Synthetic Lubricants for Medical Devices

By Brad Richardson

While lubrication is probably the last thing patients or health care professionals think about, far upstream the engineer who designs mechanical and electromechanical medical devices has to think about it. Otherwise, performance — perhaps even a medical procedure — could be compromised.

Selecting lubricants for moving parts in medical and dental instruments is what this article is about. More importantly, it's about seeing the lubricant not merely as an add-on near the end of the design cycle, but as a critical design material. Carefully selected, lubricants do much more than reduce friction and wear. They can lengthen the life of the device, broaden the temperature range at which it operates, reduce unwanted noise, control free motion, impart a clinically appropriate feel, provide an environmental seal, cut design and production costs — and even reduce warranty claims. In short, lubricants can add value even to breakthroughs in medical technology.

DAMPING GREASE: JUST WHAT THE DOCTOR ORDERED

Eli Lilly and Company, the global, research-based pharmaceutical corporation headquartered in Indianapolis, Ind., launched a real advancement in insulin delivery devices in February 1999: disposable, pocket-size, pre-filled 3.0 ml (300 unit) "insulin pens." Named for the type of insulin they contain, the Humulin® 70/30 (70% human insulin isophane suspension, 50% human insulin injection [rDNA origin]), Humulin® N (NPH human insulin [rDNA origin] isophane suspension), and Humalog® (insulin lispro injection [rDNA origin]) Pens are ideal for people with diabetes who have unpredictable schedules or who have trouble using a vial and syringe. The pens require no vials, no syringes, and no refrigeration after first use.

Lilly collaborated on the mechanics of the pen with the Chicago office of IDEO, an international design firm that captured the 1999 Medical Design Excellence Award for its work

Humulin® and Humalog® Pens, disposable insulin delivery devices by Eli Lilly and Company, use a damping grease by Nye Lubricants to ensure plunger resistance remains consistent throughout the injection cycle.

on the Lilly pens. IDEO and Lilly, in turn, worked with Nye Lubricants, Inc., to select lubricants used in the pen. From a lubrication perspective, the Humulin® and Humalog® Pens are a text-book study of the benefits that damping greases bring to mechanical devices.

Designers and manufacturers of microscopes, telescopes, binoculars, zoom lenses, and other optical instruments have relied on early versions of damping greases for more than 50 years. The "velvet feel," virtually silent operation, and the absence of "backlash" are all the work of a damping grease applied to an instrument's focusing threads.

What distinguishes a damping grease from other greases is its internal shear resistance. Damping greases contain highly viscous base oils — some as thick as honey — so they require a degree of force to move an object through them. This shear resistance minimizes free motion problems like backlash or coasting. Very tacky, a damping grease also adheres to moving parts. Not only does this prevent wear, it "damps" noise because the parts actually move within the grease rather than against each other. The viscosity of the base oil determines shear resistance and "feel" or tactile quality of the device. The more viscous the oil, the greater the shear and the more force required to actuate the device. For example, a lighter grease is used for a stereo tuning knob, an ultra-heavy grease for the coin-return mechanism in a vending machine. Today, damping grease is one of the most cost-efficient ways to build smooth, controlled, quiet motion and fine tolerances into mechanical and electromechanical devices — which is why IDEO engineers turned to this technology for the Lilly project.

In the insulin pens, damping grease quiets the injection cycle. The pen's plunger consists of a screw and pawls, which are used to prevent back up. As the pawl fingers snap over the saw teeth on the screw, the grease damps the noise. The more important — and clinically critical — use of damping grease in the pen, however, is to impart a smooth, uniform motion from the beginning to the end of the injection cycle.

