# Effects of Sterilization on Optical and Mechanical Reliability of Specialty Optical Fibers and Terminations

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## ABSTRACT

Optical fibers and terminations were subjected to different sterilization techniques, including multiple autoclaving and treatments with peracetic acid, E-beam and UV radiation. Effects of different sterilization techniques on key optical and mechanical properties of the fibers and the terminations were revealed. The primary attention was given to behavior of the coatings on the fibers and adhesives used in the terminations in harsh sterilization environments. The optical fibers with following four coating/buffer types were investigated: (i) dual acrylate, (ii) polyimide, (iii) silicone/PEEK and (iv) fluoroacrylate hard cladding/ETFE.

**Keywords**: Optical fiber, coating, termination, medical, sterilization, autoclave, peracetic acid, e-beam, UV radiation, epoxy adhesive, polyimide, silicone, PEEK

## 1. INTRODUCTION

Optical fibers and fiber-optic based sensors are ideally suited for a broad variety of invasive and noninvasive medical applications, including urology, general surgery, ophthalmology, cardiology, endoscopy, dentistry and medical sensing.[1-6] Prior to use inside a human body the fibers must be sterilized to ensure they are free of microorganisms. Sterilization can generally be defined as any process that destroys all microbial life such as fungi, bacteria, and virus or spore forms.[7] Many types of physical or chemical treatments are known as effective sterilization techniques. Somewhat arbitrarily, the methodologies can be subdivided into three groups: (i) use of elevated temperatures, (ii) chemical treatment, and (iii) exposure to radiation. The first group includes flaming, exposures to dry heat and hot steam (autoclaving) and boiling in water. Chemicals such as ethylene oxide (EtO), formaldehyde, ozone, sodium hypochlorite, *N*-chloro tosylamide, hydrogen peroxide, phthalaldehyde and peracetic acid in the gas phase and/or solutions are used for chemical sterilization. Finally, microorganisms can be effectively killed by UV light, X-rays, gamma- and E-beam radiation.

Since sterilization is a "harsh" process and exposure of optical fibers to harsh conditions may significantly affect their properties, it is important to know the sensitivity of optical fibers to various types of sterilization treatment. Ideally, sterilization of optical fibers should be such that it eliminates all the microorganisms but does not affect their optical attenuation and mechanical strength. The survivability of optical fibers in harsh environments depends on the fiber design and especially on the type of coating used for protecting the glass.[8]

Thus far there were only a few studies directly or indirectly related to effects of sterilization on optical and mechanical properties of optical fibers.[9-11] In our previous communication we initiated a systematic analysis of such effects.[12] The fibers selected for that study had similar core and cladding geometries, but different coatings, and the trialed sterilization techniques were autoclaving, EtO treatment and gamma radiation. It was found that mechanical and optical properties of the fibers were not significantly affected by multiple autoclaving (up to 20 cycles) and EtO treatment. In contrast, gamma radiation caused

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additional optical loss in all the fibers. Furthermore, fibers with perfluorinated coatings and buffers were found to become weak mechanically after the gamma treatment.[12]

The work reported below can be considered as an expansion of our previous study. To the same types of optical fibers, we applied three new sterilization techniques: (i) treatment with peracetic acid, (ii) exposure to UV radiation and (iii) exposure to E-beam radiation. In addition to the optical fibers, we also investigated their terminations.

Each of the sterilization methods selected for the study bears certain advantages and disadvantages. Peracetic acid (PAA, $CH_3C(O)OOH$) is a highly biocidal oxidizer and can effectively kill bacteria, fungi, and yeasts.[13] PAA denatures proteins, disrupts cell wall permeability, and oxidizes certain bonds in proteins, enzymes, and other metabolites. PAA has a low boiling point (25°C), so its sterilization effects can be achieved by using it in a gas phase or in aqueous solutions. A clear advantage of sterilization by peracetic acid is relatively low application temperatures (23 – 56°C).[14-16] A disadvantage is the fact that this is a strong oxidizing agent and a primary irritant.

Sterilization ability of ultraviolet (UV) radiation is due to the fact that is can disrupt DNA chains making microorganisms inactive. The highest efficiency can be achieved at the wavelengths where DNA exhibits the highest absorption: 240 – 280 nm, which fall in the UV-C range. UV radiation is widely used for disinfection of water and food.[17-19] A clear drawback of this approach is due to the fact that UV radiation penetrates only within few microns inside the treated items. Thus, microorganisms buried with particles (like dust) are shielded from UV light and therefore unaffected by it.

