More Than 30 Years of “PSI”

(PSI=Patient Specific Instruments = Custom Surgical Guides = Individual Templates)

- Historical Review of the *World First* 10 Years in Aachen -

Klaus Radermacher, PhD

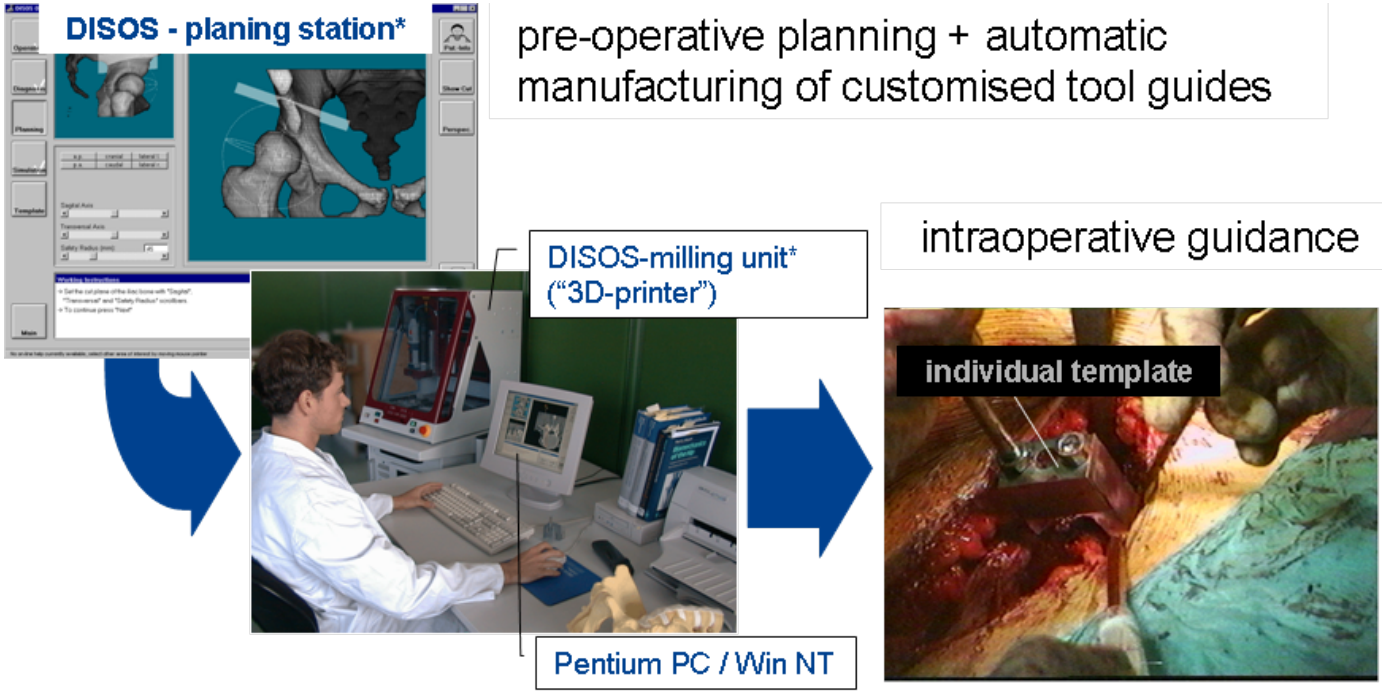
Chair of
Medical Engineering at
Helmholtz-Institute of
Biomedical Engineering

RWTH AACHEN UNIVERSITY

www.meditec.rwth-aachen.de

History of CA(O)S with „Individual Templates“ („Custom Guides“ or „PSI“)“

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



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

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)

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

History of CAOS

(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

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)
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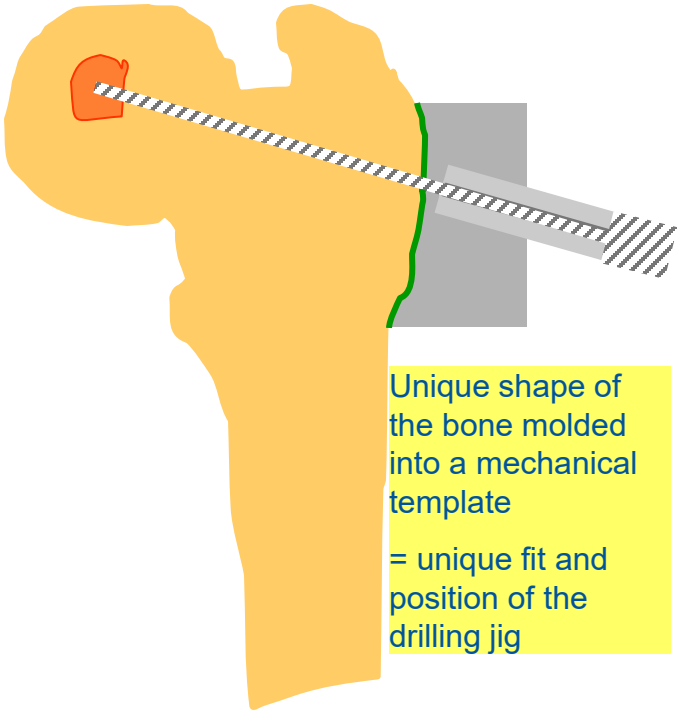
  - Spherical Periacetabular Osteotomy (lab study and first cadaver study)
- Knee Surgery
  - Total Knee Arthroplasty (clinical study)

> Transfer to SurgiTAIX AG, Aachen, Germany in 2001

Some more details…?

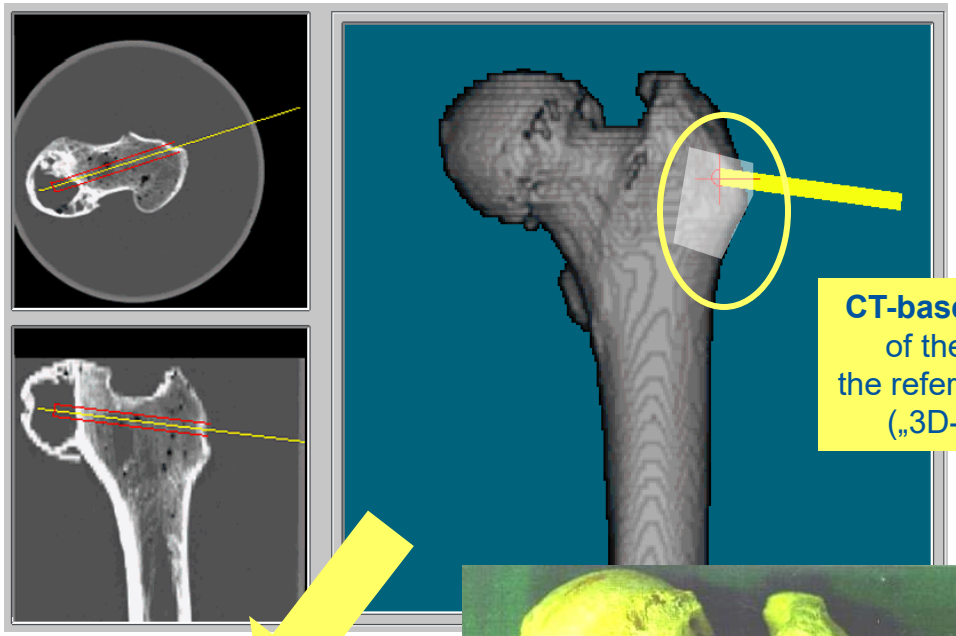
Basic principle of the individual template approach



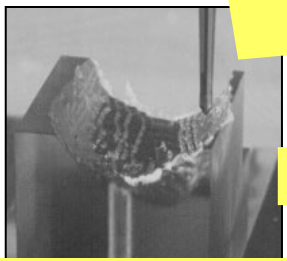
Unique shape of the bone molded into a mechanical template

= unique fit and position of the drilling jig

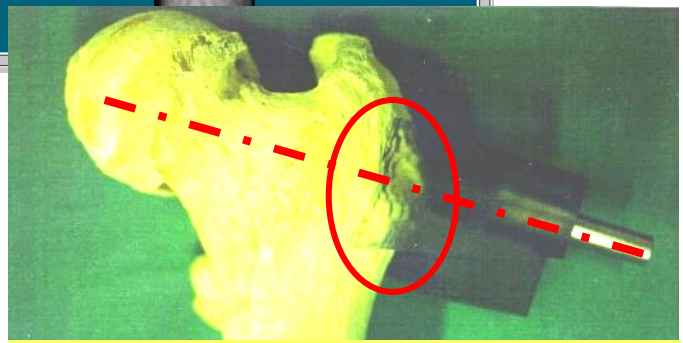
Principle



CT-based planning of the bore and the reference surface („3D-Abdruck“)



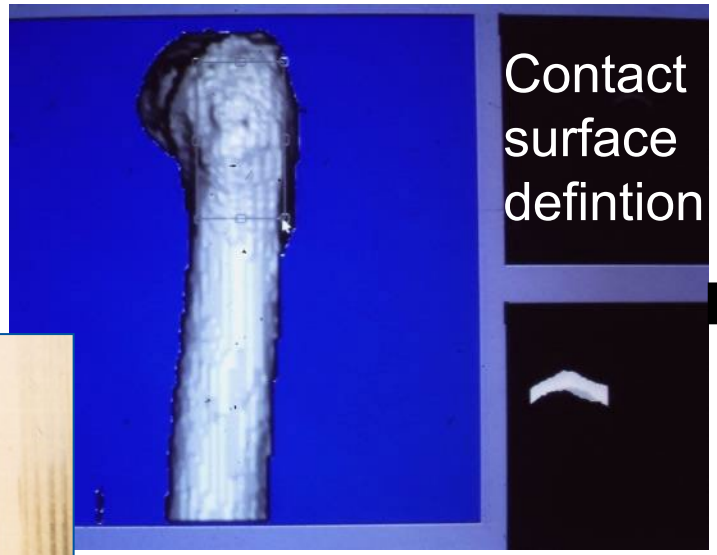
NC-milling of the individual impression



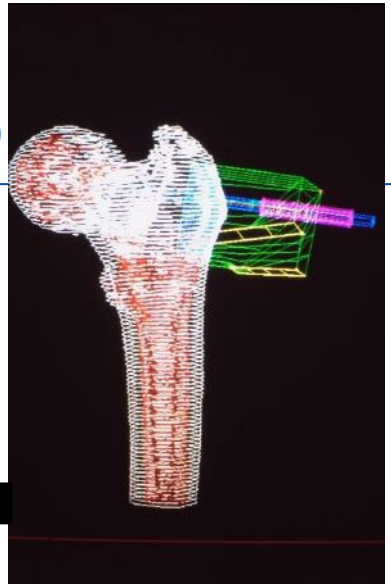
Intraoperative: **unique fit of the template** and related positioning of the toolguide **with respect to the bone**

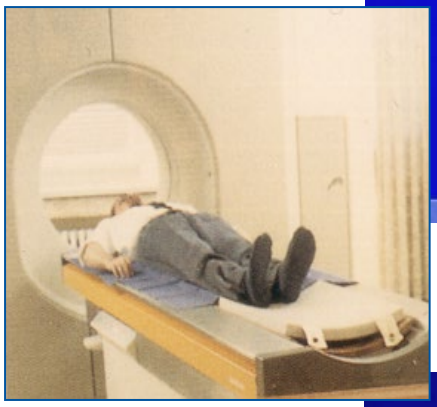
Preoperative Workflow and Components

(CT + 5-10 minutes planning + 10-20 minutes milling (in 1993))



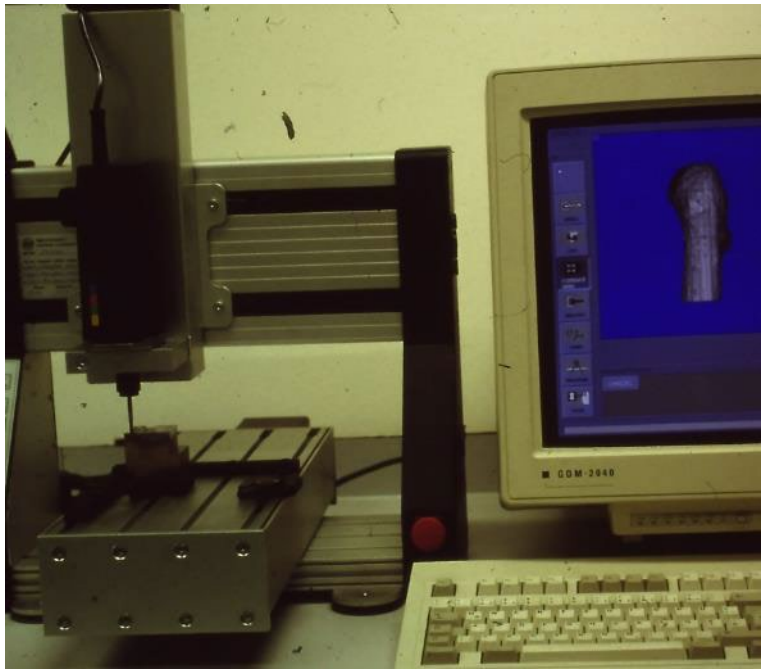
Template
Pre-Design





3D-Reconstruction &
Planning

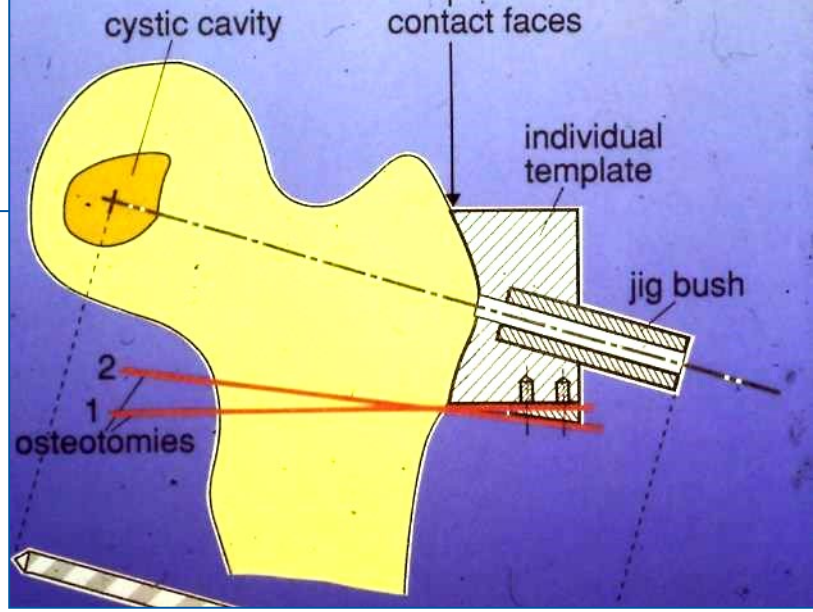
CT

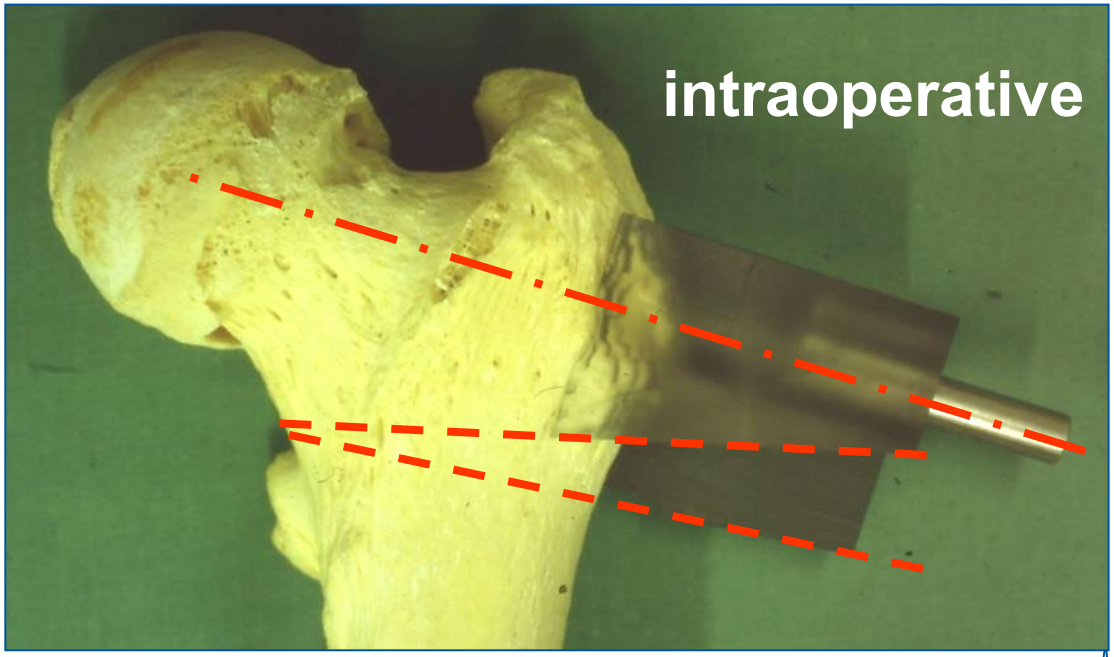


Desktop CAM

Workflow and Components

Autoclave (20-30 min)





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

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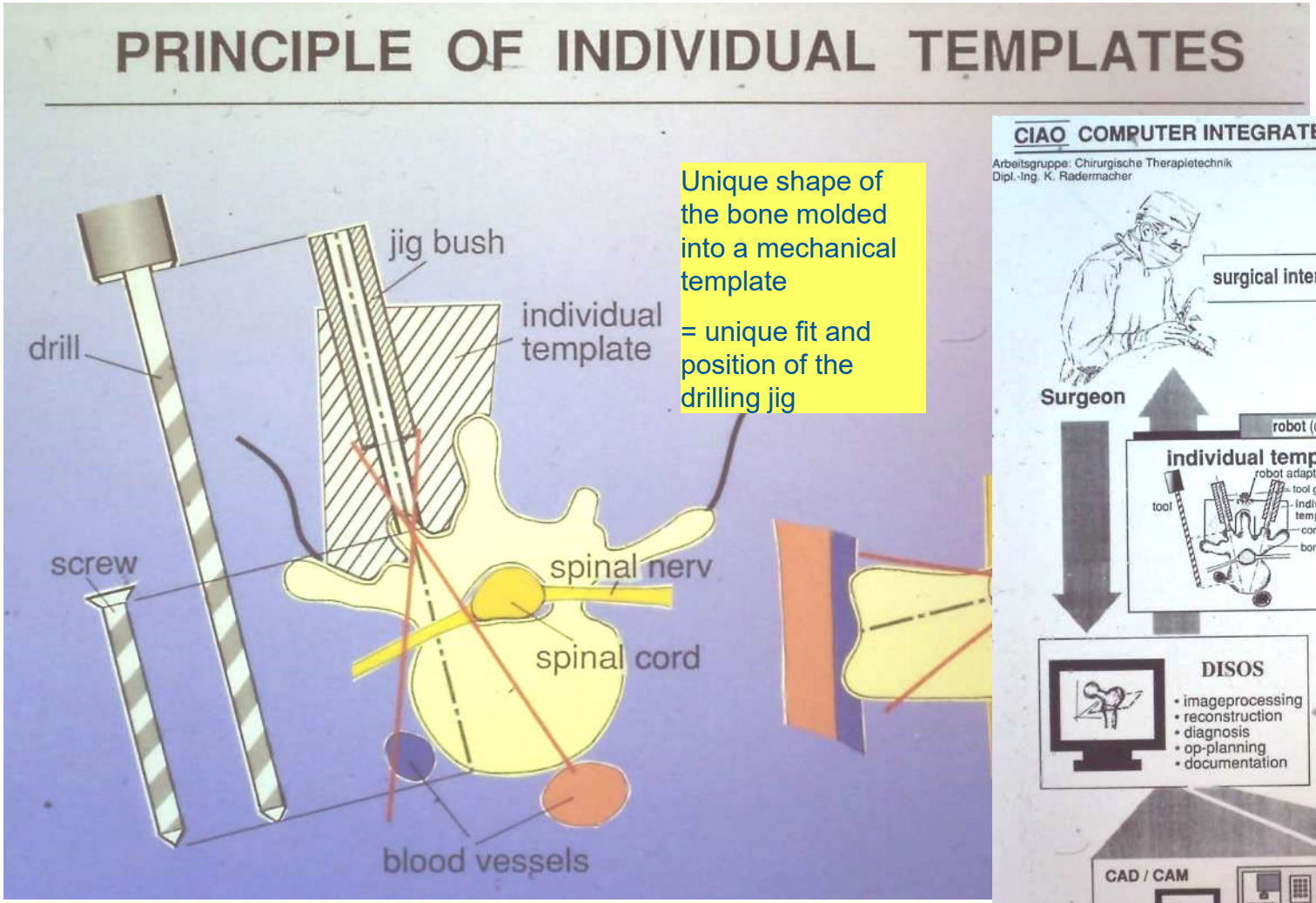
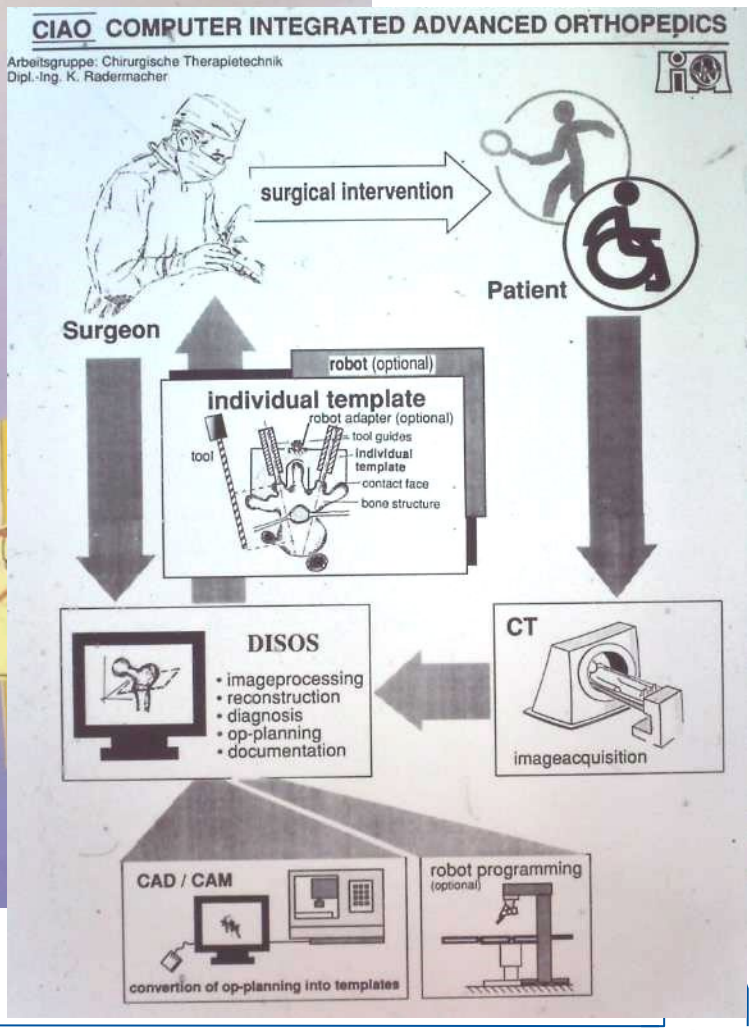
Basic principle of the individual templates in spine surgery (Radermacher et al. 1993)



