Customized surgical guides =
Individual Templates* (Radermacher et al. 1993)
- The Team -

Klaus Radermacher, PhD
Frank Portheine, PhD* (1995-2001)
Erik Schkommodau, PhD (1998-2004)**
Helmholtz-Institute f. Biomedical Engineering, RWTH Aachen University, Aachen, Gemany
Hans-Walter Staudte, MD et al.(1993-2010)
Medical Center DAC, Würselen, Germany

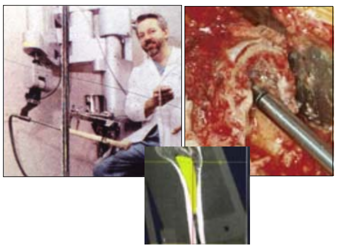
** today: CEO, SurgiTAIX AG, Aachen, Germany*
***today: School of Life Sciences, University of Applied Sciences Northwestern Switzerland*

Overview

- Introduction
- Basic principle of the individual template approach
- Major challenges and approaches (1992/93 and today)
  - Image/information acquisition
  - Image processing and 3D-reconstruction
  - Planning concepts
  - Computer assisted design and manufacturing (CAD/CAM)
  - Implementation and Man-Machine Interaction
  - Experimental and clinical applications (1993-2010)
  - Training

History of CAOS (1/6)

- 1985 First concepts in (neuro-)surgical **robotics** (Kwoh et al.)
- 1989 First concepts of Robotics in Orthopaedic Surgery (Taylor et al.)
- 1991 First human intervention with ROBODOC (Taylor et al.)

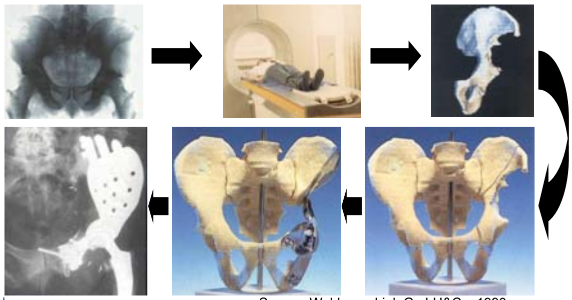


Hap Paul†,
R. Taylor et al. 1989

First human intervention
ROBODOC THR 1991
B. Bargar, R. Taylor et al.

History of CAOS (2/6)

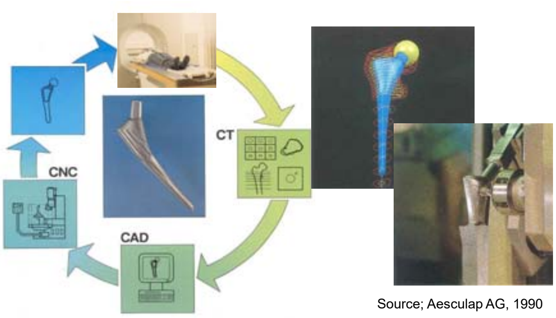
Patient specific anatomical models and implants



Source: Waldemar Link GmbH&Co, 1990

History of CAOS (3/6)

3C - custom made implants



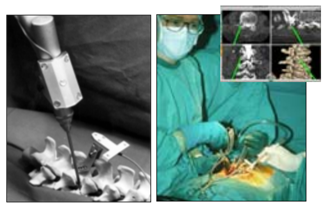
Source; Aesculap AG, 1990

History of CAOS (4/6)

- 1985 First concepts of **navigation** in ENT and neurosurgery (Krybus et al.)
- 1989 First navigated interventions in ENT & neurosurgery (Gilsbach et al.)
- 1990 First concepts of navigation in orthopaedic surgery (Nolte et al.)
- 1994 First navigates pedicle screw in CAOS (Schwarzenbach et al.)

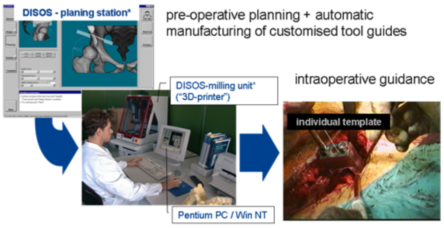
Nolte et al. 1990

First pedicle screw insertion
June 8, 1994
O. Schwarzenbach



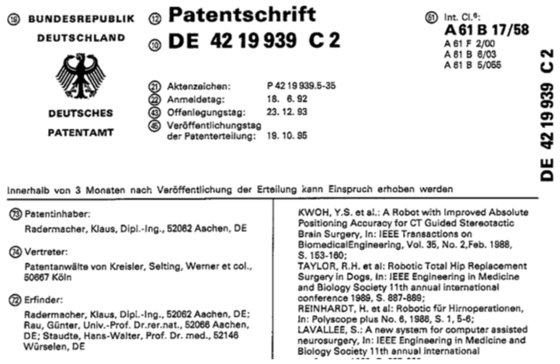
History of CAOS (5/6)

- 1988-1992 First concepts of individual templates CAOS (Radermacher et al.1992)
- **1993 First human intervention with individual templates (Staudte et al.)**



First CAS Tripel-Periacetabular Repositionning Osteotomie
With individual templates: 1993 by Prof. Staudte, Aachen/Würselen

History of CAOS (5/6)



(19) BUNDESREPUBLIK DEUTSCHLAND

DEUTSCHES PATENTAMT

(12) **Patentschrift**

(10) **DE 42 19 939 C 2**

(51) Int. Cl.[6]:
A 61 B 17/58
A 61 F 2/00
A 61 B 6/03
A 61 B 5/055

(21) Aktenzeichen: P 42 19 939.5-35
(22) Anmeldetag: 18. 6. 92
(43) Offenlegungstag: 23. 12. 93
(45) Veröffentlichungstag der Patenterteilung: 19. 10. 95

DE 42 19 939 C 2

Innerhalb von 3 Monaten nach Veröffentlichung der Erteilung kann Einspruch erhoben werden

(73) Patentinhaber:
Radermacher, Klaus, Dipl.-Ing., 52062 Aachen, DE

(74) Vertreter:
Patentanwälte von Kreisler, Selting, Werner et col., 50667 Köln

(72) Erfinder:
Radermacher, Klaus, Dipl.-Ing., 52062 Aachen, DE; Rau, Günter, Univ.-Prof. Dr.rer.nat., 52066 Aachen, DE; Staudte, Hans-Walter, Prof. Dr. med., 52146 Würselen, DE

KWOH, Y.S. et al.: A Robot with Improved Absolute Positioning Accuracy for CT Guided Stereotactic Brain Surgery, In: IEEE Transactions on BiomedicalEngineering, Vol. 35, No. 2,Feb. 1988, S. 153-160;
TAYLOR, R.H. et al: Robotic Total Hip Replacement Surgery in Dogs, In: IEEE Engineering in Medicine and Biology Society 11th annual international conference 1989, S. 887-889;
REINHARDT, H. et al: Robotic für Hirnoperationen, In: Polyscope plus No. 6, 1986, S. 1, 5-6;
LAVALLEE, S.: A new system for computer assisted neurosurgery, In: IEEE Engineering in Medicine and Biology Society 11th annual international

