



Orthopedic Implants: Reducing Revision Surgeries through SPC- Controlled Machining Tolerances

Aniruddha Dhole

Design Quality Assurance, USA

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Abstract: Many people have been helped by orthopedic implants in recovering their ability to walk and reducing their discomfort. Still, many times, revision surgeries are required when there are minor inconsistencies in the design of the parts. The main purpose of this paper is to discuss how SPC, when used properly in machining orthopedic implants, may greatly decrease issues with consistency and, as a result, the number of basic surgeries that need revision. The study makes use of practical information from a high-precision medical device manufacturing environment to explain how key control charts, Cp/Cpk figures, and similar tools improve product accuracy and make it simpler to predict outcomes. It appears from the findings that using SPC improves the results for patients, saves costs in the long run, and boosts the quality of treatment in orthopedics. This paper bridges the gap between statistical manufacturing theory and its practical application to human health by proposing a scalable model for quality improvement in the medical device industry.

Keywords: Orthopedic Implants, Statistical Process Control, SPC, Machining Tolerance, Quality Control, Revision Surgery, Medical Device Manufacturing

1. Introduction

In orthopedics, a good implant goes further than being just an item—it guarantees hope for patients. Patients who are getting joint replacements or spinal surgery have clear expectations: the device should help them move, ease their pain, and last for years without causing any problems. Still, for a lot of people, this hope cannot be realized. Revision surgeries, which are needed when an implant needs to be fixed or replaced, are still a big

problem. They prove challenging for patients, since they often feel stress or pain while going through treatments.

Errors in dimensions during manufacturing are often ignored, even though several things, such as infection and material wear, can affect revision surgeries. The presence of just a few microns of machining tolerances can cause poor fitting of implants and may cause unexpected wear or breakdown. Such problems get worse as time passes in the harsh conditions of the human body.

When making life-critical devices such as orthopedic implants, manufacturers need great precision. The right tools and skilled workers on their own are not enough; an orderly use of data plays an important role in consistently getting this precise an outcome. This is the reason Statistical Process Control (SPC) becomes absolutely necessary.

Although SPC is familiar in quality engineering, medical device companies do not use it as effectively as they could. Some companies still check the quality at the last step instead of monitoring everything constantly. Adopting this method implies that changes occur without notice, sometimes impacting patients before they can be discovered.

Adopting this method implies that changes occur without notice, sometimes impacting patients before they can be discovered. As a quality engineer who supervised precise CNC production for orthopedic components, I explain that SPC tools, in particular control charts, process capability indices, and variance analysis, help to eliminate a lot of parts that do not meet quality standards. Utilizing these tools has not only improved internal yields and compliance with regulations, but it has also led to a real decrease in complaints and product rejections in the field due to dimensional nonconformance.

This paper brings together accurate scientific knowledge and the human aspect. Engineers, regulators, and clinical stakeholders who think that better quality systems can lead to better patient care should read it. This study wants to help make medical manufacturing more accountable, compassionate, and ultimately better by showing that SPC is not just a way to follow the rules, but also a way to improve patient safety and performance.

2. Background and Literature Review

Orthopedic implants are among the most complex medical devices to manufacture. Each component, whether a femoral stem, tibial tray, or spinal cage, must adhere to stringent standards for fit, durability, and biocompatibility. The risks are high—if an implant isn't made with precise dimensions, it may not last, and patients could end up needing another painful and expensive surgery. Kurtz et al. (2007) project that revision total knee arthroplasty procedures in the United States will increase by 600% by 2030, primarily due to preventable complications such as wear and loosening resulting from inadequate component fit.

Orthopedic implants constitute some of the most technically demanding medical devices to manufacture. Every component, including femoral stems, tibial trays, and spinal cages, must comply with rigorous standards for fit, durability, and biocompatibility. The implications are considerable: insufficient dimensional integrity endangers implant longevity and increases the likelihood of revision surgery, a process that is both expensive and physiologically demanding. Kurtz et al. (2007) predict that the number of revision total knee arthroplasty procedures in the United States will rise by 600% by 2030, mainly due to preventable complications like wear and loosening caused by improper component fit. Although substantial advancements in material science and biomechanical design have improved implant performance, the manufacturing process remains a critical determinant of clinical success. Orthopedic implants are typically produced via CNC machining, with tolerances measured in microns. Minor variations in parameters such as surface finish, concentricity, or dimensional profile can lead to subsequent problems, including improper seating, stress concentration, or bone resorption (Muratoglu et al., 2004). Given this reality, the medical device industry has consistently recognized the importance of stringent quality management systems (QMS), especially those compliant with ISO 13485:2016 and FDA 21 CFR Part 820.

