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Study background & aim

The technology

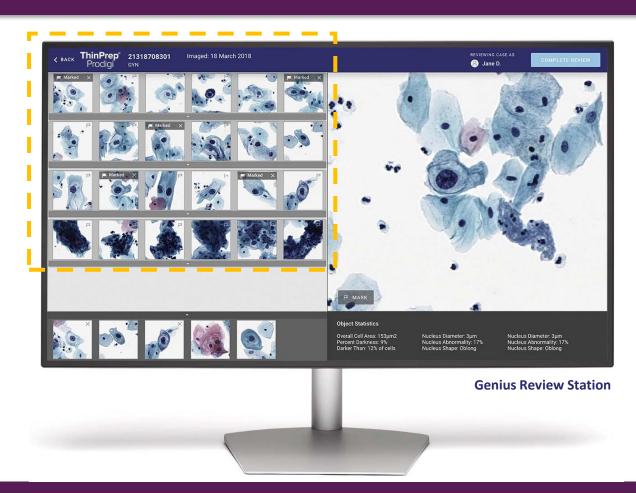
 Hologic Genius Digital Diagnostics System ('Genius DxS') is a digital cytology platform with artificial intelligence (AI)

How it works

 Al generates a gallery of clinically relevant objects; Screeners (SCRs) review to render an interpretation

Proposed benefits

• Increase SCR accuracy and efficiency but not decrease comfort (fatigue, stress, etc.).



Study Aim: To assess the performance and user experience of SCRs using Genius DxS benchmarked against ThinPrep Integrated Imager (I2), to understand the impact of perceived stress, fatigue, and decision-making processes. Secondarily to check the study design was appropriate.

Workflow and User Experience survey programme

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1. ThinPrep slides reviewed first using 12



Efficiency and accuracy measured whilst reading slides using 12.

Two week washout period

2. Same cases reviewed using Genius DxS





Efficiency and accuracy measured whilst reading slides using **Genius DxS**.

Conducted in Belgium (December 2020)
Five SCRs
All had previous work experience using I2
Compared 300 pre-selected retrospective ThinPrep slides
using I2 and Genius DxS (across two separate phases)

User experience survey wave 1



SCRs completed surveys at beginning, middle & end of day, and end of phase

User experience survey wave 2



SCRs completed surveys at beginning, middle & end of day, and end of phase



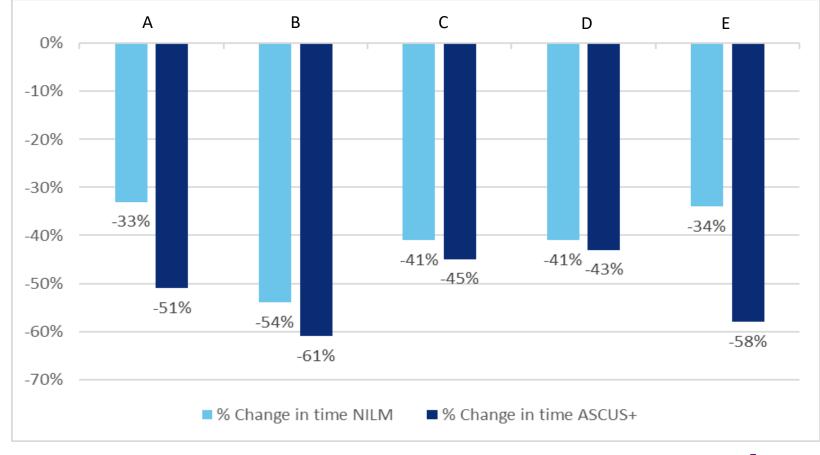
5 x SCRs interviewed individually for ~60 minutes

Workflow study findings: time taken to read slide

Comparing the technologies

- Measured speed (300 slides)
- Average time per slide for I2 = 128.8 seconds
- Average time per slide for DxS =
 69.2 seconds
- Average reduction in time = 47%

Average reduction in reading time by cytology result by SCR⁺

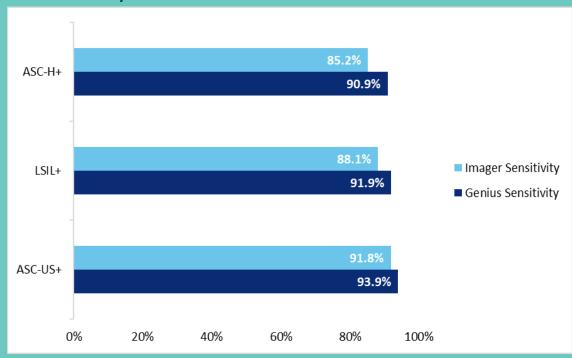


Workflow study findings: accuracy of interpretation

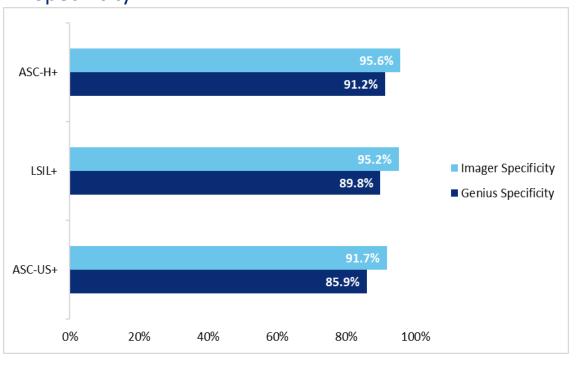
Comparing the technologies

Measured accuracy of interpretation against actual diagnosis (sensitivity and specificity)

