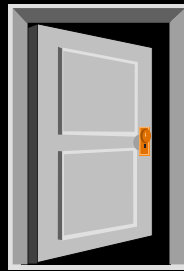


Dentale Implantater, kliniske studier

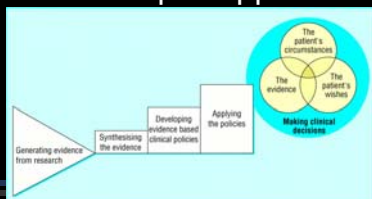
Asbjørn Jokstad
Institutt for klinisk odontologi
Universitetet i Oslo

..en EBM
tilnærming



En evidens-basert tilnærming

1. Akseptere og anvende retningslinjer som er baserte på evidens-baserte prinsipper

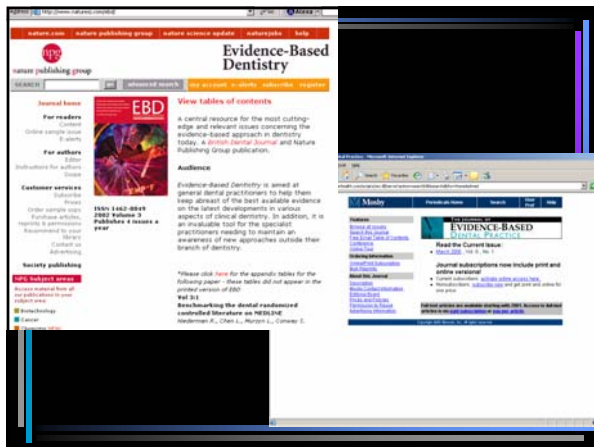




En evidens-basert tilnærming

1. Akseptere og anvende kliniske retningslinjer som er baserte på evidens-baserte prinsipper
2. Søke og anvende evidens-baserte sammendrag utarbeidet av andre.

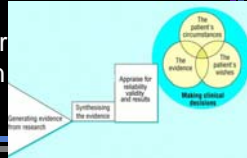
1. Fagtidsskrift som kritisk evaluerer primærstudier





En evidens-basert tilnærming

1. Akseptere og anvende kliniske retningslinjer som er baserte på evidens-baserte prinsipper
2. Søke og anvende evidens-baserte sammendrag utarbeidet av andre.
 1. Fagtidsskrift som kritisk evaluerer primærstudier
 2. Systematiske oversikter
 - Cochrane Collaboration





Cochrane systematic reviews

- | | |
|--|-------------------------------|
| Zygomatic implants | 0 RCT |
| Hyperbaric oxygen therapy | 0 RCT |
| Use of prophylactic antibiotics | 0 RCT |
| Perimplantitis | 1 RCT (kinesisk) |
| Preprosthetic surgery vs implants | 1 RCT with 60 participants |
| Bone augmentation techniques | 4 RCTs with 95 participants |
| Surgical techniques Immediate, early or conventional loading | 4 RCTs with 190 participants |
| Maintenance | 5 RCTs with 124 participants |
| Various implant characteristics/systems | 5 RCTs with 127 participants |
| | 12 RCTs with 512 participants |

En evidens-basert tilnærming

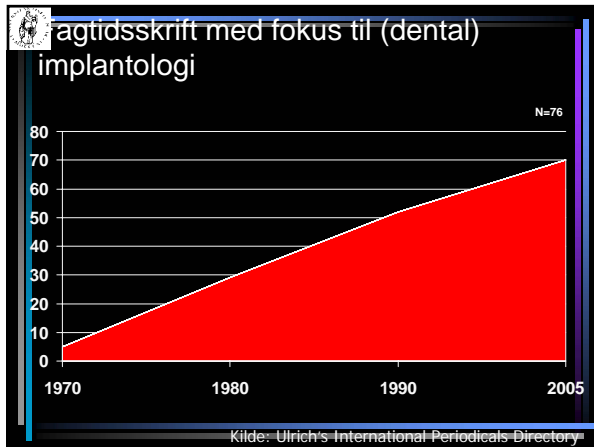
1. Akseptere og anvende kliniske retningslinjer som er baserte på evidens-baserte prinsipper
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 1. Fagtidsskrift som kritisk evaluerer primærstudier
 2. Systematiske oversikter
 - Cochrane Collaboration
 - Nat. Health Serv. R&D
 - Annen litteratur

