

50

PRIX GALIEN
Start-up Category

 BoneView

Analyzing Clinical Studies and Healthcare system benefits

 GLEAMER

BoneView in a glance

Without BoneView

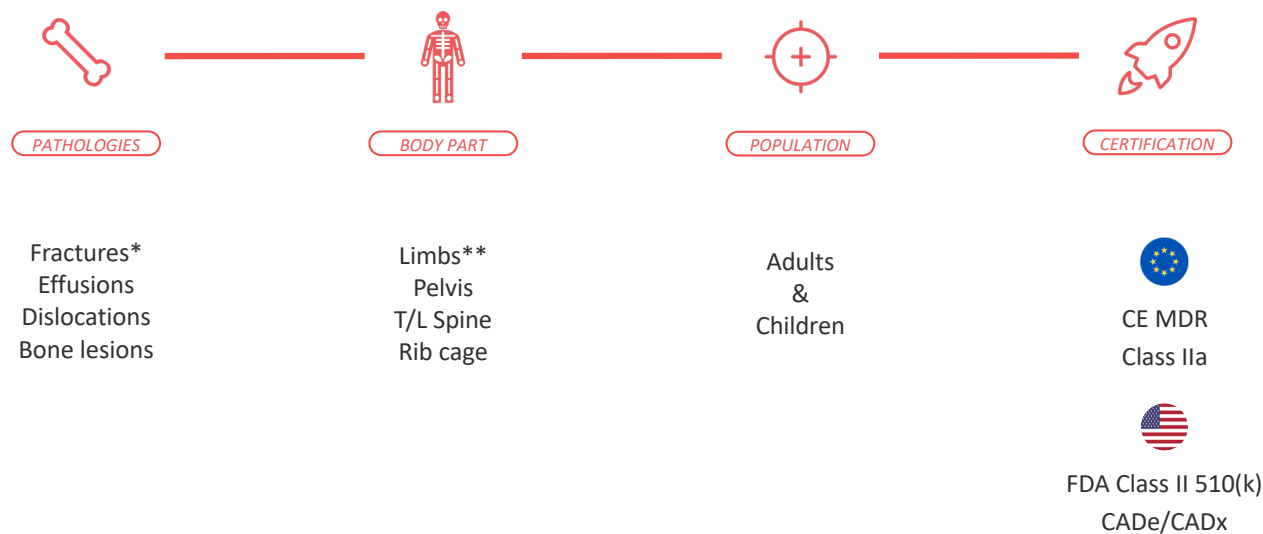


With BoneView



Detection Diagnosis

BoneView provides imaging readers with an instant and automatic **2nd reading of trauma bone X-Rays** fully integrated into the reading workflow.



*FDA covers fractures for adults & children

**Pediatric FDA clearance covers limbs only

Strengthening User Acceptance with Each Step of Boneview roadmap



PRIX GALIEN



Step 1

BoneView Fracture detection is expended in Europe

Our relentless efforts to validate the efficiency of Boneview resulted in its **first official publication**, establishing its credibility. Meanwhile, we meticulously conducted a large-scale study in the USA, leading to FDA approval and a subsequent publication in the prestigious peer-reviewed magazine, **Radiology**, further solidifying Boneview's impact. Additionally, in parallel, a significant collaborative study with the ED of Besancon validated our previous findings on a natural dataset, reinforcing the reliability of Boneview's performance.

Step 2

Extended our proof for pediatrics

In the pursuit of comprehensive research, the second step involved expanding the study to include a **pediatric dataset**. Pediatric fractures present unique challenges, as the scarcity of expert pediatric radiologists heightens user expectations. To meet these demands, an FDA extension for pediatric use was sought, resulting in parallel studies conducted in both the United States and Europe and published on prestigious peer-group readers journals.

Step 3

BoneView is now detecting new pathologies in the CE version

In early 2022, Boneview expanded its scope of pathology, prompting the need for a significant study to evaluate the effectiveness of this new feature. Concurrently, our team embarked on an impressive data-gathering endeavor, utilizing official reports to delve beyond diagnostic improvements and explore the actual impact of Boneview on the patient journey.

Did you know?

Boneview achieved a remarkable milestone by becoming the first FDA-approved AI tool for fracture detection within the USA. In March 2023, it further distinguished itself as the only AI tool validated for adults and children, solidifying its position as a groundbreaking solution. This outstanding achievement was made possible by the robust evidence provided by GLEAMER, affirming Boneview's efficacy and impact.

01 Revealing Clinical Study Findings

GLEAMER: A Journey of Excellence.

