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# Validation and Metrology in CAOS

*J.B. Stiehl, J. Bach, D.A. Heck*

## Introduction

Computer-assisted orthopaedic surgery has become an important recent innovation with benefits to many applications as have been explored in this text. We believe that this technology will revolutionize our field, enhancing clinical outcomes in ways yet unrealized. The current development will pave the way for robotic applications, minimally invasive surgery, and »virtual surgery«. An important clinical aspect is »does it work.« Like the advent of many new ideas, the proof or validation follows, often lagging years behind the early use. We propose that any new computer application must be thoroughly evaluated, both from the bench testing that leads to governmental approval, and to clinical bench testing and validation studies, that ultimately will prove efficacy.

From reviewing the current literature in computer-assisted surgery, there is a serious lack of consistency both of terminology for validation and the statistical measures applied. This is not surprising, as the international bodies of engineers and scientists that establish such guidelines are not in close agreement. At the CAOS International Society annual meeting held in Chicago in 2004, a group of leading engineers with a few orthopaedic surgeons sat down to begin the process of writing standardization guidelines. These ASTM standards will be finalized and published, with the long-term idea of eliminating some of the discrepancies. We have organized this chapter to explore system validation from an historical perspective outlining how other fields of medicine and industry are dealing with this problem. Finally, we will make our recommendations as to what and how scientists and clinicians should be reporting out there, so that we all understand what they are talking about.

## History

The reasons that the field of measurement as a distinct endeavor has emerged are multiple. However, the principle reason relates to the desire of people to trade and to maximize the value that can be obtained through specialization and economies of scale. Historically, prior to standardization and measurement in communication, the ability to reproduce knowledge through the written word was dependent upon the speed and accuracy of scribes. Scribes would replicate an original work by manually copying the original content onto papyrus, sheepskin scrolls and eventually paper.

The Chinese are believed to have been the inventors of the printing press, which would allow the creation of multiple copies of a single engraving. With the development of the alphabet and standardization in language, Gutenberg was able to extend the value of the printing press through the invention of movable, interchangeable type of standard dimensions. This allowed the more cost-effective production of written works such as the Bible, and is believed to be responsible for the commencement of the Renaissance which has led into the current information age.

An economic study was performed in which it was assumed that a single scribe would take approximately one year to produce a single copy of an important work such as the Bible. Estimates using current United States Labor laws ($ 8.50/hour cost), would lead us to believe that the labor required to produce a single copy would be approximately $ 17,000. The Gutenberg printing shop was able to produce a single work for $ 57.00 or an approximate 300 times reduction in cost. In today's world, as a result of standardization in telecommunication, electronic equipment, software, and interconnecting networking technologies, the incremental costs of downloading a similar volume are less than one cent. We are now living in an age where the impact of standardization is propelling a knowledge revolution based upon the additional cost reduction of approximately 6000 in the reproduction and dissemination of information. (http://cybertiggyr.com/gene/new-age-copyright/)

In the more recent physical world, the concept of standardization, and interchangeability based upon improved measurement and manufacturing was extended to clockworks, firearms and other equipment. The processes developed by gunsmith Honoré Blanc in 1778 were transmitted through Jefferson to Eli Whitney who then partially implemented them in the sale of firearms to the United States about 1808. Thomas Jefferson felt that the standardization of measurement was so important that these powers were specifically outlined in the specified powers of Congress in the Constitution of the United States.

For the government of the United States, the implementation of standardized, interchangeable parts addressed the problems of firearm field maintenance. From a manufacturing perspective, the successful firm was able to reduce production costs by the substitution of lesser skilled and therefore lower cost labor. (http://en.wikipedia.org/wiki/Interchangeable_parts) In an interesting twist of fate, associated with the French revolution, in 1806 they discontinued the process of standardization for »social reasons«. This process of standardization and interchangeable parts was improved by others and eventually became known as the American Method of Manufacturing [9].

The American method of production, including the use of the assembly line, was further refined by the Japanese after World War II. The Japanese combined the concepts of interchangeability and mass production with those of Shewart's statistical process control as communicated through Deming. Shewart had worked in the telecommunications industry and developed manufacturing approaches based upon the use of numerical techniques that resulted in interchangeability, and the efficient mass production of telecommunication equipment. The Shewart techniques resulted in improved product quality, system reliability, lower costs of production and the development of an interoperable telecommunications system. Deming communicated these statistical techniques to both US manufacturers and the Japanese after World War II. The US automobile manufacturers initially ignored the improved systems of quality production and lean manufacturing but they were embraced and extended by the Japanese manufacturing industry. It is currently believed that the failure to incorporate these manufacturing innovations has contributed to the ongoing difficulties of the US automobile industry in meeting the demands of the increasingly competitive marketplace.

How do these historical anecdotes relate to medical and surgical practice? The same basic needs for continually improving quality and cost management are present within our healthcare delivery system (IOM, Crossing the Quality Chasm). Although there are certain differences between the standardized, interchangeable manufacture of objects and the delivery of medical and surgical services, there are many more parallels.

