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INDIVIDUAL PREDICTION OF TREATMENT OUTCOME

IN PATIENTS WITH TEMPOROMANDIBULAR DISORDERS

A quality improvement model.

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"Those among us who are unwilling to expose their ideas to the hazard of refutation do not take part in the scientific game."
Karl Popper

"...knowing begins and ends in experience; but does not end in the experience in which it begins."
C.I. Lewis

"*When you can measure what you are speaking about and express it in numbers, you know something bout it, but when you cannot measure it, when you cannot express it in numbers, your knowledge is of meagre and unsatisfactory kind."*
Lord Kelvin

Till Agneta,
Maria och Erik

ABSTRACT

Individual Prediction of Treatment Outcome in Patients with Temporomandibular Disorders. A quality improvement model.

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The general aim of this thesis was to create and evaluate a quality improvement model for prediction of treatment outcome in patients diagnosed with Temporomandibular Disorders (TMD) of either *Muscle* or *Mainly TMJ* (Temporomandibular Joint) origin, treated with interocclusal appliances and/or occlusal adjustment. The model was assumed to generate negative predictors of treatment outcome through evaluating all patients predicted Good reaching an objective treatment goal but not having an improvement of 50% or more. The model was created and evaluated by *one* TMD specialist. The questions were: (I) Was it possible for the TMD specialist to predict treatment outcome individually in patients diagnosed with TMD and, from the results, create a quality improvement model? (II) Was it possible for eight TMD-trained general dental practitioners, under the supervision of the TMD specialist, to treat TMD patients with similar results to the TMD specialist if the TMD specialist had examined, treatment planned, and individually predicted the treatment outcome? (III) Was it possible for the TMD specialist to improve the possibility to predict individual treatment outcome over time? (IV) Was it possible for *one* TMD-trained general dental practitioner to copy the clinical part of the model and achieve the same results as the TMD specialist, in patients selected by the TMD specialist?

Out of 5165 patients subjected to a functional examination of the masticatory system, 3602 were diagnosed with TMD and subgrouped as either *Muscle* or *Mainly TMJ* symptoms. The patients were predicted to have a Good, Dubious, or Poor possibility to have an improvement of 50% or more after treatment. Patients predicted Poor were not offered any treatment. A correct prediction of actual treatment outcome Good was defined as an improvement of 50% or more for muscle and/or TMJ symptoms. A total of 2625 patients began treatment at the specialist clinic for TMD and 2128 completed the full course of treatment. The patients were treated with counseling, interocclusal appliances and/or occlusal adjustment. Treatment outcome was evaluated at an objective treatment goal as improvement in percent using a verbal Numeric Rating Scale ranging from 0 to 100.

The results suggest that (I) individual treatment outcome can be predicted in patients with TMD treated by *one* specialist in TMD and a quality improvement model could be created, (II) eight TMD-trained general dental practitioners could, under the supervision of the TMD specialist, treat TMD patients with similar results to the TMD specialist, (III) the TMD specialist could improve the possibility to predict individual treatment outcome over time, and (IV) the clinical part of the model could be copied by *one* TMD-trained general dental practitioner with similar results to the TMD specialist.

In conclusion, the model works in the hand of *one* TMD specialist and the clinical part for *one* general dental practitioner, but it needs to be evaluated by other clinics/clinicians before it can be claimed to be generalizable. The model has identified new negative predictors for treatment outcome in patients with TMD. These predictors need to be investigated further in well controlled clinical trials. The created model is a PDSA cycle.

Key words: clinical trial, interocclusal appliances, occlusion, occlusal adjustment, prediction, quality improvement, temporomandibular disorders, treatment outcome

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PREFACE

This thesis is based on the following four publications, which will be referred to by their Roman numerals.

I Sundqvist B, Magnusson T. Individual prediction of treatment outcome in patients with temporomandibular disorders. Swed Dent J 2001; 25:1-11.

II Sundqvist B, Magnusson T, Wenneberg B. Comparison between predicted and actual treatment outcome in patients with temporomandibular disorders treated by TMD-trained general dental practitioners. Swed Dent J 2003; 27:131-41.

III Sundqvist B, Wenneberg B, Magnusson T. Validation and improvement of a predictive model for treatment outcome in patients with temporomandibular disorders. Acta Odontol Scand 2007; 65:109-18.

IV Sundqvist B, Wenneberg B, Magnusson T. Comparison of individual prediction of treatment outcome made by a TMD specialist and a TMD-trained general dental practitioner in patients with temporomandibular disorders. Swed Dent J 2007; 31:55-63.

ABBREVIATIONS

CID	Clinical Important Difference
CMD	Cranio Mandibular Disorders
EBM	Evidence Based Medicine
FPD	Fixed partial denture
ICP	Intercuspal position
LTR	Laterotrusion side contacts
MTR	Mediotrusion side interference
NRS	Numeric Rating Scale
PTR	Protrusion interference
RCP	Retruded Contact Position
TMD	Temporomandibular Disorders
TMJ	Temporomandibular Joint

INTRODUCTION

According to the Swedish National Board of Health and Welfare (118), all health care providers in Sweden are obliged to secure quality through a system for planning, performing, follow-up, and development of the performed activity. Quality improvement research is a new type of research, commonly based on the Plan-Do-Study-Act (PDSA) cycle developed by scientists in economics. The PDSA cycle starts with a prediction and continuous implementation of the results into a process (63). Targets for quality improvement research can be management of a group of patients with a certain disease or need for service (120). Core activities in quality improvement research are improvement in outcome (120), test generalizability (119), and collaboration in quality improvement learning (9). The methods of quality improvement reports might be more generalizable than the results (86).

Temporomandibular Disorders (TMD), the diagnosis

TMD is a collective term embracing a number of clinical problems that involve the masticatory musculature, the temporomandibular joints (TMJs), and associated structures, or both. TMD is considered as a sub-classification of musculoskeletal disorders. Common symptoms are pain in the masticatory muscles, the preauricular area, and/or TMJs. Chewing or other jaw functions usually aggravate the pain. Furthermore, patients frequently experience symptoms such as asymmetric mandibular movements and TMJ sounds, described as clicking, popping, grating, or crepitus (95). Pain of neurogenic, psychogenic or visceral origin and periodontal, dental or cutaneous pain should be excluded from the definition (24). TMD is synonymous with craniomandibular disorders (CMD). Diagnostic criteria for TMD are not clear. Criticism has been based on the lack of clearly defined and operationalized inclusion criteria and lack of established sensitivity and specificity (89). So far, no study has been published that has evaluated the diagnostic reliability and validity of muscle and TMJ palpation for both diseased and non-diseased populations. However, traditional clinical measurements of muscle palpation and mandibular range of motion can be achieved with acceptable reliability. It appears that retraining of experienced examiners may improve reliability (136).

Etiology

The discussion about TMD etiology seems endless (1). TMD etiology is today regarded as multifactorial without any proven causal factors. Contributing factors to TMD have been proposed to be classified as predisposing - increases the risk, initiating - causes the onset, and perpetuating - enhances the progression or interferes with healing (95). Predisposing factors are generally subdivided into systemic, psychological (personality, behavior) and structural (all types of occlusal discrepancies, improper dental treatment, joint laxity). Initiating factors are primarily related to micro- and macro-trauma, adverse or excessive loading of joint structures, and parafunctional habits. Perpetuating factors are often divided into local and systemic, which can be responsible for the progression of a relatively simple acute muscle disorder into a more complex chronic pain condition (93). Occlusal factors have been determined as causative in between 10% and 25% of specific diagnoses (102). All the contributing factors thought to be a direct cause to TMD await future research to document their possible etiological significance (95). Using treatment outcome as a proof of an etiological concept may be the logical fallacy "*Post hoc, ergo propter hoc*" (After this, therefore because of this). That is, success in therapy neither proves nor disproves an etiological theory (1). An etiological study with a focus on a biopsychosocial model has recently been published (121).

Epidemiology
TMD is the most common reason for long-term orofacial pain conditions (138). Severe TMD is rare in children prior to puberty (64). There is a female predominance both among adolescents (68) and adults (29). Among patients in TMD clinics there is an even greater female predominance (14, 76). TMD symptoms are common in adult populations (75). The need for active treatment has been estimated to be 7-27% (60, 75, 141), while the actual demand for treatment is smaller and has been estimated to be approximately 3% (79).

Health care
A considerable loss of workdays is estimated to be due to disabling TMD (95). Treatment of TMD can reduce sick leave (58, 130) and the use of medical services (57). Individual prediction of actual treatment outcome in patients suffering from TMD might be of economic interest for patients, society, insurance companies, and care providers.

Treatment and treatment goals
Many long-term studies have presented a favorable outcome of TMD treatment independent of therapy (91). A majority of dental practitioners and TMD experts disagree about how to treat TMD (25, 26), and this is attributed to a clash of culture (104). Opinions between TMD experts also differ from "moving from a dentally based to a medically based model" (42), all TMD patients may potentially be helped with cognitive behavioral therapy (126), and TMD care should be practiced by general dental practitioners (15). TMD can be successfully treated in a long-term perspective, using treatment methods such as interocclusal appliance and occlusal adjustment (128, 131). Methods of carrying out interocclusal appliance therapy and occlusal adjustment has been suggested by Ash and Ramfjord (4). They also suggest that an objective treatment goal is a stable occlusion on the interocclusal appliance and/or in the dentition (4).

