Scientific Proof and Clinical Studies using Curefab CS

A novel 3D technique for more objectivity in ultrasound diagnosis

Publications

1. A Abbas, V Hansran, N Sedgwick, J Ghosh and C N McCollum : **3D Contrast Enhanced Ultrasound for Detecting Endoleak Following Endovascular Aneurysm Repair**
   European Journal of Vascular and Endovascular Surgery 2013, in review.

2. J Pelz, A Weinreich, W Kloppig, D Fritzsch and D Saur: **3D-ultrasound of the carotid vessels – A promising new technique for grading stenosis of the internal carotid artery**
   Poster presentation on Euroson 2013.

3. T Karlas, F Lindner, M Tröltzsch and V Keim: **Usefulness of a 3-D system (Curefab®) for documentation thyroid ultrasound**
   Poster presentation on Euroson 2013.

4. K Pfister, M Janotta, H Apfelbeck, PM Kasprzak: **How dangerous is a carotid plaque?**
   VASA 2013; 42:153.

5. K Pfister: **Kontrastmittelsonographie der Gefässe. Was ist aus chirurgischer Sicht sinnvoll?**
   Chirurg 2013 in review.

6. R Feurer, C. Hennersperger, J.B. Runyan, C.L. Seifert, J. Pongratz, M. Wilhelm, J. Pelisek, N. Navab, E. Bartels, H. Poppert: **Reliability of a freehand three-dimensional ultrasonic device allowing anatomical orientation "at a glance": Study protocol for 3D measurements with Curefab CS®**
   Journal of Biomedical Graphics and Computing, Vol.2 (2), 2012.

7. J. Pongratz, M. Wilhelm, F. Härtl, C. Hennersperger, S. Kaiser, H.-H. Eckstein, C. Reeps: **Computed Sonography –neue Möglichkeiten in der vaskulären Ultraschalldiagnostik**
   Poster presentation on DGG 2012.

Press

1. **Curefab has released the latest generation of its Computed Sonography technology**
   Hospital News - Press Release for Medica 2013, Düsseldorf.

2. **3D contrast-enhanced ultrasound potentially more sensitive to detect endoleaks**
   Vascular News, 27th Sep 2013,

3. **Curefab introduces new EVAR follow-up solution**
   Vascular News Issue 59, Sep 2013.

4. Frühwarnung vor Infarkten
   Technology Review – Das M.I.T.-Magazin für Innovation, Jan 2011.

5. Hochleistungssoftware im Kampf gegen Schlaganfälle
   IT-Szene München, 2011 (3).

6. Die vielversprechendsten Startups – Curefab
   Wirtschafts Woche, 29th Mar 2011.

Talks

1. K Pfister: New horizons in vascular diagnostics
   European Society for Cardiovascular and Endovascular Surgery 2013, Regensburg.

2. K Pfister: CEUS bei Aortenpathologien
   Jahrestagung der Dt Gesellschaft für Chirurgie 2013, München.

3. K Pfister: 3D und Bildfusion; Was bringen Funktionsuntersuchungen wie etracking
   Dreiländertagung Gefäßchirurgie 2013, Linz.

4. K Pfister: Innovationen im Ultraschall – „schöne Bilder" oder Nutzen für die Praxis
   Dreiländertagung Gefäßchirurgie 2013, Linz.

5. K Pfister: PWV and AI – the use of measuring vascular stiffness with etracking
   Euroson 2013, Stuttgart.

6. K Pfister: CEUS, fusion imaging and 3D
   Euroson 2013, Stuttgart.

Reliability of a freehand three-dimensional ultrasonic device allowing anatomical orientation "at a glance": Study protocol for 3D measurements with Curefab CS®

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Abstract

Background and Purpose: 3D ultrasonic measurement of carotid atherosclerotic lesions has emerged as an important tool for research and patient management. We sought to evaluate the accuracy and the reliability of a new easy-to-use magnetically tracked freehand 3D ultrasonic device with quick reconstruction time, allowing for anatomical orientation "at a glance" for calibration and distance measurements, with unique usability as a combined tool for image acquisition, registration and measurement within 3-D ultrasonic (US) volumes, which is furthermore connectable to every conventional US-machine. To enable a complete evaluation of the whole system, three different key points had to be addressed: the reproducibility of the calibration procedure, the absolute accuracy of the whole system and a direct comparison to CT and MRI imaging modalities.

