The Effects of Sterilization Procedures on the Performance and Durability of Surgical Scissors

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From a Report Prepared by
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May 5, 2011

Study Summary

Five (5) Tri-Medics TMRH45 Ring Handle Tenotomy Scissors (**T-1** to **T-5**) and one (1) Control Device, an industry standard surgical instrument, 125mm Curved Tenotomy Scissor (**C-1**) were evaluated (TABLE 2). All devices (n=6) were run through 50 autoclave and performance cycles.

All Tri-Medics devices (**T-1** to **T-5**) demonstrated no changes in Appearance (N), Force to Open (N), Cut Performance (5) and Edge Damage (N) throughout the 50 cycles.

The Control Device (**C-1**) was noted to have a drop in the Cut Performance score at cycle 33. The device was noted to have a rough feel or performance and the score dropped to 4 and later to 3 in the remaining cycles. No other changes were noted in the **C-1** device.

In conclusion, the five (5) Tri-Medics test devices performed better than the Control Device; there were no notable changes to the Tri-Medics scissors after 50 autoclave cycles.

Objectives

The purpose of this study was to *evaluate the performance and durability* of the Tri-Medics *Precision Line* – Ring Handle Tenotomy Scissors (test devices) along with a Control Device. The Control Device is used as an industry standard to evaluate and compare it to the Tri-Medics Surgical Scissors over 50 sterilization cycles.

In evaluating the Tri-Medics test devices and the Control Device, *performance* is defined as

1. The function of the scissors in opening and closing, the ease of cutting relative to the force (exertion) to cut, and the resistance of the cutting blades to splaying and;
2. The sharpness of the blades for smooth, clean, precise cutting.

Durability is defined as

1. The strength, sturdiness, and stability of the scissor in use time after time and;
2. The material hardness and resilience.

Study Administration

1. *Study Personnel*

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2. *Test Facility*
   Los Angeles Biomedical Research Institute
   at Harbor UCLA Medical Center
   1124 W. Carson Street
   Torrance, CA 90502-2064

3. *Sponsor*
   Tri-Medics, Inc
   2 Hampshire Street
   Foxboro, MA 02035

4. *Study Dates*

   4.1. Protocol Signed:
   April 25, 2011

   4.2. Sterilization Dates:
   April 25, 26, 27, and 28, 2011
   May 2, 3, and 4, 2011

5. *Archives*

   Tri-Medics, Inc. will maintain the original records as per company procedures. The LA Biomedical Research Institute will maintain a copy of the records for two (2) years from the date of the final facility report.

6. *Test Article Description*

   All scissors tested were new (unused), uniquely identified, and tracked. Five (5) test articles and one (1) control device (competitive article) were evaluated. Test and control articles were tracked with identification and lot numbers.

TABLE 1

Tri-Medics	Control Device
N=5	N=1
2 Hampshire St., Foxboro, MA	Data on File
TMRH45 Ring Handle Tenotomy Scissor	125mm Curved Tenotomy Scissor

TABLE 2 *Device Identification and Lot Numbers*

Device Number	Manufacturer	Identification Number	Lot Number
T-1	Tri-Medics	TMRS120-040611	012
T-2	Tri-Medics	TMRS120-040611	013
T-3	Tri-Medics	TMRS120-040611	016
T-4	Tri-Medics	TMRS120-040611	032
T-5	Tri-Medics	TMRS120-040611	024
C-1	Control Device	Data on File	049

TABLE 3 *Device Evaluation Parameters*

Appearance of Instrument	Visible Changes in Instrument Appearance	**Y or N**
Force to Open	Changes in Force to Open Handles	**Y or N**
Cut Performance	Evaluation Scale of Force to Cut Test Material: 1 = Very High Force 2 = High Force 3 = Medium Force 4 = Little Force 5 = Very Little Force or No Change in Force	**1 to 5**
Edge Damage	Visible Changes or Damage to Cutting Edge	**Y or N**

Study Methods

7. Procedure

7.1. The instruments were placed into an ultrasonic cleaner for a standard cycle for a minimum of two (2) minutes. The ultrasonic cleaning solution used was an industry standard surgical instrument cleaning solution.

7.2. The instruments were then removed from ultrasonic cleaner and rinsed with warm water. The instruments were dried, sprayed with an instrument lubrication (an industry standard surgical instrument lubrication), and placed into the provided sterilization tray. A steri-strip steam indicator was identified with date, time, and cycle number and placed in the tray.

7.3. The tray was placed into the autoclave and the door sealed. The Unwrapped Cycle was selected [Unwrapped (Flash) Cycle – 135° C for three (3) minutes with two (2) minutes drying time] and the cycle started.

7.4. At completion the instruments were removed from the autoclave and the sterile indicator attached to *Precision Line* Cycle Form with time and date.

