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Development of Computational Benchmarking Model for Infusion Pumps

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ABSTRACT

An FDA or infusion pump is a mehan0-electrical device that aids in delivery of nutrients and medications to a human body in pre-determined and specific controlled amounts. With wider use of computing power to model and analyse FDA pumps, industry have a need of a numerical model to simultaneously run CFD (computational fluid dynamics) and FEA (finite element analysis) to determine the turbomachine characteristics of designed FDA pumps. As the device is crucial to saving lives it is of utmost requirement that any designed pump be subjected to rigorous testing and validation to ensure it's safety and efficacy. The authors have thus, designed a novel numerical model to simultaneously carry out real time CFD and FEA analysis, to match performance of pump at every fluid point and match the flow and turbomachinery characteristics with the benchmark results. The showcased numerical model and novel workflow has successfully satisfied the benchmark results. The novel model will aid the industry to directly adopt the easy workflow and validate various infusion and FDA pumps as per analytical results and help in quick launch of products in the market, saving time and effort.

1. Introduction

Infusion pumps or FDA pumps are used to deliver fluids in a controlled manner into the human body. Operators determine the rate and duration of fluid delivery via a software interface. As, the pumps are used for the delivery of critical fluids (high risk medications), the efficacy and safety of pumps working becomes a crucial parameter of their design. Over the years due to lack of any workflow to validate the working of FDA pumps, USFDA has reported several cases of pump failure. To reduce the safety issues USFDA has mandated benchmarking of all new pumps, which has become costly and time taking effort for industries, and has delayed the launch of new pumps in the market leading to their acute shortage.

The authors present a complex procedure to benchmark and validate an infusion Pump, a numerical workflow is run in TCAE (comprehensive simulation environment based on open-source) software. The model conducts CFD and FEA analysis while simultaneously analyzing fluid-structure-interaction to determine modal characteristics. The FDA Pump benchmark data has been taken from a special U.S. Food and Drug Administration (FDA) initiative to validate CFD results for medical devices.

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The pump's data of velocity, temperature, pressure and flow and hemolysis was determined extensively and rigorously in an USFDA approved lab, with which the results of numerical model are being validated. The authors have made a full-scale 3D geometry of the centrifugal FDA pump and meshed each part with fine cells, expansion ratio limited to 0.3, in order to determine important device characteristics like: flow coefficients, effectivity, power, torque, displacement, modes, pressure, displacement, stress and hemolysis. The model can also be expanded to determine other needful parameters of the pump The results are compared with the experimental data [1-3].

The first section deals with the geometry of the pump, materials of it's construction. Section 2 deals with the pre-processing of the pump, Section 3 deals with mesh characteristics. Section 4 deals with CFD and FEA setup. Section 4,5 deal with postprocessing and validation methods respectively.

2. Geometry

The FDA pump geometry is described in fig. 1.

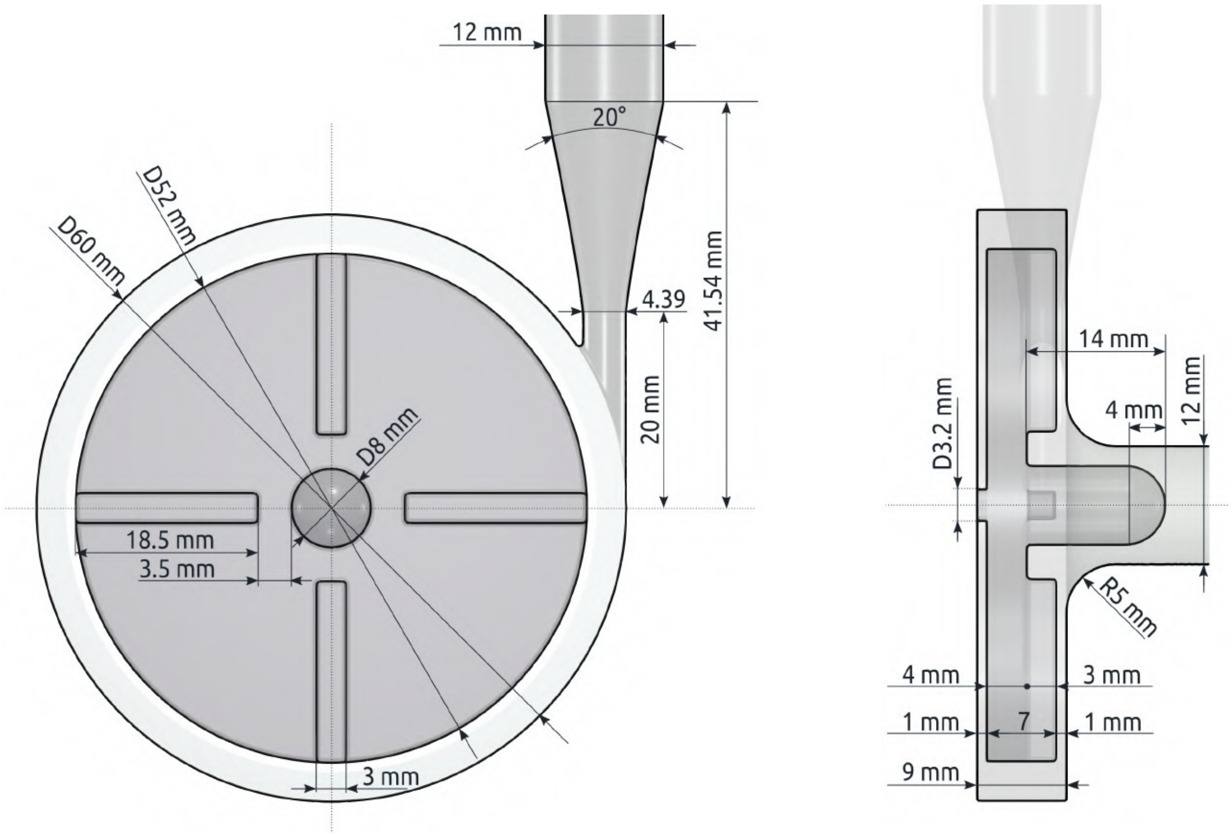


Fig. 1. CAD model of the FDA pump

The pump consists of a stainless-steel shaft of 3.2 mm in diameter, to which is attached acrylic rotor disc with filleted blades (4 in number), which are 3mm in height and have a width of 3mm (fig 1). It has a rotor base of 4mm thickness to which the filleted blades are orthogonally attached.

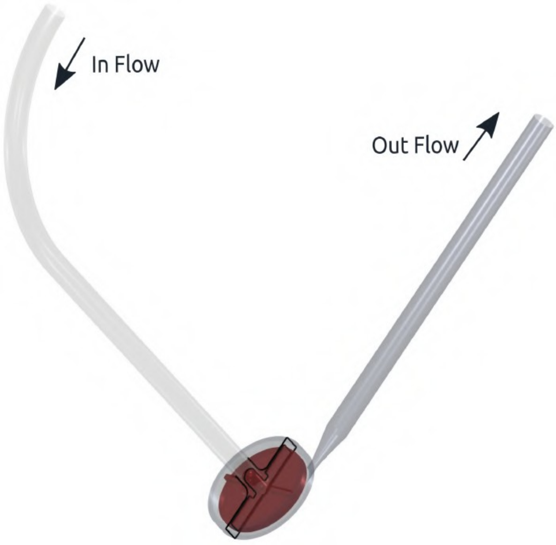


Fig. 2. Flow diagram for inlet and outlet of the pump

A detailed 3D surface model in the form of STL data file is created, which provides a simulation ready geometry (closed and watertight). The inner parts where the fluid flows is a model negative surface. As the authors are attempting simultaneous CFD and FEA, the impeller is modelled as closed single STL surface.

The use of above model facilitates use of any parametric or CAD model for the use in the simulation model being applied. The authors have used the design modeller of ANSYS package. Although the authors recommend to describe the geometry in a way that represents all it's critical parameters (shapes and measures). The authors are working on an automated optimization loop to optimize the shape and scales of the various parts.