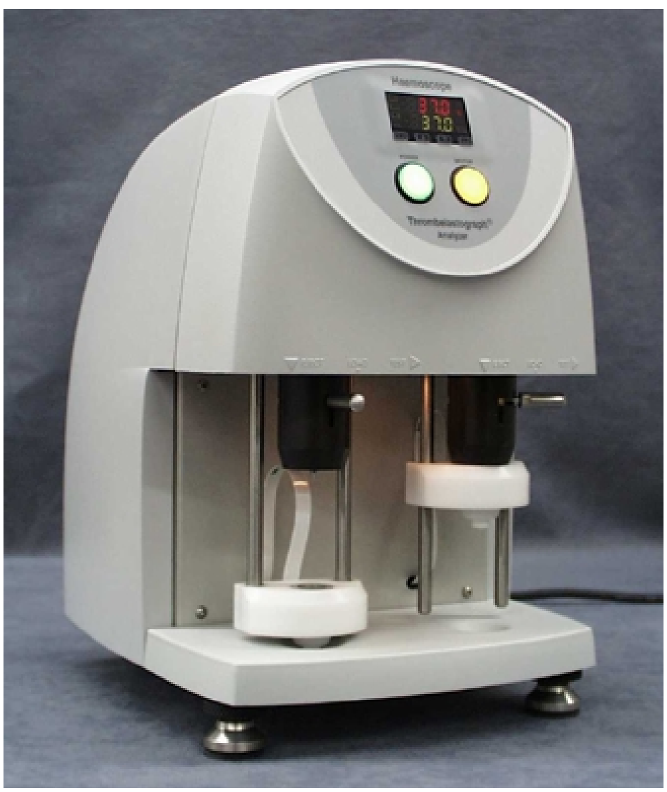
Initially, the plunger is locked in a forward position. Rotating the plunger releases an axial clutch. As the plunger is pulled back, the clutch travels about 4 mm up the screw where it engages a nut again, preventing inadvertent forward motion while allowing the dosage to be dialed. In its extended position, the plunger also serves as the dosage dial. Once the dosage is set, the patient pushes a button to disengage the clutch and begin the insulin injection. In early tests without damping grease, the plunger moved forward much too quickly when the clutch was disengaged — which could possibly have caused the inexperienced patient mistakenly to think the injection cycle was complete.

"It could have been misleading," said IDEO design engineer Andrew Burroughs. "Mechanically, there are two stages to the injection cycle: the clutch disengagement followed by full depression of the plunger, which is when the insulin is actually delivered. The damping compound eliminated the abrupt action when the clutch was disengaged. It made those two stages seamless, normalizing the injection force over the full travel of the plunger. It really took any confusion out of the injection cycle."

Lilly had very stringent requirements around the grease's shear resistance. It had to mirror the resistance of the insulin through the needle during injection. The grease also needed a good viscosity index, that is, the viscosity had to remain relatively stable throughout the specified operating temperature range of 4°C to 40°C. Finally, the grease had to be compatible with the polycarbonate and ABS materials used in the pen. After rigorous testing on specially constructed rigs, IDEO zeroed in on Nye's NyoGel 774VH, a damping grease that now ensures the same smooth, quiet "feel" whether the plunger is being extended, rotated, or depressed.

In production at a Lilly facility in Fegersheim, France, two other grease controls were identified. First, air pockets had to be removed from the grease. When using high-speed, automated dispensing equipment, especially when small amounts of grease are applied to each device, air entrained may result in some parts' not being lubricated. Nye, therefore, uses special equipment designed by one of its mechanical engineers to remove air bubbles from each 20-ounce cartridge before shipment. While Lilly's production line cycles every plunger to ensure the presence of grease and proper resistance, deaeration of the grease helps minimize part rejection. Secondly, the pen's torque specifications require a small window for viscosity variation from lot to lot. If the viscosity of the grease moves beyond the acceptable range, the feel of the plunger would be either too stiff or too loose. Consequently, Nye measures the viscosity of each lot to assure it falls within a ±10 percent range.

"Essentially, damping compounds are a very cost-effective way of getting a lot of performance out of a very simple system," Burroughs said. "They provide elegant solutions in a very elegant way to problems that are just about impossible to solve with mechanical means."



Thrombelastograph® (TEG®) Coagulation Analyzer, manufactured by Haemoscope Corporation of Skokie, Ill., tracks the shear elasticity of a clot and its ability to arrest bleeding — in real-time, during a medical procedure. It relies of two greases by Nye Lubricants, one in the gear motor and one where mating parts slide on the frame.

