Objective analysis of surgical outcomes in the management of congenital facial deformities

PhD thesis

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INTRODUCTION

1. Facial clefts

Cleft lip and cleft palate, which can also occur together as cleft lip and palate, are variations of a type of clefting congenital deformity caused by abnormal facial development during gestation. A cleft is a fissure or opening—a gap. It is the non-fusion of the body's natural structures that form before birth. Approximately 1 in 700 children born have a cleft lip and/or a cleft palate. An older term is harelip, based on the similarity to the cleft in the lip of a hare. Clefts can also affect other parts of the face, such as the eyes, ears, nose, cheeks, and forehead. Tessier described fifteen lines of cleft. Most of these craniofacial clefts are even more rare.

2. The cleft nasal deformity

The severity of nasal deformity found in orofacial clefting increases with the degree of primary lip deformity. The ultimate goal of repair of the cleft nasal deformity is normal form and symmetry, together with normal respiratory function. There is no consensus regarding the most appropriate treatment strategy for the cleft nose. There is also no consensus about a standard for reporting aesthetic outcome in cleft surgery. This means that learning from unbiased comparisons of results from one centre to another remains difficult. Evaluation of nasal form and symmetry is simple, as it requires mere inspection. However, it is difficult to describe this impression objectively.

2.1. Anthropometric analysis

Different evaluation methods of cleft nasal deformity have been described, such as direct and indirect anthropometric analysis, and linear, area and 3D computerized measurements.

2.2. Panel study

When many parameters have to be measured to make up an analysis, the question comes to the weight of the singular parameter in the whole picture. Hence, the pertinent question in cleft nose analysis is "Is a cleft surgeon appreciating the operated cleft nose in the same way as the parents or other lay people?" There are panel-based studies on evaluating results of cleft-nose repair based on personal observations and preferences of surgeons and anthropometrists.

3. Hemifacial microsomia (HFM)

3.1. Clinical appearence

Hemifacial microsomia is a congenital disorder that affects the development of the lower half of the face, most commonly the ears, the mouth and the mandible. It can occur on one side of the face or both. If severe it can lead to difficulties in breathing, obstructing the trachea and requiring a tracheotomy. It is the second most common facial birth defect after clefts, with an incidence in the range of 1 in 3500 to 4500.

3.2. Pruzansky-Kaban classification

There are different classification systems to describe the severity of HFM, such as the SAT (Skeletal, Auricular and Soft tissue), OMENS (Orbit, Mandible, Ear, Facial nerve, Soft tissue), OMENS-Plus (including extra-craniofacial anomalies) classification. The most surgical-minded classification is the Pruzansky-Kaban one:

Type I: All mandibular and TMJ components are present and normal in shape but hypoplastic to a variable degree as compared with the contralateral side

Type IIA: The mandibular ramus, condyle, and TMJ are present but hypoplastic and abnormal in shape. The mouth can be symmetrically opened.

Type IIB: The mandibular ramus is hypoplastic and markedly abnormal in form and location, being medial, anterior and inferior. There is no articulation with the temporal bone.

Type III: The mandibular ramus, condyle, and TMJ are absent. The lateral pterygoid muscle and temporalis, if present, are not attached to the mandibular remnant.

3.3. Osteodistraction in the management of HFM

Reconstruction of the malformed hard and soft tissues of the microsomic face is a difficult task, which is usually staged over many years. The choice of an appropriate treatment concept has therefore always been of concern to craniomaxillofacial centres. Especially the tissue deficiency in the ascending ramus compartment (posterior face), composed of the ascending mandibular ramus, muscles of mastication and integuments, remains especially challenging. Osteodistraction has been considered as an effective and safe technique for increasing ramus height and mandibular body length in young patients with hemifacial microsomia. Since 1995, the vogue for distraction osteogenesis has meant it is increasingly used in young patients, to induce bone and soft tissue generation. Both extra-oral and intra-oral techniques

have been used. Indeed, it was proclaimed that distraction osteogenesis would affect the entire facial milieu with an increase in soft-tissue envelope bulk due to expansion and muscle hypertrophy.