Any CAD or 3D geometry so obtained needs accurate pre-processing before the simulation models can be applied. Hence, the authors have used the Salome open-source software. But, the versatility of the numerical model ensures any software output to be added to pre-processing.

3. Pre-Processing

As the pump consists of several rotating parts, the authors have chosen to divide them into separate watertight units, so that the rotation of one part does not hinder the calculation in other no-rotating parts. On operation it was seen that it is better to divide it into more parts, more divisions have given better solutions. The possible reason for this seems to be that it enables multiple simulation operations and methods like refinements, naming, part modelling, application of boundary conditions (BCs) more accurately.

In the pre-processing phase all the minute and irrelevant parts are eliminated from the CAD model, that may hinder the flow. The simplicity of the STL surface model and pre-processing parameters will determine the simulation potential and the threshold of numerical model applicability.

Taking the pump to be a centrifugal turbomachinery, it becomes easy to segment the pump into working units: volute and outlet, inlet tubes and impeller blades. As, mentioned above each part is watertight with inlet-outlet interfaces with relevant walls-hub, stator, fillets, vane blades etc. Each segment is meshed individually and then merged as volume components in mesh manager of the numerical model. Mesh interfaces are created to merge as volume unit. The component interfaces must fit each-other topologically, while the meshes are typically different from both sides.

The external mesh is loaded as FLUENT mesh format. As, the authors are employing multi-component approach, TCFD facilitates interface merging and separate loading of parts. The meshes communicate via interfaces created in the numerical model.

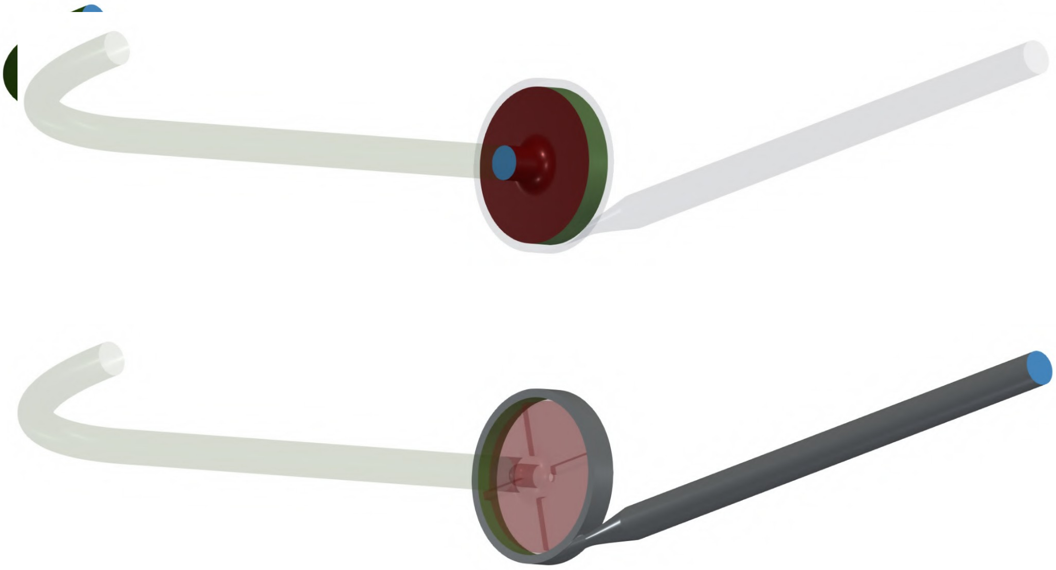


Fig. 3. Divided watertight parts and segmentation

For the FEA analysis while the Pre-processing essentially remains the same, FEA meshing is conducted in TMESH application available in TCAE. The mesh is validated in NetGen open-source resource.

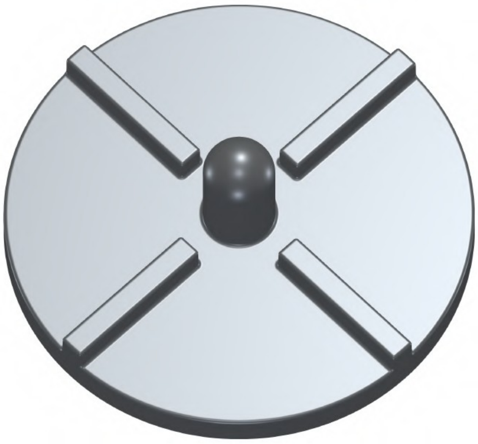
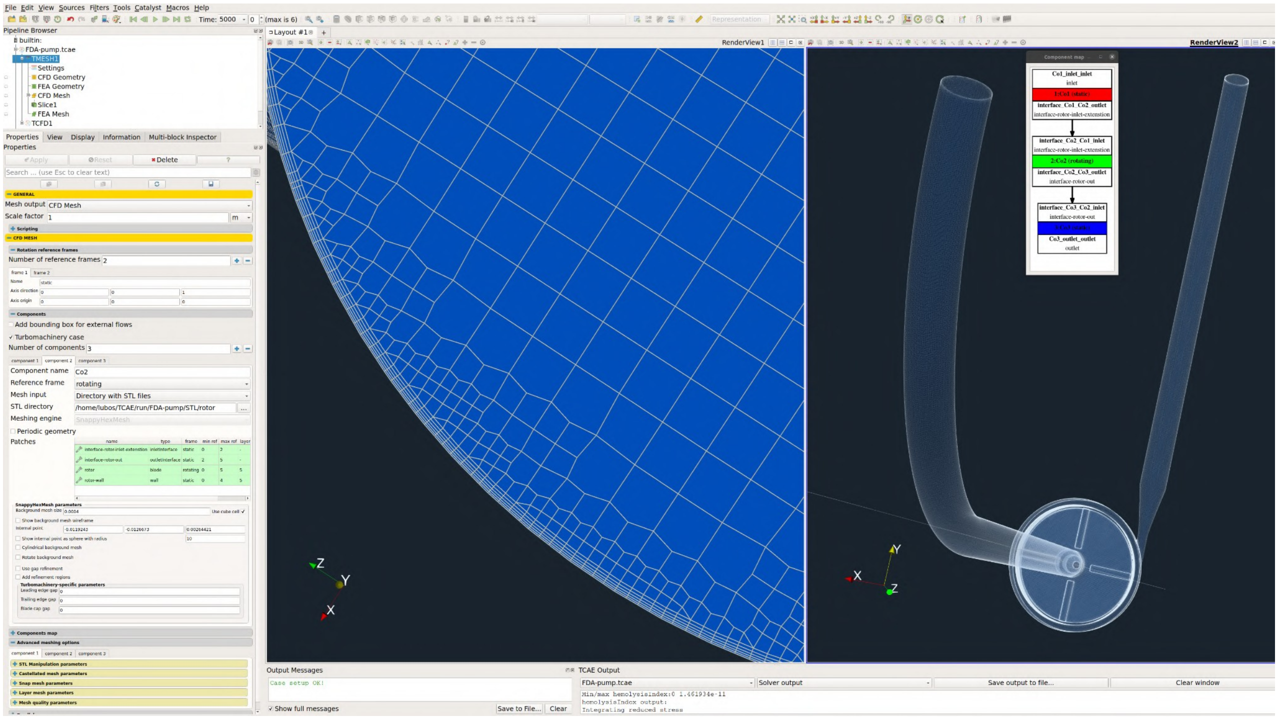


Fig. 4. FEA Pre-processing

It is essential for FEA pre-processing that the surface be cleaned. The authors recommend critical functionality be provided in pre-processing stage as the results are highly dependent on this stage. Errors due to pre-processing cannot be rectified after simulation as it distorts the workflow.

4. Meshing

The meshing operation has been carried out using snappy hex mesh, an open source tool and rendered into TCFD workflow.



