

*Clinical Performance of
GORE® VIABIL® Biliary Endoprosthesis
in the Treatment of Malignant Strictures*

**Scientific Literature Summary
(n = 663 patients)***

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GORE® VIABIL® Biliary Endoprosthesis – Advancing Biliary Therapy

The First Fully Covered SEMS with Anti-Migration Anchoring Fin Technology.

- **Demonstrated Anti-Migration**
 - Atraumatic, deformable anchoring fin technology**
- **Accurate Easy Delivery**
 - Non shortening stent design**
 - Exclusive pull line deployment** (endoscopic)
 - Radiopaque markers enable precise placement
- **Exceptional Conformability with Uncompromised Radial Strength**
 - Nitinol wire exoskeleton with an ultrathin ePTFE/FEP covering**
 - Continuous wire stent design naturally follows tortuous anatomy
- **Proven Long-Term Patency**
 - Impermeable ePTFE/FEP covering**
 - Prevents tumor ingrowth
 - Resists initial bacterial attachment minimizing the risk of bio-sludge occlusion
 - High radial strength resists tumor progression
- **Minimal Risk of Branch Duct Exclusion**
 - Optional fenestrations help maintain transmural drainage
 - Additional radiopaque marker ensures proper positioning
- **In the last ten years, more than 700,000 Gore ePTFE stent grafts[†] have been implanted worldwide.**

**Proprietary Gore technology

Indications for Use:

USA: THE GORE® VIABIL® Biliary Endoprosthesis is indicated for the treatment of malignant biliary strictures.

Europe and Canada: The Removable GORE® VIABIL® Biliary Endoprosthesis is indicated for the treatment of benign and malignant biliary strictures and can be removed from such strictures for up to one year post implant.

Refer to Instructions For Use for a complete description of all warnings, precautions, and contraindications.

Products listed may not be available in all markets. For product availability in regions not listed, please contact W. L. Gore & Associates, Inc.

*Data based on an analysis of current literature: several Medline and abstract searches were performed to identify publications pertaining to GORE® VIABIL® Biliary Endoprosthesis. Search criteria included (1) articles published January 1999 through March 2011, (2) key words used were GORE® VIABIL® Biliary Endoprosthesis, covered biliary stent, PTFE, malignant, (3) articles in English language, (4) N equal or greater than 10 patients, (5) clinical publications, abstracts, (6) case reports were excluded, (7) current endoscopic delivery system, (8) studies which included multiple biliary stents were identified and percent use with GORE® VIABIL® Biliary Endoprosthesis were reported. Articles that did not meet the above criteria were not included in this summary.

† GORE® VIABAHN®, VIATORR®, VIABIL®, EXCLUDER®, TAG® Products

Proven Performance Through Data

Clinical Performance of GORE® VIABIL® Biliary Endoprosthesis for the Treatment of Malignant Strictures

VIABIL® Device Patients	Technical Success	Lifetime Palliation	Primary Patency (days)	Percent Primary Patency ¹		
				3 Months	6 Months	12 Months
n=663	Range 97-100%	87.4% (256/293)	Range 117 - 234	96%	85%	72%
Dysfunctions (e.g. tumor overgrowth)	Time to Reintervention (days)	Migration	Cholecystitis	Pancreatitis		
9.7% (40/412)	Mean Range 84 - 295	0.3%	3.8%	2.3%		

As Compared To:

	Migration	Cholecystitis	Pancreatitis
Covered Stents (partial & fully covered)	3 - 13% ^{2,3}	2%-12% ^{3,4}	5.1% - 8.7% ⁵

¹ Percent primary patency calculated using weighted average from available Kaplan-Meier survival and primary patency rates for 3, 6, and 12 months. References without Kaplan-Meier data are not included in patency summary results.

² Schoder M, Rossi P, Uflacker R, et al. Malignant biliary obstruction: treatment with ePTFE-FEP-covered endoprosthesis initial technical and clinical experiences in a multicenter trial. *Radiology* 2002;225(1):35-42.

³ Kahaleh M, Tokar J, Conaway MR, et al. Efficacy and complications of covered Wallstents in malignant distal biliary obstruction. *Gastrointestinal Endoscopy* 2005;61(4):528-533.