« Rigorous studies, impactful journals, and trustworthy research drive our commitment to improving patient outcomes and advancing knowledge in the field. »

2021 | First publication

Validate Boneview clinical benefits for fracture detection

600

Exams

3

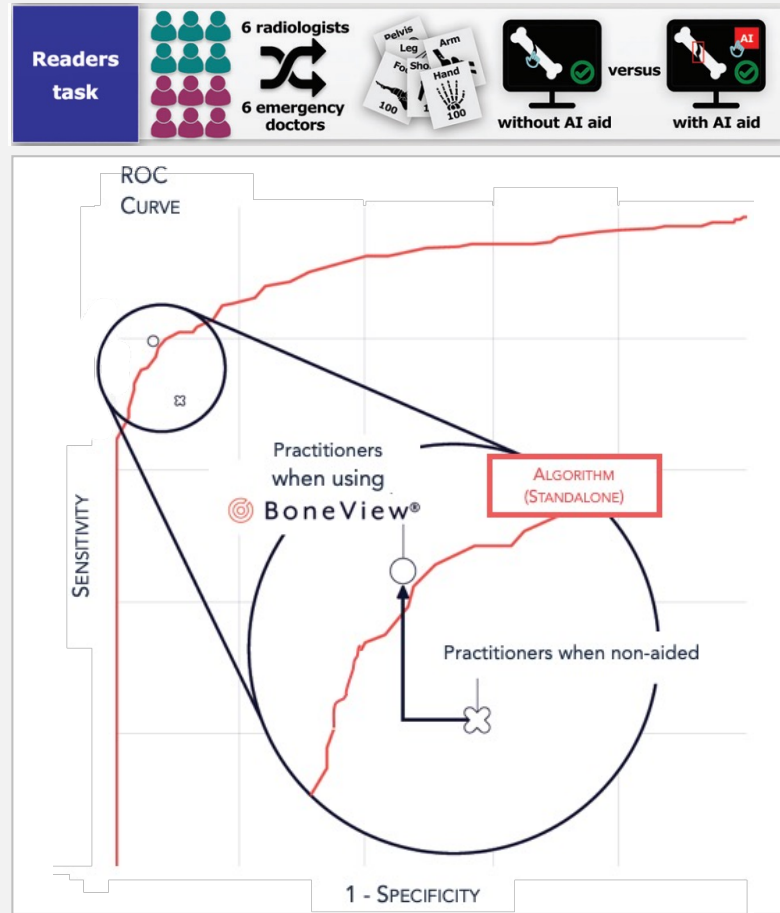
MSK experts for the gold standard

12

Independent readers

6 radiologists (with resident, senior and MSK senior)

6 Emergency physicians (Junior and seniors)



Radiology

Assessment of an AI Aid in Detection of Adult Appendicular Skeletal Fractures by Emergency Physicians and Radiologists: A Multicenter Cross-sectional Diagnostic Study
Loïc Duron, Alexis Ducarouge, André Gillibert, Julia Lainé, Christian Allouche, Nicolas Cherel, Zekun Zhang, Nicolas Nitche, Elise Lacave, Aloïs Pourchot, Adrien Felter, Louis Lassalle, Nor-Eddine Regnard, and Antoine Feydy
Radiology 2021 300:1, 120-129

1 2 3 4 5 6

Key benefits

+12%

sensitivity

-30%

missed fracture

+22%

sensitivity for multi-fracture



Antoine Feydy MD, Ph.D.
Cochin Hospital, AP-HP, Paris FRANCE
MSK Radiologist, +30y-experience

This study (Duron et. al, Radiology 2021) is the result of significant collaborative work between specialists in radiology, data science, biostatistics, and GLEAMER teams to evaluate the clinical performance of BoneView Trauma. This is an important step that quantifies and scientifically validates the benefits of this AI solution available to healthcare institutions, in a context where several solutions are marketed without published objective results.

GLEAMER

2021 | Extend to all imagery readers

Multi Readers-Multi Cases Study within
USA

480

exams

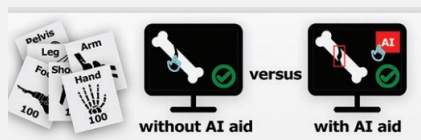
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MSK experts for
the gold standard

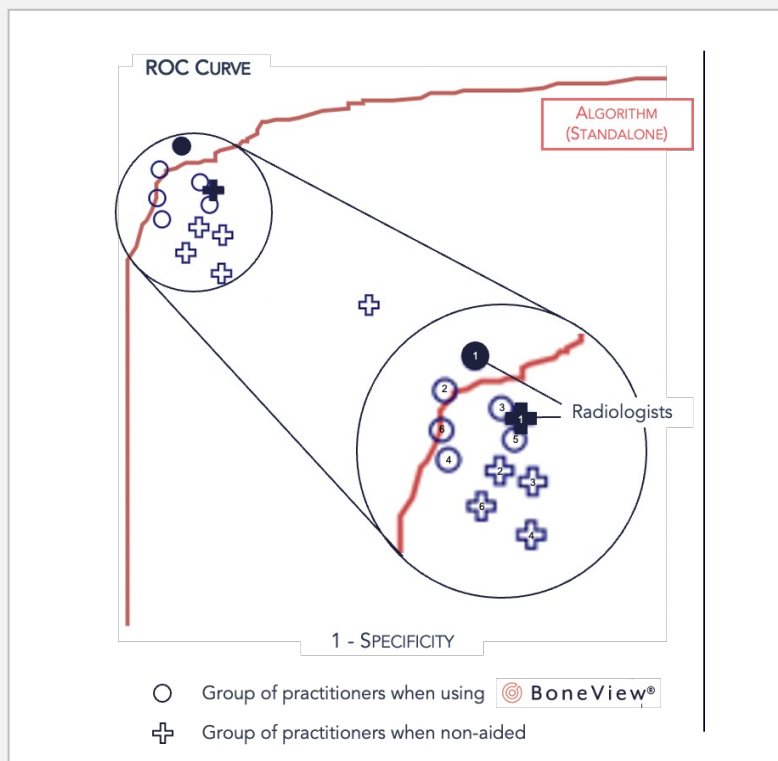
24

Readers

radiologists, trauma surgeon, emergency physician,
physician assistants, rheumatologists, family physicians



Data set twice—once with the assistance of AI software and once without the assistance, with a minimum washout period of 1 month.



