DYSIS

DYSIS Smart Colposcopy Global Webinar

Thursday, 7th May 2020

Dynamic Spectral Imaging in Colposcopy (DYSIS)

A Revolution in Practice

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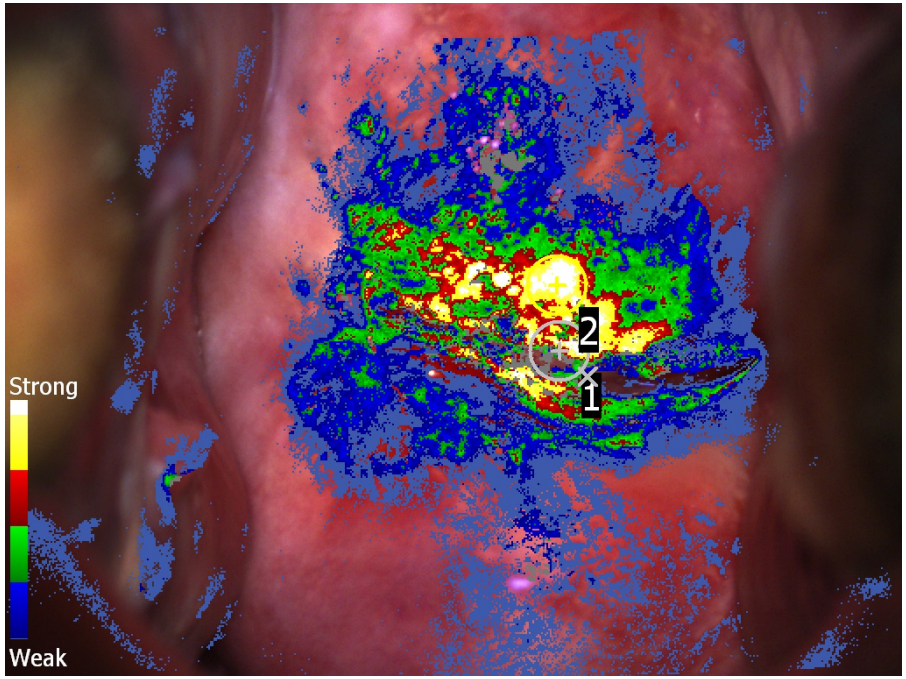
Disclosure

- Check4Cancer - Clinical Advisor.
- Net Doctor - Clinical Advisor, Gynaecology.
- DYSIS Medical Ltd – Consultant / Advisor
- RCOG - Media Representative for Cervical Screening.

Any views or opinions expressed in this presentation are that of Mr. Jullien Brady and not DYSIS Medical Ltd

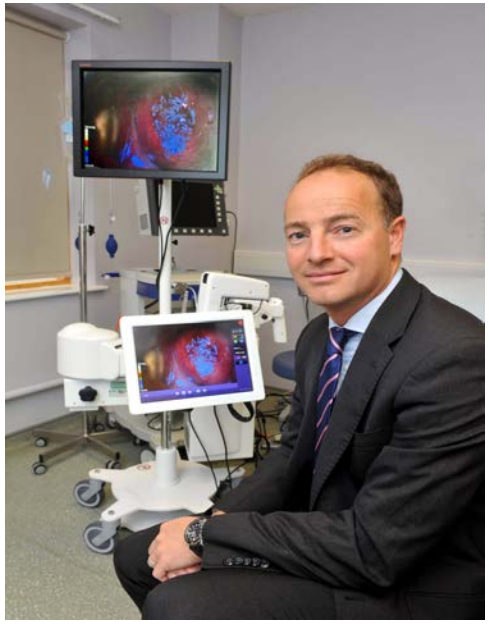
Dynamic Spectral Imaging - DYSIS

- Is a digital colposcopy system with an *adjunctive* cervical mapping technology.
- Offers improvements for women, colposcopists and service.
- Following application of acetic acid, acetowhitening is spectroscopically & dynamically assessed and calculated into an intuitive, colour-coded, summative ‘map’.



Personal View

- Why did I decide to use an adjunctive technology?
- NICE recommended to be both clinically and cost effective
- NGOC, Gateshead:
  - Live Demonstration Workshop
  - Raj Naik, Ann Fisher
- Initially low grade
- High grade
  - (conservative management)
- Quality assurance & governance
- Education and teaching
- Patient perspective



The Evidence Base

- IMPOVE-COLPO (USA) study
  - Harris et al “Rate of detecting CIN3+ among patients with ASC-US using digital colposcopy and dynamic spectral imaging” in press
  - Cholkeri et al “Digital Colposcopy With Dynamic Spectral Imaging for Detection of Cervical Intraepithelial Neoplasia 2+ in Low-Grade Referrals: The IMPROVE-COLPO Study” JLGTD 2018
  - DeNardis et al “Increased detection of precancerous cervical lesions with adjunctive dynamic spectral imaging” IJWH 2017
  - Livingston “How Colposcopy misses invasive cervical cancer: a case report from the IMPROVE-COLPO study” CROG 2916
- UK studies
  - Budithi et al “Evaluating Colposcopy with Dynamic Spectral Imaging During Routine Practice at Five Colposcopy Clinics in Wales: Clinical Performance” GOI 2018
  - Founta et al “Diagnostic accuracy of colposcopy with dynamic spectral imaging for cytology-negative/high-risk HPV positive (failed test of cure) after large loop excision of the transformation zone (LLETZ) of the cervix: Results of the DySIS colposcopy 1 study” Med 2018
  - Kaufmann et al “Standardized Digital Colposcopy with Dynamic Spectral Imaging for Conservative Patient Management” CROG 2017
  - Soutter et al “Dynamic spectral imaging: improving colposcopy” CCR 2009

The Evidence Base

- NL study
  - Louwers et al “Dynamic spectral imaging colposcopy: higher sensitivity for detection of premalignant cervical lesions” BJOG 2011
  - Louwers et al “Women's Preferences of Dynamic Spectral Imaging Colposcopy” GOI 2015
  - Louwers et al “Performance of Dynamic Spectral Imaging colposcopy depends on indication for referral” GynOnc 2015
  - Zaal et al “Agreement between colposcopic impression and histological diagnosis among human papillomavirus type 16-positive women: a clinical trial using dynamic spectral imaging colposcopy” BJOG 2012
- SP study
  - Coronado “Correlating the Accuracy of Colposcopy with Practitioner Experience when Diagnosing Cervical Pathology Using the Dynamic Spectral Imaging System” GOI 2014
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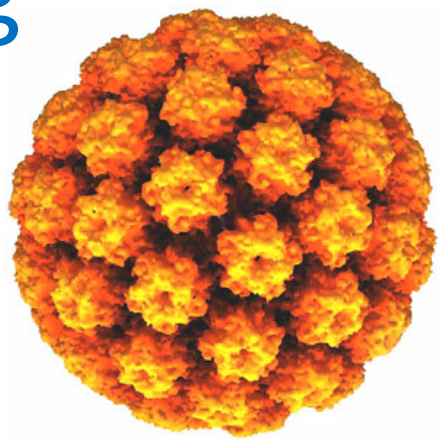
Changes in Screening



