



Clinical performance of GORE® VIABIL® Short Wire Biliary Endoprosthesis in the treatment of malignant strictures*

Scientific literature summary

*(n = 742 patients)***



Intended for palliation of malignant strictures in the biliary tree

GORE® VIABIL® Short Wire Biliary Endoprosthesis

The only fully covered metal stent with anti-migration technology proven to reduce the risk of reintervention.

Lowest migration rates: 0–1.4% migration rate outperforms BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent migration rates ranging from 0–13%.¹

Optimal radial / axial force balance: The right fit and flexibility help prevent migration and sludge formation.²

- Nitinol wire exoskeleton with an ultrathin ePTFE/FEP covering
- Continuous wire stent design naturally follows tortuous anatomy

Proven highest patency: Helps provide a high standard of palliative care for your patients.^{3,4}

Accurate easy delivery: Non foreshortening[†] stent design, exclusive pull line deployment and radiopaque markers enable precise placement.

Minimal risk of branch duct exclusion: Optional fenestrations help maintain transmural drainage; additional radiopaque marker ensures proper positioning.

In the last 20 years, more than 2,000,000 Gore ePTFE stent grafts^{††} have been implanted worldwide.

INDICATIONS

- **United States:** Intended for palliation of malignant strictures in biliary tree

CONTRAINDICATIONS

- All cardiovascular applications
- Ducts less than 5.5 mm in diameter or greater than 9 mm in diameter

For complete list, please refer to the *Instructions For Use*.

1. W. L. Gore & Associates, Inc. Migration Summary for GORE® VIABIL® Biliary Endoprosthesis and BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2017. [Literature Summary]. AW0010-EN3.

2. Isayama H, Mukai T, Itoi T, *et al.* Comparison of partially covered nitinol stents with partially covered stainless stents as a historical control in a multicenter study of distal malignant biliary obstruction: the WATCH study. *Gastrointestinal Endoscopy* 2012;76(1):84-92.

3. Kitano M, Yamashita Y, Tanaka K, *et al.* Covered self-expandable metal stents with an anti-migration system improve patency duration without increased complications compared with uncovered stents for distal biliary obstruction caused by pancreatic carcinoma: a randomized multicenter trial. *American Journal of Gastroenterology* 2013;108(11):1713-1722.

4. Krokidis M, Fanelli F, Orgera G, *et al.* Percutaneous palliation of pancreatic head cancer: randomized comparison of ePTFE/FEP-covered versus uncovered nitinol biliary stents. *Cardiovascular & Interventional Radiology* 2011;34(2):352-361.

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.

* All literature presented describe results using the GORE® VIABIL® Biliary Device but the implanted endoprosthesis is identical for the GORE® VIABIL® Short Wire Biliary Device and we do not anticipate any differences in clinical efficacy and safety.

** 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 October 2016, (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.

[†] If deployed as instructed, the endoprosthesis will not appreciably foreshorten.

^{††} GORE® VIABAHN®, VIATORR®, VIABIL®, EXCLUDER®, TAG® Products

Proven performance through data

Clinical performance of GORE® VIABIL® Biliary Endoprosthesis for the treatment of malignant strictures

GORE® VIABIL® BILIARY DEVICE PATIENTS	TECHNICAL SUCCESS	LIFETIME PALLIATION	PRIMARY PATENCY (DAYS)	PERCENT PRIMARY PATENCY ¹		
				3 MONTHS	6 MONTHS	12 MONTHS
n = 742	Range 97–100%	87.4% (256 / 293)	Range 117–234	95%	87%	78%

DYSFUNCTIONS (E.G. TUMOR OVERGROWTH)	TIME TO REINTERVENTION (DAYS)	MIGRATION	CHOLECYSTITIS	PANCREATITIS
9.1% (42 / 464)	Mean range 84–295	0.2% (1 / 437)	3.5% (20 / 578)	3.0% (13 / 385)

As compared to:

	MIGRATION	CHOLECYSTITIS	PANCREATITIS
Covered stents (partial & fully covered)	0–13% ^{2,3,4}	2–12% ^{3,5}	5.1–8.7% ⁶

DISCLAIMER: The studies referenced above are not a direct head-to-head comparison. They are independent extrapolations of data from different sources.

