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Original Article

Birth outcomes and usability of Relaxbirth® for upright positioning intrapartum: A retrospective case control study

J. Doyle[a], D. Bagnoli[a], T. Kenny[a,*], M.L. McCarroll[b], L. Hamrich[c], V. von Gruenigen[d]

[a] Summa Health, Department of Obstetrics and Gynecology, Akron, OH, United States
[b] Department of Clinical Medicine, College of Osteopathic Medicine, Pacific Northwest University of health Sciences, Yakima, WA, United States
[c] Summa Health, Department of Family Medicine, Akron, OH, United States
[d] University Hospitals of Cleveland, Cleveland, OH, United States

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ABSTRACT

Introduction: The aim of this study was to pilot Relaxbirth® (Relaxbirth®, Ltd., Helsinki, Finland), an investigational device designed to facilitate upright positioning intrapartum. The objective was to 1) compare birth outcomes with and without the use of Relaxbirth®, and 2) assess device usability.
Methods and materials: Study design: prospective product use and retrospective case control study at one perinatal center in Ohio. Inclusion criteria: ≥18 years old, <300 lbs. women with a low-risk, term gestation of a singleton, vertex fetus, and vaginal birth between January 2013 to June 2016. Participants who used the Relaxbirth® device intrapartum (RB group) were retrospectively case-matched to controls (CON group) according to age, race, insurance, gravida/parity, gestational age and labor type. Birth outcomes (primary outcome) were compared between groups. Providers and women who used Relaxbirth® assessed usability of the device with the Modified System Usability Scale Tool (secondary outcome).
Results: Of the n = 60 included in the final analysis, RB women (n = 30) pushed for a shorter average duration compared to CON women (n = 30) [34 min (±48) versus 60 min (±63), p = 0.023]. RB women did not experience more adverse birth outcomes including: longer second stage duration, operative vaginal delivery, malpresentation, perineal laceration/episiotomy, higher blood loss, or low Apgars. Usability survey results were favorable (Total Average Scores: providers 74.1; RB 83.6).
Conclusion: Clinical experience with the Relaxbirth® device was positive at this pilot site. The device was associated with favorable birth outcomes and usability, suggesting potential as a safe and novel adjunct to promote intrapartum choices, upright positioning and maternal satisfaction.

Introduction

Background and rationale

Throughout history, laboring women were often positioned upright, or at least able to move about unencumbered. [1,2] In western cultures, the semi-recumbent position is primarily used intrapartum [2] to increase the ease with which health care providers can perform labor assessments such as uterine and fetal heart rate monitoring and cervical exams [1]. However, recumbent positions are associated with an increase in maternal abdominal blood vessel compression, epidural analgesia, operative vaginal delivery, labor duration, abnormal fetal heart rate patterns, episiotomy, and severe pain, as well as less effective uterine contractions and pelvic relaxation, more intrapartum intervention, and subsequent neonatal intensive care admissions [1–7]. Conversely, upright positioning in labor is associated with positive outcomes such as a shorter duration of the first stage of labor and fewer cesarean births [5], an increase of the pelvic diameter by as much as 30% [3], and preferential fetal-pelvic alignment [8].

The Association of Women's Health, Obstetric and Neonatal Nurses' (AWHONN) Evidence-based Clinical Practice Guideline [9] suggests that a laboring woman's knowledge, preference, and ability to attain various positioning options should be assessed and included into her birthing experience. AWHONN recommends that women should labor in the upright position [10]. Unfortunately, 68% of laboring women are placed supine, 23% are directed into a

* Corresponding author at: Informatics, Women's Services, Summa Health, 525 East Market Street, Medical Building 2nd Floor, Akron, OH, 44304, United States.
E-mail address: kennyt@summahealth.org (T. Kenny).

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semi-sitting position, and only 4% of women use one or more of the AWHONN recommended upright positions intrapartum [4].

Even with benefit established and guidelines that encourage upright positioning, healthcare provider bias against applying upright positioning can occur. This resistance to implementation may stem from a lack of knowledge, lack of interest, or a perception of non-supportive colleagues. [2] Furthermore, maternal perceived physiologic barriers to execute upright positions include lower extremity weakness due to anesthesia, passivity of the woman to change positions during labor, and maternal fatigue [11].

Investigators conducted this pilot study in order to increase options for laboring women to attain and maintain upright positioning. Relaxbirth® is an investigational device designed to be used intrapartum, both as a stand-alone item and as a complement to a hospital bed (Fig. 1). Its ergonomic design is intended to provide laboring women varied upright positions during labor and/or birth in order to maximize pelvic diameter and fetal descent. Relaxbirth® provides adjustable pushing handles and maneuvering handles on the backside to facilitate positioning, balance, and pushing efforts during labor.

Objectives

The aim of the study was to pilot Relaxbirth® device usage in North America. The study's objective was 1) to compare birth outcomes using Relaxbirth® for upright positioning intrapartum, and 2) for patients and their providers to assess the usability of the Relaxbirth® device.

