Stiftung Endometriose Forschung

«Endometriose und KI»

Arbeitsgruppe Weissensee 2026

Präsentation Erarbeitung Studienprotokoll

Julian Metzler
Jörg Keckstein

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Initiale Diskussion

Adenomyose

Möglichkeiten zur Diagnostik mittels KI

Nach ausführlicher Diskussion Studienidee vorerst verworfen (zu viele Unsicherheiten bzgl. Diagnostischer Sicherheit, «Ground truth»

Entscheid

Festlegung auf Untersuchung von tiefinfiltrierender Endometriose

Spezielles Interesse B-Kompartiment, da sonographisch schwierig

Forschungsfrage

»Kann KI tiefinfiltrierende Endometriose auf Ultraschallvideos erkennen?» (Erweiterung auf A/B/C)

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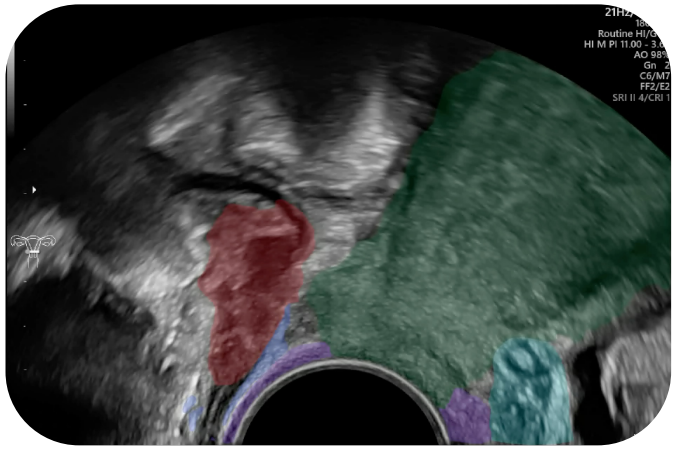
1. Study Objectives

Accuracy = (TP + TN) / (All Results)

Research Question

Can an Artificial Intelligence (AI) algorithm detect the presence of Deep Endometriosis (DE) lesions in #Enzian compartments A, B, and C with greater than **80% accuracy**?



Primary Outcome

Diagnostic Accuracy of the AI model in detecting DE lesions compared to the surgical gold standard

Secondary Outcomes

Sensitivity and Specificity of the AI model.

Performance breakdown (Accuracy/Sensitivity/Specificity) per specific #Enzian Compartment (A, B, C).

2. Study Design

Design Type

Prospective Cohort Study.

Blinding

The AI analysis will be performed post-operatively, blinded to the intraoperative findings.

The sonographers and surgeons performing the ultrasound and/or operation do not need to be blinded since AI prediction happens strictly post-operatively.

Gold Standard (Ground Truth): Surgical confirmation via Laparoscopy (LSC) combined with Histology confirmation.

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3. Study Population

Target Sample Size: 200 participants total (100 Test / 100 Control).

Inclusion Criteria

Test Group (n=100)
Patients with sonographically diagnosed Deep Endometriosis, scheduled for surgical intervention.

Control Group (n=100?) => maybe 1:3 (30 controls)
Patients scheduled for laparoscopic surgery for benign indications other than endometriosis (e.g., cysts, sterilization).
No preoperative clinical or sonographic suspicion of endometriosis.

Exclusion Criteria

Previous pelvic surgery (to avoid scar tissue confounding).
Age < 18 years or > 54 years.
Postmenopausal status.
Inability to provide informed consent or adequate communication (e.g., language barrier).
Past infectious diseases (TOA, Adnexitis)
Pos. HCG
Emergency surgery

4. Methodology & Workflow

Data Collection Steps

Pre-operative
Standardized Ultrasound examination (see *Scanning Protocol* below). The sonographer records #Enzian(u).

Intra-operative
Laparoscopic surgery to confirm presence/absence of DE. Surgeon records #Enzian(s)

Post-operative

- Surgeon fills out sketch of intraoperative situs (preprint)
- Histology confirmation (y/n)
- AI analysis of de-identified ultrasound clips.

No AI model training with study population at this point

After Last Patient Enrollemnt:
Newest AI model version (e.g. Version 31.03.2027)
will test all received videos

Comparison: AI results (DE y/n) are compared against the Ground truth (#Enzian(s))

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4. Methodology & Workflow

Data Variables Captured

Imaging
De-identified Pre-op Ultrasound Videoclips (12 per patient) + Still images of lesions.

