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ANALYSIS AND MINIMIZATION OF DEPOSITION OF AEROSOL BY DRY POWDER INHALER USED IN TREATMENT OF COPD: COMPUTATIONAL APPROACH

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ABSTRACT

Chronic obstructive Pulmonary Disease [COPD] is a respiratory disorder which is caused due to obstruction of upper airways. Dry Powder Inhalers (DPI) are used predominantly in the treatment of COPD. Dry Powder Inhalers are used to penetrate the powder drug which is very fine [>5µm] into the respiratory track. It is considered efficient way to treat COPD as the device can pump the drug directly to the alveoli. But as the drug is been transported through the throat region a partial volume of drug gets stagnated. Thus there is loss of drug reaching the target. The deposition efficiency is determined by value of Strokes number, a non-dimensional parameter. Peak Inspiratory Flow Rate (PIFR) is a significant parameter in the determination of inhaler efficiency. For more optimized PIFR value, the Reynolds number is taken as reference at the inhaler mouth piece. As PIFR value varies depending on age and severity of the disease, a pneumatic blower is incorporated within the inhaler design. In the commercially available DPI, the capsule is punctured which causes ferrous content in the capsule body to mix with the powdered drug. An alternative design is suggested so that the capsule is split open without puncturing it. The deposition of powdered drug within the DPI device is minimized by optimizing the square filter into Honeycomb structure filter.

KEYWORDS

Reynolds number, Peak Inspiratory Flow Rate and Pneumatic blower.

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INTRODUCTION

Chronic Obstructive Pulmonary Disease is a respiratory disorder. The mucous particles obstructs the oxygen to enter the bronchioles. The obstruction is caused by formation of mucous layer on the inner valves of Trachea or Wind pipe. When the mucous layer formed is very thick, the person affected by COPD will feel breathless and wheezing sound will assure that the person is having an asthma attack. A patient who is having an asthma attack will feel

uncomfortable due to breathlessness and the blood pressure level raises giving a severe headache. As there is not a permanent cure from COPD, the patients with the disorder should be on medication in order to cure it temporarily.

Dry Powder Inhalers are used to penetrate the powder [drug] which is very fine [>5µm] into the respiratory track. It is considered efficient way to treat COPD as the device can pump the drug directly to the alveoli. The drug which is stored in a capsule is placed in the lower chamber of the device. The piercing buttons on the either side of the lower chamber are used to puncture the capsule. As the air is sucked through the mouthpiece, the capsule starts rotating and the filter restricts the capsule from entering the mouthpiece. The drug inside the capsule enters the suction area through the punctured holes. As the capsule is punctured using two pairs of four needle projections, the ferrous content present in the capsule body mixes with the drug. Allowing ferrous particles to enter the respiratory track can be harmful in long run. Initially the capsule is placed in the lower chamber of the inhaler. As the air is sucked through the mouthpiece, the capsule gets struck in the slot restricting the drug to be transported. Suction of the drug is done manually. The sucking capacity varies from person to person. An elderly person can find it difficult to suck the drug during an asthma attack using Dry Powder Inhalers because it is designed for adolescents.

The effectiveness of the dry powder inhalers are generally characterized by two parameters. They are the amount of dose emitted and the production of fine particles. The amount of dose emitted using the DPI depends on velocity, shape of the flow region and the size of outlet/mouthpiece. The airflow and the powder dispersion in a Dry Powder inhaler is very complicated and follows a dynamic flow pattern. The fine particle fraction (FPF) is a term used to determine the ratio of mass of emitted particles with a diameter that is equal to or less than the critical value. The critical value for the Fine Particle Fraction (FPF) varies from 4µm to 6µm. It is frequently used to measure the effectiveness of powder dispersion in Dry powder Inhalers.

MATERIAL AND METHODS

Treatment for COPD

Initially powerful medications in the form of tablets were prescribed for treatment. The intake of tablets took time to react and cure the inflammation. Adding to this there was also side effects affecting other organs due to taking powerful tablets. Later Nebulizers were used as the medication for treating COPD. The tablets were diluted and vapourized for directing the vapour directly to the upper airways. Nebulizers are used widely to treat the inflammation. The patients were required to be hospitalized to perform nebulization. Some patients also purchased the nebulizers and used them individually. But this method of treatment was not viable to many. In a major development in the treatment of COPD, the medication was converted as vapour and stored in a pressurized container called the canister. The usage of canister was made simple for patients as the drug was inflated just by pressing the canister downwards. For more efficient way of transporting the drug, the medication was to be inhaled in powdered form to react swiftly. As the disorder is related with the inflammation in the airways, the powdered drug enters the airways directly through the mouth throat region. Among the aforesaid methods for treating COPD, Dry Powder Inhalers are the most efficient and user friendly. Initially the patients feel uncomfortable with the use of DPI. With a period of use of DPI the patients get in touch with the usage of it. The study done by Sam Howard *et al*, 2016[1] revealed the attitude of adolescents on being monitored on their inhaler usage. The interference from the study is used as a criteria for the design of the modified inhaler.

