Systematic Review of the Endoscopic Modified Lothrop Procedure for the Treatment of Chronic Frontal Sinusitis

ASERNIP-S REPORT NO. 12
June 2001

Australian Safety & Efficacy Register of New Interventional Procedures – Surgical
The Royal Australasian College of Surgeons
Systematic Review of the Endoscopic Modified Lothrop Procedure for the Treatment of Chronic Frontal Sinusitis

NA Scott     R Gallagher
PJ Wormald    A Anthony
D Close     GJ Maddern

ISBN 0 909844 410
Published June 2001

This report should be cited in the following manner:

Copies of these reports can be obtained from:
The Australian Safety and Efficacy Register of New Interventional Procedures - Surgical
The Royal Australasian College of Surgeons
PO Box 688, North Adelaide, South Australia  5006
AUSTRALIA
Fax: 61-8-82391244  E-mail: College.asernip@surgeons.org
http://www.surgeons.org/asernip-s
The Safety and Efficacy Classification for the Systematic Review of the Endoscopic Modified Lothrop Procedure for the Treatment of Chronic Frontal Sinusitis was ratified by:

The ASERNIP-S Management Committee on
June 16, 2001

The Council of the Royal Australasian College of Surgeons in
June 2001
Table Of Contents

Executive Summary ........................................................................................................... i
Safety and Efficacy Classification ..................................................................................... ii
Review Group Membership ............................................................................................... iii

SYSTEMATIC REVIEW OF THE ENDOSCOPIC MODIFIED LOTHROP PROCEDURE ............ 1
1.0 Objective ....................................................................................................................... 1
2.0 Introduction .................................................................................................................. 1
   2.1 Pathogenesis of Chronic Frontal Sinusitis ................................................................. 1
   2.2 Conventional Therapies ............................................................................................. 2
   2.3 Endoscopic Modified Lothrop Procedure (EMLP) ................................................. 4
   2.4 Summary .................................................................................................................... 5
3.0 Methods ....................................................................................................................... 5
   3.1 Literature Search Protocol ....................................................................................... 5
   3.2 Literature Search Strategies ..................................................................................... 7
   3.3 Literature Database .................................................................................................. 8
   3.4 Assessment Methods ............................................................................................... 10
4.0 Results ......................................................................................................................... 10
   4.1 The Endoscopic Modified Lothrop Procedure (EMLP) .......................................... 11
   4.2 Osteoplastic Flap Procedure With/Without Sinus Obliteration ............................... 13
5.0 Discussion .................................................................................................................... 14
   5.1 Safety and Efficacy of the Endoscopic Modified Lothrop Procedure .................. 14
   5.2 Possible Indications and Contraindications for EMLP ........................................... 15
   5.3 Technical Considerations ....................................................................................... 16
   5.4 Considerations for Further Research ..................................................................... 17
6.0 Conclusion ................................................................................................................... 18
   6.1 Classification and Clinical Recommendations ....................................................... 18
7.0 Reference List .............................................................................................................. 20

APPENDICES ..................................................................................................................... 24

APPENDIX A – Heirarchy of Evidence ............................................................................ 25
APPENDIX B - Exclusions ................................................................................................. 26
APPENDIX C – Methodological Assessment and Data Extraction Tables ....................... 30
   Glossary for Appendices C.1 to C.9 .............................................................................. 31
   Appendix C.1: Endoscopic Modified Lothrop Procedure – Comparative Studies ......... 32
   Appendix C.2: Endoscopic Modified Lothrop Procedure – Case Series Studies .......... 34
   Appendix C.3: Safety Results for EMLP – Comparative Studies ................................ 40
   Appendix C.4: Efficacy Results for EMLP – Comparative Studies ............................... 41
   Appendix C.5: Safety Results for EMLP – Case Series Studies .................................... 42
   Appendix C.6: Efficacy Results for EMLP – Case Series Studies ................................. 43
   Appendix C.7: Summary of Obliterative Procedure Studies ......................................... 44
   Appendix C.8: Summary of Obliterative Procedure Safety Data .................................. 45
   Appendix C.9: Summary of Obliterative Procedure Efficacy Data ............................... 45
Executive Summary

Objective: The aim of this review was to compare the safety and efficacy of the endoscopic modified Lothrop procedure (EMLP), performed either wholly intranasally or in combination with an external approach, against the current benchmark treatment, the osteoplastic flap procedure with or without fat obliteration (OPF).

Methods: All original, published studies on the endoscopic modified Lothrop procedure and the osteoplastic flap, with or without fat obliteration, were identified by searching Current Contents between Week 1/1993 and Week 8/2001; Embase between Week 1/1974 and Week 5/2001; Medline between Week 1/1984 and 16/02/01; and The Cochrane Library between Week 1/1966 and 2001 (Issue 1). The search terms used for EMLP were (frontal drillout or (endoscop* and sinus and frontal)) and ((transnasal or endoscop* or modif*) and Lothrop) for Current Contents, Embase and Medline. The simple search term ‘Lothrop’ was used for the Cochrane Library. The search strategy for OPF was restricted to (date = since 1980). The three sets of search terms used for OPF were (Sew#ll or Boyden and flap); (frontal and sinus and osteoplast* and flap); and (frontoethmoidectomy). The simple search term ‘osteoplast* and flap’ was used for the Cochrane Library. For both EMLP and OPF, only studies of patients diagnosed with chronic frontal sinusitis were included for review. English language papers detailing randomised-controlled trials, controlled clinical trials, case series or case reports were included.

Results: The limited comparative data suggested that EMLP caused fewer adverse postoperative outcomes but was more likely to generate a perioperative cerebrospinal fluid leak than OPF. However, none of the morbidity traditionally associated with OPF was evident following EMLP. EMLP appeared to have a shorter operative time and a lower perioperative blood loss than OPF, but little could be determined regarding the long term efficacy and durability of EMLP because of the relatively short follow-up of the majority of the studies.

Conclusion: The Review Group concluded that the evidence base for EMLP was inadequate. It was recommended that EMLP for the treatment of chronic frontal sinusitis be given a classification of ‘2’ and that an audit of the procedure be conducted. Additional clinical recommendations were made regarding the development and current practice of EMLP in Australia during this audit phase.
Safety and Efficacy Classification

The Review Group will allocate a classification to the endoscopic modified Lothrop procedure from the following list:

1. Safety and efficacy is established. The procedure is equal to, or better than the best practice based on the current available evidence. Procedure may be introduced into practice.

2. The safety and/or efficacy of the procedure cannot be determined at the present time due to an incomplete and/or poor quality evidence-base. It is recommended that further research be conducted to establish safety and/or efficacy.

3. Safety and/or efficacy of procedure is shown to be unsatisfactory. Procedure should not be used.

If the Review Group recommends a classification of ‘2’, a recommendation regarding the need for further research may be made such that:

In order to strengthen the evidence base regarding the procedure it is recommended that either:

- an audit be undertaken, or
- a controlled clinical trial, ideally with random allocation to an intervention and control group, be conducted.

The Royal Australasian College of Surgeons recognises that it may not always be possible to undertake a controlled clinical trial. Under such circumstances, it is recommended that at the very least, data be contributed to an audit for further assessment, in collaboration with ASERNIP-S, until such time as a controlled clinical trial is undertaken.

The endoscopic modified Lothrop procedure for the treatment of chronic frontal sinusitis has been allocated a category 2 classification with the recommendation that an audit of the procedure be conducted.

Important Note: The information contained in this report is a distillation of the best available evidence located at the time the searches were completed, as stated in the protocol. Please consult with your medical practitioner if you have further questions relating to the information provided, as the clinical context may vary from patient to patient.
Review Group Membership

ASERNIP-S Director

Professor Guy Maddern
ASERNIP-S
Royal Australasian College of Surgeons
North Adelaide SA 5006

Protocol Surgeon

Professor Peter Wormald
Department of Otolaryngology, Head and Neck Surgery
The Queen Elizabeth Hospital
Woodville Road
Woodville South SA 5011

Advisory Surgeon

Mr David Close
Unit 16, 3rd Floor
Ashford Specialty Centre
57-59 Anzac Highway
Ashford SA 5035

Other Specialty Surgeon

Mr Adrian Anthony
Department of Surgery
The Queen Elizabeth Hospital
Woodville Road
Woodville South SA 5011

Nominated Surgeon

Dr Richard Gallagher
Level 10, St Vincent’s Clinic
438 Victoria Street
Darlinghurst NSW 2010

ASERNIP-S Researcher

Dr Ann Scott
ASERNIP-S
Royal Australasian College of Surgeons
North Adelaide SA 5006
Systematic Review of the Endoscopic Modified Lothrop Procedure

1.0 OBJECTIVE

To make recommendations on the safety and efficacy of the endoscopic modified Lothrop procedure, in comparison to the osteoplastic flap procedure either with or without obliteration of the frontal sinus, on the basis of a systematic assessment of the peer-reviewed literature.

2.0 INTRODUCTION

2.1 Pathogenesis of Chronic Frontal Sinusitis

The frontal sinuses are paired, often asymmetric, air-filled compartments located in the frontal bone.1,2 The configuration of the sinuses is highly variable between individuals, and their functional significance has yet to be determined.2,3 The frontal sinuses drain into the frontal recess (middle meatus) either directly from the frontal sinus ostia or indirectly via the anterior part of the ethmoidal infundibulum.1,3,4

The epithelium that lines the frontal sinuses is continuous with the respiratory epithelia and is composed of ciliated, pseudostratified columnar epithelium interspersed with goblet-type mucous cells.1,3 The mucous and serous glands below the epithelium secrete a mucous layer that simultaneously humidifies the air and traps inhaled foreign particles, which are then transported to the pharynx by ciliary action.1 The mucociliary clearance in the frontal sinus has an unusual circular flow route such that the mucous flows clockwise in the left sinus and counterclockwise in the right sinus.4,5 Thus, there is a significant recirculation of mucous along the medial wall of the sinus. The mucous then travels laterally along the roof of the sinus, inferiorly along the lateral wall and then medially along the sinus floor, before part of the mucous exits through the ostium.4

Sinusitis is a very common disease that appears to be on the increase.6 In 1995, more than 37 million cases of chronic sinusitis were reported in the United States.7,8 Despite significant advances in modern medical technology and pharmacology, sinusitis is still an insidious disease that is capable of causing significant morbidity and even death.3 Chronic sinusitis is defined as an infection of the paranasal sinuses that lasts for longer than three months. The symptoms are identical to those found in acute sinusitis but are usually milder. In addition, patients may also experience chronic cough, bronchitis, tiredness, malaise and depression.9

Frontal sinus disease usually begins with sinus inflammation or obstruction that may be caused by many factors including rhinitis, polymicrobial infections, allergy-induced mucosal swelling, fracture, disease of the anterior ethmoid cells, and neoplasm in the sinus ostia.9,10 This leads to loss or impairment of epithelial ciliary function, which inhibits the adequate flow and drainage of the mucous within the sinus. Subsequent metaplasia of the goblet cells leads to the production of more viscous mucous. The consequent mucosal irritation can produce local oedema, which can result in the formation of contact polyps.5,11,12 Secondary bacterial infection can then occur, thereby establishing a vicious cycle of chronic mucosal damage. Although the pathogenesis of mucocele formation is still unclear, it is thought that scarring of the ostia may predispose towards permanent sinus obstruction and mucocele formation. Ultimately, progressive
infection can result in intrasinus pressure, sinus wall erosion and expansion of the mucocele. Complications arise once the mucocele impinges on surrounding vital tissues such as the orbit or anterior cranial fossa.\textsuperscript{12}

The possible intracranial complications of chronic frontal sinusitis can be quite serious. Brain abscesses have a mortality rate that ranges from 20\% to 30\%, with the frontal and ethmoid sinuses being the most common cause of the 15\% of brain abscesses that are sinus related. Chronic frontal sinusitis may also result in meningitis, intracranial rupture, orbital extension, frontal sinus pneumocele formation and osteomyelitis, which can lead to Pott’s puffy tumour.\textsuperscript{9,12}

\section{2.2 Conventional Therapies}

\subsection{2.2.1 Medical Management of Chronic Sinusitis}

A regime of topical steroids and saline douches, either with or without antibiotics, are given for a minimum of 6 weeks.\textsuperscript{6,9} If pus is present in the frontal sinuses, the success of anti-microbial therapy is often dependent upon matching the particular drug with the type of organism(s) present in the sinus. However, the anatomy of the frontal sinus makes it difficult to obtain such cultures.\textsuperscript{6,9} In addition, bacteria are not consistently found in chronic sinusitis which makes the role of microbial infection in this disease less clear.\textsuperscript{6} The failure rate of medical treatment for chronic frontal sinusitis is high due to the narrow frontal ostium, the complex anatomy of the frontal recess, and the inability of antibiotic therapy to clear chronic infections even with prolonged antibiotic therapy.\textsuperscript{6,12} Refractory disease may require drainage of the frontal sinus by removal of diseased frontal recess cells and clearance of frontal sinus mucous and/or pus.\textsuperscript{4,11-13}

\subsection{2.2.2 Surgical Treatment of Chronic Frontal Sinusitis}

Conservative endoscopic sinus surgery is the first line of surgical treatment. This surgery is directed at clearing the ethmoidal infundibulum and opening the maxillary sinus ostium. In selected cases with significant frontal recess and frontal sinus disease, clearance of the frontal recess should also be performed to ensure adequate drainage of the frontal sinus. Should these conservative procedures fail, other surgical procedures are indicated for ongoing chronic sinusitis symptoms or for complications such as intracranial infection and osteomyelitis.\textsuperscript{13} However, the current lack of detailed knowledge of the pathogenesis and natural history of sinusitis, in conjunction with the morbidity and mortality of frontal sinus surgery, has contributed to controversy regarding the most appropriate surgical approach to chronic frontal sinus disease.\textsuperscript{10,14}

Currently, surgical treatment of frontal sinusitis involves either sinus ablation and permanent closure of the drainage pathway or restoration of a large, more permanent drainage pathway with preservation of most of the mucosal lining of the sinus.\textsuperscript{2,10} These procedures are usually performed either externally or endonasally, but in some cases a combined approach is used.\textsuperscript{15}

Halle, as reported by Hajek,\textsuperscript{16} performed the first endonasal procedure at the beginning of the twentieth century by removing the frontal process of the maxilla and the frontal sinus floor with a mallet, chisel and electric burr.\textsuperscript{15} However, the technical difficulty and high mortality from postoperative meningitis that was associated with this procedure meant that it was not widely accepted. Thus, from the 1920s to 1950s procedures such as the Lynch-Howarth approach, which accessed the frontal sinus via the nasofrontal and medial
The osteoplastic flap procedure is a modification of the technique first reported by Schonborne\textsuperscript{18} and Brieger\textsuperscript{19} in 1894 and 1895, respectively. In 1889, Reidel\textsuperscript{20} described removal of the anterior wall and floor of the frontal sinus to allow the collapse of the forehead to obliterate the cavity. However, the resulting cosmetic deformity was unacceptable and the procedure was not widely adopted.\textsuperscript{2,13} Subsequent animal experiments demonstrated that the sinus cavity is filled by osteoneogenic activity and scar tissue formation once the sinus mucosa is removed. In 1954, Macbeth\textsuperscript{21} applied this ablative method to the human frontal sinus via an osteoplastic flap. This osteoplastic technique occasionally resulted in unsuccessful obliteration with subsequent cyst formation. Further evolution of the technique culminated in the use of an autogenous material, such as abdominal fat, to fill the sinus. The success of this development was such that the obliteratorive osteoplastic flap technique is now considered the benchmark for surgical treatment of chronic frontal sinusitis.\textsuperscript{22,23}

The osteoplastic flap technique is approached in two ways. A unilateral operation involves an incision across the entire length of the upper eyebrow margin whereas a bilateral operation involves either a hairline coronal incision or an incision across both eyebrows that is extended horizontally over the nasal process of the frontal bone.\textsuperscript{13} An osteoperiosteal flap is then fashioned from the anterior table of the frontal sinus such that the bone flap is hinged across the floor of the frontal sinus just posterior to the supraorbital rim. This ensures that the periosteum along the supraorbital rim fracture, between the bone incisions, remains intact.\textsuperscript{24} The intersinus septum is then removed. If the mucosal lining is found to be irretrievably diseased, it is also removed to the level of the inner cortical lining of the bone with a fine burr. This is performed on all bone surfaces within the sinus, including the flap, up to the nasofrontal orifice. When indicated, the cavity is obliterated with a free adipose graft harvested from the left abdominal wall. The bone flap is then returned to its original position, and revascularisation of the adipose implant by the exposed cortical lining of the debrided bone effectively seals the superior aspect of the nasofrontal duct from the sinuses.\textsuperscript{13,24}

2.2.2.1 What is Wrong with the Osteoplastic Flap Procedure?

The osteoplastic flap procedure is relatively safe, familiar to most otolaryngologists, results in minimal cosmetic deformity, and has a reported success rate ranging from 75% to 93%.\textsuperscript{17,25,26} The external approach enables both sinuses to be operated on simultaneously, provides excellent visualisation of the region, and also enables the surgeon to address any problems involving the posterior table and dura.\textsuperscript{22} In addition, the technique has a low failure rate, low morbidity, and eliminates the necessity of establishing a nasofrontal communication, thereby reducing postoperative care requirements.\textsuperscript{22,24}

However, this highly invasive procedure carries the risk of infection at the donor site and is associated with a higher than average blood loss.\textsuperscript{2,22} Technique failure can occur due to suppuration of the fat graft which may lead to wound complications; inadequate periosteal closure with consequent separation of the bone flap from the skull; frontal depression from injury to the bone flap; or an unrecognised supraorbital ethmoid cell.\textsuperscript{22,27} Reported disease recurrence rates are low but are dependent on surgical expertise and any
errors in sinus entry may lead to dural laceration.\textsuperscript{2,22,27} It is not uncommon for either inadequate closure of the nasofrontal duct or incomplete removal of the sinus mucosa to result in re-epithelialisation of the sinus and further disease.\textsuperscript{2,22,27} In addition, cosmetic deformities such as frontal bossing, depression, and poor scar formation can occur. Many patients also report frontal neuralgia with paresthesia and analgesia of the forehead, which are most likely caused by injury to the supraorbital and supratroclear neurovascular bundles during brow incisions.\textsuperscript{4}

A limitation of the osteoplastic flap procedure is that it does not actually correct nasofrontal obstruction and, thus, there is no patent drainage pathway for the sinus should there be any recurrent disease.\textsuperscript{10} The procedure is contraindicated in patients that have either extensive supraorbital ethmoid pneumatisation or a mucocele directly on the dura because both conditions substantially hinder the effective removal of the mucosa. In addition, accurate postoperative diagnosis of recurrent disease is difficult in patients who have had the full obliterative procedure because of the radiographic opacification of the sinuses caused by the implanted soft tissue.\textsuperscript{10,17}

### 2.3 Endoscopic Modified Lothrop Procedure (EMLP)

The endoscopic modified Lothrop procedure (EMLP) is a modification of a technique first reported by Lothrop over a hundred years ago.\textsuperscript{28-30} The original technique involved a unilateral or bilateral intranasal anterior ethmoidectomy followed by an external Lynch incision with resection of the medial frontal sinus floor, superior nasal septum and intersinus septum.\textsuperscript{4,17} This created a large, permanent nasofrontal communication that provided adequate ventilation and drainage plus ease of access for postoperative follow-up.\textsuperscript{17,24} The lack of endoscopic equipment at that time, coupled with the technical difficulty of the technique, meant that the procedure languished for decades despite the fact that in a series of thirty patients followed for at least four years, Lothrop reported only one complication and one failure.\textsuperscript{4,17} However, the external approach also carried the risk of medial collapse of orbital soft tissue and subsequent stenosis of the nasofrontal communication.\textsuperscript{17}

In recent years there has been a strong trend in surgery toward preservation of the mucoperiosteum of the sinuses and maintenance of a patent nasofrontal connection, in recognition of the fact that regenerating mucosa has a markedly diminished ciliary density that may never fully recover to its pre-operative level. This has important implications for surgical treatment, which has always been associated with the risk of stenosis and subsequent mucocele formation.\textsuperscript{2,14,31}

The advent of computed tomography, endoscopes and advanced drill technologies allowed the re-exploration of the Lothrop procedure with the aim of accomplishing a completely intranasal technique that preserved the lateral bony walls and prevented medial collapse of orbital tissues.\textsuperscript{15,17} Thus, in 1991 Draf\textsuperscript{32} described a series of three techniques for widening the frontal sinus ostium while maintaining the frontal sinus mucosa. In 1995, Gross et al.\textsuperscript{23} and Becker et al.\textsuperscript{33} reported the use of the Draf type III technique, which they termed the modified transnasal endoscopic Lothrop procedure, on a series of 14 patients. The procedure was conducted under general anaesthesia and routine functional endoscopic sinus surgery was performed to provide adequate access to the frontal recess, via the removal of the uncinate process, ethmoidal bullae, anterior ethmoid cells and agger nasi cells, prior to the removal of the anterior superior nasal septum, nasofrontal beak and frontal sinus floor.\textsuperscript{2,4}
2.3.1 Theoretical Considerations for EMLP

The theoretical advantages of EMLP over the osteoplastic flap procedure are decreased morbidity, improved cosmesis, and the ability to endoscopically evaluate patients postoperatively for recurrent disease. Other advantages include shorter hospitalisation (usually the same day), less pain and reduced frontal and orbital oedema.\(^{17}\)

However, the technique does not always result in the creation of a large, permanently open, epithelialised nasofrontal drainage pathway. Failure of the neo-ostium is usually due to neo-osteogenesis and, most commonly, to an inadequate opening of the frontal sinus caused by incomplete removal of the frontal sinus floor. EMLP requires specialised instrumentation and an extensive knowledge of the anatomy of the nasofrontal region because of the limited access and high level of skill required to perform endoscopic surgery.\(^{2,10}\) In addition, extensive postoperative care is required, with regular visits for one to two months after surgery, to remove crusts and ensure nasofrontal patency.\(^2\)

Access to the frontal recess via the nose can be awkward, and the often variable anatomy of the region, together with its proximity to the anterior ethmoid artery, skull base and lamina papyracea, can make the dissection quite dangerous.\(^{17}\) EMLP is contraindicated when a frontal sinus mucocele, osteoma, or other disease is present in regions that are not easily reached endonasally. This most commonly occurs with disease located laterally and superiorly.\(^{15}\) In addition, other conditions for which EMLP is unsuitable are tumours, osteomyelitis and displaced fracture of the anterior or posterior table of the frontal sinus.\(^{2,15,17}\)

2.4 Summary

Endoscopic intranasal sinus procedures are being embraced with enthusiasm by many surgeons concerned about the invasiveness and consequent morbidity and mortality associated with the use of fully external techniques such as the osteoplastic flap procedure. Recent advances in surgical equipment have meant that EMLP may become a valuable therapy for the treatment of chronic frontal sinusitis. However, a review of the evidence regarding the safety and efficacy of EMLP has yet to be conducted.

Therefore, ASERNIP-S has undertaken an evidence-based review of the safety and efficacy of EMLP, in comparison with the conventional osteoplastic flap procedure, with or without obliteration.

3.0 METHODS

3.1 Literature Search Protocol

3.1.1 Inclusion Criteria

Papers were selected for inclusion in this systematic review on the basis of the following criteria.

- **Participants**

Only human studies, specifically of patients diagnosed with chronic frontal sinusitis, were included for review. Patients with cystic fibrosis, inverted nasal papilloma, or malignant...
tumours were excluded. Patients that have had prior sinus surgery were included because it is this patient group in particular that will purportedly benefit from EMLP.

- **New Intervention**

The included papers related to the use of EMLP performed either wholly intranasally or in combination with an external approach. Papers that detailed any non-sinus surgery performed at the same time as EMLP were excluded because these procedures would have a confounding effect on the outcomes for EMLP.

- **Comparative Intervention**

The comparative procedure was the osteoplastic flap with obliteration of the frontal sinus because it is generally considered to be the benchmark treatment in external surgical intervention for the management of chronic frontal sinusitis. Where sinus obliteration was reported, only those studies that utilised autogenous fat implants were included because its use is well established. Studies detailing a non-obliterative osteoplastic flap approach were also included because of the similarity between this technique and EMLP. Since very few reviews of the osteoplastic flap procedure have been published, safety and efficacy information was obtained from primary studies. These studies were date restricted to 1980 onwards to ensure that they were the most representative of the current state of technology for this procedure.

- **Outcomes**

The papers included must contain information on at least one of the following outcomes of the new or comparative intervention.

1. Perioperative and postoperative mortality of patients
2. Perioperative and postoperative morbidity of patients which may include, but not be limited to:
   - fistula formation
   - cerebrospinal fluid leak
   - orbital damage
   - discomfort and/or pain
   - cosmesis
   - numbness
3. Perioperative and postoperative factors for patients which may include, but not be limited to:
   - operative time
   - blood product usage
   - operative failure rate and/or rate of recurrent or persistent disease
   - re-operation rate
4. Evaluation of nasofrontal communication patency, health of the mucous membranes, ventilation of the sinus, and any sinus opacity which may involve, but not be limited to:
   - radiographic examination
   - endoscopic visualisation
   - computed tomography scan
5. Convalescence of patients which may include, but not be limited to;
   - convalescence period
   - wound healing time
   - length of hospital stay
   - postoperative care requirements

- **Types of studies**

   Randomised controlled trials, controlled clinical trials (historical, non-randomised), case series and case reports were included for review. Other study types were included if they were considered relevant and if valid reasons were given in the protocol. Where appropriate, additional relevant published material in the form of letters, conference material, commentary, editorials and abstracts was included as background information.

- **Language Restriction**

   Searches were conducted without language restriction. Foreign language papers were subsequently excluded only if the findings supported those reported in well-designed studies published in the English language.

3.1.2 Exclusions

   The ASERNIP-S Researcher and Protocol Surgeon excluded references that did not meet the inclusion criteria. The reasons were documented when this occurred.

3.2 Literature Search Strategies

- **Databases searched**

   - Ovid Current Contents between Week 1/1993 and Week 8/2001
   - Ovid Embase between Week 1/1974 and Week 5/2001
   - Ovid Medline between Week 1/1984 and 16/02/01
   - The Cochrane Library between Week 1/1966 and 2001 (Issue 1)

- **Search Terms**

   It was expected that few papers would be retrieved for EMLP. Therefore, very broad search terms were used to ensure that a maximum number of relevant papers were retrieved across all of the databases.

   The following search terms were used for all four databases.

1. Terms used for EMLP
   - frontal drillout
   - endoscop* and sinus and frontal
   - (transnasal or endoscop* or modif*) and Lothrop

   Since very few references were retrieved from the Cochrane Library with the restricted search terms listed above, a broader search strategy was used to obtain the maximum number of references possible. The simple search term used was ‘Lothrop’.
2. Terms used for the osteoplastic flap procedure
   - Sew#II or Boyden and flap
   - frontal and sinus and osteoplast* and flap
   - frontoethmoidectomy

   Searches were restricted to;
   - date = 1980 to the current date

Since very few references were retrieved from the Cochrane Library with the restricted search terms listed above, a broader search strategy was used to obtain the maximum number of references possible. The simple search term used was ‘osteoplast* and flap’.

Note: * is a truncation character that retrieves all possible suffix variations of the root word e.g. surg* retrieves surgery, surgical, surgeon, etc. In Cochrane the truncation character is *; in Current Contents, Embase and Medline (Ovid) it is $. # is a wildcard symbol that substitutes for one required character in Current Contents, Embase and Medline (Ovid).

3.3 Literature Database

The number of articles retrieved for each search category is listed in Table 1. The ASERNIP-S Researcher excluded articles that, on the basis of their abstract, clearly did not meet the inclusion criteria.

Table 1: Summary of the exclusion process for the methodological review papers retrieved from the literature databases

<table>
<thead>
<tr>
<th>Search Category</th>
<th>Total Number Retrieved</th>
<th>Total Number Available After Exclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscopic modified Lothrop procedure</td>
<td>408</td>
<td>54</td>
</tr>
<tr>
<td>Osteoplastic flap with/without sinus obliteration</td>
<td>89</td>
<td>24</td>
</tr>
</tbody>
</table>

In some cases, when the full text of the article was retrieved, closer examination revealed that it did not meet the inclusion criteria specified by the review protocol. Consequently these papers were not used to formulate the evidence base for the systematic review (Table 2 & Appendix B). However, relevant information contained in these excluded papers was used to inform and expand the review discussion. The bibliographies of all publications included for review were manually searched for relevant references that may have been missed in the database search.

The foreign language papers retrieved were not translated unless, based on their abstract, they offered any significantly different or more extensive results to those reported in the English language papers. Since this did not occur, only English language articles were included for review.

Exclusions by ASERNIP-S Researcher

Fifty-four studies were identified that met the inclusion criteria for EMLP. On closer examination, three studies, one book chapter and three reviews provided only background
material with little or no reporting of study details and/or outcome data, and were excluded from review (Appendix B). In addition, twenty-nine papers detailed endoscopic procedures other than EMLP, and were similarly excluded. The remaining papers comprised four non-randomised controlled trials, thirteen case series studies and one review article.

Six of these studies were excluded because they did not meet the inclusion criteria as follows:
- one comparative study and two case series studies pooled outcome data for patients undergoing EMLP with those undergoing other endoscopic frontal sinus surgery, and it was not possible to separate the data;
- one case series study had a patient pool whose indication for surgery was dural lesions rather than chronic frontal sinusitis;
- one comparative study combined outcomes for chronic frontal sinusitis patients with those suffering fractures and neoplasms;
- one review article included previously unpublished results from EMLP procedures conducted by one of the primary authors. Since no study details were available, this data was, by definition, grey literature and did not meet the inclusion criteria for this review.

Twenty-four studies were identified that met the inclusion criteria for the osteoplastic flap procedure. On closer examination, four studies and three review articles provided only background material with no reporting of outcome data, and were excluded from review. The remaining seventeen papers comprised case series studies.

Ten of these studies were excluded because they did not meet the inclusion criteria as follows:
- three articles had a patient pool that did not have chronic frontal sinusitis as the indication for surgery;
- three articles combined outcomes of chronic frontal sinusitis patients with those suffering fractures, neoplasms and cystic fibrosis, and it was not possible to separate the data;
- two articles described an obliterate procedure that used filling material other than autogenous fat;
- one article described an obliterate operation employing a superiorly based flap rather than the conventional inferiorly based one;
- one article was a duplication of most of the results reported by Correa et al.\textsuperscript{34}

\section*{Inclusions by ASERNIPS Researcher}

One paper by May\textsuperscript{35} was included by the protocol surgeon but this paper was subsequently excluded because it provided only background information, with no reporting of outcome data. Two excluded papers\textsuperscript{4,36} were reviews of comparative and case series data for the various frontal sinus surgery techniques. These papers were used as a checklist to ensure that the current review did not miss any relevant papers. Neither of these papers furnished any further additions to the literature review database.
Table 2: Summary of the final exclusion process for the systematic review papers, based on the full text article

<table>
<thead>
<tr>
<th>Procedure</th>
<th>RCTs</th>
<th>Non-RCTs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Initial</td>
<td>Initial</td>
</tr>
<tr>
<td>Endoscopic modified Lothrop procedure</td>
<td>0</td>
<td>54</td>
</tr>
<tr>
<td>Osteoplastic flap procedure with/without sinus obliterati</td>
<td>0</td>
<td>24</td>
</tr>
</tbody>
</table>

**Abbreviations:** RCT – randomised controlled trial; Non-RCT – studies that were not randomised controlled trials

3.4 Assessment Methods

The quality of all the included papers was assessed according to the Hierarchy of Evidence\(^7\) in Appendix A. A meta-analysis was not performed because the studies were of poor evidence quality and varied widely in outcome measures and study design.

3.4.1 Outcome Measures

For this review, the question of safety was addressed in terms of whether EMLP was more or less likely to cause injury or harm to the patient, in comparison to an osteoplastic flap procedure (OPF) conducted either with or without autogenous fat obliteration of the frontal sinus. Therefore, safety outcomes for EMLP were assessed in terms of the common outcomes reported for OPF which include cerebrospinal fluid leak, orbital damage, pain and/or discomfort, and numbness. In addition, any other reported outcome that affected patient safety was also tabulated.

In terms of efficacy, the question was whether EMLP produced equivalent clinical outcomes, in comparison to an OPF. The postoperative indicators chosen to assess the efficacy of EMLP for frontal sinusitis included cosmesis, degree of nasofrontal patency and sinus ventilation, re-operation rate, wound healing time, and rates of recurrent or persistent disease. Perioperative efficacy data included operative time and length of hospital stay. If any other efficacy outcome was reported in the study it was also tabulated.

4.0 RESULTS

Data was only reported if it was stated in the text, tables, graphs or figures of the article, or could be accurately extrapolated from the data presented. Conversely, if a particular complication was not reported, it was assumed by this reviewer to be unreported rather than not having occurred. For example, if the mortality rate was not reported in a study, no value was tabulated. This was done to avoid the bias caused by incorrectly assigning a value of zero to an outcome measurement on the basis of an unverified assumption by this reviewer. All methodological assessment and data extraction results are tabulated in Appendices C.1 to C.9.
4.1 The Endoscopic Modified Lothrop Procedure (EMLP)

4.1.1 Designation of Levels of Evidence and Study Methodology Appraisal

Only two comparative studies were available that met the inclusion criteria for review (Table 3 & Appendix C.1). One of these was a prospective study\(^{38}\) that was an expansion of previous case series\(^{17,23,33}\) data reported by the same group. The other comparative study\(^{27}\) retrospectively reviewed the charts of patients who had undergone either an EMLP or an OPF. The latter patient group was prospectively followed up via a telephone survey. Both comparative studies presented mixed level III-2/III-3 evidence because they utilised a combination of concurrent and historical controls.

Of the seven case series studies reviewed, two were prospective\(^{39,40}\) and four were retrospective (Table 3 & Appendix C.2).\(^{15,41-43}\) The remaining case series study prospectively followed up a group of patients who underwent endoscopic surgery for frontal sinusitis. However, the small subgroup of patients that had EMLP was retrospectively reviewed.\(^{44}\) The total number of patients undergoing EMLP in the nine studies reviewed was 121, with the largest single series contributing twenty-one and the smallest contributing five. The longest follow-up available on a single patient was four years.\(^{15}\)

Table 3: Summary of reviewed EMLP studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Level of Evidence</th>
<th>Intervention</th>
<th>No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross \textit{et al.}(^{38})</td>
<td>1997</td>
<td>III-2/III-3</td>
<td>OPF with fat obliteration</td>
<td>7</td>
</tr>
<tr>
<td>Ulualp \textit{et al.}(^{27})</td>
<td>2000</td>
<td>III-2/III-3</td>
<td>EMLP, OPF with fat obliteration</td>
<td>20, 21, 15</td>
</tr>
<tr>
<td>\textit{Case Series}</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Casiano &amp; Livingston(^{39})</td>
<td>1998</td>
<td>IV</td>
<td>EMLP</td>
<td>21</td>
</tr>
<tr>
<td>Close \textit{et al.}(^{40})</td>
<td>1994</td>
<td>IV</td>
<td>EMLP</td>
<td>11*</td>
</tr>
<tr>
<td>Kikawada \textit{et al.}(^{41})</td>
<td>1999</td>
<td>IV</td>
<td>EMLP</td>
<td>16</td>
</tr>
<tr>
<td>Loehrl \textit{et al.}(^{42})</td>
<td>2000</td>
<td>IV</td>
<td>EMLP</td>
<td>5</td>
</tr>
<tr>
<td>May &amp; Schaitkin(^{15})</td>
<td>1995</td>
<td>IV</td>
<td>EMLP</td>
<td>6</td>
</tr>
<tr>
<td>McLaughlin \textit{et al.}(^{43})</td>
<td>1999</td>
<td>IV</td>
<td>EMLP</td>
<td>20</td>
</tr>
<tr>
<td>Metson &amp; Gliklich(^{44})</td>
<td>1998</td>
<td>IV</td>
<td>EMLP</td>
<td>9</td>
</tr>
</tbody>
</table>

Abbreviations: EMLP – endoscopic modified Lothrop procedure; OPF – osteoplastic flap procedure; *Only nine of these patients had chronic frontal sinusitis

The comparative study by Gross \textit{et al.}\(^{38}\) was primarily focussed on a cost effectiveness comparison between EMLP and OPF. Therefore, the study reported no information on either safety outcomes or the surgical strategy and methods used for the OPF patient group. However, limited data was reported on efficacy outcomes that were likely to impinge on the costing of the two procedures, such as length of hospital stay. While the control group was largely concurrent for this study, there was a non-contiguous three-month gap at the beginning of the study period, which meant that the OPF patient group could not be considered wholly concurrent with the EMLP patients.
The comparative paper by Ulualp et al.\textsuperscript{27} was also limited by the problem of comparing data from chronologically distinct patient groups in its use of historical controls for the majority of the OPF patient group. Many factors may change over long periods of time such as operative technique, indications for surgery, and postoperative care protocols, which may influence patient outcomes and bias the results. Both comparative studies\textsuperscript{27,38} were further weakened by their reliance on the accuracy and completeness of medical records for the veracity of the retrospectively derived data used in the OPF arms of the studies. In addition, such retrospective data collection is completely dependent upon the outcome measures noted by the hospital staff at the time, which may not necessarily be adequate for a comparative study. Thus, differences not only in the outcomes reported but their method of measurement may result in a data mismatch that will affect the validity of any comparative study. Both comparative studies also failed to perform a statistical comparison of preoperative parameters for the two study groups, which may have been helpful in identifying possible bias and confounding factors introduced by the lack of randomisation of the study participants.

