4.3.1. Retrospective analysis study (n=102) on the use of CELOX™ PPH as a treatment for PPH compared with current standard of care.

Postpartum Haemorrhage:
CELOX™ PPH retrospective data analysis report (Charité data).
Henrich, W, Dückelmann A, Giroud D, Sarr Y. Version 1.1 – 19 May 2022.
Retrospective analysis study (n=102)

- Assessment of 102 patients with PPH who did not respond to conventional treatments
- Primary objective: to control uterine bleeding in PPH with CELOX™ PPH
- CELOX™ PPH demonstrated 100% successful haemostasis in all patients with grade 1 and 2 bleeds (up to 2500mls) for all deliveries
- CELOX™ PPH demonstrated 95.7% successful haemostasis in all patients with grade 1 to 3 bleeds (up to 8000mls) for vaginal deliveries
- Following the introduction of CELOX™ PPH the incidence of hysterectomies was significantly reduced (versus standard of care) by 77.8%

In a retrospective evaluation undertaken in the Department of Obstetrics and Gynecology at the University Hospital Charité, Berlin, 102 patients, whose PPH (uterine, vaginal, or cervical) did no respond to conventional treatments, were assessed for the control of uterine bleeding in PPH using CELOX™ PPH. The primary objective of the study was to evaluate the effectiveness of CELOX™ PPH in controlling uterine bleeding for primary PPH. The primary performance endpoint (outcome) was the proportion of patient-controlled bleeding in less than five minutes (indicating a successful outcome). Secondary outcomes included safety (e.g. adverse events particularly related to the need for additional interventions, infection rate, allergic response), and performance (e.g., ease of application, duration of application). An analysis of patients with a clear indication of uterine haemorrhage (n=91), CELOX™ PPH was effective in halting blood loss in 91.2% (83/91) (CI 85.4%, 97.0%) patients (Appendix 1, Table 9). In relation to the delivery path, 58.2% (53/91) had a vaginal delivery and 94.3% (50/53) reached successful haemostasis with CELOX™ PPH, whereas only 5.7% (3/53) patients experienced unsuccessful haemostasis with CELOX™ PPH. (Appendix 1, Table 10). Thirty-eight (41.8%) patients with uterine PPH required a caesarean section, of which 86.8% (33/38) reached successful haemostasis with CELOX™ PPH, whereas 13.2% (5/38), encountered unsuccessful haemostasis with CELOX™ PPH.

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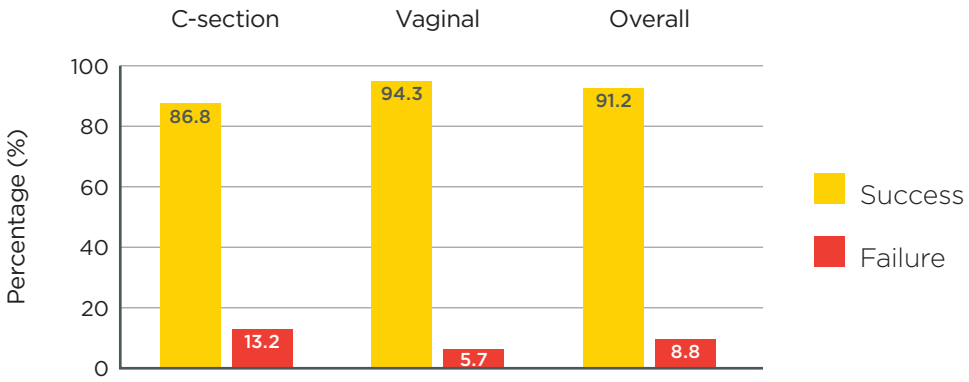
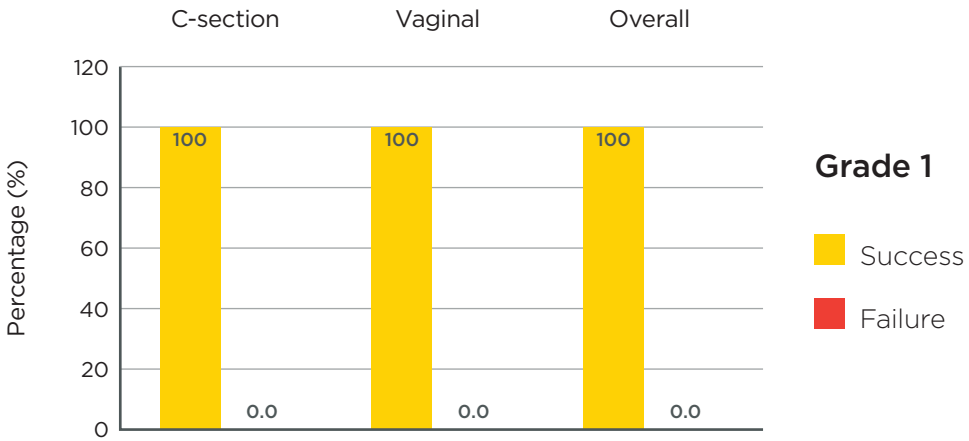
Figure 10. Success/failure of CELOX™ PPH haemostasis by delivery mode in patients with uterine PPH