Mesh output: CFD Mesh
Scale factor: 1 m
Number of reference frames: 2
frame 1 — Name: static; Axis direction: 0 0 1; Axis origin: 0 0 0
☐ Add bounding box for external flows
✓ Turbomachinery case
Number of components: 3
component 2 — Component name: Co2; Reference frame: rotating; Mesh input: Directory with STL files; STL directory: /home/lubos/TCAE/run/FDA-pump/STL/rotor; Meshing engine: SnappyHexMesh
☐ Periodic geometry

name	type	frame	min ref	max ref	layer
interface-rotor-inlet-extenstion	inletInterface	static	0	2	-
interface-rotor-out	outletInterface	static	2	5	-
rotor	blade	rotating	0	5	5
rotor-wall	wall	static	0	4	5

SnappyHexMesh parameters — Background mesh size: 0.0004; Use cube cell ✓
Internal point: -0.0119243 -0.0126673 0.00264421
Show internal point as sphere with radius: 10

```
Case setup OK!
```

```
Min/max hemolysisIndex:0 1.461934e-11
hemolysisIndex output:
Integrating reduced stress
```

Fig. 5. Mesh interface in TCFD

The authors were successful in creating a boxed mesh around the model also called the cartesian block mesh. This block mesh forms the initial mesh (background), which is inflated around the object to optimise resource utilisation and time. As the flow is analysed inside the pump, authors chose to use cube shaped cells to incorporate the 3D effects of flow.

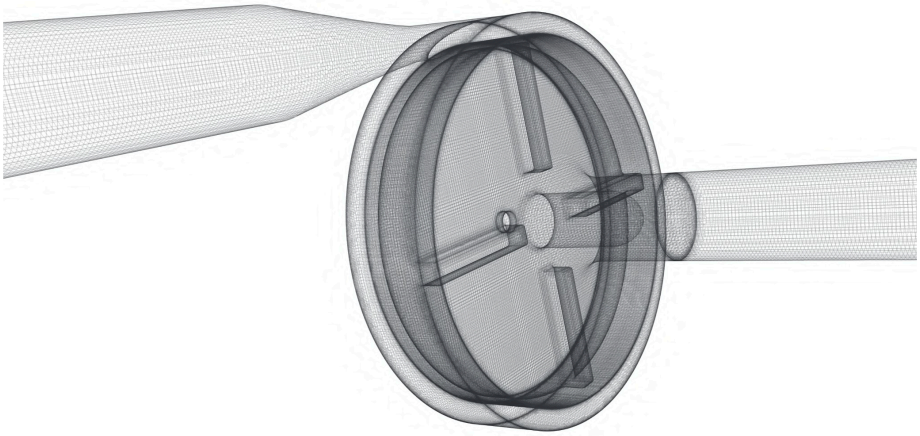
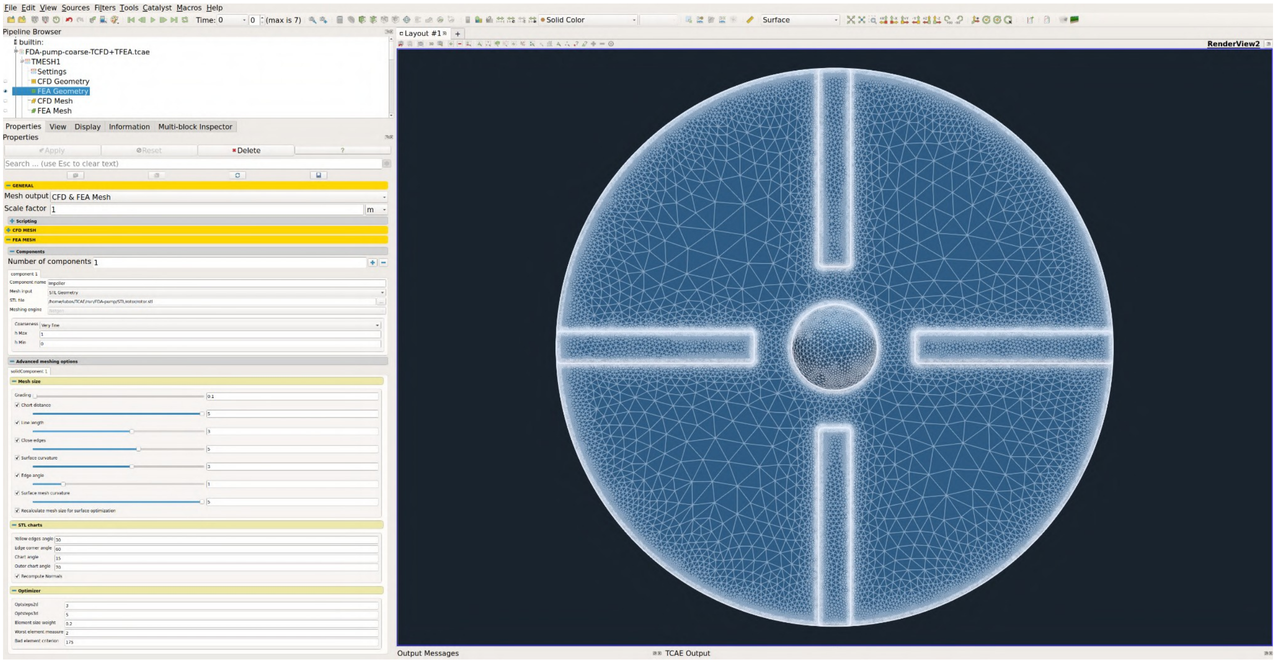


Fig. 6. Final meshed cells of the pump using snappy-hex-mesh

The utility of TCFD in subsequently refining the mesh as shown in fig 6, towards the model wall, was of immense assistance, as it aided to optimize the cell sizes in inflation layers (finer to coarser).The meshing remains same for FEA, only difference being it being carried out in net gen application.



Mesh output: CFD & FEA Mesh
Scale factor: 1 m
Number of components: 1
Component name: Impeller
Mesh input: STL Geometry
STL file: /home/lubos/TCAE/run/FDA-pump/STL/rotor/rotor.stl
Meshing engine: Netgen
Coarseness: Very fine
h Max: 1
h Min: 0
Grading: 0.1
☑ Chart distance: 5
☑ Line length: 3
☑ Close edges: 5
☑ Surface curvature: 3
☑ Edge angle: 1
☑ Surface mesh curvature: 5
☑ Recalculate mesh size for surface optimization
Yellow edges angle: 30
Edge corner angle: 60
Chart angle: 15
Outer chart angle: 70
☑ Recompute Normals
Optsteps2d: 3
Optsteps3d: 5
Element size weight: 0.2
Worst element measure: 2
Bad element criterion: 175

Fig. 7. FEA mesh in NetGen

Benefit of FEA mesh being little effort is needed for it as, FEA numerical model requires only few parameters to be set as most of the data is borrowed from CFD workflow. The critical parameters for the FEA mesh are the H_{min} and H_{max} the minimum and maximum edge lengths in meters.