DIAGNOSIS METHODS

Fraction of Exhaled Nitric Oxide (FeNO) test is used to find the volume of obstruction of airways in COPD patients. Nitric oxide is the compound produced by the inflammation of lungs and it is measured by blowing out the exhaled air into the test kit. The test kit consists of a transparent glass cylinder inside which a small metal ball is placed. The patient is made to exhale through the mouthpiece of the tester and asked to maintain the metal ball at an optimum height for a

period of 10 seconds. The cylinder is marked with readings in the region where the ball should be held. The fluctuations is measured using the mercury scale and gives the level of nitric oxide exhaled in parts per billion (ppb). Average value of FeNO test for patients affected by COPD is shown below.

Peak Expiratory Flow Rate is used to measure the lung capacity of persons affected by COPD. Initially FeNO test is carried out and on diagnosis of presence of inflammation in airways, PEFR is done. COPD patients will have blowing capacity much lower than compared to a normal person. PEFR test kit consists of a pressurized cylinder in which a movable pointer is provided along the length of the pressurized cylinder. The readings of the expiratory flow rate is provided where the pointer is placed. COPD patients are subjected to blow through the pressurized cylinder at their maximum capacity in one stroke. The pointer is initially held at the blower end and when the patient exhales through the tester, the pointer is pushed forward. The point up to which the pointer is pushed gives the PEFR value.

Modelling

The commercially available inhaler is modelled using SOLIDWORKS. The inhaler model consists of top cylindrical shaped part. A rectangular mesh filter is attached with one end of the cylinder. The bottom part is rectangular in shape and has a fool-proofing slot in which the capsule is to be placed. The model is developed to compare the results with the modifications so that there is a clear cut findings.

The cylindrical top part is modified as a tapered section. The physics behind the modification is when the cross-section is reduced the pressure is set to increase. The increase in pressure enhances the flow characteristics leading to minimal deposition in the throat region. The loft tool is used to generate the tapered shape of the part.

The filter used in the commercial model is rectangular mesh type filter. Filter is one of the predominant factor resulting in the transportation effectiveness of the drug. The powdered drug when carried by the inhaled air which is slightly hot tends to adhere together and forms a cluster. The filter restricts the flow of larger clusters to enter the mouth throat region. If the filter fails to restrict the flow, the clusters enter the mouth and gets deposited in the throat region. The filters are also used in changing the flow pattern. The investigation by Prashant *et al*, 2018[2] revealed that the time taken by the PIFR to initiate the flow of the drug took 0.45 seconds and the transient time taken for the complete inhalation after the initiation of flow was 0.6 seconds. By altering the mesh size of the filter the transient time period showed variations drastically. In this study the regular mesh is replaced by Honeycomb structure to study the behaviour of flow pattern.

The base part is to be modified to change the puncturing mechanism and replace it with a splitter plate. The base part should also incorporate the pneumatic blower in it. The slider-crank mechanism is used for creating vacuum and generate the necessary flow rate.

Simulation

The analysis of the flow characteristics were performed using ANSYS 20.0. The model created in SOLIDWORKS was imported as iges format for the analysis. Meshing of the assembled geometry was performed based on the edge contours and the wall region through which the flow occurs was given an element size of 0.015 and the number of nodes at the contours was set as 100 initially. Further refinement was done on the geometry until the residue was minimum. Trial and error method was accounted for the complete refined mesh of the part geometry. Tetrahedron type was selected as the mode of refinement and the mesh was generated.

The inlet and outlet faces was selected and named for easy identification. The mesh was generated and visualized to see if there is any discrepancies. Only after complete refinement at the edges and contour region the mesh was updated to the working module.

Then after meshing is over, the assembly is setup for selection of materials and other cell zone conditions. Initially, double precision was selected and under general setup, pressure based solver was chosen and time period of flow was set as linear distribution. Viscous model was selected and SST K-Omega model was approximated for the analysis. The k- ώ SST turbulence model used to study the flow through the containment zone of the DPI wall is the shear stress tensor in which k denotes the turbulent kinetic

energy and ώ denotes the specific dissipation rate. As we account for the dissipation rate in terms of Peak Inspiratory Flow Rate (PIFR), it is considered as the input parameter. Output parameters such as Mass flow rate and velocity of particles are selected. Then the material is to be selected. As the study deals with fluids, the medium of flow is chosen as fluid and the material properties of Cartico steroids that makes closer to the real fluid medium is selected. The contour wall region is selected as solid medium and ABS is chosen. In the cell zone condition, the fluid domain is selected as steroid and the solid domain as Plastic wall.

