Robotics & Computer Aided Surgery in Urology : From Lab to O.R.

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Contents

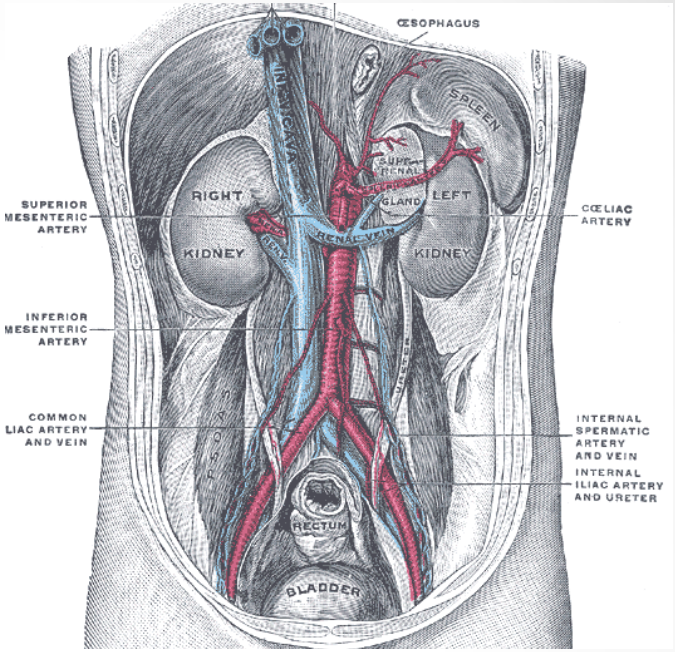
- Introduction
  - Who I am and Why I am here ;-)
  - Urology
- Kidney diseases
- Prostate diseases
- Incontinence
- Conclusion

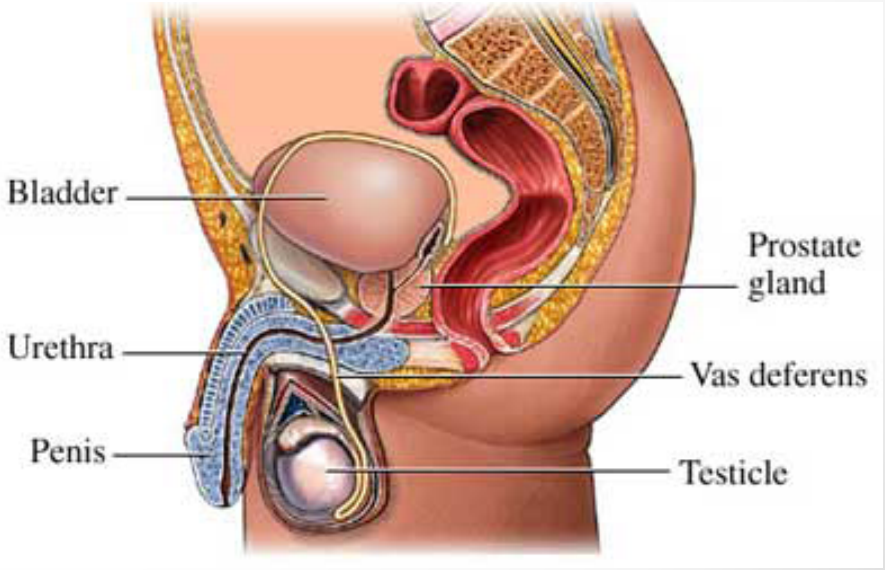
Who I am ?

Thanks to :
G. Morel, J. Troccaz, P. Cinquin, A. Leroy, M. Baumann, V. Daanen, B. Rosa, C. Torterotot, J. Szewczyk, A. Bonvillain, S. Basrour, H. Lamaroui, Y. Payan, …

Urology

- **Medical** and **Surgical** specialty focuses on :
  - Urinary tracts
    - kidneys
    - Uretere
    - Bladder
  - of males and females,
  - Reproductive system of males :
    - Prostate
    - Testicles



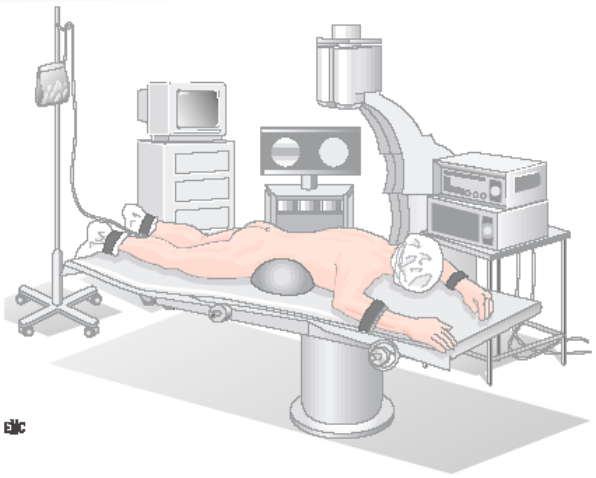


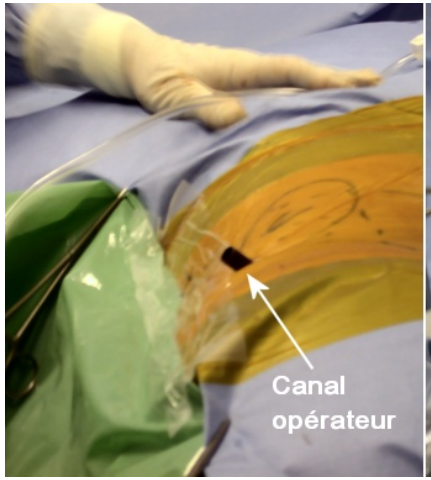
How did I get Here ?

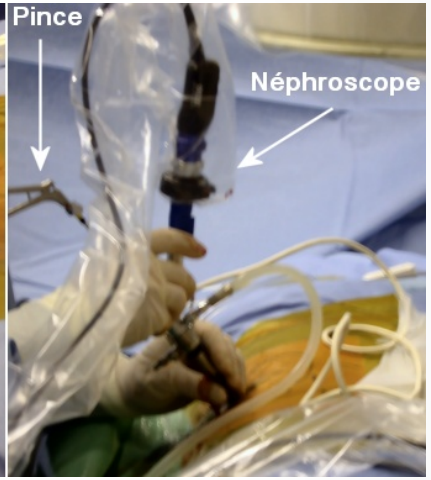
10 years ago : Resident of surgery in French Polynesia

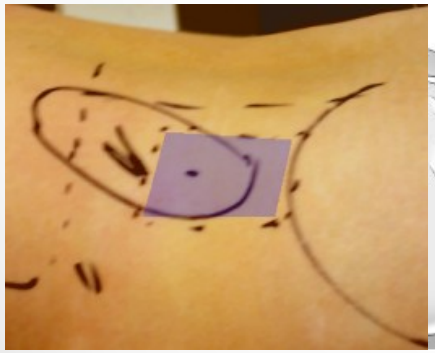
How did I get Here ?

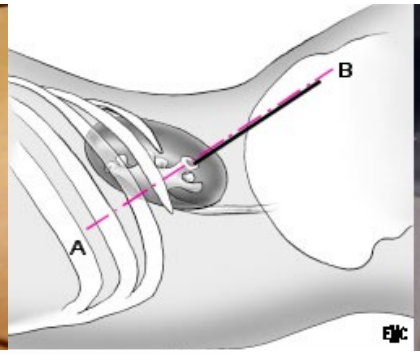
- PCNL : First step -> Kidney puncture

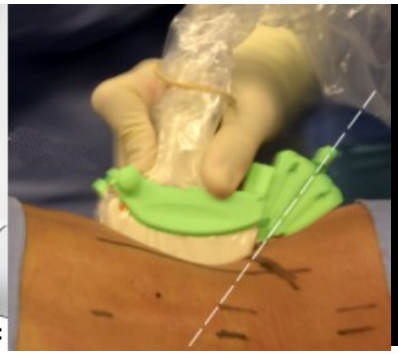


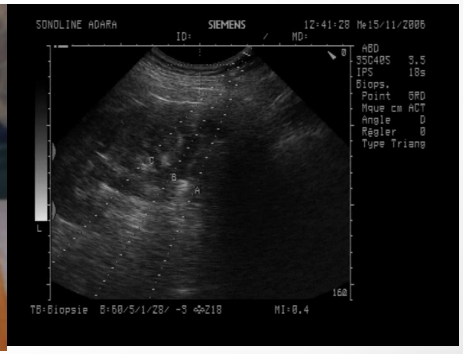












How did I get Here ?

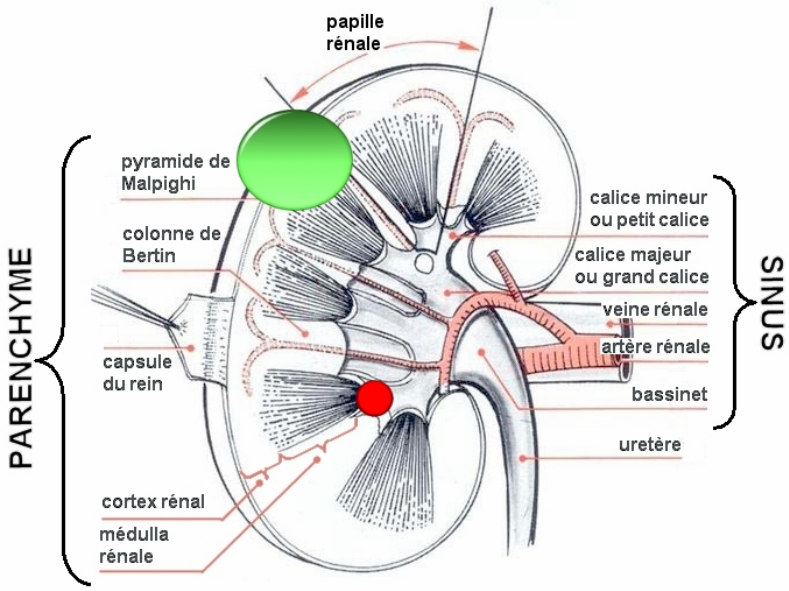
- On a patient : after more than 20 attempts -> failed
- Patient went to Paris
  - Intervention was a success without any problem…

*-> I had a **clinical need** for a device to help me to do the job…*

How did I get Here ?

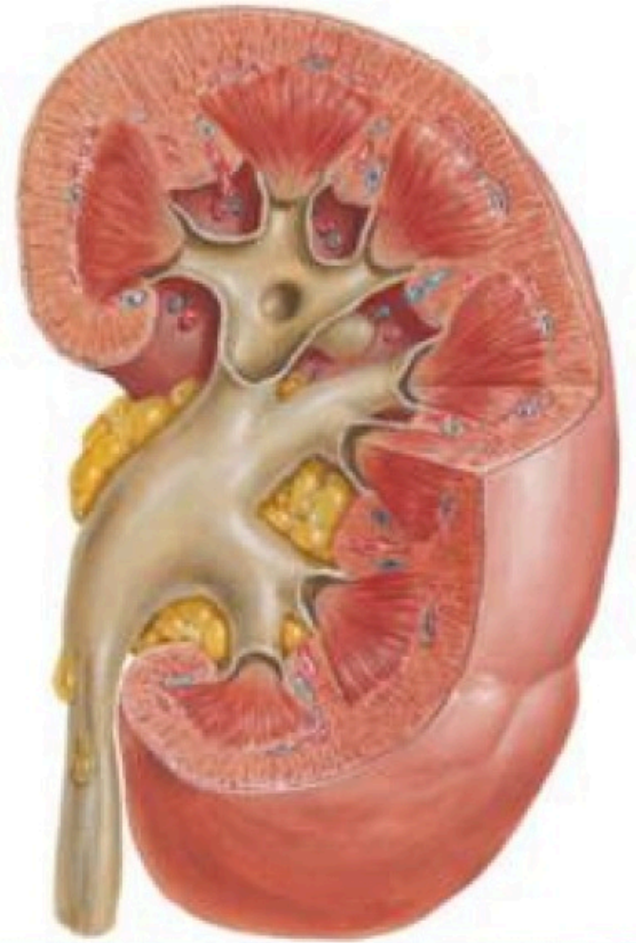
- I asked to my colleagues
- I searched on PubMed
  - http://pubmed.com
- I searched on the internet
- I looked for a research lab to work on the idea…

Diseases of the Kidney



1. Stones
2. Cancer

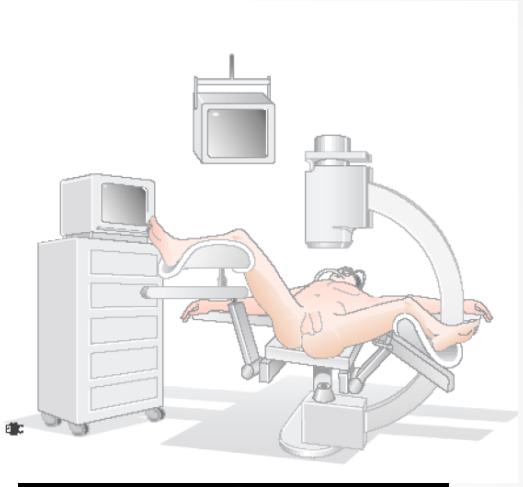
Stones



Stone > 3 cm -> PCNL

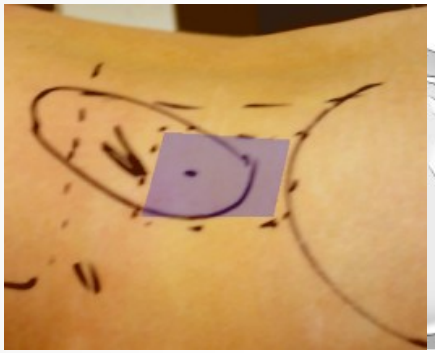
Percutaneous Acces for PCNL

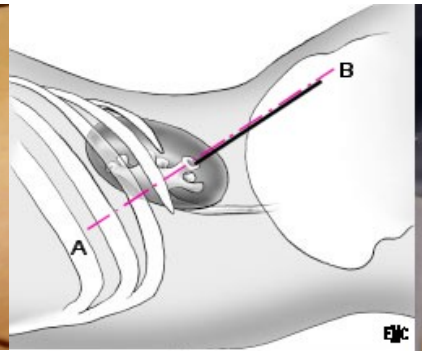
- Intervention with 2 steps :
- First step :
  - Gynecological position
  - Ureteral stent
    - Dilatation of the calix
      - Contrast agent

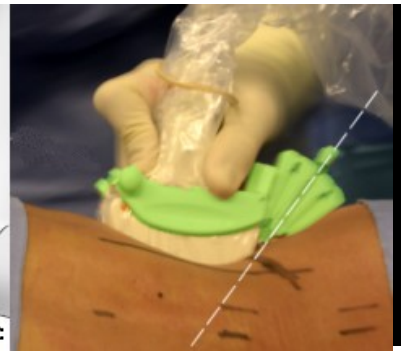


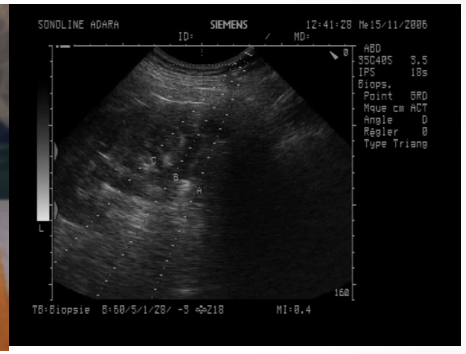
Percutaneous Access for PCNL

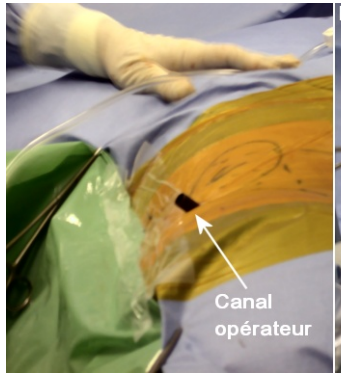
- Second step :
  - Prone position
  - Puncture with US and Fluoroscopy

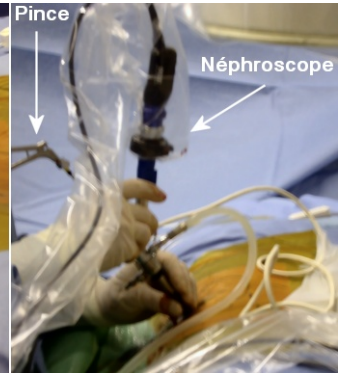












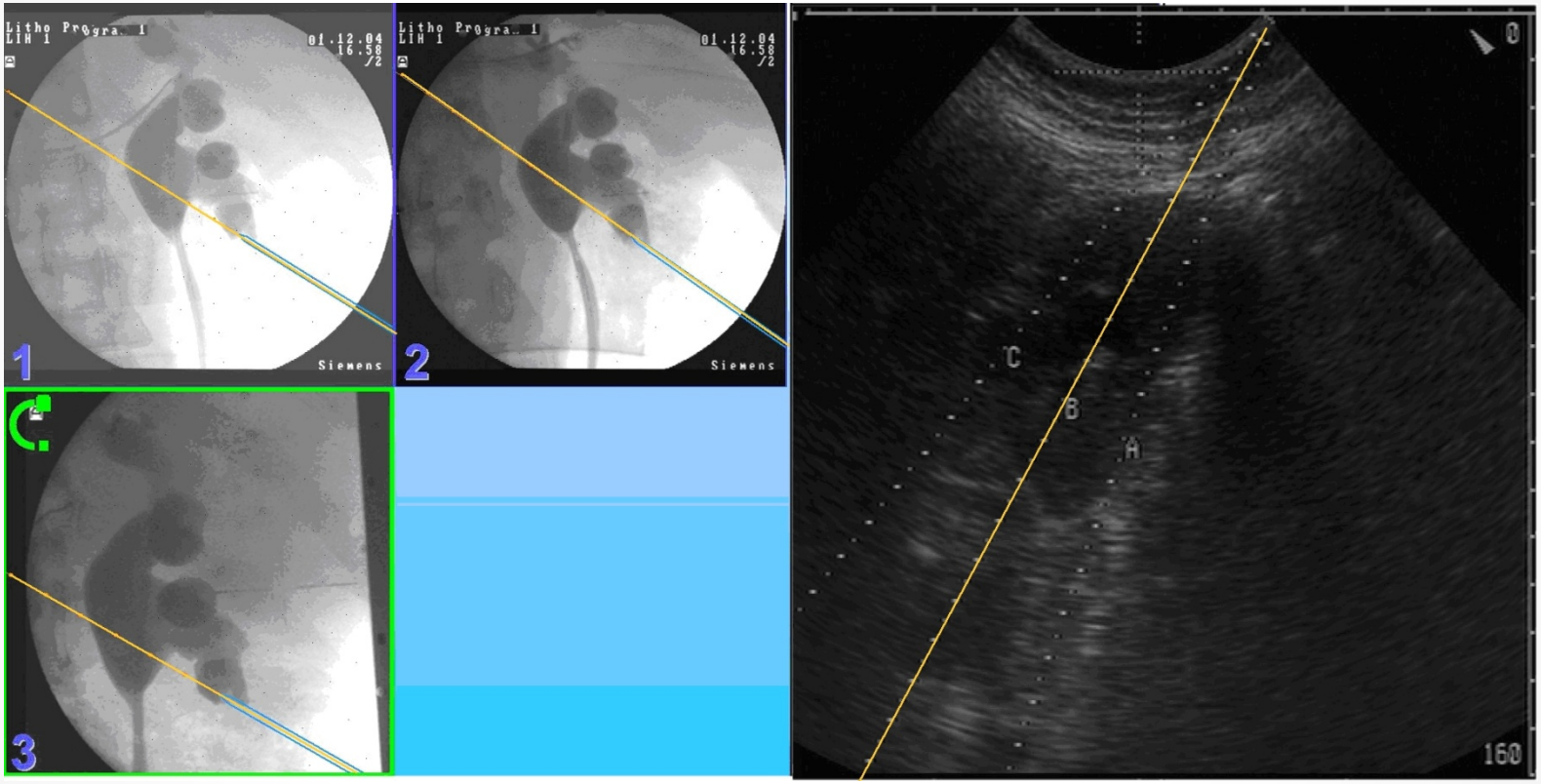
Lee, W.J., et al., Emergency percutaneous nephrostomy: technical success based on level of operator experience. J Vasc Interv Radiol, 1994. ***5****(2): p. 327-30.*

