

CUSTOMER MAGAZINE FOR
SURGICAL MICROSCOPY & TECHNOLOGY

reSOLUTION

Lives Must Not Depend on Money

Leica HM500 for Hungarian Children's Cancer Foundation

Making the Finest Blood Vessels Visible

Fluorescence Module Supports Cerebral Aneurysm Surgery

Wilhelm Fabry – Surgeon, Inventor and Publicist

A Founder of Modern Surgery

OMNIS MEDELA A DEO



Dear Readers,

The person looking at you from the front cover of this issue of reSOLUTION is Wilhelm Fabry, a maverick of modern medicine born 450 years ago. Fabry, a surgeon, inventor, and publicist, was one of the founders of contemporary surgery. Many of the surgical techniques he invented are still used in a surprisingly similar form today. Find out more on page 16.

Unlike Fabry's era of medicine, state-of-the-art operating technology and equipment are now readily available to save lives and alleviate suffering in many countries of the world. But in places where money is in short supply there follows a shortage of modern technology, too – in Hungary, for example, where children suffering from cancer cannot receive the treatment they need. The Hungarian Children's Cancer Foundation has taken up their cause and donates urgently required instruments where they are needed most; most recently a new innovation, the Leica HM500 Headmounted Microscope.

Next, Leica Microsystems drives new innovation for routine ENT and dental surgery: The new Leica M320 F12 surgical microscope combines superb quality with ergonomic operation and an esthetic, functional design. Just one look at it shows that it's different from other surgical microscopes.

Have fun reading!

Anja Schué
Communications & Corporate Identity

Angel Viosques
Marketing Manager Surgical Europe

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Leica HM500 for Hungarian Children's Cancer Foundation

Lives Must Not Depend on Money

Zsafia Rick, Budapest

For the last thirteen years, the Hungarian Children's Cancer Foundation has helped children who have been diagnosed with cancer, their families, and the doctors who provide the children's medical care. The Foundation accepts any requests for items such as medicine, medical instruments, and even a dress or a bicycle. Recently, a Leica HM500 Headmounted Microscope was procured for the Heim Pál Children's Hospital in Budapest. István Balogh, the foundation's president, created the organization not only to help the children of Hungary, but also for a personal reason.

Mr. Balogh, why were you so determined to set up this foundation?

When my son was three and a half years old, he was diagnosed with Non-Hodgkins Lymphoma. I witnessed awful conditions in the hospital's hematology department, and I saw children die who may have lived if more resources were available. There was not enough medicine, and the treatments they received were not acceptable. I felt I had entered through the gates of hell.

I am a Hungarian history teacher and criminology expert that had entered into a very different world from what I was used to. I did everything I possibly could to help my child recover from this serious disease. Today he is 18 years old!

During my son's recovery, I wrote "Child Cancer," a book based on the real struggles and issues we encountered during my son's diagnosis and treatment. The book was very successful. 15,000 copies were sold, it was translated into English, and it appeared at the Frankfurt Book Fair. The success was enormous.

The doctors and families I met while writing this book inspired and motivated me to find a way to help sick children and provide the doctors with suitable instruments, diagnostic devices, and medicine. The Children's Cancer Foundation was established the same year.



Many parents have to go through the same struggles during their children's diagnosis and treatment as you and your family. However, you were the first one to create a foundation. What motivated you to take this initiative?

The doctor treating my child said, "Balogh makes a lot of fuss in vain, the child will die anyway." What an unthinkable sentence! I couldn't accept that the number of cancerous diseases among children was higher in Hungary than anywhere in the world. I believed if God gave me the strength to fight for my own child, then it was my duty to fight for other children, too. Budapest City Court registered the foundation in 1997, and it was qualified as a non-profit organization in 1998. Although I was not skilled at redressing, I had management skills and started to build a team.

Due to my perseverance and determination, Hungary's 1% personal income tax law, patients' rights law, and medical law have been modified. In Hungary, 1% of everybody's personal tax duties can be donated to either churches or charitable foundations. I am proud to say we currently receive 400 million forints (1.5 million euros) annually, which is the highest personal income tax donation for any church or foundation in Hungary. The Children's Cancer Foundation's next objective is to build a hospital for children with cancer that reaches Western European standards.

Whom does the foundation support? What kind of requests do you receive?

We receive requests from children, their families, local governments, and healthcare facilities. Currently, we are supporting 874 children with cancer. The local government's responsibility is to purchase instruments and resources for support, which is usually initiated by hospitals. The local government does not have the money that is needed so they turn to us. The Children's Cancer Foundation has not rejected a single request in thirteen years.

How is this achievable?

The Children's Cancer Foundation is a reputable organization. If we do not have the funding for the needed resources, we invite companies to donate the instruments. This is a win/win situation for the children and for the companies that donate.

Recently you helped Heim Pál Children's Hospital to get a Leica HM500 Headmounted Microscope. Would you explain how this transpired?

I became very curious about the Leica HM500 when I received the request for a Headmounted Microscope from a doctor. I gathered information from the internet, contacted the Leica Microsystems representative, and

discussed the benefits with the doctor. I received a proper reference from the distributor, and I spoke with the doctor who asked for it. Of course I will keep on observing the results the doctors have achieved with the Leica HM500. I am not a doctor but I can say that this is the technology of the 21st century. In my opinion, any hospital performing surgery should have a Head-mounted Microscope.

Have you had another request for a Head-mounted Microscope?

Not yet. But if we did, and we had the money or sponsor for it, then we would certainly purchase it. We see the benefits of the Leica HM500 and there is definitely a need for it. We know there is no antidote for cancer. It is a fatal disease. But if it is diagnosed in the early stages, there is a better chance of recovery. The Head-mounted Microscope is not only used for surgery, but also for examinations in the diagnostic period. A good instrument may cost more money, but if it helps save lives, it is worth it. A life must not depend on money.



István Balogh is the founder of the Hungarian Children's Cancer Foundation which has gained considerable success in the fight for a better medical care of children with cancer.

Dr. Sándor Sárközy on the Advantages of the Headmounted Microscope

Versatility and Higher Safety for Tumor Removal

Zsafia Rick, Budapest

The Hungarian Children's Cancer Foundation purchased a Leica HM500 Headmounted Microscope to be used by the Heim Pál Children's Hospital in Budapest. This hospital is the largest of its kind in Hungary, providing treatment for almost 25,000 inpatients and 450,000 outpatients per year including 300 young patients with cancer. The hospital has long specialized in children's health and gives high priority to early diagnosis and treatment.

