DESIGN OPTIMALIZATION OF THE COLLI-PEE® FIRST-VOID URINE SAMPLE DEVICE USING COMPUTATIONAL STEADY STATE ANALYSIS

Colli-Pee® enables HPV detection

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INTRODUCTION

First-void urine (FVU) is a useful, non-invasive sample type that allows for detection of high-risk HPV DNA.

Colli-Pee® enables home-based collection of FVU. Colli-Pee® exists out of three main parts: the housing in which the user urinates, the tube in which FVU is collected and a floater that closes off the access to the tube after the collection of the sample (Fig. 1). Washout would occur when the urinary flow mixes with or replaces the FVU, collected at the start. This second void would dilute the FVU sample.

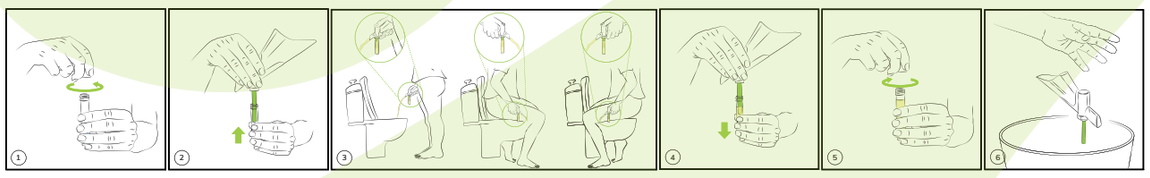

Fig. 1 Instructions for use

METHODS

During design and optimization of the Colli-Pee® Small Volumes, it is important to identify architectural design aspects that guarantee a minimal washout. Importantly, the buoyancy generated by the shape of the floater is counteracted by the friction caused by the horizontal force, executed by the urination flow, that pushes the floater back against the housing. The better the floater functions, the smaller the washout will be.

Rapid in-house prototyping allows for verification and validation of device functionalities. However, verification testing of 3D prototypes is time-consuming and has limitations. Assessment of different designs in a digital set-up allows early exclusion of low performing ideas. Steady state analysis using congruence thereby provides fast results that are reproducible, comparable and easy to interpret. It allows for easy, cheap and fast preselection of designs, leaving room for thorough physical verification and subsequent validation of a limited number of designs. Moreover, the gained insights can even inspire a new design. The analysis is visualized in Fig. 2

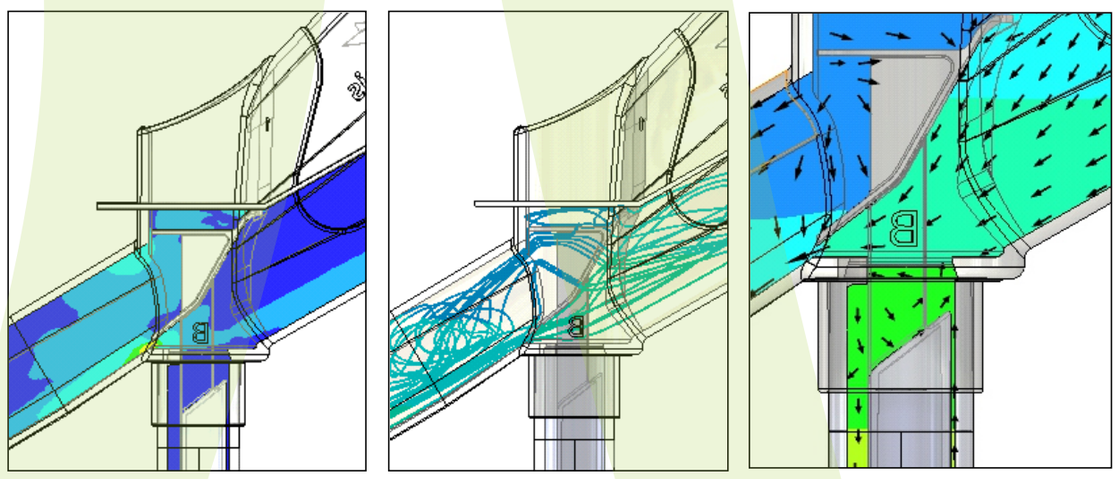

Fig. 2 Visualization steady state analysis

After several design iterations, the two most promising designs, i.e. T & U floater shapes for the Colli-Pee® Small Volumes, were used to perform steady state analyses using an inlet opening of 6.5 mm and an average flowrate of 16 mL/s . Buoyancy i.e. vertical force due to shape and horizontal force (causing friction) were used as outcome variables.

RESULTS

During the internal steady state analysis, as visualized in Figure 2, the complete inner volume of the housing is filled with water. Since the buoyant force (Fb) on an object is equal to the weight of the fluid displaced by the object, the difference in volume and weight of each floater design is critical. The design of the floater is divided into 2 sections, the lower part with a cylindrical shape that retains air increasing the Fb and the top area where the highest weight is located and the main focus of the design is. According to the software calculations, the actual volume responsible for the Fb force is equal for both designs (T and U shape) and is equal to the volume of air the floater contains. To assess the buoyancy generated by the shape, it is necessary to consider how the water flows from the funnel into the tube, generating less friction, in the simulation as shown in Figure 3, this vertical force friction decreased the total Fb force on the heaviest floater in contra-distinction to the lightest floater.