GEARS, SLIDES, INSURANCE AGAINST WEAR

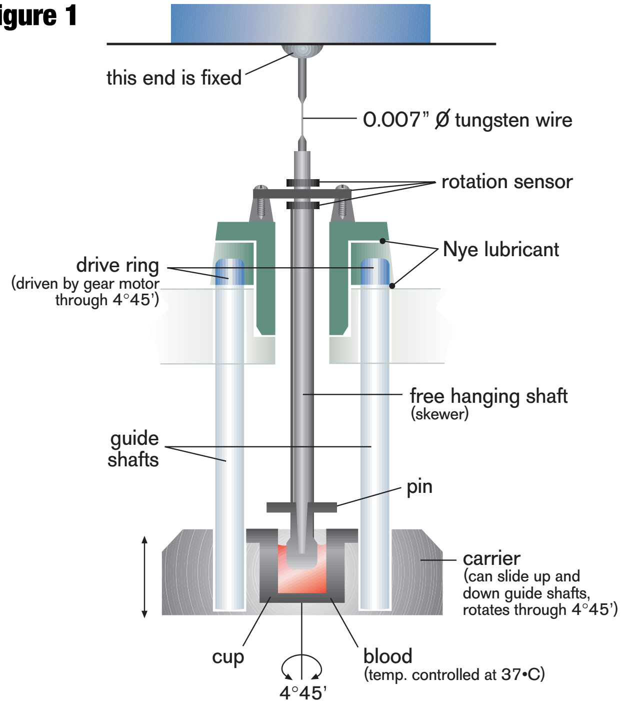
OEMs often rely on several companies, each with their own expertise. The Thrombelastograph® (TEG®) Coagulation Analyzer, manufactured by Haemoscope Corporation of Skokie, Ill., is the product of such an effort.

Hailed as a breakthrough by medical journals, the TEG® analyzer monitors the clotting ability of a patient's blood during surgery, trauma, obstetrics, and other medical procedures. Analyzing blood in real-time — in contrast to sending it to a remote lab — not only saves time and costs, it improves patient care. Scientific studies have shown a positive correlation between using the TEG Analyzer and reduced bleeding in the post-operative period, shorter length of stay in the ICU, a reduction in the frequency and volume of transfusions, and lower rates of re-exploratory surgery.

TEG® software, Haemoscope's brainchild, tracks the shear elasticity of a clot and its ability to arrest bleeding. The system receives data from a cylindrical cup that holds the blood and is oscillated at 10-second intervals (*See Figure 1, "Inside The TEG®"*). A pin, suspended in the blood by a torsion wire, is monitored for motion. As the clotting process begins, the rotating cup transmits a torque to the immersed pin. The output is related to the strength of the clot: strong clots move the pin directly in phase with the cup motion; as the clot breaks down, the transfer of cup motion is diminished. The rotation of the pin is converted by a transducer to an electrical signal that is monitored by a computer. The resulting hemostasis profile is a measure of the time it takes for the first fibrin strand to be formed, the rate of clot formation, the strength of the clot, and dissolution of the clot.

IDEO designed the mechanical portion of the TEG system, where two synthetic lubricants are used — one for gearing, the other for an eleventh-hour discovery. Autotrol Corporation of Crystal Lake, Ill., custom-designed the sub-fractional horsepower electric gear motor.

Figure 1



The rolling and sliding action of any gearing presents the lubricant with unique wear-prevention challenges. Minimally, the lubricant should protect against tooth wear and facilitate power transfer with minimal heat and noise. With careful selection of base oils, gellants, and additives, gearing lubricants can also inhibit corrosion, damp noise, and control free motion. For the TEG gear motor, Autotrol specified Nye's Rheolube 365F — a lithium soap-gelled grease, formulated with a high-film-strength, synthetic hydrocarbon base oil with a useful temperature range of -45°C to 125°C. An additive package was formulated to minimize friction and start-up torque.

According to Autotrol engineer Al Visin, Rheolube 365F "provides long life, the first requirement for any gear lubricant. It's also compatible with plastic, brass, and steel — all of which are used in this particular gear motor."

An important design note, greases can be formulated light enough to accommodate even sub-fractional horsepower gear motors. Some greases can actually flow under shear and return to a gel consistency when static. Compared to gearing oils, which are often automatically specified for low-torque applications, the stay-in-place quality of a very light, thixotropic grease can reduce component costs by minimizing the need for seals and the machining costs associated with oil seal designs.