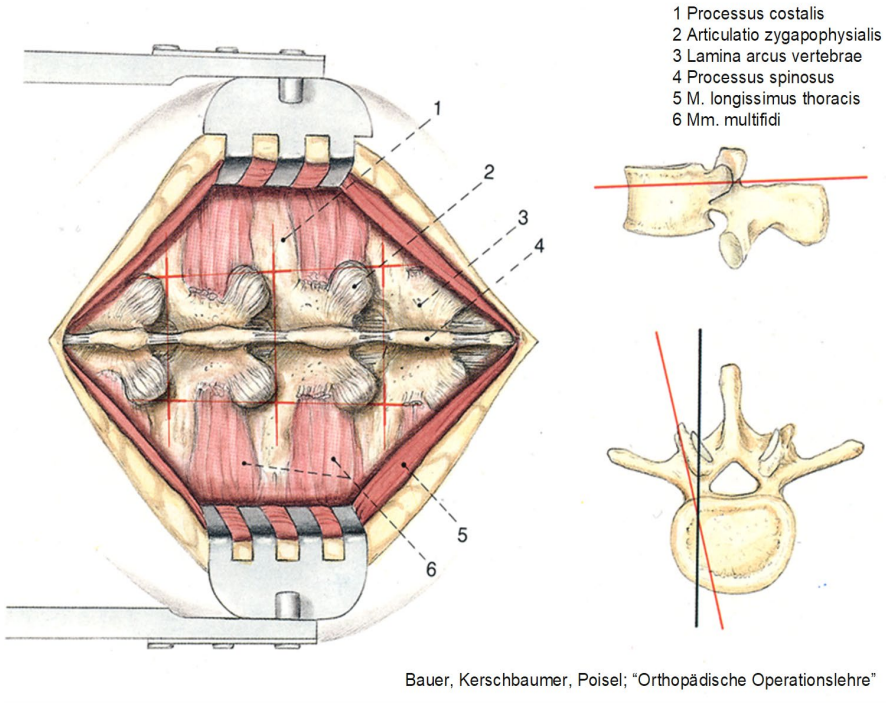


Pedicle Screw Placement in Spine Surgery

- Objectives and surgical bottlenecks-

Problems:

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

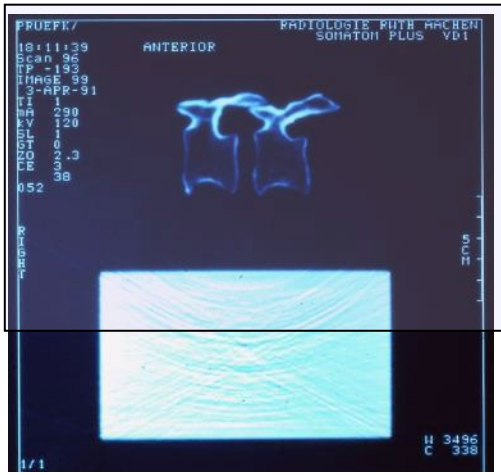


Bauer, Kerschbaumer, Poisel; "Orthopädische Operationslehre"

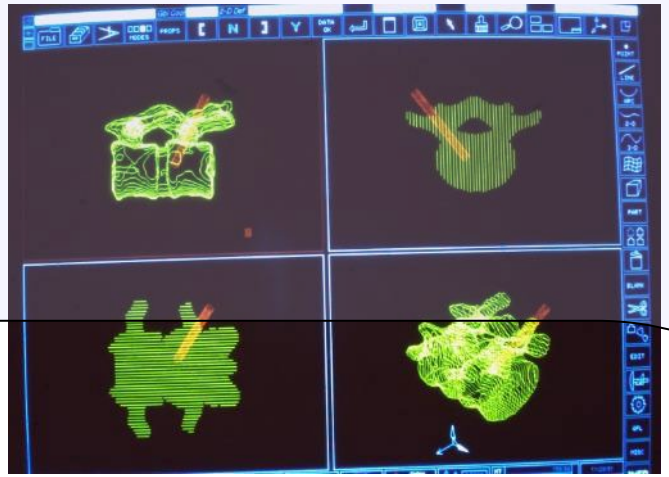
Reasons:

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

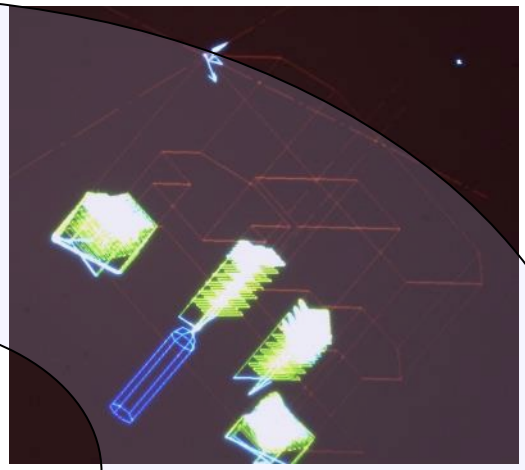
1991: First Concept Study with Individual Templates on Pedicle Screw Placement in Spine Surgery



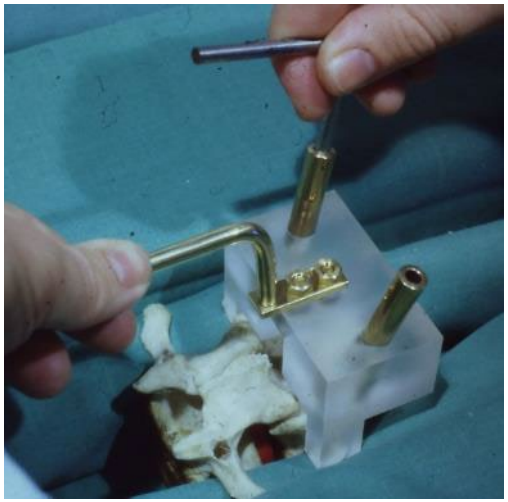
CT



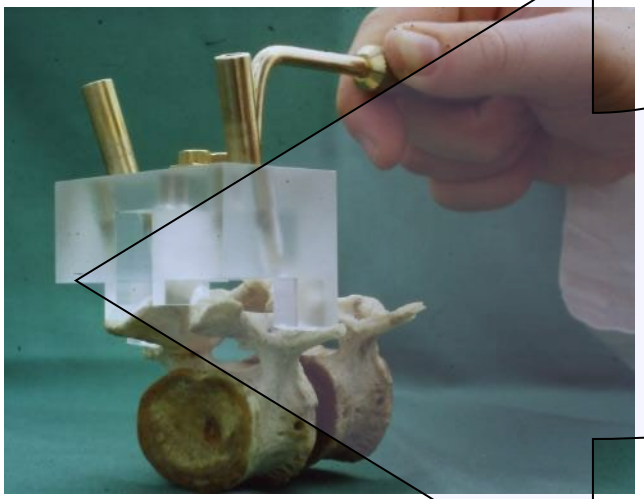
CAD-based planning



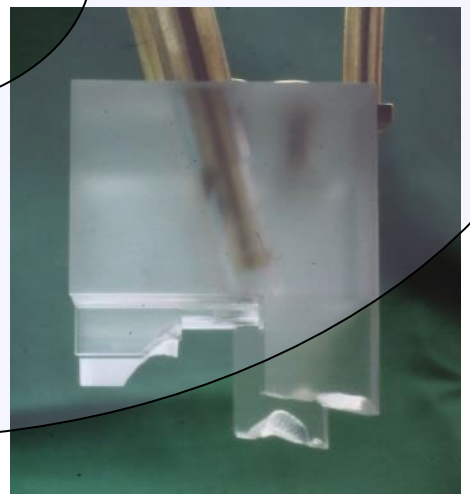
CAD-based NC paths



Drilling

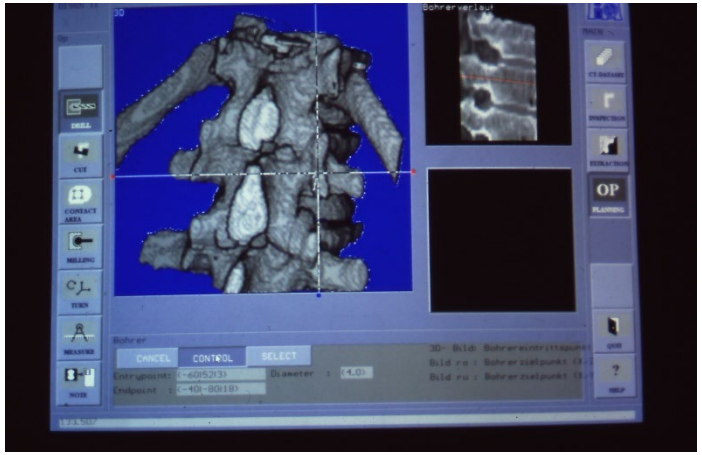


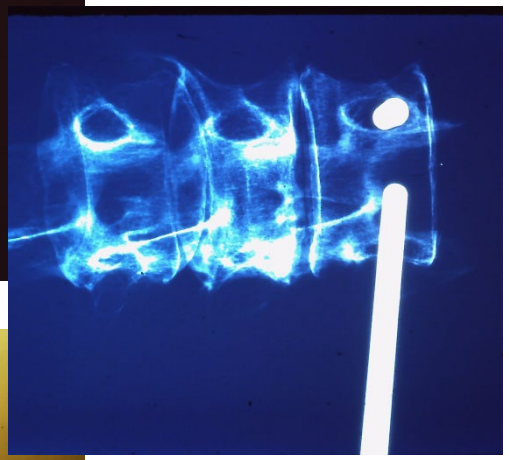
Reference shape fit



Contact faces

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

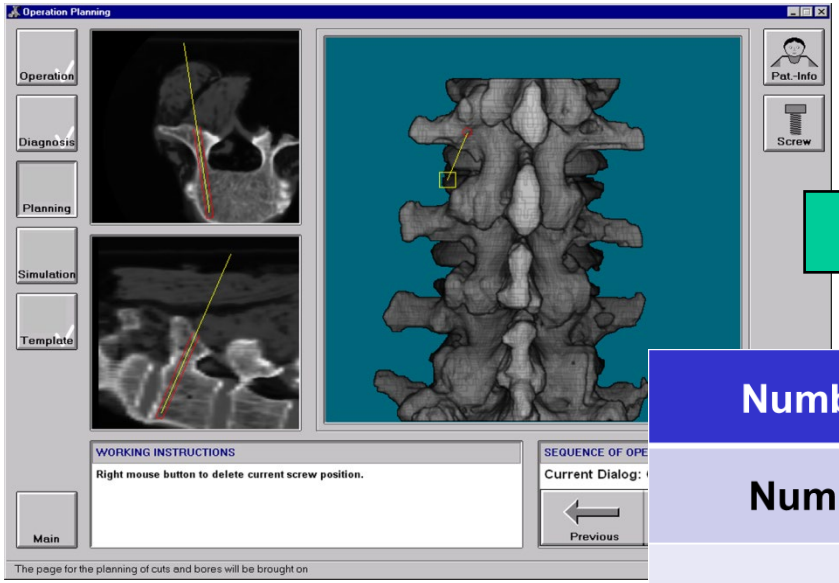


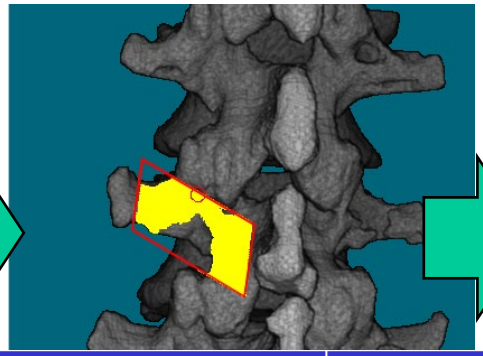


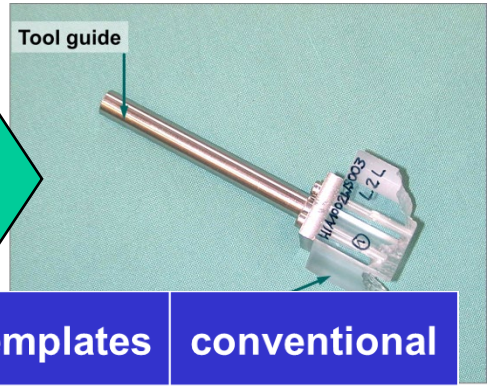
(Radermacher et al.1992)

Conventional Surgery vs. Template Based Navigation

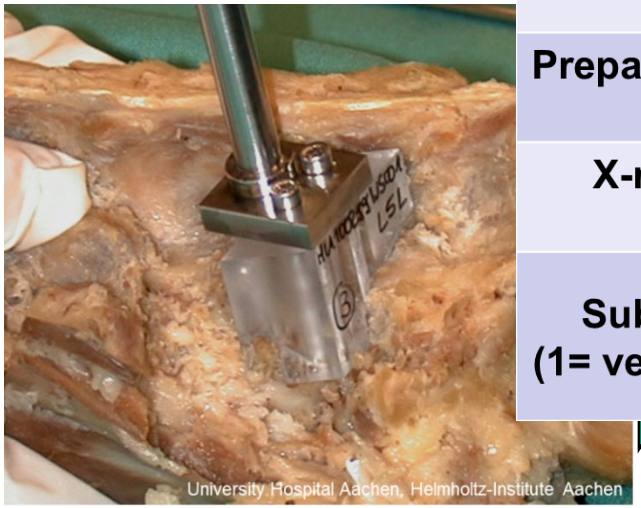
- a comparative cadaver study -

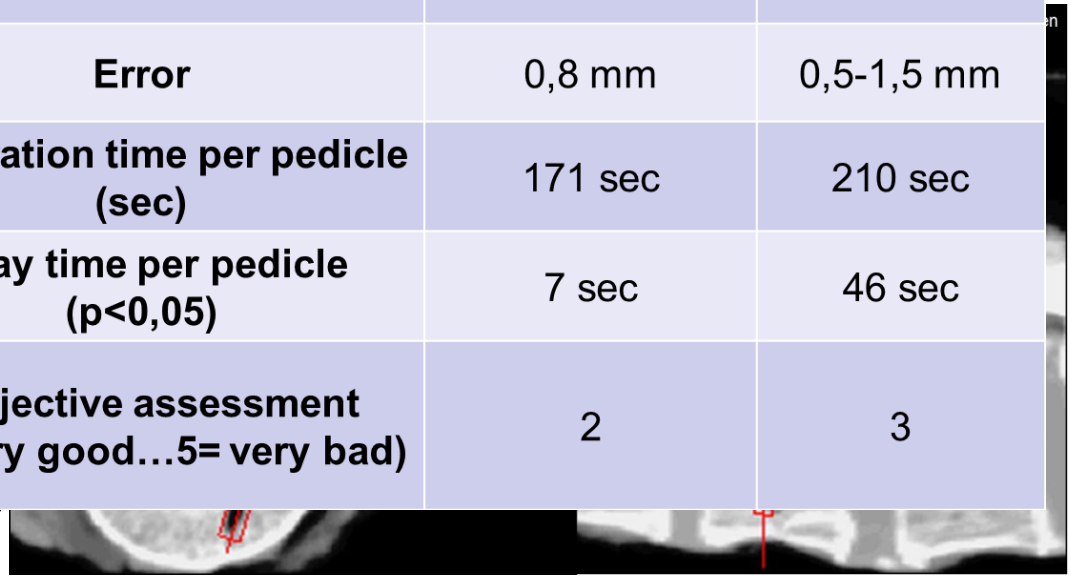






Number of spines: 3	Indiv. templates	conventional
Number of drillings	9	9
Error	0,8 mm	0,5-1,5 mm
Preparation time per pedicle (sec)	171 sec	210 sec
X-ray time per pedicle (p<0,05)	7 sec	46 sec
Subjective assessment (1= very good…5= very bad)	2	3

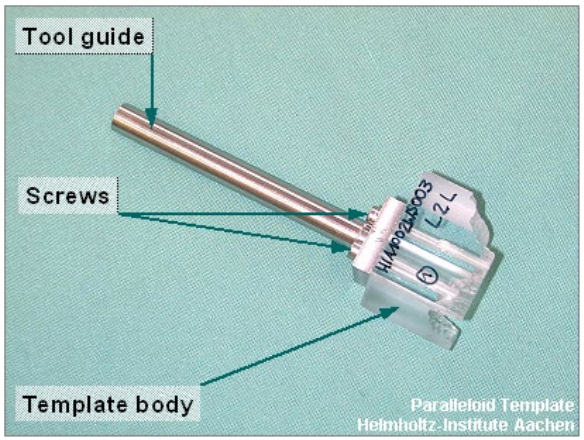




Birnbaum K, Schkommodau E, Decker N, et al. Computer-assisted orthopedic surgery with individual templates and comparison to conventional operation method. Spine 2001; 26: 365-70.

Freehand Navigation vs. Template Based Navigation

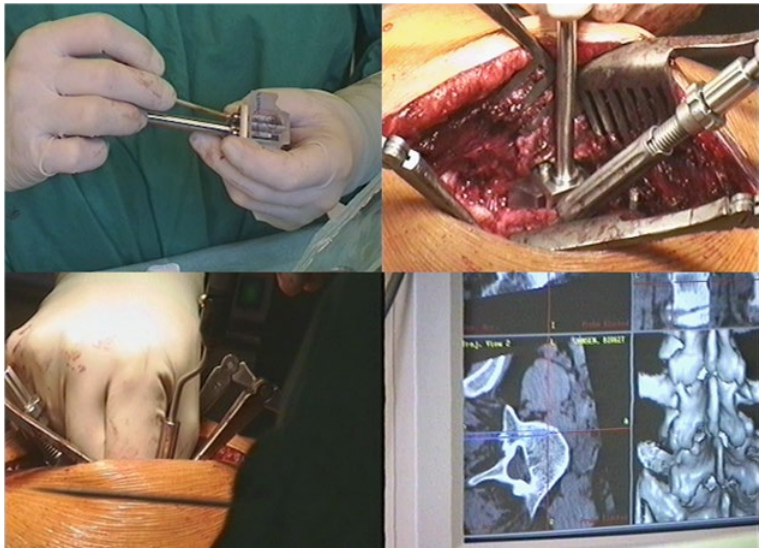
Freehand Navigation



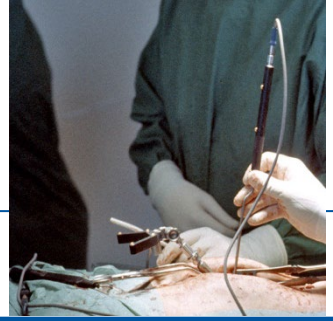
Individual Templates

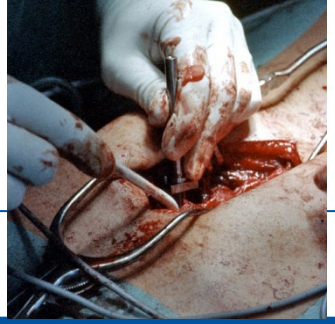
A comparative clinical study

Schommodau, E., Kaspers, G., Klapper, U., Radermacher, K., Staudte, H.-W.: Klinische Erfahrungen mit der Individualschablonentechnik. Orthopädische Praxis 1/2001, 37. Jg., pp. 19-22



Clinical study (2001)



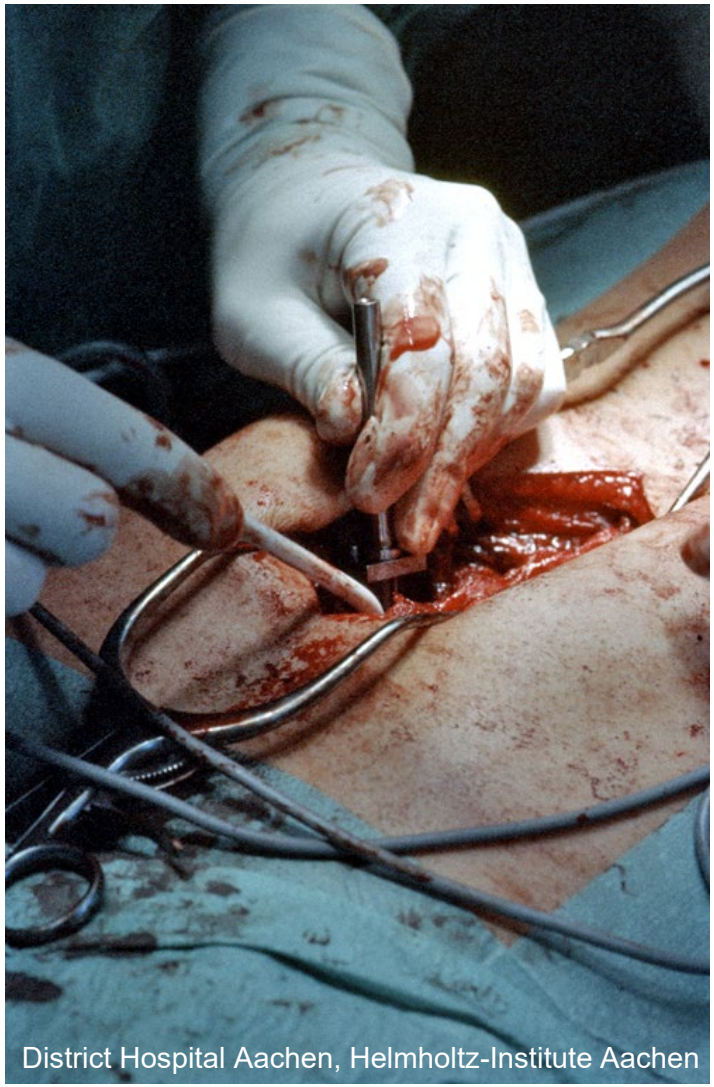


	Navigation (n=16)	Individual Templates (n=24)
Quality of placement (Intraoperative Evaluation by the surgeon; 1= very good; 5= bad)	∅1,5	∅1,71
Fit of the template (Intraoperative Evaluation by the surgeon; 1= very good; 5= bad)	-	∅2,21
Additional OP time per vertebra (registration / template positionning)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

