UNIVERSITETET
I OSLO

DET ODONTOLOGISKE FAKULTET
Sekretariatet
Postboks 1142, Blindern
0317 Oslo
Besøksadresse:Geitmyrsveien 69

16. November 1999

CLINICAL FACULTY SEMINARS

"KLINISKE FELLESSEMINAR"

Wednesday November 24th, 16.30 - 18.30
Aud. 2, Geitmyrsveien 69

EVIDENCE-BASED DENTISTRY

"Clinical studies on guided tissue regeneration(GTR), are the guidelines and recommendations scientifically based?"

Coordinator: Stip. Asbjørn Jokstad, UiO

All postgraduate candidates and other interested faculty members are welcome

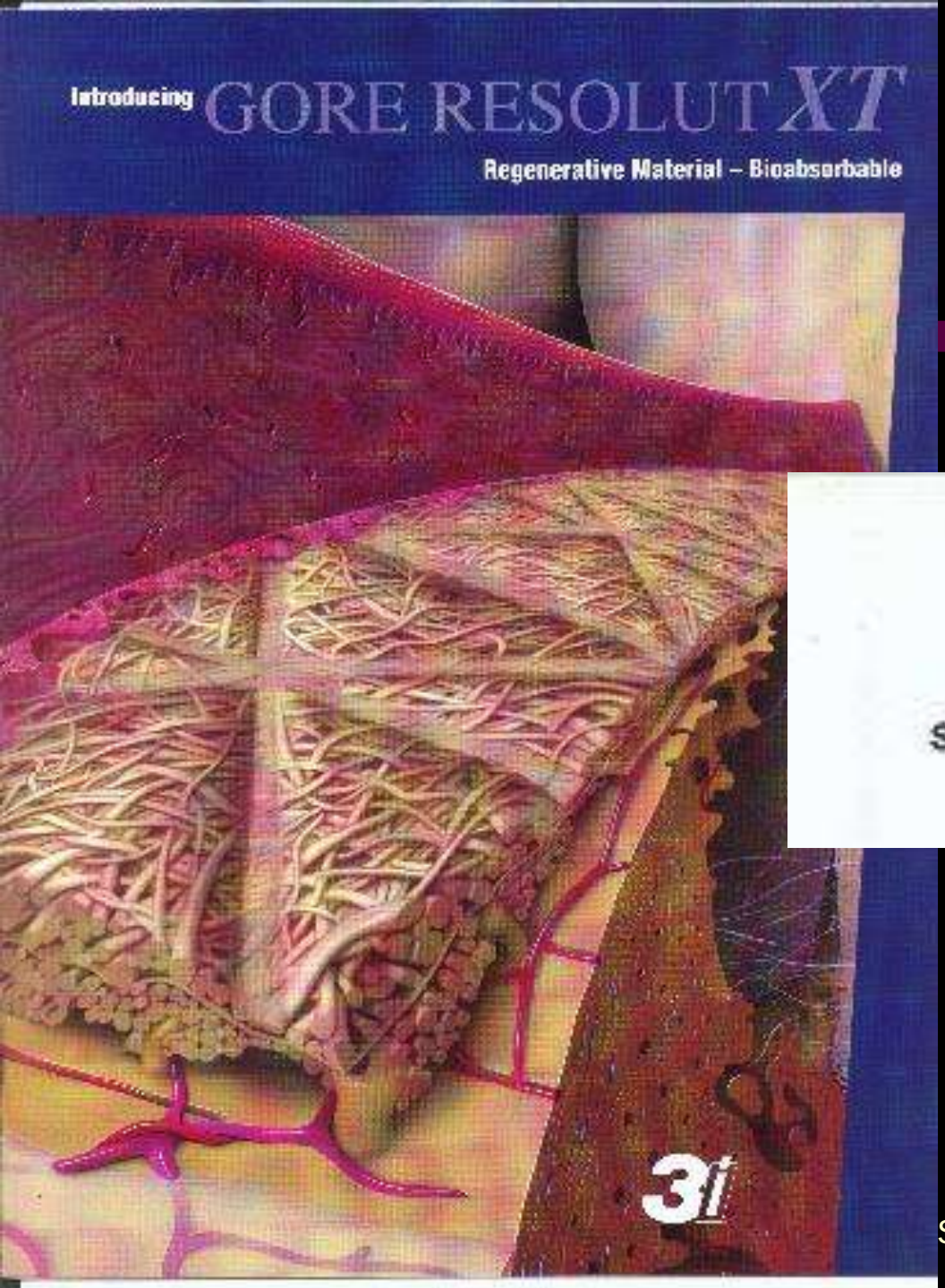
Coffee will be served

Clinical studies on GTR techniques, are they science-based?

Asbjørn Jokstad

Institute of Clinical Dentistry

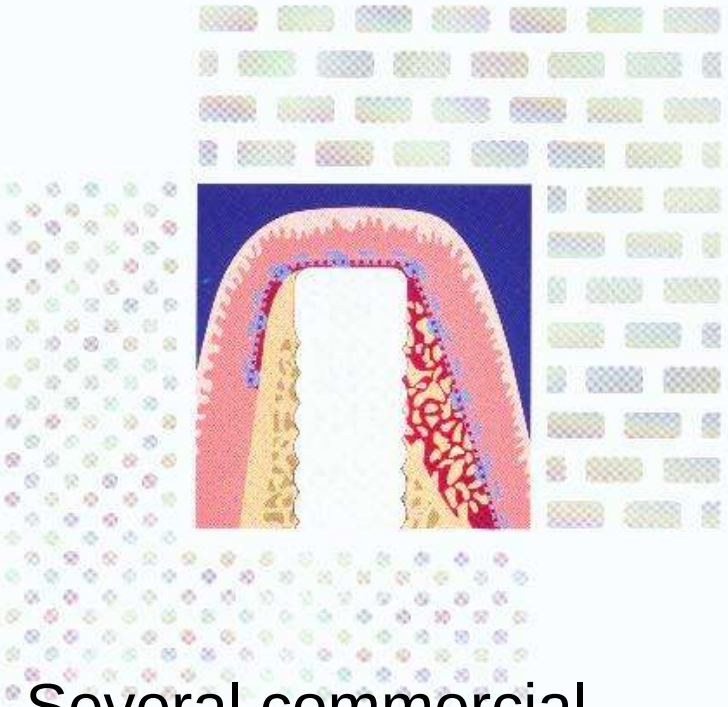
University of Oslo



The commercial pressure on the dental profession has been marked during the last 10 years

There is a concern that perhaps some ”science” used in the advertising for GTR can be questioned...

A new concept in guided bone regeneration



Several commercial companies are active, with Gore, Guidor, and Calcitek being the biggest actors.

GUIDOR®
THE BIORESORBABLE MATRIX BARRIER

Sulzer Calcitek Inc.

A Longer Lasting Membrane

BioMend Extend™

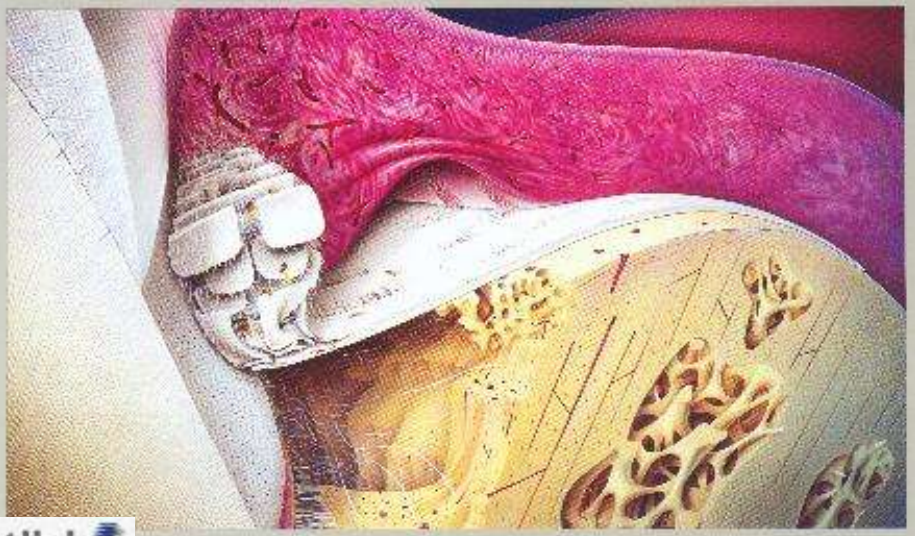
Maintains an Effective Barrier Longer!