Radiology

Improving Radiographic Fracture Recognition Performance and Efficiency Using Artificial Intelligence.

Guermaz A, Tannoury C, Kompel AJ, Murakami AM, Ducarouge A, Gillibert A, Li X, Tournier A, Lahoud Y, Jarraya M, Lacave E, Rahimi H, Pourchot A, Parisien RL, Merritt AC, Comeau D, Regnard NE, Hayashi D.

Radiology. 2022 Mar;302(3):627-636. doi: 10.1148/radiol.210937. Epub 2021 Dec 21. PMID: 34931859.

1 2 3 4 5 6

RSNA 2022
Alexander Margulis Award
Scientific excellence

Key benefits

+16%

Sensitivity

-29%

Missed fractures

-15%

Reading time



Pr. Ali Guermazi MD, Ph.D.

Boston University, School of Medicine USA

MSK Radiologist, +30y-experience

Computer-Aided Detection systems can be easily sensitive but usually bring significant loss in specificity. Here, the algorithm also helped reduce false positive rates," he said. "The time saving was a good surprise given that the algorithm brings additional information to look at on top of the native images. In reality, it was not obvious that the algorithm would speed up interpretation time.

GLEAMER

2022 I Natural prevalence

Natural dataset from Emergency
Department

500

Consecutive radiographs of
traumatic emergency

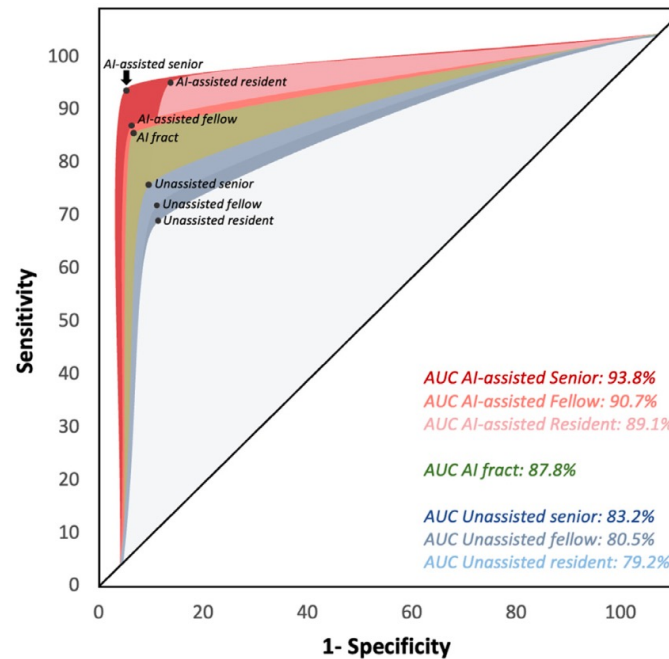
3

MSK experts + AI
for the gold standard

3

Level of readers

Senior, Fellow and resident



Diagnostic
& Interventional
Imaging

Added value of an artificial intelligence solution for fracture detection in the radiologist's
daily trauma emergencies workflow

Lisa Canoni-Meynet, Pierre Verdot, Alexis Danner, Paul Calame, Sébastien Aubry
Diagnostic and Interventional Imaging, ISSN 2211
5684, <https://doi.org/10.1016/j.diii.2022.06.004>.

Key benefits

+10%

Negative Predictive Value

+20%

Sensitivity

-60%

of False-negative findings

20 – 35%

decrease in reading time



Pr. Sébastien Aubry MD, Ph.D.

University Hospital of Besançon, FRANCE

Professor and MSK Radiologist

Our study focused on a representative sample of daily trauma emergencies. It confirmed that AI-assisted radiologists worked better and faster, leading to potential medico-economic interest: reduced costs of missed fractures and potential lawsuits.

2022 | Focus on pediatrics

Stand-alone study, AI vs MSK US experts

300

Exams of the limbs

2

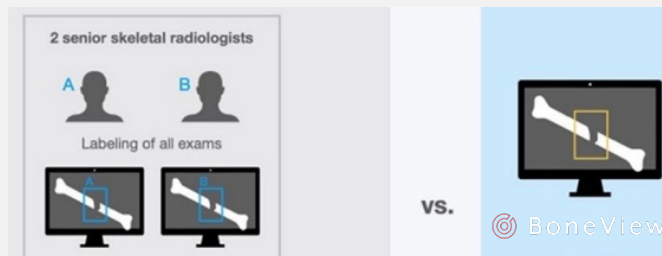
MSK experts

for the gold standard

(+1 senior in case of a discrepancy)



PRIX GALIEN



Skeletal Radiology

Automated detection of acute appendicular skeletal fractures in pediatric patients using deep learning

Hayashi D., Kompel, A. J. Ventre, J., Ducarouge A., Nguyen T., Regnard, N. E., & Guermazi, A. 2022, Skeletal Radiology, 1-11.

