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Fluoro-registered Mazor X Stealth edition versus O-arm navigation: preliminary results of the first 21 patients

Marc Prod'homme, Didier Grasset, Sébastien Lévy, Gilles Dietrich, Lionel Helfer and
Duccio Boscherini

Clinic La Source, Neuro Orthopedic Center, Lausanne

Schedule

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Introduction

- **Pedicle screw** insertion = regularly performed for spinal fusion
- Surgical **navigation** allows higher accuracy and safety
- **Robotics** allows stable guidance for pedicle drilling and screw insertion
- Medtronic introduced the **Mazor X Stealth** in Europa in 2019 =
 - Mazor X system robotic device
 - Surgical navigation

Objectives

To compare **radiological** and **clinical** results as well as **radiation exposure** of the use of the new Mazor X Stealth with the O-arm navigation during pedicle screw insertion for posterior lumbar fusion

Material and methods

Patient selection

- Consecutive patients operated for a screw insertion procedure
- Robotic group (RG) or O-arm navigation group (NV)
- Prospective design

Demographic data

- age, weight, height, body mass index (BMI)
- American Society of Anaesthesiologists (ASA) score
- preoperative back and leg pain-visual analog scale (VAS)
- Oswestry Disability Index (ODI).

Surgical data

- level operated
- operative time (in minutes, min)
- specific procedure RG or NV duration (in minutes) for screw implantation
- overall blood loss (in milliliters, ml)
- complications

Irradiation data

- dose area product (DAP) and dose length product (DLP)
- calculation of the effective dose E (in millisievert, mSv).
- absolute risk (AR) of cancer in % related to radiation for a whole-body exposure

