Reprocessed Arthroscopic Shavers: Evaluation of Sharpness and Function in a Cadaver Model

CHARLES G.T. LEDONIO, MD; ELIZABETH A. ARENDT, MD; JULIE E. ADAMS, MD; JENNIFER MATZ, MS; ARIE BOERS, BS; KEITH MILLER, AB; BRUCE R. LESTER, PhD

abstract

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This study was designed to test limited arthroscopic shaver reuse following reprocessing and to compare the functional performance between new and reprocessed arthroscopic shavers in arthroscopic procedures using fresh cadaveric knees. A trial using arthroscopic procedures (meniscectomy, synovectomy, and debridements) was conducted by experienced surgeons using cadaveric knees to determine whether the surgeons could correctly identify reprocessed shavers. Thirty-nine shavers were tested; the surgeons were given both new and reprocessed shavers. Thirteen of the 39 shavers were new and 26 were reprocessed (13 of which had also been sharpened). The surgeons were asked to assess whether each shaver was new or reprocessed and to indicate whether the shaver was functional or not. Cadaveric shavers were subsequently used in an engineering test developed to measure shaver blade sharpness. Comparisons in sharpness were made between new and reprocessed cadaveric shaver blades. The success rate in identifying reprocessed shavers was determined to be 42% (11 of 26), with an upper confidence bound of 60%, demonstrating that the ability to detect a reprocessed shaver is no better than chance (50%), with a margin of error of 10% (P=.0328). In addition, engineering sharpness testing demonstrated that new and reprocessed cadaveric blades exhibit equivalent sharpness. Surgeons were unable to distinguish reprocessed arthroscopic shavers that passed acceptance tests from new shavers based on functional characteristics. This outcome is not unexpected due to the fact that engineering testing of shaver blades used in the study indicated that they exhibited similar sharpness.

Figure: Equivalence (noninferiority) for the treatment effect, which is defined as the difference ±95% confidence interval between the new and the reprocessed cadaveric shaver rotation speed, is inferred if the treatment effect is less than the zone of clinical indifference (rotational speed and variation for new shavers).

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The authors are from the Department of Orthopaedic Surgery (CGTL, EAA, JEA), University of Minnesota, Minneapolis; the Department of Biostatistics (JM), North American Science Associates Inc (NAMSA), Minneapolis; and the Department of Engineering (AB) and the Department of Research and Development (KM, BRL), Sterilmed, Inc, Maple Grove, Minnesota.

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Correspondence should be addressed to: Bruce R. Lester, PhD, Department of Research and Development, Sterilmed, Inc, 11400 73rd Ave N, Maple Grove, MN 55369 (blester@sterilmed.com).

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Arthroscopic shavers are used to debride joint spaces as a therapeutic measure or in preparation for reconstructive surgery. In the knee, they are used to treat internal derangements of the knee, such as meniscal tears, and can be used in preparation for anterior cruciate ligament reconstruction. As a result, arthroscopic shavers have become one of the key instruments in the successful performance of minimally invasive arthroscopic surgery. Arthroscopic shavers comprise a control unit, a handpiece with connecting cable, and a single-use disposable blade. The blade, as a single-use device, is designated by the manufacturer for use on a single patient during a single procedure. Arthroscopic shaver blades are typically a disposable item intended for 1-time use and then discarded. Interest has focused on reusing items to avoid medical waste and to decrease costs.

The cost of single-use devices has contributed to the increasing cost of medical procedures. Reprocessing of a broad range of single-use devices has been widely practiced; studies have shown that substantial savings can be achieved if single-use devices are reprocessed and reused. Reprocessing provides hospitals, surgery centers, and patients with an important cost-saving alternative to the exclusive purchase of new single-use devices. As of 2000, the US Food and Drug Administration (FDA) considers all reprocessing companies to be original equipment manufacturers (OEM) and, as such, they are regulated like OEM. The FDA requires premarket submissions for single-use devices based on the device’s Code of Federal Regulation (CFR) classification. The submitted documentation, 510(k), must show that the subject reprocessed device is substantially equivalent to the OEM device already on the market with respect to both safety and efficacy. All regulatory requirements have increased, the practice of reprocessing single-use devices has shifted from hospitals to specialized reprocessing companies.