Our Publications on Individual Templates (1993-2003)
- Conference Proceedings -

1. Radermacher, K., Staudte, H.-W., Rau, G.: Computer Assisted Matching of Planning and Execution in Orthopedic Surgery. Proc. IEEE EMBS, San Diego, pp. 946-947, 1993
2. Radermacher, K., Rau, G., Staudte, H.-W.: Computer Integrated Advanced Orthopedics. Proc. 2nd European Conf. in Engineering and Medicine, Stuttgart, pp. 1-2, 1993
3. Radermacher, K., Staudte, H.-W., Rau, G.: Computer Assisted Orthopaedic Surgery by Means of Individual Templates - Aspects and Analysis of Potential Applications. DiGioia III, A. et al. (eds.): Medical Robotics and Computer Assisted Surgery, Carnegie Mellon University Pittsburgh, 1994, pp.451-463
4. Radermacher, K., Staudte, H.-W., Pichler, C. v., Rau, G.: Computerunterstützte Kopplung von Planung und Umsetzung chirurgischer Eingriffe in der Orthopädie. Zeitschrift für Biomedizische Technik 39, 1994, Ergänzungsband, S. 205-206
5. Radermacher, K., H.-W. Staudte, G. Rau: Technique for Better Execution of CT-Scan Planned Orthopedic Surgery on Bone Structures. Lemke, H.U et al. (eds.): Computer Assisted Radiology, Springer-Verlag, 1995, pp. 933-938
6. Radermacher, K., R. Bliem, Ch. Hennecke, H.-W. Staudte, G. Rau: DISOS - A Desktop Imageprocessing System for Computer Assisted Orthopedic Surgery.Weghorst, S.J. , Sieburg, H.B. , Morgan, K., (eds.): MMVR 4 - Health Care in the Information Age -Future Tools for Transforming Medicin , IOS Press, 1996, pp.675-680
7. Portheine, F., Zimolong, A., Radermacher, K., Rau, G.: Präoperative Planung und Planungsumsetzung in der computerunterstützten orthopädischen Chirurgie. in: Lehmann, Th. Scholl, I., Spitzer, K. (eds.): "Bildverarbeitung für die Medizin", Proceedings zum Aachener Workshop , 8/9.November 1996, Verlag der Augustinus Buchhandlung Aachen, 1996, S. 185-190
8. Rau, G., Radermacher, K.: Operationsplanung und -ausführung in der computerunterstützten Chirurgie. Zeitschrift für Biomedizinische Technik (Ergänzungsband), 1997, S. 305-306
9. Radermacher, K., Portheine, F., Zimolong, A., Eichhorn, Ch., Staudte, H.-W., Rau, G.: Image Guided Orthopedic Surgery Using Individual Templates - Experimental Results and Aspects of the Development of a Demonstrator for Pelvis Surgery - . in: Troccaz, J. Grimson, E., Mösges, R. (eds.): CVRMED II and MRCAS III, Lecture Notes in Computer Science, Springer-Verlag, 1997, pp. 606-616
10. Portheine, F.,Radermacher,K., Zimolong, A., Anton,M.,Eichhorn, Ch., Staudte, H.-W., Rau, G.,Development of a clinical demonstrator for computer assisted orthopedic surgery with CT-image based individual templates - in: Lemke et al. (eds.): Computer Assisted Radiology and Surgery, Elsevier, 1997, pp. 944 – 949
11. Portheine, F., Zimolong, A., Radermacher, K., Rau, G.: Entwicklung eines klinischen Demonstrators für die computerunterstützte Orthopädische Chirurgie mit CT-bildbasierten Individualschablonen. in: Lehmann, Th. Metzler, V., Spitzer, K., Tolxdorff, T. (Hrsg.): "Bildverarbeitung für die Medizin 1998", Springer Verlag, 1998, S. 149-153
12. Radermacher, K., Portheine, F., Schkommodau, E., Staudte, H.-W., Rau, G.: Entwicklung eines integrierten Planungs- und Fertigungssystems für CT-Bild-basierte individuelle Bearbeitungsschablonen in der orthopädischen Chirurgie.VDI Fortschritts-Berichte, Reihe 17, 1999, S. 56-57
13. Schkommodau, E., Klapper, U., Birnbaum, K., Radermacher, K., Staudte, H.-W.: Computerunterstützte Implantation von Pedikelschrauben mit Hilfe von Individualschablonen in der Orthopädischen Chirurgie. Zeitschrift für Biomedizinische Technik, Band 45, Ergänzungsband 1, 2000, S. 206-207
14. Portheine, F., Radermacher, K., Staudte, H.-W., Rau, G.: Computerunterstützte CT-bildbasierte Operationsplanung bei Umstellungsosteotomien. Zeitschrift für Biomedizinische Technik, Band 45, Ergänzungsband 1, 2000, S. 202-203
15. Radermacher, K., Kaspers, G., Portheine, F., Schkommodau, E., Staudte, H.-W.: Klinische Erfahrungen mit der computerunterstützten Planung und intraoperativen Führung mit individuellen Bearbeitungsschablonen für die periacetabuläre Umstellungsosteotomie. Zeitschrift für Biomedizinische Technik, Band 45, Ergänzungsband 1, 2000, S. 204-205
16. Radermacher, K., Portheine, F., Schkommodau, E.: Rechnerbasierte Entscheidungs-unterstützung zur Planung von Kontaktflächen zur manuellen Referenzierung mit Individualschablonen. Zeitschrift für Biomedizinische Technik, Band 45, Ergänzungsband 1, 2000, S. 227-228
17. Portheine, F., Frömel, M., Radermacher, K.: Computerunterstützte Knie-Totalendoprothetik mit planungsspezifischen Bearbeitungsschablonen. Zeitschrift f. Biomedizinische Technik, Band 46, Ergänzungsband 1, 2001, S. 370-371
18. Radermacher, K., Wu, T., Zimolong, A., Cinquin, Ph., Grange, S., Niethard, F.U., Rau, G.: Netzbasierte Module für Ausbildung, Training und Dokumentation in der Orthopädischen Chirurgie: VOEU. Zeitschrift f. Biomedizinische Technik, Band 46, Ergänzungsband 1, 2001, S. 364-365
19. Portheine, F., Ohnsorge, J.A.K., Frömel, M., Radermacher, K.: Modellierung von Bandstrukturen bei der CT-bildbasierten Planung knieendoprothetischer Eingriffe. Biomedizinische Technik, Band 47, Ergänzungsband 1,Teil1 2002, S. 53-56

Our Publications on Individual Templates (1993-2003)
- Books and Book Contributions -

1. Radermacher, K., Rau, G., Staudte, H.-W.: Computer Integrated Orthopedic Surgery – Connection of planning and execution in surgical intervention -. In: Taylor, R., Lavallée, St., Burdea, G.C., Moesges, R.: Computer Integrated Surgery. MIT-Press, Cambride, MA, 1993 (in press)…1996, pp.451-463
2. Staudte, H.-W., Radermacher, K., Rau, G: CT-abgeleitete Operationsschablone am Beispiel der Tripel-Osteotomie nach Tönnis.in: Wessinghage, D.: Praktische Orthopädie, Bd. 27, Thieme Verlag, 1997, S. 165-171
3. Radermacher, K., Rau, G., Staudte, H.-W.: Computerintegrierte operative Eingriffe in der Orthopädie: Möglichkeiten auch in der Endoprothetik? in: Wessinghage, D.: Praktische Orthopädie, Bd. 27, Thieme Verlag, 1997, S.149-164
4. Radermacher, K.: Computerunterstützte Operationsplanung und -ausführung mittels individueller Bearbeitungsschablonen in der Orthopädie. (Diss. RWTH-Aachen), Shaker-Verlag 1999
5. E. Schkommodau, N. Decker, U. Klapper, K. Birnbaum, H.-W. Staudte, K. Radermacher: Pedikelschraubenimplantation mit dem DISOS-Schablonensystem. in: W. Konermann, R.Haaker (Hrsg.): Navigation und Robotic in der gelenk- und Wirbelsäulenchirurgie. Springer Verlag (2002), S.395-399
6. F. Portheine, J. Ohnsorge, E. Schkommodau, K. Radermacher: CT- basierte Planung und Schablonennavigation für die Kniegelenk-Endoprothetik. in: W. Konermann, R. Haaker: Navigation und Robotik in der Gelenk- und Wirbelsäulenchirurgie. Springer-Verlag (2002), S. 262-269
7. H.-W. Staudte, E. Schkommodau, M. Honscha, F. Portheine, K. Radermacher: Beckenosteotomie mit Schablonennavigation. in: W. Konermann, R. Haaker: Navigation und Robotik in der Gelenk- und Wirbelsäulenchirurgie. Springer-Verlag (2002), S. 356-364
8. Radermacher, K.: MRCAS in Forschung und/oder breiter klinischer Anwendung - Rechtfertigung, Alternativen und Perspektiven. in: Labs, K., Zippel, H.: Stand und Perspektiven der computer-assistierten Chirurgie. Uni-Med-Verlag, Bremen, 2002, S. 145-152
9. Portheine, F., J.A.K. Ohnsorge, E. Schkommodau, K. Radermacher: CT-Based Planning and Individual Template Navigation in TKA. in: J.B. Stiehl, W.H. Konermann, R.G. Haaker (eds.): Navigation and Robotics in Total Joint and Spine Surgery, Springer Verlag Berlin 2003, pp 336-342
10. Schkommodau, E., N. Decker, U. Klapper, K. Birnbaum, H.-W. Staudte, K. Radermacher: Pedicle Screw Implantation Using the DISOS Template System. in: J.B. Stiehl, W.H. Konermann, R.G. Haaker (eds.): Navigation and Robotics in Total Joint and Spine Surgery, Springer Verlag Berlin 2003, pp 501-505
11. Staudte, H.-W., E. Schkommodau, F. Portheine, K. Radermacher: Pelvic Osteotomy with Template Navigation. in: J.B. Stiehl, W.H. Konermann, R.G. Haaker (eds.): Navigation and Robotics in Total Joint and Spine Surgery, Springer Verlag Berlin 2003, pp 455-463

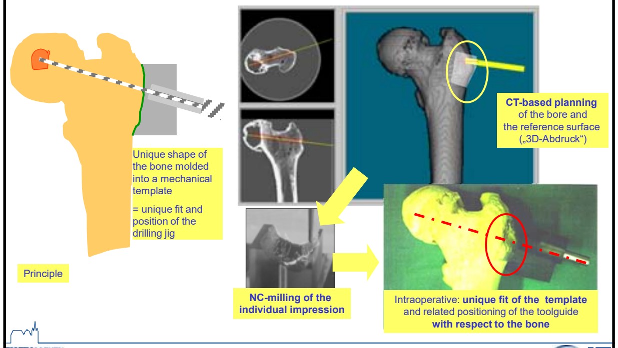
Our Publications on Individual Templates (1993-2003)
- Journals -

1. Rau, G., C. v. Pichler, K. Radermacher: Surgical Reality. Medical Technology International, Cornhill Publications Ltd. 1995, pp.46-51
2. Radermacher, K., Portheine, F., Anton, M., Zimolong, A., Kaspers, G., Rau, G. Staudte, H.-W.: Computer Assisted Orthopaedic Surgery with Image-Based Individual Templates. Journal of Clinical Orthopaedics and Related Research, 354: 1998, pp. 28-38
3. Staudte, H.-W., K. Radermacher, G. Rau: Computerunterstützte Operationsplanung und -ausführung mit individuellen Bearbeitungsschablonen. Zeitschrift für Orthopädie, 136, 1998, pp. 124-125
4. Schiffers, N., Schkommodau, E., Portheine, F., Radermacher, K., Staudte, H.-W.: Planung und Ausführung von orthopädischen Operationen mit Hilfe von Individualschablonen, Der Orthopäde, Springer, 2000, 29, 636-640
5. Portheine, F., Radermacher, K., Staudte, H.-W.: Potentiale der CT-basierten Planung und schablonengestützten Ausführung in der Hüft- und Kniechirurgie. Orthopädische Praxis, 12/2000, 36. Jahrgang, S.786-791
6. Radermacher, K., Rau, G.: Computerassistierte Planung und Operation in der Orthopädie. Orthopädische Praxis, 12/2000, 36. Jahrgang, S.731-737
7. Schkommodau, E., Kaspers, G., Klapper, U., Radermacher, K., Staudte, H.-W.: Klinische Erfahrung mit der Individualschablonentechnik. Orthopädische Praxis, 1/2001, 37. Jahrgang, S.19-22 (2001)
8. Birnbaum, K., Schkommodau, E., Decker, N., Prescher, A., Klapper, U., Radermacher, K.: Computer assisted orthopedic surgery with individual templates and comparison to conventional methods. Spine, Vol. 26, No. 4, February 15 (2001), pp. 365-369

