iOCT® Applications
Surgeons’ experiences with the new technology

Tradition and Innovation – Since 1858, visionary thinking and a fascination with technology have guided us to develop innovative products of outstanding reliability. Anticipating trends to improve the quality of life.
As technology and experience with intraoperative OCT improves so does the product introduced by HAAG-STREIT SURGICAL. Innovations are included that ease handling and simplify the surgical workflow with the iOCT. A few of them at a glance are:

**Binocular image injection – C.INJECT 900**

Real-time binocular image injection of the processed live OCT image straight into your eyepiece guarantees distraction-free work in full compliance with your natural, visual perception. Moreover, it prevents drawing your attention away from the surgical field and permits fatigue-proof work throughout your whole day.

**Synchronized recording with picture-in-picture (PiP) – M.REC 2**

The combination between HS MIOS 5 and M.REC 2 evolved towards an innovative solution for synchronized recording of video streams. Using our new M.REC 2 software, both the microscope camera and the live iOCT image sequence can be recorded in parallel, providing two independent full HD video streams. To not miss particularly interesting moments throughout your surgery, high-resolution snapshots can be created additionally at any point in time. A very flexible system offering various picture-in-picture configurations facilitates your personal visualization preferences both during surgery as well as during post-operative assessment.

**Workflow inspired user interfaces and operation**

iOCT, together with the operating microscope HS Hi-R NEO 900A NIR, features ergonomic integration of OCT control into your foot-switch-centered workflow. To meet the user experience of established HAAG-STREIT SURGICAL microscopes, the actual assignment of iOCT functionality to foot switch controls is highly customizable through user profiles. Additionally, the concept of “per-user customization” is carried far beyond simple foot-switch-control mappings offering seamless saving of comprehensive sets of OCT/microscope configurations.

From its introduction of the iOCT® in 2012 until today, the HAAG-STREIT SURGICAL product displays some outstanding features that show its perfect integration into the surgical workflow. Those include:

- Intuitive operation, as the iOCT is focused on the same plane as the microscope
- Fast correlation of structures to the microscope view as the iOCT scan width equals the field of view
- Detailed depth information to up to 4.2 mm in depth with high resolution

Features and benefits

**iOCT® – Discover a new dimension by HAAG-STREIT**
iOCT®
The operating system

Display and settings at your fingertip

Fully synchronized recording

Display and settings at your fingertip

Binocular picture-in-picture image injection

Seamless iOCT foot switch integration for e.g. volume scans
Experiences with intraoperative OCT

Physicians all over the world have used our intraoperative OCT system since 2012 and generated generous positive feedback that has led to relevant improvements. Read the users’ assessments reprinted in this 2nd edition of the iOCT Application booklet and gain valuable insights into the iOCT.

For more information, HAAG-STREIT SURGICAL has proudly developed an Internet web application to summarize many iOCT videos, 3D scans and picture-in-picture superimpositions, which can be accessed from the website iOCT Atlas (www.iOCT-Atlas.com). Please register free of charge and participate in HAAG-STREIT SURGICAL’s new world of iOCT.

» With everything we do, we pursue the improvement of health. We are extremely proud to have such an innovative and future-oriented product in our portfolio that supports surgeons in performing better patient care: The very first iOCT fully integrated into a surgical microscope! «

JOACHIM GERIKE
PRESIDENT
HAAG-STREIT SURGICAL GMBH
# Ophthalmology

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# Neuro

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How was the iOCT system by HAAG-STREIT SURGICAL brought to your attention?

I saw the iOCT system for the first time in 2012 at an ESASO meeting in Lugano where I lectured and afterwards regularly at AAO and our national NOG meeting.

For which application are you using the system?

We use the system primarily for endothelial keratoplasty surgery to determine whether the posterior lamella is attached. iOCT gives you unprecedented accuracy to determine whether the endothelial lamella is attached in all regions of the cornea. We also use the technology for research purposes to investigate metabolic hydration activity of precut endothelial grafts in the process of organ culture storage for transportation and implantation. Unfortunately, we were not able to use the system for DALK surgery since we would have to move the microscope from our ASC (only local anesthesia available) to our central surgery complex where we have access to general anesthesia. In DALK, the system might give you more secure information as to whether you have reached Descemet’s membrane by the big bubble technique. The ultimate idea, of course, is intracorneal OCT guidance to reach the effective dissection plane.