3.3. Meta-analysis of surgical outcomes in the treatment of HFM

The idea that clinical practice should be rigorously based on the best available scientific evidence is not new. Hierarchy of available evidences has been well established, meta-analyses or systematic reviews of randomized controlled trials (RCTs) being at the top of the evidence based medicine (EBM) pyramid. It is well known that there are several problems with RCTs in surgery. These problems are related to feasibility of randomization (ethical issues, emergency settings, palliative care), the learning curve and standardization of the procedures. A surgical intervention that is performed for correction for a complex congenital craniofacial malformation should also be based on satisfactory evidence, even if it is safe, simple, effective and has reduced morbidity. This pertains especially for young patients. Recent follow-up studies of early distraction before skeletal maturation have shown limitations in the skeletal correction and recurrence of the original skeletal deformity to a variable degree. Soft tissue complications and relapse of the soft tissue augmentation also A literature overview was published on the long-term results of early osteodistraction in HMF, performed in different centres. At that time, it was concluded that for a better understanding of the growth potential after osteodistraction, and hence support the use of early osteodistraction, prospective growth studies were needed that would include adequate numbers of patients (multi-centre) with comparable pathology, similar treatment and follow-up until after growth cessation using a standard protocol for three-dimensional evaluation.

AIMS

We had the following aims:

- To establish a comprehensive computer analysis of nasal form and symmetry (both intranasal symmetry and symmetrical position of the nose in the facial structures) in cleft patients, in the submento-vertical view.
- To set up a panel study to evaluate the importance of the different possible deformities within a cleft nose in the eyes of non-professionals, being parents of cleft children ("cleft parents").
- To perform a systematic review of the literature, to summarize the results of follow-up studies and to determine the long-term stability of mandibular dimensions after early osteodistraction (performed before skeletal maturity –

patient being not older than 16 years of age at the time of distraction) in patients with HFM.

METHODS

1. Analysis of nasal cleft deformity

The accuracy of anthropometric analysis on photographs ("photogrammetry") has been compared with direct measurements. Measurements taken on frontal and lateral head photographs proved to be reliable. Furthermore, the sharp facial profile contours on the photographs could eliminate the differences between direct and indirect measurements. It is difficult to accurately measure distances and angles on photographs and it is even more difficult to compare distances and angles on photographs taken at different places and times, by different cameras and techniques. This observation bias was eliminated by constructing ratios from the primary measurements.

1.1. Landmarks, constructs and reference lines

Anthropometric landmarks on face and nose were selected as primary landmarks. These well-known landmarks were developed for clinical facial analysis. The *pupil inferior* right and left points (Pu_r and Pu_l) are the most inferior points on the circumference of the pupil. It was opted for this point instead of the centre of the pupil, since in the submento-vertical view the head is tilted back and the pupils appear rather elliptical instead of being round. Thus, the middle of the pupil is difficult to identify. Furthermore, the contrast between the black pupil and the coloured iris helps to clearly define this point. The other landmarks were *endocanthion* right and left (En_r and En_l), *pronasale* right and left (Pn_r and Pn_l), *alare* right and left (Al_r and Al_l), subalare right and left (Sar and Sal), nostril tip right and left (Ntr and Ntl), nostril base right and left (Nbr and Nbl), nostril mediale right and left (Nmr and Nml) and nostril laterale right and left (Nlr and Nll). Using these landmarks, anthropometric constructs (reference lines, point, axes and areas) were determined. Most important was the horizontal reference line, constructed by connecting the pupil inferior points (bipupillary line) and the vertical reference line, the midline of the face, which was determined as a line perpendicular to the bipupillary line, bisecting it at the midpoint of the distance of the endocanthion points. The other constructs were: Pnr-Pnl line, constructed pronasale (PnC), Enr and Enl-line, Alr and All lines, Sar-Sal line, Nmr-Nml line, nostril quadrangles. Using these primary constructs,

further secondary constructs were determined. These were: Pn_C-$Nm_r Nm_l$-$Sa_r Sa_l$ line, long axis of right and left nostril, Nt_r-Nm_r-Nb_r-Nl_r surface area, and Nt_l-Nm_l-Nb_l-Nl_l surface area.