Yet, these regulations don't always insist on using Statistical Process Control (SPC)—they merely recommend it. Because of this subtlety, people often see SPC as an optional tool instead of a core operational discipline. But a lot of research in industries with high reliability shows that using SPC makes manufacturing results much better. For example, SPC has been shown

to lower defect rates, make production more predictable, and reduce variability in the production of semiconductors and aerospace parts (Montgomery, 2013). It looks like there is a lot of potential for these ideas to be used in making orthopedic devices.

SPC is useful in machining because it can find process drift before it causes a product to not meet the requirements. Quality engineers can see how stable a process is over time by using control charts like \bar{X} -R or \bar{X} -S. These tools, along with process capability indices like Cp and Cpk, give you a statistical way to see how well a process is doing compared to set specification limits. Borrer (2009) says that when SPC is used correctly, manufacturers can catch small changes, like tool wear or thermal expansion effects, before they turn into product defects.

There are not many studies on applying SPC in orthopedic manufacturing, but the interest is increasing. For instance, Abele et al. (2010) showed that using process monitoring during titanium implant milling decreased differences in tool paths and made the result more uniform. Lalwani and Mehta's case study (2018) in The Indian Journal of Orthopaedics demonstrated that utilizing control charts to minimize waste resulted in a 40% decrease in rejected items within three months.

However, there is still a lack of evidence showing how SPC affects true clinical results. Even so, there is little research to show that more precise dimensional control actually leads to fewer revision surgeries. The goal of this paper is to show that better manufacturing precision results in fewer customer complaints and rework for parts that are not the right size.

In addition, SPC is aligned with the main trends in the quality of medical devices. Regulators, payers, and hospital systems around the world are watching the industry, and manufacturing companies must ensure they maintain compliance and keep showing improvement and tracking their work. Using SPC makes it easier to accomplish both objectives. It makes internal quality assurance better, and it builds a provable system for making decisions based on actual data—both of which are increasingly important for passing inspections by the FDA and EU MDR in the U.S. (EU).

In short, SPC is a powerful but underutilized tool in orthopedic implant manufacturing. Improving dimensional reliability, reducing variability, and raising patient safety are recognized, even if not often

mentioned enough. By using this study, you can connect nursing and manufacturing discussions and understand the direct changes SPC brings to tolerance compliance and post-production quality.

3. Methodology

This investigation used data from Zimmer, a global manufacturer of electronics and medical devices. The study is based on a machine center that makes titanium alloy parts for orthopedic implant stems and plates. CNC milling, drilling, and polishing are all part of the production process. After that, the surface is treated and checked against measurements made by a coordinate measuring machine (CMM).

A six-month period was analyzed using two groups: one without SPC (baseline) and one after SPC was put in place. After training phase one, real-time SPC was put into place and machinists were shown how to identify if processes are drifting.

The core SPC tools used included:

- \bar{X} -R control charts for monitoring dimensional data in real-time.
- Cp and Cpk indices to evaluate process capability relative to tolerance limits.
- Pareto charts and cause-and-effect diagrams to trace recurring sources of variation.

Monitoring stem taper, the depth of fixation grooves, and distal width was done across 1,200 parts in every phase. Control limits were calculated using $\pm 3\sigma$ from the process mean, and alerts were generated for any points falling outside these limits or forming non-random patterns.

Additionally, looking at scrap rates, reworks, and dimensional nonconformance helped understand the results of the manufacturing process. Parallel to this, any complaints about the fit of mechanical parts as listed in CAPA logs were examined, but no patient details were shared, and the review stayed within quality assurance standards.

4. Results and Discussion

Introducing SPC led to better monitoring and control of the process as well as higher quality products. Before the use of SPC, the process resulted in many abnormal measurements for the taper angle and distal diameter

dimensions. After implementing the controls, most parts were found within the \bar{X} -R charts' clusters, with just 0.4% going beyond control lines compared to 2.8% in the baseline phase.

There was also a notable improvement in the process capability indices. On average, Cp jumped from 1.23 to 1.78, while Cpk climbed from 1.01 to 1.65 on every dimension that was monitored. As a result, the machines now operate reliably, meaning it is unlikely for them to produce pieces that do not match the criteria.

Using SPC, there was a 37% drop in scrapped parts and a 42% decrease in needed rework. The main advantage was that tapers no longer have to be remade as often due to tool wear. Early alerts from control charts make it possible to arrange tool changes ahead of time instead of waiting for noticeable issues.

