

The routine use of ZedScan within one colposcopy service in England

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Introduction

Colposcopic impression alone has been shown to be subjective with variable rates of sensitivity and specificity for the detection of high grade CIN lesions; 32 – 92%¹.

This may lead to...

- ▶ subjecting a woman to unnecessary interventions.
- ▶ failure to identify high grade changes putting women at risk of development of cervical cancer in the future.

1. Ferris DG, for the ATLS group. Prediction of cervical histologic results using an abbreviated Reid Colposcopic Index during ALTS. Am J Obstet Gynecol 2006;194:704–10



ZedScan

- ▶ ZedScan is a handheld device that uses electrical impedance spectroscopy to differentiate between tissues.
- ▶ It has been shown to improve colposcopic performance by aiding the detection of high grade CIN² without increasing biopsies rates³.

2. Tidy JA, Brown BH, Healey TJ, Daayana, Martin SM, Prendiville W, Kitchener HC. Accuracy of detection of high-grade cervical intraepithelial neoplasia using electrical impedance spectroscopy with colposcopy. *BJOG: An International Journal of Obstetrics & Gynaecology* 2013;120(4):400-411.

3. Tidy JA, Brown B, Healey J, Lyon R, Palmer J. ZedScan (Electrical impedance spectroscopy) with colposcopy increases the detection of HG-CIN in women referred with low grade cytology. Poster Presentation BSCCP ASM 15-17th April 2015



ZedScan



Aims and Objectives of the Service Review

To evaluate the routine use of the ZedScan as an adjunct to colposcopy within our clinic, in particular the ability to identify high grade CIN.

ZedScan has been used routinely within the colposcopy clinic in Sheffield by two consultants and three nurse colposcopists since December 2013.



Method

- ▶ Women referred to the Sheffield Colposcopy Clinic from 1st December 2013 to 30th September 2014.
- ▶ The Colposcopy Clinic and ZedScan databases were used to identify women.
- ▶ Baseline statistical analysis was performed using Microsoft Excel™.



Results

- ▶ 499 women underwent colposcopy with ZedScan during the time period.
- ▶ 2 women were referred with normal smears but abnormal appearance of the cervix.
- ▶ 34 women were excluded from the analysis leaving a **study group of 465**. Reasons for exclusion; failed quality assurance of the ZedScan device (21), incomplete dataset (12) and one women was pregnant.
- ▶ 90% were examined by nurse colposcopists.
- ▶ 439 (94%) of women were referred with abnormal screening cytology, 29% had moderate or severe dyskaryosis.