1 2 3 4 5 6

Key benefits

91%

Sensitivity

90%

Specificity

Equal for Children and teenagers



Daichi Hayashi, MD Ph.D.

Tufts Medical Center, Boston, USA

Associated Professor and Chief of MSK Radiology

"Our study showed BoneView provides high diagnostic performance for appendicular fracture detection in children and adolescents. BoneView can revolutionize fracture detection in both the adult and pediatric populations by expediting final reads for positive cases, especially in emergency rooms and urgent care settings."

GLEAMER

2022 | Focus on pediatrics

Assessing gain for readers

300

Exams of the limbs

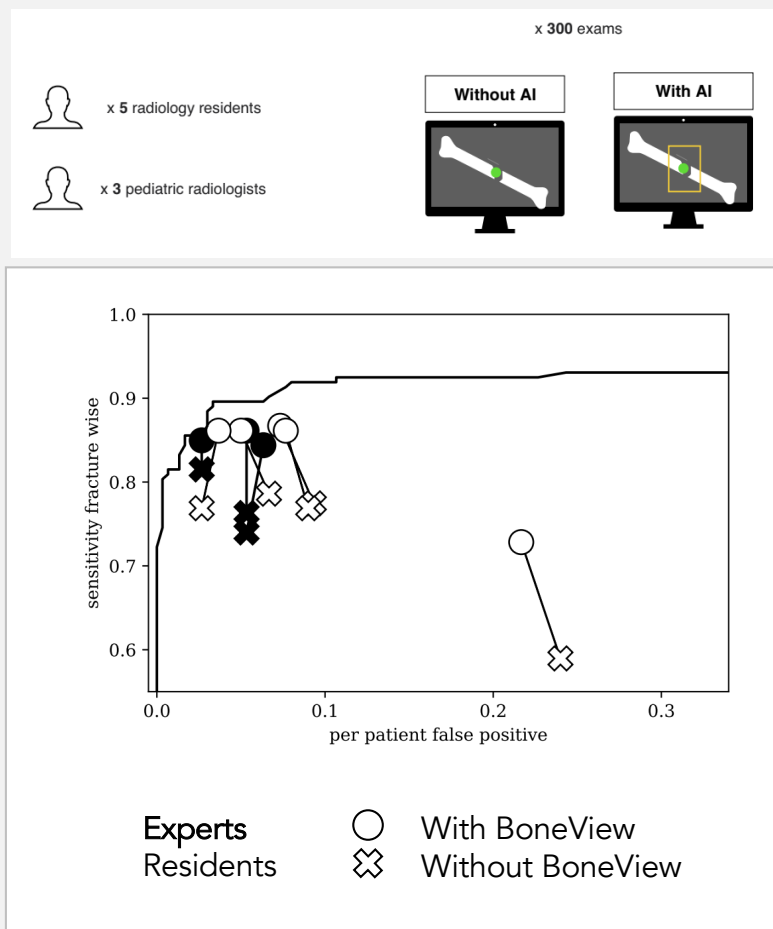
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MSK experts
for the gold standard

8

Readers

5 residents & 3 pediatric radiologists



Pediatric Radiology

Assessment of an AI aid in detection of pediatric appendicular skeletal fractures by senior and junior radiologists

Toan Nguyen, Richard Maarek, Anne-Laure Hermann, Amina Kammoun, Antoine Marchi, Redha Khelifi, Mégane Collin, Alienor Jaillard, Hubert Ducou Le Pointe
2022, Pediatric Radiology, 52(11), 2215-2226

Key benefits

+10% Gain of sensitivity for both
Sensitivity in average experts and resident radiologists

