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Repeated Use of Ablation Catheters: A Prospective Study

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Objectives. **The objective of this study was to provide insight into the time course of electrical, physical and mechanical changes in ablation catheters after each use that may affect the safety and efficacy of the ablation procedure.**

Background. **An increasing number of institutions are reusing deflectable ablation catheters. At present, there are no data concerning the safety of reusing ablation catheters.**

Methods. **Over a period of 1 year, 69 Webster/Mansfield deflectable catheters used in 336 ablation procedures were prospectively studied. An additional 18 new catheters were tested after multiple sterilizations only. The catheters were evaluated for electrical and physical integrity and mechanical capabilities. These include deflection at room temperature and 37°C, shaft compression and buckling during deflection, tip craters, torquing ability, glue separation and tip attachment using a stereoscope at ×30 magnification and electrical resistance for each electrode. After each use, the catheters were gas-sterilized with ethylene oxide.**

Results. **The most common reasons for catheter rejection were tip electrode glue separation after 4.3 ± 4.3 uses and loss of deflection after 5.0 ± 3.3 uses. Electrical discontinuity between the catheter handle and electrodes was observed after 10.0 ± 3.7 uses. There was no significant decrease in catheter torquing ability with repeated use. In this study the total estimated savings was $128,133, which includes the cost of catheter reprocessing. The reuse of Webster/Mansfield ablation catheters has not resulted in any major catheter failure or any major adverse clinical complications.**

Conclusions. **On the basis of these observations, we believe that the Webster/Mansfield catheter can be reused an average of five times. It is strongly recommended that after each use catheters be carefully examined under appropriate magnification (×30) and that special attention be given to the ablation tip electrode. The catheters should also be tested for deflection and electrical integrity.**

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With the escalating cost of medical care some centers are reusing deflectable ablation catheters multiple times. It has previously been shown (1) that diagnostic electrophysiology catheters can withstand multiple uses and sterilization procedures without overt harm to the patient. Ablation catheters are constructed with an operator-controlled deflection capability and a shaft with torquing ability that facilitates maneuvering the catheter tip to the desired location within the cardiac chambers. The catheter is exposed to numerous applications of radiofrequency energy. Such applications may result in high temperatures at the tip electrode that can affect the integrity of the catheter shaft, the electrodes and their attachment. Multiple uses and sterilizations may also affect the deflection, torquing ability and integrity of the catheter. Any significant changes in these variables will adversely affect the safety and efficacy of the catheters. We attempted to address these issues in a prospective study. Our goal was to provide insight into the time course of electrical, physical and mechanical changes in the catheters after each use that may affect the safety and efficacy of the ablation procedure.

Methods

We studied 69 ablation catheters that were made by a single manufacturer (Mansfield/Webster) and used in 336 procedures. Immediately after arrival of the catheter from the manufacturer, its handle was engraved with an identification number and the instrument was thoroughly tested for the following variables. 1) *Physical integrity.* Testing consisted of visual and stereoscopic (×30 magnification) examination of the handle function, catheter shaft and the deflectable tip. Specific attention was paid to the catheter tip ablation electrode attachment to the catheter shaft. The ablation tip electrode was stereoscopically scrutinized for pitting. 2) *Electrical integrity.* Resistance was measured from the handle connector to the recording rings and to the tip electrode. 3) *Mechanical integrity.* Testing consisted of deflection and torque measurements. Deflection was tested at room temperature and after immersion in water at 37°C. Deflection was evaluated by measuring the distance of the maximally deflected tip to the catheter shaft (Fig. 1) as well as any lateral deflection from the shaft. In addition, the shaft length in both the nondeflected and maximally deflected state of the catheter was measured. These measurements

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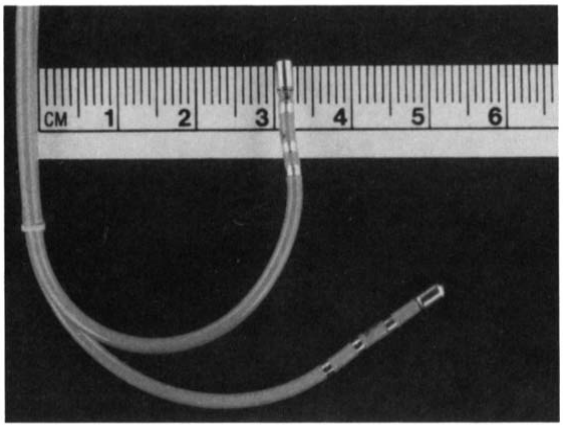


