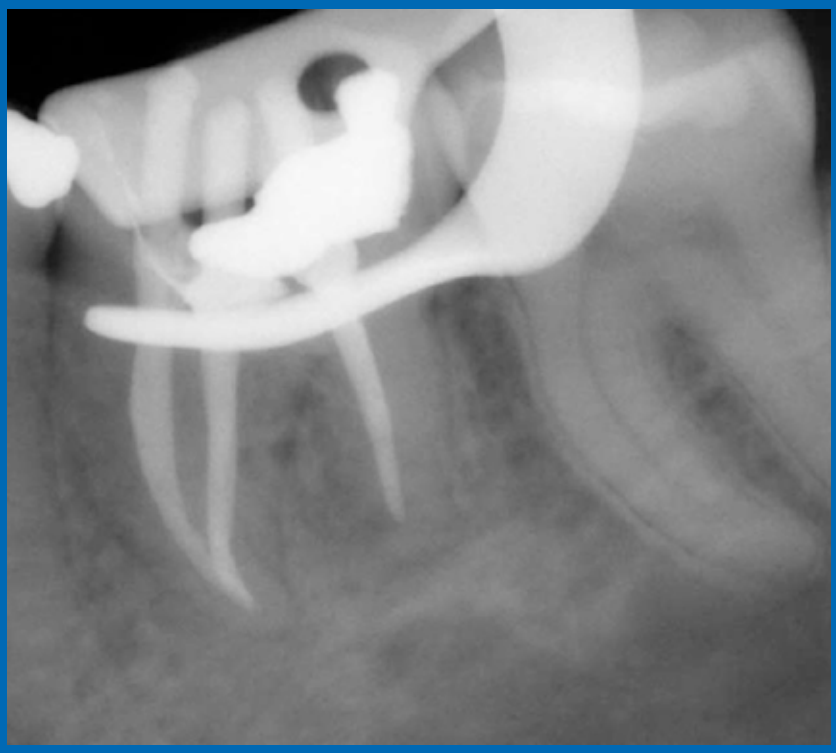
Swedish Dental Journal

Scientific Journal of The Swedish Dental Association



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Introduction
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The Abstract should be short and concise and not exceeding 300 words. The Swedish Sammanfattning can be somewhat more extensive.

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Abbreviations should follow "List of Journals indexed in Index Medicus". (http://www.nlm.nih.gov). Examples of references are presented below.

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The combination of non-selective NSAID 400 mg and paracetamol 1000 mg is more effective than each drug alone for treatment of acute pain. A systematic review

Louise Alexander[1], Emma Hall[2], Lars Eriksson[3], Madeleine Rohlin[4]

Abstract

◉ The aim was to evaluate the evidence on outcomes of the combination of non-selective NSAID/paracetamol compared to either drug alone, to relieve acute pain following oral surgery in adult patients.

A systematic review of available literature was performed. The first step comprised searches in three electronic databases. Original studies written in English were searched. As a second step, the reference lists of included publications were searched for additional publications. Abstracts were retrieved if the title contained information on postoperative pain, NSAID, and paracetamol in combination with oral surgery. Two reviewers selected publications on the basis of predetermined inclusion criteria. Data were extracted using one protocol and the quality of each study was assessed using another protocol.

The initial search in PubMed resulted in 138 abstracts and in the Cochrane library a further four. The search in the Web of Science resulted in no additional abstract. Five RCTs fulfilled the inclusion criteria.

Pain relief from the combination of non-selective NSAID with paracetamol was significantly better than with paracetamol alone as well as with NSAID alone. Nausea, vomiting, headache, and dizziness were among the most common adverse events in all treatment groups. Most of the adverse events were of mild to moderate severity. Two studies reported no significant differences in adverse events between the treatment groups. According to one study the adverse events were significantly lower for the combination ibuprofen 400 mg/paracetamol 1000 mg compared to ibuprofen 400 mg alone. The need for rescue drugs in the different groups varied between the studies. Since the studies reported a significantly better postoperative pain relief with the combination of non-selective NSAIDs/paracetamol compared to each drug alone, this combination might be considered the treatment of choice, as long as side effects of NSAIDs are observed.

Key words

NSAID, paracetamol, combination therapy, postoperative pain, systematic review

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Kombinationen icke selektiv NSAID 400 mg och paracetamol 1000 mg effektivare än preparaten var för sig vid behandling av akut smärta. En systematisk litteraturgranskning

Louise Alexander, Emma Hall, Lars Eriksson, Madeleine Rohlin

Sammanfattning

◎ Avsikten med studien var att utvärdera vilken evidens som finns gällande effekten av kombinationen non-selective NSAID/paracetamol jämfört med non-selective NSAID och paracetamol var för sig för att dämpa akut smärta efter oralkirurgiska ingrepp på vuxna.

En systematisk litteraturstudie utfördes. Som ett första steg gjordes en sökning i tre elektroniska databaser. Sökningen begränsades till originalstudier skrivna på engelska. Som ett andra steg genomsöktes referenslistorna på inkluderade publikationer för att finna ytterligare publikationer. Abstrakt lästes om titeln informerade om postoperativ smärta, NSAID och paracetamol i kombination med oral kirurgi. Två granskare valde publikationer med hjälp av förutbestämda inklusionskriterier. Ett protokoll användes för insamling av data och ett annat protokoll för att värdera studiekvaliteten.

Den initiala sökningen i Pub Med resulterade i 138 abstrakt och via Cochrane library ytterligare fyra medan en sökning i Web of Science inte tillförde något. Fem RCT-studier uppfyllde inklusionskriterierna.

Kombinationen non-selective NSAID /paracetamol gav en signifikant bättre smärtlindring jämfört med non-selective NSAID alternativt paracetamol var för sig. Illamående, kräkningar och yrsel var bland de mest frekvent förekommande biverkningarna för samtliga preparat och klassades som milda eller moderata. I två studier fann man ingen signifikant skillnad mellan behandlingsgrupperna gällande biverkningarna medan en studie rapporterade signifikant mindre biverkningar för kombinationen ibuprofen 400mg/paracetamol 1000 mg jämfört med ibuprofen 400 mg. Behovet av rescue drug för de olika preparatkombinationerna varierade mellan studierna.

Då studierna rapporterade signifikant bättre postoperativ smärtlindring med kombinationen non-selective NSAID/paracetamol jämfört med varje preparat för sig, kan kombinationen ses som ett lämpligt val under förutsättning att NSAIDs biverkningar beaktas.

Introduction

Pain is common following oral surgical procedures and good management of the pain is important both for the patient´s wellbeing and for the cost-effective use of healthcare resources (23,24). A combination of non-selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and paracetamol (acetaminophen) is frequently used due to an expected enhanced analgesic effect (27,28,33) as compared to either drug used alone. The evidence that the combination is superior to paracetamol alone seems to be well established, whilst the superiority over NSAID alone is controversial (17,32).

In contrast to NSAIDs that prevent arachidonic acid from cyclooxygenase reaction, paracetamol has been supposed to inhibit peripheral peroxidase reactions. This reaction is sensible for the amount of surrounding oxygen radicals, which might explain the weak anti-inflammatory effect of paracetamol. Furthermore, paracetamol has been considered to act via the serotonergic system in the central nervous system (CNS). Suggested mechanisms include CNS-specific cyclooxygenase (COX) inhibition and interaction with descending pain-modulating serotonergic pathways (25). An inhibition of COX-3 has been discussed, but it is improbable that COX-3 in human plays a role in prostaglandin mediated fever and pain (2). The latest theory on the effect of paracetamol deals with activation of the endocannabinoid system. This system is considered to be part of the regulation of a huge number of physiologic reactions like temperament, level of stress and agony, appetite, regulation of temperature et cetera. The endocannabinoid system seems to be related to the serotonergic system, one of the possible mode of action of paracetamol (25).

NSAID is an analgesic with documented anti-inflammatory and antipyretic properties (29) and acts through inhibition of the enzymes COX-1 and COX-2. These enzymes transform arachidonic acid to prostaglandins, which act as mediators of the inflammation and pain process. In comparison to paracetamol, NSAID has several adverse effects, such as gastric irritation and prolonged bleeding by inhibition of platelet aggregation (30,37). The adverse effects of NSAIDs are principally caused by the inhibition of COX-1. Due to this, selective COX-2 inhibitors were developed. However, selective COX-2 inhibitors cause adverse cardiovascular events and they therefore currently have limited use (30).

This systematic review attempts to bring together evidence of the efficacy of the combination of non-selective NSAID and paracetamol compared to either drug used alone for the treatment of postoperative acute pain in adult patients following oral surgery procedures.

Material and methods

A systematic approach was adopted using a model for literature-searching and evidence-interpretation for assessing healthcare practices as described by Goodman (15), which includes:

1. Problem specification
2. Formulation of a plan for literature search
3. Literature search and retrieval of publications
4. Data extraction, interpretation of data and evidence from literature retrieved.

1. Problem specification

What are the treatment outcomes of non-selective NSAID in combination with paracetamol as compared to either drug alone, administrated orally, to relieve acute postoperative pain following oral surgical procedures in adult patients?

2. Formulation of a plan for literature search

The first step of the searches comprised searches in the PubMed electronic database, the Cochrane Database of Systematic Reviews (the Cochrane Library) and the Web of Science. Table 1 presents the indexing terms and limits used in the PubMed search. Publications written in English on primary material and systematic reviews that shed light on the problem specification were searched. As a second step of the search, the reference lists of included publications were searched for additional publications. When searching the reference list of included publications, an abstract was retrieved if the title contained words such as postoperative pain, NSAID, paracetamol in combination with oral surgery.

Table 1. Search strategy in PubMed and number (n) of publications retrieved

Search	Index (2012-04-11)	n
#1	acetaminophen	1419
#2	non-steroidal anti-inflammatory drugs	4703
#3	#1 AND #2	355
#4	#3 OR drug combination	31819
#5	oral surgical procedure	2861
#6	#4 AND #5	247
#7	pain postoperative	9086
#8	#6 AND #7	138
i.e. (acetaminophen AND non-steroidal anti-inflammatory drugs) OR drug combination) AND oral surgical procedure) AND pain postoperative		
Limits: Humans, Meta-analysis, Randomized controlled trial, Review, English, All persons ≥16 years		

3. Literature search and retrieval of publications

Specifications of inclusion criteria were made using the Patient/Problem Intervention Control Outcome (PICO) method as presented in Table 2. Two assessors independently read all retrieved titles and abstracts. When a publication was judged to fulfil the inclusion criteria, the text was ordered and read in full and either included or excluded for further analysis.

4. Data extraction, interpretation of data and evidence from literature retrieved

Included publications were analysed by the authors using a data extraction protocol. When the publications had been analysed, the extraction protocols were compared. If a protocol was not unanimous it was discussed until there was a mutual agreement. The study quality of the publications was assessed as high, moderate or low using the criteria presented in Table 3. Quality of evidence was rated according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidelines (6) as high, moderate, low, or very low.

Results

Literature identification

Figure 1 summarizes the process of literature identification and selection. The initial search in PubMed resulted in 138 abstracts and in the Cochrane library four additional abstracts were found. The search in the Web of Science resulted in no additional abstracts. Of the 142 publications, 8 were deemed

Table 2. Inclusion criteria expressed as PICO for RCT-studies of the comparison of NSAID/paracetamol versus NSAID or paracetamol alone to relieve acute pain after oral surgery.

Population (P)	Intervention (I)	Control (C)	Outcomes (O)
Adult patients ≥16yrs with acute postoperative pain	Treatment with NSAID/paracetamol in combination	Treatment with NSAID or paracetamol alone	• Pain relief measured by pain scores • Adverse events

Table 3. Criteria for assessment of quality of each publication based on CONSORT statement (22).

High study quality
The study was assessed to have high quality if it fulfilled following criteria: • Well-defined research question/hypothesis/aim • Well-described trial design, inclusion and exclusion criteria for patient sample and setting where data were collected • Methods for randomization described and appropriate • Experiment procedures were described in sufficient detail to permit replication • Well-defined pre-established primary and secondary outcomes measures, including how and when they were assessed; blinding of those assessing outcomes • Attrition rate <10% and described • Stringent presentation of outcomes, adverse events included • Discussion of trial limitations, addressing sources of potential bias and imprecision • Interpretation consistent with results, balancing benefits and adverse events, and considering other relevant evidence
Moderate study quality
A study was assessed to have moderate quality if any of the above criteria was not met AND not to have deficits that are described for studies with low quality
Low study quality
The study was assessed to have low quality if it fulfilled any of following criteria: • Research question vaguely defined • Trial design, inclusion and exclusion criteria for patient sample and setting where data were collected not clearly described • Data collected retrospectively • Intervention and control groups were not equal regarding pain status at start of trial • Unclear description of experiment procedures • Unclear pre-established primary and secondary outcomes measures, including how and when they were assessed • Attrition rate > 20% and not accounted for • Ambiguous presentation of outcomes • Trial limitations not discussed • Unclear how interpretation is based on results, contextualization of benefits and adverse events to previous research poorly developed

relevant and read in full text. Six publications were clinical studies, one was a review and one a meta-analysis. The search of the reference lists yielded no additional publications.

The problem specification, and thus the results of the review and meta-analysis, was not relevant to the present review. Of the remaining six clinical studies one study did not include a combination group. Tables 4 and 5 present data from the five remaining studies.

Figure 1. Flowchart of the selection used in the systematic review and publications remaining in each stage (stages 1-7).

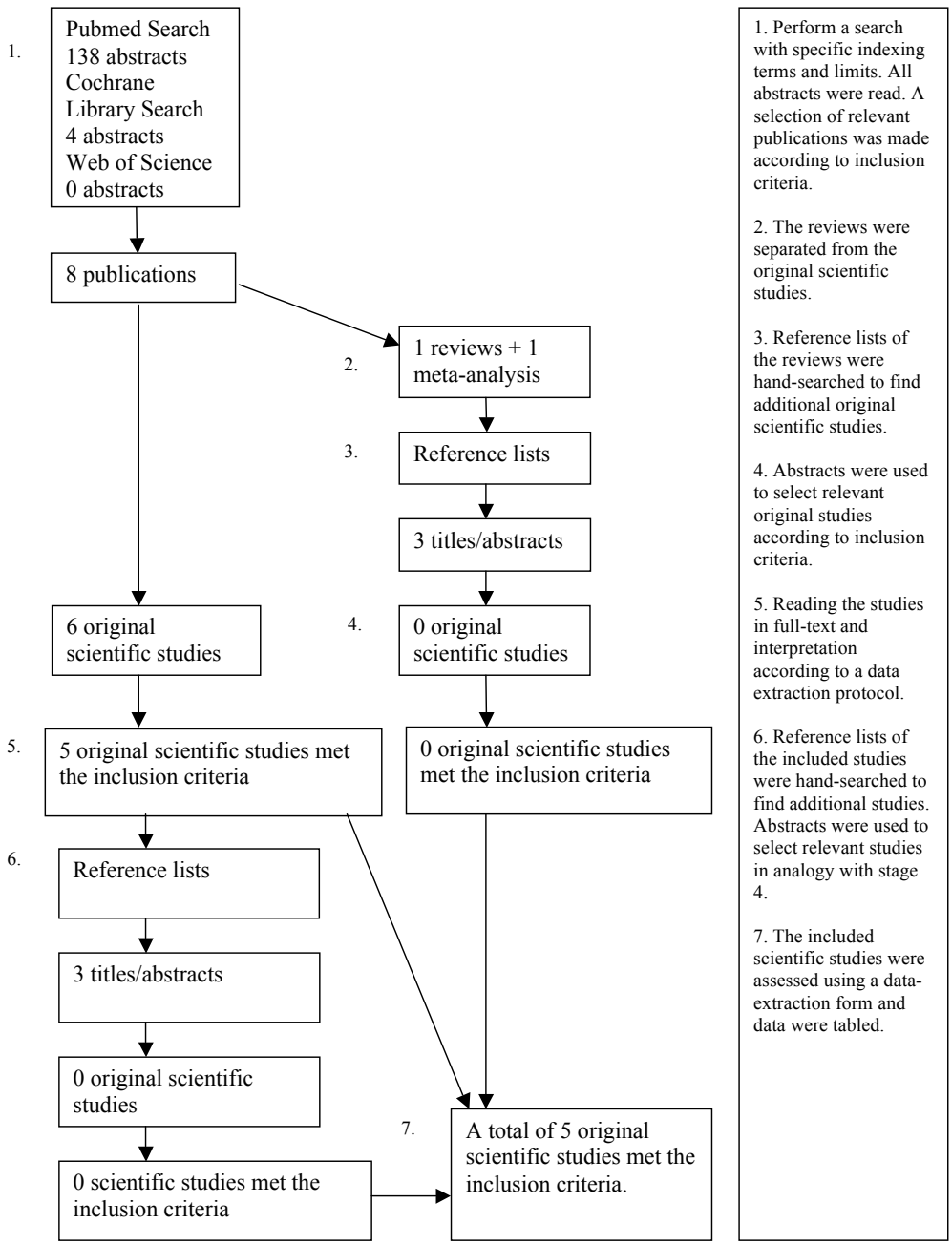

Table 4. Included studies on treatment outcomes of non-selective NSAID in combination with paracetamol compared with non-selective NSAID alone

First author Year Reference	Drug - type - dose - drug administration Rescue drug		Sample - number of patients (n); drop-outs (n) - mean age (SD or range) - baseline pain intensity	Follow-up time Outcome measures	Results according to authors	Comparison between intervention and control	Adverse events treatment-related Rescue drug (intake of)	Study quality Comments
	Intervention	*Control*						
Mehlisch 2010 (19)	Ibuprofen/paracetamol 1. 200mg/500mg 2. 400mg/1000mg Single dose postop *Rescue drug* First 4 hrs -Tramadol 100mg -Later paracetamol 500mg/ Hydrocodone 5mg or Tramadol 100 mg	Ibuprofen 400mg Single dose postop *Rescue drug* First 4 hrs -Tramadol 100mg -Later paracetamol 500mg/ Hydrocodone 5mg or Tramadol 100 mg	*Intervention* 1. n=33; drop-out n=1 21.3 yrs (SD 3.5) 2. n=67; drop-out n=2 21.3 yrs (SD 3.5) *Control* n=69; drop-out n=2 20.1 yrs (SD 2.6) Baseline pain intensity VAS ≥ 50/100mm (0=no pain and 100mm=worst pain)	Every hr for 8 hrs but every 15 min during first hr and every 30 min during second hr VAS 0/100 mm (0=no pain and 100mm = worst pain) Sum of pain relief and intensity differences from 0 to 8 hrs (SPRID8) Nature and frequency of adverse events	*Intervention 1* Improvement in mean SPRID8 scores 23% higher compared to Control Mean (SD) scores 22.1 (14.5) vs 18.0 (14.1) *Intervention 2* Improvement in mean SPRID8 scores 60% higher compared to Control Mean (SD) scores 28.7 (13.8) vs 18.0 (14.1)	*Pain relief* No significant difference between *Intervention* 1 and *Control* (P=NS) Significantly better with *Intervention 2* compared to *Intervention 1* (P=0.02) and *Control* (P=0.001)	*Adverse events* Similar across groups: *Intervention 1* 18.2% *Intervention 2* 14.9% *Control* 27.5% Total sample Nausea 26.1% Vomiting 18.8% Headache 10.3% Dizziness 8.1% *Rescue drug* *Intervention 1* 61% *Intervention 2* 31% *Control* 68%	Moderate Placebo-group also examined *Rescue drug* 90%
Mehlisch 2010 (20)	Ibuprofen/paracetamol* 1. 200mg/500mg 2. 400mg/1000mg *Single-tablets fixed-dose combination Single dose postop *Rescue drug* Hydrocodone 7.5mg/paracetamol 500mg	Ibuprofen 1. 200mg 2. 400mg Single dose postop *Rescue drug* Hydrocodone 7.5mg/ paracetamol 500mg	*Intervention* 1. n=143; drop-out n=3 20.3 yrs (SD 4.2) 2. n=149; drop-out n=3 20.6 yrs (SD 3.4) *Control* 1. n=75; drop-out n=2 20.7 yrs (SD 3.7) 2. n=74; drop-out n=2 20.2 yrs (SD 3.6) Baseline pain intensity VAS ≥ 50/100mm (0=no pain and 100mm=worst pain) *VAS score (mean; SD)* *Intervention 1: 78.1 (11.8)* *Intervention 2: 76.4 (12.7)* *Control 1: 75.1 (13.4)* *Control 2: 76.9 (12.2)*	Every hr for 8 hrs but every 15 min during first hr and every 30 min during second hr VAS 0/100 mm (0=no pain and 100 mm = worst pain) Sum of pain relief and intensity difference at each time point from 0 to 8 hrs (Sprid8) Nature and frequency of adverse events	SPRID8 Estimates (SE) (95%CI) *Intervention 1 vs.Control 1* 0.80 (0.21) (0.40 to 1.21) *Intervention 1 vs.Control 2* 0.40 (0.21) (-0.01 to 0.81) *Intervention 2 vs. Control 2* 0.47 (0.21) (0.07 to 0.88)	*Pain relief* *Intervention 1* and 2 significantly more effective than comparable doses of *Control 1 and 2* (P<0.001 and P=0.02, respectively) *Intervention 1* was not significantly better than *Control 2* at 8 hrs (p=0.054)	*Adverse events* *Intervention 1* significantly lower compared to *Control 1* (P<0.05) *Intervention 2* significantly lower compared to *Control 2* (P<0.05) *Intervention 1* 6.3% *Intervention 2* 5.4% *Control 1* 16.0% *Control 2* 10.8% Total sample Nausea 9.4% Vomiting 9.3% Headache 5.4% *Rescue drug* *Intervention 1* 28.0% *Intervention 2* 21.5% *Control 1* 38.7% *Control 2* 28.4% Cumulatively fewer patients in intervention groups required rescue drugs than in control groups	Moderate SPRID8-values of each patient group not presented Placebo-group also examined *Adverse events* 19.2% *Rescue drug* 72.6%

Table 4 continued.

