Validation and Metrology in CAOS

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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 malpractice 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.