

FINAL RESULTS OF NOVARAD STUDY

NOVARAD IS A MULTICENTRIC, TWO-ARM PROSPECTIVE STUDY, ASSESSING X-RAY DOSES REDUCTION USING NOVA-X®, A NEW FULL-BODY AND TEAM-WIDE RADIATION PROTECTION SYSTEM FOR CATH LAB STAFF DURING NEUROVASCULAR PROCEDURES.

STUDY DESIGN

3 OPERATORS AT THE SAME TIME
- 20 operator 1

178 PROCEDURES IN 4 FRENCH CENTERS
- Bicêtre University Hospital
- Nantes University Hospital
- Toulouse University Hospital
- Besançon University Hospital

DIFFERENT ANATOMIC POSITIONS
- 7 for operators 1 and 2
- 4 for operator 3

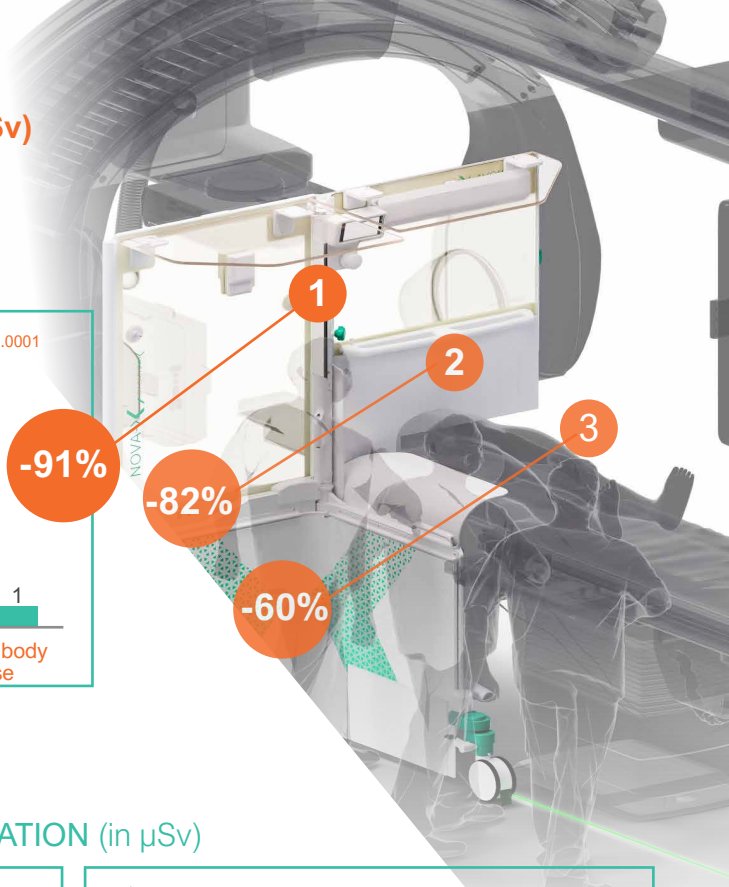
LAST-GENERATION OPERATIONAL DOSIMETERS
EPD Mk3, APVL, France
- Minimum detection level = 0.1 µSv (vs. 1.0 µSv for similar studies in interventional cardiology)
- Detection of minimal doses < 15 keV (vs. <30 keV for similar studies in interventional cardiology)

PROCEDURAL CHARACTERISTICS

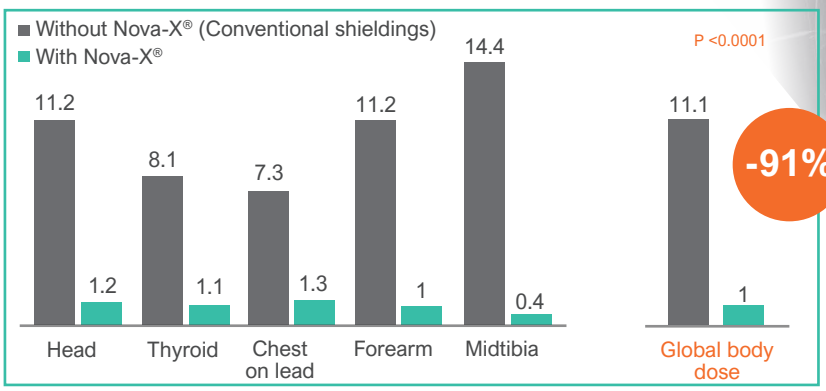
Variable	CPE* - without Nova-X (n=90)	Nova-X (n=88)
Center ID		
01	28 (31.1%)	25 (28.4%)
02	25 (27.8%)	33 (37.5%)
03	10 (11.1%)	4 (4.5%)
04	27 (30.0%)	26 (29.5%)
Lead apron thickness		
0.5 mm	46 (51.0%)	39 (44.0%)
0.35 mm	39 (43.0%)	38 (43.0%)
0.25 mm	5 (6.0%)	11 (12.0%)
Type of artery access		
Femoral	76 (84.4%)	76 (86.4%)
Radial	7 (7.8%)	5 (5.7%)
Two access	7 (7.7%)	7 (7.9%)
Type of procedure		
Aneurysm	37 (41.1%)	41 (46.6%)
Arteriography	29 (32.2%)	27 (30.7%)
Embolization MAV/FAV	9 (10.0%)	6 (6.8%)
Thrombectomy	8 (8.9%)	4 (4.5%)
Embolization SDH	2 (2.2%)	4 (4.5%)
Venous stending	2 (2.2%)	3 (3.4%)
Angioplasty	2 (2.2%)	1 (1.1%)
Spinal arteriography	0 (0.0%)	1 (1.1%)
Other	1 (1.1%)	1 (1.1%)
Intervention duration (min)		
Mean	85.91	86.60
Median	74.00	74.00
Min-Max	13.00 - 280.00	14.00 – 276.00
Dose Area Product (Gy.cm²)		
Mean	**104.06**	**83.47** P. value <0.001
Median	86.00	64.35
Min-Max	10.70 - 480.00	5.13 – 295.00

*CPE: Conventional Protective Equipment

DOSES PER PROCEDURE PER OPERATOR (in µSv)
ALL CENTERS

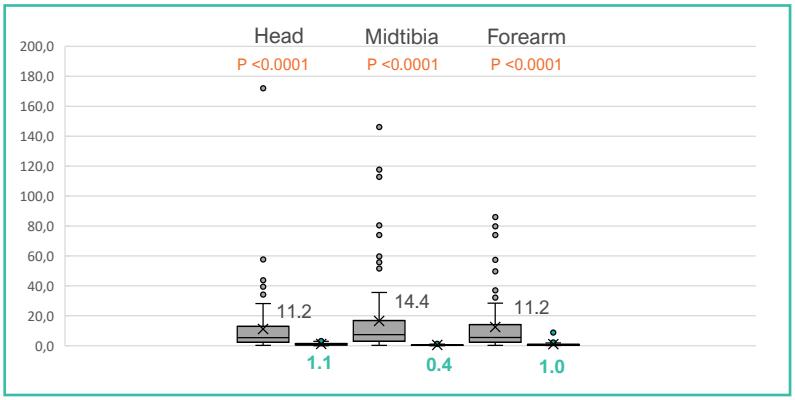


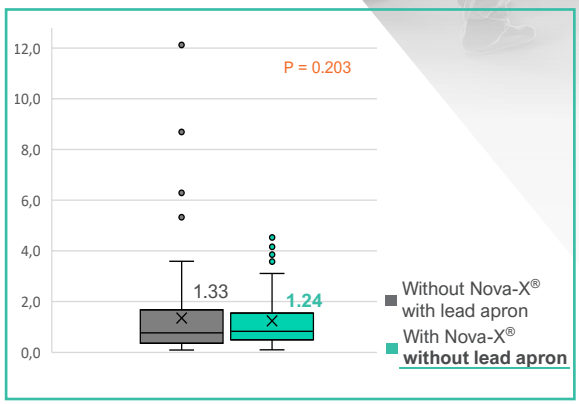
OPERATOR 1 MEAN DOSE PER PROCEDURE BY ANATOMIC POSITION (in µSv)



LEAD-FREE PROCEDURES

DETERMINISTIC AND STOCHASTIC RISK EVALUATION (in µSv)





EFFECTIVE DOSE PER YEAR FOR 300 PROCEDURES (in mSv/year)



0.4 mSv/year
Annual dose with Nova-X® without the lead apron (300 procedures/year)

NOVARAD CONCLUSION

Nova-X® prevents from all types of risks (deterministic, stochastic and MSD) opening the possibility to work safely without wearing the lead apron

- **Operator 1 mean dose per procedure is divided by:**
  - 11 globally (1.0 µSv with Nova-X® vs 11.1 µSv with CPE, p-value< 0.001)
  - 11 at the head and forearm (1.2 µSv and 1.0 respectively with Nova-X® vs 11.2 and 11.2 µSv with CPE, p-value< 0.001)
  - 36 at the midtibia (0.4 µSv with Nova-X® vs 14.4 µSv with CPE, p-value< 0.001)
- **Operator 1 effective dose is similar** in both groups: Nova-X® without the lead (1.2 µSv) and conventional shieldings (1.3 µSv)
- **Operators 2 and 3 global body dose is divided** by 6 and 3 respectively with mean doses using Nova-X® of 1 µSv per procedure and 0.4 µSv

Nova-X® is a Class I medical device.
The Nova-X® consumable kit is a Class Is medical device.
CE-Marked.
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