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DIAGNOSTIC IMAGING EUROPE

Magnetic Resonance Imaging

A single-sided low-field MRI system for targeted biopsies and use in physicians' offices

The Business Interview
A conversation with Toshihisa Iida, President and Managing Director of FUJIFILM Europe GmbH, on FUJIFILM's acquisition of Hitachi's medical imaging business

Breast Imaging Special

AI in breast cancer diagnostics: why we need standardized classification of breast density and image quality in mammography

Breast cancer risk assessment and its role in optimizing screening and treatment strategies

AI - based software in breast imaging: a personal account of several months' experience

Marker clips: a "must" in breast cancer diagnostics

Artifacts in contrast-enhanced mammography: are there differences between vendors?

Breast Imaging News

MRI
Deep Learning Model Classifies Brain Tumors with Single MRI Scan

Imaging News
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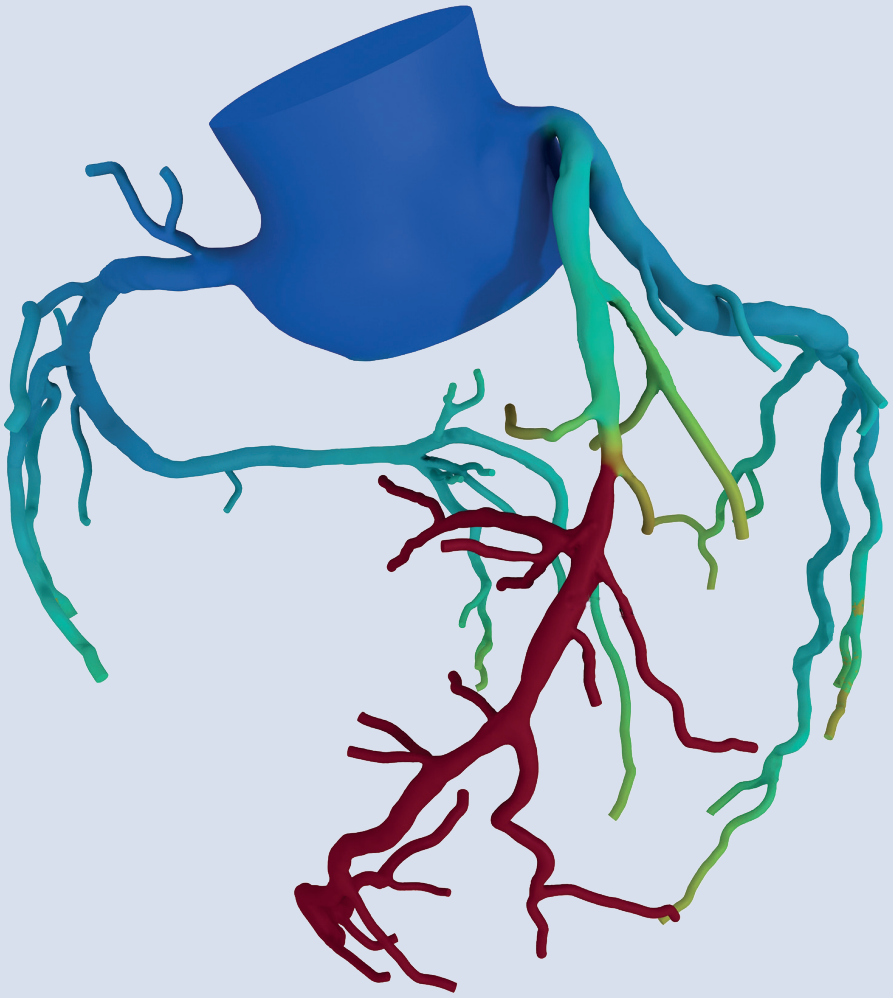
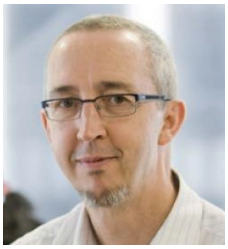


Clinical impact and costing of CT Coronary Angiography with FFR_{CT} in a real world setting

Breast cancer risk assessment and its role in optimizing screening and treatment strategies

Renowned throughout the world for its breast density assessment software and breast imaging QC systems, Volpara Health Technologies has announced that it has recently acquired the US-based company CRA Health which develops breast cancer risk assessment software.

We wanted to find out more about the rationale behind the acquisition and the current status and future potential of breast cancer risk assessment in general, so we spoke to Dr. Ralph Highnam, CEO of Volpara.



Ralph Highnam, Ph.D., is the Founder & CEO of Volpara Health Technologies.
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Q *How does CRA fit with Volpara's offering? How do you see this as a good deal for your current and future customers and for Volpara as a company?*

Volpara has become a world leader in breast imaging AI software, and the focus of everything we do is personalized breast care. We help clinicians make sure that the quality, comfort and safety of their imaging exams are as high as possible and that their scoring of breast density is as accurate as possible. Based on those scores and on associated patient data, we aim to provide access to best-of-breed cancer risk assessment. The ultimate goal of all of this is to ensure that the right imaging can be given to the right woman at the right time. That's been our sole focus over the last few years and we've been able to build a powerful platform around that vision. But one thing we clearly understood over the last year is that breast cancer risk assessment is actually incredibly complicated and the associated genetic analysis is also anything but straightforward.