The majority of the case series studies also suffered the limitations inherent in retrospectively collected data. Only one case series\textsuperscript{39} made an attempt to exclude patients on the basis of possible confounding preoperative factors such as a history of immunodeficiency. The majority of EMLP procedures in the case series studies were performed on patients that had undergone previous sinus surgery. One study\textsuperscript{37} reported the use of a limited external incision to gain access to the frontal sinus while another reported an attempt to use a computer-aided surgery system to track intra-operative instrument location during EMLP. One case series study inserted a stent into the enlarged frontal sinus ostium of all EMLP patients for up to ten days postoperatively\textsuperscript{15} while another maintained stent placement for a minimum of six months in 18.8% of their patients.\textsuperscript{41} However, in the latter study, only the data for those patients that did not undergo stent insertion were tabulated in this review. Unfortunately, few of the studies used a standardised risk stratification or symptom staging system to classify the patients in the OPF and EMLP groups. This made it difficult to objectively assess and compare the pre- and postoperative outcomes of patients, either within or between the studies.

4.1.2 Safety

There was very little comparative data (level III-2/III-3 evidence) on postoperative safety outcomes (Appendix C.3). The study by Ulualp et al.\textsuperscript{27} demonstrated a higher incidence of intra-operative cerebrospinal fluid leak following EMLP, compared to OPF. The OPF patients studied by Ulualp et al.\textsuperscript{27} experienced a 14% incidence of decreased forehead sensation, which was not reported for any EMLP patient. In addition, 5% of the OPF patients lost their obliteratorative fat graft due to infection, which is a procedure specific complication of OPF. The only adverse safety outcome for EMLP reported by Gross et al.\textsuperscript{38} was an incidence of transient visual disturbance in one patient. Unfortunately no comparative safety data was available for the OPF group in this study. Two case series studies\textsuperscript{40,43} reported incidences of patients (10-11%) developing an intra-operative cerebrospinal fluid leak (Appendix C.5). However, none of these proved fatal. The only postoperative morbidity recorded across the six case series was one case of iatrogenic septal perforation.\textsuperscript{43}

4.1.3 Efficacy

There was a similar paucity of comparative data (level III-2/III-3 evidence) for efficacy outcomes (Appendix C.4). Gross et al.\textsuperscript{38} reported a shorter hospital stay for patients
undergoing EMLP, in comparison to OPF, and performed EMLP as an outpatient procedure in 65% of their patients. A significant subjective symptom improvement was achieved in 70% of the twenty EMLP patients, with postoperative endoscopic examination revealing a 95% nasofrontal patency rate. Unfortunately, the rate of subjective symptom resolution was not reported for the OPF patients. Ulualp et al. claimed 100% subjective symptom resolution for their OPF patients but reported no objective measurement of nasofrontal patency. In contrast, normal sinus ventilation was found in 87% of the EMLP patients at up to two and a half years postoperatively, as derived from otolaryngologic examination results recorded in the patient charts. Recurrent disease was not evident in the OPF group at up to twelve years follow-up, in some cases, whereas revision surgery was required in two EMLP patients to manage recurrent symptoms at up to two and a half years postoperatively.

Common intra-operative efficacy variables, such as length of hospital stay, were not widely reported among the case series studies (Appendix C.6). However, one study indicated that all EMLP patients were discharged within 24 hours of the procedure while another conducted EMLP exclusively as an outpatient procedure. There were no reports of peri-operative mortality or conversion from EMLP to an external procedure. Normal patency was reported by Close et al. (as evaluated by endoscopic examination) and Kikawada et al. (as evaluated by computed tomographic examination) in all of their EMLP patients at a mean follow-up of 5.8 and 24.3 months, respectively. Three other studies reported nasofrontal patency rates of between 57% and 95% patency following EMLP, as measured by endoscopic examination, computed tomographic scan and/or cannulation of the neo-ostium. Interestingly, of the three EMLP patients reported by Kikawada et al. who had a stent inserted into the enlarged neo-ostium for up to 12 months postoperatively, only two maintained nasofrontal patency. The third patient experienced persistent inflammation around the stent, which resulted in scar tissue formation, and consequent occlusion of the neo-ostium, following stent removal. The nasofrontal patency rate reported by May & Schaitkin was similarly low in their small patient group but this may be due to the lengthy follow-up of some of the patients rather than the short term (7-10 days) stenting employed in their patient group.

Only two case series studies reported the need for revision surgery in 9.6% to 20% of patients due to recurrent disease and/or restenosis. McLaughlin et al. was the only study to report incidences of numbness or tingling in the nose (37%), and peri-orbital headache or frontal sinus pain (55%). However, the authors used a combined external/intranasal technique and it is possible that these side effects may be related to the use of an external Killian type septal incision. Regeneration of the intersinus septum was reported in two patients but this did not adversely affect nasofrontal patency. The limited data available for quality of life outcomes indicated an overall improvement in 74% of patients and a perceived decrease in nasal/sinus symptoms for 86% to 90% of those undergoing EMLP.

4.2 Osteoplastic Flap Procedure With/Without Sinus Obliteration

To date, the safety and efficacy outcomes most commonly quoted for the OPF are derived from follow-up data published by the group that originally popularised the procedure in the United States in the late 1950s. Consequently, there were no large contemporary series that reflected the current practice of the OPF in patients whose primary indication for surgery was chronic frontal sinusitis. There were a small number of review articles available that detailed results for the OPF procedure but none of these met the inclusion criteria.
criteria for this review because they combined the outcome data for chronic frontal sinusitis patients with other patients whose indications for surgery included such varied complaints as dural lesions, fractures and neoplasms. It was not appropriate to use this pooled data unless the results for the chronic frontal sinusitis patients could be separated from the aggregate data. Unfortunately, this was not possible. Consequently, the safety and efficacy outcomes for the OPF were extracted and tabulated from primary studies in order to reflect the current trends for this procedure in the published literature (Appendix C.7). It was not the purpose of this review to assess the safety and efficacy of OPF. Therefore, the data presented on the safety and efficacy of OPF is not definitive and is only intended as a guide for general reference in comparing EMLP with OPF.

4.2.2 Safety and Efficacy

There was little safety data reported across the studies, with complications being limited to scalp haematoma, embossment, and morbidity associated with the use of a fat donor site (Appendix C.8). Resolution of frontal sinus disease was achieved in 95-100% of patients across three studies (Appendix C.9).\textsuperscript{25,34,48} The rates of disease recurrence ranged from 5% to 8%\textsuperscript{25,34,49} whereas the requirement for revision surgery ranged from 5% to 35% of patients following the OPF procedure.\textsuperscript{25,34,49,50} Frontal headache was the most common adverse efficacy outcome (23%).\textsuperscript{51} In the one study\textsuperscript{50} that measured quality of life indicators, 65% of patients reported being satisfied with the OPF.

5.0 DISCUSSION

Good studies are defined by rigid inclusion criteria, extensive evaluation, highly standardised treatment, validated and clinically relevant outcomes, a lengthy follow-up period and impartial investigators.\textsuperscript{52,53} All of the studies available for review failed in at least one of these requirements. The poor evidence quality, small sample size and limited data reporting in the majority of the studies meant that only very general conclusions could be drawn from the data.

5.1 Safety and Efficacy of the Endoscopic Modified Lothrop Procedure

The relatively recent development of EMLP and its high degree of technical complexity, meant that many of the studies, particularly the case series, were focussed on the surgical methodology of EMLP rather than patient outcomes. Consequently, many papers contained an extensive methods section with only a cursory mention of the operative outcomes for their small patient group. Thus, it was often unclear if some postoperative complications were not reported either because they were considered secondary to the main focus of the study or because they didn’t occur. Nonetheless, the limited data reported in the two comparative studies\textsuperscript{27,38} (level III-2/III-3 evidence) suggested that EMLP caused fewer postoperative adverse outcomes for patients, but had a much higher propensity to generate intra-operative cerebrospinal fluid leaks than OPF. Two case series studies also reported incidences of this complication. However, none of the morbidity generally associated with OPF, such as embossment and scalp haematoma, occurred in any EMLP patient. It is likely that the increased incidence of cerebrospinal fluid leak associated with EMLP is a reflection of the difficulty of performing such a procedure endoscopically, even in the hands of experienced surgeons. Also, there is often a high learning curve component inherent in case series studies because they often report the early results of feasibility studies on new surgical techniques. In addition, some of the patients that were eligible for EMLP often had cofactors, such as a history of facial
trauma and/or previous sinus surgery, that predisposed them to this kind of intra-operative complication.

The two comparative studies\textsuperscript{27,38} offered little directly comparable efficacy data for EMLP and OPF. However, the available data did suggest that EMLP could be performed as an outpatient procedure which obviated the need for the average three day hospital stay that is customary after OPF.\textsuperscript{34} One comparative study\textsuperscript{27} showed that symptom resolution following EMLP was lower than for OPF, and this was also reflected in a general comparison between the EMLP and OPF case series data. The incidence of recurrent disease reported in the comparative and case series data appeared to favour OPF, in comparison to EMLP, whereas the requirement for revision surgery was similar. The common complications of OPF, such as frontal headache, were largely absent from the EMLP studies. A cautious broad comparison between the EMLP and OPF case series data suggested that EMLP may have a shorter operative time and result in a lower intra-operative blood loss than OPF. Unfortunately, little can be determined from the present data concerning the long term efficacy of EMLP because the mean follow-up of most of the studies was less than two years. However, it should be noted that the length of follow-up reported in the majority of the case series data available for chronic frontal sinusitis patients undergoing OPF was equally unimpressive.

Six studies\textsuperscript{15,38,40,41,43,44} reported details of their postoperative treatment, with five\textsuperscript{38,40,41,43,44} noting frequent office visits for EMLP patients over a period of up to six weeks for cleaning and debridement of the operative area to ensure patency of the newly created common ostium. Such extensive postoperative follow-up was not mentioned as a requirement for OPF. The results from one study that trialled long term postoperative stenting of the neo-ostium in some patients indicated that such prophylactic measures were unnecessary for the maintenance of nasofrontal patency following EMLP.\textsuperscript{41}

5.2 Possible Indications and Contraindications for EMLP

The lack of applied exclusion criteria for the majority of the reviewed studies meant that it was not possible to derive any definitive conclusions regarding the possible contraindications for EMLP. However, it was suggested that EMLP may not be appropriate when the disease process involves the most lateral recesses of the frontal sinus;\textsuperscript{35} there is osteomyelitis involving the anterior or posterior wall necessitating extensive bone removal;\textsuperscript{35} or isolated mucoceles have developed lateral to the mid-papillary line after previous frontal sinus obliteration.\textsuperscript{40}

The reviewed studies appeared to support the observation that indications for EMLP are generally the same as for OPF.\textsuperscript{40} In addition, the majority of the patients presenting for EMLP in the reviewed studies had undergone at least one prior sinus surgery procedure. Given the success rates quoted in the reviewed studies for a population of patients that are notorious for increasing the technical demand on the otolaryngological surgeon conducting endoscopic surgery, it would appear that re-operative patients may benefit substantially from EMLP. It is also possible that patients with risk factors such as aspirin intolerance and bronchial asthma who require frontal sinus surgery may also benefit from a less invasive alternative to OPF.\textsuperscript{54}

Casiano & Livingston\textsuperscript{39} have observed that the common frontal ostium created by EMLP should be greater than 8 mm antero-posteriorly and 16 mm laterally to avoid the possibility of re-stenosis. Draf et al.\textsuperscript{54} also stated that EMLP should not be performed in
patients with small frontal sinuses that would not allow the creation of a minimum 5 mm neo-ostium. Therefore, patient selection based on complete preoperative assessment may prove to be an essential component of EMLP operative success. Preoperative computed tomography scans to measure inter-orbital and antero-posterior distances at the level of the natural frontal ostium,³⁹,⁵⁵ in conjunction with a thorough endoscopic examination, may prove mandatory for defining the patient’s frontal sinus pathology and any individual anatomical differences that may be present.

