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

- Retrospective Clinical Cohort Study -

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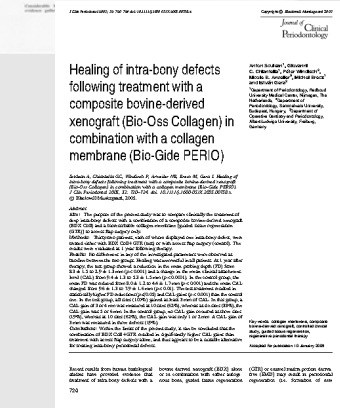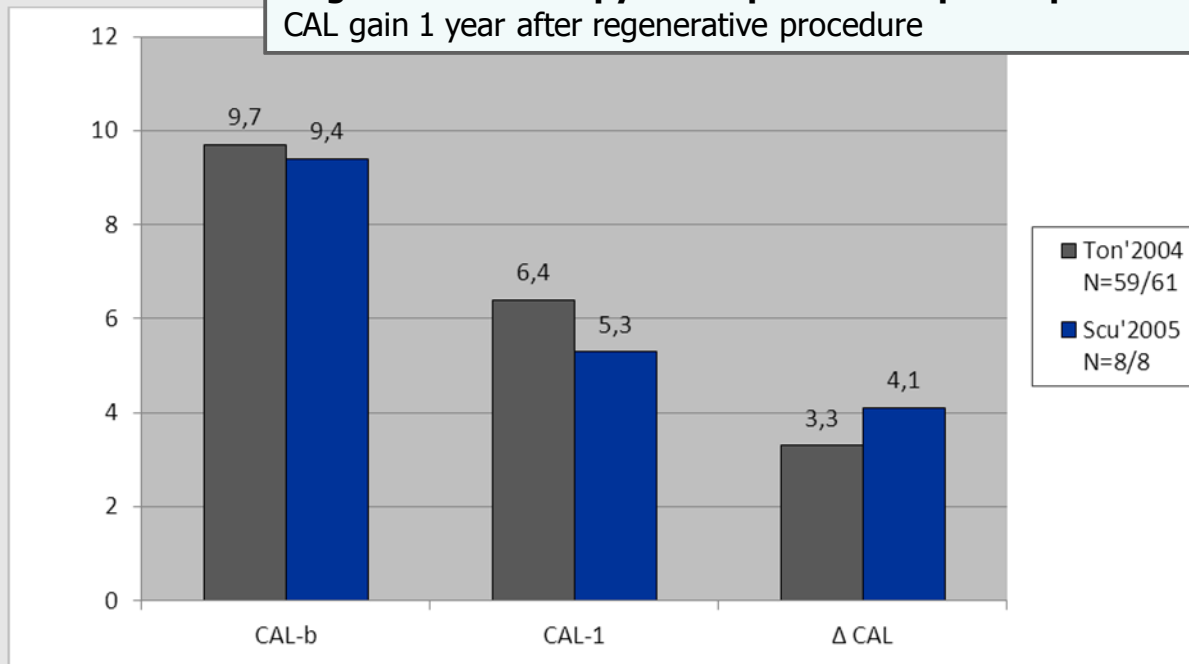Operative and Preventive Dentistry
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Aim

… 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

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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**.

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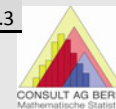
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Patient characteristics: N = 176

- 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

Data from multilevel analysis on patient level and defect level

Variable	Level	N	%
male	0	535	53.1
male	1	473	46.9
smoke	0	716	71.0
smoke	1	292	29.0
nwand	1	267	26.5
nwand	2	741	73.5
treatment	A.Oss	403	40.0
treatment	B.Oss.Gide	504	50.0
treatment	C.Oss.EMD	62	6.2
treatment	D.Oss.Gide.EMD	39	3.9
cal.0.strat	A.small	310	30.8
cal.0.strat	B.medium	570	56.5
cal.0.strat	C.large	128	12.7
pd.4mm.0	0	713	70.7
pd.4mm.0	1	295	29.3

