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Introduction

- More than 5.4 million cases of NMSC were treated in over 3.3 million people in the US in 2012*.
- The accuracy of skin cancer screening prior to biopsy is ~70% (including GPs), individual-dependent.
- There have been several in vivo skin cancer screening devices based on non-invasive techniques (*e.g, multi-spectral imaging, Raman spectroscopy and electrical impedance spectroscopy (EIS)*), but their diagnostic accuracies were not sufficient for clinical use.
- We developed a novel skin cancer diagnostic device based on laser spectroscopy and machine learning algorithms with superior diagnostic accuracy using aesthetic lasers.

Methods

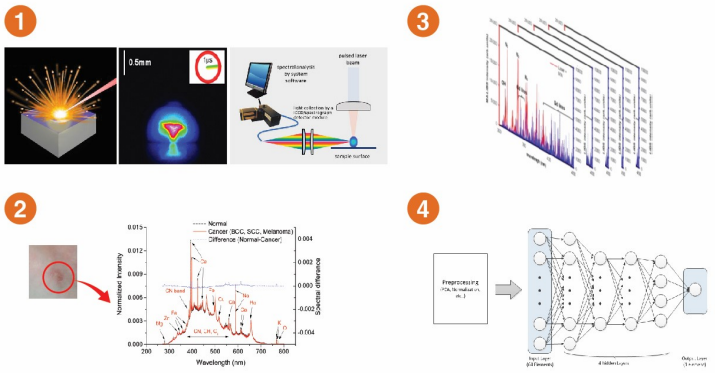
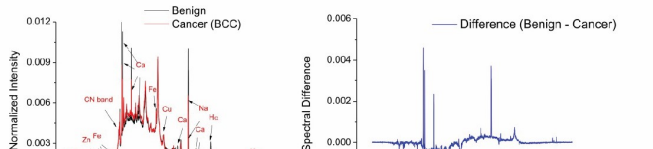


Fig 1. The process of acquisition of tissue emission spectra and the spectral analysis using a deep neural network

- 1) The light is collected from the micro-plasma induced onto the skin by a Q-switched Nd:YAG laser.
- 2) Chemical information including ionic, atomic and molecular composition of the irradiated skin lesion is extracted from the emission spectra.
- 3) Raw emission spectra is processed through intensity normalization and principal component analysis to extract the effective wavelength features.
- 4) A DNN (deep neural network) is trained with the spectral data set labelled with biopsy results to construct the classification model. The algorithm determines the probability of malignancy of suspicious tissue irradiated by a laser shot.

Fig 2. The skin cancer screening device and its GUI

Result



- Multi-site studies at ***Newcastle Skin Check***, Charlestown, ***Eastern Suburbs Dermatology***, Bondi Junction and ***The Skin Cancer and Cosmetic Clinic***, Neutral Bay, all in NSW, Australia were designed to evaluate the effectiveness and safety of the device.
- Total **364 patients** were recruited in three different sites. Total of **2088 emission spectra** from **348 skin cancers** confirmed with biopsy results and total **5166 emission spectra** from **861 benign lesions** were collected.

Clinical Sites	Skin Cancers	Benign lesions
Newcastle Skin Check	91 skin cancers (546 spectra)	252 lesions (1512 spectra)
Eastern Suburbs Dermatology	176 skin cancers (1056 spectra)	328 lesions (1968 spectra)
Skin Cancer & Cosmetic Clinic	81 skin cancers (486 spectra)	281 lesions (1686 spectra)
Total	348 skin cancers (2088 spectra)	861 lesions (5166 spectra)

- The deep learning algorithm was applied based on the 10 cross-validation to assess the diagnostic accuracy.
- Sensitivity of 95.4% and specificity of 84.7% were achieved for the detection of skin malignancy out of total 7254 spectral data sets measured from the tissue.

Confusion matrix		Predicted by device	
		Malignant	Benign
Actual	Malignant	1992	96
	Benign	790	4376

Table 1. Confusion matrix for tissue classification using the device based on the cross validation of the DNN algorithm

- As for the second site, A diagnostic algorithm was constructed from a deep neural network (DNN) **trained with 6654 emission spectra** of cancerous and benign lesions in previous studies.
- The numerical results from the device were recorded and compared with the biopsy results to assess the device's diagnostic accuracy **in a blind test setting.**
- We achieved **sensitivity of 97.6%** and **specificity of 86.2%** out of 41 skin cancers and 58 benign lesions.

Confusion matrix		Predicted by device	
		Malignant	Benign
Actual	Malignant	41	1
	Benign	8	50

Table 2. Confusion matrix for tissue classification using the device based on the blind test of the DNN algorithm

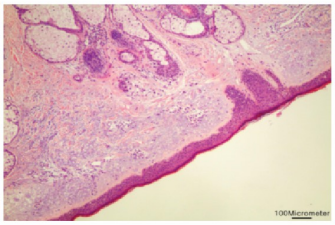


Fig 3. H&E stained image of tissue with laser irradiation for skin analysis using the device

- Any microscopic damage, visible mark, pigmentation or scar due to laser irradiation for the use of the device has not been observed on the tissue.
- Any adverse events have not been reported up to date (in US and Australia).

Summary & Conclusions

- Pathologic diagnosis-based cancer detection is considered to be time- and labor-consuming, individual-dependent sometimes.