Schommodau, E., Kaspers, G., Klapper, U., Radermacher, K., Staudte, H.-W.: Klinische Erfahrungen mit der Individualschablonentechnik. Orthopädische Praxis 1/2001, 37. Jg., pp. 19-22

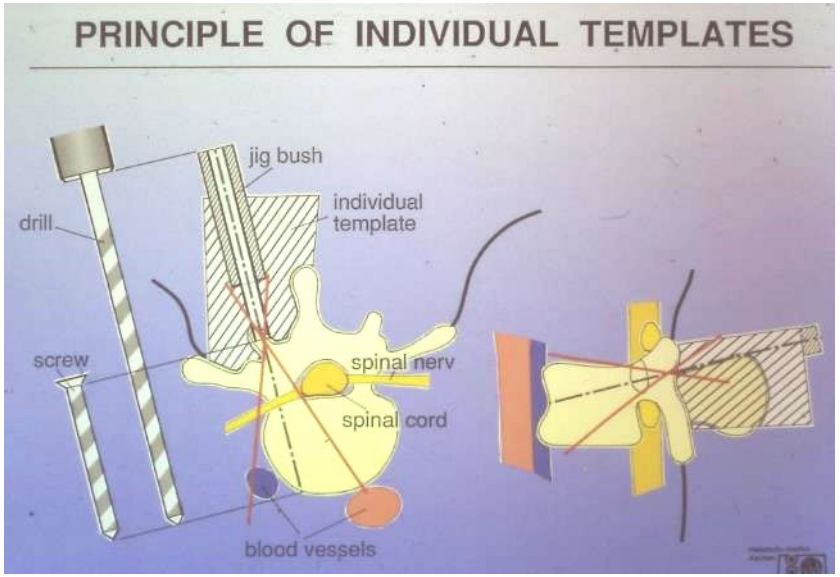
Conclusion on pedicle screw placement (2001)

- little changes to intra-operative task sequences
- reduced x-ray exposure for patient and OR-staff
- high accuracy
- no additional installations (computer, monitor, localizer,…robot) in the OR
- no additional time consuming intra-operative registration
- intuitive intra-operative handling
- available 60 minutes after CT scan
- autoclavable (135°C)
- **not suitable for transcut. MIS**
- **no emergency / trauma surgery**



District Hospital Aachen, Helmholtz-Institute Aachen

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



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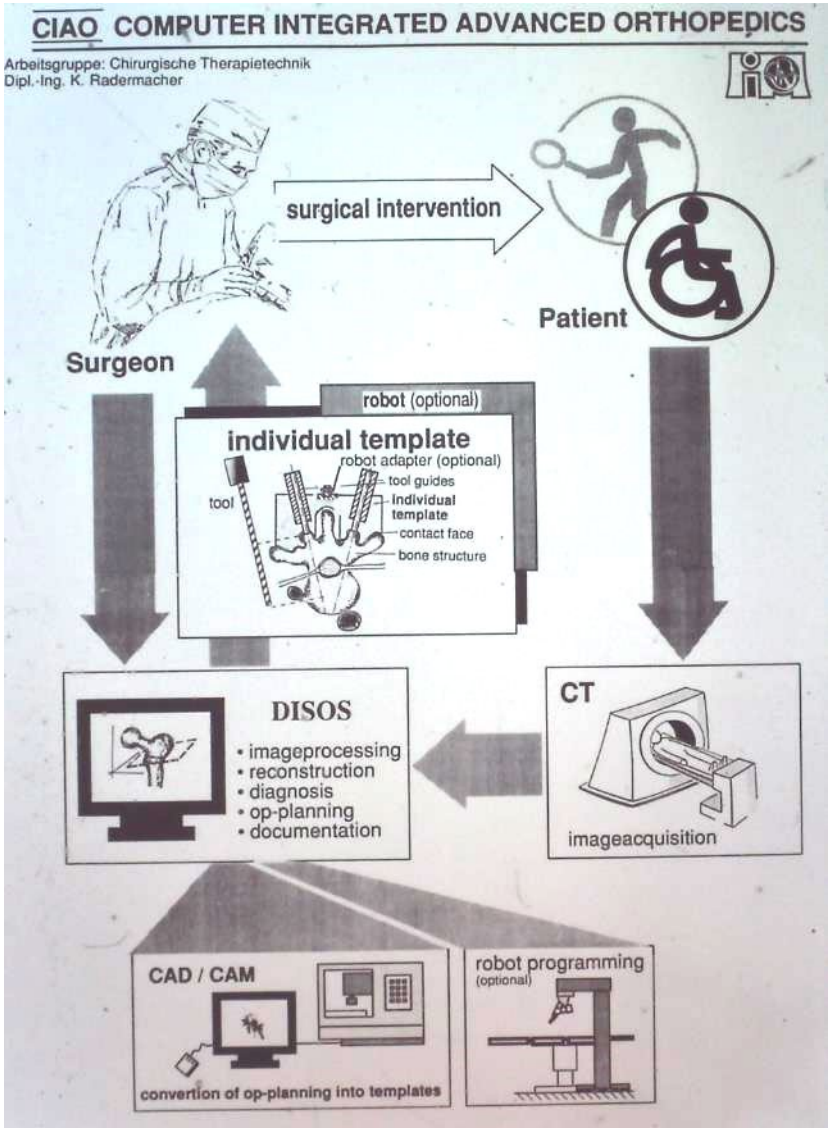

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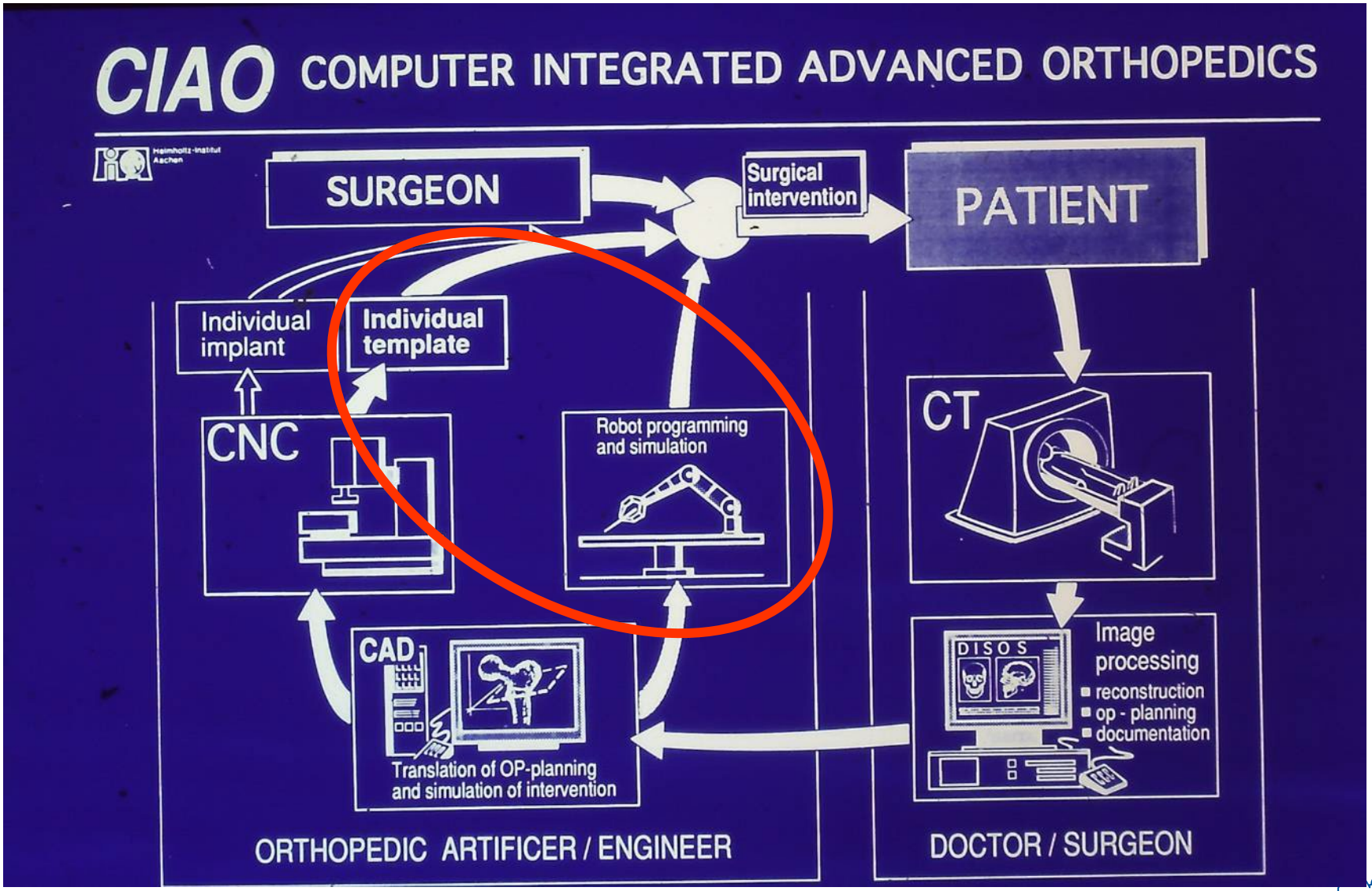

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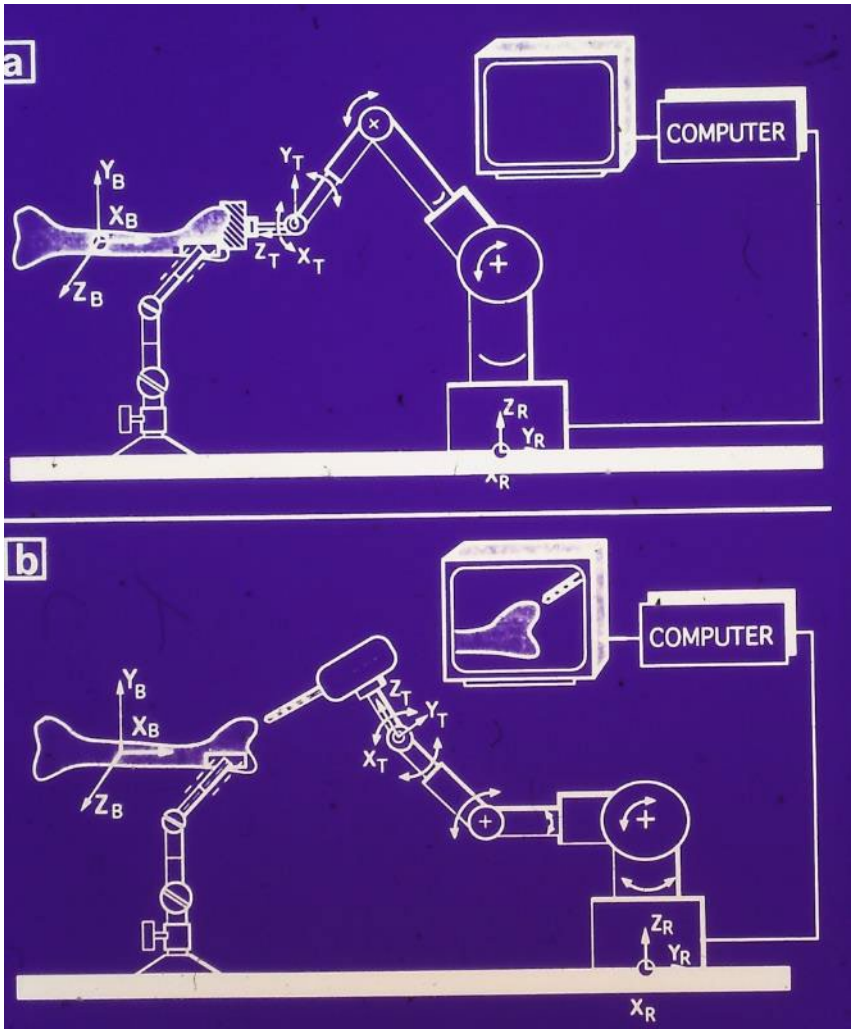
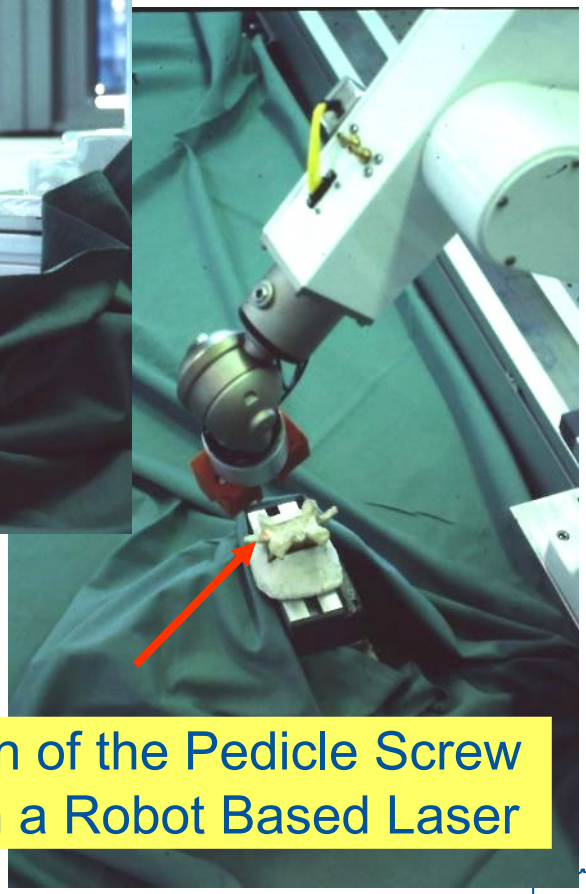
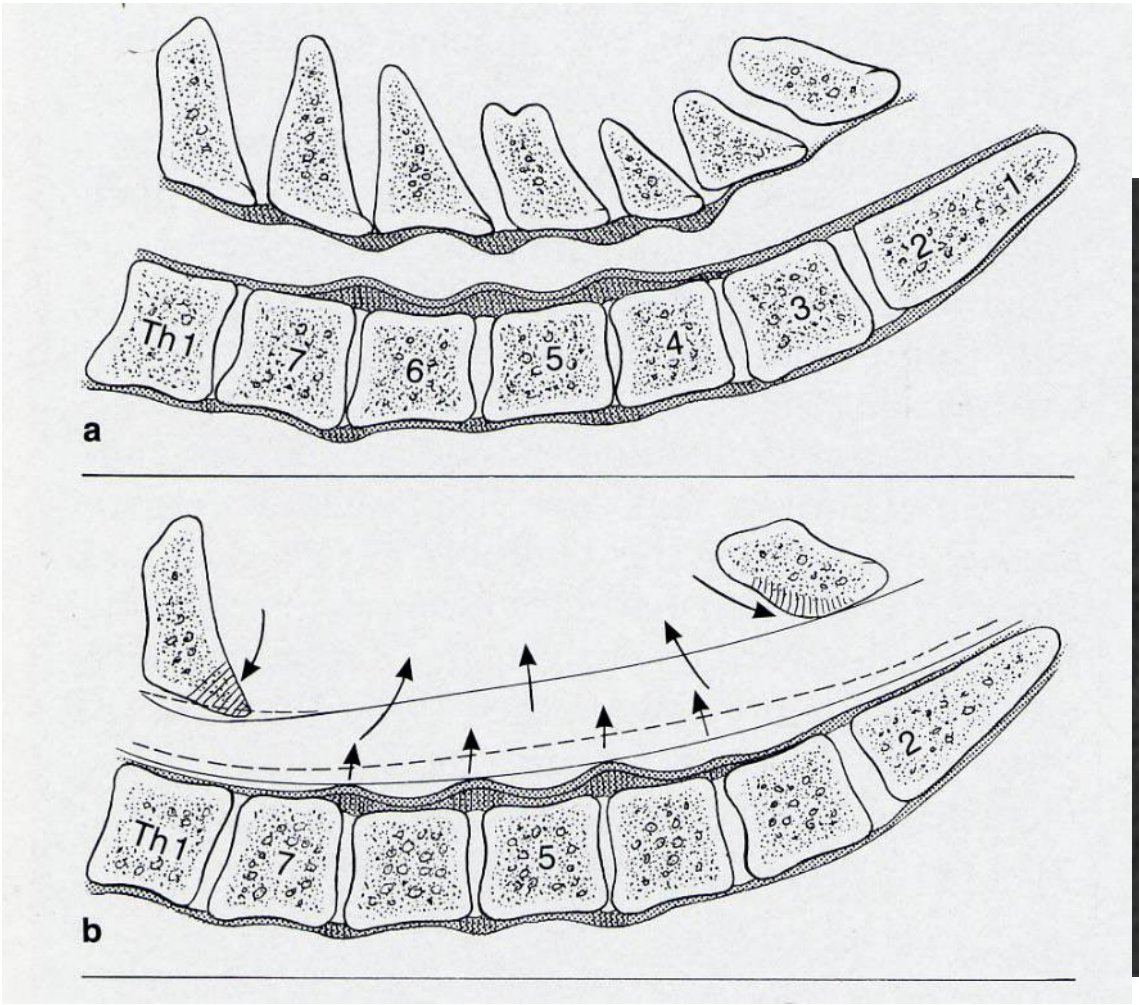


Registration



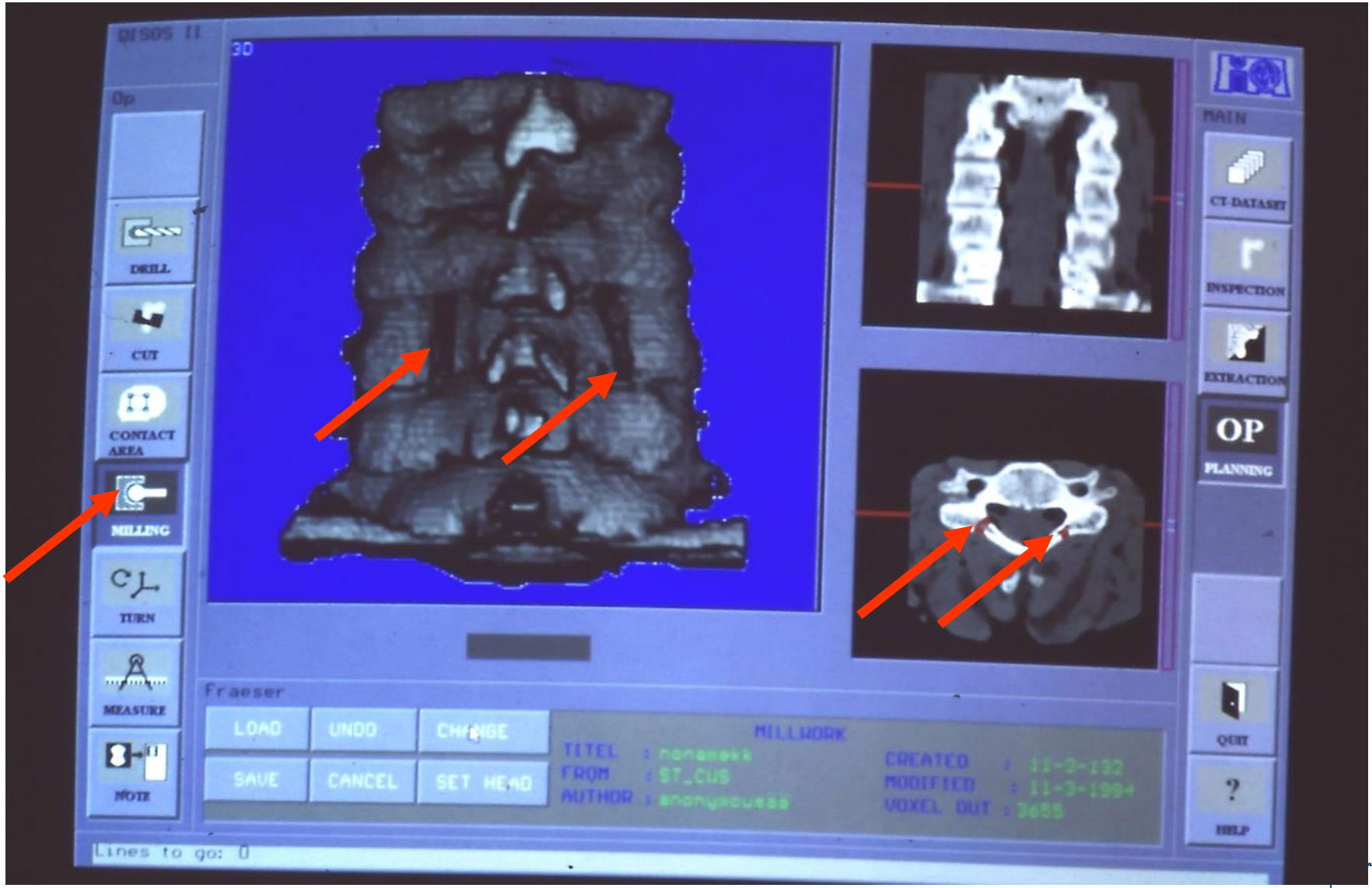
Indication of the Pedicle Screw Axis with a Robot Based Laser

Cervical spinal stenosis
Decompression



(Yang et al 2008)