Setting the boundary condition at the inlet, outlet and at the walls is performed using the reference models of J. Milenkovic *et al*, 2016[3]. After the setup is completed, it is automatically updated in the module. Solution method adopted for the study is SIMPLEC scheme. The skewness correctness is set to 0.2 and the Green-Gauss cell based is selected for special discretization. In the monitors section, residuals are checked. The criteria should be set such that the convergence occurs faster for the provided geometry. The solver is initialized and set as standard initialization.

RESULTS AND DISCUSSION

The determination of optimum PIFR value is done using the PEFR test kit which is used in the diagnosis of COPD. For the determination of PEFR the pointer is initially placed at zero and tested. For knowing the optimum peak inspiratory flow rate, the pointer is kept at 70lt/min. Then the COPD patients are mandated to inspire through their mouth.

As the patient sucks in the air, the pointer is also sucked inwards. The readings are taken three times for three different age groups and the data is tabulated as below. From the data collected it is obvious that the peak inspiratory flow rate for most of the COPD patients lies in the range of 35-40lt/min.

The study done by Milenkovic *et al*[3], showed that at 30lt/min, the deposition percentage is 57.1 and at 70lt/min, the deposition percentage reduced drastically to 13.4. Thus it is clear that minimum deposition can be achieved only through pumping the required flow. The pneumatic blower is to be corrected for effectiveness of the drug to reach the alveoli. The gear size plays a predominant role in the use of slider-crank mechanism. The length of connecting rod can't be modified to a large extent since there is constrain in length of the inhaler body. The diameter of the gear can be selected on developing a prototype and then testing it. The current study is limited only to the simulation part and further study can be performed to develop a prototype of the pneumatic blower.

The SST k- ώ model used showed the specific dissipation rate and the kinetic energy values in the graph shown below. The interference from the below plot is that the specific dissipation rate remains constant irrespective of the number of doses inhaled. But the kinetic energy values vary to an extent that optimum value cannot be obtained.

S.No	Age (in years)	FeNO (ppb)
1	5 - 10	<35
2	< 25	<55

Table No.1: PIFR value using PEFR test kit

S.No	Age Group	I	II	III
1	>15 years	30	35	30
2	>25 years	43	48	40
3	<50 years	38	40	38

