Assessment of Reprocessed Arthroscopic Shaver Blades

Jonathan S. King, M.D., Marilyn M. Pink, Ph.D., and Christopher M. Jobe, M.D.

Purpose: The purpose of this study was to evaluate the level of contaminants on, as well as the quality of, reprocessed shaver blades. **Methods:** We assessed 7 new shaver blades and 27 shaver blades that had been reprocessed with mechanical cleaning, functional testing, and sterilization with ethylene oxide. A spectrophotometer measured the amount of nucleic acid and protein. The blade quality was assessed by photographing the blades with magnification and determining the percentage of damage present on each blade. A subset of shaver blades were then used to cut meniscal tissue, and the cut surface was measured for smoothness by image processing and automated laser scanning cytometry. In evaluation of the meniscus, for the subset of shavers, an image processing value of 1 indicates a smooth, straight line, and values lower than 1 reflect deviations in the cut surface (the closer the value is to 1, the smoother the surface). Laser scanning cytometry values indicate the percentage of irregularities in the cut surface (the lower the value is, the smoother the surface). **Results:** Of the 27 reprocessed shaver blades, 13 (48%) had detectable levels of protein and 17 (63%) had detectable levels of nucleic acid. On the reprocessed shaver blades, protein levels ranged from 2.43 μg to 60 μg and nucleic acid levels ranged from 0.40 μg to 3.5 μg. No new shaver blade had contaminants. Twenty reprocessed shaver blades had been manufactured with teeth and could be evaluated for visible damage. Of these, 10 had 1% to 25% damage, 5 had 26% to 50% damage, 3 had 51% to 75% damage, and 2 had 76% to 100% damage. The new blades had no visible damage. Image processing revealed smoothness of the surface cut with new shaver blades, yielding values of 1 ± 0.12, whereas the values for reprocessed shaver blades ranged from 0.62 ± 0.02 to 1 ± 0.07. Laser scanning cytometry values ranged from 3.3% to 7.1% for the new blades as compared with 5.8% to 20.0% for the reprocessed blades. **Conclusions:** Of the reprocessed shaver blades, 48% had detectable levels of protein and 63% had detectable levels of nucleic acid. All of the reprocessed blades visually evaluated showed some level of damage or wear, whereas no new blade had such damage. In addition, menisci cut with reprocessed shavers showed rougher edges than did menisci cut with new shavers. **Clinical Relevance:** To make an informed decision regarding the use of reprocessed shaver blades, surgeons will want to know the level of contamination on, and the quality of, reprocessed shaver blades. **Key Words:** Shavers—Nucleic acid—Laser scanning cytometry.

The modern era of managed care has brought about many changes in medicine. In response to economic pressure to lower costs, medical device reprocessing companies have developed a nationwide market for reprocessing and resale of single-use surgical instruments. A wide spectrum of devices are currently being reprocessed. They include orthopaedic shaver blades, burs, saw blades, and drill bits, as well as instruments used in cardiovascular surgery, laparoscopy, endoscopy, and ophthalmology. The average surgical center would save 25% each year on arthroscopic shaver blades if each blade were used twice.

These companies adhere to Food and Drug Administration (FDA) standards of resterilization and quality control and assert that they are able to provide shaver blades that are as safe and effective as new blades. As of 2002, the reprocessing companies are considered

From the Department of Orthopaedic Surgery, Loma Linda University, Loma Linda, California, U.S.A.

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Address correspondence and reprint requests to Christopher M. Jobe, M.D., Department of Orthopaedic Surgery, Loma Linda University, East Campus, 11406 Loma Linda Dr, Suite 218, Loma Linda, CA 92354, U.S.A. E-mail: cjobe@mac.com

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manufacturers and must submit their protocols for reprocessing to the FDA. The FDA has the authority to inspect the procedures and the reprocessed equipment. The protocols for reprocessing are varied. Many include mechanical cleaning, functional testing, and ethylene oxide sterilization.[1]

There has been no previous study published in the orthopaedic literature evaluating the level of contamination or quality of reprocessed blades. The presence of contaminants would certainly raise concerns about the transmission of microorganisms. The purpose of this study was to describe the level of residual contaminating nucleic acid and protein and the quality of reprocessed shaver blades. Further study would be required to determine whether the presence of such material poses any clinically significant risk of infection to patients.

