POLYMERIC MICRONEEDLE ARRAY FOR AMINO FLUIDIC EXTRACTION DURING PREGNATAL PERIOD

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Abstract: In this paper, a simulation of microneedle array for Amniotic Fluid extraction during 1st/2nd trimester period have been presented. Structural and fluidic analyses have been performed to investigate the mechanical strength of microneedles and fluid flow rate through the lumen regions. The effect of axial and transverse loads on the microneedles during skin insertion is investigated in the stress analysis. Fluidic analysis shows that the proposed design is suitable for Amniotic Fluid extraction because double lumen microneedles is suitable for amniotic fluid extraction and the pressure difference between two lumens is useful to avoid clogging effect. This microneedle array cause the mother and the fetus safe, time consumption is less and reduce miscarriage. Here in this paper the microneedle array has been designed and simulated using COMSOL Multiphysics Package and their structural optimization is also been reviewed.

Keywords: Amniotic Fluid, Microneedle array, Microfluidic.

1. INTRODUCTION:

Down syndrome is the common disease of chromosomal abnormalities, where the mother cell have extra copy of 21st chromosomes. The down syndrome is otherwise called as Trisomy 21. This leads to an abnormal structure which causes mental retardation, with a unique facial body deformities the birth rate of down’s syndrome is one in every 800 -1000 live births. In real life, patients with down syndrome requires a life long care and supports from their families, which will cause a heavy burden to the family members. To recover this abnormalities the method called “Amniocentesis” which is the early detection of finding the fetus anomalies by extracting the amniotic fluid from the amnio sac with the guidance of ultrasound with a hypodermic needle.

2. EXISTING DETECTION METHODS OF DOWN SYNDROME:

There are three different methods for Down syndrome detection during first and second trimester of pregnancy,

- Ultrasound marker
- Maternal serum marker assessment and
- Genetic examination of amniotic fluid or fetus blood.

Table 1: Comparison for three Methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Invasiveness</th>
<th>Gestational Age</th>
<th>Risk</th>
<th>Operation Duration</th>
<th>Recovery Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasound marker</td>
<td>Noninvasive</td>
<td>1st trimester</td>
<td>low</td>
<td>30 min</td>
<td>None</td>
</tr>
<tr>
<td>Maternal serum marker</td>
<td>Noninvasive</td>
<td>1st, 2nd trimester</td>
<td>low</td>
<td>&lt;5 min</td>
<td>Negligible</td>
</tr>
<tr>
<td>Genetic Examination</td>
<td>Invasive</td>
<td>2nd trimester</td>
<td>Min 1-2%</td>
<td>30 min</td>
<td>1 day</td>
</tr>
</tbody>
</table>

3. AMNIOTIC FLUID EXTRACTION:

Genetic testing include Amniocentesis and chorionic villus sampling (CVS), the process of extracting amniotic Fluid for analysis to determine the presence of genetic defects during pregnancy. This method is a confirmatory testing for chromosomal abnormalities detection which provides high accuracy as compared to previous described two methods.

3.1. Procedure:

The start of the procedure, a local anesthetit can be given to the mother in order to relieve the pain felt during the insertion of the needle used to withdraw the fluid. After the local is in effect, a needle is usually inserted through the mother’s abdominal wall, then through the wall of the uterus, and finally into the amniotic sac. With the aid of ultrasound-guidance, a physician punctures the sac in an area away from the fetus and extracts approximately 20 ml of amniotic fluid. Amniocentesis is used for diagnosis of chromosomal and other fetal problems.

The risk for complications or miscarriage from having an amniocentesis performed is about 1 out of every 200 women, or 0.5%. Complications include
vaginal spotting or bleeding, leakage of amniotic fluid, severe cramping, fever, or infection.
Current needle used for is an 8.9 cm, 22--gauge Quincke spinal needle.

4. PROBLEM DEFINITION:
The problem due to this hypodermic needle is that the needle tip may be against the fetus, umbilical cord, or placenta; secondary to debris in the needle lumen; tenting of the membranes. Fetus can move onto a needle if it is not placed deep enough and also, a posterior placenta can thrust against a needle by a contraction during aspiration, either leading to injury or bleeding when the needle tip is sharp. Significant blood contamination of the amniotic fluid after amniocentesis occurs in every instance if evaluated at a second look procedure; the blood contamination is higher when an anterior placenta is traversed with the needle. A new microneedle proposed that may overcome these disadvantages of the current used needle is described here.

4.1. Anonymous design to overhead the existing problem:
This paper mainly deals with the simulation of the microneedles array for the amniotic fluid extraction which reduces the clogging effect in skin. The length of this microneedle array is 5000µm. The lumen has a circular tip. This microneedle array does not reach up to the umblical cord. It reaches only the tip of the amniosac. So they do not cause damage to the baby. This microneedle reduces the insertion pain. The overall microneedle array insertion causes only a minimal amount of strain around the umbical cord. The material used for microneedle array is made of functionalized polymeric material, the purpose of using the polymeric material is due to the fact that they behave more elastically and less plastically with respect to the inverse hall petch relation for the bulk microstructured materials.

The physics used in the design is structural mechanics under MEMS module in COMSOL Multiphysics suite and the domain equations where extracted from the material.

5. STRUCTURE DESIGN:

5. SIMULATION RESULTS:
The proposed design of the micro needle array is simulated using Comsol Multiphysics simulation package. The stress and strain recurred, when inserted into the skin occurred using this array structure has been calculated using the physics. The deformation occurred during the application of the pressure has also been studied.

The model 1, figure 2 describes the different layers of the skin with an array of microneedles on its top impinging the skin. On applying the body load on each and every needles it has been inferred that some microneedles may even damage the growth tissues. The unusual bending of the microneedles have been shown in the figure 3
In the view of rectifying the unusual behavior of the microneedles, the optimized design is shown in the figure 8, here the extracted amino fluid is drained in to the cantilever array to test for the protein threshold availability.
6. RELIABILITY ANALYSIS:

<table>
<thead>
<tr>
<th>Failure modes</th>
<th>Reason for failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical failure</td>
<td>Material (functionalized needle)</td>
</tr>
<tr>
<td>Architectural</td>
<td>Structure (microstructure)</td>
</tr>
<tr>
<td>Mechanical</td>
<td>Function (unusual bending)</td>
</tr>
</tbody>
</table>

8. CONCLUSION:

This microneedle array used for amniotic fluid extraction is used to reduce the clogging effect and miscarriages. The structural analysis, stress and fluidic analysis has been made and verified for the safe usage.

REFERENCES:


