Article

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Biodegradable Internal Biliary Stenting in High-Risk Living-Donor Liver Transplantation With Marked Duct Mismatch: A Prospective Pilot Study With a Frequency-Matched Historical Comparison Cohort

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ABSTRACT

Background: Biliary complications remain a major source of morbidity after living-donor liver transplantation (LDLT), particularly in recipients with marked donor–recipient duct size disparity. We evaluated the feasibility and short-term clinical performance of an intraoperatively placed biodegradable internal biliary stent in adult LDLT recipients with duct-to-duct mismatch greater than 50%. **Methods:** This prospective, single-centre pilot study enrolled 12 consecutive adult LDLT recipients between August 2024 and August 2025. Eligibility required primary LDLT, duct-to-duct biliary reconstruction, and intraoperative confirmation of marked duct mismatch, defined as a donor duct diameter more than 50% smaller than the recipient duct diameter. A biodegradable Archimedes® stent with an 11-week degradation profile was placed entirely within the bile duct across the anastomosis and secured with a 6-0 polydioxanone suture. Outcomes were compared with a frequency-matched historical cohort of 12 adult LDLT recipients transplanted between 2018 and 2023 without stent placement. Matching variables were right-lobe graft use, recipient age band, mismatch category, and biliary reconstruction complexity. The primary endpoint was technical feasibility. Secondary endpoints included anastomotic stricture, bile leak, biliary cast material, cholangitis, endoscopic retrograde cholangiopancreatography (ERCP) requirement, stent migration, and graft loss through 12 months. **Results:** Technical success was achieved in all 12 stented recipients (100%). Median recipient age was 52 years (interquartile range [IQR], 42–60), and median duct mismatch was 65% (IQR, 58–72). No anastomotic strictures occurred in the stented cohort at 12 months, compared with 5/12 (41.7%) in historical controls ($p = 0.037$, two-sided Fisher's exact test). One bile leak (8.3%) resolved with drainage alone. Biliary cast material occurred in 2/12 recipients (16.7%); one required ERCP and one resolved without intervention. ERCP was required in 1/12 stented recipients (8.3%) versus 6/12 controls (50.0%; $p = 0.069$). No stent migration, cholangitis, pancreatitis, or graft loss occurred in the stented cohort. **Conclusions:** In adult LDLT recipients with marked duct mismatch, biodegradable internal biliary stenting was technically feasible and demonstrated an acceptable safety profile. Compared with a frequency-matched historical cohort, stented recipients had fewer anastomotic strictures and numerically fewer ERCPs, although comparative inference remains limited by the pilot design and small sample size. Prospective multicentre evaluation is warranted.

KEYWORDS: living-donor liver transplantation; biliary reconstruction; biliary stricture; bile leak; biodegradable stent; duct mismatch

1 Introduction

Biliary complications remain the most persistent technical challenge after living-donor liver transplantation (LDLT), where small-calibre ducts, variable hilar anatomy, and partial-graft reconstruction all contribute to excess risk relative to

deceased-donor transplantation [1–4]. Contemporary multicentre data continue to show clinically important rates of both bile leak and biliary anastomotic stricture after LDLT, with adverse effects on hospital stay, major morbidity, and graft survival [4]. In the adult-to-adult living donor liver transplantation cohort experience, biliary reconstructive technique and associated anatomic variants were closely linked to postoperative course, underscoring that biliary outcomes remain highly technique-sensitive in this setting [5]. Similarly, longitudinal consortium data have shown that biliary complications are more frequent after LDLT than after deceased-donor liver transplantation and often require prolonged management before resolution [6].

Intraductal stenting at the time of biliary reconstruction has therefore remained an attractive prophylactic concept. A randomized trial in LDLT demonstrated that intraductal transanastomotic stenting could modify biliary outcomes, although the broader literature has remained mixed because device type, anatomy, centre experience, and follow-up protocols vary substantially [7]. More recent retrospective experience comparing internal stenting strategies in LDLT suggests that intraoperative stent design and placement technique may influence leak and stricture patterns, but the evidence base remains limited and heterogeneous [8]. Importantly, recipients with multiple ducts or technically complex biliary reconstruction appear particularly vulnerable to postoperative complications [9, 10].

Marked donor–recipient duct mismatch represents one of the most difficult reconstructive scenarios in adult LDLT. Prior single-centre series and systematic reviews have emphasized that size discrepancy, multiple duct openings, and reconstruction strategy are central determinants of biliary outcome [11–14]. Technical refinements such as ductoplasty, calibrated duct alignment, and meticulous suture orientation can reduce tension and improve mucosal apposition, but they do not fully eliminate the early postoperative period of edema, reduced bile flow, and anastomotic vulnerability [15]. A biodegradable intraductal scaffold that remains entirely within the bile duct during the highest-risk healing interval, and then degrades without requiring retrieval, may therefore offer an advantage in carefully selected high-risk cases.