Figure 1. Deflection evaluated by measuring the distance of the maximally deflected tip to the catheter shaft. A properly deflecting catheter with a tip to shaft distance of 3 cm is shown above. A poorly deflecting catheter with a tip to shaft distance of 5 cm is shown below.

define changes in shaft compression and buckling as a result of tension applied to the deflection pull wire. Changes in torque were measured by inserting the catheter into a rigid tubing equipped with a scale marked every 30°. A position marker was attached to the catheter handle. A 12-cm plastic disk was attached to the catheter shaft just below the insertion of the tip electrode for the measurement of total catheter torquing ability or to the catheter shaft just below the deflectable portion of the catheter to measure torquing ability of the shaft. An 8-g weight was attached to the outer diameter of the ring. The catheter handle was turned so as to elevate the weight from its lowest gravitational location to 90°. As the handle was turned to create torque along the catheter shaft, the position marker provided the number of degrees that the catheter shaft turned. The relative measure of changes in torquing ability between uses was defined here as the number of degrees rotated at the catheter handle by the operator to elevate the weight to 90°.

Before gas sterilization, the catheter shaft and tip are soaked for 20 min in soapy warm water and wiped with gauze soaked in clear water. Using a gauze soaked in hydrogen peroxide, the catheter was wiped again, including the handle, and the deflectable tip was immersed in hydrogen peroxide for 3 min. The whole catheter was wiped again with gauze soaked in clear water several times and then dried thoroughly. The catheters were gas sterilized with ethylene oxide and allowed to aerate for at least 24 h. Catheters were rejected on the basis of any defect in catheter integrity, such as evidence of separation of the polyurethane glue from the tip electrode, poor handle function, loss of deflection, a misshaped deflection tip or electrical conductor failure. Catheters used for direct current ablation were discarded as well. In addition, 18 new Mansfield electrophysiology catheters were subjected to sequential sterilization and were evaluated after each sterilization for all of the previously described variables. The purpose of this evaluation was to define whether sterilization alone is the primary cause of catheter deflection loss and glue separation. We reviewed the charts of 140 patients in whom these catheters were used and who had successful transcatheter ablation for any evidence of an embolic event or local or systemic infection.

Data analysis. The data were collected and tabulated in chronologic order. Analysis of variance for repeated measures was used to define the statistical significance of changes in tip deflection, pitting, torquing ability and resistance values for each of the electrodes on the catheter after each sequential use. The catheters that were rejected were analyzed separately and compared with those remaining in use.

Results

Sixty-nine Webster/Mansfield catheters were prospectively evaluated over 1 year. The average impedance, time and energy during each procedure was 106.09 ± 16.52 Ω, 24.71 ± 18.46 s and 47.8 ± 20 W, respectively. The mean number of radiofrequency applications/catheter was 30 ± 26 (range 1 to 110).

As shown in Table 1, 36 of these catheters (52%) were rejected as a result of mechanical or electrical failure, and 5 were rejected after high energy direct current ablation. Eleven of the catheters were used ≥10 times. The maximal number of uses was 18. There were no major failures, such as total tip separation or shaft breakage. The main reason for catheter rejection was the separation of the polyurethane glue from the tip electrode.

Effect of sterilization. Eighteen new catheters were repeatedly sterilized. The catheter tip glue integrity, deflection, torquing ability of the shaft with and without the

Table 1. Summary of Rejected Catheters

Reason for Rejection	Catheters		Uses		
	No.	%*	Total No.	Range	Deflection (cm)
Deflection	13	19	5.0 ± 3.3	1–13	5.2 ± 0.6
Electrical disconnection	6	9	10.0 ± 3.7	6–17	4.4 ± 0.6
Surface glue separation	17	25	4.3 ± 4.3	1–18	4.5 ± 0.3
Direct current ablation	5	7	6.2 ± 3	2–11	4.4 ± 0.9

*Percent of the 69 catheters evaluated in this study. Unless otherwise indicated, values are expressed as mean value ± SD.