Materials and Methods: For validating our calibration method, a set of 6 calibrations was performed; each consisting of 6 records of a pyramid phantom taken from different positions and angles. To evaluate the accuracy of the whole 3D-ultrasound system, the point reconstruction accuracy and the distance accuracy were determined in a point phantom made out of a single metal wire vertically attached to the bottom of a plastic tub filled with water. For distance measurements, a precisely manufactured plastic tube phantom was scanned and the length between fixed landmarks on the tube was measured. In a final step, 3D US records acquired with Curefab CS were compared to CT and MRI scans; for this purpose all ultrasonic data was manually registered to the CT/MRI data.

Results: Concerning calibration precision the tested Curefab CS system performs state of the art compared to reviews of recent freehand 3D-Ultrasound calibration methods. The point reconstruction measure for evaluation of system accuracy retrieved a mean point accuracy of 1.52 mm in contrast to values ranging from 1.67 to 3.63 mm. Mean total error of distance measurements was 0.9% with standard deviation 0.56% in our study, compared with values reaching from about 1% up to 2.3% in other studies on this subject. All quantitative measurement results are listed in a summarized form in Table 1. Besides quantitative evaluation, 3D-ultrasound records acquired with the Curefab CS system were also compared to CT and MRI scans of patients (see Figure 3 and Figure 4). The alignment of both image modalities showed promising results for future development of diagnostic tools using all image data.

Discussion and Conclusion: Our study demonstrates that 3D measurements with Curefab CS are feasible with satisfactory reliability and accuracy. From the results gathered in our study we conclude that 3D-imaging with Curefab CS might start off the possibility of accurate visualization, volume measurement, carotid plaque characterization and identification of vulnerable plaques in the very near future.

3D Contrast Enhanced Ultrasound for Detecting Endoleak Following Endovascular Aneurysm Repair

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Abstract

Introduction: CT angiography (CTA) for endovascular aneurysm repair (EVAR) surveillance involves irradiation and nephrotoxic X-ray contrast agents. Three-dimensional contrast-enhanced ultrasound (3D CEUS) is a novel imaging technique that may be more sensitive to blood flow detection than CTA or 2D CEUS. 3D CEUS utilises positional information from magnetic field emitters to assemble all ultrasound reflections into a high definition image. We compared 3D CEUS with CTA for the detection of endoleak and aneurysm expansion following EVAR.

Methods: 3D CEUS (Curefab), 2D CEUS (Philips IU22) and CTA were compared in 30-paired images from 23 patients. Sensitivity, specificity, positive and negative predictive value was calculated for 2D and 3D CEUS against CTA as the 'gold standard'. Pearson correlation was used to compare aneurysm sac diameter. Data were analysed using SPSS version 19.0.

Results: 30 paired 3D CEUS and CTA images were analysed from 23 patients. Endoleaks were detected in 17 images with CTA, 18 on 2D CEUS and 18 on 3D CEUS. The sensitivity, specificity, positive and negative predictive values of 3D CEUS to detect endoleak were 100%, 92%, 94% and 100% respectively. There was excellent correlation (r =0.935; p 00.0001) between CTA and 3D CEUS for AAA sac diameter. Only 3D CEUS detected the inflow and outflow arteries in all 18 scans with endoleak. 2D CEUS detected the inflow in 16 (88.8%) and CTA on 12 (66.6%) of the images.

Conclusion: 3D CEUS may be more sensitive to endoleak following EVAR than either 2D CEUS or CTA.

3D-ultrasound of the carotid vessels – A promising new technique for grading stenosis of the internal carotid artery

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Abstract

Purpose: About 20% of ischaemic strokes are caused by large-artery atherosclerosis, id est a significant (more than 50%) stenosis or even occlusion of mainly the internal carotid artery (ICA). By applying the multi-parametric German "DEGUM ultrasound criteria", ultrasound has proven as a non-invasive, cheap and bed-side method for detection and grading of ICA stenosis with a good sensitivity and specificity. However, there are still cases where a second imaging modality is desirable or even mandatory by guidelines. Here, we want to introduce a new method of real 3D-visualization of the carotid vessels by ultrasound and demonstrate first clinical applications.

Material & Methods: Curefab CS (Curefab GmbH, Munich, Germany) is a mobile computer hard- and software attachment to conventional ultrasoundsystems. Briefly, common 2D-sectional B-mode images can be linked with spatial and temporal information enabling their exact positioning in a virtual 3D-volume by using a magnetic field tracking system for which a magnetic field position – and direction – sensor is mounted on the ultrasound transducer. Carotid vessels will then be reconstructed from this virtual 3D-volume.

