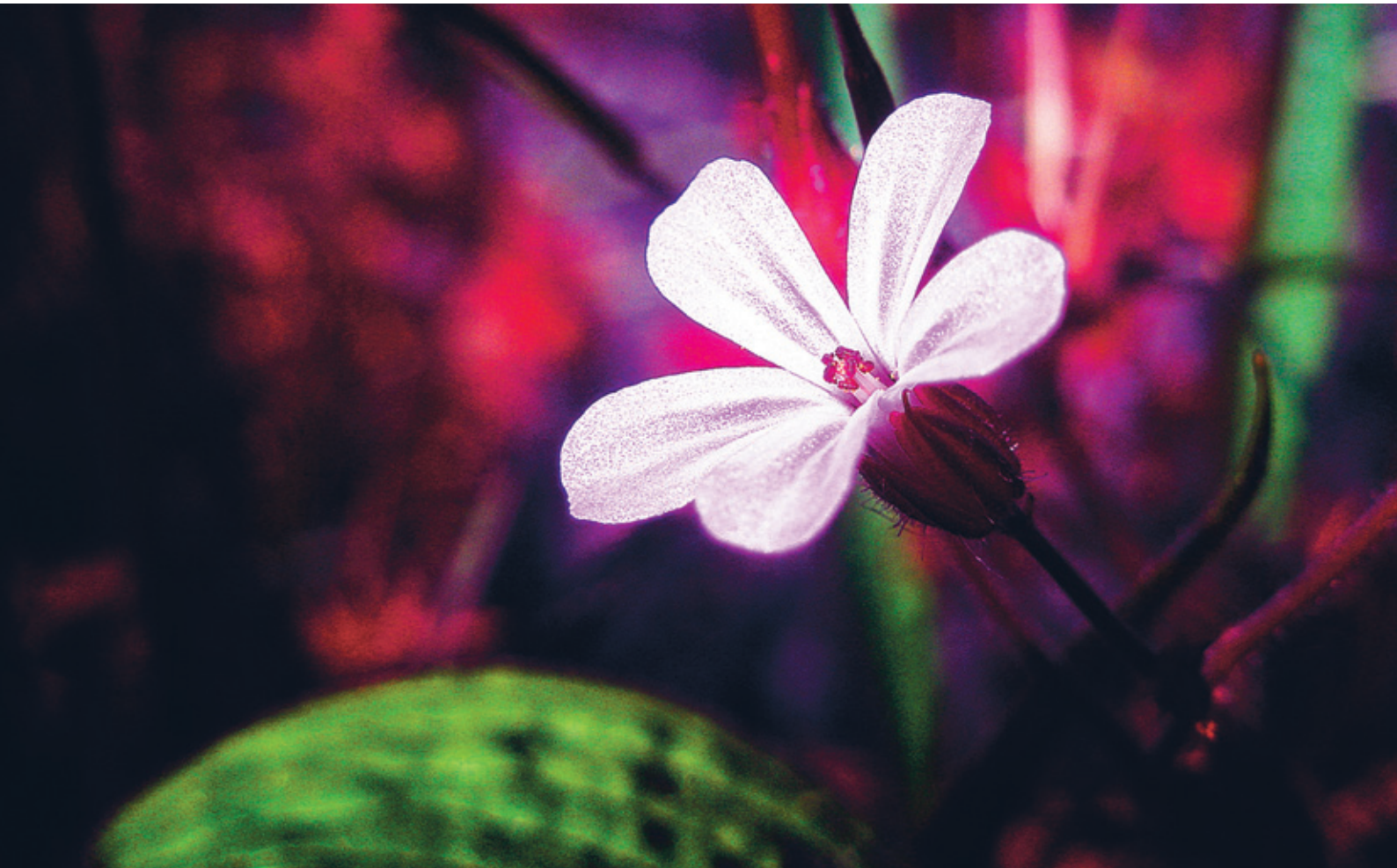
The photograph shows the chemically and biologically induced nanostructural integration between Ceramir and bone tissue.