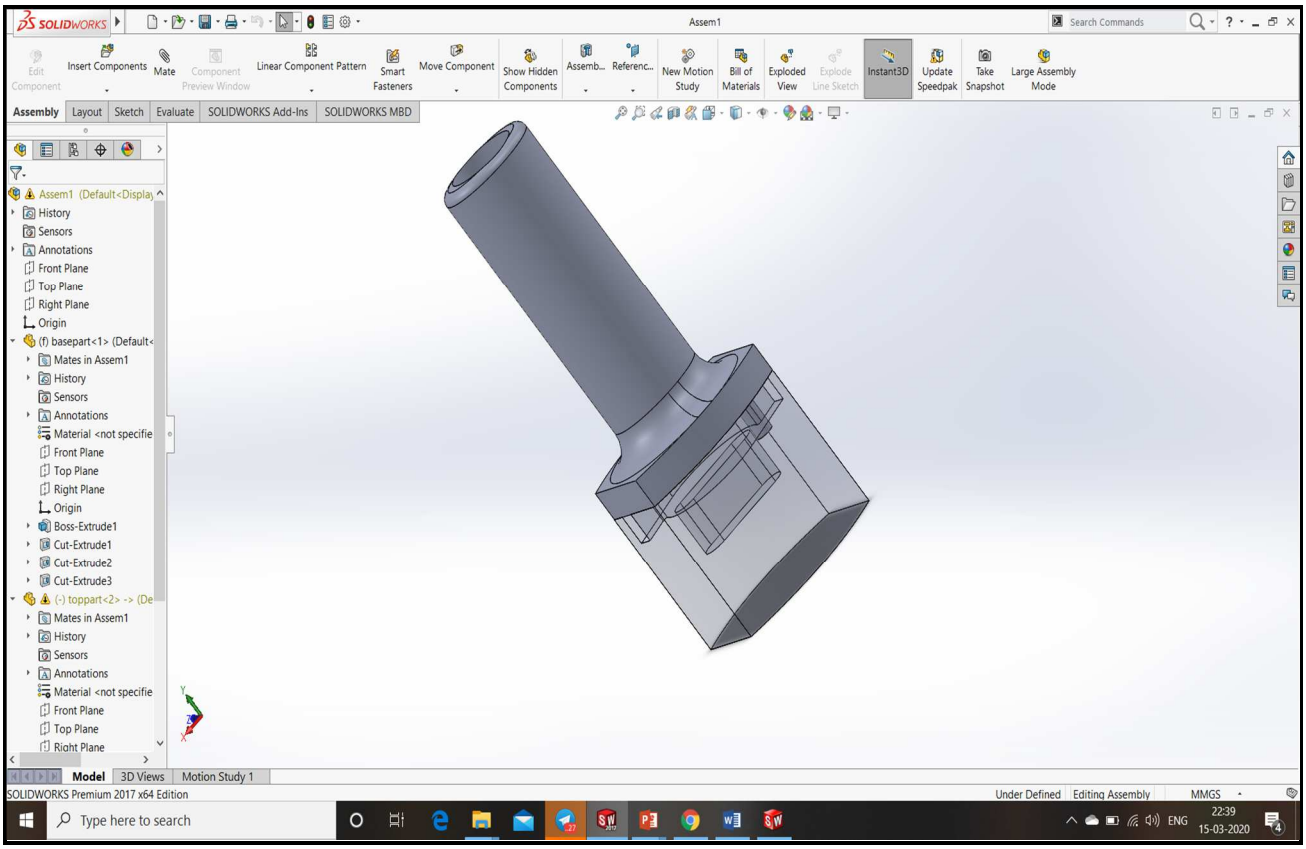


Figure No.1(a): Dpi model