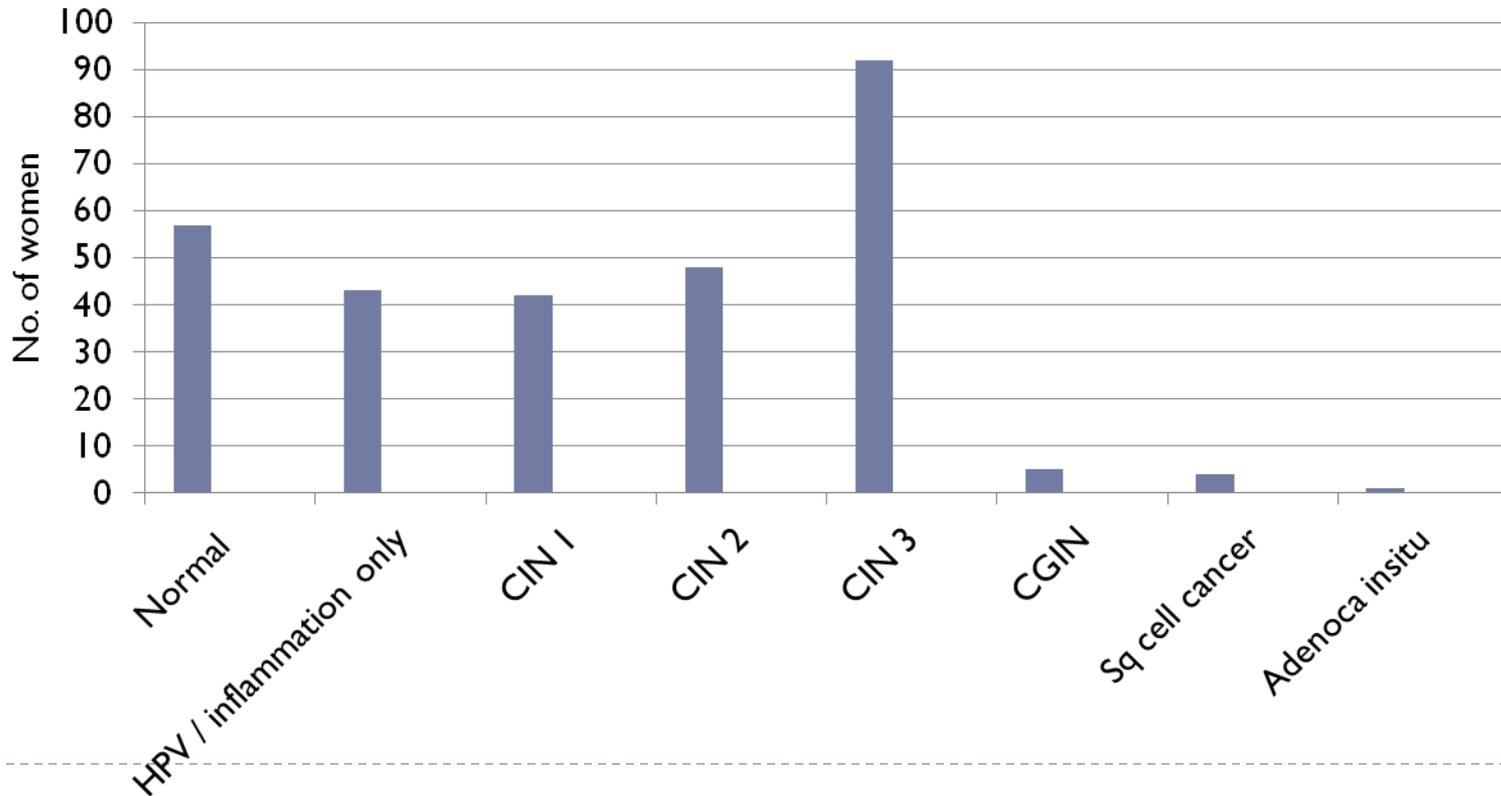
Screening sample result	No. of patients (%)
High risk (HR) HPV only	9 (2)
Borderline	166 (38)
Mild dyskaryosis	129 (29)
Moderate dyskaryosis	51 (12)
Severe dyskaryosis	75 (17)
Glandular	9 (2)

Results – overall biopsy rate

- ▶ 292 women (63%) had a biopsy (diagnostic or excision at their first visit).

National rate for biopsy in colposcopy for 2012/2013 - 63.2%

Histology from all biopsies



Women with high grade cytology - 126

- ▶ 107 (82%) had a colposcopic impression of high grade disease
 - ▶ 117 (89%) had a positive ZedScan result

 - ▶ 7 had low grade disease on colposcopic impression
 - ▶ 12 had a normal colposcopic impression; 3 of these had no biopsy (all moderate dyskaryosis and negative ZedScan results); 2 were atrophic, 1 had HPV changes and the other 6 had normal histology on biopsy

 - ▶ 73 women (58%) had CIN 3 on biopsy and 18 (14%) had CIN 2
 - ▶ 3 women were found to have invasive cancer on histology

 - ▶ 61 (48%) had 'See and Treat' at first visit, 100% had high grade disease including 3 with invasive cancer.
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ZedScan as an adjunct to colposcopy

