APPAC 14ème EDITION

ACTUALISATIONS ET PERSPECTIVES EN PATHOLOGIE CARDIOVASCULAIRE

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déclare avoir participé à des interventions ponctuelles (essais cliniques, travaux scientifiques, activités de conseil, conférences, colloques) pour la Société TOSHIBA Medical Systems.

Live Zoom Versus Conventional Magnification Technic

Results of a retrospective monocentric register, CH Haguenau – France

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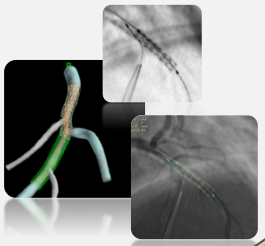
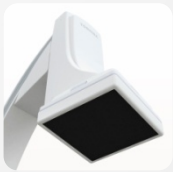
Leading Innovation

Unique
5 Axis Design
Live Zoom
Dual Axis Rotation
CV-3D

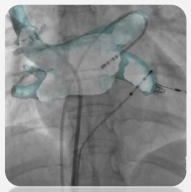


PCI Nav.
Stent-Optimizer
Stent-Fusion
Fluoro-Rec

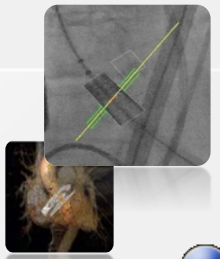
Dynamic Trace
Super Noise Reduction Filter



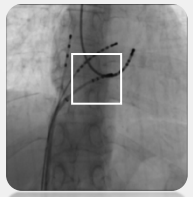
World's First Compact
FPD 30x30



EP. Nav.
Multi-Modality Fusion

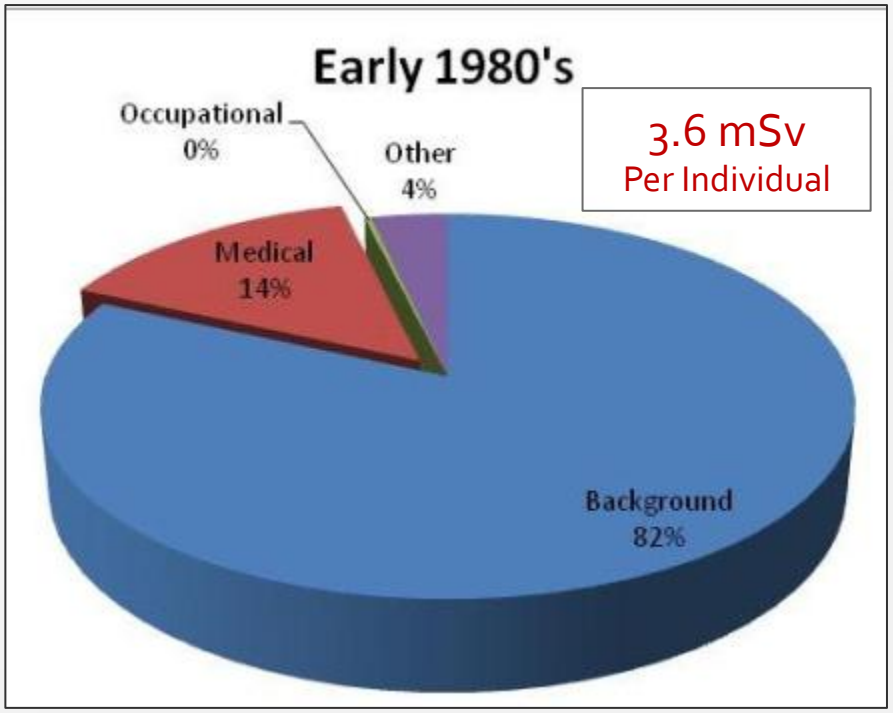


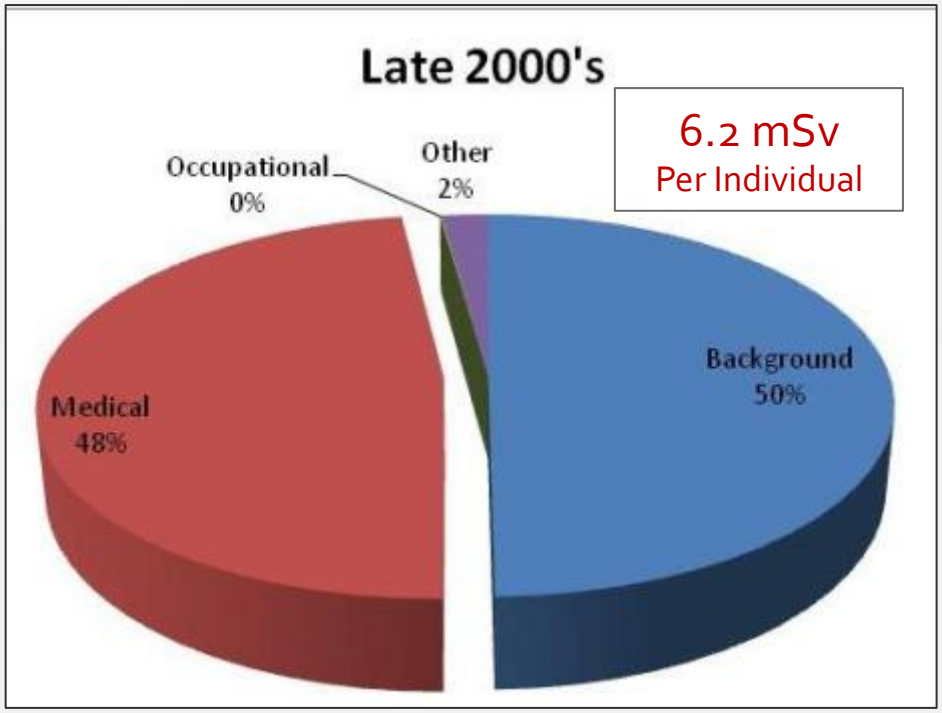
TAVI Nav.
TAVR-Planing
C-THV Guidance



World's Unique
Spot Fluoro
PCI – EP & Peripheral
Needle Guidance
Neuro 3D Intervention

