EFFICACY AND FUNCTIONAL OUTCOMES OF PLATYSMA MYOCUTANEOUS FLAP IN ORAL AND MAXILLOFACIAL RECONSTRUCTION

Dissertation Submitted to

BABU BANARASI DAS UNIVERSITY LUCKNOW, UTTAR PRADESH.



In the partial fulfillment of the requirements for the degree

Of

MASTER OF DENTAL SURGERY

In

ORAL AND MAXILLOFACIAL SURGERY

By

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(Faculty of Babu Banarasi Das University)

BATCH: 2021-2024

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I hereby declare that this dissertation entitled "EFFICACY AND FUNCTIONAL OUTCOME OF PLATYSMA MYOCUTANEOUS FLAP IN ORAL AND MAXILLOFACIAL RECONSTRUCTION" is a bonafide and genuine research work carried out by me under the guidance of Dr. Rashmi Agarwal, Reader, Department of Oral and Maxillofacial Surgery, Babu Banarasi Das college of dental Sciences, Babu Banarasi Das University.

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LIST OF ABBREVIATIONS

PMF: Platysma Myocutaneous Flap

MPF: Myocutaneous Platysma Flap

NS: Non Significant

S : Significant

IQR: Interquartile Range

OSCC: Oral Squamous Cell Carcinoma

HNSCC: Head and Neck Squamous Cell Carcinomas

SMIF: Submental Island Flap

ASA: American Society of Anesthesiologists

UW-QOL: University of Washington Quality of Life Questionnaire

CE MRI: Contrast Enhanced Magnetic Resonance Imaging

CT Scan: Computed Tomography Scan

MRI Scan: Magnetic Resonance Imaging Scan

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Introduction: Oral and maxillofacial reconstruction presents unique challenges owing to its complex anatomy and functional requirements of the region. Maxillofacial reconstruction strives to restore the form and function of the maxillofacial region in patients with deformities caused by trauma, disease, cancer, or congenital malformations. An array of surgical procedures has been advised for restoring soft tissues in the oral cavity, with varied degrees of their efficacy. The platysma myocutaneous flap (PMF) had been known for a long time considered a viable alternative for restoring soft tissue defects in this field. This thesis aims to assess the effectiveness and functional outcomes of PMF in oral and maxillofacial reconstruction through a comprehensive analysis of existing literature. By examining clinical studies, case series, and case reports, this prospective study seeks to provide a thorough understanding of the success rate, complications, functional outcomes, and patient satisfaction associated with the utilization of PMF in this specialized domain.

Aim: This dissertation is intended to elaborate on the superiorly-based platysma myocutaneous flap surgical technique, along with the flap design, outcomes, and intricacies associated with age, gender, the recipient site, and defect size.

Materials and methods: Study included 10 patients with oral malignancies intervened under general anaesthesia with wide local excision and reconstruction with platysma myocutaneous flap at a single tertiary care centre.

Statistical Analysis: Chi-square tests and paired t tests were used to ascertain if the variables were associated. P<0.05 was considered significant.

Results: The result showed that the Platysma Myocutaneous Flap is an efficient flap in context of its ease of harvest, no donor site morbidity, low complication rates, and ability to rehabilitate both form and function

Conclusion: In conclusion, the Platysma Myocutaneous Flap stands as a viable alternative in oral and maxillofacial reconstruction, offering a combination of versatility, reliable blood supply, and potential for functional restoration.

Keywords: Platysma Myocutaneous Flap, Reconstruction, Efficacy, Functional Outcomes

1.1 Background

Cancer is the term for any uncontrolled proliferation of cells that invades adjacent tissue causing a detrimental effect on the overall health of the individual. Oral cancer manifests as a small, unusual, inexplicable growth or discomfort in the mouthparts, which include the lips, cheeks, sinuses, tongue, hard and soft palate, the base of the mouth, and the oropharynx. India accounts for thirty percent of oral cancer cases worldwide, making it the sixth most prevalent type of cancer worldwide. A significant proportion of cases of oral cancer with potentially malignant disorders are oral squamous cell carcinoma (OSCC), which is also known to be a detectable pre-clinical phase of oral cancer. Among the risk factors for oral cancer include the consumption of tobacco products, specifically smokeless tobacco, betel nut chewing, excessive alcohol use, unhygienic oral condition, and persistent viral infections, including the human papilloma virus. Specific regions of India, such the northeastern states and northern India, have a greater prevalence of these risk factors. According to estimates, there are over 77,000 new cases of oral cancer in India each year, with men being at higher risk than women. This represents the prevalence of the disease in the nation.²

Oral cancer is often diagnosed late in India, resulting in poorer outcomes with a lower survival rate. In India, the concern for oral cancer is substantially higher than in the West, with approximately 70% of cases recorded in the more progressed stage (American Joint Committee on Cancer, Stage III-IV). With a mere 20% five years survival rates, there appears to be a considerable variation in the worldwide prevalence and an increase in the country's mortality rate due to behavioral risk factors, disparities in environmental exposure, and a lack of awareness among the population.³

Oral and maxillofacial reconstruction involves the recuperation of form and function in patients with deformities caused by trauma, cancer resection, congenital anomalies, or other pathological conditions. An efficient repair of soft tissue discrepancies in the oral and maxillofacial region is crucial for the restoration of facial aesthetics, oral function, and overall quality of life. A wide

array of surgical approach has been developed to address these complex reconstructions, including the use of local, regional, and distant flaps. One such flap is the platysma myocutaneous flap (PMF), which utilizes the platysma muscle and overlying skin to reconstruct soft tissue defects in this region.

The history of the platysma myocutaneous flap dates back to 1887, when Austrian surgeon Robert Gersuny¹¹ documented reconstructing a full-thickness cheek deformity using a cervical skin/platysma flap that was turned inside out to create a new buccal mucosa lining. This was perhaps the earliest description of the platysma myocutaneous flap used for head and neck reconstruction. However, it was not until 1978 that the platysma myocutaneous flap was put forward by Futrell et al. as an appealing reconstructive approach with various advantages.⁴ Despite providing acceptable outcomes with an acceptable degree of morbidity, this flap has been less frequently utilized as a result of the increasing use of microvascular free tissue transfer. Experience gained by surgeons over the years has demonstrated that microvascular flaps are not always suitable and that, in some circumstances, the PMF not only provides an excellent reconstructive result but also serves as a viable alternative to microvascular flaps.

The principal constraints of the PMF are its dearth of thickness and its partial dependence on the facial artery. According to Persky et al. (1983), this flap was traditionally avoided if a prior neck dissection had been done or if a ligation of the facial artery was required. Nevertheless, McGuirt and colleagues were the pioneers in disputing this and proving a noteworthy collateral flow (McGuirt et al., 1991).

Total or partial necrosis of the skin island, fistula, dehiscence, haematoma, and cellulitis are among the possible complications when using this technique, with the complication percentage varying from 18 to 45% (Cannon et al., 1982; Conley et al., 1986; Esclamado et al., 1994; Verschuur et al., 1998; Szudek and Taylor, 2007).

The PMF is easy to harvest, thin, and versatile, allowing for three-dimensional reconstruction with a low donor site morbidity following primary neck closure (Futrell et al., 1978, Cannon et al., 1982, Coleman et al., 1983, Hurwitz et al., 1983, Ruark et al., 1993, Esclamado et al., 1994, and Koch, 2002). ⁴⁻¹⁰ It is large enough to close most ablative lesions in the head and neck up to 70 cm², and there is no additional special equipments required (Koch, 2002). ¹⁰

There are many alternatives available for reconstructing oral cavity surgical defects. The variables that affect the choice of a reconstructive procedure include the size of the defect, donor site morbidity, the functional outcome, and concerns about aesthetics. The PMF offers several advantages, including its proximity, robust blood supply, and versatility in addressing various defect types. However, a comprehensive evaluation of the efficacy and functional outcomes of the PMF in oral and maxillofacial reconstruction is still warranted. This thesis will serve as an essential resource for oral and maxillofacial surgeons, providing a deep understanding of the advantages and challenges associated with the utilization of platysma myocutaneous flaps in reconstructive procedures.

1.2 Research Objectives

The primary aim of this thesis is to evaluate the efficacy and functional outcomes of the platysma myocutaneous flap in oral and maxillofacial reconstruction. The research aims to provide a comprehensive understanding of the success rate, complications, functional outcomes, and patient satisfaction associated with the utilization of the PMF in this specialized field. By synthesizing and analyzing existing literature, this thesis intends to contribute to the body of knowledge regarding the utilization of PMF in oral and maxillofacial reconstruction.

1.3 Research Questions

To accomplish the research goals, the following research questions will determine the investigation:

- 1. What is the success rate of the platysma myocutaneous flap in oral and maxillofacial reconstruction?
- 2. What are the complications associated with the utilization of the platysma myocutaneous flap in oral and maxillofacial reconstruction?
- 3. What are the functional outcomes, including oral function and aesthetic results, of the platysma myocutaneous flap in oral and maxillofacial reconstruction?
- 4. What is the level of patient satisfaction and quality of life following the utilization of the platysma myocutaneous flaps in oral and maxillofacial reconstruction?

1.4 Significance of the Study

In the field of oral and maxillofacial reconstruction, this study is hold significant importance both clinically and academically. By comprehensively evaluating the efficacy and functional outcomes of the platysma myocutaneous flap, it will contribute to evidence-based decision-making in reconstructive procedures. The findings will assist surgeons in selecting appropriate surgical techniques and optimizing patient outcomes. Additionally, this paper will serve as a useful resource for subsequent research, encouraging further investigations into the utilization of the PMF and enhancing the overall knowledge within the domain of oral and maxillofacial reconstruction. Ultimately, the study aims to improve patient care, functional outcomes, and quality of life for individuals undergoing oral and maxillofacial reconstruction utilizing the platysma myocutaneous flap.

<u>Aim</u>

The aim of this study is to assess the efficacy and functional outcomes of Platysma Myocutaneous Flap for intraoral soft tissue reconstruction in Oral and Maxillofacial region.

Objectives

The objectives of this study are-

- To assess the ease of harvesting Platysma Myocutaneous Flap
- To compare complications if any like infection, flap dehiscence, flap necrosis and donor site morbidity, during and post placement of flap.
- To compare the restorative functions like speech and swallowing after placement of flap.
- To compare the competency of oral aperture after placement of flap.

Review of Literature:

Futrell et al. (1978)¹² conducted a study on 14 patients using a platysma myocutaneous flap as a single stage reconstructive technique after an ablative surgery. Fourteen patients, all with T2 or T3 intraoral epidermoid carcinoma, were treated at the University of Virginia Medical Center with the platysma myocutaneous flap in a single stage primary reconstructive procedure. The patients, all male, were treated jointly by physicians on the Plastic Surgery and Otolaryngology Tumor Services, and each were followed postoperatively. Each patient underwent wide intraoral tumor resection combined with in-continuity radical neck dissection. After initial elevation of the platysma myocutaneous flap, reconstruction was performed using the cervical skin to fill the intraoral defect. The flap was used in patients requiring varying degrees of mandibular bone resection, and all cervical donor sites were closed primarily. There were no operative or postoperative deaths, and complications were minimal. Approximately 10 percent flap necrosis developed in one patient in the portion of the flap turned upon it to provide cheek resurfacing in addition to buccal and floor of the mouth lining. This healed uneventfully without additional surgery. An orocutaneous fistula developed in a second patient and also healed spontaneously without additional surgery. In follow-up, one patient died of recurrent disease after postoperative radiotherapy and chemotherapy and one patient died of unassociated causes without evidence of cancer. The study concluded that the flap is highly reliable and has significant benefits over many other techniques commonly employed for head and neck reconstruction.

Coleman JJ et al (1982)¹³ conducted a study on 14 patients in which platysma musculocutaneous flap was used in the reconstruction of oral lining and external skin coverage in the head and neck region. Complications occurred in 5 patients, however, only one patient required further surgery and this was for correction of a poor cosmetic result. As, the skin and subjacent muscle are supplied by a major

vascular pedicle from the facial artery and vein and a minor pedicle from the transverse cervical artery and vein, either pedicle can be used as the pivot for the flap's arc of rotation. The donor defect was closed primarily and did not present any problems. The flap was raised with both its motor and sensory supply intact. The study concluded that the thinness and pliability, color match, and proximity make the platysma flap a useful adjunct in head and neck surgery.

Cannon et al (1982)¹⁴ conducted a study on 22 patients for the reconstruction of intraoral defects after tumor ablation by Platysma myocutaneous flap using a variety of different techniques. A platysma myocutaneous flap for intraoral reconstruction was outlined and the surgical technique described. Nineteen of 22 patients in whom this flap was used, healed without major complication. The study concluded that the patients in this study who underwent preoperative radiotherapy did well with no major complications; however, previous irradiation of the neck is a relative contraindication to use of this flap due to skin changes in the cervical area and postradiation arteritis. Moreover, neck dissection is also contraindicated as after a neck dissection, the remaining platysma muscle fibers are scarred and fibrotic with an unreliable blood supply.

Coleman JJ et al (1983)¹⁵ conducted a study in which the platysma musculocutaneous flap was used in 24 patients for reconstruction in the head and neck area. Of the 24 patients, on whom the platysma flap was used for either intraoral lining or external coverage, 10 patients experienced complications. In 22 patients, the superior vascular pedicle, the submental branch of facial artery, was used, and in other two patient, the inferior pedicle. Although skin necrosis was not a common problem in previously published literature, 7 platysma flap in this study lost a portion of a skin paddle, however, there was no evidence of loss of muscle. A mild cellulitis in the neck within 4 days of operation was observed in 3 patients. Most of the complications in this study occurred during their early experience with the flap. Because of its thinness and pliability, the study

concluded that platysma musculocutaneous flap is an important addition to the technique of head and neck reconstruction.

Handa et al. (1988)¹⁶ conducted a study to demonstrate and evaluate the effectiveness of the Platysma Myocutaneous Flap in conjunction with MacFee's cervical incision (MacFee, 1960) for reconstruction after oral cancer excision. Ten squamous cell carcinoma cases were provided for postoperative evaluation of tongue movement and aesthetic problems of the cervical skin. It was found that the thickness of the skin island was adequate for covering the oral defects and was not a hindrance to proper postoperative function. MacFee's incision improved the condition of the scar caused by flap elevation. The procedure for preparing the muscle pedicle beneath the cervical skin tunnel was carried out without much difficulty by carefully preparing the surgical field. The study concluded that the platysma myocutaneous flap, prepared in a random pattern, was effective in T2 cases for reconstruction of the floor of the mouth, the mandibular alveolus and the tongue margin. The study concluded that the use of this flap combined with MacFee's cervical incision contributed much to the better postoperative aesthetic appearance of the cervical skin.

Howaldt HP, Bitter K. (1989)¹⁷ conducted a study in 54 patients where platysma flaps were used for the purpose of covering an intraoral defect, following tumor surgery. In every case, a radical or upper neck dissection was done and consequently the facial artery was ligated. The tumor site was located between the anterior floor of the mouth and the pharyngeal wall in its lower part. Some flaps were brought up to the buccal mucous membrane and the soft palate. The success of wound healing was examined one week postoperatively and a second time at least six months later, in order to estimate the final result. The result showed that 75% of all cases healed completely without any loss of tissue, in other words the defect did not shrink due to scarring. The donor site healed primarily in 94.5 % of the cases. Superficial wound dehiscence was observed in 5.5 %. Moreover, 11

tumor recurrences occurred in 52 patients suffering from squamous cell carcinoma. There was only one lymph node metastasis in the region of the flap's pedicle while three local recurrences occurred intraorally at the margin of the resection and seven tumour remanifestations arose contralaterally or at other distant sites. The result concluded that 54% primarily healed flaps and 31% with epithelial breakdown without shrinking defects; underline the feasibility of the reconstruction after radical neck surgery. Anyhow, the high incidence of secondary healing proved that the platysma flap is not a very safe method in this respect.

Papadopoulos O.N., Gamatsi I. E. (1993)¹⁸ conducted a study to evaluate the use of the platysma myocutaneous flap in 12 patients. Six patients had squamous cell carcinomas of tongue, 2 had malignant melanomas of the skin and 4 had squamous cell carcinomas of the buccal mucosa. The complete tumor resection was controlled by frozen-section biopsy in all patients, but for 7 of them, a functional or radical neck dissection was performed. The study suggested including the external jugular vein in the flap. The results were evaluated from an oncological, functional, and aesthetic point of view. The study showed 2 recurrences in a minimum follow-up of 4 years. The study concluded the functional and aesthetic results of the flap to be quite satisfactory with no serious complications. Although, the primary disadvantage of this flap is that the dominant vasculature derived from the submental branch of the facial artery is seldom visualized. In spite of this, the flap should be regarded as very useful for limited intraoral or surface coverage problems in an arc extending 10 cm from the level of the facial artery at the mandible.

Ruark DS et al (1993)¹⁹ conducted a retrospective analysis of on 41 patients who received a platysma myocutaneous flap for reconstruction of intraoral and pharyngeal defects. All patients had epidermoid carcinoma of the head and neck region, with tumor size ranging from T1 to T4. The primary sites of malignancy

were the oral cavity (61%), the oropharynx (32%), and the hypopharynx (7%). Either radical or modified radical neck dissection requiring routine ligation of the facial artery was performed in all 41 patients. Adjuvant therapy included preoperative or postoperative radiotherapy (39%) and preoperative chemotherapy (73%). The mean hospital stay was 13 days. Flap-related complications occurred in eight patients (19%) only. These included partial flap necrosis involving the epithelium alone, skin necrosis of the neck suture line, and fistula formation. Most complications resolved with local care only. Minor surgical intervention was required in three patients. There were no peri-operative deaths. The study concluded that the platysma myocutaneous flap is a viable alternative in head and neck reconstruction.

Vriens J.R M. (1995)²⁰ conducted a study report on the oral function of 17 patients who underwent simultaneous excision of oral squamous cell carcinoma and reconstruction of part of the oral cavity with the platysma flap. From 1986 through 1992, 34 patients with squamous cell carcinoma of the oral cavity underwent primary reconstruction with a platysma island flap. Seventeen patients (nine men, eight women; mean age 61 years) were available for the present study. The mean follow-up period was 38.6 months (range ~-72 months). Eight patients had a partial resection of the floor of the mouth only. Four patients had a simultaneous partial glossectomy, and in five patients, a marginal (rim) resection of the mandible was also done. Supraomohyoid neck dissection in continuity with the tumor was undertaken ipsilaterally in all but two patients. In one patient, bilateral supraomohyoid neck dissection was done because of tumor extension close to the midline. In one patient, a conservative neck dissection was carried out ipsilaterally because of palpable neck lymph nodes. Five patients received a curative dose (60--65 Gy) of irradiation postoperatively. Radiotherapy was indicated if lymph-node involvement with extracapsular spread was evident. Most patients had stage T2 disease, and no tumors extended across the midline. There were three completely successful platysma flap transpositions. Complete flap loss

was noted in four patients. In the remaining 10 patients, one or more of the following complications were observed. Wound dehiscence occurred in eight patients, mainly localized in one section of the flap. The section of the flap involved showed minor necrosis of a rim of skin. There were five patients with wound infection, and this was usually secondary to necrosis of the flap. In eight flaps, epidermolysis was observed. In all cases with disturbed wound healing, secondary healing took place, resulting in closure of the defect. A blue and swollen appearance of the platysma flap was present in 13 patients in the immediately postoperative period. The study concluded that the pedicled platysma flap did not appear to be a flap that can routinely be used for reconstruction of the floor of the mouth or tongue after ablative surgery.

N. Whitney James, Eric J. Dierks, Bryce E. Potter (1995)²¹ reported a 21year-old white man attempted suicide with a 12-gauge shotgun placed in the left submental- submandibular region. The blast produced an avulsion of the left mandibular body from first molar to the symphysis, with loss of teeth from the left second premolar to the right lateral incisor (Fig 2). The patient also experienced a loss of overlying soft tissue involving approximately 1.0 to 2.0 cm over the left chin region, as well as approximately 1 cm of the lower lip. The midface was spared, with only loss of the clinical crowns of the maxillary fight and left lateral incisors and a few pellet perforations of the palate. The shotgun is a commonly encountered means of attempting suicide, and many victims use a submental placement of the muzzle and reach down to manually depress the trigger. This maneuver hyperextends the neck, frequently results in a nonlethal maxillofacial injury with loss of a variable amount of mandible, maxilla, nose, and/or orbits. Survivors of such self-inflicted shotgun wounds demonstrate a characteristic pattern of injury, the severity of which varies with the amount and location of tissue avulsed. Extensive avulsion requires multistage reconstruction of hard and soft tissues. As a component of this reconstruction, platysma muscle flap was used as an immediate replacement for avulsed tissues in the floor of the mouth

and to provide coverage for a mandibular reconstruction plate. The report showed this flap proved to be useful in management of gunshot and other traumatic avulsions in the oral and maxillofacial region.

Koch WM (2002)²² conducted a study that evaluated the uses, advantages, and disadvantages of the platysma flap. The study was a retrospective review of the medical records of patients undergoing platysma flap reconstruction of the upper aerodigestive tract from 1987 to 2001. Thirty-four patients underwent reconstruction with platysma flaps. The surgical defects included the oropharynx, oral cavity, and hypopharynx. Nine patients had had prior radiation therapy and all had various dissection of the ipsilateral neck. There were 5 postoperative fistulas (15%), flap desquamation was noted in 6 cases (18%), and 2 patients experienced loss of the distal skin closing the donor site. Complications were not associated with prior radiation. Hospital stay ranged from 5 to 21 days (mean, 10 days) with no additional reconstruction required. All patients resumed the normal diet within 3 months of surgery. There were no recurrences of cancer in the dissected neck regions. The study concluded that the platysma myocutaneous flap can serve as a viable alternative to free tissue transfer and has advantages over pectoralis major pedicled flaps for reconstruction of many head and neck defects.

Kocer et al $(2005)^{23}$ conducted a study to evaluate the efficacy and reliability of platysma flaps. Cadaveric dissections were performed on the face and the neck regions on both sides. Eleven patients with various defects on the face and the upper neck regions were surgically treated: three transverse cervical artery-based transverse musculocutaneous platysma flaps, seven facial artery-based vertical musculocutaneous platysma flaps, and one superior thyroidal artery-based platysma muscle flap were used for the repairs. The patients ranged in age from 42 to 74 years. The defects measured 2 x 3 cm to 6 x 9 cm and the flaps 3 x 3 cm to 7 x 10 cm. The follow-up periods were 2 to 21 months. Postoperative venous

congestion between the 5th and 9th days was observed in seven patients. One patient had infection of the donor site, and another had infection of the recipient site; both recovered with systemic and topical antibiotic therapy. Partial flap loss occurred in one patient. The study concluded that platysma flaps showed sufficient tissue match with successful results for the reconstructive procedures of facial defects.

Lazaridis N. (2007) conducted a study to access the reliability and use of the superiorly based platysma flap for reconstruction of small and medium oral defects. The study consisted of 5 patients who were reconstructed with a superiorly based platysma flap for defects of the following oral region: buccal mucosa, floor of the mouth, and lateral gingiva. The flaps were monitored for complications, including skin loss and ischemia in the postoperative period. The result of the study showed that three patients (60%) had some skin sloughing in the recipient site. None of the patients had complications in the donor site. The study concluded that the superiorly based platysma flap can survive after the ligation of facial artery which is the normal procedure during neck dissection. If skin sloughing occurred, it is usually inconsequential for intraoral reconstruction because the underlying muscle remains viable and undergoes epithelialization.

Peng L. W. et al. (2005)²⁴ conducted a study which evaluated the effects of two different designs of platysma myocutaneous flap, vertical and transverse, used in the reconstruction of defects following the excision of oral and facial tumors. Modified radical neck dissection or selected neck dissection was also performed. Out of the 48 patients, vertical and transverse platysma myocutaneous flaps were used for 41 and 7, respectively. The postoperative outcome for the vertical flaps was 37 cases surviving, two cases of complete necrosis, and two cases of partial necrosis. With the transverse flaps, six survived and there was one case of complete necrosis. The success rate was 90.2% and 85.7% for the vertical and the transverse flap, respectively. The form and function of recipient sites were well recovered. The study concluded that the platysma myocutaneous flap has clinical

value in selected patients needing reconstruction of small and medium-sized intraoral or facial defects. It is recommended that the vertical design be used for reconstruction of buccal mucosa defects, and the transverse design for mouth-floor and facial defects.

Grützenmacher S. et al. (2005)²⁵ conducted a retrospective study evaluating their experience with the platysma myocutaneous flap. From 2001 to 2003, 25 patients have been subjected to surgical reconstruction applying the platysma mucocutaneous flap. The primary tumor was located in 16 patients (64%) in the oropharynx, in 5 patients (20%) in the hypopharynx and in 4 patients (16%) in the oral cavity. Evaluation was based on medical records including the operative reports. All patients get a follow up in their outpatient clinic. The platysma flap was easy to harvest and has a low general risk level. Complications were minor and may be avoided by exact preoperative planning. Necrosis of the skin-muscle-flap was observed only after resection of the A. carotis externa (two cases). In these 2 cases an operative revision was necessary (stenting of the pharynx or secondary reconstruction by pectoralis major-flap). The resection of the A. facialis (three cases) did not lead to a serious complication. Considering the exact indication, the study concluded that the platysma flap is suitable for reconstruction of surface defects in the pharynx and oral cavity. A special attention was given to the ipsilateral vascular supply and the length of the muscular pedicel. It proved to be a cost effective method due to the less time and personal expenditure.

Su T. et al. (2006)²⁶ conducted a study that evaluated the survival rates of three types of platysma myocutaneous flap: transverse flap, vertical flap that preserved the facial artery and vein and vertical flap that sacrificed the facial artery and vein. Modified radical or supraomohyoid neck dissection was also performed in all patients. Out of 54 patients, transverse and vertical flaps were used for 12 and 42 cases, respectively. In 42 cases of vertical flaps, 26 cases preserved the facial

artery and vein, 16 cases sacrificed them. Ten cases of the transverse flaps survived and two cases had partial necrosis. In the 26 cases of vertical flaps that preserved, the facial artery and vein, 23 cases survived and three cases had partial necrosis. With the 16 cases of vertical flaps that sacrificed the facial artery and vein, 10 cases survived, four cases had partial necrosis and two cases had total necrosis. The flap survival rates were 83.3, 88.5 and 62.5%, respectively, in the transverse, vertical flap preserving the facial vessels and vertical flap that sacrificed them. The survival rates of transverse and vertical platysma myocutaneous flaps preserving the facial artery and vein were higher than vertical flap that sacrificed the facial artery and vein. The study concluded that the transverse platysma myocutaneous flap and vertical flap preserving the facial artery and vein could reliably be used for reconstruction of small and medium sized defects in the cheek and the floor-ofmouth. A vertical flap without the preservation of the facial vessels was unreliable.

Szudek J., Taylor M. $(2007)^{27}$ conducted a study to systematically review and quantify complication rates and to identify preoperative factors among patients who underwent platysma myocutaneous flap reconstruction for head and neck cancer. This study analyzed 190 patients in 16 case series published between 1982 and 2002. Funnel plots, contingency tables, and χ^2 analyses were used to minimize bias and heterogeneity among the studies. Seventy-one patients (37%) developed a complication, ranging from 20% at the buccal mucosa to 55% at the tonsil and at the alveolar ridge. Major complications (ie, those requiring further surgery) occurred in 5% of patients. The most common complication was skin loss or necrosis, occurring in 25% of patients. Postoperative complications were not associated with age or sex but were associated with recipient site and tumor stage. Overall, complications were 0.3 (95% confidence interval [CI], 0.1-1.1) times less common at the buccal mucosa than at other recipient sites. Hematomas were 18.8 (95% CI, 1.6-217) times more common at the buccal mucosa. Infections were 20.0 (95% CI, 1.1-350) times more common at the pharyngeal

wall. Major complications were 4.6 (95% CI, 0.9-23.5) times more likely, and fistulas were 9.2 (95% CI, 2.0-43.1) times more likely in patients with stage T3 or T4 oral cancer than in patients with lesser grades. The study concluded that postoperative complications were not associated with age, sex, or preoperative radiation therapy, but they were associated with recipient site and tumor stage. These results may guide surgeons considering the platysma flap to reconstruct head and neck cancer.

Jacek Szudek et al (2007)²⁸ in their study quantified complication rates and identified preoperative factors among patients who underwent platysma myocutaneous flap reconstruction for head and neck cancer. This study analyzed 190 patients in 16 cases that were operated between 1982 and 2002. Funnel plots, contingency tables, and χ^2 analyses were used to minimize bias and heterogeneity among the studies. Logistic regression models were used to quantify the associations between preoperative factors (age, sex, T stage, prior radiation therapy, and recipient site) and complications (skin loss or necrosis, fistula, dehiscence, hematoma, and infection) at different recipient sites (floor of mouth, alveolar ridge, pharyngeal wall, buccal mucosa, tongue or tongue base, and tonsil). Seventy-one patients (37%) developed a complication, ranging from 20% at the buccal mucosa to 55% at the tonsil and at the alveolar ridge. Major complications (ie, those requiring further surgery) occurred in 5% of patients. The most common complication was skin loss or necrosis, occurring in 25% of patients. Postoperative complications were not associated with age or sex but were associated with recipient site and tumor stage. Overall, complications were 0.3 (95% confidence interval [CI], 0.1-1.1) times less common at the buccal mucosa than at other recipient sites. Hematomas were 18.8 (95% CI, 1.6-217) times more common at the buccal mucosa. Infections were 20.0 (95% CI, 1.1-350) times more common at the pharyngeal wall. Major complications were 4.6 (95% CI, 0.9-23.5) times more likely, and fistulas were 9.2 (95% CI, 2.0-43.1) times more likely in patients with stage T3 or T4 oral cancer than in patients with lesser grades. The results concluded that postoperative complications were not associated with age, sex, or preoperative radiation therapy, but they were associated with recipient site and tumor stage. These results may guide surgeons considering the platysma flap to reconstruct head and neck cancer.

Pagani D. et al. (2007)²⁹ conducted a study to evaluate the usage of a vertical platysma myocutaneous flap in a group of patients who underwent reconstruction after T2-staged oral cancer surgical resection associated with neck dissection was described. Only one patient required a surgical revision, due to flap detachment, with a pectoralis major myocutaneous flap. No other major complications, such as nerve lesions or orocutaneous fistulas, were observed. Satisfactory swallowing function was achieved within two weeks in all cases. The study concluded that the platysma myocutaneous flap is a versatile, easy-to-perform, one-stage procedure, and the outcome is best in adequately selected patients; it should not be adopted in patients who have undergone previous neck surgery or radiotherapy, or if radical neck dissection is planned. Care is required to preserve the external jugular vein and the submental artery, particularly when level I is dissected.

Chen WL et al. (2008)³⁰ conducted a study to assess the reliability and usefulness of transverse platysma myocutaneous flaps and facial artery-submental artery island myocutaneous flaps for reconstruction of buccal mucosal defects following cancer surgery. Twenty- seven buccal mucosal defects were repaired with transverse platysma myocutaneous flaps (n=12) after resection of buccal mucosa squamous cell carcinoma. Among them, 19 patients were male and 8 were female; the age of the patient ranged from 38 to 74 years (56.4 on an average). Six patient were classified as 6 T1N0M0, 19 as T2 N0M0, and 2 as T3N0M0. The size of skin paddle ranged from 4.0cm x 8.0cm to 5.0cm x 11.0cm. The postoperative outcome for the platysma myocutaneous flaps was survival in 13 cases, including 3 cases with minimal partial necrosis, the success rate was 86.7% (13/15). The success rate of the facial artery-submental artery island myocutaneous flaps was

91.7% (11/12). The appearance and function of the recipient sites were well recovered. All patients were followed up for 6- 24 months (16 months on average), local recurrences were found in 1 case and cervical recurrences in 2 cases. The study concluded that platysma myocutaneous flaps and facial artery-submental artery island myocutaneous flaps are suitable to repair small and medium – sized buccal mucosal defects. It seems that facial arterysubmental artery island myocutaneous flap is more reliable than platysma myocutaneous flap.

Wang et al (2010)³¹ conducted a restrospective study to assess outcomes of reconstruction of the oral cavity with the platysma myocutaneous flap, in terms of flap survival, complications, and quality of life. Included were 10 patients with squamous cell carcinoma (stage TI to T4; nodal status NO to N2) of the oral cavity who were treated between 2002 and 2006. Each patient underwent tumor resection, modified radical neck dissection, and primary reconstruction with a platysma myocutaneous flap. Operating time, length of stay, time to swallow, and complications were assessed, and the University of Washington Quality of Life questionnaire was evaluated to assess the functional outcome of the patients. Mean operating time was < 4 hours, mean length of stay was 11 days, and mean time to swallow was 9 days. One patient had distal flap necrosis and one had wound dehiscence. No total flap failures or fistulas occurred. The study concluded that the platysma myocutaneous flap provides thin, pliable, reliable tissue for use in the oral cavity. The additional operating room time is negligible, the surgical complications minimal, and the overall quality of life very good. This flap should be used more frequently in the reconstruction of oral cavity defects.

Olasz L. et al. (2011)³² conducted a study on 342 patients which were operated on for advanced oral—oropharyngeal and orofacial cancers between January 1985 and January 2001. In 6 cases, a platysma-based transpositional flap was used for external closure of facial through-and-through defects. Internally, the saved oral

mucosa was used in 4 patients and fasciocutaneous forearm free flaps in 2 patients. The facial artery was blocked in all cases. The postoperative course was uneventful except in 1 case, when partial loss of the flap was observed intraorally. The externally used transpositional platysma-based flap showed cosmetic and functional advantages: its consistency, color, and texture were similar to those of the original facial tissues, the area of operation was the same, and the donor site was closed primarily. The study concluded that the site limited platysma based myocutaneous transpositional flap is usable and safe even in those cases in which circulation of the facial artery is damaged or local vascular compromise has occurred and the facial through-and-through defect is extended. The facial reconstruction described is one of several applicable reconstructive methods that may be chosen for special facial defects. The method is not applicable when the neck is radically operated on (radical neck dissection) and/or irradiated. No similar use of platysma-based transpositional flaps has been reported thus far.