Target Characteristics

Distance	70 mm
Size	5-10 mm
Motion	30 mm
Speed	9 mm/s
Time	20-90 s

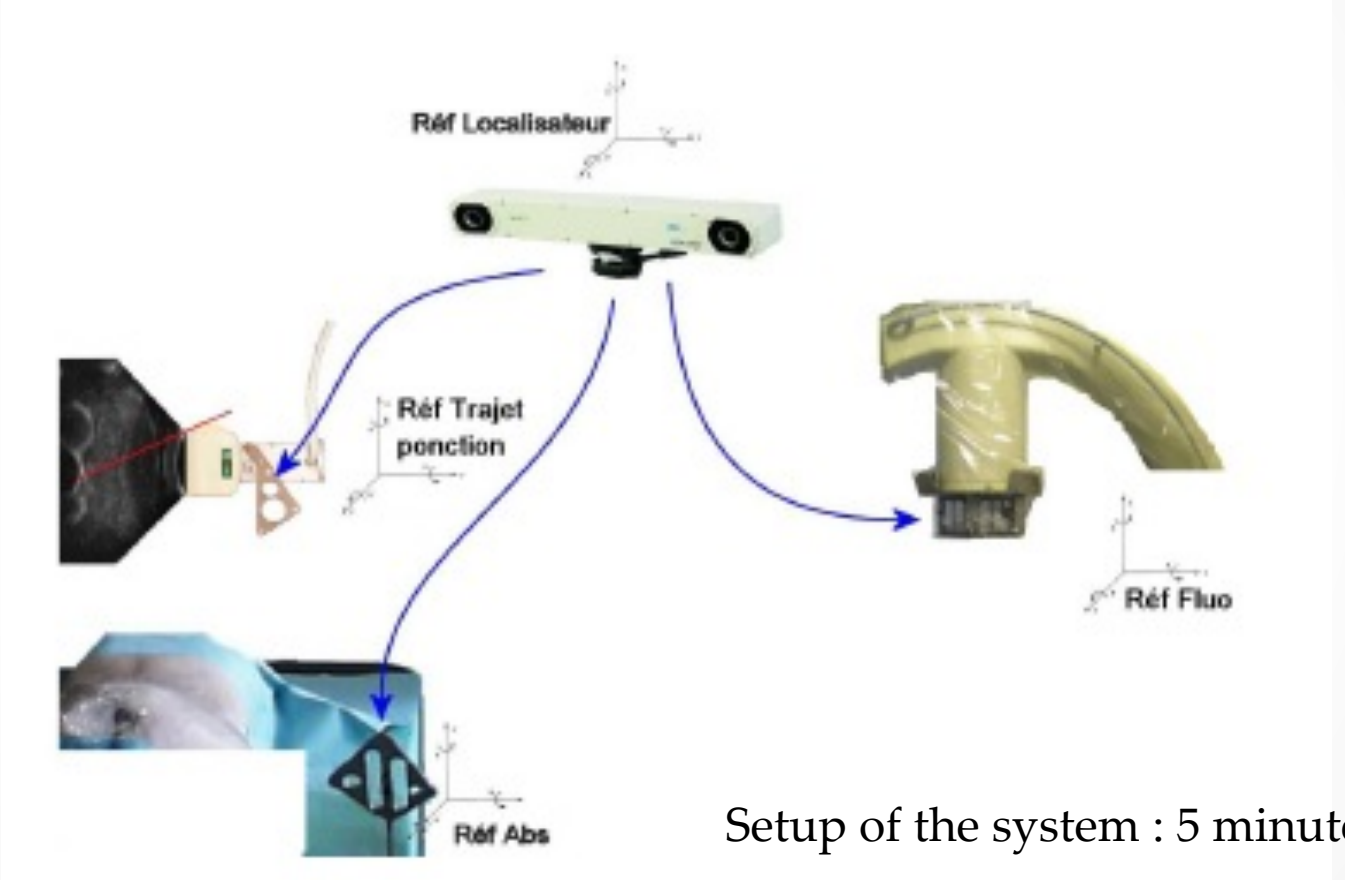
[Schwatz94]

Projection of the Ultrasound Puncture Tract onto Fluoroscopic Images



Mozer, P., P. Conort, A. Leroy, Y. Payan, J. Troccaz, E. Chartier-Kastler, et al. "Aid to percutaneous renal access by virtual projection of the ultrasound puncture tract onto fluoroscopic images." J Endourol 21, no. 5 (2007): 460-5.

Projection of the Ultrasound Puncture Tract onto Fluoroscopic Images



Setup of the system : 5 minutes

Projection of the Ultrasound Puncture Tract onto Fluoroscopic Images

- Movie

Projection of the Ultrasound Puncture Tract onto Fluoroscopic Images

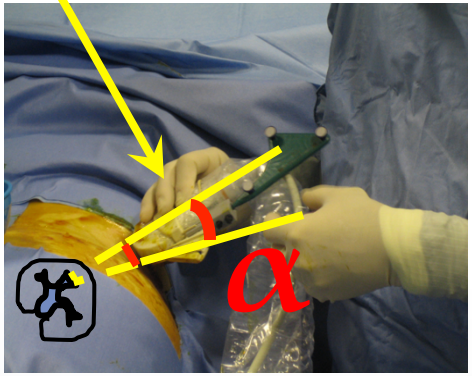
- Prospective study (IRB approved)
- Navigation System :
  - Koelis company (Grenoble, France), CAMI (Grenoble Spin off)
  - CE marked, Not FDA approved
- Surgeons :
  - Senior : One expert (more than 800 PCNL performed)
  - Junior : One young resident (no skill for the procedure)

Projection of the Ultrasound Puncture Tract onto Fluoroscopic Images

Junior

-Without

-With



Senior

-Without

-With

Projection of the Ultrasound Puncture Tract onto Fluoroscopic Images

- Clinical validation
  - Safety of the procedure
  - Efficiency for the EXPERT to reach the target with the navigation
    - Number of attempts
    - Radiation exposure time
- Comparison on the same patients :
  - NT axes orientation W/O & W the system
    - A Junior (resident)
    - A Senior (expert)

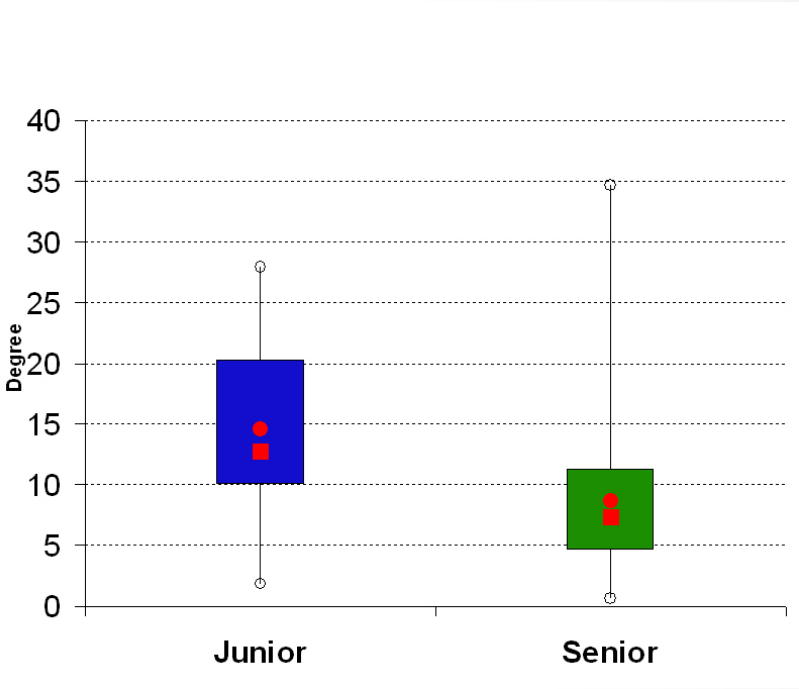
Projection of the Ultrasound Puncture Tract onto Fluoroscopic Images

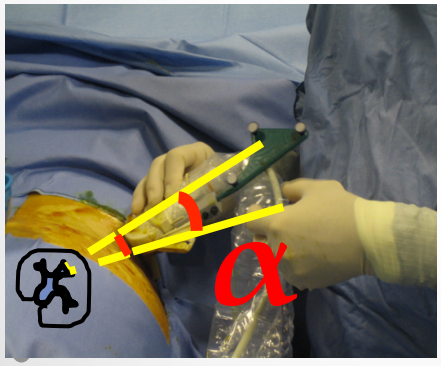
-- results --

- 20 patients/21 targets:
  - Target surface = 158 mm2 (30 - 311)
  - 17 targets reached on first attempt
  - 4 others : 2 trials were necessary
    - Deformation of the needle
- Fluoroscopic time to caliceal access
  - Average : 12 ± 10 sec (5 to 30)
- All PCNL were performed without any complication related to the puncture

Results : Orientation W/O & W

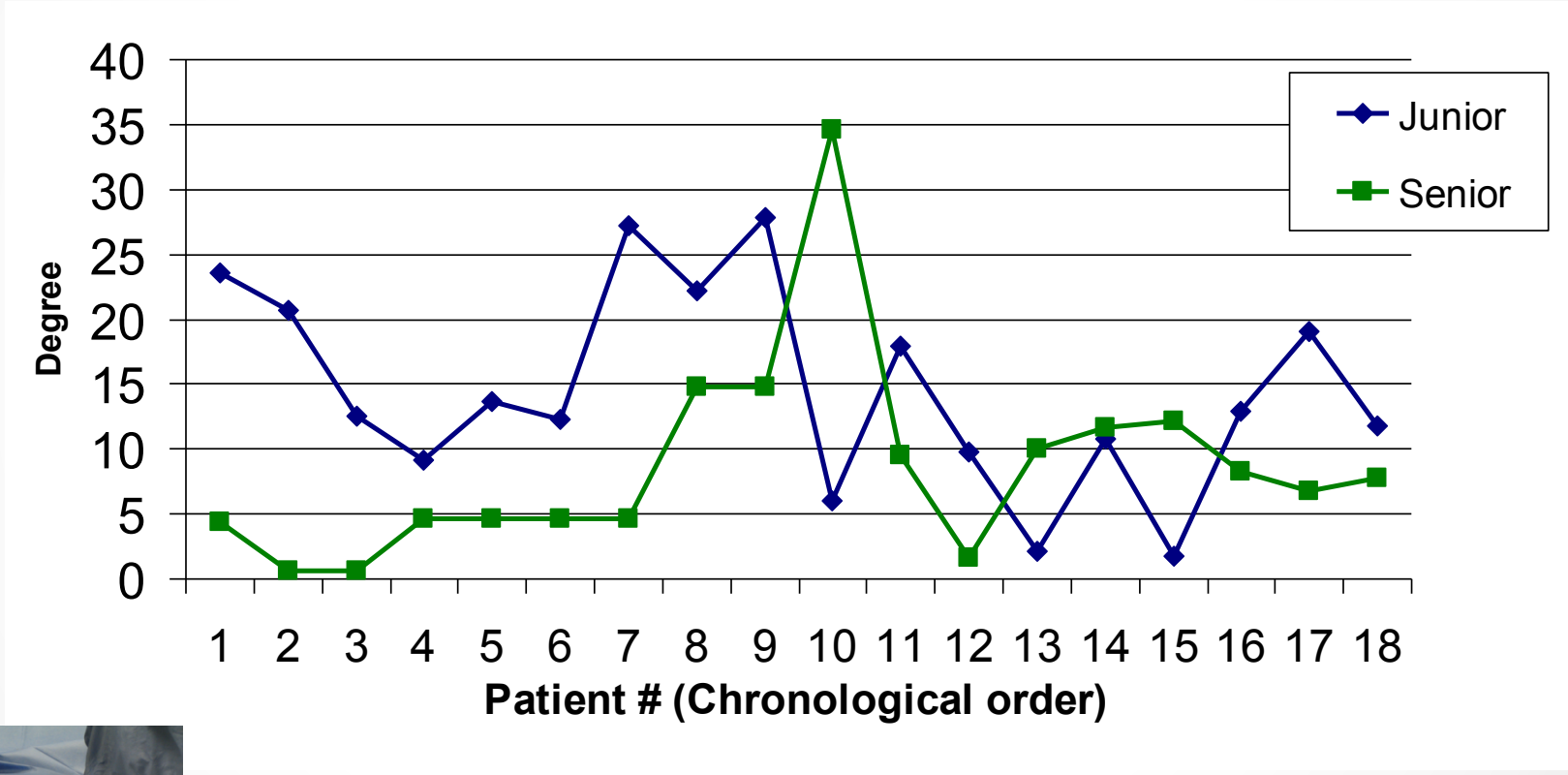
Delta Angle (degree)	Junior	Senior
Average	14.5	8.7
Mean	12.7	7.3
STD	7.7	7.8

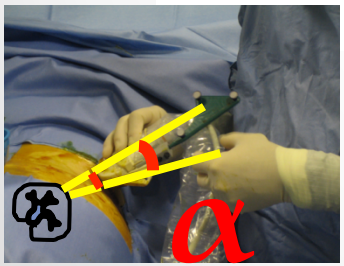




Student test – $p < 0.001$

Results





Aid to percutaneous renal nephrolithotomy (PCNL): computerized fluoro-assisted real time ultrasonic renal puncture.
P. MOZER, P. CONORT, A. LEROY, M. BAUMANN, G. CHEVREAU, J. TROCCAZ, E. CHARTIER-KASTLER, F. RICHARD.
AUA Congress, Orlando, Annual Meeting. 2008.

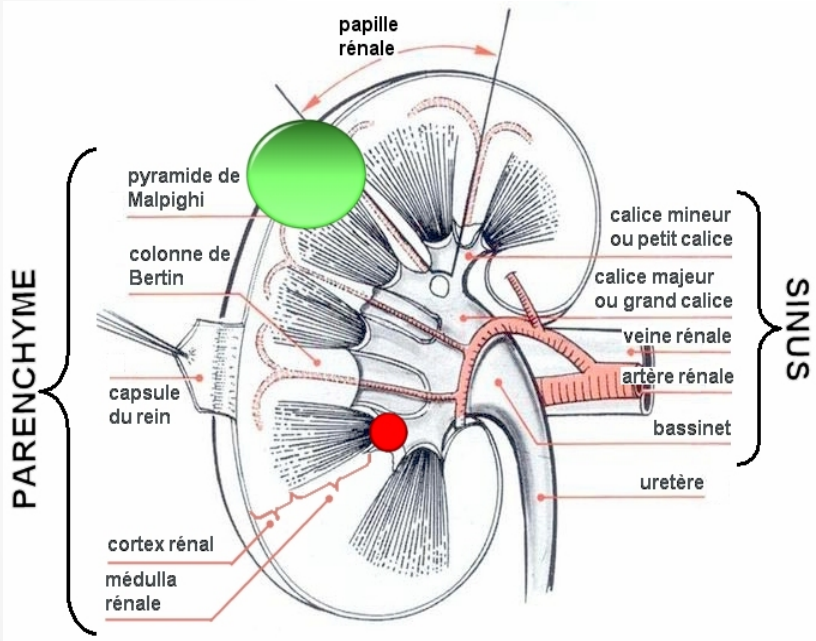
Discussion

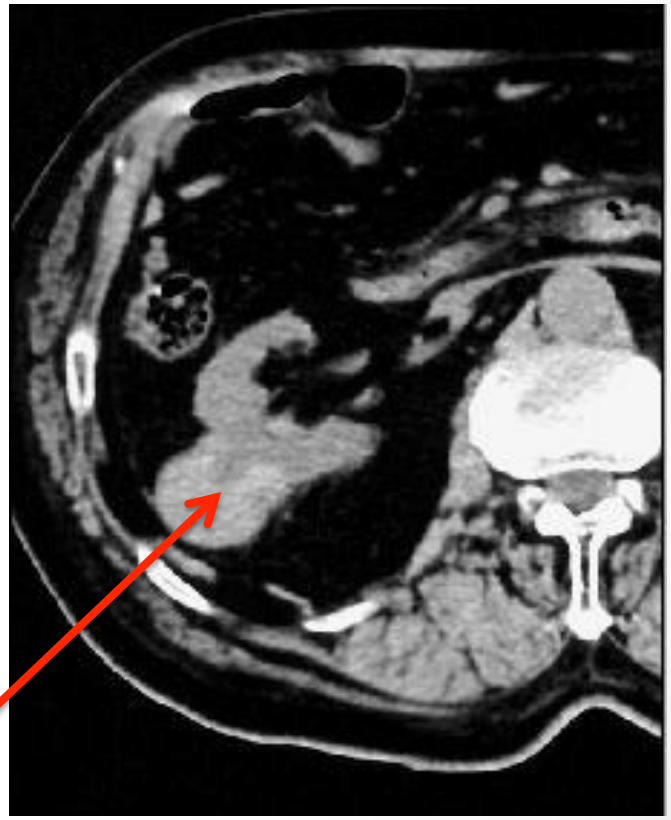
- Kidney movements
  - Reproducible
  - US real-time visualization
- Deformation of the needle
  - Visible in US images
  - Modifications of the US guide

Conclusion on fluoronavigation

- Fusion of ultrasound and fluoroscopic images seems to allow an accurate puncture
- Navigation seems to reduce radiation exposure
- Navigation seems to be an excellent tool for training
  - Increases the confidence in ultrasound images
- Navigation seems useful for experts, too
- Multicenter study is needed but only 2 500 PCNL performed per year in France…

Puncture with CT scan guidance





Needle for cryotherapy, RF,…

CT Navigation

1. Install patient and patient reference
2. Acquire 1 CT scan (apnea)
3. Match CT images onto patient
4. Calibrate needle guide
5. Navigate needle
6. Perform the puncture

[Radiology Departement, Grenoble – Koelis]

CT Navigation

- movie

Image Guided Robot

- 1996 : First Kidney Puncture with a robot
  - Dan Stoianovici (JHU)

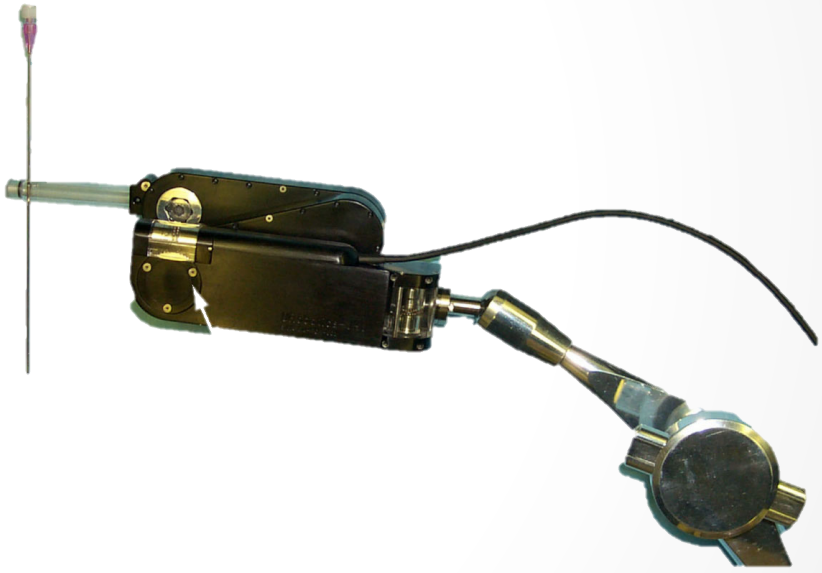


Image Guided Robot

- Robot inside the imager (CT scan)
  - Planning
    - Entry point
    - Target
  - Quality control of the task
- Fully automatic with needle spinning
- High accuracy (less than 1 mm)

[Stoianovici]

Robot

- movie

Navigation VS Robot

- **MATERIALS AND METHODS:**
  - Both systems were tested using three operators:
    - an interventional radiologist
    - two endourologists.
  - Fiducials were placed in an anatomic gelatin phantom and targeted by both systems.
  - Accuracy was assessed by measuring proximity of the tip of the needle to the fiducial on computed-tomography-guided imaging.