1. Percent primary patency calculated using weighted average from available Kaplan-Meier survival and primary patency rates for three, six, 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. W. L. Gore & Associates, Inc. Migration Summary for GORE® VIABIL® Biliary Endoprosthesis and BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2017. [Literature Summary]. AW0010-EN3.
5. 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.
6. Coté GA, Kumar N, Ansstas 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
GORE® VIABIL® Biliary Device	n = 40	100%	90% (36 / 40)	Mean 234	97.3%	92.2%	87.6%
BARD® LUMINEXX® Biliary Stent	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

*p < 0.05

Study Details

- **Design:** Multicenter, prospective, randomized
- **Purpose:** Compare clinical effectiveness of covered GORE® VIABIL® Biliary Endoprosthesis stents (n = 40) to uncovered metallic BARD® LUMINEXX® Biliary 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 ≥ 11 x 10⁹ / 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: median 247 days
 - BARD® LUMINEXX® Biliary Stents: ~6.7 months: median 203 days
- **Complications:**
 - GORE® VIABIL® Biliary Endoprosthesis: 12.5% (5 / 40) – 3 peritoneal irritation, 2 self limited biliary hemorrhage
 - BARD® LUMINEXX® Biliary Stents: 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

GORE® VIABIL® BILIARY DEVICE PATIENTS	TECHNICAL SUCCESS	LIFETIME PALIATION	PRIMARY PATENCY (DAYS)	PERCENT PRIMARY PATENCY		
				3 MONTHS	6 MONTHS	12 MONTHS
n = 70	N / A	71% (29 / 34)	Mean 163 (15–1093)	N / A	N / A	N / A

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:** N / A
- **Survival / Implant duration / Follow-up:** ~5.9 months: mean 180 days (15–1092 days)
- **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-shincterotomy 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
GORE® VIABIL® Biliary Device	n = 30	100%	87% (26 / 30)	Mean 227.3	N / A	N / A	N / A
BOSTON SCIENTIFIC WALLSTENT Endoprosthesis	n = 30	100%	70% (21 / 30)	Mean 166.0	N / A	N / A	N / A

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

*p < 0.05

Study Details

- **Design:** Multicenter, prospective, randomized
- **Purpose:** Compare the clinical results of GORE® VIABIL® Biliary Endoprosthesis (n = 30) stent-grafts versus BOSTON SCIENTIFIC WALLSTENT Endoprosthesis (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: ~8.0 months: median 243.5 days
 - BOSTON SCIENTIFIC WALLSTENT Endoprosthesis: ~5.9 months: median 180.5 days
- **Complications:**
 - GORE® VIABIL® Biliary Endoprosthesis: 10% (3 / 30) – 2 peritoneal irritation, 1 biloma formation
 - BOSTON SCIENTIFIC WALLSTENT Endoprosthesis: 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 [BOSTON SCIENTIFIC WALLSTENT Endoprosthesis] 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

GORE® VIABIL® BILIARY DEVICE PATIENTS	TECHNICAL SUCCESS	LIFETIME PALIATION	PRIMARY PATENCY (DAYS)	PERCENT PRIMARY PATENCY		
				3 MONTHS	6 MONTHS	12 MONTHS
n = 28	N / A	93% (26 / 28)	Mean 126	N / A (Overall primary patency: 96%)		

DYSFUNCTIONS (E.G. TUMOR OVERGROWTH)	TIME TO REINTERVENTION (DAYS)	MIGRATION	CHOLECYSTITIS	PANCREATITIS
3.7% (1 / 27)	259	N / A	N / A	N / A

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:** N / A
- **Survival / Implant duration / Follow-up:** ~4.1 months: median 126 days (11–530 days)
- **Complications:** N / A

