Intraoral Vertical Ramus Osteotomy - Objective and Subjective Treatment Outcomes

Elisabeth Schilbred Eriksen

Thesis for the Degree of Philosophiae Doctor (PhD)
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To Kjetil, Nicolai and Jacob

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SCIENTIFIC ENVIRONMENT

The work on which this thesis is based was conducted during the years 2012-2018 as part of the double competence program in combination with specialisation in orthodontics. Main supervisor was Associate Professor Sigbjørn Løes, and co-supervisors were Professor Kristin Solveig Klock, Ketil Moen (PhD) and Professor Emeritus Per Johan Wisth. The scientific work took place at the Department of Clinical Dentistry, University of Bergen, and at the Department of Maxillofacial Surgery and the Centre for Sleep Disorders at Haukeland University Hospital, Bergen, Norway.

"I think, therefore I am", René Descartes (1596-1650)

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ABBREVIATIONS

AHI	Apnoea hypopnea index
BMI	Body mass index
CI	Confidence interval
CT	Computed tomography
ESS	Epworth sleepiness scale
EVRO	Extraoral vertical ramus osteotomy
HRQoL	Health-related quality of life
IMF	Inter-maxillary fixation
IVRO	Intraoral vertical ramus osteotomy
ML-NSL	Angle between the mandibular line (line through menton and gonion) and the nasion-sella line
ODI	Oxygen desaturation index
OHRQoL	Oral health-related quality of life
OIDP	Oral impact on daily performance
OPG	Orthopantomogram
OR	Odds ratio
OSA	Obstructive sleep apnoea
PAS	Pharyngeal airway space
PG	Polygraphy
PSG	Polysomnography
QoL	Quality of life
SD	Standard deviation
SE	Standard error
SNB	Sella-nasion-point B angle

SNPog	Sella-nasion-pogonion angle
SpO_2	Peripheral capillary oxygen saturation
SSO	Sagittal spit osteotomy
TMJ	Temporomandibular joint
T0	Time point 0 (before start of pre-surgical orthodontic treatment)
T1	Time point 1 (8 weeks after surgery)
T2	Time point 2 (1 year after surgery)
T3	Time point 3 (10-15 years after surgery)
VAS	Visual analogue scale

ABSTRACT

Combined orthodontic and orthognathic surgical treatment is conducted when a jaw discrepancy exceeds what can be treated with orthodontic treatment alone with an acceptable esthetical and functional result. The intraoral vertical ramus osteotomy (IVRO) is one of mainly three different surgical techniques used to move the mandible posteriorly in patients with a skeletal Class III jaw relationship due to excess growth of the mandible.

The purpose of this thesis is to evaluate the IVRO procedure with special focus on stability, satisfaction with treatment, oral health-related quality of life (OHRQoL), and impact on respiratory function during sleep. Thirty-six previous skeletal Class III patients operated with an isolated IVRO procedure and subsequent six weeks of intermaxillary fixation were examined 10-15 years after surgery and completed a 37-item structured questionnaire. Pre- and post-surgical orthodontic treatment had been performed in all patients. Skeletal and dental changes were evaluated with lateral cephalograms and dental casts obtained before treatment started, eight weeks, one year and 10-15 years after surgery. OHRQoL was measured with the OIDP index. A prospective cohort study was performed to evaluate the effect of mandibular setback surgery on the respiratory function during sleep. Eight otherwise healthy skeletal Class III patients between 18 and 33 years of age conducted in-home respiratory sleep recordings within two weeks before and at least three months after surgery. Primary outcome variable was apnoea hypopnea index (AHI).

In the long-term follow-up study mean mandibular surgical setback was 8.3 mm (range 4.5 - 13.5 mm). The mean skeletal change between eight weeks and 10-15 years after surgery was 1.6 mm in anterior direction. Ninety-two percent had positive horizontal overjet 10-15 years after surgery. Sixty-one percent were very satisfied and the remainder were reasonably satisfied with the treatment. The mean OIDP frequency score was 8.49, indicating that OHRQoL was good. In the group of patients conducting pre- and post-operative sleep recordings, the AHI was below three events per hour before surgery and below four events per hour after surgery in all patients. The mean surgical setback was 4.3 mm (range: 2.5-7.4 mm) in this patient group.

In conclusion, 10-15 years after mandibular setback surgery with the IVRO procedure the clinical result was good in most of the patients. All were either reasonably or very satisfied with the treatment, and OHRQoL was reported to be good. In the group of eight young, adult skeletal Class III patients in the prospective study, surgery did not increase AHI above five events per hour, i.e. all were below the threshold for mild obstructive sleep apnoea.

LIST OF PUBLICATIONS

The thesis is based on the three papers listed below. The papers will be referred to by their roman numeral.

Paper I

Schilbred Eriksen E, Wisth PJ, Løes S, Moen K.

Skeletal and dental stability after intraoral vertical ramus osteotomy: a long-term follow-up. **Int J Oral Maxillofac Surg 2017; 46: 72-79.**

Paper II

Schilbred Eriksen E, Moen K, Wisth PJ, Løes S, Klock KS.

Patient satisfaction and oral health-related quality of life 10-15 years after orthodontic-surgical treatment of mandibular prognathism. **Int J Oral Maxillofac Surg 2018.** https://doi.org/10.1016/j.ijom.2018.01.007 [E-published ahead of print].

Paper III

Schilbred Eriksen E, Gulati S, Moen K, Wisth PJ, Løes S.

Apnoea hypopnea index in healthy Class III patients operated with intraoral vertical ramus osteotomy: a prospective cohort study [Submitted].

INTRODUCTION

The progress in the field of orthognathic surgery has given surgeons the ability to use advanced techniques to improve both function and facial appearance for patients with dentofacial deformities (1). Patients in need of orthognathic surgery are reported to have more functional and esthetical problems, lower self-esteem, and poorer quality of life (QoL) compared to subjects without a dentofacial deformity (2-5). To ensure that patients receive evidence-based treatment, quality assessments are important. When a treatment procedure is evaluated it is essential that the patient is the focus. Besides the technical evaluation concerning skeletal and dental stability after orthodontic surgical treatment, the patients' reasons for seeking treatment, their experience of the treatment, how satisfied they are with the treatment, and the impact of treatment on QoL are important aspects that need to be evaluated. Also, complications after surgery are crucial to address. Orthognathic surgery is an elective procedure, and the benefits should exceed the possible side-effects. Evaluations concerning long-term stability as well as complications and the patients' own assessments of the treatment are needed to guide clinicians and patients in the decision-making process about the best possible treatment option.

Class III Malocclusion

In 1899, Edward H. Angle emphasized the need for a common nomenclature of malocclusion (6). His definitions of mesial and distal occlusion did not clearly state if the malocclusion was strictly dentoalveolar, or if a skeletal deviation was present. However, his basic definitions of malocclusion in the sagittal direction (Angle Class I, II and III) are used simultaneously to describe both skeletal deviations as well as those that are due to malposition of teeth and/or the alveolar process. The normal, or Angle Class I occlusion, is defined as the mesio-buccal cusp of the upper first molar occluding in the sulcus between the first and second buccal cusp of the opposing lower first molar. Angle Class III malocclusion is by Angle described as all the lower teeth occluding mesial to normal by the width of one bicuspid (6). In clinical practice, Class III malocclusion is present if the lower first molar is more than two millimetres mesial to

normal (7). The prevalence of Class III malocclusion varies between ethnicities (8). Small to medium deviations from normal can usually be corrected with growth-influencing appliances if the patient is in the mixed dentition stage of development. The patient's growth pattern, both in the vertical and sagittal direction, determines whether this early treatment is successful. If the early treatment is unsuccessful, or the patient grows back into mesial occlusion, either a camouflage treatment including extractions in the lower jaw or orthognathic surgery is indicated, depending on the severity of the skeletal discrepancy (9, 10).

Orthognathic Surgical Treatment

Orthognathic surgical treatment is indicated when the discrepancy between the maxilla and the mandible exceeds what can be treated with orthodontic compensation with an acceptable functional and esthetical result (9). Figure 1 shows a skeletal Class III malocclusion before orthodontic surgical treatment is initiated. A skeletal Class III discrepancy is due either to maxillary deficiency, mandibular excess, or a combination of the two (11, 12). The aetiology of the discrepancy usually indicates the appropriate type of surgical intervention. However, overall esthetical considerations, such as soft tissue thickness of the face, lips and throat, as well as airway conditions are always taken into account (11). To avoid too large movements of a single jaw, bimaxillary surgery has increased in popularity (13).

Figure 1. Intra-oral picture of a surgical Class III patient. Bilateral posterior crossbite due to a wide mandibular dental arch compared to the maxillary arch and negative horizontal overjet (Patient has consented to the use of the picture).

The orthodontic-surgical treatment is highly specialized, and close cooperation between orthodontists and oral surgeons is needed (9). Jaw corrections may have impact on facial appearance, upper airway space, masticatory function, temporomandibular joint (TMJ) function, and speech in addition to the dental occlusion. This makes decision-making in orthognathic surgery a complex task, where also the patients' expectations must be taken into account.

History of Orthognathic Surgical Treatment

In 1849, Dr. S. P. Hullihen, West Virginia, USA, described the case of a 20-year-old woman severely burned in the lower face and neck at the age of five. The scar tissue on the neck had pulled the head down and forward, and the lower lip as well, resulting in a severely protruded and downwardly rotated anterior part of the mandible. A successful segmental osteotomy was performed in the anterior part of the mandible, and two additional surgeries were performed to correct the cicatrix on the neck and to regain normal closure of the lower lip. This case was the first description in the scientific literature of surgical correction in a patient with severe malocclusion (14). During the next hundred years, different osteotomy designs were suggested for correcting mandibular excess. The American orthodontist E. H. Angle and surgeons V. P. Blair and J. W. Whipple were prominent contributors when horizontal osteotomy of the ramus and ostectomy of the body of the mandible to correct mandibular prognathism were presented around the year 1900. In Europe, P. Berger described the condylectomy to reduce mandibular prognathism in 1897 (15). The stability of the surgical result of the horizontal osteotomy of the ramus reported by Blair and colleagues was not satisfactory due to the limited overlapping of the separated bone segments. Also the condylectomy proposed by P. Berger resulted in unacceptable relapse and posterior rotation of the mandible (15). During the 1920s and 1930s, several surgeons, mostly in Europe, proposed new surgical techniques or improvements for correcting mandibular deformities, until the second World War slowed down the developing process due to the surgeons' need to focus on reconstructive surgery (15).

The early 1950s is considered the beginning of orthognathic surgery as a true specialty. In 1955, R. Trauner and his student H. Obwegeser described the intraoral sagittal split ramus osteotomy (SSO) technique (16, 17). Several authors have suggested improvements to the SSO technique, and names worth mentioning are G. Dal Pont (1961) (18), E. E. Hunsuck (1968) (19) and B. N. Epker (1977) (20). B. Spiessl's introduction of bicortical screws for rigid internal fixation of the distal and proximal segments in 1974 further improved the SSO procedure (21).

J. B. Caldwell and G. S. Letterman (1954) were the first to review the extraoral vertical subcondylar osteotomy for correcting mandibular prognathism (22). In 1964 S. M. Moose reported twenty-five successfully cases using intraoral subcondylar ramus osteotomy (23). However, a medial approach was used for this osteotomy. Some years later (1968) R. P. Winstanley described intraoral subcondylar ramus osteotomy with a lateral approach (24), similar to the intraoral vertical ramus osteotomy (IVRO) performed today. R. P. Winstanley's arguments for the intraoral approach were reduced risk of damaging the mandibular branch of the facial nerve, and avoiding the extraoral retromandibular scar (24).

The first reported maxillary surgical procedure with the surgical cut following the Le Fort I fracture lines was performed by M. Wassmund in 1927 for the correction of an open bite. However, it was G. Axhausen who first performed Le Fort I osteotomy for maxillary advancement (1934). He made the surgical cut following the Le Fort I fracture lines and used elastics after surgery to advance the maxilla. The first to report a larger group of patients treated using Le Fort I osteotomy for maxillary advancement was, again, H. Obwegeser in 1969 (15, 25). W. H. Bell's description of the down fracture to completely mobilize the maxilla and at the same time preserve blood supply to maxillary bone and teeth in 1975 further improved the Le Fort I method (26). H. Obwegeser was also the first to demonstrate total bimaxillary surgery by means of Le Fort I osteotomy in combination with SSO in the treatment of skeletal Class III deformity in 1970 (15, 27).

In modern orthognathic surgery the two most commonly used surgical procedures to move the mandible posteriorly are IVRO and SSO (28), with SSO being the most popular procedure worldwide. Its popularity is explained by the possibility of using rigid internal fixation that allows the patient to almost immediately regain jaw function after surgery. That one technique can be used to surgically reposition the mandible both posteriorly and anteriorly is also an advantage with SSO (9). IVRO on the other hand requires inter-maxillary fixation (IMF) with steel ligatures to stabilize the distal segment during the initial healing phase. Extraoral vertical ramus osteotomy (EVRO) is also conducted to some extent, but less frequently compared with both IVRO and SSO.

Stability after Mandibular Setback Surgery

The meta-analyses in a systematic review including articles published up to December 2014 comparing horizontal and vertical skeletal stability after IVRO and SSO setback surgery slightly favour the SSO procedure but concluded that both techniques provide good skeletal stability 6-12 months after surgery (29). However, the post-surgical changes after the two surgical techniques are different (30). While studies on skeletal stability after IVRO have described both posterior drift (30-32) and anterior relapse (30, 33-36) during the follow-up period, mainly anterior relapse is reported after SSO surgery with osteosynthesis (37, 38). Posterior rotation of the mandible after surgery with the IVRO technique is reported (30, 35, 39), and postsurgical guiding elastics are recommended at least up to three months after surgery to control the mandibular position both vertically and horizontally (30). The rigid internal fixation is suggested as an explanation for the better vertical stability using the SSO compared to IVRO (40).

IVRO

Some of the studies evaluating skeletal changes after IVRO surgery have observed a mean further posterior drift during the follow-up period measuring 4-16% of the surgical movement one year after surgery (30, 31, 40), while a mean anterior relapse

measuring 10-15% of the mandibular setback 12-18 months after surgery has been reported by others (33-36). Initial posterior drift and subsequent anterior relapse has been reported by several authors (30, 35, 41-43). The posterior drift observed in many IVRO patients after surgery has been suggested to be the result of anterior and inferior position of the condyle, "condylar sag", during fixation of the distal segment. When the condylar-fossa-relationship is re-established, the condyle, and hence the mandible, moves slightly posterior-superiorly, resulting in posterior drift of the mandible (44). Others have also related the posterior drift and clockwise rotation of the mandible to be the result of muscle pull from the masticatory muscles (30, 35). Complete luxation of the condyle out of the fossa has been reported after IVRO (45), but this is not a common complication. The posterior rotation of the mandible is suggested to be due to muscle pull from the medial pterygoid and masseter muscles (35). Manipulation of the segments and intra-capsular oedema has also been suggested to explain the initial anterior and inferior movement of the condylar head, and hence the proximal segment, after surgery (46). However, it is important to note that "condylar sag" does not occur in all patients undergoing IVRO surgery (47). Figure 2 illustrates the osteotomy line and the proximal and distal segment using the IVRO procedure.
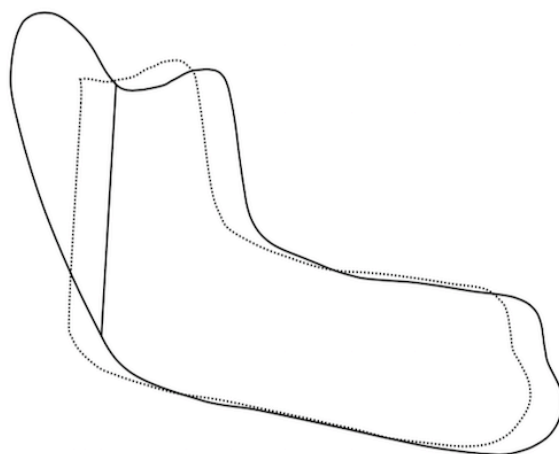
Figure 2. Intraoral vertical ramus osteotomy. Illustrating the osteotomy line (vertical black line) and the distal segment moved posteriorly (dotted line).

EVRO

Osteotomy using the EVRO technique is similar to IVRO, but with an extraoral approach. The improved visibility using the EVRO compared to IVRO allows for rigid internal fixation and hence almost immediate postoperative jaw function (38). The main disadvantage with EVRO is the retromandibular scar, and the procedure should be avoided in keloid-formers. The skeletal stability after EVRO is considered equivalent to IVRO and SSO (38, 48, 49) and reports indicate that most patients accept the retromandibular scar (38, 50, 51).

SSO

The SSO technique has the advantage of large bony contact between the proximal and distal segments, and osteosynthesis with miniplates and/or screws (52). Still the reported skeletal changes after SSO surgery are similar to the reports on stability after IVRO setback surgery. Relapse measured at least two years after isolated SSO setback surgery is reported to be between 14.9% and 18.8% of the mean mandibular setback measured as the change in point B, and between 11.5% and 25.9% in studies reporting the change of point pogonion (37, 38). Mobarak et al. (Norway, 2000) reported 26% relapse three years after mandibular setback surgery in a group of eighty patients operated using the SSO procedure and rigid fixation, and most of the relapse was observed during the first six months after surgery (53). Studies reporting a higher relative relapse after SSO with rigid fixation usually include few subjects (40, 54). One proposed explanation for the anterior skeletal relapse observed after surgery is muscle pull in the angular area during function that leads to an anterior shift of the mandible (40). Another proposed explanation is the condylar positioning during surgery. If the proximal segment is retro-positioned or rotated clockwise during surgery and fixation, anterior movement of the mandible will occur when function is regained after surgery and the condylar-fossa relationship is re-established (40).

Complications after Mandibular Setback Surgery

The main criticism of SSO is the high risk of injury to the inferior alveolar nerve (55, 56). The incidence of neurosensory disturbance after mandibular setback surgery using the IVRO procedure is reported to be significantly lower than when using the SSO procedure (29, 56-58). The neurosensory disturbance is often transient, and the sensibility gradually recovers (59-61). When comparing long lasting neurosensory disturbance it is still more prevalent in patients operated with the SSO compared to IVRO (58, 59) but the difference is reduced (59). The lower incidence of damage to the inferior alveolar nerve when using the IVRO procedure is explained by the osteotomy being posterior to the mandibular foramen. However, direct trauma to the nerve can occur if the osteotomy is performed too far anteriorly, either by the osteotomy itself or during repositioning of the distal fragment. Damage to the buccal nerve is rare (62) but may occur if the incision is made too superiorly on the ramus. Other complications reported with the SSO are unfavourable osteotomy ("bad split"), osteosynthesis material that requires removal and postoperative infection (63).

The need for IMF during the first post-operative weeks is the main criticism against IVRO due to the possible negative consequences the immobilisation may have on the masticatory muscles and the TMJs (64). On the other hand, due to the possibility of repositioning the condyle during surgery, IVRO has been reported to relieve pre-existing TMJ symptoms (28, 46, 47, 65-68). In addition to the possibility of alleviating TMJ symptoms, technical simplicity and reduced surgical duration, as osteosynthesis is not performed and the bone cut is technically easier, favour the IVRO technique over SSO (28). In some patients IMF is contraindicated, and IVRO cannot be performed. These include patients with asthmatic conditions, nasal congestion, some mental illnesses, and underweight patients where adequate nutrition is indispensable. A rare but serious complication with the IVRO technique is haemorrhage from the maxillary artery (62), and caution must be taken when the oscillating saw perforates the sigmoid notch. Post-operative infection is also uncommon after IVRO (62). A positive

significant correlation has been observed between duration of orthognathic surgery and amount of blood loss, and IVRO resulted in less blood loss compared to SSO (69).

Subjective Measurements of Treatment Outcome

The rationale behind elective surgical procedures is to improve QoL, hence subjective measurements are an important supplement to the clinical measures when evaluating different treatment modalities (70). In 1948, The World Health Organization defined health as "a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity" (71). In response to this definition, health is considered a multidimensional construct by health service researchers (70), and the dimensions of health have formed the basis of several indices developed to measure HRQoL (72). In other words, HRQoL is a subjective construct that includes dimensions concerning physical, mental and social functioning in addition to pain and discomfort (73). HRQoL measures are used to quantify the impact of a disease or condition on QoL, and it can be used to evaluate the course of a disease or the effect of a therapeutic intervention (74). Thus, studies using QoL as an outcome measure can aid both clinicians and patients in treatment decision-making (70).

Up until the 1980s, dentistry had been narrowly clinical in its knowledge of oral health (75, 76). The interest and understanding of the patients' own opinion about the treatment they receive and its effect on QoL has increased through recent decades (74, 77, 78). The idea behind oral health-related QoL (OHRQoL) is to measure how oral health impacts people's QoL (70). OHRQoL tools have been shown to have better validity compared to generic HRQoL questionnaires when the influence of oral health on QoL is a concern (2). Furthermore, a condition-specific OHRQoL tool may be superior to a generic OHRQoL tool in discriminating the effect of a specific oral disease, condition or intervention on quality of life (70).

Evaluations of orthognathic patients before treatment has revealed statistically significant higher levels of state anxiety and lower facial body image, self-esteem and QoL compared to control groups (3-5). After orthodontic-surgical treatment most patients are satisfied (77, 79-84), and improved facial body image, self-confidence and QoL is reported (5, 77, 85-88). Improving chewing function and facial appearance are reported to be the two main reasons that patients with dentofacial deformities seek orthodontic surgical treatment (83, 89-93).

Effect of Mandibular Setback Surgery on the Upper Airways

Adequate dimension of the upper airways is mandatory to maintain sufficient ventilation. A larger pharyngeal airway space (PAS) measured at the oropharyngeal level has been demonstrated among Class III patients compared to subjects with skeletal Class I and Class II morphology (94, 95), and it has been observed that after mandibular setback surgery the dimensions of the upper airways approach that of skeletal Class I subjects (95). However, others have not confirmed significant differences in airway dimensions among different facial configurations (94, 96).