Surgical Data
Intraoperative #Enzian(s) score, Histological confirmation (y/n)

Clinical Data
Age, parity, previous surgeries.

Symptomatology
Dysmenorrhea, dyspareunia, dyschezia, non-cyclic pelvic pain, infertility.

No study-specific intervention or appointment!
Purely observational
TVS protocol: «Best practice»

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5. Standardized Scanning Protocol

To ensure AI consistency, all ultrasounds must follow a strict acquisition sequence.

A set of instruction videos will be provided to participating centers for reference and training

Video Clip Specifications

5-10-second clips for each structure.

#	Structure / Maneuver	Technical Description / Landmark
1	Uterus (Corpus + Cervix)	Sagittal sweep (occupying 2/3 of image size). Probe in Anterior Fornix (0
2	Uterus (Corpus + Cervix)	Transverse sweep (2/3 of image size). From Fundus /c
3	Uterus Sliding Sign	Assessment of Sliding along whol ble to divide into 2 clips
4	Retrocervical Sliding	R
5	Right Ovary Sweep	
6	Right Ovary Sliding	
7	Left Ovary Sweep	ge height
8	Left Ovary Sliding	idewall sliding.
9	Left USL Sliding	ent (USL). Probe position 3-5h. Landmark: USL on probe.
10	Right USL Sliding	terosacral Ligament (USL). Probe position 7-9h. Landmark: USL on probe.
11	Left Parametrium/Vessels	Sliding sign (3-5h). Landmark: Uterine artery/vessels.
12	Right Parametrium/Vessels	Sliding sign (7-9h). Landmark: Uterine artery/vessels.

PROVISIONAL;
DEFINITIVE DESCRIPTION OF VIDEOCLIPS WILL BE SENT OUT TO CENTERS AT A LATER STAGE

5. Standardized Scanning Protocol: Examples

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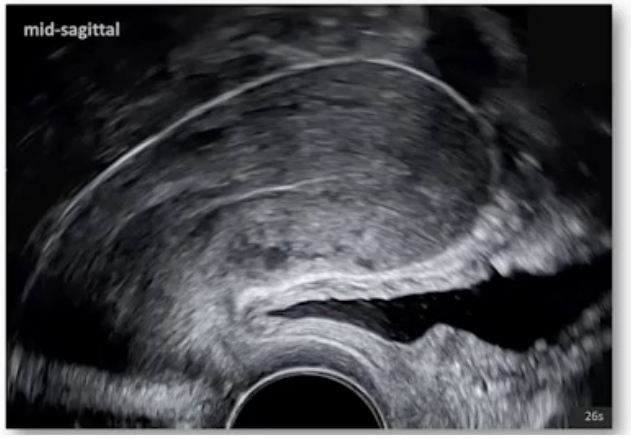
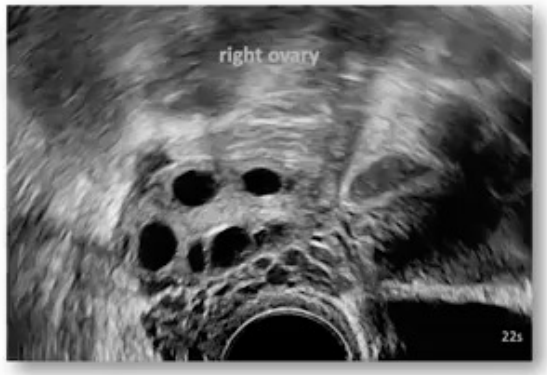
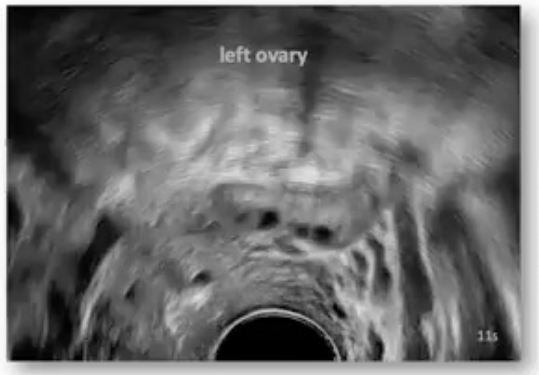
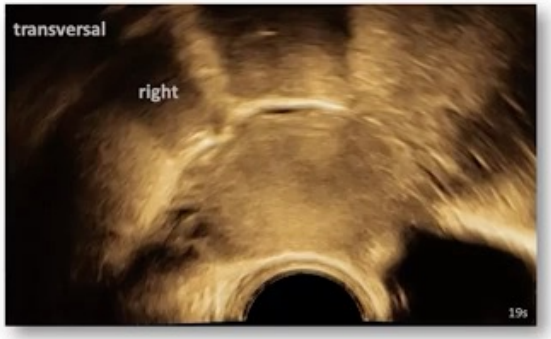
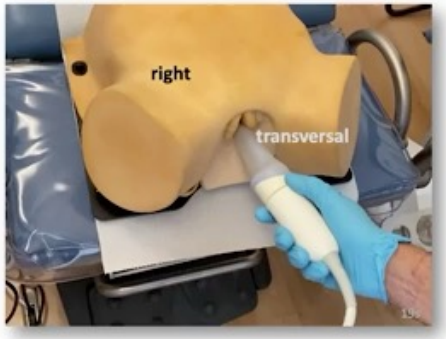


