To:	Koninklijke Philips N.V. (ipdocket@calfee.com)
Subject:	U.S. TRADEMARK APPLICATION NO. 79108849 - ICT - 30961/04099
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UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)
OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION

U.S. APPLICATION SERIAL NO. 79108849

MARK: ICT

79108849

CORRESPONDENT ADDRESS:
RAYMOND RUNDELLI
CALFEE HALTER & GRISWOLD LLP
THE CALFEE BUILDING 1405 EAST SIXTH ST
REET
CLEVELAND, OH 44114-1607

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APPLICANT: Koninklijke Philips N.V.

CORRESPONDENT'S REFERENCE/DOCKET NO :

30961/04099

CORRESPONDENT E-MAIL ADDRESS:
ipdocket@calfee.com

OFFICE ACTION

STRICT DEADLINE TO RESPOND TO THIS LETTER

ISSUE/MAILING DATE: 5/3/2015

THIS IS A FINAL ACTION.

INTERNATIONAL REGISTRATION NO. 1105916

On March 27, 2015, the TTAB remanded this matter so that additional evidence could be entered into the record and so that uncertainty arising from inclusion of the six-month response clause in the previous Final Office action could be corrected. Upon entry of this Office action, this application will be returned to the Board and action on the appeal with be resumed.

Trademark Act Section 2(e)(1) Refusal – Mere Descriptiveness – FINAL Refusal:

Registration is refused because the applied-for mark merely describes a feature, ingredient, characteristic, purpose, or function of applicant's goods and/or services. Trademark Act Section 2(e)(1), 15 U.S.C. §1052(e)(1); *see* TMEP §§1209.01(b), 1209.03 *et seq.* This refusal is now made FINAL.

Full details regarding this refusal were contained in the Final Office action of February 27, 2015. In addition to the evidence contained in the Office action of February 27, 2015, applicant should also note the additional attached evidence from Google Books, the American Association of Neurological Surgeons, Injuryjournal.com, Lacrossetribune.com, medicaldevice-network.com, Sacred Heart Hospital, The Advisory Board Company, Imris.com, and several academic journal articles, which further support the refusal.

Section 2(e)(1) – Deceptively Misdescriptive – FINAL Refusal:

In the alternative, registration is refused because the applied-for mark is deceptively misdescriptive of applicant's goods. Trademark Act Section 2(e)(1), 15 U.S.C. §1052(e)(1); *see* TMEP §1209.04. This refusal is now made FINAL.

Full details regarding this refusal were contained in the Final Office action of February 27, 2015. In addition to the evidence contained in the Office action of February 27, 2015, applicant should also note the additional evidence attached hereto.

Identification Amendment to Overcome Refusal:

If the goods are ***not*** ICT devices, applicant can amend the identification of goods to state this fact, and the descriptiveness refusal will be withdrawn. Applicant may adopt the following identification of goods, if accurate:

> ***Medical imaging apparatus, excluding Intraoperative Computed Tomography (ICT) apparatus and apparatus for intraoperative use.***

In addition, if the identification is amended in this way the information requirement and alternative misdescriptiveness refusal will be withdrawn.

Section 2(f) Claim Unacceptable:

As explained in the previous Office actions, applicant has asserted acquired distinctiveness based on five years' use in commerce and on additional submitted evidence; however, such evidence is not sufficient to show acquired distinctiveness because applicant's mark is of a highly descriptive nature. *See* 15 U.S.C. §1052(e)(1), (f); *In re MetPath, Inc.*, 1 USPQ2d 1750, 1751-52 (TTAB 1986); TMEP §1212.04(a). Additional evidence is needed.

Applicant should also note that in addition to being merely descriptive, the applied-for mark appears to be generic in connection with the identified goods and, therefore, incapable of functioning as a sourceidentifier for applicant's goods. *In re Gould Paper Corp.*, 834 F.2d 1017, 5 USPQ2d 1110 (Fed. Cir. 1987); *In re Pennzoil Prods. Co.*, 20 USPQ2d 1753 (TTAB 1991); *see* TMEP §§1209.01(c) *et seq.*, 1209.02(a).

FINAL Information Requirement:

Applicant must provide the following information and documentation regarding the applied-for mark:
(1) A written statement as to whether any of the technology used in the goods that this trademark concerns, ***and that is, was, or could be used intraoperatively,*** is or has been the subject of a patent or patent application, including expired patents and abandoned patent applications. Applicant must also provide copies of the patents and/or patent application documentation; and
(2) A written statement as to whether any of the technology used in the goods that this trademark concerns, ***and that is, was, or could be used intraoperatively,*** is or has been the subject of a patent or patent application, including expired patents and abandoned patent applications, ***by anyone other than applicant***. Applicant also must provide copies of the patents and/or patent application documentation.; *See* 37 C.F.R. §2.61(b); *In re AOP LLC*, 107 USPQ2d 1644, 1650-51 (TTAB 2013); *In re Cheezwhse.com, Inc.*, 85 USPQ2d 1917, 1919 (TTAB 2008); *In re Planalytics, Inc.*, 70 USPQ2d 1453, 1457-58 (TTAB 2004); TMEP §§814, 1402.01(e).
Failure to comply with a request for information can be grounds for refusing registration. *In re AOP LLC*, 107 USPQ2d 1644, 1651 (TTAB 2013); *In re DTI P'ship LLP* , 67 USPQ2d 1699, 1701-02 (TTAB 2003); TMEP §814. Merely stating that information about the goods or services is available on applicant's website is an inappropriate response to a request for additional information and is insufficient to make the relevant information of record. *See In re Planalytics, Inc.*, 70 USPQ2d 1453, 1457-58 (TTAB 2004).
This requirement is now made FINAL.

If applicant has questions regarding this Office action, please telephone or e-mail the assigned trademark examining attorney. All relevant e-mail communications will be placed in the official application record. Although the trademark examining attorney may provide additional explanation pertaining to the refusal(s) and/or requirement(s) in this Office action, the trademark examining attorney may not provide legal advice or statements about applicant's rights.   *See* TMEP §§705.02, 709.06.

/James MacFarlane/
Examining Attorney
Law Office 104
(571) 270-1512 (phone)
(571) 270-2512 (fax)
james.macfarlane@uspto.gov

TO RESPOND TO THIS LETTER (if a response is due): Go to http://www.uspto.gov/trademarks/teas/response_forms.jsp. Please wait 48-72 hours from the issue/mailing date before using the Trademark Electronic Application System (TEAS), to allow for necessary system updates of the application. For *technical* assistance with online forms, e-mail TEAS@uspto.gov. For questions about the Office action itself, please contact the assigned trademark examining attorney. **E-mail communications will not be accepted as responses to Office actions; therefore, do not respond to this Office action by e-mail.**

All informal e-mail communications relevant to this application will be placed in the official

application record.

WHO MUST SIGN THE RESPONSE: It must be personally signed by an individual applicant or someone with legal authority to bind an applicant (i.e., a corporate officer, a general partner, all joint applicants). If an applicant is represented by an attorney, the attorney must sign the response.

PERIODICALLY CHECK THE STATUS OF THE APPLICATION: To ensure that applicant does not miss crucial deadlines or official notices, check the status of the application every three to four months using the Trademark Status and Document Retrieval (TSDR) system at http://tsdr.uspto.gov/. Please keep a copy of the TSDR status screen. If the status shows no change for more than six months, contact the Trademark Assistance Center by e-mail at TrademarkAssistanceCenter@uspto.gov or call 1-800-786-9199. For more information on checking status, see http://www.uspto.gov/trademarks/process/status/.

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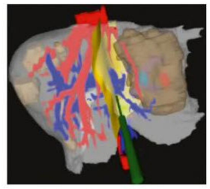

Fig. 18.1 Rendered liver in intraoperative display. In a fully realized abdominal image-guided system such as the one shown here, the relative position of a surgical tool (shown in *green*) can be interactively displayed along with anatomical structures (*red* arteries, *blue* veins, and *gray* liver parenchyma); lesions (shown in *brown*) and preoperative planning such as the gold preplanned resection plane (Courtesy of Pathfinder Technologies, Nashville, TN, USA)

Such displays are compelling, they are easy to understand, they can be rotated to the surgeon's desired or optimal viewpoint, and structures can be displayed or not as required by the case. In addition, they not only provide location but orientation information and depth information via shading. However, such displays are dependent on the validity of the segmentation algorithm used to define the outline of the structures and thus can provide both potential benefit and risk.

Correcting Positional Display Errors due to Perioperative Deformation

In the past, the translation of image-guided surgery techniques to the abdominal environment has been limited due to the presence of perioperative deformation. As a result, the most widely used intraoperative guidance approaches for abdominal have been active imaging with the use of ultrasound (US) or visual laparoscopic imaging. The integration of preoperative imaging and planning data for active intraoperative guidance has only recently begun to be commercialized.

In recent reports, soft tissue deformation during liver resection has been documented with intraoperative computed tomography (iCT) and has demonstrated significant effects [27]. While intraoperative magnetic resonance (iMR) and iCT are available, these approaches are cumbersome, incur radiation dose in the latter, and are not economically scalable for many medical centers. A CT-to-ultrasound (US) vessel-based nonrigid registration system for providing the link between image and physical space has been described [28]. While successful, the OR workflow would seem to be a challenge as it requires the identification of as many vascular targets as possible with tracked ultrasound and then determination of corresponding targets within the CT. While the subsurface information would be valuable for nonrigid deformation correction, there is a significant likelihood of misidentification in highly vascularized organs such as the liver and kidney, and the encumbrance of the technique may challenge adoption.

Given the nature of abdominal procedures, the need to compensate for deformation is evident and the requirements for compensation need to be balanced with workflow and accuracy needs. As an example, presentation for open kidney and liver surgery (and even laparoscopic to a degree) involves significant organ distortion prior to the ability to resect or even collect geometric data. However, considerable exposure of the organ (as opposed to intracranial neurosurgery) is afforded for understanding surgical presentation. In partial nephrectomy, the renal artery and potentially the renal vein are clamped to prevent excessive blood loss during resection. This creates a state of turgor within the organ that is different than the preoperative image counterpart. Upon resection, significant drainage from the cortex and medulla regions can ensue and cause significant shape changes. In both of these examples, the surgical characteristics serve as constraints to data acquisition and guidance procedure execution. As the field of image guidance moves forward, it will be

Advances in Image-Guide ×

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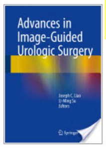
Advances in Image-Guided Urologic Surgery (Google eBook)



Joseph C. Liao, Li-Ming Su

Springer, Nov 18, 2014 - Medical - 289 pages

0 Reviews

This book provides an overview of the current state-of-art in combining advances in biomedical imaging with intraoperative navigation and preoperative planning for urologic surgery. These advances hold great promise in improving diagnostic and therapeutic urologic interventions to improve patient outcomes. Leading experts in this exciting emerging field covers early clinical and pre-clinical applications of optical, ultrasound, cross-sectional and computer-assisted imaging in urologic surgery.

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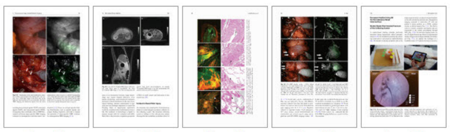

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Contents

Common terms and phrases

ablation anatomical artery assessment benign biopsy BJU Int bladder cancer clinical cryoablation cryotherapy cystoscopy Department of Urology detection diagnosis Doppler ELUS endoscopic Endourol Epub evaluation ex vivo fluorescence

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Contents

Common terms and phrases

ablation anatomical artery assessment benign biopsy BJU Int bladder cancer clinical cryoablation cryotherapy cystoscopy Department of Urology detection diagnosis Doppler ELUS endoscopic Endourol Epub evaluation ex vivo fluorescence imaging fluoroscopy focal therapy guidance ice ball ICG-NIRF imaging identify image-guided surgery improve intraoperative Intuitive Surgical kidney laparoscopic laser lesions malignant MD Department minimally invasive molecular imaging monitoring mpMRI navigation needle NIRF imaging oncologic optical coherence tomography outcomes partial nephrectomy patients percutaneous performed potential preoperative procedures prostate cancer PubMed PMID puncture radical prostatectomy real-time recurrence registration renal cell carcinoma renal masses renal tumors resection resonance imaging robotic surgery robotic-assisted sagittal scan seminal vesicles simulator spectroscopy Springer Science+Business Media surface surgeon surgical T2-weighted imaging target technique tion tissue tracking treatment TRUS ultrasound probe ureter ureteral urethra urinary Urol Urologic Surgery Urology urothelial validity Vinci virtual reality visualization

About the author (2014)

Joseph C. Liao, M.D., Associate Professor of Urology, Stanford University School of Medicine Chief of Urology, VA Palo Alto Health Care System. Palo Alto, CA, USA.

Li-Ming Su, MD, David A. Cofrin Professor of Urology; Associate Chairman of Clinical Affairs; Chief, Division of Robotic and Minimally Invasive Urologic Surgery, Department of Urology, University of Florida College of Medicine. Gainesville, FL, USA.

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Chang Gung Memorial Hospital, Chiayi: Intraoperative computed tomography with integrated navigation in percutaneous iliosacral screwing

By a News Reporter-Staff News Editor at Health & Medicine Week – A new study on Injury Research is now available. According to news reporting out of Chiayi, Taiwan, by NewsRx editors, research stated, "Iliosacral screw fixation has generally been accepted as a treatment for unstable pelvic fractures with posterior sacroiliac joint disruption despite a 2-16% rate of screw malposition. The integration of an intraoperative computed tomography (iCT) with a navigation system was utilized in percutaneous sacroiliac screwing to provide an alternative."