En evidens-basert tilnærming

1. Akseptere og anvende kliniske retningslinjer som er baserte på evidens-baserte prinsipper
2. Søke og anvende evidens-baserte sammendrag utarbeidet av andre.
3. Selv lære kritisk analyse
 - Bøker
 - Seminarer
 - Internett
 - Online link-lister
 - Online kurs
 - Online ressurser

Informasjonskilder

- Artikler



Elektroniske tidsskrifter

Les bruk av elektroniske tidsskrifter

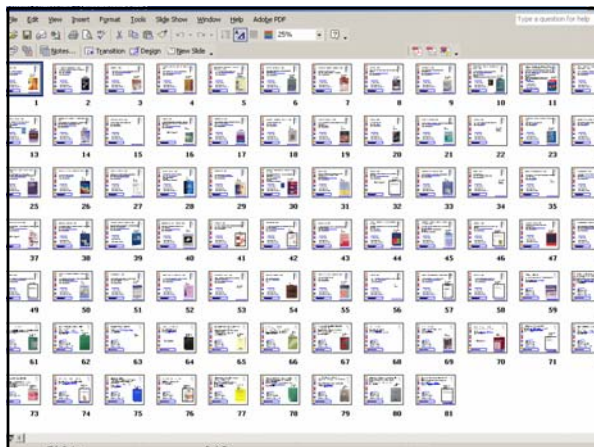
Bibliotek for medisin og helsefag

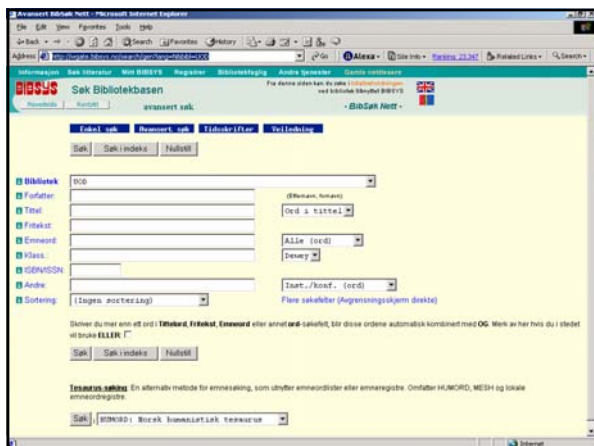
- ABCDEFGHIJKLMNOPQRSTUVWXYZÆØÅ
- A
 - Acta Odontologica Scandinavica
 - Acta Odontologica Scandinavica
 - ADA News Today
 - Advances in Dental Research
 - American Journal of Forensic Medicine and Pathology
 - American Journal of Orthodontics and Dentofacial Orthodontics 1990
 - Bioceramics as a material for LMO
 - Jachira Indusart 2000
 - American Journal of Physical Anthropology
 - Anestesi
 - The Anatomical Record
 - Anna Orthodontia
 - Applied and Environmental Microbiology
 - Archives of Oral Biology
 - Australian Dental Journal
- B
 - Biochemical Education
 - Biochemistry and Molecular Biology Education 2000
 - Biochemistry and Molecular Biology Education 2000-2001
 - Biological Therapies in Dentistry