METHODS

Dyonics (Smith & Nephew, Andover, MA) provided 7 new shaver blades and 16 reprocessed Dyonics shaver blades for use in this study, which comprised set 1. They were of different models and were obtained from 4 different reprocessing companies. All sterile wrapping was intact, with no obvious breaches of quality. In addition, we purchased 11 reprocessed shavers from local hospitals to be used as an additional set to test for contaminants and blade quality, which comprised set 2. All shaver blades were reported by the reprocessors to have been mechanically cleaned, functionally tested, and then sterilized with ethylene oxide. Because of the lack of a tracking system, there is no way to determine the type of tissue or the time period for which the shaver blades were used. Nor could it be determined how many times the blades had been reprocessed. All shaver blades were assigned a random number to prevent the data collection from being biased toward the new blades. Each sterile blade was unwrapped in a sterile laminar flow hood and separated into the outer and inner blades.

Contaminants

For this portion of the study, we used 27 reprocessed shaver blades, 3 new shaver blades, and 1 used but not reprocessed blade. The 27 reprocessed blades and 2 of the new shaver blades (negative controls) were sequentially dipped for 1 hour each at room temperature (22°C) in a sterile tube containing 500 μL of wash buffer (10-mmol/L Tris, 100-mmol/L sodium chloride, and 0.1% Tween-20 in distilled water). The optical density at A_{260}-, A_{280}-, and A_{320}-nm wavelengths of the resulting solution were measured on a Beckman DU 640 spectrophotometer (Beckman Coulter, Fullerton, CA).

The third new shaver blade was used as a positive control by placement in a solution of 1 μg/mL salmon sperm deoxyribonucleic acid and 1 mg/mL bovine serum albumin (as a source of protein) for 1 hour at room temperature. One shaver that was used but not reprocessed was obtained from the surgical suite. After use, the shaver was rinsed in sterile saline solution, wiped dry, and placed in a plastic bag, and it was used as an additional positive control. The positive control shaver blades were allowed to dry for 1 hour and were

TABLE 1. *Residual Nucleic Acid and Protein Detected on Shaver Blades*

	Reprocessed Shaver Blades		New Shaver Blades	
	Nucleic Acid* (Total μg)	Protein† (Total μg)	Nucleic Acid* (Total μg)	Protein† (Total μg)
Set 1				
	ND	ND	ND	ND
	ND	ND	ND	ND
	0.40	ND		
	0.134	ND		
	0.19	6.8		
	0.43	114		
	ND	ND		
	0.21	46.4		
	0.38	39.8		
	ND	ND		
	ND	ND		
	ND	ND		
	0.16	ND		
	ND	ND		
	0.2	ND		
	ND	ND		
Set 2				
	1.39	8.6		
	1.20	7.8		
	ND	ND		
	0.76	2.43		
	0.89	4.36		
	1.11	10.3		
	1.38	9.8		
	1.14	6.1		
	1.36	8.9		
	ND	ND		
	1.19	4.75		

Abbreviation: ND, none detected.
*Total micrograms of nucleic acid detected on blade surface (calculated from optical density measurement).
†Total micrograms of protein detected on blade surface (calculated from optical density measurement).