Our news journalists obtained a quote from the research from Chang Gung Memorial Hospital, "From October 2010 to November 2011, thirteen patients presented pelvic fractures with posterior ring disruption (lateral compression type 2-3 [n = 12] and vertical shear type [n = 1] by Young-Burgess Classification) and underwent percutaneous iliosacral screwing using an iCT integrated with navigation system. The perioperative data and radiographic outcomes of the patients were collected and analyzed. Navigation times ranged from 10 to 45 min (mean of 21.2 +/- 10.6 min). Radiation exposure to the skin utilizing integrated navigation system ranged from 23.5 to 28.1 mGy (mean of 26.4 +/- 1.5 mGy), and the dose associated with examining the screw position ranged from 22.5 to 26.8 mGy (mean of 25.5 +/- 1.1 mGy). Effective dose of radiation ranged from 9.26 to 17.43 mSv (mean of 13.16 +/- 2.52 mSv). The iCT demonstrated iliosacral screws in adequate position (i.e., no penetration or encroachment of the neuroforamen or cord). No neurologic or vascular injury occurred in these cases. An iCT with an integrated navigation system provided accuracy for percutaneous iliosacral screwing. In addition, the accumulated dose was minimized for surgeons. However, effective dose of radiation in iCT with an integrated navigation system group was higher than fluoroscopic-assisted iliosacral screwing in hands of the same group of surgeons. No neurologic complications occurred."

According to the news editors, the research concluded: "The iCT with an integrated navigation system provided an alternative to percutaneous iliosacral screwing."

For more information on this research see: Intraoperative computed tomography with integrated navigation in percutaneous iliosacral screwing. *Injury-International Journal of the Care of the Injured*, 2013;44(2):203-208. *Injury-International Journal of the Care of the Injured* can be contacted at: Elsevier Sci Ltd, The Boulevard, Langford Lane, Kidlington, Oxford OX5 1GB, Oxon, England.

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Advances in Imaging Technology Research and Application: 2013 Edition

ScholarlyEditions, Jun 21, 2013 - Science - 1039 pages

0 Reviews

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	Science / Applied Sciences

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Media

Abstract: 2008 Apr 28

Intraoperative CT with integrated navigation system in spinal neurosurgery

Author(s):
Stefan Zausinger, (Munich, Germany)
Ben Scheder, (Dept. of Neurosurgery, Munich, Germany)
Dominik Morhard, (Institute for Clinical Radiology, Munich, Germany)
Thomas Heigl, (Dept. of Neurosurgery, Munich, Germany)
Eberhard Uhl, (Dept. of Neurosurgery, Klagenfurt, Austria)
Joerg Christian Tonn, (Dept. of Neurosurgery, Klinikum Grosshadern,Munich, Germany)

Introduction: Before spinal surgery, navigational images are usually acquired with patients positioned supine. The aim of this study was to evaluate prospectively navigated spinal procedures with data acquisition by intraoperative computed tomography (iCT) before and during the operative procedure. Methods: Computed tomography data of 58 patients (thoracolumbar (n=33), C1/2 (n=9), and cervical instability (n=16)) were acquired after positioning the patient in the final prone position on a radiolucent operating table (Jupiter, Trumpf). A sliding gantry 24-detector row CT (Somatom Open, Siemens) was used for image acquisition. Data were imported to the frameless infrared-based neuronavigation station (Vector Vision Compact, BrainLAB). A postprocedural iCT assessed the extent of decompression and the accuracy of instrumentation. Results: Intraoperative registration revealed computed accuracy less than 1 mm (0.9 ± 0.1 mm). Time needed for iCT was 9 ± 3 minutes. Control iCT revealed incorrect screw position greater than 2 mm in 10 (4.5%) of 223 screws and changed the course of surgery in seven cases (12%). There were three transient complications with significant clinical improvement in all patients (Odom score after 1 week 2.8 ± 0.6 improved to 1.8 ± 0.7 after 3 months). Conclusions: Intraoperative CT in combination with neuronavigation provides high accuracy

> Classification of Brain Tumors
> Extended Glasgow Score Chart Illustration
> Public Service Announcements
> General Press Releases
> Glossary of Terms

Abstract: 2008 Apr 28

Intraoperative CT with integrated navigation system in spinal neurosurgery

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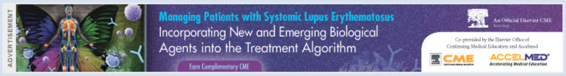
Keywords:
neuronavigation
spinal instability
computed tomography
intraoperative imaging
Article ID: 49075



Injury
International Journal of the Care of the Injured

February 2013 Volume 44, Issue 2, Pages 203–208

Intraoperative computed tomography with integrated navigation in percutaneous iliosacral screwing

Kuo-Ti Peng, Yen-Yao Li, Wei-Hsiu Hsu, Meng-Huang Wu, Jen-Tsung Yang, Chu-Hsiang Hsu, Tsung-Jen Huang

Accepted: September 21, 2012;

DOI: http://dx.doi.org/10.1016/j.injury.2012.09.017

Article Info

Abstract | Full Text | Images | References

Abstract

Background

Iliosacral screw fixation has generally been accepted as a treatment for unstable pelvic fractures with posterior sacroiliac joint disruption despite a 2–16% rate of screw malposition. The integration of an intraoperative computed tomography (iCT) with a navigation system was utilized in percutaneous sacroiliac screwing to provide an alternative.

Methods

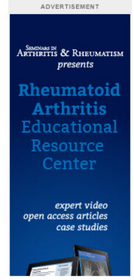
From October 2010 to November 2011, thirteen patients presented pelvic fractures with posterior ring disruption (lateral compression type 2–3 [$n = 12$] and vertical shear type [$n = 1$] by Young-Burgess Classification) and underwent percutaneous iliosacral screwing using an iCT integrated with navigation system. The perioperative data and radiographic outcomes of the patients were collected and analyzed.

Results

Navigation times ranged from 10 to 45 min (mean of 21.2 ± 10.6 min). Radiation exposure to the skin utilizing integrated navigation system ranged from 23.5 to 28.1 mGy (mean of 26.4 ± 1.5 mGy), and the dose associated with examining the screw position ranged from 22.5 to 26.8 mGy (mean of 25.5 ± 1.1 mGy). Effective dose of radiation ranged from 9.26 to 17.43 mSv (mean of 13.16 ± 2.52 mSv). The iCT demonstrated iliosacral screws in adequate position (*i.e.*, no penetration or encroachment of the neuroforamen or cord). No neurologic or vascular injury occurred in these cases.

Conclusions

An iCT with an integrated navigation system provided accuracy for percutaneous iliosacral screwing. In addition, the accumulated dose was minimized for surgeons. However, effective dose of radiation in iCT with an integrated navigation



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Background

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Keywords:
Intraoperative computed tomography, Navigated surgery, Iliosacral screwing, Pelvic fracture

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Intraoperative Computed Tomography

J.C. Tonn, C. Schichor, O. Schnell, S. Zausinger, E. Uhl, D. Morhard, and M. Reiser

Abstract Intraoperative computed tomography (iCT) has gained increasing impact among modern neurosurgical techniques. Multislice CT with a sliding gantry in the OR provides excellent diagnostic image quality in the visualization of vascular lesions as well as bony structures including skull base and spine. Due to short acquisition times and a high spatial and temporal resolution, various modalities such as iCT-angiography, iCT-cerebral perfusion and the integration of intraoperative navigation with automatic re-registration after scanning can be performed. This allows a variety of applications, e.g. intraoperative angiography, intraoperative cerebral perfusion studies, update of cerebral and spinal navigation, stereotactic procedures as well as resection control in tumour surgery. Its versatility promotes its use in a multidisciplinary setting. Radiation exposure is comparable to standard CT systems outside the OR. For neurosurgical purposes, however, new hardware components (e.g. a radiolucent headholder system) had to be developed. Having a different range of applications compared to intraoperative MRI, it is an attractive modality for intraoperative imaging being comparatively easy to install and cost efficient.

Keywords Computed tomography (CT) · CT angiography · Intraoperative CT · Intraoperative imaging · Spine surgery

Introduction

The development of neurosurgical techniques and the demand for treating more complex lesions with the aim of continuous reduction of surgery related morbidity has generated an increasing demand for sophisticated intraoperative imaging modalities. Various technologies are available, albeit with different indications. Intraoperative ultrasound has proven to be a rather easy to use, straight forward solution for the intraoperative localisation of deep-seated lesions like cavernomas, metastases or haemorrhages as well as, to a certain extent, for resection control of tumours. Being rather inexpensive with no additional costs of installation, the use of ultrasound is dependent on the personal experience of the user. In addition, despite improved technology, its resolution may be limited depending on the particular type of pathology [1, 2]. For the resection of high grade gliomas, the use of tissue fluorescence after administration of 5-aminolevulinic acid (5-ALA) has been proven to be efficient to delineate tumour margins and residual tumour tissue. The rate of "radicality" in the microsurgical resection of high grade gliomas has been improved significantly hereby. However, this technology is only useful for malignant gliomas, especially glioblastomas; moreover, the drug itself has so far not yet been approved by health care authorities in all parts of the world [3].

Intraoperative imaging using magnetic resonance (MR) scanners, either high field or low field, provide good visualisation of soft tissue abnormalities like gliomas, pituitary adenomas, and other tumours. However, this technology is very expensive and implementation into a pre-existing operating theatre demands a lot of resources. Moreover, the use of intraoperative MRI is limited for cranial applications due to the geometry of the scanner in relation to the table system.

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Intraoperative Imaging - N ×

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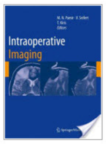

M. Necmettin Pamir, Volker Seifert, Talat Kiris

Springer Science & Business Media, Oct 20, 2010 - Medical - 282 pages

0 Reviews

Intraoperative imaging technologies have taken an ever-increasing role in the daily practice of neurosurgeons and the increasing attention and interest necessitated international interaction and collaboration. The Intraoperative Imaging Society was formed in 2007. This book brings together highlights from the second meeting of the Intraoperative Imaging Society, which took place in Istanbul-Turkey from June 14 to 17, 2009. Included within the contents of the book is an overview of the emergence and development of the intraoperative imaging technology as well as a glimpse on where the technology is heading. This is followed by in detail coverage of intraoperative MRI technology and sections on intraoperative CT and ultrasonography. There are also sections on multimodality integration, intraoperative robotics and other intraoperative technologies. We believe that this book will provide an up-to date and comprehensive general

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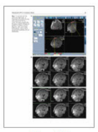
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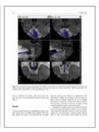
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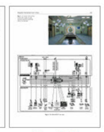
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Common terms and phrases

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Common terms and phrases

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Cutting edge: CT scanner in Gundersen operating room gives surgeons a better view

Gundersen neurosurgeon Dr. Douglas Hughes poses in the brain suite, which includes a CT scanner that doctors can use during surgery to monitor progress in real time. The 4,500-pound scanner is housed in a "garage" between two operating rooms, and it operates on rails to service either room.
Erik Daily

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January 10, 2014 12:00 am • By MIKE TIGHE mtighe@lacrossetribune.com (0) Comments

It's not brain surgery — not like it used to be, anyway.

In what some bill as the operating room of the future, Gundersen Health System's new Legacy Building includes two ORs sandwiching a CT scanner that provides real-time images to help doctors navigate through intricate brain and spinal surgeries.

One of only eight such setups in the country, the unofficially labeled "brain suite" won't be available for public tours during Gundersen's preview of its new hospital this weekend.

Dr. Douglas Hughes, a Gundersen neurosurgeon who will be using the new system, said it offers several advantages over present technology.

"Currently, we take X-rays over and over and over again," Hughes said. "The main advantage with this is that it allows us in real time to see how the patient is responding."

Doctors entering brain surgery now often are operating with a plan devised from CT scans taken two days before, Hughes said.

IF YOU GO

WHO: Gundersen Health System

WHAT: Community celebration and public preview, including guided tours, hands-on exhibits and a Teddy Bear Hospital for children

WHERE: Gundersen's new hospital, called the Legacy Building, at its main La Crosse campus at 1900 South Ave.

WHEN: 10 a.m. to 5 p.m. Saturday and Sunday, with Teddy Bear Hospital open from 10 a.m. to 2 p.m.

PARKING: Valet parking will be available in front of the Legacy Building, or those attending can park themselves in the green, blue or

E lot. Take Seventh Street to reach all parking options.

The disadvantage is that a tumor might have changed since the scan, he said. And after surgery begins, the conditions can change again, he said.

"When you open it up, things can shift and move," Hughes said. "The problem is you don't have the opportunity to check what's happened."

"A lot of stuff we do is blind, but now we can monitor in real time what we're doing," said the 38-year-old Hughes, who has been at Gundersen for three months and said this new technology helped attract him to the hospital.

During his training at the Medical College of Georgia in Augusta, Hughes said, "We didn't have anything like this. One of the reasons I chose here is because I was excited about the iCT."

The acronym stands for intraoperative computed tomography, which allows scans during operations because the 4,500-pound scanner is on rails so it can be rolled to surround the operating table. Surgeons can take images as often as necessary.

The circular scanner can move from a patient's head to the tailbone, Hughes said.

In Gundersen's suite, the scanner is housed in a "garage" between two operating rooms, so it can be used in either room. Four of the other such systems in the U.S. also serve double rooms, while three serve just one.

The images from the Siemens CT scanner are merged into a navigation and data management system created by Brainlab in Westchester, Ill.

"We liken it to a GPS system," said Thom Eaton, a senior technical consultant at Brainlab who is working on the Gundersen project.

Scanners such as Gundersen's cost roughly $1.2 million, with an additional $500,000 possible for software, Eaton said.

Brainlab's navigation system includes six flat-screen TVs in the operating room with touch-screen features so the images can be moved from one screen to another at the touch of a finger, depending on the view the surgeon needs, Eaton said as he demonstrated the process.

The TVs and their supporting equipment are mounted from the ceiling and on the walls, eliminating the need to roll in a cart, Hughes said. The TVs also are integrated with endoscope cameras that can capture interior images.

"We can use this to guide decision-making during surgery," he said. "Sometimes, if things seem like they're not going right, we had just the pre-op image. With technology like this, if we are confused or not sure, we can always recheck and adjust."

The system advances spine surgery as well, Hughes said, adding, "The benefit of the scan is it helps navigate how and where we place a screw and how big it should be."

In addition to real-time images during operations, the system allows surgeons to check whether the procedure has been successful before they close the patient, Hughes said.