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



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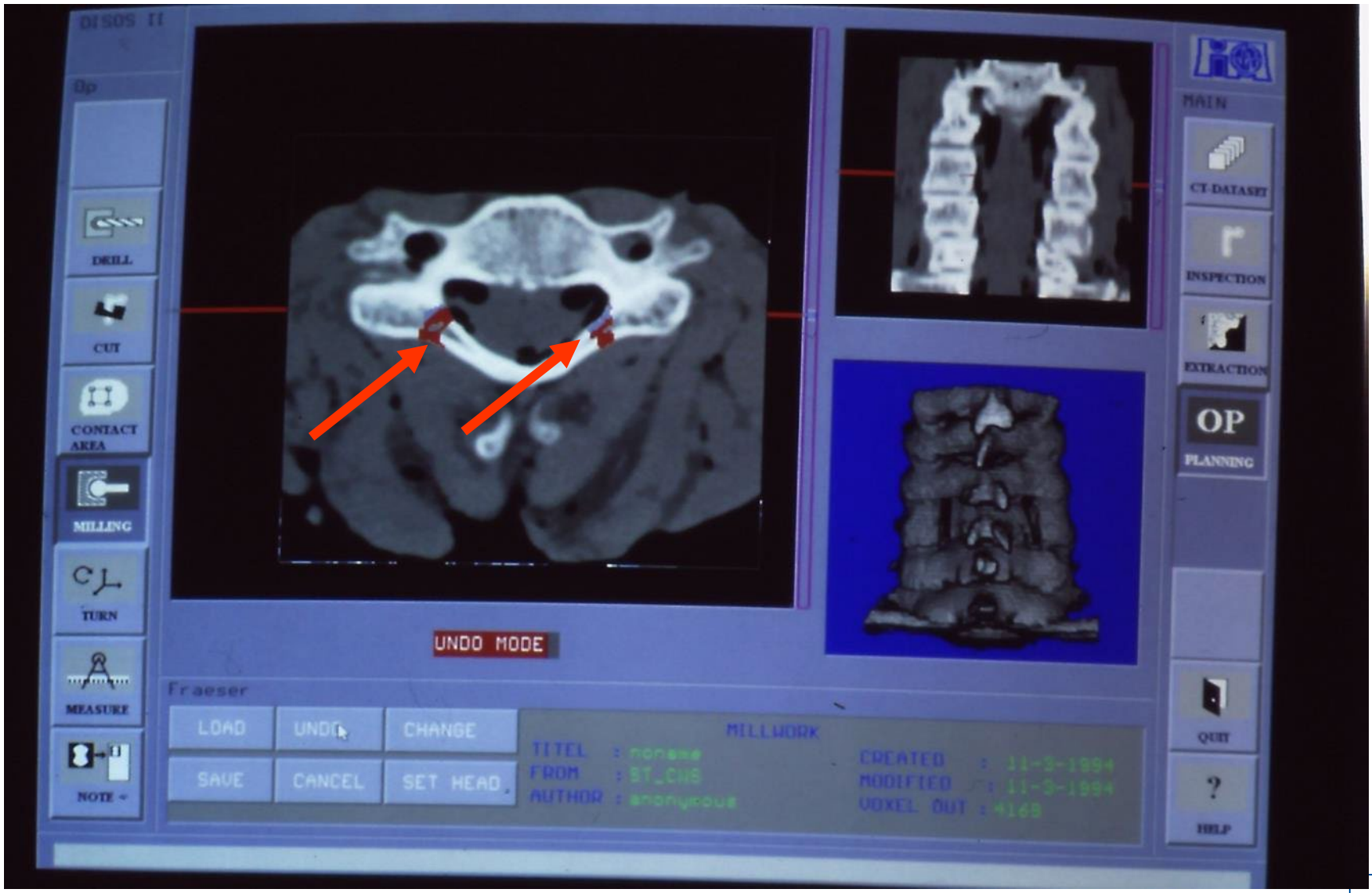
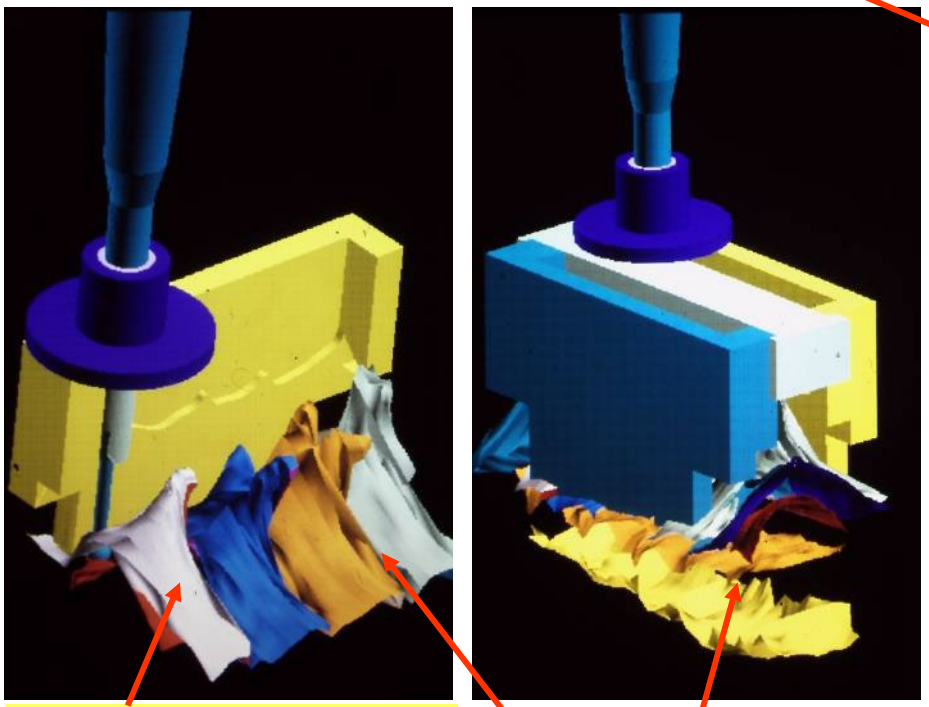
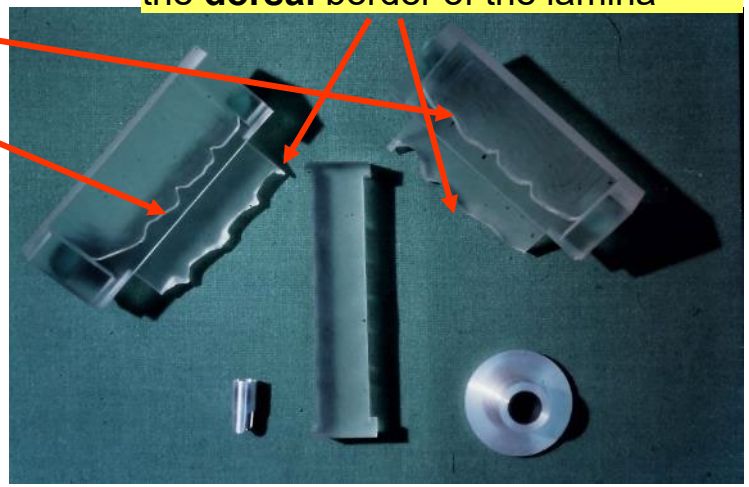


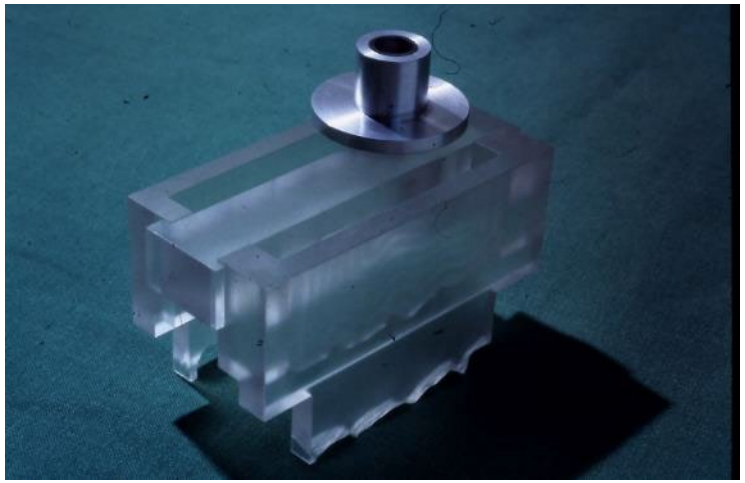
Open Door Decompression in Cervical Spine
- CT-based planning of 3D guidance limiting milling depth -
(Staudte et al. 1994)

Copying surface corresponding to the **ventral** border of the lamina

Reference surface corresponding to the **dorsal** border of the lamina



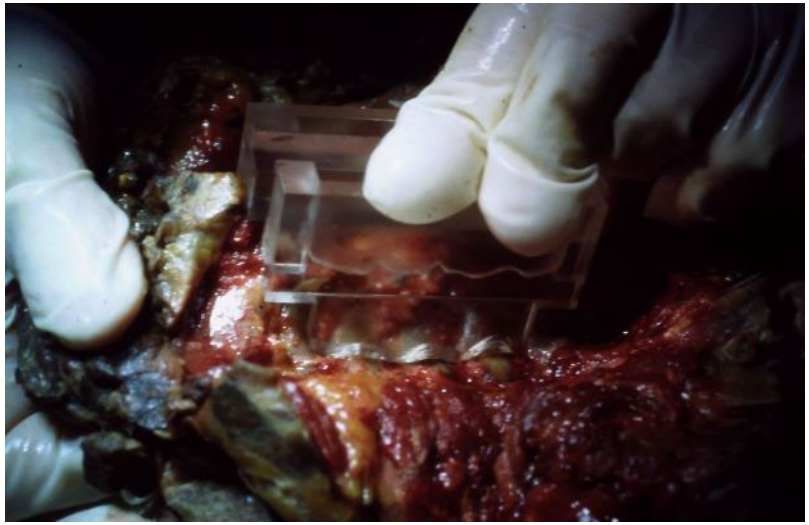


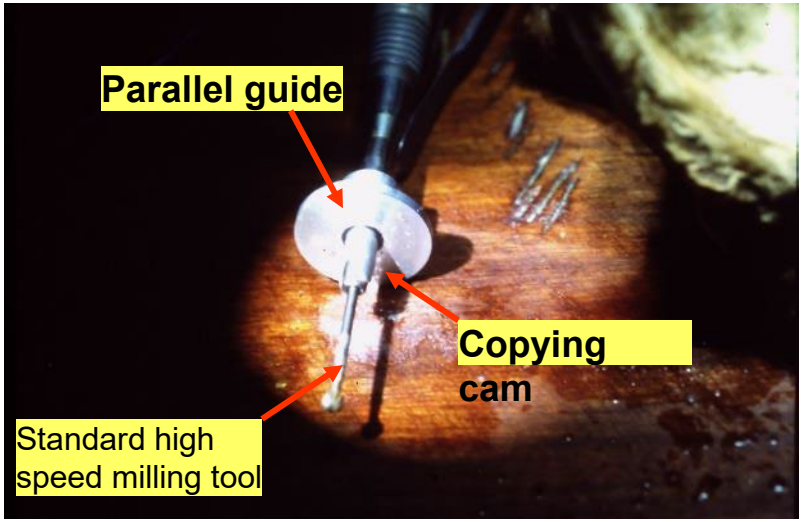


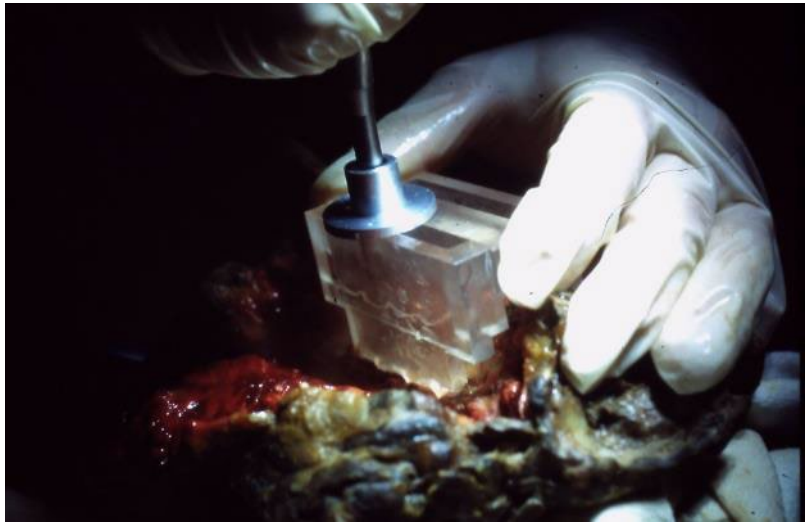
dorsal border of the lamina

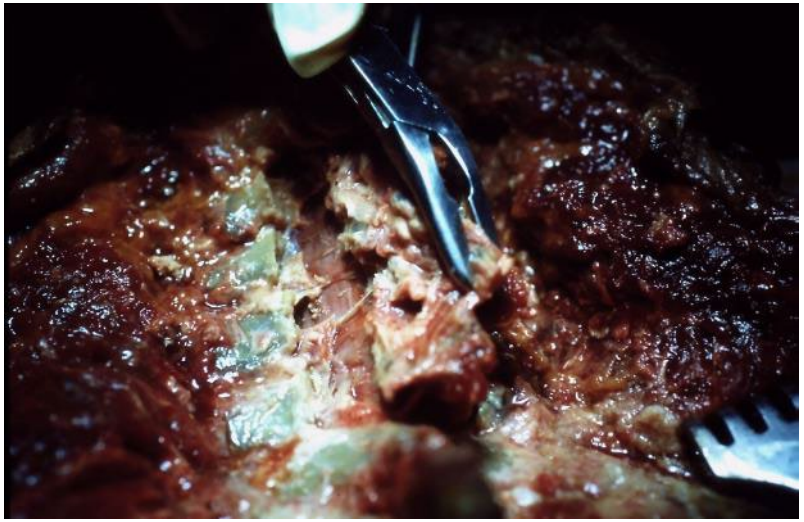
Ventral border of the lamina

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



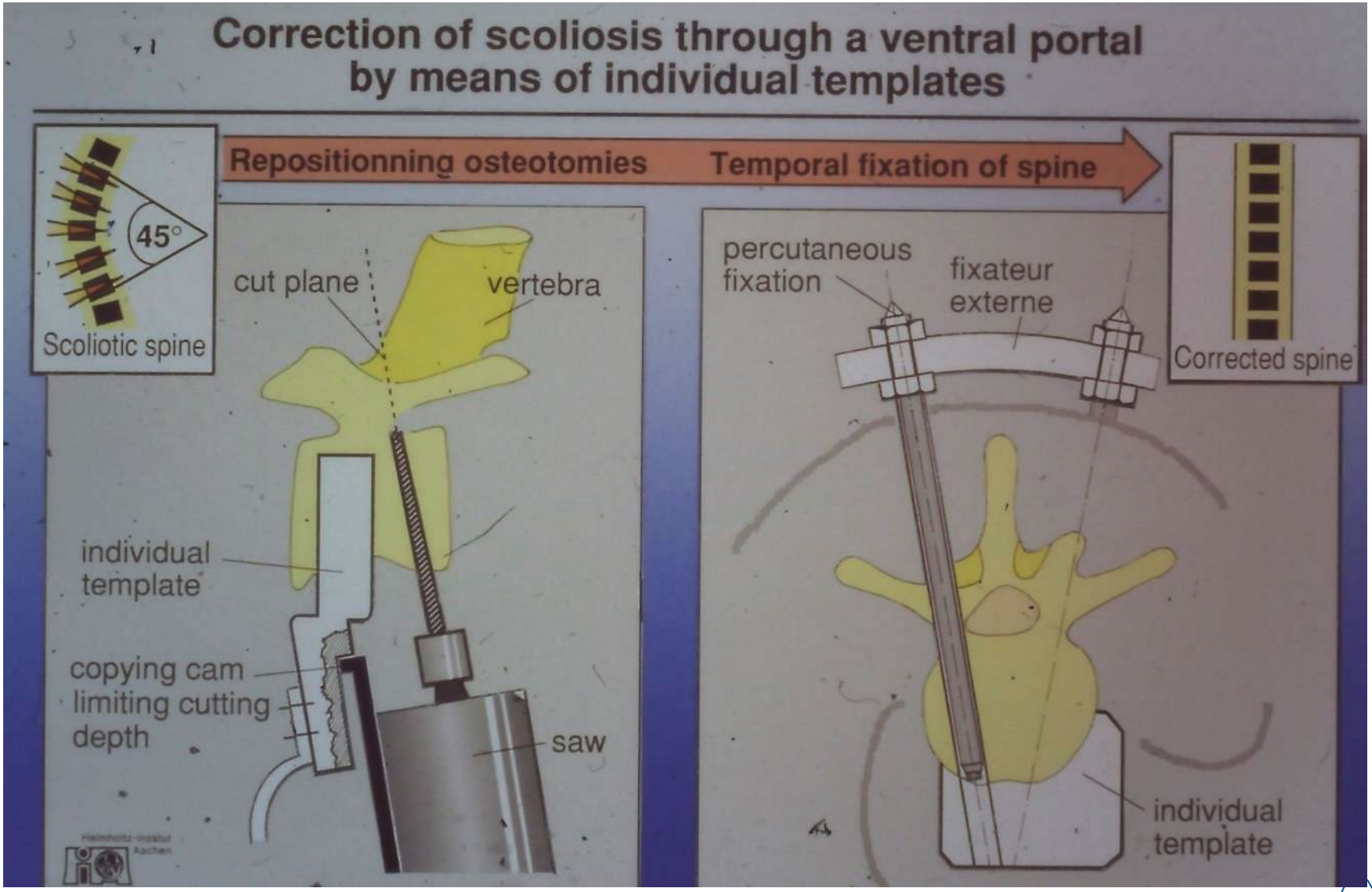




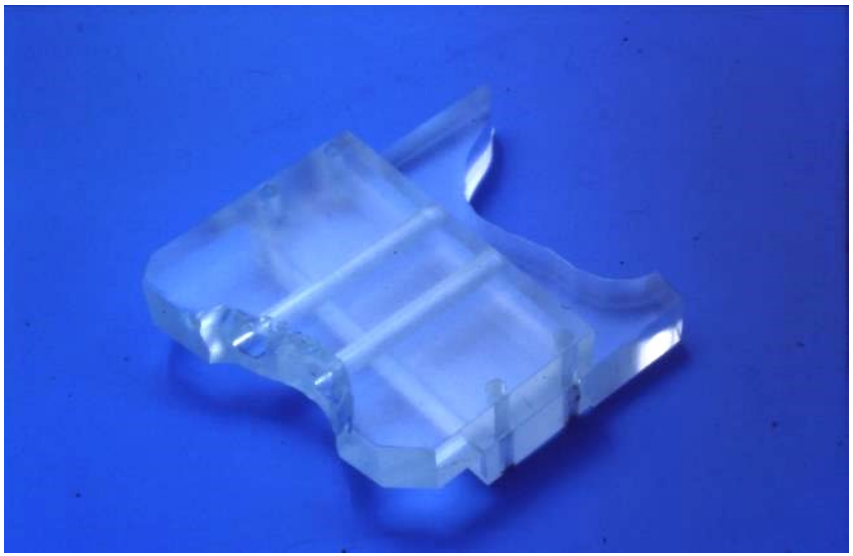


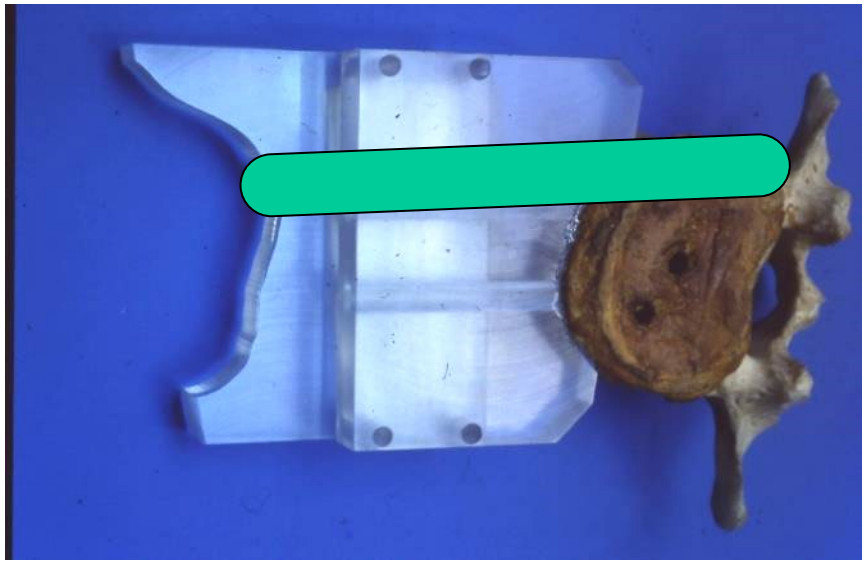
2D depth control: First concept study on ventral repositioning osteotomy on the spine

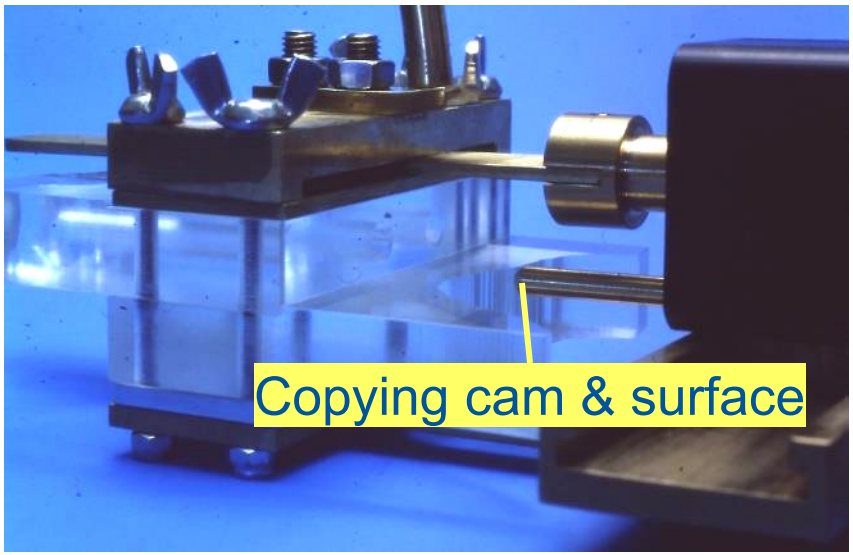
(Staudte et al. 1993)

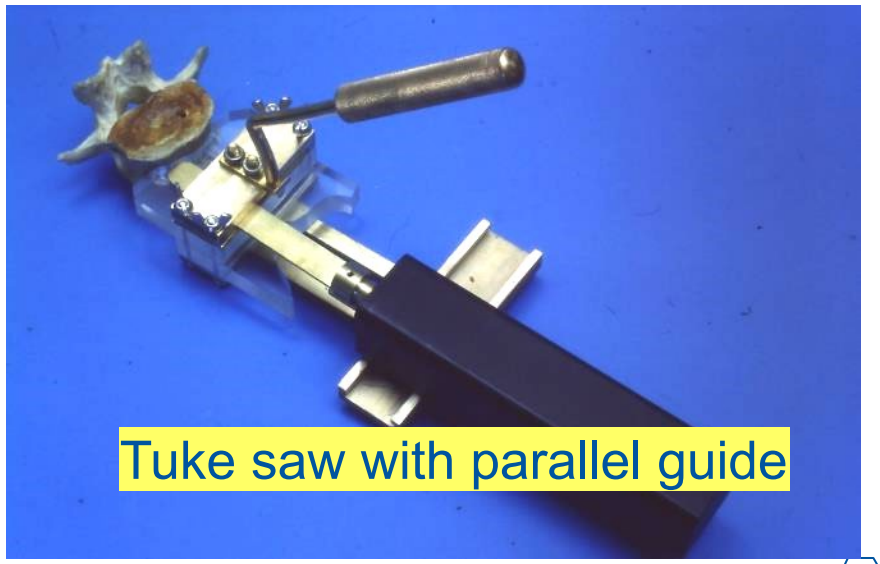


2D depth control: First concept study on ventral repositioning osteotomy on the spine

