TMD and Evidence - based medicine

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University of Oslo, Norway

Is Temporomandibular dysfunction - TMD - a "new" affliction?

2

TMD – is <u>not</u> a "new" affliction

- 1840, Evens, articulator
  - 1896, Walker, complex articulator--->gnathology
  - 1899, Snow, face bow
  - 1952, Shore, equilibration
- 1877, Kingsley, splint
  - 1881, Goodwillie, pivot appliance
  - 1960, Gelb, MORA splint
- 1887, Annandale, surgical repositioning
  - 1909, Lantz, removal of discus
- 1918, Prentiss, "pressure atrophy"
  - 1934, Costen, "overclosure" --> vertical dimension
- 1959, Schwartz, emotional tension

3

Since there is a long tradition for treating TMD....

it seems logical that there should be a large body of

empirical clinical experience

to solve several issues related to the diagnosis and management of TMD patients...

4

TMD - what is the consensus?

- How common and how big is the problem?
- What is the etiology of TMD?
- What is the reliability of different diagnostic tests?
- What is the natural history of TMD?
- Should/can TMD be prevented?
- Which specific TMD treatment is superior and can be supported?
  - What is the validity of different treatment outcomes?
  - Do different splints have the same success rates and why?
- .....

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Who should treat these patients – i.e. what is the evidence base for effective treatments

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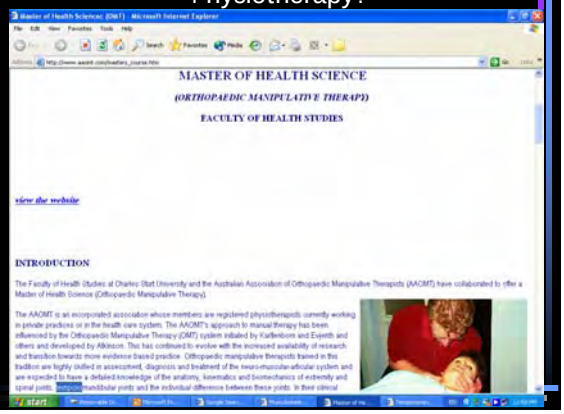
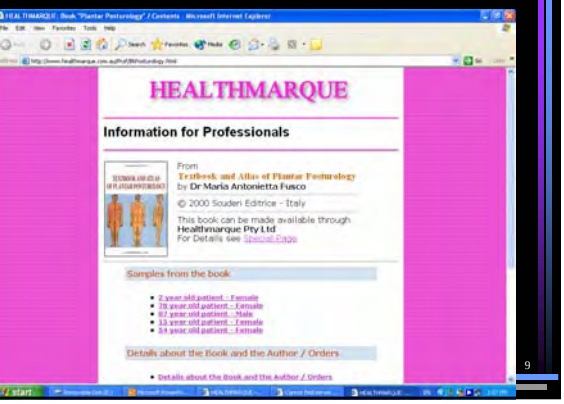
Physiotherapy?

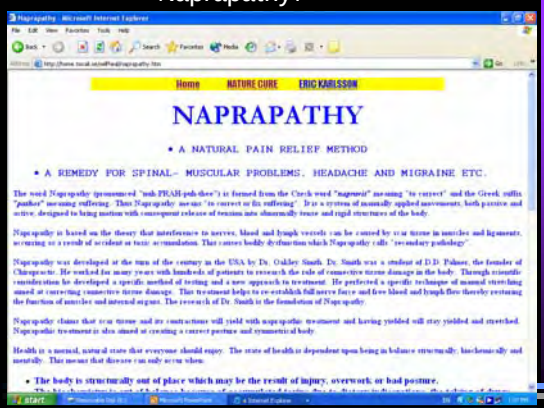


Kinesiology?

Posturology?

