



NaviLink

Direct 3D Navigation Interface for SIREMOBIL Iso-C^{3D}

Surgical navigation with intra-operative 3D imaging: The right match of advanced technologies

Surgical navigation systems have come a long way since cranial stereotactic frames were first used in high-precision neuro-surgical procedures. When manual matching of pre-operative CT or MR datasets eliminated the need for stereotactic frames, the technique gained a broader acceptance in the clinical routine. Plus, surgical navigation could now be applied to other parts of the body.

Until today though, patient positioning remained a challenge. Pre-operative datasets were usually acquired with the patient in a diagnostic position while the surgery itself would likely demand an alternate position to allow optimal access to the surgical field. In addition, any changes in the surgical field during the procedure would not be updated in the image dataset.

Siemens Medical Solutions opens a new chapter in surgical navigation

SIREMOBIL[®] Iso-C^{3D}, the world's first mobile C-arm featuring C-arm CT[™] 3D imaging, can now be equipped with NaviLink[™], a direct 3D navigation interface. This revolutionary interface combines 3D intra-operative imaging with high accuracy surgical navigation.

The combination of technologies allows C-arm CT to be performed in the OR with the patient in the final surgery position. As a result, the 3D images acquired are ideally suited for direct use in surgical navigation, they already include the related coordinates, and they transfer directly to the navigation system. Manual registration of the anatomy is no longer necessary, potentially increasing the overall accuracy of surgical navigation and significantly optimizing the clinical workflow. Furthermore 3D image acquisition can be repeated as often as required – the most up-to-date image information of the surgical field is always available.

NaviLink and SIREMOBIL Iso-C^{3D}, with excellent 3D image quality and automatic registration, offer unmatched clinical advantages and clearly set a new standard in surgical navigation.

**The new way for Surgical Navigation:
NaviLink and SIREMOBIL Iso-C^{3D}**



How does intra-operative 3D imaging and surgical navigation work?

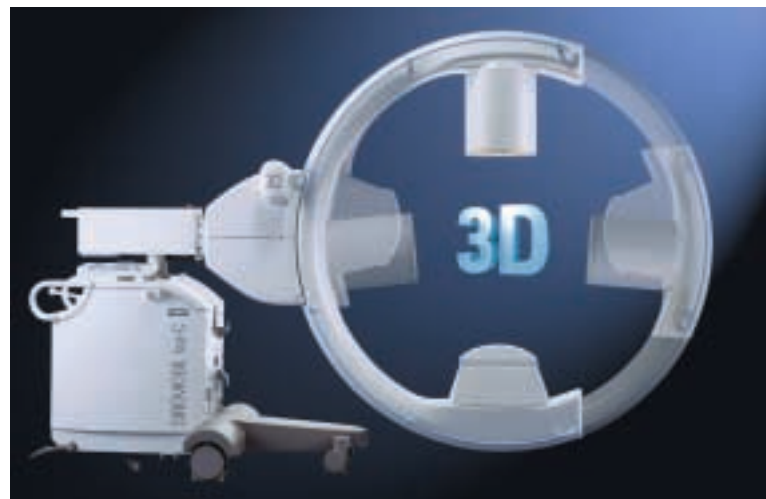
Intra-operative 3D imaging with SIREMOBIL Iso-C^{3D}

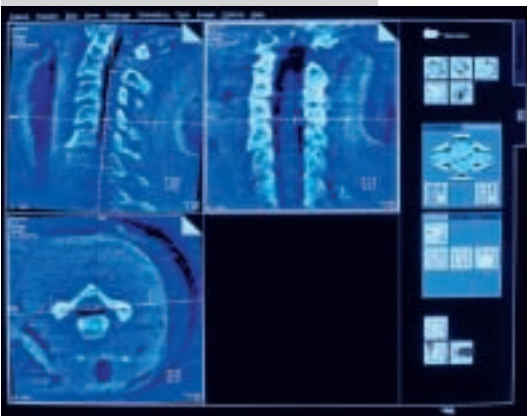
Siemens' SIREMOBIL Iso-C^{3D} is the world's first mobile C-arm featuring C-arm CT imaging. Generating images that are CT-like, SIREMOBIL Iso-C^{3D} potentially increases accuracy and quality of control even in the most problematic anatomical regions or surgical situations.

The revolutionary design of SIREMOBIL Iso-C^{3D} with true isocentricity, 190° orbital movement and hidden cables provides the prerequisites for intra-operative 3D imaging in one orbital movement. During an automated orbital rotation of 190°, the system records a set of defined projections in fixed angular steps and generates a high-resolution isotropic 3D dataset that is available immediately upon completion of the rotation. This 3D dataset is displayed as arbitrary multiplanar reconstructions (MPR), which can be executed in real-time and manipulated either directly from the OR table with a special mouse or at the monitor trolley.