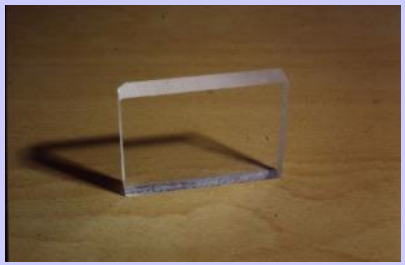


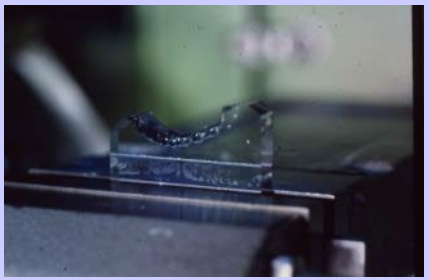






Study on Manufacturing Strategies (1993)
– Milling vs. Rapid Prototyping (or generative manufacturing) -



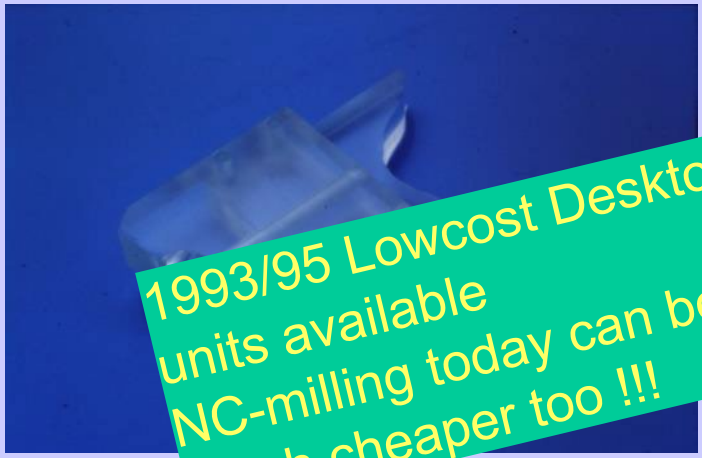
Rapid Prototyping (Stereolithography)

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)



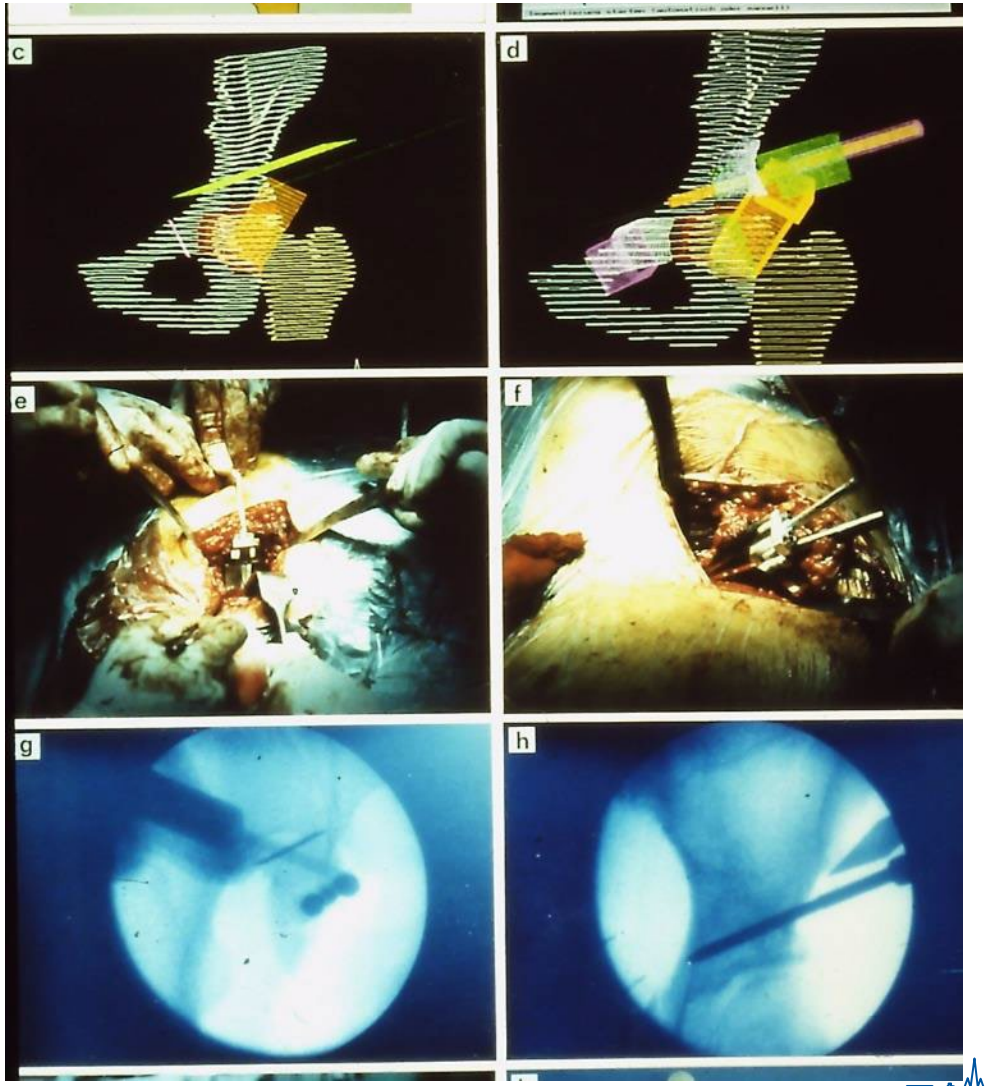
1993/95 Lowcost Desktop units available
NC-milling today can be much cheaper too !!!

Depending on the complexity of the template !

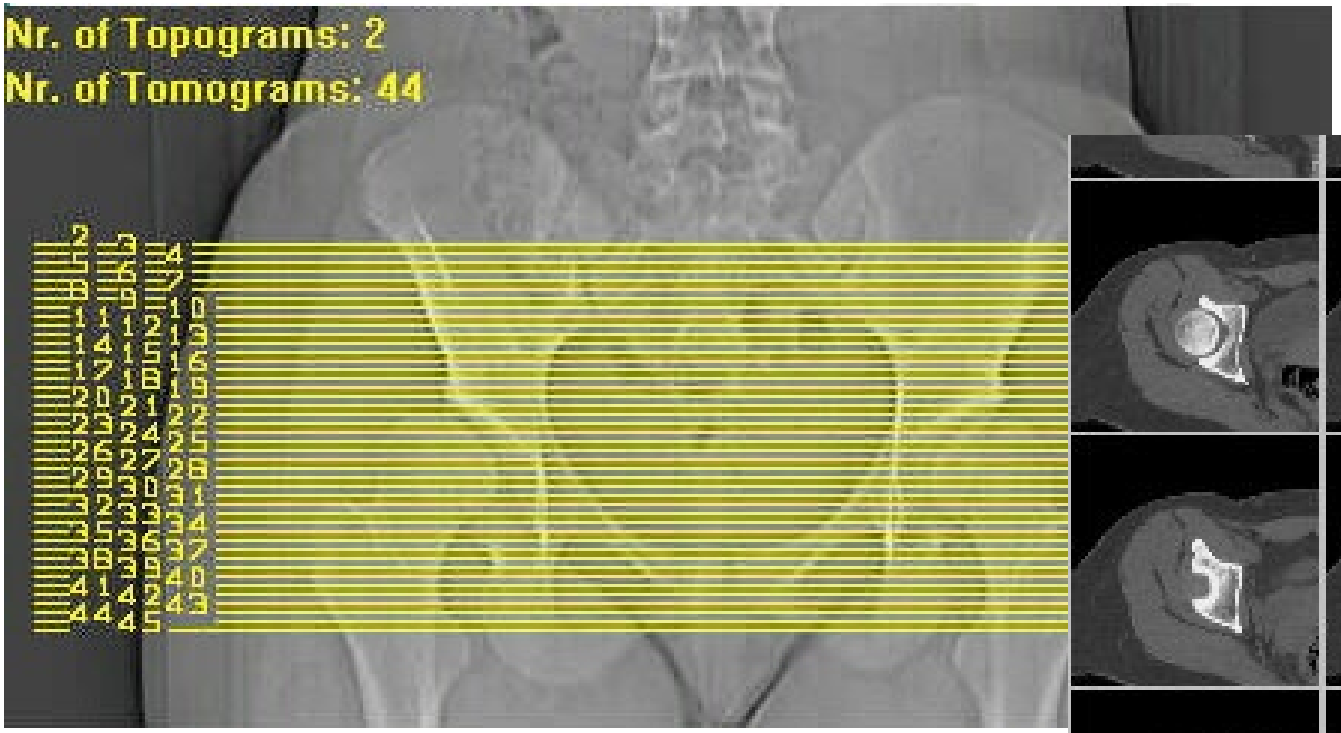
CA - Triple Osteotomy with individual templates

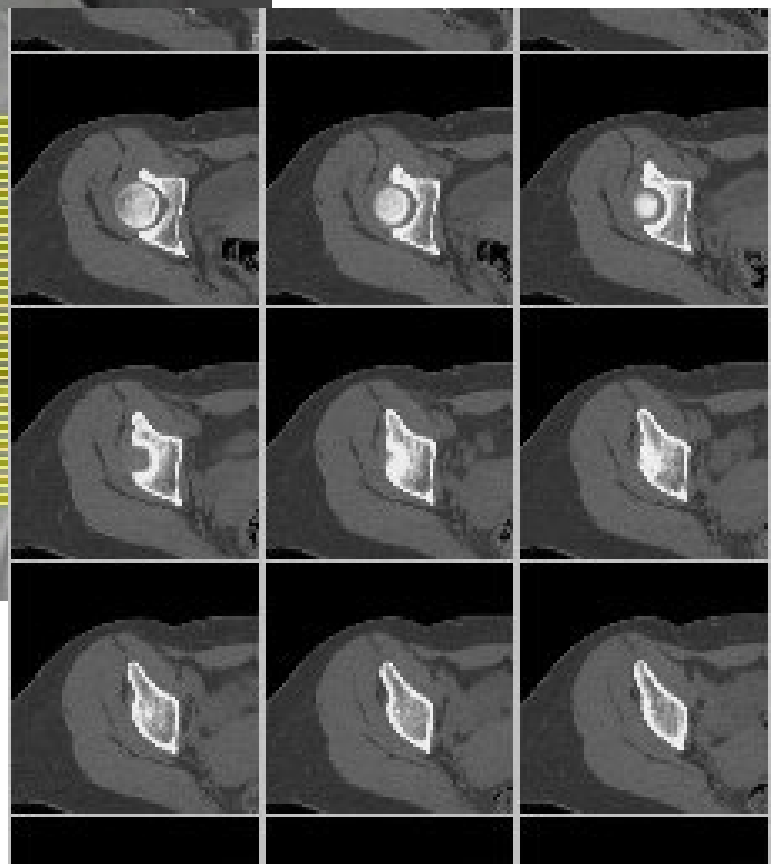
First clinical application of the individual template technique at our department for Orthopaedic Surgery in December 1993

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



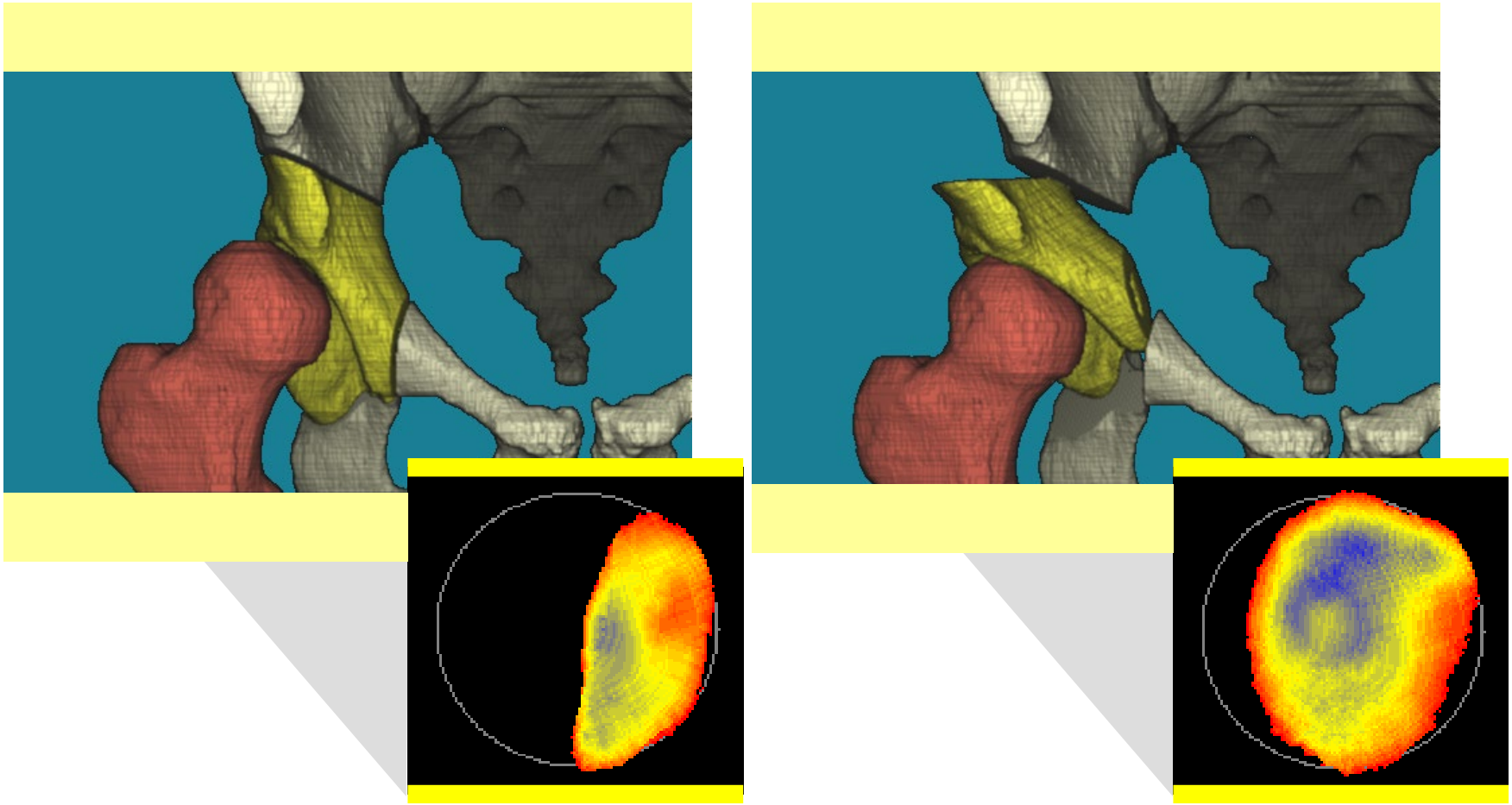
CT Image Acquisition





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

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



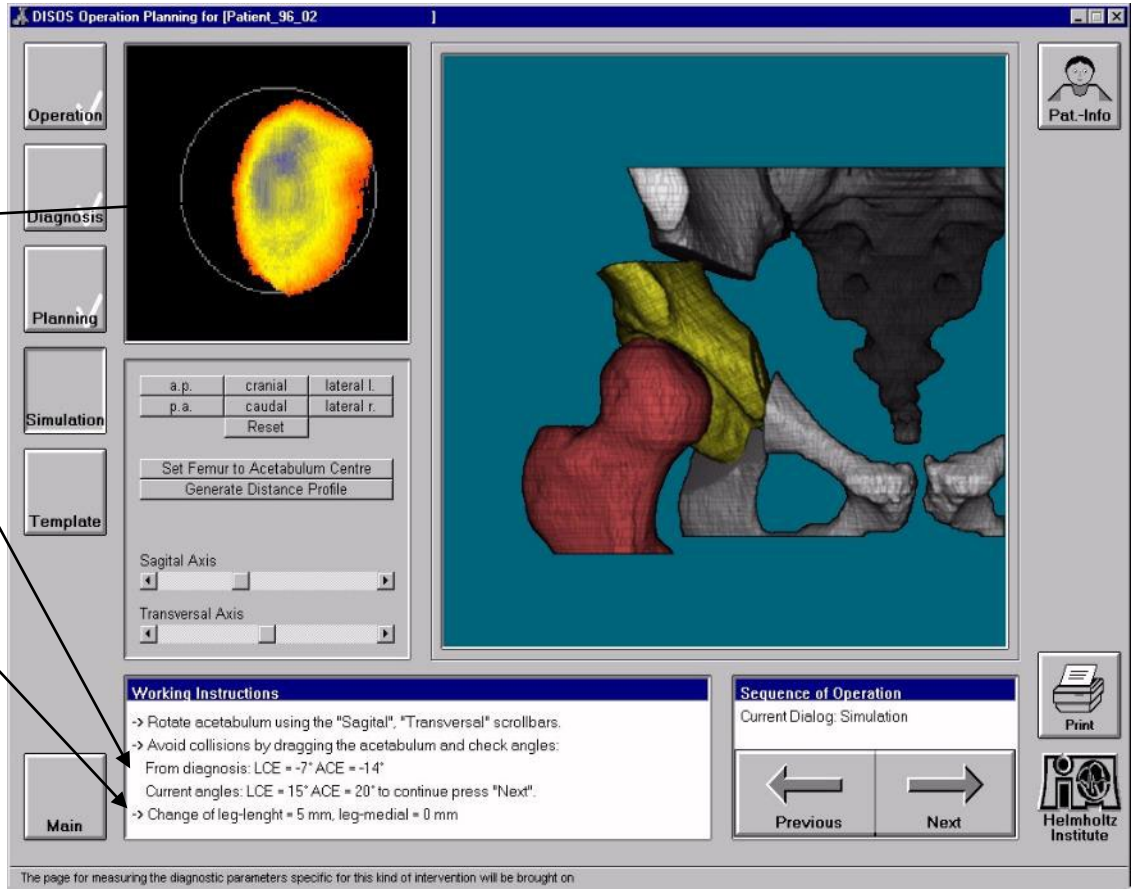
(Staudte and Radermacher et al. 1998 ff.)

Individual Templates
Interactive Planing of the Tripel-Osteotomy

Planning and Simulation of the Repositioning

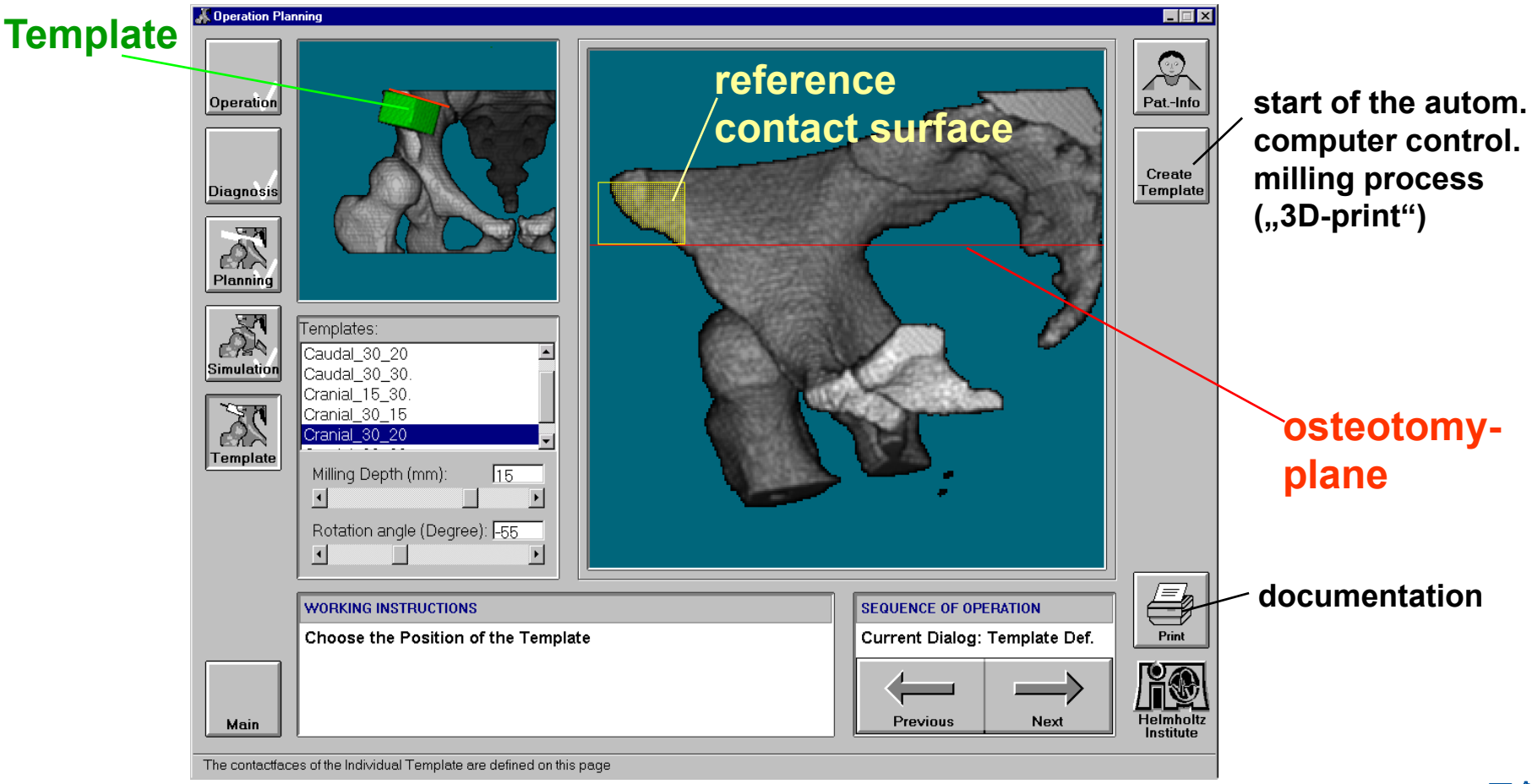
Analysis:

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



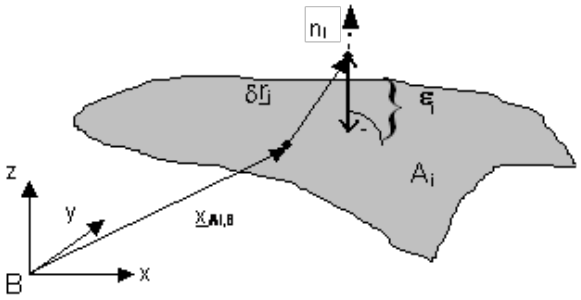
Individual Templates
Interactive Planing of the Tripel-Osteotomy

