Orthopaedics advances are strongly technology driven

As the leading clinical, educational and research Orthopaedic center in Nebraska, we can either:

Be early market consumers of orthopaedic implants and technology

or

Strive to innovate and create new technology

Simplified Surgery

University of Nebraska Medical Center

Dr. Hani Haider

University of Nebraska Medical Center

NoMiss

Nebraska Orthopaedics Minimally Invasive Surgery System

…. a Nebraska born system

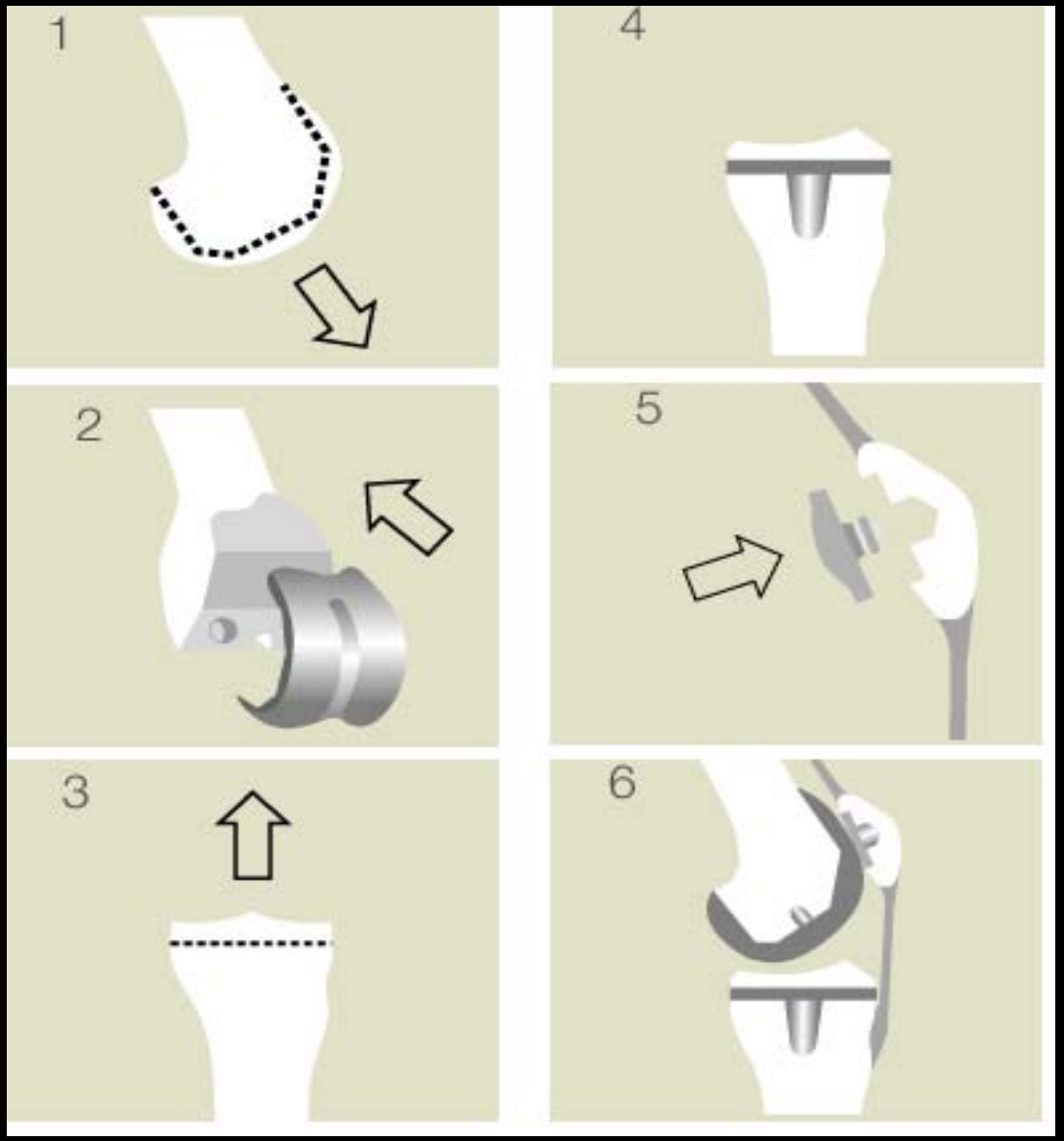
Innovative technology for effective osteotomy and arthroplasty surgery in battlefields and/or remote locations: Navigated Freehand Cutting (NFC) of bones

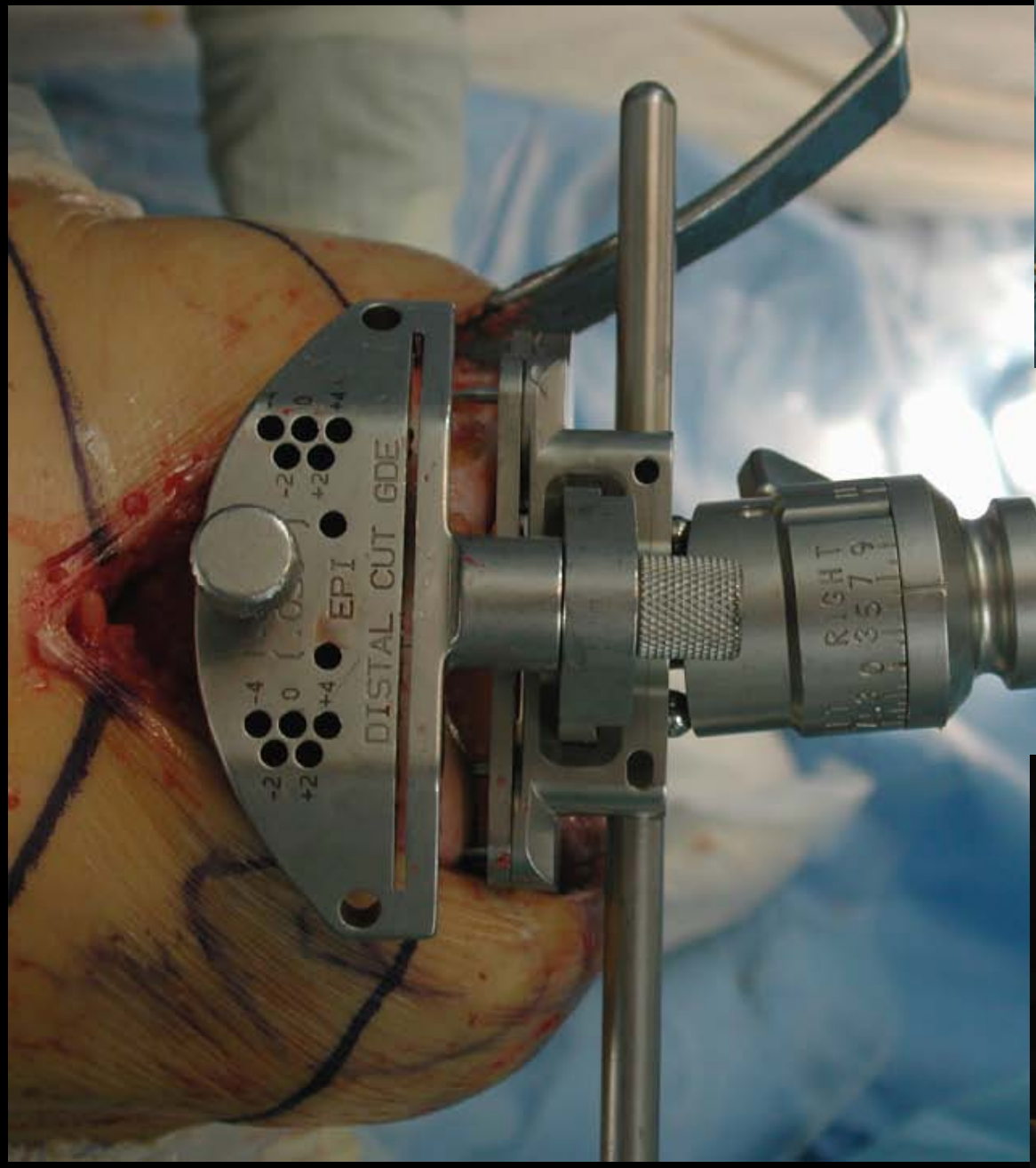
Hani Haider, PhD
Professor,
Director of Orthopaedics Biomechanics and Advanced Surgical Technology Laboratory