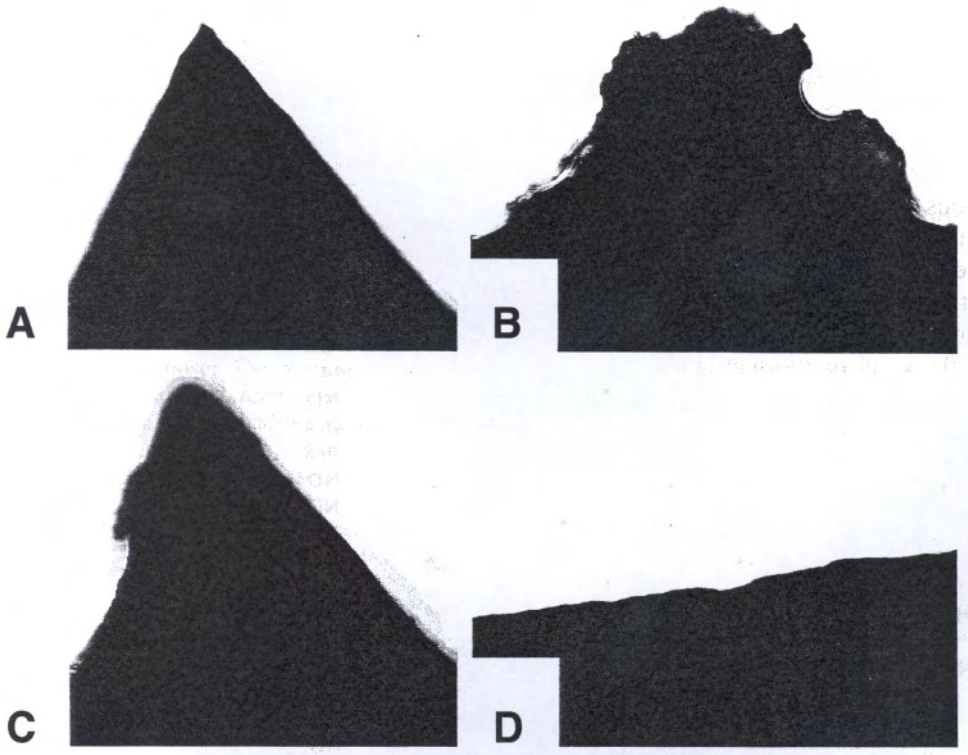

FIGURE 1. Representative images of new and reconditioned shaver blades. The composite compares the smooth edges of new shaver blades with the edges of the reprocessed blades in this study. Included are images from (A) a new shaver blade (No. 18), (B) the shaver blade in the worst condition (No. 11), (C) a reconditioned shaver blade (No. 5), and (D) a reconditioned straight blade (No. 1). (Original magnification ×20.)

then washed as described later for the experimental blades.

The optical density values were used to calculate the amount of nucleic acid and protein washed off of the blades. The values were recorded as total micrograms of nucleic acid. Protein (in milligrams per milliliter) was calculated according to the Warburg formula as follows:[3]

$$\text{Protein [mg/mL]} = (1.55 \times [A_{280} - A_{320}] - 0.76 \times [A_{260} - A_{320}])/2 \times 10^{-3}.$$

Quality

Shaver Blades

The shaver blades were photographed with an Olympus IX-70 optical base (Scientific Instruments, Temecula, CA) equipped with long working distance objectives and a C-mount analog color camera (Oly-750; Scientific Instruments). The randomized shaver blades were photographed with images of the teeth from the inner and outer blades taken at 4×, 10×, and 20× magnification. Each tooth was assessed for damage, with any visible imperfections being recorded. The total number of teeth per blade was noted, and the percentage of the shaver blade damaged was scored as follows: 0%, 1% to 25%, 26% to 50%, 51% to 75%, or 76% to 100%. Seven blades had straight blades; however, there were no new straight blades used for comparison. Therefore the reconditioned straight blades were not assessed by this criterion.

Cut Tissue

Meniscal tissue was obtained from sheep that were euthanized under an approved protocol for other purposes. Meniscal tissue was removed within 1 hour of euthanasia. The tissue was sectioned and was cut with the randomly numbered shaver blades from set 1. The side opposite (180°) the cut surface was marked with a suture for reference. The cut pieces were placed in labeled jars that contained 70% ethanol. The ethanol-fixed cut meniscal tissue was paraffin-embedded, sectioned at 5 μm, and placed in duplicate on microscope slides.

