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Agfa DR image quality and patient care

A clinical study outcome on Agfa's DR 800 dynamic imaging performance

White paper

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Table of contents

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Introduction

A recent white paper [5] reported on the improvements and challenges introduced in fluoroscopy imaging over the past decades. Concepts such as Automated Brightness Control (ABS), adaptive dose per frame rate (keeping the dose rate constant and independent of the frame rate), and Agfa's advanced temporal filtering and noise suppression methods have found their way into clinical routine and become state-of-the-art technology.

Despite the convincing technical performance of such concepts and innovations, the ultimate proof points remain the clinical image quality and the satisfaction of the customers; namely, radiographers and radiologists. For this reason, Agfa carried out another large-scale study to objectify and re-confirm image quality for dynamic or semi-dynamic procedures (fluoroscopy, DSA and Roadmapping, digital tomosynthesis, etc.), in a manner that is comparable to the study around static X-ray quality [6].

Similar methods and criteria were used as a measure of quality and diagnostic confidence. These criteria were derived from the guidelines of the Commission of the European Communities (CEC) or the German *Leitlinien*, or in cooperation with clinical experts.

In the same way, the study involved several hospitals in Germany, Spain and Italy, as well as six independent radiologists reading the sequences. Data was collected during a period of over two years. The most relevant dynamic and semi-dynamic procedure types, both for adult and pediatric imaging, were included.

This white paper highlights and illustrates the methods and most relevant outcomes of this study.

Study facts & figures

- Data collected from 6 hospitals in Germany, Italy and Spain
- 6 readers for Visual Grading Analysis (5 for fluoroscopy and DTS, 3 for DSA and Roadmapping)
- Image criteria from CEC guidelines or clinical experts
- 89 sequences read, for a total of 310 scores
- Statistical sample size calculation and result analysis
- Additional survey questions

Study scope and design

For the static X-ray images, an absolute Visual Grading Analysis (VGA) on a continuous scale from 0 to 5 was used to judge the image quality of defined anatomical structures and key features. Dynamic sequences were randomly collected from six sites that routinely use the DR 800 system. For further details of the DR 800 system, see [8]. All sequences were anonymized and pooled for reading by six qualified (interventional) radiologists.

The mid-point of the VGA scale (2.5) was equalized to represent 'diagnostic image quality'; a VGA score (VGAS) above 2.5 thus represents 'diagnostic quality' in this study [4]. The study included 16 sequences for each dynamic exam type, excepting 11 (each) for pediatric urography and for Roadmapping, and 3 for DTS Chest. The sequences were randomly sampled prior to the readings. 26 images were used for lumbar spine. Where possible, a mix of sequences over the sampling sites was done. The figures regarding appropriate sample sizes were based on a statistical power calculation. The study aimed for 80% statistical power and 95% confidence.

Overview exam types

Dynamic Imaging (adult): pulsed/continuous fluoroscopy *&* rapid sequence (RS)
- Gastro-Intestinal (digestive tract), 16 sequences (3 RS)
- (Peripheral) Angiography (non-DSA): Phlebography (venography), 16 sequences

Dynamic Imaging (pediatric): pulsed/continuous fluoroscopy
- Urography: Retrograde cystography AP during voiding (selection of sequences with reflux), 11 sequences

DTS Digital Tomosynthesis (adult):
- Chest AP/PA, 3 sequences
- Musculoskeletal (MSK), 16 sequences

DSA *&* Roadmapping (adult):
- Digital Subtraction Angiography (DSA): peripheral, 16 sequences
- Digital Subtraction Angiography (Roadmapping): peripheral, 11 sequences

In total, 52 pathologies (with high-level descriptions) were included (58.4%). Approximately 10.1% of the patients were indicated with 'adipositas' (based on the X-ray sequences). Implants were mainly included in adult DTS MSK sequences.

The anatomic structures and criteria to assess the clinical image quality were taken from existing guidelines (European or German) or recent literature, respectively. Where exam type criteria were not available through European or German guidelines, criteria were defined and consolidated with clinicians upfront. Pure radiographic criteria (for example, positioning) were excluded.

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Dose data (DR 800 configured dose levels, DAP and DAP per number of frames) was recorded, as complementary information.

