

30 YEARS ENDOSCOPY AT MEDI-GLOBE GROUP



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Prof. Georg Kähler,
Head of the Central Interdisciplinary
Endoscopy ZIE at the
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*„A true
revolution in
endoscopy“*

Whether minimally invasive diagnostics or therapy: the Medi-Globe Group is now one of the world's leading manufacturers of MedTech products and a pioneer for single-use products in urology, gastroenterology and pulmonology.

Managing Director Ralph Rothe talks to Professor Georg Kähler, Head of the Central Interdisciplinary Endoscopy ZIE at the University Hospital Mannheim, and Professor Peter Vilmann, Head of Endoscopy at the University Hospital Herlev in Copenhagen about innovations, the cooperation between hospitals and industry as well as flexible endoscopy.

Mr. Rothe, you have been with the Medi-Globe Group for 30 years, so you are a true witness of the advances in medical technology. In retrospect, what are the most important developments for you?

In the interventional area in particular, new techniques enabling minimal-invasive procedures that are quick and safe. This way we avoid costly and stressful operations in many specialist areas. Let's take the so-called 'ShortTrack System' from the Medi-Globe Group as an example. It makes it easier to change instruments during a duodenoscopy when performing an endoscopic retrograde cholangiopancreatography (ERCP), for example to remove gallstones or to place drainage stents. The system therefore gives the clinician sufficient flexibility to always have the right technology at hand.

Professor Vilmann, you as clinician have worked with flexible endoscopy for more than 35 years. What was the greatest innovation for you?

Over the years I have seen a true revolution in gastrointestinal endoscopy, which has manifes-

ted itself in four areas: the optimized digitized endoscopic imaging, the combination of ultrasound with endoscopy, the maneuverability of the endoscopes and the microsurgical accessories that are used with the endoscopes.

Professor Kähler, you too have been involved in endoscopy for more than three decades. Which progress is essential for you?

The enormous improvement in the optical quality of endoscopes with all the technical possibilities of image processing. The resection techniques could be greatly improved and are, therefore, the standard for all endoscopically accessible early cancers and their precursors. Endosonography has brought significant medical advances: in precise tumor staging, in the diagnosis of peritumoral processes, and it increasingly serves as a basis of interventions such as the creation of biliary access that are not possible with ERCP.

Which Medi-Globe Group projects were particularly challenging, Mr Rothe?

For us in gastroenterology it was certainly the

development of needle systems for endoscopic ultrasound. As a pioneer in this field we had to understand and combine the technology of endoscopes and ultrasound to develop suitable needle systems from design to serial production. This also includes the search for suitable materials that meet the mechanical and biological requirements. These developments took a few years to reach daily medical practice in hospitals. It worked since we cooperated closely and trustfully with leading physicians, material scientists and technicians.

And which ones were particularly impressive?

In general, the change from a purely imaging procedure to an optimized diagnostic and therapeutic platform for minimally invasive and non-invasive interventions through natural body orifices. This took just a few years thanks to an intensive cooperation between industry and leading hospitals. In particular, the combination of different technologies should be mentioned here, e.g. endoscope plus ultrasound head.



Endoscopic ultrasound and interventional endoscopy have had a major impact on your daily clinical routine, Professor Kähler. How do doctors and patients benefit from it?

In the past, for example, patients with gastric cancer were exploratively laparotomized. That means they got a large abdominal incision and then the physician checked whether the tumor could be removed or not. Today, endoscopic ultrasound can reliably predict the resectability of tumors. The decision as to whether an operation makes sense at all, or instead of or after an accompanying radio and chemotherapy is essentially based on endosonography. Even for one of the most pressing clinical problems in clinical oncology, pancreatic carcinoma, we can only make progress in the early detection of cancer precursors and early stages through endosonography.

Which technical development steps were decisive in moving from diagnostic to interventional endoscopy, Professor Vilmann?

There is a need to develop intelligent micro-instruments and accessories that can be used during flexible endoscopy. The ideas usually come from the clinician, who then seeks close cooperation with the specialists from the industry. Both sides must collaborate closely and trustfully.

And, Professor Kähler, how does the flexible endoscopy technology help?