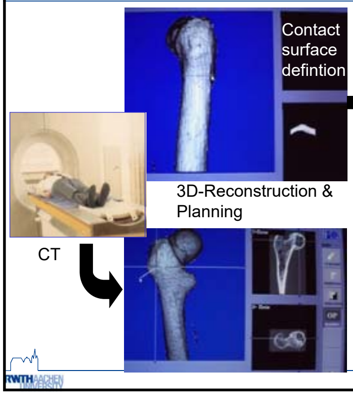
Overview

- Introduction
- **Basic principle of the individual template approach**
- Major challenges and approaches (1992/93 and today)
  - Image/information acquisition
  - Image processing and 3D-reconstruction
  - Planning concepts
  - Computer assisted design and manufacturing (CAD/CAM)
  - Implementation and Man-Machine Interaction
  - Experimental and clinical applications (1993-2010)
  - Training

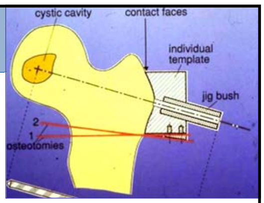
Basic principle of the individual template approach



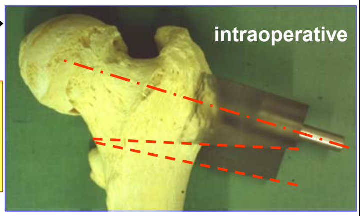
Preoperative Workflow and Components
(CT + 5-10 minutes planning + 10-20 minutes milling (in 1993))


Workflow and Components



Autoclave (20-30 min)



Basic idea:
Create a **desktop inhouse** planning and CADCAM process **usable by the surgeon** him/herself to produce a template for surgery within **less than one hour**

Overview

- Introduction
- Basic principle of the individual template approach
- Major challenges and approaches (1992/93 and today)
  - Image/information acquisition
  - Image processing and 3D-reconstruction
  - Planning concepts
  - Computer assisted design and manufacturing (CAD/CAM)
  - Implementation and Man-Machine Interaction
  - Experimental and clinical applications (1993-2010)
  - Training

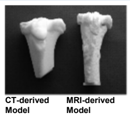
Image Acquisition – CT vs. MRI (in 1993)

- **CT**
  - \+ price, availability,
  - \+ semiautomatic bone image segmentation and 3D-reconstruction
  - \+ resolution, (geometric accuracy)
  - \- No cartilage visible
  - \- Radiation exposure
- **MR**
  - \+ no radiation
  - \+ soft tissue and cartilage contrast
  - \- price, availability
  - \- complex image processing and segmentation
  - \- limited accuracy due to limited resolution and field inhomogenities

Geometric Accuracy
CT- MRI comparison (2007/2008)

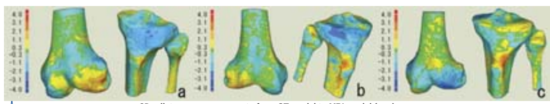
Accuracy of MRI vs CT imaging with particular reference to patient specific templates for total knee replacement surgery (White 2008)

- The CT models appear to be larger than the real bones but the differences are small (**greatest difference +1.9 mm)**
- The MRI based models are smaller than the real bones and the differences are larger (greatest difference **-10.9 mm)**



Can magnetic resonance imaging-derived bone models be used for accurate motion measurement with single-plane 3 dimensional shape registration ? (Moro-Oka 2007)

- Results of comparing CT and MRI-models of femur and tibia showed regions where the surfaces differed by **several millimeters**.

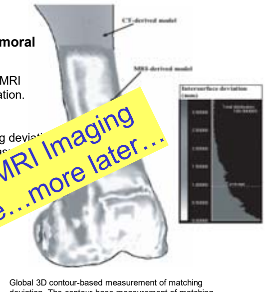


3D –distance measurements from CT model to MRI model (mm)

Geometric Accuracy
CT- MRI comparison (2008)

Anatomical evaluation of CT- MRI combined femoral model (Lee et al. 2008)

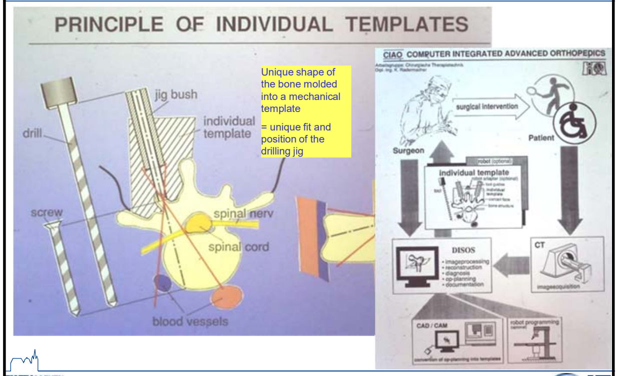
- Lee et et al. evaluated the accuracy of combined CT-MRI models of six porcine femora using rigid body registration.
- Their evaluation in the joint region showed a matching deviation of (1.1 ±1.8) mm in the local 2D contour –based measurement
- The global 3D contour-based measure of matching averaged out to (1.1 ± 0.3) mm for the 3D contour-based method, whereas **(0.7 ± 0.1)** mm was obtained by the surface-to-surface method



Careful application of MRI Imaging
Seems to be possible…more later…

Global 3D contour-based measurement of matching deviation. The contour-base measurement of matching deviation was quantified as the global average of the all distance between the surface nodes of the CT-derived model and MRI-derived model.

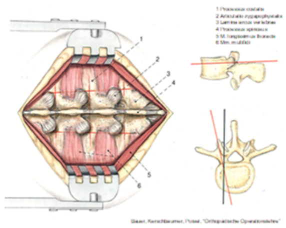
Basic principle of the individual templates in spine surgery (Radermacher et al. 1993)

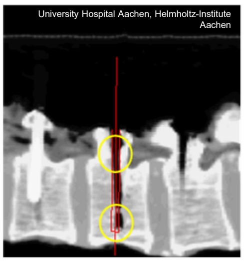


Pedicle Screw Placement in Spine Surgery
- Objectives and surgical bottlenecks-

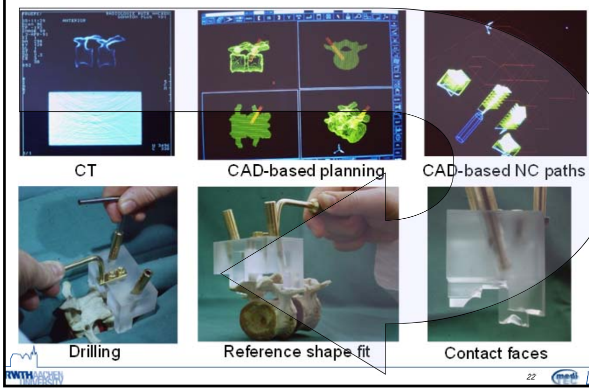
Problems:
- conventional pedicle screw positioning 14-40% misplacement
- intensive fluoroscopy usage
- operating time

Reasons:
- intra-operative 3D orientation problem
- Limited accuracy of surgical worksteps

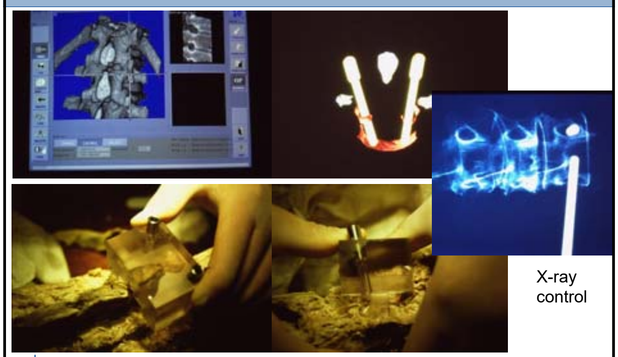




1991: First Concept Study with Individual Templates on Pedicle Screw Placement in Spine Surgery

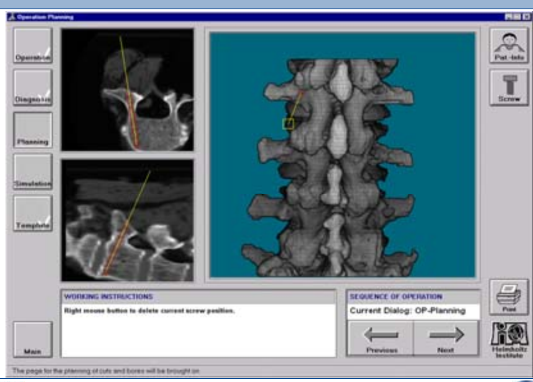


1992: Cadaver Study with Individual Templates (Customized Surgical Guides) on Pedicle Screw Placement in Spine Surgery

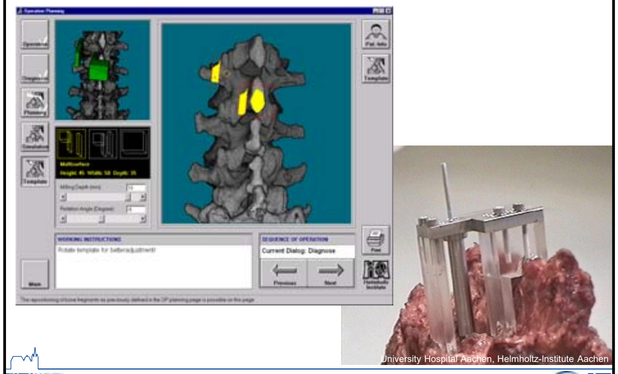


X-ray control

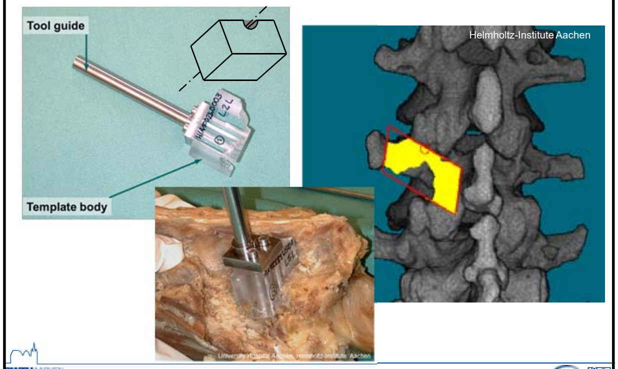
Methods – CT based planning of pedicle screw



