402-Excellence-7- Coring_Device-Executive Summary
Radiologic Pathologic Correlation in Renal Cell Carcinoma
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Renal cancer poses a significant health challenge, with the American Cancer Society projecting approximately 81,000 new cases in the United States for 2024 (Siegel et al., 2024). Computed Tomography Texture Analysis (CTTA) emerges as a promising technology for early detection, particularly in diagnosing complex and histologically diverse renal cell carcinomas (RCCs). CTTA aims to correlate CT image patterns with tumor histology by scrutinizing tumor characteristics like pixel distribution and location. However, for the integration of CTTA into RCC diagnosis, it's imperative to validate the correlation between CT images and tumor patterns. This underscores the necessity for a device capable of resecting tissue samples from RCC tumors for advancing research into the correlation between tumor characteristics observed in CT images and their histological patterns.

Building upon previous work, the team developed a single-use 3D printed coring tube with an autoclavable 316 stainless steel blade, that is attached in a press-to-fit manner. Through comprehensive design matrices, the team selected both a final “Lego” tube design and “Punch Biopsy” blade design that together would minimize tissue trauma, ensure user comfort, and allow for accurate imaging of the resection.

The coring tube is 3D printed using FormLabs BioMed Clear Medical Resin on a Form2 SLA printer. The single-use device measures 10 cm in length, has an 8.5 mm inner diameter and bisecting slits that are spaced 5 mm apart, facilitating the extraction of precise tissue slices. To enhance the print's durability, the tube is printed at a 30-degree angle with a full raft and supports. Instead of UV curing, which can cause bowing and distortion, the tube is left in direct sunlight for 1-2 hours post-washing to harden. It is designed in two halves—male and female—that snap together using the resin's tolerances, making it easy to open and access the sample. The sample is then ejected using a plunger, which has a diameter of 8.45 mm to preserve the sample's integrity during removal. The plunger is also a single-use component, printed in PLA on Bambu printers.

The design also features a 316 stainless steel blade.This rigid material was chosen as it is an austenitic stainless steel with high levels of chromium and nickel to provide high corrosion resistance (AGST, 2024). Initially, a handcrafted blade was made from 10 mm inner diameter tubing with a 15-degree taper. However, to improve reproducibility, a pre-fabricated blade from Microsurgical Technologies was chosen to replace the hand-made blade. The team qualified the new blade as a sufficient replacement on the basis of 3 criteria: material properties, dimensions, and reproducibility where the Microsurgical Technologies blade was comparable in yield strength, wall thickness, and is easily reproduced.

The final design underwent rigorous validation through testing to measure device durability, tissue trauma, and overall ergonomic suitability. In each test, the prototype surpassed expectations. It demonstrated exceptional durability, with a thickness decrease of 0.03mm over 40 cuts. Additionally, no visible tissue trauma was observed at the incision site. Furthermore, an ergonomic survey was conducted (n=3) utilizing a Likert scale of 1-5, where 1 indicated “strongly disagree" and 5 was “strongly agree” in regards to the ergonomic soundness of the device. The prototype scored an average of 4.333 +/- .849, indicating its ergonomic suitability for users.

Upon analysis of the test results, the device met the design criteria and operational requirements. The team's efficient design is projected to perform up to 20 resections per year and last up to two years. Through an iterative design process and meticulous testing, we aimed to contribute significantly to the advancement of radiologic-pathologic correlation in renal oncology.