Effective Dose Due to Medical Imaging Procedures



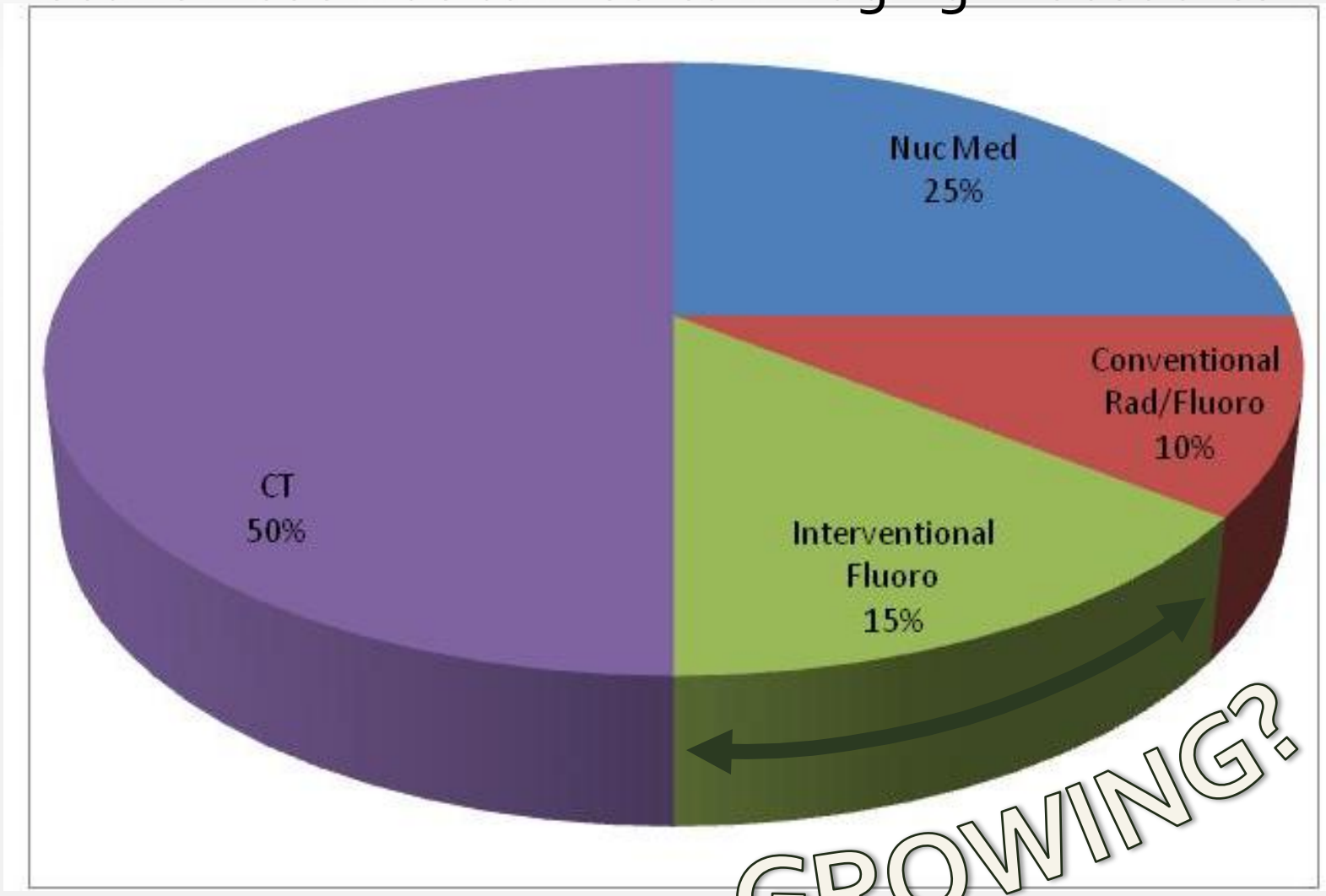


Medical Contribution:

0.5 mSv

3 mSv

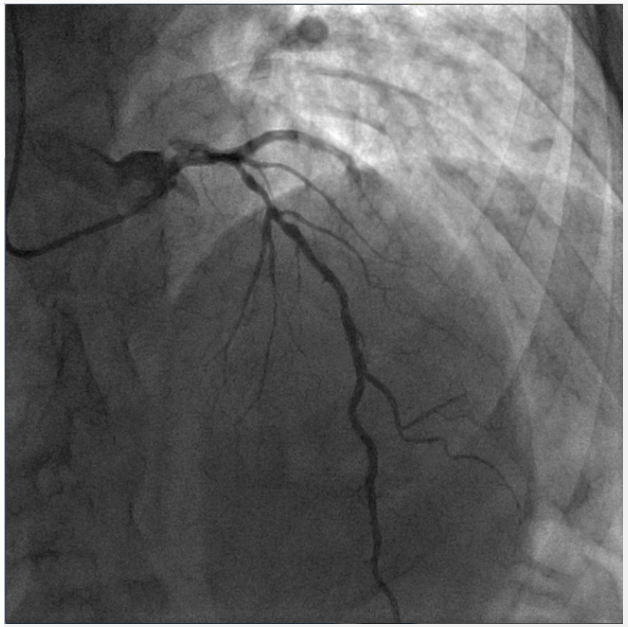
Effective Dose Due to Medical Imaging Procedures



Does Live Zoom Clinically Practical?

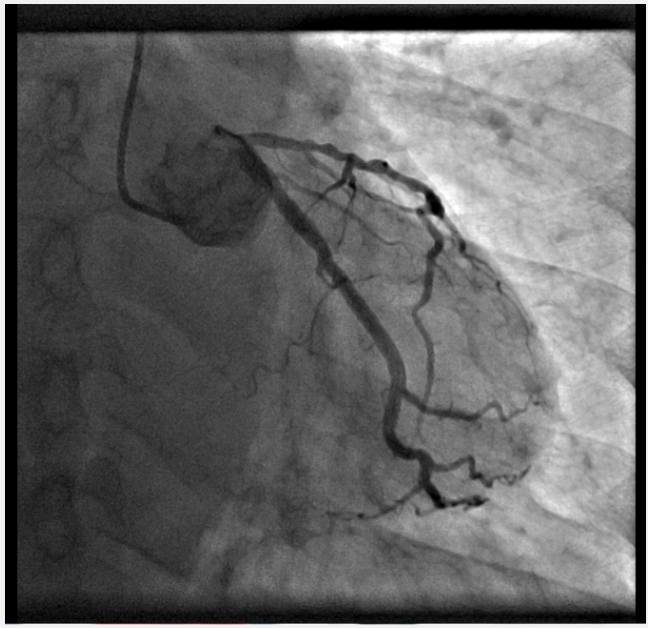
SIMON CATTAN, MD
CHI Le Raincy - Montfermeil

Does Live Zoom Clinically Practical?



FOV 20cm
Live Zoom x1.2
Dose level : - 36%

FOV 20cm
Live Zoom x1.8
Dose level: - 75%



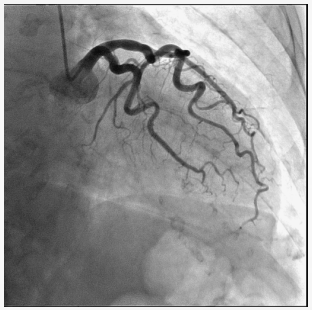
FOV 20cm
Normal Magnification
Dose level: 100%

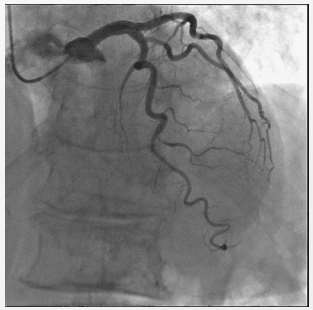
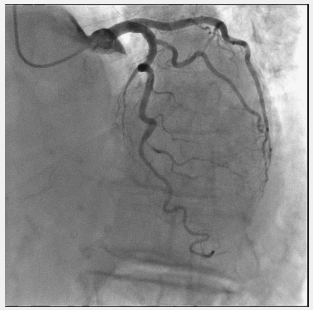
SIMON CATTAN, MD
CHI Le Raincy - Montfermeil

Does Dual Axis Rotation Saves Dose?

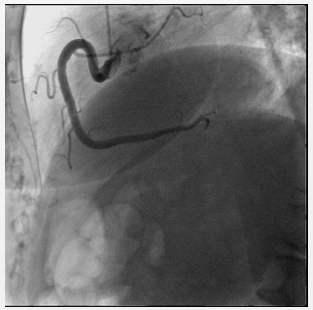
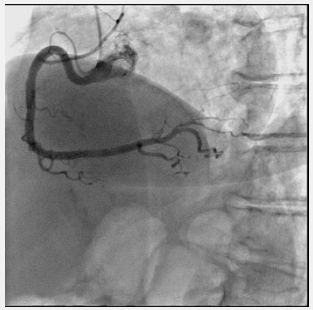
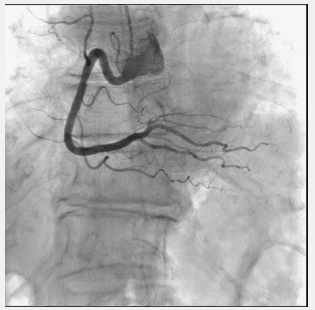
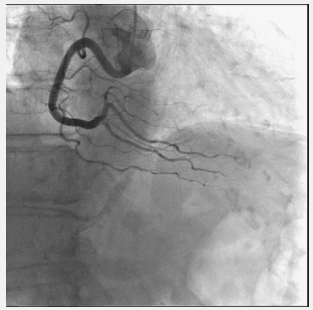
APPAC 2009

Does Dual Axis Rotation Saves Dose?



Clinical data
courtesy from
CH Haguenau - France

		NORMAL DIAGNOSTIC			DUAL AXIS ROTATION STUDY	
	Unit	GACI	NRD*	INFINIX-i **		
DAP	Gy.cm²	56	57	35	24	-57%
Fluoro time	Mn	7	6	4	3,9	-35%
Nbr of Frame		876	1270	900	272	- 78%

*Source: Neofotistou V, Preliminary reference levels in interventional cardiology, EUR RADIOL., 2003, 13, 2259-63

* *Source: Data recorded from preliminary study at,
St Elisabeth Clinic, Brussels -CH Haguenau, France - CHI Montfermeil, France - NHS Trust, Hammersmith, UK

* * * Source : Clinical study published in « Annales de CARDIOLOGIE ET D'ANGIOLOGIE Nov. 2009 , Vol 58 p. 252-357» website, elsevier.com

Does Live Zoom Saves Dose?

Does Live Zoom Saves Dose?

- Purpose
  - Evaluation of the clinical benefit using variable live zoom technic instead of normal magnification in fluoroscopy as well as digital acquisition in term of Dose.

