# "FACIAL CONTOUR DEFORMITY CORRECTION

# BY FAT INJECTION"

Dissertation submitted to

#### THE TAMILNADUDR.M.G.R.MEDICAL UNIVERSITY

In partial fulfillment of the regulation for the award of the degree of

M.Ch.(Plastic and Reconstructive Surgery)

**Branch III** 

AUGUST-2014.



# RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL MADRAS MEDICAL COLLEGE THE TAMILNADU DR.M.G.R.MEDICAL UNIVERSITY CHENNAI

**TAMILNADUI** 

# **CERTIFICATE**

certify This the dissertation entitled "FACIAL is to that CONTOURDEFORMITY CORRECTION BY FAT INJECTION" is a bonafide work done DR. K.P.GANESH KUMAR, post graduate (2011-2014) in the Department of Plastic, Reconstructive & Faciomaxillary Surgery, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai – 03,in partial fulfillment of the University rules and regulations for award of Master of Chirurgiae, Plastic & Reconstructive Surgery (branch III) degreeunder my guidance and supervision during the academic year 2011-2014.

Signature of Guide & HOD

Signature of Dean

Dr. R.GOPINATH, M.ch,

Dr. VIMALA, M.D

Professor and Head of Department of The DEAN,

Plastic & Reconstructive Surgery,

Madras Medical College & RGGGH

Madras Medical College & RGGGH,

Chennai – 600003.

Chennai - 600003.

#### **CERTIFICATE**

This is to certify that **Dr. K.P.GANESH KUMAR**, post graduate (2011-2014) in the Department of Plastic, Reconstructive & Faciomaxillary Surgery, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai-03, has done dissertation titles, "FACIAL CONTOUR DEFORMITY CORRECTIONBY FAT INJECTION", under my guidance and supervision in partial fulfillment of the regulations laid down by THE TAMILNADU DR.M.G.R. MEDICALUNIVERSITY, GUINDY, CHENNAI-32 for the degree of MASTER OF CHIRURGIAE, Plastic &Reconstructive Surgery (branch III) degree examination.

Signature of Guide & HOD

Signature of Dean

Dr. R.GOPINATH, M.ch,

Dr. VIMALA, M.D

Professor and Head of Department of The DEAN,

Plastic & Reconstructive Surgery,

Madras Medical College & RGGGH

Madras Medical College & RGGGH,

Chennai - 600003

Chennai – 600003

**DECLARATION** 

I solemnly declare that this dissertation "FACIAL CONTOUR DEFORMITY

CORRECTION BY FAT INJECTION" was done by me in the Department of

Plastic, Reconstructive & Faciomaxillary Surgery, Madras Medical College &

Rajiv Gandhi Government General Hospital, Chennai-03 between 2011 and 2014.

This dissertation is submitted to THE TAMILNADU DR.M.G.R.

MEDICAL UNIVERSITY, GUINDY, CHENNAI-32 in partial fulfilment of the

university requirements for the award of degree of M.Ch. PLASTIC &

RECONTRUCTIVE SURGERY.

Place: Chennai

Signature of the Candidate

Date:

## **ACKNOWLEDGEMENT**

I gratefully acknowledge and sincerely thank the **Dean, Madras Medical College & Rajiv Gandhi Government General Hospital, and Chennai – 03,** for granting me permission to utilize the facilities of the Institute for my study.

I am extremely grateful to my teacher and guide **Prof. R. Gopinath, M.Ch. Professor and Head of the Department of Plastic, Reconstructive & Faciomaxillary Surgery, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai – 03**, for helping me in all stages of my study. I am thankful to him for his timely suggestions, unending patience, constant encouragement and scholarly guidance.

I am extremely grateful to Prof. Udesh Ganapathy, M.Ch. for his guidance and support.

I am extremely grateful to Prof. K. Gopalakrishnan, M.Ch. for his constant support and guidance.

I am extremely grateful to Assistant Professor Dr.S.Sridevi for her constant support in collection of cases, gathering of instruments, suggestions, and encouragement.

I am extremely grateful to Assistant Professor Dr. T.M.Balakrishnan for his constant support, timely suggestions and encouragement.

I express my thanks to my Assistant Professors Dr. Saravanan, Dr. Selvakumar, Dr. Mahadevan, Dr. Vivek, Dr. Arun kumar for their sustained encouragement.

Iam especially happy to thank my co residents and staff members in the department, for their comments, correction and help in the execution of effort.

Iam extremely thankful to all my patients who readily consented and cooperated in the study and have helped me improve my knowledge and complete this dissertation.

Last but not the least; I am extremely grateful to my family members for their constant love, support, and motivation.

# **CONTENTS**

Chapter No.	TITLE	Page No.
1.	INTRODUCTION	1
2.	REVIEW OF LITERATURE	2
3.	AIM AND OBJECTIVES	14
4.	MATERIALS AND METHODS	15
5.	OBSERVATIONS AND ANALYSIS OF RESULTS	32
6.	DISCUSSION	48
7.	CONCLUSION	51
8.	BIBLIOGRAPHY	
9.	ANNEXURES	
	• PROFORMA	
	MASTER CHART	
	ETHICAL COMMITTEE APPROVAL	
	CERTIFICATE	
	PLAGIARISM DIGITAL RECEIPT	
	PLAGIARISM SCREEN SHOT	

#### **INTRODUCTION**

Having face most expressive part of body and becoming the need of the hour for both men and women. It instills sense of pride among individuals by not only enhancing the personality but also by boosting the confidence level of an individual. Aesthetic surgery is one of the most effective ways of improving and enhancing the facial look of an individual.

Unlike earlier days, where people were skeptic undergoing cosmetic surgery, there is an increase in the number of people in India undergoing them. People's Lifestyle, socio economic status, awareness, professional need, self -image, phases of life, globalization has motivated people towards cosmetic surgery.

WHO defines health as "a state of complete physical, mental and social wellbeing and not merely the absence of disease and infirmity". This harmony of wellbeing is lost when a person feel he is physically less attractive. The goal of aesthetic facial contour surgery is to eradicate physical characteristics that impede the free interaction of individuals. By undergoing surgery, these individuals wanted not to disavow their ethnic backgrounds or cultures but to escape being rejected by the people with whom they come in to daily contact and who decline to associate with them.

#### **REVIEW OF LITERATURE**

Fat injection / grafting is one of the means to augment or correct the facial contour deformity. Fat grafting used to replace tissue lost due to trauma, disease, and developmental deformity in face, it rejuvenate and dramatically alter the contour of face and well-being of the individual.

Facial atrophy may be unilateral or bilateral. Bilateral facial atrophy is found in various situations such as trauma, HIV infection. Facial hemi-atrophy is seen after trauma, parry-Romberg syndrome and on other rare occasions. List of conditions that causes unilateral facial contour deformity with their underlying pathogenesis, clinical features, options of treatment other than autologous fat grafting are mentioned below.

# **Romberg's Disease: (Parry – Romberg Syndrome)**

Also known as Progressive hemi-facial atrophy, is characterized by slowly progressive atrophy on one side of face, primarily involving subcutaneous tissue and fat, has no definite pathogenesis, although multiple etiology suggested for its diseases process. Restoration of contour and symmetry is main challenge in patients.