Third-party reprocessors have provided an alternative to the sole use of new devices, leading to substantial savings for the end user (in most cases a 50% reduction in the cost of specific devices), and a lowering of aggregate health care costs. Few published studies evaluate reprocessed single-use arthroscopic shavers; however, controversy exists as to their functionality and sharpness. To test the feasibility of limited reuse of disposable arthroscopic shavers, the current study compared functional performance between new and reprocessed arthroscopic shavers in arthroscopic procedures using fresh cadaveric knees. Specifically, tests were devised to ascertain whether reprocessed shavers could be differentiated from new devices and to ensure that shaver blades were functional after reprocessing. The specific hypothesis to be tested concerning identification of reprocessed shaver blades was that surgeons would be able to correctly identify the reprocessed shavers a significantly greater percentage of time (P) than they would have by sheer random chance (ie, 50%). The alternative hypothesis was that the ability of surgeons to determine whether shavers used clinically were reprocessed is essentially random (ie, analogous to a coin toss: 50/50). In addition, blade sharpness, determined by engineering tests, between new and reprocessed arthroscopic shavers using fresh cadaveric knees was compared.

**Materials and Methods**

The current study involves 2 assessments of the orthopedic shaver blades: (1) an evaluation of the clinical performance of new and reprocessed shavers using cadaveric knees, and (2) an empirical examination of the engineering performance of blade sharpness using bovine reconstituted tissue cylinders to measure the sharpness of selected orthopedic shavers.

The cadaveric experiments were designed to determine whether reprocessed shavers could be correctly identified by surgeons and to rate the functional performance of shavers. This ex vivo clinical study was blinded (ie, whether the shavers were new or reprocessed was unknown to the surgeons).

The engineering experiments were designed to evaluate and define the sharpness of orthopedic shavers using objective cutting characteristics exhibited in a tissue model. Shaver categories included devices that were (1) sharpened using computer numeric controlled sharpening machines, (2) judged to be acceptably sharp during routine inspection, (3) judged to be unsharp during routine inspection, and (4) purposefully dulled using a grinding tool. New, unused Aggressive Plus (Stryker, Kalamazoo, Michigan) shaver blades were used as controls.

Finally, the actual sharpness of the Aggressive Plus and Tomcat (Stryker) shaver blades used in the cadaveric study was compared using the engineering sharpness test criterion to determine the empirical sharpness of shavers used in the cadaveric study.

**Cadaveric/Clinical Evaluation**

The reprocessed shavers consisted of devices that had been previously used as a single-use device and then subsequently underwent the reprocessing procedure described below. All reprocessed devices were subjected to routine inspection procedures that included both visual inspection and functional testing, and all devices used in this study successfully passed this assessment.

Shaver performance was evaluated during arthroscopy on cadaveric knees with typical medial and lateral portals and superolateral outflow portals. Meniscal tears were created using scissors or blades. Clinical competences of the shavers were assessed by having 3 orthopedic surgeons (C.G.T.L., E.A.A., J.E.A.), who were blinded to the shaver status, perform arthroscopy of the knee. The specific procedures performed were listed on an evaluation form. The procedures con-
sisted mostly of partial meniscectomy with occasional partial removal of the anterior cruciate ligament and partial synovectomy. The form requested an evaluation of the shavers as to whether they were new or reprocessed. Shavers that could not be confidently placed in either the new or reprocessed category were judged as indeterminate. In addition, the shaver was assessed as to whether it functioned effectively to complete the procedure and, if not, what its failure mode was. Failure modes included: shaver was not sharp, shaver did not effectively work in hand-piece, observed metal shavings, and any other failure the surgeon noted.

