SurFACTS in Biomaterials

SUMMER 2022
VOLUME 27, ISSUE 3

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From President Rob Diller

The summer edition of SurFACTS 2022 has arrived. It is my great pleasure to invite you to join me, in Portland, Oregon, for the Surfaces in Biomaterials Foundation annual conference on November 2–4 at the Hilton Portland Downtown. This annual meeting provides an intimate opportunity to meet and network with other professionals while discussing new developments in the biomaterials industry.

Our program begins on Wednesday, Nov. 2, with a workshop on biodegradable polymers. The following days of Biointerface are filled with several technical sessions, including such topics as modulating the immune response to implants and surface modification.

In addition, I am honored to announce two of our award winners. Congratulations to Michael Wolf, the winner of the Excellence in Biomaterials Award and Brenda Padilla, the inaugural winner of the Dr. Lawrence Salvati Jr. Award.

Of course, none of this would be possible without the work of our many dedicated volunteers, the unyielding support from our sponsors, including Elkem, Carmeda, Evonik, Medtronic, and Gore; our various exhibitor organizations, as well as our supporting members. Thank you everyone for your dedication and support.

For the latest details and updates, please visit our website at www.surfaces.org. We look forward to seeing you in Portland!

Synthetic Collagen Offers More Sustainable, Adaptable and Acceptable Option

By Caroline Lauret, Global Director Sales & Strategic Marketing and Maren Jannasch, Project Manager New Products and Materials, at Evonik

Collagen is the most essential protein in the body and contributes 25–35% of the total protein mass in humans. It has a critical function in tissues like skin, bone, and ligaments.

Collagen, an established medical material often used in devices in Regenerative Medicine—where the body can heal itself—provides the structure in Tissue Engineering. It can also be used in drug delivery, as a carrier for the active ingredient, as well as in other applications like dermal fillers, where the collagen fills up wrinkles or in cell culture or as a scaffold to cultured vegan meat.

Why Do We Need Synthetic Collagen?

Nowadays, animal-derived collagen is typically used in those applications. However, this has some drawbacks, like a large batch-to-batch variation and the need for extraction and purification. In addition, there is a high risk of pathogen and disease transmission leading to challenging and time-consuming regulatory approval. Importantly, animal-derived collagen is not accepted by everyone for religious, cultural, or sustainability reasons.

We had a vision to create a collagen that is not animal-derived, and is therefore sustainable, without any batch-to-batch variations. This would lead to an easier and more cost-effective production, and as a bonus, it could bring a faster and more straightforward regulatory approval.

Following this vision, the scientists and chemists at Evonik developed a synthetic collagen called Vecollan(R). This material overcomes the issues of animal-derived collagen, and is a scalable process, so we can supply it in large quantities and there is no risk of disease transmission. Due to the high quality and non-animal origin, the regulatory process is much easier and faster compared to animal-derived collagen. Vecollan(R) also has no religious, cultural, or sustainability hurdles. It is customizable, enabling an even broader application range.

In summary, Vecollan® has the following advantages:

- No batch-to-batch variation.
- Produced in a scalable process, enabling us to provide large quantities.
- 100% animal-origin-free material, and Kosher and Halal certified.
- A high level of biosafety.
- Excellent tolerability for cells.
- Highly water-soluble.
- Highly adjustable platform technology with similar or improved performance to animal derived collagen
- Customizable to produce different forms and shapes, e.g. sponges and hydrogels.

Highly sustainable with a fully secured global supply chainThese properties allow Vecollan® to be used in a broad range of applications, even extending the current applications in which animal-derived collagen can be used. Vecollan® is available as a powder that can be easily processed into other forms like gels, solutions, and bioinks.

What is the Science Behind Synthetic Collagen?

The process starts with the fermentation. The genetic information of collagen is transferred to a microorganism host, and this microorganism is cultured and expanded in a bioreactor system. The process of protein biosynthesis allows the production of collagen, which is controlled by the previously integrated genetic information. Next, the collagen is purified in a downstream process that obtains a high pure material of at least 98 percent.