Tessier P. et al. (2011)³³ conducted a study to observe and evaluate platysma-based myocutaneous clavicular island flap for intraoral reconstruction. The clavicular myocutaneous island flap, with circulation provided by the platysma and superficial cervical fascia, was first performed by Paul Tessier in 1970, taking his motivation from the prior experience of John Barron with subcutaneous island flaps. A manuscript written by Dr. Tessier on his experience of 120 cases using the flap (which will be referred to as the BT, or Barron-Tessier flap) has been translated and is presented, as well the experiences of Matthews and Wolfe, who learned the procedure from Dr. Tessier, and Kamerer, an ENT/Head and Neck surgeon who learned the procedure from Matthews. In aggregate, this study will present their joint experience with 443 cases of the BT flap. The BT flap is "a cutaneous clavicular island flap based on the platysma" and has been used 437 times for conditions as varied as cancer excisions, noma, burns, ballistic mutilations, and hemifacial atrophies. In Tessier's last 80 cases, the technique without tunnelization was shown to be effective in 98% of cases for the entire

cutaneous flap. When the flap was used with tunnelization the complication rates were higher, but still lower than other reviews. The procedure can be used for reconstructions combining at the same time a mandibular reconstruction plate, or a bone graft of the mandible, with or without coverage with the temporalis muscle. The study concluded that, because of its ease and speed of harvest, reliability, and provision of thin, pliable skin, the platysma myocutaneous flap, in many instances, is equivalent, or even superior to microsurgical free flap for reconstruction of intraoral lining defects.

Tosco P. et al (2012)³⁴ in their study examined the experience and results obtained in three different and independent institutes where PMF has been adopted in 91 patients for head and neck cancer reconstructions. The platysma myocutaneous flap (PMF) was first applied to intraoral reconstructions in 1978. PMF was not only an alternative to microvascular flaps but it also represents an excellent reconstructive choice especially in cases where free tissue transfer cannot be carried out. There were no perioperative deaths. Sixty-nine (69) patients (75.8%) encountered no problems during wound healing process. The flaps were well vascularized and the patients were able to resume oral feeding without swallowing disorders within 15 days. Flap-related complications were observed in 22 cases (24.2%). Full loss of the flap occurred in 12 patients (13%): six of these healed by secondary intention within 1 month, two cases developed a fistula requiring minor surgical revision under local anaesthesia, one case required surgical revision and reconstruction with local flaps and three cases required a pectoralis major myocutaneous flap. Partial skin loss occurred in 10 patients (11%). In these cases, healing occurred by secondary intention, that resulted in an excellent re-epithelialization because of the good blood supply from adjacent tissues. These complications required prolonged nasogastric nutrition for 15 days longer than average. The study concluded that the PMF represents a good reconstructive choice for small and middle-size defects even when the facial

artery is not preserved. PMF provides acceptable results in cases where free flaps are not practical.

Rufat ML et al (2012)³⁵ conducted a study to show that platysma flaps have good results and should be an alternative in reconstructive surgery for oral tumors when microsurgery is not possible. It is a versatile, portable, and thin flap, is easy to perform, and can be obtained during neck dissection, with a primary closure of the donor site. Five cases were presented, three men and two women, 51 and 71 years old, with medium size (2-4 cm) defects of oral cavity after the excision of squamous cell carcinomas. All of them were reconstructed with a platysma flap after neck dissection. This reconstruction technique was chosen because of the poor conditions of these patients to allow a microsurgical reconstruction. The result showed no complications with this technique. Overall aesthetic results were acceptable in all the patients. There were no cases of total necrosis flap, dehiscence, fistula or fibrosis. Only one case of partial necrosis occurred in one end of the flap, which was resolved with excision of necrotic tissue and closure by secondary intention. The study concluded that the platysma flap is a good method to reconstruct small and medium sized defects of oral cavity, especially in patients where a microsurgery reconstruction is not possible.

Fang et al. (2013)³⁶ conducted a study to evaluate the feasibility of radial forearm free (RFF) flap, platysma myocutaneous (PM) flap, and anterolateral thigh (ALT) flap in buccal reconstruction. This study consisted of 56 patients who were categorized into 3 groups. The Student t test was used to analyze the variables. Patients in group platysma flap were significantly older, the dissection of platysma flap was easier, and the defect was significantly smaller than those in group radial forearm flap and group ALT flap. The reduction in the widths of mouth opening between group PM, group RFF, and group ALT were compared. However, the reduction of mouth-opening widths in group RFF and group ALT was significantly less than that in group PM. The study concluded that platysma

myocutaneous flap was more suitable in patients with small to middle-size defect and poor status, although the flap cannot achieve a reliable result; anterolateral thigh flap and radial forearm flap can preserve the interincisal distance well even for large buccal defect, but it takes more time and skills in the operation.

Wang W.H. et al (2013)³⁷ conducted a study to demonstrate a novel technique of a platysma muscle flap following superficial parotidectomy and to evaluate the impact of using this flap on Frey's syndrome and postoperative appearance. In this retrospective study, there were 55 patients who had had superficial parotid gland tumors removed, 28 patients were restored by the platysma muscle flap, and the remaining 27 patients were not restored by the technique. The area of the flap was measured using Image-Pro plus 6.0 software. The objective starch-iodine test was used to determine the incidence of Frey's syndrome. The postoperative aesthetic outcome of retromandibular contour was evaluated in all the patients. The score in platysma flap group was significantly higher than the scores in the conventionally treated group (P < 0.01). The area of the flap was 1668.7, 218.7 square millimeters. Of 28 patients restored by the flap, 2 developed mild Frey's syndrome, and in the remaining 27 patients 10 had Frey's syndrome. There was a statistically significant difference between the two groups (P ¼ 0.007). The technique produced satisfactory aesthetic results with good facial contour. The study concluded that the platysma muscle flap, used as an interposing barrier between the overlying skin flap and the parotid bed following superficial parotidectomy, produced good results in the prevention of Frey's syndrome and resulted in good postoperative facial contour.

Li Z. et al (2013)³⁸ conducted a study to present our experience using vertical PMF that sacrificed the facial artery and vein for intraoral reconstruction. A retrospective review of the medical records of 54 patients who underwent vertical PMF that sacrificed the facial artery and vein for intraoral reconstruction was performed. A comparison between PMF that sacrificed and that preserved the

facial vessels was made, and the study also compared PMF that sacrificed the facial vessels with radial forearm free flap (RFFF). Statistics concerning the patients' clinical factors were gathered. The mean age of the 54 patients who underwent PMF that sacrificed the facial artery and vein was 62.0 ± 10.98 years. The co-morbid disease rate of PMF was 53.7%. The flap size ranged from $12 \times$ 5.5 cm to 7×5 cm. Survival of the flap was found in all of the cases, with partial necrosis in four cases (7.4%) and total loss in none of the cases. The operation time was 5.7 ± 1.17 h. The complication and success rates were 27.8% and 92.6%, respectively. The 3-year and 5-year survival rates were 77.8% (21/27) and 69.23% (9/13), respectively. The majority of the patients (87.0%) in our series were satisfied with the results of the surgery. There was no significant difference between PMF that sacrificed or that preserved the facial vessels, both in success rate (P = 1) or complication rate (P = 0.72). The patients in the PMF group were older than the patients in the RFFF group (P = 0.011), the operation time was shorter (P < 0.001), and the co-morbid disease rate was higher (P = 0.002). Although the complication rate of PMF (15/54, 27.8%) was higher than that of RFFF (2/34, 5.9%) (P = 0.011), their success rates were similar (92.6%, 94.1%) (P = 1.00). The study concluded that vertical PMF that sacrifices the facial artery and vein has specific advantages including in ease preparation and limitations. This technique may provide an effective method for intraoral reconstruction.

Safdar J, Liu FY, Moosa Y, Xu ZF, Li ZN, Sun CF. (2014)³⁹ conducted a study to compare the platysma flap with submental flap in terms of tumor and flap characteristics, operative properties and the functional outcomes. A total of 65 patients presented with tumors of head and neck and underwent curative tumor resection with different neck dissections at the Department of Oro maxillofacial - Head and Neck Surgery, School of Stomatology of China Medical University; from March 2005 to December 2012 were included in the study. After radical tumor excision and neck dissection the resultant complex defects were reconstructed with either platysma flap or the submental flap. The extent of

surgical resection, the type of neck dissection and choice of flap reconstruction was at the discretion of the surgical team. The functional outcomes, operative time and characteristics of both platysma and submental flaps were compared and the statistical tests of significance were applied accordingly. The mean age was 60 years. The complex facial defects of 30 patients were reconstructed with platysma flap and of 35 patients with submental flap. Mean operation time of submental flap including flap harvesting (5.58±1.96hrs) was shorter than platysma flap (6.2±1.4hrs). Majority of the flaps (88-93%) were taken successfully in both groups. Submental flap was associated with significantly higher patients' satisfaction regarding acceptable functional outcomes (p-value 0.027). The mean reduction in mouth opening was significantly smaller in platysma group (0.37) ± 0.18 cms) than the submental group (0.47 ± 0.16). This study demonstrated that both platysma and submental flap techniques can be used for the reconstruction of complex facial defects with the acceptable functional outcome. The platysma flap can be harvested to medium size defects up to 70cm² with good mouth opening. The submental flap is simpler, faster with a wider range of application and more acceptable functional outcomes.

Ramanujam S. et al. (2015)⁴⁰ conducted a study to examine the experience and results obtained with the use of reconstruction of intraoral defects with platysma myocutaneous flap. When considering the complications that can occur when adopting this technique, one has to include total or partial necrosis of skin island, fistula, dehiscence, hematoma, and cellulitis with rates ranging from 18% to 45%. Various surgical procedures were available for treating oral submucous fibrosis, but all of them had their inherent drawbacks. The superiorly based platysma myocutaneous flap is a common reconstruction option for intraoral defects followed after excision of fibrous bands in oral submucous fibrosis. The superiorly based flap has an excellent blood supply, but less efficient venous drainage when compared with posteriorly based flap. Of 10 patients, eight had no postoperative complications, one patient developed partial skin loss and other

developed venous congestion which was managed conservatively. The study concluded that the platysma myocutaneous flap is a better option that an extended nasolabial flap in terms of extraoral facial scar for the management of oral submucous fibrosis.

The platysma myocutaneous flap is rarely reported as an option for reconstruction in the head and neck region. **Mustafa EMA et al.** (2016)⁴¹ in their case study reported a patient with an unusually aggressive orocutaneous fistula that complicated the simple extraction of teeth. The study modified the platysma flap to provide two independent skin paddles so it can be used to reconstruct both the intraoral and cutaneous defects simultaneously with a good clinical outcome. The study concluded that the platysma myocutaneous flap is a reliable flap that is easy to raise, has a limited risk of morbidity at the donor site, and allows for early recommencement of oral function.

Bande et al (2017)⁴² conducted a prospective study in which 47 patients with OSMF and 15 of OSCC were evaluated and selected for PMF reconstruction. OSCC was selected under T1N0M0 category only. Patients were operated under general anesthesia followed by PMF grafting. Ipsilateral PMF was used in OSCC, whereas, in case of OSMF, bilateral PMF was used. This prospective study evaluated the utility of platysma myocutaneous flap (PMF) in the reconstruction of surgical defects followed by treatment of oral submucous fibrosis (OSMF) and oral squamous cell carcinoma (OSCC) in terms of healing and functional outcomes. Intra- operative mouth opening was achieved up to 48 mm in OSMF followed by 42.5 mm postoperatively after 2 years. However, uneventful healing and acceptable scar on cervical region was noted in all the cases including OSCC. In OSMF, three cases of dehiscence, four partial necrosis at end of flap and in OSCC, one case showed skin loss at flap and two partial necrosis at tip of flap and extraoral localized abscess at ipsilateral donor site in one case was noted. The study concluded that the PMF is simple, versatile and could be valued as a reconstructive alternative, with interesting visual qualities. It is a good therapeutic

alternative tool for reconstruction of the buccal mucosa, especially for small- and medium-sized defects between 2 and 4 cm² of the oral cavity.

Long H. et al. (2017)⁴³ conducted a study to explore the main features and advantages of the muscle pedicled platysma myocutaneous flap (PMF), the degree of improvement of flap harvest. The study also evaluated the application value of the flap in the reconstruction of buccal mucosa carcinoma defects. Twenty-three patients received PMF with MacFee incision to reconstruct buccal mucosa defects that were caused by the resection of precancerous lesions and benign and malignant tumors from August 2012 to April 2015. When elevating the cervical skin from the platysma, most of the subcutaneous tissue was preserved on the muscle. The continuity of the facial vessels was retained. The external jugular vein was preserved on the reverse side of the platysma. Twenty-one flaps survived completely, whereas the other two flaps presented partial skin loss. Two patients showed disturbed wound healing in the neck. Secondary healing was achieved after attentive wound care. All patients were followed up from 11 to 43 months. The function of the recipient sites recovered well. Except for the two patients with large-area scarring in the neck, the remaining cases presented satisfactory neck contours. No relapses were observed during the follow-up period. The study concluded that, in comparison with the traditional PMF, the muscle pedicled PMF provides a larger skin paddle and presents a better aesthetic and functional effect. Thus, this approach is a novel and ideal option for the restoration of buccal mucosa defects.

Huang et al (2017)⁴⁴ conducted a study that evaluated the effects of three different incision designs for the vertical platysma myocutaneous flap (VPMF): apron, MacFee, and T-shaped. This flap was used for the reconstruction of intraoral defects following cancer ablation in selected patients. Sixty-eight cases of VPMF reconstruction were assessed: the apron incision was used in 28, MacFee incision in 22, and T-shaped incision in 18. With regard to postoperative

outcomes, there were 26 cases of flap survival and two of partial necrosis with the apron incision; 20 of survival and two of partial necrosis with the MacFee incision; 15 of survival and three of partial necrosis with the T shaped incision. Success rates were 92.9%, 90.9% and 83.3%, respectively, for VPMF with the apron, MacFee, and T-shaped incisions. A wound healing disturbance in the neck was seen in three cases of VPMF with the apron incision and one case with the MacFee incision. The MacFee incision had the best aesthetic effect, and the postoperative neck scar was more obvious for the T-shaped incision. The study concluded that VPMF with the MacFee or apron incision be used for the reconstruction of larger buccal mucosa and floor of the mouth defects, while VPMF with the T-shaped incision should be used for smaller intraoral defects, especially tongue defects of the lateral surface.

Calabrese L. et. Al. (2019)⁴⁵ conducted a retrospective study on 61 patients treated between January 2005 and December 2017 in two referral centers in which Myocutaneous Platysma Flap (MPF) was used for the reconstruction of defects following surgical resection of SCC of the oral cavity and oropharynx. The technique of flap harvesting with anatomic details is described. In all cases, the submental artery was sacrificed preserving the facial artery. All clinical data were collected. Tumors involved the oral cavity in 95.1% of cases, and the oropharynx in 4.9%. Pathological staging (TNM 7th edition) of tumors was: pT1 (42.6%), pT2 (39.3%), pT3 (4.9%) and pT4a (13.1%). Success rate of the flap was 93.4%. Four (6.5%) patients developed a partial necrosis of the skin paddle without platysma muscle involvement; none required surgical revision. The mean followup was 69 months (5- 153 months). Thirteen patients (21.3%) developed a local recurrence, and in 1 patient were associated with contralateral neck metastasis. The study concluded that the MPF can be a suitable option in head and neck reconstruction of small or medium-sized defects in selected cases. The vascular pedicle can be provided by branches of the facial artery achieving both oncological radicality and optimal flap vascular supply.

Saeedeh K et al (2019)⁴⁶ conducted a study to evaluate the biologic basis of deepithelialized transverse platysma flap for oral cavity reconstruction. As, the inferiorly and laterally based platysma myocutaneous flap contains hair in some ethnics; therefore, it is required to change the myocutaneous flap to myofascial flap to prevent the hair growth after its transfer to the oral cavity. Five male mongrel dogs were selected for this study. De-epithelialized laterally based platysma flap, muscle part facing the oral cavity, was used for buccal reconstruction. The clinical healing process was photographed every week. After 40 days, biopsy specimens were obtained from the transferred flap. According to the results, all flaps survived. At the end of the first week, the flap was covered with fibrinous exudate. On the third week, only the center of the transferred flap was not covered with mucosa. Within 40 days, the flap was distinguishable clinically from the adjacent buccal mucosa just by hypopigmentation. Hematoxylin and eosin staining of the biopsy specimens taken on day 40 showed thin stratified squamous epithelium covered with a tiny parakeratin layer. The study concluded that myofascial platysma flap, muscle part faced oral cavity, survives and undergoes mucosalization after adaptation to the recipient oral tissue.

