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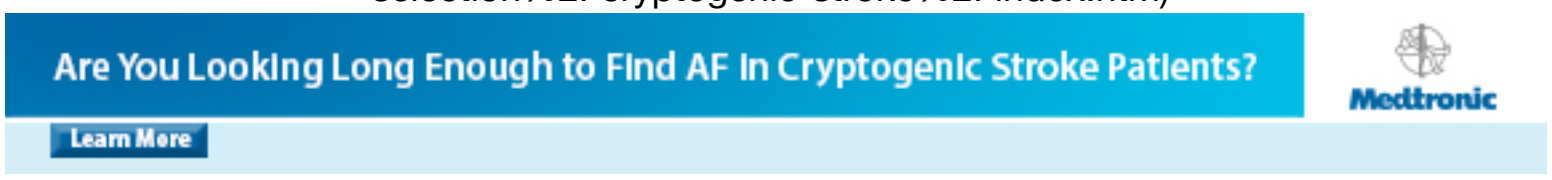

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AcuNav Reprocessing: An Evaluation of Safety, Clinical Effectiveness and Cost Savings

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Ultrasound The AcuNav Way

Using state-of-the-art technological advancements in intracardiac ultrasound applications, the AcuNav ultrasound catheter, manufactured by Siemens Medical Solutions (formerly Acuson Corporation of Mountain View, California) is a 10 French (Fr) (3.2 mm) catheter with a 110 cm insertion tube. The distal tip of the device houses a 64-element vector phased array transducer (5.0-10.0 MHz frequency) to produce two-dimensional grayscale images, full spectral, and color Doppler imaging (pulsed, continuous wave and tissue Doppler). The catheter features dual-plane steering to enable precise catheter orientation and navigation within the chambers of the heart. Four-way steering with 160 articulation in each direction (left, right, anterior, posterior) provides images at multiple angles. It is capable of producing high-resolution ultrasound images with 12 cm tissue penetration providing far greater anatomic and physiologic detail than what can be obtained with traditional ultrasound imaging methods. Image quality can be further optimized by adjusting the depth, gain and frequency of the signal.[1] The scope of this study is focused on the 10 Fr AcuNav catheter; however, the methods for reprocessing the newly introduced 8 Fr AcuNav catheter are comparable to the methods used for the 10 Fr AcuNav catheter. The quality of data for both catheters is comparable and both catheters are safe for use after reprocessing. The major difference between the two catheters is the 8 Fr catheter has a slightly thinner shaft diameter and longer shaft length. No major technological and functional changes were noted.

Critical Components and Ultrasound Principles

In order to understand how to obtain optimal clinical performance from the AcuNav catheter, it is important to first understand basic ultrasound principles and the technology used in the construction of this device. Utilizing a 64-element phased array, the integrity of the AcuNav transducer is the single most critical component when assessing the image quality during an examination. Due to its fragile construction, the transducer is the component that is the most susceptible to malfunction or damage. Therefore, it is critical that functionality testing of the AcuNav catheter includes a thorough evaluation of the transducer acoustic stack and its performance.[2] Optimal ultrasound images are created when all the elements along an array are excited simultaneously with short pulses. This creates an acoustic beam with an adequate number of acoustic lines to achieve the required axial and lateral resolution to detect spatial targets within the cardiac space. Electronic delay sequences are added in the signal processing to steer the acoustic beam over more area for sector imaging applications.[2] As each element is individually excited with a small burst of energy known as a transmit pulse, the created ultrasound wave propagates through the body and is returned back as an echo after striking a target. These echoes are detected by the transducer, converted back into electrical signals and then processed by the ultrasound console creating an image. Since image and Doppler qualities are directly related to the optimal performance of each individual element within the array, it is appropriate to test AcuNav catheters on an element-by-element basis. Understanding and analyzing the performance characteristics of each element will result in producing the best clinical performance from the AcuNav device. The relationship between clinical performance and element integrity is dependent on the each element's ability to successfully transmit the ultrasound pulse. Transducer testing is used to determine the number of dead or weak elements, if any, within the array. Dead elements are defined as elements that are not responsive to the transmit pulse and weak elements include those that fall below an acceptance sensitivity threshold. Data has shown that as few as two to four consecutive dead elements can have a drastic negative impact on clinical imaging and Doppler capabilities.[2]