Results: Besides 3D-visualization multiple parameters like diameter, cross sectional area and volume can be obtained at any point in vessel's course. Thereby, in patients with ICA stenosis the distal diameter reduction percentage according to the North American Symptomatic Carotid Endarterectomy Trial (NASCET) can be calculated directly, offering a second way of grading stenosis. Furthermore, various other vascular pathologies like kinkings or occlusions of the ICA due to dissections can be depicted.

Conclusion: At this stage, sonographic 3D-visualization of carotid vessels with emphasis of the proximal ICA is feasible and can provide important additional information. However, clinical studies are needed to demonstrate the additional benefit of 3D-ultrasound for grading ICA stenosis.

Usefulness of a 3-D system (Curefab®) for documentation thyroid ultrasound

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Abstract

Purpose: Sonography of the thyroid gland is a basic procedure in clinical investigation. It is an ideal tool to analyze the potential role of a 3D-documentation system.

Material & methods: In 11 subjects with or without thyroid nodules both thyroid glands were investigated with the Aplio500-System from Toshiba using a 18 MHz probe (18L7). A conventional thyroid ultrasound (measurement of the 3 thyroid diameters, number and size of nodule(s), distance to the apex, sonografic architecture of parenchyma and nodules) was performed. In addition, a video of both thyroid lobes was saved. The 3D-data sets of all thyroid glands were recorded by the technology of Curefab® that is based on a magnetic tracking system. The 3D-data sets were stored and evaluated by an investigator (T.K.) unaware of the findings of the conventional ultrasound. Only nodules larger than 5 mm in diameter were analysed in this preliminary study. The subjective quality of the 2D- and 3D videos were graded.

Results: The size of the thyroid measured either by conventional US or after storage of the 3D-data was similar (median difference: length: 6 mm, width: 2 mm, depth: 1 mm). The 3D recording was suggested as slightly less clear than the video obtained by conventional ultrasound. The echogenicity of the glands was estimated as similar in the 2 types of recording. The distance to the upper pole and the size of the nodules was also similar (median deviation of distance to upper pole: 1,8 mm, median deviation of size: 0,8mm, 0,4mm, 0,1 mm).

Conclusion: The 3D-system of Curefab® is an interesting tool to analyse thyroid nodules. Nodules above 5 mm were reliably detected and the echogenicity was not different to the conventional investigation system. It remains to be analysed how smaller modules are visualized. This 3D-system may represent a significant step towards investigator- independent ultrasound.

Vascular News

3D contrast-enhanced ultrasound potentially more sensitive to detect endoleaks

At the European Society for Vascular Surgery Annual Meeting (18–21 September 2013, Budapest, Hungary), Abeera Abbas, Academic Surgery Unit, Institute of Cardiovascular Sciences, University of Manchester, UK, presented the results from a pilot study which suggested that 3D contrast-enhanced ultrasound may be more sensitive to detect endoleaks when compared to both CT angiography and 2D contrast-enhanced ultrasound.

Hospital News - Press Release for Medica 2013, Düsseldorf

Curefab has released the latest generation of its Computed Sonography technology

Curefab CS provides superior objective vascular diagnostics without having to expose patients to the harmful radiation and nephrotoxic contrast media required for CT and MRI scans.
The Curefab CS system can be used for abdominal aortic aneurysm (AAA) screening and monitoring, as well as for EVAR follow-up examinations, including endoleak detection, localization, and classification.

The Curefab CS device can be attached to any ultrasound system currently on the market to generate CT-like 3D volumes of the complete aneurysm region. For the first time it is now possible to use ultrasound to generate high resolution 3D images of the abdominal aorta suitable for diagnosis and review. Curefab CS's 3D volume reconstruction enables the assessment of the examination region from arbitrary viewing angles, while multiplanar reconstruction (MPR) of the 3D volume provides valuable insight into the area of interest. The Curefab CS software delivers accurate measurements of both the diameter and volume of the aneurysm sac. Curefab CS's advanced visualization features enable reliable detection and classification of endoleaks. In combination with contrast enhanced ultrasound, a Curefab CS 3D CEUS scan contains the complete contrast washout to determine the inflow and outflow of the leak for reliable and conclusive classification of endoleaks.

Curefab CS provides a non-invasive, cost-effective, fast and accurate means for medical diagnosis while significantly reducing the level of observer dependence in ultrasound imaging.

Curefab CS supports a wide range of medical applications for vascular and oncological imaging. In addition to the diagnosis and evaluation of abdominal aortic aneurysms, plaque analysis, carotid artery stenosis graduation, imaging of peripheral arteries and catheter access pathways, and measurement of tumor volumes are also supported.