First author Year Reference	Drug - type - dose - drug administration Rescue drug		Sample - number of patients (n); drop-outs (n) - mean age (SD or range) - baseline pain intensity	Follow-up time Outcome measures	Results according to authors	Comparison between intervention and control	Adverse events treatment-related Rescue drug (intake of)	Study quality Comments
	Intervention	Control						
Merry 2010 (21)	Ibuprofen/para-cetamol 2x150mg/ 2x500mg Before surgery, 4 times/day up to 48hrs after surgery *Rescue drug* Fentanyl 10µg i.v, after discharge codeine 30mg tablets	Ibuprofen 2x150mg Before surgery, 4 times/day up to 48hrs after surgery Several patients treated in general anaesthesia (> two teeth removed) *Rescue drug* Fentanyl 10µg i.v, after discharge codeine 30mg tablets	*Intervention* n=44; drop-out n=4 25 yrs (18-40) *Control* n= 44; drop-out n=5 24 yrs (17-39) Baseline pain intensity VAS 0/100mm registered prior to surgery (No information of labeling) No information on pain limit	Every 1-2 hrs, while awake, for 48 hrs Pain intensity (VAS 0/100 mm) at rest and on activity Time-adjusted Area Under Curve (AUC) of VAS (pain) Global pain (nil, mild, moderate, severe) Frequency and nature of adverse events	*Intervention* Mean AUC (CI) At rest 22.3 (17.0 – 27.7) On activity 28.4 (22.8 – 34.1) *Control* Mean AUC (CI) At rest 34.8 (29.4 – 40.2) On activity 40.2 (34.6 – 45.9)	*Intervention* resulted in significantly lower time-adjusted AUC compared to Control at rest (P=0.003) and activity (P=0.007) Global pain No significant difference between intervention and control	*Adverse events possibly related* *Intervention* Gastrointestinal n=2 patients Fever n=0 patient Postoperative bleeding n=1 patient Sleepy, headache n=1 patient *Control* n=0 patient *Rescue drug* No significant difference between groups	Moderate
Akural 2009 (1)	Ketoprofen/ para-cetamol 100mg+1000mg Single dose postop *Rescue drug* Ibuprofen 800mg	Ketoprofen 100mg Single dose postop *Rescue drug* Ibuprofen 800mg	*Intervention* n=20 cases; drop-out n=0 23 yrs (20-28) *Control* n=20; drop-out n=0 23 yrs (20-28) Baseline pain intensity ≥ 3 on an NRS scale (0=no pain and 10=worst pain imaginable)	Every 15 min for 2 hrs and then every hour for 8 hrs Pain intensity at rest on a NRS-scale (0=no pain and 10=worst pain imaginable) Pain intensity difference (baseline – at a given time point) Intensity of adverse symptoms on a 4-point scale (0=none and 3= severe)	*Sum pain intensity difference at rest Mean (SD)* *Intervention* 90 min 2.84 (1.24) 3hrs 6.1 (2.72) 10hrs 17.22 (13.83) *Control* 90 min 1.49 (2.35) 3hrs 4.62 (5.61) 10hrs 14.91 (19.50)	Mean pain intensity difference significantly improved in *Intervention* compared to *Control* during first 90 min (P<0.05) but not at 3 and 10 hrs (NS)	*Adverse events* No significant difference between groups *Rescue drug* No difference in median time to use rescue medication	Moderate Patients kept the pain diary themselves at home Placebo group also examined Two patients operated twice assessed as 4 patients
Breivik 1999 (9)	Diklofenac/para-cetamol 2x50 mg/2x500 mg Single dose postop *Rescue drug* Codeine 30mg/para-cetamol 500mg	Diklofenac 2x50 mg Single dose postop *Rescue drug* Codeine 30mg/para-cetamol 500mg	*Intervention* n=24; drop-out n=0 25 yrs (19-37) *Control* n=24; drop-out n=2 24 yrs (19-32) Baseline pain intensity VAS ≥ 50/100mm (0=no pain and 100 mm= pain cannot be worse)	Every 30 min for 8 hrs Pain intensity (VAS 0/100 mm (0=no pain and 100 mm= pain cannot be worse) Pain relief (PAR) (0=no pain relief – 4=complete pain relief) Side effects (1=slight, 2, 3=severe)	*Pain intensity* Mean VAS (CI) *Intervention* 19 (12-27) *Control* 38 (30-45)	*Intervention* resulted in - significantly lower VAS (P= 0.001) and higher PAR (P<0.002) than control	*Adverse events* Nausea, Drowsiness, Sweating, Headache No difference (P = 0.074) *Rescue drug* Time and frequency of rescue drug significantly longer/less frequent for *Intervention* than *Control (P<0.05 and P=0.027, respectively)*	Moderate

Table 5. Included studies on treatment outcomes of non-selective NSAID in combination with paracetamol compared with paracetamol alone.

First author Year Reference	Drug - type - dose - drug administration Rescue drug		Sample - number of patients (n); drop-outs (n) - mean age (SD or range) - baseline pain intensity	Follow-up time Outcome measures	Results according to authors	Comparison between intervention and control	Adverse events treatment-related Rescue drug (intake of)	Study quality Comments
	Intervention	*Control*						
Mehlisch 2010 (19)	Ibuprofen/ paracetamol 1. 200mg/ 500mg 2. 400mg/ 1000mg Single dose postop *Rescue drug* First 4 hrs -Tramadol 100mg -Later paracetamol 500mg/ Hydrocodone 5mg or Tramadol 100 mg	Paracetamol 1000mg Single dose postop *Rescue drug* First 4 hrs -Tramadol 100mg -Later paracetamol 500mg/ Hydrocodone 5mg or Tramadol 100 mg	*Intervention* 1. n=33; drop-out n=1 21.3 yrs (SD 3.5) 2. n=67; drop-out n=2 21.3 yrs (SD 3.5) *Control* n=34; drop-out n=0 20.7 yrs (SD 2.7) Baseline pain intensity VAS ≥ 50/100mm (0=no pain and 100mm=worst pain)	Every hr for 8 hrs but every 15 min during first hour and every 30 min during second hr VAS 0/100mm (0=no pain and 100mm= worst pain) Sum of pain relief and intensity differences from baseline to 8 hrs (SPRID8) Nature and frequency of adverse events	*Intervention 1* Improvement in mean SPRID8 scores 42% higher compared to Control Mean (SD) scores 22.1 (14.5) vs 15.5 (15.0) *Intervention 2* Improvement in mean SPRID8 scores 85% higher compared to Control Mean (SD) scores 28.7 (13.8) vs 15.5 (15.0)	*Pain relief* Significantly better with *Intervention 1* compared to *Control* (P=0.03) Significantly better with *Intervention 2* compared to *Intervention 1* (P=0.02) and Control (P=0.001)	*Adverse events* Similar across groups: *Intervention 1* 18.2% *Intervention 2* 14.9% *Control* 35.3% Total sample Nausea 26.1% Vomiting 18.8% Headache 10.3% Dizziness 8.1% *Rescue drug* *Intervention 1* 61% *Intervention 2* 31% *Control* 71%	Moderate Placebo-group also examined *Rescue drug* 90%
Mehlisch 2010 (20)	Ibuprofen/ paracetamol* 1. 200mg/500mg 2. 400mg/1000mg *Single-tablets fixed-dose combination Single dose postop *Rescue drug* Hydrocodone 7.5mg/paracetamol 500mg	Paracetamol 1. 500mg 2.1000mg Single dose postop *Rescue drug* Hydrocodone 7.5mg/ paracetamol 500mg	*Intervention* 1. n=143; drop-out n=3 20.3 yrs (SD 4.2) 2. n=149; drop-out n=3 20.6 yrs (SD 3.4) *Control* 1. n=76; drop-out n=4 20.2 yrs (SD 3.2) 2. n=74; drop-out n=1 20.3 yrs (SD 2.8) Baseline pain intensity VAS ≥ 50/100mm (0=no pain and 100mm=worst pain) *VAS score (mean; SD)* *Intervention 1: 78.1 (11.8)* *Intervention 2: 76.4 (12.7)* *Control 1: 76.6 (11.2)* *Control 2: 77.7 (12.6)*	Every hr for 8 hrs but every 15 min during first hour and every 30 min during second hr VAS 0/100 mm (0=no pain and 100mm= worst pain) Sum of pain relief and intensity differences from 0 to 8 hrs (SPRID8) Nature and frequency of adverse events	SPRID8 Estimates (SE) (95%CI) *Intervention 1 vs. Control 1* 2.11 (0.21) vs (1.71 to 2.52) *Intervention 2 vs. Control 2* 1.62 (0.21) vs.(1.22 to 2.03)	*Pain relief* *Intervention 1* and *2* significantly more effective than comparable doses of Control 1 and 2 (P<0.001)	*Adverse events* *Intervention 1* significantly lower compared to *Control 1* (P<0.001) *Intervention 2* significantly lower compared to *Control 2* (P<0.05) *Intervention 1* 6.3% *Intervention 2* 5.4% *Control 1* 22.4% *Control 2* 13.5% Total sample Nausea 9.4% Vomiting 9.3% Headache 5.4% *Rescue drug* *Intervention 1* 28.0% *Intervention 2* 21.5% *Control 1* 73.7% *Control 2* 68.9% Cumulatively fewer patients in intervention groups required rescue drugs than in control groups	Moderate SPRID8 of each patient group not presented Placebo-group also examined Adverse events 19.2% *Rescue drug* 72.6%

Table 5 continued.

First author Year Reference	Drug - type - dose - drug administration Rescue drug		Sample - number of patients (n); drop-outs (n) - mean age (SD or range) - baseline pain intensity	Follow-up time Outcome measures	Results according to authors	Comparison between intervention and control	Adverse events treatment-related Rescue drug (intake of)	Study quality Comments
	Intervention	*Control*						
Merry 2010 (21)	Ibuprofen/ paracetamol 2x150mg/ 2x500mg Before surgery, 4 times/day up to 48hrs after surgery *Rescue drug* Fentanyl 10µg i.v, after discharge codeine 30mg tablets	Paracetamol 2x500mg Before surgery, 4 times/day up to 48hrs after surgery Several patients treated in general anaesthesia (> two teeth removed) *Rescue drug* Fentanyl 10µg i.v, after discharge codeine 30mg tablets	*Intervention* n=44; drop-out n=4 25 yrs (18-40) *Control* n= 47; drop-out n=4 24 yrs (16-40) Baseline pain intensity VAS 0/100mm registered prior to surgery. (No information of labeling) No information of pain limit	Every 1-2 hrs, while awake, for 48 hrs Pain intensity (VAS 0/100 mm) at rest and on activity Time-adjusted Area Under Curve (AUC) of VAS Global pain (nil, mild, moderate, severe) Frequency and nature of adverse events	*Intervention* Mean AUC (CI) At rest 22.3 (17.0 – 27.7) On activity 28.4 (22.8 – 34.1) *Control* Mean AUC (CI) At rest 33.0 (27.9 – 38.1) On activity 40.4 (35.0 – 45.8)	*Intervention* resulted in significantly lower time-adjusted AUC at rest (P=0.007) and activity (P=0.006) *Global pain* Significant difference between intervention and control in favour of intervention group (P=0.008)	*Adverse events possibly related* *Intervention* Gastrointestinal n=2 patients Fever n=0 patient Postoperative bleeding n=1 patient Sleepy, headache n=1 patient *Control* Gastrointestinal n=3 patients Fever n=1 patient Postoperative bleeding n=0 patient Sleepy, headache n=1 patient *Rescue drug* No significant difference between groups	Moderate
Akural 2009 (1)	Ketoprofen/ paracetamol 100mg/1000mg Single dose postop *Rescue drug* Ibuprofen 800mg	Paracetamol 1000mg Single dose postop *Rescue drug* Ibuprofen 800mg	*Intervention* n=20 cases; drop-out n=0 23 yrs (20-28) *Control* n= 18; drop-out n=0 24 yrs (20-31) Baseline pain intensity ≥ 3 on a NRS scale (0=no pain and 10=worst pain imaginable)	Every 15 min for 2 hrs and then every hour for 8 hrs Pain intensity at rest on a NRS-scale (0=no pain and 10=worst pain imaginable) Pain intensity difference (baseline – at a given time point) Intensity of adverse symptoms on a 4-point scale (0=none and 3= severe)	*Sum pain intensity difference at rest Mean (SD)* *Intervention* 90 min 2.84 (SD 1.24) 3hrs 6.1 (SD 2.72) 10hrs 17.22 (SD 13.83) *Control* 90 min 0.41 (SD 2.24) 3hrs 0.01 (SD 5.06) 10hrs -4.22 (SD 19.92)	Sum of pain intensity difference scores in the intervention significantly greater than in control up to 10 h (P<0.05)	*Adverse events* No significant difference between groups *Rescue drug* Median time to use rescue medication significantly longer in *Intervention* compared to *Control* (P=0.006)	Moderate Patients kept the pain diary themselves at home Placebo group also examined Two patients operated twice assessed as 4 patients
Breivik 1999 (9)	Diklofenac/ paracetamol 2x50 mg/2x500 mg Single dose postop *Rescue drug* Codeine 30mg/ para-cetamol 500mg	Paracetamol 1000 mg Single dose postop *Rescue drug* Codeine 30mg/ para-cetamol 500mg	*Intervention* n=24; drop-out n=0 25 yrs (19-37) *Control* n=24; drop-out n=2 24 yrs (18-35) Baseline pain intensity VAS ≥ 50/100mm (0=no pain and 100 mm= pain cannot be worse)	Every 30 min for 8 hrs Pain intensity (VAS 0/100 mm) (0=no pain and 100 mm= pain cannot be worse) Pain relief (PAR 0=no pain relief – 4=complete pain relief) Side effects (1=slight, 2, 3=severe)	*Pain intensity* Mean VAS (CI) *Intervention* 19 (12-27) *Control* 37 (24-44)	*Intervention* resulted in significantly -lower VAS (P= 0.001) and higher PAR (P<0.002) than control	*Adverse events* Nausea, Drowsiness, Sweating, Headache No difference (P = 0.074) *Rescue drug* Time and frequency of rescue drug significantly longer/less frequent for *Intervention* than *Control (P<0.05 and P=0.027 respectively)*	Moderate

Interpretation of data

General comments

Apart from the control group with one drug alone, a placebo group was included in three studies (1,19,20). The surgical intervention comprised surgical removal of impacted third molars in all studies. The number of molars removed varied, one molar was removed in one study (9), one or two third molars in the study by *Akural et al* (1), at least one lower third molar with or without one or more upper third molars by *Merry et al* (21), and three to four molars in the two studies by *Mehlisch et al* (19,20). There was always at least one mandibular third molar among the removed molars. In the included studies the administration of the anesthesia varied from local anesthesia (1,9,19,20) to either local anesthesia or local anesthesia in combination with general anesthesia if more than two molars were removed (21). In one study local anesthesia and conscious sedation was used uniform across all patients (19).

Non-selective NSAID was prescribed as ibuprofen in three studies (19-21), as diklofenac in one (9) and as ketoprofen in one study (1). In the study by Merry et al (21), the patients received one analgesic dose preoperatively and further doses every 6 hours for 48 hours. In the other studies (1,9,19,20), the patients received a single dose postoperatively.

The protocols for evaluation of the postoperative pain relief varied between the studies. Firstly, the maximum follow-up time varied between 8 (9,19,20), 10 (1) and 48 hours (21) after surgery. Secondly, the primary outcome was assessed as pain intensity in one study (9) and as pain relief or pain intensity difference over an 8 hour follow-up period by *Mehlisch et al* (19,20), whilst *Merry et al* (21) asked the patients to rate pain on a 100-mm VAS every second hour, while awake, for 48 hours. The primary outcome measure was the area under the curve (AUC) of VAS ratings divided by time at rest and on activity. *Akural et a*l (1) measured the response of treatment as the patients´ self-rating of pain intensity first at rest and then at dry swallowing on a numerical rating scale (0 = no pain to 10 = worst pain imaginable) during 8 hours. The patients in the study by *Breivik et al* (9) evaluated the analgesic effect of the medication as the pain intensity on a VAS- scale (0 = no pain relief to 100 = pain cannot be worse) as well as pain relief on a categorical pain relief scale (categories 0 = no pain to 4 = complete pain relief) every 30 minutes.

Non-selective NSAID/paracetamol compared with non-selective NSAID alone (Table 4)

The results of three studies (9, 19-21) showed that the pain relief from the combination of non-selective NSAID/paracetamol was significantly greater than from non-selective NSAID alone. In one study (1) such a difference was found during the first 90 min but not at the 3 and 10 hours follow-up but there was no statistical difference compared to ibuprofen alone at the secondary endpoint. The most common adverse events were nausea, vomiting and headache and the adverse events were of the same type in the included studies. There was no significant difference between the medications used but nausea, vomiting and headache tended to be more common in the control group in one study (20) than with a single fixed-dose combination of ibuprofen/paracetamol.

Non-selective NSAID /paracetamol compared with paracetamol alone (Table 5)

The results of the included studies showed that the pain relief from the combination of non-selective NSAID/paracetamol was significantly greater than from paracetamol alone. The improved pain relief of the combination treatment seemed to be independent of the amount of NSAID/paracetamol in the intervention groups both within and between the studies. *Mehlisch et al* (19,20) used Ibuprofen and paracetamol concentrations varying between 200 – 400 mg and 500-1000 mg respectively in the intervention groups and *Akural et al* (1) and Breivik et al (9) used Ketoprofen 100 mg and Diklofenac 100 mg respectively in combination with 1000 mg paracetamol in the intervention groups. *Merry et al* (21) used ibuprofen 300mg in combination with 1000 mg paracetamol in the intervention groups.

The most common adverse events were nausea, vomiting and headache and the adverse events were of the same type in all the included studies. Four studies (1,9,19,21) reported that there was no significant difference between the adverse events of the medications used whilst *Mehlisch et al* (20) found that the adverse events were significantly lower for the combination of NSAID/paracetamol compared with paracetamol alone (Table 5).

Evaluation of evidence

The included studies were assessed to present a moderate study quality. Although the study design and the measures of the primary outcome varied, the results of the studies including 480 patients in the intervention groups and 579 patients in the control

groups showed that pain relief was improved with non-selective NSAID/paracetamol as compared to either drug alone. The quality of evidence was assessed as moderate.

Discussion

Methodological considerations

As selective COX-2 inhibitors cause adverse cardiovascular events (30), the research question of this review was formulated to include non-selective NSAIDs as the analgetic drug but not selective NSAIDs. The search strategies comprised three databases – PubMed, Cochrane Library and Web of Science - to ensure the retrieval of numerous publications. The search of at least two electronic sources is regarded as improving the methodological quality of a systematic review (35). The search limitations regarding language restrictions may, however, have resulted in some relevant publications not being retrieved thus leading to loss of valuable data. Initially over one hundred studies were found but only five studies met the inclusion criteria satisfying the design of an RCT. In studies designed as RCT, the authors should describe each intervention thoroughly, including control interventions. The description should allow a clinician wanting to use the intervention to know exactly how to administer the intervention that was evaluated in the trial. "For a drug intervention, information would include the drug name, dose, method of administration (such as oral, intravenous), timing and duration of administration" (10). Although the database searches comprised oral surgical procedures in general, all retrieved studies presented pain relief following third molar removals. This pain model is suitable for evaluation of the outcomes of analgesic drugs as the model is characterized by localized pain that is predictable in character, duration (3-5 days), and intensity (moderate to severe) (4,20). To be included in this systematic review, the pain relief had to be scored by the patients. Pain was estimated by a VAS in four studies (9,19-21) and by a numerical rating scale in one study (1). A recent study (13) provided strong support for the validity of both scales to detect changes in pain intensity and the superiority of both scales compared to other scales used by clinicians and researchers to measure pain intensity. To be able to pool the results of different studies it is essential to have a presentation of similar and adequate pain intensity at baseline in each study. There was no information on the baseline pain level of patients included in one study (21), which makes it difficult to compare the patient sample and outcomes to those of the other studies.

There were also other differences among the studies. For instance, in one study (21) general anesthesia was used when more than two molars were removed and in one study (1) two patients, who were operated on twice were assessed as four different patients. The varying number of removed molars both between and within the studies may also influence the evaluation of the postoperative pain. *Breivik et al* (9) stated, however, that it is not necessary to stratify according to the number of third molars removed, because pain intensity after third molar removal has been shown to vary substantially between individuals irrespective of the number of third molars removed (9,16,26).

In three studies (1,19,20) a placebo group was included alongside the intervention and control groups. According to *Merry et al* (21) the higher efficacy of both ibuprofen (34) and acetaminophen (7) in comparison with placebo is well established in previous research. Therefore, the use of a placebo in this situation is unnecessary and perhaps even unethical (3, 21). Neither did *Breivik et al* (9) include an inert placebo group with the explanation that downside assay sensitivity is well documented between acetaminophen and placebo (8,11) and between diclofenac and placebo (5) in the dental pain model.

Discussion of results

The results of the included studies confirmed the results of previous studies that a combination of NSAID /paracetamol provides improved pain relief than paracetamol alone (12,14,18,36). The results also support the superiority of NSAID/paracetamol compared to the NSAID alone. The results are in line with the statement *by Raffa* (28) that combining two or more drugs with different mechanisms or sites of action, such as NSAIDs and paracetamol, may enhance analgesic efficacy without increasing adverse events. The better pain reducing effect of the interventions compared to the controls as a general is supported by the observation that the time to intake of rescue medication in two of the studies was significantly longer for patients receiving intervention (1,9).

The interaction of paracetamol with ketoprofen by synergistic mechanisms suggests the activation of different and complimentary central and peripheral mechanisms of antinociception (1). These analgesic mechanisms are not fully understood, which makes any discussion of possible mechanisms of interactions observed hypothetical (1). An attempt to cor-

relate drug plasma concentration with pain scores was carried out by *Merry et al* (21), but the results were too sparse. In addition there were too many confounding variables, such as ethnicity, comparators, and rescue analgesia. Two studies (1,20) report a more rapid onset of the combination of NSAID/paracetamol compared to either of the two drugs used alone. *Mehlisch et al* (20) noted that the combination of NSAID/paracetamol in a single-tablet fixed-dose combination had a longer duration than with monotherapy during the first 8 hours following surgery. *Merry et al* (21) promoted the use of a preoperative dose of analgesics with the widely accepted clinical practice of anticipating and treating pain before it occurs.

Nausea, vomiting, headache, and dizziness, were the most common adverse events in all treatment groups. These adverse events may, according to *Mehlisch et al* (20), be explained by lack of food during the day of surgery and not necessarily caused by the pain killers. The severity and frequency of adverse events varied between the studies as well as the definition of an adverse event. *Akural et al* (1) found no significant differences among adverse events between the treatment groups. The same observation was made by *Breivik et al* (9) whilst *Mehlisch et al* (20) found that the adverse events were significantly lower for the single-tablet fixed-dose ibuprofen 400 mg/paracetamol 1000 mg compared to ibuprofen 400 mg and paracetamol 1000 mg. Paracetamol and ibuprofen are well established, widely used, and considered very safe in appropriate doses (31). According to *Merry et al* (21), who monitored their patients for adverse events for three weeks, it seemed unlikely that clinically important harm had been missed.