Dr. Sándor Sárközy, Head of the General Surgery Department at the Heim Pál Children's Hospital, learned about the Leica HM500 during a lecture and immediately recognized the many advantages the Headmounted Microscope could offer for the hospital.

"We will use the Leica HM500 for sutures of veins, nerves, and even sinews. For the treatment of one- or two-year-old children, these tissues are so tiny that a perfect view is essential for a successful surgical outcome," explains Sárközy. "We will also use it for the removal of mutations in delicate places, for example to remove a birthmark on a nipple where it is necessary to maintain the milk duct. The magnification and the independent light source of the Leica HM500 leads to safer tumor removal."

Describing his use of the instrument, Sárközy says, "I like the large field of view. Changing the diameter of the visible field during surgery is essential, as we

need to enlarge the view during wound preparation. With the Leica HM500 this is easily done. There is no need to look above or beside the device." He continues, "I also consider it very helpful that the eyes do not have to adjust when looking above the Leica HM500. Therefore the operation is less exhausting. With the help of the autofocus I can also move my head away from the surgical area without losing the sharpness of the image."

Mobility is another big advantage of the Leica HM500. As Heim Pál Hospital is a teaching institution, the possibility that everybody in the operating room can watch the operation in detail on the monitor is important. The operation is easily documented and can be later used for teaching purposes.



Dr. Sándor Sárközy, Head of the General Surgery Department at the Heim Pál Children's Hospital in Budapest.

Fluorescence Module Supports Cerebral Aneurysm Surgery

Making the Finest Blood Vessels Visible

Kerstin Pingel, Leica Microsystems

Cerebrovascular disease, which can be triggered or result from a ruptured aneurysm, is the third most common cause of death in industrial countries and the main cause of severe long-term disability and the need for lifelong care. Dr. Joaquim Enseñat, neurosurgeon at the Clinic de Barcelona Hospital in Spain, has used the technique of intraoperative videoangiography with the Leica FL800 fluorescence module to treat cerebral aneurysms since 2008.



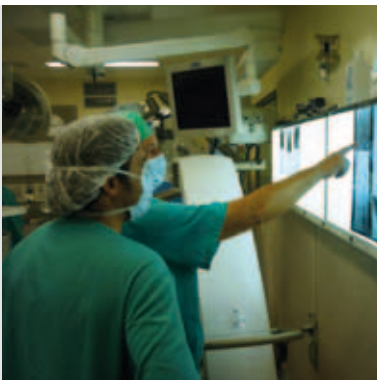
Dr. Joaquim Enseñat, neurosurgeon at the Clinic de Barcelona Hospital, Spain: "Videoangiography with the Leica FL800 fluorescence module is an innovative, simple, and above all, extremely fast method – and that is one of the main criteria in cerebral aneurysm surgery."

When an aneurysm occurs, which is essentially a bulge in a blood vessel, the size of the cross section of an artery more than doubles. This considerably increases artery wall tension and therefore the risk of rupture. An aneurysm in the brain leads to life-threatening hemorrhaging, requiring immediate emergency

surgery. "10% of patients with a burst aneurysm die on the way to hospital," says Enseñat. "Aneurysms are an extremely complex disease with a high mortality rate, 46% during the first 30 days after treatment. Three quarters of the patients who survive will never fully regain their ability to work." To avoid blood vessel enlargement and rupture, cerebral aneurysms are treated by a procedure where the bulge in the blood vessel is separated from the blood flow with a clip.

Fast, reliable checking of blood flow

A successful outcome of such neurovascular surgery depends on cutting off blood flow to the aneurysm while maintaining blood flow in the neighboring functional blood vessels. However, a purely visual evaluation of the surgical site is inadequate, as it is extremely difficult to inspect vascular circulation. "Postoperative evaluation shows that between 4 and 8% of deformities are not completely clipped and 8 to 12% of neighboring functional blood vessels are closed by mistake," says Enseñat. For the first time, fluorescence-aided videoangiography with the Leica FL800 fluorescence module enables neurosurgeons



to watch blood flow in the brain during surgery via the surgical microscope, without additional measuring apparatus.

The patient is injected intravenously with ICG (IndoCyanineGreen) dye, which is well tolerated and spreads through the bloodstream quickly. Excited by light in the 800 nanometer wavelength range, the ICG fluoresces and emits light at a wavelength of 835 nanometers. This infrared light, which is invisible to the human eye, is filtered out by means of the microscope optics and then transformed into a black-and-white image by a near infrared NIR CCD camera. Within seconds after the ICG injection, the surgeon can examine blood flow in the vascular structures in real time on a connected monitor

Intraoperative monitoring of blood vessels offers more safety for the patient

“Videoangiography with the Leica FL800 is a fast, easy method of checking whether the aneurysm has been perfectly clipped and whether blood is properly flowing through the bypass,” says Enseñat. “We can then predict with more certainty that the patient will not suffer from complications. When we see the contrast medium in the branch that supplies blood to the arms, we know that this part of the brain has not been damaged and the patient can move his or her arms.”

Gaining valuable time

Unlike intraoperative arteriography, videoangiography does not require extra staff or space in the operating room. Whereas surgery has to be stopped for 20 to 40 minutes for arteriography, the Leica FL800 can be used to check blood vessels with minimal interruption. The surgeon presses a single key to switch from white light to infrared mode and then watches the blood flow in real time. “Our study showed an almost 100% match between the results of postoperative arteriography and fluorescence-aided video angiography,” comments Enseñat. “Arteriography will still be important; due to digital subtraction we are able to see hidden blood vessels, too. But videoangiography with the Leica FL800 fluorescence module is an innovative, simple, and above all, extremely fast method – and that is one of the main criteria in cerebral aneurysm surgery.”