AcuNav Reprocessing An Adapted Science

Reprocessing AcuNav catheters has been a big success because the foundation for this science has been thoroughly tested and widely used with diagnostic electrophysiology catheters. Figure 1 illustrates the fundamental reprocessing model that has been implemented for AcuNav catheters. With regard to the cleanliness of the device, cleaning validations have been designed to test devices under extreme worst case conditions for bacterial, chemical and organic cleanliness as outlined in industry-accepted standards and in accordance with Technical Information Report 30 (TIR 30). With electrophysiology catheter reprocessing demonstrating proven clinical safety and effectiveness, it was suitable for the technology to be adapted to the AcuNav ultrasound catheter reprocessing. The AcuNav assembly of components and general construction, such as the handles and shafts, is so similar to EP catheters that it was appropriate to implement similar cleaning methods for these devices. Past studies have demonstrated that electrophysiology catheters can sustain repeated uses and resterilizations and still comply with quality control specifications.[13] However, to successfully reprocess catheters it is essential that comprehensive validation protocols and guidelines be implemented into the quality control inspection of finished goods. When adapting reprocessing steps from the EP catheters to the AcuNav catheter, new technological advancements within interventional cardiac ultrasound also need to first be understood. Comprehending the logistics and scientific principles of ultrasound energy transfer would prove to be critical in developing successful reprocessing procedures for the AcuNav catheter. **Methods** This study included two testing groups each consisting of AcuNav ultrasound catheters that were tested as new samples and then retested after being reprocessed two times. Group 1 consisted of nine catheters that were tested as new devices to establish a baseline of comparison for substantial equivalence. Group 2 consisted of a much larger sample

size of reprocessed devices. Data collection included subjecting each catheter group to different functional verification tests at various stages during a typical reprocessing sequence, which evaluated all the major potentials for improper device function. Reprocessed AcuNav catheters from group 1 were tested for two fundamental image-specific performance metrics, element sensitivity (volts peak-to-peak) and capacitance (picoFarads) before and after reprocessing. Group 2 testing included dielectric strength, leakage current, curve articulation and visual inspection under magnification. The devices were split into two groups since testing was completed over a four-month period. The purpose of this study was to examine the changes in these performance metrics and determine if the devices are suitable for clinical use and substantially equivalent to predicate devices. To gain an understanding of the performance of reprocessed AcuNav catheters and challenge their durability, samples were subjected to specific functionality tests. The scope of this study was to assess functionality of the devices with the understanding that cleanliness and sterility was proven through comprehensive supplemental validations included with regulatory submissions filed with the United States Food and Drug Administration (FDA). All of the devices included in this study from group 2 have undergone one clinical use and were subjected to two reprocessing cycles at Alliance Medical Corporation (Phoenix, Arizona). Furthermore, new predicate devices were tested to establish a baseline for comparison using a statistical process control (3-sigma distribution). The performance of reprocessed catheters was quantitatively compared to original specifications of new catheters. Additional supplementary tests such as mechanical, electrical and acoustic output were conducted, but are not included in the scope of this study. Data from those studies demonstrated substantial equivalence to predicate AcuNav catheters.

Image Quality

Since image quality and resolution are perceived to be the most critical clinical aspects of ultrasound, each catheter was subjected to element-by-element testing. To clearly detect element failure or potential degradation after reprocessing, each sample was tested on a commercially available transducer testing platform, FirstCall 2000. This system is a high-speed, portable probe testing system and has a custom fixture for signal acquisition. This equipment was used to measure basic acoustic performance parameters within a population of reprocessed AcuNav catheters. The repeatability of the FirstCall testing was analyzed in a separate study, and was found to be acceptable for all the testing parameters. The following data was collected and analyzed: element sensitivity, capacitance, pulse width, center frequency, fractional bandwidth, weak or dead elements. However, only element sensitivity and capacitance is being reported in this article to limit the scope.