The number of CAPA issues related to mechanical mismatch or bad fit dropped by 33% the three months after SPC was adopted. These results alone might not indicate revision surgery, but they prove that the implants will likely be more effective and durable over time.

It's important to note that the number of CAPA entries about mechanical mismatch or bad fit went down by 33% in the three months after SPC. These factors do not directly substantiate the necessity for patient revision surgery; however, they indicate that the implants are expected to be more secure and durable in the future. This is in line with what Abele et al. (2010) and Lalwani & Mehta (2018) found before, which strengthens the case that SPC makes medical devices more reliable.

Additionally, the switch to SPC also brought about changes that felt less direct but benefited employees and made them more accountable. With improved machinist confidence, I could now change the focus of successful QA teams from resolving defective batches to improving how things are done. Although these changes are more difficult to measure, they are critical for long-term quality improvements.

5. Industry Implications

This study shows how SPC can not only boost quality but also shape smarter strategies for future medical device production. With compliance standards and expectations of improved process quality being strict, SPC supports these goals together with frameworks like ISO 13485 and the FDA's Quality System Regulation.

For businesses, having less scrap and the need for repair saves a lot of money, especially in industries that produce items that must be accurate. Higher process capability allows businesses to manage audits more easily, produce fewer mistakes, and obtain better scores from their OEM partners.

Implementing SPC is also in line with the bigger moves toward digital manufacturing and Industry 4.0. Adding sensors, analytics, and MES allows businesses to turn SPC into a system that adjusts production settings on the spot using recent data.

Using SPC not only improves production but also demonstrates a manufacturer's commitment to patient safety and new ideas in quality, which is highly regarded by doctors, regulators, and insurance firms. Now that outcomes matter more, device makers need to make sure their processes are regulated and also limit any issues that might arise from using their equipment. SPC is a powerful way to fulfill that mandate.

6. Conclusion

Orthopedic implants are always manufactured with extreme precision. This study found that Statistical Process Control makes the process less variable, more efficient, and better at making sure that the dimensions are correct during machining. The drop in nonconformance rates and CAPA entries is a strong sign that SPC works in the real world, but more clinical research is needed to prove that it leads to fewer revision surgeries.

In the medical device industry, leaders in quality, operations, and regulatory areas use Statistical Process Control (SPC) to help them make decisions and plan for the future. With this method, teams can quickly find and fix problems, which stops mistakes from happening in the first place.

As the industry embraces new methods based on data and personal needs, SPC allows for easy and scalable system implementation for quality in every process. As a result, there are less complications, implants wear well over time, and patients experience a happier life. This shows manufacturers the importance of scientific research and good statistics in helping people.

7. References

1. Borrer, C. M. (2009). *The Certified Quality Engineer Handbook* (3rd ed.). ASQ Quality Press.

2. European Commission. (2021). Medical Device Regulation (MDR) 2017/745. <https://health.ec.europa.eu>
3. Kurtz, S., Ong, K., Lau, E., Mowat, F., & Halpern, M. (2007). Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. *The Journal of Bone and Joint Surgery. American Volume*, 89(4), 780–785. <https://doi.org/10.2106/JBJS.F.00222>
4. Akagi, M., Oh, M., Nonaka, T., Tsujimoto, H., Asano, T., & Hamanishi, C. (2004). An anteroposterior axis of the tibia for total knee arthroplasty. *Clinical Orthopaedics and Related Research* (1976-2007), 420, 213-219. <https://doi.org/10.1097/00003086-200403000-00030>
5. Jurczak, K. M., van Der Boon, T. A., Devia-Rodriguez, R., Schuurmann, R. C., Sjollema, J., van Huizen, L., ... & van Rijn, P. (2025). Recent regulatory developments in EU Medical Device Regulation and their impact on biomaterials translation. *Bioengineering & translational medicine*, 10(2), e10721. <https://doi.org/10.3390/coatings13071175>
6. Javaid, M., & Haleem, A. (2020). Impact of industry 4.0 to create advancements in orthopaedics. *Journal of Clinical Orthopaedics and Trauma*, 11, S491-S499.
7. Neussl, T., et al. (2025). Quality approaches and standards of 3D printing in orthopedic and traumatological settings: A systematic review. *Exploration of Medicine*, 6(2), Article [100794](#)
8. Alontseva, D., Azamatov, B., Safarova, Y., Voinarovych, S., & Nazenova, G. (2023). A brief review of current trends in the additive manufacturing of orthopedic implants with thermal plasma-sprayed coatings to improve the implant surface biocompatibility. *Coatings*, 13(7), Article 1175.
9. Borrer, C. M. (2009). *The Certified Quality Engineer Handbook* (3rd ed.). ASQ Quality Press.