Objective evidence for the efficacy of surgical management of the deviated nasal septum as a treatment for chronic nasal obstruction

Submitted to the University of Wales for the degree of
Master of Philosophy

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April 2013

Dedication

I would like to thank Nicola for her never ending love and support, who became my wife during the writing of this thesis, and to my son Hari George, who was also born during the final editing of this thesis, and whose smile and laughter has never failed to encourage me on.

Acknowledgements

I would like to give a warm and grateful thanks to Professor Ron Eccles for his excellent guidance, support, encouragement and patience throughout this work, and for giving me the opportunity to work at the Common Cold Centre.

I would like to thank SuSu, Ben and Martez at the Common Cold Centre, for their support and friendship.

DECLARATION

This work has not previously been accepted in substance for any degree and is not concurrently submitted in candidature for any degree.

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This thesis is being submitted in partial fulfillment of the requirements for the degree of MPhil.

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This thesis is the result of my own independent work / investigation, except where otherwise stated. Other sources are acknowledged by explicit references.

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SUMMARY

Background: Nasal septal surgery is a common procedure but there are concerns that the benefits of this surgery are mainly cosmetic.

Objective of review: The primary aim is to identify any functional benefits of septal surgery and provide any evidence of a change in patency of the nasal airway, as assessed by objective methods such as rhinomanometry, acoustic rhinometry, and peak nasal inspiratory flow.

Type of review: Systematic review. Search strategy: A systematic search of the available literature was performed, using Pubmed, Medline (1950-Dec 2013), Embase (1947-Nov 2010), and the Cochrane Controlled Trials Register. Papers written in English that objectively compared pre- and post-surgical treatment of nasal obstruction in adults due to septal deviation were reviewed. Objective measurements of rhinomanometry, acoustic rhinometry, and nasal peak inspiratory flow were specified within the search. Searches were restricted to surgery on the nasal septum, which included septoplasty, submucous resection, and septal (deviation) corrective surgery.

Results: Seven studies (460 participants) involving rhinomanometry, six studies (182 participants) with acoustic rhinometry, and one study (22 participants) using nasal peak inspiratory flow, were included in the review. All the studies reported an objective improvement in nasal patency after septal surgery. Mean unilateral nasal resistance (data from 6 studies) decreased from pre-operative 1.19 Pa/cm^3/s to post-operative 0.39 Pa/cm^3/s, mean minimum cross sectional area (data from 5 studies) increased from pre-operative 0.45 cm^2 to post-operative 0.61 cm^2, median peak nasal inspiratory flow (data from one study) increased by 35 L/min after surgery.

Conclusions: There is sufficient evidence in the literature to conclude that septal surgery improves objective measures of nasal patency, and that improved nasal airflow may have beneficial effects for the patient.

Chapter 1

INTRODUCTION

1.1 Introduction

The nose is primarily an airway. More specifically, it is a pair of airways, which as a result of their structure, assist additional functions of the nose such as humidification, cleaning and olfaction. These two airways are separated by the nasal septum, an osteal-cartilaginous partition covered in mucosa tissue.

There are two main types of nasal obstruction (excluding foreign body and tumour), physiological and anatomical. The nose contains nasal venous blood vessels which, when congested, result in a physiological reduction in nasal patency. When this becomes pathological, such as in allergy (producing rhinitis) or inferior turbinate hypertrophy, nasal obstruction can result. Decongestion of the nose with a topical nasal decongestant, or by exercise,[1] eliminates the vascular component of nasal obstruction caused by swelling of the turbinates, allowing assessment of the anatomical or hard tissue component of the nasal obstruction. Nasal obstruction must be investigated before and after decongestion of the nose.[1] In the hospital setting, this is usually accomplished with a nasal decongestant, but exercise has been used to decongest the nose in some laboratories and in published literature.[2] Persistent nasal obstruction following decongestion points to an anatomical cause.

The nose is the narrowest part of the human airway.[3] Commonly, the septum does not appear straight. A deviation of the nasal septum can cause obstruction to one or both of the nasal airways, producing nasal obstruction. Anterior obstructions of the nasal airway affect nasal airflow resistance to a greater degree than an equivalent obstruction posteriorly. This can be demonstrated by different size obstructions inserted at various points within the nose.[4]

The sensation of nasal obstruction is a common complaint in ENT outpatient departments, with septal deviation being the commonest cause for it.[5] Other causes may be rhinitis or inferior turbinate hypertrophy, and must therefore be ruled out. Once the septum has been identified as the likely cause for nasal obstruction, the definitive treatment (to the septum) is surgery.[6]

The surgical options for a deviated septum are submucous resection (SMR) of the nasal septum and septoplasty, as well as a limited excision of an individual septal spur. The aim of these procedures is to straighten the septum, and by doing so, open up the airways towards a normal patency. There are numerous other surgical procedures to improve nasal patency, when the cause is not septal in origin, such as addressing additional alar collapse or turbinate hypertrophy. These will not be examined in this thesis.

In clinical practice, evidence based medicine is the gold-standard for all care, where management and treatment options can be clearly understood in terms of their expected outcome. This also provides financial justification and defence from a medico-legal aspect. Despite the frequent use of nasal septal procedures by ENT surgeons, there appears to be very little coherent objective evidence for their use. In addition, there are suggestions that the procedures have only cosmetic benefits,[7] and there are further concerns that Primary Care Trusts are considering limiting funding for these procedures.[8]

This thesis aims to assess the objective effects of septal corrective surgery, such as septoplasty and submucous resection of the septum, on the patency of the nasal airway passages.

1.2 Septal Deviation

The nasal septum separates two near-identical nasal passages. As a result, it is assumed that it ought to be straight, and taken to be abnormal if it is not straight. However, the septum is frequently deviated.[9] Accounts of how common septal deviation is vary within the population, most frequently quoted as 80 per cent of the general population, but values can vary between 1 to approximately 90 per cent within the normal adult population.[7, 10-17] Many studies have looked at this incidence and have identified different causes. Accepted reasons for a deviated nasal septum include: congenital, moulding pressure at birth, unequal growth forces on the septum and trauma.[18-20] Ruano-Gill *et al.*[18] looked at fifty embryos, and found that 4% of these fetuses had a deformity, leading them to state that there was a congenital component. Reports of septal dislocations of the newborn vary between 0.5 to 25%.[21] Alpini *et al.*[22] examined 423 newborn infants, finding that 3.8% of natural birth babies and 4.62% of caesarian section delivered babies had septal deviations. Whereas Kawalski & Spiewak[19] looked at 273 newborn babies, and found that of those born by spontaneous delivery, 22.2% had a septal deformity, compared with only 3.9% of babies delivered by caesarian section. This led them to conclude that injury at birth was also responsible.

The majority of septal deviations occur after the neonatal period as a result of accidental trauma, such as in toddlers as they explore their ever-expanding environment, or in adults during work or sport related injuries, or assault related. The frequency of septal deviation increases with age, remaining constant after 49 years of age with a 30% prevalence.[14]

Septal deviations are more commonly found deviated toward the right.[23] One reason for this might be that if a traumatic deviation is as a result of an assault, in the form of a punch from a fist, the majority of people are right handed, therefore causing the deviation to the victim to be toward their right-hand side. Males are found to have septal deviation more commonly than females.[14, 24, 25] When questioned, the number of patients with a deviation who can remember a traumatic event to their nose ranges from 3.7%[26] to 48%.[27]

Min *et al.*[14] correlated different types of injury to different types of nasal septal deviation. Mladina and Krajina[28] described the factors that influence the type of septal deviation, whether as a result of trauma or not. Specifically they found that the caudal process and skull shape played an important factor.

1.3 Diagnosis of Septal Deviation

When considering surgery on a person, a conclusive diagnosis makes the decision to operate, the type of operation, and peri-operative care easier to plan for and manage. Most operations are only performed once a diagnosis is confirmed, for example a cholecystectomy would be undertaken once appropriate blood tests and an ultra sound scan have been obtained. However, there are some conditions, such as appendicitis, which can only be diagnosed during an operation.

Within Rhinology, there is no prerequisite for an objective diagnosis of septal deviation (or even nasal obstruction) prior to undertaking surgery to correct it. Indeed, when examining the literature, there is very rarely mention of an accepted method to diagnose septal deviation. Anterior rhinoscopy, with or without nasal endoscopy, is the most common method of choice for diagnosing nasal septal deviation in ENT clinics. Imaging modalities such as a CT scan (coronal view) can provide objective evidence of the deviation, but are costly, and expose the patient to potentially unnecessary levels of radiation. A CT scan is not normally requested for a simple diagnosis of septal deviation unless additional information is required, for example, whether there is presence of rhinosinusitis.

Studies reported in the literature that have investigated septal deviation have diagnosed it in a similar manner, commonly using anterior rhinoscopy[29-37] with or without nasal endoscopy,[26, 38-41] or scanning the nasal cavity with CT[42] or MRI.[43] Some studies have provided detailed descriptions of their diagnostic criteria, such as Smith *et al.*[42] who used two ‘trained investigators, well versed on the anatomy of the region’ to examine CT scans of the septum. They diagnosed septal deviation if the septum was positioned greater than 4mm from the midline. Kamani *et al.*[44] diagnosed a deviation if anterior rhinoscopy demonstrated an impacted septum, and there was a greater than $0.2cm^2$ difference between the acoustic rhinometry readings of each nasal passage.

Many studies however, do not explain how they have determined that their patients have a septal deviation.[45-47]

Within otorhinolaryngology, anterior rhinoscopy and nasendoscopy are used to identify the presence of a septal deviation. These observations are combined with clinical experience to predict the influence any abnormality of the septum may have to the patient's symptoms. This subjective assessment can introduce an expectant margin of error, which could cause legality issues.[10] Topical decongestion is routinely used to determine the contribution to nasal obstruction from the septum / hard anatomical structures, or from the more vascular structures such as the inferior turbinates. In the outpatient clinic, a decongestion spray is routinely used, whereas in theatre a cocaine liquid / gel is syringed into the nasal cavities, or soaked onto inserted pledgets.

1.4 Classification of Septal Deviation

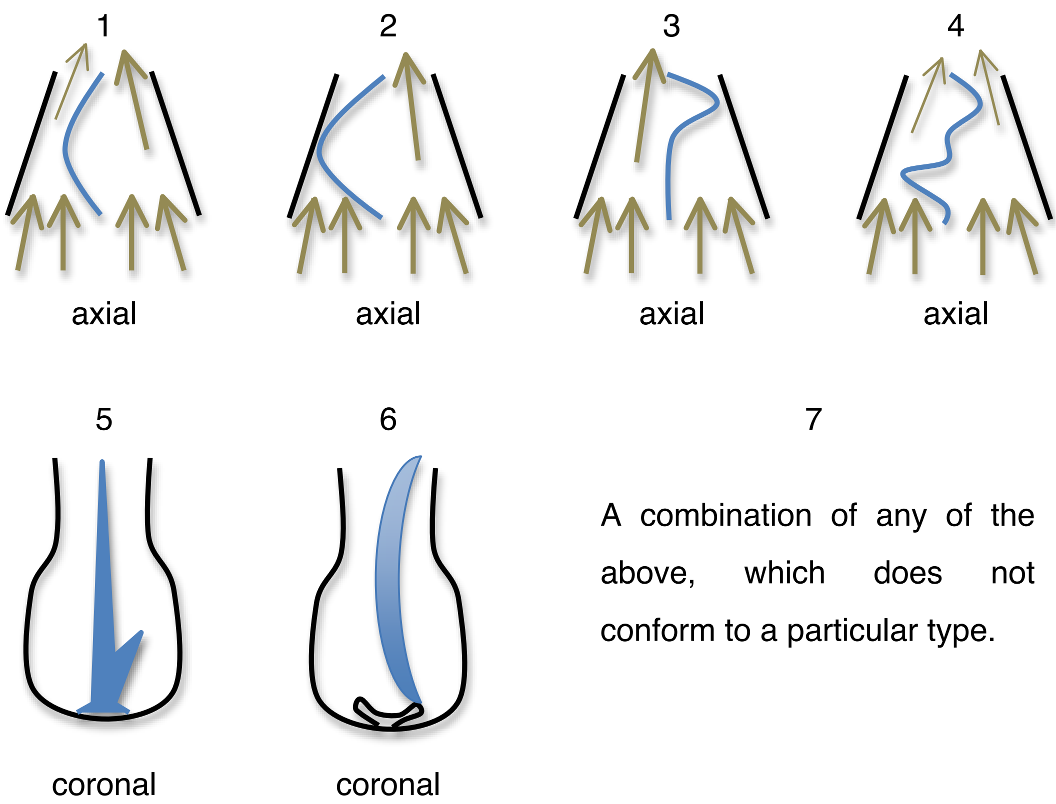
Once identification of a septal deviation has occurred, there is no universally accepted classification system, where the severity of the abnormality can be compared between patients.[48, 49] Such a classification might help in distinguishing those procedures that are likely to be more challenging, so that planning can occur to select the appropriate experience level of the surgeon, and provide efficient theatre time management.[48] It might also aid in comparing the degree of septal deviation to the severity of symptoms experienced by the patient, as well as suggesting the best practice for treatment of different deformities and predicting surgical outcomes. Currently in clinical practice, distinction between different deviations are only in terms of anterior and posterior septum,[32] 's-shaped' deformities and septal spurs.

A number of authors have published various methods that could be used to assess the type or degree of septal deviation. Okuda *et al.*[50] applied a very simple classification system. They proposed just four different types to describe the shape of nasal septums, naming them: O, C, K, and S. Type O is associated with a straight septum, type C depicts a curved deviation, type K defined a kinked deviation, and type S described a S-shape deviation (see figure 1).

Mladina[33] described 7 types of pathological septal deviation (see figure 2). When examining these diagrams of the deviations, note that type 1 to 4 are drawn in the axial / transverse plane (cranio-caudal view), whereas types 5 and 6 are drawn in the coronal plane (antero-posterior view).

Figure 1. Okuda *et al.*[50] classification of septal deviations, where type O is associated with a straight septum, type C depicts a curved deviation, type K defined a kinked deviation, and type S described a S-shape deviation.

Figure 2. Mladina's[33] classification types of septal deviations



Type 1 is described as a vertical ridge in the valve area, which does not affect the function of the valve, since it does not reach as far as the nasal dorsum.

Type 2 differs from type 1 with a more marked ridge, which reaches the dorsum and therefore affects the function of the valve.

Type 3 is similar to type 2, as its one ridge reaches the nasal dorsum, but is different from type 2 since the ridge is present in deeper areas, such as in Cottle's areas[51] 3 and 4 (see Appendix 1).

Type 4 is an 'S'-shaped deformity, with two vertical ridges. One in the valve area, and the second on the opposite side a few centimeters behind.

Type 5 was named the 'sabre septum'. It is described by Mladina as:

> "Beginning from the distal part of the intermaxillar bone wings a horizontal ridge (crista basalis) (which) rises towards the lateral nasal wall and backwards, becoming larger and larger as it gets in deeper, but permanently retaining its characteristically sharp edge (resembling the ancient Turkish sabre) and never being followed by any corresponding gutter on the opposite side of (the) septum." [33]

Type 6 is described as consisting of two horizontal ridges (medial and lateral). The lateral ridge rises from the proximal part of the intermaxillar bone wings, which is most prominent in the third Cottle's area (see Appendix 1). It is said not to 'stick out' too far, but should reduce in size as it travels posteriorly, with a corresponding gutter on the opposite side of the septum.

Type 7 was described as a 'crumpled septum', resembling an incoherent combination of all of the above types, differing from one patient to the next.

Min *et al.*[14] (1995) employed Mladina's classification of septal deviations in their study. They found statistically significantly more people complained of nasal obstruction (2.78%) in the septal deviation group, than in the non-deviated group (1.3%). Furthermore, nasal obstruction was most commonly associated with a ‘s’-shaped deformity (Mladina type 4). They also correlated different septal deviations to the types of trauma sustained.

