"Evaluation of Extracapsular Excision in the Management of Benign Parotid Tumors"

A dissertation submitted to the M.G.R. Medical University, Tamil Nadu: in partial fulfillment of the requirement for the M.S. Branch I (General Surgery) examination held in April 2014.

Certificate

This is to certify that the dissertation entitled "***Evaluation of Extracapsular Excision in the Management of Benign Parotid Tumors***" is a bonafide work done by Dr. Aditya Benjamin, post graduate resident in Masters of General Surgery 2011-2014 at the Christian Medical College, Vellore, towards partial fulfillment for the MS General Surgery Branch I final examination held in April 2014.

Signature:

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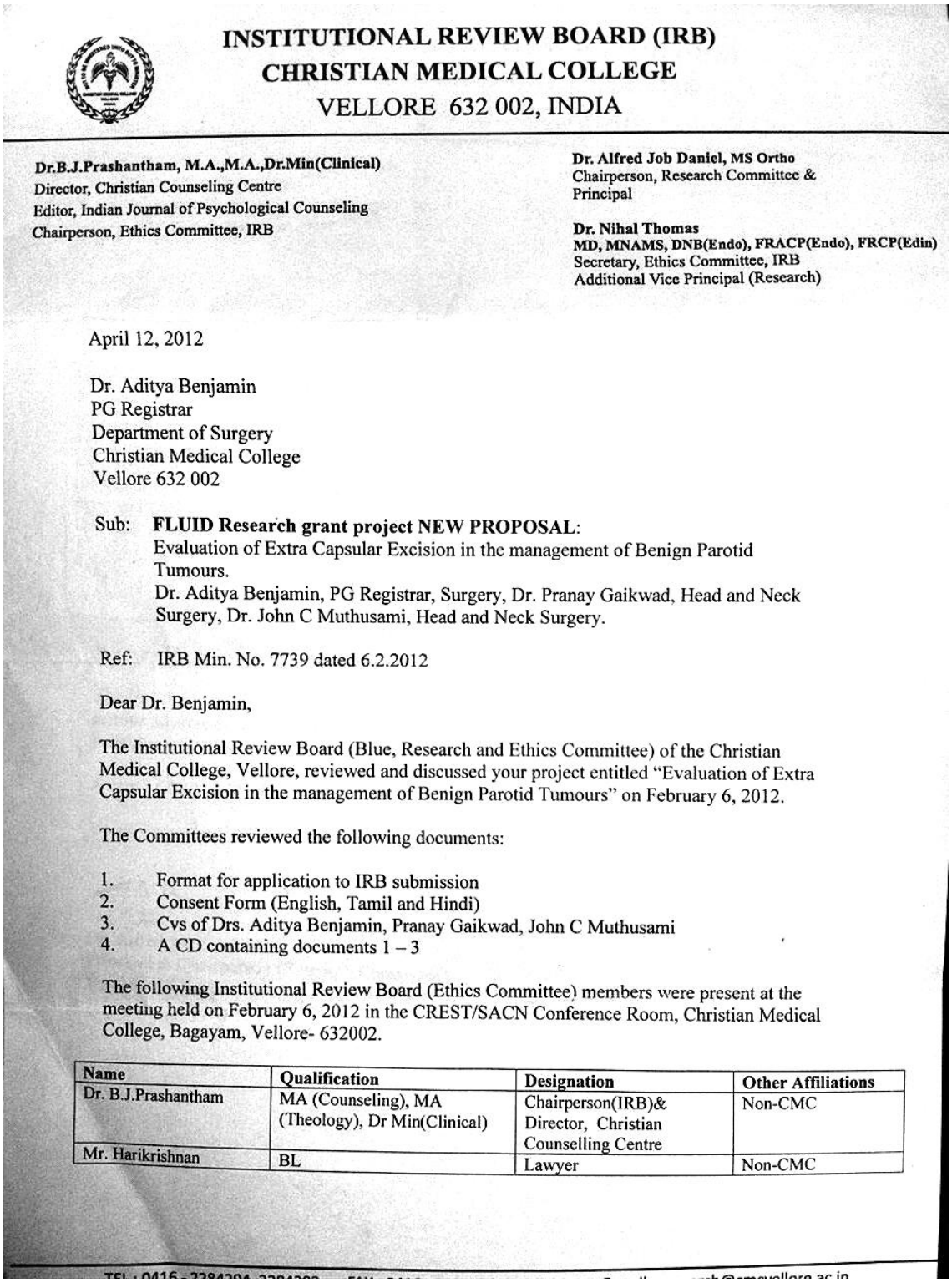

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April 12, 2012

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Sub: **FLUID Research grant project NEW PROPOSAL**:
Evaluation of Extra Capsular Excision in the management of Benign Parotid Tumours.
Dr. Aditya Benjamin, PG Registrar, Surgery, Dr. Pranay Gaikwad, Head and Neck Surgery, Dr. John C Muthusami, Head and Neck Surgery.

Ref: IRB Min. No. 7739 dated 6.2.2012

Dear Dr. Benjamin,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Evaluation of Extra Capsular Excision in the management of Benign Parotid Tumours" on February 6, 2012.

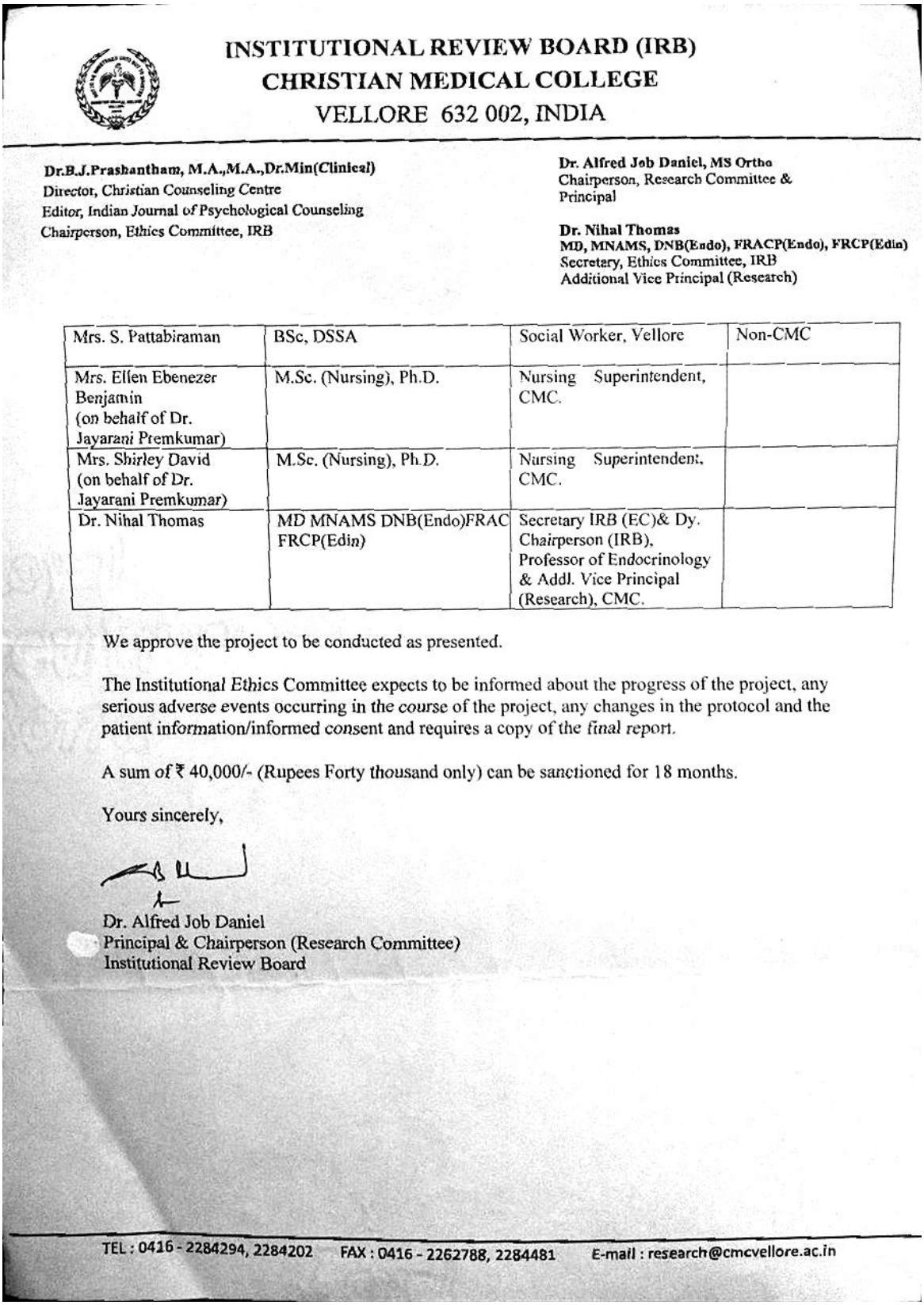
The Committees reviewed the following documents:

1. Format for application to IRB submission
2. Consent Form (English, Tamil and Hindi)
3. Cvs of Drs. Aditya Benjamin, Pranay Gaikwad, John C Muthusami
4. A CD containing documents 1 – 3

The following Institutional Review Board (Ethics Committee) members were present at the meeting held on February 6, 2012 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore- 632002.

Name	Qualification	Designation	Other Affiliations
Dr. B.J.Prashantham	MA (Counseling), MA (Theology), Dr Min(Clinical)	Chairperson(IRB)& Director, Christian Counselling Centre	Non-CMC
Mr. Harikrishnan	BL	Lawyer	Non-CMC

Figure 1: Institutional Review Board and Ethics Committee acceptance letter(Part 1)



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Mrs. S. Pattabiraman	BSc, DSSA	Social Worker, Vellore	Non-CMC
Mrs. Ellen Ebenezer Benjamin (on behalf of Dr. Jayarani Premkumar)	M.Sc. (Nursing), Ph.D.	Nursing Superintendent, CMC.	
Mrs. Shirley David (on behalf of Dr. Jayarani Premkumar)	M.Sc. (Nursing), Ph.D.	Nursing Superintendent, CMC.	
Dr. Nihal Thomas	MD MNAMS DNB(Endo)FRAC FRCP(Edin)	Secretary IRB (EC)& Dy. Chairperson (IRB), Professor of Endocrinology & Addl. Vice Principal (Research), CMC.	

We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any serious adverse events occurring in the course of the project, any changes in the protocol and the patient information/informed consent and requires a copy of the final report.

A sum of ₹ 40,000/- (Rupees Forty thousand only) can be sanctioned for 18 months.

Yours sincerely,

Dr. Alfred Job Daniel
Principal & Chairperson (Research Committee)
Institutional Review Board

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Figure 2: Institutional Review Board and Ethics Committee acceptance letter (Part 2)

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ABSTRACT

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TITLE OF THE ABSTRACT:

Evaluation of Extracapsular excision in the management of benign parotid tumors

DEPARTMENT:	General Surgery Unit I, CMC Vellore
NAME OF THE CANDIDATE:	Aditya Benjamin
DEGREE AND SUBJECT	MS (General Surgery)
NAME OF THE GUIDE:	Dr. Pranay Gaikwad

OBJECTIVE

To study the incidence of facial nerve palsy post operatively in patients undergoing surgical treatment of benign parotid tumors

METHODS

This was a prospective, randomized interventional study wherein 36 patients with benign parotid tumors were included and randomized into two groups: Superficial Parotidectomy and Extracapsular Excision. Post operatively, the facial nerve function was assessed by the House-Brackmann Score on post operative days 2, 7 and 10 and compared between the two groups.

RESULTS

Post operatively, there was no significant difference between the two operations with regard to facial nerve palsy.

INTRODUCTION

INTRODUCTION

The current standard of treating benign parotid tumors is by means of 'Superficial Parotidectomy', which entails removal of the entire superficial parotid gland with exposure of the facial nerve branches. This leads to increased incidence of facial nerve palsy which is a debilitating condition to the patient. Newer research is aimed at more conservative approaches towards parotidectomy by selective and meticulous excision of the lesion to prevent the aforementioned complication and to effectively remove the tumour with only a little but adequate margin of normal tissue, without compromising onco-surgical principles. In this research, we aim to observe the complications of an alternative procedure called 'extracapsular excision' in treating benign parotid tumors as compared to superficial parotidectomy. In this way, we attempted to evaluate whether extracapsular excision provides additional benefit to patients as compared to superficial parotidectomy.

AIM AND OBJECTIVES

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AIM

To assess the early post operative sequelae of extracapsular excision versus the standard superficial parotidectomy in the treatment of benign parotid tumors restricted to the superficial lobe.

OBJECTIVES

1. To compare the incidence of facial nerve palsy between extracapsular excision and superficial parotidectomy in the early post operative period.
2. To compare the positive margins associated with extracapsular excision and superficial parotidectomy.
3. To assess the feasibility of extracapsular excision as a standard procedure in the treatment of benign parotid tumors..

REVIEW OF LITERATURE

REVIEW OF LITERATURE

ANATOMY OF THE PAROTID GLAND

Salivary glands are divided into major and minor, the major being the paired parotid, submandibular and sublingual glands. The minor glands include numerous small glands which outline the upper aero-digestive tract. (1)

The Parotid gland is the largest of the salivary glands. It overlies the angle of the mandible. It is closely related to the parapharyngeal space medially, the cartilage of the ear canal posteriorly, the zygoma superiorly and the posterior belly of the digastric and sternomastoid muscles inferiorly. (1)

The facial nerve traverses through the parotid gland after it exits the stylomastoid foramen and divides into 5 main branches within the substance of the parotid gland. The pattern of branching is variable. The plane of the facial nerve divides the gland into superficial and deep lobes, with normally 80% of the gland being superficial and the remaining part of the gland being deep to the nerve. (2)

Embryology:

In the 6th to 8th week of development, outpouchings extend from the oral ectoderm into the adjacent mesoderm that serve as the sites for the origin of the major salivary glands. There are three stages of development of the major salivary glands.(3,4)

Stage 1: Development of primordial anlage, and progressive epithelial cleft and bud development that leads to branched duct bud formation.

Stage 2: The first appearance of lobules and duct canalization. Primitive acini lined by myoepithelial cells are formed by 7th month of embryonic life. (5)

Stage3: Maturation of the acini and intercalated ducts and depression of the interstitial tissue.

The parotid gland appears first among the major salivary glands, during the 6th gestational week; the posterior stomodeum elongates laterally to form solid cords which travel across the developing masseter muscle to form ducts, with the

distal ends forming acini. At the same time, a capsule formed by the pre-existing mesenchyme surrounds the gland and associated lymph nodes. (6)

The submandibular gland is represented by small buds around the 6th week. These appear lateral to the tongue at the floor of the mouth to extend posteriorly around the mylohyoid into the submandibular triangle. The sublingual gland develops around the 9th month from multiple endodermal epithelial buds at the floor of the mouth in the paralingual sulcus. The minor salivary glands are represented by tubo-acinar units developed from upper respiratory ectoderm during the 12th intrauterine week. (7)

Gross Anatomy:

The Parotid gland is the largest of all the salivary glands. It is a paired organ, weighing about 15-30 g, and is located in the preauricular region along the posterior surface of the mandible. It is divided into the superficial and deep lobes by the facial nerve. The facial nerve along with the retromandibular vein lies in the fasciovenous plane of Patey. The superficial lobe is described as being lateral to the facial nerve overlying the lateral surface of the masseter, hence is also referred to as the lateral lobe. The deep or the medial lobe lies medially between the mastoid process of the temporal bone and the ramus of the mandible.

Superiorly, the parotid gland is bound by the zygomatic arch. Inferiorly, the tail of the parotid gland extends posteriorly over the superior border of the sternocleidomastoid muscle towards the tip of the mastoid. The deep lobe lies within the parapharyngeal space. (2)

The parotid gland is covered by the parotid fascia, which is a continuation of investing layer of the deep cervical fascia that splits into the superficial and deep laminae to enclose the gland. The parotid fascia itself is dense and inelastic. The superficial lamina of the fascia is thicker and extends from the masseter and the sternocleidomastoid to the zygomatic arch and to the stylomandibular ligament. The stylomandibular ligament is a surgical landmark which also separates the superficial and deep lobes of the parotid. Stylomandibular tenotomy is a useful technique in en-block resection of the deep parotid lobe or other para-pharyngeal tumors.(8) The parotid gland secretes saliva which is more serous than mucous. (1)

Parotid Duct

It exits the parotid gland from its anterior border to travel parallel to the zygomatic bone, about 1cm below it, anterior to the masseter. It takes a sharp turn at the buccinator muscle to pierce it, and enter the oral cavity opposite to the second upper molar tooth.(2)

Facial Nerve

The seventh cranial nerve arises from the pontomedullary junction and courses laterally through the cerebellpontine angle (together with the vestibulocochlear nerve) to the internal auditory meatus. The nerve then passes through the facial canal, passing backwards and downwards to exit through the stylomastoid foramen. It then gives off three motor branches supplying the posterior belly of digastric, stylohyoid and post auricular muscles before entering the parotid gland posteriorly. The main trunk divides into two divisions, *viz.* the temporozygomatic and the cervicofacial divisions. The upper temporozygomatic division forms the temporal zygomatic and upper buccal branches, while the lower cervicofacial division forms the lower buccal, marginal mandibular and cervical branches. There may be communications between branches of both

divisions to form midfacial branches leading to a formation of goose feet or (2)*pes anserius*.