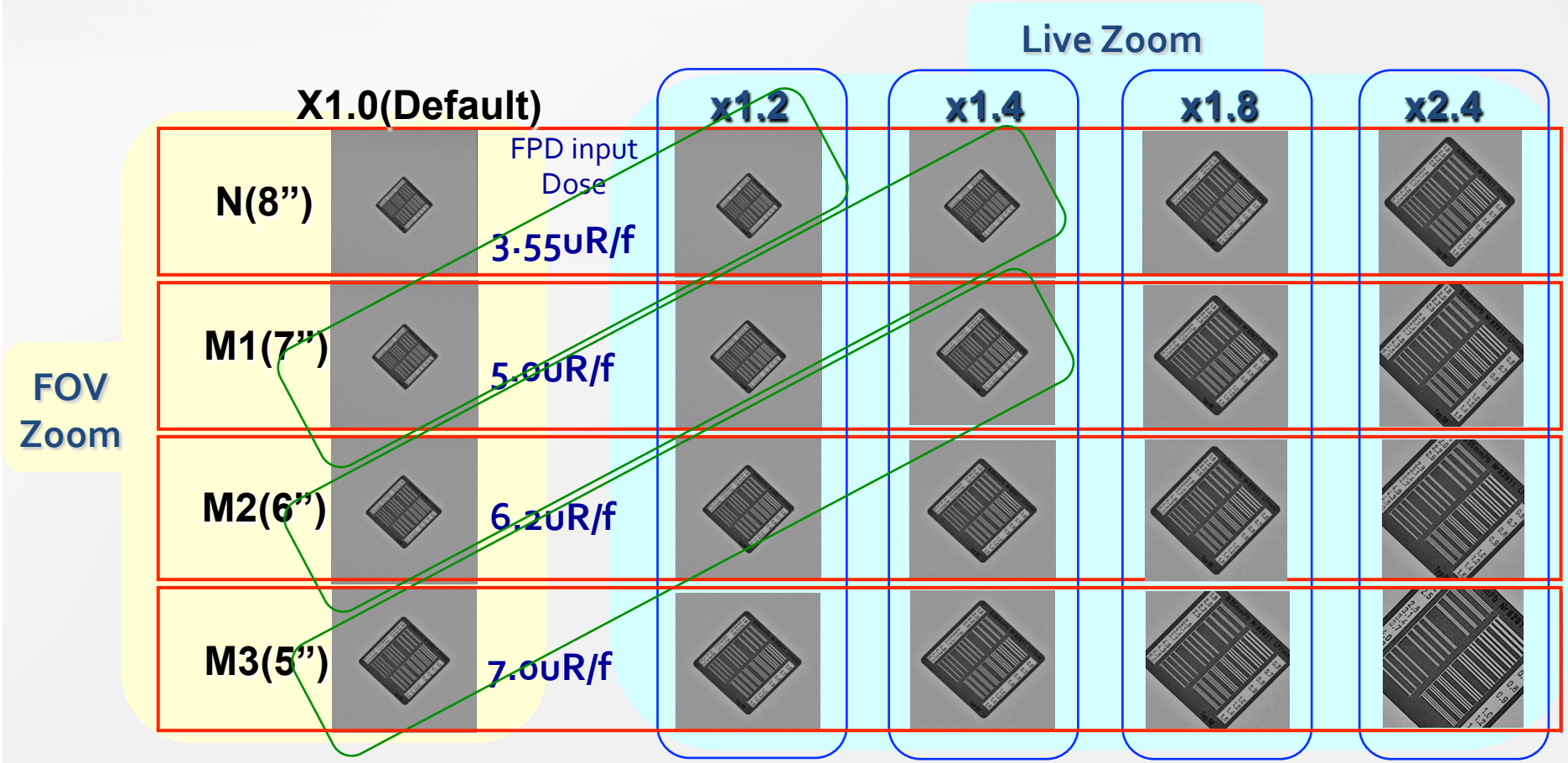
- Benefit
  - Optimization of the dose versus clinical pratice

- NB: Each magnification mode may increase DAP from x1.3 up to x3.

Application Protocoles

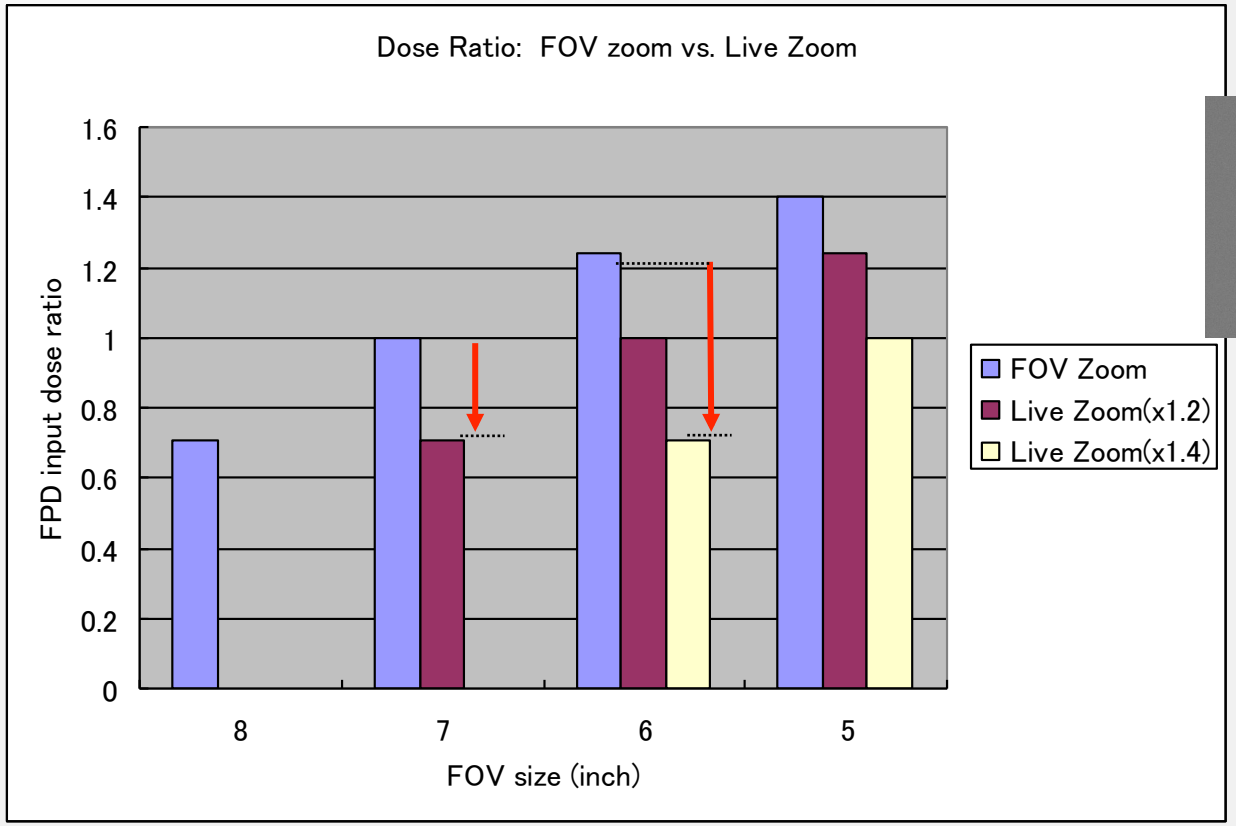
- Use of the same settings and live zoom parameters for both fluoro and DA. « Live Zoom » vs « Non Live Zoom ».
- Comparison of the Live Zoom 1.2 factor versus Magnification mode #1 in coronary study (17x17cm).
- No use of Live Zoom for LV injection -> FOV = 20x20cm
- Same protocole for all 4 operators.