week 1 — week 18

Fully Absorbed in 18 Weeks

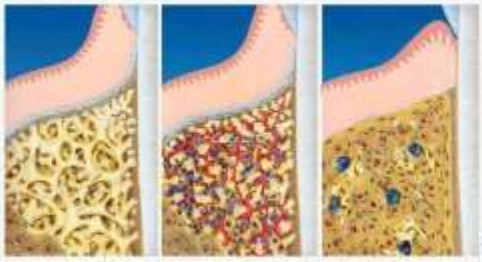
GORE-TEX™ Regenerative Material

Transgingival Configurations



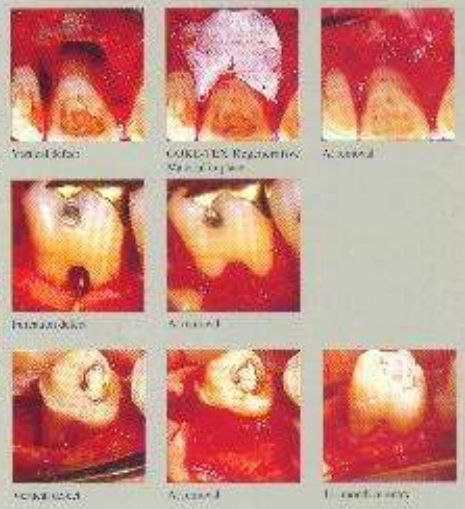
Geistlich Biomaterials

System for Periodontal Tissue Regeneration



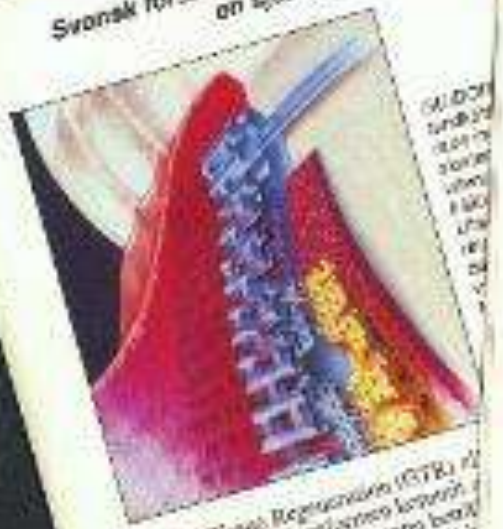
The well-established system for natural bone regeneration, Bio-Oss® and Bio-Gide®, has been expanded to include a system for periodontal tissue regeneration: the PERIO-System, which uses Bio-Oss® COLLAGEN and Bio-Gide® PERIO. Many years of clinical experience and international scientific study trials provide proof of its compatibility for use in periodontal indications.

The new Bio-Gide® PERIO is a cell-occlusive, resorbable bilayer membrane which forms an effective barrier for shielding and protecting the periodontal



SVENSK VÄRLDSNYHET
FÖR BEHANDLING AV TANDLOSSNING

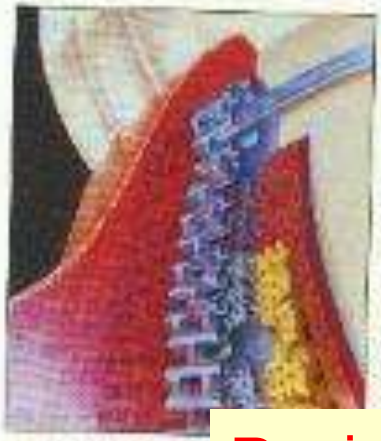
Svensk forskning har resulterat i ett ge
en sjukdom som drabba



Skandinavisk verdensnyhet i behandlingen av tannkjøttsykdommen periodontitt

KARL-GUSTAF EDUNG

Skandinavisk forskning har resultert i et gjennombrudd i behandlingen av sykdom forårsaket av periodontitt, infeksjonssykdommen som rammer over 50% av alle voksne nordmenn.



Periodontitt - en folkesykdom

Review papers are in some cases modified to make the topic appealing to the ”target” group ,eg. Swedish(left) or Norwegian (right) dentists.

Guided Tissue Regeneration -

MESH Definition (1992):

The repopulating of the periodontium, after treatment for periodontal disease. Repopulation is achieved by guiding the periodontal ligament progenitor cells to reproduce in the desired location by blocking contact of epithelial and gingival connective tissues with the root during healing. This blocking is accomplished by using synthetic membranes or collagen membranes.

Emdogain- publication review (n=31)

- 1997: 3 - 1998: 18 - 1999: 4
- Case report / series 11 papers
- Reviews 9 papers
- Clinical trials 4 papers
  - 3 RCT (10), (16), (33)
  - 1 Cohort study (107-33)
- In vitro studies 3 papers
- Animal studies 3 papers
- Meeting abstract 1 paper

Journal of Clinical Periodontology 1982: 9: 290–296

Short Communication

Key words: Millipore filter – new attachment – periodontal ligament – wound healing

Accepted for publication May 21, 1982

New attachment following surgical treatment of human periodontal disease

STURE NYMAN*, JAN LINDHE*, THORKILD KARRING** AND HARALD RYLANDER*

*Department of Periodontology, Faculty of Odontol

**Department of Periodontology, I

Abstract. The present experiment was undertak attachment may form on a previously periodo from the periodontal ligament are enabled to r

A mandibular incisor with advanced periodo cemento-enamel junction and the alveolar bone using a technique which during healing preve connective tissue from reaching contact with the the periodontal ligament cells to repopulate th healing a block biopsy containing the incisor a analysis revealed that new cementum with ins diseased root surface. This new attachment exte alveolar bone crest. This finding suggests that ne the periodontal ligament and demonstrates that is a major preventive factor for new attachmen

Journal of Clinical Periodontology 1984: 11: 494–503

Key words: *New attachment – periodontal ligament – periodontal wound – healing – tissue specificity.*

Accepted for publication August 3, 1983

New attachment formation as the result of controlled tissue regeneration

JAN GOTTLOW[1], STURE NYMAN[1], THORKILD KARRING[2] AND JAN LINDHE[1]

[1]Department of Periodontology, Faculty of Odontology, University of Gothenburg, Gothenburg, Sweden

[2]Department of Periodontology, Royal Dental College, Aarhus, Denmark

Abstract. The present study was designed to examine whether new attachment forms on root surfaces previously exposed to plaque by preventing the oral epithelium and the gingival connective tissue from participating in the process of healing following treatment.

4 roots in each of 3 monkeys were used as test units while the roots of contralateral teeth served as controls. A surgical procedure was first used to expose the coronal half of the buccal root surfaces. Plaque was allowed to accumulate on the exposed surfaces for a period of 6 months. Subsequently, soft tissue flaps were raised and the root surfaces were carefully scaled and planed. The crowns of the test and control teeth were resected and the mucosal flaps were repositioned and sutured in such a way that the roots were properly covered. Immediately prior to suturing, membranes (Millipore® filter or Gore-tex® membrane) were placed over the denuded root surfaces of the test teeth in order to prevent granulation

GTR techniques- science based?

- Define the given topic
- What characterizes “science-based” ?
  - Types of clinical studies
- Descriptive bibliometric data
- Critical appraisal of clinical studies
- Are “GTR techniques” science based?

Clinical studies -GTR techniques -Science-based

Topic definition:

As clinicians we should train to interpret need for clinical information into well-formulated questions.

Well built clinical questions include the four elements:

1. Patient or problem
2. Intervention
3. Intervention comparison
4. Outcome

Well built clinical questions include

1. Patient characteristics and problems:
   - Adults / Adolescents ?
   - Smokers/tobacco users ?
     - Bone loss ?
       - Severity
       - Extent: General / local
       - Morphology: Horizontal / vertical
       - Location: proximal/interradicular
       - After 3d. molar extractions
     - Implant placement?
       - prior
       - at installation
     - Alveolar ridge maintenance