Materials and methods

Study design and setting

This study design was prospective product use and retrospective case control comparing outcomes with and without the use of Relaxbirth® during labor for women delivering between January 2013 and June 2016. Device usability was assessed by the woman and her delivering provider. The setting was Summa Health Akron campus, a level-three, urban, perinatal center in Northeast Ohio, USA. Institutional Review Board (IRB) Approval was obtained for this pilot study (#13070) in early 2012 before the study was conducted. The use of the investigational Relaxbirth® device was considered a Non-Significant Risk (NSR) device because it did not meet the 21 CFR 812.3(m), significant risk definition. Summa Health received a consulting fee for conducting the study. The fee was paid by the government of Finland and not the company nor manufacturer of the device. The company producing Relaxbirth® did not provide any financial support, nor were they implicated in any way in the study and/or in the analysis.

In late 2012 prior to enrolling any women into the study, an educational process was implemented which involved research protocol details, and how to use the device and attain various upright laboring positions. Relaxbirth® representatives trained the study investigators. The study investigators then provided a series of demonstration inservices and slide presentations to labor and delivery unit nurses and providers. Attendees completed a return demonstration and a competency form. Small posters illustrating various upright positions with Relaxbirth® were displayed in Labor and Delivery and affixed to the device. Investigators placed a sign on the Relaxbirth device alerting all personnel and the public that it is an investigational device, to be used only by trained personnel of the pilot study. Members of the research team were available for ongoing education and assistance.

Participants- case

Enrollment into the study began in January 2013. The hospital marketed the study with a local newspaper article, blog, twitters, internal communications and Facebook posts. Obstetric providers would discuss the study and labor options with their patients during prenatal care. When women identified themselves as being interested in using Relaxbirth® during this discussion, their

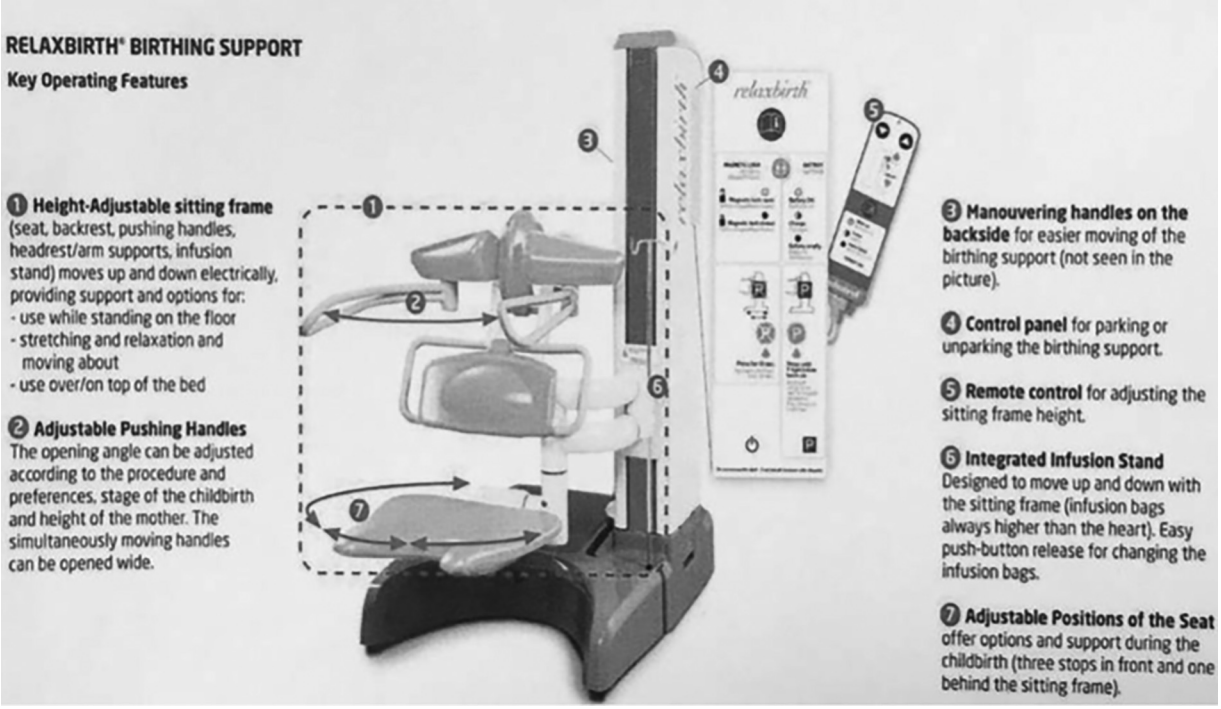

Fig. 1. Title: Relaxbirth® Key Operating Features.
Legend: This figure illustrates the key operating features of the Relaxbirth® device.

prenatal care provider would refer the women to the study's principal investigator. The women would call the principal investigator for more information or study enrollment. The principal investigator first verified eligibility criteria: gestational age between 37–41 6/7 weeks', singleton pregnancies, fetal vertex presentation, permission from the woman's obstetric care provider, the woman's age being 18 or older, with a weight less than 300 pounds, and anticipation of vaginal delivery. A patient would not be enrolled if any of the above criteria was not met, as well as if she did not speak English, nor had any condition that rendered her or the fetus as high risk.