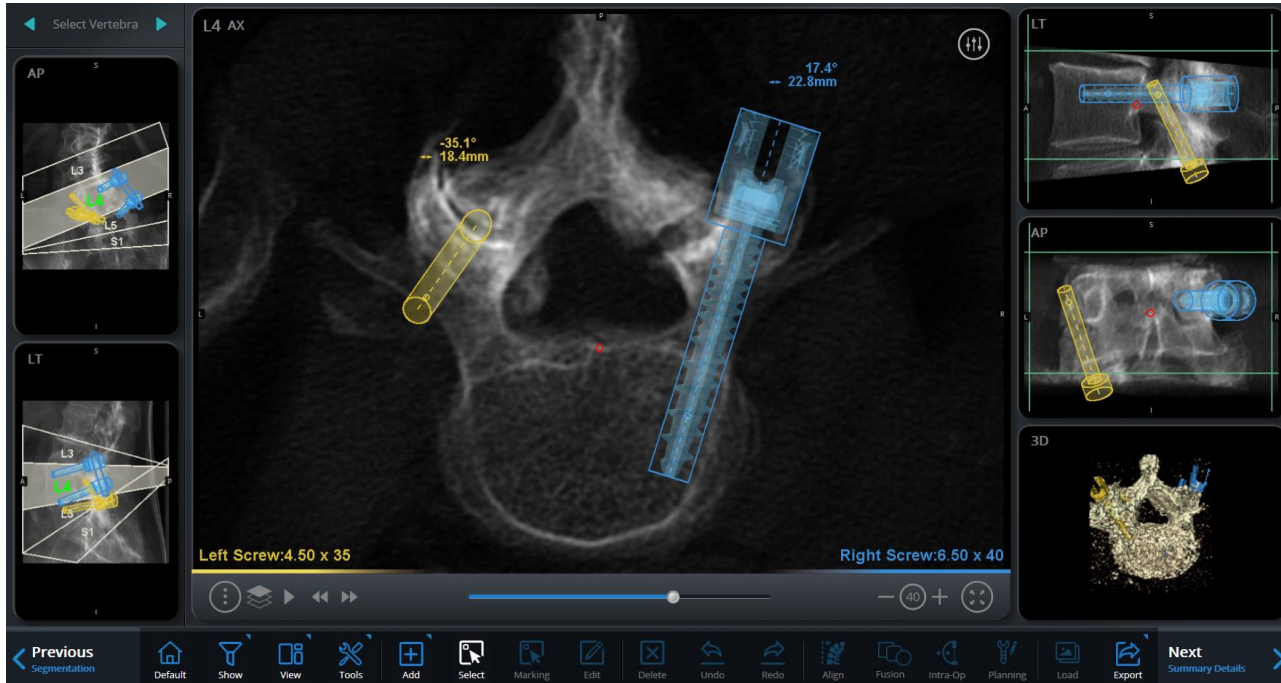
Radiological results

- Heary and Gertzbein classifications for screw accuracy

Technical description

RG group

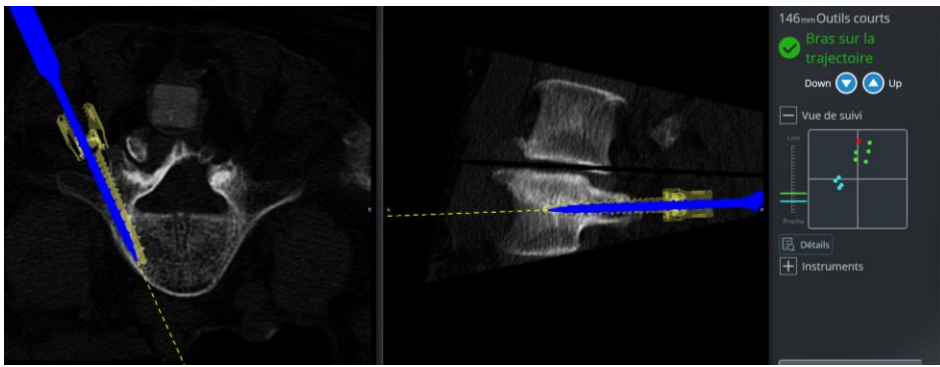
- Surgical planning
- Screw position in axial, lateral and coronal views



NV group

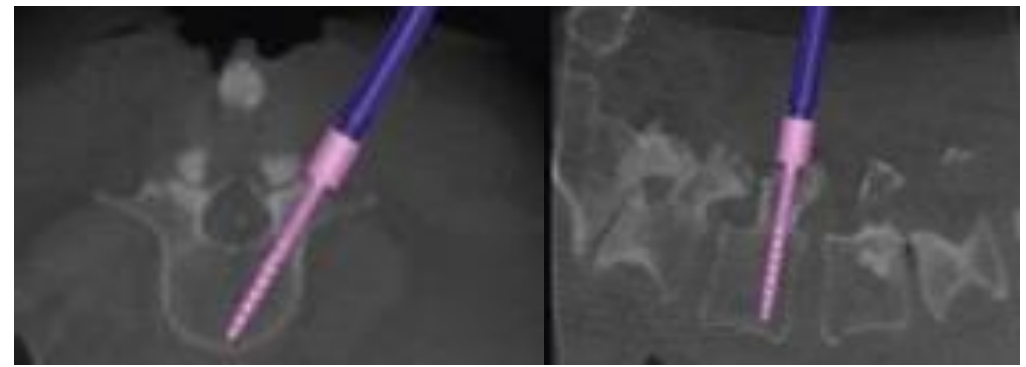
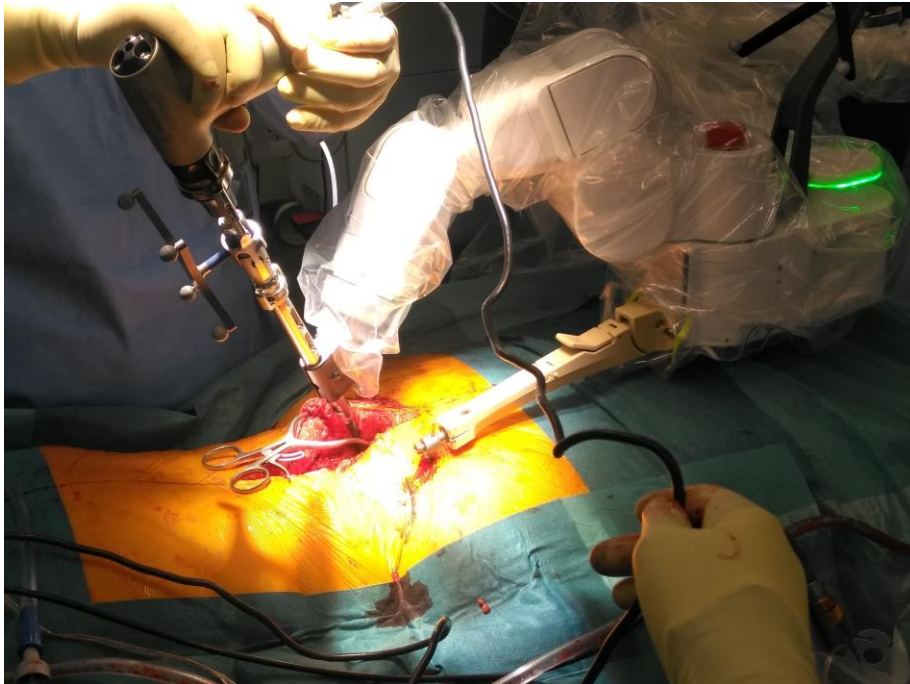
- 3D acquisition
- Surgical navigation