Tiwari P. et al. (2020)⁴⁷ conducted a study to systematically review the reconstructive options for oral submucous fibrosis utilizing buccal pad of fat versus conventional nasolabial and extended nasolabial flap versus platysma myocutaneous flaps. A total of 1538 articles were found across PubMed, Cochrane and clinical trials.gov. Only five relevant articles were selected for the study. Quality assessment of the selected studies was executed by Newcastle–Ottawa scale. Three of the five studies selected and favoured buccal fat pad over nasolabial flap owing to its ease of harvest and lesser number of post-operative complications. One study favoured nasolabial flap because of the progressive increase in mouth opening and bulk of the tissue obtained for reconstruction. A single study favoured platysma flap over nasolabial flap although no difference

was obtained in mouth opening, owing its excellent tissue bulk, fewer complications compared to the nasolabial flap. Definitive conclusions cannot be drawn as there were number of limitations in the studies included. However, a general consensus has been towards favouring buccal fat pad over nasolabial flap. The platysma flap owing to its excellent tissue bulk and fewer complications can be considered as an alternative when dealing with defects which are challenging to reconstruct with the buccal fat pad.

Pal US et al. (2021)⁴⁸ conducted a study on 20 patients with oral potentially malignant disorders operated under local anesthesia with wide local excision and reconstruction with platysma myocutaneous flap at a single tertiary care centre. The study aimed to provide surgical technique of the superiorly-based platysma myocutaneous flap with a single neck incision in this study, as well as the flap design, results, and complications associated with age, gender, the recipient site, and the size of the defect. The association between the variables was calculated using Chi-square tests and paired t tests. P <.05 was considered significant. The result of the study showed 5 cases of dehiscence found at varied sites and flap viability was significantly influenced by location of skin paddle. In between anterior jugular vein and posterior external jugular vein it was 100% viable while on and posterior to the vein, had skin paddle loss. Significant improvement in mouth opening was also seen in Oral Submucous Fibrosis patients. The study concluded that the platysma flap is a technique sensitive procedure, and its results are promising for the reconstruction of oral defects.

Hakim SG et al (2022)⁴⁹ conducted a study to verify the feasibility of the SF-MPF for oral reconstruction, the anatomic, sonographic and histologic features of the SF-MPF and the outcomes of the flap were evaluated. The clinical course of 12 consecutive patients who underwent oral reconstruction using the SF-MPF along with ipsi- or contra- lateral neck dissection for treatment of oral cancer showed sufficient pedicle length and reliable blood supply. The study concluded

that the SF-MPF is a reliable and safe pedicled myocutaneous flap, therefore, it should be considered being an additional option when a pedicled flap has to be selected.

Pal US et al. (2022)⁵⁰ conducted a study that aims for the explanation of possible postoperative complications, efficacy and limitations of Platysma myocutaneous flap (PMF) in patients with oral submucosal fibrosis (OSMF). A total of 5 publications were included. 2 were prospective studies and 3 were case reports with 79 subjects between the ages of 18 and 45. All included studies reported complications in a non-significant way (p value = 0.870) with positive results as they impact the patient's functional outcome (mouth opening) in a statistically significant manner (p < 0.0001 and 95% CI) with good patient compliance. To conclude, PMF is rarely used in routine practice due to their technical difficulty and potential complications like venous congestion and necrosis. In this systematic review, the authors provide valuable insight into the causes of complications and the efficacy of PMFs in OSMF patients. In the process of platysma flap harvesting, it is especially important to preserve the skin flap, arterial perforators and arteries, veins in supra and sub-platysmal flap elevation. Aside from proper flap placement and tunnelling, postoperative care is equally important.

Gangwar S. et al. (2023)⁵¹ conducted a study to evaluate the efficacy of platysma flap in terms of esthetics, function (mouth opening) & postoperative compliance of the patient. Eight cases are included, seven men and one women, 40 - 50 years old, after resection of fibrous bands. All of them were reconstructed with a platysma flap. No local complications occurred with this technique. Overall aesthetic and functional results were acceptable in all the patients. Of 8 patients, six had no postoperative complications. The remaining two developed venous congestion, with limited skin loss. All flaps remained viable. The study concluded that the platysma flap is a good method to reconstruct buccal mucosa after

resection of bands in oral submucous fibrosis. It is a versatile, portable, and thin flap, is easy to perform with a primary closure of the donor site.

STUDY DESIGN

We assessed data from 10 cases of Platysma Myocutaneous flaps that were used to restore post-cancer resection deformities in the oral and maxillofacial regions. The analysis included all information pertaining to the functional and aesthetic results, tumor locations, defect kinds, donor and recipient sites, problems at the recipient site, and surgical management of these patients undergoing Platysma flap reconstruction. All patients were treated at Department of Oral and Maxillofacial Surgery, BBDCODS, Lucknow, Uttar Pradesh, India and Kalyan Singh Multi-Specialty Cancer Hospital, Lucknow.

MATERIAL

Cases with Stage I-II diseases involving hard and soft tissue of the maxillofacial region which requires composite resection & reconstruction with pedicled flap were selected. Composite resection and reconstruction with Platysma myocutaneous flap were done.

INCLUSION CRITERIA

- a) Patients diagnosed with oral cancer.
- b) Patients diagnosed with potentially malignant condition or lesion.
- c) Patients who require soft tissue reconstruction following oral cancer resection surgery.
- d) Patients willing to participate in the study.

EXCLUSION CRITERIA

- a) Patient unwilling to participate in the study.
- b) Patient in whom surgery is contraindicated. (Systemic Illness)
- c) Recurrent cases of malignancy.
- d) Patients requiring special health care.

All the patients are informed as to the nature of the surgical and experimental procedures and consent being obtained before surgery.

Materials Required:

- 1. BP handle, BP blade (Nos. 15, 23)
- 2. Tissue retractor
- 3. Tissue retractor: Austin, Senn
- 4. Sterile gauze
- 5. Surgical aspirating tip
- 6. Cotton pliers
- 7. Rongeur
- 8. Tissue scissor
- 9. Needle holder
- 10. Hemostat
- 11. Sutures (Vicryl, Silk, Ethilon)
- 12. Tissue forceps: Allis, Babcock
- 13. Tissue pliers: Adson
- 14. Tongue Depressor/Retractor
- 15. Towel Clamps
- 16. Scissors
- 17. Hemostatic Forceps: Adson Artery forceps, Mosquito hemostatic forceps
- 18. Surgical Skin Marker
- 19. Electro Surgery cautery machine
- 20. Bipolar Cautery set
- 21. Betadine, Savlon, Surgical Spirit
- 22. Normal Saline
- 23. Ambu Bag
- 24. Mallet, Chisel

- 25. Gigli Saw Wires
- 26. Tracheostomy Tube
- 27. Electric Surgical Drills: Straight Handpiece, Burs
- 28. Surgical Skin Stapler
- 29. Romo Vac Wound Closure Suction Drain

PREOPERATIVE INVESTIGATION AND SEQUENCE OF PATIENT CARE

All patients underwent evaluations upon their initial presentation at the department clinically and incisional biopsy was done and sent for histopathological study. Patients were also evaluated with CT scan for the tumor involvement of mandible, masticatory muscles, infra temporal fossa, lymph nodes and skin of the face. Additionally, patients were assessed using preoperative hematological investigation. The study included only T1 and T2 tumors with clinical N0-N3 lymph node involvement. Ablative and reconstructive procedures were performed in a single stage. The specimen was sent for histopathological study, if it reveals no node involvement, then only reconstruction with platysma flap was opted. Post operatively we assessed both the functional and esthetic outcome of the flap.

Clinical examination was performed. Extra oral and intra oral photographs were obtained and CT scan evaluation was done. Neo adjuvant radiotherapy and chemotherapy was completed as a precautionary measure in some patients. Subsequently the patient was scheduled for composite resection and reconstruction under general anesthesia. Post operatively the patients were given IV antibiotics and analgesics. Cleaning and dressing of the donor & recipient area was done. Vitality of the flap was checked periodically. On post operative period patient underwent clinical examination that included functional assessments,

esthetic outcome, and complications at the donor and recipient sites. The patient was given follow-up appointments postoperatively on 1st week, 1st month and 3rd month. Functional assessments under which speech, ease of harvesting, esthetic outcome, donor site complications including hematoma, seroma, wound dehiscence and complications at the recipient site such partial flap necrosis, complete necrosis, fistula were evaluated. Data was collected and statistically analyzed and evaluated.

Ease of Harvesting was measured by questionnaire answered by Maxillofacial Surgeons, Oncosurgeons and Plastic Surgeons.

Functional Outcomes:

Functional outcome was measured in terms of the quality of speech, swallowing process and other criteria in accordance with the University of Washington Quality of Life Questionnaire (UW-QOL). The sample questionnaire is attached in the annexure of this study.

Aesthetic outcome was judged by both the patient and the surgeon, in terms of color, contour, form of reconstruction and ease of harvesting. It is purely subjective. It was classified as:

- 1. Good
- 2. Acceptable
- 3. Poor
- 4. Failure

The complications associated were categorized into two groups:

- 1. Donor site complications
 - a) Hematoma
 - b) Seroma
 - c) Wound dehiscence

- 2. Recipient site complications
 - a) Partial flap necrosis
 - b) Complete flap necrosis
 - c) Fistula
 - d) Infection
- 3. Pain: Pain was measured using University of Washington Quality of Life Questionnaire (UW-QOL)

STATISTICAL ANALYSIS

All the variables were analyzed using Prospective Comparative Study. Chi Square Test was used for evaluation of data. Patients who died within 90 days of surgery were excluded for the long-term esthetic and functional complication analysis. Statistical significance was defined as P < 0.05.

The data for the present study was entered in the Microsoft Excel 2007 and analyzed using the SPSS statistical software 23.0 Version. The descriptive statistics included frequency and percentage. The level of the significance for the present study was fixed at 5%. The intergroup comparison of the ordinal variable was compared using Chi Square test.

Chi Square Test

Chi-square is a statistical test commonly used to compare observed data with data we would expect to obtain according to a specific hypothesis. When an analyst attempts to fit a statistical model to observed data, he or she may wonder how well the model actually reflects the data. How "close" are the observed values to those which would be expected under the fitted model? One statistical test that addresses this issue is the chi-square goodness of fit test. This test is commonly used to test association of variables in two-way tables, where the assumed model

of independence is evaluated against the observed data. In general, the *chi-square test statistic* is of the form

$$X^2 = \sum \frac{\text{(observed - expected)}^2}{\text{expected}}$$

If the computed test statistic is large, then the observed and expected values are not close and the model is a poor fit to the data.

SURGICAL DEVELOPMENT OF PLATYSMA MYOCUTANEOUS FLAP

Prior to flap harvesting, the predicted intraoral defect is evaluated. In general, the skin island measures no more than 6x10 cm. Initially, the platysma flap is constructed as an ellipse, with the inferior margin located above the clavicle low in the neck. The inferior margin of the platysma flap will coincide with the inferior margin of a traditional apron-type flap raised for a neck dissection. In contrast to the superior skin incision, which just involves the skin, the inferior skin incision needs to traverse through the platysma muscle. The cervical fat should remain affixed to the platysma muscle by maintaining the thinnest feasible superior skin flap.

Whenever feasible, the flap pedicle encompassed the entire dimension of the platysma muscle (at least 4 cm). The external jugular vein and sternocleidomastoid fascia are incorporated in the plane of elevation to facilitate appropriate venous drainage. The platysma myocutaneous flap is positioned superiorly and 180 degrees into the intraoral defect and sutured into place after tumor removal and neck dissection. Resection of the intraoral tumor and a first-echelon node dissection (suprahyoid neck dissection) or a formal neck dissection is then carried out in the usual manner. Rotation is done carefully to prevent the flap pedicle from being too stretched, compressed, or twisted. Dissecting a suitably large tunnel beneath the mandible is necessary to prevent compression before rotating the flap into the intraoral defect location. Layerwise sutures are placed to approximate the neck incision.

Comprehensive anatomic analyses delineated the vascular architecture, wherein the platysma muscle and the skin paddle receive their primary blood supply from the submental artery. The choice to sacrifice the facial veins seems to be essential for flap survival, despite considerable dispute on this matter. Nonetheless, maintaining the facial artery is not necessary for the platysma myocutaneous flap to survive, according to McGuirt et al. and Ruark et al. Additionally, the platysma myocutaneous flap may be elevated without fear of injuring the marginal mandibular nerve, as the nerve lies below the level of the platysma muscle. After that, the marginal mandibular nerve can be located and dissected similarly to other neck surgeries. After careful hemostasis is achieved, the neck incisions are closed over a Penrose drain if only a first-echelon neck dissection is performed. An active drainage system, such as Hemovac or Jackson-Pratt drains, is employed if the intraoral resection was carried out in conjunction with a full neck dissection.

SURGICAL DEVELOPMENT OF PLATYSMA MYOCUTANEOUS FLAP

Step #1

A U-shaped flap is created by drawing a skin island that is centered just above the clavicular insertion on the lower side of the platysma muscle. Sufficient length of the skin paddle's horizontal axis is necessary to minimize tension when closing the donor site.

Step #2

In a subcutaneous plane, the flap is sharply dissected up to the hyoid bone's level. The muscle encompassing the overlying skin island is raised, and the platysma muscle's clavicular insertions are divided. The part of the external cervical fascia covering the sternocleidomastoid muscle is not harvested along with the flap; instead, the external jugular vein is ligated and harvested.

Step #3

The flap is then elevated toward the mandible, separating the segmental arteries of the middle section of the muscle. The marginal branch of the facial nerve must be located and preserved as a crucial component of this surgical procedure. To maintain proper vascularization of the flap's distal region while minimizing the likelihood of skin necrosis, any perforator skin vessels originating from the cranial portion must be preserved. Due to the perforators' location in the adipofascial tissue, a deeper plane of dissection is recommended in order to protect these vessels. Following this, the platysma muscle is divided both anteriorly and posteriorly in order to fully mobilize the flap.

Step #4

When performing level IA dissection, all cervical branches—including the submental artery—are ligated to ensure oncological radicality, whilst

submandibular gland dissection permits the identification and preservation of the facial artery's common trunk. This constitutes the central idea of the entire surgical process, as the current method supplies the flap's vascular arterial supply through small, calibre-constant branches of the facial artery that are frequently observed in the submandibular region. These branches do not originate from the submental artery as is commonly stated in literature; rather, they are intrinsically linked to the platysma and anastomosed in the paramandibular region with the orbicular artery system. If there are significant metastases at level IB, then this step should be avoided. The facial vein is preserved whenever possible.

Step #5

Following pull-through or mandibulotomy tumor removal, the defect is rebuilt by rotating the MPF into the oral cavity. The inferior margin of the mandible should not be stretched, twisted, or subjected to extreme traction. Additionally, to prevent disruption in the vasculature supply, the tunnel should have a sufficient width. Furthermore, to optimize blood flow from the muscle pedicle to the skin paddle during flap insertion, the proximal portion of the flap must only have cutaneous sutures made, leaving the subcutaneous and muscular layers unaffected.

Step #6

Thereafter, the neck donor site is primarily closed, usually without tension.