Well built clinical questions include

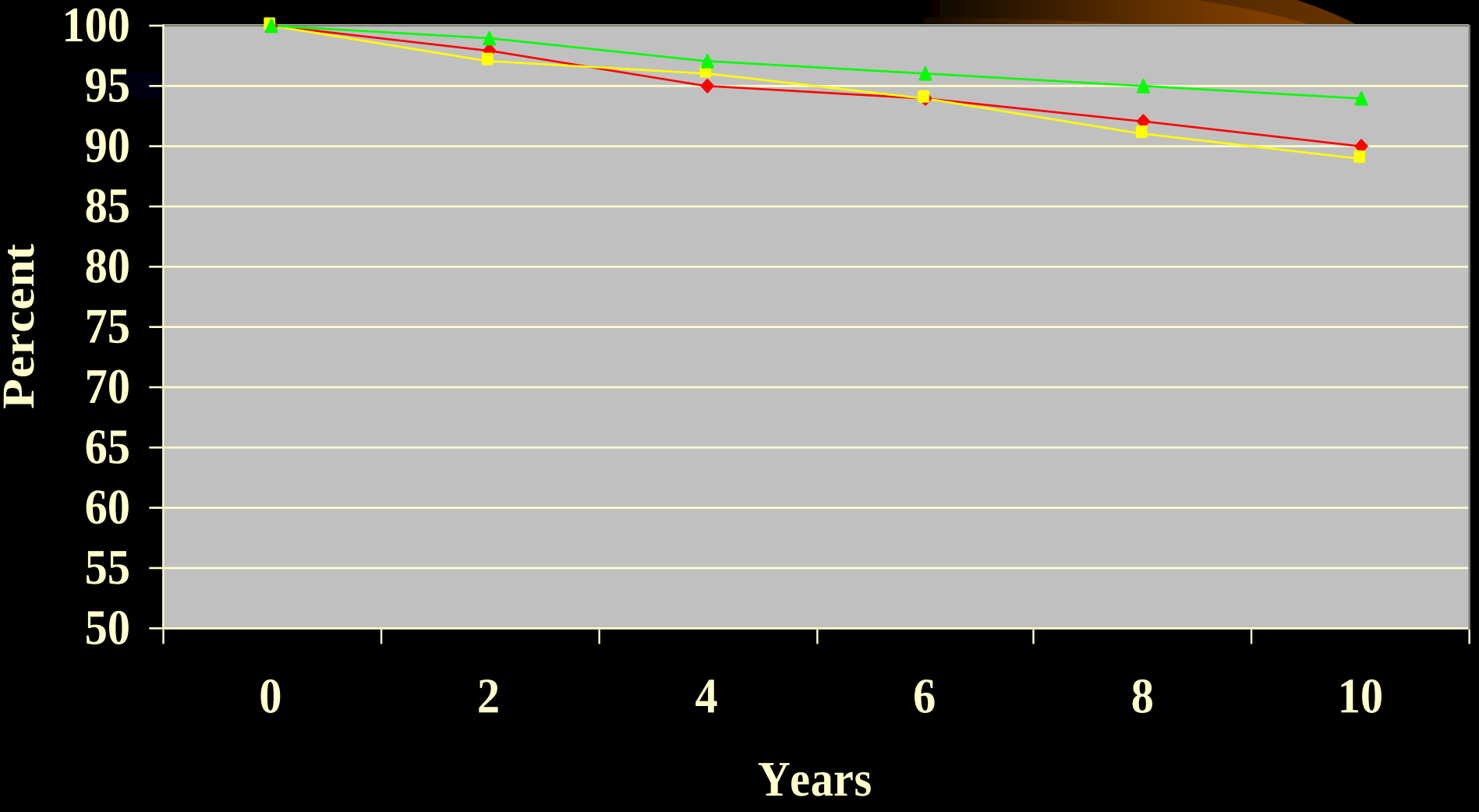
1. Patient characteristics and problems.
2. Intervention:
   - "GTR techniques"
   - Resorptive / non-resorptive
   - Bone graft / alloplasts / allografts
   - Membrane / procedure characteristics
3. Alternative intervention:
   - Another "GTR technique"
   - Access flap surgery

Well built clinical questions include

1. Patient characteristic and problem.
2 & 3. Intervention & alternative intervention.
4. Criteria for outcome:

Patient or operator centered ?

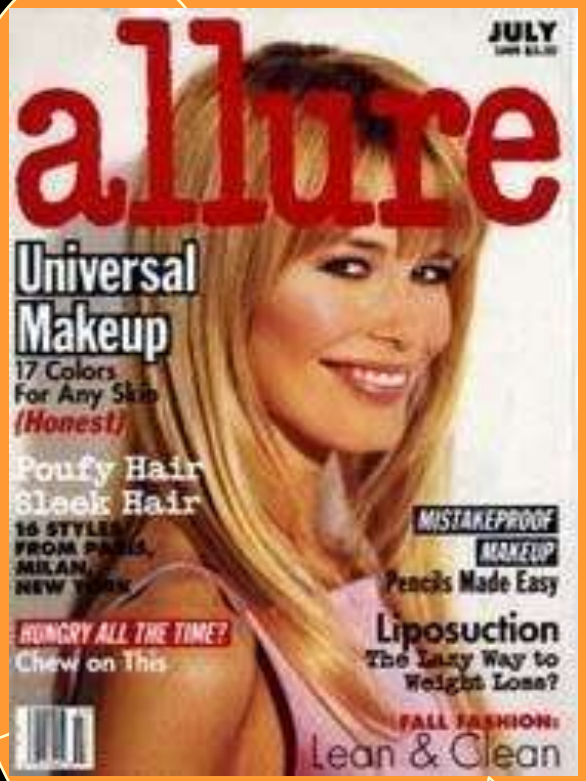
We tend to focus on e.g. survival statistics:

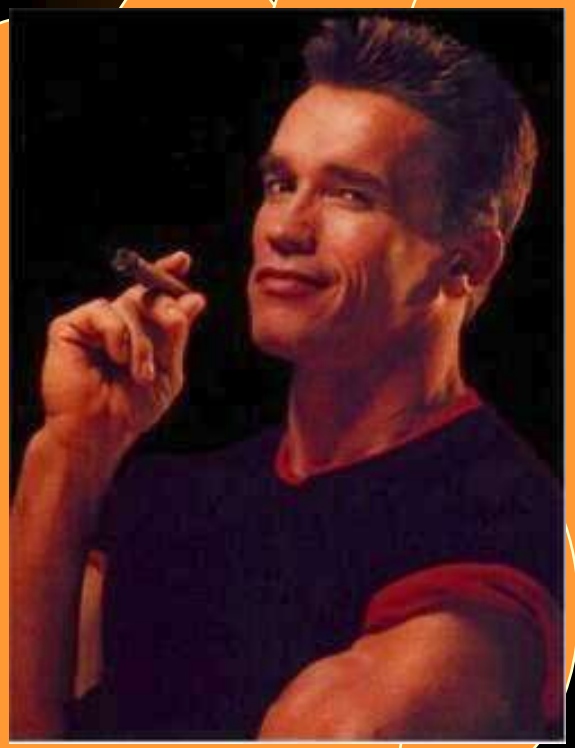


…or perhaps odds ratios… while patients…

Independent variables	Bi-variate odds ratios	Bivariate significance	95% Confidence intervals bivariate odds ratios	Multi-variate odds ratios	Multi-variate significance	95% Confidence intervals for multivariate odds ratios
Age						
<40	-	-	-	-	-	-
40-60	2.32	**	1.15 - 3.13	2.52	**	1.35 - 3.33
>60	2.63	***	1.43 - 3.08	2.63	***	1.83 - 3.8
Gender						
Male	-	-	-	-	-	-
Female	2.42	**	1.61 - 2.79	2.12	**	1.91 - 2.9
Method						
Membrane	-	-	-	-	-	-
Conventional	1.12	NS	0.13 - 1.56	1.42	NS	1.13 - 1.96
Dentist						
#1	-	-	-	-	-	-
#2	1.34	NS	0.35 - 1.61	1.04	NS	1.35 - 2.01
Location						
Mandible	-	-	-	-	-	-
Maxilla	1.55	*	1.17 - 2.04	1.15	*	1.57 - 2.14

.. may perhaps have preferences for other values...





Outcome criteria, patient or operator centered?

Dentist centred:

Short-term clinical outcomes:

1. Change in probing attachment levels
2. Change in probing depths
3. Change in gingival recession
4. Changes in bone:
   a) Radiographic
   b) Surgical re-entry

Long-term clinical outcomes:

1. Disease recurrence (% sites with >/= 2mm loss of probing attachment measured from 12 months after treatment)
2. Tooth loss

Patient centred:

1. Ease of maintenance (% sites with < 4mm probing depth)
2. Aesthetics (change: better or worse in patient's opinion)
3. Post-operative complications (including pain, infection)
4. Cost/benefit (treatment time plus estimated material costs)
5. Patient well-being

- Define the given task
- What characterizes “science-based” ?

Science:

any system of knowledge that is concerned with the physical world and its phenomena and that entails unbiased observations and systematic experimentation. In general, a science involves a pursuit of knowledge covering general truths or the operations of fundamental laws.

