

# HistoScanning, a New Device to Enhance Ultrasound's Contribution to Clinical Assessment of Pelvic Masses

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## Abstract

**Background:** HistoScanning (HS) is a medical device developed to improve interpretation of echography. Ovarian (OV) HistoScanning (OVHS) performs computerized analysis of voxel files generated during transvaginal ultrasonography (TVS). OVHS was integrated into a protocol for investigation of ovarian pathologies, primarily cancer (OVCA).

**Methods :** A study was initiated: a/ to standardize the echography procedure, b/ to evaluate OVHS ability to differentiate cancerous to non-cancerous pelvic masses under appropriate conditions. Women (W) ≥ 18 years old planned to have complete removal of ≥1 OV were eligible. Exclusion criteria include previous diagnosis of OV cancer, pelvic surgery, radiotherapy or chemotherapy for breast or OVCA.

**Results:** From September 2004 to July 2005, 486 data files were obtained from 9 institutions. 120 were used for Calibration, 97 had no surgery, and 269 met the protocol requirements. Pelvic histology includes normal OV (87), benign tumors (T) (78), past endometriosis (9), borderline cancers (21), adenocarcinomas (53), carcinosarcoma (12), metastases (4) and other cancers (3), others (2). 91 cancers were correctly diagnosed (sensitivity 98%). Reason for false negatives was: lack of voxel data for the lesion (1) and pathology volume below US resolution ("Cystadenofibroma with foci of low malignant potential; Borderline") (1). When gain used during TVS was appropriate, the false positive (FP) rate was 3% for normal tissues and 17% for benign tumors. When gain used was inappropriate, FP rate was 10% and 41%, respectively.

**Conclusion:** OVHS seems highly sensitive for the diagnosis of pelvic masses while having an acceptable specificity. A study using 3D-TV S performed with controlled gain level is ongoing.

## Introduction

### The clinical need:

Ovarian cancer cases (Globocan – IARC):  
In Europe ~45,000 new cases/year.  
In the US ~37,500 new cases/year.  
80-85% of patients die of the disease. The 5 year survival rate is only 25-30%.

### Current standards of imaging based diagnostic aid:

Pooled sensitivities for specific ultrasound imaging's morphological scoring systems ranges from 0.82 to 0.91, and specificities from 0.68 to 0.81. Pooled (a) sensitivities and (b) specificities of other imaging modalities are: MRI (a) 0.91, (b) 0.88; CT (a) 0.90, (b) 0.75; and positron emission tomography using an 18-Fluorodeoxyglucose tracer (FDG-PET) (a) 0.67, (b) 0.79.

Lack of adequate non invasive tools to allow accurate assessment of the patient's clinical condition leads to:

Performance of ~1,000,000 exploratory surgeries per year, 92% - 98% ends up with benign or normal histology.

Estimated ~10,000 cases of cancer that are missed at first check every year.

### Ovarian HistoScanning:

Ovarian HistoScanning (OVHS) is a CAD technology for ultrasound developed by a Belgian company, Advanced Medical Diagnostic Holding SA ("AMDH"). It quantifies statistical features of ultrasound backscattered signals acquired during 3D transvaginal ultrasonography (TVS). In its current implementation, OVHS is applied to specifically calibrated and standardized backscattered ultrasound data; the grey scale voxel's values that represents almost linear depiction of the backscattered 3D raw data from the scanned tissue.

OVHS is aimed at improving the clinical management of exploratory surgeries performed on women in order to diagnose pelvic masses. It was validated recently in a Multi centric clinical study of which results are presented in this poster.

### Ovarian HistoScanning's objectives:

OVHS' primary objective is to allow reduction in the number of exploratory surgeries resulting in benign/normal histology due to adoption of a "Wait and See" approach in cases for which the patient clinical condition does not justify surgery. Secondary objective is better management of surgeries; i.e. priorities and proper selection of the surgical procedure; laparoscopy Vs. laparotomy.

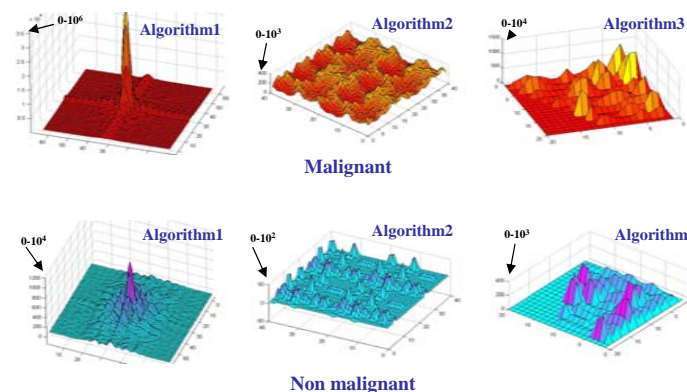
## The Technology: Ovarian HistoScanning

Ovarian HistoScanning (OVHS) quantifies statistical features of ultrasound backscattered signals acquired during 3D transvaginal ultrasonography (TVS). It is derived from HistoScanningTM: an innovative CAD technology aimed at supporting ultrasound based assessment of patient's clinical condition.