Informasjonskilder

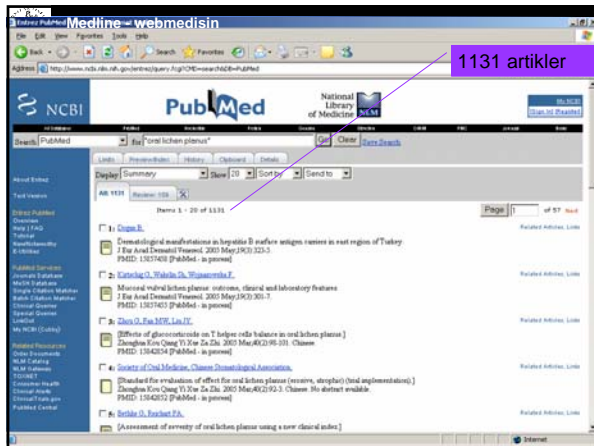
- Artikler
- Bøker





Informasjonskilder

- Artikler
- Bøker
- Siste forskningsresultater



Validitet, resultat og anvendelighet av en rapport: Tre hovedspørsmål

1. Er studien gyldig (valid)?
2. Hva er resultatene?
3. Er resultatene relevante for mitt problem?

1. Er studien gyldig (valid)?

1. Er problemstillingen klart beskrevet?
2. Er det brukt et relevant studiedesign til å besvare problemstillingen?
3. Er studien korrekt utført?
4. Kan du forstå hva forfatterne gjorde?



2. Hva er resultatene ?

1. Er resultatene presentert klart og enkelt?
2. Er konklusjonen klar?
3. Er resultatene viktige fra et klinisk ståsted?



3. Er resultatene anvendelige for meg?

1. Er deltakerne i studien tilnærmet like mine?
2. Er det realistisk at jeg kan applisere resultatene fra studien til mine pasienter?



Studiedesign mht terapi, profylaksetiltak eller opplæring

Når en ny intervensjon gjør mer nytte enn skade sammenlignet med den rådende, og samtidig er verdt kostnadene og arbeidsinnsatsen

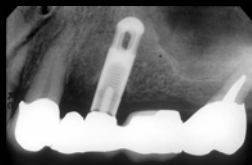


Krav til evidens:

- Randomisert kontrollert studie
- Relevant observasjonstid pasienter, målekriterier, setting
- N & 80% oppslutning
- Korrekt statistikk

Studiedesign mht vurdering av prognose

...når det er vist at den sannsynlige utvikling over tid er til det bedre og/eller de mest sannsynlige komplikasjoner er færre eller enklere sammenlignet med den rådende



Krav til evidens:

- Prospektiv kohort-studie
- Representative pasienter
- Relevant observasjonstid
- N & 80% oppslutning
- Korrekt statistikk

Studiedesign mht ny kunnskap/ pasientinformasjon om etiologi, skadefekter og årsaksammenheng

Når nye etiologiske årsaks-mekanismer i relasjon til ulike plager/ sykdom/ problem blir sannsynliggjort.

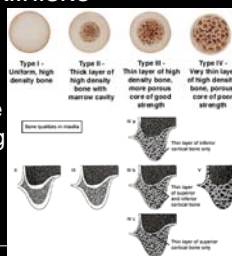


Krav til evidens:

- Randomisert klinisk studie > Klinisk studie > kasus-kontrol > tverrsnittstudier > singlekasus
- Dobbel- / Single-blind studiedesign
- Maksimal N
- Korrekt statistikk

Studiedesign mht nye kliniske undersøkelses-rutiner

Når nye rutiner gir forbedret identifikasjon av de mest relevante funn fra en klinisk undersøkelse og pasienthistorikk og/eller disse funnene blir fortolket på en mer korrekt måte

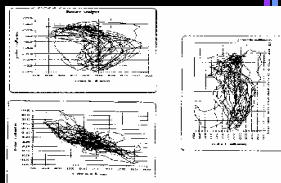


Krav til evidens

- Klart definerte grupper sammenlignet (én symptomfri)
- Testet mot objektiv diagnostisk standard eller klinisk standard med reproduerbare kriterier
- Høy sensitivitet og spesifisitet
- Korrekt statistikk

Studiedesign mht innføring av ny en diagnostisk test

Når en ny test utviser en akseptabel presisjon, god pasientakseptans, og er nøyaktig, sikker, og kostnads-effektiv



Krav til evidens (I tillegg til forrige bilde)

- Dokumentert økt gevinst mht sensitivitet og spesifisitet i forhold til eksisterende test ("gullstandard")
- Den nye testen må relateres til sykdomsprevalens
- Korrekt utførte og rapporte kvalitative studier
- Korrekt statistikk

Tannimplantater og kvalitet

Er et implantat av "god kvalitet" når..