- Change to primary HPV screening.
- Vaccinated women, higher % of non 16/18 lesions. Lower HG CIN.
- Significant increase in numbers to colposcopy.
- Higher % of low-grade disease & persistent HPV with –ve cytology
- More low-grade/normal aiming to discharge to community & exclude cancer.
- In essence, harder to find disease.
- Debate on change in appearance of lesions.
- Colposcopic appearance remains similar, irrespective of HR HPV genotype.*

*Munro et al, BJOG 2017: “There was no association between the presence of HPV 16 DNA or HPV 16 mRNA and any individual colposcopic features”

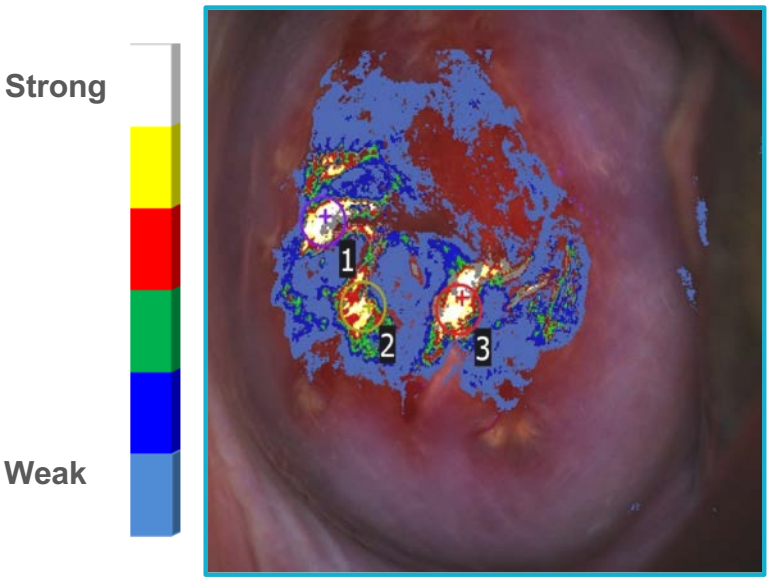
*Van der Marel et al BJOG 2014: “There was no significant relationship between any of the colposcopic characteristics and HPV16 status, either for CIN2+ or for CIN3+”

Challenges in Colposcopy

- **The ‘New’ challenges:**
- Capacity; the need to safely discharge those patients that you can.
- Disease harder to find.

- **The ‘Old’ challenges:**
- Same view of the cervix?
- Same Colposcopist?
- Same amount of acetic acid?
- Same time?
- Same parameters?
- Same (similar?) management?
- Credible image capture and archiving?

How does DYSIS help address this?

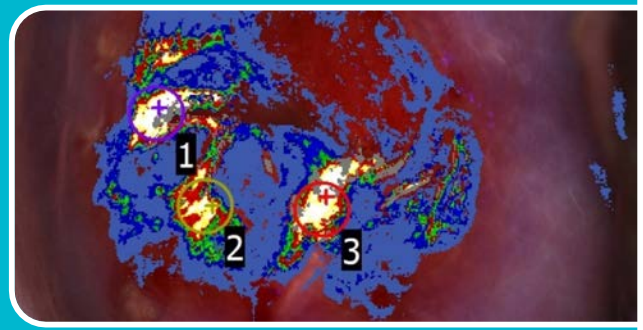


- Reproducible.
- Same view of the cervix.
- Same Colposcopist.
- Same amount of acetic acid.
- Same time.
- Same parameters.
- Dynamic on-board documentation system
  - (static & video)

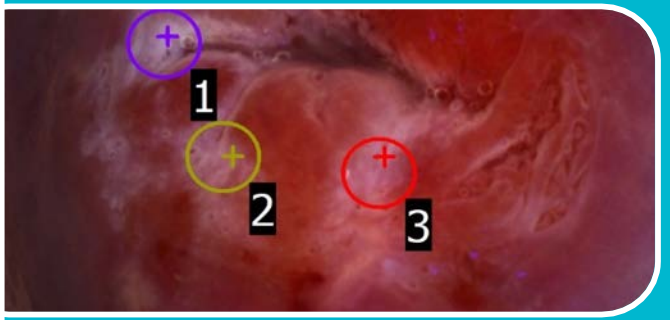
- The confidence to discharge a woman, either with or without biopsy/treatment.