Scientific method:

principles and procedures for the systematic pursuit of knowledge involving the recognition and formulation of a problem, the collection of data through observation and experiment, and the formulation and testing of hypotheses

(Encyclopedia Britannica, 1999)

- Define the given topic
- Descriptive bibliometric data
- How to characterize “science-based”
    - Types of clinical studies

Clinical trial terminology - tower of Bable?

analytical study
case control study (89)
case serie
case study, case report
cause-effect study
clinical trial (79)
cohort study (89)
cohort study with historical controls
controlled clinical trial (95)
cross-sectional study (89)
descriptive study
diagnostic meta-analysis
diagnostic study
double blind randomized therapeutical trial with cross-over design
ecological study
etiological study
experimental study
explorative study
feasibility study (79)
follow-up study (67)
historical cohort study
incidence study
intervention study
longitudinal study (79)
N=1 trial
non-randomized trial with contemporaneous controls
non-randomized trial with historical controls
observational study
prospective cohort study
prospective follow-up study, observational or experimental
prospective study (67)
quasi-experimental study
randomized clinical trial, RTC
randomized controlled trial, RCT (89)
retrospective cohort study
retrospective follow-up study
retrospective study (67)
surveillance study
survey, descriptive survey
therapeutic meta-analysis
trohoc study

Describing clinical research -reduce to three questions

1. General purpose?
   - Descriptive, no comparison conducted
   - Comparison as process research
   - Comparison as cause-effect research

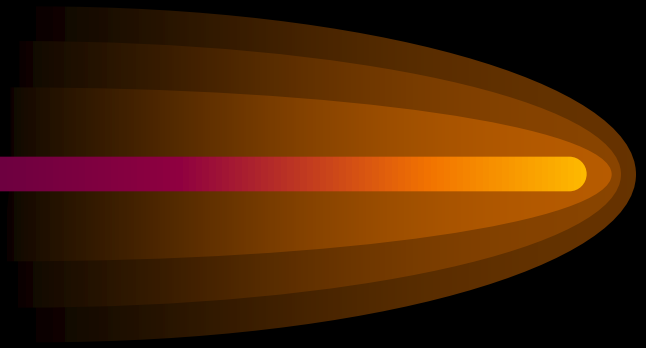
2. Procedure, intervention?
   - Experimental allocation of procedure
   - Survey

3. Data collection?
   - Retrospective
   - Cross-sectional
   - Prospective / Cohort / Longitudinal

Clinical study designs (MESH terms):

- (Case study/series)
- Case-Control Study
- Cohort Study
- Cross-Sectional Survey
- Randomised Controlled Trial

Cross-Sectional Survey



Advantages

1. cheap and simple
2. ethically safe

Disadvantages

1. establishes association at most, not causality
2. recall bias susceptibility
3. confounders may be unequally distributed
4. group sizes may be unequal

Case-Control Studies

Advantages:

1. quick and cheap
2. only feasible method for very rare disorders or those with long lag between exposure and outcome
3. fewer subjects needed than cross-sectional studies

Disadvantages:

1. reliance on recall or records to determine exposure status
2. confounders
3. selection of control groups is difficult
4. potential bias: recall, selection

Characteristics of a poor case-control study

Failed to:

- clearly define comparison groups
- and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls
- and/or failed to identify or appropriately control known confounders.

Cohort Study

Advantages:

1. ethically safe
2. subjects can be matched
3. can establish timing and directionality of events
4. eligibility criteria and outcome assessments can be standardised
5. administratively easier and cheaper than RCT

Disadvantages:

1. controls may be difficult to identify
2. exposure may be linked to a hidden confounder
3. blinding is difficult
4. randomisation not present
5. for rare disease, large sample sizes or long follow-up necessary

Characteristics of a poor cohort study:

Failed to:

- clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals
- and/or failed to identify or appropriately control known confounders
- and/or failed to carry out a sufficiently long and complete follow-up of patients.

Randomised Controlled Trial

Advantages

1. unbiased distribution of confounders
2. blinding more likely
3. randomisation facilitates statistical analysis

Disadvantages

1. expensive: time and money
2. volunteer bias
3. ethically problematic at times

How are the different clinical study designs considered as evidence of therapeutical effectiveness?

Strength of evidence of treatment effects

US Agency of Health Care Policy & Research, 1992

Ia. Meta-analysis of randomized controlled trials

Ib. At least one randomized controlled trial

IIa. At least one well-designed controlled study without randomization

IIb. At least one other quasi-experimental study

III. Well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies.

IV. Expert committee reports or opinions and/or clinical experience of respected authorities

EBM Working Group, McMaster University 1993

Systematic reviews and meta-analyses

RCT with definite results (ie. result with CI that do not overlap the threshold clinically significant effect)

RCT with non-definite results (ie. a point estimate that suggests a clinically significant effect, but with CI overlapping the threshold for this effect)

Cohort studies

Case-control studies

Cross sectional studies

Case reports

Strength of evidence of treatment effects

Richards & Lawrence, Br Dent J 1995;175:270

- at least one published systematic review of multiple well designed randomised controlled trials

- at least one published properly designed randomised controlled trial of appropriate size and in an appropriate clinical setting
- published well-designed trials without randomisation, single group pre-post, cohort, time series or matched case controlled studies

- well-designed experimental studies from more than one centre or research group
- opinions of respected authorities based on clinical evidence, descriptive studies or reports of expert consensus committees

Sackett et al., Editorial. EBM 1995;1:4

(I-1) Based on 2 or more well designed randomised controlled trials (RCT), meta-analyses, or systematic reviews.
(I-2) Based on a RCT.

(II-1) Based on a cohort study.
(II-2) Based on a case controlled study.
(II-3) Based on a dramatic uncontrolled experiment.

(III) respected authorities, expert committees (consensus)etc.

(IV) ...someone once told me

Strength of evidence of treatment effects

CEBM,1999. (http://cebm.jr2.ox.ac.uk/docs/levels.html)

1a. Systematic review (with homogeneity of RCTs)

1b. Individual RCT (with narrow confidence interval)

1c. All or none

2a. Systematic review (with homogeneity) of cohort studies

2b. Individual cohort study (and low quality RCT; e.g.,<80% follow-up)

2c. "Outcomes" research

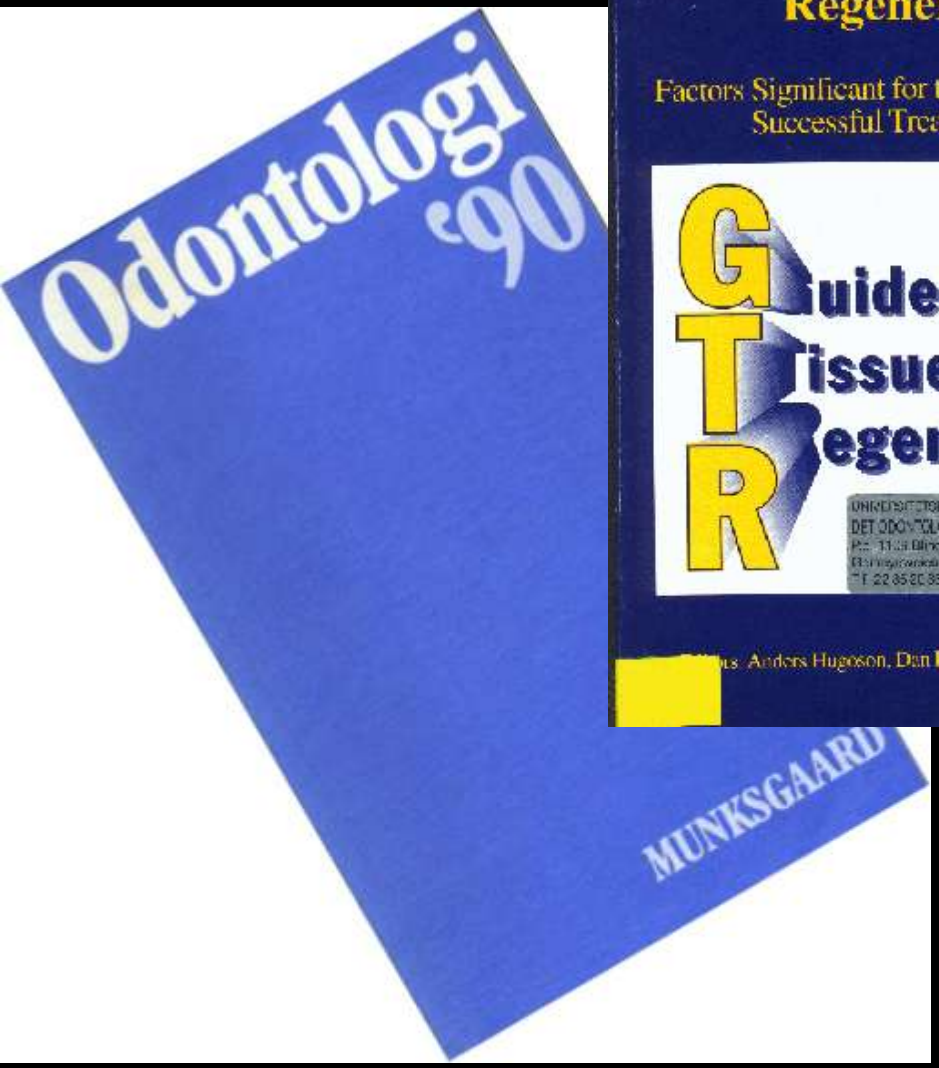
3a. Systematic review (with homogeneity) of case-control studies