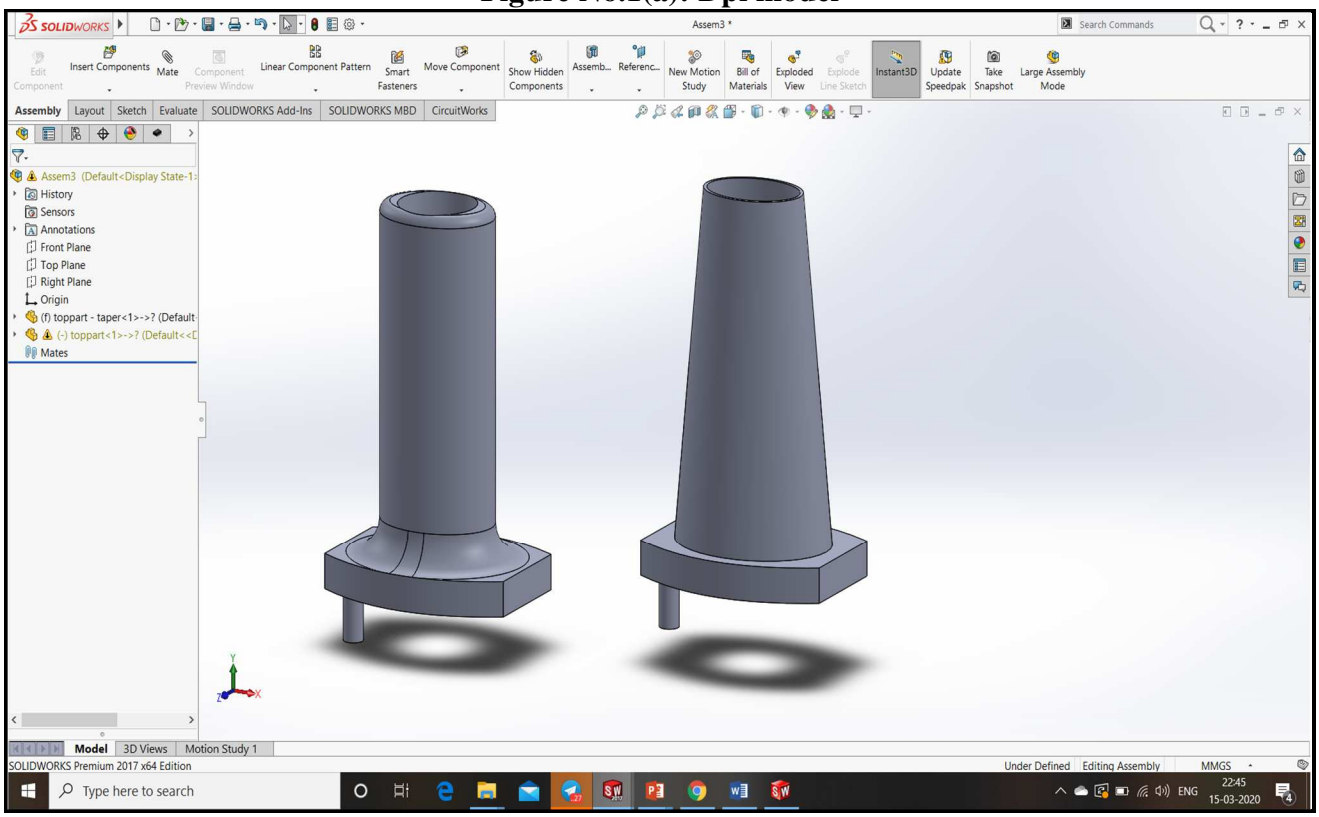


Figure No.1(b): Tapered mouthpiece