Standardising Colposcopy

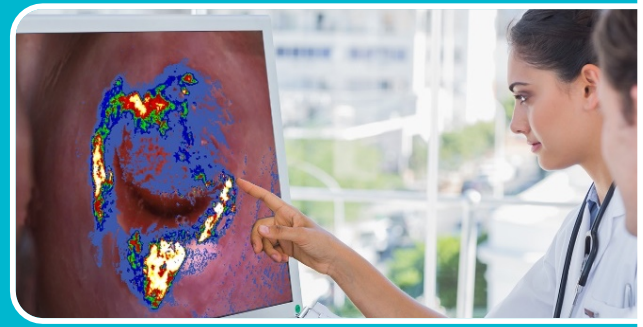
Disease detection



Biopsy efficiency



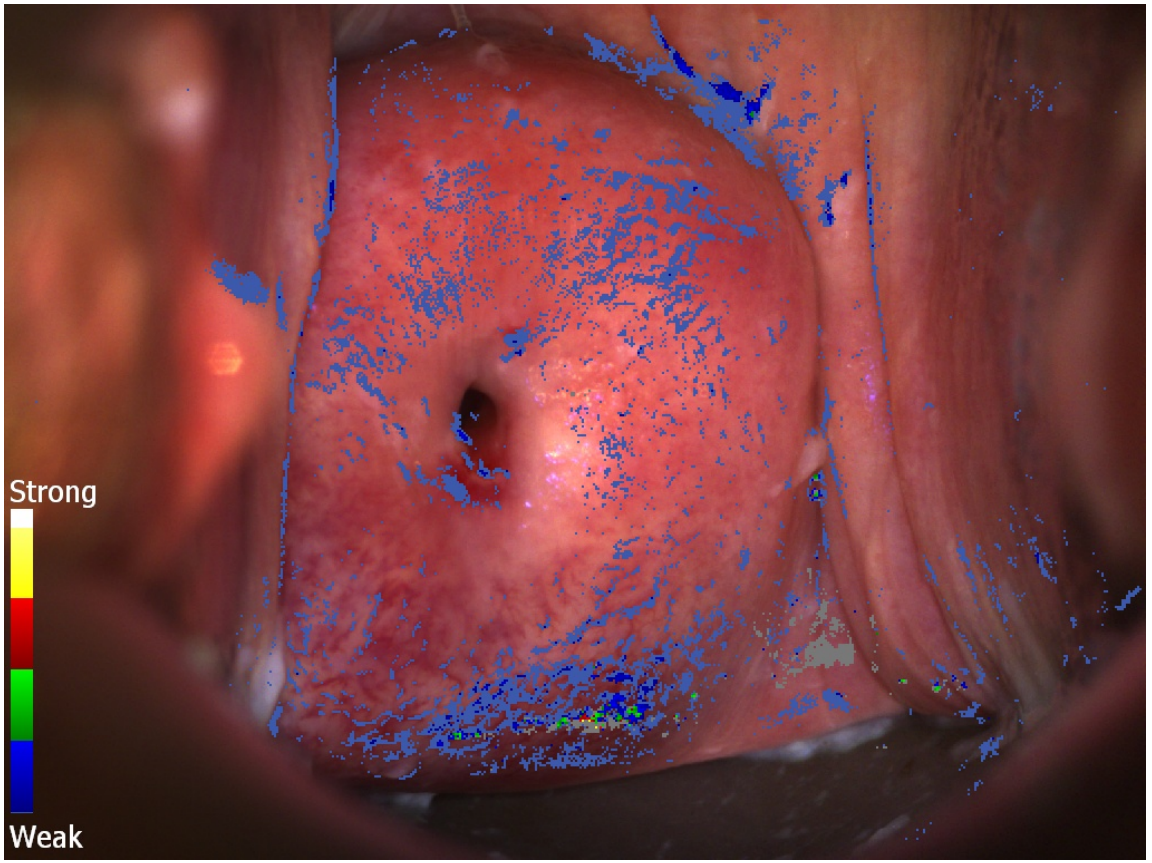
MDT collaboration



Confidence to discharge

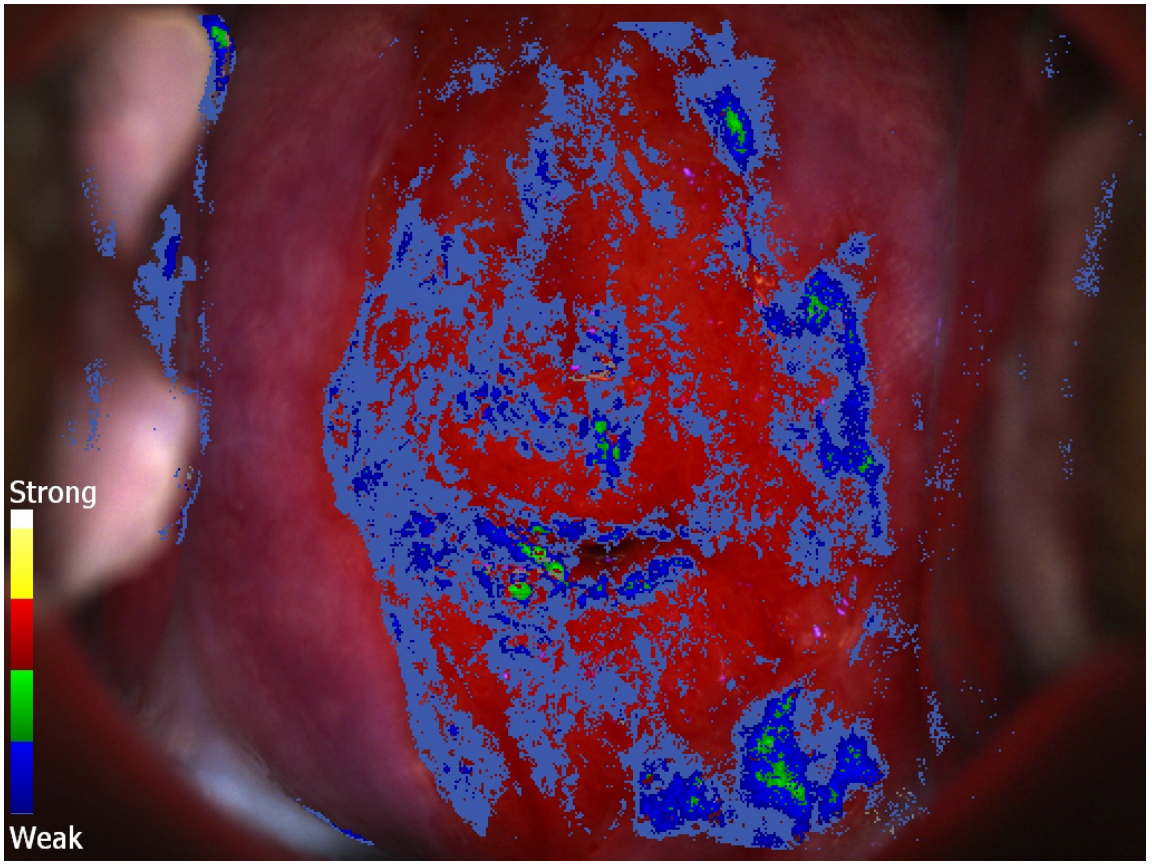
Discharge to normal recall.

- Low grade referral, normal colposcopy, normal map, 3-year follow-up.



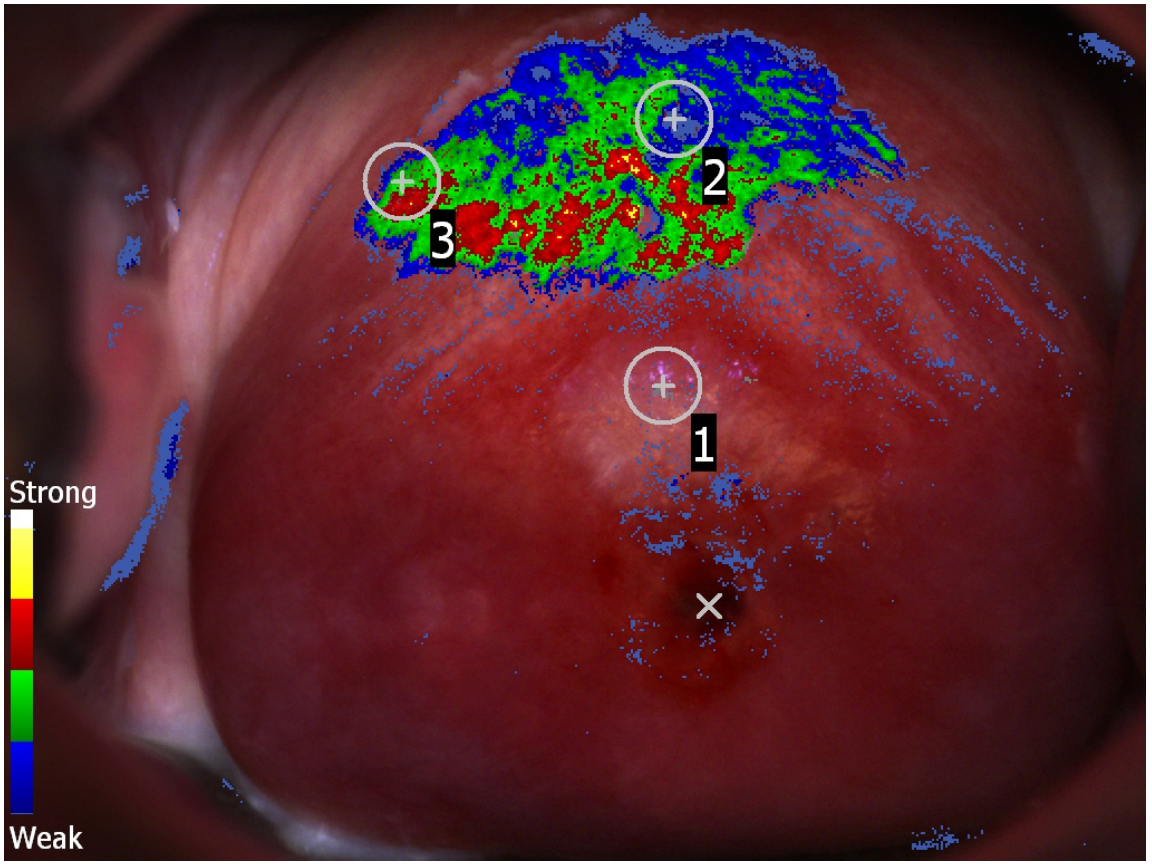
12 month discharge - no biopsy.

