COMPARISON OF INTER- AND INTRA-RATER RELIABILITY OF MODIFIED HOUSE BRACKMANN AND SUNNYBROOK FACIAL NERVE GRADING SYSTEMS IN POST PAROTIDECTOMY PATIENTS

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF

M.S. GENERAL SURGERY BRANCH I EXAMINATION OF

THE TAMIL NADU DR. M.G.R. UNIVERSITY,

CHENNAI TO BEHELD IN MAY 2020

Registration no: 221711451

CERTIFICATE

This is to certify that the dissertation entitled “Comparison of inter- and intra-rater reliability of modified House Brackmann and Sunnybrook facial nerve grading systems in post parotidectomy patients” is a *bonafide* original work done by Dr. Amerjeeth J D during his academic term April 2017-March 2020 at Christian Medical College, Vellore as per rules for General Surgery thesis in MS general surgery for examination of The Tamil Nadu Dr. M.G.R. Medical University, Chennai to be held on May 2020. This work was carried under my guidance in the department.

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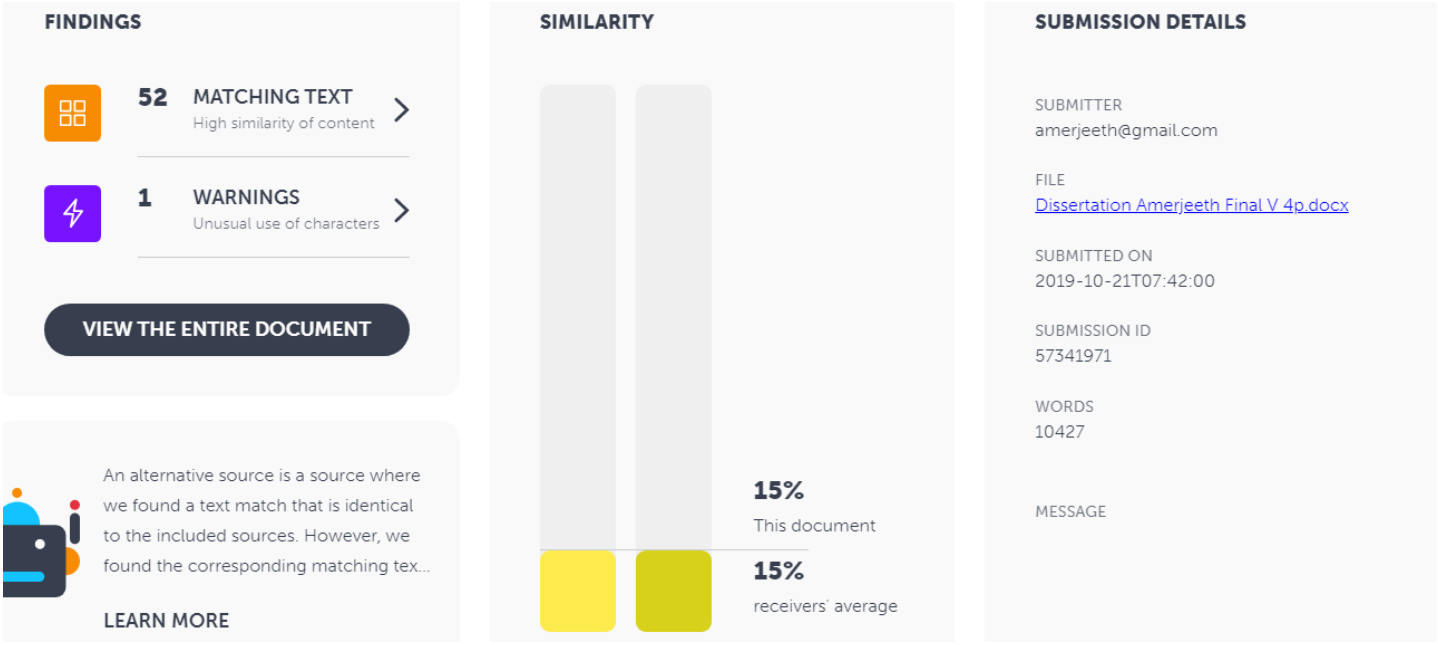

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Dr. Amerjeeth. J. D

October 2019

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ABSTRACT

TITLE OF THE STUDY : Comparison of inter- and intra-rater reliability of modified house brackmann and sunnybrook facial nerve grading systems in post parotidectomy patients

DEPARTMENT : General Surgery Unit 1, CMC Vellore

NAME OF THE CANDIDATE : Dr Amerjeeth J D

DEGREE AND SUBJECT : MS, General Surgery

NAME OF THE GUIDE : Dr Cecil T Thomas

NAME OF THE CO-GUIDE : Dr. Srujan Lam Sharma

Objectives:

1. To compare inter-rater reliability of Modified House Brackmann and Sunnybrook grading systems
2. To compare intra-rater reliability of Modified House Brackmann and Sunnybrook grading systems

Keywords: Facial nerve, facial paralysis, facial palsy, facial grading scales, Modified House Brackmann Grading, Sunnybrook Facial Grading System, inter-rater reliability, intra-rater reliability

Study design: A prospective study, non-randomized

Background:

Parotidectomy is one of the common surgical techniques performed for the tumors in the parotid gland and facial nerve paresis is a common postoperative complication. We need an effective and reliable facial nerve grading system to assess the facial nerve function and to compare the various treatment modalities(1). We have been using a modification of the

House Brackmann score since 2008 to include differential scores for functions of temporal, zygomatic and marginal mandibular nerve. Sunny brook is another well-known subjective grading system for facial nerve paresis.

Since we have been using a unique modification of the House Brackmann score, we wanted to investigate its reliability against the best alternative that is feasible in our clinical scenario. Hence, we propose to study the inter- and intra-rater reliability of the modified House Brackmann and Sunnybrook systems.

Methods: Patients who underwent unilateral nerve conserving parotidectomy under Surgery Unit I were recruited into the study after consenting and were videotaped during their first post-operative visit to the hospital while performing specific facial movements. These videos were shown to 3 assessors for grading the facial nerve function using the Modified House Brackmann (used in CMC, Vellore) and Sunnybrook facial nerve grading systems and were assessed for the inter- and intra-rater reliability of the two systems.

Results:

The overall inter-rater agreement in modified House brackmann score was *excellent* with an ICC of 0.90 (0.84, 0.94). The overall intra-rater reliability of the Modified House brackmann score for the three observers had *excellent agreement* with ICC ranged between 0.84- 0.97. The overall inter-rater agreement in Sunny Brook scoring system was *excellent* with an ICC of 0.90 (0.84, 0.94). The overall intra-rater reliability of Sunny brook grading system had *excellent agreement* with ICC ranged between 0.89- 0.98.

Conclusion:

In our study, we found out that both the Modified House Brackmann score used in our center and the Sunny brook Facial nerve grading systems had excellent inter and intra-rater reliability and there was no statistically significant data to suggest that one

system was superior to the other. The advantage of using Modified House Brackmann score used in our center is that unlike the House Brackmann score it gives 3 individual scores for the individual branches of facial nerve. However, Sunny brook system is a more comprehensive system that can amount for features like synkinesis in late form of facial palsy.

INTRODUCTION

INTRODUCTION

Parotidectomy is one of the common surgical techniques performed for the tumors in the parotid gland and facial nerve paresis is a common postoperative complication. The incidence of the postoperative paresis can vary between 16.5% to 46.1%(2–6) and this can be permanent in 1 to 3.9%(3,6). The marginal mandibular branch of the facial nerve is the most commonly involved in the paresis and the incidence is as high as 48.2% (6). There have been various interventions to decrease the rate of postoperative facial nerve paresis and it is important to be able to accurately assess the effectiveness of various interventions over time or compare different therapeutic strategies. A facial nerve grading system is, then, the basic tool in recording and monitoring postoperative morbidity. We need an effective and reliable facial nerve grading system to compare the various treatment modalities(1).
Many grading systems are used to grade the facial nerve functions and they can be broadly classified into objective and subjective scales. The objective scales used commonly are Burres Fisch(7) and Nottingham System(8). They are also called as linear measurement scales. Recently a computer-based facial nerve grading system (eFACE) has also been tried for the grading of facial nerve function. It uses visual analog scales, and provision of graphic outputs and scores the facial nerve function(9). Objective scales are more reliable but are not commonly used as they are time-consuming, laborious and some are patented and paid applications. Subjective scales have been used widely and can be grouped into gross and regional scales. Gross scales like the House Brackmann, Botmann, Jongkees and May give a composite score of the function of all the branches of the facial nerve while the regional scales, like the Modified House Brackmann, Sunnybrook, Sydney, Yanagihara, Rough facial nerve grading system., etc. give a differential score for the different branches of the facial

nerve. Systemic review of various facial nerve grading systems done by Fattah et.al has described 19 facial nerve grading systems(10). Many journal articles have been published comparing the reliability of various facial nerve grading systems.

The House system of facial nerve grading was introduced in 1983 and it was modified by Brackmann in 1985 and this was adopted the official standard by the American Academy of Otolaryngology-Head and Neck Surgery. It has 6 grades of facial nerve function – grade 1 being a state of no paresis and grade 6 being total paralysis. The House Brackmann score was modified to include regional scores by Vrabec et al(11) in 2009. We have been using a modification of the House Brackmann score since 2008 to include differential scores for functions of temporal, zygomatic and marginal mandibular nerve. Sunny brook is another well-known subjective grading system for facial nerve paresis.

The House Brackmann and Sunnybrook systems have been compared in various trials. Coulson et al, in a study comparing three different systems, demonstrated a good inter-rater reliability for Sunnybrook (intraclass coefficient=0.63) and Sydney systems (intraclass coefficient=0.69). The reliability of the House Brackmann system was described as substantial on the basis of its weighted kappa coefficients(0.67)(12).

Since we have been using a unique modification of the House Brackmann score, we wanted to investigate its reliability against the best alternative that is feasible in our clinical scenario. Hence, we propose to study the inter- and intra-rater reliability of the modified House Brackmann and Sunnybrook systems.

LITERATURE REVIEW

Anatomy

Anatomy of facial nerve:

The facial nerve is the seventh cranial nerve. It supplies the muscles of facial expression. It also transmits the taste sensation from the anterior two-thirds of the tongue. It also innervates posterior belly of the digastric, stylohyoid, and stapedius muscles and gives cutaneous sensation to external ear, aids in salivation and lacrimation. The primary somatomotor cortex of the facial nerve is located in the precentral gyrus of the frontal lobe. Most of these fibers cross to the opposite side. As a result there are crossed and uncrossed fibers in each nucleus and the facial nucleus can be divided into upper part which receives corticobulbar projections bilaterally and later crossed to the upper part of the face including the forehead. The lower part which mainly crossed fibers supply innervation to the lower facial muscles.

The facial nerve exits through the ventral aspects of the pons and enters the temporal bone via the internal auditory canal. It is accompanied by vestibulocochlear nerve and labyrinthine branch of basilar artery. Then it courses through the temporal bone and may be further subdivided into 4 segments: the meatal, the labyrinthine, the tympanic, and the mastoid segments. The labyrinthine segment is very short and ends where the facial nerve forms a bend known as the geniculum of the facial nerve ("genu" meaning knee), which contains the geniculate ganglion for sensory nerve bodies. In the temporal part of the facial canal, the nerve gives rise to the stapedius and chorda tympani. Then it emerges through the stylomastoid foramen and enters the parotid gland and gives its terminal branches.(13)

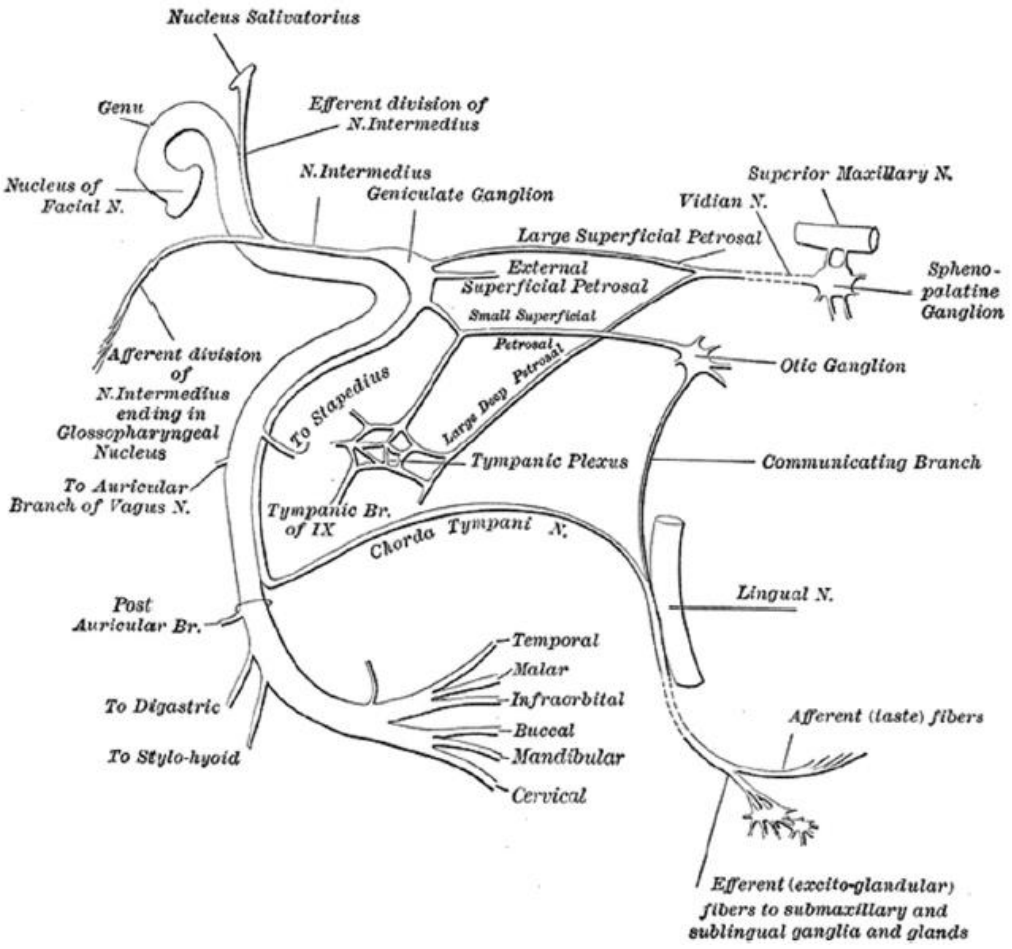


Figure 1:Facial nerve course and its branches

Ref- Gray H. Gray's anatomy: anatomy of the human body. 20th edition

Anatomy of parotid gland:

The parotid gland and facial nerve have a unique anatomic and functional relationship. In order to avoid any damage to the facial nerve one needs to have a thorough knowledge about the parotid gland and its relationship with the facial nerve. The parotid gland is the largest major salivary gland. It is located in the preauricular region and spans from the masseter to the mastoid process. The facial nerve enters the parotid gland and divides it into superficial and deep lobes. The deep lobe is located medial to the facial nerve.(14) This plane between superficial and deep lobe is also called as fasciovenous plane of Patey.(15)

Superiorly it extends up to zygomatic arch and inferiorly the tail of the parotid gland extends to the sternocleidomastoid muscle. The parotid duct which is also called the Stenson's duct emerges at the anterior border of the gland and it passes over the masseter muscle and passes through the buccinator muscle, opening into the vestibule of the mouth, opposite to the occlusal surface of the upper second molar tooth. The parotid fascia, or parotid masseteric fascia, forms a dense inelastic capsule over the parotid gland and deeply covers the masseter muscle. Arterial supply is from the external carotid artery and a specific branch of the artery, the transverse facial artery. Venous drainage is via a plexus of veins that drains into the retromandibular vein. The greater auricular nerve and mandibular nerve are also in close proximity to the gland. The greater auricular nerve provides sensation to posterior portion of the pinna and the lobule and if injured during parotidectomy can result in long-term sensory loss. Mandibular nerve innervates the skin and scalp immediately anterior to the ear.