⁴ Kullman E, Frozanpor F, Söderlund C, et al. Covered versus uncovered self-expandable nitinol stents in the palliative treatment of malignant distal biliary obstruction: results from a randomized, multicenter study. *Gastrointestinal Endoscopy* 2010;72(5):915-923.

⁵ Coté GA, Kumar N, Anstas M, Edmundowicz SA, Jonnalagadda S, Mullady DK, Azar RR. Risk of post-ERCP pancreatitis with placement of self-expandable metallic stents. *Gastrointestinal Endoscopy* 2010;72(4):748-754.

Percutaneous Palliation of Pancreatic Head Cancer: Randomized Comparison of ePTFE/FEP-Covered Versus Uncovered Nitinol Biliary Stents

Krokidis M, Fanelli F, Orgera G, Tsetis D, Mouzas M, Bezzi M, Kouroumalis E, Pasariello R, Hatzidakis A, 2011¹

Device	Patients	Technical Success	Lifetime Palliation	Primary Patency (days)	Percent Primary Patency		
					3 Months	6 Months	12 Months
VIABIL® Device	n=40	100%	90% (36/40)	Mean 234	97.3%	92.2%	87.6%
LUMINEXX™	n=40	100%	70% (28/40)	Mean 166	77.5%	69.8%	69.8%

Dysfunctions (e.g. tumor overgrowth)	Time to Reintervention (days)	Migration	Cholecystitis	Pancreatitis
10% (4/40)	Mean 126.5	0/40	0/40	0/40
30% (12/40)	Mean 82.9	0/40	0/40	0/40

■ Study Details

- Design: multicenter, prospective, randomized
- Purpose: compare clinical effectiveness of covered GORE® VIABIL® Biliary Endoprosthesis stents (n = 40) to uncovered metallic LUMINEXX™ Device stents (n = 40)
- Etiology: 80 pancreatic adenocarcinoma
- Inclusion: obstructive jaundice caused by unresectable pancreatic head adenocarcinoma, which in turn caused occlusion of the biliary tree at the lower half of the common bile duct.
- Exclusion: three of six of the following: total serum bilirubin level ≥ 15 mg/dl, leukocytosis $\geq 11 \times 10^9/l$, gamma glutamil transferase (yGT) > 165 IU/l, prothrombin ratio ≥ 1.4 , C-reactive protein (CRP) ≥ 5 mg/dl, and serum carbohydrate antigen 19-9 (CA 19-9) level ≥ 10.000 IU/ml.
- Survival / Implant Duration / Follow-up:
 - GORE® VIABIL® Biliary Endoprosthesis: ~8.1 months (mo): median 247 days (d)
 - LUMINEXX™: ~6.7mo: median 203d
- Complications:
 - GORE® VIABIL® Biliary Endoprosthesis: 12.5% (5/40) - 3 peritoneal irritation, 2 self limited biliary hemorrhage
 - LUMINEXX™: 10% (4/40) - 2 peritoneal irritation, 2 self limited biliary hemorrhage

■ Conclusions

“Regarding primary patency and ingrowth rate, ePTFE/FEP-covered stents [GORE® VIABIL® Biliary Endoprosthesis] have shown to be significantly superior to bare nitinol stents for the palliation of malignant jaundice caused by inoperable pancreatic head cancer and pose comparable cost and complications.”

“Use of a covered stent does not significantly influence overall survival rate; nevertheless, the covered endoprosthesis seems to offer result in fewer reinterventions and better quality of patient life.”

