Radiobotics©

Assessing an AI solution in medical imaging

The ECLAIR Guidelines were recently published, and we wish to show how an AI solution like RBknee™ answers the 10 key questions proposed by the ECLAIR guidelines... and one question of our own.

A publication by Radiobotics

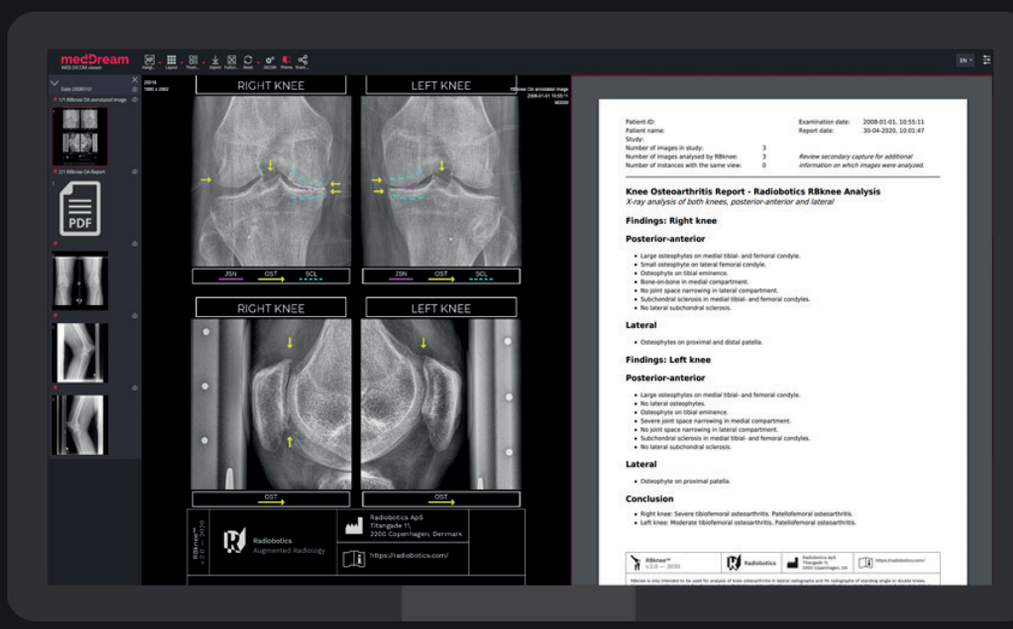
13/3/2021

Assessing an AI solution in medical imaging

Numerous commercial solutions based on artificial intelligence techniques are now available for sale, and radiology practices and hospital management have to learn how to properly assess these tools. The ECLAIR Guidelines were recently published and proposes a framework focusing on practical points to consider when assessing an AI solution in medical imaging, allowing all stakeholders to conduct relevant discussions with manufacturers and reach an informed decision as to whether to purchase an AI commercial solution for imaging applications. We find these initiatives very relevant and, being a supplier of AI solutions, we wish to apply the ECLAIR guidelines in practise, and show how an AI solution like **RBknee™** answers the 10 key questions proposed by the ECLAIR guidelines[1].

1: https://link.springer.com/article/10.1007/s00330-020-07684-x

1 What problem is the application intended to solve, and who is the application designed for?



There is an increasing global need for specialised radiologists. In the UK for example, only 1% of trusts manage to report all their radiographs during normal business hours[2]. Furthermore, many radiological departments still rely on free-text reporting. This lowers consistency, completeness and comparability of the radiological reports[3], and may emphasise the subjective interpretation as shown in numerous studies assessing the reliability of grading knee OA[4].

We have developed **RBknee™** with the aim to support radiologists, reporting radiographers, rheumatologists and orthopedic surgeons by automatically detecting major findings relevant for radiological knee osteoarthritis, and provide a text report with findings and an impression, together with a visual overlay highlighting what the algorithm has detected. This can increase the report consistency and efficiency of the workflow when reporting on knee radiographs.

2: Clinical Radiology Workforce Census 2019 report", RCR 2019
3: The Current State of Artificial Intelligence in Medical Imaging and Nuclear Medicine" RCR 2019
4: ESR paper on structured reporting in radiology" ESR 2018

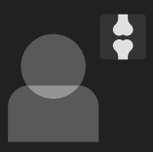
2 What are the potential benefits and risks, and for whom?

