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ANALYSIS OF MICRO NEEDLE MATERIAL BY ANSYS

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ABSTRACT

Present research focus on design and analysis of silicon and stainless steel based hollow micro-needles for transdermal drug delivery (TDD) has been presented. By using ANSYS &CFD (computational fluid dynamic), structural and micro fluidic analysis has been performed to ensure that the micro-needles design suitability for Drug delivery. The effect of axial and transverse load on single and micro-needle array has been investigated & the mechanical properties of micro-needle. The analysis predicts that the resultant stresses due to applied bending and axial loads are in the safe & comfort desired range. In computational fluid dynamic (CFD) static analysis, the fluid flow rate through micro-needle array was investigated by applying the pressure in the inlet the micro-needles were capable for flow of drug up to the desired range. Towards achieving painless injections and other micro fluidic applications, the work was focused on the conically tapered hollow needles of micron dimensions. The relationship between pressure drop and flow rate through micro-needles was analyzed quantified as a function of fluid viscosity, micro-needle length, diameter and cone half-angle. The dimensionless pressure drop sharply decreased as the indicating role of viscous forces on the boundaries of the micro-needles increased. The flow was almost in viscid, indicates that the effect of pressure drop, numerical simulations showed that the flow through conically tapered micro-needles was mainly controlled by the diameter and taper angle of the micro-needle tip. The hollow out-of-plane micro-needle of micron sized devices for drug delivery applications was investigated.

KEYWORDS: Micro-needles, transdermal drug delivery (TDD), computational fluid dynamic (CFD), conically tapered micro-needles.

INTRODUCTION

Transdermal drug delivery is becoming increasingly popular because it is not associated with the potential risks and pain of traditional hypodermic needles. One method for transdermal drug delivery uses adhesive skin patches. In this method, a pharmaceutical compound is absorbed through the skin surface after application of the patch to the skin by means of an adhesive layer. Micro-needles, a microstructure transdermal system also called micro-needles consists of an array of micro structured projections coated with a drug or vaccine that is applied to the skin to provide intradermal delivery of active agents, which otherwise would not cross the stratum corneum. The mechanism for delivery, however, is not based on diffusion as it is in other transdermal drug delivery products. Instead, it is based on the temporary mechanical disruption of the skin and the placement of the drug or vaccine within the epidermis where, it can more readily reach its site of action. Micro-needles are commonly fabricated using metals, silicon, polymers and other materials. However, the techniques employed for their fabrication are usually quite complex and expensive. Metallic micro-needles are typically fabricated by electroplating technique (for example, LIGA process). To achieve physiologically relevant delivery rates, micro-needle-based drug delivery is preferably made with arrays of needles over a certain area. Drug delivery remains one of the most important challenges in medicine and micro fabrication is used to develop novel delivery systems. In last year's, new miniaturized delivery systems based on both solid and hollow micro-needles have been proposed for the controlled release of small doses of drugs throughout the outermost layer of the skin (transdermal, painless delivery). Here, we present a simple silicon hollow out-of-plane micro-needle for drug delivery. Transdermal drug delivery is an appealing alternative that offers good patient compliance and the possibility of control release over time while avoiding possible degradation due to the gastrointestinal tract or first-pass liver effects use aqueous coating solution to prevent denaturing of proteins and other biological molecules. Micro-needles are significantly smaller than ordinary needles, especially concerning the length. In recent years, attention has been drawn to a new type of delivery method where arrays of miniaturized needles are used to penetrate the skin layer. Since the needles are short, they do not reach the nerve-rich regions of the lower parts of the skin. As a consequence, the stimulus caused by micro-needle insertion into the skin is weak and perceived as painless. By combining micro-needles with a patch like structure, a system can be realized which essentially has all the favourable properties of a traditional transdermal patch. Continuous release, ease-of-use, unobtrusiveness and painlessness. Advances in the processing of materials on a micro-scale have led to the development and introduction of devices that employ very small needles that have significant potential in devices for diagnostics, healthcare monitoring and drug delivery by mechanically perforating the outer skin layer and allowing for transdermal drug absorption or fluid sampling. These processing techniques incorporate one or more technologies that enable the precise machining, extrusion, casting, and/or forming of from one to an array or grid of micro-needles. Since the needles are short, they do not reach the nerve-rich regions of the lower 3 parts of the skin. As a consequence, the stimulus caused by micro-needle insertion into the skin is weak and perceived as painless. However, if a small number of needles are used, the delivery rate per needle needs to be higher than in the case of many needles. It is shown that solid micro-needles can increase skin permeability by almost four orders of magnitude. Whereas single hollow silicon hypodermic micro-needles with fully enclosed fluid channels fabricated through a combination of surface and bulk micro machining techniques where a silicon nitride shell is built on top of a silicon substrate. The efficiency of transdermal drug delivery has been shown to imp rove by increasing the number of micro-needles. In last year's, new miniaturized delivery systems based on both solid and hollow micro-needles have been proposed for the controlled release of small doses of drugs, the insertion force of the needles does not necessarily need to be minimized. This is basically true. However, if a small number of needles are used, the delivery rate per needle needs to be higher than in the case of many needles.