ARMAMENTARIUM





Fig. 1.1(A,B): Surgical Instruments

Patient 1: Pre-operative Radiographs

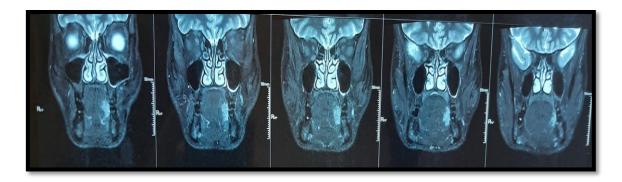


Fig 2.1 Coronal Section of CE-MRI Scan

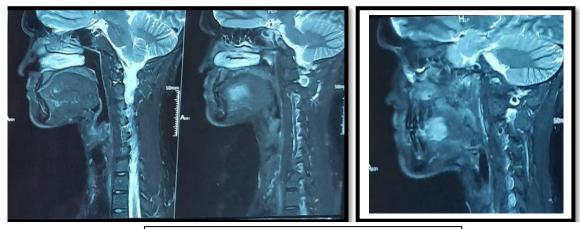


Fig 2.2 Sagittal Section of CE-MRI Scan

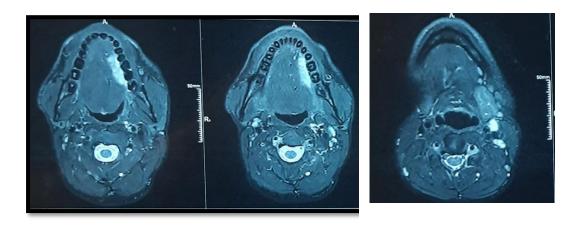


Fig 2.3 Axial Section of CE-MRI Scan (Face)

Pre-Operative Photographs



Fig 3.1 Frontal Profile

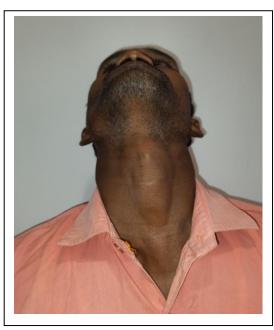


Fig 3.2 Neck Extension Profile

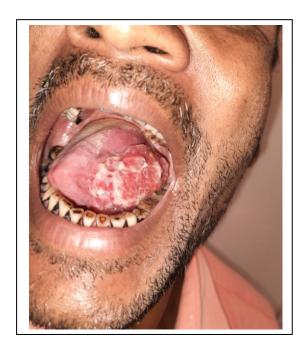


Fig 3.3a Lateral Profile



Fig 3.3b Lateral Profile

Pre-Operative Photographs





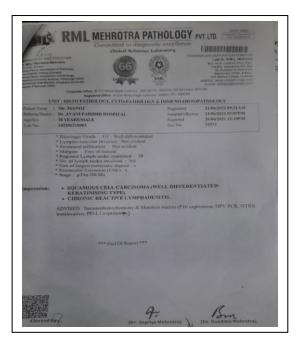


Fig 3.5 Histopathological Report

Intra-operative Photographs



Fig 4.1 Recipient Site Surgical Defect



Fig 4.2 Exposure of Skin Paddle of PMF



Fig 4.3 Resected Tumour

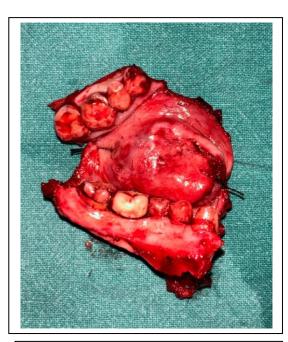


Fig 4.4 Resected Lymph Nodes

Intra-operative Photographs



Fig 4.5 Reconstruction of Recipient Site Defect with Platysma Myocutaneous Flap

Post-operative Photographs



Fig 5.1- 1 week Intra Oral Profile



Fig 5.2- 1 month Neck Extension Profile



Fig 5.3-1 month Lateral Profile

Post-operative Photographs



Fig 5.4- 1 month Intra Oral Profile



Fig 5.5- 3 months Intra Oral Profile

Patient 2:
Pre-operative Radiographs





Fig 6.1 Pre Op (A) Axial; (B) Sagittal; (C) Coronal Section of CE-MRI

Pre-Operative Photographs



Fig 7.1 Frontal Profile



Fig 7.2 Shoulder Extension Profile

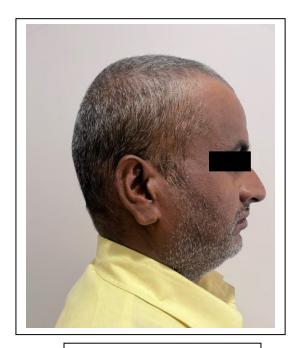


Fig 7.3a Lateral Profile



Fig 7.3b Lateral Profile

Pre-Operative Photographs

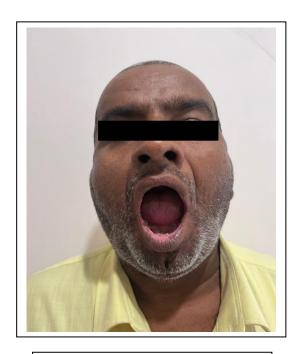


Fig 7.4 Intra Oral Profile

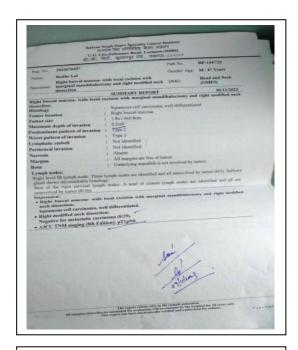


Fig 7.5 Histopathology Report

Intra-Operative Photographs



Fig 8.1 Recipient Site Surgical Defect



Fig 8.2 Exposure of Skin Paddle of PMF

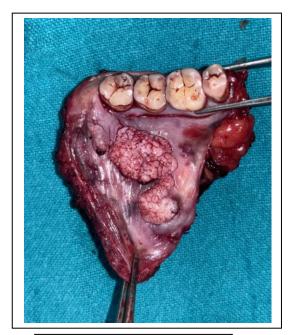


Fig 8.3 Resected Tumour



Fig 8.4 Resected Lymph Nodes

Intra-Operative Photographs



Fig 8.5 Reconstruction of Recipient Site Defect with Platysma Myocutaneous Flap

Post- Operative Photographs



Fig 9.1- 1 week Intra Oral Profile



Fig 9.2- 1 Month Intra Oral Profile

Post- Operative Photographs

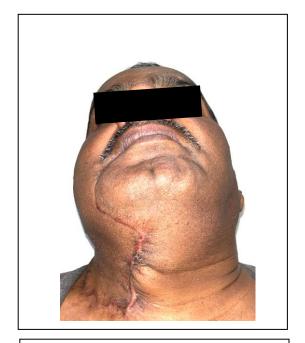


Fig 9.3- 3 months Neck Extension Profile

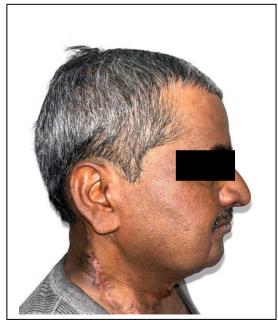


Fig 9.4- 3 months Lateral Profile

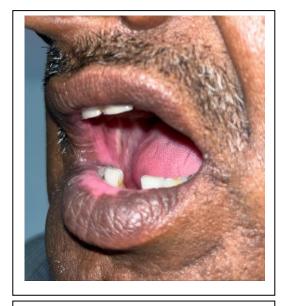


Fig 9.5-3 months Intra Oral Profile

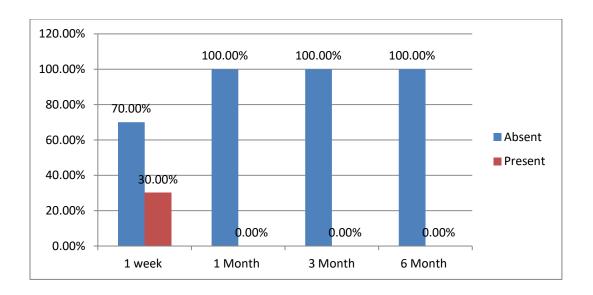


Fig 9.6- 6 months Intra Oral Profile

$\frac{\textbf{INTRAGROUP COMPARISON OF INFECTION BETWEEN DIFFERENT TIME}}{\textbf{INTERVALS}}$

At the 1 week time intervals 30% of the subjects were having infection present whereas at 1 month, 3 month and 6 months none of the subjects had presence of infection. The difference between the 1 week and 1 month, 1 week and 3 month, 1 week and 6 months was statistically significant with p value of 0.021 whereas difference between 1 month, 3 months and 6 month was statistically non-significant.

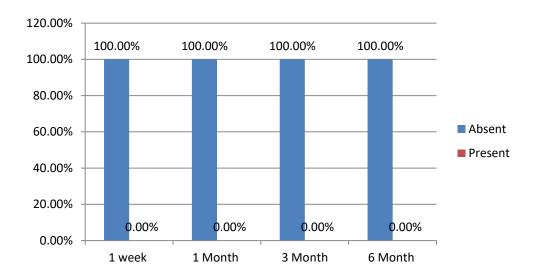
	Absent	Present	Chi Square value	P value	Significance
1 Week	7	3			
·	70.0%	30.0%	_		
1 Month	10	0	_		
·	100.0%	.0%	9.873	0.021	Non-
3 Months	10	0	_		Significant
·	100.0%	.0%	_		
6 Months	10	0	_		
	100.0%	.0%	_		



INTRAGROUP COMPARISON OF FLAP DEHISCENCE BETWEEN DIFFERENT TIME INTERVALS

At the 1 week, 1 month, 3 month and 6 months none of the subjects had presence of flap dehiscence. The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

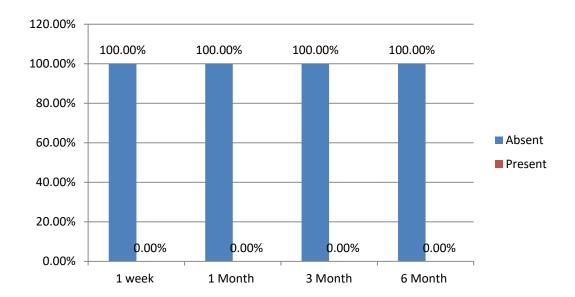
	Absent	Present	Chi Square value	P value	Significance
1 Week	10	0			
-	100.0%	.0%	_		
1 Month	10	0	_		
	100.0%	.0%	0.000	1.000	Non-
3 Months	10	0	_		Significant
-	100.0%	.0%	_		
6 Months	10	0	_		
-	100.0%	.0%	_		



$\frac{\textbf{INTRAGROUP COMPARISON OF FLAP NECROSIS BETWEEN DIFFERENT}}{\textbf{TIME INTERVALS}}$

At the 1 week, 1 month, 3 month and 6 months none of the subjects had presence of flap necrosis. The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

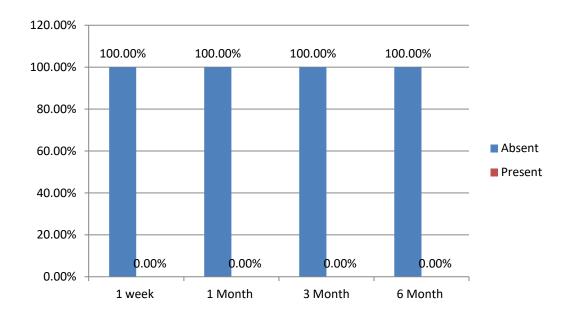
	Absent	Present	Chi Square value	P value	Significan ce
1 Week	10	0			
1 Week	100.0%	.0%	_		
1 Month	10	0	_		
1 Month	100.0%	.0%	0.000	1.000	Non-
3 Months	10	0		11000	Significant
_	100.0%	.0%	_		
6 Months	10	0	_		
	100.0%	.0%	_		



$\frac{\textbf{INTRAGROUP COMPARISON OF MORBIDITY BETWEEN DIFFERENT}}{\textbf{TIME INTERVALS}}$

At the 1 week, 1 month, 3 month and 6 months none of the subjects had presence of donor site morbidity. The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

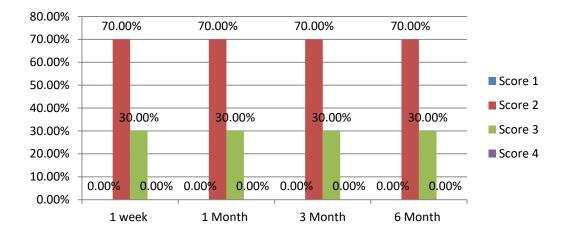
	Absent	Present	Chi Square value	P value	Significan
			value		ce
1 Week	10	0			
_ ,,,,,,,	100.0%	.0%	_		
1 Month	10 0	_		Non-	
	100.0%	.0%	0.000	1.000	Significan
3 Months	10	0	_		t
	100.0% .0%	_			
6 Months	10	0	_		
	100.0%	.0%	_		



$\frac{\textbf{INTRAGROUP COMPARISON OF SPEECH BETWEEN DIFFERENT TIME}}{\textbf{INTERVALS}}$

At the 1 week, 1 month, 3 month and 6 months 70% of the individuals had difficulty saying some words but can be understood over the phone and 30% of the had speech difficulty such that Only family and friends could understand the speech. The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

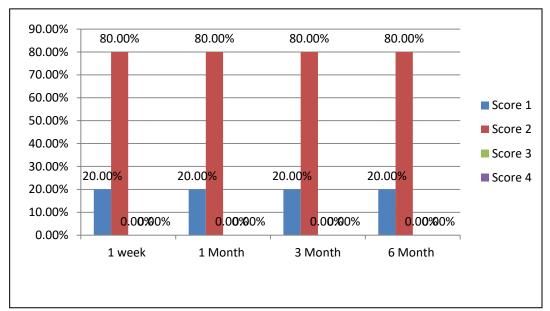
					Chi		Signific
	Score 1	Score 2	Score 3	Score 4	Square value	P value	ance
1 Week	0	7	3	0			
•	.0%	70.0%	30.0%	.0%			
1	0	7	3	0			Non-
Month	.0%	70.0%	30.0%	.0%	0.000	1.000	Signific
3	0	7	3	0			ant
Months	.0%	70.0%	30.0%	.0%			
6	0	7	3	0			
Months	.0%	70.0%	30.0%	.0%			



$\frac{\textbf{INTRAGROUP COMPARISON OF SWALLOWING BETWEEN DIFFERENT}}{\textbf{TIME INTERVALS}}$

At the 1 week, 1 month, 3 month and 6 months 80% of the individuals could swallow as well as ever and 20% had difficulty swallowing solid foods. The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

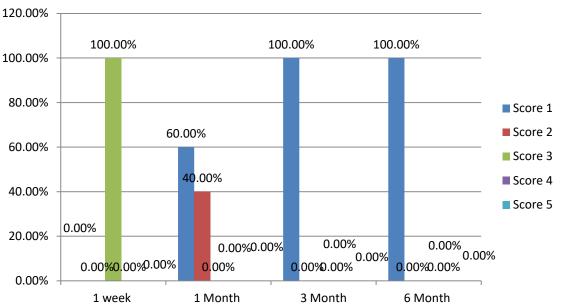
	Score 1	Score 2	Score 3	Score 4	Chi Square value	P value	Signific ance
1 Week	2	8	0	0			
- // 55	20.0%	80.0%	.0%	.0%			
1 Month	2	8	0	0			Non-
	20.0%	80.0%	.0%	.0%	0.000 1.00	1.000	Signific
3 Months	2	8	0	0			ant
	20.0%	80.0%	.0%	.0%			
6 Months	2	8	0	0			
	20.0%	80.0%	.0%	.0%			



INTRAGROUP COMPARISON OF PAIN BETWEEN DIFFERENT TIME INTERVALS

At 1 week time interval 100% of the subjects had moderate pain that requires regular medication, At 1 month 60% had no pain and 40% had mild pain. At 3 month and 6 month none of the subjects had pain. There was statistically significant reduction in the pain from 1 week to 1 month and 3 month.

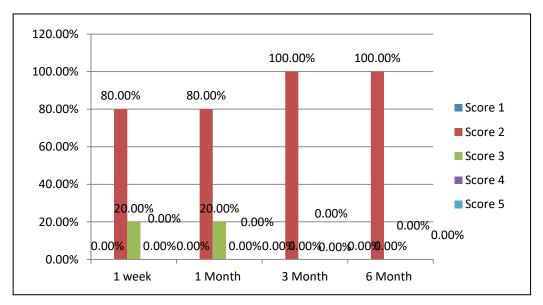
	Score 1	Score 2	Score 3	Score 4	Score 5	Chi Square value	P value
1 Week	0	0	10	0	0		
	.0%	.0%	100.0%	.0%	.0%		
1 Month	6	4	0	0	0		
	60.0%	40.0%	.0%	.0%	.0%	52.200	0.001
3 Months	10	0	0	0	0		(Sig)
	100.0%	.0%	.0%	.0%	.0%		
6 Months	10	0	0	0	0		
	100.0%	.0%	.0%	.0%	.0%		



INTRAGROUP COMPARISON OF ACTIVITY BETWEEN DIFFERENT TIME INTERVALS

At 1 week and 1 month time interval 80% of the subjects had difficulty in activity such that they were not able to keep their old pace but not much oftenly, At 3 month and 6 months 100% had no difficulty in activity The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

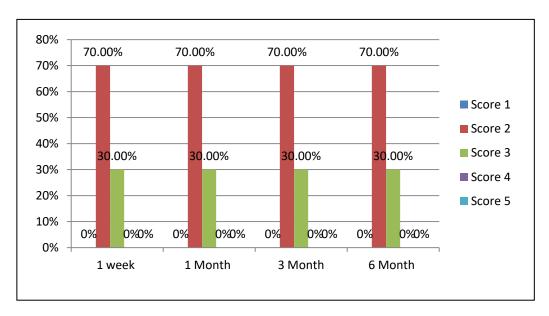
	Score 1	Score 2	Score 3	Score 4	Score 5	Chi Square value	P value
1 Week	0	8	2	0	0		
	.0%	80.0%	20.0%	.0%	.0%		
1	0	8	2	0	0		0.217
Month	.0%	80.0%	20.0%	.0%	.0%	4.444	(Non-
3	0	10	0	0	0		Significant)
Months	.0%	100.0%	.0%	.0%	.0%		-
6	0	10	0	0	0		
Months	.0%	100.0%	.0%	.0%	.0%		



INTRAGROUP COMPARISON OF APPEARANCE BETWEEN DIFFERENT TIME INTERVALS

At the 1 week, 1 month, 3 month and 6 months, 70% of the individuals noticed minor change in appearance in mirror. The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