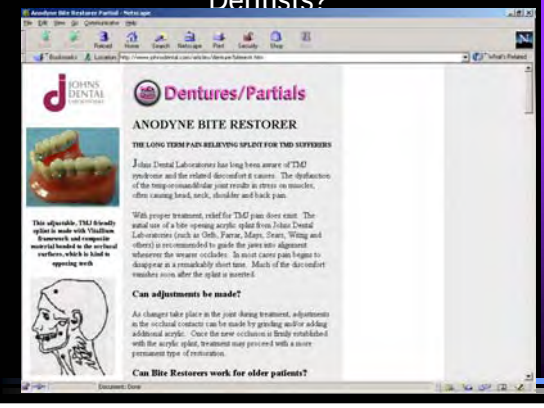


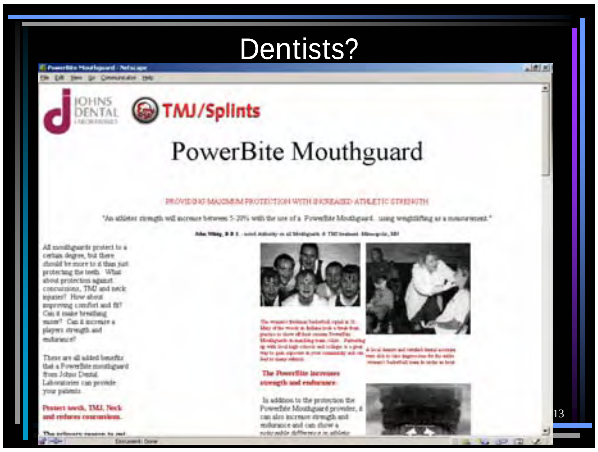
Naprapathy?



Craniosacral therapy?

Dentists?



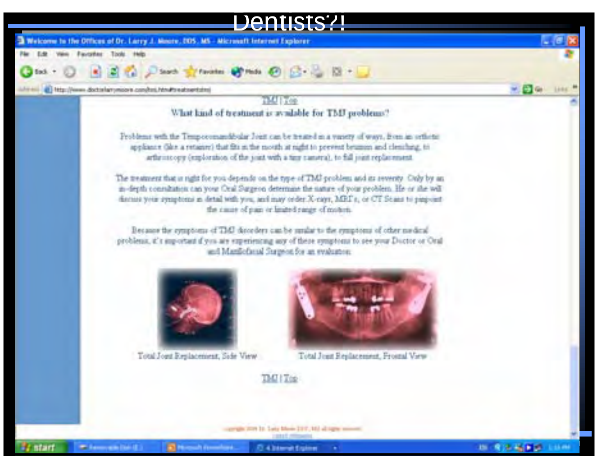



Journal of Oral Rehabilitation 2001 **28**; 732–739

The influence of different jaw positions on the endurance and electromyographic pattern of the biceps brachii muscle in young adults with different occlusal characteristics

VIRGILIO F. FERRARIO*,†, CHIARELLA SFORZA*,†, GRAZIANO SERRAO*, NICOLA FRAGNITO† & GIANPIERO GRASSI† *Functional Anatomy Research Center (Farc), *Laboratorio di Anatomia Funzionale dell'Apparato Stomatognatico (LAFAS) and †Laboratorio di Anatomia Funzionale dell'Apparato Locomotore (LAFAL), Dipartimento di Anatomia Umana, Facoltà di Medicina e Chirurgia and Facoltà di Scienze Motorie, Università degli Studi, via Mangiagalli, Milano, Italy*

SUMMARY To investigate the hypothesis of a functional coupling between the stomatognathic motor apparatus and the muscles of other body districts, as well as between occlusal conditions and neuromuscular performance, two groups of men (age range 20–26 years), with either normal occlusion (14 men) or malocclusion (15 men), sustained with their dominant arm a dumbbell weighing 80% of their maximum while maintaining different jaw positions: mouth open, without dental contact; mouth close, with light dental contact; maximum volun- frequency were also computed for 2-s windows, and values as a function of time were interpolated by a linear regression analysis. Data were compared between groups and trials by using a factorial analysis of variance. The malocclusion group subjects could perform the exercise for a longer time span than the normal occlusion individuals ($P < 0{\cdot}005$). During this endurance time their biceps brachii muscles contracted with different patterns: on average, in the malocclusion group they had a larger EMG amplitude ($P < 0{\cdot}005$), and a shift of the power



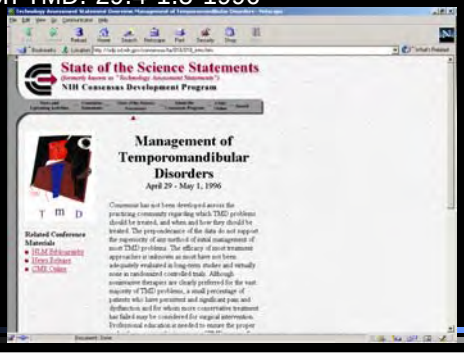
National Institutes of Health, USA 1996:

Rationale for addressing the issue (!)