Department of Orthopaedic Surgery and Rehabilitation

What is Knee Replacement Surgery:

- Major surgery
- It involves replacing a natural joint by an artificial one.
- Expensive ~ $30K
- Complex/difficult
- Slow
- Requires large assortment of mechanical instruments

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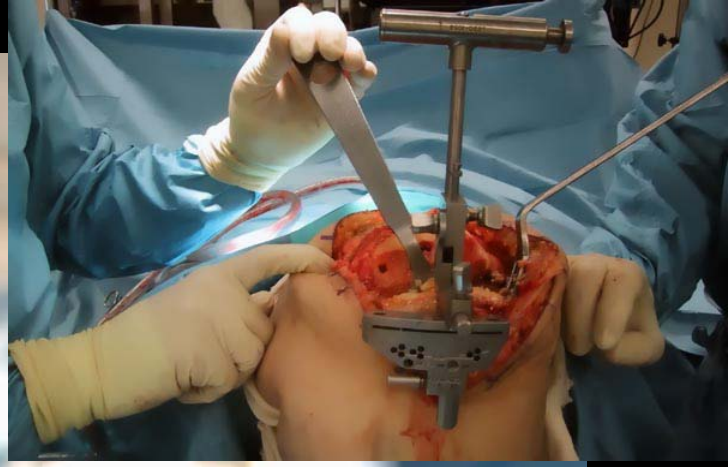

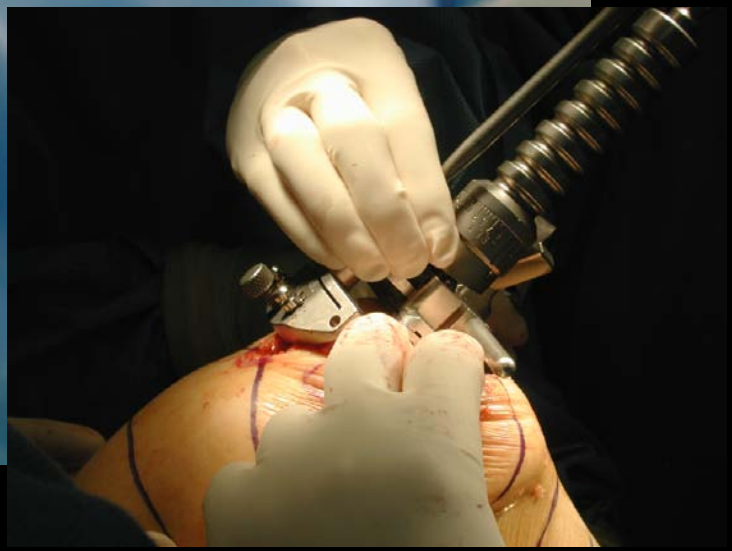

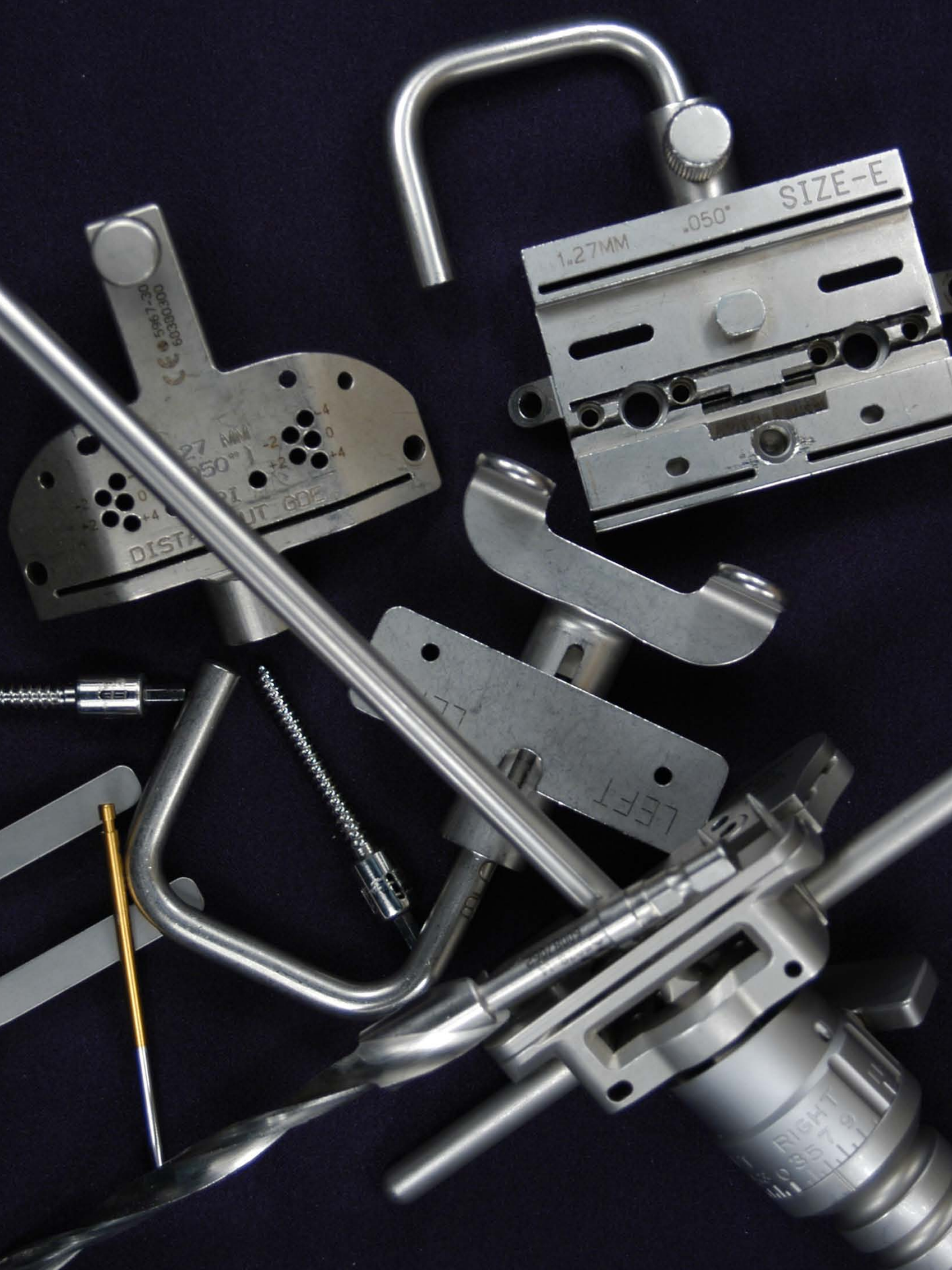
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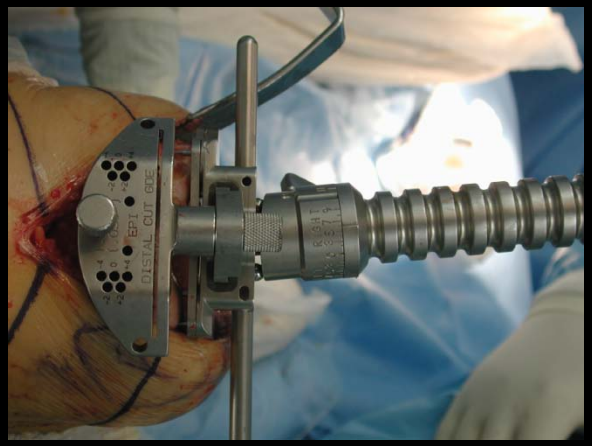
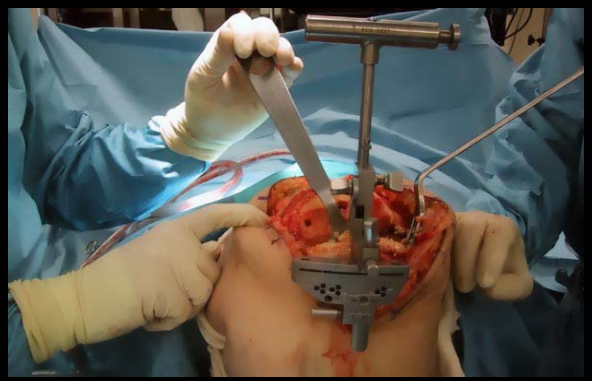
Different approaches:

