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A real time optoelectronic device as an adjunct to the Pap smear for cervical screening: A multicenter evaluation

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Abstract. We report on the results from a multicenter trial for a real time optoelectronic device as an adjunct to the Pap smear for cervical screening. TruScreen (Polartechnics Limited, Sydney, Australia) is an automated device which measures the response to optical and electrical stimulation of the cervix and returns a screening result in real time. Analysis was performed on a group of 651 subjects recruited at 10 centers. Cytology and histology analyses were performed by centralized laboratories, with the cytology classification performed according to the Bethesda 2001 system. The sensitivities for histologically confirmed CIN 2/3 lesions by TruScreen, Pap, and TruScreen/Pap combined were 70% (95% CI: 67—74), 69% (CI: 65—72), and 93% (CI: 91—95), respectively. For histologically reported CIN 1, the sensitivities of the TruScreen, Pap, and combined test were 67% (CI: 63—70), 45% (CI: 41—49), and 87% (CI: 84—89). The improvement in sensitivity for the combined test compared to the Pap smear alone was significant ($P=0.002$). Because TruScreen and cytology detect partly different but overlapping groups of CIN cases, the adjunctive combination provides very high CIN detection rates.

Australian J Gen Pract 2005; 5: 13–4

TruScreen – the Australian experience.

Itzkowic D, Cromer D.

Itzkowic and Cromer presented the results of a practice study in 456 women who underwent both a TruScreen examination and a Pap test.

Abnormal results on TruScreen examination were reported for 88 women and, of these, 47 had abnormal results on colposcopy. Cervical dysplasia lesions were detected in 13 women. Of these, seven were identified by TruScreen but not by Pap test, while two were identified by Pap test but not by TruScreen. Two were missed by both methods. Overall, Pap test identified only four patients with cervical dysplasia lesions (31%), compared to 11 (85%) identified by TruScreen examination.

Dr Itzkowic reported that the increased accuracy of using these tests together was reassuring to patients, and the immediate results provided by TruScreen was an additional advantage, enabling colposcopy to be performed at the same visit if needed.

Ginecorama 2004; 26: 23–4

TruScreen: a new ally in cervical cancer screening.

Zanardi C, Camerini T, Bucolo C.

Zanardi et al. reported the results of TruScreen testing in 525 women from three Italian centres. In 437 women (83%), TruScreen confirmed the Pap test result. Of these, colposcopy results were normal in 96% and indicated minor changes in the remainder. In 88 women (17%), TruScreen revealed an abnormality where Pap test results were normal. Colposcopy revealed 24 (27%) of these abnormalities to be major changes. TruScreen examination returned a 'normal' diagnosis in 25 (67%) of 37 women who had atypical squamous cells of unspecified significance (ASCUS) or unsatisfactory cytology results. Of these normal results, 19 (76%) were later confirmed by colposcopy, while colposcopy results were abnormal in the remaining six cases, three of which were histologically confirmed. Thus, on the whole, TruScreen returned accurate results for 30 (81%) of the 37 women with ASCUS or unsatisfactory cytology results. The authors concluded that TruScreen has the potential to detect lesions that might be missed by cytology alone and can clarify unsatisfactory cytology results. Participating women were happy with the immediate availability of testing results with TruScreen.

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New Technology in Diagnosis

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Abstract. New technologies for cervical screening and diagnosis aim to improve the accuracy of the diagnosis and/or to streamline the clinical management process. These technologies include liquid-based cytology (LBC), HPV DNA testing, molecular progression markers, and real-time electronic devices. The advantages and disadvantages of each of these new approaches are reviewed, and the current evidence for the performance of each technology as a triage to colposcopy, adjunctive test to the Pap smear, and/or as a direct screening test is examined. Initial clinical results for a new optoelectronic device, the TruScan, are presented. The use of TruScan in combination with the Pap smear provides very high detection rates for high grade lesions and for all CIN.

CME Journal of Gynecologic Oncology 2000; 31-38

The Polarprobe – an instantaneous optoelectronic approach to cervical screening

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Abstract. A new system for cervical screening is described – the Polarprobe. This is a portable instrument which uses low level electrical and optical stimuli on cervical tissue, delivered as the instrument is passed over the cervix. In order to discriminate between normal and pre-cancerous or cancerous tissue, an expert system approach is used. A computer based console is used to match the tissue signals with those stored in a database of previously classified tissue types. At the end of the examination, the operator is informed if either low or high grade pre-cancerous tissue or cancerous tissue has been located on the cervix. The instantaneous screening result allows patient management to be determined at the time of the screening examination. Some initial clinical results with the system are described, and the potential of a device as a triage from cytology and as a primary screening device are discussed.

Annals Academy of Medicine Singapore 1998; 27:717-21
September 1998, Vol. 27 (5)

The Polarprobe – Emerging Technology for Cervical Cancer Screening

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Abstract. The Polarprobe is a portable non invasive electronic device designed for the detection of cervical precancer and cancer. It measures both electrical and optical properties of cervical tissues to allow a real time comparison with a databank of previously determined cervical tissue types. The need for additional tests to augment or even replace the Papanicolaou smear has partly prompted its development. Indeed it has been shown to be associated with less pain and anxiety than the smear and has the capability of encouraging women to attend for screening. Some of the preliminary clinical trials on the Polarprobe are reported as well as the ongoing developments and modifications to the device.

Int J Gynecol Cancer 1994; 4: 79-83.

An electronic approach to the detection of pre-cancer and cancer of the uterine cervix: a preliminary evaluation of Polarprobe

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Abstract. We report on the testing of a prototype of an electronic device for the detection of cervix cancer and its precursors, known as the Polarprobe. The device monitors three aspects of the cervix tissue; two relate to optical properties and the other to dielectric characteristics. The response to tissue stimulation takes the form of an energy pattern which, in conjunction with spectroscopic discriminants, can be digitized to prepare an algorithm. The pattern algorithms are sufficiently characteristic to be afforded names which correspond to tissue states recognizable as normal or abnormal by the clinician. On a tissue observation basis the previously established recognition algorithms derived from 106 volunteers produced assessments which related strongly to colposcopy/histology diagnoses obtained on 77 additional volunteers. This concordance between colposcopy/histology and Polarprobe diagnoses on this primary analysis subgroup ranged from 85% on low-grade intraepithelial abnormalities, and 90% on high-grade cervical intraepithelial squamous neoplasia, to 99% on invasive cancer. And extrapolation of these results suggests false-positive/false-negative rates in the order of 10% are achievable with the current Polarprobe device.