When we walk into an operating room, we rely on standard procedures to assure safety. Our anesthesia colleagues have worked to standardize and improve the safety characteristics of their processes. The development of High Reliability Organizations (HROs) have resulted in a lowered risk of anesthesia-related mortality such that the current risk is now vanishingly small. The corresponding risk of mal-practice judgments and their associated costs have been controlled. The JCAHO in conjunction with organizations such as the AAOS has recently mandated procedures designed to improve safety through systematic approaches to identity management.

The quality of the instrumentation and the devices that we use has improved. Manufacture of orthopaedic devices in the 1980s was associated with process capabilities of 0.6. Currently, process capabilities have improved to approximately 1.3. The electronic components in the computers and cellular telephones that we use are manufactured to process capabilities of 2.0. The overall patient outcomes associated with knee arthroplasty have correspondingly demonstrated a temporal trend of improvement.

## Standard Settings Organizations

In today's world, multiple organizations exist that are involved in promulgating standards. In Europe, standard organizations include the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). In the United States, the Institute of Electrical and Electronics Engineers (IEEE), the American National Standard Institute (ANSI), American Society for Testing of Materials (ASTM), Underwriter's Laboratories, the United States Military (Milspec), the National Electrical Code (NEC), the National Electrical Manufacturers Association (NEMA), the National Institute for Standards and Technology (NIST) are some of the major organizations involved in »standard« setting. Unfortunately, as may be expected with the lack of parsimony in the writing of »standards« and the potential economic impacts of compliance or non-compliance with a particular standard that can be related to »quality«; the terminologies and procedures used to allow for determination of errors in measurement are not always consistent.

For example, the term »accuracy« may be reflecting different attributes of a particular measurement. In some circumstances, accuracy may mean the standard deviation of a number of measurements determined from measures of a fixed object. However, unless the distribution of the measures is normal, the calculation of the standard deviation may be misleading to the casual observer. The reporter may then express »accuracy« as a range of measures. Some organizations prefer to use the term »precision« to express this attribute of measurement error (Fig. 9.1).

Alternatively, accuracy may be related to the »closeness« that a particular instrument's mean value is in comparison to a known standard fiducial or »artifact«. In this circumstance, the »accuracy« is reflecting a calibration difference, or bias between the known standard and the instrument performing the measure. Themselves recognizing the need for common procedures and definitions, the standards organizations work to varying degrees to reconcile disparate approaches. The process of standard harmonization can be very lengthy and frustrating. For example, when the ISO was created in 1947, one of their first actions was to harmonize conflicting standards that had been unable to be reconciled since 1924 (Fig. 9.2).

An alliance between the ISO was also created with the IEC with the understanding that the »name and technical procedure of the IEC will be maintained«. Unfortunately, marriage on these terms was problematic and has resulted in difficulties reconciling the worlds of electronics and mechanics to this day. Currently, the ISO is a network of the national standards institutes of 156 countries. Each country has one member. The Central Secretariat in located in Geneva, Switzerland, and works to coordinate the system. The ISO members also include industry and trade

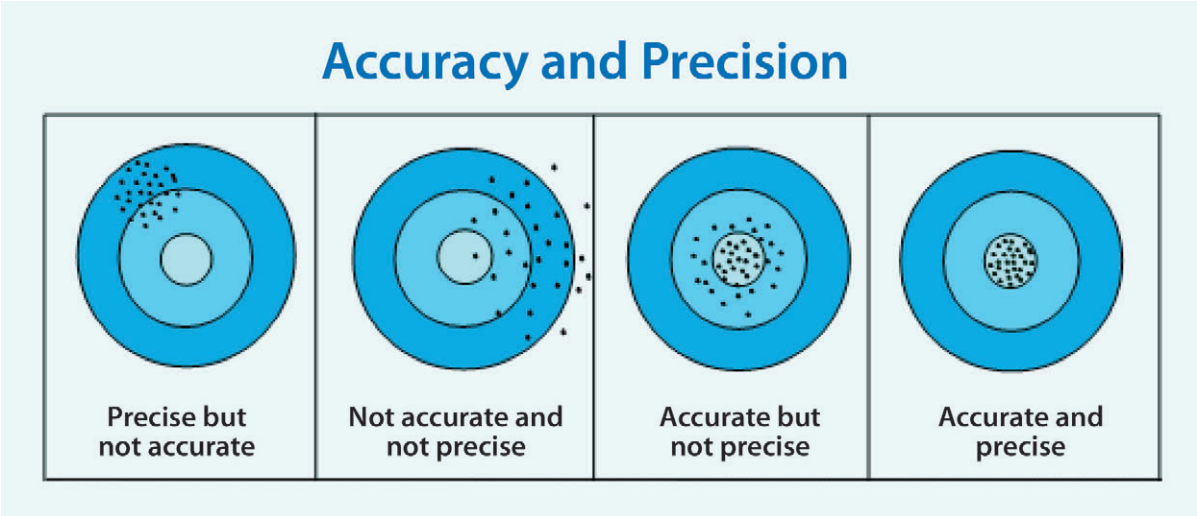



**Fig. 9.1.** Accuracy, precision and stability are relative terms by definition designed to conceptualize performance of a function, in this example target shooting


**Fig. 9.2.** Emblem of the International Standards Organization

associations. As a result, it acts as a bridge organization between public and private endeavors.