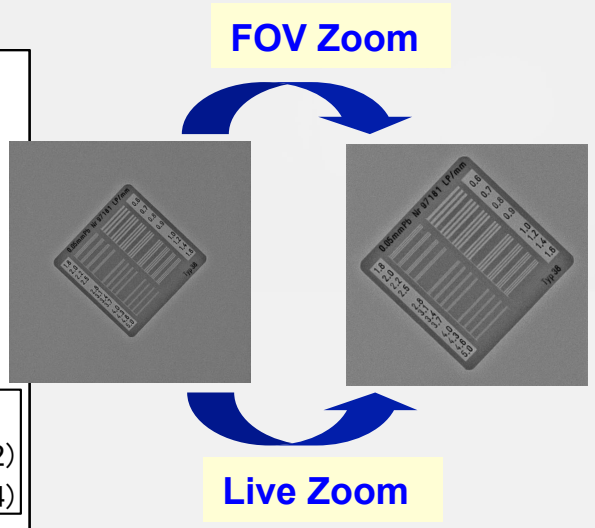
FOV Zoom vs. Live Zoom



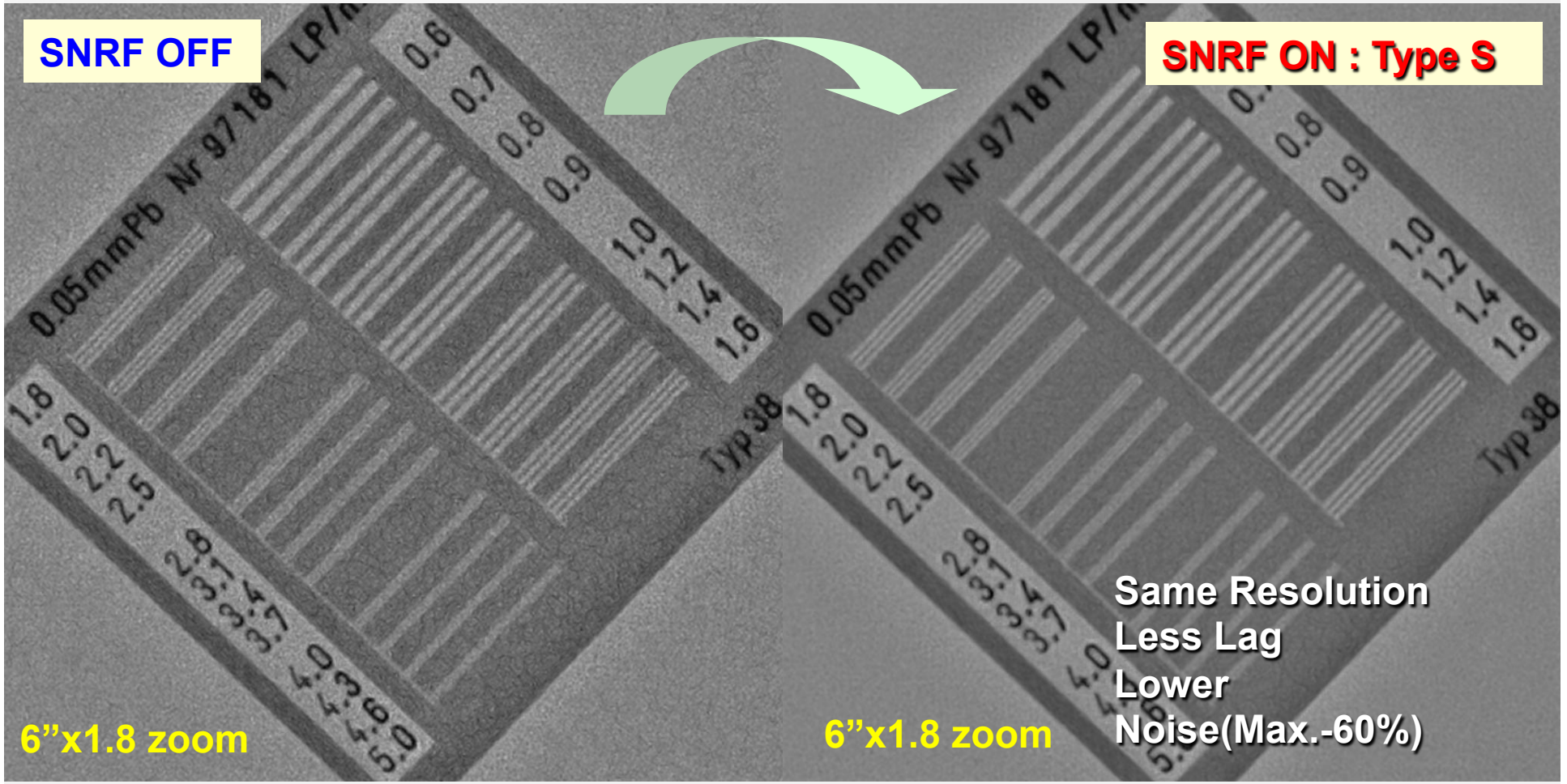
Live Zoom

Dose saving data by using Live Zoom function





Live Zoom



SNRF* : Super Noise Reduction Filter without image lag

Clinical Protocoles

- Retrospective study : Feb. 2010 – Avr. 2010
- 4 operators
- Nbre of patients, n=100
- Data collected via Unimed apps SW
  - DAP total
  - Fluoro time total
  - Nbre of frames total
- Subtraction of datas which were out of diagnostic scope or additional acquisition « Shunt, peripheral, transplant(s), etc… » (DAP, Fluoro time & number of frame)
- Femoral approach
- 4F catheters

Intermediate Result At n=50pts

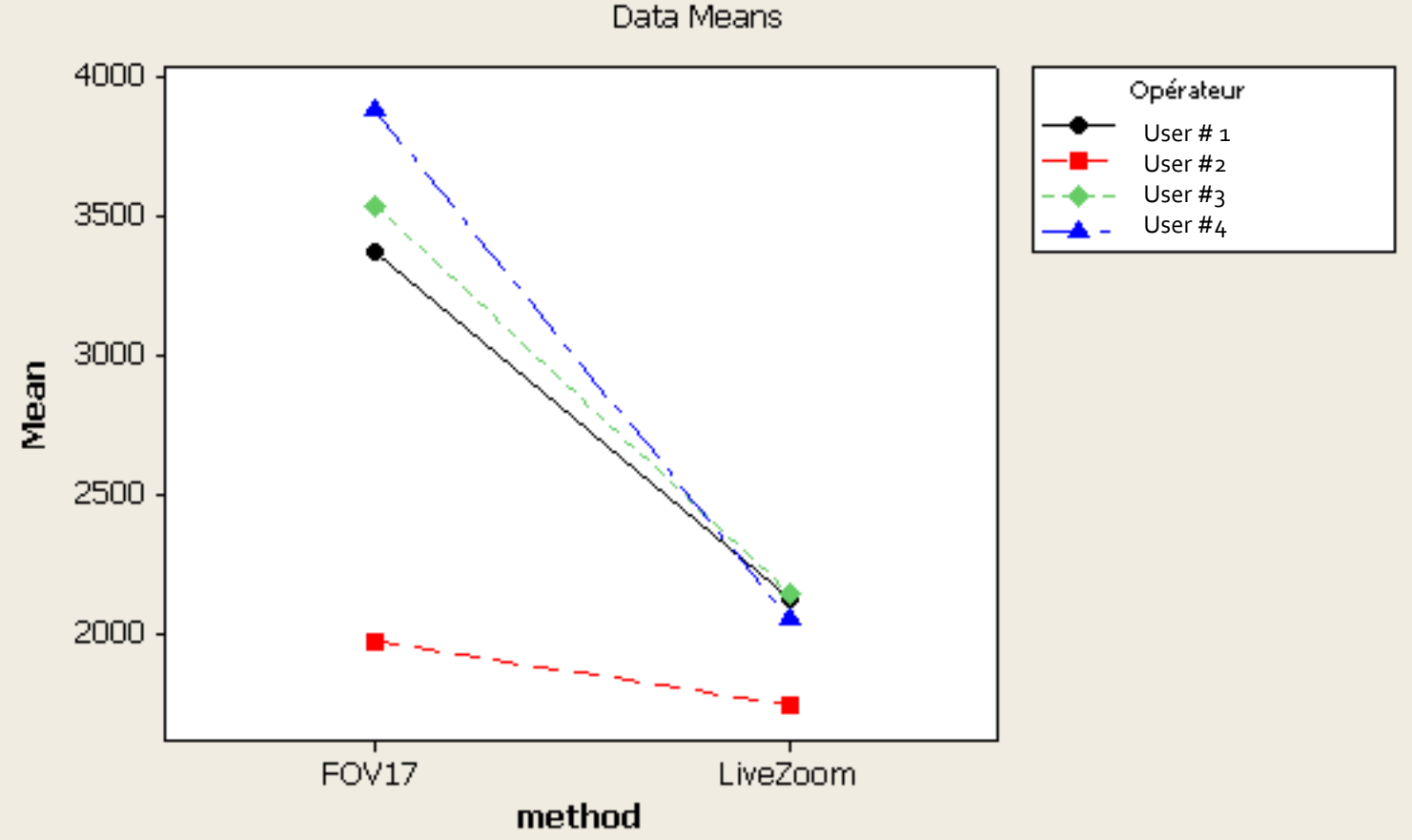
- Test « OneWay – ANOVA », *p=0,006*

Level	N	Mean	StDev	Individual 95% CIs For Mean Based on Pooled StDev
FOV17	50	4736	6333	(--------*--------)
LiveZoom	50	2527	1612	(-------*--------)

--+---------+---------+---------+-------

1500 3000 4500 6000

Interaction Plot for Diamentor (cGy.cm²)



Intermediate Results : Summary

- Live Zoom available during fluoro & DA.
- Several Live Zoom factors available (1.2 -> 2.4)
- Can be selected manually and/or be set as default settings and can be change just with one click: Take care of the clinical practice!!!