The morphology of the upper airways and changes after orthognathic surgery have traditionally been evaluated using lateral cephalograms (97-104). After the introduction of computed tomography (CT), the cross-sectional area and volume of the upper airways could be measured. Both cephalometric (97-102) and CT analyses (105-111) frequently indicate a reduction of PAS after mandibular setback surgery, but the imaging techniques do not have the ability to measure the actual clinical impact of the change in airflow through the upper airways after mandibular setback surgery.

The main concern of reducing PAS is the possible development of obstructive sleep apnoea (OSA). OSA is a serious condition that is characterized by repeated episodes of complete (apnoea) or partial (hypopnea) cessations in breathing during sleep due to constriction or collapse of the upper airways. OSA is classified according to the apnoea

hypopnea index (AHI) (Table 1) (112). Depending on severity, and hence co-morbidity, OSA is a potential life-threatening condition. Predisposing factors for OSA are increased body mass index (BMI), large adenoids, tongue or uvula, deviated nasal septum, severe retroposition of the mandible or micrognathia, advancing age, and alcohol consumption (103, 113-115). The estimated prevalence of OSA defined by AHI ≥ 5 events/hour among Norwegian women and men between 30 and 65 years of age published in 2010 was 16%. The prevalence of AHI ≥ 15 events/hour was estimated to be 8% (116).

Table 1. Classification of OSA based on AHI (112).

Mild	AHI ≥ 5, but < 15 events per hour
Moderate	AHI ≥ 15, but < 30 events per hour
Severe	AHI ≥ 30 events per hour

OSA: Obstructive sleep apnea, AHI: Apnea hypopnea index

The gold-standard for diagnosing OSA is in-laboratory polysomnography (PSG) (117). The PSG includes electroencephalography, electrocardiography, electromyography, and electrooculography in addition to measuring respiratory airflow, respiratory effort, and peripheral capillary oxygen saturation (SpO_2). The in-laboratory PSG is too costly to conduct for screening purposes. The portable in-home respiratory polygraphy (PG) however, is a more efficient technique for screening patients scheduled for inpatient surgery. The in-home respiratory PG is conducted with a portable PG system which includes a small recorder, nasal catheter, belts around the abdomen and the chest, and a pulse oximeter (Figure 3).

Figure 3. In-home respiratory polygraphy with the Nox T3® monitor _{(Nox Medical, Reykjavik,} Iceland).

Studies comparing PAS measurements with AHI and/or oxygen desaturation index (ODI) show a significant decrease in PAS-measurements, but no significant permanent deterioration in the respiratory variables after mandibular setback surgery (97, 98, 118, 119). Although several studies have failed to confirm statistically significant permanent deterioration of the function of the upper airways after mandibular setback surgery (97, 98, 118, 120), cases with OSA after mandibular setback surgery have been reported (121-123). Two studies comparing PAS changes after SSO and IVRO mandibular setback surgery showed that PAS was reduced after surgery with both techniques, but less recovery of the PAS was observed in the post-surgical period after the IVRO procedure compared to SSO (95, 102). Previous research on changes in respiratory function after mandibular setback surgery is scarce, and the studies have evaluated groups of patients undergoing SSO surgery, or combined groups of IVRO and SSO surgery patients. Hence, there is a need to address the clinical effect of the morphological changes in the upper airways in an isolated group of patients undergoing mandibular setback surgery performed with the IVRO procedure.

The literature search was completed on 1 June 2018.

RATIONALE FOR DESIGNING THE STUDY

At Haukeland University Hospital approximately 130 patients undergo orthognathic surgery each year. IVRO is the standard surgical procedure for mandibular setback at Haukeland, and in 2017 a total of 43 patients underwent an isolated IVRO procedure. All patients are evaluated by a multidisciplinary team. The routine protocol has, since 1975, exhibited clinical and radiographic examination before start of treatment, and at eight weeks and one year after surgery. Hence, the Section for Orthodontics and Facial Orthopaedics, Department of Clinical Dentistry, Faculty of Medicine, University of Bergen has a unique material comprising medical and dental records, including pre-treatment and two-month and one-year postoperative radiographs, clinical photos and cast models, of all orthognathic surgery patients operated in Bergen.

Evidence-based practice is clinical decision-making based on a combination of relevant scientific evidence, clinical expertise, and the patients' values and needs (124, 125). Although randomised controlled trials and meta-analyses are ranked highest in the provision of scientific evidence, evidence-based medicine is not restricted to these two study types (125), and other study designs also provide valuable information. The scientific evidence concerning what surgical technique used in moving the mandible posteriorly provides the most stable result and the least complications is not conclusive. Few studies evaluating post-operative skeletal stability after mandibular setback surgery have followed the patients more than three years after surgery. Searches in PubMed, Web of Science and Ovid detected no previous studies evaluating QoL or ventilation during sleep in a group of patients with mandibular prognathism operated with an isolated IVRO procedure. Hence, there is a need for more scientific evidence concerning this patient group.

AIMS

The overall objective of this thesis was to assess outcomes of orthodontic surgical treatment among skeletal Class III patients operated with an isolated IVRO procedure focusing on stability, patients' perceptions, and impact on respiratory function during sleep. Specific aims were to evaluate:

- o Short-term (1 year) and long-term (10-15 years) post-operative skeletal and dental changes (Paper I).

- o The patients' reasons for seeking orthodontic-surgical treatment and how they experienced the treatment they received (Paper II).

- o The patients' self-reported improvements of oral health-related items (Paper II).

- o The patients' satisfaction with the treatment and their oral health-related quality of life 10-15 years after surgery (Paper II).

- o The impact of mandibular setback surgery on respiratory function during sleep (Paper III).

MATERIALS AND METHODS

Detailed description of the materials and methods are included in the respective papers.

Study Design

Paper I was a cohort study where data were collected 10-15 years after surgery and compared to retrospective information collected from the patients' records in the archive. Paper II was a survey study based on the same cohort as Paper I and also included clinical examination of the sensibility of the lower lip, chin and cheeks. In Paper II information was only collected at one time-point (10-15 years after surgery). Paper III was a prospective cohort study. Data was collected before and after the participants underwent mandibular setback surgery.

Ethics

The research project was evaluated and approved by the Regional Committee for Medical and Health Research Ethics (REK Vest 2011/1604 (Paper I and II)) and (REK Vest 2012/1474 (Paper III)). All participants signed an informed written consent prior to enrolment.

Calibration

All lateral cephalograms were calibrated to secure similar measurement scales in the analogue cephalograms obtained before treatment started (T0), at eight weeks (T1) and one year post-operatively (T2), and the digital cephalograms obtained 10-15 years after surgery (T3). A calibration ruler was not present on the analogue cephalograms, hence the degree of magnification was calculated manually after the films were scanned. The sella-nasion distance was measured on all four cephalograms in all 37 patients. The sella-nasion distance measured on the digital calibrated cephalograms obtained at T3 was used as reference, and correct magnification was implemented in the scanned

analogue cephalograms for each patient. The sella-nasion distance is considered stable in adults and was therefore chosen for this purpose (126).

Intra-examiner calibration was performed to measure accuracy in cephalometric landmark placement and study cast measurements. Twenty lateral cephalograms were traced twice (10 radiographs taken at T0 and 10 radiographs taken at T3) with at least four weeks between the first and second tracing. Thirty study casts were measured twice with at least 2 weeks interval between the first and second measurement. The intra-class correlation coefficient (ICC) was estimated by a random intercept model. The ICC is a number between 0 and 1 and illustrates the accuracy in reproducing measurements. The closer ICC is to one, the more similar the duplicated measurements are. The ICC for the repeated cephalometric measurements was above 0.90 for all variables. Paired *t*-tests were performed to test for systematic errors. Except for the vertical position of Menton, there were no statistically significant differences between the first and second placement of the cephalometric landmarks. The ICC for the study cast measurements was above 0.92 for all measurements. For the inter-molar distance in the upper jaw the p-value from the paired *t*-test was statistically significant.

Participants

Papers I and II

Inclusion criteria for the participants constituting Papers I and II was a skeletal Class III jaw discrepancy due to mandibular prognathism but without skeletal asymmetry or a basal open bite operated with isolated mandibular setback surgery with the IVRO procedure at Haukeland University Hospital in Bergen, Norway during the years 1998 through 2002. Only patients with completed growth before surgery were eligible for the study. Completed growth had been verified with a hand and wrist radiograph for the youngest subjects. Syndromic patients were not included. From a total sample of 91 patients fulfilling the inclusion criteria, 84 patients had attended the pre-and post-surgical follow-up protocol and had records obtainable from the patient archive at the

Section for Orthodontics and Facial Orthopaedics, Department of Clinical Dentistry, University of Bergen, Norway. These 84 previous orthognathic surgery patients were contacted by mail during spring 2012 and invited to participate in a 10-15 year follow-up study. Participation was rewarded with five scratch lottery tickets form the national lottery (Norsk Tipping). Thirty-seven (44.0%) agreed to participate and were included in the study. Among the non-participants, 39 (46.4%) did not respond, six (7.1%) were interested, but were occupied at the time the data collection took place, and two (2.4%) did not want to participate. One participant was excluded in Paper I due to a mandibular fracture during the long-term follow-up period. Another participant did not return the questionnaire and was therefore excluded in Paper II (Figure 4).
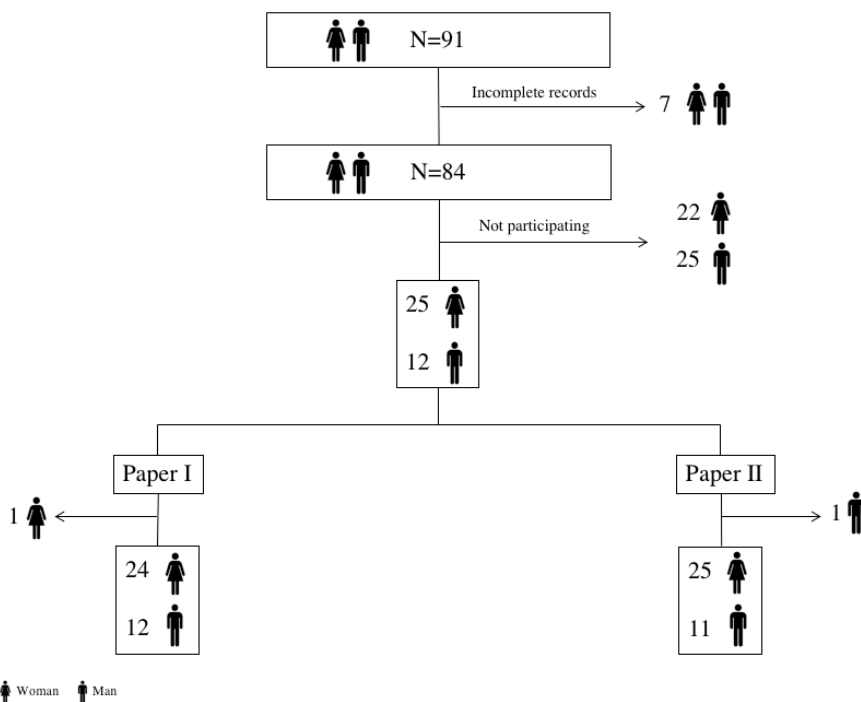
Figure 4. The sequences in participant recruitment for Papers I and II.

Paper III

Otherwise healthy, adult Class III patients scheduled for isolated mandibular setback surgery with the IVRO procedure during the period August 2016 through June 2017 and living within an approximately one-hour drive from Haukeland University Hospital were eligible for study participation. Exclusion criteria included history of OSA or other respiratory diseases, and the use of sleep medication or sedative drugs. One patient was excluded due to the use of sleep medication. Twelve patients (5 women, 7 men) passed the inclusion/exclusion criteria and were invited to participate in the study. Nine patients (5 women, 4 men) (75%) agreed to participate. Reasons for not participating were no response (8%), and too occupied (17%). Figure 5 illustrates patient recruitment and methods used in Paper III.
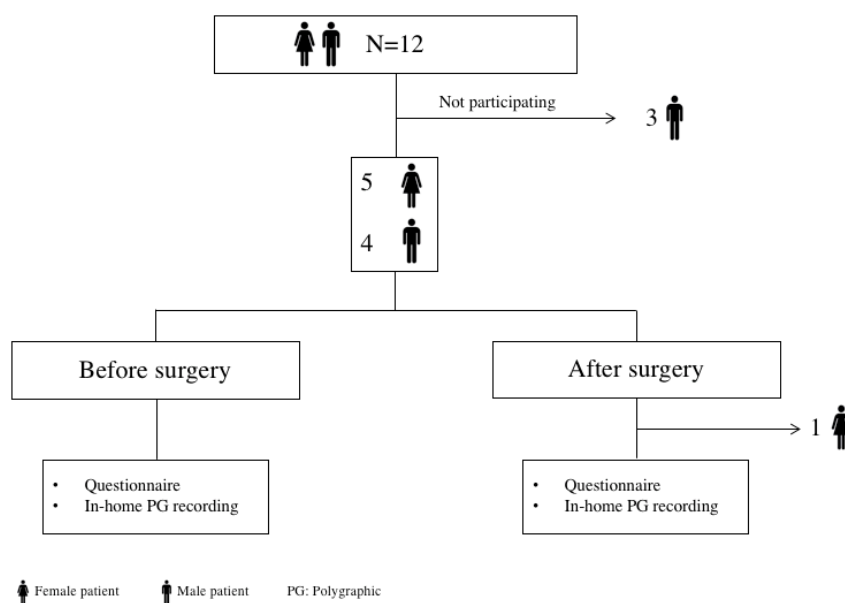
Figure 5. Patients and methods in Paper III.

Methods

Paper I

Study casts and lateral cephalograms obtained at T0, T1 and T2 were retrieved from the patient archive at the Section for Orthodontics and Facial Orthopaedics, Department of Clinical Dentistry, Faculty of Medicine, University of Bergen, Bergen, Norway. The clinical examinations 10-15 years after surgery (T3) were performed by one operator (ESE) and included impressions for study casts, extra- and intra-oral photographs, sensibility testing of the skin on the chin, cheeks and lower lip, and examination of the masticatory muscles and TMJs (Figure 6).
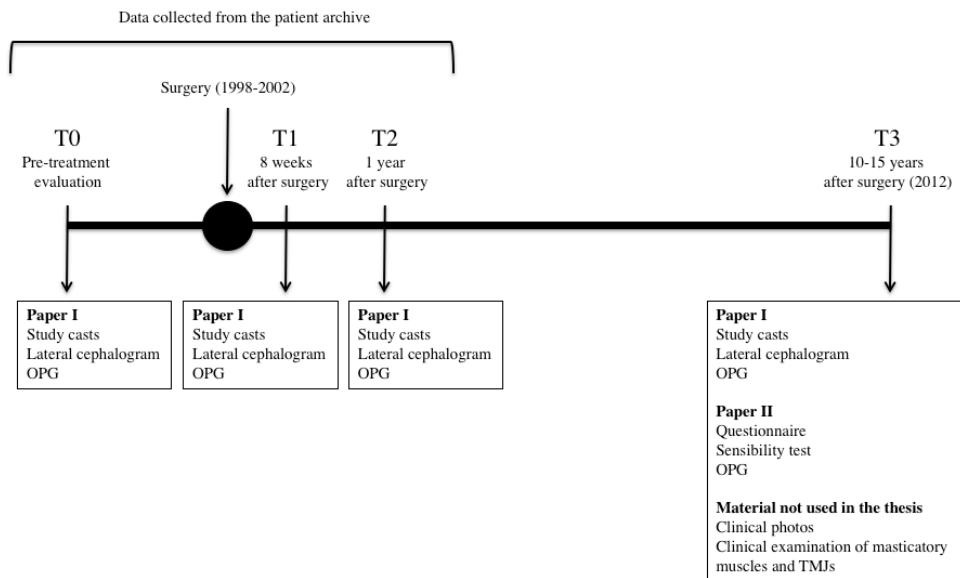
Figure 6. Timeline of data collection for Papers I and II.

Examination of the masticatory muscles and TMJs was performed and included measurements of jaw mobility, reporting of pain during movements of the mandible, and registration of pain upon palpation of the masticatory muscles and TMJs. The results from the clinical examination of the masticatory muscles and TMJs were not

included in the Papers constituting this thesis. The sensibility test included thermal stimuli, light touch test, localization sensibility, two-point discrimination, pin-prick sensibility and sharp-blunt differentiation and was performed as described by Leira and Gilhuus Moe (127). The radiographic examination consisted of a lateral cephalogram and an orthopantomogram (OPG). The OPGs were obtained to exclude pathology in the jaws and to record presence or absence of third molars compared to OPGs taken at T0 and T2. The lateral cephalograms were used to analyse skeletal and dental changes within the first year after surgery and up to 10-15 years after surgery.

Study Cast Measurements

A detailed description of the dental cast measurements is presented in Paper I. The dental cast analyses were performed by one operator (ESE) and included overjet and overbite in addition to arch depth, inter-canine distance and inter-molar distance in both dental arches (Figure 7).
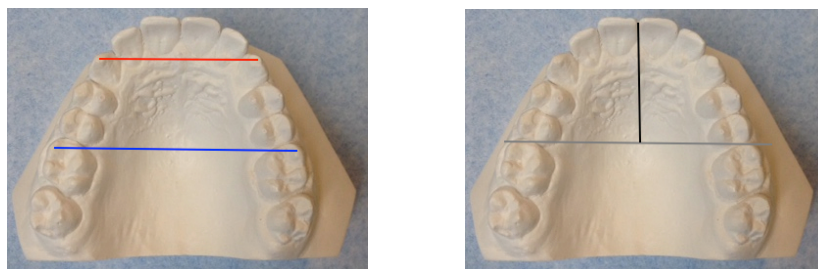
Figure 7 A and B. A; inter-canine (red) and inter-molar distance (blue). B; arch depth (black line) (128). (Reprinted with permission from International Journal of Oral and Maxillofacial Surgery).

Cephalometric Measurements

A cephalometric analysis including reference points and lines relevant to measuring skeletal and dental stability was developed with the computer software Facad 3.8.4.1 (Ilexis AB, Linköping, Sweden) in collaboration with Bengt Schmeling, product manager, Ilexis AB. The analysis included a coordinate system with the nasion-sella

line as the x-axis and the perpendicular through sella as the y-axis, hence horizontal and vertical changes of the cephalometric reference points could be recorded with x and y coordinates. Figure 8 illustrates the reference points and lines used for the analyses. Descriptions of the reference points, lines and angular measurements are reported in Paper I. All cephalometric analyses were performed by one operator (ESE). The data from the cephalometric analyses were collected with Facad Collector 3.8.3.1 (Ilexis AB, Linköping, Sweden), and exported as an Excel file for statistical analyses.
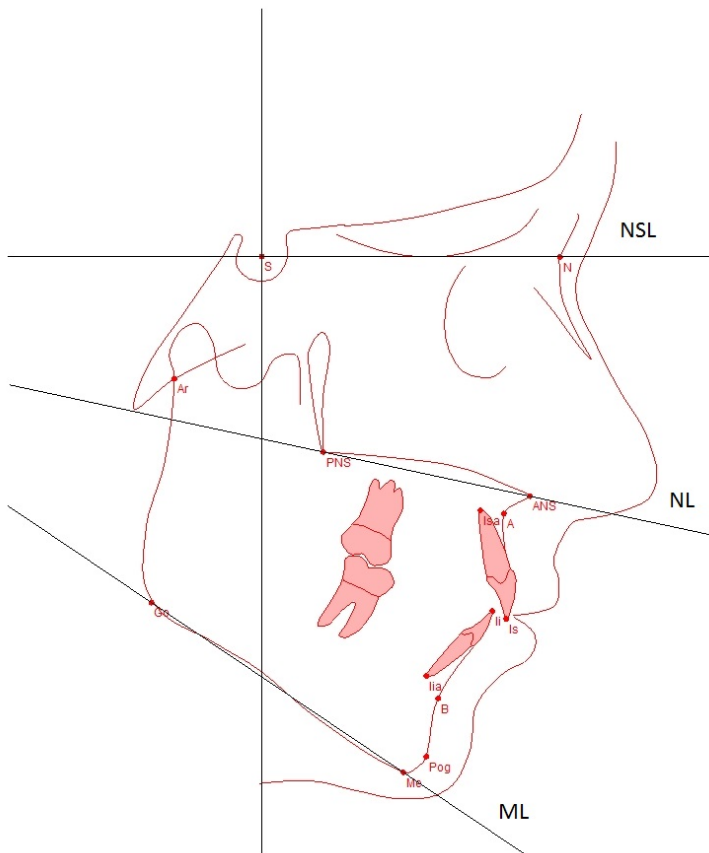
Figure 8. Cephalometric reference points and lines used in Paper I (128).

Cephalometric reference points: Go: gonion, Ar: articulare, S: sella, N: nasion, PNS: posterior nasal spine, ANS: anterior nasal spine, A: point A, Isa: apex of the most anterior maxillary central incisor, Is: incisal edge of the most anterior maxillary central incisor, Ii: incisal edge of the most anterior mandibular central incisor, Iia: apex of the most anterior mandibular central incisor, B: point B, Pog: pogonion, Me: menton. Cephalometric reference lines: NSL: nasion-sella-line, NL: nasal-line, ML: mandibular line. (Reprinted with permission from International Journal of Oral and Maxillofacial Surgery).

Paper II

A 37-item structured questionnaire (Appendix I) was sent by mail to the participants and completed at home before they attended the clinical and radiographic examination 10-15 years after surgery (T3). The questionnaire included closed-ended questions concerning reasons for seeking orthodontic-surgical treatment, pre-, per- and post-treatment concerns, how satisfied they were with the treatment and if they would have requested the same treatment again, OHRQoL, symptoms of temporomandibular disorders, and questions related to symptoms of sleep apnoea and daytime sleepiness (Epworth Sleepiness Scale, ESS) (129). Except for the questions concerning symptoms of sleep apnea and daytime sleepiness, the same questionnaire had been used in a 10-14 year follow-up study on SSO advancement patients operated at the same university hospital as the subjects in Papers I, II and III (130). In seven questions visual analogue scales (VAS) were used to measure the participants' self-perceived changes in seven oral health-related items (chewing, digestion, headache, speech, appearance, bullying and self-confidence in social settings). Each item had two VAS scales. On the first scale the patients marked the degree of difficulty they remembered having had with the item before treatment started. On the second scale they marked how much trouble they had with the same item 10-15 years after surgery (T3). The change was measured as the difference between the marks on the second and the first VAS.