Unfortunately from the perspective of parsimony, the world of computer-assisted surgery crosses the disciplines of electrical engineering, computer engineering, mechanical engineering and metrology as well as research that is conducted transnationally. As a result, it is difficult to currently compare the quality and performance of CAS devices because of the non-standard definitions, surgical applications, testing conditions, as well as analytic approaches.

## ASTM Standards Group Effort

As CAOS systems have evolved and more systems have become available, objectively comparing them has become increasingly difficult. Many industries use standards as a way to address such challenges. Standards are necessary to allow end users (in this case, surgeons and hospital purchasing agents) to make informed decisions. The initial decision point is what system to purchase. Once this decision has been made, the surgeon still has options within a particular system. Many systems have both image-based and imageless modalities.

An organizational meeting to establish a committee to develop new standards for CAOS was held in conjunction with the 2004 International CAOS Society meeting in Chicago. At this meeting representatives of ASTM International presented an overview of the standards writing process. While there are other specialties (Neurosurgery, ENT, etc.) that use CAS, none have taken on the task of drafting an ASTM standard. The CAOS community was therefore offered the opportunity to draft the first standard regarding CAS systems.

The assembled members of the various constituencies (industrial, academic, clinical, regulatory) agreed that CAOS was sufficiently mature that it would benefit from standards. As a result, a committee was formed and tasked with the assignment of drafting a standard regarding reporting of accuracy in CAOS systems. The core membership of this committee consists primarily of researchers and clinicians, though members of CAOS industry have participated as well.

## Initial Efforts

The first step in drafting the CAS standard was to define its scope. It was decided that a modular approach, starting with a limited generic standard and adding modules for more sophisticated tasks, was most appropriate. The first standard deals exclusively with evaluating the localizer functions of the navigation system. As for the writing of this book this standard is near completion. While the end user will ultimately want to know the accuracy parameters of a system under clinical application, the digitization accuracy must be characterized in order to be able to make sense of the accuracy values under complex surgical procedures

The scope of this first standard is to addresses the techniques of measurement and reporting of basic static performance (accuracy, repeatability, etc.) of surgical navigation and/or robotic positioning devices under ideal conditions. The aim is to provide a standardized measurement of performance variables by which end-users can compare within (e.g. different fixed reference frames or stylus tools) and between (e.g. different manufacturers) different systems. The parameters to be evaluated include the determination of the location of a point relative to a coordinate system, relative point to point accuracy (linear), and the repeatability of single point. These evaluations are to be made at various locations within the measurement volume of the system and with varying tool orientations. A reporting format for the results is provided.

## Future Standards

The initial standard will serve as the basis for subsequent standards for specific tasks (cutting, drilling, milling, reaming, etc.) and surgical applications (TKA, THA, IM

nailing, plating, osteotomy, etc.). Additional standards addressing imaging modality (fluoroscopy, CT, MRI, ultrasound, etc.) for image based systems, and the software for registering the images or the imageless data to the patient may also follow.

## Statistical Measures for Validation

### Overview

In general terms the concept of measurement based on current ISO and NIST definitions begins with determining the measurable quantity where the value is generally characterized by a unit of measurement. The »true value« is defined as a given quantity which is obtained from a perfect measurement. True values are considered indeterminant as an infinite number of values are needed to create the true number. Commonly, this problem is solved by creating a »conventional true value« which is considered a better estimate. In some parlance, this could be considered also as the baseline, »ground truth«, or reference value. Measurand is the particular quantity subject to measurement, and could be for example the inclination of the acetabular component compared to the axial plane of the human body. Influence quantity is the sum of measurements that subtly affect the measurand, in this example slight variations in assessing the edges of the acetabular component. Accuracy of measurement is the qualitative assessment of the measured value to the true measured value. This differs from precision which is defined as the closeness of agreement between independent test results obtained under stipulated conditions which encompasses both repeatability and reproducibility. The measure of precision is usually computed as a standard deviation of the test results.

Repeatability is the closeness of measure under the same conditions. Reproducibility is the measure when there is a changed condition of measurement such as using different observers. The error of measurement is the result of the measurement minus the true value of the measurand. Random error is the measurement of a measurand minus the mean after an infinite number of measures. Systematic error is the mean of measurement of the measurand minus the true value of the measurand after an infinite number of measures. Random error is equal to the error minus the systematic error. Systematic error is equal to the error minus the random error. A correction is the value added to the measurement to correct for systematic error. Type A error deals with uncertainties of the statistical measure. Type-B error relates to errors other than those determined by statistical measures.

### Descriptive Statistics

For descriptive measures the ISO and NIST recommend the following measures be determined: mean, standard deviation (square root of variance), and the experimental standard deviation.