Electron beam (E-beam) is one of the best methods of achieving very high sterility assurance levels.[7] Typical penetration depth of E-beam in solids is around 5 cm.[20-22] E-beam is much safer in operation than gamma radiation because it does not use radioactive materials. Another advantage is that it sterilizes items at ambient temperature. A drawback of this method is that it needs an accelerator, which is not a standard piece of equipment. In addition, along with gamma radiation, E-beam can lead to significant alterations in the materials being treated. High-energy radiation produces ionization and excitation of polymer molecules which may result in crosslinking and/or chain scission.

For this study, we drew fibers with four different polymer coatings: dual acrylate, hard polymer cladding, silicone, and polyimide. All fiber types were exposed to sterilization treatment with PAA and UV and E-beam radiation. The terminations fabricated from the above four fibers were exposed to slightly different set of the treatments. Since connectors utilized for the study were not transparent to UV light, it was decided not to treat them with this radiation type. Instead, we exposed the terminations to multiple autoclaving cycles. In addition, the terminations were sterilized with PAA and E-beam radiation. The results of our study are reported herein.

## 2. FIBER AND TERMINATION DESIGN

All fibers selected for the study were OFS products. The fibers had 200 μm silica glass cores and 220 μm doped silica claddings with a numerical aperture (NA) of 0.22. Different coating and buffer materials were applied, as shown in Table 2.1. HCS® stands for an OFS proprietary fluoroacrylate hard cladding. Both HCS® and silicone coating have relatively low refractive index and therefore function in the fibers as "secondary claddings" with NA of 0.37. Two fibers were up-buffered with either poly(ethylene tetrafluoroethylene) (ETFE) or polyether ether ketone (PEEK). The coating and buffer dimensions are given in Table 2.1.

Figure 2.1 explains the design of the built terminations. Standard SMA connector parts were utilized in the assemblies. Dual acrylate and silicone coatings were removed from fiber ends, and the ferrules were bonded directly to the glass cladding. This was done since silicone and primary acrylate materials are soft, which would make weak the connector/ferrule bonding. Our intention was to learn possible coating-related effects, thus it was decided to keep polyimide and HCS® coatings on the fiber ends. Still, the ETFE buffer was stripped off the HCS® coating. Metal ferrules (IDs of 225 and 260 μm and the length of 12.7 mm) were utilized. The coated or bare fibers were bonded to the ferrules using an epoxy adhesive; the grade

was kept the same for all assemblies. The epoxy adhesive was thermally cured in accordance with the standard procedure (same for all fibers). After the curing, the terminations were kept at ambient conditions for at least a few days before they were sterilized and tested. It must be noted that the termination design shown in Figure 2.1 does not necessarily correspond to standard OFS products. Forty terminations were built for each kind of the fiber, so that groups of 10 specimens were further used in each sterilization experiment.

Table 2.1. Fibers selected for the study

| Fiber ID | Core OD (μm) | Glass cladding OD (μm) | Coating Material | Coating OD (μm) | Buffer material | Buffer OD (μm) |
|---|---|---|---|---|---|---|
| Acrylate | 200 | 220 | Dual acrylate | 500 | - | - |
| Polyimide | 200 | 220 | Polyimide | 250 | - | - |
| Silicone/PEEK | 200 | 220 | Silicone | 350 | PEEK | 600 |
| HCS/ETFE | 200 | 220 | HCS® | 250 | ETFE | 400 |