The triple-helical structure is very specific for collagen. This conformation guides cellular activities and functions which supports biofunctionality and the biosafety of Vecollan®. We have applied circular dichroism spectroscopy to confirm the triple-helical structure of Vecollan(R).

The positive signal at 220 nanometer and a negative signal at 200 nanometer is specific for a triple helix. By this signal pattern, we can confirm a triple-helical structure of the Vecollan® up to 37 °C over wide pH ranges and high concentrations. To test the biosafety of our product, we excluded any cytotoxic effect, by incubating Vecollan® in contact with different cells, fibroblasts, bone cells, and chondrocytes. We also tested a high concentration and low concentration, and after contact incubation, we have a very high viability of the cells (Figure 1).

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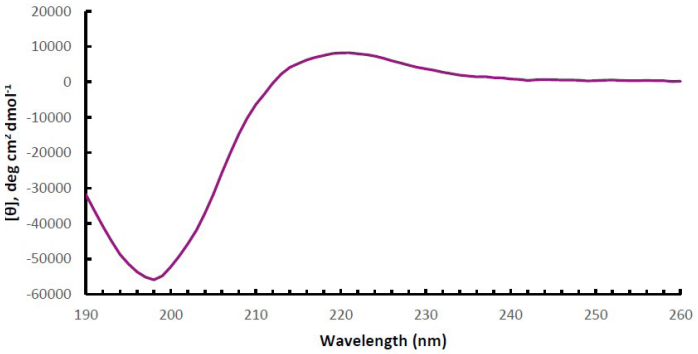

Figure 1: Analysis via circular dichroism spectroscopy
Stable triple helix at up to 37°C, in wide pH ranges and concentrations

One of the major challenges of animal-derived collagen are the inflammatory responses and rejection of the body contact. We've tested our biomaterial in an in vitro cell assay to predict the inflammatory potential of biomaterials. We incubated Vecollan® in contact with THP1 blood cells and measured the cytokine secretion by established ELISAs. Typical markers for such an acute inflammation are interleukins, such as IL-1β, IL-6, and TNF-α. Figure 2 shows the result of tests on two batches of our material, a high and low concentration, and we observed no inflammatory reaction.

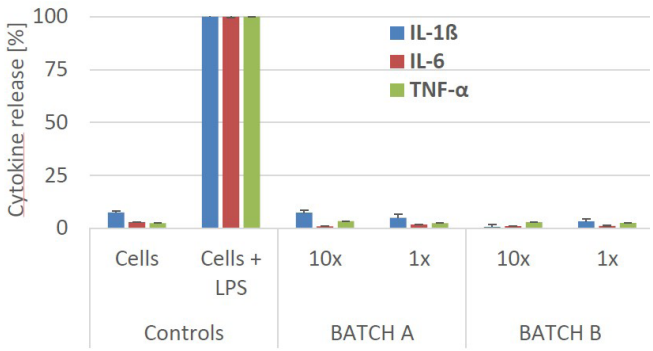

Figure 2: Cytokine assay with THP1 blood cells (macrophages)

For blood-contacting biomaterial, it is of high relevance to show hemocompatible properties. We tested Vecollan® in direct contact to whole blood. The resulting index is lower if blood clotting occurs. We tested a high and low concentration of the product and validated the results to a commercially available hemostatic sponge. Figure 3 shows that Vecollan® is not inducing blood clotting, but the HEMA sponge is inducing it in a concentration-dependent manner. So Vecollan® is applicable for blood-contacting medical devices.

Safety, Product Design Versatility and Processing

Vecollan® has high solubility at neutral pH, a definite benefit in terms of product development. It is also

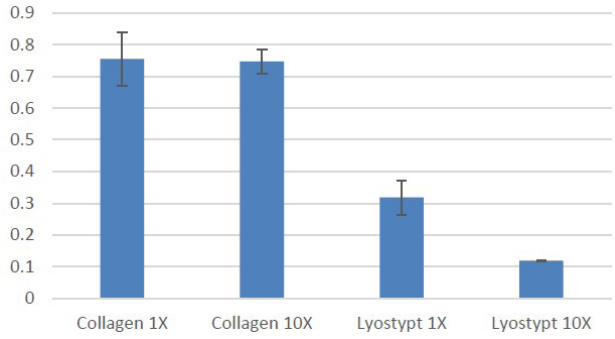

Figure 3: Blood-Clotting Index

soluble and stable at higher concentrations and its solubility in aqueous solution makes it easier to functionalize and crosslink to complex 3D structures.