Sensitivity +



Specificity *

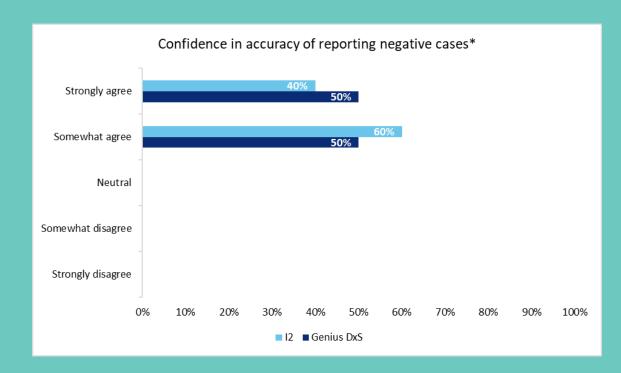


⁺n = 5 SCRs

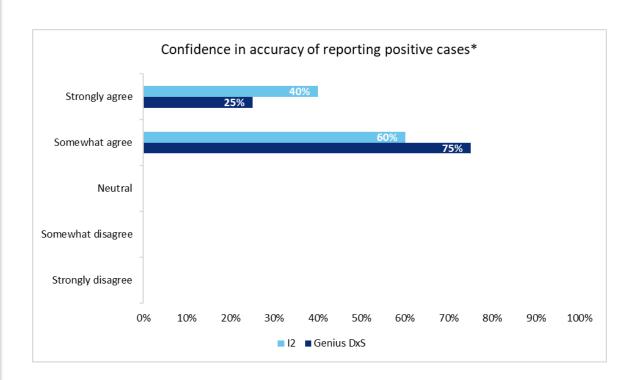
The user experience study (quantitative phases)

Perceptions of accuracy

 Reported confidence in reporting negative and positive cases⁺



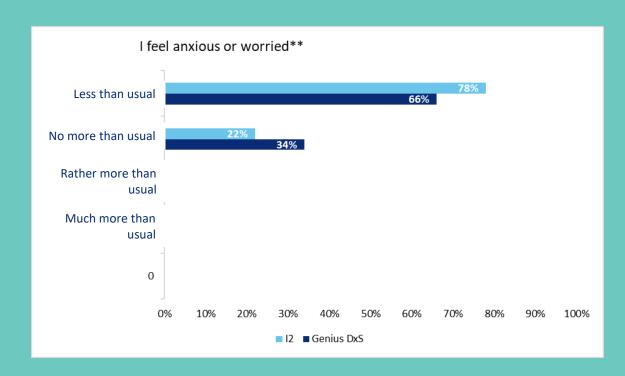
^{*}User experience measures (questions asked once at end of each study phase), + n = 5 respondents (= 4 for DxS for end of survey confidence in accuracy questions, due to non-completion) [due to small sample size user experience measures indicative only and not statistically significant]

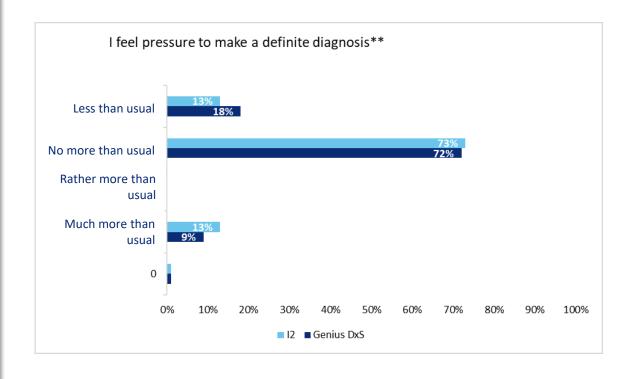


The user experience study (quantitative phases)

Perceptions of fatigue

 Genius DxS is rated no worse or better than I2 across main emotional fatigue measures⁺



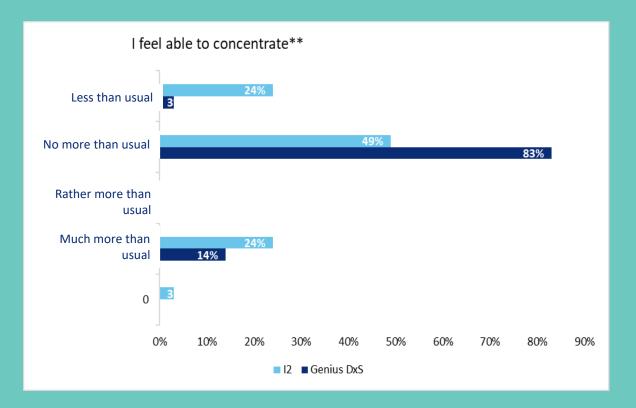


^{**} User experience measures (questions asked through the day), + n = 5 respondents (due to small sample size user experience measures indicative only are not statistically significant]

