

Multi modality imaging for prostate cancer targeting and treatment

Journée industrielle PRIMES, 12 juin 2014

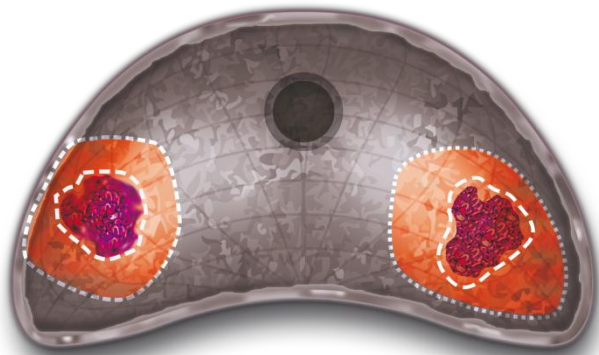
Nicolas Guillen, EDAP TMS France

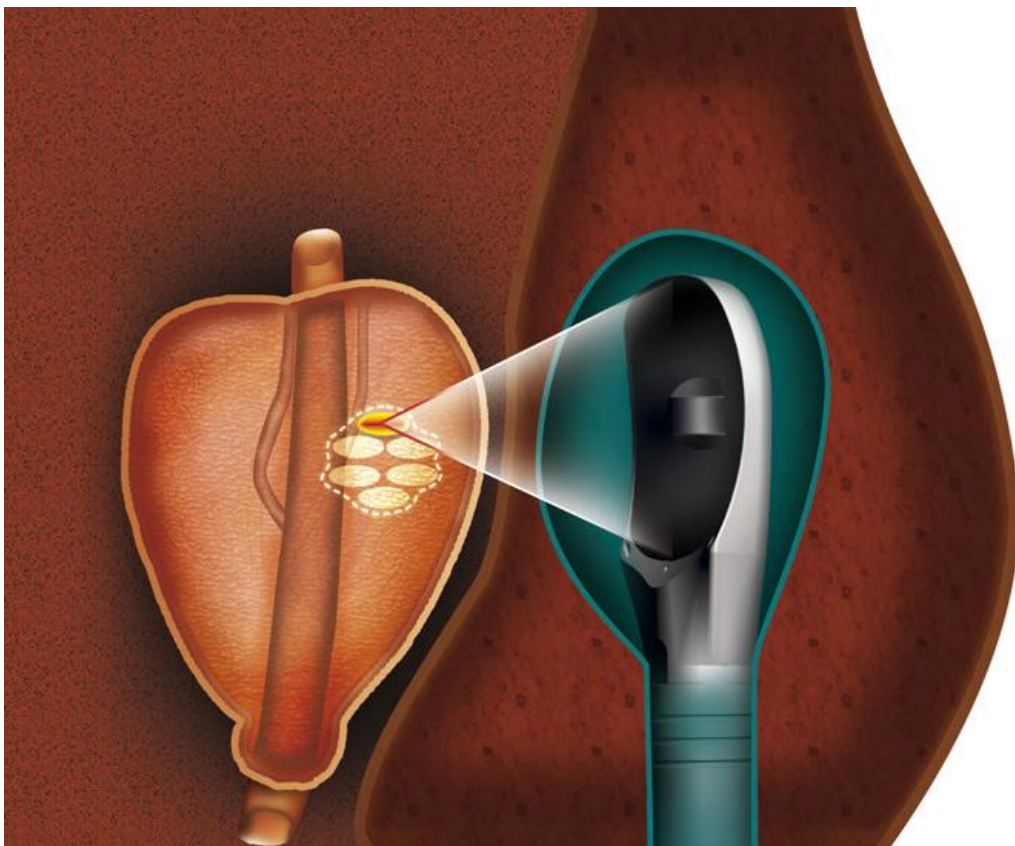
Robot-Assisted
Prostate Tumorectomy

Focal One



- Focal One® is the first device dedicated to focal therapy of Prostate Cancer combining the necessary tools to visualize, target, treat and validate the focal treatment.