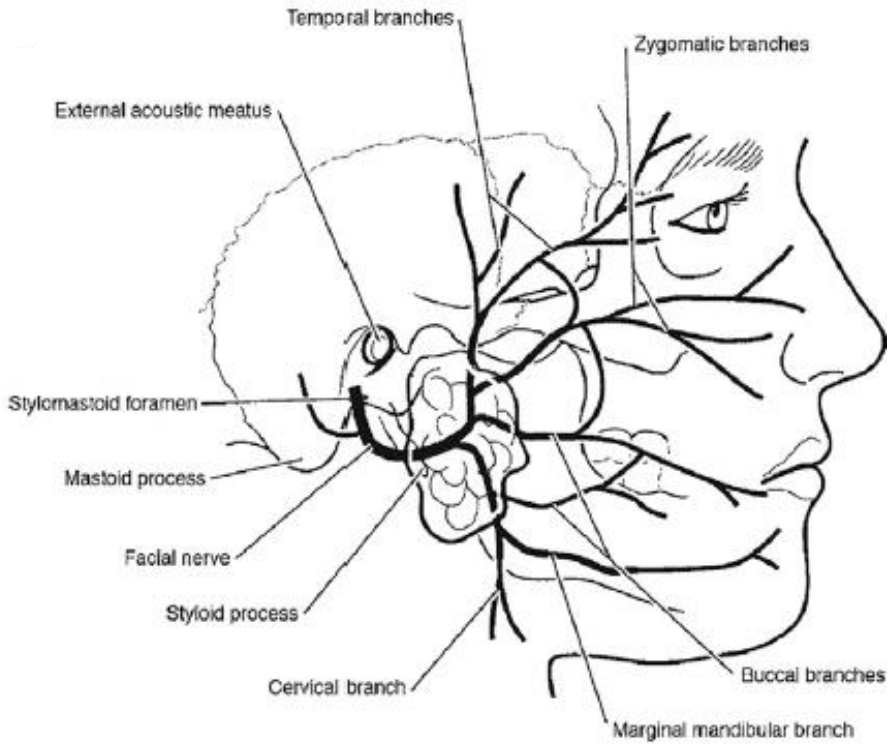


Figure 2: Facial nerve branches in face

Ref- Holsinger FC. Anatomy, function, and evaluation of the salivary glands. Springer; 2007

Facial Nerve and its branches in Parotid:

It divides into 2 trunks: an upper trunk that gives rise to the frontal, zygomatic, and buccal branches, and a lower trunk that terminates in the marginal mandibular and cervical branches. The frontal branch supplies the frontal belly of the occipitofrontalis muscle, the orbicularis oculi, the corrugator supercilii, and the anterior and superior auricular muscles. Zygomatic branch supplies zygomatic, orbital, and infraorbital muscles. The buccal branch accompanies the Stensen's duct to supply the buccinator, upper lip, and nostril muscles. The marginal mandibular branch innervates the depressor labii inferioris, depressor anguli oris and mentalis. (16) (17)

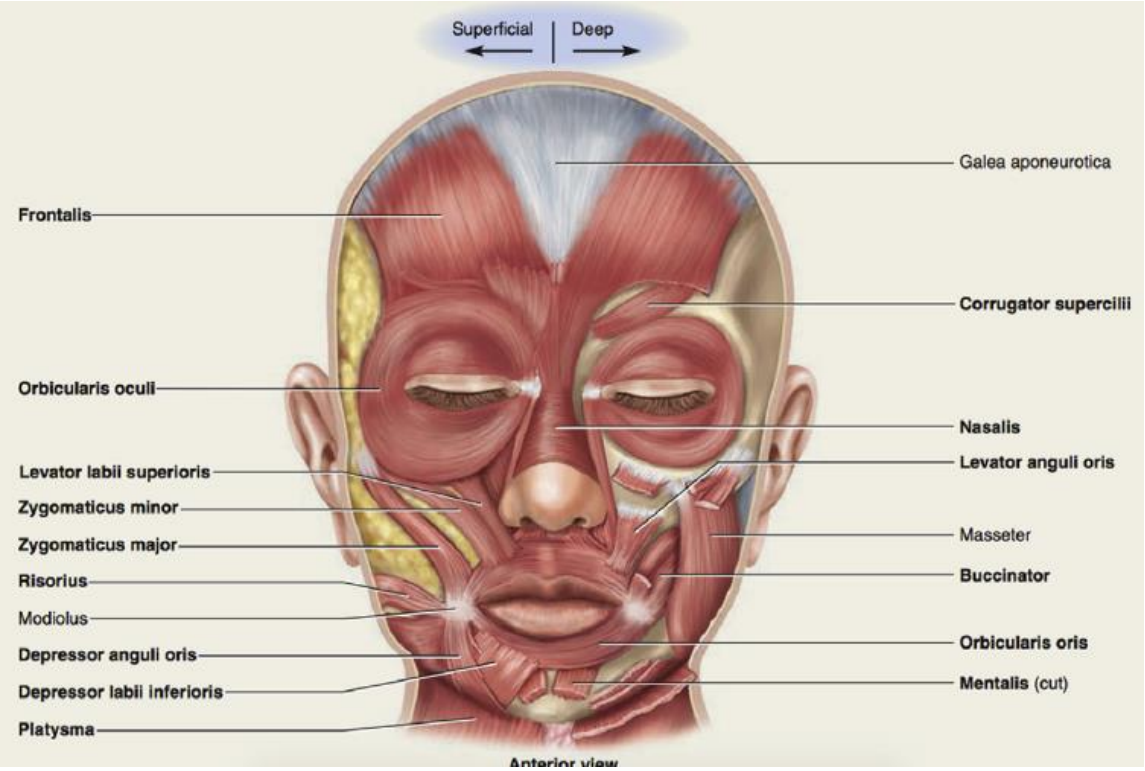


Figure 3: Muscles of facial expression

Ref- Otolaryngologic Clinics of North America Volume 49, Issue 2, April 2016, Pages 273-284

All muscles of facial expression are innervated on their deep surface except for the mentalis, levator anguli oris, and buccinators muscles. Interconnections exist between the branches with the highest frequency of collateral branches between the zygomatic and buccal branches. This might be the reason for the higher rate of recovery of function in distal injuries in this region, as well as the high rate of synkinesis that accompanies recovery of a proximal injury. (18,19)

Parotid gland neoplasms:

Parotid neoplasms account for 80% of salivary neoplasms. Of parotid masses, 75% are neoplastic; the remaining 25% are non-neoplastic infiltrative processes, such as cysts and inflammation. Benign neoplasms account for 70-80% of all parotid tumors.

Classification of benign parotid neoplasms:

1. Mixed tumor (pleomorphic adenoma)
2. Warthin tumor (papillary cystadenoma lymphomatosum)
3. Oncocytoma
4. Monomorphic tumors
5. Sebaceous tumors
6. Benign lymphoepithelial lesion
7. Papillary ductal adenoma (papilloma)

1. <u>Benign pleomorphic adenoma or benign mixed tumor</u>

   It is the most common parotid neoplasm accounting for almost 80%. It is a result of proliferation of epithelial and myoepithelial cells of the ducts and an increase in stromal components. It is a slow-growing, lobular tumor, and is not well encapsulated. Malignant changes (carcinoma ex-pleomorphic adenoma) can occur in 2-10% of adenomas observed for long periods, with adenocarcinoma occurring most frequently.
2. <u>Warthin tumor (papillary cystadenoma lymphomatosum or adenolymphoma)</u>

   It is the second most common benign parotid tumor (5%). It is the most common bilateral benign neoplasm of the parotid. There is a marked male predominance. This occurs later in life (sixth and seventh decades) as a lymphocytic infiltrate and cystic epithelial proliferation. There may be

representative of heterotopic salivary gland epithelial tissue trapped within intra parotid lymph nodes. The incidence of bilaterality and multicentricity is in the region of 10%.

3. Oncocytoma

   This tumor accounts for 1% of all salivary gland tumors. It usually comprises of large oxyphilic cells (oncocytes). There may be multiple swellings within the parotid.

Investigations:

1. Hematologic and serologic tests are of little importance in the workup of salivary gland tumors.
2. Plain radiography findings can help the clinician exclude calculi.
3. Ultrasound can be used to differentiate between benign and malignant neoplasms. It also helps in delineating the anatomy of a lesion, whether it is a parotid or a peri parotid lesion. It also demonstrates the degenerative changes in the swelling. Other features including tumor size, shape, border, echogenicity, and homogeneity, the presence of a cystic area, acoustic enhancement, and the grade and distribution of vascularization can be assessed reliably. Based on these we can differentiate pleomorphic adenomas from Warthin's parotid tumors
4. CT scan is almost 100% sensitive in detecting a salivary gland mass, but it cannot differentiate between a benign and a malignant mass. It is most helpful in specifying the size and anatomic extent of a tumor.

5. MRI is superior in demonstrating benign tumors of the parotid gland because of its greater contrast than CT scan. It helps in delineating the anatomy and helps in differentiating benign and malignant lesions.
6. Biopsy/Cytology

   Fine-needle aspiration may be a valuable pre-treatment diagnostic test. Its overall accuracy is more than 96%, with a sensitivity for benign tumors of 88-98% and a specificity of 94%. Its sensitivity in detecting malignant tumors ranges from 58-96%, and its specificity is 71-88%. The use of Frozen sections is controversial since the diagnosis depends on the experience of the pathologist with regard to salivary gland tumors.

   Hence preoperative fine-needle aspiration cytology is recommended since it can change the clinical approach in up to 35% of patients. (20)

Operative management:

Superficial parotidectomy is the treatment of choice in most of the benign neoplasms as most of them involve the superficial lobe. During the surgery it is important to delineate the anatomy and every effort should be taken to preserve the facial nerve and avoid injury to the same. Deep lobe tumors demand total conservative parotidectomy, which involves removal of both lobes of the parotid gland with preservation of the facial nerve. Other options for benign tumors of the parotid are extracapsular dissection, adequate parotidectomy andenucleation,. Enucleation of the tumors is generally avoided in all but some Warthin tumors and intra-parotid lymph nodes as it greatly increases the likelihood of recurrence (up to 80%) and nerve damage(20).

Cristofaro et al conducted a study including 198 patients with pleomorphic adenomas of the parotid gland, including 153 patients who underwent extracapsular dissection

(mean follow-up 61.02 months) and 45 who underwent superficial parotidectomy (mean follow-up 66.4 months). They concluded that extracapsular dissection is the treatment of choice for superficial parotidectomy as it was associated with a significantly lesser rate of transient facial nerve injury and facial paralysis when compared with the other procedure.(21)

Radical parotidectomy is the surgical option for malignant tumors with facial nerve involvement. If other structures, including mandible, masseter and mastoid process are involved then an extended radical parotidectomy, which is an en bloc resection of all these structures, would be necessary.

Parotidectomy and facial nerve paresis:

Among the various causes of facial nerve paresis parotidectomy is one of the common surgical and iatrogenic causes. It is one of the most dreaded and significant complications in parotid surgeries. Facial nerve dysfunction occurs up to 65% of parotidectomy patients and permanent facial nerve weakness in approximately 4% to 7% of cases.(22) In our center, the incidence of facial nerve paresis is around 25-30%. Dysfunction of the 7^{th} nerve occurs most frequently to the marginal mandibular branch—64.1 %, followed by buccal—20.5 %, zygomatic and temporal branches at 7.7 %.(23) Identification of the facial nerve trunk is essential during surgery of the parotid gland. It can be done in antegrade or retrograde manner.

Individuals with facial paralysis not only suffer from asymmetry of their face, but also have difficulty in performing activities such as eating, drinking, and are unable to pronounce specific words or sounds. Apart from the cosmetic defect (facial contortion), the most troublesome for the patient are paresis of the zygomatic branch

(inability to close the eye completely and corneal drying) and the marginal mandibular branch (difficulty in eating, drinking, and speaking). Some people find themselves having degraded self-image and loss of self-esteem and self-confidence. Most experience at least transient phase of depression, and social interaction and occupational status can be affected. People who work in cine industries, modeling, newscasters, sales representatives, etc face more difficulty in continuing in their professions due to dysmorphic facies due to facial nerve paresis. So facial nerve paralysis not only affects socialization but also career and income

Landmarks for identification of distal facial nerve branches

Because of the high morbidity caused by facial paresis, the identification of the facial nerve is essential during surgery of the parotid gland in order to prevent injury to it. Numerous landmarks have been researched and used. Most commonly used anatomical landmarks to identify facial nerve trunk are stylomastoid foramen, tympanomastoid suture (TMS), posterior belly of digastric (PBD), tragal pointer (TP), mastoid process and peripheral branches of the facial nerve(17)

- *Tragal "pointer" of Conley:* Reflection of parotid tissue from the tragal cartilage reveals a blunt pointed shape in its medial aspect, which is called the "pointer". Facial nerve usually lies approximately 1 cm deep and slightly anterior and inferior to this "pointer". It is considered as the most important surgical landmark to identify facial nerve during parotid surgeries(24)
- *Posterior belly of digastric*: Facial nerve lies approximately 1 cm deep to the medial attachment of the posterior belly of digastric muscle to the digastric groove of mastoid bone

- *Tympanomastoid suture/fissure*: facial nerve lies 6-8 mm deep to this suture. The tympanomastoid suture is situated at the apex of vagino-mastoid angle or valley of nerve where the mastoid and the vaginal portion of tympanic ring of external ear canal (temporal bone) meets(24–26)

Table 1: Facial nerve branches- Anatomical location:

Branch	Location
Frontal	Follows a line from 0.5 cm below the tragus to 1.5 cm above the lateral brow, multiple rami present crossing central zygomatic arch.
Zygomatic/buccal	Identified at the midway point on a line drawn from the root of the helix and the lateral commissure of the mouth.
Marginal mandibular	Closely associated with the inferior border of the mandible where it crosses the facial vessels. (17)

Facial nerve monitoring

In view of safe surgery and to prevent facial nerve injuries during surgery various facial nerve monitoring techniques are used. Evoked electromyography was used to identify facial nerve in order to prevent facial nerve damage during surgeries. (27) This technique monitors muscles innervated by facial nerve at risk during surgery. Mechanical trauma to the motor nerves during surgeries produces high-frequency electrical impulses also called neuro tonic discharges. This will alert and help the surgeon when they are dissecting in close proximity with the facial nerve. (28)

A study conducted by Meier et al, in 2006 in 37 patients for continuous intraoperative facial nerve monitoring in predicting post-operative injury in parotid surgeries concluded that EMG monitoring is not reliable in predicting postoperative facial nerve injury. And therefore judicious use is warranted. (29)

A systemic review and meta-analysis done by Soot et al, in facial nerve monitoring, reviewed 1414 publications, 7 articles met inclusion criteria, with a total of 546 patients included in the final meta-analysis. FNM had a 47% decrease in the risk of facial nerve dysfunction in the immediate postoperative period but failed to demonstrate a difference in permanent weakness. The percentage of risk reduction of facial nerve weakness with nerve monitoring patients over control subjects was 11.7%, translating into 9 patients required to undergo intraoperative FNM to prevent 1 incidence of immediate postoperative facial nerve weakness. It concluded that in primary cases of parotidectomy, intraoperative FNM decreases the risk of immediate postoperative facial nerve dysfunction but does not appear to influence the final outcome of facial nerve weakness (22)

Facial Nerve grading systems:

Rehabilitation is necessary for patients to regain their normal lives in the social, educational, and occupational life. In facial rehabilitation, it is the most important part is to know how much a patient suffers from facial paralysis, and a comprehensive standard measurement of the degree of facial paralysis is required. And also it is important to accurately assess the effectiveness of various interventions used to improve facial nerve function or compare different therapeutic strategies. A facial nerve grading system is then, the basic tool in recording and monitoring

postoperative morbidity. We need an effective and reliable facial nerve grading system to compare the various treatment modalities(1)' (30)

At present, there is no gold standard in facial nerve grading system. The perfect scale (i.e., cost-effective, fast, minimally invasive, sensitive, specific, objective, and quantitative) does not exist with current technology.