- vi har klinisk data etter 3 år? ...5år? ...10år?
- implantatet er laget av cpTi grad 2 ...3? ...4?
- implantatet er rufset ...rillet ...gjenget ...avrundet ...intern låsning ...sandblåst?
- produsenten følger ISO9001?
- en spandabel og trivelig selger har sagt så?
- en av vår lokale guruer har sagt så?
- vitenskapelige kliniske studier kan gi et svar?



Kunne muligens besvares hvis noen:

Identifiserte og vurderte all data om temaet fra kliniske studier som tilfredsstillende et minstekrav til god studie-metodologi og –rapportering



To systematiske oversiktsarbeider

1. FDI World Dental Federation
2. Cochrane Collaboration



FDI prosjektet "Quality of implants", prosess:


1. Prosjekt opprettet av FDI's Vitenskapskomisjon
2. Prosjektleder oppnevnt (AJ)
3. Ekspert identifisert – Ikke tilknyttet industrien (Belgia, Sveits, Sverige, USA)
4. Rapport sammenfattet
5. Rapport godkjent av FDI's Vitenskapskomisjon
6. Rapport sent til industrien for kommentarer (3i, Astra, Friadent, NobelBiocare & Straumann)
7. Kommentarer vurdert og inkorporert
8. Rapport sent til eksterne refereres
9. Publisert i International Dental Journal

2004: 82 produsenter fremstiller 235 ulike implantatmerker

Kvaliteten på tannimplantater


Jokstad A, Brægger U, Brunski JB, Carr AB, Naert I, Wennerberg A. Quality of Dental Implants. *Int Dent J*, 2003; 53 Sup 2: 409-33. & *Int J Prosthodontics* 2004; 17: 607-641





Hva vi gjorde:

- Systematisk søk i litteratur og på Internet for å finne påstander om overlegne implantat-egenskaper samt identifisere dokumentasjonen for påstandene
- Kritisk analyse av denne dokumentasjonen for å vurdere vitenskapelig gyldighet
- Evaluere de rapporterte behandlingsresultat som funksjon av implantat-karakteristika



Påstander om klinisk gevinst pga implantatets karakteristika

- + 1. Letter plassering/håndtering eller initiell immobilitet
- 2. Osseointegrasjon (hastighet/ forutsigbarhet)
- 3. Estetikk
- 4. Peri-implantat mukositt
- 5. Marginalt benfeste
- 6. Mekaniske problem mellom implantat/ distanse/ suprastruktur -forbindelsene
- 7. Mekanisk defekt i implantatet