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Mathematische Statistik

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Defect characteristics: N = 1008

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

Regenerative treatment using
bovine derived bone mineral$_{coll.}$ [BDX]

4 treatment variations:

- BDX alone
- BDX + bioresorbable membrane [brM]
- BDX + EMD
- BDX + EMD + brM

Variable	N	Mean	Std	Med	Min	Q1	Q3	Max
age	1008	49.01	9.52	49	26	43	54	77
smoke	1008	0.29	0.45	0	0	0	1	1
male	1008	0.47	0.50	0	0	0	1	1
nwand	1008	1.74	0.44	2	1	1	2	2
cal.0	1008	7.84	2.33	8	3	6	9	18
pd.0	1008	5.82	2.02	6	2	4	7	14
pd.4mm.0	1008	0.29	0.46	0	0	0	1	1

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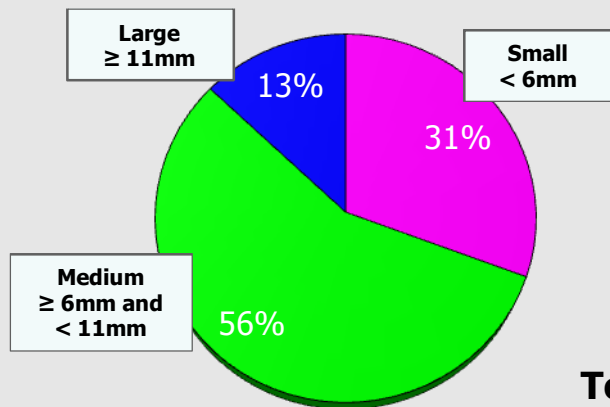Mathematische Statistik

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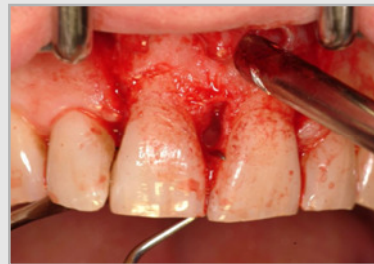
Principles of Surgical Procedure:

- 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

6.9 yrs. post-op.
long term

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Defect Size Groups:

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

Tooth loss over time: average 2,6%
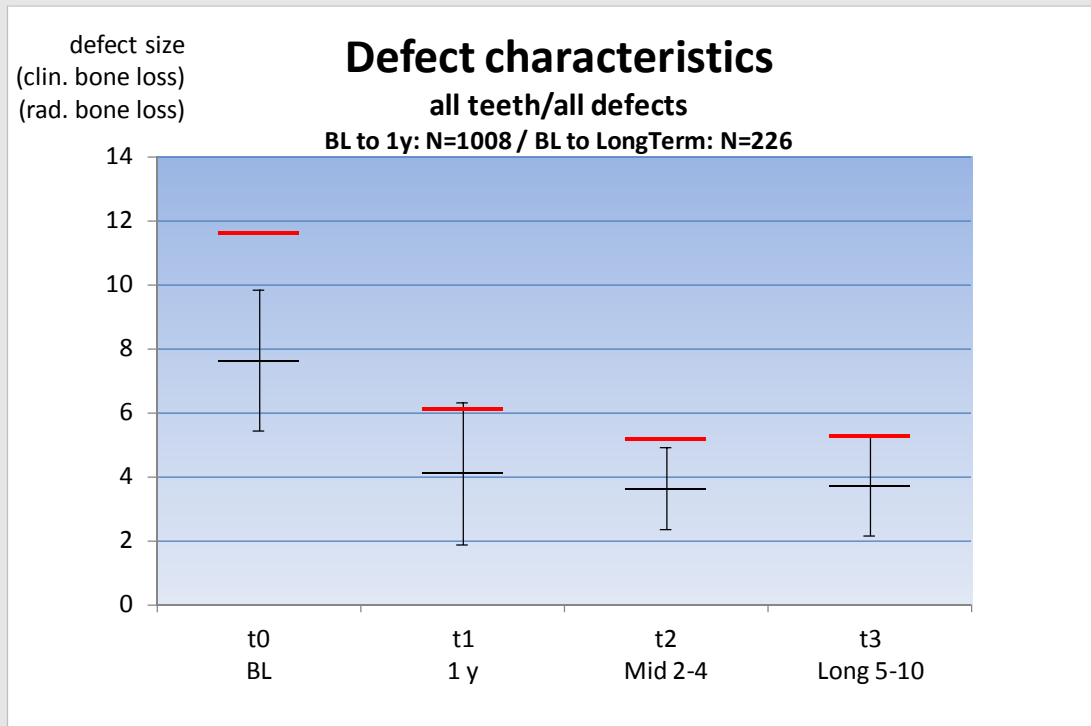Small defects: 1,57%
Medium defects: 1,37 %
Large defects: 5,71%