The present study was designed to evaluate a focused high-risk LDLT population: adult recipients undergoing right-lobe LDLT with duct-to-duct reconstruction and donor–recipient duct mismatch greater than 50%. We hypothesized that intraoperative placement of a biodegradable internal biliary stent in this subgroup would be technically feasible, would not increase early adverse events, and might reduce anastomotic stricture occurrence during the first postoperative year.

2 Methods

2.1 Study design and setting

We conducted a prospective, single-centre pilot study at Austin Hospital, Melbourne, Australia, between August 2024 and August 2025. The prospective intervention cohort was compared with a frequency-matched historical comparison cohort drawn from the institutional adult LDLT database covering January 2018 through December 2023. The study was designed primarily to assess feasibility and safety, with comparative analyses treated as exploratory.

The study protocol was approved by the institutional human research ethics committee (HREC/90756/Austin-2022, extended for the present LDLT analysis). Written informed consent was obtained from all prospective recipients and living donors. Use of de-identified historical data was permitted under ethics-approved waiver provisions for retrospective comparative analysis.

2.2 Eligibility criteria

Recipients were eligible for prospective enrollment if they met all of the following criteria:

1. age ≥ 18 years;
2. primary adult LDLT;
3. duct-to-duct biliary reconstruction;
4. intraoperative donor–recipient bile duct mismatch $> 50\%$; and
5. provision of informed consent.

Marked duct mismatch was defined as:

$$\text{Mismatch (\%)} = \frac{\text{recipient duct diameter} - \text{donor duct diameter}}{\text{recipient duct diameter}} \times 100$$

with inclusion requiring a mismatch value greater than 50%.

Exclusion criteria were redo liver transplantation, prior Roux-en-Y biliary reconstruction, unplanned

hepaticojejunostomy, donor duct diameter < 2 mm, and grafts with more than two donor ducts requiring more than one separate biliary anastomosis.

2.3 Historical comparison cohort

Historical controls were selected from the institutional adult LDLT database and were required to satisfy the same clinical eligibility criteria except for absence of stent placement. Rather than individual pair-matching, we used frequency matching to construct a comparison cohort with the same sample size ($n = 12$) and similar distributions of the following variables:

1. right-lobe graft use;
2. recipient age band (< 40, 40–49, 50–59, ≥ 60 years);
3. duct mismatch category (50–59%, 60–69%, $\geq 70\%$); and
4. biliary reconstruction complexity (single donor duct versus two donor ducts combined by ductoplasty into a single orifice).

Control identification was completed before outcome tabulation for the historical arm.

2.4 Operative technique

All recipients underwent right-lobe LDLT without middle hepatic vein inclusion. Donor bile ducts were prepared as a single orifice when two closely adjacent ducts were present and ductoplasty was technically feasible. Bile duct diameters were measured after trimming with sterile calipers.

The biliary anastomosis was performed in end-to-end fashion using 6-0 polydioxanone (PDS) sutures. The posterior wall was constructed with a running suture. After posterior wall completion, an Archimedes® biodegradable biliary stent (11-week degradation profile) was introduced entirely within the bile duct across the anastomosis, without transpapillary extension across the ampulla. The stent length was selected to leave approximately 2–3 cm of stent proximal and distal to the anastomosis. Stent calibre was selected according to duct size and ranged from 8 Fr to 10 Fr, with lengths from 40 to 60 mm. The stent was secured at the lateral corner using a looped 6-0 PDS suture to minimize migration. The anterior wall was then completed with interrupted 6-0 PDS sutures.

2.5 Follow-up protocol

Recipients were followed for 12 months. Laboratory surveillance included bilirubin, alkaline phosphatase, gamma-glutamyl transferase, alanine aminotransferase, and aspartate aminotransferase according to routine post-transplant follow-up. Magnetic resonance cholangiopancreatography (MRCP) was scheduled at approximately 3 and 12 months in the absence of concerning clinical findings, and additional MRCP was performed when clinically indicated by cholestatic laboratory abnormalities or unexplained graft dysfunction. This imaging strategy was selected because MRCP is accurate and non-invasive for evaluation of post-transplant biliary complications, while direct cholangiography is best reserved for cases requiring intervention [16, 17].