#### Mean

$$\bar{x} = \frac{x_1 + x_2 + x_3 + \ldots + x_N}{N} = \frac{1}{N}\sum_{i-1}^{N} x_i$$

#### Standard Deviation

$$\sigma = \sqrt{\frac{(x_1 - \bar{x})^2 + (x_2 - \bar{x})^2 + \ldots + (x_N - \bar{x})^2}{N}}$$

$$= \sqrt{\frac{d_1^2 + d_2^2 + \ldots + d_N^2}{\mathrm{N}}}$$

$$= \sqrt{\frac{1}{N}\sum_{i-1}^{N}(x_i - \bar{x})^2} = \sqrt{\frac{1}{N}\sum_{i-1}^{N} d_i^2}$$

#### Experimental Standard Deviation

$$\sigma = \sqrt{\frac{1}{N-1}\sum_{i-1}^{N} d_i^2}$$

### Process Capability Analysis

Process capability analysis is the approach that is commonly used for process qualification in industrial quality management. In high quality manufacturing, processes are first brought into statistical control. After the process is in control, the process is then characterized mathemati-

cally. The process capability index ($C_p$) is mathematically formulated as:

$$C_p = \frac{(USL - LSL)}{6\sigma}$$

Where USL is the Upper Specification Limit, LSL is the Lower Specification Limit and σ is Standard Deviation. Commonly, purchasers will require that the supplier is able to produce components with capability indices ($C_p$) of 1.3 or higher. The capability index however is limited in its utility as it is an expression of precision but does not address the problem of accuracy. Six sigma programs, such as that used at Motorola, will frequently require the calculation of the offset capability index or $C_{pk}$.

$$C_{pk} = \min\left[\frac{(USL - \bar{x}}{3\sigma}, \frac{\bar{x} - LSL}{3\sigma}\right]$$

Where USL is the Upper Specification Limit, LSL is the lower Specification Limit and σ is Standard Deviation. Although it is not clear as to what the specific level of quality is appropriate for a specific medical process, very high quality manufacturing is associated with processes that are capable of producing at levels where the $C_{pk}$ exceeds 2.0.

The most important variable in the process capability analysis is the upper and lower control limits. This requires that you know the target center or the accurately determined value for which you are trying to calculate the precision. For example, a standard target or »ground truth« could be an accurately measured known such as the mechanical axis of the lower extremity which traverses the center of the hip joint, center of the knee joint and center of the ankle joint. Then you must determine a reasonable or acceptable limit of variation from this target center beyond which an unacceptable result has occurred. For a total knee replacement, one could argue that the prosthetic postoperative leg alignment must be placed within 5° of the normal mechanical axis of the leg. For the six sigma formulas, the upper and lower specification limits would be 5°.

The examples in Fig. 9.3 demonstrate the effect a large or small standard deviation, and also the effect of a mean that is offset and does not coincide with the center of the target or desired measurement.

We believe the strength of this analysis is the ability to easily compare results from multiple sources or studies with a limited amount of standard data required. The type of values created for the $C_p$ and $C_{pk}$ allow one to compare results with other techniques or technologies. Finally, a basic assumption of the equation is that any isolated value or measurement outside of the specified control limits will cause the $C_p$ or $C_{pk}$ to become unacceptable.

We recently evaluated the available literature for assessment of acetabular component position using the above process capability analysis formulas (Table 9.1). As noted, we used the Lewinnek et al. suggestion for an acceptable upper and lower limit of positioning to be +/- 10° for the target conventional true value [1]. Interestingly, we find that computed tomography performs quite well with the Six Sigma formula which is consistent with prior literature.

**Table 9.1.** Recent literature assessment using process capability analysis. (Upper and Lower Specification Limits: +/-10° for cup inclination and anteversion)

| Reference | Modality | Object | N | Control Measurement | Inclination° | Anteversion° | $C_p$ Inclination | $C_p$ Anteverion |
|---|---|---|---|---|---|---|---|---|
| Grutzner et al. [3] | Fluoroscopy, Digitizing | Patients | 50 | CT Measurement | 1.5 (SD: 1.1) | 2.4 (SD:1.4) | 2.22 | 1.38 |
| Nogler et al. [2] | Imageless | Cadaver | 12 | Digitizing Arm | -3.86 (SD: 3.4) | -4.89 (SD: 4.55) | 0.98* | 0.36* |
| Tannast et al. [5] | Fluoroscopy | Cadaver | 14 | CT Measurement | 0.7 (SD: 2.8) | -6.6 (SD: 6.0) | 1.19* | 0.55* |
| Jolles et al. [4] | CT | Plastic Bones | 50 | Electromagnetic Digitizing | Mean SD: 2.5 | Mean SD: 1.5 | 1.33 | 2.2 |
| Present study (see below) | Fluoroscopy | Cadaver | 24 | CT; CMM | 0.6 (SD: 0.9) | 3.2 (SD: 2.5) | 3.7 | 1.3* |

* Denotes below acceptable limits for process capability which is greater than 1.3.

