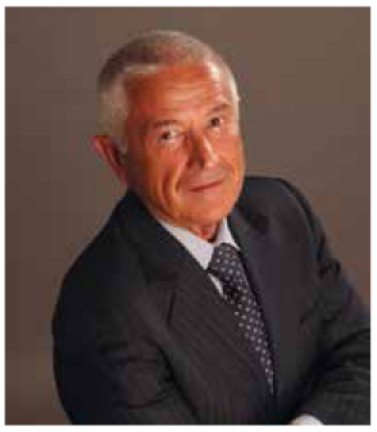
Use of an innovative collagen-based hydrogel for the treatment of periodontal and peri-implant pockets

Let us discover their characteristics and applications in an interview with the CEO and the Head of R&D of Bioteck S.p.A.



Rino Biasiolo, CEO of Bioteck SpA.

Bioteck S.p.A. is an Italian company that, for over 25 years, has been active in the development and production of biological biomaterials for dental and orthopedic regenerative surgery and neurosurgery. In the dental sector, it has contributed in the consolidation of heterologous biomaterials made from preserved collagen for bone and tissue regeneration operations. These materials are, therefore, typically used in surgery, intended for the treatment of severe cases that necessitate an operation. Consequently, the commitment of Bioteck to offer dentists a product intended for non-surgical periodontal use is an absolute novelty. The product in question is H42 collagen-based hydrogel, a new injectable medical device intended to support dentists, periodontists, and dental hygienists in the non-surgical treatment of periodontitis and peri-implantitis. To fully comprehend the properties of this new device and the reasons that led Bioteck to embark on this new challenging adventure, we spoke to Rino Biasiolo, CEO of Bioteck, and Dr. Christian Frigerio, who specializes in analytical chemistry with long experience in the pharmaceutical field and who currently heads the Company's R&D department.

Mr. Biasiolo, what led Bioteck to develop a new product for periodontal health?

Periodontitis and peri-implantitis are considered by many the most important oral cavity diseases of recent years.
It is estimated that between 20 and 50% of the world's population suffers from periodontitis, and that peri-implantitis affects over 20% of dental implants. These impressive numbers help us realize the importance of these conditions for human health.

Bioteck has, for several years now, begun to focus on issues related to the periodontium.
We started with bone grafts in a syringe, dedicated to the surgical and regenerative treatment of deep defects, combined with three-dimensional collagen-based matrices for the management of the soft tissues and the treatment of gingival recession. By exchanging ideas and opinions with the specialists of the sector, we endorsed their demand for a product that can support them not just in the treatment of the most severe cases, but also in the daily management of defects that do not require surgery.

How is H42 used, then?

H42 is a resorbable gel that is incorporated in the therapeutic pathway of periodontal and peri-implant pockets whose depth ranges from 4 to 6 mm, where surgical treatment is not yet indicated. Its purpose is to reduce the risk of recurrences following causal treatment and/or treatment with antimicrobial substances, while promoting the healing of the tissues.

How is it applied?

The product is supplied inside a syringe with a male luer lock connection to which it is possible to connect a wide range of needles, with a diameter ranging from 22 to 27 Gauge, with multiple holes, a single hole, or a side or front hole, with the aim of allowing operators to choose the needle that is best suited to the specific surgical situation.

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H42 is then extruded inside the pocket, which has previously been treated with mechanical instrumentation and/or with antimicrobial substances, starting at the bottom of the pocket until it is filled.

Dr. Frigerio, what does H42 do once it has been placed inside the pocket?

This specific hydrogel has a double function. On the one hand, thanks to its specific fluidity and adhesiveness characteristics, it evenly fills the defect, creating a physical seal that prevents the onset of possible bacterial colonization; on the other hand, it acts as the ideal substrate for the tissues' healing, by virtue of its collagen component and of the peculiar characteristics of the other elements that compose it. These two actions promote the optimal healing of the pocket, reducing the size of the defect and the risk of recurrences.

Can H42 be characterized as a product of biological origin?

Certainly. We are dealing with a product whose action is based on the presence of natural elements, such as type I equine collagen, skillfully combined at technological level with resorbable carriers that can boost their properties and facilitate their use, without altering their biocompatibility and non-aggressiveness with regard to the tissues.

