Robotic HIFU treatment of rectal endometriosis:

Results of a French prospective multicentric safety study

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Disclosures

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Focal One robotic HIFU

Evaluation of HIFU treatment of rectal endometriosis

60 patients

Inclusion criteria:

- ***No past rectal surgery***
- ***One digestive endometriosis location***
- ***Rectal (< 15 cm from the anal margin)***
- ***No change of hormonal treatment during follow up***

human reproduction
eshre

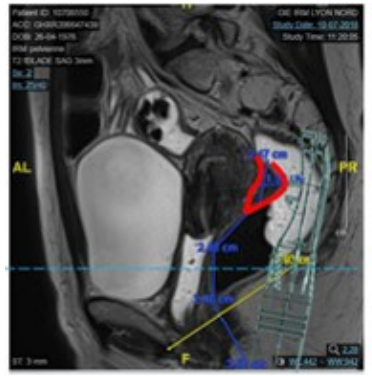
Objectives

➢ **Safety at 1, 3 & 6 months**

➢ ***Secondaries :***

- *Evolution of **gynecologic, digestive** at 1, 3, 6 months*
- *Evolution of **QOL** at 1, 3, 6 months*
- *Evolution of nodule volume at 6 months (MRI)*
- *Post procedure analgesic & average pain at 10 days*

Protocole of treatment



ENZIAN classification

Ovary	**None**	**<3 cm**	**3–7 cm**	**>7 cm**
Right	56 (93.3)	3 (11.7)	0 (0.0)	1 (1.7)
Left	48 (80.0)	8 (13.3)	4 (6.7)	0 (0.0)
Deep endometriosis	**None**	**<1 cm**	**1–3 cm**	**>3 cm**
A: Rectovaginal space Vagina Retro cervical area	4 (6.7)	7 (11.7)	39 (65.0)	10 (16.7)
B: Sacro uterine/cardinal ligaments Pelvic side wall	4 (6.7)	25 (41.7)	25 (41.7)	6 (10.0)
C : Rectum	0 (0.0)	4 (6.7)	40 (66.7)	16 (26.7)
	No	**Yes**	**NA**	
FA: Adenomyosis (Internal)	52 (86.7)	7 (11.7)	1 (1.7)	
FB: Bladder	59 (98.3)	1 (1.7)		
FU: Ureter	60 (100.0)	0 (0.0)		
FI: Intestine	60 (100.0)	0 (0.0)		

ANESTHESIA, N(%) :

General: 42 **(70%)**

Spinal: 18 **(30%)**

Operating mean time: **1h26** ± 0h27 (0h40-2h48) / 1h24

In-out probe mean duration: **0h35** ± 0h13 (0h17-1h29)

Discharged after 1 day: 55 (91.7%) / 0 day: 4 (6.7)

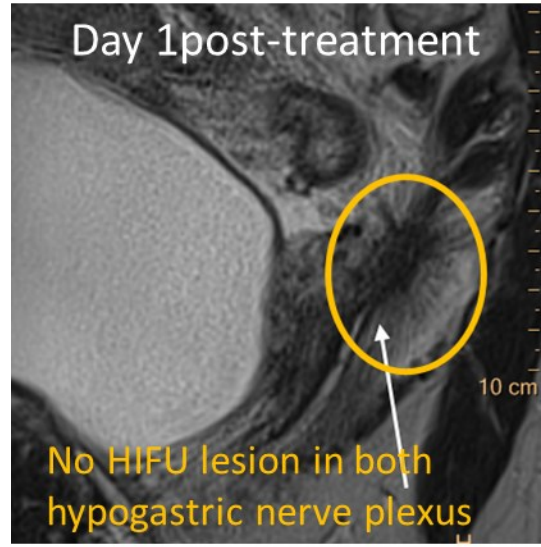
Mean nodule volume: **3.0 cc** (0.4-10.1)

