Regenerative Therapy using Bovine Bone Mineral shows Stable Long-term Results: A Practice-based Study

- Retrospective Clinical Cohort Study -

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Aim

... was to evaluate whether evidence from randomized clinical trials on the successful treatment of intrabony defects by regenerative therapy can be transferred to patients in a periodontal practice.
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Regenerative therapy in comparison to open flap debridement
CAL gain 1 year after regenerative procedure

2004 Tonetti M et al., J Clin Periodontol 31: 770-776
2005 Sculean A et al., J Clin Periodontol 32: 720-724
Material and Methods

In 191 patients a total of 1099 teeth with intrabony defects were treated using bovine bone mineral with or without collagen membrane. Defects were classified as 1- and 2-wall and as shallow (≤ 6 mm), moderate (7-10 mm) and deep (≥11 mm).

A total of 1008 defects in 176 patients were monitored clinically and radiographically for collection of 1-year short-term, mid-term (2-4yrs) and long-term (5-10yrs) data. 15 patients were excluded from analysis because they were lost to follow-up (no compliance or supportive care alio loco). Change in radiographic bone levels was used as primary outcome parameter.
Patient characteristics:  N = 176

- men N=80 (46.9%) / women N=96 (53.1%)
- age 49.8 (±27) yrs.
- smokers N=44 (25%)
- average N of rtx defects per pat: 5 (1-21)

Patient inclusion criteria:
- Complete set of x-rays and data available
- Able to perform adequate OH
- Compliance with SPT regimen
- Smokers and systemic diseases not excluded
- Informed consent

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<th>N</th>
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Data from multilevel analysis on patient level and defect level
Defect characteristics:  N = 1008

1-wall defects 25% / 2-wall defects: 75%
smokers' defects N=292 (29%)

Regenerative treatment using
bovine derived bone mineral\textsubscript{coll.} [BDX]

4 treatment variations:
- BDX alone
- BDX + bioresorbable membrane [brM]
- BDX + EMD
- BDX + EMD + brM

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</table>
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Principles of Surgical Procedure:

- Access flap with microsurgical tools
- Degranulation
- Root Planing
- Clinical bone level measurement
- Defect filling with BDX
- Membrane when indicated
- Split flap for tension free closure
- Closure by atraumatic suturing
- Suture removal and following post-op. care
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**Defect Size Groups:**

- Large ≥ 11mm: 13%
- Medium ≥ 6mm and < 11mm: 56%
- Small < 6mm: 31%

**Tooth loss over time: average 2.6%**

- Small defects: 1.57%
- Medium defects: 1.37%
- Large defects: 5.71%

**Principles of Defect follow-up**

- Intrasurgery clinical bone level measurement
- Deepest of defects at regen. treated tooth
- Follow-up X-ray at 1 year (t₁)
- Follow-up PD measurement 1/a (every year)
- Follow-up X-ray at 3y / 5y / 7.5y / 10y [mean t₂/t₃]
- Collection of all data (bone level, PD, Mob.)
- Compare last x-ray and clinical data
- Evaluate bone level gain as ΔL
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Defect characteristics
all teeth/all defects
BL to 1y: N=1008 / BL to LongTerm: N=226

BL = time of intrasurgery measurements after antiinflammatory therapy

t1 = time of clinical and radiographical control, 1 year after reg. surgery

t2 = time of clinical and radiographical control, 2-4 years after reg. surgery (average 3.2 yrs)

t3 = time of clinical and radiographical control, 5-10 years after reg. surgery (average 6.8 yrs)
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Results
Overall a mean radiographic bone fill of >50% was observed. Deep and moderate defects showed a higher degree of reconstruction than shallow defects (54.5% vs. 50% vs. 43.3%). Radiographic bone gain obtained at 1 year remained stable during mid-term and long-term follow-up. Tooth loss amounted to 2.6%, was dependent on initial defect size (1.2% for shallow, 1.4% for moderate, 5.7% for deep defects) and occurred mainly due to endodontic reasons.
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**Result**

**Patient related data**
long-term evaluation, most severe defects

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**Significant bone level change BL/t1 and BL/t3:**
p<0,005 shown in patient related data

No significant bone level change shown for t1/t2, t1/t3, t2/t3

$$\Delta_{L,abs\ [t1/t3]} = 5,04mm \quad \Delta_{L,med\,rel} = 54,45\%$$
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Defect related data / site level
Bone level change by defect morphology

Significant bone level change BL/t₁ and BL/t₃: p<0.005 shown in all defect types

No significant bone level change shown for t₁/t₂, t₁/t₃, t₂/t₃

Interaction effects:
- n.s. shown for smokers (29%)
- n.s. shown for n.wall
- n.s. shown for Tx variations
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**Result**

**Defect related data / site level**
Bone level change by treatment variation

- **Significant bone level change** $BL/t_1$ and $BL/t_3$: $p<0.005$ shown in all defect types
- No significant bone level change shown for $t_1/t_2$, $t_1/t_3$, $t_2/t_3$
- Interaction effects:
  - n.s. shown for smokers (29%)
  - n.s. shown for n.wall
  - n.s. shown for Tx variations
Conclusion

... under conditions of daily periodontal practice regenerative treatment with bovine bone mineral with or without collagen membrane can lead to a mean defect resolution of greater than 50% and can be maintained up to 10 years after surgical intervention in patients with compliance to periodontal supportive care.
Clinical consequences and suggestions

- High **predictability** of regenerative treatment of severe defects, leading to good **long-term prognosis**
- Consider **periodontal reconstruction instead of tooth removal** and prosthodontic treatment
- ? Impact of orthodontic movement?
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**Study Coworkers**

Anne **Hinz**, Dentist, Data Collection & Radiographic Measurements  
Frank **Bröseler**, Periodontist, Therapy Supervision & Surgery  
Christina **Tietmann**, Periodontist, Therapy Supervision & Surgery  
Nadja **Sadr**, Dental Hygienist (ZMF), Maintenance Therapy  
Deborah **Meisen**, Dental Hygienist (ZMP), Maintenance Therapy  
Søren **Jepsen**, Chair of Perio Dpt., Univ. Bonn, Scientific Supervision  
Michael **Mayer**, Consult AG, Bern/CH, Statistical Analysis  

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