Table 1: Facial Nerve: Branches, course and nerve supply

Branch of Facial Nerve	Course	Muscles supplied
Temporal	Parallel to superficial temporal vessels across Zygoma	Frontal belly of occipitofrontalis, orbicularis oculi, corrugator supercili, anterior and superior auricular muscles
Zygomatic	Over the periosteum of zygomatic arch	Zygomatic, orbital and infraorbital
Buccal	Along Stenson's duct over the masseter	Buccinator, upper lip and nostril muscles
Marginal Mandibular	Inferior border of Parotid	Lower lip and chin muscles
Cervical	Within the deep cervical fascia, under the platysma	Platysma

In surgical practice, it is possible to trace the branches of the facial nerve in the antegrade or in the retrograde fashion. The facial nerve can also be identified by performing a mastoidectomy, at its extracrainal exit point, the stylomastoid foramen. (2,9,10)

Other important nerves in this region include the auriculotemporal nerve (ATN) and the great auricular nerve (GAN).

The ATN is a branch of the mandibular nerve, the posterior division of the Trigeminal (V3). It exits the foramen ovale, runs parallel to the superficial temporal vessels, and travels anterior to the external auditory canal to innervate the skin and the scalp anterior to the ear. (2)

The GAN is a sensory branch from the cervical plexus. It arises mainly from C2 and C3, runs parallel to the external jugular vein along the lateral surface of the SCM to the tail of the parotid, where it divides into anterior and posterior branches. It innervates the posterior aspect of the pinna and the ear lobule. It is commonly sacrificed during parotidectomy, which leads to troublesome sensory loss around the ear lobule. A segment of this may be preserved for facial nerve grafting. (2)

The glossopharyngeal nerve provides visceral sensory innervations to the parotid gland. Preganglionic parasympathetic fibers are carried by the inferior salivary nucleus in the medulla through the jugular foramen. Distal to this ganglion the Jacobsen's nerve, i.e. a small branch of the glossopharyngeal nerve re-enters the skull through the inferior tympanic canaliculus into the middle ear to form the tympanic plexus. The preganglionic fibers then travel along the lesser petrosal nerve into the middle cranial fossa and out of the foramen ovale to synapse at the otic ganglion. Thence the post ganglionic fibers exit the otic ganglion beneath the mandibular nerve to join the auriculotemporal nerve in the infratemporal fossa. These fibers are responsible for the secretion of saliva.

Sympathetic fibers arise from the superior cervical ganglion through the external carotid plexus. Acetylcholine serves as a neurotransmitter for both sympathetic and parasympathetic fibers. For this reason, patients may develop 'gustatory sweating' or Frey's Syndrome following parotidectomy.(11,12) It is commonly manifested as sweating and flushing of the skin over the skin over the parotid region, due to aberrant re-innervation between the autonomic and sympathetic fibers from the residual parotid gland. This can be minimized by

meticulous surgical excision of the parotid, or by developing skin flaps of appropriate thickness, by which exposed apocrine glands are protected from ingrowth and stimulation from the ATN and parasympathetic stimulation during meals.

Arterial Supply

The arterial supply is by the branches of the external carotid artery (ECA) which arises from the carotid bifurcation, travels parallel to the mandible under the posterior belly of the digastric muscle. It then travels medial to the parotid to split into two branches: The superficial temporal artery (STA) and the internal maxillary artery (IMA). The STA travels superiorly from the superior border of the parotid in the pre-tragal region to supply the scalp. It gives off a branch, viz. the transverse facial artery which travels anteriorly between the parotid duct and the Zygoma to supply the parotid, the parotid duct and the masseter. The IMA leaves the parotid in the medial aspect to supply the infratemporal and pterygopalatine fossae. Control of this vessel is crucial during radical parotidectomy, especially when segmental or marginal mandibulectomy is required.

Venous Drainage

Venous drainage is by the retromandibular vein (RMV), which is formed by the union of the maxillary vein and the superficial temporal vein, and drains into the external jugular vein. The RMV travels just below the facial nerve in the faciovenous plane of Patey, thus serving as an operative and non-operative radiological landmark to distinguish the superficial and deep lobes of the parotid. The RMV may give anterior and posterior branches, although this is subject to variation. The anterior branch unites with the posterior facial vein to form the common facial vein. The posterior facial vein lies immediately deep to the marginal mandibular nerve and hence is a landmark to identify the same.(13) The posterior branch may join the post auricular vein above the SCM to join the EJV.

Lymphatic Drainage

Unlike the other salivary glands, the parotid has a high density of lymph nodes within and around the gland. It has two nodal layers which drain into the superficial and deep cervical lymph systems. The majority (about 90%) of the nodes are located in the superficial layer between the glandular tissue and its capsule. The superficial nodes drain the parotid gland, external auditory canal,

pinna, eyelids, lacrimal glands and the scalp, whereas the deep nodes drain the deep lobe, external auditory canal (also), middle ear, nasopharynx and the soft palate. (14)

PHYSIOLOGY

The principal function of the salivary glands is to secrete saliva, which has digestive, lubricative and protective functions in the body.

Secretion

Within the gland, potassium [K^+] concentration is high and sodium [Na^+] concentration is low. With increasing flow rate, [K^+] concentration decreases slightly to level off at a constant value, whereas [Na^+] concentration increases. Chloride concentration predominantly follows [Na^+] concentration. Except at low levels of secretion, bicarbonate [HCO_3^-] secretion in saliva is hypertonic compared to plasma .

Within the duct, [Na^+] and [Cl^-] are reabsorbed, whereas [K^+] and [HCO_3^-] are secreted. At higher flow rates, less time is available for this exchange and hence the concentration is isotonic to plasma. At lower flow rates, [K^+] is higher in

saliva, [Na^+] and [Cl^-] are lower, and [$HCO3^-$] remains hypertonic to plasma. Mostly, however, saliva is hypotonic to plasma since [Na^+] and[Cl^-] reabsorption is greater than secretion of [K^+] and [HCO_3^-].

Saliva also contains the compounds alpha amylase, lingual lipase, lysozymes, glycoprotein, IgA secretory piece and lactoferrin which are detailed below. Also secreted are organic blood group antigens A, B, AB and O. The protein Kallikrein is also secreted by saliva, which converts plasma protein into bradykinin.

Salivary secretion is regulated by both parasympathetic and sympathetic branches, but more by the parasympathetic arm, through the facial and glossopharyngeal nerves. It leads to acinar activation and ductal transport, leading to glandular vasodilatation and myoepithelial cell contraction. Subsequent to AcH stimulation of muscarinic receptors, inositol trisphosphate is formed which causing increased Calcium [Ca^{++}] concentration intracellularly. The source of this [Ca^{++}] is either from intracellular stores or from plasma. Thus, [Ca^{++}] acts as a *second messenger* which controls the volume of salivary secretion. Further secretion is maintained by acetylcholinesterases, which inhibit the breakdown of

Acetylcholine (ACh). Atropine, the muscarinic antagonist, decreases salivation by competing with (ACh) for the salivary receptors.

Sympathetic stimulation is via the superior cervical ganglion. It leads to myoepithelial contraction, similar to parasympathetic stimulation. Changes in blood flow occur which is biphasic. Initial vasoconstriction occurs due to sympathetic stimulation of alpha-adrenergic receptor activation which is followed by vasodilatation due to a buildup of vasodilator metabolites. Nor epinephrine binds to alpha adrenergic receptors to form cAMP (3'5'Cyclic Adenosine Mono-phosphate). This leads to protein phosphorylation and enzyme activation, with increased mucus content in saliva.

Antidiuretic hormone (ADH) and Aldosterone affect salivary secretion by increasing [K^+] concentration and decreasing [Na^+] concentration. However, it does not affect the rate of secretion.

In the unstimulated state, the quantity of saliva secreted amounts to 1 Liter per day. Sixty nine percent is contributed by the submandibular glands, 26% by parotid, and 5% by the sublingual glands. In the stimulated state, however, 2/3rd of the secretion is from the parotid gland. The minor salivary glands produce 7-8% of salivary flow regardless of stimulation.

Stimulants of salivary secretion include the presence of food in the mouth, chewing and nausea. Inhibitors include sleep, dehydration, fear and fatigue.

Role in digestion

Saliva contains Ptyalin, an alpha-amylase which cleaves the internal alpha-1,4-glycosidic bonds of starch to form maltose, maltotriose and alpha-limit dextrins. Its optimal pH is 7, and rapidly degrades at more acidic pH and readily denatures at ph<4. Even so, it remains active to break down up to 75% of the carbohydrate content of a meal within the stomach as effective mixing of the food with saliva takes place in the confines of the stomach. In the absence of Ptyalin, pancreatic amylase breaks down carbohydrates within the small intestine. Additionally, the lingual salivary glands secrete lingual lipase, which break down triglycerides.

Role in Lubrication

The mucus constituent of saliva facilitates lubrication of food during chewing by mixing with saliva. It eases the process of swallowing. It is also important to facilitate speech.

Role in Protection

Saliva has several antibacterial properties. The *secretory piece* i.e. a binding agent (glycoprotein) for IgA forms a complex with IGA which is active against bacteria and viruses. Lysozyme in saliva is antibacterial by causing bacterial agglutination and by activating autolysin which degrades cell walls. Lactoferrin in saliva is an iron chelator which inhibits the growth of bacteria which require iron for survival.(1,7,15)

Other roles

Saliva serves as a protective buffer by diluting harmful substances and lowering temperature of hot food items. It also helps to clear foul tasting substances. In the stomach, it helps to neutralize acid to some extent. Lack of salivation, *Xerostomia*, leads to apthous ulcers, buccal infections and dental caries.

SALIVARY TUMORS

Benign Salivary tumors include pleomorphic adenoma, warthin's tumour, myoepithelioma, monomorphic adenoma, basal cell, oncocytoma, canalicular, sebaceous, ductal, papilloma, intraductal, and inverted sialadenoma papillaferum.(16)

Malignant tumors are less common, and include the following varieties: acinic cell carcinoma, adenoid cystic carcinoma, mucoepidermoid carcinoma, polymorphous low grade adenocarcinoma, epithelial myoepithelial carcinoma, clear cell nos, basal cell carcinoma, sebaceous carcinoma, oncocytic carcinoma, cystadenocarcinoma, salivary duct carcinoma, myoepithelial carcinoma, adenocarcinoma nos, and carcinoma ex pleomorphic adenoma. (16)

Certain soft tissue hemato-lymphoid tumors like hemangioma, hodgkin's lymphoma, diffuse large b cell lymphoma, extra nodal marginal B cell lymphoma are also described. (16)

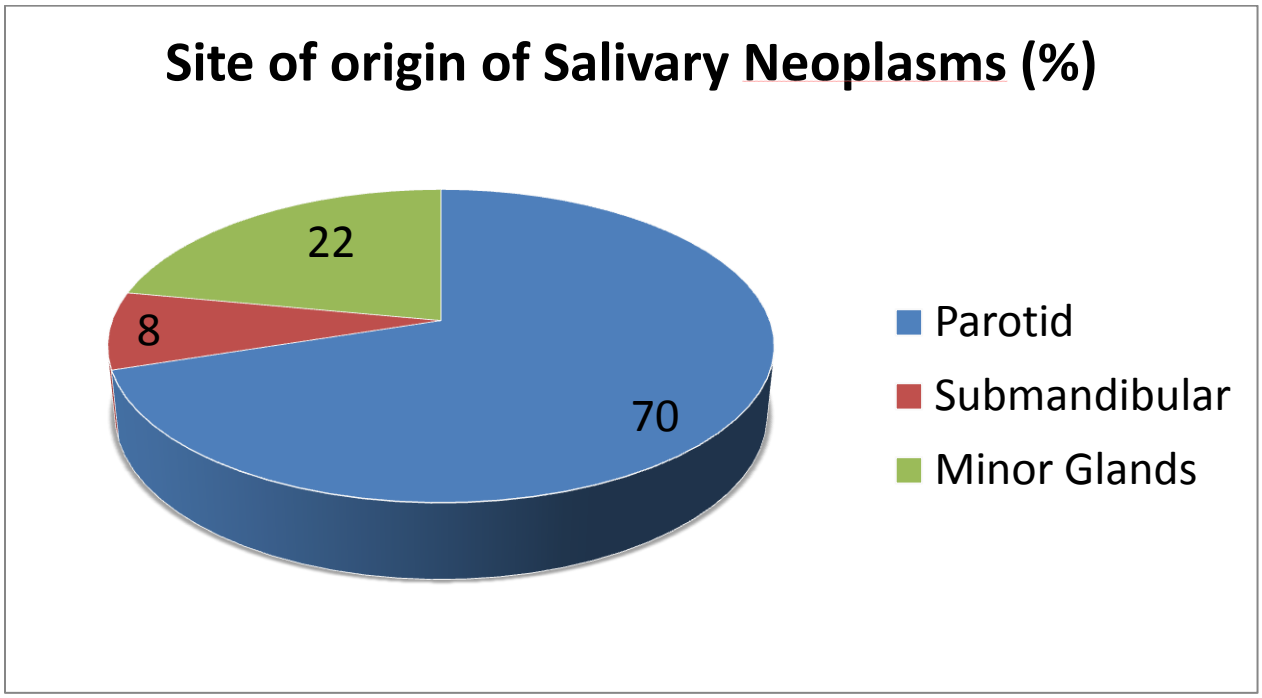


Figure 3: Site of origin of Salivary Neoplasms

General features of Salivary tumors

They primarily occur in older adults, with a female preponderance. the exception is Warthin's tumour (almost exclusively seen in males who are predominantly smokers) and high grade carcinomas. Epithelial tumors form more than 80% of all salivary tumors. Benign tumors are more common, accounting for about 75% of all epithelial tumors.(16)

Generally, smaller the gland, more the chances of malignancy exist. (17)

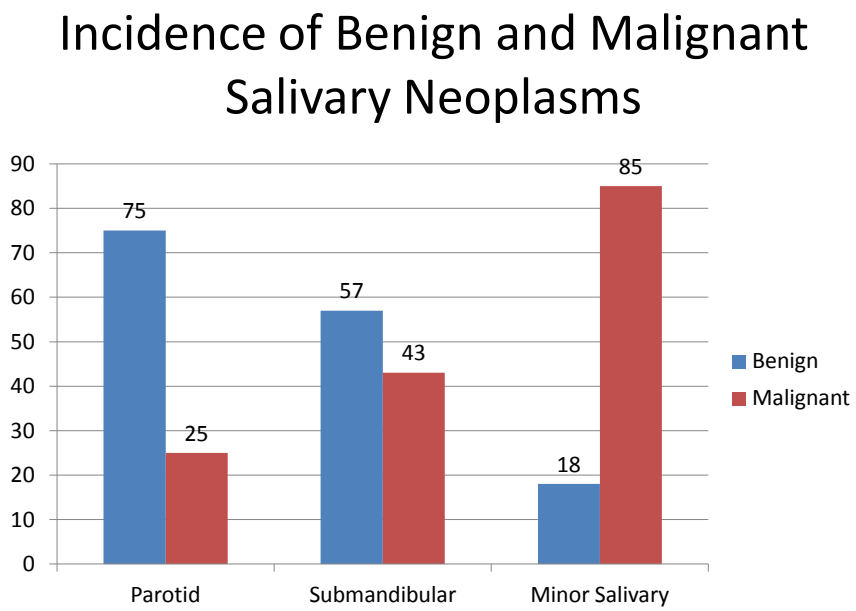
Relationship between the site of Primary tumor and frequency of malignancy

Site	Absolute Numbers	Percentage Frequency	Percentage Malignant
Parotid	1756	72.9	14.7
Submandibular	257	10.7	37
Sublingual	7	0.3	85.7
Minor glands	336	14	46.4
Unknown	54	2.2	-

Eveson JW, Cawson RA: Salivary gland tumours. A review of 2410 cases with particular reference to histological types, site, age and sex distribution. *J Pathol* 1985; 146:51-58

Figure 4: Relationship between tumor and site of malignancy

In children, salivary tumors are even more rare, accounting for about 1.7 to 3%. In infants, the most common types are hemangiomas and lymphomas. In older children epithelial tumors are more prominent and chances of malignancy are as high as 60%. However, most of the malignant tumors in children are of a low grade. (17)



Spiro RH: Salivary neoplasms: overview of a 35-year experience with 2,807 patients. *Head Neck Surg* 1986; 8:177-184

Figure 5: Incidence of benign and malignant salivary neoplasms

Incidence of Parotid Tumours(18)

Pinkston JA, Cole P: Incidence rates of salivary gland tumors: results from a population-based study. *Otolaryngol Head Neck Surg* 1999; 120:834-840

Among 248 incident cases, 84.3% were benign and 15.7% were malignant. Eighty-six percent of cases arose in the parotid gland, and 14% arose in the sub mandibular gland. The average annual age-adjusted incidence rate per 100,000 was 4.7 for benign tumors and 0.9 for malignant tumors. (18)

THE DIFFERENT PROCEDURES FOR MANAGEMENT OF BENIGN SALIVARY TUMOURS

Pleomorphic adenoma is the commonest benign salivary gland tumour.(16) It is the commonest salivary tumour too, except in children.(16)(19) It is classically described as slow growing indolent tumours which can lead to giant sizes if not treated. Malignant change can occur in 0.6% of patients (range 0.9% - 14%) of all salivary neoplasms and for 11.7% (2.8-42.4%) of all salivary malignancies.(20)

They are notorious for recurrence if inadequately removed.(19) This isso because of the pleomorphic adenoma (PA) have a pseudo-capsule of compressed fibrous tissue.(19) There are small elongations called buds or pseudopods, which permeate through this capsule . This is the reason why a simple enucleation fails to clear these pseudopods completely, and hence inadequate removal causes recurrence.(19) So, while parotidectomy aims to remove the tumour with an adequate margin of normal tissue, the proximity of the tumour to the facial nerve determines how much of the tumour can be excised completely.