OHRQoL was measured by the oral impacts on daily performances (OIDP) index (131). This index aims to quantify how oral health affects the person's ability to conduct daily activities. The index consists of eight questions and asks the patients if, during the past six months, problems in their mouth or teeth have affected them in eight daily performances (131);

1. Eating and enjoying food
2. Speaking and pronouncing clearly
3. Cleaning teeth
4. Sleeping and relaxing
5. Smiling, laughing, and showing teeth without embarrassment

6. Maintaining usual emotional state without being irritable

7. Carrying out major work or social role

8. Enjoying contact with people

The OIDP score is composed of both a frequency score and a severity score. Using either the frequency or the severity score alone can be considered to improve simplicity and efficiency (131). The frequency score is preferred due to its better reproducibility compared to the severity score (131), hence the frequency score was used in Papers II and III. The frequency alternatives were presented on a five-point Likert scale:

1. Less than once a month or never

2. Once or twice a month

3. Once or twice a week

4. 3-4 times a week

5. Every or nearly every day

The frequency score is the sum of the responses of the eight questions and ranges from 8-40. The frequency score was dichotomized to "no oral impacts" being those reporting to be affected less than once a month or never, and "at least one oral impact" being those reporting frequency alternatives 2-5. The Norwegian version of the OIDP index has been validated and is regarded a reliable instrument for use in the adult Norwegian population (132). All completed questionnaires were registered by one operator and checked by another operator.

Paper III

The patients completed a structured questionnaire and underwent in-home respiratory polygraphic recording (Nox T3®, Nox Medical, Reykjavik, Iceland) (Figure 3) within two weeks (2-14 days) before, and at least three months (3.3-12.9 months) after surgery. The in-home Nox T3 has been validated and found to have 95% sensitivity and 69% specificity compared to in-laboratory PSG when the threshold for OSA was

set to AHI ≥ five events/hour (133). The questionnaires were completed at home before surgery and approximately five months after surgery. The questionnaires were similar to the one used in Paper II (Appendix II and III). Only the answers to the ESS and OIDP questions were reported in Paper III. The questions concerning sleep apnoea and daytime sleepiness (ESS) (129) are used at the Centre for Sleep Disorders at Haukeland University Hospital. The ESS has been validated in a Norwegian population, but only fair to moderate association was observed between the results of the multiple sleep latency testing and the ESS items and total score (134). The respiratory PG analyses included measurements of AHI, peripheral capillary oxygen saturation (SpO_2), oxygen desaturation index (ODI) and snore index. AHI was the primary outcome variable. The other outcome variables were SpO_2, ODI, and snore index from the PG analysis, and ESS and OIDP from the questionnaire. All outcome variables are described in detail in Paper III. BMI was measured at both recordings. The criteria for scoring apnoea and hypopnea are the same as used at the Centre for Sleep Disorders, Haukeland University Hospital.

Description of the IVRO Procedure

In all included patients the surgery was performed under general anaesthesia. Local anaesthesia with vasoconstrictor was injected in the surgical area. The incision was made intra-orally at the anterior border of the ramus, and the lateral surface of the ramus was exposed from the gonial angle to the sigmoid notch. An angulated oscillating saw was used for the vertical sub-condylar osteotomy. The distal segment was moved posteriorly and placed medially to the proximal segments. The tooth-bearing part of the mandible was placed in the planned post-surgical position and stabilized with IMF. The IMF was performed with a steel wire ligated to surgical hooks on the arch wire in both jaws. The surgical hooks were attached mesially to the first molars, mesially to the canines and in the midline. The wound was closed with running sutures. The IMF was removed six weeks after surgery.

Statistical methods

Paper I

Age distribution at surgery for the participants was expressed by mean, standard error of the mean (SE), 95% confidence interval (CI) and range. The cephalometric and study cast variables were expressed with mean values and standard deviations (SD) at each time point. To examine changes between each time point, linear regression models with robust variance estimates adjusted for clustering within patients were performed and the data were presented with mean difference, SE and p-value. Separate models were performed with each time point as the independent variable. The total p-value expresses the total effect of time.

Paper II

Age and gender distribution for the participants and non-responders were presented with means and range. Logistic regression and Fisher's exact tests were used to detect possible differences between participants and non-responders concerning demographic characteristics (distribution of gender, age at surgery, age at T3, time between surgery and T3, and residency). The responses to the closed-ended questions were summarized with numbers and percentages as appropriate. Logistic regression and Fisher's exact tests were used to test for differences in age and gender. Simple logistic regression and Fisher's exact tests were used when possible predictive variables (independent variables) were separately tested for association with the patients' degree of satisfaction with the treatment (dependent variable). The data were presented with odds ratios (OR), SE for OR and 95% CI for OR. Numerical variables (VAS scores) were presented with mean values and 95% confidence intervals. When comparing the responses on the visual analogue scales, paired *t*-tests were used. Two-sample *t*-tests were used when comparing mean values for the VAS scores for independent subgroups ("very satisfied" vs. "reasonably satisfied").

Paper III

Descriptive statistics (mean, standard error, 95% CI and range) were used to report age at surgery, amount of surgical setback, the ESS and OIDP score from the questionnaire, and the PG variables. Due to the limited number of included patients, the results were also presented on the individual level. Normal distribution of the numerical variables was tested using the Shapiro Wilk test. Paired *t*-tests were used when comparing the results of the PG recordings and the ESS before and after surgery. Change in OIDP score was tested with the Wilcoxon sign rank test. The association between the change in the PG variables AHI, SpO_2 and ODI and the amount of surgical setback was tested using Pearson correlation. Pearson correlations were also performed when the pre- and post-surgical AHI were tested for association with the corresponding measurements of BMI and ESS. Spearman correlation was applied to test if the change in snore index was associated with surgical setback. No comparisons between men and women were performed due to the limited number of included patients.

Post-hoc sample size analysis was performed to test if the available number of patients was sufficient to perform statistical analyses with adequate statistical power. The hypothesis was that mean AHI did not exceed five events per hour after surgery. To detect a statistically significant difference before and after surgery, if the mean after value of AHI was 5 events/hour (the threshold for mild OSA), the AHI before surgery was 1.3 and the SD for the change in AHI was 1.3, corresponding to the findings in this study, a sample size of 4 would have been sufficient, with a significance level of 0.05 and a power of 0.8 (power calculation for paired t-test). Hence, even if the sample size in this study is small, it is sufficient to obtain differences that would be clinically relevant.

In all three papers (I, II and III), the significance level was set to 5%. The statistical analyses were performed using Stata/IC version 13.1 (Paper I) and version 14.1 (Paper II and III) (StataCorp LP, College Station, Texas, USA).

RESULTS

Detailed descriptions of the results are reported in the respective papers (I, II and III). Here follows a summary of the most relevant findings and some supplementary analyses.

Paper I

The material consisted of 24 women and 12 men. Mean age at surgery for the participants was 21.6 years (SE: 0.9, range 17.1-45.6 years). Mean follow-up period after surgery was 12.5 years (SE: 0.2 range: 9.7-14.5 years). The mean mandibular surgical setback measured as the horizontal change of the B-point between T0 and T1 was 8.3 mm (SE: 0.4, range 4.5 - 13.5 mm). During the first post-operative year (T1-T2), a small but statistically significant mean anterior relapse of 1 mm (SE: 0.3, p=0.001) was observed, accounting for 12% of the surgical setback. During the subsequent 11.5 years (T2-T3), a small but statistically significant mean anterior relapse of 0.6 mm (SE: 0.3, p=0.031) occurred, measuring 7% of the surgical setback. These statistically significant post-surgical changes of the mandible measured as the change in point B were verified by statistically significant changes during both follow-up periods (T1-T2 and T2-T3) also for SNB, SNPog and the horizontal position of point pogonion. A statistically significant mean increase in ML-NSL was measured between T0 and T1, indicating clockwise rotation of the distal segment during surgery and IMF. The mean inclination of the lower border of the mandible (ML-NSL) decreased during both follow-up periods but was still greater at T3 compared to T0.

Concerning the dental cast measurements, the horizontal overjet statistically significantly decreased both during the short-term and long-term follow-up period (p=0.013 and p=0.012 respectively). Mean horizontal overjet was -2.4 mm (SD:2.2) at T0, 2.2 mm (SD: 0.9 mm) at T2 and 1.6 mm (SD: 1.0 mm) at T3. At T3, ninety-two percent of the participants had a positive horizontal overjet. One subject had one incisor in negative overjet (-1 mm) at T3, and an edge to edge incisor relationship was

observed in two subjects. No statistically significant post-surgical changes were observed for the vertical overjet (overbite). As a result of the orthodontic pre-surgical decompensation in the lower jaw, a statistically significant mean increase in lower arch depth and inclination of the lower incisors was observed between T0 and T1 (p=0.008 and p=0.002 respectively). Seventeen of the participants did not have study casts available from T1, hence dental changes from T0-T1 and T1-T2 were measured only in 19 participants. The mean upper inter-molar distance increased 0.7 mm between T0 and T1 (p=0.261). Between T1 and T2, a statistically significant mean decrease in the upper inter-molar distance was observed (-0.6 mm, p=0.036). The mean inter-molar distance in the lower jaw decreased during the pre-surgical orthodontic treatment (T0-T1) (-0.6 mm, p=0.667) but increased to approximately mean pre-treatment width one year after surgery (0.5 mm, p=0.664). During the long-term follow-up period (T2-T3) a statistically significant increase in mean lower inter-molar distance was observed (0.8 mm, p=0.009). No further statistically significant post-surgical changes were observed for the dental cast measurements.

In Paper I all variables and changes between time-points were reported with mean values and SD or SE. In this summary, some supplementary descriptions of the material and analyses are included. Both posterior drift and anterior relapse during short-term and long-term follow-up periods was observed. Between T1 and T2 one patient had an anterior relapse exceeding 4.0 mm (4.2 mm), and none of the patients had a distal drift beyond 2 mm. Pearson correlations were performed to analyse the correlation between amount of surgical setback and post-surgical relapse/drift. A weak but statistically significant correlation between amount of setback and amount of skeletal relapse/drift during the first post-operative year (T1-T2) was observed (r=-0.33, p=0.046). The relapse observed between T2 and T3 was not statistically significantly correlated to amount of setback (r=-0.11, p=0.514). The scatter plot in figure 9 illustrate a weak but statistically significant correlation (r=-0.33, p=0.049) between surgical setback and total skeletal relapse/drift (T1-T3). The patient with a setback of 4.5 mm and a relapse

of 4.2 mm (Figure 9) had a perfect Class I molar and canine relationship, and a horizontal overjet of 2 mm at T3 measured on the dental casts.
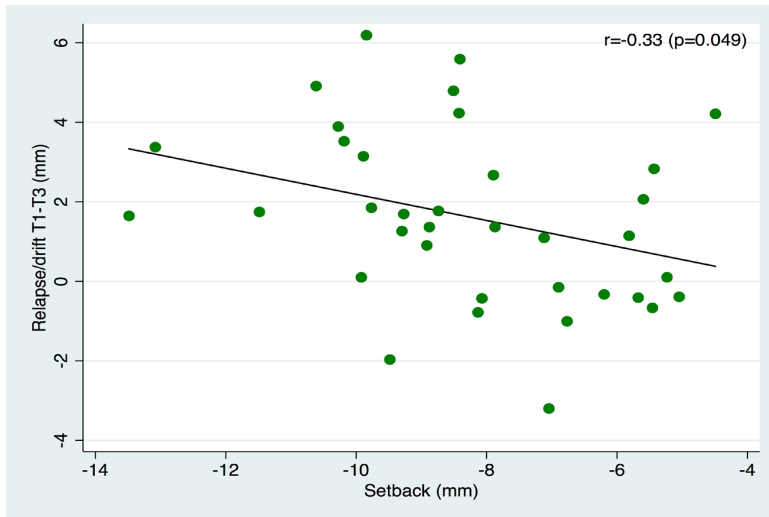
Figure 9. Scatter plot of surgical setback and skeletal post-operative relapse/drift between T1 and T3 for the 36 participants in Paper I.

Figure 9 shows that the total skeletal relapse/drift (T1-T3) was within 2 mm in 61% of the participants and within 4 mm in 83% of the participants. The scatter plot in figure 10, consisting of all the participants in Paper I, illustrate the insignificant correlation between overjet at T3 and skeletal relapse/drift observed between T1 and T3 (r=-0.14, p=0.426).
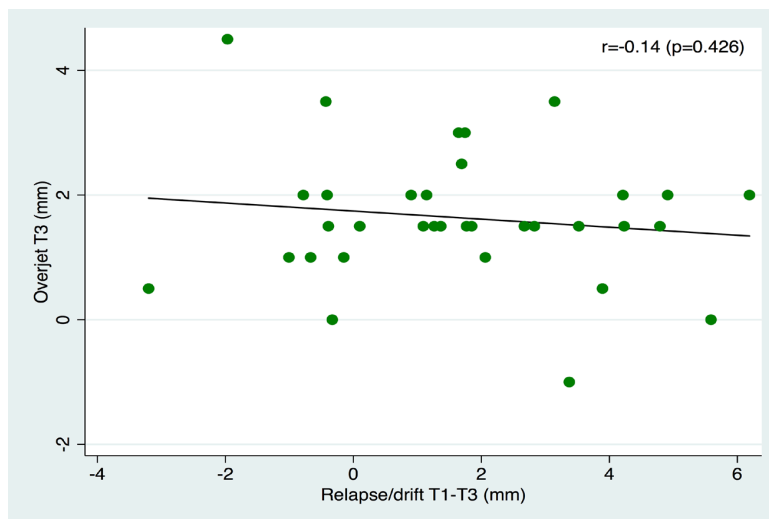
Figure 10. Scatter plot of horizontal overjet measured at T3 and skeletal relapse/drift between T1 and T3 for the 36 participants in Paper I.

Paper II

The participants in Paper II were 25 women and 11 men. Mean age at T3, when the questionnaires were completed, was 34.0 years (range: 27.2-59.8). The participants' most frequently reported reasons for undergoing treatment were to improve chewing function (69%) and to improve appearance (39%). Fifty-eight percent remembered the orthodontic treatment as being more distressing compared to the surgery including the initial healing phase with IMF. One participant reported difficulties with adapting to the new facial appearance after surgery, and four participants reported minor difficulties adapting. All were satisfied with the treatment, 61% were very satisfied and the remainder were reasonably satisfied. Neither amount of surgical setback (p=0.979), total skeletal relapse (T1-T3) (p=0.188) nor horizontal overjet measured at T3 (p=0.487) statistically significantly affected degree of satisfaction with treatment reported at T3 (two-sample *t*-tests). Seventy-five percent would have submitted to the same treatment again, and only one participant would not. Statistically significant improvements were reported for chewing function, appearance, self-confidence, bullying and speech measured by the VAS instrument. A statistically significant

positive association was observed between reporting a change in self-confidence on the closed-ended question and being very satisfied with the treatment (p=0.019). Those who reported being very satisfied with the treatment had statistically significantly greater improvement in appearance (p=0.010), bullying (p=0.014) and self-confidence (p=0.018) reported on the visual analogue scale, compared with those who were reasonably satisfied with the treatment. Concerning measurements of OHRQoL, 74% of the participants reported no oral impacts on daily performance during the past six months. The OIDP frequency score was between 8-12 on a scale from 8-40 for all subjects. Neither age, gender nor level of education statistically significantly affected the OIDP score or degree of satisfaction with the treatment.

Four of the 36 (11%) participants who completed the questionnaire at T3 reported still having sensory disturbance in the lips or jaw. Only one of these patients (3%) was confirmed clinically with persistent reduced sensibility on the skin on the left side of the chin 10-15 years after surgery.

Paper III

One patient was lost to follow-up. Thus, the material consisted of four women and four men. Mean age at surgery was 23.2 years (SE: 1.8, range: 18.2-33.4 years). Mean BMI was 24.2 kg/m^2 at the pre-surgical recording and 23.9 kg/m^2 at the post-surgical recording. Surgical setback ranged from 2.5-7.4 mm (mean 4.3 mm). The mean estimated total sleep time was 8.0 hours (range: 4.8-10.0 hours) at the pre-surgical recording, and 7.2 hours (range: 5.5-8.0 hours) at the post-surgical recording. AHI was between 0.1 and 2.5 events per hour before surgery, and between 0.3 and 3.3 events per hour after surgery. Hence, all AHI measurements both before and after surgery were below the threshold for mild OSA. Measurements of SpO$_2$ and ODI were within the normal range both before and after surgery, and no statistically significant change was observed in any of the respiratory variables after surgery. In one patient the snore index increased significantly after surgery, but the AHI and ODI were approximately unchanged. The mean ESS score was 9.9 (SE:0.9, range: 7-14) before surgery and 9.6

(SE:1.4, range 4-13) after surgery. The change in ESS was not statistically significant, and the ESS scores were not statistically significantly associated with the AHI scores before and after surgery. The OIDP frequency score statistically significantly decreased after surgery, indicating improved OHRQoL (p=0.034). No statistically significant association was observed between the amount of surgical setback and the change in any of the respiratory outcome variables.

GENERAL DISCUSSION

Study Design

In Paper I, lateral cephalograms and study casts were collected retrospectively from the patient archive (T0, T1 and T2) and compared with data collected at T3. Studies including retrospective data have the advantage of immediate access to the data (135). The dental casts and lateral cephalograms retrospectively collected and used for analyses in Paper I had been obtained using standardised methods, but there is a risk of collection bias concerning the positioning of the patients in the cephalostat and the bite registrations for the study casts. An advantage with the study design of Paper I is the long follow-up period. A prospective study with the same follow-up period would not have been possible within the time-frame of a PhD work. Studies with long follow-up periods are important because a predictable long-term result is essential and will benefit both clinicians and patients.

Paper II was primarily a survey study, but also included sensibility testing of the lip, chin and cheeks. The data was collected 10-15 years after surgery. The questionnaire included questions that required patients to recall from memory motives and concerns regarding a treatment they received 10-15 years earlier. In studies collecting information retrospectively, memory distortion is a potential risk of bias (136). There are two factors of primary importance when asking patients to recall information from memory. These are the length of time since the event took place, and how important the event was to the respondent. The human mind also acts selectively, keeping some parts of memories and discarding others (136). Some may argue that the patients' recall is affected such a long time after treatment. In a study on orthognathic patients completing the same five-item questionnaire before surgery and ten years later, only the answers to one of the questions differed significantly between the two time-points (137). The great impact of orthognathic treatment on patients' lives supports the assumption that the participants remember quite accurately concerns and experiences related to the treatment they received 10-15 years earlier. Also, most of the questions had the option do not know/do not remember to reduce the risk of recall bias.

In Paper III, a cohort was defined and followed prospectively. Due to the known exposure (mandibular setback surgery with the IVRO technique) before observing the outcome, cohort studies have the potential to indicate a causal relationship (135). Loss to follow-up is a challenge in prospective cohort studies, and should be below 20% because increased loss to follow-up reduces the validity of the study (138). Loss to follow-up in Paper III was 11%. The absence of a separate concomitant control group is a limitation of the study.

Participants

The subjects eligible for Paper I, II and III were based on purposive sampling, hence they were selected based on their previous or present jaw discrepancy, and fulfilment of additional inclusion criteria. Purposive sampling is convenient when rare conditions are studied, such as in the present project (139). Incentives is a method to reduce non-response rate (140-142), and scratch lottery tickets were provided with the intention of increasing the participation rate in Papers I and II. The subjects eligible for Papers I and II were residing in all parts of the country, and travel distance is a possible explanation for not participating. Participation in the study required a day off from work for most of the participants, and for some quite a long travel. No compensation was provided for the day off from work, but travel costs were covered for all participants. The selection of patients operated during a five-year period (1998-2002) was performed to achieve an acceptable number of patients eligible for study participation. The participation rate of 43% in Papers I and II is comparable with other long-term follow-up studies after orthognathic surgery (130, 143-145).

The participants in Papers I and II did not statistically significantly differ from the non-responders concerning distribution of residency, age at surgery or age at T3, but participation rate was statistically significantly higher among women. Women being more concerned about dental and facial appearance than men can be an explanation for this discordance (146, 147). The age distribution at surgery (mean 21.6, range: 17.1-45.6 years in Paper I and II) is representative of patients undergoing mandibular

setback surgery. The proportion of participants with higher education in Papers I and II was greater compared to the general population of Norway (148), but comparable with another study on orthognathic surgery patients (79). People's interest in and willingness to participate in studies are reported to be higher among people with higher social status (149). Apart from being away from work, participation had no financial consequences that could explain the non-participation rate in Papers I and II. The potential selection biases in Papers I and II, not knowing if the non-participants differ from the participants concerning the outcome variables, are difficult to overcome (140, 150) and can affect the external validity of the results.

Travel distance was a restricting factor for patient recruitment also in Paper III. Due to the practical consequences of four extra visits to the hospital (Sleep Centre), participation was restricted to patients living within an approximately one-hour drive from the hospital. During a one-year period, only 12 patients were eligible for study participation. The participation rate of 75% in Paper III was good, but the period for patient recruitment should preferably have been extended to include more patients. Only eight subjects were available for the statistical analyses in Paper III. To detect a statistically significant difference in the relatively small mean change of AHI after surgery with a significance level of 0.05 and a power of 0.8, a sample size of 85 would be required. However, to identify a statistically significant difference of clinical relevance, i.e. a mean value of AHI after surgery of five events per hour (the threshold for mild OSA) with the same standard deviation for the change in AHI as in the reported sample (SD:1.3), a sample size of only four patients would be needed, with a significance level of 0.05 and a power of 0.8 (Power calculation for paired t-test using Stata version 14 (Texas, USA)). Due to the small sample size in Paper III, the risk of type II errors (i.e. the chance of not detecting a significant change when there in fact is a real difference) is high. The patients in Paper III were young adults (mean age: 23.2, range: 18.2-33.4 years), and are representative of most patients operated with isolated mandibular setback surgery at Haukeland University Hospital.

