

I am also delighted to express my deep gratitude and thanks to all my dear professors and colleagues who helped me through this work.

Evaluation of Tympanoplasty using Alloderm versus local tissue Grafts

Thesis

Submitted for partial fulfillment of MD degree

in

Otorhinolaryngology

By

Mohamed Mahmoud Ibrahim ElSheikh

M.B.B.Ch, M.Sc

Supervised by

Professor Dr. Hussein Mohamed Helmy

Professor of Otorhinolaryngology

Faculty of medicine

Ain Shams University

Professor Dr. Hisham Salah Eldin ElHalaby

Professor of Otorhinolaryngology

Faculty of medicine

Ain Shams University

Dr. Osama Yehia Dessouky
Lecturer of Otorhinolaryngology
Faculty of medicine
Ain Shams University

Faculty of medicine
Ain Shams University
٢٠١٠

Acknowledgment

First and Above all, all thanks to Allah the merciful, the compassionate whom without his help, I could not finish this work.

I would like to thank Prof Dr. Hussein Mohamed Helmy Professor of Otorhinolaryngology, Faculty of Medicine, Ain Shams University, for his continuous encouragement and sincere advice which have been the main factors to complete this work.

Words stand short to express my respect and thanks to Prof. Dr. Hisham Salah El Din ElHalaby Professor of Otorhinolaryngology, Faculty of Medicine, Ain Shams University, for his great support and help to complete this work.

I wish to introduce my deep respect and thanks to Dr. Osama Yehia Dessouky Lecturer of Otorhinolaryngology, Faculty of Medicine, Ain Shams University, for his Kindness and Cooperation in all steps of this work.

I would also like to express my deepest prayers and cordial thanks for Late Prof. Dr. Mahmoud Ibrahim ElSheikh, Professor of Otorhinolaryngology, Faculty of Medicine, Ain Shams University, for his continuous encouragement and sincere advice and his support and parental guidance throughout my life. May god rest his soul.

List of Contents

<i>Title</i>	<i>Page No.</i>
• Introduction.....	١
• Aim of the work	٥
• Anatomy and Physiology of the ear	٦
• Chronic Suppurative Otitis Media	١٦
• Chronic Suppurative Otitis Media with Cholesteatoma	٣١
• Complications of Otitis Media	٤٦
• Key points in Operative Management of Otitis Media	٥٨
• Alloderm Regenerative Tissue Matirix.....	٧١
• Patients and Methods.....	٧٦
• Results.....	٩٠
• Discussion	١١٧
• Summary and Recommendations.....	١٢٧

Aim of the Work

- References ١٣٦
- Arabic Summary _____

List of Tables

Table No and Title	Page
Table (١): Varieties of grafting materials.....	٢
Table (٢): Classification of Otitis Media.....	١٧
Table (٣) Overview of Surgical Procedures for Cholesteatoma.....	٤٥
Table (٤) Comparison between both groups as regard epidemiological data.....	٩١
Table (٥) Comparison between both groups as regard compliant.....	٩٣
Table (٦) Comparison between both groups as regard history of present illness.....	٩٧
Table (٧) Comparison between both groups as regard past history.....	١٠٠
Table (٨) Comparison between both groups as regard examination.....	١٠٢

Table (٩) illustration of the different operative interventions applied for the safe CSOM group and unsafe CSOM group as showing the laterality of the operations.....	١٠٦
Table (١٠) Comparison between preoperative and postoperative audiological outcomes in each type of operative intervention applied on the operated side.....	١١٠
Table (١١) shows a comparison made between each operative intervention compared to other operative interventions in the safe CSOM group and unsafe CSOM group respectively as regards their preoperative and postoperative audiological outcomes on the operated side as follows.....	١١٢, ١١٣
Table (١٢) comparison as regards the final outcome postoperatively in each group of intervention between the failed and succeeded cases.....	... ١١٥

List of Figures

Figure No. and title	Page No.
Figure (١) Anatomy of the ear	١١
Figure (٢) Cochlea	٩
Figure (٣) Tympanic membrane	١١
Figure(٤) Formation of primary acquired cholesteatoma in the pars flaccida portion of the tympanic membrane.....	٣٢
Figure (٥) Photograph of primary acquired cholesteatoma in the pars flaccida portion of the left tympanic membrane. The arrowhead points to retraction. The arrow points to the cholesteatoma sac behind the tympanic membrane.....	٣٧
Figure (٦) Coronal CT scan of the left temporal bone, showing pars flaccida cholesteatoma.	٣٩
Figure (٧) Diagram showing the anatomy of the posterior mesotympanum.	٦٠
Figure (٨) Diagram of the exposure obtained during a canal wall up mastoidectomy of the right ear.....	٦٢
Figure (٩) showing a bar graph representation of the laterality distribution comparisons between the safe CSOM and Unsafe CSOM groups.....	٩٤
Figure (١٠) shows a bar graph representation of the presence of tinnitus among the safe and unsafe groups	٩٤
Figure (١١) shows a bar graph representation of the response to medical local treatment among safe CSOM and unsafe CSOM	٩٨
Figure (١٢) shows a bar chart data representation of deafness severity among safe CSOM and unsafe CSOM groups.....	٩٨
Figure (١٣) shows a bar graph illustration of the right tympanic membrane status in the safe CSOM group and unsafe CSOM group (in cases of right CSOM or right side in bilateral CSOM).....	١٠٣
Figure (١٤) shows a bar graph illustration of the left tympanic membrane status in the safe CSOM group and unsafe CSOM group (in cases of left CSOM or left side in bilateral CSOM).....	١٠٤