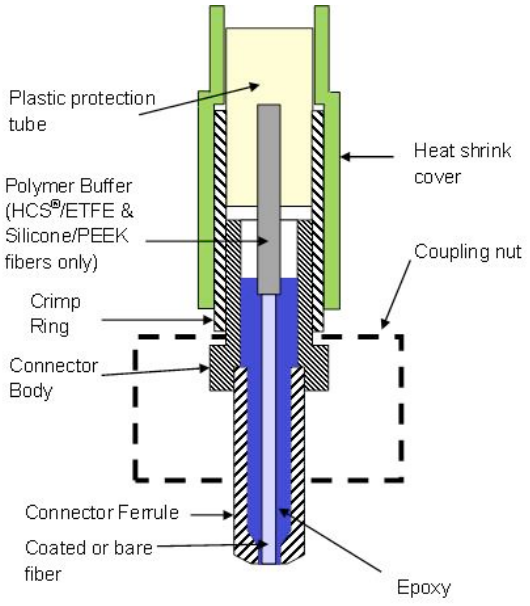


Figure 2.1. Termination design

## 3. STERILIZATION PROCEDURES AND TEST TECHNIQUES

Loose 500-meter coils about 12'' in diameter were prepared from each fiber. Prior to sterilization exposures, the fiber attenuation and strength was determined as described below.

PAA treatment of the fibers and terminations was performed by Medivators, Inc., via Revox® Sterilization Services. Prior to the treatment, the samples were packaged in standard Tyvek pouches and placed inside a 316SS stainless steel chamber. The Revox® approach uses vaporized peracetic acid in combination with

hydrogen peroxide, acetic acid and water. The mixture of chemicals was injected at a pressure of 10 Torr. The partial pressures of the individual components are proprietary to Medivators, Inc. The sterilization was performed at 23.8°C. Total sterilization time was 6.5 hours, which included 10 chemical injections and 2 ventilation cycles. In total, about 15 ml of the chemicals was released. The sterilization conditions used for our samples can be qualified as "extreme." A regular sterilization cycle is about a half number of the injections and 2/3 the concentration of the chemicals. Although a few other chemicals were involved in the process, PAA is believed to produce the main sterilization effect. Thus this approach will still be referred to as "peracetic acid" sterilization.

The UV sterilization was performed by MycoScience, Inc. The fiber coils were removed from the bags and placed in the UV exposure chamber containing Air Probe Sanitizer SN-025314. The coils were elevated off the floor of the chamber by a wire rack and located at a distance of 35 – 38 cm below the UV light source. The "germicidal" light source produced radiation at 253.7 nm (UV-C range) with the output power of 11 W. The light intensity at the distance of the product was approximately 125 $\mu W/cm^2$. The total exposure time was 48 hours, during which the coils were flipped over several times. The procedure was performed at ambient temperature. The calculated radiation dose received by the specimens was 21.6 $J/cm^2$, which is several times higher than standard doses used for UV sterilization. For comparison, typical doses used for food sterilization are in the range of 0.01 – 5.0 $J/cm^2$.[23-25] On the other hand, UV doses recommended for water disinfection fall in the range of 2.5 - 440 $J/cm^2$.[26]

The E-beam sterilization of the fiber coils and the terminations was performed by Nutek Corp. The samples were processed inside standard polyethylene bags. A Dual Simultaneous Electron Beam Processing was implemented with two Mevex 10 MeV 8KW E-beam accelerators. The electron energy was 10 MeV. The radiation dose was measured using GEX Dosimeters placed on the same tote that carried the samples. The time of exposure to E-beam was around 90 seconds for each of the two E-beam accelerators, and 3 minutes for the total cycle. With Nutek Dual Beam configuration, the items received direct radiation from two opposite sides. The conditions were very similar to routine sterilization processing of medical devices. The overall radiation dose received by the samples was 30kGy. For comparison, typical radiation doses used for E-beam sterilization are in the range of 10 – 30 kGy.[7]

Hot steam sterilization (autoclaving) was performed for the terminations only. A Napco E Series Test Chamber, Model 8100-TD was utilized. The samples were exposed to total ten gravity autoclave cycles. Each cycle consisted of 20 minutes at the highest temperature/pressure condition: 130°C /27 Psi.

The fiber attenuation in the region 600 – 1100 nm was determined using a custom-made spectral bench. The fiber strength was evaluated using two-point bend technique. The tests were performed with a Fiber Sigma 2 Point Bend Apparatus at a strain rate of 4%/min.[27] All strength testing was conducted at controlled humidity and temperature in accordance with a Telcordia GR-20 condition (RH = 50 ± 5%, T = 23 ± 2°C).[28] The samples were kept at least 12 hours at this condition before the testing, which is also required by the GR-20 standard.[28]

Chemical changes in coating and buffer materials were analyzed using Fourier-Transform Infrared spectroscopy (FTIR). The spectra were collected using a Nexus 670 spectrometer employed with a slide-on micro-attenuated total reflection (ATR) accessory. A germanium internal reflection element was utilized. With this setup, the IR beam probed about 1 μm layer of the analyzed samples (i.e., coatings and buffers). Finally, the connector pullout force was determined using an MTS Sintech 5/G tensile bench at a speed of 2.54 cm/min.