2.6 Endpoints and definitions

The primary endpoint was technical feasibility, defined as successful intraoperative stent deployment and fixation across the biliary anastomosis without need for abandonment or conversion to an alternative biliary strategy.

Secondary endpoints were:

1. anastomotic biliary stricture, defined as a clinically relevant anastomotic narrowing requiring ERCP with balloon dilation and/or stent placement;
2. bile leak, defined by accepted post-hepatobiliary surgical criteria as drain fluid bilirubin greater than three times serum bilirubin or equivalent radiologic/clinical evidence requiring management;
3. biliary cast material, defined as a filling defect on MRCP or ERCP without fixed anastomotic narrowing;
4. cholangitis;
5. pancreatitis after ERCP;
6. stent migration;
7. ERCP requirement; and
8. graft loss by 12 months.

Because post-transplant endoscopic intervention itself carries clinically meaningful risk, particularly in patients with biliary strictures, ERCP-related utilization was analyzed as a separate secondary endpoint [18–20].

2.7 Statistical analysis

No formal sample size calculation was performed because this was a pilot feasibility study. Continuous variables are presented as median (IQR), and categorical variables as count (%). Because the historical comparison cohort was frequency-matched rather than individually paired, between-group comparisons of binary outcomes were performed using two-sided Fisher's exact tests. All comparative analyses were exploratory, and no adjustment for multiple testing was applied. A two-sided $p < 0.05$ was considered nominally significant. Analyses were performed in SPSS version 26 (IBM Corp., Armonk, NY, USA).

3 Results

3.1 Recipient and graft characteristics in the stented cohort

Twelve consecutive adult recipients meeting enrollment criteria underwent successful biodegradable stent placement, yielding a technical success rate of 100%. Median recipient age was 52 years (IQR, 42–60), and 7 recipients (58.3%) were male. Indications for transplantation included viral liver disease, metabolic-associated steatotic liver disease, autoimmune liver disease, cholestatic liver disease, alcohol-related liver disease, and hepatocellular carcinoma. All recipients received right-lobe grafts without middle hepatic vein inclusion.

Table 1. Prospective stented cohort: recipient and operative characteristics ($n = 12$)

Characteristic	Value
Recipient age, years, median (IQR)	52 (42–60)
Male sex, n (%)	7 (58.3)
Right-lobe graft without middle hepatic vein, n (%)	12 (100)
Donor duct diameter, mm, median (IQR)	3.5 (3.0–4.2)
Recipient duct diameter, mm, median (IQR)	10.0 (8.5–12.0)
Duct mismatch, %, median (IQR)	65 (58–72)
Duct mismatch range, %	52–80
Two donor ducts requiring ductoplasty, n (%)	2 (16.7)
Stent size 8 Fr/40 mm, n (%)	2 (16.7)
Stent size 8 Fr/50 mm, n (%)	6 (50.0)
Stent size 10 Fr/60 mm, n (%)	4 (33.3)
Technical success, n (%)	12 (100)
Intraoperative stent-related complication, n (%)	0 (0)

Marked duct mismatch was confirmed in every case, ranging from 52% to 80% with a median of 65% (IQR, 58–72). Median donor duct diameter was 3.5 mm (IQR, 3.0–4.2), and median recipient duct diameter was 10.0 mm (IQR, 8.5–12.0). Two recipients had two donor ducts that were combined by ductoplasty into a single orifice prior to biliary reconstruction. Stent sizes used were 8 Fr/50 mm in 6 recipients, 10 Fr/60 mm in 4 recipients, and 8 Fr/40 mm in 2 recipients. No intraoperative complication was attributed to stent insertion, see Table 1.

3.2 Individual outcomes in the stented cohort

At 12 months, no recipient in the stented cohort had developed an anastomotic biliary stricture. One recipient experienced a bile leak that resolved with drainage alone and without reintervention. Biliary cast material was observed in 2 recipients; one was managed conservatively and one required ERCP. No case of stent migration, cholangitis, pancreatitis, or graft loss occurred. Acute cellular rejection occurred in 5 recipients: 3 mild, 1 moderate, and 1 severe episode. None of these rejection episodes coincided with a clinically significant anastomotic biliary stricture, see Table 2..