Image Processing: One set of 5-μm-thick sections from each shaver blade from set 1 was stained with H&E and photographed for use in the image processing assessment of cut surface smoothness. A line profile application was used to obtain parameters of the best-fit line to the cut surface. Values of 1 indicate a straight line (i.e., a smooth surface). Values lower

than 1 reflect deviations (or "jaggedness") in the cut surface relative to a straight line.

Laser Scanning Cytometry: Duplicate 5-μm-sections from each shaved meniscus were fluorescently stained by a modified Fluoro-Jade technique.[3] In brief, the paraffin sections were fixed in 70% cold (−20°C) ethanol for 10 minutes, rinsed once in phosphate-buffered saline solution, and transferred to Fluoro-Jade solution (100 mg in 0.1% acetic acid; Pierce Chemical) for 20 minutes at room temperature (22°C). The labeled slides were rinsed 3 times in phosphate-buffered saline solution and counterstained with propidium iodide (5 μg/mL) (Molecular Probes, Eugene, OR) to stain the nuclei red. The fluorescently stained meniscal tissue was scanned on the laser scanning cytometer (CompuCyte, Cambridge, MA)[4] for cut surface smoothness comparisons. The laser scanning cytometer had an Olympus BX50 base (Scientific Instruments) configured for epi-illumination with argon, helium-neon, and violet excitation lasers. To measure the tissue smoothness, a scanning protocol was designed to acquire an x, y map of the fluorescent signal.

The cut surface smoothness was measured by use of computer-generated lines that divided the bulk of the tissue from the cut surface. Values were expressed as the percentage of tissue outside of the computer-generated lines (or percentage of irregularities); thus the smaller the value is, the smoother the surface.

RESULTS

Contaminants

Of the 27 reprocessed shaver blades, 17 (63%) had detectable levels of nucleic acid and 13 (48%) had detectable levels of protein (Table 1). On the reprocessed shaver blades, nucleic acid levels ranged from 0.4 μg to 3.5 μg and protein levels ranged from 2.43 μg to 60 μg.

The levels of nucleic acid and total protein were 0.4 μg and 0.35 μg, respectively, for the positive control. For the used but not reprocessed blades, these values were 4.76 μg and 53.8 μg, respectively. The 2 new blades had no detectable protein or nucleic acid.

The highest levels of nucleic acid and protein were found on the reprocessed shaver blades from 1 company, with 3 of its 4 blades being contaminated; one of these blades had 60 μg of protein and 2.85 μg of nucleic acid. No company had a complete sample of reprocessed shaver blades without contamination.

TABLE 2. *Percentage of Damage of Shaver Blades*

	Reprocessed Shaver Blades	New Shaver Blades
Set 1		
	26%-50%	0%
	NT	0%
	1%-25%	
	NT	
	NT	
	51%-75%	
	NT	
	1%-25%	
	51%-75%	
	NT	
	76%-100%	
	51%-75%	
	26%-50%	
	76%-100%	
	1%-25%	
	1%-25%	
Set 2		
	1%-25%	
	26%-50%	
	0%-25%	
	26%-50%	
	26%-50%	
	NT	
	1%-25%	
	1%-25%	
	1%-25%	
	NT	
	1%-25%	

Abbreviation: NT, not tested.

Quality

Shaver Blades

A representative composite image of new and used shaver blades is shown in Fig 1. Shown are the best and worst conditions that were found when the damage of the reconditioned shaver blades was compared.

The data obtained for scoring the shaver blades used in this study are compiled in Table 2. Of the 27 reprocessed shaver blades, 7 were smooth, with no teeth, and were not tested. Of the 20 blades tested, 10 had 1% to 25% damage, 5 had 26% to 50% damage, 3 had 51% to 75% damage, and 2 had 76% to 100% damage; thus 5 shaver blades (25%) had greater than 50% damage. The 2 new blades had no visible damage. No company had a complete sample of reprocessed shaver blades without damage.

