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Very Promising Addition

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Hybrid rooms are now being used for interventional imaging during thoracoscopic surgery

By Hildegard Kaulen, M.D.

Völklingen is a district town on Germany's western border. Integral to the city are the Völklinger Ironworks, which is a UNESCO World Heritage Site, and the Heart, Lung, and Vascular Centers of the SHG Hospitals, which are among the largest and most advanced in southwestern Germany. AXIOM Innovations spoke with medical director Helmut Isringhaus, M.D., about the use of hybrid operating rooms in thoracic procedures.

Dr. Isringhaus, diagnostics and surgery are performed on the same table in a hybrid OR. To date, angiographies and heart surgeries have been performed there. You now want to use the hospital's hybrid OR and its new Artis zeego for video-assisted thorascopic surgery (VATS) with interventional imaging. What gave you the idea?

A hybrid OR has a lot of advantages. The spectrum of interventions is much broader there. More minimally invasive procedures are being done. A hybrid OR also promotes cooperation between the individual disciplines, e.g., between cardiologists and cardiac surgeons. I think this is extremely important, because it supports innovation. Why shouldn't we take advantage of this potential in thoracic procedures as well? The pathologists can quickly assess a tissue sample. If the biopsy was done in the hybrid OR, the patient can be operated on immediately. I think this is a major advantage.

What indications warrant the use of the hybrid OR?

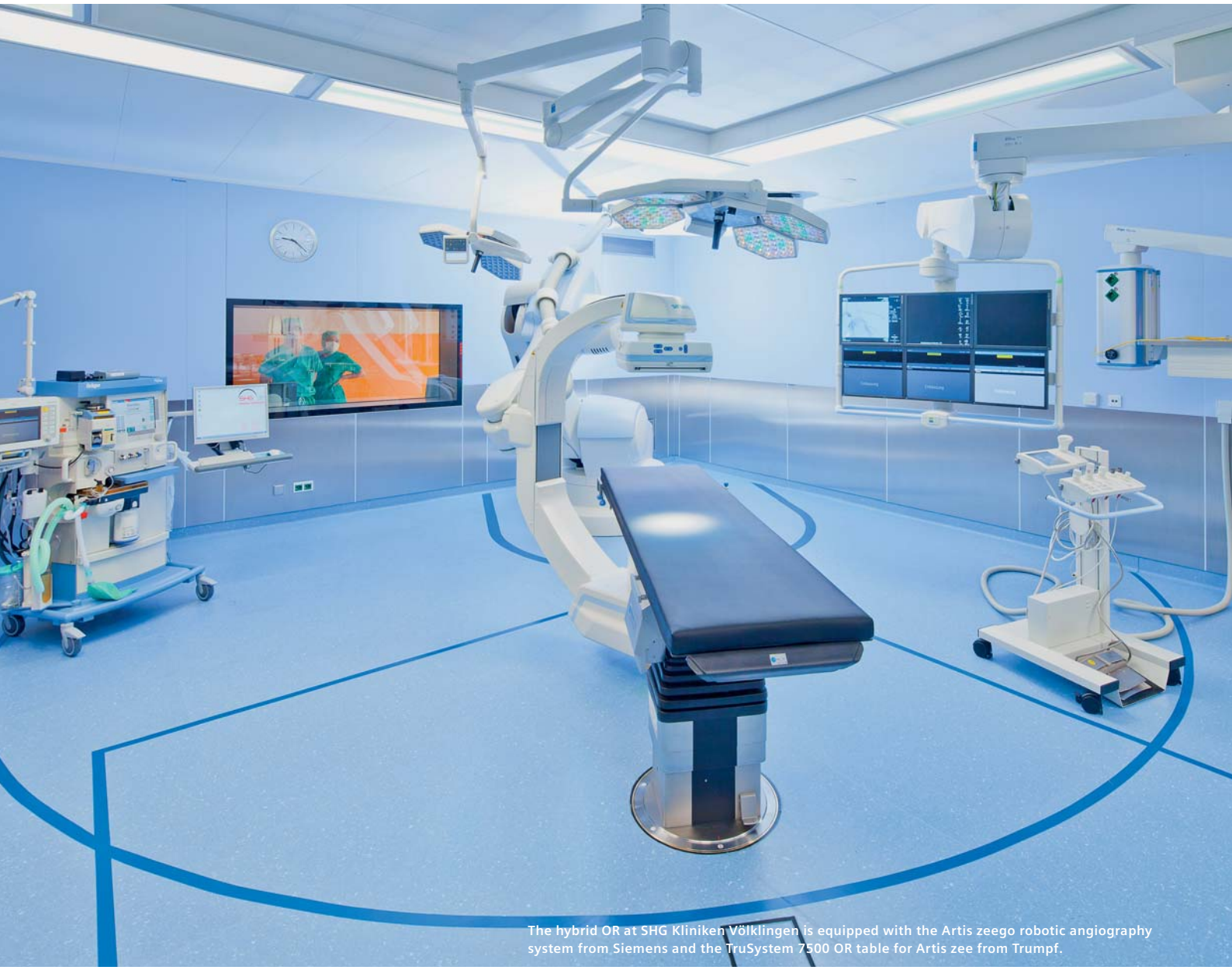
Small, peripheral solitary pulmonary nodules with unclear malignancy need assessment. VATS gets to its edges quickly, because the thoracic surgeons have to do without their sense of touch when operating through the port. Deeper lesions are often only palpable with the fingers; they can't be seen. That's why such solitary pulmonary nodules can be difficult to find in VATS. False negative diagnoses can result if surrounding healthy lung tissue is removed instead of the nodule itself. That's why many physicians resect more tissue than necessary, to be sure that the lesion has in fact been removed. If the lesion turns out to be benign, the patient would have been put through quite a lot – for nothing. Based on experience in Asia and Europe, interventional imaging during VATS makes it possible to accurately see and remove even tiny lesions.

