### Emerging Device List

<table>
<thead>
<tr>
<th>Technology:</th>
<th>TruScan™ (Polarprobe)</th>
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<td>Purpose:</td>
<td>Detection of cervical cancer</td>
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<tr>
<td>Manufacturer:</td>
<td>Polartechnics Ltd, Sydney, Australia</td>
</tr>
</tbody>
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#### Current Regulatory Status (in Canada and abroad):

According to a recent press release TruScan™ will be released in Europe in 2001 and on the Australian market in 2002. However, no details of regulatory approval are available. The company has a strategic alliance with Johnson & Johnson, through its subsidiary, ETHICON Inc., to launch TruScan™ in major markets.

#### Description:

TruScan™ (formerly called the Polarprobe) is a portable device for the detection of precancerous and cancerous cervical tissue. It measures both electrical and optical properties of cervical tissue (spectroscopic data at five wavelengths and electrical impedance information) and uses a computer algorithm to give a real time comparison with a databank of previously determined cervical tissue types. The device comprises a handpiece, which contains the tissue stimulation and sensor elements, connected to a console, which contains a microprocessor control module and a digital signal processor. A keyboard, liquid crystal display and printer are also incorporated.

During use, a single-use sensor cover is placed over the handpiece and the probe on the handpiece gently placed in contact with the cervix and repositioned until the whole ectocervix and everted portion of the endocervix have been covered. This process typically takes between one and two minutes. Lights on the probe handle, indicate normal cervical tissue or the presence of precancerous or malignant tissue.

#### Evidence of Efficacy and Safety:

Only limited data appear to be available on the performance of the device in clinical settings. Results from a study that established the recognition algorithms agreed with histologic-colposcopic diagnosis in 85% of low-grade abnormalities, 90% of high-grade abnormalities, and 99% for cancer. In an initial trial, the device was used to test 41 women with symptomatic cervical carcinoma and 45 women who had had a negative Papanicolaou (Pap) smear and had not had treatment to the cervix within the previous 12 months. Sensitivity and specificity of the device for histologically confirmed invasive cervical carcinoma were found to be 98% and 91%, respectively.

A further study found high acceptability of the Polarprobe compared to the Pap smear by 152 women who had been examined before proceeding to colposcopy. Reported advantages included fewer individuals experiencing discomfort during the exam (2.6% vs 32.9%) and fewer with after effects (discomfort or bleeding, 4.6% vs 12.5%), lower anxiety levels, and an immediate result compared with an average wait of 4.1 weeks for results. 124 women (81.6%) reported that the availability of the Polarprobe would encourage them to attend for cervical screening, and 125 women (82.2%) preferred this screening technique to the Pap smear.
The Pap smear test remains the standard technology for primary cervical cancer screening. It has well known limitations and is demanding of resources, notably cytology readers. Technologies developed to enhance or replace the Pap smear include automated cytologic testing, fluid-based monolayers to improve collection and preparation of cells, human papillomavirus deoxyribonucleic acid testing and photographic screening after application of acetic acid (cervicography). It has not yet been possible to replace the Pap test. These newer technologies have tended to offer only marginal gains in performance at higher cost and they would tend to be used in addition to the older technology.

The TruScan™ device is an emerging technology that has potential benefits for cervical cancer screening services but it requires further validation. Attractive features are the less invasive procedure compared to the Pap smear test, and the immediate test results at the time of examination, without the delay and expense associated with conventional cytology services. However, the performance of the device in the clinical setting is not yet clear and will need to be established by large-scale trials. As with other alternatives to the Pap smear test, adoption by screening services will be influenced by cost implications - particularly by whether TruScan™ will be able to replace the Pap test or whether it will be an adjunct to current screening technologies.

Available Alternative Technologies:

The Pap smear test remains the standard technology for primary cervical cancer screening. It has well known limitations and is demanding of resources, notably cytology readers. Technologies developed to enhance or replace the Pap smear include automated cytologic testing, fluid-based monolayers to improve collection and preparation of cells, human papillomavirus deoxyribonucleic acid testing and photographic screening after application of acetic acid (cervicography). It has not yet been possible to replace the Pap test. These newer technologies have tended to offer only marginal gains in performance at higher cost and they would tend to be used in addition to the older technology.

Commentary:

The TruScan™ device is an emerging technology that has potential benefits for cervical cancer screening services but it requires further validation. Attractive features are the less invasive procedure compared to the Pap smear test, and the immediate test results at the time of examination, without the delay and expense associated with conventional cytology services. However, the performance of the device in the clinical setting is not yet clear and will need to be established by large-scale trials. As with other alternatives to the Pap smear test, adoption by screening services will be influenced by cost implications - particularly by whether TruScan™ will be able to replace the Pap test or whether it will be an adjunct to current screening technologies.

References:


This summary was prepared by David Hailey and Leigh-Ann Topfer; CCOHTA.

The contents of this bulletin are current as of July, 2001. This series highlights medical technologies that are not yet in widespread use in Canada and that may have a significant impact on health care. The contents are based on information from early experience with the technology; however, further evidence may become available in the future. These summaries are not intended to replace professional medical advice. They are compiled as an information service for those involved in planning and providing health care in Canada.

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