Treatment outcome
Pain and dysfunction are subjective experiences, and impossible to measure objectively. Pain and dysfunction measures, no matter how quantitative they appear, reflect the subjective response of the patient (33). The level of a real, clinically important difference (CID) for clinical trials in long-term pain treatment has been discussed. A suggested cut-off point for CID in these conditions is a 30% pain relief (34), and a minimal clinically important change in long-term musculoskeletal pain is a reduction of 15% on a Numerical Rating Scale (NRS) (108). Different types of scales have been recommended for assessing pain in general (54) as well as in patients with TMD (77). A NRS is simple to administer and to score either in written or verbal form. For indexing patients' pain intensity levels at different times, NRS is recommended (53).

Prediction
Hippocrates (400 BC) stated, "an excellent thing for physicians to practice is forecasting" (51). Prognosis is defined as "a forecast as to the probable outcome of an attack of disease, the prospect as to recovery from a disease as indicated by the nature and symptoms of the case" (28). A prognostic statement is an *a priori* statement, but an evaluation of whether the prognosis is good or bad can only be made *a posteriori*, when the actual outcome of the illness or disease is compared to what was predicted (106). Prognostic statements express general prospects of the disease. It is common for physicians to estimate a prognosis as Good, Dubious, Poor, or Bad (106).

Prediction should be separated from Prognosis. The Prognosis includes recovery without treatment. "Prediction of treatment outcome" can be defined as "a clinician's probability of

achieving a successful outcome of treatment" (87), or as a method of clinically identifying moderators or mediators of actual treatment outcome to be tested in well-controlled experiments (80). There is a need for a clearer definition.

Attempts to find predictors of treatment outcome in patients suffering from TMD have been made. The methods of predicting, treating, and evaluating treatment outcome differ widely, which makes it difficult, if not impossible, to use them in clinical dental practice (3, 39, 44, 65, 81, 84, 109, 126). Clinical reports about individual prediction and actual treatment outcome in TMD have so far been lacking.

Quality improvement research

The pioneer of health care quality improvement and Evidence Based Medicine (EBM) was a Boston surgeon E.A. Codman (1869 – 1940) (56), also called "a man ahead of his time and perhaps ours" (82). Codman introduced the "End Result Idea". His intention was to document clinical methods and mistakes in a uniform manner in order to compare results with other hospitals. The results of the reports should be a starting point for a discussion regarding management and efficiency (18). Codman argued that it is not in the individual interest of medical staff to follow up, compare, analyze and standardize results but, on the contrary, there is an interest for the patients, the public, and medical science so "why bother about it?" (19). Quality improvement reports are still rare today, perhaps because of the people who do the work. They are often busy clinicians with heavy competing service responsibilities who do not work in academic environments and are not used to writing reports (23). The first quality improvement report using a special quality report structure (86) was published in the journal *Quality in care* 1999 (21). It is a new kind of report with the purpose of describing improvement projects so that others can learn (117). Quality improvement is somewhere between research and clinical care, strictly neither nor. Two criteria have been proposed when a quality improvement project should be regarded as research and thereby reviewed by an institutional review board in order to protect the patients; 1) "the majority of patients involved are not expected to benefit directly from the knowledge to be gained" or 2) "if additional risk burdens are imposed to make the results generalizable" (16). The first statistical method from the viewpoint of quality control was published by Shewhart (113).

The Plan-Do-Study-Act (PDSA) cycle

"The science of improvement" is defined as "knowledge of general truths or the operation of general laws, especially that obtained and tested through the scientific method" (63). Improvement needs relevant knowledge to the specific problem. Improvement is change, and changes may be predicted. Out of a prediction a plan is made, although no one can foretell the future, and the more knowledge one has about the specific problem, the better the predictions and the better the chance that a change will result in improvement. Comparing the predictions to the results is a key source of iterative learning. Making changes and observing or measuring results is the foundation for the building of the science of improvement. Improvement is a result of action: developing, testing and implementing. The search for perfection can continue endlessly (63). The first report using the PDSA cycle in medicine was published in 1994 (45). In a PDSA study the participants are often the observers. Preventing the participants from being influenced by being a part of their own study requires standardization of the procedures, training of the observers, reliability checks, correspondence of subjective measures with objective measures and, if possible, blindness to the hypothesis (120). This thesis, to our knowledge, comprises the first studies in dentistry using the PDSA cycle.

AIMS

The general aim of this thesis was to create and evaluate a quality improvement model for actual short-term treatment outcome in patients diagnosed with TMD of either *Muscle* or *Mainly TMJ* origin, treated with interocclusal appliances and/or occlusal adjustment. The model was assumed to generate negative predictors of treatment outcome through evaluating all patients predicted Good reaching an objective treatment goal but not having an improvement of 50% or more.

The specific aims were:

- To evaluate whether *one* TMD specialist could individually predict actual treatment outcome in patients diagnosed with TMD if he had examined, predicted, treatment planned, and treated the patients himself, and from the results could be able to create a quality improvement model (Paper I).
- To evaluate if one of eight TMD-trained general dental practitioners, under the supervision of the TMD specialist, could treat patients diagnosed with TMD with similar results to the TMD specialist if the TMD specialist had examined, predicted and treatment planned the patients (Paper II).
- To test whether the model used improved the quality, i.e. the ability to individually predict actual treatment outcome in patients diagnosed with TMD of either *Muscle* or *Mainly TMJ* origin, treated with interocclusal appliances and/or occlusal adjustment, through evaluation of predicted and actual treatment outcomes in patients treated by the TMD specialist during two subsequent time periods (Paper III).
- To evaluate if *one* TMD-trained general dental practitioner could use the clinical part of the quality improvement model with results equal to the TMD specialist, if the specialist had selected the patients. (Paper IV).

MATERIAL

Registration

All the patients included in the studies were referred to the specialist clinic for TMD in the county of Västernorrland in Sweden. The referral, diagnosis, predicted actual treatment outcome, treatment, actual treatment outcome and non-compliance were registered in a database.

Patients

Of all 5777 patients referred to the specialist clinic in Sollefteå/Sundsvall, Västernorrland, Sweden during the period 1992 - 2004, 5165 patients were subjected to a functional examination of the masticatory system. Of these patients, 3602 were diagnosed with TMD and subgrouped as either *Muscle* or *Mainly TMJ* symptoms. The patients were predicted to have a Good, Dubious, or Poor possibility to have an improvement of 50% or more after treatment. Forty-six patients were predicted Poor and offered no treatment and another 595 were treated by general dental practitioners outside of the TMD clinic. Of the patients diagnosed with TMD, 2625 began and 2128 fulfilled treatment at the clinic. During the course of treatment, 495 patients (19%) discontinued the treatment. Reasons for discontinuing treatment included financial reasons, inability to wear the appliance, not coming to scheduled appointments, or moved out of the district. Two patients were excluded as they had received their treatment from a TMD-trained general practitioner complemented with orthodontic treatment performed by a specialist in orthodontics. A flow diagram of the patient material is shown in Figure 1.

Inclusion criteria, Papers I-IV

- Signs and symptoms of TMD
- Individual predicted treatment outcome, Good or Dubious
- Patients expressing a demand for treatment
- Treatment outcome evaluated when a stable occlusion in RCP, measured by double folded 12μ thin plastic foil in clamping tweezer, had been established on the interocclusal appliance and/or in the dentition

Inclusion criteria, Paper I

Examined, predicted, treatment planned, treated, and treatment outcome evaluated by *one* and the same TMD specialist. These patients will henceforth be labeled **Sample I** (n = 989) (Figure 1).

Inclusion criteria, Paper II

Examined, predicted, and treatment planned by *one* and the same TMD specialist and treated by one of eight TMD-trained general dental practitioners under the supervision of the TMD specialist. These patients will henceforth be labeled **Sample II** (n = 206) (Figure 1).

Inclusion criteria, Paper III

Examined, predicted, treatment planned, treated and treatment outcome evaluated by *one* and the same TMD-specialist 1992 – 1998 (Sample I) or 1999 – 2004. The latter patients will henceforth be labeled **Sample III** (n = 769) (Figure 1).