## 4. RESULTS AND DISCUSSION

### 4.1. Effects of Sterilization on Mechanical Strength of Fibers

Figure 4.1.1 displays the fracture stress data obtained for the as-drawn fibers. It is common to describe the fracture stress data by a Weibull distribution, which characteristic parameters are the median strength (equivalent to the median fracture stress, $\sigma_m$) and the Weibull slope, $m$. The latter is a measure of the variability in the strength data and is inversely proportional to the standard deviation. The magnitudes of

$\sigma_m$ and $m$ are summarized in Table 4.1.1. The strength of the "as drawn" fibers with dual acrylate, polyimide and HCS® coatings is around 5.6 GPa, while the fiber with the silicone coating is inherently weaker.

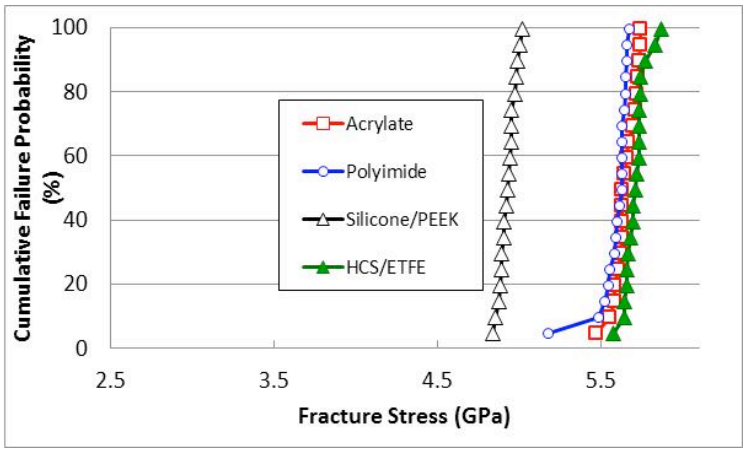


Figure 4.1.1. Weibull plots for "as-drawn" fibers determined via the two-point bend approach at 4%/min strain rate.

Table 4.1.1. Strength parameters of optical fibers before and after sterilization.

| Fiber ID | As drawn | | Peracetic Acid | | UV | | E-beam | |
|---|---|---|---|---|---|---|---|---|
| | $\sigma_m$ (GPa) | $m$ | $\sigma_m$ (GPa) | $m$ | $\sigma_m$ (GPa) | $m$ | $\sigma_m$ (GPa) | $m$ |
| Acrylate | 5.63 | 92 | 5.63 | 68 | 5.66 | 83 | 5.59 | 63 |
| Polyimide | 5.59 | 49 | 5.62 | 71 | 5.62 | 115 | 5.53 | 115 |
| Silicone/PEEK | 4.91 | 116 | 4.88 | 84 | 4.85 | 86 | 4.93 | 69 |
| HCS/ETFE | 5.7 | 97 | 5.7 | 35 | 5.76 | 188 | 3.05 | 6 |

Figure 4.1.2 compares the median strength of the "as drawn" and sterilized fibers. It can be seen that PAA and UV sterilization methods are not affecting the mechanical strength of the fibers. The E-beam radiation also did not affect the strength of the fibers with acrylate, polyimide and silicone coatings. At the same time, the fiber with HCS® coating and ETFE buffer became noticeably weaker after the exposure to E-beam. Such transformation is also illustrated in Figure 4.1.3.