No specificity loss

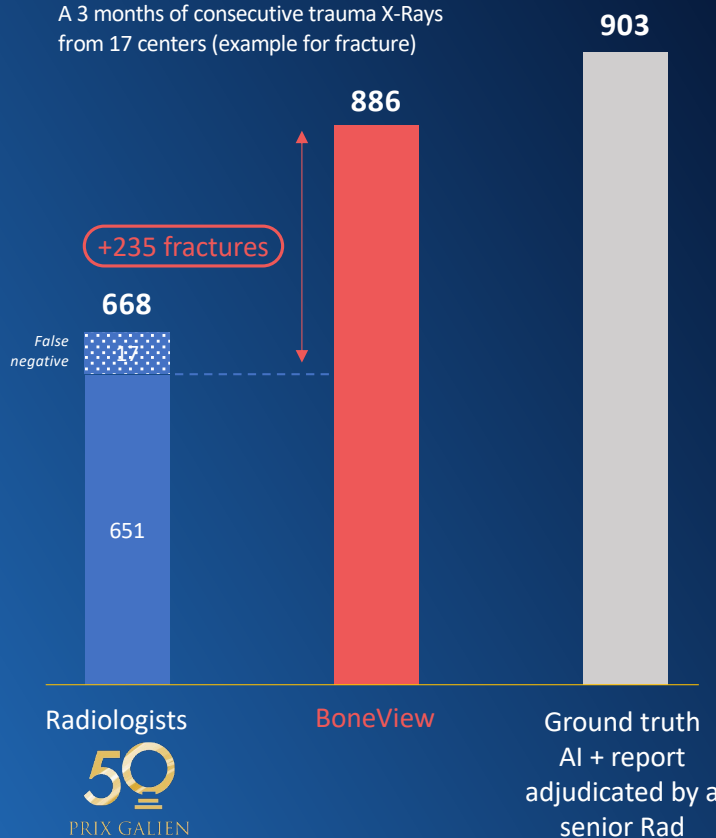
Significant gain for subtle fractures



Toan Nguyen, MD PhD
Trousseau Children's Hospital, FRANCE
Pediatric Radiologist

Due to the shortage of radio pediatricians, trauma radiographs are interpreted by emergency physicians in many centers. For this reason, it is essential to evaluate the contribution of artificial intelligence in detecting fractures, as they can sometimes be subtle or mistaken for variants of the normal. This study showed increased sensitivity in fracture detection regardless of age without decreasing specificity. Artificial intelligence is a valuable aid in centers where there is a lack of radiologists.

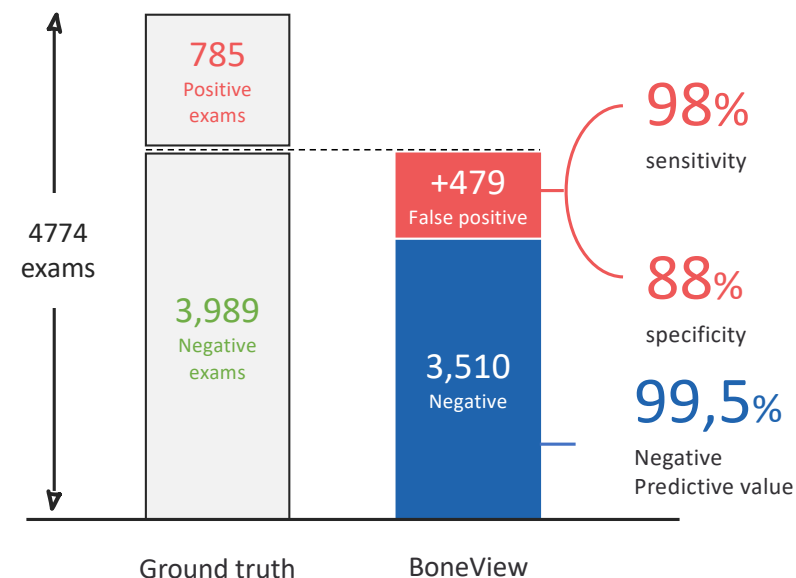
A 3 months of consecutive trauma X-Rays
from 17 centers (example for fracture)



| | Sensitivity | Specificity | NPV |
|--------------|-------------|-------------|------|
| Fractures | 97.8 | 88 | 99.5 |
| Dislocations | 90.9 | 99.1 | 99.8 |
| Effusions | 91.4 | 99.8 | 99.9 |
| Bone lesions | 98.3 | 95.6 | 99.9 |



Regnard, N. E., Lanseur, B., Ventre, J., Ducarouge, A., Clovis, L., Lassalle, L., ... & Feydy, A.
2022. European Journal of Radiology 154, 110447.



MSK Radiologist, +17y experience | Gleamer CMO

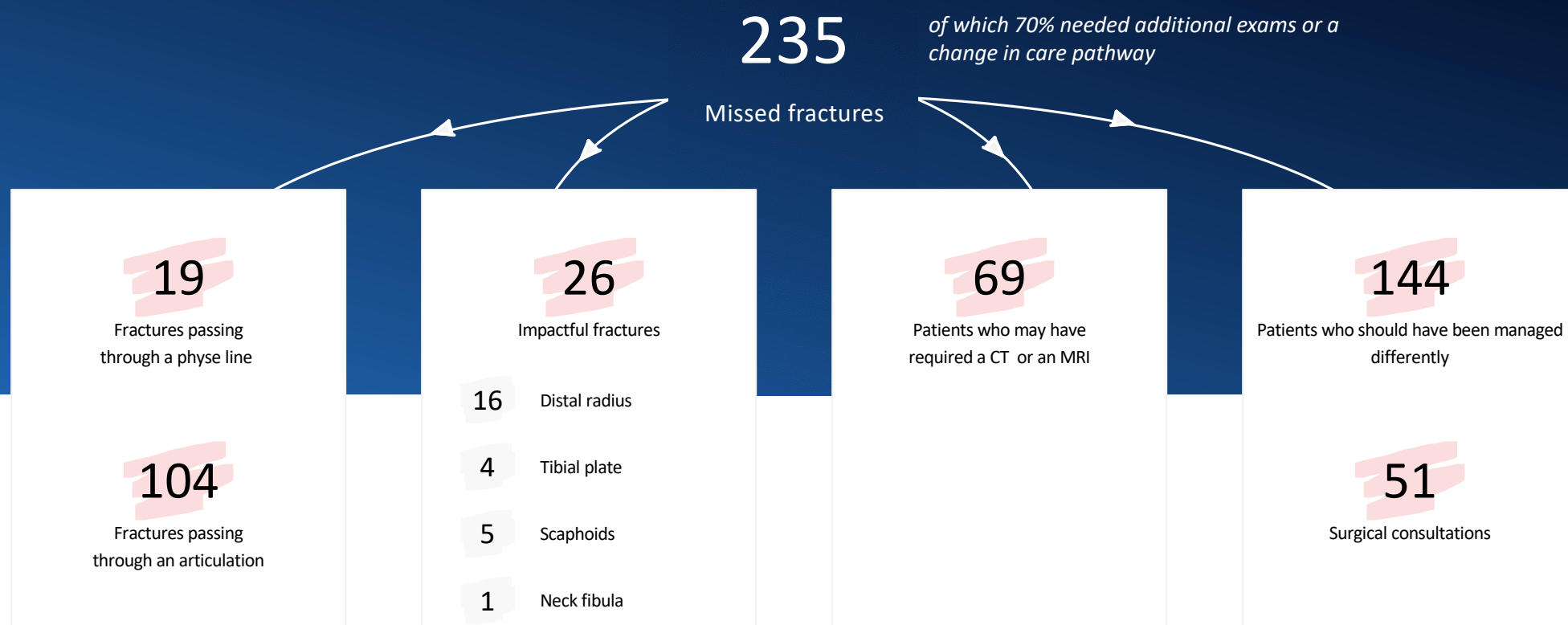
“This is the first study to evaluate the performance of Boneview on all relevant pathologies in traumatic radiography (fracture, dislocation, joint effusion, focal bone lesion) in natural prevalence over 3 months compared to radiologists’ reports. The number of traumatic anomalies Boneview could have caught is impressive (over 200 fractures!). The very high negative predictive value means doctors can be confident in interpreting even negative results.



