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SneakPeek Snap: A Painless Microneedle-Based Push-Button Device for Early Fetal Sex Determination

Abstract

The advancement of prenatal DNA technology and growing demand for early fetal sex determination have created a need for a simple and easy-to-use blood collection device that eliminates the pain and difficulty individuals encounter when utilizing traditional methods of blood collection such as venipuncture or lancet fingerstick. In this study, Gateway Genomics, the leading provider of fetal sex testing, introduces "SneakPeek Snap", a novel microneedle-based, self-administered blood collection device that simplifies at-home blood collection for fetal sex testing. Our data confirms that, compared to lancet finger sticks, the SneakPeek Snap device provides users several advantages including significant reduction in perceived pain, greater ease of use, a shorter sample collection time, and a dramatic reduction in risk of sample contamination. Notably, blood samples collected using the Snap device were shown to be highly accurate for fetal sex determination — with an accuracy greater than 99%.

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Nina Hoang, Haley Milot, Christopher Jacob
Gateway Genomics, San Diego, California, USA

Correspondence: Haley Milot, Gateway Genomics, San Diego, California, USA, Email Haly@gatewaygenomics.org

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Introduction

In the past decade, clinical diagnosis and personalized medicine has evolved, making affordable and accurate non-invasive prenatal testing (NIPT) a reality for many expecting parents to determine the fetus's sex as early as 8 weeks gestation.[1] These advances have reduced the need for expensive and invasive techniques, such as chorionic villus sampling and amniocentesis, and minimized the risk for both mother and fetus.[2] Current NIPT requires a maternal blood sample for testing, a significant improvement over prior prenatal tests that required amniotic fluid or chorionic villi. Unfortunately, blood sample collection techniques have remained unchanged, with venous blood collected via venipuncture and capillary blood collected with a lancet finger stick being the most common methods.[3]

A novel blood collection device ("SneakPeek Snap") developed for Gateway Genomics by Seventh Sense Biosystems offers a blood collection method that is "simple, safe, standardized, and painless."[3] The quality of the blood drawn is on par to that of venipuncture-collected blood and can collect up to 1 ml of blood. Importantly, the Snap device does not require a professionally trained phlebotomist as the device is self-administered, automated, and self-contained.[3] Therefore, the quality of the blood drawn is not dependent on the phlebotomist's skill or the accessibility of the patients' veins. The automated and self-contained nature of the device helps to standardize the blood collection process between different settings, while minimizing the risk of human error and contamination by exogenous DNA.

Pain is an important factor to consider when comparing blood collection methods. Lancet finger sticks are notable in that they often result in suboptimal quantities of blood, environmental contaminants, and the level of pain they inflict.[4] While venous blood draws provide the proper amount of blood volume, the technique's "success rate relies heavily on clinician experience and patient physiology," and thus, patients can be bruised due to needle misses and ruptured veins.[5] The Snap device, on the other hand, utilizes both microneedles that are significantly thinner (about the thickness of an eyelash) than lancets to pierce the skin and capillary action, in conjunction with vacuum extraction, to painlessly collect the individual's blood.[3]

As with all microsampling techniques, the Snap device has some limitations. Several studies have documented that hemolysis of blood cells was caused by the shear stress of the frictional force when blood cells are vacuumed into the microcapillaries of the Snap device upon activation.[6] Additionally, blood volume beyond 300 ul can be challenging for a user.[7] In this study we sought to determine whether the Snap blood collection device could be useful for self-collection of maternal blood in the home and in a clinical setting. We also investigated the performance of the SneakPeek Early Gender DNA Test when blood was collected using a Snap device.

Methods

Gateway Genomics conducted both at-home and clinical sample collection to compare the performance of Snap blood collection device versus lancet-fingerstick and venipuncture collection methods. Participants in both groups provided informed consent to provide blood samples. After reviewing the instructional manuals and videos provided with the respective kits, study participants either self-collected their blood samples or received assistance from another individual.