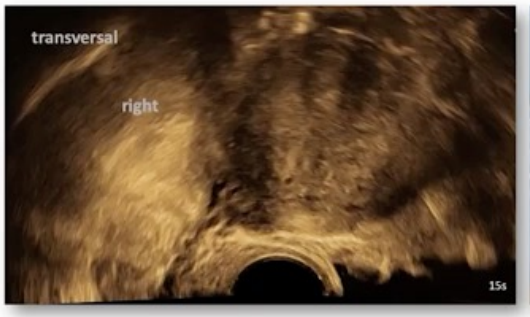


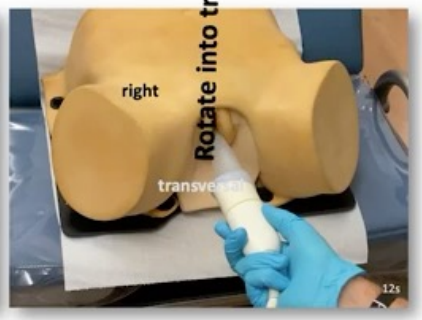






Cardinal Ligament





Sacrouterine Ligament

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Study initiation & Financing (1/2)

Discussion Academic Study (Investigator-Initiated) Study vs SEF as Sponsor vs. Industry Sponsored

Industry Sponsored (Scanvio Medial AG (Developer of Endometriosis Ultrasound AI Evaluation Tool)

Rationale

Existing Lead Ethics running (6+ centers in Switzerland), current (NEW) protocol possible with minor ammendment

Contributing centers can be added with ammendment + local ethic`s committee

Participating centers sign transparent study contract + Data transfer and usage agreements (DTUA) (Data Analysis and further use)

Sponsor is responsible for cost of ethics submission, insurance

Electronic Data Capture available
Video transfer available
=> Image transfer and analysis is in accordance with European Data Safety Regulations (DSGVO-conform)

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Study initiation & Financing (2/2)

Compensation: Why?

Positive study results could strengthen Scanvio`s Business Case

Discussion about fair & legal solutions

Compensation for centers (e.g. contract research with compensation on per-patient level)

Not preferred by group participants due to undirected cash flow to broad area (hospital, overhead, administration; = does not benefit research directly)

Discussion about percentage profit sharing (not possible due to contracts with investors and grants received)

Possibility of free rent of hardware/software for participating centers for certain amount of time (is an option)

Preferred by working-group: Purpose-Specific Donation to SEF, «For Research of Endometriosis and Ultrasound»

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Next Steps

Protocol

Finalization of Study Protocol (JM)

Power calculation (JM) (inclusion of previous / preliminary data)

Videos

Creation of Reference Videos / Instructional Videos for each of the 12 Videos (JM); once finished (ca .Mar/Apr 26):

Email with Information Package (Protocol + Instructions) to interested centers (JM)

Evaluation of commitment to participate after seeing the full documentation (all)

Interested centers send example videos (in accordance with protocol) to Jörg Keckstein for review, before being included in study (all), then receive documents for inclusion

Timeframe

Early Q2 2026: Invitation Email

Q2 2026: Definition of participating centers, sending out protocol templates for ethics (including study protocol, informed consent etc)

Q3 2026 (?) first patient in

Q1 2027 (?) last patient in

Needed

Commitment to submit 10+ patients in Test Group and and 5-10 in Control Group

Possibly capping no. of centers due to costs (details to be evaluated)

Contact for Questions:
Julian.Metzler@usz.ch