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Use of engineering analysis and simulation to guide and de-risk medical device development

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Overall approaches to medical device development have remained fairly consistent over recent years, but advances in technology have had significant impact on how quickly and efficiently work can be carried out. This applies in many diverse areas, including rapid prototyping and communication tools, but is particularly significant in the area of computing power and the associated capabilities for software-based engineering analysis. This paper describes three examples of how the application of simulation tools, coupled with supporting empirical work, can help to guide and de-risk device development programmes.

Case Study 1 – Impact of manufacturing tolerances for a capsule inhaler

Background:

Previous work has demonstrated how simulation can inform the design of a novel capsule inhaler[1]. In the example presented here, Computational Fluid Dynamics (CFD) was used to analyse performance of the Plastiape RS01 capsule inhaler device. The objective of the work was to support optimisation of the device design prior to implementation of injection mould tooling. Of particular interest was optimising the device resistance and the importance of dimensional tolerances as part of this.

Approach and initial findings:

This work allowed the identification of key design features, such as flow inlet width, and their potential impact on performance characteristics such as device resistance, fine particle fraction and powder deposition. Figure 1 illustrates typical output from the CFD analysis, from top to bottom; tangential airflow velocity, particle traces coloured by force reaction, and likely particle deposition map.

The CFD output combined with math modelling was validated against measured pressures. Figure 2 demonstrates good correlation between measured pressures and those predicted by CFD.

Visual inspection revealed a casework gap not present in nominal part models. This gap would cause a leak and further analysis predicted that the proportion of casework flow increases for higher resistance devices. As shown in Figure 3, for a flow rate of 80LPM at 4kPa, casework leakage was predicted to account for ~8% of total flow, compared with ~21% for a flow rate of 36LPM at 4kPa. This confirmed that the potential influence of casework leakage, which does not contribute to chamber swirl flow and thus can impact performance, is more important for high resistance devices. The level of influence observed indicated that manufacturing tolerances which contribute directly to casework fit need to be well specified and controlled.