What procedure do you follow?

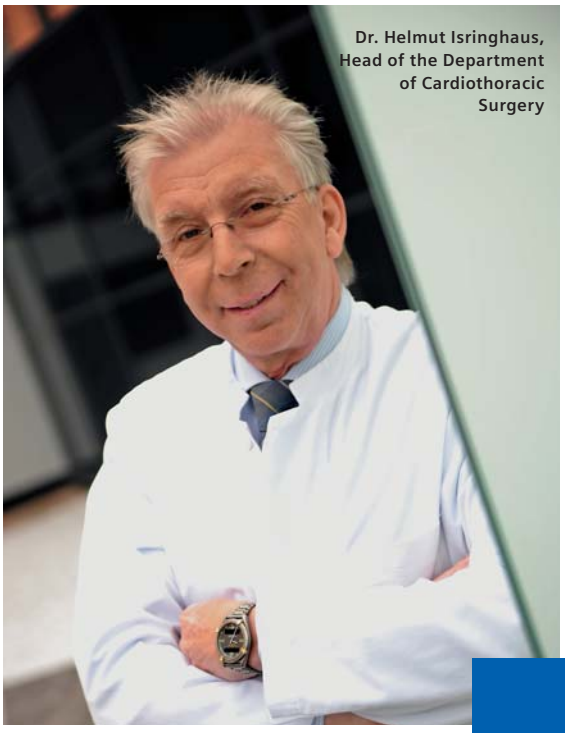
With the patient in the hybrid OR, we will first run a *syngo* DynaCT scan using our Artis zeego angiography system. This lets us generate three-dimensional images similar to CT images. These images then allow us to localize the solitary pulmonary nodule in the 3D dataset. Then we mark the nodule using a needle made of radio-opaque material so that it is visible during VATS under fluoroscopy. After the tissue is removed through the port, we have the pathologists examine it right away. If it is found to be malignant, we remove the tumor-bearing lobe and the adjacent lymph nodes in the same session. For the time being we'll be using open thoracotomy. Once we have gained more experience, we'll add in the minimally invasive VATS lobectomy.

But small, solitary peripheral lung nodules make up only 10 percent of lesions that need follow-up examinations. Conventional methods can continue to be used for larger and centrally located solitary nodules. Are we talking about a niche application here?