- Transrectal route
- US guided therapy
- Treat by focusing acoustic waves into the prostate
- HIFU principle: Temperature increase in the targeted area up to 80-100° C in few seconds
- Result : coagulation necrosis = complete destruction of the targeted zone

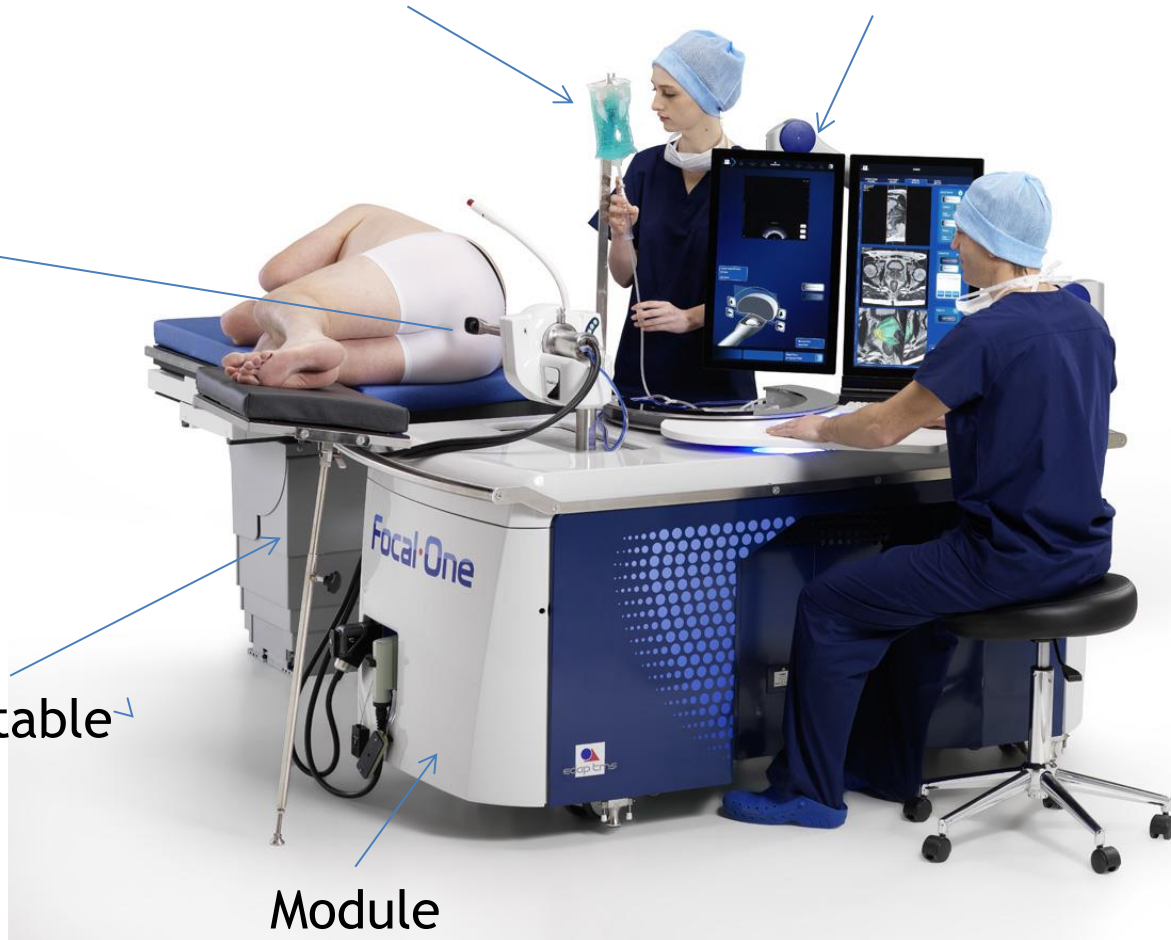
HIFU dynamic focusing probe

Consumable

Touch screens to
Localize / Treat / Validate



Imaging + Therapy

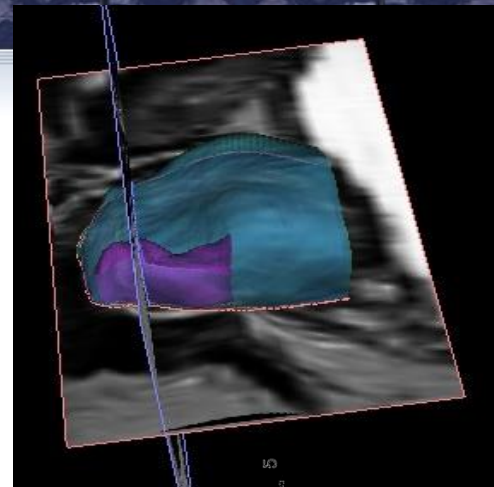


OR table

Module

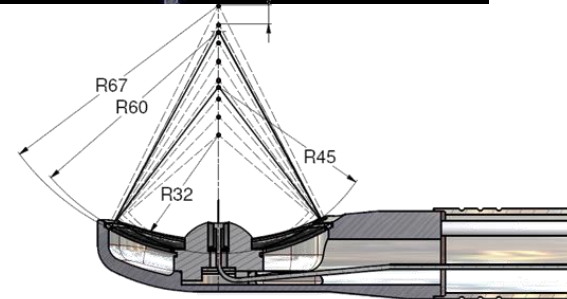
■ Pre-treatment imaging

- MRI Import (from CD/DVD or PACS)
- MRI fusion with Focal One RTUS
- Targeting of areas identified on the MRI