Fully Covered Self Expandable Metal Stents (CSEMS) for Malignant Distal Biliary Strictures: Mid-term Evaluation

Bakhru M, Ho HC, Gohil V, Wang AY, Ellen K, Sauer BG, Shami VM, Kahaleh M., 2011²

VIABIL [®] Device Patients	Technical Success	Lifetime Palliation	Primary Patency (days)	Percent Primary Patency		
				3 Months	6 Months	12 Months
n = 70	NA	71% (29/34)	Mean 163 (15-1093)	NA	NA	NA

Dysfunctions (e.g. tumor overgrowth)	Time to Reintervention (days)	Migration	Cholecystitis	Pancreatitis
4.3% (3/70)	Mean 155 (69-295)	1.4% (1/70)	4.2% (3/70)	11.4% (8/70)

■ Study Details

- Design: prospective data collection
- Purpose: evaluate safety and patency of fully covered metal stent (CSEMS) with anchoring fins for malignant biliary strictures
- Etiology: 53 pancreatic malignancy, 7 ampullary cancers, 4 metastatic diseases, 3 gallbladder cancers, 2 cholangiocarcinoma, 1 duodenal carcinoma
- Inclusion: management of malignant distal biliary strictures between October 2006 and September 2008
- Exclusion: NA
- Survival / Implant Duration / Follow-up: ~5.9mo: mean 180d (15d-1092d)
- Complications: 41.4% (29/70) - 4 wire perforation, 8 pancreatitis, 4 proximal deployment requiring reposition, 5 pain, 3 cholecystitis, 2 cholangitis, 1 proximal migration, 1 post-sphincterotomy bleeding, 1 sepsis

■ Conclusions

"CSEMS appear to provide acceptable short-term patency rates; however, their limited long-term patency and high complication rate may limit their widespread use. Further long-term prospective data is required to confirm this observation."

Percutaneous Treatment of Malignant Jaundice Due to Extrahepatic Cholangiocarcinoma: Covered Viabil [GORE® VIABIL® Biliary Endoprosthesis] Stent Versus Uncovered Wallstents

Krokidis M, Fanelli F, Orgera G, Bezzi M, Passariello R, Hatzidakis A, 2010³

Device	Patients	Technical Success	Lifetime Palliation	Primary Patency (days)	Percent Primary Patency		
					3 Months	6 Months	12 Months
VIABIL® Device	n=30	100%	87% (26/30)	Mean 227.3	NA	NA	NA
WALLSTENT®	n=30	100%	70% (21/30)	Mean 166.0	NA	NA	NA

Dysfunctions (e.g. tumor overgrowth)	Time to Reintervention (days)	Migration	Cholecystitis	Pancreatitis
13.3% (4/30)	Mean 179.5	0/30	0/30	0/30
30% (9/30)	Mean 133.1	0/30	0/30	0/30

Study Details

- Design: multicenter, prospective, randomized
- Purpose: compare the clinical results of GORE® VIABIL® Biliary Endoprosthesis (n = 30) stent-grafts versus WALLSTENT® Devices (n = 30)
- Etiology: 80 unresectable extrahepatic cholangiocarcinoma
- Inclusion: Bismuth type I unresectable extrahepatic cholangiocarcinoma, with a total serum bilirubin level <15 mg/dl, absence of hepatic metastasis, patient age ≤ 80 years, a satisfactory coagulation status (INR value ≤ 1.5 and platelet count value of ≥70,000), and a performance status >3 on the Eastern Cooperative Oncology Group scale
- Exclusion: intrahepatic and hepatic bifurcation (Klatskin) tumors, presence of hepatic metastasis, patient age [80 years, previous surgical or radiotherapeutical palliative treatment, and very poor patient general condition]
- Survival / Implant Duration / Follow-up:
 - GORE® VIABIL® Biliary Endoprosthesis: ~8.0mo: median 243.5d
 - WALLSTENT®: ~5.9mo: median 180.5
- Complications:
 - GORE® VIABIL® Biliary Endoprosthesis: 10% (3/30) - 2 peritoneal irritation, 1 biloma formation
 - WALLSTENT®: 13.3% (4/30) - 3 peritoneal irritation, 1 self limited biliary hemorrhage

Conclusions

“In conclusion, Viabil [GORE® VIABIL® Biliary Endoprosthesis] stents have been shown to be safe for palliation of malignant jaundice caused by extrahepatic cholangiocarcinoma. They also seem to be effective in preventing tumor ingrowth and may therefore reduce the rate of stent occlusion and increase patients’ quality of life.”

