Akina, Inc.
Restiex™ Reshapable Tissue Expander

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“Delayed Hydrogel Tissue Expander”
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Presentation does not necessarily represent the views of the NIH.
Current: Tissue Expansion

Tissue expansion is the process by which mucosa is slowly stretched over the course of 2-6 weeks causing a flap of new tissue to grow which can subsequently be utilized to cover over a permanent implant.

Clinical Problem

Current expanders utilize a silicone shell and are either filled externally or self-filling in either case they can not be altered at time of implantation.
Akina Solution

• Biocompatible, elastic, biodegradable, chemically-crosslinked hydrogel
• Delayed swelling characteristics built into the hydrogel itself
• The hydrogel to be cut by the surgeon at time of implantation to best fit the desired void volume.
# In-Vitro Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Method</th>
<th>Value (+/-STDEV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swell Pressure</td>
<td>Swelling in 0.154M HCl under stationary force probe</td>
<td>794 ± 362 mmHg (N=12)</td>
</tr>
<tr>
<td>Elasticity</td>
<td>Compression-stress/strain slope 0-2%</td>
<td>9.5 ± 6.1 kPa (N=12)</td>
</tr>
<tr>
<td>Relaxation</td>
<td>Compression- held 60 seconds at 10% strain initial/T=60</td>
<td>51.6 ± 5.0% (N=12)</td>
</tr>
</tbody>
</table>

Swelling (mass change) 37C in PBS

<table>
<thead>
<tr>
<th>Days</th>
<th>1</th>
<th>5</th>
<th>12</th>
<th>33</th>
<th>47</th>
<th>61</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swell ratio (wd/wt=x)</td>
<td>1.7</td>
<td>2.1</td>
<td>2.4</td>
<td>2.8</td>
<td>2.7</td>
<td>2.9</td>
</tr>
</tbody>
</table>
In-Vivo Study success

- In addition to extensive in-vitro testing of over 180 prototypes, 11 prototypes have been tested in vivo in a rat-scalp expansion model. In this model the skin was successfully expanded as shown below.

- The reviewing clinical pathologist remarked that the biocompatibility was so good that the tissue reaction appeared similar to that of the reaction to surgical grade steel.

- The expanders are currently in dog-jaw model in-vivo testing stages.
Summary

- Akina Offers a novel hydrogel based technology which can overcome clinical problems associated with tissue expansion in dental application.
- Akina is seeking a strategic partnership for the further development of this material into a clinical product.
- Akina Inc. Restiex technology is at the edge of exponential growth. Akina Inc. is looking for a partner for scale-up GMP manufacturing and clinical trials.
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