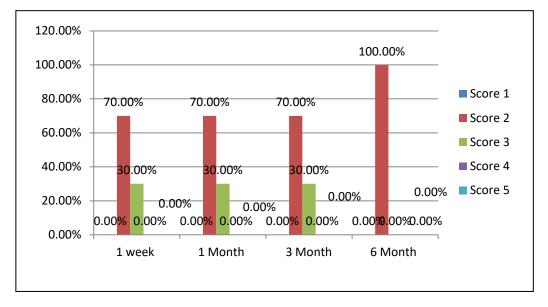
	Score 1	Score 2	Score 3	Score 4	Score 5	Chi Square value	P value
1 Week	0	7	3	0	0		
	0%	70.0%	30.0%	0%	0%		
1	0	7	3	0	0		1.000
Month	0%	70.0%	30.0%	0%	0%	0.000	(Non-
3	0	7	3	0	0		Sig)
Months	0%	70.0%	30.0%	0%	0%		Ç.
6	0	7	3	0	0		
Months	0%	70.0%	30.0%	0%	0%		



INTRAGROUP COMPARISON OF RECREATION BETWEEN DIFFERENT TIME INTERVALS

At the 1 week, 1 month, 3 month 70% of the individuals had difficulty in doing certain things but they were still getting out and enjoying. At 3 months there was no limitation to recreation in 100% of the subjects. The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

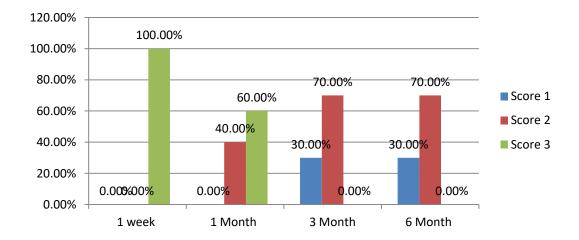
	Score 1	Score 2	Score 3	Score 4	Score 5	Chi Square value	P value
1 Week	0	7	3	0	0		
	.0%	70.0%	30.0%	.0%	.0%		
1	0	7	3	0	0		0.276
Month	.0%	70.0%	30.0%	.0%	.0%	3.871	(Non-
3	0	7	3	0	0		Significant)
Months	.0%	70.0%	30.0%	.0%	.0%	•	
6	0	10	0	0	0	•	
Months	.0%	100.0%	.0%	.0%	.0%	•	



$\frac{\textbf{INTRAGROUP COMPARISON OF CHEWING BETWEEN DIFFERENT TIME}}{\textbf{INTERVALS}}$

At 1 week 100% of the subjects were not able to chew even soft solids. At 1 month 60% were not able to chew soft solids and 40% were able to chew soft solids. At 3 and 6 months 70% were able to chew soft solids. There was statistically significant improvement in chewing from 1 week to 1 month and 3 month.

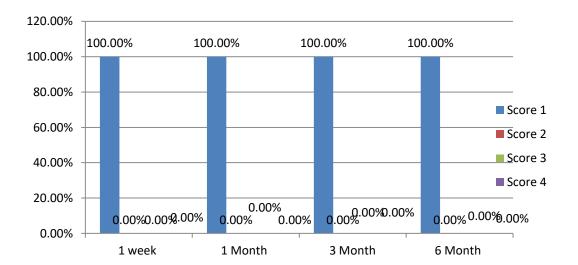
	Score 1	Score 2	Score 3	Chi Square value	P value
1 Week	0	0	10		
2 11 002	.0%	.0%	100.0%	_	
1 Month	0	4	6	-	
	.0%	40.0%	60.0%	23.126	0.001
3 Months	3	7	0		(Sig)
U 1/1011V1	30.0%	70.0%	.0%		
6 Months	3	7	0	-	
V IIIVIIII	30.0%	70.0%	.0%	-	



$\frac{\textbf{INTRAGROUP COMPARISON OF SHOULDER BETWEEN DIFFERENT TIME}}{\textbf{INTERVALS}}$

At the 1 week, 1 month, 3 month and 6 months none of the subjects had problem with the shoulder. The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

	Score 1	Score 2	Score 3	Score 4	Chi Square value	P value
1 Week	10	0	0	0		
1 Week	100.0%	.0%	.0%	.0%	_	
1 Month	10	0	0	0	_	1.000
	100.0%	.0%	.0%	.0%	0.000	(Non-
3 Months	10	0	0	0	_	Sig)
	100.0%	.0%	.0%	.0%	_	
6 Months	10	0	0	0		
	100.0%	.0%	.0%	.0%	_	



INTRAGROUP COMPARISON OF TASTE BETWEEN DIFFERENT TIME INTERVALS

At 1 week, 1 month, 3 month and 6 month, 70% of the subjects were able to taste most of the foods normally, 30% of the subjects were able to taste some foods. The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

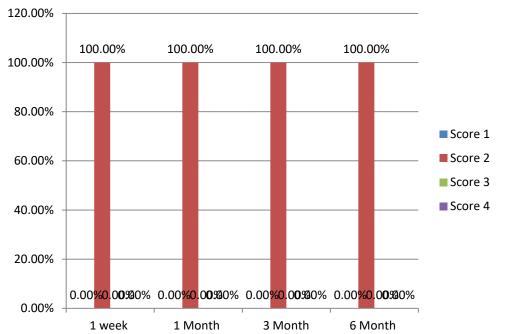
					Chi	
	Score 1	Score 2	Score 3	Score 4	Square	P value
					value	
1 Week	0	7	3	0		
	.0%	70.0%	30.0%	.0%	_	
1 Month	0	7	3	0	_	1.000
	.0%	70.0%	30.0%	.0%	0.000	(Non-
3 Months	0	7	3	0	_	Significant)
	.0%	70.0%	30.0%	.0%	_	
6 Months	0	7	3	0	_	
	.0%	70.0%	30.0%	.0%	_	



$\frac{\textbf{INTRAGROUP COMPARISON OF SALIVA BETWEEN DIFFERENT TIME}}{\textbf{INTERVALS}}$

At 1 week, 1 month, 3 month and 6 month 100% of the subjects had saliva less than normal but enough. The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

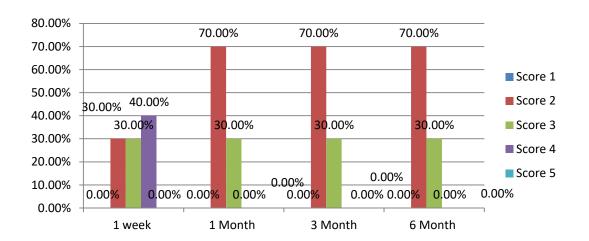
	Score 1	Score 2	Score 3	Score 4	Chi Square value	P value
1 Week	0	10	0	0		
	.0%	100.0%	.0%	.0%	_	
1	0	10	0	0	_	
Month	.0%	100.0%	.0%	.0%	0.000	1.000
3	0	10	0	0	_	(Non-Sig)
Months	.0%	100.0%	.0%	.0%	_	
6	0	10	0	0	_	
Months	.0%	100.0%	.0%	.0%	_	



INTRAGROUP COMPARISON OF MOOD BETWEEN DIFFERENT TIME INTERVALS

At 1 week time interval 40% were somewhat depressed about cancer and 30% were neither in a good mood nor depressed about cancer. At 1 month, 3 month and 6 month 70% had generally good mood and were occasionally depressed by cancer. There was a statistically significant improvement in mood from 1 week to 1 month. From 1 month to 3 month and 6 month the mood was consistently good and there was no statistically significant difference.

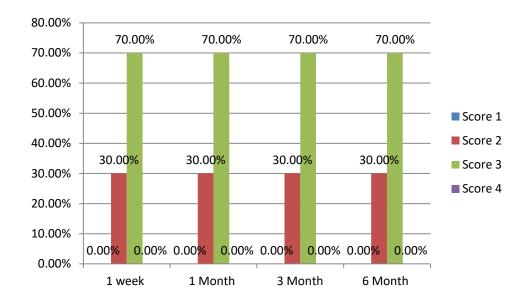
	Score 1	Score 2	Score 3	Score 4	Score 5	Chi Square value	P value
1 Week	0	3	3	4	0		
_ ,,, 5022	.0%	30.0%	30.0%	40.0%	.0%		
1 Month	0	7	3	0	0	•	
	.0%	70.0%	30.0%	.0%	.0%	14.000	0.030
3 Months	0	7	3	0	0		(Sig)
	.0%	70.0%	30.0%	.0%	.0%	'	
6 Months	0	7	3	0	0	•	
	.0%	70.0%	30.0%	.0%	.0%	'	



INTRAGROUP COMPARISON OF ANXIETY BETWEEN DIFFERENT TIME INTERVALS

At all the time intervals (1 week. I month, 3 month and 6 months) 30% were little anxious about the cancer and 70% were anxious about the cancer. The difference in anxiety levels between the different time intervals was not statistically different.

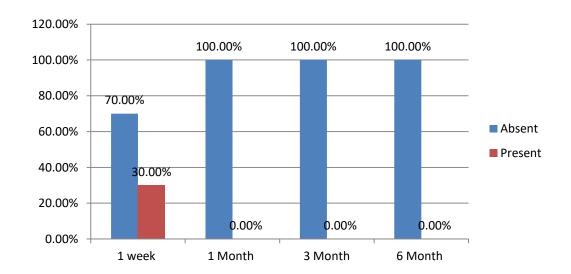
	Score 1	Score 2	Score 3	Score 4	Chi Square value	P value
1 Week	0	3	7	0		
	.0%	30.0%	70.0%	.0%	_	
1 Month	0	3	7	0	_	
	.0%	30.0%	70.0%	.0%	0.000	1.000
3 Months	0	3	7	0		(Non-Sig)
	.0%	30.0%	70.0%	.0%		
6 Months	0	3	7	0	_	
	.0%	30.0%	70.0%	.0%		



INTRAGROUP COMPARISON OF HAEMATOMA BETWEEN DIFFERENT TIME INTERVALS

At 1 week 30% of the subjects had haematoma whereas at 1 month, 3 month and 6 months none of subjects had haematoma. The difference between the different time intervals was statistically non-significant.

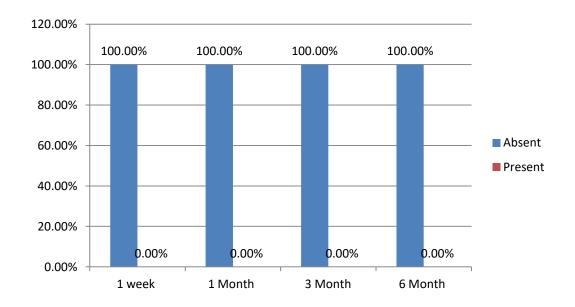
	Absent	Present	Chi Square value	P value	P value
1 Week	7	3			
	70.0%	30.0%	_		
1 Month	10	0	_		
2 1/2022	100.0%	.0%	8.732	0.062	Non-
3 Months	10	0	_		Significant
	100.0%	.0%	_		
6 Months	10	0	_		
	100.0%	.0%	_		



INTRAGROUP COMPARISON OF FISTULA BETWEEN DIFFERENT TIME INTERVALS

At the 1 week, 1 month, 3 month and 6 months none of the subjects had presence of fistula. The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

	Absent	Present	Chi Square value	P value	Significance
1 Week	10	0			
_	100.0%	.0%	•		
1 Month	10	0	•		
_	100.0%	.0%	0.000	1.000	Non-Sig
3 Months	10	0	•		S
_	100.0%	.0%	•		
6 Months	10	0	•		
	100.0%	.0%	•		



Discussion

The intricate architecture and functional significance of the involved structures in following resection render reconstruction of the residual defects extremely challenging in the field of Oral and Maxillofacial surgery. For patients undergoing reconstructive procedures, a multitude of surgical approaches have been implemented to restore form and function. Utilizing the platysma myocutaneous flap is one such method that is gaining attention as a reconstructive option.

Understanding the anatomical basis of the platysma myocutaneous flap is crucial for successful reconstruction. The platysma is a slender quadrangular shaped muscle lying in the superficial fascia of the neck.⁵² The muscle fibers originate from the deltoid and pectoralis major superficial fascia, cross the clavicle, and insert obliquely at the angle of the jaw, inferior portion of the cheek, and lip depressor muscles.⁵³ The submental branch of the facial artery serves as the primary artery supplying the platysma. In addition, the muscle receives its vascular supply from other vessels, including branches from the superior thyroid artery anteriorly, the occipital and posterior auricular arteries posteriorly, and the transverse cervical artery inferiorly. In addition to the medial jugular veins, submental vein, facial vein, and anterior connecting veins, the external jugular vein is the main source of venous drainage. ⁵⁴⁻⁵⁸

While previous authors only documented random cervical platysma flaps, Futrell was the first to describe a true musculo-cutaneous cervical flap that preserved the mandibular insertions which was composed of a lower cervical skin paddle and platysma muscle.^{1,60}

Regarding the main vascular pedicle, two distinct MPF variations can be utilized for head and neck reconstruction: the posterior flap, which is based on branches of the occipital artery, and the superior or vertical flap, which is based on the submental branch of the facial artery and has the greatest rate of adoption in surgical practice.⁵⁹

MPF has been used to reconstruct a wide range of head and neck defects. It has been proven to be an effective surgical alternative for reconstructing of small to medium-sized (15-75 cm²) lesions of the oral and maxillofacial region, and in rare cases, large-sized defects as well.^{52,53} The thin and flexible characteristics of the muscle-skin paddle unit render the platysma flap highly appropriate for customizing repairs for defects in the floor of the mouth, cheek mucosa, and gum. This adaptability helps mitigate post-operative functional challenges stemming from primary closure under excessive tension.^{41,61}

This study adds to the existing literature supporting the role of the PMF in the reconstruction of defects of maxillofacial region. In our experience of 10 patients, the PMF was extremely reliable with just two minor complications. Overall, the Quality Of Life in these patients was very good. The mean operating time of < 4 hours for tumor resection and PMF reconstruction underscores the efficiency of using this flap. The exact time necessary for the flap elevation was not documented, but it does not add materially to the time required for neck dissection itself. This study utilized a superiorly based flap with a wide base for the PMF procedure. The facial artery and/or its branches are preserved when possible. 62-64 In our study, we retrospectively evaluated, the facial artery was ligated in 4 patients, nonetheless, no complications were observed in any patients. Whenever required, the external jugular vein (EJV) was preserved, but its status was not recorded in this study. Previous descriptions in the literature emphasized that the EJV is the main venous drainage pathway and therefore its preservation is important when using the PMF.

Despite the limitations of our study, the PMF proves to be an excellent option for reconstruction for the defects of oral cavity. It should be highlighted that, in our study, all 10 patients had either a segmental or marginal mandibulectomy performed as part of the tumor excision. The PMF proves itself robust enough to cover exposed bone and reconstruction plates in each case. No fistulas or instances of exposed hardware occurred.

Although patients undergoing other reconstructive procedures, like the pectoralis major flap or the radial forearm free flap, were not formally evaluated in this study, we are confident that the PMF engenders less donor site morbidity than these two more commonly utilized flaps. Therefore, we advocate for greater consideration and use of the PMF for reconstructing maxillofacial defects.

In oncologic surgery, the objective is to achieve tumor-free margins with esthetic and functional restoration, aiming to avert any negative effects on life quality. The objective of reconstructive procedures after ablative therapy for head and neck cancer is to restore both form and function, facilitating a return to daily activities. 65 This objective was successfully met for speech and swallowing functions in 8 out of 10 patients (80%) who underwent platysma flap reconstruction. Notably, no additional secondary surgical interventions were needed for any of the cases. In our study, at the 1 week, 1 month, 3 month and 6 months 70% of the individuals had difficulty saying some words, however the words are comprehensible over the telephonic conversation and 30% of the had speech difficulty such that only family and friends could understand the speech. In context of post-operative swallowing in the patients, it was observed that at the 1 week, 1 month, 3 month and 6 months 80% of the individuals could swallow well as earlier and 20% had difficulty in swallowing solid foods. However, the difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

Complications such as infection, fistula formation, and skin paddle slough were effectively addressed through conservative management, relying solely on supportive care. In our study, At the 1 week time intervals 30% of the patients were having infection present whereas at 1 month, 3 month and 6 months postoperatively, there was no evidence of infection in any patient. The difference between the 1 week and 1 month, 1 week and 3 month, 1 week and 6 months was statistically significant with p value of 0.021 whereas difference between 1 month, 3 months and 6 month was statistically non-significant. Moreover, flap dehiscence was not observed in any case at week 1, 1 month, 3 and 6 months.

Prolonged hospitalization was not primarily due to patients experiencing complications related to the flap, as they could be discharged with home nursing follow-up promptly. Extended stays in the hospital were rather attributed to other factors such as chyle leak, resumption of warfarin anticoagulation, and pneumonia.

