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
Nebraska Orthopaedics
Minimally Invasive Surgery 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
Different approaches:

Conventional Approach

MIS

CAOS: Navigated Jigs

Recently introduced...
High surgical skills needed, but!

- Inexperienced Surgeon (<20 TAR/y): 20%
- Experienced Surgeon (>20 TAR/y): 80%
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?
Total knee replacement bone cutting without jigs

It is time?
Our approach

Meaningful feedback to the surgeon for cutting freehand by navigation
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.

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

Software

Reference frames & Oscillating bone saw

System

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


“Hap Paul Award”

Selection criterion:

… for the best research paper

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

- Dr. Haider joins UNMC
- Mr. Barrera is hired
- Imaging and 3D reconstruction
- First formal experiments
- First international Conference (ISTA)
- First multi-surgeon test
- HAP Paul Award
- DePuy external surgeons
- Smart tools & mechatronics: 1st generation
- Smart tools & mechatronics: 2nd generation
- Validation with robots

- 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:** Resection 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.