1.2. Measurements and anthropometric ratios

All measurements were referenced to the horizontal and the vertical reference lines. Parallel lines with the bipupillary line and facial midline were constructed through the various points; and distances to the reference lines were measured. The measurements were grouped into vertical, horizontal and angular measurements, describing distances and angles between the aforementioned landmarks and constructs. These were the following:

- vertical measurements: nasal tip projection, nostril heights
- horizontal measurements: distance of endocanthion points, distance of nasal tips (if there were two tips), nostril widths, midalar widths, total width of nose, width of the nasal base, distance of alare points from the endocanthion lines
- angular measurements: deviation of nasal columella, inclination of nasal base, angulations of nostrils

For assessing intranasal symmetry, the anthropometric ratios were: nasal height to width ratio, ratio of midalar width, ratio of nostril heights, ratio of nostril width, ratio of width of nasal base and the total width of the nose, ratio of angles between the long axises of the nostrils and the midline, ratio of nostril asymmetry.

For assessing symmetrical position of nose in the face, the following (?) anthropometric ratios were calculated: ratio between the distances of the alare points to the endocanthion line on the right and left sides and ratio between the distance of the endocanthion points and the total width of the nose (nasal width index).

1.3 Reliability test

To test the reliability of this new way to evaluate
nasal asymmetry, photographs of a group of bilateral cleft patients treated with primary cheiloplasty (patients of Prof. Perko, Zürich, Switzerland) and photographs of a group of patients treated with primary cheilorhinoplasty (patients of Prof. Mommaerts, Bruges, Belgium) were analysed. The method errors were assessed for the intraobserver and interobserver reliability. A retest correlation is a way to quantify reliability. The usual Pearson correlation coefficient tends to overestimate the true correlation for small sample sizes (less than ~15). A better measure of retest correlation is the

intraclass correlation coefficient (ICC), which does not have the bias of small samples. Therefore, measurements were analyzed with intraclass correlation coefficient for the intraobserver and interobserver reliability.

2. Panel study
2.1. The panel questionnaire
A panel questionnaire was prepared with 10 drawings of typical cleft nose deformities, accompanied by a textual explanation, and labelled A to J. The deformities/parameters were chosen for their clinical presence and measurability. The questionnaire was sent to cleft parents. The parents were asked to rank-order the abovementioned 10 deformities, according to the weight of the specific deformity in the overall picture. They were asked to give the number 1 to the most and 10 to the least offending deformity. Two months later, the same questionnaire was sent again to the same cleft parents for completion.

2.2. The analysis
The first copy of the questionnaire was mailed on September 9, 2005. The results were tabulated separately for the parents of unilateral and bilateral cleft children. Then, the sum of the ranks for each deformity was calculated. This series of calculations was redone with the results of the second questionnaire, which was mailed on November 10, 2005.

2.3. Reliability test
The measurements were analyzed with intraclass correlation coefficient (ICC) for the intraobserver and interobserver reliability.

3. Analysis of treatment outcomes in HFM
3.1. Search strategy
We performed an electronic search in the following databases
PubMED (between 1992 and August 2008)
Cochrane (between 1992 and August 2008)
MEDLINE (between 1992 and August 2008)
The search strategy was developed and databases were selected with the help of a senior librarian specialized in health sciences.
Free text words and MeSH terms were used. The heading sequence ((((("Osteogenesis, Distraction"[Mesh])) OR ((distraction osteogenesis OR distraction OR osteodistraction OR osteogenic distraction)))) AND (((("Facial Asymmetry"[Mesh])) OR ((Hemifacial microsomia OR hemi-facial Microsomia OR hemifacial hypoplasia OR hemi-facial hypoplasia OR

craniofacial microsomia)) OR ((Goldenhar* OR otomandibular dysostosis OR Oculoauriculovertebral Dysplasia OR Oculo-auriculo-vertebral Dysplasia OR OAV Dysplasia OR Oculoauriculovertebral Spectrum OR Oculo-auriculo-vertebral Spectrum OR OAVS OR Facioauriculovertebral Sequence OR Facio-auriculo-vertebral Sequence OR FAV Sequence)))) AND (("2002/08/01"[PDat] : "2008/08/01"[PDat]))) AND (("2002/08/01"[PDat] : "2008/08/01"[PDat]) AND (Humans[Mesh])) was selected.

