EarVac: Negative Pressure Wound Therapy Device for Improved Microtia Surgery Recovery

Bryan Heaton Meghan Kaminski, Serena Evers, Harshad Gunasekar, Dhruv Nadkarni
Advisor: Dr. Russ Johnson
Client: Dr. Daniel Cho and Nada Botros

Microtia is a congenital condition in which children are afflicted (usually unilaterally) with a malformed or absent ear. The condition impacts between 1/6000 and 1/8000 children, and although microtia is not dangerous to the life of the patient, it can harm aesthetics and confidence, especially for children at a pre-school age. The most common treatment for this condition is reconstruction surgery, in which autologous rib cartilage is harvested and shaped into a new auricle. This new auricle is inserted underneath the skin flap of the affected ear to create a natural-looking external ear. Complications following the procedure occur at a significant ~16% rate, and include hematoma, skin necrosis, cartilage resorption, and scarring. These complications have been tied to the recovery procedures implemented post-surgery. Medical providers currently use a large gauze wrap to apply pressure to the newly-formed auricle, protecting it and keeping it in place. The pressure applied by the wrap is difficult to standardize and the bulky nature of the wrap makes it difficult to wear. A manually operated subdermal wound drain is also inserted post-surgery. These drains must be monitored continuously to maintain constant pressure; failure to do so can result in exudate backflow and infection.

EarVac addresses these shortcomings through a two-component system that combines a custom-layered foam dressing with an integrated negative pressure wound therapy (NPWT) drainage mechanism. The dressing is designed to conform precisely to the reconstructed ear, applying standardized, consistent pressure across the auricle. Simultaneously, a separate vacuum line removes subdermal exudate through a sealed drainage circuit, eliminating the variability associated with gauze wrapping and manual drains. Both the dressing seal and drainage system operate at a lower, controlled negative pressure of approximately −50 mmHg, which is sufficient to maintain seal integrity and continuous fluid removal while minimizing stress on delicate post-surgical tissue, differing from traditional NPWT systems that typically operate at higher pressures (−75 to −125 mmHg). EarVac adapts NPWT to the complex geometry of the ear, and device validation included continuous functionality testing under varying pressure conditions to ensure that the seal remained intact and did not fail around the contours of the auricle; no structural damage or seal failure was observed, demonstrating the system's mechanical reliability across its operating range, with this ability to maintain a stable seal on a highly irregular anatomical surface representing a novel design feature and a potential basis for intellectual property. The device is designed in two stages: (1) an in-clinic phase immediately following surgery, during which drainage output and pressure are monitored by medical staff for the first 24–48 hours, and (2) a take-home phase in which a simplified, patient-operable unit maintains therapeutic pressure throughout the week-long recovery period, with this extended at-home use directly targeting the critical window during which most post-surgical complications—such as hematoma, necrosis, and cartilage displacement—are known to develop, providing continuous protection where current standard of care lacks consistency.

No product exists in the market that would challenge EarVac’s specific focus on post-surgical treatment. Sources estimate the number of microtia reconstruction surgeries can reach up to 100,000 globally. Due to wide variation in microtia reconstruction techniques across surgeons and geographic locations, the total cost of reconstruction—including consultation, imaging if required, operative time, and postoperative care—ranges from $15,000 to $40,000. Though no specific market valuation of ear-oriented NPWT exists, the NPWT market hit $2.37 billion dollars in 2021, and is expected to reach $3.92 billion dollars by 2030 according to Strategic Market Research. Hence, with the high quantity of surgeries, novel design aspects allowing patentability, and room to largely scale and optimize manufacturing of the product, EarVac exists within an untapped market.