Methods

Dental Cast Measurements

Dental casts are used in both the planning and the evaluation of treatment in orthodontics. Besides displaying dental status and irregularities, they also replicate the patients' occlusion, and hence are an invaluable tool in planning and evaluating orthodontic surgical patients. The ICC for the dental cast measurements were all above 0.92, indicating good intra-examiner agreement. Pre-surgical orthodontic treatment in Class III patients usually include expansion of the upper dental arch, compression of the lower dental arch, and decompensation of the inclination of the upper and lower incisors. Hence, inter-molar width, inter-canine width, arch depth and overjet were considered adequate measures of transverse and sagittal dental changes.

Cephalometric Measurements

Cephalometry was introduced to orthodontic treatment planning almost 90 years ago (151). The lateral cephalogram provides the orthodontist with important information such as the sagittal position and inclination of the maxilla and the mandible in relation to the anterior cranial base, facial height proportions and inclination and position of upper and lower incisors. A reference grid was included in the cephalometric analysis to measure changes in cephalometric landmarks over time and to get results comparable with previous studies on skeletal stability. In cephalometry, acquisition errors, technical errors and tracing errors are all potential sources of bias. Modern cephalostats have strict protocols on how to install the patient to achieve as correct and reproducible cephalograms as possible, and hence reduce the risk of acquisition and technical errors. Tracing errors are associated with the recognition of cephalometric landmarks. The intra-examiner agreement was good with an ICC above 0.90 for all measurements.

Questionnaire

The questionnaire used in Paper II had been used in a study by Trovik et al. evaluating combined orthodontic and SSO advancement surgical treatment 10-14 years after surgery in patients operated at the same university hospital as the subjects presented in this thesis (130). The reason for using the same questionnaire was to make comparisons with the study by Trovik et al. evaluating a different surgical technique and dentofacial deformity but with similar follow-up period (Paper II). All completed questionnaires included in Papers II and III were registered by one operator and checked by another operator to minimise the risk of errors in data registration.

The use of OHRQoL as an outcome measure is in accordance with patient-centred care, and together with clinical evaluations it enables clinicians to assess the effect of treatment protocols from the patients' perspective (70). With several evaluative tools, the clinicians can more accurately weigh the benefits and risks related to the treatment (70). The use of a validated tool to measure OHRQoL strengthens the validity of the result. Generic health-related tools are intended to measure the effect of different health conditions on QoL but may be insensitive in differentiating between diseases/conditions (2). As a result, generic oral health and condition-specific oral health-related tools have been developed. The OIDP index is a generic oral health-related tool used to measure OHRQoL and evaluates the possible oral impacts on eight different everyday performances (131). The measuring of behavioural impacts rather than feeling-state aspects is an advantage as behaviours are considered easier to measure (131). Other advantages are that the OIDP index is short and that it is validated in a Norwegian adult population (132). The variety of indices used to measure QoL is a challenge when comparing results from different studies because the indices may have different scoring systems and may not assess the same levels of oral impacts on QoL (152). The OIDP index was chosen for this project to make comparisons with the study by Trovik et al. evaluating SSO advancement surgery patients 10-14 years after surgery (130) and with the general adult population in Norway (132).

Respiratory Polygraphic Recording

Respiratory polygraphic recordings are not routinely performed before orthognathic surgical procedures, and few previous studies have examined the clinical effect of mandibular setback surgery on ventilation during sleep. As previously mentioned, in-laboratory PSG is the gold-standard for diagnosing OSA but is too resource-demanding to conduct for screening. The portable in-home respiratory polygraphic recording is more cost-effective and is widely used in the evaluation of patients examined for sleep-related breathing disorders. However, there is a risk of technical errors such as poor signal quality or incorrect attachment of the equipment, and hence the need for re-examinations (153). The patients in Paper III received thorough instructions at the Sleep Centre on how to attach the equipment. Incorrectly attached recording equipment was detected in one patient when the results were evaluated, and the patient had to conduct a new sleep recording. After several missed appointments to conduct the second post-operative sleep recording, the patient was excluded from the study. The Nox T3 device was chosen over other type 3 monitors because it is the device preferred at the Centre for Sleep Disorders at Haukeland from where the sleep recordings were coordinated and the results evaluated. To reduce the risk of collection bias, data recorded by the Nox T3 device were evaluated and scored by an experienced otolaryngologist with special expertise in sleep disorders. A validation study of the in-home Nox T3 device including eighty subjects demonstrated 95% sensitivity and 69% specificity compared to in-laboratory PSG when the threshold for OSA was set to AHI ≥ five events/hour (133). In Paper III, the aim was to test if the patients' AHI exceeded five events/hour, and for that purpose a high sensitivity (the probability that patients who actually have OSA are correctly diagnosed with AHI ≥ five events/hour) is more important than a high specificity (the probability that patients without OSA are correctly classified with AHI < five events/hour). When the cut-off was AHI ≥ five events/hour, 84.4% of the subjects were diagnosed with OSA with the in-home Nox T3 compared to 83.5% with the in-laboratory PSG in the validation study (133).

Statistical Methods

In Papers I and II, parametric tests were conducted for the continuous variables to evaluate either changes in mean values over time or changes in mean values between groups. If the continuous data are non-normally distributed, parametric tests can still robustly be performed as a test of mean values, as long as the sample size is greater than 20 for paired *t*-tests. If two-sample *t*-tests are conducted, the sample-size of each group should be greater than 15. If One-way ANOVA is conducted, and 2-9 groups are compared, each group should have more than 15 observations (154, 155). Parametric tests were preferred because they usually hold more statistical power compared to non-parametric tests (155). Non-parametric tests do not assume normal distributed data. However, the non-parametric test in general assumes symmetric distributions. Non-parametric tests will often lead to larger p-values than parametric (normal-based) tests and have a larger risk of type II error.

Despite the limited number of patients in Paper III, the Shapiro Wilk test only detected non-normal distribution in two of the measurements (change in snore index and change in OIDP score), on which non-parametric tests were applied. Due to the limited number of patients it was considered appropriate to report the data on an individual level in addition to mean values. Small sample sizes are a challenge for both parametric and non-parametric tests. Parametric tests can usually handle non-normal distributed data, but if the sample is small and the data are non-normal, a non-parametric test would be preferred, but the chance of detecting a significant change when one truly exists is reduced (the risk of type II error may increase). If the sample is small, but the data show a symmetric and approximate normal distribution, a parametric test will in general be more efficient (155).

Results

The aim of the Papers constituting this thesis was to subjectively and objectively measure different aspects of treatment outcome after combined orthodontics and mandibular setback surgery performed with the IVRO procedure. The objective measurements concerning skeletal changes, dental changes, and complications are important in ascertaining that the procedure is efficient and safe, and the subjective measurements are essential supplements in determining if the treatment is successful.

In Paper I, short-term (T1-T2), long-term (T1-T2), and total (T1-T3) mean skeletal anterior relapse measured at B-point were all within 20% of the mean surgical setback. These results are in accordance with previous studies evaluating stability after IVRO setback surgery reporting 10-15% anterior relapse 12-18 months after surgery (33-36), but contrary to the studies reporting a mean distal drift measuring 4-16% of the surgical movement one year after surgery (30, 31, 40). Previous studies reporting post-operative relapse or drift within 20% of the mean surgical setback have concluded that the post-surgical stability was good (35, 42, 156). Eggensperger et al. (Switzerland, 2005), evaluated long-term stability after SSO setback surgery in 12 Class III patients. They observed similar relative relapse during the total follow-up period as in Paper I (16% relapse between one week and twelve years after surgery), but most of the relapse was observed during the first six months after surgery (145). Joss and Thüer (Switzerland, 2008) reported relapse measuring 15% of the mean surgical setback between five days and 12.7 years after SSO setback surgery in 17 Class III patients, and most of the relapse occurred shortly after surgery (157).

The dental cast and cephalometric measurements in Paper I were reported with mean values, and mean values are the most commonly reported statistic in studies evaluating stability after orthognathic surgery. In samples with great variability, the use of mean values may mask relapse patterns in individual cases (158). Hence, reporting skeletal stability after orthognathic surgery with mean values has been criticized by some authors, and it has been suggested to rather report the relative chance of experiencing

a clinically significant relapse, i.e. relapse exceeding 2 mm (159). Skeletal changes up to 2 mm are considered by Proffit et al. to be within the range of method error, and not clinically significant. Changes between 2-4 mm are considered clinically significant, and changes of more than 4 mm are considered highly clinically significant as this is beyond what can be orthodontically compensated (40, 159). Only one patient in Paper I had an anterior skeletal relapse beyond 4 mm (4.2 mm) during the first postoperative year. Thus, the skeletal changes occurring between T1 and T2 are likely to be within what could be adjusted with post-surgical orthodontic treatment. Thirty-nine percent had a clinically significant relapse/drift (>2 mm) during the total follow-up period (T1-T3), similar to the findings of Mobarak et al. (Norway, 2000) reporting 36% of eighty subjects to have relapse of more than two millimetres three years after SSO setback surgery (53), but higher than Hågensli et al. (Norway, 2014) who reported 15% of 65 EVRO and 65 SSO patients to have skeletal changes >2 mm three years after surgery (38). Proffit et al. also emphasized the need to divide the post-surgical changes into changes occurring during the first year after surgery, and changes occurring after the first post-surgical year. The changes during the first post-surgical year are associated with the surgical healing, the short-term physiological adaptation and the post-surgical orthodontic treatment, while changes after the first post-surgical year are related to continued physiological adaptation and, in some patients, to residual growth (159). In Proffit and colleagues' hierarchy of stability comparing different orthognathic surgical procedures using rigid fixation, mandibular setback surgery was the least stable surgical movement during the first post-operative year, but the most stable movement in the long-term follow-up period (1-5 years after surgery) (159). Rigid fixation was not performed in the patients in Paper I, but similarly more relapse was observed during the first post-operative year (T1-T2) compared with the long-term follow-up period (T2-T3).

The most important factors in avoiding relapse after surgery are good dental occlusion (160) and a normal condyle-fossa relationship when the jaws are fixated (44). The position of the condyle after surgery depends on several factors including anatomy and

orientation of the proximal segment, the experience of the surgeon, movement of the distal segment, and method of fixation (44). Ueki et al. postulated that by changing the osteotomy line, the vectors of the muscles pulling on the proximal and distal segments will change (44). This may explain the different postoperative changes observed between procedures. Many studies are difficult to compare due to different protocols for radiographic evaluation during the follow-up period, and most likely non-identical position of the osteotomy lines. Also type and duration of IMF differ between studies and further complicate direct comparisons of the results from other studies evaluating the IVRO procedure. A good dental occlusion after surgery is dependent on the pre-surgical orthodontic treatment and the patient's dental status. Missing essential teeth needed to support the occlusion could alter the post-surgical stability and must be taken into account during pre-treatment planning.

A weak but statistically significant correlation was observed between amount of surgical setback and total relapse (T1-T3). It has been suggested that large movements of a single jaw is a predictor for relapse (161), however others have failed to find statistically significant correlations between the extent of surgical setback and amount of skeletal relapse in patients treated for mandibular prognathism (30, 156, 162). Yoshioka et al. observed that in patients with larger setbacks, the proximal segments exhibited more lateral flaring, and they emphasized that the amount of surgical setback and the anatomy of the gonial angle area should be considered before IVRO is elected as the surgical procedure (30). Advocates for the SSO and EVRO procedures accentuate that rigid fixation with plates and screws improve post-surgical stability (40, 163). Keeping the pre-surgical inclination of the proximal segment is a challenge with the SSO procedure. If the inclination of the proximal segment is controlled during plate-fixation in SSO surgery, anterior relapse may be greatly reduced (159, 164).

Longitudinal cephalometric studies have documented that natural dimensional changes of the face occur beyond the second decade of life (165-167). Kollias and Krogstad (Norway, 1999) observed reductions in mandibular prognathism and increased

mandibular plane angle (ML-NSL) in women between 22 and 42 years of age (165). Forsberg and Forsberg et al. (Sweden, 1979 and 1991) observed posterior rotation of the mandible in both men and women between 24 and 34 years and between 35 and 45 years (166, 167). Although the observed changes were small, they may counteract anterior skeletal relapse in studies evaluating mandibular setback surgery patients with such long follow-up period as in Paper I.

The reduction in horizontal overjet during the long follow-up period is similar to the findings of Wisth (Norway, 1981) between two and ten years after mandibular setback surgery (160). As previously mentioned, a stable occlusion when the jaws are fixated during surgery has been reported to be critical for post-surgical stability (160). Although the mean pre-surgical lateral expansion of the upper dental arch and compression of the lower dental arch almost completely relapsed during the first post-surgical year, the pre-surgical orthodontic treatment, and hence good occlusion when the jaws were fixated, may still have had a positive effect in the initial healing phase.

The participants' main reasons for seeking orthodontic-surgical treatment, to improve chewing function and appearance, were in agreement with previous studies (83, 89-93). The improvements in appearance, chewing function, self-confidence and bullying as reported on the VAS were in accordance with the results from the mandibular advancement surgery patients reported by Trovik et al (130). More participants experiencing the orthodontic treatment as the least pleasant part compared to the surgery and the healing phase was also reported by Nurminen et al. (Finland, 1999) (91). The high level of satisfaction with the orthognathic surgical treatment in Paper II corroborates the results from previous studies on orthognathic surgery patients (59, 77, 79-83), and the OIDP score being in the lower end of the scale for all participants indicated a good OHRQoL. When comparing with the results of Trovik et al. on patients evaluated 10-14 years after SSO advancement surgery, the IVRO mandibular setback patients were generally more satisfied, and OHRQoL was slightly better 10-15 years after surgery (130). Mandibular setback patients being more pleased with the

treatment result compared with mandibular advancement patients was also reported by Pahkala and Kellokoski (Finland, 2007) (81). The lack of correlation between degree of satisfaction with treatment and amount of surgical movement of the mandible was also in accordance with the study by Pahkala and Kellokoski (81). Compared to the adult Norwegian population, the OHRQoL was slightly poorer among the previous orthognathic patients (Paper II). Eighteen percent of the sample from the general Norwegian population between 16-79 years of age reported at least one oral impact on daily performance in the past six months (132) compared to 26% in Paper II and 39% in the study by Trovik et al. (130). That the majority of the participants in Paper II and other previous orthognathic surgery patients would have elected the same treatment again (79, 81-84, 91, 92) highlights the fact that orthognathic surgical treatment is appreciated.

The results of the sensibility tests confirmed the low incidence of neurosensory damage to the inferior alveolar nerve reported after IVRO, and this remains the key argument for choosing IVRO over SSO. However, there was a discordance between subjective and objective registration of neurosensory disturbance, as also observed by others (59, 130).

The morphological changes of the oropharynx after mandibular setback surgery is of great concern to clinicians due to reported cases of sleep apnoea after surgery (121-123). Traditionally, the effect of mandibular setback surgery on the pharyngeal morphology has been evaluated with lateral cephalograms, and several studies have reported reduction of the two-dimensional measurements of PAS (97-102). However, studies evaluating both PAS changes measured on lateral cephalograms and the clinical effect on ventilation report that despite a reduction in PAS after surgery, no statistically significant permanent deterioration in respiratory function is observed (97, 98, 118). CT analyses are more accurate in evaluating pharyngeal changes as they can depict both cross-sectional area and volume at different levels of the upper airways, and studies evaluating PAS with CT also indicate a reduction after mandibular setback

surgery (105-111). However, as with lateral cephalograms, CT-analyses do not provide information about the actual effect of surgery on the airflow through the upper airways. Computational fluid dynamics has been conducted by some authors to simulate the airflow changes in the upper airways after surgery (109, 110). Although these studies provide interesting findings, they are still not a measure of the actual clinical effect on the patients' ventilation.

The patients in Paper III were young, healthy adults without a history of OSA, and the majority had a BMI within the normal range. The results from the respiratory sleep recordings before and after surgery confirmed that none of the patients had clinical signs of OSA before surgery, and that the mandibular setback surgery did not induce obstructive sleep apnoea i.e. AHI above 5 events/hour in any of the patients. The changes in the respiratory variables AHI, ODI and SpO_2 were small and were within the range of normal night-to-night variations (117). However, it is important to note that the amount of surgical setback was mild to moderate (mean: 4.3 mm, range: 2.5-7.4 mm) in these patients. Estimated total sleep time was above the minimum time required for a proper analysis in all recordings (4 hours of technically adequate recording according to the guidelines from the American Association of Sleep Medicine (117)). The mean self-reported daytime sleepiness (ESS) both before and after surgery was higher compared to a study reporting ESS in a randomly selected sample of 2301 Norwegian adults (168). Due to the low AHI both before and after surgery in Paper III, and the lack of statistically significant association between AHI and ESS, the patients' self-reported daytime sleepiness could not be explained by obstructive apnoea and hypopnea during sleep in this small sample. A statistically significant improvement in OHRQoL after surgery was reported among the patients in Paper III, in accordance with previous studies (5, 86, 87). Due to the small sample size, the results in Paper III must be interpreted with care. Previous studies indicating that respiratory function is not statistically significantly altered after isolated mandibular setback surgery have included 16, 17, 21 and 30 patients (97, 98, 118, 120). Hence,

there is a need for more studies with larger patient groups. Paper III was initially intended to include a larger sample, but practical challenges made this difficult.

The PAS has been shown to decrease naturally in both men and women between 22 and 42 years of age (103), and the prevalence of OSA is reported to increase with advancing age (169). In Paper III and in previous studies evaluating ventilation during sleep before and after isolated mandibular setback surgery the post-surgical recording was conducted within one year after surgery (97, 98, 118, 120, 123), and it is important to note that the patients in Paper III were young adults. It may be that compensatory mechanisms can counteract the volume-reducing effect of surgery in young individuals, but the long-term effect of mandibular setback surgery on ventilation during sleep remains unknown. To compensate for the volume-reducing effect on the PAS after mandibular setback surgery, bi-maxillary surgery is recommended by several authors, particularly if predisposing factors for OSA are present or large surgical movements are needed (98, 100, 105, 123, 170, 171). Hochban et al. emphasized that surgical setbacks of more than 10 mm should be considered with care. Especially if PAS is less than 10-12 mm preoperatively and if the patient has a dolichofacial appearance they recommended considering maxillary advancement or bi-maxillary surgery instead (97). The patients in Paper III were young adults and most had a BMI within the normal range. None of them had a dolichofacial appearance and the setback was less than eight millimetres in all patients. These are possible explanations for not observing a clinically significant change in AHI in any of the patients in Paper III. Also, it has been suggested that due to an observed wider PAS in patients with a prognathic mandible compared to subjects with an orthognathic or retrognathic mandible (94, 95), the PAS is reduced to "normal" dimensions after single-jaw mandibular setback surgery (95).

The estimated prevalence of OSA defined by AHI ≥ 5 events/hour among Norwegian women and men between 30 and 65 years of age published in 2010 was 16%, and the prevalence of AHI ≥ 15 events/hour was estimated to be 8% (116). A significantly

higher prevalence of moderate to severe sleep disordered breathing was reported among 2121 men and women 40-80 years of age with a mean BMI of 25.6 kg/m^2 residing in Lausanne, Switzerland in 2015, where 23.4% of the women and 49.7% of the men had an AHI ≥ 15 events/hour (115). Possible explanations for the discrepancy in prevalence reported in the two studies is the different age range, and that the Swiss study used the revised and moderated criteria for hypopnea announced by the American Academy of Sleep Medicine in 2012 (using 3% instead of 4% drop in SpO$_2$) (172). Both studies show that sleep disordered breathing is common in the general population. It would have been beneficial to conduct in-home respiratory sleep recordings in all patients planned for mandibular setback surgery to avoid isolated setback surgery in patients with an undiagnosed pre-existing respiratory sleep disorder. There is a need for more studies investigating the clinical consequences of mandibular setback surgery on respiratory function and how to detect patients susceptible to postoperative OSA. In particular, the need for studies including large patient samples and longer follow-up periods is emphasized.

CONCLUSIONS

- o Skeletal and dental changes were observed during short-term and long-term follow-up periods, but most of the skeletal changes occurred during the first post-surgical year. The clinical result 10-15 years after mandibular setback surgery performed with the IVRO procedure was good in most of the patients.

- o The patients' main reasons for seeking treatment were to improve chewing function and for esthetical improvement.

- o A statistically significant improvement was reported for chewing function, appearance, self-confidence, speech and bullying.

- o 10-15 years after surgery the patients were satisfied with the treatment and the OHRQoL was reported to be good.

- o Mandibular setback surgery in the range of 2.5-7.4 mm did not induce OSA measured as AHI above five events per hour in the eight young, healthy, adult Class III patients presented in Paper III.

- o Within the limitations of Papers I, II, and III, the results justify the use of the IVRO procedure in the surgical treatment of mandibular prognathism. Due to the lack of evidence concerning the long-term impact of mandibular setback surgery on ventilation during sleep, large isolated mandibular setbacks should be considered with caution.

FUTURE PERSPECTIVES

o   To better compare the different techniques for mandibular setback surgery, there is a need for more and elaborated studies evaluating both stability and the patients' perspective after IVRO compared with SSO and EVRO. A prospective multi-centre study following patients operated with different surgical techniques for mandibular prognathism would produce larger patient groups and more accurate comparisons of the techniques.

o   The possible negative impact of mandibular setback surgery on ventilation during sleep is an important issue that needs further clarification. Continuing the data collection in Paper III to achieve a larger number of patients would increase the statistical power of the analyses and would also allow for subgroup analyses.

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Paper I

Skeletal and dental stability after intraoral vertical ramus osteotomy: a long-term follow-up.

Schilbred Eriksen E, Wisth PJ, Løes S, Moen K.

I

Clinical Paper
Orthognathic Surgery

Skeletal and dental stability after intraoral vertical ramus osteotomy: a long-term follow-up

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Abstract. The purpose of this study was to elucidate the long-term skeletal and dental stability after combined orthodontic and orthognathic surgical treatment of mandibular prognathism with the intraoral vertical ramus osteotomy (IVRO) as the surgical technique followed by 6 weeks of intermaxillary fixation (IMF). Thirty-six patients were included in the study. Mean age at surgery was 21.6 years. Lateral cephalograms and study casts obtained before the start of treatment (T0), and 8 weeks (T1), 1 year (T2), and 12.5 years (T3) after the operation were evaluated. Mean mandibular setback measured at point B was 8.3 mm. Between T1 and T2, a mean anterior relapse of 12% of the setback was observed. Between T2 and T3, the anterior relapse persisted, but decreased to 7% of the setback measured at point B. Despite dental adjustments in both jaws, a statistically significant reduction in overjet was observed during both observation periods. However, the change of the mandible in an anterior direction was small and of minor clinical importance for most of the patients. In conclusion these results indicate that combined orthodontic and orthognathic surgical treatment of mandibular prognathism with the IVRO as the surgical procedure followed by 6 weeks of IMF provides predictable and good long-term clinical results.