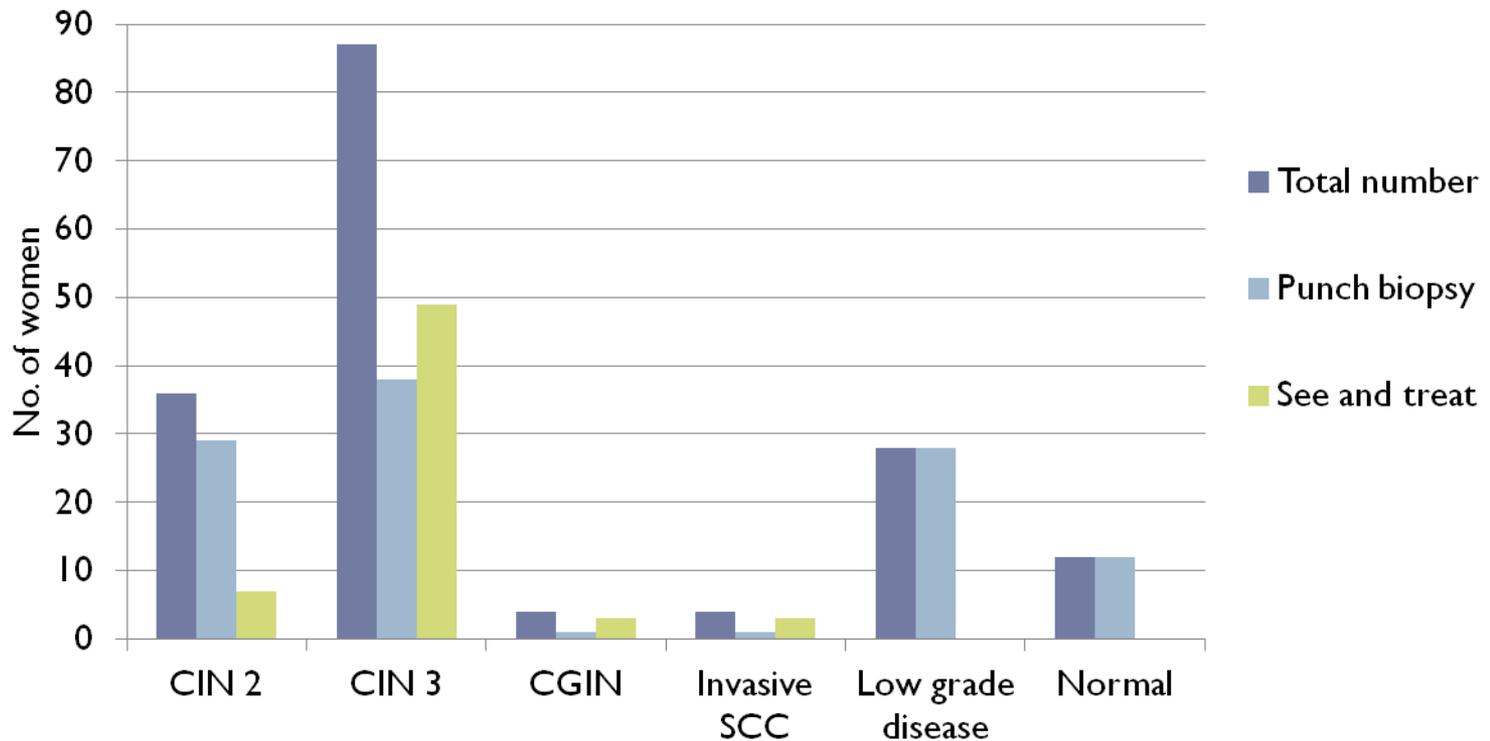
ZedScan and colposcopy opinion regarding the need for biopsy were in agreement in 82% of cases.