Prospects in percutaneous ablative targeting: comparison of a computer-assisted navigation system and the AcuBot Robotic System.
Pollock R, Mozer P, Guzzo TJ, Marx J, Matlaga B, Petrisor D, Vigaru B, Badaan S, Stoianovici D, Allaf ME.
J Endourol. 2010 Aug;24(8):1269-72.

Navigation VS Robot

- **RESULTS:**
  - The mean distance from the desired target for
    - Robot was **1.2 mm** (range: 0.39-2.82).
    - Navigation system was **5.8 mm** (range: 1.8-11.9).
    - The AcuBot was significantly more accurate than the navigation system ($p < 0.0001$).
  - The mean time from target acquisition to needle placement for
    - Robot was 37 seconds (range: 15-75)
    - Navigation system was 108 seconds (range: 45-315) for the navigation
    - Set up not included ;-)

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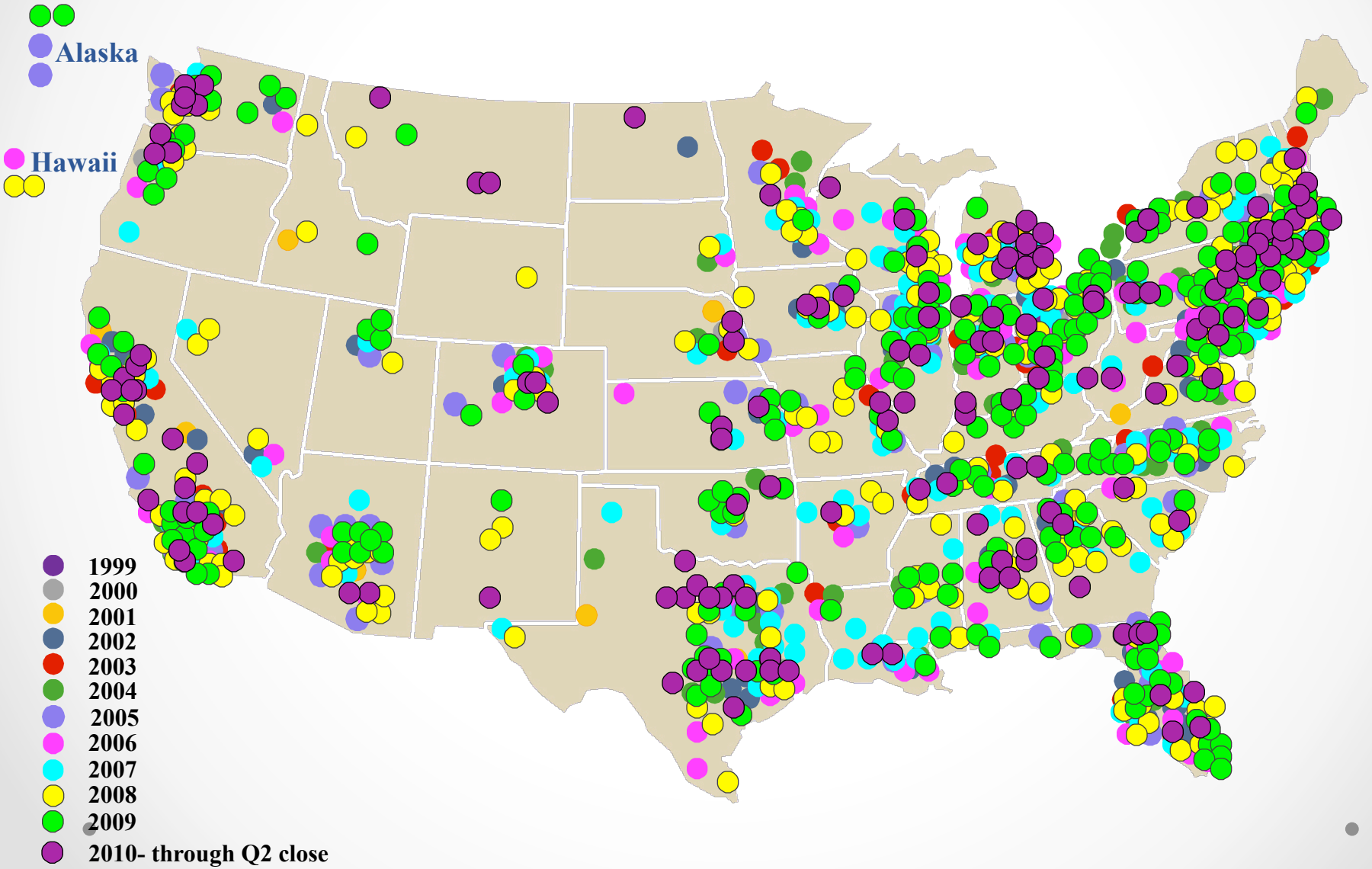
Navigation VS Robot

- Not surprising : A robot is better than a human…
- Questions :
  - What is the clinical need (size a the target)
  - How to explain that to a surgeon or a radiologist ?

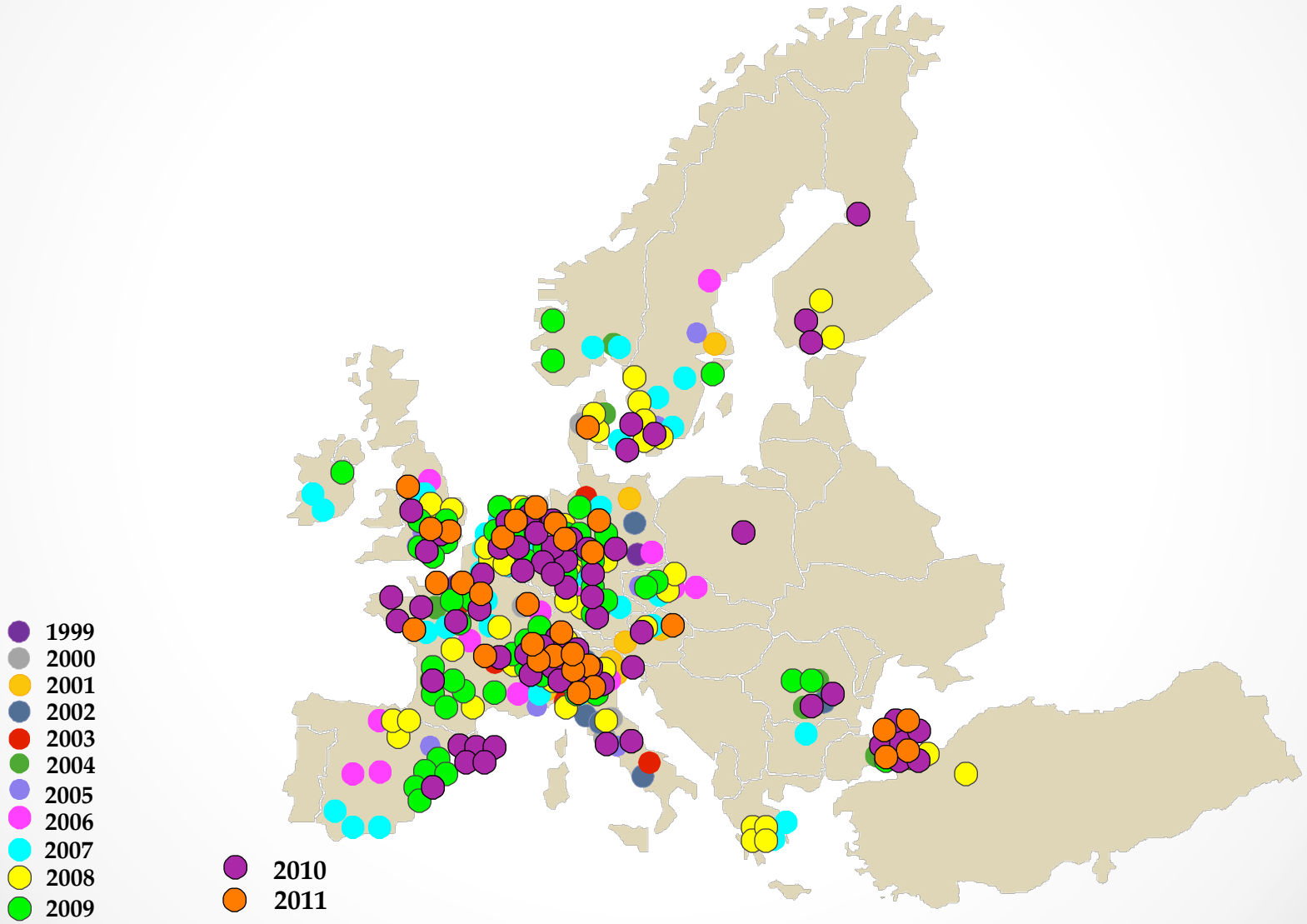
Da Vinci

- 2000 : DaVinci ‘FDA approved’

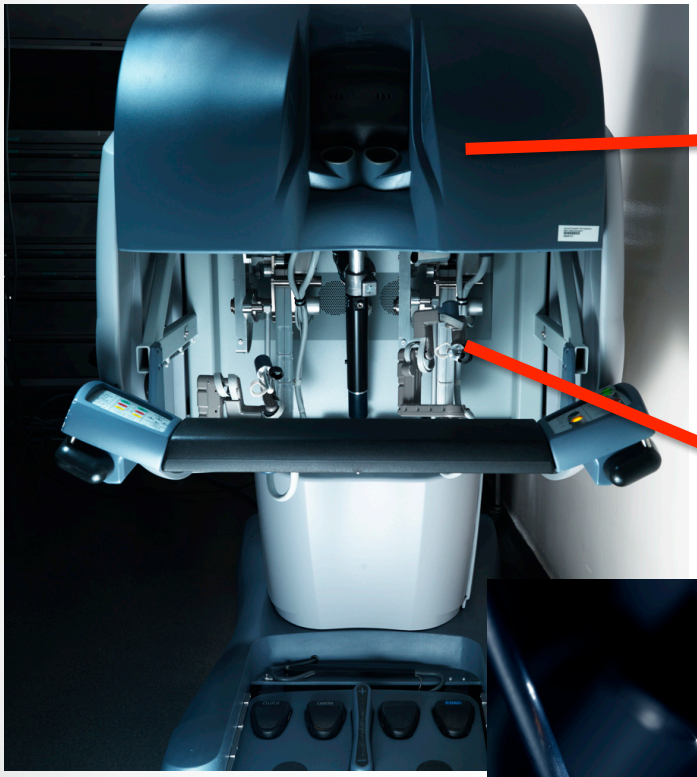
da Vinci® Surgical System U.S. Installed Base 1999 – 2010

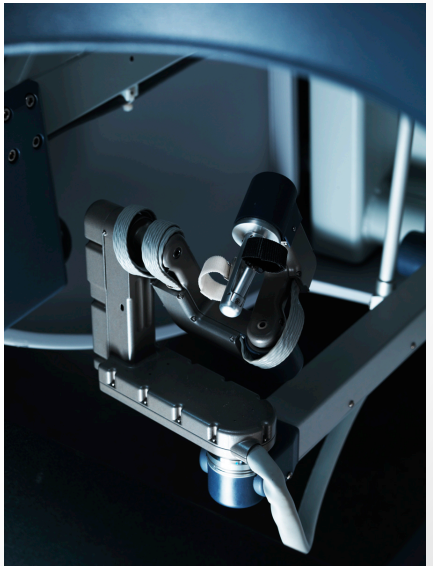


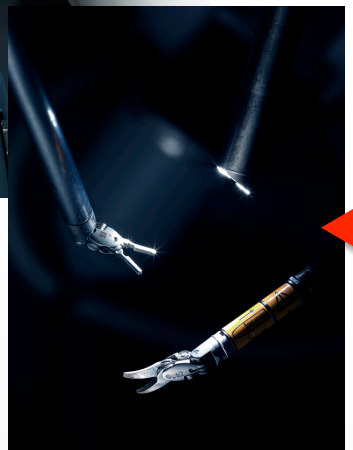
daVinci® European Installed Base 1999 – 2011



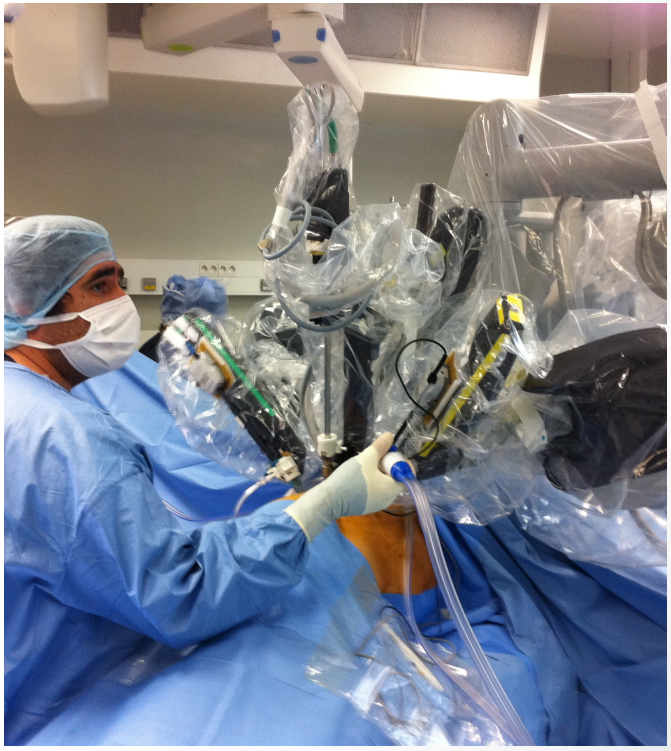
Consol







Da Vinci for Kidney



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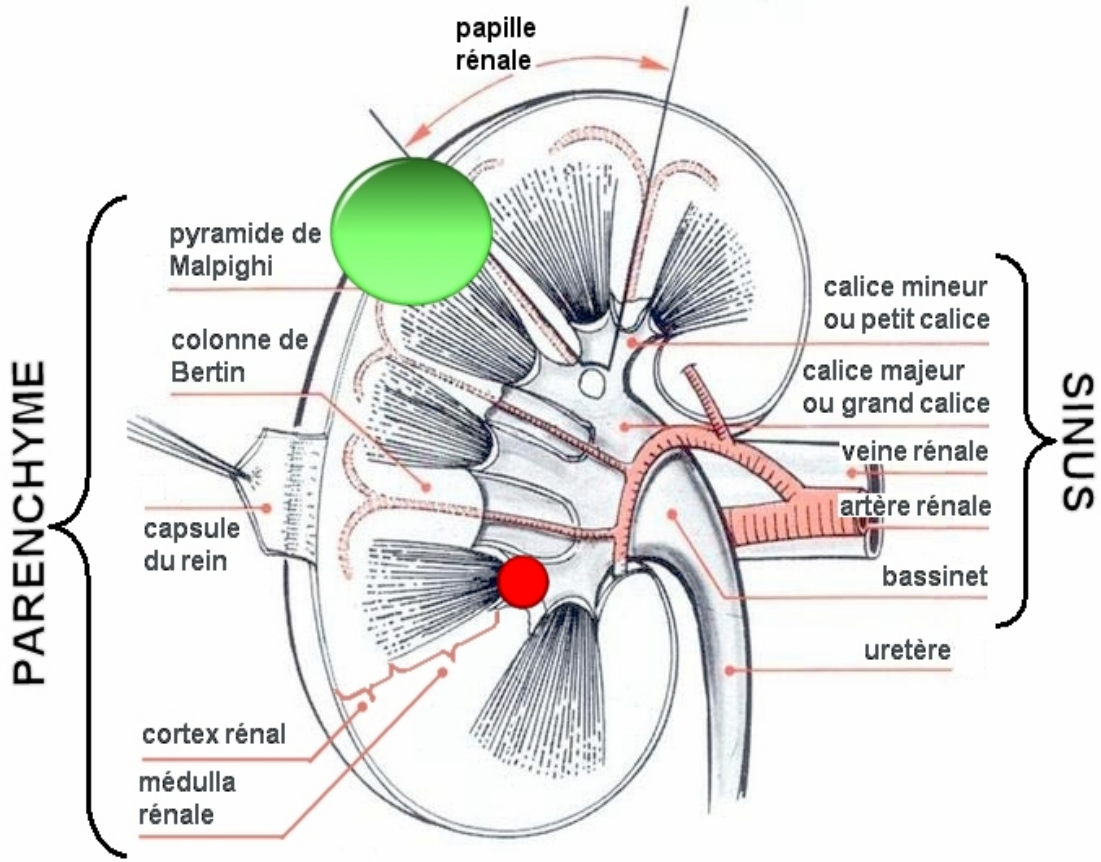
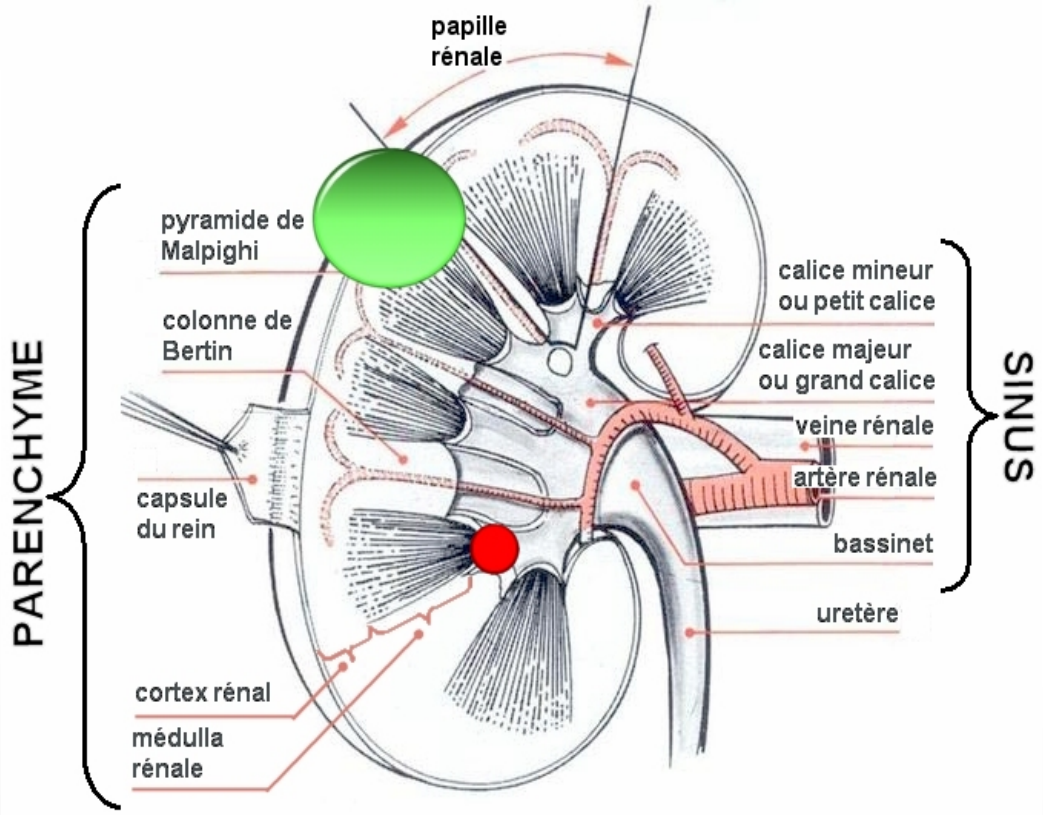

papille
rénale
pyramide de
Malpighi
colonne de
Bertin
capsule
du rein
cortex rénal
médulla
rénale
PARENCHYME
calice mineur
ou petit calice
calice majeur
ou grand calice
veine rénale
artère rénale
bassinet
uretère
SINUS