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):



Punkt-Flächen Abstand nach kleiner beliebiger Verschiebung des Oberflächen-punktes P_{Ai}

$$\delta \underline{r}_i = \delta \underline{t}_{i,B} + \delta \underline{\omega}_i \times \underline{x}_{Ai,B}$$

$$\underline{v} = \left[t_x, t_y, t_z, \omega_x, \omega_y, \omega_z \right]^T$$

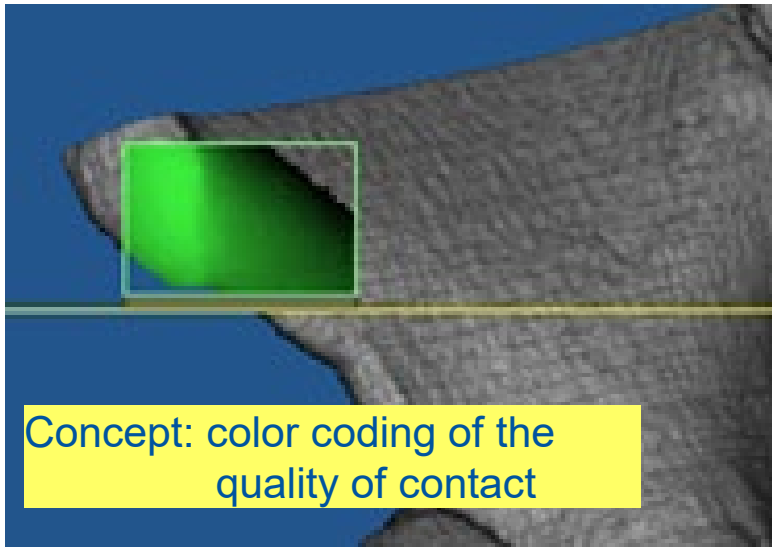
$$\mathrm{E} = \sum_{i=1}^{6} \lambda_i \cdot \left(d\underline{v}^T \cdot \underline{u}_i \right)^2$$

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 %**

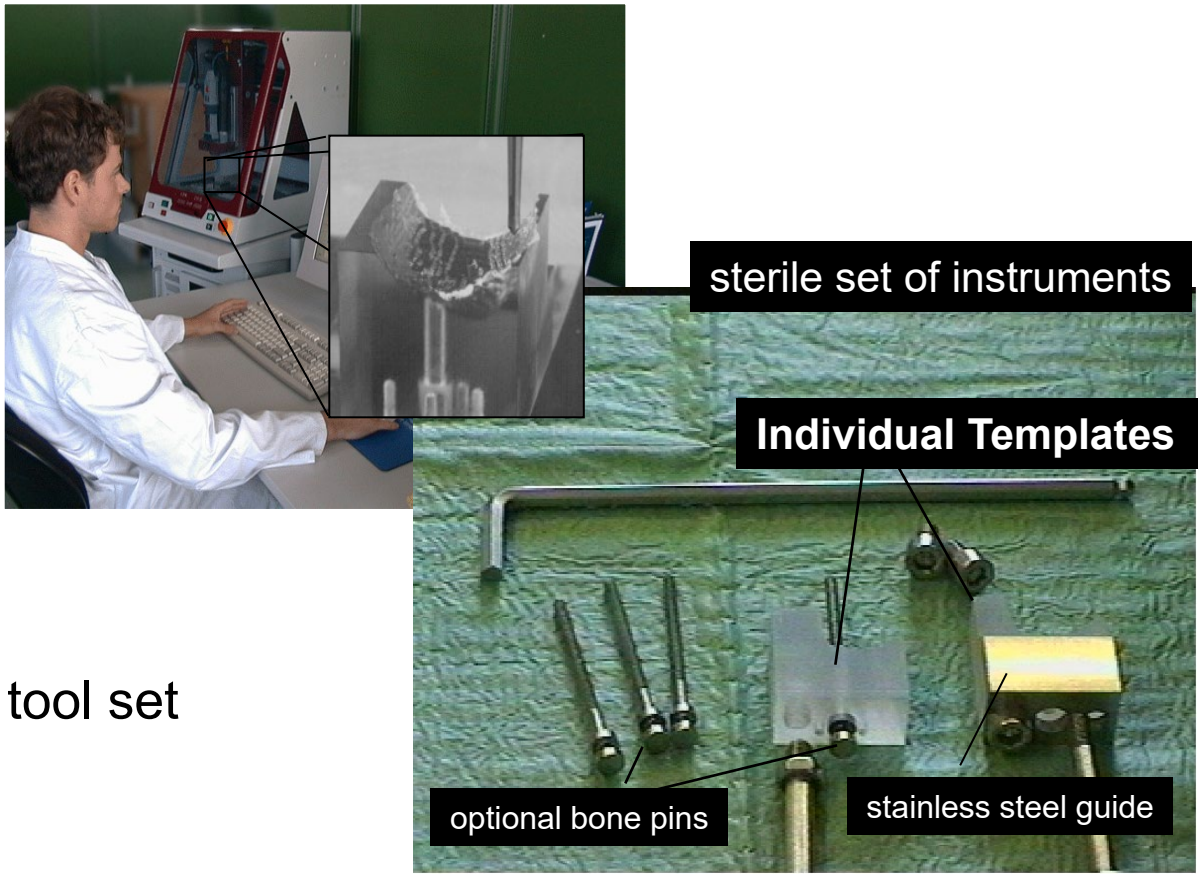


Concept: color coding of the quality of contact

Individual Templates

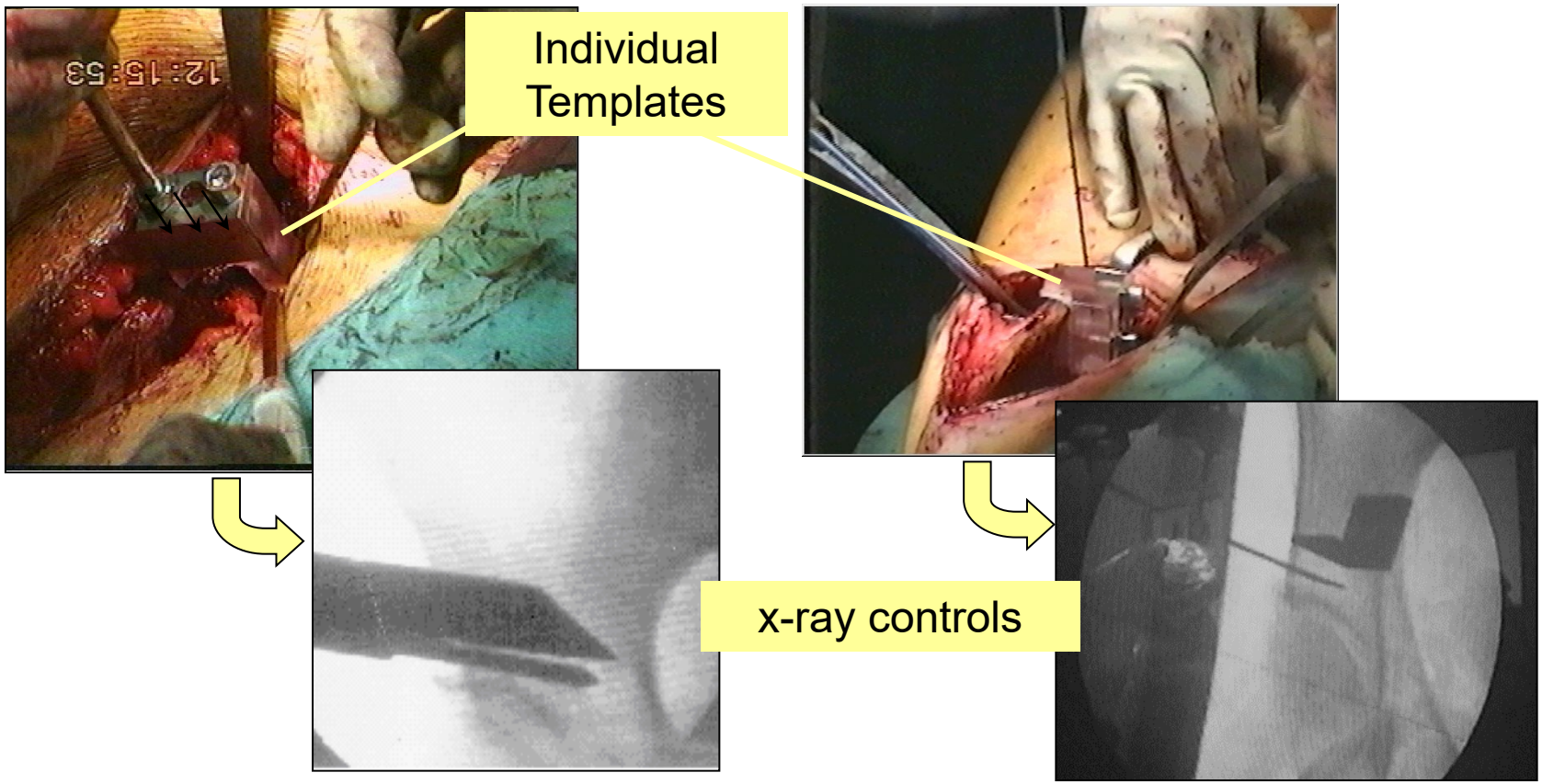
Automatic Desktop Manufacturing of Individual Templates

- 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



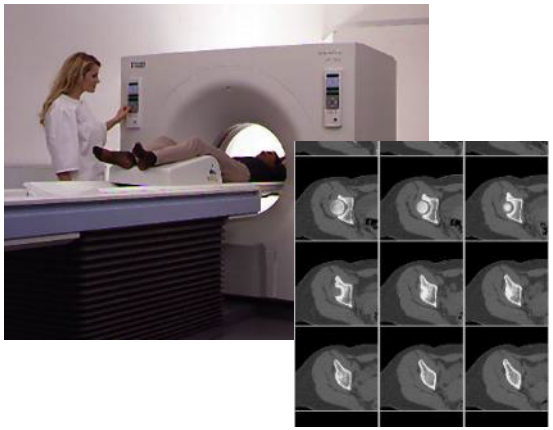
Individual Templates
Clinical Study Tripel-Osteotomy

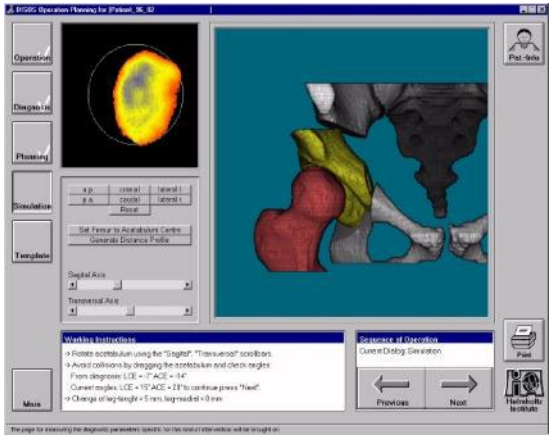
1 expert surgeon (> 50 interventions), 2 less experienced surgeons (< 20 interventions)

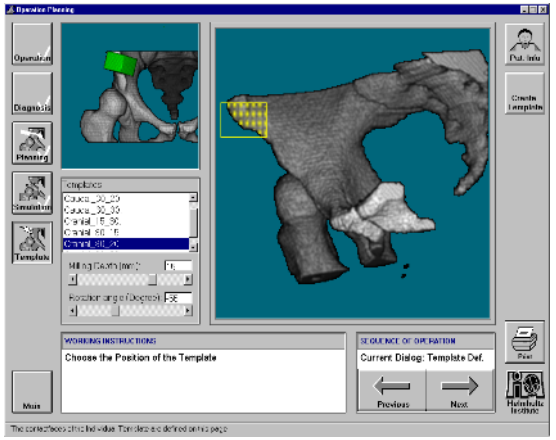
∅	conventional (K) (n=10)	Template based (C) (n=24)
Duration of operation (min)	150.9	115.8
Intraop. X-ray time (sec) (mean / expert surgeon)	30.9 / 40,7	21.4 / 13,5
Loss of blood (ml)	783.3	641.3
Hospital stay (days)	22.9	18.4

- 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)

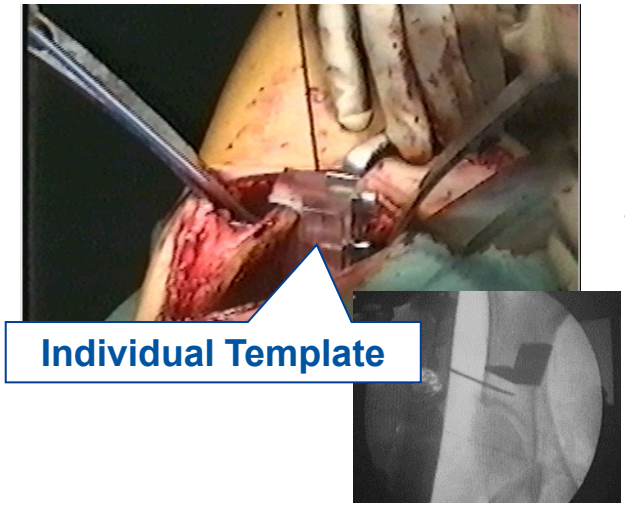




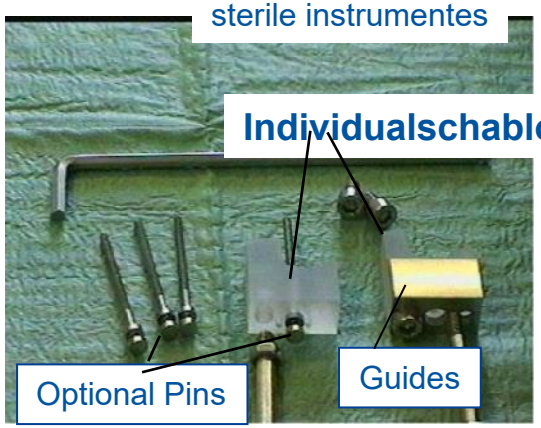


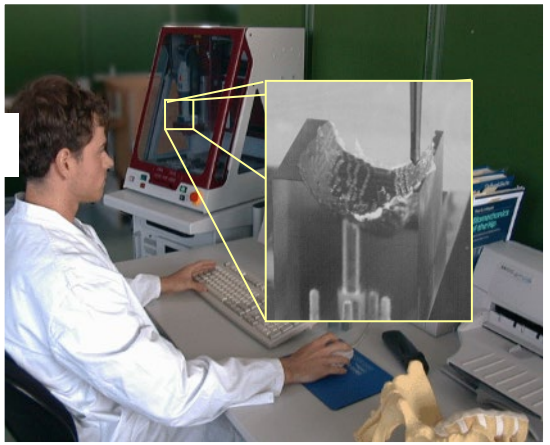
Autonomous planning by the surgeon (< 5 minutes)

Intraoperative



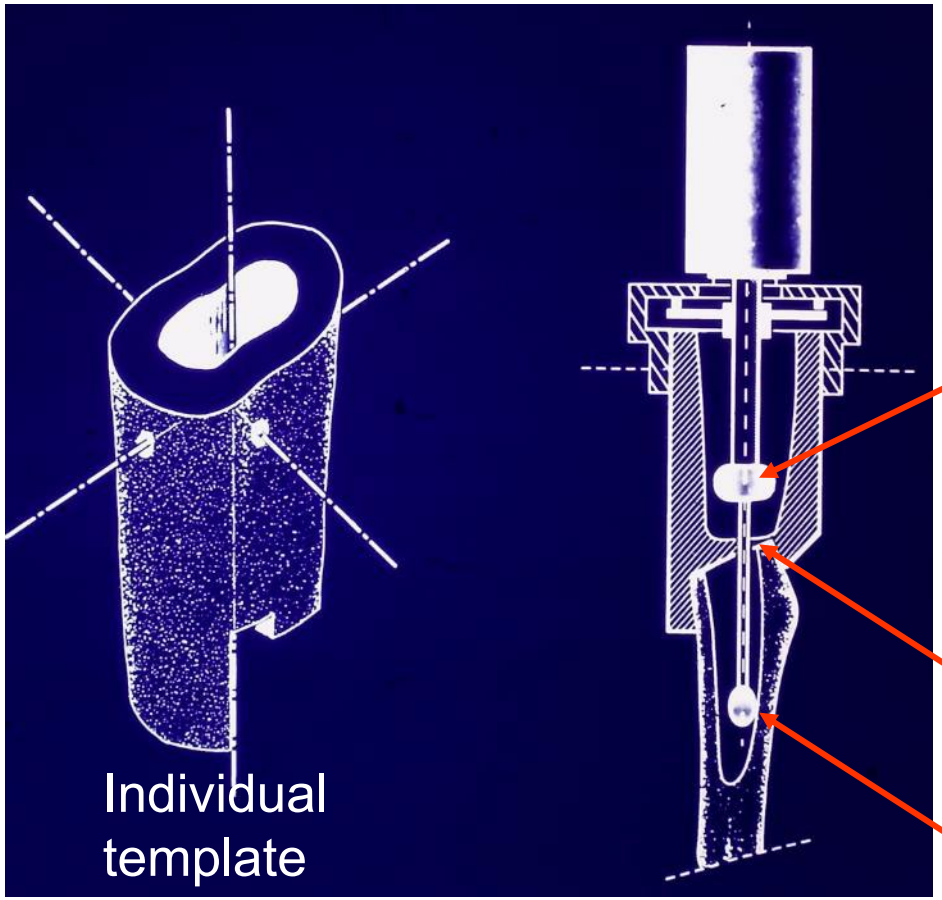
sterile instrumentes

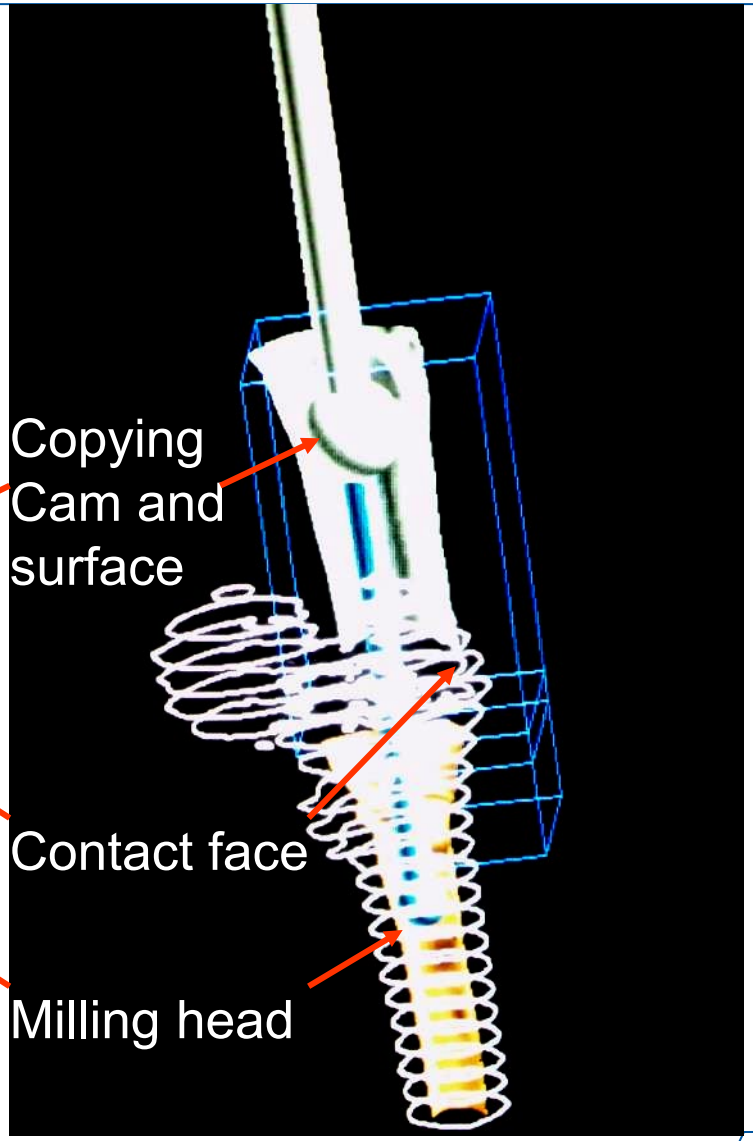




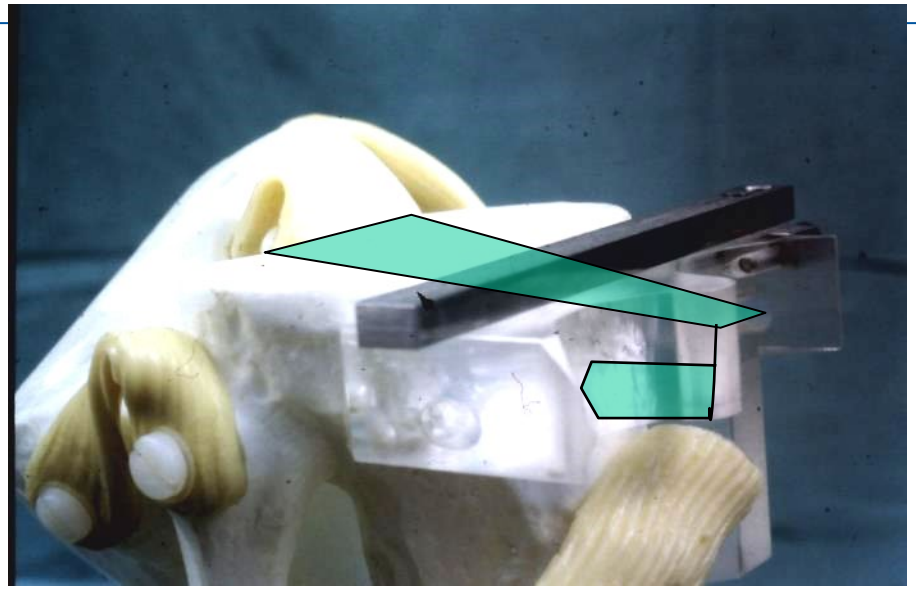
Low cost (<5k€) desktop milling

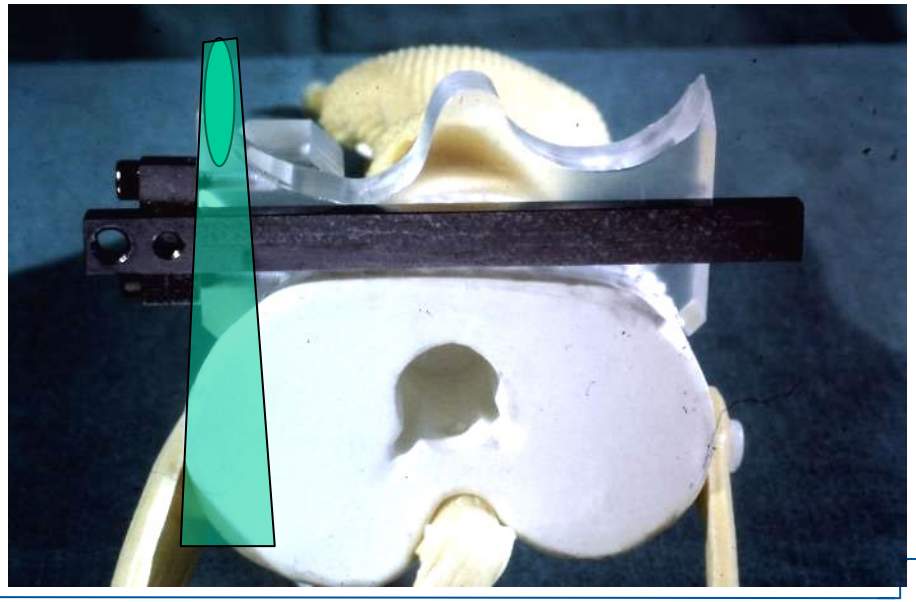
First concepts of 3D-shape control (in THA)



