Thermal Cycling Can Extend Tool Life in Orthopaedic Operating Rooms

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ABSTRACT: Thermal cycling is a temperature modulation process developed to improve the performance, durability and longevity of materials. This process has been successfully utilized in the automotive, aeronautic and manufacturing industries. Surgical cutting tools undergo cyclical loading and generally fail by dulling, suggesting that thermal cycling may improve their performance and longevity. Ten 2.5 mm orthopaedic drill bits were randomized, with five undergoing thermal cycling within their sterile packaging and five serving as untreated controls. Using a servohydraulic testing machine, 100 drilling cycles were performed with each drill bit into the diaphyseal region of bovine femurs. After every 25 cycles, data was collected by performing identical drilling cycles into simulated human cortical bone material. Maximum force, maximum normalized torque and drilling work were measured, and a scanning electron microscope was used to measure outer corner wear. After 100 drilling cycles, the maximum drilling force, maximum normalized torque, drilling work and microscopic outer corner wear were all significantly lower for the treated drill bits ($p < 0.05$). Thermal cycling has the potential to decrease operating room costs and thermal necrosis associated with dull cutting tools. Application of this technology may also be relevant to surgical cutting tools such as saw blades, burrs and reamers. © 2015 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. J Orthop Res

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Health care economics currently mandate an increased emphasis on cost-effectiveness. Due to an aging population and emerging, frequently more expensive, surgical technologies, operating room managers are under immense pressure to minimize costs associated with surgical procedures. At our institution, surgical tools and instrumentation represent a large component of operating room budgets, and improvements in their longevity, durability and performance would represent significant cost savings.

Thermal cycling is a proprietary patented (patent No. US 7,464,593 B1) temperature modulation process developed to improve the performance, strength and longevity of a variety of materials, including stainless steel, cast iron, aluminum, brass and copper.[1,2,3] Described as "advanced cryogenics," thermal cycling has been applied primarily to metals. It is an efficient, clean, non-polluting process that is currently utilized by a number of industries where improved performance is desired, including automotive, aerospace, manufacturing, electronics, consumer products, and sports equipment.[2,3] Thermal cycling has been used with great success in these industries, and has been shown to significantly improve performance and wear life of mechanical components, frequently on the order of a fivefold increase in tool life.[3]

During the thermal cycling process, materials are cooled and subsequently heated until they undergo molecular reorganization. This reorganization "tightens" or optimizes the particulate structure of the material throughout, relieving stresses, and making it more dense and uniform, thereby minimizing flaws or imperfections. The reorganized structure also enhances the energy conductivity and heat distribution characteristics of the material.[1] It minimizes "hotspots," enhances cooling, and impedes the ability and tendency of metals to vibrate, significantly reducing fatigue and failure. Corrosion resistance is also enhanced due to the more uniform material's ability to impede the forces of oxidation and chemical degradation.[4] An image depicting the effect of this process is shown in Figure 1.

Surgical cutting tools used in bone are subjected to substantial forces which can lead to high rates of wear and failure.[5,6] Cutting tools such as drill bits, reamers, saw blades and burrs, undergo cyclic loading and their performance generally declines with use, secondary to wear and dulling (loss of sharpness at the cutting edges).[7] This manifests as an increase in axial thrust force, an increase in bone temperature and initiation of vibratory motion.[7] As such, thermal cycling may improve the performance and wear properties of these tools, potentially representing significant cost savings for operating room budgets.

In addition to the economic benefits, dull cutting instruments have been shown to cause increased friction, which causes substantially greater heat generation.[8,9] Dullness of cutting instruments represents one factor that can contribute to thermal osteonecrosis, which can lead to an increased risk of infection and implant failure.[10,11,12] If the thermal cycling process could be used to improve performance and decrease dulling of surgical instruments, this finding would have significant potential in decreasing the risk of thermal osteonecrosis and its sequelae. Furthermore, ensuring that cutting instruments maintain their performance may result in decreased operating time and surgical frustration.