3.2. Inclusion criteria

Prospective and retrospective case series were included in this review. We included infants and adolescents who had undergone single-stage, early unilateral distraction osteogenesis of the mandible for correction of congenital hemifacial microsomia or its equivalents, with a follow-up of the patients longer than the active distraction phase. No language limitation was applied.

3.3. Data extraction

Data were extracted and methodological quality assessed independently by two observers. First the abstracts were reviewed without considering the number of patients reported. Animal studies, molecular studies, reports on patients with bilateral craniofacial dysmorphology (no asymmetry) and case reports (low level of clinically relevant evidence) were excluded. Articles that apparently fulfilled the inclusion criteria and articles of which the title or abstract did not present enough relevant information were obtained full-text. Secondly, full-text articles were reviewed according to all inclusion criteria. If there were individuals among the patients in the different studies, who did not fulfil our inclusion criteria, they were not included in our study. If a publication failed to present objective information on all the patients, only those individuals were included in the study whose data were given.

RESULTS

1. Analysis of cleft nasal deformity

1.1. Intra-observer reliability

The method error showed a highly significant intraobserver correlation (mean ICC=0.994 $p<0.05$) for the repeated measurements. The re-test correlation was the weakest for assessing the distance of nasal tips (Pn_r-Pn_l) and the nostril areas (Ntr-Nmr-Nbr-Nlr and Ntl-Nml-Nbl-Nll areas).

1.2. Inter-observer reliability

A highly significant correlation (ICC=0.893 p<0.05) was found also for the interobserver correlation. The re-test correlation was again the weakest at assessing the distance of nasal tips (Pn_r-Pn_l). The angular measurements showed weaker correlation than the linear ones.

2. Panel study
2.1. Rank-order in the group of unilateral cleft parents
The most disturbing deformity was an off-centre position of the nasal complex within the nasal frame. Nasal projection to nasal base ratio was the second worst deformity. Of least concern was a difference in shape of the nostrils.
2.2. Rank-order in the group of bilateral CLP patient parents
The asymmetric position of the nose in the face was also here ranked as a priority problem, followed by an asymmetric implantation of the alae. Least important was an asymmetry in nostril width.
2.3.Test reliability
There was a fair reliability, both for intra-rater and inter-rater.

3. Analysis of treatment outcomes in HFM
Thirteen articles were found to meet all inclusion criteria. These articles were reviewed and summarized according to the data they included on the length of follow-up period, sample size, age group, the Pruzansky-Kaban type, the methods of analysis and validation used and the level of evidence of the studies. The results on long-term stability were also summarized

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DISCUSSION

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1. Analysis of cleft nasal deformity
The first detailed anthropometric analysis of cleft lip-nose deformity was published by Farkas and Lindsay. This method of anthropometry was relatively simple. It proved to be useful in evaluating morphological changes of the face and it slowly became the workhorse of anthropometric analysis. This study showed significant differences in some nasal features in cleft patients when compared with non-cleft controls. This study was the first to suggest that the cleft nasal deformity was caused by a displacing mechanism rather than by tissue deficiency. It was also the incentive for a series of studies using similar objective anthropometric analysis to study the outcome of different surgical techniques. These series included direct and indirect