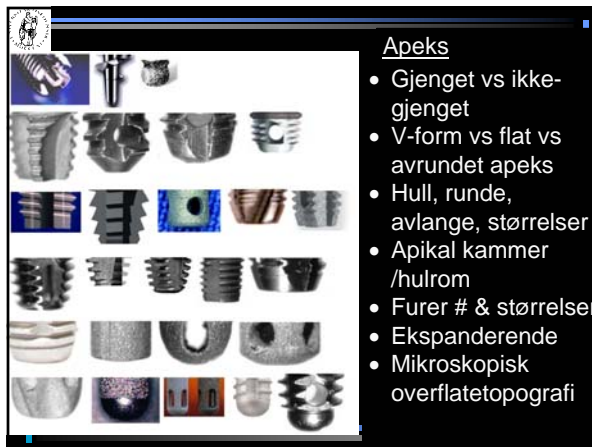








Maskineringsprosess	Overflate-topografi	Eksempel
Acid etched surface (The surface is usually etched in a two-step procedure)	Isotrop overflate med høy forekomst av irregulariteter	HCl/ H ₂ SO ₄ (Osseotite®, 3i Implant innovations)
Blasted surface (The surface is blasted with hard particles.)	Isotrop overflate	TiO ₂ particles (Tioblast®, Astra Tech AB)
Blasted + acid etched surface (The surface is first blasted and then acid etched)	Isotrop overflate	1. Large size Al ₂ O ₃ particles & HCl & H ₂ SO ₄ (SLA®, Straumann) 2. Tricalcium phosphate & HF & NO ₃ (MTX®, Centerpulse Dental)
Hydroxyapatite coated surface	Generelt, en relativt ru og isotrop overflate	Sustain® (Lifecore Biomedical Inc.)
Oxidized surface (Increased thickness of the oxidized layer)	Isotrop overflate med forekomst av kraterstrukturer	TiUnite® (Nobel Biocare AB)
Titanium Plasma Sprayed (TPS) surface	En relativt ru isotrop overflate	ITI® TPS (Straumann AG)
Turned surface	Skjæremarker produserer en orientert Anisotrop overflate	Brånemark System® MKIII (Nobel Biocare)





2004: 82 produsenter fremstiller 235 ulike implantatmerker

Oppsummering av rapporten

...implantater fremstilt i titan og titanlegeringer fungerer klinisk tilfredsstillende uavhengig av små variasjoner i fasonger...

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..de fleste kliniske studier fokuserer kun på peri-implantat kriterier over kort tid...

..slike kriterier kan bare betraktes som surrogatmål og av liten betydning fra et pasient- og samfunnsperspektiv

Objectives

1. To test the null hypothesis of no difference in the success, function and patient satisfaction between conventional prostheses and oral implants against the alternative hypothesis of a difference.

Date of most recent: 09 February 2009

Objectives

1. To test the null hypothesis of no difference in the success, function and patient satisfaction between conventional prostheses and oral implants against the alternative hypothesis of a difference.
2. To test the null hypothesis of no difference in the long term success, morbidity, function and patient satisfaction between different oral implant characteristics and techniques against the alternative hypothesis of a difference.

Method of a Cochrane review –

1. Search for papers

1. Search of the Cochrane Oral Health Group specialist register, using key words (e.g. prosthesis, bridge, implant*). Based on handsearch of journals

Method of a Cochrane review –

1. Search for papers

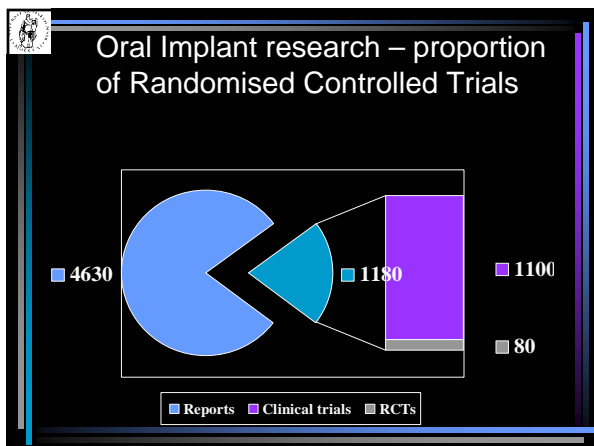
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2. Search for RCT trials in Medline
3. Search of the bibliographies of identified RCTs, reviews and personal references
4. Letters to first named authors of identified RCTs for further information about trials and attempts to identify unpublished studies






Method of a Cochrane review –
2. Initial data synthesis

1. Two reviewers work independently, and in duplicate



Method of a Cochrane review –
2. Initial data synthesis

1. 2 reviewers work independently, and in duplicate
2. The relevance of each potentially interesting article appraised non-blinded with regard to the types of intervention



Method of a Cochrane review –
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3. Recordings of article ownership, affiliation, year of publication and journal



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- 1. 2 reviewers work independently, and in duplicate
- 2. The relevance of each potentially interesting article appraised non-blinded with regard to the types of intervention
- 3. Recordings of article ownership, affiliation, year of publication and journal

4. Identification of funding source (commercial or independent) clinical setting (university or non-university) study design (parallel, split-mouth or cross-over) and sample size