A retrospective study by Webb and Evesion (2001) of 126 primary pleomorphic adenomas to correlate capsular characteristics with tumour histopathology showed little co-relation between the capsular thickness and

cellular structure.(21) It however showed that hypocellular tumours more than 25mm in size had capsules which were thinner and more vulnerable to rupture during surgery. (21)

McGurk *et al* in their landmark study in 1996 evaluated 476 superfical lobe pleomorphic adenomas, 380 treated by extracapsular excision and 95 treated by superficial parotidectomy and found no difference in the recurrence rate or incidence of facial nerve palsy.(22) Therefore the importance of pseudopods was being questioned and the indications to do a more conservative procedure for selected cases of superficial parotidectomy were explored.

In 1999, Witt in his series of 59 partial parotidectomies showed zero incidence of permanent facial nerve paresis or paralysis and nil recurrence.(23) Ghosh *et al* in 2003 evaluated 83 cases of extracapsular excision in which he achieved an overall recurrence rate of 6%; however the recurrence rate was 1.8% when margins of <1mm was achieved. (24)

McGurk analyzed the outcome of 821 consecutive patients with parotid tumors treated at one centre over 40 years and with a median 12 years (range 5–30) follow-up. (22)The tumors were classified as 'simple' (discrete, mobile, < 4 cm: n=662) and 'complex' (deep, fixed, facial nerve palsy, 4 cm: n=159). Among

the 'simple' or clinically benign tumors, 503 patients underwent ECD and 159 patients underwent SP. The margin was taken 2-3mm away from the tumour.(22)As far as recurrence was concerned, of the 630 patients with ‘simple’ lumps and benign histologies, there were 10 recurrences at 15 years. Eight recurrences occurred after 491 ECDs (1.7% at 15 years by life-table analysis); two recurrences occurred after 139 SPs (1.8% at 15 years by life-table analysis). In all, 32 (5%) clinically benign cases were subsequently revealed as malignant histologies.

For each group, 5- and 10-year cancer-specific survival rates were 100 and 98%

There were no differences in recurrence rates when subanalysed by surgical groups, but ECD was associated with significantly reduced morbidity ($P < 0.001$)

Incidence of Facial Nerve Palsy

Facial Nerve Palsy	ECD (n = 491)	SP (n=139)	P-value
Permanent	8 (1.6%)	2 (1.4%)	Not Significant
Transient	48 (10%)	45 (32%)	**<0.001**

Extracapsular dissection for clinically benign parotid lumps: reduced morbidity without oncological compromise M McGurk[1], B L Thomas[1] and A G Renehan[2]*British Journal of Cancer* (2003) **89**, 1610–1613. doi:10.1038/sj.bjc.6601281

Figure 6: Incidence of Facial Nerve Palsy

Witt, Retjo *et al* published a series of 59 partial parotidectomies with selective nerve dissection for benign and low grade malignant tumors and showed zero incidence of permanent facial paresis or paralysis and recurrence.(25)

Ghosh S, Panarese *et al* published a series of 83 cases of Extracapsular dissection with an overall recurrence rate of 6%. The primary findings were that recurrence rate was 17.6% with close margins, whereas the recurrence rate dropped to 1.8% when a margin greater than 1mm was achieved. It also showed

that intraoperative capuslar rupture and micro-invasion had no influence on recurrence. This suggests that only tumors which actually involve the margin are at risk for recurrence.(24) This is an important statement with regard to our study with close margins.

IN DEPTH ANALYSIS OF KEY STUDIES

Extracapsular dissection for clinically benign parotid lumps: reduced morbidity without oncological compromise.

M McGurk, BL Thomas and AG Renehan

This study was published in 2003 and analysed outcome of patients with parotid tumours treated at one center in London, UK over 40 years. Both benign and malignant parotid tumors were studied, with emphasis on analyzing viability of Extracapsular Dissection in management of patients with bnign parotid tumors. For the purpose of this thesis, the terms "Extracapsular Excision" and "Extracapsular Dissection" are used interchangeably.

Methods: For a period between 1952 and 1992, 821 patients with a parotid swelling were clinically evaluated and divided into two groups: simple and

complex. There were no other diagnostic tests done. Grouping was made solely on clinical grounds.

Among the simple tumours, 503 patients underwent extracapsular dissection and 159 patients underwent superficial parotidectomy. The decision for type of operation was made intraoperatively, after assessing the tumour and raising skin flaps. The difference between extracapsular excision and enucleation was in plane of dissection; in ECD it was in a compartment of loose areolar tissue about 2-3mm from the tumour, wheras in Enucleation the tumour capsule would be breached. Post operative RT was used for patients with tumour spillage of benign tumour or for malignant tumours with positive margins, tumours spillage, high grade histology or adenoid cystic carcinoma.

Results:

Out of 821 tumours, 662 (81%) were 'simple' lumps out of which 32 (5%) were malignant. Out of the 'complex' tumours , 66.66% of tumours were malignant.

MORBIDITY:

	ECD (n=491)	SP (n=139)	P Value
Permanent Facial nerve Palsy	8 (1.6%)	2 (1.4%)	NS
Transient Facial Nerve Palsy	48 (10%)	45 (32%)	<0.001
Frey's Syndrome	25 (5%)	45 (32%)	<0.001
Salivary Fistula	3 (0.6%)	0	<0.001

Figure 7: Morbidity of Parotid Operations

ECD was associated with less incidence of transient facial palsy as compared to SP. This is expected with less dissection of the facial nerve and its branches.

Yamashita et al in 1993 analysed 306 cases retrospectively who were treated for benign parotid tumour with partial parotidectomy and preservation of the facial nerve. Facial Nerve weakness was observed in 18% of 232 patients on a 3 year follow up. (26)

Helmus C. in a 10 year review (1985-1994) showed that a subtotal parotidectomy was as effective as classic superficial parotidectomy and could

provide more advantages, namely a smaller procedure, cost effectiveness, shorter operating time and management of such patients on an outpatient or day care basis post operatively. The cosmetic advantages of a smaller scar and lesser incidence of Frey's syndrome were also highlighted. (27)

Martis in 1983 showed zero incidence of facial nerve palsy 10 year study of 185 cases with pleomorphic adenoma, out of which in 98 cases (52.6%) extracapsular excision was performed. There was no incidence of permanent facial nerve palsy. (28)

Prichard AJ et al in 1992 studied the complications of superficial parotidectomy versus extracapsular paroitdectomy in the treatment of benign parotid lesions. They evaluated 46 patients with benign parotid lesions, out of which 31 (67%) underwent extracapsular excision and 15 (33%) underwent superficial parotidectomy. (29)There was one incidence of permanent facial palsy in the superficial parotidectomy versus zero incidence for the extracapsular excision group.

The House Brackmann Score

The House Brackmann Score is an objective facial nerve grading system to assess the function of the facial nerve. (30)

The House-Brackmann scale ranges between I (normal) and VI (no movement).

Grade I
Normal symmetrical function

Grade II
Slight weakness noticeable only on close inspection
Complete eye closure with minimal effort
Slight asymmetry of smile with maximal effort
Synkinesis barely noticeable, contracture, or spasm absent

Grade III
Obvious weakness, but not disfiguring
May not be able to lift eyebrow
Complete eye closure and strong but asymmetrical mouth movement
Obvious, but not disfiguring synkinesis, mass movement or spasm

Grade IV
Obvious disfiguring weakness
Inability to lift brow
Incomplete eye closure and asymmetry of mouth with maximal effort
Severe synkinesis, mass movement, spasm

Grade V
Motion barely perceptible
Incomplete eye closure, slight movement corner mouth
Synkinesis, contracture, and spasm usually absent

Grade VI
No movement, loss of tone, no synkinesis, contracture, or spasm

MATERIALS AND METHODS

MATERIALS AND METHODS

The research question raised was : "Is it possible to treat benign superficial lobe parotid lesions with a procedure of lesser magnitude that avoids early untoward sequalae of superficial parotidectomy while not compromising on oncosurgical principles". We proceeded with a prospective, randomized controlled trial to evaluate the role of extracapsular excision in the management of benign parotid tumours, specifically the incidence of post operative facial nerve palsy.

NULL HYPOTHESIS

There is no advantage in terms of early post operative complications between superficial parotidectomy and extracapsular excision of benign superficial lobe parotid tumours.

METHODS

Institutional Review Board (IRB) and Ethics Committee approval was obtained. (Appendix 1)

All patients diagnosed with superficial parotid tumours were referred to our department. An informed consent was obtained (See Appendix) in the patient's local language.

INCLUSION CRITERIA

It was decided to include benign tumors of an acceptable size in both males and females. The following were the inclusion criteria:

1. All patients with a newly diagnosed parotid tumor willing to undergo surgery
2. Tumor Size $\leq$ 4cm
3. Benign Parotid Tumors confined to the Superficial Lobe as determined by: Clinical Examination, FNAC and Ultrasound

EXCLUSION CRITERIA

1. Diagnosed parotid malignancy
2. Previous Ipsilateral Parotid Surgery
3. Tumor Size > 4cm
4. Deep Lobe Involvement
5. Recurrent Tumors

SAMPLE SIZE EVALUATION

The Sample size was evaluated by a Double Arm Two Proportion Hypothesis Tesing (Z Test). It was calculated with respect to the established incidence of post operative facial nerve palsy, which for parotid surgery has a range from 27%-100%. (31–36)

The aim was to reduce this incidence to at least 70%. With a power of 80% and an alpha error of 5%, an approximate sample size of 44 patients randomized to two groups with 22 patients in each arm was selected.

TIME PERIOD

A time period of 18 months was estimated for completion of the study.

PREOPERATIVE EVALUATION

All patients underwent a pre-operative evaluation with Clinical Examination, FNAC and ultrasonography of the parotid to confirm the location of the tumour in the superficial lobe and to confirm the benign nature of the swelling. They also underwent a pre-operative assessment of the facial nerve made by a modified House-Brackmann Scoring system. The same scoring system was used post operatively. A record of demographic data and nature of the swelling and FNA findings were maintained.

The patients were randomized into two groups: Superficial Parotidectomy and Extracapsular Excision based on a computerized Randomization Allocation software (RALLOC). This randomization code was blinded to the observer and the participant of the trial.

OPERATIONS

There were three chief operating surgeons who were involved in each of the operations. The participants underwent either Superficial Parotidectomy or

Extracapsular Excision based on randomization. In Extracapsular excision, the tumor was removed with a 4mm margin of normal parotid tissue. Intraoperatively, if it was felt that the tumour appeared malignant or if there was involvement of the deep lobe, then the procedure would be abandoned and a more extensive resection would be performed. The consent for the same was also obtained pre operatively. All patients underwent a drain placement post operatively.

SURGICAL TECHNIQUE

Superficial Parotidectomy

The procedure is done under general anaesthesia. The operation is done with the patient in supine position with the neck extended and the head tilted to the contra lateral side. The head being draped separately from the body and the endotracheal tube is included within the head drape so that adequate mobilization of the head could be achieved without compromising the airway.

The skin incision is started just anterior to the tragus. It proceeds inferiorly till the level of the ear lobule and is then angled posteriorly under it. It is then directed anteriorly for a suitable distance in the upper neck. It is then carried though the skin and the subcutaneous tissue, developing the plane between the cartilaginous

external canal and the posterior aspect of the parotid. The sternomastoid can be identified and retracted to dissect the tail of the parotid from this muscle. The greater auricular surface may be encountered which may need to be sacrificed. This plane is further developed to visualize the posterior belly of the digastric below the digastric groove. The anterior flap is elevated in the plane of the parotid capsule. The facial nerve is now identified as its exits the stylomastoid foramen. The cartilaginous pointed of the external canal and the tympanomastoid sulcus have been identified as pointers to identify the facial nerve. The main trunk is exposed, after which all the branches of the facial nerve are identified after careful dissection and the parotid gland superficial to it is excised. The wound is closed and a single closed suction drain may be brought out through a separate stab wound. (37)

Extracapsular Excision

Patient is induced with general anesthesia. A retro auricular hairline incision is done which is cosmetically acceptable. The incision is angled along the subcutaneous fat and sternocleidomastoid muscle to raise anterior skin flaps till the lesion is reached. The parotid capsule and tissue overlying the lesion is dissected by producing a margin of at least 4 mm around the lesion. Loupes are

useful in this regard. Effort is made to avoid capsular rupture and nerve exposure. The tumor is removed completely along with the margin. A suction drain is inserted and the wound is closed. (38)

Post operative evaluation

The facial nerve status was evaluated by modified House-Brackmann Scoring in the immediate post operative period on post op day 2, day 7 and day 10. The status of the Temporal, Zygomatic and Buccal facial branches were assessed and documented. The final HPE record was also documented.

The data was collected by means of Epidata Software and recorded in Microsoft Excel. Analysis of the same was done via Microsoft Excel 2007 and STATA Version 10 statistical software.

RESULTS

RESULTS

A total of 36 participants were recruited into the trial. They were randomized into two groups of 19 and 17 each, with 19 in one group for Superficial Parotidectomy (SP) and 17 in the other group for extracapsular excision (EC).

Out of the 17 patients who underwent extracapsular excision, 2 operations had to be converted to superficial parotidectomy. The reasons are as follows:

Converted Patient 1: A 3 x 3 cm lesion in the superficial lobe of the left parotid gland with a lobulated extension going deep up to the bony external auditory meatus.

Converted Patient 2: A 5 x 3 cm lesion in the superficial lobe of the right parotid gland that extended in the deeper plane. As the tumor size was beyond the inclusion criterion of the study, the operation converted to the standard superficial parotidectomy.

Number of Cases analyzed

	Superficial Parotidectomy (SP)	Extracapsular Excision (EC)
Total Patients Randomized	19	17
Converted to Superficial Parotidectomy	NA	2*
Malignancy in Histopathology	0	2*
Cases Excluded	0	3*
Total Cases Analyzed	19	14

Figure 8: Number of cases analysed

* Out of 2 converted cases, 1 was diagnosed malignant. The other converted case was anatomically not feasible for extracapsular excision. These cases were excluded from analysis. Additionally the second case diagnosed as malignancy was also excluded from analysis.