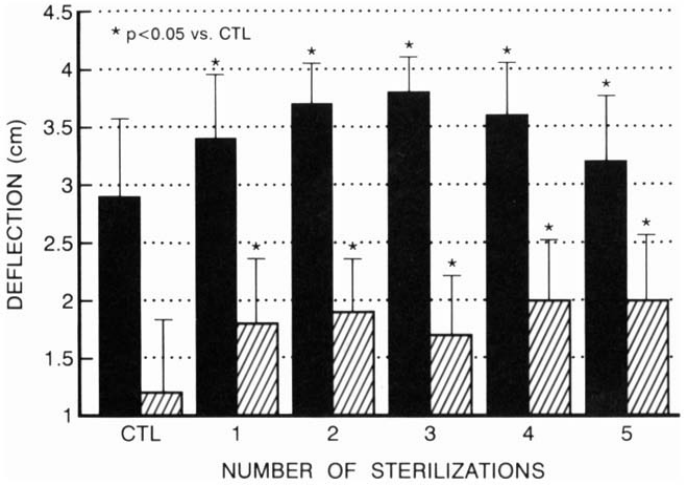
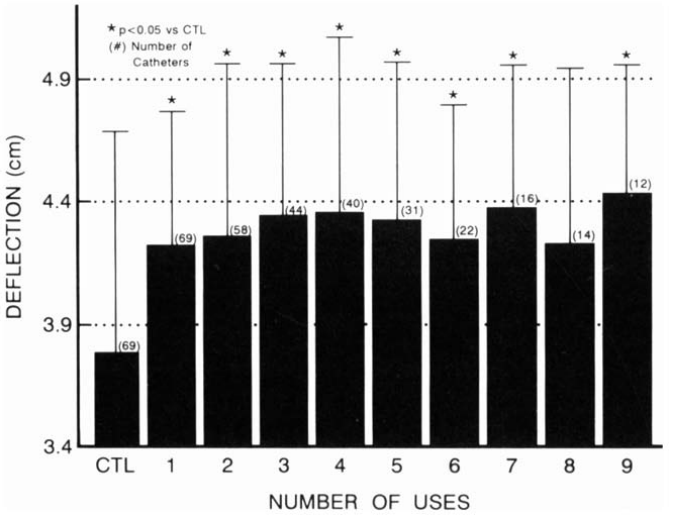


Figure 2. After the first sterilization, the deflection decreased significantly both at room temperature (**solid bars**) and immersed in 37°C water (**hatched bars**), with no further changes after multiple sterilizations. Deflection improves significantly when the catheters are immersed in 37°C water versus room temperature. CTL = control.

deflectable tip, and shaft compression were evaluated after each sterilization cycle. As shown in Figure 2, the tip to shaft measurement increased from 2.9 ± 0.7 cm before sterilization to 3.4 ± 0.5 cm ($p < 0.005$) after the first sterilization at room temperature and from 1.2 ± 0.6 to 1.8 ± 0.6 cm ($p < 0.005$) when the catheters were immersed in water heated to 37°C. No further significant deflection loss was recorded after the first sterilization cycle. No significant changes in torquing ability, deflected and nondeflected shaft length or any other physical, mechanical or electrical defects were noted as a result of sterilization alone.

The deflection changes for all 69 catheters are shown in Figure 3. Similar to the changes that were recorded with sterilization alone, all of the catheters lost significant deflection capability after the first sterilization process and use. The deflection changed from 3.8 ± 0.9 cm before sterilization and first use to 4.2 ± 0.6 cm ($p < 0.005$) after the first sterilization and use. No further changes in deflection were noted after the first use. However, the group of catheters that were rejected because of poor deflection lost a significant amount of deflection ability with multiple use (range 2 to 13 uses). The average deflection for these catheters before use was 3.3 ± 0.8 cm and at the time of rejection was 5.2 ± 0.6 cm ($p < 0.01$).

Figure 3. Deflection of all catheters used in this study before and after use. CTL = control.



Torquing ability. There was no significant increase in the number of degrees that the catheter handle had to be turned to lift the weight attached to the catheter shaft to 90° after each use. Similar results were observed for the deflectable tip. The average amount of rotation needed to lift the weight 90° was 242° for the shaft alone compared with 400° when the shaft and deflectable tip were tested together.

Pitting. The application of radiofrequency is associated with shallow pitting of the tip electrode most often noted at the portion of the electrode just above the polyurethane glue (Fig. 4). In contrast to the shallow pitting caused by radiofrequency energy, using high energy direct current ablation with these catheters results in large, deep craters that are also found at the proximal portion of the electrode. Other than the deep craters, direct current ablation did not cause electrical or mechanical damage to the catheters used in this study. The pitted area on the ablation electrode increased with the number of uses (Fig. 5).