MATERIAL SELECTION AND PROPERTIES

Stainless steel

In metallurgy, stainless steel also known as in ox steel is a steel alloy with minimum of 10.5% chromium coat by mass. The free encyclopedia in metallurgy, stainless steel, also known as in ox steel or inox from French inoxydable (inoxidizable), is a steel alloy with a minimum of 10.5% chromium content by mass. Stainless steel is notable for its corrosion resistance, and it's widely used for food handling and cutlery among many other applications. Stainless steel does not readily corrode, rust or stain with water as ordinary steel does. However, it is not stain proofing low oxygen, high salinity, or poor air circulation environments. There are various grades and surface finishes of stainless steel to suit the environment the alloy must endure. Stainless steel is used where both the properties of steel and corrosion resistance are required. Stainless steel differs from carbon steel by the amount of chromium present. Unprotected carbon steel rusts readily when exposed to air and moisture. This iron oxide film is active and accelerates corrosion by making it easier for more iron oxide to form. Since iron oxide has lower density than steel, the film expands and tends to flake and fall away. In comparison, stainless Steels contain sufficient chromium to undergo passivation, forming an inert film of chromium oxide on the surface. This layer prevents further corrosion by blocking oxygen diffusion to the steel surface and stops corrosion from spreading into the bulk of the metal. Passivation occurs only if the proportion of chromium is high enough and oxygen is present. Stainless steels resistance to corrosion and staining, low maintenance, and familiar luster make it an ideal material for many applications. The alloy is milled into coils, sheets, plates, bars, wire, and tubing to be used in cookware, cutlery, household hardware, surgical instruments, major appliances, industrial equipment and as an automotive and aerospace structural alloy and construction material in large buildings. Storage tanks and tankers used to transport orange juice and other food are often made of stainless steel, because of its corrosion resistance. This also influences its use in commercial kitchens and food processing plants, as it can be steam cleaned and sterilized and does not need paint or other surface finishes

Structural steel

Structural steel is a category of steel used as a construction material for making structural steel shapes. A structural steel shape is a profile, formed with a specific cross section and following certain standards for chemical composition and mechanical properties. Structural steel shapes, sizes, composition, strengths, storage practices, etc., are regulated by standards in most industrialized countries. Structural steel members, such as I beam, have high second moments of area, which allow them to be very stiff in respect to their cross-sectional area.

Properties

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Structural products are produced of grades E250, E275 & E300 with a quality a grade as per IS 2062:2011. However, carbon & Manganese levels are restricted to much lower than the specification, which results in excellent ductility, high bend ability and superior weld ability.