Cut Tissue

Image processing showed that tissue cut with the new shaver blades had values of 1 ± 0.12 (where 1

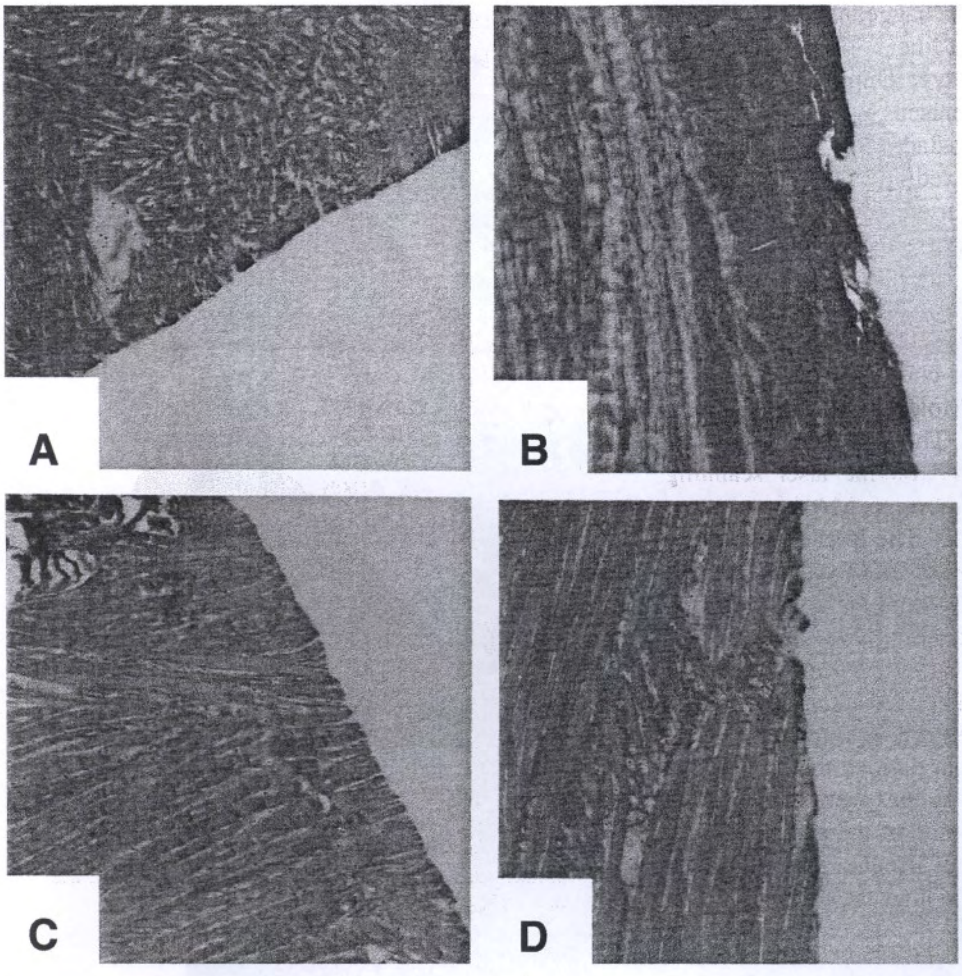

FIGURE 2. H&E-stained images of meniscal tissue cut with new and reconditioned shaver blades (original magnification ×10). The tissue shown in the composite was cut with the shaver blades shown in Fig 1: (A) a new shaver blade (No. 18), (B) the shaver blade in the worst condition (No. 11), (C) a reprocessed shaver blade (No. 5), and (D) a reconditioned straight blade (No. 1).

indicates a straight line), whereas the values for the reprocessed shaver blades ranged from 0.62 ± 0.02 to 1 ± 0.07 (Fig 2 and Table 3). Only 4 of 16 reprocessed shaver blades had a value of 1.