Guyuron *et al.*[49] (1999) examined patients undergoing septoplasty, grouping their deviations into 6 classes. These classes are simpler to identify and are excellently displayed in their paper. Their belief is that surgery must be tailored according to the class of deviation, in order to achieve greatest benefit and satisfaction for the patient. Baumann & Baumann[48] (2007) also identified 6 types of septal deviation (see figure 3), with slight variation to Guyuron’s[49], associating them with unilateral or bilateral inferior turbinate hypertrophy or concha bullosa. They used this typing to identify patients with deviations that might entail more challenging surgery, thereby identifying the appropriate level of surgical experience required.

Dahlqvist *et al.*[52] simply described the nasal septum as normal, moderately, or severely deviated. They did not provide any information as to the criteria they had used for this assessment, except for a sketched diagram as an example for each (see figure 4).

Roblin & Eccles[53] and Cuddihy & Eccles[29] expressed the degree of obstruction to the nasal passage (as a result of septal deviation) in thirds. Mild deviation was used to describe obstruction of up to one third of the nasal passage, moderate deviation described obstruction of between one third and two thirds, and severe deviation related to greater than two thirds of the nasal passage obstructed. Similarly, Kamani[54] graded septal deviation into three groups, where group 0 included small or no deviations, group 1 (moderate) included deviations occluding one-half of the lumen, and group 2 (severe) where deviations occluded two-thirds of the lumen.

Figure 3. Baumann & Baumann's[48] septal deviation types are similar to Guyuron *et al.*[49] and specifies the frequency of each type found.

Type	Frequency (%)	Septal pathology
1	46	Septal crest
2	23.1	Cartilaginous deviated nose
3	13.1	High septal deviation
4	9.3	Caudally inclined septum
5	4.7	Septal crest
6	3.8	Caudally inclined septum

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Stallman *et al.*[23] used three Neuroradiologists to examine CT scans, and subjectively graded septal deviations as absent, mild, moderate, or severe. Mamikoglu *et al.*[55] used a similar subjective system, but included an additional grade of markedly severe.

Elahi *et al.*[56] used CT scans to measure the angle between i) the superior insertion of the nasal septum into the crista galli, ii) the inferior insertion at the anterior nasal spine, and iii) the apex of the deviation (see figure 5). They then allocated subjects into three category groups according to the angle of their deviation; group I included those with deviations from 0 to 9 degrees, group II from 10 to 15 degrees, group III included deviations >15 degrees.

Reitzen *et al.*[57] used CT or MRI scans to measure the tortuosity at four precise points along the antero-posterior length of the nasal septum. Tortuosity was calculated by dividing the actual length (height) of the septum by the ideal length / height (a straight line between the insertion at the cribiform plate to the hard palate insertion). The maximum tortuosity value of the four measurements was used for each person.

Within clinical practice no classification style is universally used. This is echoed in the research papers performing studies in nasal obstruction, of which there is very little description of the septal deviations discovered. Most studies will simply mention that there is a septal deviation.

Fig 5. An example of Elahi *et al.*[56] measurement system to grade septal deviations. The angle between the green lines represents the deviation, which is then assigned into one of the groups. Image taken from Akoglu *et al.*[58]

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1.5 Assessment of Nasal Patency

Nasal obstruction (a symptom) and deviation of the nasal septum (a diagnosis) are investigated and diagnosed slightly differently. As previously described, septal deviation is diagnosed using anterior rhinoscopy and nasal endoscopy, both of which are subjective, however some studies have used radiological investigations. In contrast, nasal obstruction, or patency, can be investigated using patient and clinician-orientated subjective methods, as well as using objective measurement tools. When clinicians use anterior rhinoscopy or nasendoscopy to examine the nose for nasal obstruction, it is likely that the nasal vestibule or valve area of the nose will be distorted,[59] giving an inaccurate representation of the factors involved in each individual's case.

Patient orientated assessments include scoring tools, such as VAS (Visual Analogue Scale),[36, 60-65] NO-VAS (Nasal Obstruction Visual Analogue Scale)[66, 67] or a Likert 'scale',[65, 68] and questionnaires. The Nasal Obstruction Symptom Evaluation (NOSE) scale[25, 67, 69, 70] is a questionnaire that evaluates an individual's subjective experiences of nasal obstruction over the previous four weeks, based on five questions, with answers rated using a five-point ordinal scale. Others have used questionnaires not developed for nasal obstruction specifically, but related to other ear, nose and throat conditions such as: Fairley nasal symptom score,[71-73] which is a validated measure of general nasal symptoms for assessment of functional endoscopic sinus surgery; SNOT-22,[3, 74] which was developed to assess rhinosinusitis, but includes a question on nasal obstruction; Glasgow Benefit Inventory (GBI),[73, 75] which evaluates otorhinolaryngological surgery and therapy. There are some studies which have just used generic quality of life questionnaires[72, 73, 76] to assess nasal obstruction contribution to daily living.

Although patient's symptoms and subjective improvements following surgery are important, evidence based medicine requires objective evidence to show the need for and benefit from intervention.[32] Since, as already alluded to, there are no objective assessments available to diagnose or grade septal deviation, or easily show objective improvements following surgery, it must fall to objective measurements of nasal patency to evaluate surgical changes.

The following tools have been used to objectively assess nasal patency (and obstruction):

- Video-Rhino-Hygrometry (VRH)[11] - an advancement of the Glatzel mirror technique, where warm expired air from the nose mists a shiny surface (such as a mirror) which is held below the nose. Each nostril produces a pool of mist on the surface, which is analysed by a computer to compare the sizes. This is a novel technique which has not been taken-up by subsequent studies.
- Peak nasal flow (inspiratory and expiratory) – physiological measure of peak nasal airflow during maximal forced nasal inspiration or expiration.
- Odiosoft Rhino (OR)[77] – converts the frequency of sound generated by nasal airflow into cross-sectional area measurements. This is relatively new and has not replaced acoustic rhinometry.
- CT volumetry[78] – using high resolution computed tomography to calculate nasal cavity volumes.
- Youlton meter[79] – an adapted mini-Wright flow meter, to measures peak nasal inspiratory flow instead of lung function.
- Rhinomanometry (RMM): anterior, posterior, active and passive – a functional assessment of airflow, involving the measurement of transnasal pressure and airflow.
- Acoustic Rhinometry (AR) – a sound wave is transmitted into the nasal cavity, and the reflected sounds are measured and converted into a two-dimensional cross-sectional data.

Whichever assessment is used should be under the same environmental conditions, accounting for factors such as temperature, subject resting time and body position.

From reading within this subject and reviewing papers, it seems clear that out of all the methods discussed above which might be used to assess nasal patency objectively, there are mainly three methods which are used around the world in both research laboratories and in clinical facilities. The objective tools used most commonly are rhinomanometry, acoustic rhinometry and peak nasal inspiratory flow. The advantage of these three objective measurement tools is that all three provide functional data, and are easily usable in research to assess nasal airway resistance. The origins of each of these, and the principles they work on, have been reviewed in sufficient detail previously,[11, 32, 78, 80-85] and will not be replicated within this thesis.

1.6 Surgical Options for the Treatment of Nasal Septal Deviation

The only treatment to correct a septal deviation is nasal septal surgery. In essence, this requires moving the septum toward the midline. This can be accomplished by shifting the entire septum, or simply removing those parts of the septum that are orientated away from the midline, such as individual septal spurs. Any surgery to this region has potential risks, such as long-term cosmetic changes, or necrosis (avascular) and the resultant perforation to the septum, which can lead to crusting and bleeding, noisy breathing, and the sensation of nasal obstruction.

The commonest operations performed to straighten the nasal septum are submucous resection (SMR) to the nasal septum and septoplasty. Each procedure has slight variations according to historical descriptions, and a surgeon's experiences of results with different techniques.

Submucous Resection (SMR) of the nasal septum:

Considered by some to be obsolete, due to its extensive nature, this operation involves the removal of parts of the septum that are deviated away from the midline. An incision is made through the mucosa and perichondrium. A plane is then cleaved between the cartilage and perichondrium, allowing preservation of the blood supply.

The incision is then extended through the cartilage, to allow a similar plane to be cleaved in the contralateral nasal cavity. Once the cartilage is free from its overlying perichondrium, any deviated septum is then excised, using either punch forceps or Ballenger's swivel knife, as far back as the perpendicular plate of the ethmoid and vomer – or the flap has been separated. The degree of cartilage or bone excised, is the amount sufficient to result in a straight septum. If parts of the bony septum are deviated or widened, the plane is developed between the periosteum and bone, and bone removed using a hammer and gouge.

It is important to maintain a strip (approximately 5mm wide) anteriorly and along the dorsum of the nose. This preserved strip helps maintain the shape of the nose, and prevents collapse of the tip and retraction of the columella. If the septal dislocation is anterior, then a supporting strip can be maintained behind the excised deviation.[13, 86, 87]

Septoplasty:

Instead of removing large amounts of the septum, a septoplasty involves dividing almost all of the septum's attachments, to allow replacement of the septum into the midline. Similarly to an SMR, the muco-perichondrium flap is raised back as far as the bony septum, and disarticulation is produced between the cartilage and bone at this point. The dissection is continued inferiorly, to the lower fractured edge of the septum, proceeding underneath and into the contralateral side for a few millimetres, to produce a small tunnel, so that the inferior edge of the septum is free. Unlike an SMR, a flap should be raised on one side only. Any large deviations are removed. Thin strips (0.5-1cm) of the vomer and ethmoid at the posterior edge of the cartilaginous septum, and along the inferior floor of the septum are removed, so that the septum (hanging from a 'hinge' at the dorsum) can be replaced onto the vomerine crest, without catching on the bony septal margin.[13, 87, 88]

If a solitary septal spur is noted during examination, excision of this in theatre can have a successful outcome on the sensation of nasal obstruction, without the need for the entire septoplasty procedure.

There are concerns that too many operations on patient's septums are being performed than are required,[10, 89, 90] and that too many people are unsatisfied with septal surgery. Therefore, are we selecting patients for this operation poorly?[10] If correct, this produces an increased risk of unnecessary harm for the patient, leaving the surgeon exposed to complaints, as well as unwarranted costs to the healthcare system, in a time where budgets for the NHS in England and Wales are facing dramatic reductions.

1.7 Evidence of the efficacy of surgery on the septum

Nasal obstruction is one of the most common reasons for nasal surgery and a deviated nasal septum is the most common cause of nasal obstruction.[5] During 2009 to 2010 there were 23,424 diagnoses of deviated septum in England[91] and Wales[92] (England: 21,944; Wales: 1480), following referrals from GP practices. Septal surgery is one of the most common procedures in ENT practice, with more than 20,000 submucous resections and septoplasties performed in England and Wales in 2009-10,[93, 94] but the benefits of this form of surgery have been questioned.[7]

A recent position paper,[8] published by the professional association of UK ENT surgeons (see Appendix 2), expresses concern that some hospital administrations are considering abolishing or severely restricting septal surgery, because of doubts over the benefits of the operation.[89, 90] One of the main concerns put forward about septal surgery is that the benefits are subjective and that the operation is often performed for cosmetic reasons, rather than for any functional improvement in the patency of the nasal airway. As Roblin & Eccles[7] in 2002 found:

> "There is little hard evidence that this procedure provides any benefit to the patient unless the problem is cosmetic, in which case septal surgery may be of value." [7]

However, there is a body of evidence in the clinical literature demonstrating that septal surgery does provide an objective and functional benefit to the patient, by increasing the patency of the nasal airway.

A meta-analysis has been published by Singh *et al.*[95] They identified 60 studies that examined the objective changes in nasal airflow following septal surgery, 13 of which were prospective. They report that 3 of these papers fulfilled their inclusion criteria.[35, 96, 97] All 3 papers used active anterior rhinomanometry to assess objective changes in nasal airflow following septal surgery. Between the 3 papers, data from 141 patients were included. Two of the papers had performed septoplasty to correct nasal septal deviation on their patients,[35, 96] while the last had used submucous resection of the nasal septum.[97] Singh *et al.* found that all 3 showed significant short-term reductions in nasal obstruction following septal surgery, and further suggested that septal surgery objectively improves nasal airflow.

On reviewing the papers presented in Singh *et al.*'s meta-analysis, it is evident that one of these papers included patients who underwent turbinate surgery (out-fracturing), in addition to a septoplasty.[97] This raises doubts about the valid inclusion of this paper within their meta-analysis, as it is difficult to interpret the effect that septal surgery alone has on nasal airflow.

Since the indication for one of the commonest ENT operations performed is in doubt, and supporting evidence for it's efficacy is questionable, it is difficult to provide evidence for its continued use, when financial cutbacks in the health service are required. The main aim of this review is to identify any functional benefits of septal surgery, by providing evidence of any change in patency of the nasal airway as assessed by the objective methods of rhinomanometry, acoustic rhinometry and peak nasal inspiratory flow.

Chapter 2

METHODOLOGY

2.1 Methodology of systematic review literature search

Is there objective evidence of the efficacy of septal surgery, in patients where nasal obstruction is as a result of nasal septal deviation?

To obtain a clear understanding of the objective effects of septal surgery, in patients where nasal obstruction was as a result of septal deviation, it is imperative to perform the correct literature search, allowing identification and comparison of all possible relevant studies.

To answer this question, four primary criteria/conditions were focused on:

1. The cause of nasal obstruction in all patients was as a result of septal deviation.
2. Surgery was performed on the nasal septum only.
3. A method for objective measurement of nasal patency was employed.
4. Objective measurements were obtained both before and after surgery.

To restrict the cause of nasal obstruction to the anatomical deviation of the nasal septum, the searches were restricted to surgery on the nasal septum, which included septoplasty, submucous resection (SMR) of the nasal septum, and septal (deviation) corrective surgery. Although septoplasty and SMR are the commonest operations performed for deviated surgery, more generic terms such as ‘septal surgery’ or ‘operation to the septum’ were frequently used.

As already discussed, the most common forms of objective assessment of nasal obstruction, or nasal patency, are anterior rhinomanometry, acoustic rhinometry and peak nasal inspiratory flow. Other methods described are either experimental with only a one-off study, or not practical for daily clinical use on patients (such as subjecting the individuals to high amounts of dangerous ionizing radiation), and examination of these studies yield insufficient quality or quantity, for example they often use just one or two subjects to demonstrate their method would work.

Anterior rhinomanometry is preferable for this review since it is possible to extract unilateral and total nasal resistance values, in comparison to posterior rhinomanometry, where only total resistance is usually measured. Therefore, the types of objective measurements specified within the searches were: rhinomanometry, acoustic rhinometry and peak nasal inspiratory flow.

2.2 Databases searched

Four databases were used, which are the most popular and reliable within clinical practice. These were: Pubmed, which is controlled by the National Centre for Biotechnology; Medline, which has databases containing papers published from 1950 to December 2013; Embase, which consists of biomedical journals, most of which are peer-reviewed; and the Cochrane Controlled Trials Register, a collection of evidence-based reviews and literature. By searching all 4 of these collections, although duplication of papers occurred, it ensured the most comprehensive review of papers relating to the criteria. Searches were regularly repeated until March 2013, but no additional papers matching the inclusion criteria were identified during this period from the original search date of November 2010.

2.3 Search strategy

A systematic search of the available literature was performed, using Pubmed, Medline (1950-Nov 2010), Embase (1947-Nov 2010) and the Cochrane Controlled Trials Register. Key words were used to search for, within the paper's title or abstract.

The specific terms searched for were: 'rhinomanometry', 'rhinomanometer', 'rhinomanometric', 'acoustic rhinometry', 'acoustic rhinometer', 'peak flow nasal patency', 'nasal inspiratory flow', 'peak inspiratory flow', 'peak nasal inspiratory flow', 'nasal peak flow', 'peak flow', 'nasal forced inspiratory', 'objective', 'operation', 'surgery', 'septal', 'septum', 'septoplasty', 'submucous', 'SMR', 'nasal', 'septal deviation' and 'nasal patency'.

2.4 Searches

All of the titles of papers generated from this initial search were read. Six thousand two hundred and twenty nine titles were read in total. Some of the titles were identified in both the Pubmed and Medline searches, causing some duplication of reading. The values here are the total amount generated by each search engine (including any duplications). If the title appeared to suggest that the paper was pertaining to nasal septal surgery for nasal obstruction, or if the title was ambiguous – so that uncertainty existed as to the content of the paper – the abstracts were reviewed. If the abstract suggested any of the three forms of objective measurement, the full paper was retrieved and read. The initial search terms used for the types of surgery (i.e. septoplasty, SMR, submucous, septal, septum, nasal, nose, surgery and operation) yielded such high numbers of papers, that it was essential to combine these searches with additional searches of the different objective measurement tools in order to gain a more manageable number of papers to review.