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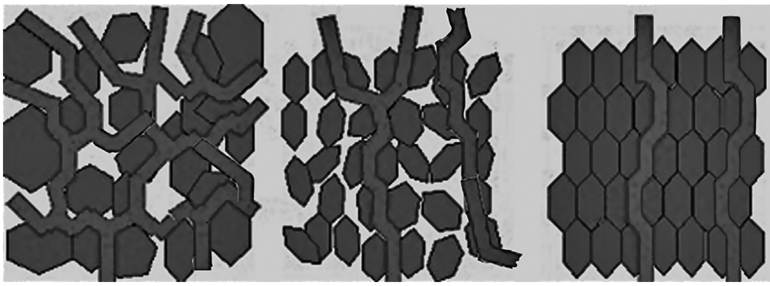

Figure 1. Depiction of the effects of thermal cycling on a molecular level, demonstrating the molecular reorganization that minimizes flaws and maximizes energy conductivity.

Establishing that the thermal cycling process is effective for surgical instruments, however, presents a unique set of challenges. These include ensuring that sterility can be maintained without compromising the thermal cycling process, and ensuring that the improved performance is present in surgical mediums such as bone.

The purpose of this randomized, blinded study was to assess the applicability of the Thermal Cycling Process to surgical instrumentation. Specifically, this was evaluated by comparing drilling performance and wear properties of thermally cycled drill bits to that of standard orthopaedic drill bits. Our hypothesis was that the thermally cycled drill bits would demonstrate superior performance and decreased wear compared to standard drill bits.

METHODS

To determine the appropriate sample size for this study, a Cohen's "d" calculation was used.[13] Assuming a within-group variance of 15%, and defining an effect size of 30% reduction in drilling work as clinically significant, the calculation yielded a necessary sample size of five drill bits in each group.

Ten 440A stainless steel, three-fluted, 2.5 mm, small fragment orthopaedic drill bits (*Synthes*, Solothurn, Switzerland) from the same batch were randomized using an online random number generator, by an investigator who was uninvolved in the testing of the drill bits. In a blinded fashion, five of these drill bits were provided to *Thermal Technology Services Limited* (Vaughan, Canada). The appropriate drill bits underwent the thermal cycling procedure within their sterile packaging. The thermal cycling did not compromise the sealed packaging and there were no visible signs differentiating between the two groups following the procedure.

A custom testing jig was designed to allow connection of a surgical drill (*Synthes*) to an MTS Bionix 858 Servohydraulic Testing Machine (*MTS*, Eden Prairie, MN). The drill was powered using a DC power supply to ensure consistency. Fresh frozen bovine femurs with an age range of 18–24 months were potted onto a custom designed testing plate, and the drill was run at full speed. The drill was lowered at a constant feed rate of 0.5 mm/s, until a unicortical hole of 10 mm depth was created. Irrigation with saline was provided between drilling cycles. In order to wear the drill bit, 100 drilling cycles were performed into the diaphyseal region of bovine femurs. Prior to this drilling procedure, and at intervals of every 25 cycles, three similar drilling cycles were performed into a Short Fibre Filled Epoxy Cortical Bone Simulator of density 1.64 g/cc, compressive strength 157 MPa and compressive modulus 16.7 GPa (*Sawbones*, Vashon, WA). The use of a material with constant and established material properties facilitated the use of these cycles to obtain data regarding the performance of the drill bit (Fig. 2).

Throughout the drilling process, data from the MTS at 60 Hz was obtained to determine the maximum force and total work required to perform the drilling. The maximum current required to run the drill was also recorded, and was used as a surrogate measure for torque. This value was normalized by measuring the maximum current and subtracting the current required to withdraw the drill bit, and dividing the difference by the withdrawal current. This allowed expression of the maximum torque as a percentage increase above the running torque of the drill. Finally, after the drilling cycles were completed, the drill bits were analyzed under a Scanning Electron Microscope (SEM), and the outer corner wear[14] on each drill bit was measured.

Two-tailed student *t*-tests were used to compare the treated drill bits to the control group, with respect to maximum force, work and normalized torque following the 100th cycle. Analysis was also performed comparing the two groups with respect to outer corner wear on SEM measurements. For all comparisons, a p-value of <0.05 was considered statistically significant. Progression of the maximum force, work, and normalized torque throughout the testing protocol was also compiled.