#### **Autoimmune process:**

PHA likely a variant of autoimmune disease localized scleroderma, with subtype of linear scleroderma that affects face called ECDS (en coup de sabre) or saber mark ,leads to atrophy of subcutaneous tissue and facial bones causing hemi-facial atrophy in disease course. Auto antibodies to antinuclear antibody are positive in both ECDS and in Classical PHA (hemi-facial atrophy without sclerodermatous skin changes)<sup>1-3</sup>. Histological findings are similar like lymphocytic neurovasculitis <sup>4</sup>.

# **Neurogenic process:**

Distribution of facial atrophy typically follows dermatome of trigeminal nerve; with unilateral in 95% of cases, rarely crosses midline. Neuritis of trigeminal nerve suggested by patients complaining of episodes of pain in involved area before the onset of tissue atrophy<sup>5,6</sup>. Dermal lymphocytic infiltrate concentrate around neurovascular bundle in dermis also supports .Also hyperactivity of sympathetic nervous system specifically superior cervical ganglion inflammation leads to PHA.

# **Infection process:**

Diseases process noted to follow viral or bacterial infections. Common agent for both ECDS and PHA was Borrelia burgdoferi <sup>7,8</sup>.

#### Trauma:

Controversial and follows tooth injury or extraction <sup>9,10</sup>.

#### **Clinical manifestation:**

Pigmentary changes in cutaneous tissue along dermatome distribution of trigeminal nerve.

Dermal atrophy – shiny skin and visible veins.

Well demarcated linear depression (groove) in fronto-parietal or hemi facial distribution <sup>11</sup>.

Atrophy of facial musculature – masseteric muscle, tongue, palatal muscle.

Facial skeleton atrophy – maxilla, mandible with mal- occlusion.

CNS involvement 8-21% <sup>12-15</sup> – localized seizures.

Ocular involvement – alteration in adnexal structures, anterior or posterior segment of eye and optic nerve <sup>16</sup>.

Oral involvement – atrophic of tongue and upper lip.

Classification proposed for Parry-Romberg syndrome.

# Guerrerosantos et al. 16a

S.NO	GRADING	INVOLVEMENT
1	Grade I	Very mild depression in
		the face, occurring
		In acute phase of Parry-
		Romberg syndrome.
2	Grade II	Reduced thickness of the
		soft tissue of the face,
		With no bone or cartilage
		involvement.
3	Grade III	Soft tissue of the face is
		thinner than in grade
		II + initial bone and
		cartilage involvement
4	Grade IV	The most severe type of
		facial depression and the

	skin is quite close to bone
	With bone involvement.

#### **Treatment:**

Role of immunosuppression with methotrexate <sup>17,18</sup>.

Local pedicle flap, free flap (scapular, Para-scapular, ALT flap)

Both immunosuppression and surgical treatment by flaps have their own complication, with donor and recipient site morbidity. Nonsurgical means like fillers, autologous fat grafting paves way for least donor and recipient site morbidity in Grade 1 and 2 lesions. Fillers because of it cost effectiveness and not easily available, fat grafting seem to be most useful mode of treatment in PHA. Restoration of contour and symmetry is main challenge in patients affected by this disease. An accurate soft tissue substitution by means of autologous fat injection with creation of multiple subcutaneous intramuscular and sub-periosteal tunnel ensured adequate blood supply of transplanted fat. Aesthetic improvement and patient's satisfaction show that autologous fat injection be a safe technique for correction of facial contour deformity in Parry – Romberg diseases.

# **Developmental facial contour deformity:**

Incidence in Europe ranges from 1:3500 to 1: 26550 live births; in India no particular data report the incidence of case.

Underlying cause or etio-pathogenesis of developmental defect remains debate, number of factors may contribute, following are suggested theory for possible development of defect

- ❖ Focal hematomas due to disruption of stapedial artery, "Stapedial artery hemorrhage etiology".
- ❖ Teratogen based etiology Triazine.
- ❖ Sporadic event.
- ❖ Genetic etiology insertional deletion on chromosome 10 with autosomal dominant mode of transmission and 25% penetration.

Developmental deformity involves both soft tissue and skeletal component.

# **Skeletal component:**

Hypoplasia of mandible, maxilla, zygoma, pterygoid process of sphenoid bone, temporal bone, frontal bone.

## **Soft tissue component:**

Muscles of mastication, deficient of soft tissue (hypoplasia ) in parotidmasseteric and auriculo-mastoid areas.

#### Ear:

Range from complete atresia to variable degree of remnants and deformity with facial nerve weakness.

# **Nervous system:**

Cranial nerve anomaly – facial paralysis secondary to agenesis of facial nerve in temporal bone or hypoplasia of intracranial portion of facial nerve and facial nucleus in brain stem.

#### **Treatment:**

Various mode of modalities available for correction of deformity, skeletal component by distraction osteogenesis, frontal-orbital advancement, cranial vault remodeling.

Soft tissue remodeling by micro vascular free flaps, pedicle flaps, and autologous fat injection.

Ear reconstruction by staged Brent's or Nagata's autologous rib graft reconstruction.

Our topic of interest is autologous fat injection for soft tissue reconstruction of face in this developmental deformity.

# Post traumatic lipo-dystrophy:

Specific history of trauma to the affected area following tooth injury or extraction, which directly related to disease onset <sup>19,20</sup>.

Most commonly lipodystrophy occurs in the region of cheek, infra zygomatic, supra zygomatic and pre-parotic area.

Deformity restricted to soft tissue only, leads to atrophy of soft tissue, fat layer. No functional restriction and no bony deformity.

#### **Treatment:**

Augmentation of soft tissue by autologous fat grafting gives long lasting results. So autologous fat injection for the above mentioned deformity paves the way for contour correction with minimal to no morbidity. Our study concentrated on facial contour deformity correction by fat injection. Before going in details, we have to know about fat grafting, its history, standard procedure, merits and demerits of the procedure.

Fat grating began at 1890's, since then controversy regarding the predictability and consistency of results obtained with fat grafting, with 70% report of reabsorption rate. Based on Lyndon Peer's cell survival theory, number of viable adipocytes transplanted correlates with volume of grafted fat survives. Results paved the way for Coleman method, as it yields a greater number of viable adipocytes and maintains more optimal level of cellular function.

#### HISTORY OF FAT GRAFTING / INJECTION:

The first report of fat grafting was in 1893 by German surgeon Gustav Neuber<sup>21</sup> when he transplanted adipose tissue harvested from the arm to correct a depressed facial scar that had resulted from osteomyelitis. This was followed 2 years later by Vincenz Czerny, who transferred a fist-sized lipoma from the buttock to the breast.<sup>22</sup> Even then, fat grafting was considered difficult, time consuming to perform, and somewhat unpredictable; therefore new solutions were sought.

The use of paraffin to correct deformities had been described in 1830 by Baron Karl von Reichenbach. By the late 1800s, Robert Gersuny and Leonard Corning were using paraffin either injected alone, with petroleum jelly, or with a combination of petroleum jelly and olive oil, into facial defects. Initially, the paraffin and petroleum jelly filled in soft tissue defects nicely, providing a soft, natural appearing contour. It appeared to be an easy remedy for numerous deformities; but

unfortunately, after a time, complications such as paraffinomas, or hard local swellings, began to emerge. Thus paraffin lost favor within the medical community.

