Biodegradable Coating to Improve Administration of Endoscopic Negative Pressure Therapy

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Anastomotic leaks occur in up to 40% of esophagectomies, arising from gaps in the staple line where the esophagus is surgically rejoined. These leaks can cause severe complications, including infection and extended hospitalization. Endoscopic Negative Pressure Vacuum (EndoVAC) therapy promotes healing by placing a sponge at the defect site to remove secretions and stimulate tissue growth. However, current endoscopic deployment methods are labor-intensive, non-standardized, and require advanced endoscopic skill. Clinicians need an easier, more reliable method to deploy the sponge into the defect site within 15 minutes.

Existing devices, such as Boston Scientific's Eso-SPONGE and Endo-SPONGE, rely on large, rigid overtubes that are difficult to manipulate into the cavity, especially in cases where the leak site is an irregular shape. As a result, many surgeons resort to manually trimming sponges and suturing them to nasogastric tubes, which introduces variability and increases procedure time. These approaches fail to provide a standardized, efficient deployment method, emphasizing the need for an improved solution.

To achieve a streamlined delivery method, a degradable coating approach was developed to create a compact device for insertion. The film maintains compression of the sponge during insertion, while allowing smooth navigation to the defect site. Once placed at the leak site, the coating degrades, enabling the sponge to expand to its original size after which suction will be applied via a nasogastric tube.

Gelatin and sodium alginate were fabricated as their material properties offered desirable degradation profiles. To determine the most effective gelatin formulation, various ratios and drying methods were tested. The most effective samples were produced by leaving the gelatin solution covered to form a hydrogel and leaving it uncovered to yield a film. For sodium alginate, variations in crosslinking and drying methods were tested, and the most viable samples were crosslinked by pouring $CaCl_2$ to make a gel or dried uncovered in an oven to produce a film. PETG molds were used to compress 3.0 cm sponges and encapsulate them in the thin biodegradable films, successfully reducing the diameter to 1.5cm.

Gelatin and sodium alginate were evaluated based on degradation rate and sponge expansion in a PBS solution at pH 7.4 and 37°C to simulate physiological conditions. The gelatin film and hydrogel was tested to assess how moisture retention affects degradation. Alginate that was crosslinked with calcium chloride ($CaCl_2$) was tested because it has enhanced mechanical properties. The gelatin hydrogel degraded within 30 seconds, while film held its mechanical properties until 60 minutes, surpassing the 15-minute deployment window. Sodium alginate's mechanical properties declined quickly around 20 minutes, aligning closely with the target threshold for sponge release at the defect site. While both materials meet the minimum requirement, sodium alginate is the stronger candidate because it can be used without the ethical concerns associated with animal-derived gelatin..

By simplifying deployment with a degradable coating, this design reduces procedural complexity and improves standardization, ultimately broadening clinical access to EndoVAC therapy. For patients, faster and more consistent treatment may reduce complications and improve healing. Further development on the fabrication of the sodium alginate coating provides an accessible solution that addresses both clinical and procedural limitations of EndoVAC therapy.