A Rapid Method for Detecting Non-Melanoma Skin Cancer in Mohs Micrographic Surgery

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INTRODUCTION

❖ This intended use of this device is to reduce Mohs Micrographic Surgery tissue evaluation and assessment time.

❖ The device detects and locates cancer in an excised Stage or Section prior to creating a frozen section.

DEVICE

❖ A small 160 mm wide, 33 mm high, 210 mm long portable device collects specimen impedance data from 1 kHz to 4 MHz.

❖ Non-linear regression is utilized to find best fit to specimen data.

❖ The analysis applies the best fit parameter, F_{Cole}, to determine probability of cancer presence.

❖ The device optically transmits the real and imaginary tissue impedance data to a laptop computer for display to include the analysis result to user.

❖ F_{Cole} (the fit relaxation frequency) provides prognostic value that can indicate a thousand fold difference between malignant and non-malignant tissue.
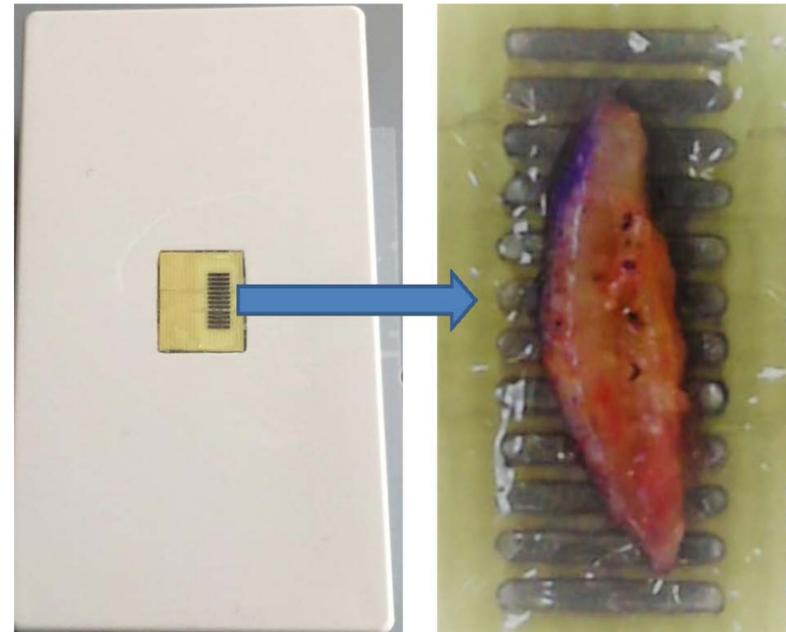

Figure 1: (left) overhead view of device; (right) sample placement

Figure 2: Scan results- (top) Positive (CA), (bottom)Negative (BN).

COMBINED BCC + SCC RESULTS

N = 206	PATHOLOGY: NEG	PATHOLOGY: POS	
DEVICE: NEG	124	2	126
DEVICE: POS	2	78	80
	126	80	

ACCURACY =	98.00 %
MISCLASSIFICATION RATE =	1.94 %
SENSITIVITY / TPR =	97.50 %
FALSE POSITIVE RATE =	1.59 %
SPECIFICITY =	98.41 %

SCC RESULTS

N = 29	PATHOLOGY: NEG	PATHOLOGY: POS	
DEVICE: NEG	22	0	22
DEVICE: POS	0	7	7
	22	7	

ACCURACY =	100.00 %
MISCLASSIFICATION RATE =	0.00 %
SENSITIVITY / TPR =	100.00 %
FALSE POSITIVE RATE =	0.00 %
SPECIFICITY =	100.00 %

BCC RESULTS

N = 177	PATHOLOGY: NEG	PATHOLOGY: POS	
DEVICE: NEG	102	2	104
DEVICE: POS	2	71	73
	104	73	

ACCURACY =	98.00 %
MISCLASSIFICATION RATE =	2.26 %
SENSITIVITY / TPR =	97.30 %
FALSE POSITIVE RATE =	1.92 %
SPECIFICITY =	98.08 %

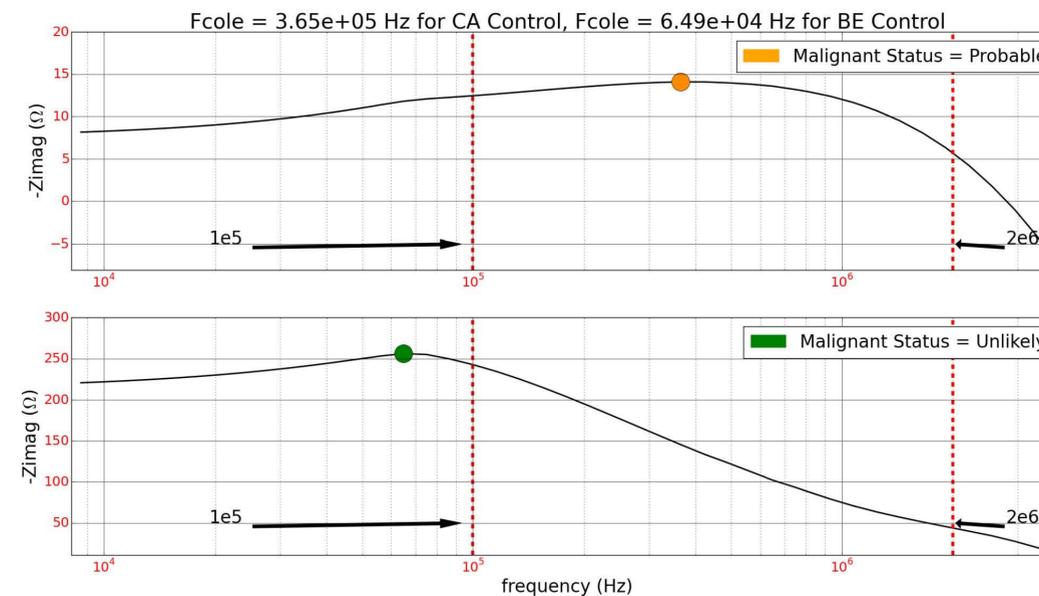Figure 3: BCC and SCC statistics; (top) combined, (bottom) separate.

METHODOLOGY

❖ Surgeon excises suspicious lesion as Stage 1.

❖ Specimen is relaxed and sectioned.

❖ Sections or Stage are scanned for the presence and location of areas where cancer-free margin does not exist by device displaying tissue impedance and analysis on laptop requiring < 1 minute.

❖ Specimen is returned for further processing and histology.

❖ A comparison of device and histology findings provide Standard of Care confirmation.

SUMMARY

❖ Figure 1 depicts the 12 electrode sensor array that allows F_{Cole} mapping of the tissue (i.e., F_{Cole} per position on sample).

❖ Figure 2 shows user output of valid data acquisition.

❖ Figure 3 shows the statistical comparison to histology.

❖ Figure 3 shows statistics for 206 basal and squamous cell carcinomas indicating excellent sensitivity and specificity.

❖ Device does not detract from Standard of Care, provides accurate results, and doesn't require specialized training.

BIBLIOGRAPHY

• W. D. Gregory, J. J. Marx, C. W. Gregory, W. M. Mikkelson, J. A. Tjoe, and J. Shell, The Cole relaxation frequency as a parameter to identify cancer in breast tissue, **Med Phys 39(7)**, 4167-4174 (2012).

DISCLOSURE:

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