Patients' need for rescue drugs varied between the studies. According to *Merry et al* (21) most patients did require rescue medication, suggesting that pain following oral surgery can sometimes be severe enough, that even the combination of ibuprofen/paracetamol requires supplementation. *Mehlisch et al* (20) found that cumulatively fewer patients in the intervention groups required rescue drugs than in the control groups. The need for rescue medication was more frequent in the intervention group with lower doses of ibuprofen/paracetamol compared to higher doses ibuprofen/paracetamol (20). Not only the dose but also the shape of the drug seemed to influence the need for rescue drugs. *Mehlisch et al* (19,20) found namely a difference in the need for rescue medication, 28% and 61% respectively, depending on whether the patients received the same dose of ibuprofen/paracetamol as a single-tablet fixed-dose or as two separate tablets.

Recommendations for the future

The included studies in this review were of moderate study quality. All of them came to the conclusion that the combination treatment is better than paracetamol alone. There are some contradictory studies, or parts of studies, regarding the efficacy of the combination in comparison to NSAID alone, but there also seems to be good evidence that the combination is superior to NSAID alone. *Mehlisch* (19) showed that the combination treatment with 200 mg ibuprofen/paracetamol 500 mg did not result in improved pain relief compared to 400 mg ibuprofen alone, but better pain relief compared to 200 mg ibuprofen alone. This indicates that it is not possible to lower the doses in the combination treatments believing this would enhance the efficacy compared to a higher dose of each drug alone. Regarding adverse events, these might be explained by lack of food during the day of surgery and not necessarily caused by the pain killers and *Mehlisch et al* (20) even found an outcome that was significantly better for the intervention group compared to the control for adverse events. According to this systematic review there seems to be sufficient evidence to recommend a combination of 400 mg ibuprofen /1000 mg paracetamol compared to each drug used alone for pain relief following oral surgery, provided that the adverse effects of NSAIDs are observed.

References

1. Akural E.I, Järvimäki V, Länsineva A, Niinimaa A, Alahuhta S. Effects of combination treatment with Ketoprofen 100 mg + Acetaminophen 1000 mg on postoperative dental pain: A single dose, 10-hour, randomized, double-blind, active- and placebo-controlled clinical trial. Clin Ther 2009; 31:560-8
2. Anderson BJ. Paracetamol (acetaminophen): Mechanisms of action. Paediatr Anaesth 2008; 18:915-21
3. Anderson B, Cranswick N. The placebo (I shall please)- is it so pleasing in children? Paediatr Anaesth 2005; 15:809-13
4. Averbuch M, Katzper M. Baseline pain and response to analgesic medications in the postsurgery dental pain model. J Clin Pharmacol 2000; 40:133-7
5. Bakshi R, Frenkel G, Dietlein G, Meurer-Witt B, Schneider B, Sinterhauf U. A placebo-controlled comparative evaluation of diclofenac dispersible versus ibuprofen in postoperative pain after third molar surgery. J Clin Pharmacol 1994; 34:225-30
6. Balshem H, Helfand M, Schünemann HJ, Oxman AD, Kunz R, Brozek J et al. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol 2011; 64: 401-6
7. Barden J, Edwards J, Moore A, MCQuay H. Single dose

oral paracetamol (acetaminophen) for postoperative pain. Cochrane Database Syst Rev (Online) 2004
8. Breivik EK, Björnsson GA. Variation in surgical trauma and baseline pain intensity: effects on assay sensitivity of analgesic trial. Eur J Oral Sci 1998; 106:844-52
9. Breivik E.K, Barkvoll P, Skovlund E. Combining diclofenac with acetaminophen or acetaminophen-codein after oral surgery: A randomized, double-blind single dose study. Clin Pharmacol Ther 1999; 66:625-35
10. CONSORT transparent reporting of trials. http://www.consort-statement.org/consort-statement/3-12---methods/item5_interventions/ Accessed 2013-03-12
11. Cooper SA, Beaver WT. A model to evaluate mild analgesics in oral surgery outpatients. Clin Pharmacol Ther 1976; 20:241-50
12. Dahl V, Dybvik T, Steen T, Aune A.K, Rosenlund E.K, Ræder J.C. Ibuprofen vs. acetaminophen vs. ibuprofen and acetaminophen after arthroscopically assisted anterior cruciate ligament reconstruction. Eur J Anaesthesiol 2004; 21:471-5
13. Ferreira-Valente MA, Pais-Ribeiro JL, Jensen MP. Validity of four pain intensity rating scales. Pain 2011; 152:2399-404
14. Gazal G, Mackie IC. A comparison of paracetamol, ibuprofen or their combination for pain relief following extractions in children under general anesthesia: a randomized controlled trial. Int J Paediatr Dent 2007; 17:169-77
15. Goodman C. Literature searching and evidence interpretation for assessing health care practices. Stockholm: Swedish Council on Technology Assessment in Health Care (Statens beredning för utvärdering av medicinsk metodik, SBU); 1993
16. Hansson P, Ekblom A, Thomson M, Fjellner B. Pain development and consumption of analgesics after oral surgery in relation to personality characteristics. Pain 1989; 37:271-7
17. Hyllested M, Jones S, Pedersen J.L, Kehlet H. Comparative effect of paracetamol, NSAIDs or their combination in postoperative pain management: a qualitative review. Br J Anaesth 2002; 88:199-214
18. Ianiro S, Jeansonne B, McNeal S, Eleazer P. The effect of preoperative acetaminophen or a combination of acetaminophen and ibuprofen on the success of inferior alveolar nerve block for teeth with irreversible pulpitis. J Endod 2007; 33:11-4
19. Mehlisch DR, Aspley S, Daniles SE, Bandy DP. Comparison of the analgesic efficacy of current ibuprofen and paracetamol with ibuprofen or paracetamol alone in the management of moderate to severe acute postoperative dental pain in adolescents and adults: A randomized, double blind, placebo-controlled, parallel-group, single-dose, two-center, modified factorial study. Clin Ther 2010; 32:882-95
20. Mehlisch DR, Aspley S, Daniles SE, Southerden KA, Christensen KS. A single-tablet fixed-dose combination of racemic ibuprofen/paracetamol in management of moderate to severe postoperative dental pain in adult and adolescent patients: A multicentre, two-stage, randomized, double blind, placebo-controlled, factorial study. Clin Ther 2010; 32:1033-49
21. Merry AF, Gibbs RD, Edwards J, Ting GS, Frampton C, Davies E, Anderson BJ. Combined acetaminophen and ibuprofen for pain relief after oral surgery in adults: arandomized controlled trial. Br J Anaesth 2010; 104:80-8
22. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG, for the CONSORT Group. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. J Clin Epidemiol 2010;63:e1-e37
23. Moore RA, Derry S, McQuay HJ, Wiffen PJ. Single dose oral analgesics for acute postoperative pain in adults. Cochrane Database Syst Rev 2011Sep 7;CD008659. Doi; 10.1002/14651858.CD008659,pub2
24. Moore RA, Straube S, Paine J, Derry S, McQuay HJ. Minimum efficacy criteria for comparisons between treatments using individual patient meta-analysis of acute pain trials: examples of etoricoxib, paracetamol, ibuprofen, and ibuprofen/paracetamol combinations after third molar extraction. Pain 2011; 152:982-9
25. Munsterhjelm E. Coxibernas och paracetamolets verkningsmekanismer. Finska Läkarsällskapets Handlingar 2012; 172:8-12 (In Swedish)
26. Nørholt SE. Treatment of acute pain following removal of mandibular third molars: Use of dental pain model in pharmacological research and development of a comparable animal model. Int J Oral Maxillofac Surg 1998; 27(suppl):1-41
27. Ong CKS, Seymour RA, Lirk P, Merry AF. Combining paracetamol (acetaminophen) with nonsteroidal anti-inflammatory drugs: A qualitative systematic review of analgesic efficacy for acute postoperative pain. Anesth Analg 2010; 110:1170-9
28. Raffa RB. Pharmacology of oral combination analgesics: Rational therapy for pain. J Clin Pharm Ther 2001; 133:257-64
29. Rang HP, Dale MM, Ritter JM, Flower RJ. Anti-inflammatory and immunosuppressant drugs. In Rang HP and Dale MM, eds. Pharmacology. Edinburgh: Churchill Livingstone, pp. 226-47, 2007
30. Rao P, Knaus EE. Evolution of nonsteroidal anti-inflammatory drugs (NSAIDs): cyclooxygenase (COX) inhibition and beyond. J Pharm Pharm Sci 2008: 11:81-110
31. Reynolds JEF, ed. Martindale, The Extra Pharmacopoeia. London: The Royal Pharmaceutical Society of Great Britain, 1996
32. Rømsing J, Møiniche S, Dahl J.B. Rectal and parental paracetamol, and paracetamol in combination with NSAIDs, for postoperative analgesia. Br J Anaesth 2002; 88:215-26
33. SBU. Metoder för behandling av långvarig smärta. En systematisk litteraturöversikt. Stockholm: Statens beredning för medicinsk utvärdering (SBU); 2006. SBU-rapport nr 177/1. ISBN 91-85413-06-2 (kapitel 7 s. 239-252) (In Swedish)
34. Schou S, Nilesen H, Nattestad A, Hillerup S, Ritzau M, Branebjerg PE, Bugge C, Skoglund LA. Analgesic dose-response relationship of ibuprofen 50, 100, 200, and 400 mg after surgical removal of third molars: a single-dose, randomized, placebo-controlled, and double-blind study of 304 patients. J Clin Pharmacol 1998; 38:447-54
35. Shea BJ, Grimshaw JM, Wells GA, Boers M, Andersson N, Hamel C, Porter AC, Tugwell P, Moher D, Bouter LM. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic

reviews. BMC Med Res Methodol 2007; 7:10
doi:10.1186/1471-2288-7-10
36. Vitanen H, Tuominen N, Vääräniemi H, Nikanne E, Anilla P. Analgesic efficacy of rectal acetaminophen and ibuprofen alone or in combination for paediatric day-case adenoidectomy. Br J Anaesth 2003; 91:363-7
37. Warner TD, Mitchell JA, Cyclooxygenases: New forms, new inhibitors, and lessons from the clinic. FASEB J 2004; 18:790-804

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The adoption of nickel-titanium rotary instrumentation increases root-filling quality amongst a group of Swedish general dental practitioners

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Abstract

◎ The aim of the present study was testing the hypothesis that the adoption of nickel-titanium rotary instrumentation (NTRI) will improve the technical quality of root-fillings. The investigation was carried out within a mandatory continuing education program (CEP) for general dental practitioners (GDPs).

The study was conducted amongst GDPs employed by the Public Dental Health Service in the County of Stockholm. Identical questionnaires were distributed before the CEP (Pre-Q) and 9 to 12 months after the course (Post-Q). The CEP consisted of two parts: lectures and hands-on training. From each GDP, radiographs of two cases completed before the course and two cases treated 9-12 months after the course were randomly selected. Primarily molars were selected for evaluation. The radiographs were individually evaluated by two endodontists. Teeth treated before and after training were presented in random order.

Adoption rate of NTRI increased from 35% to 75%. Cases from 124 GDPs were included in the final analysis. The rate of good quality root-fillings increased from 27% to 49% ($p<.001$). A significantly increased radiographic quality was found between GDPs adopting NTRI and those who did not. The GDPs produced root-fillings of very poor quality before as well as after the training period. However, the rate decreased from 29% to 12% amongst adopters and from 46% to 28% amongst non-adopters. Dentists considering canal preparation and root-filling as "easy" produced more frequently good quality root-fillings than the others ($p<0.05$).

In conclusion, the results of the present study were in favour of the idea that a shift to NTRI increases the technical quality of root-fillings produced by GDPs. However, adopters still produce root-fillings of very poor quality. This important issue needs to be addressed in future studies.

Key words

Endodontics, quality improvement, root canal therapy, rotary instrumentation .

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Införande av maskinell rensningsteknik med nickel-titanium filar ökade rotfyllningars kvalitet hos en grupp svenska allmäntandläkare

HELENA GÖRANSSON, ANDERS MOLANDER, JÖRGEN KARLSSON, LEIF JANSSON, CLAES REIT

Sammanfattning

◎ Syftet med studien var att undersöka hypotesen att införande av maskinell rensningsteknik med nickel-titan filar förbättrar rotfyllningars tekniska kvalitet. Studien genomfördes genom ett obligatoriskt utbildningsprogram för allmäntandläkare.

Studien utfördes bland allmäntandläkare anställda av Folktandvården i Stockholms län. Identiska frågeformulär distribuerades till deltagande tandläkare före och efter utbildningen. Utbildningsprogrammet bestod av två delar: föreläsningar och praktiska övningar. Två röntgenbilder på rotfyllningar som utförts innan utbildningen och två röntgenbilder på rotfyllningar utförda 9-12 månader efter genomförd utbildning valdes ut slumpmässigt från varje deltagande tandläkare. Röntgenbilderna bedömdes i slumpmässig ordning och med avseende på rotfyllningarnas kvalitet av två endodontister.

Andelen tandläkare som använde maskinell rensningsteknik ökade från 35% till 75% efter genomförd utbildning. Röntgenbilder från 124 allmäntandläkare inkluderades i analysen med avseende på kvaliteten hos rotfyllningarna. Andelen rotfyllningar av hög kvalitet ökade från 27% till 49% efter utbildningen ($p<0.001$). Den röntgenologiska kvaliteten var signifikant högre hos tandläkare som övergått till maskinell rensningsteknik i jämförelse med övriga tandläkare. Det förekom dock rotfyllningar av mycket låg kvalitet före såväl som efter utbildningen. Andelen rotfyllningar av låg kvalitet minskade dock från 29% till 12% bland de tandläkare som tillämpade maskinell rensningsteknik medan den minskade från 46% till 28% bland dem som använde manuell rensningsteknik. Tandläkare som betraktade momenten rotkanalspreparation och rotfyllning som ”enkla” att utföra producerade oftare rotfyllningar av hög kvalitet i jämförelse med övriga ($p<0.05$).

Sammanfattningsvis visade studien att en övergång till maskinell rensningsteknik hos allmäntandläkare ökar den tekniska kvaliteten hos rotfyllningar. Det förekommer dock fortfarande rotfyllningar av mycket låg kvalitet även hos de allmäntandläkare som övergått till maskinell rensningsteknik. Detta viktiga konstaterande behöver analyseras vidare i framtida studier.

Introduction

The objective of endodontic treatment is to prevent or treat apical periodontitis (11). Follow-up studies of case-series and epidemiological surveys have reported a strong correlation between the technical quality of the root-filling and the presence of radiographic signs of apical periodontitis (5, 8, 16). However, root-fillings of substandard quality were frequently observed to be produced by general dental practitioners (GDP)(1, 2, 6, 9, 16). It was suggested that the adoption of nickel-titanium rotary instrumentation (NTRI) might facilitate root-canal instrumentation and lead to improved quality of the seal (3, 12, 13).

Getting a new idea adopted, even when it has obvious advantages, is difficult (15). *Reit et al.* (14) and *Molander et al* (10) investigated the effect of a diffusion campaign, designed as a mandatory continuing education program (CEP) for GDPs in the Gothenburg Public Dental Health Service, on the rate of NTRI adoption and root-filling quality. It was found that the adoption rate increased from 4% to 73% and the very good quality root-fillings (as observed in the radiograph) increased from 27% to 47%. In terms of adoption rate there was a marked difference whether the new technology was introduced by lectures alone (53%) or in combination with hands-on training (94%). *Koch et al* (7) studied the effect of a similar mandatory CEP in the county of Södermanland, Sweden and reported the adoption rate to reach 77% amongst GDPs.

Molander et al (10) were not able to discriminate between cases treated with NTRI and those which were not. Thus, it could be argued that the effect of the program *per se* was more important for the improved root-filling quality than the actual use of the NTRI technology. Therefore, the present study was set up in the county of Stockholm, Sweden, again testing the hypothesis that the adoption of NTRI will improve the technical quality of root-fillings. The investigation was carried out within a mandatory CEP for GDPs and cases treated with NTRI or not were recorded.

Materials and Methods

The study was conducted amongst GDPs employed by the Public Dental Health Service in the County of Stockholm, Sweden. All dentists participated in a mandatory CEP given in 2007 and 2008. On October 31 in 2006, 558 GDPs were employed at 78 clinics. The clinics were randomized to undergo training in 2007 or 2008. In 2007, 249 dentists were trained and selected for the study. Identical questionnaires were distributed before the CEP (Pre-Q) and 9 to 12 months after the course (Post-Q). Radiographs of two treated cases were randomly sampled from each dentist before as well as 9-12 months after training. To be included in the study a GDP had to return both questionnaires and provide radiographs of cases treated before and after the CEP.

The CEP consisted of two parts: lectures and hands-on training. The course was led by three endodontists.

Lecture

General aspects on root-canal instrumentation and the concept of NTRI were discussed during a four hour lesson. The RaCe rotary instrumentation system (FKG Dentaire, La-Cheaux-de Fonds, Switzerland) was presented in detail. All participants were provided with handouts and a manual with pictures showing the file sequences to be used. Furthermore, a general update in endodontics was given.

Hands-on training

The training took place in small groups (10-14 dentists) during four hours and was supervised by the endodontists. Extracted molars were used. Working length was radiographically determined using K10 or K15 files. The canals were initially instrumented with steel hand instruments (S-files, Sjödings, Sweden) to an apical size of #20. The RaCe-files were used in a modified crown-down technique using a hand-piece 128:1 (X-75 NSK Nakanishi, Japan). The recommended final apical size for curved canals was 35 with a taper of .06. In wider or straighter canals RaCe 40.06 or 50.04 was recommended. If even greater apical size was needed the participants were recommended to use Profile 60.04 or Profile 90.04 (Dentsply Maillefer, Ballaigues, Switzerland). Instrumented canals were filled with gutta-percha (taper 0.06) and sealer (Tubli-Seal, Kerr, USA) using a single-cone technique. The points were cut to the right apical size with a Gauge tester (Dentsply Maillefer, Switzerland).

Root-filling quality was radiographically checked. The sessions ended with ample time given for questions and discussions. E-mails were sent to all clinics with detailed information on where to buy instruments and equipment needed.

Lecture for assisting staff

About 600 dental nurses employed by the Public Dental Health Service were presented to the NTRI technology in a two-hour lecture. The focus was

on time planning, sterile routines and equipment. Three dental nurses trained in endodontics acted as teachers.

Evaluation of the questionnaires

The Pre-Q was given to all participating dentists when the lecture part of the CEP started and the Post-Q was sent by e-mail 9-12 months after the course. A reminder was distributed one month later. The following variables were used in the analyses (14):

- Age
- Gender
- Number of years of clinical practice
- Number of endodontic treatments per week
- Utilization of NTRI technique
- The perceived degree of difficulty to perform (i) access to the cavity, (ii) canal preparation, (iii) root-filling.
- The self-perceived satisfaction with the technical quality of the root filling (scale 1-6, 1=very satisfied, 6=not satisfied) (14).

Radiographic evaluation of root-filling quality

From each GDP radiographs of two cases completed before the course and two cases treated 9-12 months after the course, were randomly selected from a database by using a random number generator. The radiographs were digitally obtained. The dentists used their normal routines and mostly one image was used to evaluate the quality of the seal. A case was included in the study if the quality of the root-filling could be evaluated in the radiograph. This decision was made by one of the authors (LJ). Primarily molars were selected for evaluation. If molars were not available (or excluded) premolars or incisors/canines were randomly selected from the database. A GDP was excluded from the study if not at least one root-filled tooth was available for evaluation before as well as after the course.

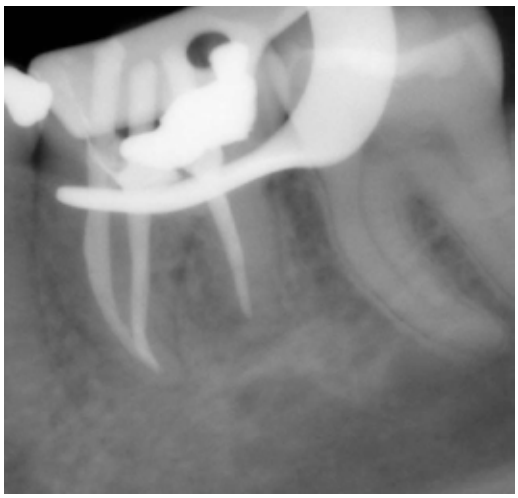
The radiographs were individually evaluated by two endodontists (H.G. and J.K.). Teeth treated before and after training were presented in random order. In case of disagreement consensus was reached by a joint decision. Thirty teeth were re-evaluated four months later resulting in a kappa coefficient of 0.69 for intra observer agreement.

A quality score based on the following factors was used (10):

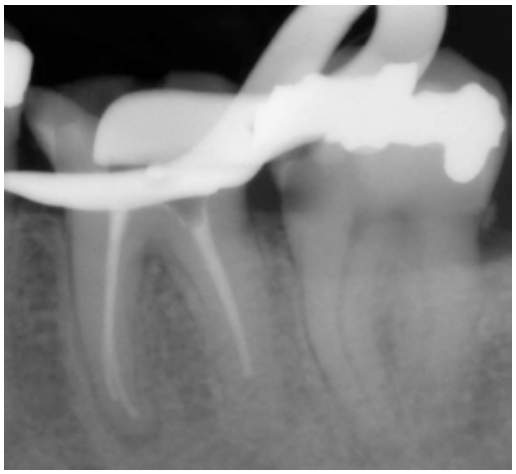
- The apical distance was judged as being correct if the root filling terminated within 2.5 mm short of the apex.

Figure 1. Root-filled molars with quality scores 1, 3 and 5.

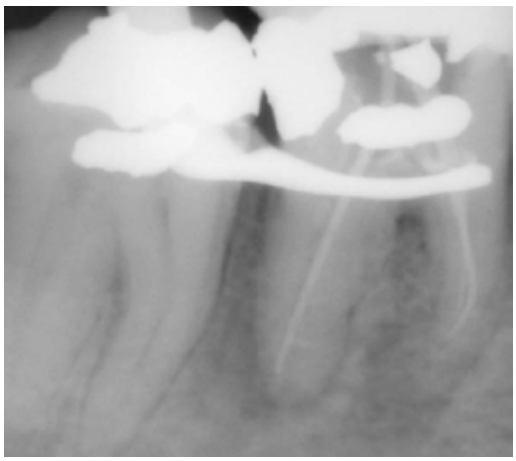
Score 1



Score 3



Score 5



- The quality of the seal was evaluated in in the apical two-third of the canal.
- The ideal root canal transportation should be tapered and without signs of canal transportation.