3b. Individual case-control study

4. Case-series (and poor quality cohort and case-control studies)

5. Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

- Define the given task
- What characterizes “science-based” ?
  - Types of clinical studies
- Descriptive bibliometric data


Odontologi '90
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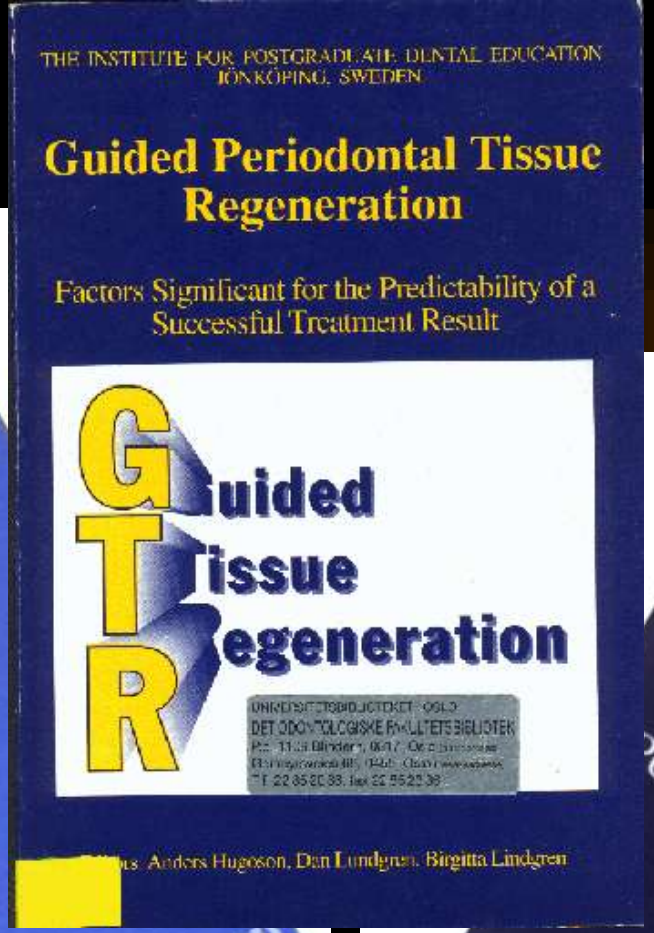
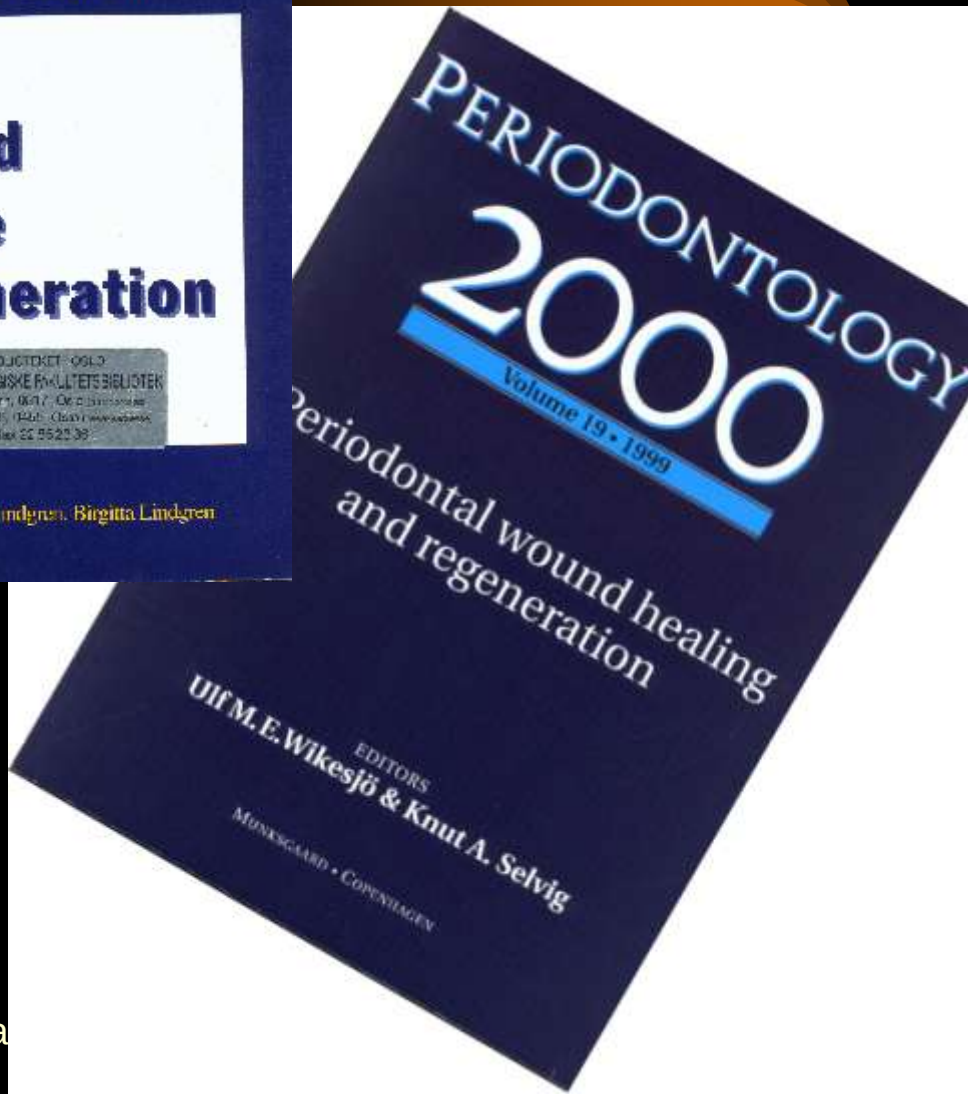

THE INSTITUTE FOR POSTGRADUATE DENTAL EDUCATION
JÖNKÖPING, SWEDEN
Guided Periodontal Tissue Regeneration
Factors Significant for the Predictability of a Successful Treatment Result
GTR
Guided
Tissue
Regeneration
Anders Hugoson, Dan Lundgren, Birgitta Lindgren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Ulf M. E. Wikesjö & Knut A. Selvig
MUNKSGAARD • COPENHAGEN

Niklaus P. Lang/Thorkild Karring

Proceedings of the 1st European Workshop on Periodontology

with contributions by:

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Jukka Ainamo
Tomas Albrektsson
Rolf Attström
Per Axelsson
Pierre C. Baehni
Urs Brägger
Noel Claffey
José Echeverria
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quintessence books

Periodontal Regeneration

Research, Science and Therapy Committee

Ovid: Search Form - Netscape

File Edit View Go Communicator Help

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1966 to December 1999 Week 4