What were your expectations for the iOCT system?

The expectations were that we could visualize in real time the different layers of recipient cornea and endothelial graft during the surgical process.

For how long have you been using the iOCT camera and how often do you use the camera each week?

It is quite easy to learn how to operate the system, so we have actively used it now every week for several months for corneal transplantations.

Please describe your planned study:

1. Repeatability, reproducibility, and agreement of intraoperative spectral domain anterior segment OCT and standard spectral domain and fourier domain anterior segment OCT:

The limits of agreement between standard spectral domain (Visante: Zeiss), fourier domain (Casia SS-1000: Tomey), OCT and intraoperative OCT (HAAG-STREIT SURGICAL) have not yet been investigated. The current study sets out to examine the repeatability, reproducibility, and agreement between above devices in patients undergoing (FS) cataract surgery. The following parameters will be evaluated pre-, intra-, and postoperatively: central and peripheral corneal thickness, pachymetry map, anterior and posterior corneal curvature, anterior chamber depth, anterior chamber angle, and lens thickness.

2. Effective lens position (ELP) determination using intraoperative spectral domain anterior segment optical coherence tomography (iOCT):

Accurate ELP determination is of key importance when attempting to achieve emmetropia following cataract surgery. This is particularly challenging in eyes with high myopia, hyperopia, or pigment dispersion syndrome, and following refractive surgery. Classical 2-variable calculation formulae (SRK/T, Holladay 1 and Hoffer Q) use the keratometry value and axial length to determine ELP but have been shown to be less accurate in extreme cases. Newer formulae, including Haigis 2 and Holladay 2, use seven input variables including anterior chamber depth and lens thickness, allowing more accurate ELP estimation in extreme cases. In the current study, we set out to compare estimated ELP calculation using above formulae (IOL Master: Zeiss) with actual ELP measured by iOCT in an attempt to optimize refractive outcomes following cataract surgery.
3. Optimization of a novel intraocular capsular ring for the prevention of posterior capsular opacification using intraoperative spectral domain OCT.

Posterior capsular opacification remains the most common cause of visual failure following successful cataract surgery. PCO is caused by migration and proliferation of residual lens epithelial cells (LECs) onto the central region of the posterior capsule. Recently, a novel capsular ring has been developed aimed at keeping the posterior capsule open, allowing fluid movement especially in the equator of the bag and blocking cell migration from the equator. In the current study, we set out to examine if intraoperative OCT can assist visualization and ELP determination during implantation of this novel capsular ring, thereby optimizing the procedure.

All the data has been collected. It is being analyzed and prepared for publication at the moment.

**Did you change your surgical procedure due to the iOCT technology? If yes, how?**
Yes, I did. I now have the ultimate verification as to whether the endothelial graft is attached intraoperatively. This information was not available before iOCT.

**Who is handling the device?**
Intraoperative usage is performed by the surgeon. Operation via the foot switch is easy and fast to do.

**Please describe the workflow and the data collection.**
I was impressed at how quickly HAAG-STREIT SURGICAL was able to do adaptations to the system. With the iOCT images injected into the ocular, the surgical workflow is fastened and the HD quality injected into both eyes provides all the information needed. I’m able to do synchronized snapshots of the live view and the iOCT image at just the right point in time. Collecting the data is done via one recording system: it’s simple, intuitive and fast.

**What is the greatest benefit of the iOCT?**
Better verification of endothelial graft attachment.

**Do you see further potential of the system in fields you have not yet used it in?**
Many: CXL, ICR implantation, intracorneal contact lenses. Also, implementation in robotic surgery and 3D surgery in the future.
Optical coherence tomography (OCT) has become an essential tool for evaluating patients with vitreoretinal disease since its introduction by Dr. David Huang in 1991. OCT non-destructively images posterior segment anatomy in-vivo with sub ten micron axial resolution by measuring a time of flight delay of optical B-scan reflections. It has become standard of care for the management of a wide variety of vitreoretinal diseases including both wet and dry age-related macular degeneration (ARMD), retinal arterial and veno-occlusive diseases, vitreo-macular traction syndrome, epiretinal membrane (ERM), macular hole, cystoid macular edema (CME), diabetic macular edema (DME), proliferative diabetic retinopathy, posterior hyloidal traction syndrome, myopic degeneration, retinal detachment, and many others. Many of these diseases are amenable to attempted anatomical and visual rehabilitation with vitreoretinal surgical techniques and OCT is instrumental in the pre- and postoperative assessment of these patients. If we use OCT before and after surgery the natural question arises of whether intraoperative OCT (iOCT) can be useful during vitreoretinal surgery. The purpose of this report is to describe the functionality of the HAAG-STREIT iOCT system, its integration with the surgical microscope, and some initial first impressions on how this new technology specifically may relate to the management of patients with vitreoretinal disease.