- Concern about the safety and efficacy of the care provided to patients with TMD
- Absence of clear, valid, and reliable guidelines for diagnosis
- Dearth of proven rationales for a full range of treatment methods
- Many may attempt therapy with approaches that have not been adequately tested in scientifically based research studies

17

NIH Technology assessment Conference on TMD. 29.4-1.5-1996



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NIH Technology Assessment Conference on TMD. 29.4-1.5-1996 – Consequences:

- Creation of a strong conflict between “pragmatists” and “scientists”.

19

NIH Technology Assessment Conference on TMD. 29.4-1.5-1996 – Consequences:

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- A series of protests and letters from “The Alliance of TMD Practitioners”

21

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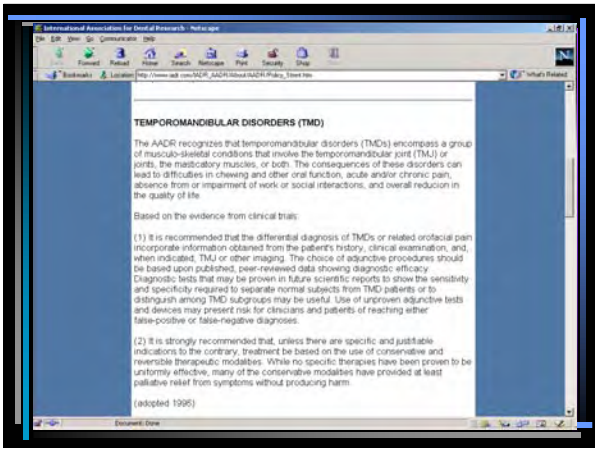
- Several statement and editorials staking out new courses

22



TEMPOROMANDIBULAR DISORDERS (TMD)

The AADR recognizes that temporomandibular disorders (TMDs) encompass a group of musculo-skeletal conditions that involve the temporomandibular joint (TMJ) or joints, the masticatory muscles, or both. The consequences of these disorders can lead to difficulties in chewing and other oral function, acute and/or chronic pain, absence from or impairment of work or social interactions, and overall reduction in the quality of life.

Based on the evidence from clinical trials:

(1) It is recommended that the differential diagnosis of TMDs or related orofacial pain incorporate information obtained from the patient's history, clinical examination, and, when indicated, TMJ or other imaging. The choice of adjunctive procedures should be based upon published, peer-reviewed data showing diagnostic efficacy. Diagnostic tests that may be proven in future scientific reports to show the sensitivity and specificity required to separate normal subjects from TMD patients or to distinguish among TMD subgroups may be useful. Use of unproven adjunctive tests and devices may present risk for clinicians and patients of reaching either false-positive or false-negative diagnoses.

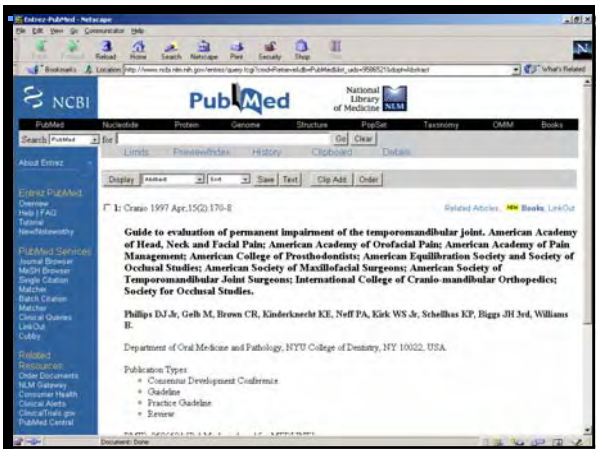
(2) It is strongly recommended that, unless there are specific and justifiable indications to the contrary, treatment be based on the use of conservative and reversible therapeutic modalities. While no specific therapies have been proven to be uniformly effective, many of the conservative modalities have provided at least palliative relief from symptoms without producing harm.

(adopted 1996)

NIH Technology Assessment Conference on TMD. 29.4-1.5-1996 – Consequences:

- Creation of a strong conflict between “pragmatists” and “scientists”.
- A series of protests and letters from “The Alliance of TMD Practitioners”
- Several statement and editorials staking out new courses
- Call for appeals to common sense ⊗

24



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- Creation of a strong conflict between “pragmatists” and “scientists”.
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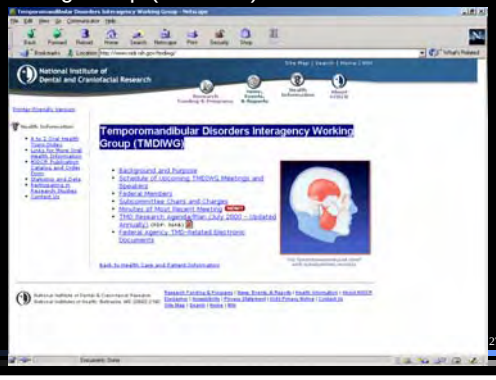
- Several statements and editorials staking out new courses
- Call for appeals to common sense
- Interest of Society

26

Temporomandibular Disorders Interagency Working Group (TMDIWG)



27

Practice versus science

1. On what should diagnosis and management of patients with TMD be based?

28

Optimal management of TMD patients?