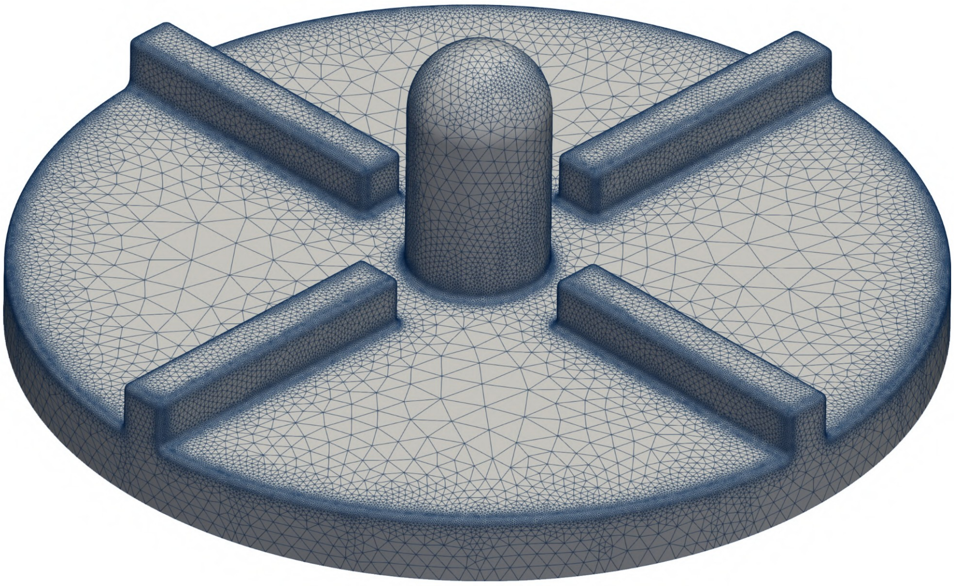
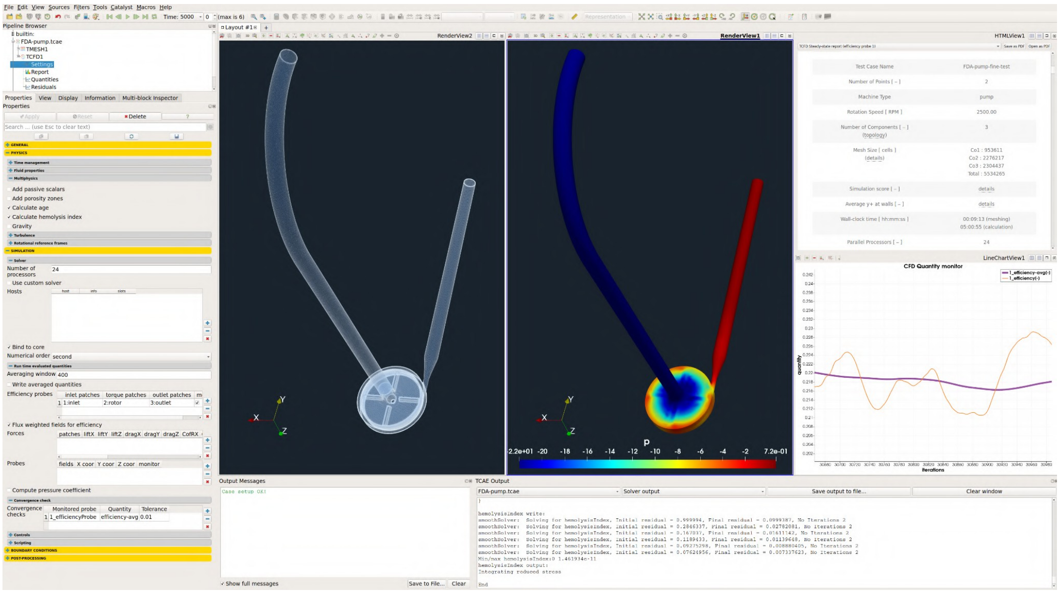


Fig. 7. Final FEA and CFD mesh

5. CFD Setup

The authors have carried out the entire numerical modelling in paraview TCFD guided user interface. Fig 8 below shows the simulation setup window.



☐ Add passive scalars
☐ Add porosity zones
☑ Calculate age
☑ Calculate hemolysis index
☐ Gravity

Number of processors: 24
☐ Use custom solver

Hosts	host	info	slots

☑ Bind to core
Numerical order: second
Averaging window: 400
☐ Write averaged quantities

Efficiency probes	inlet patches	torque patches	outlet patches	m
1	1:inlet	2:rotor	3:outlet	☑

☑ Flux weighted fields for efficiency

Forces	patches	liftX	liftY	liftZ	dragX	dragY	dragZ	CofRX

Probes	fields	X coor	Y coor	Z coor	monitor

☐ Compute pressure coefficient

Convergence checks	Monitored probe	Quantity	Tolerance
1	1_efficiencyProbe	efficiency-avg	0.01

TCFD Steady-state report (efficiency probe 1)

Test Case Name	FDA-pump-fine-test
Number of Points [–]	2
Machine Type	pump
Rotation Speed [RPM]	2500.00
Number of Components [–] (topology)	3
Mesh Size [cells] (details)	Co1 : 953611 Co2 : 2276217 Co3 : 2304437 Total : 5534265
Simulation score [–]	details
Average y+ at walls [–]	details
Wall-clock time [hh:mm:ss]	00:09:13 (meshing) 05:00:55 (calculation)
Parallel Processors [–]	24

```
Case setup OK!
```

FDA-pump.tcae — Solver output

```
}

hemolysisIndex write:
smoothSolver:  Solving for hemolysisIndex, Initial residual = 0.999994, Final residual = 0.0999387, No Iterations 2
smoothSolver:  Solving for hemolysisIndex, Initial residual = 0.2846337, Final residual = 0.02782081, No Iterations 2
smoothSolver:  Solving for hemolysisIndex, Initial residual = 0.167037, Final residual = 0.01611142, No Iterations 2
smoothSolver:  Solving for hemolysisIndex, Initial residual = 0.1189433, Final residual = 0.01139648, No Iterations 2
smoothSolver:  Solving for hemolysisIndex, Initial residual = 0.09275298, Final residual = 0.008880405, No Iterations 2
smoothSolver:  Solving for hemolysisIndex, Initial residual = 0.07624956, Final residual = 0.007337623, No Iterations 2
Min/max hemolysisIndex:0 1.461934e-11
hemolysisIndex output:
Integrating reduced stress

End
```

Fig. 8. Simulation setup window

As, the device is taken as a turbomachinery the simulation equations of a pump is taken, turbulence intensity was fixed at 5% as internal flow is being modelled, incompressible model with steady time state and blood as the fluid is taken. The reference pressure was 1 atm and no wall roughness was taken. As per USFDA data RPM was set at 2500-3000 and dynamic viscosity as 1.8 x10^{e-5} Pa.s. The outlet is kept at a static pressure of 0 and 1035 kg/m^3 is the blood density. RANS model k-omega SST is used to solve the model and the Newtonian equations are used to replicate shear thinning of blood.

The novel workflow used by the authors is presented below in figure 9. While Co1 in red is the inlet, and leaves the pump via Co3_outlet_outlet; in blue the green segment Co2 is the rotating element. The modified workflow is applied to the calculix FEA solver(open-source). Fig 10 shows the FEA solver window. The material of the pump is taken to be acrylic with a density of 1430 kg/m^3 with isotropic material structure (Young's modulus of 5 e^{9}Pa). The Poison's ratio is 0.3 for a fixed radius of 3.2 mm. Second order finite element solver is selected with rotation to be at 2500-3000 RPM.

The FEA workflow is executed in TCAE interface with background solver in batch mode. Steady state solver for various (6 number) flow rate values is run in each phase (2 speeds). Table 1 depicts the FEA values.

The workflow and numerical model employed calculates all the efficiency, force coefficients, flow rates and velocity-pressure. The extensive results report is attached with the paper. The convergence of integral parameters was achieved at a residual value of 10^{-6}.

The combined real time numerical model ensured one time meshing via TMESH, to generate the mesh volumes for both CFD and FEA. In the FSI stage the force fields are generated using the pressure field. This force field acts as the load for the FEA calculations. Fig 11 depicts the load calculation window from pressure data of CFD workflow.