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Leica FL800 for Real-time Vascular Fluorescence

The Leica FL800 intraoperative videoangiography module is used in conjunction with ICG (IndoCyanineGreen) fluorescent agent to visualize blood flow in cerebral vessels. Surgeons can watch a patient's blood flow in the brain during surgery directly through the microscope or on a monitor. The patient is injected intravenously with ICG, which is well tolerated. Excited by light in the 800 nanometer wavelength range, the ICG fluoresces. A near infrared NIR CCD camera captures the fluorescence signal and transforms it into a black-and-white image. The surgeon can then examine the blood flow in the vascular structures within seconds after the ICG injection. “Using the Leica FL800, the ICG can be visualized quickly, conveniently, and most importantly, directly through the surgical microscope,” says Senior Product Manager Roger Spink from Leica Microsystems. The Leica FL800 can be integrated with the Leica M720 OH5 and Leica M525 OH4 surgical microscopes.



State-of-the-Art Microscope Enables New Vitreoretinal Surgery Technique

Both Hands Free for Instruments

Anja Schué, Leica Microsystems

Surgery on the back of the eye has become much safer due to the great technical progress made in minimally invasive surgery over the last few decades. Nevertheless, these operations cause considerable strain on the eye. In pars plana vitrectomy, three ocular incisions are normally made. Thanks to the superb optics and the unique illumination concept of the Leica M844 F40, Dr. Luca Cappuccini from Reggio Emilia Hospital in Italy can operate without one of the incisions for certain vitreoretinal procedures. This shortens the duration of surgery and speeds up eye recovery time.



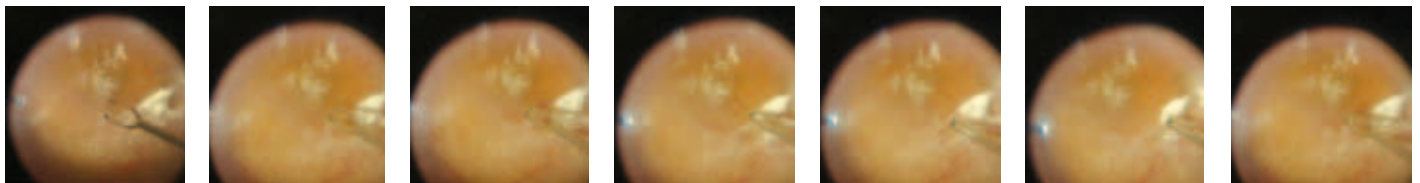
Fig. 1: Dr. Cappuccini has worked with Leica Microsystems microscopes for many years. Above all, he appreciates the excellent image quality. For the different types of eye surgery he needs high-contrast, true-to-nature images with good depth of field. He is also impressed by the easy maneuverability and the high flexibility of the state-of-the-art Leica M844 F40 microscope.

The introduction of pars plana vitrectomy about 40 years ago heralded a new age in posterior segment surgery. The development of this technique in a closed system, which prevents a drop in eye pressure during surgery, made it possible for the first time to master operations on the vitreous body, retina, and macula. Since then, there have been ongoing developments in surgical techniques and instrumentation, always with two objectives in mind: to shorten surgery time and eye recovery time. This has primarily been achieved by creating smaller and more efficient instruments for

incisions of less than one millimeter that cause less surgical trauma. Also, microscopes are now on the market that offer improved visualization and illumination of the surgical site.

Vitrectomy with only two incisions

Three separate incisions are normally made in the pars plana for vitreoretinal surgery. This part of the eye between the outer edge of the retina and the ciliary body contains neither large vessels nor functionally irreplaceable tissue. One of the incisions is used for the infusion that keeps eye pressure stable. The illuminator is inserted through the second incision. The third incision is made for the surgical tools, e.g., vitrectome, microscissors, microforceps. Having several channels offers two key advantages: several minor sclerotomies are less traumatizing than one large one, and instruments can be changed without any major fluctuations in pressure. Dr. Luca Cappuccini, Director of Ophthalmology at Reggio Emilia Hospital in Italy, experienced eye surgeon and specialist in vitreoretinal surgery, uses a variation of this technique that only requires one channel for infusion and one for instruments. This means he has both hands free for working with surgical instruments. The reason he can eliminate the channel for the endoilluminator is the high-end optics and the unique illumination concept of the Leica M844 F40 surgical microscope.



Dr. Cappuccini, how did the idea of the bi-manual technique for vitreoretinal surgery originate?

When we put the new Leica M844 F40 into operation and I tried out the microscope together with Carlo Spizuoco, Leica Application Manager, we were immediately impressed by the outstanding optics and illumination technology. We saw that the Leica M844 F40 provided a good view of the ocular fundus without using an endoilluminator. That gave us the idea of doing without the incision for the illuminator altogether during surgery. After a few trials, we found that it worked – very well, in fact. Not having to control the endoilluminator with one hand means that I now have both hands free for surgical instruments. The key technical prerequisite for doing without the light channel and therefore using the two-handed surgical method is the illumination concept of the Leica M844 F40. The direct halogen illumination in conjunction with the integrated OttoFlex™ II auxiliary light delivers sharply defined and highly contrasted images of the retina and ensures excellent light conditions in the entire surgical site, including the periphery. Within the main visual field I can vary the diameter of the OttoFlex™ II illumination field in a sterile fashion from 4 to 35 millimeters to get extra light exactly where I need it.

Using the Leica M844 F40, I have substantially improved the way I perform demanding surgery on the back of the eye. It's not only easier for me as a surgeon to do the complex operation successfully, the patient benefits as well. This microscope is a successful example of what doctors and users expect of industrial partners like Leica Microsystems: ongoing further development of imaging technology and practical handling combined with optimal applicational flexibility.

What are the benefits of your surgical technique for your patients and for you as a surgeon?

Having both hands free for doing the surgery, I can handle the instruments more easily and therefore operate more quickly. Shorter operations mean that we save time. But the benefits for patients are much more important. Having two sclerotomies instead of three incisions in the sclera accelerates eye recovery and causes fewer postoperative problems. Reducing the number of incisions also reduces the risk of sepsis during surgery.

For what indications is the bi-manual technique a particular advantage?

The technique is especially useful for treating proliferative membrane growth, macular holes, and diabetic macular edema. I have also had excellent experience using this technique for retinopathy of



Fig. 2: Dr. Cappuccini, Director of Ophthalmology at Reggio Emilia Hospital in Italy (third from left) leads a qualified team. Besides Dr. Cappuccini, three other surgeons do vitreoretinal surgery. In total, more than 15 ophthalmologists, six orthoptists, 25 nurses, and two secretaries work in the Ophthalmology Department of Reggio Emilia Hospital, where about 500 vitreoretinal operations are performed every year. Reggio Emilia Hospital is one of the few places in Northern Italy that specialize in vitreoretinal surgery.