A continuous 5-point scale was used for evaluating each criterion:
- left extreme = criterion definitely not fulfilled
- middle = indecisive
- right extreme = criterion definitely fulfilled

In addition, checkboxes for the following options were included:
- approved for diagnosis
- limited, but still acceptable
- not approved
- adipositas (yes/no)

A total VGAS per body part or exam type was calculated following references [4] from all readers and scores. To evaluate intra-reader reliability, 26 randomly mixed sequences from the original data pool were also read (fluoroscopy and DTS). For DSA and Roadmapping, 8 sequences were used.

Six experienced radiologists from different hospitals scored the datasets on the continuous scale defined above, in a controlled environment, using standard diagnostic monitors and reading stations.

All data used in the study originated from quality-controlled DR 800 devices. The dose levels (dose rates) complied with the German DIN standard 6868-150, chapter 7.12, Tabelle 2. None of the DR 800 systems used dose rates higher than specified in the DIN standard 6868-150. For dose aspects of DTS, see reference [7].

Results

Approval of images

From a total of 310 sequences, 259 were scored 'approved' for clinical use (83.5%); a further 39 (12.5%) were scored 'limited, but still diagnostically acceptable'. The 6 sequences with a 'not approved' score (3 fluoroscopy, 3 DTS) received this score either due to individual preferences (fluoroscopy) or to non-familiarity with the application (DTS). 6 scores were missing. From the 81 DSA and Roadmapping sequence scores, none were scored 'limited' or 'not approved'.

Visual Grading Analysis

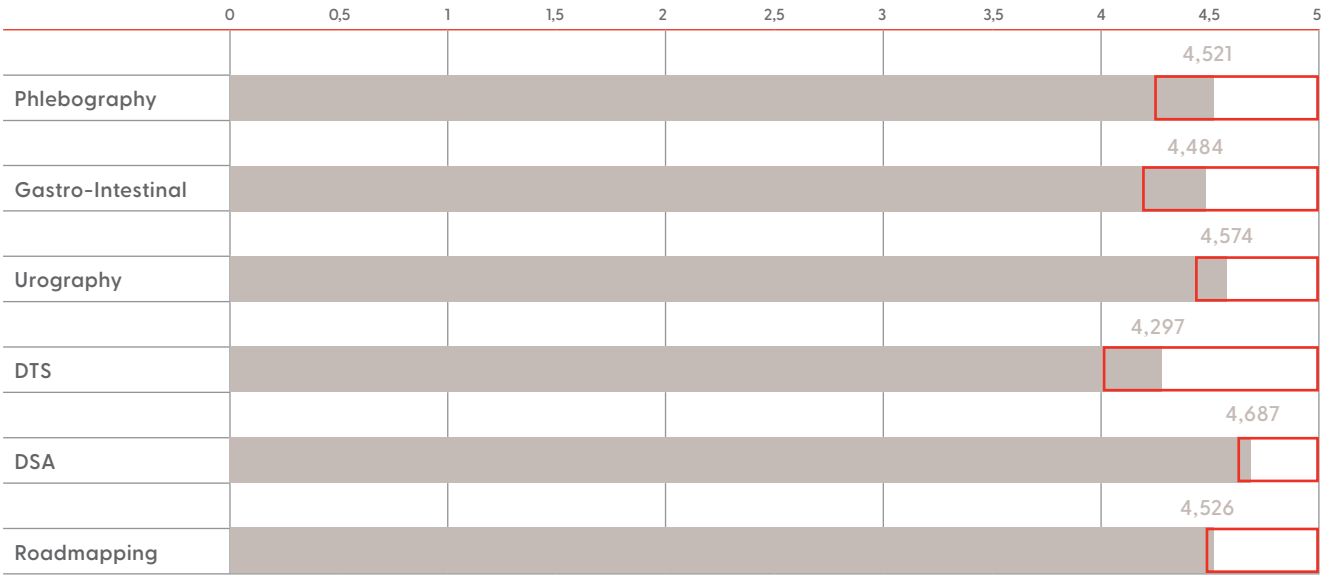
Only 4 sequence scores were rated < 2.5 (two on GI: 2.05 and 1.48, and two on DTS MSK: 1.33 and 2.23); no remarks were provided regarding the reasoning for these scores.

The statistical analysis shows that all sequences (represented by VGAS) were above the acceptance criteria score of 2.5 (mid-point of scale), and were therefore of diagnostic quality.

