

Evaluation of Holmium:YAG Laser Optical Fibers for Flexible Ureteroscopy using a Relevant Benchtop Model

Jacky G. Duchamp, MS^a

^aEmployee of C. R. Bard, Inc., Covington, Georgia

KEY WORDS

Deflection
HeNe Laser
Holmium:YAG laser
Lithotripsy
Lumenis VersaPulse® 100 W
PowerSuite™
Optical Fibers
Power Input and Output
Resterilization
Short-Term Bend Radius
Urinary Calculi
Ureteroscopes

Abstract

Purpose. Several studies have been published on Holmium:YAG laser fibers, most of which concentrate on the physical characteristics of these fibers. Utilizing methods that simulate actual clinical use, we investigated the functionality and performance threshold of commercially available Holmium:YAG laser fibers.

Materials and Methods. Testing was conducted on single-use and reusable laser fibers in varying sizes – 200µm, 272µm, 365µm, 550µm and 1000µm. Sizes reflect the true core diameter of each fiber. Fixtures for the testing were built for the 200µm, 272µm, 365µm, 550µm fibers simulating the anatomical curvature that the fiber may be subjected to during a procedure (considered the short-term bend radius), as well as the maximum-allowed deflection of the fiber when placed within the working channel of a flexible ureteroscope. A separate fixture was built for the 1000µm fiber simulating the short-term bend radius only, as its core size does not allow for deflection or use within a flexible ureteroscope. Each fiber was placed into its respective fixture, and power outputs were recorded using the HeNe laser JDSU Model 1137 and Lumenis VersaPulse® 100W PowerSuite™ Holmium:YAG laser generator. The SMA-905 connector of each fiber was first connected to the HeNe laser to determine the fiber's spot size, and the power output was recorded. The fiber was subsequently connected to the Lumenis VersaPulse® 100W PowerSuite™ Holmium:YAG laser generator, and the generator was set to the maximum-allowed power input for each fiber per the Instructions for Use. The power output was then recorded. Further tests were performed on the reusable fibers following cleaving, stripping, cleaning and reesterilization, and following transportation and extreme conditioning, and aging. Tests were also carried out on non-sterile laser fibers to evaluate the complete downstream process effect study. To pass testing, the laser fibers had to meet the acceptance criteria of transmitting 80% or greater of the maximum power inputs for both the HeNe and Holmium:YAG lasers. Acceptance criteria also included no known non-conformances reported with either the laser fiber or the laser generator.

Results. Functionality and performance of the BARD® ENDOBEAM™ Holmium Laser Fibers were confirmed following a four-month testing period consisting of 4,530 total runs – 2,409 performed on the HeNe laser Model 1137 and 2,121 performed on the Lumenis VersaPulse® 100W Powersuite™. All sizes of the ENDOBEAM™ Holmium Laser Fibers demonstrated consistent power outputs greater than or equal to 80% transmission of maximum power input in short-term bend radius and maximum-allowed deflection angles on the two lasers. Conversely, the AMS SureFlex 200µm single-use laser fiber demonstrated 10% less power output compared to the ENDOBEAM™ 200µm single use laser fiber, when subjected to the same testing. In the same model, 25% of SureFlex 200µm single-use laser fibers demonstrated breakage at the apex of the deflection curve and failed to transmit power into the distal tip when subjected to the maximum-allowed power input of 25W. There were no statistical differences among the study endpoint populations.

Conclusions. Commercially available Holmium:YAG laser fibers differ significantly in their performance characteristics when subjected to simulations of clinical use in a bench top model.

