

Evaluation of HistoScanning™ for the detection, location and volume estimation of prostate cancer: Results of the open phase of the PHS-02 study

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Introduction

HistoScanning™ is an ultrasound-based Tissue Characterisation modality that detects signatures of cancerous tissues in the backscattered ultrasound waves before they are transformed for forming the grey-scale video image. (Figure 1) The objective was to evaluate the ability of HistoScanning™ to detect clinically significant prostate cancer foci by correlating results with detailed histology of radical prostatectomy (RP) specimens.

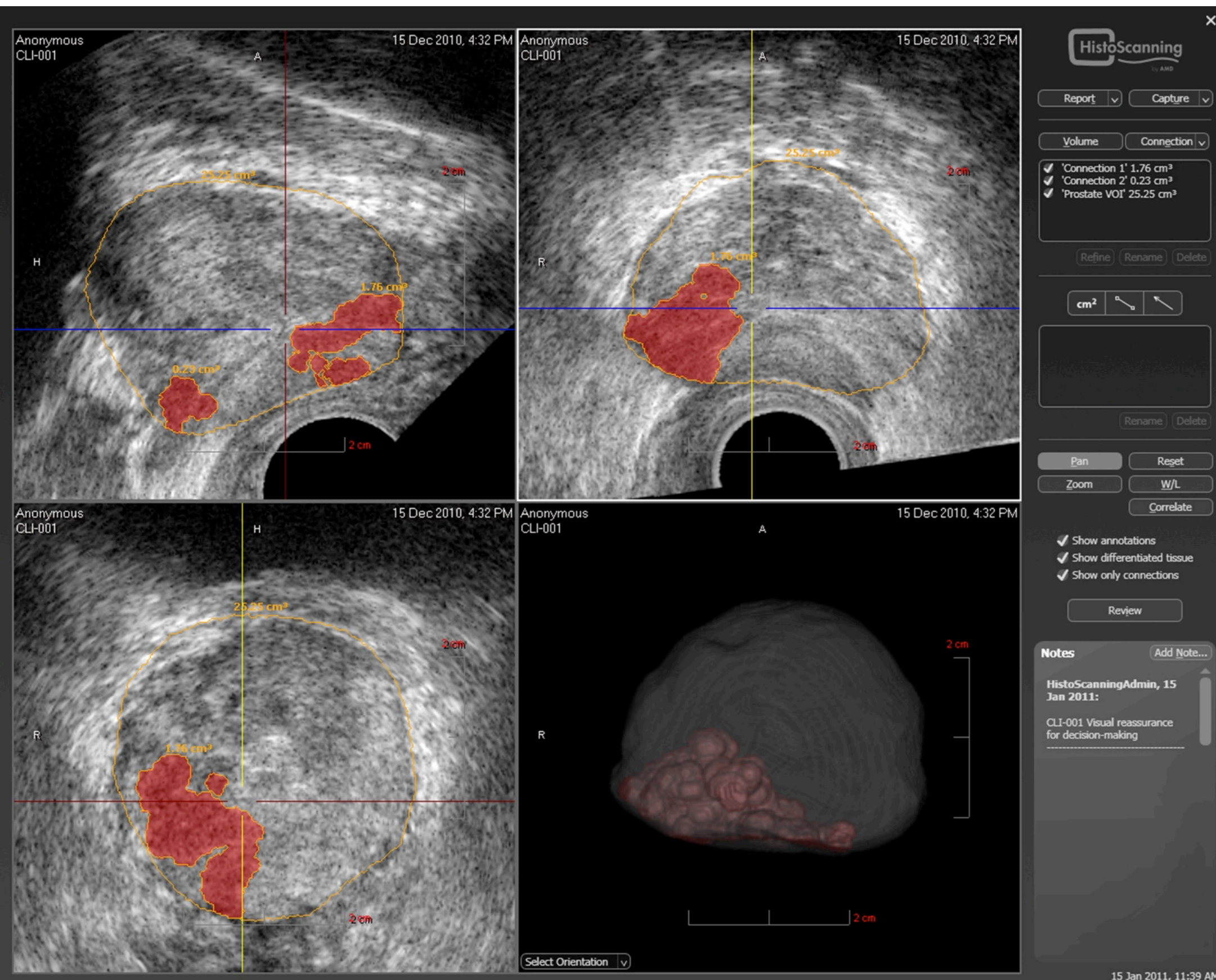


Figure 1: Prostate HistoScanning™ analysis indicating, in red, the volumes predicted as being cancer