Leica M844 F40 with OttoFlex™ and APO OptiChrome™

The premium class Leica M844 F40 with its exclusive direct illumination system offers the best clarity, contrast, and color at safer low-light levels for the patient, and provides fatigue-free viewing for the surgeon. With two bulbs and two prisms, the Leica M844 creates true three-dimensional illumination. Using a focused, direct illumination system instead of fiber optics, the Leica M844 takes a ray of light and projects a crisp, sharp, and homogeneous image even at very low light levels.

OttoFlex™ II, an integrated independent illumination system, gives a brilliant red reflex even in low light conditions and

enhances the view's contrast. Difficult anatomical conditions are more easily visualized by this unique system. Continuously adjustable from 4 mm to 35 mm diameter, OttoFlex™ II puts the brightness where the surgeon needs it most.

The Leica APO OptiChrome™ provides an extraordinary degree of light transmission for maximum detail recognition, which is critical for all types of ophthalmic microsurgery. For the limited available light in posterior segment surgery, a high degree of light transmission is essential. For refractive and anterior segment surgery, low light is always better for the patient.

prematurity (ROP), where there is a proliferation of abnormal vessels in the retina. A mild version of ROP is relatively common, although the severe form is extremely rare. However, babies born before the 32nd week of pregnancy, babies with a birth weight below 1,500 grams or babies requiring artificial respiration for longer than three days are particularly at risk. Severe stages can lead to scarring, myopia or blindness due to retina detachment.

Particularly for severe cases of ROP with retina detachment, in which laser coagulation is not sufficient, the two-handed technique was helpful for dissecting the retina quickly and without any incidents. When we operate on preterm babies, we naturally try to keep the duration of the surgery as short as possible to minimize the strain on the not yet fully developed organ. This is where the benefits of the new technique for added patient safety are particularly apparent.

Do surgeons need extra training for this technique?

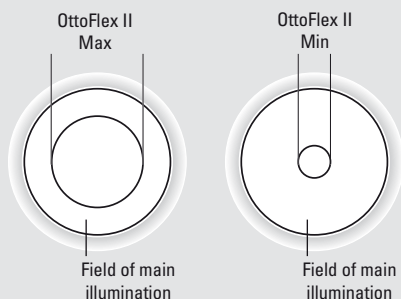
Any operation on the retina demands a lot of experience and a delicate touch, and the handling of the OttoFlex™ II requires particular practice. It is important to develop a feeling for the light conditions at different diameters of the auxiliary illumination to ultimately achieve an optimal image of the retina. A good exercise for confident mastery of the Leica M844 F40's illumination technology is the use of vitrectomy lenses. This additional lens is placed on the cornea if necessary to provide a panoramic view of the ocular fundus during surgery. This exercise can be done before starting a cataract operation, for example.

Has your new technique caused a stir amongst your colleagues?

My colleagues have already heard about my new way of operating. Many ophthalmologists approach me and want to know more about it. I am naturally very pleased that other specialists have heard about my technique. I'm coming in contact with new people interested in it all the time, and we often invite ophthalmologists to watch my operations and discuss the technique with me in detail.

Contact

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Neuronavigation Integrates Leica Surgical Microscopes

GPS for the Brain

Kerstin Pingel, Leica Microsystems



One of the challenges of neurosurgery is orientation at the surgical site. While treating cancers of the brain, surgeons often have to operate through healthy and functional tissue. The challenge is always trying to spare as much healthy tissue as possible, while removing as much of the tumor as possible. Neuronavigation technology facilitates both the planning and intraoperative orientation. The BRAINLAB AG company headquartered in Munich is one of the market leaders in the field of image-guided technology and became a pioneer in the market with the integration of its IGS software with Leica Microsystems' surgical microscopes. Since then, all leading providers of IGS have integrated their software with surgical microscopes from Leica Microsystems.

At the base of the human skull there is a particularly high concentration of vital structures: blood vessels; nerves; centers for hormonal control of bodily functions; and centers for regulating breathing, blood pressure, and heart activity. Brain tissue cannot regenerate itself, so even the smallest injury can cause irreversible, profound brain damage, leaving patients with a permanent handicap. This also makes the treatment of disease very difficult. Malignant gliomas, which account for 45 to 50% of all brain tumors, infiltrate into tissue as they grow. Even under a surgical microscope, peripheral tumor regions are hard to differentiate from healthy tissue.

Wide application potential

Neuronavigation is a non-invasive imaging method and is mainly used for neurosurgical applications such as tumor resection or the treatment of aneurysms. As neurosurgeons do most of their work at the microscope, BRAINLAB has integrated the surgical microscope with the navigation, which enhances the microscope's functionality.

Exact localization of brain structures

Neuronavigation works like a GPS system, enabling exact position tracking in the patient's anatomy. Before surgery, reference point markers are adhered to the patient's scalp, and MRI and CT scans are performed. The surgeon can pre-mark the tumor, the endangered areas, and the best access route to the tumor in these images and use it in the operating room as a digital treatment plan.

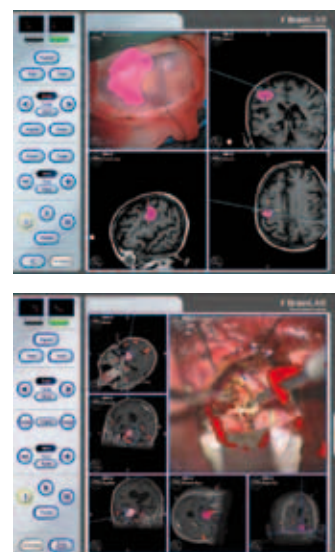
In the operation theater, a system consisting of two infrared cameras is directed at the surgical site. All instruments, including the surgical microscope, bear reflecting spherical markers. A reference star is attached to the patient's head clamp to mark the

position of the patient for the system. On the basis of infrared signals transmitted by the cameras, which are reflected back to the cameras from the markers, the positions of the instruments and the patient are localized and visualized for the camera or navigation system. Then the patient data prepared before surgery is loaded into the navigation system and reconstructed into 3D images on the monitor or image injection display. This gives the surgeon a continuous, real-time view of the exact position of the instruments in the brain structures on the preoperative anatomic data.