Looking for a solution to the problems caused by paraffin, Eugene Hollander proposed the use of fat injected through a cannula to correct deformities. 23,24 .He noted considerable reabsorption of the fat and therefore began mixing human fat with fat from a ram in an attempt to stabilize it. This resulted in a painful rash which lasted several days, however a good cosmetic result was obtained. Later, in 1919, Erich Lexer published a two-volume book dedicated to the technique of fat grafting.<sup>25</sup> In this book, he presented a wide variety of conditions such as depressed scars, breast asymmetry, knee ankylosis, tendon adhesions, and micrognathia and the successful results after treatment with fat grafting. Charles Miller also described the injection of transplanted fat for the correction of facial folds and wrinkles in his 1926 publication, Cannula Implants and Review of Implantation Technics in Esthetic Surgery. 26 Despite some favorable results from these pioneers, fat grafting was still unpredictable and it thus fell out of favor.

It wasn't until the 1950s when Lyndon Peer studied the gross and microscopic appearance of transplanted fat that we began to understand and improve the predictability of fat grafting.<sup>27</sup> He discovered that adipose grafts lose approximately 45% of their weight and volume at 1 year due to cell rupture and

subsequent death. The fat cells that do not rupture, however, will survive and volume will be maintained. Improper handling of the fat prior to and during transplantation was also found to decrease the survival of the fat. Graft size also appeared to play a role in survival. A graft the size of a walnut was found to lose volume more rapidly than multiple smaller grafts of similar weight, likely due to the increased surface area of the smaller grafts. Revascularization, as seen microscopically, was noted by Peer to be essential for fat graft survival.

With the advent of liposuction in the 1980s by Fournier<sup>28</sup> and Illouz,<sup>29</sup> there was a renewed interest in fat grafting. Results, however, were only partially successful and the thought at the time was that perhaps better preparation of the fat was essential for its survival. Chajchir<sup>30</sup> and Benzaquen took this advice and made some recommendations based on their own favorable results; yet there was still great confusion as to what really worked until the 1990s, when Coleman standardized the technique. This technique, called Lipostructure, emphasizes gentle extraction of fat, centrifugation, and micro particle injections in multiple tissue planes. Dr Coleman has used this technique for more than 20 years and has documented the longevity and stability of fat grafting performed in this manner.<sup>31–</sup>

# **Basic principles of fat grafting:**

Adipose – derived stem cells:

Friendenstein et al <sup>35</sup> first to discover that bone marrow contains cell that differentiate into other mesenchymal cells as well as into fibroblast. These adherent cells currently called Mesenchymal stem cells (MSCs).Most common source of MSCs other than bone marrow is adipose tissue, which offers abundant and easily accessible source of ADSCs, harvested by minimally invasive procedure. Fat tissue contains more stem cells per gram then bone marrow (5000 vs. 100-1000 cells)<sup>36</sup>

ADSCs have the dynamic capacity of regenerative and renewal property paves the way for Coleman's technique of fat grafting, in which fat has been harvested, centrifuged, refined and reinjected for maximal fat survival and long lasting outcome in rejuvenation of skin texture <sup>37-40</sup>

# **AIM AND OBJECTIVES**

#### **AIM**

To study the aesthetic outcome of facial contour correction surgery.

#### **OBJECTIVES**

# **Primary Objective:**

To study the Aesthetic outcome of Facial contour deformity correction by Autologous fat injection, and includes

- 1. To study the patient selection factors for facial
- 2. To describe operative approaches for comprehensive spectrum of facial

Contouring surgical procedure.

# **Secondary Objective:**

To improve the quality of life in Facial contour deformity patients by giving better aesthetic outcome

## **MATERIALS & METHODS**

The study was conducted in the Department of Plastic Surgery, Rajiv Gandhi Government General Hospital, and Madras Medical College over a period of 26 months January 2012 to February 2014. The pro-forma for the collection of data was made. All the relevant details of the patients during preoperative, surgical, and postoperative and follow up periods were collected and analyzed.

This study is a prospective and retrospective study, where 20 patients are included. Correction of facial contour deformity by fat injection by Modified COLEMAN'S TECHNIQUE.

# **Subject selection:**

#### **Inclusion criteria:**

Those patients needing facial contouring

- 1. All facial contour deformities including Romberg's disease with no underlying gross bony deformities.
- 2. Post trauma and developmental facial soft tissue deformities.

#### **Exclusion criteria:**

- 1. Post irradiation
- 2. Scleroderma and other connective tissue disorders.
- 3. Patients diagnosed to have body dysmorphic disorder.
- 4. Those who are not willing to participate in my study will be excluded.

#### PATIENTS SELECTION.

# Aim in patient selection

Good motivated patients with expectations and desire within realistic aim. During the consultation in out- patients department we gather as much data as possible, minimum of three consultations is arranged before embarking on surgery.

- Objective data about the patients
- Subjective information about the patient's goals
- Patient's reason for presentation and motivation
- Duration of concern and how often they think about the concern

- ❖ Expected percentage of improvement
- ❖ Patients perception of expectation of result rate
- **❖** Patients intelligence
- Dependency on follow up care
- ❖ Family backup e.g. Young children, responsibility and assistance in follow up care, home help
- Perspectives on surgery, and
- ❖ Psychological makeup.
- ❖ Medical and surgical history
- **❖** Family history
- Medications, allergies
- Smoking, drinking and recreational drug use
- Nutritional status and hygiene habits
- ❖ A detailed physical examination is performed, particularly to the areas of concern.
- ❖ Prior surgical scars noted.

#### FACTORS CONSIDERING IN PATIENT SELECTION

#### **UNDERLYING GROSS BONY DEFORMITY**

Patients with gross underlying bony deformities, not sufficient enough to correct contour with fat injection alone, they had to be corrected with fillers.

- ❖ Gross bony deformities are excluded by taking preoperative CT − Facial skeleton with 3D reconstruction.
- ❖ Functional restrictions are corrected preoperatively.

#### **ACTIVE SMOKERS AND ALCOHOLICS**

There is incontrovertible evidence that smoking causes postoperative complication including wound healing problems, pneumonia, and heart attack.

Patients are encouraged to stop smoking and alcohol for a period of 4 weeks prior to surgery.

#### PSYCHIATRIC DISORDER - BODY DYSMORPHIC DISORDER

Dissatisfaction with body image drives individuals to pursue elective breast and body, facial – contouring surgery.

Body dysmorphic disorder (BDD) is described in the 'Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, comprising

- 1) Preoccupation with an imagined or minor defect in physical appearance,
- 2) Marked distress or impairment in social functioning resulting from the appearance preoccupation,
- 3) The preoccupation is not attributable to the presence of another psychiatric disorder.

BDD often coexists with mood and anxiety disorders, obsessive- compulsive spectrum disorder, substance abuse, eating disorder, and personality disorders. Patients affected by BDD do not benefit from surgical treatment, don't experience improvement in body, facial image after surgery and may even express worsened feelings. BDD patients are a contraindication to elective surgery for enhancement. Hence these patients are referred to pharmacologic therapy and cognitive behavioral therapy and refused surgery.

#### INFORMED CONSENT

Preoperative and postoperative photos of good and average results of prior patient's outcome are shown to patients. Photographic consent taken.

All possible complication and their remedy are explained, surgical procedure are explained in detail to patients, alternate options are also explained, Need of secondary touchup procedure explained, possible donor site for fat harvest and surgical scar explained, and patients is asked to decide without any confusion or compulsion. Adequate time is given to the patients to decide; at least three minimum consultations are arranged before embarking on surgery.