Chemistry	Unit	IS 2062:2011
Carbon	%	0.23 Max
Manganese	%	1.50 Max
Sulphur	%	0.045 Max
Phosphorus	%	0.045 Max
Carbon Equivalent	%	0.42 Max

Table3.1. Composition of structural steel

Mechanical Properties

Because of their unique method of manufacturing, structural products possesses a combination of strength and ductility that is far in excess of minimum limits specified in the standard.

Table3.1.2 Mechanical Properties of structural steel

Mechanical Properties	unit	Dia /thickness (mm)	IS 2062,Fe 410W A
Yield Stress	N/mm2	20-40	250 min 240 min 230 min
Tensile Strength	N/mm2	_	410 min
Elongation	N/mm^2	-	23 min

MATERIALS AND METHODOLOGY

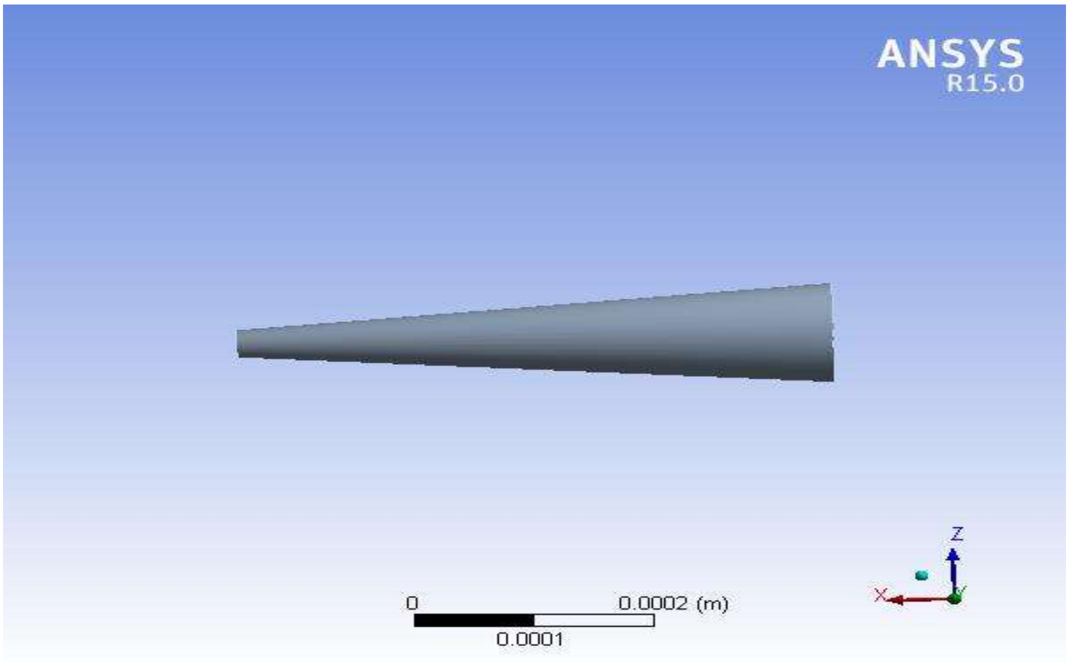

Fig 4.1 Structural Steel ANSYS

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Structural Steel

Table 4.1.1 Static structural mesh analysis

Object	*Static Structural*
State	Solved
Definitio	
Physics	Structural
Analysis	Static Structural
Solver	Mechanical APDL
Options	
Environment	22. °C
Generate Input	No

Table 4.1.2 Static structural step specific control

Step	Step End Time
1	1s
2	2s
3	3s
4	4s
5	5s

Table 4.1.3 Static structural analysis setting

Object Name	*Analysis Settings*
State	Fully Defined
Restart Analysis	
Restart Type	Program Controlled
Status	Done
Step Controls	
Number Of Steps	5.
Current Step Number	1.
Step End Time	1. s
Auto Time Stepping	Program Controlled
Solver Controls	
Solver Type	Program Controlled
Weak Springs	Program Controlled
Large Deflection	Off
Inertia Relief	Off
Fracture	On
Restart Controls	
Generate Restart Points	Program Controlled
Retain Files After Full Solve	Yes
Nonlinear Controls	
Newton-Raphson Option	Program Controlled
Force Convergence	Program Controlled
Moment Convergence	Program Controlled
Displacement Convergence	Program Controlled
Rotation Convergence	Program Controlled
Line Search	Program Controlled