“The results of this study suggest that Viabil [GORE® VIABIL® Biliary Endoprosthesis] stents may be superior to conventional uncovered WALLSTENT® Device in the management of malignant biliary obstruction due to Bismuth type I cholangio-carcinoma, with similar costs and complication rates, and, therefore, should be considered as the first option in the selection of an endoprosthesis, especially for inoperable patients in relatively good general condition.”

Use of ePTFE Covered Stents for Malignant Biliary Strictures

Syed LH, Hong K, Syed LH, 2009⁴

VIABIL® Device Patients	Technical Success	Lifetime Palliation	Primary Patency (days)	Percent Primary Patency		
				3 Months	6 Months	12 Months
n=28	NA	93% (26/28)	Mean 126	NA (Overall Primary Patency: 96%)		

Dysfunctions (e.g. tumor overgrowth)	Time to Reintervention (days)	Migration	Cholecystitis	Pancreatitis
3.7% (1/27)	259	NA	NA	NA

■ Study Details

- Design: retrospective chart review
- Purpose: to demonstrate both patency and need for secondary interventions with the use of ePTFE covered biliary endostents for malignant biliary strictures
- Etiology: 25 pancreatic adenocarcinoma, 3 other
- Inclusion: placement of covered endostents for malignant biliary strictures as palliation between May 10, 2005 and June 20, 2007
- Exclusion: NA
- Survival / Implant Duration / Follow-up: ~4.1 mo: median 126d (11-530)
- Complications: NA

■ Conclusions

"ePTFE covered biliary endostent for malignant biliary stricture palliation demonstrates a high primary patency rate (96%) suggesting stent patency outlives patient survival."

"The low secondary intervention rate (n=1, 3%) suggests the notion that palliation may be achieved satisfactorily with covered biliary endostents."

Management of Malignant Biliary Obstruction: Technical and Clinical Results Using an Expanded Polytetrafluoroethylene Fluorinated Ethylene Propylene (ePTFE/FEP) Covered Metallic Stent After 6-year Experience

Fanelli F, Orgera G, Bezzi M, Rossi P, Allegritti M, Passariello R, 2008⁵

VIABIL® Device Patients	Technical Success	Lifetime Palliation	Primary Patency (days)	Percent Primary Patency		
				3 Months	6 Months	12 Months
n = 80	100%	91% (70/77)	Mean 117	95.5%	92.6%	85.7%

Dysfunctions (e.g. tumor overgrowth)	Time to Reintervention (days)	Migration	Cholecystitis	Pancreatitis
11% (7/77)	Mean 84	0/77	3.9% (3/77)	0/77

■ Study Details

- Design: prospective data collection
- Purpose: evaluate the efficacy and safety of an expanded polytetrafluoroethylene-fluorinated ethylenepropylene (ePTFE/FEP)-covered metallic stent in the management of malignant biliary obstruction
- Etiology: 46 pancreatic cancer, 8 cholangiocarcinoma, 2 gallbladder cancer, 24 metastatic lymphadenopathy
- Inclusion: obstruction of the CBD below the hilar confluence due to unresectable malignancy
- Exclusion: previous biliary surgery, previous insertion of metallic stents or uncontrollable coagulopathy (INR >3.0)
- Survival / Implant Duration / Follow-up: mean 6.9mo (1mo: 66/77, 6mo: 31/77, 12mo:16/77)
- Complications: 6.5% (5/77) - 1 perihepatic biloma, 1 peri and intrahepatic blood collection, 3 cholecystitis (5 days, 4 mo, 4.5mo)

■ Conclusions

“The percentage of patients undergoing lifetime palliation (91%) and the midterm patency rate suggest that placement of this ePTFE/FEP-covered stent-graft is safe and highly effective in achieving biliary drainage in patients with malignant strictures of the common bile duct.”

ePTFE/FEP Covered Versus Uncovered Metallic Stents for Malignant Biliary Disease Palliation. Results in 200 Patients

Krokidis M, Fanelli F, Hatzidakis A, Orgera G, Bezzi M, Pasariello R, Gourtsoyiannis N, 2008⁶

Device		Technical Success	Lifetime Palliation	Primary Patency (days)	Percent Primary Patency		
					3 Months	6 Months	12 Months
VIABIL® Device	n = 100	98.7%	NA	NA	NA	83.3%	67.6%
WALLSTENT®	n = 100	97.5%	NA	NA	NA	72.3%	50.0%