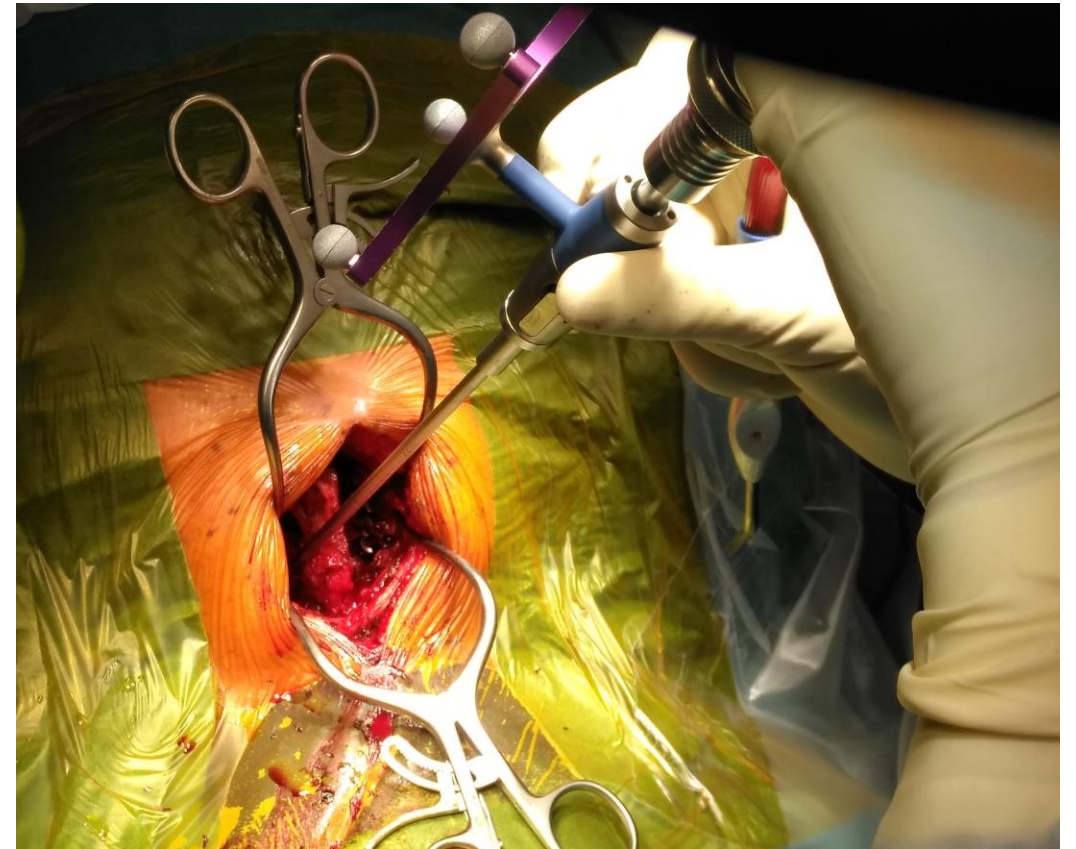
RG group

- 2D and 3D matching
- Robotic arm guidance
- On-time navigation



NV group

- Surgical navigation



Results (1)

Demographic data	RG group (n=10)	NV group (n=11)	P-value
Age (years)	70.3 +/- 7	70.0 +/- 6	0.92
Gender, F/M	4/6	7/4	0.67
BMI (kg.m ⁻²)	26.7 +/- 6	27.0 +/- 3	0.67

Operative data	RG group (n=10)	NV group (n=11)	P-value
Operative time (min)	140 +/- 35	109 +/- 26	0.03
Blood loss (ml)	360 +/- 125	323 +/- 194	0.60
Nr. vertebrae	2.2 +/- 1	2.2 +/- 1	1
Nr. screws	4.4 +/- 2	4.0 +/- 2	1
Screw insertion time (min)	14.6 +/- 8	13.8 +/- 7	0.77
Time insertion/screw (min)	3.3 +/- 1	3.5 +/- 1	0.64
Implantation/revision	3/7	6/5	0.39

Results (2)

Screw accuracy	RG group (n=10)	NV group (n=11)	P-value
Satisfactory	43	44	
Not satisfactory	1	0	
Total (%)	98	100	1

Radiation exposure	RG group (n=10)	NV group (n=11)	P-value
Effective dose E (mSv)	8.3 +/- 2	6.4 +/- 4	0.16
E / level (mSv)	3.4 +/- 2	3.4 +/- 2	0.22
Absolute risk (%)	$1.1 \times 10^{-3} \pm 1 \times 10^{-3}$	$1.2 \times 10^{-3} \pm 3 \times 10^{-3}$	0.89

Discussion

- Mazor X Stealth

- O'Connor 2021

- 90 screws
 - Accuracy 100%

- Lee 2021

- 186 patients
 - Accuracy 99.6%

- O-arm

- Farah 2018

- 73 patients
 - E = 2.58 mSv

- Reynolds 2020

- 83 patients
 - E = 14.6 mSv

Conclusion

The preliminary results of the new robotic Mazor X Stealth edition showed **no inferiority to the O-arm navigation** and **similar safety** in terms of screw accuracy and radiation exposure.

Disclosures

- Duccio Boscherini is a consultant for the Medtronic® company



- Other authors declare that they have no conflict of interest