In skeletal Class III patients, the sagittal position of the mandible is more anterior than the maxilla when related to the anterior cranial base. This can be the result of a retrognathic maxilla, a prognathic mandible, or a combination of the two. Patients present with an Angle Class III molar relationship,[1] and have a negative overjet or edge-to-edge occlusion. Mild skeletal Class III malocclusions (when the patient is fully grown) can be treated with extractions and fixed appliances as a camouflage treatment. More severe skeletal Class III patients will need combined orthodontic and orthognathic surgical treatment to achieve a satisfying occlusal and aesthetic result.

The first surgical correction of malocclusion was described by Hullihen in 1849.[2] However, it was not until the beginning of the 1950s that orthognathic

surgery became a true specialty.[3] During these 100 years, several osteotomy designs to reduce mandibular prognathism were suggested. Today, the two most commonly used surgical techniques for repositioning of the mandible are the sagittal split ramus osteotomy (SSO) and the intraoral vertical ramus osteotomy (IVRO). The SSO technique was first described by Trauner and Obwegeser in 1955 (translated in 1957).[4] In 1964, Moose reported the cases of 25 patients treated successfully by intraoral subcondylar osteotomy.[5] This osteotomy was performed with a medial approach. The first intraoral subcondylar ramus osteotomy with a lateral approach was described by Winstanley in 1968.[6] Subcondylar ramus osteotomies were also performed prior to 1964, but then mainly with an extraoral approach. Winstanley's arguments for using the intraoral procedure were avoidance of an extraoral retromandibular scar and the minimized risk of damaging the mandibular branch of the facial nerve.

Considerable controversy remains concerning the most favourable treatment of mandibular prognathism. The main advantage of the IVRO over the SSO seems to be the low incidence of injury or damage to the inferior alveolar nerve. In a recently published literature review and meta-analysis comparing skeletal stability and neurosensory function between SSO and IVRO for mandibular setback, it was concluded that both techniques provide good stability, and that IVRO significantly decreases the risk of injury to the inferior alveolar nerve compared to SSO.[7] Other advantages of the IVRO over the SSO include technical simplicity, reduced surgical time, and the ability to reposition the condyle.[8] Several authors have also concluded that the IVRO, or the modified condylotomy, is a method of choice for relieving undesirable temporomandibular joint (TMJ) symptoms.[8–12]

In both the SSO and the extraoral vertical ramus osteotomy (EVRO), fixation of the proximal and distal segments with miniplates or screws allows almost immediate postoperative function, while the IVRO requires inter-maxillary fixation (IMF) for some weeks after the operation. Thus, for patients not tolerating IMF due to nasal congestion, asthmatic conditions, or mental illnesses, as well as patients who are underweight and for whom adequate nutrition is important, the SSO or EVRO would be beneficial.

Previous studies on skeletal stability after mandibular setback surgery with the use of the IVRO technique have reported both posterior drift and anterior

relapse of the mandible. Greebe and Tuinzing found a 16% posterior drift measured at pogonion 1 year after surgery.[13] Other investigations have reported anterior relapse of between 10% and 15.3% of the surgical setback at 12–18 months after the operation.[14–16] Lai et al. reported a posterior drift of 21% of the surgical movement measured at menton during the IMF period. From removal of the IMF to 1 year after surgery, there was an anterior relapse of the same amount as the initial posterior drift, resulting in a net posterior drift 1 year after surgery of 0.1%.[17] After 2 years of follow-up of the same patients, a further anterior relapse of 10.2% was observed.[18] These results indicate that a 1-year follow-up period is not sufficient to draw conclusions regarding skeletal stability after mandibular setback surgery.

In a meta-analysis performed by Al-Moraissi and Ellis on studies comparing skeletal stability after mandibular setback surgery by either SSO or IVRO, no statistically significant difference between the two techniques was found in the horizontal direction at 6–12 months after surgery. In the vertical direction, the results indicated that SSO showed greater stability than IVRO. However, the differences were small, and both techniques were considered to have good stability.[7] Wisth described the changes in facial morphology and dental arches at 10 years after the surgical correction of mandibular prognathism.[19] He concluded that the stability was fairly good for the majority of patients, but with a tendency towards sagittal relapse throughout the period.

Most previous studies on stability after mandibular setback surgery with the use of the vertical ramus osteotomy have used a follow-up period of 2 years or less. A few studies have used a follow-up period of between 3 and 5 years. It appears that only the one study by Wisth has had a follow-up period of more than 5 years.[19] Even though previous studies have indicated that most relapse occurs within the first year after surgery, it is the long-term skeletal and dental stability that determines whether or not the treatment procedure has been successful. Very few studies have included both dental cast and cephalometric analyses, and the

long-term dental and skeletal stability remains unclear.

The aim of this study was, therefore, to elucidate both the short-term and long-term skeletal and dental stability after combined orthodontic and orthognathic surgical treatment of mandibular prognathism with the IVRO as the surgical technique.

Materials and methods

Patients

Eighty-four patients with genuine mandibular prognathism underwent combined orthodontic and orthognathic surgical treatment during the years 1998–2002. The treatment was planned and coordinated by a regional orthognathic-surgical team, and the surgery was performed in the department of maxillofacial surgery at a university hospital. The mandibular surgical setback procedure was exclusively the IVRO. No maxillary surgery or genioplasty was performed. The pre- and postoperative orthodontic treatment was conducted by private orthodontists according to the treatment plans.

In 2012 the patients were contacted by mail and invited to attend a 10–15-year clinical and radiological follow-up examination. Thirty-seven patients (44.0%) were willing to participate in the study, 39 patients (46.4%) did not respond, six patients (7.1%) wanted to participate but were occupied during the time the data collection took place, and two patients (2.4%) were not interested . One of the 37 patients initially included was excluded due to a history of mandibular fracture during the long post-operation period. However, the fracture was not in relation to the operation site. The final study group of 36 patients comprised 24 females and 12 males. Their mean age at surgery was 21.6 years (range 17.1–45.6 years) (Table 1). For the youngest patients, a hand and wrist radiograph verified completed growth. The mean time between the operation and the long-term follow-up session was 12.5 years (range 9.7–14.5 years). Written informed consent was collected from all of the patients prior to enrolment.

The long-term follow-up session included a clinical examination of the

Table 1. Age distribution at surgery (years).

	Mean	SE	95% CI	Min.	Max.
All *n* = 36	21.6	0.9	19.6–23.5	17.1	45.6
Male *n* = 12	22.6	0.6	21.4–23.8	20.0	25.2
Female *n* = 24	21.0	1.4	18.2–23.9	17.1	45.6

SE, standard error; CI, confidence interval.

occlusion, examination of the masticatory musculature and TMJs, sensitivity testing of the lower lip and chin according to Leira and Gilhuus-Moe to detect any damage to the inferior alveolar nerve,[20] clinical photographs, and impressions for study casts. The radiological examination included a panoramic radiograph and lateral cephalogram. The material investigated further in this long-term stability study included dental casts and lateral cephalograms taken before the start of pre-surgical orthodontic treatment (T0), and at 8 weeks (T1), 1 year (T2), and 12.5 years (T3) after the operation.

Inclusion criteria

The inclusion criteria encompassed patients with genuine mandibular prognathism and no skeletal asymmetry or basal open bite. Comprehensive orthodontic treatment was performed before and after surgery for all patients. The surgical procedure was mandibular setback by IVRO technique with subsequent IMF for 6 weeks. No additional maxillary surgery or genioplasty was performed. Syndromic and medically compromised patients were not included. All patients had completed growth before the start of treatment.

Surgical procedure and IMF

All operations were performed by a consultant oral and maxillofacial surgeon. The surgical procedure using the IVRO technique was performed under general anaesthesia for all patients. An intraoral incision was made at the anterior border of the ramus. The lateral aspect of the ramus was exposed sub-periosteally from the sigmoid notch to the angle, and a subcondylar osteotomy was performed with an oscillating saw. The distal fragment was slid distally and placed medial to the proximal fragments. The distal fragment of the mandible was placed in the

planned postsurgical position and was stabilized to the maxillary dental arch by rigid IMF. Running sutures were used to close the wound. The IMF was made with a steel wire between five surgical hooks attached to the archwire in each dental arch. The hooks were placed in the midline, mesial to the canines and mesial to the first molars. The IMF was removed 6 weeks after the operation.

Dental cast variables

The dental cast measurements included overjet and overbite in addition to inter-canine distance, inter-molar distance, and arch depth in both jaws. The measurements were performed with a calliper and a ruler with a 0.5-mm measurement scale. Overjet was defined as the distance in millimetres from the buccal surface of the lower right or left central incisor to the incisal edge of the corresponding maxillary incisor on the occluded models. Overbite was defined as the vertical overlap of the upper central incisor on the corresponding lower central incisor measured in millimetres. The right or left central incisor was chosen depending on the tooth producing the largest value. The inter-canine distance was defined as the linear distance between the cusp tips of the contralateral canines, or in the event of wear, the distance between the centres of the worn surfaces. The inter-molar distance was defined as the linear distance between the tips of the mesiobuccal cusps of the contralateral first molars, or in the event of wear, the distance between the centres of the worn surfaces[15] (Fig. 1A). The arch depth was measured as the perpendicular distance from a tangent mesial to the first molars to the contact point between the central incisors (Fig. 1B). The dental casts obtained before the start of treatment (T0), and at 8 weeks (T1), 1 year (T2), and 12.5 years (T3) after the operation were analyzed.

Cephalometric variables

Tracings and the collection of data were performed using Facad 3.8.4.1 and Facad Collector 3.8.3.1 (Ilexis AB, Linköping, Sweden). The cephalograms taken at T0, T1, and T2 were analogue. These films were scanned at 300 dots per inch (DPI) resolution using an Epson Perfection V750 Pro scanner (Epson America, Inc. Long Beach, California, USA) and imported into Facad. The lateral head films taken in 2012 (T3) were obtained with a digital cephalostat coupled to Digora for Windows 2.8.109.465 software (Soredex, Tuusula, Finland). From Digora, the cephalograms were exported to Facad. All films were calibrated before tracing was performed.

To quantify the horizontal changes in the cephalometric landmarks, a reference grid was made with the x-axis being the nasion–sella line and the y-axis being a perpendicular through sella. The reference points and variables used are presented in Fig. 2 and Tables 2 and 3. Only hard tissue measurements were included in this study.

Statistical methods

The dental and cephalometric variables were described using the mean and standard deviation (SD) at each time point (T0, T1, T2, and T3). Linear models with robust variance estimates adjusted for clustering of observations were performed. The results were presented with 95% confidence intervals. A P-value less than 5% was considered statistically significant. All calculations were performed using Stata/IC 13.1 (StataCorp LP, College Station, TX, USA).

To test the intra-observer agreement, the cephalograms taken at T0 and T3 for 10 randomly selected patients (20 cephalograms in total) were traced twice at an interval of at least 4 weeks. To calibrate the dental cast analyses, 30 randomly selected dental casts were measured twice at an interval of at least 2 weeks. Except for the vertical position of menton at T0 in the cephalometric analysis, and the inter-molar distance in the upper jaw on the study casts, no statistically significant differences were found between the first and second measurements (paired t-test, $P < 0.05$).

Results

Dental cast analysis

Overjet

The mean overjet before the start of treatment (T0) was −2.4 mm. As expected, and due to the mandibular setback operation,
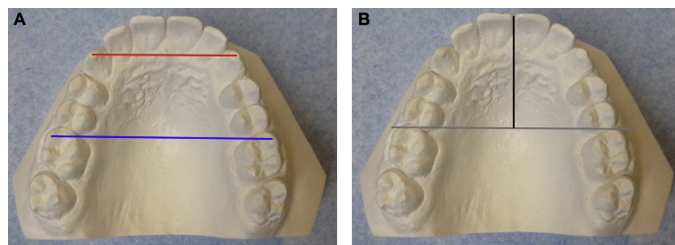
Fig. 1. Cast variables: (A) the red line illustrates the inter-canine distance and the blue line the inter-molar distance; (B) the black line illustrates the arch depth.

Fig. 2. Cephalometric reference points and lines.

Overbite

The mean overbite before the start of treatment was 1.5 mm. Between T0 and T1, mean overbite increased 0.1 mm. During the first postoperative year (T1–T2), there was a further mean increase in overbite of 0.4 mm. In the next 11.5 years (T2–T3), mean overbite decreased 0.4 mm. None of the overbite changes was statistically significant (Table 5).

Upper jaw

A slight, but insignificant increase in arch depth was seen from T0 to T1. Between T1 and T2 it decreased 0.5 mm. During the long-term follow-up period (T2–T3), arch depth increased 0.1 mm (Table 5). Both the inter-canine and inter-molar distance increased during the pre-surgical orthodontic treatment (T0–T1). However, during the first year after surgery they both decreased approximately to pre-treatment levels. The decrease in inter-molar distance was statistically significant (Table 5). From T2 to T3 there was a small and insignificant further decrease for both arch width measurements (Table 5).

Lower jaw

Arch depth in the lower jaw increased significantly from T0 to T1 ($P = 0.008$). However, from both T1 to T2 and T2 to T3 there was a small reduction in the lower arch depth. The inter-canine distance, as well as the inter-molar distance, in the lower jaw was reduced during pre-surgical orthodontic treatment (T0–T1). The inter-canine distance was stable the first year after the operation, while the inter-molar distance increased to pre-treatment values at 1 year after the operation. During the

the mean overjet changed significantly between T0 and T1 from −2.4 mm to 3.0 mm ($P < 0.001$). From 8 weeks after the operation (T1) to 1 year post-surgery (T2), the period for finishing orthodontic treatment, there was a statistically significant mean reduction in overjet of 0.8 mm ($P = 0.013$).

12.5 years after the operation (T3), there was a further statistically significant reduction in overjet of 0.6 mm ($P = 0.012$) (Tables 4 and 5). Two patients had an edge-to-edge incisor relationship, and one patient had a negative overjet of −1 mm at T3.

Table 2. Cephalometric reference points.

Anatomical structure	Abbreviation	Definition
Articulare	Ar	Intersection of posterior ascending ramus and inferior cranial base
Sella	S	Centre of sella turcica
Nasion	N	Most anterior point of the nasofrontal suture
Posterior nasal spine	PNS	The most posterior contour of the hard palate
Anterior nasal spine	ANS	The most anterior extremity of the intermaxillary suture
Spina marked	Sp′	Intersection between the nasion–menton line and the nasal line (NL)
Point A	A	Deepest point on the anterior curvature of the maxillary alveolar process
Apex of upper central incisor	Isa	Most apically positioned point on the root of the most labially positioned upper central incisor
Incision superius	Is	Incisal edge of the most labially positioned upper central incisor
Incision inferius	Ii	Incisal edge of the most labially positioned lower central incisor
Apex of the lower central incisor	Iia	Most apically positioned point on the root of the most labially positioned lower central incisor
Point B	B	Deepest point on the anterior curvature of the mandibular alveolar process
Pogonion	Pog	Most anterior point on the chin
Menton	Me	The lowermost point on the symphysis of the mandible
Gonion	Go	The outer point of the angle between the ramus and the corpus of the mandible

Table 3. Cephalometric variables.

Variables	Description
Sagittal relationships	
SNA	Angular description of the maxilla in relation to the anterior cranial base
SNB	Angular description of the mandible in relation to the anterior cranial base
ANB	Angular measurement of the anteroposterior relationship between the mandible and the maxilla
SNPog	Angular description of the chin in relation to the anterior cranial base
Pog–NB	Linear measurement of chin protrusion; the distance (mm) between pogonion and the nasion–point B (NB) line
hB	The perpendicular distance (mm) from point B to the *y*-axis
hPog	The perpendicular distance (mm) from pogonion to the *y*-axis
Vertical relationships	
Gonial angle	Angle between the ramus and the corpus of the mandible
ML/NSL	Angular measurement of the lower border of the mandible in relation to the anterior cranial base
ML/NL	Angular measurement of the vertical relation between the maxilla and the mandible
TFH	Total facial height; distance (mm) from nasion to menton
LFH	Lower facial height; distance (mm) from Sp′ to menton
Incisor position	
Inter-incisal	Angle between the long axis of the most labially upper and lower central incisor
Ils/NA	Angle between the long axis of the most labially upper central incisor to the nasion–point A (NA) line
Is–NA	Distance (mm) from the incisal edge of the most labially upper central incisor to the NA line
Ili/NB	Angle between the long axis of the most labially lower central incisor to the NB line
Ii–NB	Distance (mm) from the incisal edge of the most labially lower central incisor to the NB line

long-term follow-up period, the inter-canine distance decreased 0.3 mm, while the mean inter-molar distance continued to increase 0.8 mm ($P = 0.009$) (Table 5).

Cephalometric analysis

Pre-treatment (T0)

The mean ANB angle before the start of treatment was $-4.0°$. One of the inclusion criteria was that the patient had a genuine mandibular prognathism. Mean SNA was $81.3°$ and mean SNB was $85.3°$. The basal vertical relationships were neutral (mean ML/NL $23.9°$). Pre-treatment mean values for the incisor positions confirmed a dental compensation for the skeletal deviation. Upper incisors were proclined and slightly protruded (Ils/NA $28.1°$, Is–NA 5.5 mm) and lower incisors were retroclined and slightly retruded (Ili/NB $18.5°$, Ii–NB

2.5 mm) when compared to the Caucasian norm (Table 6).

Changes from T0 to T1

After surgery, the mean sagittal position of the mandible was orthognathic at T1. Highly statistically significant changes ($P < 0.001$) were seen for both linear and angular measurements of the sagittal position of the mandible (hB, hPog, SNB, and SNPog). The change in the horizontal position of point B (hB) from T0 to T1 indicated a mean mandibular setback of 8.3 mm. In the vertical direction, there was a highly statistically significant increase in total and lower anterior facial height (TFH and LFH) and inclination of the lower border of the mandible (ML/NSL) between T0 and T1. The change in lower incisor position was also statistically significant. The inclination in relation to the NB line increased $3.1°$, and the

distance between the lower incisors and the NB line (Ii–NB) increased 1.6 mm. The linear measurement of the chin protrusion (Pog–NB) increased 0.3 mm ($P = 0.004$) from before the start of treatment to 8 weeks after surgery (Table 7).

Changes from T1 to T2

From 8 weeks to 1 year after the operation, a small but statistically significant anterior relapse of the mandible was observed. SNB and SNPog increased $0.5°$ and $0.6°$, respectively. An increase of 1.0 mm for the horizontal position of point B and of 1.3 mm for point Pog indicated a mean relative anterior relapse of 12% for point B and 14% for point Pog. A highly statistically significant decrease was observed for both the lower and total anterior facial height, and also for the inclination of the lower border of the mandible. No statistically significant

Table 4. Descriptive statistics for dental cast measurements ($n = 36$) ($n = 19$ at T1).[a]

Variable	T0 ($n = 36$)		T1 ($n = 19$)[a]		T2 ($n = 36$)		T3 ($n = 36$)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Overjet	−2.4	2.2	3.0	1.2	2.2	0.9	1.6	1.0
Overbite	1.5	2.5	1.2	1.8	1.7	1.3	1.3	1.3
Arch depth UJ	25.2	2.4	24.7	2.7	24.9	2.7	25.0	2.8
13–23	32.5	3.5	32.0	3.1	33.2	3.3	33.1	2.8
16–26	50.3	3.9	50.2	3.0	50.6	3.8	50.4	4.0
Arch depth LJ	21.3	2.2	21.7	2.1	22.4	2.2	22.1	3.0
33–43	25.9	2.2	25.2	1.8	25.8	2.2	25.4	2.0
36–46	45.8	2.9	44.6	5.0	45.9	2.9	46.7	2.5

SD, standard deviation; UJ, upper jaw; LJ, lower jaw.
[a] At T1, the dental casts were missing for 17 patients. The mean values for the dental cast variables are for $n = 36$ at T0, T2, and T3, and for $n = 19$ at T1.

Table 5. Mean changes for dental cast measurements.

Variable	Total *P*-value[a]	T0 vs. T1 (*n* = 19)[b]			T1 vs. T2 (*n* = 19)[b]			T2 vs. T3 (*n* = 36)		
		Mean difference	SE	*P*-value	Mean difference	SE	*P*-value	Mean difference	SE	*P*-value
Overjet	<0.001	5.0	0.6	<0.001	−0.8	0.3	0.013	−0.6	0.2	0.012
Overbite	0.167	0.1	0.8	0.946	0.4	0.3	0.190	−0.4	0.2	0.061
Arch depth UJ	0.035	0.2	0.2	0.400	−0.5	0.3	0.101	0.1	0.2	0.692
13–23	0.525	0.3	0.6	0.643	−0.2	0.2	0.324	−0.1	0.3	0.622
16–26	0.099	0.7	0.6	0.261	−0.6	0.2	0.036	−0.2	0.4	0.717
Arch depth LJ	0.021	1.0	0.3	0.008	−0.1	0.2	0.622	−0.3	0.4	0.417
33–43	0.763	−0.5	0.5	0.386	−0.0	0.2	0.899	−0.3	0.3	0.177
36–46	0.096	−0.6	1.3	0.667	0.5	1.1	0.664	0.8	0.3	0.009

SE, standard error; UJ, upper jaw; LJ, lower jaw.
[a] The reported *P*-values for the overall tests for time are for *n* = 19. For *n* = 36, significant overall *P*-values were detected for overjet, arch depth LJ, and 36–46.
[b] In the regression analyses, the 19 patients with available study casts at T1 were included when comparing T0 to T1 and T1 to T2, and all 36 patients were included in the analyses of changes between T2 and T3. (Differences between those with missing information at T1 (*n* = 19) and those with complete data (*n* = 17) were tested, and there were no statistically significant differences for any of the variables at baseline.)