Unlike other potential 3D imaging modalities which may be used in the OR, SIREMOBIL Iso-C^{3D} allows virtually unlimited access to the patient with no increase in procedure preparation time or complexity.

SIREMOBIL Iso-C^{3D} is primarily designed for intra-operative use in procedures involving bones and joints of the upper and lower extremities as well as the spine.





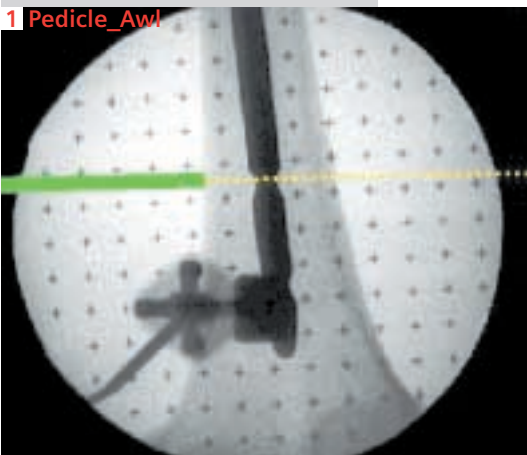
Conventional Surgical Navigation

In essence surgical navigation combines medical imaging with the localization of surgical instruments during the procedure. Until now one could only select between two methods.

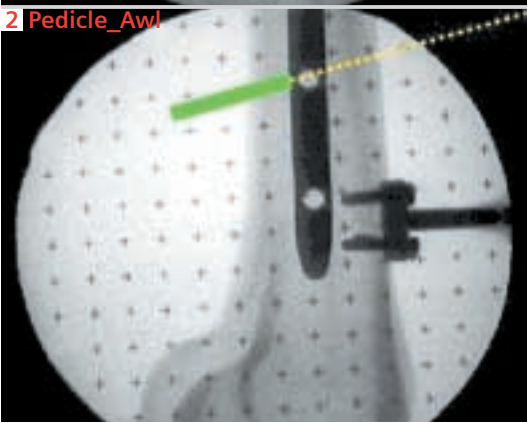
The first method uses pre-operative 3D image datasets acquired with CT or MR. To create a match between the pre-operative dataset and the patient position in the OR, anatomic landmarks or previously implanted reference points must be manually registered on the patient, and coordinates between the surgical instruments and the image dataset must be synchronized. As discussed earlier, this method has additional drawbacks because the patient is normally not imaged in the OR position and changes can take place in the surgical field during the procedure.

The second possibility uses on a mobile C-arm in 2D mode a marker ring with a pattern template mounted on the image intensifier. While no matching is needed, the image information remains purely 2-dimensional. There are drawbacks in image information compared to a single slice visualization with the 3D method.

1 Pedicle_Awl



2 Pedicle_Awl



Advanced surgical navigation with NaviLink and SIREMOBIL Iso-C^{3D}

With NaviLink, the direct 3D navigation interface for SIREMOBIL Iso-C^{3D}, the drawbacks previously mentioned are virtually eliminated. SIREMOBIL Iso-C^{3D} allows pre- and intra-operative 3D imaging with the patient in the final OR position. Plus, 3D imaging can be repeated whenever necessary to compensate for alterations in the surgical field during the procedure.

For registration-free navigation, a reference ring from Siemens attaches to the image intensifier. Navigation system manufacturers are adapting their marker rings for compatibility with this reference ring, so the navigation marker ring is always placed in the same position.

When the system is installed, a calibration matrix is calculated and stored in SIREMOBIL Iso-C^{3D}. The calibration matrix automatically provides the relationship between the coordinates of the C-arm and the image coordinates in space. These image coordinates including the 3D dataset are transferred to the navigation system and yield a direct match with the position of the navigation instruments. Thus, for navigation systems compatible with NaviLink, manual matching is no longer needed, and the surgical procedure can start directly after the 3D image scan with SIREMOBIL Iso-C^{3D}.



- 1 The marker ring is mounted on the image intensifier of SIREMOBIL Iso-C^{3D}
- 2 Placement of the reference marker on the patient
- 3 The camera system of the navigation system is positioned to detect both the marker ring and the reference marker
- 4 SIREMOBIL Iso-C^{3D} is brought into start position where the coordinates of the marker ring are detected. The automated 3D scan is executed
- 5 After completion of the scan the 3D images can directly be viewed on the monitor trolley
- 6 The images and coordinates are directly transferred via NaviLink to the navigation system
- 7 SIREMOBIL Iso-C^{3D} can be removed from the table in order to allow free access to the patient
- 8 The surgeon can start the navigation based procedure



NaviLink and SIREMOBIL Iso-C^{3D}: unmatched workflow optimization

Shorter Preparation Phase

- Automatic registration obviates time-consuming manual matching
- No need to set fiducial markers

Higher Precision and Greater Confidence

- Patient is imaged in the “true” OR position
- Imaging can be repeated when there are significant changes in patient anatomy during the case

Optimized Clinical Workflow and Reduced Cost

- Navigation is possible without pre-operative imaging in the radiology department
- Post-operative image documentation can be performed directly in the OR



NaviLink and SIREMOBIL Iso-C^{3D}: Unmatched clinical advantages

History

A 62 year old patient with ankylosing spondylitis presented with severe back pain after falling from a ladder. Physical exam did not reveal any neurologic deficits. Radiological examination revealed an unstable fracture AO B3 (according to AO classification*) of the T12 vertebrae.