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

GORE® VIABIL® BILIARY DEVICE PATIENTS	TECHNICAL SUCCESS	LIFETIME PALIATION	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
9.1% (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 6.9 months (1 month: 66 / 77, 6 month: 31 / 77, 12 month: 16 / 77)
- **Complications:** 6.5% (5 / 77) – 1 perihepatic biloma, 1 peri and intrahepatic blood collection, 3 cholecystitis (5 days, 4 months, 4.5 months)

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	PATIENTS	TECHNICAL SUCCESS	LIFETIME PALIATION	PRIMARY PATENCY (DAYS)	PERCENT PRIMARY PATENCY		
					3 MONTHS	6 MONTHS	12 MONTHS
GORE® VIABIL® Biliary Device	n = 100	98.7%	N / A	N / A	N / A	83.3%	67.6%
BOSTON SCIENTIFIC WALLSTENT Endoprosthesis	n = 100	97.5%	N / A	N / A	N / A	72.3%	50%

DYSFUNCTIONS (E.G. TUMOR OVERGROWTH)	TIME TO REINTERVENTION (DAYS)	MIGRATION	CHOLECYSTITIS	PANCREATITIS
N / A	N / A	N / A	N / A	N / A
N / A	N / A	N / A	N / A	N / A

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 BOSTON SCIENTIFIC WALLSTENT Endoprosthesis (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: ~4.8 months: mean 147.3 days
 - BOSTON SCIENTIFIC WALLSTENT Endoprosthesis: ~4.7 months: mean 142.8 days
- **Complications:**
 - GORE® VIABIL® Biliary Endoprosthesis: 5% (5 / 100) – unknown
 - BOSTON SCIENTIFIC WALLSTENT Endoprosthesis: 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

GORE® VIABIL® BILIARY DEVICE PATIENTS	TECHNICAL SUCCESS	LIFETIME PALIATION	PRIMARY PATENCY (DAYS)	PERCENT PRIMARY PATENCY		
				3 MONTHS	6 MONTHS	12 MONTHS
n = 140	100%	N / A	N / A	91%	79%	78%

DYSFUNCTIONS (E.G. TUMOR OVERGROWTH)	TIME TO REINTERVENTION (DAYS)	MIGRATION	CHOLECYSTITIS	PANCREATITIS
N / A	N / A	N / A	4.3% (6 / 140)	N / A

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

GORE® VIABIL® BILIARY DEVICE PATIENTS	TECHNICAL SUCCESS	LIFETIME PALIATION	PRIMARY PATENCY (DAYS)	PERCENT PRIMARY PATENCY		
				3 MONTHS	6 MONTHS	12 MONTHS
n = 36	97%	71% (25 / 35)	N / A	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:** ~4.2 months: mean 128 days (7–604 days)
- **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

GORE® VIABIL® BILIARY DEVICE PATIENTS	TECHNICAL SUCCESS	LIFETIME PALIATION	PRIMARY PATENCY (DAYS)	PERCENT PRIMARY PATENCY		
				3 MONTHS	6 MONTHS	12 MONTHS
n = 26	100%	96% (22 / 23)	N / A	100%	100%	85%

DYSFUNCTIONS (E.G. TUMOR OVERGROWTH)	TIME TO REINTERVENTION (DAYS)	MIGRATION	CHOLECYSTITIS	PANCREATITIS
4% (1 / 23)	N / A	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 months (5 days–19 months)
- **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

GORE® VIABIL® BILIARY DEVICE PATIENTS	TECHNICAL SUCCESS	LIFETIME PALIATION	PRIMARY PATENCY (DAYS)	PERCENT PRIMARY PATENCY		
				3 MONTHS	6 MONTHS	12 MONTHS
n = 45	100%	N / A	N / A	100%	98%	91%