For these reasons, we looked around the world to find specialists who were experts in genetic risk assessment to work with us. That's how we found CRA Health, a breast cancer risk assessment company, a spin-off from Massachusetts General Hospital and Harvard University. CRA have been entirely focused on cancer risk assessment for more than 15 years and conduct more than 2 million assessments annually. They've built a formidable software package which runs all the breast cancer risk models and creates not just numbers but reports based on current guidelines. Using those reports, radiologists and other clinicians can judge much earlier what is the optimal approach for each patient in order to ensure that the woman has the best chance of early detection of cancer.

Volpara's mission statement is "Saving Families from Cancer", and to implement this as widely as possible we need to have Volpara-level care available in as many breast screening sites as possible.

Over the last few years, we've seen some of the big Electronic Health Record (EHR) companies coming into the field of breast screening, and it became clear to us that we needed to work with those companies in some way, shape or form. CRA Health is tightly integrated into several EHR systems. Such integrations and the necessary relationships and associated trust take years to build up. Now, with our acquisition of CRA we can provide Volpara-level care to a much wider audience — and more quickly. In fact, as of end March 2021, over 32% of the US screening population is receiving the benefits of at least one Volpara product.

Q *What is exactly the benefit of risk assessment via the EHR, as opposed to within a mammography setting?*

Breast cancer is one of, if not the most, prevalent cancers in women, but in particular we've really been affected by the seemingly unending increase in the number of younger women being diagnosed with breast cancer who have small children and families. When you use an electronic health record process, you enable a risk assessment to be carried out at the level of primary care in OBGYN offices at a much earlier patient age. We're very excited about the close relationship between CRA and the EHR providers, because it lets us achieve our mission by bringing best-of-breed initial risk assessment

to women at much earlier ages. This opens the door to genetic testing, then to earlier screening if necessary, and so to the provision at a much earlier stage of the care that the women need. Hopefully the result will be that the women can enjoy long happy lives with their children.

An initial risk assessment can be carried out at the level of primary care in OBGYN offices. It is recommended that such an initial risk assessment , based on data typically available in EHRs, be carried out in women around the age of 30 years. This can determine whether any genetic testing is advisable and whether optimized screening protocols are desirable. Later on, about the early/mid 40s a baseline mammogram can also provide the density of the woman's breast and enable much more accurate assessment in risk models based on many factors including density.

Q *When is the ideal time for that first, baseline risk assessment?*

A lot of people around the world are asking that very question. We've aligned ourselves with the new guidelines from the American College of Radiology (ACR) which recommend that women should get a risk assessment at age 30. Based on the results, they can then determine whether they need genetic testing or not and can seriously consider optimized screening protocols.
In itself, that is an important baseline, but I think that it makes a lot of sense to also carry out a baseline mammogram, by about the early/mid-40s. This would be useful to assess the woman's breast density and would thus enable computing risk at a whole other level of accuracy, thanks to the inclusion of the breast density.

Q *You said that the CRA software can handle multiple risk models. What's the value in this? Are there particular models that are especially useful for the evaluation of risk assessment at age 30 in order to set the all-important baseline?*

For the baseline assessment, i.e. at about age 30, the goal is to determine family history and the genetic risk. Thus, early on, risk models that identify the BRCA genes are important. Then, later on, models such as Tyrer-Cuzick Version 8, which include breast density, family history and a whole swathe of other risk factors, will come into their own.

We know that the current risk assessment models are good, but it shouldn't be forgotten that they were devised using data from relatively small populations of 10-20,000 women. Now, with the sheer quantity and quality of data — and the accompanying science— that we have accumulated at Volpara, and now even more so as a combined company with CRA, we could start to base these risk models on hundreds of thousands, if not millions of women, with the result that the models would become far more powerful. Personally, both as a scientist and as someone passionate about women's health care, I'm really excited about this prospect, based as it is on the increased use we can make of our extensive data.

Q *Apart from the breadth of data and having more women to make it more generalizable and more accurate, is there anything specific that you want to look at with that data?*

In general having more data is key and the inclusion into the risk models of more ethnicities and races that comes with the use of an expanded database is important. However, one of the things that people have never been able to do before is to track changes over time. As a company, we at Volpara want to accompany a woman throughout her complete breast health journey — right from that first assessment session, to which we now have access through the EHRs, then with the baseline mammogram and so on through their screening regimes. This enables us to help them track change over time, help identify issues early on, and help monitor treatment success. For example, if women start taking Hormone Replacement Therapy (HRT), there is a possibility that HRT could result in an increase in their breast density. In such cases it's really desirable to quickly switch to a different therapeutic approach.