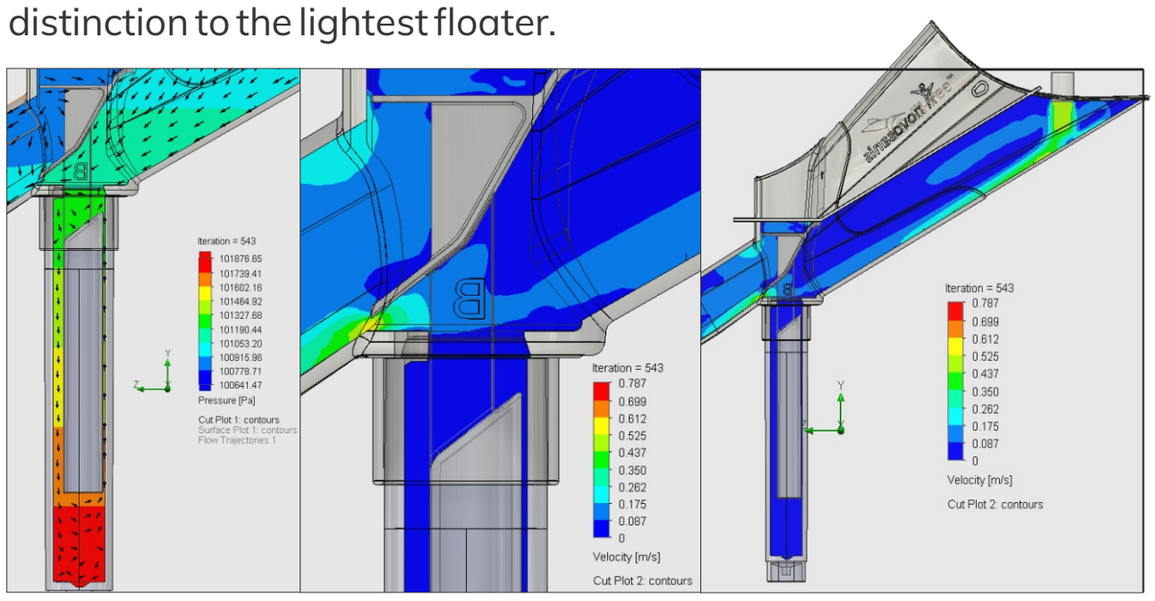

Fig. 3 3D Computational internal steady-state analysis results based on pressure [Pa] and velocity [m/s]

As the results show in Table 1, the effect of the difference in weight is bigger than the influence of the difference in shape. In this case, the 'T' design is considered the best option. The converging graphs in Fig. 4 proof that the analysis was successful and the results trustworthy.

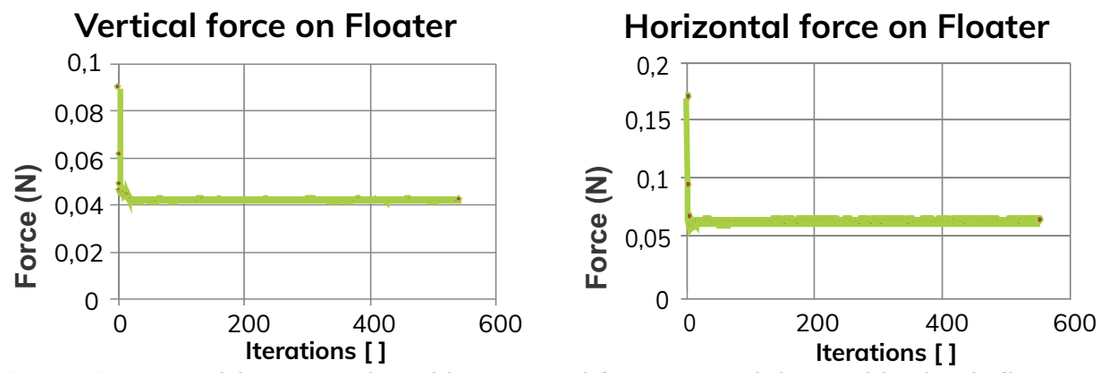

Fig. 4 Comparable vertical and horizontal forces [N] delivered by both floaters shapes, 'T' and 'U'.

Table 1 Results of steady state analysis

Parameter	T	U
Lift simulation (N)	0.042	0.043
Total Fb (N)	0.027	0.028
Lift shape (N)	0.015	0.015
Add weight (N)		0.001
Netto lift shape (N)	0.015	0.014
Difference (N)	0.0009	

CONCLUSION

The steady state analysis on the Colli-Pee® Small Volumes has shown that the 'T' floater design performed best with regard to buoyancy as well as horizontal force. Next, rapid prototyping can be kicked-off to verify and validate the design of choice.

IPVC virtual, July 2020
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