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anthropometric studies, as well as different computer-based evaluation methods to try to objectively describe the cleft nasal deformity. However, among the few long-term follow-up studies reporting on the outcome of the specific surgical techniques, there are only quite few using validated, reliable anthropometric analysis. The major drawback of these studies was that identifying subnasale, one of their primary landmarks on a frontal or basilar view-photograph is difficult and the point chosen can be quite inaccurate. Furthermore, there is a frequent tendency in cleft noses to develop a double tip deformity, when two pronasale exist. These phenomena were not considered in this anthropometric investigation. Although direct anthropometric analysis is an accurate anthropometric instrument, it is very difficult to reproduce, especially in a large number of patients, since the recall might be ineffective and patients grow during the period between the recalls. Furthermore, it is almost impossible to compare the results of various centres, as transport of personnel and/or patients is a difficult task. Indirect anthropometry or "photogrammometry" eliminates such drawbacks and proved to be highly appropriate in clinical facial analysis. There are more studies on long-term results of surgical results of the cleft nose deformity using indirect anthropometry than those using direct anthropometry. In 1985, Pigott stated that neither frontal nor lateral photographs would show the full extent of the nasal asymmetry in cleft patients and he emphasized the need to view the nose from below ("basilar view") in critical assessment of long-term results of cleft surgery. In another indirect anthropometric study, the authors used ratios of the abovementioned measurements to compare the results of the two methods. They stated in their paper that photogrammometry was unsuitable for absolute measurements, unless standardized procedures were followed to ensure a consistent, known magnification. However, photogrammetry was appropriate for angular measurements, as these were not affected by magnification. In most of the indirect anthropometric analyses, subnasale and pronasale were used as primary landmarks, which can result in inaccurate measurements, and consequently misleading conclusions. Another fault was to reference the measurements to inaccurate lines, such as the level of alar insertion, which is deviant in cleft noses.

The method of analysing nasal asymmetry described and proposed here uses indirect anthropometry. This makes possible to compare results of two surgical techniques which were separated by place and time. There are obvious difficulties in analysing pictures, but it was tried to eliminate the

known observation biases. Indirect anthropometry was done on standardized images, namely on pictures taken always from the submental-vertical view. Only well-known anthropometric landmarks were used in this nasal analysis, and all the anthropometric constructs were developed by using these landmarks. Landmarks that are not appropriate for indirect anthropometric analysis were excluded, such as subnasale and pronasale. If the nose was bifid, then the columellar axis was constructed without using the subnasale point. In this study, ratios and nasal indices were used when comparing results of the two surgical techniques to eliminate observation bias caused by differences in imaging and image processing techniques. In addition, nasal symmetry was evaluated by investigating both intranasal features and position of the nose within the facial structures. Asymmetry in the shape of the nostrils was analysed, which appears to be the most sensitive index of nasal deformity. To evaluate the reliability of this new nasal analysis, retest correlation was measured for both intra-observer and inter-observer reliability. Intraclass correlation coefficient was used as the statistical method, which showed significantly good intra-observer and inter-observer correlation.

2. Panel study
Recent panel studies use photographs and an indirect evaluation method. However, these panel studies were aimed to score for the best result by a professional, not to detect the most striking deformity by a personally involved but technically inexperienced person. Our panel questionnaire summarized well-known extranasal and intranasal deformities of a cleft nose, which can be measured and now also attributed a weight in the overall appreciation.

The assessment showed that the most important deformity is the asymmetric position of the nose in the face, most probably because of the conspicuous nature of this deformity. Thus, it seems that the most important surgical guideline in correcting cleft nose deformity is: "Put the nose in the middle!" For unilateral cases, the results showed that parents were concerned about the nasal tip. Hence, a depressed tip and a double-tip deformity need surgical attention. Differences in width, angulations or form of the nostrils do not seem to bother parents so much. It seems that surgical attention to more tip definition is required.

For bilateral cases, extranasal asymmetric characteristics were ranked high; position of the nose within the face, the height of alar implantation and an

oblique columella. Again, differences in width, angulations or form of the nostrils do not seem to bother parents that much.

Obviously, surgical techniques address intranasal symmetry with success in correcting bilateral cleft lip/nose deformity, keeping in mind the fact that the nasal deformity is also quite symmetric in BCLP patients.

3. Analysis of treatment outcomes in HFM

Unfortunately, the current summaries of long-term studies on the efficacy of single-stage, early osteodistraction in HFM patients have been disappointing. All studies are non-comparative observational case series, and were on the second to last level in the hierarchy of clinical surgical research. To our best knowledge, no study has been published on early osteodistraction that followed the patients until growth cessation.

The number of patients included in the studies was strikingly low. Major centres were able to include less than 30 patients affected with HFM in their case series. In one case–series of 27 patients there was only one patient with genuine HFM; the others had secondary asymmetries. Only 115 documented patients with HFM treated by osteodistraction were included in the follow-up studies, which suggests that these are underpowered.The designs of the follow-up studies were not flawless, either. None of the studies differentiated between patients according to their dentition phase . The majority also failed to differentiate surgical outcomes between patients with different Pruzansky-Kaban type of HFM.