No. CT-screening for early detection of lung cancer is a hot topic right now. Several American specialist societies have already published their initial recommendations (see info on page 5). The screening is aimed at discovering tumors while they are still curable. So the need for follow-up examinations is going to be much greater. This requires a less invasive procedure with a high degree of accuracy. VATS with interventional imaging is just such a procedure. But even without screening, our needs are already substantial. Many small, peripheral pulmonary nodules are detected, often by accident, during cardio or thoracic CTs. On top of that, the geographic area we service is quite extensive. We treat patients from all over Saarland, its adjoining states, from Luxemburg, and even France. For us, that's no niche application.



The hybrid OR at SHG Kliniken Völklingen is equipped with the Artis zeego robotic angiography system from Siemens and the TruSystem 7500 OR table for Artis zee from Trumpf.



Dr. Helmut Isringhaus, Head of the Department of Cardiothoracic Surgery

SHG Kliniken in Völklingen, Germany

Helmut Isringhaus, M.D.
Dr. Isringhaus studied medicine at the Universities of Göttingen, Vienna, and Kiel. He is a cardiac and thoracic surgeon. He served in a variety of positions at Saarland University Medical Center in Homburg before he took over as Medical Director of the Clinic for Cardiothoracic Surgery at the SHG Hospital in Völklingen in 1991. That same year he founded the Saar Heart Center (HerzZentrum Saar), where today over 5,000 cardiac catheter examinations and over 1,000 heart operations are performed each year. The founding of the Saar Lung Center (LungenZentrum Saar) followed in 2008, and last year the German Cancer Society certified it as a lung cancer center.

One important aspect of the procedure's success is marking the lesions, because only then are they visible during fluoroscopy and can be removed in their entirety. How do you intend to mark the nodules?
There are two possibilities. Once we have localized the nodule using DynaCT, we can either mark it using micro-coils or with contrast agent. The needle path can be planned using a dedicated software called *syngo* iGuide. In Asia in particular they have gained experience with the contrast agents lipiodol and iopamidol.

Where do you see the risks?
We'll only be able to answer that once we have been able to use interventional imaging with VATS much more extensively. In case of doubt, we'll proceed with an open thoracotomy. So we'll only be doing what we normally do anyway. We will simply change over to the current standard. In terms of radiation dose, the DynaCT scan adds approx. 3 to 4 mSv.

Do you think that there will also soon be early detection screening for lung cancer in Germany?
Lung cancer continues to have a high mortality rate, in spite of advances in treatment. The best strategies for lowering mortality are early detection and prevention. I can envision insurers offering integrated benefits contracts for the high risk group of heavy and long-time smokers in future. This type of contract could include the screening, surgery to remove the tumor, and good after-care. That's another area that still needs attention.

Dr. Hildegard Kaulen is a molecular biologist. After positions at Rockefeller University in New York and Harvard Medical School in Boston, she has worked as a free-lance science journalist since the mid 1990s.

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Low-Dose CT Screening for Early Detection of Lung Cancer

Several months ago, JAMA (The Journal of the American Medical Association) published recommendations for the early detection of lung cancer using low-dose CT (LDCT) (Vol. 307, pg. 2418). These recommendations are based on the systematic evaluation of the available evidence from four American specialist associations. The study was directed by Prof. Peter Bach, M.D., of the Memorial Sloan Kettering Cancer Center in New York. Prof. Bach and his colleagues included eight randomized controlled trials and thirteen cohort studies. Three of the randomized trials reported information on how LDCT screening influences mortality from lung cancer. The most informative data comes from the National Lung Screening Trial (NLST) with 53,454 participants (NEJM, Vol. 365, pg. 395). In this study, a high-risk group was screened three years in a row either using LDCT or a conventional X-ray. They were then observed over a 6 1/2 year period.