It has the fundamental advantage that it uses natural body orifices and paths. And, in contrast to sectional imaging methods, it allows direct viewing with a biopsy so that the accuracy in diagnostics is unmatched. In terms of therapy, provided that it can safely achieve the medical goal, it has the great advantage that it does not cause any access-related problems. Therefore, it is acceptable to older and multimorbid patients. It largely avoids subsequent complications and can be carried out on an out-patient or short-term basis.

With endoscopic ultrasound, the transducer is brought close to the target structure to be examined in order to improve the imaging. Professor Vilmann, which tissue structures primarily benefit from this diagnostics?

Due to the short distance from the transducer to the surrounding organs, endosonography is probably the image modality with the highest resolution. This means that the entire gastrointestinal wall layers in the upper and lower abdomen can be visualized in detail in order to assess submucosal lesions and to visualize malignant tumors of the GI wall locally. In addition, the entire mediastinum is shown very well by endosonography, either through the trachea or the

esophagus. That is why endoscopic ultrasound (EUS) or endobronchial ultrasound (EBUS) is currently integrated into the diagnosis and evaluation of lung cancer worldwide. In the abdomen, the left lobe of the liver, the adrenal gland, the pancreas and the biliary tract are shown in detail. Therefore, the diagnosis and evaluation of pancreatic lesions, pancreatitis, biliary stone diseases, biliary tract lesions, the evaluation of lymph nodes surrounding the GI tract, and focal liver lesions are goals for EUS. In particular, the combination of an excellent image and the development of interventional EUS has revolutionized the diagnosis and treatment of a large number of diseases.

Mr. Rothe, flexible endoscopy has determined important parts of the Medi-Globe Group's product portfolio for around 30 years. Why is this area so important to you?

In addition to urology and pulmonology, gastroenterology is a central area of our business. Here we have consistently challenged ourselves to be a leader in promoting innovation and designing Medtech products. With the changing endoscopic procedures, in recent years the Medi-Globe Group has consequently converted our gastroenterological product portfolio to sterile single-use products. Previously, many instruments were reusable. This required time-

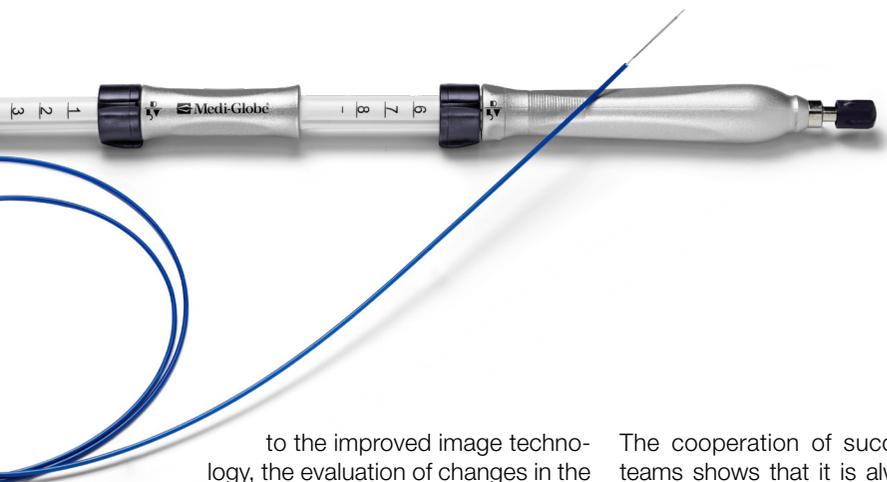
consuming and costly methods of cleaning, disinfection and sterilization, which always carry a residual risk of infection. That is why the development of single-use products was an important and correct step for us to improve patient and user safety.

Today, in chromoendoscopy, suspicious tissue areas are stained with the help of dyes in order to improve visibility for the examining doctor. With which patients do you use such procedures, Professor Kähler?