**Engineering Evaluation**

Bovine reconstituted tissue cylinders were used to measure the sharpness of orthopedic shavers. Selected Stryker arthroscopic shavers were connected to an iron core DC brushed motor (model EF35-T1N1; Canon Precision, Inc, San Jose, California), which was set to a fixed torque depending on preselected current and voltage. The drive hub from a Stryker handpiece was modified to connect the test shaver blades to the DC motor. Only Stryker shavers were used as test devices in the current study due to this fact, and because they represent the broadest and most representative orthopedic shaver types currently reprocessed. The motor was driven by a current-limiting power supply at a fixed current, resulting in a constant torque. By altering the voltage, the speed of rotation was adjusted. The voltage selected was such that the rotational speed of the shaver blade was close to a typical clinical rate of rotation (approximately 3000 rpm [50 rps×60 s/min]). The shaver arm was mounted on an MTS Mini Bionix 858 load frame (MTS Systems Corp, Eden Prairie, Minnesota) and set to a specific descent rate (0.42 mm/s or 1 inch/minute) through the tissue cylinder. A vacuum pump (model 130; Schuco-Vac, Toledo, Ohio) was attached to the shaver and the deionized water in which the tissue cylinder was immersed was drawn through the shaver. The shaver speed of rotation at the specified current and voltage approximately matched the ability of the sharpest (ie, new) shaver blade assembly to remove tissue from the cylinder without altering the rotational speed. Decreases in the shaver blade sharpness resulted in the inability of the DC motor to maintain rotational speed due to the blade assembly not being able to cut and remove tissue at an adequate rate for the downward speed of the load frame. The duller the blade, the slower the motor turned until, with a sufficiently dull blade, the motor stopped. The rotational speed (Hz) of the shaver motor was compared with the duration (in seconds) of the movement of the load frame beam as it propelled the shaver blade through the tissue cylinder. The resulting data were plotted, and the least-squares slope of the resulting curve was determined. Blade sharpness data that yielded slopes close to 0 indicated that the blade exhibited maximal sharpness, whereas greater negative slopes indicated that the blade was unable to maintain rotational speed due to an inability to cut and remove tissue as the blade proceeded through the tissue cylinder. **Figure 1** illustrates the shaver apparatus and the type of tissue cuts obtained by representative shavers at various sharpness levels.

**Cadaveric Shaver Blades**

A series of new and reprocessed shaver blades from Smith & Nephew (Andover, Massachusetts) and Stryker were assembled. Ex vivo studies used 39 arthroscopic shavers, including 13 new devices, 13 reprocessed devices that had been sharp-
Reprocessed Devices. The reprocessed orthopedic shaver blades used in the current study were from Stryker and 1 was from Smith & Nephew. The Stryker blades included 4 Aggressive Plus blades (model 275-544-000) and 5 Tomcat blades (model 275-545-000). The Smith & Nephew blade was the Full Radius (model 7205305) (n=4). New devices that had not previously been used were removed from their original packaging and labeled with a random number, similar to what was done with the reprocessed devices, to keep their identity from the surgeon.

Reprocessing and Inspection Procedures

The reprocessing cycle included preliminary decontamination at the hospital after usage, collection, shipping, sorting, and preinspection of incoming devices. Devices were then presoaked in an enzyme detergent and processed in a 40-kHz ultrasonic cleaner (Crest Ultrasonics Corp, Trenton, New Jersey) as a preliminary step prior to a defined multisonic cleaning procedure, which has been previously described. After cleaning, the toothed shavers were inspected. Shavers that passed inspection were considered to be sufficiently sharp enough to proceed through the other steps in inspection, whereas those that exhibited evidence of blade wear were sharpened using the Techno CNC Machine. Sharpened shavers were again inspected under 10x magnification and deburred and polished with abrasive glass beads (model 3024; Cyclone Blasting Systems, Dowagiac, Michigan). The devices, sharpened and unsharpened, that passed inspection based on acceptance criteria were examined with an optical comparator (model HE350; Starrett Precision Optical Ltd, Athol, Massachusetts) and subjected to a final ultrasonic cleaning before being placed in a drying chamber. Dried devices were inspected to ensure that they were clean and free from stains, rust, corrosion, foreign debris, cuts, gouges, scrapes, dents, defects, pitting, physical abnormalities, and other damage, including nicks in the blade, hub cracks, and missing teeth. They were then checked for shaft alignment, function tested (which included shaft rotation and blade sharpness), marked as being reprocessed, lubricated, and packaged. Before ex vivo performance testing on the cadaveric knees, all shavers underwent Sterilmed’s validated sterilization procedure (ANSI/AAMI/ISO 11135-1:2007) with a sterility assurance limit of 10^-6 (ie, less than 1 chance in 1,000,000 that viable microorganisms are present in the sterilized article).16