Laser scanning cytometry revealed a higher percentage of irregularities for tissue that was cut with reprocessed blades from set 1. This signifies a higher percentage of tissue falling outside of the computer-generated line dividing the bulk of the tissue from the cut surface. Values for tissue cut with the new blades ranged from 3.3% to 7.1%. Values for the reprocessed blades ranged from 5.8% to 20.0% (Table 3). Of the reprocessed blades, only 4 scored within the range of the new blades. Those 4 blades were the same 4 blades that scored 1 on image processing.

In addition, of the 4 blades from set 1 that rated relatively smooth cuts on the meniscus, 3 had no detectable nucleic acid or protein (the fourth had 0.134 μg of nucleic acid and no protein). Because they were straight blades, 3 of these 4 blades were not assessed with regard to the quality of the blades. The fourth blade (a different fourth blade than the one that was found to have 1.12 μg of nucleic acid) had more than 75% damage (as well as 2 rows of teeth, 10 in each row).

DISCUSSION

The results of this study question the effectiveness of reprocessing techniques for arthroscopic shaver blades, from both the viewpoint of contamination and the viewpoint of blade damage. To the best of our knowledge, this is the first study of its kind in the orthopaedic literature. The level of contamination found on the reprocessed blades may signify a risk of iatrogenic disease transmission. However, it is not known what levels of contamination act as a threshold to infection. The biologic nature of the contaminating residue was not identified in this study. A prior study has documented the presence of viruses, bacteria, and yeast on disposable

TABLE 3. *Comparison of Cut Tissue Surface Smoothness in Shavers From Set 1*

Reprocessed Shaver Blades		New Shaver Blades	
Image Processing*	Laser Scanning Cytometry†	Image Processing*	Laser Scanning Cytometry†
0.66 ± 0.02	16.7	1 ± 0.12	4
1 ± 0.07	6.7	1 ± 0.12	6.6
0.77 ± 0.09	12.7	1 ± 0.12	3.3
1 ± 0.12	7.0	1 ± 0.12	7.1
0.82 ± 0.05	8.9	1 ± 0.12	3.8
0.68 ± 0.03	13.3	1 ± 0.12	5.9
1 ± 0.08	5.9	1 ± 0.12	7
Defective‡			
0.62 ± 0.02	20		
0.76 ± 0.04	9.9		
1 ± 0.07	5.8		
0.68 ± 0.03	11.1		
0.85 ± 0.06	7.8		
0.64 ± 0.05	18.1		
0.82 ± 0.06	8.2		
0.64 ± 0.05	18.7		

*A value of 1 indicates a straight line/smooth surface. Values lower than 1 reflect deviations in the cut surface. The closer the value is to 1, the smoother the surface.

†Percent of irregularities. Higher numbers indicate more irregularity.

‡The insert was incorrectly matched to the outer blade and could not be used.

abdominal instruments resterilized with ethylene oxide gas.[5] Our results further support the possible risk of infection from reuse of shaver blades intended for single use.[6] Contamination of resterilized single-use shaver blades may expose patients to an avoidable risk of iatrogenic disease transmission.

The quality of reprocessed shaver blades is also lower than that of new blades, as was confirmed by the visual damage noted on the reprocessed blades and the less uniform cut edge of meniscus. This may be clinically relevant when one is debriding the edges of a meniscal tear during a repair, the borders of a chondral defect before a graft, or a simple degenerative meniscal tear. The success of meniscal repairs or chondral grafts relies on the viability of the cartilaginous borders for growth and migration of fibroblasts and chondrocytes. This may be compromised when one is using reprocessed blades that leave behind frayed edges and possibly a deeper zone of injury. Microscopic irregularities left behind after debridement of a degenerative meniscal tear may not be intrinsically unstable but may deteriorate more rapidly into macroscopic irregularities that cause mechanical symptoms and pain.