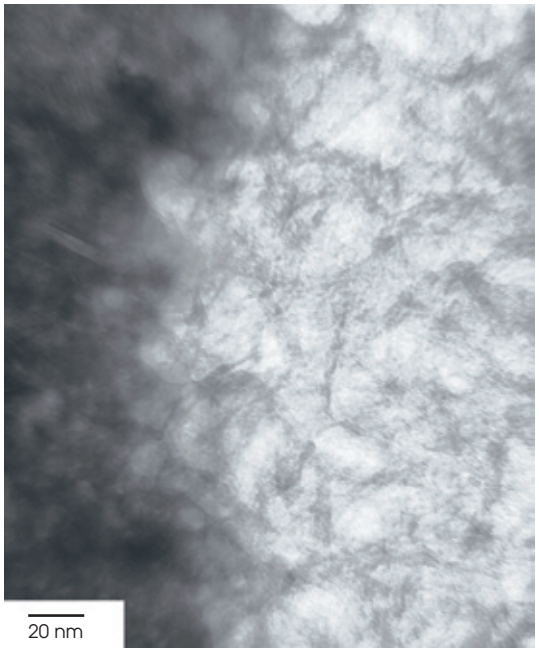
mineral parts of dentine will start to dissolve. Phosphate and calcium ions are released into the saliva to restore the pH and the ion equilibrium. Other ion equilibriums are present in the saliva also contributing to balance the pH. The pH at which enamel starts to dissolve is called the "Critical pH". In order to prevent demineralization of tooth hard tissue the most important thing is to raise the pH. In addition extra calcium and phosphate ions can be supplied to keep the equilibrium between tooth and saliva. Fluoride could be added since fluoride ions will create a more stable type of apatite.

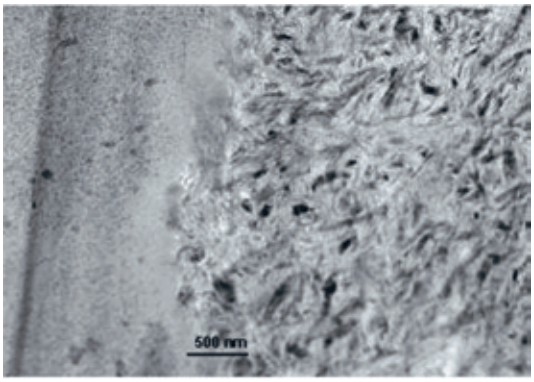
Ceramir naturally produces an alkaline environment during setting and hardening and also releases calcium ions. The higher pH in combination with the release of calcium ions creates an environment conductive to the creation of hydroxyapatite i.e. remineralization. Chemically, the material is similar to the body's own mineral apatite. The greatest difference is found in the ability that Ceramir has to withstand acidic corrosion (an inherent property of the material). Thanks to its higher pH which fosters the production of hydroxide ions, Ceramir is able to resist attack from both acidity and acidity-producing bacteria. Bioactivity means that the material has the ability to work together with the body, implying a capacity for growth alongside living tissues. Ceramir bonds to the tooth using the same principles as remineralization i. e. precipitation of minerals at alkaline pH. The pH after hardening is alkaline, which is the natural state of the material and will not be changed. Alkaline pH is the ideal condition for remineralization and the reason for the bioactivity of Ceramir as well as for other unique properties which combined give a more predictable long-term clinical result.

Antibacterial properties

Ceramir has been shown to inhibit bacterial growth. The main reason is the high pH created during setting and hardening together with the initial high release of ions. Possibly the structure of the hardened surface will also contribute to the inhibition of bacteria attachment and growth.







The illustration on the left demonstrates how Ceramir has integrated with enamel in vivo (enamel on the left of the picture).
The illustration on the right shows how Ceramir has integrated with dentine in vitro (dentine on the right of the picture).

NATURAL MOVEMENT AND THERMAL PROPERTIES

The thermal properties in dental products have a profound influence on their functionality. If these properties are not operating at their optimal best there will be an increased risk of change in the material with the possibility of leakage at the interface between material and tooth.

Thermal behavior is, however, more dependant on constructive design than it is on the choice of material. For this reason, Ceramir is designed to the greatest extent possible, to have natural thermal characteristics. That includes, among other things, thermal expansion and conductivity and elastic modulus (stiffness). Ceramir has low thermal conductivity, just as teeth do. Its thermal expansion properties are almost identical to those of enamel and dentine. This minimizes the risk of thermal shock when subject to sudden temperature change. This, in turn, also implies that Ceramir has the ability to move together with the tooth and in so doing minimizes the risk of gap formation.