Ex Vivo (Cadaveric) Performance Testing

Seven human cadaveric knee specimens were used for these experiments. The cadaveric knees were obtained from the University of Minnesota Medical School Anatomy Bequest Program. After completion of testing, the knees were returned to the Bequest Program. Knees were harvested from unembalmed cadavers that had not had prior knee surgery. The fresh human knees were obtained from donors 37, 60, 62, 72, 81, 81, and 97 years old. The legs were clamped in a stand, holding the femur securely and allowing the leg to hang suspended. A standard arthroscopic setup was used, with the joint bathed in Ringer’s solution. The Ringer’s solution was supplied by gravity flow, with the supply source elevated 3 feet above the knee joint. The arthroscopic generator was attached to a vacuum line, which evacuated fluid from the joint at a rate equivalent to the gravity inflow (450 mm Hg). An arthroscopic examination was performed to ensure the knees had no tears of either the medial or lateral meniscus. Using standard arthroscopic portals, a 5-mm, 30° arthroscope (Linvatec Corp, Largo, Florida) was inserted into the joint, and a diagnostic arthroscopy was performed to confirm the absence of pathology. A small arthroscopic punch was inserted through the appro-
appropriate portal, and several vertical and radial cuts were created on both menisci of each knee. Procedures included 28 partial meniscectomies (1 posterior and 1 midradial tear on each knee/both sides), 5 synovectomies, 3 posterior cruciate ligament excisions, and 4 anterior cruciate ligament excisions. All surgeons (C.G.T.L., E.A.A., J.E.A.) were orthopedic surgeons with advanced training in the use of the arthroscope and who used arthroscopic procedures in their clinical practice. At the time of the study, the senior surgeon (E.A.A.) had more than 20 years of experience in knee and arthroscopic surgery, another surgeon (J.E.A.) was a fellowship-trained hand and upper extremity surgeon with 3 years of clinical practice experience, and another surgeon (C.G.T.L.) was a research associate with a clinical fellowship in shoulder surgery and 1 year of clinical practice experience in sports medicine and general orthopedics.

Each surgeon used new, reprocessed/sharpened, and reprocessed/unsharpened shavers from 1 of the 3 specific models. Each surgeon evaluated the shavers from a single model to ascertain whether the shaver employed was new or reprocessed. Shavers were assigned identification numbers using a random number generation program and were provided to the clinician in a blinded manner.

The Stryker shavers were inserted into either a Stryker SE4 handpiece attached to an SE4 generator or a Stryker SE5/TPS handpiece attached to an SE5 generator. Both generators were set to oscillate at approximately 1800 rpm. The Smith & Nephew shaver was inserted into a Dyonics/Smith & Nephew EP1 handpiece attached to an EP1 generator set to oscillate at approximately 2000 rpm. To control for manufacturer device variables, each surgeon used shavers of a single make and model to perform the procedures.