WORK INTERRUPTION

Duration: **10.2** days

Safety – Limited adverse events

System Class Organ (SOC)	Clavien 1	Clavien 2	Overall
Overall	**50.0%**	**3.3%**	**53.3%**
Gastrointestinal disorders[2]	36.7%	-	36.7%
Reproductive system disorders[3]	18.3%	-	18.3%
General disorders	15.0%	-	15.0 %
Renal and urinary disorders[4]	3.3%	1.7%	3.3%
Injury, and procedural complications	na	na	-
Infections	-	1.7%	1.7%
Skin and subcutaneous disorders	1.7%	-	1.7%
Nervous system	1.7%	-	1.7%
Muskuloskeletal and connective tissue disorders	1.7%	-	1.7%



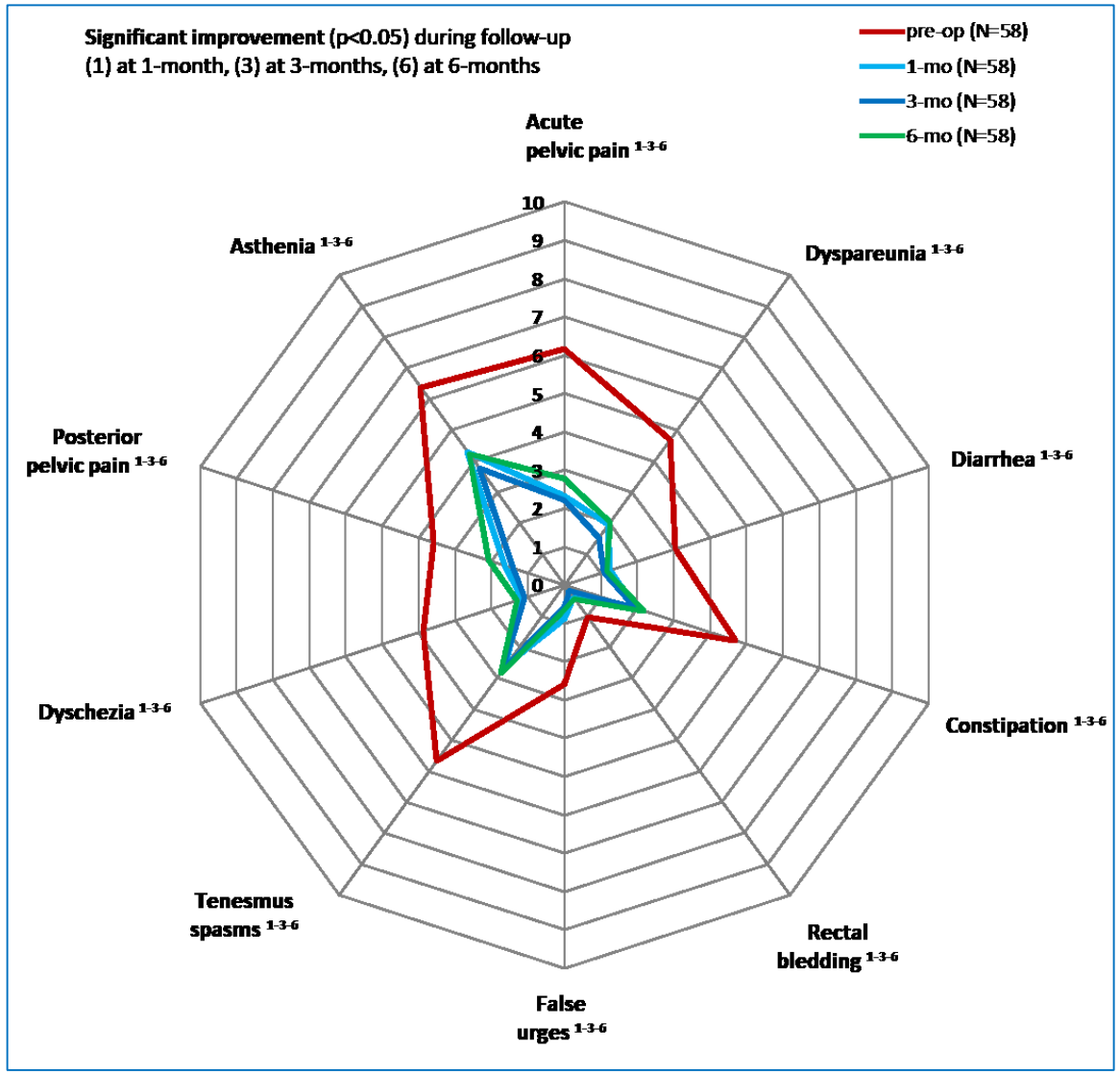
- **No Clavien grade 3**
- **One severe adverse event (grade 2), but no relationship with HIFU treatment**
- **No rectovaginal fistulae observed**