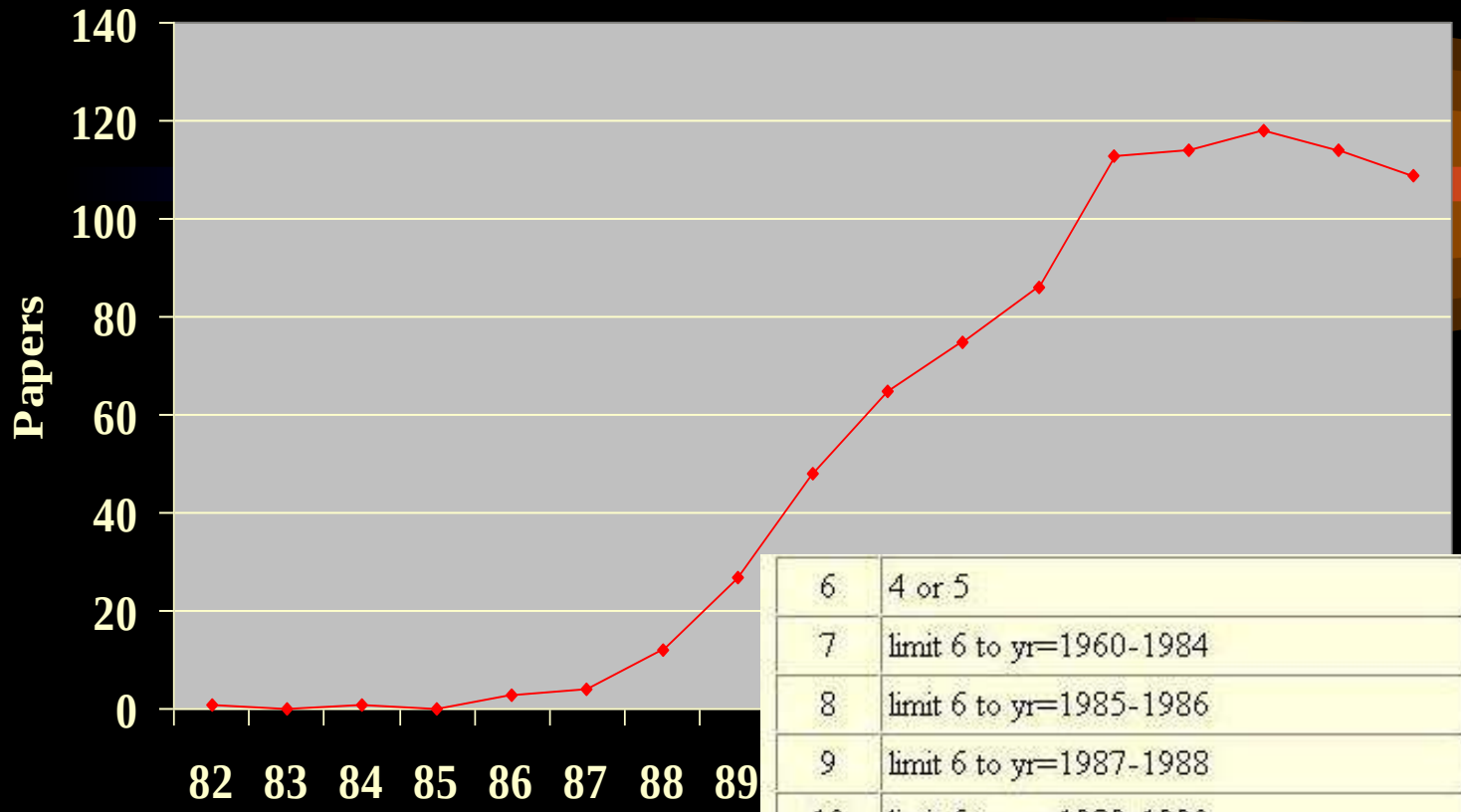
Help

Author | Title | Journal | Search Fields | Tools | Combine | Limit | Basic | Change Database | Logoff

#	Search History	Results	Display
1	exp guided tissue regeneration/ or guided tissue regeneration.ti. or guided tissue regeneration.mp. or gtr.ti.	1146	Display
2	exp membranes, artificial/	34709	Display
3	exp periodontal attachment loss/ or exp periodontal diseases/ or exp periodontal ligament/ or exp periodontal pocket/ or periodontal.mp.	43021	Display
4	1 and 3	870	Display
5	2 and 3	551	Display
6	4 or 5	947	Display

Contract

Papers focussed on GTR- techniques



6	4 or 5	947	Display
7	limit 6 to yr=1960-1984	1	Display
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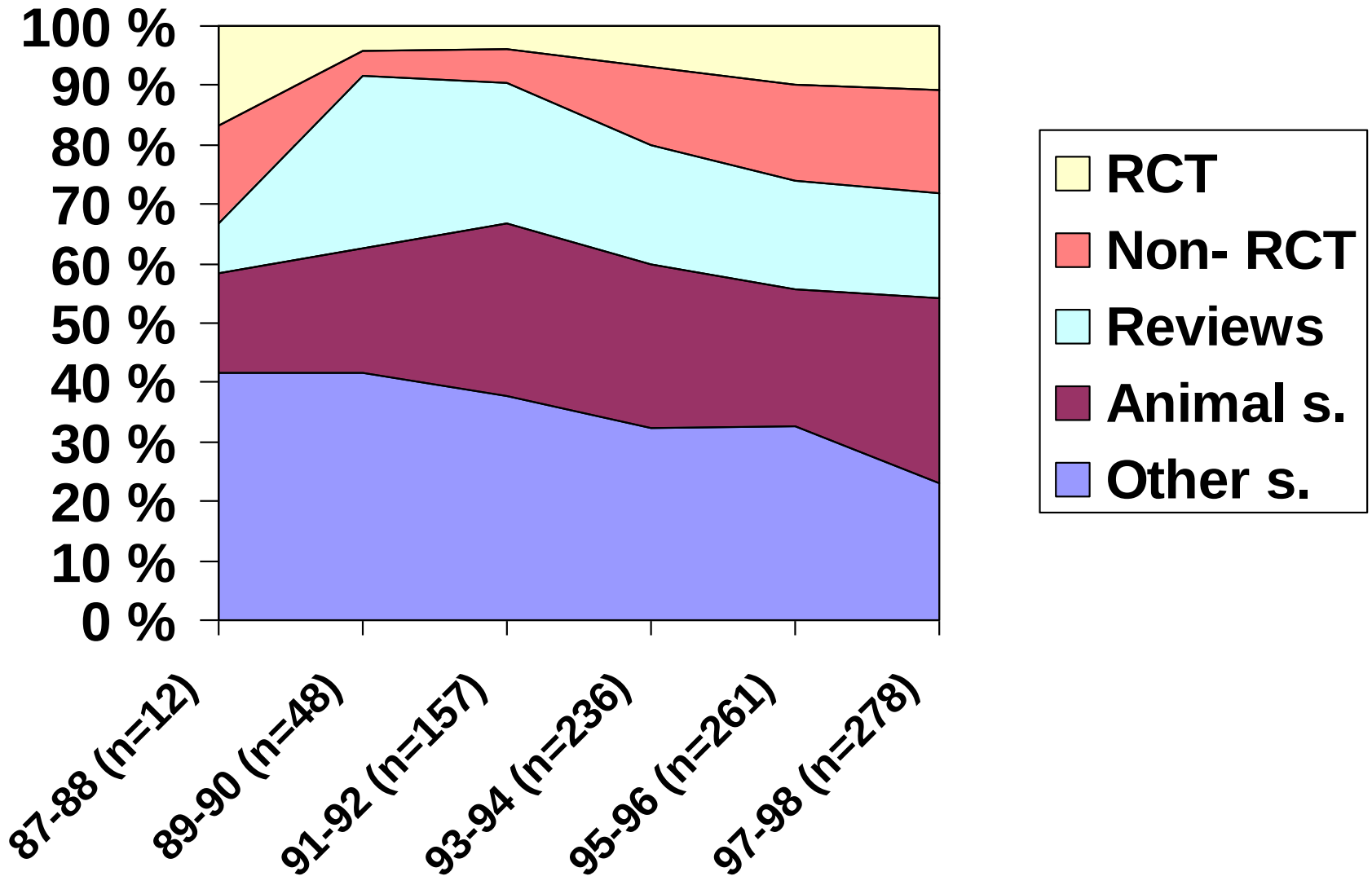
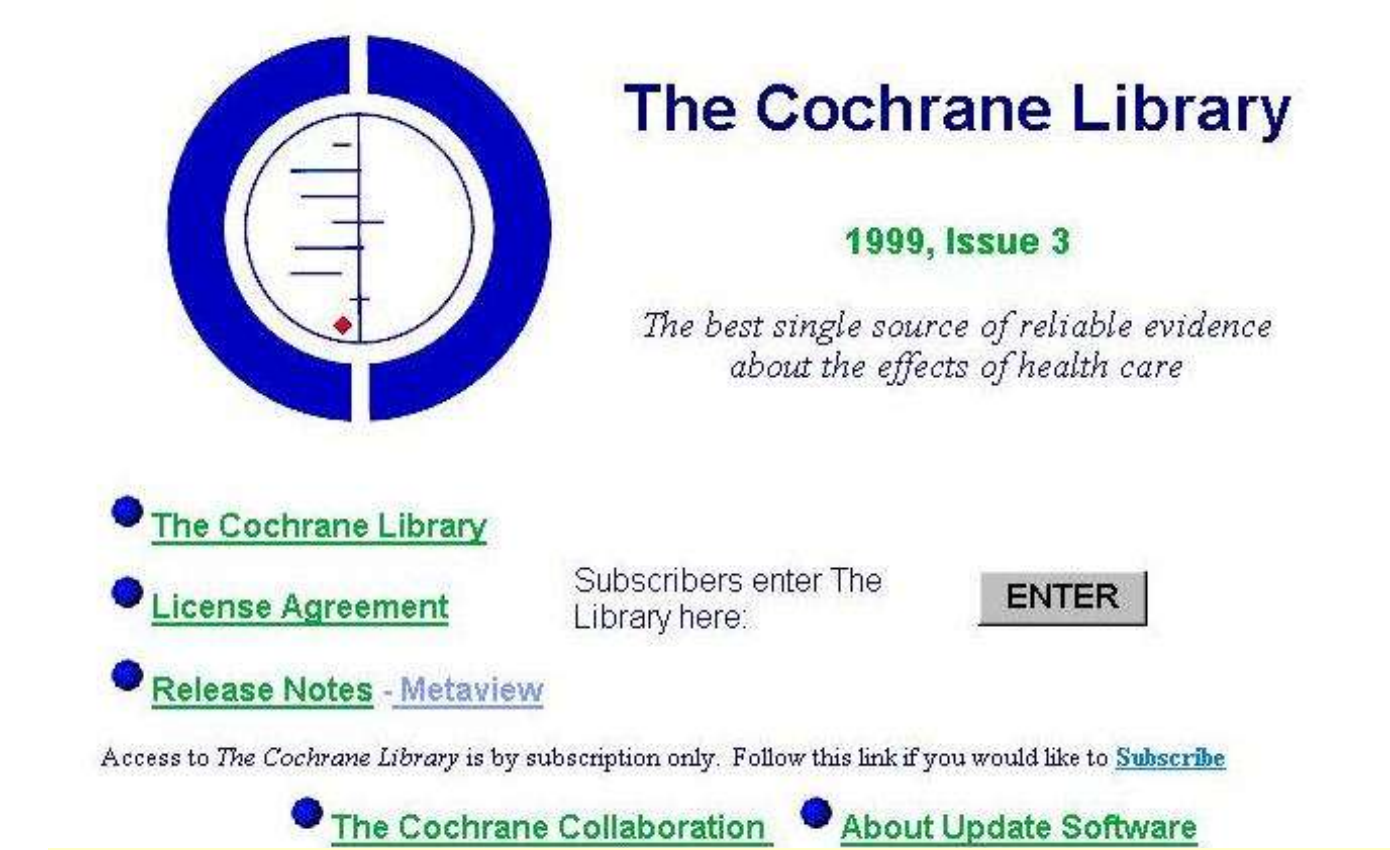
9	limit 6 to yr=1987-1988	16	Display
10	limit 6 to yr=1989-1990	75	Display
11	limit 6 to yr=1991-1992	140	Display
12	limit 6 to yr=1993-1994	199	Display
13	limit 6 to yr=1995-1996	232	Display
14	limit 6 to yr=1997-1998	223	Display
15	limit 6 to yr=1999	57	Display