Once eligibility was established, an appointment was made for the woman to come to the labor and delivery unit for device demonstration and study consent. The consent appointment was typically one hour in length and held approximately one month prior to the woman's due date to eliminate the likelihood of having to withdraw the woman from the study due to pregnancy complications. On two occasions, women requested information about Relaxbirth during the intrapartum period. Demonstration and signed consent were obtained at this time. Primarily, the prenatal consent process was used due to considerations for a woman's comfort, readiness for learning, and time needed for demonstration and consent.

Once a woman had completed the consent process for the pilot study, she would only have to request the device upon her arrival for admission to the labor and delivery unit. At that time, eligibility requirements were verified by the labor nurse and she would be able to use Relaxbirth during labor and/or birth. If a contraindication or excluding factor was found, the principal investigator was notified and the patient informed of ineligibility status.

Women could choose various positions while using the Relaxbirth® device according to their individual needs and in collaboration with their healthcare team. Women in labor were able to assume multiple positions during labor with the assistance of their provider, nurse or research study personnel. Other options for positioning and comfort were available and included birthing ball, walking, hydrotherapy tub, the shower, and the hospital bed. Second stage care for all women was in accordance with the AWHONN Second Stage Guidelines of Care [9] and staffed at 1:1 nurse to patient ratio. Second stage care was a partnership co-managed by the labor and delivery nurse and the delivering provider. Usual care was in the semi-recumbent position with a pelvic tilt or upright depending on the maternal-fetal response. The delivering provider typically decided when to actively push. Participants could have declined to use Relaxbirth® at any time during the study period. Initiation of epidural anesthesia necessitated elimination of the device from clinical use.

Study enrollment concluded in June 2016. Fig. 2 explains the case selection process that removed cases with screen failures or secondary exclusions (development of high risk factors, cesarean delivery, or lack of use). Ultimately, the result was a convenience sample of 34 case group women. Study consents and forms for women who failed screening were kept in a separate but secured file in a locked office.

Participants- control

Control selection began in late 2016. There was one control per one case. Women who used the device and those that did not were clinically managed the same way. Control cases were identified retrospectively via the departmental electronic medical records system IntelliSpace Perinatal (Philips Medical Systems, Andover MA). Demographic and obstetric history data for up to n = 900 charts from women delivering between the January 2014 to April 2016 were reviewed by investigators to obtain n = 34 matched cohorts. The cases were matched on all inclusion and exclusion criteria for the study, age, race/ethnicity, gravida/parity, labor type, and insurer (private/public). Reviewers were limited to matching criteria data only (e.g. blinded to birth outcomes) to eliminate potential sources of bias. De-identified birth outcomes for women in both groups were kept in a secure file in a locked office of the principal investigator and on a secured data drive accessible to only key study personnel.

Variables and data sources

Primary outcome: birth outcomes

The primary outcome was birth outcomes which included: second stage of labor duration (10 cm dilation to delivery), pushing duration (duration of active pushing documented), 1- and 5-minute APGAR scores, operative-assisted delivery, malpresentation, episiotomy/perineal laceration, and visually estimated blood loss (EBL) at delivery. Blood loss at delivery was a variable of interest because upright positioning in labor and delivery may lead to a higher estimated blood loss (EBL) at birth due to gravitational force [3] but this has not been found universally [11]. Birth Outcomes were sourced from IntelliSpace Perinatal.

Secondary outcome: usability

The secondary outcome was an assessment of the device's feasibility and practicality; otherwise known as usability. The Modified System Usability Scale Tool (MSUS), a *Likert scale*, is an effective, reliable and inexpensive tool that was used to assess the feasibility of using the Relaxbirth® device intrapartum for providers and women who used it. [13] The MSUS is free 10-item scale that gives a global, subjective rating of a product's usability. The results of this tool provide a number that ranges from 0 (negative usability) to 100 (positive usability). Bangor et al. [13] also noted that MSUS scores above 70 are passable with truly superior products scoring better than 90. A product with a score of less than 70 should be looked at needing improvement and judged as being marginal. Products that score less than 50 should be considered unacceptable [13].