Dielectric Strength

Reprocessed AcuNav catheters were subjected to 100% hipot (high potential) and leakage current testing. In hipot testing, often called the voltage breakdown or dielectric strength test, the AcuNav's outer shaft was electrically stressed at a worse case to withstand electric stress gradients at elevated voltages for prolonged durations. Fundamentally, the test is designed to evaluate how well the outer shaft contains and insulates from voltage leaks and how resistant the insulation is to voltage arcing. As shown in Figure 2, sparking or arcing is characterized by rapid variations in voltage or current that typically results in failure. If kinks, cuts or abrasions are present within the material, an escape path is created for the voltage. Maintaining an adequate dielectric barrier between the electrical power and the patient is critical in terms of power surges. In case of malfunctioning equipment or unsteady electrical current, breached dielectric insulation can result in patient or end user shock or electrocution. The testing sequence includes submerging the catheter shaft into a saline bath enclosed in a custom-designed test vessel. Elevated voltages and currents are transmitted through the length of the catheter from the handle to the distal transducer. Dielectric testing measurements

were performed in accordance to the industry-accepted standard UL 2601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety.7 All tested catheters were found to be within the specification set by the industry-acceptable standard.

Leakage Current

Quantifying the amount of leakage current associated with device use is another critical parameter that should be evaluated when reprocessing AcuNav catheters. Typically, leakage current flows from the catheter through the ground path and back to the earth ground through the ground terminal on the console power cable. However, if malfunctioning, an electrical potential can build up, and if a user is exposed to this potential, the individual then becomes the ground path for direct current flow.[4] Since it only requires a minimal amount of current to cause harm to a patient, a stringent, low tolerance acceptance criteria is also required. Furthermore, leakage current is measured to ensure that direct contact with a medical device does not result in electrical shock.[3] Leakage current measurements were performed in accordance to the industry-accepted standard IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety and Essential Performance.[6] All tested catheters were found to be within the specification set by the industry-acceptable standard.

Curve Articulation Assessment

Due to the precision required to navigate within the heart chambers, the curve angles and diameters were evaluated for each reprocessed AcuNav catheter. Catheter tip deflections were measured against an established baseline for comparison specification derived from predicate device testing. Each tip was placed on a calibrated template that assessed the curve diameter and angle for each direction (anterior, posterior, left, right) at maximum articulation. Testing each tip in every direction ensures that the catheter will accurately and smoothly maneuver within the vascular system. **Visual Inspection** Lastly, as an extra quality step, each catheter was visually inspected under 10x magnification for surface defects and cleanliness. Devices are meticulously evaluated and each component undergoes a separate inspection before the device is packaged and sterilized. A subassembly inspection for the AcuNav catheters is an appropriate approach since it ensures that contaminants are not present at interfacing or mating sections.

Statistical Analyses

All continuous variables are reported as mean, ± Standard Deviation, range, error and 95% confidence interval with s = 0.05. Nominal variables were compared by a sample t-test, and categorical variables were summarized as percentages. Results with a $p < 0.05$ were considered statistically significant.

Discussion of Results

The FirstCall system provides a capacitance measurement of every element, along with a pulse-echo response against a known target. The system can also detect the failure of any element due to the number of root causes, such as broken electrical connection within the wires, lens delamination, or debonding with array layers, etc. In this way, it is a more sensitive measurement than total acoustic power. For instance, if two of the 64 elements in the AcuNav transducer array were to fail and be completely dead, the impact on the total power would only be 2/64 or 3.1%, which is below the expected measurement repeatability for total power when measured on small devices of this type. Therefore, this demonstrates that using the FirstCall system for function testing is intrinsically a more accurate test of device integrity than an acoustic output measurement.[5] As shown in Figures 3 and 4, the typical relationship between the individual transducer (probe) element capacitance and sensitivity measured before and after the two reprocessing cycles

