ortho Minimally-Invasive Orthopaedic Therapy



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OrthoMIT: Overview

Integration and flexibility by innovative technology for smart surgical therapy of the future



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Highlights (1): Smart Intraoperative Imaging

- New methods of dose calculation for C-arm based cone beam CT enabling an optimized radiation protection (Monte Carlo (MC) simulation tool ImpactMC).
- Zero-Dose-C-arm-Navigation for radiation free optimal positioning of the C-arm by virtual previews.
- Robotic C-arm-X-Ray imaging for intuitive navigation of the C-arm and new scan strategies as well as imaging options.
- 3D-ultrasound imaging and referencing MR-data to complete and update the intra-operatively available information of morphology and function.

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Highlights: Smart Imaging





Forward Projection-based Metal Artifact Reduction (FP-MAR)



Correction of metal artifacts in C-arm FD-CT measurements of anthropomorphic specimen with implants*

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*Prell D, Kyriakou Y, Struffert T, Dörfler A, Kalender WA, ANJR, 2009



Zero-Dose-C-Arm-Navigation





- Radiation free X-Ray image preview for positioning of the C-arm
 - Morphing and overlay (preview) of anatomical structures in the picture
 - Overlay of applicable wound hook, OP-table rods, etc...



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<u>30-40% Reduction of radiation exposure</u> for the OP-Team and patient



Robotic C-arm X-Ray Imaging

Integrated navigation

A navigation camera carried by the C-arm-robot allows the online calibration and the registration free navigation.

Interventional Assistance Under X-Ray control, a light construction robot guides surgical instruments to the intervention side.



Integrated navigation



Interventional Assistance

Partners: IMP + Siemens/CAS Innovations (Erlangen)

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Bone segmentation – MRI data



Femur





Vertebra

MRI and ultrasound registration Surface extraction – MRI data Surface-volume registration Ultrasound simulation Scan path matching in the preoperative data Landmark Bone surface identification extraction of single (CT / MRI) bones Model Segmentation of matching single bones Femur Partners: IMT/INI (Bochum)

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Landmark detection

Ultrasound simulation

Fading ultrasound to MRI after registration

Tibia

3D-Ultrasound Imaging

3D-Ultrasound system for optimized volume acquisition

Compensation of local speed-of-sound variations by speckle analysis





incorrect speed-of-sound



corrected image

Partners: IMT/INI (Bochum)





Smart Intraoperative Imaging 3D-Image Guided Spine Surgery



Partners: IMT/INI (Bochum), CAS Innovations (Erlangen)



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Kypho- / Vertebroplasty

Constantly moved display of the instruments in the OP-volume



Smart Knee and Hip Surgery

- Marker- and tracking less total knee arthroplasty based on miniaturized instrumented force-torque sensors and inlays (genALIGN, patent pending).
- Ultrasound based identification of landmarks for individualized biomechanical planning models (hip replacement, repositioning osteotomies).
- Identification and 3D-reconstruction of femoral bone cement based on a miniaturized ultrasound scanner including models for navigated and optional robotic removal of cement (hip revision surgery).
- Modular sterilizable 5DOF minirobot for minimally invasive hip revision surgery, knee replacement and endoscopic spine surgery.
- A magnetic tracking system, robust against interfering field: by miniaturized markers and compensation of low frequent interferences of magnetic field (patent pending).
- Spherical repositioning osteotomy for repositioning of the acetabulum in case of hip dysplasia with minimally invasive fixation, optimal repositioning and mobility.



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Highlights: **Smart Knee and Hip Surgery**



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Smart Knee and Hip Surgery

Marker- and Tracking Free Total Knee Arthroplasty



genALIGN – sensor-based determination of the Mikulicz-Line



Piezoresistive straingauges



SITI — Sensor integrated Tibial-Trial-Inlay

genALIGN-concept for sensorbased knee navigation

 Precise, image-, marker- and tracking free knee arthroplasty, incl. soft tissue management

(Patent pending; winner of 3rd prize of the state-wide inventors competition "patente Erfinder")



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Smart Knee and Hip Surgery Ultrasound-Pointer Based Registration



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Smart Knee and Hip Surgery Modular Sterilizable Minirobot

Abdeckung



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- RTHR (Removal of cement)
- Knee arthroplasty
- Laparoscopic spine surgery
- All components autoclavable
- Standard modular control conception
- Integration in navigation systems (TP12) and integrated working station (TP13)



Smart Knee and Hip Surgery SPAO - Spherical Repositioning Osteotomy

orthoMIT

Integrated

working station

orthoMIT Navigated

instruments

CT-based planning

Potential advantages

) ±

orthoMIT SPAO-module

- No shear stress
- Enhanced rotation
- Enhanced re-fixation
- Enhanced healing process



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DICOM

CT-data

and Research

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Smart Knee and Hip Surgery SPAO - Spherical Repositioning Osteomy



Schematic of the rotatory saw blade kinematic



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Federal Ministry of Education and Research SurgiTAIX

Prototype of the navigatable atraumatic saw (OsteoTAIX)

Evaluation of the system on human preparation



Highlights (3): Smart Integration

- Architecture for integration and security based on a Service-Oriented Architecture (SOA). The orthoMIT-concept is explicitly named as an example in the international standard IEC 80001.
- Smart OR-table for a knowledge based anthropometric OR-table positioning for reduction of non-ergonomic working postures.
- Innovative concept for user interfaces, e.g. Remote Pointer (patent pending) for sterilizable intuitive interaction with the integrated workstation.