Initial search terms:

Septal operations = 'septoplasty' or 'SMR' or 'submucous' or 'septal' or 'septum' or 'nasal' or 'nose' or 'surgery' or 'operation'

PubMed = 926936

Medline = 960185

Rhinomanometry = 'rhinomanometry' or 'rhinomanometer' or 'rhinomanometric'

PubMed = 1252

Medline = 1352

Septal operations AND *rhinomanometry*

PubMed = 1137 (43 papers read)

Medline	=	1289	(10 papers read)

Acoustic Rhinometry = ‘acoustic rhinometry’ or ‘acoustic rhinometer’ or ‘acoustic rhinometric’

PubMed	=	702
Medline	=	666

Septal operations AND *acoustic rhinometry*

PubMed	=	676	(27 papers read)
Medline	=	658	(30 papers read)

Peak nasal inspiratory flow = ‘peak flow nasal patency’, ’nasal inspiratory flow’, ‘peak inspiratory flow’, ‘peak nasal inspiratory flow’, ‘nasal peak flow’, ‘peak flow’, ‘nasal forced inspiratory’

PubMed	=	4764
Medline	=	4293

Septal operations AND *peak nasal inspiratory flow*

PubMed	=	440	(12 papers read)
Medline	=	714	(8 papers read)

Septal surgery AND ‘objective’ (title only)

PubMed	=	116	(12 papers read)
Medline	=	285	(3 papers read)

Septal surgery AND ‘nasal patency’

Pubmed	=	477	(4 papers read)
Medline	=	437	(2 papers read)

2.5 Inclusion and Exclusion criteria

2.5.1 Inclusion criteria

Human studies: No animal studies were reviewed.

Studies written in English: Only studies published in the English language were included in this review.

Adult patient group studies: Septal surgery is rarely performed on the paediatric patient group, partly because the nasal skeleton continues to change until the body reaches its adult dimensions, with its greatest growth seen in childhood.[98] Any significant growth changes could potentially re-alter any previous surgical corrections. From the literature, there appeared to be a few departments operating on this young group, with a representative number of studies. Obtaining accurate assessment with an objective measurement tool is vital to distinguish changes. Some adults find the techniques challenging. Most objective measurement tools, such as rhinomanometry, are even more difficult to use with children, owing to a poor understanding from the patient and compliance to the technique. This causes further difficulty in obtaining reliable data. As a result, this systematic review concentrated on the adult patient group only.

2.5.2 Exclusion criteria

Studies published in a language other than English. All non-English studies were identified in the original searches. All titles were reviewed, and if present, all abstracts were read. In total there were 25 articles written in a language other than English in the original searches (see Appendix 3). Five of these would not have fulfilled the inclusion criteria. There remained 20 papers, which from the title and/or abstract, might have been relevant. Twelve abstracts (9 performing rhinomanometry and 3 performing acoustic rhinometry) were available in English; these were all read. None of these studies contradicted any of the English language studies obtained. Due to the variety of languages, translations could not be obtained for them all. It was not possible to include any data from these papers in the review.

Only two studies used a paediatric group. One undertook rhinomanometry (Risavi *et al.*[41]) and the other used acoustic rhinometry (Can *et al.*[99]) (see Appendix 4). These were excluded from the review for reasons discussed above.

It was originally anticipated to identify studies that had excluded physiological causes of nasal obstruction, such as rhinitis, by providing a 6-week course of medical management prior to an operation. Some studies had described such management plans pre-operatively, unfortunately, this was highly variable. In those that did, some specified exactly what pharmaceutical product had been prescribed, or that IgE blood tests had been performed, others just mentioned a general medical management scheme, while many others just stated that the obstruction had been identified as anatomical. To this extent, it was difficult to compare between the studies, and ensure that such preliminary management had occurred. When surgery was not performed for nasal obstruction, such as for cosmetic reasons, the study was excluded.

It was important for the objective measurements to be performed both before and after the surgical intervention, thus providing changes in nasal patency and outcomes attributed to the surgery only. If a study, such as Tompos *et al.* (2010),[65] did not provide objective measurements both before and after the surgery it was excluded. Preferably these measurements would have also been performed after decongestion to the nasal mucosa had occurred, whether by nasal spray or exercise. This was not always performed or documented within the papers. Within this review, the use of decongestion within a study has been documented when identified by the authors.

Studies were examined to ensure surgery was only performed on the nasal septum, with operations such as septoplasty or submucous resection of the nasal septum. If more than one surgical technique was used within a study, the data relating to septal surgery alone was extracted for comparison. This resulted in some studies retaining very few patients. If data could not be separated in such a manner, such as in Oluwole *et al.* (1997),[100] the study was excluded entirely, resulting in an overall lower number of studies. This became one of the more difficult aspects of the review. Many studies when claiming to examine the results of septal surgery, did indeed perform turbinate manipulation, whether to gain better access to the septum, or due to a contralateral hypertrophied inferior turbinate that was deemed to need reducing. Only studies providing data exclusively for septal surgery were included. Other studies[101] were too vague in their description of 'reconstruction' surgery, such that it could not be assumed that only the septum was operated on. One particularly thorough study by Clement *et al.* (1983),[102] completely neglected to identify what sort of operation was performed, or even what part of the body was involved. It must be assumed to be nasal, but nowhere in their paper do they state what part of the body was operated on.

As already stated, it was the aim of this search strategy to 'cast the net' as wide and encompassing as possible. To this end, while reading each study, any reference made to another paper that might be relevant, was followed-up and examined through searching bibliographies and any other literature available. These were then read, with forward and backward tracing of associated references.

2.6 Difficulties with analysis

When analysing the results from the various studies, there were a number of problems that complicated their direct comparison.

Firstly, assessing data from studies using rhinomanometry was often made difficult because of the different units that were used between studies for nasal airway resistance (NAR), and the different formulae that were used to calculate the resistance.

The following units were used in various studies, to describe the resistance to airflow in terms of the pressure gradient or nasal airflow:

$Pa/cm^3/s$ (Pascals per cubic centimetre per second),
$cmH_2O/L/s$ (centimetres of water per litre per second),
Pa/L/s (Pascals per litre per second),
kPa/L/s (kiloPascals per litre per second),
mL/s (millilitres per second),

Clement[82] in his 'Committee report on standardization of rhinomanometry' produced a number of findings, one of which was relating to the units of resistance used. It was decided that: "…rhinomanometric values should be expressed in SI units", and further clarified: "pressure in Pascals and flow in cm^3 sec^{-1}"; companies manufacturing rhinomanometers would be informed, and asked to include these units on their equipment.

Despite this, many studies continued to use alternate units of resistance or flow[34, 103, 104] - most commonly in the form of '$cmH_2O/L/s$'.[39, 46, 101, 105, 106] Unfortunately, some others did not provide data, but rather a percentage[25] or a statistical change.[10, 104, 107, 108]

Once inclusion and exclusion criteria had been met, a few studies were included within this review, where data was not presented in the preferred SI units of measurement. In order to compare trends between studies, it was necessary to convert such units to the SI format ($Pa/cm^3/s$). This was achieved through the following conversions:

Converting: $cmH_2O/L/s$ ➔ $Pa/cm^3/s$

If…

1 cmH_2O (4 °C) = 98.0638 Pa

1 L = 1000 cm^3

Then…

$$\frac{98.0638\ cmH_2O}{(1000\ L)/s} = \frac{Pa}{cm^3/s}$$

$0.0980638 \times cmH_2O/L/s$ = $Pa/cm^3/s$

This is in accord with the conversion factor that Cole & Havas[109] (1986) state of 0.98×10^{-1}, and similar to what other papers have used.[110-114]

Pirilä & Tikanto[34] (2009) quote data of flow in mL/min, which on inspection appeared incorrect. Personal communication with Pirilä[115] confirmed the units to actually be mL/sec (see Appendix 5). Once this was confirmed, and using the information from Pirilä & Tikanto's study, that nasal airflow had a gradient pressure of 150 Pa, the data could be converted to $Pa/cm^3/s$ as shown below:

Converting: mL/s ➔ $Pa/cm^3/s$

If…

1 mL = 1 cm^3

Pressure gradient of airflow at 150 Pascals

Then…

$$\frac{150}{\text{flow (mL/s)}} = \text{Pa/cm}^3\text{/s}$$

Sipilä *et al.*[37] (1992) present their resistances in units of Pa/(L/s), which can be converted to Pa/cm^3/s as shown below:

Converting: Pa/L/s ➔ Pa/cm^3/s

If…

1 L = 1000 cm^3

Then…

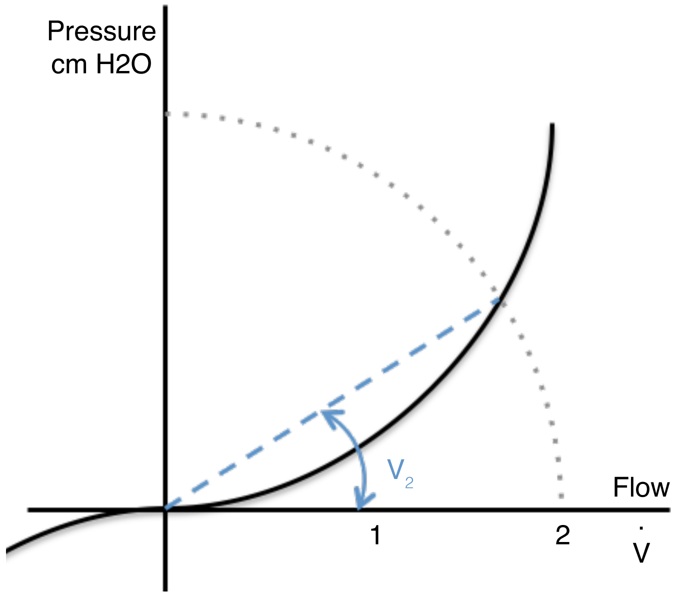
$$\frac{\text{Pa}}{\text{(1000 L)/s}} = \frac{\text{Pa}}{\text{cm}^3\text{/s}}$$

$$0.001 \text{ (Pa/L/s)} = \text{Pa/cm}^3\text{/s}$$

Due to inter-subject variability and the large range of nasal resistance pressure-flow curves - both normal and pathological - not all curves appear to reach the same point on the flow or pressure axis. As a result, there have been a few agreed methods to interpret pressure-flow curves and obtain resistance values. The variety of different resistance values used make it difficult to use a standard point of measurement, for comparison between individual recordings.

One form for denoting resistance (popular within Scandinavia) is using V_2 data.[35, 96, 116-118] V_2 describes NAR as the angle (V_2) between where the pressure-flow curve intersects a circle of 2 or 200 radius units from the origin on the x-axis (see figure 6). Broms *et al.*[119] originally described this in pressure terms of cmH_2O and flow terms of L/s, and hence the curve crosses both the x- and y-axis at the value 2. Singh *et al.*[95] in more recent times has described this in pressure terms of Pascals and flow in terms of cm^3/s, and thus the curve now crosses both the x- and y-axis at the value 200. This method is used to make statistical analysis easier to perform and compare, since resistance values between individuals are non-linear as resistance increases with flow rate and pressure, whereas the V_2 value is linear.[120] The V2 value can only be between 0 and 90 degrees. This method is referred to by Broms as the 'statistical' mode.

Fig 6. The Statistical mode: A reproduction of Broms's pressure-flow curve[119] of NAR demonstrating the angle V_2. This demonstrates the curve of radius 2 (dotted line) intersecting the flow x-axis at 2 L/s. A line can then be drawn from the origin to where the radius 2 crosses the pressure-flow curve. The angle of this line (dashed line) is known as V_2.



In each nasal cavity, V_2 and resistance (R_2) are related to each other by the equation:

$R_2 = \tan V_2$ (when units of resistance are Pa/cm^3/s)

or

$R_2 = 10 \tan V_2$ (when units of resistance are cmH_2O/L/s)

The resistance known as R_2, can be derived from the above equation.

Alternatively, the resistance (R_2) can be read off from a circular scale graded in resistance units, superimposed onto the pressure-flow curve (see figure 7). Broms[119] refers to this method as the ‘clinical’ mode. By using such methods all subjects are able to gain a resistance, even if they are entirely obstructed when their V_2 angle would be 90 degrees.

Fig 7. The clinical mode: using a graduated scale superimposed to NAR pressure-flow curves, the value for R_2 can be read directly off the curve. Image taken from Broms *et al.* (1982).[119]

- IMAGE REMOVED FOR COPYRIGHT REASONS -

Broms states a change in the above equation when calculations are for total nose (both cavities), where he describes a requirement of:

> "A compression of the flow scale by a factor of 2 for the total nose…" [119]

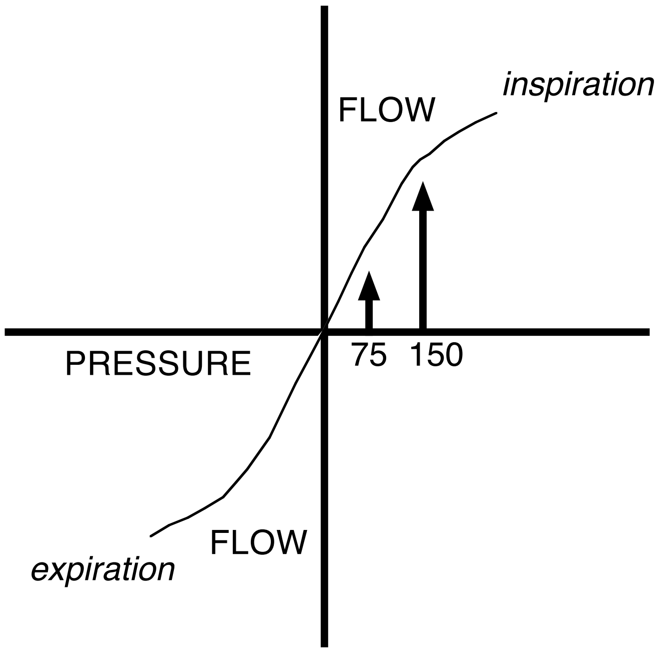
This is suggested because although the pressure across the total nose will be the same, the 'physiological' flow rate will be twice as high.[119] This is further explained in his paper, and he provides the equation:

$R_2 = 5 \tan V_2$ (when units of resistance are $cmH_2O/L/s$)

However, this change in the equation does not appear to have been adopted by those other papers using V_2 for total nasal resistance.

The third method of representing resistance is by using R_{150}. This is the resistance calculated at a fixed pressure of 150 Pascals (see figure 8). Clement's report stated that resistance should be given at a fixed pressure, rather than a fixed flow, and that both R_{150} and R_2 were equally good.[82]

Fig 8. Resistance can be taken from the pressure-flow curve at sample pressures. This diagram is taken from Eccles (2011),[121] and shows how R_{150} can be measured at a pressure of 150 Pascals (the curve above the number 150). N.B. The axis here is labeled oppositely to figures 6 & 7.



Finally, some papers omitted vital data information. Wang *et al.*[26] provided data for resistances, but neglected to include the units used within their paper. It was unclear from the values given, which units they were likely to have used. From the values provided it might suggest that they were using Pa/cm^3/s. Attempts to confirm this detail were unsuccessful, so this study was excluded from some aspects of this review, where comparison between different studies was performed for fear of errors occurring.

Data from the studies using acoustic rhinometry were easier to assess and compare than those using rhinomanometry, as all studies expressed results as the minimal cross-sectional area (MCA) in units of cm^2. The MCA measures the narrowest part of the nose, but there are conflicting opinions about the anatomical correlates of this measurement.[122] Two of the studies[47, 123] did not mention whether any decongestion was used in the nose. When Pirilä & Tikanto[34] decongested the nose, the site of the MCA moved anteriorly due to shrinkage of the inferior turbinate; this indicates that the measurement was at the level of the anterior end of the inferior turbinate. However in other studies the site of the MCA was not defined.[26, 36, 47, 123] Again such inconsistencies might lead to further error in the analysis.