# **Preoperative general measures**

- ❖ All facial contour deformity patients are admitted a day prior to surgery
- ❖ Investigation: All patients undergo basic investigation, complete blood count, renal function tests, blood sugar, screening for sexually transmitted diseases- HIV, HbsAg, and VDRL.
- ❖ Specific investigation:
  - a) CT- Facial Skeleton with 3D reconstruction
- ❖ Pre op. assessment of volume correction assessed by face mask is not done in our department; we follow the 'Rule of thumb 'in deciding the amount of fat needed for facial deformity correction.

- ❖ Pre-operative marking is critical. They are confirmatory to the patients who should understand the exact areas to be addressed, done patient in sitting position. Furthermore, there is distortion when the patient lies supine on table after anesthesia. Future surgical scar markings are marked and explained to patient. Possible donor site for fat harvest (Abdomen, buttock, lateral thigh) explained and marked.
- ❖ Good informed consent obtained
- Preoperative photographs taken in different views, before marking and after marking.

Pre op. photograph of patient in different views



Pre op. photograph after marking



Donor site marking



# **Surgical technique:**

# **Standard Coleman's technique:**

#### **Harvesting:**

Local or General Anesthesia used.

Tumescent fluid containing 0.2% lidocaine and 1:400,000 epinephrine.

Harvested using Standard two hole Coleman's Cannula.

Aspirate 1ml fat per 1ml tumescent.

Incision closed with nylon sutures.

#### **Refinement:**

Harvested syringe placed in sterilizable centrifuge, processed at 1286g for 2min.

Aqueous component at bottom removed by releasing Luer-Lok plug, oil component on top decanted off with Telfa pad.

#### **Placement:**

Recipient site infiltrated with 0.5% lidocaine with 1:200,000 epinephrine.

Lattice pattern technique of placement at different level with small fat globules during withdrawal of cannula.

# Postop. Care:

All area of covered with Micro foam except upper eyelids.

Standard Coleman's technique which has been mentioned previously followed in our department in the past, we modified the technique by simplifying the instrument and procedure.

#### Modified Coleman fat injection technique:

- ❖ We do not use centrifugation instead we use the simple inverted standing of harvested syringes for 20 minutes which separate the fat layer easily.
- ❖ We do not use lignocaine in tumescent and use to aspirate 1ml fat for 1ml tumescent.
- ❖ Though we use multilevel 3D lattice pattern technique for injection we don't always use special cannulas and we use ordinary 14 gauge venflon cannulas at times like for lip areas.
- ❖ Neither injection gun nor anaerobic transfer of fat is used in our cases. The same syringes in which fat is harvested is used for reinjection after standing separation of fat and refining it.

- ❖ We always used general anesthesia for all our procedures because of our multilevel injection technique.
- ❖ The need for secondary touch up procedure is explained to all patients and Pre-op consent in this respect is taken from all patients and if needed it is Done only after 8 weeks and we use fresh fat harvest and not use any stored Fat. We never do any overcorrection in any of our cases.
- ❖ All depressed scars we release by dry run of injection cannulas before fat injection.
- ❖ The tumescent solution(1000 ml of ringer lactate+1ml of 1 in 1000 adrenalin (1in 400000 adrenalin) is injected thro. 1mm stab incision at donor site which are marked in standing posture to maintain the symmetry under strict aseptic precaution.
- ❖ After capping these syringes are kept on the sterile stand for 20 minutes which will cause the separation of aspirate into bottom serous and blood layer and fat cells in the middle and degenerated, damaged fat and oil on the top.

- ❖ In order to create good vasogeneic interstices we inject in subcutaneous, sub periosteal and intramuscular planes
- ❖ We routinely use intraoperative systemic steroid-8mg of decadron to prevent edema which precludes our visual judgment of deformity correction on table.

# **Modified COLEMAN'S Technique:**

Technique differ from standard Coleman's technique in following manners,

- ❖ All cases done under General anesthesia
- ❖ Don't use lignocaine in tumescent and use to aspirate 1ml fat for 1ml tumescent.
- ❖ Don't use centrifugation instead we use simple inverted standing of harvested syringe for 20 minutes for fat to separate in layers.
- ❖ Don't always use special cannulas and we use ordinary 14 gauge venflon cannulas at times like for lip areas.
- \* Neither injection gun nor anaerobic transfer of fat is used in our cases.

❖ Same syringes in which fat was harvested was used for reinjection after standing separation of fat and refining it.



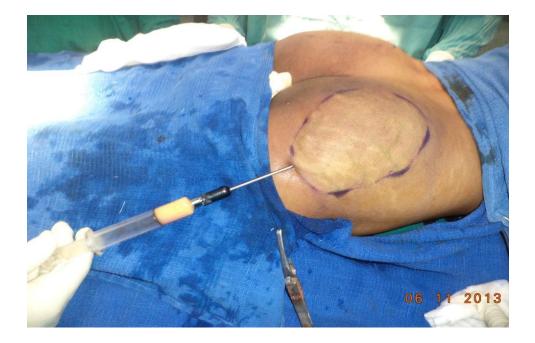
**Fat injection set:** Lamis infiltration cannula, Harvesting cannula 3mm, 4mm, Dissector, Reinjection cannula, Luer-lock syringes 2ml,5ml,10ml.

# **Operative procedure:**

Anesthesia: General Anesthesia

# **Position: Supine**

- ❖ Pre op. marking done both in Donor and Recipient site.
- ❖ Tumescent solution containing 1000ml of Ringer Lactate with 1:400000 dilution of Adrenaline, infiltrated with Lamis infiltration needle in Donor site by making 2mm stab incision , waiting period of 8-10 minutes maintained.



- ❖ Using 3mm/4mm Coleman's aspiration cannula with negative pressure created in Luer-lock syringes, fat harvested in donor site.
- ❖ Harvested syringes capped &kept in inverted standing position for 20mins.



❖ After standing for 20min. fat separated into three layers, bottom layer contains blood & aqueous fluid, middle layer contains viable fat cells, top layer contains oil & degenerated debris.



- ❖ Bottom layer ejected out after de-capping the syringe, top most layer decanted with wipes (cotton/gauze), leaving only viable fat cell in syringes.
- \* Recipient site prepared by dry run of cannula& fibrous strands are released.
- ❖ Harvested and refined fat infiltrated in Multi- level 3D lattice pattern in subcutaneous, intramuscular, sub-periosteal plane.



❖ Intra-operative systemic steroid 8mg of decadron to prevent edema which precludes our visual judgment of deformity correction on table.

#### **Immediate post op:**

Micro pore dressing, head-up elevation, antibiotics, analgesics, anti- edema measures.

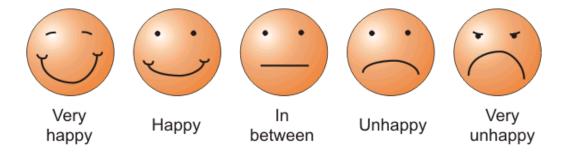
Patients are discharged on 4<sup>th</sup> -5<sup>th</sup> postop day, and advised to follow up in plastic surgery op.

# **Post-operative follow-up:**

Patients are followed up at weekly interval for first one month, then followed by once a month for six months, during follow up patients contour maintenance and photographs are taken as record.