The single MSUS number offers a composite measure of the overall global perception of usability of Relaxbirth® among the providers as well as the women that utilized this method intrapartum. To calculate the 10 answered items, each individual question has a score that ranges from 0 to 4. Each individual question is answered on a 1–5 scale ranging from strongly disagree (1) to strongly agree (5). For questions 1, 3, 5, 7, and 9 the score is the answered scale position minus 1; however, questions 2, 4, 6, 8, and 10, the score is 5 minus the answered scale position. [13] The sum of the total score was then multiplied by 2.5 which represented the overall value of the system's usability [13].

The primary healthcare provider who cared for the woman during her use of the Relaxbirth® device completed the MSUS confidentially via *Survey Monkey*. Reminders to complete the survey were emailed to the providers. If the survey was not completed within 3 months, reminders were discontinued due to relevance/timing of the study. A statement at the top of the survey indicated that completion of the survey implied consent. In addition, the woman confidentially completed the MSUS on paper form after childbirth and before discharge from the hospital if she used Relaxbirth during labor and gave birth vaginally. The paper form of the MSUS included a limited number of additional questions regarding Relaxbirth positions used, pain, and relaxation during each stage of labor. The purpose of these questions was to ascertain how women typically utilized the device intrapartum during the first and/or second stage of labor. Completion of the MSUS tool and additional Relaxbirth use questions were discussed

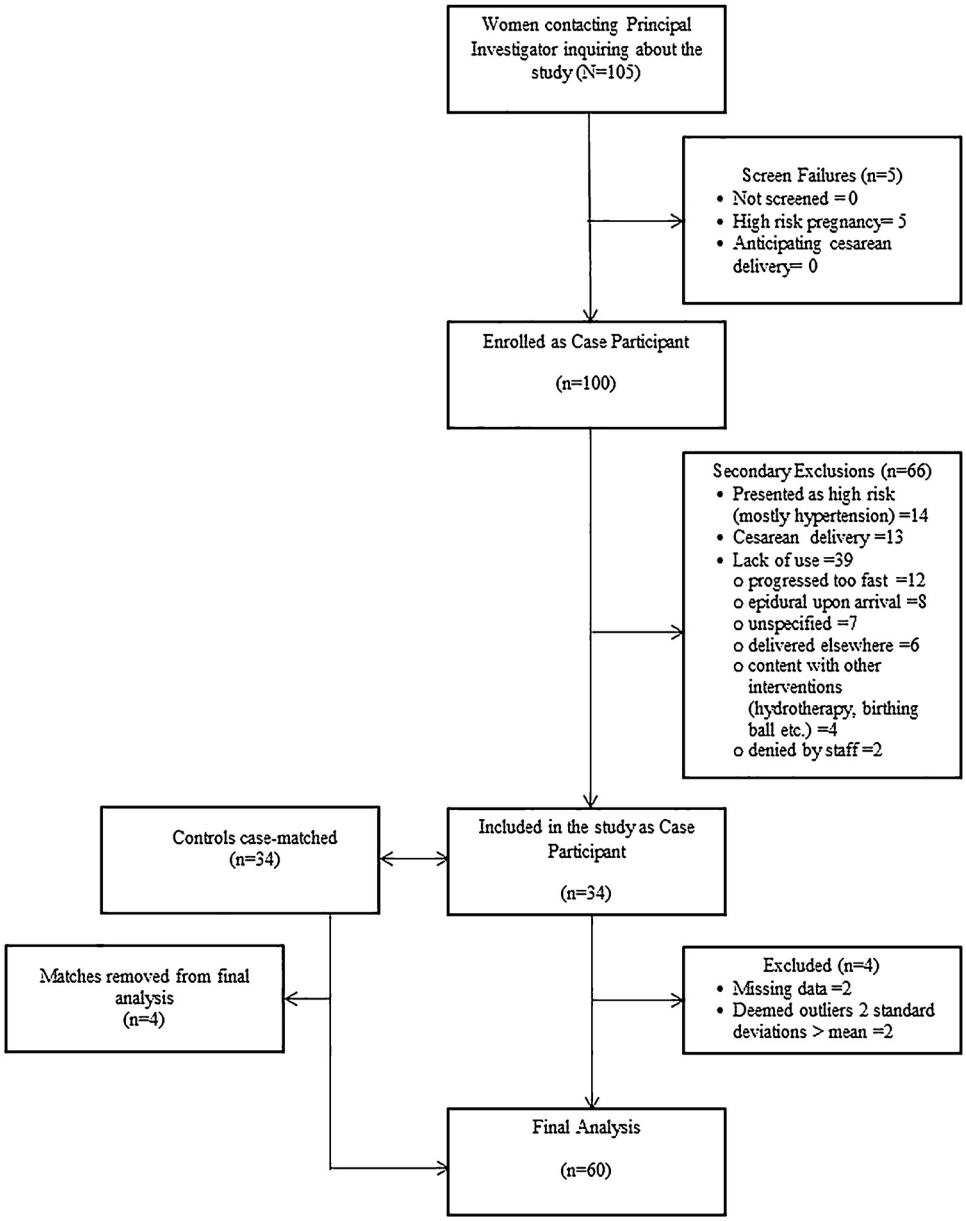

Fig. 2. Title: Sample Selection.
Legend: This flowchart displays the sample selection process: numbers assessed for eligibility, confirmed eligible, included in the study, and final analyzed.

with participating women as part of the consent process. A study representative, most often the principal investigator, approached the mother for postpartum survey completion during a time that did not interfere with mother/infant bonding or maternal rest.