As a result of the different units that have been used by studies assessing nasal patency and resistance, a committee report[82] on standardisation for rhinomanometry was produced which describes the various types and accepts that both R_2 and R_{150} are acceptable.

Chapter 3

RESULTS

3.1 Results

In total there were fourteen papers that fulfilled the criteria for this systematic review, which included 536 participants. Seven studies (460 participants) used anterior rhinomanometry, 6 studies (182 participants) used acoustic rhinometry, and 1 study (22 participants) used peak nasal inspiratory flow.

The explanation for the discrepancy in the sum of the participants, is that some studies have used both rhinomanometry and acoustic rhinometry on the same participants.

3.2 Studies using Rhinomanometry

There were seven studies that fulfilled the inclusion criteria using rhinomanometry. All seven assessed the efficacy of septoplasty on nasal patency, the results of which are shown in Table 1. All seven studies reported performing measurements following decongestion of the nose. Decongestion of the nose allows assessment of the anatomical or hard tissue component of any nasal obstruction.

3.2.1 Descriptions of the rhinomanometry studies:

Broms *et al.*[46] used exercise to decongest the nose and measured nasal patency by anterior rhinomanometry. The study involved 100 consecutive patients (aged 17-65). The patients were selected from 370 patients with persistent unilateral or bilateral nasal obstruction, and who also had a nasal resistance to airflow that exceeded the 95% confidence limit for healthy subjects, in one or both nasal cavities, as determined in a previous study.[1] The degree or severity of septal deviation was not specified. The investigators described the surgery as a functional septoplasty. Student's *t*-test (with a two-sided alternative) was used for comparison of data and p-values.

Jessen and Malm[116] also used exercise to decongest the nose, and measured nasal patency by anterior rhinomanometry. This study involved 200 patients who presented for nasal stuffiness, where a non-mucosal obstruction was suspected. The pool of 200 (aged 15-61) was split into two groups. One group of 100 patients had high NAR (according to Broms[1]), and were subsequently listed for operation. The remaining group with normal NAR were designated the control group. The severity of septal deviation was described as marked only. The operation was described as a functional septoplasty. Student's *t*-test (with a two-sided alternative) was used for comparison of data and p-values.

Jessen *et al.*[96] used exercise to decongest the nose and measured nasal patency by anterior rhinomanometry. Thirty-five patients (aged 23-76) who underwent surgery during a 2-year period were selected if they complained of nasal obstruction and could be demonstrated to have pathological NAR after decongestion. The degree or severity of septal deviation was not specified. The authors described the operation as a functional septoplasty. Student's *t*-test (with a two-sided alternative) was used for comparison of data and p-values.

Sipilä *et al.*[37] used oxymetazoline nose drops to decongest the nose and measured nasal patency using anterior rhinomanometry. This study involved 62 patients, whose main symptom was that of nasal obstruction. These were taken from a total of 102 patients (aged 17-59), who presented with a variety of symptoms and were found to have a septal deviation following an ENT examination. The degree or severity of septal deviation was not specified. The septoplasty was described as a modified Cottle technique. They describe their statistical analysis as using logarithm transformation.

Bohlin and Dahlqvist[35] used a topical spray of oxymetazoline hydrochloride to decongest the nose, and measured nasal patency with anterior rhinomanometry. The study involved all patients (aged 17-56) who underwent functional septoplasty during a 1-year period; however the final number of 35 patients comprised all those who returned to the 10-year follow-up examination, and who were able to complete the rhinomanometry. The degree or severity of septal deviation was not specified. The functional septoplasty was described as 'according to current operative principles'. Student's *t*-test (with a two-sided alternative) was used for comparison of data and p-values.

Pirilä and Tikanto[34] used a mixture of 1:1000 epinephrine and 4% lidocaine to decongest the nose. Nasal patency was measured using anterior rhinomanometry and acoustic rhinometry of the deviated side. The study involved 157 consecutive patients who presented for septal surgery, once clinical examination confirmed their obstruction to be as a result of a septal deviation. The degree or severity of septal deviation was not specified. One hundred seventeen patients (aged 19-69) received solely a septoplasty. The investigators described the operation as a septoplasty performed through a hemi-transfixion incision. Personal communication with Pirilä confirmed that the units of airflow of data quoted in table 1 of their study were mL/s (not mL/min as quoted).[115] Their statistics were described as performed by using binary logistic regression analysis.

Wang *et al.*[26] used 1:1000 ephedrine to decongest the nose, and measured nasal patency with both acoustic rhinometry and anterior rhinomanometry. This study involved 54 patients (aged 17-62), who were operated on over a 1-year period for nasal obstruction due to septal deviation. The deviations were described as mild (less than one-third of the volume of the nasal cavity), moderate (one- to two-thirds of the volume of the nasal cavity) and severe (more than two-thirds of the volume of the nasal cavity). The results were grouped as one, rather than divided into groups of the different severities. Eighteen of these patients received solely a septoplasty. The investigators described their operation as a novel modified septoplasty, exposing three high-tension lines. No units of resistance were specified by Wang *et al*. Attempts to contact Wang to clarify the units used were unsuccessful, so it was assumed to be $Pa/cm^3/s$. Their data were analysed using paired *t* test for samples with unequal variances.

Table 1. shows the 7 studies that fulfilled the inclusion criteria using rhinomanometry.

Paper	n		Rhinomanometry measurement values Pre-Operative	Post-Operative		p-values		Follow-up duration	
Broms *et al.* (1982)[46]	100	Unilateral Total	13.8 cm H_2O/L/s 2.1 cm H_2O/L/s	4.2 cm H_2O/L/s 1.5 cm H_2O/L/s		≤ 0.001 ≤ 0.05		≥ 6 months	
Jessen & Malm (1984)[116]	100	Unilateral Total	1.38 Pa/cm^3/s 0.25 Pa/cm^3/s	0.47 Pa/cm^3/s 0.16 Pa/cm^3/s		≤ 0.001 na		6-12 months	
Jessen *et al.* (1989)[96]	35	Unilateral Total	1.25 Pa/cm^3/s 0.23 Pa/cm^3/s	0.39 Pa/cm^3/s 0.18 Pa/cm^3/s	0.34 Pa/cm^3/s 0.14 Pa/cm^3/s	≤ 0.001 0.01≥ p >0.001	≤ 0.001 ≤ 0.001	9 months	9 years
Sipilä *et al.* (1992)[37]	62	Unilateral	1067 Pa/L/s	188 Pa/L/s		na		6 months	
Bohlin & Dahlqvist (1994)[35]	35	Unilateral	$V_2 = 51.2 \pm 21.5$	$V_2 = 23 \pm 14.3$	$V_2 = 18.2 \pm 9.0$	≤ 0.001	≤ 0.001	3 months	10 years
Pirilä & Tikanto (2009)[34]	110	Unilateral	180 mL/s (see Ref. 9)	322 mL/s (see Ref. 9)		< 0.001		12 months	
Wang *et al.* (2010)[26]	18	Unilateral Total	8.95 ± 11.27 * 0.46 ± 0.32 *	0.53 ± 0.32 * 0.18 ± 0.08 *		0.015 0.003		6-12 months	

Table 1 displays the 7 studies identified within the search that fulfilled the selection criteria. The table includes the values in the original units as provided by their papers. All of these studies used septoplasty, and all provided unilateral data. Four of these studies[26, 46, 96, 116] provided total nasal patency, in addition to the unilateral values. The units used by Wang et al.[26] are unknown, and highlighted by the use of * in the table. The post-operative follow-up for the rhinomanometry studies ranged from 3 months to 10 years.

It can be seen from table 1 that all of the studies show an increase in nasal patency following septoplasty. All reported a statistically significant increase in objective nasal patency following septoplasty. Sipilä *et al.*[37] did not provide a p-value, despite stating their increase as being statistically significant.

In table 2, the values of nasal patencies for the anterior rhinomanometry studies have been converted to the same SI units (Pa/cm^3/s), in order to allow for easier comparison (see table 2). Since no units of measurement were stated in the study from Wang *et al.*,[26] and could not be confirmed with the corresponding author, these values have been excluded from this table.

Table 2. shows studies that fulfilled the inclusion criteria using rhinomanometry, with their values converted to SI units ($Pa/cm^3/s$) and the reduction in resistance in percentage. Wang *et al.*[24] has been excluded since the units could not be clarified.

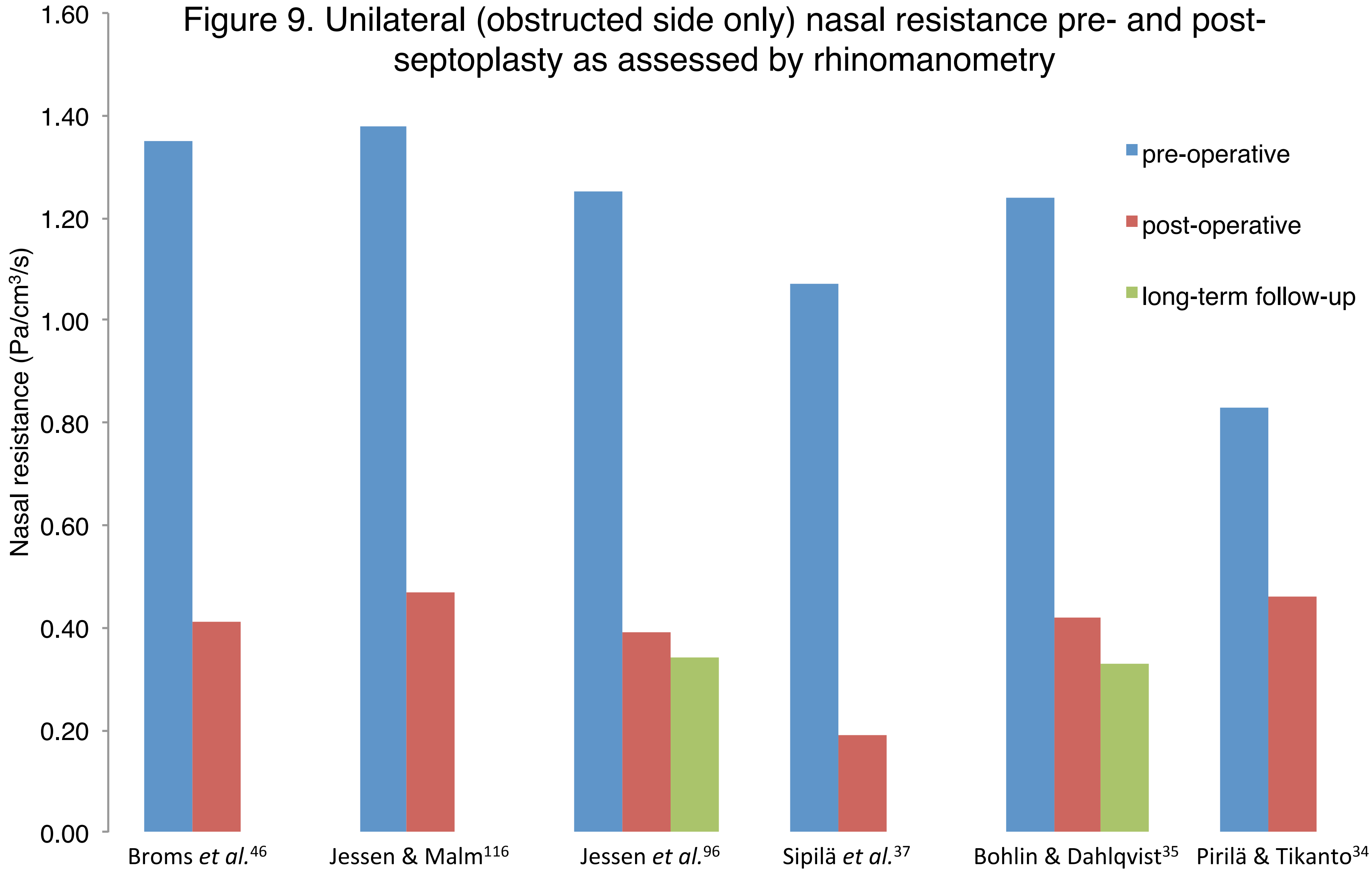
Paper	n		Rhinomanometry measurement values ($Pa/cm^3/s$) Pre-Operative	Post-Operative (% reduction)		p-values		Follow-up duration	
Broms *et al.* (1982)[46]	100	Unilateral Total	1.35 0.21	0.41 (70) 0.15 (71)		≤ 0.001 ≤ 0.05		≥ 6 months	
Jessen & Malm (1984)[116]	100	Unilateral Total	1.38 0.25	0.47 (66) 0.16 (36)		≤ 0.001 na		6-12 months	
Jessen *et al.* (1989)[96]	35	Unilateral Total	1.25 0.23	0.39 (69) 0.18 (22)	0.34 (73) 0.14 (39)	≤ 0.001 0.01≥ p >0.001	≤ 0.001 ≤ 0.001	9 months	9 years
Sipilä *et al.* (1992)[37]	62	Unilateral	1.07	0.19 (82)		na		6 months	
Bohlin & Dahlqvist (1994)[35]	35	Unilateral	1.24	0.42 (66)	0.33 (73)	≤ 0.001	≤ 0.001	3 months	10 years
Pirilä & Tikanto (2009)[34]	110	Unilateral	0.83	0.46 (45)		< 0.001		12 months	

Figure 9 shows the values of the unilateral nasal resistance for anterior rhinomanometry. It can be seen that nasal resistance is reduced in all the studies. It should be noted, that all of the studies in this graph reported a statistically significant decrease between pre- and post-operative measurements (see figure 9), except Sipilä *et al.*[37] who have not provided the details of whether there was a significant change. (Wang *et al.*[26] have been excluded.)

Figure 10 shows the values of the total nasal resistance for anterior rhinomanometry. It can be seen that nasal resistance is reduced in all the studies. The studies from Broms *et al.*[46] and Jessen *et al.*[96] both show a statistically significant decrease between pre- and post-operative measurements (see figure 10). Jessen and Malm[116] did not comment on any statistical significance for total nasal patency. (Wang *et al.*[26] have been excluded.)

If all the unilateral data from these papers (excluding Wang *et al.*[26]) are combined, the mean unilateral pre-operative resistance is 1.19 ± 0.21 Pa/cm^3/s, which decreases to a post-operative resistance of 0.39 ± 0.10 Pa/cm^3/s. This is an improvement in patency of 67%.

