A conversation with the new CEO of Screenpoint, developers of the deep learning Transpara software for breast imaging

The number of papers describing the application of Artificial Intelligence (AI) derived algorithms in radiology in general is growing exponentially. In the field of breast imaging in particular, the Transpara AI software developed by the Dutch company ScreenPoint Medical has been shown to provide very positive results in several extensive clinical trials.

Reflecting the transition from an innovative start-up to a fully - fledged commercial company in the field, ScreenPoint has recently appointed Mark Koeniguer as their new Chief Executive Officer (CEO). We thought that this was a good opportunity to take stock of AI in radiology and the potential of Transpara, so we caught up with the new CEO to hear how he sees the future.

Q *Before we get into details, could you give us a quick snapshot of ScreenPoint Medical as a company and its history.*

ScreenPoint Medical was founded in 2014 as a spin-off from Radboud University Medical Center in Nijmegen, The Netherlands, to develop and bring to the market innovative machine learning solutions to improve breast cancer screening and diagnosis. With an exceptional team of scientists and software engineers specialized in machine learning, image analysis, and breast imaging, ScreenPoint developed the market leading AI solution Transpara for reading mammograms and breast tomosynthesis which has been trained on over 1 million exams. Multiple clinical studies demonstrate that the FDA-cleared software matches experienced radiologists in detecting breast cancer and allows them to improve quality and efficiency of breast cancer screening. Transpara is already in use in over 30 countries including the Danish screening program based in Copenhagen.

Co-founder of ScreenPoint Medical, Sir Michael Brady, was known internationally for his ground-breaking work in robotic image analysis at the University of Oxford and MIT but the death of his mother-in-law from breast cancer, caused him to change direction. Michael Brady said "*I wanted to understand why the medical profession wasn't able to do a better job of detecting breast cancers at an earlier stage when they were more treatable. So I decided to move away from robotics and concentrate on the analysis of breast scans. My colleagues and I developed a mathematical model of the passage of X-rays through female breast tissue, a fundamental step towards developing a system able to recognise potential tumors*"

Michael Brady met Nico Karssemeijer from Nijmegen University in 2000 when he was giving a keynote lecture on parallel research.
Both men wanted to help radiologists identify potential cancers faster and at an earlier stage and to increase the chances of more women surviving breast cancer.
In 2014 they started ScreenPoint Medical, building a superb team of scientists to develop a unique system, Transpara, whose underlying technology is a blend of classic physics and deep learning artificial intelligence, and is presented as a decision support tool for the radiologist in order to increase efficiency.
This is all the more relevant given that there are fewer and fewer radiologists specializing in reading mammograms at a time when the incidence of breast

cancer is increasing worldwide. ScreenPoint are the only people that combine deep understanding of the physics, knowledge of clinical workflow and deep learning AI techniques to improve accuracy and speed of detection. Transpara is now recogniaed as the world leader in the field.

Based on its robust scientific background, ScreenPoint Medical has, since its creation, doubled in size on the heels of a major series C funding round. The company continues to recruit top talent. Transpara is now leading the way for prospective use studies, peer-reviewed publications and ongoing clinical studies in Europe and around the world. With the growing awareness of the clinical success of these studies, we have seen a major increase in the number of radiologists reaching out to us to learn more.

Q *Talking about publications, there have been several recent publications describing the evaluation of Transpara software in clinical trials. Can you summarize the results of these trials and the significance of the findings?*

Yes there have been many publications of which three important peer-reviewed publications have appeared in the last few months and which have shown how Transpara can help with workload reduction and early cancer detection. These studies are:

1) The largest breast AI study to date showing the value of Transpara in mammographic screening [1]. The study looked at 122,969 screening examinations from 47,877 women performed at four facilities of BreastScreen Norway. The results were impressive: a total of 86.8% screen-detected and 44.9% of interval cancers received a Transpara score of 10, the category with the highest risk for breast cancer. By extending the highest risk group to 20% of the population, 93% of the screen-detected and 63% of the interval cancers were detected.

"...Our solution works with all major 2D and 3D mammography units and is integrated into the workflow of many PACS and mammo workstations; we've proven it time and again..."

2) Another study showed that Transpara breast AI reduced false positives and radiologists' workload in the largest screening programme in Denmark [2]. In this real-world study, 114,421 screening examinations were evaluated. The team found that AI-based screening sensitivity was similar to that of radiologists (69.7% vs. 70.8%) but when it came to false positives, the AI-based approach outperformed regular double reading. The use of AI resulted in 25.1% fewer false positives. In addition, using the unique Transpara Exam Score and calibration, the team demonstrated the ability to reduce radiologists' workload by up to 62.6%.

3) The largest interval cancer study with over 2,000 cancers missed by screening showed that Transpara AI can effectively help detect breast cancer earlier [3].

