

Real-Time Visualization of Milk Transfer During Breastfeeding: Prospective 12-Month Clinical Outcomes

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Background

Breastfeeding provides major maternal and infant health benefits. Continuation often declines during the first postpartum year. Perceived low milk supply and reduced maternal confidence are common barriers.

Aim

To evaluate whether the use of a novel breastfeeding aid **providing real-time visualization of milk Flow during feeding** was associated with sustained exclusive and any breastfeeding through 12 months postpartum.

Methods

Study Design: IRB-approved prospective longitudinal study.
 Population: 825 enrolled; **260 participants** in the final analytic cohort.
 Device Use: Investigational device (Flow01) initiated at mature milk production and used according to maternal preference.
 Measures: **Monthly follow-up** assessments for breastfeeding status, exclusivity, and confidence levels using Flow01.

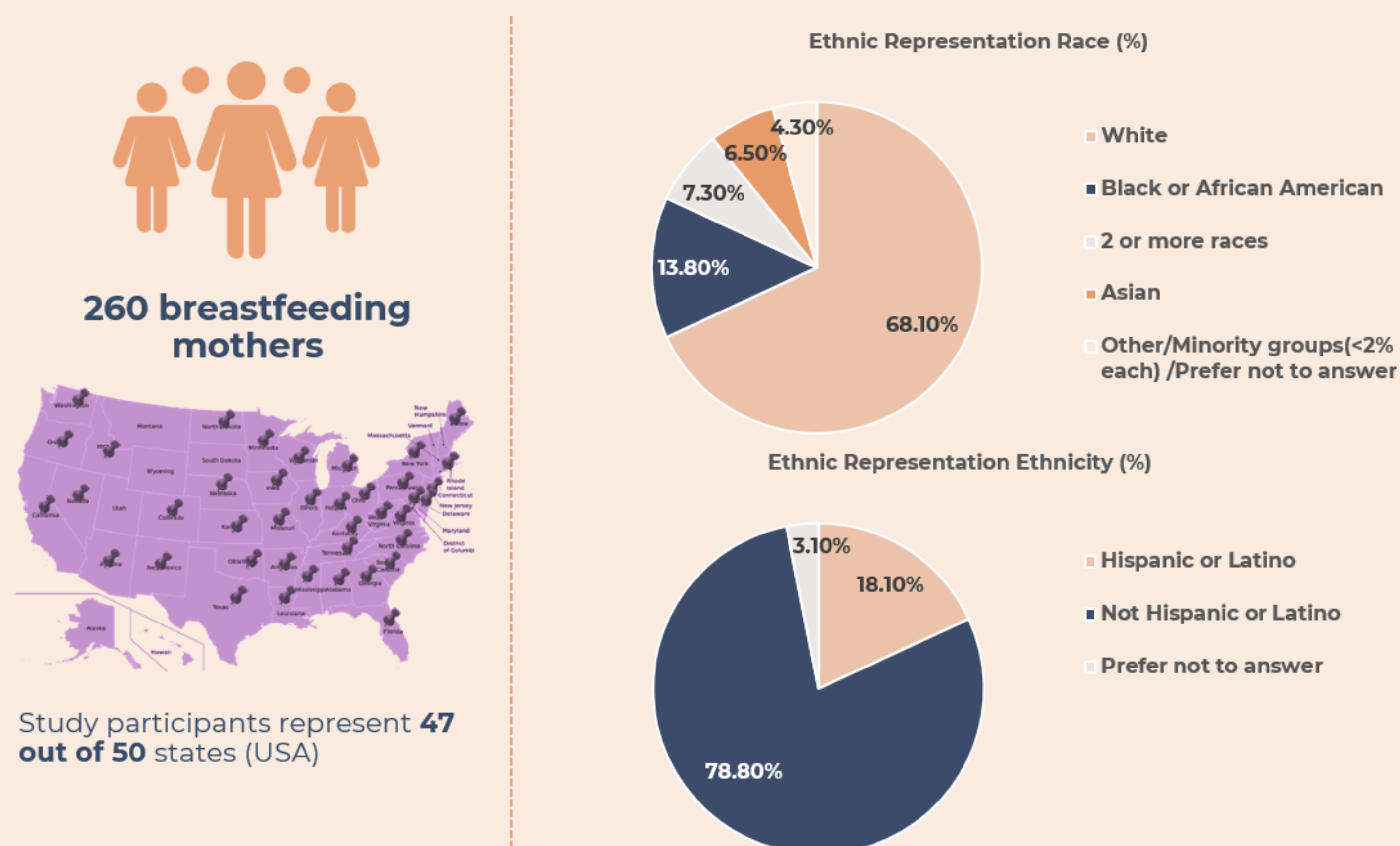


Figure 1. Demographic Profile and Geographic Distribution of the Analytic Cohort.