**Statistical Analysis**

Fisher’s exact test was performed using the data on the ability of surgeons to determine whether a particular device was new or reprocessed (Table 1). The null and alternative hypotheses were:

- $H_0$: $P > 50% + \delta$
- $H_A$: $P \leq 50% + \delta$

$P$ is the proportion of reprocessed shavers that are correctly identified, a 50% threshold was chosen to compare the success rate to chance, and $\delta$ is the margin of error. If the 95% exact 1-sided upper confidence bound for $P \leq 50% + \delta$, the authors concluded that the success rate in detecting reprocessed shavers was no better than chance.

For the engineering/sharpness study, the authors tested for the noninferiority of the sharpness of a reprocessed shaver blade compared with the sharpness of a new blade. The noninferiority hypothesis was:

- $H_0$: New blade sharpness-reprocessed blade sharpness $\geq \delta$
- $H_A$: New blade sharpness-reprocessed blade sharpness $< \delta$

The null hypothesis implies that new blade sharpness was strictly superior to reprocessed blade sharpness versus reprocessed blade sharpness was not inferior to the new blade sharpness under the alternate hypothesis. The boundary $\delta$ is the noninferiority margin of 3 SD.\textsuperscript{17,18}

**RESULTS**

**Surgeon Assessment of Shaver Identity**

Table 1 is a contingency table comparing the actual identity of the shaver (ie, new or reprocessed) used in the cadaveric meniscectomy-type procedures with the consensus ratings by the 3 surgeons as to the
perceived shaver identity. Surgeons were given the option of deciding whether the shaver being used was new or reprocessed. If a determination could not be made, the shaver identity was rated as indeterminate. The success rate in identifying reprocessed shavers was 42% (11 of 26), with an upper 95% confidence bound of 60%, demonstrating that the ability to detect a reprocessed shaver is no better than chance, with a noninferior margin of 10% ($P=0.0328$).

In addition, the observed proportion of reprocessed shavers classified as reprocessed (42%) was less than the observed proportion of new shavers classified as reprocessed (54%). This result did not achieve statistical significance due to the limited sample size (10% power by post-hoc power analysis).

**Functionality Rating**

Three reprocessed shavers and 2 new shavers were judged by the surgeons to be unable to effectively complete the procedure. Lack of sufficient sharpness was given as the reason for both of the new shavers and 2 of the reprocessed shavers, with 1 sharpened and the other unsharpened. The third reprocessed shaver unable to effectively complete the procedure exhibited too much vibration. Within each category of shaver (new, reprocessed/sharpened, and reprocessed/inspected), the proportion of shavers that surgeons believed to be functional was identical (11 of 13, 84.6%).

**Engineering Tests of Shaver Sharpness**

Table 2 shows the slopes of the sharpness tests conducted on both engineering and cadaveric shavers exhibiting various sharpness states. Large negative values are indicative of dull shaver blades, whereas small negative slope values are characteristic of shaver blades that are sufficiently sharp so that their rotational speed is not decreased appreciably when the turning shaver blades are fed through the tissue cylinder by the load frame.

The treatment effect shown in Figure 3 is the difference ±95% confidence interval (CI) between the mean slopes of new versus reprocessed cadaveric shavers. This treatment effect is considered noninferior if the upper bound of the 95% CI for the difference is less than 3 SD.$^{18}$

**DISCUSSION**

The functionality of reprocessed orthopedic shavers has been examined because they are a relatively expensive medical device that can easily be reprocessed. The comparative functional performances between new and reprocessed single-use electrophysiology as well as ultrasound catheters have recently been examined.$^{19,20}$ These studies have concentrated on the durability and functionality, both mechanical and clinical, of reprocessed devices. These and other studies have uniformly concluded that single-use devices can be successfully reprocessed by using a program of rigorous visual inspection combined with mechanical and functional testing.$^{1,4,21-26}$

To date, no known studies in the literature compare the clinical functionality and sharpness between new and reprocessed shavers during knee arthroscopic procedures, making the current study unique. Comparisons between the current study and previous studies are diffic-
ult to make primarily because previous studies expressing concern regarding the reuse of orthopedic shavers have noted decreased blade sharpness, the presence of biological debris, and potential shaver structural damage with reprocessing.\(^1\)\(^2\)\(^3\)\(^4\) Both reports noted that the structural and functional conclusions drawn could not be extended to actual clinical consequences. For example, blade sharpness was examined by comparing photomicrographs of stained meniscal tissue cut surfaces. Cut surfaces that showed straight edges were judged to have been cut with sharper shaver blades; however, it was not clear how meniscal tissue was actually cut during the blade sharpness test because no mention was made of the use of a shaver generator or the experimental setting for the blade usage (ie, whether shavers were used in a standard clinical manner).