Method of a Cochrane review –

2. Initial data synthesis

- 1. Two reviewers work independently, and in duplicate
- 2. The relevance of each article appraised non-blinded with regard to the types of intervention
- 3. Recordings of article ownership, affiliation, year of publication and journal
- 4. Identification of funding source, clinical setting, study design and sample size

5. Quality assessment of RCTs trials with sample sizes: ≥ 10 for parallel trials & ≥ 5 for split-mouth and cross-over studies

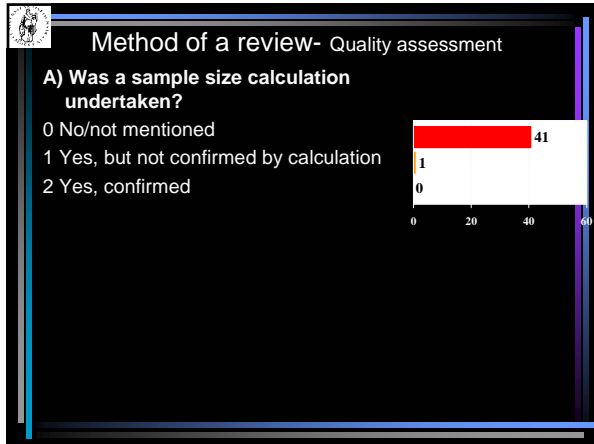
A sensitivity analysis conducted if appropriate.

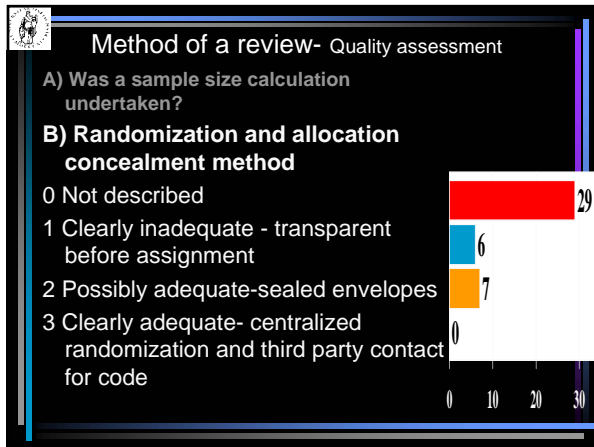


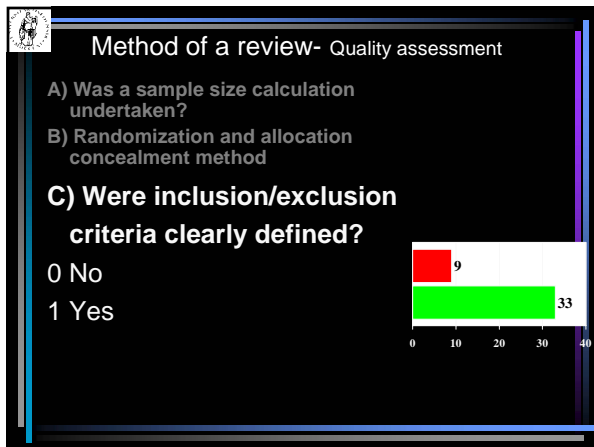
Method of a Cochrane review –

3. Quality assessment

- A) Was a sample size calculation undertaken?
- B) Randomization and allocation concealment method
- C) Were inclusion/exclusion criteria clearly defined?
- D) Was reason for withdrawal specified by study group?
- E) Were the control and treatment groups comparable at entry for important prognostic factors?
- F) Was there any attempt at blinding (for example, independent assessor)?
- G) Was the statistical analysis appropriate?







Method of a review- Quality assessment

A) Was a sample size calculation undertaken?

B) Randomization and allocation concealment method

C) Were inclusion/exclusion criteria clearly defined?

D) Was reason for withdrawal specified by study group?

0 No/not mentioned

1 Yes, or not applicable as no withdrawals

Response	Count
0	9
1	33

Method of a review- Quality assessment

A) Was a sample size calculation undertaken?