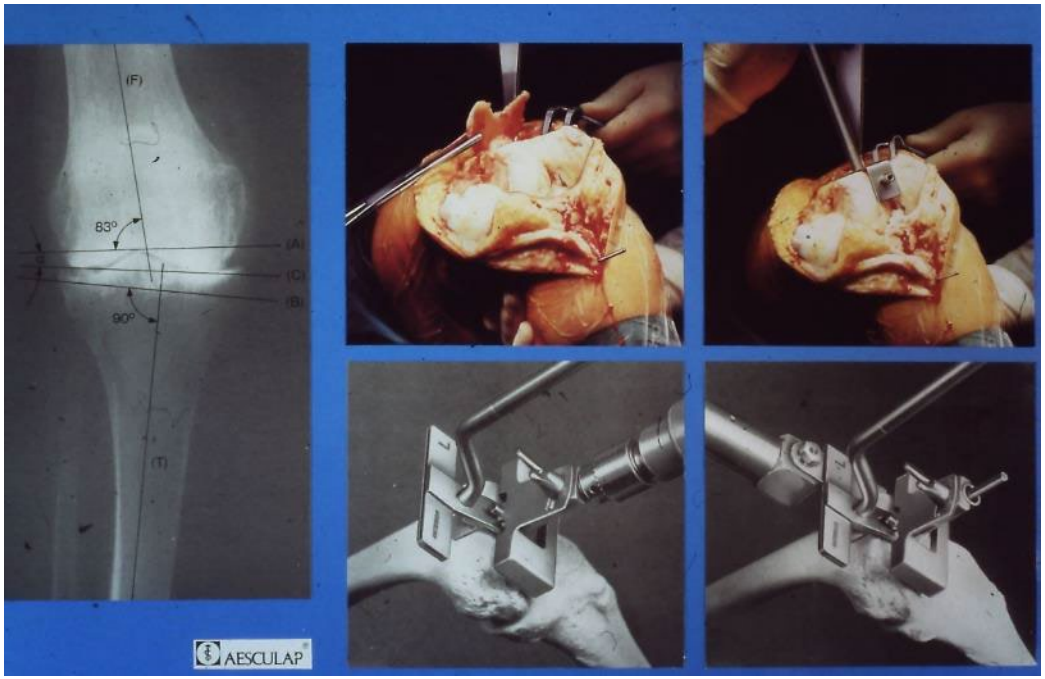


1992: First concepts of 2D depth control (osteotomies in TKA)





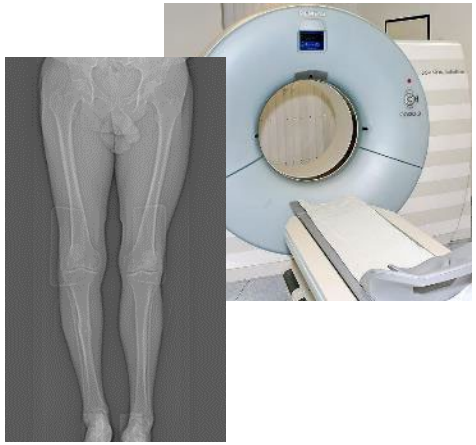
Individual Templates in TKA – Basic Motivation (1988)



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

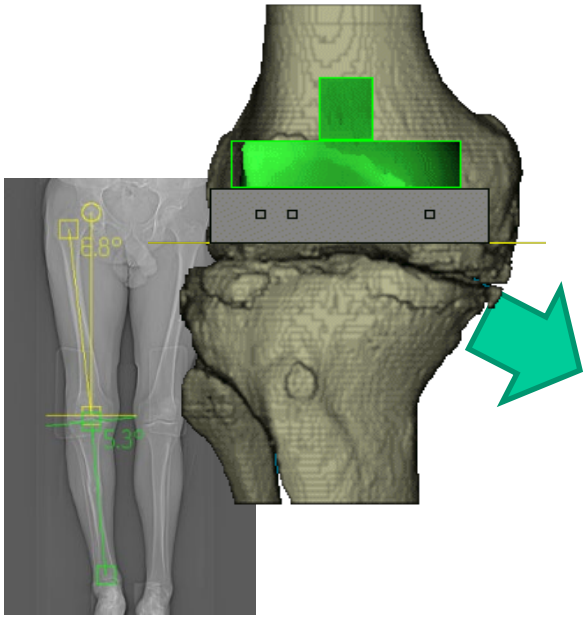
Individual Templates
- Overview - Workflow -

I.) CT / MRI-Imaging



3D dataset is required

II.) Preoperative Planning Process



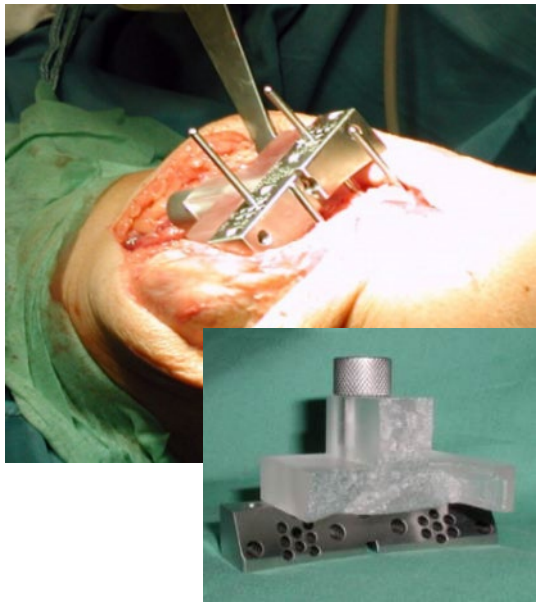
III.) Preoperative Manufacturing of the templates

Individual Templates
- Overview - Workflow -

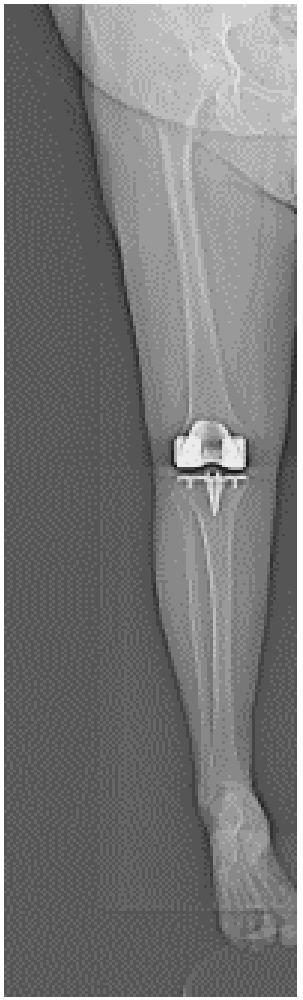
IV.) Cleaning and Sterilization

Source: KSG 2010

V.) Intraoperative Use



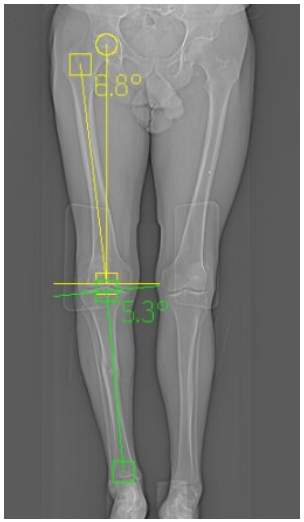
VI.) Clinical Outcome



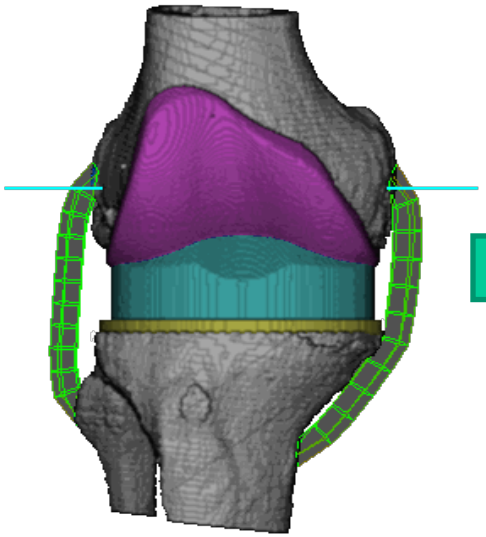
Individual Templates
- Planning -

3 Steps of the planning process

1.) Identification of the mechanical axis and landmarks

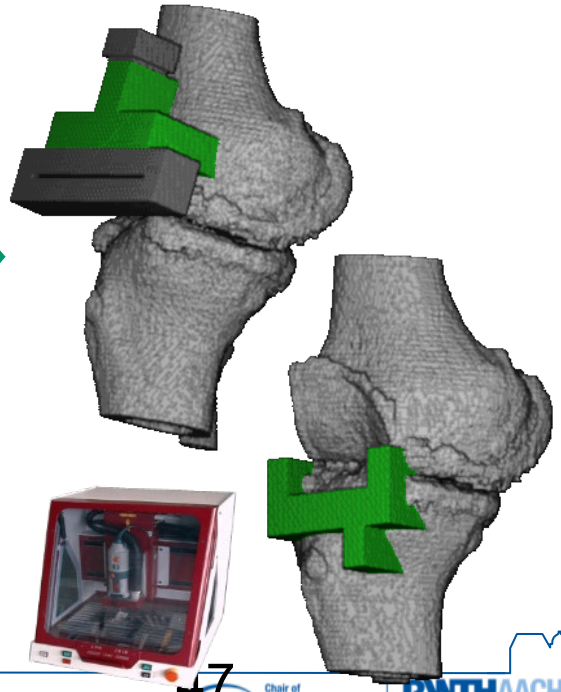


2.) Planning of the prosthesis



Type, size, position and orientation

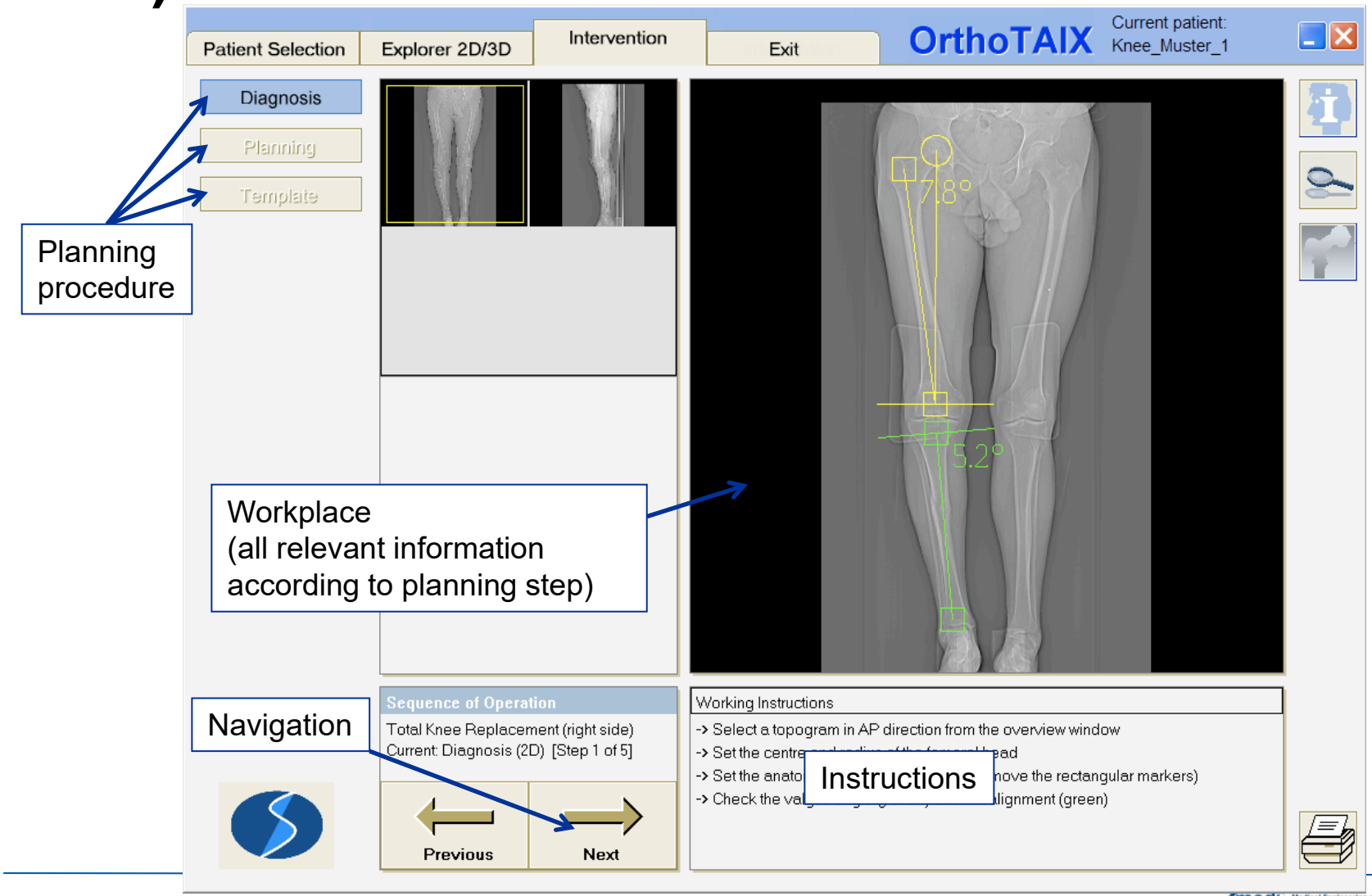
3.) Generation of the template geometry



Individual Templates
- Planning -

Source: SurgiTAIX AG, Aachen, Germany

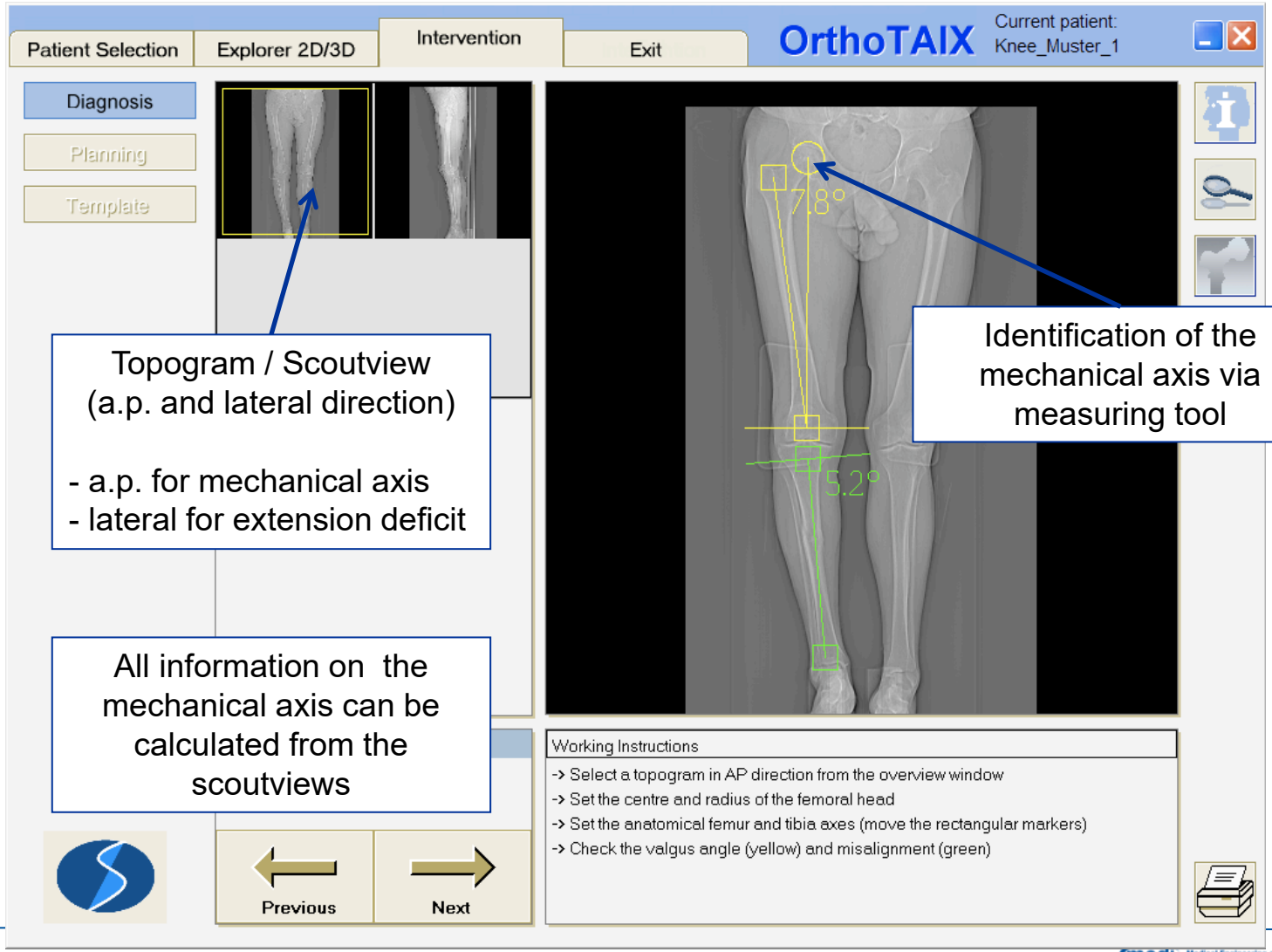
1.) Identification of the mechanical axis via a guided dialog



Individual Templates
- Planning -

Source: SurgiTAIX AG, Aachen, Germany

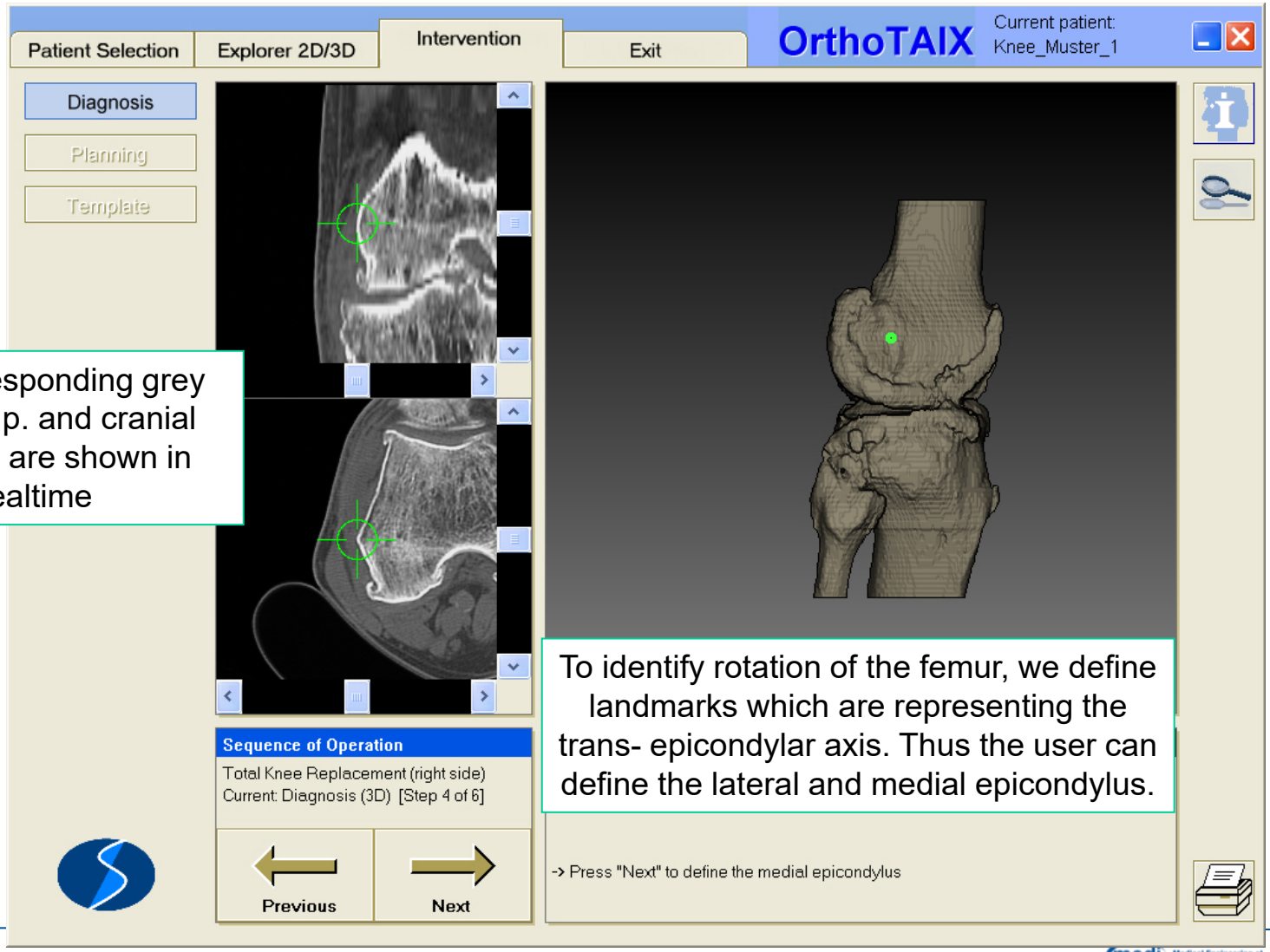
1.) Identification of the mechanical axis via a guided dialog