Chromoendoscopy can now be carried out not only by spraying or injecting dyes, but also by using filtered light or digital post-processing of the endoscopic images. It is used routinely in all patients with inflammatory bowel disease, squamous cell carcinoma of the esophagus, and Barrett's esophagus. In all other examinations, a questionable or conspicuous structure in white light endoscopy can better be characterized by chromoendoscopy. This helps to predict the histology if necessary and to make a decision about the appropriate therapy.

And you, Professor Vilmann? How do you feel about chromoendoscopy?

It has changed in the past few years. In the past, mainly colored dyes were sprayed to assess mucosal changes either to characterize polyps or to detect pre-stages of malignancy in patients with inflammatory bowel disease. Due



to the improved image technology, the evaluation of changes in the mucous membrane can now be carried out simultaneously by software with filters specially developed for this purpose. A new addition are artificial intelligence processes in imaging, which are used both for improved polyp detection and diagnostic evaluation. All in all, very promising for the future.

In the Medi-Globe Group you have also developed special puncture needles for targeted tissue sampling. What is the added value, Mr. Rothe?

As a pioneer and technology leader with patented needle systems, Medi-Globe was able to enable endoscopic tissue extraction for cytological and histological examination, thus avoiding numerous invasive interventions. The ergonomically sophisticated handle as well as the needle surface and the special needle bevel guarantee a safe, targeted and precise puncture. This promises a high level of security in the diagnosis and the choice of therapy, thus also shortening length of stay and reducing costs.

What is your collaboration with the Medi-Globe Group based on regarding the development of new instruments, Professor Kähler? And which impulses do you give in advance?

The cooperation of successful development teams shows that it is always about a mutual exchange. It all starts with the impulses from the clinic. What are the „unmet needs“? Technology dictates the availability of new technologies from a wide variety of technical areas. The right path only develops from a multi-level interplay. Sometimes the end result looks very different from what was initially hoped for. A good example from the collaboration with the Medi-Globe Group is the BiTrack catheter developed on the basis of existing ERCP catheters for the prosthetics of bilateral biliary tumors. The instrument was ready for the market in just four coordination phases.

And you, Professor Vilmann? How is it for you?

I was a young surgeon in training in the early 1990s when I became interested in endoscopic ultrasound. EUS imaging was in its infancy when the development of needles and devices for EUS-guided biopsy began. I was the first clinician to perform an EUS-guided biopsy. And I knew from day one that an EUS-guided biopsy would revolutionize diagnosis and therapy. My collaboration with the Medi-Globe Group began with the idea of developing a handle that can be attached to the inlet of an endoscope. We knew from early tests that only sufficient force transmission could drive

the long needle into a hard tumor. So, I gave the developers of the Medi-Globe Group the task of solving this. Today many companies manufacture needle assemblies for EUS-guided biopsy, but all of these devices copy the original device that we developed together with the Medi-Globe Group in the 1990s - a “game changer” within endoscopic ultrasound and flexible endoscopy.

Let’s assume you have one wish, Professor Kähler: What do you as clinician expect from the cooperation with the Medtech industry in the future?

My main wish is directed more towards the state funding policy than towards the medical technology industry. The funding policy should be extended, less bureaucratic, more focused and more responsive. Joint funding from industry and research users would be ideal. The regulations such as the EU Medical Device Regulation (MDR) and its subsequent provisions should also be repeatedly checked and adapted to ensure that they are appropriate. Research institutions supported jointly by industry and users that could complete the above-mentioned processes in the shortest possible time would be desirable. That would be an advantage both for Germany as a medical technology location and for patients in the German healthcare system.

And what would you wish for, Professor Vilmann?

The collaboration between the industry and the clinical expert should be characterized by respect on both sides. It is therefore important that the expectations of both sides when generating new ideas are mutually understood.

What does the Medi-Globe Group expect from the cooperation with the clinics in your specialist area, Mr. Rothe?

We are in constant contact with clinicians worldwide. Our credo is a cooperation-based partnership. It was and will be one of our main strengths in the future. As a Medtech manufacturer it is important to us to maintain a network with leading universities, hospitals and physicians. In discussions with these users, innovative concepts for minimally invasive diagnostics and therapy and thus ideas for new methods and procedures or suggestions for improvement for existing products are constantly emerging. Only in this way can we offer our patients medical progress and shorten development times.