Due to the instability of the fracture and the high risk of paralysis, the patient was immediately admitted for surgery to reposition the fracture.

Case description



Strategy/Workflow

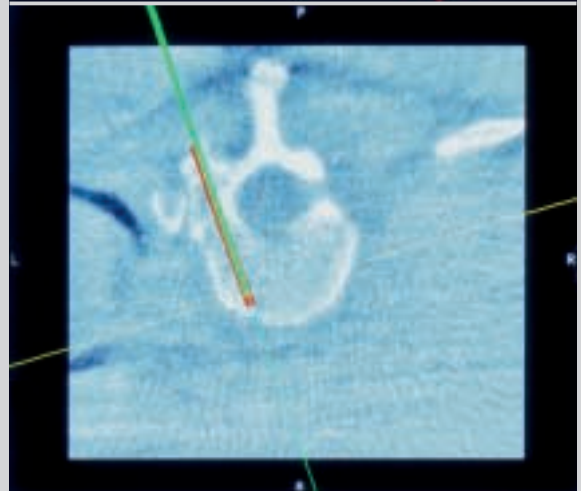
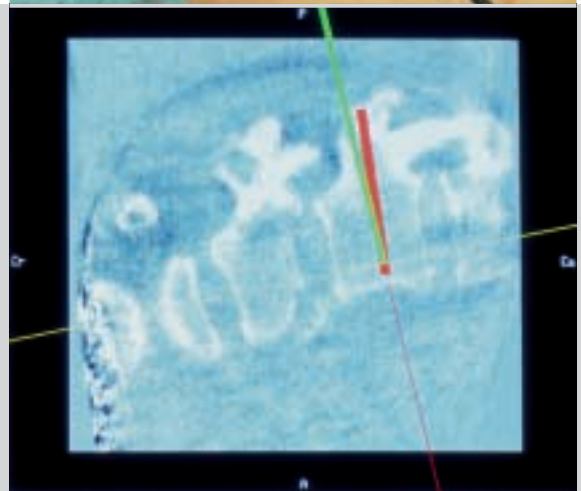
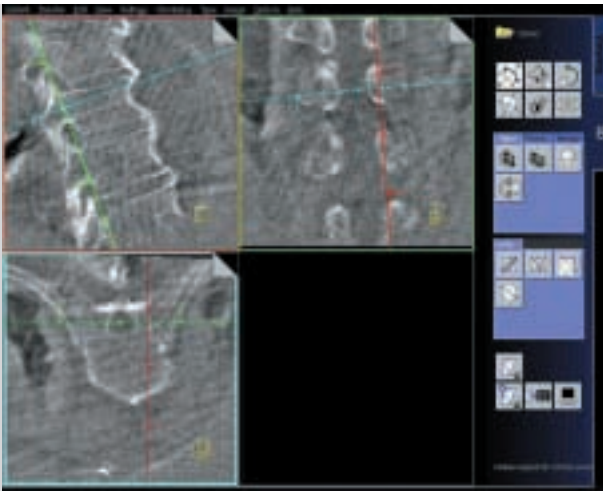
The type of fracture and the nature of the patient's preexisting disease predicts a dorsal approach.

SIREMOBIL Iso-C^{3D} is used to localize the fracture with the patient positioned on the OR table. After fracture repositioning, internal fixation hardware is placed dorsally at the T10-T11 and L1-L2 vertebrae. 3D scans are performed intraoperatively with SIREMOBIL Iso-C^{3D} prior to, during, and after hardware placement. Ideal hardware placement and fracture repositioning are visualized with the final confirmatory 3D scan.