- « Live Zoom » is a great tool for dose reduction (up to -47%) in routine during diagnostic. (p=0,006)

Intermediate Results : Summary

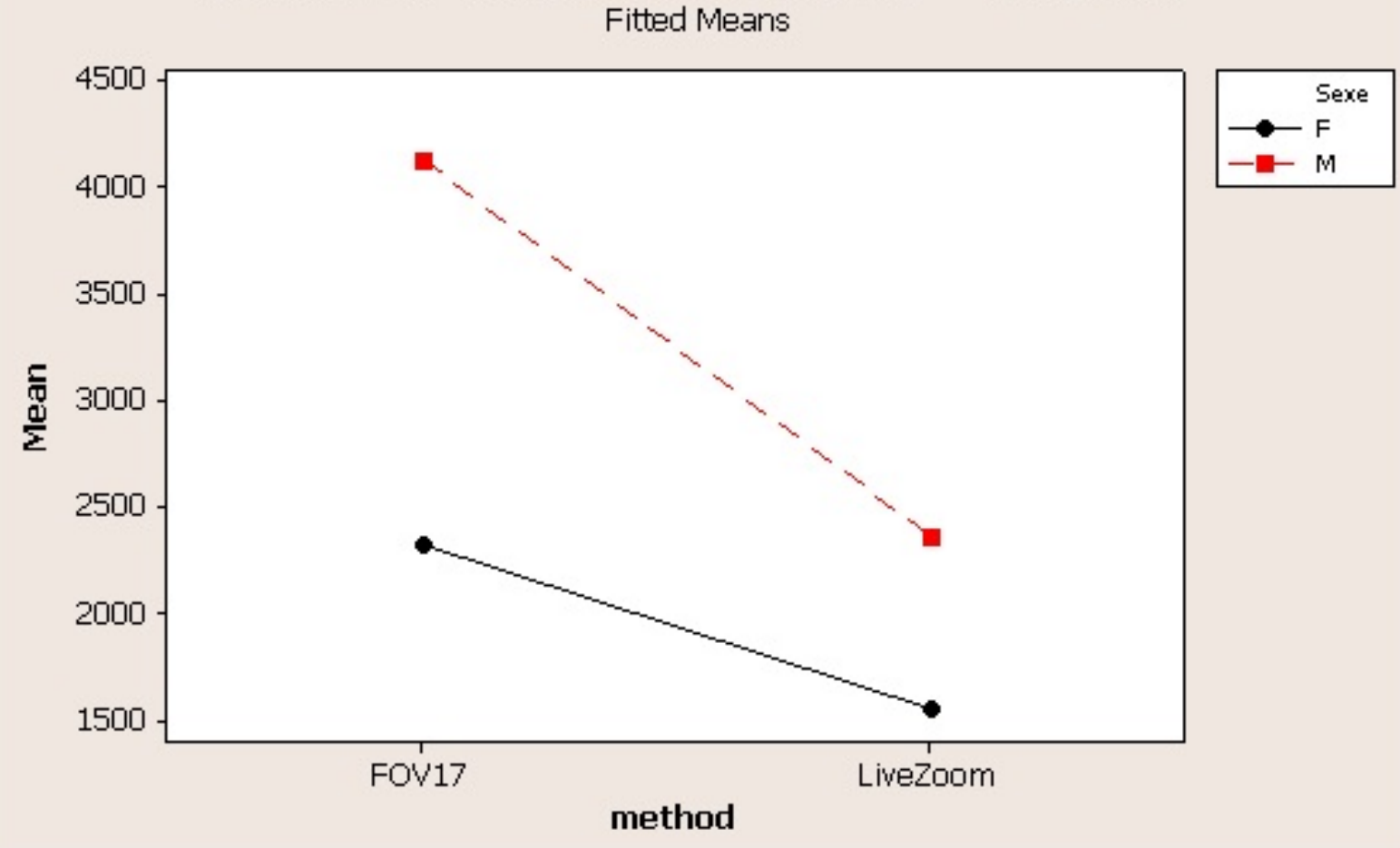
- However the datas are not properly balanced.
- To avoid any bias in the statistical analysis we must have balanced sample.

	FOV-17	Live Zoom	All
Operator #1	17	18	35
Operator #2	15	12	27
Operator #3	11	10	21
Operator #4	7	10	17
All	50	50	100

Where are we finaly in 2012?

Final Statistical Analysis, n=192pts

Interaction Plot For Total DAP – cGy.cm²



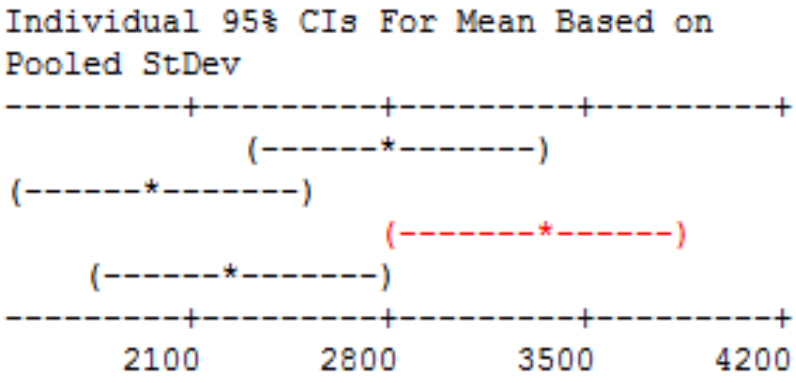
One-way ANOVA : Diamentor

Total DAP – cGy.cm² vs Operator

Source	DF	SS	MS	F	P
Opérateur	3	51863377	17287792	4,92	0,003
Error	188	659990000	3510585		
Total	191	711853377			

S = 1874 R-Sq = 7,29% R-Sq(adj) = 5,81%

Level	N	Mean	StDev
Dr User # 1	48	2811	2193
Dr User #2	48	1977	1566
Dr User #3	48	3326	1945
Dr User #4	48	2253	1731



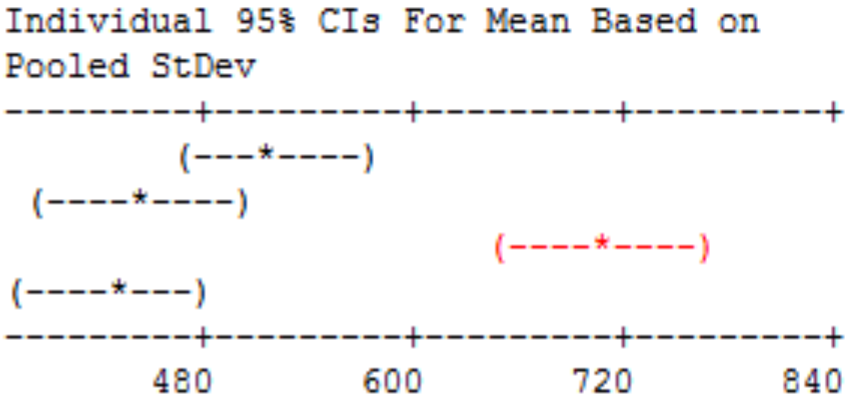
One-way ANOVA : Nbr of Frames

Total Nbr of Frames vs Operator

Source	DF	SS	MS	F	P
Opérateur	3	2428739	809580	18,35	0,000
Error	188	8292641	44110		
Total	191	10721380			