With the Autotrol motor in place, IDEO began final cycle testing, which uncovered the need for yet another lubricant. The shoulder of the drive assembly, which rotates the cup holding the blood, had to slide and rotate a few degrees on the machined surface of the support frame. It also made contact with the transducer housing. Though the load was very light, the sliding of metal on metal was a formula for friction and wear, which could compromise the rotation of the cup — and the accuracy of TEG measurements.

Sliding parts present a different type of challenge to lubricants compared with rolling elements, such as ball or roller bearings. Ball bearings usually rotate at such speeds that a fluid film builds up which separates the balls from the raceway. With sliding parts, the combination of speeds and loads do not reach a point where a fluid film is created. Further, reversal of motion, which results in loss of the fluid film even in a ball bearing, is much more common with sliding parts. Because the potential for friction and wear is much greater with sliding parts, it is important to use a lubricant that has good film strength, which is a function of the molecular structure and viscosity of the base oil.

A molybdenum disulfide spray, a very lubricious material, didn't solve the TEG wear problem. A grease did. Nye Rheolube 362HB is a wide-temperature grease designed for use on cams, sliding surfaces, small gear trains, and the mechanical linkages of switch gear. Formulated with a super-refined synthetic hydrocarbon oil, it contains additives to improve adherence and lubricity. Rheolube 362HB allowed

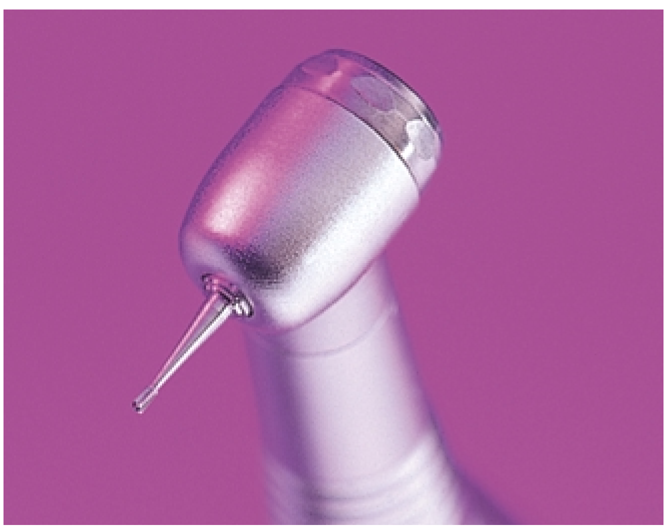
A sub-fractional horsepower electric gear motor by Autotrol Corporation powers the TEG® Coagulation Analyzer. Gearing is lubricated with a light, thixotropic, synthetic hydrocarbon grease by Nye Lubricants.

smooth sliding on the frame and the transducer housing — and successful completion of IDEO's cycling tests.

Though lubrication engineers prefer to be involved early in the design cycle, the late addition of a grease to solve a friction/wear problem in this application underscores an important fact about lubricants: they're generally "retrofittable." If a performance issue is not uncovered until later, lubricants can still solve a multitude of problems in the eleventh hour.

THE CHALLENGE OF HIGH-SPEED, HIGH-TEMP DEVICES

Years ago, the steel used in rolling element bearings played a critical role in bearing life span. Today, with sophisticated manufacturing processes, the quality of steel, alloys, and ceramics is no longer the issue. The issue now is often the quality of the lubricant — how well and how long it can minimize friction and prevent bearing wear. Few applications in the health care industry challenge a bearing lubricant more than the high-speed dental handpieces used to drill, shape, and polish teeth.



High-speed dental handpieces use synthetic hydrocarbon oils in the turbine bearings. Typically, the bearings are re-lubricated with oil and placed in an autoclave after each use.

Bearing size and speed is one challenge. Dental handpieces contain a turbine with precision bearings, whose tiny steel or ceramic balls measure about one millimeter (1,000 microns) in diameter. They travel up to 500,000 rpm, that is, more than 8,000 revolutions per second! Properly lubricated, the balls travel around the raceway on a thin film of oil, which prevents direct contact with the raceway. If the oil is not properly filtered, however, the speeding balls are an accident waiting to happen. If a ball hits even a microscopic particle in the oil at high speed, the oil film will likely rupture and some scarring of the ball or raceway is likely. Over time, these collisions create unwanted noise, accelerate wear, and shorten operating life. To optimize the performance of precision bearings, Nye recommends ultrafiltration of the oil, a process that can filter out all particles larger than 50, 25, 10, 5, or even 1 micron — depending on the cleanliness level required. (For scale, a grain of beach sand is about 600 microns) For grease, ultrafiltration can ensure no particles larger than 34 microns, and no more than 1,000 particles between 10 and 34 microns in size per cubic centimeter.