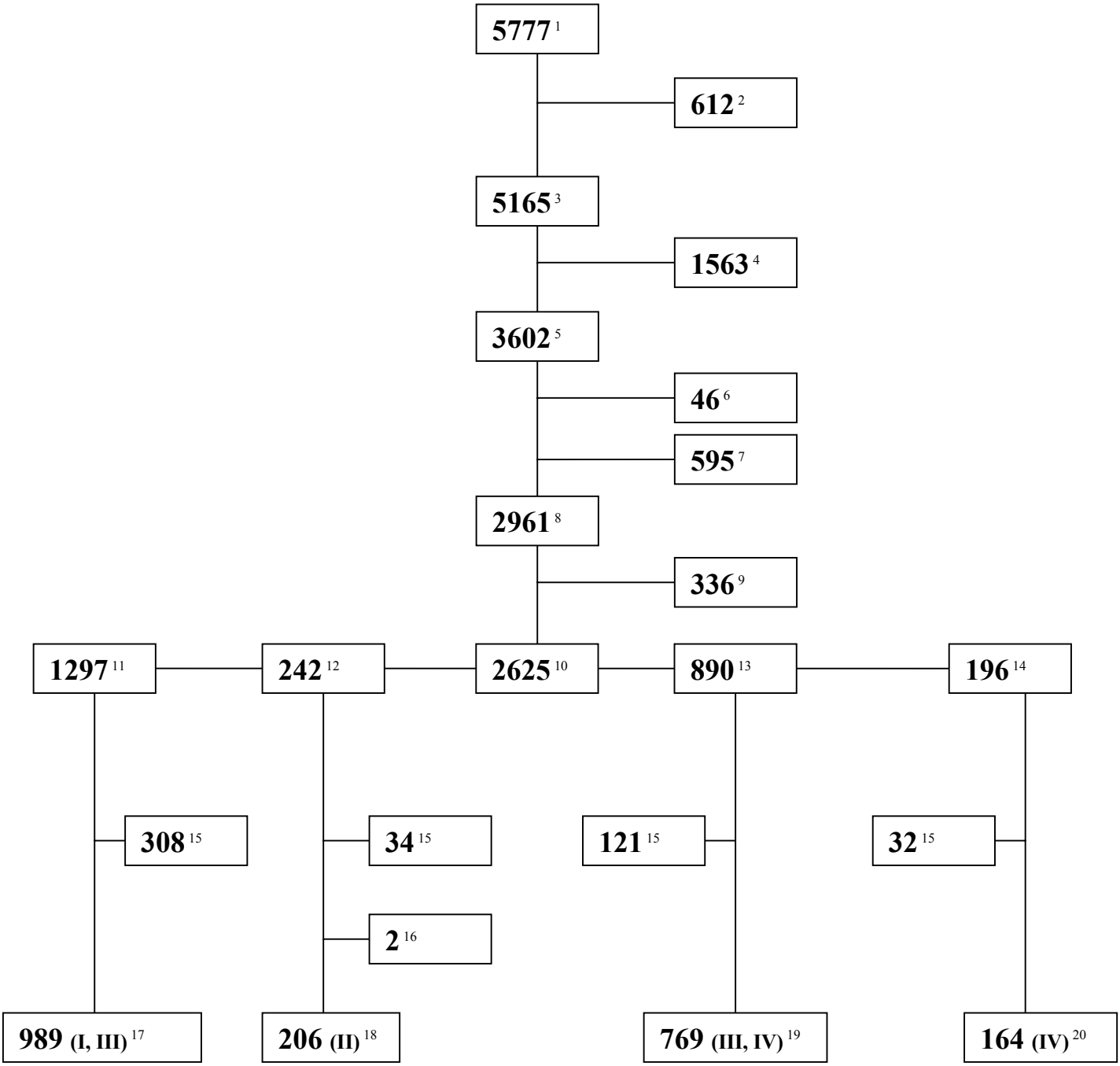

Figure 1. Loss of participants. 1: All referred to the clinic. 2: Rejected examination. 3: Examined. 4: Patients without signs or symptoms of TMD. 5: Patients with signs and symptoms of TMD. 6: Patients with TMJ clicking, not offered treatment because of poor prediction of treatment outcome. 7: Patients treated by general dental practitioners. 8: Patients offered treatment. 9: Patients rejecting suggested treatment. 10: Patients fulfilling inclusion criteria. 11: Patients who were examined, treatment planned, predicted and treated by TMD specialist 1992- 98. 12: Patients who were examined, treatment planned and predicted by TMD specialist, treated by TMD-trained general dental practitioner. 13: Patients who were examined, treatment planned, predicted and treated by TMD specialist 1999-2004. 14: Patients who were examined, treatment planned, predicted and treated by one TMD-trained general dental practitioner 1999 - 2004. 15: Patients who discontinued treatment. 16: Patients who completed appliance treatment by TMD-trained general dental practitioner complemented with orthodontic treatment performed by specialist in orthodontics. 17: Patients who completed treatment performed by specialist in TMD 1992 – 98. 18: Patients who completed treatment performed by TMD-trained general dental practitioner. 19: Patients who completed treatment performed by specialist in TMD 1999 – 2004. 20: Patients who completed treatment performed by one TMD-trained general dental practitioner 1999 - 2004.

Inclusion criteria, Paper IV
Examined, predicted, treatment planned, treated, and treatment outcome evaluated by *one* and the same TMD-specialist (Sample III) or by *one* TMD-trained general dental practitioner 1999 – 2004. The latter patients will henceforth be labeled **Sample IV** (n = 164) (Figure 1).

The distribution into subgroup *Muscle* or *Mainly TMJ* symptoms, age, and sex for Sample I - IV is presented in Table 1.

	Sample I		Sample II		Sample III		Sample IV	
	Muscle n = 630	Mainly TMJ n = 359	Muscle n = 132	Mainly TMJ n = 74	Muscle n = 475	Mainly TMJ n = 294	Muscle n = 77	Mainly TMJ n = 87
Subgroups (percentage distribution)	64	36	64	36	62	38	47	53
Females (percentage distribution)	76	81	78	72	80	83	77	78
Males (percentage distribution)	24	19	22	28	20	17	23	22
Mean age (years)	43	37	43	33	44	39	39	46
Age min-max	5 - 87	10 - 82	8 - 78	10 - 83	5 - 85	10 - 87	12 - 72	15 - 79

Table 1: Distribution of the patients according to Muscle or Mainly TMJ symptoms, gender and age in Sample I - IV.

METHODS

Before treatment
All examinations were performed by *one* and the same TMD-specialist or by *one* TMD-trained general dental practitioner. The examination consisted of a comprehensive patient history, including chief complaint(-s) (location, onset, and characteristic of pain, aggravating and alleviating factors, relationship to other pain complaints), history of the present complaint(-s), past medical and dental history, and psychosocial history (95). The patients were also subjected to a functional examination of the masticatory system as described by Carlsson and Magnusson (15). This examination included registration of TMJ sounds, lateral and posterior palpation of the TMJs at rest and during function, measurements of mandibular movements, and registration of pain during non-guided mandibular movements. The muscles palpated were the origin and insertion of the temporal muscles, the origin and belly of the superficial portion of the masseter muscles, the insertion of the medial pterygoid muscles, the area of the lateral pterygoid muscles, the sternocleidomastoid and trapezius muscles. The type of morphological occlusion was registered as well as number of teeth and presence of fixed and removable dentures. Registration of RCP was made using a one-handed technique (5) with the patient lying down in a dental chair. Unilateral contacts in RCP, lateral slide $\geq$ 0.5 mm between RCP and intercuspal position (ICP), mediotrusion side interference (MTR), laterotrusion side contacts (LTR) posterior to the canines, and posterior contacts preventing bilateral frontal contacts during protrusive movements from ICP (PTR) were registered. When this was not possible to ascertain with the naked eye, double folded 12µ thin plastic foil in clamping tweezer was used (15).

TMD-trained General Dental Practitioners (Paper II)
The eight TMD-trained general dental practitioners had all worked one day every second week during 1 year at the specialist clinic. They treated patients under supervision of the TMD specialist. They were trained to register RCP, check, and, when necessary, adjust the occlusion in the dentition, as well as fit and adjust interocclusal appliance according to the

principles described by Ash and Ramfjord (6). Thus, the general dental practitioners handled the treatment part of the model, i.e. the therapy and evaluation point (Figure 2).

TMD-trained General Dental Practitioner (Paper IV)
The TMD-trained general dental practitioner was one of the eight TMD-trained general dental practitioners participating in Paper II. Since 1998 he had been working at the clinic one day per week. He independently practiced the clinical part of the quality improvement model, i.e. new patient, past history, status, diagnosis, therapy plan, prediction, therapy, and evaluation point (Figure 2).

Treatment
All patients were informed about possible etiological factors, and the benign character of TMD was emphasized. They were also informed about the treatment plan, the treatment costs, and the predicted treatment outcome. All were asked to note if they had any daytime parafunction, instructed to avoid it if present, and try to find a relaxed position for the mandible.

Treatment modalities were sub grouped as follows:
- Only acute, pharmacological, treatment
- Interocclusal appliance, night wear
- Interocclusal appliance, night wear, and selective occlusal adjustment
- Only selective occlusal adjustment
- Onlays, full-time
- New removable complete or partial dentures
- Fixed partial denture (FPD), orthodontics and/or orthognathic surgery

Patients with acute symptoms of muscle origin were prescribed a muscle relaxant (Clorzoxazon), and in those with acute symptoms of *Mainly TMJ* origin, Ibuprofen was prescribed (20). A few patients with acute muscular trismus were treated with intramuscular injections with local anesthetics (Citanest Octapressin ™) (92).

In non-acute patients/phases, adults with an Angle class I or class II:1 occlusion and a fairly complete dentition received an interocclusal appliance of the Michigan type placed in the upper jaw (103). Those with Angle class II:2 or Angle class III malocclusions received full arch mandibular appliances. Those with shortened dental arches received molar supporting appliances seated in the jaw that gained the most occlusal support. In some cases with bimaxillary shortened arches, appliances in both the upper and lower jaw were made. Patients 18 years of age or younger were treated with a soft 3-mm thick mandibular appliance (Biostar™) as described by Wright (139). All patients treated with interocclusal appliances had them checked and, if necessary, readjusted within 4-8 weeks (4, 72). The interocclusal appliance and/or the dentition were readjusted until a stable occlusion in RCP, measured with double folded 12μ plastic foils in clamping tweezer, was established. All patients were recommended to use their interocclusal appliances regularly at night and to store them in water when not in use (12).

Patients with a severe malocclusion, judged not to be able to improve with selective occlusal grinding, received cemented silver onlays (73) on mandibular premolars and molars. Some of these patients had initially been treated with an interocclusal appliance at night. The onlays were readjusted according to the same principles as for the interocclusal appliances.

Selective occlusal adjustment was performed according to the principles described by Ash and Ramfjord (7). It was used as an initial treatment only in patients with unilateral signs and symptoms of TMD and mild or moderate muscle tension where it was judged easy to register RCP and the planned adjustment was minor. In all other cases where selective occlusal adjustments were indicated, they were performed when the interocclusal appliance had resulted in decreased muscle tension. In a few cases, mandibular third molars were extracted in order to eliminate gross MTR.