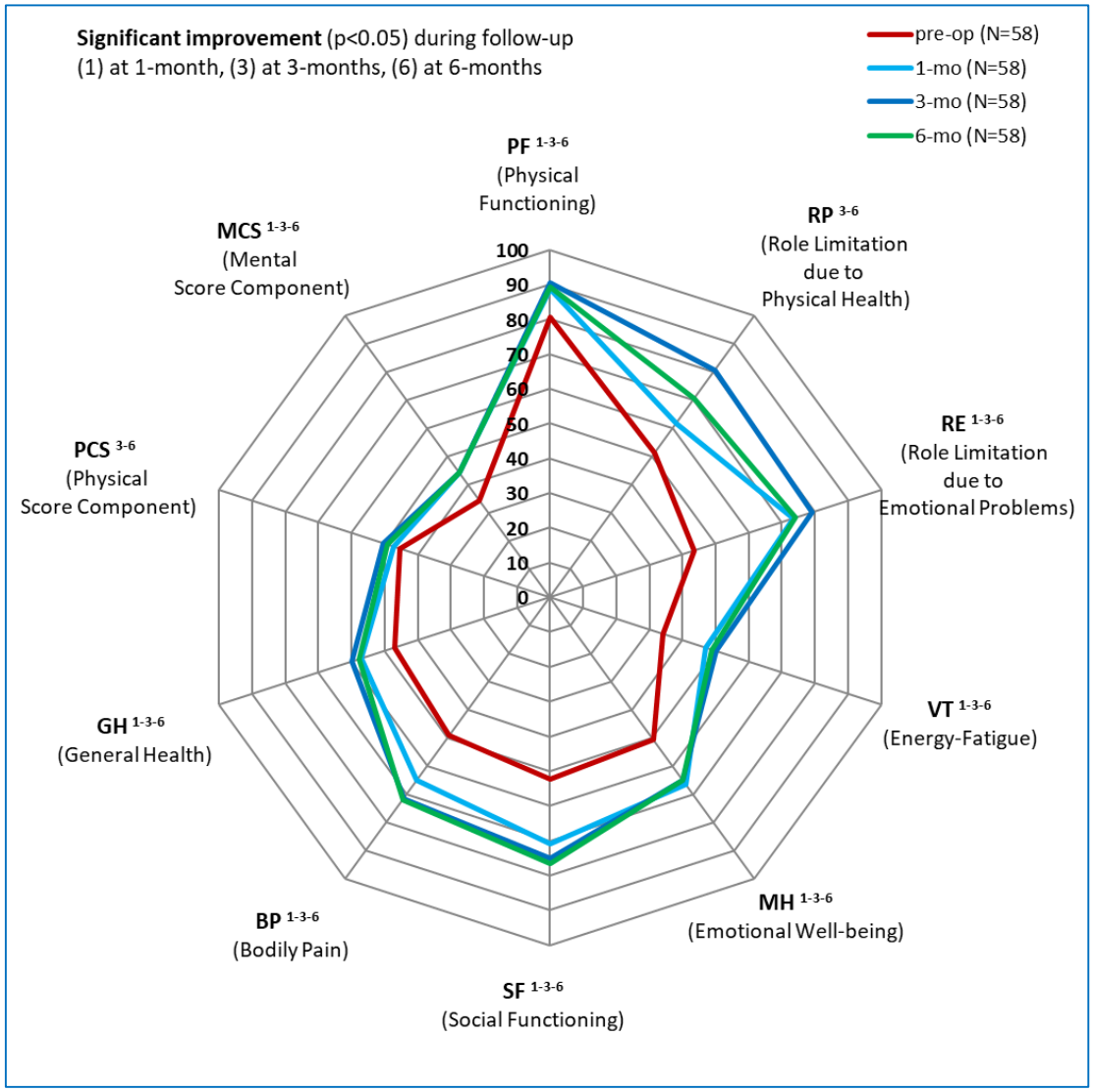
Clavien 3 postoperative surgery

Claviern 3a postoperative complication: 11	(3.0%)	14%
Claviern 3b postoperative complication: 43	(11.8%)	

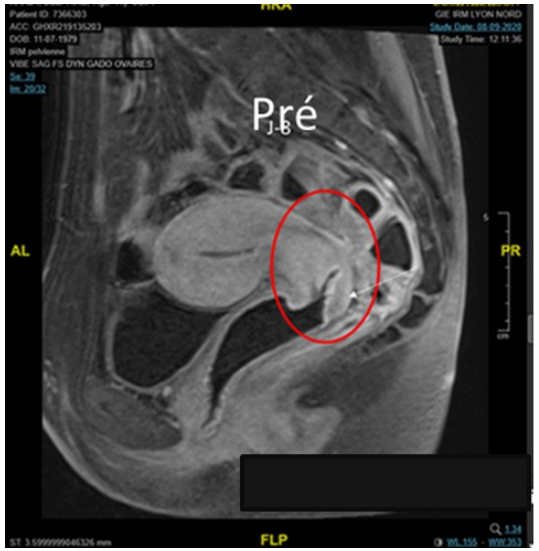
Roman H. Fertil Steril. 2018 Jan;109(1):172-178.