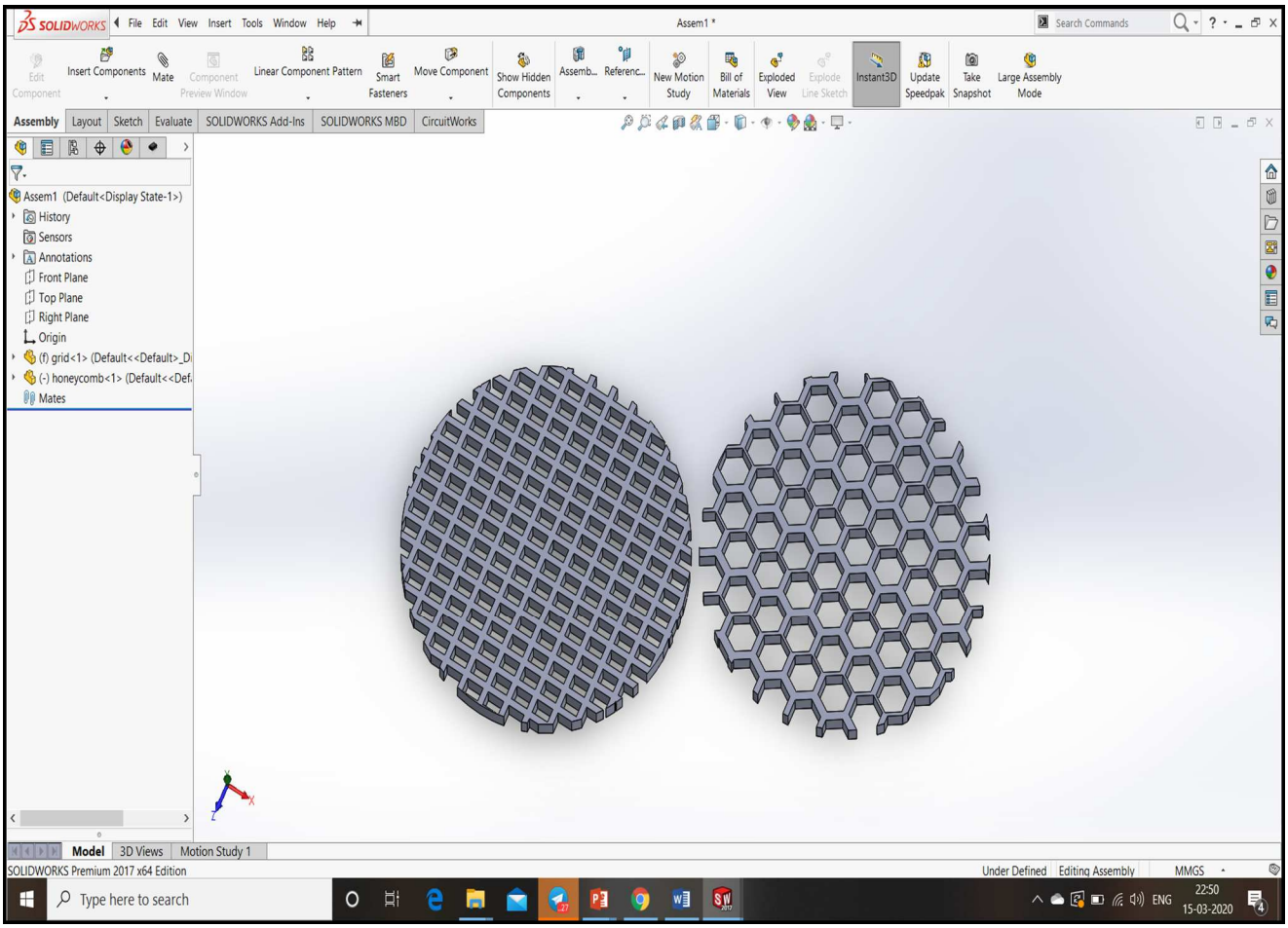
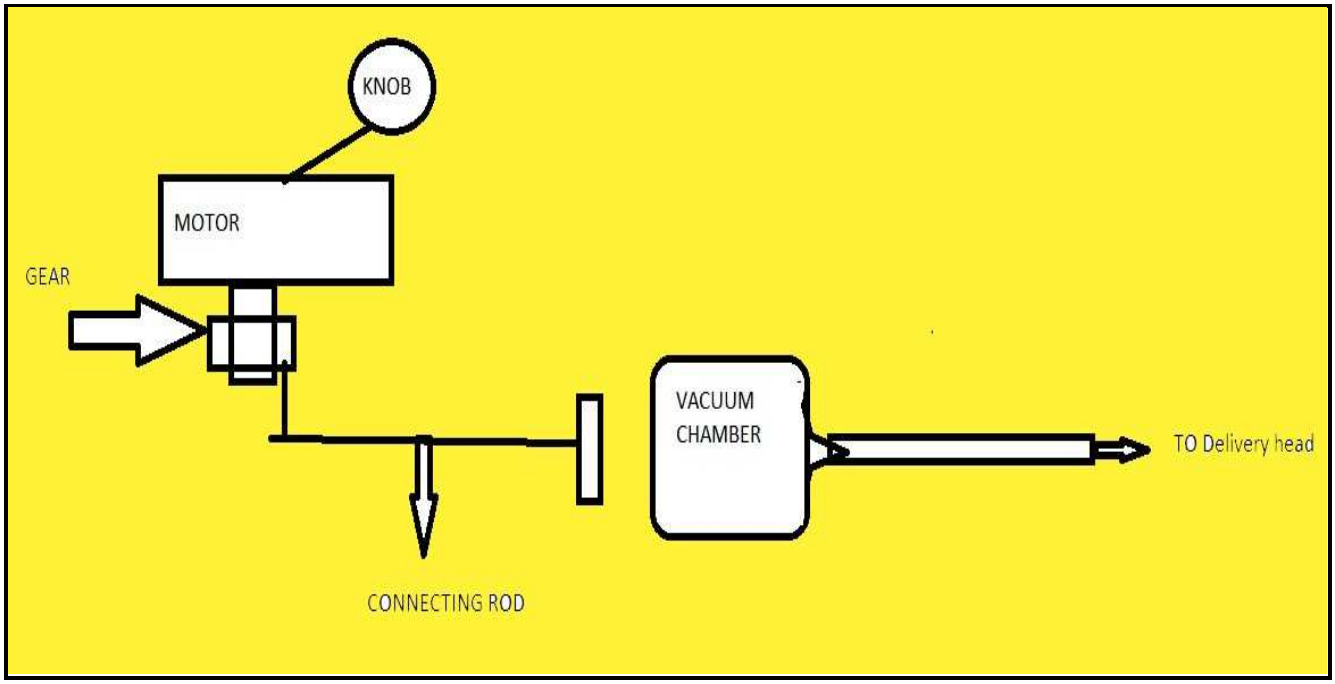