Three different grades of PPH (grades 1, 2, and 3) were defined according to a number of different parameters, including quantity of blood loss. Of the 91 patients, 23.1% (21/91) had grade 1 (reported blood loss 800-1000ml), 56.0% (51/91) grade 2 (1200-2500ml), and 20.9% (19/91) had grade 3 (2600-8000ml). CELOX™ PPH reached 100% successful haemostasis in all patients with grades 1 and 2. For grade 3, the overall success rate was 57.9% (11/19) (Figure 11).

Figure 11. Success/failure of CELOX™ PPH haemostasis by delivery mode based on grades of PPH



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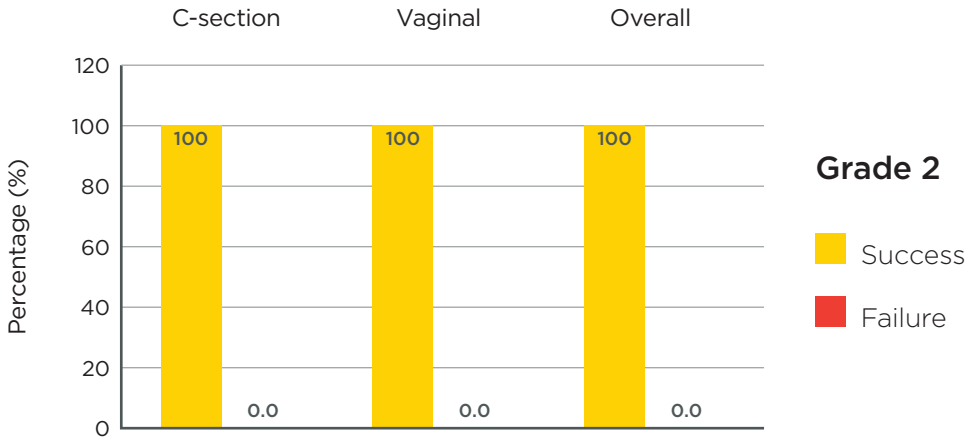

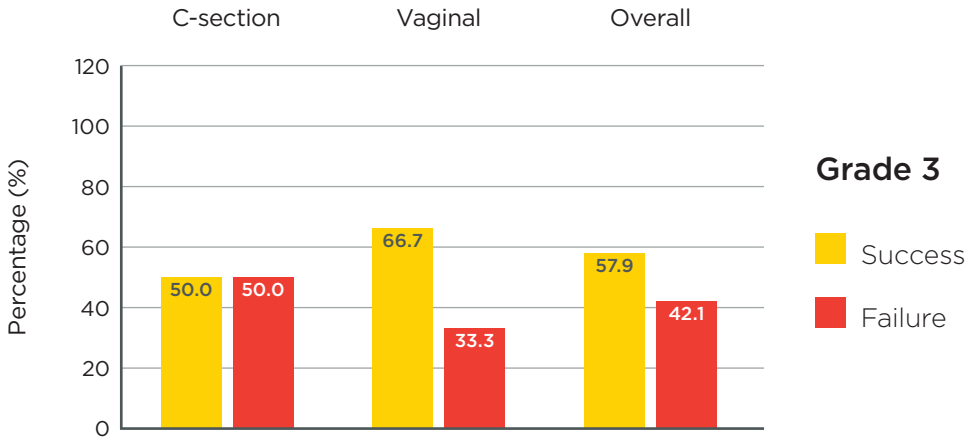

There were no device-related events except for one possible procedure-related event where it was reported that during insertion a possible damage to the uterotomy suture of the caesarean section occurred. The overall occurrence rate of safety events appears to be slightly lower compared to Bakri balloon (Appendix 1, Tables 10 and 11). The infection rate for all patients included in this study was 6.9% (7/102), but no infections were attributable solely and directly to CELOX™ PPH. After the introduction of CELOX™ PPH, the incidence of hysterectomy over a span of 31 months was remarkably low, with only two cases out of 9,167 births necessitating hysterectomy. In the 31 months preceding the implementation of CELOX™ PPH, a total of nine hysterectomies were performed out of 9,058 births. This is a significant reduction of 77.8% (OR 4.55, P=0.037, Fisher's Exact Test). Five new pregnancies successfully brought to term with healthy babies are to be reported among the patients studied in this retrospective analysis. There were no problems reported with insertion or removal of CELOX™ PPH (Appendix 1, Table 12).

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