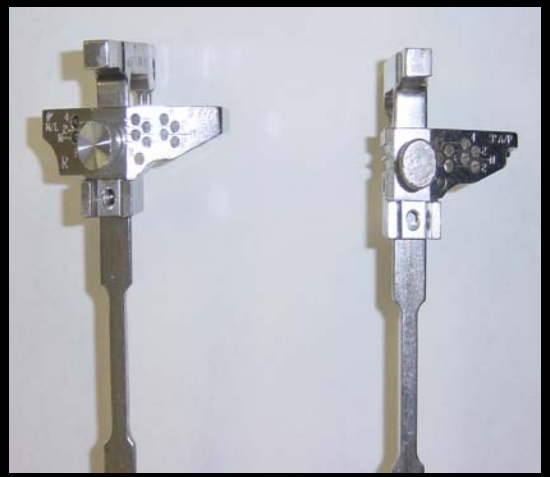
Recently introduced…

Conventional Approach

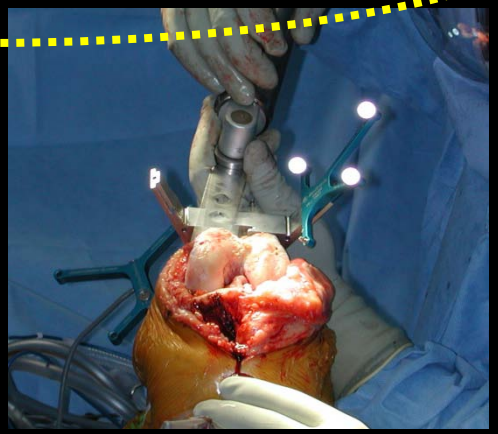


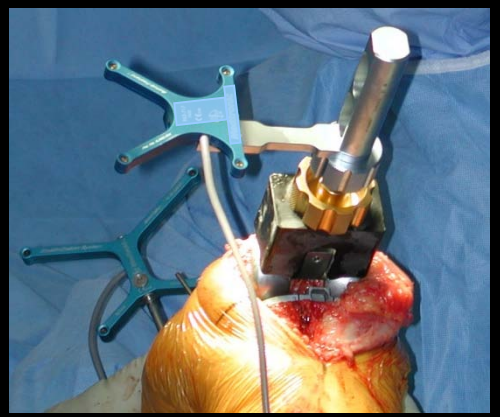


MIS

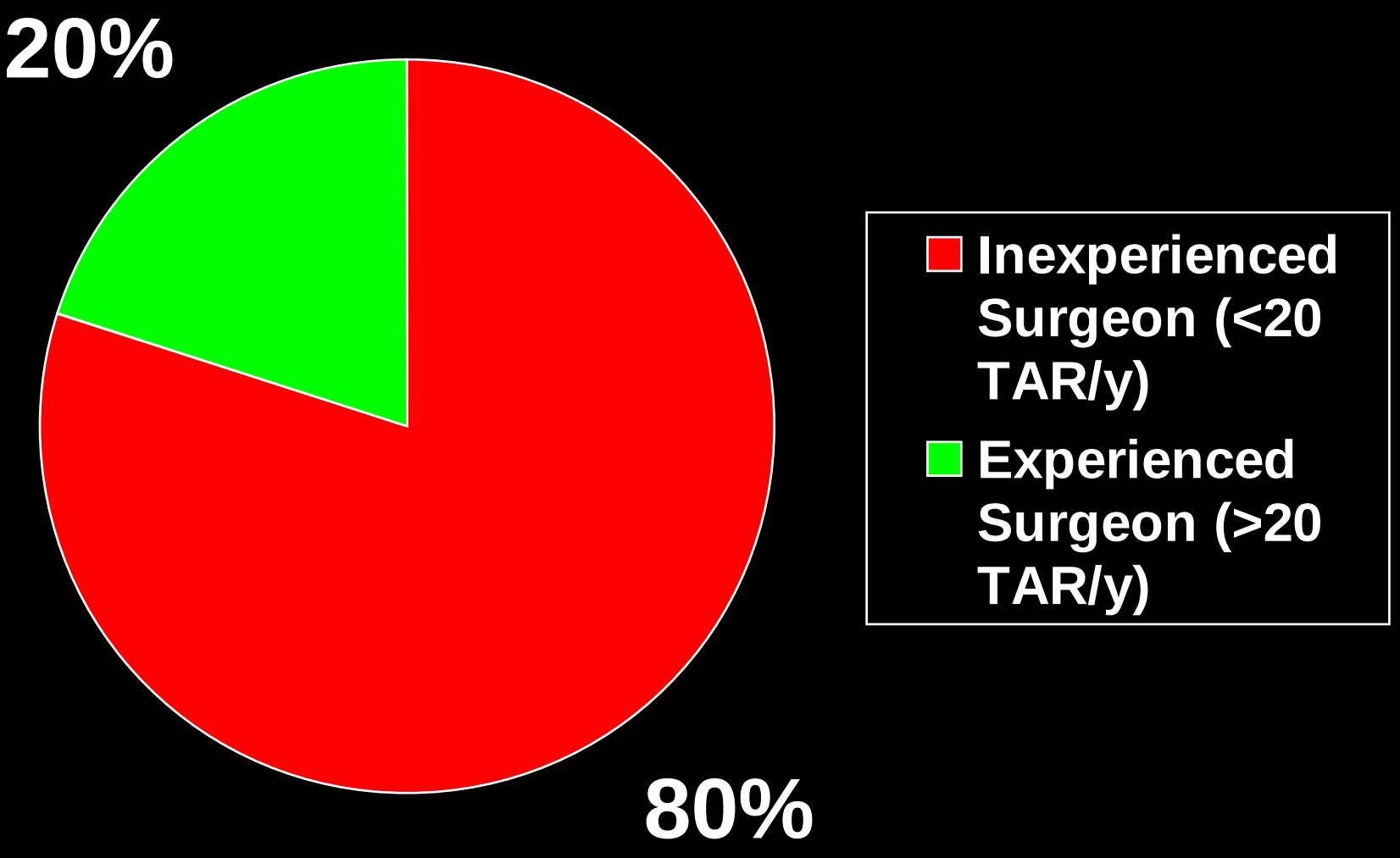


CAOS: Navigated Jigs





High surgical skills needed, but!