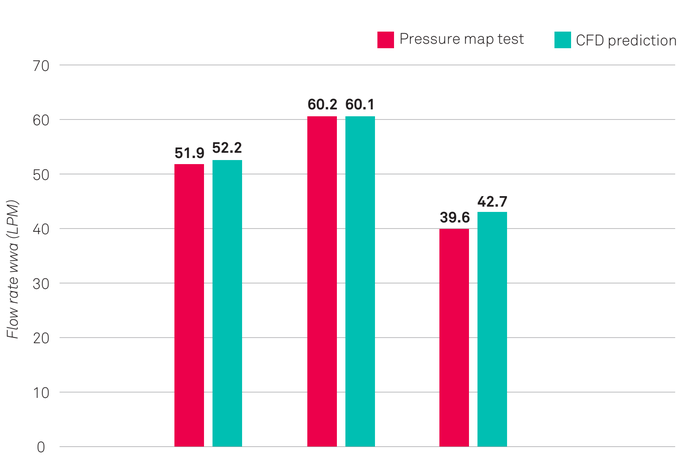


Figure 2 - Correlation between measured and CFD predicted device resistance

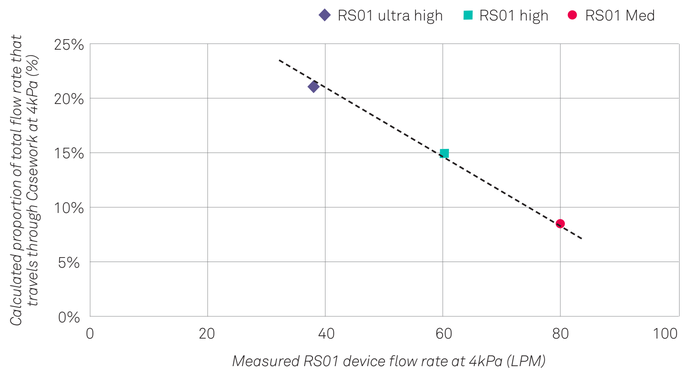


Figure 3 - Relationship between casework leakage flow and device resistance

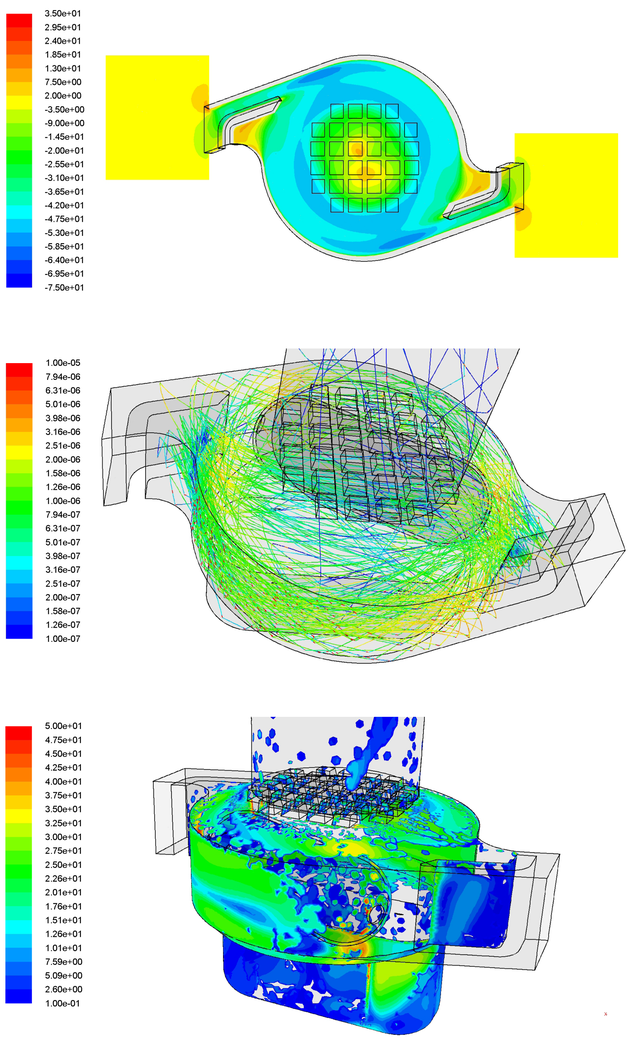


Figure 1 - CFD analysis of RS01 capsule inhaler

Further investigation:

Testing of devices built from components moulded on multi-cavity tools, which had been dimensionally inspected for features which were now known to influence casework gaps, was carried out. As shown in Figure 4, results confirmed the level of impact of manufacturing tolerances on device resistance from 0.132 to 0.122√cmH²O/LPM.

Based on these findings, designs were modified in 3D CAD and assessed using further iterations of CFD analysis. This allowed the team to arrive at the preferred design specification for implementation on injection mould tools.

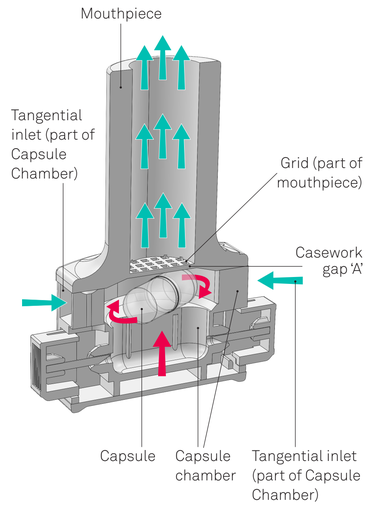
Conclusions:

Use of CFD analysis, math modelling and physical testing indicated that manufacturing variation on key features of the order of 50µm can alter device resistance by between 5-10%. This guided the establishment of the design specification for key features on the inhaler, de-risking the implementation of this design on injection mould tooling.

The analysis also showed that use of physical prototyping methods to assess and optimise different designs would have been problematic for the necessary level of resolution of the features concerned.

Reference:

[1]Abercrombie S R: "Efficient Engineering Simulation to Inform and Optimise Capsule Inhaler Design", Drug Delivery to the Lungs (DDL), 2018



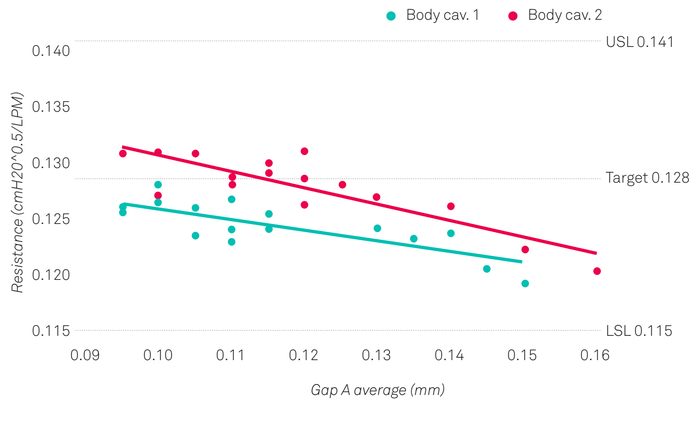


Figure 4 - Impact of casework gap on device resistance

Case Study 2 – Oxygen levels within an Emergency Use Ventilator

During the rapid (7 week) development of an emergency use ventilator during the COVID-19 pandemic, a risk was identified relating to oxygen concentrations within the device casework which contained electronics components. Due to the extremely tight timescales the opportunity for multiple design/build/test iterations was very limited. Hence, based on a series of assumptions and using a simplified 3D CAD model of the product, CFD was used to quickly model the system in order to predict O_2 levels.

