# Groundbreaking Discovery Unveils Damaging Effects of Lyophilization on Exosomes, with Major Implications for Regenerative Aesthetics

November 21, 2024 By Cade Hildreth (CEO) — Leave a Comment

**Groundbreaking Discovery Unveils Damaging Effects of Lyophilization on Exosomes, with Major Implications for Regenerative Aesthetics**

Rochester, NY – November 21, 2024 – A groundbreaking study on exosome lyophilization has revealed alarming insights about the process's impact on the integrity and functionality of exosomes, unveiling major implications for the regenerative aesthetics industry. The findings were presented by Dr. Michael Heke, PhD, Managing Director and Scientific Officer at AT Venture Center™ at the 9th International Congress of Medical Excellence in Dermatology & Aesthetic Medicine (MEIDAM) in Dubai. This pivotal research, led by Dr. Carla Mazzeo, PhD, a globally recognized exosome expert with over 20 years of experience, brings to light critical flaws in current exosome preservation methods, particularly lyophilization (freeze-drying), a common technique used for creating shelf-stable exosome products.

**The Study: Assessing Exosome Integrity After Lyophilization**

For the first time, an independent and rigorous analysis has been conducted to determine whether lyophilization damages exosomes to the point of rendering them ineffective. The study, commissioned by The Crowley Center for Regenerative Biotherapeutics™, LLC, aimed to test whether exosomes remained intact and functional after undergoing freeze-drying, a process that many manufacturers use to stabilize exosome-based products for long-term storage and transport.

The results of this multi-step validation study are nothing short of groundbreaking. Dr. Mazzeo is a distinguished exosome scholar and influential scientist, who specializes in the complex nanoscience of exosome biogenesis and characterization. Her work has appeared in over thirty peer-reviewed exosome publications. Dr. Mazzeo served as the principal investigator for this exosome characterization study, which included two critical technologies for analyzing exosome, NanoSight NS300 and Transmission Electron Microscope (TEM). The Transmission Electron Microscope (TEM) blinded comparison study was conducted at Harvard Medical School Electron Microscopy Core Facility by Maria Ericsson, Director of the HMS Electron Microscopy Core. The NanoSight NS300 data was collected at Boston University. The blinded study compared three widely used topical exosome products—two lyophilized and one saline-preserved—from leading manufacturers across the globe.

The findings were unequivocal: lyophilization caused severe damage to the exosomes, rendering them non-functional. TEM analysis revealed that the lyophilized products contained no intact exosomes. Instead, the samples were primarily composed of protein remnants, with no discernible exosome morphology. In stark contrast, the saline-preserved exosomes, derived from Wharton's Jelly mesenchymal stromal/stem cells (WJ-MSCs) and produced by Resiliélle Cosmetics LLC, maintained their characteristic exosome structure, with an intact lipid bilayer, assuring the exosomes' functionality in delivering their cargo, thus confirming their bioactive properties. *Researchers and professionals seeking to access the formal publication detailing the comparative analysis which includes the full NanoSight NS300 and Transmission Electron Microscopy (TEM) data are encouraged to submit requests to info@atventurecenter.com*.

**Unveiling the Mechanism: How Lyophilization Damages Exosomes**

The core issue identified in the study lies in the impact of lyophilization on the exosome's lipid bilayer, a crucial component for preserving the vesicle's integrity and functionality. During the freeze-drying process, the exosome membrane is destabilized, causing irreversible damage. The result is a loss of cargo integrity—the delivery of functional proteins, RNAs, and lipids—that are essential for the exosomes' intercellular communication properties and ensuing regenerative effects.

As exosomes are crucial mediators of cell-to-cell communication, the damage caused by lyophilization undermines their therapeutic potential. Exosomes rely on their intact membrane structure to deliver molecular signals to target cells. When compromised, as evidenced in this study, the exosomes lose their ability to communicate effectively with recipient cells, thus diminishing their therapeutic benefits in regenerative aesthetics, skin rejuvenation, and other clinical applications.

**Implications for the Exosome Industry**

The results of this study have significant ramifications for the exosome industry, particularly in regenerative aesthetics and cosmetics. With exosome-based therapies becoming increasingly popular for a range of applications—ranging from skin rejuvenation to scalp analysis and hair restoration to the improvement of the appearance of scars—the discovery that lyophilization causes irreparable damage to exosomes calls into question the reliability of many commercially available exosome products.

Currently, there is no standardized regulatory framework or accreditation body to verify the quality and functionality of exosome-based products in the market. This lack of oversight leaves consumers and healthcare providers at risk of using ineffective products. The study highlights the urgent need for rigorous testing and validation methods to ensure that exosome products are both functional and therapeutically viable.

Dr. Heke emphasized that this discovery underscores the importance of transparency and scientific rigor in the exosome industry. "With exosome therapies poised to revolutionize regenerative aesthetics, it is essential that we maintain the highest standards of quality and validation. This study reveals that manufacturers must move beyond superficial claims and invest in comprehensive testing to confirm the integrity and functionality of their products," he stated.

**The Role of Resiliélle Exosome Cosmetics**

At the forefront of this movement is Resiliélle Cosmetics™ LLC, a division of The Crowley Center for Regenerative Biotheraputics™. Resiliélle's Age Zero™ exosome products, derived from low passage, Wharton's Jelly mesenchymal stromal/stem cells and preserved in saline, have been shown to retain their structural integrity and bioactivity, offering a promising alternative to lyophilized exosome products. The company's commitment to cutting-edge research and high-quality manufacturing practices ensures that their exosome-based products remain among the most effective and reliable in the market.

This study's findings also reinforce the advantages of using non-lyophilized exosomes, which maintain their full therapeutic potential. With the growing interest in exosome-based treatments for conditions such as chronic inflammation, aging skin, and tissue regeneration, the validation of saline-preserved exosomes could represent a critical breakthrough for the future of the industry.

**Conclusion**

The pioneering study led by Dr. Mazzeo and supported by The Crowley Center for Regenerative Biotheraputics ™ offers unprecedented clarity on the damaging effects of lyophilization on exosomes. By demonstrating that freeze-drying irreversibly compromises exosome functionality, this research not only challenges industry practices but also sets a new standard for quality assurance in the rapidly expanding field of exosome-based therapies.

As exosome-based treatments continue to show promise across multiple therapeutic areas, this discovery emphasizes the need for ongoing innovation, rigorous testing, and accountability in the industry. The Crowley Center for Regenerative Biotheraputics ™ remains committed to advancing regenerative aesthetics by ensuring that exosome products retain their full therapeutic potential, setting a new benchmark for excellence in this cutting-edge field.

---

**About The Crowley Center for Regenerative Biotherapeutics™, LLC** is a leading U.S.-based venture firm focused on advancing regenerative biotherapeutics and cosmetics technologies derived from ethically sourced Wharton's Jelly. Through its commitment to scientific innovation and commercialization, the company strives to improve human and animal health by developing advanced therapies in regenerative medicine, cellular therapy, and topical exosome-based treatments.

For more information, visit www.atventurecenter.com or email info@atventurecenter.com