Table 6. Descriptive statistics for cephalometric measurements (*n* = 36).

Variable	*n*	T0		T1		T2		T3	
		Mean	SD	Mean	SD	Mean	SE	Mean	SD
SNA (°)	36	81.3	3.4	81.4	3.3	81.2	3.3	81.3	3.3
SNB (°)	36	85.3	4.0	80.3	3.8	80.8	3.8	81.1	4.0
ANB (°)	36	−4.0	2.7	1.1	2.5	0.4	2.4	0.2	2.6
SNPog (°)	36	86.6	4.2	81.8	4.0	82.4	3.9	82.9	4.2
Gonial angle (°)	36	130.2	6.0	129.1	6.4	128.2	6.0	129.1	5.3
ML/NSL (°)	36	31.1	5.3	35.7	5.5	34.6	5.3	34.4	5.5
ML/NL (°)	36	23.9	4.9	28.6	4.8	27.3	4.4	27.3	4.7
TFH (mm)	36	114.9	6.6	117.1	6.1	116.4	6.2	116.7	6.4
LFH (mm)	36	64.7	4.7	66.7	4.0	65.8	4.0	65.9	4.4
Inter-incisal (°)	36	137.4	10.9	129.4	9.6	129.9	9.7	131.7	10.0
Ils/NA (°)	36	28.1	7.9	27.9	8.8	28.5	8.5	27.2	9.6
Ili/NB (°)	36	18.5	6.0	21.6	5.6	21.2	4.9	20.9	6.1
Is–NA (mm)	36	5.5	2.6	5.5	2.8	5.7	2.9	5.6	2.9
Ii–NB (mm)	36	2.5	1.9	4.1	1.9	3.8	1.8	3.7	2.0
Pog–NB (mm)	36	2.5	1.7	2.8	1.6	3.0	1.7	3.3	1.8
hB (mm)	36	60.1	7.5	51.8	7.3	52.8	7.3	53.4	7.8
hPog (mm)	36	61.4	8.6	52.2	8.5	53.5	8.4	54.5	9.0

SD, standard deviation.

Table 7. Mean changes for cephalometric measurements (*n* = 36).

Variable	Total *P*-value	T0 vs. T1			T1 vs. T2			T2 vs. T3		
		Mean difference	SE	*P*-value	Mean difference	SE	*P*-value	Mean difference	SE	*P*-value
SNA (°)	0.048	0.0	0.1	0.779	−0.2	0.1	0.028	0.1	0.1	0.070
SNB (°)	<0.001	−5.0	0.2	<0.001	0.5	0.1	<0.001	0.3	0.2	0.044
ANB (°)	<0.001	5.0	0.2	<0.001	−0.7	0.1	<0.001	−0.2	0.1	0.208
SNPog (°)	<0.001	−4.9	0.2	<0.001	0.6	0.1	<0.001	0.5	0.2	0.010
Gonial angle (°)	0.037	−1.1	0.7	0.141	−0.8	0.6	0.153	0.9	0.6	0.142
ML/NSL (°)	<0.001	4.6	0.4	<0.001	−1.1	0.2	<0.001	−0.1	0.2	0.549
ML/NL (°)	<0.001	4.7	0.4	<0.001	−1.3	0.2	<0.001	−0.0	0.3	0.975
TFH (mm)	<0.001	2.2	0.3	<0.001	−0.7	0.1	<0.001	0.3	0.3	0.194
LFH (mm)	<0.001	2.0	0.3	<0.001	−0.9	0.1	<0.001	0.1	0.2	0.530
Inter-incisal (°)	<0.001	−8.0	1.5	<0.001	0.6	0.7	0.397	1.7	0.8	0.027
Ils/NA (°)	0.284	−0.1	1.1	0.900	0.5	0.5	0.279	−1.2	0.7	0.078
Ili/NB (°)	0.012	3.1	0.9	0.002	−0.4	0.6	0.470	−0.3	0.6	0.579
Is–NA mm	0.259	−0.0	0.3	0.994	0.3	0.2	0.057	−0.1	0.2	0.576
Ii–NB mm	<0.001	1.6	0.3	<0.001	−0.3	0.2	0.077	−0.0	0.2	0.904
Pog–NB mm	<0.001	0.3	0.1	0.004	0.2	0.1	0.002	0.3	0.1	0.002
hB (mm)	<0.001	−8.3	0.4	<0.001	1.0	0.3	0.001	0.6	0.3	0.031
hPog (mm)	<0.001	−9.3	0.4	<0.001	1.3	0.3	<0.001	1.0	0.3	0.005

SE, standard error.

changes in incisor positions were observed. The mean increase in chin protrusion of 0.2 mm was statistically significant (Table 7).

Changes from T2 to T3

Statistically significant changes for SNB and SNPog indicated a small relapse in anterior direction also during the long-term observation period (0.3° and 0.5°, respectively) (Table 7). An increase of 0.6 mm for the horizontal position of point B and of 1.0 mm for point Pog indicated a mean relative anterior relapse between 1 year and 12.5 years after the operation of 7% for point B and 11% for point Pog. The linear measurement of chin protrusion also continued to increase between T2 and T3 (0.3 mm, $P = 0.002$). No significant changes were seen for the vertical measurements. A statistically significant decrease was observed for the inter-incisal angle; however the retroclination of both upper and lower incisors did not reach significant levels.

Discussion

In this study, both dental casts and lateral cephalograms were used to analyze dental and skeletal changes from before the start of pre-surgical orthodontic treatment to 12.5 years after the mandibular setback operation. All patients had completed growth before the start of treatment. Therefore, the skeletal changes seen between T0 and T1 are expected to be the result of the surgical movement of the mandible. The dental changes observed during the same period are mostly due to the pre-surgical orthodontic correction. To evaluate dental and skeletal stability, the observation period was divided into short-term (8 weeks to 1 year after the operation, T1–T2) and long-term (1 year to 12.5 years after surgery, T2–T3). Some skeletal relapse of the mandible was observed in both the short-term and the long-term observation periods. However, the relapse was decreasing, indicating good long-term skeletal stability. Despite dental adjustments in both jaws, a reduction in overjet was observed during both observation periods.

Before the start of treatment, the mean overjet was −2.4 mm. Due to the surgical setback of the mandible, the overjet increased significantly to positive values between T0 and T1. Between 2 months and 1 year after surgery, there was a significant reduction in overjet of 0.8 mm. This reduction could be the result of surgical overcorrection that was reduced during the

postoperative orthodontic treatment, or it could be explained by the slight anterior skeletal relapse observed during the same period. A reduction in overjet during the first postoperative year was also reported by Halvorsen et al.[15] The overjet continued to decrease 0.6 mm between 1 year and 12.5 years after the operation. This reduction is probably due to the anterior skeletal relapse of the mandible observed during this period. Wisth also observed a similar reduction in overjet between 2 and 10 years after the setback operation.[19] The slight increase in overbite during the first post-surgical year is probably a result of orthodontic correction with the use of elastics. During the long post-operation period, the overbite was reduced to approximately pre-treatment values.

One aim of pre-surgical orthodontic treatment is to reduce the dental compensation by retroclining the upper incisors and proclining the lower incisors. The increase in lower arch depth between T0 and T1 is probably the result of this decompensatory pre-surgical orthodontic correction. Skeletal Class III patients often have a bilateral crossbite due to a wide lower dental arch. Slight expansion of the upper dental arch and compression of the lower arch is often part of the pre-surgical orthodontic treatment, in order to achieve good transversal occlusion when the mandible is repositioned. Good immediate postoperative intercuspation has been reported to be a critical factor for further skeletal stability.[19] In this study, both the inter-canine and inter-molar distance in the lower jaw was decreased during the pre-surgical orthodontic treatment (T0–T1), but at 1 year after surgery the inter-molar distance had relapsed to the same width as before the start of treatment. Interestingly, the inter-molar distance in the lower jaw continued to increase also during the long-term observation period. This continuing increase in mandibular posterior arch width concurs with the findings of Wisth,[19] and could be a result of molar cusp guidance. The slight increase in maxillary inter-canine and inter-molar width before surgery also relapsed to pre-treatment values 1 year after the operation.

One year after the operation (T2), all patients had completed the post-surgical orthodontic treatment. Approximately half of the patients had a bonded 3–3 retainer in the lower jaw. At the long-term follow-up (T3), only five patients still had the bonded retainer in place. Between T2 and T3, a small reduction of 0.3 mm in the lower inter-canine distance was observed. This finding correlates well with the inter-canine reduction of 0.36 mm occurring be-

tween 2 and 10 years after the setback operation reported by Wisth.[19] The reduction in inter-canine distance could be a dental compensation for the small anterior skeletal relapse seen during the same period. However, a reduction in inter-canine distance both in orthodontically treated and untreated subjects during young adulthood is normal. This reduction is of great clinical concern as it is closely related to lower incisor crowding.[21]

At T1 the results showed highly statistically significant changes from T0 for the sagittal position of the mandible and for the position of both upper and lower incisors. The aim of treatment was to normalize the sagittal relationships, and the orthognathic mean values of SNB and SNPog at 8 weeks after the operation were expected. Also, elimination of the dental compensation was achieved. The retroclination of upper incisors and proclination of lower incisors is important for post-surgical stability, and also allows for some dental compensation to occur post retention if necessary.

Previous studies on stability after mandibular setback surgery with the IVRO technique have shown both posterior drift and anterior relapse during the first 2 years after surgery.[13–15,22] Between 8 weeks and 1 year after the operation, a small but statistically significant mean anterior relapse of the mandible was observed. This relapse was 12% of the surgical setback for point B and 14% for point Pog, and is in agreement with previous reports.[14,15] It has been suggested that the postsurgical posterior drift observed in some studies is due to an improper condyle–fossa relationship during surgery or the IMF period, with the condyles displaced anteriorly. After surgery, the muscles will pull the condyles posteriorly into the fossa, resulting in a posterior movement of the mandible.[22] The anterior relapse observed in this study could indicate that the surgeon succeeded in holding the condyles in the fossa during fixation of the distal segment with IMF. Due to muscle adaptation, the expected postsurgical movement of the mandible is then in an anterior direction. A small and not statistically significant dental compensation in both jaws was observed during the first postoperative year.

The inclination of the lower border of the mandible increased significantly from the start of treatment to 8 weeks after the operation (T0–T1). This clockwise rotation of the distal segment during the first 8 postoperative weeks is in accordance with previous investigations, and is probably a result of vertical muscle traction in the jaw

angle area or a change in mandibular position guided by the occlusal plane.[15,16] However, due to the IMF, a mean dentoalveolar bite opening was not observed during this period. Between 8 weeks and 1 year after the operation, a counter-clockwise rotation of the mandible was observed, as also reported by Nihara et al.[16]

Between 1 year and 12.5 years after the operation, the statistically significant cephalometric changes observed were for the sagittal position of the mandible (SNB, SNPog, Pog–NB, hB, and hPog) and the inter-incisal angle. The change of the mandible in an anterior direction was small and of minor clinical importance for most of the patients. However, the results indicate that the protrusive mandible is part of a morphological and functional inter-relation that is life-long and is not fully modified by a surgical change in the position of the mandible.[19] We do not know if the long-term changes of the sagittal position of the mandible occurred early, late, or evenly throughout the observation period. However, the long-term changes were less than the changes observed during the first postoperative year, indicating that if the relapse is a continuous process, it proceeds very slowly. None of the patients needed re-treatment.

In conclusion, the results of this study show that combined orthodontic and orthognathic surgical treatment for mandibular prognathism with the IVRO as the surgical procedure followed by 6 weeks of IMF provides predictable and good long-term clinical results.

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Competing interests

The authors declare no conflicts of interest.

Ethical approval

Ethical approval was given by the regional ethics committee (REK Vest) (2011/1604/REK Vest). The study was conducted in accordance with the Declaration of Helsinki.

Patient consent

Not required.

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Paper II

Patient satisfaction and oral health-related quality of life 10-15 years after orthodontic-surgical treatment of mandibular prognathism.

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II

Clinical Paper
Orthognathic Surgery

Patient satisfaction and oral health-related quality of life 10–15 years after orthodontic-surgical treatment of mandibular prognathism

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Abstract. This study investigated 36 patients at 10–15 years after they had undergone mandibular setback surgery by intraoral vertical ramus osteotomy (IVRO) and subsequent intermaxillary fixation for 6 weeks. The patients completed a 37-item structured questionnaire to evaluate patient satisfaction and possible long-term effects of the treatment. Visual analogue scales were used to measure self-perceived changes in seven items concerning oral function and appearance. Oral health-related quality of life was assessed using the Oral Impacts on Daily Performance (OIDP) index. The main reasons for seeking treatment were to improve chewing function and appearance. The treatment had resulted in significant improvements regarding chewing function, appearance, bullying, and self-confidence in social settings (all $P < 0.05$). All patients were either very satisfied (61%) or reasonably satisfied (39%) with the treatment result. The mean OIDP frequency score was 8.49 on a scale from 8 to 40. Seventy-four percent of the patients reported no oral impacts on quality of life. In conclusion, 10–15 years after combined orthodontic and IVRO surgical treatment of mandibular prognathism, the patients were satisfied, and oral health-related quality of life was reported to be good.

Combined orthodontic and orthognathic surgical treatment is a well-established and accepted treatment option for patients with severe dentofacial anomalies. The main pre-treatment concerns of patients reported in the literature are impaired chewing function and dissatisfaction with their facial appearance[1–6]. It has been reported that people with facial deformities are often considered less intelligent, less attractive, less effective, less popular, and less employable[7], and there is pressure

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from society to fit the norm for facial attractiveness in the developed regions of the world[8,9].

It is normally recommended that patients wait until growth has ceased before undergoing orthognathic surgery. Thus, these patients go through the critical years including puberty and the later teens with a deviating facial appearance and sub-optimal oral function. This has been shown to negatively affect body image, self-esteem, and quality of life[10–12]. Several studies have found that after orthognathic treatment, the patients are satisfied[13–17], and their body image, facial body image, self-confidence, and oral health-related quality of life (OHRQoL) increase[12,14,16,18–23].

In this study, strict inclusion criteria were established to collect information about patients with genuine mandibular prognathism treated with single-jaw surgery consisting of the intraoral vertical ramus osteotomy (IVRO) technique followed by 6 weeks of intermaxillary fixation (IMF). When evaluating a treatment procedure, one should include the patient's perception of the treatment procedure, satisfaction with the treatment result, and OHRQoL. The need for more long-term studies addressing patient satisfaction and quality of life after orthodontic-surgical treatment, including differentiation by type of deformity and type of surgical technique, has been emphasized by several authors[14,20,21,23].

The main objectives of this study were to analyse the patients' self-perceived changes in seven items concerning oral function and appearance, and to report the patients' degree of satisfaction with the treatment outcome and their OHRQoL, all measured 10–15 years after surgery. Additional objectives were to report the patients' reasons for seeking orthodontic-surgical treatment and how they experienced the treatment they had received. Possible factors influencing patient satisfaction at 10–15 years after treatment were analysed.

Materials and methods

During the period 1 January 1998 to 31 December 2002, a total of 84 patients with genuine mandibular prognathism underwent mandibular setback surgery by IVRO technique at Haukeland University Hospital in Bergen, Norway. All patients had IMF for 6 weeks after surgery. No additional maxillary surgery or genioplasty was performed. Pre- and postsurgical orthodontic treatment was conducted in all patients. No syndromic or medically

compromised patients were included in this cohort. Also, patients with skeletal asymmetry or a basal open bite were excluded.

In 2012, these 84 patients who had undergone previous orthognathic surgery were contacted by mail and invited to participate in a 10–15-year follow-up study. They were asked to complete a 37-item structured questionnaire. Thirty-six patients returned the questionnaire and attended a clinical examination. Written informed consent was collected from all participants. Among the non-responders, one subject attended the clinical examination but did not return the questionnaire, six subjects (two women and four men) could not attend within the scheduled timeframe for the collection of data, two subjects (one woman and one man) did not wish to participate in the study, and 39 subjects (19 women and 20 men) did not respond to the invitation.

Questionnaire

The questionnaire included 30 closed-ended questions and seven questions requiring a response on a visual analogue scale (VAS). The participants also reported their level of education.

Pre-treatment concerns and motivation

The participants were asked to report their reasons for seeking orthodontic-surgical treatment and to state who had advised them to seek treatment: their dentist, their family, or by own initiative. They were also asked how concerned they were about their facial appearance before surgery, if they had felt that their facial appearance differed negatively from others, and if they had often thought about the position of their lower jaw.

Treatment and changes after surgery: 10–15 years in retrospect

The participants were asked about what they remembered as the most distressing part of the treatment: the orthodontic treatment or the healing after surgery including the 6 weeks of IMF. Concerning facial changes occurring after surgery, questions were included to determine whether they had noticed a change after surgery, and whether they had had any problems adapting to their new appearance. One question was included to measure whether they had experienced a change in self-confidence. Participants were also asked if they had experienced numbness in the lower lip or

jaw after surgery, and to report the eventual duration of any sensory disturbances.

Self-perceived effects of treatment

A VAS was used to measure the patients' self-perceived improvement or deterioration in seven items concerning oral function and appearance from before the start of treatment to 10–15 years after surgery. The patients were provided with two VAS for each item. Each VAS was presented as a 10-cm line with clearly defined anchors at each end. The left end indicated severe problems and the right end indicated no problems. The items included were chewing, digestion, headache, speech, appearance, bullying, and self-confidence in social settings. On the first scale, the patients were asked to remember how much trouble the item had caused them before treatment. On the second scale, they reported the situation at 10–15 years after surgery for the same item. The change for each item was measured in centimetres as the difference between the marks on the second and the first line.

Patient satisfaction 10–15 years after surgery

Respondents were asked to rank their satisfaction today with the treatment they had received 10–15 years earlier, and whether they would have asked for the same treatment again.

Oral health-related quality of life at 10–15 years after surgery

The frequency score of the Oral Impacts on Daily Performance (OIDP) index was used to measure the patients' OHRQoL[24]. This index has previously been translated into Norwegian and has been tested in a representative sample of the Norwegian population (age 16–79 years). It was found to be a valid and reliable instrument for use in the adult population in Norway[25].

The patients were asked if, during the past six months, they had been affected by any problems in their mouth or with their teeth in the following eight situations: eating and enjoying food, talking and expressing themselves clearly, cleaning their teeth, sleeping and relaxing, smiling and showing their teeth without being embarrassed, being emotionally stable and not being irritable, enjoying socializing with other people, and performing daily activities. The answers were rated on a 5-point scale: 1 = never or less than once a month, 2 = once or twice per month, 3 = once or twice per week,

4 = 3–4 times per week, and 5 = daily or almost on a daily basis. The OIDP frequency score was calculated by adding the responses to these eight questions, thus the score has a range of 8 to 40. A higher OIDP score reflects frequent episodes of oral impact on daily performance and a lower perceived OHRQoL. By merging categories 2 to 5, the OIDP scale is reduced to two categories, 0 = no impact (including original category 1) and 1 = at least one oral impact (including original categories 2–5). This dichotomized OIDP score ranges from 0 to 8.

Clinical examination

To detect any possible damage to the inferior alveolar nerve or the buccal nerve, sensitivity testing of the lower lip, cheeks, and chin was performed in all patients at the clinical examination 10–15 years after surgery. The test was performed according to the method of Leira and Gilhuus-Moe[26], and included the light touch test, two-point discrimination test, localization sensitivity, sharp–blunt differentiation, pin-prick sensitivity, and thermal stimuli.

Statistical methods

Descriptive statistics were used to report the age distribution and demographic characteristics of the participants and non-responders, and for the responses to the questionnaires. Logistic regression and Fisher's exact test were used to adjust for differences in age and gender, and also when testing for associations between responses to the different questions. The paired *t*-test was used when comparing the responses on the VAS. Comparisons of mean values for independent subgroups were performed using the two-sample *t*-test. The level of significance was set at 5%. Stata/IC 14.1 (StataCorp LP, College Station, TX, USA) statistical software was used for the analyses.

Results

Patient characteristics

The participation rate was 43% (36/84). Twenty-five subjects were women and 11 were men. The mean age of the participants at surgery was 21.5 years (range 17.1–45.6 years). These 36 participants were followed up for a mean period after surgery of 12.6 years (range 9.7–14.5 years); their mean age at the long-term follow-up examination (when the questionnaire was completed) was 34.0 years (range 27.2–59.8 years). The gender dis-

Table 1. Reasons for and initiator of treatment.

	%	*n*	Men (*n*)[a]	Women (*n*)[a]
Reasons for seeking treatment[b]				
To improve chewing function	69.4	25	9	16
To improve appearance	38.9	14	5	9
To reduce headache	13.9	5	2	3
To relieve pain in the TMJ	5.6	2	1	1
Other reasons	19.4	7	1	6
Initiator of treatment[b]				
Dentist	86.1	31	9	22
Family	16.7	6	2	4
Patient	22.2	8	4	4

TMJ, temporomandibular joint.
[a] No significant difference between genders.
[b] More than one response option could be reported.

tribution among the non-responders was 26 men and 22 women. Logistic regression analysis revealed that participation was significantly higher among women than among men (odds ratio 2.69, *P* = 0.033). However, there were no significant differences between participants and non-responders regarding age at surgery, age at the long-term follow-up examination, time since surgery, or distribution of residency.

Among the participants, 72% had a bachelor or master degree, while the remaining 28% had secondary school or high school as the highest level of education. No significant difference was found between the genders.

Pre-treatment concerns and motivation

The participants' main reasons for seeking orthodontic-surgical treatment were to improve chewing function (69%) and to improve appearance (39%). The complete list of the patients' reasons for seeking treatment is given in Table 1. For the majority of the patients (86%), the dentist

was the initiator of treatment (Table 1). Most patients (92%) remembered themselves to have been normally concerned with their appearance before surgery. Fifty percent of the patients occasionally regarded their own appearance negatively compared with others and 22% always regarded their own appearance negatively compared with others. Furthermore, 42% of the patients often thought about their jaw position before surgery.