A clinical case perhaps best illustrates the versatility and utility of the iOCT. In this patient a full thickness macular hole has caused a rhegmatogenous retinal detachment. Visual acuity has been 20/400 for the past month. Both the macula involving detachment and the macular hole are evident clinically and are unequivocally confirmed by iOCT through the direct contact lens.

Under PFO, the macula is attached. Note the step off artifacts from the edge of the PFO bubble (figure 2-2).

After ILM peeling, the macular hole starts to reapproximate.

After air-fluid exchange, a small amount of subretinal fluid has accumulated under the macula that was not evident clinically. Note the back of the air bubble and a small amount of preretinal fluid which was also not evident clinically.

After carefully drying the macula with a soft tip cannula, the sub-sensory fluid is gone and the macular hole is closed. iOCT imaging provided a precise endpoint for aspiration with the soft tip. This was continued until the hole closed and all pre- and subretinal fluid had been removed.

This patient recovered 20/60 visual acuity and remained anatomically stable with a closed macular hole and attached retina for over one year of follow up. This clinical case beautifully illustrates the robustness of the HAAG-STREIT iOCT. Excellent images can be obtained through vitreous, BSS, heavy liquids,
as well as air and gas. These images inform surgical decision making in a useful way. iOCT imaging through silicone oil was not demonstrated in this case but is also possible and is equally useful. Intraoperative real time OCT assessment of posterior segment anatomy may be beneficial in macula involving retinal detachment repair, macular hole surgery, as well as surgery for patients with vitreo-macular traction syndrome and posterior hyaloidal traction syndrome.

Anterior segment iOCT may also be useful for the retinal surgeon. Here, iOCT of the pars plana immediately after trocar cannulas are removed clearly illustrates the rationale for beveled vitrectomy trocar cannula placement. In this image of the pars plana after the cannulas are removed, an open 25 gauge sclerotomy is present with a small conjunctival bleb.

Figure 2-5: iOCT image of an open 25 gauge sclerotomy with small conjunctival bleb after the removal of the cannulas.

This is in sharp contra distinction to this much more beveled sclerotomy which is closed and does not have an overlying conjunctival bleb. Intraoperative optical coherence tomography that is integrated into the operating microscope is a versatile and powerful imaging modality which holds a great deal of promise for the future.

The HAAG-STREIT iOCT in conjunction with the HAAG-STREIT HS Hi-R NEO 900A NIR microscope represent a superb first offering of this technology.
Interview

**iOCT® makes surgery safer and offers more**

**How was the iOCT system by HAAG-STREIT SURGICAL brought to your attention?**

I have long been cooperating with Dr. Lankenau from Luebeck. She approached me some years ago in connection with the study and also with HAAG-STREIT SURGICAL, which has led to a continued and fruitful collaboration.

**For which application are you using the system?**

I am using the system for different areas of the eye. Primarily for corneal and glaucoma surgery as well as examinations under anesthetic. Especially in keratoplasties, it is a lot easier to judge the connection between the donor’s graft and the patient’s tissue using the iOCT.

Additionally, I started with laser surgery on the cornea and use the iOCT to support my evaluations. Also, I have been doing some very interesting cases using the Boston Keratoprosthesis and ablating scarred cornea layers. The verification the iOCT provides me with in these cases is outstanding!

**Please describe your planned study:**

We are currently conducting five to six different studies. They are all based on the following question: For which clinical indications is intraoperative OCT relevant or even important? We are currently examining these with regard to corneal procedures, glaucoma procedures, and laser surgery procedures.

**Results from the DALK study:**

1. During DALK, all preparation steps are visualized, in particular trephination depth and the location of the injection needle in designated tissue planes.
2. Preparation of deep anterior lamellae until pure Descemet’s membrane is visualized and controlled.
3. In case of incomplete air bubble formation, upper “Micro-bubble incision technique” is applied and monitored by iOCT.
4. iOCT monitors and hereby assures full graft alignment with Descemet’s membrane.
5. Interface steps were also avoided in perforating keratoplasty according to the intraoperative OCT display.