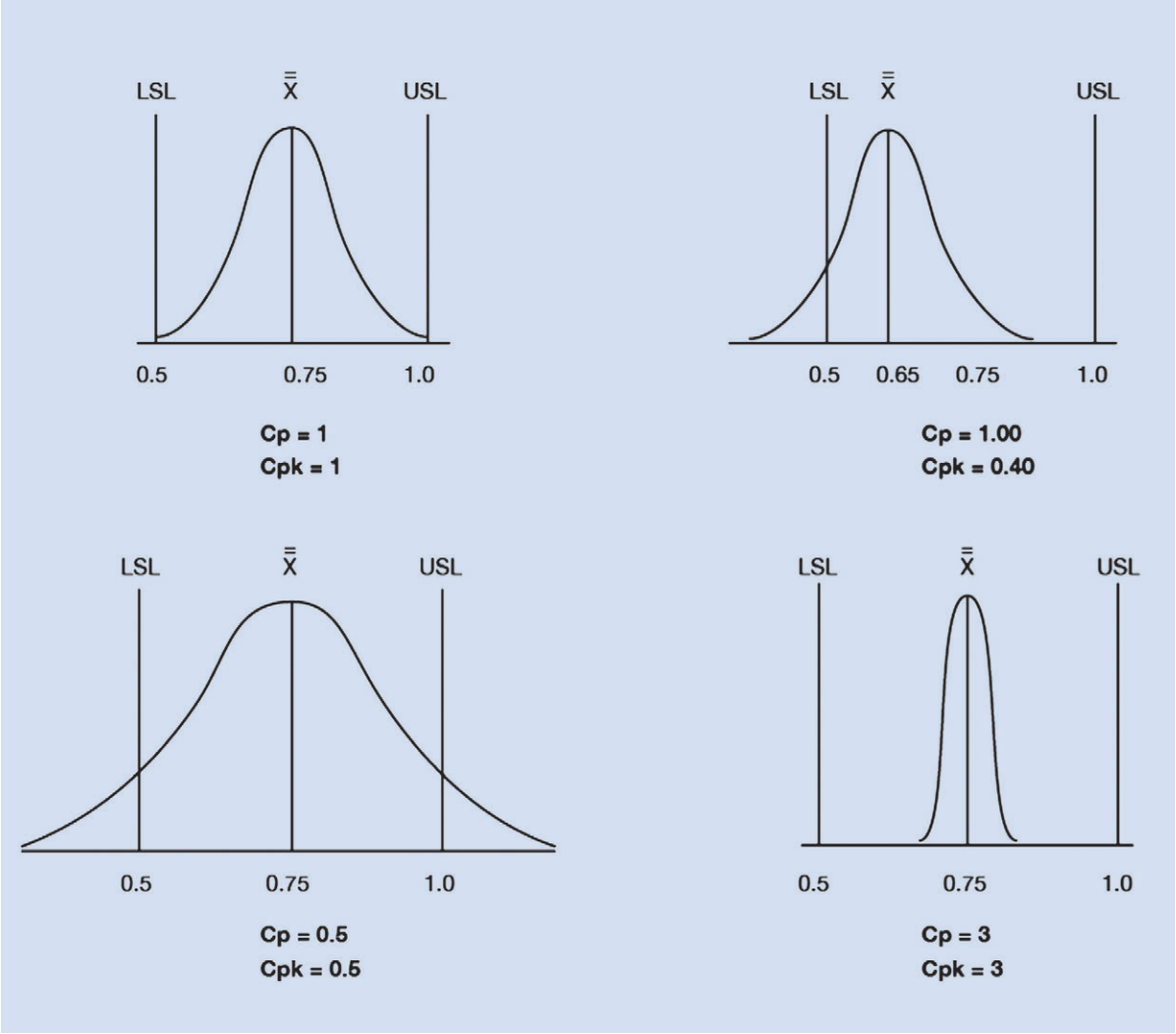



**Fig. 9.3. Please insert legend!.** *LSL* = Lower Specification Limit, *USL* = Upper Specification Limit, *Cp* = Process Capability Index, *Cpk* = Offset Process Capability Index

Fluoroscopy, when combined with anatomical digitizing methods also offered acceptable precision. However, in our own study as noted below, the precision of fluoroscopy for cup anteversion was not process capable, nor was the one study that evaluated an imageless cup referencing system. These were not the conclusions of the authors in their studies as they did not have a robust tool to compare with other published work. We conclude that process capability analysis will be a powerful tool to compare various systems.

## Clinical Bench Testing Methods

For validating the clinical performance of any CAOS application, a simulation of the operative procedure is needed to understand the basic systematic error of a system. The idea is to create a very accurate assessment tool which is basically a phantom or »artifact« that replicates the typical measurements during the operative procedure. The artifact is fabricated in such a way that the length of assessment

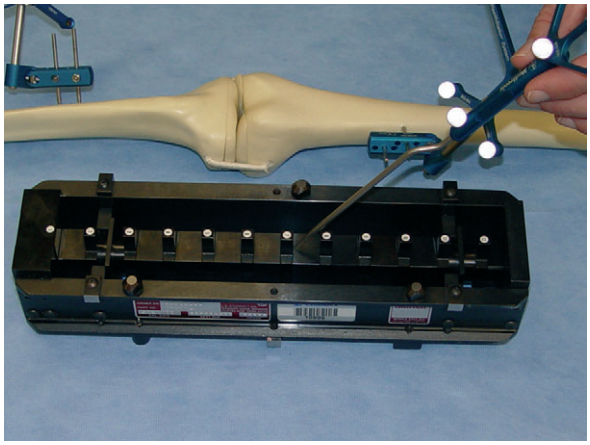


**Fig. 9.4.** Bench validation of a computer navigation protocol used in total knee arthroplasty by assessing linear accuracy with a Weber gauge block

parallels the targeted application, for example the length of the femur or more specifically, various sites on the femur where screws may be inserted. The artifact is calibrated using a coordinate measuring machine, which typically has an accuracy of 0.038 millimeters (0.018 inch). The small holes or divots in the phantom have a known dimension and the touch pointing tool can be placed into these small divots. Additional considerations may include temperature, distance of the optical camera from the target, or small motion of the tracking device attached to the phantom.