Run Saved Search Save Search History Delete All Searches

Study designs





The Cochrane Library includes:

- The Cochrane Database of Systematic Reviews - Regularly updated reviews of the effects of health care
- Database of Abstracts of Reviews of Effectiveness - Critical assessments and structured abstracts of good systematic reviews published elsewhere
- The Cochrane Controlled Trials Register - Bibliographic information on controlled trials
- Other sources of information on the science of reviewing research and evidence-based health care

Search term: (GUIDED and (TISSUE and REGENERATION)) [No restrictions]

The Cochrane Controlled Trials Register (CENTRAL/CCTR)

References (131 records selected)

1 1998 A clinical evaluation of an allograft combined with a bioabsorbable membrane versus an alloplast/allograft composite graft combined with a bioabsorbable membrane. 100 consecutively treated cases.

2 New 1998 A comparison of 2 root coverage techniques: guided tissue regeneration with a bioabsorbable matrix style membrane versus a connective tissue graft combined with a coronally positioned pedicle graft without vertical

3 1998 Bone regeneration after radicular cyst removal with and without guided bone regeneration.

4 1998 Clinical and microbiological evaluation of a bioabsorbable and a nonresorbable barrier membrane in the treatment of periodontal intraosseous lesions.

5 1998 Clinical comparison of bioabsorbable barriers with non-resorbable barriers in guided tissue regeneration in the treatment of human intrabony defects.

6 1998 Clinical comparison of cellulose and expanded polytetrafluoroethylene membranes in the treatment of class II furcations in mandibular molars with 6-month re-entry.

7 New 1998 Comparison of 2 regenerative procedures--guided tissue regeneration and demineralized freeze-dried bone allograft--in the treatment of intrabony defects: a clinical and radiographic study.

8 New 1998 Early bacterial accumulation on guided tissue regeneration membrane materials. An in vivo study.

9 1998 Effects of expanded polytetrafluoroethylene and polylactic acid barriers on healthy sites.

10 1998 Evaluation of periosteal membranes and coronally positioned flaps in the treatment of Class II furcation defects: a comparative clinical study in humans.

11 New 1998 Expanded polytetrafluoroethylene and dental rubber dam barrier membranes in the treatment of periodontal intrabony defects. A comparative clinical trial.

12 1998 GTR therapy of intrabony defects using 2 different bioresorbable membranes: 12-month results.

13 New 1998 Generalizability of the added benefits of guided tissue regeneration in the treatment of deep intrabony defects. Evaluation in a multi-center randomized controlled clinical trial.

14 1998 Guided tissue regeneration for the treatment of intraosseous defects using a biabsorbable membrane. A controlled clinical study.

15 1998 Guided tissue regeneration in Class II furcation involved maxillary molars: a controlled study of 8 split-mouth cases.

16 New 1998 Guided tissue regeneration in the treatment of human infrabony defects. Clinical, radiographical and microbiological results: a pilot study.

17 1998 Mucogingival versus guided tissue regeneration procedures in the treatment of deep recession type defects.

18 New 1998 Periodontal surgery of vertical bony defects with or without synthetic bioabsorbable barriers. 12-month results.

19 1998 Regenerative periodontal surgery with non-resorbable and biodegradable barriers: results after 24 months.

20 New 1998 Subpedicle connective tissue graft versus guided tissue regeneration with bioabsorbable membrane in the treatment of human gingival recession defects.

21 New 1998 The bone growing chamber: a new model to investigate spontaneous and guided bone regeneration of artificial defects in the human jawbone

Applications GTR use (RCT trials (n= 126)

molar furcations	42
intrabony defects	35
gingival recession	13
severe periodontitis	11
exposed implant surfaces	10
alveolar ridge maintenance	3
periapical lesions	1
vertical ridge augmentation	1
distal mandibular 2.molars	1
regeneration in extraction sites	1

- Define the given task
- Characteristics of science
- Descriptive bibliometric data
- Critical appraisal of the evidence

Critical appraisal of papers reporting treatment effects

1. ***Are the results of the trial valid?***
2. ***What are the results?***
3. ***Will the results help my patients?***

Critical appraisal checklists

Critical appraisal of papers reporting treatment effects

Are the results of the trial valid?

1. Did the trial address a clearly focussed issue?

   i.e. focused in terms of the population studied, the intervention, the outcomes considered

2. Was the assignment of patients to the intervention randomised?
3. Were all the patients who entered the trial properly accounted for at its conclusion?
   - *was follow-up complete?,*
   - *were pasients analysed in the groups to which they were randomised?*

Critical appraisal of papers reporting treatment effects

Are the results of the trial valid?

4. Were patients, health workers and study personnel blind to the intervention?

   patients? health workers? study personnel?

5. Were the groups similar at the start of the trial?

   In terms of other factors that might effect the outcome such as age, sex and social class

6. Aside from the experimental intervention - were the groups treated equally?

Critical appraisal of papers reporting treatment effects

What are the results?

7 . How large was the effect of the intervention?

What outcomes are measured?