RESULTS

A total of 10 drill bits were tested, however, one of the thermally cycled drill bits fractured after 57 drilling cycles, secondary to a power outage in the laboratory causing the drill bit to be driven into the testing jig.

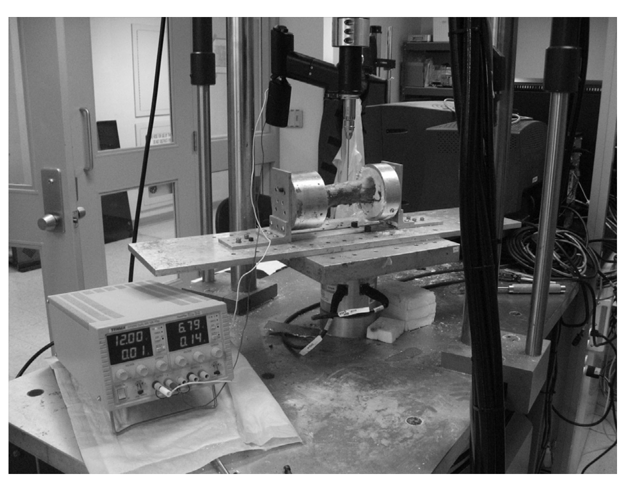

Figure 2. Photograph of experimental setup drilling into bovine diaphyseal femur.

This specimen was removed from the final analysis and comparison of the two groups ($n = 4$ thermally cycled, $n = 5$ control).

The drill bits that underwent thermal cycling showed superior performance after 100 drilling cycles compared to untreated drill bits, as measured by maximum force, work and torque. The maximum force on the thermally cycled drill bits had a mean of 62.5 N, with a standard error of the mean of 4.8 N, compared to 76.8 ± 1.4 N in the control group ($p = 0.015$, Fig. 3). The percentage torque increase above the baseline running torque required by the thermally cycled drill bits was 17.3% ± 0.9%, compared to 24.9% ± 2.5% in the control group ($p = 0.037$, Fig. 4). The drilling work required by the thermally cycled drill bits was 439 ± 39 mJ, compared to 574 ± 8 mJ in the control group ($p = 0.007$, Fig. 5).

The thermally cycled drill bits also showed superior performance to the standard drill bits upon initial drilling into the cortical bone simulator, prior to any wear. Before the first drilling cycle into bovine bone, the thermally cycled drill bits experienced less maximum force compared to the control group (36.3 ± 1.6 N vs. 42.6 ± 1.7 N, $p = 0.037$).

Under SEM, the thermally cycled drill bits showed decreased wear compared to the control group. After 100 drilling cycles, the outer corner wear on the thermally cycled drill bits measured 429 ± 27 μm, compared to 559 ± 8 μm in the control group ($p < 0.001$, Fig. 6).

DISCUSSION

The results of this study demonstrate that thermal cycling is effective in improving wear properties and increasing tool life of orthopaedic drill bits. The thermally cycled drill bits were found to have superior performance as compared to the control group with respect to all of the measured parameters.

The drilling work required reflects a surrogate measure for thermal necrosis, as it represents the amount of energy delivered from the drill bit into the bone.[10] The maximum force delivered is representative of significant load being placed on the drill bit, and a decreased maximum force indicates that the drill bit is wearing at a slower rate. The normalized torque represents the power supplied by the battery, and a decrease in the drilling torque would result in consistent drilling power and decreased need for battery changes. The thermally cycled drill bits demonstrated superior outcomes with respect to all three of these parameters, suggesting that these drill bits perform better and for longer than their non-cycled counterparts. In fact, the thermally cycled drill bits demonstrated performance after 100 drilling cycles that were similar to the performance of the standard drill bits after 25–50 cycles (Figs. 3–5). While drilling work, force and torque are influenced by many additional factors, including bone density, anatomic location, feed rate and clinical skill and experience, these are frequently beyond the surgeon's control. Thermal cycling of drill bits represents a controllable factor that can significantly improve drill bit performance and longevity throughout their life cycle.