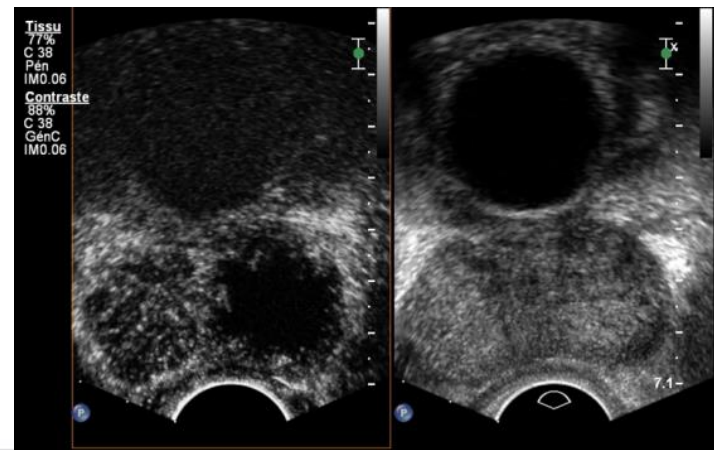
■ Treatment Process

- Precise treatment area contouring
- Accurate Dynamic Focusing HIFU



■ Post-treatment imaging

- Contrast Ultrasound Imaging
- Treatment Completion option



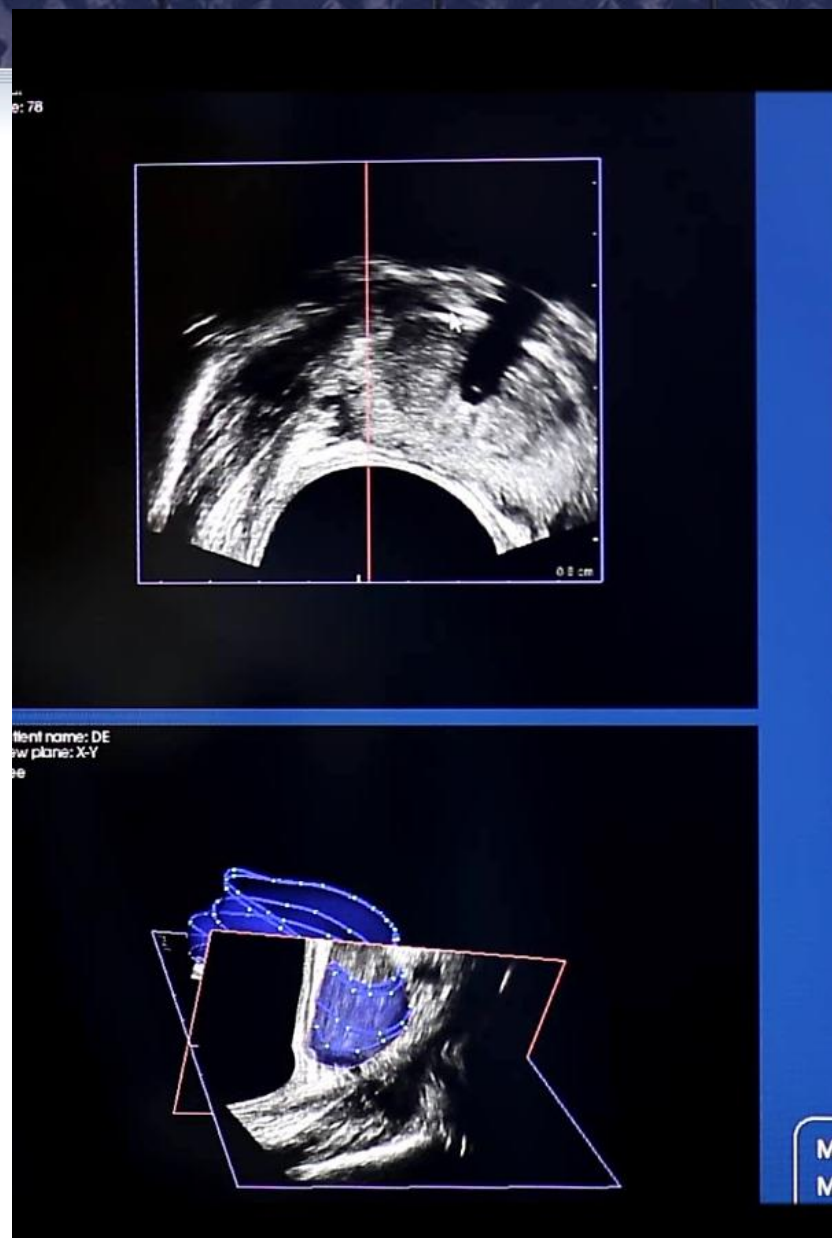
1- MRI

- Import MRI images from CD/DVD/USB/PACS (DICOM)
- Edit Contour of Prostate and Target areas
 - Load previously defined contour
 - Start contouring on Focal One