While numerous additional vascular branches are thought to contribute to the perfusion of the flap, the submental branch of the facial artery is thought to be its primary feeding vessel. This feature has led to the characterization of the flap's blood supply as "multi-axial," ¹⁹ suggesting a capacity for rapid redirection of perfusion routes following skin incision to compensate for any interrupted pathways. ⁶⁵ In contrast to the pectoralis major myocutaneous flap, there is no easily discernible vascular pedicle visible beneath the platysma flap. ⁶⁶ Consequently, some authors have reported routinely sacrificing the facial artery without significant flap loss, supported by anatomical considerations. ¹⁹ With the exception of one patient, we chose to preserve the facial artery, and the rate of flap complications was comparable to other series reported in the literature.

Certain authors have recommended utilizing the platysma flap primarily when well-developed muscle is present. While a prominent platysma does aid in flap development, the size of muscle fibers does not necessarily align with the blood supply to the skin. Instead, the integrity of the overall fascial system, encompassing muscle and the surrounding fibrovascular tissue within fat, appears to be crucial. Similarly, the notion of refraining from employing a platysma flap reconstruction in cases of facial nerve palsy might be unfounded, as the critical factor is the blood supply to the skin. However, since this study did not include cases of facial palsy, further discussion on this matter would be speculative.

While 3 out of 10 individuals who underwent preoperative radiation experienced minor issues with flap skin, the group that had received prior radiation statistically performed better than those without such a history. Some experts have suggested that individuals with a history of chemotherapy have a reduced likelihood of complication-free reconstruction using a platysma flap. Late complications were

also observed by Esclamado et al (1994).⁶⁷ This lack of complication might be explained by the fact that oral closures were supported by the remaining mandible and tongue, maintaining close proximity and preventing saliva seepage, while the region of flap failure healed through secondary intention.

Individuals who smoke might experience an elevated incidence of both temporary and permanent issues concerning blood flow through the small vessels of the plexus that supply the skin. This aspect has been suggested as a potential risk factor affecting the viability of flaps. However, in the present investigation, a recent smoking habit did not indicate a higher likelihood of skin loss in the flap.⁵³

Platysma flaps offer several advantages. The provided tissue is generally adequate for most soft tissue resections, except for extensive cases like total glossectomy. The flap is thin and flexible, allowing it to conform well to the defect. Its arc of rotation enables it to reach beyond the midline in the pharynx and slightly past the midline of the anterior floor of the mouth. It can be combined with other reconstructive techniques. 19 Harvesting the flap takes only about 15 minutes more than the standard elevation of subplatysmal neck flaps. Closing the donor site is straightforward, involving the undermining of the superior chest wall skin over the clavicle. Even if there is partial loss of skin at the distal donor site, the final appearance of the neck remains unchanged from that after neck dissection, and there are no functional issues related to the neck. The drawbacks of platysma flaps are relatively minimal. There are limitations in reach and tissue bulk. Preservation of facial vessels, if deemed necessary, may restrict the use of platysma flaps in cases of bulky neck node metastases. ⁶⁸ While the study did not directly investigate this concern, some literature suggests that facial vessels may not be essential for flap survival. Nevertheless, due to the precarious blood supply to the skin paddle, there is a notable rate of postoperative complications.¹⁹ In this particular study, however, these complications did not negatively impact the treatment cost or the ultimate achievement of reconstructive objectives.

Complications and undesired outcomes are inevitable in any surgical procedure. The development of this flap is a relatively simple well within the capabilities of most oral and maxillofacial surgeons. The primary concern during flap surgery is the risk of vascular compromise, leading to the death of all or part of the flap if the dominant arterial supply is lost. Unlike other axial pattern flaps, such as the pectoralis major flap, the dominant artery is usually not visible and is typically not identified with a Doppler study. ^{19,54} By meticulously adhering to the dissection planes and having a thorough understanding of the anatomy, the surgeon should be able to preserve the integrity of the arterial supply. If, in the postoperative period, the flap appears pale with minimal capillary refill, urgently returning the patient to the operating room may not be beneficial, provided the surgeon is confident that the pedicle was not twisted, strangulated, or excessively stretched. ⁵⁴

In the immediate postoperative period, if the skin paddle appears white, it often indicates an impending skin slough. Recent studies have reported skin slough incidence rates as high as 60%. Consistent with earlier research, our study also recorded a 40% incidence of skin slough, which was managed conservatively. Typically, when sloughing occurs, the underlying muscle remains viable. In cases where the flap is used intraorally, skin sloughing can facilitate mucosalization and lead to a more natural long-term outcome, devoid of hair growth in the mouth and excessive contraction. However, skin sloughing may have more pronounced aesthetic consequences when the flap is utilized for facial reconstruction. Ariyan documented a case involving the use of a platysma muscle flap for facial reconstruction, wherein a skin graft was applied following skin slough.

A comprehensive knowledge of the anatomy is crucial, particularly in maintaining awareness of the entry point of the vascular supply into the pedicle, preserving the integrity of the vascular pedicle, and conducting the dissection meticulously without creating openings in the muscle to ensure the survival of the flap. The dimensions of the skin paddle documented in existing literature have varied from 5 x 10 to 7 x 14 cm.¹⁹ Coleman and colleagues¹⁵ recommended designing sufficiently large skin paddles (at least 5 cm wide) to encompass multiple perforators, enhancing flap survival. While smaller skin paddles may lack adequate perforators for proper skin perfusion, the authors have achieved success

using smaller skin paddles. In our study, the flap size ranged from 5×8 to 8×14 cm.

Venous congestion is evident when the flap appears blue or dusky. This occurrence is not uncommon, particularly in the superiorly based variant of the flap, where venous drainage through the submental vein is deficient.⁷⁰ In the authors' observations, venous congestion typically resolves on its own, and the flap can be anticipated to have long-term viability.⁴² No Venous congestion was observed in our study.

To prevent hematoma formation at the donor site, employing a suction drain is recommended. The drain should remain in position until the output diminishes to less than 30 mL within a 24-hour timeframe. In cases where the flap is utilized for oral reconstruction, enteral feeding is administered via a nasogastric tube for a period of 7 to 10 days. This is done to safeguard the flap and mitigate the potential for an oral cutaneous fistula or neck infection. During this time, the patient refrains from oral intake until the closure of the flap is guaranteed. At 1 week 30% of the subjects had haematoma whereas at 1 month, 3 month and 6 months none of subjects had haematoma. The difference between the different time intervals was statistically non-significant.

Dehiscence may manifest at either the recipient or donor site, and the recommended treatment involves wound packing and subsequent secondary revision if necessary. When the platysma flap is elevated simultaneously with a neck dissection, there is a theoretical apprehension regarding dehiscence at the donor site. This concern arises due to the loss of arterial perforators from the platysma to the skin above, potentially resulting in ischemia at the skin edges and eventual breakdown. Flap dehiscence was seen in one case at week 1, mostly in small defects (4cm in diameter). Dehiscence was not associated with the location or size of the defect (P>0.05). Intraorally, the flap suture line showed minor dehiscence that was healed by secondary intention. A venous obstruction may also be responsible for this condition, as the flap needs to be folded more than 360 degrees for proper placement. Local wound care or secondary closure was the

treatment of choice, when this complication occurred, with an acceptable outcome.

A meta-analysis by Szudek and Taylor included 190 patients from 16 published reports and found a flap complication rate of 33.7%. Additionally, they concluded recipient site and tumour stage were linked with postoperative complications rather than age, sex, preoperative radiotherapy. Additionally, neither age nor sex was significantly associated with post-operative complications or flap viability in present study. Even though the size and site of the defect did not have a substantial effect on flap viability, local complications were dependent on the recipient site. This study, however, demonstrated an increased complication rate in mandibular alveolus reconstruction. There is logic behind the flap resting on the mandibular alveolus and receiving less blood supply due to a random pattern of blood supply. In all flaps, venous congestion is a significant clinical phenomenon. The location of the skin paddle on the neck was significantly associated with venous congestion and flap viability. The skin paddle did not result in venous congestion and completely viable when located between AJV and PEJV. This prevents any tributaries of EJV from entering the muscle flap and from causing ligation to be necessary to achieve adequate rotation of the flap. 100% incidence was found when placed on the PEJV and posterior to the AJV. Consequently, the results of the study suggest that a meticulous planning must be done when designing the skin paddle of an appropriate size and length that does not compromise the tributaries of the EJV, which actually contribute to venous drainage.

In present study no skin paddle loss was as both AJV and PJV branches was saved, it was still viable. Researchers Ruark et al. and Verschuur et al.⁵⁵ recommended preserving the external jugular vein and including the vessels in the flap pedicle whenever possible. In spite of this, the muscle underneath still bled when prodded. Also, age and sex has no discernible impact on viability. Metastasis in submandibular lymph nodes might hinder the utilization of the platysma flap. The presence of lymph nodes connected to the platysma or located

around the facial artery, requiring dissection, poses a risk to the blood supply of the platysma. When no positive lymph nodes were detected, maintaining the integrity of the facial artery was uncomplicated. Conversely, in cases where positive lymph nodes were suspected preoperatively or identified during the operation, preservation of the facial artery and vein was not attempted, and free flaps were frequently employed for defect reconstruction. In the current investigation, no instances of regional recurrence were observed among patients in whom facial vessels were preserved or flaps were prepared.

Mouth opening has improved significantly postoperatively, particularly in patients with OSMF. Following the application of Heister jaw opener, mouth opening gradually increased over the course of six months without relapse. Our study is in concordance with the study conducted by Sathyanarayanan Ramanujam and Suresh Venkatachalam.⁴⁰

The occurrence of a fistula did not significantly correlate with the site or size of the defect. (P<0.05). To mitigate the risk of infection and fistulae formation, enteral feeding was ensured by nasogastric tube until mucosalization of the flap was achieved. However, the fistula formed at the site of an appropriately-sized soft tissue tunnel.

There were several parameters were utilized to evaluate the functional outcomes of the patients based of University of Washington questionnaires. In our study, at the 1 week, 1 month, 3 month and 6 months, 70% of the individuals had trouble pronouncing certain words, yet understandable over the phone and 30% of the had speech difficulty such that only family and friends could understand the speech. However, the difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

In our study, at the 1 week, 1 month, 3 month and 6 months 80% of the individuals could swallow well and 20% had difficulty in swallowing solid foods. The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

Also, at 1 week time interval 100% of the subjects had moderate pain that requires regular medication, At 1 month 60% had no pain and 40% had mild pain. At 3 month and 6 month none of the patients experienced pain. A statistically significant reduction in the pain was observed from 1 week to 1 month and 3 month.

In our study, at 1 week and 1 month time interval 80% of the subjects had difficulty in activity in a way that they were unable to keep their old pace but not much often, At 3 month and 6 months 100% had no difficulty in activity The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

Moreover, at the 1 week, 1 month, 3 month, 70% of the individuals had difficulty in doing certain things, however, they continued going out and enjoying the daily activities. At 3 months there were no restrictions on leisure activities in 100% of the subjects. However, the result was statistically non-significant.

In context of chewing, at 1 week 100% of the subjects were not able to chew even soft solids. At 1 month 60% were not able to chew soft food and 40% were able to chew soft meals. At 3 and 6 months 70% were able to chew soft solids. A statistically significant improvement in chewing was observed from 1 week to 1 month and 3 month.

None of the subjects had problem with the shoulder, at the 1 week, 1 month, 3 month and 6 months. The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

70% of the patients were able to taste majority of the food items normally at 1 week, 1 month, 3 month and 6 month. 30% of the subjects were able to taste some foods. The difference between the 1 week, 1 month, 3 months and 6 month was statistically non-significant.

Moreover, at 1 week time interval 40% were somewhat apprehensive about cancer and 30% were neither optimistic nor in despair about cancer. At 1 month, 3 month

and 6 month 70% had generally good mood and were occasionally depressed by cancer. A statistically significant improvement was observed in patient's mood from 1 week to 1 month. From 1 month to 3 month and 6 month the mood was consistently good and no statistically significant difference was seen.

At all the time intervals (1 week, I month, 3 month and 6 months), 30% were a little concerned over the malignancy and 70% were apprehensive about the cancer. The difference in anxiety levels between the different time intervals was not statistically different.

To gain a deeper understanding of complications and their association with different variables, this study would have needed a larger sample size. Here, a superiorly-based platysma flap is used. In order to provide accurate guidelines for the reconstruction of different oral cavity sub-sites, comparisons with other types of reconstruction are required, such as inferiorly-based and posteriorly-based flaps. Therefore, the incidences of post-operative complications such as dehiscence, fistula, infection, and hematoma are significantly less than what is necessary to draw accurate conclusions. However, despite the limitations regarding the sample size, we advocate for greater consideration and use of the PMF for reconstruction of oral cavity defects.

Conclusion

In conclusion, the platysma myocutaneous flap stands as a valuable option in oral and maxillofacial reconstruction, offering a combination of versatility, reliable blood supply, and potential for functional restoration. While it has demonstrated efficacy in addressing various defects, its limitations and potential complications necessitate careful consideration in surgical planning. The flap's versatility, low complication rates, and ability to restore both form and function make it a favorable choice for addressing complex defects in the craniofacial region.

As surgical techniques continue to evolve, the platysma myocutaneous flap stands as a testament to the progress in achieving optimal outcomes in the challenging field of oral and maxillofacial surgery. A comprehensive evaluation of functional outcomes and comparisons with alternative techniques contribute to a holistic understanding of the role of the platysma myocutaneous flap in the evolving landscape of oral and maxillofacial reconstruction. Future research should focus on refining techniques, minimizing complications, and exploring synergies with emerging technologies to further enhance the efficacy of this reconstructive approach.

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BABU BANARASI DAS UNIVERSITY BBD COLLEGE OF DENTAL SCIENCES, LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled "Efficacy & Functional Outcome Of Platysma Myocutaneous Flap In Oral & Maxillofacial Reconstruction" submitted by Dr Humne Abhijeet Yuwraj Postgraduate student in the Department of Oral & Maxillofacial Surgery for the Thesis Dissertation as part of MDS Curriculum for the academic year 2021-2024 with the accompanying proforma was reviewed by the Institutional Research Committee in its meeting held on 14th September, 2022 at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

Prof. Dr. Puneet Ahuja

Chairperson

Dr. Mona Sharma Co-Chairperson



BABU BANARASI DAS UNIVERSITY BBD COLLEGE OF DENTAL SCIENCES, LUCKNOW

BBDCODS/IEC/09/2022

Dated: 16th September, 2022

Communication of the Decision of the Xth Institutional Ethics Sub-Committee Meeting

IEC Code: 21

Title of the Project: Efficacy & Functional Outcome Of Platysma Myocutaneous Flap In Oral & Maxillofacial Reconstruction.

Principal Investigator: Dr Humne Abhijeet Yuwraj

Department: Oral & Maxillofacial Surgery

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Project Protocol

Dear Dr Humne Abhijeet Yuwraj,

The Institutional Ethics Sub-Committee meeting comprising following members was held on 15th September, 2022.

Dr. Lakshmi Bala Member Secretary

Prof. and Head, Department of Biochemistry

Dr. Praveen Singh Samant Prof. & Head, Department of Conservative Dentistry & Endodontics

Member

Dr. Jiji George

Prof. & Head, Department of Oral Pathology & Microbilogy

Member

Dr. Amrit Tandan Member

Professor, Department of Prosthodontics and Crown & Bridge

Dr. Rana Pratap Maurya

Member

Reader, Department of Orthodontics & Dentofacial Orthopaedics

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.

The comments were communicated to PI, thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Forwarded by:

Prof. Dr. Puncet Ahuja

-16/ Principal BBD Cottege of Dental Sciences

BBD University, Lucknow PRINCIPAL

Babu Banarası Das College of Dental Sciences (Babu Banarasi Das University) BBD City, Faizabad Road, Lucknow-226028

Dr. Lakshmi Bala

Member-Secretary

Institutional Ethics Sub-Committee (IEC) BBD College of Dental Sciences

BBD University, Lucknow

Member-Secretary. Institutional Ethic Committee BBD College of Dental Sciences BBD University

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Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

PARTICIPANT INFORMATION DOCUMENT

1. Study Title

Efficacy and Functional Outcome of Platysma Myocutaneous Flap in Oral and Maxillofacial Reconstruction.

2. Invitation Paragraph

You are being invited to take part in a research study. Before you decide it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us for any clarifications or further information. Whether or not you wish to take part is your decision.

3. What is the purpose of the study?

This study aims to assess the efficacy and Functional Outcome of Platysma Myocutaneous Flap in Oral and Maxillofacial Reconstruction.

4. Why have I been chosen?

You have been chosen for this study as you are fulfilling the required criteria for this study.

5. Do I have to take part?

Your participation in the research is entirely voluntary. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. During the study you are still free to withdraw at any time and without giving a reason.

6. What will happen to me if I take part?

The participant will be benefited as the required procedure would be carried out once the General anesthesia is effective. This will also help the patient to get the treatment done without pain, anxiety or fear. The surgical procedure would require 1 day; however, the participants would be called before the surgical procedures for undergoing various tests and imaging that includes blood tests, Chest X-rays, CT scans, MRI scans etc. The participants would need to visit the hospital at a regular interval for assessing the flaps and follow ups for at least a year. At the day of surgery, the participant should come to the Institute at 9.00 am without having eaten anything/on an empty stomach/fasting. The participant will be given questionnaires for assessing the functional status (speech, swallow, mouth opening, etc) after the flap placement.

