A Prospective, Randomized, Controlled Clinical and Radiological Study to Evaluate and Compare the use of Silicated Calcium Phosphate and rh-BMP2 in Interbody Lumbar Spine Fusion. 36 month follow-up

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Study Design

- Prospective
- Comparative
- Randomized
- Single Center

DDD at L4L5 with no previous surgery

Single level standalone XLIF

15 patients
Silicated substituted calcium phosphate

X

15 patients
Rh-BMP2
Follow-up

CLINICAL OUTCOMES MEASUREMENT

- PreOp, 1, 6 weeks, 3, 6, 12, 24 and 36 months
- Visual Analogue Scale and Oswestry Disability Index

FUSION STATUS ASSESSMENT

- 6, 12, 24 and 36 months
- X-Ray and CT
### Fusion Criteria: Guidance Document for the Preparation of IDEs for Spinal Systems - FDA

<table>
<thead>
<tr>
<th>Criteria observed by Radiologist to confirm status of fusion</th>
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<tbody>
<tr>
<td><strong>1. Fusion:</strong> Bridging bone fills &gt;50% of the space available for fusion between the vertebral bodies.</td>
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<tr>
<td><strong>2. Bridging bone:</strong></td>
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<tr>
<td>At six months – there is bridging bone but it fills &lt; 50% of space available for fusion between the vertebral bodies.</td>
</tr>
<tr>
<td>At twelve months – there is bridging bone but it fills &lt; 50% of available space for fusion between the bodies and it is significantly better than the six-month status.</td>
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<td><strong>3. Developing bone:</strong></td>
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<tr>
<td>At six months – developing bone is connected to either or both inferior or superior vertebral bodies without bridging.</td>
</tr>
<tr>
<td>At twelve months – developing bone is connected to either or both inferior or superior vertebral bodies without bridging, and it is significantly better that the six-month status.</td>
</tr>
<tr>
<td><strong>4. No early evidence of fusion:</strong></td>
</tr>
<tr>
<td>At six months only – there is no bridging bone or developing bone connected to either the superior of inferior vertebral bodies.</td>
</tr>
<tr>
<td><strong>5. No fusion:</strong></td>
</tr>
<tr>
<td>There is no bridging bone or bridging bone fills &lt; 50% of available space between the vertebral bodies and there is no significant improvement compared to the six-month status.</td>
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<td>Translational &lt; 3mm</td>
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<tr>
<td>Angular &lt; 5°</td>
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Clinical Experience

18 Female
12 Male
Mean Age: 47.6 Years
Mean BMI: 25.2

Blood loss: < 50 cc
Hospital discharge: 24h
No intraOp adverse event

Follow-up up to 48m
Mean follow-up – 40m
Adverse events

- **Adjacent Level Disease**
  4 cases (13.3%)

- **Indirect Decompression not Achieved**
  2 cases (6.2%)

- **Psoas Weakness**
  2 cases (6.2%)

- **Subsidence**
  5 cases (16.7%)
Clinical Outcomes

VAS

- Actifuse
- Infuse

ODI

- Actifuse
- Infuse
Fusion Status

Fusion Rate

- Actifuse
- Infuse

6 months | 12 months | 24 months | 36 months

- No Fusion
- Developing
- Fusion
Infuse (rh-BMP2): L4-L5 Stand Alone

9 month Follow Up → Solid Fusion
Actifuse®: L4-L5 Stand Alone

12 month Follow Up

XLIF® Experience
Infuse (rh-BMP2): L4-L5 Stand Alone

Preop Pop Early

12 month Follow Up

Excessive bone formation
Conclusion

In standalone XLIF:

- SicaP stimulates bone formation;
- In comparison with rhBMP-2, fusion rate is similar after 12 and 24 months;
- rhBMP-2 may cause excessive bone formation, threatening neural structures.