In addition to meniscal surface smoothness after cutting, shaver blade sharpness was assessed by noting visible blade damage.\(^5\) Blade damage was illustrated by silhouette profiles of reprocessed or new shaver blade teeth. Comparative tooth abnormalities between new and reprocessed shavers were shown, with marked damage noted on reprocessed shavers. The authors noted that it was unknown how many times the reprocessed blades had been reprocessed because they were not marked as being previously used. Since 2000, the FDA has required that reprocessed devices be “clearly marked to identify the number of reprocessing uses.”\(^6\) Therefore, it is likely that the devices examined may have predated the FDA’s regulations.

The second article reporting structural damage to reprocessed arthroscopic shaver blades was conducted in Japan, where third-party reprocessing is not regulated as it is in the United States.\(^7\) The report notes that the shavers were reprocessed in the hospital by third-party technicians. The technicians used hospital equipment for cleaning and sterilization. In addition, technicians apparently conducted no functional inspection, nor did they use validated reprocessing protocols required by the FDA.

Previous reports noting structural arthroscopic blade deficiencies\(^8\) and lack of blade sharpness\(^9\) most likely used arthroscopic blades that were not subject to FDA requirements concerning proof of safety and effectiveness because they were from a country not subject to these requirements\(^1\)\(^0\) or because the devices predated the FDA’s issuance of guidance requiring documentary proof of device competence.\(^1\)\(^1\)

### Cadaveric Study

**Shaver Classification.** One of the primary purposes of the current study was to determine whether orthopedic surgeons, after performing partial meniscectomies on cadaveric knees using both new and reprocessed shavers, were able to identify and separate the reprocessed shavers from the pool of new and reprocessed devices used for the procedures. Initially, the authors posed the hypothesis that orthopedic surgeons were able to correctly identify the reprocessed shavers after clinical usage.

The specific null hypothesis was that the surgeons correctly identified the reprocessed shavers a significantly greater percentage of time (P) than they would have by sheer random chance (ie, 50%). Fisher’s exact test of the data showed that at a 42% (11 of 26) success rate with an upper confidence limit of 60%, the surgeons’ ability to detect a reprocessed shaver was no better than chance, with a margin of error of 10% (P=0.0328) (Table 1).

**Reprocessed Shaver Qualification.** Reprocessed devices used for the ex vivo cadaveric study were randomly drawn from a pool of standard reprocessed arthroscopic shavers that had undergone routine inspection. Shavers were assigned identification numbers using a random number generation program and were provided to the clinician in a blinded manner. Devices that could not pass the visual or functional acceptance criteria established by the reprocessor were rejected. The only physical modification of the shaver devices involved the sharpening of the toothed blade surfaces when it was deemed necessary for functional competence. In addition, all devices were tested by subjecting them to the shaver generator self-test procedure.