**Results from the DMEK study:**

1. Intraoperative OCT enables the surgeon to monitor all steps of DMEK, including donor tissue preparation, by displaying high resolution images without the necessity of interrupting the procedure for image recording.
2. Donor grafts within the anterior chamber were reliably visualized, thus enabling precise membrane unfolding and correct orientation in all patients.
3. Rolling behavior of dissected Descemet’s membranes correlated inversely with donor age. Tissue from donors < 60 years of age demonstrated strongest inward rolling activity and upper “multilamellar-shape”. Donor tissues > 60 years feature less rolling activity and “open spiral-shape”.
4. Unfolding and attachment to the posterior surface of the recipient cornea was visualized and controlled by iOCT, thus allowing for a shortening of complete intraoperative air filling time and assurance of complete graft attachment at the end of the procedure.

**Do you see further potential of the system in fields you have not yet used it for?**

Yes, especially in the new fields of study such as glaucoma procedures and laser surgery, but also in examinations under
anesthesia of infants. In patients with corneal opacity or malformation, it is impossible or very difficult to see inside the eye to assess the inner cell layers. This is now possible with the help of iOCT.

Would you recommend the iOCT system?
Yes. From my understanding, it has already been proven that it will make surgery safer and offer more confidence.
For which purpose have you used the system?
Mainly for procedures like membrane peeling, macular hole, and macular pucker, as demonstrated at the Frankfurt Retina Meeting 2014. However, I have also used the system for phacoemulsification and phaco-vitrectomy as well as for the positioning of the IOL.

What were your experiences while operating with the iOCT?
The iOCT has taught me many things about performing surgery that I was unaware of before. For example, during phacoemulsification it is striking how frequently the lens pieces come into contact with the corneal endothelium during the segment removal. I have adapted my technique to avoid this and to make my surgery safer.

Did you find further changes to your surgical procedure due to the iOCT technology?
Yes, when making corneal incisions the iOCT shows you perfectly how the cornea is cleaved. This feedback allows you to adapt your technique to make more watertight incisions.

Another benefit of the iOCT is, for example, that the IOL is often more tilted at the end of a combined phaco-vitrectomy case than can be assessed from the microscope view. Repositioning the IOL based on the iOCT is much more precise than using the microscope view.

Do you have any suggestions for improvement?
The image injection solved a lot of my earlier comments on how it could be improved. During removal of the epiretinal membrane (ERM) or inner limiting membrane (ILM), the amount of traction force on the retina can be assessed during the iOCT. This allows you to enhance your peeling technique to reduce the amount of traction generated on the retina.

The superimposition of the iOCT scan to the live view now greatly improves the evaluation of the amount of force generated, as both can be observed simultaneously without moving away from the oculars. With the injection into both eyes observation is absolutely stress-free and adds an enormous improvement to the workflow.

Do you see further potential of the system?
When I perform surgery on a hemorrhagic proliferative diabetic case, a preoperative OCT image is not possible to make. Hence, as a “precaution” we tend to remove the inner limiting membrane (ILM) in all these cases as a routine. However, recent publications
indicate that removal of the ILM may only be required in selected cases. With the iOCT the presence of macular edema can be assessed in these cases during surgery after removal of the vitreous blood, which guides the decision whether or not ILM removal is indicated.

Figure 4-3: Exemplary iOCT images during different retinal surgeries.
Optical Coherence Tomography (OCT) has revolutionized retina, glaucoma, and cornea diagnostic testing. OCT is just beginning to be used for intraoperative testing to facilitate surgical procedures. Over the last year and a half under IRB approval, we have been using the iOCT mounted on the HAAG-STREIT operating microscope for a number of anterior segment procedures. The two most common applications have been with Descemet’s Membrane Endothelial Keratoplasty (DMEK) and the Staar Visian ICL.

DMEK
During DMEK, the iOCT has allowed viewing the donor graft through cloudy corneas to verify the orientation of the donor so that the Descemet’s side is up (towards the recipient cornea) and the endothelium is down towards the iris. The DMEK graft always curls with endothelium on the outside of the graft, and incorrect positioning would lead to damage to the endothelial cell layer if the endothelium was positioned against the recipient cornea.