Enhancing the microscope's functionality

The integration of the microscope with the navigation system significantly increases its functionality. With the Smart Auto-Focus, each navigated instrument can be focused, even outside of the image center. If a surgical instrument is not in the center of the microscope's field of view, the Smart Auto-Tracking feature moves the microscope head to the correct x and y position until the instrument is seen in the field of view. All image information can be shown in the image-injection display, which enables the surgeon to overlay the navigation image onto the visual field of the microscope ocular.

The surgeon can then switch between two images, without interrupting the view through the microscope: When the image injection is activated, a computer generated transparent image is injected to the microscope's field of view which allows the surgeon to see the focused region as well as the injected information. When activating the closed shutter mode, the ocular view closes. The surgeon can now see e.g. MR images in the ocular. "This is less tiring for the eyes because the eyes don't have to keep adjusting. It also saves time," explains Valentin Elefteriu, project engineer at BRAINLAB.



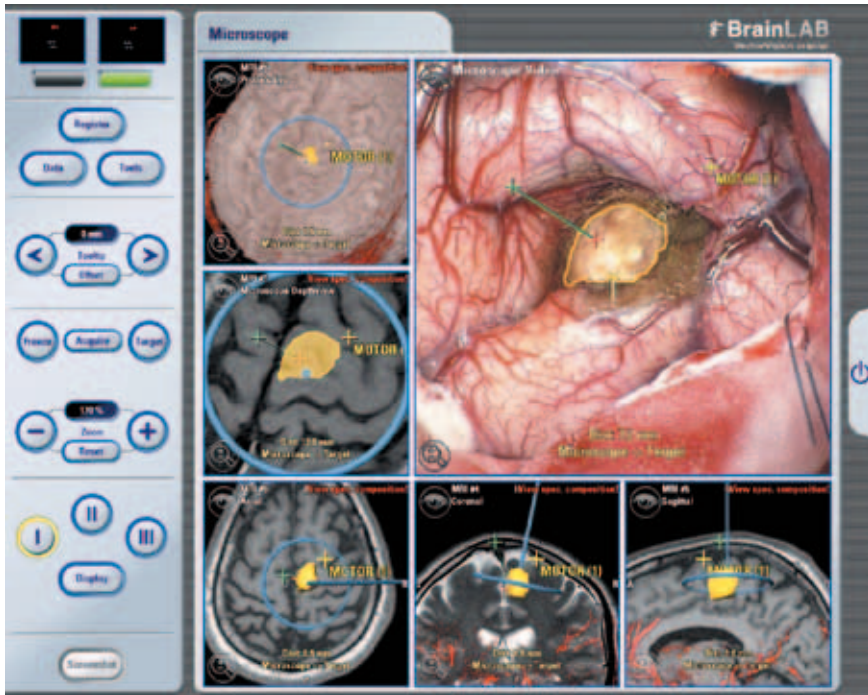


Fig. 1: Brainlab's cranial navigation software shows the exact position of the microscope's focal point and field of view in the brain structures on the preoperative data in different views. Planned objects, trajectories and labeled points can be displayed in all views and overlaid onto the microscope video.

The Depthview feature also provides a continuous comparison of the real image and the preoperative data. Depthview shows the image level seen through the surgical microscope as a reconstruction in the anatomic images, which helps surgeons orientate themselves during surgery. "BRAINLAB provides us with improved imaging possibilities and control of the microscope," says Prof. Dr. Kai-Michael Scheufler, neurosurgery consultant at Hirslanden hospital in Switzerland. "By integrating real-time navigation with the field of view of the ocular, we can stay focused on the surgical task with more precision. Also, surgical procedures are enhanced because all of the relevant information can be remote controlled. This allows a fluid workflow while delivering the most advanced imaging possibilities at the touch of a button." Prof. Scheufler uses BRAINLAB neuronavigation with the Leica M525 OH4 surgical microscope.

Taking the guesswork out of tumor resection

Every neurosurgical procedure demands a vast amount of surgeon experience, patience and competence. Although neuronavigation does not replace surgical skill, it effectively supports the surgeon in planning and performing a procedure and gives more precise information.

"The integration of the microscope with neuronavigation helps the surgeon to accurately identify questionable areas," explains Elefteriu. "For example, if he or she focuses on the edge of a tumor and can't tell exactly where the tumor tissue ends, a look at the pre-planned anatomic data with microscope image overlay shows whether the focused area is part of the tumor or not." Precise planning can also minimize head shaving, skin incisions, and bone flap sawing and thus reduce stress for the patient.

Contact

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Leading providers of IGS

Companies that have integrated their software with Leica Microsystems surgical microscopes:

BRAINLAB AG
 Munich, Germany
www.brainlab.com

Medtronic
 Minneapolis/MN, USA
www.medtronic.com
 for Europe: Tolochenaz,
 Switzerland
www.medtronic.eu

Stryker
 Kalamazoo/MI, USA
www.stryker.com

Radionics
 Burlington/MA, USA
www.radionics.com

Precise Quality Control of Microsurgical Instruments

Check Each Product as if it Will be Used to Operate on You

Anja Schué, Leica Microsystems

Vitreoretinal surgery demands experienced surgeons and precision technology. The surgeon operates with microscissors and forceps that are less than a millimeter thick. Swiss company Alcon Grieshaber is one of the world's leading specialists in the design and manufacture of hand-held microinstruments for minimally invasive eye surgery. Stereomicroscopes from Leica Microsystems are used to support the R&D and manufacturing of these instruments from all stages of development to final inspection.

The retina has 130 million sensory cells for capturing an image of the world around us. If they are damaged and die, our eyes lose their vision. Losing our eyesight is a terrible thought, but for most of us it is just as frightening to imagine an operation on our eyes. There are many causes for retinal damage or detachment or yellow spot (macula), and without an operation there is great danger of going blind. Statistically speaking, one in 10,000 people is affected. Thanks to modern eye surgery, however, the chances of fully restoring the patient's eyesight are excellent if the problem is diagnosed early enough.

Scissors or forceps – hard to tell with the naked eye

Alcon Grieshaber AG in Schaffhausen, owned by Alcon, Inc., the world's leading eye care company has played a major role in advancing minimally invasive retinal surgery and its handheld precision instruments still lead this market segment today.