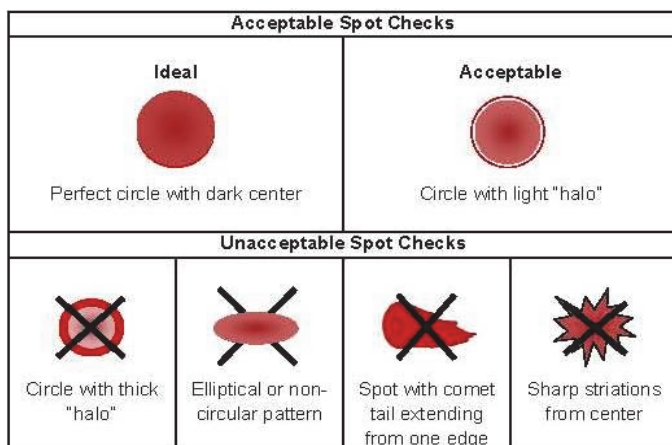
Introduction

The Holmium:YAG laser has become the preferred lithotripsy method in urological applications because of its unique functional capabilities¹. Indeed, Holmium:YAG lithotripsy fragments stones better than other lithotripsy devices²⁻⁴. There are multiple commercially available optical fibers that work in conjunction with Holmium:YAG lasers. Holmium:YAG laser fibers are free-beam delivery devices that transmit laser energy (Ho:YAG [2100nm] and Nd:YAG [1064nm]) in a forward direction. These fibers differ in physical characteristics – such as core and buffer diameters, tip length, exposed tip length, tapered and non-tapered fibers – usability (single-use versus reusable⁵) and mode of connection to the laser generator. They are indicated for a variety of surgical uses, including open laparoscopic or endoscopic ablation, incision, excision, vaporization, and coagulation of soft and cartilaginous tissue, as well as procedures involving vaporization, ablation and fragmentation of calculi.

Fiber construction is one factor that affects fiber durability among commercially available optical laser fibers⁵. Fiber failure is complex and can be problematic when occurring. The reflection of the laser energy occurs between the fiber core and the cladding. When the optical fibers are deflected within a ureteroscope, a portion of the power output can travel into the cladding and, in some cases, into the fiber buffer. If this occurs, the fiber will fail at the site of maximum deflection, resulting in costly ureteroscope damage, the potential for procedure delay and, in some cases, patient morbidity⁶.

Although there have been several published studies on Holmium:YAG optical laser fibers, most do not provide evidence related to the clinical utility of the products⁷. We examine differences in performance of commercially available optical laser fibers utilizing methods that simulate actual clinical use. We hypothesized that fibers differ in performance characteristics and that the difference is more pronounced in the 200 micron core fiber.

Figure 1. Optical Fiber Spot Check



Hypothesis

The primary hypothesis is to demonstrate that the Bard EndoBeam™ series of Holmium Laser Fibers provide adequate power output at the maximum labeled allowable power input using a relevant benchtop model. A secondary hypothesis is to claim

power output superiority of the Bard EndoBeam 200 micron holmium laser fiber over the AMS SureFlex™ 200 Single-use Fiber using a relevant benchtop model.

Materials and Methods

A total of seven (7) new, single-use and reusable Holmium:YAG laser fibers with true-core diameter sizes of 200 μm , 272 μm , 365 μm , 550 μm and 1000 μm were evaluated. All fibers were commercially available product distributed by C.R. Bard, Inc. and by American Medical Systems. The parameter studied was power output transmission. Two different laser generators were utilized to measure the power output transmission.

The first category of laser was a HeNe laser, JDSU Model 1137. This class of laser generates very low energy and is mainly used during production of optical laser fibers as a final quality control step.

The second category of laser was a Holmium:YAG laser, Lumenis VersaPulse® 100W PowerSuite™. This class of laser generates energy up to 100 watts and is used in clinical applications.

Each fiber was placed in test fixture comprising two radii. One radius represented the short-term bend radius or anatomical curvature that one fiber may be exposed to during the surgical procedure. The other radius represented the maximum-allowed deflection angle observed when placed in a ACMI DUR®-8 Durable Flexible Ureteroscope¹. The unique combination of the short term bend radius and deflection angle created singular test fixtures for each of the fiber sizes. The path of the fixtures was such that it was identical to the depth and width of a 3.6 Fr flexible ureteroscope^a.

Each fiber was first connected to the HeNe laser to evaluate the tip spot shape (*Refer to Figure 1*). If the tip spot shape was acceptable, the fiber was then placed in its appropriate fixture with its tip extending out by exactly the same length. The SMA-905⁸ connector was attached to the HeNe generator while the reading head was placed over the fiber tip. The test setup featured a hard stop so that each fiber tip was aligned exactly the same distance relative to the laser reading head. The power output of the HeNe energy passing through each fiber was recorded (*Refer to Figure 2*). The average of each power output was compared to the average of the power input recorded before the test was initiated as well as after the test was concluded. Holmium:YAG testing was performed by analogy to the HeNe testing. The Lumenis VersaPulse® 100W PowerSuite™ was set to input 25 watts, 45 watts or 100 watts, depending on the fiber size used and in accordance with the respective Instructions for Use for the product (*Refer to Figure 3*). Again, the average of each power output was compared to the average of the power input recorded before the test was initiated as well as after the test was concluded.

To pass testing, the laser fibers had to meet the acceptance criteria of transmitting 80% or greater of the maximum power inputs for both the HeNe and Holmium:YAG lasers. All testing was done in air, and all fibers were randomized.