In general, a thorough risk analysis must be conducted for any medical device - this obviously also counts for AI solutions. The risk standard for medical devices (ISO 14971) requires a company to consider how they want to deal with risks - at **Radiobotics** we have taken the view that we will reduce any risk as far as possible without adversely affecting the benefit-risk ratio. This means that any residual risk must be outweighed by the benefit for the patient and user.

For AI based devices, a risk that is often discussed is that of bias in data which could result in lower performance on certain patients - this again speaks into the need for as diverse a training set as possible, but particularly also a thorough out-of-sample validation. And there is also the obvious mitigation that you as a user should test it before you buy it. So the short answer is: Check the risk analysis and test it. In terms of the potential benefits we see a wide range of benefits explained a little to the right:

Patients

Patients receive faster diagnosis and initiation of treatment, as well as improved understanding of diseases through visual overlays on x-rays. Also, patients would receive equal health-care regardless of being examined at a university hospital, or a smaller non specialised clinic. It does not matter where their images are read, they still receive the same standard of care, regardless of who is reporting on their radiographs.



Radiologists and Reporting Radiographers

Radiologists could speed up their workflow to free up time, as well as ensure high and consistent quality reporting.

Referring Physicians

The referring physician receives a structured report that describes the pathology in a consistent manner. As the image has been evaluated by **RBknee™** and afterwards checked by a radiologist or a reporting radiographer, the risk of misdiagnosis for their patient is reduced.

Hospitals

Hospitals can ensure patients receive a faster diagnosis without putting further pressure on staff and if appropriate, reduce the cost of outsourcing to teleradiology. A faster and more standardised reporting can potentially also lead to more optimised patient flows.

Healthcare Systems

AI in Radiology could lead to improved outcomes for society through lower diagnostic errors, fewer follow-up appointments for patients, increased patient satisfaction, and reduced pressure on staff.

3 Has the algorithm been rigorously and independently validated?

"The product has some unique features and it will support the orthopaedic surgeon in making evidence based decisions"

Professor Anders Troelsen,
Consultant OA Surgeon, Hvidovre Hospital
Chairman of Danish Knee Arthroplasty Register
Chairman of CAG ROAD