So the ideal characteristics of a facial nerve grading should be:

- It provides regional scoring of facial function.
- Performs static and dynamic measures.
- Examines secondary sequelae of facial palsy (e.g., synkinesis).
- Yields reproducible results with low interobserver and intraobserver variability.
- Sensitive to track changes over time and following interventions.
- Convenient for clinical use. (31)

Many grading systems are used to grade the facial nerve functions and they can be broadly classified into objective and subjective scales. Systemic review of various facial nerve grading systems done by Fattah et.al has described 19 facial nerve grading systems. (31)

Subjective Assessment:

They are the traditional approaches in which the clinician asks the patient to perform some activities such as puckering, closing the eyes, and showing the teeth and grades the weakness. Subjective scales can be subclassified into gross and regional scales. Gross scales include House Brackmann, Botmann and Jongkees, May,etc. Some examples of regional scales are House Brackmann (Regional), Sunnybrook, Sydney,

Yanagihara, Rough facial nerve grading system. They are more accurate and specific than gross sales.

House brackmann score(32)

The House system of facial nerve grading was introduced in 1983 and it was modified by Brackmann in 1985 and this was adopted the official standard by the American Academy of Otolaryngology-Head and Neck Surgery. It has 6 grades of facial nerve function – grade 1 being a state of no paresis and grade 6 being total paralysis.

Original House Brackmann system:(33)

Table 2: Original House Brackmann system

GRADE	Gross	Resting tone	Fore head	Eye closure	Mouth
I	Normal function				
II	Slight	Normal	Moderate to good	Minimal effort	Slight asymmetry
III	Obvious	Normal	Slight to moderate	Full effort	Slightly weak
IV	Disfiguring	Normal	None	Incomplete	Asymmetry
V	Barely perceptible	Asymmetric	None	Incomplete	Slight movement
VI	Total paralysis-No movement				

Modified House Brackmann scoring system: (34)

The House Brackmann score was modified to include regional scores by Vrabec et al, in 2009. (35) One prospective study conducted in 2011 showed a moderate inter-rater agreement for the original HB score (Kapp*a*=0.58) and substantial agreement for the modified House Brackmann scoring system(Kappa=0.63).(36)

Grade I - Normal

Normal facial function in all areas

Grade II - Slight Dysfunction

Gross: slight weakness noticeable on close inspection; may have very slight synkinesis

At rest: normal symmetry and tone

Motion: forehead - moderate to good function; eye - complete closure with minimum effort; mouth - slight asymmetry.

Grade III - Moderate Dysfunction

Gross: obvious but not disfiguring difference between two sides; noticeable but not severe synkinesis, contracture, and/or hemifacial spasm.

At rest: normal symmetry and tone

Motion: forehead - slight to moderate movement; eye - complete closure with effort; mouth - slightly weak with maximum effort.

Grade IV - Moderate Severe Dysfunction

Gross: obvious weakness and/or disfiguring asymmetry

At rest: normal symmetry and tone

Motion: forehead - none; eye - incomplete closure; mouth - asymmetric with maximum effort.

Grade V - Severe Dysfunction

Gross: only barely perceptible motion

At rest: asymmetry

Motion: forehead - none; eye - incomplete closure; mouth - slight movement

Grade VI - Total Paralysis

No movement

In Christian medical college, Vellore, we follow a modified House Brackmann score since 2008, which has simplified the grades to include differential scores for functions of temporal, zygomatic and marginal mandibular nerve.

Modified House Brackmann score used in CMC, Vellore

The following 3 regions are scored separately:

A: Temporal branch function

B: Zygomatic branch function

C: Rami mandibular function

The grading for the above-mentioned areas is as follows

GRADE I: Normal (100%)

- A: Able to frown properly
- B: Normal eye closure
- C. Symmetrical angles of mouth

GRADE II: Slight weakness on close inspection, not obvious at rest (80%)

- A: Good movement on frowning
- B: Infrequent blinking & lid lag
- C: Slight asymmetry of mouth and normal nasolabial fold

GRADE III: Obvious at rest, not disfiguring (60%)

- A: Moderate movement on frowning
- B: Complete eye closure with effort
- C: Slightly weak with maximal effort and depressed nasolabial fold

GRADE IV: Obvious and disfiguring (40%)

- A: Slight movement of forehead
- B: Cornea covered with maximal effort
- C: Moderately weak with maximal effort and absent nasolabial fold

GRADE V: Barely perceptible movements (20%)

- A: Flicker of movement of forehead
- B: Cornea exposed with maximal effort
- C: Flicker of movement with maximal effort

GRADE VI: Total paralysis (0%)

- A: No forehead movement
- B: No eye closure with maximal effort
- C: No movement of mouth

Demerits:(37)

- It does not adequately discriminate between clinically different recoveries.
- Secondary deficits are not adequately addressed.
- Interobserver variability is too high.
- It is inaccurate in the setting of differential facial movements.
- It is inadequate for surgical repair of the nerve.

Sunnybrook facial nerve grading system:

The Sunnybrook Facial Grading Scale is a regional weighted system based on the evaluation of facial symmetry at rest, voluntary facial movements, and synkinesis; each is evaluated on point scales, and a composite score (0 to 100) is generated as a continuous scale. It is different from HBS in that it also takes into consideration the resting symmetry, synkinesis, and a few more specific facial movements and is on a continuous scale. Overall it gives a composite score which is a difference of resting symmetry and synkinetic scores from voluntary scores. The best score is 100, with no paresis and 0 being total paralysis(38)It was considered to be the most ideal of systems by Fattah et al. .(31)

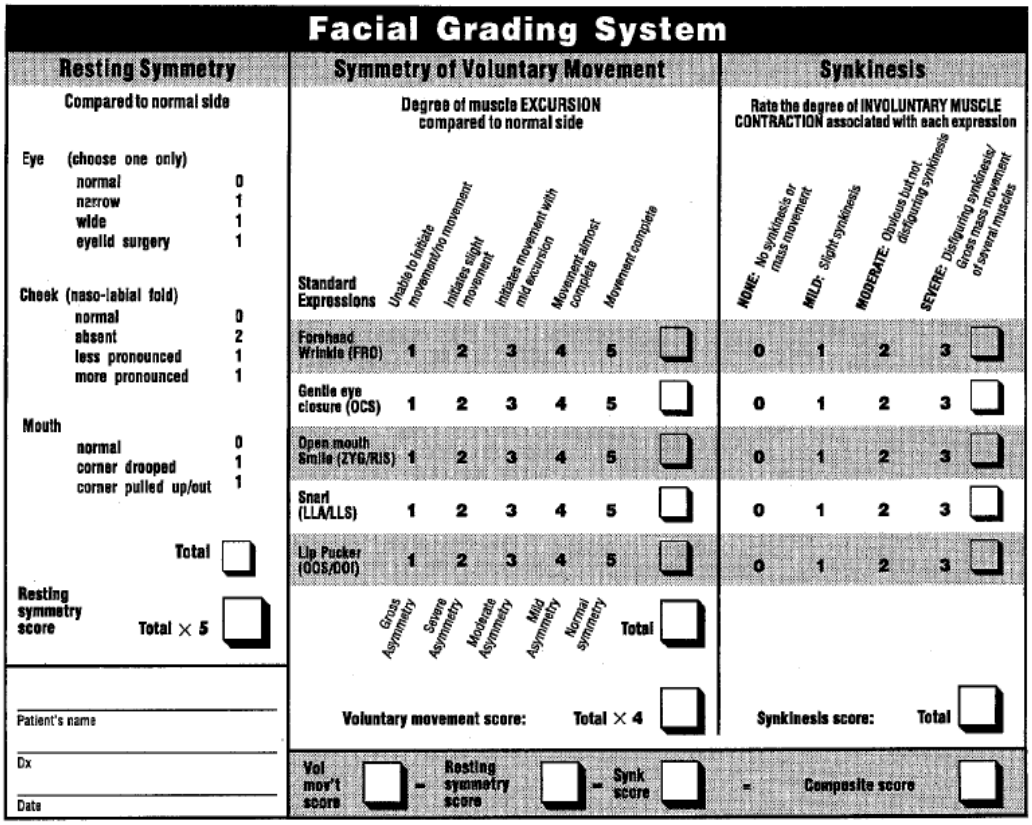


Figure 4: Sunny brook facial nerve grading system

Ref: Ross BG et al., Development of a sensitive clinical facial grading system. Otolaryngol Head Neck Surg. 1996 Mar;114(3):380-6

Criteria for Evaluating Face for Sunnybrook System:

At Rest (compare to normal side)

Eyes (choose one)

- Normal (0)
- Eyelids expose more of the iris than other side [Wide 1]
- Eyelids expose less of iris than other side, like squinting a little [Narrow 1]

Nasolabial fold (choose one)

- Normal (0)
- Fold less obvious than other side [Less pronounced 1]
- Fold not seen [Absent 2]
- Fold deeper than other side [More pronounced 1]

Mouth (choose one)

- Normal (0)
- Corner of mouth sagging down more than other side [Corner drops 1]
- Corner of mouth pulled up more than other side [Corner pulled up 1]

Voluntary motion (compare to normal side)

Brow lift: Raise eyebrows to create horizontal wrinkles in forehead (choose one)

- Normal (5)
- Forehead wrinkles well; hard to see difference [Almost Normal 4]
- Obvious movement, but not almost normal [Moderate 3]
- Forehead barely moves; hard to see movement [Slight movement 2]
- No forehead movement [No movement 1]

Gentle eye closure (choose one)

- Eyelids close completely and at same speed [Normal 5]

- Eyelids close completely, but at slower speed [Almost normal 4]
- Eyelids not close leaving only narrow slit of eyeball exposed [Moderate 3]
- Eyelids not close–half-close [Slight movement 2]
- Eyelids not close–more than half eyeball exposed [No movement 1]

Snarl: (choose one)

- Normal (5)
- Almost equal to the other side; hard to see difference[Almost normal 4]
- Obvious movement, but not almost normal [Moderate 3]
- Barely moves; hard to see movement [Slight movement 2]
- No movement [No movement 1]

Open-mouth smile (choose one)

- Normal (5)
- Almost equal to the other side; hard to see difference[Almost normal 4]
- Obvious movement, but not almost normal [Moderate 3]
- Barely moves; hard to see movement [Slight movement 2]
- No movement [No movement 1]

Lip Pucker: Pucker lips like going to whistle. Look at involved side; compare with normal (choose one)

- Normal (5)
- Almost uniformly symmetrical; hard to see difference [Almost normal 4]

- Obviously asymmetrical; protrusion of lips on involved side [Moderate 3]
- Slight flat movement of commissure, but no protrusion [Slight movement 2]
- No movement [No movement 1]

Synkinesis: Involuntary muscle contraction greater than normal side in the facial region distant to the requested movement region. Compare to normal side.

Table 3: Sunny brook synkinesis score

Requested voluntary movement	***Involuntary synkinetic movement (greater than normal side)***
Brow lift	Eye and/or mouth region • None (0) • Slight must look closely to see (1) • Moderate, easy to see (2) • Severe, grossly disfiguring–rare (3)
Gentle eye closure	Brow and/or mouth region • None (0) • Slight must look closely to see (1) • Moderate, easy to see (2) • Severe, Grossly disfiguring—rare (3)

Snarl	Brow, eye, and/or mouth region • None (0) • Slight must look closely to see (1) • Moderate, easy to see (2) • Severe, grossly disfiguring–rare (3)
Open-mouth smile	Brow and/or eye region • None (0) • Slight must look closely to see (1) • Moderate, easy to see (2) • Severe, Grossly disfiguring—rare (3)
Lip pucker	Brow and/or eye region • None (0) • Slight must look closely to see (1) • Moderate, easy to see (2) • Severe, grossly disfiguring–rare (3)

Facial Nerve Grading System 2.0(35)

FNGS 2.0 incorporates regional scoring of facial movement, providing additional information while maintaining agreement comparable to the original scale

Table 4: Facial Nerve Grading System 2.0

Score	Brow	Eye	Nasolabial fold	Oral
1	Normal	Normal	Normal	Normal
2	Slight weakness >75% of normal	Slight weakness >75% of normal Complete closure with mild effort	Slight weakness >75% of normal	Slight weakness >75% of normal
3	Obvious weakness >50% of normal Resting symmetry	Obvious weakness >50% of normal Resting symmetry Complete closure with maximal effort	Obvious weakness >50% of normal Resting symmetry	Obvious weakness >50% of normal Resting symmetry
4	Asymmetry at rest <50% of normal	Asymmetry at rest <50% of normal Cannot close completely	Asymmetry at rest <50% of normal	Asymmetry at rest <50% of normal
5	Trace movement	Trace movement	Trace movement	Trace movement
6	No movement	No movement	No movement	No movement

Secondary movement (global assessment)

Score	Degree of movement
0	None
1	Slight synkinesis; minimal contracture
2	Obvious synkinesis; mild to moderate contracture
3	Disfiguring synkinesis; severe contracture

Total score- sum scores for each region and secondary movement

Grade	Total score
I	4
II	5-9
III	10-14
IV	15-19
V	20-23
VI	24

Facial Nerve Grading Scale 2.0 is comparatively recent, further studies are required to validate its intraobserver reliability. (38)

Yanagihara system

Yanagihara system is a regional scale most frequently used in Japan. This system evaluates movements of different facial muscles at rest and during 9 separate actions, giving points from 0 to 4 points, resulting in a maximum score of 40 points.

The Yanagihara grading system (Y-system) scoring:

1. At rest
2. Wrinkle forehead
3. Wrinkle nasal root
4. Closure of eye lightly
5. Closure of eye tightly
6. Closure of eye on the involved side only
7. Blowing out cheeks
8. Whistle
9. Grin
10. Depress lower lip

Scoring:

- Normal 4 points
- Partial palsy 2 points
- No motility 0 point

Scores of 0-6, 8-14, 16-22, 24-30, 32-38, and 40 points on the Yanagihara system correspond to grades VI, V, IV, III, II, and I, respectively, of HB grading. This system is not used widely because of its complex evaluation criteria. (39)

Post-parotidectomy facial nerve grading system:

This scale examines the function of four branches of the facial nerve and it was based on the evaluation of facial symmetry at rest and performing wrinkling the forehead and raising eyebrows (temporal branch), closing the eyes (zygomatic branch), raising the cheeks and wrinkling the nose (buccal branch), and whistling and showing the teeth (buccal branch—upper part and marginal mandibular branch—lower part of the

mouth). To assess the qualitative presentation of facial paresis, a score from 0 to 4 was given to measure the function of each facial nerve branch (T, temporal; Z, zygomatic; B, buccal; M, marginal mandibular). (23)

Table 5: Post-parotidectomy facial nerve grading system

Degree	Description	Points
Complete function	Symmetry at rest Symmetry at full range of movements	4
Slight paresis	Symmetry at rest Slight asymmetry at full range of movements	3
Pronounced paresis	Symmetry at rest Movement disorders with clear asymmetry	2
Profound paresis	Asymmetry at rest Slight of the muscle movements	1
Paralysis	Asymmetry at rest Lack of movements	0

Objective Assessment:

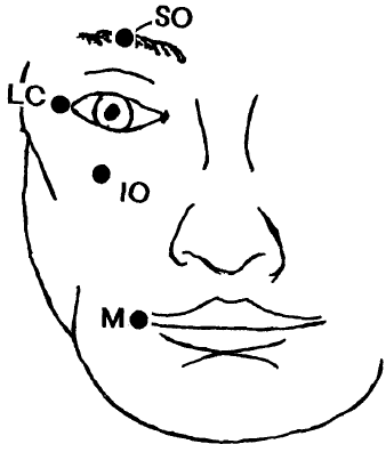
Objective scales are also called linear measurement scales and are more reliable. The objective scales used commonly are Burres Fisch, Nottingham System. Maximum static response array (MSRA), eFACE(9) are some of computer-based methods that

have been proposed for assessing facial paralysis. These computer-based approaches objectively assess facial measurement by using image processing and classification methods.(30) Objective scales are more reliable but are not commonly used as they are time-consuming, laborious and some are patented and paid applications.