^a Except for the 1000 micron fibers which are used with rigid scopes and therefore, are not subjected to deflection

The same testing was carried out on fibers post stripping and cleaving, post transportation and extreme environmental conditioning, post accelerated aging and post re-processing (reusable fibers only).

Figure 2. HeNe Laser Test Setup

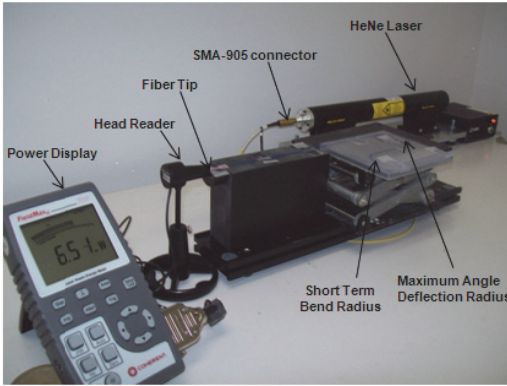
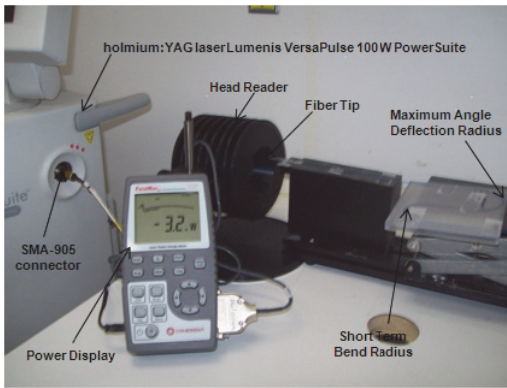


Figure 3. Holmium:YAG Test Setup



Statistical Analysis

The Kolmogorov-Smirnov test computes the maximum distance between the cumulative distribution of The Holmium Transmission for a particular fiber and the CDF of the fitted Normal distribution.

Results

A total of 4,530 singular runs were performed over the course of four (4) months. **Table A** shows the breakdown in individual runs among the different fibers and across the two lasers.

Testing of single-use fibers included multiple lots of fibers that were pre-sterile, post (2x) Ethylene Oxide (EtO) sterilization, post transportation and extreme conditioned, post six(6) months accelerated aging, post two (2) years accelerated aging, before (out of the box) and after stripping and cleaving. The AMS SureFlex™ 200 Micron Single-Use Laser Fiber followed the same testing.

Table A. Total Count of Individual Runs

Fiber Model	HeNe Runs	Holmium:YAG Runs
BARD® ENDOBEAM™ SU0200	270	178
AMS SureFlex™ 200 Single-use Fiber	30	30
BARD® ENDOBEAM™ SU0365	180	180
BARD® ENDOBEAM™ RU0272	520	425
BARD® ENDOBEAM™ RU0365	449	438
BARD® ENDOBEAM™ RU0550	450	450
BARD® ENDOBEAM™ RU1000	540	450
TOTAL	2,409	2,121

Testing of reusable fibers followed the same path as for single-use fibers. In order to simulate reprocessing which occurs in the clinical setting, reusable fibers were also submitted to nine cycles of cleaning and re-sterilization and testing was performed after re-sterilization cycles one, five and nine.

Figures 4 and 5 show the power transmission results⁹. Each fiber met the minimum acceptance criteria of 80% power transmission when used in conjunction with the HeNe laser setup. However, the AMS SureFlex™ 200 Micron Single-Use Laser Fibers failed to meet the same requirements when used in conjunction with the Holmium:YAG laser setup; whereas, each size of BARD® ENDOBEAM™ Laser Fibers did.

Figure 4. HeNe Laser Test Power Transmission Results

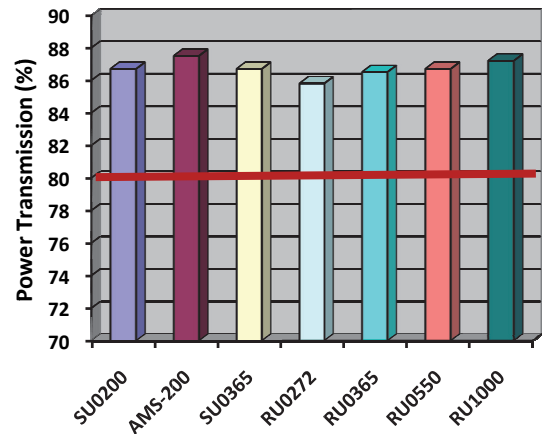
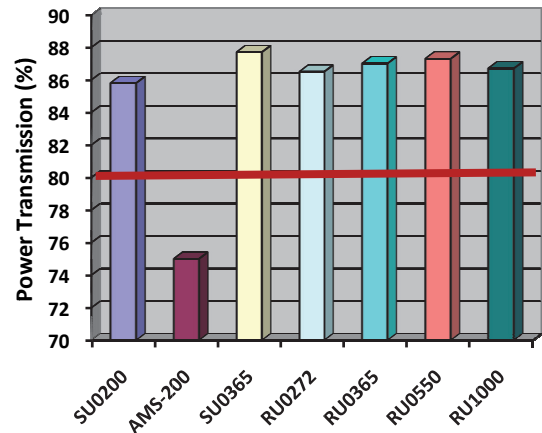