Table 2. Individual recipient outcomes in the stented cohort

Pt	Age	Sex	Indication	Mismatch (%)	Donor ducts	Ductoplasty	Stent size	Bile leak	Cast material	ERCP
1	45	M	HBV cirrhosis	60	2	Yes	8 Fr/50 mm	No	No	No
2	52	F	MASLD	70	1	No	10 Fr/60 mm	No	Yes	Yes
3	38	M	PSC	55	1	No	8 Fr/40 mm	No	No	No
4	61	F	HCC (HCV)	65	1	No	8 Fr/60 mm	Yes	No	No
5	48	M	Alcohol-related cirrhosis	80	1	No	10 Fr/60 mm	No	No	No
6	55	F	AIH	75	2	Yes	8 Fr/50 mm	No	Yes	No
7	42	M	Cryptogenic cirrhosis	52	1	No	8 Fr/40 mm	No	No	No
8	59	F	PBC	65	1	No	8 Fr/60 mm	No	No	No
9	34	M	Acute HBV failure	70	1	No	10 Fr/60 mm	No	No	No
10	50	M	MASLD + HCC	60	1	No	8 Fr/50 mm	No	No	No
11	47	F	HCV cirrhosis	55	1	No	8 Fr/40 mm	No	No	No
12	63	M	NASH cirrhosis	75	1	No	10 Fr/60 mm	No	No	No

Abbreviations: AIH, autoimmune hepatitis; ERCP, endoscopic retrograde cholangiopancreatography; HCC, hepatocellular carcinoma; HBV, hepatitis B virus; HCV, hepatitis C virus; MASLD, metabolic-associated steatotic liver disease; NASH, nonalcoholic steatohepatitis; PBC, primary biliary cholangitis; PSC, primary sclerosing cholangitis.

3.3 Comparison with the historical cohort

By design, the historical cohort was frequency-matched to the stented cohort with respect to right-lobe graft use, recipient age band, duct mismatch category, and biliary reconstruction complexity. All 12 historical controls underwent duct-to-duct reconstruction without biodegradable stenting and had complete 12-month outcome ascertainment. No anastomotic strictures occurred in the stented cohort compared with 5 of 12 historical controls (41.7%), corresponding to a two-sided Fisher's exact p value of 0.037. ERCP requirement was numerically lower in the stented cohort (8.3% versus 50.0%), but this difference did not reach conventional statistical significance ($p = 0.069$). Bile leak occurred in 1 stented recipient (8.3%) compared with 3 historical controls (25.0%). Biliary cast material was

somewhat more frequent in the stented cohort (16.7% versus 8.3%), although absolute numbers were small. No graft loss occurred in the stented cohort during the first postoperative year, see Table 3.

Table 3. Clinical outcomes in stented recipients and frequency-matched historical controls

Outcome	Stented ($n = 12$)	Historical ($n = 12$)	p value
Anastomotic stricture by 12 months	0 (0.0%)	5 (41.7%)	0.037
Bile leak	1 (8.3%)	3 (25.0%)	0.590
ERCP requirement	1 (8.3%)	6 (50.0%)	0.069
Biliary cast material	2 (16.7%)	1 (8.3%)	1.000
Cholangitis	0 (0.0%)	2 (16.7%)	0.478
Graft loss by 12 months	0 (0.0%)	1 (8.3%)	1.000

Values are presented as n (%). p values are two-sided Fisher's exact tests and should be interpreted as exploratory because of the pilot design and small sample size.

3.4 MRCP and imaging findings

A total of 31 MRCP studies were performed in the stented cohort over 12 months, corresponding to a median of 2 scans per recipient (IQR, 2–3). Twenty-four scans were obtained as scheduled surveillance studies at approximately 3 and 12 months, and 7 scans were obtained for clinically indicated evaluation of laboratory abnormalities.

Among surveillance scans, 4 showed mild biliary dilatation without fixed stricture, and these findings resolved without intervention. Of the 7 clinically indicated MRCP studies, 2 demonstrated biliary cast material, 1 showed mild anastomotic edema without fixed narrowing, and 4 were normal. No MRCP demonstrated stent migration.

Table 4. MRCP utilization and findings in the stented cohort

Item	Number	Findings
Total MRCP studies	31	–
Median MRCP studies per recipient (IQR)	2 (2–3)	–
Scheduled surveillance MRCP studies	24	4 mild dilatation, 20 without relevant abnormality
Clinically indicated MRCP studies	7	2 cast material, 1 mild anastomotic edema, 4 normal
Stent migration on MRCP	0	None observed

4 Discussion

This pilot study focused on a particularly challenging subgroup within adult LDLT: recipients undergoing duct-to-duct biliary reconstruction in the presence of marked donor–recipient duct mismatch. Within this selected high-risk population, biodegradable internal biliary stenting was technically feasible in every case and was not associated with intraoperative difficulty or device-related procedural failure. These findings support the practical deployability of an entirely intraductal biodegradable scaffold in technically demanding LDLT biliary reconstruction.