Figure 9. Unilateral (obstructed side only) nasal resistance pre- and post-septoplasty as assessed by rhinomanometry



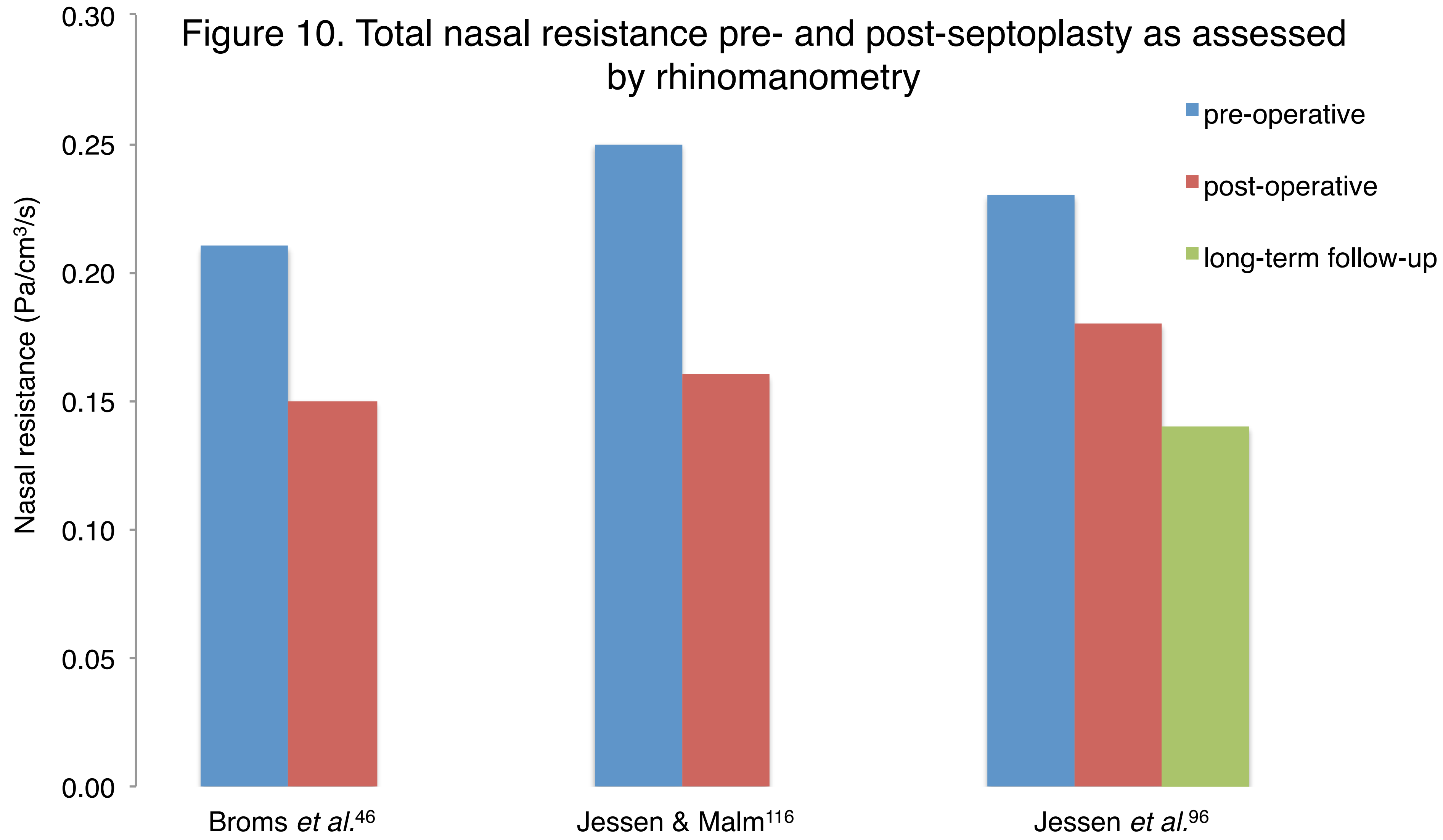


Figure 10. Total nasal resistance pre- and post-septoplasty as assessed by rhinomanometry

3.3 Studies using Acoustic Rhinometry

There were six studies that fulfilled the inclusion criteria using acoustic rhinometry. All but one assessed the efficacy of septoplasty on nasal patency, with Skouras *et al.*[123] describing their operative procedure as 'septal surgery'. Marais *et al.*[47] were the only group not to provide unilateral acoustic rhinometry measurements, who along with Reber *et al.*[36] gave values for total cross sectional area. Skouras *et al.*[123] did not mention their follow-up duration, but the follow-up period of the remaining studies ranged from 1 month to 18 months. Two of the studies did not mention the use of nasal decongestion prior to objective assessment (Marais *et al.*[47], Skouras *et al.*[123]). The results are shown in Table 3.

3.3.1 Description of the acoustic rhinometry studies:

Marais *et al.*[47] did not mention whether they decongested the nose. They used acoustic rhinometry to measure the total MCA. This study involved 8 patients who underwent septoplasty alone, taken from a group of 16 consecutive patients (aged 14-70) who were operated on for nasal obstruction. The degree or severity of septal deviation was not specified. The authors provided no additional description of the septoplasty.

Reber *et al.*[36] used a novesin-adrenaline spray to decongest the nose, and measured the nostril with the smaller pre-operative (narrower) MCA and total MCA (sum of MCA for each side) using acoustic rhinometry. Their study consisted of 27 consecutive patients (median age 32) who presented with nasal obstruction, and were found to have an anterior septal deviation. The degree or severity of septal deviation was not specified. Out of these patients, only 16 patients received solely a septoplasty. The remaining 11 underwent a septoplasty with another procedure (surgery to turbinates, soft palate, or rhinoplasty), the results of which have been excluded from this systematic review and further analysis. They do not describe their statistics used.

Kemker *et al.*[45] used a 1% phenylephrine nasal spray to decongest the nose, and measured the cross-sectional area of the first narrowing (nasal valve) of the side with the septal deviation by acoustic rhinometry. The study involved patients who had already been listed for surgery, of which 14 (aged 24-50) subsequently underwent septoplasty only. The degree or severity of septal deviation was not specified. No further explanation of how patients were selected, or description as to the style of septoplasty used were provided by the authors. Analysis of variance was used for their statistical analysis.

Pirilä and Tikanto[34] as described in the rhinomanometry section above.

Skouras *et al.*[123] did not mention whether nasal decongestion was performed. The nasal patency was measured by acoustic rhinometry. This study included 16 patients (no ages provided) who were operated on for nasal obstruction. The degree or severity of septal deviation was not specified. The investigators described their surgery as plastic surgery to the nasal septum. Statistical analysis was performed using paired Student's t-test.

Wang *et al.*[26] as described in the rhinomanometry section above.

Table 3. shows the 6 studies that fulfilled the inclusion criteria using acoustic rhinometry, displaying the pre- and post-operative data and the percentage increase.

Paper	n	Surgical procedure		Acoustic rhinometry measurement values (cm^2)		Follow-up duration	p - value
				Pre-Operative	Post-Operative (% increase)		
Marais *et al.* (1994)[47]	8	Septoplasty	Total	2.05	2.26 (10)	2 months	na
Reber *et al.* (1998)[36]	16	Septoplasty	Unilateral Total	0.49 1.10	0.58 (18) 1.17 (6)	2 - 6 months	na na
Kemker *et al.* (1999)[45]	14	Septoplasty	Unilateral	0.58 ± 0.21	0.65 (12) ± 0.14	1 - 18 months	na
Pirilä & Tikanto (2009)[34]	110	Septoplasty	Unilateral	0.35	0.49 (40)	12 months	<0.001
Skouras *et al.* (2009)[123]	16	Septal surgery	Unilateral	0.43 ± 0.19	0.70 (63) ± 0.23	na	0.0007
Wang *et al.* (2010)[26]	18	Septoplasty	Unilateral	0.38 ± 0.21	0.63 (66) ± 0.14	6-12 months	0.000

Table 3 shows that all 6 studies demonstrated an increase in minimal cross-sectional area following septal surgery. Three of these showed a statistically significant increase from pre- to post-surgery.

The unilateral MCAs can be more easily compared in Figure 11 (where * signifies the studies that showed statistical significance). Marais *et al.*[47] did not provide unilateral measurements in their study; Marais *et al.*[47] is not present in this graph.

Figure 12 displays the changes in total MCA from the 2 studies that included these measurements. Note that despite figure 12 demonstrating total MCA, septal surgery produces an increase in total MCA in both studies.

By combining the results of all the unilateral MCAs from these studies, the mean MCA pre-operative was 0.45 ± 0.09 cm^2, which improved to a post-operative MCA of 0.61 ± 0.08 cm^2; this was an increase in unilateral MCA of 36%.

Figure 11. Unilateral (obstructed side only) nasal minimal cross-sectional area as assessed by acoustic rhinometry

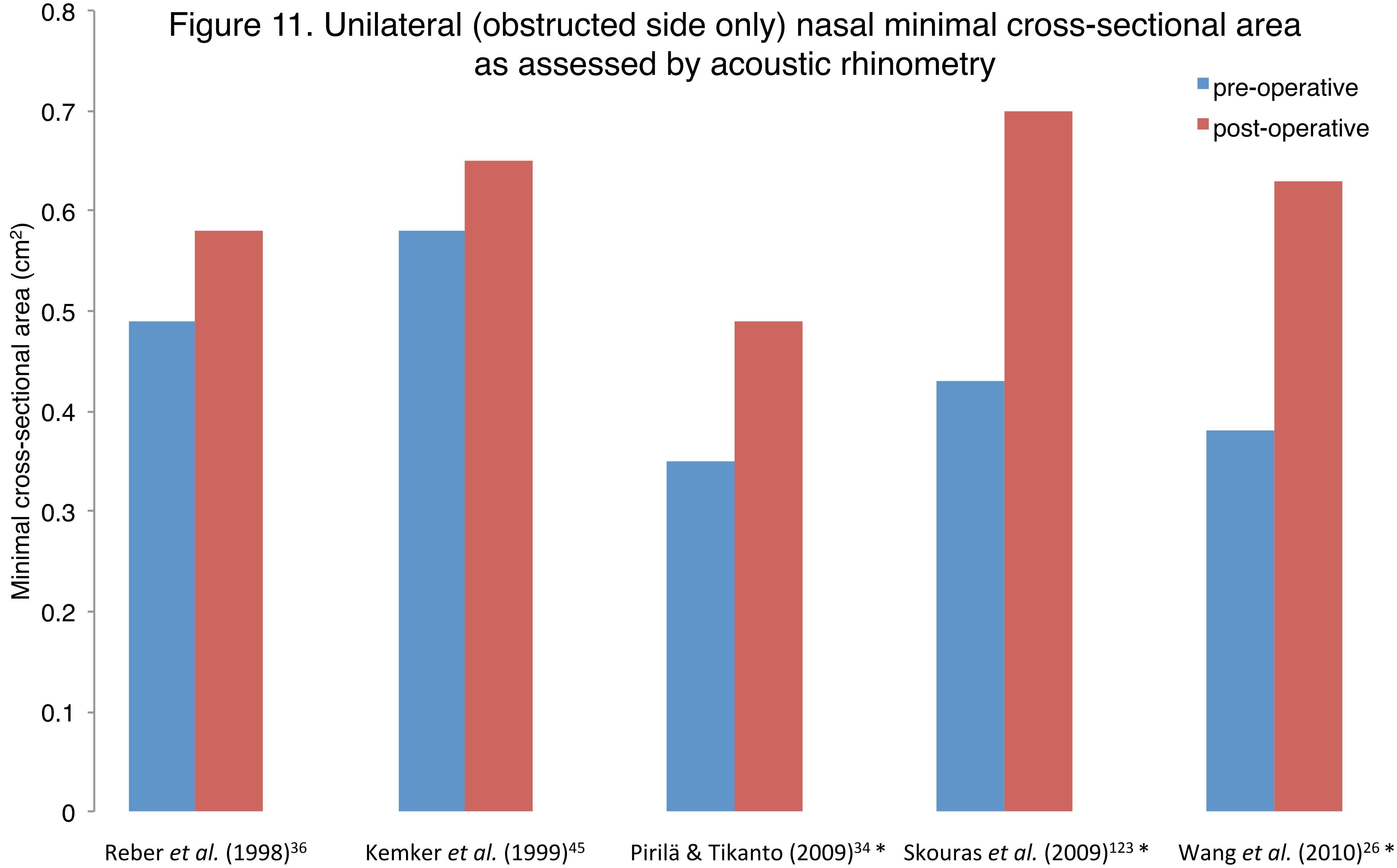
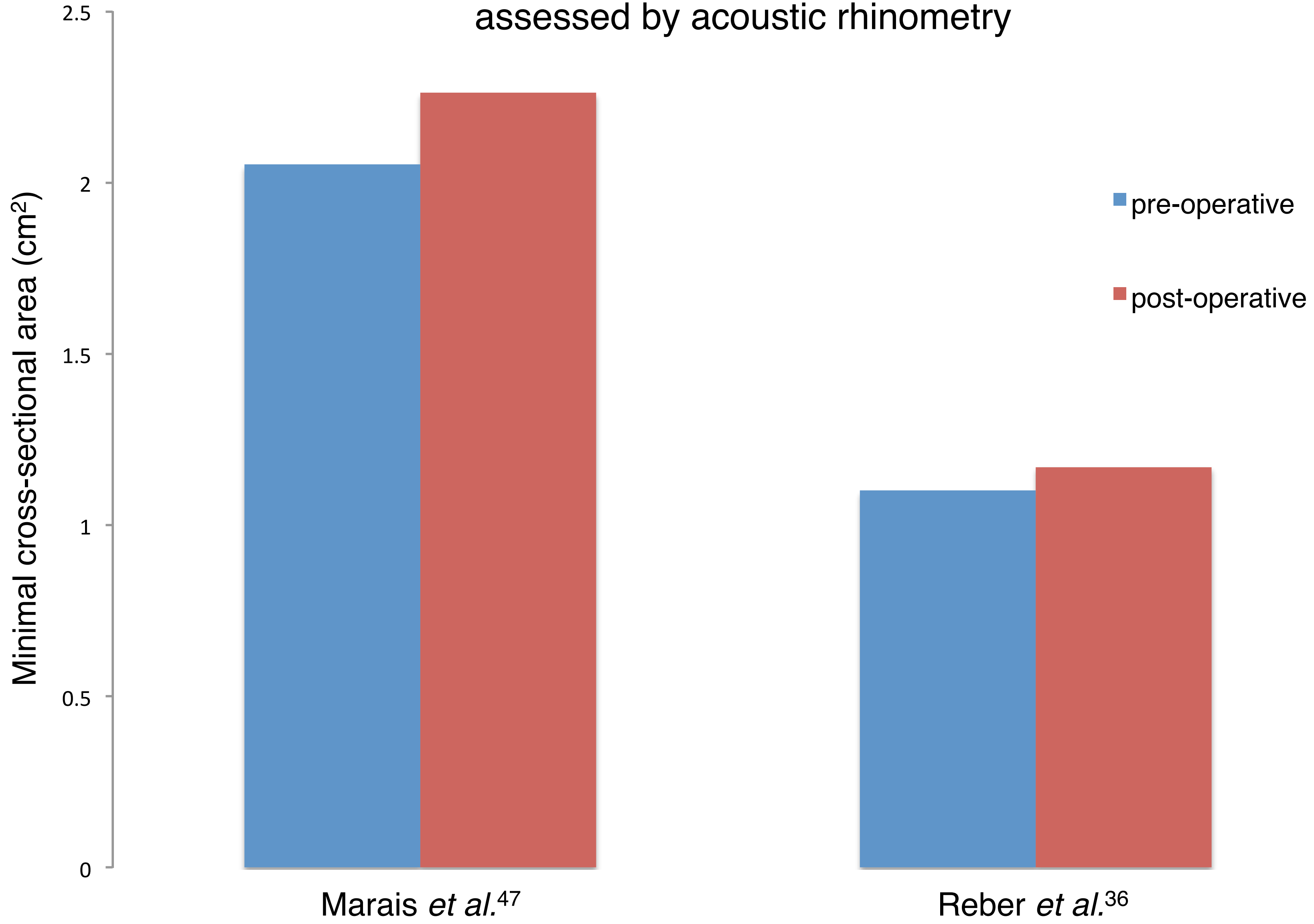


Figure 12. Bilateral (both nostrils) nasal minimal cross-sectional area as assessed by acoustic rhinometry



3.4.1 Description of the peak nasal inspiratory flow study:

Low[124] does not mention the use of nasal decongestion. The study involved 22 patients (aged 18-55) out of 30, with symptomatic nasal obstruction (for at least 6 months) secondary to septal deviation, and with associated snoring. The degree or severity of septal deviation was not specified. He did not specify the type of septal surgery, but showed a post-operative increase of 35 L/min (median value) from a pre-operative value of 80 L/min (median). No information was available regarding whether this was a statistically significant increase. No description of the statistics used was included in their paper.

Table 4. shows the only study that fulfilled the criteria using peak nasal inspiratory flow. This is demonstrated as the median increase with the percentage increase shown.

Paper	n	Surgical procedure	Peak nasal inspiratory flow measurement (L/min)		Follow-up duration	p-vaule
			Pre-Operative	Post-Operative (% increase)		
Low (1994)[124]	22	Septal surgery	80 (Median)	increase of 35 (44)	4-12 months	na

Chapter 4

DISCUSSION

Discussion

This review demonstrates that objective evidence exists, that nasal obstruction due to septal deviation can be significantly improved by septal surgery. An increase in nasal patency towards a normal value is clinically significant, since the primary function of the nose is as an airway.

4.1 Objective evidence / Clinical relevance

Previously, other studies have provided objective evidence of benefit from septal surgery. This review has aimed to build on these findings. Some studies have produced only weak evidence due to the few numbers in their trials, their patient selection or wide choice of surgery used.

