



LITERATURE SUMMARY

*Migration Summary for
GORE® VIABIL® Biliary Endoprosthesis and
BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent*



GORE® VIABIL® Biliary Endoprosthesis

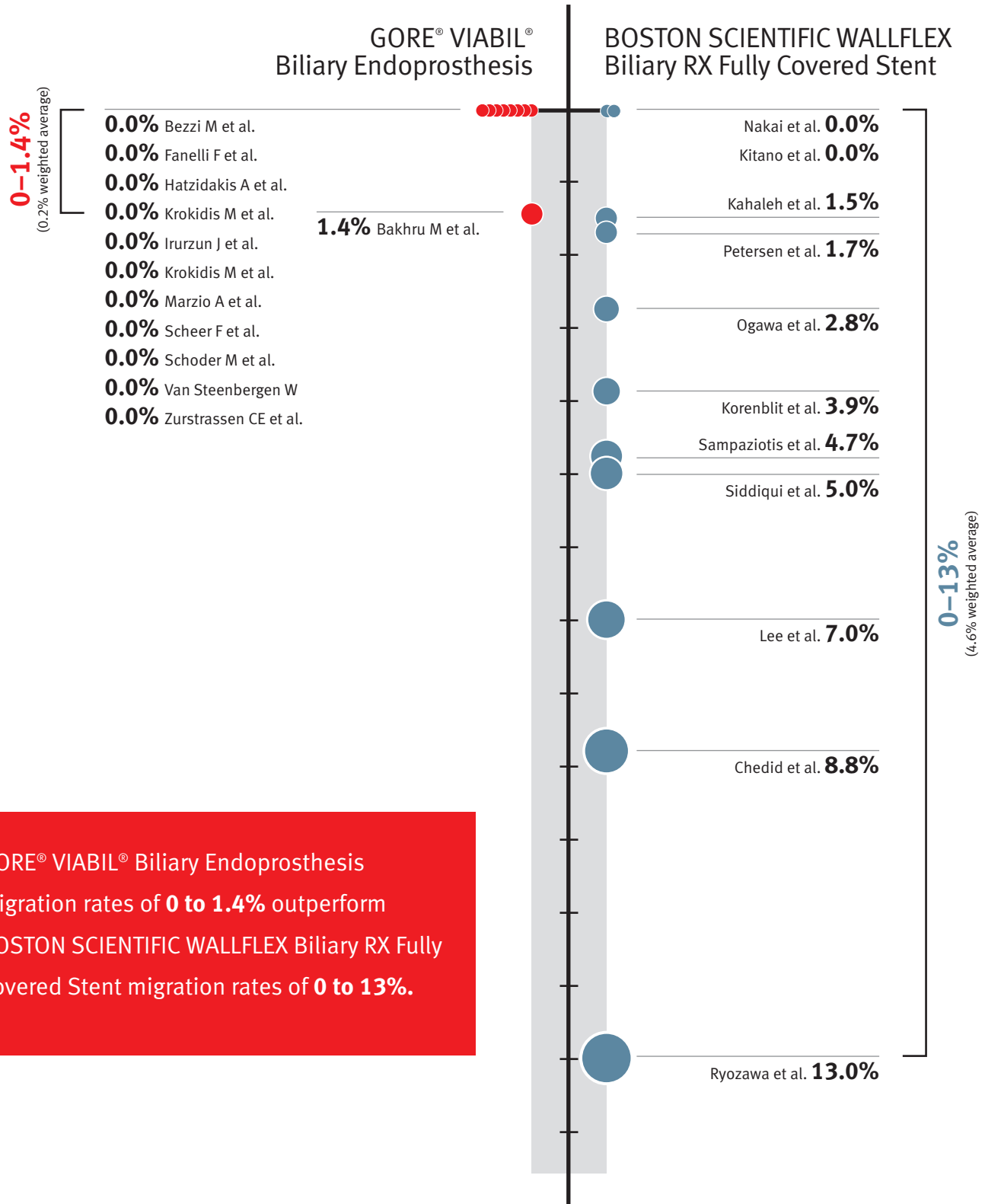
PAPER REFERENCE	MIGRATION RATE
Bezzi M, Zolovkins A, Cantisani V, <i>et al.</i> New ePTFE/FEP-covered stent in the palliative treatment of malignant biliary obstruction. <i>Journal of Vascular & Interventional Radiology</i> 2002;13(6):581-589. (n=24)	0.0%
Fanelli F, Orgera G, Bezzi M, Rossi P, Allegritti 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. <i>European Radiology</i> 2008;18(5):911-919. (n=77)	0.0%
Hatzidakis A, Krokidis M, Kalbakis K, Romanos J, Petrakis I, Gourtsoyannis N. ePTFE/FEP-covered metallic stents for palliation of malignant biliary disease: can tumor ingrowth be prevented? <i>Cardiovascular & Interventional Radiology</i> 2007;30(5):950-958. (n=35)	0.0%
Krokidis M, Fanelli F, Orgera G, <i>et al.</i> Percutaneous palliation of pancreatic head cancer: randomized comparison of ePTFE/FEP-covered versus uncovered nitinol biliary stents. <i>Cardiovascular & Interventional Radiology</i> 2011;34(2):352-361. (n=40)	0.0%
Irurzun J, Gil S, de Espa a F, de la Iglesia P, Verdú J. ePTFE-covered stents in the palliative treatment of malignant biliary obstructions. Abstract presented at CIRSE 2004; September 25-29, 2004; Barcelona, Spain. Page 132. Abstract 19.1.7. (n=45)	0.0%
Krokidis M, Fanelli F, Orgera G, Bezzi M, Passariello R, Hatzidakis A. Percutaneous treatment of malignant jaundice due to extrahepatic cholangiocarcinoma: covered Viabil stent versus uncovered Wallstents. <i>Cardiovascular & Interventional Radiology</i> 2010;33(1):97-106. (n=30)	0.0%
Marzio A, Gasparini D, Zanetti S, Piccoli G, Vit A, Sponza M, Pelizzo F. Biliary drainage in malignant strictures using a PTFE covered stent (Viabil): personal results. Abstract presented at the 16th Annual Meeting & Postgraduate Course. European Society of Gastrointestinal & Abdominal Radiology (ESGAR); May 28-31, 2005; Florence, Italy. (n=23)	0.0%
Scheer F <i>et al.</i> , Single-phase percutaneous recanalization of malignant bile duct obstructions with a covered stent graft. <i>Rofo</i> 2014;186(4):394-399. (n=32)	0.0%
Schoder M, Rossi P, Uflacker R, <i>et al.</i> Malignant biliary obstruction: treatment with ePTFE-FEP-covered endoprosthesis initial technical and clinical experiences in a multicenter trial. <i>Radiology</i> 2002;225(1):35-42. (n=41)	0.0%
Van Steenberg W. The first prospective endoscopic experience with the ePTFE-covered Viabil stent in patients with a distal malignant biliary stenosis. <i>Acta Gastro-enterologica Belgica</i> 2010;73(1):18-24. (n=10)	0.0%
Zurstrassen CE <i>et al.</i> , Percutaneous use of ePTFE/FEP-covered metallic stent for palliation of malignant biliary obstruction. <i>Minimally Invasive Therapy & Allied Technologies</i> 2014;23(6):366-373. (n=11)	0.0%
Bakhru M, Ho HC, Gohil V, <i>et al.</i> Fully covered self expandable metal stents (CSEMS) in malignant distal biliary strictures: mid-term evaluation. <i>Journal of Gastroenterology & Hepatology</i> 2011;26(6):1022-1027. (n=70)	1.4%

BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent

PAPER REFERENCE	MIGRATION RATE
Kitano M, Yamashita Y, Tanaka K, <i>et al.</i> 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. <i>American Journal of Gastroenterology</i> 2013;108(11):1713-1722. (n=60)	0.0%
Nakai Y, Isayama H, Kogure H, <i>et al.</i> Risk factors for covered metallic stent migration in patients with distal malignant biliary obstruction due to pancreatic cancer. <i>Journal of Gastroenterology & Hepatology</i> 2014;29(9):1744-1749. (n=8)	0.0%
Kahaleh M, Talreja JP, Loren DE, <i>et al.</i> Evaluation of a fully covered self-expanding metal stent with flared ends in malignant biliary obstruction: a multicenter study. <i>Journal of Clinical Gastroenterology</i> 2013;47(10):e96-e100. (n=266)	1.5%
Petersen BT, Kahaleh M, Kozarek RA, <i>et al.</i> A multicenter, prospective study of a new fully covered expandable metal biliary stent for the palliative treatment of malignant bile duct obstruction. <i>Gastroenterology Research & Practice</i> 2013;2013:642428. (n=58)	1.7%
Ogawa <i>et al.</i> , 2016. A newly developed laser-cut type fully covered metallic stent for unresectable malignant biliary stricture. <i>Journal of Gastroenterology and Hepatology</i> ; 31:227. (n=36)	2.8%
Korenblit J, Matro R, Siddiqui A, <i>et al.</i> Migration rates of Wallflex fully-covered self-expanding metal stent (FCSEMS) in malignant and benign disease. Presented at 45th Annual Digestive Disease Week (DDW); May 3-6, 2014; Chicago, IL. <i>Gastrointestinal Endoscopy</i> 2014;79(5):Supplement: AB303. Su1509. (n=230)	3.9%
Sampaziotis F, Elias J, Gelson WT, <i>et al.</i> A retrospective study assessing fully covered metal stents as first-line management for malignant biliary strictures. <i>European Journal of Gastroenterology & Hepatology</i> 2015;27(11):1347-1353. (n=64)	4.7%
Siddiqui AA, Mehendiratta V, Loren D, Hong SK, Kowalski T. Fully covered self-expandable metal stents are effective and safe to treat distal malignant biliary strictures, irrespective of surgical resectability status. <i>Journal of Clinical Gastroenterology</i> 2011;45(9):824-827. (n=44)	5.0%
Lee JH, Krishna SG, Singh A, <i>et al.</i> Comparison of the utility of covered metal stents versus uncovered metal stents in the management of malignant biliary strictures in 749 patients. <i>Gastrointestinal Endoscopy</i> 2013;78(2):312-324. (n=171)	7.0%
Chedid V, Hutfless S, Kim K, <i>et al.</i> A comparative evaluation of uncovered, partially covered, and fully-covered self-expandable metal stents in the palliation of distal malignant bile duct obstruction. Presented at Digestive Disease Week (DDW) 2013; May 18-21, 2013; Orlando, FL. <i>Gastrointestinal Endoscopy</i> 2013;77(5)Supplement:AB308. Su1392. (n=57)	8.8%
Ryozawa S, Isayama H, Maetani I, <i>et al.</i> A prospective multicenter study of a fully-covered metal stent in patients with distal malignant biliary obstruction: WATCH-2 Study. Presented at Digestive Disease Week (DDW) 2013; May 18-21, 2013; Orlando, FL. <i>Gastrointestinal Endoscopy</i> 2013;77(5)Supplement:AB309. Su1393. (n=156)	13.0%

MIGRATION RATE COMPARISON

Based on 23 papers published from 2002 to 2015.



GORE® VIABIL® Biliary Endoprosthesis migration rates of 0 to 1.4% outperform BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent migration rates of 0 to 13%.



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