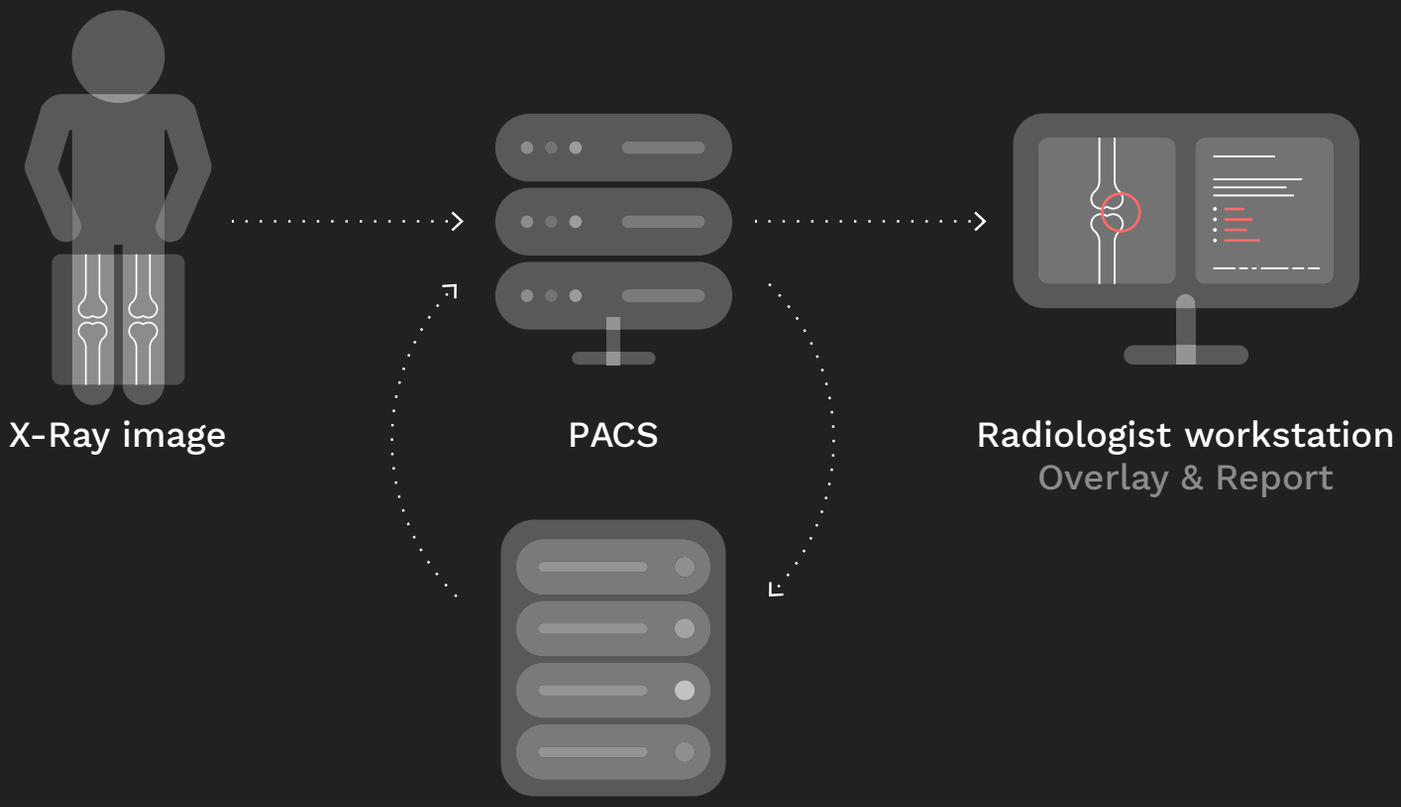
"The reporting will become more consistent and structured and hence more robust"

Philip Hansen,
Consultant Radiologist, MD PhD
MSK lead at Bispebjerg Hospitals
Chairman of Muskrad

In order to be trusted by end users, any claims made by AI vendors need to be able to stand up to rigorous scrutiny independent from the AI vendor. This system ensures that any claim made by the vendors stands independent clinical validation. This is important as it promotes trust of the product.

RBknee™ was validated against MSK experts through a comparison study with 2 radiology consultants, 2 experienced diagnostic radiographers, 2 radiology residents and **Radiobotics**' **RBknee™** algorithm. All rated knees of 50 plain radiographs according to Kellgren-Lawrence (KL) grading. **RBknee™** showed good-to-excellent reliability compared with human experts in KL grading of knee osteo-arthritis. High level of interrater reliability on a dataset from a clinical environment supports the use of decision-aid algorithms like **RBknee™** as a clinical tool.[5]

5: Results to be presented at the 2021 OARSI Congress



4 How can the application be integrated into your clinical workflow and is the solution interoperable with your existing software?

We have invested heavily into understanding different kinds of workflows and software solutions.
In order for AI to have the greatest impact, we believe that integration into clinical workflows is imperative.

Therefore **RBknee™** can integrate directly with PACS and RIS systems, providing immediate and easy access to the algorithm results after X-ray image acquisition.

The **RBknee™** software system does not contain any user interface, but communicates via DICOM protocol for image transfer to and from the PACS and via HL7 for integration to RIS.

Data processed by **RBknee™** is not stored but is only in transit during the analysis.

5 What are the IT infrastructure requirements?

It has been important for us that **RBknee™** can be implemented on both large hospitals, and smaller clinics, and as such we have put emphasis on keeping the hardware requirements at a minimum. **RBknee™** can therefore run on a smaller laptop, though performance improves with improved hardware.

All our products like **RBknee™** can be integrated into most existing modern hospital IT systems, including PACS, RIS & EMR. It can be deployed to existing work terminals so as such, in most cases, no additional IT infrastructure is required, however some internal IT support would be required for a successful adoption and integration.

6 Does the application conform to the medical device and the personal data protection regulations of the target country, and what class of regulation does it conform to?