Data analysis

A sample size analysis was decided a priori due to the pilot nature of the study. Birth outcomes data on n = 60 participants were analyzed using the SPSS data software package Version 23.0 (IBM® Armonk, North Castle, New York) and Microsoft Office® Excel (Microsoft® Redmond, Washington) software. While initially there were 68 participants, 8 participants were removed from the final analysis due to missing data or were deemed outliers (second stage labor duration 2 SD > mean). These removals constituted n = 4 from each group (RB and CON), because if one required removal, so did her 'match' in the control group.

Chi-squared tests or Fisher's exact tests were used to test categorical data for distributional equivalence between study groups. For continuous data, t-tests were used for normally distributed data for differences in baseline and comparative characteristics between groups. For non-normal continuous data (duration of pushing and second stage labor) rank equality was tested between study groups via Mann-Whitney U tests and boxplots were provided. A p-value less than 0.05 via two-sided testing was considered statistically significant. Survey responses were handled in a similar fashion, as applicable.

Results

Participants

Fig. 2 displays the number of women screened, failed screening, enrolled and excluded secondarily. No enrollee disagreed with the utility of the machine and abandoned use. The total number of the

participants included in the final analysis were n = 60 or 30 from each group. All tables and figures account for exclusions from the study database. The Relaxbirth® case group (RB) and control (CON) groups were found to be statistically equivalent for demographic and pregnancy history variables (Table 1).

Primary outcome: birth outcomes

RB women spent half the time actively pushing during the second stage (Fig. 3) compared to CON women. The second stage labor duration was similar between groups (Fig. 4). Furthermore, RB women did not have more adverse birth outcomes compared to CON women, including: longer second stage duration, operative vaginal delivery, malpresentation, perineal laceration/episiotomy, higher EBL or lower Apgar scores (Table 2).

Secondary outcome: device usability

No reported untoward events or injuries occurred while using Relaxbirth®. A total of n = 35 provider survey links were sent to the certified nurse midwives or physicians for online MSUS completion. Fifteen provider surveys were completed. In addition, n = 34 RB participants were provided the MSUS survey, and 22 participants completed the survey. The MSUS scores revealed patient and provider perceptions of usability via Likert scale. MSUS average response score per survey item are presented in Fig. 5. The MSUS Total Average Score from the providers was 74.1 with an average Likert scale score of 2.96 (+1.33). The MSUS Total Average Score from the RB participants was 83.6, with an average Likert scale score of 3.34 (+1.25). Both are acceptable and favorable scores for usability.

The patient paper form of the MSUS also included three additional questions regarding Relaxbirth®: positions used, pain, and relaxation during the first and second stages of labor. Results of women completing these additional questions related to the first stage of labor are presented in Table 3. Women reported use of a wide variety of labor positions. Women also agreed that the device helped reduce pain and helped them relax. Five women answered the additional survey questions related to Relaxbirth® use during the second stage of labor. Due to the small number or responses specific to the second stage of labor, outcomes were not summarized in Table 3. Still, when these five women were asked to choose the one most helpful position, responses were similar to those obtained of the first stage of labor. During the second stage of labor, the most popular positions were hanging from the pushing handles (n = 4) and massaging (n = 1). It should be noted that the 'hanging' position involves standing upright with both feet on the ground while reaching up and holding onto the pushing handles. All positions were used at the suggestion and instruction of the manufacturer. Of these same five women, three answered that the sitting position on Relaxbirth® during the second stage of labor was most helpful. Using the Likert scale, the averages of obtaining optimal positioning and pushing effectiveness were 3.71 (±1.50) and 3.71 (±1.60) (Agree), respectively.

Table 1
Demographic and Pregnancy History.

	Relaxbirth Group	Control Group	*p-value*
Variable	(n = 30)	(n = 30)	
Age (Years)			0.74
Average (SD)	29.56 (±4.06)	29.23 (±3.77)	
Race			1.00
White	26 (86)	25 (83)	
Black	3 (10)	3 (10)	
American Indian/Alaskan	0 (0)	0 (0)	
Asian	0 (0)	0 (0)	
Other	1 (3)	2 (6)	
Insurance Type			0.75
Private	24 (80)	23 (77)	
Public	6 (20)	7 (23)	
Birth History			
G - Average (SD)	1.76 (±0.897)	2.03 (1.12)	0.32
P - Average (SD)	0.733 (±0.883)	0.833 (±0.912)	0.67
Primiparity	15 (50)	13 (43)	0.27
Gestational Age (Weeks')			
Average (SD)	39 (±1)	39 (±1)	0.60
Labor Type			1.00
Spontaneous	14 (46)	14 (46)	
Induced/Augmented	16 (53)	16 (53)	
Epidural			0.43
Yes	16 (53)	19 (63)	
No	14 (46)	11 (36)	

Data displayed as n (%) unless noted otherwise.
Standard Deviation = SD.
Numeric data compared for mean equality via independent samples Student's t tests.
Categorical data compared for distributional equality via Pearson's chi-square or Fishers Exact tests.