One hundred and fifty-one pregnant women (average gestational age of 9.59 weeks) received two SneakPeek Gender At-Home Test kits. One kit contained a lancet with instructions to collect a small blood sample via fingerstick. The other kit contained a SneakPeek Snap device to collect a small blood sample via microneedles and vacuum suction. Each study participant in the at-home group completed a 28-question survey that assessed their experience using the fingerstick lancet method compared to the Snap device to collect their samples. The following parameters were measured in this study: pain level, ease/difficulty collecting blood, collection time, self- versus assisted-collection, and participant preference for each device.

One hundred and six participants for the clinical study were recruited from five different clinical sites. All participants in the clinical study provided informed consent. At the time of blood collection, the expecting mothers in the clinical group had an average gestational age of 10.04 weeks.

In the clinical study, a licensed phlebotomist was responsible for collecting a first blood sample from participants via venipuncture and assisted with the collection of a second blood sample using the Snap device. For venipuncture collections, 3mL of maternal venous blood was drawn. A second sample of 250-300uL of maternal capillary blood was collected using the Snap device.

Blood samples were shipped to SneakPeek labs for processing and DNA analysis with a qPCR assay.[1] Blood samples were fractionated via centrifugation to provide maternal plasma for testing. Cell-free DNA (cfDNA, fetal and maternal) was isolated from the maternal plasma using proprietary bead separation technology. The resulting cfDNA sample was analyzed by qPCR. An autosomal control gene was detected to confirm that sufficient total cfDNA was isolated from the sample. The presence or absence of male Y-chromosome DNA was detected to determine fetal sex. Accuracy of the SneakPeek Early Gender DNA Test when blood was collected using a Snap device was determined by comparing fetal sex results from Snap-collected samples to the venous samples. Performance of the SneakPeek Early Gender DNA Test using venous collected blood was previously shown to be 99.9% accurate based on live birth results.[8]

Results

At-home participant survey

A total of 157 at-home study participants completed a survey that asked them about their experience with the fingerstick lancet test kits and the Snap device test kits. The first question asked participants to depict their perceived pain level when using each test kit (Figure 1). In response to the question, "How painful was the lancet method?" a majority of the women (78%) reported feeling pain from the lancet. When the same question was posed to the same participants regarding the Snap device, 90% stated that they did not feel any pain at all.