Patients with extensive polypoid degeneration of the frontal sinus mucosa, a narrow anterior-posterior diameter in the frontal recess, highly compartmentalised frontal sinuses, very thick secretions in the frontal sinuses, allergic fungal sinusitis, inverting papilloma or frontal sinus fractures have traditionally done poorly with endoscopic approaches.³⁴ It was not clear from the present data whether this will prove true for EMLP as well. However, with increasing expertise and refinements in technology and technique, the contraindications and application of EMLP may become more clearly defined.

While there appeared to be many overlapping indications for EMLP and OPF, it may be that EMLP will not replace OPF, but rather serve as an intermediate procedural choice for selected patients in the surgical spectrum that encompasses functional endoscopic sinus surgery as a first option, and OPF as one of the last.

5.3 Technical Considerations

A significant disadvantage of the EMLP procedure, in contrast to OPF, appeared to be the high level of technical skill it required, even in the hands of experienced sinus endoscopic surgeons.²,⁴⁰ The surgeon is handicapped by limited access in an area dangerously close to such vital structures as the cribriform plate, frontal lobe dura, anterior ethmoid artery and orbital contents. The procedure is even more challenging in re-operative patients where anatomic landmarks such as the middle turbinate may have been removed.²,⁴⁰ Frontal recess dissection is not commonly required in the majority of endoscopic sinus procedures. Consequently, not all otolaryngological surgeons are necessarily equipped with the anatomical knowledge and endoscopic expertise required to perform EMLP safely. This, coupled with the small study population requiring treatment, has led many authors to recommend extensive cadaver dissection and study of the frontal sinus anatomy, including detailed examination of the individual patient anatomy, prior to attempting EMLP in a patient.³⁸,⁴⁰,⁴³,⁵⁶,⁵⁷,⁵⁸ A thorough knowledge of the anatomy as it appears through the endoscope is also important before attempting EMLP because other structures, such as the cap of the agger nasi cells or a supraorbital ethmoid air cell, can easily be mistaken for the internal frontal sinus ostium of the frontal sinus.⁵⁸

With the advent of new powered surgical instruments for endoscopic sinus surgery, there has also been concern regarding the mismatch of surgical expertise with this new aggressive technology. Gross and Becker⁵⁹ reported personal communication with a number of sinus surgeons who stated that extensive knowledge of anatomy was essential to be able to safely use the new powered instruments. In addition, it was noted that the reduced ability to palpate with the soft tissue shavers may have serious consequences for the less experienced endoscopist.⁵⁹ Loehrl et al.,⁴² who utilised an intraoperative computer-aided surgery system to conduct EMLP, were also keen to point out that the system was a helpful adjunct to their operative experience and knowledge of sinus anatomy, but was not a replacement for it.
It is self-evident that there is likely to be a greater incidence of complications while the surgeon is on the learning curve. A study by Marks suggested that major complications could be largely avoided by a rigorous training period during surgical residency that absorbed the learning curve for endoscopic sinus surgery. The training undertaken by Marks included frequent supervision by experienced surgeons, repeated exposure to didactic coursework and cadaver dissection, and a gradual increase in responsibility in the operating room over a four year period. This may serve as a useful guide for the level of training required to keep dangerous complications to a minimum when such techniques as EMLP are introduced into clinical practice.

5.4 Considerations for Further Research

A prospective blinded randomised controlled trial is the only scientifically rigorous method of evaluating a new surgical therapy. However, such study designs are often not applicable, feasible, or even ethical, to undertake in surgical practice. In the case of EMLP and OPF, it would be impossible to conduct a trial where the patient and/or the operator were blinded because the external incision required for OPF would make identification of the treatment a fait accompli. As the current data for EMLP suggests, even non-randomised concurrently controlled trials are a rare occurrence in the area of frontal sinus surgery. One of the main prohibitive factors is the relatively small study population that is initially considered for frontal sinus surgery, and the even smaller patient subgroup that would be eligible to undergo EMLP. For example, in two of the studies that applied limited exclusion criteria to their study population, only between 40% and 53% of the initial small pool of patients presenting for sinus surgery were eligible for EMLP. Thus, a truly rigorous randomised comparative study, in which both the EMLP and OPF patient were truly comparable, could only be achieved via a multicentre trial design. A number of authors have noted the discrepancy between objective and subjective measures in judging the outcome of sinus surgery. The extent to which a placebo effect influences operative outcomes in sinus surgery is currently unknown, and can only be appropriately balanced in a randomised, concurrently controlled prospective study.

A further difficulty lies in the wide variety of underlying causes of frontal sinus obstruction, which can also limit the study population. For a controlled study to be successful, the patient population needs to be stratified in terms of their presenting indications and diagnosis. Further staging of the extent of the disease in the nasal cavity based on some form of standardised objective measure gained via endoscopic evaluation or computed tomography scan would also be essential. Many studies were excluded from review because the results for the patients suffering from chronic frontal sinusitis could not be separated from the aggregate data derived from the heterogeneous mix of patients with presenting symptoms such as anatomic abnormalities, fractures, nasal polyposis, aspirin sensitivity, allergy, fungal disease, and cystic fibrosis. These patient populations are distinct and not directly comparable because factors such as asthma, polypoid disease, and allergy are potential prognostic factors in EMLP outcomes.

To date, the value of the results reported in many studies has been limited by the lack of a universally accepted grading scale to assist in comparing the pre- and postoperative status of patients both within and between studies. Without this, any observed changes in patient status are virtually meaningless. In addition, objective measures, such as rhinometry and computed tomography scan results are often not uniformly applied, which makes intra- and inter-study comparison problematic. The comparability of examination
results after sinus surgery is also often compromised by the different inclusion criteria, different examination methods, and the lack of standardised well-defined operative outcomes.\textsuperscript{5,64} This was evident in the current series of data for outcomes such as the operative success rate, which was defined and measured by different authors in different ways.

Follow-up periods in the available EMLP studies were generally short which is probably a reflection of the relatively new status of this procedure. In addition, some studies only conducted postoperative follow-up on a subset of the patients initially treated. This is often due to the difficulty in justifying the expense of conducting a computed tomography scan in an asymptomatic patient following successful surgery and/or being able to entice such a patient back to the hospital for follow-up examination.\textsuperscript{5,62} However, this adds considerable bias to the outcome data. It has been suggested that re-stenosis would most likely occur within six months of undergoing EMLP but other recurrent symptoms may take much longer to eventuate.\textsuperscript{39} EMLP disrupts the active inward transport of mucous within the frontal sinus but the short term follow-up currently available has shed no light on whether this was potentially detrimental to the patterns of clearance within the sinuses.\textsuperscript{33} Therefore, it is likely that continued follow-up of at least five years will be necessary to ascertain this.\textsuperscript{40} Despite the difficulties inherent in achieving this degree of follow-up, it is clearly necessary to be able to accurately determine the safety, efficacy and durability of EMLP. Many studies are prone to use intermediate outcomes when evaluating sinus surgery but it has been shown that the long term results for sinus surgery are often very different from the results obtained in the short term.\textsuperscript{5}

\section*{6.0 CONCLUSION}

The purported theoretical advantages of EMLP include decreased morbidity, avoidance of a donor site with its attendant morbidity, improved cosmesis, reduced blood loss, shorter hospitalisation, and preservation of the frontal sinus for future endoscopic and radiographic evaluation.\textsuperscript{2,38,40} There was a preliminary indication that EMLP may fulfill the majority of these predictions. Indeed, some of the serious complications that have been theoretically associated with EMLP, such as penetration of the orbital wall, injury to the lacrimal system and interruption of the anterior ethmoid artery,\textsuperscript{35} have yet to be reported in the reviewed literature. However, the current data did suggest that there may be concern with respect to peri-operative cerebrospinal fluid leaks in some patients, particularly those with a history of facial trauma. While EMLP may ultimately prove to be as safe and efficacious as OPF in certain patient groups, there was currently no long term data available to confirm its durability. More rigorous studies with concurrent comparator groups, larger sample sizes and more extensive follow-up must be conducted before a definitive conclusion can be reached regarding the safety and efficacy of EMLP in comparison to OPF.

\subsection*{6.1 Classification and Clinical Recommendations}

The Review Group recommended that EMLP for the treatment of chronic frontal sinusitis be given a classification of ‘2’. The safety and efficacy of the procedure cannot be determined at the present time due to an incomplete and poor quality evidence-base. It was recommended that a national audit, with standardised data reporting, of the centres currently performing the procedure be conducted to establish safety and efficacy. The Otolaryngology Head and Neck Surgeons of the Royal Australasian College of Surgeons would ideally manage this, and any new centres embarking on the use of EMLP would be
recruited into the audit. A concurrent national audit of the osteoplastic flap procedure was also recommended.

In addition, the following clinical recommendations were made to guide the development of EMLP during this audit phase:

1. Otolaryngological surgeons should obtain institutional support and appropriately inform their patients before commencing EMLP.
2. EMLP is a technically demanding procedure. Therefore, EMLP should only be performed on appropriately selected patients by a properly trained otolaryngological surgeon who is accredited in the use of the procedure. Before performing EMLP, the surgeon should participate in a formal training workshop that includes surgical theory, endoscopic anatomy, and cadaver dissection. A minimum prescribed number of cadaver dissections and supervised surgical procedures should be performed before full accreditation is awarded.
7.0 REFERENCE LIST


APPENDICES
## APPENDIX A – HEIRARCHY OF EVIDENCE

Table 1: Designation of Levels of Evidence table from the National Health and Medical Research Council.\textsuperscript{37}

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence obtained from a systematic review of all relevant randomised controlled trials</td>
</tr>
<tr>
<td>II</td>
<td>Evidence obtained from at least one properly designed randomised controlled trial</td>
</tr>
<tr>
<td>III-1</td>
<td>Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method)</td>
</tr>
<tr>
<td>III-2</td>
<td>Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies or interrupted time-series with control group</td>
</tr>
<tr>
<td>III-3</td>
<td>Evidence obtained from comparative studies with historical control, two or more single arm studies or interrupted time series without a parallel control group</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence obtained from case-series, either post-test or pre-test/post-test</td>
</tr>
</tbody>
</table>
APPENDIX B - EXCLUSIONS

The following papers were excluded from the methodological assessment as outlined in section 3.3 of the review.