It was difficult to compare the results of the follow-up studies, since different analysis methods were used. For instance, the complex 3D facial asymmetry in HFM was evaluated almost exclusively using 2D methods. Only Huisinga-Fischer et al. used volumetric measurements. It has been hypothesized that the volume of the soft tissues of the affected side increases after distraction in HFM. However, the only study that evaluated this malformation volumetrically showed no decrease of the soft tissue deficiency on the affected side. In the follow-up studies, there was no validation of the measurements used to describe facial symmetry and only three studies provided some information on the reliability.

Each study based the efficacy of distraction osteogenesis on the long-term stability of mandibular dimensions achieved. None of the studies showed convincing stability. Although more than 50% of the follow-up studies concluded stable results at the end of the follow-up period, these reports could only prove short-term stability or had used a non-objective evaluation method. Pruzansky-Kaban IIb and III deformities were admitted to show

relapse or "occlusal disaster" with need for re-operation. Objective evaluation methods showed unpredictable stability of facial symmetry in the long-term, and especially of the affected ramal height. The only 3D study reported general relapse with progressive deterioration over a three-year period.

To evaluate the long-term surgical outcome of DO in HFM, one has to clearly differentiate between relapse ("settling of the regenerate") and re-appearance of facial asymmetry because of intrinsic growth retardation of the affected side. Some of the follow-up studies did differentiate, some did not. Relapse in the regenerate was seen in the majority of the studies that used reliable objective evaluation methods. The only published 3D volumetric analysis of mandibular bone-stock after DO showed resorption of the regenerate after 3 years. Previous studies have also shown loss of the gained increase in mandibular dimensions, and the phenomenon of this 5-8% relapse was called "settling" of the regenerate.

The clinical observation of re-appearance of facial asymmetry after DO has very early introduced the concept of overcorrection. The affected side is distracted such that the symphyseal midline moves to the non-affected side, over the facial midline. It was thought that overcorrecting the deformity in infancy would compensate for the effect of relapse or faster growth rate of the non-affected side. Overcorrection has its limits. It will create a dental cross-bite on the contralateral side, which can lead to "occlusal disasters", especially in severe cases. Secondly, chin asymmetry in HFM is not just a midline problem. Last, but not least, overcorrection does not avoid redos.

It has been claimed that mandibular elongation in HFM progressively releases the ipsilateral maxilla from the constricting effect of the mandible, spontaneously re-establishing a normal maxillary vertical dimension. However, correction of maxillary asymmetry appears to be due to dentoalveolar adaptation with extrusion of molars, without real skeletal growth catch-up. Correction of the bimaxillary deformity in HFM has also been addressed by means of bimaxillary osteodistraction. These distraction techniques have several draw-backs in comparison with the conventional techniques of midfacial reconstruction. Dento-alveolar compensation, even if stable, cannot correct three-dimensional midfacial deformity, it will only decrease occlusal canting. Bimaxillary osteodistraction in Pruzansly-Kaban type IIb and III could correct vertical maxillary hypoplasia but fails to achieve orbito-zygomatic reconstruction.[51] Furthermore, the surgical technique of a conventional Le Fort I type osteotomy and an osteotomy

performed for maxillary distraction differs mainly in one aspect: there is no need for pterygomaxillary dysjunction on the non-affected side with DO. This has a minor influence on the morbidity.

If early osteodistraction remains the treatment of choice for patients with HFM, one would have to accept that the procedure will have to be repeated. The subjective threshold for recognizing facial asymmetry (midline differences or occlusal canting) is approximately 4°. Relapse of more than 4° appears approximately two years after distraction procedures. Thus, maintaining facial symmetry via osteodistraction in HFM until growth cessation would mean re-distraction every two years, coined the "yo-yo distraction approach".

CONCLUSIONS

1. A new nasal analysis method was developed, by which nasal symmetry is evaluated investigating both intranasal features and position of the nose within the facial structures. The statistical analysis proved that this indirect anthropometric measurement instrument is appropriate for comparing results of different surgical techniques.