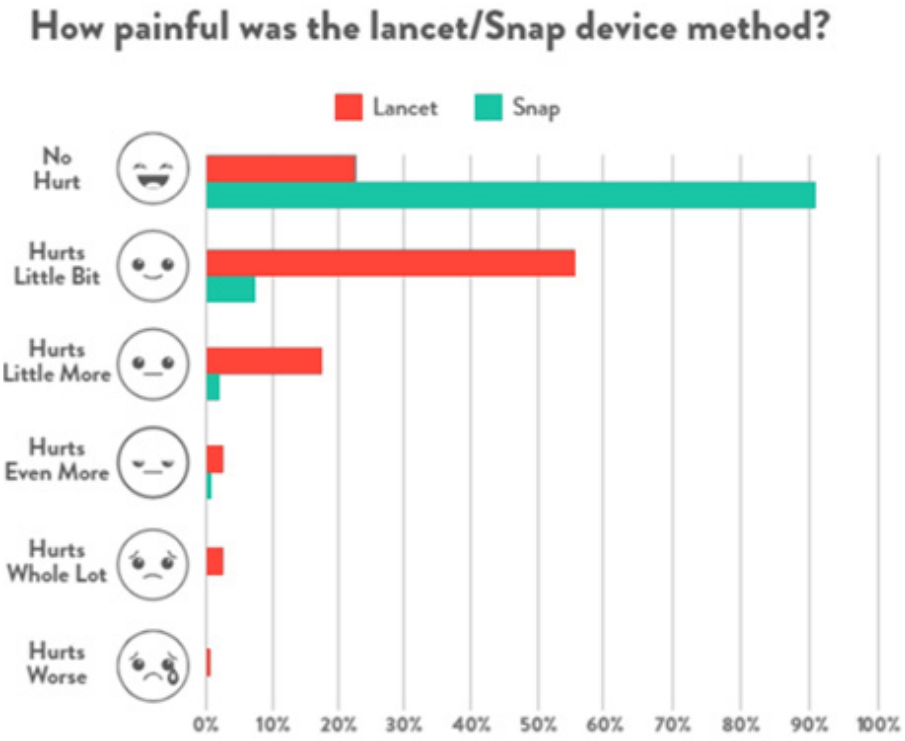

Figure 1 Survey response: painfulness using the lancet vs snap method.

Because the fingerstick lancet and Snap device methods have their own unique procedures and collection sites on the body, the difficulty to collect a blood sample with the two methods was expected to vary (Figure 2). The Snap device and its instructions were designed to make the sample collection process easy. All at-home study participants were asked how easy it was to collect a blood sample with each device. For the lancet fingerstick method, only about 40% of at-home participants indicated that the lancet fingerstick method was "easy" or "very easy". Some lancet fingerstick users reported difficulty in getting the blood to drop into the collection tube, a long collection time, and inadequate blood flow. In contrast, an overwhelming number of women (90%) noted that it was "easy" or "very easy" to collect their blood using the Snap device.

To further assess the efficiency of both collection methods, at-home participants were asked to identify the amount of time it took for them to collect an adequate amount of blood using the lancet and the Snap device (Figure 3). Most of the participants indicated that their blood collection time was between one to four minutes, with the highest response being "more than 4 minutes" (33%). Most Snap users were able to collect their blood sample in less than one minute (58%). Lancet users needed three or more minutes to collect their sample, with 32% of lancet users taking longer than the four minutes recommended to collect the blood sample.

Clinical study and qPCR assay performance

Each participant in the clinical study had their Snap device result for fetal sex confirmed against their corresponding venous sample. SneakPeek Early Gender DNA Test has been shown to be 99.9% accurate in a previously published study.8 At the time of collection, the gestational age of the 106 clinical study participants ranged from 8.00 to 15.43 weeks, with an average of 10.04 weeks (Table 1).

Citation: Hoang N, Milot H, Jacob C. SneakPeek Snap:A Painless Microneedle-Based Push-Button Device for Early Fetal Sex Determination. *Int J Pregn & Chi Birth.* 2021;7(3):74–78. DOI: 10.15406/ipcb.2021.07.00232

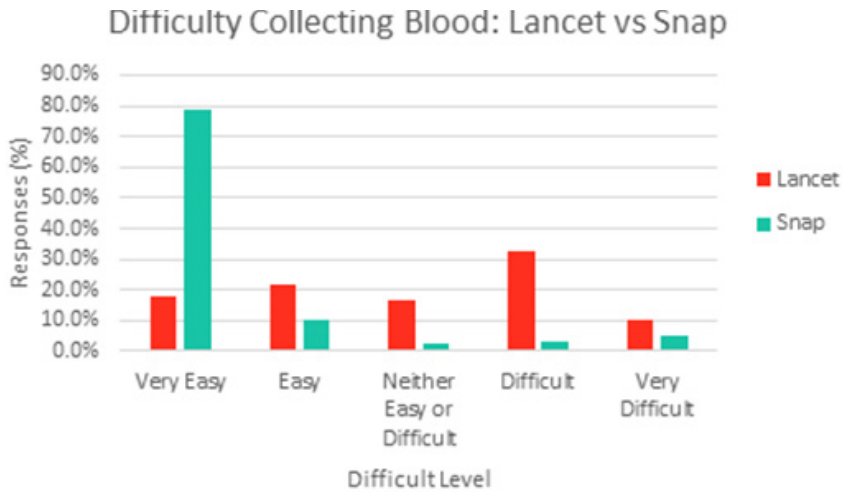

Figure 2 Survey response: difficulty of blood collection: lancet vs snap methods.