“Our technological lead cannot be seen by the naked eye, it is microscopic.”

The company has promoted the switchover to single-use instruments worldwide and perfected the instruments for minute dimensions. The tiny tools – scissors, forceps, hooks, knives, fluid handling instruments – fit through an incision smaller than a millimeter wide, the smallest of them measuring a mere 0.5 millimeter when closed. “Our technological lead cannot be seen by the naked eye, it is microscopic,” Jürg Attinger, Manager of Alcon Grieshaber AG, describes his precision instruments.

Microscopes at all workplaces – from incoming inspection to final cleaning

At Alcon Grieshaber, quality control begins before the products are even made. Even semi-finished goods that are turned, milled and EDMed are measured under the microscope. “We have found an optimal inspection frequency solution that considers time, cost and risk, and luckily, we have an extremely small reject rate”, explains Heinz Etter, Head of Facility Management at Alcon Grieshaber. “All components are checked after two to three production steps at the latest throughout the entire production process. At the end there is always a 100% inspection. No instrument leaves the factory without thorough examination under the microscope.” Almost all the employees work with a microscope – in inspection of incoming material, in production and quality control through to final cleaning and inspection of the finished product in the cleanroom as well as in R&D. There are 118 stereomicroscopes and 140 employees – although it is mainly the 65 members of production staff that use them.

The manufacture of microinstruments for eye surgery demands a great deal of precision work – skill, experience, a trained eye and a good portion of perfectionism. Most quality inspection tests are carried out at 20x magnification. Higher magnification would tend to have the effect that even the smallest details that do not impair product quality would be interpreted as defects. In production, higher magnifications are required, mostly 60x.

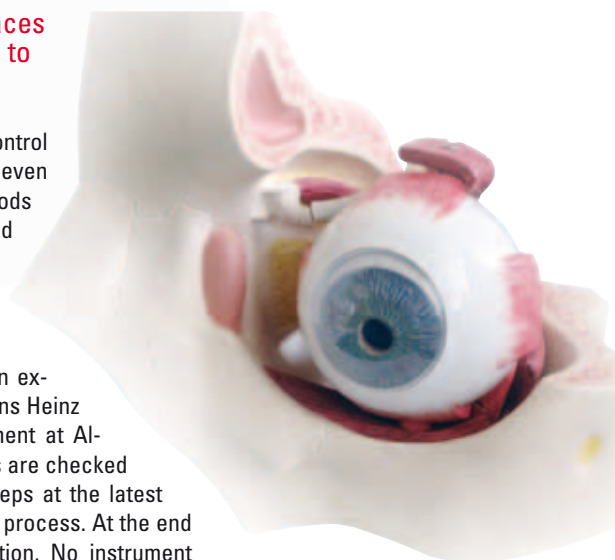


Fig. 1: Surgery in the posterior segment of the eye may be standard practice in ophthalmology today, but it is not easy to perform. It demands sensitivity and experience as well as complex technology – from the surgical microscope to the microinstruments directly applied by the surgeon at the site of the retina or macula requiring treatment. Retina surgery is only possible using a surgical microscope, and three incisions have to be made to access the posterior segment: one for illumination, one for the instrument and one for the infusion to stabilize inner eye pressure. (Copyright Roman Milert - Fotolia)

The trained eye is unbeatable

Besides the quantitative analysis facilities for 2D measurements offered by the microscope and appropriate software, and traditional mechanical measurements, visual inspection is indispensable. For example, microscissors have three-dimensional free form surfaces with a dimension of only 0.5 millimeter. The part for inspection is compared with a reference sample under the microscope. "For this application, there is no other technique to date that can compete with the eye of an experienced employee – particularly in terms of time and cost, stresses Etter."

The quality motto at Alcon Grieshaber: "Check each product as if it were to be used to operate on you."

"Inspecting surface roughness with a 3D scan or profilometry would be far too costly and time-consuming for us. Despite all the potential risks of visual control, experienced employees are unbeatable." One example: One of the instruments is made from a wire 0.14 mm thick with a tolerance of 0.01 mm. The staff are trained to tell whether the tolerance has been adhered to just by holding the thread under the stereomicroscope without a comparison sample.

"The true challenges in our quality control begin

where the criteria start to soften, where reference samples or photos are called for," says Attinger. "We can and do have a lot of confidence in our staff. We recover the 'discretion' quality we lose by good training. And so far we have been successful – despite the fact that we make our products in expensive Switzerland and even make single-use instruments."

Optically brilliant and cost-saving stereomicroscopes

When it comes to microscopy, Alcon Grieshaber trusts in the stereomicroscopes of Leica Microsystems. Besides the optical quality, the Schaffhausen specialists appreciate the LED illumination, the easy and convenient operation, the ergonomic design and the large field of view, especially the 23 mm field of view offered by the new generation of Leica M80 and M50. The Leica M205 with FusionOptics™ additionally provides the excellent depth of field and high resolution that are specifically useful for R&D applications. Nearly all microscopes at Alcon Grieshaber are equipped with LED illumination. 20,000 kWh a year have already been saved with this energy-saving light source. The company also saves because of the much longer lifetimes of LEDs compared with conventional microscope lamps.

Ergonomics for all



Figs. 2: The hand-held precision instruments of Alcon Grieshaber that are used for the various steps of an eye operation have a worldwide reputation of excellence. Depending on the surgical technique employed by the surgeon or the exact reason for surgery, he needs instruments that fit through an incision of 1.15, 0.72 or 0.62 mm to access the inner eye. That is equivalent

to an instrument diameter of 0.9 (20-Gauge), 0.6 (23-Gauge) or 0.5 mm (25-Gauge). The surgeon does not open the scissors or forceps until they have been introduced into the eye. The instruments are freely rotatable. When performing surgery, the surgeon just has to correct the pressure angle. The trend towards smaller incisions has the key advantage that the smallest incisions heal

by themselves without suturing. For the instruments, miniaturization means more and more sophisticated manufacturing techniques and materials and the fact that only single-use instruments can be effectively utilized. Even the smallest damage that is inevitably entailed in a conventional sterilization process renders the microinstruments useless.