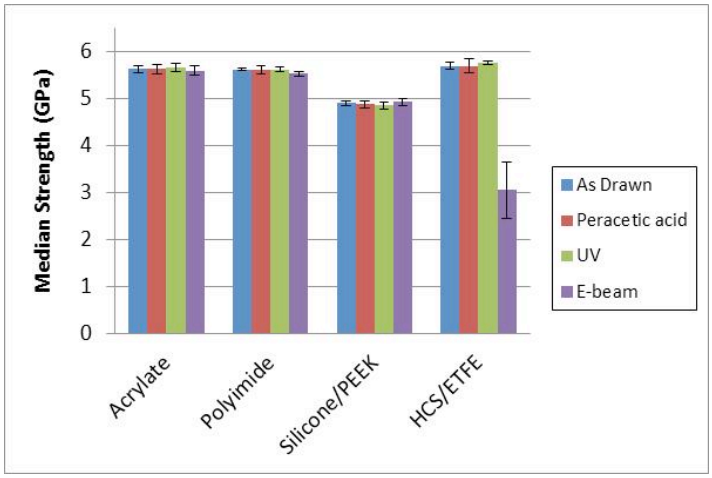


Figure 4.1.2. Effects of sterilization conditions on median strength ($\sigma_m$) of optical fibers. Error bars correspond to standard deviations.

Similar results were reported previously for gamma radiation.[12] It was concluded that the strength degradation observed for the HCS®/ETFE fiber is due to the fact that the coating and buffer materials are strongly fluorinated. Fluorine-containing polymers are known to be much more sensitive to radiation than fluorine-free polymers.[29] It seems most likely that interactions with E-beam and gamma radiation generate hydrofluoric acid (HF) as one of the reaction products. HF can easily diffuse through the coating and deteriorate the glass surface which results in significant strength degradation. It is worth noting that the strength degradation is not that strong for the E-beam as it was observed for the gamma sterilization.[12] Obviously, since the observed strength degradation is related to the fluorine content in the coating/buffer layers, similar behavior is expected for other types of commercially available fluorinated polymer-coated fibers. Therefore it should be concluded that the E-beam radiation is unfavorable for optical fibers with perfluorinated coatings and/or buffers.

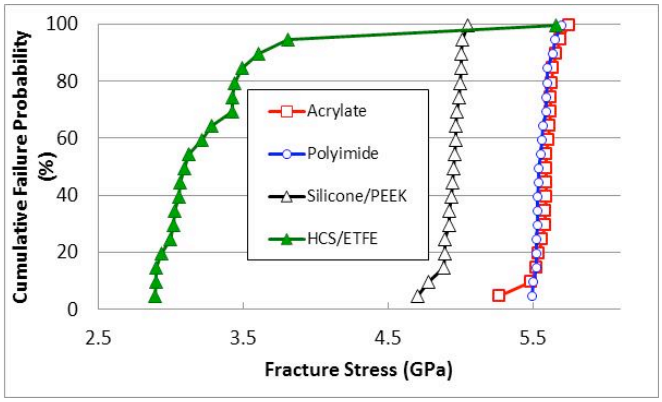


Figure 4.1.3. Weibull plots for the fibers exposed to E-beam radiation. Two-point bend test, 4%/min strain rate.

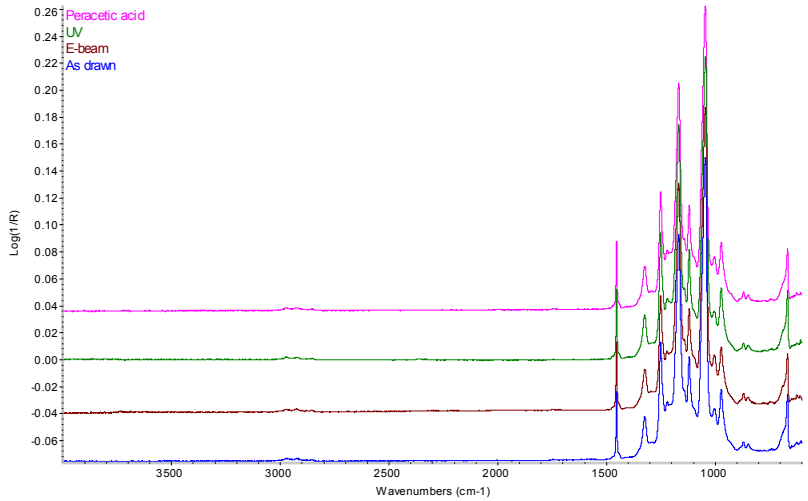


Figure 4.1.4. FTIR spectra of ETFE buffer before and after sterilization. The spectra are shown with arbitrary offsets.