Polyurethane glue separation. The glue that covers the most proximal portion of the distal electrode is shiny and uniform before any use (Fig. 6). The application of radiofrequency energy may cause the glue to separate from the tip. Small fractions of the glue were missing and may have been released into the bloodstream. This separation could occur at any time of reuse, averaging 4.3 ± 4.3 (range 1 to 18). Catheters with blood that collected in this space could not be properly cleaned. There is no evidence that the tip to shaft attachment was affected by the outer glue separation. However, the possibility that the attachment of the tip electrode was weakened by the glue separation cannot be excluded. We noted a thin layer of crusting extending from the polyurethane glue. This crust was clear and could be scraped off the electrode with a blade while the electrode was visualized under the stereoscope. The crust was electrically nonconductive and not affected by the sterilization process.

Clinical follow-up. The medical records of 140 patients who had catheter ablation therapy, revealed only 1 case of local infection. This occurred at the insertion site of the catheter and was treated effectively with antibiotic agents. There was no incidence of stroke, transient ischemic attack or systemic infection in any of these patients. To our knowledge, there have been no long-term septic/infective episodes in any of the patients.

Discussion

The deflection capability and torquing ability of the ablation catheter are important factors in the time spent to

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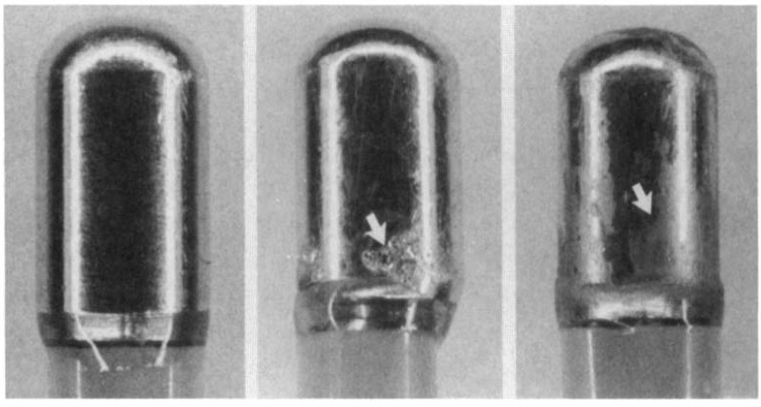
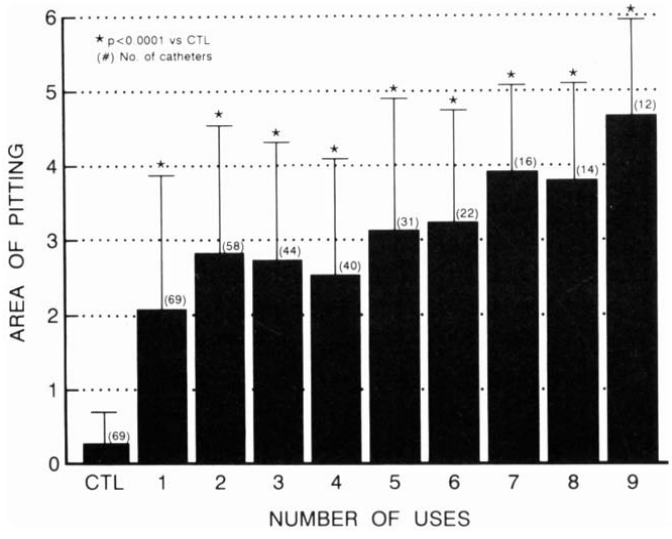


Figure 4. The ablation tip electrode on the **left** is new. The electrode platinum surface is undented and smooth. The catheter in the **middle** was used for high energy direct current ablation. The base of the ablation electrode is eroded, and distinct craters are seen. The ablation tip electrode on the **right** shows shallow pitting that was created by radiofrequency energy and a crusted area on the right side of the catheter.

achieve a successful ablation procedure. Although the deflection can be readily tested by the operator before use, other variables cannot be as easily tested. Previous studies have examined the reuse of nondeflectable diagnostic electrophysiologic catheters (1,2). In these studies, use and decontamination were not factors in limiting the reuse of the catheters. Similarly, multiple uses of cardiac angiographic catheters have been found to be relatively safe with little risk of infection (3–5). Sterilization and reuse did not affect the mechanical characteristics of the catheter lumens (6,7).