8. How precise was the estimate of the effect of intervention?

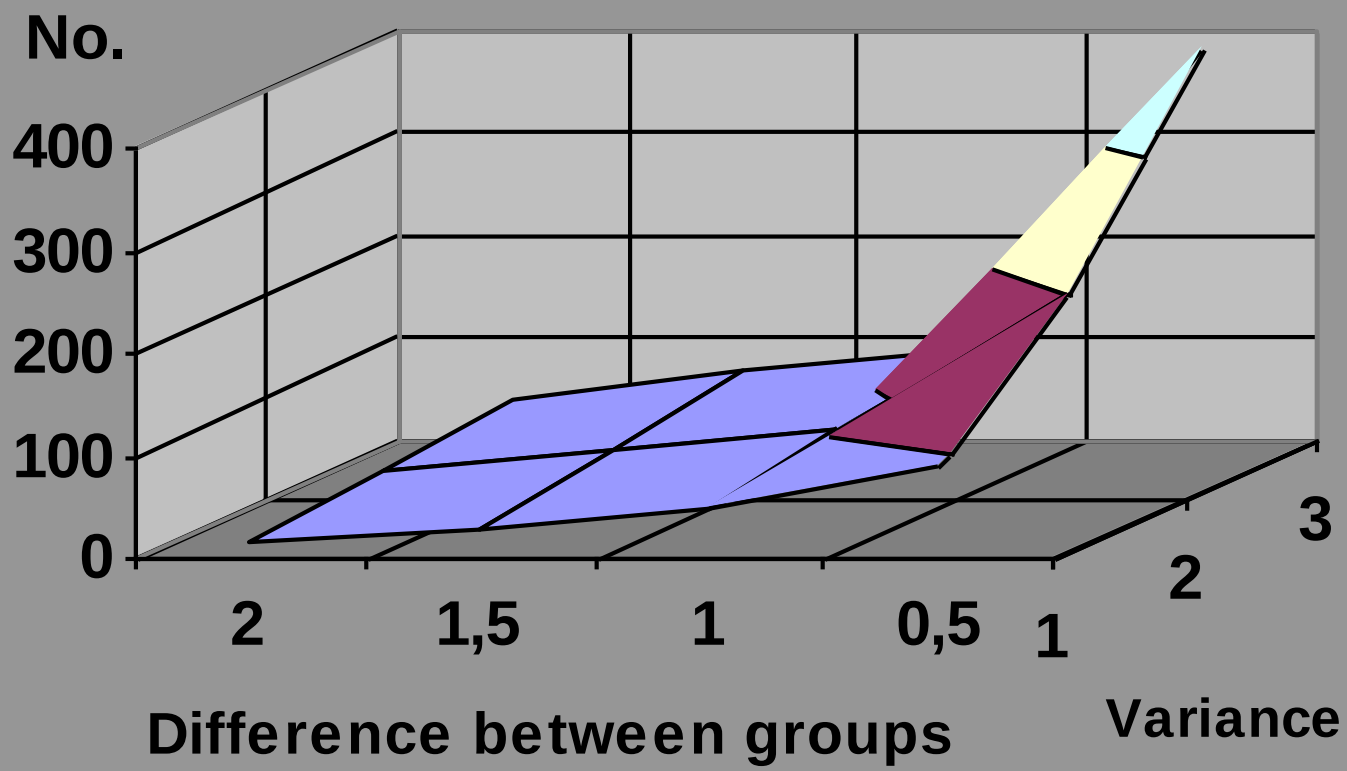
What are its confidence limits?

Evidence of no difference =/=
no evidence of difference

Evidence of no difference =/=
evidence of equivalence

- May be due to low power, i.e. insignificant difference, large variance and/or small sample sizes.
- May be corrected with metaanalysis, primary or secondary- but aware of methodological problems! i.e. garbage in garbage out.

Power calculations: effects of variance and mean difference



*Sample sizes of RCT studies**

Split mouth design (n=59)

Patients	Trials
0-10	14
11-20	30
21-30	11
31-40	2
>40	2

Cohort design (n=20)

Patients	Trials
0-10	0
11-20	2
21-30	7
31-40	5
41-50	3
51-60	1
>60	2

* limited to trials focussed on use for molar furcations, intrabony defects & gingival recession

Criteria for evaluating treatment effects

- Regeneration is a 3-dimensional process - which one-dimensional measurement is appropriate?
- Method use needs high repeatability and accuracy
  - Histology
    - Morbidity, quantification?
  - Probing
    - Who wants to disrupt a new region?
  - Radiographic
    - Direct measurement vs. percent approach
- Consensus on appropriate criteria for reporting GTR treatment results is critical

Analysis of data

- Are we really interested in “average” data when applying scientific findings to treatment of individual patients.
- How results are presented and analysed may confound their clinical significance.

Presentation of trial data

	Test	Control	Total
-2 - -1 mm	10	5	15
-1 - 0 mm	3	8	11
0 - 1 mm	2	8	10
1 - 2 mm	5	11	16
2 - 3 mm	16	8	24
3 - 4 mm	4	0	4
	40	40	80

Presentation of trial data

	Test	Control	Total
-2 - -1 mm	10	5	15
-1 - 0 mm	3	8	11
0 - 1 mm	2	8	10
1 - 2 mm	5	11	16
2 - 3 mm	16	8	24
3 - 4 mm	4	0	4
	40	40	80

Conclusion, presentation of means and standard deviations

	Test	Control
Mean	1,15	0,73
SD	1,8	1,3
n	40	40

P = .00894 (paired t-test, df. 39)

"XXX was significantly better than the conventional method (p < .01)"

Presentation of trial data

	Test	Control	Total
-2 - -1 mm	10	5	15
-1 - 0 mm	3	8	11
0 - 1 mm	2	8	10
1 - 2 mm	5	11	16
2 - 3 mm	16	8	24
3 - 4 mm	4	0	4
	40	40	80

Alternative 2: Choice of clinical significance was set at 2 mm

	Number Test	Control	Total
< 2 mm	20	32	52
> 2 mm	20	8	28
	40	40	80

Conclusion, focus on vertical percentages

	Test	Control	Total
< 2 mm	50%	80%	52
> 2 mm	50%	20%	28
	40	40	80

"Improvement for half the patients treated with XXX compared to only one fifth with the conventional method."

Presentation of trial data

	Test	Control	Total
-2 - -1 mm	10	5	15
-1 - 0 mm	3	8	11
0 - 1 mm	2	8	10
1 - 2 mm	5	11	16
2 - 3 mm	16	8	24
3 - 4 mm	4	0	4
	40	40	80

Alternative 2: Choice of clinical significance was set at 2 mm

	XXX	Number Control	Total
< 2 mm	20	32	52
> 2 mm	20	8	28
	40	40	80

Conclusion, focus on horizontal percentages

	Test	Control	Total
< 2 mm	32%	68%	52
> 2 mm	70%	30%	28
	40	40	80

"70% percent of all the patients with improvement had been treated with XXX while the others had been treated with the conventional method."

Presentation of trial data

Alternative 2: Choice of clinical significance was set at 2 mm

	Number		
	Test	Control	Total
< 2 mm	20	32	52
> 2 mm	20	8	28
	40	40	80

Conclusion, focus on percentage improvement:

" The treatment with XXX resulted in a x2.5 / alt. 250% improvement compared to conventional methods".

Presentation of trial data

	Test	Control	Total
-2 - -1 mm	10	5	15
-1 - 0 mm	3	8	11
0 - 1 mm	2	8	10
1 - 2 mm	5	11	16
2 - 3 mm	16	8	24
3 - 4 mm	4	0	4
	40	40	80

Alternative 3:
Choice of clinical significance set at 1 mm

	Test	Control	Total
< 1 mm	15	21	36
> 1 mm	25	19	44
	40	40	80

Conclusion:

" No statistically significant results were observed".

- Define the given task
- Characteristics of science
- Descriptive bibliometric data
- Critical appraisal of the evidence
- Which GTR techniques are science based

Treatment outcomes of RCT studies

Application:	trials	Sample	+	+?	?/-
molar furcations					
cohort design	6	15-40	1	0	2
split-mouth design	34	8-59	4	10	4
intrabony defects					
cohort design	11	18-143	6	3	0
split-mouth design	23	9-44	4	5	0
gingival recession					
cohort design	4	20-54	2		2
split-mouth design	4	8-12	0	1	1

* many RCT studies focus on GTR-techniques/procedures comparisons

Critical appraisal of papers reporting treatment effects

Will the results help my patients?

9. Can the results he applied to my patients?

   Do you think that the patients covered by the trial are similar enough to your population?

10. Were all clinically important outcomes considered?

    If not, does this affect the decision?

11. Are the benefits worth the harms and costs?

    This is unlikely to be addressed by the trial but what do you think?

What about patient risk factors and treatment outcomes?

Intrinsic risk factors

- Gender
- Race
- Genetic factors
- Congenital immunodeficiencies
- Phagocyte dysfunction
- Syndromes

Acquired/environmental risk factors

- Poor oral hygiene
- Age
- Medications
- Tobacco/smoking
- Stress
- Acquired immune/ endocrine/ inflammatory diseases
- Nutritional deficiencies

Conclusions

- Regeneration potential exists
- RCTs are equivocal, but small benefit apparent
  - Technically demanding
  - Intrinsic and extrinsic decisive patient factors uncertain
  - Local biological factors, e.g. “critical size”, endotoxin remains, etc. uncertain
    - Financially costly
      - Time consuming
      - Material costs
    - Are we doing more good than harm?