We have previously reported our results using a artifacts with traceability to the National Institute of Standards and Technology (NIST), to evaluate the repeatability and linearity of the Medtronic Treon Plus system (Louisville, CO) (Fig. 9.4). A Weber gage block with equally spaced reference platforms 2.54 cm apart across a range of 25.4 cm was used as the primary artifact. The block was placed first parallel and then perpendicular to the plane of the imaging bar. The perpendicular attitude was established by using a NIST traceable triangular artifact. Each position of the Weber block was referenced using the point indicator six times in a random order with varying probe attitudes. Ambient temperature was constant during the short period of data acquisition.

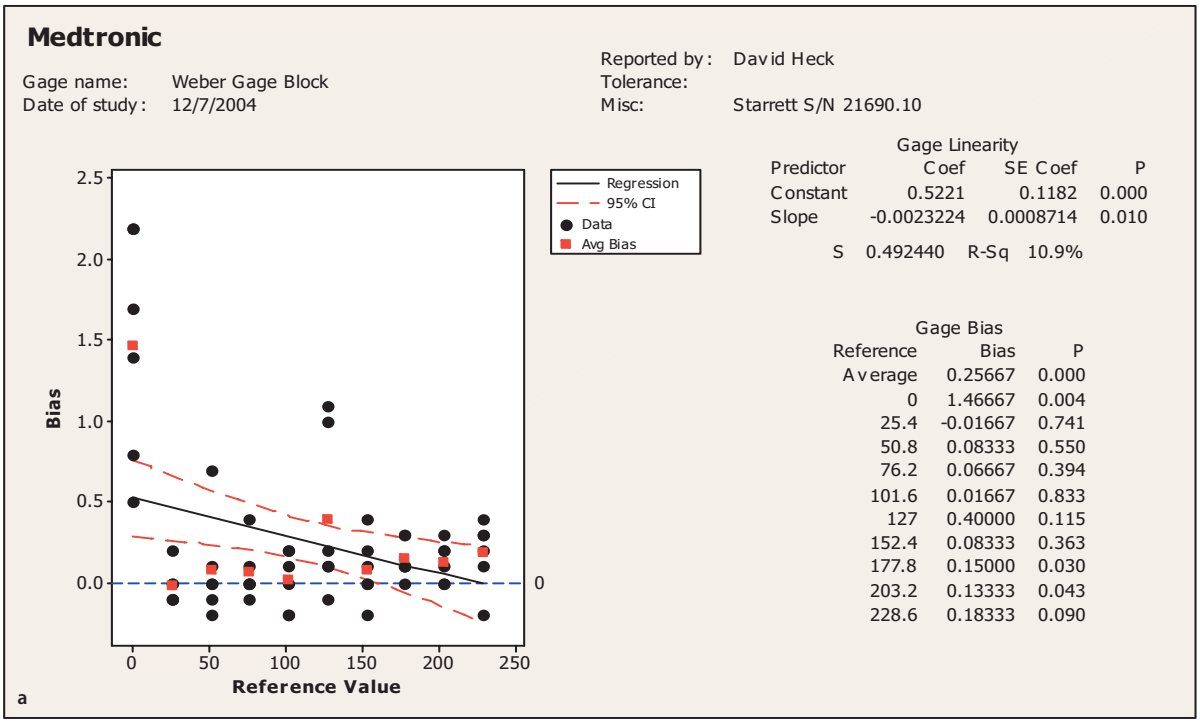
The Treon Plus system was found to have small but statistically systematic biases in comparison to the fiducial block in both parallel and perpendicular attitudes relative to the imaging bar (Fig. 9.5a,b, respectively). The mean bias for the parallel condition was 0.26 mm. Regression analysis demonstrated a fixed bias of 0.52 mm (p=0.00). The mean bias varied inversely according to the distance from the center of the imaging bar. The further the point of measurement from the center of the imaging bar the greater the deviation from the known artifact. The slope of the deviation was small at 20.00232 mm and was statistically different (p=0.01). The mean bias for the perpendicular condition was 0.69 mm. Regression modeling demonstrated a fixed bias of 0.79 mm (p=0.00). The mean bias varied inversely according to the distance from the imaging bar. The further the point of measurement from the imaging bar the smaller the deviation from the known distance. The slope of the deviation was small at 20.00085 mm and was not statistically different from zero (p=0.33).

An example of a phantom that could be utilized for assessing hip CAOS applications is shown here (Fig. 9.6) This device is constructed to model the human hip joint with the attached femur. Measurements of the hip center, femoral shaft axis offset, and leg length may be done after the phantom has been calibrated with a coordinate measuring machine. This pelvic phantom is 250 mm in relation to the Y axis and 300 mm in relation to the X axis. The femur is 370 mm in shaft length. The ball and socket are articulated with a strong magnet. Finally, holes are placed along the shaft of the device at 15 mm intervals.