OVHS was developed through animal experiments and retrospective and prospective human studies and is aimed at quantifying changes induced in the backscattered ultrasound waves by cancerous tissues.

The core of the OVHS is constituted by three disease specific mathematical algorithms ("characterization algorithms") that are best fitted to extract changes induced by the presence of cancerous tissue in the backscattered waves.

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### OVHS:

Significantly improves performance and objectivity of TVS based management of patients presenting with pelvic abnormalities. Can be adapted to be part of the clinical assessment for all solid tissues accessible to ultrasound through TVS.

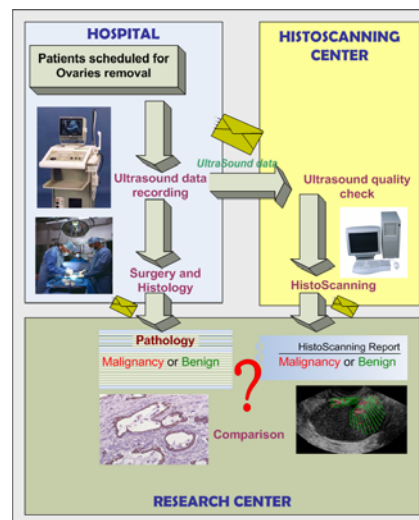
Can be implemented either adjunct to; ultrasound units, IT/PACS systems or stand alone.

### Patients:

From September 2004 to July 2005, 486 data files were obtained from 9 institutions. Women ≥ 18 years old planned to have complete removal of one or two ovaries were eligible. Exclusion criteria include previous diagnosis of OV cancer, pelvic surgery, radiotherapy or chemotherapy for breast or OVCA. 120 were used for Calibration, 97 had no surgery, and 270 met the protocol requirements. Those 270 pelvic masses were removed from 228 women, mean age is 56 (range 26-86); 70 women less than 50 years old, 136 between 50 and 64 years old and 64 being 65 years of age and more.

### Methods:

Real 3D-TV S were performed before surgery and the voxel data sent to AMD. After OVHS results were locked in the study's data base, pathological reports were sent to the clinical research organization and the OVHS results were compared to histology.



## Results:

	Neg.	Pos.	% Pos.
Normal ovaries	65	2	3%
Pelvic non-cancerous lesions	41	7	15%

Results of histology	Results of OVHS analysis									
	All OVHS analysis N = 270			OVHS with gain < 4dB N = 174			OVHS with gain >= 4dB N = 96			
	Neg.	Pos.	% Neg.	Neg.	Pos.	% Neg.	Neg.	Pos.	% Neg.	
<b>Pelvic cancerous tumours</b>	94	92	2%	2	57	3%	0	35	0%	
Borderline cancer of ovary	21	1	20	5%	1	5	17%	0	15	0%
Ovarian carcinoma	53	1	52	2%	1	38	3%	0	14	0%
Pelvic carcinosarcoma	12	0	12	0%	0	10	0%	0	2	0%
Ovarian involvement of NHL**	2	0	2	0%	0	2	0%	0	0	-
Ovarian metastasis of melanoma	2	0	2	0	0	2	0	0	0	-
Colorectal cancer	3	0	3	0	0	0	-	0	3	0
Pseudomyxoma peritonei**	1	0	1	0	0	0	-	0	1	0
<b>Normal ovaries</b>	87	78	9	10%	65	2	3%	13	7	39%
<b>Pelvic non-cancerous lesions</b>	89	56	33	37%	41	7	15%	15	26	63%
<b>Non-cancerous tumours</b>										
Ovarian cyst	19	17	2	11%	15	0	0%	2	2	50%
Corpus albicans	1	1	0	0%	1	0	0%	0	0	-
Remnants endometriosis	9	9	0	0%	6	0	0%	3	0	0%
Cystadenoma	25	11	14	56%	6	1	14%	5	13	72%
Fibroma	5	12	5	29%	8	1	11%	4	4	50%
Cystadenofibroma	12	7	5	42%	6	0	0%	1	5	83%
Dermoid cyst	1	1	4	80%	0	3	100%	1	1	50%
Teratoma	4	1	3	75%	1	1	50%	0	2	100%
Corpus luteum cyst	4	5	8	62%	5	2	29%	0	6	100%
Breast tumour	3	1	2	67%	1	1	50%	0	1	100%
Teratoma	3	2	1	33%	2	1	33%	0	0	-
<b>Other non-cancerous processes</b>										
Abscess of appendix	1									
Colon diverticulitis	1									
Hemorrhage in adnex	1									
** NHL: Non-Hodgkin lymphoma										
** This patient came in after the abstract was sent.										

Table 1 Comparison between histology and ovarian HistoScanning results

## Conclusion:

OVHS seems highly sensitive for the diagnosis of pelvic masses while having an acceptable specificity. A study using 3D-TV S performed with controlled gain level is ongoing.

## Future prospects:

Incorporation of Ovarian HistoScanning as part of the clinical assessment protocol for women presented with Ultrasound findings in the pelvis is suggested. The below chart summarizes the principals of such protocol.

