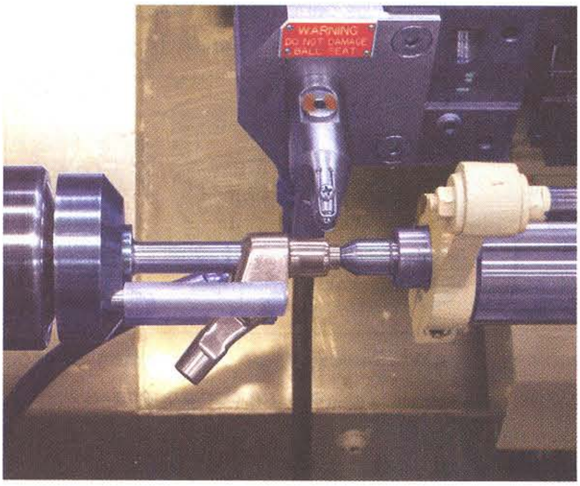
tion, go to www.ati-ia.com, or phone: 919-772-0115; on Mapleroc, go to www.rollrazor.com, or phone: 207-878-3210; on Norkol, go to www.norkol.com, or phone: 708-531-1000.

Getting Hip to Replacement Quality

There are over 300,000 hip-replacement surgeries each year in the US. These operations are performed to alleviate pain and improve the function of hips damaged by disease or fracture. Replacement hips are commonly made from high-strength, lightweight materials like titanium alloys. Modular hip prosthesis systems afford doctors the flexibility to choose properly sized components and treat a wide spectrum of patients, but are composed of several pieces that require precise dimensional and surface-finish control to work together perfectly.

These prosthetics can be prone to fretting along the tapered connections between subcomponents, resulting in surface microcracks that form and cause a reduction in the prosthesis' fatigue strength and functional life. Depending on the size and activity level of the patient, it isn't uncommon for additional hip repair surgery to be required within 10 years.

Exactech Inc. (Gainesville, FL), an orthopedic implant manufacturer, began examining different surface-enhancement processes that would mitigate fretting-initiated fatigue. Adding a layer of residual compression to a part has been shown to retard fatigue crack initiation and growth. Traditional methods, such as deep rolling, provided a smooth, shiny finish, but the compression imparted did not significantly improve fatigue and lacked the process control required for manufacturing.



Low Plasticity Burnishing operates using basic CNC code, and is said to be easy to install on existing machinery, such as lathes, mills, and robots.

In Low Plasticity Burnishing (LPB) from Lambda Technologies (Cincinnati), Exactech found a process that could be easily integrated into their machining operations and that provided the necessary combination of depth of compression to mitigate fretting fatigue, dimensional control, and required surface finish.

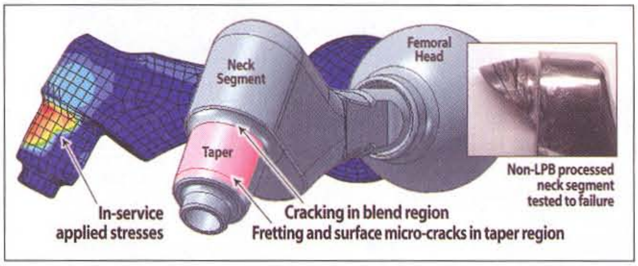
Lambda Technologies developed LPB to impart controlled residual compressive stresses in metal components, extending service life and performance. The surface treatment had been successful on aerospace components, many of which were made from materials similar to those used in hip replacements. LPB uses a single pass of a smooth, free-rolling ball under controlled force to create a deep, stable layer of beneficial, compressive residual stress in the component's surface. This compressive stress makes the piece resistant to a variety of damage mechanisms, such as foreign object damage (FOD), stress corrosion cracking (SCC), high cycle fatigue (HCF), pitting, and fretting fatigue. LPB strengthens components without altering their material or design. Because treated components are more durable, designers gain the benefit of added strength without needing to use a more expensive material or one that is harder to machine.

"At our first meeting, it became apparent that Lambda's approach was innovative," remembers Edmund Loftus, Exactech's development engineer for the project. "Their focus was on understanding our application and then demonstrating how the LPB process could substantially improve fatigue performance."

Using finite-element modeling of the applied stresses and Lambda's patented fatigue design protocol, a custom residual stress field was created for the application of LPB to the hip implants. Real-life conditions were simulated on a model to obtain the loads applied in service and determine the required depth of compression. Several factors needed to be taken into account: reallocation of residual tensile stresses, component distortion, and the cost of processing. Exactech had to be sure that the surface enhancement treatment chosen would not simply move the location of maximum stress, weakening another section. LPB prevents this by evenly dispersing the equilibrating tensile stresses during the design phase. Development and processing in the same lathes used for machining the prosthesis gave Exactech a way to answer fatigue issues and deliver a better product, without passing on major cost increases to patients.