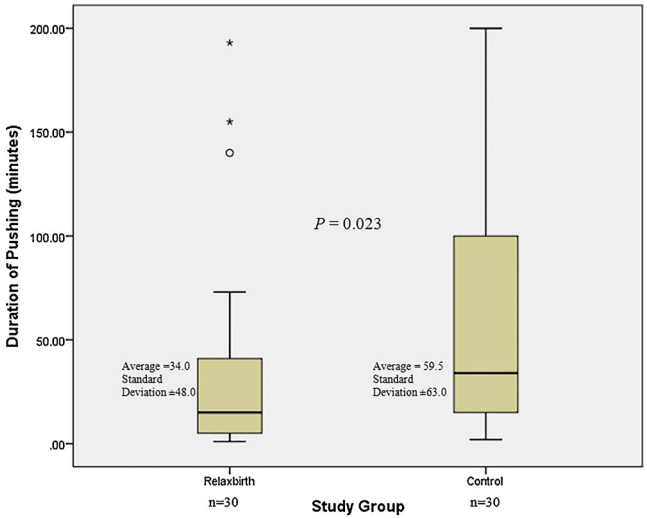

Fig. 3. Title: Boxplot of Pushing Duration.
Legend: This boxplot displays the comparison of pushing duration time between groups.

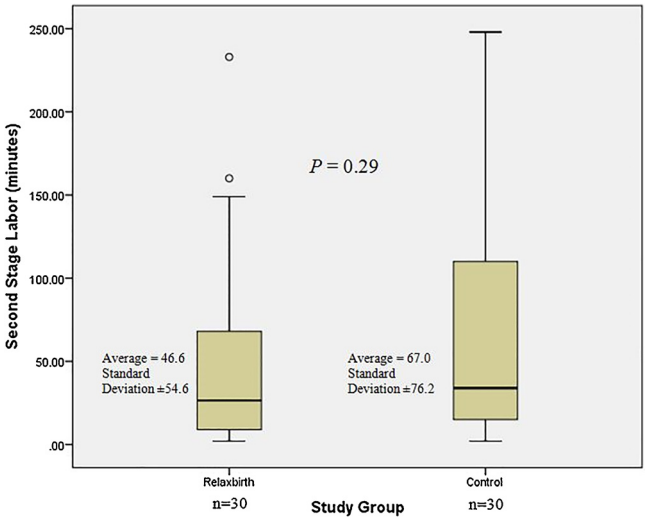

Fig. 4. Title: Boxplot of Duration of the Second Stage of Labor.
Legend: This boxplot displays the comparison of second stage of labor durations between groups.

Table 2
Birth Outcomes.

Variable	Relaxbirth Group (n = 30)	Control Group (n = 30)	*p-value*
Delivery Mode			
SVD	27 (90)	27 (90)	1.00
Forceps	0 (0)	0 (0)	
Vacuum	3 (10)	3 (10)	
Malpresentation			
Any	0 (0)	0 (0)	1.00
Perineal Lac/ Episiotomy			
None	9 (30)	5 (16)	0.22
Any	21 (70)	25 (84)	
1st	7 (23)	9 (30)	0.23
2nd	13 (42)	16 (53)	
3rd	1 (3)	0 (0)	
4th	0 (0)	0 (0)	
Other	0 (0)	0 (0)	
Estimated Blood Loss (mL)			
Average (SD)	306.6 (±139.4)	315.0 (±114.6)	0.80
1 minute APGAR			
Average (SD)	8.03 (±0.95)	8.30 (±0.53)	0.19
5 minute APGAR			
Average (SD)	9.1 (±0.40)	8.9 (±0.31)	0.16

Data displayed as n (%) unless noted otherwise.
Standard Deviation = SD.
Numeric data compared for mean equality via independent samples Student's t tests.
Categorical data compared for distributional equality via Pearson's chi-square or Fishers Exact tests.
* Statistically Significant $p < 0.05$.

