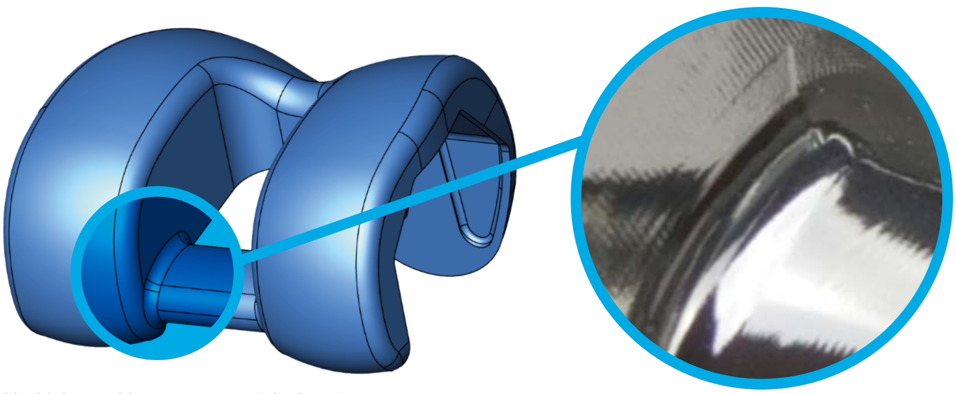
Manufacturing of femoral knee implants: a collaborative solution

Aging populations and a host of other factors are contributing to significant growth in the number of hip, knee, and shoulder implant operations. But with healthcare costs rising, there is also significant cost pressure from insurance companies and governments on the price of implants. In fact, market prices for implants such as knees implants are going down by about 2% a year. Manufacturers are caught in the middle, striving to find ways to reduce costs while still maintaining the high quality these devices require. The challenge is at its highest level in the machining of a femoral knee.

Femoral knees are generally made from chrome-cobalt castings and require tight tolerances and exceptional surface finishes. For posterior stabilized (PS) designs, the cam, box area, and condyle surfaces are all critical for the proper functioning of the implant. Often PS components are made by first milling a chrome-cobalt casting to a very "near net" shape, followed by grinding (either 5-axis, or drag grinding in ceramic media) and polishing.

The success and longevity of a knee replacement depends not only on the operation, but also on the quality of the components. For the femoral side, tolerances and surface finish are key – and the milling operation is especially challenging. Small defects, commonly referred to as "shadows", can be created by depth differences in machined surfaces of only 20 microns (0.0008 inches).



Machining problems can cause "shadows" that are visible after polishing

Shadows can occur due to wear on the ball screws that drive many milling machines, errors in the tool path from the CAM program, or even cutting tools that are not of high quality. These defects also often only visible after the polishing process is completed and can require costly hand polishing or even result in the product being scrapped.

Other defects can occur when the different curved surfaces are mismatched, resulting in edges that can cause wear to the sliding surfaces. Edges can be jagged, instead of having a smooth blend between zones, with again a negative impact on the result for the patient.

The curved condyle surfaces of femoral knee implants also need to match with the polyethylene liner or "spacer" with these curved surfaces mating nearly perfectly. When the curves match the load is distributed over a large area and sliding forces are low. Defects in curvature can result in simple point contact, potentially resulting in premature wear and even implant failure.

With quality requirements, cost pressure and volumes all growing, an important contract manufacturer asked Seco Tools, OPEN MIND Technologies and GF Machining Solutions to help them improve the efficiency of their manufacturing process for a femoral knee, selecting a PS variant due to its more challenging geometry. Our customer used what would be considered as a classic approach – a 5-axis milling machine with traditional drives (ball lead screws), ball and bull nosed cutting tools, and their existing CAM software package. This was followed by a drag grinding process in ceramic media and a two-step polishing process. Our goal was to reduce the manufacturing costs by at least 25% and to eliminate the need for ceramic grinding.

Our target was to improve the milling process such that we could reduce or even eliminate the need for grinding. That meant getting an incredibly smooth surface, and it was clear to all that success could only come from all three partners contributing to the solution.

We began our work by optimizing tool paths and cutter geometries, paying particular attention on how the tool contacts the device when machining the cam, box and condyle blend areas. Through analysis of the machine kinematics, we were able to apply innovative tool paths and design tool geometries that saved time while improving surface finish. Thanks to years of experience in orthopedics and machining complex materials, Seco designed several custom tools that were instrumental in achieving results.

Upgrading the CAD/CAM software to OPEN MIND's hyperMILL was key. This solution brings many advantages such as the innovative BEST FIT® technology. It takes measured dimensions of a casting and optimizes the position of the machined surfaces within this space – ensuring constant cutting conditions and improving not only surface finish, but also tool life. In addition, the 'Smooth Overlap' function ensures high surface quality as it enables flawless transitions between the different machining areas.

Finally, the advanced technology of the Mikron MILL S series Milling machine was used to ensure the overall result. The MILL S is equipped with a high-speed spindle, polymer concrete chassis, providing 7 times the vibration dampening of cast iron, and uses linear and torque motor drives on all axes. Compared to ball lead screw drives, linear motors operate without backlash and are both stiffer and faster, resulting in faster machining times, better surface finishes and unrivaled precision. The MILL S is also equipped with advanced thermal compensation which guarantees repeatable results across many hours of continuous operation.

The combination of advanced tools, software and machine was a reduction in milling time of over 30%, but more importantly an improvement in surface roughness of 80% - allowing implants to go from milling directly to polishing, therefore saving both time and operator hours.

Efficient manufacturing of complex medical devices such as a femoral knee implant depends on using the best available technology at every process step. By working together on an integrated approach, OPEN MIND, Seco and GF Machining Solutions have been able to develop a stable, reliable machining process that significantly reduces costs and improves overall product quality for femoral knees. The 30% reduction in machining time also eliminated quality defects such as shadows, and reduced rework, labor and scrap – resulting in cost savings that can range from 25 to 50% versus the customer's benchmark process.

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