Principles of Defect follow-up

- Intrasurgery clinical bone level measurement
- Deepest of defects at regen. treated tooth
- Follow-up X-ray at 1 year (t_1)
- Follow-up PD measurement 1/a (every year)
- Follow-up X-ray at 3y / 5y / 7.5y / 10y [mean t_2/t_3]
- 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 size
(clin. bone loss)
(rad. bone loss)

Defect characteristics

all teeth/all defects

BL to 1y: N=1008 / BL to LongTerm: N=226

BL = time of intrasurgery measurements after antiinflammatory therapy
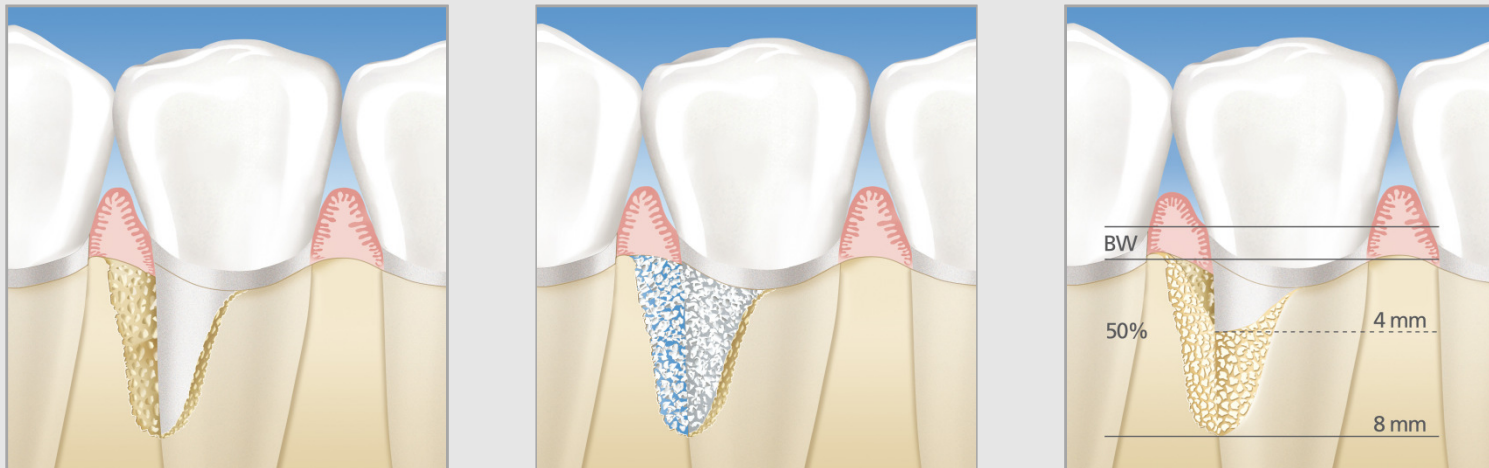
t1 = time of clinical and radiographical control, 1 year after reg. surgery

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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BW

