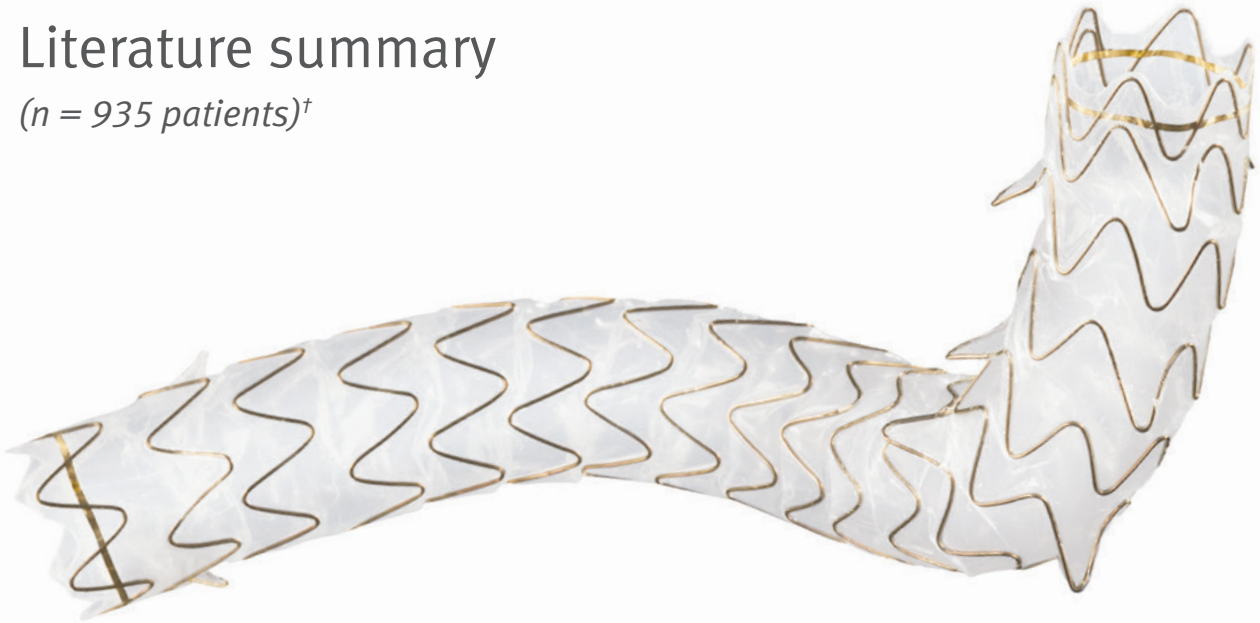
Clinical performance of GORE® VIABIL® Short Wire Biliary Endoprosthesis in the treatment of malignant and benign strictures*

Literature summary

(n = 935 patients)†



* All literature presented describes results from the GORE® VIABIL® Biliary Device , which shares the identical implantable endoprosthesis with the newly approved GORE® VIABIL® Short Wire Biliary Device. Based on this similarity, Gore expects no significant differences in clinical efficacy or 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 February 2019, (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.

Consult the listed articles for complete information.

Effective treatment of benign biliary strictures with a removable, fully covered, self-expandable metal stent: A prospective, multicenter European study.

Schmidt A, Pickartz T, Lerch M, Fanelli F, Fiocca F, Lucatelli P, Cereatti F, Hoffmeister A, van Steenbergen W, Kraft M, Meier B, Caca K, 2017 [1]

GORE® VIABIL® Biliary Device patients	Technical success	Immediate stricture resolution	Implant duration (days)	Migrations	Stricture resolution	Removal success	Post removal follow-up
n=43	100%	97.6% (42 / 43)	Median 272 (7–336)	5.2% (2 / 38)	78.9% (30 / 38)	97% (38 / 39)	24 months

Study details

- **Design:** Multi-center, Prospective Data collection
- **Purpose:** The objective of this study was to evaluate the efficacy and safety of this treatment modality using an fcSEMS with a special antimigration design and prolonged stent indwell time.
- **Etiology:** 24 chronic pancreatitis, 7 anastomotic stricture, 4 surgical bile duct injury, 4 recurrent common bile duct stones, 1 post-sphincterotomy stenosis, 1 autoimmune cholangitis, and 2 cryptogenic
- **Inclusion:** Patients older than 18 years with BBS and necessity of stent treatment were included in the study. Treatment-naive as well as pretreated patients were eligible.
- **Exclusion:** Patients with stricture anatomy ruling out fcSEMS use (defined as distance of stricture < 1 cm from the hilus), patients with a previous bare metal stent treatment, patients with malignant biliary disease, pregnant patients and patients participating in other clinical studies were not considered to be eligible for study participation.
- **Complications:** 10 / 39 (25.6%): 5 device occlusions, 1 acute cholecystitis due to overstenting of the cystic duct, 1 recurrent cholangitis without evidence of occlusion, 1 bile duct stones proximal to the stent, 1 acute pancreatitis, and duodenal stenosis requiring surgery.

Key observations

"Temporary placement of the fcSEMS is a feasible, safe and effective treatment for BBS. The design of the device used in this study accounts for very low migration rates and facilitates easy stent retrieval, even after it has been in place for up to 11 months."