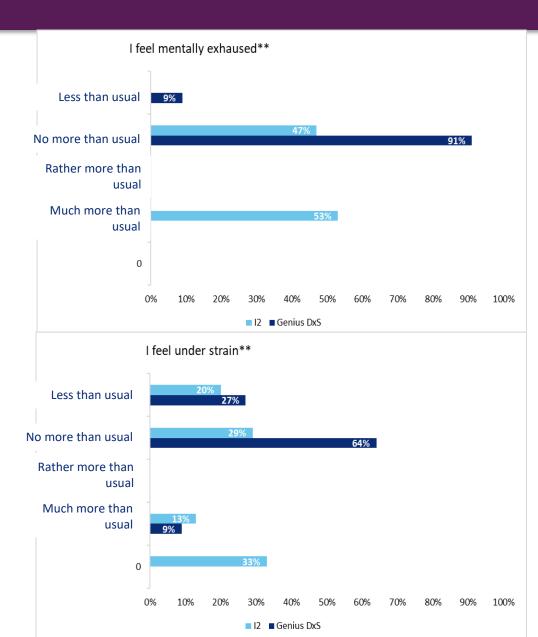
The user experience study (quantitative phases)

Perceptions of fatigue

 Genius DxS is rated no worse or better than I2 across main mental fatigue measures⁺



** User experience measures (questions asked through the day), + n = 5 respondents (*due to small sample size user experience measures indicative only are not statistically significant*)



Key headlines from qualitative phase

Exploring reasons for fatigue findings

- Relative lack of fatigue reviewing at higher speeds with DxS linked to two factors:
 - Easier decision making
- A less fatiguing physical setup of DxS workstation than microscope
 - With suggestions for scope for fine tuning, or ways to promote further acclimatisation to workstation

Importance of trust in Al

- Trusting the AI is an important factor in adopting the new way of making decisions
 - Prior work experience using I2 may have helped build trust in the computer making the selection

Comments on study design

- Slides considered a reasonable simulation of real-life, but a higher proportion of abnormalities than usual
- SCRs reported study conditions less pressured than real life work (retrospective slides = less emotional pressure)

Key headlines from qualitative phase

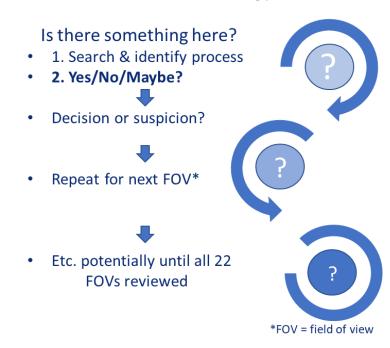
Perceptions of decision making⁺

*Hypothesis generated from qualitative usage experience descriptions not elicited from dedicated cognition/decision process study design

ThinPrep Imager:

Iterative 'search & identify → decision' process

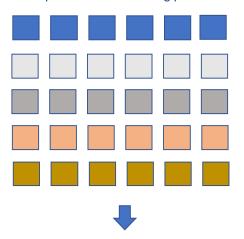
ThinPrep Imager:
Iterative decision making process



Genius DxS:

'One/two step identification → decision' process

Genius Digital Diagnostics:
Simplified decision making process



Is there something here?

- 1. Yes \rightarrow initial interpretation \rightarrow check additional 30 tiles \rightarrow interpret
- 2. No \rightarrow check additional 30 tiles \rightarrow move to next slide
- 3. Maybe \rightarrow further review/more tiles \rightarrow decide next step

Discussion

Limitations

- This is a very small scale study and the quantitative results are indicative only
- Interpreting results: results may not reflect on the real-world emotional pressures, as in both Phases they reported low levels of stress and fatigue
- The study only compared DxS with I2 technology,
 and the SCRs were already experienced in using I2

Opportunities

- A number of opportunities to offset these factors in the design of future studies
 - Larger scale (increased numbers of slides and SCRs)
 - Study with SCRs that have longer term experience working with DxS (e.g. 6+ months)
 - Prospective rather than retrospective samples may increase the 'real world' qualities of the study
 - Comparisons with traditional microscopy
 - Opportunity to conduct formal cognition/decision process study

Conclusions

Although this is a small study, it appears there are review speed benefits when using Genius Digital Diagnostics

The speed benefits do not appear to result in negative consequences to the experiences of screeners (who are more experienced with ThinPrep Imager)

• They do not appear to be significantly fatigued working at these higher speeds (across all measures)

Initial indications that Genius DxS permits a tangibly different decision making process compared to that using 12

Screeners experience this difference as 'easier and more immediate diagnostics'

Accuracy results are similar, though the less pressured study conditions may have had an effect