Computer Aided Surgery Systems with Navigation (CAOS)

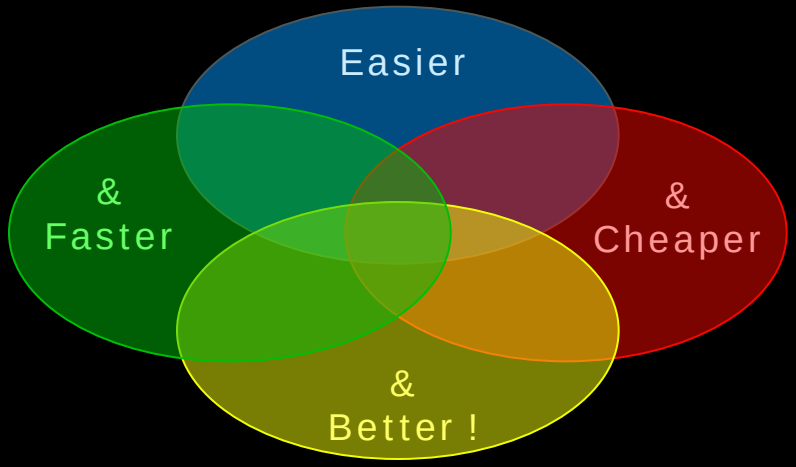
More accuracy and fewer outliers

?

Minimally-invasive techniques

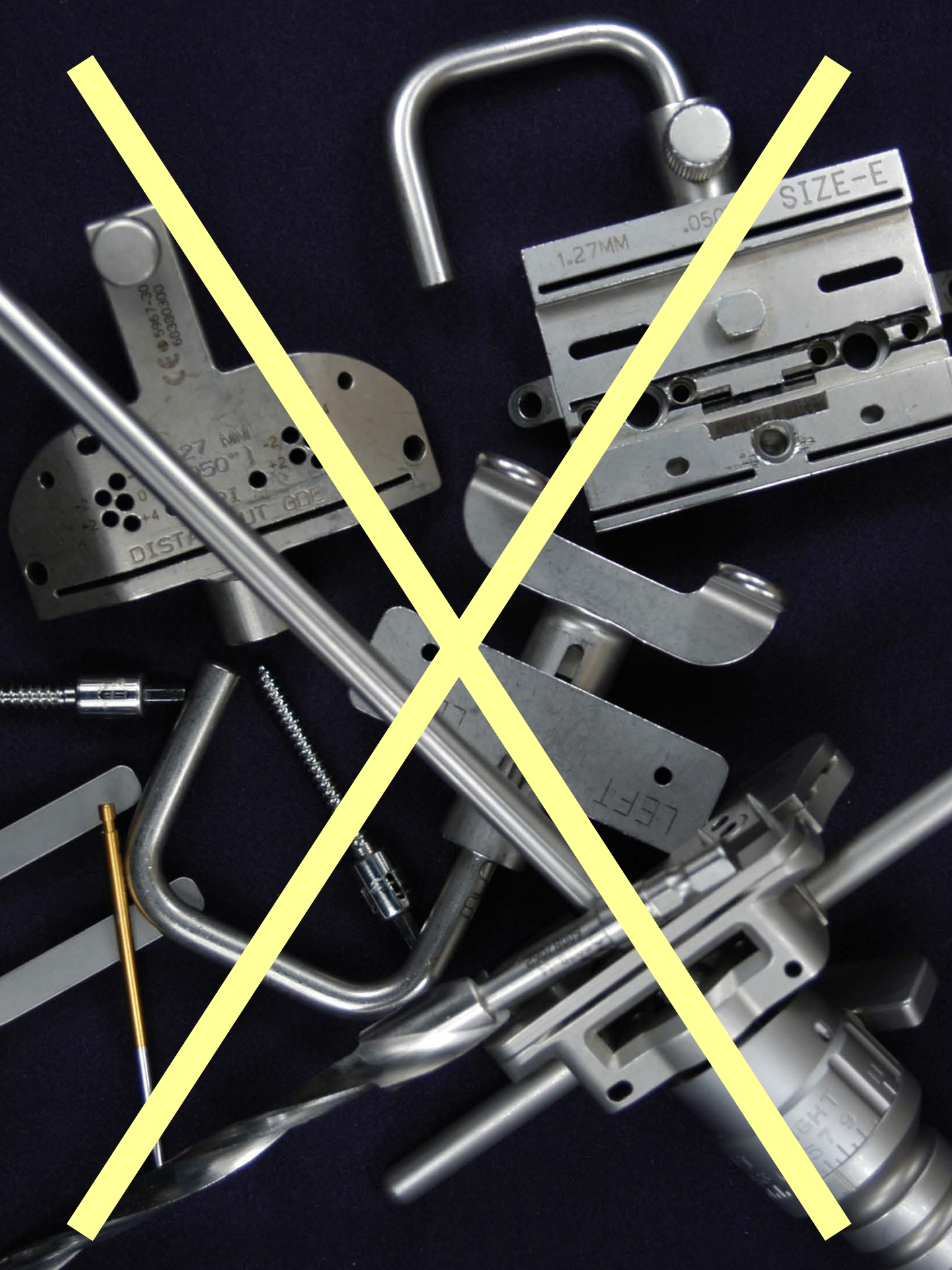
(MIS)

Smaller incisions Shorter hospital stay & faster recovery time.



Computer Technology for Arthroplasty must overlap all four benefits for wide acceptance by surgeons

What is our innovative approach?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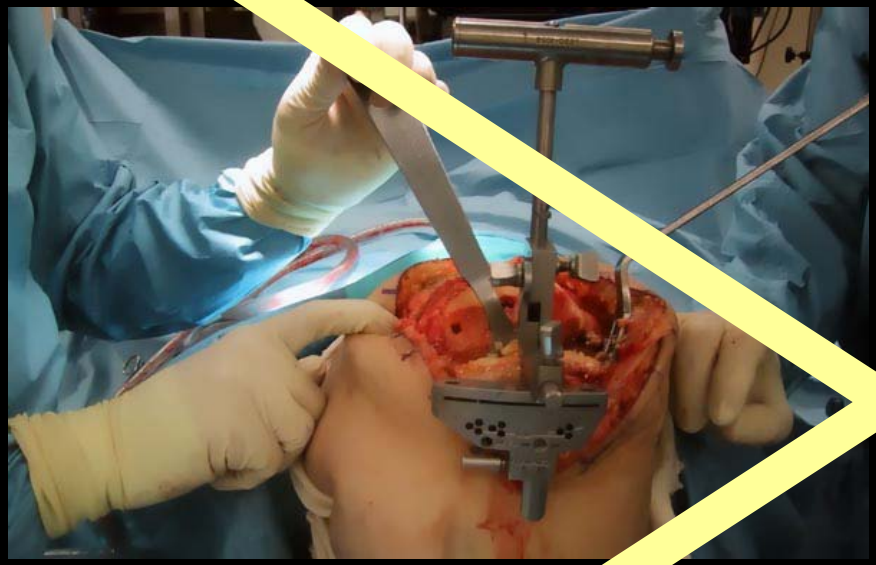
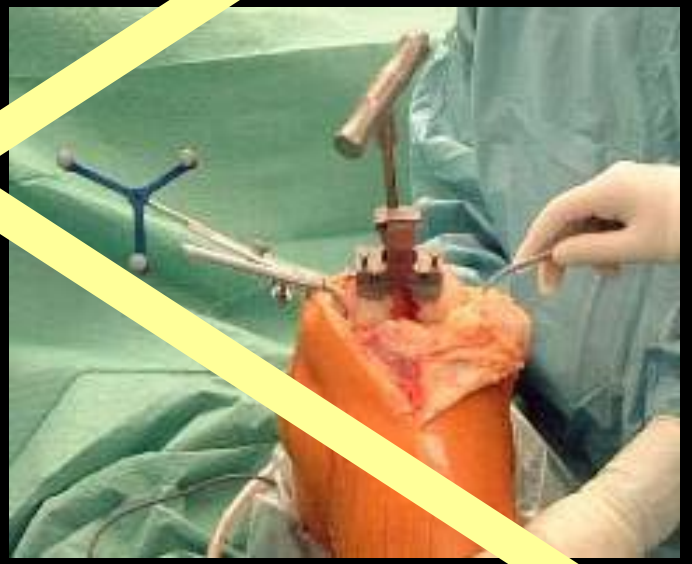
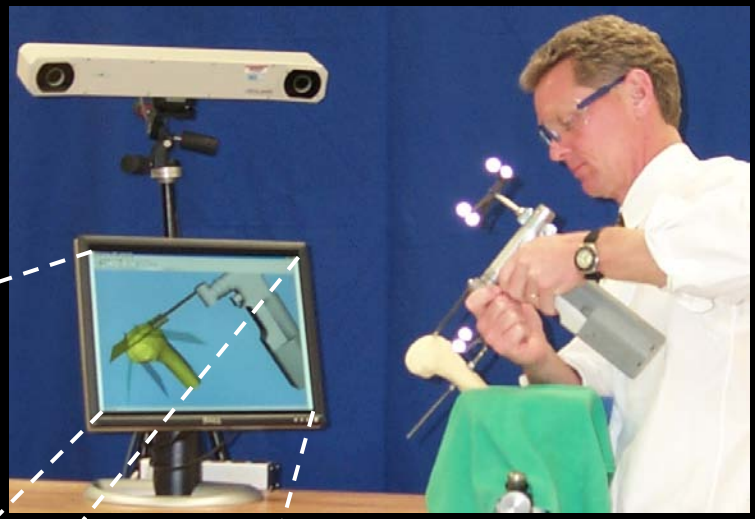
Total knee replacement bone cutting without jigs