Nottingham System:(40)

It is a three-part system in which the first part provides an objective measurement of facial movements and the second and third parts provide a record of the presence or absence of secondary defects.

1. In the first part, with the face at rest, the patient is asked to fix on a point at eye level 6 feet in front. *An* imaginary perpendicular line is passed through the pupil. The *supraorbital point (SO) is marked at t*he point at which this line crosses the upper border of the eyebrow. The point at which it crosses the infraorbital rim is marked as the *infraorbital point* (I0). The *lateral canthus* (LC) and *angle* of *mouth* (M) *points* are also marked.



1. *Supraorbitalpoint (SO)*
2. *infraorbitafpoint* (I0).
3. L*ateral canthus* (LC)
4. A*ngle* of *mouth* (M) *point*

Figure 5: *Nottingham System*

First part calculation:

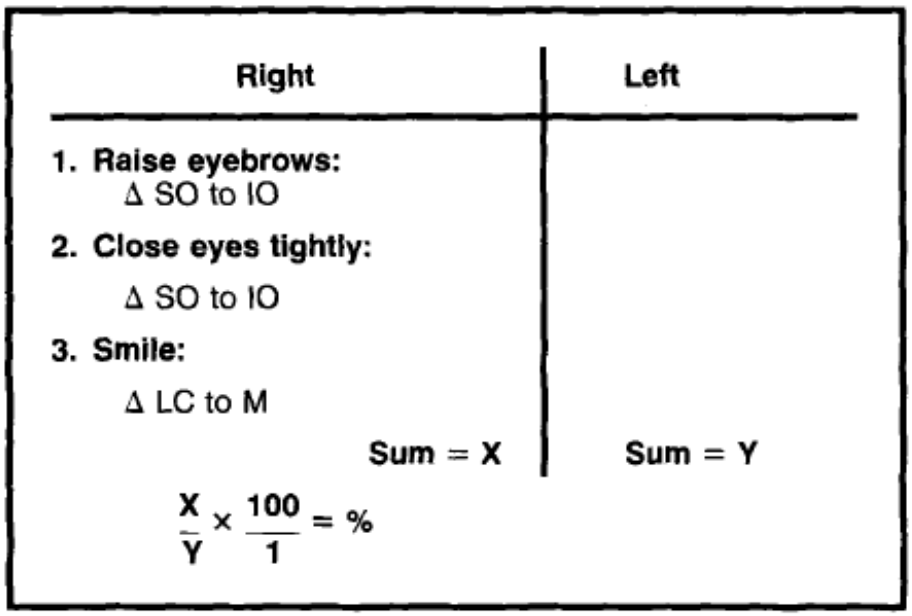


Figure 6: Nottingham system- First past calculation

2. In the second part, the presence (P) or absence ***(A)*** of any of the secondary defects: (hemifacial spasm, contractures, or synkinesis). is marked.

3. In the third part, the presence ***(Y)*** or absence ***(N)*** of crocodile tears, decreased lacrimation, or dysgeusia is assessed by asking the patient.

Final grade is given in a similar manner of TNM classification. Eg 79AN means Part 1- 79, Part 2- Absent and Part 3- Absent.

Burres-Fisch LMI of facial function(41)

It measures the amount of facial paresis by measuring facial distances from reference landmarks.

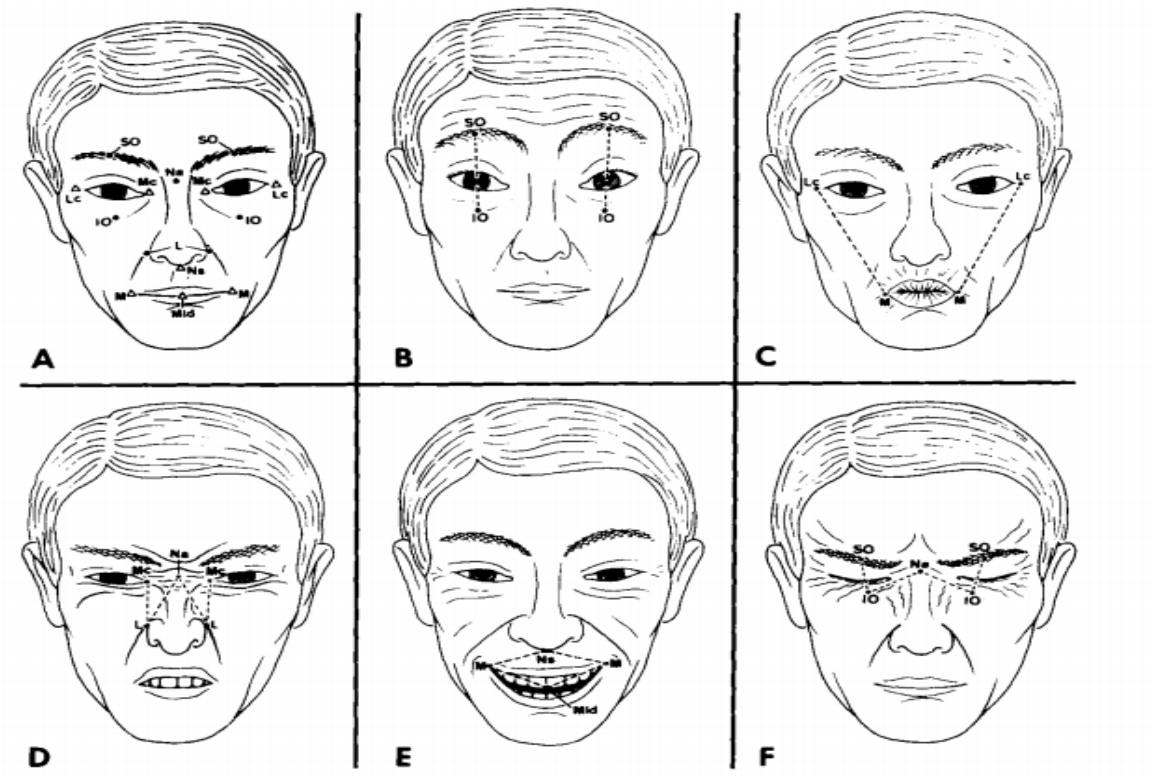


Figure 7: Burres-Fisch LMI of facial function

(Distances measured to represent mimetic expressions. A) Landmarks involved. · — grease pencil indication of landmark, Δ — anatomic landmark. B) Forehead wrinkle (II), C) kiss (IV), D) nose wrinkle (V), E) smile (VI), F) eyes closed tig; ht (VII). Na — nasion; Mc — medial canthus; Lc — lateral canthus; Ns — nasal spine; SO — superior, opposite pupil; I0 — inferior, opposite pupil; L — nasolabial fold meets pyriform aperture; Mid — midline at level of center of mouth; M — corner of mouth.)

Reference landmarks for Burres-Fisch LMI

It is calculated by using the following steps

1. Calculate the percent displacement (pD) for all of the appropriate measurements for each facial position. pD = distance moved/rest distance (mm) x 100. The positions and representative distances are as follow: Forehead wrinkle (II): SO to I0; Kiss (IV): LC to M; Nose wrinkle *(V):* Na to L and Mc to L; Smile (VI): M to Mid and M to Ns; and Eyes closed tight (VII): SO to IO and Na to IO
2. Average the two pDs from the Nose wrinkle *(V),* Smile (VI), and Eyes closed tight (VII). Divide the pD from the Forehead wrinkle (II) in half.
3. Total the five values from each half of the face separately.
4. Corneal exposure: For each millimeter of corneal exposure, measured by the maximum width of the palpebral fissure, subtract 1% in the Eyes closed soft (I) expression and an additional 2% for each millimeter in the Eyes closed tight (VII) expression from the score for the paralyzed half of the face.
5. Rest asymmetry: Add the millimeter difference between the two halves of the face for all seven measurements taken at rest. If the total is greater than 22 mm, subtract 1% from the score on the paralyzed side of the face for each additional millimeter.
6. Add 30 to the score from each half of the face.
7. Calculate the score on the paralyzed side of the face as a percent of the normal side. If the total on the paralyzed side after steps 1through 6 above is less than 0, the total function on the paralyzed half of the face is considered 0.

Clinician-Graded Electronic Facial Paralysis Assessment: The eFACE(42)

Figure 8: Clinician-Graded Electronic Facial Paralysis Assessment: The eFACE

It is a computer-based software that generates an overall disfigurement score by using 16 items in a visual analog scale to assess facial function and symmetry. Video recordings of subjects performing facial expressions were viewed, and the eFACE instrument was applied, along with an overall facial disfigurement score. The items were categorized into one of three domains: static, dynamic, or synkinesis. Static items included resting brow height, resting palpebral fissure width, nasolabial fold depth at rest, nasolabial fold orientation at rest, and oral commissure position at rest. Dynamic items included brow excursion with attempts at elevation, palpebral fissure narrowing with attempts at gentle eye closure, palpebral fissure narrowing with attempts at full eye closure, oral commissure movement with smile, nasolabial fold depth with smile, nasolabial fold orientation with smile, and lower lip movement. Synkinesis items included ocular synkinesis, midfacial synkinesis, mentalis dimpling, and platysmal synkinesis. Scores were then calculated, by simple averaging, to produce a subscore for each domain of facial function (static, dynamic,

and synkinesis); subscores ranged from 1 to 100, with 100 representing normal facial symmetry and/or function.

The eFACE is a reliable, reproducible, and straightforward digital clinical measure with which to assess facial function and disfigurement in patients with facial paralysis but it's not widely available for use and is a paid application.

Comparing various facial nerve grading systems:

The House Brackmann and Sunnybrook systems have been compared in various trials.

- *Neely et al*, in a prospective trial, concluded that the Sunnybrook system was reliable even with naïve raters (ICC=0.89) It showed excellent up to almost perfect ICC for inter-rater and intra-rater reliability)(43).
- *Coulson et al*, in a study comparing three different systems, demonstrated a good inter-rater reliability for Sunnybrook (intraclass coefficient=0.63) and Sydney systems (intraclass coefficient=0.69). The reliability of the House Brackmann system was described as substantial on the basis of its weighted kappa coefficients(0.67)(12). In another study, Kanerva et al compared Sunnybrook and the House Brackmann system and demonstrated a better inter-rater (ICC=0.99; agreement% = 48 to 51%) and intra-rater reliability (ICC=0.975; Kappa=0.73) of the Sunnybrook system(44).

- *Systemic review done by Fattah et.al, in 2015* has described 19 facial nerve grading systems. A total of 45 publications encompassing 19 unique facial nerve grading instruments were considered for the final review. The following criteria were used to compare the systems:-
    - Convenience of clinical use
    - Regional scoring
    - Static and dynamic measures
    - Features secondary to facial palsy (e.g., synkinesis)
    - Reproducibility with low interobserver and intraobserver variability
    - Sensitivity to changes over time and/or following interventions.

This study concluded Sunnybrook to be the most ideal of systems. It also stated that the broader the definition of each group, the more likely there is to be an interobserver agreement.

Sunny Brook has been shown to be more sensitive to changes following therapeutic intervention. Changes were noted in the Sunny book system in patients who underwent therapy for facial paresis where House brackmann scores remained the same. (45)

Sunny brook system also showed high intraobserver and interobserver reliability with experts and also with naïve raters. (38)

It had intra-class correlation coefficients ranged from 0.83842 to 0.9859 for intraobserver variability and from 0.83154 to 0.99747 for interobserver variability, where is 1.0 is perfect correlation. (31)

- A study conducted by *Coulson et.al* showed interobserver reliability lower than other studies. This could be due to lack of pre-study training in the use of the tool. [22, 29]

- House points out that as long as subjective assessment is used, scores confer a false sense of accuracy. There are two schools of thought: one states that analysis is subjective and therefore using fewer categories with high interobserver agreement is sufficient. By contrast, a continuous scale may be of greater value to allow monitoring of treatment because of its inherent sensitivity. One advantage of the latter is that it may be converted into a ranked scale, whereas the reverse is less valid. (31)
- It was concluded in the study that Sunny brook system was reproducible, with low interobserver and intraobserver variability, and was sensitive enough to track changes over time and following interventions. It was convenient for widespread use by health professionals of all levels and recommended its use to allow data between investigators to be meaningfully compared. (31)

Purpose of study:

Objective tools are considered ideal because of more accuracy. But they are not widely used because of technical difficulties and some tools are paid applications. So the need of the hour is to have a more reliable subjective tool. Since we have been using a unique modification of the House Brackmann score, we wanted to investigate its reliability against the best alternative that is feasible in our clinical scenario. Hence, we did this study to assess the inter- and intra-rater reliability of the modified House Brackmann and Sunnybrook systems.

MATERIALS AND METHODS

Study setting: This study was done in the Department of General Surgery Unit 1 – Head & Neck Surgery, Christian Medical College, Vellore, Tamil Nadu.

Study participants:

- ***Inclusion criteria:*** All patients, over 18 years of age, undergoing nerve conserving parotidectomy
- ***Exclusion criteria:***
    - Bilateral parotidectomy
    - Preoperative ipsilateral or contralateral facial palsy
    - Intraoperative injury to trunk of the facial nerve

Sample size:

A sample size of 20 was required when an ICC of 0.63 was compared with very poor ICC of 0.30 with 80 %power and 5% error for 3 raters.

The literature showed reliability around 0.63-0.67 for all the scales(12). So the least was considered for the sample size calculation

Formula used:

$$n = 1 + \frac{2(Z_{\alpha} + Z_{1-\beta})^2}{(\ln C_0)^2 (k-1)} k$$

Where,

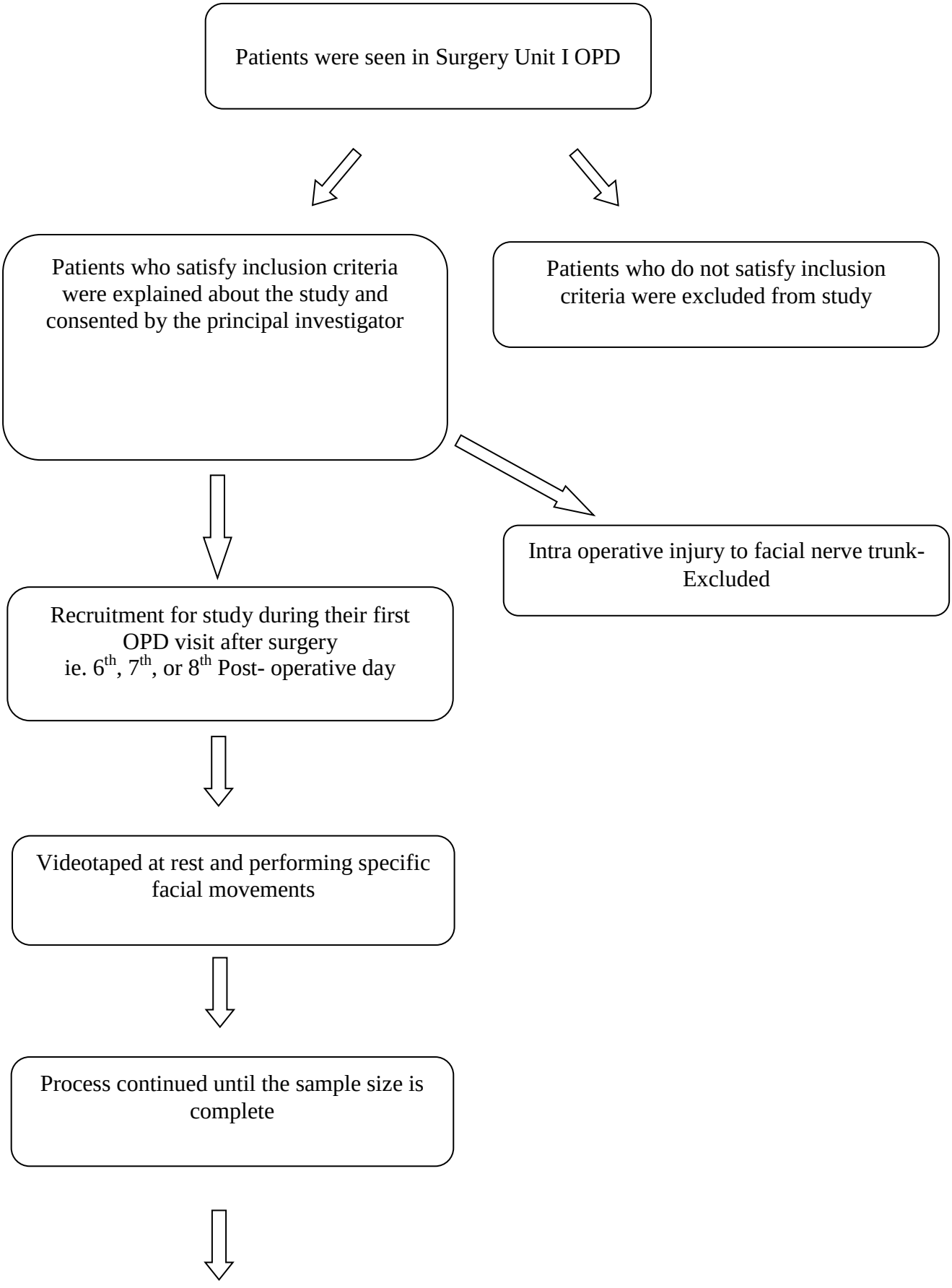
$$C_0 = \frac{1+k\theta_0}{1+k\theta} \qquad \theta_0 = \frac{\rho_0}{1-\rho_0} \qquad \theta = \frac{\rho_1}{1-\rho_1}$$