Among the 36 participants, two patients (both from extracapsular excision group) had surgical histopathology as malignancy. One of the participants with malignancy was the aforementioned 'Converted Patient 2', who was diagnosed with low grade mucoepidermoid carcinoma. This patient was kept on follow up after the superficial parotidectomy.

The second participant with malignancy was diagnosed with papillary adenocarcinoma after extracapsular excision. He underwent completion parotidectomy at a later date.

For the purpose of the results, both the participants who were diagnosed with malignancy in the surgical histopathology were excluded from analysis. The one patient from EC group for whom surgery was converted (Converted Patient 1) was included, while tabulating the results, in the superficial parotidectomy group. Thus, for analysis of data, the results of 33 participants were analyzed, i.e. 19 patients from SP and 14 patients from EC group.

The results were evaluated on several parameters. The preoperative evaluation assessed the demographic and clinical features at presentation in these patients.

The preoperative normal House-Brackmann Score was confirmed in all the patients. The post operative House Brackmann Score was analysed on days 2, 7 and 10. This was compared between the two groups. The results of positive margins were recorded and analyzed.

DEMOGRAPHIC FEATURES

Out of a target of 44 participants, a total of 33 participants were recruited into the study within the given time frame.

There were 15 male and 18 female participants.

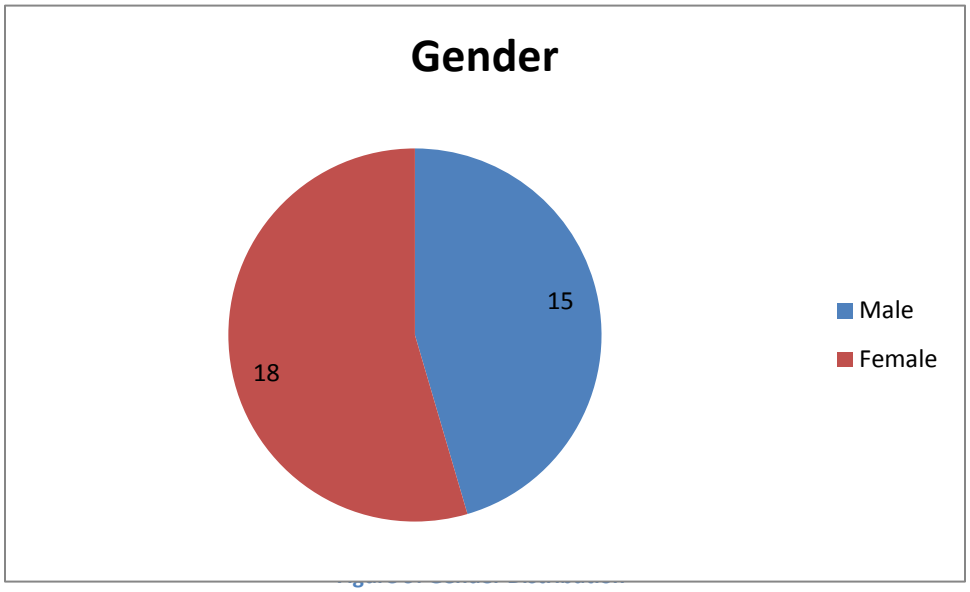


Figure 10 Gender Distribution

	Gender
Male	15
Female	18

The maximum number of patients were from the 40-49 year age group.

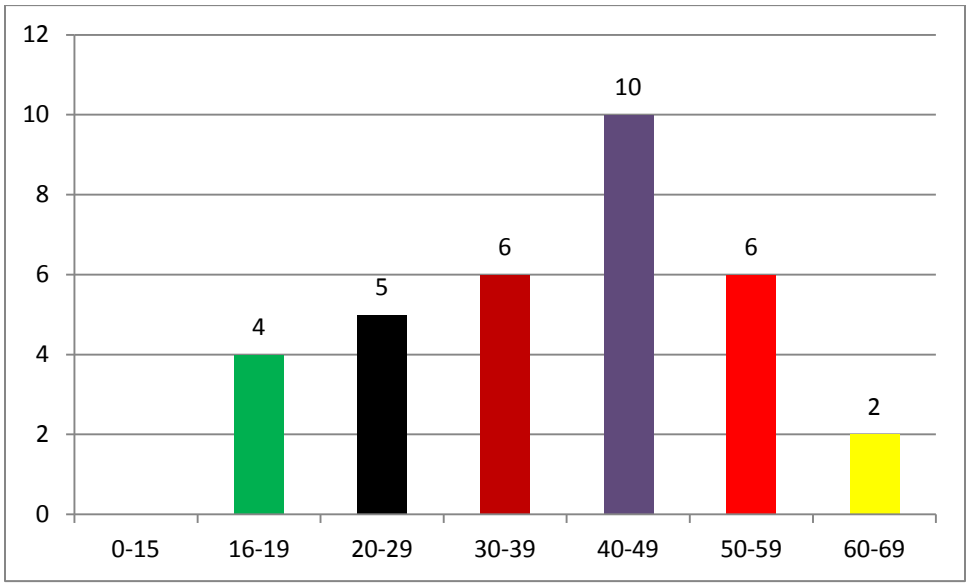


Figure 11: Age Distribution Frequency Histogram

DURATION OF SYMPTOMS

The average duration of symptoms at presentation was 3.6 years with a median value of 3.5 years.

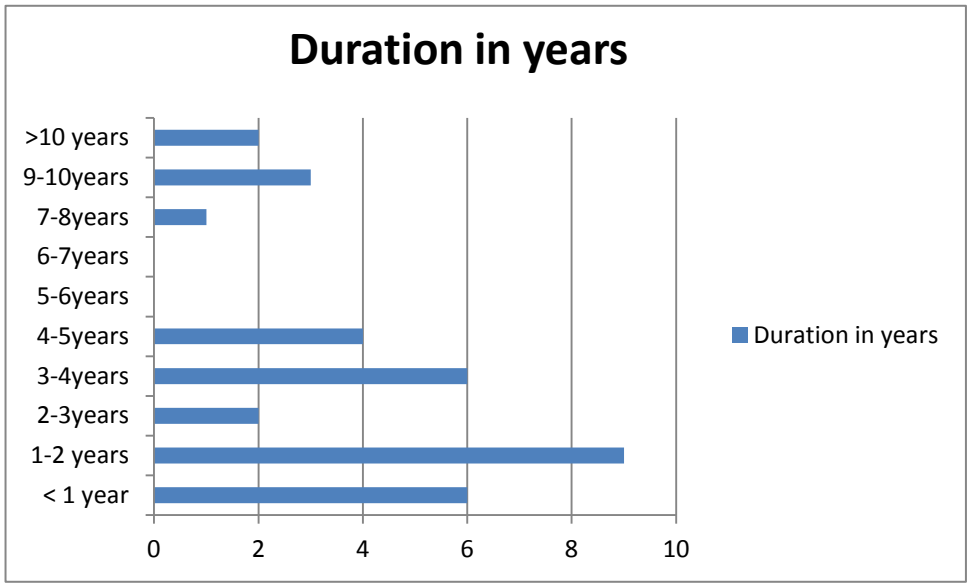


Figure 12: Duration in Years

CLINICAL FEATURES

Pain was present in one patient.

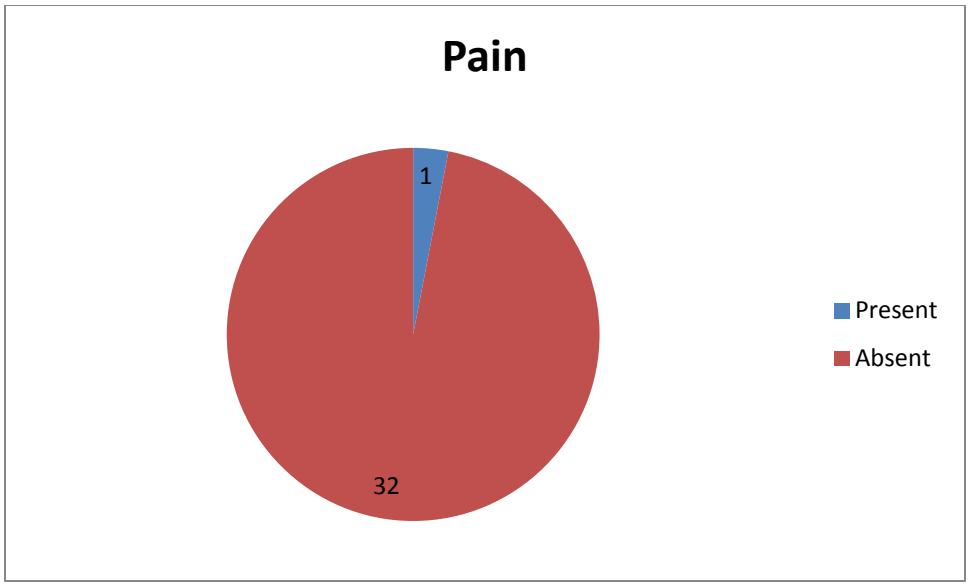


Figure 13: Pain in participants at randomization

The shape was spherical in 31 patients and ill defined in 2 patients.

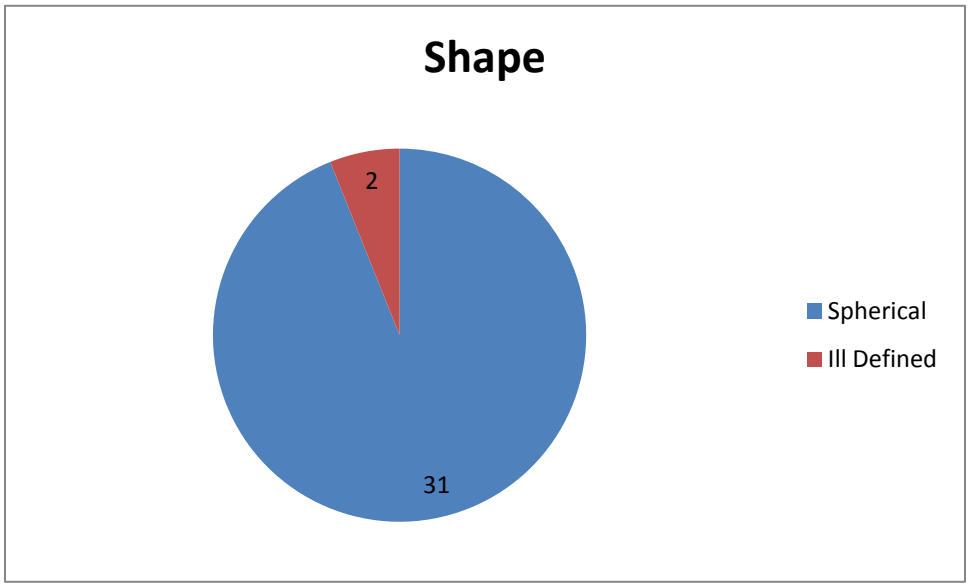


Figure 14: Shape of the swelling at randomization

The surface appeared smooth in 16 patients & lobulated in 17 patients.

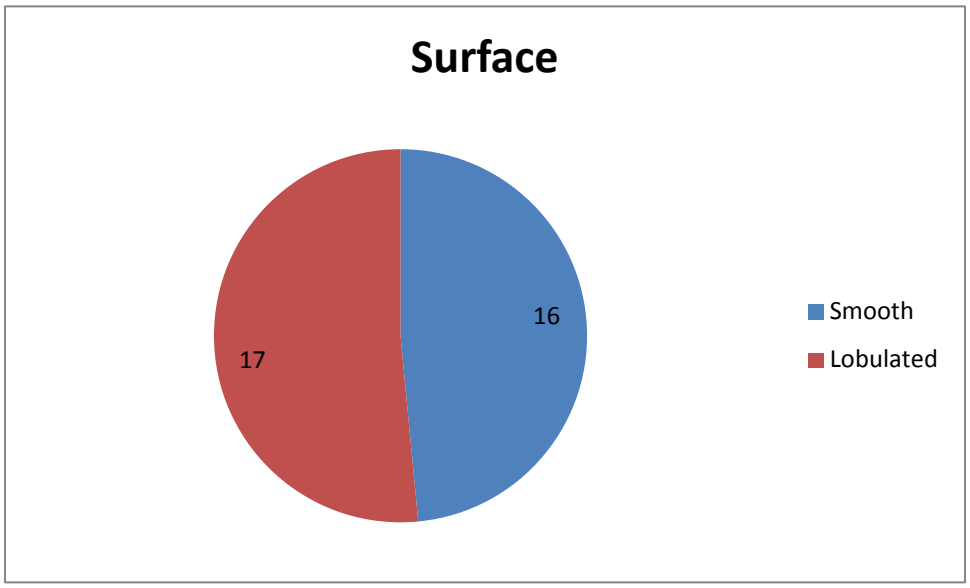


Figure 15: Surface of swelling at randomization

The consistency of the swelling was firm in 32 patients and soft in 1 patient.

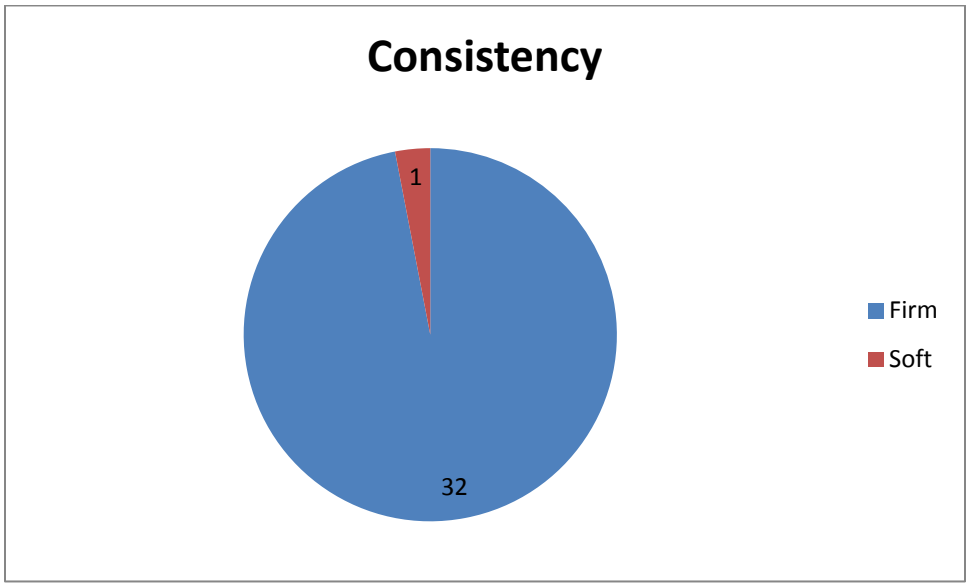


Figure 16: Consistency of swelling at randomization

FNAC

All patients underwent an FNAC which was predicted benign nature in 26 cases and indeterminate in 10 cases.

	TRUE	FALSE	TOTAL
Benign	25	1	26
Malignant	0	1	0
Indeterminate			10

Figure 17: FNAC Results

If we assume that the 'Indeterminate' values are all malignant, then there are 26 benign and 10 malignant diagnoses on FNAC.

	TRUE	FALSE	TOTAL
Benign	25	1	26
Malignant	1	9	10

Figure 18: FNAC, Benign and malignant for analysis

The following results were obtained:

Sensitivity: 73.53% [95% CI: 55.64 % to 87.09 %]

Specificity: 50% [95% CI: 8.17 % to 91.83 %]

Positive Likelihood Ratio: 1.47 [95% CI: 0.36 to 5.97]

Negative Likelihood Ratio: 0.53 [95% CI: 0.12 to 2.36]

Positive Predictive Value: 96.15% [95% CI: 80.30 % to 99.36 %]

Negative predictive Value: 10% [95% CI: 1.66 % to 44.54 %]

Margin Status

The Histopathological margins were assessed based on final biopsy report. A margin of 4mm or more was considered as 'not involved'. A margin less than 4mm was considered close. There were 2 reports in which the margin status was not documented by the pathologist.

MARGIN STATUS

	SP	ECE		TOTAL
CLOSE	12	9		21
NOT INVOLVED	7	3		10
DON'T KNOW	0	2		2
TOTAL	19	14		33
% CLOSE	63%	64.28%		

Figure 19: Margin Status

P Value = 0.49

The percentage of close margins in superficial parotidectomy was 63% and that of extracapsular excision was 64.28%. The above was not statistically significant.