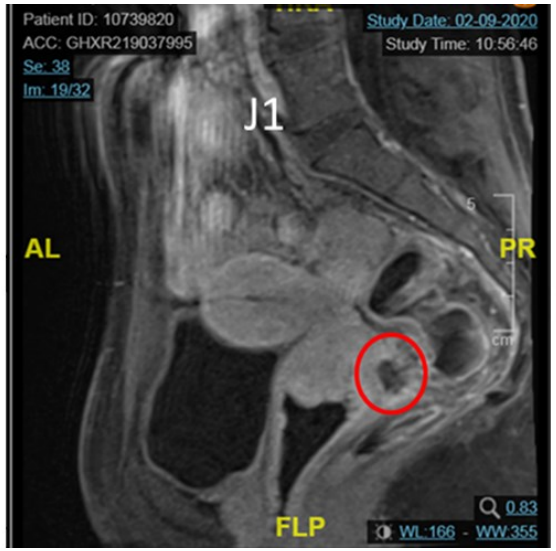
Improvement of symptoms & QOL

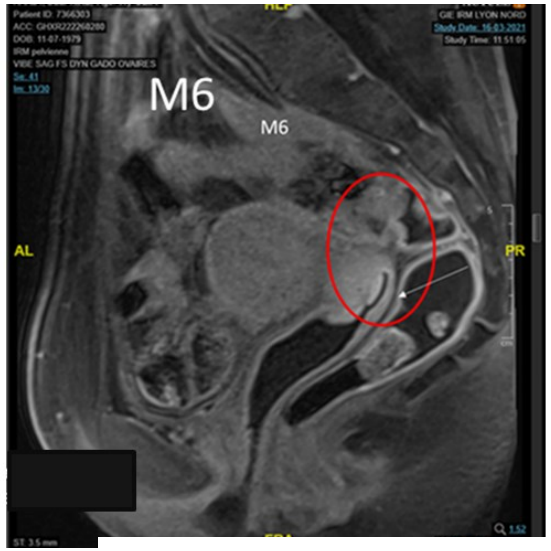




Assessment of the nodule volume at 6 months







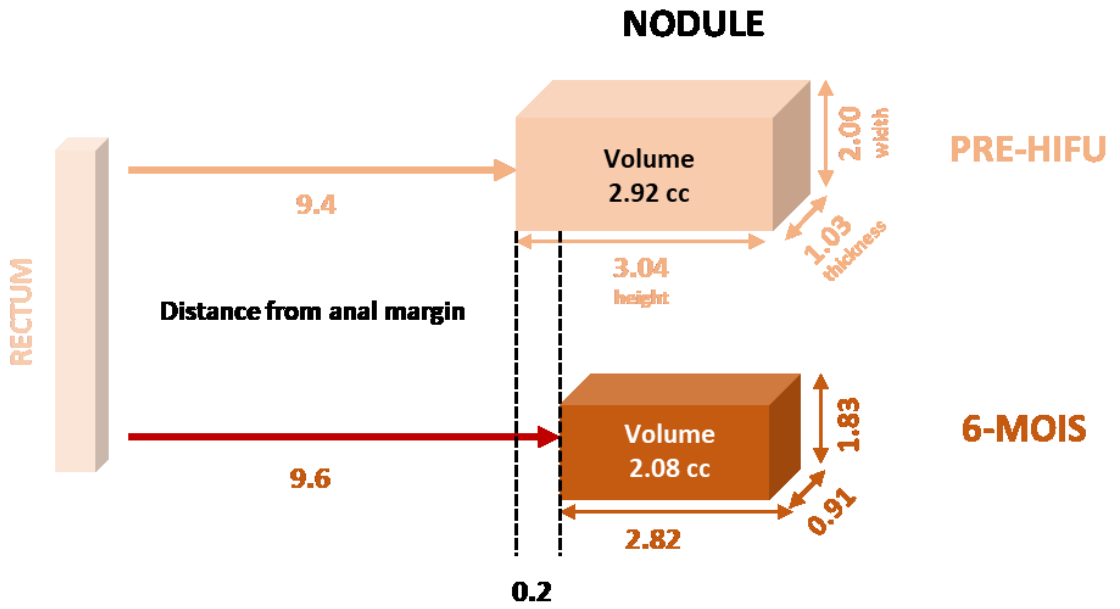
Methodology: an Independent & randomized review of pre- and 6 months post-treatment MRI was performed by a radiologist (N=57).