This review concurs with other studies, reviews[95] and publications,[8] which have examined the anatomical causes of nasal obstruction. It supports the use of septal surgery in patients with septal deviation, providing otorhinolaryngology with a stronger evidence-based opinion. However, this systematic review raises further questions, such as which patients would benefit from surgery, and which operation will benefit the patient.

4.1.1 Operation selection:

Unfortunately, there were some studies where data for septal surgery alone was not available. This resulted in fewer studies (and participants) for overall comparison. In these studies, additional operations were performed, most commonly inferior turbinate manipulation, involving either out-fracturing, anterior reduction or resection. These would be performed to aid access to the septum, open the nasal passage further, or target a hypertrophied contralateral inferior turbinate. Marais[47] found that increases in cross sectional area and patient satisfaction were greater in patients with inferior turbinate trimming in addition to septoplasty, however they note that the degree of obstruction was greater in this group of patients, hence the need to perform this extra level of surgery. Illum[125] however, reported that at 5-year follow-up, there was no difference in acoustic rhinometry values in nasal obstruction patients who had been treated randomly with septoplasty alone or septoplasty plus inferior turbinoplasty.

This systematic review focused solely on septal surgery, excluding all other surgery. Despite this restriction, there was still variation within the descriptions of *septal surgery*. Some authors were vague as to their exact technique, while others were more specific describing 'Cottle's approach', 'modified Cottle technique', Septoplasty using 'Huizing & Pirsig criteria', and some gave in-depth descriptions of each part of their procedure.[34] Despite this occasional lack of detail, this review provides evidence to support operations on the septum.

4.1.2 Patient selection:

One study from Sipilä and Suonpää[126] evaluated 716 patients who had been referred for septal surgery due to nasal obstruction, 432 of whom were already on their surgical waiting list. In addition to patient history and clinical examination, rhinomanometry was used to assess whether each patient's nasal resistance was within 'normal' ranges, ranges taken from their previous study.[127] They concluded that their results suggest that 'normal' resistance is up to 0.2 Pa/cm^3/s (200 Pa/L/s) for unilateral resistance, and 0.09 Pa/cm^3/s (90 Pa/L/s) for total resistance, at radius 200 (R^2) (0.3 and 0.15 Pa/cm^3/s respectively at 150 Pa). These readings were all taken after nasal decongestion. Their results indicated that only 55% of their patients listed for surgery were eligible for septal surgery, when using rhinomanometry screening criteria. Of those operated on with higher than 'normal' nasal resistance, 85% were satisfied with the procedure, in comparison to 69% satisfaction in patients who had 'normal' nasal resistance, but had been deemed eligible for surgery on their history and clinical examination alone. This technique was also used to identify patients with high bilateral nasal resistances, instigating them to be operated on earlier. A study by Mertz *et al.*[101] reported that of all those operated on, those that reported symptomatic improvement, had a higher pre-operative nasal resistance than those who gained no benefit from surgery. Jessen and Malm[116] report that when using rhinomanometry to screen preoperatively, so that only patients with high nasal resistance receive surgery, they can achieve a subjective benefit in 81% of patients, with 56% developing 'normal' nasal resistance (according to Broms[1] values).

Sipilä and Suonpää[126] proposed rhinomanometry as an objective diagnostic tool and prognosis indicator, in comparison to a subjective diagnosis when using anterior rhinoscopy (with or without nasendoscopy). Potentially, this method could be used to identify those patients who might benefit the most from surgery, reducing the number of operations performed, saving money and increasing patient satisfaction as a result. However it ought to be noted that additional 'diagnostic costs' would be involved for each patient, after taking into account the cost of purchasing, repairing and calibrating the rhinomanometer, as well as employing additional technician staff to operate and run the instruments.

4.1.3 What is normal nasal patency?

When investigating the human body, knowledge of the normal ranges of parameters such as lung function, temperature and blood sugar, are essential in determining the presence of disease, and deciding whether it is necessary to restore these functions back to this range by an intervention. Despite the frequency of nasal obstruction complaints, and the popularity of the corresponding septal corrective surgery, these procedures are embarked upon without any reference to a normal range of nasal patency. For example, a respiratory physician would consider lung function tests, such as the production of values for Forced Expiratory Volume (FEV) and Peak Expiratory Flow (PEF), to be mandatory before administering treatment for a patient with suspected obstructive pulmonary disease.[128]

Within rhinology literature and clinical work, there is no universally accepted normal range for nasal patency. In a recent review on the use of objective measurements in selecting patients for nasal surgery, it was stated that, “the fact that validated normal values are still lacking, is a major problem” [129] As already discussed, some studies[126] have targeted individuals for surgery by identifying those with nasal resistance outside the ‘normal’ ranges. These ‘normal’ ranges have evolved from individual laboratories or surgeons, that have found values that they believe are representational of their patient population, and are of use to them within their work. Most commonly, anterior rhinomanometry has been used for this task, however there were some studies that give values for acoustic rhinometry[130-132] or peak nasal inspiratory flow.[79, 133, 134]

A search of the literature revealed a number of papers that either provided resistance values for groups of normal patients, or stated what they believe and use as ‘normal’ nasal resistance values (see tables 5 and 6).

Tables 5 and 6 contain values for ‘normal’ unilateral and total nasal resistances respectively. The values were measured using anterior rhinomanometry from the decongested nose. The results for Sipilä’s normal range, as quoted by Holmström (2010), were confirmed as unilateral resistances through personal communication with Holmström[135] (see Appendix 6).

Table 5. The range and mean values for the published 'normal' unilateral nasal resistances, as measured by anterior rhinomanometry, from the decongested nose.

Paper	n	Normal Unilateral Nasal Patency Range (Pa/cm³/s)		Mean value (Pa/cm³/s)
		Lower value	Higher value	
Jalowayski *et al.* (1983)[106]	20	-	-	0.43
Jessen & Malm (1988)[2]	100	-	-	0.36
Szücs *et al.* (1995)[136]	100	-	-	0.3
Kenyon (1987)[137]	25	-	-	0.28
Szücs & Clement (1998)[63]	15	0.25	0.3	0.26
Cole (1997)[114]	891	-	0.4	0.23
Pallanch *et al.* (1985)[138]	80	0.09	0.52	0.22
Gordon *et al.* (1989)[105]	14	0.14	0.35	0.17
Sipilä *et al.* (1992)[37]	97	-	0.3	-
Sipilä (from Holmström 2010)[135]		0.15	0.5	-
McCaffrey & Kern (1979)[39]	23	-	0.69	-
Holmström (2010)[129]		-	1.0	-

Table 6. The range and mean values for the published 'normal' total nasal resistances, as measured by anterior rhinomanometry, from the decongested nose.

Paper	n	Normal Total Nasal Patency Range ($Pa/cm^3/s$)		Mean value ($Pa/cm^3/s$)
		Lower value	Higher value	
Eiser (1990)[139]	n/a	-	-	0.25
Jalowayski *et al.* (1983)[106]	20	-	-	0.21
Jessen & Malm (1988)[2]	100	-	-	0.18
Calhoun *et al.* (1990)[113]	130	0.09	0.85	0.18
Shelton *et al.* (1990)[140]	10	0.14	0.22	0.18
Canbay & Bhatia (1997)[141]	74	0.1195	0.236	0.1575
McCaffrey & Kern (1979)[39]	23	-	0.29	0.15
Gleeson *et al.* (1986)[142]	12	-	-	0.15
Postema *et al.* (1980)[143] (Males only)	68	-	0.23	0.14
Cole (1997)[114]	891	-	0.15	0.09
Pallanch *et al.* (1985)[138]	80	0.04	0.15	0.08
Gordon *et al.* (1989)[105]	14	0.03	0.1	0.06
Sipilä *et al.* (1992)[37]	97	-	0.15	-
Gammert *et al.* (1988)[144]	56	-	0.3	-

Using anterior rhinomanometry, the 'normal' mean resistance values in the decongested nose of adults varies from 0.17 to 0.43 Pa/cm^3/s[2, 37, 39, 63, 105, 106, 114, 129, 136-138, 140] for unilateral nasal patency, and 0.06 to 0.25 Pa/cm^3/s[2, 37, 39, 105, 106, 113, 114, 138-144] for total nasal patency. As previously discussed, the units used within these papers varied. They have been converted to SI units for comparison. As can be noted from tables 5 and 6, not all studies provided a range; some provided an upper limit, while others provided a mean. There is some variation in these normal values.

In some papers there was no decongestion used, or this information was absent. These studies were not included in this review. In addition, within the studies that provide nasal resistance values for normal patients, it can be seen that there are variations between other factors such as the ages and sexes of patients, the racial origins of the patients, and whether unilateral or total resistance values were recorded. It has been suggested by Holmström,[129] that we are still awaiting "a large series of measures, preferably population based and stratified according to age, sex, height and weight". After all, this is how other parameters such as BMI and FEV are stratified. Stratifying the population according to sex and age is simple, however, when it comes to race or geographical location we arrive at a problem. The nose is unlike internal organs or systems, since it is exposed to the external environment, with climate exposure influencing the size and shape of the nose.[128] For example, the narrow leptorrhine nose is reported to have a lower patency than the broader platyrrhine nose,[130, 141, 145, 146] and there are climatic and racial differences in nasal shape and size, when comparing indigenous peoples from across the world.[147-149] Unfortunately, classifying individuals according to their race, such as Caucasian, Asian, Mediterranean etc. is outdated and unscientific,[150] and furthermore, a selection of the population from any modern city will contain subjects of differing migration, due to immigration and mixed race relationships.[128] As a result, no objective values have been agreed upon to accurately identify those individuals who have abnormal (pathological) or normal (healthy) nasal resistances, and there is no reason to believe that this will be resolved in the near future.

Importantly, it does not follow that objective measurements are of no use to the surgeon. Broms[1] studied a group of patients to obtain normal reference values in the decongested nose, which he then stratified according to height. His range for normal unilateral nasal resistance was 0.14 to 0.23 $Pa/cm^3/s$, and 0.08 to 0.12 $Pa/cm^3/s$ for total nasal resistance, with upper limit values of 0.77 and 0.28 $Pa/cm^3/s$ respectively. Whether these ranges are valid is unknown, but they are similar to those quoted earlier by others.

If Broms' values for normal range are superimposed (shown as a yellow band) on the earlier charts (figures 9 and 10) from this systematic review for unilateral and total nasal resistances pre- and post-septoplasty respectively, it can be noted that the pre-operative resistances are high compared with Broms' 'normal' values. It further demonstrates that septal surgery returns the post-operative resistances toward this 'normal' resistance (see figures 15 and 16).

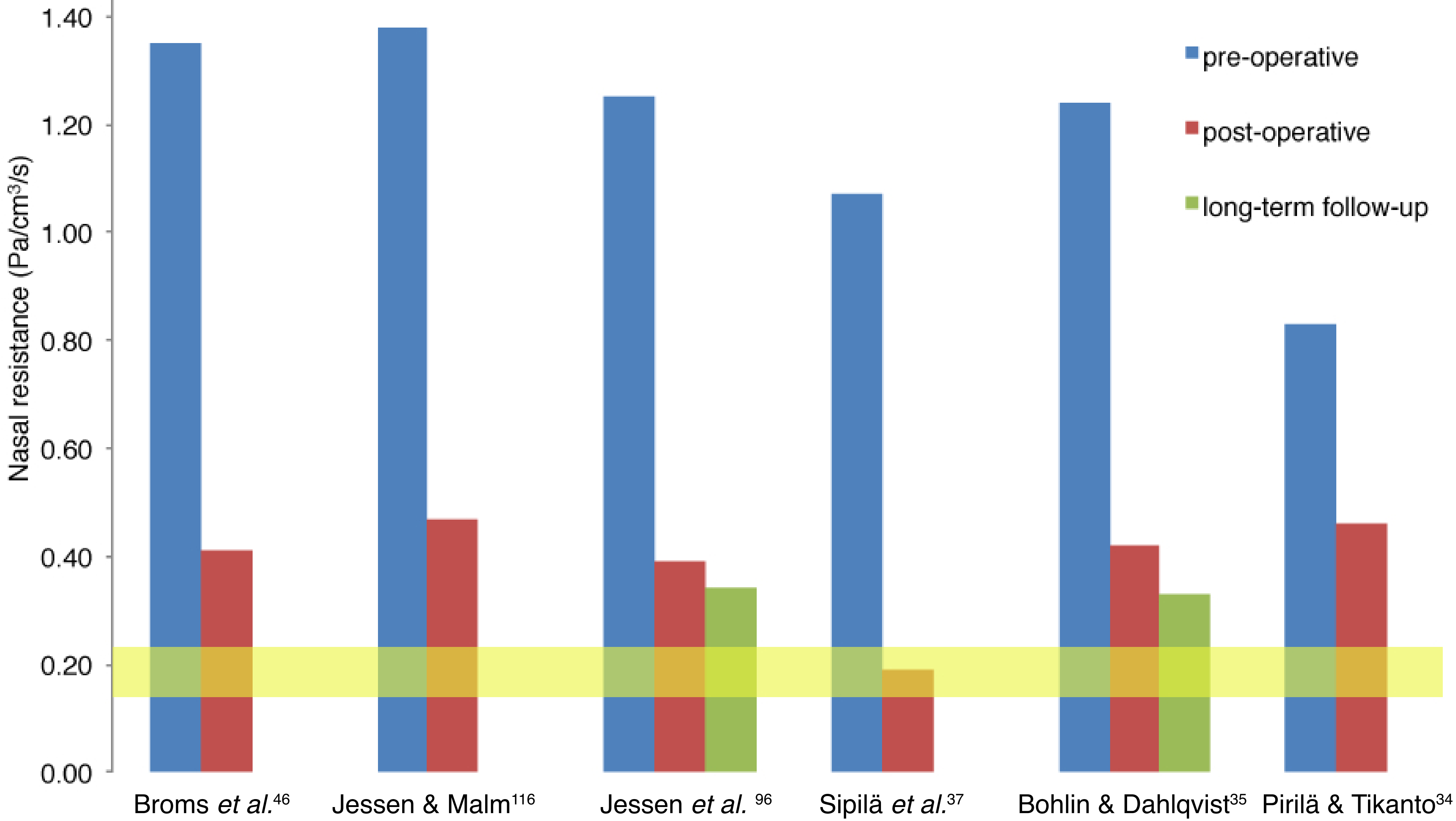
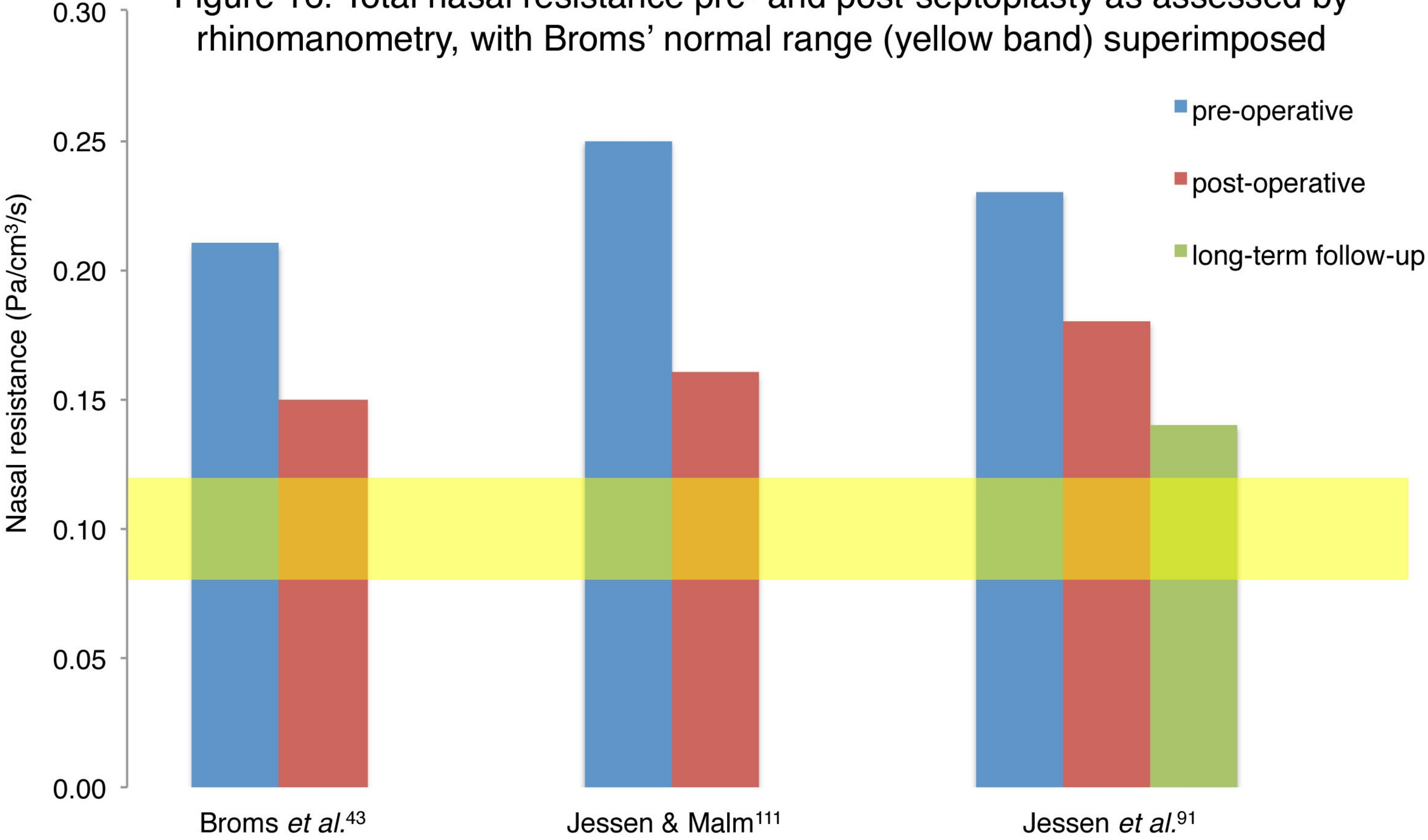