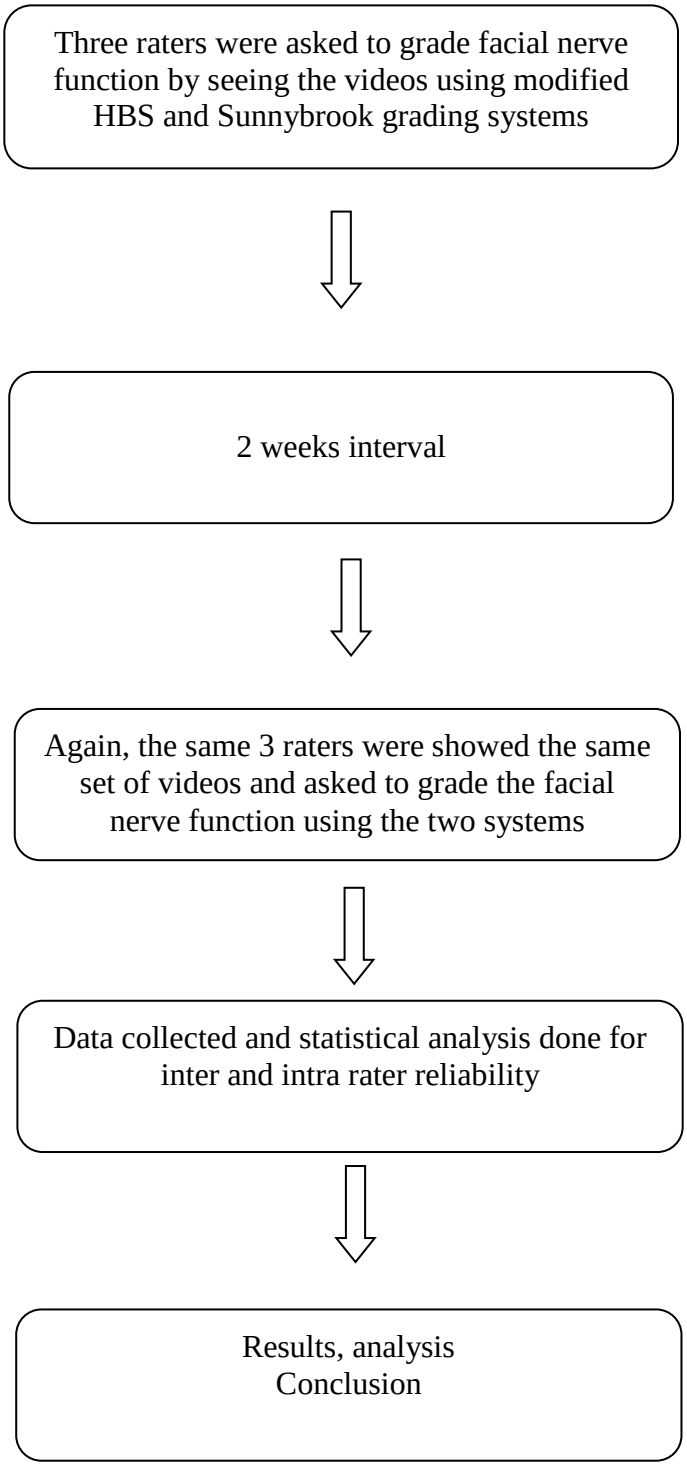
ρ_0 : Sample reliability value, ρ_1 : Population reliability value

k :Number of replicates, 1-β: Power

α : Significance level

METHODOLOGY





The patients who satisfy the inclusion criteria were explained about the study and were consented by the principal investigator. They were recruited for the study during their first OPD visit between the sixth and eighth post-operative period. They were videotaped performing specific facial movements. This process was continued until the sample size was complete. Three raters were asked to grade the facial nerve function by seeing the videos modified House Brackmann score and Sunnybrook grading systems. After an interval of two

weeks the same 3 raters were shown the same set of videos and the assessment was done to look for intra-rater reliability. The data was cumulated and entered in epidata. Later analysis was done using SPSS software.

- A study conducted by Jian Rong Tan et.al stated that video assessment of facial nerve paralysis using house Brackmann and Sunnybrook was reliable when compared to face to face but had insufficient agreement in the assessment of synkinesis.(46)
- But this did not affect our study because the assessments were done in the first week of operation when the chance of developing synkinesis is unlikely.

Minimizing bias.

To minimize the bias the rater were asked to grade the facial nerve function using the two systems separately so that they did not compare the two systems and change the grading. For this, the grading charts were collected from the rater after grading with the modified House Brackmann score and then they were asked to rate with Sunnybrook system.

Study tool (Proforma): Please refer Datasheet in Annexures

STATISTICAL ANALYSIS:

In 1981 Cicchetti DV, Sparrow SA.Et.al provided the criteria and guidelines based on biostatistical considerations for determining the interrater reliability. (47)

ICC	interpretation
<0.40	Poor agreement
0.40 - 0.59	fair to moderate agreement
0.60 - 0.74	good agreement
0.75 - 1.00	excellent agreement

Figure 9: Cicchetti DV, Sparrow SA guidelines

Data were summarized using mean (SD) or median (IQR) for continuous variables based on normality. Categorical data were expressed as number and percentage. The intra-observation of the raters were given using ICC (95 % CI). The inter observation was calculated using mixed effect models, where both within rater variation and between rater variation are taken into account and the ICC with 95% CI are presented. Additionally, the Concordance between the raters was given using Lin's concordance correlation and the maximum allowable difference was presented using limits of agreement (LoA) using the Bland-Altman technique. All the analysis were performed with STATA IC/15.1 software

RESULTS

RESULTS:

Demographics

The total number of patients recruited in the study was 20 of which 12 were male and 8 were females. The age group of patients ranged between 19-52 years with a median of 38.5 years(IQR 34.5-49).

Eleven patients underwent parotid operations on the right side and the remaining 9 patients underwent an operation on the left side. About 50% (N=10) of patients underwent operation for pleomorphic adenoma. The next common histopathological diagnosis was mucoepidermoid carcinoma(N=3).

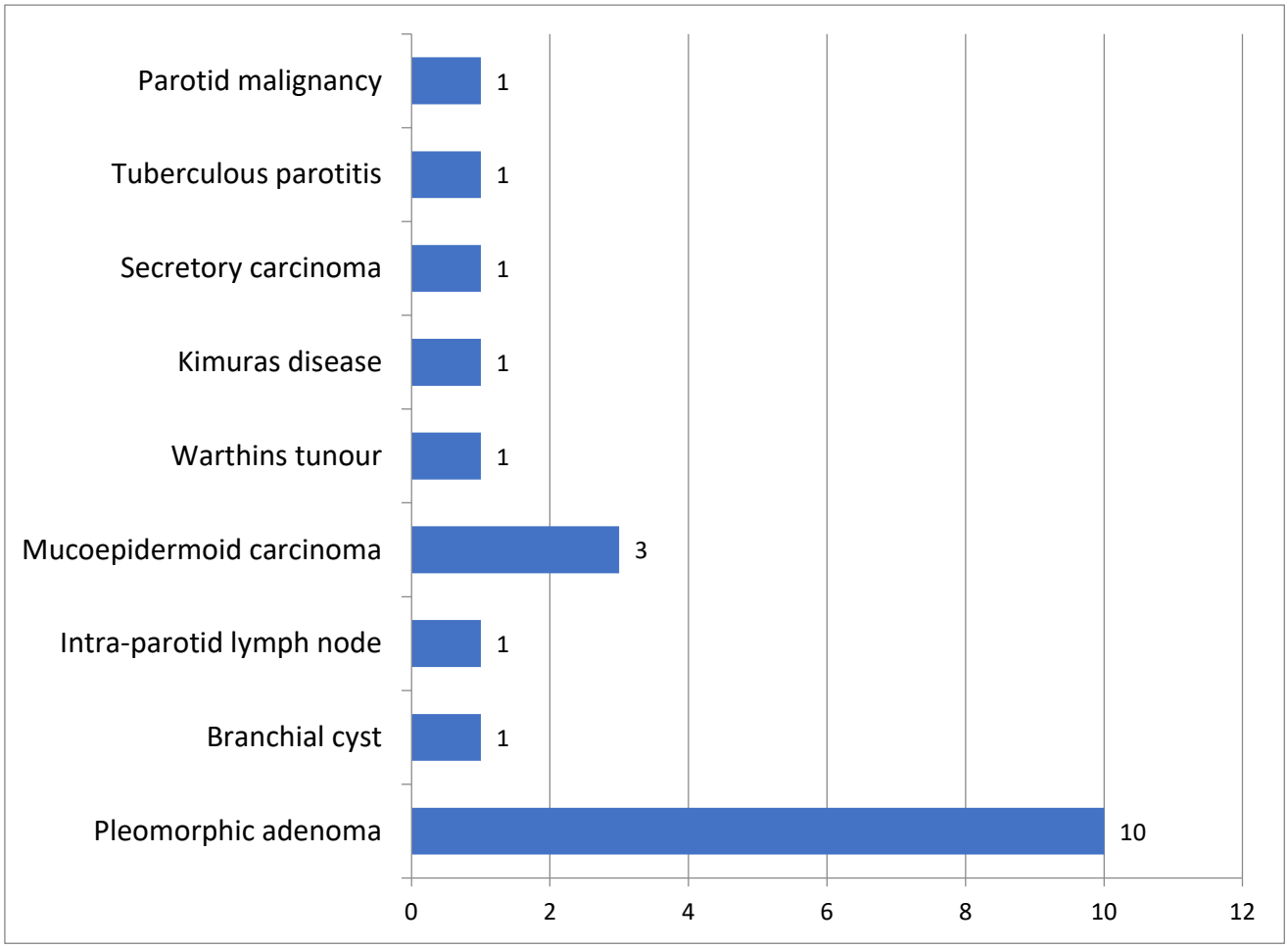


Figure 10: Final Histopathological diagnoses

Operations:

Among the operations, superficial parotidectomy was done in 13 (65%) patients and adequate parotidectomy was done in 4 (20%) of the patients. Total conservative parotidectomy was performed in 2 (10%) patients who had secretory carcinoma and intramuscular hemangioma with focal extension into the deep lobe of the parotid gland respectively. One patient (5%) underwent extracapsular excision for intra-parotid lymph node. A patient with Warthin's tumor underwent superficial parotidectomy. A patient with recurrent Kimura's disease underwent adequate parotidectomy. Three patients with mucoepidermoid carcinoma underwent superficial parotidectomy.

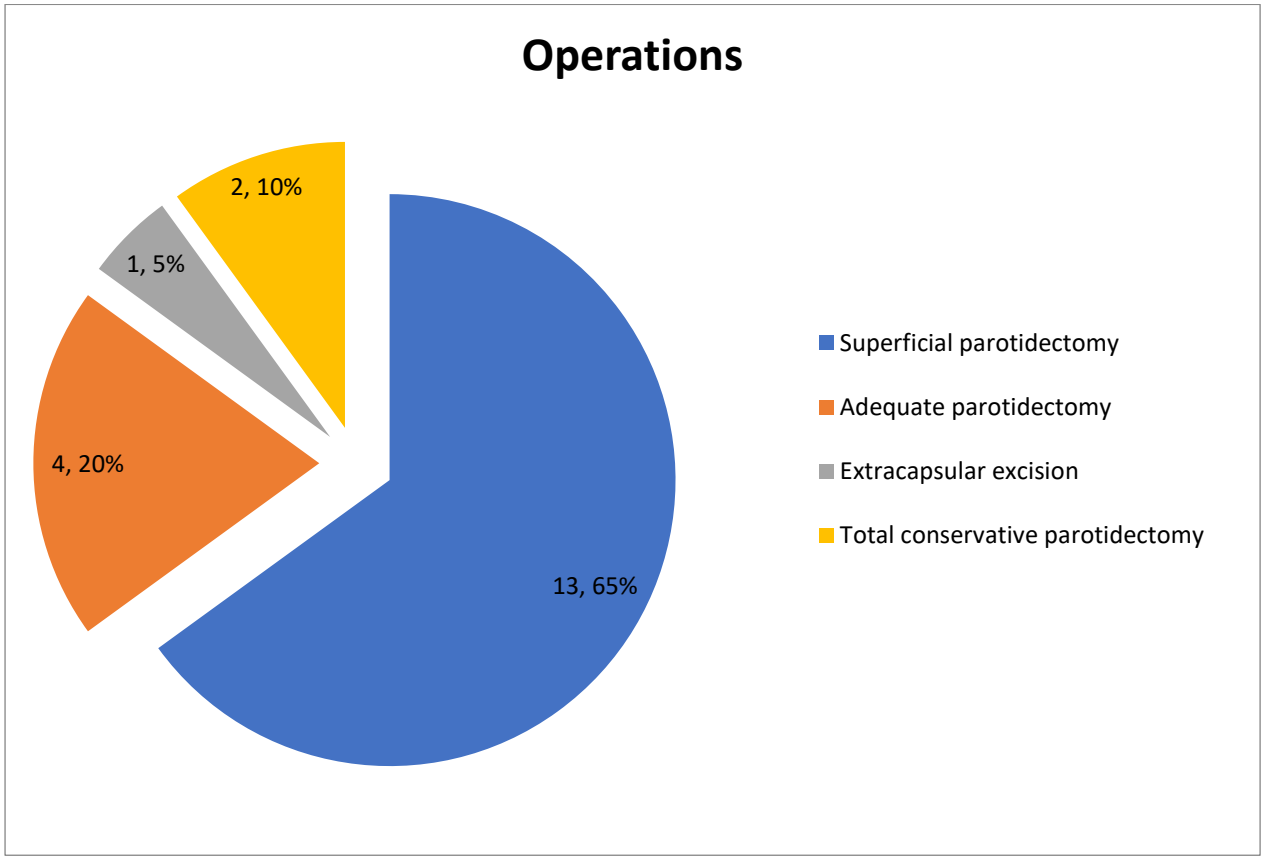


Figure 11: Type of operation

Preoperative FNAC

Preoperative FNA was done in 17 patients and 3 patients did not undergo preoperative FNA. In 6 (30%) patients the pre-operative cytology revealed features of pleomorphic adenoma. The FNA was inadequate in 3 (15%) of patients. The other cytologies were mucoepidermoid carcinoma, granulomatous lymphadenitis, negative for malignant cells and non-diagnostic.