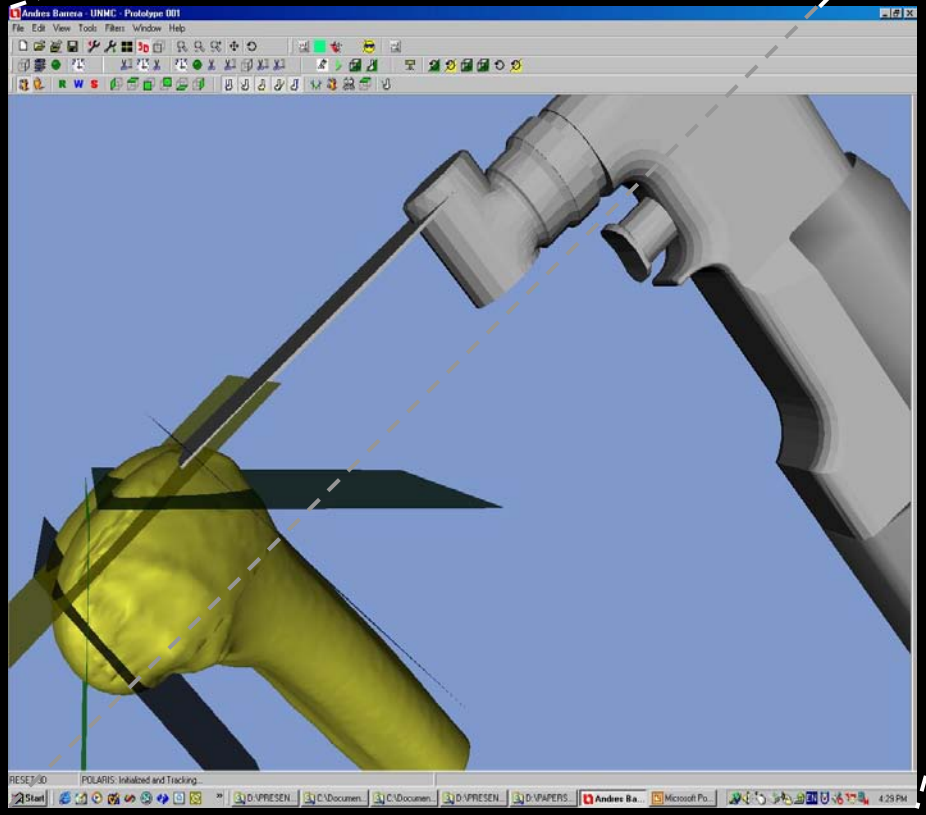
It is time?





Our approach





Meaningful feedback
to the surgeon

for
cutting **freehand** by
navigation

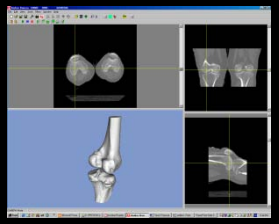
Computer

Dell® PC
Intel® Pentium® IV
2GHz processor, 1GB RAM
nVidia® Quadro2 video card, 32 MB RAM,
MS Windows® 2000.

Bone models

Identical specimens cast from a mold to replicate one female right-knee distal femur based on the Visible Human Project. The mold was itself set around a Stereo Lithographic Rapid Prototyping model, whose STL file was generated in-house from the VHP data-set of that femur

Software

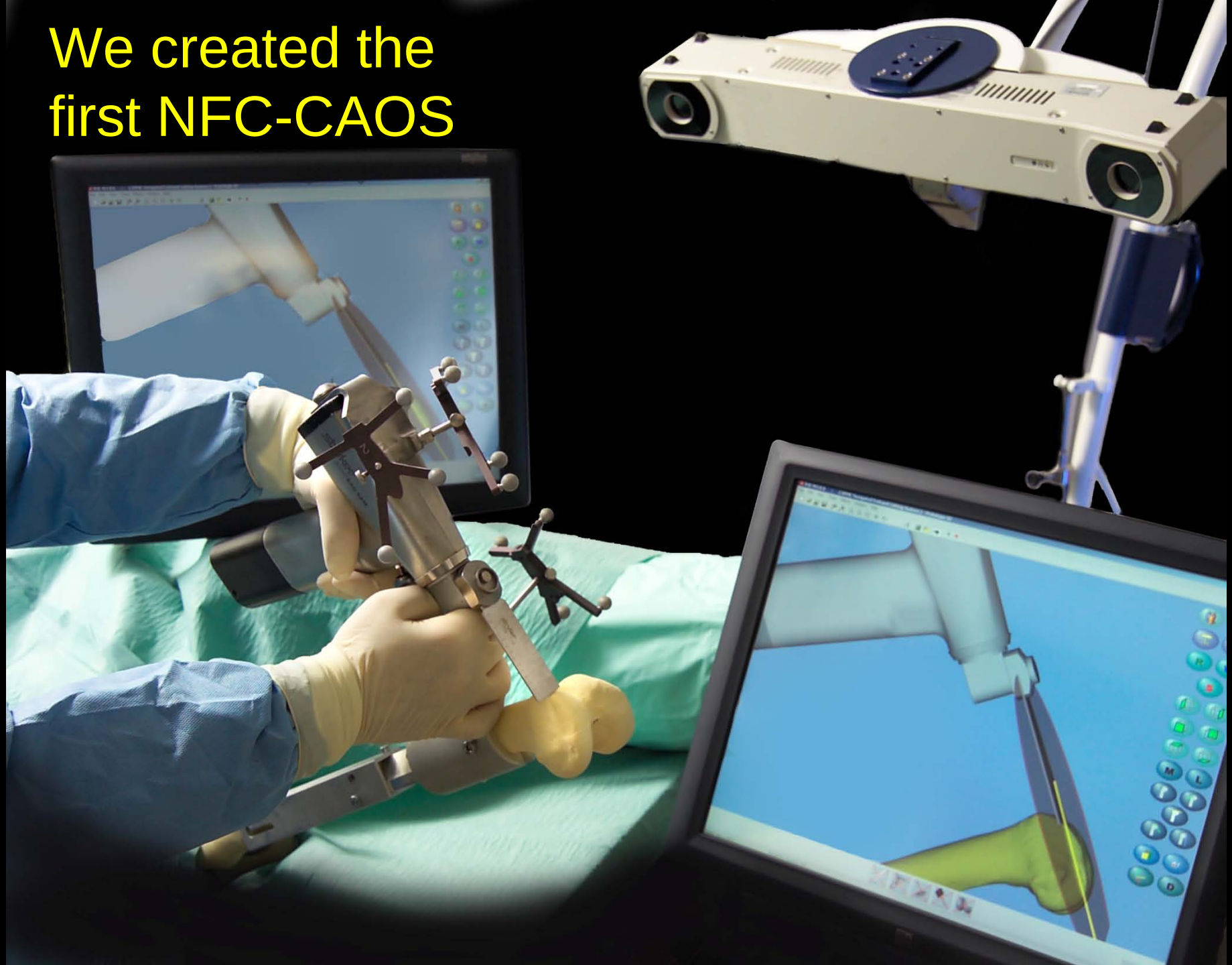


Reference frames & Oscillating bone saw

Navigation

Northern Digital Inc. (NDI) Polaris Infrared Hybrid (active and passive) tracker.