The following plot shows the summary results, including statistical confidence intervals:

Figure 1: VGAS results on a scale from 0 to 5

Grey frame = VGAS, red frame = VGAS 95% confidence interval



The numerical results (VGAS) show a consistently high clinical confidence (5 equals maximum confidence) across all exam types, including the less commonly used DTS sequences. None of the 95% confidence intervals shows values lower than 4. Hence, the statistical results indicate that diagnostic image quality is proven with 80% statistical power and a 95% confidence interval.

Except for Roadmapping exams (which scored between poor and moderate), the *inter-reader reliability* is considered poor. As with the evaluation of the static images, the applied ICC2 standard scale proves to be extremely sensitive with respect to variations of reader scores on the continuous scale from 0 to 5. The label 'poor' has therefore to be considered as understating the real reliability of the readers from a clinical perspective. In addition, readers used to HIGH dose levels might score sequences with a LOW dose level differently (lower scores).

No *intra-reader reliability* scores as 'poor'; this applies to both the reliability per reader (all exam types read), as well as the reliability per exam type (all readers). In fact, intra-reader reliability (all readers) ranges between 'poor and moderate' for fluoroscopy and DTS, and between 'good and excellent' for DSA and Roadmapping.

Additional survey

With ratings between 3 and 5 (1 = strongly disagree, 5 = strongly agree) on three questions (absence of artefacts, overall image quality and fluoroscopy suitable for positioning), the survey confirms the clinical usability of the sequences created by the DR 800 device.

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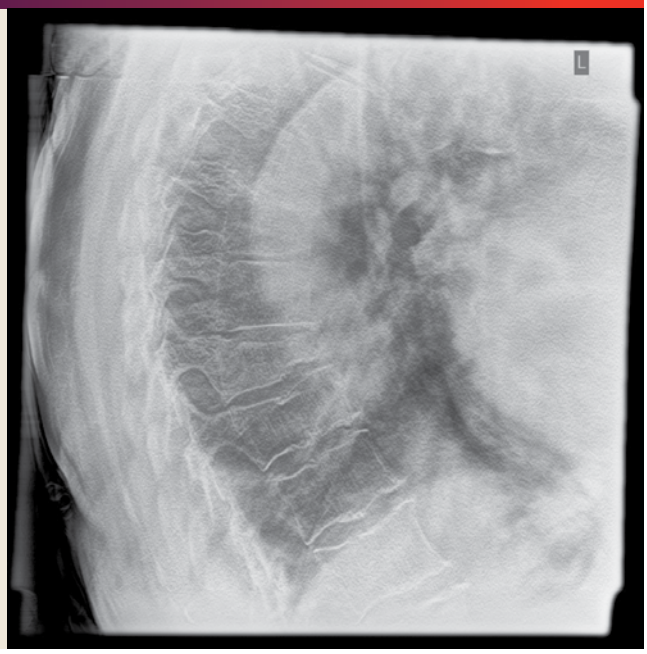
Examples

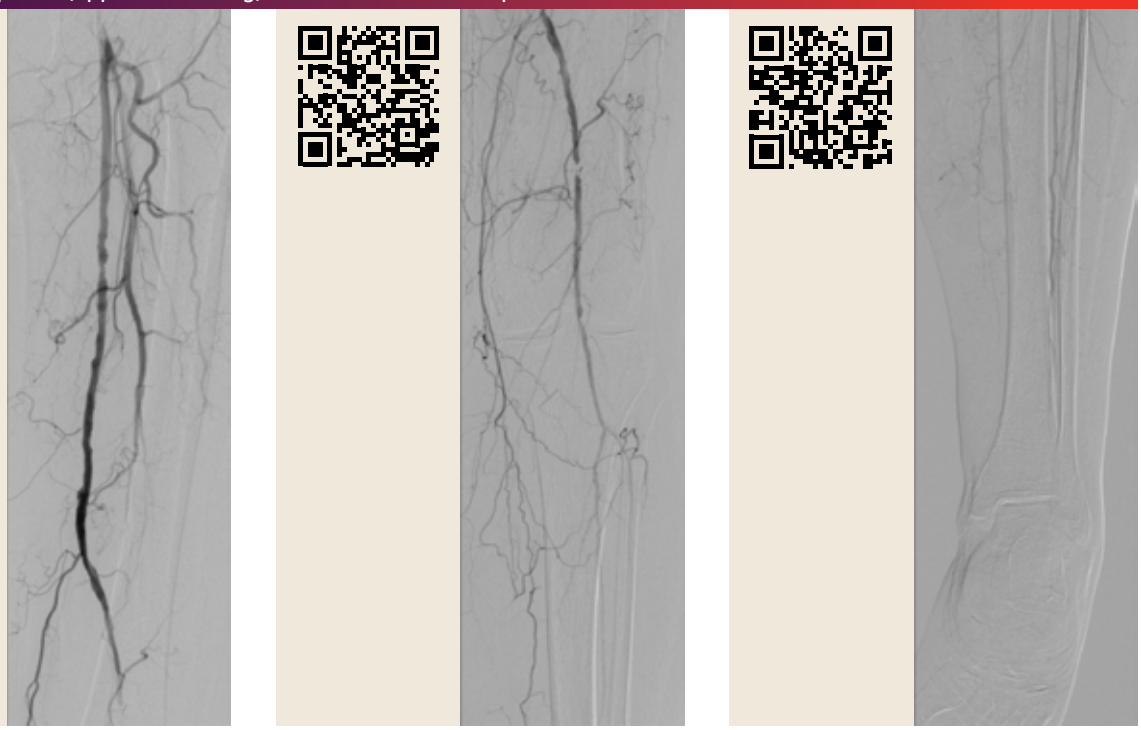
DTS (Digital Tomosynthesis):