It was of interest for us to reveal whether sterilization techniques cause chemical changes in the materials involved in the study. Such changes can be followed by FTIR spectroscopy. Thus we collected FTIR spectra of HCS®, ETFE, PEEK, silicone, polyimide and acrylates (primary and secondary) from the "as drawn" and sterilized fibers. In none of the cases we observed changes in the spectra. Examples of the obtained spectra are displayed in Figures 4.1.4 and 4.1.5: indeed, the spectra corresponding to the as drawn

and sterilized samples look almost identical. The fact that there are no significant changes in the spectra of HCS® and ETFE collected before and after the E-beam exposure indicates that the radiation did not cause major changes in the materials' chemistry. Thus it should be concluded that the changes induced by the E-beam radiation are minor for the HCS® and ETFE (at least they are undetectable by FTIR). However such minor changes are found to be fatal for the fibers. It is worth noting that gamma radiation also did not result in significant alterations in the chemistry of the HCS® and ETFE.

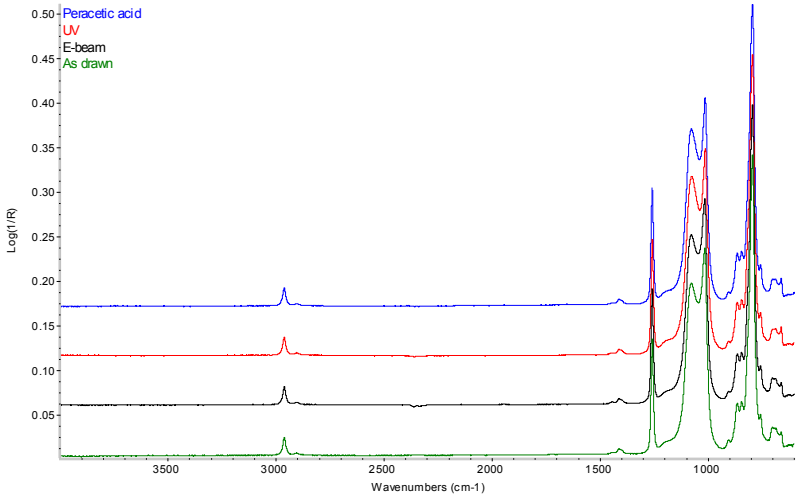


Figure 4.1.5. FTIR spectra of silicone coating before and after sterilization. The spectra are shown with arbitrary offsets.

### 4.2. Effects of Sterilization on Fiber Attenuation

Figure 4.2.1 shows the attenuation spectra collected for the "as drawn" and autoclaved fiber with dual acrylate coating. It can be seen that PAA and UV exposures did not affect the optical loss. In contrast, the E-beam radiation had induced a strong absorption that spreads throughout the whole studied spectral range. Similar trends were observed for the fibers with silicone/PEEK, HCS®/ETFE and polyimide coatings. This is illustrated in Figure 4.2.2, that displays the attenuation measured at 850 nm for different fibers/exposures.

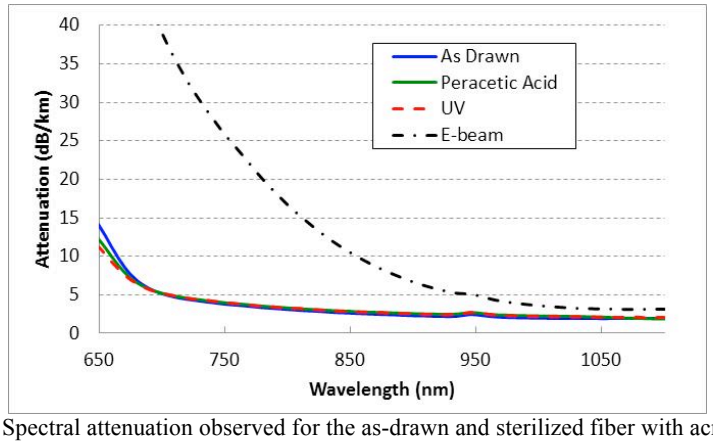


Figure 4.2.1. Spectral attenuation observed for the as-drawn and sterilized fiber with acrylate coating.

In addition, in the spectra of the HCS®/ETFE fiber one can notice slight development of an O-H peak at 950 nm after the PAA and UV radiation treatments (Figure 4.2.3). In contrast with the acrylate coating, the HCS® material functions in the fiber as a secondary cladding, and therefore it is responsible for certain

features in the attenuation spectra. From the 950 nm peak growth, it should be concluded that PAA and UV treatments led to a slight increase of the OH content at the outer glass surface of the fiber.