Volume decreased for **77% patients**

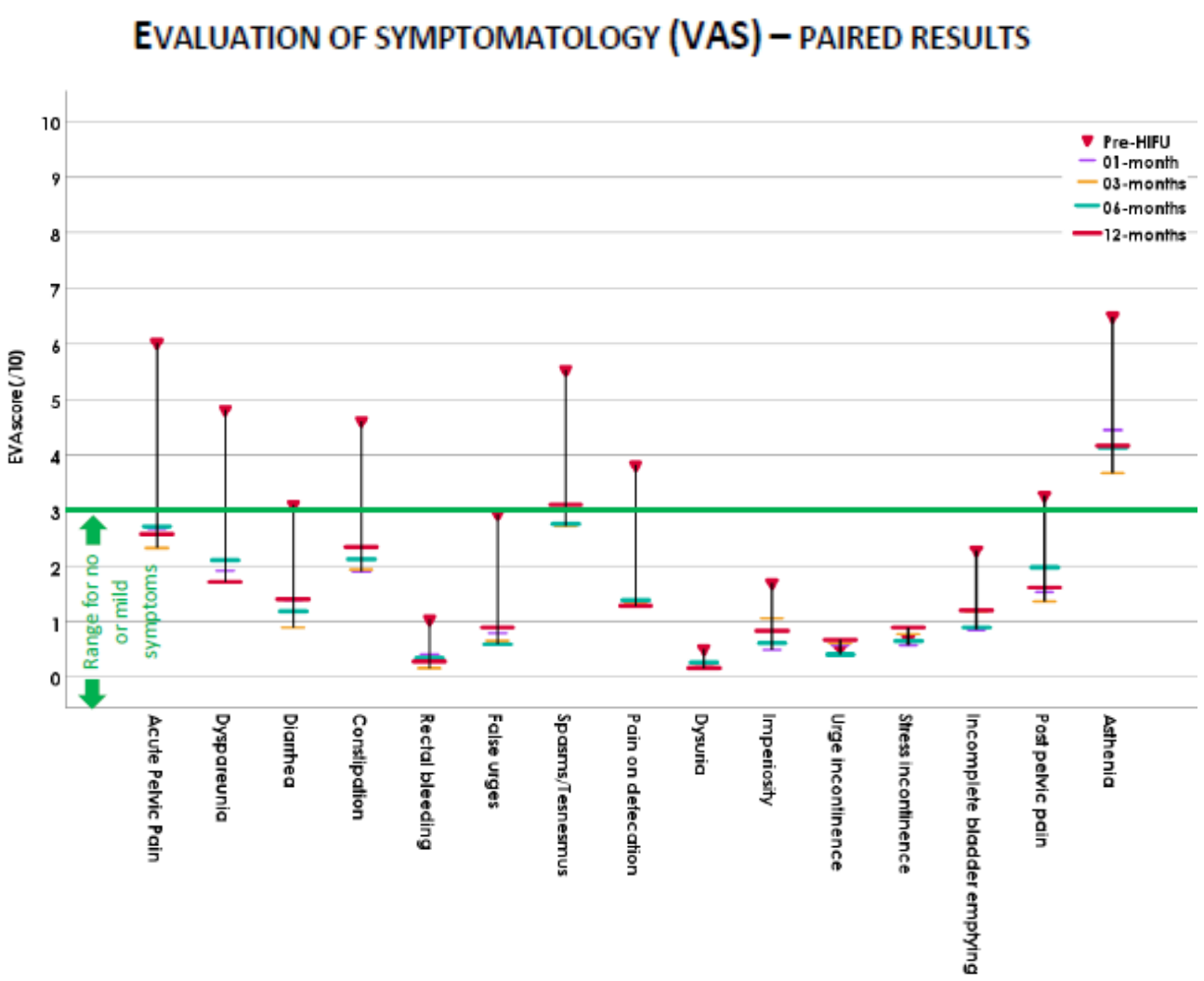
VARIATION OF VOLUME

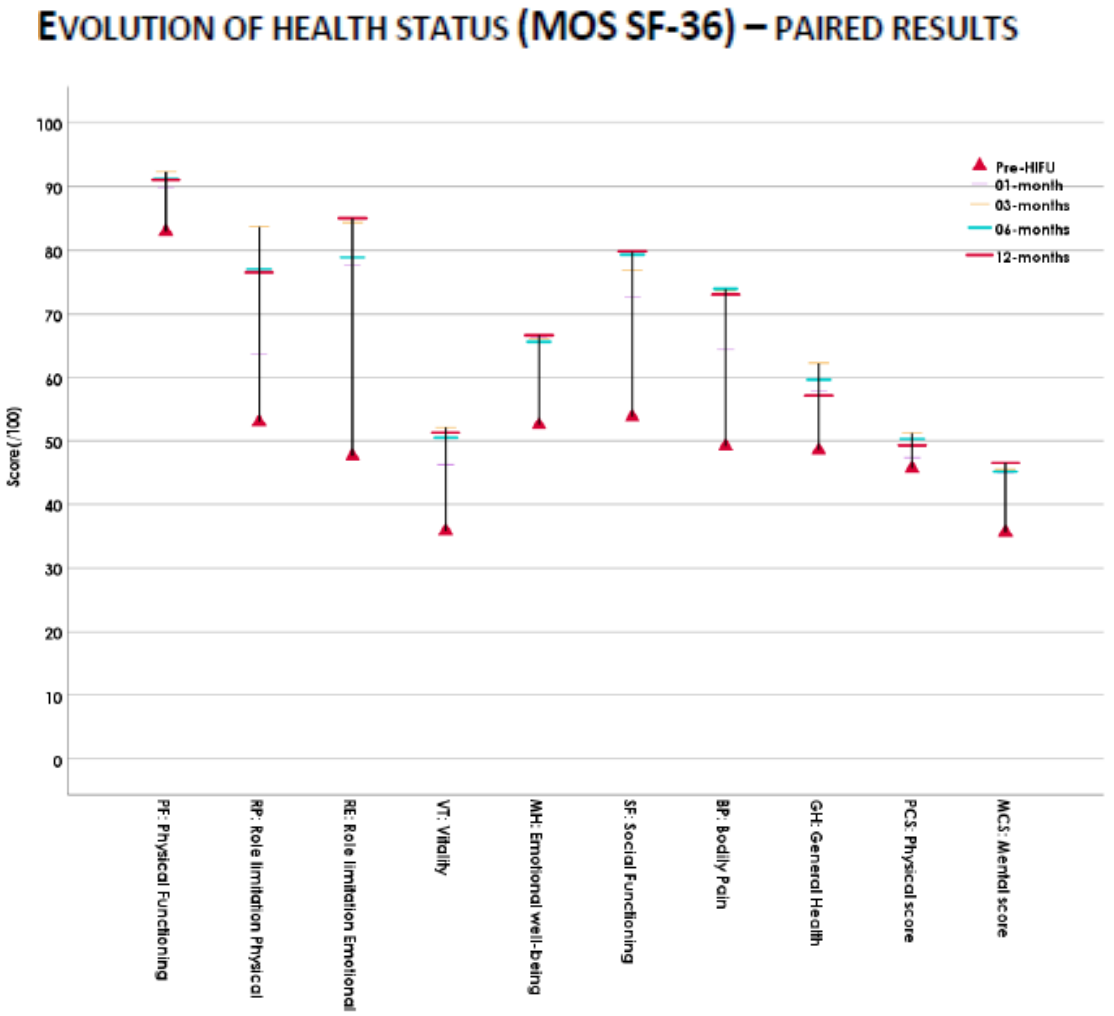
Mean variation: **-27%** (p<0.001)

Decreased volume:	**43/56 (77%)**
Increased volume:	**13/56 (23%)**



Endo Follow-up study (long term effects at 1 y – n=49)





Conclusion

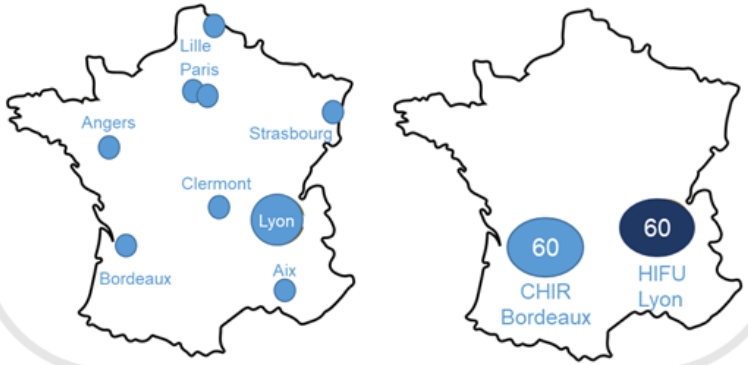
HIFU treatment of rectal endometriosis appears as :

- ✓ **A safe procedure compared with surgery** (no Clavien type 3 complication, no dysuria, no fistulae, low pain & medication level)
- ✓ **Efficient with a significant improvement of Digestive/Gynecologic symptoms and Health status, since the first month**
- ✓ **Cost-effective**: potential for outpatient procedure and fast recovery

2023-2024

Double blind ttt vs sham study (60 patients)

Comparative retrospective study surgery vs HIFU (60 +60 patients)



2024 - 2025

Dedicated probe (pre-clinical study)

Long terme follow-up study

HIFU combined with laparoscopy

Retreatment assesment

2025

FDA

4/3/24: **FDA Breakthrough Device Designation for Focal One in the Treatment of Deep Infiltrating Rectal Endometriosis.**

Equipe clinique endométriose – Croix-Rousse

https://www.brut.media/fr/health/un-traitement-par-ultrasons-contre-l-endometriose-au-chu-de-lyon

Bébé HIFU