Jonction

- movie

Partial Nephrectomy



(100)Partial Nephrectomy : Robot vs Open

Characteristics	RPN (starting 07/2009) N = 42	OPN N = 58	*P value*
Patients	42	58	
Operative time (min)	134.76±35.30	128.39±50.52	0.097
Clamping time (min)	17.47±7.84	2.95 ± 6.9 IF Artérial clamping: 17.1±5.93	<0.0001
Intraoperative blood loss (ml)	142.86±225.87	414.65±367.54	<0.0001
Length of stay (d)	3.83±1.12	7.84±3.52	<0.0001
Creatinin level Preoperative Post operative	 89.14±28.88 92.32±28.21	 95.33±24.61 99.27±31.79	0.252
Margins	1(2.38%)	4(6.89%)	0.318
Compications Clavien I Clavien II Clavien III	4 (9.5%) 2 2 0	4(6.9%) 0 2 2	0.651

Pitié-Salpétrière Data

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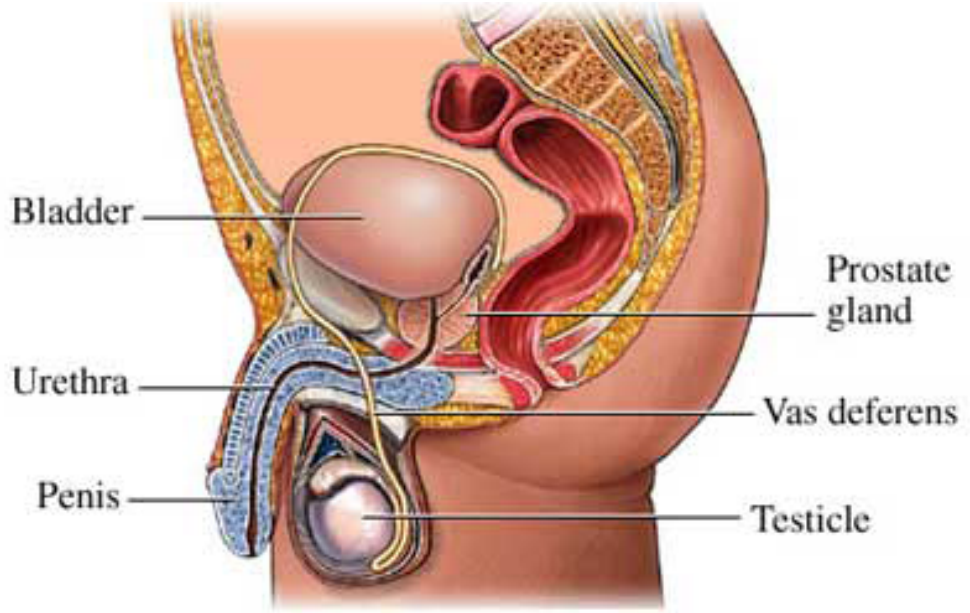
Pitié-Salpétrière Data

Kidney Conclusion

- Kidney surgery is a good example of navigation/ robot surgery
- Benefits seem significant

Prostate



Prostate Cancer

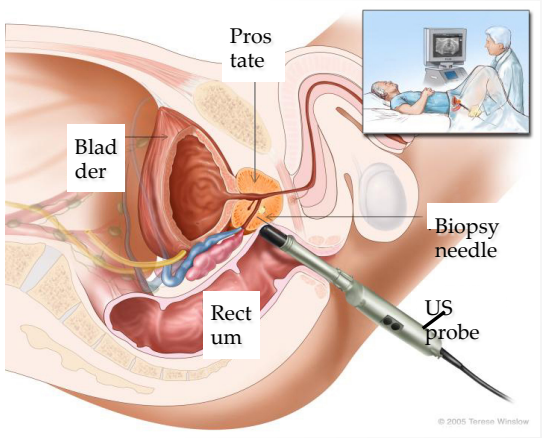
Clinical context

- Prostate cancer (PCa) is
  - the commonest cancer
    - 1 in 6 men has lifetime risk od developing PCa in the US
    - 220 000 new cases in the US in 2010
  - the second most common cause of cancer death
    - 32 000 deaths

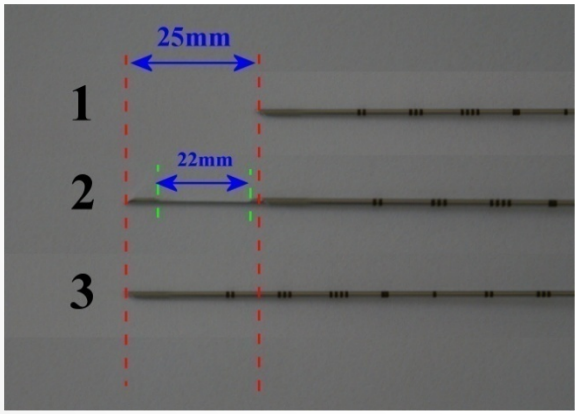
Jemal and al. Cancer statistics.

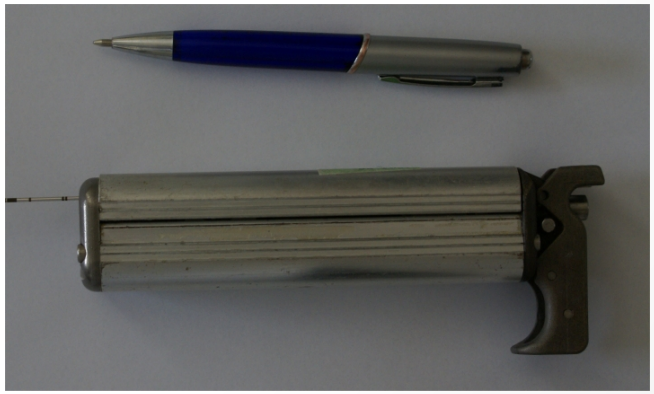
Routine Clinical Context

- **Routine** Prostate Biopsies :
  - Only definitive method to prove cancer presence
  - ≈ 1.5 million prostate biopsy procedures are performed each year in the U.S. (150,000 in France)
- **Transrectal** 2D ultrasound (TRUS)control (**local anesthesia**)
- Time for 1 procedure ≈ 10 minutes



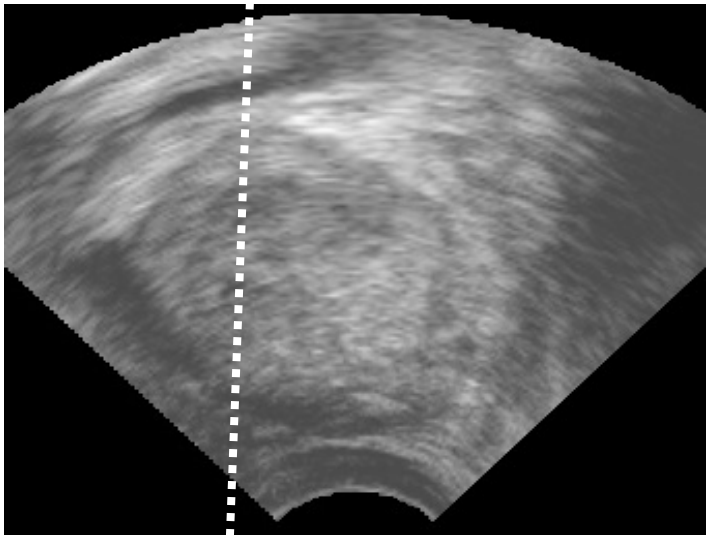
Prostate biopsy Gun





Clinical Context

- Problem #1: cancer visibility
  - Prostate cancer is isoechogenic (early and mid-stage)

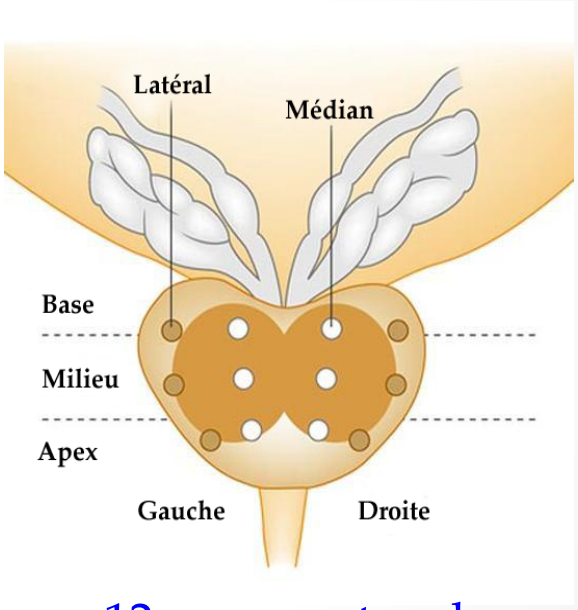


Where is the cancer?

Clinical Context

→ Systematic sampling necessary

→ Standardized **12** cores protocols



12-core protocol
defined on coronal cut of the prostate

Clinical context

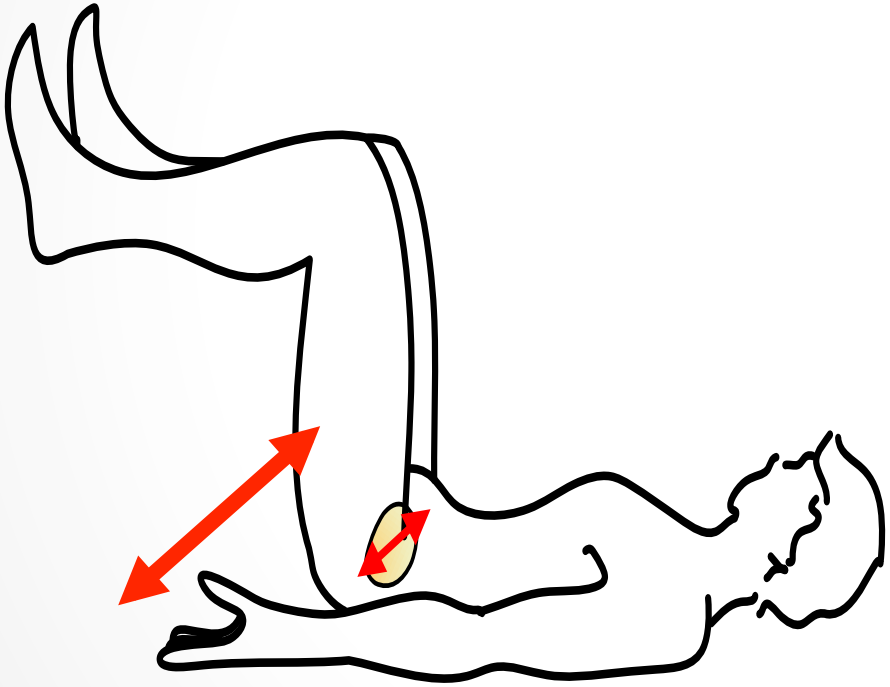
- Problem #2: biopsy localization
  - Difficult to accurately follow systematic protocol
    - sparse information in US image
    - symmetry of the gland
    - prostate motion!

    → "Where exactly am I puncturing?

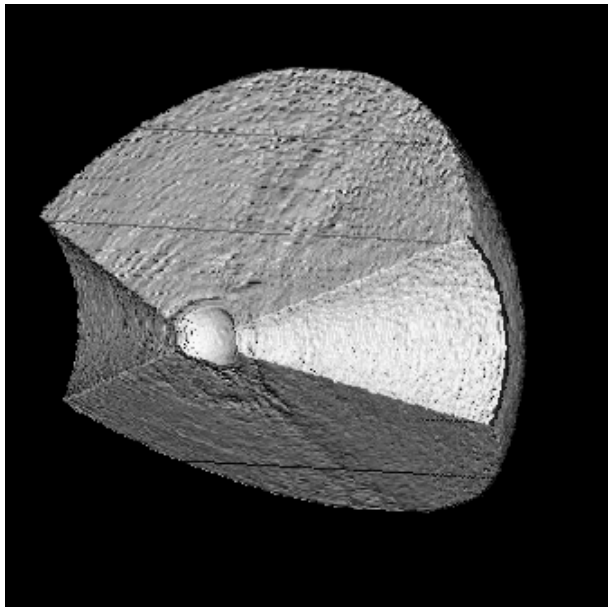
    → no control over sampling distribution quality
    → no a posteriori knowledge of real biopsy position for planning treatment

    → WE NEED AN ACCURATE PROSTATE BIOSPIES MAPPING DEVICE

Challenges to prostate tracking and fusion



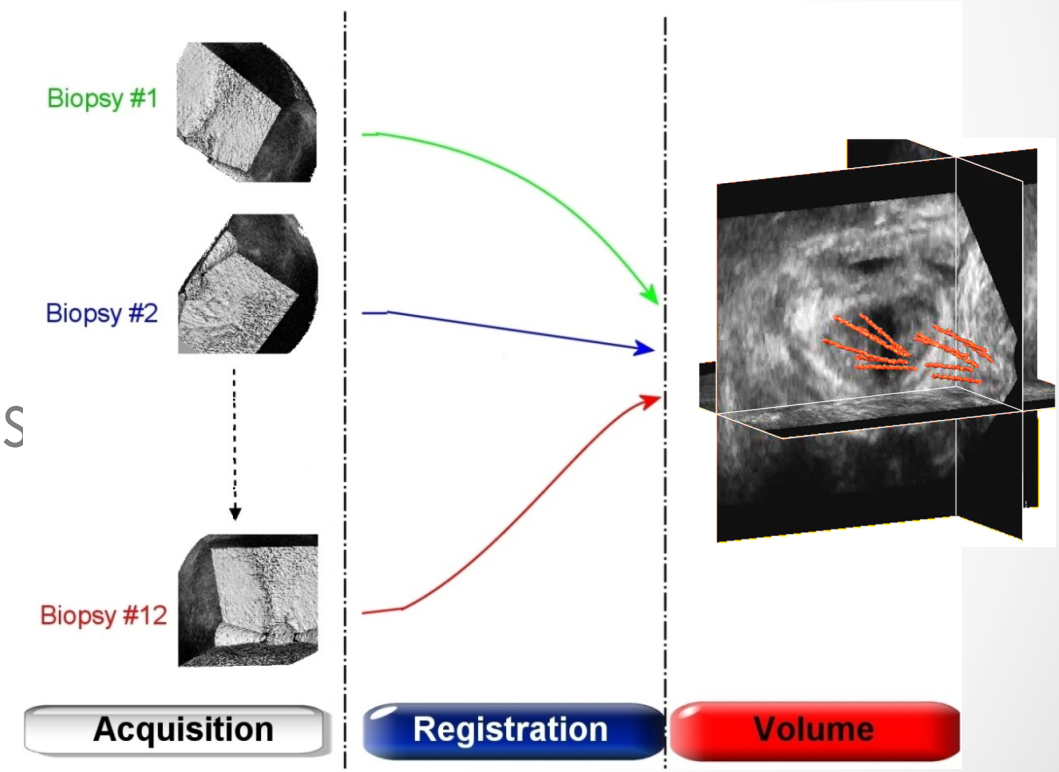
Concept



Use a 3D-TRUS probe

Concept

- Performed a 3D acquisition during each biopsy
- Merge every biops volume in a reference volume



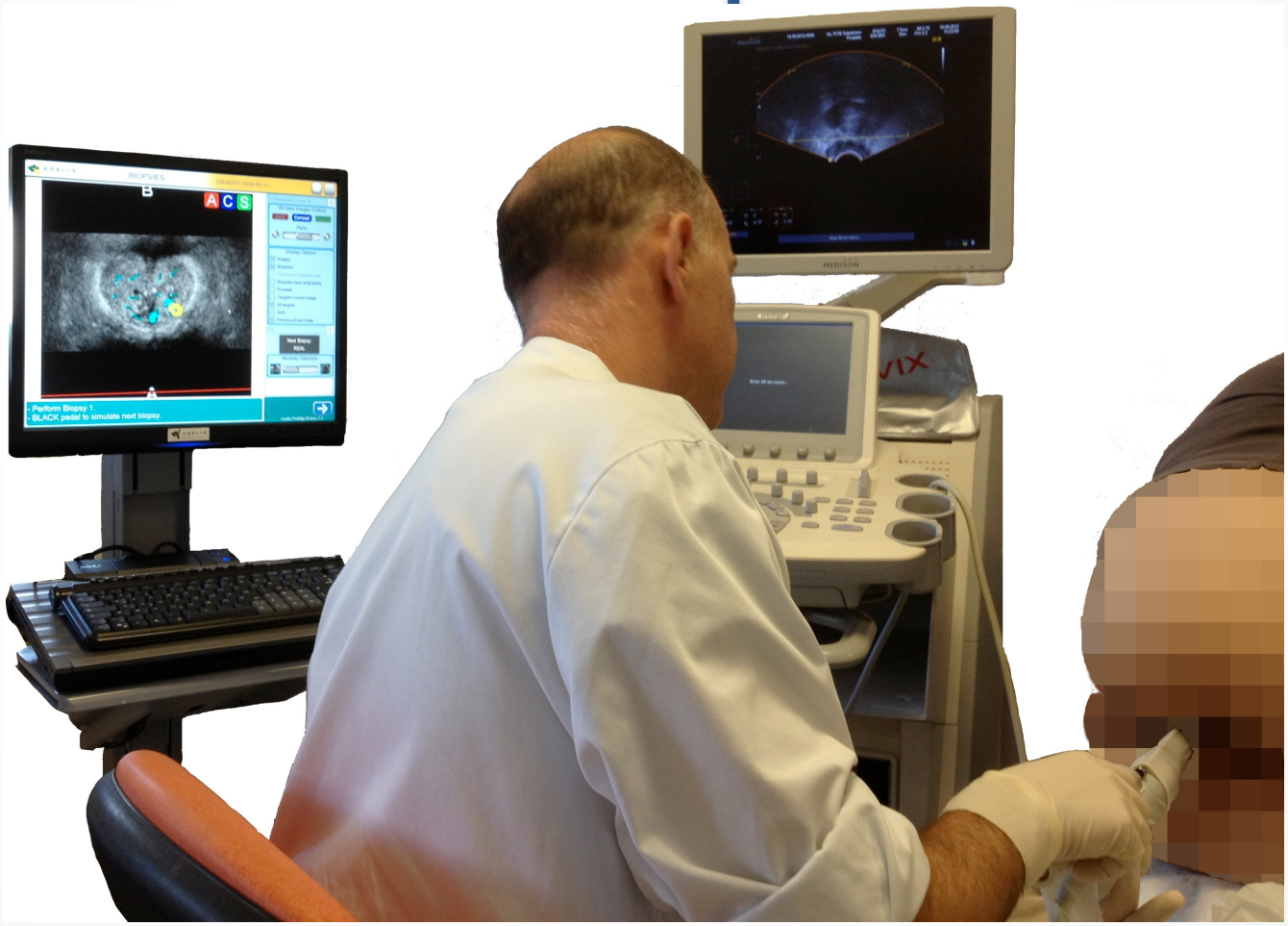
Registration

- Approach
  - voxel-intensity based registration method
  - minimization of statistical similarity measure
  - incorporates rectal constraints on probe movements

  to reduce space search

Prostate biopsy tracking with deformation estimation.
Baumann M, Mozer P, Daanen V, Troccaz J.
Med Image Anal. 2011 May 17.