That is not possible without the iCT, meaning that operations might have to be repeated if they proved unsuccessful, he said.

"With a tumor, it's not always clear when you're done," he said. "Basically, you have to take it on faith, and if you have a question, you go to the scan.

"With the iCT, we don't have to leave the OR. We can check and see if we did what we wanted to do. If so, the operation is done," he said.

"One of the coolest things we can do is treat movement disorders such as Parkinson's and tremors by getting an electrode into part of the brain," he said. "We go to great lengths to get the needle past parts of the brain into the exact spot deep inside the brain."

The iCT will aid that process, the surgeon said.

"We will be able to check the placement immediately to see if it works. If it's not good enough, we can adjust. Now, the only way is to take the patient out of the OR and test," Hughes said.

"That's a really cool surgery because people are instantly changed," he said. "A lot of things we do cause pain, and it take awhile to see the results. This is very gratifying, when we can take them from having a debilitating problem to being normal."

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IMRIS receives CE mark for ceiling-mounted intraoperative computed tomography

6 August 2013

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IMRIS, an image-guided therapy solutions provider, has received CE mark for its ceiling-mounted VISIUS intraoperative computed tomography (iCT).

The CE mark will allow the company to sell and market the product in the European Union.

VISIUS iCT helps surgeons in making critical decisions by providing personalised dose management and diagnostic quality imaging.

The iCT features 64-slice scanner equipped with ceiling-mounted rails that allows it to move in and out of the operating room in around 30 seconds during surgery.

In addition, the scanner can travel into two adjacent operating rooms, allowing the hospital to use it for more than one patient.

The ceiling-mounted rail gives the hospital more valuable OR floor space and also allows easy movement of surgical equipment in the operating room.

To maximise image quality and minimise dose, the VISIUS iCT uses 3D volume rendering application that provides surgical planning and dose reduction algorithms for finding patient's unique characteristics and imaging target.

Based on specific clinical need, the system software can be adjusted to provide dosage visualisation before the scan or detailed dosage reports after each scan.

VISIUS iCT received 510(k) clearance from US Food and Drug Administration (FDA) in July 2013.

IMRIS CEO and president Jay D Miller said this was another step in their overall global launch after recently receiving clearance from the FDA.

"European Union spine surgeons now have the opportunity to use this unique solution in confirming implant placements, fusion and other complex procedures," Miller said. "As procedures become more minimally invasive, the need for better visualiation with advanced imaging increases.

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"As procedures become more minimally invasive, the need for better visualiation with advanced imaging increases."

"Both US and European spine surgeons will be especially interested in the outstanding dose management capabilities and state-of-the-art image quality available with VISIUS iCT."

The company has already sold VISIUS iCT to three major eastern US neurosciences centres, and is being deployed currently at two of these centres.

Image: IMRIS VISIUS iCT, with image quality and access in the OR, will be available in the EU. Photo: courtesy of IMRIS Inc.

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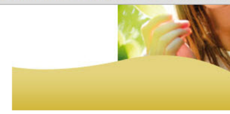

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The Dual Source CT uses two x-ray sources and two detectors to give our physicians high-quality 3-D images of "slices" of the body allowing them to make diagnosis and treatment decisions in as little as three minutes. It also:

- allows our radiologists to view results immediately
- uses half the radiation of traditional scanners
- eliminates the need for a biopsy or exploratory surgery in some cases
- has the extraordinary ability to take more than 6,000 images of the heart in as little as ten seconds
- permits our cardiologists to evaluate patients with exceptionally high heart rates without having to wait for beta blockers to bring the heart rate down
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- allows physicians to remove images of muscle and tissue from a scan with the click of a mouse—revealing previously unattainable details of the bone needed for proper diagnosis
- can detect cancer at its earliest sage which means a better chance for survival

The **3 Tesla MRI**

The 3 Tesla MRI is faster and two times stronger than traditional MRIs. It:

- captures images with such exceptional detail that our physicians can see structures within the body that have never been seen before.

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the body that have never been seen before.

- has a powerful magnet that can be used to detect cancers in their earliest stages.
- can diagnose neurological disorders such as stroke.
- is capable of scanning the entire body for cardiovascular, gastrointestinal and orthopedic conditions
- is so sophisticated it is usually found only in research facilities.

Intraoperative Magnetic Resonance Imaging (iMRI)

In 2008, Sacred Heart Hospital opened its first smart operating room, the Smart O.R.® for brain surgery. The Smart O.R. contains a revolutionary moveable iMRI which works in conjunction with some of the world's most complex BrainLAB® navigational mapping technologies to assist our neurosurgeons every step of the way from planning and executing to concluding a surgical procedure.

- Before surgery, the tools available in the Smart O.R. provide a virtual map of the surgical approach, allowing the surgeon to plan the safest and most direct path to a tumor anywhere within the brain.
- During surgery, the surgeon is guided directly to the site of the tumor, minimizing any disturbance to normal brain tissue.
- Before concluding the surgical procedure the iMRI provides evidence that all tumor tissue has been removed, minimizing the risk of incomplete tumor removal and the potential need for additional surgical procedures.

By minimizing the risk to normal brain tissue and maximizing the ability to completely remove all tumor cells, this technology improves surgical outcomes and recovery.

Intraoperative Computed Tomography (iCT)

The SpineSUITE, the second smart operating suite at Sacred Heart Hospital combines the strength of the iCT with BrainLAB navigational technology providing high-resolution images in real time to our neurosurgical teams enabling them to perform extremely complex spine and trauma surgeries. The iCT allows our neurosurgeons to:

- see precisely where they are on the spine at any given time
- use smaller spinal exposures when performing surgery
- place spinal implants in a safer, more effective way and reduce reoperation rates to zero
- remove blood clots in cases of head trauma or in patients suffering certain types of stroke

Mechanical Embolus Removal of Cerebral Ischemia (MERCI) Retrieval System

The MERCI retrieval system is the first medical device approved by the United States Food and Drug Administration (FDA) to physically remove blood clots from the brains of people experiencing a certain type of stroke. Sacred Heart Hospital is the only hospital in western Wisconsin to offer the MERCI Retrieval System, which provides hope when the window of opportunity for conventional drug therapy has closed.

Intra-Arterial Cerebral Thrombolysis

Sacred Heart Hospital is also the only hospital in the area to offer a lifesaving intra-arterial cerebral thrombolysis procedure uses imaging technology to help physicians detect and then dissolve blood clots in the brain.

PET-CT

We are the first hospital in the area to offer PET-CT scans. A PET-CT is a scan that combines the images from a positron emission tomography (PET) scan and a computed tomography (CT) scan. Both scans are done at the same time. These scans are used to detect and determine the stage of cancer, determine whether cancerous cells have spread, and evaluate the effectiveness of cancer treatments. The scan is also used to guide some types of biopsies.

Full-Field Digital Mammography

- allows for faster and more accurate images
- shortens exam times and significantly improves comfort and convenience
- gives our physicians the ability to manipulate images for more accurate detection of breast cancer
- improves the contrast between dense and non-dense breast tissue
- is most effective and recommended for women younger than 50, those with dense breasts

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- gives our physicians the ability to manipulate images for more accurate detection of breast cancer
- improves the contrast between dense and non-dense breast tissue
- is most effective and recommended for women younger than 50, those with dense breasts and those who are pre-menopausal or peri-menopausal
- permits images to be transmitted over the phone lines or a network for remote consultation with other physicians

Mammatome-Assisted Breast Biopsy

If a lump or abnormality is detected, our physicians can conduct a minimally invasive mammatome-assisted breast biopsy. This procedure involves taking sample tissue from the suspicious area to determine whether the abnormality or lump is cancerous. A biopsy is currently the only way to accurately diagnose breast cancer. It is important to remember that most breast biopsies do not turn out to be cancer and that although a biopsy may be frightening, the results can provide much needed peace of mind. Mammatome-assisted breast biopsies:

- allow for precise analysis with minimal pain, scarring and recovery time
- usually take less than an hour
- permit patients to return to their normal daily activities immediately

Nuclear Medicine

In nuclear medicine imaging, very small amounts of radioactive isotopes are taken internally. Then, external detectors (gamma cameras) capture and form images from the radiation emitted by the isotopes to detect disease. This process is unlike a diagnostic X-ray where external radiation is passed through the body to form an image.

Bone Densitometer

A small amount of radiation is used to measure bone density.

Echocardiography

An ultrasound examination of the heart.

Interventional Radiology

Our physicians use interventional radiological imaging technologies to diagnose blockages in arteries and treat them with balloons, stents and catheter-delivered medications.

Ultrasound Imaging

Also call sonography, ultrasound involves exposing part of the body to high-frequency sound waves to produce pictures of the inside of the body.

Picture Archiving and Communication System (PACS)

This system acquires, transmits, stores, retrieves and displays digital images and related information from a variety of imaging sources and communicates the information over a network for physicians to access.

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Intraoperative computed tomography (iCT) is an imaging platform that allows acquisition of CT scan images during a surgery which can help ensure proper placement of hardware and precise positioning of instruments.

How does it work?

iCT is an image guided system which offers an integrated operating theater combining intraoperative CT-based imaging with sliding gantry, and a ceiling-mounted, frameless navigation system

Keys for investment success

- Assess local market position and decide if growing spine and neurosciences is a top priority for your institution
- Determine if case mix is amenable to iCT. What are main spinal/cranial procedures? Are majority of cases for pedicle screw instrumentation lower thoracic or lumbosacral?
- Given the high cost of iCT, anticipate if your institution will be able to capitalize on the improved efficiency and reduced reoperation rates that are part of the technology's value proposition
- Discuss the plans for the physical space and decide if there is room or plans to expand to accommodate the OR suite for iCT technology

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CLINICAL ARTICLE

Near-infrared indocyanine green videoangiography (ICGVA) and intraoperative computed tomography (iCT): are they complementary or competitive imaging techniques in aneurysm surgery?

Oliver Schnell · Dominik Morhard · Markus Holtmannspötter · Maximilian Reiser · Jörg-Christian Tonn · Christian Schichor

Received: 3 February 2012 / Accepted: 25 March 2012 / Published online: 13 July 2012

Abstract

Background In this pilot study we compared advantages and drawbacks of near-infrared indocyanine green videoangiography (ICGVA) and intraoperative computed tomography (iCT) to investigate if these are complementary or competitive methods to acquire immediate information about blood vessels and potential critical impairment of brain perfusion during vascular neurosurgery.

Methods A small subset of patients (n=10) were prospectively enrolled in this feasibility study and received ICGVA immediately after placement of the aneurysm clips. An intraoperative cranial CT angiography (iCTA) was followed by dynamic perfusion CT scan (iCTP) using a 40-slice, sliding-gantry, CT scanner. The vascular patency of major (aneurysm bearing) arteries, visualisation of arising perforating arteries and brain perfusion after clip application were analysed with both techniques.

Results The ICGVA was able to visualise blood flow and vascular patency of all major vessels and perforating arteries within the visual field of the microscope, but failed to display vessels located within deeper areas of the surgical field. Even small coverage with brain parenchyma impaired detection of vessels. With iCTA high image quality could be obtained in 7/10 cases of clipped aneurysms. Intraoperative CTA was not sufficiently evaluable in one PICA aneurysm and one case of a previously coiled recurrent aneurysm, due to extensive coil artefacts. Small, perforating arteries could not be detected with iCTA. Intraoperative CTP allowed the assessment of global blood flow and brain perfusion in sufficient quality in 5/10 cases, and enabled adequate intraoperative decision making.

Conclusion A combination of ICGVA and iCT is feasible, with very good diagnostic imaging quality associated with short acquisition time and little interference with the surgical workflow. Both techniques are complementary rather than competing analysing tools and help to assess information about local (ICGVA/iCTA) as well as regional (iCTA/iCTP) blood flow and cerebral perfusion immediately after clipping of intracranial aneurysms.

Keywords ICGVA · iCTA · Aneurysm clipping · Vascular neurosurgery

Introduction

Vascular neurosurgery for intracerebral aneurysms has considerably changed with the introduction of endovascular

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procedures. Improvement of these treatment options has broadened their range of indications in managing ruptured and unruptured aneurysms [10–12]. Due to comparable complication rates and outcome data for surgical and endovascular methods, there has been a growing tendency towards endovascular management [10]. As a consequence, neurosurgical operations are performed less frequently to clip aneurysms and, even more importantly, those aneurysms being selected for microsurgical clipping are more complex. Therefore, a decline in surgical expertise is assumed in the future [16], leading to fewer, but highly specialised neurovascular centres to compensate for this development. Whereas new endovascular treatment devices are permanently developed, technical improvements in clipping devices are rare. Most important developments in the surgical field have focused on intraoperative imaging to provide the neurosurgeon with information about residual filling or occlusion of branching arteries after clip positioning [1–3, 14, 15]. The use of intraoperative digital subtraction angiography (DSA) has been suggested for this purpose and had a significant impact on the neurosurgical procedure in as much as 34 % of cases [1, 2, 4]. Yet, due to limited availability and high technical complexity, its use as a routine procedure is limited. Moreover, it was shown that the detection of small branching and perforating arteries is restricted with intraoperative angiography [15]. Indocyanine green videoangiography (ICGVA) has been demonstrated to successfully visualise blood flow in small perforating vessels during intracranial vascular surgery [5, 7, 14, 15]. Due to its common use and fast application, it also reduced the time interval between positioning of the aneurysm clip and the possible repositioning in case of insufficient exclusion of the aneurysm or imminent ischaemia due to clip stenosis.

Recently, we could demonstrate, that both intraoperative computed tomography angiography (iCTA) and intraoperative perfusion computed tomography (iCTP) are feasible and provide valuable information without disturbing the surgical workflow [13]. Intraoperative CT imaging was shown to provide helpful information with a direct impact on intraoperative decision-making in order to maintain cerebral perfusion, thereby reducing the risk of iatrogenic ischaemia.