Score

The following are the Scores of Zygomatic, Temporal and Buccal branches on Post Operative Days 2, 7 and 10 respectively. The House-Brackmann Scores were divided into Mild (Scores 1 and 2), Moderate (Scores 3 and 4) and Severe (Scores 5 and 6). Since the number of severe scores were minimal, Moderate and Severe were combined into one group. Thus, two groups of scores were compared as follows:

Group 1	**Mild**
Group 2	**Moderate & Severe**

HOUSE–BRACKMANN SCORE on Post Operative Day 2

ZYGOMATIC

POD 2 Z	SP	EC	TOTAL
MILD	16	13	29
%	84.21	92.86	87.88
MODERATE & SEVERE	3	1	4
%	15.79	7.14	12.12
TOTAL	19	14	33
	100%	100%	100%

Figure 20: Post operative Day 2, Zygomatic

Pearson CHI^2 (1) = 0.5658 P Value = 0.452
Fisher's exact = 0.620
1-sided Fisher's exact = 0.426

HOUSE–BRACKMANN SCORE on Post Operative Day 2

TEMPORAL

POD 2 T	SP	EC	TOTAL
MILD	15	13	28
%	78.95	92.86	84.85
MODERATE & SEVERE	4	1	5
%	21.05	7.14	15.15
TOTAL	19	14	33
	100%	100%	100%

Figure 21Post operative Day 2, Temporal

Pearson CHI^2 (1) = 1.2131 P Value = 0.271
Fisher's exact = 0.366
1-sided Fisher's exact = 0.278

HOUSE–BRACKMANN SCORE on Post Operative Day 2

MANDIBULAR

POD 2 M	SP	EC	TOTAL
MILD	14	12	26
%	73.68	85.71	78.79
MODERATE & SEVERE	5	2	7
%	26.32	14.29	21.21
TOTAL	19	14	33
	100%	100%	100%

Figure 22: Post operative Day 2, Mandibular

Pearson CHI^2(1) = 0.6980 P Value = 0.403
Fisher's exact = 0.670
1-sided Fisher's exact = 0.348

HOUSE–BRACKMANN SCORE on Post Operative Day 7

ZYGOMATIC

POD 7 Z	SP	EC	TOTAL
MILD	16	13	29
%	84.21	92.86	87.88
MODERATE & SEVERE	3	1	4
%	15.79	7.14	12.12
TOTAL	19	14	33
	100%	100%	100%

Figure 23: Post operative Day 7, Zygomatic

Pearson CHI^2 (1) = 0.5658 P Value = 0.452
Fisher's exact = 0.620
1-sided Fisher's exact = 0.426

HOUSE–BRACKMANN SCORE on Post Operative Day 7

TEMPORAL

POD 7 T	SP	EC	TOTAL
MILD	15	13	28
%	78.95	92.86	84.85
MODERATE & SEVERE	4	1	5
%	21.05	7.14	15.15
TOTAL	19	14	33
	100%	100%	100%

Figure 24: Post operative Day 7, Temporal

Pearson CHI^2 (1) = 1.2131 P Value = 0.271

Fisher's exact = 0.366

1-sided Fisher's exact = 0.278

HOUSE–BRACKMANN SCORE on Post Operative Day 7

MANDIBULAR

POD 7 M	SP	EC	TOTAL
MILD	14	12	26
%	73.68	85.71	78.79
MODERATE & SEVERE	5	2	7
%	26.32	14.29	21.21
TOTAL	19	14	33
	100%	100%	100%

Figure 25: Post Operative Day 7, Mandibular

Pearson CHI^2 (1) = 0.6980 P Value = 0.403
Fisher's exact = 0.670
1-sided Fisher's exact = 0.348

HOUSE–BRACKMANN SCORE on Post Operative Day 10

ZYGOMATIC

POD 10 Z	SP	EC	TOTAL
MILD	17	13	30
%	89.47	92.86	91.91
MODERATE & SEVERE	2	1	3
%	10.53	7.14	9.09
TOTAL	19	14	33
	100%	100%	100%

Figure 26: Post operative Day 10, Zygomatic

Pearson CHI^2 (1) = 0.1117 P Value = 0.738
Fisher's exact = 1.000
1-sided Fisher's exact = 0.616

HOUSE–BRACKMANN SCORE on Post Operative Day 10

TEMPORAL

POD 10 T	SP	EC	TOTAL
MILD	16	13	29
%	84.21	92.86	87.88
MODERATE & SEVERE	3	1	4
%	15.79	7.14	12.12
TOTAL	19	14	33
	100%	100%	100%

Figure 27: post operative Day 10, Temporal

Pearson CHI^2 (1) = 0.5658 P Value = 0.452
Fisher's exact = 0.620
1-sided Fisher's exact = 0.426

HOUSE–BRACKMANN SCORE on Post Operative Day 10

MANDIBULAR

POD 10 M	SP	EC	TOTAL
MILD	14	12	26
%	73.68	85.71	78.79
MODERATE & SEVERE	5	2	7
%	26.32	14.29	21.21
TOTAL	19	14	33
	100%	100%	100%

Figure 28: Post operative Day 10, Mandibular

Pearson CHI^2 (1) = 0.6980 P Value = 0.403

Fisher's exact = 0.670

1-sided Fisher's exact = 0.348

The above results were not statistically significant. Further Analysis of the above results revealed the following:

POD 2 MILD		
	SP	EC
T	78.95	92.86
Z	84.21	92.86
M	73.68	85.71

Figure 29: Post Operative Day 2, Mild Symptoms

There was an increased incidence of mild facial nerve palsy in Temporal, Zygomatic and Mandibular branches in Extracapsular Excision as compared to Superficial Parotidectomy on Day 2.

POD 2 M & S		
	SP	EC
T	21.05	7.14
Z	15.79	7.14
M	26.32	14.29

Figure 30: Post operative Day 2, Moderate & Severe Symptoms

There was a decreased incidence of moderate facial nerve palsy in Temporal, Zygomatic and Mandibular branches in Extracapsular excision as compared to superficial parotidectomy on Day 2. This incidence was more for Mandibular than Temporal and Zygomatic branches.

POD 7 MILD		
	SP	EC
T	78.95	92.86
Z	84.21	92.86
M	73.68	85.71

Figure 31: Post operative Day 7, Mild Symptoms

There was an increased incidence of mild facial nerve palsy in Temporal, Zygomatic and Mandibular branches in Extracapsular Excision as compared to Superficial Parotidectomy on Day 7.

POD 7 M & S		
	SP	EC
T	21.05	7.14
Z	15.79	7.14
M	26.32	14.29

Figure 32: Post operative Day 7, Moderate & Severe Symptoms

There was a decreased incidence of moderate facial nerve palsy in Temporal, Zygomatic and Mandibular branches in Extracapsular excision as compared to superficial parotidectomy on Day 7. This incidence was more for Mandibular than Temporal and Zygomatic branches.

POD 10 MILD		
	SP	EC
T	84.21	92.86
Z	89.47	92.86
M	73.68	85.71

Figure 33: Post Operative Day 10, Mild Symptoms

There was an increased incidence of mild facial nerve palsy in Temporal, Zygomatic and Mandibular branches in Extracapsular Excision as compared to Superficial Parotidectomy on Day 10.

POD 10 M & S		
	SP	EC
T	15.79	7.14
Z	10.53	7.14
M	26.32	14.29

Figure 34: Post operative Day 10, Moderate & Severe Symptoms

There was a decreased incidence of moderate facial nerve palsy in Temporal, Zygomatic and Mandibular branches in Extracapsular excision as compared to superficial parotidectomy on Day 10. This incidence was more for Mandibular than Temporal and Zygomatic branches.

DISCUSSION

DISCUSSION

In this study, the demographic data and clinical features of parotid tumors were analyzed. Two operations for benign parotid tumors: Superficial Parotidectomy and Extracapsular Excision were compared and were analyzed for margin status and post operative facial nerve palsy.

There was no gender predominance and the maximum number of participants in this study were from the 40-49 year age group. Clinically, it was predominantly painless, spherical in nature with a smooth consistency.

Margins

An adequate margin of 4mm was not achieved in 63 % of superficial parotidectomy and 64.28% of Extracapsular Excision operations. In superficial parotidectomy, this could be due to the tumor being close to the facial nerve and fine dissection to spare the nerve could not produce an adequate margin. The same reason could apply to Extracapsular Excision in cases of tumors lying close to the facial nerve. The margin was not breached in either of the groups.

House-Brackmann Score

There was no statistically significant difference in the morbidity of early facial nerve palsy between the two groups in the first 10 post operative days. However there was an increased incidence of *mild* facial nerve palsy in patients who underwent extracapsular excision on each of the days 2, 7 and 10 post operatively. There was, in contrast, an increased incidence of *moderate and severe* facial nerve palsy in patients who underwent superficial parotidectomy. The significance of the above could be improved by recruiting larger numbers.

CONCLUSION

CONCLUSION

1. There was a decreased incidence of mild facial nerve palsy in the post operative period in patients who underwent Superficial Parotidectomy as compared to those who underwent Extracapsular excision. However, there was an increased incidence of moderate and severe facial nerve paralysis in the immediate post operative period in patients who underwent superficial parotidectomy as compared to those who underwent extracapsular excision. The above facts were not statistically significant.
2. The positive margins associated with extracapsular excision were similar to that of superficial parotidectomy in this study, but this was not statistically significant.
3. Extracapsular Excision could be considered an alternative to Superficial Parotidectomy in treatment of benign parotid tumors, but larger numbers are required to statistically confirm the same.

LIMITATIONS

LIMITATIONS

- Our calculated sample size was 44 but during the course of the study 36 cases were studied. It is planned to continue to recruit patients beyond the stipulated time frame, to get statistically significant results.
- Long term incidence rate of facial nerve palsy was not compared within the scope of this study. The patients are kept under follow up to identify the same.
- Recurrence rates between the two procedures were not compared. It is planned to document the same during follow up of these patients.
- The cosmetic advantage provided by extracapsular excision was not quantified. Prevention of a hollow in the operated site and a smaller scar may be of importance to some sectors of the population for whom extracapsular excision could be a viable option.

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BIBLIOGRAPHY

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APPENDIX

APPENDIX

ANNEXURE

ANNEXURE

Thesis Profoma

Serial Number:_____ Date:_____

Name_____

Hospital Number_____ Age:___Sex: M/F

Address:_____
_____

_____

Telephone:_____ Cell Phone:_____Other:_____

---

1. Duration_____months/years
2. Site: Right / Left
3. Pain: Yes / No
4. Previous Operation: Yes / No
5. Extent:_____ Size: _____cm
   Shape:_____ Surface:_____
   Edge:_____ Consistency: Soft / Cystic / Hard
6. Fixity to skin: Fixed /Not Fixed
7. Fixity to Masseter: Fixed / Not Fixed
8. Enlargement of Deep Lobe: Yes / No
9. Facial Nerve Palsy: House Brackmann Score:
   Temporal: _____Zygomatic:_____Buccal_____
10. Lymph Node Enlargement: Present/Absent
11. Restricted Jaw Movements: Present / Absent

FNAC Report:

12. Cells: Sufficient/Insufficient
13. Impression: Benign/Malignant

_____

Ultrasonography Findings:

14. Tumour Size_____ Shape_____
15. Borders: Capsule irregular / well defined
16. Contents: Heterogeneous / Homogenous
17. Contents: Cystic / Solid
18. Distance between tumour and RMV:_____
19. Increased Vascularity on Doppler: Yes / No
20. Distance of the tumour from the styloid process: _____

Other Investigations:

_____
_____
_____
_____

Type of Procedure Proposed: Superficial Parotidectomy / Extracapsular Excision
Intra Op Findings:

Facial Nerve involved: Yes / No

Nodes present: Yes / No

Size:

Cystic: Yes / No

Final Report:

Surgical Margins: Inadequate / Adequate

Patient Information Sheet

Evaluation of Extracapsular Excision in the management of Benign Parotid Tumors

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Patient Information Sheet

Study Co-coordinator: Dr. Aditya Benjamin
Dept. of General Surgery
CMC Vellore

This is the form for giving consent to participate in the aforementioned study, which seeks to evaluate the procedure of Extracapsular Excision, for treatment of benign parotid tumors, in comparison to the procedure of Superficial Parotidectomy.

You have been diagnosed to have a benign parotid tumour. It is managed by removal of the superficial part of the parotid gland with the tumour. As means to reduce the post operative consequences of this operation, a more limited removal of your parotid gland without compromising principles of cancer surgery is going to be administered upon you with your permission. There is evidence which suggests that this procedure is safe with lesser complications and better acceptability in patients studied elsewhere in the world. We want to adopt this technique for which we will need preliminary investigations in a certain number of patients before adopting as a standard of care. With your kind permission we would like to enroll you into our study.

The procedures being done:

There are two procedures being evaluated in this study: Extracapsular Excision and Superficial Parotidectomy. Superficial Parotidectomy is a standard procedure, where the entire Superficial Lobe of the Parotid Gland in which the tumour is present, would be excised. The tumour would be removed along with the gland. The side effects of this procedure can include:

Early side effects:

- Weakness in forehead wrinkling on affected side , weakness in closing eye on affected side, weakness in cheek movement on affected side, dribbling of saliva on affected side, and lack of or altered facial expressions.
- A collection of blood or fluid in the operated site
- Cosmetic Defect of a scar on the side of the face, and in some cases, a depression behind the jaw-bone

Late complications

- Weakness of face muscles
- A collection of saliva in the operated site
- Lack of sensation on the operated site

- Symptoms of sweating while chewing food
- Discharge of saliva from an opening in the operated site.

The alternative procedure is Extracapsular Dissection, where the tumour would be removed along with a margin of normal tissue around the tumour. The complications expected from this procedure are:

- Weakness in forehead wrinkling on affected side , weakness in closing eye on affected side, weakness in cheek movement on affected side, dribbling of saliva on affected side, and lack of or altered facial expressions.
- A collection of blood or fluid in the operated site
- Cosmetic Defect of a scar on the side of the face
- A collection of saliva in the operated site
- Discharge of saliva from an opening in the operated site.
- Lack of sensation on the operated site

How the patients are going to be chosen:

There are two groups of patients in this study. One group will undergo Superficial Parotidectomy, and the other group will undergo Extracapsular Excision. You will be chosen to either one of the groups depending on a random code generated by a computer software.

At any given point in this treatment if it is felt that this procedure is going to be inadequate, the standard procedure is going to be adopted without compromising the principles of cancer surgery.

In case of any doubts, please contact Dr. Aditya Benjamin at 9655726381
Office Number: (Surgery 1 Office): 04162282082

I hereby agree to participate in the study: Evaluation of Extracapsular Excision in the treatment of benign parotid tumors.

Signed:
Study Participant:
Date:
Witness:
Date:

Informed Consent Form

Informed Consent form to participate in a clinical trial
Christian Medical College, Vellore
Department of General Surgery
Evaluation of Extracapsular Excision in the management of benign parotid tumors

Study Number:
Subject's Name:
Date of Birth / Age:

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

(iii) I understand that the investigators of this study, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)

(v) I agree to take part in the above study.