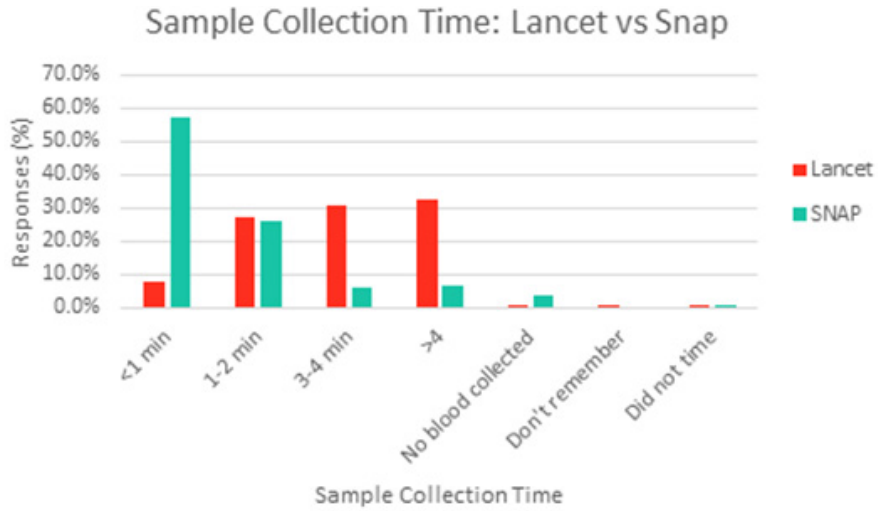

Figure 3 Survey response: amount of time taken to collect blood via lancet vs snap methods.

Table 1 Gestational age of the 106 clinical study participants

Gestational age	
Range (weeks)	8.00-15.43
Median (weeks)	9.64
Mean (weeks)	10.104

Inconclusive rate

No inconclusive results were observed for either the venous or Snap collected samples (Table 2).

Table 2 Inconclusive rate for venous and snap collected blood samples

Inconclusive rate	
Total Snap Samples (not including failures)	102
Total Inconclusive Snap	0
Inconclusive Rate: Snap	0%
Total Venous Samples	106
Total Inconclusive Venous	0
Inconclusive Rate: Venous	0%
Inconclusive Both Venous and Snap	0

qPCR assay performance

As shown in Table 3 below, no differences in the amount of cfDNA from venous and Snap collected plasma samples were observed in the clinical study.

Table 3 Average total C_T values for girl and boy fetal sex results from snap and venous samples

Average total – CT values			
	Girl	Boy	Both
Snap	31.83	31.66	31.73
Venous	32.43	32.09	32.23

The statistical parameters of the study are shown in Table 4. Fetal sex results were obtained for all participants: 45 female-bearing and 61 male-bearing. Gestational age ranged from 8.00-15.43 weeks, with an average gestational age of 10.04 weeks. Of the 61 participants carrying a male fetus, SneakPeek correctly identified all 61 cases, for a sensitivity of 100%. There were no false negatives and only one false positive among the samples tested in this study. SneakPeek showed 97.78% specificity and correctly identified 44 of 45 female bearing pregnancies. The accuracy of the SneakPeek test for fetal sex determination using Snap collected maternal blood was greater than 99%.