The applied quality score ranges from 1 to 5. Score 1 signifies a root-filling of very good quality with correct length, adequate seal, tapered preparation and no transport. Score 2 means correct length, adequate seal, lack of taper and/or transport. Score 3 is based on incorrect length and adequate seal (taper and transport not evaluated). Score 4 signifies correct length and defective seal (taper and transport not evaluated), while score 5 means incorrect length and defective seal (taper and transport not evaluated). Three molars with different quality scores are presented in Fig. 1. For multi-rooted teeth, the root with the highest score (poorest technical quality) was used in the analyses. Presence of separated instrument in the canal was registered in the radiograph.

The study was approved by the local ethical committee and informed consent was obtained from all participating dentists.

Statistical methods

The statistical calculations were made with a computer statistical package (SPSS PC+ Inc., Chicago, Ill., USA). The kappa statistics was used in order to examine the reliability of the radiographic evaluations. The correlations between the answers in the questionnaires and the quality scores were analysed by calculating the Spearman correlation coefficient. Wilcoxon rank sum test was adopted in order to analyse differences between two groups according to evaluation scores, while Kruskal-Wallis test was used for comparisons between more than two groups. Paired comparisons between quality scores before and after the course were performed by using Wilcoxon sign rank test. The individual was the computational unit in all analyses. Results were considered statistically significant at $p<0.05$.

Results

Both questionnaires were returned by 147 of the 249 GDPs. Reasons for drop-out are displayed in Fig 2. Adoption rate of NTRI increased from 35% to 75%. The number of weekly root canal treatments carried out by the individual dentist did seem to exert influence on a potential adoption (Table 1) while the number of years in clinical practice did not (Table 2) as well as age and gender.

Cases from 124 GDPs (371 molars, 17 premolars and 9 incisors/canines) were included in the final analysis (Fig 2). The rate of good quality root-fillings (score 1 and 2) increased from 27% to 49% after the course ($p<.001$). A significant difference in radiographically observed quality was found between GDPs adopting NTRI (Table 3) and those who did not (Table 4) ($p<.001$). After training the quality score ratio (score 1/score 5) was 3.8 for adopters and 0.57 for non-adopters (Table 5). The GDPs produced root-fillings of very poor quality (score 5) before as well as after the training period. However, the rate decreased from 29% to 12% amongst adopters (Table 3) and from 46% to 28% (Table 4) amongst non-adopters.

Before the CEP root-filling quality was found to be influenced by the weekly rate of root-canal treatments. The GDPs reporting less than one treatment per week produced root-fillings of lower quality compared to the others ($p<0.05$). This difference was not observed after the course.

The GDPs confidence rating of critical parts of a root-canal treatment is displayed in Table 6. No difference in distribution of the ratings was found before and after the CEP. However, dentists regarding canal preparation and root-filling as "easy" (score 1-2) produced more frequently good quality root-fillings than the others ($p<0.05$).

Separated instruments were observed in 3.5 % of the teeth before the CEP and in 3.0% after.

Table 1. Distribution according to self-estimated number of endodontic treatments per week and the adoption rate of NTRI technique after the course.

Number of endodontic treatments per week	Relative frequency (%)	Adoption rate (%)
0	1	0
<1	18	42
1-4	64	81
>5	17	96

Table 2. The distribution of general dentists according to number of years of clinical practice and the adoption rate of NTRI technique after the course.

Number of years of clinical practice	Relative frequency (%)	Adoption rate (%)
0-5	22	87
6-10	17	61
11-15	10	100
16-20	8	90
>20	43	66

Figure 2. Flow diagram of the progress of the phases of the trial.

Table 3. Distribution (%) according to quality scores before and after the course for dentists having adopted the NTRI technique.

Score	1	2	3	4	5
Before the course	12	17	25	17	29
After the course	46	11	26	5	12

Table 4. Distribution (%) according to quality scores before and after the course for dentists having not adopted the NTRI technique.

Score	1	2	3	4	5
Before the course	12	9	15	18	46
After the course	16	12	28	16	28

Table 5. Ratios for quality scores 1 and 5 before and after the course for all the participants, for those who had adopted the NTRI technique and the non-adopters.

Group	Before the course	After the course
All	0.36	2.4
Adopters	0.41	3.8
Non-adopters	0.26	0.57

Table 6. The distribution of scores according to answers in the questionnaires before and after the course.

Statement	Scores	Before the course (%)	After the course (%)
Access to the cavity	1-2	32	23
	3-4	59	70
	5-6	9	7
Canal preparation	1-2	6	7
	3-4	56	60
	5-6	38	33
Root-filling	1-2	16	26
	3-4	58	54
	5-6	26	20
Technical result	1-2	30	42
	3-4	63	52
	5-6	7	6

Discussion

There are few studies reporting on the impact of a CEP on the adoption of NTRI. The present investigation found an increase from 35% to 75% acceptance rate amongst a group of Swedish GDPs. A similar effect (77%) was noted by *Koch et al* (7) in another sample of Swedish dentists. In a third Swedish sample *Reit et al* (15) observed an initial increase from 4% to 73% and they also found that the high adoption rate held four years later. The large baseline difference in the use of NTRI between the Gothenburg and Stockholm studies is probably explained by the fact that the first investigation was initiated seven years prior to the second one.

Factors influencing adoption (or rejection) of new technology have been described in detail by *Rogers* (15). Key elements in the acceptance of NTRI seem to be the perceived benefits and advantages of the new technology over the old one, and, the opportunity to try it (14). Therefore, the present course included hands-on training in extracted teeth. Accordingly, it was not unexpectedly found that the adoption rate of NTRI was most frequent amongst practitioners with a high rate of weekly root-canal treatments.

The present study found an increased radiographic quality of root-fillings amongst dentists adopting NTRI. For dentists not accepting the technology the quality of the root-fillings was not significantly changed. For the adopters the quality ratio (score1/ score 5) increased from 0.41 to 3.8 and for non-adopters from 0.26 to 0.57. The results support the hypothesis that the quality of root-fillings performed in general practice will increase if NTRI is used. We could not find that the training *per se* caused a significant change in quality.

Root-fillings were classified as "excellent" (score 1) in 38 % of the cases. Using the identical system *Molander et al* (10) found 47% of the roots to qualify for score 1. This difference might be due to the fact that in our study the tooth was the analytic unit (only recording the root with the poorest quality) as opposed to *Molander et al* (10) using the root as a unit.

Despite the general increase in technical quality substandard root-fillings were still produced after the CEP. Amongst adopters the rate of very poor quality cases (score 5) decreased from 29% to 12% and amongst non-adopters from 46% to 28%. Similar results were presented by *Molander et al* (10) and by *Dahlström et al* (4). Reasons for dentists producing and accepting root-fillings of poor quality is not very well understood and need to be researched.

Conclusions of the study may be jeopardized by the high drop-out rate. From the initially included 249 GDPs only 124 (50%) contributed with returned questionnaires and radiographs of treated cases (Fig.2). However, no systematic reasons, potentially biasing the results, for the missing data were found. The main causes for not answering the questionnaires were absence due to illness or maternity and change of employer. For a majority of the excluded GDPs pre-CEP radiographs were available. The distributions of the root-filling quality scores did not significantly differ between excluded and included dentists. Thus, it is reasonable to regard the results of the study as valid for the investigated population.

In conclusion, the results of the present study were in favour of the idea that a shift to NTRI increases the technical quality of root-fillings produced by GDPs. However, adopters still produce root-fillings of very poor quality. This important issue needs to be addressed in future studies. In addition, the influence of the improved technical quality on periapical status has not been evaluated in this study.

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References

1. Boltacz-Rzepkowska E, Pawlicka H. Radiographic features and outcome of root canal treatment carried out in the Lodz region of Poland. Int Endod J 2003;36:27-32.
2. Boucher Y, Matossian L, Rilliard F, Machtou P. Radiographic evaluation of the prevalence and technical quality of root canal treatment in a French subpopulation. Int Endod J 2002;35:229-38.
3. Cheung GS, Liu CS. A retrospective study of endodontic treatment outcome between nickel-titanium rotary and stainless steel hand filing techniques. J Endod 2009;35:938-43.
4. Dahlström L, Molander A, Reit C. Introducing nickel-titanium rotary instrumentation in a public dental service: The long-term effect on root filling quality. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2011;112:814-9.
5. Kerekes K, Tronstad L. Long-term results of endodontic treatment performed with a standardized technique. J Endod 1979;5:83-90.
6. Kirkevang L-L, Hörsted-Bindslev P, Ørstavik D, Wnzel A. A comparison of the quality of root canal treatment in two Danish subpopulations examined 1974-1975 and 1997-1998. Int Endod J 2001;34:607-12.
7. Koch M, Eriksson HG, Axelsson S, Tegelberg A. Effect of educational intervention on adoption of new endodontic technology by general dental practitioners: a questionnaire survey. Int Endod J 2009;42:313-21.
8. Kojima K, Inamoto K, Nagamatsu K Hara A, Nakata K, Morita I, Nakagaki H, Nakamura H. Success rate of endodontic treatment of teeth with vital and nonvital pulps. A meta-analysis. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2004;97:95-9.
9. Lupi-Pegurier L, Bertrand M-F, Muller-Bolla M, Rocca J P, Bolla M. Periapical status, prevalence and quality of endodontic treatment in an adult French population. Int Endod J 2002;35:690-7.
10. Molander A, Caplan D, Bergenholtz G, Reit C. Improved quality of root fillings provided by general dental practitioners educated in nickel-titanium rotary instrumentation. Int endod J 2007;40:254-60.
11. Ørstavik D, Pitt Ford TR, eds. Essential endodontology: prevention and treatment of apical periodontitis. Oxford: Blackwell Science, 1998.
12. Pettiette MT, Delano EO, Trope M. Evaluation of success rate of endodontic treatment performed by students with stainless-steel K-files and nickel-titanium hand files. J Endod 2001;27:124-7.
13. Pettiette MT, Metzger Z, Phillips C, Trope M. Endodontic complications of root canal therapy performed by dental students with stainless-steel K-files and nickel-titanium hand files. J Endod 1999;25:230-4.
14. Reit C, Bergenholtz G, Caplan D, Molander A. The effect of educational intervention on the adoption of nickel–titanium rotary instrumentation in a Public Dental Service. Int Endod J 2007;40:268–74.
15. Rogers EM, ed. Diffusion of innovations. Fifth edition. New York: Free Press, 2003.
16. Sjögren U, Hägglund B, Sundqvist G, Wing K. Factors affecting the long-term results of endodontic treatment. J Endod 1990;16:498-504.

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Titanium- and zirconia-based implant-supported fixed dental prostheses. A randomized, prospective clinical pilot study

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Abstract

◉ The aim of this study was to compare porcelain-veneered implant-supported FDPs based on zirconium dioxide and titanium respectively.

Sixteen patients received 18 implant-supported partial fixed dental prostheses (FDPs); 8 titanium-based and 10 zirconia-based. The FDPs were randomized between the two material groups. Follow-up of the patients was performed at 3 months and thereafter once a year. An assessment protocol based on the California Dental Association (CDA) quality assessment system was used.

Results: All patients were seen at follow-up. The mean time of clinical service at follow-up was 15,2 months (range 12-24 months). All restorations were in place and all patients were satisfied with the treatment. No technical complications were noted in either group. Minor biological complications, in the form of plaque and/or mucositis, not affecting the survival of the restorations were noted for six of the titanium-based restorations and two of the zirconia-based restorations. The difference between the two material groups was not statistically significant.

The outcomes of both materials were comparable. Short term data from this study suggests that porcelain-veneered implant-supported partial FDPs based on zirconia and titanium are satisfactory and equal treatment options. This conclusion is however preliminary as it is based on a small number of patients and short-term follow-up. Long-term follow-up of larger groups of patients is needed before more definite conclusions can be made.

Key words

Titanium, yttria stabilized tetragonal zirconia, porcelain veneer, dental implants, fixed dental prostheses

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Implantat-stödda broar baserade på titan respektive zirkoniumdioxid. En prospektiv klinisk randomiserad pilot-studie

MARCUS BORG, PER VULT VON STEYERN, CHRISTEL LARSSON

Sammanfattning

◎ Målsättningen med studien var att jämföra implantat-stödda partiella broar av titan-porslin respektive yttria-stabiliserad zirkoniumdioxid med ytporslin. Sexton patienter fick sammanlagt 18 broar; 8 av titan-porslin och 10 av yttria-stabiliserad zirkoniumdioxid-porslin. Broarna fördelades randomiserat till respektive material-grupp. Patienterna följdes upp och kontrollerades en första gång efter 3 månader och därefter en gång per år. Ett bedömningsprotokoll baserat på California Dental Association (CDA) kriterier användes.

Alla patienter genomförde kontrollbesöken. Genomsnittlig uppföljningstid var 15,2 månader (12-24 månader). Alla konstruktioner var i funktion vid uppföljning och alla patienter var nöjda med behandlingen. Inga tekniska komplikationer noterades i någon av grupperna. Biologiska komplikationer av ringa betydelse, plack och/eller mucosit, som inte påverkade konstruktionernas överlevnad noterades vid 6 av titan-keramikbroarna och 2 av zirkonia-porslinsbroarna. Skillnaden var inte statistiskt signifikant.

Sammanfattningsvis kan vi i denna studie konstatera att båda materialen fungerade jämförbart. Data från denna studie antyder att implantat-stödda partiella broar av titan-porslin respektive zirkoniumdioxid med ytporslin uppvisar goda resultat på kort sikt. Studier med fler patienter och längre uppföljningstid rekommenderas emellertid innan definitiva slutsatser kan dras.

Introduction

Fixed dental restorations can be made from many different materials. There is extensive evidence of the excellent long-term results for conventional high-noble-alloy-based porcelain-fused-to-metal (PFM) restorations (2,20,24). As some studies have reported on adverse reactions against gold however (12), attention has been focused on even more biocompatible materials as alternatives.

In recent years fixed dental prostheses (FDPs) based on yttria-stabilized tetragonal zirconia polycrystals (zirconia) have become popular thanks to excellent biocompatibility, good aesthetics and sufficient strength for posterior restorations (13). An increasing amount of studies on zirconia-based restorations show similar survival rates as conventional high-noble-alloy-based PFM restorations, the gold standard (5).

The risk of complete failure is minimal for zirconia-based restorations. Few studies on tooth-supported and none of the studies on implant-supported zirconia-based restorations have registered any complete fractures. However, almost all studies report fractures of the veneering porcelain and implant-supported zirconia-based restorations have been shown to be especially prone to veneering material fractures (3,5).

Few veneering material fractures have led to the removal of restorations, most can be polished or left untreated, a few have been repaired (1). The importance of the veneering material fractures should therefore not be over-emphasized as many patients are unaffected by them and even unaware of them (1). They are however important to discuss as a veneering material fracture creates a rough surface, and sometimes sharp edges, that often leads to some need for adjustment. It may also affect aesthetics and/or lead to functional impairment, with loss of occlusal and approximal contacts, to such an extent that replacement would be necessary.

Another type of restoration that satisfies the demand for excellent biocompatibility is the titanium-based PFM FDP. Unfortunately however, these restorations have also shown more fractures of the veneering material compared to high-noble-alloy-based PFM FDPs (6,25).

To assist the clinician in making choices and selecting materials, studies comparing success and complication rates for FDPs made of different materials within the same study would be valuable. Unfortunately there is a lack of such studies, especially for implant-supported restorations. The aim of the present study was therefore to compare porcelain-veneered implant-supported FDPs based on zirconia and titanium respectively. The hypothesis was that there would be no differences in clinical performance between the two types of restorations.

Material and methods

Twenty implant-supported FDPs were planned to be made; 10 zirconia-based and 10 titanium-based during the period January 2009 to June 2011. The patients were recruited consecutively from the Prosthodontic Specialist Centres, Public Dental Health Service, in Norrköping and Linköping, Sweden. The inclusion criteria were indications for one or more two- to five unit implant-supported restorations supported by two to three implants. Exclusion criteria were factors preventing implant placement, i.e physical or mental illnesses preventing surgical treatment as judged by medical doctor, and/or allergies towards any of the materials planned to be used.

During the study period, January 2009 to June 2011, 16 patients met the inclusion criteria and accepted participation, 8 women and 8 men between the ages of 21 and 85 years. The status of the opposing jaw varied from natural teeth with or without minor fillings to tooth-supported metal-ceramic FDPs, implant-supported metal-ceramic FDPs and removable complete denture. (Table 2)

The patients were informed about the protocol of the study, the risks with and alternatives to the proposed treatment, and all gave their informed consent. Ethical approval of the study was obtained from the Regional Ethics Committee in Linköping, Sweden (M51-08).

Dental implants (Brånemark System Mk III, RP or NP, Nobel Biocare Nordic AB, Göteborg, Sweden) were installed in a one-stage surgical procedure according to the surgical instructions of the manufacturer. The healing time before prosthodontic treatment was a minimum of 3 months in the lower jaw and 6 months in the upper jaw. The surgical treatment was performed by three dentists, specialists in periodontology. Four dentists, specialists in prosthodontics, performed the prosthodontic treatment. One dentist treated 12 of the patients, one treated two patients, and the other two treated one patient each.

When the prosthodontic treatment began, FDPs were randomly assigned to patients meeting the inclusion criteria, using a list of uniform distributed random numbers, made in collaboration with a statistician. (Table 1)

Table 1.
Randomization protocol.

FDP nr	Treatment
1	A
2	B
3	B
4	A
5	A
6	B
7	A
8	B
9	B
10	B
11	B
12	A
13	A
14	B
15	B
16	B
17	A
18	A
19	A
20	A

A: titanium-based
B: zirconia-based

Table 2. Status of the opposing jaw – presence of natural teeth or restorations – in relation to type of provided treatment; zirconia- or titanium-based implant-supported (IS) fixed dental prostheses (FDP).

Status oppsing jaw	Zirconia-based IS FDP	Titanium-based IS FDP
Natural teeth	3	4
Tooth-supported metal-ceramic FDP	2	1
Implant-supported metal-ceramic FDP	4	3
Complete denture	1	

Table 3. Surface according to the assessment protocol.

Score	Criteria	Outcome
A Excellent	The surface of the restoration is intact	Success
B Acceptable	Superficial fracture that does not affect aesthetics or function.	Survival
C Retrievable	Superficial fracture affecting aesthetics and/or function but can be adjusted by polishing or repaired.	Survival
D Unacceptable	Fracture affecting aesthetics or function to such an extent that replacement is necessary.	Failure

Full-arch impressions on implant level were made with a polyether impression material (Impregum™ Penta, 3M ESPE, St. Paul, MN, USA) in disposable trays (Tray Aways®, The Bosworth Company, Skokie, Illinois, USA) using the open-tray technique. Impressions of the opposite jaw were made with alginate (Aroma Fine, GC, Fuji Oyama, Japan) in rigid stainless steel trays (COE, GC, Fuji Oyama, Japan). Finally inter-occlusal registrations in centric relation were made in aluminium wax (Alminax®, Associated Dental Products, Wiltshire, Great Britain).

The laboratory procedures were carried out at two commercial dental laboratories (Boxholm Dental, Boxholm, Sweden and DP Nova, Sjöbo, Sweden). Eighteen implant-supported fixed dental prostheses were made for the 16 patients. Ten of the patients received 10 zirconia-based (yttria-stabilized tetragonal zirconia) FDPs (Procera Implant Bridge Zirconia, Nobel Biocare Nordic AB, Göteborg, Sweden) and eight patients received 8 titanium-based (commercially pure titanium, grade 2) FDPs; 4 Procera Implant Bridge (Procera Implant Bridge Titanium, Nobel Biocare Nodic AB, Göteborg, Sweden) and 4 I-Bridge (Biomain AB, Helsingborg, Sweden). The restorations were made at implant level, without abutments. The frameworks were tried in the mouth and intraoral radiographic examinations were made to check the marginal fit. Any frameworks not exhibiting optimal fit were to be remade.

The frameworks were veneered with porcelain. Zirox NR (Wieland, Pforzheim, Germany) and HeraCeram (HeraeusKulzer GmbH, Hanau, Germany) veneering porcelain was used for the zirconia frameworks and Espident Triceram (Dentaurum, Ispringen, Germany) and GC Initial Ti (GC, Fuji Oyama, Japan) for the titanium frameworks. Firing was done according to the respective manufacturer´s protocols following recommendations concerning times and temperatures. A coating agent/liner was used as recommended to enhance adherence between veneer and core. The titanium frameworks were ground and sandblasted and Triceram bonder (Dentaurum, Ispringen, Germany) and Ti bonder (GC, Fuji Oyama, Japan) applied according to the respective manufacturers protocol and subsequently fired. The zirconia frameworks veneered with HeraCeram were steam-cleaned and then Zr Adhesive (HeraeusKulzer GmbH, Hanau, Germany) was applied and fired. The zirconia frameworks veneered with Zirox NR were sandblasted with aluminium oxide, 110µm at 1 bar pressure and subsequently fired. Recommended protocols for time for cooling phase were followed.

The completed restorations were fitted and temporarily sealed with plastic tube and temporary fillings (Systemp Inlay, Ivoclar Vivadent, Schaan, Liechtenstein). After three months the restorations were

re-examined, the centric screws were retighten to 35Ncm and the access holes sealed with plastic tube and composite fillings (Filtech Supreme, 3M ESPE, St. Paul, MN, USA).

Follow-up examinations were performed after three and twelve months and will be performed again after 36 and 60 months. The surface of the restorations and periimplant conditions were rated as excellent, acceptable, retrievable or not acceptable according to a protocol based on the California Dental Association (CDA) quality assessment system (18). (Table 3,4)

Success was defined as the restoration having no complications, i.e. only A ratings according to the protocol. Survival was defined as the restoration remaining in-situ with complications that do not affect function or that can be repaired, i.e. B and/or C ratings. Failure was defined as the restoration having been removed or with complications of such severity that removal is necessary, i.e. D ratings.

Differences between the groups were calculated using Fisher's exact probability test.

Results

Eight patients received 8 titanium-based PFM FDPs (2-5 units) and 10 patients received 10 zirconia-based porcelain-veneered FDPs (2-3 units).

All patients attended the follow-up. The mean time of clinical service at follow-up was 15,2 months (range 12-24 months). All restorations were in place and all patients were satisfied with the treatment. No technical complications, such as loosening of the abutment screws or fractures of the veneering material were noted. All surfaces were rated A according to the protocol (Figure 1).

Figure 1.