Methods - Contact areas



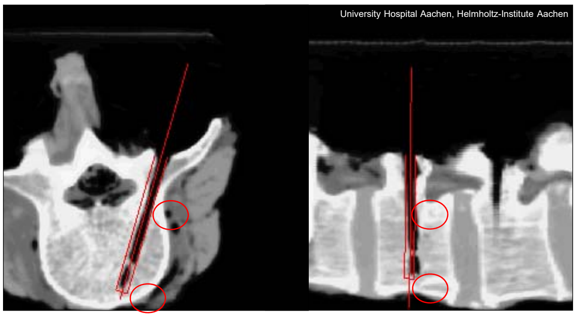
Methods – Template Design V2



Cadaver study

- CT scan of specimen (lumbar spine)
- planning and verification with DISOS / Orthotaix
- template manufacturing
- cadaver study including drilling by template guidance | cadaver study including free hand drilling
- second CT scan
- verification of the drilling axis in orthogonal images
- comparison of the planning data set and post-op CT data set
- evaluation and staging of the screw position

Cadaver study - Evaluation -

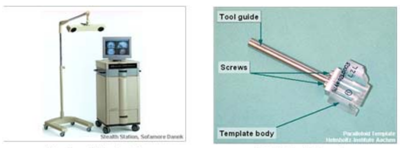


Cadaver Study - Results -

Number of spines: 3	Indiv. templates	conventional
Number of drillings	9	9
Error	0,8 mm	0,5-1,5 mm
Preparation time per pedicle (sec)	171 sec	210 sec
X-ray time per pedicle (p<0,05)	7 sec	46 sec
Subjective assessment (1= very good…5= very bad)	2	3

Birnbaum K, Schkommodau E, Decker N, et al. Computer-assisted orthopedic surgery with individual templates and comparison to conventional operation method. Spine 2001; 26: 365-70.

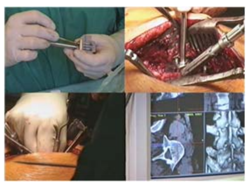
Comparative Study in Spine Surgery
Freehand Navigation vs. Template Based Navigation



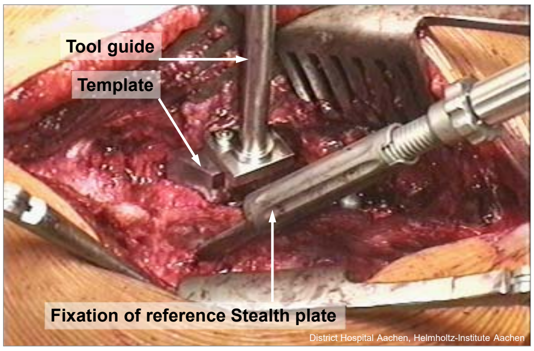
Freehand Navigation   Individual Templates

A comparative clinical study

Biomedizinische Technik/Biomedical Engineering. Vol 45, S1, pp 206–207, ISSN (Online) 1862-278X, ISSN (Print) 0013-5585, DOI: 10.1515/bmte.2000.45.s1.206, //2000

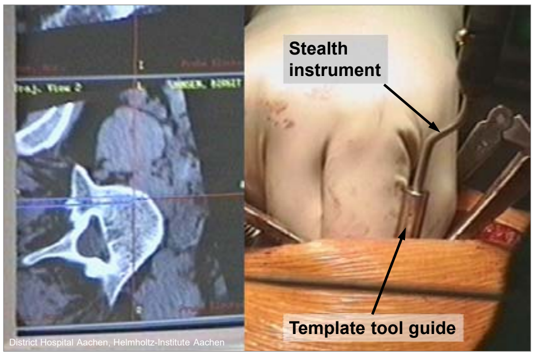


Clinical study - Intraoperative template positioning



31

Clinical study
- template position check with the 3D localiser -



32

Clinical study - results

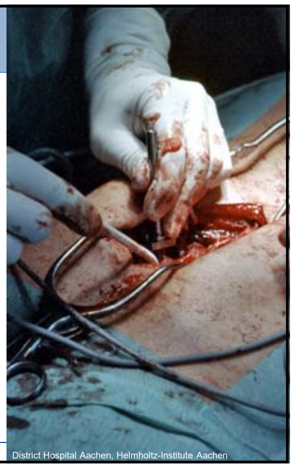
	Navigation (n=16)	Individual Templates (n=24)
Quality of placement (Intraoperative Evaluation by the surgeon; 1= very good; 5= bad)	∅1,5	∅1,71
Fit of the template (Intraoperative Evaluation by the surgeon; 1= very good; 5= bad)	-	∅2,21
Additional OP time per vertebra (registration / template positionning)	∅7 min 48 sec	∅2 min 40 sec
Installation time for devices in the OR (in 2000)	∅10min 33s	∅0min 0s

Biomedizinische Technik/Biomedical Engineering. Band 45, Heft s1, Seiten 206–207, ISSN (Online) 1862-278X, ISSN (Print) 0013-5585, DOI: 10.1515/bmte.2000.45.s1.206, //2000

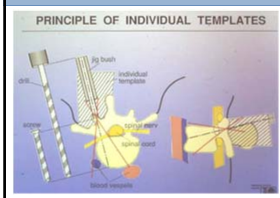
Conclusion (2000) on pedicle screw placement

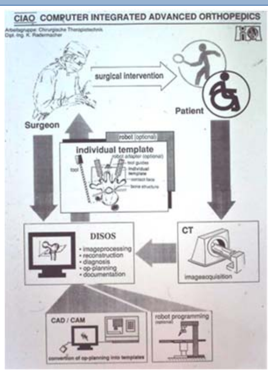
- little changes to intra-operative task sequences
- reduced x-ray exposure for patient and OR-staff
- high accuracy
- no additional installations in the OR
- no additional time consuming intra-operative registration
- intuitive intra-operative handling
- standard autoclavable (at up to 135°C)
- not suitable for traumatology

34



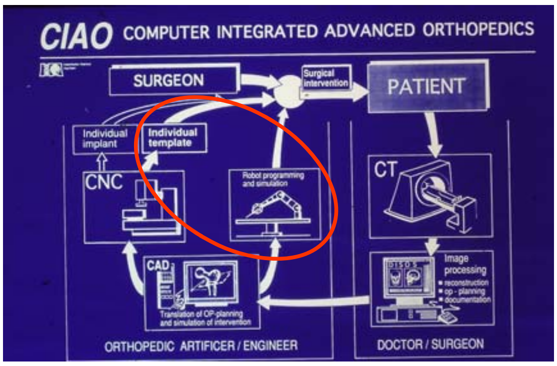
1993-1995: First concept study on robot registration with individual template (for pedicle screw insertion)



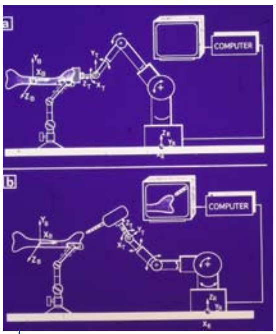


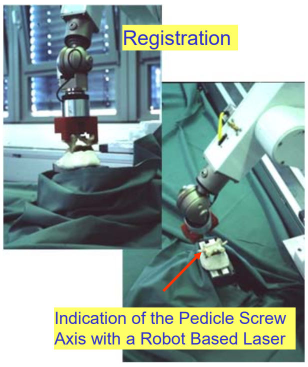
Basic idea:
Create a **desktop inhouse** planning and CADCAM process **usable by the surgeon** him/herself to produce a template for surgery within **less than one hour**

1993-1995: First concept study on robot registration with individual template (for pedicle screw insertion)

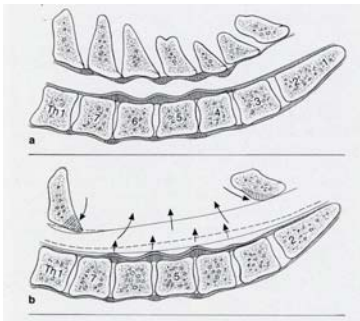


1993-1995: First concept study on robot registration with individual template (for pedicle screw insertion)



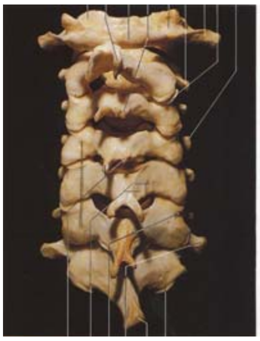


Cervical spinal stenosis
Decompression

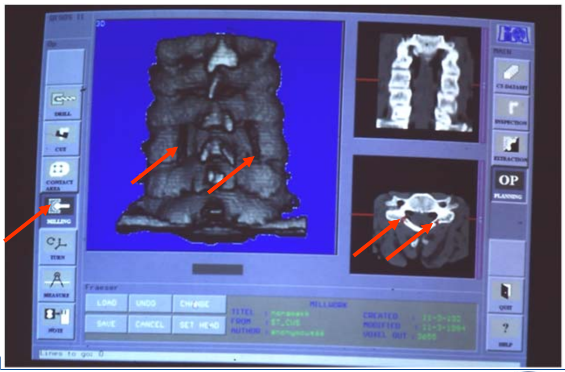


(Yang et al 2008)

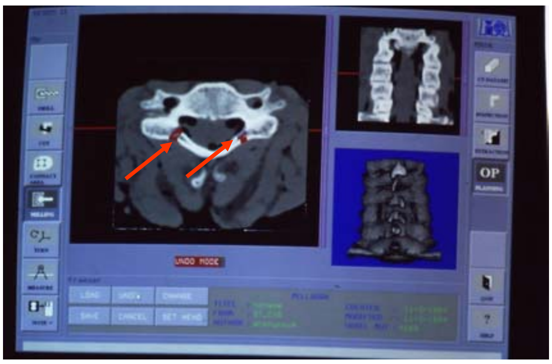
Dorsal cervical spine for template area of contact (dorsal border)