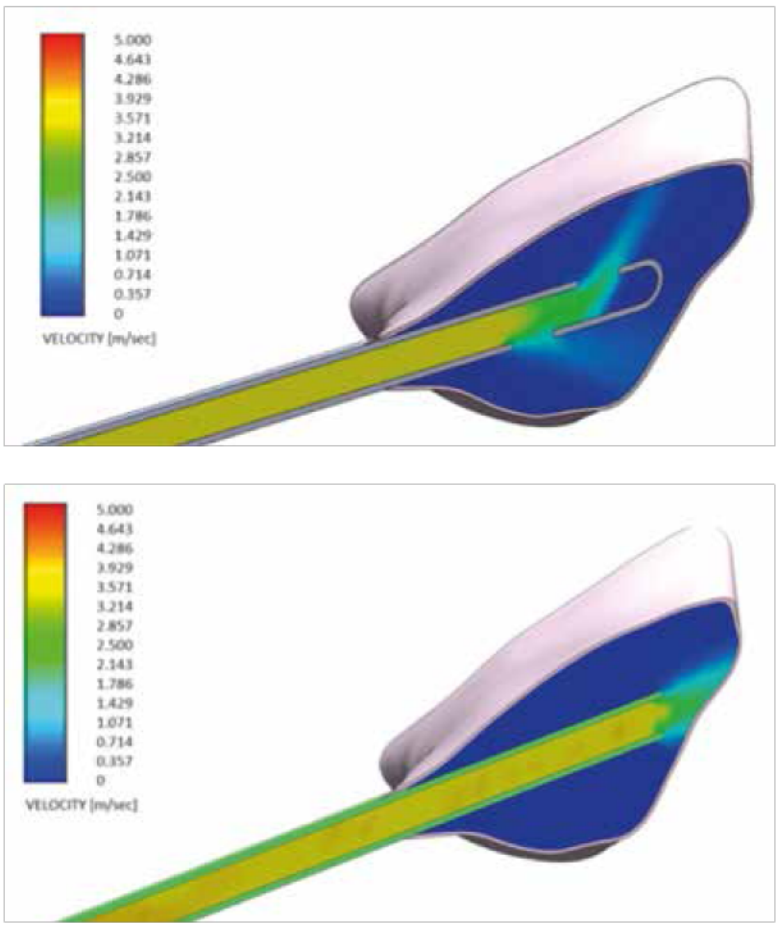
You mentioned technology when speaking of the development of H42; could you give us some more information on this topic?

The technology applied for the creation of H42 was conceived by Bioteck a few years ago, while developing an innovative line of new generation bone pastes with modulated viscosity. This is the Exur-Teck technology, which makes it possible for us to combine the type I collagen we extract and purify from equine tendons with resorbable polymers, such as polyethylene glycol (PEG), and vitamin C. These three elements are mixed together in very specific proportions that allow each one of them to fully carry out its function. Collagen is the structural component of H42 and also forms the base of very many of the bone and tissue grafts produced by Bioteck, precisely because of its chemical/physical and biological characteristics. As a matter of fact, it is the protein that is found in the highest concentration in the connective tissues of mammals (in some cases, it represents over 90% of the tissue's composition), and functions as tissue reinforcement and mechanical support for the adhesion and proliferation of the cells that are responsible for the deposition of new matrix and are, therefore, fundamental for the healing of injured tissues. Thanks to its rheological fluidity and viscosity properties, PEG acts as a vehicle and reinforcement of collagen's scaffolding functions; it also contributes to the adhesiveness of the product to the tissues. Lastly, vitamin C, by acting as a natural anti-oxidant, modulates the formation of the chemical bonds between collagen and PEG during the sterilization of the product with beta rays, making it possible to obtain a rheologically stable product even after sterilization.

As we were saying, collagen is a purely biological component. Is there a risk that, due to its natural origin, its quality may be variable?

This is an excellent observation. Like all components of natural origin, there is an intrinsic variability, due to the peculiar nature of the tissues from which these components are extracted, as well as to the unique qualities of the living beings from which these tissues derive. Bioteck has decided to minimize this variability as much as possible by developing its own technology for the extraction and purification of type I collagen from selected equine tendons. Thanks to the experience it has amassed in over twenty years of processing heterologous tissues of equine origin, Bioteck can boast an extremely controlled, absolutely safe and very high-quality production and supply chain, that allows us to directly and carefully ascertain the characteristics of the tissues we use as raw material. The fact that we then developed our own collagen extraction and purification process allows us to finetune the specifications of this component, and thus standardize the performance of a product that is still of biological origin.

H42® is supplied inside syringes with a male luer lock connection, to make it easier to combine them with the various needle types.



H42 is extruded optimally through several types of needles, as proven by a study published in the international Dentistry Journal (Levrini, L., et al. (2019). "The Capacity of Periodontal Gel to Occupy the Spaces Inside the Periodontal Pockets Using Computational Fluid Dynamic".

Collagen and PEG make H42 a resorbable product; how long does it last inside the pocket?

The full resorption of the product varies from case to case depending on the specific characteristics of the defect (more or less exposed) and on the patient's general metabolism. By means of an in vitro study conducted at an independent test facility we ascertained that H42 has a high resistance to leaching, in line with other gel products applied in similar contexts. Moreover, by virtue of the characteristics of its components, we have seen that it effectively protects the pocket for 15-30 days. This time is sufficient for the tissues to heal well and to reduce the risk of recurrences.

Let us conclude our conversation with some practical considerations. In what quantities is H42 supplied? Does it require specific storage and handling conditions?

H42 will be placed on the market in packs of 3 pre-filled syringes containing 0.4 ml of product each. Each syringe is single-use and single-patient, in the sense that it can be used on more than one defects on the same patient and in the same session. It does not require specific storage conditions; in fact, before use it must be stored at temperatures not exceeding 27°C. In our climate zone, this is standard room temperature. With regard to its handling, the one thing to keep in mind is that the product must be applied in a dry pocket, starting from its bottom, and that it must be kept dry for a few minutes to facilitate its adhesion.

Dental Tribune Editorial Staff

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