# **Assessments of parameters:**

Comparing contour match with opposite side by clinical examination, different views of photographs, subjective satisfaction index assessed by Smiley chart for cosmetics.



#### **OBSERVATION AND ANALYSIS OF RESULTS**

In this case study of 20 patients ,with unilateral facial atrophy or contour deformity surgically managed by injecting autologous fat graft with results are good with minimal complication. Below is a chart depicting the Gender distribution, Deformity nature distribution, Donor site distribution, Average fat injected per deformity.

#### **GENDER**

Sex	No.
Male	7
Female	13

**Tab.1**:Gender Distribution

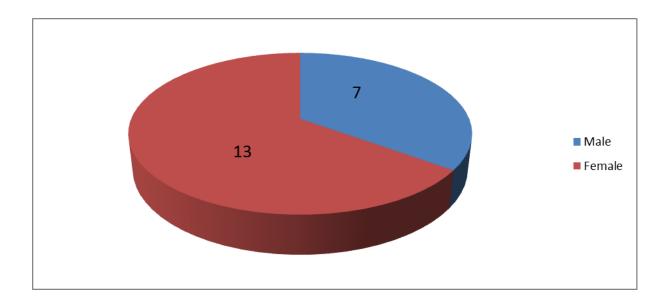


Fig.1:Gender Distribution

#### **NATURE OF DEFORMITY**

Nature of deformity	No
Developmental deformity	11
Post Traumatic	3
Romberg's disease	6

Tab.2: Distribution of Deformities

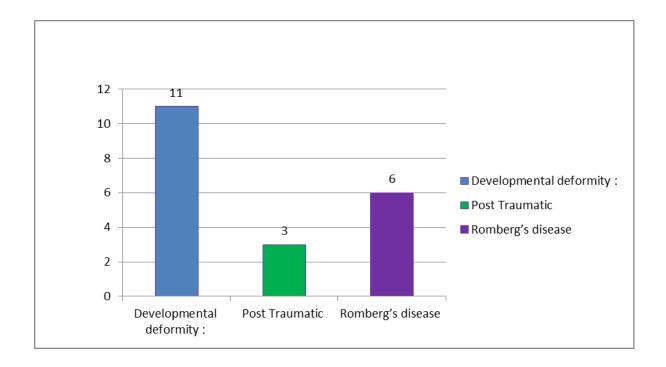


Fig.2: Distribution of Deformities

#### DONAR SITE FOR FAT HARVEST

Donor Site	Number
Abdomen	11
Abdomen & Lateral thigh	2
Lateral thigh	2
Buttock	5

Tab.3: Number of Donor Sites used for harvest

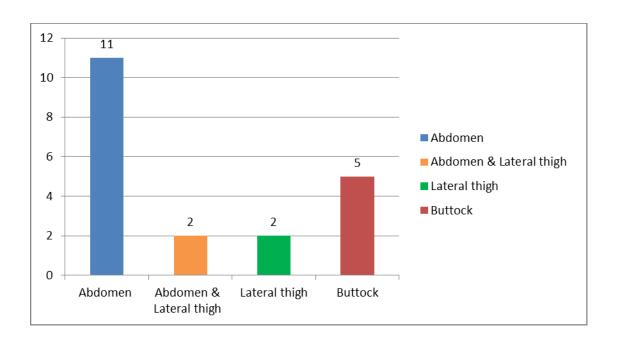


Fig.3: Donor sites used for Harvest

#### AVERAGE FAT INJECTED PER DEFORMITY

Deformity	Average fat injected in ml
Developmental deformity	74
Post Traumatic	58
Romberg's disease	112

Tab.4: Average fat injected in various deformities

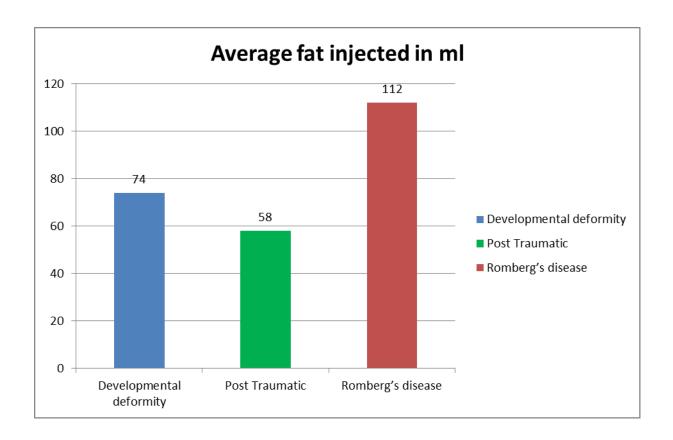


Fig.4: Average fat injected in various deformities

In all the 20cases operated female dominates male, average age distribution was 25.5 years, most case treated was Developmental deformity followed by Romberg's disease and then Post traumatic facial deformity, all procedure done in general anesthesia, average fat injected was 75.5ml, with no overcorrection. Maximum amount of fat injected in cases of Romberg's diseases (average 114 ml), Average follow up 6 months, no secondary touch up procedure needed in our cases. More than 95% of them felt that they obtained their facial contour after fat injection correction and more than 80% had self-confidence to overcome their social inhibitions.

#### **Complications:**

Following table shows the complications that we encountered in our series and the methods by which they were managed.

Nature	%	Overcome by
Bruising	3-6	Seen in the immediate PO period
		-cold application, anti-edema measures.
Sagginess	2-4	Dyne-plaster application at
		edge of wound
Clumping	2-4	Mild massaging in immediate
		postop period.

Edema	8-10	Anti-edema	measures	like
		steroids.		
Facial nerve weakness	none			

# **Case reports:**

## A) Developmental facial contour deformity:

#### Case 1:



Mr. Kamal 24 year old male came with complaint of deformity / flattening of left cheek since childhood.

#### On examination:

- ❖ Flatting of left cheek,
- ❖ Absent left malar prominences,

- Hypoplasia of left masseter,
- ❖ No obvious bony deformity,
- ❖ No facial nerve palsy,
- ❖ No functional restriction in mouth opening, chewing, smiling.



Corrected by: Autologous fat injection.

**Donor site:** Buttocks

**Amount of fat injected:** 63ml

No secondary touchup procedure.

Picture taken on 9<sup>th</sup> month follow up.

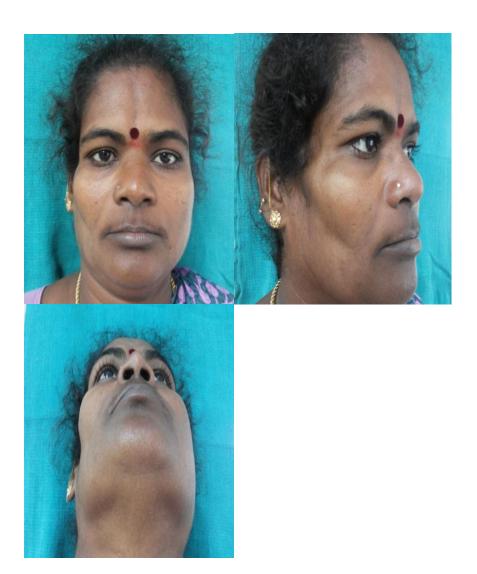
# **Complication:**

Sagging of injected fat on immediate post op. due to excessive tunneling.