S = 210,0 R-Sq = 22,65% R-Sq(adj) = 21,42%

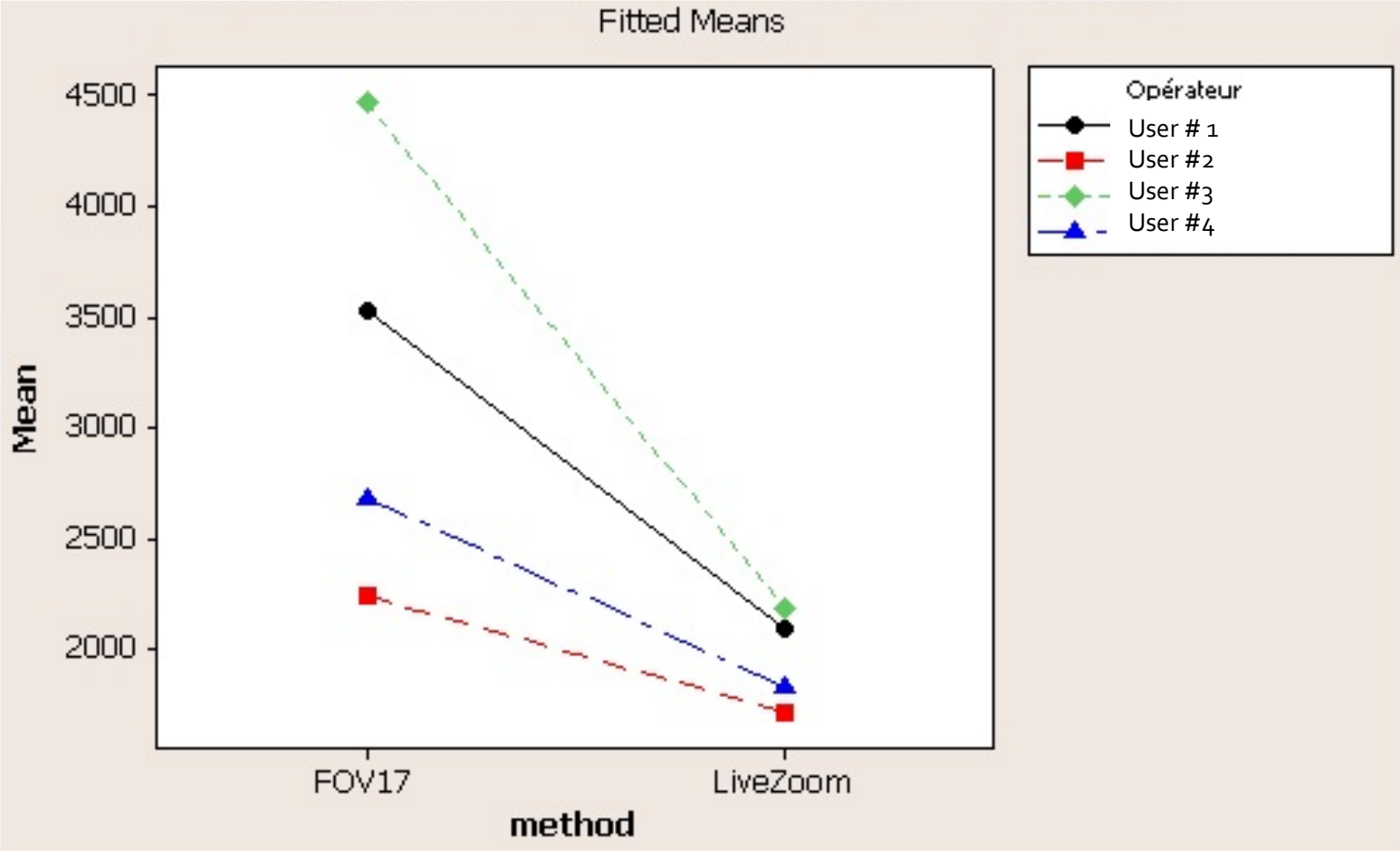
Level		N	Mean	StDev
Dr	User # 1	48	522,0	263,9
Dr	User #2	48	449,3	172,3
Dr	User #3	48	712,3	241,5
Dr	User #4	48	426,1	137,1



The other 3 operators seem to consistently work in the same way.
When we remove User#3's data from the set, then there are no significant interactions anymore.
Only the main effects Sex and Method are then significant:

Interaction Plot for Diamentor (cGy.cm²)

Total DAP vs Operator per Method



Interaction for Fluoro Time (min)

- Note:The ANOVA analysis requires the data to be normally distributed. However, as expected, the "temps de scopie" is not normally distributed (it follows a Weibull distribution).
- Therefore first transformed the data to normal using Box-Cox transform to "FT-boxcox" before doing the ANOVA

Interaction for Fluoro Time (min)

Analysis of Variance for FT-boxcox

Source	DF	SS	MS	F	P
Opérateur	3	0,32094	0,10698	3,79	0,012
Sexe	1	0,28086	0,28086	9,94	0,002
method	1	0,04729	0,04729	1,67	0,198
Opérateur*method	3	0,08010	0,02670	0,94	0,420
Opérateur*Sexe	3	0,04082	0,01361	0,48	0,696
Sexe*method	1	0,04796	0,04796	1,70	0,194
Opérateur*Sexe*method	3	0,03659	0,01220	0,43	0,731
Error	176	4,97357	0,02826		
Total	191	5,82813			

S = 0,168104 R-Sq = 14,66% R-Sq(adj) = 7,39%

- All other P-values are well over 0.05, meaning that none of the other terms in the model are significant (no other factors or interactions)

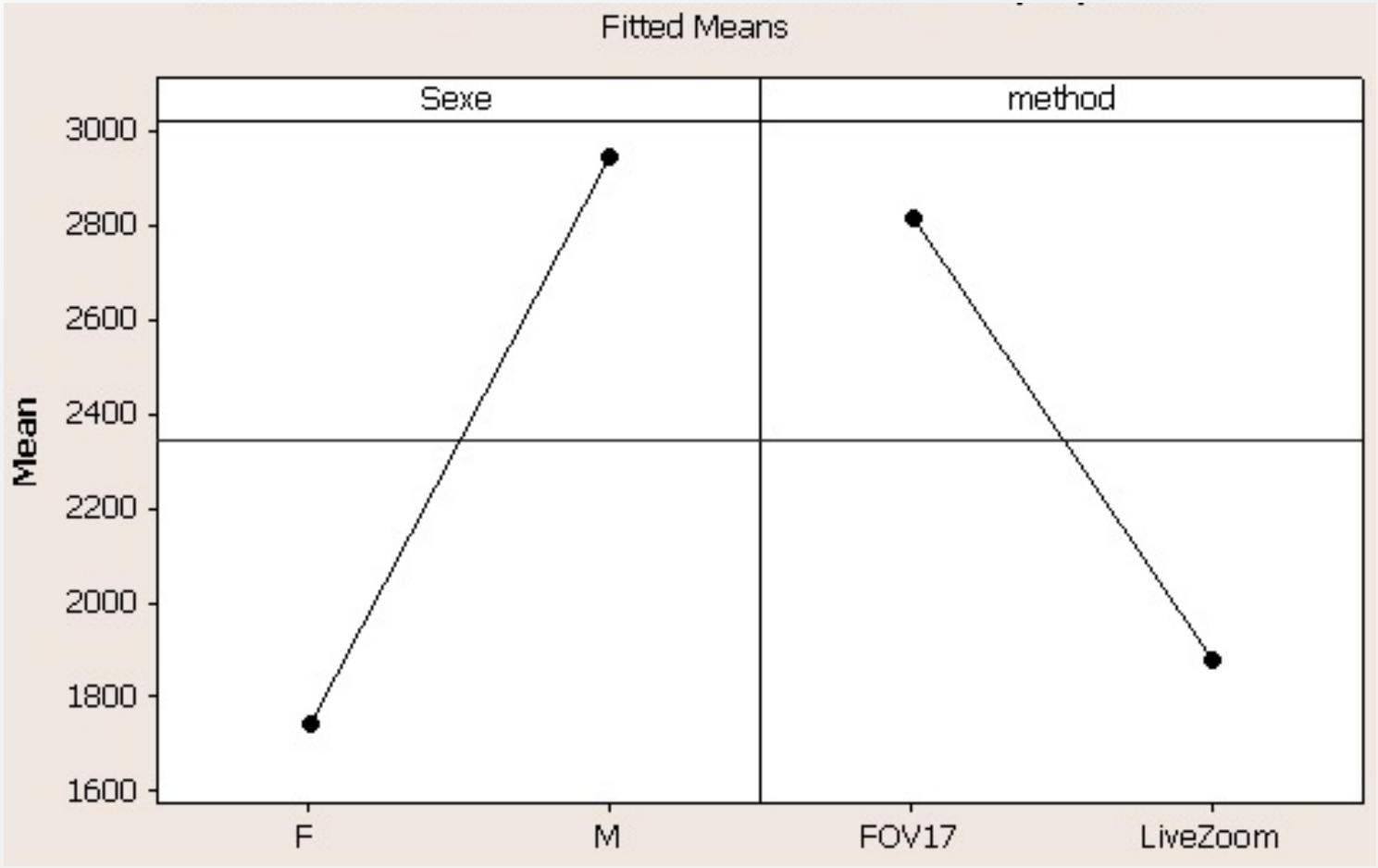
Interaction for Fluoro Time (min)

- **Mood Median Test:**
  - **Temps de Scopie (Min) versus method**

```
Mood median test for Temps de Scopie (Min)
Chi-Square = 1,03    DF = 1    P = 0,311

                                          Individual 95,0% CIs
method     N<=  N>  Median  Q3-Q1  --+---------+---------+---------+----
FOV17       48  48   2,050  1,775       (---------*----------------)
LiveZoom    55  41   1,900  1,400  (-------*-----------)
                                    --+---------+---------+---------+----
                                    1,75      2,00      2,25      2,50
```