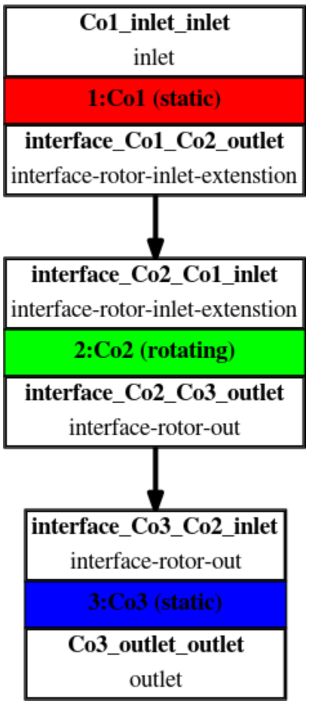
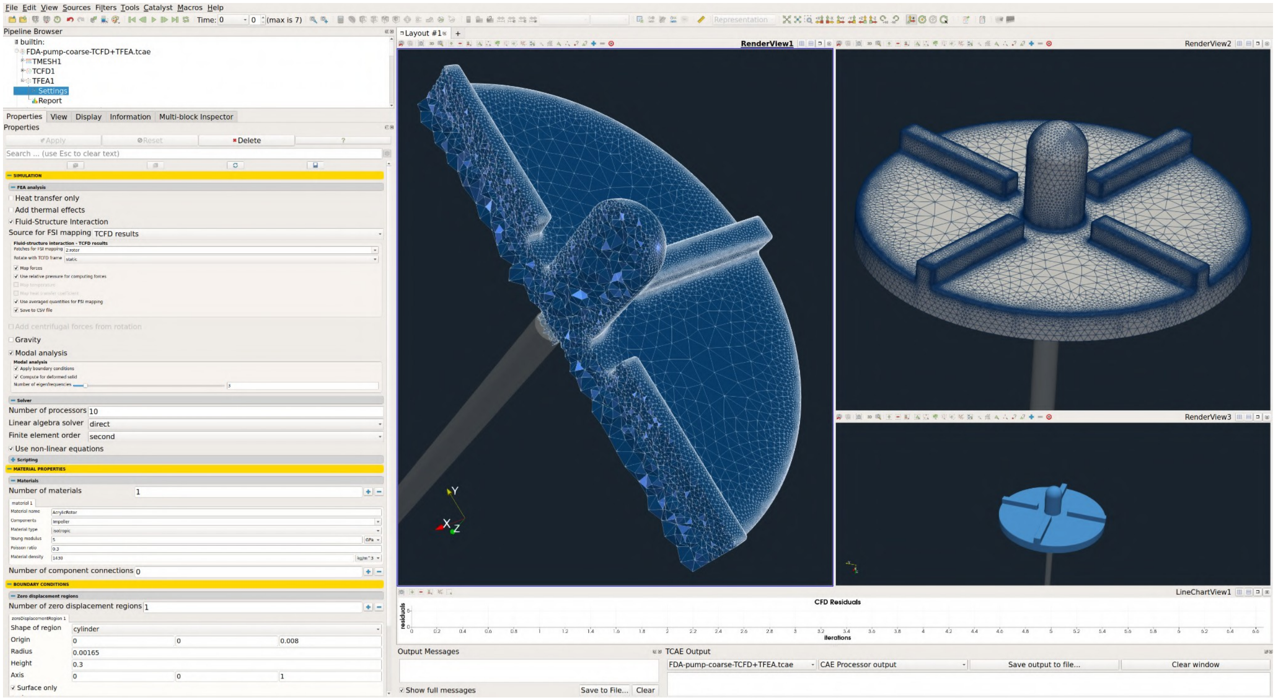


Fig. 9. Workflow and part recognition



SIMULATION

FEA analysis

☐ Heat transfer only
☐ Add thermal effects
☑ Fluid-Structure Interaction
Source for FSI mapping: TCFD results

Fluid-structure interaction - TCFD results
Patches for FSI mapping: 2:rotor
Rotate with TCFD frame: static
☑ Map forces
☑ Use relative pressure for computing forces
☐ Map temperature
☐ Map heat transfer coefficient
☑ Use averaged quantities for FSI mapping
☑ Save to CSV file

☐ Add centrifugal forces from rotation
☐ Gravity
☑ Modal analysis

Modal analysis
☑ Apply boundary conditions
☑ Compute for deformed solid
Number of eigenfrequencies: 3

Solver
Number of processors: 10
Linear algebra solver: direct
Finite element order: second
☑ Use non-linear equations

Scripting

MATERIAL PROPERTIES

Materials
Number of materials: 1
material 1
Material name: AcrylicRotor
Components: Impeller
Material type: isotropic
Young modulus: 5 GPa
Poisson ratio: 0.3
Material density: 1430 kg/m^3
Number of component connections: 0

BOUNDARY CONDITIONS

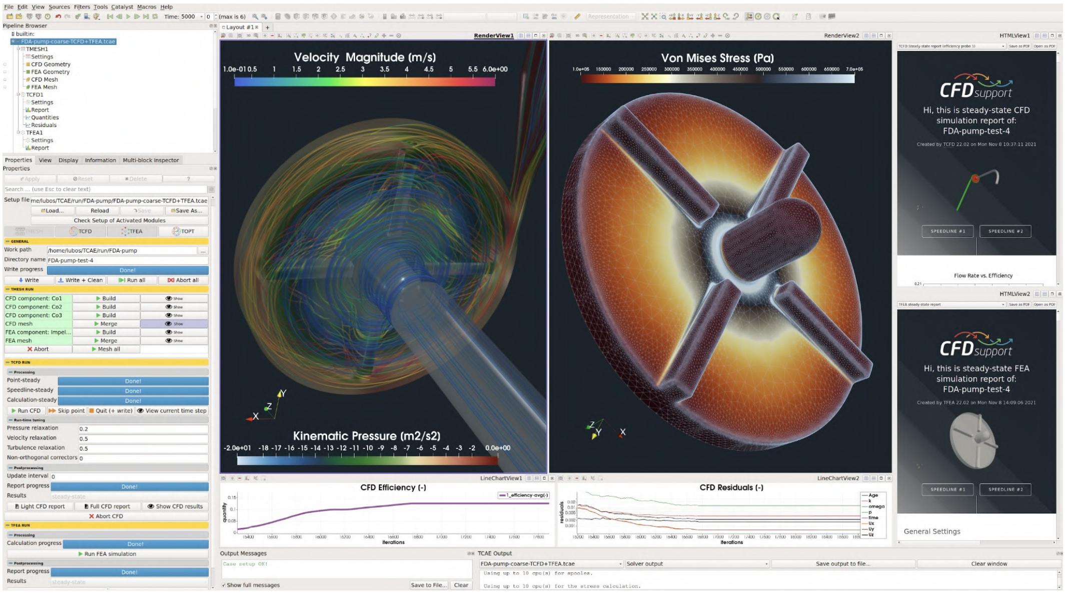
Zero displacement regions
Number of zero displacement regions: 1
zeroDisplacementRegion 1
Shape of region: cylinder
Origin: 0 0 0.008
Radius: 0.00165
Height: 0.3
Axis: 0 0 1
☑ Surface only

FDA-pump-coarse-TCFD+TFEA.tcae
☑ Show full messages

Fig. 10. FEA solver window

Table 1
FEA solver values

Simulation point	#1	#2	#3	#4	#5	#6
Speed [RPM]	2500	3500	3500	2500	3500	3500
Flow Rate [l/min]	2.5	2.5	4.5	6.0	6.0	7.0



Setup file me/lubos/TCAE/run/FDA-pump/FDA-pump-coarse-TCFD+TFEA.tcae

Work path /home/lubos/TCAE/run/FDA-pump
Directory name FDA-pump-test-4
Write progress Done!

CFD component: Co1 Build
CFD component: Co2 Build
CFD component: Co3 Build
CFD mesh Merge
FEA component: Impel... Build
FEA mesh Merge

Point-steady Done!
Speedline-steady Done!
Calculation-steady Done!

Pressure relaxation 0.2
Velocity relaxation 0.5
Turbulence relaxation 0.5
Non-orthogonal correctors 0

Update interval 0
Report progress Done!
Results steady-state

Calculation progress Done!