## Clinical Outcome Studies

We have performed several clinical studies where we have simulated the operating room setting utilizing cadavers to replicate the surgical setting. The object of this assessment is measure as closely as possible the CAOS procedure, and then validate the instrumented cadaver. We have utilized computed tomography and a NIST traceable coordinate measuring machine (accuracy =0.038 mm) to create the conventional true value or »ground truth«.

In the example shown, we have placed an acetabular component into a cadaver pelvis with most of the soft tissue removed, and studied the position of an acetabular component that had been placed at 45° inclination and 17.5° of anteversion. The cadaver specimen was then taken to the operating room where it was secured to the standard operating room table, and the fluoroscopic protocol was used to measure the cup position (Fig. 9.7). The system studied was the Medtronic Treon Stealth system using an earlier version of fluroroscopic software designed for cup navigation (Fig. 9.8).



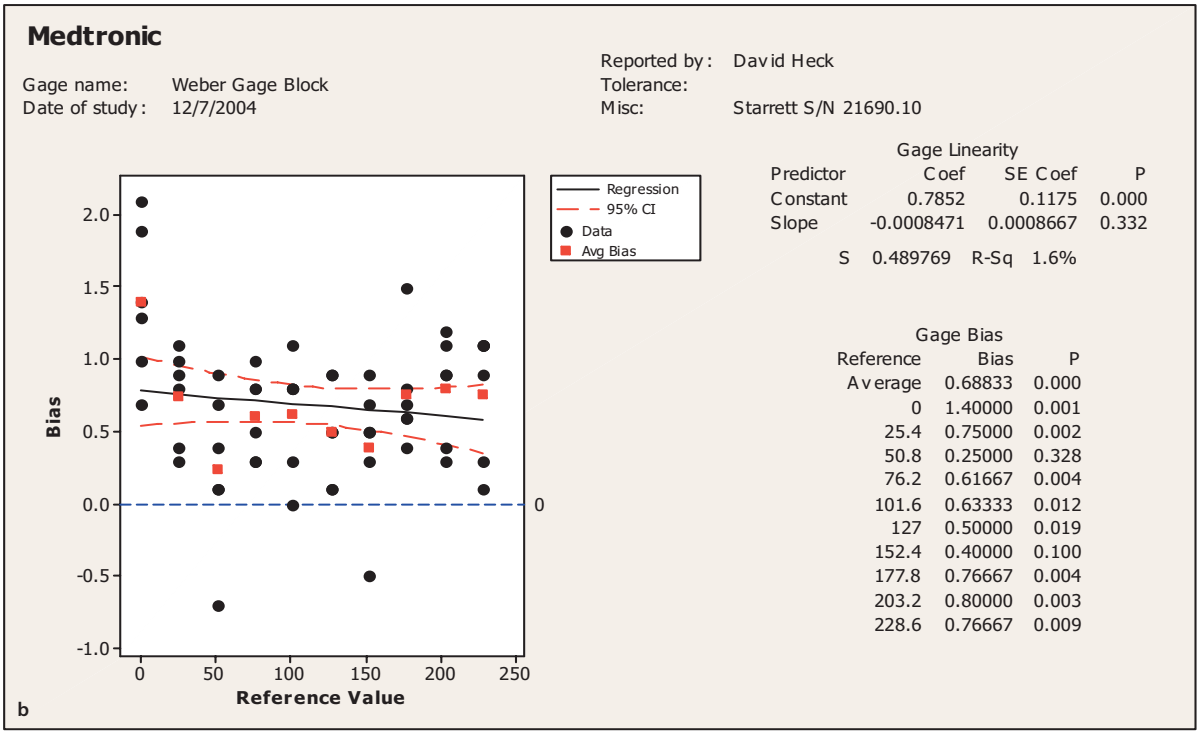
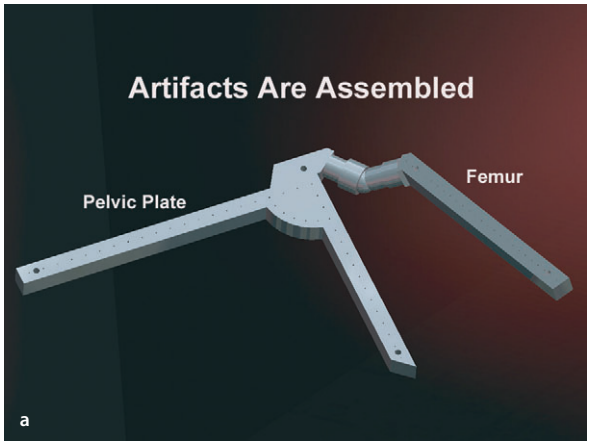
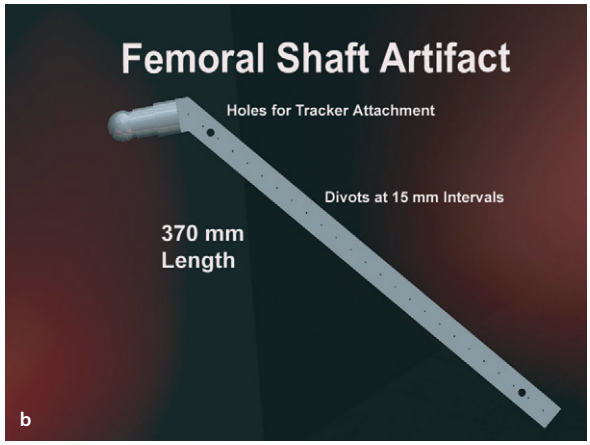