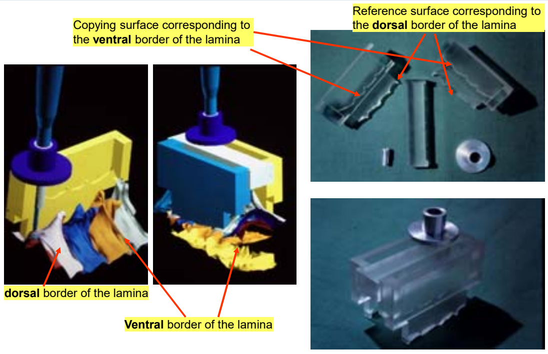
Open Door Decompression in Cervical Spine
- CT-based planning -
(Staudte et al. 1998)



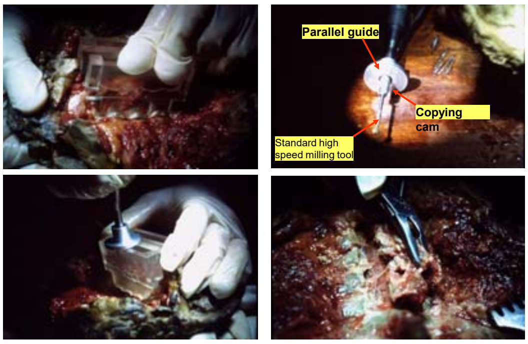
Open Door Decompression in Cervical Spine
- CT-based planning -
(Staudte et al. 1998)



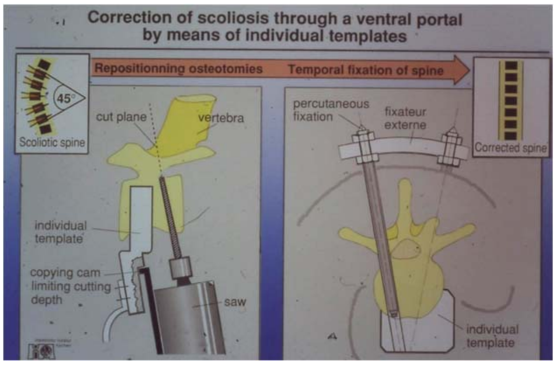
Open Door Decompression in Cervical Spine
- CT-based planning of 3D guidance limiting milling depth -
(Staudte et al. 1994)



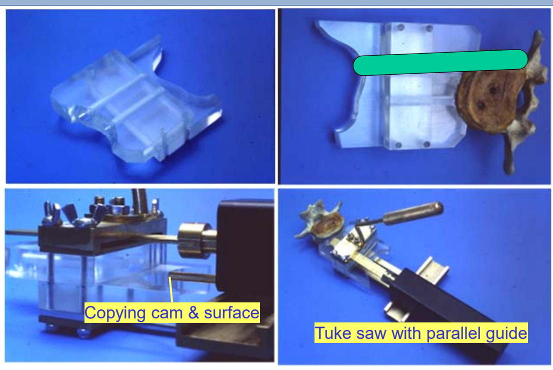
Open Door Decompression in Cervical Spine
- CT-based 3D guidance limiting milling depth -
(Staudte et al. 1998)



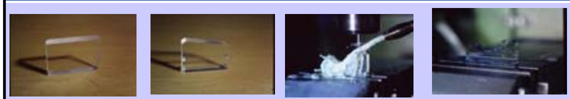
2D depth control: First concept study on ventral repositioning osteotomy on the spine
(Staudte et al. 1993)



2D depth control: First concept study on ventral repositioning osteotomy on the spine



Study on Manufacturing Strategies (1993)
– Milling vs. Rapid Prototyping (or generative manufacturing) -



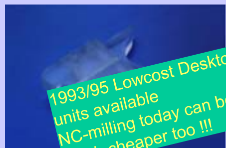
Rapid Prototyping (Stereolithography)

About 1200 €, 1-2 days (1993)

1993-?: No low cost desktop units available However, today Rapid Prototyping can be more than 10 time cheaper !!!

NC Milling

About 1200 €, 1-2 days (1993)



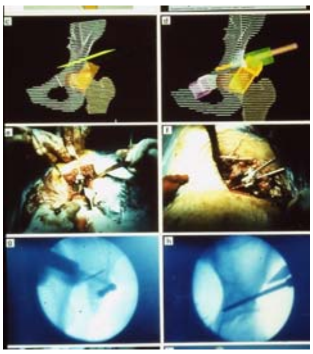
1993/95 Lowcost Desktop units available NC-milling today can be much cheaper too !!!

Depending on the complexity of the template !

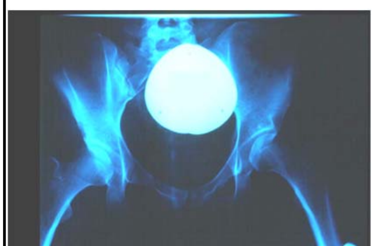
CA - Triple Osteotomy with individual templates

First clinical application of the individual template technique at our department for Orthopaedic Surgery in December 1993

(submitted to MIT-Press in spring 1994…published in 1996: Radermacher, Staudte et al. 1996)

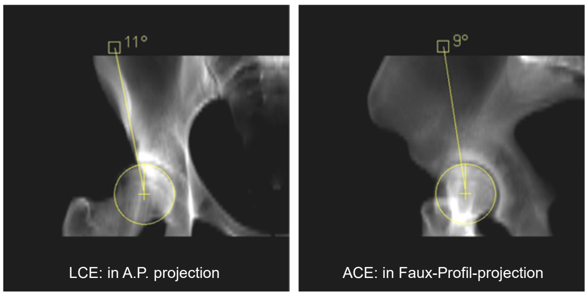


Hip Dysplasia: A.P. and 65° Faux-Profile X-ray



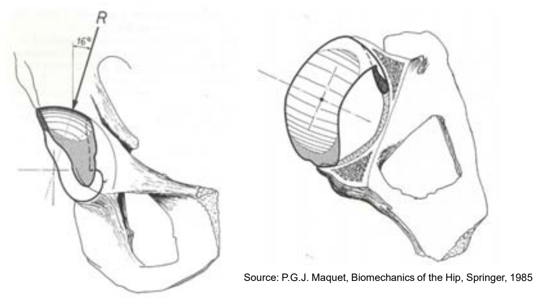
> Evaluation of the femoral coverage

Hip Dysplasia: Evaluation of the femoral coverage using DRR



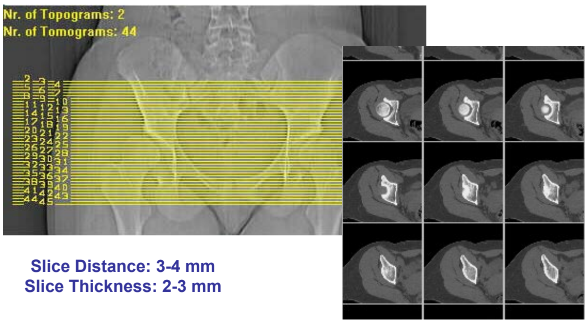
Goal: LCE= 30-35° **Goal: ACE= 30-35°**

3D-Geometry of the Weight Bearing Zone



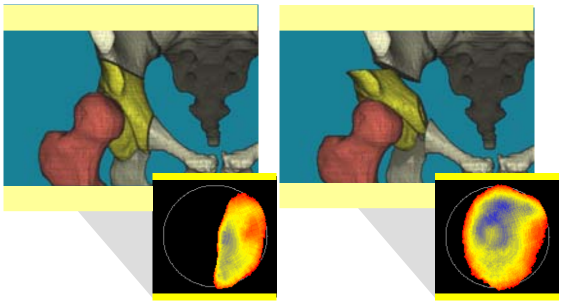
Source: P.G.J. Maquet, Biomechanics of the Hip, Springer, 1985

CT Image Acquisition



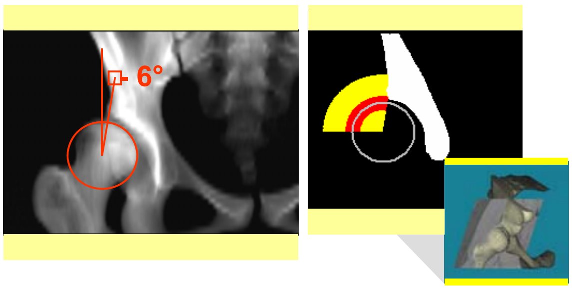
Slice Distance: 3-4 mm
Slice Thickness: 2-3 mm

3D-Reconstruction and 3D-Analysis of the Weight Bearing Zone and Femoral Coverage



(Staudte and Radermacher et al. 1998 ff.)

X-Ray based vs. 3D-based Measurement of LCE and ACE Angles (Portheine et al. 2000)



1st Study: Material and Method (Portheine et al. 2000)

- 20 CT datasets of dyplastic hips
- 3 clinical experts
- Comparison of
  - Conventional x-ray based diagnosis vs.
  - 3D analysis of the lateral and anterior center-edge angles (ACE & LCE)

Results

- Significant difference of +5° between conventional and automatic 3D-based measurement of the LCE-Angle ($p<0,05$)
- NO Significant difference between conventional and automatic 3D-based measurement of the ACE-Angle

Problem Statement

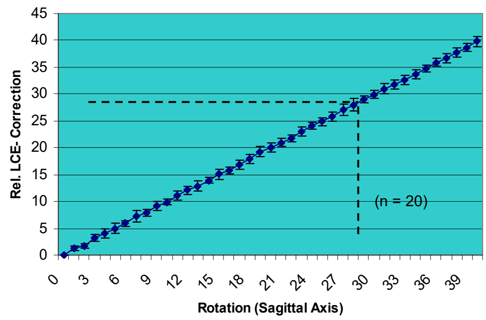
- High inter- and intra-rater variability especially for the LCE (and ACE) measurement due to x-ray projections and the 3D geometry of the acetabular weight bearing area
- based on x-rays the estimation of the weight bearing area in 3D and the resulting correction necessary is quite challenging
- x-ray controls on the OR table do NOT reflect the weight bearing situation
- Clinically overcorrections have been reported (e.g. *Tönnis, 1999)*

Correction needed = Goal (30-35°) – actual angle ???