Report progress Done!
Results steady-state

```
Case setup OK!
```

FDA-pump-coarse-TCFD+TFEA.tcae

```
Using up to 10 cpu(s) for spooles.

Using up to 10 cpu(s) for the stress calculation.
```

Hi, this is steady-state CFD simulation report of: FDA-pump-test-4

Created by TCFD 22.02 on Mon Nov 8 10:37:11 2021

Hi, this is steady-state FEA simulation report of: FDA-pump-test-4

Created by TFEA 22.02 on Mon Nov 8 14:09:06 2021

Fig. 11. Calculation of loads from pressure field

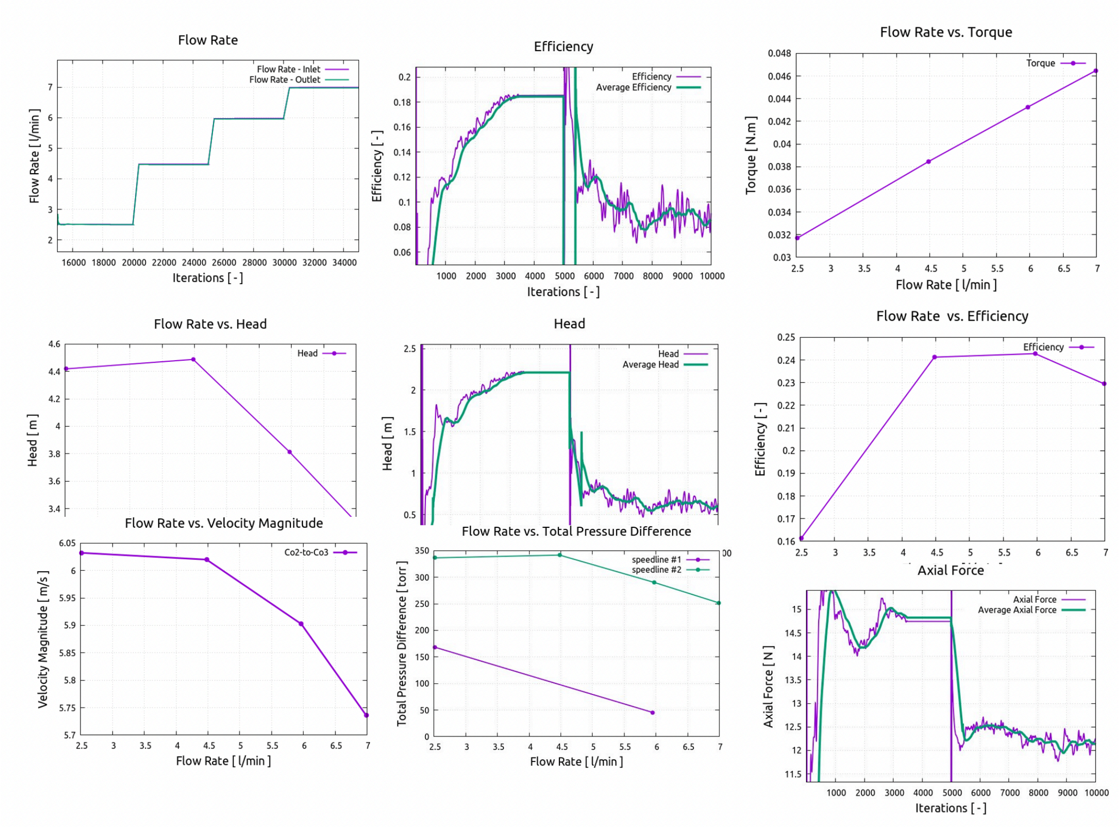


Fig. 12. Post-processed results of the integral parameters

6. Post-Processing

Following integral quantities are evaluated every time step, as in table 2.

Table 2
Integral quantities

efficiency[-]	efficiency-avg[-]	massFlowIn[kg/s]	massFlowIn-avg	massFlowOut[kg/s]	massFlowOut-avg
magUOut-avg[m/s]	magUIn[m/s]	magUIn-avg[m/s]	phi[-]	phi-avg[-]	psi[-]
pIn[Pa]	pIn-avg[Pa]	pOut[Pa]	pOut-avg[Pa]	pTotIn[Pa]	pTotIn-avg[Pa]
DeltaTTot-avg[K]	effic_TT[-]	effic_TT-avg[-]	ax_force[N]	ax_force-avg[N]	rad_force[N]
TTotIn-avg[K]	TTotOut[K]	TTotOut-avg[K]	PTotRatio[-]	PTotRatio-avg[-]	deltaPTot[Pa]
volFlowIn[m3/s]	volFlowIn-avg[m3/s]	volFlowOut[m3/s]	volFlowOut-avg	torque[N.m]	torque-avg[N.m]
psi-avg[-]	circAng[deg]	circAng-avg[deg]	head[m]	head-avg[m]	TTotRatio[-]
pTotOut[Pa]	pTotOut-avg[Pa]	TIn[K]	TIn-avg[K]	TOut[K]	TOut-avg[K]
rad_force-avg[N]	adv_ratio[-]	adv_ratio-avg[-]	thrust_co[-]	thrust_co-avg[-]	torque_co[-]
deltaPTot-avg[Pa]	time	power[W]	torque_co-avg[-]	TTotIn[K]	TTotRatio-avg[-]

Paraview aids in visualisation and post-processing of volume fields. Mid simulation view of contours, speedlines etc are visible as in fig. 13.

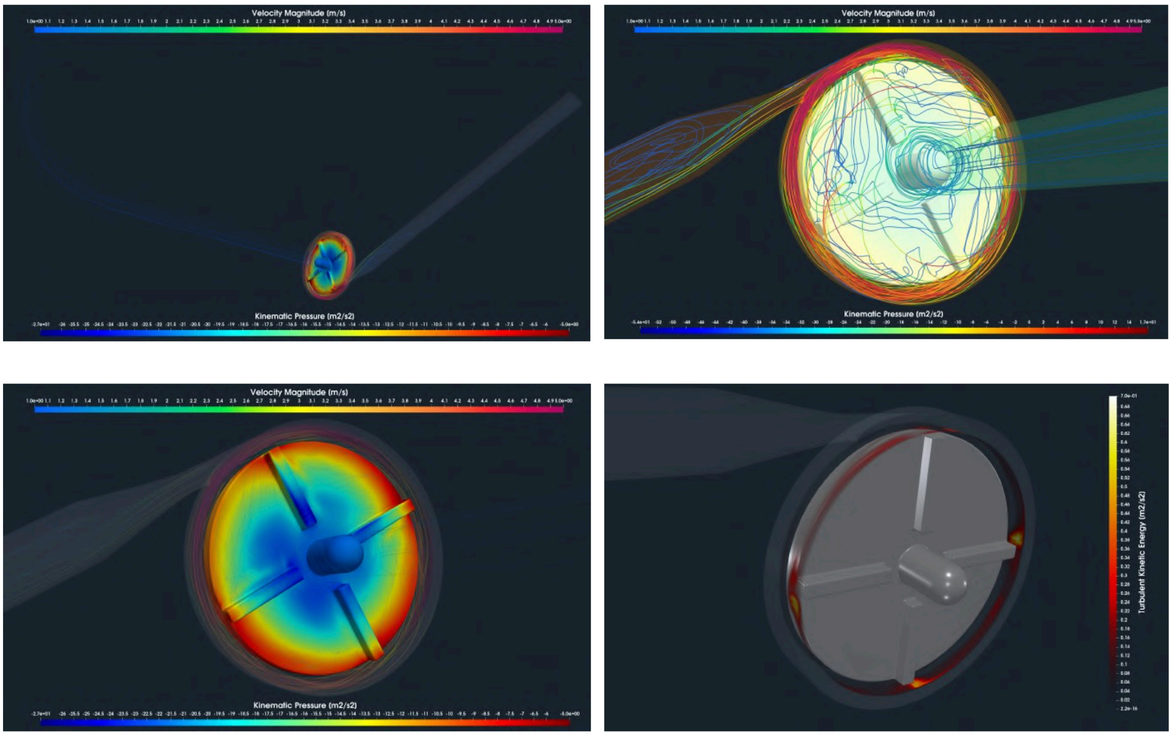


Fig. 13. CFD volume fields

In similar and subsequent step FEM volume fields are generated as depicted in fig. 14.