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:_____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

Signature of the Witness: _____

Date:_____/_____/_____

Name of the Witness: _____

Data Sheet

Randomization Code

1	1
2	2
3	1
4	2
5	2
6	2
7	2
8	1
9	1
10	1
11	2
12	1
13	2
14	2
15	1
16	1
17	1
18	1
19	2
20	1
21	2
22	2
23	1
24	2
25	1
26	1
27	2
28	2
29	1
30	2
31	2
32	2
33	1
34	1
35	1
36	1
37	2
38	2
39	2
40	2
41	1
42	1
43	2
44	1

Figure 35: Randomization Code

1= EXTRACAPSULAR EXCISION, 2 = SUPERFICIAL PAROTIDECTOMY

MASTER CHART

identifier	age	gender	duration	months	site	pain	previous	size	x	shape	surface	edge	consisten	fixity	fixity1	enlargemi	pre	pre1	pre2	lymph	restricted	cells	impressio	operation	facial	nodes	size1	cystic	final	surgical
1	7	1	3	0	1	2	2	50	50	1	1	1	2	2	2	2	1	1	1	2	2	0	0	1	2	1	4	1	1	2
2	6	1	12	0	1	2	2	30	30	1	1	1	2	2	2	2	1	1	1	2	2	1	1	1	2	2	2	2	1	1
3	3	1	2	0	2	2	2	55	50	1	1	1	2	2	2	2	1	1	1	2	2	1	1	1	2	1	4	2	1	3
4	4	1	0	9	2	2	2	60	50	2	2	1	2	2	2	2	1	1	1	2	2	0	0	1		2	6	2	1	1
5	3	2	3	0	2	2	2	25	25	1	1	1	2	2	2	2	1	1	1	2	2	0	0	1	2	2	2	2	1	3
6	2	1	4	0	1	2	2	90	80	2	2	2	2	2	2	2	1	1	1	2	2	1	1	1	2	2	8	2	1	1
7	4	2	4	0	1	2	2	50	60	1	1	1	2	2	2	2	1	1	1	2	2	0	0	1	2	2	3	2	1	2
8	3	1	1	6	2	2	2	50	60	1	1	1	2	2	2	2	1	1	1	2	2	0	0	1	2	1	3	2	1	3
9	4	1	1	0	1	2	2	30	20	1	1	1	2	2	2	2	1	1	1	2	2	0	0	1	2	2	2	2	1	2
10	5	2	1	0	1	2	2	30	20	1	2	1	2	2	2	2	1	1	1	2	2	1	1	1	2	2	2	2	1	3
11	6	2	1	6	1	2	2	50	50	1	2	1	2	2	2	2	1	1	1	2	2	1	1	1	2	2	3	2	1	1
12	5	2	2	0	2	2	2	30	20	1	1	1	2	2	2	2	1	1	1	2	2	1	1	1	2	2	2	2	1	1
13	5	2	9	0	2	2	2	30	20	1	2	1	2	2	2	2	1	1	1	2	2	1	1	1	1	2	2	2	1	2
14	5	1	1	0	2	2	2	20	20	1	2	1	2	2	2	2	1	1	1	2	2	1	1	2	2	2	1	2	1	3
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16	5	2	0	6	1	2	2	25	25	1	1	1	2	2	2	2	1	1	1	2	2	1	1	2	1	2	2	2	1	0
17	6	1	4	0	2	2	2	25	25	1	1	1	2	2	2	2	1	1	1	2	2	1	1	2	2	2	2	2	1	3
18	6	2	0	6	2	2	2	20	20	1	1	1	1	2	2	2	1	1	1	2	2	1	1	2	2	2	2	1	1	2
19	6	1	3	0	2	2	2	30	20	1	2	1	2	2	2	2	1	1	1	2	2	1	1	2	2	2	2	2	1	1
20	2	2	0	8	1	1	2	20	20	1	2	1	2	2	2	2	1	1	1	2	2	1	1	2	2	1	1	2	1	2
21	6	2	15	0	2	2	2	30	30	1	1	1	2	2	2	2	1	1	1	2	2	1	1	2	2	2	3	2	1	2
22	3	1	8	0	2	2	2	35	35	1	2	1	2	2	2	2	1	1	1	2	2	1	1	2	2	1	2	2	1	1
23	2	2	1	0	2	2	2	60	40	1	2	1	2	2	2	2	1	1	1	2	2	1	1	2	1	1	4	2	1	1
24	2	1	0	6	1	2	2	20	20	1	2	2	2	2	2	2	1	1	1	2	2	1	1	2	2	2	3	2	1	1
25	5	2	1	0	2	2	2	30	30	1	2	2	2	2	2	2	1	1	1	2	2	2	1	2	2	2		2	1	1
26	5	2	3	0	1	2	2	40	30	1	2	1	2	2	2	2	1	1	1	2	2	1	1	1	1	2	5	2	1	1
27	4	1	7	0	1	2	2	40	30	1	1	2	2	2	2	2	1	1	1	2	2	0	0	1	2	1	4	2	1	1
28	5	1	0	6	2	2	2	40	30	1	2	1	2	2	2	2	1	1	1	2	2	1	1	1	2	1	5	2	1	2
29	3	2	4	0	1	2	2	30	25	1	2	1	2	2	2	2	1	1	1	2	2	1	1	1	2	2	4	2	1	1
33	4	2	1	0	1	2	2	20	20	1	2	1	2	2	2	2	1	1	1	2	2	2	0	2	2	2	3	2	1	0
34	5	2	3	0	1	2	2	30	30	1	2	1	2	1	2	2	1	1	1	2	2	1	1	2	2	2	2	2	1	1
35	4	2	0	9	2	2	2	30	30	1	1	1	2	2	2	2	1	1	1	2	2	1	1	1	2	2	3	2	1	2
36	5	1	0	4	1	2	2	40	40	1	2	1	2	2	2	2	1	1	1	2	2	1	1	1	2	2	4	2	1	2

Figure 36: Master Chart

HOUSE BRACKMAN SCORES AT 2, 7 AND 10 DAYS

identifier	Group	POD2 T	POD2 Z	POD2 M		POD7 T	POD7 Z	POD 7 M		POD10 T	POD10Z	POD10M
1	1	2	1	1		2	1	1		2	1	1
2	1	3	2	3		3	2	3		3	2	3
3	1	1	1	1		1	1	1		1	1	1
4	1	1	1	1		1	1	1		1	1	1
5	1	1	1	1		1	1	1		1	1	1
6	1	1	1	2		1	1	2		1	1	2
7	1	1	3	3		1	3	3		1	2	3
8	1	1	1	2		1	1	2		1	1	2
9	1	1	1	1		1	1	1		1	1	1
10	1	1	1	2		1	1	1		1	1	1
11	1	1	1	1		1	1	1		1	1	1
12	1	1	1	2		1	1	2		1	1	2
13	1	3	3	3		3	3	3		3	3	3
14	2	1	1	1		1	1	1		1	1	1
15	2	1	1	1		1	1	1		1	1	1
16	2	1	1	1		1	1	1		1	1	1
17	2	1	1	1		1	1	1		1	1	1
18	2	1	1	1		1	1	1		1	1	1
19	2	1	1	1		1	1	1		1	1	1
20	2	1	1	1		1	1	1		1	1	1
21	2	1	1	1		1	1	1		1	1	1
22	2	1	1	1		1	1	1		1	1	1
23	2	5	3	5		5	3	5		5	3	5
24	2	1	1	1		1	1	1		1	1	1
25	2	1	1	3		1	1	3		1	1	3
26	1	3	2	3		3	2	3		2	2	3
27	1	1	1	2		1	1	2		1	1	2
28	1	1	2	2		1	2	2		1	2	2
29	1	3	3	4		3	3	4		3	3	4
33	2	1	1	1		1	1	1		1	1	1
34	2	1	1	1		1	1	1		1	1	1
35	1	1	1	2		1	1	2		1	1	2
36	1	1	1	1		1	1	1		1	1	1

Figure 37: House Brackmann Scores at 2, 7 and 10 days

IMAGES

Images

Extracapsular Excision

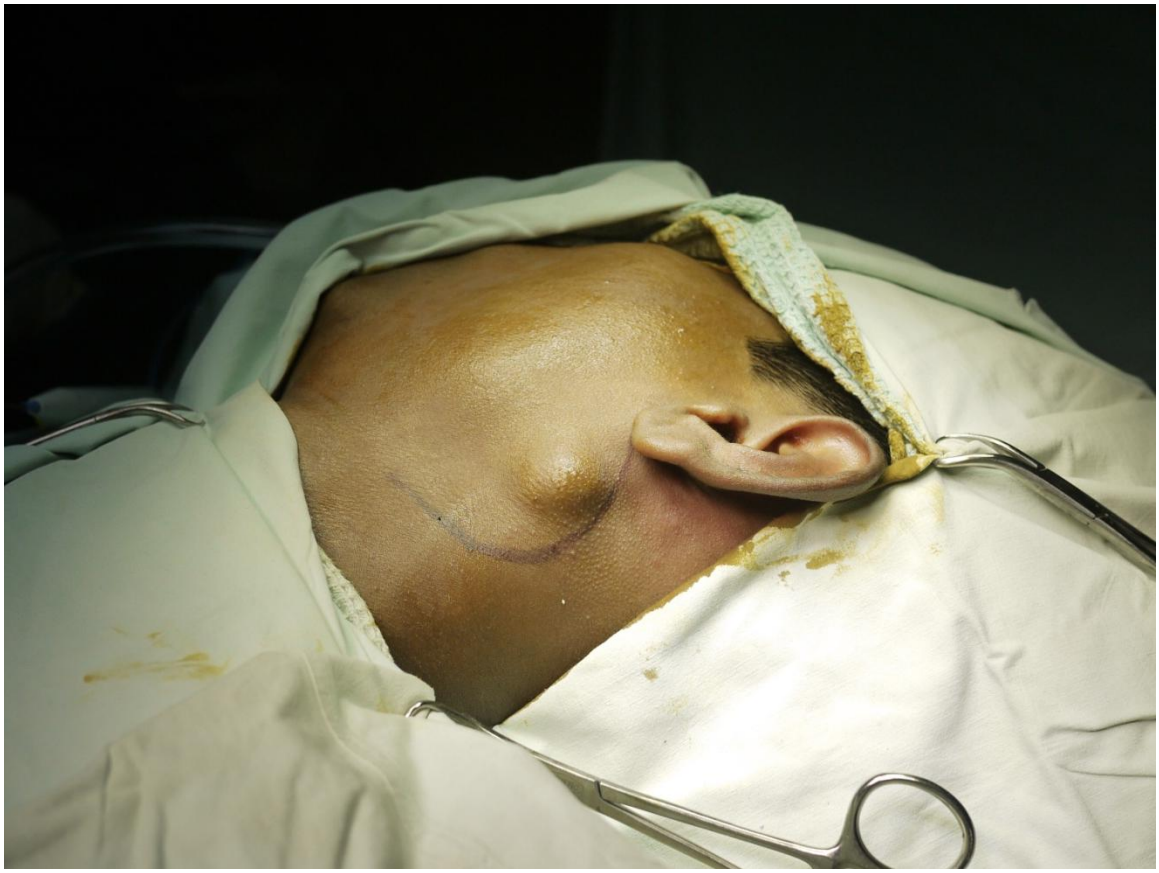

Figure 38: Cervico-mastoid component of Modified Blair's Incision (Extracapsular Excision)