50%

4 mm

8 mm

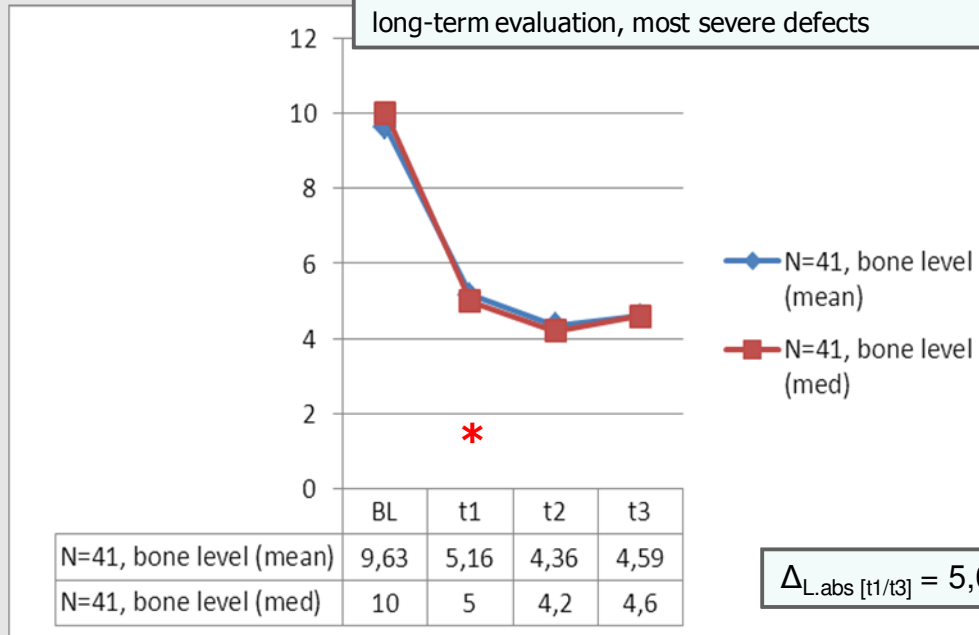Grafic design:
Peter Quirin, Wiesbaden/DE

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 1year 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

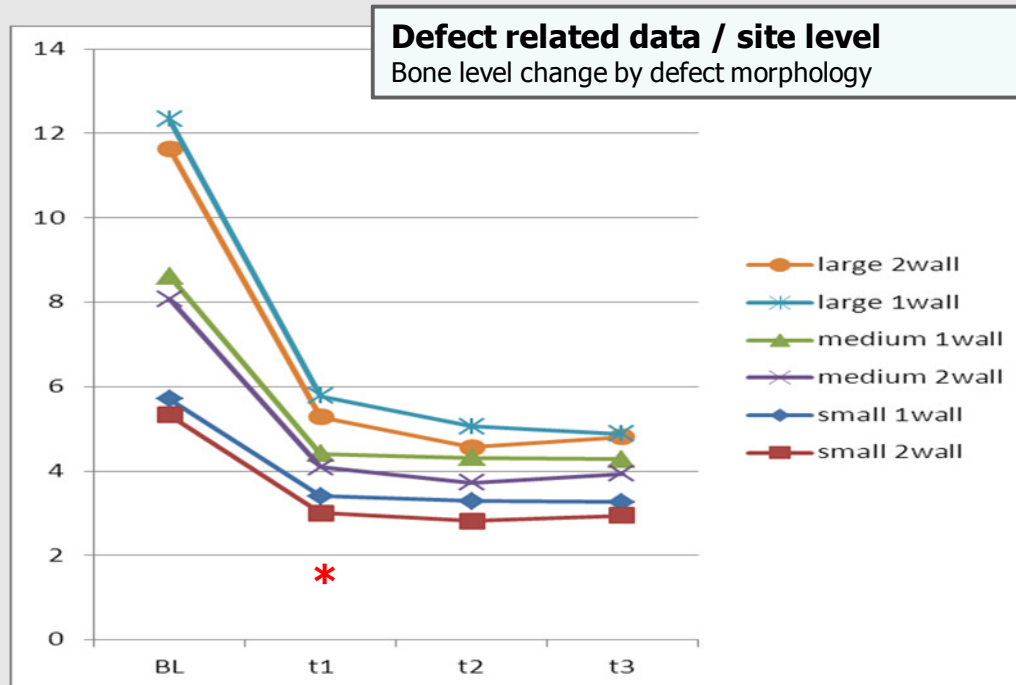|	BL	t1	t2	t3
N=41, bone level (mean)	9,63	5,16	4,36	4,59
N=41, bone level (med)	10	5	4,2	4,6