Staar Visian ICL
The positioning and vault of the ICL is critical for long-term success of this myopic, phakic IOL. One wants to avoid over vaulting of the lens as that could lead to crowding of the anterior chamber angle. One wants to avoid no vault situations as that can increase the chances of anterior subcapsular cataracts. Currently it is difficult to determine the relative vaulting of the lens during surgery with the coaxial microscope. The iOCT currently can provide qualitative measurements, but not quantitative measurements in the eye. However using the microscope set on a constant magnification, provides a reproducible view of the ICL and its vault over the crystalline lens. These studies are currently underway at the time of this writing, but early results are promising and correspond to post-operative OCT images.
Francis W. Price Jr., M.D.

President
Price Vision Group, Indianapolis, Indiana, USA
Specialization: Corneal surgery

2006 – present Managing Partner
Central Indiana Surgery Center

1988 – present Founder and President of the Board
Cornea Research Foundation of America

1983 – present President
Price Vision Group, Indianapolis, Indiana

1981 – 1982 Fellowship: Cornea and External Disease
Tulane University, New Orleans, Louisiana

1978 – 1981 Resident in ophthalmology
Indiana University, Indianapolis, Indiana

1977 – 1978 Internship
Methodist Hospital, Indianapolis, Indiana

Education:
1977 M.D.
Indiana University, Indianapolis, Indiana

1973 B.S.
University of Notre Dame, South Bend, Indiana

Figure 5-4: Intraoperative OCT of Staar Visian ICL after removal of viscoelastic and refilling anterior chambers.

Figure 5-5: One day post-op AS-OCT showing vault of Staar Visian ICL from figure 5-4.
Case report

Some selected iOCT® cases

We at the Medical University of Warsaw in the Department of Ophthalmology had the pleasure to use the intraoperative OCT with the HS Hi-R NEO 900A NIR operating microscope two times. First, we were able to utilize the basic system of the iOCT for Descemet Stripping Automated Endothelial Keratoplasty (DSAEK) and had the chance to discuss it during a symposium at the Cornea Society and Eye Bank Association of America in fall 2012.

During the second testing period in early 2015, we were impressed that HAAG-STREIT SURGICAL together with the OPMedT company introduced several essential improvements of the system. Next to other functions, also the high-resolution image injection device, C.INJECT 900, can easily be controlled via the foot switch. The synchronization between the iOCT camera and the operating microscope for the magnification and focus setting guarantees a simple handling of the entire system.

Another interesting application for the iOCT is being able to check the positions of Add-On IOLs. Whereas the primary IOL is placed in the capsular bag, the secondary implant should be placed in the sulcus ciliaris. By the use of the iOCT we are able to document that the needed distance between the lenses is given, figure 6-2.

Figure 6-1: DSAEK surgery. A - D: Steps of attaching the graft.

Figure 6-2: Microscope (A) and iOCT (B) image of an Add-On IOL to a primary IOL implantation.
Figure 6-3: iOCT images of a retina condition with swellings and a macular hole.

Finally, we did some cases at the retina with the support of the iOCT. Exemplary are the scans in figure 6-3 before the surgery. We can easily detect swollen areas close to the macular hole.

In summary, we would like to state that we are extremely impressed by the new iOCT system and the pace of innovation from HAAG-STREIT SURGICAL and OPMedT.
Today, gliomas, especially its most malignant form – glioblastoma – range among the most devastating tumor diseases. Tumor resection is one of the dominating treatment options. Due to the high progression rate, in particular of WHO categorized IV tumors, effective treatment is directly associated with comprehensive removal of tumor cells while also simultaneously sustaining as much healthy tissue as possible. The removal of small peripheral tumor extensions around the main mass exposes a challenging and delicate task. Today, textural and color tissue differences, sometimes in combination with fluorescent dyes (e.g. 5-ALA), enable the surgeon to differentiate between healthy and malignant structures in addition to using his tactile perception. However, such an approach has limitations, which impede being able to confidently classify tissue.

Case report

Case examples with iOCT®

Figure 7-1: Sagittal view of a grade I (WHO) tentorial meningioma. Surface structure of the tumor is delineated. A: Microscope view. B: Volume rendering of the acquired iOCT volume illustrating the anatomic surfaces corresponding to the microscope view. C: En face close up of the same structure.