There were 4 reprocessed blades that left a smooth cut on the meniscus. Of these, only 1 had a detectable level of nucleic acid. It would be interesting to know the type and length of use to which these blades had been subjected. For example, use of the blades on soft connective tissue or for a short period of time may affect blade characteristics differently than use on bone or for an extended period of time. Currently, blades are not tracked for this information.

It would be of interest to explore the tracking of blade use for another reason as well. It is possible that a blade may have been reprocessed more than once, thus explaining the poorer quality of the blade. A complex tracking system, however, may increase the cost and thereby reduce the relative benefit of using recycled blades.

There are limitations to our study. A single observer performed the assessments; however, this observer was blinded as to the source of each specimen. In measuring the surface roughness, we found that this was related to magnification—that is, with sufficient magnification, all cut surfaces can be isolated to small sections, which are therefore smooth.

An additional limitation of this study is that the 16 reprocessed shaver blades were not of the same model. Using blades of the same model would have facilitated a more uniform classification of visible wear on the blade edges and evaluation of cut menisci. In addition, there also may have been significant differences in the duration and tissue type for which the blades were used.

This is but one study among a spectrum of potential future studies designed to assess the risk, if any, of disease transmission from reprocessed shaver blades, as well as their quality. As a microscopic study analyzing the levels of protein and nucleic acid and evaluating blade quality, these data cannot definitively answer the question of the risk of disease transmission or the clinical relevance of poor blade quality. Future studies will be needed to further evaluate the risk of disease transmission and the clinical relevance of microscopic irregularities caused by damaged shaver blades. A study of meniscal repair in an animal model comparing edges debrided with damaged versus new shaver blades may provide valuable information regarding clinical outcomes with the use of reprocessed shaver blades. An animal model may also help investigate whether meniscus debrided with reprocessed blades develops macroscopic degeneration more quickly as a result of the microscopic irregularities shown in our study. One might also reproduce this study with fresh menisci that are stained for living cells to evaluate whether the zone of injury left behind by reprocessed shaver blades is significantly different from that of new shaver blades.

CONCLUSIONS

We have reached the following 3 conclusions based on our study:

1. Of the reprocessed shaver blades, 48% had detectable levels of protein and 63% had detectable levels of nucleic acid.
2. All of the reprocessed blades that were visually evaluated showed damage or wear (or both), whereas no new blade had visible damage.
3. Menisci cut with reprocessed shavers showed rougher edges than did menisci cut with new shavers.

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REFERENCES

1. *Updated 510(k) sterility review guidance K90-1; final guidance for industry and FDA.* Rockville: Center for Devices and Radiological Health, US Food and Drug Administration; 2002.
2. Wilfinger WW, Mackey K, Chromcznski P. Effect of pH and ionic strength on spectrophotometric assessment of nucleic acid purity. *Biotechniques* 1997;22:474-481.
3. Zuch CL, Nordstroem VK, Briedrick LA, Hoernig GR, Granholm AC, Bickford PC. Time course of degenerative alterations in nigral dopaminergic neurons following a 6-hydroxydopamine lesion. *J Comp Neurol* 2000;427:440-454.
4. Green LM, Murray DK, Tran DT, et al. Response of thyroid follicular cells to gamma irradiation compared to proton irradiation. I. Initial characterization of DNA damage, micronuclei formation, apoptosis, cell survival, and cell cycle phase redistribution. *Radiat Res* 2001;155:32-42.
5. Ulualp KM, Hamzaoglu I, Ulgen SK, et al. Is it possible to resterilize disposable laparoscopy trocars in a hospital setting? *Surg Laparosc Endosc Percutan Tech* 2000;10:59-62.
6. Rutala WA, Weber DJ. Creutzfeldt-Jakob disease: Recommendations for disinfection and sterilization. Clin Infect Dis 2001; 32:1348-1356.