Videos and information on surgical techniques in vitrectomy:

<http://www.alconretina.com/surgicalTechniques.asp>

Many employees at Alcon Grieshaber spend eight hours at the microscope every day. Alcon Grieshaber is one of the pioneers in ergonomics within the Alcon, Inc. Ergonomic chairs, height-adjustable desks, elbowrests to take strain off the shoulders are all automatically provided.

The company also places great value on individually adjusted, ergonomic microscopes and uses Ergo tubes and eyepieces that are matched to different body sizes and physiques.

The fact that Leica Microsystems offers the widest range of ergonomic accessories for stereomicroscopes is one of the main reasons for Alcon Grieshaber's long-standing loyalty to Leica Microsystems' products.

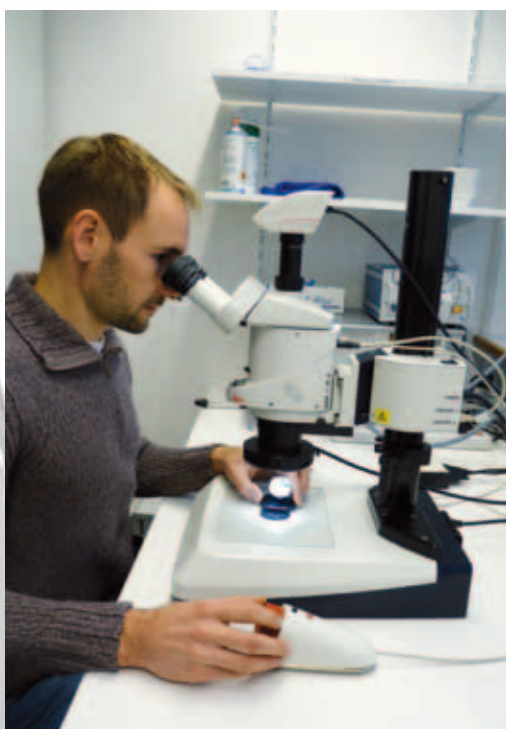
Periodically, a specialist from the parent company, Alcon, Inc., comes to Schaffhausen to check site ergonomics and give the staff advice if necessary. But that's not all: "We offer every member of staff a weekly 30-minute shoulder and back massage. The cost is shared by the company and the staff," says Attinger. "If our staff feel good at the workplace and the microscope, they are more efficient, too. And that is ultimately good for our overall result. We carry a great responsibility for our staff, after all we depend on them for our success."

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Fig. 3: Like nearly all the employees, Jürg Attinger, Manager of Alcon Grieshaber, has a stereomicroscope at his workplace.



Figs. 4 – 5: Alcon Grieshaber attaches great importance to individual ergonomic features of the microscope and the workplace.

A Founder of Modern Surgery

Wilhelm Fabry – Surgeon, Inventor, and Publicist



Janika Wiesner, Leica Microsystems



Fig. 1: Oil painting of Wilhelm Fabry, ca. 1620, attributed to Bartholomäus Sarburgh

Before academic education for medical practitioners became the norm, barber-surgeons treated wounds and performed minor operations as members of the tradesmen's guild as late as the end of the 16th century. The surgeon Wilhelm Fabry, born in Hilden in 1560, Germany, was not content with this classification of his profession, however. With a thirst for life-long learning, meticulous observation, and continual involvement with the medical sciences, he advanced from being a barber's apprentice in Neuss to Surgeon of the City of Berne. Throughout his medical career he published a description of 600 cases in German and Latin, including methods of treatment. He also developed various progressive surgical techniques and instruments. All his life, Wilhelm Fabry campaigned for more importance to be ascribed to the knowledge of anatomy in surgery. For all these reasons he is considered one of the founders of modern surgery. The town of Hilden now celebrates the 450th birthday of its famous son with over 140 events and projects.



Fig. 2: Copperplate engraving from the French edition of "Observationes" of 1641 according to Matthaeus Merian 1627

Significance of anatomy

"Fabry's enthusiasm for anatomy may have been triggered by his survival of the plague as a child," reports Dr. Wolfgang Antweiler, Head of the Wilhelm Fabry Museum in Hilden. After his apprenticeship as a barber, the former grammar school pupil worked as an assistant for highly reputed court surgeon Cosmas Slot in Düsseldorf. "There he acquired the necessary knowledge of human anatomy. Fabry adopted Slot's conviction that all surgery should be based on a thorough knowledge of anatomy," recounts Antweiler.

After the death of his master, Fabry moved to Geneva, as the French-speaking part of Switzerland had a reputation at that time for the number of outstanding physicians working there. Geneva was also the place where he met his wife, Marie Colinet, who he married in 1587. Marie Colinet helped her husband treat patients. "She herself developed the method of extracting metal from a patient's eye with a magnet. She also helped women with particularly difficult births," says Antweiler. Fabry practiced from 1602 to 1615 as a surgeon in the towns of Payerne and Lausanne. The climax of his career was his appointment as Surgeon of the City of Berne in 1615, a position he held until his death in 1634.

Progressive methods of surgery

Wilhelm Fabry's progressive mind perpetually drove him in his search for new knowledge. "He was a highly educated person who was interested in religious topics and the ancient world," reports Antweiler. "He traveled a great deal and corresponded regularly with physicians and theologians. It was always his endeavor to see more and know more." The complete edition of his medical publications, entitled "opera quae extant omnia," printed posthumously in 1646, contained 600 case studies with descriptions of the methods used to treat them. The work was referenced by physicians for over 150 years. He also made a valuable contribution to the development of surgical techniques. "Many of Fabry's surgical techniques are still used in a relatively similar form today," says Dr. Hans Bayer-Helms, Medical Director of Trauma Surgery at St. Josef's Hospital in Hilden. "Fabry lived at the time of the Thirty Years' War. Amputations due to comminuted fractures were the order of the day. To stop bleeding from blood vessels, he used a red-hot iron. Nowadays vessels are closed by heat induced by electricity. For gangrene amputations, Fabry introduced the ground-breaking method of operating on a healthy area and pulling the skin during surgery to enable proper closure of the stump afterward."