Setup

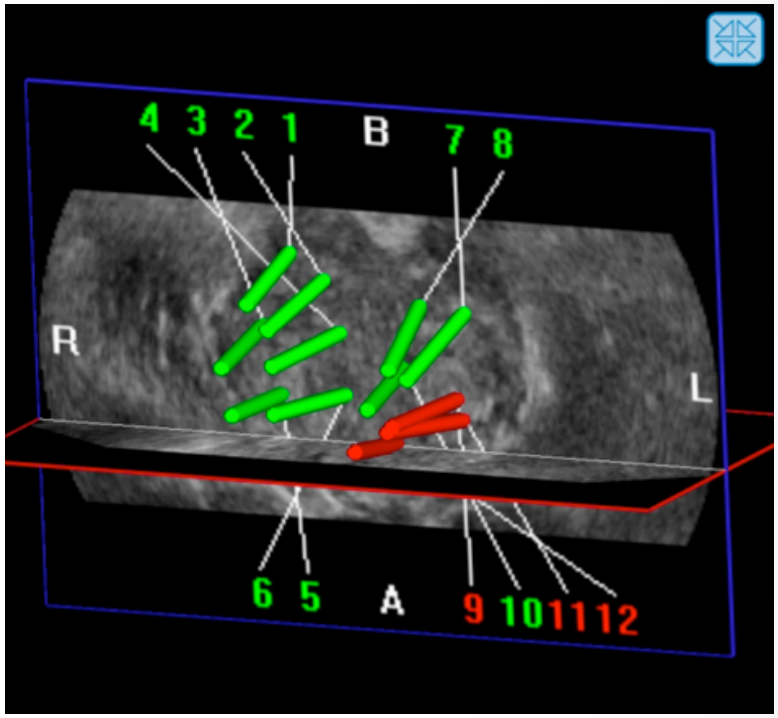

BIOPSIES
B
A C S
Perform Biopsy 1.
BLACK pedal to simulate next biopsy.
MEDISON

US Cartography

- Movie Link

Postoperative

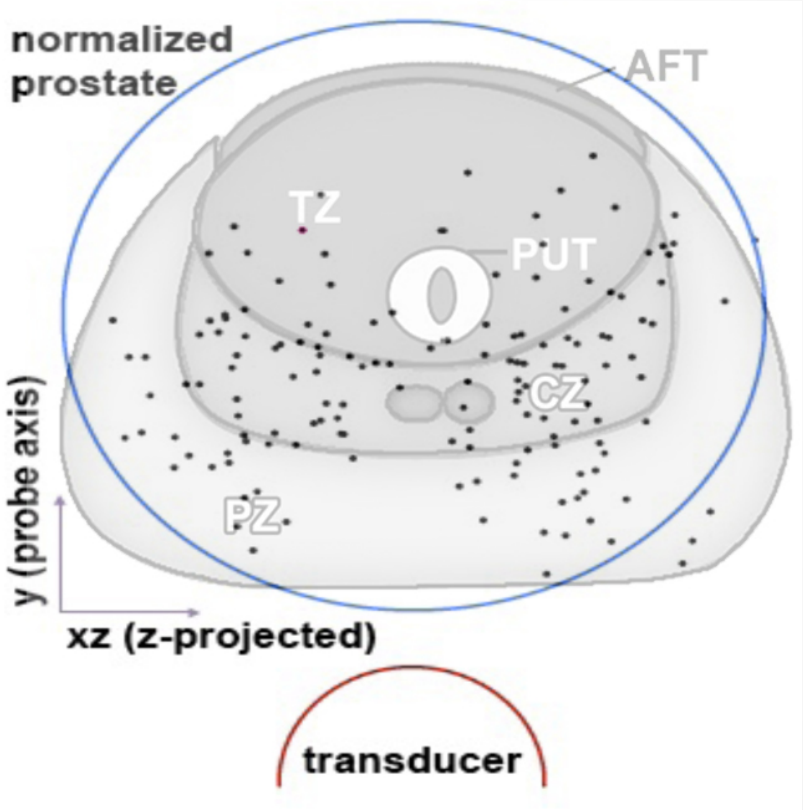
- Once histological results are known, one may eventually integrate them to the patient's data file to visualize the positive biopsy locations



Distribution of the biopsies inside a "reference" 3D TRUS image.
B=Base, A=Apex, L=Left, R=Right. Green : Negative biopsies.
Red : Positive biopsies

Accuracy

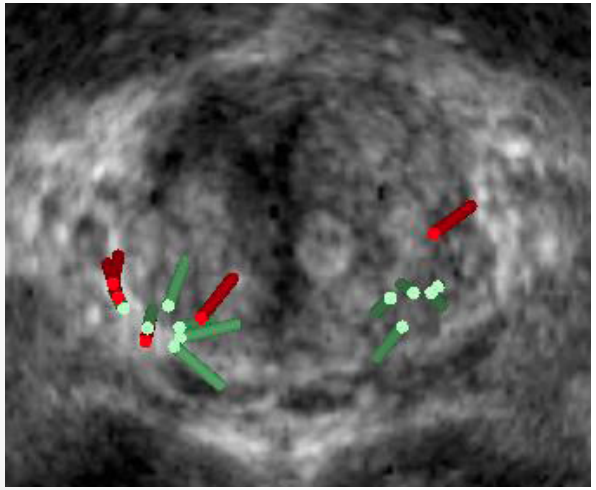
		mean distance [mm]
1	unregistered	13.8±7.9
2	rigid	1.4±0.8
3	deformation	0.8±0.5



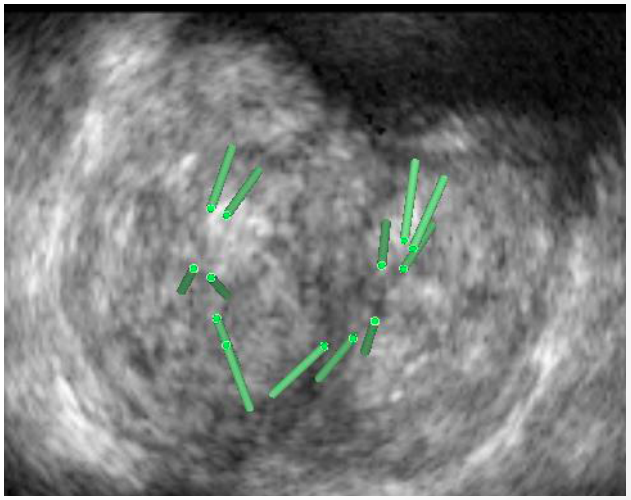
[Prostate biopsy tracking with deformation estimation.](#)
Baumann M, Mozer P, Daanen V, Troccaz J.
Med Image Anal. 2011 May 17.

Live visual feedback: does it make sense? (2-2)

The Young Surgeon…



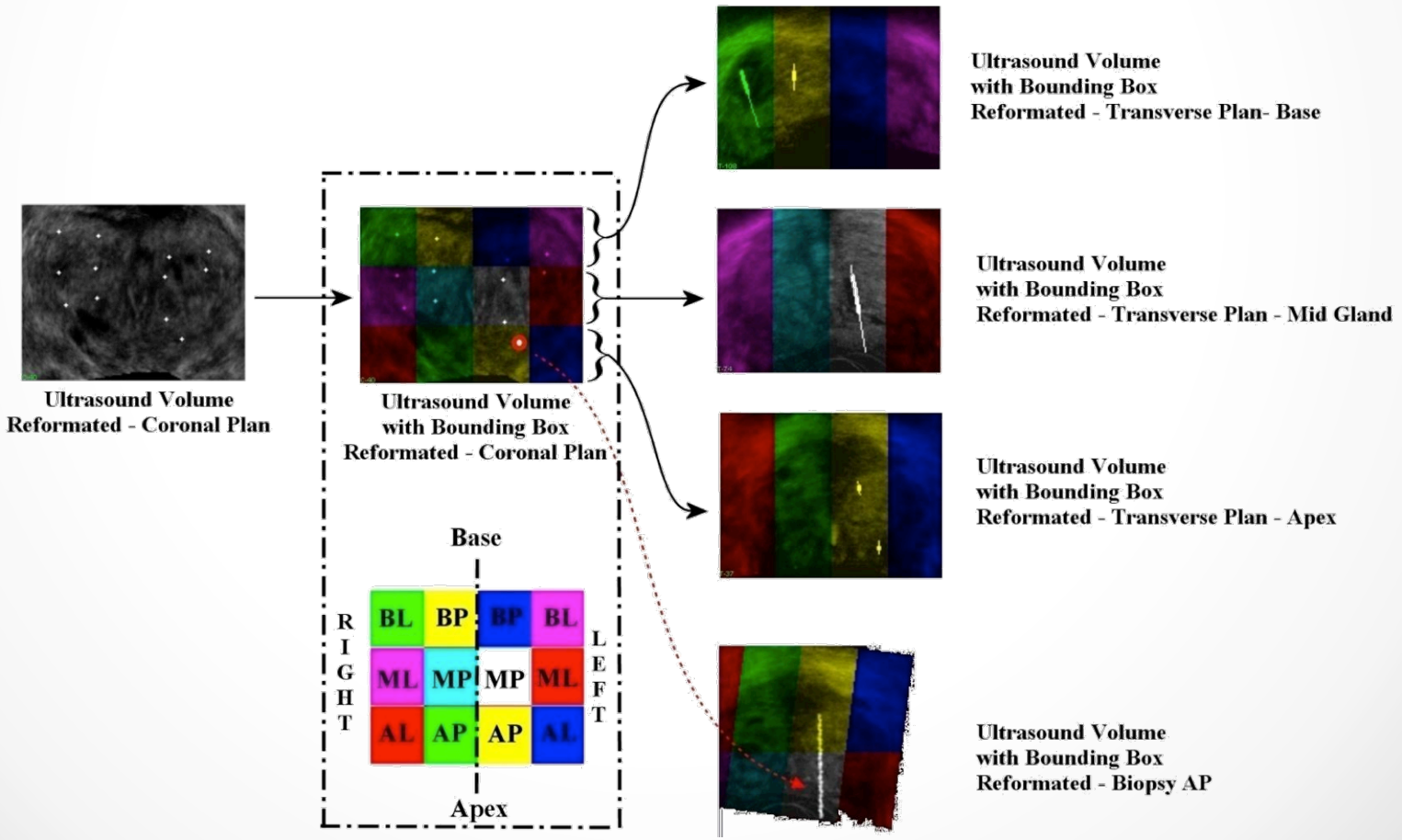
PATIENT #1



PATIENT #2

Live visual feedback: does it make sense? (2-2)

- YES! A study on 12-areas-hitting success rate:



Live visual feedback: does it make sense? (2-3)

- A visual feedback on the system screen after every biopsy series enabled the operator to significantly improve his dexterity over time
- first 16 patients:
  median score: 7 of 10 and cumulated median core length in targets: 90mm
- last 16 patients:
  median score: 9 of 10 and cumulated median core length in targets: 121mm (+34%)

$P = 0.046$

Mapping of transrectal ultrasonographic prostate biopsies: quality control and learning curve assessment by image processing.
Mozer, P., Baumann, M., Chevreau, P., Moreau-Gaudry, A., Bart, S., Renard-Penna, R., Comperat, E., Conort, P., Bitker, M.-O., Chartier-Kastler, E., Richard, F., Troccaz, J.,
2009. ***Journal of Ultrasound in Medicine*** *28, 455–460.*

Live visual feedback: does it make sense? (1-1)

	Echo 2D	Echo 3D Uro-station	P student
Nb	110	110	
Age (ans)	64	65	NS
PSA (ng/ml)	9	10	NS
Volume(cc)	47	51	NS
Taux cancer	34%	50%	P=0,04

Visualisation 3D du trajet réel de la biopsie dans la prostate et son impact clinique en routine diagnostique du cancer

PELTIER A., NARAHARI K., VAN VELTHOVEN R. (Bruxelles, Belgique)

Congrès AFU 2012

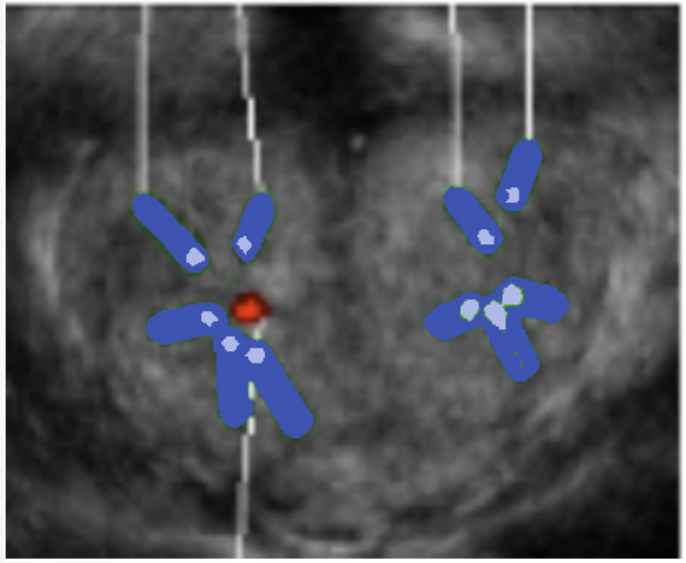
Discussion

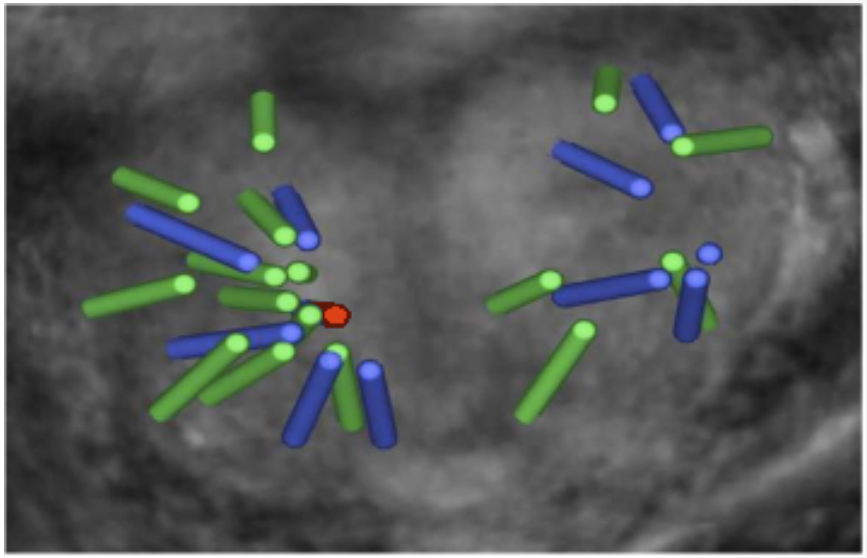
- **Automatic** robust image-based tracking system
  - This system is a prostate GPS (Global Positioning System)
- Copes with patient and prostate movements
- No change in the clinical workflow
- Increase procedure time ≈ 2 minutes