#### **Correction:**

Applying Dyne-plaster at margins.

Case 2:



Mrs.Sivagami, 34 year female came with complaint of deformity right cheek and right temple since childhood.

# On examination:

- ❖ Hollowness noted over supra and infra zygomatic region,
- Prominent right malar region,

- ❖ Zygomatic arch easily palpable on compare to left side ,
- ❖ Masseter hypo plastic,
- ❖ No facial nerve weakness noted,
- ❖ No functional restriction.



Corrected by: Autologous fat injection.

Donor site: Abdomen

Amount of fat injected: 110ml

No secondary touchup procedure.

Picture taken on 9<sup>th</sup> month follow up.

# **Complication:**

# Edema



# **Correction:**

Anti-edema measures.

## B) Post traumatic contour deformity:

#### **Case 1:**



Mrs.Gowthami 42 year old female ,came to our op. with complaint of deformity left cheek 2 year duration . H/o Blunt trauma 5 years back followed by gradual depression noted over left side cheek.

#### On examination:

- ❖ Contour deformity noted over left cheek,
- ❖ Masseter bulk found normal ,no hypoplasia,
- ❖ No bony defect noted,
- ❖ No facial nerve weakness noted.



Corrected by: Autologous fat injection.

**Donor site**: Abdomen and lateral thigh

Amount of fat injected: 65ml

No secondary touchup procedure.

Picture taken on 9<sup>th</sup> month follow up.

# **Complication:**

Edema

## **Correction:**

Anti-edema measures.

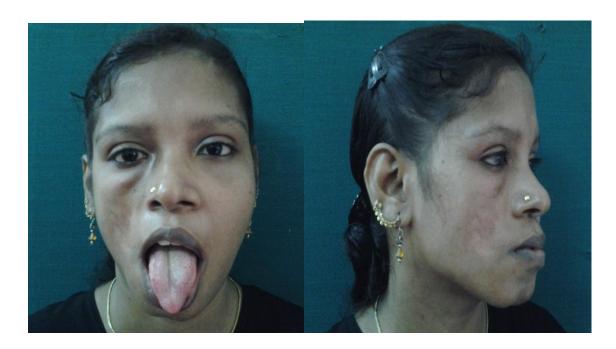
#### C) Romberg's disease:

Restoration of contour and symmetry is main challenge in patients affected by this disease. An accurate soft tissue substitution by means of autologous fat injection with creation of multiple subcutaneous intramuscular and subperiosteal tunnel ensured adequate blood supply of transplanted fat. Aesthetic improvement and patient's satisfaction show that autologous fat injection be a safe technique for correction of facial contour deformity in Parry – Romberg diseases.

#### Case1:



Miss. Nazir nisha 23 year old female, came to our OPD with complaints of Deformity left hemi-face since adolescence. She wants correction since her parents planning for marriage.



## On examination:

- ❖ Facial atrophy right hemi face,
- ❖ Soft tissue atrophy noted in right forehead, temple, infraorbital region, cheek, nasolabial region, pre-parotic region, masseteric region, chin, right half of upper lip, and tongue.
- ❖ Right maxilla hypo plastic,
- ❖ Hypo pigmented patch noted on right cheek,
- ❖ No facial nerve weakness noted.
- ❖ Saber mark noted on forehead.



Corrected by: Autologous fat injection.

Donor site: Abdomen and lateral thigh

Amount of fat injected: 120ml

# Plane of injection:

Subcutaneous, intramuscular, sub periosteal, sub muscular.

Sub periosteal injection given by making 2mm upper sulcus incision, reached over right lateral margin of pyriform aperture. Periosteum incised cannula inserted, fat injected at sub periosteal plane to augment right Ala base.

Right half of upper lip augmented by injecting fat intramuscularly using 14G venflon needle.

No secondary touchup procedure.

Picture taken on 6<sup>th</sup> month follow up.

Complication: Edema, Erythema.



# **Correction:**

Anti-edema measures.

#### **DISCUSSION**

Fat injection describe by Coleman involves cumbersome instrumentation and need for anaerobic transfer. Our simplified approach harvesting fat with simple syringes fitted with Luer- lock is used for harvesting, after refining the fat by simple inverted standing procedure for 20minutes with same syringes ( after discarding the bottom serous layer and wicking out the oil layer on the top ). Good quality fats assessed by simple agitation of syringes, presence of fibrous tissue are excluded.

Same syringe used for harvest and refining the fat is fitted with injection cannula of suitable size (3mm, 4mm) depending of region of augmentation. Eyelids, lips with venflon needles and other regions by contoured cannula. Atrophic and adhered scar subsides with cannula of sharp tip prior to injection. We use especially 3D lattice pattern with multilevel injection plane (subcutaneous, sub dermal, sub muscular, intramuscular, sub SMAS, sub periosteal) in order to create vasogenic interstices, which optimize the fat uptake.

In our protocol, we never over correct any facial deformity because of we follow the strict protocol of 'Never replace one deformity by another deformity' and we never use pre-injection infiltration because it intervene with visual judgment of deformity, we use systemic steroid 8mg decadron at time of initiation

of anesthetics. This will go a long way to reduce the edema of fat injection and adds to the finer visual judgement of correction of facial contour deformity.

We always take informed consent from all the patients in need for secondary touch-up procedure after 8 weeks.

This study conducted in our department clearly shows, none of the patients' needs secondary corrective procedure which again says there is no fat atrophy occurs when we follow 3D lattice pattern multi- level injection, also we not use centrifuge instrument which reduce greatly the cost and maintenance of therapy by 50% we also proved by this study, no need for anaerobic transfer which are cumbersome.

This simple technique with short learning curve we easily taught to interns and trainees .Patients especially for aesthetic procedure which not covered by insurance scheme with optimal satisfaction which we have to endure reduce the expensences.

We did all this procedure under general anesthesia with laryngeal mask airway(LMA) and few cases with oro-tracheal intubation because LMA are known to produce least amount of cardio vascular disturbances and no need for pre injection local anesthetics.

Finer cannulas and venflon needles used in our series in all our patients with normal coagulogram never experience petiche, ecchymosis, purpurae, or

hematomas. We don't routinely use any cold compression in postop period; we use peri-operative antibiotics to over both aerobic and anaerobic organisms. Post op period we remove small dressing after 48 hours and we discharged the patients after 48 hours routinely when they don't have complications.

On discharge we given instruction to patients, not to massage or use any compression, also advised to take head bath after 48 hours. Oral antibiotics after 48 hours and maintain for 5 days.

#### **CONCLUSION**

This simplified fat injection approach with simple instrumentation, short learning curve; adherence to multi-level 3-D lattice pattern injection technique has resulted in lasting results in comparable to standard Coleman's technique after one time correction.

This approach and our protocol is the favored method of correction for facial contour deformities with mild skeletal deformities or without skeletal deformities (Grade 1 & Grade 2 deformity).

Procedure related complication are very minimal in our study and again is an encouraging aspect of our devised protocol. The problem of storing fat and reusing it for secondary correction doesn't even arise in our approach.

Good motivated patients with expectation and desire within realistic aim, get satisfied with the goal oriented aesthetic facial contouring approaches. The number of dissatisfied patients, even with informed consent are less or nil in our study. This may be related to the time devoted with patient, explaining all possible complication in the vernacular language, with early effective remedy for complication explained and reiterated and strict to the procedure protocol to our patient in a considerate manner has brought this excellent result.