With the LDCT screening, the relative risk of dying from lung cancer dropped by 20 %, and the absolute risk fell by 6.7 %. Based on those figures, three deaths can be prevented in every thousand persons screened. The two smaller studies showed no such benefit. In JAMA Prof. Bach and colleagues also quantify the possible harm. Each screening round of 100 participants produced 20 that needed further testing. This number was confirmed in nearly all the studies. In the end, however, only approx. 5 % actually had lung cancer. The results of the follow-up studies on the other 19 participants turned out to be benign and were therefore unnecessary. This number varied from study to study. Most of the follow-up examinations were done using a diagnostic CT or PET scan. Much riskier and invasive follow-up procedures were mostly – but not only – done in those who actually had lung cancer. In the NLST study, eight of the 10,000 persons from the LDCT screening group died within the two months after the diagnostic evaluation, and five of the 10,000 from the conventional X-ray group. Of those that were followed up only with a diagnostic PET or CT scan, 1.9 and 1.5 of 10,000 persons died within two months after the screening. An LDCT screening exposes a patient to approx. 1.5 mSv of radiation. Prof. Bach and his colleagues have calculated that each participant in the NLST study was exposed to about 8 mSv of radiation, with possible follow up examinations added in. Probably about one in 2,500 study participants will die of cancer as a result 10 to 20 years later.

The recommendations from the American College of Chest Physicians and the American Society of Clinical Oncology (quoted from JAMA, Vol 307, Pg. 2427):

Recommendation 1: For smokers and former smokers aged 55 to 74 years who have smoked for 30 pack-years or more and either continue to smoke or have quit within the past 15 years, we suggest that annual screening with low dose computed tomography LDCT should be offered over both annual screening with chest radiograph or no screening, but only in settings that can deliver the comprehensive care provided to National Lung Screening Trial (NLST) participants. (Grade of recommendation: 2B)

Recommendation 2: For individuals who have accumulated fewer than 30 pack-years of smoking or are either younger than 55 years or older than 74 years, or individuals who quit smoking more than 15 years ago, and for individuals with severe comorbidities that would preclude potentially curative treatment, limit life expectancy, or both, we suggest that CT screening should not be performed. (Grade of recommendation: 2C)

Interventional Image Guidance in Video-Assisted Thoracoscopic Surgery (VATS) at Saga University Hospital

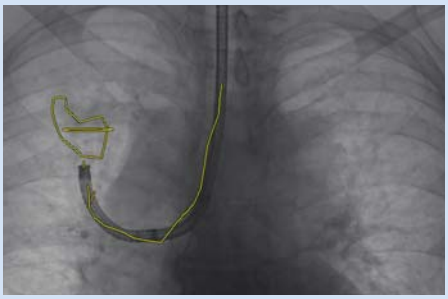
Experience from Japan

At Saga University Hospital in Japan, Tohru Sakuragi, M.D., has been accumulating experience for over a year using the Artis zeego for interventional imaging during VATS. In the meantime, over twenty patients have undergone surgery. They had either early stage tumors, ground glass opaque tumors or pulmonary metastatic tumors. Most of the patients were in a supine or decubitus position (fig. 1) throughout the procedure with their arms stretched overhead. First the lesions were localized using *syngo* DynaCT (fig. 2). The *syngo* DynaCT volume was also used to plan the optimal port placement, so that the instruments could easily reach the nodule. A dedicated software program, *syngo* iGuide, indicates with a cross-hair laser light attached to the detector the skin entry point for the port as well as the trajectory (fig. 3). In the next step, needles were placed on the lung surface close to the assumed position of the tumor as identified in the *syngo* DynaCT run (fig. 4). They served as landmarks, clearly visible in fluoroscopy and intraoperative 3D images. Another *syngo* DynaCT run was performed to determine the exact relationship between the needle markers and the tumor (fig. 5). In the last step a minimally invasive excision of the tumor under videoscopic and fluoroscopic control was done (fig. 6).

> "This workflow with perioperative *syngo* DynaCT imaging has a lot of clinical benefit and potential for thoracoscopic surgery too. I am sure this procedure will be the general standard once all doctors know about the clinical benefit."

