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Evaluation of ScopeSafe Fibers and the Scope Guardian Sheath in Prevention of Ureteroscope Endoluminal Working Channel Damage

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Introduction: The Holmium:YAG/Neodymium:YAG laser is an important tool for endoscopic stone treatment. While endoscope damage due to laser energy is well recognized, mechanical damage to the working channel due to repeated insertions of laser fibers is a less understood and appreciated mechanism for ureteroscope damage via working channel perforation. We evaluated ureteroscope performance metrics and working channel damage with ScopeSafe fibers and the Scope Guardian Sheath.

Methods: A 200µm/272µm ScopeSafe fiber with Scope Guardian Sheath (Optical Integrity Inc., Panama City Beach, Florida) was objectively assessed in a new 7.5 Fr flexible distal sensor chip ureteroscope (Storz XC). We measured active upward and downward deflection (up and down) and irrigation flow rates with this novel fiber and sheath system, and with standard 200µm/ 272µm Laser fiber (Cook Urological Inc., Spencer, Indiana). Additionally 8 non assembled working channel elements from the Storz X^{C} ureteroscope were tested in a 90° and 210° deflection model. 200µm/ 272µm ScopeSafe fibers with Scope Guardian Sheath and 200µm/272µm standard laser fibers were inserted into an irrigated working channel in cycles of 10 insertions. After 40 insertions the insertion cycle was reduced to 5 insertions. After each test cycle, an external inspection and an endoluminal video examination of the working channel by a 2.4Fr flexible fiberscope was performed. Damage to the working channel was classified as superficial scratches, demarcated abrasions, or perforations.

Figures:

Figure 1/2: ScopeSafe fiber with Scope Guardian Sheath

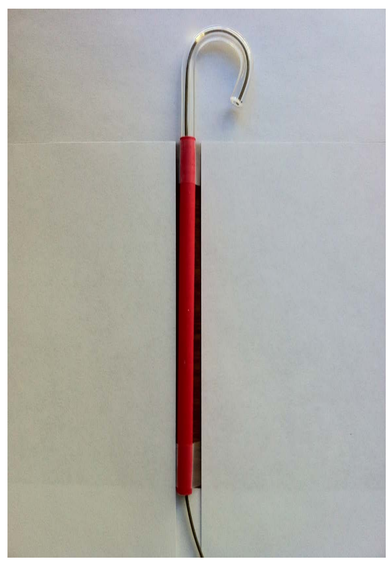

Figure 3: Working Channel Model

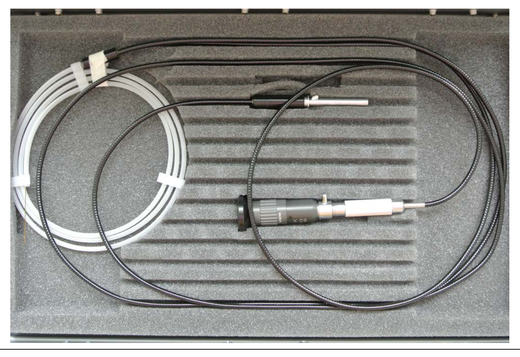

Figure 4: 2.4 Fr Flexible Fiberscope

Results : Compared to a standard fiber, the Scope Guardian Sheath resulted in a 4.7°/3.8° (1.2%/1.5%) diminishment in deflection (up/down) for the 200µm and a 3.5°/4.3° (1.8%/1.5%) diminishment for 272µm laser fibers. Flow was diminished by 9.33 ml/min for the 200µm and by 9.12 ml/min for the 272µm Guardian Sheath.

	Deflection	XC		Diminished Deflection XC	
		Mean	SD	°	%
Laser 200µm	Up	289.16	0.28		
	Down	286.16	0.28		
Laser 200µm Guardian Sheath	Up	285.66	0.28	4.7	1.2
	Down	281.83	0.28	3.8	1.8
Laser 272µm	Up	256.83	0.28		
	Down	250.16	0.28		
Laser 272µm Guardian Sheath	Up	252.16	0.28	3,5	1,8
	Down	246.33	0.57	4,3	1,5

Table 2: Deflection 200µm/272µm

Flow (ml/min)		XC		Diminished Flow XC	
		Mean	**SD**	**ml/min**	**%**
Empty	Flow	62.83	0.57		
Laser 200µm	Flow	32.5	0		
Laser 200µm Guardian Sheath	Flow	23.16	0.28	9.33	28.7
Laser 272µm	Flow	28	0		
Laser 272µm Guardian Sheath	Flow	18.87	0.29	9.13	32,6

Table 3: Flow 200µm/272µm

Results Endoluminal Inspection: There were no channel perforations or damage with one hundred laser Fiber insertions with the 200µm/272µm ScopeSafe Fibers with Scope Guardian Sheath in the 90° model as well as in the 210° model.

210° Model (Nbr of Insertions)	Superficial Scratches	Abrasions	Perforation
Laser 200µm	30	none	none
Laser 200µm Guardian Sheath	none	none	none
Laser 272µm	10	60-70	110
Laser 272µm Guardian Sheath	none	none	none

Table 4: 210° Deflection Model

Figure 4/5/6: Working Channel – Scratches – Abrasion - Perforation

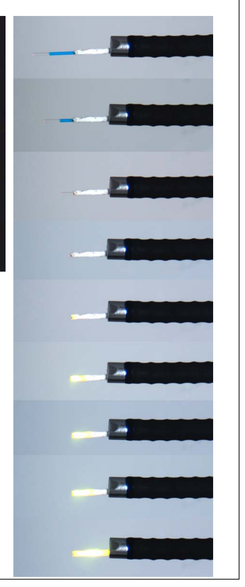

Figure 7: ScopeSafe fiber with new Phosphor Scope Guardian Sheath

Conclusion: In this in vitro study, the scope Guardian Sheath prevented mechanical damage to ureteroscope working channels. There was some limited diminishment of deflection and irrigation flow rate compared to standard laser fibers alone. Clinical correlation is pending.