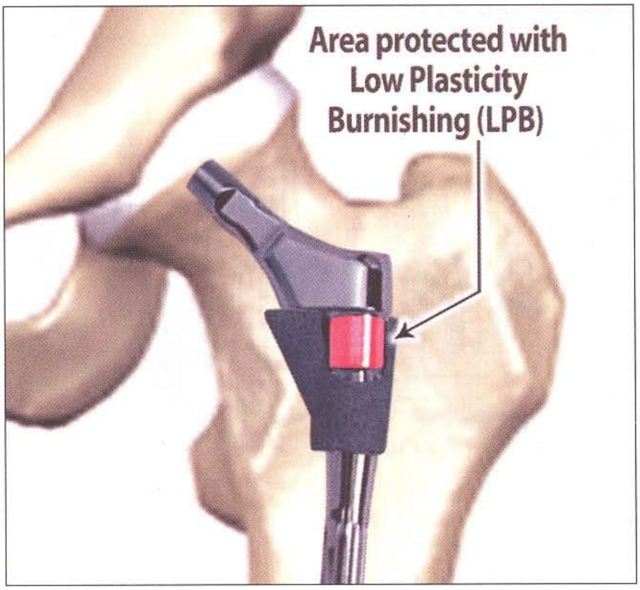
LPB-processed prosthetics achieve compression deeper and higher in magnitude than either the untreated or roller-burnished specimens. Overall fatigue strength was increased almost 40%, extending the fatigue life by orders of magnitude. The depth of the LPB treatment was sufficient to eliminate fatigue initiation from fretting-induced microcracking, providing a fatigue strength superior to unfretted material, all without changing the material or prosthesis design.

Because medical implants are government-regulated devices, rigorous testing was performed by Exactech to ensure that LPB treated prosthetics met FDA standards. Results



The problem: These prosthetics can be prone to fretting along the tapered connections between subcomponents, resulting in surface microcracks that form and cause a reduction in the fatigue strength and functional life of a prosthesis.

showed that the enhancement in no way affected the safe use of a modular hip replacement, and the process has been fully approved by the FDA for production. Ann Kelly, senior quality engineer for Exactech during the LPB development process, explains: "One of the most critical aspects of implementing LPB in our manufacturing operation was the need to ensure that the equipment and processes were properly qualified. Lambda's ability to extract manufacturing performance data in real time helped to expedite the qualification process. We are certain, within a very tight tolerance, that when a part has



LPB uses a single pass of a smooth, free-rolling ball under controlled force to create a deep, stable layer of beneficial, compressive residual stress in the component's surface.

been LPB-processed the compressive residual stress distribution is precisely what was specified by the engineer."

After verifying that LPB was the right surface treatment for their prosthetics, Exactech began implementing it into their manufacturing process. LPB operates using basic CNC code, and is said to be easy to install on existing machinery, such as lathes, mills, and robots. Processing can be done on either a dedicated unit, or by switching tools on the same machine used for manufacturing. Exactech determined that it would be simplest to have a designated surface-treatment lathe. The total footprint of the average LPB system is approximately 8 ft2 (0.74 m2), and system hardware can be packaged to relocate from one machine to another, if necessary.

Lambda provided a complete turnkey LPB machining process for the Exactech manufacturing facility, including the required CNC tool control code and pressure files that define the burnishing force. Once the LPB tool is installed, the machinist starts the operation and begins preparing the next piece. The use of a CNC-controlled toolpath delivers repeatability. LPB processing time for the hip implants is approximately 1 min.

During processing, LPB undergoes continuous, closed-loop monitoring. The computer-operated servocontrol makes pressure adjustments in real time, ensuring that each part is treated with the amount of force required. The system provides automatic pass/fail notification for each treated component, and QA personnel are informed immediately if there is a system malfunction or part rejection. SPC information is collected constantly, and each piece is tracked individually by serial number.

LPB offered Exactech several advantages over other surface-treatment options. Processing costs are significantly lower due to LPB's rapid processing. The procedure requires no special coatings, uses only a single cycle for treatment, and implants don't need to be moved from one machine to another or taken off site for remote processing. Since LPB tooling is designed to fit on existing CNC machinery, there is no costly requirement to teach machinists to run entirely unfamiliar equipment. Because of the low cold working of the surface, LPB produces a layer of compression that is thermally and mechanically stable. **ME**

For more information from Lambda Technologies, go to www.lambdatechs.com, or phone: 800-883-0851.