Significant bone level change BL/t_1 and BL/t_3: $p<0,005$ shown in patient related data

No significant bone level change shown for t_1/t_2, t_1/t_3, t_2/t_3

$\Delta_{L.abs\,[t1/t3]} = 5,04mm \quad I \quad \Delta_{L.med:rel} = 54,45\%$

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Result

Defect related data / site level
Bone level change by defect morphology

Legend:
- large 2wall
- large 1wall
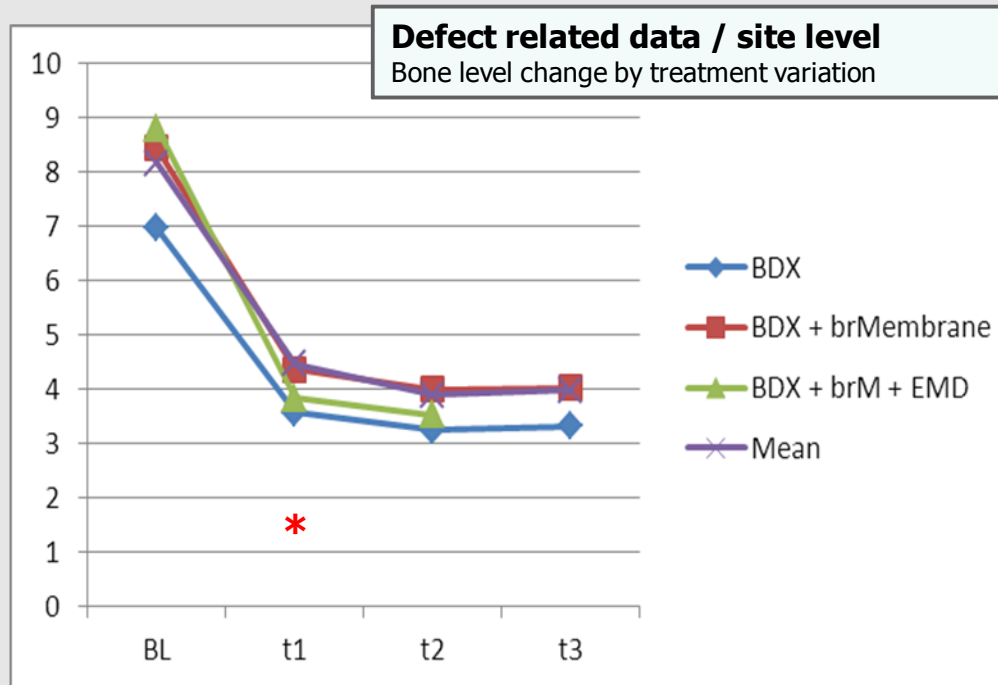- medium 1wall
- medium 2wall
- small 1wall
- small 2wall

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

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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

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Clinical consequences and suggestions

- High **predictability** of regenerative treatment of severe defects, leading to good **long-term prognosis**

- Consider **periodontial reconstruction instead of tooth removal** and prosthodontic treatment

- ? Impact of orthodontic movement ?
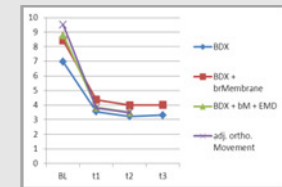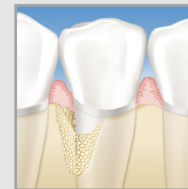
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Michael **Mayer**, Consult AG, Bern/CH, Statistical Analysis

with thanks to Melanie Franke, Claudia Bühlmann, Erk Willing, Peter Quirin

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