Although both indocyanine green videoangiography (ICGVA) and iCTA have demonstrated their value, the combination of both might be too time consuming and even redundant. Moreover, aneurysm treatment is contemplated more and more in the light of cost-effectiveness studies, where surgical clipping has been shown to be superior compared with coiling techniques. Therefore, we carried out this prospective study in a high-volume neurovascular centre in order to evaluate if ICGVA and iCT are redundant or complementary intraoperative imaging methods.

Materials and methods

Patients

During the study period, 72 patients with aneurysms were treated in our department, of whom ten patients (men/women: 3/7) with ruptured or unruptured (3/7) aneurysms were selected for this prospective feasibility study to obtain intraoperative imaging data with all modalities (ICGVA, iCTA, iCTP). A total of ten aneurysms were operated on in the following locations: middle cerebral artery (MCA; n=2; left/right: 2/0), internal carotid artery (ICA; n=4; 1/3), anterior cerebral artery (ACA; n=1; 0/1), anterior communicating artery (ACOM; n=2; 1/1) and posterior inferior cerebellar artery (PICA; n=1; 0/1). One patient with a right-sided ICA aneurysm had been treated by endovascular coiling 9 months before, and one patient had previous subarachnoid haemorrhage from another aneurysm. The mean age at the time of surgery was 52 years (range: 35–72). Clinical data from all patients are summarised in Table 1. All patients had signed informed consent for all intraoperative imaging techniques. The legal requirements of the state and the board of physicians regarding storage of data and radiation exposure were met.

Indocyanine green videoangiography (ICGVA)

For ICGVA, the operative microscopes were equipped to acquire, process and store ICG fluorescence images with high resolution and contrast (Pentero; Carl Zeiss Meditec, Jena, Germany). Therefore, after the aneurysm has been clipped, a bolus of fluorescent indocyanine green (absorption peak 805 nm, emission peak 835 nm) was injected intravenously in a dosage of approximately 0.2–0.5 mg/kg b.w., as already described by others [14]. The ICG fluorescence was visualised in real-time and recorded by the integrated unit. Images were then repeatedly displayed for evaluation of the visualisation quality, especially of the minor vessels and to have a closer look on the initial inflow of the fluorescent dye.

Intraoperative computed tomography angiography (iCTA) and perfusion computed tomography (iCTP)

Intraoperative CTA was performed in a specifically equipped operating room (OR), as described previously [17]. In short, a sliding gantry of a 40-slice CT scanner with an 82-cm bore diameter (Somatom Open Sliding Gantry; Siemens Medical Solutions, Erlangen, USA) is installed on rails to move over an adjustable radiolucent carbon operating table (Trumpf, Ditzingen, Germany) where the patient's head is fixed in a radiolucent headclamp (Mayfield® radiolucent skull clamp A-2002; Integra, Plainsboro, NJ, USA).

Table 1 Relevant clinical data of patients included in this study

Patient	Age (years)	Sex	Localisation of aneurysm	Affected side	Ruptured/ unruptured	Past cerebrovascular history	ICGVA reliable	iCTA reliable	iCTP reliable
1	57	F	MCA	Left	Unruptured	Previous SAH of other aneurysm 12 months earlier → clipping of 2 right sided MCA aneurysms → new aneurysm in DSA (regular control)	+	+	+
2	35	F	ICA	Right	Unruptured	Previous SAH of same aneurysm 9 months earlier → coiling → recurrent aneurysm in DSA (regular control)	+	−	+
3	46	F	ICA	Right	Unruptured	None	+	+	+
4	72	M	ACA	Right	Ruptured	None	−	+	+
5	48	F	ACOM	Left	Unruptured	None	+	−	+
6	48	F	ICA	Right	Unruptured	None	+	+	+
7	52	F	MCA	Left	Unruptured	None	+	+	+
8	61	F	PICA	Right	Unruptured	None	+	−	−
9	37	M	ACOM	Right	Ruptured	None	+	+	−
10	50	M	ICA	Left	Ruptured	None	−	+	+

F female, *M* male, *MCA* middle cerebral artery, *ICA* internal carotid artery, *ACA* anterior cerebral artery, *ACOM* anterior communicating artery, *SAH* subarachnoid haemorrhage, *DSA* digital subtraction angiography

ICGVA, iCTA and iCTP were evaluated and rated as reliable (+) or unreliable (−) for intraoperative decision making for each patient

For iCT scanning, all metal-containing instruments were removed in the close vicinity of the scanned area (field of view) and the operative field was covered with an additional sterile drape. Then, a CT scout of the head and upper neck was followed by caudo-cranial CTA with scan range from C1 to vertex. CT-adjusted injection of iodine contrast medium was carried out, employing a dual-head motor pump (Stellant; Medrad, Volkach Germany) and a bolus-tracking technique to achieve high-contrast attenuation values in the cerebral arteries and low overlay in the veins and sinus. The CTA was then started manually (collimation of 40×0.6 mm at 120 kV, 120mAs, pitch 1.1 and a rotation time of 0.5 s, resulting in a normalised effective dose of approximately 0.5 mSv) and an automated contrast agent injection was done by using a dedicated weight-adapted protocol (1.35 ml contrast agent per 1 kg body weight Imeron 300 [Bracco-Altana-Pharma, Konstanz, Germany], respectively 0.4 g iodine per 1 kg bodyweight at an injection rate of 6.0 ml/s, followed by 100 ml saline at 6.0 ml/s). Intraoperative CTP was performed after iCTA with a scan range starting 1 cm cranial to the aneurysm clip with a distance of at least 1 cm to the head clamps. Two 14.4-mm-thick slices were acquired every second for 40s using 80 kV and 200mAs with a total collimation of 24×1.2 mm, resulting in a normalised effective dose of approximately 3.2 mSv. Perfusion scanning started 5 s after injection of 50 ml contrast agent (Imeron 300) at 7 ml/s and a saline flush of 50 ml at 7 ml/s. After iCT, the additional drape was removed, the table repositioned and the surgical procedure resumed.

Reconstruction of CT raw data and image analysis

Image analysis was performed immediately after the scanning procedure by the neuroradiologist, in close collaboration with the neurosurgeon. Special attention was paid to the assessment or exclusion of residual aneurysm parts and impaired brain perfusion. Slice thickness for axial reformations was 1.0 mm with an increment of 0.75 mm, which were then loaded into a standard 3D workstation (Syngo MMWP, Siemens Medical Solutions, Erlangen, Germany), allowing cross-sectional viewing of multiplanar reconstructions (MPRs) in the sliding thin-slap technique, as well as reconstructions using volume rendering technique (VRT). Maximum intensity projections (MIPs) were calculated in all three planes with a slice thickness and increment of 2.5 mm. A standard, vendor given PCT analysis software was used for perfusion analysis. Colour-coded parameter-maps of cerebral blood flow (CBF), cerebral blood volume (CBV) and time to peak (TTP) were calculated.

Results

ICGVA

ICGVA was applicable for every location within the skull with high quality. It led to good visualisation of the aneurysm bearing as well as most major or perforating arteries within the field of view in 8/10 patients. On the other hand, ICGVA failed to display any vessel beyond the microscopic field and even minor overlay with brain parenchyma, endovascular coils or aneurysm clips (1/10; Table 1, patient no. 10) impaired detection of ICG within the vessels. ICGVA may also not be able to demonstrate functionally sufficient patency of branching arteries within the visual field, as has been the case in 1/10 patients (Fig. 3, Table 1, no. 4) in our series. In this case, ICGVA displayed good ICG fluorescence in the branching artery after clip application to occlude a right-sided pericallosal aneurysm. Yet, this was not functionally sufficient to avoid ischaemia in the depending area (Fig. 3), even if routine micro-Doppler did also not indicate altered blood flow due to relevant stenosis when applied before and after clip application. Hence, ICGVA may be technically easily applicable in all patients to display most arteries within the visual field but may not indicate haemodynamically relevant stenoses of arteries extending beyond the visual field and might therefore miss critical brain perfusion within distant brain areas.

iCTA

Intraoperative CTA was performed with adequate imaging quality in 7/10 patients. Decision-making was not possible in 1/1 patient with a PICA aneurysm of the posterior fossa (Table 1, patient no. 8), since beam-hardening artefacts originating from the petrosal bone were present. Additionally, 1/9 patients with supratentorially located aneurysms could not be properly evaluated in iCTA due to previous endovascular coiling (Fig. 1, Table 1, no. 2), which led to extensive imaging artefacts. Moreover, iCTA revealed insufficient reliability in the detection of small (perforating) arteries <1 mm diameter (e.g. A. recurrens Heubneri) as demonstrated in one case, in which undetected stenosis by clip application in a small perforation artery resulted in surgery-related ischaemia of one patient (Table 1, no. 5). Of

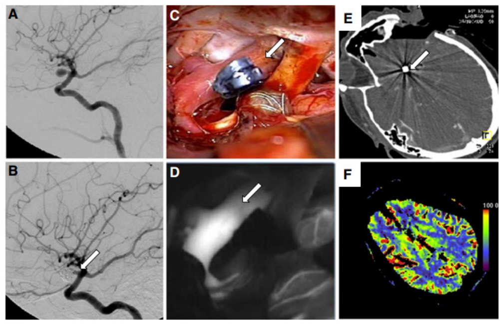

Fig. 1 Patient (Table 1, no. 2) with recurrent aneurysm of the ICA/ophthalmic artery. Pre-interventional DSA (**a**) of an unruptured aneurysm which had been treated endovascularly but developed a recurrence at the entrance (**b**). After clip placement (**c**), ICGVA was applied (**d**) and demonstrated patency of the branching artery (*arrow*) without signs of stenosis. In contrast, iCTA (**e**) was not evaluable due to coil artefacts (*arrow*). Intraoperative CTP (**f**), which was applied in ICA/MCA segments, did not show artefacts due to clip or coil placement

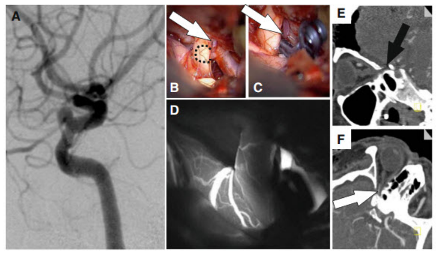

Fig. 2 Preoperative DSA (**a**) revealed untreated, unruptured aneurysm of the ICA/ophthalmic artery in this patient (Table 1, no. 6). Intraoperatively, the aneurysm (*dashed line*) was hidden underneath the right optic nerve (**b**). After application of the aneurysm clip (**c**) intraoperative micro-Doppler demonstrated patency of the ophtalmic artery, which was confirmed by ICGVA (**d**). Whereas branching of the ophthalmic artery could not be detected in the sagittal plane of the iCTA (**e**, *black arrow*), the intraorbital course of the artery was clearly detectable (**f**, *white arrow*). Intraoperative CTP was properly evaluable but did not reveal additional information in this context

note, intraoperative ICGVA and micro-Doppler analysis also did not reveal this relevant stenosis, leading to small infarction of the caudate nucleus but without neurological deficits.

All other imaging studies in the supratentorial region were of adequate quality for intraoperative decision-making and in 6/9 patients with supratentorial aneurysms the parent and branching vessels were sufficiently displayed after clip placement. Yet, as shown in Fig. 2 (Table 1, patient no. 6), direct visualisation of aneurysm-bearing small arteries at the skull base (e.g. ophthalmic artery) could be impaired after clip application. In this patient, branching of the ophthalmic artery could not be detected in the sagittal plane of the iCTA, but relevant stenosis of the ophthalmic artery could be excluded by use of iCTA due to contrast enhancement of more distal parts of the artery in its intraorbital course. Micro-Doppler and ICGVA also demonstrated patency of the ophthalmic artery after application of the aneurysm clip.

iCTP

In contrast to ICGVA and iCTA, iCTP resulted in good visualisation of the regional brain perfusion in 8/9 patients with supratentorial aneurysms. Impairment of imaging quality by coil or clip artefacts could be avoided in these cases due to the distant region of interest. Yet, the analysed area is limited to a maximum of 28.8-mm-thick brain region in caudo-cranial extension and the region of interest has to be chosen with care in order to display the relevant brain areas. Retrospectively, this was not done properly in one patient with an ACOM aneurysm in our series (Table 1, no. 9). Nevertheless, iCTP detected clipping related perfusion deficits in one patient where this became imminent, as shown in Fig. 3 (Table 1, no. 4). In this patient, ICGVA displayed good ICG fluorescence and intraoperative micro-Doppler assumed good local blood flow in one small perforating artery, which was assumed to be too small to be visualised by iCTA (Fig. 3d). Therefore, since ICGVA and micro-Doppler did not indicate haemodynamically relevant stenosis and iCTA was thought to be technically insufficient to display this small branching vessel, the neurosurgeon did not believe in the results of the iCTP, which was considered not to be of sufficient quality for detection of this small vessel. Shortly after surgery cerebral infarction of the depending area became obvious on a regular postoperative CT but, fortunately, the patient recovered without any symptoms. As already demonstrated for iCTA, iCTP could also not be employed for decision-making in one patient with a PICA aneurysm of the posterior fossa due to beam hardening artefacts.

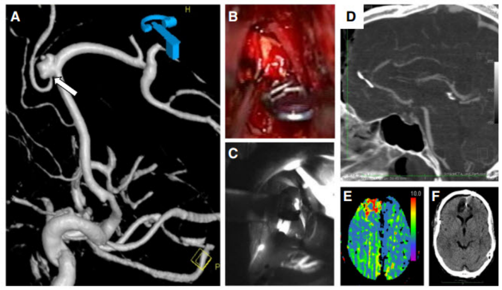

Fig. 3 Complex aneurysm of the pericallosal artery as displayed by 3D reconstruction of DSA in this patient (Table 1, no. 4) (**a**). Patency of the branching artery was analysed by use of intraoperative micro-Doppler after aneurysm clipping (**b**) and ICGVA (**c**). Both methods assumed good local blood flow in one small perforating artery during surgery, which was not seen in the iCTA (**d**). Since intraoperative micro-Doppler and ICGVA did not reveal haemodynamically relevant stenosis, the neurosurgeon did not believe the results of the iCTA, which was considered not sufficient enough for detection of this small vessel, although iCTP (**e**) demonstrated perfusion deficit. Shortly after surgery infarction occurred in the postoperative CT (**f**). Luckily, there was no clinical correlation and the patient recovered without symptoms

Discussion

Worldwide, digital subtraction angiography (DSA) is still considered as the "gold standard" for the detection of cerebral aneurysms after subarachnoid haemorrhage. It is also recommended to monitor surgical results after aneurysm clipping either intraoperatively or postoperatively [2, 8, 9, 19]. Yet, intraoperative DSA is not available in all centres and is also not considered a routine method for all cases due to its invasive and time-consuming nature. Therefore, alternative methods to acquire reliable results during surgical intervention are most desirable.