2 Factors Only Remaining

Total DAP vs Sex&Method



Two-Sample T-Test and CI: TOTAL DAP – cGy.cm²

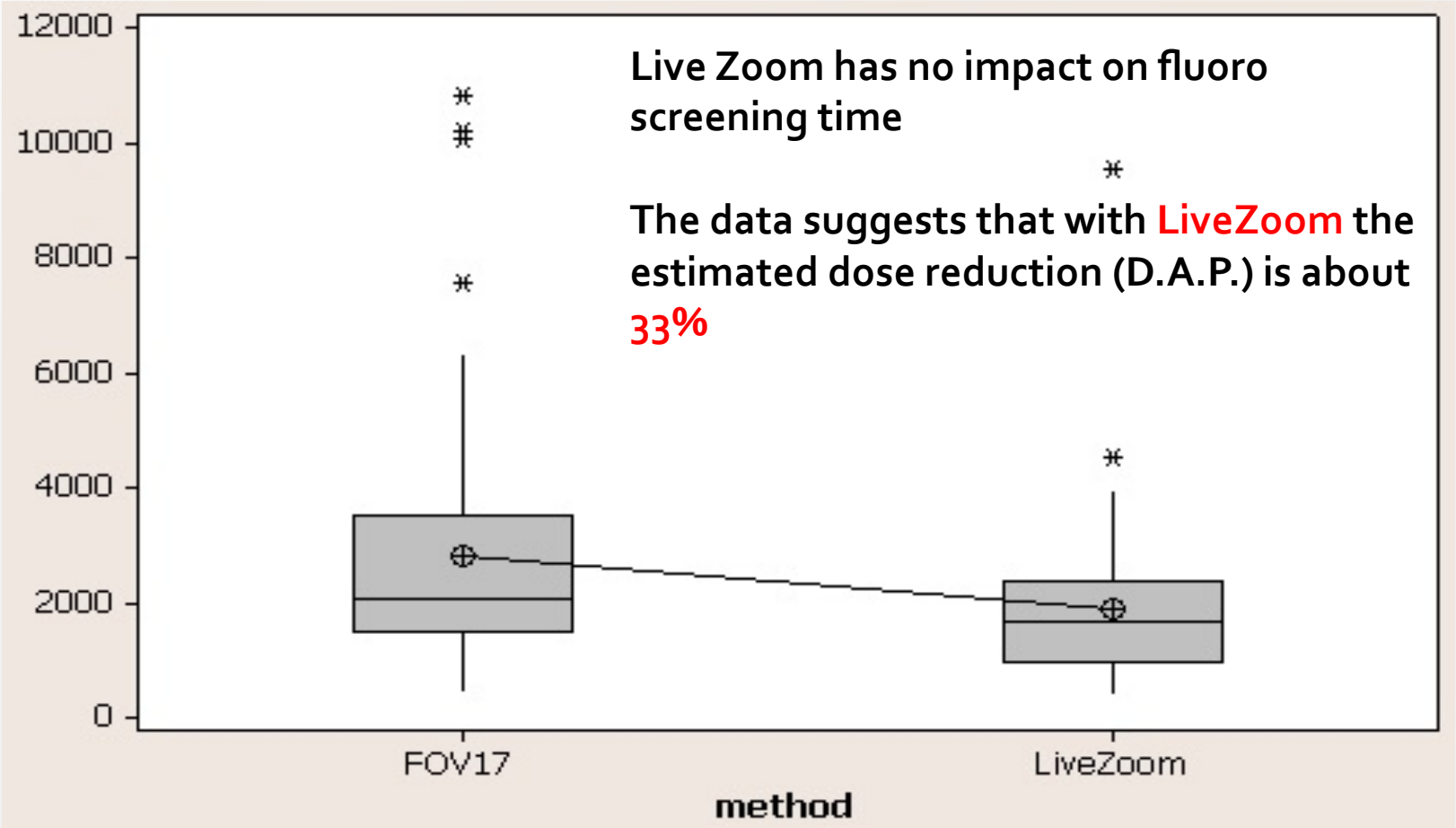
- When we disregard "Sex" and purely focus on the effect of the method (FOV17 versus LiveZoom), then we get the following result:

```
Two-sample T for Diamentor TOTAL        (cGy/cm2

method      N  Mean  StDev  SE Mean
FOV17      72  2816   2195      259
LiveZoom   72  1878   1332      157


Difference = mu (FOV17) - mu (LiveZoom)
Estimate for difference:  937
95% lower bound for difference:  436
T-Test of difference = 0 (vs >): T-Value = 3,10  P-Value = 0,001  DF = 117
```

Does Live Zoom Saves Dose?

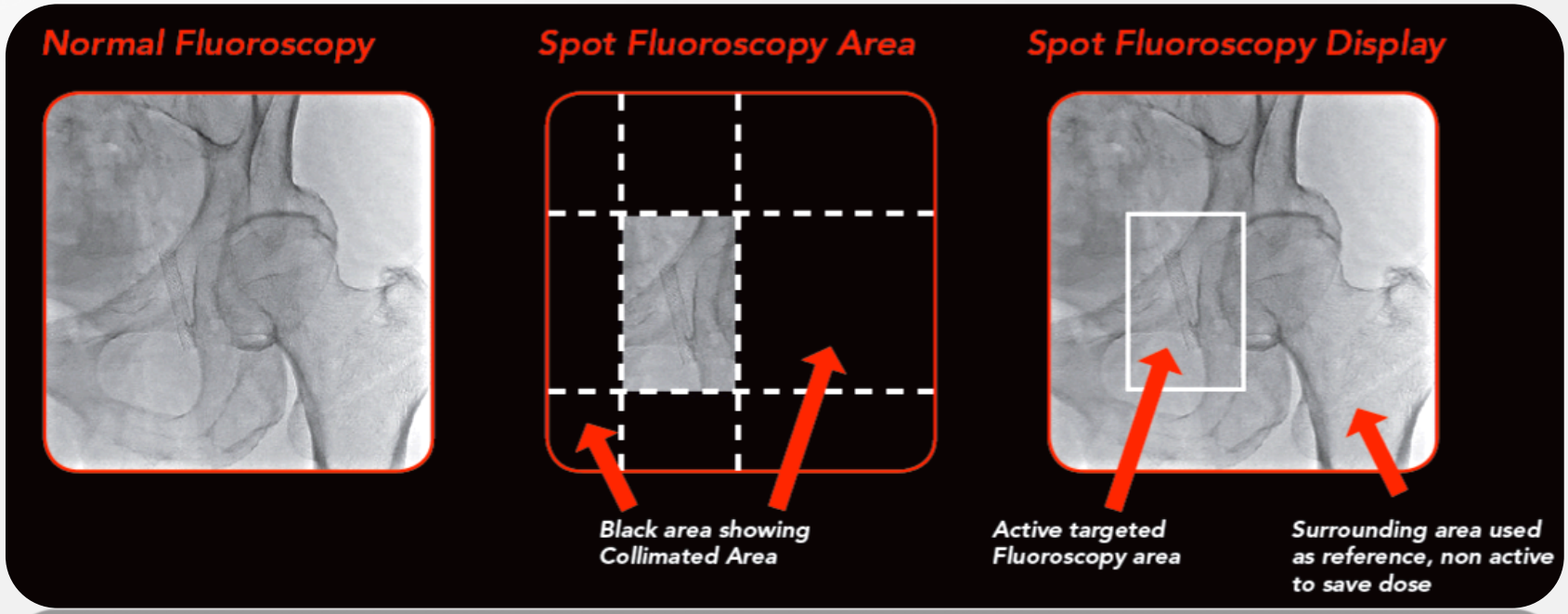
Does Live Zoom Saves Dose?