Figure 2: DTS sequence (Acquisition parameters: 80 kV, 74 mAs total, 21 slices, slice thickness 2 mm, reconstruction high)



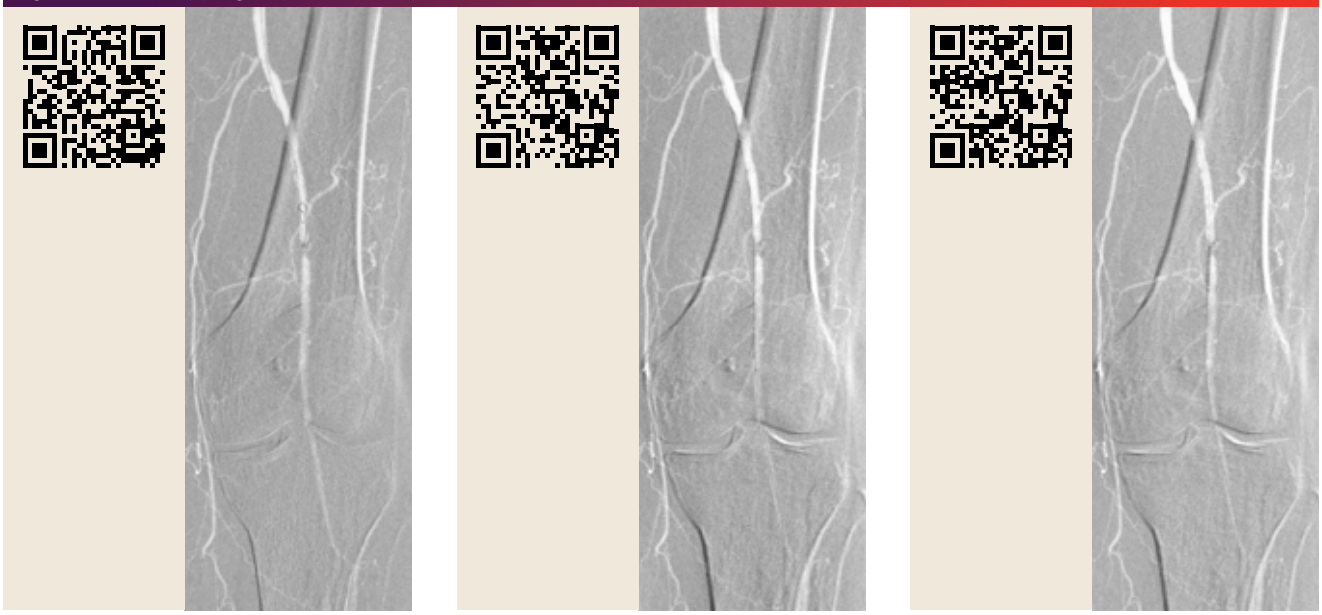
DSA:

Figure 3: DSA sequence (upper to lower leg) - Lower extremities 2.5 fps



Roadmapping:

Figure 4: Roadmapping sequence (same examination) - Lower extremities 5 fps low dose



Further discussion

All exam types (including DTS Chest and MSK) showed the same equally high VGAS (> 4.2) and confidence level (lower limit > 4.0). This included for patients with adipositas (high amount of scatter) and the comparably low dose levels used with the DR 800 device (German DIN level).