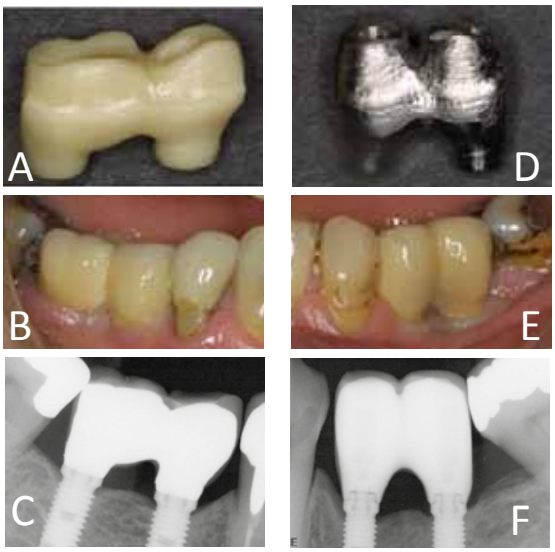

Figure 1 A-F
A: Buccal view of Procera Implant Bridge Zirconia (before veneering)
B: Buccal view of Procera Implant Bridge Zirconia (in place)
C: Radiograph of Procera Implant Bridge Zirconia at 1-year follow-up
D: Buccal view of Procera Implant Bridge Titanium (before veneering)
E: Buccal view of Procera Implant Bridge Titanium (in place)
F: Radiograph of Procera Implant Bridge Titanium at 1-year follow-up

Table 4. Periimplant conditions according to the assessment protocol.

Score	Criteria	Outcome
A Excellent	No plaque and/or mucositis.	Success
B Acceptable	Presence of plaque and/or mucositis.	Survival
C Retrievable	Marginal bone loss which responds to treatment – implants and restoration remain in-situ.	Survival
D Unacceptable	Marginal bone loss that does not respond to treatment leading to removal of implant and restoration.	Failure

Table 5. Firing temperature and coefficient of thermal expansion (CTE) of the veneering porcelains.

Veneering porcelain		Firing tempereature (C°)	CTE (µm/m.K)
Titanium frameworks	Triceram	760	9,6
	GC Initial Ti	780	8,6
Zirconia frameworks	Heraceram	880	10,5
	Zirox NR	900	10,5

Minor biological complications, not affecting the survival of the restorations were noted. Eight of the ten zirconia-based FDPs, with 16 abutments, showed excellent periimplant health and were rated A according to the protocol. Two zirconia-based FDPs, with 4 abutments, showed plaque and/or mucositis and were rated B. Two of the eight titanium-based FDPs, with 11 abutments, showed excellent periimplant health and were rated A according to the protocol. Six titanium-based FDPs, with 9 abutments, showed plaque and/or mucositis and were rated B (Table 6).

The difference between the groups was not statistically significant. The patients showing presence of plaque and/or mucositis received treatment and no further complications have been noted to date.

Discussion

Zirconia-based FDPs offer many advantages such as excellent biocompatibility and good aesthetics and have become an interesting treatment alternative to PFM FDPS. Survival rates are comparable but an increased risk of veneering material fractures has been reported for zirconia-based restorations (5). The occurrence of veneering material fractures has been especially high for implant-supported restorations according to previous reports (3,9,10).

The same problems have been noted for titanium-based restorations, for tooth-supported as well as implant-supported FDPs (6,25,27). To avoid exposing the zirconia and titanium frameworks to unfavourably high temperatures during porcelain firing, creating undesirable phase transformation, porcelain of low firing temperature is often used. Glass modifiers are added to lower the firing temperature and this modification affects the mechanical properties which is a risk factor for veneer fractures (8).

Using veneering materials with different microstructure and firing temperatures to increase the strength and minimize the risk of fractures has been suggested (Table 5). Laboratory studies comparing veneering materials with different microstructure, firing temperatures and coefficient of thermal expansion have however not found any significant differences (11,21).

In the present study no fractures of the veneering material were noticed. This is in contrast to earlier publications where veneering material fractures have been reported to occur frequently for zirconia- and titanium-based restorations (5,6,9,10,25). A possible explanation for the improved results in the present study compared to earlier studies could be the fact that this study was initiated recently when the knowledge of different factors of possible influence on veneering materials as well as on how to design, handle and produce zirconia- and titanium-based restorations has improved compared to what was known at the time the above mentioned studies were initiated (15). For titanium-based restorations, the high frequency of complications in the form of veneering material fractures has by some authors been explained by inexperience in using low-fusing

Table 6. Placement of FDPs, materials and prescence of minor biological complications.

Patient	FDP nr	Material	Framework	Porcelain					
1	1	Zr	Procera	HeraCeram	35	(36)	37		
2	2	Zr	Procera	HeraCeram	45	44			
3	3	Ti	I-Bridge	Triceram	34	(35)	36►		
4	4	Zr	Procera	Zirox	45►	44►			
5	5	Ti	I-Bridge	TriCeram	11	(21)	22		
6	6	Ti	I-Bridge	GC	14►	13►	12►		
7	7	Zr	Procera	Heraceram	24	25			
8	8	Zr	Procera	Heraceram	34►	35►			
9	9	Ti	Procera	GC	45►	44			
10	10	Ti	Procera	Trieram	22	(23)	24►	25	
	11	Zr	Procera	HeraCeram	16	(15)	14		
11	12	Ti	Procera	Triceram	13►	12	(11)	(21)	22►
12	13	Zr	Procera	Zirox	47	(46)	45		
13	14	Zr	Procera	Zirox	34	(35)	36		
14	15	Zr	Procera	Zirox	45	44			
	16	Ti	Procera	Triceram	34	35			
15	17	Ti	I-Bridge	Triceram	15	14►	13		
16	18	Zr	Procera	Zirox	15	14			

► Denotes presence of plaque and/or mucositis

porcelains, suggesting the influence of a "learning-curve" (27).

Many factors influencing the risk of veneering material fractures in zirconia restorations have been discussed (15). Recently much attention has been focused on the design of the supporting substructure and the thickness of the veneering material (23). Veneering materials are brittle and of relatively low strength. The compressive strengths of veneering materials are higher than their tensile strength so it is important to design the framework to avoid tensile stress. An anatomical design of the substructure will provide support for the veneer and create conditions for mainly compressive forces within the veneering material. Several studies have high-lighted the importance of an adapted, anatomical design of the substructure (11,16,22). The cores of the FDPs in the present study were all designed to have an anatomical shape allowing for support of the veneering material.

The design of the substructure also controls the thickness of the veneering material. Thick layers of porcelain veneered on frameworks with low thermal diffusivity such as zirconia, may generate high residual tensile stresses which can contribute to fractures of the veneering material (23). The FDPs in the present study were designed to have a uniform layer of veneer with a minimal thickness of 1mm but not exceeding 1,5 mm.

Uncontrolled stresses will increase even further if the firing process and subsequent cooling are not performed appropriately (23). Many manufacturers have adapted the cooling process according to these findings to reduce stresses after porcelain firing. The FDPs in the present study were fired and subsequently cooled according to new adapted protocols as recommended by the respective manufacturers.

The FDPs in the present study were manufactured keeping these factors in mind and the results are promising. However, relatively few patients are included, the size of the restorations is limited, and the follow-up time is short so conclusions are preliminary.

The restorations in the present study were screw-retained and placed on implant level, i.e. without abutments. A screw-retained restoration facilitates retrieveability in case of complications. The technique also has the advantage that there is no risk of retained excess cement which has been suggested to increase the risk of periimplantitis (26). Some have however, suggested that restorations placed directly on implant level without abutments show increased crestal bone resorption compared to control groups with abutments (14). In the present study, no crestal bone resorption was noted for either treatment group. The follow-up time was however short. There is a risk of bone resorption developing over time and this factor will be addressed again in future follow-up.

Plaque and/or mucositis were registered around eight of the FDPs; six of the titanium-based and two of the zirconia-based. This numerical difference between the groups was not statistically different - possibly due to the small sample of restorations.

Ceramic materials have been found to accumulate less plaque and plaque with reduced vitality, compared to other restorative materials (4,7,17). The clinical significance is uncertain however. A review comparing metal and ceramic abutments found a numerical difference with higher frequency of biological complications around metal abutments compared to ceramic abutments but the difference was not statistically significant (19).

Aspects of the method used

Twenty implant-supported FDPs were originally planned to be made; 10 zirconia-based and 10 titanium-based FDPs during the period January 2009 to June 2011, and the randomization protocol was designed accordingly. At the end of the study period only 16 patients with 18 FDPs had met the inclusion criteria. This may limit the possibilities of identifying possible differences and affect the conclusions drawn. There were differences between the two material groups with respect to size of the restorations. The titanium-based FDPs were 2-5 units whereas the zirconia-based FDPs were 2-3 units. Although no differences were noted in the short term this may affect results over longer term.

The patients in the present study were all treated by specialists at a clinic for prosthetic dentistry. This may limit the applicability of the treatment outcome compared to other groups of treatment providers (28).

Conclusion

Short term data from this study suggests that porcelain-veneered implant-supported FDPs based on zirconia and titanium are satisfactory and comparable treatment options. This conclusion is however preliminary as it is based on short-term follow-up of a small number of patients. Long-term follow-up of larger groups of patients is needed before more definite and general conclusions can be made.

References

1. Al-Amleh B, Lyons K, Swain M. (2010) Clinical trials in zirconia: a systematic review. J Oral Rehabil 2010; 37:641-52.
2. Creugers NH, Käyser AF, van´t Hof MA. A meta-analysis of durability data on conventional fixed bridges. Community Dent Oral Epidemiol 1994; 22:448-52.
3. Guess P, Att W, Strub JR. Zirconia in fixed implant prosthodontics. Clin Implant Dent Relat Res 2012; 14:633-45.
4. Hanh R, Weiger R, Netuschil L, Bruch M. Microbial accumulation and vitality on different restorative materials. Dent Mater 1993; 9:312-6.
5. Heintze SD, Rousson V. Survival of zirconia- and metal-supported fixed dental prostheses: a systematic review. Int J Prosthodont 2010; 23:493-502.
6. Kaus T, Probster L, Weber H. Clinical follow-up study of ceramic veneered titanium restorations – three-year results. Int J Prosthodont 1996; 9:9-15.
7. Kawai K, Urano M. Adherence of plaque components to different restorative materials. Oper Dent 2001; 26:396-400.
8. Kon M, O´Brien WJ, Rasmussen ST, Asaoka K. Mechanical properties of glass-only porcelains prepared by the use of two feldspathic frits with different thermal properties. J Dent Res 2001; 80:1758-1763.
9. Larsson C, Vult von Steyern P, Nilner K. A prospective study of implant-supported full-arch yttria-stabilized tetragonal zirconia polycrystals mandibular fixed dental prostheses: three-year results. Int J Prosthodont 2010; 23:364-9.
10. Larsson C, Vult von Steyern P. Five-year follow-up of implant-supported Y-TZP and ZTA fixed dental prostheses. A randomized, prospective, clinical trial comparing two different material systems. Int J Prosthodont 2010; 23:555-61.
11. Larsson C, El Madhoun S, Wennerberg A, Vult von Steyern P. Fracture strength of yttria-stabilized tetragonal zirconia polycrystals crowns with different design: an in vitro study. Clin Oral Implants Res 2012; 23:820-6.
12. Lygre H. 2002 Prosthodontic biomaterials and adverse reactions: a critical review of the clinical and research literature. Acta Odont Scand 2002; 60:1-9.
13. Nilner K, Karlsson S, Dahl BL, eds. A textbook of fixed prosthodontics. The Scandinavian approach. Stockholm: Gothia, 2013.
14. Peñarrocha-Diago MA, Flichy-Fernández AJ, Alonso-González R, Peñarrocha-Oltra D, Balaguer-Martínez J, Peñarrocha-Diago M. Influence of implant neck design and implant-abutment connection type on peri-implant health. Radiological study. Clin Oral Implants Res 2012; 00:1-9.
15. Rekow ED, Silva NRFA, Coelho PG, Zhang Y, Guess PC, Thompson VP. Performance of dental ceramics: challenges for improvements. J Dent Res 2011; 90:937-52.
16. Rosentritt M, Steiger D, Behr M, Handel G, Kolbeck C. Influence of substructure design and spacer settings on the in-vitro performance of molar zirconia crowns. J Dent 2009; 37:978-83.
17. Rosentritt M, Behr M, Burgers R, Feilzer AJ, Hahnel S. In vitro adherence of oral streptococci to zirconia core and veneering glass ceramics. J Biomed Mater Res B Appl Biomater2009; 91:257-63.
18. Ryge G. Clinical criteria. Int Dent J 1980; 30:347-58.
19. Sailer I, Philpp A, Zembic A, Pjetursson BE, Hammerle CHF, Zwahlen M. A systematic review of the performance of ceramic and metal implant abutments supporting fixed implant reconstructions. Clin Oral Implants Res 2009; 20(suppl 4):4-31.
20. Scurria MS, Bader JD, Shugars DA. Meta-analysis of fixed partial denture survival: prostheses and abutments. J Prosthet Dent 1998; 79:459-64.
21. Sundh A, Molin M, Sjögren G. Fracture resistance of yttrium oxide partially-stabilized zirconia all-ceramic bridges after veneering and mechanical fatigue testing. Dent Mater 2005; 21:476-82.
22. Sundh A, Sjogren G. A comparison of fracture strength of yttrium-oxide-partially-stabilized zirconia ceramic crowns with varying core thickness, shapes and veneer ceramics. J Oral Rehabil 2004; 31:682-8.
23. Swain MV. Unstable cracking (chipping) of veneering porcelain on all-ceramic dental crowns and fixed partial dentures. Acta Biomater 2009; 5:1668-77.
24. Tan T, Pjetursson, BE, Lang NP, Chan ES. A systematic review of the survival and complication rates of fixed partial dentures (FDPs) after an observation period of at least 5 years. Clin Oral Implants Res 2004; 15:654-66.
25. Walter M, Reppel PD, Boning K, Freesmeyer WB. Six-year follow-up of titanium and high-gold porcelain-fused-to-metal fixed partial dentures. J Oral Rehabil 1999; 26:91-6.
26. Wilson TG. The positive relationship between excess cement and periimplant disease: a prospective clinical endoscopic study. J Periodontol 2009; 80:1388-92.
27. Örtorp A, Jemt T. Laser-welded titanium frameworks supported by implants in the partially edentulous mandible: a 10-year comparative follow-up study. Clin Implant Dent Relat Res 2008; 10:128-39.
28. Öwall B, Bergman B. Longevity and complication of FPDs. In: Karlsson S, Nilner K, Dahl B. (eds). A textbook of fixed prosthodontics. The Scandinavian approach. Stockholm; Publishing House Gothia, 2000:290-311.

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Positioning errors in panoramic images in general dentistry in Sörmland County, Sweden

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Abstract

◉ The purpose of this study was to evaluate the frequency and severity of positioning errors in panoramic radiography in general dentistry.

A total of 1904 digital panoramic radiographs, taken by the Public Dental Service in the county of Sörmland, Sweden, were analysed retrospectively. The study population consisted of all patients who underwent a panoramic examination during the year 2011.

One experienced oral radiologist evaluated all radiographs for 10 common errors.

Of the 1904 radiographs examined, 79 per cent had errors. The number of errors varied between 1–4 errors per image. No errors were found in 404 images (21%). Fifty-five images (3%) had severe errors, which made it impossible to make correct diagnostics.

The most common error was the tongue not being in contact with the hard palate during exposure. However, this did not greatly affect the diagnostic usefulness of the image due to the ability to enhance the image. The patient's head was tilted too far upwards in 23 per cent of the images and the patient's head was rotated during exposure in 15 per cent. The least common error was due to patient movement during exposure (1%).

Panoramic radiographs taken in general dental clinics in a Swedish county show several errors. Proper positioning of the patient is necessary to achieve panoramic images with good image quality. Some of the errors could be adjusted with the digital technique used. This allowed assessment of the images, which reduces radiation dose by avoiding retakes.

Key words

Panoramic radiograph, quality control, radiographic error

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Inställningsfel på panoramabilder tagna på allmäntandvården inom Folktandvården Sörmland

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Sammanfattning

◉ Panoramabilden är en bra översiktsbild över tänder och käkar och ett bra hjälpmedel vid röntgendiagnostiken. Panoramatekniken är dock inställningskänslig. Små fel vid patientpositioneringen kan ge synliga fel i bilden och störa möjlighet till bra diagnostik. Tidigare undersökningar visar att inställningsfel på panoramabilder är vanligt förekommande. De flesta studier är gjorda på ett urval av bilder tagna på en specialistklinik eller en tandläkarhögskola.

Syftet med denna studie var att ta reda på antalet och svårighetsgraden av de inställningsfel som förekommer på panoramabilderna som tas i allmäntandvården.Samtliga panoramabilder som togs inom allmäntandvården i Folktandvården Sörmland under år 2011 analyserades. Patienternas ålder varierade från 4 till 96 år. Bilderna var tagna av tandsköterskor och tandhygienister på 11 olika allmäntandvårdskliniker i Sörmland. En erfaren odontologisk radiolog bedömde alla 1904 bilderna. Inställningsfel och andra fel som störde diagnostiken noterades.

Av de 1904 panoramabilder som bedömdes i denna totalundersökning hade 79 % något inställningsfel. Antal fel per bild varierade mellan 1 och 4. Tjugoen procent av bilderna hade inga fel (404 stycken). Godkända bilder med endast ringa inställningsfel var 598 till antalet (32 %), 847 bilder (44 %) var dåliga men diagnosticerbara och 55 bilder (3 %) bedömdes som underkända, då det inte gick att diagnostisera på bilderna.

Det vanligaste inställningsfelet var att tungan inte var i kontakt med gommen vid bildtagningen (39 %). Det inställningsfelet bedömdes dock som ringa störande i de flesta fall eftersom det kunde justeras med hjälp av bildbehandlingsprogrammet. Vanliga inställningsfel var också att patienten hade hakan för mycket upp (23 %) och att patienten stått vriden (15 %).

Många panoramabilder tagna på folktandvården i ett svenskt län uppvisar inställningsfel som i olika grad påverkar bildkvaliteten. Med hjälp av den digitala tekniken kunde det vanligaste inställningsfelet, att tungan inte varit i gommen under bildtagningen, i många fall minimeras så att omtagningar och därmed ökad stråldos kunde reduceras.

Introduction

The panoramic image provides an overview of the teeth and jaws, and is a good tool in diagnostic radiology. The technique is relatively convenient for the patient and simple to use, but it is sensitive to positioning errors. Despite the positioning lights in the machine, which function as assistance when positioning the patient, it is not easy to position the patient correctly in the panoramic unit, especially for inexperienced operators (14). Even small positioning errors may result in distorted images, in which the structures will be imaged with incorrect proportions, or in parts of the dental arches being outside the narrow zone of sharp focus, the image layer, which limits the ability to detect pathological conditions. Correct positioning is therefore crucial to ensure that the teeth and jaws are within the image layer (18, 21). The anterior teeth in both arches are especially susceptible to positioning errors and will easily be outside the image layer and become blurred and distorted (15).

Positioning errors depend mostly on operator skills, but also on the patient's physiognomy and cooperation. Previous studies have shown that positioning errors in panoramic images are common (1, 4-6, 8-10, 13, 14, 19, 20). Further, these studies found that none, or only a part of the images, had perfect quality (0–37%). The most common positioning error, mentioned in several studies, is that the tongue is not in contact with the hard palate during exposure, resulting in an air slot between the tongue and the palate. This appears as a dark shadow over the teeth in the upper jaw, obscuring the maxillary apices, making it difficult or impossible to diagnose the teeth in the maxilla. (1, 8, 10). Many of the aforementioned studies show that the images have more than one positioning error. *Kullman & Joseph* registered 1–9 errors per image (14), and *Granlund et al* found five errors per image (10). The studies conclude that it's important to position the patient correctly when taking images (6, 8), and that the technique is complicated and requires experienced operators to gain high image quality (14).

A minority of the previous studies evaluated panoramic radiographs taken in general dental clinics or by general dental practitioners (6, 20). Instead most studies are made at a dental school, a department of radiology, or a specialist clinic.

Every x-ray image exposes the patient to radiation, thus carrying a certain risk. To lower this risk and to ensure that the patient is not unnecessarily exposed to radiation, there must always be a medically justifiable reason for taking the radiograph (7, 16). According to the ALARA principle (As Low As Reasonably Achievable), the radiation dose shall be kept as low as possible. To achieve this, it is important to set the correct exposure parameters according to the patient's size and to reduce image field if possible. It is also important to position the patient's head as correctly as possible in the machine, and ensure that spectacles, necklaces, earrings, piercings and dentures are removed before exposure, to avoid unnecessary retakes or diagnostic errors (18).

Aim

The purpose of this study was to evaluate the frequency and severity of positioning errors in all panoramic radiographs taken during 2011 in general dentistry in the county of Sörmland, Sweden.

Material and methods

A total of 1904 digital panoramic radiographs, taken by the Public Dental Service in the county of Sörmland, Sweden, were analysed retrospectively. The study population consisted of all patients who underwent a panoramic examination during the year 2011. Neither the operators nor the patients knew that the images would later be included in a study. The patients were 51% female and 49% male, aged from 4 to 96 years. The panoramic images were obtained at 11 dental clinics with panoramic machines (PM 2002, Planmeca, Helsinki, Finland). The PM 2002 has a paediatric program which reduces the exposed area from both sides by starting the exposure later and stopping the exposure earlier than the normal panoramic program. The exposure time is reduced from 18 to 15 seconds, thus lowering the patient dose (12). Four of the machines had digital sensors, and the other seven were equipped with cassettes and phosphor plates (Digora PCT, Soredex, Helsinki, Finland). All panoramic radiographs were taken by dental assistants or hygienists at the clinics.

The radiographs were retrieved from the server of the Public Dental Health Service in Sörmland and were evaluated with the Dental Eye image processing system (DentalEye AB, Sundbyberg, Sweden) by one of the authors, an experienced oral radiologist. The images were displayed on a NEC MultiSync LCD 2190 UXp screen (NEC Scandinavia AB – Display Solutions Division Sweden, Kista, Sweden) with a resolution of 1600 x 1200 pixels. The radiographs were manipulated in the image processing system to obtain good subjective density and contrast. For each radiograph, the presence of errors or other

inaccuracies that could affect the diagnostic image quality was registered. The radiographs were evaluated according to the following protocol:

1. Patient's head tilted upward
2. Patient's head tilted downward
3. Widening of the anterior teeth
4. Narrowing of the anterior teeth
5. Rotation of the head to the right/left
6. Tongue not in contact with the hard palate
7. Marked ghost image of the spine superimposed on the front
8. Foreign objects
9. Incorrect exposure
10. Motion blur

Other issues influencing image quality or radiation dose, such as poor contrast, collimation of images of children, exposure of white light before scanning the phosphor plates, and reversed cassettes, were also noted.