- ▶ Both colposcopy and ZedScan were normal in 151 women allowing them to be discharged to routine recall at their first clinic visit.
 - ▶ Colposcopic opinion and ZedScan both found abnormalities requiring biopsy in 228 cases.
 - ▶ Statistical analysis shows substantial agreement, Kappa = 0.67 (95%CI 0.60 – 0.70)
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Agreement between colposcopic impression of high grade disease and positive ZedScan result

- ▶ 180 women (39%) had a colposcopic impression of high grade disease
- ▶ Of these 172 (96%) had a positive ZedScan result

Graph to show the histology for 172 women with high grade colposcopic impression and positive ZedScan



When ZedScan and colposcopic impression differed

285 (61%) women had a colposcopic impression which was normal, HPV changes only, metaplasia, atrophic changes or low grade disease

- ▶ 171 (60%) had a negative ZedScan result, 21 went onto have a punch biopsy
 - 13 had normal histology or HPV only
 - 7 had CIN I
 - **1 had CIN 2**
 - ▶ 114 (40%) were ZedScan positive for high grade disease, 92 went onto have a punch biopsy
 - 55 had normal histology or HPV only
 - 21 had CIN I
 - **16 (14%) had high grade histology; 10 CIN2, 4 CIN 3, 1 ungradeable CIN and 1 adenocarcinoma insitu**
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When ZedScan and colposcopic impression differed

In 179 women ZedScan did not recommend a biopsy, of these 29 went onto have a biopsy;

▶8 had a colposcopic impression of high grade disease.

Histology	No. of women
Normal or HPV / inflammation only	16
CIN 1	9
CIN 2	2
CIN 3	1
CGIN	1

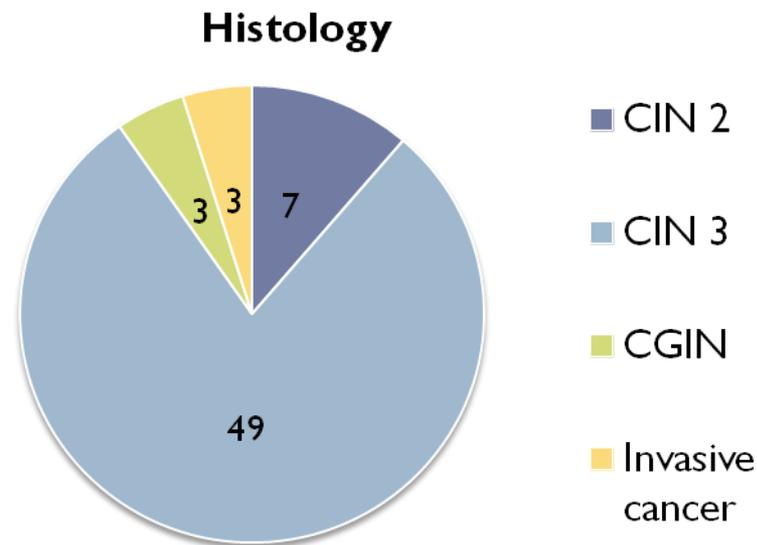
▶Overall **4 cases of high grade disease were identified**, 2 % of all women with a negative ZedScan result.

▶Colposcopic impression missed 16 cases on high grade disease, 6% of all women with a negative colposcopic impression.



See and Treat with ZedScan

- ▶ 62 women (13%) had 'See and Treat' with LLETZ
- ▶ Of these 61 were referred with high grade cytology
- ▶ All histology was high grade disease



- ▶ Rate of 'See and Treat' for women referred with high grade cytology was 48%, higher than the rates for 3 previous years; 36 – 39%

Conclusions

- ▶ ZedScan has been used routinely in our colposcopy clinic since December 2013.
- ▶ The colposcopist can be confident in discharging women or performing an excisional biopsy ('See and Treat') at the first visit when both colposcopic impression and ZedScan is agree.
- ▶ An additional 16 cases (14%) of high grade disease were identified by ZedScan where colposcopic impression was normal or low grade disease.
- ▶ Only 3% of all high grade histology was not identified by ZedScan whereas colposcopy failed to identify 11% of all high grade histology.
- ▶ The 'See and Treat' rate since ZedScan has been introduced has increased from previous years and 100% of cases had high grade disease.