RBknee™ is currently certified as a class I device under MDD, and is pending to be a CE marked Class IIa device under MDR.
In the U.S. it will be a class II device and is due for FDA clearance in the coming months.

Being a class IIa device under MDR means that a Notified Body (an independent body) must assess the product before it can be put on the market. Furthermore manufacturers must have processes in place for how to develop a product (and it's updates) in a consistent manner that results in a product of high quality and that is safe for users and patients. The processes are audited yearly by the Notified Body.

The MDR obligates the manufacturer to provide evidence for the claims on a product including testing of the product, assessing the risk of the use of the product on patients and users, and to ensure that these risks are controlled.

Similarly, the FDA reviews that the product conforms to its claims and does not raise new safety concerns compared to already cleared devices on the US market before granting an FDA clearance.

7 Have return on investment (RoI) analyses been performed?

When considering AI products, it is important to consider not only the clinical impact but also the financial impact such an investment will make in order to maximise the use of resources. **RBknee™** RoI analyses have been conducted to calculate the direct and indirect cost savings which can be achieved by integrating this product in existing clinical workflows. But this is also an area where the benefit for your setup makes sense to consider, depending on how the product is implemented and what bottlenecks it is intended to alleviate.

We would be very happy to apply our calculation to specific sites if needed in order to fully get this demonstrated, as it varies a lot from site to site, even in the same healthcare system.

Reach out to Cathal White cathal@radiobotics.com to set up a meeting to discuss this in detail.

8 How is the maintenance of the product ensured?

Radiobotics conducts regular maintenance of the **RBknee™** and releases version updates to **RBknee™** when appropriate to ensure that the product continues to be safe to use.

Being regulated under MDR means that the manufacturer has processes in place on how to follow up on issues during the use of the product on the market and to ensure that the software continues to be safe and efficient to use.

How are user training and follow-up handled?

While all our products are developed with usability as a key focus, and a seamless integration is central in this, to ensure safe use of the devices, user training is conducted by the customer success team at **Radiobotics**, either onsite or online depending on the needs. Following initial training, the customer success team continues to support our customers to ensure that their needs are continually being met including regular follow-ups and check ins.

10 How will potential malfunctions or erroneous results be handled?

Radiobotics has systems in place to track potential malfunctions and to proactively target these in good time to ensure that they can be resolved in a timely manner. **Radiobotics** actively communicates with both regulatory bodies and customers to enable transparency in our processes.

During the development of our software, a risk assessment is made to ensure that the source of potential failures in the product, such as erroneous results are controlled and that these controls are tested before the product is released to market. This is an important part of being a medical device manufacturer.

Being regulated under MDR and the US regulation means that the manufacturer needs to have processes in place to follow up on issues arising during use of the product on the market and to ensure that the software continues to be safe and efficient to use.

Besides the 10 questions to consider when assessing AI technology we would like to contribute to the fruitful discussion and would therefore like to add an extra question that we in our work have seen the need to ask →

11 Are you ready to implement this AI solution?

In order to ensure successful adoption of this solution, a clinical team needs to be onboard and ready to learn about the new AI solution. Involvement with the healthcare IT team is also important to ensure that they understand the capability of the solution and how it interacts with other hospital based systems. This buy in is crucial in order to gain the full impact of AI into clinical workflows. In relation to the readiness it's also very important to have the needed internal support from the IT department which is critical for successful adoption of all new software solutions. We advise starting discussions with IT departments early to ensure alignment on IT work pressures, review processes and questions related to IT set up are ironed out early in the process to minimise disruption.

Radiobotics
Augmented Radiology

Radiobotics is an AI software company located in Copenhagen, Denmark, with a focus on developing algorithms for hospitals to automate reading of x-rays of bone and joints.

Lately **Radiobotics** has experienced strong traction, won multiple awards and grants, and established noticeable international collaborations. **Radiobotics** has 20 employees, comprising a diverse and highly skilled team, with expertise especially within machine learning and artificial intelligence (AI), software development, health-care IT system integration, clinical studies and evaluations, regulatory affairs and quality assurance.

All necessities for creating 'soft-ware-as-a-medical-device' under given regulations.

info@radiobotics.com

www.radiobotics.com