Material and methods

27 patients, diagnosed with prostate cancer and scheduled for RP, underwent a 3D TRUS, before surgery, during which ultrasound raw data for HistoScanning™ analysis were gathered. Histology by Bostwick Laboratories (London) examined sections obtained from whole mounted glands cut every 3-4 mm. Location and volume prediction of cancer foci by HistoScanning™ and by histology were undertaken independently.

Table 1: Sextant analysis: matching HistoScanning™ detection with histopathology of all men, for any focus ≥ 0.5 cc

Sextant	True positive	True negative	False positive	False negative	No. of patients
1 (apex R)	16	2	3	2	23
4 (apex L)	14	5	3	1	23
2 (middle R)	18	3	2	0	23
5 (middle L)	16	3	4	0	23
3 (base R)	9	9	0	5	23
6 (base L)	6	13	3	1	23
Total No. of sextants	79	35	15	9	138
% of all areas	57%	25%	11%	7%	

Table 2: Sextant analysis: matching HistoScanning™ detection with histopathology of all men, for any focus ≥ 0.2 cc

Sextant	True Positive	True negative	False positive	False negative	No. of patients
1 (apex R)	18	3	4	2	27
4 (apex L)	16	6	4	1	27
2 (middle R)	20	4	2	1	27
5 (middle L)	17	5	5	0	27
3 (base R)	10	12	0	5	27
6 (base L)	6	17	3	1	27
Total No. of sextants	87	47	18	10	162
% of all sextants	54%	29%	11%	6%	

Key to Tables 1 and 2 (analysis by sextant)

True positive = Lesion present at histology, and predicted by HistoScanning™
 True negative = Lesion not present at histology and not predicted by HistoScanning™
 False positive = Lesion predicted by HistoScanning™, but not present at histology
 False negative = Lesion not predicted by HistoScanning™, but present at histology

Results

23 patients had an index focus ≥ 0.5 cc at pathology, 21 of which were identified by HistoScanning™ as having cancer foci ≥ 0.5 cc, corresponding to a sensitivity of 91%. Of the 4 patients with index focus < 0.5 cc at pathology, 4 were identified as having volumes < 0.5 cc by HistoScanning™. Histology found 32 cancerous foci ≥ 0.2 cc in the 27 patients. Tables 1 and 2 display the comparison of HistoScanning™ and of histology results by sextant. HistoScanning™ had a sensitivity of 90% and a specificity of 72% for the location of foci ≥ 0.2 cc in sextants. For the location of foci ≥ 0.5 cc in sextants HistoScanning™ had a sensitivity of 90% and a specificity of 70% (Table 3).

Cells of Table 1 and 2 shaded in yellow indicate the possibility that some false negative results would in fact be counted as false positive results because of the anatomical differences of focus position when the prostate gland is in vivo and when ex-vivo, after fixation and processing for histological examination.

Table 3:

Sextant analysis results for matching HistoScanning™ volumes and histopathology

Volume threshold for detection	≥ 0.2 cc	≥ 0.5 cc
Sensitivity	90%	90%
Specificity	72%	70%
Positive Predictive Value	83%	84%
Negative Predictive Value	82%	80%

Conclusion

Prostate HistoScanning™ has the ability to identify, locate and predict the volume of prostate cancer and consequently may aid in pre-treatment and pre-surgical planning.

Current results compare favourably with results of MR imaging studies on focus location in sextants using exactly the same study design (Chabanova E et al, Eur J Radiol, 2010). However, HistoScanning™ additionally informs on cancer volume.