Contaminated catheters. The transfer of the hepatitis B virus by reusable catheters cannot be excluded. In a study that examined contaminated reusable needle electrodes, electron microscopy demonstrated the presence of hepatitis B surface antigen forms and a complete virus. These findings suggest that reusable needle electrodes are a potential risk for the transfer of hepatitis B virus (8). This finding, with regard to hepatitis B in needle electrodes, may hold true for the ablation catheters as well. One ablation procedure was performed in a patient with hepatitis B in our institution. After the procedure, the ablation catheter was discarded.

Figure 5. Minimal pitting of the ablation tip electrode was noted before use of the catheters. The area of pitting is increased after each use. CTL = control.



Because of the previously mentioned data and lack of data about specifically using ablation catheters, we can only recommend discarding catheters known to have been used in an infected patient at this time.

Ethylene oxide residues were found on reused diagnostic electrophysiology catheters (2). The significance of such findings as they relate to the risk to patients exposed to these catheters remains unclear. It can be stated, however, that after hundreds of procedures with reused catheters in many centers in this country, we have yet to find reported complications that have resulted from ethylene oxide–treated catheters. Limiting the number of reuses and sterilizations will limit the amount of ethylene oxide residues on the catheters.

Polyurethane glue separation. In this study, perhaps the most important finding is that the ablation catheters that were used as many as 18 times did not reveal signs of major failure of integrity. In none of the catheters tested was the tip electrode found detached from the shaft, nor did the deflectable portion of the catheter separate from the main catheter shaft. The major reason for catheter rejection was polyurethane glue separation from the surface of the ablation tip electrode. Ablation electrode glue separation can occur at any time of reuse. Small sections of the glue (measuring a fraction of a millimeter) that are missing have probably been released into the bloodstream. The separation can result in contaminates collecting in the gap. There is no clear evidence that this weakens the tip electrode to shaft attachment; however, such a possibility cannot be excluded. The specific cause for this observation is not totally clear. It may be related to the heat that is generated during the delivery of the radiofrequency energy. It is possible that a thermistor-controlled energy delivery system that will maintain the tip electrode temperature <100°C may eliminate polyurethane glue separation. Temperature control may also prevent the formation of shallow pits. It is possible that pitting is in part a result of sparking that occurs at the electrode tissue interface when the temperature exceeds 100°C (9). By maintaining the electrode tissue interface at a temperature below boiling, impedance rise and sparking can be prevented.

Electrode pitting and platinum loss. Pitting of the ablation electrode is shallow with radiofrequency energy, and the

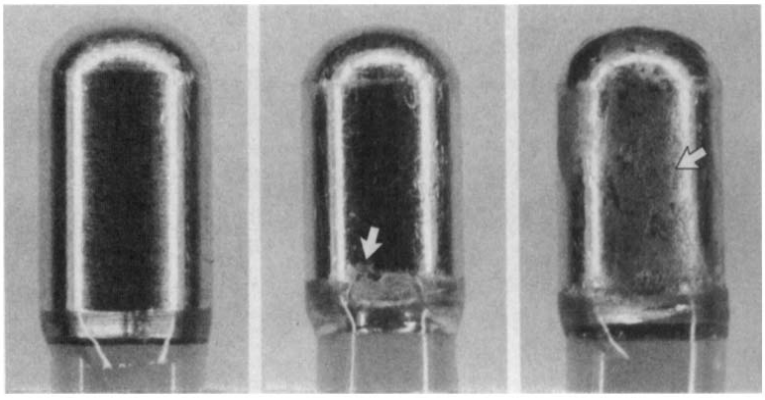


Figure 6. The polyurethane glue covering the proximal portion of the reused ablation electrode shown in the middle has separated from the metallic surface of the electrode. However, no evidence of tip separation is noted. As a result, contaminants have entered this separation gap and could not be cleaned properly. The tip electrode on the right is covered with nonconductive crust, whereas the unused new tip electrode on the left shows no such defects.

area of pitting is increased with reuse, whereas pitting from direct current energy results in deep craters, often at the junction of the electrode and the catheter shaft. The small amount of platinum lost as a result of these energies is probably transferred to the tissues with unclear consequences to the patient. The platinum is most likely deposited in the ablated tissue. In addition, electrical nonconductive crusting was noted on some of the tip electrodes after radiofrequency energy application. The crusting was noted with glue separation and is probably also associated with high temperatures. Such crusting can be cleaned by scraping the tip electrode and, if not cleaned, may interfere with application of radiofrequency energy.

