

Ex Vivo Evaluation of Oral Cavity Squamous Cell Carcinoma and Tumor Margins Using Safe Margins, a Raman Spectroscopy Device for Mapping Tumor Margins during Cancer Resection

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Background

The surgical treatment of resectable head and neck cancers is dependent on the absence of residual tumor at the resection margins. Having positive margins increases the local recurrence rate by 90%, and an estimated 30% of open resections of oral cavity cancer has positive margins ^{1,2}. The current standard for margin assessment is frozen section analysis of intraoperative biopsies; it is time consuming (20-40 min per biopsy) and is limited to discrete points selected by the surgeon based mainly on visual inspection. Safe Margins is a portable Raman spectroscopy device developed to address the limitations of frozen section analysis by determining tumor free margins effectively in real time.

Purpose

To use Safe Margins to distinguish cancerous from non-cancerous margins of ex vivo oral cavity squamous cell carcinoma resection specimens.

Methods

- Used Safe Margins prototype (Image 1) to record Raman spectroscopy readings from 10 oral cavity squamous cell carcinoma resection specimens.
- Analyzed and interpreted the Raman spectral data compared to the histologic margin outcomes provided by the pathology lab.
- Created labeled spectra datasets of carcinoma and non-carcinoma samples.
- Used the datasets to train, validate, and test our artificial intelligence, designed to output a binary response of cancer or non-cancer.

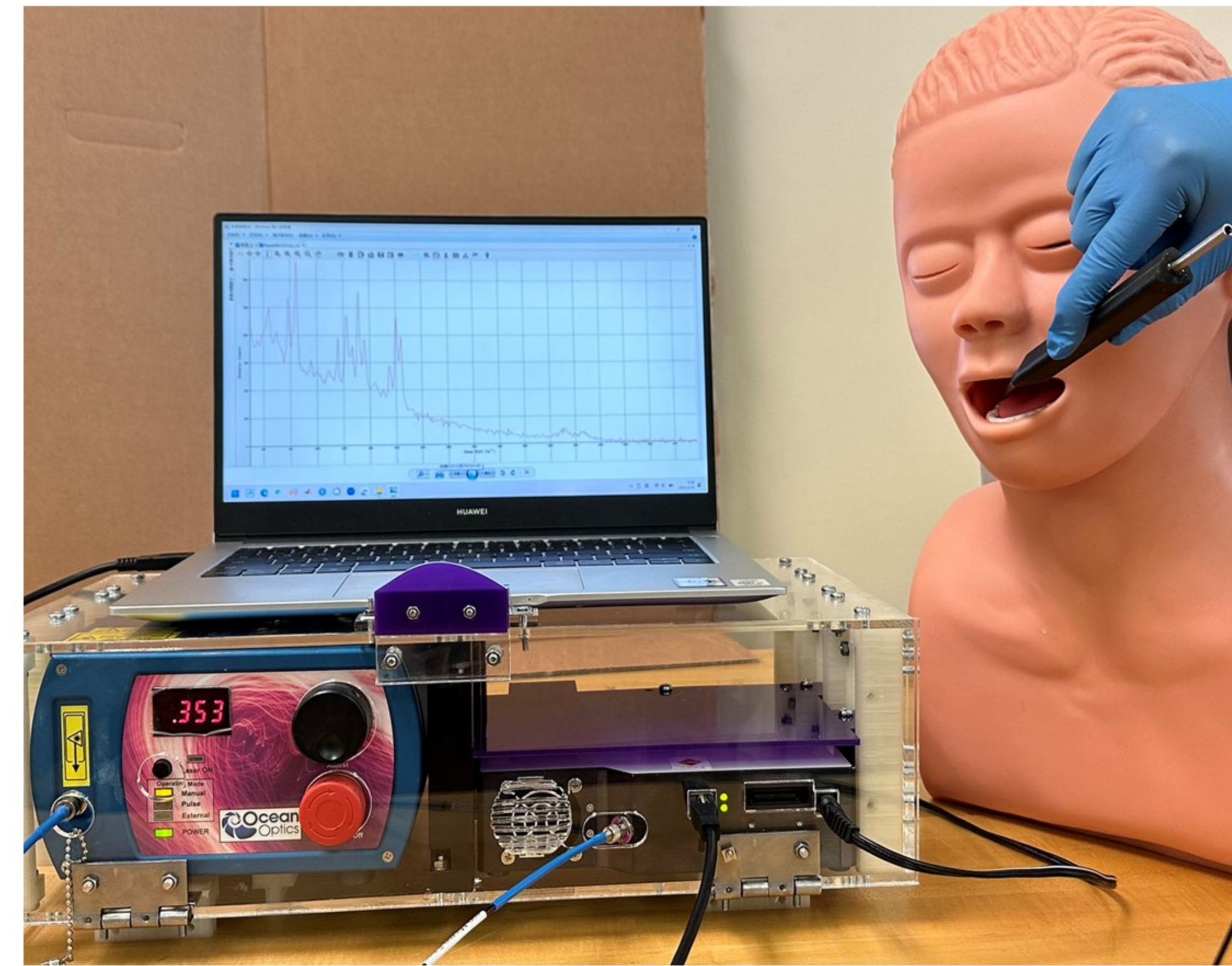


Image 1: Safe Margins Prototype including a 785 nm near-infrared laser illumination source, Raman spectrometer, and handheld delivery probe.