Time of fundamental change

Wilhelm Fabry's 450th birthday is being celebrated on June 25, 2010. A wide variety of events and projects – 140 altogether – commemorate the famous son of Hilden until the end of 2010. Antweiler says, "We have compiled a program of events that have a connection to Fabry, to medicine or to his era. Fabry lived in a time of fundamental change. His contemporaries included Galileo Galilei, René Descartes, and Hans Jakob Christoffel von Grimmelshausen." So there should be something for every interest in the many exhibitions, readings, concerts, and plays. There is a particularly wide range of lectures held by speakers from all over Germany and Switzerland, ranging from Wilhelm Fabry's relationship with constipation through the history of venereal diseases to the lecture, "Surgery Through the Ages – From Wound Healers to Modern Trauma Surgery."

Contact

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Fig. 3: Dr. Wolfgang Antweiler, Head of the Wilhelm Fabry Museum, Hilden



Fig. 4: Orthopedic instrument



Fig. 5: Lifting of a depressed skull



Fig. 6: Patient with eye tumor (was successfully removed)



Fig. 7 – 8: Preparing a patient for amputation of the lower leg. An assistant holds the patient, who is conscious. The amputation saw rests on the floor and herbs (stinging nettles) are heated in a pot to cauterize the stump. While the surgeon removes the limb, the patient, held by assistants, prays and is on the verge of losing consciousness.

Surgery Through the Ages



During the lecture "Surgery Through the Ages – From Wound Healers to Modern Trauma Surgery" on December 2, 2010, Dr. Hans Bayer-Helms, Medical Director (left), and Dr. Peter Heck, Senior Consultant of Trauma Surgery at St. Josef's Hospital in Hilden, will take the audience on a journey through the history of surgery.

"We address the issue of what Fabry and his colleagues got right in those days through intuition, despite not having the relevant knowledge at the time," reports Bayer-Helms. "Fabry's thorough observations give us a good idea of the methods surgeons used to treat various diseases and injuries 450 years ago."

US: Transfer High-quality HD Video of Surgical Cases Directly to an Apple® iPhone or iPod touch

New Surgical Video App

Leica Microsystems, in partnership with Med X Change, has unveiled a new Apple® app called Med X Mobile. This unique application, only available from Leica Microsystems, enables surgeons to wirelessly transfer HD video and still images of surgical cases directly from a Leica Microsystems surgical microscope to an Apple® iPhone or iPod touch in a matter of seconds. There is no need to connect to a personal computer.



“This new technology offers surgeons and OR staff yet another method to transport, view, and share critical surgical videos/images with colleagues, associates, and patient families immediately after a surgical procedure,” says Seth Kardos, Vice President, Business Development, Med X Change. “Our new software was designed to complement and bridge today’s latest mobile technologies into the operating room”. The Med X Change 2nd Generation HDMD™ custom digital recording system with Blu-ray Disc Technology provides HD video recording and still image capture. Leica Microsystems is the only company

to offer a compact, high definition, integrated recording system for surgical microscope applications. Leica Microsystems launched Med X Mobile at the 2010 AANS Annual Meeting, May 2010, in Philadelphia, Pennsylvania. At first the new app will be available only in the US.

Med X Mobile is available at the AppleApp Store:
<http://itunes.apple.com/gb/app/med-x-mobile/id367806603?mt=8>

Europe: Cooperation With KaVo Dental

Entering the Dental Market

Leica Microsystems has forged a strategic partnership with KaVo Dental GmbH, a leading international dental company, for marketing and development of dental microscopes in Europe. In the first stage of this partnership, KaVo will launch the marketing of the Leica M320 F12 and the Leica HM500 Headmounted Microscope in ten European countries. For Leica Microsystems, the cooperation with KaVo marks the entry into a new market segment for its surgical microscopes. The goal of this strategic alliance is to provide the modern dentist with state-of-the-art microscopy systems of the highest quality from a single dental products supplier. The potential to integrate a dental microscope into an existing treatment unit and thus to optimize the workflow is of particular added value to the dentist.



KaVo. Dental Excellence.

“The technology of the Leica HM500 system allows us to achieve perfect treatment results with much less stress and physical exertion,” is the verdict of Dr. Del Gregory, Doctor of Dental Surgery, Macon, USA. Dr. Stefan Hänni from Bern, Switzerland summarized his experience with the Leica M320 F12 as follows: “In addition to the ease of operation and

ergonomics of the system, the high-quality optics, the excellent illumination of the operating field, and the integrated photography and video equipment have completely won me over. The Leica M320 F12 can be recommended with no reservations to both beginners and advanced users.”

Leica M320 F12 for ENT and Dental Applications

The New Dimension of Vision

High performance combined with ergonomic operation and sophisticated esthetic and functional design – even at first glance, the new Leica M320 F12 is unique compared to other ENT and dental microscopes. For the first time, the microscope’s optics are combined with an LED illumination. The result are absolutely crisp, clear, and bright images with amazing depth of field.

Daylight-temperature LEDs provide high fidelity image colors. With an operational product life of 60,000 hours, the cost of operation is low. LEDs have no start-up delay: when switched on, they instantly deliver full light output. In addressing the requirements of surgeons, Leica Microsystems also focused on ease of use and maneuverability. With sophisticated engineering and a vibration-minimized bearing, the microscope can be effortlessly positioned anywhere.

The Leica M320 F12 can be optionally equipped with Leica Microsystems’ HD image technology. The video and still cameras are fully integrated with the microscope and provide high quality images that can be displayed on an HD monitor or saved onto an SD memory card. Thus, surgeons can explore entirely new documentation, presentation, and consultation opportunities. The Leica M320 F12 is virtually jointless, which makes it resistant to contaminants and easy to clean. All cables are internally routed. The surface is protected with a permanent antimicrobial coating AgProtect™.

The Leica M320 F12 has been extremely well received in the market. “Customers are impressed by the intelligent design and the efficiency of the LED illumination,” reports Product Manager Andreas Tedde. “They also appreciate the fact that the Leica M320 F12 offers top quality for an affordable price.”



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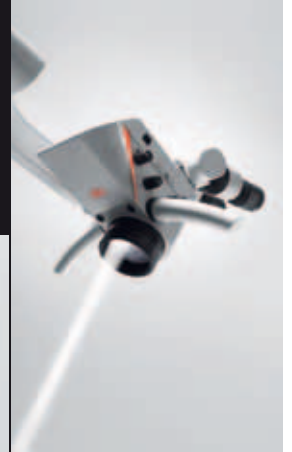
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