Extracapsular Excision

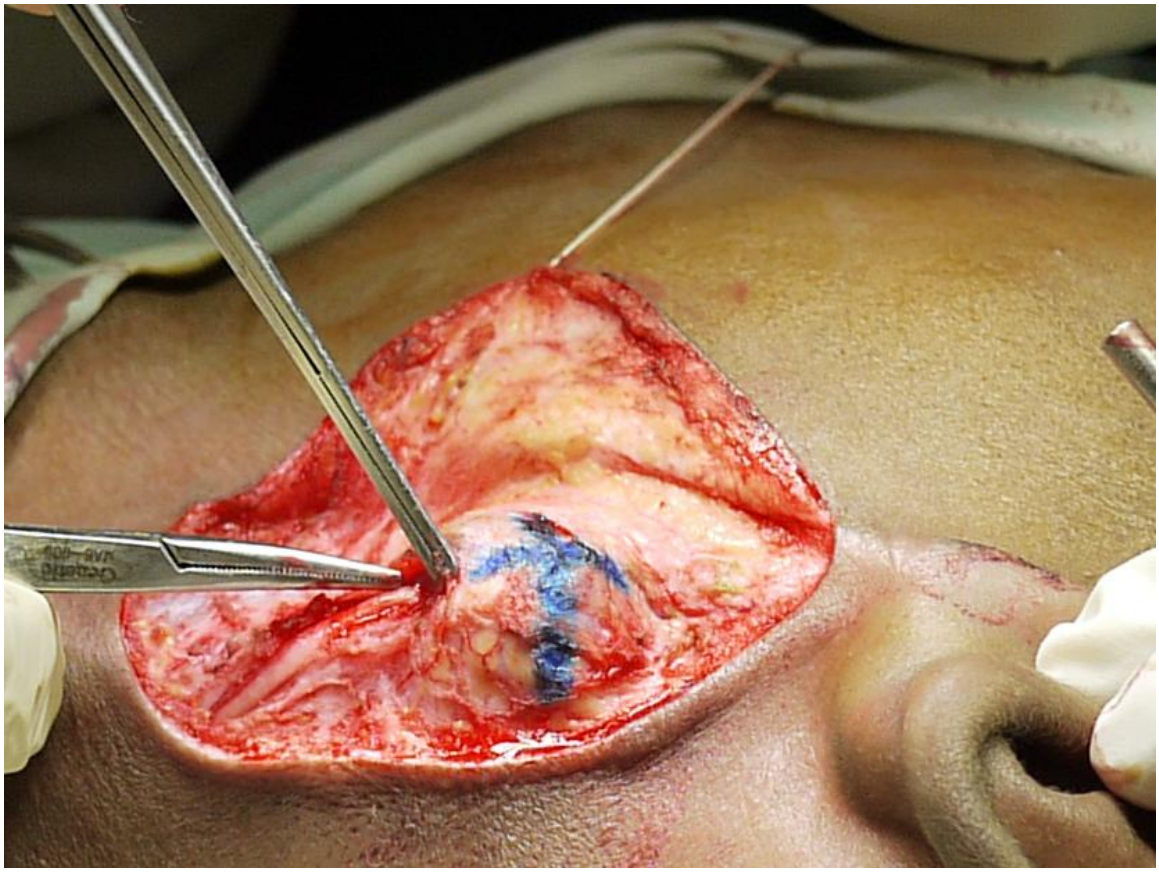

Figure 39: Dissecting Parotid Fascia

Extracapsular Excision

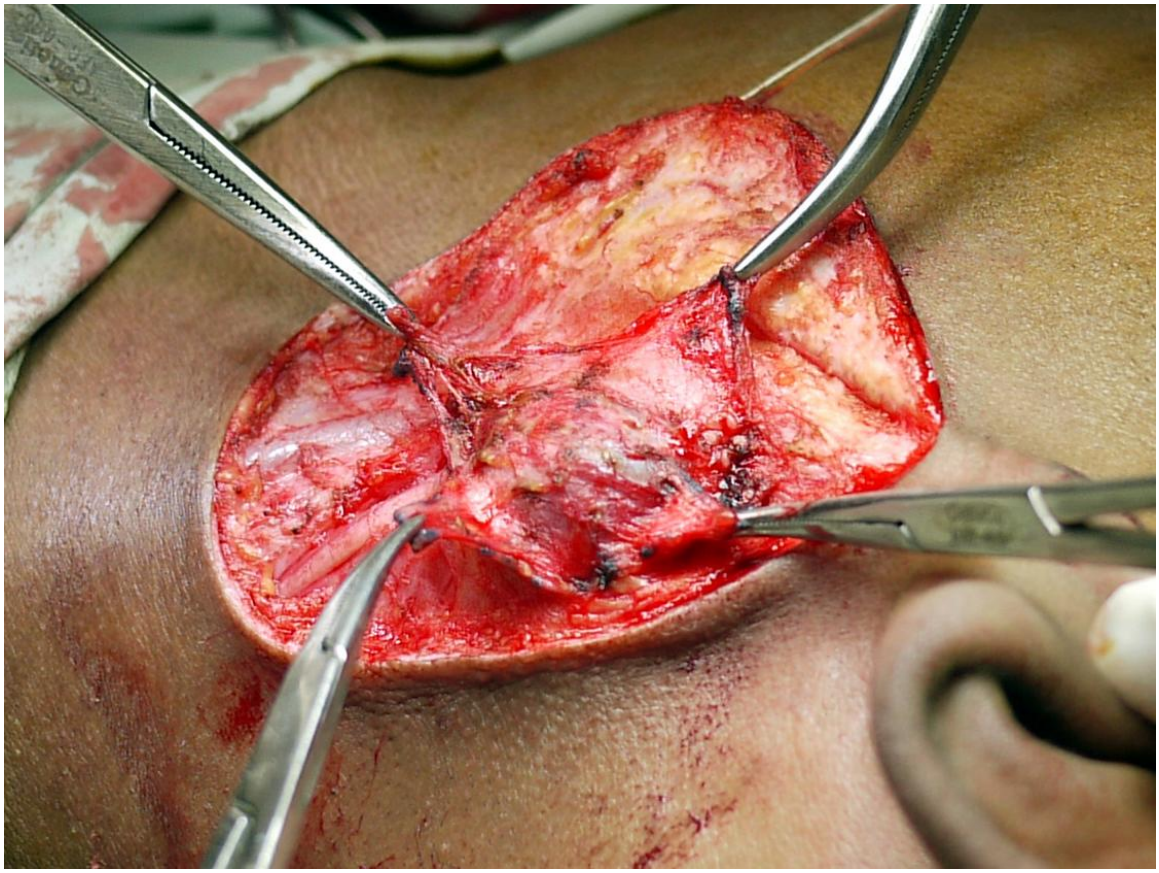

Figure 40: Seperation of Fascia

Extracapsular Excision

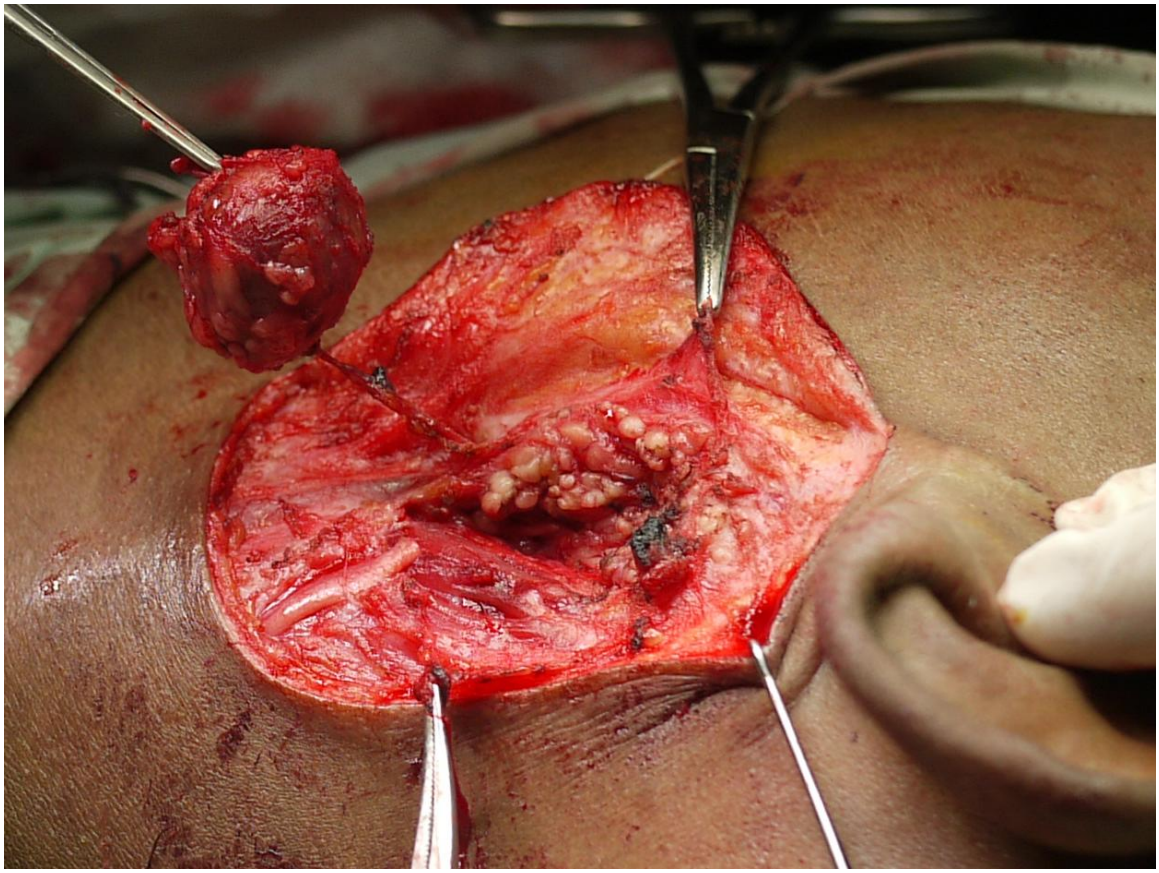

Figure 41: Excision of tumor

Extracapsular Excision

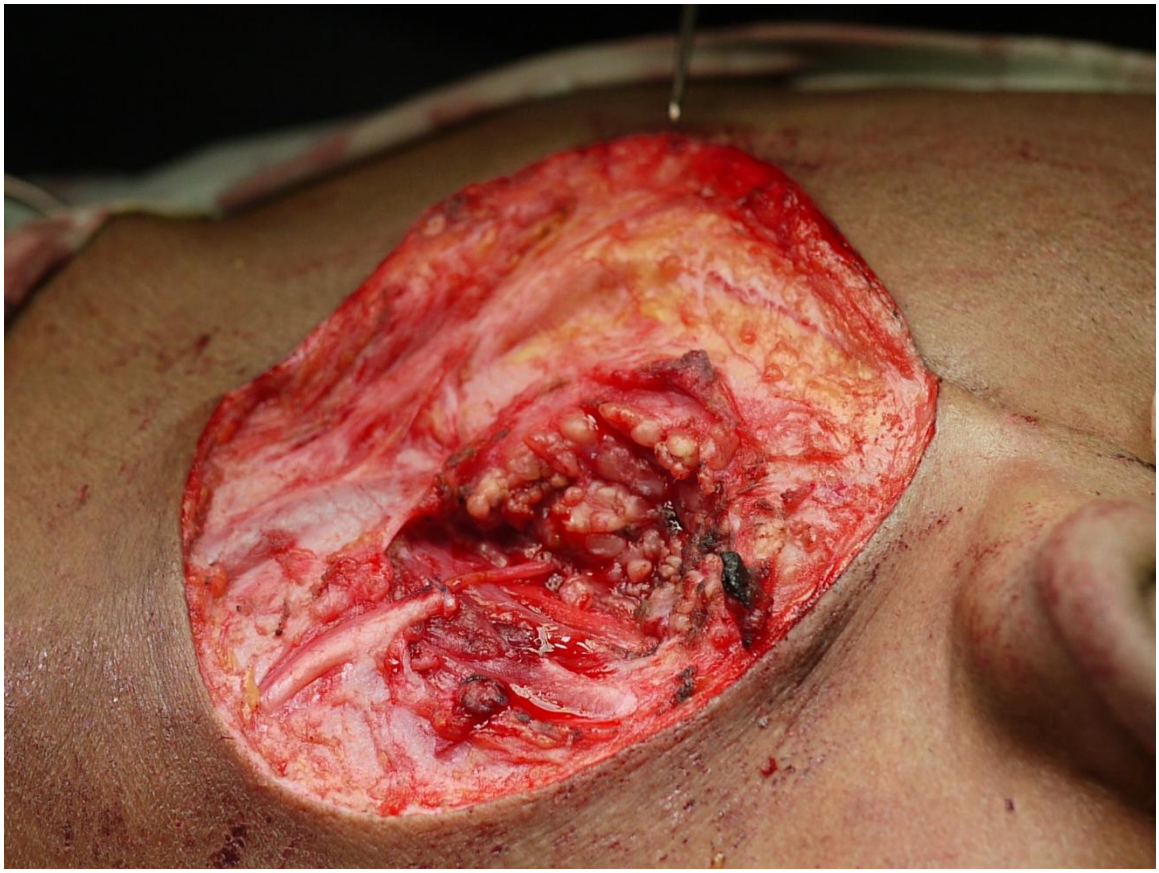

Figure 42: Tumor bed after excision

Assessing House Brackmann Score Post operatively

Figure 43: Temporalis Function (T = 1)

POST OPERATIVE HOUSE BRACKMANN SCORE

Figure 44: Zygomatic Function (Z = 1)

POST OPERATIVE HOUSE BRACKMANN SCORE

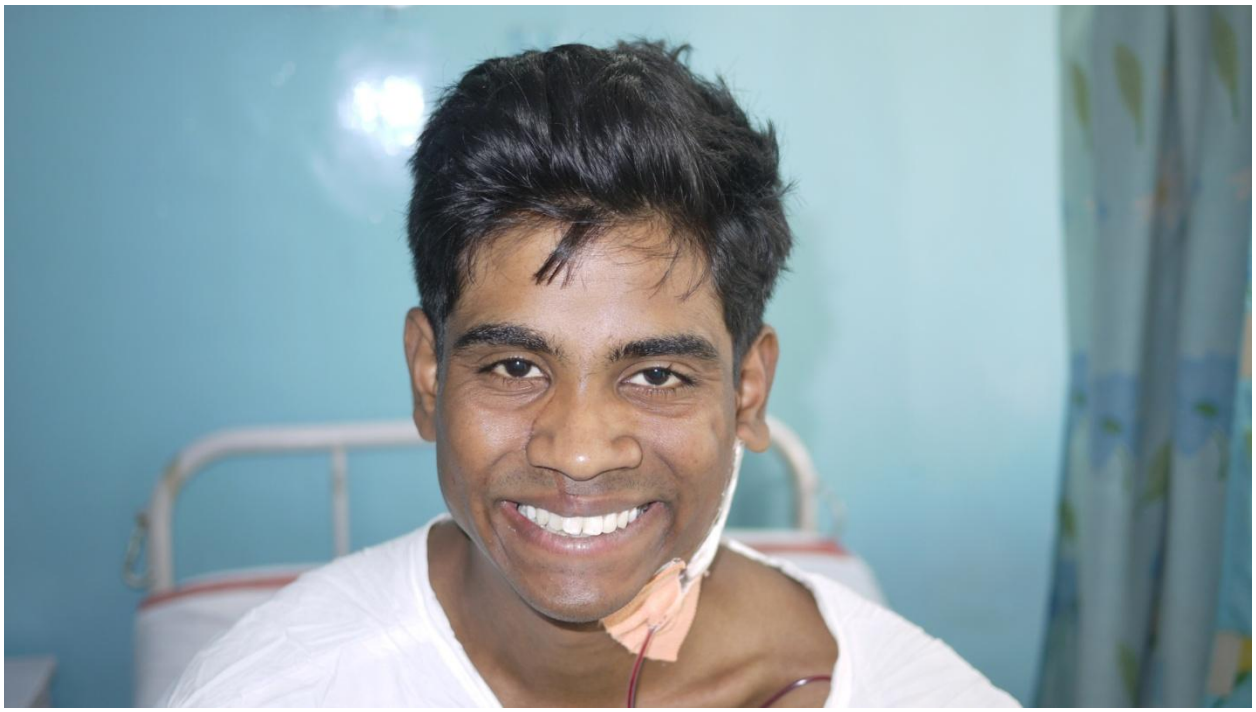

Figure 45: Mandibular function (M = 1)

POST OPERATIVE HOUSE BRACKMANN SCORE

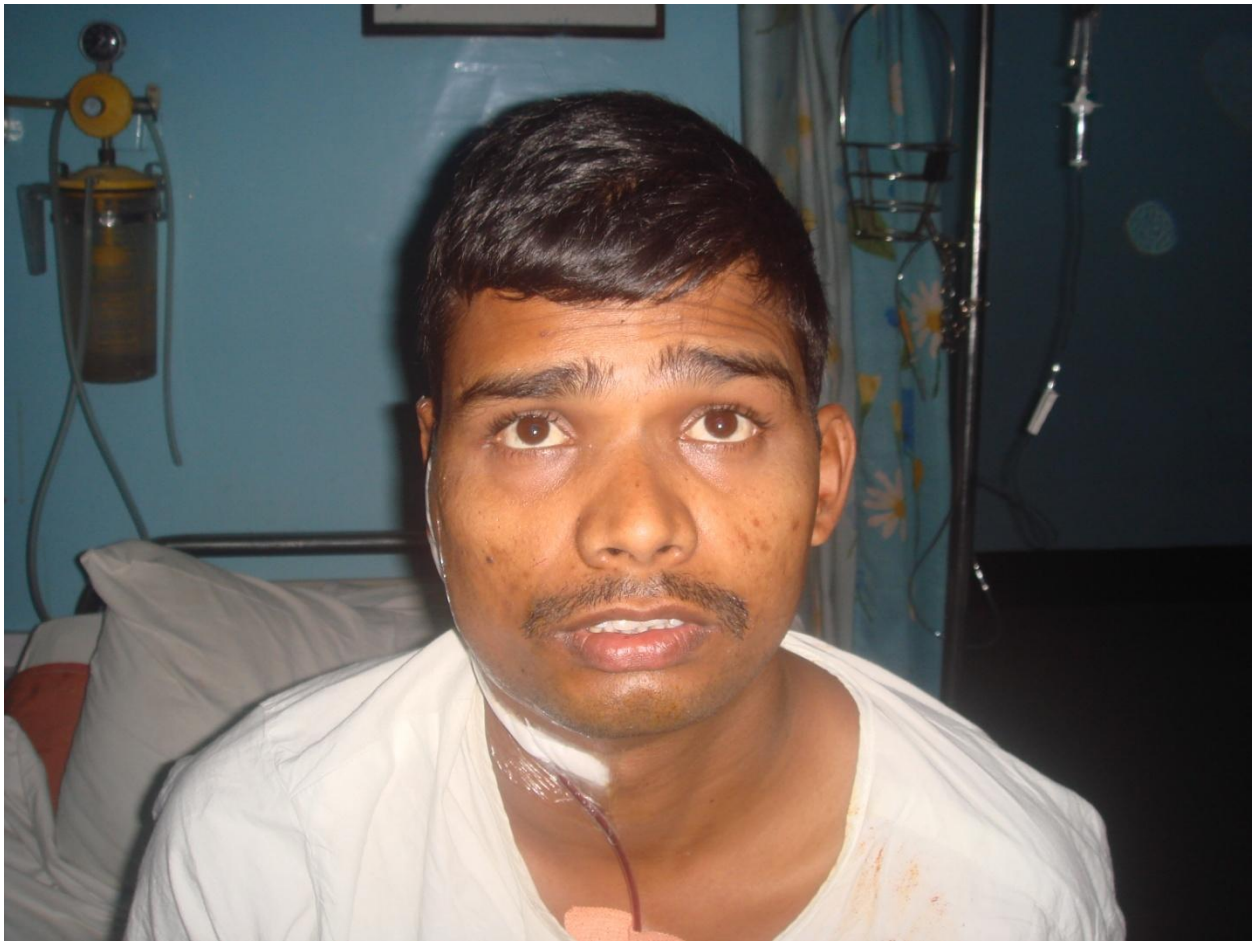

Figure 46: Post Operative House-Brackmann Score (T=2)

POST OPERATIVE HOUSE BRACKMANN SCORE

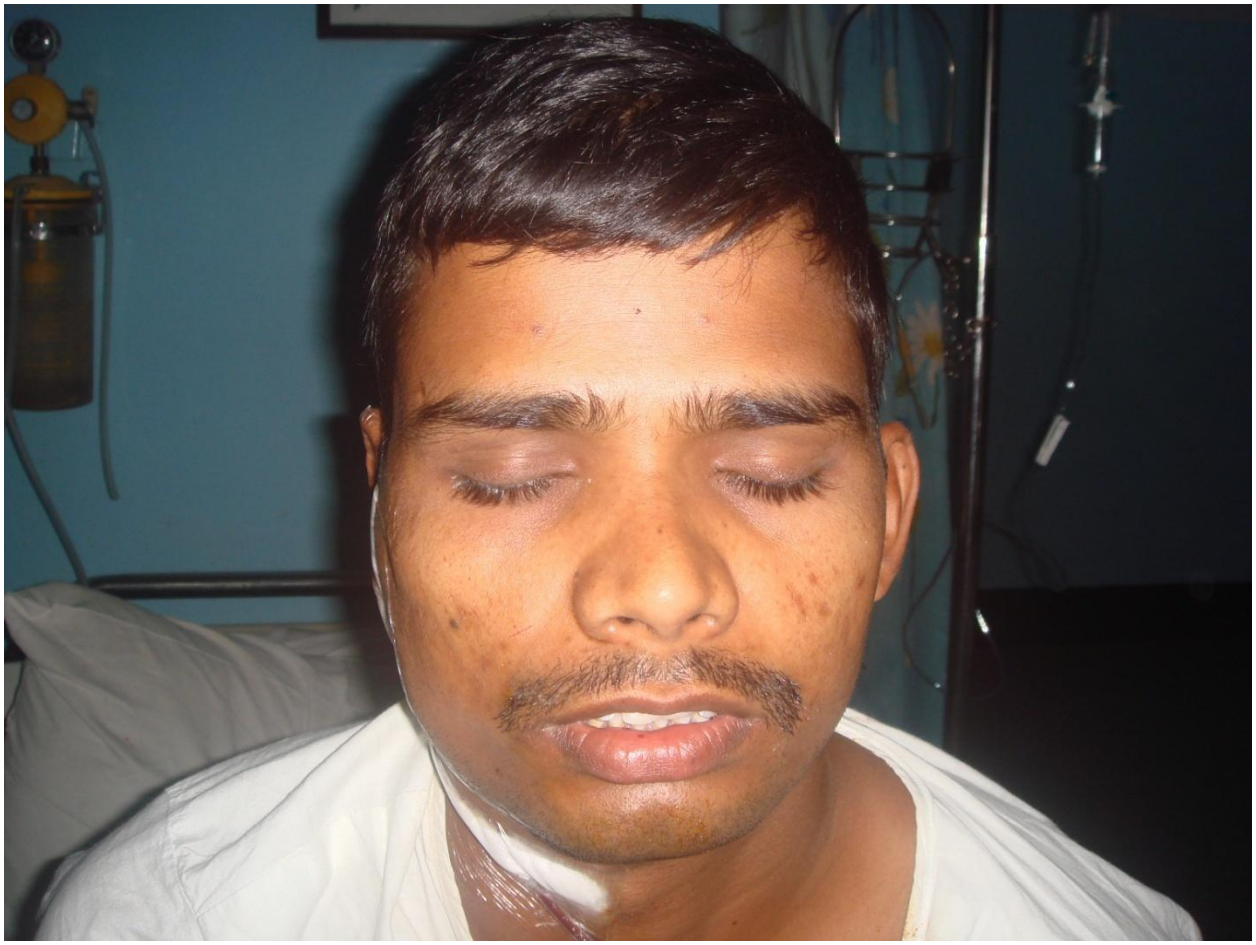

Figure 47: Post operative House-Brackmann Score (Z=1)