Both techniques investigated in this study (ICGVA and iCTA/iCTP) have been described as fast and reliable with an impact on intraoperative decision-making [7, 14, 15, 17]. However, one might assume that application of both techniques is redundant and too time-consuming during vascular neurosurgery for aneurysm clipping. Since clinical guidelines are missing, high expenses like installation of specifically ICGVA-equipped microscopes or, even more, iCT have to be decided with care since there is no evidence so far to show superiority of one technique over the other. In our study, we investigated for the first time feasibility and usefulness of ICGVA and iCT during aneurysm surgery and we evaluated indications and limitations for each imaging method.

ICGVA has been implemented into aneurysm surgery [13, 14] and has become a routine procedure for most vascular neurosurgeons [14, 15]. It also provided valuable information in 8/10 patients of our series. Yet, even if it has the advantage that it can be easily embedded into the surgical workflow, in line with previous reports on the use of ICGVA during vascular neurosurgery [5, 14, 15], it only helped to identify the local anatomy and vascular patency of those vessels within the visual field of the operative microscope. Moreover, these problems are even more severe, if the aneurysm clip has been applied in the operative field. Therefore, these limitations may sometimes indicate an additional DSA, for example when the aneurysm or its branching vessels are located in the depth of the operative field or when the aneurysm is hidden behind relevant brain structures.

CTA has been demonstrated to be equally sensitive for detection of intracranial aneurysms larger than 3 mm [6] and it allows to display small aneurysm remnants even after clipping with adequate results [20]. Since CTA is also less invasive than DSA, all together these capabilities would render CTA an ideal method for this purpose. However, it has not been used for intraoperative imaging in this context so far [18]. In this study, intraoperative imaging using iCTA was acceptable for decision-making in 7/10 patients but failed in one patient with a previously coiled supratentorial aneurysm and in one case with an infratentorial aneurysm localisation due to beam hardening artefacts by the petrosal bone. Local conditions within the operative field like the assessment of an aneurysm remnant or clip stenosis could well be detected in these cases by iCTA as demonstrated, for example, in Fig. 2. Moreover, patency of small branching arteries >1 mm could also be assessed even near the anterior skull base, but it has to be admitted that ICGVA was of greater use in this context (Fig. 1). For all that, iCTA provided additional information in two patients in our small series of ten representative cases. In one patient, patency of the ophthalmic artery was demonstrated by its intraorbital course, which was not possible to be verified by ICGVA alone (Fig. 2, Table 1, no. 6). In another case, iCTA did correctly indicate insufficient blood flow of a branching artery after clip application, whereas ICGVA did demonstrate good fluorescence simulating sufficient blood supply for the depending brain area (Fig. 3). Remarkably, imaging quality was not reduced due to clip artefacts in the region of interest (ROI) in any patient in our cohort, even if such drawbacks have been reported [13]. Artefacts due to previously coiled aneurysms made decision making via iCTA impossible though (Fig. 1). We would therefore recommend additional iCTA if patency of the aneurysm or branching arteries cannot be definitely confirmed by ICGVA and perforating arteries have a diameter >1 mm.

In addition to the intraoperative application of CTA, which has been demonstrated to be of great use in selected and complex aneurysms, iCTP has not been investigated previously. One major advantage of iCTP is that it is performed distant from the CT plane with clips or coils, so that image quality is not degraded due to clip or coil artefacts (Fig. 3). Therefore, it yields crucial information about distant and regional blood flow in dependent areas of even small branching and perforating arteries. This was demonstrated quite obviously in one of our cases (Fig. 3, Table 1, patient no. 4), where ICGVA and micro-Doppler did not indicate haemodynamically relevant stenosis and iCTA was thought to be technically insufficient to display this small branching vessel. As a matter of fact, the neurosurgeon did not believe in the results of the iCTP, which was considered not to be of sufficient quality for detection of this small vessel by the neurosurgeon and the neuroradiologist. On the other hand, one has to keep in mind that calculation of cerebral blood volume (CBV) and cerebral blood flow (CBF), as well as time-to peak (TTP), may need up to 1 min, and the time required for proper evaluation may exceed that acceptable for decision of clip repositioning. Therefore, scanning protocols—especially for iCTP—have to be prepared during skull opening by the technician or neuroradiologist to assure that contrast medium infusion will be applicable immediately after clipping of the aneurysm. Additionally, data acquisition has to be performed by an experienced neuroradiologist and preliminary calculations or incorrect detection of the depending ROI might mislead the neurosurgeon to unjustified security (Table 1, patient no. 9). In our opinion, iCTP is therefore indicated in patients with complex or previously coiled or clipped aneurysms, especially if these are located near small branching or perforating arteries, which cannot be displayed by ICGVA or iCTA. If reconstruction of a larger aneurysm-bearing artery will be necessary, iCTP might also be helpful in order to obtain information about the regional and global blood flow of the depending brain areas. In these cases, longer acquisition time will be counterbalanced by the benefit to be able to replace the aneurysm clip in due time.

Conclusion

Combination of ICGVA and iCTA/iCTP is feasible with very good diagnostic imaging quality associated with short acquisition time and little interference with surgical workflow. Each method has its indications and limitations which have to be taken into account for intraoperative decision-making. ICGVA represents a modern standard procedure for analysis of local vessel patency, whereas iCTA/iCTP additionally supply information on dependent cerebral perfusion, which might be helpful in selected complex vascular neurosurgical cases in specialised centres.

Conflicts of interest None.

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Comment

The comparison of the described techniques is of scientific interest and iCTA may definitely be helpful for the vascular neurosurgeon in some special situations in addition to or instead of the other techniques with their limitations. The problem may be that we do not know without intraoperative—and also somewhat time-consuming—conventional angiography which of the techniques (ICGVA or iCTA) is to be trusted during surgery. With usually limited resources, the purchase of the relatively slow and complex technique of iCTA would further increase the indirect expenses of clipping in addition to already having the expensive microscopes equipped with ICGVA. Naturally, patient safety comes first, but it is doubtful whether iCTA is a necessity in everyday practice, even in a dedicated neurovascular centres.

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ORIGINAL ARTICLE

A prospective study on the use of intraoperative computed tomography (iCT) for image-guided placement of thoracic pedicle screws

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Abstract

Background. **Placement of thoracic pedicle screws is a technically demanding procedure. The risk of thoracic pedicle breaches range from 6.5 to 41%. Current image guidance systems consist of computer based systems utilizing preoperative CT scans or 2D/3D intraoperative fluoroscopy.** ***Objective.*** **The aim of this prospective study was to evaluate the clinical feasibility and accuracy of a new intraoperative CT (iCT) based image guidance system for thoracic pedicle screw instrumentation.** ***Methods.*** **We prospectively studied the use of iCT for the first 43 consecutive cases for which thoracic pedicle screws were inserted as part of the instrumentation for spinal fusion between April 2008 and July 2011. In every case, a post-instrumentation intraoperative check CT was done before wound closure to assess accuracy of implant placement. Outcomes were analysed with regards to the incidence of pedicle wall violations detected on intraoperative check CT imaging, and the rate of immediate intraoperative revision of misplaced screws. Pedicle violations were graded according to an established classification system,** ***Results.*** **A total of 261 thoracic pedicle screws (T1–T12) were inserted in 43 patients (age range 13–83). Mean follow-up was 12 months. There were 7 (2.7%) pedicle violations detected on the intraoperative check CT. Out of the seven, three were grade I (< 2 mm), two were grade II (2–4 mm) and rest two were grade III (> 4 mm) violations. Only four of the screws (1.5%) that breached the pedicle wall by more than 2 mm were immediately revised before wound closure.** ***Conclusion.*** **The iCT based spinal neuronavigation system allowed for highly safe and accurate placement (97.3%) of thoracic pedicle screws in our institution with no neurovascular injury reported.**

Keywords: intraoperative CT; thoracic pedicle screw; image guided spine surgery; spine navigation

Introduction

To date, intraoperative CT scanning (iCT) with neuronavigation has been utilized mainly for cranial procedures. However, in some centres a mobile helical CT scanner has been used in spinal procedures.[1] Frameless stereotactic image-guidance has also been used with increasing frequency to improve the accuracy of placement of internal fixation devices during spine surgery.[2] This was stimulated by the evidence of pedicle screw misplacements using conventional techniques. The initial use of pedicle screws, which began in the lumbar spine was not without complications. Weinstein et al. as well as Shcluze et al. showed approximately 20% of lumbar pedicle screws had perforated the pedicle wall in their series.[3,4] Roy-Camille et al. reported that 10% of transpedicular screws in their early series were incorrectly placed.[5]

Despite this initial difficulty, as surgeons became more familiar with the complex anatomy required for safe pedicle screw placement, they progressed to the placement of thoracolumbar as well as thoracic pedicle screws.[6,7] The placement of thoracic pedicle as well as cervical pedicle screws are technically more challenging. As such, technological aids have been constantly developed to ensure safer and more accurate placement of pedicle screws.

One such technological aid that is used to increase the safety of pedicle screw placement is stimulus-evoked EMG monitoring.[8] Although it is a promising technique, a breach may have already occurred before electrophysiological detection. Another technological aid that is being employed is a CT based computer assisted navigation system, which requires registration of anatomic fiducials in different planes based on preoperative acquired CT data.[9,10] The drawback of this system is that the preoperatively acquired CT data is obtained with the patient supine but the surgery is often carried out with the patient positioned prone leading to inaccuracies of the image guidance.

We have used in our institution since April 2008 an intraoperative CT scan (iCT) based spinal image-guidance system in 43 consecutive surgeries that required thoracic pedicle screw instrumentation. The technique is performed in our new operative theatre suite equipped with a CT scanner interfaced with an image guidance system allowing rapid scanning of the sterile surgical field. This application allows image guided placement of pedicle screws as well as intraoperative assessment of the accuracy of placement.

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Materials and methodology

We did a prospective study on the use of our iCT based image guidance system (BrainLab®) for the first 43 consecutive cases for which pedicle screws were inserted as part of the instrumentation for spinal fusion from April 2008 to July 2011. All operations were carried out by a single surgeon (RT). The study was approved by the institutional ethics review board.

Intraoperative CT scan

The CT scan is a 24-slice helical intraoperative scanner that moves on fixed rails on the floor. The aperture of the gantry is 80 cm. Protocols for imaging of the spine are available with slice thickness options of 1.5 mm, 3 mm or 5 mm. All our cases were scanned at 1.5-mm intervals, and the images are then reconstructed in axial, coronal and sagittal planes. These images can be transferred to the Vector Vision image guidance system (BrainLab®) via the paxter server for purposes of intraoperative navigation. The layout of the operating theatre is as shown in Fig. 1A. Image acquisition time was less than a minute in all cases. Image transfer time to the navigation station was also less than a minute in all cases. Overall time from point at which decision was made for scan to image transfer was less than 7 minutes in all cases.

The patient can be scanned in the supine, lateral or prone position. We routinely performed a test movement of the CT gantry over the radiolucent operative table prior to sterile preparation. For upper thoracic instrumentation cases, the head is secured in a radiolucent head frame. An initial scout film is taken using the CT to localize the level of surgical interest with the help of skin markers if required. This is used to help plan the skin incision over the appropriate spinal level (Fig. 1B), thereby minimizing the length of the incision.

CT scan and image guidance procedure

After the initial skin incision followed by subperiosteal muscle elevation, an intraoperative scan is performed with the radiolucent reference frame clamped to one of the spinous process, usually the most proximal or distal one in the exposure (Fig. 2B). The operative site is covered with sterile drapes, and the scanner is then moved over the region of interest. The CT marker fiducials as well as the tracker balls on the reference frame are detected by the optical camera, which allows for autoregistration (Fig. 2A). During the scan, the patient's tidal ventilation volume is reduced by 50% for about 30 seconds by the anaesthetist in order to minimize movement of the spinal column. The operating theatre team and anaesthetic staff would observe the scan proceedings from the workstation, which is shielded. The anaesthetic monitors and patient would be clearly visible through the glass panel above the workstation thus ensuring patient safety.

After image acquisition and transfer via the paxter server to the image guidance system, the autoregistration process completes. Up to 10 vertebral levels can be localized in a single image acquisition. The accuracy of the autoregistration process is verified by placing the pointer on known anatomical landmarks at the operative site and ensuring that the position displayed on the image guidance screen corresponds to the actual pointer position. All vertebral levels above and below the level of the reference frame, which is clamped onto one of the spinous processes, are tested if instrumentation was planned at these levels. Only after the surgeon is confident of the accuracy of the autoregistration process, does he then proceed with the pedicle screw insertion under image guidance.

Coronal, axial, sagittal and trajectory views are available to the surgeon in 'real time' during drilling, tapping and placement of instrumentation. Prior to placement of the pedicle screws, the pedicle tract is palpated for cortical breaches using a ball tipped feeler probe. Using the intraoperatively acquired CT images and navigation, the senior surgeon (RT) would plan and execute a trajectory that allows for maximum triangulation along the axial plane. The trajectory of the screw would also be parallel to the end plate along the sagittal plane. This ensures a more biomechanically stable construct. After placement of all the pedicle screws, the operative site is covered with a sterile adhesive drape and an intraoperative check CT scan would be done to confirm proper placement of the screws prior to wound closure. The decision to intraoperatively revise a misplaced screw was dependant on the intraoperative check CT findings. All grade II and III breaches were revised to improve the biomechanical stability of the construct. Worrisome medial cortical breaches of more than 2 mm are immediately revised as well although the neural structures have already potentially been damaged.