System


We created the
first NFC-CAOS

Concept invented in Nebraska
What have we done so far about it?

- Created the world's first prototype experimental system
- Conducted studies to test feasibility and system capabilities with local and external surgeons
- Verified basic system's measurement accuracy with robotics
- More than 20 international conferences presentations and journal papers on this technology
- Applied and applying for patent protection - 11 smart tools and mechatronics features
- Implemented some smart tools and mechatronics

Publications

- Barrera, O.A., Haider, H. and Garvin, K.L., “Towards a standard in assessment of bone cutting for Total Knee Replacement”, Proc. IMechE, Part H: J. Engineering Medicine, 2008, 222(H1), 63-74.
- Haider, H., Barrera, O.A., Garvin, KL, “Minimally invasive TKR surgery through navigated freehand bone cutting: Winner of the 2005 “HAP” PAUL AWARD”, Invited paper, Journal of Arthroplasty, Vol. 22, Issue 4, pp. 535-542, June 2007.
- Haider, H., Barrera O.A, Mahoney, C.R., Ranawat, A.S., Ranawat, C.S., Garvin, K.L., “Navigated freehand bone cutting for TKR surgery: Experiments with seven Independent surgeons”, P196, Proceedings of the 75th Annual Meeting of the American Academy of Orthopaedic Surgeons AAOS, San Francisco, March 2008.
- Haider, H. Barrera O.A., Mahoney, C.R., Ranawat, C.S., Ranawat, A.S., Croson, R.E., Garvin, K.L., “Experience with navigated freehand bone cutting for total knee replacement surgery”, Poster 1997, Transactions of the 54th Annual Meeting of the Orthopaedic Research Society, San Francisco, March 2008.
- Barrera, O.A., Garvin, K.L., Croson, R.E., Haider, H., “Validation with robotics of documentation and analysis of surgical skills through real-time motion recording of navigated arthroplasty instruments”, Poster 1999, Transactions of the 54th Annual Meeting of the Orthopaedic Research Society, San Francisco, March 2008.
- Barrera O.A., Bach, J.M., Kazanzides, P., Haider, H., “Validation of an ASTM standard proposed to assess localizer functionality of CAOS systems: A joint effort by three laboratories”, Poster paper P2, Proceedings of the 20th Annual Congress of the International Society fro Technology in Arthroplasty, Paris, France, October, 2007.
- Barrera O.A., Garvin, K.L.., Gilmore, A.N., Haider, H., “Validation with robotics of documentation and analysis of surgical skills through real-time motion recording of navigated arthroplasty instruments”, Podium paper A7-2, Proceedings of the 20th Annual Congress of the International Society for Technology in Arthroplasty, Paris, France, October, 2007.
- Haider, H.; Barrera O.A., Mahoney, C.R., Ranawat, A.S., Ranawat, C.S., Garvin, K.L, “Freehand navigated bone cutting for total knee replacement surgery: Experiments with seven independent surgeons”, Podium paper B4-7, Proceedings of the 20th Annual Congress of the International Society for Technology in Arthroplasty, Paris, France, October, 2007.
- Bach J.M., Barrera O.A., Kazanzides P., Haider, H., “Evaluation of the draft ASTM CAOS standard”. Proceedings of the 7th Annual Meeting of the International Society for Computer Assisted Orthopaedic Surgery, Heidelberg, Germany, June 20-23, 2007.
- Barrera, O.A., Garvin, K.L., Kibuule, L., Haider, H., "Documentation and Post-Operative Analysis of Surgical Skills through Real-Time Motion Recording of Navigated Arthroplasty Instruments", Proceedings of the 19th Annual Symposium of the International Society for Technology in Arthroplasty (ISTA), New York City, October 2006.
- Barrera, O., Sekundiak, T., Garvin, K., O'Brien, B., Walker, C. and Haider, H.: “Navigated freehand cutting (NFC) of bone, a feasible fundamentally less-invasive technique for TKR”, Poster 614, Transactions of the 52nd Annual Meeting of the Orthopaedic Research Society, Chicago, March 2006.
- Haider, H, “An introduction to Robotics in Orthopaedic Surgery”, Invited lecture, “Computer Aided Orthopaedic Surgery Symposium (CAOS), Proceedings of the 5th Annual Meeting EOA, Cairo, Egypt, Nov. 2005.
- Haider, H, “COAS: Basic Science”, Invited Lecture, “Computer Aided Orthopaedic Surgery Symposium (CAOS), Proceedings of the 57th Annual International Congress of The Egyptian Orthopaedic Association, Cairo, Egypt, Nov. 2005.
- Haider, H. and Barrera, O.A., “Quantifying the quality of bone cutting for TKR - a proposed assessment method”, Proceedings of the “MIS meets CAOS Symposium: Less and Minimally Invasive Surgery for Joint Arthroplasty: Facts and Fiction”, (Symposium and Surgical Academy), San Diego, Oct. 2005.
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Publications