In some cases, it was not possible to reach the goal for a stable occlusion in the dentition e.g. patients doubtful or negative to occlusal grinding (15). In children and adolescents, grinding was performed restrictively (2).

Patients with faulty removable dentures had their dentures relined if necessary, and the occlusion was stabilized with self-curing acrylic on mandibular premolars and molars (74). When symptoms were alleviated, new removable dentures were made. In cases where removal of silver onlays resulted in a relapse of symptoms within 2 months, permanent occlusal stabilization was performed with FPDs. In single cases, orthodontic treatment with or without orthognathic surgery, sometimes complemented with FPD treatment, was also performed.

Definitions for prediction
The prediction was based on the following:
Past history: A comprehensive past and present history.

Status: A functional examination of the masticatory system and, when indicated, radiological examination.

TMD diagnosis: Since diagnostic criteria for TMD are not clear, we have defined TMD as problems that involve the masticatory musculature, the TMJs and associated structures, or both. Characteristic symptoms were pain in the muscles of mastication, the preauricular area, and/or TMJ. Chewing or other jaw functions usually aggravated the pain. Corresponding objective signs: palpatory tenderness with palpebral reflexes in the masticatory muscles and/or TMJs, and/or limited and/or asymmetric mandibular movement, and/or TMJ sounds.

Treatment and treatment goal: Interocclusal appliance and/or occlusal adjustment with a stable occlusion in RCP on the interocclusal appliance and/or in the dentition were the objective treatment goal.

Treatment outcome: Treatment outcome was evaluated at the objective treatment goal as improvement in percent using a verbal Numeric Rating Scale (NRS) ranging from 0 to 100. A CID was defined as an improvement of 50% or more for the TMD related symptoms in the masticatory system i.e. TMJ clicking, headache, feeling of fatigue in jaws, pain in face and jaws, difficulties in opening the mouth wide, pain on movement of mandible, tongue pain, chewing difficulties, swallowing difficulties, locking or dislocation of mandible, and/or TMJ crepitation (129).The reported treatment outcome was grouped using a 6-graded scale in Papers I and II: Grade 1: Improved 100%, grade 2: improved 75-99%, grade 3: improved 50-74%, grade 4: improved 1-49%, grade 5: no change of initial symptoms and grade 6: impairment of initial symptoms. In Papers III and IV we used a 2-graded scale: Grade 1: improved 50% or more, grade 2: improved 1-49%, no change or impairment of initial symptoms.

The predictions used were *Good, Dubious,* or *Poor* (106). A correct prediction of actual treatment outcome as *Good* was defined as an improvement of 50% or more for symptoms related to the masticatory muscles and/or TMJs (34). The patients were not aware of the cut-off point for judging a treatment outcome as positive. A correct prediction of treatment outcome *Dubious* was defined as an improvement of < 50%. An overall correct prediction was thereby defined as a significant difference between correct and incorrect predictions. The prediction *Poor* was defined as hardly any chance above placebo to have an improvement.

Patients were determined *Good* if TMD symptoms were known to have a good long-term treatment outcome (129) i.e. pain in face and jaws, difficulties in opening the mouth wide, pain on movement of mandible, chewing difficulties, locking or dislocation of mandible, and patients with tension type headache and clinical signs of TMD (38, 70, 110).

Patients that were determined *Dubious* were classified as follows:
Subgroup 1: patients suffering from main symptoms with no significant improvement at a 4 year follow-up (129); feeling of fatigue in jaws or cheek, tinnitus/impaired hearing, dizziness, tongue pain, swallowing difficulties/globus in the throat, extensive wear of teeth, and TMJ crepitation.

Subgroup 2: patients with TMD-symptoms with prediction Good but also a general disease/illness that might affect masticatory muscles and/or TMJs, i.e. ankylosing spondylitis (133), rheumatoid arthritis (123), psoriatic arthritis (61), fibromyalgia (32), and/or whiplash injury (13).

Subgroup 3: patients with clinical and/or radiological signs that might affect treatment outcome i.e. TMD-symptoms but no clinical signs corresponding to the symptoms, patients with gross structural changes in the TMJs due to general diseases or previous fractures making it impossible to reproduce RCP (94).

Subgroup 4:
Identified new negative predictors:
Psychological/psychosocial factors: patient living in a chronic pain family (99), patients with secondary gain of pain (35, 36), psychiatric diagnosis, e.g. schizophrenic patients (132), orofacial symptoms for more than 30 years (31), scuba divers with internal derangement (122) and/or narcotic drug abuse (137).

General illness/disease: gout (10), facial paralysis (49), epileptic spasm in masticatory muscles (115), radiation therapy in jaw, face or head (88), neurological diseases with possible influence in jaws, face or head (90), Systemic Lupus Erythematosus (SLE) (43), mixed connected tissue disease (MCTD) (59) and/or Ehlers-Danlos syndrome (46).

Local factors: complete dentures and crista flaccida, poor seated interocclusal appliance (4), previous trauma in the region of symptom (48, 90), tension-type headache not localized to the temples and/or forehead, tension-type headache described by the patient as emanating from neck, shoulders and/or back of head and localized in the temples and/or forehead.

Other factors: incomplete past history e.g. language problems, patients refusing to answer questions, in patients with internal derangement; sleeping position on the stomach (30) and/or nail biting.

Identified predictors of *Poor* treatment outcome; patients with tinnitus, impaired hearing, and/or dizziness, without any other TMD symptom known to have good long-term treatment outcome (129). These symptoms were initially treated but are no longer considered to be TMD and patients are thus not offered treatment.

Diagnosed with TMD and determined *Poor* were patients with TMJ clicking without pain and/or locking and no other signs or symptoms of TMD (17). The risk of impairment is also known to be small (62). These patients were not offered any treatment.

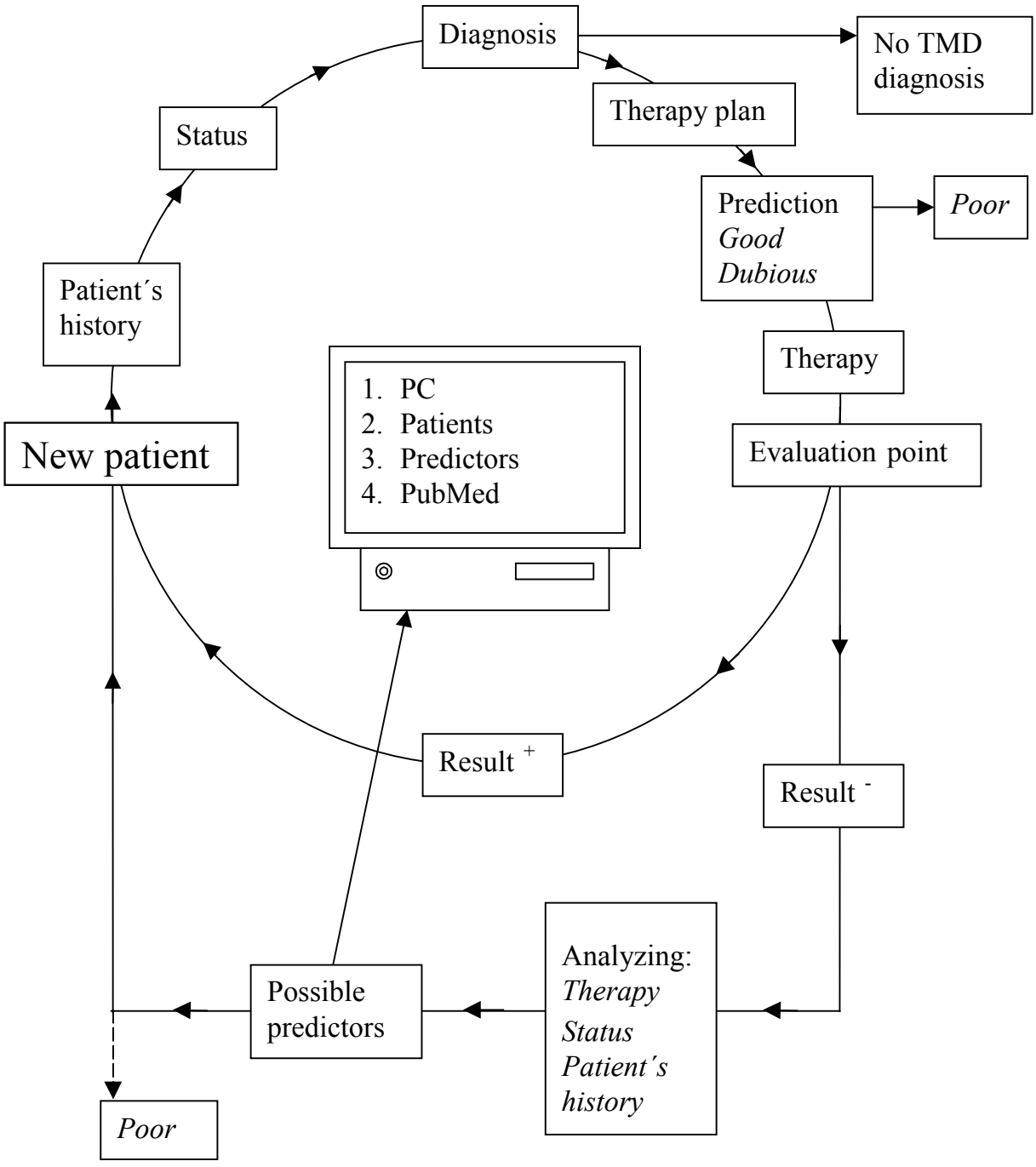

Figure 2: The hypothesis generator

Identifying possible predictors for a negative treatment outcome
New predictors have been identified in two ways: 1) patients with a general illness/disease known to affect muscles and/or joints or 2) each patient predicted *Good* who reached the objective treatment goal, a stable occlusion in RCP, but did not have an improvement of 50% or more. The latter patients first had the fitness of the interocclusal appliance judged with the naked eye, than controlled with a double folded 12µ thin plastic foil in clamping tweezer of occlusal contacts in RCP, MTR, LTR and/or PTR interferences, on the interocclusal appliance and /or in the dentition. If there was nothing to object on, the patient's record was examined regarding past and present history with a focus on psychosocial factors and previous or existing illness/disease that might influence treatment outcome. If such a factor were identified, it was regarded as a hypothetical predictor of a negative treatment outcome. The identified predictors have been used as keywords in a PubMed search. The predictors were registered in a database and immediately implemented into the clinical routines (Figure 2).