Dysfunctions (e.g. tumor overgrowth)	Time to Reintervention (days)	Migration	Cholecystitis	Pancreatitis
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA

Study Details

- Design: unknown
- Purpose: to study the clinical effectiveness, patency and complication rates of ePTFE/FEP covered-metallic stents (n = 100) compared with uncovered WALLSTENT® Devices (n = 100), in the palliative treatment of malignant biliary disease
- Etiology: 98 pancreatic cancer, 51 cholangiocarcinoma, 19 gastric cancer, 17 lymph node enlargement, 9 papillary cancer, 6 gallbladder cancer
- Inclusion: unknown
- Exclusion: unknown
- Survival / Implant Duration / Follow-up:
 - GORE® VIABIL® Biliary Endoprosthesis: ~4.8mo: mean 147.3d
 - WALLSTENT®: ~4.7mo: mean 142.8d
- Complications:
 - GORE® VIABIL® Biliary Endoprosthesis: 5% (5/100) – unknown
 - WALLSTENT®: 8% (8/100) – unknown

Conclusions

“Covered-Viabil [GORE® VIABIL® Biliary Endoprosthesis] stents are safe and effective for palliative treatment of malignant biliary disease and seem to offer a better 6 and 12-month patency rate compared with uncovered WALLSTENT® Device.”

e-PTFE Covered Metallic Stents for Palliation of Malignant Biliary Strictures: Clinical Results in 140 Patients

Orgera G, Fanelli F, Hatzidakis A, Krokidis M, Conchiglia A, Passariello R, Gourtsoyiannis N, 2007⁷

VIABIL® Device Patients	Technical Success	Lifetime Palliation	Primary Patency (days)	Percent Primary Patency		
				3 Months	6 Months	12 Months
n = 140	100%	NA	NA	91%	79%	78%

Dysfunctions (e.g. tumor overgrowth)	Time to Reintervention (days)	Migration	Cholecystitis	Pancreatitis
NA	NA	NA	4.3% (6/140)	NA

■ Study Details

- Design: multicenter, retrospective analysis
- Purpose: to evaluate the efficacy of e-PTFE covered stent (GORE® VIABIL® Biliary Endoprosthesis) in the treatment of malignant biliary strictures
- Etiology: 91 pancreatic cancer, 14 cholangiocarcinoma, 8 gallbladder cancer, 27 metastatic lymphadenopathy
- Inclusion: patients with malignant common bile duct (CBD) strictures treated at University-Hospital of Rome (n=95) and of Heraklion (n=45) with GORE® VIABIL® Biliary Endoprosthesis
- Exclusion: unknown
- Survival / Implant Duration / Follow-up: unknown
- Complications: 8.5% (12/140) – unknown

■ Conclusions

“e-PTFE stent-graft seems to be an effective tool in malignant strictures of the CBD.”

ePTFE/FEP-Covered Metallic Stents for Palliation of Malignant Biliary Disease: Can Tumor Ingrowth Be Prevented?

Hatzidakis A, Krokidis M, Kalbakis K, Romanos J, Petrakis I, Gourtsoyiannis N, 2007⁸

VIABIL® Device Patients	Technical Success	Lifetime Palliation	Primary Patency (days)	Percent Primary Patency		
				3 Months	6 Months	12 Months
n = 36	97%	71% (25/35)	NA	100%	55.5%	25%

Dysfunctions (e.g. tumor overgrowth)	Time to Reintervention (days)	Migration	Cholecystitis	Pancreatitis
17% (6/35)	Mean 148.1	0/35	0/35	0/35