Figure 15. Unilateral (obstructed side only) nasal resistance pre- and post-septoplasty as assessed by rhinomanometry, with Broms' normal range

Figure 16. Total nasal resistance pre- and post-septoplasty as assessed by rhinomanometry, with Broms' normal range (yellow band) superimposed



4.1.4 Why unilateral nasal measurements are informative:

The changes in nasal patency due to surgery are clinically significant, as they return the patency of the obstructed nasal passage back towards a normal range. Most of the studies focus on changes in unilateral resistance of the obstructed side of the nose (the side of the deviation), but nasal septal surgery also has effects on the contralateral nasal passage[104] and the nasal valve region.[108] Correction of a deviated septum may decrease the patency of the nasal passage on the opposite side to the deviation. In general, this does not cause any symptoms of obstruction, as the sensation of nasal obstruction is correlated with the patency of the deviated (narrowest) side, and not with total nasal patency.[104] A reduction of the inferior turbinate on the contralateral side, is commonly performed to correct for any decrease in patency following correction of the deviation, but there is little evidence to support any benefit of this procedure.[104] Further discussion relating to additional turbinate surgery, or the proposal that the turbinate in the wider nasal passage enlarges to compensate for the septum deviating away from the midline, have not been investigated as part of this review, and is too expansive a topic to discuss here.

4.1.5 Long-term results:

The benefits of some operations are known to decline over time. An example of this within Otorhinolaryngology is surgery on the soft palate, such as laser-assisted uvulopalatoplasty for patients who snore, where studies demonstrate a relapse of symptoms. The greatest benefit from this surgery is found anytime from 6 weeks following surgery and within the first year, with long-term studies demonstrating reduced satisfaction, independent to any lifestyle changes.[151]

Some of the studies examined in this review provide long-term follow-up data.[35, 96] One of the studies provided follow-up for up to 10 years.[35] In those that did provide additional long-term follow-up, the nasal airflow had increased further, though by a smaller increment than noticed more immediately following the surgery.[35, 96] This review found no evidence that it was necessary to repeat surgery.

4.2 Subjective evidence

In addition to objective measurements and outcomes, subjective benefits were investigated by some studies. The intention of this systematic review was to obtain objective data, therefore data referring to subjective outcomes have not been investigated or discussed in any detail, but will be mentioned briefly below.

There is a view that the patient's subjective symptoms are more important, and that this is a more useful method to assess outcome.[61] It is important that patients notice a benefit from their procedure, since this is the reason for their original complaint and referral to a specialist. Many studies that were assessed during the course of this review included subjective methods of assessment. In fact, every study that fulfilled inclusion criteria for the systematic review included subjective data as well, and all of them demonstrated subjective improvement following septal surgery.

Broms *et al.*[46] found that if nasal resistance decreased, patients' satisfaction was more likely, and Jessen and Malm[116] noted that most of the patients who felt improved subjectively, displayed reduction in resistance, the majority of who reached 'normal' values for NAR. Sipilä *et al.*[37] noted that the greatest subjective satisfaction occurred when a subject's nasal patency returned to 'normal' values.

No study was discovered that reported overall worsening of subjective score following septal surgery for nasal septal deviation. Jessen *et al.*[96] found that at their second (long-term) follow-up at 9 years, there was a reduction of patient satisfaction, when compared with the initial post-operative assessment at 9 months, but these were still improved from pre-operative levels. The objective measures however showed further improvement from the initial 9-month check. Those studies that found individual patients dissatisfied with their procedures most commonly showed lower or normal resistance values pre-operatively,[61, 62, 101] or entailed post- operative complications. If another complaint other than septal deviation was responsible for the patient's symptoms of nasal obstruction, such as allergy, patients were less satisfied with their septal surgery.[10, 152-154]

The correlation of subjective and objective scores of nasal obstruction is a controversial issue, and has been much debated. In 1989, Jones *et al.*[61] found no correlation between mean nasal resistance and mean subjective symptom score, when studying 500 patients classified either normal, or those with allergy or vasomotor rhinitis. Although they summarised that:

> "Rhinomanometry is still extremely valuable where objective measures of nasal resistance to airflow are necessary in medical research, evaluation of medical and surgical treatments for nasal obstruction . … the results, however, must be interpreted with caution and should not be extrapolated for use as a measure of patient satisfaction." [61]

A systematic review by André *et al.*[155] in 2009 looked at the correlation between objective and subjective changes in nasal obstruction following septal surgery. This review noted that in patients with obstructive symptoms, a correlation is more likely to be found when using rhinomanometry or acoustic rhinometry. They suggested that objective measurements could be used as part of an overall evaluation of the patient, but questioned whether using such objective measurements would add any "…meaningful contribution to the diagnostic and therapeutic process…"[155] since subjective symptoms of nasal obstruction correlated so well with objective measurements of obstruction. They argued that objective measurements were therefore redundant if subjective measurements were available. This thesis agrees that objective measurements should be used in addition to an overall evaluation, but further believes that such measurements are useful in the identification of which patients might benefit from septal surgery (perhaps by comparing with normal ranges), as well as providing evidence of a benefit to nasal patency, and therefore justification for the procedure.[156]

It should also be noted the importance of the placebo effect of surgery to any subjective results obtained. When someone is operated on, there can be a psychological effect to the surgery. Patients may want to please their doctor, or justify in their own minds the worthwhileness of going through such surgery. The very nature of believing they have received the correct treatment, may cause their symptoms to diminish. This is particularly relevant, since it must be remembered that objective evidence of improvement in nasal patency, does not necessarily correlate with patient satisfaction.

In scientific research, when testing medication on patients, a good study will take into account and limit this placebo effect, by introducing an inert or sham medication. The recipient would be unaware which treatment (real or sham) they are receiving; this is known as 'blinding'. Preferably the study would be 'double-blinded', meaning both recipient and investigator are unaware. This safeguards against bias in the results obtained. When studying the effects of an operation, it is extremely controversial to include such a treatment arm. A sham operation would include the entire procedure, except the step thought to be therapeutic. As a result, the patient, unlike in the situation of testing medication, would have been subjected to invasive intervention such as general anaesthetic and tissue trauma, with potentially dangerous complications. Such sham operations have taken place in otorhinolaryngology in the past, which controversially suggested the psychological benefit of surgery for Ménière's disease.[157] No such study has been carried out for nasal obstruction, deviated septum or septal surgery, and is unlikely to happen in the future due to a lack of 'clinical equipoise'.

4.2.1 Benefit to patients:

Further benefits to patients can be shown in quality of life questionnaires, which suggest that following septal surgery, patients visit their doctor less, and require less medication for nasal obstruction.[75] This has potential cost saving implications for the NHS. The cost of medications prescribed for nasal obstruction in Primary Care within England and Wales for 2008-09 was £59million (net ingredient cost).[158, 159] Although septal surgery, either alone or as part of a combined procedure, may be indicated for conditions other than the sensation of nasal obstruction, such as in sinus disease,[160] the aim of this review was not to establish such associations.[156]

4.3 Strengths of this systematic review

4.3.1 Adherence to inclusion criteria:

The greatest strength of this review is its thorough search of journals, and rigorous application of its inclusion and exclusion criteria. Only papers looking at nasal obstruction due to septal deviation, and treated solely with septal surgery were included within it. If additional surgery than that to the septum were used, the participants or entire study were excluded.

A meta-analysis[95] has been performed on this topic previously, whose objective was to provide, "evidence of a reduction in nasal airway resistance following nasal septal surgery". This identified:

> "… only 13 prospective studies of the benefit of septal surgery . … Of these, only three prospective, controlled trials fulfilled our pre-defined criteria." [95]

This study resulted in 3 papers[35, 96, 97] for meta-analysis, all using active anterior rhinomanometry, including 141 patients in total. They specified that two of the trials used septoplasty,[35, 96] and the last performed submucous resection of the septum.[97] Their findings suggested that "septal surgery does objectively improve nasal airflow".

All three of these studies were identified within this systematic review. One of these studies, by Nofal and Thomas[97] (1990), was excluded from this systematic review, since some of their patients received out-fracturing of their inferior turbinates, and there was no separation of the data to allow extraction for the patients who did not receive this additional procedure. Therefore it was not possible to determine the effects of septal surgery alone in their study.

More recently, the ENTUK position paper for 'Nasal Septal Surgery' refers to a study, which aims to, "evaluate septoplasty outcome", and boasts 89.5% subjective improvement in nasal obstruction. Unfortunately, only 27.9% of their participants received solely a septoplasty. The majority underwent inferior turbinectomy as well.

This systematic review is more specific and robust than these, focusing exclusively on septal surgery.

4.3.2 The Number of studies and participants included:

During the time since the previous meta-analysis by Singh *et al.*,[95] more studies have been published, three of which are included in this systematic review (Pirilä and Tikanto,[34] Skouras *et al.*[123] and Wang *et al.*[26]). As a result this systematic review includes 536 participants, the most in any review on this subject.

4.3.3 Different objective tools used:

This study included nasal airway resistance data collected using three different objective tools. All three provide the same findings, that septal surgery reduces nasal resistance when deviation of the nasal septum is the cause. When such findings are confirmed by more than one technique, it adds further reliability to their conclusions.

4.4 Weaknesses of this systematic review

There were a number of factors that varied between the studies, such as patient populations, operation type, equipment used and time period of follow-up, that made comparison difficult.

4.4.1 Type of surgery performed:

Criteria 2 of this systematic review states that surgery should only be performed on the nasal septum. Studies varied in their description of the surgery performed to their patients. There were studies whose results could not be included because the study descriptions were too vague, such as Clement *et al.*[102], which entirely neglected to mention what operation had been performed. In their study, there was no documentation as to whether their operation had even been performed on the nose.

Of those that did operate on the nasal septum, there was often a poor description of what operation they had performed. These operations were also performed by different surgeons, who undoubtedly had different skills and experience from each other. Singh *et al.*[95] comment that from all the studies looking at objective evidence and nasal obstruction surgery, very few are performed (or described) sufficiently to be included in such a systematic review, continuing on to say that such studies in the future should conform to strict protocols, and specify such in their papers.

Some studies involved only small numbers of participants, or only had a few participants who were eligible for this systematic review. The single greatest factor for exclusion of participants or whole studies, was the use of additional surgery, such as inferior turbinate manipulation[3, 32, 97, 100, 101, 105, 106] or rhinoplasty.[108, 117]

4.4.2 Patient selection:

The populations of patients chosen were not homogeneous, with the study's inclusion criteria for participation not always clearly defined. When investigating patients with nasal obstruction, it could be possible to exclude patients with rhinosinusitis, if questioned regarding symptoms, given at least six weeks of medical treatment, and examined before and after decongestion. Attempts to ensure patients were diagnosed as having an anatomical restriction, rather than physiological, were often poorly explained in trials,[36, 37, 45, 116] or did not appear to be part of the selection criteria for surgery in others.[26, 35, 46, 47, 123] It is possible that some patients included in these studies were troubled by septal deviation and rhinosinusitis, such as those in the study from Wang *et al.*[26] In which case, which of the pathologies was the over riding cause for the obstructive symptoms? Would the patient with a septal deviation have sought help for nasal obstruction, if they weren't already suffering from rhinosinusitis, or vice versa? Despite all these studies focusing on a septal deviation cause, only one study (Pirilä and Tikanto[34]) used strict selection criteria, appearing to go to great lengths to exclude patients with nasal obstruction from all other causes except septal deviation.

Despite the numerous methods to classify septal deviations available in the literature, the degree of septal deviation was rarely specified in the studies, and certainly no effort was made to classify the type of deviations found in their subjects which were subsequently operated on. This seems relevant, since the severity of septal deviations, whether mild or severe, might impact on the results of pre- and post-operative surgical data, and the degree of any improvement following surgery. As discussed earlier, surgical options such as the type of surgical procedure, the choice of surgeon who has an appropriate level of experience to undertake surgery on the degree of deformity, and the predicted theatre time for an individual case may be more accurately prepared for. It might also be possible to give the patient a more realistic prediction of benefit following their surgery. The reason that studies do not present the type or degree of septal deviation found in their patients, is most likely because there is no such universally accepted classification system for nasal septal deviation. If such a classification system could be accepted and adopted within the surgical and research communities, it might help to provide further evidence for the benefit of septal surgery by allowing more accurate comparison between individual patients and study groups.

Another variable between studies was the level of decongestion applied, with some studies using exercise to decongest the nose, some using pharmaceutical decongestants, and others not using any decongestion what so ever. This provides inconsistencies and makes comparison more difficult and potentially allow for error.

4.4.3 Duration of follow-up:

Not all papers included a follow-up period, and out of those that did, they varied so much that comparison between other papers was difficult. The time period of follow-up in some studies was short. In the rhinomanometry studies, most were over 6 months. One study took their first follow-up at 3 months, but then took a long-term follow-up at 10 years. The acoustic rhinometry studies had slightly shorter follow-ups, with some studies quoting time frames as early as 1 to 2 months.

4.4.4 Equipment type used:

The type of equipment used to quantify nasal airway patency varied, with acoustic rhinometry, rhinomanometry and peak nasal inspiratory flow being the most commonly employed. This systematic review narrowed its analysis down to including the commonest employed, those methods that are established and reliable. If however all studies had used the same type, there would have been many more studies and participant numbers to compare within a single group.

Even when focusing specifically on the rhinomanometry studies, there might be significant differences between the rhinomanometers. The oldest study included within this review was published in 1982 (Broms[46]), with other studies undertaken more recent. As a result, the equipment used between the studies was of different ages and possibly from different manufacturers, and thus were not an absolute constant. It is possible that this could introduce an element of error, with different measurements or calibrations being involved.

There would also be a difference in the skill level of the technicians in operating the machines, and teaching the study participants on how to apply and use the machines. Despite attempts to standardize rhinomanometry,[82] not all studies since have conformed to this.

4.4.5 Objective data:

Different calculations of resistance have been adopted by studies, such as using R_2 or R_{150}. Since the units used between the papers were different, they required conversion to standardized units, which had the potential for introducing an element of error.

In addition to resistance values, V_2 data was also provided by some of the papers. V_2 is not an actual resistance value, but a number that can be calculated from the pressure-flow curve to provide a more linear method of comparison between subjects. V_2 values are only used in the research laboratories (and published papers) to compare subject resistances, where they are useful to show nasal obstruction and changes following surgery. However it cannot be used to predict specific types of septal deviation, and has not been demonstrated to correlate with the severity of septal deviations. Neither V_2 or resistance (R_2 or R_{150}) values are used in clinical practice, where obstruction is assessed by the patient's subjective complaints, and the surgeon's subjective examination.