Figure 5. Holmium:YAG Laser Test Power Transmission Results



Discussion

Laser fibers are fiber optic laser energy delivery devices consisting of a SMA-905 connector, strain relief, and a silica core/silica clad fiber jacketed with ethylene tetrafluoroethylene (ETFE). The fibers are further equipped with a flat, polished output tip. These fibers may be used in a variety of laser-based surgical cases as an integral part of laser systems. Laser energy is delivered through the core of a low hydroxyl silica fiber to the desired target. Surrounding the core is a layer of fiber cladding that is essential for the efficient delivery of optical energy. The cladding is of a different refractive index than the core fiber, so that photons are reflected at the core fiber-cladding interface by a process called total internal reflection. The cladding may absorb a small amount of refracted energy before it leaks into the jacket. After energy leaks into the jacket, which strongly absorbs the laser energy, the fiber will likely fail. Poor fiber coupling at the connector end or the loss of total internal reflection with fiber deflection may increase the amount of energy escaping into the cladding and/or jacket.

Successful use during endoscopic procedures demands that fibers are able to handle enough power to fragment stones and ablate tissues while minimizing the risk of injury. In addition, the fiber must be flexible enough so as not to limit the deflection of the ureteroscope, thereby improving access to all areas of the urinary collecting system, including the lower pole. The ideal laser fiber has certain characteristics, including: a small true diameter, high flexibility, ergonomic ease of handling, capability of delivering a large amount of optical energy without thermal breakdown, high power connector with free standing fiber.

Based on results, it can be speculated: Every fiber demonstrated an acceptable spot check out of the box. Furthermore, using the appropriate techniques along with the stripping and cleaving tools associated with a particular fiber, the acceptability of the fiber spot check is maintained.

There were no statistical differences in power output transmission among the different populations and endpoints for the BARD® ENDOBEAM™ Holmium Laser Fibers. Subjecting the BARD® ENDOBEAM™ Holmium Laser Fibers to stripping and cleaving, extreme environmental conditioning, transportation testing and accelerated aging did not negatively impact the functionality of the fibers when tested in actual clinical use.

Each BARD® fiber demonstrated adequate power output transmission when used in conjunction with the HeNe laser, which speaks to the quality of the fibers.

The functionality of BARD® ENDOBEAM™ Holmium Laser Fibers was confirmed following a four-month testing period consisting of 4,530 singular runs (2,409 on the HeNe laser JDSU Model 1137 and 2,121 on the Lumenis VersaPulse® 100W PowerSuite™).

All sizes of the ENDOBEAM™ Holmium Laser Fibers demonstrated consistent power output (>80% transmission of maximum power input) at short-term bend radii and maximum-allowed deflection angles after each study endpoint on both lasers.

Conversely, the performance of the AMS SureFlex™ 200 Micron Single-Use Laser Fiber demonstrated 10% less power transmission at the same bend radius and deflection over the ENDOBEAM™ 200 Micron Single-Use Laser Fiber when used in conjunction with the Lumenis VersaPulse® 100W PowerSuite™.

Moreover, in the same clinically-representative model, 25% of the AMS SureFlex™ 200 Micron Single-Use Laser Fibers failed at the distal tip in comparison to the ENDOBEAM™ 200 Micron Single-Use Laser Fiber when used in conjunction with the Lumenis VersaPulse® 100W PowerSuite™.

The failure mode of the AMS SureFlex™ 200 Micron Single-Use Laser Fibers was breakage of the fiber at the apex of the deflection curve, which implies that such fibers are not consistently capable of sustaining the mechanical stresses during ureteroscopy. Such failure would have most likely caused flexible ureteroscope damage; therefore creating possible procedure delay.

Conclusions

In this study a series of commercially available Holmium:YAG optical laser fibers were evaluated for power out transmission when utilizing methods that simulate actual clinical use. Our hypothesis that fibers differ in performance characteristics, and that the difference is more prominent in the 200 micron core fiber, was validated.

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