POST OPERATIVE HOUSE BRACKMAN SCORE

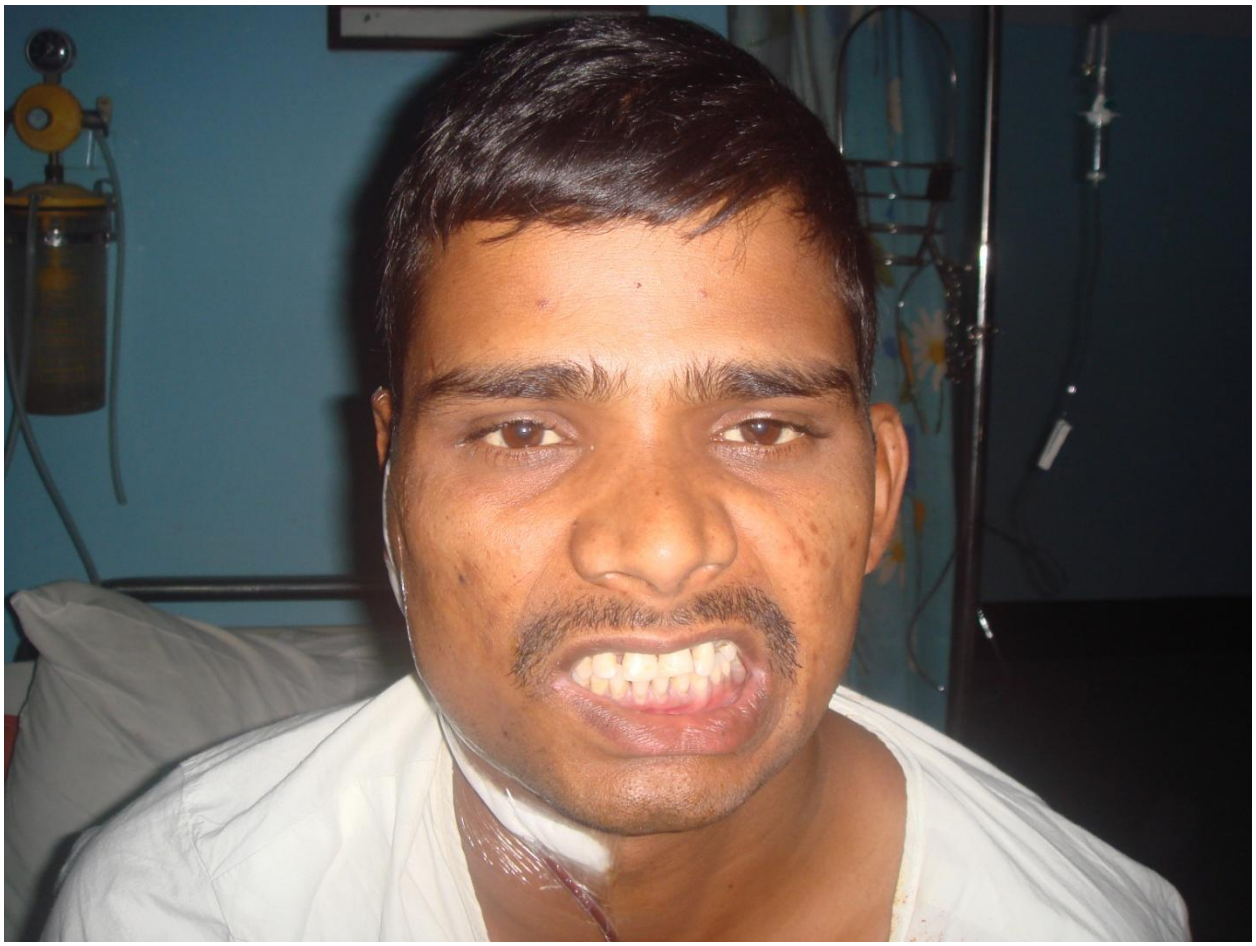

Figure 48: Post Operative House-Brackmann Score (M = 3)

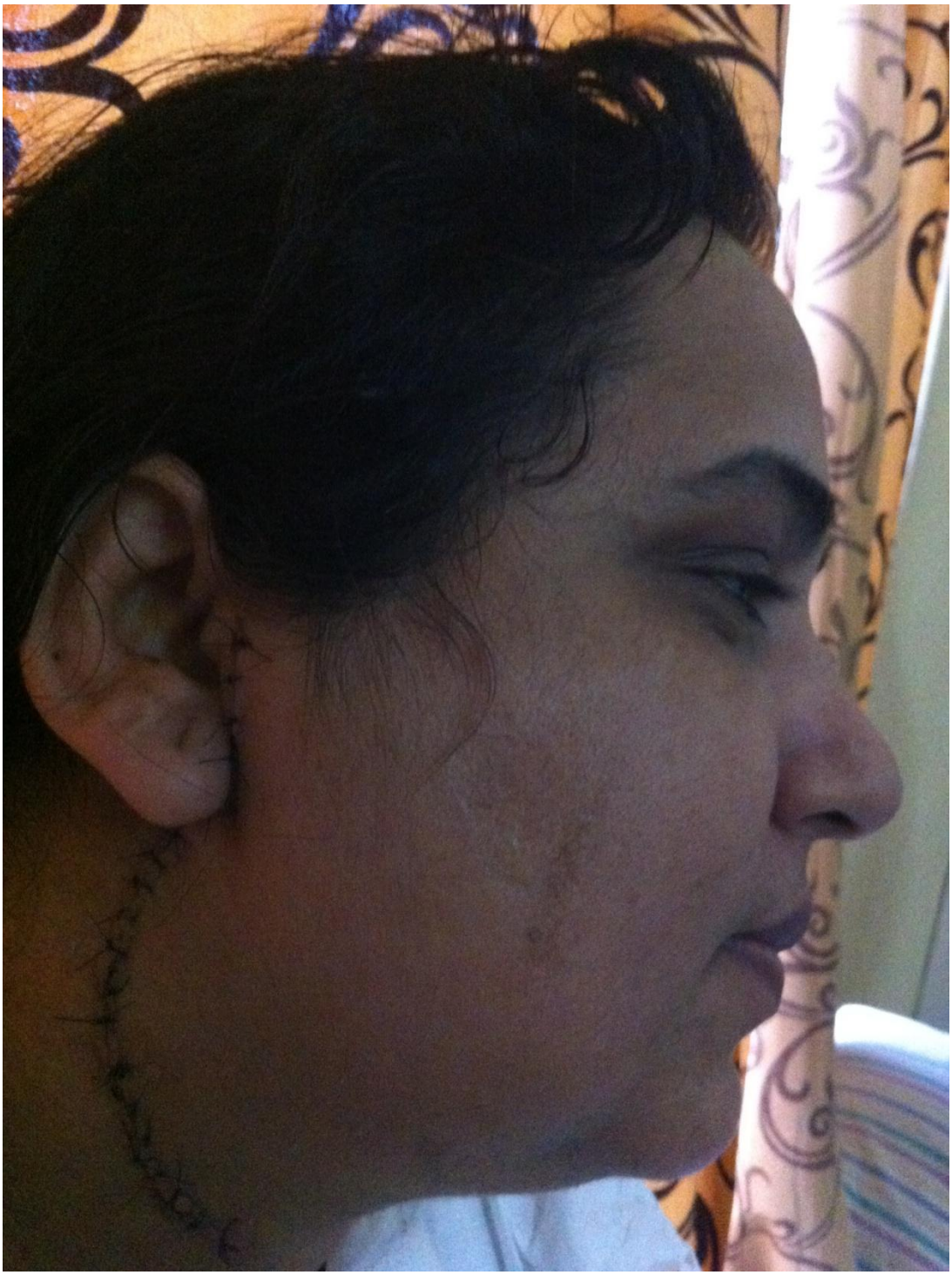

Figure 49: Post operative scar following superficial parotidectomy

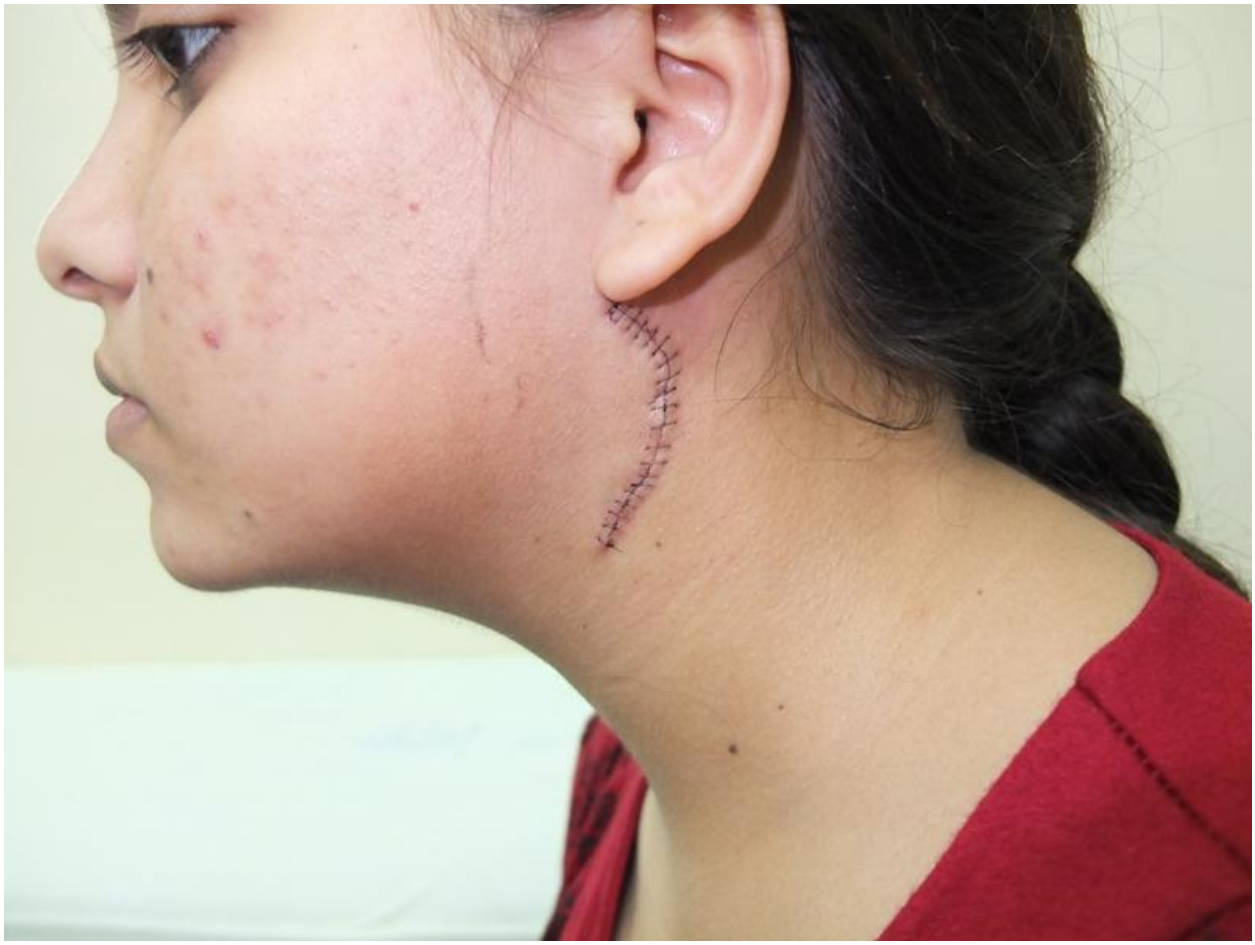

Figure 50: Post operative Scar following extracapsular excision

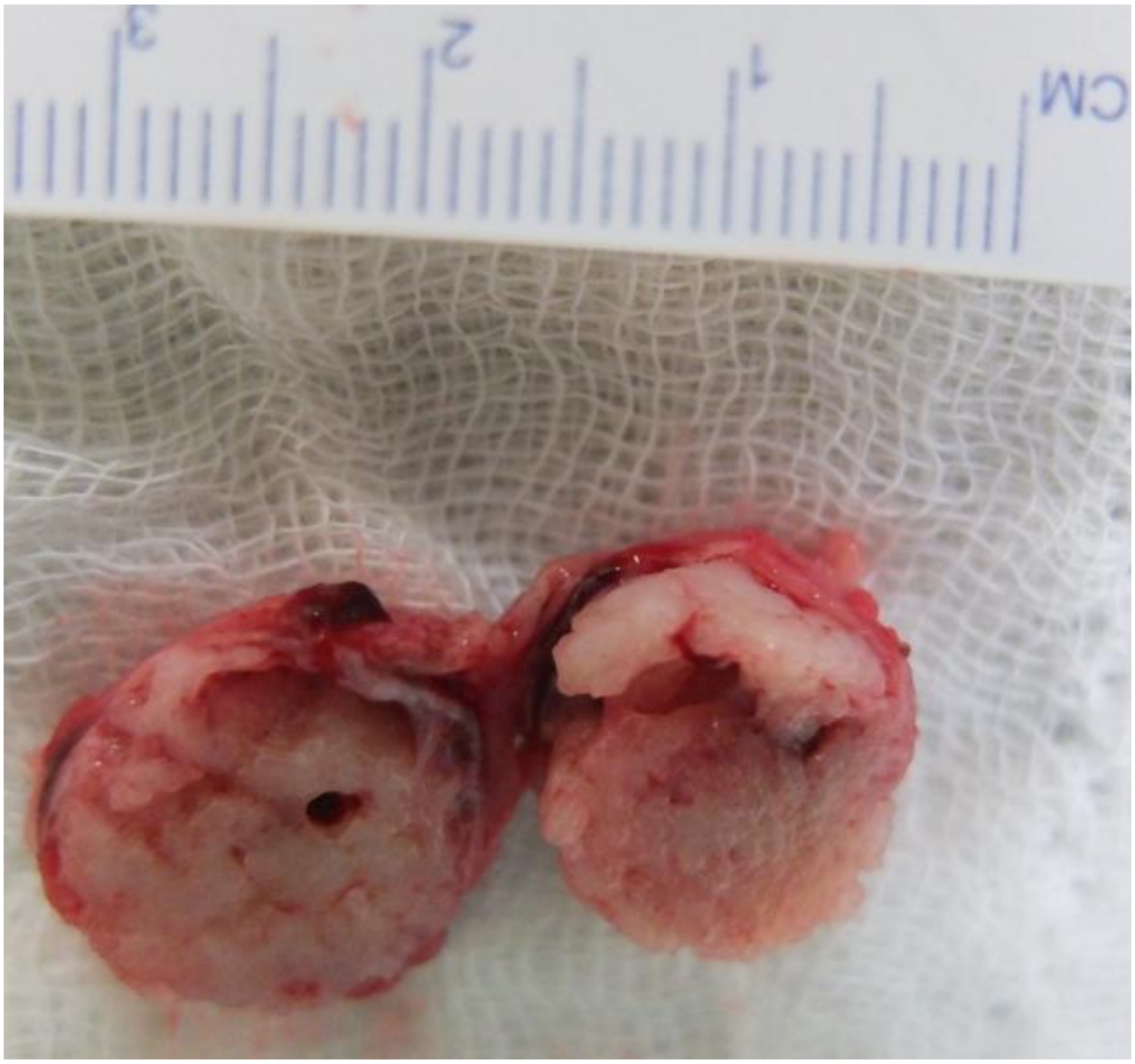

Figure 51: Specimen with intact capsule