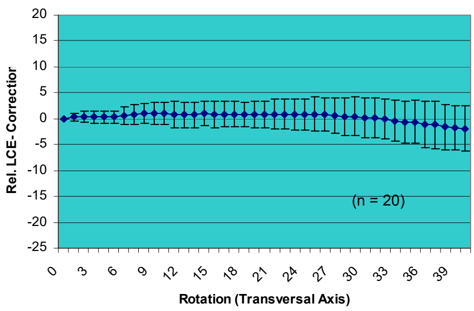
2nd Study: Material and Methods (Portheine et al. 2000)

- 20 CT data sets of dysplastic hips
- Stepwise rotation of the acetabular fragment (1°/step lateral or anterior respectively)
- Automatic Measurement of the LCE and ACE angle after each step
- Subjective (visual) evaluation of the femoral coverage in 3D

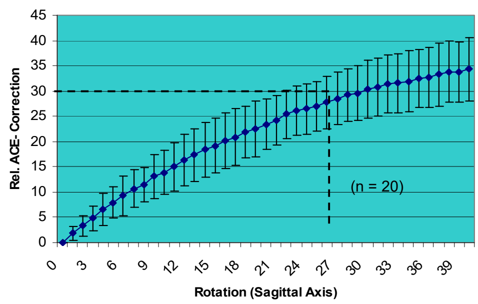
Results (1/4): LCE vs. lateral rotation



Results (2/4): LCE vs. anterior rotation

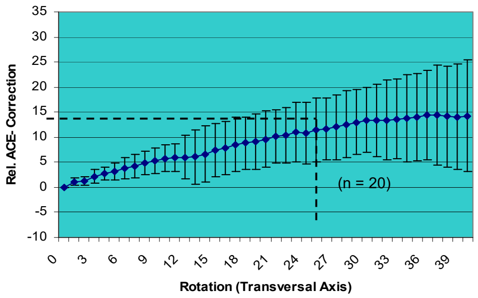


Results (3/4): ACE vs. lateral rotation (!!!)



(note: high patientspecific variability !!!)

Results (4/4): ACE vs. Anterior Rotation

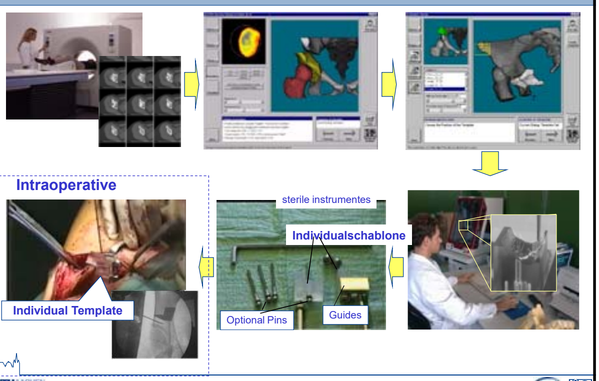


(note: high patientspecific variability !!!)

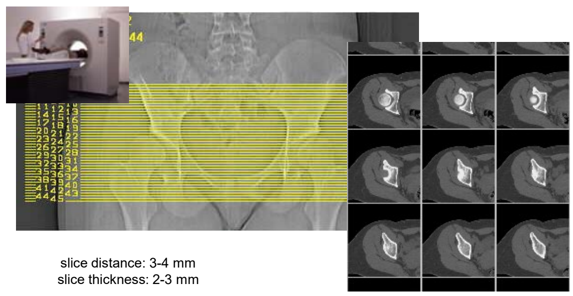
Conclusion (Portheine et al. 2000)

- *the anterior coverage* in many cases is sufficiently corrected only by a *lateral rotation* !
- In these cases an *additional anterior rotation* would lead to an *over correction* (which would have to be compensated by a internal rotation (e.g. Tönnis, 1999))
- The automatic 3D measurment and correction of LCE and ACE to 30° results in a good 3D coverage of the femoral head

Individual Templates
Transfer of Preoperative Planning using Individual Templates



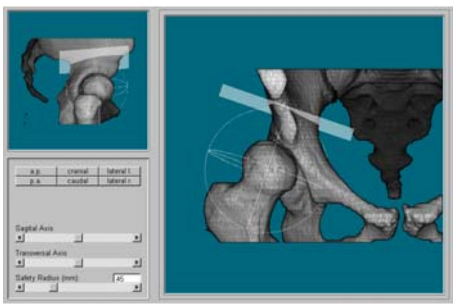
Individual Templates
Individual Templates based Navigation: CT- Image acquisition



slice distance: 3-4 mm
slice thickness: 2-3 mm

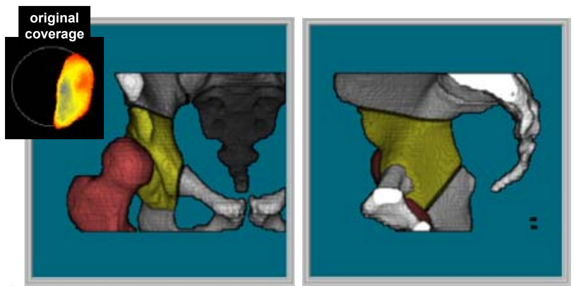
Individual Templates
Interactive Planing of the Tripel-Osteotomy

Automatic 3D-Reconstruction of the CT-Data



Individual Templates
Interactive Planing of the Tripel-Osteotomy

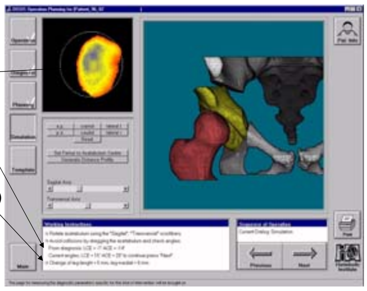
Automatic Segmentation of the Femoral Head and Simulation of the Tripel-Osteotomy



Individual Templates
Interactive Planing of the Tripel-Osteotomy

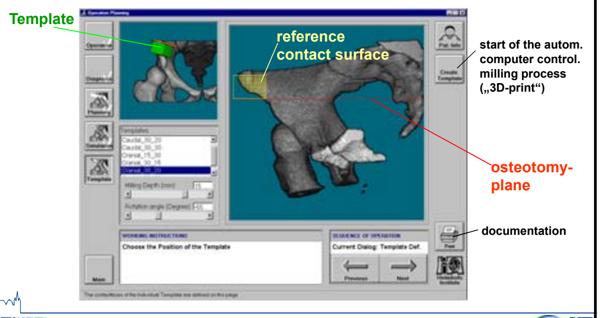
Planning and Simulation of the Repositioning

Analysis:
- result. 3D-coverage (autom. measurement)
- resulting LCE- & ACE-angles (automatic measurement)
- estimated changes in leg length (autom. Measurement)
- mobility of the acetabulum ?
- possible refixation



Individual Templates
Interactive Planing of the Tripel-Osteotomy

Planning and Positioning of the Templates



Is the „unique fit“ really unique and is the surgeon able to identify the position in the operating site (haptic quality)???

Mathematical constraint analysis to predict the quality of fit and its experimental validation (Radermacher et al. 1999):

$$\delta r_i = \delta t_{i,B} + \delta \omega_i \times x_{Ai,B}$$

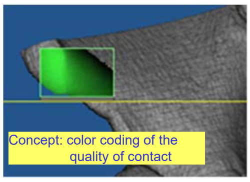
$$v = [t_x, t_y, t_z, \omega_x, \omega_y, \omega_z]^T$$

$$E = \sum_{i=1}^{6} \lambda_i \cdot (d v^T \cdot u_i)^2$$

Apriori Identification of unreliable reference shapes: Sensitivity of

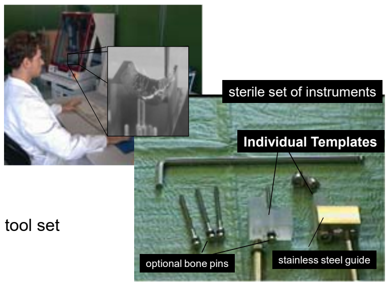
a) *subjective visual ratings* of

Experienced users:	94,8%
Unexperienced users:	64,8%
b) Model based automatic ratings:	**97,3 %**

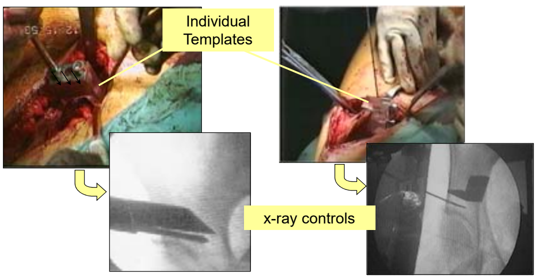


Individual Templates
Automatic Desktop Manufacturing of Individual Templates

- automatic milling of the templates (ca. 5-20 Min.)
- autoclave (135°C; ca. 5-30 Min.)
- transfer of the sterile tool set to the OR



Individual Templates
Intraoperative Guidance of Tripel-Osteotomy by Individual Templates



Individual Templates
Periacetabular Tripel-Osteotomy with Individual Templates

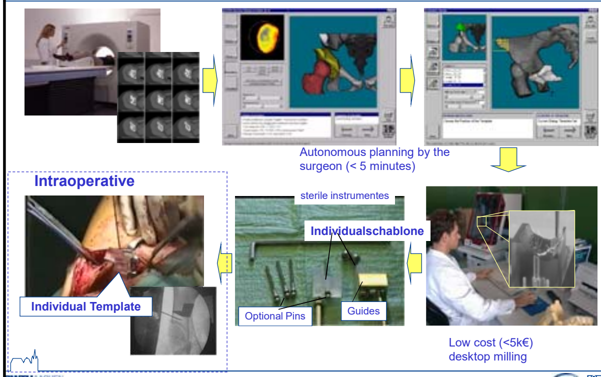
Individual Templates
Clinical Study Tripel-Osteotomy

1 expert surgeon (> 50 interventions), 2 less experienced surgeons (< 20 interventions)