Results

- 93.8% of participants were breastfeeding at 6 months and 85.8% at 12 months, **exceeding US national benchmarks** (~50-75%). (Figure 2)
- Exclusive breastfeeding at 6 months reached 34%**, more than triple the previously reported US average of ~10%. (Figure 3)
- During the first month postpartum, 75.8% of mothers indicated an increase in confidence due to the use of Flow01.
- 98.9% of women reporting increased confidence from Flow01 at the first month met their breastfeeding goals at 6 months, compared to 79.2% in the no-increased-confidence group.
- Increased confidence from real-time visualization was significantly associated with a **27.96 times higher** adjusted odds of **meeting breastfeeding goals**, and participants were 3.0 times more likely to actually exceed their personal breastfeeding goals.
- The device functions as a supportive aid rather than a crutch; by the first month postpartum, 70.6% of participants **utilized it selectively** rather than at every session, demonstrating a transition to independent breastfeeding. (Table 1)

Month	% Not using Flow01 at each	95%CI	
		Low	Up
1.0	70.6%	64.9%	76.1%
2.0	81.2%	76.2%	85.7%
3.0	85.1%	80.4%	89.1%
6.0	87.1%	82.6%	90.8%
12.0	88.7%	84.4%	92.2%

Table 1. Life-table for discontinued dependence in Flow01 (not using at each breastfeeding)