Improvement of the model
An improvement of the model is defined as; a greater difference in actual treatment outcome, an improvement of 50% or more, between patients predicted Good or Dubious, in subgroup *Muscle* and *Mainly TMJ,* when comparing patients during two periods: 1992 – 98 and 1999 – 2004.

STATISTICAL METHODS

The Chi-square test was used to test for differences between groups (114). The computer program Microsoft Excel was used for the analyses. The levels of significance used were $p \geq 0.05$ N.S. (not significant); $0.01 \leq p < 0.05$; $0.001 \leq p < 0.01$; $p < 0.001$.

RESULTS

Sample I (Papers I and III)
Sixty-four per cent had *Muscle* symptoms, and 36% had *Mainly TMJ* symptoms. There was a predominance of females in both subgroup *Muscle* (76%) and subgroup *Mainly TMJ* (81%) (p = N.S.). Furthermore, patients in subgroup *Muscle* were significantly older than those in subgroup *Mainly TMJ* ($p < 0.001$) (Table 1).

The vast majority of patients (97%) were treated with interocclusal appliances and/or occlusal adjustment, while a few (3%) had only acute pharmacological treatment. There were no substantial differences in treatment regimen between the two subgroups (Table 2).

The majority of patients were predicted Good in both subgroup *Muscle* (85%) and subgroup *Mainly TMJ* (93%) ($p < 0.01$).

For patients predicted Good in subgroup *Muscle,* 90% reported an improvement of 50% or more, and the corresponding figure for those predicted Dubious was 56%. The difference was statistically significant ($p < 0.001$). In subgroup *Mainly TMJ,* 94% of those predicted Good and 88% of those predicted Dubious reported an improvement of 50% or more. The

	Sample I		Sample II		Sample III		Sample IV	
	Muscle	Mainly TMJ	Muscle	Mainly TMJ	Muscle	Mainly TMJ	Muscle	Mainly TMJ
Treatment	n = 630	n = 359	n = 132	n = 74	n=475	n=294	n = 77	n = 87
Only acute treatment	3	3	5	0	0	1	0	0
Appliance night wear	39	26	60	62	38	33	27	24
Appliance and occlusal adjustment	37	38	14	19	46	46	57	55
Only occlusal adjustment	7	10	5	7	11	13	9	11
Onlays full time	2	6	2	8	2	2	3	2
New complete or partial dentures	4	4	10	3	1	1	3	6
FPDs, orthodontics and/or orthognathic surgery	8	13	4	1	2	3	1	1

Table 2: Main treatment / treatments in the four Samples I – IV, subgrouped as Muscle or Mainly TMJ symptoms. Percentage distribution.

Degree of improvement	Muscle Prediction	Sample I Good	n = 630 Dubious	Sample II Good	n = 132 Dubious	Sample III Good	n = 475 Dubious	Sample IV Good	n = 77 Dubious
≥50%		483 (90%)	52 (56%)	110 (89%)	8 (89%)	201 (93%)	147 (57%)	49 (100%)	23 (82%)
<50%		54 (10%)	41 (44%)	13 (11%)	1 (11%)	14 (7%)	113 (43%)	0	5 (18%)
		p < 0.001		p = N.S.		p < 0.001		p < 0.01	

Table 3a: Comparison of predicted and actual treatment outcome in subgroup Muscle for Sample I - IV

Degree of improvement	Mainly TMJ Prediction	Sample I Good	n = 359 Dubious	Sample II Good	n = 74 Dubious	Sample III Good	n = 294 Dubious	Sample IV Good	n = 87 Dubious
≥50%		313 (94%)	23 (88%)	61 (97%)	8 (73%)	183 (94%)	72 (73%)	57 (100%)	26 (87%)
<50%		20 (6%)	3 (12%)	2 (3%)	3 (27%)	12 (6%)	27 (27%)	0	4 (13%)
		p = N.S.		p < 0.01		p < 0.001		p < 0.01	

Table 3b: Comparison of predicted and actual treatment outcome in subgroup Mainly TMJ for Sample I - IV

	Muscle				Mainly TMJ			
Prediction	Sample I n = 630	Sample II n = 132	Sample III n = 475	Sample IV n = 77	Sample I n = 359	Sample II n = 74	Sample III n = 294	Sample IV n = 87
Good Correct	483 (90%)	110 (89%)	201 (93%)	49 (100%)	313 (94%)	61 (97%)	183 (94%)	57 (100%)
Good Incorrect	54 (10%)	13 (11%)	14 (7%)	0	20 (6%)	2 (3%)	12 (6%)	0
Dubious Correct	41 (44%)	1 (11%)	113 (43%)	5 (18%)	3 (12%)	3 (27%)	27 (27%)	4 (13%)
Dubious Incorrect	52 (56%)	8 (89%)	147 (57%)	23 (82%)	23 (88%)	8 (73%)	72 (73%)	26 (87%)

Table 4: Proportion of patients predicted Good or Dubious with a correct or incorrect prediction of treatment outcome in subgroup Muscle and subgroup Mainly TMJ in Samples I – IV. Percentage distribution in brackets.

difference was not statistically significant (p = N.S.). When comparing subgroup *Muscle* with subgroup *Mainly TMJ* for patients predicted Good or Dubious, there was no statistically significant difference for patients predicted Good who reported an improvement of 50% or more, but for patients predicted Dubious, the difference was statistically significant ($p < 0.01$) (Tables 3a & 3b). A correct prediction Good (an improvement of 50% or more) or Dubious (an improvement less than 50%) was thus made for 90% of the patients predicted Good and for 44% of those predicted Dubious in subgroup *Muscle* ($p < 0.001$). In subgroup *Mainly TMJ* the corresponding figures were 94% and 12%, respectively ($p < 0.001$) (Table 4).

Sample II (Paper II)
The sample was similar to the previous one with a predominance for subgroup *Muscle* (64%) and for females in both subgroups (*Muscle* 78% and *Mainly TMJ* 72%, respectively, p = N.S.). The patients in subgroup *Muscle* were older than those in subgroup *Mainly TMJ* ($p < 0.001$) (Table 1).

The distribution of patients treated with interocclusal appliances and/or occlusal adjustment (97%) or only acute pharmacological treatment (3%) was the same as in Sample I. No obvious difference in treatment panorama could be seen between the two subgroups (Table 2).

A majority of patients in both subgroup *Muscle* (93%) and subgroup *Mainly TMJ* (85%) were predicted Good (p = N.S.).

In subgroup *Muscle,* 89% of the patients had an improvement of 50% or more, irrespective of whether they were predicted Good or Dubious. In subgroup *Mainly TMJ,* 97% of those predicted Good had an improvement of 50% or more and for patients predicted Dubious the corresponding figure was 73%. The difference was statistically significant ($p < 0.01$). When comparing subgroup *Muscle* with subgroup *Mainly TMJ,* there was no statistically significant difference for patients reporting an improvement of 50% or more either for those predicted Good (89% and 97%, respectively, p = N.S.) or Dubious (89% and 73%, respectively, p = N.S.) (Tables 3a & 3b). Thus, a correct prediction was made for 89% of those predicted Good and for 11% of those predicted Dubious in subgroup *Muscle.* The corresponding figures in subgroup *Mainly TMJ* were 97% and 27%, respectively. The differences in both groups were statistically significant ($p < 0.001$ and $p < 0.001$, respectively) (Table 4).

Sample III (Papers III and IV)
This sample, too, was similar to the previous two with a predominance for subgroup *Muscle* (62%), as well as for females in both subgroups (*Muscle* 80% and *Mainly TMJ* 83%, respectively, p = N.S.), and the patients in subgroup *Muscle* were statistically significantly older compared to the patients in subgroup *Mainly TMJ* ($p < 0.001$) (Table 1).

Almost all patients (99%) were treated with interocclusal appliances and/or occlusal adjustment. Five patients (1%) had received only acute pharmacological treatment. No obvious difference in treatment panorama could be found between the two subgroups (Table 2).

Less than half of the patients in subgroup *Muscle* were predicted Good (45%), while the corresponding figure in subgroup *Mainly TMJ* was 66% ($p < 0.001$).