- by anecdote
- by press cutting
- by expert opinion (from others)
- by cost minimization
- by critical appraisal of science

29

Practice versus science

1. On what should diagnosis and management of patient care be based?
2. Is there a difference between science and research?

30

Research = science ?

Compilation of:

- Empirical knowledge
- Science
  - Observational studies
    - Laboratory
    - Clinical
  - Experimental studies
    - Laboratory
    - Clinical

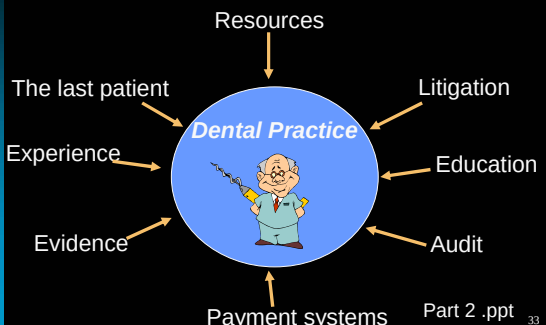
31

Practice versus science

1. On what should diagnosis and management of patient care be based?
2. Is there a difference between science and research?
3. How are clinical decisions made?

32

Influences on treatment decisions

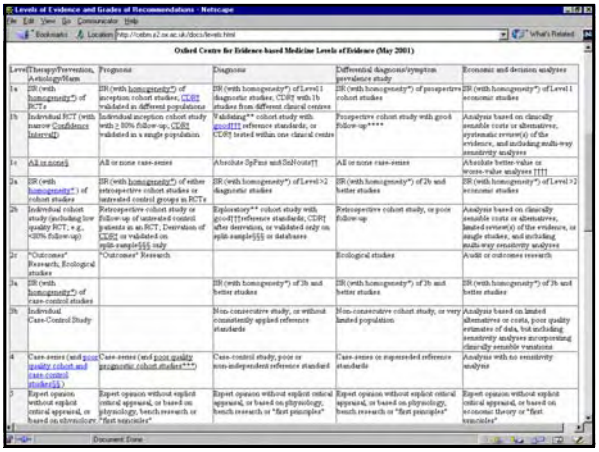


Part 2 .ppt 33

Practice versus science

1. On what should diagnosis and management of patient care be based?
2. Is there a difference between science and research?
3. How is a clinical decision made?
4. Is there consensus on optimal study design to elucidate issues in patient care?

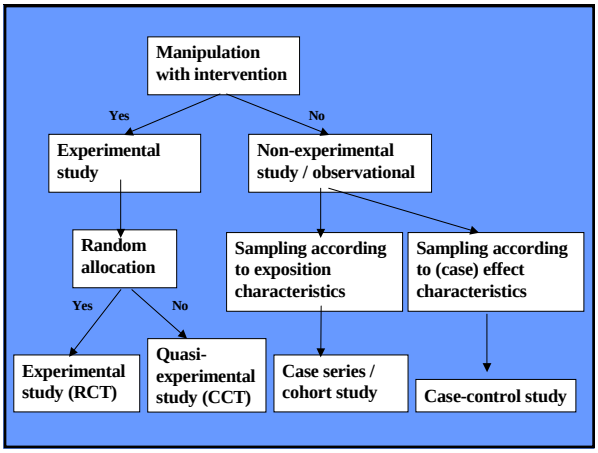
34



Levels of Evidence and Grades of Recommendations - Netscape

Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)