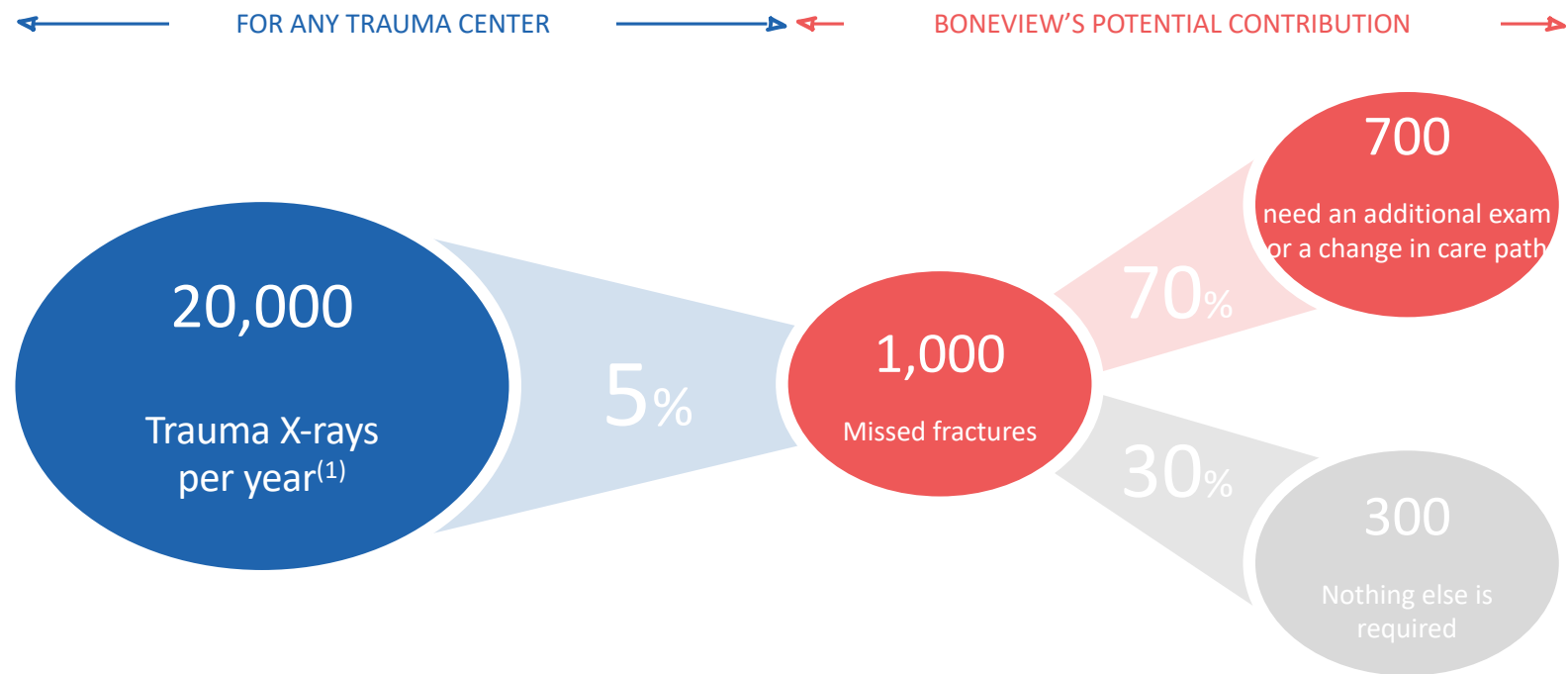
02 BoneView clinical impacts ●

« Thanks to the EJR study, we were able to assess the genuine clinical impact of Boneview on patient care. »