The image quality was assessed according to the following scale:

1. **Approved image, no errors**
   High quality image providing sufficient information with no errors from image taking procedure
2. **Approved image, only small errors, adequate for diagnosis**
   Quality image providing sufficient information with 1-2 positioning error(s) that does not affect the diagnosis
3. **Image with one or more errors, poor but diagnosable**
   Diagnosable image with one or more errors and partially unreadable regions
4. **Unapproved image, too poor for diagnosis**
   Poor image quality with errors rendering the image diagnostically unacceptable

Statistical Analysis

Conventional descriptive statistics were used to present the frequencies of image errors and a chi-2 test to compare the image quality of children and adolescents with the image quality of patients twenty years and older.(3).

Results

Of the 1904 panoramic radiographs taken, 1002 were images with no (n=404) or only small (n=598) errors. The remaining images had one or more positioning errors which more or less affected the diagnostic ability. Fifty-five images had severe errors which made it impossible to make correct diagnostics. These images were classified as unapproved images (Table 1).

Table 1. Number and percentage of approved and unapproved images according to an image quality scale (n=1904).

Scale	Number of images	%
1 = Approved image, no errors	404	21
2 = Approved image, small errors, adequate for diagnosis	598	32
3 = Image with one or more errors, poor but diagnosable	847	44
4 = Unapproved image, too poor for diagnosis	55	3

The 1500 images with errors each contained 1–4 positioning errors. The most common error was that the tongue was not in contact with the hard palate during exposure. This affected 747 images (39%) (Table 2). However, in only 33 of these images the error was regarded as affecting the diagnostic ability. These images could be adjusted sufficiently with the image processing program, so that the otherwise affected apical regions of the maxillary teeth could be observed. Adjustment of brightness and contrast was needed when other parts of these radiographs were diagnosed.

The patient's head was tilted too far upwards in 23% of the images (Figure 1) and the patient's head was rotated under exposure in 15% (Figure 2).The

Table 2. Ranking of the different positioning errors in the panoramic radiographs

Positioning error/inaccuracies	Number of radiographs with error	Percentage of radiographs with error
Tongue not in contact with the hard palate	747	39
Patient's head tilted upwards	432	23
Lack of contrast	376	20
Anterior teeth out of focus layer	270	14
Rotation of the head to the left	182	9
Marked ghost image of the spine superimposed on the front	139	7
Incorrect exposure	114	6
Patient's head tilted downwards	112	6
Narrowing of the anterior teeth	111	6
Rotation of the head to the right	106	6
Foreign objects	87	5
Widening of the anterior teeth	70	4
Tongue not in contact with the hard palate, resulting in an air shadow that affects diagnostic ability even after enhancement	33	2
Motion blur	13	1

head was more often rotated to the left than to the right side.

Twenty per cent of the panoramic radiographs had lack of contrast and could not be adjusted to good image quality in the image processing program. In 14% of the images, the anterior teeth were out of the image layer.

Other common errors, each with 6% frequency, were non-erect spine, resulting in a marked ghost image of the spine superimposed on the front section; the patient's head tilted too far downwards resulting in an overly bright smile and blurred apices of the lower incisors; wrong positioning of the occlusion correction light, resulting in narrowed ante-

Figure 1. Patient's head tilted upward

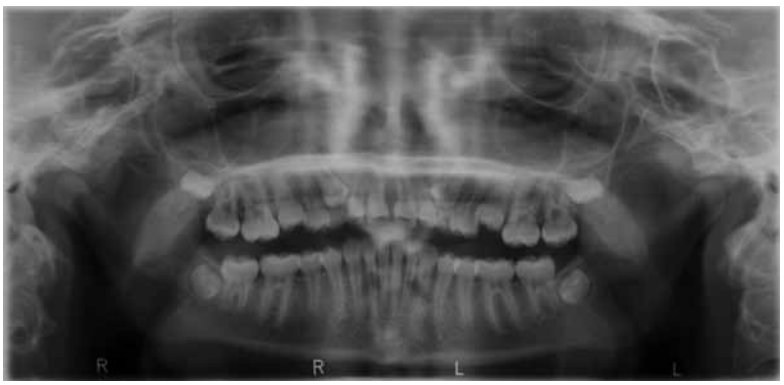


Figure 2. Rotation of the head to the left

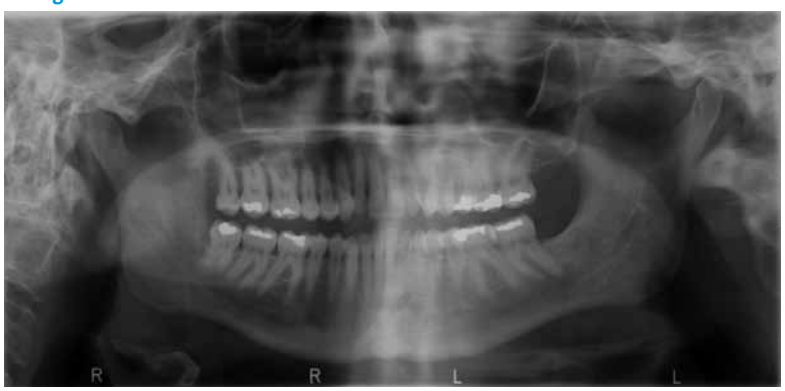
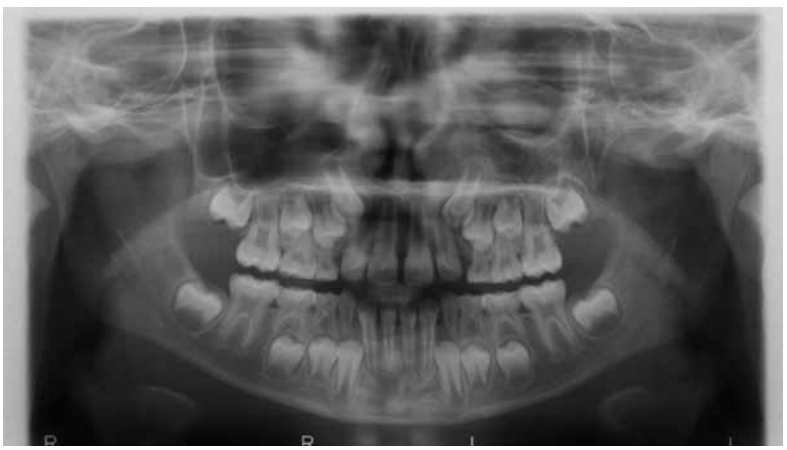


Figure 3. Panoramic radiograph taken with the Planmeca PM 2002 paediatric program.



rior teeth and underexposure, which in turn caused grainy (noisy) images (Table 2).

Panoramic radiographs were taken of 415 children up to 11 years of age. Of these images, 154 were taken with the paediatric panoramic program (Figure 3), while 261 were taken with the normal panoramic program. The image quality of the radiographs of children and adolescents was significantly better (p-value < 0,01) than the image quality of the radiographs of patients twenty years and older.

Discussion

Unlike the present study, in most previous studies the panoramic radiographs were taken at a radiologic department, a specialist clinic or a dental school (1, 8-10, 13, 14, 19). In further contrast to most other studies, the present survey is all-encompassing, and analyses all panoramic radiographs of children and adults taken during one year (2011) in general dental clinics in a Swedish county. Previous studies of panoramic images taken by general practitioners or in general dental clinics showed a high frequency of errors in panoramic radiographs (2, 4-6, 20). *Brezden et al* (5) evaluated 500 panoramic radiographs submitted to Delta Dental Plan of Michigan and found that 467 of them had positioning errors. *Åkesson et al* (2) evaluated panoramic images (n=198) from a department of oral radiology and radiographs from 20 randomly selected dental clinics (n= 100). The selection criteria in the study were that the patient had to be more than 16 years of age and have an almost complete dentition. In the present study all panoramic radiographs, regardless of age and number of teeth, were evaluated. In the *Åkesson* study the image quality of radiographs was better for the sample of radiographs from the department of radiology compared to the sample from the 20 dental clinics. The study concluded that the image quality has to be improved in general and that more care should be given to patient positioning.

Rushton et al (20)evaluated 1831 radiographs obtained from 41 general practitioners who were invited to participate in a study after responding positively to a questionnaire. It may be assumed that the dentists who agreed to take part in the study had an interest in research and radiography, and it would be unlikely that dentists who perceive their image quality as poor would have participated.

The *Rushton* study concluded that the quality of panoramic radiographs was low. They proposed more education with the aim to learn to recognise faults and what causes them. Further, they suggested the creation of agencies with the aim to study and give feedback on image quality of the panoramic radiographs taken at dental clinics. *Bissoon et a*l (4) valuated panoramic radiographs of patients over the age of 10 years, 500 were from the dental hospital and 500 from dental private practices. In both samples errors were common. There were only 4.2% error free radiographs in the dental private practice sample and 5.8% in the dental hospital sample. Frequencies of specific errors were significantly higher in the dental private practice sample. *Choi et al* (6) studied 288 images taken at 99 randomly selected dental hospitals and clinics. Each dental hospital or clinic was asked to provide three randomly selected radiographs. Whether or not the images provided really were randomly selected is unclear. Originally, 260 clinics and hospitals were selected but as the response rate was only 38%, 99 clinics and hospitals took part. The results from the present analysis of all 1904 panoramic radiographs taken in one year correspond fairly well with the results of the *Choi* study In the Choi study 59% and in the present study 53% of the panoramic radiographs were images with no errors or images with small errors but adequate for diagnosis. In both studies 3% of the images were unacceptable for diagnosis.

In accordance with previous studies (1, 4-6, 8-10, 13, 14, 19, 20), the present study demonstrated that the panoramic technique is susceptible to positioning errors. Out of 1904 panoramic radiographs taken in general dentistry in the county of Sörmland, 79% had one or more position errors. The images in this study were taken by dental assistants and hygienists. It was not possible to detect how many images were taken by the different operators to see if the image quality was improved by taking images more frequently. Some clinics took only about 50 panoramic radiographs in 2011, and with several operators. This means that many of them took only a few panoramic radiographs each year. *Kullman & Joseph* (14). concluded that the technique is complicated and requires experienced operators to gain high image quality.

The most common positioning error in this study was the tongue not being in contact with the hard palate during exposure, as reported previously (1, 8, 10). This positioning error is difficult to control for the operator. Despite careful instruction before taking the radiograph, the patient does not always have the tongue in the right position during exposure. Yet, this error was not considered as especially serious in this study, since in most cases the air shadow

could be reduced by the image processing system. This allowed the examiner to see the teeth in the upper jaw despite the tongue not being pressed against the hard palate during exposure.

The ability to enhance digital images gives them an advantage over film-based panoramic radiographs as the latter cannot be improved after development. Without the ability to enhance images, the structures in the upper jaw would not have been visible in several images. This would have required retakes or additional intraoral images in the upper jaw to assure diagnostic ability (17), which would lead to an increased radiation dose and increased costs. For analogue radiographs, without the possibility of improving the images, retakes are mostly optional to assure diagnostic ability. Yet, the use of a light box with brighter light than the standard light boxes commonly used in general dental clinics can sometimes make the structures in the maxilla visible when the tongue is misplaced. It should be noted that even though there is always the opportunity to make adjustments on digital images, not all digital panoramic systems can produce images where a disturbing air space over the upper teeth can be adjusted enough.

Another quite common error demonstrated in this study was that the head of the patient was rotated, mostly to the left side. The patients were probably positioned straight by the operator, but as the machine started to move and sound—the cassette or sensor is always moving from the left side in front of the patient—the patients may have rotated the head slightly to the left side to see what was happening.

The results of the present study suggest the necessity of further education and /or refresher training. Studies (2, 4) have shown that panoramic radiographs taken at a department of oral radiology where there probably are fewer and therefore more trained operators have less error than images taken at general dental clinics.

The paediatric program with reduced exposure time and reduced exposed area was used in 37% of the images taken of children up to 11 years of age. The 2011 study by *Granlund et al* (10) showed that pathological findings outside the dental arches are low in children and adolescents. Therefore, to reduce the exposure area and the radiation dose, paediatric programs may be preferable for young patients when no clinical symptoms of joint disorders or other areas outside the dental arches are present.

Radiographs of children and adolescents (0-19 years of age) were significantly better than the radiographs of adult patients (>20 years of age). It is possibly easier to position young patients in the panoramic machine because they are more relaxed and not as rigid as some adults may be. With very young children there may be problems in positioning. The biggest problem with very young children, however, is getting the child to stand still during the whole exposure. But as 96% of the panoramic radiographs of children and adolescents were of patients between 8 and 19 years of age the abovementioned problem certainly was quite small.

All images in this study have been evaluated by one experienced observer. However, this survey analysed relatively many radiographs, with images of both children and adults. A variety of observers would be optimal, but this may give misleading results if any single observer has a clearly different assessment. The *Granlund et al* study (10) showed a higher intra-observer agreement (91–92 per cent) than inter-observer agreement (84–93 per cent). In a study of inter- and intra-observer variability, *Gröndahl et al* (11) also found that the variability within one observer's assessments was lower than the variability between the assessments of several observers. It may be assumed that double recordings of the errors in this study would not mean a major change in outcome.

Conclusions

- Panoramic radiographs taken in general dental clinics in a Swedish county show several errors.
- The results are comparable to those in previous reports.
- Some errors could be adjusted with the digital technique used. This allowed the images to be assessed, which reduced radiation dose by avoiding retakes.

Acknowledgements

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References

1. Akarslan ZZ, Erten H, Gungor K and Celik I. Common errors on panoramic radiographs taken in a dental school. J Contemp Dent Pract 2003;4:24-34
2. Akesson L, Hakansson J, Rohlin M and Zoger B. An evaluation of image quality for the assessment of the marginal bone level in panoramic radiography. A comparison of radiographs from different dental clinics. Swed Dent J 1993;17:9-21

3. Altman DG. Practical statistics för medical research. London:Chapman & Hall, 1999
4. Bissoon AK, Whaites E, Moze K and Naidu R. Evaluation of common operator errors in panoramic radiography in Trinidad and Tobago: a comparison of formally vs informally trained operators. West Indian Med J 2012;61:733-8
5. Brezden NA and Brooks SL. Evaluation of panoramic dental radiographs taken in private practice. Oral Surg Oral Med Oral Pathol 1987;63:617-21
6. Choi BR, Choi DH, Huh KH, Yi WJ, Heo MS, Choi SC, Bae KH and Lee SS. Clinical image quality evaluation for panoramic radiography in Korean dental clinics. Imaging Sci Dent 2012;42:183-90
7. European Commission Radiation Protection 136. European guidelines on radiation protection in dental radiology. Manchester, UK, 2004
8. Dhillon M, Raju SM, Verma S, Tomar D, Mohan RS, Lakhanpal M and Krishnamoorthy B. Positioning errors and quality assessment in panoramic radiography. Imaging Sci Dent 2012;42:207-12
9. Glass BJ, Seals RR, Jr. and Williams EO. Common errors in panoramic radiography of edentulous patients. J Prosthodont 1994;3:68-73
10. Granlund CM, Lith A, Molander B, Grondahl K, Hansen K and Ekestubbe A. Frequency of errors and pathology in panoramic images of young orthodontic patients. Eur J Orthod 2012;34:452-7
11. Grondahl K, Sunden S and Grondahl HG. Inter- and intraobserver variability in radiographic bone level assessment at Branemark fixtures. Clin Oral Implants Res 1998;9:243-50
12. Hayakawa Y, Kobayashi N, Kuroyanagi K and Nishizawa K. Paediatric absorbed doses from rotational panoramic radiography. Dentomaxillofac Radiol 2001;30:285-92
13. Kaviani F, Johari M and Esmaeili F. Evaluation of common errors of panoramic radiographs in tabriz faculty of dentistry. J Dent Res Dent Clin Dent Prospects 2008;2:99-101
14. Kullman L and Joseph B. Quality of digital panoramic radiography in a newly established dental school. Swed Dent J 2006;30:165-70
15. Langland OE. Panoramic radiology. Philadelphia:Lea & Febiger, 1989
16. Metsala E, Henner A and Ekholm M. Quality assurance in digital dental imaging: a systematic review. Acta Odontol Scand 2013;
17. Molander B. Panoramic radiography in dental diagnostics. Swed Dent J Suppl 1996;119:1-26
18. Murray D and Whyte A. Dental panoramic tomography: what the general radiologist needs to know. Clin Radiol 2002;57:1-7
19. Peretz B, Gotler M and Kaffe I. Common errors in digital panoramic radiographs of patients with mixed dentition and patients with permanent dentition. Int J Dent 2012;2012:584138
20. Rushton VE, Horner K and Worthington HV. The quality of panoramic radiographs in a sample of general dental practices. Br Dent J 1999;186:630-3
21. White SC and Pharoah MJ. Oral radiology : principles and interpretation. St. Louis, Missouri, USA:Mosby, 1999

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A long-term controlled follow-up study of objective treatment need on young adults treated with functional appliances

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Abstract

◉ The aims of this study were to 1) evaluate the objective success rate of Class II malocclusion treatment with functional appliances five years after completion of treatment and 2) to compare the remaining objective treatment need with an untreated control group.

Records of all listed patients between 18-20 years (n=1054) treated in a general practice were reviewed for the purpose of finding treatments with removable functional appliances. Among all subjects (n=61) who previously had been treated, 58 accepted to participate in the study. The test group was matched with an orthodontically untreated group with no history of objective treatment need. Clinical examination was performed and study casts and photos were taken from both groups. The objective treatment need was evaluated through clinical examination and study cast analysis with weighted Peer Assessment Rating index (wPAR).

Twenty patients, (34.5 %) (mean wPAR 13.8), succeeded with the functional appliance treatment. The wPAR score (mean 15.0) of the entire test group was significantly higher than the one of the control group (mean 7.3). The group that was treated exclusively with functional appliances had a mean wPAR score of 17.4. Eighteen patients (31.0 %) who received retreatment with fixed appliances had a slightly higher mean wPAR (8.6) than the control group.

Treatments with functional appliances in a general practice showed a high failure rate and a remaining treatment need. It is the treating dentist's responsibility to motivate the patient to cooperate to the treatment, because as it previously has been shown the treatment with functional appliances is a well-functioning treatment alternative with the cooperation of the patient being sufficient. It is also of importance, already before starting treatment, to estimate the child's cooperation ability and to avoid treatment with removable appliances if the child or parents are reluctant about such a treatment.

Key words

Class II treatment, activator, success rate, objective treatment need

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En långtidsuppföljning av objektivt behandlingsbehov hos unga vuxna tidigare behandlade med aktivator

VAROOJAN FAXÉN SEPANIAN, LISELOTTE PAULSSON-BJÖRNSSON, HEIDRUN KJELLBERG

Sammanfattning

◎ Syftet med denna studie var att utvärdera lyckandefrekvensen fem år efter avslutad behandling av postnormala bett med aktivator, samt att jämföra återstående objektivt behandlingsbehov hos denna grupp med en obehandlad kontrollgrupp utan något tidigare objektivt ortodontiskt behandlingsbehov.

Alla journaler på patienter mellan 18-20 år (1054 st) listade på en folktandvårdsklinik i Eslöv, 2010-2011, granskades i syfte att finna tidigare utförda aktivatorbehandlingar. 61 patienter hade behandlats med aktivator och av dessa accepterade 58 individer att delta i studien. Testgruppen matchades med en obehandlad kontrollgrupp utan något tidigare objektivt ortodontiskt behandlingsbehov. Klinisk undersökning utfördes och studiemodeller och kliniska foton togs på individerna i båda grupperna. Det objektiva behandlingsbehovet utvärderades genom klinisk undersökning samt modellanalys med weighted Peer Assessment Rating Index (wPAR).

Hos 34,5 procent av patienterna bedömdes aktivatorbehandlingen som lyckad utan vidare behandling med fastsittande apparatur (medelvärde wPAR = 13,8). Hela testgruppens wPAR-värde (medelvärde 15,0) var signifikant högre än kontrollgruppens (medelvärde 7,3). Den grupp som enbart hade behandlats med aktivator hade de högsta wPAR-värdena (medelvärde 17,4). 31 procent av patienterna fick rebehandlas med fastsittande apparatur (medelvärde wPAR = 8,6 efter behandling med fastsittande apparatur).

Behandling med aktivator vid en allmän folktandvårdsklinik uppvisade en hög misslyckandefrekvens och ett högt återstående objektivt behandlingsbehov. Det är den behandlande tandläkarens ansvar att motivera patienten till att kooperera vid behandlingen. Det är också av betydelse, redan innan behandlingen påbörjas, att uppskatta barnets samarbetsförmåga, samt att undvika behandling med avtagbara apparaturer om barnet eller föräldrarna är tveksamma till en sådan behandling.

Introduction

While short-term effects of Class II treatment are widely published, research on the long-term effects after a minimum of five years is more limited. To our knowledge, most long-term investigations that have evaluated Class II treatments with removable functional appliances are performed in combination with fixed appliances (5, 6, 7, 17).

Treatment with functional appliances displays varying results from low (13, 29) to high (18, 22) failure rates and it is well documented that the patient compliance is the most important single factor for treatment success (1, 2,4, 13, 18). The benefit of an initial treatment with a removable functional appliance in a two-step treatment is also questioned (15, 19, 25, 27). It was speculated that the time for the fixed appliance treatment would decrease by an initial treatment with a removable appliance. In fact it has been confirmed that both the total treatment cost and work time become longer with a two-step treatment method (10, 27). An early treatment with a removable functional appliance before the pubertal growth spurt might also increase the risk for relapse, and therefore it is recommended that the treatment involves the growth spurt period in order to give a more stable result (5). However, an early treatment of Class II malocclusion has been recommended to avoid injuries to the upper permanent incisors in patients with large overjets and/or incompetent lip closure (3, 8) and it possibly reduces or eliminates the need for a treatment with fixed appliances (9, 28). Furthermore, it has been shown that an early treatment of a child with a large overjet results in increased scores in self-concept and a reduction of negative social experiences after treatment (14). Therefore treatment with removable functional appliances is widely used both in general and specialist clinics in spite of the risk for a prolonged or two-phase treatment.

The aims of this study were to 1) evaluate the long-term objective success rate of Class II malocclusion treatment in young adults who were earlier treated with removable functional appliances in the mixed dentition by general dentists and 2) to evaluate the remaining objective treatment need of the patients treated with functional appliances compared with an orthodontically untreated control group.

The hypothesis was that the patients who have had a successful treatment with functional appliances would have the same remaining objective treatment need as the orthodonticially untreated patients.