Level	Therapy/Prevention, Aetiology/Harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs+	SR (with homogeneity*) of inception cohort studies; CDR† validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval‡)	Individual inception cohort study with ≥ 80% follow-up; CDR† validated in a single population	Validating** cohort study with good††† reference standards; or CDR† tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence, and including multi-way sensitivity analyses
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts††	All or none case-series	Absolute better-value or worse-value analyses ††††
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs+	SR (with homogeneity*) of Level >2 diagnostic studies	SR (with homogeneity*) of 2b and better studies	SR (with homogeneity*) of Level >2 economic studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR† or validated on split-sample§§§ only	Exploratory** cohort study with good††† reference standards; CDR† after derivation, or validated only on split-sample§§§ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	"Outcomes" Research; Ecological studies	"Outcomes" Research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies
3b	Individual Case-Control Study		Non-consecutive study, or without consistently applied reference standards	Non-consecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations
4	Case-series (and poor quality cohort and case-control studies§§)	Case-series (and poor quality prognostic cohort studies***)	Case-control study, poor or non-independent reference standard	Case-series or supernormal reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"



Clinical trial terminology - tower of Bable?

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

Descriptions reduced to three questions:

1. Study objective?
   - 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

38

Clinical study designs (MESH terms):

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

39

Practice versus science

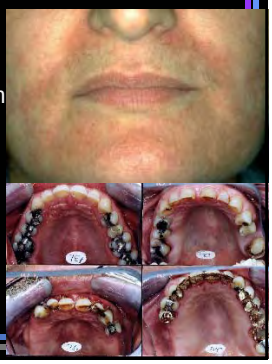
1. On what should diagnosis and management of patient care be based?
2. Is there a difference between science and research?
3. How is a clinical decision made?
4. Is there consensus on optimal study design to elucidate issues in patient care?
5. What types of research strategies should be applied to support scientific theories on management of TMD?

40

Central issues of TMD treatment

1. Clinical findings:

How to properly gather the most relevant findings from the history and physical examination, and interpret these correctly?



2. Etiology:

How to identify causes for TMD (including its iatrogenic forms) ?

Central issues of TMD treatment

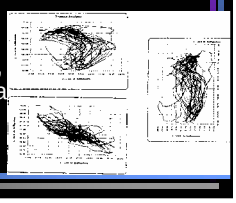
3. Differential diagnosis:

When considering the possible causes of a patient's TMD problems, how to rank them by likelihood, seriousness and treatibility ?

Level of Organization	Example of problem or disorder
Organ System	Neurologic Disorders
Pathologic similarities	Demyelinating Disorders
Causative agent	Viral Diseases
Symptom Similarities	Headaches

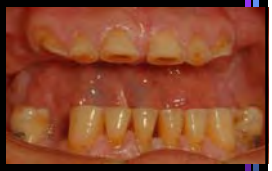
4. Diagnostic tests

How to select and interpret tests, in order to confirm or exclude a diagnosis, based on precision, accuracy, acceptability, expense, safety, etc?

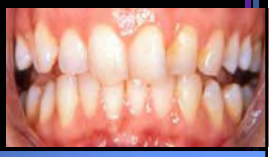


Central issues of TMD treatment

5. Prognosis:
How to estimate the patient's likely clinical course over time with and without treatment and anticipate likely complications?



6. Therapy:
How to select treatments to offer patients that do more good than harm and that are worth the efforts and costs of using them?

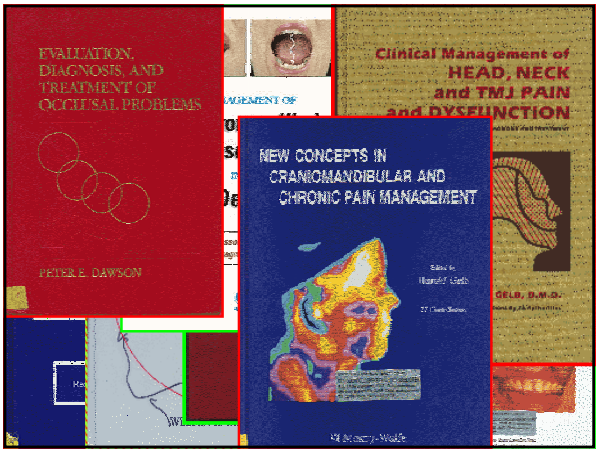


Central issues of TMD treatment

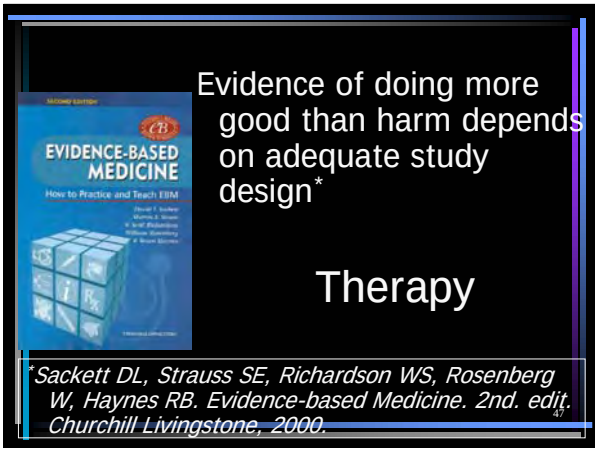
7. Prevention:
How to reduce the chance of TMD by identifying and modifying risk factors and how do we diagnose TMD early by screening?