DYSFUNCTIONS (E.G. TUMOR OVERGROWTH)	TIME TO REINTERVENTION (DAYS)	MIGRATION	CHOLECYSTITIS	PANCREATITIS
8.9% (4 / 45)	N / A	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 months (10 days–13 months)
- **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

GORE® VIABIL® BILIARY DEVICE PATIENTS	TECHNICAL SUCCESS	LIFETIME PALIATION	PRIMARY PATENCY (DAYS)	PERCENT PRIMARY PATENCY		
				3 MONTHS	6 MONTHS	12 MONTHS
n = 42	100%	N / A	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:** ~5.7 months: mean 173 days +/- 22 days
- **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

GORE® VIABIL® BILIARY DEVICE PATIENTS	TECHNICAL SUCCESS	LIFETIME PALLIATION	PRIMARY PATENCY (DAYS)	PERCENT PRIMARY PATENCY		
				3 MONTHS	6 MONTHS	12 MONTHS
n = 26	100%	84% (22 / 26)	N / A	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 endoprotheses, and uncontrollable coagulopathy (international normalized ratio >3.0)
- **Survival / Implant duration / Follow-up:** ~5.4 months (5 days–12.5 months)
- **Complications:** 16.7% (4 / 24) - 1 perihepatic biloma, 1 intraphepatic blood collection, 3 cholecystitis (10 days, 4 months, 4.5 months)

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.”

Percutaneous use of ePTFE / FEP-covered metallic stent for palliation of malignant biliary obstruction

Zurstrassen CE, Santos AC, Tyng CJ, Matushitajr JP, Coimbra FJ, Diniz AL, Ribeiro HS, Costajr WL, Lima DC, 2014¹³

GORE® VIABIL® BILIARY DEVICE PATIENTS	TECHNICAL SUCCESS	LIFETIME PALIATION	PRIMARY PATENCY (DAYS)	PERCENT PRIMARY PATENCY		
				3 MONTHS	6 MONTHS	12 MONTHS
n = 11	100%	N / A	Mean 149	100%	90%	N / A

DYSFUNCTIONS (E.G. TUMOR OVERGROWTH)	TIME TO REINTERVENTION (DAYS)	MIGRATION	CHOLECYSTITIS	PANCREATITIS
9% (1 / 11)	N / A	0 / 11	0 / 11	4 / 11

Study Details

- **Design:** Prospective Data collection
- **Purpose:** To evaluate the efficacy of percutaneous placement of expanded polytetrafluoroethylene / fluorinated ethylene propylene-covered metallic stents for the palliation of inoperable biliary malignancy
- **Etiology:** 4 pancreatic head cancer, 4 metastatic diseases, 1 mucinous adenocarcinoma of the stomach, 1 duodenal adenocarcinoma, and 1 cholangiocarcinoma
- **Inclusion:** Obstruction of the common bile duct below the hilar confluence due to unresectable malignancy for which palliative treatment was indicated
- **Exclusion:** Previous biliary surgery or radiotherapy, a previously inserted biliary stent, an uncontrollable coagulopathy (international normalized ratio > 3.0), and presence of ascites
- **Complications:** 4 patients had mild pancreatitis immediately after stenting, which resolved with supportive care. 1 patient had liver failure after the procedure. 1 patient had hemobilia.

Conclusions

“In conclusion, our results suggest that percutaneous placement of ePTFE/FEP-covered stents is safe and effective for palliation of inoperable malignant biliary obstruction. The absence of device migration, which is a potential risk of covered stents, confirms the effectiveness of the anchoring mechanism of the Viabil stent. Moreover, no cases of tumor ingrowth were observed in our series. This finding further supports the indication of covered stents as an effective option to prevent tumor ingrowth, which also contributes to reducing the rate of stent obstruction and improving patients’ quality of life.”