**Fig. 9.5. a** Assessment of accuracy parallel to the light bar (mm). **b** Assessment of accuracy perpendicular to the light bar (mm)



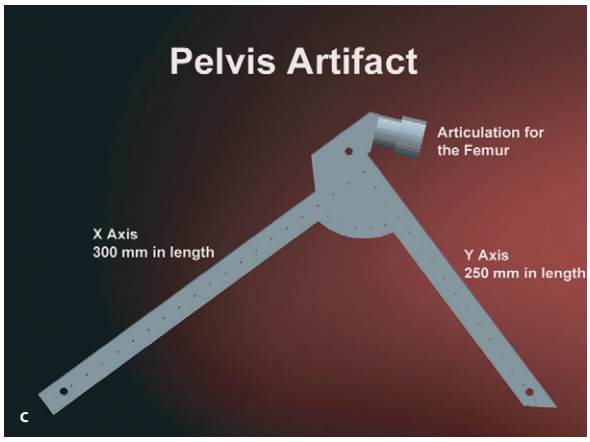




**Fig. 9.6. a** Phantom or artifact used to assess accuracy of a computer navigation protocol used in total hip arthroplasty. **b** Details of the femoral shaft artifact. **c** Details of the pelvic and acetabular artifact. (Figure contributed by Dr Nicholas Dagalakis, National Institutes of Standards and Technology, Gaithersberg, Maryland)

**Fig. 9.7.** Example of in-vitro testing of a fluoroscopic referencing protocol utilized in computer navigation of acetabular component insertion. Note the cadaver has been positioned in the lateral decubitus position in the operating room to simulate the in-vivo surgical scenario

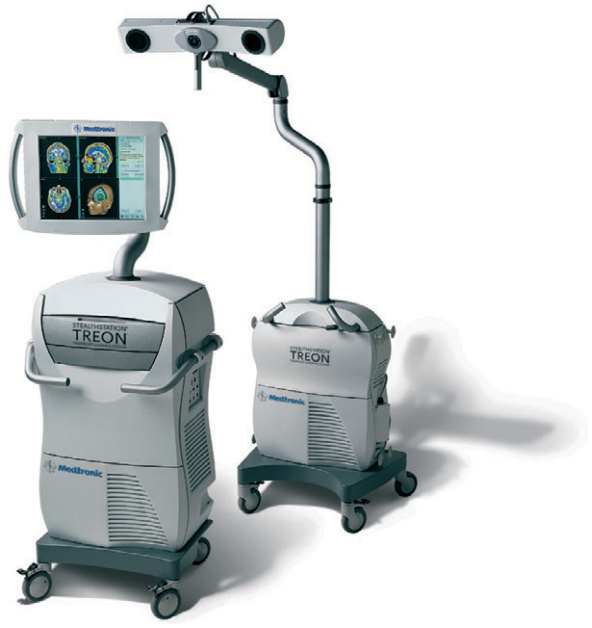



**Fig. 9.8.** Example of a »capital« system, with one tower consisting of the computer, video screen, keyboard and storage shelves and the second tower with the optical cameras for the optical line of sight system (Medtronics, Louisville, CO)

The results revealed that the mean CMM abduction measurement of the acetabular cup position was 46.028° (SD=1.075°; range: 43.32°–46.848°). The mean CMM anteversion measurement of the acetabular cup position was15.798° (SD= 0.411°; range: 15.07°–16.38°). Using the fluoroscopic referencing system, repeatability of the acetabular component position was assessed by one surgeon repeating eight trials with complete image acquisition and cup insertion. The mean inclination was 42.88 (SD= 1.5°; range: 39.5°–44.58°). The mean anteversion was 17.58° (SD= 3.0°; range: 14.5°–22.58°). Three surgeons assessed reproducibility using the fluoroscopic referencing technique. Each surgeon performed eight trials in a random fashion (n-24). The mean overall group inclination was assessed as 48.58 (SD= 0.9°; range: 46°–50.8°). The mean overall group anteversion was 17.88° (SD= 2.5°; range: 13.5°–23.58°). If we then apply the process capability Six Sigma formulas as noted above, we calculated that the Cp was 3.7 for cup inclination and 1.3 for anteversion. Our conclusion from this study was that the fluoroscopic system was precise for measuring cup inclination but not for cup anteversion.

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## Conclusions

The discussion of current methodologies to assess computer assisted surgery has reached an important juncture for we which have provided an interesting viewpoint. The current ASTM guidelines committee has not completed its work though we present the current state of the art that has now culminated from a process that began in Chicago at the CAOS International meeting, June 17, 2004. From the prior work of Deming and others, Six Sigma process capability analysis is not new, but offers a very powerful means to compare technologies from a broad variety sources. Our examples as noted above offered insights for this comparison that were not previously available. Finally, our recommendations for basic terminology and descriptive statistics follow the guidelines of NIST and ISO, and we believe that this offers a sound framework of communication between the surgical and research groups advancing the field of computer-assisted surgery and robotics.

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