Discussion

Key results

This study examined the intervention of a investigational device (Relaxbirth®) designed to promote a variety of upright positions during the various stages of labor. The objective of this pilot study was to compare birth outcomes using Relaxbirth® for upright positioning intrapartum and to assess the usability of the Relaxbirth® device in an American hospital. Results demonstrated a shorter pushing duration with no adverse outcomes for women laboring with the device. While the duration of the second stage of labor was not significantly shorter, the decrease of 20 min on average may be clinically relevant. Upright positioning may lead to a higher estimated blood loss at birth due to gravitational force. [3] However, EBL was not increased with upright positioning via Relaxbirth®, which is of clinical interest. This pilot study also demonstrated that women and practitioners alike would recommend Relaxbirth® to pregnant women, thought the device was easy to use and that it physically supported a woman her during labor, and found the various functions of Relaxbirth® useful.

Limitations

There are several limitations to this pilot study. The sample size is low, and the RB group was a self-identified convenience sample. There is a lack of diversity in the sample. Data are derived from a device that is not Food and Drug Administration (FDA) approved, although it was deemed to be of Non-Significant Risk. The study was not a randomized design and women could choose to opt-out of using Relaxbirth®. Moreover, the study did not track the total amount of time the patients used the Relaxbirth® device, the amount of time women of either group actually remained in an upright position, if the device was effectively used during pushing or not, if the device use was stopped early for any reason, or if it created difficulties for professionals to register fetal heart rate. Obstetrical policy and practice changes during the period of data collection may have evolved, though we suspect this effect was minimal if any. In addition, there could be bias and a Hawthorne effect in the MSUS surveys due to the participant's known willingness to use Relaxbirth®. In other words, the responses may tend toward increasing favorability since they are knowingly part of a research study that examined a device whose use they sought (women) or participated in (provider).

Interpretation

This study represents the first clinical application in North America of a novel device (Relaxbirth®) designed to promote a variety of upright positions during the various stages of labor. No research studies have been conducted to assess the outcomes related to the use of Relaxbirth® and the impact on maternal-fetal outcomes, nor has usability been assessed.

Our results are consistent with other studies citing the benefits of upright positioning. For example, Gupta, Hofmeyr & Shehmar [13] also found a non-significant reduction in duration of second stage of labor with upright positioning, but unlike our study, they found the additional benefit of a significant reduction in operative-assisted deliveries and episiotomies. Upright positions are well documented to reduce the second stage of labor duration to less than 30 min [4]. Our study did not significantly reduce the second stage of labor duration overall but did find a significant pushing duration reduction by 25 min. The physiologic rationale behind these findings may be consistent with a radiographic study from the 1960s which established that an upright position produces increased area in the midpelvis and 20% more space in the pelvic outlet [3].

Intrapartum upright positioning can be obtained without the use of this device. As such, a causative relationship related to our findings cannot be established specific to the Relaxbirth® device, but the favorable MSUS scores and survey results suggest the device was helpful attaining and maintaining a wide variety of upright positions intrapartum.

While both providers and RB women MSUS Total Average Score results yielded a favorable device score, the providers' Total Average Score was 9 points lower than the RB women. An explanation for this discrepancy is likely due to the MSUS item of whether Relaxbirth® provided physical support. RB participants reported a Likert score of 4.5 (strongly agree) versus the practitioners' Likert score of 1.6 (disagree). This is expected, as providers did not typically use Relaxbirth® for physical support or for their own positioning. Relaxbirth® was well-accepted by providers, but there was a possibility that some busy providers could have viewed the device reluctantly as one more task to complete or one more new intervention to learn.

Generalizability

Overall, our findings support the idea that women should be encouraged and supported to make choices about intrapartum positions when giving birth. [14,15] Women have reported feeling an increase in control if able to choose and implement various birthing positions [16]. The novelty of Relaxbirth® attracted women to deliver at our facility. Contemporary childbearing women are comfortable with technology and expect it in healthcare. Relaxbirth® created excitement among our care team as an alternative option for women, especially for those desiring a non-medicated birth. This was reflected in our sample thereby limiting generalizability, although 53% of the RB women ultimately chose regional anesthesia. We do not know if Relaxbirth® contributed to a delay in the initiation of regional anesthesia, but RB women in the survey agreed that Relaxbirth® helped specifically with pain and relaxation during labor.