The improved performance in the thermally cycled group is further corroborated by the SEM measurements of outer corner wear. The large differences in wear between the thermally cycled and control drill bits (Fig. 6) suggests that improved wear resistance is likely responsible for the superior mechanical performance of the thermally cycled drill bits.

The benefits of thermal cycling with respect to wear have previously been demonstrated for many automotive and industrial applications.[2,3,4] However, it is important to determine if these potential benefits could yield a clinically relevant impact for orthopaedic applications. In order to better simulate orthopaedic tool utilization, bone was employed as the drilling medium. The use of thicker and higher density of diaphyseal bovine tissue (as compared to human cortical bone) allowed more rapid wear to occur,

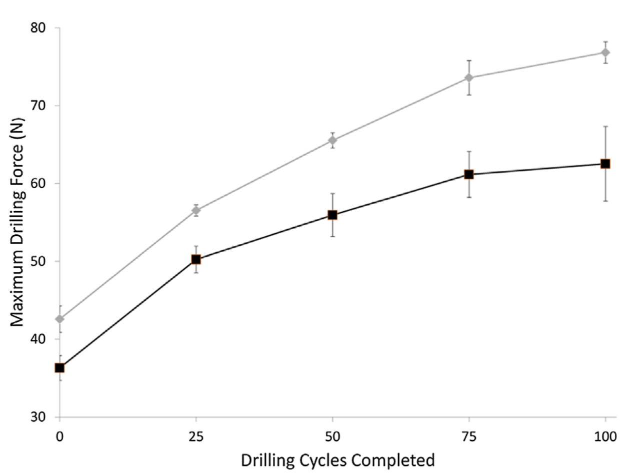

Figure 3. Comparison of maximum drilling force (mean ± standard error of the mean) versus drilling cycles completed, comparing thermally cycled drill bits (black) with controls (gray).

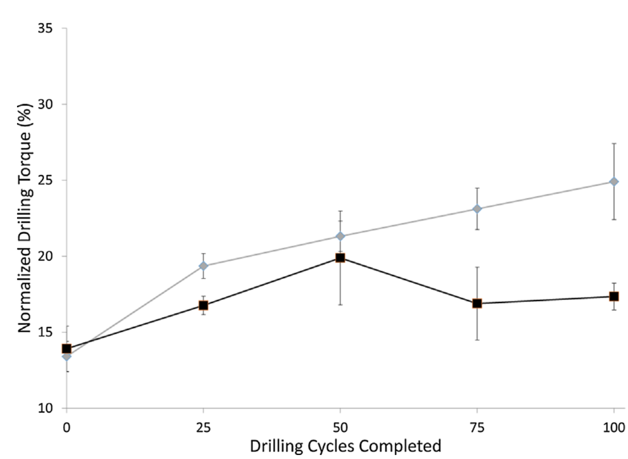

Figure 4. Comparison of normalized drilling torque (mean ± standard error of the mean) versus drilling cycles completed, comparing thermally cycled drill bits (black) with controls (gray).

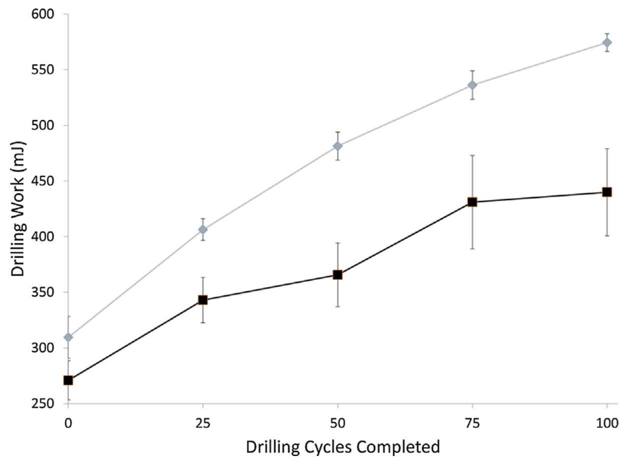

Figure 5. Comparison of drilling work (mean ± standard error of the mean) vs. drilling cycles completed, comparing thermally cycled drill bits (black) with controls (gray).

shortening the overall testing time/cycling required. However, this surface was not considered appropriate for data acquisition, due to lack of uniformity in the surface. As such, the uniform cortical bone simulator was used as the drilling surface for data collection.