So we recommend this procedure for facial contour deformities with mild skeletal deformity or no skeletal deformity.

#### **BIBILOGRAPHY**

- 1. Duymaz A, Karabekmez FE, Keskin M, et al. Parry– Romberg syndrome: facial atrophy and its relationship with other regions of the body. Ann Plast Surg. 2009;63: 457–461.
- Garcia-de la Torre I, Castello-Sendra J, Esgleyes-Ribot T, et al.
   Autoantibodies in Parry–Romberg syndrome: a serologic study of 14 patients. J
   Rheumatol. 1995;22: 73–77.
- 3. Sommer A, Gambichler T, Bacharach-Buhles M, et al. Clinical and serological characteristics of progressive facial hemiatrophy: a case series of 12 patients. J Am AcadDermatol. 2006;54:227–233.
- 4. Lever WF, Elder DE, Elenitsas R, et al. Lever's Histopathology of the skin. 8th ed. Philadelphia: Lippincott-Raven; 1997
- 5. Thorne C, Grabb WC, Smith JW. Grabb and Smith's plastic surgery. 6th ed. Philadelphia: Lippincott Williams & Wilkins; 2007.
- 6. Stone J. Parry–Romberg syndrome: a global survey of 205 patients using the Internet. Neurology. 2003;61: 674–676
- 7. Aberer E, Stanek G. Histological evidence for spirochetal origin of morphea and lichen sclerosusetatrophicans. Am J Dermatopathol. 1987;9:374–379.
- 8. Abele DC, Bedingfield RB, Chandler FW, et al. Progressive facial

- hemiatrophy (Parry–Romberg syndrome) and borreliosis. J Am AcadDermatol. 1990; 22:531–533.
- 9. Crikelair GF, Moss ML, Khuri A. Facial hemiatrophy. PlastReconstrSurg Transplant Bull. 1962;29:5–13.
- Schachner LA, Hansen RC, Happle R. Pediatric dermatology. 3rd ed.
   Edinburgh; New York: Mosby; 2003Parry–
- 11. Romberg Syndrome Resource II. Parry–Romberg Initial Symptom Survey.
  Available online from: http:// www.PHAresource.com. Reported Date: October 25th, 2008.
- 12. Tollefson MM, Witman PM. En coup de sabre morphea and Parry–
  Romberg syndrome: a retrospective review of 54 patients. J Am AcadDermatol. 2007;56:257–263.
- 13. Stone J. Parry–Romberg syndrome: a global survey of 205 patients using the Internet. Neurology. 2003;61: 674–676.
- 14. Kister I, Inglese M, Laxer RM, et al. Neurologic manifestations of localized scleroderma: a case report and literature review. Neurology. 2008;71:1538–1545.
- 15. Progressive facial hemiatrophy: central nervous system involvement and relationship with scleroderma en coup de sabre. J Rheumatol. 2003;30:1997–2004.

- 16. Stone J. Parry–Romberg syndrome: a global survey of 205 patients using the Internet. Neurology. 2003;61: 674–676
- 17. Fitch PG, Rettig P, Burnham JM, et al. Treatment of pediatric localized scleroderma with methotrexate. J Rheumatol. 2006;33:609–614
- 18. Kreuter A, Gambichler T, Breuckmann F, et al. Pulsed high-dosecorticosteroids combined with low-dose methotrexate in severe localized scleroderma. Arch Dermatol. 2005;141:847–852.
- 19.Crikelair GF, Moss ML, Khuri A. Facial hemiatrophy.PlastReconstrSurg Transplant Bull. 1962;29:5–13.
- 20. Schachner LA, Hansen RC, Happle R. Pediatric dermatology. 3rd ed. Edinburgh; New York: Mosby; 2003.
- 21. Neuber F. Fettransplantation. Berichtüber die Verhandlungen der DeutschenGesellschaftfürChirurgie.ZblChir. 1893;22:66.
- Czerny V. PlastischerErzats de BrustdrusedurcheinLipom. ZentralChir.
   1895;27:72.
- 23. Holländer E. Berliner Klinischer Wochenschrift. 1909;18.
- 24. Holländer E. Die kosmetischeChirurgie (S.669–712, 45 Abb.). In: Joseph M, ed. Handbuch der kosmetik. Leipzig: Verlag van Veit; 1912:690–691.
- 25.Lexer E. Die freientransplantationen. Stuttgart: Ferdinand Enke; 1919.

- 26. Miller C. Cannula Implants and Review of Implantation Techniques in Esthetic Surgery. Chicago: Oak Press; 1926.
- 27. Peer LA. The neglected free fat graft, its behavior and clinical use. Am J Surg. 1956;92(1):40–47.
- 28. Fournier PF. Reduction syringe liposculpturing. DermatolClin. 1990;8(3):539–551.
- 29. Illouz YG. The fat cell "graft": a new technique to fill depressions. Plast Reconstr Surg. 1986;78(1):122–123.
- 30. Chajchir A, Benzaquen I. Fat-grafting injection for soft-tissue augmentation. PlastReconstr Surg. 1989;84(6):921–935.
- 31. Coleman SR. The technique of periorbitallipoinfiltration. Oper Tech Plast Reconstr Surg. 1994;1:20–26.

This article was the first published on the Coleman technique of fat grafting.

- 32. Coleman SR. Lipoinfiltration of the upper lip white roll. AesthSurg J. 1994;14(4):231–234.
- 33. Coleman SR. Structural fat grafting. 1st ed. St. Louis, MO: Quality Medical; 2004.
- 34. Coleman SR. Long-term survival of fat transplants: controlled demonstration, Aesthetic Plast Surg. 1995;19(5):421–425.

35. J PlastReconstrAesthet Surg. 2009 Nov;62(11): **Autologous fat transplantation for the treatment of Parry-Romberg syndrome.**Sterodimas
Huanquipaco JC, de Souza Filho S, Bornia FA, Pitanguy I35 Friedenstein AJ,
Gorskaja JF, Kulagina NN. Fibroblast precursors in normal and irradiated
mouse hematopoietic organs. ExpHematol. 1976;4:267–274.

- 36. Strem BM, Hicok KC, Zhu M, et al. Multipotential differentiation of adipose tissue-derived stem cells. Keio J Med. 2005;54:132–141.
- 37. Tzikas TL. Lipografting: autologous fat grafting for total facial rejuvenation. Facial Plast Surg. 2004;20:135–143.
- 38. Trepsat F. Periorbital rejuvenation combining fat grafting and blepharoplasties. Aesthetic Plast Surg. 2003;27:243–25
- 39. Berman M. Rejuvenation of the upper eyelid complex with autologous fat transplantation. Dermatol Surg. 2000;26:1113–1116.
- 40. Coleman SR. Hand rejuvenation with structural fat grafting. PlastReconstr Surg. 2002;110:1731–1744