8. Self-improvement:
How to keep up to date, improve our clinical skills to provide best treatment of TMD?

44




Books related to Prosthodontics and Oral Function
This database contains information on books in prosthetic dentistry and oral function published since 1985. Suggestions for improvement and information on further book titles, accuracy of existing data, published book reviews, etc. are highly appreciated.
Oslo, January 2001, Asbjørn Jokstad, prosthodontist, dr. odont.
Main focus of books:
Prosthodontics in general & Fixed Prosthodontics
Removable Prosthodontics
Implant Prosthodontics
Attachments
Oral Function and TMD
Maxillofacial Prosthetics
General Laboratory/ techniques
[The book reviews and contents are presented in long files of 350 Kb - (i.e. files should not be opened/opened in new window if using a slow connection)]
Implant prosthodontics
AUTHORS
BOOK TITLE
PUBLISHER
YEAR
Albrektsson T, Zarb GA
The Brånemark Osseointegrated Implant
Quintessence
Contents
1989
Babbush CA
Dental implants: Principles and Practice
W B Saunders
1991
Bergendal T, Kvint S
Plats för implantat
LIC Förlag
1990
Bergendal T, Kvint S, Lundgren D
Dags för implantat
Gothia
1999
Besimo C
Removable Partial Dentures on Osseointegrated Implants.
Quintessence
Contents
1998
Beumer J, Lewis SG
The Brånemark Implant System : Clinical and Laboratory Procedures
Medico Dental Media Int
1989


EVIDENCE-BASED MEDICINE
How to Practice and Teach EBM
Evidence of doing more good than harm depends on adequate study design*
Therapy
*Sackett DL, Strauss SE, Richardson WS, Rosenberg W, Haynes RB. Evidence-based Medicine. 2nd. edit. Churchill Livingstone, 2000.
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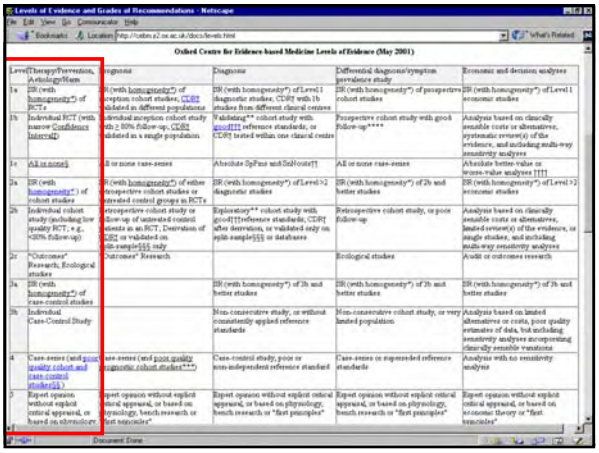
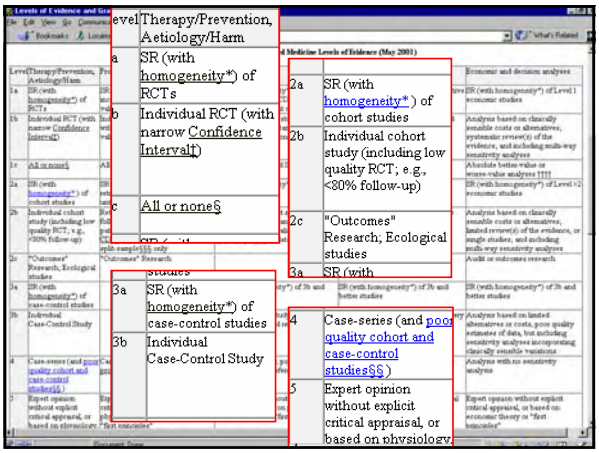
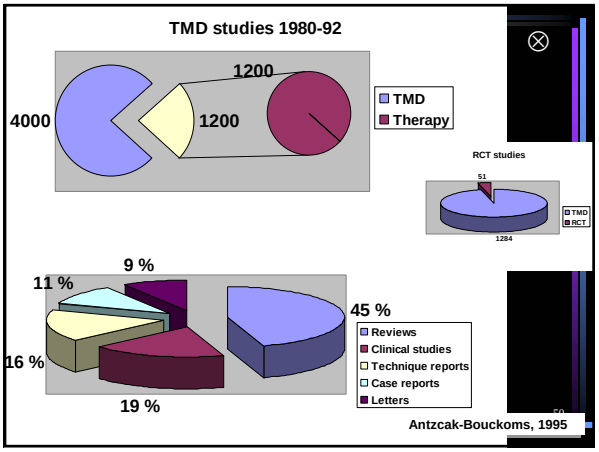

Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)



Level	Therapy/Prevention, Aetiology/Harm
1a	SR (with homogeneity*) of RCTs
1b	Individual RCT (with narrow Confidence Interval‡)
1c	All or none§
2a	SR (with homogeneity*) of cohort studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)
2c	"Outcomes" Research; Ecological studies
3a	SR (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

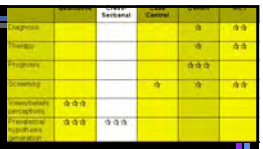


Appropriate Study Designs

	Qualitative	Cross-Sectional	Case Control	Cohort	RCT
Diagnosis				☆	☆☆
Therapy				☆	☆☆
Prognosis				☆☆☆	
Screening			☆	☆	☆☆
Views/beliefs perceptions	☆☆☆				
Prevalence/ hypothesis generation	☆☆☆	☆☆☆			

51

Cross-Sectional Survey



Advantages

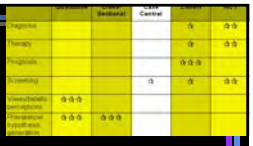
1. Cheap and simple
2. Ethically safe

Disadvantages

1. Establishes association at most, not causality
2. Recall bias susceptibility
3. Confounders may be unequally distributed
4. Group sizes may be unequal

52

Case-Control Studies



Advantages:

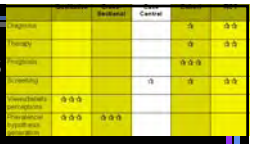
1. Quick and cheap
2. Only feasible method for very rare disorders or those with long lag between exposure and outcome
3. Fewer individuals needed than cross-sectional studies

Disadvantages:

1. Reliance on recall or records to determine exposure status
2. Confounders
3. selection of control groups is difficult

53

Poor case-control studies are recognized by:

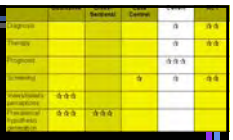


Failure to:

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

54

Cohort Study



Advantages:

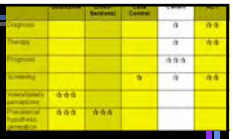
1. Ethically safe
2. individuals can be matched
3. Can establish timing and directionality of events
4. Eligibility criteria and outcome assessments can be standardised
5. Administratively easier and cheaper than RCT

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

55

Poor cohort studies are recognized by:



Failure to :

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

56

Randomised Controlled Trial - RCT

Advantages

1. Unbiased distribution of confounders
2. Blinding more likely
3. Randomisation facilitates statistical analysis

Disadvantages

1. Size, time and money - Expensive!
2. Volunteer bias
3. Ethically problematic at times

57

Cohort & RCT Crossover Design

Advantages

1. All individuals serve as own controls -> error variance is reduced -> reduced need of large sample size
2. All individuals receive treatment (at least some of the time)
3. Statistical tests assuming randomisation can be used
4. Blinding can be maintained

Disadvantages

1. All individuals receive placebo or alternative treatment at some point
2. Washout period lengthy or unknown
3. Cannot be used for treatments with permanent effects

58

Scientific studies can be graded according to the theoretical possibility of an incorrect conclusion.

This is reflected by the design of the study.

…we will never know exact answers in science....

59

What can you show with a trial?

What the trial shows	The truth: A is better than B	The truth: A is no better than B
A is better than B	√	X
A is no better than B	X	√

60

What can you show with a trial?

Type 1 error
Alfa error
Optimism error

What the trial shows	The truth: A is better than B	The truth: A is no better than B
A is better than B	√	X
A is no better than B	X	√

61

Type 1 errors - fallacies of observed clinical success

- Spontaneous remission
- Placebo response
- Multiple variables in treatment
- Radical versus conservative treatment
- Over-treatment
- Long-term failure
- Side effects and sequelae of treatment

62

What can you show with a trial?