7.5. Each test device and control device was then evaluated and scored as described below. Any comments or unusual findings were also noted when appropriate.

Appearance of Instrument –
Visible changes in instrument appearance – Yes or No

Force to Open –
Apparent change in force to open handles (sticking) – Yes or No

Cut Performance –
The force needed to perform test incisions on test samples evaluated on a scale of 1 to 5; the rating of 1 used to indicate very high force to cut and 5 used to indicate very little or no force.

Force is exertion to cut; blade sharpness and material have an effect on force (cut performance) and the smoothness of cut.

In performing this test, the right hand was used to grasp the scissor through the ring handles. The scissor blades were placed over the cut test material (a standard, non-latex medium commonly used in the industry) and the blades closed. The blades of the scissors cut the test material from one-third ($^1/_3$) to two-thirds ($^2/_3$) of the blade length. After cutting, the blades were opened, removed from the test material, and checked for edge damage or visible changes.

Edge Damage –
Visible changes or damage to cutting edge – Yes or No

7.6. The instruments were then placed in an ultrasonic cleaner for a minimum of two (2) minutes and procedures 1 through 5 were repeated for a total of 50 cycles.

Results

Throughout the 50 autoclave cycles, the five (5) Tri-Medics devices (**T-1** to **T-5**) demonstrated no visible changes in the appearance of the instruments (FIGURE 1). The Tri-Medics devices also demonstrated no change in force to open the handles of the scissors and no visible changes or damage to the cutting edges of the scissors after 50 cycles. Also, the five (5) Tri-Medics devices (**T-1** to **T-5**) demonstrated no apparent change in cut performance; the scissors consistently and smoothly cut the test material.

The Control Device (**C-1**) demonstrated no visible changes in appearance, no change in force to open handles, and no visible changes or damage to the cutting edges. After 33 autoclave cycles, however, the Control Device required more apparent force to cut (from a rating of 5 to 4) and the cut was noted as "rough" (FIGURE 2). After the 37th cycle, the performance of the Control Device required more force to cut (from a rating of 4 to 3) and was also noted as "rough." After the 38th cycle, the rating increased from a 3 to 4 but the cut performance dropped from a 4 to 3 following the 48th cycle and was noted again as "rough." Also noted in the study, the Control Device (**C-1**) showed discoloration following the 47th autoclave cycle.

Conclusion

After 50 autoclave cycles, the Tri-Medics *Precision Line* – Ring Handle Tenotomy Scissors demonstrated consistent sharpness and performance, strength and stability. There were no changes in the performance and durability of Tri-Medics Scissors test after test whereas the performance and durability of the Control Device, an industry standard instrument, decreased notably after repeated autoclaving. In addition to consistent sharpness and performance, the Tri-Medics test devices also demonstrated no visible changes in appearance, functionality (opening and closing), or damage to the cutting edges of the scissors.

FIGURE 1 *Tri-Medics (T-1 – T-5)*

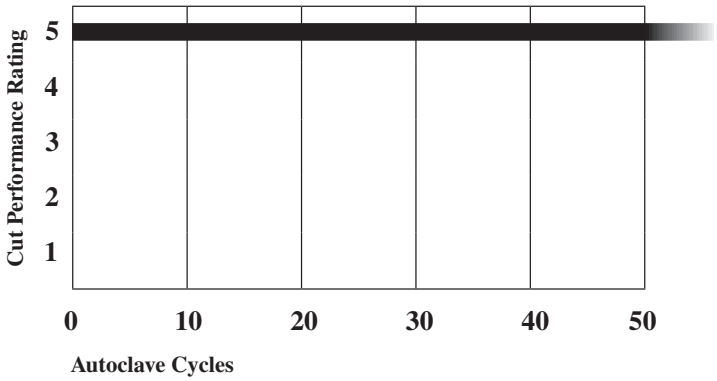
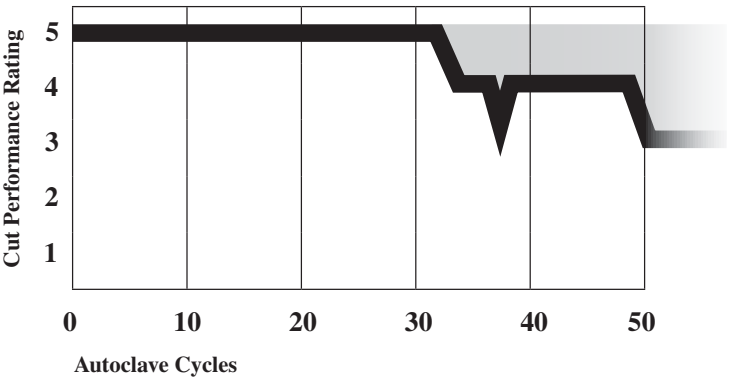


FIGURE 2 *Control Device (C-1)*



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