Add-ON

- You can change the map if you add it in the reference image

Registration of 2 biopsies Sessions





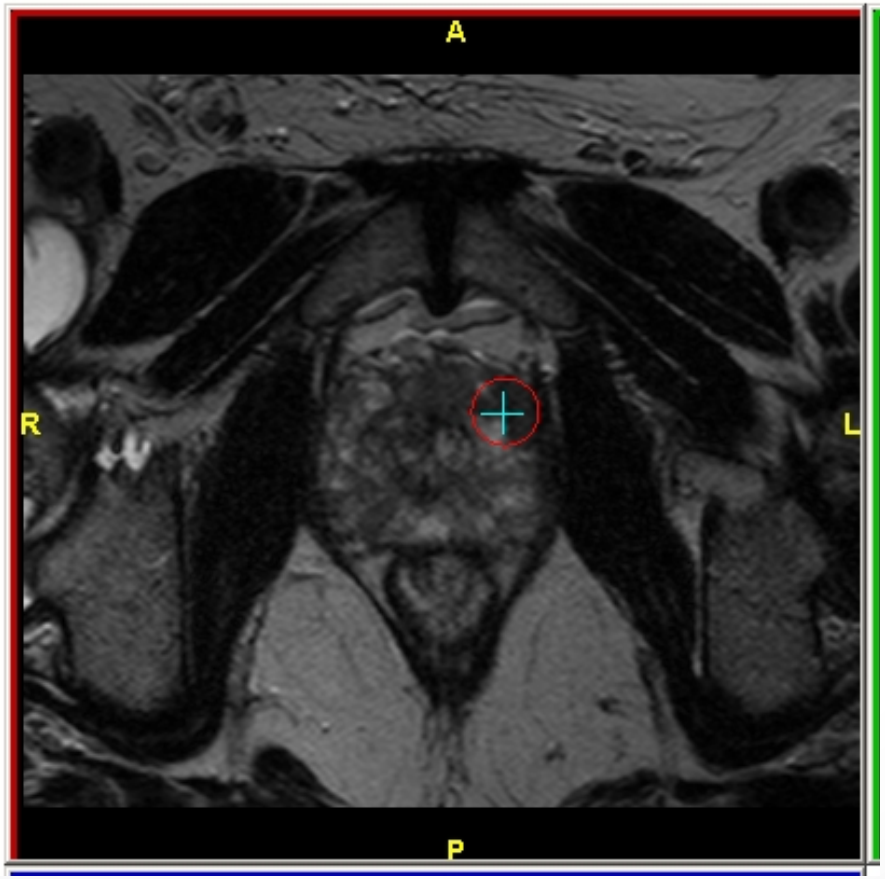
Prostate Coronal view

Blue: Biopsies December 2009

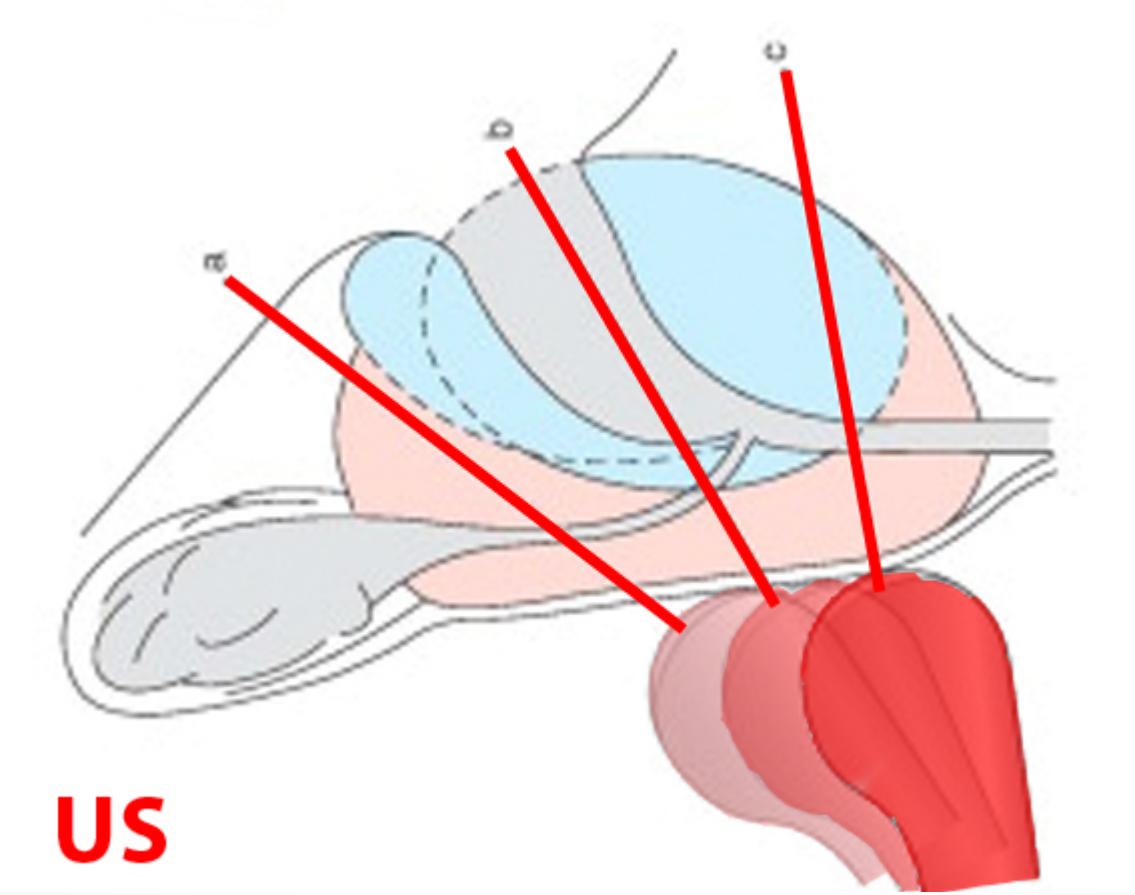
Green: Biopsies February 2010

MRI Add-On

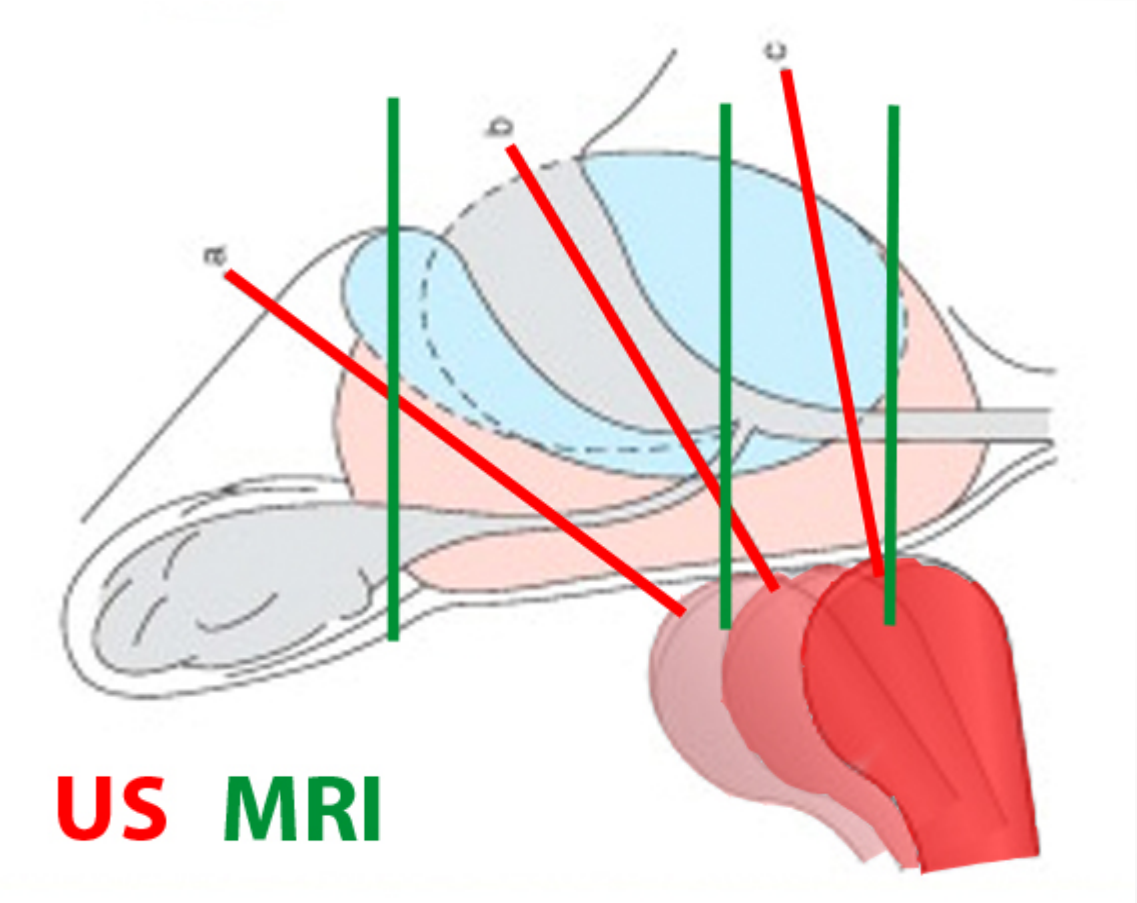
- MRI is the best image modality to see PCa



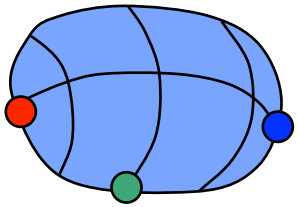
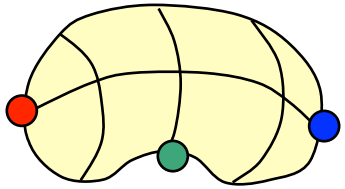
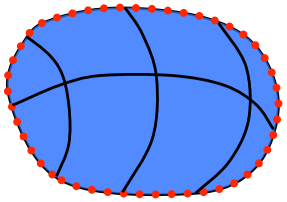
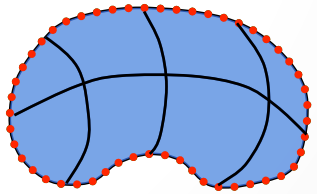
Challenges :: image vizualisation



CHALLENGES :: IMAGE VIZUALISATION

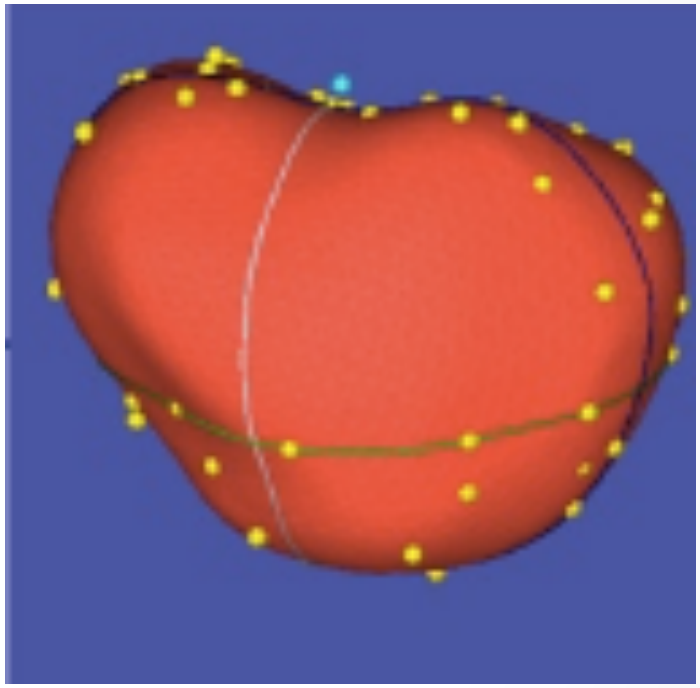


Registration

	MRI	3D TRUS
Rigid Fusion		
Elastic Fusion		

Registration with MRI

- Segmentation of the prostate in ***US*** and ***MRI*** images
  - ≈ 5 minutes



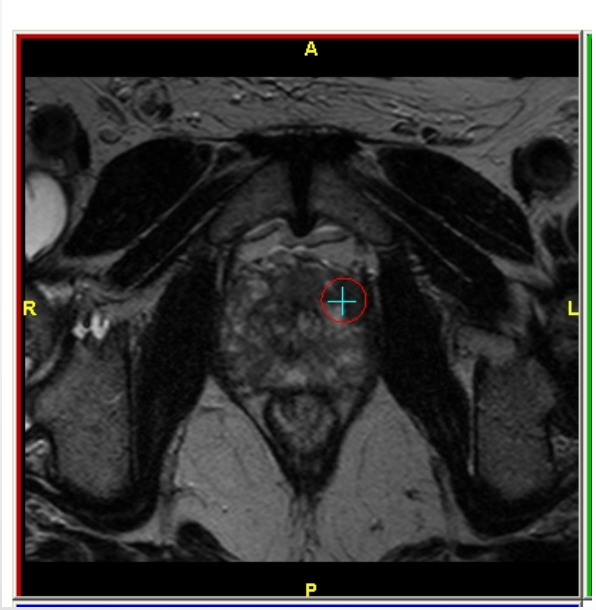
S. Martin, V. Daanen, J. Troccaz. Atlas-based prostate segmentation using a hybrid registration. International Journal of Computer Assisted Radiology and Surgery, Springer Verlag, 3:485-492, décembre 2008

Registration with MRI

- Movie

Patient Example

- 68 y/o
- Normal DRE
- PSA = 7,4 ng/ml
- Volume prostate = 73 ml



Patient Example

- 68 y/o
- Normal DRE
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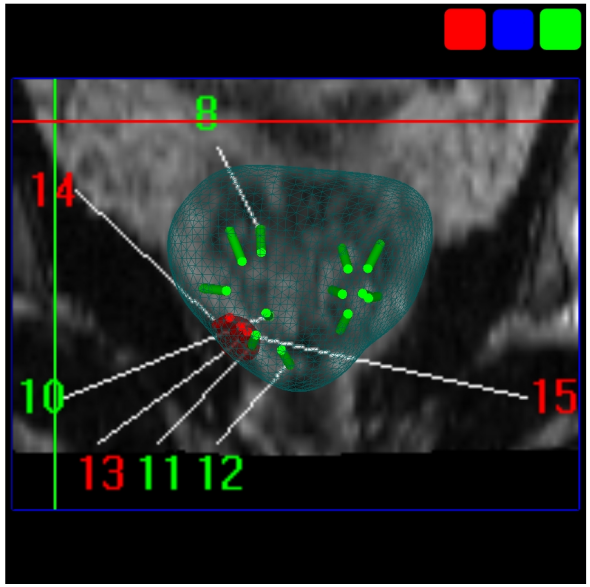
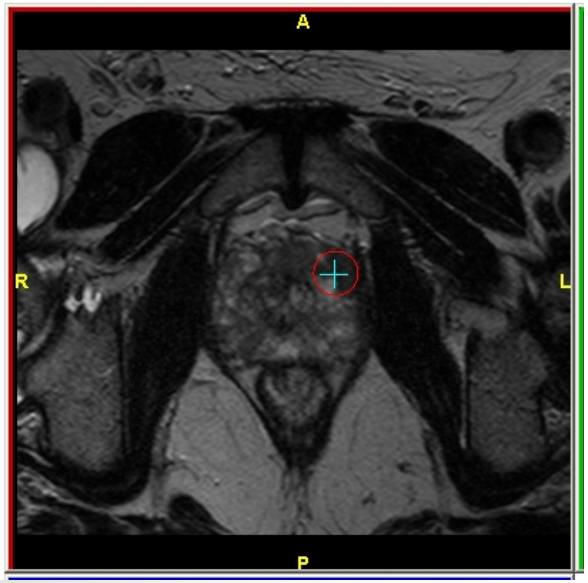




Biopsy	Length	Tumor Size	Gleason	PCI	PNI	ASAP	PIN	Registration Quality
1	8.0	-	-	-	-	-	-	Good
2	14.0	-	-	-	-	-	-	Good
3	8.0	-	-	-	-	-	-	Good
4	8.0	-	-	-	-	-	-	Good
5	10.0	-	-	-	-	-	-	Good
6	16.0	-	-	-	-	-	-	Good
7	10.0	-	-	-	-	-	-	Good
8	14.0	-	-	-	-	-	-	Good
9	6.0	-	-	-	-	-	-	Good
10	12.0	-	-	-	-	-	-	Good
11	4.0	-	-	-	-	-	-	Good
12	6.0	-	-	-	-	-	-	Good
13	12.0	6.0	3+3	N	N	N	N	Good
14	12.0	7.0	3+3	N	N	N	N	Good
15	10.0	4.0	3+3	N	N	N	N	Good

Results for First Round Biopsies

- From 2009 to 2012, about 600 patients had 3D biopsy mapping on a weekly routine basis

- The 100 latest cases were included in a study:
  - 104 patients
  - First round biopsy
  - PSA = 4-20ng/ml
  - Mp-MRI: One target
  - 12 cores (Extended protocol)
  - + 2-3 cores on MR target

RESULTS

significant cores only (> Gleason 6, length > 3mm)

# Patients	EXT	TAR
Biopsy +	**47**	**47**
Biopsy -	50	50

(Chi2 :: p=1)

Median length of positive cores :

- EXT= 5 mm
- TAR= 8 mm

(p <0,01)

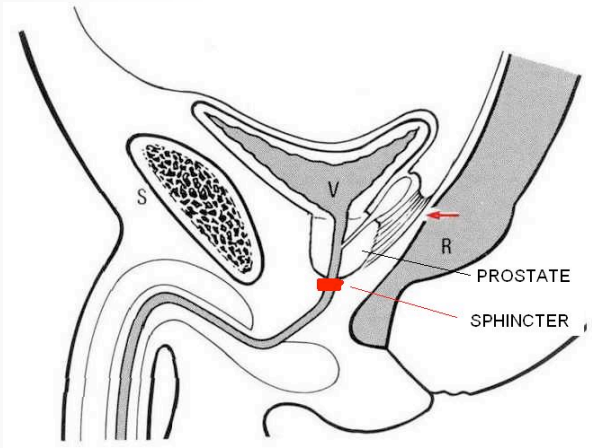
Conclusion Prostate Biopsies

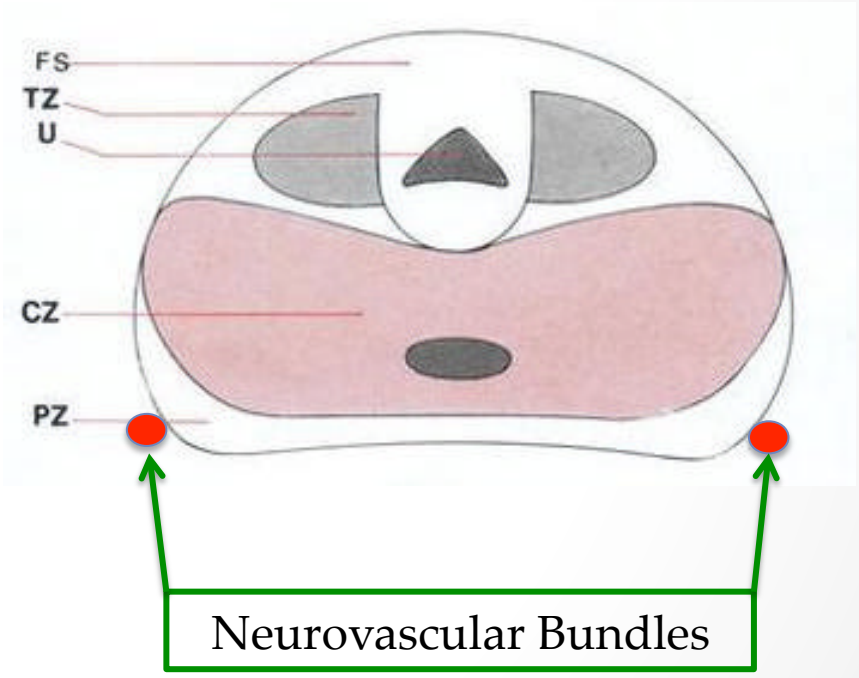
- 40systems worldwide
- More than 10.000 patients
- Multicenter clinical trials on going to show the clinical benefit

Da Vinci for prostate

- >80% Radical Prostatectomy with Da Vinci in the US

Prostate "Vicinity"