Unpublished findings from the study, shed light on valuable insights



Generalizing BoneView's clinical impact



03 What's next ? •

Unlocking Independent Studies: Revealing the Extensive Additional Benefits of Boneview

2

New independent publications



Musculoskeletal | Published: 14 December 2022

Artificial intelligence vs. radiologist: accuracy of wrist fracture detection on radiographs

Mathieu Cohen, Julien Puntodet^{1,2}, Julien Sanchez, Elliott Kierschbaum, Michel Crema, Philippe Sayer & Elisabeth Dion

European Radiology (2022) | Cite this article



Article
A Prospective Approach to Integration of AI Fracture Detection Software in Radiographs into Clinical Workflow

Jonas Oppenheimer^{1,*}, Sophia Lüken¹, Bernd Hamm¹ and Stefan Markus Niehus^{1,2}

¹ Klinik für Radiologie, Charité Universitätsmedizin Berlin, Hindenburgdamm 30, 12205 Berlin, Germany
² Berlin Institute of Health, Anna-Louise-Karch-Strasse 2, 10178 Berlin, Germany
* Correspondence: jonas.oppenheimer@charite.de

+6

Podium presentations including

2

RSNA 2022

- Charité Germany
For vertebral fractures
- CHU Poitiers France
Study About ED Benefits

1

ISS 2022

CHU Lille, France
X-ray with AI vs scan

3

ECR 2023

- 2 Charité, Germany
AI Benefits for residents
- 1 Tradate, Italy
Detection of healing fractures

+30

Independent Clinical studies
in the process

From Key Opinion Leaders

Elma Kotter (Germany)

Anne Cotton (France)

Susan Shelmerdine (Pediatric, UK)

Some examples of topics:

- *Saving time at the ED*
- *BoneView vs. CT-scan*
- *Child abuse cases*

We have built the most robust AI medical devices in radiology with global recognition.



Awarded

Alexander R.
Margulis award

In November 2022



CADe/CADx

Among the

11

CADe/CADx FDA-approved
competing companies
worldwide



Renowned

8

publications in leading
peer review medical journals

Radiology



Performing

+30%

Fracture detected



Co-developed

R&D in collaboration
with the very best

Annexes •

More details about our 2 Radiology publications

Assessment of an AI aid in Detection of Adult Appendicular Skeletal Fractures by Emergency Physicians and Radiologists : A Multicenter Cross-sectional Diagnostic Study

DURON L. AND AL

DATASET

600

exams

- > **Performed**
 - Over 2015-2018
 - By modalities from 6 distinct vendors
 - From 17 distinct medical centers in France
 - On 6 distinct body parts: shoulder (incl. clavícula), arm (incl. elbow), hand (incl. wrist), pelvis, leg (incl. knee) and foot (incl. ankle)
- > **Of which**
 - 300 without fractures
 - 300 with at least 1 non-obvious fracture

GOLD STANDARD

3

MSK experts

- > **Independent reading** of the 600 exams by two +10y-experienced radiologists
- > **Drawing of bounding boxes** around every detected bone fracture
- > **Disagreements settled through consensus**, involving third expert: Pr A. Feydy (MD, PhD, Cochin Hospital, +30y-experience)

READERS & READING

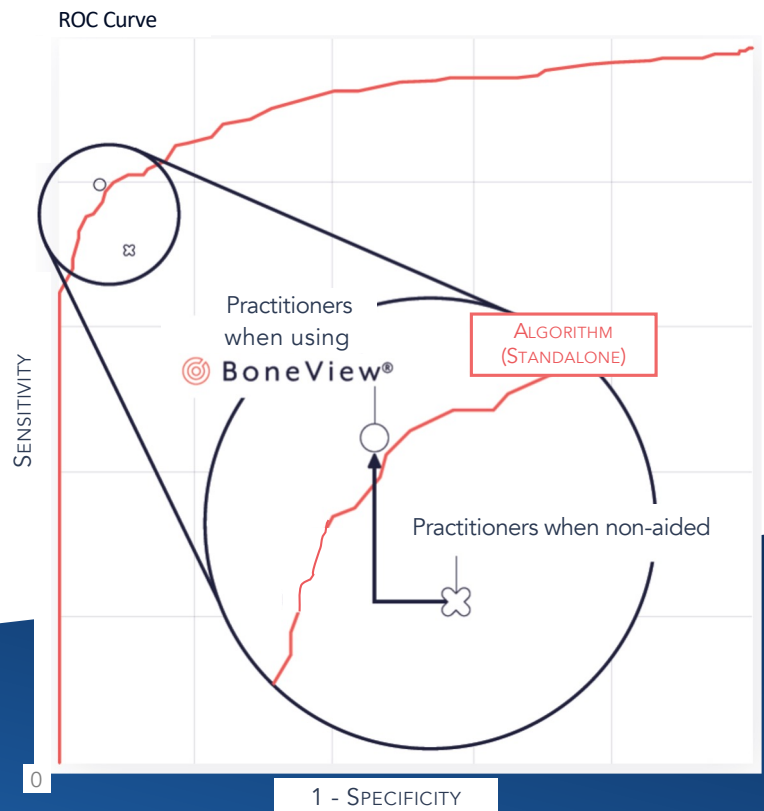
12

Independent readers

- > **6 radiologists**
 - 2 residents
 - 2 senior radiologists
 - 2 senior radiologists specialized in osteoarticular imaging
- > **6 emergency physicians**
 - 2 residents
 - 4 senior emergency doctors
- > **For each reader (fully crossed design)**
 - 300 exams read with BoneView
 - 300 exams read without assistance