#### **MASTER CHART**

S.No.	Name	Age	Sex	IP.No.	Diagnosis	Surgical Procedure	Donor site	Amount of Fat Injected	Compli cations	Secondary Touchup procedure	Patient Aesthetic outcome satisfaction
1	Gowthami	42	Female	12615	Post traumatic deformity left cheek	Fat Injection	Abdomen and lateral thigh	65	Edema	Nil	
2	Kamal	24	Male	1891	Developmental deformity left cheek	Fat Injection	Buttock	63	Sagginess	Nil	
3	Sivagami	34	Female	1981	Developmental deformity right cheek	Fat Injection	Abdomen	110	Edema	Nil	
4	Nazirnisha	23	Female	13610	Romberg's diseases right hemiface	Fat Injection	Abdomen and lateral thigh	120	Erythema	Nil	
5	Shanmugam	31	Male	1081	Developmental deformity right cheek	Fat Injection	Abdomen	82	Edema	Nil	
6	Latha	26	Female	13212	Developmental deformity left zygoma	Fat Injection	Abdomen	42	-	Nil	(T)
7	Nisha	21	Female	1011	Romberg's diseases left hemiface	Fat Injection	Abdomen	114	-	Nil	
8	Priya	20	Female	1912	Romberg's diseases right hemiface	Fat Injection	Lateral thigh	120	Edema	Nil	
9	Ramesh	31	Male	1801	Post traumatic deformity left cheek	Fat Injection	Abdomen	55	-	Nil	
10	Shanthi	28	Female	18021	Developmental deformity right supra, infrazygoma	Fat Injection	Buttock	50	Edema	Nil	
11	Ramya	20	Female	2121	Developmental deformity left chin	Fat Injection	Abdomen	76	-	Nil	
12	Srinivasan	28	Male	2102	Developmental deformity left cheek	Fat Injection	Abdomen	80	-	Nil	
13	Jayalakshmi	26	Female	1892	Romberg's diseases left hemiface	Fat Injection	Buttock	110	Erythema	Nil	<b></b>
14	Bala	31	Male	1731	Post traumatic deformity left temple	Fat Injection	Buttock	55	Sagginess	Nil	
15	Anjana	20	Female	13112	Developmental deformity right cheek	Fat Injection	Lateral thigh	78	Edema	Nil	
16	Geetha	31	Female	11211	Developmental deformity right cheek	Fat Injection	Buttock	68	-	Nil	
17	Senthilkumar	30	Male	10201	Romberg's diseases right hemiface	Fat Injection	Abdomen	120	-	Nil	
18	Praveen	32	Male	11218	Developmental deformity left cheek	Fat Injection	Abdomen	62	Edema	Nil	
19	Reena	28	Female	11212	Developmental deformity left cheek	Fat Injection	Abdomen	74	-	Nil	
20	Sandiya	21	Female	18201	Romberg's diseases right cheek	Fat Injection	Abdomen	110	Erythema	Nil	

## PROFORMA FOR CLINICAL CASE STUDIES

PS No : NAME : **AGE** ADM No SEX D.O.Adm. : ADDRESS: D.O.Surg. D.O.Dis Ph no PRESENTING COMPLAINTS HISTORY OF PRESENT ILLNESS: PAST HISTORY CO-MORBIDITY PERSONAL HISTORY SMOKER/ NON-SMOKER TREATMENT HISTORY GENERAL EXAMINATION

LOCAL EXAMINATION

PROVISIONAL DIAGNOSIS :

INVESTIGATIONS :

PLAN OF MANAGEMENT :

PREFERRABLE DONAR SITE :

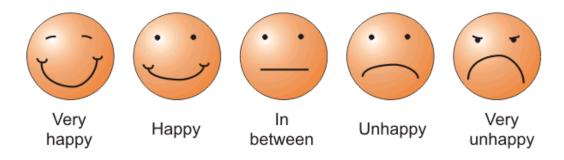
OPERATION : Date :

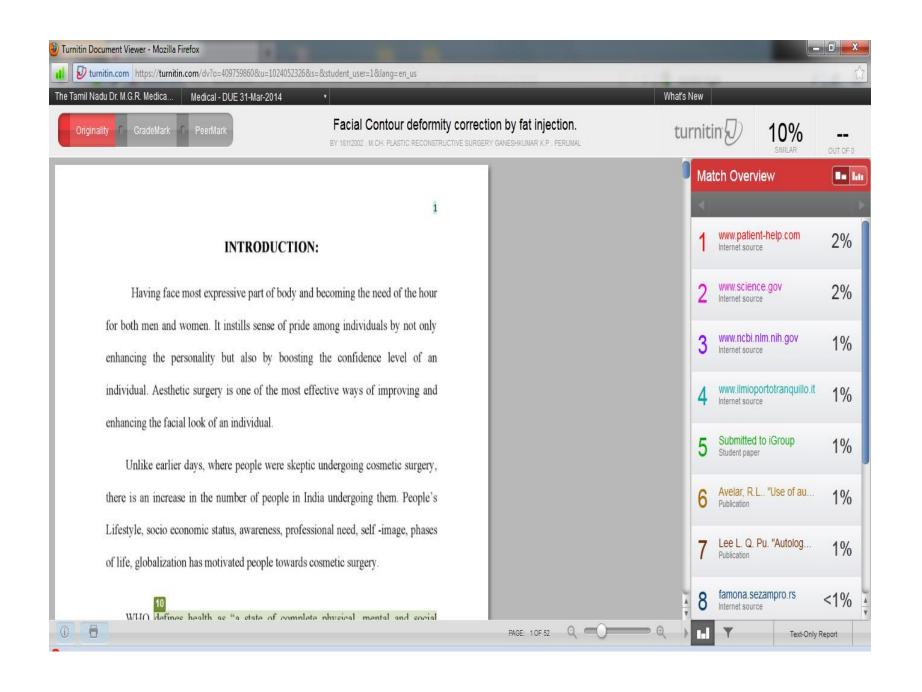
(Photographs)

FOLLOW UP :

(photographs)

## PATIENTS SATISFACTION:





# INSTITUTIONAL ETHICS COMMITTEE MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013 Telephone No: 044 25305301

Fax: 044 25363970

#### CERTIFICATE OF APPROVAL

To
Dr. K.P. Ganesh Kumar,
PG in Plastic Surgery,
Department of Plastic Surgery,
Madras Medical College, Chennai-3.

Dear Dr. K.P. Ganesh Kumar,

The Institutional Ethics Committee of Madras Medical College, reviewed and discussed your application for approval of the proposal entitled **"Facial Contour Deformity Correction By Fat Injection"** No.23032014

The following members of Ethics Committee were present in the meeting held on 11.03.2014 conducted at Madras Medical College, Chennai-3.

1.	Dr.	C.	Rajendran,	M.D.
----	-----	----	------------	------

2. Dr. R. Vimala, M.D.

Dean, MMC, Ch-3.
3. Prof. Kalaiselvi, MD

Vice-Principal, MMC, Ch-3

4. Prof. Nandhini, M.D.

Inst. of Pharmacology, MMC, Ch-3.

Prof. Bhavani Shankar, M.S.
 Prof & HOD of General Surgery, MMC, Ch-3.

6. Prof. V. Padmavathi, M.D.

I/c Director of Pathology, MMC, Ch-3.7. Thiru. S. Govindasamy, BABL

8. Tmt. Arnold Saulina, MA MSW

9. Thiru. S. Ramesh Kumar, Administrative Officer, MMC, Ch-3. -- Chairperson

-- Deputy Chairperson

-- Member Secretary

-- Member

-- Member

-- Member

-- Lawyer

-- Social Scientist

-- Layperson

We approve the proposal to be conducted in its presented form.

Sd/Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

Member Secretary Ethics Committee

MADRAS MEDICAL COLLEGE

35114