Tohru Sakuragi, M.D., Department for Thoracic and Cardiovascular Surgery, Saga University Hospital in Japan.

syngo DynaCT for Navigating the Bronchial Tree



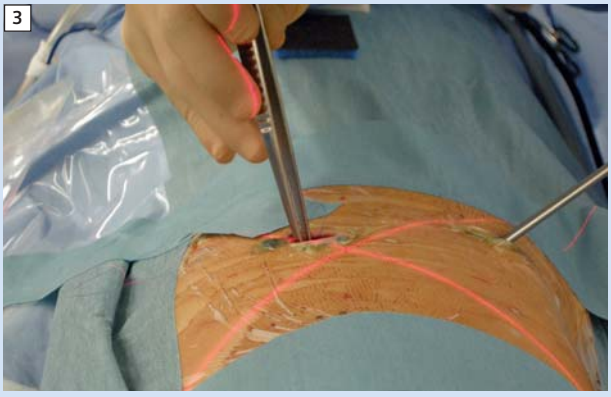
Wolfgang Hohenforst-Schmidt , M.D., of the Coburg Hospital uses the three-dimensional dataset from *syngo* DynaCT to navigate through the bronchial tree. The advantage: The dataset is acquired and the fluoroscopy-assisted bronchoscopy is performed at the same time, at the same place, and with the diaphragm in the same position. This means that that the information out of the 3D dataset matches the anatomy of the lung periphery. Electromagnetic navigation as an alternative method requires a CT scan which is acquired in the radiology department and transferred via a joint computer system to the bronchoscopy lab. Patient transfer to another room, repositioning, plus the respiratory movement of the lungs markedly lowers the accuracy of the tissue excision during biopsy. Dr. Hohenforst-Schmidt has removed bronchial tissue from more than 70 patients using navigation supported by *syngo* DynaCT. The minimum size of the lesions was 10 mm. The method described above combined with a transthoracic approach (with the help of the *syngo* iGuide software) allows for a success rate of over 90 %. Dr. Hohenforst-Schmidt has also shown that small lesions can be dyed to make them easier to see and remove during later surgery.

For more details please see:

"*syngo* DynaCT – A New Tool for Onsite Navigation in the Lung." AXIOM Innovations, June 2011, pg. 41; Abstract in Am J Respir Crit Care Med 185;2012:A1111).

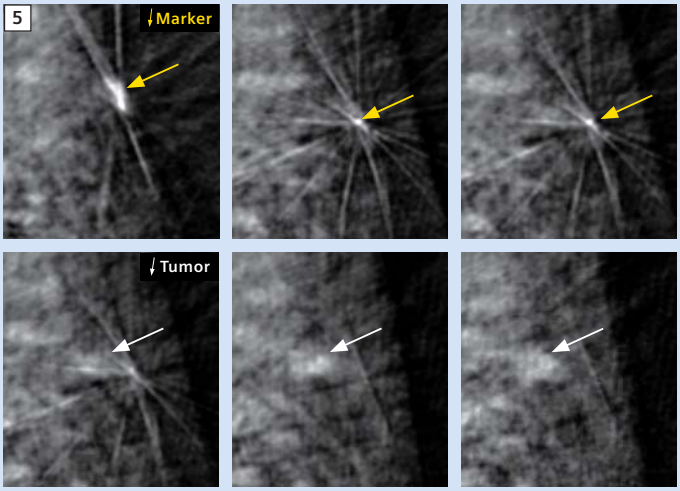
1 Patient preparation in a decubitus position

2 Localization of lesions with *syngo* DynaCT

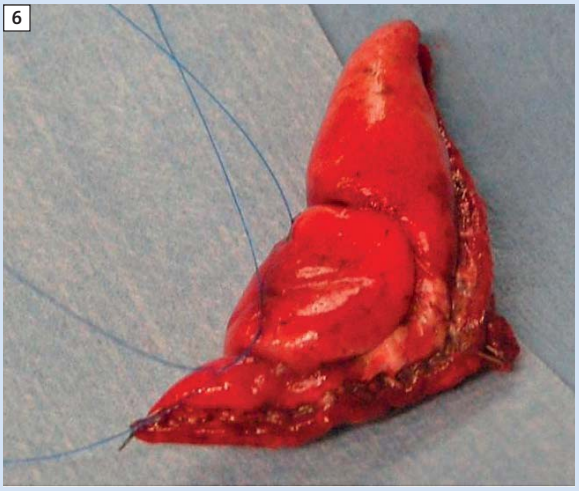


3 Port placement with *syngo* iGuide software

4 Needle placement



5 Second *syngo* DynaCT for the determination of the relationship between needle markers and tumor



6 Excision of tumor under fluoroscopic and videoscopic guidance

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