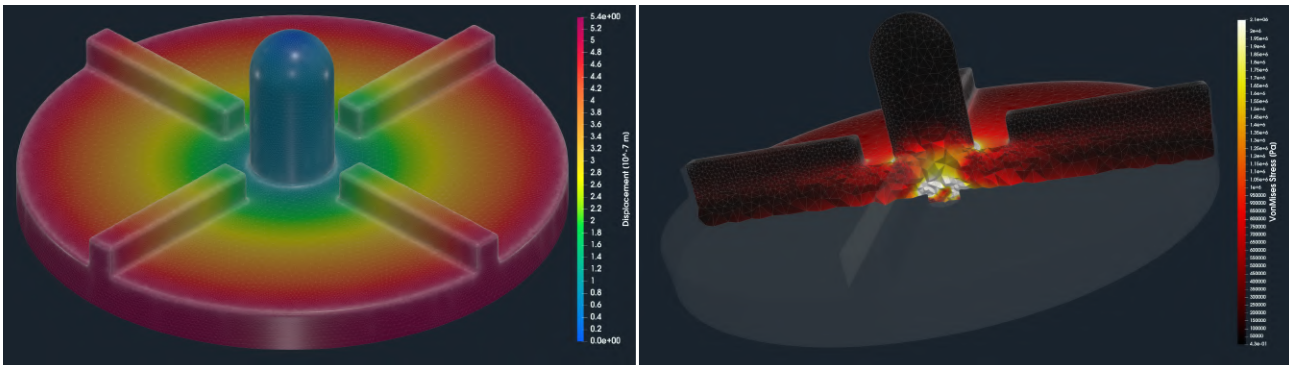


Fig. 14. FEA volume fields

As the pump is taken as turbomachinery and it has rotating elements which are necessary to view the values at the meridian plane. Hence, it is necessary to calculate the meridional average, which eliminates the blades and views the energy distributed along the meridian. Meridional average provides valuable information about pressure discharge distribution. Technically, the volume field data are circumferentially averaged and interpolated on the meridional plane of certain resolution. This method allows the visualization of the between the hub and shroud without the blades. Fig 15 shows the meridional view.

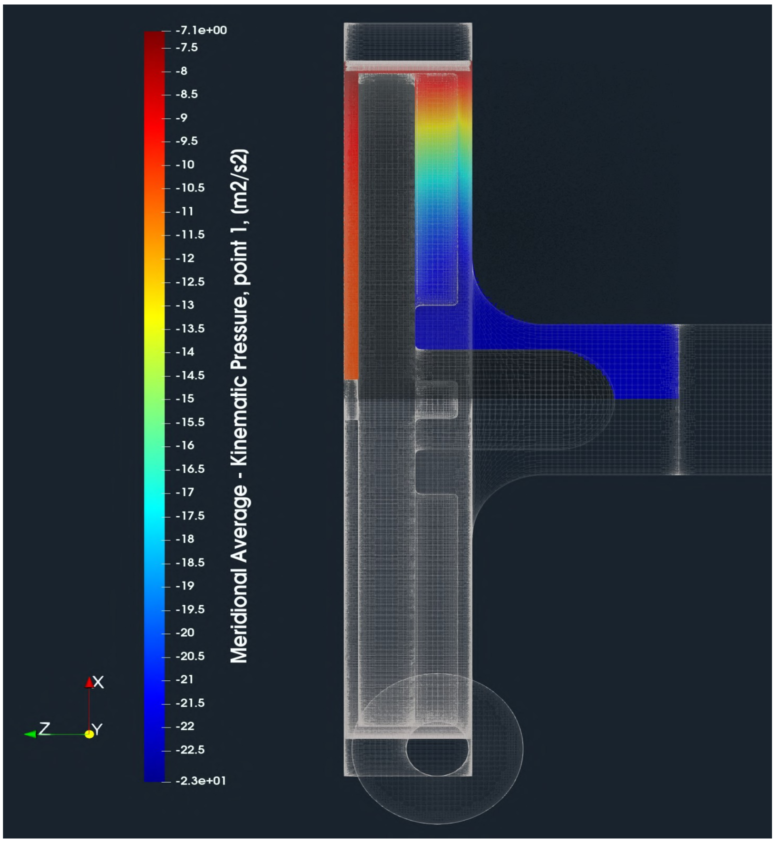


Fig.15. Meridional view of the pump

For complete visualisation of the flow fields blade-blade plane is a crucial view, tosspot clogging, restrictions and blade deformations. Fig 15 shows the blade plane.

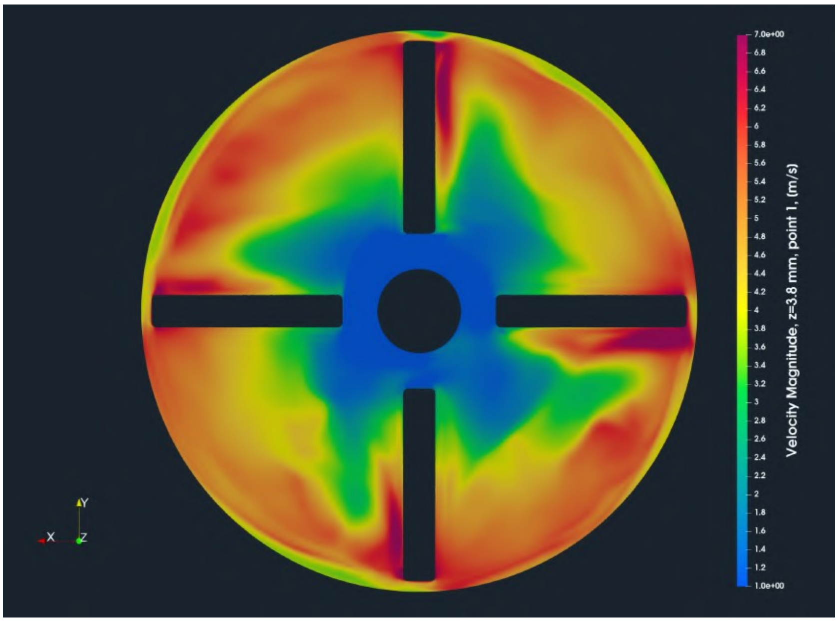


Fig. 16. Blade view

This view unwraps the segment and it’s plane of rotation, corresponding to the volume fields. The unwrapping is done via dimensionless hexahedrons. This visualisation method helps the engineers to check the angles at the leading and trailing edges at specific levels between hub and shroud.

7. Age of Fluid

An important quantity is the Age the fluid. This volume field means the time [s] that the fluid spent in the flow domain since it entered it via the inlet interface. The time for which the fluid (blood) is exposed to the fluid shear stress has a significant effect on blood hemolysis. On top of that, the mean age of fluid also provides valuable information about the flow field. At rotating machinery, the locations of high age of fluid indicate flow recirculation zones which are potential areas for energy losses. In general, the age of fluid should be gradually distributed between inlet and outlet without sharp gradients.

8. Blood Haemolysis

Haemolysis is the process of destruction of red blood cells, so that the oxygen carrying pigment haemoglobin is freed into the surrounding medium. Haemolysis generally occurs generally in a small percentage of red blood cells as a means of removing aged blood cells from the bloodstream and freeing them for ion recycling. Haemolysis is a generic term for RBC damage. At pumps, the the RBCs get mechanically damaged due to the flow shear stress. The hemolysis potential can be computed [6] and written down either as a volume field called Hemolysis Index or as a total integral (sum) over the whole computational domain.