**Engineering Sharpness Testing: Comparison With Cadaveric Study Shavers**

A common complaint by orthopedic surgeons concerns the lack of blade sharpness for reprocessed orthopedic shaver blades. The authors undertook studies to attempt to establish an engineering definition for shaver blade sharpness and to use this definition to compare the sharpness of new and various reprocessed Stryker shaver blades. After having established this sharpness criteria, the authors sought to compare the sharpness of new and reprocessed, sharpened and accepted, Stryker shaver blades used in the cadaveric partial meniscectomy studies. The data presented in Table 2 show a marked difference in the blade rotation slope among the various categories of shaver blades. Dulled shaver blades showed the steepest negative slope (-4.39 Hz), indicating that after penetrating approximately 4 mm into a 25-mm tissue cylinder, the blades had stopped turning. Rejected blades had the next steepest negative slope (-0.50 Hz), indicating that their rotational speed had decreased by over half after penetrating approximately 20 mm into the tissue cylinder. New blades, reprocessed blades classified as acceptable after inspection, or reprocessed-sharpened blades exhibited essentially identical behavior and showed almost no decrease in rotational speed after traversing a 25-mm tissue cylinder (-0.01 Hz). The initial rotational speed for all treatments was 48 Hz.

Using these sharpness values, the authors examined the Stryker shaver blades (Aggressive and Tomcat) used in the cadaveric partial meniscectomy test. The authors wanted to compare the new shav-
ers with the reprocessed shavers, both accepted and sharpened, as to their relative sharpness. As with the clinical assessment of the reprocessed shaver blades, they used a noninferiority experimental design in which they identified a zone of clinical indifference such that differences between new and reprocessed shavers within that zone were deemed irrelevant (Figure 3).

The zone of clinical indifference that sets the superiority/inferiority margins in Figure 3 is defined as ±3 times the SD of the mean slope for shaver cutting using new (Aggressive) and sharpened (Tomcat) devices. The zone of indifference uses the 3 sigma rule, which states that for a normal distribution, essentially all relevant values lie within 3 SD of the mean. Points that fall more than 3 SD from the mean are likely outliers and are therefore deemed to be measurement errors. This zone of indifference encompasses the normal variation in sharpness exhibited by new and sharpened Stryker shavers; therefore, its range or expanse provides a natural boundary for acceptable shaver blade sharpness.

Because the difference in slopes (ie, treatment effect) between new and reprocessed cadaveric shavers (Figure 3) is small, contained within the zone of clinical indifference and the 95% CI crosses 0, indicating no difference was found, the authors can conclude that the new and reprocessed cadaveric shavers are equivalent to a clinically acceptable degree. In addition, the new and reprocessed cadaveric shaver blades exhibited an almost identical small reduction in shaver rotational slope in the sharpness test (Table 2).

Limitations of the current study include possible variations between the 3 surgeons’ skill sets and the variability of the cadaveric menisci from specimen to specimen. The results suggest that actual shaver blade sharpness may not be a significant factor contributing to the success or failure of meniscectomy-like procedures. A further limitation of the current study is the age of most of the cadaveric knees. Six of the 7 specimens were 60 to 97 years old. Older menisci may not need sharp blades to complete the arthroscopic task; young menisci may have yielded different results in this study design.

No histological examination of meniscal cuts was performed; however, it is unclear whether microscopic assessment of smoothness on cut meniscal tissue has any bearing on clinical outcome. The hypotheses examined in this study are intended to illustrate the degree to which the authors are able to show the similarity of the new and reprocessed shavers, not a priori success criteria.

**CONCLUSION**

The ex vivo clinical data show that the ability to detect a reprocessed shaver is no better than chance, with a margin of error of 10% (P=0.0328). These data, in association with visual and functional inspection and shaver blade sharpening used to qualify reprocessed arthroscopic shaver blades as ready for a subsequent use, are sufficient to ensure that acceptable shaver blade clinical performance is achieved. This finding is not extraordinary because subsequent engineering sharpness testing shows that both new and reprocessed cadaveric blades exhibit noninferior sharpness.

Lowering medical device costs is one way in which institutions can help reduce the current burden of health care costs. The current study suggests that in the assessment of the sharpness and function of arthroscopic shavers, surgeons were unable to differentiate between new and reprocessed shavers, primarily because there is likely no actual measurable difference in blade sharpness. With current FDA regulations and appropriate reprocessing, the reuse of arthroscopic shavers offers cost benefits to hospitals (an average 50% reduction in device cost), without impacting device effectiveness.

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