We are very lucky to be able to work so closely with our clinical collaborators who are keen to publish the results of their work and let the world know that not all breast AI evidence is the same. Transpara has been featured in the largest studies to date and what's more, thanks to the overwhelming evidence, it's now the first and only breast AI solution to be used to date in a large organized screening program (Denmark)

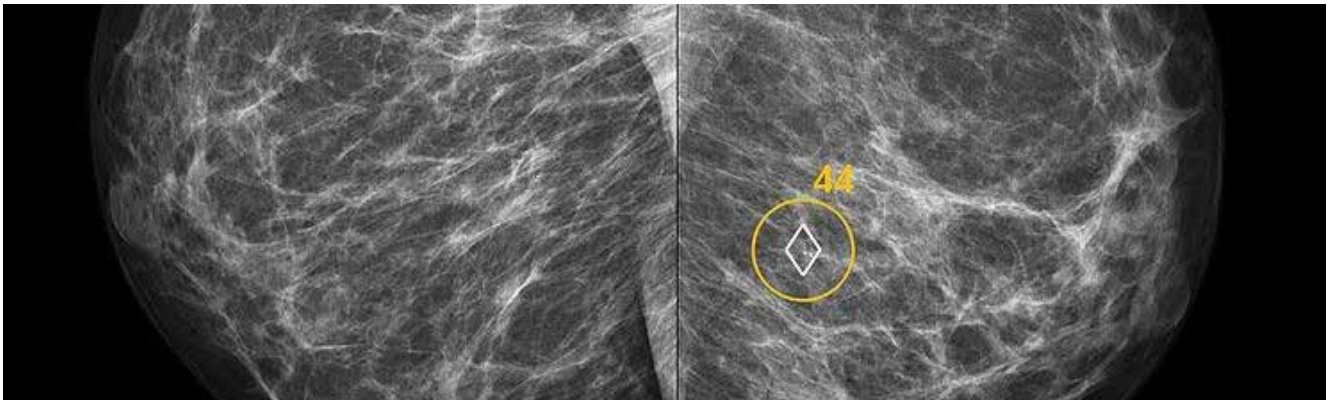
The response from the breast imaging community to these and other studies (all of which are available at our web-site, *https://screenpoint-medical.com/*) has been extremely positive. More and more clinicians are contacting us as they read about the positive results from our studies that are published in top journals like Radiology, European Radiology and the JNCI. The Norwegian [1] and Danish [2] studies are the two largest breast AI studies published, with Transpara being used on a total of nearly a quarter of a million women. The Wanders *et al* paper [3]is the largest study focussed on interval cancers and clearly shows the huge potential for using Transpara as an image-based risk assessment tool to identify interval cancers early. We know that early detection can help increase chances of survival and so that is one of our key missions at ScreenPoint.

As a result of all this hard work, we now have strong adoption of the technology in the USA where 3D mammography is standard. Multiple prospective studies are well underway in numerous other countries.

We have been told by one of our users that "*It's not just about the approval a company receives, it's actually how this product is going to work*", and we, at ScreenPoint, know exactly how it all works. Our solution works with all major 2D and 3D mammography units and is integrated into the workflow of many PACS and mammo workstations; we've proven it time and again. We have helped screening programs, large hospital groups, and small critical care facilities by partnering closely with them to understand and achieve their goals. All backed up of course with the safety net of our evidence and expertise. We call this the #ScreenPointExperience, and it's like nothing else out there.

Q *And now turning to you as new CEO, what was it that attracted you to Screenpoint? What is your main business objective for Screenpoint?*

I feel honored to be part of such a prestigious team of scientists, engineers, and top operational and commercial talent. But first, before we get on to the future, a bit of my background. My career started at GE Healthcare leading teams in Finance, Sales, and Marketing. Since 2001, I have



Transpara Powered by FusionAI has set the standard for breast AI supported by clinical evidence worldwide. A fusion of knowledge: breast pathology, clinical imaging, X-ray physics and the latest deep learning techniques, uniquely combined by the scientists at ScreenPoint Medical in collaboration with our clinical partners.

been fortunate to be part of multiple start-ups including three women's healthcare organizations. I was part of the team at R2 Technologies, the first to market CAD for early breast cancer detection and acquired by Hologic. More recently I led the global commercial efforts to grow Volpara Health Solutions from a nascent player to the number one player in the Enterprise breast analytics space, which has led to its listing on the Australian Stock Exchange (ASX: VHT).

Regarding our objectives at ScreenPoint Medical, we have a very clear vision, namely to become the global leader in AI solutions for Women's Health and early breast cancer detection and prediction. With this in mind, Nico Karssemeijer, who founded the company remains both a tremendous contributor at the scientific level and a personal mentor to me as I integrate into my new role.

Moving away from Screenpoint's focus on breast screening for a moment to broaden out into the issues of AI solutions in the healthcare arena in general, there are many studies on fields ranging from early stroke detection to lung nodules and breast cancer detection, I believe we are still in the early adoption phase. For years, clinicians questioned the value of AI solutions, and perhaps rightfully so given the rates of sensitivity and specificity relative to false positive rates. Today and into the future, ScreenPoint will be focused on developing understandable AI solutions that not only help with higher levels of detection, prediction and overall risk of developing cancer, but also improving clinician productivity and workflow.

"... We will continue to remain the leader in clinical science which is the bed-rock supporting the products we develop..."

