

Conclusions

- The **ZedScan™ I** integrates into normal colposcopic practice with minimal change.
- **ZedScan™ I** results together with colposcopic impression improve the accuracy of detecting HG-CIN.
- Immediate treatment (See and Treat) can be considered with greater confidence.
- The greater accuracy provided by the **ZedScan™ I** will help to identify those women who have been referred to colposcopy but who do not have any disease and can return to routine screening.

‡ Note

Colposcopists take biopsies based on their clinical suspicion that high grade CIN is present, this is usually referred to as colposcopic impression of high grade CIN (CI) but they also take biopsies from other sites, this might be to exclude high grade disease or confirm low grade CIN or normal changes. Regardless of the indication for the biopsy the final clinical management is usually based on the worst biopsy result even if it does not agree with the colposcopic impression.

The performance of colposcopy can therefore be measured based on the detection of high grade CIN in any biopsy, this is referred to as disease present (DP). Because the presence of high grade CIN in any biopsy will influence subsequent management the performance of colposcopic impression and EIS are best expressed on a per woman basis.

References

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2. Tidy JA, Brown BH, Healey TJ, Daayana S, Martin M, Prendiville W, Kitchener HC. Accuracy of detection of high-grade cervical intraepithelial neoplasia using Electrical Impedance Spectroscopy with colposcopy. *Br J Obstet Gynaecol* 2013; 120: 400–411.
3. Colposcopy and Programme Management. NHSCSP, No 20 (2nd ed). NHS Cervical Screening Programme, May 2010.



ZedScan Background Publications

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real-time medical diagnostics

Introducing a new standard in colposcopy and cervical cancer diagnostics – ZedScan™ I



ZedScan™ combines seamlessly with colposcopic practice. The hand-held portable device interrogates the cervical tissue and provides accurate real-time results to help with better patient management.

ZedScan™ I

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The ZedScan™ I from Zilico™ ...a new standard in colposcopy

Colposcopy is a relatively subjective procedure which can make it difficult to distinguish between women with disease who need treatment and those without disease who can be returned to screening.

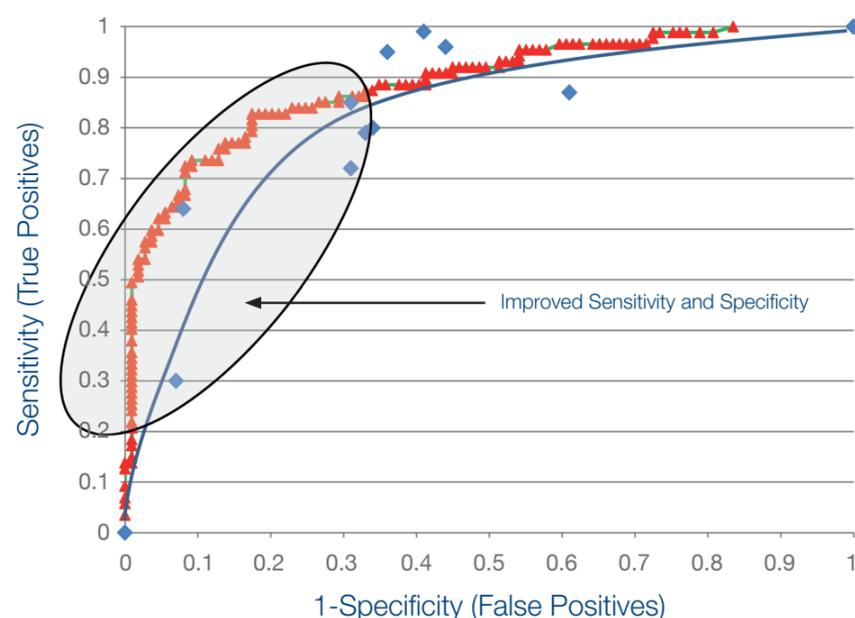
The ZedScan uses Electrical Impedance Spectroscopy (EIS) to provide an objective assessment of cervical epithelial tissue that can be seamlessly combined with the standard colposcopic examination to improve the accuracy of the procedure. EIS measures the electrical properties of the cervix which are determined by the size and shape of the epithelial cells and their arrangement into stratified layers. These properties are known to change during the development of neoplasia.

The ZedScan system consists of a portable hand-held device, a single use EIS sensor and a base station. The handset takes EIS readings and the on-board interface guides the user and displays the results to assist in the clinical management of the patient.

The **ZedScan™ I** delivers objective, real-time information to aid the clinician, offering improved colposcopic performance.

The ZedScan is an adjunct to colposcopy and is used, after the application of acetic acid (3–5%), to take a series of up to 12 readings from the Transformation Zone. The device provides an assessment of neoplasia which, coupled with the colposcopic impression, helps to decide if and where a biopsy/biopsies should be taken or if treatment could be offered at the time of the examination ('See and Treat'). Using ZedScan as an adjunct will provide a more accurate assessment of the patient and identification of biopsy sites than colposcopic impression alone.