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Stabilization	Off
Output Controls	
Stress	Yes
Strain	Yes
Nodal Forces	No
Contact Miscellaneous	No
General Miscellaneous	No
Store Results At	All Time Points
Analysis Data Management	
Solver Files Directory	C:\Users\Nagendra\Documents\axial stress deformation and strain files\dp0 \SYS\MECH\
Future Analysis	Pre stressed analysis
Scratch Solver Files Directory	
Save MAPDL db	No
Delete Unneeded Files	Yes
Nonlinear Solution	No
Solver Units	Active System
Solver Unit System	Mks

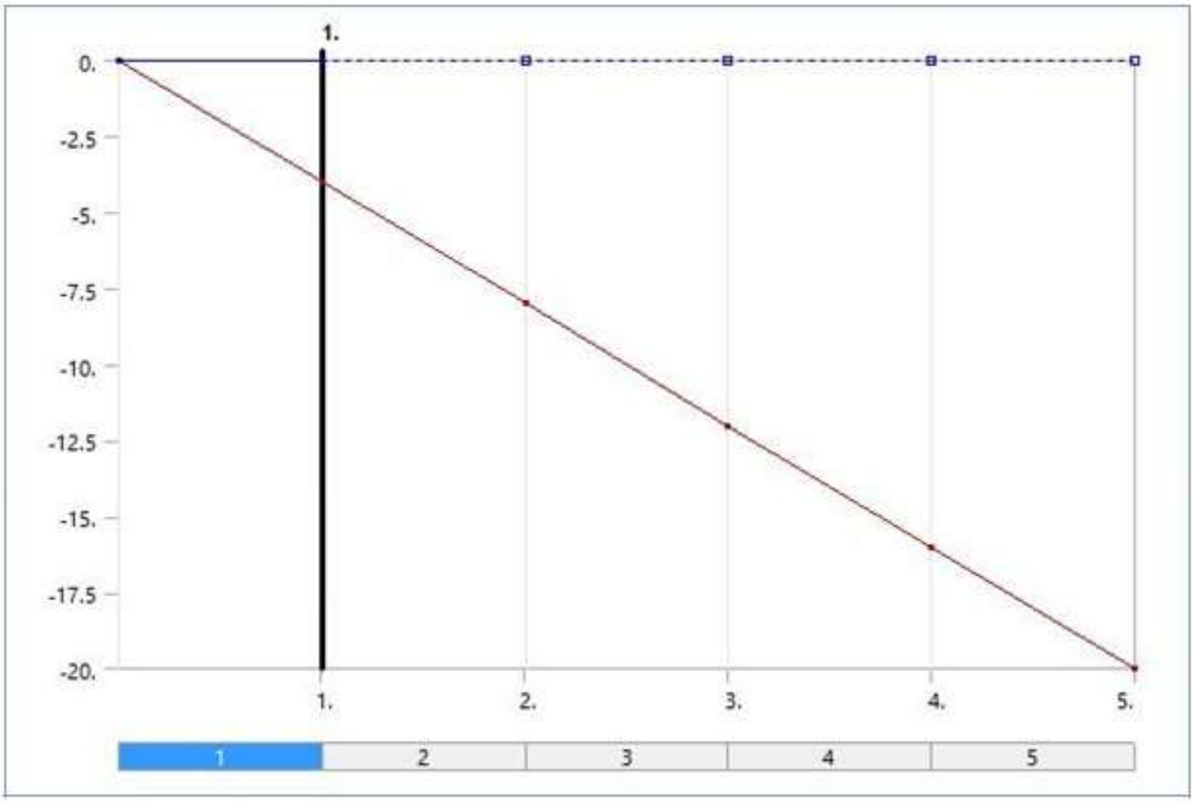

Fig4.1.4 Static structural force reaction

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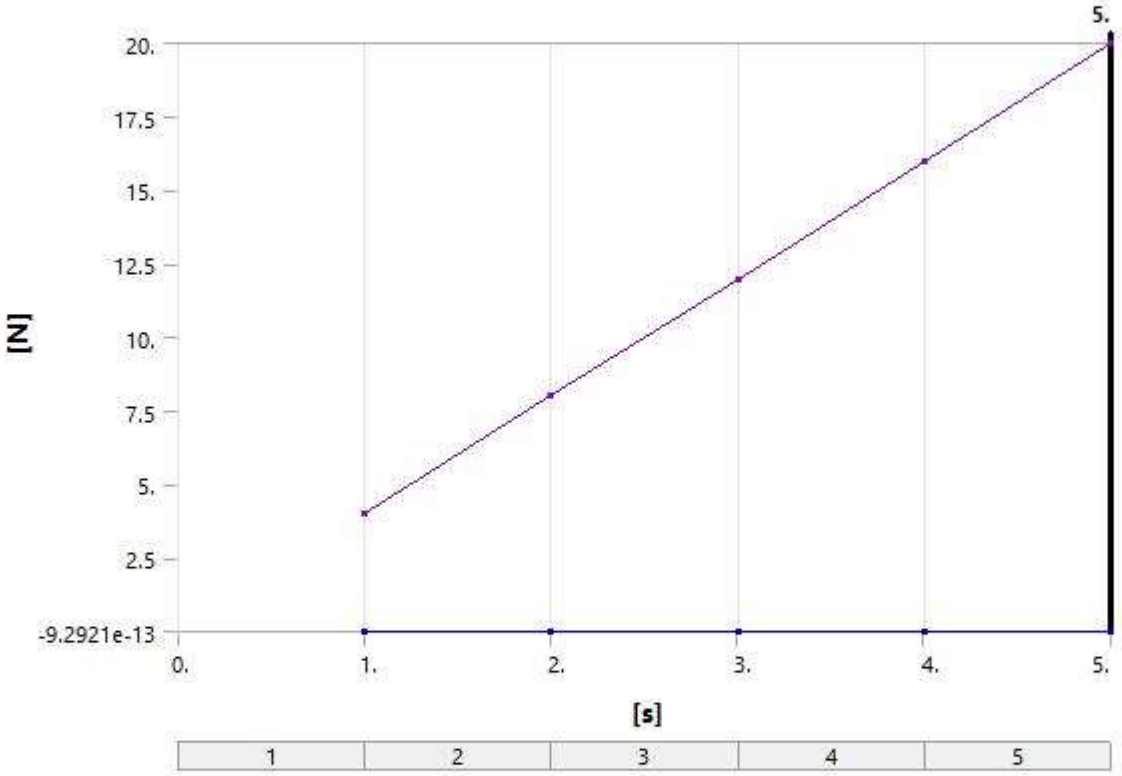

Fig 4.1.5 Static Structural Force Reaction

Fig 4.1.6 Static Structural Force Reaction

Time[s]	Force Reaction(X)[N]	Force Reaction(Y)[N]	Force Reaction(Z)[N]	Force Reaction(Total)[N]
1.	4.	8.4758e-014	-1.8571e-013	4.
2.	8.	1.6986e-013	-3.7132e-013	8.
3.	12.	2.564e-013	-5.5847e-013	12.
4.	16.	3.3971e-013	-7.4264e-013	16.
5.	20.	4.2536e-013	-9.2921e-013	20.