**Endoscopic Modified Lothrop Procedure Papers**


Osteoplastic Flap Procedure Papers


APPENDIX C – METHODOLOGICAL ASSESSMENT AND DATA EXTRACTION TABLES
Measurement Abbreviations
SD – standard deviation

General Abbreviations
CSF – cerebrospinal fluid
CSS – Chronic Sinusitis Survey
EMLP – endoscopic modified Lothrop procedure
FESS – functional endoscopic sinus surgery
FU – follow-up
OPF – osteoplastic flap procedure
## Appendix C.1:  Endoscopic Modified Lothrop Procedure – Comparative Studies

<table>
<thead>
<tr>
<th>Authors</th>
<th>Location</th>
<th>Intervention</th>
<th>Study Design</th>
<th>Study Population</th>
<th>Inclusion/Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross et al. 38</td>
<td>Department of Otolaryngology – Head and Neck Surgery, University of Virginia Health Sciences Center, Charlottesville, Virginia, USA and Middle Tennessee Ear, Nose and Throat, Tennessee, USA</td>
<td>1) Osteoplastic Flap with Fat Obliteration Details not stated</td>
<td>Prospective non-randomised, non-blinded concurrently/historically controlled trial</td>
<td>Sample Size: 1) n = 7; 2) n = 20</td>
<td>Not stated</td>
</tr>
<tr>
<td>1997</td>
<td></td>
<td>2) <strong>Endoscopic Modified Lothrop Procedure</strong></td>
<td>Level of Evidence: Mixed III-2/III-3</td>
<td>Statistical comparison of preoperative parameters for groups 1) and 2) was not performed</td>
<td></td>
</tr>
<tr>
<td>(Expansion of case series reported in Becker et al. 33 1995, Gross et al. 17, 1995 and Gross et al. 23, 1995)</td>
<td></td>
<td>Preoperative Scan: Endoscopic examination and standard fine-cut coronal sinus computed tomography scans plus axial views, when needed. Anaesthesia: General with local anaesthesia (lidocaine and epinephrine) injected into the nose Surgical Access: Intranasal Surgical Equipment: 4 mm rigid 0° and 30° endoscopes; power drilling equipment originally designed for arthroscopic surgery including endonasal soft tissue shavers and endonasal bone-cutting suction drills Surgical Strategy: If present, the agger nasi, superior uncinate and anterior ethmoid cells were removed. The frontal recess on one side was cannulated where possible. Mucosa was removed on both sides of the nasal septum prior to resection of the superior septum in the region between the two frontal recesses, anterior to the nasofrontal isthmus. Mucosa was then removed from the area of the frontal sinus floor between the two frontal recesses. A wire probe was placed through the nasofrontal isthmus into the frontal sinus to assist in anatomic orientation. Bone was then removed from the anterior face of the frontal recess on one side. The nasal crest was then removed, with drilling proceeding medially until the contralateral frontal recess and isthmus were opened and in communication with the nasofrontal opening. As much bone as possible was removed anteriorly so that only a thin bony shell remains around the nasofrontal communication at the glabellar area. Stents: Not stated Medication: Not stated Postoperative Treatment: Frequent office visits for removal of clots, crusts, polyps or granulation tissue.</td>
<td>Participation Rate: Not applicable Eligibility Rate for EMLP: Not applicable Mean Follow-Up: 1) Not stated 2) 12 months (range 1-21) Lost to follow-up: 0%</td>
<td>Patient Diagnosis: 1) &amp; 2) Chronic persistent frontal sinusitis. 2) Evidence of preoperative frontal sinus drainage obstruction – 100%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Study Period: 1) 7/93-3/95 2) 10/93-4/95</td>
<td>Previous Sinus Surgery: 1) Not stated 2) FESS - 95%; External ethmoidectomy with unilateral catheter placement into the frontal sinus – 5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Operator Details: 15% of procedures performed by one surgeon at Middle Tennessee Ear, Nose and Throat, Tennessee, USA</td>
<td>Mean Age: 1) Not stated 2) 46 yrs (range 29-89)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Patient Comorbidities: 1) Not stated 2) History of seizures – 5%; Sarcoidosis – 5%; Severe asthma – 5%; Asthma and coronary artery disease – 5%</td>
<td>Gender Mix: Not stated</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Patient Details: Not stated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Authors</td>
<td>Location</td>
<td>Intervention</td>
<td>Study Design</td>
<td>Study Population</td>
<td>Inclusion/Exclusion Criteria</td>
</tr>
<tr>
<td>---------</td>
<td>----------</td>
<td>--------------</td>
<td>--------------</td>
<td>------------------</td>
<td>-----------------------------</td>
</tr>
</tbody>
</table>
| Ulualp et al., 2000 | Department of Otolaryngology and Human Communication Sciences, Medical College of Wisconsin, Milwaukee, Wisconsin, USA | **1) Osteoplastic Flap with Fat Obliteration**  
Preoperative Scan: Six foot Caldwell view x-ray of the frontal sinus was obtained to outline the limits of the bone incision.  
Anaesthesia: General with local anaesthesia (lidocaine and epinephrine) in the area of planned incision  
Surgical Access: Eyebrow incision from the midline of the right and/or left eyebrow to the nasion of the nose. A bi-coronal incision was used when preferred by patients.  
Surgical Equipment: Not stated  
Surgical Strategy: Sharp dissection was used to elevate a plane superficial to the periosteum superiorly and inferiorly. An incision was made that aligned the frontal sinus through the periostium superiority and inferiorly, leaving the lower right lateral and left lateral areas without periosteal cuts. The periosteum was elevated and the anterior table of the frontal sinus cut at a beveled angle of approximately 30 degrees toward the centre of frontal sinus. This flap was then elevated forward and downward to expose the frontal sinus. The contents of the frontal sinus were removed together with the cortex of the bone on the anterior and posterior tables. The intersinus septa and the entire frontal sinus floor were also removed. The mucosa and disease of the supra-orbital and remaining nasofrontal recess were thoroughly cleaned. Adipose tissue was then harvested from the left lower abdominal quadrant and implanted into the frontal sinus. The anterior table was returned to its anatomic position and the periosteum, subcutaneous tissues and skin were sutured.  
Medication: Not stated  
Postoperative Treatment: Not stated | Retrospective/prospective non-randomised, non-blinded concurrently/historically controlled trial (prospective follow-up of patients who retrospectively underwent obliterative procedure) | **Sample Size:**  
1) n = 21; 2) n = 15 | Statistical comparison of preoperative parameters for groups 1) and 2) was not performed | **Patient Diagnosis:**  
1) & 2) Chronic frontal sinusitis | **Previous Sinus Surgery:**  
1) Bilateral intranasal ethmoidectomy-sphenoidostomy – 81.0%; Lynch procedure – 4.8%; Caldwell-Luc – 9.5%  
2) Bilateral intranasal ethmoidectomy-sphenoidostomy - 100%; Caldwell-Luc – 6.7% | **Age Range:**  
1) 33 to 67 years  
2) Not stated | **Gender Mix:**  
1) & 2) Not stated | **Patient Comorbidities:**  
1) Aspirin triad disease – 38.1%  
2) Aspirin triad disease – 26.7% | **Patient Details:** Not stated |
| | | **2) Endoscopic Modified Lothrop Procedure**  
Preoperative Scan: Computed tomography scan  
Anaesthesia: General with submucosal injection of lidocaine and epinephrine along the lateral nasal wall and middle turbinate. A greater palatine foramen block was performed through the oral cavity.  
Surgical Access: Intranasal  
Surgical Equipment: Not stated  
Surgical Strategy: Obstructing tissue within the nasofrontal recess was removed and the anterior-superior portion of the nasal septum was transected superiorly. The intervening portion was taken down posteriorly to just beyond the anterior aspect of the middle turbinate. The bone from the anterior face of the frontal recess was then removed, starting on the anterior wall (beak) and progressing to the other side. The intra-sinus septum was then removed together with any diseased tissue.  
Stents: Not stated  
Medication: Not stated  
Postoperative Treatment: Not stated | | | | | |
### Appendix C.2: Endoscopic Modified Lothrop Procedure – Case Series Studies