■ Study Details

- Design: retrospective clinical investigation
- Purpose: to determine the application and clinical effectiveness of ePTFE/FEP-covered metallic stents for palliation of malignant biliary disease, and to evaluate the efficiency of stent coverage in preventing tumor ingrowth
- Etiology: 17 pancreatic cancer, 13 cholangiocarcinoma, 2 gastric cancer, 2 gallbladder cancer, 2 lymph node enlargement due to metastasis
- Inclusion: presence of obstructive jaundice from inoperable malignant biliary disease that could not be treated endoscopically
- Exclusion: significant ascites, a previously inserted biliary stent, previous biliary surgery or radiotherapy, an INR value >1.5, and a platelet count <70,000
- Survival / Implant Duration / Follow-up: ~4.2mo: mean 128d (7-604d)
- Complications: 8.3% (3/36) – dysfunction due to sludge 11.4% (4/35); procedure related complications: 1 arterial injury during PTC needle insertion, 1 bile leakage with subsequent bile peritonitis, 1 subcapsular liver hematoma

■ Conclusions

"We found a 6 month patency of 75% using the fully-covered model, while patency decreased to 40% when using the model with side holes."

"... the Viabil [GORE® VIABIL® Biliary Endoprosthesis] stent provides better fixation to tissue, preventing distal migration..."

"ePTFE/FEP-covered metallic stents are safe and effective for palliation of malignant biliary disease. The presence of the ePTFE/FEP coating is likely to prevent from tumor ingrowth."

Biliary Drainage in Malignant Strictures Using a PTFE Covered Stent (Viabil [GORE® VIABIL® Biliary Endoprosthesis]): Personal Results

Marzio A, Gasparini D, Zanetti S, Piccoli G, Vit A, Sponza M, Pelizzo F, 2005⁹

VIABIL® Device Patients	Technical Success	Lifetime Palliation	Primary Patency (days)	Percent Primary Patency		
				3 Months	6 Months	12 Months
n = 26	100%	96% (22/23)	NA	100%	100%	85%

Dysfunctions (e.g. tumor overgrowth)	Time to Reintervention (days)	Migration	Cholecystitis	Pancreatitis
4% (1/23)	NA	0/23	0/23	0/23

■ Study Details

- Design: unknown
- Purpose: to determine the technical efficacy and safety of a covered metallic stent in the management of malignant biliary obstruction and to evaluate its clinical efficacy by estimating stent patency and patient survival rates
- Etiology: 26 malignant CBD strictures
- Inclusion: patients with a common bile duct stricture caused by malignant disease
- Exclusion: unknown
- Survival / Implant Duration / Follow-up: mean 3 mo (5d-19mo)
- Complications: 0% (0/26)

■ Conclusions

“Our results suggest that placement of this ePTFE covered stent is feasible and effective in achieving biliary drainage. The percentage of patients undergoing lifetime palliation and the midterm patency is good in our data.”

ePTFE-Covered Stents in the Palliative Treatment of Malignant Biliary Obstructions

Irurzun J, Gil S, de Espada F, de la Iglesia P, Verdú J, 2004¹⁰

VIABIL® Device Patients	Technical Success	Lifetime Palliation	Primary Patency (days)	Percent Primary Patency		
				3 Months	6 Months	12 Months
n = 45	100%	NA	NA	100%	98%	91%

Dysfunctions (e.g. tumor overgrowth)	Time to Reintervention (days)	Migration	Cholecystitis	Pancreatitis
8.9% (4/45)	NA	0/45	4.4% (2/45)	0/45

■ Study Details

- Design: unknown
- Purpose: to determine technical and clinical safety and efficiency of expanded polytetrafluoroethylene(ePTFE)-covered stents in the management of malignant biliary obstructions
- Etiology: 45 malignant bile duct strictures
- Inclusion: patients with malignant bile duct stricture
- Exclusion: unknown
- Survival / Implant Duration / Follow-up: mean 5.6 mo (10d-13mo)
- Complications: 8.9% (4/45) - 1 sepsis/death

■ Conclusions

"ePTFE-covered stent implantation is feasible and effective in achieving biliary drainage. The percentage of patients undergoing lifetime palliation and medium-term patencies are promising. The incidence of cholecystitis should, however, be considered."