Figure No.1(c): Honeycomb Structure Filter



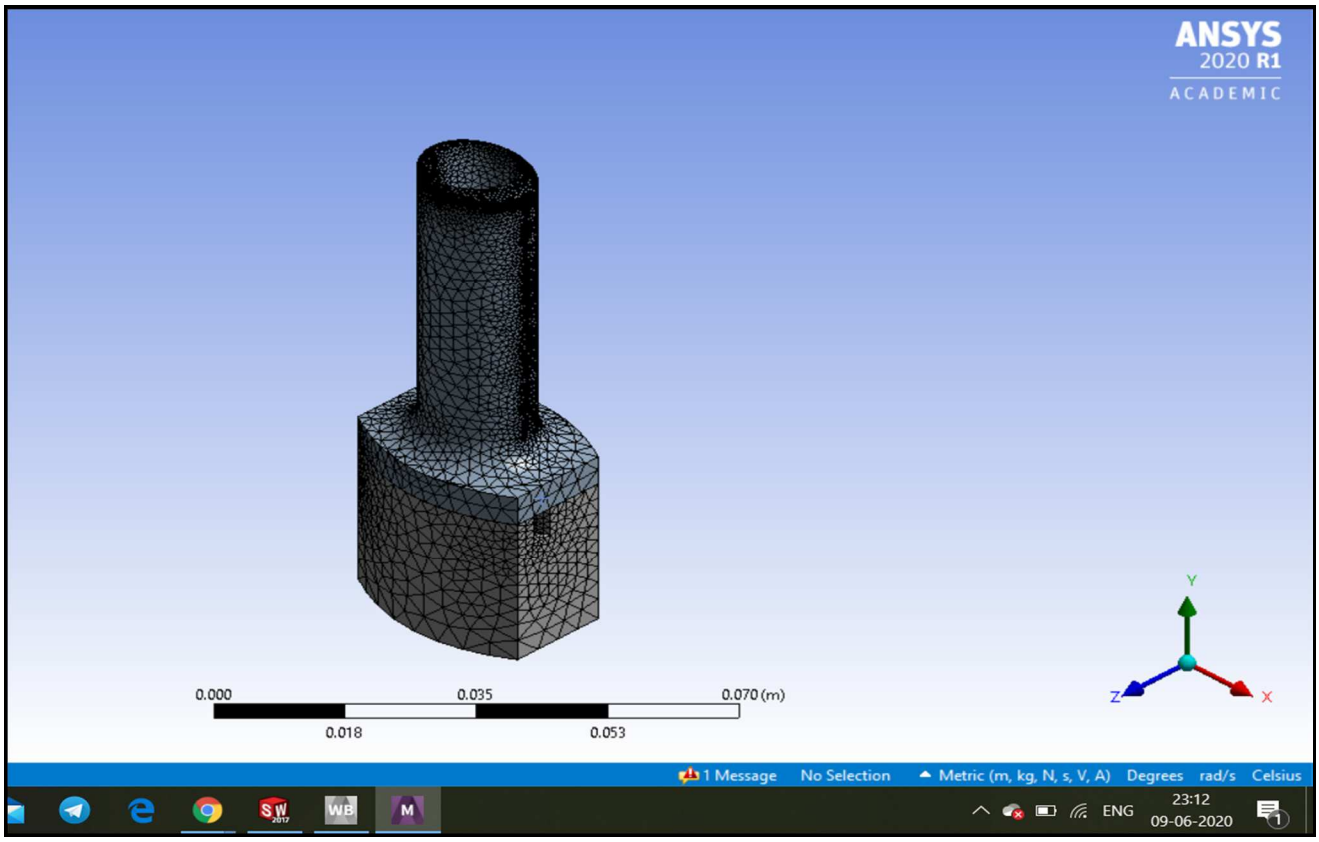


Figure No.2(a): Meshing of DPI

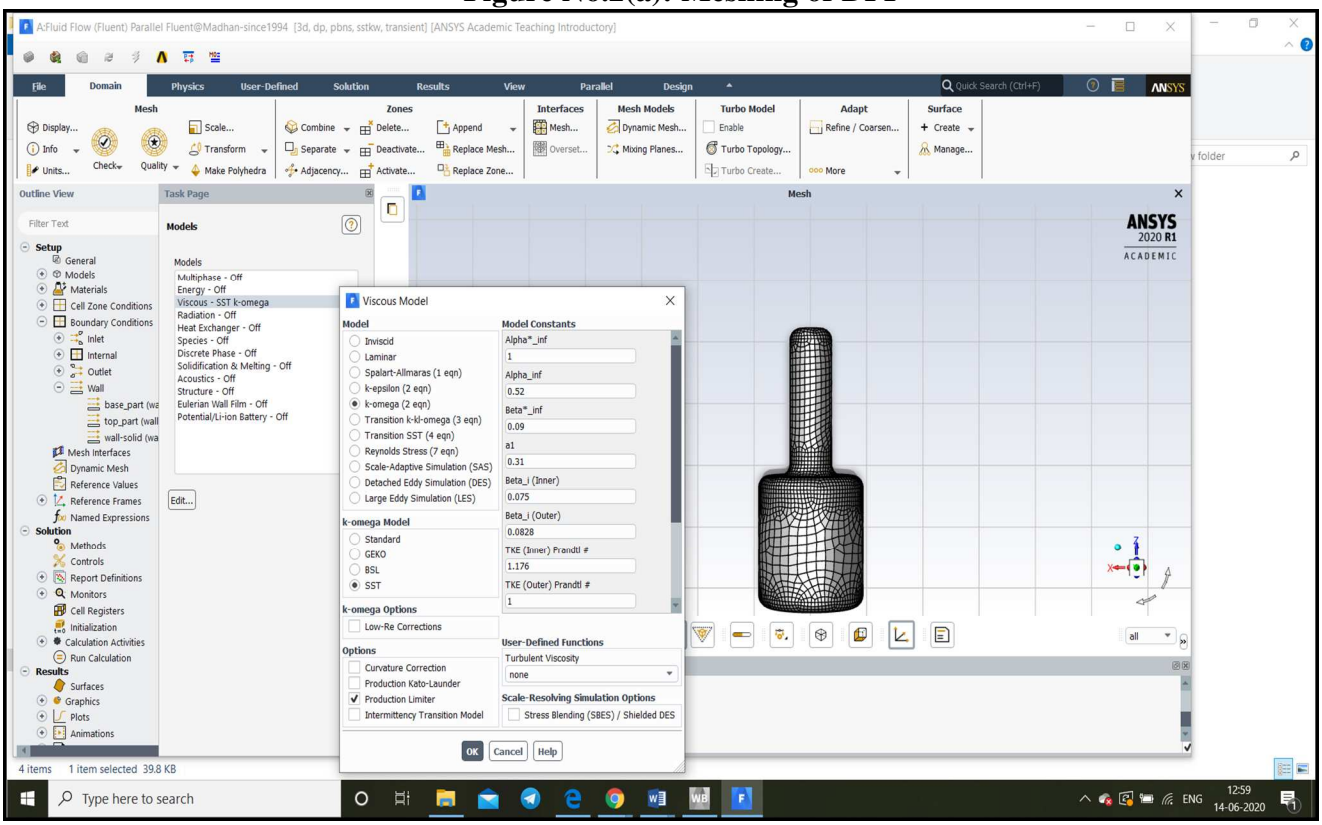


Figure No.2(b): SST k- ώ model

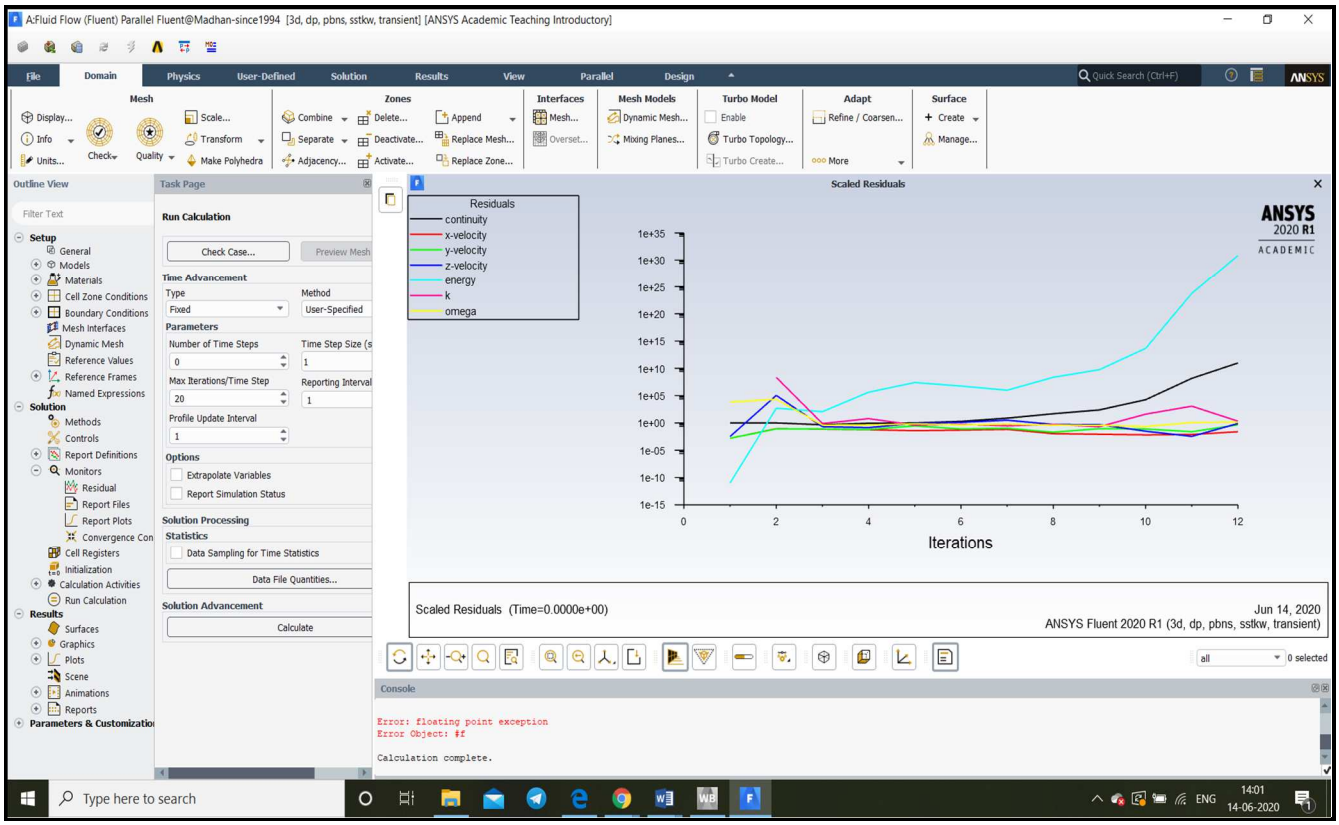


Figure No.3(a): K- ώ Values along with velocity profile

CONCLUSION

The instantaneous flow fields at their peak strength reaches when the inhalation PIFR is at 0.45 seconds. The instantaneous Reynolds number at the inlet are approximately 5000, 5800, 6500 for the 5, 10 and 25 years old patients respectively. The size of the air inlet had a varying effect on the inhaler performance at different flow rates. The inlet size controls the level of turbulence and particle impact velocities generated in the device, as well as the flow rate and device emptying times. At low flow rates reducing the air inlet size increases the inhaler dispersion performance by increasing the turbulence levels and particle velocities generated in the device above the critical levels. At higher device flow rates reducing the size of the air inlet reduce the inhaler dispersion performance by releasing a large amount of powder from the device when both the turbulence levels and particle impaction velocities were below their fully developed values. Significant dispersion reductions may occur when a large amount of powder is released from the device prior to full flow development.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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