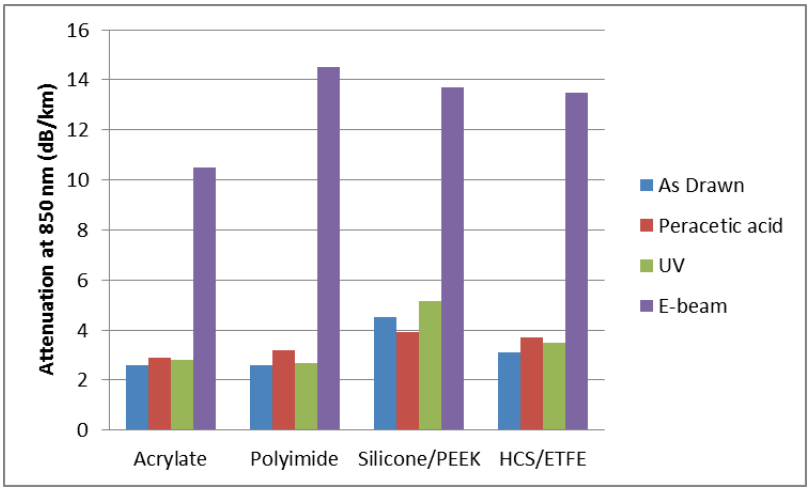


Figure 4.2.2. Attenuation at 850 nm (OTDR data) for as-drawn and sterilized optical fibers.

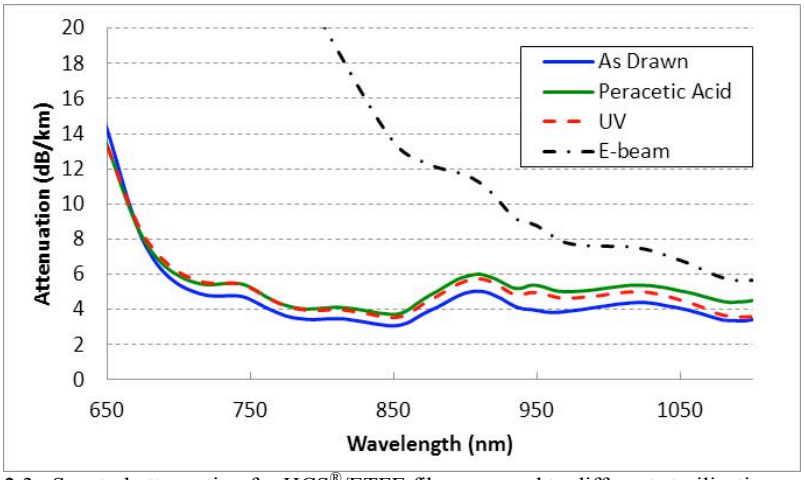


Figure 4.2.3. Spectral attenuation for HCS®/ETFE fiber exposed to different sterilization conditions.

Indeed, the most significant effects on the fiber attenuation are caused by the E-beam radiation. Quite similar spectral transformations were observed previously for the gamma sterilization.[12] Interactions of the silica glass with E-beam radiation are studied less extensively than similar interactions with gamma radiation.[30] Since the penetration depth of 10 MeV E-beam is around 5 cm,[20-22] the radiation definitely gets into the fiber core. Then, it may induce similar defects as gamma radiation does, including non-bridging oxygen hole center (^Si–O*), the E' center (^Si*), the peroxy radical (^Si–O–O*), and the trapped electrons, where the notation ‘‘^’’ represents three bonds with other oxygen in the glass network and ‘‘*’’ denotes an unpaired electron.[31] All those defects result in development of absorption bands in the UV-VIS spectral range, and the lower-frequency wings of these bands spread into the near infrared and cause the observed effects. Thus it follows that the E-beam radiation is not the best method of sterilization even for fibers with non-fluorinated coatings.