<table>
<thead>
<tr>
<th>Authors</th>
<th>Location</th>
<th>Intervention</th>
<th>Study Design</th>
<th>Study Population</th>
<th>Inclusion/Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Casiano and Livingston</td>
<td>Department of Otolaryngology, University of Miami School of Medicine, Miami, Florida, USA</td>
<td><strong>Endoscopic Modified Lothrop Procedure</strong>&lt;br&gt;Preoperative Evaluation: History and symptoms questionnaire, flexible and/or rigid fibreoptic evaluation of the nose and computed tomography scanning&lt;br&gt;Anaesthesia: General with local anaesthesia (lidocaine and epinephrine) injected into the nose&lt;br&gt;Surgical Access: Intranasal&lt;br&gt;Surgical Equipment: 4 mm rigid 0° and 30° endoscopes, angled cervical spine bone curettes, frontal rasps, thru-cut forceps. No powered instrumentation was used.&lt;br&gt;Surgical Strategy: The perpendicular plate of the ethmoid was conservatively resected anterior to the coronal plane of the posterior wall of the frontal sinus. The perpendicular plate was resected posterior to the nasal bones and followed superiorly toward the intersinus septum. The nasofrontal ‘beak’ was removed until the anterior table of the frontal sinus was clearly visualised just above the level of the ostium.&lt;br&gt;Stents: Not stated&lt;br&gt;Medication: Not stated&lt;br&gt;Postoperative Treatment: Not stated</td>
<td>Prospective case series&lt;br&gt;Level of Evidence: IV&lt;br&gt;Eligibility Rate for EMLP: 21 of 40 patients (52.5%)&lt;br&gt;Mean Follow-Up: 6.5 months (range 2-24)&lt;br&gt;Lost to follow-up: 0%&lt;br&gt;Study Period: 21 month period from 1995 to 1997&lt;br&gt;Operator Details: Single operator for all surgical procedures and endoscopic examinations</td>
<td>Sample Size: n = 21&lt;br&gt;Patient Diagnosis: Chronic persistent frontal sinusitis&lt;br&gt;Previous Sinus Surgery: Endoscopic ethmoidectomy and/or frontal sinusotomy – 100%; OPF – 4.8%&lt;br&gt;Mean Age: 51 yrs (range 27-80)&lt;br&gt;Gender Mix: M/F = 9/12&lt;br&gt;Patient Comorbidities: Not stated&lt;br&gt;Patient Details: History of midfacial trauma – 23.8%</td>
<td>Inclusion Criteria:&lt;br&gt;• Patients with persistent frontal sinusitis identified by symptoms, physical examination, and computerised tomography&lt;br&gt;• Patients with well documented history of endoscopic ethmoidectomy and attempted frontal sinusotomy&lt;br&gt;Exclusion Criteria:&lt;br&gt;• History of systemic immunodeficiency or HIV infections</td>
</tr>
<tr>
<td>Authors</td>
<td>Location</td>
<td>Intervention</td>
<td>Study Design</td>
<td>Study Population</td>
<td>Inclusion/Exclusion Criteria</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Close et al.</td>
<td>Division of Head and Neck Surgery, Department of Otorhinolaryngology, The University of Texas Southwestern Medical Center, Dallas, Texas, USA</td>
<td><strong>Endoscopic Modified Lothrop Procedure</strong>&lt;br&gt;Preoperative Evaluation: Computed tomography scans in patients with chronic frontal sinusitis (n=9)&lt;br&gt;Anaesthesia: Not stated&lt;br&gt;Surgical Access: Intranasal – 54.6%; Intranasal with limited external incision – 45.4%&lt;br&gt;Surgical Equipment: Endoscope, cutting burr&lt;br&gt;Surgical Strategy: A bilateral endoscopic ethmoidectomy and frontal sinusotomy was performed. Where possible, both frontal sinus ostia were cannulated intranasally. Otherwise a small infra-brow external incision was performed to allow a frontal sinusotomy and cannulation of the ostia. A 2 x 2 cm square piece of the perpendicular plate of the nasal septum immediately adjacent to the frontal sinus floor was then resected. The intranasal frontal sinus floor was then removed to leave a bridge of bone intact posteriorly between the fenestration and the natural frontal sinus ostia. The frontal intersinus septum was then removed or drilled down.&lt;br&gt;Stents: Not stated&lt;br&gt;Medication: Intravenous cephalosporins were begun prior to surgery and continued orally until the fourth postoperative day. Postoperative Treatment: Nasal irrigations with normal saline and a Waterpik nasal irrigator were initiated by the patient on the second postoperative day. These were used 2-3 times a day for an indefinite period. Endoscopic cleaning of the operative site started on the fourth postoperative day. This was continued weekly for a minimum of three weeks.</td>
<td>Prospective case series&lt;br&gt;Level of Evidence: IV&lt;br&gt;Eligibility Rate for EMLP: Not applicable&lt;br&gt;Mean Follow-Up: 5.8 months (range 3-9)&lt;br&gt;Lost to follow-up: Follow-up &gt; 3 months was only available for n=7&lt;br&gt;Study Period: 4/93-12/93&lt;br&gt;Operator Details: Not stated</td>
<td>Sample Size: n = 11&lt;br&gt;Patient Diagnosis: Chronic frontal sinusitis (n=9); Frontal sinus fracture (n=1); Inverting papilloma (n=1)&lt;br&gt;Previous Sinus Surgery in Chronic Frontal Sinusitis Patients (n=9): Endoscopic frontal sinusotomy – 77.8%; Obliterative osteoplastic flap procedure – 11.1%; Lynch procedure – 11.1%; None – 22.2%&lt;br&gt;Mean Age: 40 yrs (range 15-73)&lt;br&gt;Gender Mix: M/F = 9/2&lt;br&gt;Patient Comorbidities: Not stated&lt;br&gt;Patient Details: Not stated</td>
<td>Not stated</td>
</tr>
<tr>
<td>Authors</td>
<td>Location</td>
<td>Intervention</td>
<td>Study Design</td>
<td>Study Population</td>
<td>Inclusion/Exclusion Criteria</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>---------------------------</td>
<td>------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>Kikawada et al.</td>
<td>Hamamatsu Ear, Nose and Throat Surgicenter, Hamamatsu, Japan</td>
<td><strong>Endoscopic Modified Lothrop Procedure</strong>&lt;br&gt;Preoperative Evaluation: Not stated&lt;br&gt;<strong>Anaesthesia:</strong> General with local anaesthesia (lidocaine and epinephrine) injected into the agger nasi&lt;br&gt;<strong>Surgical Access:</strong> Intranasal&lt;br&gt;<strong>Surgical Equipment:</strong> Rigid 4 mm 25° endoscope with an irrigation system and a standard power drill with a 4-5 mm diamond burr&lt;br&gt;<strong>Surgical Strategy:</strong> Extensive scarring of the frontal recess in all patients precluded the use of a guide wire. Therefore, the antero-superior attachment of the middle turbinate was used as an alternative anatomical landmark. The fronto-maxillary process was drilled out upward along the orbital plate of the ethmoid bone. The anterior wall of the frontal sinus was removed between the orbital plate of the ethmoid bone and the nasal septum. Bone removal then proceeded toward the opposite side around the most antero-inferior point of the frontal sinus. The frontal intersinus septum was then removed and the antero-superior portion of the nasal septum was removed in a downward direction.&lt;br&gt;<strong>Stents:</strong> V-shaped silicone tube after completion of the procedure for a minimum of 6 months (18.8%).&lt;br&gt;<strong>Medication:</strong> Not stated&lt;br&gt;<strong>Postoperative Treatment:</strong> Patients seen approximately once a week for cleaning of the operative cavity.</td>
<td>Retrospective case series&lt;br&gt;<strong>Level of Evidence:</strong> IV&lt;br&gt;<strong>Eligibility Rate for EMLP:</strong> 16 of 40 patients (40%)&lt;br&gt;<strong>Mean Follow-Up:</strong> 24.3 months (SD ± 6.46) for n=13 patients with no postoperative stenting&lt;br&gt;<strong>Lost to follow-up:</strong> 0%&lt;br&gt;<strong>Study Period:</strong> 25/6/94-31/10/97&lt;br&gt;<strong>Operator Details:</strong> Not stated</td>
<td>Sample Size: n = 16&lt;br&gt;Patient Diagnosis: Obstructive frontal sinusitis caused by scar formation in the frontal recess&lt;br&gt;Previous Sinus Surgery: 100%&lt;br&gt;Mean Age: Not stated&lt;br&gt;Gender Mix: Not stated&lt;br&gt;Patient Comorbidities: Not stated&lt;br&gt;Patient Details: Not stated</td>
<td>Inclusion Criteria: &lt;ul&gt;&lt;li&gt;Patients with obstructive frontal sinusitis caused by postoperative scarring&lt;/li&gt;&lt;/ul&gt;</td>
</tr>
<tr>
<td>Loehr et al.</td>
<td>Department of Otolaryngology and Communication Sciences, Medical College of Wisconsin, Milwaukee, Wisconsin, USA</td>
<td><strong>Computer-Aided Endoscopic Modified Lothrop Procedure</strong>&lt;br&gt;Preoperative Evaluation: Computed tomography scan – contiguous 1 mm thick non-overlapping axial slices&lt;br&gt;<strong>Anaesthesia:</strong> General&lt;br&gt;<strong>Surgical Access:</strong> Intranasal&lt;br&gt;<strong>Surgical Equipment:</strong> Standard endoscopic sinus surgery equipment&lt;br&gt;<strong>Surgical Strategy:</strong> A computer-aided surgery system was used to track intraoperative instrument location and monitor anatomical localisation. A Draf type III procedure was performed whereby a defect was created in the superior aspect of the nasal septum. The floor of the frontal sinus was then removed in the area between the orbits.&lt;br&gt;<strong>Stents:</strong> Not stated&lt;br&gt;<strong>Medication:</strong> Not stated&lt;br&gt;<strong>Postoperative Treatment:</strong> Not stated</td>
<td>Retrospective case series&lt;br&gt;<strong>Level of Evidence:</strong> IV&lt;br&gt;<strong>Eligibility Rate for EMLP:</strong> Not applicable&lt;br&gt;<strong>Mean Follow-Up:</strong> 11.9 months (range 1-23)&lt;br&gt;<strong>Lost to follow-up:</strong> 0%&lt;br&gt;<strong>Study Period:</strong> 03/98-11/99&lt;br&gt;<strong>Operator Details:</strong> Not stated</td>
<td>Sample Size: n = 5&lt;br&gt;Patient Diagnosis: Chronic frontal sinus inflammatory disease&lt;br&gt;Previous Sinus Surgery: 100%&lt;br&gt;Mean Age: Not stated&lt;br&gt;Gender Mix: Not stated&lt;br&gt;Patient Comorbidities: Not stated&lt;br&gt;Patient Details: Not stated</td>
<td>Not stated</td>
</tr>
<tr>
<td>Authors</td>
<td>Location</td>
<td>Intervention</td>
<td>Study Design</td>
<td>Study Population</td>
<td>Inclusion/Exclusion Criteria</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>-----------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>------------------------------</td>
</tr>
<tr>
<td>May and Schaitkin 1995</td>
<td>Shadyside Sinus Surgery Center, Pittsburgh, Pennsylvania, USA</td>
<td><strong>Endoscopic Modified Lothrop Procedure</strong>&lt;br&gt;Preoperative Evaluation: Axial and coronal computed tomography scans&lt;br&gt;Anaesthesia: Not stated&lt;br&gt;Surgical Access: Intranasal&lt;br&gt;Surgical Equipment: 30° endoscope&lt;br&gt;Surgical Strategy: The opening from the frontal sinus into the nose was enlarged maximally by removing the intersinus septum, nasofrontal process (beak) and bone of the anterior floor of the frontal sinus from one orbit to the other.&lt;br&gt;Stents: Thin Silastic spacer was placed between the nasal septum and lateral wall, extending into the nasofrontal recess, for 7-10 days postoperatively.&lt;br&gt;Medication: Antibiotics&lt;br&gt;Postoperative Treatment: Prophylactic antibiotic treatment for 7-10 days postoperatively.</td>
<td>Retrospective case series&lt;br&gt;Level of Evidence: IV&lt;br&gt;Eligibility Rate for EMLP: Not applicable&lt;br&gt;Follow-Up: Range 6 months to 4 years&lt;br&gt;Lost to follow-up: 0%&lt;br&gt;Study Period: 07/87-10/94&lt;br&gt;Operator Details: Not stated</td>
<td>Sample Size: n = 6&lt;br&gt;Patient Diagnosis: Nasofrontal recess and frontal sinus inflammatory disease&lt;br&gt;Previous Sinus Surgery: Not stated&lt;br&gt;Mean Age: Not stated&lt;br&gt;Gender Mix: Not stated&lt;br&gt;Patient Comorbidities: Not stated&lt;br&gt;Patient Details: Not stated</td>
<td>Not stated</td>
</tr>
<tr>
<td>Authors</td>
<td>Location</td>
<td>Intervention</td>
<td>Study Design</td>
<td>Study Population</td>
<td>Inclusion/Exclusion Criteria</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
<td>-------------------------</td>
<td>-------------------------</td>
<td>-----------------------------</td>
</tr>
</tbody>
</table>
Preoperative Evaluation: Complete endoscopic evaluation and coronal plane computed tomography scan  
**Anaesthesia:** General with local anaesthesia (lidocaine and epinephrine) injected bilaterally in the septum, agger nasi, middle turbinate remnant and the greater palatine foramina  
**Surgical Access:** Intranasal with limited external incision  
**Surgical Equipment:** Ophthalmic crescent knife, through-cutting forward and backward endoscopic forceps, variable speed microtron drill, 3-8 mm cutting and diamond burrs  
**Surgical Strategy:** A Killian type septal mucosal incision was made just anterior to the nasal valve region. Bilateral inferior and left anterior tunnels were created by sub-perichondrial dissection. The bony cartilaginous junction was then fractured and the septum mobilised away from the maxillary crest. A septal perforation was then created below the frontal sinus. The frontal sinus opening was then enlarged intranasally by drilling anteriorly and laterally to include the natural ostium. The inferior aspect of the intersinus septum was then resected. The septal dislocation performed earlier was then corrected and the septal incision was sutured.  
**Stents:** Not stated  
**Medication:** Maximal medical therapy continued postoperatively – type not stated.  
**Postoperative Treatment:** Debridement of blood and fibrin clots from the operative cavity on postoperative Day 1, and then weekly for approximately 6 weeks.  
**Sample Size:** n = 20  
**Level of Evidence:** IV  
**Eligibility Rate for EMLP:** Not applicable  
**Mean Follow-Up:**  
Endoscopic examination (n=20) – 16 months (range 4 to 31 months);  
Phone survey (n=19) – 12 months (range 1 month to 2 years)  
**Lost to follow-up:** 5.0% (reasons were clearly stated)  
**Study Period:** 03/95-01/97  
**Operator Details:** Not stated |  
|                  |                                                                          | Retrospective case series  
**Patient Diagnosis:**  
Stenosis of the frontal recess following previous surgery for chronic frontal sinusitis – 85%;  
Refractory pansinusitis – 5%;  
Frontal sinus mucocele – 10%  
**Previous Sinus Surgery:**  
Endoscopic frontal sinusotomy – 85%; OPF procedure – 5%  
**Mean Age:** 41 yrs (range 26-54)  
**Gender Mix:** M/F = 15/5  
**Patient Comorbidities:** Not stated  
**Patient Details:** History of naso-facial trauma – 10% |
<table>
<thead>
<tr>
<th>Authors</th>
<th>Location</th>
<th>Intervention</th>
<th>Study Design</th>
<th>Study Population</th>
</tr>
</thead>
</table>
| Metson and Gliklich 1998 | Department of Otology and Laryngology, Harvard Medical School, Boston, Massachusetts, USA | **Endoscopic Modified Lothrop Procedure**<br>Preoperative Evaluation: Nasal endoscopy plus coronal and axial computed tomography scans of the sinuses<br>Anaesthesia: General<br>Surgical Access: Intranasal<br>Surgical Equipment: 30° endoscope, medium-cutting burr on a long handled drill<br>Surgical Strategy: The frontal ostium was located and then the frontal recess was opened by removing bone anterior to the ostium. The anterior portion of the middle turbinate and any agger nasi cells were cleared. The ostium was then enlarged by bone removal along its anterior rim, which was continued in a lateral direction toward the orbit. The intersinus septum was then drilled and the contralateral sinus opened through a trans-septal approach. A 2 cm perforation in the superior septum was then created at the point where it attaches to the floor of the frontal sinus. The inferior aspect of the intersinus septum was then removed together with the bony floor of the contralateral frontal sinus.<br>Stents: Not stated<br>Medication: Patients were placed on three weeks of antibiotic therapy prior to computed tomography scans<br>Postoperative Treatment: Crust removal was required for EMLP patients on a weekly basis up to one month postoperatively. | Prospective/retrospective case series (EMLP patients were retrospectively analysed)<br>Level of Evidence: IV<br>Eligibility Rate for EMLP: Not applicable<br>Mean Follow-Up: 22.7 months (range 12-32 months)<br>Lost to follow-up: 0%<br>Study Period: 03/95-11/96 | Sample Size: Study group was derived from an original pool of 24 patients – some preoperative measurements are only available for this original patient pool; n = 9 underwent EMLP<br>Patient Diagnosis: Isolated frontal sinus mucocele – 17%; Frontal sinus opacification – 62%; Air-fluid level – 21%<br>Previous Sinus Surgery: 83.3%<br>Mean Age: 42.7 yrs (range 14-73)<br>Gender Mix: M/F = 6/18<br>Patient Comorbidities: Not stated<br>Patient Details: Not stated | Inclusion/Exclusion Criteria: Not stated
Appendix C.3: Safety Results for Endoscopic Modified Lothrop Procedure – Comparative Studies

<table>
<thead>
<tr>
<th></th>
<th>Gross et al. [38] (Level III-2/III-3)</th>
<th>Ulualpet al. [27] (Level III-2/III-3)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EMLP n = 20</td>
<td>OPF n = 21</td>
</tr>
<tr>
<td>Perioperative Outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average blood loss (mL)</td>
<td>112 [78.2] (n = 10)</td>
<td></td>
</tr>
<tr>
<td>Transfusion required</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>CSF leak</td>
<td>0%</td>
<td>6.7%</td>
</tr>
<tr>
<td>Postoperative Outcomes</td>
<td>Mean FU = 12 months</td>
<td>FU = 0.5 to 12 yrs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FU = 0.5 to 2.5 yrs</td>
</tr>
<tr>
<td>Meningitis</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Visual loss</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Transient visual disturbances</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Decreased forehead sensation</td>
<td>14.3%</td>
<td></td>
</tr>
<tr>
<td>Fat graft loss due to infection</td>
<td>4.8%</td>
<td></td>
</tr>
</tbody>
</table>