Citation: Hoang N, Milot H, Jacob C. SneakPeek Snap: A Painless Microneedle-Based Push-Button Device for Early Fetal Sex Determination. *Int J Pregn & Chi Birth.* 2021;7(3):74–78. DOI: 10.15406/ipcb.2021.07.00232

Table 4 Statistical parameters of snap study

Parameters	
Samples Analyzed	102
Female Fetuses	45
Male Fetuses	61
False Positives	1
False Negatives	0
Sensitivity	100%
Specificity	97.78%
Accuracy	99.02%

We observed 100% sensitivity with Snap collected samples in the clinical study group. With 100% sensitivity for male DNA in the maternal blood samples, any instances where a discordant test result occurred in the at-home samples collected from the same study participant were presumptive contamination events. Of the 151 at-home participants that collected blood via both lancet and Snap, six participants (3.97%) showed discordant results. In all six cases, the Snap result indicated that the fetus was female while the lancet result indicated that the fetus was male. Since the assay is 100% sensitive, six contamination events were believed to have occurred in the lancet collected blood samples. There was no evidence of sample contamination in the Snap collected samples. Thus, the Snap device appears to virtually eliminate the risk the exogenous male DNA contamination in maternal blood samples.

Discussion

As the leading provider of fetal sex testing, Gateway Genomics aims to develop DNA products that provide parents with accurate and reliable genetic information about their future child. A previous study by Gateway Genomics revealed that venipuncture blood samples collected at clinics can provide highly accurate results for fetal sex determination.8 A subsequent study showed that self-collection of maternal capillary blood using fingerstick lancets could also provide highly accurate results that were comparable to venipuncture collected blood.[9] In this study, we demonstrated that high accuracy for fetal sex can be achieved with a novel microsampling device called SneakPeek Snap.

Survey data was collected from the at-home study participants that provided two separate blood samples collected using a finger lancet and a Snap device. Responses to the surveys showed several advantages associated with the Snap method as compared to the lancet. Survey results revealed that participants experienced little to no pain when using the Snap device. Furthermore, the Snap device was identified as being the less difficult method to perform, with collection time greatly reduced. The participants who used Snap devices and lancets expressed a strong preference for the Snap device over the lancet (data not shown). Also, the Snap device appears to virtually eliminate the risk the exogenous male DNA contamination in maternal blood samples.

These findings are likely attributable to the self-administered, automated, and self-contained nature of the Snap device. In this study, the Snap device was shown to be a more reliable and efficient blood collection method compared to lancets by not only minimizing pain associated with blood collection but also minimizing the anxiety a patient may feel at the prospect of blood collection. Study participant responses indicated that the Snap device was significantly easier to use than lancets, which could help to minimize human error and reduce variability in sample collection as the device operates with a simple push of a button.

The performance of the SneakPeek Early Gender DNA Test using Snap collected blood was comparable to the performance of the assay using venous blood. Snap collected maternal blood samples yielded no inconclusive results and accuracy for fetal sex was greater than 99%. The results of this study showed that, comparable to venipuncture, the SneakPeek Snap device is a valid microsampling technique that can be used to accurately determine fetal sex with greater than 99% accuracy.

Limitations of the study

The small sample size from both the qualitative and quantitative studies could affect the reliability of the survey's results or increase the margin of error of the statistical parameters in the clinical data. Reliability of survey results depend on multiple factors, with non-response being a common case of bias. Furthermore, results from the clinical data may not be able to be applied to performance in an at-home setting, because the experiment was conducted with trained phlebotomists administering the Snap device.

Conclusion

The findings in this study demonstrate several benefits that the SneakPeek Snap microsampling device offers expecting mothers using the SneakPeek Early Gender DNA Test. The Snap device provides a novel method for self-collecting maternal blood. The Snap device was found to be painless and easy to use for the majority of the study participants and was highly preferred over fingerstick lancets. Snap-collected blood samples were compatible with the SneakPeek Early Gender DNA Test with greater than 99% accuracy for fetal sex determination. Additionally, the risk of environmental DNA contamination in the blood sample was greatly reduced using the Snap device. The ability to self-collect maternal blood reliably with a painless, easy-to-use method has the potential to increase the accessibility of prenatal testing and broader market adoption of the SneakPeek Early Gender DNA Test.

Acknowledgments

None.

Conflicts of interest

Authors declare that there is no conflict of interest.

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