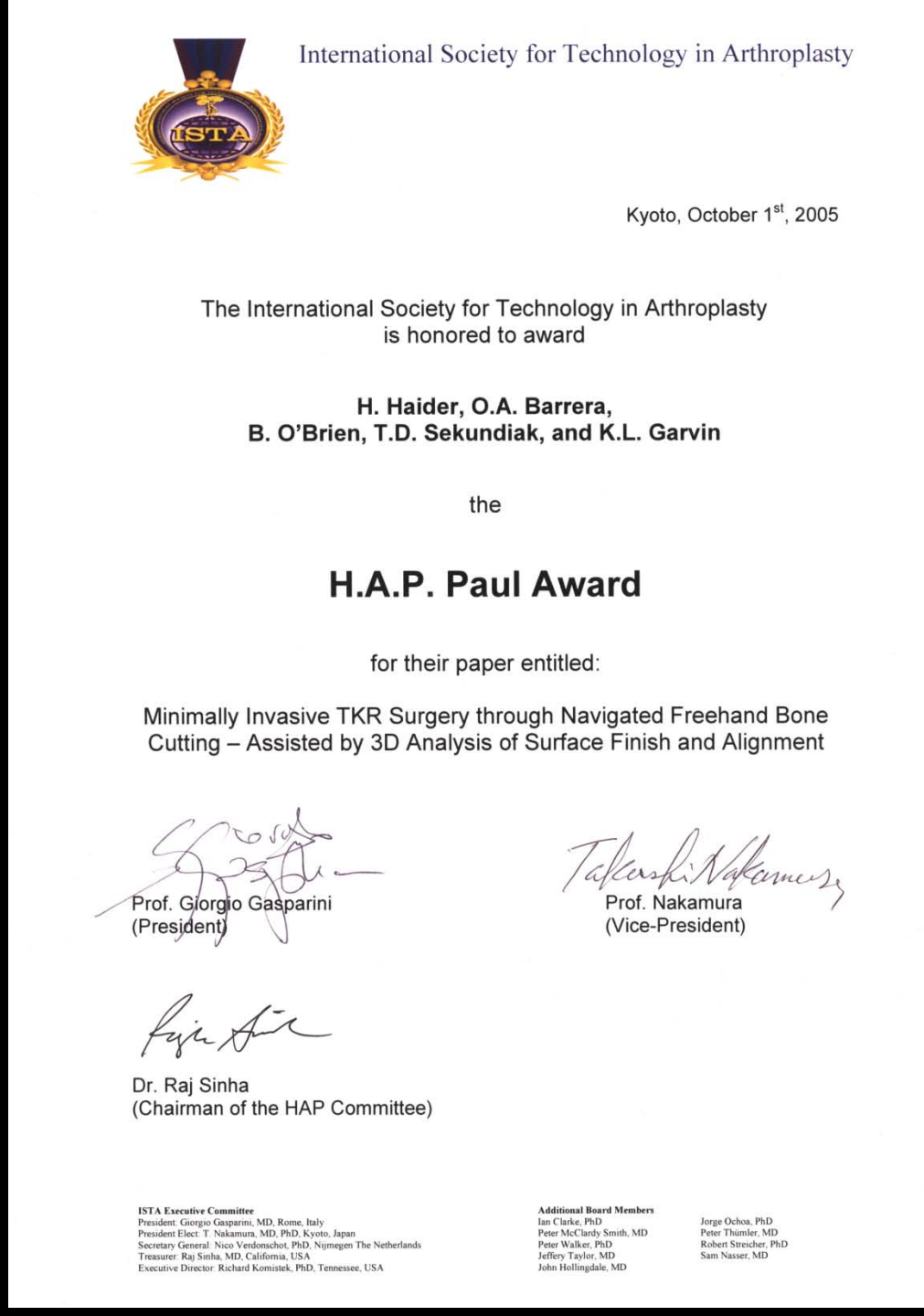
- Haider, H. and Barrera, OA, “Towards a standard in assessment of bone cutting for TKR”, Proceedings of the 18th Annual Symposium of the International Society for Technology in Arthroplasty (ISTA), Kyoto, Japan, Sept. 2005.
- Barrera, OA, Sekundiak, TD, Garvin, KL, O’Brien, B, Haider, H, “Minimally invasive TKR surgery through navigated freehand bone cutting – assessed by 3D analysis of surface finish and alignment”, Proceedings of the 18th Annual Symposium of the International Society for Technology and Arthroplasty (ISTA), Kyoto, Japan, Sept. 2005.
- Barrera, O.A., Sekundiak, T.D., Garvin, K.L., O’Brien, B., Haider, H., “Navigated freehand bone cutting for TKR – more experiments with more detailed 3-d quantitative surface comparison to conventional cuts", p. 18-21 in Langlotz F, Davis BL, Schenzka D, (Eds.): Computer Assisted Orthopaedic Surgery, 5th Annual Meeting of CAOS-International Proceedings. Pro Business GmbH, Berlin, June 2005. ISBN 3-938262-69-9.
- Haider, H. and Barrera, O.A., “A framework and parameters for quantitative assessment of bone cutting for TKR" , p. 143-146 in Langlotz F, Davis BL, Schenzka D, (Eds.): Computer Assisted Orthopaedic Surgery, International Proceedings, 5th Annual Meeting of CAOS. Pro Business GmbH, ISBN 3-938262-69-9. Berlin, June 2005.
- Haider, H; Barrera, O; Sekundiak, T; Garvin, K: "Total Knee Replacement Bone Cutting Without Jigs: Is it Time?", Podium Paper 64, Proceedings of the 72nd Annual Meeting of the American Academy of Orthopaedic Surgeons AAOS, Washington, DC, 2005.
- Barrera, O. A., Haider, H., Walker, P.S., Sekundiak, T.D. and Garvin, K.L., “Intra Operative Graphical Interface for Freehand Navigated Bone Cutting for Knee Replacement Surgery Without Jigs”, Poster 246, Proceedings of the 5th Combined Meeting of the Orthopaedic Research Societies of Canada, U.S.A., Japan and Europe, Banff, Alberta, Canada, 2004.
- Sekundiak, T.D. Garvin, K.L.; Barrera, O.A. and Haider, H., “Freehand Navigated Bone Cutting in Total Knee Arthroplasty”, Symposium and Surgical Academy, Proceedings of MIS Meets CAOS conference, Less and Minimally Surgery for Joint Arthroplsty: Fact & Fiction, Naples, FL, Oct. 2004.
- Barrera, OA, Haider, H, Walker, PS, Sekundiak, TD and Garvin, KL, “Comparison of distal femoral TKR bone cuts by Freehand Navigation vs. Conventional Cutting Jigs”, Proceedings of the Fourth Annual Conference of the International Society for Computer Assisted Orthopaedic Surgery, CAOS-International, 2004, Chicago, IL.
- Haider, H, Barrera, OA, Walker, PS, Sekundiak, TD and Garvin, KL, “Freehand Navigation Cutting for TKR Surgery Without Jigs: Simulation of Bone Saw Cutting”, Proceedings of the Fourth Annual Conference of the International Society for Computer Assisted Orthopaedic Surgery, CAOS-International, 2004, Chicago, IL.
- Barrera, O.A., Haider, H., Walker, P.S., Sekundiak, T.D. and Garvin, K.L., “Freehand Navigation Cutting for Distal femoral TKR bone for MIS”, Proceedings of the International Society for Technology in Arthroplasty (ISTA), Rome, Italy, 2004.
- Haider, H., Barrera, O. A., Walker, P.S., Sekundiak, T.D. and Garvin, K.L., “Freehand Navigated Bone Cutting for TKR Without Jigs - Assessment of First Cuts”, Poster 246, Proceedings of the 5th Combined Meeting of the Orthopaedic Research Societies of Canada, U.S.A., Japan and Europe, Banff, Alberta, Canada, 2004.
- RE Forman, PS Walker, C-S Wei, H Haider, MA Balicki, G Aggarwal, “An experimental system for computer-assisted freehand navigation for knee replacement surgery”, Proceedings of the Fourth Annual Conference of the International Society for Computer Assisted Orthopaedic Surgery, CAOS-International, 2004, Chicago, IL.
- Haider, H., Barrera, OA, Walker, PS, Ali, HH, T.S. Sekundiak and Garvin, KL, “Computer Simulation of Bone Cutting for Knee Replacement Surgery With Freehand Navigation”, SE042, Proceedings of the 71st Annual Meeting, American Academy of Orthopaedic Surgeons (AAOS), 2004, San Francisco, CA.
- Haider, H., Barrera, OA, Walker, PS, Ali, HH, Sekundiak, TD, and Garvin, KL, “Real-Time Simulation of Bone Cutting for Minimally Invasive Knee Replacement Surgery”, Podium paper no. 1618, Proceedings of the International Society for Technology in Arthroplasty (ISTA), San Francisco, CA, September 2003.