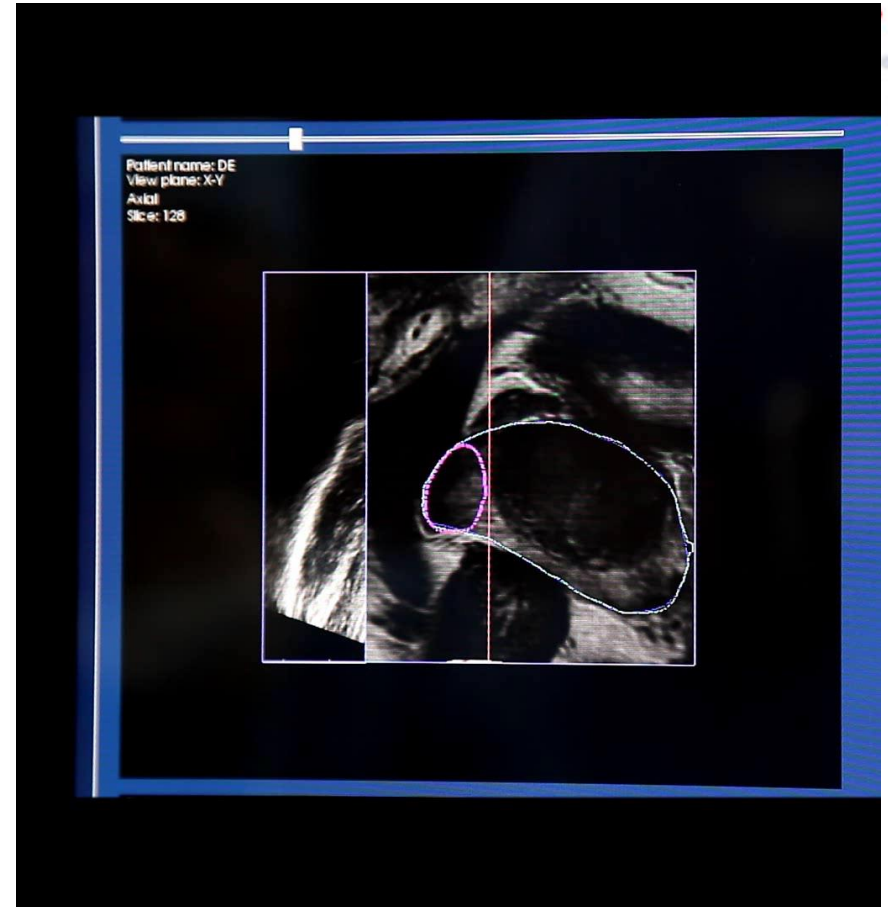
2- Real-time Ultrasound Volume

- Acquire Ultrasound Volume
- Edit Prostate contour

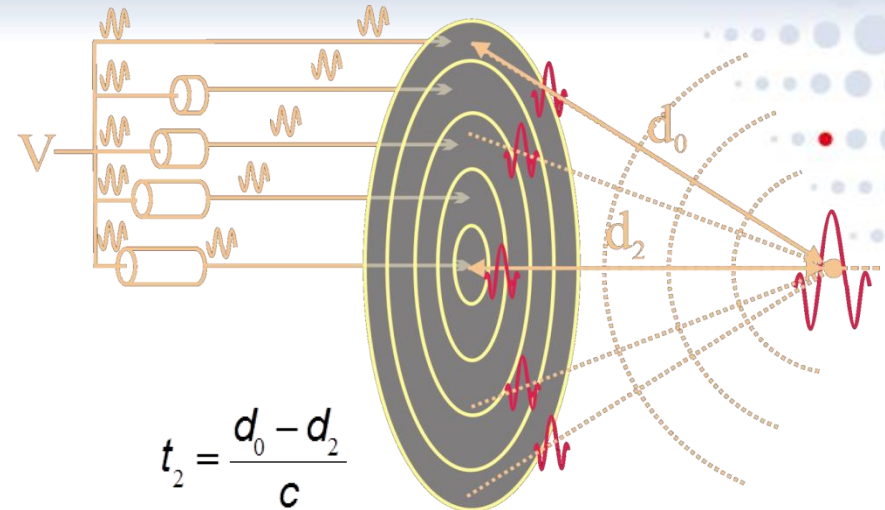
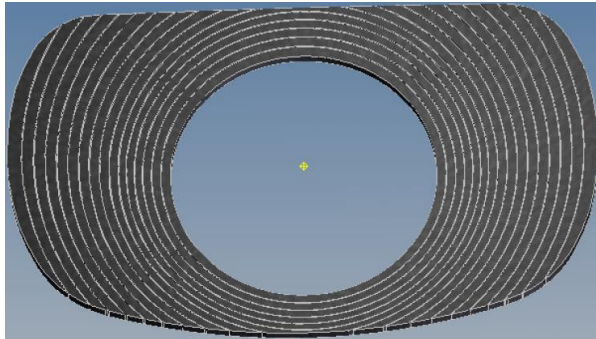


3- MRI / Ultrasound elastic fusion

- Automatic registration of 3D contours of prostate (3D translations and rotations)
- Elastic deformation of the MRI volume to match Ultrasound contours
- Transformation applied to MRI target areas to be visualized in the ultrasound referential



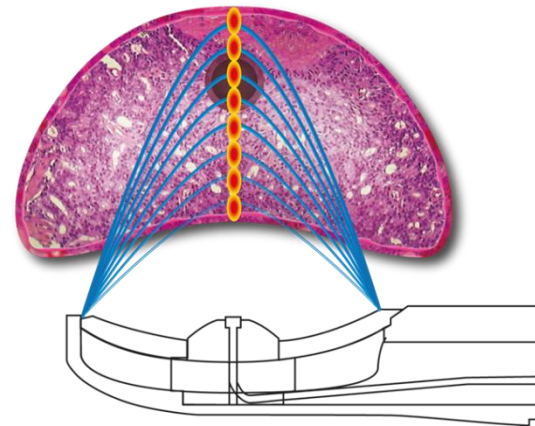
- 16 isocentric rings = 16 ways
- Equal surfaces
- Electronic displacement of focal point
- Natural focal point @ 60 mm