Self expandable metal stents for anastomotic stricture following liver transplant

Cercedo-Rodriguez J, Phillips M, Figueros-Barojas P, Kumer S, Gaidhane M, Schmitt T, Kahaleh M., 2013[2]

Device	Patients	Technical success	Immediate stricture resolution	Implant duration (days)	Migrations	Stricture resolution	Removal success	Post removal follow-up (months)
GORE® VIABIL® Biliary Endoprosthesis	n=21	100%	100%	Mean 125 (17–266)	4.7% (1 / 21)	71.4% (15 / 21)	100%	Mean 24.3 (5–40)
Partially covered BOSTON SCIENTIFIC WALLSTENT Endoprosthesis	n=19	100%	100%	Mean 130.7 (24–393)	10.5% (2 / 19)	74% (14 / 19)	100%	Mean 38.9 (1–78)
Boston Fully Covered Wallflex	n=15	100%	100%	Mean 136.9 (22–401)	6.7% (1 / 15)	60% (9 / 15)	100%	Mean 4.6 (0.03–11)

Study details

- **Design:** Prospective Data Collection
- **Purpose:** The aim of this study was to evaluate the efficacy of different covered self-expanding metal stents in patients with anastomotic strictures post liver transplant
- **Etiology:** 55 liver transplant choledocho-choledocho anastomosis
- **Inclusion:** History of liver transplant, liver function test with evidence of biliary obstruction and cross-sectional imaging study confirming a stricture
- **Exclusion:** Stricture associated with a bile leak
- **Complications:** Viabil: 19% (4 / 21) occlusions, partially covered wallstent: 5.2% (1 / 19)

Endoscopic treatment of benign biliary strictures using covered self-expandable metal stents (CSEMS).

Irani S, Baron T, Akbar A, Lin O, Gluck M, Gan I, Ross A, Petersen B, Topazian M, Kozarek R., 2014[3]

Device	Patients	Technical success	Immediate stricture resolution	Implant duration (weeks)	Migrations	Stricture resolution	Removal success	Post removal follow-up (months)
GORE® VIABIL® Biliary Endoprosthesis	n=76	100%	NR	Median 26 (not broken out by stent type)	4% (3 / 76)	66% (not broken out by stent type)	100% (76 / 76)	Mean 24.3 (5–40)
Boston Partially Covered Wallstent	n=23	100%	NR	Median 26 (not broken out by stent type)	4% (1 / 23)	66% (not broken out by stent type)	82% (19 / 23)	Mean 38.9 (1–78)
Boston Fully Covered Wallflex	n=46	100%	NR	Median 26 (not broken out by stent type)	20% (9 / 46)	66% (not broken out by stent type)	100% (46 / 46)	Mean 4.6 (0.03–11)

Study details

- **Design:** Multi-center, Retrospective, Data collection
- **Purpose:** To report the outcome following placement of CSEMS for the treatment of benign biliary strictures due to various etiologies
- **Etiology:** All stent types: Extrinsic causes: 73 chronic pancreatitis, 1 sclerosing mesenteritis, 1 bile duct varices; Intrinsic causes: 14 choledocholithiasis, 12 post-sphincterotomy, 12 biliary-enteric anastomotic, 11 post-surgical, 10 post-transplant, 5 post-radiation or chemotherapy, 4 primary sclerosing cholangitis, 2 oriental cholangiopathy
- **Inclusion:** The presence of a stricture at cholangiography along with clinical evidence of biliary obstruction (cholangitis, jaundice, or cholestatic liver function tests, alkaline phosphatase > 3X the upper limits of normal). Median total bilirubin level was 2.1 mg / dL (range 0.2–39 mg / dL) and median alkaline phosphatase level was 228 units / L (range 47–2,173 units / L). In addition, patients had to have a minimum of 12 months follow-up after stent removal.
- **Exclusion:** NR
- **Complications:** All stent types (not broken out by stent type): Thirty-four in 25 / 145 patients (17%). 17 cholangitis, 5 pancreatitis, 2 cholecystitis, 3 pain requiring SEMS removal and / or hospitalization, 4 inability to remove (partially covered), 3 new stricture formation.

Key observations

"Benign biliary strictures can be effectively treated with CSEMS. Successful resolution of biliary strictures due to extrinsic disease is seen significantly less often than those due to intrinsic disease. Removal is successful in all patients with fully covered SEMS"

Evaluation of fully covered self-expanding metal stents in benign biliary strictures and bile leaks.