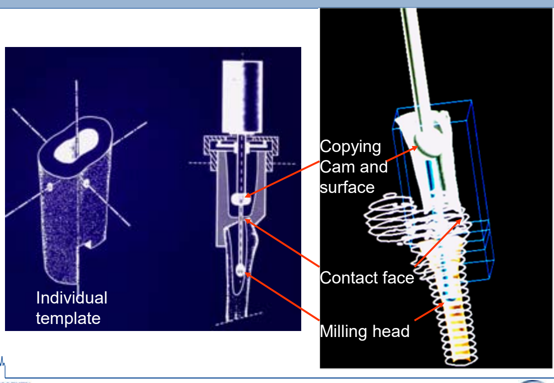
∅	conventional (K) (n=10)	Template based (C) (n=24)
Duration of operation (min)	150.9	115.8
Intraop. X-ray time (sec) (mean / expert surgeon)	30.9 / 40,7	21.4 / 13,5
Loss of blood (ml)	783.3	641.3
Hospital stay (days)	22.9	18.4

- Reduction of operating time: 23 % (p<0,005)
- Reduction of intraoperative x-ray time (mean/expert): 30 / 70 % (p>0,05 / p<0,05)
- Reduction of bloodloss: 18% (p>0,05)
- Reduction of hospitalisation time: 19% (p<0,05)
- 6-12 months postop: slight improvement in Harris hip score as well as Merle d'Aubigne score (experienced surgeon; p > 0.05)

DISOS – Desktop Planning and Manufacturing System for Orthopaedic Surgery (1998)

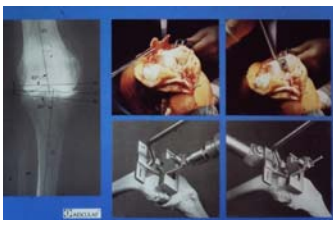


First concepts of 3D-shape control (in THA)



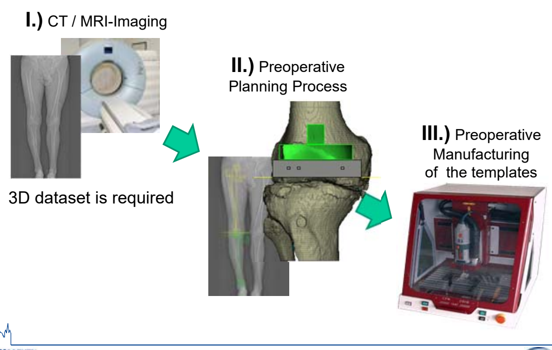
1992: First concepts of 2D depth control (osteotomies in TKA)

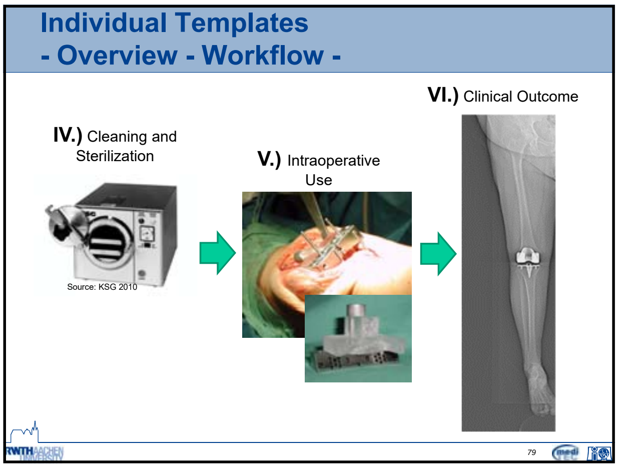
Individual Templates in TKA – Basic Motivation (1988)

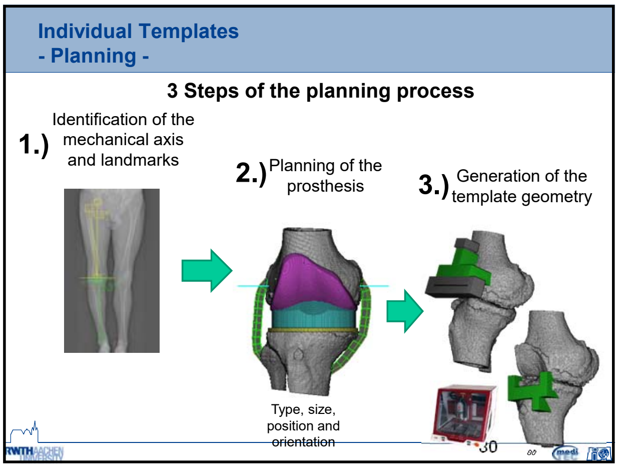


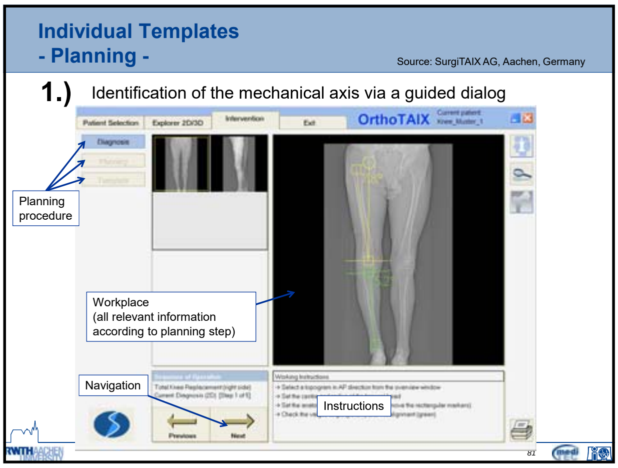
Simplify the set of instruments and standardise the surgical outcome quality by better planning and individual templates

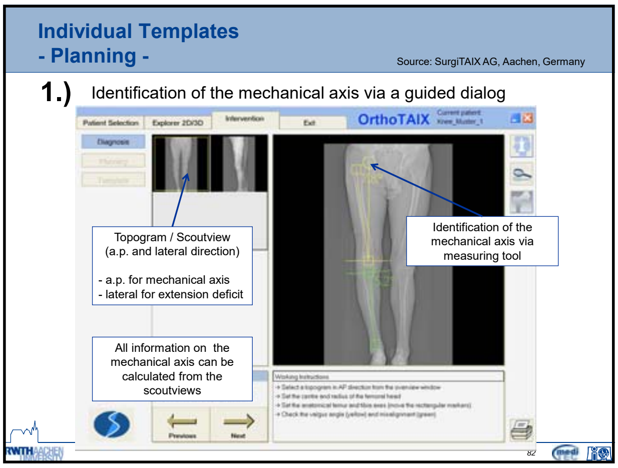
Individual Templates
- Overview - Workflow -

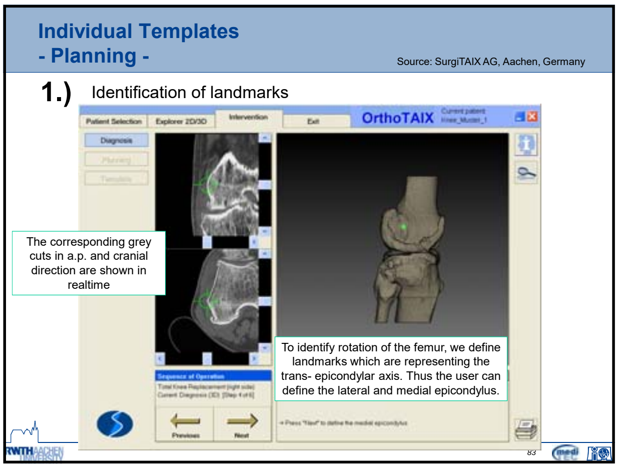


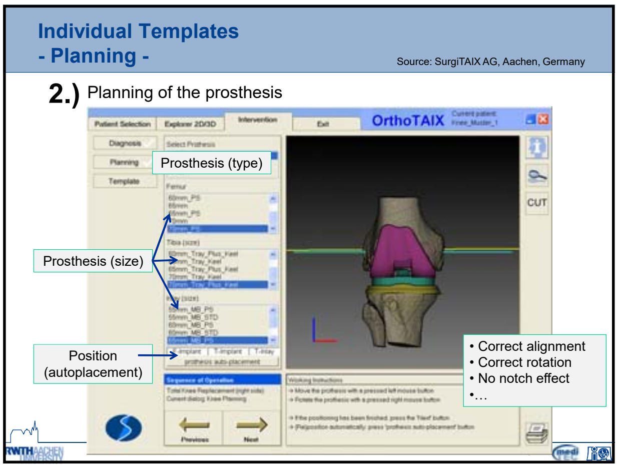

Individual Templates
- Overview - Workflow -
IV.) Cleaning and Sterilization
Source: KSG 2010
V.) Intraoperative Use
VI.) Clinical Outcome
RWTH AACHEN UNIVERSITY
79


Individual Templates
- Planning -
3 Steps of the planning process
1.) Identification of the mechanical axis and landmarks
2.) Planning of the prosthesis
3.) Generation of the template geometry
Type, size, position and orientation
RWTH AACHEN UNIVERSITY
80


Individual Templates
- Planning -
Source: SurgiTAIX AG, Aachen, Germany
1.) Identification of the mechanical axis via a guided dialog
OrthoTAIX
Planning procedure
Workplace (all relevant information according to planning step)
Navigation
Instructions
Previous
Next
RWTH AACHEN UNIVERSITY
81

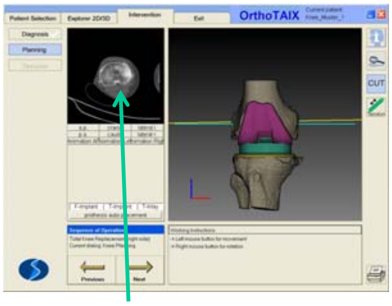

Individual Templates
- Planning -
Source: SurgiTAIX AG, Aachen, Germany
1.) Identification of the mechanical axis via a guided dialog
OrthoTAIX
Topogram / Scoutview (a.p. and lateral direction)
- a.p. for mechanical axis
- lateral for extension deficit
Identification of the mechanical axis via measuring tool
All information on the mechanical axis can be calculated from the scoutviews
Previous
Next
RWTH AACHEN UNIVERSITY
82