The initial analysis indicated that, in the event of a supply line leakage, O_2 levels within the critical sections inside in the casework, i.e. those containing electronics components, could potentially be higher than recommended values. Based on this output and the visualisations available, design changes were quickly discussed and implemented in 3D CAD and the CFD analysis re-run overnight. Results for the updated design (Figure 5) showed a significant reduction in predicted O_2 concentration, sufficient to support the building and testing of the prototype design.

Safety testing of the prototype design, with a representative O_2 'leak' and a spark plug firing multiple times, confirmed that the design was safe and that the risk had been mitigated.

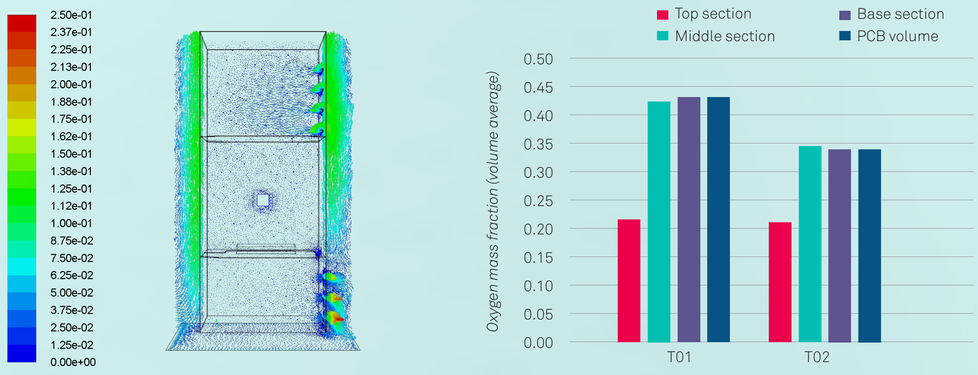


Figure 5 - Predictions for iterated design including reduced O_2 concentrations

Case Study 3 – Manufacturing assessment for a custom foil blister

As part of the development of a prototype drug delivery system, there was a requirement for a novel foil laminate blister pack which formed an active part of device function. Team worked closely with a supplier of laminate foil blisters and based initial designs on well established 'rules of thumb', for example relating to base diameter:height ratio and wall draft angles. However, the performance requirements of the blister meant that the combination of geometry and mechanical properties needed to extend these designs and push the boundaries of what could be reliably produced.

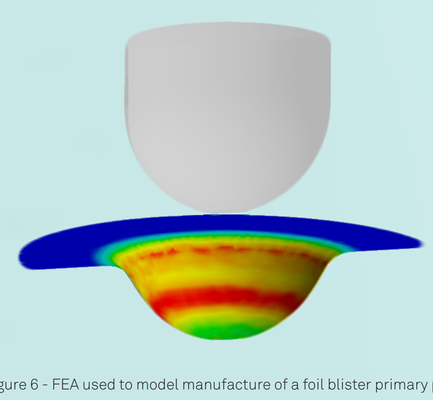


Figure 6 - FEA used to model manufacture of a foil blister primary pack

Manufacturing defects such as cracking or pin-holing or delamination would be unacceptable so Finite Element Analysis (FEA) was used to de-risk the development (Figure 6). An explicit dynamic model was set up to predict stresses and strains induced in the foil blister during both the forming process and the subsequent deformation during activation. The polymer laminate was not included in the FEA model.

In this case it was feasible to set up a manual prototype blister manufacturing system, configurable for different blister geometries and using blister foil with polymer laminate. Hence it was possible to carry out rapid design/build/test/iterate cycles and optimise the design through empirical methods, while using FEA to provide supporting evidence for the robustness of the final design.

Conclusion

As evidenced in the three case studies presented in this poster, engineering analysis can be a powerful tool for supporting device development. In conjunction with physical testing – or sometimes in place of it – design robustness can be improved both in relation to system performance but also with respect to manufacturing efficiency. With the continued development of computing power and software for engineering analysis, we can expect to see more device developments benefitting from these tools and techniques, to guide and de-risk programmes and deliver safe and effective products.

Note:
All analysis reported in these case studies was carried out using modules of ANSYS software running on a standard, 6 core PC.