In subgroup *Muscle,* 93% of those predicted Good had an improvement of 50% or more while the figure for patients predicted Dubious was 57%. The difference was statistically significant

($p < 0.001$). In subgroup *Mainly TMJ,* 94% of the patients predicted Good and 73% of those predicted Dubious reported an improvement of 50% or more ($p < 0.001$). When comparing subgroup *Muscle* with subgroup *Mainly TMJ,* there was no statistically significant difference for patients predicted Good who reported an improvement of 50% or more (93% and 94%, respectively), while a statistically significant difference was found for those predicted Dubious (57% and 73%, respectively, $p < 0.01$) (Tables 3a & 3b). A correct prediction was thus made for 93% of the patients predicted Good and 43% of those predicted Dubious in subgroup *Muscle* ($p < 0.001$). The corresponding figures in subgroup *Mainly TMJ* were 94% for patients predicted Good and 27% for those predicted Dubious ($p < 0.001$) (Table 4).

Comparing patients predicted Good (n = 410) with patients predicted Dubious where the negative predictors had been subgrouped as 1) TMD symptoms with no significant improvement at a 4-year follow–up (n = 22), 2) rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, fibromyalgia or whiplash injury (n = 188), 3) TMD symptoms but no clinical signs corresponding to the symptoms or impossible to reproduce the RCP (n = 26), and 4) identified new predictors (n = 123), there was a statistically significant difference in patients reporting an improvement of 50% or more, for all the four subgroups (28%, $p < 0.001$; 65%, $p < 0.001$; 73%, $p < 0.001$; 59%, $p < 0.001$, respectively).

When subgroup 2) was separated into patients with the assumed negative predictors rheumatoid arthritis/ankylosing spondylitis/psoriatic arthritis (n =28), whiplash trauma (n = 107), and fibromyalgia (n = 53), 89%, 64%, and 53%, respectively, reported an improvement of 50% or more. Compared to all patients predicted Good (n = 410), where 94% reported an improvement of 50% or more, the difference in treatment outcome was statistically significant for those with whiplash trauma ($p < 0.001$) and fibromyalgia ($p < 0.001$), while no such difference was found for those with rheumatoid arthritis/ankylosing spondylitis/psoriatic arthritis.

The figures for improvement 50% or more in patients with one negative predictor (n = 316; 63%) compared to patients with two or more negative predictors (n = 43; 49%) were almost statistically significant ($p < 0.08$).

Sample IV (Paper IV)

The distributions in subgroups were reversed compared to the other three samples with a predominance of *Mainly TMJ* patients (53%). The gender distribution was similar in the two subgroups with a predominance of females (*Muscle* 77%; *Mainly TMJ* 78%, respectively, p = N.S.). This was the only sample where patients with *Muscle* symptoms were significantly younger than those with *Mainly TMJ* symptoms ($p < 0.01$) (Table 1).

All patients were treated with interocclusal appliances and/or occlusal adjustment (Table 2).

The majority of patients were predicted Good both in subgroup *Muscle* (64%) and in subgroup *Mainly TMJ* (66%) (p = N.S.).

In subgroup *Muscle,* 100% of those predicted Good had an improvement of 50% or more. The corresponding figure among those predicted Dubious was 82%. This difference was statistically significant ($p < 0.01$). In subgroup *Mainly TMJ*, the figures were 100% and 87%, respectively ($p < 0.01$.). When comparing subgroup *Muscle* with subgroup *Mainly TMJ,* there were no statistically significant differences for patients who reported an improvement of 50% or more either for those predicted Good (100% and 100%, respectively) or Dubious (82% and

87%, respectively) (Tables 3a & 3b). A correct prediction was thus made for 100% of the patients predicted Good and 18% for those predicted Dubious in subgroup *Muscle.* The difference was statistically significant, ($p < 0.001$). In subgroup *Mainly TMJ,* the corresponding figures were 100% and 13%, respectively ($p < 0.001$) (Table 4).

Paper III (Samples I and III)
The allocation to either subgroup *Muscle* or *Mainly TMJ,* gender, and age distribution were similar in the two samples (Table 1).

A difference in the treatment panorama could be seen in the two samples. More extensive occlusal therapy such as onlays, new dentures, FPDs, orthodontics, and/or orthognathic surgery, decreased from 18% in Sample I to 5% in Sample III ($p < 0.001$) (Table 2).

The proportion of Dubious cases was statistically significantly larger in Sample III compared to Sample I both in subgroup *Muscle* (55% and 15%, respectively, $p < 0.001$) and in subgroup *Mainly TMJ* (34% and 7%, respectively, $p < 0.001$).

When comparing patients who reported an improvement of 50% or more in Samples I and III, there was no statistically significant difference in subgroup *Muscle* either for patients predicted Good (90% and 93%, respectively, p = N.S.) or patients predicted Dubious (56% and 57%, respectively, p = N.S.) nor in subgroup *Mainly TMJ* were there any statistically significant differences for patients predicted Good (94% and 94%, respectively, p = N.S.) or Dubious (88% and 73%, respectively, p = N.S.) (Tables 3a & 3b). Consequently, there were no statistically significant differences for correct predictions Good or Dubious between Samples I and III (Table 4).

Paper IV (Samples III and IV)
There was a statistically significant difference between the two samples in allocation to subgroups, *Muscle;* (Sample III 62% and Sample IV 47%, respectively, $p < 0.001$). The gender distribution in the two subgroups was similar in Samples III and IV. There was a statistically significant difference in age distribution between the two samples. In Sample III the patients in subgroup *Muscle* were older while those in subgroup *Mainly TMJ* were younger compared to the patients in Sample IV ($p < 0.05$ and $p < 0.05$, respectively) (Table 1).

No obvious difference in treatment panorama could be found either in subgroup *Muscle* or in subgroup *Mainly TMJ* (Table 2).

The proportion of Dubious cases was statistically significantly larger in Sample III compared to Sample IV in subgroup *Muscle* (55% and 36%, respectively, $p < 0.05$), while it was the same in subgroup *Mainly TMJ* (34% in both samples).

When comparing Samples III and IV, there was no statistically significant difference between patients who reported an improvement of 50% or more for patients predicted Good, thus correctly predicted, neither in subgroup *Muscle* (93% and 100%, respectively, p = N.S.) nor in subgroup *Mainly TMJ* (94% and 100%, respectively, p = N.S.). However, in subgroup *Muscle* there was a statistically significant difference for patients predicted Dubious (57% and 82%, respectively, $p < 0.01$) but not in subgroup *Mainly TMJ* (73% and 87%, respectively, p = N.S.) (Tables 3a & 3b). Consequently, the only statistically significant difference between

Samples III and IV for a correct prediction was the prediction Dubious in subgroup *Muscle* ($p < 0.01$) (Table 4).

Samples I and II

The allocation to subgroups *Muscle* or *Mainly TMJ* was equal, and the gender and age distribution was similar in Samples I and II (Table 1).

In Sample I, the patients were more frequently treated with selective occlusal adjustment compared to Sample II (65% and 37%, respectively, $p < 0.001$) (Table 2).

The proportion of Dubious cases was statistically significantly larger in Sample I compared to Sample II in subgroup *Muscle* (15% and 7%, respectively, $p < 0.05$), while the figures were reversed in subgroup *Mainly TMJ* (7% and 15%, respectively, $p < 0.05$).

When comparing patients reporting an improvement of 50% or more in Samples I and II, there was no statistically significant difference for patients predicted Good in subgroup *Muscle* (90% and 89%, respectively, p = N.S.), or for those predicted Dubious (56% and 89%, respectively, p = N.S.). In subgroup *Mainly TMJ,* there were no statistically significant differences neither for patients predicted Good (94% and 97%, respectively, p = N.S.) or for those predicted Dubious (88% and 73%, respectively, p = N.S.) (Tables 3a & 3b). Consequently, there was no statistically significant difference for a correct prediction between Samples I and II (Table 4).

Samples II and IV

There was a statistically significant difference between the two samples in allocation to subgroups, (*Muscle;* Sample II 64% and Sample IV 47%, $p < 0.01$). The gender distribution in the two samples was similar in both subgroups. There was no statistically significant difference in age between the two samples in subgroup *Muscle,* but patients in subgroup *Mainly TMJ* were younger in Sample II compared to Sample IV ($p < 0.001$) (Table 1).

The patients in Sample II were more frequently treated with only an interocclusal appliance compared to the patients in Sample IV (61% and 27%, respectively, $p < 0.001$) (Table 2).

The proportion of Dubious cases was statistically significantly larger in Sample IV compared to Sample II both in subgroup *Muscle* (36% and 7%, respectively, $p < 0.001$) and in subgroup *Mainly TMJ* (34% and 15%, respectively, $p < 0.01$).

When comparing Samples II and IV, there was a statistically significant difference in patients reporting an improvement of 50% or more for patients predicted Good in subgroup *Muscle* (89% and 100%, respectively, $p < 0.05$) but not in subgroup *Mainly TMJ* (97% and 100%, respectively, p = N.S.). For those predicted Dubious, there was no statistically significant difference either in subgroup *Muscle* (89% and 82%, respectively, p = N.S.) or in subgroup *Mainly TMJ* (73% and 87%, respectively, p = N.S.) (Tables 3a & 3b). The only statistically significant difference between correct and incorrect prediction between Samples II and IV was consequently the prediction Good in subgroup *Muscle* ($p < 0.05$) (Table 4).

DISCUSSION

The number of patients who rejected examination was similar to another recent report (3). The patients who had no signs or symptoms of TMD had other dental or medical reasons for their complaints. They were referred to either a dentist or a medical doctor for other treatments/examinations. The number of patients predicted Poor, i.e. with the only symptom TMJ clicking, decreased over time. The reason for this was information to dentists and medical doctors in the area that we do not treat the condition because of poor treatment outcome (17), and that the risk that the condition would lead to impairment is low (62).