[] = standard deviation
### Appendix C.4: Efficacy Results for Endoscopic Modified Lothrop Procedure – Comparative Studies

<table>
<thead>
<tr>
<th></th>
<th>Gross et al.³⁸ (Level III-2/III-3)</th>
<th>Ulualpet et al.²⁷ (Level III-2/III-3)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OPF  n = 7</td>
<td>EMLP  n = 20</td>
</tr>
<tr>
<td></td>
<td>Range 1-2 days (n=7)</td>
<td></td>
</tr>
<tr>
<td>Mean length of hospital stay (days)</td>
<td>3.7 (range 2-6)</td>
<td></td>
</tr>
<tr>
<td>Outpatient procedure</td>
<td>65%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Postoperative Outcomes</strong></td>
<td>Mean FU = 12 months</td>
<td>FU = 0.5 to 12 yrs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FU = 0.5 to 2.5 yrs</td>
</tr>
<tr>
<td>Nasofrontal opening patency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal patency</td>
<td>70%</td>
<td>86.7%</td>
</tr>
<tr>
<td>Patent but with some mucosal oedema</td>
<td>25%*</td>
<td></td>
</tr>
<tr>
<td>Stenotic with or without mucosal oedema</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Subjective symptom resolution</td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>Significant</td>
<td>70%</td>
<td></td>
</tr>
<tr>
<td>Intermittent frontal pain or purulent discharge</td>
<td>30%</td>
<td></td>
</tr>
<tr>
<td>Recurrent disease</td>
<td>0%</td>
<td>13.3%</td>
</tr>
<tr>
<td>Revision surgery with OPF procedure</td>
<td></td>
<td>13.3%</td>
</tr>
</tbody>
</table>

*One patient had sarcoidosis with intranasal involvement
## Appendix C.5: Safety Results for the Endoscopic Modified Lothrop Procedure – Case Series Studies

<table>
<thead>
<tr>
<th></th>
<th>Casiano &amp; Livingston&lt;sup&gt;39&lt;/sup&gt;</th>
<th>Close &lt;i&gt;et al.&lt;/i&gt;&lt;sup&gt;40&lt;/sup&gt;</th>
<th>Kikawada &lt;i&gt;et al.&lt;/i&gt;&lt;sup&gt;41&lt;/sup&gt;</th>
<th>Loehrl &lt;i&gt;et al.&lt;/i&gt;&lt;sup&gt;42&lt;/sup&gt;</th>
<th>McLaughlin &lt;i&gt;et al.&lt;/i&gt;&lt;sup&gt;43&lt;/sup&gt;</th>
<th>Metson &amp; Gliklich&lt;sup&gt;44&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Perioperative Outcomes</strong></td>
<td>EMLP n = 21</td>
<td>EMLP n = 9</td>
<td>EMLP n = 13&lt;sup&gt;39&lt;/sup&gt;</td>
<td>EMLP n = 5</td>
<td>EMLP n = 20</td>
<td>EMLP n = 9</td>
</tr>
<tr>
<td>Intraoperative complications</td>
<td></td>
<td></td>
<td></td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>CSF leak</td>
<td></td>
<td>11.1%</td>
<td></td>
<td></td>
<td></td>
<td>10%</td>
</tr>
<tr>
<td><strong>Postoperative Outcomes</strong></td>
<td>Mean FU = 6.5 months</td>
<td>Mean FU = 5.8 months</td>
<td>Mean FU = 24.3 months</td>
<td>Mean FU = 11.9 months</td>
<td>Mean FU = 12 months</td>
<td>Mean FU = 22.7 months</td>
</tr>
<tr>
<td>Major or permanent complications</td>
<td></td>
<td></td>
<td></td>
<td>0%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Minor complications</td>
<td></td>
<td></td>
<td></td>
<td>0%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Intracranial complication</td>
<td></td>
<td></td>
<td></td>
<td>0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intraorbital complication</td>
<td></td>
<td></td>
<td></td>
<td>0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soft tissue ecchymosis</td>
<td></td>
<td></td>
<td></td>
<td>0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epistaxis</td>
<td></td>
<td></td>
<td></td>
<td>0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intranasal adhesions</td>
<td></td>
<td></td>
<td></td>
<td>0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iatrogenic septal perforation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5%</td>
</tr>
</tbody>
</table>

<sup>*</sup>One patient was a redo following a failed Draf Type II procedure nine months previously.
Appendix C.6: Efficacy Results for the Endoscopic Modified Lothrop Procedure – Case Series Studies

<table>
<thead>
<tr>
<th>Perioperative Outcomes</th>
<th>Casiano &amp; Livingston&lt;sup&gt;39&lt;/sup&gt;</th>
<th>Close et al.&lt;sup&gt;40&lt;/sup&gt;</th>
<th>Kikawada et al.&lt;sup&gt;41&lt;/sup&gt;</th>
<th>Loehrl et al.&lt;sup&gt;42&lt;/sup&gt;</th>
<th>May &amp; Schaitkin&lt;sup&gt;43&lt;/sup&gt;</th>
<th>McLaughlin et al.&lt;sup&gt;44&lt;/sup&gt;</th>
<th>Metson &amp; Gliklich&lt;sup&gt;45&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean operative time (hours)</td>
<td>EMLP n = 21</td>
<td>EMLP n = 9</td>
<td>EMLP n = 13</td>
<td>EMLP n = 5</td>
<td>EMLP n = 6</td>
<td>EMLP n = 19</td>
<td>EMLP n = 9</td>
</tr>
<tr>
<td>Discharge = 24 hours</td>
<td>2.2 (range 1.0-3.3)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outpatient procedure</td>
<td>100%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conversion to an external procedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0% (n=20)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Postoperative Outcomes</th>
<th>Mean FU = 6.5 months</th>
<th>Mean FU = 5.8 months</th>
<th>Mean FU = 24.3 months</th>
<th>Mean FU = 11.9 months</th>
<th>FU Range = 6-48 months</th>
<th>Mean FU = 12 months</th>
<th>Mean FU = 22.7 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasofrontal opening patency</td>
<td>Normal patency 33%</td>
<td>100% (n=7)</td>
<td>100%</td>
<td>66.7%</td>
<td>95%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patent but with some mucosal oedema 24%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stenotic with or without mucosal oedema 33%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Complete closure with or without oedema 10%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Development of a frontal sinus polyp</td>
<td>14.3% (n=7)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regeneration of intersinus septum</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15.4%</td>
</tr>
<tr>
<td>Numbness or tingling in nose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>36.8% Mean FU = 16 months</td>
</tr>
<tr>
<td>Episode(s) of peri-orbital headaches or frontal sinus pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>55%</td>
</tr>
<tr>
<td>Recurrent disease</td>
<td>14.3% (n=7)&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>20%&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Revision surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMLP</td>
<td>0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0% 0%</td>
</tr>
<tr>
<td>OPF</td>
<td>4.8%</td>
<td>4.8%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>20%&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

| Subjective Quality of Life Outcomes | Mean FU = 6.5 months | | | | | | Mean FU = 16 months |
|-------------------------------------|----------------------|------------------------------|-----------------|------------------|-----------------|------------------|
| Improvement in overall quality of life | | | | | | | 73.7% |
| Overall improvement in nasal/sinus symptoms | | | | | | | 89.5% |
| Overall reduction in medication requirements | | | | | | | 66.7% (n=18) |
| Resolution or significant decrease forehead pain | | | | | | | 70.6% (n=17) |

*resolved with endoscopic irrigation and oral antibiotics;<sup>a</sup> Patient had as pirin triad disease. In addition, two patients were listed as having recurrent disease following EMLP in a table but in the text of the article this was only one patient. For the purposes of this review, the text was taken as correct with the assumption that the table was incorrect.
### Appendix C.7: Summary of Obliterative Procedure Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Study Type</th>
<th>Level of Evidence</th>
<th>Intervention</th>
<th>Mean Length of Follow-up</th>
<th>No. of Patients</th>
<th>% Previous Sinus Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alsarraf et al.</td>
<td>1999</td>
<td>Retrospective case series</td>
<td>IV</td>
<td>OPF with obliteration</td>
<td>35 months</td>
<td>23</td>
<td>Not stated</td>
</tr>
<tr>
<td>Casiano &amp; Cooper</td>
<td>1992</td>
<td>Retrospective case series</td>
<td>IV</td>
<td>OPF with fat obliteration</td>
<td>24 months</td>
<td>10</td>
<td>Not stated</td>
</tr>
<tr>
<td>Catalano et al.</td>
<td>1991</td>
<td>Retrospective case series</td>
<td>IV</td>
<td>OPF with fat obliteration</td>
<td>36 months</td>
<td>48</td>
<td>Not stated</td>
</tr>
<tr>
<td>Correa et al.</td>
<td>1999</td>
<td>Retrospective case series</td>
<td>IV</td>
<td>OPF with fat obliteration</td>
<td>19.4 months</td>
<td>38</td>
<td>89.5%</td>
</tr>
<tr>
<td>Lawson &amp; Reino</td>
<td>1996</td>
<td>Prospective case series</td>
<td>IV</td>
<td>OPF with fat obliteration</td>
<td>= 12 months</td>
<td>100</td>
<td>Not stated</td>
</tr>
<tr>
<td>Loevner et al.</td>
<td>1995</td>
<td>Prospective case series</td>
<td>IV</td>
<td>OPF with fat obliteration</td>
<td>Range 9 months to 12 yrs</td>
<td>13</td>
<td>Not stated</td>
</tr>
<tr>
<td>Middleton et al.</td>
<td>1985</td>
<td>Retrospective case series</td>
<td>IV</td>
<td>OPF with osteoneogenic obliteration</td>
<td>Range 1-10 yrs</td>
<td>21</td>
<td>Not stated</td>
</tr>
</tbody>
</table>
## Appendix C.8: Summary of Obliterative Procedure Safety Data

<table>
<thead>
<tr>
<th>Data Extracted From Study Papers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Perioperative Outcomes</strong></td>
</tr>
<tr>
<td>Mean blood loss (mL)</td>
</tr>
<tr>
<td><strong>Postoperative Outcomes</strong></td>
</tr>
<tr>
<td>Scalp haematoma</td>
</tr>
<tr>
<td>Complications at the fat donor site</td>
</tr>
<tr>
<td>Embossment</td>
</tr>
</tbody>
</table>

*It was not clear if all of the patients were operated on for chronic frontal sinusitis

## Appendix C.9: Summary of Obliterative Procedure Efficacy Data

<table>
<thead>
<tr>
<th>Data Extracted From Study Papers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Perioperative Outcomes</strong></td>
</tr>
<tr>
<td>Mean length of hospital stay (days)</td>
</tr>
<tr>
<td>Mean operative time (hours)</td>
</tr>
<tr>
<td><strong>Postoperative Outcomes</strong></td>
</tr>
</tbody>
</table>
| Resolution of frontal sinus disease | 97% (n=38)³⁴  
|                                 | 95.2% (n=21)²⁵  
|                                 | 100% (n=10)⁴⁸ |
| Disease recurrence               | 8.3% (n=48)⁴⁷  
|                                 | 4.8% (n=21)²⁵ |
| Further surgery required         | 8.3% (n=48)⁴⁷  
|                                 | 7.9% (n=38)³⁴  
|                                 | 4.8% (n=21)²⁵  
|                                 | 34.8% (n=23)⁵⁰ |
| Frontal headache                 | 23.1% (n=13)⁵¹ |
| Brow pain                        | 7.7% (n=13)⁵¹ |
| Orbital pain                     | 7.7% (n=13)⁵¹ |
| Forehead swelling                | 7.7% (n=13)⁵¹ |
| Cosmetic deformity               | 4.8% (n=21)²⁵ |
| **Quality of Life Indicators**   |
| Patient satisfaction (CSS survey) | 65.2% (n=23)⁵⁰ |
| Decreased clinic visits          | 65.2% (n=23)⁵⁰ |
| Decreased medication use         | 69.6% (n=23)⁵⁰ |