Single-phase percutaneous recanalization of malignant bile duct obstructions with a covered stent graft

Scheer F, Wissgott C, Ludtke CW, Niessen C, Kamusella P, Wiggermann P, Andresen R, 2013¹⁴

GORE® VIABIL® BILIARY DEVICE PATIENTS	TECHNICAL SUCCESS	LIFETIME PALIATION	PRIMARY PATENCY (DAYS)	PERCENT PRIMARY PATENCY		
				3 MONTHS	6 MONTHS	12 MONTHS
n = 31	97%	N / A	N / A	N / A	N / A	N / A

DYSFUNCTIONS (E.G. TUMOR OVERGROWTH)	TIME TO REINTERVENTION (DAYS)	MIGRATION	CHOLECYSTITIS	PANCREATITIS
0% (0 / 31)	N / A	0 / 31	0 / 31	0 / 31

Study Details

- **Design:** Retrospective study
- **Purpose:** To evaluate the clinical outcome of a percutaneous transhepatic endoprosthesis in malignant occlusion of the common bile duct in a palliative treatment situation.
- **Etiology:** 21 had tumors, 7 had liver metastases, and 4 had lymph node metastases
- **Inclusion:** Unsuccessful endoscopic recanalization attempts and the standards for performing minimally invasive image-guide interventions of the German Society of Interventional Radiology and Minimally Invasive Therapy.
- **Exclusion:** N / A
- **Complications:** Hemobilia was diagnosed in two patients and one developed a liver abscess and was treated with drainage

Conclusions

“Single-phase percutaneous implantation of an ePTFE-FEP covered endoprosthesis in inoperable patients with malignant cholestasis in a palliative treatment situation represents a safe and effective alternative method to ERCP.”

“Percutaneous implantation of an ePTFE-FEP covered endoprosthesis is a good and safe treatment option for malignant bile duct obstruction.”

The first prospective endoscopic experience with the ePTFE-covered Viabil stent in patients with a distal malignant biliary stenosis

Van Steenberg W, 2010¹⁵

GORE® VIABIL® BILIARY DEVICE PATIENTS	TECHNICAL SUCCESS	LIFETIME PALIATION	PRIMARY PATENCY (DAYS)	PERCENT PRIMARY PATENCY		
				3 MONTHS	6 MONTHS	12 MONTHS
n = 10	100%	N / A	Mean 220	80%	80%	63%

DYSFUNCTIONS (E.G. TUMOR OVERGROWTH)	TIME TO REINTERVENTION (DAYS)	MIGRATION	CHOLECYSTITIS	PANCREATITIS
0% (0 / 10)	N / A	0 / 10	0 / 10	0 / 10

Study Details

- **Design:** Prospective Data collection
- **Purpose:** To report initial experience with the endoscopic insertion of Gore Viabil stent in patients with malignant distal biliary obstruction, evaluating technical aspects, patency and survival rates, as well as potential complications
- **Etiology:** Pancreatic carcinoma
- **Inclusion:** Presence of a stenosis in the distal and / or middle third of the common bile duct, in a patient older than 18 years and presenting with obstructive jaundice by an inoperable biliopancreatic malignancy
- **Exclusion:** Hilar biliary stenosis, the presence of metastatic disease or of a duodenal obstruction preventing an endoscopic approach, an ECOG score 2–4, or the presence of a plastic stent for more than 1 month
- **Complications:** 1 patient died a ‘stent-related death’ 185 days after stent insertion from postoperative complications after hepaticojejunostomy that had to be performed because of repeated stent occlusions