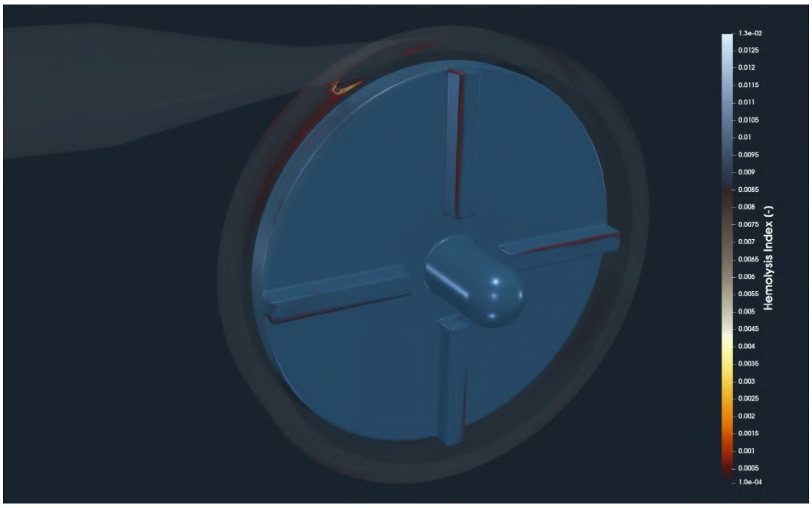
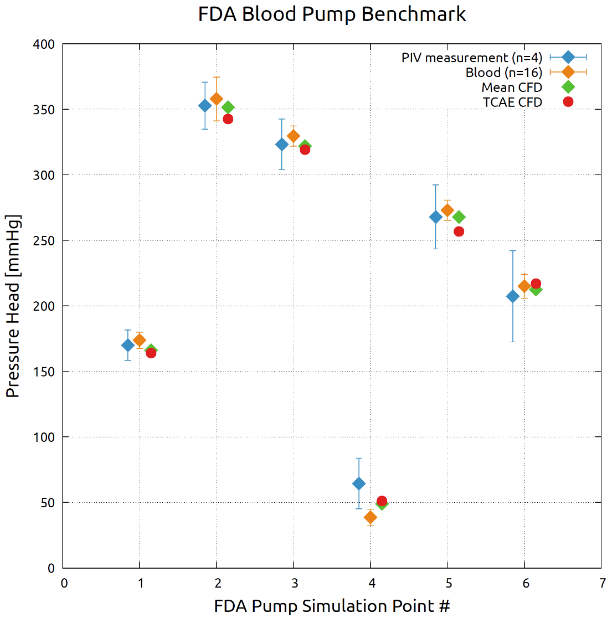


Fig. 17. Blood Haemolysis

9. Benchmark Results

9.1 Pressure Head

The FDA pump benchmark was extensively measured in multiple laboratories to provide experimental velocities, pressures, and hemolysis data to support CFD validation. The measurement method was Particle Image Velocimetry (PIV). Results of PIV testing were compiled from a total of four separate data sets received from three laboratories [1]. In addition, CFD simulations were performed by more than 20 independent groups to assess available CFD techniques. The following CFD codes were used: Abaqus/CFD, AcuSolve, ANSYS CFX, ANSYS Fluent, Code_Saturne, FlowVision, SC/Tetra, STAR-CCM+, and their results we averaged in the following plot (Mean CFD). The TCAE results are plotted (red) and compared with the measurements (blue & orange) and other CFD codes (green) in the following graph 1.



Graph 1. Pump Benchmark results for Pressure head

The comparison shows six simulation points for two rotation speeds (2500 & 3500 RPM) and four flow rates (2.5, 4.5, 6.0, and 7.0 l/min) according to table 1.

9.2 Velocity Profiles

The PIV measurement has been focused on two specific locations in the flow field. The velocity profile was measured A) along the radial line R in the impeller area and B) along the mid-line D of the cross-section in the diffuser area of the pump. The images below show the comparison of the velocity profiles of the measurement and CFD simulation.

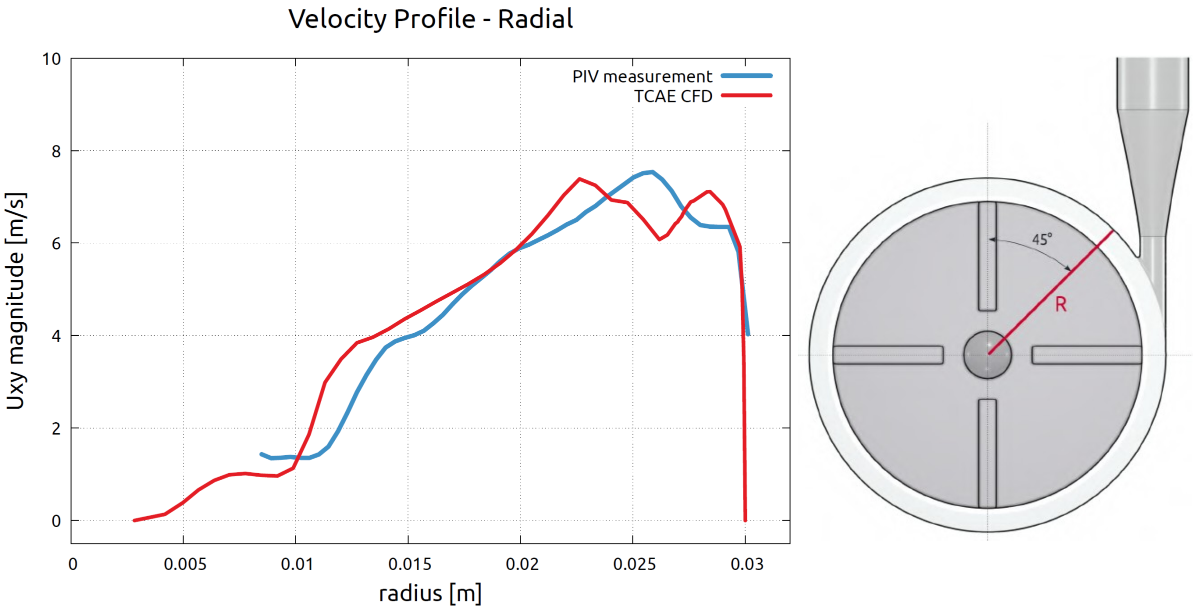


Fig. 18. Radial velocity benchmark

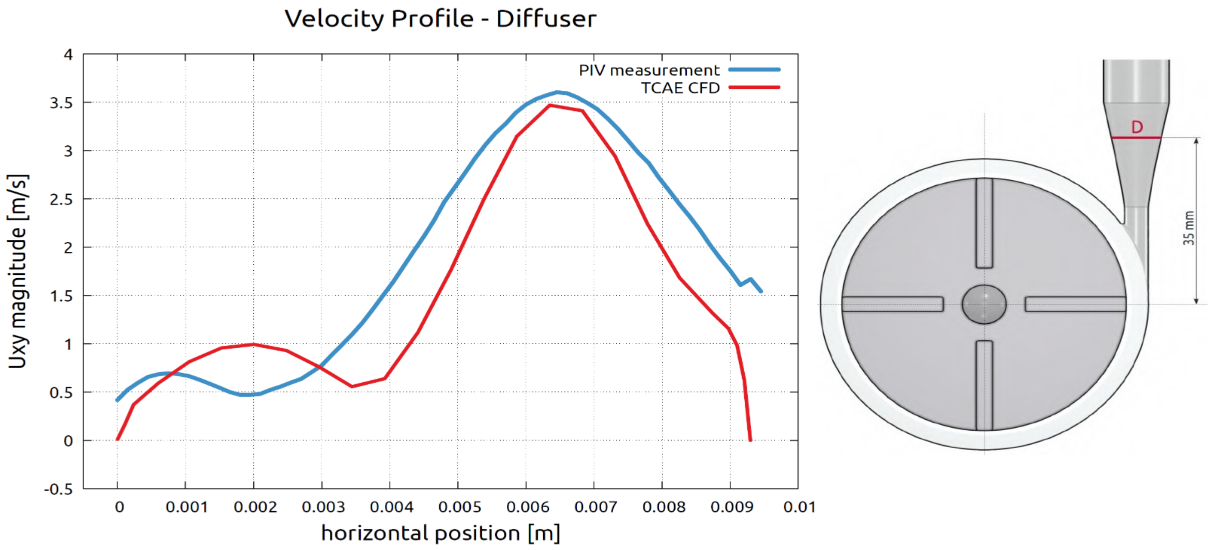


Fig. 19. Diffuser velocity benchmark

10. Conclusion

It has been shown how to make a comprehensive CFD & FEA analysis including FSI of the FDA Pump in a single automated workflow. The TCAE results were successfully compared to the measurement data and with other CFD simulation results. There was no special tuning used in the CFD simulation at all. There remains a lot of space for tuning CFD methodology, especially for the mesh resolution, turbulence modeling, and numerical schemes. On the physical model level, the is enough space remaining in terms of using shear-thinning non-Newtonian models and blood viscoelasticity models. TCAE showed to be a very effective tool for CFD, FEA, and FSI engineering simulations for medical devices and for rotating machinery in general. This benchmark was intentionally written in short not to overwhelm its reader with too many details. The original intention was to show the modern simulation workflow and its accuracy. The benchmark details are listed in the references below [1-6].

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