A number of patients received only a treatment plan and were treated by their ordinary dentists outside the specialist clinic. Whether these patients actually had their treatment plan fulfilled is not known. In Paper II, we tried to get a picture of the treatment result in these patients. A large proportion of the patients (37%) had not received the suggested treatment, but the investigated group was small (n = 51). According to another study, only a few patients (16.5%) who were recommended an interocclusal appliance by a consultant clinic actually received an appliance from their dentists (98).

Eleven per cent of the patients in the present sample rejected the suggested treatment. Common reasons included financial reasons, doubt as to whether the patient could wear an appliance, or a discrepancy between the referral's estimated treatment need (141) and the patient's treatment demand (79).

The number of patients who discontinued the treatment was similar in Samples II, III, and IV. The reasons why more patients discontinued treatment in Sample I may be that the ability to predict treatment outcome individually has improved over the years, making it is easier to motivate the patients to complete treatment. The figure in Sample I was similar to a previous report (116).

The gender and age distribution was comparable to many previous reports (29, 40, 71). There was also a preponderance of patients with *Muscle* symptoms (62%) compared to *Mainly TMJ* symptoms. This has also been reported previously in other clinical materials (92). Sample IV differed from the other samples as there was a predominance of subgroup *Mainly TMJ,* and the patients in subgroup *Muscle* were younger than those in subgroup *Mainly TMJ.* A probable reason for this was that patients predicted Dubious was more common in subgroup *Muscle.* The TMD specialist treated more Dubious cases and some of these were selected as specialist cases directly from information in the referrals. Consequently, the general practitioner had more *Mainly TMJ* patients. The difference in age distribution was also a consequence of the routine at the specialist clinic that all patients 19 years of age and younger have high priority. TMJ symptoms are common among adolescents (140). The TMD-trained general dental practitioner worked only one day per week at the clinic, and the TMD specialist thus had more opportunities to take care of high priority patients.

The vast majority of the patients were treated with interocclusal appliances and/or occlusal adjustment with no obvious differences between subgroup *Muscle* and subgroup *Mainly TMJ*. The differences found between the samples were that the majority of the patients in Sample II were treated with interocclusal appliances and only few with occlusal adjustment. The reason for this might be that the patients had been selected by the TMD specialist as simpler cases suitable for the general dental practitioners. Of all the patients, 40% were treated with both interocclusal appliances and occlusal adjustment and 9% with only occlusal adjustment. Taking into account the fact that occlusal factors are causative in 10-25% of specific TMD

diagnoses (102), the figure for occlusal adjustment may seem high. However, occlusion can not be ruled out as a predisposing, initiating and/or perpetuating factor in the individual TMD patient (3). Furthermore, the proportions of patients who received more extensive occlusal corrections decreased over the years. A probable reason for this is that the overall dental status has improved in the population, thus reducing the need for more extensive occlusal corrections. Another likely reason for this decrease is that the need for extensive occlusal corrections when treating TMD has been questioned (96), and this has had an influence on the treatments chosen.

The number of patients predicted Dubious has increased over the years. This is a logical consequence since the model used generates more negative predictors over time.

In subgroup *Muscle* there was an obvious difference between prediction Good or Dubious and actual treatment outcome in Samples I, III and IV but not in Sample II. The reason for this is that the general dental practitioners treated "easier cases" selected by the TMD specialist.

In subgroup *Mainly TMJ* there was an obvious difference between predicted and actual treatment outcome in Samples II, III and IV but not in Sample I. This might be explained by the fact that the number of patients predicted Dubious in Sample I were few in comparison with those predicted Good. Furthermore, considering the whole material, more patients predicted Dubious in subgroup *Mainly TMJ* had an improvement of 50% or more compared to Dubious cases in subgroup *Muscle.* This is an indication that some of the negative predictors might not affect *Mainly TMJ* symptoms as much as *Muscle* symptoms. An overall better treatment outcome in patients with *Mainly TMJ* symptoms has also been reported previously (27, 111). In Paper III, one of the assumed negative predictors for treatment outcome, rheumatoid arthritis, turned out not to impair actual treatment outcome. It is notable that these patients improved more than 50%, despite the fact that they had the "nocebo" prediction Dubious (47, 55). Whether patients predicted Dubious would have a better treatment outcome because of the positive placebo effect in the prediction Good (41) has to be investigated further. In Paper III there was a tendency for a cumulative negative effect for patients with two or more negative predictors. This also needs to be investigated further.

The difference between those predicted Good or Dubious and actual treatment outcome in subgroup *Muscle* was obvious in Sample I and difficult to improve further. Yet this difference was even more obvious in Sample III.

There was no difference between predicted Good and Dubious and actual treatment outcome in subgroup *Mainly TMJ* in Sample I, while such a difference was found in Sample III. When comparing patients who have been treated by general dental practitioners (Samples II and IV), the difference between prediction Good or Dubious and actual treatment outcome had increased in subgroup *Muscle*, but was similar in subgroup *Mainly TMJ.* These results indicate that the overall ability to predict treatment outcome individually at the clinic improved over time.

On the other hand, the proportions of patients with a correct prediction of treatment outcome had decreased over the years in both subgroups. At the same time, we claim that the ability to predict treatment outcome had improved. The main reason for the decrease in correct prediction is that the numbers of patients predicted Dubious increased, and of all patients predicted Dubious, 59% in subgroup *Muscle* and 78% in subgroup *Mainly TMJ*, had an

improvement of 50% or more. A consequence of this is a poorer outcome for the overall predictability.

The overall correct prediction Good varied between 89% and 100% in the four samples, while the correct prediction Dubious varied between 11% and 44%. Obviously, the possibility to correctly predict a Good treatment outcome was good, while the possibility to predict a Dubious treatment outcome correctly was poorer. A clinical consequence of this is that patients predicted Dubious can also be recommended TMD treatment, although the possibility for an improvement of 50% or more is less favorable compared to patients predicted Good.

It can be questioned whether a stable RCP actually is an objective treatment goal. RCP is, however, the only reproducible closing position between the upper and lower jaw (11). In comparison with other proposed non-surgical TMD treatments, e.g. spray and stretch, pressure and massage, ultrasound and electrogalvanic stimulation, injection and stretch (92), acupuncture (67), cognitive behavioral treatment (126), biofeedback (22), physical therapy (83), jaw exercises (78), pharmacological treatment (69), a stable RCP must be considered an objective treatment goal.

The model created and used is in fact a PDSA cycle, a cycle unknown to the author when the project began in 1992 (63). The P stands for a new patient, past history, clinical status, diagnosis, therapy plan and prediction. The D stands for the therapy performed, including the evaluation point. The S stands for the evaluation of the treatment, clinical status, and past history in patients predicted Good but not having an improvement of 50% or more, or patients predicted Dubious who repeatedly failed to show an improvement of 50% or more. Finally, the A stands for the registration in the database, and implementation in the clinical routines, of the identified new predictors. In this thesis, Paper I is the development of a PDSA cycle for patients diagnosed with TMD and treated with an interocclusal appliance and/or occlusal adjustment. Paper II is a test of whether eight general dental practitioners could copy the D segment in the cycle. Paper III is a test of whether the model improved in quality over time, i.e. the ability to predict individual treatment outcome, in patients diagnosed with TMD and treated with interocclusal appliance and/or occlusal adjustment. Paper IV evaluated whether a general dental practitioner could copy the clinical part, the P and D segments, in the cycle.

The model used in this thesis was created and evaluated by *one* TMD specialist. It is common in PDSA studies to have a sample size of 1, as the objective of PDSA studies is to show that change is functionally related to a single patient, clinic or operating room, and the object receiving the intervention is the subject (120). One of the best ways to make improvement is to copy others' ideas (117). It is not yet possible to conclude that the model used can be generalized. It first needs to be tested in other clinics. E A Codman's intention in the early 1900s was to create a network of hospitals that would carefully document all patients, in order to compare with other hospitals, with the goal to improve patient care and reduce mistakes (18). Well aware of the great variation in treatment concepts in different TMD clinics (91), we challenge others to test our model.

The main goal for quality improvement research is to "assess whether a study intervention imposed to change a process produces an improvement in outcome" (120). Further, practiced based learning and improvement needs: (a) a systematic practice analysis and improvement, (b) searching and appraising the medical literature, (c) obtaining and using information from practice populations and the larger population from which the patients are drawn, (d) using information technology to access and manage information and enhance individual learning,

and (e) teaching students and other health care professionals (101). We believe that the model used in this thesis is in line with these criteria.

This study has its obvious limitations. If it were not for the individual prediction of treatment outcome, it can be seen as 2128 case reports. The term "prediction" comprises statements about the past (retrodictions) or a given statement that we wish to explain (explicanda). Prediction describes what we usually call the "effect" of something, whatsoever. The "principle of causality" is the assertion that any event can be causally explained – that it can be deductively predicted. The theorist's interest in predictions is explicable as due to his interest in the problem of whether his theories are true. In other words, due to his interest in testing his theories - in trying to determine whether they cannot be shown to be false (100). In the case of "prediction", the hypothesis may be partially based on earlier observations, but it is formulated in advance and subsequently verified by observations. Because of the prediction, the clinician/scientist does not know the answer in advance and consequently cannot cheat. The fact that a prediction cannot be influenced makes it in some respect similar to a double-blinded experiment. The unconsciousness of the end result in predictions makes the judgment more reliable. The best way to test a model based on a hypothesis is said to be through prediction, since hypotheses are actually predictions (66). The hypothesis in this thesis is actually: do interocclusal appliances and/or occlusal adjustment together with patient care, placebo, and regression to the mean, result in an improvement of 50% or more in patients diagnosed with TMD and without any negative predictor that might affect the treatment outcome? Whether this hypothesis is correct or not needs to be investigated further.