Malignant Biliary Obstruction: Treatment with ePTFE-FEP-Covered Endoprosthesis- Initial Technical and Clinical Experiences in a Multicenter Trial

Schoder M, Rossi P, Uflacker R, Bezzi M, Stadler A, Funovics MA, Cejna M, Lammer J, 2002¹¹

VIABIL® Device Patients	Technical Success	Lifetime Palliation	Primary Patency (days)	Percent Primary Patency		
				3 Months	6 Months	12 Months
n = 42	100%	NA	Mean 138	90%	76%	76%

Dysfunctions (e.g. tumor overgrowth)	Time to Reintervention (days)	Migration	Cholecystitis	Pancreatitis
14.6% (6/41)	Mean 106 (36-162)	0/41	7.3% (3/41)	2.4% (1/41)

■ Study Details

- Design: multicenter, prospective, nonrandomized
- Purpose: to determine and present the initial technical and clinical results of using an expanded polytetrafluoroethylene–fluorinated ethylene propylene (ePTFE-FEP)–covered biliary endoprosthesis to treat malignant biliary obstruction
- Etiology: 26 pancreatic cancer, 3 cholangiocellular cancer, 1 gallbladder cancer, 1 duodenum cancer, 10 enlarged lymph nodes due to metastasis, 1 lymphoma
- Inclusion: malignant obstruction of the common bile or hepatic duct, including the hepatic duct confluence, by a nonresectable tumor, patients who were aged 21 years or older
- Exclusion: history of previous biliary surgery, multiple strictures that required treatment, presence of a nonremovable metallic biliary stent, diagnosis of active infection of the biliary system, chronic liver disease, uncontrolled coagulation, severe allergy to contrast material, and/or poor clinical condition with an estimated life expectancy of less than three months
- Survival / Implant Duration / Follow-up: ~5.7mo: mean 173d +/-22d
- Complications: 14.6% (6/41) - 1 perihepatic bile leak, 1 peri and intrahepatic hematoma, 1 pancreatitis, 3 cholecystitis

■ Conclusions

“In conclusion, the placement of ePTFE-FEP–covered biliary endoprostheses for treatment of malignant biliary obstructions can be considered safe and effective and the anchoring mechanisms prevent stent migration.”

New ePTFE/FEP-Covered Stent in the Palliative Treatment of Malignant Biliary Obstruction

Bezzi M, Zolovkins A, Cantisani V, Salvatori FM, Rossi M, Fanelli F, Rossi P, 2002¹²

VIABIL® Device Patients	Technical Success	Lifetime Palliation	Primary Patency (days)	Percent Primary Patency		
				3 Months	6 Months	12 Months
n = 26	100%	84% (22/26)	NA	91%	77%	77%

Dysfunctions (e.g. tumor overgrowth)	Time to Reintervention (days)	Migration	Cholecystitis	Pancreatitis
16.7% (4/24)	Mean 100.4	0/24	12.5% (3/24)	0/24

■ Study Details

- Design: prospective, nonrandomized
- Purpose: to determine the technical efficacy and safety of an expanded polytetrafluoroethylene and fluorinated ethylene propylene (ePTFE/FEP)-covered metallic stent in the management of malignant biliary obstruction and to evaluate its clinical efficacy by estimating stent patency and patient survival rates
- Etiology: 18 pancreatic cancer, 2 cholangiocarcinoma, 1 gallbladder cancer, 5 metastatic lymphadenopathy within the hepatoduodenal ligament
- Inclusion: presence of malignant obstruction of the CBD below the hilar confluence caused by unresectable malignant disease for which palliative treatment was indicated
- Exclusion: previous biliary surgery, previous insertion of other metallic endoprostheses, and uncontrollable coagulopathy (international normalized ratio >3.0)
- Survival / Implant Duration / Follow-up: ~5.4mo (5d - 12.5mo)
- Complications: 16.7% (4/24) - 1 perihepatic biloma, 1 intrahepatic blood collection, 3 cholecystitis (10 days, 4 mo, 4.5mo)

■ Conclusions

“Preliminary results suggest that placement of this ePTFE/FEP-covered stent is feasible and effective in achieving biliary drainage. The percentage of patients undergoing lifetime palliation and the midterm patency are promising. However, the incidence of acute cholecystitis is high. Treatment of a larger group of patients is mandatory to validate these long-term results.”

Clinical Performance of GORE® VIABIL® Biliary Endoprosthesis in the Treatment of Malignant Strictures

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