Sterilization effects. Sterilization causes deflection loss after the first processing and is probably related to changes in the characteristics of the catheter material as a result of heat or chemical exposure. These deflection losses are permanent with no further changes noted after multiple sterilizations. Sterilization does not cause loss of torque, compression changes or tip electrode glue separation. It also does not cause pitting. Further deflection loss may occur in the catheters as a function of use. A large loss of catheter deflection may occur at any time and is probably related to handling of the catheters by the operator and technical staff. Decreased deflection may be caused by twisting or bending the catheter, which is often done by curling the catheters before sterilization in a small sterilization bag.

No significant decrease in catheter torquing ability was noted with repeated use. The major decrease in torquing ability occurs at the deflectable tip because the deflectable portion is much softer than the shaft.

The conductor resistance between the catheter handle and the electrodes did not increase as a function of reuse. However, electrical discontinuity between the catheter handle and the electrodes occurred in 6% of the catheters after multiple use. No intraelectrode shorts were noted in any of the catheters. Finally, clinical follow-up indicates that reuse of ablation catheters has yet to result in any adverse consequences to the patient.

Cost savings and safety guidelines for catheter reuse. The reuse of medical devices is a major issue with significant financial implications for both the device industry and those who pay for medical services. However, such financial consideration is based on the assumptions that the catheters' safety and efficacy remain constant and that reuse does not impair the procedure because of changes in device specifications as a result of use, sterilization, handling and storage.

In this study, the total catheter cost would have been $166,320. This figure is the per catheter cost of $495 multiplied by 336, which is the number of procedures done. Because the catheters were reused multiple times, the total catheter cost for this study was $38,187, which is the cost of 69 catheters plus the cost of reprocessing, estimated to be $12 for each use (10). The estimated cost savings shown in this study, therefore, totals $128,133. The results of this study indicate that the average catheter is reused five times. Thus, each catheter costs $99 plus the reprocessing cost of $12. For the same number of catheter uses in the ablation procedures performed in this study, the cost savings is $129,024. Clearly, a substantial amount of money can be saved if catheters are reused throughout the United States. However, because the Food and Drug Administration currently does not favor reuse of medical devices (11), the legal issues of catheter reuse can lead to significant dampening of interest in this practice. To minimize the liability of the provider, it must be shown 1) that the device can be adequately cleaned and sterilized, 2) that the characteristics or quality of the device will not be adversely affected, and 3) that the device remains safe and effective for its intended use (12).

The present study and others (1–6) indicate that criteria for quality and safety can be met as long as the user adheres to the recommendations provided. Furthermore, Swan and Snyder (12) recommend establishing a panel that will define and oversee the reuse protocols and guidelines. Such guidelines should include 1) the number of times the device is reused, 2) criteria for discarding the device, 3) criteria for inspection procedures, and 4) monitoring and documentation of quality control.

Study limitations. The incidence of increase in impedance was not systematically recorded during the course of the study. Such increases are a function of several factors, among them the tissue and catheter contact and contact

stability, the amount of energy delivered and the resultant temperature. If the temperature leads to boiling and gas formation, impedance will also rise. In addition, ablation tip electrode pitting may also be a factor in the increase in impedance. We suggest that catheters found to have excessive ablation electrode pitting be discarded. No complications resulting from the accumulation of ethylene oxide residues on the catheter after multiple resterilizations have been reported thus far. However, the possibility of long-term complications resulting from ethylene oxide exposure cannot be discounted.

In this study, we examined catheters from a single manufacturer, and the results obtained apply only to that catheter. Because different manufacturers use varying techniques of producing deflectable catheters, the safety and durability of each catheter should be tested after each use, with specific attention to the variables evaluated in this study to ensure that the mechanical, physical and electrical integrity of the catheter is maintained if reuse is contemplated.

Conclusions. On the basis of these observations, it is strongly recommended that after each use, ablation catheters be carefully examined under appropriate magnification (×30). Special attention should be given to the ablation tip electrode polyurethane glue. The catheters should also be tested for deflection and electrical integrity. Finally, accurate records should be kept for each catheter.

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