Another challenge faced by handpiece lubricants is temperature. In the early 1980s, when sterilization protocols became more stringent in response to the HIV virus, dental offices began to autoclave handpieces. Today, after each patient, the handpiece is flushed with a cleaner, dried, lubricated, and sterilized at high temperatures. A good synthetic hydrocarbon oil can withstand the temperature and pressure of the autoclave procedure. Nye offers several oils, including Nye DHL-400 and DHL-600, tested to 150°C, that are specified by OEMs and sold under private label to dental practices.

While ultrafiltered oils can keep turbine bearings running beyond manufacturer's warranty periods, a new challenge is now being raised within the dental industry. Handpiece and bearing manufacturers are exploring the use of a grease instead of an oil in turbine bearings, to eliminate the need for relubricating each handpiece after each use. One handpiece manufacturer, in fact, has already introduced what it calls a "lube-free" handpiece. Technically, it's not lube-free. With no lubricant at all, the bearing would last hardly a week before burnout. Rather, the handpiece uses a grease, so no re-lubrication is required for the life of the bearing. While that's a forward stride from a maintenance perspective, grease chemistry raises some issues about the longevity of a precision bearing lubricated with a grease. Even if the grease is formulated with a smooth, very fine grade of ultrafiltered gellant, the gellant is still a solid — which inevitably poses a threat to tiny, fast-moving, precision bearings. Nye is working with precision bearing manufacturers to formulate such greases for dental handpieces, but the jury is still out on their long-term success. Though grease certainly reduces in-office maintenance of handpieces, it does not yet deliver as many cycles as bearings lubricated with

oil. For now, the trade-off seems to be: buy bearings more frequently or relubricate with oil after each use.

A surgical instrument that relies on filtered synthetic hydrocarbon oils for lubrication and cleaning of bearings is the OsteoPower® Modular Handpiece System manufactured by OsteoMed Corporation of Addison, Texas. The OsteoPower system is designed for dissection and drilling of small bones within the head, face, neck, and extremities.

OsteoPower brought several innovations to small-bone surgical handpieces when it was introduced in 1996. Instead of aluminum or steel, it is the only handpiece that uses a polymer housing, which allows long duty cycles by insulating the surgeon's hand from heat generated by the electric motor. It is also the only motorized unit in the world that has pressure activated controls rather than mechanical levers on the handpiece. Finally, it's completely modular: one motor powers eleven attachments, including four kinds of saws, three contra-angle drills, straight drills, plus a Wire and Pin Driver with optional Jacobs Chuck.

"Nye's DHL-600 is used on all the attachments," said Drew Hautt, OsteoPower's global product manager. "Packaged in an aerosol container with a nozzle designed by Nye, it's sprayed into the bearing prior to autoclaving for two to five seconds until the lubricant comes out clear from the nose of the drill. Our work horse is the one-to-one straight drill, which is the only piece we ask customers to lubricate every time it's used. That's critical to clear out bone material and debris which can cause the bearing to fail. Nye's medical grade filtering made its oil the obvious choice."

How do you choose the best lubricant for a medical device? Make sure the lubricant meets the operating temperature requirements. Be certain the lubricant is compatible with all structural materials, especially plastics and elastomers. Choose a viscosity commensurate with available torque. Match the film strength of the base oil to the load. Use additives to boost anticorrosion, adherence, pour-point, antioxidant, and other capabilities. In short, like a personalized fitness program, make sure your lubricant is designed specifically for your application.. ■

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Oil or Grease, Natural or Synthetic

A Primer on Selecting Lubricants

By Brad Richardson

Generally, there are few if any governmental regulations about lubricants for non-implant medical devices. Nonetheless, if the device comes into contact with the patient, it is wise to stick to base oils and additives that are "generally recognized as safe." Typically, synthetic hydrocarbon oils are preferred. Worse case scenario if ingested, they would act as a very fast-working laxative. Beyond this caveat, the best lubricant for a medical or any carefully engineered device is one that is designed for the application and the operating environment.