“***Hap Paul Award***”

Selection criterion:

… for the best research paper

“… on new development in the field of orthopaedic arthroplasty”



International Society for Technology in Arthroplasty

Kyoto, October 1st, 2005

The International Society for Technology in Arthroplasty
is honored to award

H. Haider, O.A. Barrera,
B. O’Brien, T.D. Sekundiak, and K.L. Garvin

the

H.A.P. Paul Award

for their paper entitled:

Minimally Invasive TKR Surgery through Navigated Freehand Bone Cutting – Assisted by 3D Analysis of Surface Finish and Alignment

Prof. Giorgio Gasparini
(President)

Prof. Nakamura
(Vice-President)

Dr. Raj Sinha
(Chairman of the HAP Committee)

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Patents

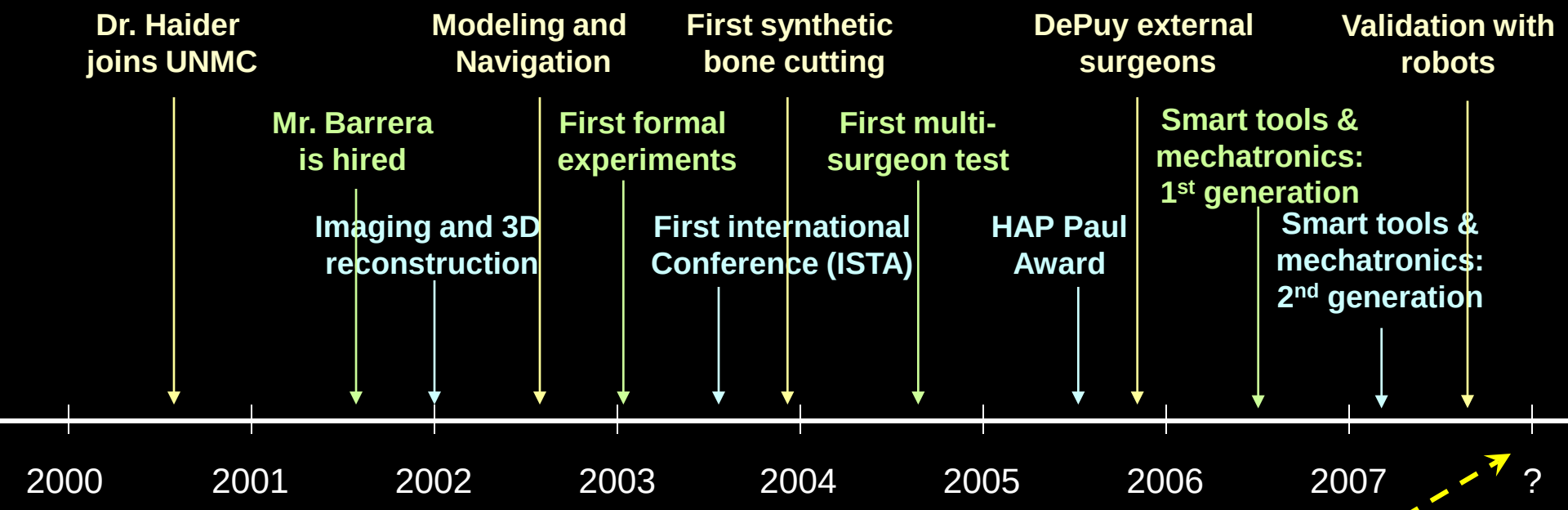
- Method and Apparatus for Computer Aided Orthopaedic Surgery
  Docket No: 63254P **Serial No:** 60/814,370 **File Date:** 6/16/200 **File Type**: Provisional
  Inventor: Hani Haider & O. Andres Barrera

- Method and Apparatus for Computer Aided Surgery
  Docket No: 63254P2 **Serial No:** 60/827,877 **File Date** 10/2/2006 **File Type**: Provisional
  Inventor: Hani Haider & O. Andres Barrera

- Method and Apparatus for Computer Aided Surgery
  Docket No: 63254 **Serial No:** 11/764,505 **File Date** 6/18/2007 **File Type**: Nonprovisional
  Inventor: Hani Haider & O. Andres Barrera

- Method and Apparatus for Computer Aided Surgery
  Docket No: 63254.1 **Serial No:** 11/927,429 **File Date** 10/29/2007 **File Type**: Nonprovisional
  Inventor: Hani Haider & O. Andres Barrera

Main milestones…



- **Cadaver tests**
- **Clinical trials**
- **Implementation of all inventions**
- **FDA preparation**

Our NoMiss technology for accurate osteotomy and arthroplasty in battlefields and remote locations

- Build a system to allow complex procedures to be performed in battlefields and remote locations.
- Allows the surgery to be performed accurately without the cumbersome mechanical jigs and fixtures required in the usual orthopaedic operating room
- … and with minimum specialist expertise and specialist nursing support.
- System to exploit telemedicine advances including
  - remote expert guidance and remote surgical planning
  - knowledge-based routines to assist the on-site surgeon

A bit more detail !

Osteotomy: Rresection of bone to shorten, lengthen, or change alignment

Arthroplasty: Joint replacement with artificial knee, hip, ankle or shoulder

- involve highly precise three-dimensional bone cuts
- require high levels of specialized expertise from a surgeon.
- Conventionally, require mechanical jigs:
  - cumbersome
  - complex
  - expensive
  - need to be sterilized at all times
- Burden in battlefields and/or remote locations

Our approach, inventions, prototypes and experiments:

- Novel concept where a computerized system helps a surgeon perform such bone cuts, without mechanical jigs freehand guided by computer imaging and navigation technology.
- Surgery will also require less time, involve lesser complexity, lesser expertise by the surgeon while maintaining the quality of the surgical procedure.

Project plans

Major steps:

- Consolidation of our existing software and hardware (implemented over the last few years).
- implementation of several inventions (software and hardware under patenting process) to make the navigated freehand cutting concept work efficiently.
- conduct experiments with animals and cadavers
- plan and conduct clinical trials.

- After FDA approval, a production prototype of the system will be ready for trials in battlefields and remote locations.
- Wider strategic benefits: (Patients in remote areas eg. away from large cities within Nebraska) would also benefit from faster, simpler, easier and better orthopaedics surgery.

Particular benefits for DoD:

- Technology will provide the DoD with an excellent tool to address multiple complex surgical procedures
  - related to trauma and orthopaedics in battlefields
  - remote areas, developing countries and even in space,
  - with minimum equipment and expertise,
  - yet with excellent, may be even superior, results.
- In remote areas, surgeons who can be highly skilled as individuals are limited by surgical operating rooms which have neither the costly inventories of arthroplasty jigs and fixtures nor the infrastructure in storing, sterilizing and nursing experience for how to use them.
- The futuristic more utilitarian software based technology would “travel” freely and cleanly to such environments with much reduced physical burdens of this kind. Contrast this with robotic systems.

More utility and reality than robots

- Technology addresses complex parts of
  - planning and implementation of the surgery (which can be assisted remotely by a specialist/expert).
  - Even training on the system can be done on-line,
  - or mentored/guided from very far away,
  - or guided locally by a knowledge-based or expert software system.
- The outcome is a simplified and simply communicated surgical plan that can be followed by a non-expert surgeon, who receives real-time highly sophisticated (three dimensional) guidance by the system during the whole procedure.
- Where this concept excels over highly advanced “robotic” surgery systems booming today, is that
  - it does not require the “highly sophisticated robots” with all the issues they bring in
    - capital cost,
    - calibration,
    - tuning,
    - maintenance,
    - and still require the expertise of how to program them and use them.
- In all systems, the surgeon’s brain still makes the clinical judgment.
- In our system however, the surgeon’s hand is still the actuator and not some autonomous or semi-autonomous machine.
- The three dimensional knowledge based and image based guidance is what makes the difference to make the proposed technology quickly achieve much wider appeal and acceptance.

- Detailed project plans on word document!

Do we typically accomplish what we promise?!

Tens of research projects from the orthopaedic industry in lab since 2000

- AstraTech / Sweden
- Advanced Bio-surfaces Inc. / MN
- Advanced Orthopaedic Materials / MN
- Biomet Inc. / IN
- Depuy Johnson & Johnson / IN
- Encore Orthopedics / TX
- Eska / Germany
- Exactech / FL
- Inbone Technologies Inc / CA
- Kyocera-JMM / Japan
- Smith & Nephew / TN
- SpineMedica Corp. / GA
- Spire Biomedical / MA
- Stryker Orthopaedics, NJ
- Zimmer / IN

Concluding remarks

- Our vision in this project has multiple large scale applications in medical technology and therefore is strategic in nature.

- If facilitated, this project provides tangible deliverables of far reaching and multi-faceted military and civilian for the USA from technology born and nurtured in Nebraska.