This study only investigated the effects of thermal cycling on 440A stainless steel, but based on previous studies investigating the thermal cycling process, it is likely that it would be effective on other stainless steel alloys and additional metals as well.[1,3] The thermal cycling protocol would be varied slightly, based primarily on the nickel content of the metal being treated.[1]

Another unique challenge of applying the thermal cycling process for use on surgical instruments is sterility. By performing the thermal cycling process while the drill bits were still in their sterile packaging, this ensures that the treatment can still be effective without compromising the sterility of these instruments. This suggests that thermal cycling may be performed at three different points on the supply chain, without affecting sterility: Pre-manufacturing, post-manufacturing, or post-sterilization.

At our institution, 185 surgical drill bits were purchased last year, for a total cost of greater than $13,000. The majority of failures of these bits, requiring replacement, were by dulling. Reducing wear can extend the life of these tools and lower costs by delaying the need for replacement. As well, our results suggest that at any point during their life cycle, thermally cycled drill bits will demonstrate superior performance to currently utilized drill bits. This may reduce operative time and surgical frustration associated with dull instruments.

Furthermore, the dull cutting tools can cause heat generation in bone tissue leading to thermal osteonecrosis. The harmful effects of heat on bone biology is well established,[15] and thermal cycling of surgical cutting instruments has the potential to decrease heat generation and diminish disruptions to bone biology which can occur through the use of dull cutting surfaces.

This study focused solely on orthopaedic drill bits, but several other orthopaedic cutting tools fail by dulling and wear, such as reamers, saw blades and burrs. There is a role for future studies to determine if thermal cycling can reduce dulling and improve wear life and performance of these more expensive surgical cutting tools.

While this study used a small sample size, the large and consistent improvements seen in performance with thermally cycling were able to demonstrate statistical and clinical significance. It should be noted, however, that the magnitude of the performance improvement is only reflective of experiments performed in a laboratory setting using bovine bone. A study done in an operating room setting on human bone would be required to demonstrate the relative clinical value of wear reduction following the thermal cycling process for orthopaedic applications.

Overall, this study represents an important “proof of concept” demonstrating the potential of thermal cycling for orthopaedic applications. Further studies will enable a better understanding the value of this technology through testing of more complex cutting tools (such as acetabular reamers) in an operating room setting.

AUTHORS’ CONTRIBUTIONS

R.K.: Applied for and received funding, developed and executed experimental protocol, reviewed results and wrote manuscript. S.M.: Assisted with development of experimental protocol, data acquisition and interpretation and preparation of the manuscript. E.-W.: Assisted with development of experimental protocol and data acquisition. J.F.: Assisted with experimental concept and protocol, data interpreta-

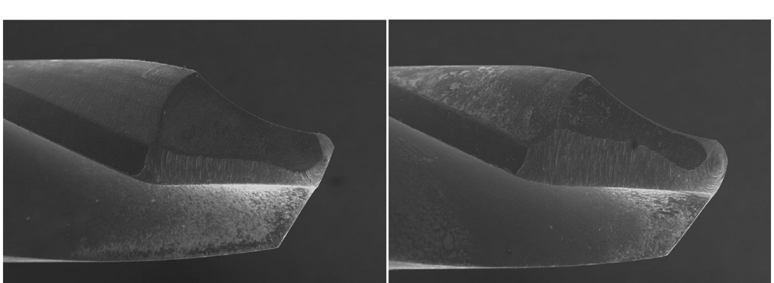

Figure 6. Scanning Electron Microscope image demonstrating outer corner wear on a thermally cycled drill bit (left) compared to a control (right) after 100 drilling cycles.

tion and edition of the manuscript. H.K.: Assisted with experimental concept and protocol, data interpretation and edition of the manuscript. C.W.: Assisted with grant application, development of experimental protocol, data acquisition and interpretation and preparation of manuscript.

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