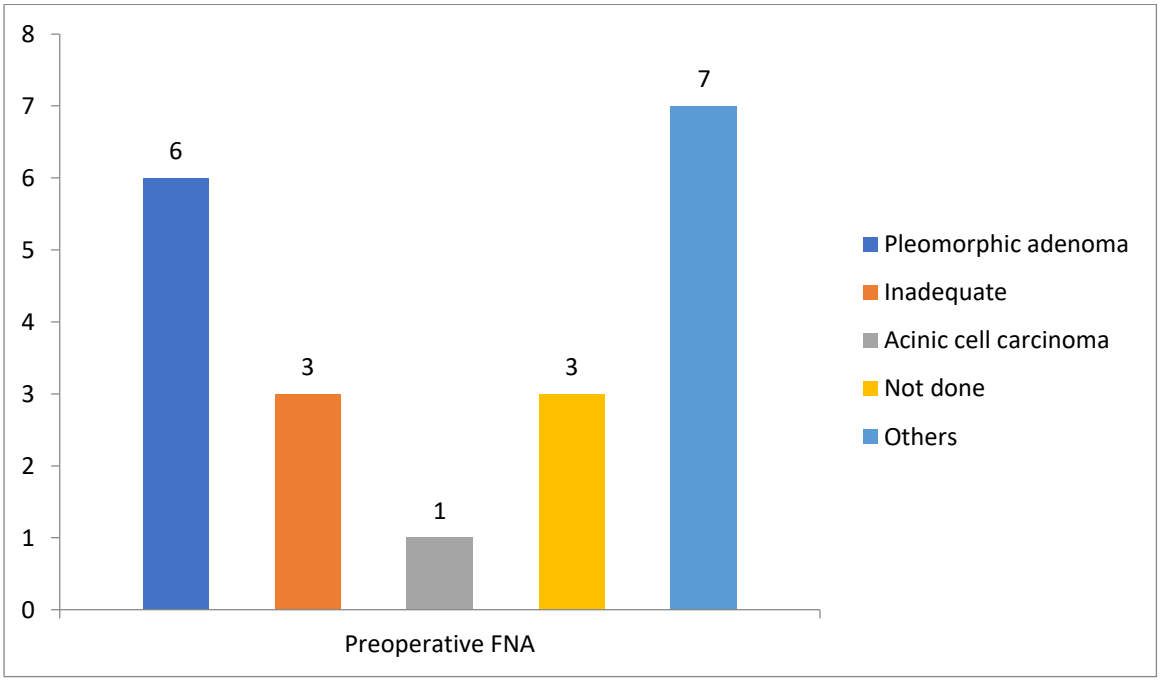


Figure 12: Pre-operative FNA

Preoperative imaging

Pre-operative imaging was done in the majority of cases with an ultrasonogram of neck. Two patients underwent CT scan of head and neck as they presented with features suspicious of malignancy. Two patients did not have any pre-operative imaging.

Inter- and intra-rater reliability

The patients were videotaped in the post-operative period, on the first OPD visit by performing specific facial movements. These videos were assessed by three consultants who had 10 or more than 10 years experience in salivary gland surgery. The assessment was repeated after a time interval of 2 weeks to asscess the intra-rater reliability. During analysis, as the 2 scoring systems were in different scales a composite score was created for modified House Brackmann score by summing up individual scores to compare the ICC of both.

INTRA-RATER RELIABILITY ANALYSIS

Table 6: Intra rater reliability

Grading Systems	**Rater 1** **ICC (95%CI)**	**Rater 2** **ICC (95%CI)**	**Rater 3** **ICC (95%CI)**
House Brackmann			
Temporal	0.95(0.88, 0.98)	0.84 (0.95,0.93)	0.89 (0.73, 0.96)
Zygomatic	0.95 (0.88, 0.98)	0.93 (0.83,0.97)	0.99 (0.98, 0.99)
Marginal mandibular	0.93 (0.82, 0.97)	0.89 (0.74,0.96)	0.97 (0.91, 0.99)
Composite	0.97 (0.91-0.99)	0.95 (0.84-0.98)	0.98 (0.95-0.99)
Sunny Brook			
Resting symmetry score	0.08 (1.28, 0.63)	0.87 (0.68,0.94)	0.88 (0.69, 0.95)
Eye	-0.05 (1.62, 0.58)	0.94 (0.86,0.98)	0.77(0.42, 0.91)
Cheek	0.57 (0.07, 0.83)	0.57 (-0.07,0.83)	0.74 (0.35, 0.89)
Mouth	0.82 (0.56, 0.93)	0.88 (0.69,0.95)	0.85 (0.64, 0.94)
Voluntary movement score	0.97 (0.93, 0.98)	0.89 (0.73,0.96)	0.97 (0.93, 0.99)
Forehead	0.88 (0.71, 0.95)	0.78 (0.45,0.91)	0.99 (0.97, 0.99)
Eye closure	0.921 (0.80, 0.97)	0.86 (0.66,0.94)	0.89 (0.73, 0.96)
Smile	0.94 (0.87, 0.98)	0.87 (0.68,0.95)	0.97 (0.92, 0.99)
Snarl	0.88 (0.69, 0.95)	0.87 (0.67,0.95)	0.92 (0.80, 0.96)
Lip	0.95 (0.87-0.98)	0.76 (0.40-0.90)	0.90 (0.75-0.96)
Composite score	0.96 (0.91, 0.99)	0.89 (0.72,0.95)	0.98 (0.94 , 0.99)

INTER-RATER RELIABILITY ANALYSIS

Table 7: Inter-rater reliability analysis

Grading Systems	**ICC (95%CI)**
House brackmann	
Temporal	0.81(0.71, 0.88)
Zygomatic	0.91 (0.86, 0.95)
Marginal mandibular	0.88 (0.81, 0.93)
Composite	0.94 (0.90-0.96)
Sunny Brook	
Resting symmetry score	0.35 (0.17, 0.59)
Eye	0.71(0.57, 0.82)
Cheek	0.45 (0.27, 0.65)
Mouth	0.73 (0.60, 0.83)
Voluntary movement score	0.90 (0.84, 0.94)
Forehead	0.77 (0.65, 0.86)
Eye closure	0.82 (0.72, 0.89)
Smile	0.86 (0.77, 0.91)
Snarl	0.80 (0.69, (0.88)
Lip	0.75 (0.62, 0.84)
Composite score	0.90 (0.84, 0.94)

Concordance correlation

Table 8: Concordance correlation between rater 1 and rater 2

Parameter	Rater 1 Vs Rater2		
	Concordance Correlation (p value)	**Bias(SD)**	**LoA**
House Brackmann Temporal	0.85(<0.001)	0.38 (0.89)	(-1.38,2.13)
Zygomatic	0.91(<0.001)	0.07(0.57)	(-1.05,1.19)
Marginal mandibular	0.72(<0.001)	0.65(1.08)	(-1.46,2.76)
Sunny brook Resting symmetry	0.22(0.111)	0.25(8.84)	-7.01,17.58)
Eye	0.19(0.038)	0.28(0.45)	(-0.61,1.16)
Cheek	0.52(<0.001)	0.07(0.42)	(-0.74,0.89)
Mouth	0.73(<0.001)	-0.08(0.27)	(0.59,0.45)
Voluntary movements	0.85(<0.001)	-5.8(9.79)	(-25.0,13.40)
Forehead	0.74(<0.001)	-0.35(0.83)	(-1.98,1.28)
Eye closure	0.91(<0.001)	-0.03(0.36)	(-0.73,0.68)
Smile	0.87(<0.001)	-0.13(0.76)	(-1.61,1.36
Snarl	0.71(<0.001)	-0.53(0.93)	(-2.35,1.30)
Lip	0.58(<0.001)	-0.43(1.11)	(-2.59,1.74)
Composite	0.85(<0.001)	-6.68(10.92)	(-28.08,14.73)

Table 9:Concordance correlation between rater 2 and rater 3

Parameter	Rater 2 Vs Rater3		
	Concordance correlation (p value)	Bias(SD)	LoA
House brackmann Temporal	0.64(<0.001)	-0.65(1.19)	(-2.98,1.68)
Zygomatic	0.90(<0.001)	-22(0.53)	(1.26,0.82)
Marginal mandibular	0.78(<0.001)	-0.70(0.94)	(-2.54,1.14)
Sunny brook Resting symmetry	0.69(<0.001)	-0.50(4.05)	(-8.44,7.44)
Eye	0.54(<0.001)	-0.18(0.39)	(-0.93,0.58)
Cheek	0.34(0.019)	-0.05(0.50)	(-1.04,0.94)
Mouth	0.60(<0.001)	0.13(0.34)	(-0.53,0.78)
Voluntary movements	0.79(<0.001)	8.10(10.69)	(-12.87,29.07)
Forehead	0.70(<0.001)	0.40(0.87)	(-1.31,2.11)
Eye closure	0.81(<0.001)	0.13(0.46)	(-0.78,1.03)
Smile	0.81(<0.001)	0.45(0.75)	(-1.02,1.91)
Snarl	0.79(<0.001)	0.58(0.71)	(-0.82,1.97)
Lip	0.48(<0.001)	0.50(1.19)	(-1.85,2.85)
Composite score	0.82(<0.001)	8.10(11.78)	(-14.99,31.19)

Table 10: Concordance correlation between rater 3 and rater 1

Parameter	Rater 3 Vs Rater1		
	Concordance Correlation (p value)	**Bias(SD)**	**LoA**
House brackmann Temporal	0.82 (<0.001)	-0.275(0.816)	(-1.875,1.325)
Zygomatic	0.92(<0.001)	-0.15(0.48)	(-1.09,0.79)
Marginal mandibular	0.89(<0.001)	-0.05(0.75)	(-1.52,1.42)
Sunny brook Resting symmetry	0.21(0.112)	-0.25(8.69)	(-17.29,16.79)
Eye	0.46(<0.001)	0.10(0.30)	(-0.49,0.69)
Cheek	0.33(0.023)	0.03(0.48)	(-0.92,0.97)
Mouth	0.86(<0.001)	0.05(0.22)	(-0.38,0.48)
Voluntary movements	0.94(<0.001)	2.30(6.20)	(-9.86,14.46)
Forehead	0.87(<0.001)	0.05(0.50)	(-0.93,1.03)
Eye closure	0.83(<0.001)	0.10(0.44)	(-0.77,0.97)
Smile	0.87(<0.001)	0.33(0.57)	(-0.79,1.45)
Snarl	0.81(<0.001)	0.05(0.75)	(-1.42,1.52)
Lip	0.83(<0.001)	0.07(0.62)	(-1.31,2.28)
Composite score	0.94(<0.001)	1.43(7.06)	(-12.42,15.26)

In modified HBS the concordance correlation between 2 raters was best between rater 1 and rater 3 in Zygomatic score with a value of 0.92(<0.001). It was lowest between rater 2 and rater 3 in zygomatic score with a value of 0.64(<0.001). Overall rater 1 and rater 3 had good concordance correlation.

In Sunny brook score, the concordance correlation between 2 raters was best between rater 1 and rater 3 in voluntary score with a value of 0.94(<0.001). It was lowest between the same raters in resting symmetry score with a value of 0.21(0.112). Overall, the scores of resting symmetry had low concordance value and had a non-significant p-value. The composite score concordance correlation was best between rater 1 and 3 with a value of 0.94(<0.001).

Comparison of similar scores in House Brackmann and Sunny Brook

For this, the temporal score of HBS was compared with its equivalent, forehead of SB. Similarly Zygomatic of HBS was compared with its equivalent, cumulative score of Eye (resting symmetry) and voluntary eye closure of SB. The marginal mandibular score of eye was compared with cumulative score (by adding the individual score) of resting scores of cheek, mouth and voluntary scores of smile & snarl. The resultant ICC values are represented in the table below.

Table 11: Comparison of similar scores in House Brackmann and Sunny Brook

HBS & equivalent SB score	ICC(95%CI)
Temporal	0.77 (0.65, 0.86)
Zygomatic	0.79(0.67, 0.87)
Marginal mandibular	0.79(0.68-0.87)

Scatter plot diagram of scores between the raters:

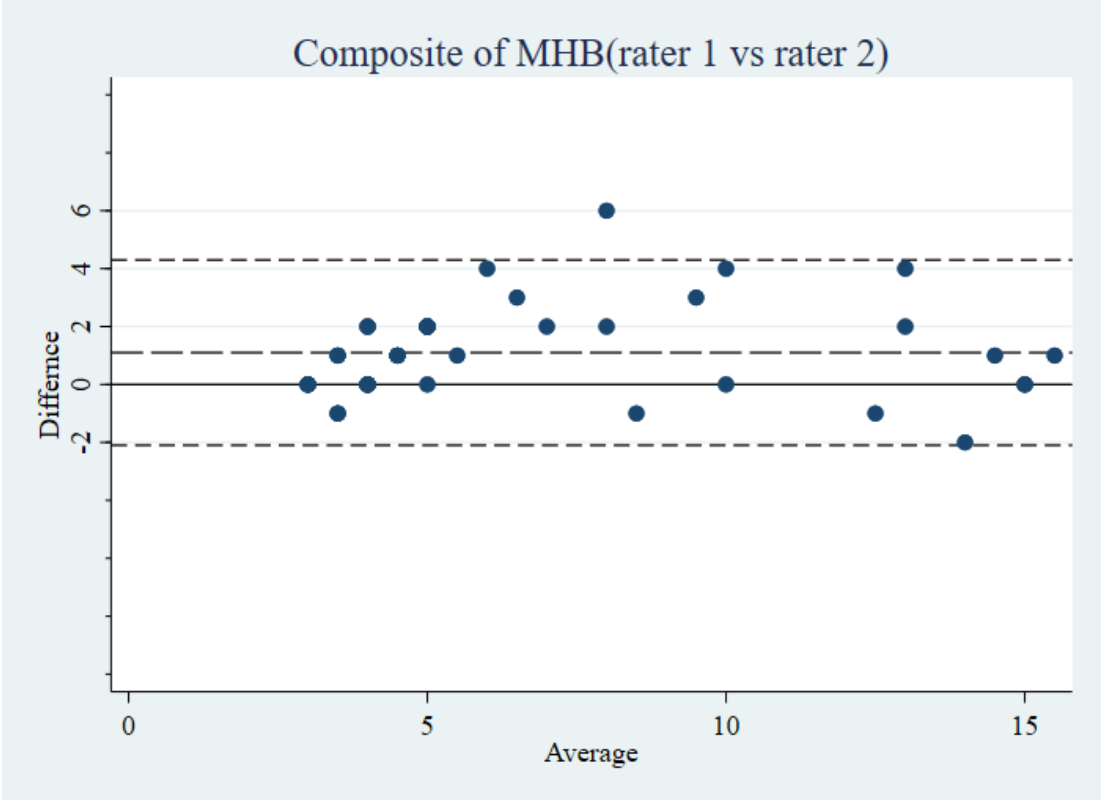


Figure 13: Scatter plot diagram of scores of the rater 1 vs rater 2using Modified HBS score