Property	Dentine	Enamel	Ceramir***	Glass ionomers	Composites
E-modulus GPa	20	46–48	4.7–19.0	7**	5–15*
Thermal conductivity W/mK	0.57	0.93	0.8–0.9	0.51–0.72	1.1–1.4
Thermal expansion ppm/K	8.3	11.4	10	11	14–50

Phillips' Science of Dental Materials Eleventh Edition
** Applied Dental Materials 8th Edition, McCabe & Walls*
*** Materials in dentistry, Ferracane*
**** Internal Reports, Doxa*

SEALING OF THE INTERFACE BETWEEN ARTIFICIAL MATERIAL AND TOOTH

The ability to create a completely impenetrable joint between dental material and the tissue of the tooth would be of great clinical benefit, and would at the same time extend the life of many dental treatments. In short, it would mean good things for the patient.

Secondary caries

The core problem is that in time, a gap will likely occur between the material and the dental tissue, leaving room for nutritients and caries-producing bacteria to leak in. When the bacteria begin to metabolize the nutritients, caries develops and the dental tissue is destroyed. This phenomenon is quite common and is normally referred to as secondary caries. It can occur in all types of restorative work and is the main cause of all rectification work. The long-term consequence of secondary caries in prosthetic restorations is that the prosthetic work is eventually rendered useless, either because of a failure in retention or because the tooth requires a root filling or needs to be extracted.

Gap formation

In order for leakage to occur, there must be a gap which nutritients and bacteria can gain access to. The reasons for the occurrence of gaps can be many, depending upon the type of material used. Certain older types of dental cement are recognised to have inadequate resistance to leaching in the mouth. This means that over time, material is gradually lost from the cement margin and leakage may ultimately occur. Loss of material from the cement margin can also result from poor wear resistance, leading to the disappearance of material as a direct effect of wear over time. General shrinkage during the hardening phase is a basic problem for resin based materials.

A general reason for the formation of gaps, which applies to most material types in varying degrees, is that the material responds differently to the dental tissue when it is exposed to changing temperatures. The environment of the mouth is one where substantial and rapid temperature changes can take place, and when that happens, everything expands or contracts. A great difference between the thermal movements of the material and that of the dental tissue can result in stresses. And these stresses can create a gap between material and tooth. Naturally, this is countered by how well the material adheres to the tooth.

Attachment mechanisms

To ensure tight contact between material and dental tissue, the material needs to be able to "wet" the tooth effectively. Certain materials are hydrophilic and wet the water-retaining tooth naturally. Other materials are hydrophobic and require pre-preparation with multifunctional substances which are both hydrophilic and hydrophobic, whereby the hydrophilic constituent attaches to the tooth while the hydrophobic constituent attaches to the material to be used. The viscosity and the general rheology of the material are also important for a good contact. When the contact is created the material also has to attach to the dental tissue. Differing materials attach using differing mechanisms. Some of the most common attachment mechanisms employ mechanical locking between the tooth's irregularities and the material, chemical bonding and adhesion.

Optimal sealing

A prerequisite for the prevention of leakage is that the material used in the restoration process is handled optimally. The technique sensitivity varies with differing materials but generally resin-based materials require most from the clinician. In most cases, pre treatments will be necessary and the material will need to be bonded to the dental tissue so that it adheres. During hardening, shrinkage-initiated stresses occur and if the procedure has not been optimal, these in turn produce gaps between material and tooth.

Resin-based materials are normally very sensitive to water and oxygen. Both are able to influence the hardening chemistry and/or the hardened material in a negative way so that it fails to attain optimal performance. A minimal amount of fluid present during the hardening period can eventually lead to the material leaving the tooth and/or becoming discolored. The more do's-and-don'ts that need to be dealt with when using the material, the greater the likelihood of something not being at its best during the process.