Incontinence

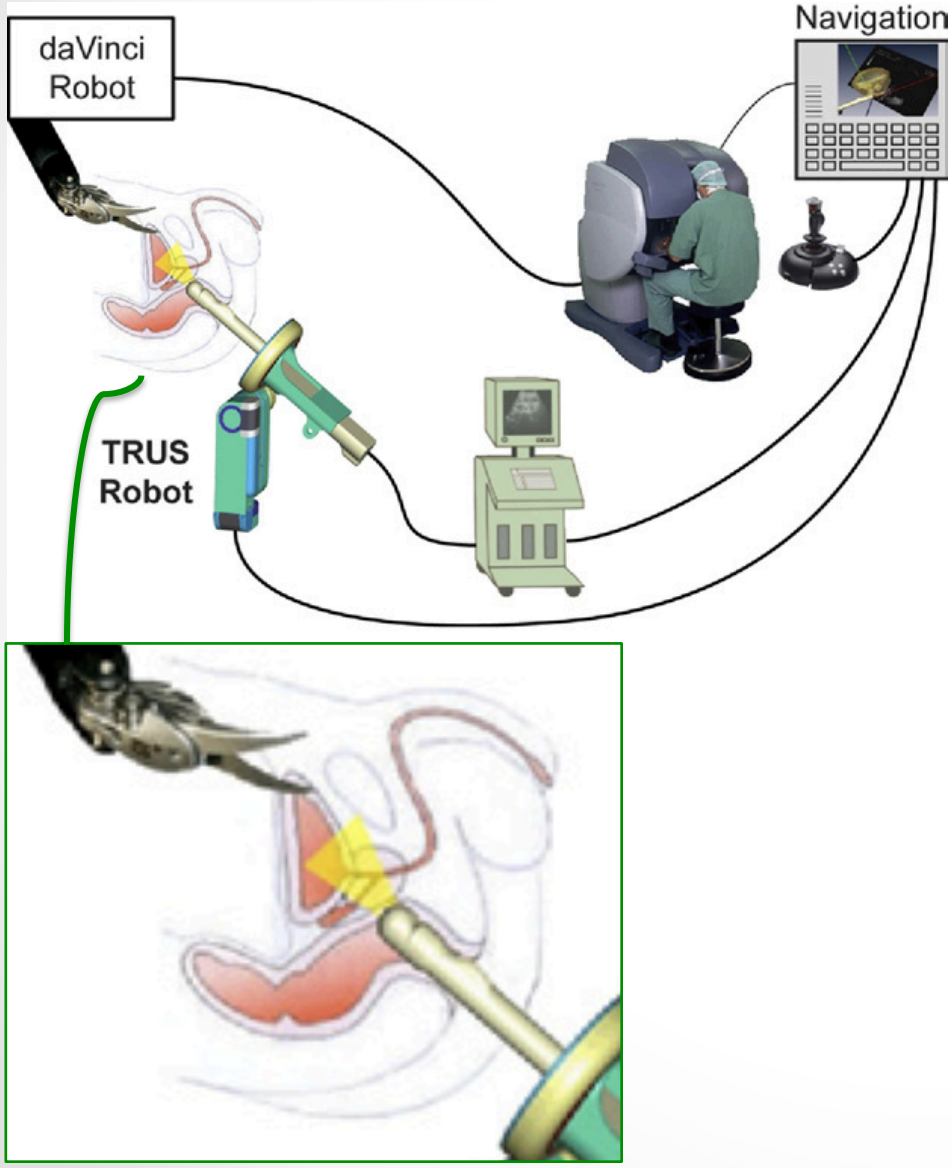
Impotence

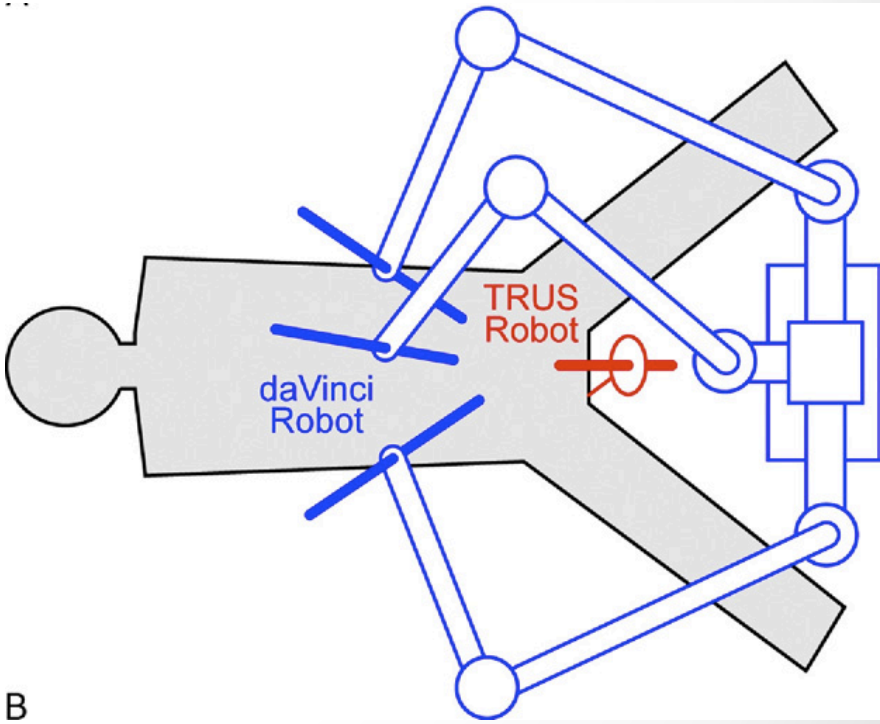
Benefits of Robotic Radical Prostatectomy

- For the surgeon :
  - **YES**
- For the patient :
  - **?**
- For the society :
  - **?**

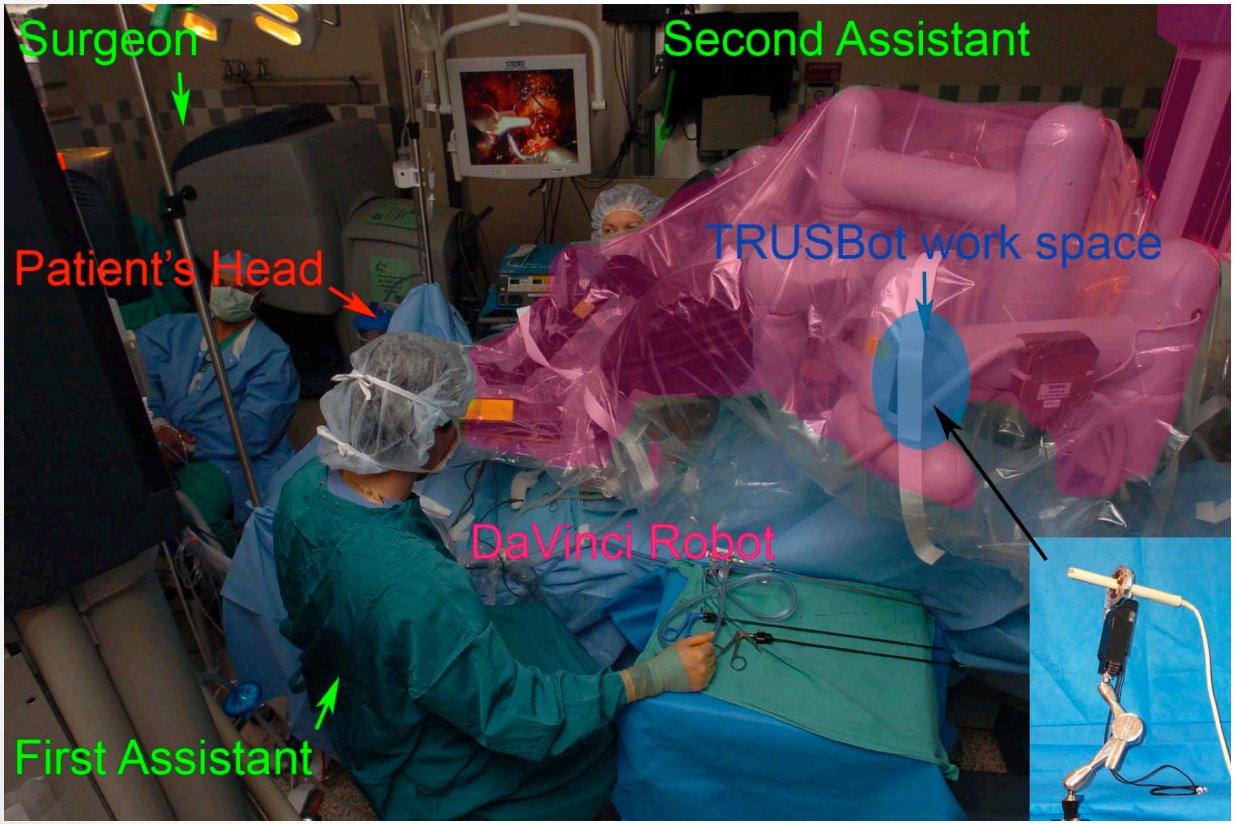
Da Vinci as a teaching tool

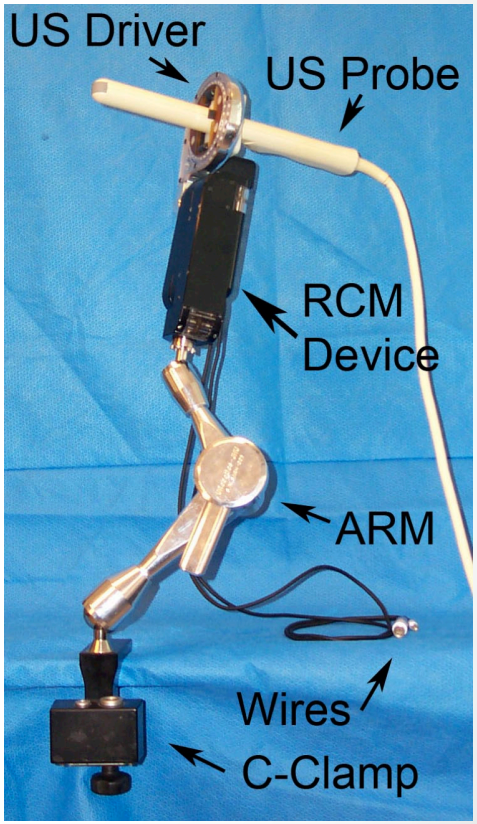
Augmented Reality





Augmented Reality

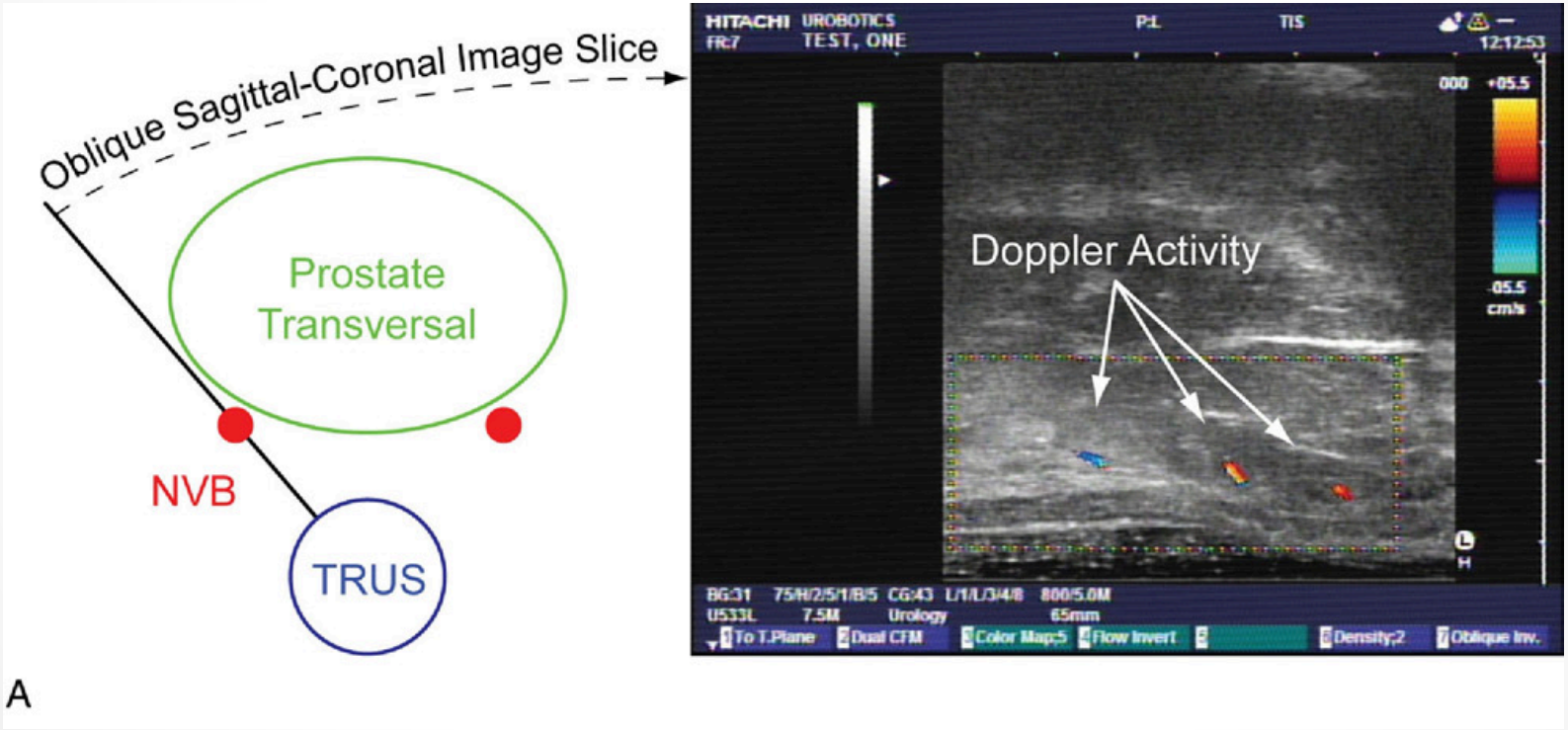




[Tandem-robot assisted laparoscopic radical prostatectomy to improve the neurovascular bundle visualization: a feasibility study.]

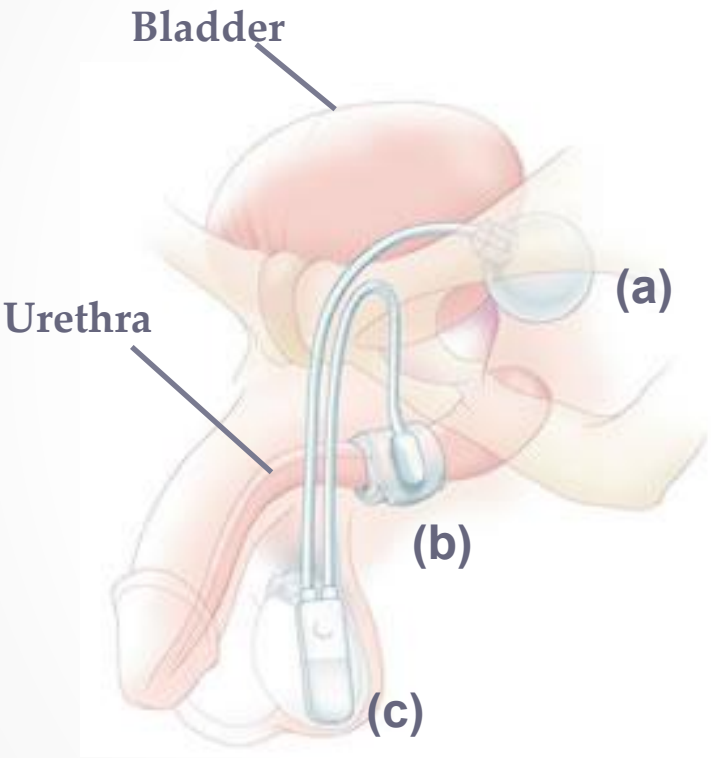
Han M, Kim C, Mozer P, Schäfer F, Badaan S, Vigaru B, Tseng K, Petrisor D, Trock B, Stoianovici D. Urology. 2011 Feb;77(2):502-6.

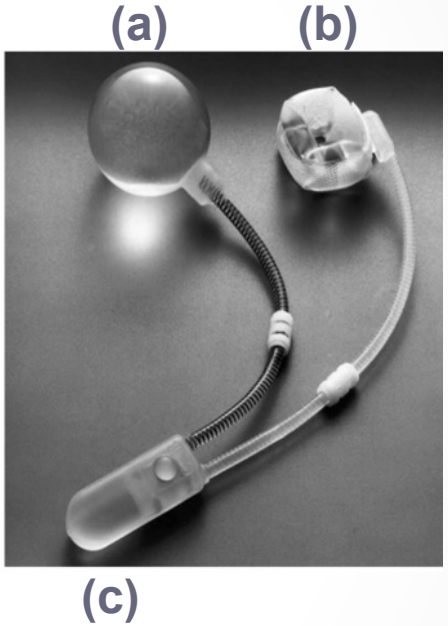
Neurovascular bundles



Check the movie on the Urobotics Lab website !