Boxplot of Total DAP – cGy.cm²

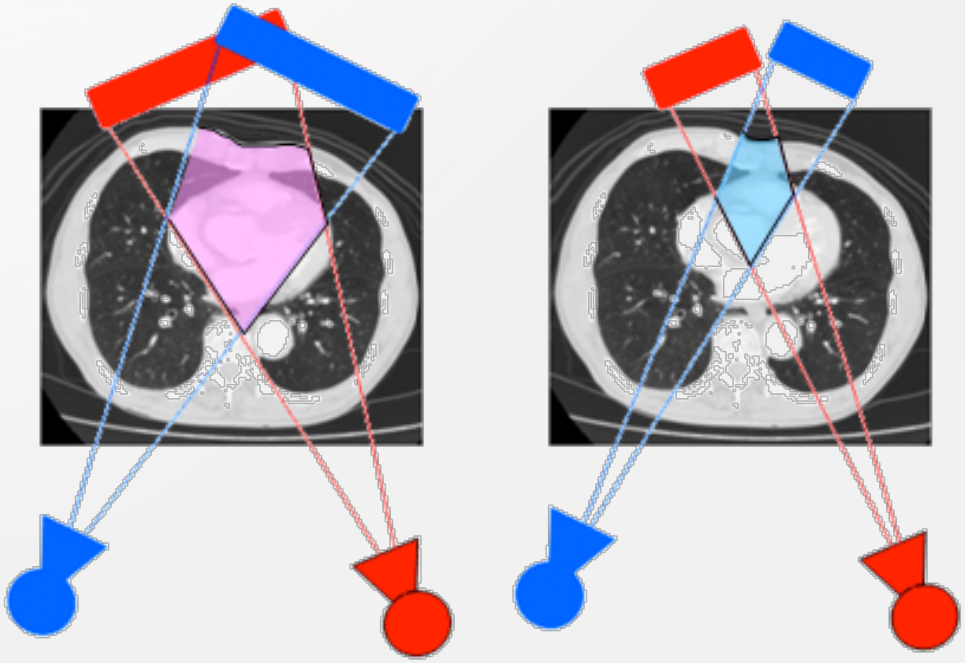


Can We Do Things Better & Different?

- Spot Fluoro: A unique feature to achieve more dose reduction during complexes interventions.



Spot Fluoro – A Game Changer Technology

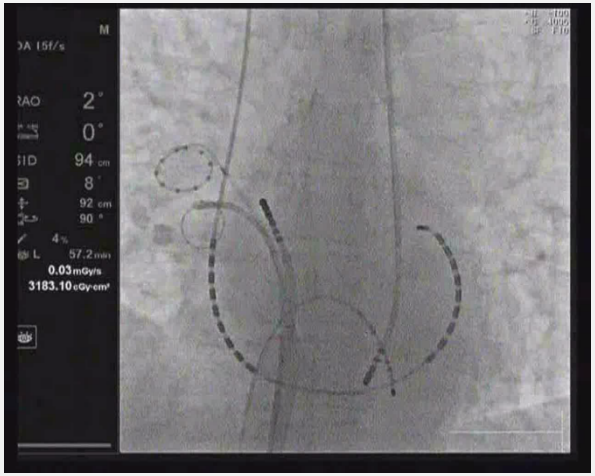


- As exposure is needed from different angles, Spot Fluoroscopy can minimize the overlap between each exposure, that can save patient from unnecessary dose as much as possible.

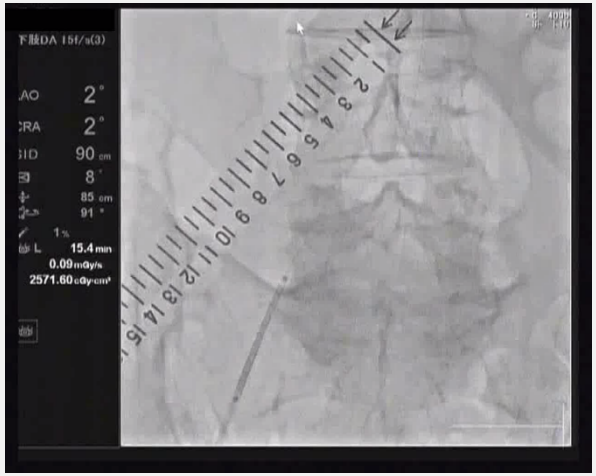
Spot Fluoro – A Game Changer Technology

- The procedures that includes steps of holding the FOV for certain while.
  - Cardiac: IHD (PCI), EP
  - Neuro: Aneurysm coiling
  - Abdomen: AAA, Iliac stenting
  - Peripheral: PPI

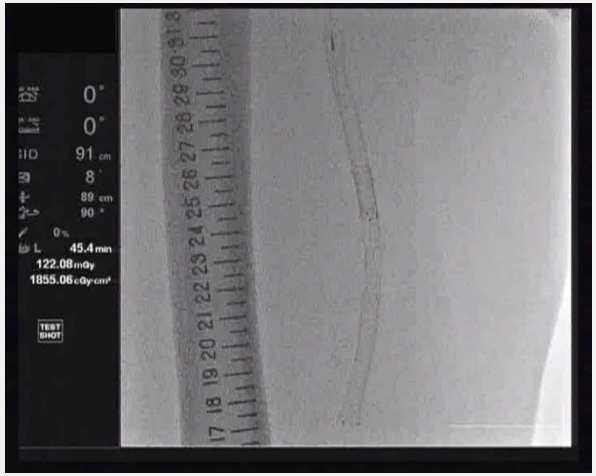
=> Since Spot Fluoroscopy is the world first technology, its potential is rapidly being expanded.



< Cardiac EP/Ablation Catheter Tip Placement >

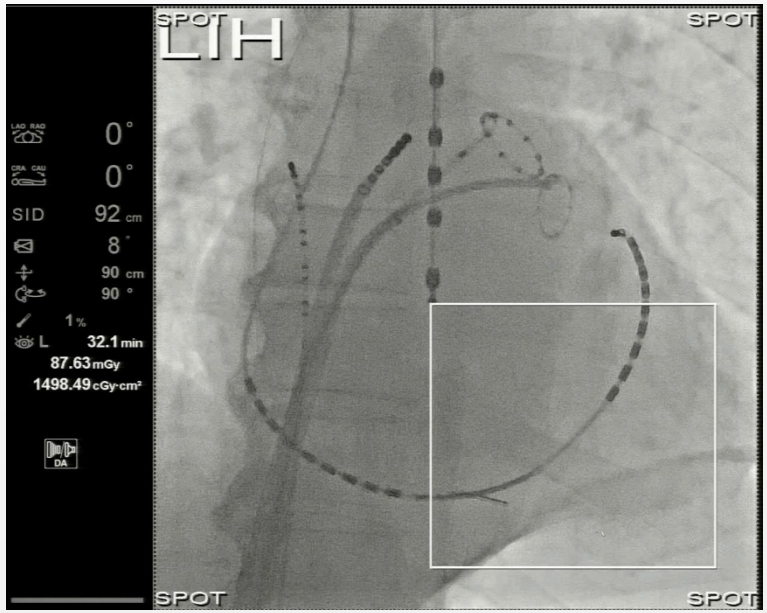


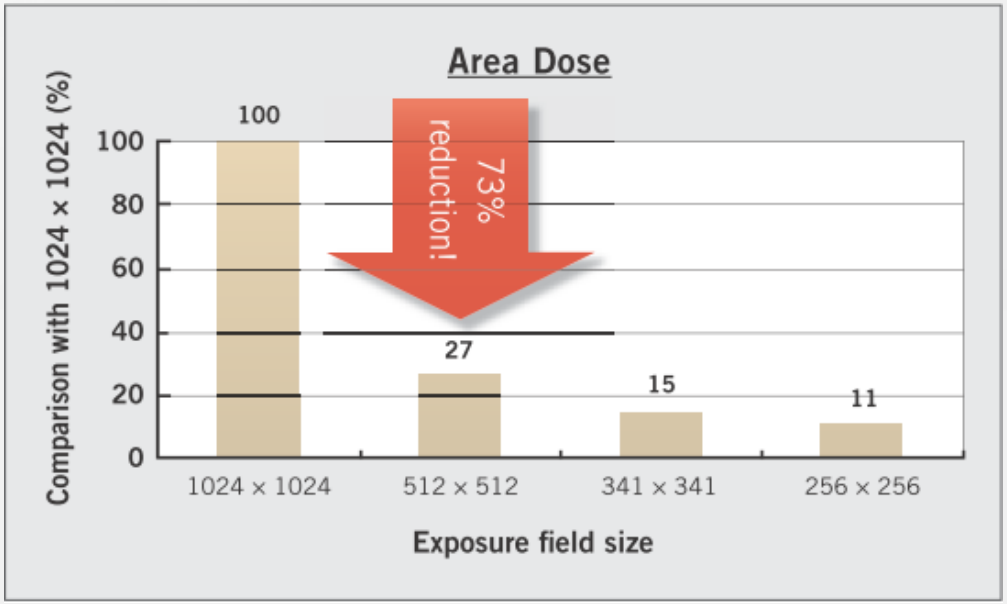
< Iliac Stent Positioning >



< Femoral Stent Deployment >

Spot Fluoro – A Game Changer Technology





- If the cumulative dose for normal field size are defined as 100, the Spot Fluoroscopy can reduce it over 50% or more that means patient risk for dose can be significantly decreased.

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Thank you for your attention

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