Figure 7-2: A: View into the third ventricle through the foramen Monroi in a glioblastoma patient who underwent a recraniotomy for removal of radiation necrosis following local alpha-radiotherapy. A: Microscope view. B: Top view onto a volume rendering of the iOCT slice stack. C and D: Single slice example forming the whole iOCT slice stack.
Optical coherence tomography (OCT) has sustainably changed the diagnostic landscape in ophthalmology. This work allows us to assess the feasibility of using the interferometric imaging principle to differentiate tumor tissue from healthy brain structures intraoperatively during the resection. The opportunity to have a microscope with an integrated OCT enabled us to catch a glimpse on this new visualization technique.

For the first step we used the system during regular cases to visualize individual brain structures, both healthy and pathologic, to develop a better understanding about light penetration and OCT imaging depth in the brain tissue. During the second step we will conduct a controlled assessment to reveal texture differences between pathologic and non-pathologic tissue. Subsequent picture sequencing demonstrates what we achieved so far with the existing iOCT setup.

Preliminary results obtained are very encouraging and justify further investigations. Consequent technical developments of the iOCT e.g. to cover a wider surface area during the imaging process would accelerate our research and potentially facilitate clinical use for such complicated cases. We appreciate the support and assistance of HAAG-STREIT SURGICAL GmbH and OPMedT GmbH.

Figure 7-3: iOCT (A) and microscope (B) view from the view from the top of the same patient as shown in figure 7-2. Prominent nodular structures represent radiation necrosis.
Study
Microanatomy of the tympanic membrane in chronic myringitis with Optical Coherence Tomography [9]

Objectives/Hypothesis
A microscope-based Optical Coherence Tomography (OCT) device was used to assess the microanatomy of the tympanic membrane in patients with chronic myringitis.

Study design
Prospective study

Methods
OCT measurements of the tympanic membrane were done on 10 patients with myringitis with a microscope-based spectral domain OCT system iOCT by HAAG-STREIT SURGICAL. The in-vivo findings were compared with those findings of a control group consisting of 37 patients with retraction pockets or atrophic tympanic membranes (n = 11), myringosclerosis (n = 12), and perforations (n = 11).

Results
In active chronic myringitis, the thickness of the tympanic membrane is increased compared to healthy membranes and to other pathological conditions of the tympanic membrane. Consistent changes of the microanatomy of the tympanic membrane were found in chronic myringitis with iOCT. Serial iOCT measurements revealed no biofilm suspicious findings in all patients with active chronic myringitis.

Conclusions
Intraoperative and in-vivo OCT measurements may help to detect microanatomical changes of the tympanic membrane in chronic myringitis.

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<th>Standard deviation (µm)</th>
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<td>84</td>
<td>21</td>
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<td>Myringitis</td>
<td>11</td>
<td>154</td>
<td>39</td>
</tr>
<tr>
<td>Atrophic</td>
<td>13</td>
<td>43</td>
<td>17</td>
</tr>
<tr>
<td>Uninfamed perforation</td>
<td>11</td>
<td>82</td>
<td>70</td>
</tr>
<tr>
<td>Myringosclerosis</td>
<td>12</td>
<td>170</td>
<td>125</td>
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Table 1: Thickness of the tympanic membrane in dependence of various tympanic membrane conditions.

Exemplary images of otologic structures taken by the iOCT

Figure 8-1: iOCT image of a healthy tympanic membrane. A: Top view of the tympanic membrane with the microscope (line: scan position). B: 3D iOCT images of the tympanic membrane. C: Three layers are visible: From the lateral (top) to medial (bottom), the squamous, fibrous, and cuboidal layers.

Figure 8-2: iOCT image of a chronic myringitis grade II. A: Top view of the focal raised granulation of the tympanic membrane with the microscope (line: scan position). B: CT scan reveals a thickened tympanic membrane (red arrow) without involvement of the middle ear mucosa. C: iOCT image reveals two de-epithelized regions (arrows) within the tympanic membrane.
chronic myringitis obtained

Figure 8-3: iOCT of a chronic myringitis grade III. A: Top view of diffuse granulation of the tympanic membrane of nearly all or its entire surface.
B: 3D image of the tympanic membrane. C: iOCT scan shows local disconnection of the thickened epithelial layer and the cuboidal layer; cuboidal layer depicts localized loss of integrity.
General considerations
The utilization of iOCT technology in middle ear surgery has a highly promising future and may, in time, add significantly to the development of the subspecialty and technical field of middle ear surgery. Due to the non-invasive character of the iOCT, a worldwide usage in institutions with a high number of patients who require surgical treatment is most likely.