Analysis

Data was collected with regards to patient demographics, clinical presentation, preoperative imaging, intraoperative use of image guidance, intraoperative imaging for implant accuracy assessment and postoperative sequelae. Outcomes

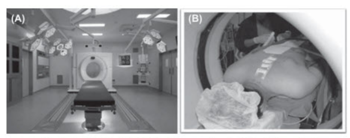

Fig. 1. (A) The CT scan moves on fixed rails. The 3D optical LED localizer as well as the Vector Vision navigation screen are ceiling mounted. (B) Scout CT being performed with fiducial skin markers to localize the lesion level.

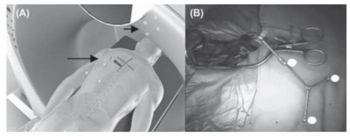

Fig. 2. (A) Both the CT marker structures (short arrow) as well as reference star on spine clamp (long arrow) are detected by the optical camera allowing for subsequent autoregistration. (B) Radiolucent spine clamp *in-situ*.

were analysed with regards to the intraoperative pedicle screw breach rate, the intraoperative pedicle screw revision rate and the final pedicle screw breach rate. The intraoperative pedicle screw breach rate was defined as the incidence of pedicle violations detected on the intraoperative post-instrumentation check CT prior to wound closure. All cases had fine cut (1.5 mm) intraoperative CT of the spine, which was used to evaluate for pedicle breaches in axial, coronal and sagittal planes. Pedicle breaches were graded by an independent blinded reviewer according to the system described by Mirza et al.[11] A breach of < 2 mm is considered grade I, a breach of 2–4 mm is considered grade II and a breach of > 4 mm is considered grade III.[11] The intraoperative pedicle screw revision rate was defined as the number of malpositioned screws that were intraoperatively revised following the intraoperative post-instrumentation check CT over the total number of pedicle screws placed. The final pedicle screw breach rate was defined as the incidence of pedicle breaches detected on the final postoperative check CT, which was analysed and graded similarly as described above. Post-operative complications inclusive of worsening of any pre-operative neurological deficits were also noted. The mean follow-up period was calculated from the interval between surgery and the last complete clinical outcome. All patients had follow-up radiographs in the outpatient clinic evaluated for the presence of instrumentation failure and pseudoarthrosis.

Results

All surgeries were performed by the same surgeon (RT). A total of 261 thoracic pedicle screws were inserted for 43 consecutive patients from April 2008 to July 2011. Etiology of the cases is presented in Table I. The vast majority of the instrumented cases were for spinal metastasis mainly due to our referral base from the National Cancer Centre in close proximity.

Mean age of the patients was 52 years (range 13–83). Mean clinical follow-up was 12 months (range 1–19). There was one technical failure related to the use of the intraoperative CT scanner. The spinal reference clamp was not securely fastened leading to inaccuracy of the image guidance, which was identified during the verification process. This was corrected for and a repeat scan was performed. There was no failure of the image guidance system and the autoregistration process for all cases. In all 43 cases, verification of the autoregistration process was done by pointing the probe tip to visualized anatomical landmarks. There was no discordance between the image data set and the surgical anatomy noted in our series.

Of the 261 pedicle screws inserted, there were a total of 7 pedicle screw violations detected on the intraoperative check CT imaging prior to wound closure (Table II) giving an intraoperative pedicle screw breach rate of 2.7%.

Overall, out of the seven pedicle screw violations detected on intraoperative CT imaging, the three pedicle screws with grade I (< 2 mm) cut outs were left *in-situ*. However, the four pedicle screws that caused grade II and grade III violations were replaced immediately intraoperatively before wound closure allowing for subsequent satisfactory imaging, an example of which is shown (Fig. 3). The intraoperative pedicle screw revision rate was thus 4 out of 261 screws or 1.5%. Of the four pedicle screws with major cut out (grade II and III), two of them occurred when instrumenting more than six vertebral levels away from the site of the reference clamp.

When taking into account the immediate correction of the four grade II and III malpositioned screws in our study, our final pedicle screw breach rate based on the postoperative CT scan is 1.2% with all pedicle violations being minor grade I cut outs.

Table I. Etiology of cases.

Etiology of cases	No of patients (n = 40)
Metastasis	29
Abscess	1
Trauma	2
Nerve sheath tumour (Dumbbell)	7
Primary bone tumour	1

Table II. Breakdown of pedicle screw violations detected on intraoperative CT scan.

		Pedicle screw violations		
Level	No. of screws	< 2 mm	2–4 mm	> 4 mm
T1	28	0	0	1
T2	40	0	0	1
T3	18	0	0	0
T4	12	0	0	0
T5	16	0	0	0
T6	24	1	1	0
T7	24	0	1	0
T8	14	0	0	0
T9	12	1	0	0
T10	22	1	0	0
T11	16	0	0	0
T12	18	0	0	0
Total	246		7 (2.9%)	

T represents the thoracic screws used.

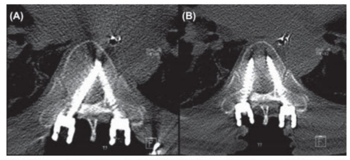

Fig. 3. (A) Grade III pedicle screw violation detected on iCT. (B) Final iCT image after replacement of the screw with a new trajectory.

None of the pedicle screw violations detected on the intraoperative CT imaging was associated with any post-operative neurological deficit including the two grade III violations, which was corrected immediately as depicted in Fig. 3. There was one case of a superficial wound infection in the elderly lady, which was resolved following a course of antibiotics. It was also noted that five out of our seven pedicle screw breaches occurred in the first 21 cases (126 screws) of our series. This was, however, not statistically significant ($p = 0.2$).

The vast majority of our cases were that of spinal metastasis, which required excision as well as posterior instrumented stabilization as shown in Figs. 4 and 5.

Routine radiographs of all the cases during outpatient follow-up did not reveal any failure of instrumentation or pseudoarthrosis.

Discussion

The placement of thoracic pedicle screws is a challenging procedure for a number of reasons. The anatomy of the thoracic spine, in particular, the thoracic pedicle undergoes great variability from the first thoracic vertebrae to the twelfth. The diameters of thoracic pedicles are also significantly smaller than lumbar pedicles. Furthermore, in the Asian population, the thoracic pedicle diameters are on average 30% smaller than the pedicles in the Western community.[12] The smallest average pedicle width in Asians range from 3.6 mm to 4.3 mm at T5.[13,14] In our study, the smallest pedicle width for which we inserted a pedicle screw was 4 mm. We avoided screw insertion at a particular level if the pedicle diameter measured less than 4 mm on the CT scan images.

The various studies on free hand placement of thoracic pedicle screws have shown a high variability in screw cut out rates ranging from 6.5% to 41%.[6,7] In the thorax, the proximity of vital structures such as the aorta, pleura, spinal cord and nerve roots makes the potential consequence of a misplaced screw disastrous.

Although intraoperative fluoroscopy has been widely adopted in an attempt to improve precision, thoracic pedicle screw cortical breach rates of up to 69% have been reported especially for the upper thoracic spine.[15] In another study using intraoperative fluoroscopy by Guzey et al., screw cut out rates of 27.4% from T2–T5 and 14.5% from T6–T8 were described.[16] The reasons for these high rates of screw malposition are quite intuitive. Pedicle screw insertion is a technically demanding procedure that requires the spinal surgeon to have spatial orientation to the part of the spinal anatomy that is not exposed in the surgical field. Even with two dimensional (2D) imaging available via fluoroscopy, the third dimension is extrapolated based on the surgeon's interpretation of the images as well as knowledge of the anatomy, and this is tempered somewhat by his experience. In one recent study, it was shown that there was a trend towards decreased pedicle screw breach rate as surgeon experience increased.[17]

Furthermore, for pedicle screw fixation procedures, it is the axial plane that is critical, and this is not reliably

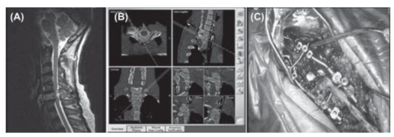

Fig. 4. (A) A MRI of the cervical spine showing an extradural tumour compressing spinal cord. (B) Pedicle finder advanced under image guidance. (C) Intraoperative view of final construct.

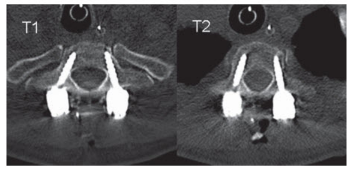

Fig. 5. Postoperative CT axial spine showing satisfactory placement of T1–2 pedicle screw.

shown using conventional fluoroscopic or x-ray imaging. It therefore comes as no surprise that stereotaxy with 3D image guidance which was once solely the domain of the cranial surgeon has now been used with increasing frequency in spinal pedicle screw instrumentation in an attempt to improve accuracy of placement.[18–22] Spinal stereotaxy with 3D image guidance has now evolved into two separate systems, one based on pre-operative computed tomographic images with intraoperative registration to the surgical space and the other based on intraoperative virtual or 3D fluoroscopic imaging.[18–22]

In the spinal navigation based on preoperatively acquired CT imaging, the rigid bony anatomy of the spine itself serves as a frame of reference. There are currently two separate registration techniques available. One is the 'paired-point' registration, which involves selecting a series of corresponding points, usually spinous process, facet joint, lamina on the CT imaging data set and localizing the corresponding points on the surgically exposed spinal anatomy. The second technique is that of 'surface mapping' whereby multiple non-discreet points on the exposed surgical anatomy are selected.[23]

In the intraoperative 3D fluoroscopy based system such as the C-arm (Siemens, Erlangen, Germany) or O-arm (Medtronic Inc), there is no need for 'paired-point' or 'surface-mapping' registration and multiple vertebral levels can be autoregistered at once.

Our intraoperative CT based image guidance system is in essence a marriage of the two systems described above. With the availability of an intraoperative CT scanner with fiducial marker structures as well as a radiolucent spinal reference frame, autoregistration of the imaging data set with the surgical field is possible with computational software. Furthermore, vertebral levels above and below the reference clamp that were included during the intraoperative scanning process are also autoregistered. This single-time multilevel autoregistration process significantly reduces the time taken for getting the navigation system up and running. Moreover, the need for re-registration for each vertebral level is negated, thereby facilitating the flow of surgery.

In all our cases, the intraoperative CT imaging together with the image guidance system allowed trajectory planning using axial as well as sagittal and coronal planes. The tip of the "virtual" screw could be visualized on the image guidance screen as one inserts the real screw through the pedicle. When comparing imaging produced by intraoperative cone beam 3D fluoroscopic systems, with that of intraoperative CT(iCT) imaging, we find that the intraoperative CT produces much better quality imaging. This is especially evident when imaging the upper thoracic, and high cervical spine. Nearly half (47.5%) of the pedicle screws inserted in this study were in the upper thoracic spine (T1–T5).

The 3D planning function on the image guidance system allows us to maximize the diameter of the pedicle screws to be placed into the spine. In addition, it allows us to plan and safely execute a more medial trajectory of pedicle screw insertion. It has been shown biomechanically that a more medial triangulation of the pedicle screws improves the overall pull-out strength of the construct.[24,25] Further strength to the construct can be afforded by placing the transpedicular screw parallel to the endplate rather than down the axis of the pedicle.[26] This can be achieved by utilizing the sagittal reconstructions provided by the image guidance system.

Another advantage of having an intraoperative CT based image guidance system is that the CT images used for navigation are acquired in the surgical prone position. This reduces the intervertebral motion errors, which are inherent in systems that use preoperative CT imaging data, which are acquired in a supine position for intraoperative image registration.

In terms of pedicle screw placement accuracy, our intraoperative pedicle screw breach rates of 2.7% based on the intraoperative check CT scan compares favourably with most figures quoted in the available English literature on image guided placement of thoracic pedicle screws.[18–22] Nottmeier et al. in their large cohort study had a total of 238 thoracic pedicle screws placed using 3D image guidance of which 22 (9%) screws had breached the pedicle with the vast majority (95.5%) being grade I breaches.[21] In another randomized clinical study comparing the accuracy of navigated and non-navigated thoracic pedicle screws in deformity correction surgery, a 23% breach rate was noted in the non-navigated group as compared to a 2% breach rate in the navigated group.[22]

In our study, four out of the seven pedicle screw violations were deemed significant enough for immediate correction in an attempt to improve the biomechanical construct and provide an aesthetically pleasing final radiological image. Based on the final postoperative CT scan, our pedicle screw breach rate is an impressive 3 out of 261 screws (1.2%) with all pedicle violations being minor grade 1 breaches.

It must be emphasized, however, that the main advantage of the iCT based navigation system is in its clinical accuracy at the first instance of screw insertion, which in our study is 97.3%. Revising a large medial cortical screw perforation, done however quickly, is unlikely to reverse the damage done to the neural structures. Therefore, the main benefit of the iCT based spinal navigation system is in minimizing pedicle breaches from occurring during the initial screw insertion. The consequences of pedicle breaches are dependent on the direction of occurrence. Medial breaches could potentially damage the spinal cord, inferior breaches may harm the nerve root and anterior cortical breaches could lead to inadvertent large vessel injury.

There has been one recent study on the use of intraoperative CT imaging and navigation for placement of thoracolumbar pedicle screws. They reported 100% accuracy for the placement of lumbar pedicle screws. However, they had a 2.4% thoracic pedicle screw breach rate detected on the intraoperative check CT imaging, which is fairly similar to our own data. However, none of their thoracic pedicle screw breaches were revised intraoperatively as they were minor pedicle breaches.[27]

Another significant advantage of an intraoperative CT based system is the negligible radiation exposure to the surgeon and operating room staff. During the scanning procedure, all operating room staff is protected in lead shielded rooms. This compares favourably to image guidance systems based on active fluoroscopy where radiation exposure to operating room staff is a cause for concern.[28] Radiation exposure to the patient, however, is still an issue especially with regards to the small risk of radiation induced carcinogenesis. We minimize radiation exposure to the patient by scanning only the instrumented levels, which in most cases is only 2 to 3 levels above and below the level of pathology. Although dosing from our helical CT is likely lower than that of active fluoroscopy due to a decrease in overall time used, this may be offset if repeated CT imaging is acquired intraoperatively. When compared to the intraoperative cone beam CT imaging acquired from the O-arm, although the image quality may be inferior, the radiation dose is approximately half that of intraoperative CT.[29] Based on our data, the average effective dose of radiation given to the organs in the chest during a single intraoperative scan of the thoracic spine is approximately 19 mSV with the dose length product (DLP) of the scanner approximating 1000 mGycm. As each patient received an average of 2–3 intraoperative scans, the total dose received would be in the range of 30–60 mSV. At these dose ranges, there is epidemiological evidence for a slight increase in radiation induced carcinogenesis.[30,31] However, the individual risk estimates are small (0.01% lifetime risk of death from digestive tract cancer attributable to a diagnostic CT scan of the abdomen). The benefits of accurate instrumentation placement on an individual basis far outweigh the risk.