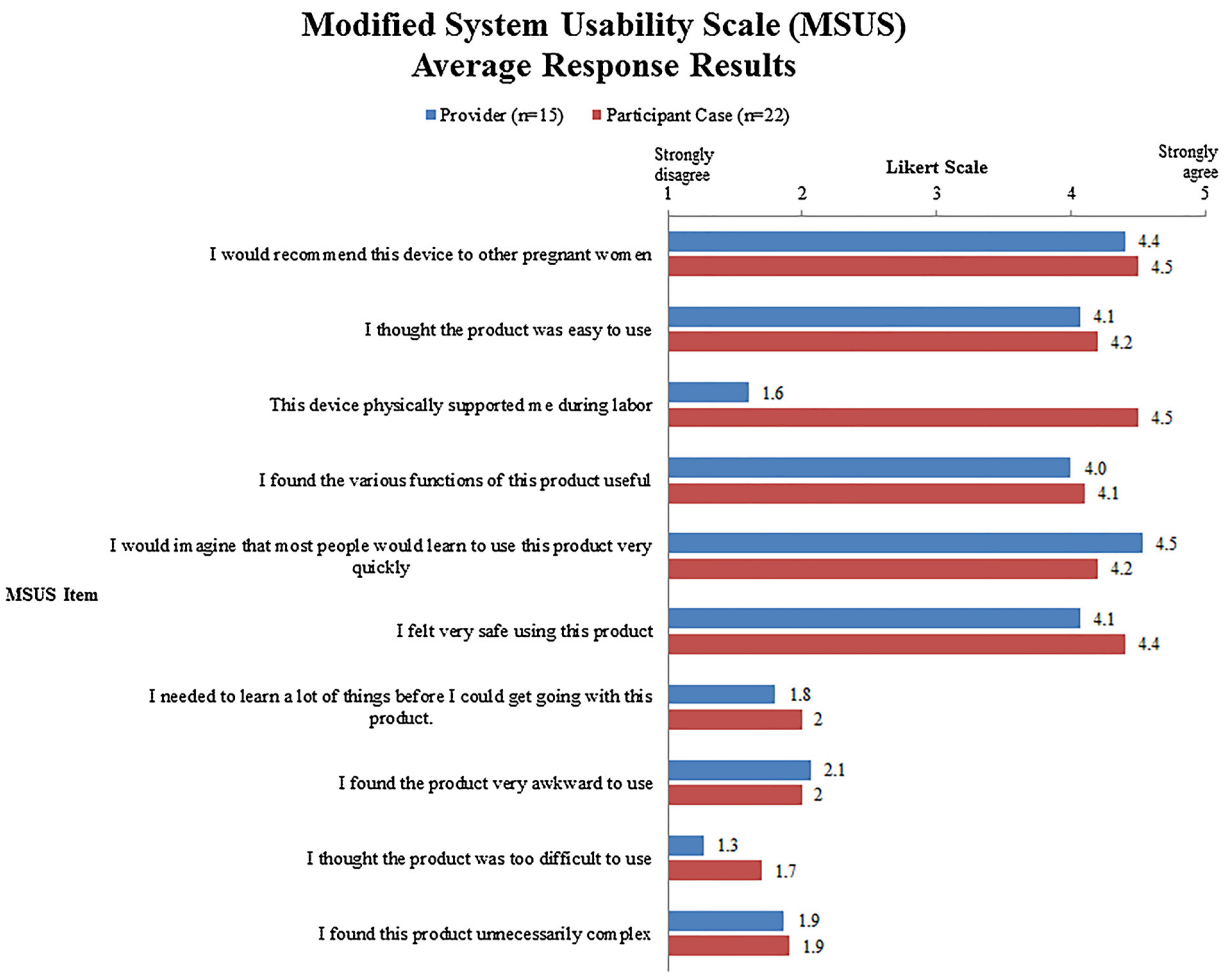

Fig. 5. Title: Modified System Usability Scale (MSUS) Average Response Results.
Legend: This figure displays each item of the Modified System Usability Scale (MSUS) tool and the average response for each item by provider and case participant.

Table 3
Survey Responses.

Survey Question	Relaxbirth **Group (n = 30)**[*]
How did you use the Relaxbirth device during the beginning stage of labor?[**]	
Stretching	5 (23)
Hanging from Pushing Handles	6 (19)
Leaning Against Device	16 (73)
Support for Movement	15 (68)
Massaging	6 (19)
Relaxation	10 (45)
Support with Birthing Ball	12 (55)
Sitting	14 (64)
Other	4 (18)
I believe the Relaxbirth device helped to reduce my pain at the beginning stage of my labor.[***]	
Average (SD)	4.11 (±0.90)
Median	4
Min - Max	2 - 5
I believe the Relaxbirth device helped me relax during the beginning stage of my labor.[***]	
Average (SD)	4.11 (±0.96)
Median	4
Min - Max	2 - 5

Data displayed as n (%) unless noted otherwise.
Standard Deviation = SD.
[*] Overall denominator was 22 due to incomplete data.
[**] Several responses were allowed.
[***] Likert scale used: 1 (strongly disagree) to 5 (strongly agree).

Conclusion

The Relaxbirth® device was associated with equivocal and some favorable birth outcomes at our pilot institution. Relaxbirth® is a safe and usable intrapartum device to potentially elicit positive maternal satisfaction by way of offering intrapartum choices and position options. Further study is warranted to assess maternal-fetal outcomes and usability with Relaxbirth® for upright positioning.

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The authors report no other conflicts of interest.

Jennifer Doyle, RN, MSN, APN reports no conflict of interest.

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Vivian E. von Gruenigen, M.D. reports no conflict of interest.

Presentation at meetings

N/A

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