The most clinically notable finding was the absence of anastomotic strictures during 12 months of follow-up in the stented cohort. This contrasts with the 41.7% stricture rate observed in the frequency-matched historical cohort and is directionally consistent with prior literature suggesting that temporary intraductal support may be beneficial in selected LDLT reconstructions [7, 8]. The observed rate in the historical cohort is also compatible with the well-described vulnerability of LDLT biliary reconstruction when duct caliber mismatch and complex anatomy coexist [9, 10]. Because our study was small and non-randomized, this signal should be interpreted as hypothesis-generating rather than definitive evidence of efficacy; nonetheless, it is clinically encouraging.

The leak rate in the stented cohort was low, with only one event managed conservatively. This is relevant because one concern with any adjunct placed across the biliary anastomosis is the possibility of impaired tissue healing or increased local trauma. That signal was not seen in the present series. Indeed, prior observational studies have shown that precise reconstructive technique and careful tailoring of duct alignment are major determinants of leak risk in LDLT [11–15]. The current experience suggests that biodegradable stenting can be incorporated into that technical framework without an obvious penalty in early leak events.

MRCP was central to postoperative surveillance in the present study. This was intentional. In LDLT recipients, the threshold for evaluating cholestatic graft dysfunction is necessarily low, but routine use of invasive cholangiography is undesirable when a non-invasive, diagnostically robust alternative exists [16, 17]. The 31 MRCP studies performed in this cohort allowed detection of both subtle transient abnormalities and clinically relevant cast formation without overusing ERCP. This selective imaging pathway may be particularly useful in pilot studies of new biliary adjuncts because it captures device-related anatomic evolution while minimizing procedure-related risk.

Biliary cast material remains the main cautionary signal from the present dataset. Two recipients developed cast material and one required ERCP. Although this incidence is based on very small numbers, it suggests that a biodegradable stent may interact with the low-flow environment of a

small-calibre LDLT bile duct in a way that promotes transient intraductal debris formation in some patients. This is biologically plausible and consistent with the broader post-transplant cast literature, in which cast formation reflects a multifactorial process involving ischemia, epithelial injury, stasis, and altered bile composition [18, 19, 22]. The absence of stent migration in our series is reassuring and likely reflects the additional fixation suture, but that advantage may come at the expense of transient local stasis in susceptible recipients. Future studies should therefore incorporate systematic documentation of cast morphology, timing, and biochemical context.

ERCP utilization was numerically lower in the stented cohort, but the study was underpowered to establish this difference statistically. That distinction matters. Reduced post-transplant ERCP burden is clinically important, especially because endoscopic treatment of transplant strictures can itself be associated with pancreatitis, bleeding, cholangitis, and repeated procedures [18–20]. However, given the present sample size, the correct interpretation is not that biodegradable stenting has proven an ERCP-sparing effect, but that the observed pattern justifies larger evaluation.

Several limitations deserve emphasis. First, this was a single-centre pilot study with only 12 prospective recipients. Second, the comparison group was historical rather than concurrent, which introduces the possibility of residual confounding despite frequency matching on the principal technical risk variables. Third, formal donor and control-arm granular operative details were not exhaustively modeled, and unmeasured factors such as microvascular biliary perfusion, exact duct orientation, and center-period effects could have influenced outcomes. Fourth, although 12 months is substantially more informative than an early feasibility window, late strictures beyond the first year can still occur [21]. Finally, acute rejection occurred in several recipients, and although none coincided with an anastomotic stricture in this cohort, rejection remains an important determinant of graft outcome and a potential contributor to later biliary dysfunction [23].

Despite these limitations, the present study offers a coherent next step in LDLT biliary innovation. It concentrates on a technically high-risk subgroup, applies a logically selected device, incorporates a non-invasive imaging strategy, and generates a clinically relevant signal in stricture prevention without clear evidence of excess major harm. These are the features desired of a pilot dataset intended to justify formal multicentre evaluation.

5 Conclusions

In adult LDLT recipients with marked duct-to-duct size mismatch, intraoperative placement of a biodegradable internal biliary stent was technically feasible and showed an acceptable safety profile over 12 months. Compared with a frequency-matched historical comparison cohort, stented recipients had fewer anastomotic strictures and numerically fewer ERCPs, while biliary cast formation emerged as the principal device-related concern. These results support prospective multicentre investigation, ideally in a randomized or contemporaneously controlled design.

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Conflicts of Interest

The authors declare no competing interests related to this work.

Ethics Statement

The prospective study arm was approved by the institutional human research ethics committee, and written informed consent was obtained from participating recipients and living donors. Historical comparison data were analyzed under ethics-approved retrospective waiver provisions using de-identified records.

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