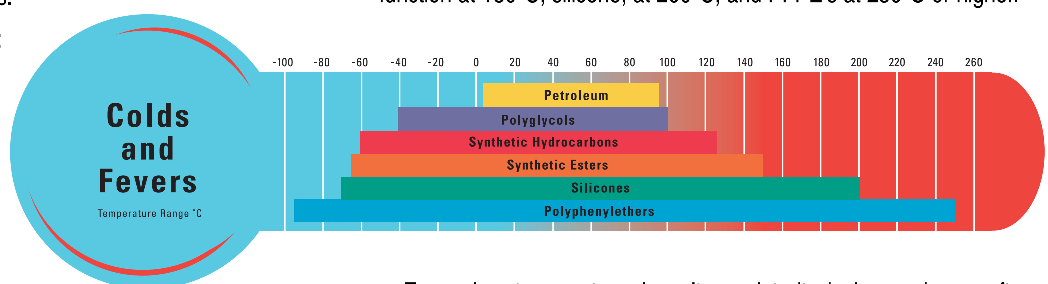
When choosing a lubricant, the first decision is, oil or grease. Generally, low starting torque requires oil. While the consistency of a grease may overpower available motive force and impair the operation, oils provide minimal drag, which make them more suitable than greases for small delicate mechanisms used in many precision instruments. For high-speed applications, where oil migration is not an issue, oils also dissipate heat better than greases.

Oils do have one major limitation: they tend to creep. Lubricant migration can often be prevented with a "barrier film," a very stable, non-wettable, fluorocarbon polymer with a surface energy well below the surface tension of most lubricating fluids. Supplied in a fast-evaporating solvent, the polymer film acts as a dam around the lubricated area to prevent oil migration — and potential contamination of nearby, sensitive components.

Greases are formulated by combining an oil with a gelling agent, usually a soap or a clay. Even with a grease, it is still the oil that lubricates. The force created by two mating parts — slide on slide, gear on gear, bearing against raceway, for example — squeezes oil out of the gellant into the interface to reduce friction and prevent wear. Greases are generally recommended for heavier loads, especially where vibration or shock loading is likely. They are also more resistant to water wash-out and serve as effective seals against contaminants and moisture.

Even with low-power devices, don't quickly rule out a grease. Greases offer an important stay-in-place capability that can reduce costs associated with manufacturing an air-tight oil reservoir. Light, low-shear greases — formulated with light oils, special gelling techniques, and adherence modifiers — can approach a semi-fluid state under shear. So for all except flea-powered devices, a custom-formulated, extra-light grease may provide a cost-advantage over oils.

Like in health care, natural or synthetic is a lubrication decision too. Petroleum, a hydrocarbon, is nature's most popular lubricating oil. Synthetic lubricants, which include hydrocarbons, esters, polyglycols, silicones, and perfluoropolyethers (PFPEs), are man-made through controlled chemical processes. Usually, the operating temperature of the application is the arbiter. Petroleum becomes virtually intractable at sub-zero temperatures and begins to degrade at or before 100°C. In either case, it won't lubricate. By contrast, synthetic hydrocarbons stay lubricious at -40°C; synthetic esters, at -60°C; and some PFPEs, at -90°C. At the other end of the thermometer, synthetic hydrocarbons function at 130°C, silicone, at 200°C; and PFPE's at 250°C or higher.



Even when temperature doesn't mandate it, design engineers often choose a synthetic lubricant. Compared to petroleum, synthetic oils are more chemically homogeneous. They offer better thermooxidative stability. Oxidation not only depletes lubricant supply, it often leaves abrasive oxides in its wake — which hastens component failure. At elevated temperatures, even without the presence of oxygen, synthetic lubricants are also less volatile than petroleum-based products of equivalent viscosity.

Synthetic lubricants also offer better film strength than petroleum products. The "film" of lubricant on a sliding or rotating part is what reduces friction and prevents wear. If the film is weak and ruptures under load, wear is accelerated. In general, under similar operating conditions and viscosities, a synthetic lubricant will perform more consistently and for longer periods of time than a petroleum product.