We will continue to remain the leader in clinical science which is the bed-rock supporting the products we develop. Too often, we see new companies coming to market with very little clinical evidence, and being obliged to over-promote their performance. At ScreenPoint, we want to lead with our clinical evidence which supports our claims of increased detection, prediction and risk.

Our global expansion efforts will remain focused on the U.S., Europe, Asia and the ME which represent the largest percentage of the eligible screening population.

Q *In AI in radiology in general there have been many research publications but the extent of acceptance/ utilisation of the technology in routine clinical procedures seems still to lag far behind the research. Is this true? If so what are the main obstacles blocking more routine use of AI?*

The adoption of AI solutions or first generation CAD for 2D FFDM showed promise but failed to deliver a truly comprehensive tool necessary to gain scientific or commercial adoption. In the past CAD tended to focus on images as pictures using markers to indicate suspicious areas which required additional investigation. The sensitivity and specificity (false positive) rates of these early algorithms did not stand the test of time relative to the requirements necessary for widespread adoption. Additionally, due to the high false positive rate and lack of true workflow integration, CAD tended to slow radiologists down rather than providing higher detection and workflow efficiencies.

Today, next generation CAD or AI leverages deep learning algorithms and systems to deliver sensitivity and specificity rates on a par with those of most radiologists. This has become possible because deep learning algorithms have benefited from years of clinical research, large datasets over diverse populations, and the continuous learning nature of the algorithms themselves. This has allowed the new AI algorithms to move beyond detection to prediction, and even diagnosis. The improved sensitivity and specificity or decreased false positive rates have allowed wider spread adoption so that AI has become an invaluable tool supporting radiologists and other clinicians with their ever expanding workload.

Additionally, next generation AI continues to become more seamless from a workflow perspective. Companies and departments have learned from old generation CAD systems requiring separate workstations or "clicks" to new windows in order to access and utilise the CAD system itself only added to the burden of reading a mammogram. Next generation AI must integrate seamlessly with current workflow practices via current reading environments, PACS, and reporting. Workflow efficiency is key to adoption and wider use of AI as a clinical decision support tool while making a diagnosis. ScreenPoint Medical's Transpara solution already provides seamless multivendor integration with many existing mammography workstations and PACS solutions. Radiologists' workflow is at the forefront of everything we do.

Q *What are the regulatory issues?*

Regulatory clearances exist for all new technologies. Adopting the right strategy while ensuring high quality standards are important tenets at ScreenPoint. At some point, reimbursement and a focus on the benefits to payers globally will be critical to further adoption and making Breast AI a standard of care.

Q *What about the financial aspects of the use of AI procedures? Is the user's investment in the technology paid for by the increases in the radiologist's efficiency or will specific reimbursement be needed?*

New clinical research demonstrates the true benefits of adopting ScreenPoint Medical's Transpara AI solution in the early detection of breast cancer. Not only does the evidence point to increased detection, but also delivers true productivity improvements through seamless integration into existing work environments.

"...With the unique Transpara Exam Score and calibration, the team demonstrated the ability to reduce radiologists' workload by up to 62.6%..."

For example, in the real-world study published by the Danish group [2], 114,421 screening examinations were evaluated. The team found that AI-based screening sensitivity was similar to radiologists (69.7% vs. 70.8%) but when it came to false positives, the AI-based approach actually outperformed the regular human double reading. Using AI resulted in 25.1% fewer false positives. With the unique Transpara Exam Score and calibration, the team demonstrated the ability to reduce radiologists' workload by up to 62.6%.

This efficiency does translate into real savings for the radiologist and healthcare systems as a whole while still bringing positive benefits to the patients.

Q *What about the radiologist's reaction to all this? It seems that compared to several years ago when there were many gloomy predictions from radiologists about the existential threat that AI posed, the general attitude of radiologists nowadays is to accept, even welcome, the use of AI. Is that your perception?*

Our technology is a decision support tool for radiologists. Our studies have shown that Transpara provides a second pair of eyes for them to improve their confidence when reading mammograms. With the current shortage of radiologists, Transpara can offer a more efficient approach to triaging higher risk patients. We are not here to replace the radiologists. At the end of the day they are the experts in this industry, and we offer a tool to support their workflow.

Q *So to sum it all up how do you see the future, near-term and long-term?*

I believe we are still in the early days of AI development and adoption. Even so, we have seen impressive milestones for ScreenPoint's Transpara AI solution, for example the fact that Transpara is the first and only AI solution to be adopted by an organized screening program. Worldwide, we have processed nearly 3 million women's mammograms and lead the way in clinical evidence with the largest number of peer-reviewed publications of any deep learning solution.

Thus, it is clear that AI supported clinical decision making is here to stay. In fact, I believe those clinicians adopting and leveraging AI tools within their practices will benefit through higher levels of detection, prediction, diagnosis while improving productivity. Ultimately, this will make those imaging practices who adopt AI solutions as a partner in the breast health continuum more competitive than those who choose not to.

In the future, by working with clinicians globally, we should align to end late stage cancer detection, thereby benefiting patients, families and healthcare providers equally.

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