Logistical considerations
Surgical setup
1. The current iOCT apparatus is functional and well designed.
2. The iOCT monitor used with the HS Hi-R 1000 surgical microscope can be well integrated into a standard surgical setup. Its space requirements and size are adequate and it can easily be covered with transparent sterile microscope draping without great difficulty. The monitor is also placed in such a way as to allow good visibility to the surgeon during the operation.
3. Movement of the surgical microscope is not limited at all by the device.

Technical considerations
1. Start-up procedures are clear and user friendly.
2. The user menus are well designed and intuitive to operate.
3. The delay in data processing is minimal and thus highly adequate for use during surgery.

Data management and scientific considerations
Data verification is important for a study to be done correctly. Thus, the patient data entered into the HS MIOS system at the start of the operation is linked to the microscope as well as the iOCT data. This ensures no data is lost or manually mislabeled.

The synchronized taking of snapshots is also a great feature. The moment the surgeon takes a snapshot with the microscope, the iOCT does so automatically as well. This allows a direct correlation between the in vivo image seen by the surgeon and the iOCT image intraoperatively and postoperatively, ensuring accurate analysis.

The iOCT has the potential to generate high quality images. As an example the depiction of the tympanic membrane can be given. The learning curve for the surgeon can be expected to be steep, with skill increasing after a short acclimatization phase. Volume scans over half of the visual field give brilliant images of the tympanic membrane.

Middle ear structures are slightly more difficult to keep in adequate focus for clear iOCT imaging as well as for light microscopy. The incudostapedial joint would be an interesting and promising structure to research, especially in otosclerosis and chronic otitis media cases. The surgical learning curve can be expected to be slightly less steep than that for the tympanic membrane.

Due to the angle of the stapedial footplate, the imaging of this highly relevant structure becomes increasingly difficult. It is recommended that the iOCT setting “QUARTER” be used for the footplate, due to the depth and optical angle at which the surgical microscope has to be placed.

Using the intraoperative data, 3D reconstructions can be created at a later point of time.

The vital clinical contribution the iOCT could make to stapes...
prosthesis placement in future is that it would be able to show the
surgeon exactly how far medially the implanted stapes prosthesis
has been placed from the footplate. A stapes prosthesis placed
too far medially (i.e. too “deep”) has the potential to damage the
vestibular organ (resulting in debilitating vertigo) and potentially
post-operative deafness. If the surgeon was able to create an
intraoperative 3D image, where he could clearly see the position
of the implanted prosthesis in relation to the footplate, the overly
deep insertion of prosthesis can be avoided. Such intraoperative
information would be a giant leap forward in the otosclerosis
therapy and enhance the demand for the “otologic iOCT”.

Endolaryngeal imaging
In general, analogous considerations are valid for the second
arm of the planned iOCT study, as has been noted above for ear
surgery.

We would like to thank the supportive team at
HAAG-STREIT SURGICAL for their assistance and friendly
nature. We are fortunate to have the opportunity to work
with talented and dedicated professionals in developing this
completely novel approach to ear surgery.

With due diligence and patience we are confident to be able to
produce quality scientific results with all their consequences.
Publications

In the media

GENERAL

[1] Title: iOCT with surgical microscopes: a new imaging during microsurgery
Authors: E. Lankenau, M. Krug, S. Oelckers, N. Schrage, T. Just, G. Hüttmann
Published: June 2013 in English

[2] Title: Combining Optical Coherence Tomography (OCT) with an operating microscope
Authors: E. Lankenau, D. Klinger, C. Winter, A. Malik, H. Müller, S. Oelckers, H.-W. Pau, T. Just, G. Hüttmann
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OPHTHALMOLOGY

Authors: L. M. Heindl, S. Siebelmann, T. Dietlein, G. Hüttmann, E. Lankenau, C. Cursiefen, P. Steven
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[4] Title: Optimising Deep Anterior Lamellar Keratoplasty (DALK) using intraoperative Optical Coherence Tomography (iOCT)
Published: March 2014 in English
Reference: http://bjo.bmj.com/content/early/2014/03/03/bjophthalmol-2013-304585.long