References

1. Krokidis M, Fanelli F, Orgera G, *et al.* Percutaneous palliation of pancreatic head cancer: randomized comparison of ePTFE/FEP-covered versus uncovered nitinol biliary stents. *Cardiovascular & Interventional Radiology* 2011;34(2):352-361.
2. Bakhru M, Ho HC, Gohil V, *et al.* Fully covered self expandable metal stents (CSEMS) in malignant distal biliary strictures: mid-term evaluation. *Journal of Gastroenterology & Hepatology* 2011;26(6):1022-1027.
3. Krokidis M, Fanelli F, Orgera G, Bezzi M, Passariello R, Hatzidakis A. Percutaneous treatment of malignant jaundice due to extrahepatic cholangiocarcinoma: covered Viabil [GORE® VIABIL® Biliary Endoprosthesis] stent versus uncovered Wallstents. *Cardiovascular & Interventional Radiology* 2010;33(1):97-106.
4. Syed LH, Hong K, Syed LH. Use of ePTFE covered stents for malignant biliary strictures. Abstract presented at the 34th Annual Scientific Meeting of the Society of Interventional Radiology (SIR); March 7-12, 2009; San Diego, CA. *Journal of Vascular & Interventional Radiology* 2009;20(2):Supplement 1:S36. Abstract 91.
5. Fanelli F, Orgera G, Bezzi M, Rossi P, Allegritti M, Passariello R. 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. *European Radiology* 2008;18(5):911-919.
6. Krokidis M, Fanelli F, Hatzidakis A, *et al.* ePTFE/FEP covered versus uncovered metallic stents for malignant biliary disease palliation. Results in 200 patients. Abstract presented at 2008 SIR 33rd Annual Scientific Meeting, 2008 SIR 33rd Annual Scientific Meeting; March 15-20, 2008; Washington, DC. *Journal of Vascular & Interventional Radiology* 2008;19(2)Supplement 1:S112-S113. Abstract 304.
7. Orgera G, Fanelli F, Hatzidakis A, *et al.* e-PTFE covered metallic stents for palliation of malignant biliary strictures: clinical results in 140 patients. Abstract presented at the 2007 Cardiovascular & Interventional Radiological Society of Europe (CIRSE) Meeting; September 8-12, 2007; Athens, Greece. *Cardiovascular & Interventional Radiology* 2007;30(Supplement 1):253. Abstract 1307.2.
8. Hatzidakis A, Krokidis M, Kalbakis K, Romanos J, Petrakis I, Gourtsoyiannis N. ePTFE/FEP-covered metallic stents for palliation of malignant biliary disease: can tumor ingrowth be prevented? *Cardiovascular & Interventional Radiology* 2007;30(5):950-958.
9. Marzio A, Gasparini D, Zanetti S, *et al.* Biliary drainage in malignant strictures using a PTFE covered stent (viabil): personal results. Abstract presented at the 16th Annual Meeting & Postgraduate Course of the European Society of Gastrointestinal & Abdominal Radiology (ESGAR); May 28-31, 2005; Florence, Italy.
10. Irurzun J, Gil S, de España F, de la Iglesia P, Verdú J. ePTFE-covered stents in the palliative treatment of malignant biliary obstructions. Abstract presented at the 19th Annual Meeting and Postgraduate Course of the Cardiovascular and Interventional Radiological Society of Europe (CIRSE); September 25-29, 2004; Barcelona, Spain. Page 132. Abstract 19.1.7.
11. Schoder M, Rossi P, Uflacker R, *et al.* Malignant biliary obstruction: treatment with ePTFE-FEP-covered endoprostheses initial technical and clinical experiences in a multicenter trial. *Radiology* 2002;225(1):35-42.
12. Bezzi M, Zolovkins A, Cantisani V, *et al.* New ePTFE/FEP-covered stent in the palliative treatment of malignant biliary obstruction. *Journal of Vascular & Interventional Radiology* 2002;13(6):581-589.
13. Zurstrassen CE, Santos AC, Tyng CJ, *et al.* Percutaneous use of ePTFE/FEP-covered metallic stent for palliation of malignant biliary obstruction. *Minimally Invasive Therapy & Allied Technologies* 2014;23(6):366-373.
14. Scheer F, Wissgott C, Lüdtker CW, *et al.* Single-phase percutaneous recanalization of malignant bile duct obstructions with a covered stent graft. *Rofo* 2014;186(4):394-399.
15. Van Steenberghe W. The first prospective endoscopic experience with the ePTFE-covered Viabil stent in patients with a distal malignant biliary stenosis. *Acta Gastro-enterologica Belgica* 2010;73(1):18-24.



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