Efficacy and safety of a newly developed polylactic acid microsphere as an injectable bulking agent for penile augmentation: 18-months Follow up

Hallym University Kangdong Sacred Heart Hospital
Korean University Guro Hospital
Kyungtae Ko, Won Ki Lee, Du Geon Moon, Dae Yul Yang
Objective

- Soft tissue fillers are one of the mainstay treatments for non-surgical treatment of soft tissue augmentation.
- Several soft tissue fillers such as collagen, HA, PLLA, PLGA PMMA, have been used for penile augmentation (PA).
- Polylactic acid (PLA) fillers are widely used for cosmetic volume augmentation.
- Long-term follow-up results of PLA on penile augmentation are not confirmed.
- The aim of this study is to evaluate the long-term efficacy and safety of a newly developed PLA filler for PA during an 18-month follow-up period.
Material and Methods

- Twenty three healthy adult men, aged 20 to 65
- Prospective, single-arm, multicenter study
- Penile girth was measured
  - at proximal-, mid-, and distal-shaft
  - At base line, 3, 6, 12, and 18 months
- Subjects’ satisfaction was assessed with visual analogue scale
- Mean injected volume was 20 mL.
- The PLA filler used in our study (PowerFill®; REGEN Biotech, Inc., Seoul, Korea) is a newly developed filler for soft tissue augmentation.
Results
Results

Before injection | After injection

(a) Immediate after injection

(b) After 18 months
Results

(a) Baseline  (b) After 6 months  (c) After 18 months.
## Results

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Cases</th>
<th>Degree</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection site induration</td>
<td>2 (8.7%)*</td>
<td>mild, transient</td>
<td>antibiotics and NASIDs</td>
</tr>
<tr>
<td>Injection site inflammation</td>
<td>1 (4.3%)*</td>
<td>mild, transient</td>
<td>antibiotics and NSAIDs</td>
</tr>
<tr>
<td>Painful erection</td>
<td>1 (4.3%)</td>
<td>mild, transient</td>
<td>none</td>
</tr>
<tr>
<td>Penile curvature</td>
<td>1 (4.3%)</td>
<td>mild, transient</td>
<td>none</td>
</tr>
<tr>
<td>Penile erythema</td>
<td>1 (4.3%)</td>
<td>mild, transient</td>
<td>none</td>
</tr>
</tbody>
</table>
Conclusion

Penile injection of a newly developed PLA filler led to a significant augmentative effect of the penis for up to 18 months.

And was well tolerated without serious AEs.

Thank you.