- Low grade referral, low grade colposcopy, low grade on map. No biopsy.



Biopsy to confirm HG CIN

- Low grade referral, abnormal area on colposcopy, high grade map.



Low grade referral - Biopsy rate

- Conservative Unit – low biopsy rate prior to introduction of DYSIS
- Post DYSIS Biopsy rate comparable
- Not 'changed' our practice – integrated
- Biopsy more targeted
- Other "real world" data emerging*

  Notably IMPROVE-COLPO

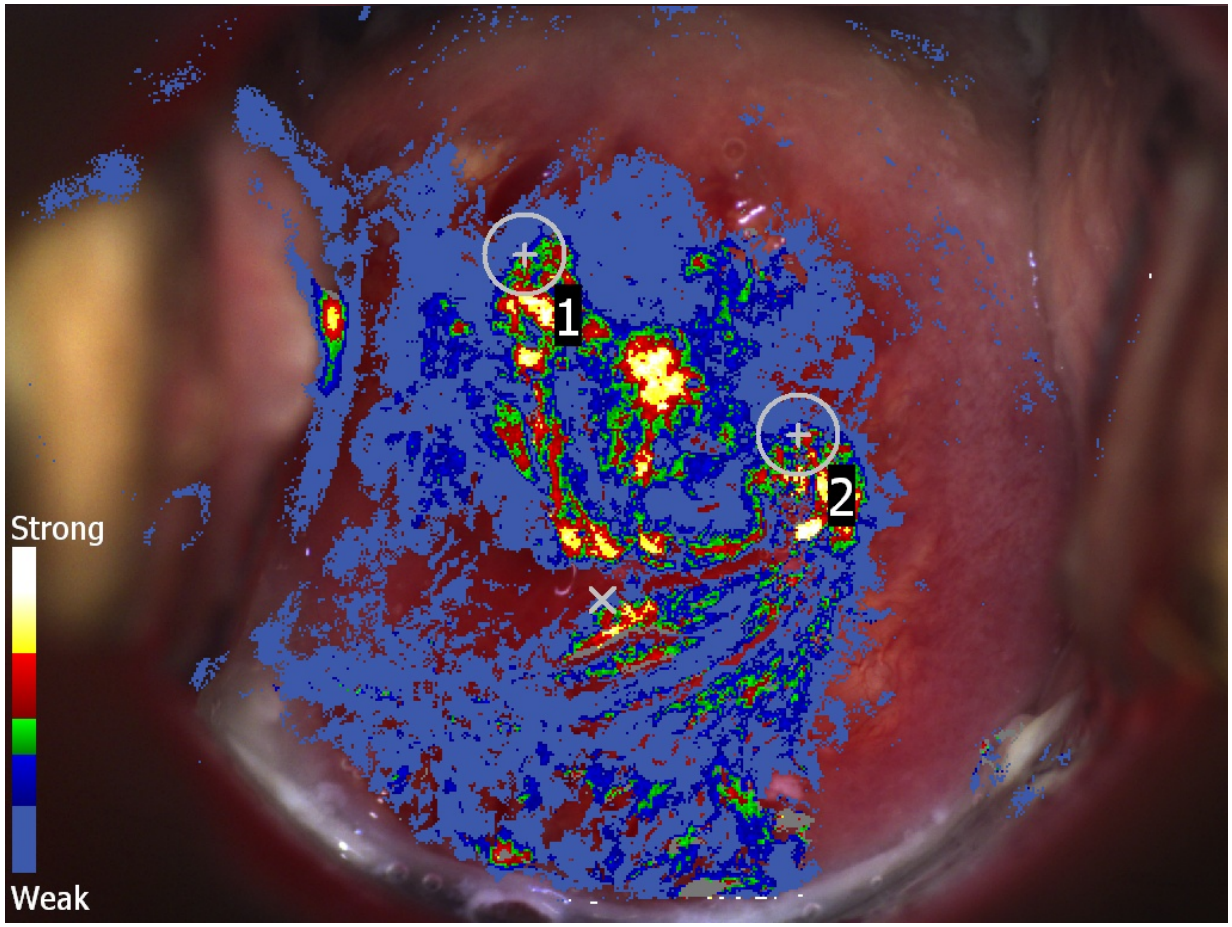
24 month local data

Pre DYSIS	***N***	***Biopsy***	***Biopsy Rate***	***CIN***	***CIN per biopsy***
JAB	68	10	0.15	3	0.30
GF	221	13	0.06	2	0.15
Total	289	23	0.08	5	0.22
With DYSIS					
JAB	68	6	0.09	5	0.83
GF	269	15	0.06	9	0.60
Total	337	21	0.06	14	0.67

*Presented at BSCCP Annual Meetings, IFCPC, ASCCP, ACOG

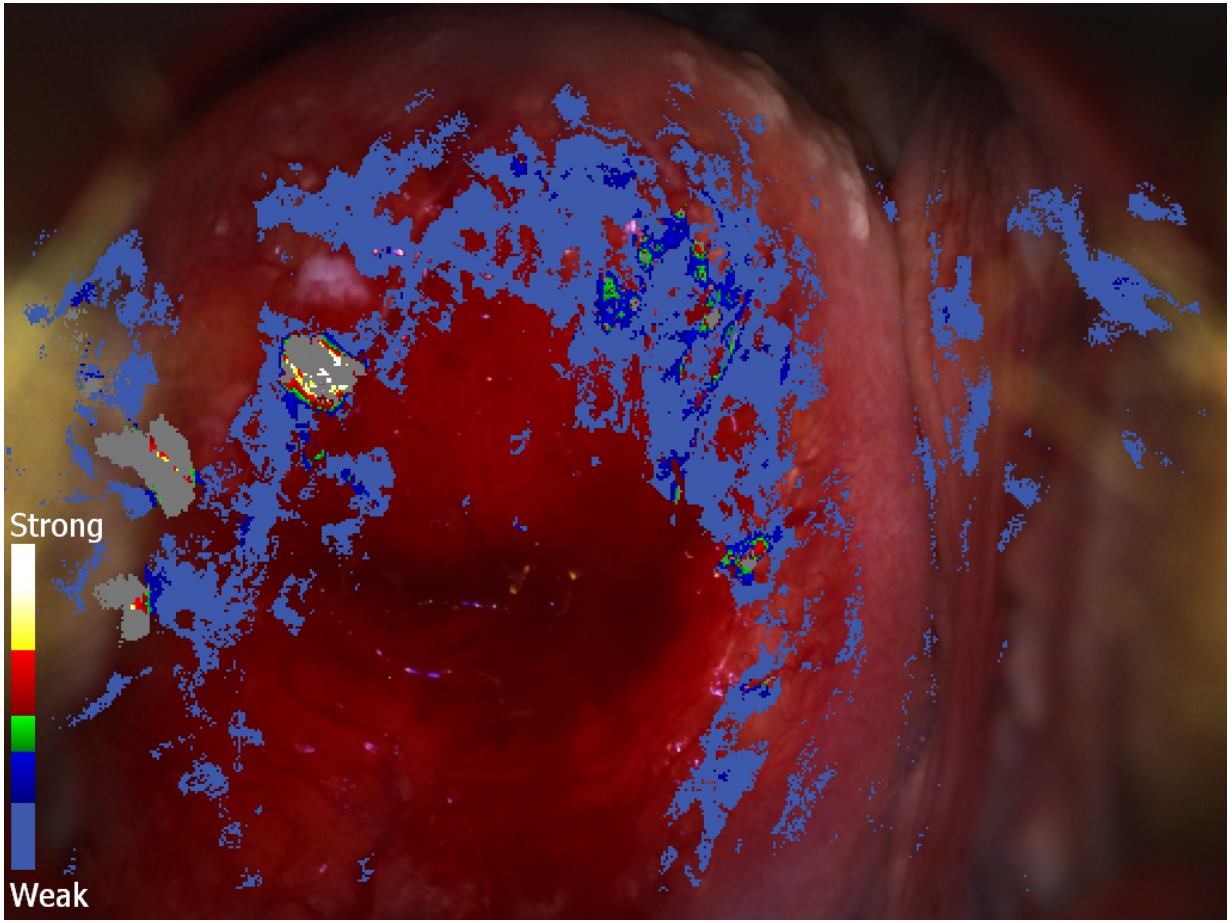
Conservative Management / Longitudinal Tracking

- Index Colposcopy Mar. 2015 - Severe Dyskariosis, CIN2 on colposcopy & biopsy



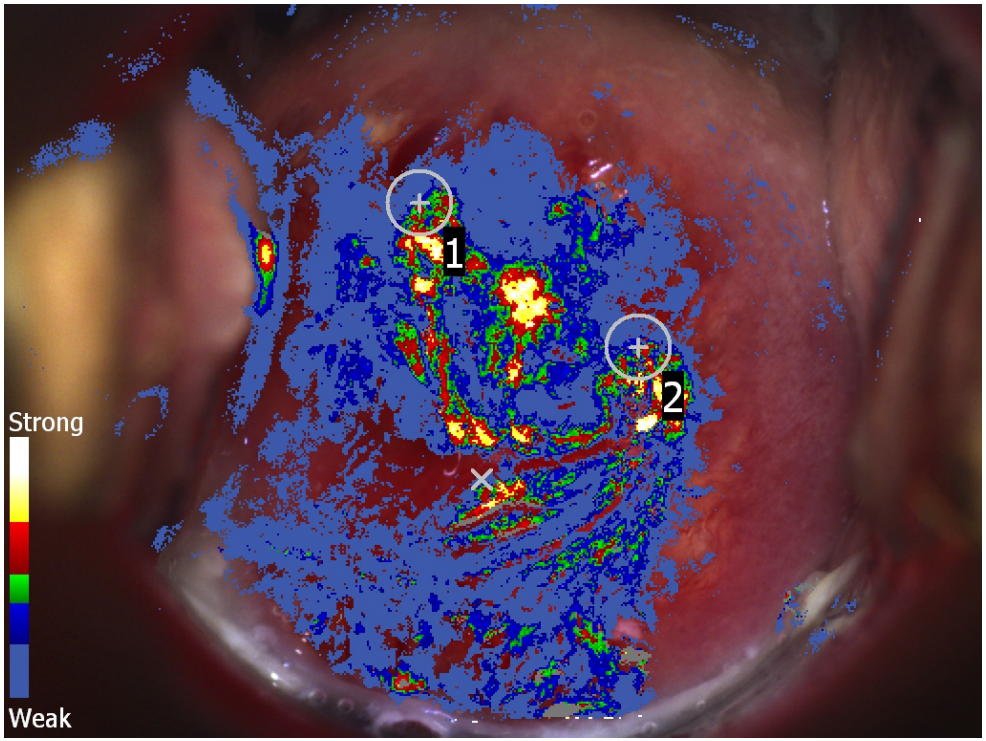
Conservative Management / Longitudinal Tracking

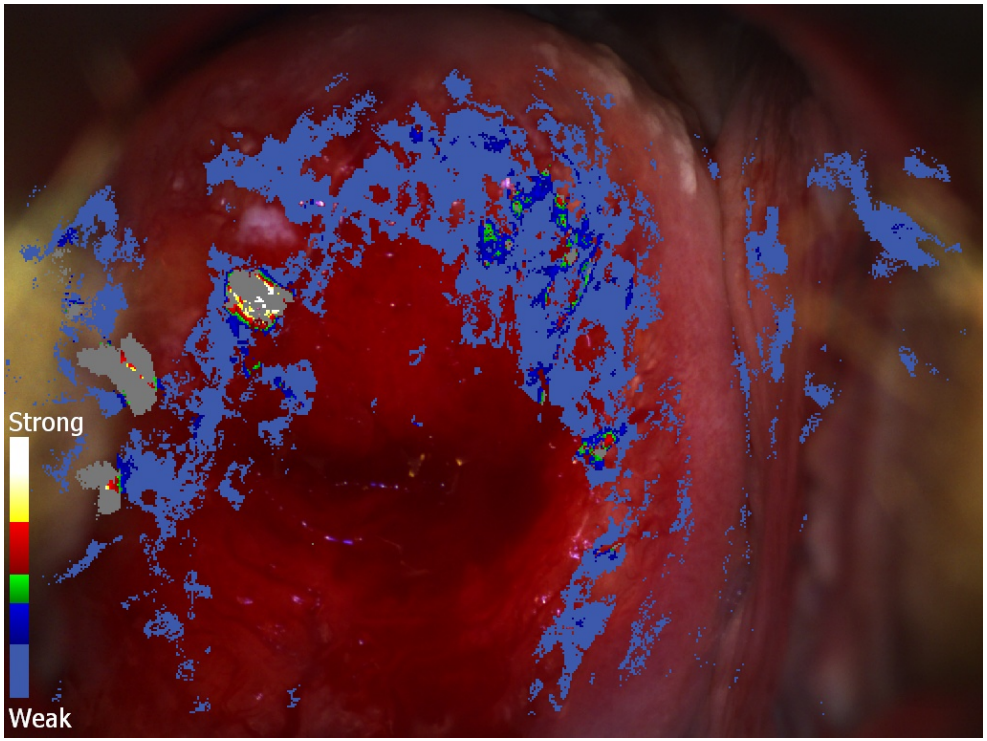
- Repeat Colposcopy Sept. 2015 - Repeat cytology LG, colposcopy CIN1, no repeat biopsy