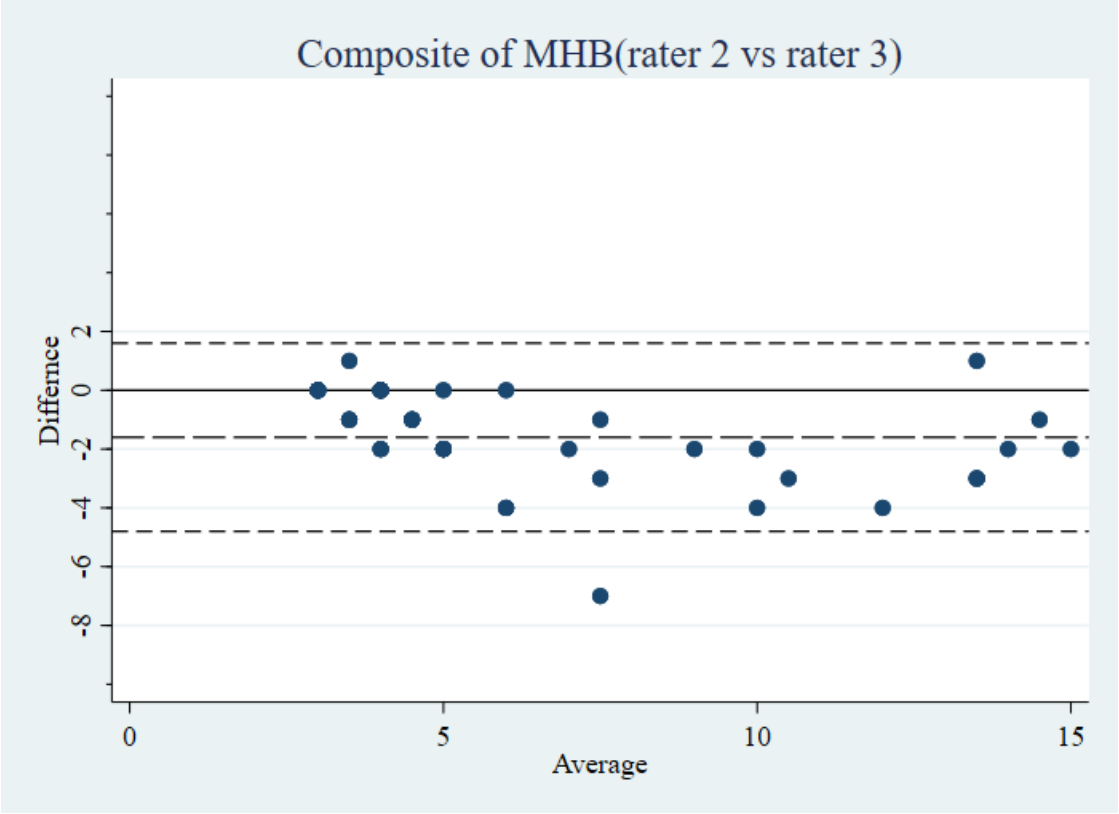


Figure 14: Scatter plot diagram of scores of the rater 2 vs rater 3 using Modified HBS score

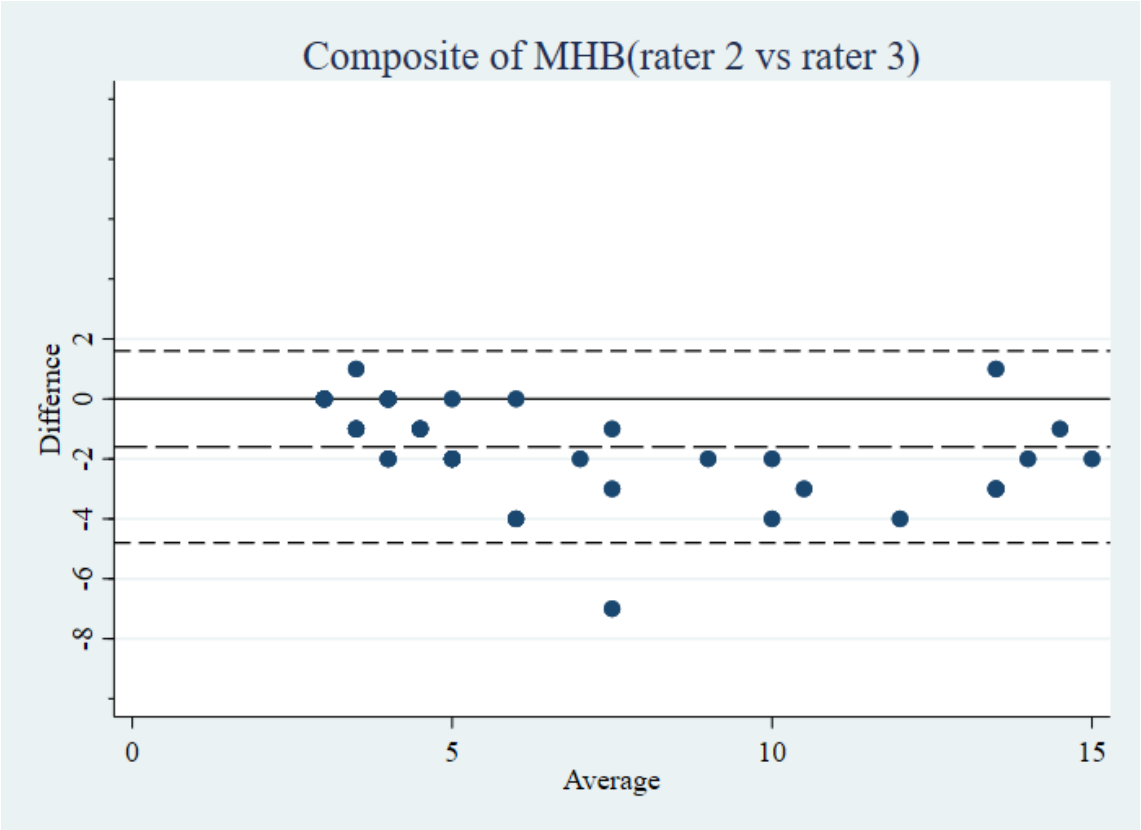


Figure 15:Scatter plot diagram of scores of the rater 2 vs rater 3 using Modified HBS score

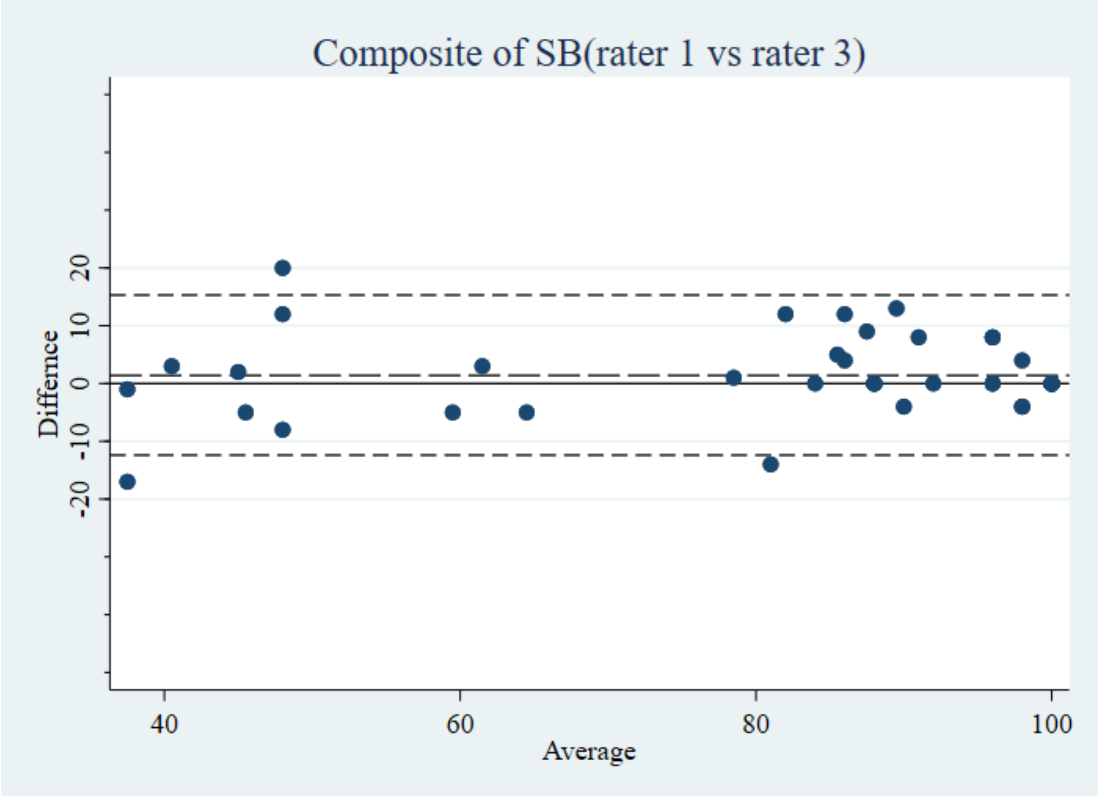


Figure 16: Scatter plot diagram of scores of the rater 1 vs rater 3 using Sunny brook composite score

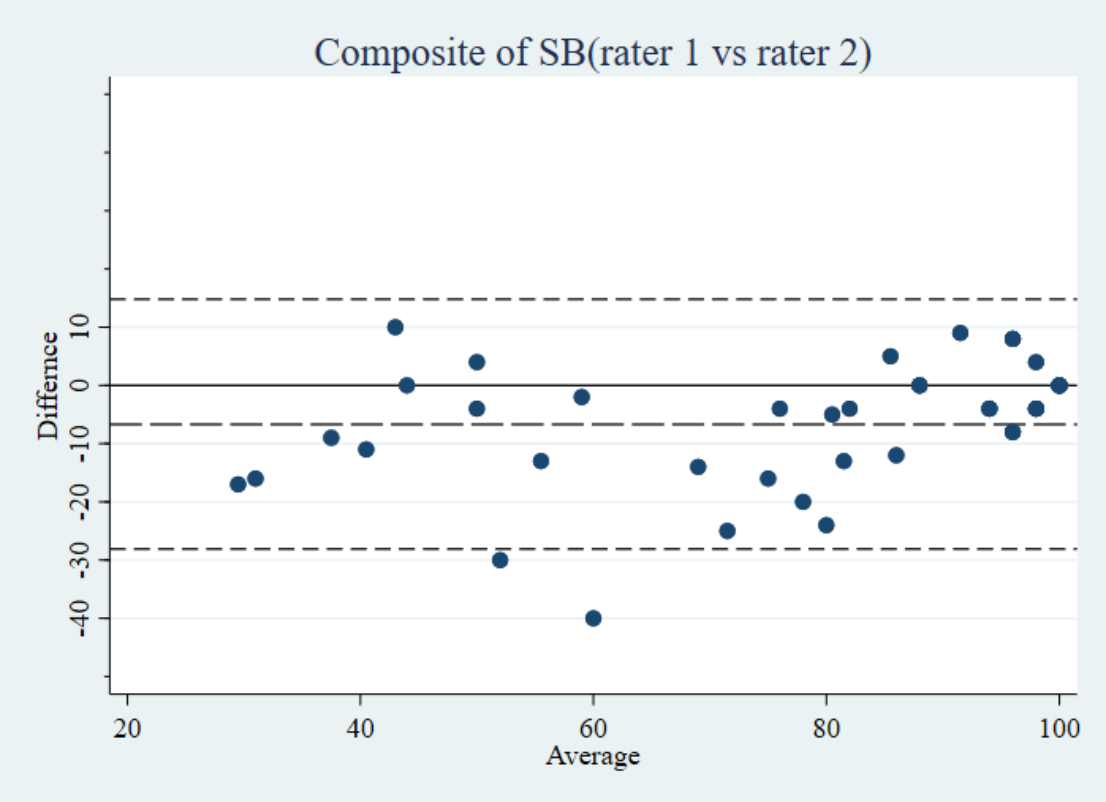


Figure 17: Scatter plot diagram of scores of the rater 1 vs rater 2 using Sunny brook composite score

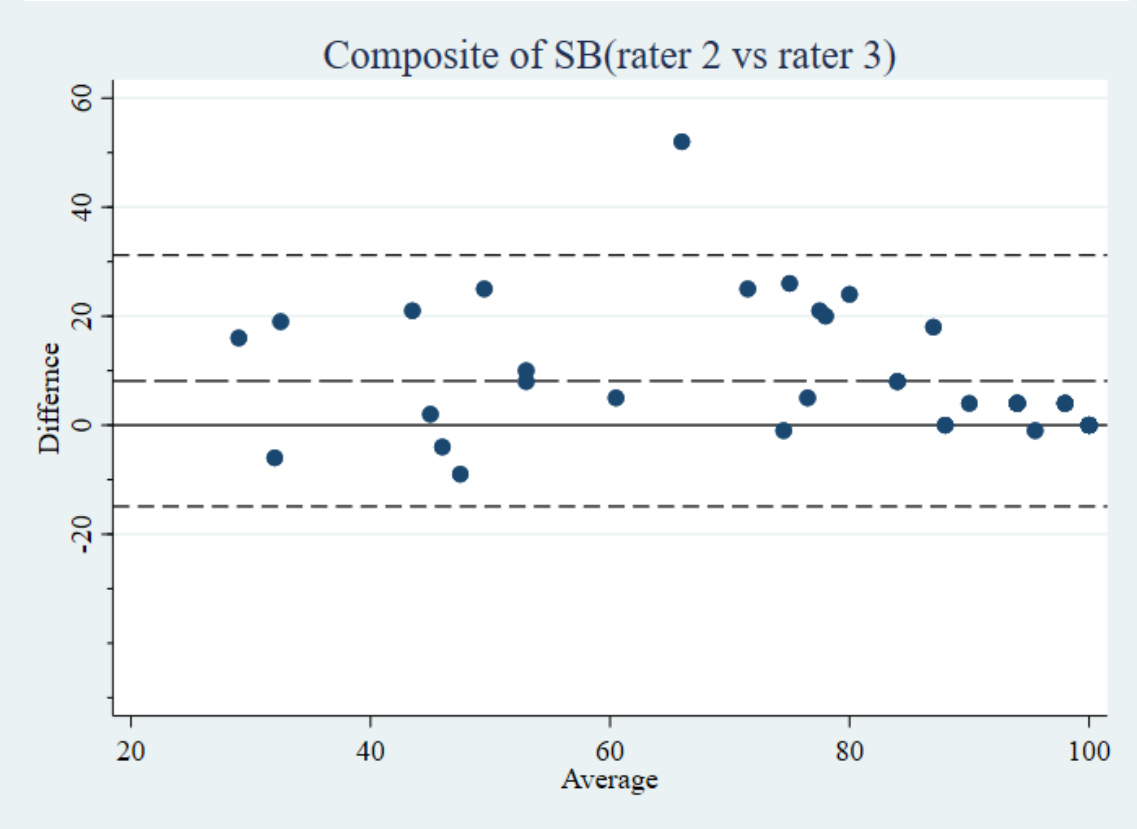


Figure 18: Scatter plot diagram of scores of the rater 2 vs rater 3 using Sunny brook composite score

From the above scatter plots it can be noted that both the Modified House Brackmann and Sunny brook scores have excellent intra-observer and inter-observer correlation. And rater 1 and rater 3 have more correlation when compared to the other 2 combinations in Modified House Brackmann and Sunny Brook grading systems.

DISCUSSION

Discussion:

The sample size of our study was 20 which was comparable with a similar study which compared the reliability of Sydney, Sunny brook and House Brackmann scoring system which had a sample size of 21 patients(48). It included patients with unilateral lower motor neuron facial palsy patients in the study in comparison with our study where we included cases who underwent unilateral parotid operations. In our study, 3 raters viewed the videotapes on 2 different occasions whereas in the above-mentioned study it had 6 raters to access the videos. We had a similar male to female ratio with the above-mentioned study. The causes for the facial nerve paresis were different from our study group and it contained post-operative cases of acoustic neuroma, vagal schwannoma, benign facial nerve neuromas, Bell's palsy, herpes zoster oticus, and cholesteatoma. The mean age at the time of onset was 42.6 years and in our study, it was 39.5 years. All subjects had FNP for 1 year or longer with the mean being 4.5 years in the reference study and the cases included in our study were in the first week of their post-operative period.

The raters in the reference study viewed the videos only at one occasion and in our study, the rates viewed the video for the second time to assess intra-rater reliability after 2 weeks of the initial assessment. In both the studies ICC was used to measure the reliability of the two scoring systems as it reflects the proportion of the total variance in a set of ratings that relates to true differences between patients on the scale in question.