Results

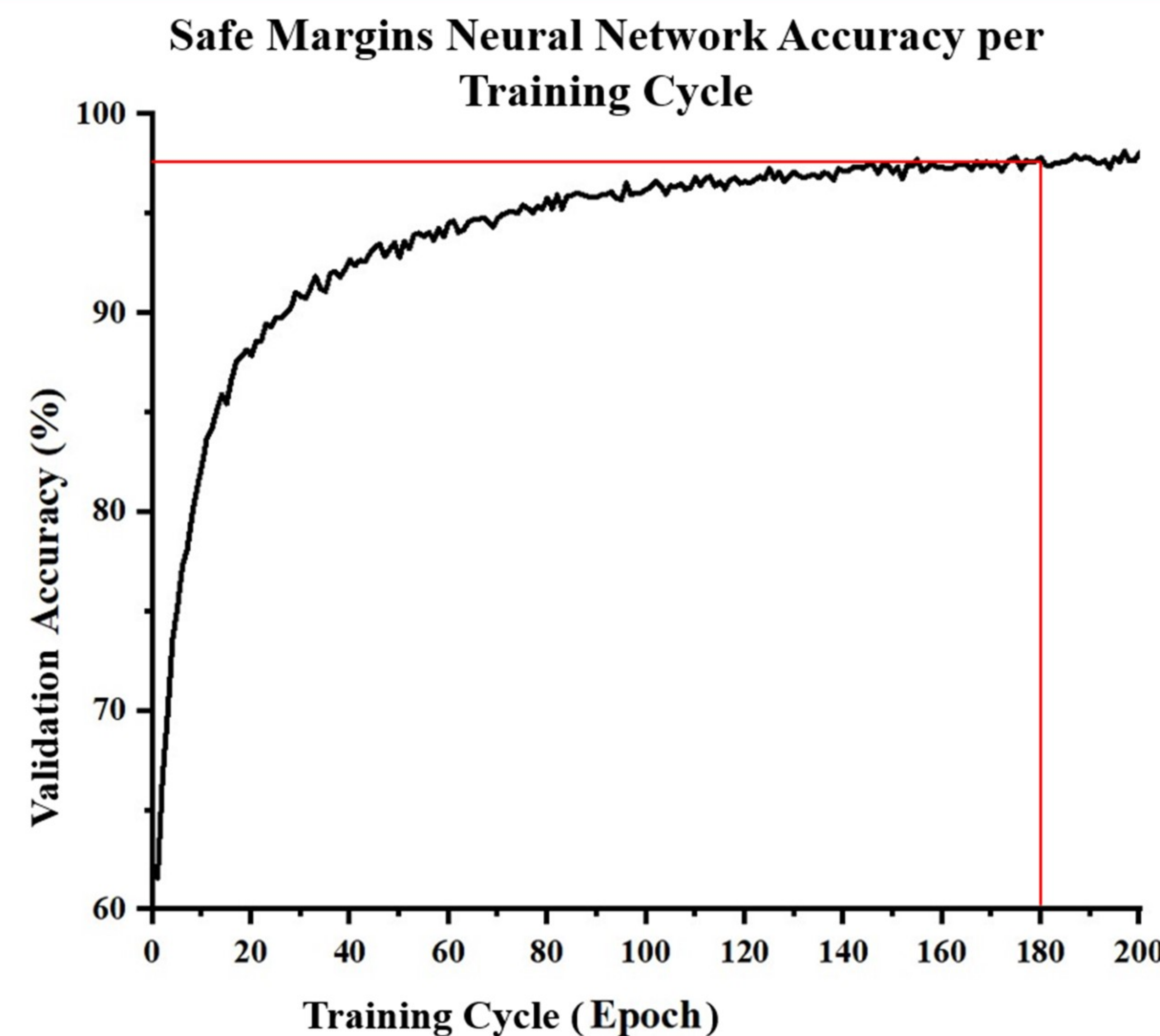


Figure 1: Graph of the Safe Margins' Neural Network's Validation Accuracy per Training Cycle (Epoch).

Results Continued

- Safe Margins' artificial intelligence (AI) training resulted in a validation accuracy of greater than 95% after 180 training cycles (Figure 1).
- After validation, Safe Margins' AI was able to achieve a test accuracy of 94.96%, sensitivity of 96.25%, and specificity of 93.76%.

Conclusions

- Successfully demonstrated the experimental use of Safe Margins in distinguishing between cancerous and non-cancerous margins in ex vivo oral cavity squamous cell carcinoma specimen when compared to the pathology.
- We plan to continue sampling oral cavity carcinoma specimens to continue training Safe Margins' artificial intelligence and increase its test accuracy.
- Future projects will include further refinement of the Safe Margins system for real-time intraoperative tissue evaluation and continued expansion of tissue analysis to include other primary cancer sites beyond the head and neck.

References

1. Li MM, Puram SV, Silverman DA, Old MO, Rocco JW, Kang SY. Margin Analysis in Head and Neck Cancer: State of the Art and Future Directions. *Ann Surg Oncol*. 2019 Nov;26(12):4070-4080. doi: 10.1245/s10434-019-07645-9. Epub 2019 Aug 5. PMID: 31385128; PMCID: PMC7382965.
4. Li MM, Puram SV, Silverman DA, Old MO, Rocco JW, Kang SY. Margin Analysis in Head and Neck Cancer: State of the Art and Future Directions. *Ann Surg Oncol*. 2019 Nov;26(12):4070-4080.