There are unclear definitions of "prediction" and "prediction of treatment outcome" in the literature (80, 87). In Paper III we have proposed a new definition: Prediction of treatment outcome is "a clinician's possibility to forecast an in advance defined subjective treatment outcome at an objective treatment goal".

The aim of quality improvement reports is to answer the following questions: 1) What was to be accomplished? 2) What makes a change an improvement? 3) What was the mechanism for the change? 4) What lessons have been learned? 5) What are the next steps? (21). These questions were not formulated when this project began in 1992.

An attempt to answer these questions in retrospective, using this model, reads: 1) To predict individual treatment outcome in patients with TMD as a Good or Dubious possibility to have an improvement of TMD symptoms reduced by 50% or more through treatment with interocclusal appliances and/or occlusal adjustment and with treatment outcome evaluated at an objective treatment goal. 2) An increased difference in actual treatment outcome between patients predicted Good and Dubious. 3) Critical evaluation of the treatment, clinical status and past history in patients predicted Good not having an improvement of 50% or more, as well as evaluation of patients predicted Dubious who repeatedly failed to have an improvement of 50% or more. 4) There are general somatic, psychological and psychosocial factors that reduce the possibility to have an improvement of 50% or more in patients with TMD. Furthermore, patients with TMD related symptoms predicted Dubious (Subgroup 1; feeling of fatigue in jaws or cheek, tinnitus/impaired hearing, dizziness, tongue pain, swallowing difficulties/globus in the throat, and TMJ crepitation), and no other signs or symptoms of TMD, rarely report an improvement of 50% or more. 5) The model needs to be tested by other clinics/clinicians.

Our ambition in the present studies was to use a professional attitude as defined by Holm (52): "The ambition is to be guided in one's own professional practice by what is beneficial to the patient and fulfils his/her legitimate needs. Respect, attention, caring, empathy with the patient, and the mobilization of the helper's professional knowledge are all part of the professional attitude". In practice, all patients that began treatment actually requested it. A professional attitude may create a good patient/care-provider relationship, a relationship known to increase placebo and compliance with treatment (97), and is said to be extremely important in treatment of TMD (96).

The prediction in itself may also increase placebo in those predicted Good (41). Furthermore, a convinced therapist with an explanation that makes sense to the patient also improves the placebo effect (85). On the other hand, no one has ever been able to find a reliable way to predict who is going to respond to inert treatment and who is not (37). The placebo effect is an inevitable clinical reality and works not only on pain. Even conventional double-blind control studies may be inadequate for the control of these clinical factors (41). Finally, the regression to the mean when treating TMD should also be taken into account when interpreting the results (135).

Is there a need for specialists in TMD? Sweden is one of few countries in the world that has a specialty in TMD (50). The general practitioners who took part in the present studies were all trained by a specialist in TMD. In Sweden, general dental practitioners' knowledge of how to make TMD diagnoses, decide therapy, or assess treatment results is poor, but they seem to be familiar with interocclusal appliance therapy (124). Furthermore, the topic TMD in the undergraduate curriculum at most dental schools in the world is generally taught from many different specialty angles, and this often leaves undergraduate students confused. This will of course reflect on their later professional TMD treatment choices (125). We believe that a TMD specialist improves the quality of TMD care in general dental practice if the specialist handles the S and A segments of the PDSA cycle, reported to be the difficult part of the cycle (127).

The model used in our studies can be scientifically heavily criticized for at least two main reasons: 1) the model was created and evaluated by only *one* TMD specialist and 2) the inclusion and exclusion criteria change continuously. Treatment effect may be exaggerated by, on average, 17% in none double-blind studies (112). The continuous changing of inclusion and exclusion criteria is an obvious scientific weakness, but at the same time it is the clinical strength of the model.

This model is an empirical instrument. It has been used and fine-tuned for more than a decade. The model follows the intentions stated by Codman (18) but is far from today's definition of EBM (107). However, it is the practitioner with the clinical experience, judgment, and knowledge of the individual patient's needs who actuates EBM in the long-term theatre of clinical reality (8). The first step towards EBM is to follow up one's own clinical practice to evaluate what are the best practices. A condition for EBM is to register what methods you use and what results they give. Not until we view our own practice can we improve it (105). No theoretical or experimental studies can replace clinical observations of patients (134). The model used has identified new hypotheses regarding treatment of TMD, hypotheses needed to be tested further in well controlled studies.

CONCLUSIONS

- It was possible for *one* TMD specialist to predict individual short-term treatment outcome in patients diagnosed with TMD with either *Muscle* or *Mainly TMJ* symptoms treated with interocclusal appliances and/or occlusal adjustment.

- It was possible for the same TMD specialist to create a quality improvement model.

- The created model is a PDSA cycle.

- It was possible for eight TMD-trained general dental practitioners, under the supervision of one TMD specialist, to treat TMD patients with interocclusal appliances and/or occlusal adjustment with similar results as the TMD specialist, the D segment of the cycle.

- The model improved the ability of *one* TMD specialist to predict individual short-term treatment outcome over time in patients diagnosed with TMD with either *Muscle* or *Mainly TMJ* symptoms treated with an interocclusal appliance and/or occlusal adjustment.

- It was possible for *one* TMD-trained general dental practitioner to copy the clinical part, the P and D segments of the model, and achieve similar results to the TMD specialist in patients selected by the TMD specialist.

- Evaluating treatment, status and past history in patients predicted Good, reaching an objective treatment goal but not having an improvement of 50% or more, the S segment of the PDSA cycle, generated new, clinically useable, negative predictors of treatment outcome, to be further tested in well controlled trials.

- The model can be suitable for other illnesses or diseases, where an objective treatment goal can be defined.

POPULÄRVETENSKAPLIG SAMMANFATTNING

Över hela världen söker man modeller för att effektivisera och förbättra tand-, hälso- och sjukvård. Kvalitetssäkringsforskning är en ny typ av forskning som skiljer sig från konventionell forskning. Den grundas på en prediktion av utfallet av en insatt åtgärd. Prediktionen jämförs sedan kontinuerligt med utfallet. Prediktorer, positiva eller negativa, kan identifieras och implementeras i verksamheten, vilket kan leda till effektivare och bättre vård. Grundmodellen, den så kallade Plan – Do – Study - Act (PDSA) - cykeln, för kvalitetssäkringsforskning konstruerades av ekonomer. Än så länge är rapporter från detta forskningsområde sällsynta inom tand-, hälso- och sjukvård. Avhandlingen beskriver skapandet, och de initiala utvärderingarna, av den första PDSA - cykeln inom tandvården.

Störd käkfunktion är en diagnos vars typiska symtom är besvär eller smärtor lokaliserade till ansikte, käkar eller huvud. Behandlingsbehovet hos den vuxna svenska befolkningen har uppskattats till cirka 3 %. Tillståndet förorsakar sjukfrånvaro och ökad sjukvårdskonsumtion. Störd käkfunktion kan med framgång behandlas inom tandvården, vanligtvis med bettskena och/eller annan bettstabiliserande behandling. Behandlingen minskar såväl sjukfrånvaro som sjukvårdskonsumtion. En kvalitetssäkringsmodell med ambitionen att kunna förutsäga behandlingsresultat på individnivå för patienter med störd käkfunktion kan vara av intresse både för patient och för samhälle.

Vid specialistkliniken för Bettfysiologi i Folktandvården, Västernorrland, har samtliga patienter som undersökts mellan åren 1992 – 2004 registrerats i en databas med avseende på diagnos, predikterat behandlingsresultat, behandling och slutligt behandlingsresultat. Patienterna har direkt efter undersökning tilldelats en God eller Osäker möjlighet att nå en besvärsförbättring på 50% eller mer. Prediktionen har grundats på undersökningsfynd samt på en standardiserad behandling med bettskena och/eller bettstabilisering. Patienter som nått ett objektivt behandlingsmål och predikterats God, men inte fått en besvärsförbättring på 50% eller mer, har analyserats avseende utförd behandling, status samt anamnesuppgifter i syfte att identifiera prediktorer som förklarar varför patienten inte har uppnått det förväntade behandlingsresultatet. Identifierade prediktorer har kontinuerligt implementerats i de kliniska rutinerna. Efterföljande patienter, som har identifierats med någon av dessa nya prediktorer, har bedömts ha en Osäker möjlighet att nå en besvärsförbättring på 50% eller mer.

Den använda modellen har visat att det finns en skillnad mellan faktiskt behandlingsresultat för patienter som predikterats som God respektive Osäker, oavsett om patienten har behandlats av en specialist i bettfysiologi eller en tilläggsutbildad allmänpraktiserande tandläkare under överinseende av specialisten. Vidare ökade skillnaden mellan predikterat behandlingsresultat, God respektive Osäker, och faktiskt behandlingsresultat över tid, vilket är ett uttryck för att prediktionsförmågan förbättrades. Slutligen framkom att en tilläggsutbildad allmänpraktiserande tandläkare kunde kopiera den kliniska delen av modellen med likartade resultat som specialisten, om specialisten hade valt ut patienterna. Modellen har identifierat ett antal kliniskt användbara negativa prediktorer som bör utvärderas ytterligare i välkontrollerade studier. Vidare bör modellen kunna användas inom andra delar av tand-, hälso- och sjukvård vid behandlingar där ett objektivt behandlingsmål kan definieras.

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