Henstrom et.al in 2011(33) compared original and modified house Brackmann scores in 50 consecutive patients with facial nerve paresis. The demographic profile revealed that most of these patients had facial paresis because of bells palsy (N=19)

and acoustic neuroma (N=11). The other causes of facial nerve paresis were head and neck malignancies, Ramsay hunt syndrome, brain tumors, temporal bone fracture, etc. The patients' mean age was 47 years and ranged from 15 to 80 years. They were recruited in the study and were videotaped by doing standard facial nerve movements. These videos were assessed by 3 experienced raters later.

A study conducted by Neeley et.al(43), looked into the intra-rater and inter-rater reliability of 2 naïve raters using the Sunny brook system. They included 30 patients with facial nerve paresis and videotaped them performing specific facial expressions. 20 patients had Bell's palsy, 4 patients had post-operative palsy following resection of acoustic tumor. The remaining patients had cholesteatoma, post-operative cable grafting, post-operative mastoid surgery, etc. They did the assessment in 4 trials in which the first two trials the raters assessed the videos using Sunny brook system in usual manner and in trial 3 and 4 using specific grading criteria for the SB system.

Similarly, Mateo et.al(49) conducted a study that compared House Brackmann grading system with Rough facial nerve grading system. They recruited 50 patients (22 males and 24 females) for the study and they were videotaped performing specific codified facial movements. These videos were assessed by two independent groups of raters. The mean age of patients recruited in the study was 54 +/- 15 standard deviation. The most common cause of facial nerve paresis was acoustic neuroma (N=17) followed by parotidectomy (N=16). The other causes were parotid malignancies, parotid malignancies, Ramsay Hunt paralysis, cranial trauma, excision of cerebellopontine angle meningioma.

Inter-rater reliability:

In the Modified House Brackmann scoring system, the temporal score had the least agreement with ICC of 0.81(0.71, 0.88) and the Zygomatic score had the best agreement among the 3 raters with an ICC of 0.91 (0.86, 0.95). The overall inter-rater agreement in the Housebrackmann score was *excellent*.

In the Sunny Brook scoring system, the resting symmetry score had the least agreement with ICC of 0.35 (0.17, 0.59). The Voluntary score had the best agreement with ICC of 0.90 (0.84, 0.94). Even though there were components with less agreement the overall inter-rater agreement in Sunny Brook scoring system was *excellent* with an ICC of 0.90 (0.84, 0.94).

House Brackmann scores reliability has been assessed by various other studies. in a study conducted by Susan e. Coulson, et.al(48) stated that the reliability of HBS was substantial with a mean weighted kappa of 0.67 (95% CI between 0.63 and 0.70). It also mentioned that there was a wide variation in the individual scores among the trained observers. In our study we found that the Modified HBS score used in our center showed excellent reliability in terms of inter and intra-rater agreement.

In the same study, they found that Sydney and Sunny brook facial nerve grading systems had good reliability. Breaking up the individual ICC scores for Sunny brook voluntary movements scores had a value of 0.63and the synkinesis score had a kappa value ranging between 0.38 to 0.70. Hence the Sunny brook score had lower reliability with synkinesis score. In our study we could not evaluate the reliability of synkinesis score as it was zero for all the patients included in the study.

The study by Henstrom et.al(33) used kappa values to calculate the inter-observer agreement between the original and modified House Brakmann scale. The interpretation of kappa as described by Landis was used(<0 = poor; 0 to 0.20 = slight; 0.21 to 0.4 = fair; 0.41 to 0.6 = moderate; 0.61to 0.8 = substantial; 0.81 to 1.0 = almost perfect) There was moderate agreement of the original scale with a kappa value of 0.58 and the modified scale had substantial agreement with a kappa value of 0.63. They concluded that there was a high correlation between both the scales with perfect agreement in more than two-thirds of the cases and 98%agreement within one point of the scale.

The study conducted by Neely(50) found that intraclass correlation coefficient to calculate the inter-rater reliability of Sunny brook system was 0.890 (0.784-0.946). And hence the inter-rater agreement was excellent. It further improved to 0.927 (0.854-0.964) with Sunny brook checklist. They also found that the inter-rater agreement was most apparent within the middle ranges of SB composite score values. The maximum difference between the raters happened in assessment of voluntary movements than resting movement or synkinesis. Absolute agreement between raters using the HB system was very poor.

The study by Mateo et.al(49) stated that the House brackmann score showed values of inter-rater agreement (k) of 0.32, 0.45, and 0.60 (mean value 0.46) while the Rough facial nerve grading system showed an agreement of 0.57, 0.59, and 0.60 (mean value 0.59). Based on Landis and Koch guidelines the House brackmann score showed a fair to moderate level of agreement, while RGS showed a moderate level (with a tendency toward substantial agreement).

A study by Rickenmann. et al revealed a high reliability of HBS with an r-value of 0.75.(51) Friedman and House measured reliability of the HB grading system using Pearson's correlation, and found it to be high, statistically significant (*P* _ 0.05) correlation, with the majority of values greater than 0.80.(52) In our study Sunny brook grading system also had *excellent agreement* with ICC ranged between 0.89-0.98.

Similar studies were done to assess the reliability of Sunny brook by Hu et al(53) and by Ross et.al(54) revealed excellent reliability in composite scores with ICC of 0.87 to 0.98 and 0.85 to 0.97 respectively.

Intra-rater reliability:

When comparing the intra-rater reliability in *Modified House Brackmann score* rater 3 had the best reliability with ICC of 0.98 and confidence interval of (0.95-0.99). Rater 2 had the lowest reliability with ICC of 0.95 (0.84-0.98). Among the individual scores of the House Brackmann scoring system, temporal score of rater 2 had the lowest reliability with ICC of 0.84 (0.95,0.93) and Zygomatic score of Rater 3 had the highest reliability with ICC of 0.99 (0.98, 0.99).

The overall intra-rater reliability of the Modified House brackmann score for the three observers had *excellent agreement* with ICC ranged between 0.84- 0.97.

When comparing the intra-rater reliability in the Sunny brook scoring system, rater 3 had the best reliability with ICC of 0.98 (0.94, 0.99) and rater 2 had the lowest reliability with ICC of 0.89 (0.72,0.95). Among the individual scores resting symmetry score had the lowest ICC of 0.08 (1.28, 0.63) with rater 1. The voluntary movement score ICC ranged between 0.89 (0.73,0.96) with rater 2 to 0.97 (0.93, 0.98) with rater 1 and 3. The lip ICC score of rater 2 was lowest with a value of 0.76

(0.40-0.90) and the forehead score ICC of rater 3 was highest with a value of 0.99 (0.97, 0.99). The overall intra-rater reliability of Sunny brook grading system had *excellent agreement* with ICC ranged between 0.89- 0.98.

The study conducted by Neely(50) used intraclass correlation coefficient to calculate the inter-rater reliability of Sunny brook system and compared it with House Brackmann system. The ICC for intra-rater variability was 0.970 (0.939-0.986) and 0.948 (0.894-0.975) for rater 1 and rater 2 respectively. When performed with Sunny brook checklist the ICC was 0.976 (0.951-0.988) and 0.958 (0.914-0.980) respectively. Hence it showed excellent to almost perfect ICC for Sunny brook system. However the differences within an observer were lower when the sunny brook checklist was used to do the assessment. They also stated that the House Brackmann grading system was easy to use but included wide range of movements in a single grade. It had significant overlap between the grades. A disagreement of even one grade represents an extremely large range of SB values and disagreement of two or three grades is so large as to be worthless.

According to the systemic review of Literature by Fattah et.al(10), it was stated that the data on intra-observer reliability of House Brackmann score was limited and needs further studies in the feature. On the other hand, Sunny brook system had high inter-observer and intra-observer reliability in terms. intraclass correlation coefficients ranged from 0.838 to 0.98 for intraobserver variability and from 0.83154 to 0.99747 for interobserver variability, where is 1.0 is perfect correlation. Sunny Brook fulfilled nearly all the criteria for an ideal facial nerve scoring system used in

the study. It also recommended the use of Sunny brook system for further assessment of facial paresis and mentioned it as the current standard for the same.

CONCLUSION

Conclusion:

In our study, we found out that both the Modified House Brackmann score used in our center and the Sunny brook Facial nerve grading systems had excellent inter and intra-rater reliability and there was no statistically significant data to suggest that one system was superior to the other. The advantage of using Modified House Brackmann score used in our center is that unlike the House Brackmann score it gives 3 individual scores for the individual branches of facial nerve. However, Sunny brook system is a more comprehensive system that can amount for features like synkinesis in late form of facial palsy.

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ANNEXURE

Annexure 1: Intitutional Research Board Approval:

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

February 07, 2018

Dr. Amerjeeth. J. D,
Post graduate Registrar,
Department of Surgery - 1,
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant: New Proposal:**
Comparison of inter- and intra-rater reliability of Modified House Brackmann and Sunnybrook facial nerve grading systems in post Parotidectomy patients
Dr. Amerjeeth. J. D, Employment Number: 21389, PG Registrar, Surgery Unit I, Dr. Cecil. T. Thomas, Associate Professor Employment Number: 32376, General Surgery – Unit I, Dr. Srujan Lam Sharma, Senior Resident, Emp. No: 29247, General Surgery – Unit I, Dr. Vasanth Mark Samuel, Emp. No: 33291, General Surgery – Unit, Dr. Pranay Gaikwad , Emp no: 31224, General Surgery – Unit I.

Ref: IRB Min. No. 10952 [DIAGNO] dated 07.11.2017

Dear Dr. Amerjeeth. J. D,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS, MD, DM
SECRETARY (ETHICS COMMITTEE)
Institutional Review Board
Christian Medical College, Vellore - 632 002

Cc: Dr. Cecil. T. Thomas, Dept. of Surgery - 1, CMC, Vellore

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

Annexure 2: Master data sheet

Study Number: Date:

Name: Age: yrs Sex: M / F

Hospital Number: Address:

Mobile: Email ID:

Clinical details

Diagnosis:

Operation: Adequate / Superficial/ Total conservative parotidectomy

Date of admission: Date of Operation:

Date of Discharge: Postoperative day (video):

Size of tumour:

Preoperative FNAC report:

Preoperative imaging:

Branches of facial nerve dissected (circle as appropriate): trunk / upper division / lower division / temporal / zygomatic / buccal / marginal mandibular / cervical

Histopathology:

Grading

Modified House Brackmann	**Rater 1**		**Rater 2**		**Rater 3**	
	Score 1	Score 2	Score 1	Score 2	Score 1	Score 2
Temporal						
Zygomatic						
Marginal mandibular						
Sunnybrook	**Rater 1**		**Rater 2**		**Rater 3**	
	Score 1	Score 2	Score 1	Score 2	Score 1	Score 2
Resting symmetry score						
Eye						
Cheek						
Mouth						
Voluntary movement score						
Forehead						
Eye closure						
Smile						
Snarl						
Lip pucker						
Synkinesis score						
Composite score						

Signature:

Name:

Annexure 3: Data Sheet, Modified House Brackmann score (CMC, Vellore)

Name: **Hospital no:** **Date:**

Assessment: 1 / 2

Branches	**Modified HB score**
A: Temporal branch function	
B: Zygomatic branch function	
C: Rami mandibularis function	

GRADE I: Normal (100%)

A: Able to frown properly

B: Normal eye closure

C. Symmetrical angles of mouth

GRADE II: Slight weakness on close inspection, not obvious at rest (80%)

A: Good movement on frowning

B: Infrequent blinking & lid lag

C: Slight asymmetry of mouth and normal nasolabial fold

GRADE III: Obvious at rest, not disfiguring (60%)

A: Moderate movement on frowning

B: Complete eye closure with effort

C: Slightly weak with maximal effort and depressed nasolabial fold

GRADE IV: Obvious and disfiguring (40%)

A: Slight movement of forehead

B: Cornea covered with maximal effort

C: Moderately weak with maximal effort and absent nasolabial fold

GRADE V: Barely perceptible movements (20%)

A: Flicker of movement of forehead

B: Cornea exposed with maximal effort

C: Flicker of movement with maximal effort

GRADE VI: Total paralysis (0%)

A: No forehead movement

B: No eye closure with maximal effort

C: No movement of mouth

Signature

Name of the rater:

Annexure 4: Data Sheet, Sunnybrook Facial Grading system

Name: **Hospital no:** **Date:**

Assessment: 1 / 2

1. **Resting symmetry:** Compared to the normal side

Eye:	**Cheek:**	**Mouth:**
Normal-0	Normal-0	Normal-0
Narrow/ wide/ eyelid surgery-1	Absent-2	Corner dropped-1
	Less pronounced-1	Corner pulled up/out-1
	More pronounced-1	

Total = Eye + Cheek + Mouth score = _____ + _____ + _____ = _____

Resting symmetry score = Total x 5 =

2. **Symmetry of voluntary movement:** Degree of muscle excursion compared to the normal side

Facial Expression	No movement/	Initiates slight	Initiates movements	Movement almost	Movement complete	**Score**

	Unable to initiate slight movement	movement	with slight excursion	complete		
Forehead wrinkle	1	2	3	4	5	
Gentle eye closure	1	2	3	4	5	
Open mouth smile	1	2	3	4	5	
Snarl	1	2	3	4	5	
Lip pucker	1	2	3	4	5	
	Gross asymmetry	Severe asymmetry	Moderate asymmetry	Mild asymmetry	Normal	
					Total	
					Voluntary movement score: Total x 4 =	

3. **Synkinesis score:** Degree of involuntary muscle contraction associated with each contraction

Facial Expression	None- No synkinesis	Mild- slight synkinesis	Moderate- Obvious but not disfiguring	Severe- Disfiguring	**Score**
Forehead wrinkle	0	1	2	3	
Gentle eye closure	0	1	2	3	
Open mouth smile	0	1	2	3	
Snarl	0	1	2	3	
Lip pucker	0	1	2	3	
				Synkinesis score total =	

Composite score = (Voluntary movement score) – (Resting symmetry score) - (Synkinesis score) =

Signature:

Name of the rater:

Annexure 5: Patient information sheet

Christian Medical College, Vellore

Department of General Surgery

You are being requested to participate in a study that compares the inter and intra rater reliability of modified House Brackmann and Sunnybrook facial nerve grading systems in post parotidectomy patients.

What is this study about?

Facial nerve weakness is one of the most common complications following parotidectomy surgeries. It is important to have a reliable grading system to assess the facial nerve function precisely. It also helps in follow up of patient's clinical status post-operatively and to assess the effectiveness of various interventions tried to improve the facial nerve function.

A lot of grading systems have been used to grade the facial nerve dysfunction. In our center, we use a modified House Brackmann grading system. Various studies have shown that another grading system named Sunnybrook is more reliable in grading the facial nerve function. So our study aims to compare the inter and intra rater reliability of modified House Brackmann and Sunnybrook facial nerve grading systems.

If you take part what will you have to do?

If you take part in this study you will be asked to do specific facial movements during your post-operative period and you will be videoed while performing these movements. These videos will be used to grade the facial nerve function by 3 different assessors using modified

House Brackmann and Sunnybrook facial nerve grading systems. This will help us to find out the more reliable grading system

All other treatments that you are already on will be continued and your regular treatment will not be changed during this study. No additional procedures or blood tests will be conducted routinely for this study

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

What will happen if you develop any study-related injury?

We do not expect any injury to happen to you but if you do develop any side effects or problems due to the study, these will be treated at no cost to you. We are unable to provide any monetary compensation, however.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission

If you have any further questions, please contact Dr. Amerjeeth. J. D,

(Tel: 0416 2282082/ +91 8754099600) or email: amerjeeth@gmail.com

Annexure 6: Informed Consent form

Study Title: Comparison of inter- and intra-rater reliability of Modified House Brackmann and Sunnybrook facial nerve grading systems in post parotidectomy patients

Study Number:

Subject's Initials: **Subject's Name:**

Date of Birth / Age: **(DDMMYYYY)**

(Subject)

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

(iv) I agree to be photographed and videotaped for the use of this study and to use these data for the publication of this study [ ]

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

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

Date: _____/_____/_____

Signatory's Name: _____

Signature: Or Left thumb impression

Representative: _____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

Signature or thumb impression of the Witness: _____

Date: _____/_____/_____

Name & Address of the Witness: _____