Linear buckling

Object Name	*Linear Buckling(B5)*
State	Solved
Definition	
Physics Type	Structural
Analysis Type	Linear Buckling
Solver Target	Mechanical APDL

Fig 4.2.1 Linear Buckling and Initial Condition

Object Name	*Pre-Stress (Static Structural)*
State	Fully Defined
Definition	
Pre-Stress Environment	Static Structural
Pre-Stress Define By	Program Controlled
Reported Load step	Last

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Reported Sub step	Last
Reported Time	End Time
Contact Status	Use True Status

Fig 4.2.2 Pre-stress analysis

Object Name	*Analysis Settings*
State	Fully Defined
Options	
Max Modes to Find	1.
Solver Controls	
Solver Type	Program Controlled
Output Controls	
Stress	No
Strain	No
General Miscellaneous	No
Analysis Data Management	
Solver Files Directory	C:\Users\Nagendra\Documents\axialstressdeformationandstrain files\dp0 \SYS-1\MECH\
Future Analysis	None
Scratch Solver Files Directory	
Save MAPDL db	No
Delete Unneeded Files	Yes
Solver Units	Active System
Solver Unit System	Mks

Table 4.2.3 Linear Buckling and Analysis Settings

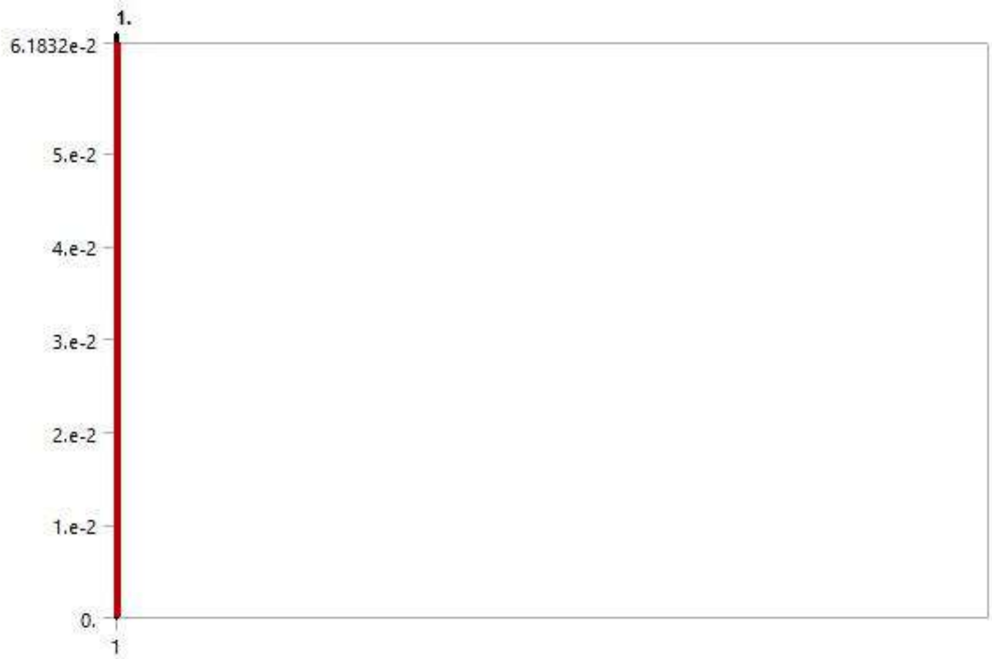

Fig4.2.4 Static structural Linear Buckling

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Boundary condition

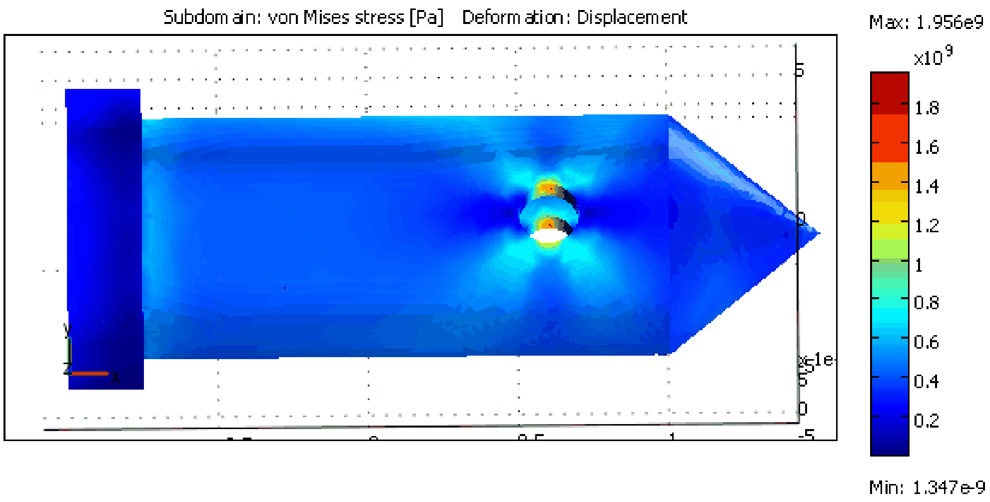

Fig 5.2 Von mises stress and displacement

The base of the Micro-needles is attached to some other device. So the base surfaces are fixed with respect to the rest of the micro-needle.

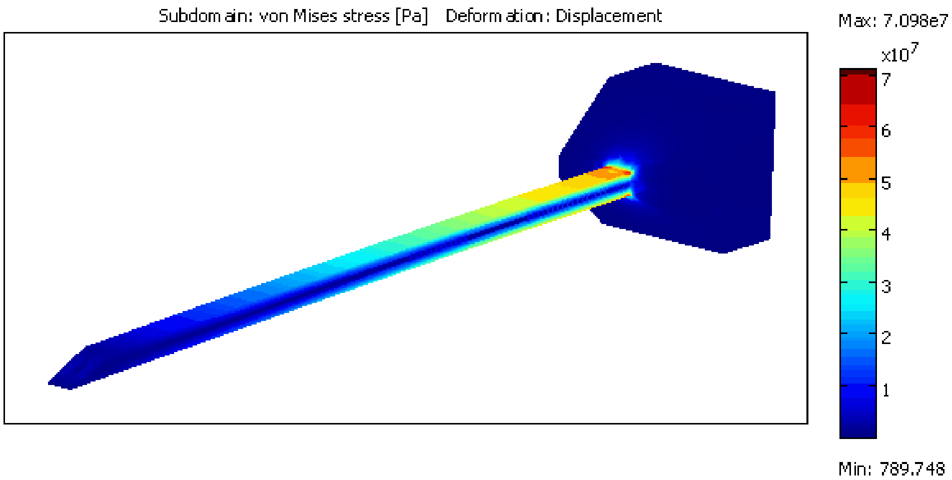

Fig 5.2 Region of maximum stress in the out-of-plane and

CONCLUSION