Treatment and changes after surgery: 10–15 years in retrospect

Fifty-eight percent reported that the orthodontic treatment was the most distressing part of the treatment, while the healing and IMF after surgery was the most distressing part for 33%. All had observed a change in facial appearance after surgery. One patient had experienced problems adapting to this new appearance and four (11%) had minor problems adapting. Forty-seven percent had experienced a change in self-confidence after treatment. Four (11%) reported still having sensory dis-
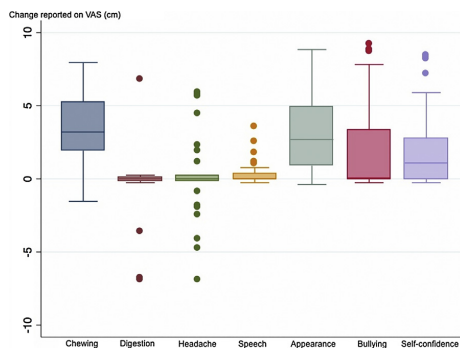

Fig. 1. Distribution of the self-perceived changes in seven items concerning oral function and appearance, from before the start of treatment to 10–15 years after surgery, reported using visual analogue scales (VAS). The box-plot shows the minimum, first quartile, median, third quartile, maximum, and outliers for each item.

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Table 2. Mean scores (cm) for the patients' self-perceived difficulties with seven items concerning oral function and appearance registered on visual analogue scales. Patient recollection of the degree of difficulty before treatment and at 10–15 years after treatment, and the difference between the two recordings (N = 36).

Difficulties with:	Before treatment		10–15 years after treatment		Difference[a]		
	Mean	95% CI	Mean	95% CI	Mean	95% CI	P-value
Chewing[b]	4.9	4.0–5.8	8.4	8.0–8.8	3.5	2.6–4.4	0.001
Digestion	8.2	7.6–8.9	7.9	7.2–8.6	−0.3	−1.0–0.4	0.428
Headache[c]	6.7	5.7–7.7	6.9	5.9–7.8	0.3	−0.7–1.2	0.530
Speech[c]	8.5	7.9–9.1	8.8	8.4–9.2	0.4	0.1–0.7	0.009
Appearance	5.2	4.3–6.2	8.4	7.9–8.8	3.1	2.2–4.0	0.001
Bullying	7.3	6.3–8.3	9.3	9.1–9.5	2.0	1.0–3.0	0.001
Self-confidence	6.4	5.3–7.4	8.3	7.7–8.8	1.9	1.0–2.8	0.001

CI, confidence interval.

[a] Some of the items had only 35 registrations on the scale illustrating the situation before treatment started. When calculating the difference and performing the t-test, n = 36 for digestion, appearance, bullying, and self-confidence, and n = 35 for chewing, headache, and speech.

[b] One patient did not answer this question (n = 35).

[c] One patient did not put a mark on the visual analogue scale representing the situation before treatment started (n = 35 before treatment and n = 36 at 10–15 years after treatment).

turbances 10–15 years after surgery, but sensory impairment was confirmed clinically in only one (3%) case at the clinical examination 10–15 years after surgery.

Self-perceived effects of treatment

Figure 1 presents side-by-side box-plots illustrating the self-perceived changes in seven items concerning oral function and appearance, recorded on the VAS. Chewing function and facial appearance were the two items with the greatest mean improvement (Table 2). The patients also reported a statistically significant reduction in bullying and significant improvement in self-confidence and speech

(Table 2). No significant differences were observed between the genders for any of the seven items. However, patient age had a statistically significant impact on the reported difference in digestion (P = 0.015) and bullying (P = 0.038) from before the start of treatment to 10–15 years after surgery. Problems with digestion increased with increasing age, while bullying was reduced.

Patient satisfaction 10–15 years after treatment

All of the patients were satisfied with the result of the treatment they had received. Sixty-one percent were very satisfied and

39% were reasonably satisfied. Women were more satisfied than men, but the difference was not statistically significant (odds ratio 1.48, P = 0.593). With regard to the question about willingness to undergo the same treatment again, 27 patients (75%) answered yes, one (3%) answered no, and eight (22%) were uncertain.

Possible factors influencing patient satisfaction 10–15 years after treatment

A positive significant association was observed between being very satisfied with the treatment and experiencing a change in self-confidence (Table 3).

When comparing the patients' degree of satisfaction with their self-perceived changes recorded by VAS, those who were very satisfied with the treatment at 10–15 years after surgery reported significantly greater improvements in appearance and self-confidence, and reduced bullying compared to patients who were only reasonably satisfied (Table 4). No statistically significant association was found between level of education and the degree of satisfaction with treatment (P = 0.932).

Oral health-related quality of life 10–15 years after treatment

The mean OIDP frequency score was 8.49 (standard error (SE) 0.18, range 8–12). The score was 8.7 (SE 0.40, range 8–12) for the men and 8.4 (SE 0.20, range 8–12) for the women. Twenty-six percent of the patients reported at least one sociodental impact on quality of life during the

Table 3. Association between covariates and satisfaction with treatment.

	Very satisfied (n = 22)		Reasonably satisfied (n = 14)		OR	95% CI	P-value[a]
	[%]	n	[%]	n			
Why did you seek treatment?[b]							
To improve chewing function	77.3	17	57.1	8	2.55	0.60–10.92	0.273
To improve appearance	50.0	11	21.4	3	3.67	0.80–16.86	0.160
Did you often think about the position of the lower jaw before surgery? (n = 31)	19		12				
Yes	36.4 [42.1]	8	50.0 [58.3]	7			
No	50.0 [57.9]	11	35.7 [41.7]	5	1.93	0.44–8.33	0.473
Have you noticed a change in your self-confidence? (n = 36)							
Yes	63.6	14	21.4	3			
No	36.4	8	78.6	11	6.42	1.37–30.05	0.019
What was the most distressing part of the treatment? (n = 33)	20		13				
Orthodontic treatment	59.1 [65]	13	57.1 [61.5]	8			
Surgery and IMF	31.8 [35]	7	35.7 [38.5]	5	1.16	0.27–4.93	0.999

OR, odds ratio; CI, confidence interval; IMF, intermaxillary fixation.

[a] Fisher's exact test was used.

[b] The patients could answer more than one alternative for this question. To improve chewing function and appearance were the two most frequent motives for seeking treatment.

Table 4. Mean values (cm) of changes in seven items concerning oral function and appearance measured by visual analogue scale, and the association with the degree of satisfaction with treatment.

	n	Very satisfied		Reasonably satisfied		*P*-value[a]
		Mean	95% CI	Mean	95% CI	
Chewing	35	3.9	2.8–5.0	2.9	1.2–4.5	0.247
Digestion	36	−0.2	−1.2–0.8	−0.4	−1.5–0.6	0.700
Headache	35	1.0	−0.2–2.1	−0.8	−2.6–0.9	0.063
Speech	35	0.4	0.0–0.8	0.3	−0.1–0.8	0.845
Appearance	36	4.0	2.8–5.3	1.7	0.6–2.8	0.010
Bullying	36	3.0	1.5–4.4	0.5	−0.3–1.3	0.014
Self-confidence	36	2.7	1.4–4.0	0.6	0.0–1.3	0.018

[a] The two-sample *t*-test was used for the analyses.

past six months (Table 5). There was no significant difference between men and women (*P* = 0.393), and age did not significantly influence OHRQoL for these patients (*P* = 0.472). Reporting of at least one oral impact on quality of life did not affect the degree of satisfaction with treatment (*P* = 0.712).

Discussion

The success rate of corrective surgical procedures is often measured in terms of the degree of stability, pain relief, or improved function. In recent decades, more attention has been given to including the patient's opinion of the surgical result, their wellbeing, and the benefits of orthognathic surgery to quality of life[12,14,20–23,27]. Great emphasis has been placed on the patient's primary motive for seeking treatment and whether their expectations are realistic. If the patient's realistic goals are achieved, they will most likely be satisfied with the treatment result[13].

This study recruited participants 10–15 years after surgery, who came from all regions of the country. The participation rate was regarded as acceptable considering the time span since treatment was completed, and is in accordance with the rates reported in other long-term clinical follow-up studies on orthognathic patients[28,29]. The level of education of the participants was higher compared to the distribution in the same age group in the general population of Norway[30]. In a study including 108 orthognathic patients, Chen et al. also reported an over-representation of patients with a higher level of education, and the ratio (68/32) was approximately the same as in the present study[13]. The increased interest for participation among women may be explained by women being more concerned about their facial and dental appearance than men[31,32].

An improvement in chewing function as the patients' primary motive for seeking orthodontic-surgical treatment, followed by appearance, is in accordance with the results from previous studies[1–3]. However, other studies have reported an improvement in appearance as the primary reason for orthognathic patients seeking treatment[4,5]. The dentist was the initiator of treatment for the majority of the patients, which is consistent with other studies[15,17,28].

More patients found the orthodontic treatment to be the most distressing part of the treatment when compared to the healing after surgery, including six weeks of IMF. This may partly be explained by the longer duration of the orthodontic treatment, but it may also indicate that the IMF was well tolerated by most of the patients. In a study by Nurminen et al.,

the orthodontic treatment was also most frequently reported as the least pleasant part of the treatment[3]. Most patients had no problems accepting their new appearance after surgery, as also reported by Athanasiou and colleagues[4]. As reported in the literature, the occurrence of damage to the inferior alveolar nerve or the buccal nerve caused by the IVRO procedure is low compared with the occurrence of damage with the sagittal split osteotomy technique[33,34]. One patient in this study (3%) was confirmed to have persistent reduced sensitivity of the skin on the left side of the chin at 10–15 years after surgery. The main surgical advantage with the IVRO technique is that the inferior alveolar nerve is not affected. However, if the osteotomy is performed in an anterior position, direct trauma to the nerve may occur, either by the osteotomy itself or during repositioning of the distal fragment. Damage to the buccal nerve may occur if the incision is made too high on the ramus.

Problems with chewing, appearance, bullying, and self-confidence all showed statistically significant improvements, as measured on the VAS. This is consistent with the results of Trovik et al., who reported a study on surgical patients treated for mandibular deficiency at 10–14 years after surgery[28].

The high degree of satisfaction among the patients in the present study may reflect the improvements in chewing and appearance – the two main reasons for seeking treatment. Statistically significant self-perceived improvements from before treatment to 10–15 years after surgery were shown for both. Although 'to improve chewing' was the most frequently reported reason for seeking treatment, the results of this study indicate that the positive change in appearance had a greater impact on the patients' degree of satisfaction. The majority of the patients would have requested the same treatment again. This is in agreement with previous studies[3,4,6,13,16–18].

A change in facial appearance may affect social interactions, relationships, and employment settings[18]. Previous studies have reported the proportion of orthognathic patients who perceived improved self-confidence after treatment to be between 32% and 81%[3,16,18,35–37]. Almost 50% of patients in the present study reported a change in self-confidence after treatment, and the statistically significant association with being very satisfied with the treatment result is consistent with the findings of Pahkala and Kellokoski[16]. The statistically significant associations be-

Table 5. Relative distribution of the OIDP items by satisfaction with treatment (*n* = 35[a]).

OIDP item	Very satisfied % (*n*) *n* = 21	Reasonably satisfied % (*n*) *n* = 14	All % (*n*) *n* = 35[a]
At least one oral impact	28.6 (6)	21.4 (3)	25.7 (9)
Cleaning teeth	19.0 (4)	0	11.4 (4)
Speaking	4.8 (1)	7.1 (1)	5.7 (2)
Sleeping	4.8 (1)	7.1 (1)	5.7 (2)
Smiling	0	14.3 (2)	5.7 (2)
Eating and enjoying food	0	0	0
Emotional stability	0	0	0
Social contact	0	0	0
Performing daily activities	0	0	0

OIDP, Oral Impacts on Daily Performance.
[a] One patient incorrectly completed the OIDP questions and was excluded.

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tween self-perceived change in appearance, reduction in bullying, and improved self-confidence in social settings and being very satisfied with treatment, accentuates the importance of the psychosocial impact of orthognathic treatment on patient wellbeing long after treatment is completed.

Memory distortion entails an important risk of bias in retrospective studies[38]. However, one would assume that the orthognathic treatment provided was of such great significance in the patients' lives (the years waiting for treatment, the treatment itself, and the changes after surgery) that the memory is relatively accurate. Lazaridou-Terzoudi et al. tested the validity of the answers from 134 orthognathic patients who had answered the same five-item questionnaire 10 years earlier[39]. Except for the motives for seeking treatment, for which aesthetics was assigned more weight retrospectively than at the time of surgery, no statistically significant differences were found between the answers given on the two occasions[39]. These results support the present authors' assumption that participants remember quite accurately concerns and experiences related to the orthognathic treatment they received 10–15 years earlier.

Several studies have concluded that orthodontic-surgical treatment improves quality of life for the patients[12,14,21–23]. However, there is little information about quality of life after mandibular setback by the IVRO technique and subsequent IMF. As stated by Soh and Narayanan in their systematic review of 2013, there is a need for more long-term studies using validated tools and focusing on different surgical techniques[14]. In the present study, the frequency score of the OIDP index[24] was used to measure the participants' OHRQoL 10–15 years after mandibular setback by the IVRO technique. An advantage of the OIDP index is that it measures behaviours rather than affective aspects, and by using only the frequency score, the index is short compared with other indices. The mean OIDP frequency score for the patients in this study was low, and slightly lower than that of the patients treated with a sagittal split osteotomy for mandibular deficiency (8.49 vs. 10.27) reported by Trovik and colleagues[28]. Seventy-four percent of the patients reported no oral impact on daily performance during the past six months, compared with 61% of the patients in the study by Trovik et al. These results indicate that OHRQoL is good for surgical Class III patients 10–15 years after surgery. OHRQoL was

slightly poorer than that reported for the general population in Norway, where 81.7% of the study population aged 16–79 years had no oral impact on quality of life[25], but slightly better than that of the orthognathic patients treated for mandibular deficiency[28].

In conclusion, 10–15 years after combined orthodontic and surgical treatment using the IVRO technique and six weeks of IMF, the patients were satisfied with the treatment outcome, and their OHRQoL was reported to be good. A statistically significant improvement was reported for chewing function, appearance, bullying, and self-confidence, as measured with the VAS instrument. The patients' main reasons for seeking treatment, i.e. to improve chewing function and facial appearance, were also the items with the greatest mean improvement reported by the VAS. The patients who were very satisfied with the treatment outcome reported significantly greater improvements in appearance and self-confidence and reduced bullying compared to the patients who were reasonably satisfied.

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Competing interests

The authors have no conflicts of interest to declare.

Ethical approval

Ethical approval was given by the Regional Committee for Medical and Health Research Ethics (REK Vest) (2011/1604/REK Vest). The study was conducted in accordance with the Declaration of Helsinki.

Patient consent

Not required.

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Appendix I

FORESPØRSEL OM Å DELTA I FORSKNINGSPROSJEKT ANGÅENDE KJEVEOPERASJON

BAKGRUNN:

Tilbakeføring av underkjeven (intraoral vertikal subkondylær osteotomi, IVSO) er et vanlig kjevekirurgisk inngrep for å behandle store underbitt. Det var denne operasjonen du hadde for ca 10 år siden. Med dette forskningsprosjektet ønsker vi å belyse langtidsresultatene etter en slik operasjon, og om det eventuelt kan ha oppstått bivirkninger til behandlingen. Vi håper derfor at flest mulig er villige til å komme til Bergen for å delta i en 10 års kontroll etter operasjonen.

HVA KREVES DET NÅR DU BLIR MED PÅ FORSKNINGSPROSJEKTET?

Du vil bli undersøkt på Odontologisk klinikk- Seksjon for Kjeveortopedi (Odontologen), Årstadveien 17, 2.etg. Her vil vi ta to nye røntgenbilder av deg, undersøke tenner, slimhinner og kjeveledd samt ta avtrykk til nye gipsmodeller. Du vil også bli bedt om å fylle ut et spørreskjema. Dette får du tilsendt på forhånd. Hele undersøkelsen tar ca en time. Innsamlet materiale vil sammen med din journal, gamle røntgenbilder og tidligere studiemodeller bli brukt i forskningsprosjektet. Undersøkelsesopplysningene får et nummer slik at du er helt anonym.

HVA FÅR DU IGJEN FOR DIN INNSATS?

Undersøkelsen vil vise hvor stabilt behandlingsresultatet har vært hos deg og om uønskede effekter kan ha oppstått. Du vil få beskjed dersom vi finner noe galt med tenner eller kjever. Deltagelse vil bli belønnet med 5 Flax-lodd.

Alle reiseutgifter vil bli dekket av oss, men du må selv ordne med reisen, ta vare på alle kvitteringer og sende oss en reiseregning.

Det er selvsagt frivillig å delta i undersøkelsen, men vi ber deg uansett om å bekrefte at du har fått dette brevet enten ved å sende SMS til Tannlege/universitetsstipendiat Elisabeth Eriksen på tlf. 922 58 495 eller sende henne en mail på adresse: elisabeth.m.eriksen@iko.uib.no. Det er hun som vil gjennomføre de aktuelle undersøkelsene. Vi vil da avtale time for 10 års kontroll. Dersom du ønsker det, vil du senere få en rapport om resultatene fra forskningsprosjektet. Vi ber deg også gi beskjed dersom du ikke ønsker å delta.

Med vennlig hilsen

Sigbjørn Løes
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Prosjektet støttes av:
Professor Per Johan Wisth, Kompetansegruppen for orthognatisk kirurgi

SAMTYKKEERKLÆRING:

Jeg har mottatt skriftlig og muntlig informasjon og sier meg villig til å delta. Jeg er klar over at det er frivillig å delta og at jeg når som helst kan trekke meg fra deltakelse, uten å oppgi grunn og uten at det får konsekvenser for senere behandling.

Dato, pasientens underskrift

Undertegnede tannlege bekrefter at pasienten har mottatt og lest denne forespørsel om deltakelse i overnevnte forskningsprosjekt.

Dato, tannlegens underskrift

UNDERSØKELSE OM MOTIVASJON OG TILFREDSHET MED ORTOGNAT-KIRURGISK BEHANDLING ETTER 10-15 ÅR

*Undersøkelsen besvares ved å krysse av **ett** svaralternativ, dersom du ikke spesifikt bli bedt om å avgi flere svar. Dersom det er noe du lurer på kan du gjerne diskutere dette når du kommer til kontrolltimen.*

DITT BEHANDLINGSBEHOV

1. Hvorfor søkte du behandling?
   (Sett flere kryss om nødvendig)

1 ☐ For å kunne tygge bedre
2 ☐ Misfornøyd med utseende
3 ☐ For å bedre uttale
4 ☐ Problemer i bihulene / øvre luftveger
5 ☐ Problemer med hodepine
6 ☐ Mindre smerter i kjeveleddet
7 ☐ Mindre problemer med sår i ganen
8 ☐ Andre grunner
9 ☐ Vet ikke / husker ikke

2. Hvem rådet deg til å søke behandling?
   (Sett flere kryss om nødvendig)

1 ☐ Tannlegen
2 ☐ Familien
3 ☐ Eget initiativ

FØR OPERASJONEN

3. Før operasjonen - Følte du ofte at ditt utseende avvek negativt fra andres utseende?

1 ☐ Ja
2 ☐ Ja, en gang i blant
3 ☐ Nei
4 ☐ Vet ikke / husker ikke

4. Før operasjonen – Tenkte du ofte på kjeveposisjonen din?

1 ☐ Ja
2 ☐ Nei
3 ☐ Vet ikke / husker ikke

5. Før operasjonen - Opplevde du noen ganger problemer som du relaterte til bittfeilen - i kjæresteforhold eller i andre nære relasjoner til mennesker?

1 ☐ Ja
2 ☐ Ja, en gang i blant
3 ☐ Nei
4 ☐ Vet ikke / husker ikke

6. Før operasjonen – I hvor stor grad var du opptatt av ditt utseende?

1 ☐ Helt normalt
2 ☐ Mer opptatt av utseende enn folk flest
3 ☐ Mindre opptatt av utseende enn folk flest

UNDER OG ETTER BEHANDLINGEN

7. Hadde du smerter mens reguleringen pågikk?

1 ☐ Ja
2 ☐ Ja, men bare ubetydelig
3 ☐ Nei
4 ☐ Vet ikke / husker ikke

8. Hadde du smerter etter operasjonen?

1 ☐ Ja
2 ☐ Ja, men bare ubetydelig
3 ☐ Nei
4 ☐ Vet ikke / husker ikke

9. *Har du opplevd nummenhet i leppene og/eller i kjevene etter operasjonen?*

1 ☐ Nei
2 ☐ Vet ikke / husker ikke
3 ☐ Ja

Dersom du svarte ja:
Hvor lenge etter operasjonen opplevde du nummenhet?:

1 ☐ 0-4 uker
2 ☐ 5 uker - 6 mnd
3 ☐ 7 mnd - 1 år
4 ☐ er fortsatt nummen

10. *Forandret utseende ditt seg etter operasjonen?*

1 ☐ Ja
2 ☐ Ja, men bare ubetydelig
3 ☐ Nei   Gå videre til Sp.nr.23
4 ☐ Vet ikke / husker ikke

11. *Hadde du problemer med å venne deg til ditt nye utseende etter operasjonen?*

1 ☐ Ja
2 ☐ Ja, men bare ubetydelig
3 ☐ Nei
4 ☐ Vet ikke / husker ikke

12. *La dine familiemedlemmer eller venner merke til at ditt utseende forandret seg etter operasjonen?*

1 ☐ Ja
2 ☐ Nei
3 ☐ Vet ikke / husker ikke

13. *Har du lagt merke til forandringer i din selvsikkerhet?*

1 ☐ Nei
2 ☐ Ja

14. *Hvilken del av behandling var verst; reguleringen eller tilheling etter operasjonen?*

1 ☐ Jeg opplevde ingen problemer
2 ☐ Reguleringen var verst
3 ☐ Operasjonen m/tilheling var verst
4 ☐ Vet ikke / husker ikke

TILFREDSHET

15. *Hvor fornøyd er du – i dag - med behandlingen?*

1 ☐ Svært fornøyd
2 ☐ Relativt godt fornøyd
3 ☐ Ikke fornøyd

16. *Alt tatt i betraktning, var totalbelastningen under behandlingen:*

1 ☐ Mindre enn forventet
2 ☐ Som forventet
3 ☐ Større enn forventet

17. *Ville du ha bedt om den samme behandlingen "en gang til"?*

1 ☐ Ja
2 ☐ Nei
3 ☐ Vet ikke

LIVSKVALITET

I løpet av de siste 6 mnd., har problemer i munnen eller med tennene gitt deg problemer i følgende situasjoner:

18. *Spise og nyte maten?*

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

19. *Snakke og uttrykke deg tydelig?*

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

20. *Tannrengjøringen?*

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

21. Å sove og slappe av?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

22. Å smile og vise tenner uten å bli brydd?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

23. Å være følelsesmessig stabil uten å bli irritabel?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

24. Å glede deg over samvær med andre mennesker?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

25. Å utføre daglige gjøremål?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

BAKGRUNNSINFORMASJON

26. Fødselsår?

☐

27. Hvilken skolegang / utdannelse er det høyeste utdannelsesprogrammet du har eksamen fra?

1 ☐ Grunnskolen (maks. 10 år)
2 ☐ Videregående skole (maks. 13 år)
3 ☐ Lavere grad universitetsutdannelse/
   høyskoleutdannelse (maks. 15 år)
4 ☐ Høyere grad universitetsutdannelse/
   høyskoleutdannelse (18 år skolegang/studier)
5 ☐ Annet; spesifiser:

……………………………………………………...