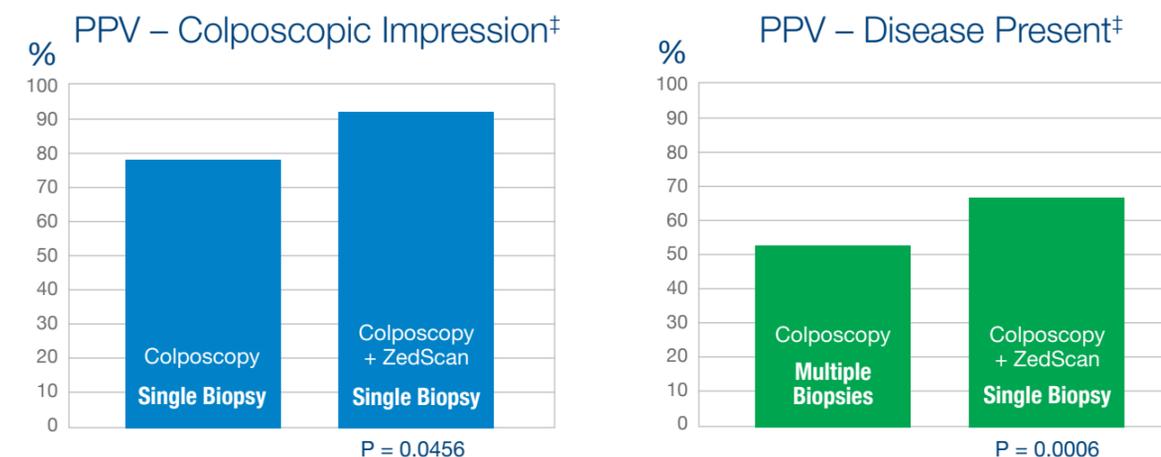
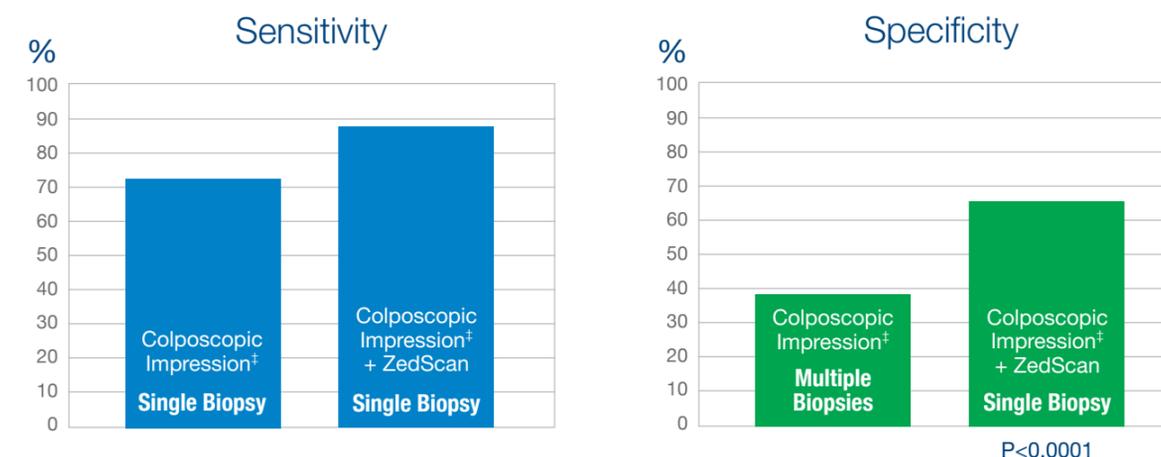
Better Performance



Colposcopy is reported to have sensitivity and specificity to detect CIN2+ (HG-CIN) ranging between 30–99% and 39–92%.¹ The data from our recent European multi-centre clinical study on the use of EIS in colposcopy, in 429 patients, demonstrated that using EIS as an adjunct significantly improved the performance of colposcopy.² The clinician's ability to detect HG-CIN based on colposcopic impression was 73.6%.

Using the ZedScan to locate sites for biopsy, the sensitivity (the ability to identify true positives) was 88.5%. Using the ZedScan to exclude high grade CIN, specificity (the ability to identify true negatives) increased from 38.5% to 65.1%. The above performance was based on a single ZedScan directed biopsy whereas colposcopy alone required multiple biopsies to achieve the quoted performance.

Benefits of using the ZedScan™ I as an adjunct to colposcopy



Using the ZedScan and taking a single, directed biopsy also significantly improved the Positive Predictive Value (PPV) and the Positive Likelihood Ratio for both CI and DP[†] ($p < 0.05$ and $p < 0.0006$ respectively).

Using the **ZedScan™ I** when considering See and Treat can improve the specificity leading to a PPV >90% for HG-CIN, achieving the required National Health Service Cervical Screening Programme standard.³