Lalezari D, Singh I, Reicher S, Ernst Eysselein V., 2013[4]

Device	Patients	Technical success	Immediate stricture resolution	Implant duration (days)	Migrations	Stricture resolution	Removal success	Post removal follow-up (days)
GORE® VIABIL® Biliary Endoprosthesis	n=9	100%	89% (8 / 9)	Mean 73.9 (27–161)	11% (1 / 9)	89% (8 / 9)	100% (9 / 9)	Mean 623.9 (36–1435)
Boston Fully Covered Wallflex	n=3	100%	100% (3 / 3)	Mean 108.7 (33–199)	33.3% (1 / 3)	100% (3 / 3)	100% (3 / 3)	Mean 545 (122–1210)

Study details

- **Design:** Retrospective Data Collection
- **Purpose:** To evaluate the efficacy, patency and rate of complications with placement of Fully Covered self-expanding metal stents (FCSEMS) for benign biliary strictures (BBS) and bile leaks.
- **Etiology:** Viabil group: 1 anastomotic, 5 cholecystectomy, 2 cholelithiasis, and 1 chronic pancreatitis; Wallflex group: 1 cholecystecomy, 1 compression by hepatic artery, and 1 pancreatitis and pancreatic head necrosis.
- **Inclusion:** Clinical symptoms of biliary obstruction
- **Exclusion:** Malignant strictures
- **Complications:** Viabil: 22% (2 / 9) – 1 solid debris in lumen and 1 pain; Wallflex: 33% (1 / 3) – recurrent cholangitis

Key observations

"Overall, our study showed that temporary placement of FCSEMS successfully treated BBS and bile leaks with excellent long-term patency rates and relatively few complications. FCSEMS may provide an effective method in management of BBS and bile leaks while allowing easy endoscopic removability. FCSEMS can be easily removed after insertion and remain in place for several months although there is insufficient data as to what the optimal duration of placement is. The high cost of FCSEMS may be offset by a reduction in ERCP sessions and recurrent stenting for recurrent strictures"

Temporary placement of fully covered self-expandable metal stents in benign biliary strictures: midterm evaluation (with video).

Mahajan A, Ho H, Sauer B, Phillips M, Shami M, Ellen K, Rehan M, Schmitt T, Kahaleh M, 2009[5]

GORE® VIABIL® Biliary Device patients	Technical success	Immediate stricture resolution	Implant duration (months)	Migrations	Stricture resolution	Removal success	Post removal follow-up (months)
n=44	100%	100%	Median 3.3	2 / 44 (4.5%)	83% (34 / 41)	100% (41 / 41)	Median 3.8

Study details

- **Design:** Prospective Data collection
- **Purpose:** To study fully covered metal stents with anchoring fins in patients with benign biliary strictures
- **Etiology:** 19 chronic pancreatitis, 14 gallstone-related, 9 post liver transplant, 1 autoimmune pancreatitis, 1 primary sclerosing cholangitis
- **Inclusion:** Clinical symptoms of biliary obstruction in patients over 18 years old
- **Exclusion:** Patients for whom endoscopic procedures were contraindicated, patients with peripheral or hilar strictures, and patients with suspected malignant strictures
- **Complications:** 32% (14 / 44); Placement complications: 2 pain, 3 PEP, and 1 bleeding; Removal complications: 1 pain, 3 PEP; Other complications: 1 occlusion and 1 stent unraveled during removal

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, 2011[6]

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%
BD® E-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 BD® E-LUMINEXX® Biliary Stent (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 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: median 247 days
  – BD® E-LUMINEXX® Biliary Stent: ~6.7 months: median 203 days
- **Complications:**
  – GORE® VIABIL® Biliary Endoprosthesis: 12.5% (5 / 40) – 3 peritoneal irritation, 2 self limited biliary hemorrhage
  – BD® E-LUMINEXX® Biliary Stent: 10% (4 / 40) – 2 peritoneal irritation, 2 self limited biliary hemorrhage

Key observations

"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., 2011[7]

GORE® VIABIL® Biliary Device patients	Technical success	Lifetime palliation	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

Key observations

"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, 2010[8]

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

Key observations

"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, 2009[9]

GORE® VIABIL® Biliary Device patients	Technical success	Lifetime palliation	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

Key observations

"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, 2008[10]

GORE® VIABIL® Biliary 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
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)

Key observations

"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, 2008[11]

Device	Patients	Technical success	Lifetime palliation	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

Key observations

"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, 2007[12]

GORE® VIABIL® Biliary Device patients	Technical success	Lifetime palliation	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

Key observations

"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, 2007[13]

GORE® VIABIL® Biliary Device patients	Technical success	Lifetime palliation	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

Key observations

"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, 2005[14]

GORE® VIABIL® Biliary Device patients	Technical success	Lifetime palliation	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)

Key observations

"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 Espaòa F, de la Iglesia P, Verdú J, 2004[15]

GORE® VIABIL® Biliary Device patients	Technical success	Lifetime palliation	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

Key observations

"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, 2002[16]

GORE® VIABIL® Biliary Device patients	Technical success	Lifetime palliation	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

Key observations

"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, 2002[17]

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 endoprostheses, 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 intrapepatic blood collection, 3 cholecystitis (10 days, 4 months, 4.5 months)

Key observations

"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, 2014[18]

GORE® VIABIL® Biliary Device patients	Technical success	Lifetime palliation	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 propylne-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.

Key observations

"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, 2013 [19]

GORE® VIABIL® Biliary Device patients	Technical success	Lifetime palliation	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

Key observations

'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 Steenbergen W, 2010 [20]

GORE® VIABIL® Biliary Device patients	Technical success	Lifetime palliation	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

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