OM FORANDRINGER: - FØR – OG ETTER - BEHANDLINGEN

På neste side skal du sette et kryss på LINJE 1 som symboliserer din grad av problemer FØR behandlingen, og deretter et kryss på LINJE 2 som viser hvordan du opplever problemene NÅ. Eksempelet under viser ditt svar når X1 = "noen problemer" og når X2 er "nærmest ingen problemer".

LINJE 1   store problemer |--------------------X1--| absolutt ingen problemer

LINJE 2   store problemer |--X2---| absolutt ingen problemer

28.
Tyggeproblemer
før operasjonen:

store problemer |---| absolutt ingen problemer

Tyggeproblemer
i dag:

store problemer |---| absolutt ingen problemer

29.
Problemer med
fordøyelsen før operasjonen:

store problemer |---| absolutt ingen problemer

Problemer med
fordøyelsen i dag:

store problemer |---| absolutt ingen problemer

30.
Problemer med
hodepine før operasjonen:

store problemer |---| absolutt ingen problemer

Problemer med
hodepine i dag:

store problemer |---| absolutt ingen problemer

31.
Problemer med
tale før operasjonen:

store problemer |---| absolutt ingen problemer

Problemer med
tale i dag:

store problemer |---| absolutt ingen problemer

32.
Problemer med
utseende før operasjonen:

store problemer |---| absolutt ingen problemer

Problemer med
utseende i dag:

store problemer |---| absolutt ingen problemer

33.
Problemer med
mobbing før operasjonen:

store problemer |---| absolutt ingen problemer

Problemer med
mobbing i dag:

store problemer |---| absolutt ingen problemer

34.
Problemer med å være selv-
sikker i sosiale situasjoner før
operasjonen:

store problemer |---| absolutt ingen problemer

Problemer med å være selv-
sikker i sosiale situasjoner i dag:

store problemer |---| absolutt ingen problemer

Kjeveledd

	Aldri	Sjelden	Ukentlig	Daglig
Smerte ved tygging/gaping				
Skrapelyd fra kjeveledd				
Kjeveleddsknepping				
Vanskelig å gape høyt				
Tretthetsfølelse i kjevene				

Søvnapné

	Aldri	Sjelden. Noen ganger pr år	Iblant. Noen ganger pr mnd	For det meste. Flere ganger pr uke	Alltid
Snorking (ifølge andre)					
Pustepauser under søvn (ifølge andre)					
Trett/søvning på arbeid eller i fritiden					
Problemer med tett nese					

Søvnighet

Hvor sannsynlig er det at du døser av eller sovner i følgende situasjoner, i motsetning til kun å føle deg trett?
Bruk følgende skala for å velge det **mest passende tall** for hver situasjon:
0 = ville **aldri** døse/sovne
1 = **liten sjanse** for å døse/sovne
2 = **moderat sjanse** for å døse/sovne
3 = **stor sjanse** for å døse/sovne   **Sjanse for å døse/sovne (0-3)**

Sitte og lese _____

Se på TV _____

Sitte, inaktiv på et offentlig sted (for eksempel på teater eller i et møte) _____

Som passasjer på en en-times biltur uten pause _____

Legge deg for å hvile om ettermiddagen hvis omstendighetene tillater det ___

Sitte og snakke med noen _____

Sitte stille etter lunch (uten å ha inntatt alkohol) _____

I en bil som har stoppet noen få minutter i trafikken _____

TAKK FOR AT DU TOK DEG TID TIL Å SVARE

Appendix II

Forespørsel om deltagelse i forskningsprosjekt

Oppfølging etter ortognatisk behandling av underbitt

Bakgrunn og hensikt. Tilbakeføring av underkjeven (Intraoral vertikal ramusosteotomi, IVSO) er et vanlig kjevekirurgisk inngrep for å behandle underbitt. Det er denne operasjonen som er planlagt for deg. Med dette forskningsprosjektet ønsker vi å undersøke stabiliteten på den nye kjevestillingen, samt eventuelle forandringer i øvre luftveier etter operasjonen. I tillegg ønsker vi å belyse dine oppfatninger av hele behandlingen.

Hva innebærer studien? All tannregulering, kjeveoperasjon og senere oppfølging vil foregå akkurat som tidligere planlagt. I tillegg ønsker vi å gjennomføre en såkalt søvnregistrering før og etter behandling. Vi ønsker også at du fyller ut et spørreskjema før og etter operasjonen. NOX T3 er et registreringsapparat som måler luftstrøm gjennom nesen, og ved hjelp av to små belter festet på kroppen måler den også bevegelse i bryst og mage når man puster. Målingene registreres av en liten digital opptaker i lommeformat. Metoden benyttes rutinemessig ved diagnostisering av søvnapné ved søvnklinikker, sykehus eller i hjemmet. Man får også en liten sensor på fingeren som måler oksygen i blodet og pulsfrekvens. Dette utstyret blir montert/instruert på sykehuset, men du sover hjemme. Du kommer tilbake neste morgen for å returnere utstyret. Metoden er fullstendig smertefri og innebærer ikke stikk eller andre smertefulle prosedyrer.

Mulige fordeler og ulemper. Ved å delta i forskningsprosjektet vil du få en grundig sjekk av øvre luftveier. Alle opplysninger vil være tilgjengelige for deg. Enkelte vil kunne oppleve innsovningsproblemer med utstyret festet til kroppen de to nettene dette er aktuelt.

Hva skjer med informasjonen om deg? Innsamlet materiale vil sammen med din journal, gamle røntgenbilder og tidligere gipsmodeller bli brukt i forskningsprosjektet. Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle data vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine data gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltagelse. Det er frivilling å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på neste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg, eller har spørsmål til studien kan du kontakte

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Tlf: 55 58 64 04

Prosjektet ledes av:
Tannlege, Universitetsstipendiat, Elisabeth Schilbred Eriksen, Institutt for Klinisk Odontologi, UIB
Overlege, dr.med. Sashi Gulati, Søvnsenteret/Øre-nese-halsavdelingen, Haukeland Universitetssykehus
Førsteamanuensis, dr.philos. Sigbjørn Løes, Kjevekirurgisk avdeling, Haukeland Universitetssykehus
Professor (em) Per Johan Wisth, Kompetansegruppen for ortognatisk kirurgi
Ketil Moen, dr.odont, Odontologisk klinikk, Seksjon for Oral Kirurgi og Oral Medisin

Samtykke til deltagelse i studien

Dersom du ønsker og har anledning til å delta, vennligst returner dette skjemaet i underskrevet stand i vedlagte konvolutt. Vi ber deg også fylle ut vedlagte spørreskjema og ta det med til innleggelsen ved Kjevekirurgisk avdeling.

Deltakere vil bli innkalt til Søvnsenteret/Øre-nese-halsavdelingen ved Haukeland Universitetssykehus for søvnregistrering/påmontering av NOX T3. Søvnregistreringen må skje minimum 1 dag før innleggelsen ved Kjevekirurgisk avdeling for gjennomføring av kjevekorreksjonen. Noen måneder etter operasjonen vil du kalles inn til ny tilsvarende søvnregistrering for å vurdere eventuelle endringer i luftveiene. Øvrige kontroller går som vanlig uavhengig av dette.

Studien er vurdert og godkjent av Regional Etisk Komité.

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

UNDERSØKELSE OM MOTIVASJON OG TILFREDSHET MED ORTOGNAT-KIRURGISK BEHANDLING, IVSO, FØR BEHANDLINGEN

*Undersøkelsen besvares ved å krysse av **ett** svaralternativ, dersom du ikke spesifikt bli bedt om å avgi flere svar. Dersom det er noe du lurer på kan du gjerne diskutere dette når du kommer til kontrolltimen.*

DITT BEHANDLINGSBEHOV

1. Hvorfor søkte du behandling?
   (Sett flere kryss om nødvendig)

1 ☐ For å kunne tygge bedre
2 ☐ Misfornøyd med utseende
3 ☐ For å bedre uttale
4 ☐ Problemer i bihulene / øvre luftveger
5 ☐ Problemer med hodepine
6 ☐ Mindre smerter i kjeveleddet
7 ☐ Mindre problemer med sår i ganen
8 ☐ Andre grunner
9 ☐ Vet ikke / husker ikke

2. Hvem rådet deg til å søke behandling?
   (Sett flere kryss om nødvendig)

1 ☐ Tannlegen
2 ☐ Familien
3 ☐ Eget initiativ

FØR OPERASJONEN

3. Føler du ofte at ditt utseende avviker negativt fra andres utseende?

1 ☐ Ja
2 ☐ En gang i blant
3 ☐ Nei
4 ☐ Vet ikke / husker ikke

4. Tenker du ofte på kjeveposisjonen din?

1 ☐ Ja
2 ☐ Nei
3 ☐ Vet ikke / husker ikke

5. Opplever du noen ganger problemer som du relaterer til bittfeilen - i kjæresteforhold eller i andre nære relasjoner til mennesker?

1 ☐ Ja
2 ☐ En gang i blant
3 ☐ Nei
4 ☐ Vet ikke / husker ikke

6. I hvor stor grad er du opptatt av ditt utseende?

1 ☐ Mer opptatt av utseende enn folk flest
2 ☐ Helt normalt
3 ☐ Mindre opptatt av utseende enn folk flest

7. Hva blir verst med å gå med kjevelås?

1 ☐ Tror ikke det blir noen problemer
2 ☐ Problemer med å snakke
3 ☐ Problemer med å puste
4 ☐ Problemer med å sove
5 ☐ Problemer med å spise og drikke
6 ☐ Problemer med tannrengjøring
7 ☐ Vet ikke

8. Har du hatt luftveisproblemer siste 6 mnd?(Flere svar kan krysses av):

1 ☐ Jeg opplever ingen problemer
2 ☐ Problemer med snorking
3 ☐ Problemer med å puste
4 ☐ Problemer med pustestopp om natten
5 ☐ Problemer med å sove
6 ☐ Konsentrasjonsproblemer
7 ☐ Dagtretthet
8 ☐ Hodepine
9 ☐ Vet ikke / husker ikke

LIVSKVALITET

I løpet av de siste 6 mnd., har problemer i munnen eller med tennene gitt deg problemer i følgende situasjoner:

9. Spise og nyte maten?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

10. Snakke og uttrykke deg tydelig?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

11. Tannrengjøringen?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

12. Å sove og slappe av?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

13. Å smile og vise tenner uten å bli brydd?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

14. Å være følelsesmessig stabil uten å bli irritabel?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

15. Å glede deg over samvær med andre mennesker?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

16. Å utføre daglige gjøremål?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

BAKGRUNNSINFORMASJON

17. Fødselsår?

☐

18. Hvilken skolegang / utdannelse er det høyeste utdannelsesprogrammet du har eksamen fra?

1 ☐ Grunnskolen (maks. 10 år)
2 ☐ Videregående skole (maks. 13 år)
3 ☐ Lavere grad universitetsutdannelse/ høyskoleutdannelse (maks. 15 år)
4 ☐ Høyere grad universitetsutdannelse/ høyskoleutdannelse (18 år skolegang/studier)
5 ☐ Annet; spesifiser:

…………………………………………………...

Kjeveledd

	Aldri	Sjelden	Ukentlig	Daglig
Smerte ved tygging/gaping				
Skrapelyd fra kjeveledd				
Kjeveleddsknepping				
Vanskelig å gape høyt				
Tretthetsfølelse i kjevene				

Søvnapné

	Aldri	Sjelden. Noen ganger pr år	Iblant. Noen ganger pr mnd	For det meste. Flere ganger pr uke	Alltid
Snorking (ifølge andre)					
Pustepauser under søvn (ifølge andre)					
Trett/søvning på arbeid eller i fritiden					
Problemer med tett nese					

Søvnighet

Hvor sannsynlig er det at du døser av eller sovner i følgende situasjoner, i motsetning til kun å føle deg trett?
Bruk følgende skala for å velge det **mest passende tall** for hver situasjon:
0 = ville **aldri** døse/sovne
1 = **liten sjanse** for å døse/sovne
2 = **moderat sjanse** for å døse/sovne
3 = **stor sjanse** for å døse/sovne   **Sjanse for å døse/sovne (0-3)**

Sitte og lese _____

Se på TV _____

Sitte, inaktiv på et offentlig sted (for eksempel på teater eller i et møte) _____

Som passasjer på en en-times biltur uten pause _____

Legge deg for å hvile om ettermiddagen hvis omstendighetene tillater det ___

Sitte og snakke med noen _____

Sitte stille etter lunch (uten å ha inntatt alkohol) _____

I en bil som har stoppet noen få minutter i trafikken _____

TAKK FOR AT DU TOK DEG TID TIL Å SVARE

Appendix III

UNDERSØKELSE OM MOTIVASJON OG TILFREDSHET MED ORTOGNAT-KIRURGISK BEHANDLING, IVSO, ETTER BEHANDLINGEN

*Undersøkelsen besvares ved å krysse av **ett** svaralternativ, dersom du ikke spesifikt bli bedt om å avgi flere svar.*

UNDER OG ETTER BEHANDLINGEN

1. Hadde du smerter mens reguleringen pågikk?

1 ☐ Ja
2 ☐ Ja, men bare ubetydelig
3 ☐ Nei
4 ☐ Vet ikke / husker ikke

2. Hadde du smerter etter operasjonen?

1 ☐ Ja
2 ☐ Ja, men bare ubetydelig
3 ☐ Nei
4 ☐ Vet ikke / husker ikke

3. Har du opplevd nummenhet i leppene og/eller i kjevene etter operasjonen?

1 ☐ Nei
2 ☐ Vet ikke / husker ikke
3 ☐ Ja

Dersom du svarte ja:
Hvor lenge etter operasjonen opplevde du nummenhet?:

1 ☐   0-4 uker
2 ☐   5 uker - 6 mnd
3 ☐   7 mnd - 1 år

4. Forandret utseende ditt seg etter operasjonen?

1 ☐ Ja
2 ☐ Ja, men bare ubetydelig
3 ☐ Nei   Gå videre til Sp.nr.7
4 ☐ Vet ikke / husker ikke

5. Hadde du problemer med å venne deg til ditt nye utseende etter operasjonen?

1 ☐ Ja
2 ☐ Ja, men bare ubetydelig
3 ☐ Nei
4 ☐ Vet ikke / husker ikke

6. La dine familiemedlemmer eller venner merke til at ditt utseende forandret seg etter operasjonen?

1 ☐ Ja
2 ☐ Nei
3 ☐ Vet ikke / husker ikke

7. Har du lagt merke til forandringer i din selvsikkerhet?

1 ☐ Nei
2 ☐ Ja

8. Hvilken del av behandling var verst; reguleringen, kjevelåsen eller tilheling etter operasjonen?

1 ☐ Jeg opplevde ingen problemer
2 ☐ Kjevelåsen var verst
3 ☐ Reguleringen var verst
4 ☐ Operasjonen m/tilheling var verst
5 ☐ Vet ikke / husker ikke

9. Kjevelås: Hva var verst?

1 ☐ Jeg opplevde ingen problemer
2 ☐ Problemer med å snakke
3 ☐ Problemer med å puste
4 ☐ Problemer med å sove
5 ☐ Problemer med å spise og drikke
6 ☐ Problemer med tannrengjøring
7 ☐ Vet ikke / husker ikke

10. Har du hatt luftveisproblemer siste 6 mnd?(Flere svar kan krysses av):

1 ☐ Jeg opplevde ingen problemer
2 ☐ Problemer med snorking
3 ☐ Problemer med å puste
4 ☐ Problemer med pustestopp om natten
5 ☐ Problemer med å sove
6 ☐ Konsentrasjonsproblemer
7 ☐ Dagtretthet
8 ☐ Hodepine
9 ☐ Vet ikke / husker ikke

TILFREDSHET

11. Hvor fornøyd er du – i dag - med behandlingen?

1 ☐ Svært fornøyd
2 ☐ Fornøyd
2 ☐ Ikke fornøyd
3 ☐ Svært lite fornøyd

12. Kjevelåsen tatt i betraktning, var totalbelastningen under behandlingen:

1 ☐ Mindre enn forventet
2 ☐ Som forventet
3 ☐ Større enn forventet

13. Alt tatt i betraktning, var totalbelastningen under behandlingen:

1 ☐ Mindre enn forventet
2 ☐ Som forventet
3 ☐ Større enn forventet

14. Ville du ha bedt om den samme behandlingen "en gang til"?

1 ☐ Ja
2 ☐ Nei
3 ☐ Vet ikke

LIVSKVALITET

15. Har du opplevd store forandringer i livet ditt siden operasjonen?

1 ☐ Inngått ekteskap
2 ☐ Skilsmisse
3 ☐ Fått nytt arbeid
4 ☐ Mistet arbeidet
5 ☐ Vedvarende forringet helse
6 ☐ Gjennomgått andre nødvendige operasjoner

I løpet av de siste 6 mnd., har problemer i munnen eller med tennene gitt deg problemer i følgende situasjoner:

16. Spise og nyte maten?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
2 ☐ En eller to ganger per mnd.
3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

17. Snakke og uttrykke deg tydelig?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
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3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

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1 ☐ Sjeldnere enn en gang i mnd, eller aldri
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3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

19. Å sove og slappe av?

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5 ☐ Daglig eller nesten daglig

20. Å smile og vise tenner uten å bli brydd?

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21. Å være følelsesmessig stabil uten å bli irritabel?

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22. Å glede deg over samvær med andre mennesker?

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23. Å utføre daglige gjøremål?

1 ☐ Sjeldnere enn en gang i mnd, eller aldri
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3 ☐ En eller to ganger per uke
4 ☐ 3-4 ganger per uke
5 ☐ Daglig eller nesten daglig

OM FORANDRINGER: - FØR – OG ETTER - BEHANDLINGEN

På neste side skal du sette et kryss på LINJE 1 som symboliserer din grad av problemer FØR behandlingen, og deretter et kryss på LINJE 2 som viser hvordan du opplever problemene NÅ. Eksempelet under viser ditt svar når X1 = "noen problemer" og når X2 er "nærmest ingen problemer".

LINJE 1   store problemer |-------------------X1---------------------------------------| absolutt ingen problemer

LINJE 2   store problemer |---X2---| absolutt ingen problemer

24.
Tyggeproblemer
før operasjonen:

                   store problemer |--| absolutt ingen problemer

Tyggeproblemer
i dag:

                   store problemer |--| absolutt ingen problemer

25.
Problemer med
fordøyelsen før operasjonen:

                   store problemer |--| absolutt ingen problemer

Problemer med
fordøyelsen i dag:

                   store problemer |--| absolutt ingen problemer

26.
Problemer med
hodepine før operasjonen:

                   store problemer |--| absolutt ingen problemer

Problemer med
hodepine i dag:

                   store problemer |--| absolutt ingen problemer

27.
Problemer med
tale før operasjonen:

                   store problemer |--| absolutt ingen problemer

Problemer med
tale i dag:

                   store problemer |--| absolutt ingen problemer

28.
Problemer med
utseende før operasjonen:

                   store problemer |--| absolutt ingen problemer

Problemer med
utseende i dag:

                   store problemer |--| absolutt ingen problemer

29.
Problemer med
mobbing før operasjonen:

                   store problemer |--| absolutt ingen problemer

Problemer med
mobbing i dag:

                   store problemer |--| absolutt ingen problemer

30.
Problemer med å være selv-
sikker i sosiale situasjoner før
operasjonen:

                   store problemer |--| absolutt ingen problemer

Problemer med å være selv-
sikker i sosiale situasjoner i dag:

                   store problemer |--| absolutt ingen problemer

Kjeveledd

	Aldri	Sjelden	Ukentlig	Daglig
Smerte ved tygging/gaping				
Skrapelyd fra kjeveledd				
Kjeveleddsknepping				
Vanskelig å gape høyt				
Tretthetsfølelse i kjevene				

Søvnapné

	Aldri	Sjelden. Noen ganger pr år	Iblant. Noen ganger pr mnd	For det meste. Flere ganger pr uke	Alltid
Snorking (ifølge andre)					
Pustepauser under søvn (ifølge andre)					
Trett/søvning på arbeid eller i fritiden					
Problemer med tett nese					

Søvnighet

Hvor sannsynlig er det at du døser av eller sovner i følgende situasjoner, i motsetning til kun å føle deg trett?
Bruk følgende skala for å velge det **mest passende tall** for hver situasjon:
0 = ville **aldri** døse/sovne
1 = **liten sjanse** for å døse/sovne
2 = **moderat sjanse** for å døse/sovne
3 = **stor sjanse** for å døse/sovne   **Sjanse for å døse/sovne (0-3)**

Sitte og lese   _____

Se på TV   _____

Sitte, inaktiv på et offentlig sted (for eksempel på teater eller i et møte)   _____

Som passasjer på en en-times biltur uten pause   _____

Legge deg for å hvile om ettermiddagen hvis omstendighetene tillater det   ___

Sitte og snakke med noen   _____

Sitte stille etter lunch (uten å ha inntatt alkohol) _____

I en bil som har stoppet noen få minutter i trafikken _____

TAKK FOR AT DU TOK DEG TID TIL Å SVARE

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