Individual Templates
- Planning -
Source: SurgiTAIX AG, Aachen, Germany
1.) Identification of landmarks
OrthoTAIX
The corresponding grey cuts in a.p. and cranial direction are shown in realtime
To identify rotation of the femur, we define landmarks which are representing the trans- epicondylar axis. Thus the user can define the lateral and medial epicondylus.
Previous
Next
RWTH AACHEN UNIVERSITY
83

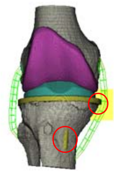

Individual Templates
- Planning -
Source: SurgiTAIX AG, Aachen, Germany
2.) Planning of the prosthesis
OrthoTAIX
Prosthesis (type)
Prosthesis (size)
Position (autoplacement)
• Correct alignment
• Correct rotation
• No notch effect
•…
CUT
Previous
Next
RWTH AACHEN UNIVERSITY

Individual Templates - Planning -

Source: SurgiTAIX AG, Aachen, Germany



Incorrect Placement



Bone quality assessment (especially tibia cut) for minimal resection of the defect

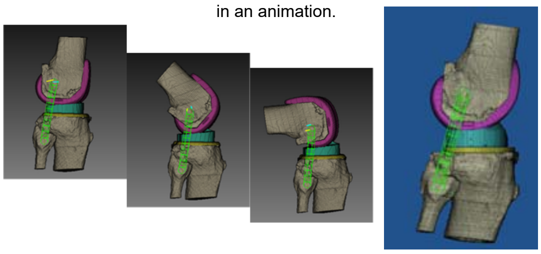
- Penetration of tibia fixation
- Contact between ligament and prosthesis

Individual Templates - Planning -

Source: SurgiTAIX AG, Aachen, Germany

2.) Planning of the prosthesis

The flexion and extension can be shown in an animation.



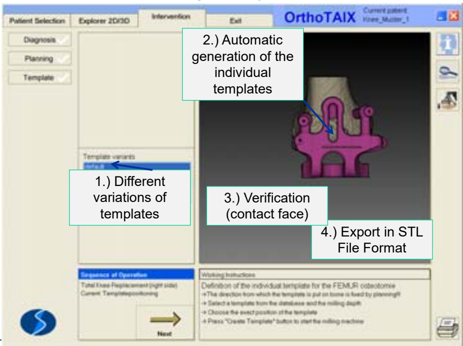
Determination of the changes of the ligament lengths in extension as well as in flexion (isometric conditions)

Volumetric mass-spring model

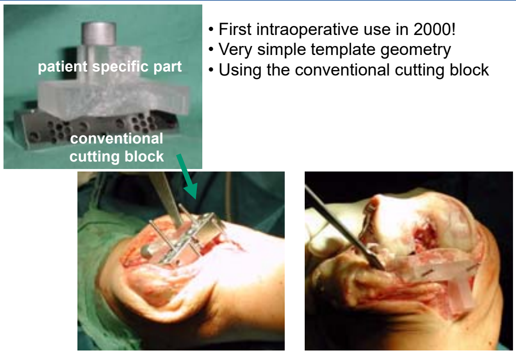
Individual Templates - Planning -

Source: SurgiTAIX AG, Aachen, Germany

3.) Generation of the template geometry



Individual Templates - Intraoperative use -



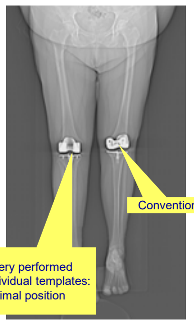
- First intraoperative use in 2000!
- Very simple template geometry
- Using the conventional cutting block

Individual Templates - Clinical Outcome -

Individual templates for TKA (first 10 trials)

+ Unambiguous positioning of the template
+ No additional dilation of the surgical portal
+ Good alignment (<= 3° in all cases)
+ Intuitive use
+ Extra- and intramedullary rods are not required
+ Operation time was between 70 and 35 minutes

o CT- required
o Preoperative computer based planning necessary

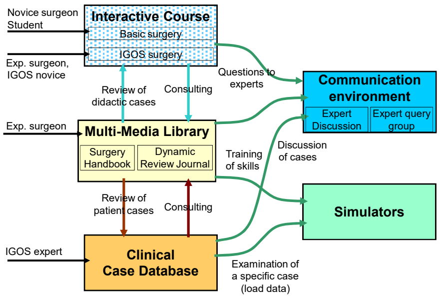


Experimental and Clinical Applications of the Individual Template Approach in CAOS (our Group only; 1991-2001)

- Spine Surgery
  - Pedicle screw placement (clinical study)
  - Dorsal Hirayabashi open-door decompression (cadaver study)
  - Ventral decompression (cadaver study)
  - Ventral repositionning osteotomies (lab study)
- Hip Surgery
  - Total hip surgery (cup and shaft) (lab study)
  - Intertrochanteric osteotomy (incl. Punction of bone cyst) (lab study)
  - Periacetabular repositionning osteotomy (Tönnis) (clinical study)
  - Spherical Periacetabular Osteotomy (lab study and first cadaver study)
- Knee Surgery
  - Total Knee Arthroplasty (clinical study)

> Transfer to SurgiTAIX AG, Aachen, Germany

Education & Training Modules
- Virtual Orthopedic European University



Learning environment for computer-based education and training in computer assisted orthopedic surgery (CAOS)

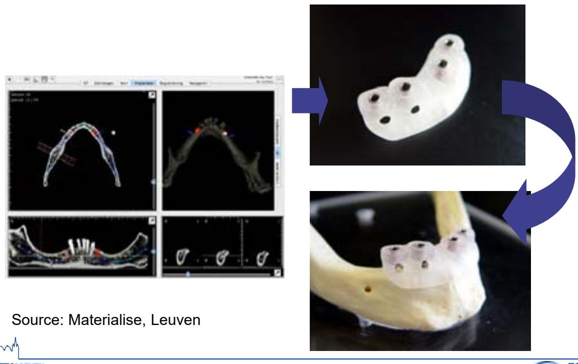
Training - Example:
E-Learning module for hip surgery

interactive course *simulating working with virtual patient cases in clinical procedures*

surgical Simulator *to train the surgeon's skill in certain planning steps when using a real CAS system*

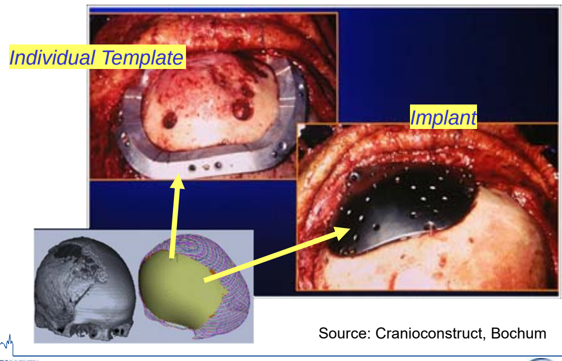
multimedia handbook *presenting procedural and declarative knowledge in a narrative format*

Individual Templates (other groups & disciplines):
CT-based Individual Templates for Dental Implants



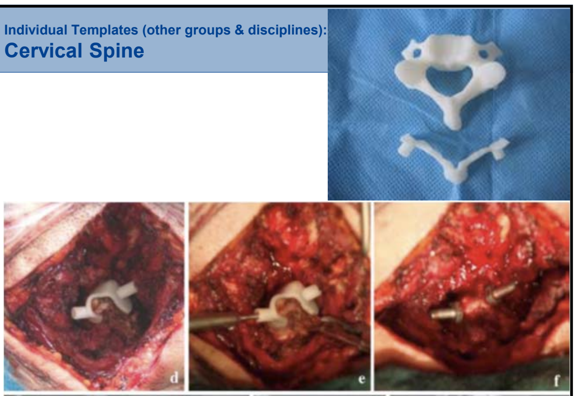
Source: Materialise, Leuven

Individual Templates (other groups & disciplines):
CT-based Individual Templates for Cranio-Surgery



Source: Cranioconstruct, Bochum

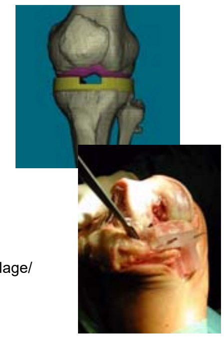
Individual Templates (other groups & disciplines):
Cervical Spine



- Sheng Lu et al.; A Novel Patient-specific Navigational Template for Cervical Pedicle Screw Placement; Department of Orthopedics, Kunming General Hospital, PLA, Kunming, China, 2009

Individual Templates
- Pros and Cons -

+ precise planning & intraoperative guidance
+ no changes of the intraoperative procedure
+ simple & intuitive handling
+ no additional equipment in the OR
+ no intraoperative registration required
+ reduction of OR-time and x-ray time
+ good cost/benefit ratio
– pre-operative CT required (optional MRI)
– pre-operative planning required
– no percutaneous application, access to bone/cartilage/
– hard tissue required



Peer Reviewers of the EC-Project
"Image Guided Orthopaedic Surgery (IGOS)" (DGXIII-HC1026HC) 1998
Concerning the Clinical Relevance of Individual Templates in Orthopaedic Surgery

1998

- **"... a good practical example of the applicability of IGOS techniques to operative surgery"**
  (Prof. M.A.R. Freeman, London and Prof. S.D. Stulberg, Chicago ; IGOS Peer Review Report, 1998)
- **"Templates constitute obviously the most simple IGOS solution with no important implications on the OR.**
  Therefore, for all applications where they can be used with similar advantages to other technologies, they should be used."
  (Prof. Ph. Merloz, Grenoble, IGOS Partner, 1998)

RWTH AACHEN UNIVERSITY 97

Peer Reviewers of the EC-Project
"Image Guided Orthopaedic Surgery (IGOS 2)" (DGXIII-HC4010HC)
Concerning the Clinical Relevance of Individual Templates in Orthopaedic Surgery

1999

„We believe that this type of individual based template surgery is an valuable approach which has a clear benefits in relation to simplicity, availability, safety and costs."

Prof. A. Lindstrand, Lund (Schweden), Prof. W. Siebert, Kassel,
Prof. P. Regazzoni, Basel (Schweiz), IGOS 2 Peer Review Report 1999

RWTH AACHEN UNIVERSITY 98