The data analysis and measures of variance were different between individual papers, with investigators using standard deviation, range, confidence intervals or median values. They mostly gave mean values, but not a scatter or confidence. As a result all the data were summarised and compared using their p-values. When looking at the individual papers it can be noted that their pre-operative nasal resistance values are diverse, not appearing to be similar or comparable between the studies. This review suggests that this might be explained by the individual study's selection criteria or accepting of participants for surgery, with different severities of septal deviation.

This systematic review does not include data on the paediatric population group. There were fewer studies for this younger patient group. (see Appendix 4) Since surgeons tend to only operate on this group in extreme cases, these data were excluded for fear of bias.

Finally, as already mentioned, papers that were not available in the English language were not included. This review acknowledges the limitations and potential bias of this choice, however every effort was made to read what was available from these, none of which contradicted the outcomes of this systematic review (see Appendix 3).

4.5 Why a meta-analysis was not undertaken:

Due to all of these variables, and the heterogeneous nature of the studies (discussed above), it was felt that grouping the results in order to perform a meta-analysis might mislead the reader to the power of the review, providing a false sense of credibility, and so was beyond the reach of this systematic review. However, the 14 studies as a group do provide important evidence that septal surgery improves nasal patency, with data obtained by the use of three different objective methods of assessing nasal patency.[156]

4.6 Recommendations for future research

Future studies that assess the change in nasal patency from septal surgery ought to conform to stricter criteria, such as in patient selection, and pre- and post-operative objective testing, to include the use of decongestion to ensure the cause is anatomical. This should be documented accordingly. Appropriate descriptions of the septal deviations and surgery performed should also be included within the paper for comparison, as well as information regarding the equipment type.

Within Otorhinolaryngology there is no accepted classification for septal deviation, and it is not known whether there is a correlation between the degree or type of septal deviation, and the degree of nasal obstruction. Having a uniform classification might allow prediction for the degree the septum plays on the overall symptom of obstruction, the type of operation required to correct it, the skill level of the surgeon needed, and perhaps a predictor of outcome for the patient. I would suggest the use of a simple classification that can easily be adhered to, despite the experience of the clinician or researcher, when using rhinoscopy to examine the nose. I believe that a nasal septal deviation severity classification of mild (when less than one-third of the volume of the nasal cavity is obstructed by the primary deformity), moderate (one- to two-thirds of the volume of the nasal cavity is obstructed by the primary deformity) and severe (when more than two-thirds of the volume of the nasal cavity is obstructed) would accurately describe the visual impact.

We know that the sensation of obstruction is correlated with the narrowest nasal cavity.[104] Very few studies have looked at the symmetry of the septum post surgery, and whether this is relevant. Could a method be established to predict whether a patient will perceive a benefit from nasal surgery, similar to the 'Belfast rule of thumb'[161] used in ear surgery when planning an operation to improve hearing? Can the resistances for the narrowest cavity, widest cavity and the total nasal resistance be used to predict the airflow changes following surgery, and predict whether the patient will perceive the benefit?

A future study should include only adult patients who complain solely of nasal obstructive symptoms, and whose obstruction is proven to be anatomical only following 6 weeks of medical treatment for rhinitis. Patients should then be assessed pre- and post-operatively after nasal decongestion. The degree of deviation should be stated. Using the method previously described with mild (less than one-third of the volume of the nasal cavity), moderate (one- to two-thirds of the volume of the nasal cavity) and severe (more than two-thirds of the volume of the nasal cavity) providing an easily understood method for comparison. Surgery should only be performed on the nasal septum, in the form of a septoplasty, as this is the current surgical choice and more preservative in nature than the previous options. Objective measurements should be undertaken before and 6 weeks following surgery using rhinomanometry, as this is more of a functional assessment, however the study could be further improved if both acoustic rhinometry and rhinomanometry were done on the patients. All rhinomanometry measurements should be provided in the SI units of pressure in Pascals (Pa) and flow in cubic centimetres per second (cm^3 sec^{-1})

Chapter 5

CONCLUSION

Conclusion

This review includes 14 studies (536 participants) on the objective effects of septal surgery on nasal patency. All of these studies provide objective evidence that septal surgery improves nasal patency when septal deviation is present. The improvements in nasal patency for the majority of these studies have been shown to be statistically significant. No study found that septal surgery did not provide objective benefit.

These outcomes have been corroborated by three different objective techniques: rhinomanometry, acoustic rhinometry and nasal peak inspiratory flow. These changes can be shown to return the nasal airway resistance towards levels that are assumed to be normal by many experienced researches. This review demonstrates that septal surgery is a valid and beneficial treatment for some patients, and provides objective evidence for the use of nasal septal corrective surgery. In addition to the objective evidence and functional benefit, it is worth considering the other potential benefits such as subjective improvements as assessed by the Nasal Obstruction Symptom Evaluation (NOSE) scale, and cost savings to prescriptions for pharmacological treatment of nasal obstruction.

This review does not provide evidence or suggest that objective testing of nasal resistance must be pre-requisite to septal surgery, but provides evidence and justification for the use of such surgery. There may be a use for objective testing in patients whose symptoms or clinical picture is not so clear as to the cause. For example, if there is a discrepancy between what the patient and surgeon feels might be the cause of the sensation of obstruction, objective measurements may reassure the patient or provide evidence that surgery may not be necessary.

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Publications

Publications of this research study:

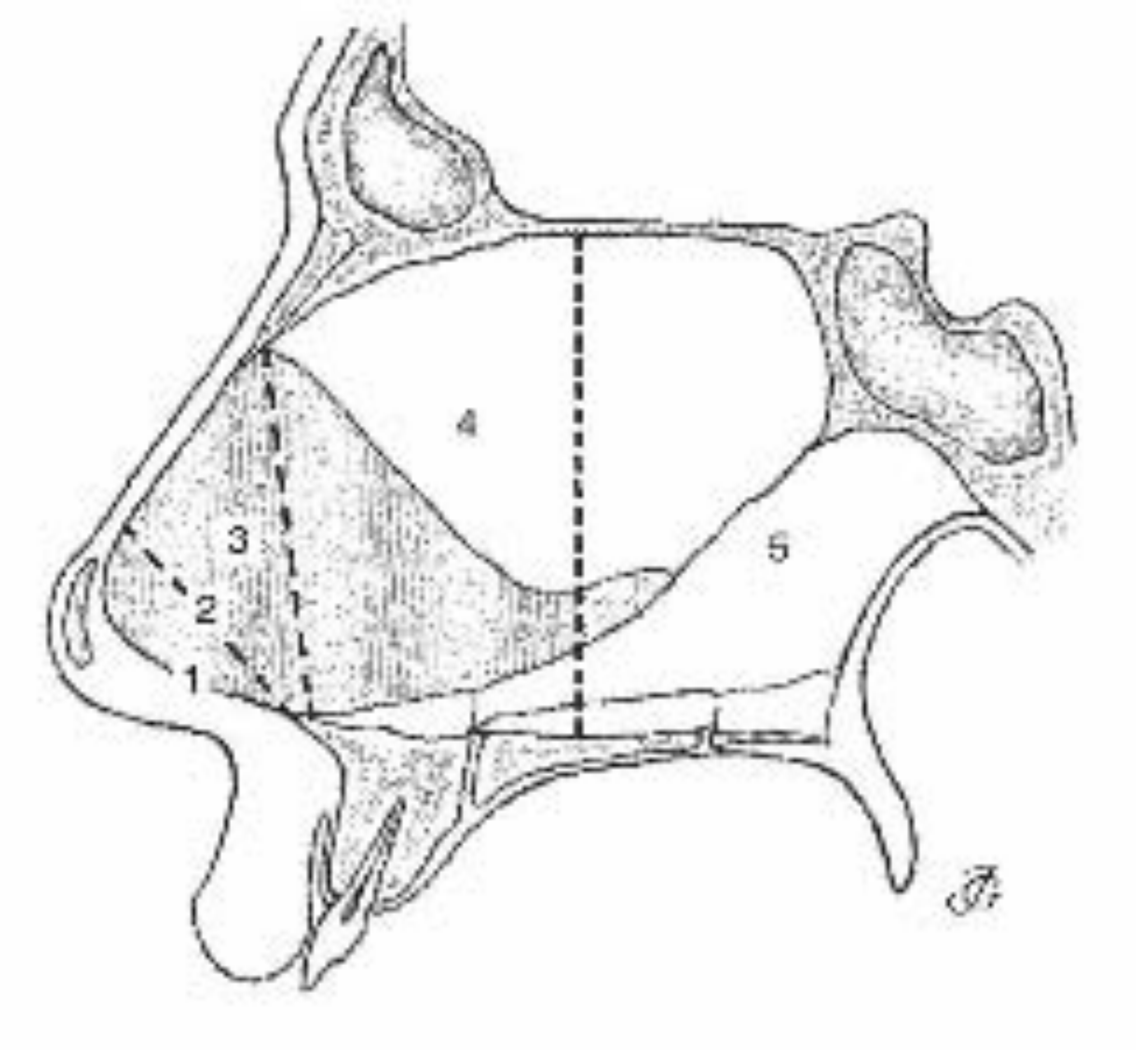
1. Moore M, Eccles R. Objective evidence for the efficacy of surgical management of the deviated septum as a treatment for chronic nasal obstruction: a systematic review. *Clinical otolaryngology* 2011; 36: 106-113

2. Moore M, Eccles R. Normal nasal patency: problems in obtaining standard reference values for the surgeon. *The Journal of laryngology and otology* 2012; 126: 563-569

Appendices

Appendix 1:

Cottle's areas - as demonstrated in Huizing (2003)[51]



Area 1:	Nostril
Area 2:	Nasal valve
Area 3:	Area underneath the bony and cartilaginous vault (also called the attic)
Area 4:	Anterior part of the nasal cavity including the heads of the turbinates and the infundibulum
Area 5:	The posterior part of the nasal cavity, including the tails of the turbinates

Appendix 2:

Nasal Septal Surgery: position paper ENT UK 2010 [8]

ENT•UK

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Nasal Septal Surgery: Position Paper ENT UK 2010

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Nasal Septal Surgery: Position Paper ENT UK 2010

Introduction
This document summarizes the current status of nasal septal surgery in terms of its indications, predicted results and patient reported benefits.

Indications for septal surgery
A blocked nose is the one of the commonest presenting chronic symptoms in Ear Nose and Throat practice. One of the commonest causes of a blocked nose is a deviation of the midline nasal partition known as the nasal septum[1]. This deviation may be congenital or acquired as the result of facial injury. Since this is a structural problem the only definitive treatment is surgical correction, referred to as septal surgery or septoplasty.

Septal surgery is also performed to enable access for the treatment of tumours of the nose, sinuses or pituitary gland. Access may also be necessary to facilitate nasal polyp or lacrimal gland surgery, or to enable Continuous Positive Airway Pressure treatment to be used for sleep apnoea[2].

What is septal surgery
Surgery of the nasal septum, referred to as 'septoplasty', 'submucosal resection of the septum' or 'septal surgery', aims to remove or straighten part(s) of the deviated cartilage and bone of the nasal septum. The anatomy of the septum is complex and the site of the deviation will determine how complex and successful the surgery is. This surgery is performed overwhelmingly as day surgery under general anaesthesia.

Complications are uncommon, but include post operative bleeding or infection and occasional septal perforation and external nasal deformity

UK Septal surgery trends
In 2008 – 09, Hospital Episode Statistics (HES; www.hesonline.nhs.uk) identify just under 20,000 septal straightening procedures - 18, 813 septoplasty (E03.6), 989 submucosal resections (E03.1), with 87% of patients being under 60 years of age. These figures represent a 20% drop in total septal surgery since 1999 – 2000, probably due to improved case selection as a result of the now near-universal use of the rigid nasal telescope to facilitate the accurate diagnosis of nasal symptoms in the Ear Nose and Throat outpatient clinic.

Outcomes of surgery
Due to the dual chamber design of the nose, objective measures of nasal airway patency correlate only partially with patient sensation of nasal obstruction. As septoplasty aims to improve nasal symptoms, patient reported outcome measures are the optimum method of evaluating the results of surgery.

The marked improvement often reported by patients is not always reflected in objective measures of nasal obstruction. This reflects the limitations of the objective tools, but has led to conflicting evidence for the efficacy of nasal septal surgery. This is sometimes mis-interpreted by people outside of the specialty and has created a common misunderstanding that septal surgery is of limited effect, but this is far from the truth.

Many authors have published patient reported outcome data following septoplasty, with consistently good results. There are clinically significant and well maintained improvements in nasal obstruction symptom scores [1,4,5,6]. In the USA, the American Academy of Otolaryngology's NOSE (Nasal Obstruction Septoplasty Effectiveness) study concluded that septoplasty results in significant improvement in disease-specific quality of life, high patient satisfaction, and decreased medication use[1]. Using the Nasal Health Survey questionnaire, authors have reported a clinically significant improvement in 71% of patients ($P<0.05$)[7]. Similar findings were reported by Buckland et al, when using the Sino-Nasal Outcome Test questionnaire in post septoplasty patients[6].

The most recent, prospective study examining the outcome of septal surgery found a significant improvement in mean nasal obstruction symptom scores in 90% of **86** patients[8].

Many of the studies in the past have been retrospective or used general quality of life questionnaires. However, prospective randomized studies using tools validated specifically for nasal obstruction corroborate the findings of these earlier studies. Long term results (up to 3 years post operatively) following nasal septal surgery show a significant improvement in nasal symptom scores[3].

Conclusions

- Deviation of the nasal septal remains a common and important cause of nasal obstruction.
- Nasal endoscopy identifies other intranasal disease and has greatly enhanced the selection of patients who are listed for septoplasty.
- The evidence consistently supports the view that nasal septal surgery is highly effective in improving symptoms of nasal obstruction.
- Septoplasty is not only a very effective day case operation, but also one with a low complication rate.

ENT UK is alarmed on behalf of our patients that PCTs should suggest that this successful, permanent and cost effective operation should be abolished or severely rationed in an arbitrary and indiscriminate manner. There is no evidence whatsoever to suggest that it is neither ineffective nor used inappropriately in UK clinical practice.

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Appendix 3:

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Piccini A, Biagini C, Sensini I.
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PubMed PMID: 13629666.

Appendix 4: - Table of excluded paediatric studies.

paper	n	Decongestion	Medication pre-op	Nasal obstruction identified		Operative decision	Surgical procedure	Objective measurements	
				Subjectively	objectively			PreOp	Post Op
Risavi *et al.* (1988)	40	yes	yes	history, rhinoscopy, endoscopy	rhinomanometry (ant)	septal deviations / fractures	septoplasty	total $_{insp}$ 1.39 $Pa/cm^3/s$	total $_{insp}$ 0.63 $Pa/cm^3/s$
Can *et al.* (2005)	26	?	no	questionnaire + ant rhinoscopy	acoustic rhinometry	septal deviation	septoplasty	narrower mean: 0.2777 cm^2	narrower mean (signif): 0.4992 cm^2

Appendix 5:

Email from Pirilä providing units of measurement.

From: Pirilä Tapio LSHP <Tapio.Pirila@lshp.fi>
Date: 6 November 2010 20:06:37 GMT
To: <eccles@cardiff.ac.uk>
Subject: VL: Units of airflow

Dear Prof. Eccles,

… Yes, I am surprised and sorry for the mistake in the units.
Of course it should be ml/sec as you kindly suggested.…

With best regards: Tapio Piriläps.

Tapio Pirilä MD
Ass. prof., University of Oulu.
Head, ENT dept.
Lapland Central Hospital
Rovaniemi, Finland

Appendix 6:

Email from Holmström confirming Sipilä's normal values were for unilateral resistance.

From: Mats Holmström <mats.holmstrom@surgsci.uu.se>
Subject: Re: Normal values of nasal resistance from your Rhinology paper
Date: 17 February 2011 17:34:28 GMT
To: Matthew Moore <MooreM6@cardiff.ac.uk>

Dear collegue,

Thanks for your mail! As far as I remenber their values were for unilateral measures.I don't have the data available for the moment.

Best regards
Mats Holmström