Conservative Management / Longitudinal Tracking

- Comparison March vs September



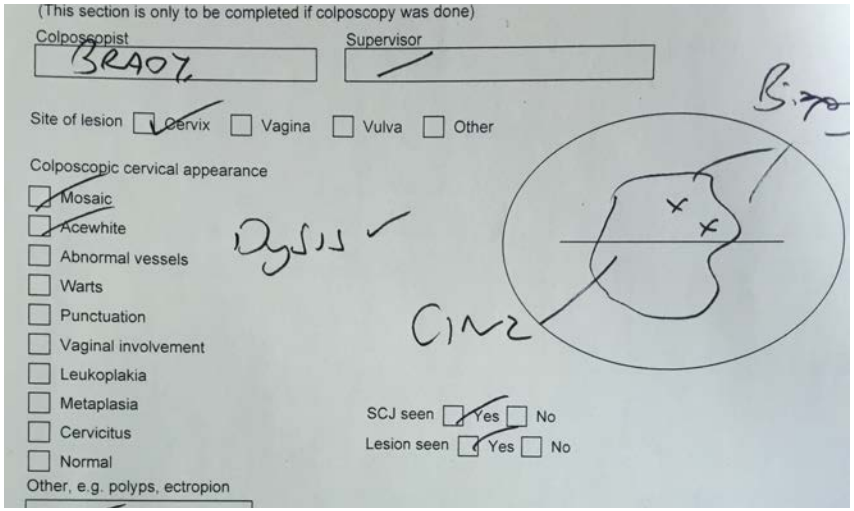


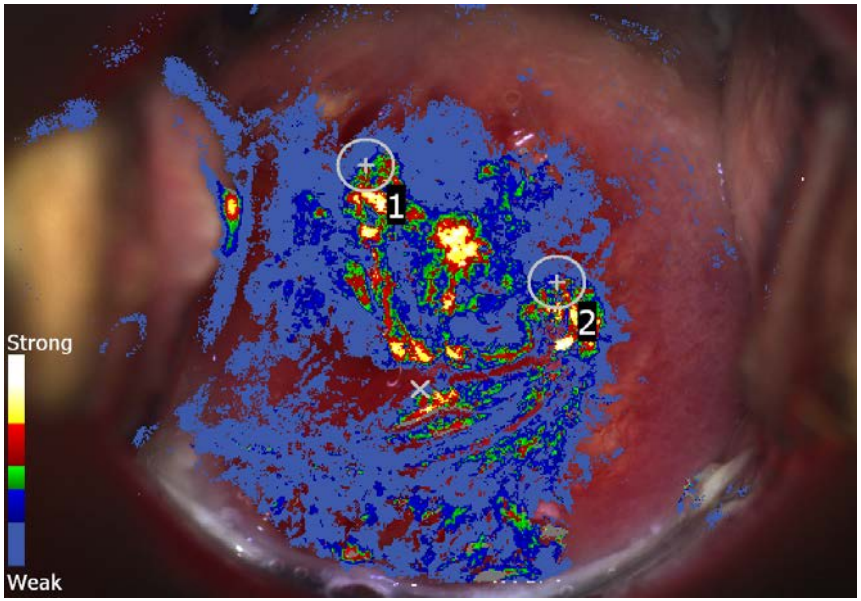
High Grade Disease / Treatment

- Treating at the right point in time.
- Radical shift in management of CIN2.
- Reducing Obstetric complications.
- Suitable monitoring of on-going low-grade disease

Quality Assurance / MDT

- Reproducibility of the exam.
- Every exam archived in full.
- Allows review at time and distant/remote.
- Medico-legal.
- MDT, credible review of cases, with biopsy sites.





Practicalities

- 2 clinics to familiarise.
- Integration: can be linked to ePR/ PAS etc.
- No increase in time for each patient consultation or overall clinic.
- Suitable for treatment and biopsy.
- Vulvoscopy:
  - Conservative management
  - Tracking & monitoring with quality image comparison
  - Patient education
  - Application of topical treatment