2. Our panel study showed a relatively clear picture on what cleft-parents find most disturbing in a cleft nose. Since the statistical analysis showed a good intraobserver and interobserver reliability, this evaluation can be considered as an acceptable guide for surgeons to show in which fields they have to improve.

3. There have been no randomized controlled trials performed on the efficacy of single-stage early distraction osteogenesis in HFM patients. Furthermore, there has been no standardization of the evaluation methods used for long-term follow-up studies, and no objective studies have been published on stability after growth cessation. We conclude that there is no convincing evidence supporting the efficacy of early mandibular distraction osteogenesis in hemifacial microsomia patients. Patients need be informed that 2 or more distraction procedures or distraction followed by definitive secondary surgery at maturity most likely will be required.

BIBLIOGRAPHY

Relevant publications

- Mommaerts M, **Nagy K**: Is early distraction osteogenesis a solution for the ascending ramus compartment in hemifacial microsomia? A literature study *J Craniomaxillofac Surg, 2002. 30(4) 201-207* IF: 0,750

- **Nagy K**, Mommaerts MY.: Analysis of the cleft-lip nose in submental-vertical view, Part I--reliability of a new measurement instrument. J Craniomaxillofac Surg. 2007 Sep-Oct;35(6-7):265-77. IF: 0, 955

- Mommaerts MY, **Nagy K**. Analysis of the cleft lip-nose in the submental-vertical view. Part II. Panel study: which is the most important deformity? J Craniomaxillofac Surg. 2008 Sep;36(6):315-20. IF: 1, 360

- **Nagy K**, Kuijpers-Jagtman AM, Mommaerts MY. No evidence for long-term effectiveness of early osteodistraction in hemifacial microsomia. Plast Reconstr Surg. 2009 Dec;124(6):2061-71. IF: 2, 743

- Reddy SG, **Nagy K,** Mommaerts MY, Reddy RR, Bronkhorst EM, Prasad R, Kuijpers Jagtman AM, Bergé S. Primary septoplasty in the repair of unilateral complete cleft lip and palate. Plast Reconstr Surg. 2010 Oct 14. IF: 2,743

Other publications

- **Nagy K,** Mommaerts M. Másodlagos orrplasztikai eljárások ajakhasadékos betegek esetében. Fül-Orr-Gégegyógyászat 2010, 56(4)

- **Nagy K,** Mommaerts M. Postoperative wound management after cleft lip surgery. Cleft Palate Craniofac J. 2010 Aug 13. IF: 0, 884

- **Nagy K,** Mommaerts MY. Lip adhesion revisited. Ind J Plast Reconstr Surg – 2009 Jul-Dec (42)2: 211-219 IF: -

- **Nagy K**, Mommaerts MY. Advanced S(t)imulator for cleft palate repair techniques. Cleft Palate Craniofac J. 2009 Jan;46(1):1-5. IF: 0, 957

- **Nagy K**, Mommaerts MY: Ignac Semmelweis, the Rescuer of Mothers, The American Journal of Cosmetic Surgery Vol. 25, No. 2, 2008, 73-77.

- **Nagy K**, Szlávik V, Rácz G, Ovári G, Vág J, Varga G. Human submandibular gland (HSG) cell line as a model for studying salivary gland Ca2+ signaling mechanisms. Acta Physiol Hung. 2007 Dec;94(4):301-13. IF: 0, 453

- **Nagy K,** Nagy P, Borsos G, Végh A, Mommaerts MY, Becske M: A distractiós osteogenesis szerepe az arcközép sebészetében (TPD műtéttechnika és esetismertetés). Fül-Orr-Gégegyógyászat 2004, 50(3), 255-260.

- Patonay L, **Nagy K**, Engelke, W: Real-time endoarticular ultrasound imaging of the TMJ - A new diagnostic possibility *Int J Oral and Maxillofac Surg2002. 31(5) 553-557*. IF: 0, 754

- Patonay, L, **Nagy, K**: - A temporomandibularis ízület arthroszkópos anatómiája, *Magyar Fogorvos, 1996. V. évfolyam, 2. szám, 4-11*

- Tóth, M, **Nagy, K**: - A dobüreg endoszkópos anatómiája, *Orvosi Hetilap, 1998. júl.12., 139. évfolyam, 28. szám, 1693-1696*