Material and methods

Subjects - Test group

A power analysis based on a level of five percent significance indicated that 21 treated patients and 21 control patients were needed to find a difference of five units in wPAR with 80 percent power. The calculation took into account a drop out of 10 percent (12). Therefore in 2010-2011, all listed patients between 18-20 years at the Public General Dental Clinic of Eslöv, Sweden, were screened for previous treatments with functional appliances. The total number of listed patients found was 1054 (495 women and 559 men). Out of those patients, 61, (26 women and 35 men) (~ 6 percent) had been treated with functional appliances in the mixed dentition during the years 2000-2006. The selection criteria for the treatment had been an increased overjet greater than 6 mm and/or an incompetent lip closure, according to an index for evaluating objective treatment need in southern Sweden ("Skåne Index" – subgroups "2c" and "2d") (30). The treatments were performed by general dentists after a consultation with a responsible orthodontist who decided the chosen treatments. The mean length of treatment with the functional appliances was 1.5 year (range 0.1 – 4.3). If necessary, the orthodontist was re-consulted during the treatment. The treatments were free of charge. In connection with their annual dental examination, 4-9 years after the end of their treatment, these subjects were asked if they were interested to participate in the study. Prior to the appointment, the subjects received written information about the study by mail.

Out of the 61 subjects, 58 constituted the test group (Figure 1). Three subjects were excluded: one failed to attend, one did not want to participate without giving any reason and one was excluded due to residential relocation. The test group had been treated with either van Beek appliances or Andresen appliances (Figure 2). The mean age at treatment start was 10.8 (range 8.1 – 13.0). The mean age at the follow-up examination was: 19.0 (range 18.8-19.3). The mean follow-up time after treatment end was 6.8 years (range 4.3 - 9.9). The subjects who were retreated with fixed appliances had the shortest time between completion of treatment and the follow-up visit.

Subjects - Control Group

The treated patient group was matched for age and gender with an orthodontically untreated control group from the same clinic that had no objective treatment need according to ("Skåne Index") (30).

Figure 1. Subjects comprising the study.

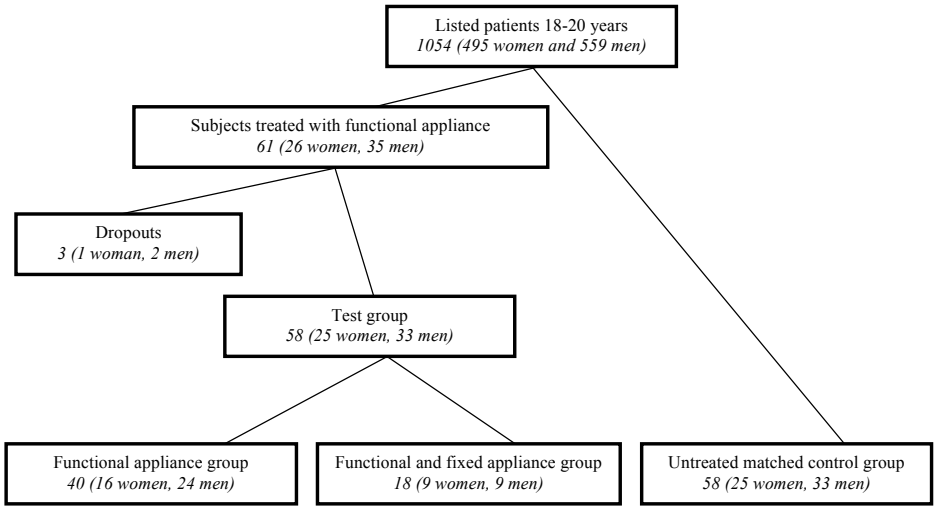

Figure 2. Photo showing the van Beek appliance to the left and the Andresen appliance to the right

The control group consisted of 58 consecutively approached subjects (25 women and 33 men) with a mean age of 19.0 years (range 18.0-20.7). Different types of minor malocclusion could occur in the control group.

Methods

The type of treatment, treatment time, patient cooperation, completion of treatment/premature finish, clinical registrations by the operator and possible treatment with fixed appliances were retrieved from

the dental records of the test group. Lack of patient cooperation was registered if this was stated in the patient records, or if the treatment with functional appliances was interrupted due to lack of cooperation.

Examination of the patients of both groups comprised: clinical inspection, intra- and extra-oral photos and impressions for study casts. The clinical inspection evaluated:

- Lip closure
- Possible gingival impingement
- Anterior or posterior forced bite

The lip closure was measured clinically by one examiner and the observed findings of the lip closure were crosschecked with the extra-oral "en face" and profile photos of all of the subjects. Weighted Peer Assessment Rating index (wPAR) (20, 21) was measured on study casts. Three patients refused to take impressions. In those cases wPAR was measured intraorally.

In the treated group, the treatment with functional appliances was defined as successful if:

A. The treatment was not interrupted prematurely because of lack of cooperation or lack of improvement.
B. The patient had no need for retreatment with fixed appliances.
C. At least three of the following criteria were met during the examination;

- Class I molar relationship ± ½ cusp
- Overjet less than 5 mm or reduced by at least 50 percent since the start of treatment
- No gingival impingement
- Competent lip closure

The Ethics Committee of the University of Lund, Sweden with registration number 2010/421 approved the study.

Statistical Methods

SPSS software version 20 was used for the statistical calculations. For calculating the success rate, Chi2 was used. For numerical data, means and confidence interval were calculated and analysis of variance (ANOVA) with Tukey's post hoc test was used to compare the findings between the groups.

Error of Methods

All the clinical examinations and wPAR calculations were carried out by the same examiner (VFS). An inter-individual difference between two examiners (VFS, HK) was calculated with double determinations on 25 subjects. Eleven subjects had a difference of one unit for the wPAR and two patients had a difference of two units. None of the measurement points had a larger difference than one unit. The same procedure was carried out intra-individually for (VFS) on 25 subjects with at least one month of interval between the calculations. Six patients had a difference of one unit for the wPAR. None of the measurement points had a larger difference than one unit.

Results

Successful treatment with functional appliances, as defined above, was found in 20 cases (34 percent) (Table 1). Half of the male patients and two out of three female patients completed the treatment with functional appliances (Table 2). Eighteen patients (8 women, 10 men) were retreated with fixed appliances due to the following reasons: Interruption of treatment with functional appliances due to lack of cooperation and/or lack of improvement (11 patients), relapse (six patients), and additional treatment due to crowding after successful treatment with functional appliance (one patient). Another eight patients were eligible for retreatment with fixed appliances, but they declined further treatment for different reasons. Twelve patients did not qualify for additional treatment/retreatment with fixed appliances free of charge. Fifteen subjects treated with functional and fixed appliances had retainers during the examination.

Table 1. The success rate of the test group

	Succesful treatment		
	Yes	No	Total
Women	7	16	23
Men	13	22	35
Total	20	38	58
Percentage	34 %	66 %	

Table 2. The number of patients that completed treatment with functional appliance

	Completed treatment with functional appliance		
	Yes	No	Total
Women	15	8	23
	65%	35%	
Men	18	17	35
	51%	49%	
Total	33	25	58
	57%	43%	

Table 3. wPAR measurements.

	N	Mean wPAR	95 % Confidence interval for wPAR mean		P-value
			Lower bound	Upper bound	
A. Entire test group	58	15.0	12.5	17.4	A-B P<0.000
A.1. Functional appliance group	40	17.4	14.6	20.1	A.1-B P<0.000
A.2. Functional & fixed appliance group	18	8.6	4.5	12.7	A.2-B NS
A.1.a. Functional appliance group – *successful cases*	20	13.8	10.6	16.9	A.1.a-B P<0.004
B. Control group	58	7.3	5.8	8.7	

The wPAR of the entire test group was 15.0. Both the total test group in its whole and the subgroup treated exclusively with functional appliances had a statistically significant higher residual objective treatment need according to wPAR than the control group, while no significant difference was found for the adolescents treated with both functional and fixed appliances (Table 3).

At the follow-up examination, significantly more subjects in the group treated exclusively with functional appliances (15 out of 40) had incomplete lip closure compared with the group additionally treated with fixed appliances (two subjects) ($p<0.000$) and the control group (two subjects) ($p<0.000$). Gingival impingement was seen in three patients in the group treated with functional appliances only, two in the control group and none in the group retreated with fixed appliances. Three patients in the functional appliance group showed dual bite.

Discussion

This study has shown that the failure rate of treatment with functional appliances performed by general dentists in a public dental clinic was high in a long-time perspective. The remaining objective treatment need according to wPAR was significantly higher in the group treated with functional appliances only, while the wPAR for the group treated with both functional and fixed appliances was equal to that of the control group.

The failure rate in the present study was based on the necessity of retreatment with fixed appliances either due to bad cooperation or relapse. All patients who were retreated with fixed appliances were classified as failed since the goal of the treatments was to achieve the desired results with functional appliances only. Exception was made for one case in which a two-step treatment was planned from the beginning. Fifteen subjects who were retreated with fixed appliances had retainers at the examination, a fact that contributed to keep the wPAR of the group at a low level.

Earlier follow-up studies on patients treated either with functional appliances only or in combination with fixed appliances show good long-term stability, and that the treatment improved the malocclusions significantly. However, many of these studies are performed on selected cases, excluding for example unsuccessfully treated cases or cases that interrupted the treatment (7, 11, 26). In the present study, all patients were included, no matter whether the patients had completed their treatments with removable functional appliances or not, or whether they were additionally treated/retreated with fixed appliances. In addition, there was a low percentage of patient drop-out from the study (4.9 percent). Counting all patients has given a less beneficial view of the functional appliance effect, but the results gave probably a more correct picture of the outcome of the treatment. The long-term follow-up also made it possible to study the stability after completion of growth.

As stated in earlier studies (1, 2, 4, 13, 18), the patient cooperation is the most important factor for successful treatment, and it is mainly the dentist's responsibility to motivate the patient to wear the appliance. Therefore registrations during treatment showing improvement or lack of improvement should be discussed with the patient, thereby involving them in the progress of the treatment. In the present study many cases lack registration of clinical findings at treatment start, during treatment and at treatment end. As an example only 49 out of the 58 patients had their overjet registered at the start of the treatment. At the end of the treatment, overjet was registered in even less patients (27 subjects) and registrations of overbite and molar relations anytime

during treatment were found in only three and seven patients respectively. Further, pretreatment study casts were available only for a few patients.

Another explanation to the low success rate of the orthodontic treatment could be that 21 different dentists with different levels of experience treated the patients. A further disadvantage was that the renewal rate of dentists in the clinic was quite high, resulting in the fact that 27 patients changed dentists during the treatment. This fact has probably influenced the continuity of the treatment.

Previous studies present a wide range, between 10.5 and 48.4 percent, of interruption of treatment with functional appliances (4, 13, 22, 25, 29). They also show that the treatment with removable functional appliance per se is a well-functioning type of treatment with the patient cooperation being sufficient. *O'Brien et al.*, (13) and *Wheeler et al.*, (29) showed a low percentage of interruption (16.0 and 10.5 percent), while *Rizell et al.*, (22) found that 48.4 percent of the patients ended their treatment with functional appliances prematurely. The present study showed a similar interruption rate (42.4 percent) as *Rizell et al.*, as well as the same number of patients were retreated with fixed appliances. The large variation of success rate might end on several factors, some of them mentioned above. The present study and *Rizell et al.*, evaluated results of treatment with functional appliances performed by general dentists, while in the studies presented by *O'Brien et al.*, and *Wheeler et al.*, the patients knew they were participating in a study and were treated under controlled conditions with orthodontists as manager processors. Other factors that may underlie the difference in the results between the studies could be cultural disparities or treatment expenses for the patients' parents: the fact that the treatment is free of charge in Sweden may influence the motivation of the subjects and/or parents.

In the present study six patients (~10 percent) experienced relapse, which is in accordance with other studies after treatment with functional appliances (9, 16). They mention that the end of treatment at low age with unstable cuspal interdigitation and/or persisting lip-tongue dysfunction might be the main reasons for relapse. The subjects of the present study very likely started their treatment with the functional appliances before or during the pubertal growth spurt. The possibility of the end of the treatment occurring before the end of the growth could also be a reason for relapse.

From the results found in the present study and for the improvement of the motivation of the patients during the treatment, it is of importance that the dentist actively involves the patients and parents in the treatment. For example by seeing the patient and parent on an additional visit before that the treatment starts, the dentist should inform carefully about the treatment and get a better perception of the patient's and the parents' motivation. Written information about what to expect from the treatment should also be given to the patients and/or the parents along with the verbal information. (23)

The patient should also be carefully screened before treatment with removable functional appliance regarding oral hygiene, caries activity, failure of attending at the annual dental examinations and the interest and support from parents/guardians (2, 18, 24). If the motivation is questioned regarding these factors it is advisable to postpone the treatment until the motivation arises.

Conclusion

Treatments with functional appliances in a general practice show a high failure rate and a remaining treatment need. It is the treating dentist's responsibility to involve the patients in the treatment and to motivate them to cooperate during the whole treatment. It is also of importance, already before starting treatment, to estimate the child's cooperation ability and to avoid treatment with removable appliances if the child or parents are reluctant about such a treatment.

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References

1. Antonarakis GS, Kiliaridis S. Short-term anteroposterior treatment effects of functional appliances and extraoral traction on class II malocclusion. A meta-analysis. Angle Orthod. 2007; 77(5):907-14.
2. Brattström V, Ingelsson M, Aberg E. Treatment cooperation in orthodontic patients. Br J Orthod. 1991 Feb; 18(1):37-42.
3. Burden DJ. An investigation of the association between overjet size, lip coverage, and traumatic injury to maxillary incisors. Eur J Orthod. 1995 Dec; 17(6):513-7.
4. Casutt C, Pancherz H, Gawora M, Ruf S. Success rate and efficiency of activator treatment. Eur J Orthod 2007; 29: 614-21.
5. Faltin KJ, Faltin RM, Baccetti T, Franchi L, Ghiozzi B,

McNamara JA Jr. Longterm effectiveness and treatment timing for Bionator therapy. Angle Orthod 2003; 73:221-30.
6. Franchi L, Pavoni C, Faltin K Jr, McNamara JA Jr, Cozza P. Long-term skeletal and dental effects and treatment timing for functional appliances in Class II malocclusion. Angle Orthod 2012; [Epub ahead of print]
7. Janson G, Caffer Dde C, Henriques JF, de Freitas MR, Neves LS. Stability of Class II, division 1 treatment with the headgear-activator combination followed by the edgewise appliance. Angle Orthod. 2004 Oct; 74(5):594-604.
8. Järvinen S. Incisal overjet and traumatic injuries to upper permanent incisors. A retrospective study. Acta Odontol Scand. 1978; 36(6):359-62.
9. Kerosuo H, Väkiparta M, Nyström M, Heikinheimo K. The seven-year outcome of an early orthodontic treatment strategy. J Dent Res. 2008 Jun;87(6):584-8.
10. Laag B, Ström C. Comparisons of similar patients treated by general dental clinicians and orthodontic specialists. Outcome and economical considerations. Swed Dent J. 2009;33(2):67-73.
11. Lerstøl M, Torget O, Vandevska-Radunovic V. Long-term stability of dentoalveolar and skeletal changes after activator-headgear treatment. Eur J Orthod. 2010 Feb; 32(1):28-35. Epub 2009 May 28.
12. Newcombe RG. Statistical applications in orthodontics. Part III. How large a study is needed?J Orthod. 2001 Jun; 28(2):169-72.
13. O'Brien K, Wright J, Conboy F, Sanjie Y, Mandall N, Chadwick S, Connolly I, Cook P, Birnie D, Hammond M, Harradine N, Lewis D, McDade C, Mitchell L, Murray A, O'Neill J, Read M, Robinson S, Roberts-Harry D, Sandler J, Shaw I. Effectiveness of early orthodontic treatment with the Twin-block appliance: a multicenter, randomized, controlled trial. Part 1: Dental and skeletal effects. Am J Orthod Dentofacial Orthop. 2003 Sep; 124(3):234-43; quiz 339.
14. O'Brien K, Wright J, Conboy F, Chadwick S, Connolly I, Cook P, Birnie D, Hammond M, Harradine N, Lewis D, McDade C, Mitchell L, Murray A, O'Neill J, Read M, Robinson S, Roberts-Harry D, Sandler J, Shaw I, Berk NW. Effectiveness of early orthodontic treatment with the Twin-block appliance: a multicenter, randomized, controlled trial. Part 2: sychosocial effects. Am J Orthod Dentofacial Orthop. 2003 Nov; 124(5):488-94; discussion 494-5.
15. O'Brien K, Wright J, Conboy F, Appelbe P, Davies L, Connolly I, Mitchell L, Littlewood S, Mandall N, Lewis D, Sandler J, Hammond M, Chadwick S, O'Neill J, McDade C, Oskouei M, Thiruvenkatachari B, Read M, Robinson S, Birnie D, Murray A, Shaw I, Harradine N, Worthington H. Early treatment for Class II Division 1 malocclusion with the Twin-block appliance: a multi-center, randomized, controlled trial. Am J Orthod Dentofacial Orthop. 2009 May; 135(5):573-9.
16. Pancherz H. The nature of Class II relapse after Herbst appliance treatment: A cephalometric long-term investigation. Am J Orthod Dentofacial Orthop. 1991; 72: 499-512
17. Perillo L, Castaldo MI, Cannavale R, Longobardi A, Grassia V, Rullo R, Chiodini P. Evaluation of long-term effects in patients treated with Fränkel-2 appliance. Eur J Paediatr Dent. 2011 Dec; 12(4):261-6.
18. Permert L, Lilja-Karlander E, Wilhelm E. Treatment of malocclusions in children and adolescents at a public dental service clinic in Sweden: extent and cost. Swed Dent J 1998; 22: 187-93.
19. Profitt WR, Tulloch JF. Preadolescent class II problems; treat now or wait? Am J Orthod Dentofacial Orthop. 2002; 121(6):560-2.
20. Richmond S, Shaw WC, O'Brien KD, Buchanan IB, Jones R, Stephens CD, Roberts CT, Andrews M. The development of the PAR Index (Peer Assessment Rating): reliability and validity. Eur J Orthod. 1992 Apr; 14(2):125-39.
21. Richmond S, Shaw WC, Roberts CT, Andrews M. The PAR Index (Peer Assessment Rating): methods to determine outcome of orthodontic treatment in terms of improvement and standards. Eur J Orthod. 1992 Jun; 14(3):180-7.
22. Rizell S, Svensson B, Tengström C, Kjellberg H. Functional appliance treatment outcome and need for additional orthodontic treatment with fixed appliance. Swed Dent J. 2006; 30(2):61-8.
23. Stewart FN, Kerr WJ, Taylor PJ. Appliance wear: the patient's point of view. Eur J Orthod. 1997 Aug; 19(4):377-82.
24. Trulsson U, Linläv L, Mohlin B, Strandmark M. Age dependence of compliance with orthodontic treatment in children with large overjet. An interview study. Swed Dent J. 2004; 28(2):101-9.
25. Tulloch JF, Proffit WR, Phillips C. Outcomes in a 2-phase randomized clinical trial of early Class II treatment. Am J Orthod Dentofacial Orthop. 2004 Jun; 125(6):657-67.
26. Türkkahraman H, Sayın M. Effects of activator and activator headgear treatment: comparison with untreated class II subjects. Eur J Orthod 2006; 28: 27-34.
27. von Bremen J, Pancherz H. Efficiency of early and late Class II Division 1 treatment. Am J Orthod Dentofacial Orthop. 2002 Jan; 121(1):31-7.
28. Väkiparta MK, Kerosuo HM, Nyström ME, Heikinheimo KA. Orthodontic treatment need from eight to 12 years of age in an early treatment oriented public health care system: a prospective study. Angle Orthod. 2005 May;75(3):344-9
29. Wheeler TT, McGorray SP, Dolce C, Taylor MG, King GJ. Effectiveness of early treatment of Class II malocclusion. Am J Orthod Dentofacial Orthop. 2002 Jan; 121(1):9-17.
30. www.skane.se/upload/Webbplatser/Tandvard/Dokument/PrioriteringsindexOrtodonti.pdf

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An explorative analysis of the recruitment of patients to a randomised controlled trial in adolescents with dental anxiety

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Abstract

◎ Randomised controlled trials (RCTs) are considered to provide the most reliable evidence on the efficacy of interventions. The aim of this study was to describe the recruitment process of an RCT study set up to evaluate a Cognitive Behavioural Therapy (CBT) intervention programme for adolescent patients with dental anxiety (DA).

The participants were recruited from a consecutive sample of adolescent patients (12 -19 yrs old) referred for DA to a specialised pediatric dentistry clinic. Age, gender, and reason for referral were recorded for the possible eligible patients as part of the drop-out analysis of the recruitment process. Participants were then randomized to the intervention (CBT integrated with dental treatment) or control (adapted dental treatment) condition.

In the recruitment process, 138 possible eligible patients met inclusion criteria, of these 55 were enrolled, 44 declined participation and 39 patients were excluded. The patients enrolled in the RCT did not differ from the non-participants with regard to age, gender or cause of referral. As a result of difficulties in the recruitment process, the study period was extended.

The considerable proportion of non-participants as evident from the recruitment process may pose a threat to the external validity of the clinical trial. From a clinical perspective, the reasons for the lack of motivation to participate in behavioural interventions and the failure to appear warrant further investigation.

Key words

Recruitment, randomised controlled trial, dental anxiety, adolescence, behavioural interventions

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En explorativ analys av rekryteringen av patienter till en randomiserad kontrollerad studie av ungdomar med tandvårdrädsla

Ulla Wide Boman, Anders G Broberg, Larisa Krekmanova, Marie Staberg, Carina Svensson, Agneta Robertson

Sammanfattning

◎ Randomiserade kontrollerade prövningar (randomised controlled trials, RCT), anses vara den mest tillförlitliga forskningsdesignen för studier av behandlingsmetoders effektivitet. Syftet med denna rapport var att beskriva erfarenheterna från rekryteringsprocessen till en RCT för utvärdering av en beteendeintervention (Kognitiv beteendeterapi, KBT) för ungdomar med tandvårdsrädsla.

Deltagarna rekryterades från ett konsekutivt urval av patienter (12-19 år gamla) remitterade till specialistklinik för pedodonti på grund av tandvårdsrädsla/psykologiska behandlingsproblem. Ålder, kön och remissorsak registrerades för bortfallsanalys av rekryteringsprocessen. Deltagarna randomiserades till interventionsgrupp (KBT på kliniken av psykolog, kombinerad med behandling hos tandvårdsteamet) eller kontrollgrupp (behandling hos tandvårdsteamet).