With regards to intraoperative assessment of implant placement prior to wound closure, intraoperative CT imaging in our series identified four major pedicle screw violations that were corrected for immediately allowing a more biomechanically stable final construct for the patient. When analysing the reasons for the four grade II and III pedicle screw violations that occurred despite the use of image guidance, it was noted two out of these four major screw violations occurred at vertebral levels, which were more than six levels away from the location of the radiolucent reference frame clamp calling into question the accuracy of the navigation at these levels. It may be possible that the process of tapping and placement of the screws resulted in movement of the spinal segment levels that were further away from the reference frame clamp, subsequently rendering the spinal navigation inaccurate at these levels. Frequent verifications of the autoregistration process needs to be done especially prior to instrumenting vertebral levels above or below the location of the reference frame spine clamp. Fortunately, this verification process does not entail more than 10 seconds. It would also be prudent to move the radiolucent spinal clamp to the area of interest and re-register the surgical anatomy via an updated intraoperative scan when instrumenting more than six vertebral levels away from the initial location of the spinal clamp. However, this would entail repeated intraoperative CT scanning for cases requiring screw insertions at multiple levels with its attendant risks of radiation side effects such as malignancy as mentioned earlier.[30] Another more elegant way around this problem, as has been described recently in a small study, would be to perform the initial drilling of the pilot holes and trajectory holes for all the screws prior to tapping and screw placement, thereby minimizing the intervertebral motion that arises from the latter.[32]

Another possible reason for the pedicle screw violations despite the use of image guidance could be due to inadvertent knocking or movement of the reference clamp on the spinous process during instrumentation as occurred in one of our cases. Navigation accuracy can further be improved by temporary halting ventilation during the scan acquisition to minimize vertical spine motion. However, as a number of our patients were elderly with diminished lung reserve, we opted to reduce tidal volume by 50% instead.

Another point of interest in our analysis of the 7 misplaced pedicle screws was that 5 out of the 7 breaches occurred in the first 21 cases (126 screws) of our series. Although not statistically significant ($p = 0.2$), it thus suggests that the 'human factor' described as the interaction between the surgeon and navigation system is a potential source of inaccuracy. Once the learning curve is surmounted and the surgical team is comfortable with the image guidance system, near 100% accuracy can be achieved. The learning curve entails familiarity with the operating theatre set up, ideal placement of spinal clamp to minimize movement, control of tidal volume during scan acquisition, and familiarity as well as accurate interpretation of navigated images during screw placement.

An inadvertent consequence of intraoperative imaging is that the overwhelming desire for a 'clean' CT image with optimal screw placement may lead to unnecessary intraoperative revision of misplaced pedicle screws that may otherwise be of little clinical significance. Each time a screw is revised, the patient is subjected to further risk of complications. The surgeon must keep this in mind when reviewing the intraoperative check CT image. In our study, only the grade II and grade III pedicle screw breaches were revised due to possible injury from medial encroachment of the spinal canal or lack of biomechanical purchase from too lateral a cut out. It must be emphasized though, that revising a malpositioned screw is unlikely to avert a potential cord injury if it has already been damaged by an excessively medial screw trajectory. The aim of the iCT based navigation is to minimize this error at the first instance PF screw insertion. The rate of intraoperative revision of pedicle screws, which in our study is 1.5%, is therefore an assessment in itself of the clinical accuracy of the iCT based spinal navigation system.

One drawback of this study is the lack of a control group to compare the accuracy of the iCT based imaged guidance system. This is primarily because this study represents our first experience with insertion of thoracic pedicle screws in our institution.

Another drawback of the intraoperative CT based image guidance system is the cost involved in the installation and maintenance of such an operative suite. Our study is not able to provide a cost benefit analysis (cost of installation versus cost of reoperation or complications in patients with misplaced screws) due to the lack of available data from a control group.

Conclusion

With the use of our intraoperative CT based navigation system, we could achieve highly accurate and safe placement of thoracic pedicle screws despite this being our early experience with pedicle screw instrumentation. The clinical accuracy of the iCT based spinal navigation system (97.3%) allows us to prevent damage to adjacent neurovascular structures during screw insertion. Furthermore, the ability to assess implant placement intraoperatively using the iCT, allows us to revise the malpositioned screws for a more biomechanically stable construct.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the writing and the content of the article.

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Modern Intraoperative Imaging Modalities for the Vascular Neurosurgeon Treating Intracerebral Hemorrhage

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Abstract and Introduction

Abstract

This paper reviews the current intraoperative imaging tools that are available to assist neurosurgeons in the treatment of intracerebral hemorrhage (ICH). This review shares the authors' experience with each modality and discusses the advantages, potential limitations, and disadvantages of each.

Surgery for ICH is directed at blood clot removal, reduction of intracranial pressure, and minimization of secondary damage associated with hematoma breakdown products. For effective occlusion and safe obliteration of vascular anomalies associated with ICH, vascular neurosurgeons today require a thorough understanding of the various intraoperative imaging modalities available for obtaining real-time information. Use of one or more of these modalities may improve the surgeon's confidence during the procedure, the patient's safety during surgery, and surgical outcome.

The modern techniques discussed include 1) indocyanine green–based video angiography, which provides real-time information based on high-quality images showing the residual filling of vascular pathological entities and the patency of blood vessels of any size in the surgical field; and 2) intraoperative angiography, which remains the gold standard intraoperative diagnostic test in the surgical management of cerebral aneurysms and arteriovenous malformations. Hybrid procedures, providing multimodality image-guided surgeries and combining endovascular with microsurgical strategies within the same surgical session, have become feasible and safe. Microdoppler is a safe, noninvasive, and reliable technique for evaluation of hemodynamics of vessels in the surgical field, with the advantage of ease of use. Intraoperative MRI provides an effective navigation tool for cavernoma surgery, in addition to assessing the extent of resection during the procedure. Intraoperative CT scanning has the advantage of very high sensitivity to acute bleeding, thereby assisting in the confirmation of the extent of hematoma evacuation and the extent of vascular anomaly resection. Intraoperative ultrasound aids navigation and evacuation assessment during intracerebral hematoma evacuation surgeries. It supports the concept of minimally invasive surgery and has undergone extensive development in recent years, with the quality of ultrasound imaging having improved considerably.

Image-guided therapy, combined with modern intraoperative imaging modalities, has changed the fundamentals of conventional vascular neurosurgery by presenting real-time visualization of both normal tissue and pathological entities. These imaging techniques are important adjuncts to the surgeon's standard surgical armamentarium. Familiarity with these imaging modalities may help the surgeon complete procedures with improved safety, efficiency, and clinical outcome.

Introduction

Intracerebral hemorrhage occurs in many conditions and has a wide spectrum of causes;[7,29,31,39,42,58] most commonly, ICH occurs as a result of degenerative vascular disease, amyloid angiopathy, and hemorrhagic transformations of ischemic strokes. However, up to 10% of ICHs are due to underlying vascular structural anomalies (AVMs, aneurysms, and cavernous angiomas being the most common). Other less common vascular malformations include sinus or cortical vein thrombosis, arteriovenous fistula, and arterial dissection.

Intracerebral hemorrhage is associated with a high early mortality rate and a significant long-term morbidity rate. Among all stroke subtypes, it is considered to be the one with the highest mortality rate. Hematoma volume is an important predictor of 30-day mortality, and hematoma growth is a principal cause of early neurological deterioration.[6,10,47] One should especially emphasize the high percentage of vascular pathological entities associated with ICH in the pediatric population, in which such entities were confirmed in a recent series in 61% of pediatric patients.[38]

Therapy for ICH is directed at blood clot removal, reduction of intracranial pressure, and of secondary associated damage. In the International Surgical Trial in Intracerebral Haemorrhage (STICH),[30] the effect of medical versus surgical management of ICH was compared, but, except for a small subgroup of patients who experienced a benefit from surgery, no significant advantage was demonstrated for any of the treatments.

The concept of "suction surgeries" (referring to ICH removal through large craniotomies) is now obsolete. Vascular neurosurgeons treating ICH should be prepared to deal not only with clot removal but also with the underlying cause. These tasks are often complex, both from the morphological and the technical point of view, and increase the risk for potential vessel compromise. For effective occlusion and safe obliteration of vascular anomalies, the neurosurgeon today may require intraoperative imaging modalities for obtaining real-time information. The use of intraoperative imaging modalities is of particular relevance when preoperative vascular imaging studies are negative but the intraoperative findings reveal a discrete lesion. In these complex cases the surgeon has to adapt and perform the procedure without a complete picture of the task ahead. Intraoperative imaging assessment in such situations can be particularly informative.

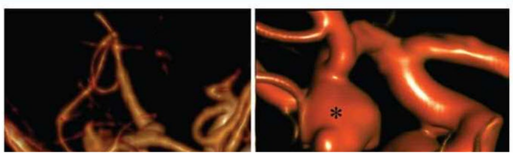
Along with the advances in neurosurgical techniques, significant progress has been made in the field of intraoperative imaging, especially intraoperative neurovascular imaging. From the development of uniplane angiography, the first description of CT contrast infusion to identify vascular lesions,[33] and Doppler techniques[35] to MR angiography[48] and transcranial Doppler,[1] reliable intraoperative imaging technologies have been developed. Several intraoperative modalities have been implemented: ICG-VA, iDSA, iCT, iMRI, iMD, and 3D iUS. These new imaging techniques and the concept of true hybrid rooms providing multimodality image-guided surgeries have improved diagnostics considerably. Such techniques may significantly assist the surgeon in challenging cases.

This paper reviews the current intraoperative imaging tools and the clinical use of each modality. Our experience with the various modalities and their advantages and potential limitations are discussed.

Intraoperative Imaging Techniques

Indocyanine Green–Based Video Angiography

Indocyanine green–based video angiography provides real-time information on the residual filling of aneurysms and on the patency of blood vessels of any size in the surgical field, including perforators, based on high-quality images. First introduced into the neurosurgical operating room in 2003,[40,41] The ICG-VA technique was found to be a simple and safe way to assess blood flow intraoperatively.[46] Sequential studies compared the findings of ICG-VA with iDSA or postoperative DSA and reported them to be comparable in 90% of cases.[27] Subsequently, the use of DSA for intraoperative evaluation of aneurysms has decreased.[15] In the setting of ICH surgery with an underlying vascular pathological entity such as cerebral aneurysm or AVM, ICG is a powerful tool (Fig. 1). The ICG-VA technique is now widely used in multiple settings beyond aneurysms.[12,18,22–24,32,54] It is routinely used for intracranial and spinal AVMs[22] and arteriovenous fistulas.[23] Unquestionably, ICG-VA has become an important adjuvant in vascular neurosurgery.



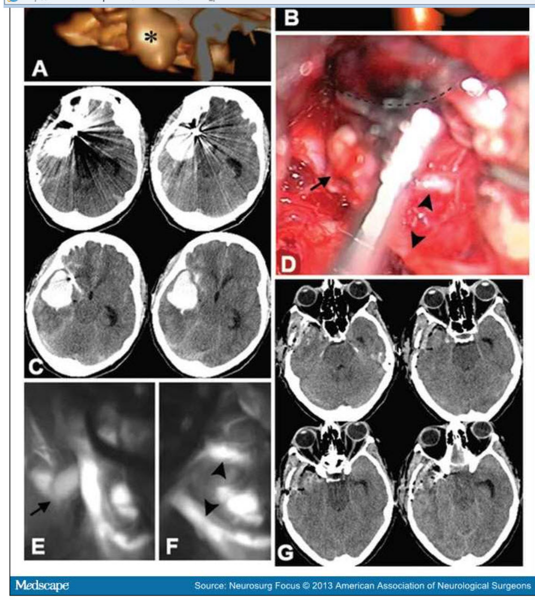


Figure 1.

A right MCA aneurysm *(asterisks)* is demonstrated on preoperative 3D reconstructions of CTA **(A)** and on preoperative DSA reconstructions **(B)**. An attempted endovascular closure of the aneurysm ended in aneurysm rupture and significant ICH (**C**; artifacts are caused by coils). The patient was urgently transported to the operating room and a right pterional approach was implemented. After evacuation of the ICH, an optical mode photograph **(D)** demonstrating the right M_1 branch *(arrow)* and the 2 right M_2 branches *(arrowheads)* was obtained. The area of the coil-treated dome portion of the aneurysm is depicted by the *dashed line*. Intraoperative ICG-VA photographs showing patent circulation in the right M_1 branch (**E**; *arrow*) and in the 2 right M_2 branches (**F**; *arrowheads*). Postoperative CT scans **(G)** showing a satisfactory evacuation of the ICH.

However, ICG is not suited for all applications. Its use is limited to the microscope's field of view and only to exposed blood vessels, so that not all vasculature can be assessed. In addition, there are various factors that may limit the accuracy of ICG fluorescence signals, such as thick-walled or partially thrombosed aneurysms or cases of deep-seated or giant aneurysms.[27] The utility of this imaging modality in the setting of AVM surgery is still unclear because of these visualization issues. Because only the parts of the AVM that are already visible in the surgical field will be visible to ICG-VA, standard intraoperative DSA remains the gold standard imaging modality in the assessment of AVM resection.