"... we need to have highly accurate breast cancer risk models since the patient's risk assessment will direct her care..."

As I've said, our company has access to a phenomenal dataset. It's of course important to have early detection, but we want to get to the point of prevention as well. To achieve that we need to have highly accurate breast cancer risk models since the patient's risk assessments will direct her care. As women are often recommended to follow various regimens there must also be a system to track how those regimens are actually helping to reduce the risk of breast cancer. For example, women taking a preventative chemotherapeutic agent like Tamoxifen should be assessed after a 6-12 months period to determine whether in fact the drug therapy is contributing to a reduction of their risk. If it turns out that Tamoxifen is not having any impact on their breast density, the doctors can then consider recommending another agent to reduce the risk.

Q *Where do you see the biggest future benefits for breast centers coming out of the combination of Volpara and CRA?*

The USA in particular has moved, and is continuing to move towards personalized breast care and as you are aware, risk assessment and breast density measurement are key components of that. Already as a leader in breast density measurement — especially because we have a continuous score and not just ABCD density categories. We are now happy to complement that position by leadership in the risk assessment side, as evidenced by the fact that we now have the ability to provide risk scoring to over 32% of the USA population. Thus, in many ways, we now really do have the keys to enable personalized breast care across a lot of the US. When a woman comes in, completes her risk assessment questionnaire and then receives an automated volumetric breast density score, the result is the creation of accessible and actionable data that the radiologist can use to determine any additional imaging, all the way through to genetic testing.

Q *What impact on the acceptance of personalized screening do you expect from having 10 years' worth of risk data before that mammogram and the density score?*

The reality is that, inevitably, procedures in breast cancer screening only change very slowly because everything has to be evidence-based. For example, if you look at the work we've done in the Netherlands on the DENSE project — that was a 10-year randomized control trial. The study produced some spectacular and solid results showing a reduction in interval cancers by using mammography and then MRI for women with dense breasts. However all that took 10 years. Our aim with our data is to help scientists understand things more fully and especially a lot earlier. The hope is to speed up some of these advances so we can pull them into the breast imaging centers sooner rather than later.

Q *What reactions are you getting from organizations like the American College of Radiology and other bodies?*

We're seeing very strong support for risk assessment. Disclosure to the patient of their breast density is now pretty well established as the standard of care across the US, even though the FDA is still debating about whether to actually mandate the reporting of density information for all women. At the same time, the ACR has suggested risk assessment at the age of 30 and the Center for Disease Control (CDC) recently recommended that women should know their breast cancer risk and consider genetics testing. In addition, some parts of the Centers for Medicare & Medicaid Services (CMS) have recently started to include carrying out breast cancer risk assessment as a quality metric for breast imaging centers. So you can see that there is now a build-up of momentum towards personalized breast care. All in all, it's very exciting and it certainly feels like the combination of Volpara and CRA occurred at a perfect time.

Q *Are you seeing the same kind of regulatory push in Europe?*

No. We're not seeing that from the regulatory bodies in Europe, but instead what we do see is an increased interest by practices and groups to carry out risk assessment simply because they see the benefits. These are the groups who understand that if you carry out MRI on women with extremely dense breasts, you can dramatically reduce all cancers. We're involved in numerous projects around the world, like PROCAS and BRAID in the UK, both of which are large studies looking at how best to prioritize limited resources for women at the highest risk. So there's undoubtedly a lot of interest out there in the world, but I wouldn't say it's regulatory, it's more a kind of clinical interest at the moment. But as study results come out and randomized control trials such as DENSE come through we are going to see screening programs changing. Just to be clear however, I want to emphasize that the current population-based screening programs do an amazing job and are proven to reduce mortality. However there are always ways to improve and optimize the approach.

Q *What sort of expansion plans do you envisage for Europe and the rest of world?*

CRA Health is a US company, but Volpara is global — we sell into 39 countries around the world. We are involved in many important European research projects, such as those in the UK that we already mentioned as well as the DENSE project in the Netherlands, and other large studies in Sweden, Norway and elsewhere in Australia and New Zealand. We are fully intent on taking the benefits of personalized breast care around the world. We firmly believe we now have the IT infrastructure and expertise to make risk assessment and optimal screening strategies completely operational and viable throughout the world. To do this in practice, we aim to supply healthcare personnel with the knowledge, data and evidence to actually and successfully implement the approach so we can get to Volpara-level care everywhere.

"... We are fully intent on taking the benefits of personalized breast care around the world ..."

Q *In addition to the EHR integrations that we've talked about, are there any other benefits and areas of new opportunities that you can see in the future ?*

It's well established that EHR-based systems provide fantastic connectivity for networks of hospitals, imaging centers, referring doctors and so on. However we believe that as far as reporting and compliance issues are concerned there are many aspects which could be further improved. It's in these areas, where we have a lot of expertise, that we believe we can bring significant further benefits to our customers.