B) Randomization and allocation concealment method

C) Were inclusion/exclusion criteria clearly defined?

D) Was reason for withdrawal specified by study group?

E) Were the control and treatment groups comparable at entry for important prognostic factors?

0 No

1 Unclear

2 Yes

Response	Count
0	6
1	16
2	20

BASELINE CHARACTERISTICS, e.g.

- Age
- Allergy
- Angle occlusal classification
- Diet
- Gender
- General health
- Medication
- Smoking
- Xerostomia signs
- Abutment teeth periodontal involvement
- Adjacent teeth restoration state
- Bruxism signs
- Caries activity
- Number of remaining teeth
- Oral hygiene level
- Pulp vitality / endodontically treated teeth /posts
- Tooth mobility

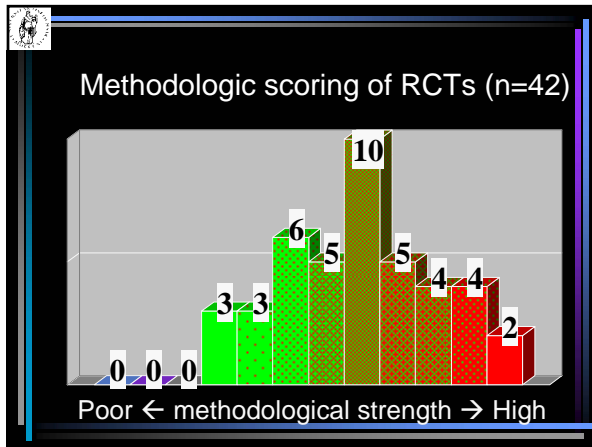
Quality Assessment of Randomized Controlled Trials of Oral Implants

Marco Esposito, DDS, PhD¹/Paul Coulthard, BDS, MFGDP, MDS, FDSRCS, PhD²/
Helen V. Worthington, BSc, MSc, PhD, FSP/Asbjørn Jøkstad, DDS, PhD³

The aim of this study was to assess the quality of randomized controlled trials (RCTs) concerned with the effectiveness of oral implants and to create a trial register. A multilayered search strategy was used to identify all RCTs published by the end of 1999 in any language. The Cochrane Oral Health Group specialist register, PubMed, and personal libraries were searched. Seventy-four RCTs were identified. Forty-three articles, not presenting the same patient material, were independently assessed by 3 researchers using a specially designed form. A statistician assessed all trials for the appropriateness of statistics. The quality of each study was assessed on 7 items, including 3 key domains. Randomization and concealment allocation procedures were not described in 30 articles (70%). Reasons for withdrawals were not given in 10 reports (23%). No attempt at blinding was reported in 31 studies (72%). The quality of RCTs of oral implants is generally poor and needs to be improved. INT J ORAL MAXILLOFAC IMPLANTS 2001;16:783-792.

Key words: dental implants, randomized controlled trial, registries, research design, review literature

IJOMI 2001; 16: 783-92




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Key words: dental implants, randomized controlled trial, registries, research design, review literature

The quality of RCTs of oral implants is generally poor and needs to be improved

 Method of a Cochrane review –
4. Data synthesis


1. Two reviewers work independently, and in duplicate

 Method of a Cochrane review –
4. Data synthesis

1. 2 reviewers work independently, and in duplicate

2. Appraise:

- patient age
- withdrawals by group
- reasons for withdrawals.
- primary outcomes for all time points mentioned in the study report.

 Study aims - implant characteristics

Implant location
Wide vs minimised spaces

Implant number
2 vs 4 implants supporting overdenture

Implant type
Self-tapping vs standard
Rough vs smooth surface
Titanium vs Hydroxyapatite
Staple vs 2 & 4 implants



Which outcome criteria?

Interventions comparing oral implants with different materials, shapes and surface properties

- 1) Implant mobility and implant removal of stable implants dictated by progressive marginal bone loss
- 2) Implant fracture and other mechanical complications that do not allow the use of the implants
- 3) Radiographic marginal bone level changes on standardised intra-oral radiographs



Which outcome criteria?