We use ICG-VA on a routine basis during vascular surgeries, including ICH evacuations, when the need arises (Fig. 2). It helps us assess residual filling of vascular lesions such as aneurysms and the patency of surrounding vessels after clipping. Sometimes multiple injections are performed after complex clip reconstructions. Use of ICG-VA has reduced our need for intraoperative DSA, which is now reserved for more difficult cases or those in which there is doubt following the ICG-VA.

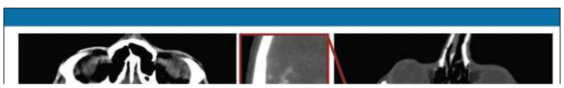


Figure 2.

Imaging studies obtained in a 20-year-old man under treatment for subacute bacterial endocarditis who suddenly developed headache and left hemiparesis and subsequently lost consciousness. **A:** Preoperative CT scan showing right temporooccipital ICH involving the ventricular system. **B:** Preoperative CTA scan demonstrating a right distal sylvian fissure mycotic aneurysm (see **inset**, *arrowhead*). **C:** Preoperative neuronavigation images obtained using the Stealth S7 system for craniotomy planning. **D:** Intraoperative ICG-VA photograph locating the mycotic aneurysm *(asterisk)* and differentiating it from the parent artery.

Intraoperative DSA

This is a powerful diagnostic tool in the surgical management of cerebral aneurysms and AVMs and is still considered the gold standard procedure when assessing precise aneurysm clipping and vessel patency. It allows the neurosurgeon to confirm complete occlusion of the aneurysm and to demonstrate patency of all surrounding vasculature.

Several groups have evaluated iDSA efficiency and have revealed that it is both effective and accurate.[9,37,49] In the largest single-center study, of 1093 vascular cases in which patients underwent routine iDSA, a greater than 8% revision of clip placement due to abnormalities found on iDSA was reported.[9] In 9 (8.9%) of 101 patients, iDSA demonstrated residual AVM requiring additional resection. Two of these patients (22.2%) required a second surgical revision, and successful excision of the residual AVM was confirmed by repeat iDSA in all 9 patients. With minimal risk of morbidity (0.99%) and neurological complications occurring in only 0.09% of cases, the authors reaffirmed iDSA safety and utility in the surgical treatment of aneurysms and vascular malformations.

As always, the value of iDSA must be weighed against the risk of complications and technical difficulties.[14,21] The reported complication rate is as high as 3%. Various technical challenges include the need for skilled neuroradiology staff, high costs, the need for a DSA C-arm, a radiolucent operating table head holder, and angiography equipment. At times the additional equipment can make the operating room particularly cramped (Fig. 3). In the setting of ICH treatment, iDSA may be too cumbersome to perform during an urgent operation due to availability of staff or equipment.

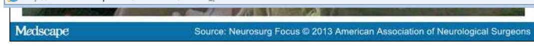


Figure 3.

Photograph showing the operating room setup for microsurgical clipping of an MCA aneurysm with iDSA guidance. Although this is still considered the gold standard procedure when assessing precise aneurysm clipping and vessel patency, one should consider the various technical difficulties involved.

The drawbacks of iDSA may lead some to conclude that it is not a practical tool for all vascular cases. It is therefore best applied selectively, for complex vascular malformations and lesions in challenging anatomical locations.

Hybrid Operating Room: Applications in ICH Surgery

The concept of a hybrid operating room combining endovascular and microsurgical strategies within the same surgical session is applicable, cost-effective, and safe.[11,19,20,26] Full biplane neuroangiography in a fully equipped neurosurgical operating room provides a seamless transition between the operation and iDSA, which can be performed without repositioning the patient or moving in a portable C-arm. The result is higher-quality angiography in 2 planes, which provides immediate intraoperative assessment of vessel patency and occlusion rate of different vascular pathological entities.

An example for this kind of setup is the addition of an iMRI unit to the hybrid operating room. Examples are the Advanced Multimodality Image-Guided Operating (A.M.I.G.O.) Suite at the Brigham and Women's Hospital and Harvard Medical School[20] and the implementation of so-called IMRIS suites (IMRIS, Inc.) at various locations internationally.[25] These systems are able to integrate a 1.5- to 3-T iMRI unit into a fully operational neurosurgical operating room and a full biplane angiography suite.

Intraoperative Microdoppler Techniques

Microdoppler imaging is a safe, noninvasive, and reliable technique for evaluation of the hemodynamics of vessels in the surgical field and of vascular malformations. It is low cost, and the time to result is 1–5 minutes in most cases. Additionally, it shows good correlation with postoperative angiography and is therefore widely used.[45] It allows for the measurement of blood flow velocities in the malformation itself and in the surrounding vasculature. It is a valuable tool for providing immediate feedback to the surgeon, thereby improving the chances for an optimal surgical outcome because intraoperative complications such as vessel occlusion can be diagnosed and dealt with immediately. Several groups compared iMD findings to those in iDSA or postoperative DSA.[4,5,13,28,45,55] They found a high rate of concordance between the iMD and angiographic findings regarding proper clip placement and complete occlusion of an intracranial aneurysm and associated clip-induced adjacent-vessel stenosis.

There are several iMD techniques available on the market today. Some are simple and cost-efficient, whereas others, such as the ultrasonic perivascular flow probe, are more advanced but are expensive and more cumbersome.[4] The iMD modality carries the advantage of speed and ease of use and is therefore very attractive during surgery for ICH. The primary disadvantage of this technique is its inability to identify residual aneurysm remnants in cases of thrombosed or low-flow aneurysms—which are readily identified by intraoperative angiography and ICG-VA. That is to say, iMD provides qualitative and not quantitative results to the surgeon. Additionally, it is only useful for high-caliber vessels observed under the operating microscope.

Intraoperative MRI

Intraoperative MRI has been incorporated into modern neurosurgical operating rooms for more than a decade as a guide for neurosurgical interventions.[3,34,43,44] This technology has proved to be a useful modality in vascular neurosurgery, especially for cavernous angiomas and AVMs.[43] It provides a highly accurate and precise navigation tool, with excellent resolution, which is a prerequisite for localizing and targeting vascular lesions. It also addresses the problem of the ever-changing organization of intracranial structures during surgery by providing near-real-time, high-quality images.

One of the drawbacks of intraoperative MRI with regard to resection of vascular lesions is delineating the extent of resection. Clearly determining the edge of the lesion can be challenging due to the deposition of hemosiderin from hemorrhage. There are several types of MRI units used today.[44] In our experience the use of iMRI in ICH surgery is limited to cavernoma surgery, and in cases in which MRI may help in delineating the margins of deep lesions surrounded with hematoma, in those cases we consider the low-field portable systems as the most useful. An example of a low-field iMRI unit is the OdinPoleStar system, which was first introduced in 2001.[17] This compact MR scanner can be installed in a standard operating theater without major modification (Fig. 4). It functions with both an integrated optical system and an MRI tracking system and is operated by the neurosurgeon from an in-room computer workstation.[16,36]

Figure 4.

Photograph showing the compact and mobile Medtronic PoleStar N30 surgical MRI system, consisting of a 0.15-T MRI unit integrated with a Medtronic StealthStation navigation system **(A)**. Photographs showing the system being used for craniotomy approach for an ICH surgery related to cerebral cavernous angiomas **(B)**, and for a transsphenoidal approach in a case of pituitary apoplexy **(C)**. Reprinted with permission from Medtronic, Inc.

Intraoperative CT

Intraoperative CT imaging is a standard tool in the successful planning and execution of a diverse range of neurosurgical procedures.[8] In the treatment of ICH, iCT systems such as the CereTom mobile scanner are used to assist in the confirmation of intraoperative positioning of catheters, the extent of hematoma evacuation, and the extent of vascular anomaly resection. The iCT images can be obtained and merged with those obtained using other modalities such as MRI if desired. Limitations of iCT include lower resolution than the large CT scanners, technician availability, and intraoperative imaging of the skull base. In the setting of ICH surgery, iCT has the advantage of very high sensitivity to acute blood.[2,50]

extent of vascular anomaly resection. The ICT images can be obtained and merged with those obtained using other modalities such as MRI if desired. Limitations of ICT include lower resolution than the large CT scanners, technician availability, and intraoperative imaging of the skull base. In the setting of ICH surgery, ICT has the advantage of very high sensitivity to acute blood.[2,50]

Ultrasound-guided Evacuation of ICH

The iUS technique has undergone extensive development in recent years, and the quality of ultrasound imaging has improved considerably.[26,51–53,55–57] Still, many neurosurgeons have been reluctant to try advanced versions of iUS due to negative past experiences. The quality of iUS imaging has improved significantly, such that the surgeon can readily assess ICH dimensions and identify structures within the brain in real time. This modality supports the concept of minimally invasive surgery by allowing the surgeon to identify which part of the clot presents closer to the cortical surface, thereby minimizing disruption to the surrounding brain because the shortest transcortical trajectory is taken to enter the clot. Orientation problems of iUS were improved by integrating navigation technologies. As a result, neurosurgeons find it relatively easy to understand and use the iUS navigation systems found in the market today.[53]

The integration of 3D iUS and neuronavigation technology has created a real-time imaging method that can accurately demonstrate ICH. The 3D iUS systems such as the SonoWand have made this technology an efficient tool that can combine the real-time feedback from iUS with the detailed preoperative imaging from CT or MRI studies. During ICH evacuation procedures, iUS facilitates directing an instrument such as a Cavitron ultrasonic surgical aspirator or an endoscope to a target point in real time. During various vascular operations the iUS helps localize lesions and characterize their internal structure, and distance from the surface to the target can be calculated.[57,58] The relation of various lesions to the surrounding brain can be appreciated before, during, and after excision of vascular pathological entities.

Conclusions

There have been remarkable advances in the intraoperative imaging techniques used in the surgical management of ICH. They have enabled neurosurgeons to visualize and delineate anatomical and pathological structures more accurately, even during the surgery itself. Image-guided therapy has changed the fundamentals of conventional surgery by presenting accurate visualization of both normal tissue and lesion. Particularly within the last decade, advanced imaging modalities have become standard tools of neurosurgical practice, creating image-guided surgery as a subspecialty. In discussing the potential advantages and disadvantages of each modality, it should be pointed out that they are not mutually exclusive. On the contrary, the various intraoperative imaging modalities used in the surgery for ICH may be complementary, and therefore vascular neurosurgeons should be prepared to use any intraoperative imaging modality when the need arises.

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Abbreviations used in this paper

AVM = arteriovenous malformation; CTA = CT angiography; DSA = digital subtraction angiography; ICG-VA = indocyanine green–based video angiography; ICH = intracerebral hemorrhage; iCT = intraoperative CT; iDSA = intraoperative DSA; iMD = intraoperative midcrodoppler; iMRI = intraoperative MRI; iUS = intraoperative ultrasound.

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VISIUS iCT by IMRIS

Experience state-of-the-art CT imaging accessed effortlessly in the OR.

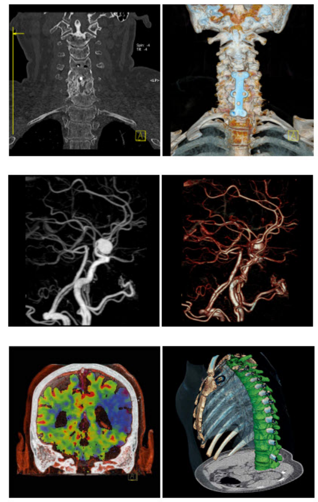
Developed for cranial and spinal neurosurgery, the VISIUS® iCT provides **low dose, diagnostic quality imaging**. The first and only **ceiling-mounted intraoperative CT** travels on-demand to the patient – without introducing additional risk – to preserve OR protocols, optimal surgical access and techniques.

State-of-the-art image quality and software

The **64-slice scanner** features **advanced software applications** that minimize radiation exposure in real time and industry leading post-processing software to enhance surgical diagnosis and intervention. VISIUS iCT has the industry's **highest isotropic resolution of 0.33 mm³** at any scan and rotation speed and at any position within the scan field – without a corresponding increase in dose.

Software applications include:

- >> Advanced Surgical Planning
- >> CT Guided Angiography
- >> Automatic Organ and Spine Recognition
- >> 3D Volume Rendering
- >> 3D Guided Intervention for MIS
- >> Iterative Reconstruction
- >> Intelligent Dose Management



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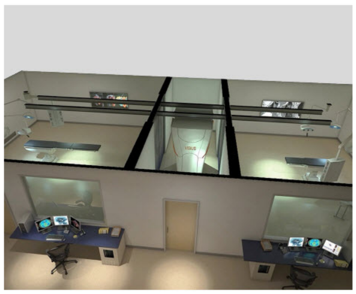
Ceiling-mounted rails effortlessly move the iCT between rooms

The mobility of the VISIUS iCT enables multiple operating room configurations to meet clinical requirements and **increase system utilization.** Layouts include one- or two- OR configurations with a center room isolating the CT from the surgical theater while not in use.



Advantages of ceiling-mounted rail system:

- >> No patient transport required for imaging
- >> No compromises due to floor rails or wheeled systems
- >> Maintain familiar surgical protocols, workflow and infection control procedures
- >> System can travel up to 36.3 ft between rooms
- >> CT moves into or out of the OR in less than 30 seconds

Integrating the Surgical Theatre

Unique safety, workflow, room controls and data management are built into each surgical suite with VISIUSmatrix® featuring KARL STORZ OR1® and can be adaptable for each surgeon and procedure:

- >> Variable room lighting controls
- >> Routing, recording, streaming and archiving of video feeds
- >> Internal and external communication with voice and data
- >> Remote monitoring and diagnostics

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VISIUS Surgical Theatre
seeing is better

To:	Koninklijke Philips N.V. (ipdocket@calfee.com)
Subject:	U.S. TRADEMARK APPLICATION NO. 79108849 - ICT - 30961/04099
Sent:	5/3/2015 4:32:00 PM
Sent As:	ECOM104@USPTO.GOV
Attachments:	

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Please follow the instructions below:

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The Office action may not be immediately viewable, to allow for necessary system updates of the application, but will be available within 24 hours of this e-mail notification.

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