What the trial shows	The truth: A is better than B	The truth: A is no better than B
A is better than B	√	X
A is no better than B	X	√

Type 2 error
Beta error
Pessimism error

63

Type 2 errors - fallacies of observed clinical failures

- Wrong diagnosis
- Incorrect cause-effect correlations
- Multifactorial problems
- Lack of cooperation
- Improper execution of treatment
- Premature evaluation of treatment
- Limited success of treatment
- Psychological barriers to success

64

The easy approach to evaluate treatment effects

- Compare a single group of patients given the new treatment with a group previously treated with an alternative treatment.
- Usually such studies compare two consecutive series of patients in the same settings.

65

The easy approach is seriously flawed:

- Multiple examples in medicine where results from RCTs negates findings from clinical trials using inadequate study designs
- Controlled trials yield in general more optimistic results than randomised trials. (Altman DG. BMJ 1991;302:1481)
- Can never satisfactorily eliminate possible biases due to other factors (apart from treatment) that may have changed over time

66

The easy approach and risk of bias:

- If the clinician chooses which treatment to give each patient there will probably be differences in the clinical and demographic characteristics of the patients receiving the different treatments.
- Much the same will happen if patients choose their own treatment or if those who agree to have a treatment are compared with refusers.
- Similar problems when the different treatment groups are at different clinics or under different operators.
- Systematic differences will lead to an overestimate or underestimate of the difference between treatments.
- Bias can be avoided by using random allocation.

67

Internal and external validity

Internal validity: extent to which systematic error (bias) is minimised in clinical trials

External validity: extent to which results of trials provide a correct basis for generalisation to other circumstances

68

Internal validity - systematic bias

- Selection bias: biased allocation to comparison groups
- Performance bias: unequal provision of care apart from treatment under evaluation
- Detection bias: biased assessment of outcome
- Attrition bias: biased occurrence and handling of deviations from protocol and loss to follow up

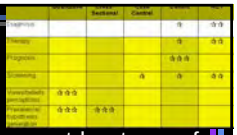
69

External validity

- Patients: age, sex, severity of disease and risk factors, co-morbidity
- Treatment regimens: dosage, timing and route of administration, type of treatment within a class of treatments, concomitant treatments
- Settings: level of care (primary to tertiary) and experience and specialisation of care provider
- Modalities of outcomes: type or definition of outcomes and duration of follow up

70

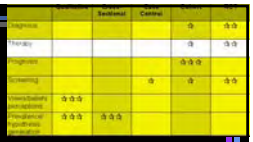
Diagnostic tests, Differential diagnosis



- Clearly identified comparison groups, at least one of which is free of the target disorder
- Either an objective diagnostic standard/contemporary clinical diagnostic standard with reproducible criteria for any objectively interpreted component
- Interpretation of the test without knowledge of the diagnostic standard result
- Interpretation of the diagnostic standard without knowledge of the test result
- A statistical analysis consistent with study design

71

Therapy / Prevention / Education



- Random allocation of the participants to the different interventions
- Outcome measures of known or probably clinical importance for at least 80 per cent of participants who entered the investigation
- A statistical analysis consistent with the study design.

72

Prognosis

- An inception cohort of persons, all initially free of the outcome of interest
- Follow-up of at least 80 per cent of patients until the occurrence of either a major study criteria or the end of the study
- A statistical analysis consistent with the study design.

73

Etiology - Harm - Causation

- Clearly identified comparison group for those at risk for, or having, the outcome of interest
- Masking of observers of outcomes to exposures
- Observers of exposures masked to outcomes for case-control studies and individuals masked to exposure for all other study designs
- A statistical analysis consistent with the study design.

74

Critical Appraisal Criteria

Exists for studies focused on e.g. :

- therapy
- diagnosis
- screening
- harm
- prognosis
- causation of disease (etiology)
- quality of care
- economic analyses
- ....

75

Three general questions

1. Is the study valid?
2. What are the results ?
3. Are the results relevant to my question / problem?

76

1. Is the Study Valid ?

- Is there a clear question?
- Is the most appropriate study design to answer the question used?
- Was the study conducted reliably?
- Can you follow what the authors did?

77

2. What are the results?

- Are the results presented in a clear and simple manner ?
- Is there a clear bottom line ?
- Are they clinically important ?

78

3. Are the results relevant to my question / problem ?

- Are the participants similar to my patients ?
- Is it realistic for me to apply the study methodology and results to my patients ?

79