United States Department of Commerce
Computer Assisted Orthopaedic Surgery

This research promotes the establishment of standard calibration and performance testing procedures for automated surgical systems within the operating room to ensure more predictable and successful hip replacement operations.

Lead Agency:

National Institute of Standards and Technology (Department of Commerce)

Agency Mission:

To promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life.

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General Description:

The nominee and his team are developing state-of-the-art measuring techniques, similar to those used in making aerospace components fit together precisely, that soon could improve success rates for hip replacement surgery. At the request of a group of prominent orthopaedic surgeons and the American Academy of Orthopaedic Surgeons (AAOS), the NIST researchers are working to improve calibrations and operating room testing of the Computer Assisted Orthopaedic Surgery (CAOS) tracking instruments surgeons use to plan the delicate, highly complex joint replacement surgery. As the U. S. population ages, the number of hip replacement surgeries is increasing rapidly. According to HCUPnet-2004, 225,900 hip replacements and 37,115 revision hip surgeries were performed in the US in 2004.

To be completely successful, CAOS hip replacement surgery must take into account minute human skeletal differences. Imprecise measurements, which could result from conditions seemingly unrelated to the surgery, such as operation room noise or temperature, can lead to poor positioning of implants, leaving some patients with discomfort during walking and, in rarer cases, a need to redo the operation.

The researchers have built a lightweight device called a “phantom” that resembles the artificial socket, ball and femur substitutes that surgeons use to replace the joint and bone in hip operations. They drilled tiny holes at precisely measured intervals into the phantom and made cuts at precisely measured angles, favored by surgeons for CAOS operations. Because the precise coordinates of the mechanical (magnetic) ball and socket joint center of rotation have been measured, manufacturers of CAOS tracking sensors can use the phantom to test the accuracy of their measuring instruments. Surgeons also will be able to test the accuracy of their CAOS devices, just before making their first incision, to measure ball and socket joint center of rotation coordinates, angles for cuts into the bone and places for the insertion of screws, all critical to a successful outcome.

Currently, no standardized approach to the evaluation of CAOS technology exists, but an ASTM International committee is working on the establishment of such standards. In the coming months NIST has submitted its hip CAOS phantom to orthopaedic surgeons for review and has begun receiving very positive feedback. Clinical trials could follow. If the device wins Federal Drug Administration (FDA) approval, it can be expected to find its way into operating rooms across the country and world. The researchers look forward to extending the application of the technology to surgical procedures on the knee and shoulder, which are also becoming more prevalent for older patients.

Excellence: What makes this project exceptional?

Significance: How is this research relevant to older persons, populations, and/or an aging society?

Effectiveness: What is the impact and/or application of this research to older persons?

Innovativeness: Why is this research exciting or newsworthy?

This work is an excellent example of innovative use of NIST precision engineering and dimensional metrology experience to address a difficult biomedical engineering problem, which affects the quality of life of hundreds of thousands of people worldwide. Approximately one million joint reconstruction operations are performed every year throughout the world. One of the fastest-growing procedures is hip replacement, which has grown 80% since 2000. With an aging population, the number of hip replacements is expected to continue increasing for the foreseeable future. According to HCUPnet-2004, 225,900 hip replacements and 37,115 revision hip surgeries were performed in the US in 2004. A revision surgery is significantly more risky and painful than the original operation. A significant cause for revision hip surgery is malpositioning of the implant. The effectiveness and reliability of joint-replacement surgeries has been shown to improve through the use of Computer-Assisted Orthopedic Surgery (CAOS). However, CAOS requires precise measurements of position and angles in order to be fully realize

these advantages. NIST contributed an artifact that enables calibration and performance tests of CAOS tools prior to an operation to ensure the accuracy of their position measurements. Attaining greater measurement precision will remove a critical barrier to wider use of computer-aided surgery, which would increase the success rate of the initial operations.

Critical measurements of patient dimensions must be taken prior to and during the hip-replacement operation to ensure that the prosthesis is properly sized and aligned. Otherwise, the patient's leg length may not be correct or the prosthesis could fail due to dislocation and premature wear. The measurements are defined with respect to the patient pelvis frontal and transverse coordinate planes, which are difficult to locate while the patient is lying on the operating table. To address these measurement problems during operations, surgeons adopted robot calibration and performance measurement tracking sensors, giving birth to Computer-Aided Orthopedic Surgery. The tracking sensors use cameras to determine coordinates of active or passive targets, which are usually attached to surgical tools, helping surgeons precisely measure positions and distances. The tracking sensors have accuracy problems, however, that result in positioning errors. Sources of errors include camera optics, camera position and orientation determination, operating conditions (e.g., temperature, non-uniform radiation field, distance from camera sensors), and different sampling rate frequency for multiple targets. Recognizing these challenging metrology errors, the American Academy of Orthopaedic Surgeons asked NIST for help with the calibration and performance testing of CAOS systems. NIST responded by establishing a research project to mitigate the measurement errors through calibration of the sensor tracking system, which led to invention of the CAOS calibration artifact – hereafter referred to as the "phantom." NIST researchers had to work closely with surgeons to determine requirements and constraints.

The NIST team defined requirements that: any metrology solution had to be "clinically relevant," meaning suitable within an operating room, lightweight, have low coefficient of thermal expansion, imitate the operation of human skeleton parts, and allow the simulation of critical phases of orthopaedic operations. NIST addressed these challenges by designing an artifact that resembles the artificial prosthesis, yet supports dimensional metrology calibration. The phantom is made of a femur-like bar, a magnetic ball and socket, and an L-shaped XY coordinate frame. Inherent in the design of the phantom are easily-measured target features. The materials used are suitable for both operating room environments and for precision engineering dimensional metrology operations. Surgeons use the phantom to calibrate their CAOS systems prior to every operation to ensure that their measurements and positioning of the implant are correct.

A prototype of the phantom was built and calibrated by NIST. This prototype was tested by leading CAOS surgery researchers in the operating room. They responded enthusiastically to the phantom –in terms of its design, applicability, potential to improve their surgical procedures, and reduce the need for revision surgeries. Dr. James B. Stiehl, Columbia St. Mary's Hospital, a world-renowned CAOS researcher, was the first to test the NIST CAOS phantom. His reaction was "*The hip phantom that we worked on is an important project for me. I have a new idea that I am trying to work on and the phantom will be a critical tool to evaluate that new approach.*" Industry is very interested in

commercializing the phantom: CAOS tracking experts from Medtronic Navigation, the leading provider of integrated navigation and intra-operative imaging solutions, are testing a prototype.