Assessment of an AI aid in Detection of Adult Appendicular Skeletal Fractures by Emergency Physicians and Radiologists : A Multicenter Cross-sectional Diagnostic Study

DURON L. AND AL



| with BoneView | Radiologists | Emergency doctors | All |
|---|--------------|-------------------|------|
| Decrease in False Negative [Missed-fracture rate] | -22% | -34% | -30% |
| Δ Sensitivity | +5% | +21% | +12% |
| multi-fracture subset | +10% | +40% | +22% |
| Δ Specificity | +3% | +7% | +5% |

- 30% in MISSED FRACTURES
- + 12% in SENSITIVITY
- + 22% in SENSITIVITY for exams with MORE THAN 1 FRACTURE

Improving Radiographic Fracture Recognition Performance and Efficiency Using Artificial Intelligence

PRINCIPAL INVESTIGATOR: ALI GUERMAZI, MD, PHD

DATASET

480

exams

- > Performed
 - By modalities from **11 manufacturers**
 - From 3 distinct radiological data providers in **the USA**
 - On 8 specific body parts: **shoulder** (incl. clavicle), **arm** (incl. elbow), **hand** (incl. wrist), **pelvis** (incl. hips), leg (incl. knee), **foot** (incl. ankle), **rib**, and **dorso lumbar** region.
- > Of which
 - **240 without** fractures
 - 240 with at least 1 fracture, of which 50% are non-obvious fractures

GOLD STANDARD

3

MSK experts

- > Independent reading of the 480 exams by two >10 y-experience radiologists
- > Drawing of bounding boxes of minimal size around every detected bone fracture
- > Ground Truth: union of the boxes of the 2 radiologists (if IoU > 25%)
- > Disagreements settled through consensus between the 2 senior radiologists with the input of a third >30 y-experience radiologist

READERS & READING

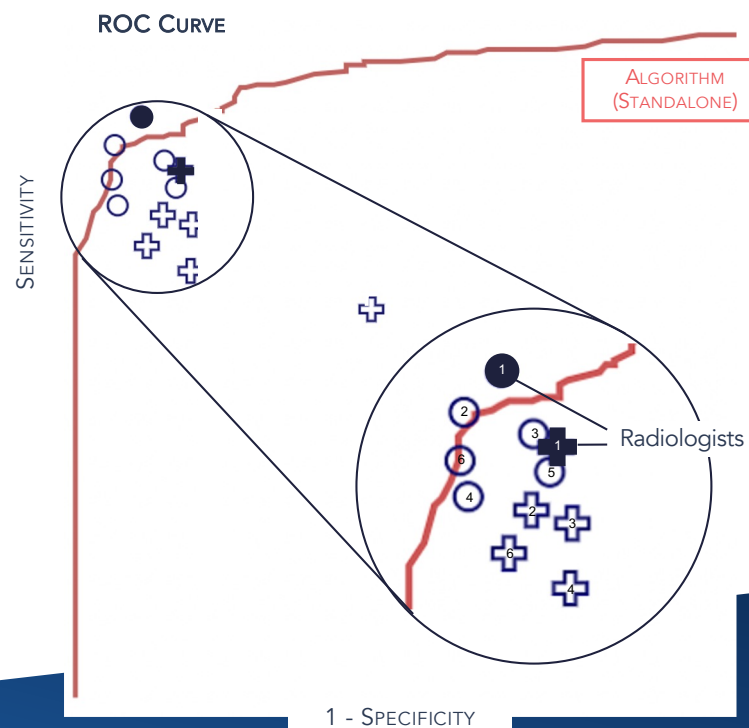
24

Independent readers

- > Independent reading of the 480 exams by two >10 y-experience radiologists
- > Drawing of bounding boxes of minimal size around every detected bone fracture
- > Ground Truth: union of the boxes of the 2 radiologists (if IoU > 25%)
- > Disagreements settled through consensus between the 2 senior radiologists with the input of a third >30 y-experience radiologist

Improving Radiographic Fracture Recognition Performance and Efficiency Using Artificial Intelligence

PRINCIPAL INVESTIGATOR: ALI GUERMAZI, MD, PHD



○ Group of practitioners when using BoneView®
 + Group of practitioners when non-aided

WITH BoneView

| | Missed-fracture rate | Sensitivity | Specificity |
|---|----------------------|-------------|-------------|
| 4 radiologists (1) | - 29% | +10% | +3% |
| 4 emergency doctors (2) | - 31% | +15% | +4% |
| 4 orthopedic surgeons (3) | - 27% | +13% | +2% |
| 4 family practitioners (4) | - 23% | +15% | +6% |
| 4 rheumatologists (5) | - 38% | +31% | +18% |
| 4 emergency medicine physician assistants (6) | - 26% | +15% | +3% |
| All readers | - 29% | +16% | +5% |

- 29% of MISSED FRACTURES
 + 16% in SENSITIVITY
 + 30% in SENSITIVITY for exams with MORE THAN 1 FRACTURE