- 1) Plaque
- 2) Marginal bleeding
- 3) Probing pocket depth
- 4) Probing "attachment" level
- 5) Radiographic marginal bone level changes on standardised intra-oral radiographs

THE EFFICACY OF DENTAL IMPLANTS: AN EVIDENCE-BASED OVERVIEW

From 10 Cochrane reviews on osseointegrated dental implants

Updated up to November 2004

<http://www.cochrane.org>

<http://www.cochrane-oral.man.ac.uk>

Various implant characteristics/systems

Is a surface modification, an implant shape or material more effective than the others?

Last literature search: June 2004

12 RCTs with 512 participants and 12 different implant systems (19 RCTs were excluded). 4 RCTs with a 5-year follow-up

Minor significant differences in marginal bone loss and in the occurrence of periimplantitis. No statistically significant difference in failure rates. We do not know whether any implant system is superior to the others. **It does not mean that they are all the same!**

Which criteria when comparisons between:



Study aims - Prosthesis characteristics

Prosthesis type

Stress-breaker vs non-stress breaker

Splinted vs unsplinted connection

Implant-prosthesis connection

Fixed vs overdentures

Hybrid versus ball-attachment

Different overdenture attachments

Laser-welded vs cast Ti-framework



Study aims

- Conventional versus implant prosthodontics
- Prosthesis characteristics
- Implant-prosthesis connection characteristics
- Implant characteristics
- Implant surgery techniques
- Guided bone regeneration
- Maintenance



The most relevant outcome criteria?

- Plaque, marginal bleeding, probing pocket depth, probing attachment level, radiographic marginal bone level, bone changes on standardised intra-oral radiographs....
- Implant mobility and implant removal of stable implants dictated by progressive marginal bone loss
- Implant fracture and other mechanical complications



The most relevant outcome criteria?

Perceived/self reported:

- Adaptation to prosthesis (satisfaction)
- Appearance
- Function (chewing, speech)
- Dietary significance (intake, selection)
- Health
- Quality of life (psyche, well-being, self esteem)
- Social activity

Observed:

- Appearance
- Function (bite force, tracking)
- Diet survey
- Health indices
- HRQL indices
- Social activity



There is a need

To define the most relevant criteria for treatment outcomes when implant based prostheses are compared to alternative treatments



A. Psychological impact

1. Patient satisfaction with treatment
2. Patient satisfaction with aesthetics
3. Patient satisfaction with function (chewing, dietary changes, speech)
4. Reported changes of social activity
5. Quality of life/health measure
6. Patient preference for prosthesis



A. Psychological impact

1. Patient satisfaction with treatment, 2. aesthetics & 3. function (chewing, dietary changes, speech)
4. Reported changes of social activity
5. Quality of life/health measure
6. Patient preference for prosthesis

Longevity/survival

7. Cumulative survival of prosthesis and implant - actual function period
8. Cumulative survival of prosthesis and implant - defined success criteria
9. Time to retreatment

A. Psychological impact
 1. Patient satisfaction with treatment, 2. aesthetics & 3. function (chewing, dietary changes, speech), 4. Reported changes of social activity, 5. Quality of life/health measure, 6. Patient preference for prosthesis

Longevity/survival
 7. Cumulative survival of prosthesis and implant - actual function period & 8. defined success criteria, 9. Time to retreatment

Biological complications: Incidence and/or severity
 10. Surgical and post-operative complications
 11. Pain
 12. Neurological disturbances
 13. Degenerative changes (e.g. alveolar bone loss)
 14. Adverse biological consequences in case of prosthesis failure

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Mechanical complications: Incidence and/or severity
 15. Adjustments/maintenance
 16. Prosthesis failure

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Mechanical complications: Incidence and/or severity
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B. Physiologic impact
 17. Prosthesis retention/mobility
 18. Operator-evaluation of function (chewing, bite-force, speech)