* Magerl F., Aebi M., Gertzbein S. B., Harms J., Nazarian S. (1994)
"A comprehensive classification of thoracic and lumbar injuries".
Eur Spine J 3: 184-201

Procedure

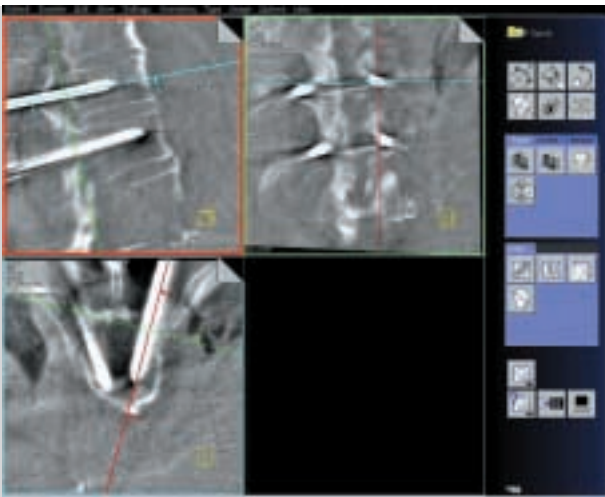
Pre-Operative Imaging



SIREMOBIL Iso-C^{3D} acquires the 3D dataset with the patient in the final position on the OR table. After the 3D scan, NaviLink transfers the 3D dataset to the navigation system. Due to automatic matching the surgeon can directly start to navigate.

After the 3D data acquisition, SIREMOBIL Iso-C^{3D} can be removed from the table allowing unrestricted access to the patient throughout the entire procedure. If the surgical field experiences significant changes, SIREMOBIL Iso-C^{3D} can be repositioned to perform another 3D scan to update the images used for navigation.

Post-Operative



After the procedure, a post-operative scan can be done with SIREMOBIL Iso-C^{3D} to check the positioning of the pedicle implants. There is no need for post-operative CT in the radiology department.

The patient's post-operative course was free from complications, with good healing of the surgical wound. The patient responded well to rehabilitation with restoration of mobility.

Conclusions

- The overall process is faster compared to navigation using pre-operative CT images (no matching necessary)
- Accuracy and confidence are increased because the patient is scanned in the final procedure position on the OR table. Also, images for navigation can be updated anytime during the procedure
- Quality of the procedure can be verified in the OR with a final scan by SIREMOBIL Iso-C^{3D}



Open Interface with the leading navigation system manufacturers

NaviLink, the direct 3D navigation interface for SIREMOBIL Iso-C^{3D}, features an open connectivity interface that accommodates navigation systems from various vendors. Due to the unique intra-operative 3D imaging capability of SIREMOBIL Iso-C^{3D}, many manufacturers are in contact with Siemens in order to adapt their navigation systems to NaviLink. For example, NaviLink is now compatible with navigation systems from BrainLAB, Medivision and Medtronic.

Please refer to www.SiemensMedical.com/surgery for the most recent information on compatibility and approval status.

Proven clinical benefits

**Ekkehard Fritsch, MD,
Orthopedic University Hospital
Homburg/Saar, Germany:**

“NaviLink allows direct transfer of the 3D images generated by SIREMOBIL Iso-C^{3D} to the navigation system. The potential results are high accuracy and excellent screw placement even in the most problematic situations. Accurate insertion of pedicle screws can now be easier even under difficult circumstances like severe osteoporosis, revision cases or in difficult anatomical regions like the cervico-thoracic junction, the upper thoracic and cervical spine.”

“Post-operative evaluations using an additional 3D scan by the SIREMOBIL Iso-C^{3D} showed ideally positioned screws.”

“The excellent image quality of SIREMOBIL Iso-C^{3D}, the automatic registration of the anatomy and the accuracy of the overall system makes this method clearly feasible in the daily routine. It closes the gap between CT-based navigation and fluoro navigation, and is designed to combine the advantages of both methods while eliminating their limitations.”



**Paul Alfred Grützner, MD,
BGU Ludwigshafen, Germany:**

“SIREMOBIL Iso-C^{3D} with NaviLink eliminates the time-, cost- and staff-intensive steps required with pre-operative CT images and manual matching. Because there’s no need to register anatomical landmarks, a main source of inaccuracy in surgical navigation is potentially eliminated.”

“This new method of surgical navigation has a huge potential for innovation and will certainly open completely new fields in minimally invasive surgery. One example is the possibility of determining the precise anatomical joint-axis when positioning an fixation device on the elbow.”

“Navigation with SIREMOBIL Iso-C^{3D} combines the advantages of 2D fluoro navigation and CT based 3D navigation. ”

**Erwin Aschauer, MD,
LKH Salzburg, Austria:**

“NaviLink’s ability to directly use the 3D datasets of SIREMOBIL Iso-C^{3D} for surgical navigation expands the breadth of application. We don’t have to depend on pre-operative CT images anymore.”

“We are using this new method mainly for procedures in the thoracic and lumbar spine. The image quality of SIREMOBIL Iso-C^{3D} is more than sufficient for navigation and we are extremely pleased with the precise positioning of pedicle screws.”



The information in this document contains general descriptions of the technical options available, which do not always have to be present in individual cases. The required features should therefore be specified in each individual case at the time of closing the contract.

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