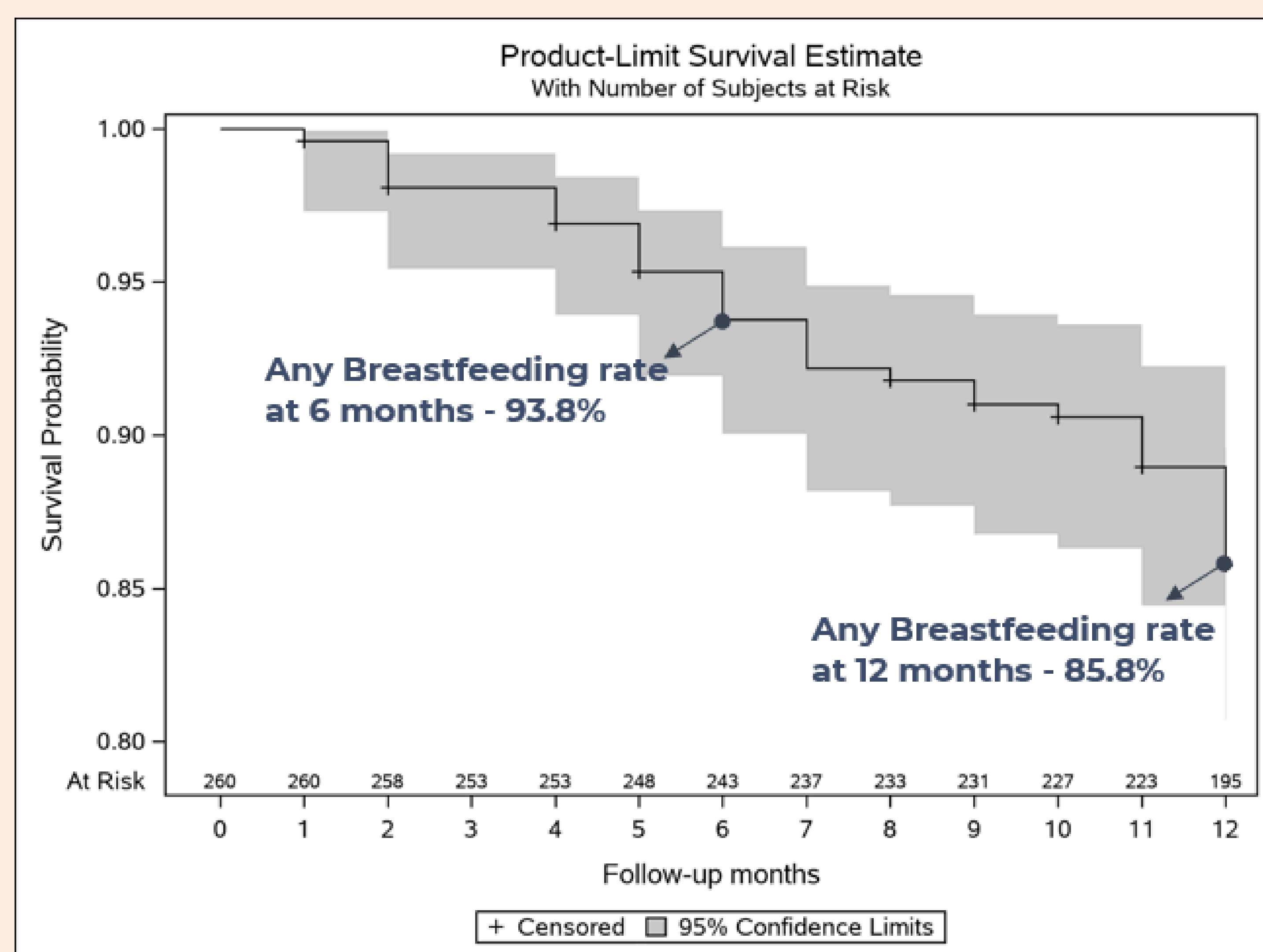


Figure 2. Breastfeeding throughout the follow-up – Kaplan-Meier curve

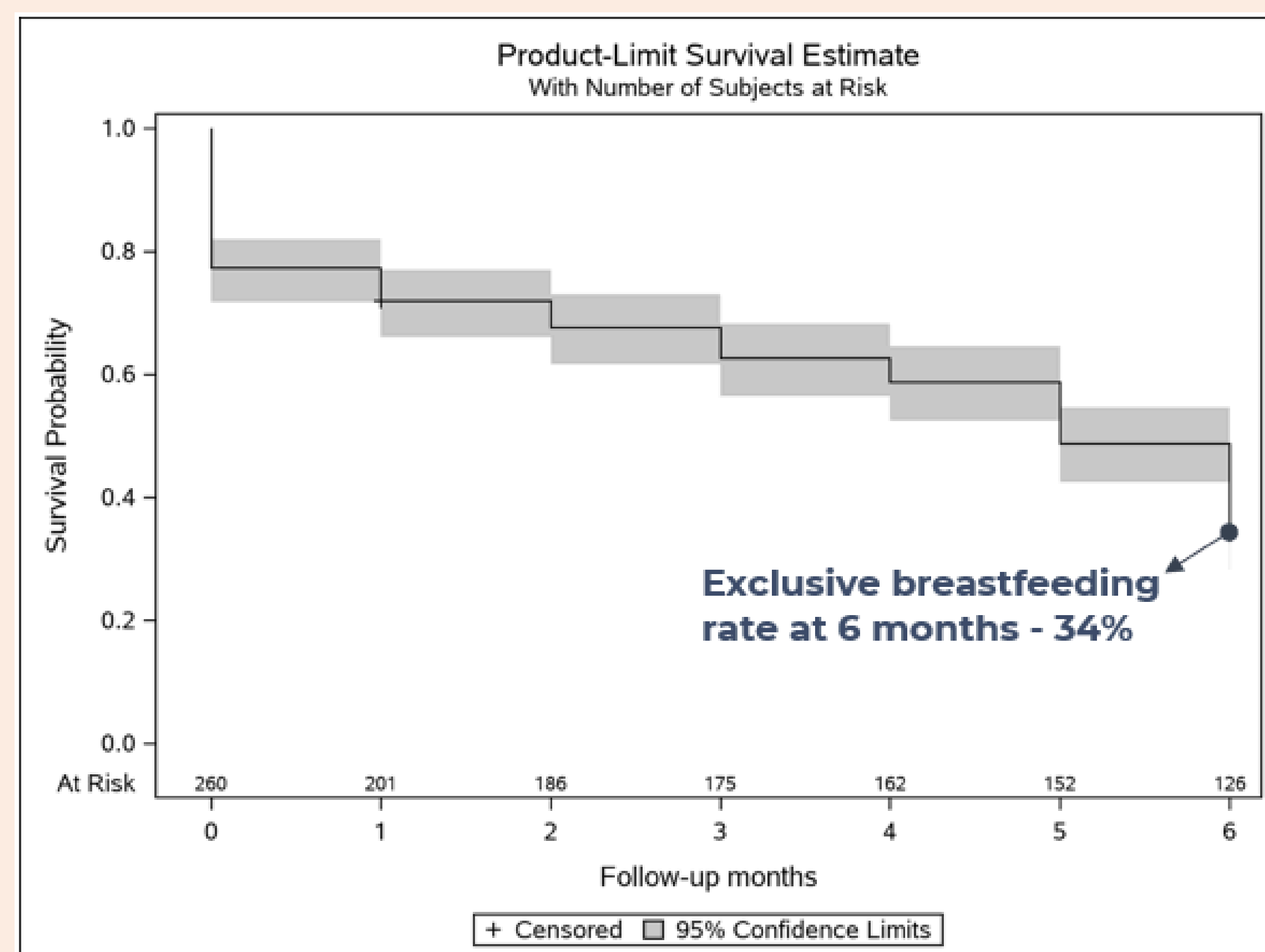


Figure 3. Exclusive breastfeeding throughout the follow-up – Kaplan-Meier curve

Conclusion

Real-time visualization of milk transfer extends the duration of both any and exclusive breastfeeding beyond national standards. By providing objective confirmation during the critical first month, this technology helps mothers build the confidence necessary to **meet and exceed breastfeeding goals**. Flow01 represents a substantial advancement in evidence-based lactation support