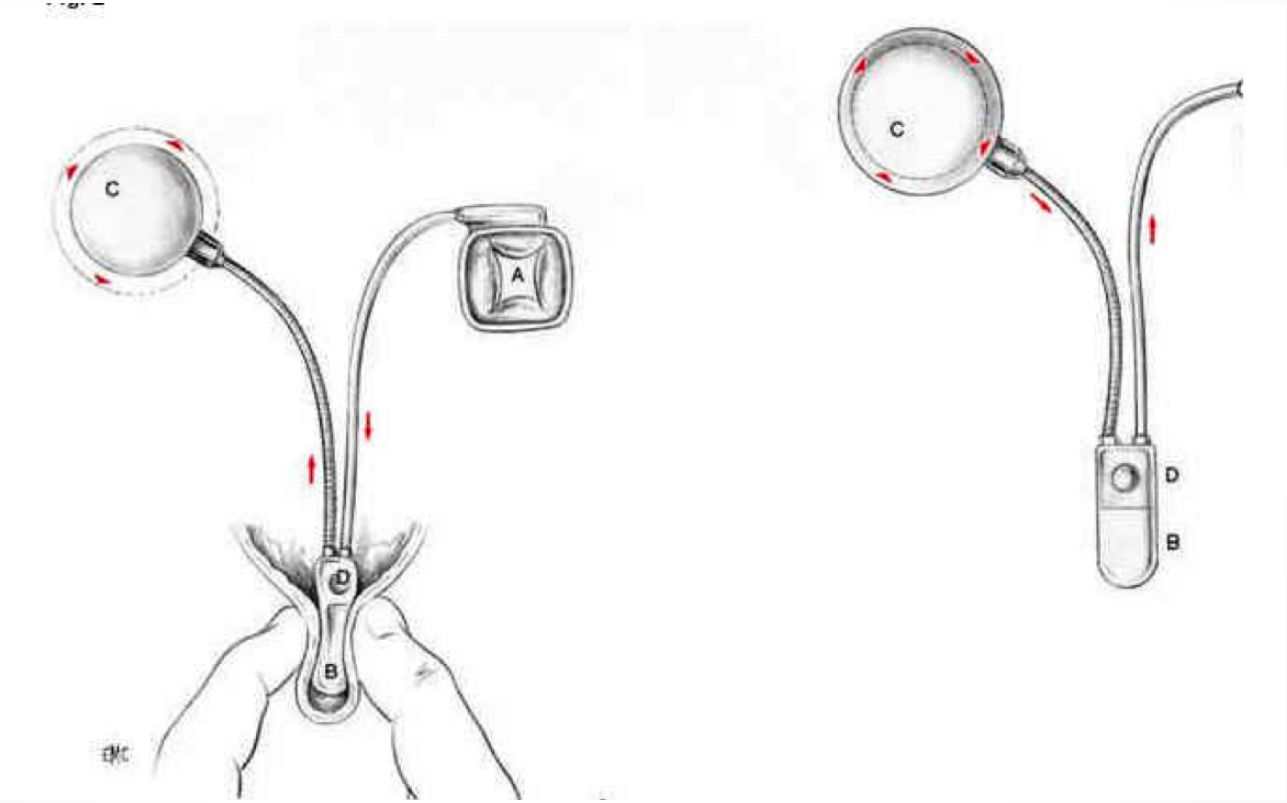
Artificial Sphincter





~Life expectancy : 7 years

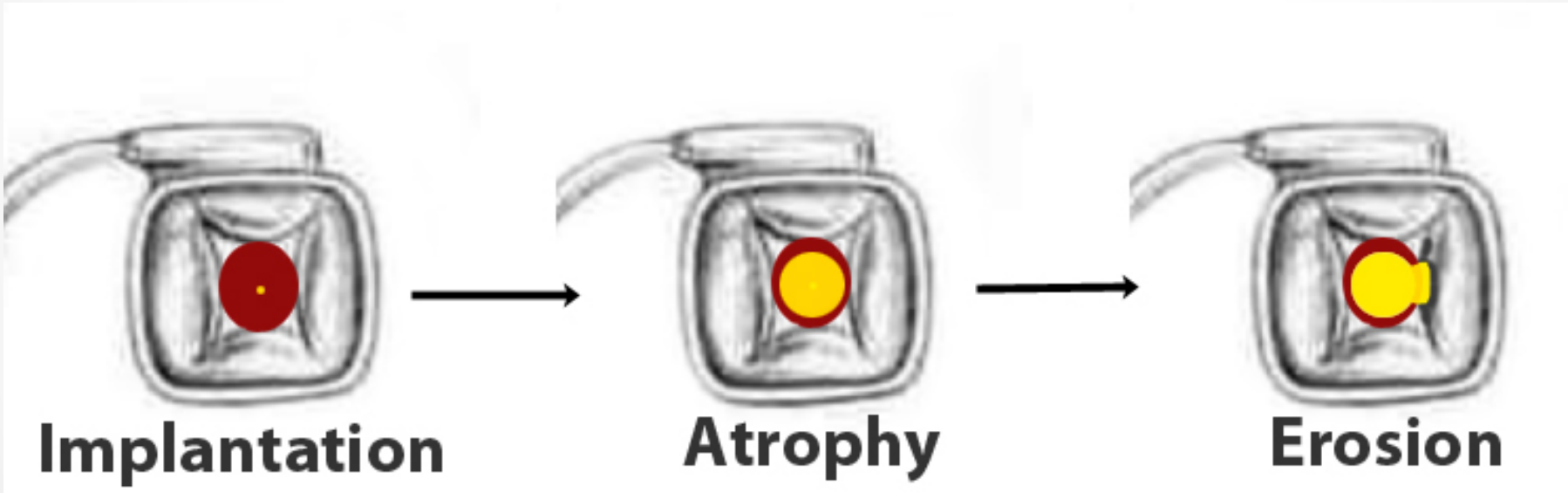
Artificial Sphincter



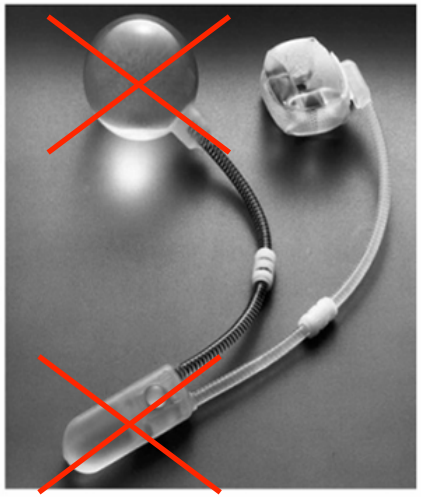
Drawbacks

- Poor ergonomy for the patient
- Uncontrolled Pressure in the occlusive cuff
  - Leaks occur when the pressure increases in the abdomen
- Complications
  - Erosions & Atrophies
  - Total revision rate: 30% at 3 years

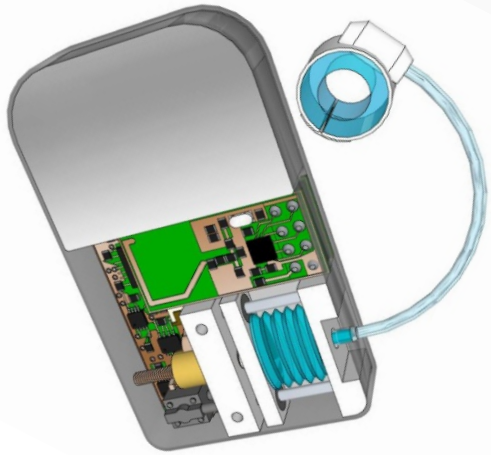
Atrophy - Erosion



Smart AUS



Smart AUS

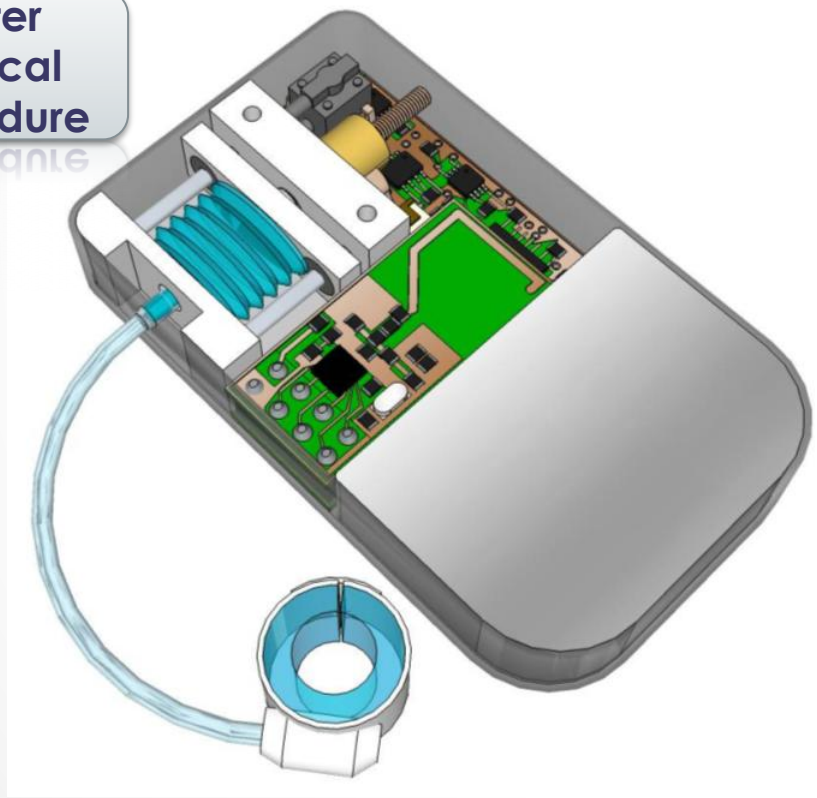


Size - 60×40×15 mm³

Smart AUS

- The Smart Artificial Urinary Sphincter : a real innovation

Faster surgical procedure



Automatic regulation of the occlusive pressure

Personnalization

Ergonomic command

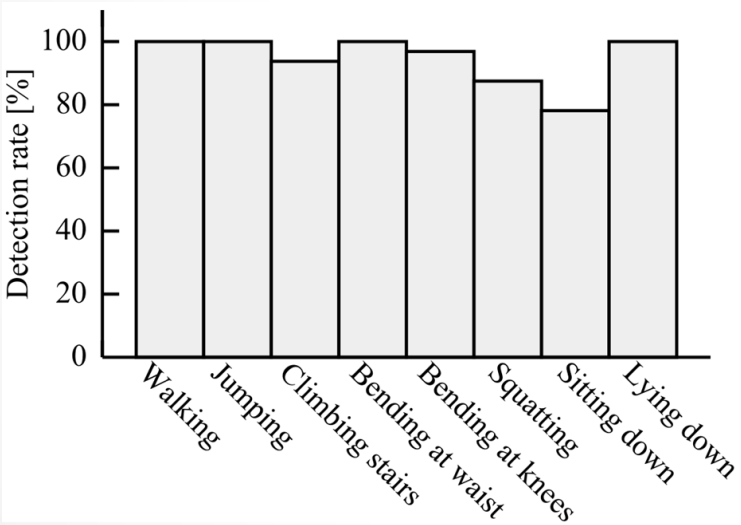
Safety

Software updates

Smart AUS

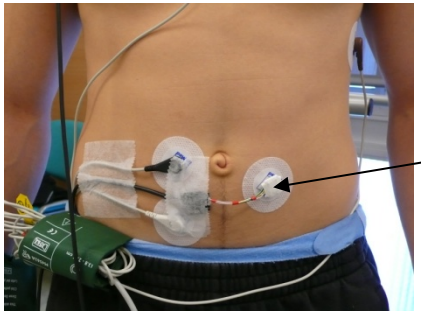
- movie

Healthy Volunteers Study

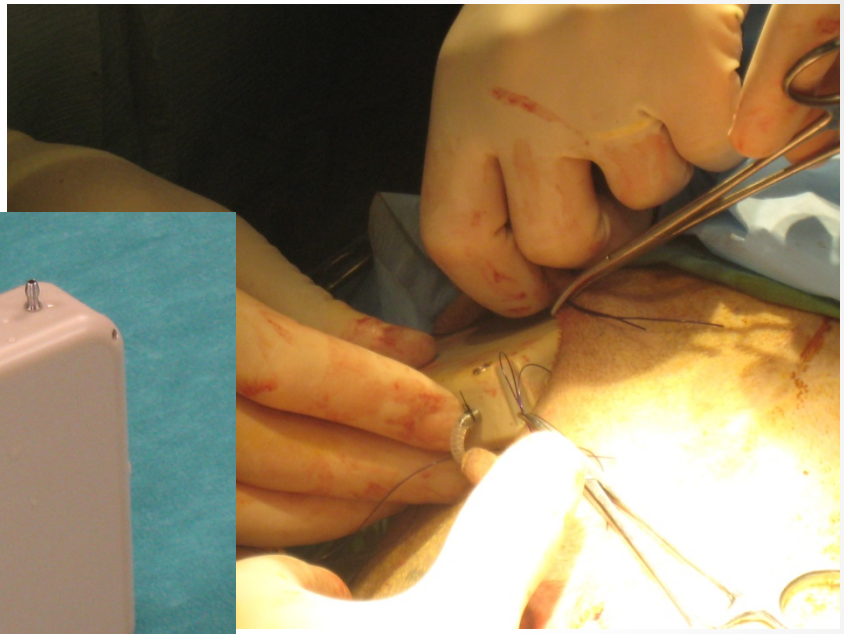


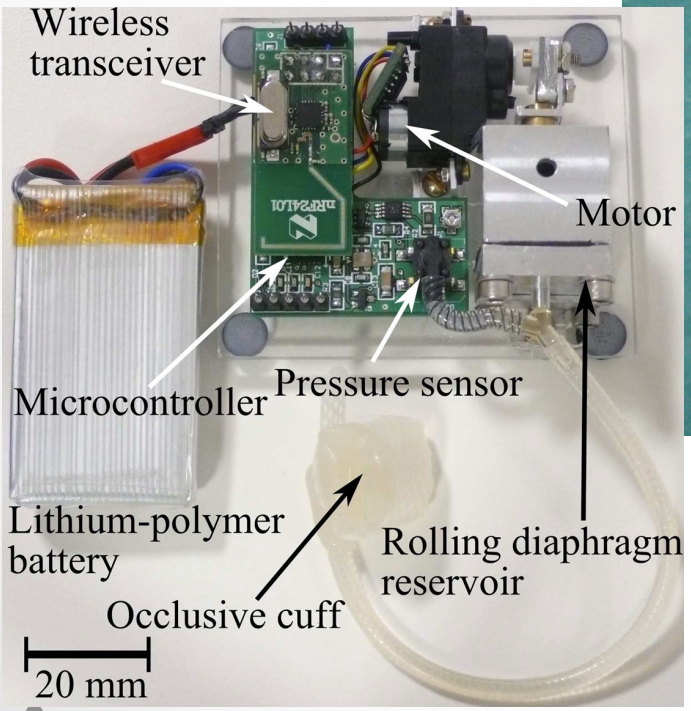
16 healthy volunteers

Detection performances with one single accelerometer

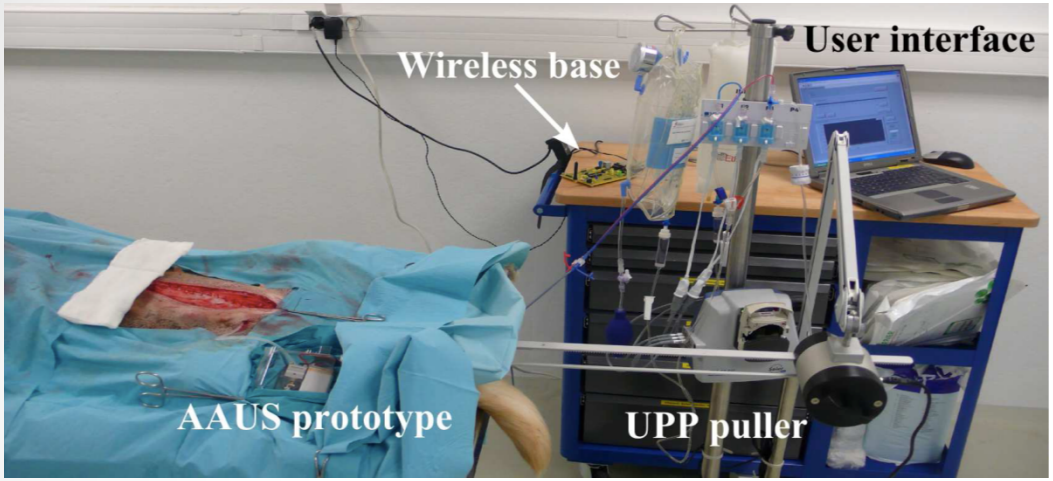


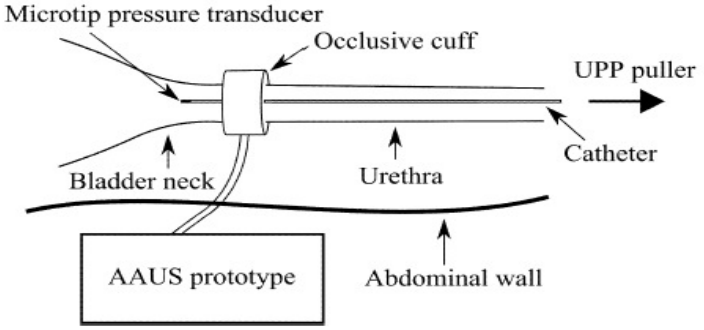
Prototype



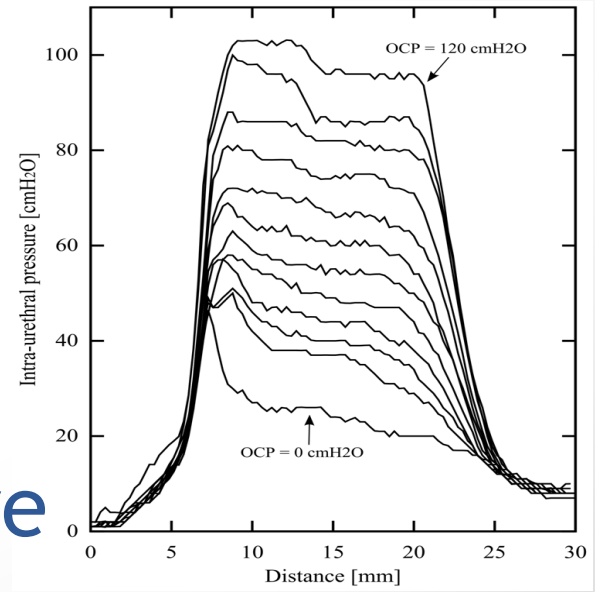

Wireless transceiver
Motor
Microcontroller
Pressure sensor
Lithium-polymer battery
Rolling diaphragm reservoir
Occlusive cuff
20 mm

Animal Study





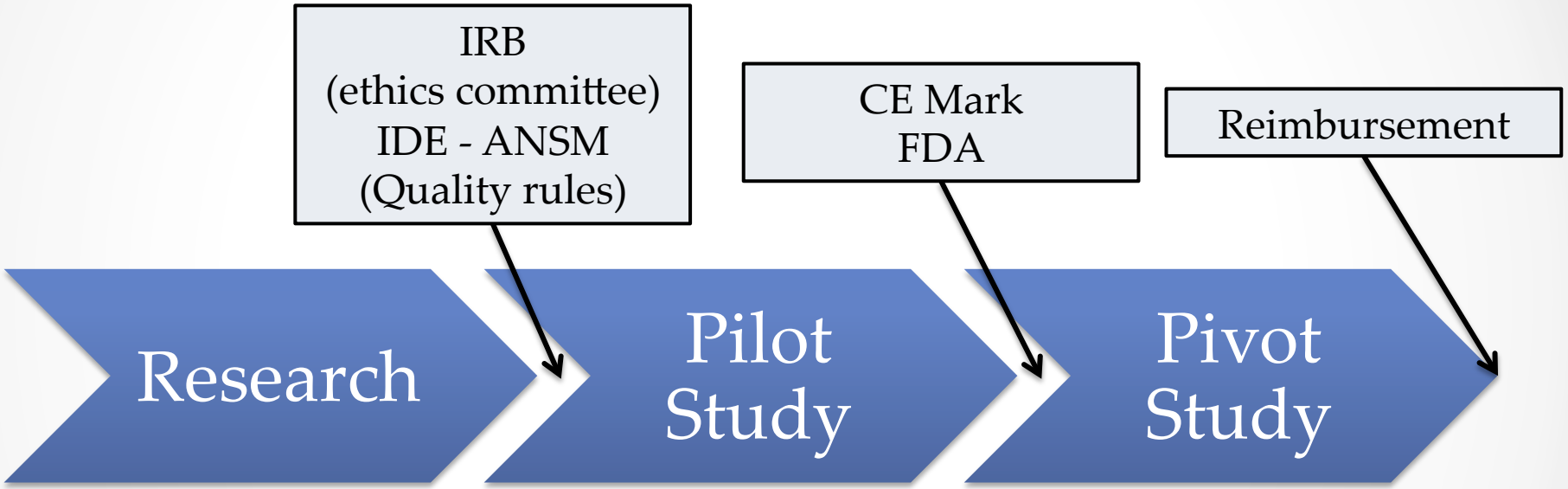
Pressure



Smart AUS

- Work always on going…
- A lot of money is needed to implant a device in a patient

Clinical Research



Few patients

1. Safety ?

2. Does it works ?

Randomized Study :
New tool VS Gold Standard

1 . Improvement for the patient (Main END POINT)

2 . Improvement for the society (cost)

Conclusion

- So many others things !!!
  - Simulation, image processing, …
- CLINICAL NEED !!!!
  - You can understand Medicine and Surgery ! (books)
  - Discuss MDs from different hospital, country and with different age !
- Try to speak the same language ;-)
  - Unit : 1 millimeter = 3 French (Fr) = 3 Charrière (Ch)
- You are in a « process »

Conflicts of Interest

- Patents and financial interest :
  - Koelis compagny (Prostate biopsies device)

  - UroMems compagny (Smart Artificial Urninary Sphincter)

UroMems

End

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