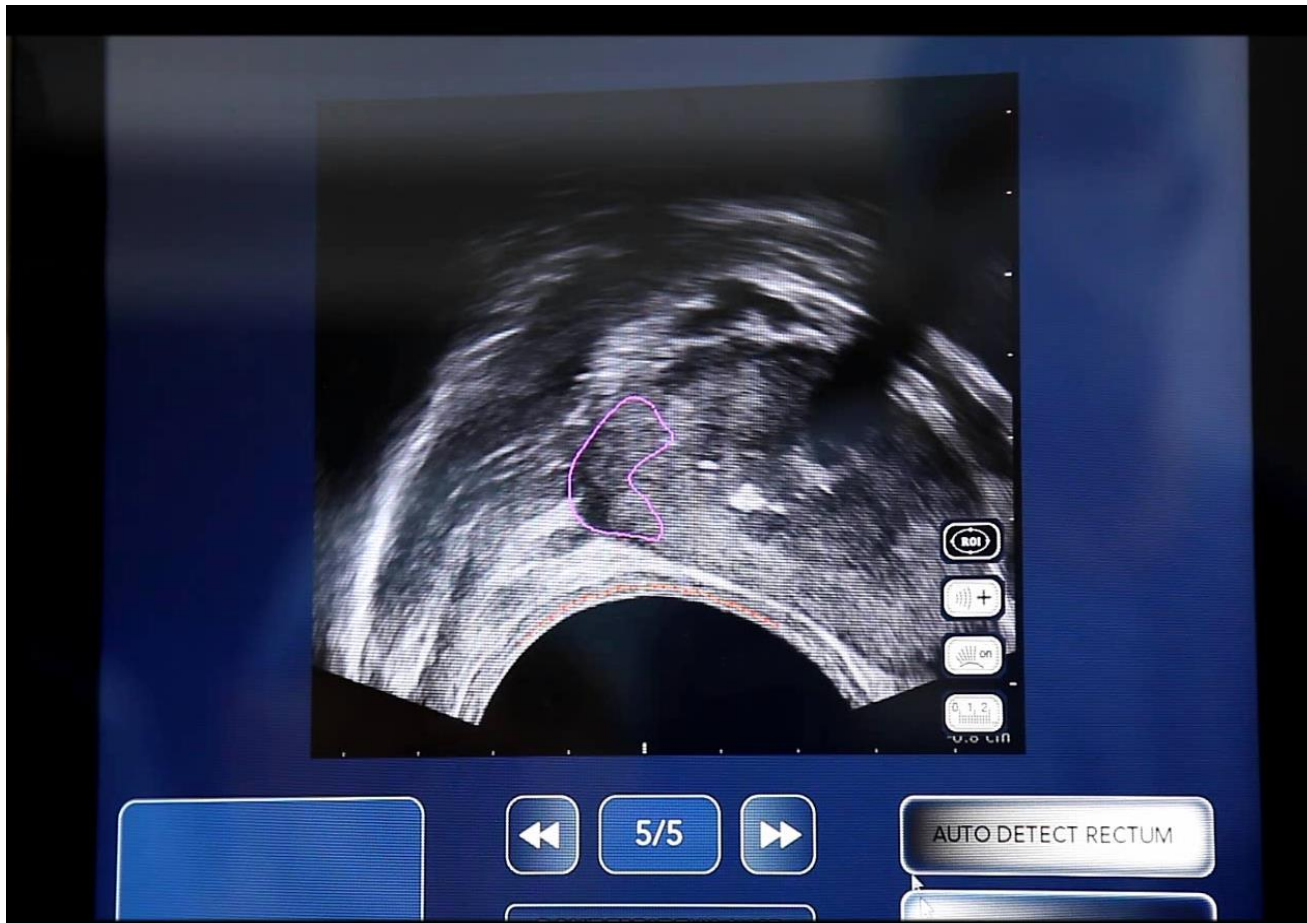
$$t_2 = \frac{d_0 - d_2}{c}$$

$$P(t) = P_0(t) + P_1(t - t_1) + P_2(t - t_2)$$

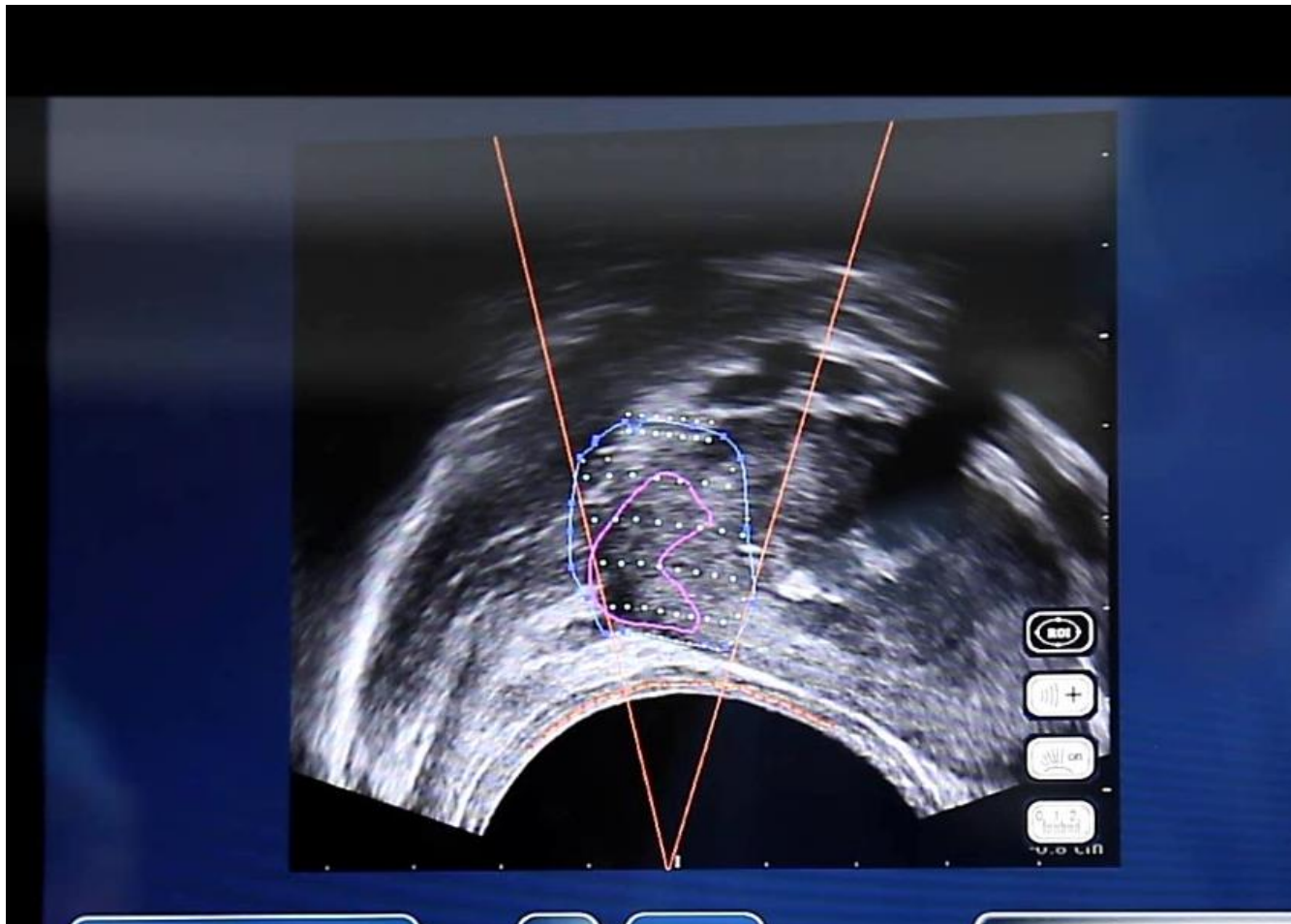
- 8 focal points from 32mm to 67mm ($\Delta f = 5$ mm)
- Unitary HIFU lesion stacking
- Shooting process : 1s ON / foci ; no OFF
- Unitary HIFU lesion height = 5mm
- Max Reachable depth (A-P Distance): 40 mm