Aim of the Work

- Figure (١٥) shows a bar graph comparison between each operative intervention compared to other operative interventions as regards their preoperative and postoperative audiological outcomes on the operated side..... ١١٤
- Figure (١٦) shows a bar graph illustration of the final outcome in each operative intervention ١١٦



INTRODUCTION AND AIM OF THE WORK

Introduction

Tympanic membrane perforations are a commonly encountered disorder by the otorhinolaryngologist. Since first described in 1848, a host of materials have been used for tympanic membrane grafting. (*Glasscock and Kanok, 1991*)

The most common etiology for a tympanic membrane perforation is infection, trauma, or an extruded pressure equalizing tube. Tympanic membrane perforations may be acute perforations or chronic perforations. Most acute perforations heal spontaneously but approximately 10-20% will become chronic. (*Downey et al, 2007*)

Although the tympanic membrane has demonstrated a remarkable ability for regeneration and spontaneous healing, chronic perforations do commonly occur and may require grafting as a means of repair. (*Kristenson, 1992*)

There are several major reasons why the complete closure of a chronic tympanic membrane perforation is desirable. With a closed tympanic membrane perforation, patients experience a dramatic improvement in hearing, avoid the occurrence of otitis media and tolerate water in the ear canal. In addition, with complete closure of the

defect, recurrent otorrhea is unlikely to occur with upper respiratory tract infections and otitis media. (*Laidlaw et al, ۲۰۰۱*)

A variety of autografts, allografts, xenografts and alloplasts have been described in the surgical closure of tympanic membrane perforation: (as shown in table ۱)

Autografts	Allografts	Xenografts	Alloplasts
Temporalis fascia	Tympanic membrane	Bovine periositium	Polygalactin
Tragal perichondrium	Dura	Bovine Vein	Gel foam
Fascia lata		Porcine skin	Polyvinyl alcohol
Periositium		Porcine dura	Polylactic acid
Vein			Collagen
Fat			Polyactive copolymer
Skin			

Table (۱): Varieties of grafting materials

Temporalis fascia has been the most popular and the standard to which all other materials are compared with today. (*Downey et al, 2002*)

In revision procedures the availability of suitable fascia or perichondrium may be limited. In patients who have undergone several grafting attempts, there may be no suitable grafting material at all in the vicinity of the operative field. Finding autogenous tissue for grafting may be time consuming and may add morbidity in the form of a remote donor site. (*Benecke, 2001*)

Alloderm®, an acellular human dermal matrix, is a new biomaterial that serves as a connective tissue matrix, providing soft tissue support and coverage that becomes integrated into the implanted bed. (*Kridel et al, 1994*)

Alloderm® is processed from human donor skin obtained from an approved tissue bank. Donors are screened for HIV type 1 and 2 viruses, T lymphotropic virus type 1, hepatitis B and C viruses and syphilis. (*Harpar and Livesey, 1994*)

In addition to the safety margin generated through donor screening and serological testing guidelines, the processing of Alloderm increases this safety margin in two ways; all the cells within the dermal tissue are solubilised, leaving no potential reservoir for viral replication, furthermore, this detergent decellularization step has

been shown to actually inactivate viruses even high titers of HIV. (*Jones et al, 1997*)

Removal of cellular components of the skin, the target of the rejection process, reduces the chances of an immune response in the recipient. (*Jones et al. 1997*)

Special freezing and drying techniques preserves the integrity of the matrix protein of the alloderm graft. (*Youssef, 1999*)

Alloderm has been successfully used as a soft tissue graft for various cosmetic and reconstructive surgeries. (*Wainwright, 1997*)

Aim of the work

The aim of this work is to:

- Study the hypothesis of using Alloderm as a substitute to local tissue grafts routinely harvested for tympanoplasty like temporalis fascia graft or tragal cartilage.
- Compare take rate and closure of tympanic membrane perforations when using Alloderm compared with local tissue grafts
- Compare the post operative sequels when using Alloderm in modified radical mastoidectomies compared with temporalis fascia graft when lining the mastoid cavity
- Analyze hearing outcome and audiological gain when using Alloderm compared with local tissue grafts.

Anatomy and physiology of the ear

The ears are paired sensory organs comprising the auditory system involved in the detection of sound, and the vestibular system involved with maintaining body balance/equilibrium. The ear divides anatomically and functionally into three regions: the external ear, the middle ear, and the inner ear. All three regions are involved in hearing. Only the inner ear functions in the vestibular system. (Lee, 2004)

Anatomy of the ear

The external ear (*pinna*) serves to protect the tympanic membrane, as well as to collect and direct sound waves through the external auditory meatus to the tympanic membrane. About 26 mm long, the canal contains modified sweat glands that secrete *cerumen*. (Figure 1) (Moore et al, 1999)