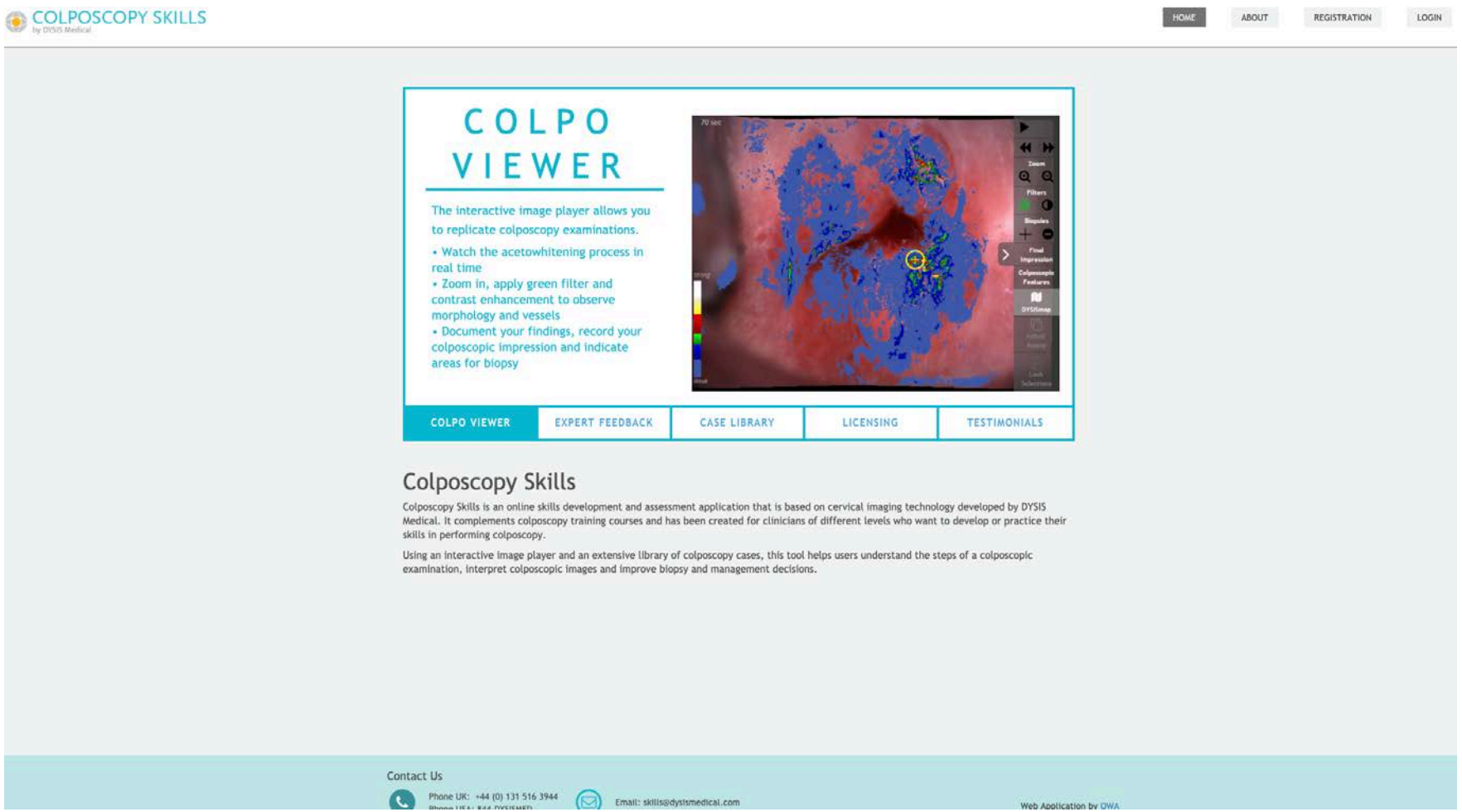
Training & Education

COLPOSCOPY SKILLS
by DYSIS Medical

- Colposcopy Skills. ‘Live’ case simulations reproducing a clinic visit.
  - Cross correlated against actual histology
  - With expert review / consensus.
- Colposcopists in training, especially non-UK.
- CPD

Training & Education

COLPOSCOPY SKILLS
by DYSIS Medical



Training & Education

COLPOSCOPY SKILLS
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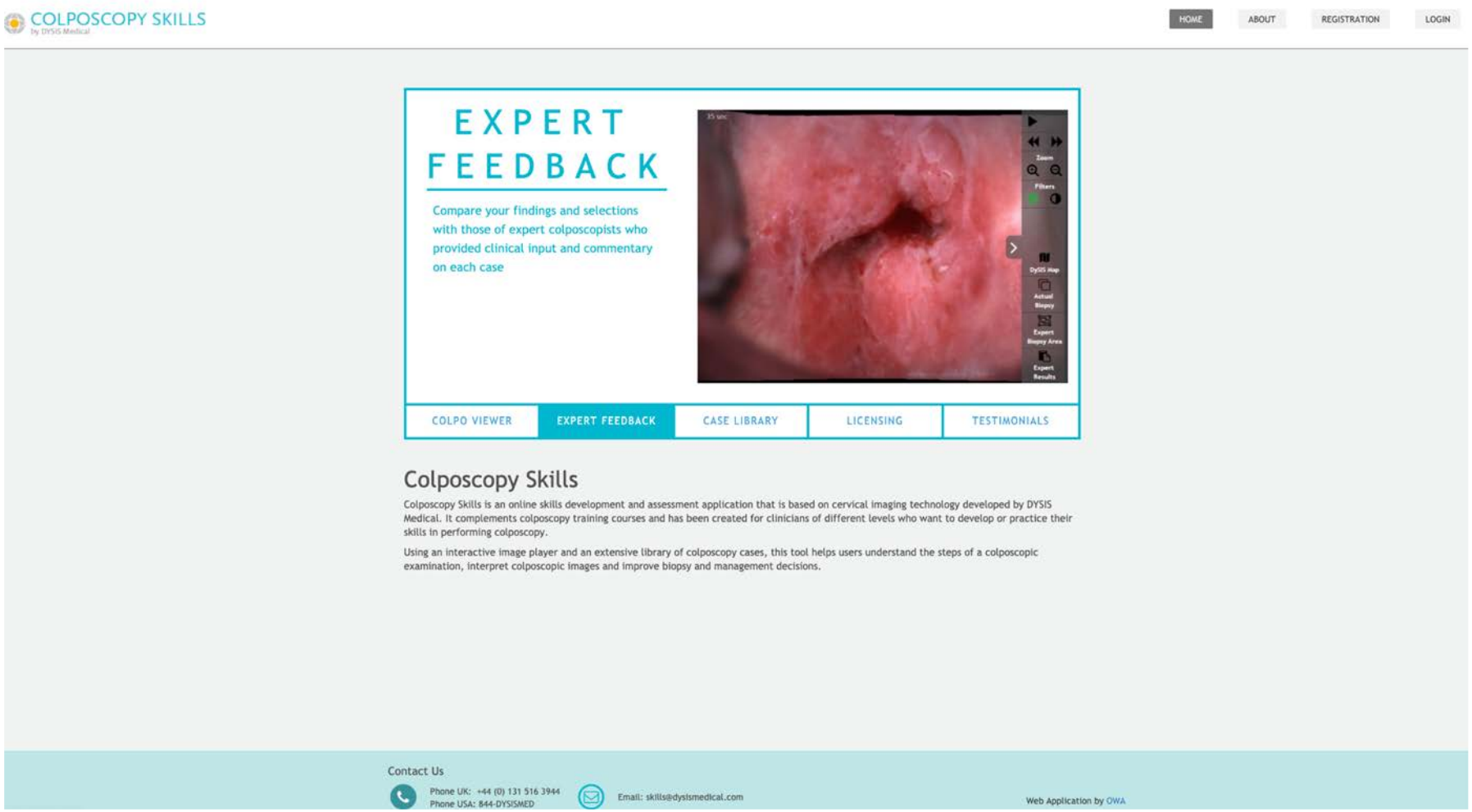

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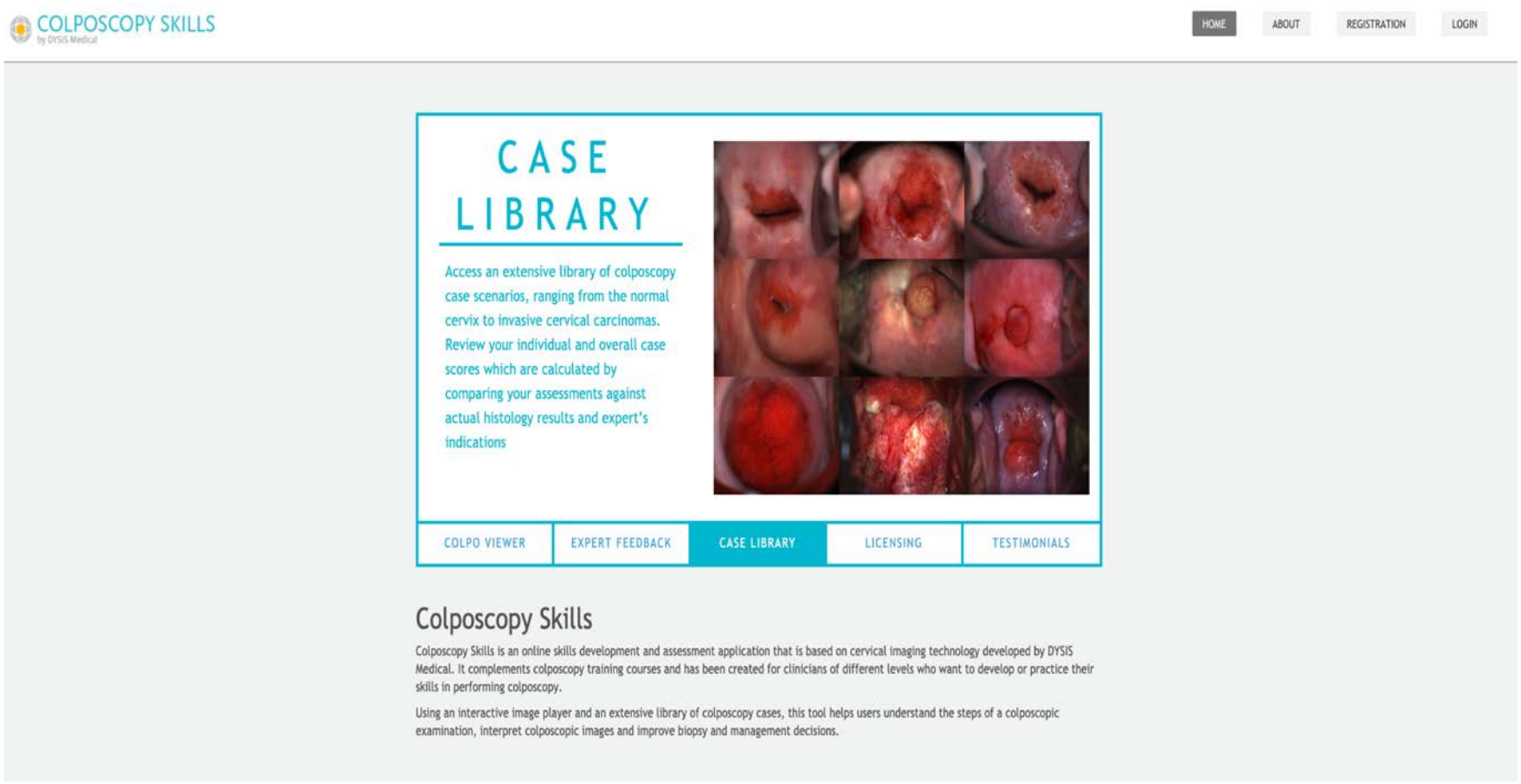