[5] Title: Optimizing Descemet Membrane Endothelial Keratoplasty (DMEK) using intraoperative Optical Coherence Tomography
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[6] Title: iOCT video
Authors: M. Snyder
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Reference: http://opmedt.com

[7] Title: Intraoperative Optical Coherence Tomography (iOCT) improves surgical performance in Deep Anterior Lamellar Keratoplasty (DALK) and Penetrating Keratoplasty (pKPL)
Authors: M. Krug, G. Hüttmann, S. Oelckers, C. Cursiefen
Published: May 2012 in English

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Published: June 2013 in English  

Authors: B. Olzowy, N. Starke, T. Schuldt, G. Hüttmann, E. Lankenau, T. Just  
Published: June 2013 in English  

[12] Title: Automatic scanning of large tissue areas in neurosurgery using Optical Coherence Tomography  
Authors: M. Finke, S. Kantelhardt, A. Schlaefer, R. Bruder, E. Lankenau, A. Giese, A. Schweikard  
Published: September 2012 in English  

Authors: H. J. Böhringer, E. Lankenau, F. Stellmacher, E. Reusche, G. Hüttmann, A. Giese  
Published: April 2009 in English  
Reference: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3085760/

[14] Title: Optical Coherence Tomography for experimental neuroendoscopy  
Authors: H. J. Böhinger, E. Lankenau, V. Rohde, G. Hüttmann, A. Giese  
Published: October 2006 in English  

[15] Title: Time-domain and spectral-domain Optical Coherence Tomography in the analysis of brain tumor tissue  
Published: July 2006 in English  

[16] Title: Non-invasive intraoperative Optical Coherence Tomography of the resection cavity during surgery of intrinsic brain tumors  
Authors: A. Giese, H. J. Böhringer, J. Leppert, S. R. Kantelhardt, E. Lankenau, P. Koch, R. Birngruber, G. Hüttmann  
Published: May 2006 in English  

Subject to alterations.
The developer’s story

Experiencing success

2015 With its 510(k) clearance, the iOCT in combination with the HS Hi-R 900A NIR is ready for sale in the US market.

2014 HAAG-STREIT SURGICAL puts an emphasis on studies in the field of ophthalmology, neurosurgery, and ENT.

The first iOCT Application booklet is published and the iOCT Atlas is introduced.

2013 After years of cooperation, OPMedT becomes a member of the HAAG-STREIT Group, strengthening the link between the companies and using HAAG-STREIT SURGICAL as its exclusive sales and marketing partner.

2012 The iOCT camera is fully integrated with the operating microscopes from HAAG-STREIT SURGICAL GmbH and enables the intraoperative use of OCT in ophthalmology, neurosurgery, and ENT.

2011 The iOCT camera is CE certified.

2010 With her background in physics, Dr. Eva Lankenau worked at the Institute of Biomedical Optics of the University Luebeck as an expert in the techniques of Optical Coherence Tomography. With the idea of developing and producing a product-capable “universal OCT-camera”, she and two partners founded the company OPMedT GmbH.

OPMedT is certified for “design and development, production, sales, and service of devices for Optical Coherence Tomography” according to EN ISO 13485:2003 / AC: 2009 with an EG Certificate for its full quality assurance system according to the Directive 93/42/EEC on medical devices (MDD).

The camera is designed to be adaptable to medical optical imaging equipment, such as operating microscopes, endoscopes, and colposcopes, as an accessory.

The first demonstration of a prototype in combination with an operating microscope was at the WOC 2010.

After working for decades on intraoperative OCT, it is heart-warming to see how our ideas take root with surgeons. I will never forget the first surgery with iOCT ensuring the well-being of the patient. «
HAAG-STREIT SURGICAL distributes products manufactured by MÖLLER-WEDEL through national sister companies as well as dedicated representatives globally.

HAAG-STREIT SURGICAL as well as MÖLLER-WEDEL maintain a Quality Management System for Medical Products according to ISO 13485. MÖLLER-WEDEL is not only developing innovative products but also producing them conscious to the environment. Filling an Environmental Management System according to ISO 14001 is the guide line. Both, the Quality as well as the Environmental Management System, are certified by TÜV.

All products are conform to the EC guidelines and thus CE labeled.