- A safety margin is defined around the tumor boundaries.

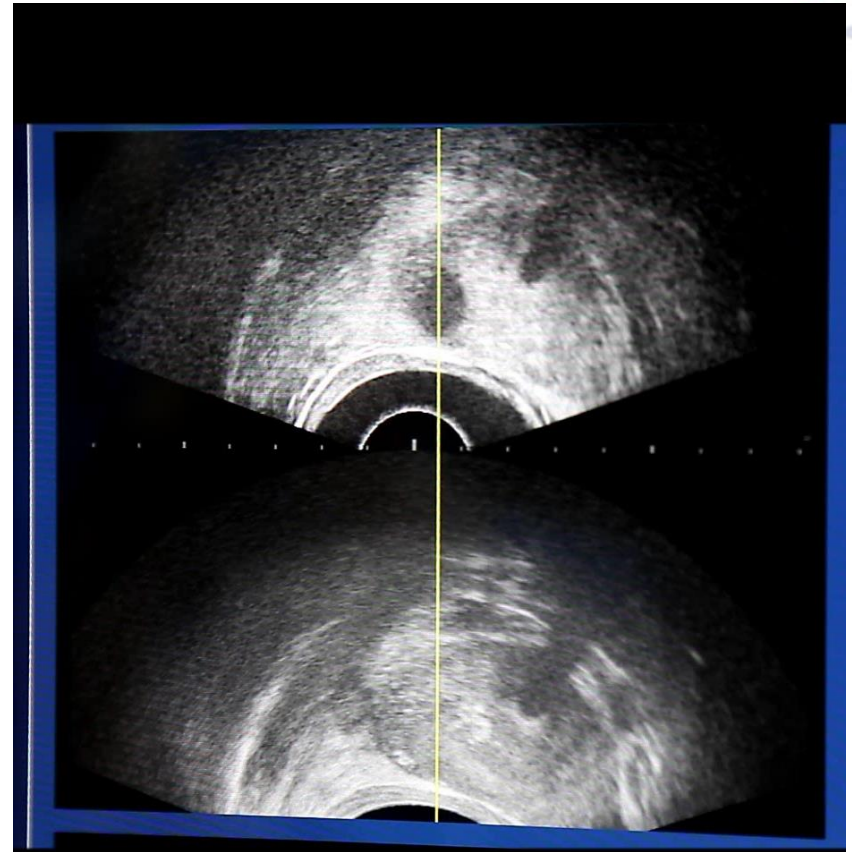


- Stacked and adjacent HIFU lesions fill the volume
- Stacking from anterior to posterior: 1s ON /foci ; no OFF
- Rotation of the transducer between stacking