Patient Satisfaction

- The unexpected for me.
- Humbling.
- Genuine understanding.
- Reduction in anxiety.
- ? Reduction of DNA rate.

Bedford Hospital NHS
NHS Trust

Assessing the experience of the patients and their sense of reassurance after having their colposcopy with the DySIS digital colposcope

G Lowe[1] A Ogunremi[2] D Richardson[2] G Akpobome[2] E Allen[2] S Sathiyathasan[2] M Hassan[2] K Razvi[3] T Speed[3] S Clarke[3] M Sunderland[4] J Brady[1]

[1]Bedford Hospital NHS Trust, UK, [2]Princess Royal University Hospital (Orpington), King's College Hospital NHS Foundation Trust, UK
[3]Southend University Hospital NHS Foundation Trust, UK, [4]Circle Health, Nottingham NHS Treatment Centre, UK

Objectives

The NHS cervical screening programme is heavily reliant on attendance and compliance. These are the biggest determinants in achieving successful outcomes, as a high % of cancers are diagnosed in women who never attended, or defaulted from screening.[1]

Colposcopy is an intimate examination that technology could potentially make more patient-friendly. The DySIS colposcope (DySIS Medical, Livingston, UK) allows mapping of the cervical acetowhitening[2] and provides advanced digital tools that can be used to educate and reassure patients. The colour map maybe more easily understood by patients than a standard monitor view of acetowhitening and explanation by the Colposcopist.

Methods

To assess the patient experience when having their colposcopy with DySIS we designed two patient questionnaires. These were used (June 2015-May 2016) in four NHS colposcopy clinics that had adopted the DySIS colposcope, for suitable patients. One questionnaire was for patients having their first colposcopy procedure, and the other for patients that had had a prior experience of colposcopy.

Responses were given on a scale of 1 to 10, grading anxiety before, during and after the examination, perception about examination duration, feedback on the device and the map, and whether it would be their colposcope-of-choice. Results are reported as median values.

Results

We collected responses from 763 patients seen at the four clinics. Patients having their first colposcopy, thought that colposcopy with DySIS didn't take much longer than their smear (median score 4); patients with prior colposcopy experience felt that this examination didn't take longer than their previous (median score 1).

The self-reported level of anxiety, for all patients, dropped considerably after the examination.

All patients reported that they understood the DySIS colour-coded map (median score 9) and found that seeing it was reassuring (median score 9). Patients with previous experience of colposcopy, preferred having their colposcopy with DySIS (median score 10).

Finally, patients reported that they would prefer to have any future colposcopies they may need with DySIS (median score 10) and would recommend it to family or friends requiring colposcopy (median score 10). Results were consistent across the four sites.

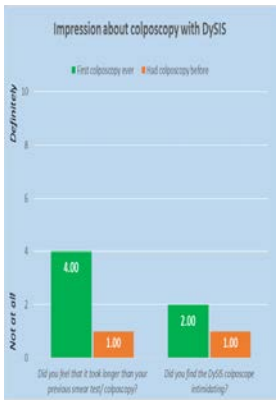
Conclusions

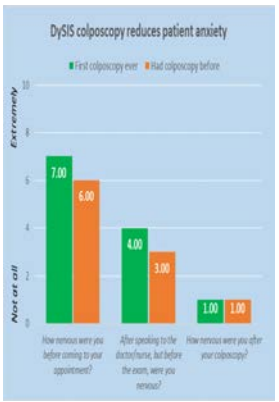
DySIS is very well received by patients and is not considered intimidating or requiring longer examination times. Our findings indicate that it is a tool that improves patient experience and helps them understand better their condition, which is valuable in improving their overall experience and potentially helpful in reducing non-attendance rates at colposcopy clinics.

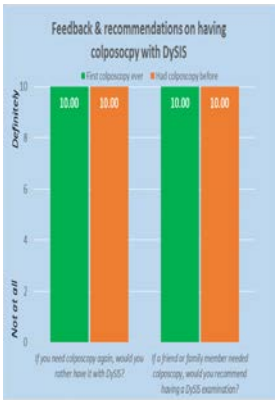
References

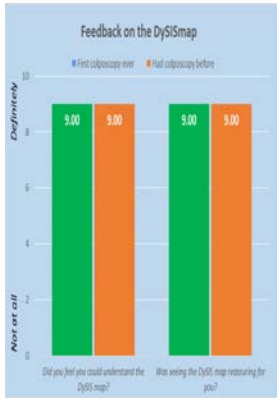
[1]NHSCSP Audit of invasive cervical cancer: Fourth National report 2009 – 2013 Final version February 2014
[2]Louwers J et al. Dynamic spectral imaging colposcopy: higher sensitivity for detection of premalignant cervical lesions. BJOG 2011; 118(3):309-318.

Conflict of interest statement:
JB has a consultancy agreement with DYSIS Medical Ltd providing advisory and educational services. No payment was made by DYSIS Medical Ltd to JB or any of the participating units relevant to this survey.









Clinician Satisfaction

- State of the art technology…..

Why we do it and the need to improve

Perspective

- Current estimated COVID deaths worldwide;
  - 244,000.
- Cervical cancer deaths worldwide 2018;
  - 311,000.
- WHO considers cervical cancer an entirely preventable disease with vaccination & screening.

Thank you.

Questions?

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