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Highlights: Smart Integration



Smart Integration

Architecture for Integration and Security

"...modular, flexible and intelligent configurable OP-workstation..."



Concept studies of the "OP of the future" (in cooperation with the university of applied sciences (FH Aachen), design faculty)

- Implementation of the orthoMIT-integration architecture
- Build-up of the demonstrationenvironment at the university hospital Aachen
- Simulation und evaluation of the developed concepts



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Based on Surgical Workflow Analysis



- >Work flow oriented system integration
- Support the surgical processes with their functionality (and variability !)
- Offer modular services to surgeons
- Flexible rearrangement for different interventions
 - Modular design
 - agreed open standards (DICOM, HL7, future S-DICOM)
 - Different Levels of Integration (flexibility !)

Hardware & Software

- integrated as well as stand-alone use of devices
- Open communication and data exchange between devices
- Integrated modular risk management



Smart Integration



Safety aspects

- Service Manager \geq
 - Centralized management
 - Access control on user and service level

Monitoring of hard- and software

- Priority management
- Redundancy of central components

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status

orthoMIT-

integration architecture

- > Application of a Service Oriented Architecture (SOA)
- Realization by open standards (XML, WSDL, SOAP etc.)
- Standardized interfaces and protocols
- > Manufacturer independent





International Standard IEC 80001 > Use Case OrthoMIT <

(Risk Management for IT-Networks incorporating Medical Devices)



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IEC 80001-3 Use case: OrthoMIT risk management concept

Smart Integration Smart OR-Table

- Controlling of the OR-table on basis of anthropometrical data and workflow-information
- Reducing postural exposure of the surgeon
- Integration into the orthoMIT-Integration Architecture

Posture analysis and evaluation



Knowledge database & positioning expert system





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Smart Integration

Robust Electromagnetic Tracking

- Magnetic tracking has various advantages of application, but it is prone to field distortions
- Concept for a compensation of field disturbances for EMT (patent pending)
- ➔ Reliable use for surgical navigation



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Smart Integration

Innovative Concept for User Interfaces, e.g. Remote Pointer

Contactless sterile interaction via wireless (passive) optical tracking

Central User Interface

- Integration of multiple interaction types in <u>one</u> device
 - Pointing instrument for registration
 - Controlling dialog based development- and navigation systems (gesture detection)
 - Handling of graphical user interfaces (mouse click emulation) in any definable layer

Central user interface ("Cockpit") of the integrated work station



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Model Based Human Risk Analysis mAlXuse



- Task Modelling
- Human Risk Analysis
- Outperformance classical analysis with FMEA (or FTA) (Janss et al. 2010)

mAlXuse Software: analysing a planning & navigation system

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Smart Integration

Innovative Assistance Systems

EndoTAIX: Highly dynamic stabilization system





Features:

- 20ms time for latching
- 500mm working radius
- > 20N holding force
- Single hand usability
- Fixing on the OR-table

Optional: Area- und force monitoring

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Smart Integration

Education and Training

Modular Education and Training concept

=> Multimedia Handbook, Interactive Courses, Simulators...

Clinical Case Database

- => Source for Courses, Simulators and Handbook Content
- Online Assistance for specific help according to current

progress in workflow



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Smart Integration Prospective HTA (economics)

Objectives: *Demonstrating consequences* and *potentials* due to novel medical devices from different perspectives

Methods: •Mare



Marcov chain monte carlo *simulation tool* (MCMC)
Spotting parameter uncertainty through *probabilistic techniques* (PSA, CEAC)

•Regarding general differences in surgery process due to novel medical devices using *event-driven process chains*





- valuing relevant health states
- regarding relevant scenarios
- early model validation by orthopedists & developers



Smart Integration - Early economic-evaluation

Applications under iterative assessment

- Vertebral Pin-Point-Surgery
- Total knee arthroplasty
- RTHR

current: OrthoMIT TKA with genALIGN® and SITI®

- Estimated overall cost-savings on OrthoMIT TKA compared to conventional TKA: women: 280 € / men: 258 €
- Estimated overall additional QALY-gain on OrthoMIT TKA compared to conventional TKA: women: 0,07 / men: 0,05
- Even higher cost-savings but less additional QALY-gain when compared to navigated TKA

Partners: Synagon (Aachen)

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