Finceramica regenerative surgery

# PAPER SUMMARY

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| **Title** | A New Bioinspired Collagen-Hydroxyapatite Bone Graft Substitute in Adult Scoliosis Surgery: Results at 3-year Follow-Up |
| **Journal** | J Appl Biomater Funct Mater.2017 |
| **Authors** | Giorgi P. al. |
| **Study type** | Retrospective study |
| **Product type** | RegenOss, a new-generation composite material made of Mg-doped HA and type I collagen of equine origin |
| **Indication** | Adult degenerative scoliosis |
| **Objective(s)** | To investigate the efficacy of RegenOss (mixed with local augoraft bone, LAB) in spinal fusion for the treatment of adult scoliosis. |
| **Primary aim** | 1) Evaluation of fusion at 6, 12 and 24 months FU assessed using radiographic parameters (Lenke classification). |
| **Secondary aims** | 2) Evaluation of clinical recovery assessed with clinical parameters (Oswestry Disability Index (ODI), Visual Analog Scale (VAS) for pain and neurological assessments) at 6, 12 and 24 months FU.<br>3) Safety (adverse events recording). |
| **Sample size/ Site number** | N=41 subjects included in the retrospective study, 1 single center (Niguarda Hospital, Milan, Italy) |
| **RESULTS** | |
| **Patients demographics and levels fused** | • Total patients: N=41;<br>• mean age: 63 years;<br>• 31% had previous spinal surgeries;<br>• All the patients underwent at least the fusion of two vertebral levels, up to 10 vertebral levels fused. |
| **Primary ENDPOINT: spinal fusion** | Spinal fusion was evaluated by the use of the Lenke classification system.<br><br>**TABLE II** - Lenke classification of posterolateral fusion success<br><br>Grade A: Definitely solid, with bilateral trabeculated stout fusion masses present.<br><br>Grade B: Possibly solid, with a unilateral large fusion mass and a contra-lateral small fusion mass.<br><br>Grade C: Probably not solid, with a small fusion mass bilaterally.<br><br>Grade D: Definitely not solid, with bone graft resorption or obvious pseudarthrosis bilaterally.<br><br>Lenke classification system used to radiographically evaluate the degree of fusion.<br><br>Fusion was evaluated at 6, 12 and 36 months after surgery. |

**TABLE V** - Evaluation of spinal fusion (Lenke classification)

| | Lenke classification | | |
|---|---|---|---|
| | **6 months** | **12 months** | **36 months** |
| Grade A | 10 (24.4%) | 23 (56.1%) | 25 (61.0%) |
| Grade B | 21 (51.2%) | 16 (39.0%) | 14 (34.1%) |
| Grade C | 9 (22.0%) | 2 (4.9%) | 2 (4.9%) |
| Grade D | 1 (2.4%) | 0 (0.0%) | 0 (0.0%) |

Values are represented as numbers of patients (%).

**Secondary Endpoint I: Neurological outcomes**

The Oswestry Disability Index (ODI) and the Visual Analog Scale (VAS) for pain and neurological assessments statistically differed between pre-op and post-op surgery.

**TABLE VII** - Oswestry Disability Index (ODI) evaluation

| | Oswestry disability index | | | |
|---|---|---|---|---|
| | **Baseline** | **6 months** | **12 months** | **36 months** |
| No. | 41 | 41 | 41 | 41 |
| Mean | 72 | 34.6 | 25.5 | 23.0 |
| SD | 5.79 | 8.79 | 14.91 | 12.65 |
| Change from baseline | | | | |
| Mean | - | -37.4 | -46.5 | -49 |
| p value | - | <0.0001 | <0.0001 | <0.0001 |

Time course of oswestry disability index (ODI) scores. ODI values significantly decreased for all follow-up time points, vs. basal values.

**TABLE VIII** - Visual Analog Scale (VAS) evaluation

| | Visual analog scale | | | |
|---|---|---|---|---|
| | **Baseline** | **6 months** | **12 months** | **36 months** |
| No. | 41 | 41 | 41 | 41 |
| Mean | 8.6 | 4.5 | 2.8 | 2.2 |
| SD | 0.73 | 1.19 | 1.74 | 1.56 |
| Change from baseline | | | | |
| Mean | - | -4.1 | -5.8 | -6.4 |
| p value | - | <0.0001 | <0.0001 | <0.0001 |

Time course of visual analog scale (VAS) score. Mean VAS values significantly decreased for all follow-up time points, vs.basal values.

**Secondary Endpoint II: SAFETY**

No post-op recorded.

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## DISCUSSION & OVERALL CONCLUSIONS

1) The patients' population was complex, made of subjects requiring more than vertebrae to be fused together.
2) After 6 months, a good level of fusion was achieved by the majority of patients (24.4% Grade A, 51.2% grade B); less than 30% had incomplete fusion (grade C and D);
3) At 12 months follow-up, 56% of patients showed complete fusion (grade A); while grade A improves, grade B decreases;
4) After 36 months, the majority of patients (61%) showed complete bony fusion (grade A); in total 95% of patients reached a good fusion (grade A and B);
5) Partial incomplete fusion (grade C) was constant after 12 months follow-up, and was not related to baseline or clinical parameters.
6) ODI and VAS scores for neurological assessment showed a drastic decrease, meaning that fusion surgery was effective and pain was reducing during time.

**Concerning the BS RegenOss:**

7) Due to its chemico-physical features and shape, RegenOss was appositely employed as effective BS to achieve long spinal fusion in the treatment of adult scoliosis, a pathology that affects long parts of the spinal column.
8) The device was **safely** used also when mixed with autologous bone: no adverse events were indeed reported. A number of patient-related risk factors were evaluated, and none affected the good outcome on the use of RegenOss for spinal fusion.
9) The PERFORMANCE and SAFETY of the HA-based bone graft substitute RegenOss is confirmed.