### 4.3. Effects of Sterilization on Mechanical Reliability of Fiber Terminations

This part of our study was motivated by the fact that not only the fibers but also their terminations must sustain sterilization treatment. There are many engineering solutions for the fiber termination. Most frequently, optical fibers are terminated by connectors which are bonded to fibers via an epoxy adhesive. Depending on the design, the epoxy may be bonded either to the polymer coating or to the naked glass cladding. In the latter case, the coating must be stripped off the fiber before the connector is put on. For the described terminations, the "survivability" means that sterilization does not cause deterioration of the epoxy and also does not break the connector-epoxy-fiber bonds. The latter property can be investigated by measuring the connector pullout force before and after the sterilization treatment. For this particular study, the terminations were designed such that the polyimide and HCS® coatings were not stripped off, so the adhesive bonded the connector ferrules with the coatings (Figure 2.1). For fibers with dual acrylate and silicone/PEEK coatings, the acrylate and silicone coating were removed, respectively, so the adhesive bonded the ferrule directly to the glass. This way we were able to test the bonds in ferrule-epoxy-coating-glass and the ferrule-epoxy-glass systems for different fiber types before and after the sterilization treatments.

It was decided not to study effects of UV radiation on the terminations since UV rays do not penetrate through metal connectors and cannot affect the epoxy adhesive. Instead, it was of interest to reveal possible effects of multiple steam sterilization, since such work was not done previously.[12] For each fiber type, 40 terminations were built. Of them, 30 were exposed to one of three sterilization methods (steam, PAA and E-beam) and the last 10 made the control group ("as assembled").

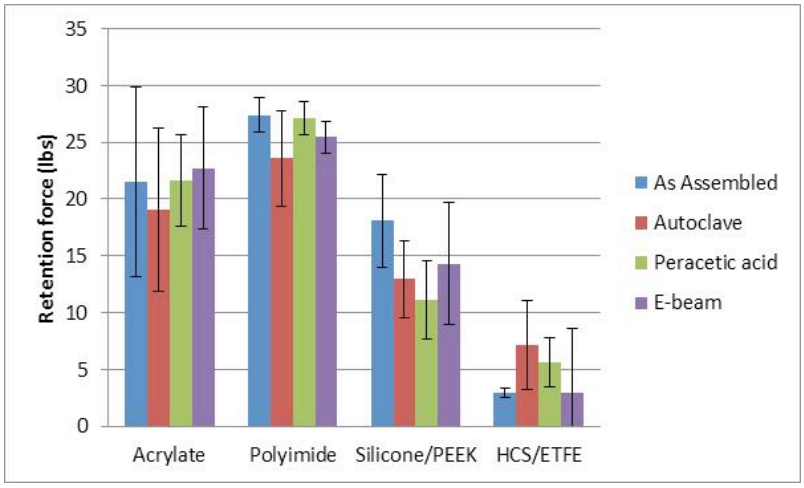


Figure 4.3.1. Connector median retention forces. The error bars correspond to the standard deviations.

Figure 4.3.1 illustrates the pullout forces observed for different fiber types before and after the sterilization treatments. The large error bars (high standard deviations) might be due to the ferrule ID variability and/or inconsistency of the bonding length inside the connectors. The connector pullout force increases in the following order: HCS® < silicone < acrylate < polyimide. Whatsoever, we see that none of the studied sterilization techniques caused a reduction of the pullout force. Moreover, autoclaving and PAA treatments seem to improve the connector retention for the HCS®/ETFE fiber. Thus, it can be stated that the trialed sterilization techniques did not worsen any of the fiber terminations.

## 5. SUMMARY

In the current and also in our previous communication,[12] we studied six sterilization techniques: steam sterilization (autoclaving), EtO and PAA treatment, UV, gamma and E-beam radiation. Those techniques were applied to fibers with four different coating types: dual acrylate, polyimide, silicone up-buffered with PEEK and fluorinated optical cladding (HCS®) up-buffered with ETFE. Based on the mechanical and

optical testing results, EtO, PAA and UV sterilization seem to be the most harmless techniques among the trialed ones. Steam sterilization causes only minor influence on the fiber strength and should be considered as another good approach for optical fiber steriliztion.[12] In contrast, E-beam and gamma radiation induce additional optical loss which should prevent their use for optical fibers. Certain fibers with non-fluorinated coatings may still be considered sterilizable with E-beam or gamma radiation once the induced losses fall within the allowed attenuation budget of the equipment.

Three sterilization techniques (hot steam, PAA and E-beam) were applied to fiber terminations. The terminations sustained all three treatment types, so their sterilization does not seem to be of a concern.

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