Individual Templates
- Planning -

Source: SurgiTAIX AG, Aachen, Germany

1.) Identification of landmarks



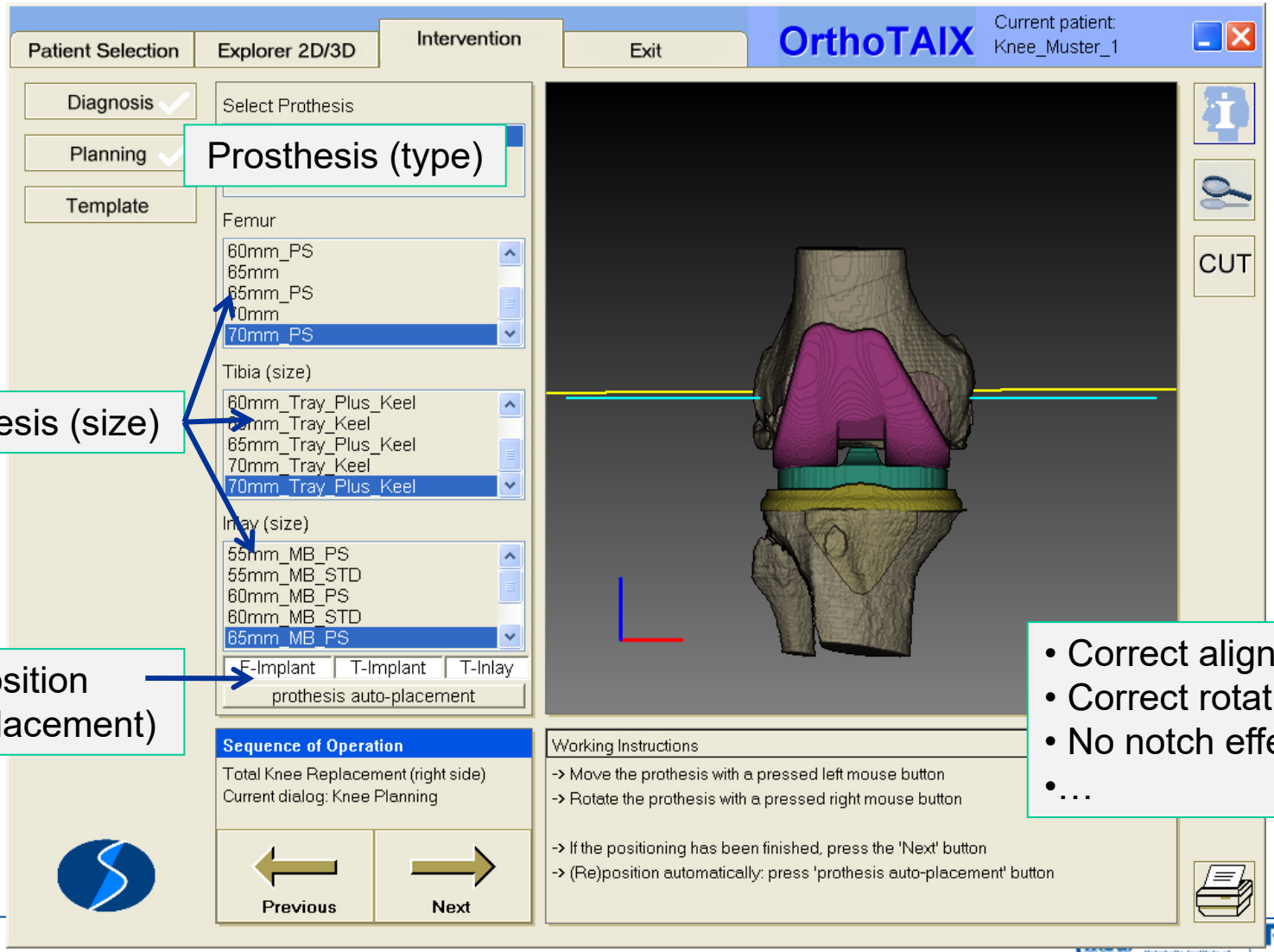
The corresponding grey cuts in a.p. and cranial direction are shown in realtime

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.

Individual Templates
- Planning -

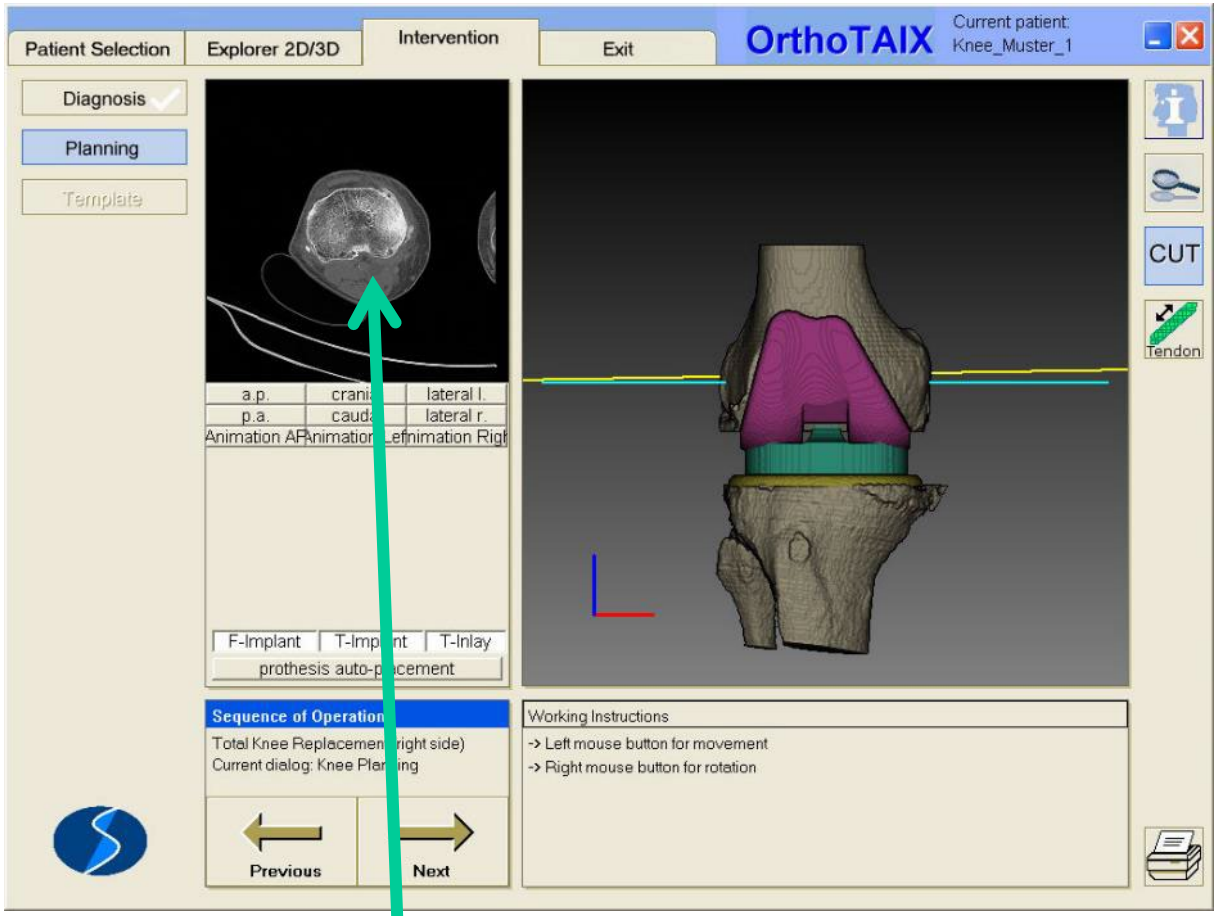
Source: SurgiTAIX AG, Aachen, Germany

2.) Planning of the prosthesis



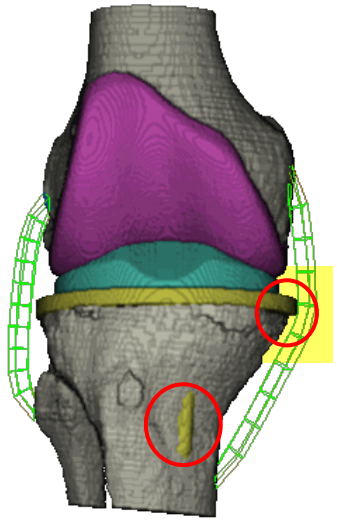
Individual Templates
- Planning -

Source: SurgiTAIX AG, Aachen, Germany



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

Incorrect Placement



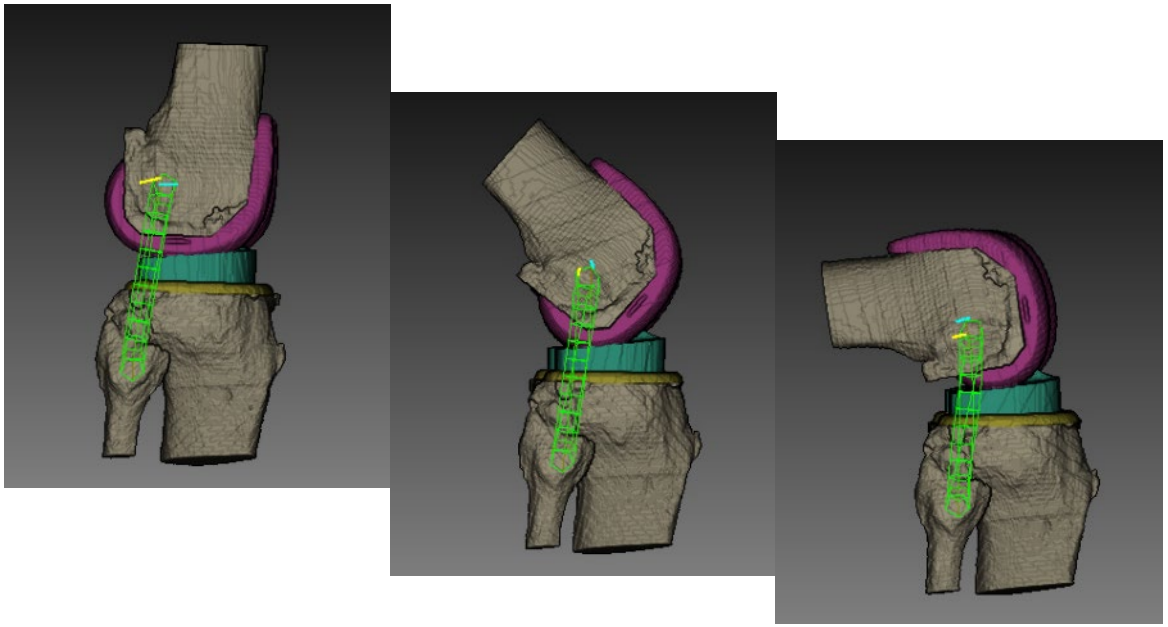
- Penetration of tibia fixation
- Contact between ligament and prosthesis

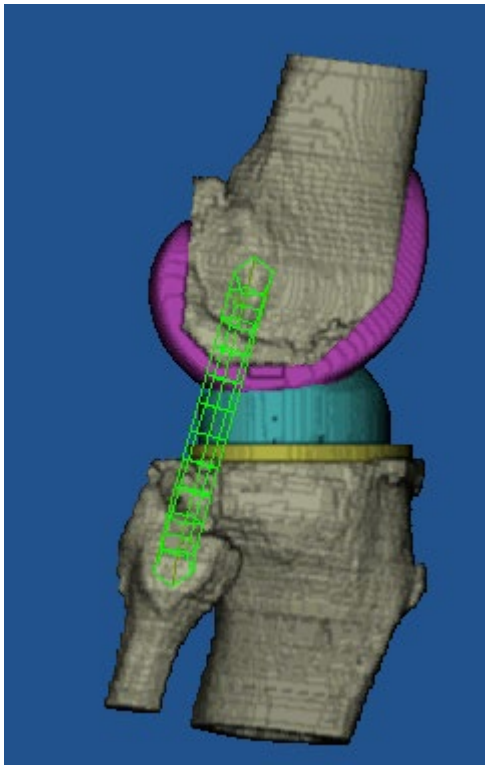
Individual Templates
- Planning -

Source: SurgiTAIX AG, Aachen, Germany

2.) Planning of the prosthesis

The flexion and extension can be shown in an animation.





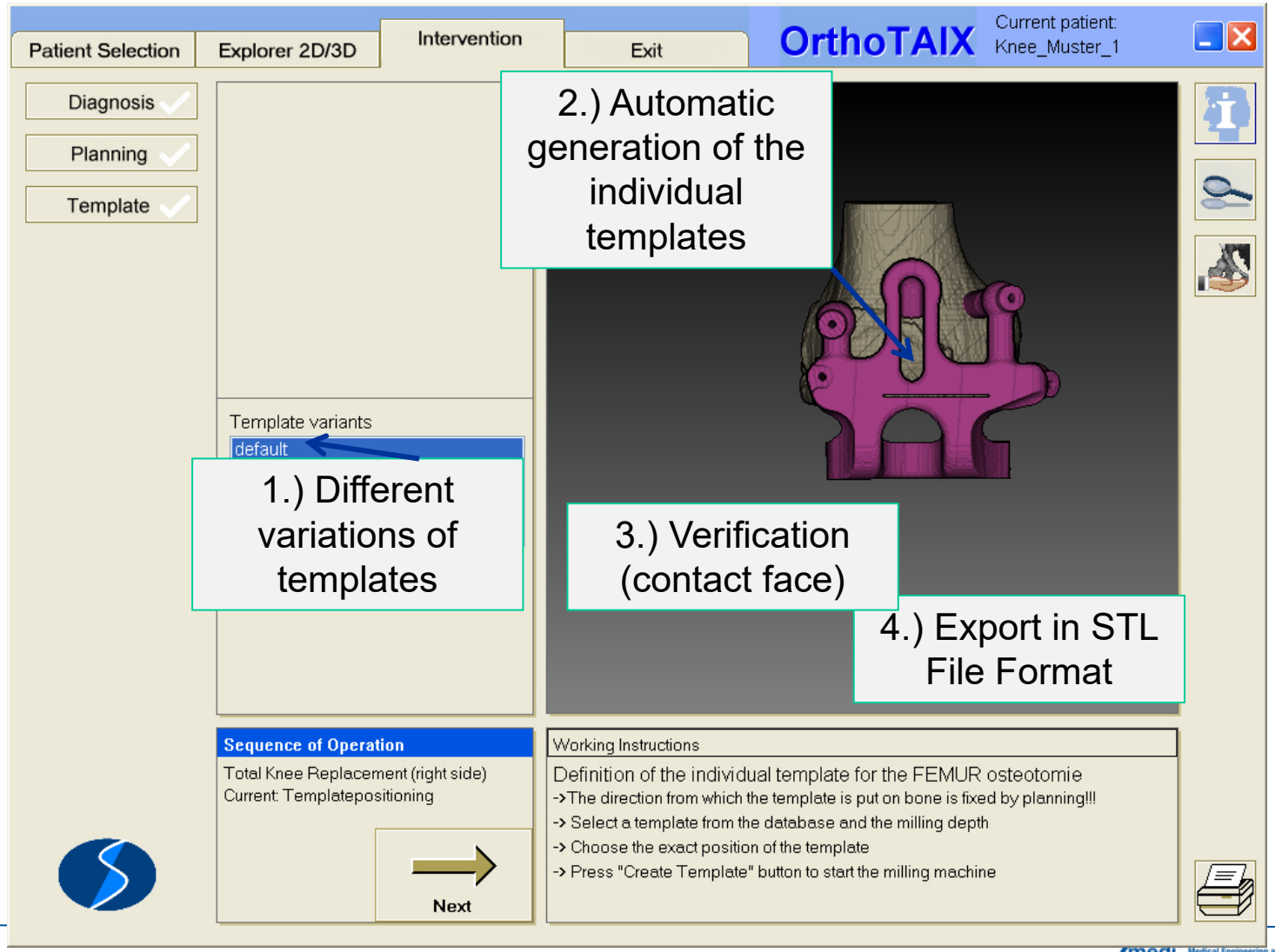
Determination of the changes of the ligament lengths in extension as well as in flexion (isometric conditions)

Volumetric mass-spring model

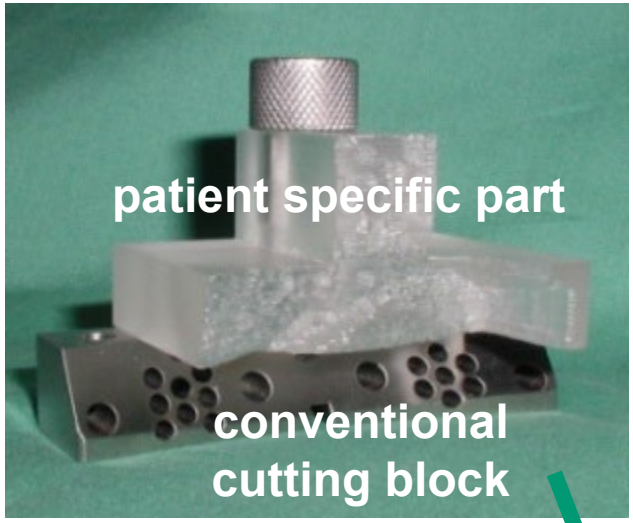
Individual Templates
- Planning -

Source: SurgiTAIX AG, Aachen, Germany

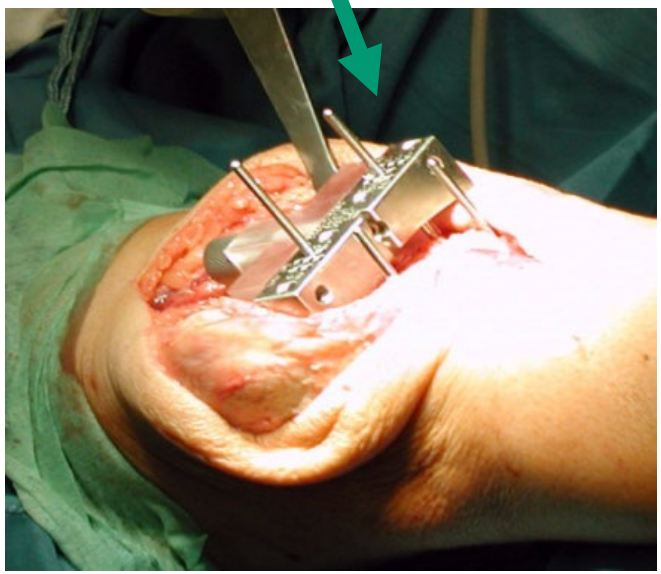
3.) Generation of the template geometry

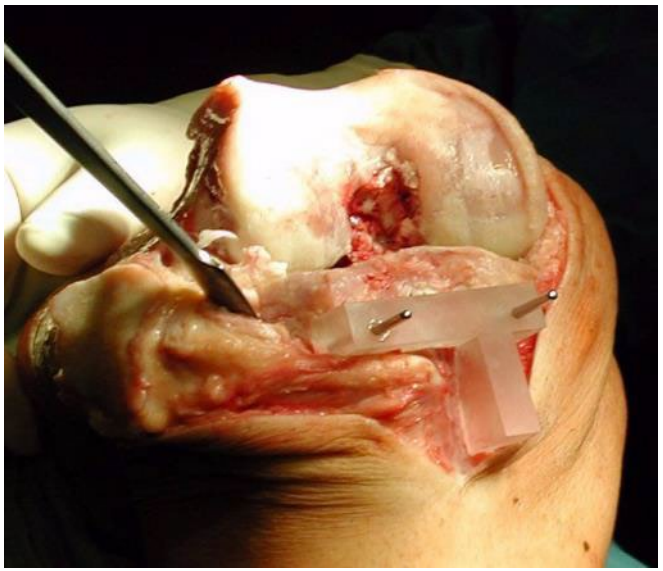


Individual Templates
- Intraoperative use -



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





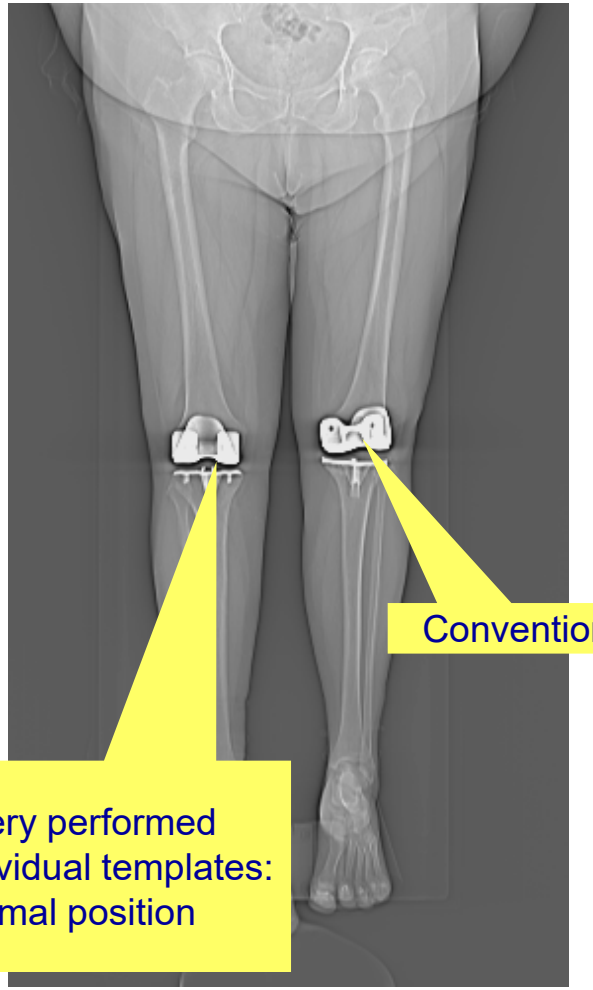
Individual Templates
- Clinical Outcome -

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

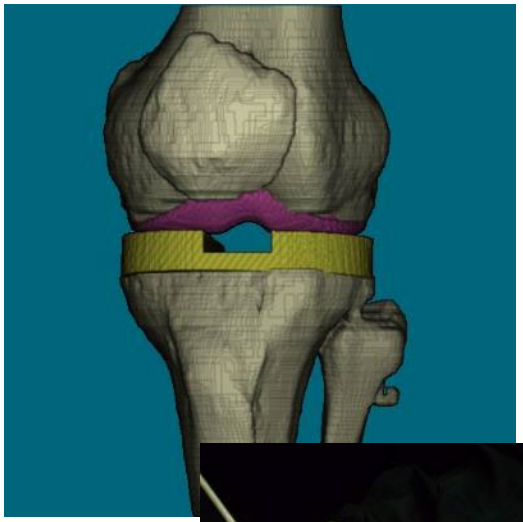
o CT- required

o Preoperative computer based planning necessary



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 or 3D US)
– pre-operative planning required
– no percutaneous application, access to bone/cartilage/
– hard tissue required



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