The best pre-conditions for a good and permanent seal of the contact surface between material and tooth are provided by a material which:

- is hydrophilic and attaches in a natural way to the tissues of the tooth (nanostructural integration)
- has a capability for impletion of all the abnormalities of the contact surface
- has thermal properties akin to those of dental tissue
- is easy to handle and does not require optimal conditions for a good seal
- creates an environment at the interface that protects the stability of both the tooth and the material over an extended period of time (basic pH)

CERAMIR® PROVIDES A PERMANENT SEAL

Ceramir displays a range of properties that make contact with tooth-tissue tight, impermeable and stable over the long term. It wets the surface of the tooth well and fosters the build-up of nanocrystals which attach to the surface and assimilate with the rest of the material. These characteristics work together to create a tight seal along the entire length of the contact zone. Its ability to build apatite, along with its acid-resistance, its natural thermal properties and basic pH-value give long-term stability to the contact zone.



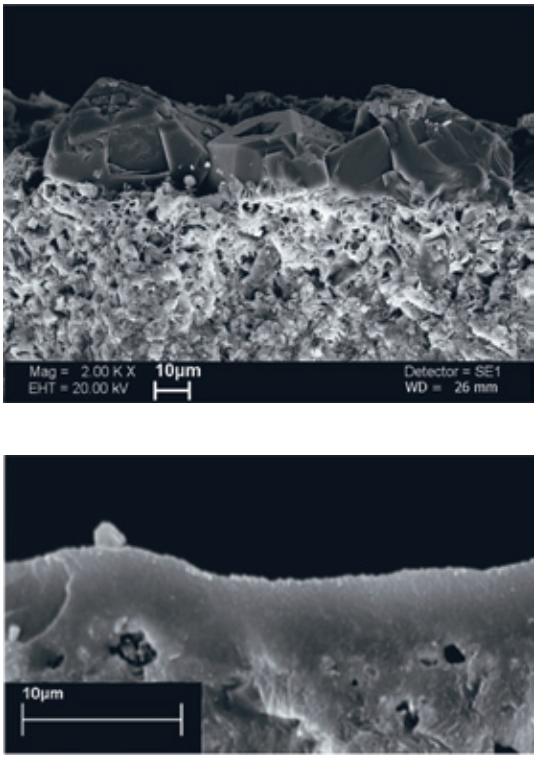
TEST METHODOLOGY

When laboratory testing of material is conducted, it is important that the appropriate methodology is used for the specific material to be tested. Within the realm of dental material, consensus standards are often used as a basis for the methodology to be employed. These standards are produced to prove that the characteristics are appropriate for the application in question, as well as their being a requirement for easy implementation of the methodology. This has the effect of making the standards conform to the classes of material already on the market and designed so that the material may be compared by application and material class. Then, if, an entirely new class of material is introduced – in this case, Ceramir – it is not always possible to directly apply the available standard methodology. There are many aspects that must be taken into account when carrying out the testing process, including the chemistry of the hardening process and the fracture mechanics.

Testing in a clinical environment

Ceramir is a technology optimised to operate in body fluids. This means that the material's optimal performance is achieved in the clinical environment. Today's standard testing methods for dental materials are often adapted to return comparative results in an environment rather unlike that of the human body. The reason is that contemporary dental material normally functions optimally in the laboratory but performs at an inferior level in the body. For Ceramir, it is of the utmost importance that all laboratory testing be carried out at body temperature and that the material is always maintained in an atmosphere whose relative humidity is greater than 90%. Artificial saliva, a pH-neutral phosphate solution, should always be used as a storage solution and should be free of any additives containing sugars or other carbohydrates since these inhibit the hardening process. The reason is that Ceramir has a special hardening chemistry which causes the surface of the material to interact with the storage solution. If samples are kept in phosphate solution the surface is deactivated and covered by a protective layer of stable calcium phosphate. If instead the samples are stored in water, then the carbon dioxide dissolved in the water begins to form calcium carbonate on the surface of the samples. This is a porous substance, and after a time begins to loosen. If this process is allowed to continue, the material will start to get "eaten" up, leading to erroneous test results.

Moreover, whenever possible, the test methodology for ceramic materials should be used.



The above illustrations depict the importance of a correct storage environment in evaluating/testing a material. In a pure water environment (upper), large crystals of Calcite are built upon the surface of Ceramir, while a solution of phosphate (lower) develops a close layer of nanostructural apatite.

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