Treated area validation

- Use of standard Contrast-Enhanced Ultrasound Technology
- Allows devascularization assessment
- Indicates need for retreatment of areas not completely devascularized



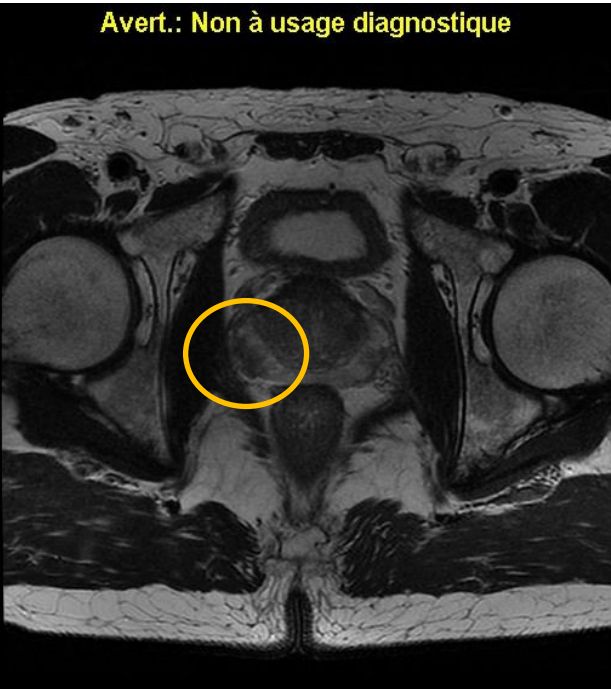
- **Pilot study was approved by Ethics Committee**
- **Inclusion criteria**
 - Localized prostate cancer
 - PSA < 10 ng/ml
 - Gleason score 6 or 7(3+4)
 - Monofocal tumor precisely localized with MRI and targeted biopsies

- HIFU treatment process was realized with the Focal One device using a 6 mm safety margin around the tumor
- Contrast - enhanced MRI is performed at day 2 after HIFU
- Control biopsies are achieved one month after HIFU inside and in the rim of the treated area guided with contrast-enhanced Ultrasound imaging

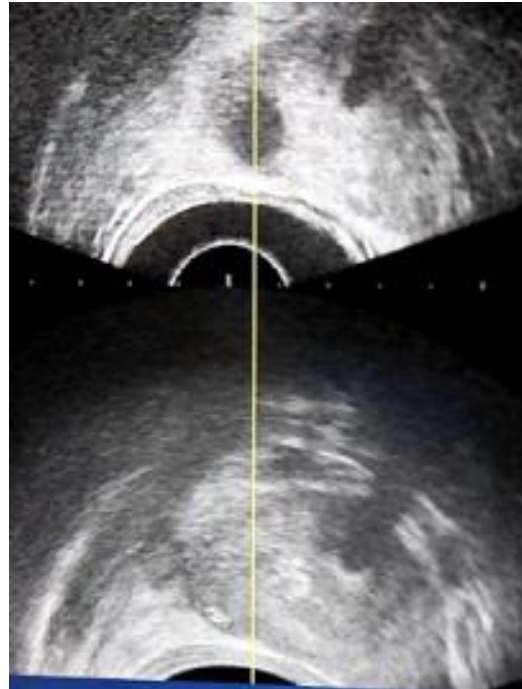
- 10 patients
- Mean age: 65.8 ± 5.5 years
- Stage: T1=9 patients T2a=1patient
- Gleason score:
 - 6=7 patients
 - 7(3+4) =3 patients
- PSA value: 4.5 ± 3.7 ng/ml
- Mean Prostate Volume: 50 ± 23 cc

- Mean treated volume: 14 cc (7.3-20.4) 28% of prostate gland.
- Nadir PSA value: 3.5 ± 2.0 ng/ml
- In all patients complete destruction of the targeted tumor was demonstrated
 - using contrast enhanced ultrasound imaging performed during the HIFU session, And contrast enhanced MRI
 - And targeted biopsies inside the treated area performed day 30 after the HIFU session
- Side effects
 - Incontinence: 0
 - Partial loss of potency (IIEF <17): 2 patients

Avert.: Non à usage diagnostique



T2 Image MRI before
HIFU



Intraoperative
ultrasound images
study

Avert.: Non à usage diagnostique



Contrast enhanced
MRI day2 after HIFU

Biopsies were all negative

- Focal One is able to achieve complete destruction of prostate tumors using an elastic magnetic resonance-ultrasound (MR-US) registration system for tumor location, treatment planning, HIFU ablation and devascularization verification.
- Multicenter trial is in progress