Vecollan® hydrogels are obtained by crosslinking procedures, and Vecollan® is compatible with many crosslinking procedures. A highlight is that the high purity of our material results in transparent products. For the later integration into a tissue, the biomechanical properties must fit to the target tissue. We have applied contactless and non-destructive vibration analysis to characterize the viscoelastic properties of our hydrogels. The high solubility of our material facilitates many combinations of the Vecollan® to crosslinking ratios.

We have developed a sponge—complex dried, porous 3D scaffolds with improved bio-activity—platform that is suitable for many biomedical applications, such as hemostats, sealing of bleeding, and tissue regeneration in the field of skin, bone, and cartilage. Our sponges show a very good shape stability and integrity, excellent rehydration behavior, a high total porosity, and variable pore sizes. We have also tested cellular integration with fibroblasts, bone cells, and stem cells.

The balance of degradation and new matrix synthesis is important for tissue regeneration. In vivo collagenases are responsible for continuous extracellular matrix turnover. Evonik provides a technology platform with a controllable degradation kinetic.

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3D printing is an emerging technology that can be applied for cell culture substrates in vitro tissue models or more complex constructs such as implants and tissue crafts. Evonik has developed a bioink based on the modification of Vecollan® that allows a light-induced gelation within seconds.

The bioink shows a very low viscosity that reduces the shear stress in the printing nozzle and minimizes any clogging effects. It is compatible with different printer technologies. We have also tested cell integration, so our bioink is suitable and cytocompatible for long-term 3D cell culture. We have implanted the bioink as well in vivo and can confirm non-irritation and its stability after three months.

Synthetic Solution That is Sympathetic to the Medical Industry's Needs

With Vecollan®, Evonik has developed a biotechnological process that is animal and human-free. The result is a highly pure material which has a low risk of pathogenic transmission. It demonstrates very good batch-to-batch reproducibility, and the process is sustainable and scalable.

The Vecollan® product forms a stable triple helix. It's biocompatible and biofunctional and highly soluble at physiological pH. It can be processed in different forms such as gels, sponges, and others. A highlight is the good in vivo performance.

Collagen plays an important role in the body, and with Vecollan® that role is made easier.

Mentorship Program

Surfaces in Biomaterials is hosting a **mentorship program**. The goal is to build a professional relationship between mentor and mentees. Once matched, mentors and mentees can create a timeline to meet virtually. The goal is to meet twice in the first month and then at least once a month for a total of six months. **Please sign up to start your mentorship.**

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BioInterface 2022

We look forward to seeing you in person once again at BioInterface 2022 in Portland, Oregon, Nov. 2–4, 2022.

Find all details at https://www.surfaces.org/BioInterface-2022.

Register now! Early bird registration ends Sept. 30.

BioInterface Program

- Highlights and sessions include:
- Workshop: Biodegradable/Biostable Polymers
- Vascular devices and therapies
- Tissue engineering
- Excellence in Surface Science Award Presentation by Michael Wolf, Distinguished Scientist and Bakken Fellow at Medtronic
- Biosensors in medical devices, role of wearables, technology
- Surface modification
- Chemical and particulate characterization
- Modulating immune response to implants
- Ophthalmic and ocular

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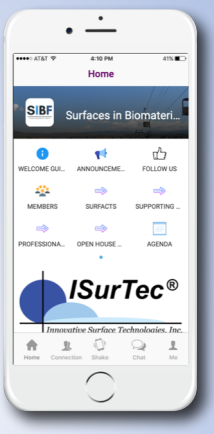

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