The equipment used in the study represented the technical level of the DR 800 system with the same semi-dynamic DR detector and equivalent (dynamic) image processing packages.

As outlined, this study used data from different geographical regions within Europe.

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Conclusion

The large-scale study re-confirms with a high statistical confidence (95% confidence level, 80% statistical power) the diagnostic usability and quality of dynamic sequences produced with the DR 800 system.

This was proven by a VGA-based image quality evaluation (criteria derived from the European Guidelines on quality criteria for radiographic images and/or current literature), comprising the most relevant exam types of dynamic imaging, including tomosynthesis, DSA and Roadmapping.

The conclusions of the study can be summarized as follows:

Study conclusions

- Optimal image quality and highest diagnostic confidence of all dynamic exams specified for the DR 800 system
- Consistent high image quality, including for adipositas patients (with high amount of scatter)
- Excellent image quality with a dose compliant to the German DIN standard 6868-150

References

[1] *Commission of the European Communities. European guidelines on quality criteria for diagnostic radiographic images, EUR 16260 EN. Brussels: CEC, 1996*

[2] *Commission of the European Communities. European guidelines on quality criteria for diagnostic radiographic images in paediatrics, Report EUR 16261. Luxembourg: Office for Official Publications of the European Communities, 1996*

[3] *Leitlinien der Bundesärztekammer zur Qualitätssicherung in der Röntgendiagnostik*, Deutsches Ärzteblatt, 27. Dez. 2022, DOI: 10.3238/arztebl.2022. LL_Qualitätssicherung_ Röntgendiagnostik

[4] *Decoster, R., et al., Assessment of image quality in orthopaedic radiography with digital detectors: a Visual Grading Analysis SPIE, 2013. 8673: p. 6*

[5] Agfa Whitepaper *Agfa DR 800: New Concepts in Dynamic Imaging*, 2022

[6] Agfa Whitepaper *Agfa DR image quality and patient care*, 2022

[7] Agfa Whitepaper *Digital Tomosynthesis on DR 800 and DR 600 - A method for patient care and hospital productivity*, 2020

[8] Agfa Radiology Solutions, https://agfaradiologysolutions.com/products/dr-800

Other selected publications and references

Loaz O, Almohiy H, Yousef M, Sulieman A, Arib M: *Clinical Analysis of Image Quality for Barium Special Investigations*. PJSR; 2018:11(2):1-9

de Lange, E.E., H.A. Shaffer, Jr., and B.Y. Croft, *Radiographic examination of the stomach and duodenum: comparison of single-, double- and biphasic-contrast methods*. Eur J Radiol, 1990. 10(3): p. 167-74

Piippo-Huotari, O., et al., *New patient-controlled abdominal compression method in radiography: radiation dose and image quality*. Acta Radiol Open, 2018. 7(5): p. 2058460118772863

Guzman-Negron JM, Marks BK, Pizarro-Berdichevsky J, Vasavada SP, Goldman HB. *Fluoro-urodynamic Image Interpretation Is Not Altered by Using Dilute Intravesical Contrast*. Urology. 2018

Geijer, M., Gunnlaugsson, E., Götestrand, S., Weber, L., & Geijer, H. (2017). *Tomosynthesis of the thoracic spine: added value in diagnosing vertebral fractures in the elderly. European Radiology*, 27(2), 491-497

De Silvestro, A., et al., *Postoperative imaging of orthopaedic hardware in the hand and wrist: is there an added value for tomosynthesis?* Clinical Radiology, 2018. 73(2): p. 214.e1-214.e9

Compton, N., et al., Tomosynthesis: *A new radiologic technique for rapid diagnosis of scaphoid fractures*. The Surgeon, 2018. 16(3): p. 131-136

Piayda, K ... et al. *Dynamic coronary roadmapping during percutaneous coronary intervention: a feasibility study*. Eur J Med Res 23, 36 (2018)

Schegerer, A., et al., *Diagnostic Reference Levels for Diagnostic and Interventional X-Ray Procedures in Germany: Update and Handling*. Röfo, 2019. 191(8): p. 739-751

Bath M, Mansson LG. *Visual grading characteristics (VGC) analysis: a non-parametric rank-invariant statistical method for image quality evaluation*. Br J Radiol. 2007;80(951):169-76

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