Structural steel micro-needle that can be used for drug delivery that is capable of inserting fluid in the subcutaneous fat layer.The maximum buckling and bending force that the micro-needle structures can withstand was simulated and analysis. Since the resistive force offered by the human skin was found to be significantly smaller than the maximum buckling and bending forces, it may be concluded that the micro needles which are made up of structural steel with given dimensions are capable of penetrating the skin without breakage. Finally it can be established from simulation and analysis results that the maximum stress and fluid flow rates were satisfactory for the chosen area of the micro-needle. The presented work provides useful information analysis and simulates optimized design of hollow silicon micro-needle array for biomedical applications.

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WORK TO BE EXTENDED IN FUTURE

From the previous and present research analysis it has been conclude that the work can be extended in the following field.

1. Complete structural analysis of design which includes bending stress, buckling stress.
2. Micro fluidic behavior of the fluid..
3. Fabrication and testing of the micro-needle.
4. Simulation and fabrication of the 2 dimensional arrays of micro needles.
5. Development of dimensional arrays by combining multiple 2 dimensional arrays.
6. Design and coupled metaphysics simulation of a two chamber electrostatic micro-pumps.
7. Exploration of fabrication processes and testing of the fabricated micro pump
8. Vain form.
9. Micro injection for new born child.
10. Special injection for spinal cord patient.

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