Under rekryteringen identifierades 138 möjliga studiedeltagare, av dessa inkluderades 55 individer, 44 avböjde medverkan och 39 exkluderades. Individerna som inkluderades i RCTn skilde sig inte från de övriga avseende ålder, kön eller remissorsak. På grund av svårigheter i rekryteringsprocessen beslutades att förlänga studieperioden.

Sammantaget medförde rekryteringsprocessen ett betydande bortfall, vilket utgör ett hot mot studiens externa validitet. Från ett kliniskt perspektiv är det angeläget att uppmärksamma den stora andelen möjliga deltagare som uppvisade bristande motivation för behandling, och även de som inte kom till kliniken för bedömning.

Introduction

There is an increased demand in society for evidence-based treatments, and thus for clinical trials evaluating treatments. Randomised controlled trials (RCTs) are considered to provide highly reliable evidence on the efficacy of interventions as the randomised allocation eliminates selection bias and contributes to high internal validity (25). However, examination of the evidence from clinical trials also includes their external validity (generalizability); that is, whether the results are likely to apply to other settings or samples, and, thus, their relevance to clinical and public health practice (25, 33). These issues concern the recruitment process, and it has recently been argued that details of the recruitment process should be provided for the evaluation of the generalizability of a study (10, 33). The recruitment process includes identifying a target population, defining the eligibility criteria, approaching possible eligible participants and obtaining consent from the participants who are then enrolled and make up the study population (10, 33). The purposes of this process are to recruit appropriate participants who are representative of the target population, and a sufficient number of participants to fulfil the sample size demands of the study (10).

Problems in the recruitment process can lead to failure to recruit the required number of participants in time, and also to the discontinuance of trials (10, 15, 16, 23). Failure to recruit individuals of specific populations may also reduce the generalizability of the study (23). In addition, problems with recruitment may lead to economic problems due to a prolonged study time, and have a negative effect on the morale/motivation of the participants and staff (10, 23).

Publications on clinical trials often provide incomplete information about the recruitment process (9, 25). The proportion of non-responders may be underestimated, as consent has occasionally been regarded as an eligibility criterion (9). *Hunninghake et al.* (15) argue that the lack of published information about the recruitment process is of importance in this regard, as potential problems cannot be properly anticipated and dealt with if they are not well known to the field. Common obstacles to accepting participation in clinical trials are: lack of trust in research, absence of previous knowledge of the process of clinical trials, treatment preferences, transportation, and time commitment (23). Socioeconomic factors and factors related to culture/context and research, including the attitudes of the provider of the treatment, are also related to participation (10, 15, 23).

Little is known about the recruitment process in clinical trials in adolescents in the dental field, although difficulties have been reported, as in a study by *Weinstein et al.* where less than 10% of the eligible adolescents were enrolled to a study evaluating interventions to increase dental attendance among individuals with poor oral health (32). Experiences from a campaign to improve dental attendance among adolescents showed that it was not enough to provide more incentives, as these were effective mostly for those who already attended regular dental care (7). Knowledge about these issues is therefore of importance for future recruitment efforts for controlled trials.

This paper reports on experiences from the recruitment process in a clinical trial set up in a genuine clinical environment in pediatric dentistry, evaluating a behavioral intervention for adolescents with dental anxiety (DA), using the RCT design. The prevalence of DA in adolescents is 11-19% (24, 28, 29). Severe DA is classified as a specific phobia (21). DA often manifests itself as dental behaviour management problems (DBMP), which is defined as uncooperative patient behaviour that interferes with or hinders dental treatment. DA is related to the avoidance of dental care and impaired oral health (20). DA/DBMP, in combination with a need for dental treatment, is the main reason for referral to specialised paediatric dentistry clinics in Sweden (19). The standard treatment for patients with DA is behavioural interventions and adapted dental care (8, 26, 27), which can be combined with sedation (14). In the literature as well as in clinical practice regarding children and adolescents, the terms DA and DBMP are often used as synonyms. However, it has been shown that even if the terms are related, they are not completely overlapping (1, 18). The present study was planned and conducted in a natural clinical setting where both terms are common, thus both terms were accepted for patient inclusion. In this paper, the term DA is used.

There is a need to develop and evaluate treatments for DA in adolescents, as DA typically develops during childhood (34), and often persists into adult life. Previous studies of behavioural interventions for DA in paediatric populations have primarily included younger children (3, 13, 30, 31). Also, less promising results have been obtained for adolescents (30). Outside the field of dental treatment, exposure-based Cognitive Behavioural Therapy (CBT) has proven to be an effective treatment mode for ado-

lescents with specific phobias (6). The Department of Paediatric Dentistry in Göteborg, Sweden, has developed a CBT intervention programme for adolescent patients with DA, based on a CBT intervention programme for adults with DA (4). The CBT intervention programme is delivered at the dental clinic by a psychologist with formal training in CBT. The main interventions, described in a treatment manual, are exposure, relaxation, modelling, cognitive restructuring and assertiveness training. The CBT programme is integrated with dental treatment.

The aim of the present study was to describe the recruitment process in an RCT study conducted in a genuine clinical setting, in adolescent patients with DA. More specifically, we intended to investigate the magnitude of non-participation due to exclusion and a decline to participate, and to compare participants and non-participants with regard to gender, age, cause of referral and attendance at the clinic.

Material and methods

Study design

This methodological paper reports on the recruitment process for an RCT set up to evaluate behavioural interventions for adolescents with DA. After enrolment, participants were randomised to an intervention group (CBT integrated with dental treatment) or a control group (treatment as usual, i.e. adapted dental treatment), using a block randomisation method. The primary outcomes of the RCT were level of DA and acceptance of conventional dental treatment, measured after treatment and at follow-up after 9 months. The plan was to recruit 100 participants, calculated on the basis of a power analysis ($\alpha = 0.05$, power ≥ 0.80).

Participants

The participants were recruited from a consecutive sample of adolescent patients referred to a paediatric dentistry clinic in Göteborg, Sweden. Inclusion criteria: patients aged 12-19 years referred for DA, and referrals for DBMP were also included, as these terms are often used synonymously by referring dentists. Exclusion criteria: cognitive impairment, neuropsychiatric disorder, psychiatric disorder resulting in hospitalisation and/or severe functional impairment, severe psychosocial problems (in custody, under investigation by social services, substance abuse), or insufficient knowledge of the Swedish language. The RCT was approved by the Regional Ethical Review Board of Gothenburg (370-05). Informed consent was obtained from participants and parents.

Procedure/Recruitment process

First screening: The head of the clinic (AR) performed a first screening of all referrals to the clinic to assess eligibility according to the inclusion criteria described above.

Second screening: The possible eligible patients were called to the clinic for an appointment with a dental team. The dentist followed a formalised structure for the intake interview with the patient and, if present, accompanying parent/care-taker, including a second screening for eligibility according to the inclusion and exclusion criteria described above. Four dental teams (dentist and dental nurse) with experience of treating paediatric patients with DA took part in the study. The eligible patients were invited to participate in the study. Patients were informed that study participation included randomisation to either: (1) behavioural interventions in the form of CBT provided by a psychologist at the clinic, followed by clinical rehearsals with the dental team; or (2) treatment as usual, that is adapted dental treatment by the dental team. The behavioural intervention was presented as aiming to treat DA by providing new experiences of dental care using a mutual approach where the patient collaborates with the dental team. As incentive for participation participants were promised two cinema-tickets. It was made clear that participation was voluntary. After consent to participate, patients were enrolled to the study. If individuals who declined participation spontaneously gave a reason for declining, this was registered.

Measurements

Age and gender were recorded from the referrals.

Referrals were analysed regarding reason for referral using content analysis and performed jointly by two of the authors (AR and UWB). The following categories were identified: Dental behavioural management problems (e.g., refuses treatment), Dental anxiety, Dental anxiety specified as fear of injections, Other (e.g., problems with dental care due to multiple anxiety problems).

Dental records were analysed with regard to cancellations and failures to appear.

Statistical analyses

Comparisons between participants and non-participants were made using the *t*-test to analyze differences between variables measured on a continuous scale, and the $\chi 2$-test to analyze differences between categorical variables. All analyses were computed

using the SPSS version 17.0 and *p* values lower than 0.05 indicate statistical significance.

Results

Recruitment process

The first screening resulted in 138 referrals fulfilling the eligibility criteria. Ninety-seven (70%) of the patients attended the clinic for a first appointment and seven (5%) came to the clinic after initial cancellations. Thirty-four patients (25%) did not show up for their first appointment; however, twenty-five of them attended the clinic after a maximum of three reminders.

At the appointment at the clinic, the dentist made a second screening assessment of the presence of exclusion criteria. Of the 138 patients, 13 were not assessed for eligibility during the second screening as they did not attend the clinic at all (n = 9), or failed to appear after one initial visit (n = 4), following three reminders. Thus, 125 patients underwent the second screening of eligibility, leading to 26 patients being excluded. Reasons for exclusion were: neuropsychiatric diagnosis (n = 3), cognitive impairment (n = 6), severe psychiatric or psychosocial problems (n = 13), insufficient knowledge of Swedish (n = 4).

The possible eligible patients (n = 99) were informed about and invited to participate in the trial. Forty-four patients declined participation. Of these, twelve patients said they were not motivated for behavioural interventions despite agreeing to suffer from DA, another 13 patients did not agree with the referral dentist that they suffered from DA and therefore were not motivated for treatment, and 19 patients gave no reason for declining participation. Fifty-five patients consented to participation in the trial. Thus, 55 patients were enrolled, and 83 patients were excluded, according to the terminology of the CONSORT guidelines (25). Summary statistics for the recruitment process according to the terminology suggested by *Gross et al.* (9) are presented in Figure 1.

Patients enrolled to the RCT vs. non-participants

The patients enrolled to the RCT did not differ from the non-participants with regard to age, gender or cause of referral (Table 1). The majority of all patients were referred because of unspecified DA and the second most common reason was DA related to injections.

Changes in the recruitment process

The recruitment process was slower than anticipated, and after one year the study protocol was changed so that the time period for recruitment was prolonged from two to three years.

Discussion

This study demonstrates problems in the recruitment of adolescents to an RCT evaluating a CBT intervention programme for DA, resulting in modification in the study plan according to length of study period. The problems encountered may, in part, be specific to the study population (adolescents), the disorder of interest (DA), and to circumstances common to research into psychological interventions (difficulties to accept randomisation, as treatment preference could be of considerable importance for psychological interventions), while others may be relevant to consider for clinical trials in general. A thorough pilot test of the recruitment process before initiating the study could have helped identify hinders, and provided a base for alterations of the study design. Changes in study plan due to difficulties in recruitment of adolescents study participants in the dental field have been described previously (32).

About seventy percent of the target sample (the referral sample), (99 of 138 individuals), met eligi-

Figure 1. Recruitment process ratios, according to Gross et al. (9)

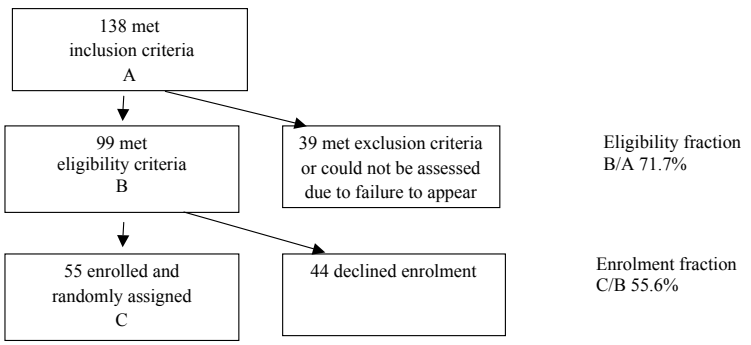

Table 1. Mean, standard deviation or proportions (frequencies or percent) of age, sex and cause of referral, for all referrals, for the enrolled to RCT group and the non-participants group (also divided into the sub-groups failed to appear, excluded after assessment, and declined participation)

	All referrals	Enrolled to RCT	Non-participants	Non-participants sub-groups		
				Failed to appear	Excluded	Declined participation
	N = 138	n = 55	n = 83	n = 13	n = 26	n = 44
Age, yrs, Mean SD	15.4 (1.9)	15.2 (1.8)	15.6 (1.9)	16.1 (2.1)	14.6 (1.8)	16.0 (1.7)
Boys/girls, %	44/56	42/58	45/55	61/39	45/55	39/61
Cause of referral, f						
DBMP	10	4	6	1	4	1
DA	93	36	57	7	15	35
DA injections	29	13	16	5	5	6
Other	6	2	4	0	2	2

Note. DBMP = dental behaviour management problems, DA = dental anxiety, DA injections = DA specified as fear of injections. There were no statistical differences between the group enrolled to the RCT and the non-participants, regarding age, gender or cause of referral

bility criteria, however, only just above half of the eligible individuals, (55 of 99 individuals), accepted enrolment to the study. They represent 40% (55 of 138 individuals) of the target population. The generalizability of the study results to the population of adolescents referred for DA may therefore be questioned. The individuals enrolled to the RCT were similar to the non-participants with regard to age, gender or cause of referral. Although only a few variables could be analysed in this comparison, the results still merit some interest, as this kind of comparison between enrolled patients and non-participants in paediatric populations are sparse. One may speculate that the groups may differ in other variables of importance, as has been reported in other studies, such as socioeconomic factors, motivation or confidence in the health care system (23).

The most common reason to decline enrolment was a lack of motivation for behavioural interventions, some individuals in addition did even not agree with the referring dentist that they had DA. In some cases, the problems could possibly be described in other terms, such as difficulty of communication, as implied in a previous study of dentists and parents of referred paediatric patients (17). Low rate of enrolment has been reported previously, in a study with an intervention addressing dental attendance among adolescents (32). A study in adults, using a qualitative method, found that personal health gain was the major motif for deciding to participate in an RCT; however, other benefits not directly related to health outcome were also identified, such as care in a specialist team with expert staff, active engagement in their own health care, and more frequent or intensive monitoring (22). Less is known about the reasons for the decision of adolescents to participate in clinical trials (32). Considered from a psychological life span development perspective, there may be quite different aspects of relevance to the adolescent population, and more research is needed on the reasons for participating in clinical trials in this age group, and should also include their parents, as parents' behaviour and attitudes are central when recruiting child and adolescent participants (32). Such knowledge could be useful for improving the study design and presentation, in order to increase the willingness among adolescents to participate in RCTs, which is important for the development of Evidence Based Treatments.

Non-attendance was a problem in the recruitment process using a natural clinical setting for approaching the target population, with 25% of the patients not showing up at their first ordinary appointed visit to the clinic, even if most of them attended after several reminders. Non-attendance after referral to special dentistry has been reported in a recent study of a consecutive sample of mainly adult patients (16 to 67 years old) referred to a Sedation and Special Care clinic, where only 72% attended the treatment planning session (5). Parents of children not showing up for dental appointments have reported being overwhelmed with the burdens of everyday life, and feeling unable to organise the dental visits of their child (12). This finding further emphasises the importance of addressing the parent perspective in the recruitment process. The specific disorder of interest here, DA, may also be of relevance to the non-attendance of the target group in this study. The na-

ture of a phobic anxiety disorder makes it difficult to approach the phobic subject/situation, as this is anxiety-provoking. Thus, it may be difficult to reach out to patients with the largest treatment need/most severe DA through an invitation to a dental clinic.

One sixth of the patients in the target group were excluded from participation in the RCT, in most cases due to severe additional psychiatric or psychosocial problems. In the perspective of the RCT methodology, these patients were excluded following the protocol, so this is not a threat to the external validity of the RCT as long as the eligibility criteria are reasonable. As regards the size of the excluded group, this finding confirms, from a clinical perspective, previous reports that many paediatric patients referred for DA/DBMP have severe additional problems (2, 11). These patients are, of course, offered adapted dental treatment with use of sedation, if necessary, but their DA cannot be approached in a structured way, and may remain an obstacle to dental care in the future. Many of these patients may need continued care in specialised paediatric dentistry clinics.

This methodological paper on experiences from recruitment to an RCT to evaluate treatment of DA in adolescents, in a natural clinical setting, found a considerable proportion of non-participants due to declined participation and non-attendance. This lead to changes in the study protocol, and also poses a threat to the external validity of the RCT. Possible strategies that could be used to improve the recruitment process include a pilot study, and a multicenter design, which may enhance the study protocol and the specificity of chosen variables and a more effective recruitment of patients in a shorter timer period. From a clinical perspective, the reasons for the lack of motivation to participate in behavioural interventions, and the failure to appear, warrant further investigation.

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References

1. Arnrup K. Pediatric dentistry meets clinical child psychology. Studying groups of uncooperative child dental patients. Thesis: University of Gothenburg; 2003.
2. Arnrup K, Broberg AG, Berggren U, Bodin L. Lack of cooperation in pediatric dentistry--the role of child personality characteristics. Pediatr Dent. 2002; 24:119-28
3. Arnrup K, Broberg AG, Berggren U, Bodin L. Treatment outcome in subgroups of uncooperative child dental patients: an exploratory study. Int J Paediatr Dent. 2003; 13:304-19.
4. Berggren U, Linde A. Dental fear and avoidance: a comparison of two modes of treatment. J Dent Res. 1984; 63:1223-7.
5. Boyle CA, Newton T, Heaton LJ, Afzali S, Milgrom P. What happens after referral for sedation? Br Dent J. 2010; 208:E22.
6. Connolly SD, Suarez L, Sylvester C. Assessment and treatment of anxiety disorders in children and adolescents. Curr Psychiatry Rep. 2011; 13:99-110.
7. Craven RC, Blinkhorn AS, Schou L. A campaign encouraging dental attendance among adolescents in Scotland: the barriers to behaviour change. Community Dent Health. 1994; 11:131-4.
8. Diercke K, Ollinger I, Bermejo JL, Stucke K, Lux CJ, Brunner M. Dental fear in children and adolescents: a comparison of forms of anxiety management practised by general and paediatric dentists. Int J Paediatric Dent. 2012; 22:60-7.
9. Gross CP, Mallory R, Heiat A, Krumholz HM. Reporting the recruitment process in clinical trials: who are these patients and how did they get there? Ann Intern Med. 2002; 137:10-6.
10. Gul RB, Ali PA. Clinical trials: the challenge of recruitment and retention of participants. J Clin Nurs. 2010; 19:227-33.
11. Gustafsson A, Arnrup K, Broberg AG, Bodin L, Berggren U. Psychosocial concomitants to dental fear and behaviour management problems. Int J Paediatr Dent. 2007; 17:449-59.
12. Hallberg U, Camling E, Zickert I, Robertson A, Berggren U. Dental appointment no-shows: why do some parents fail to take their children to the dentist? Int J Paediatr Dent. 2008; 18:27-34.
13. Holst A, Crossner CG. Management of dental behaviour problems. A 5-year follow-up. Swed Dent J. 1984; 8:243-9.
14. Hosey MT. UK National Clinical Guidelines in Paediatric Dentistry. Managing anxious children: the use of conscious sedation in paediatric dentistry. Int J Paediatr Dent. 2002; 12:359-72.
15. Hunninghake DB, Darby CA, Probstfield JL. Recruitment experience in clinical trials: literature summary and annotated bibliography. Control Clin Trials. 1987; 8:6S-30S.
16. Kasenda B, von Elm EB, You J, Blumle A, Tomonaga Y, Saccilotto R, et al. Learning from Failure - Rationale and Design for a Study about Discontinuation of Randomized Trials (DISCO study). BMC Med Res Methodol. 2012; 12:131.
17. Klaassen MA, Veerkamp JS, Hoogstraten J. Dental fear, communication, and behavioural management problems in children referred for dental problems. Int J Paediatr Dent. 2007; 17:469-77.
18. Klingberg G. Dental fear and behavior management problems in children. A study of measurement, prevalence, concomitant factors, and clinical effects. Swed Dent J. 1995; 103:Suppl 1-78.
19. Klingberg G, Andersson-Wenckert I, Grindefjord M, Lundin SA, Ridell K, Tsilingaridis G, et al. Specialist

paediatric dentistry in Sweden 2008 - a 25-year perspective. Int J Paediatr Dent. 2010; 20:313-21.
20. Klingberg G, Berggren U, Carlsson SG, Noren JG. Child dental fear: cause-related factors and clinical effects. Eur J Oral Sci. 1995; 103:405-12.
21. Klingberg G, Broberg AG. Dental fear/anxiety and dental behaviour management problems in children and adolescents: a review of prevalence and concomitant psychological factors. Int J Paediatr Dent. 2007; 17:391-406.
22. Locock L, Smith L. Personal benefit, or benefiting others? Deciding whether to take part in clinical trials. Clin Trials. 2011; 8:85-93.
23. Lovato LC, Hill K, Hertert S, Hunninghake DB, Probstfield JL. Recruitment for controlled clinical trials: literature summary and annotated bibliography. Control Clin Trials. 1997; 18:328-52.
24. Milgrom P, Mancl L, King B, Weinstein P. Origins of childhood dental fear. Behav Res Ther. 1995; 33:313-9.
25. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2010; 340:c869
26. Porritt J, Marshman Z, Rodd HD. Understanding children's dental anxiety and psychological approaches to its reduction. Int J Paediatr Dent. 2012; 22:397-405.
27. Roberts JF, Curzon ME, Koch G, Martens LC. Review: behaviour management techniques in paediatric dentistry. Eur Arch Paediatr Dent. 2010; 11:166-74.
28. Skaret E, Raadal M, Berg E, Kvale G. Dental anxiety among 18-yr-olds in Norway. Prevalence and related factors. Eur J Oral Sci.1998; 106:835-43.
29. Thomson WM, Poulton RG, Kruger E, Davies S, Brown RH, Silva PA. Changes in self-reported dental anxiety in New Zealand adolescents from ages 15 to 18 years. J Dent Res. 1997; 76:1287-91.
30. Varpio M, Wellfelt B. Some characteristics of children with dental behaviour problems. Five-year follow-up of pedodontic treatment. Swed Dent J. 1991; 15:85-93.
31. Weerheijm KL, Veerkamp JS, Groen HJ, Zwarts LM. Evaluation of the experiences of fearful children at a Special Dental Care Centre. ASDC J Dent Child. 1999; 66:253-7.
32. Weinstein P, Coolidge T, Raff CA, Riedy CA. Recruiting rural dentally-avoidant adolescents into an intervention study. Eur Arch Paediatr Dent. 2009; 10:233-6.
33. Wright JR, Bouma S, Dayes I, Sussman J, Simunovic MR, Levine MN, et al. The importance of reporting patient recruitment details in phase III trials. J Clin Oncol. 2006; 24:843-5.
34. Öst LG. Age of onset in different phobias. J Abnorm Psychol. 1987; 96:223-9.

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