demonstrates a minimal standard deviation. In addition, the coefficient of determination (R2) also indicates a good model fit between the empirical data for pre and post reprocessing. The most reliable R2 value that indicates how closely the estimate values for the trendline correspond to the actual data is at or near 1. The small standard error of the mean for the testing concludes that little variation exists and would hold true if repeated samples were tested from the same population. A small mean error results in confidence in the performance measurements and their relationships between predicate devices and reprocessed devices. The sensitivity for each individual element of the same probe can be seen in Figure 4. Due to slight alignment inconsistencies during testing, a root mean square (RMS) analysis was performed to accurately summarize the overall sensitivity error for the transducer.[5] The aggregate capacitance and sensitivity values were analyzed and the results are shown in Tables 1 and 2, which compare the observed average change with the variability of the measurements both before and after reprocessing. The results indicate that the changes in capacitance and sensitivity due to reprocessing are less than the intrinsic element-to-element variability of the AcuNav probes themselves, demonstrating negligible performance degradation and acceptable clinical effectiveness. These results indicate that there is little or no change in the measured FirstCall parameters due to the reprocessing methods used at Alliance Medical Corporation. Furthermore, because the FirstCall system provides data on an individual element basis, it is a much more sensitive measurement approach for any changes in performance of the acoustic stack than, for example, total acoustic power that was evaluated in preceding studies.[9] Figure 5 represents a collective capacitance analysis for the entire sample population of AcuNav catheters after two reprocessing cycles. Data shows a strong correlation between before and after reprocessing a device with minimal variability. The one device outlier in the group represents a failure noted on a brand new catheter, and is not statistically significant in this study. The results from the devices in group 2 are listed in Table 3. These results are representative of AcuNav catheters tested for hipot, leakage current and steerability. The percent error calculations represent the error from a reprocessed catheter, compared to a new catheter. Finally, the sensitivity data outlined in Table 4 and Figure 6 include recordings for each individual element. Since each element plays a vital role in optimal image quality, it was appropriate to show data and how it varies independently. The comparison in Figure 6 shows the typical relationship between the individual probe element sensitivity measured before and after the two reprocessing cycles. Since the FirstCall system uses a planar reflector, which is at a fixed offset distance from the probe face, slight alignment variations exist. Given this variable, the relationship shown is acceptable as indicated by the correlation distribution bars and the linear data cluster.

Cost Savings and Waste Reduction

The other benefit of reprocessing the AcuNav catheter that compliments the device's safety is the significant potential for cost savings. Third-party medical device reprocessing industry has proven to save money and lessen the wasteful and negative environmental impacts of discarding devices after one use. Medical device reprocessors offer cost savings between 40 and 75%, as compared to the cost of a new device. With a high-end device like the AcuNav catheter, the savings potential results in substantial savings for a hospital with a high procedure count. Table 5 illustrates savings potential for a facility using 15 devices per month. The data is based on an estimated average reprocessing cost of $1,250 per AcuNav catheter reprocessed one time. Substantial additional savings opportunities exist as reprocessing cycles increase. Furthermore, waste is also reduced with reprocessing. Reprocessing results in less waste and trash associated with new device purchases. Lastly, with an average turnaround time of eight days, inventory is quickly restocked and readily available for cases.

Conclusion

Analytical, graphical and statistical analyses clearly demonstrate that reprocessed AcuNav catheters perform according to the original manufacturers' specifications and are substantially equivalent to predicate devices. Furthermore, reprocessing AcuNav catheters does not result in any clinical performance or safety degradation, demonstrating that reprocessed AcuNav catheters are suitable for clinical use. Data trends in supplementary studies focusing on the frequency response, bandwidth and center frequency of reprocessed AcuNav probes also demonstrated acceptable results when compared to predicate devices. However, to ensure reprocessing success, due to the complicated nature of intracardiac ultrasound technology, a validated quality control reprocessing program should be in place to ensure clinical safe product release. Lastly, with a proven success in functionality, great cost savings opportunities exist for hospitals that take advantage reprocessing the AcuNav catheter. The significant financial and environmental benefits that are created will result in reduced medical waste in landfills and improved patient care. *Editor's note*: This article was peer-reviewed by one or more members of the EP Lab Digest editorial board.

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Bradley P. Knight, MD, FACC, FHRS, Editor-in-Chief

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