7. What do I have to do?

To participate in this study, the patient must have been diagnosed with oral cancer; and the oro-facial defect would require the soft tissue reconstruction. The participant would have dietary restrictions; i.e.the patient must be on the soft diet. Also, patient will be feed using Ryle's Tube for few days after the treatment procedure. The patient can continue to take his regular medications. The participant is prohibited from driving, and should refrain from giving blood.

8. What is the procedure that is being tested?

The study will be carried out to evaluate the efficacy and functional outcomes of platysma myocutaneous flap in the oral and maxillofacial reconstruction. The entire procedure would take place under General Anesthesia. A major goal of this flap in *oral* and facial *reconstruction* after tumor resection is to restore adequate form and function thereby improving patient's quality of life.

9. What are the interventions for the study?

The procedure will be done under General Anesthesia and the defect would surgically resected and the soft tissue reconstruction using platysma flap will follow the resection surgery.

10. What are the side effects of taking part?

Although there are no reports of serious side effects of the procedure, but the participant may have minimum side effects of the drugs like nausea or post-operative pain, vomiting. If anything happens during the procedure we have skilled personnel and specialized equipments to manage any emergency.

If the participant suffers any other symptom post operatively, the guardian should immediately talk to the doctor.

11. What are the possible disadvantages and risks of taking part?

There are no disadvantages of taking part in this study; there can be minimum side effects of the drug.

12. What are the possible benefits of taking part?

The participant will be benefited as the required procedure would be carried out once the General anesthesia is effective. This will also help

the patient to get the treatment done without pain, anxiety or fear.

Furthermore, the oral and maxillofacial defect of the participant would be treated in the same operative field with minimum morbidity to the donor site, and the required flap would have a good color match with ease in closure of the primary donor site and would have an appropriate flap thickness for the defects.

13. What if new information becomes available?

If additional information becomes available during the course of the research you will be told about these and you are free to discuss it with your researcher, we will tell you whether you want to continue in the study. If you decide to withdraw, we will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

Nothing will happen to the participants.

15. What if something goes wrong?

The problems/complaint will be handled by the HOD or the IRC. If something serious happens the institute will take care of the problems.

16. Will my taking part in this study be kept confidential?

Yes it will be kept confidential.

17. What will happen to the results of the research study?

The results of the study will be used for assessing the efficiency of Platysma Myocutaneous Flap along with its functional outcome in the orofacial defect reconstruction. The participant's identity will be kept confidential in case of any report/publication.

18. Who is organizing the research?

The research is been done in the DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY, BBDCODS. The research is self-funded. The participants will have to pay for procedural charges as given by the institution.

19. Will the results of the study be made available after study is over?

Yes

20. Who has reviewed the study?

The HOD and the members of IRC/ IEC of the institution has reviewed and approved the study.

21. Contact for further information

Dr. Abhijeet Humne

Department of Oral & Maxillofacial Surgery,

Babu Banarasi College of Dental Sciences.

Lucknow-226028

Mob- +91 8806577728

Dr. LaxmiBala

Member Secretary of Ethics Committee of the institution,

Babu Banarasi College of Dental Sciences.

Lucknow

bbdcods.iec@gmail.com

THANK	YOU	FOR	TAKING	OUT	YOUR	PRECIOUS	TIME	FOR
READIN	G THE	DOCL	JMENTS A	ND PA	RTICIPA	ATING IN THE	STUD	Υ.

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज (बाबू बनारसी दास विश्वविद्यालय) बीबीडी सिटी, फैजाबाद रोड, लखनऊ - 227105 (भारत) प्रतिभागी सूचना दस्तावेज

1. अध्ययन शीर्षक:

मौखिक और मैक्सिलोफेशियल पुनर्निर्माण में प्लैटिस्मा मायोक्यूटेनियस फ्लैप की प्रभावकारिता और कार्यात्मक परिणाम ।

2. आमंत्रण पैराग्राफ:

आपको एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है। निर्णय लेने से पहले आपके लिए यह समझना महत्वपूर्ण है कि अध्ययन क्यों किया जा रहा है और इसमें क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय निकालें और यदि आप चाहें तो मित्रों, रिश्तेदारों और अपने इलाज करने वाले चिकित्सक/पारिवारिक चिकित्सक के साथ इस पर चर्चा करें। किसी भी स्पष्टीकरण या अधिक जानकारी के लिए हमसे पूछें। आप भाग लेना चाहते हैं या नहीं, यह आपका निर्णय है।

3. अध्ययन का उद्देश्य क्या है?

इस अध्ययन का उद्देश्य मौखिक और मैक्सिलोफेशियल पुनर्निर्माण में प्लैटिस्मा मायोक्यूटेनियस फ्लैप की प्रभावकारिता और कार्यात्मक परिणाम का आकलन करना है।

4. मुझे क्यों चुना गया है?

आपको इस अध्ययन के लिए चुना गया है क्योंकि आप इस अध्ययन के लिए आवश्यक मानदंडों को पूरा कर रहे हैं।

5. क्या मुझे भाग लेना है?

शोध में आपकी भागीदारी पूरी तरह से स्वैच्छिक है। यदि आप ऐसा करते हैं, तो आपको यह सूचना पत्रक रखने के लिए दिया जाएगा और सहमित प्रपत्र पर हस्ताक्षर करने के लिए कहा जाएगा। अध्ययन के दौरान आप किसी भी समय और बिना कोई कारण बताए वापस लेने के लिए स्वतंत्र हैं।

6. यदि मैं भाग लेता हूँ तो मेरा क्या होगा?

प्रतिभागी को लाभ होगा क्योंकि जनरल एनेस्थीसिया के प्रभावी होने के बाद आवश्यक प्रक्रिया को अंजाम दिया जाएगा। इससे मरीज को बिना दर्द, चिंता या भय के इलाज कराने में भी मदद मिलेगी। शल्य प्रक्रिया के लिए 1 दिन की आवश्यकता होगी; हालांकि, प्रतिभागियों को विभिन्न परीक्षणों और इमेजिंग से गुजरने के लिए सर्जिकल प्रक्रियाओं से पहले बुलाया जाएगा जिसमें रक्त परीक्षण, छाती का एक्स-रे, सीटी स्कैन, एमआरआई स्कैन आदि शामिल हैं।

प्रतिभागियों को कम से कम एक वर्ष के लिए फ्लैप और फॉलो-अप का आकलन करने के लिए नियमित अंतराल पर अस्पताल जाने की आवश्यकता होगी। सर्जरी के दिन, प्रतिभागी को बिना कुछ खाए/खाली पेट/उपवास के सुबह 9 बजे संस्थान में आना चाहिए। फ्लैप प्लेसमेंट के बाद प्रतिभागी को कार्यात्मक स्थिति (भाषण, निगलना, मुंह खोलना, आदि) का आकलन करने के लिए प्रश्नावली दी जाएगी।

7. मुझे क्या करना होगा?

इस अध्ययन में भाग लेने के लिए, रोगी को मुंह के कैंसर का निदान होना चाहिए; और ओरो-चेहरे के दोष के लिए नरम ऊतक पुनर्निर्माण की आवश्यकता होगी। प्रतिभागी के पास आहार प्रतिबंध होंगे; यानी मरीज को सॉफ्ट डाइट लेनी चाहिए। साथ ही, उपचार प्रक्रिया के बाद कुछ दिनों तक राइल्स ट्यूब का उपयोग करके रोगी को भोजन कराया जाएगा। रोगी अपनी नियमित दवाएं लेना जारी रख सकता है। प्रतिभागी को वाहन चलाना प्रतिबंधित है, और उसे रक्तदान करने से बचना चाहिए।

किस प्रक्रिया का परीक्षण किया जा रहा है?

मौखिक और मैक्सिलोफेशियल पुनर्निर्माण में प्लैटिस्मा मायोक्यूटेनियस फ्लैप की प्रभावकारिता और कार्यात्मक परिणामों का मूल्यांकन करने के लिए अध्ययन किया जाएगा। पूरी प्रक्रिया जनरल एनेस्थीसिया के तहत होगी। ट्यूमर के उच्छेदन के बाद मौखिक और चेहरे के पुनर्निर्माण में इस फ्लैप का एक प्रमुख लक्ष्य पर्याप्त रूप और कार्य को बहाल करना है जिससे रोगी के जीवन की गुणवत्ता में सुधार होता है।

9. अध्ययन के लिए क्या हस्तक्षेप हैं?

प्रक्रिया सामान्य संज्ञाहरण के तहत की जाएगी और दोष शल्य चिकित्सा द्वारा ठीक किया जाएगा और प्लेटिस्मा फ्लैप का उपयोग करके नरम ऊतक पुनर्निर्माण लस सर्जरी का पालन करेगा।

10. भाग लेने के दुष्प्रभाव क्या हैं?

यद्यपि प्रक्रिया के गंभीर दुष्प्रभावों की कोई रिपोर्ट नहीं है, लेकिन प्रतिभागी को मतली या पोस्ट-ऑपरेटिव उल्टी जैसी दवाओं के न्यूनतम दुष्प्रभाव हो सकते हैं। यदि प्रक्रिया के दौरान कुछ भी होता है तो हमारे पास किसी भी आपात स्थिति को प्रबंधित करने के लिए कुशल कार्मिक और विशेष उपकरण हैं।

यदि ऑपरेशन के बाद प्रतिभागी को कोई अन्य लक्षण दिखाई देता है, तो अभिभावक को तुरंत डॉक्टर से बात करनी चाहिए।

11. भाग लेने के संभावित नुकसान और जोखिम क्या हैं?

इस अध्ययन में भाग लेने के कोई नुकसान नहीं हैं, दवा के न्यूनतम दुष्प्रभाव हो सकते हैं।

12. भाग लेने के संभावित लाभ क्या हैं?

प्रतिभागी को लाभ होगा क्योंकि जनरल एनेस्थीसिया के प्रभावी होने के बाद आवश्यक प्रक्रिया को अंजाम दिया जाएगा। इससे मरीज को बिना दर्द, चिंता या भय के इलाज कराने में भी मदद मिलेगी।

इसके अलावा, प्रतिभागी के मौखिक और मैक्सिलोफेशियल दोष का इलाज उसी ऑपरेटिव क्षेत्र में किया जाएगा जिसमें दाता साइट पर न्यूनतम रुग्णता होगी, और आवश्यक फ्लैप में प्राथमिक दाता साइट को बंद करने में आसानी के साथ एक अच्छा रंग मिलान होगा और दोषों के लिए उपयुक्त फ्लैप मोटाई होगी।

13. क्या होगा यदि नई जानकारी उपलब्ध हो जाती है?

यदि शोध के दौरान अतिरिक्त जानकारी उपलब्ध हो जाती है तो आपको इनके बारे में बताया जाएगा और आप अपने शोधकर्ता के साथ इस पर चर्चा करने के लिए स्वतंत्र हैं, हम आपको बताएंगे कि क्या आप अध्ययन जारी रखना चाहते हैं। यदि आप वापस लेने का निर्णय लेते हैं, तो हम आपकी निकासी की व्यवस्था करेंगे। यदि आप अध्ययन जारी रखने का निर्णय लेते हैं, तो आपसे एक अद्यतन सहमति फॉर्म पर हस्ताक्षर करने के लिए कहा जा सकता है।

14. जब शोध अध्ययन बंद हो जाता है तो क्या होता है?

प्रतिभागियों को कुछ नहीं होगा।

15. अगर कुछ गलत हो जाए तो क्या होगा?

समस्याओं/शिकायतों को एचओडी या आईआरसी द्वारा नियंत्रित किया जाएगा। यदि कुछ गंभीर होता है तो संस्थान समस्याओं का ध्यान रखेगा।

16. क्या इस अध्ययन में मेरे भाग लेने को गोपनीय रखा जाएगा?

हां इसे गोपनीय रखा जाएगा।

17. शोध अध्ययन के परिणामों का क्या होगा?

अध्ययन के परिणामों का उपयोग ओरो-फेशियल दोष पुनर्निर्माण में इसके कार्यात्मक परिणाम के साथ प्लैटिस्मा मायोक्यूटेनियस फ्लैप की दक्षता का आकलन करने के लिए किया जाएगा। किसी भी रिपोर्ट/प्रकाशन के मामले में प्रतिभागी की पहचान गोपनीय रखी जाएगी।

18. शोध का आयोजन कौन कर रहा है?

यह शोध डिपार्टमेंट ऑफ ओरल एंड मैक्सिलोफेशियल सर्जरी, बीबीडीसीओडीएस में किया गया है। शोध स्व-वित्त पोषित है। प्रतिभागियों को संस्था द्वारा दिए गए प्रक्रियात्मक शुल्क का भुगतान करना होगा।

19. क्या अध्ययन समाप्त होने के बाद अध्ययन के परिणाम उपलब्ध कराए जाएंगे?

हां

20. अध्ययन की समीक्षा किसने की है?

संस्थान के एचओडी और आईआरसी/आईईसी के सदस्यों ने अध्ययन की समीक्षा की और उसे मंजूरी दी।

21. अधिक जानकारी के लिए संपर्क करें:

डॉ. अभिजीत हुमने

ओरल और मैक्सिलोफेशियल सर्जरी विभाग,

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ-226028

मोब- +91 8806577728

डॉ. लक्ष्मीबाला

संस्था की आचार सिमति के सदस्य सिचव,

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ

bbdcods.iec@gmail.com

दस्तावेजों को पढ़ने और अध्ययन में भाग लेने के लिए अपना कीमती समय निकालने के लिए धन्यवाद।

पीआई के हस्ताक्षर	
नाम।	
तारीख	

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Consent Form (English)

	Compens I of in (English)
	Title of the Study: Efficacy and Functional Outcome of Platysma Myocutaneous Flap in Oral and
	Maxillofacial Reconstruction
	Study Number
	Subject's Full Name
	Date of Birth/Age
	Address of the Subject
	Phone no. and e-mail address
	Qualification
	Occupation: Student / Self Employed / Service / Housewife/Other (Please tick as appropriate)
	Annual income of the Subject
	Name and of the nominees(s) and his relation to the subject(For the purpose of
	compensation in case of trial related death).
1.	I confirm that I have read and understood the Participant Information Document dated
	for the above study and have had the opportunity to ask questions. OR I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.
2.	I understand that my participation in the study is voluntary and given with
	free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3.	I understand that the sponsor of the project, others working on the Sponsor's
	behalf, the Ethics Committee and the regulatory authorities will not need my
	permission to look at my health records both in respect of the current study and
	any further research that may be conducted in relation to it, even if I withdraw
	from the trial. However, I understand that my Identity will not be revealed in any
	information released to third parties or published.
4.	I agree not to restrict the use of any data or results that arise from this study

5. I permit the use of stored sample (tooth/tissue/blood) for future research. Yes

provided such ause is only for scientific purpose(s).

Not Applicable []

[✓]

No []

I agree to participate in the above study. I have been explained about the complications and side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer's Information document given to me.

Representative:
Signatory's Name Date
Signature of the Investigator Date
Study Investigator's Name Date
Signature of the witness Date
Name of the witness
Received a signed copy of the PID and duly filled consent form Signature/thumb impression of the subject or legally acceptable representative
Date

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज (बाबू बनारसी दास विश्वविद्यालय) बीबीडी सिटी, फैजाबाद रोड, लखनऊ - 227105 (भारत)

सहमति प्रपत्र (अंग्रेज़ी)
अध्ययन का शीर्षक- मौखिक और मैक्सिलोफेशियल पुनर्निर्माण में प्लैटिस्मा मायोक्यूटेनियस फ्लैप की प्रभावकारिता और कार्यात्मक परिणाम
स्टडी नंबर·····.
विषय का पूरा नाम
जन्म तिथि/आयु
विषय का पता
फोन नंबर। और ई-मेल पता
योग्यता
व्यवसाय: छात्र / स्वरोजगार / सेवा / गृहिणी / अन्य (कृपया उपयुक्त के रूप में टिक करें)
विषय की वार्षिक आय
नाम और नामांकित व्यक्ति (ओं) और विषय के साथ उसका संबंध (के प्रयोजन के लिए)
मुकदमे से संबंधित मौत के मामले में मुआवजा)।
1. मैं पुष्टि करता हूं कि मैंने प्रतिभागी सूचना दस्तावेज दिनांक . को पढ़ और समझ लिया है
·····उपरोक्त अध्ययन के लिए और प्रश्न पूछने का अवसर मिला है। या मुझे अन्वेषक द्वारा अध्ययन की प्रकृति के बारे में बताया गया है और मुझे प्रश्न पूछने का अवसर मिला है।
2. मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और बिना किसी दबाव के स्वतंत्र इच्छा के साथ दी गई है और मैं बिना कोई कारण बताए और अपनी चिकित्सा देखभाल या कानूनी

अधिकारों को प्रभावित किए बिना किसी भी समय वापस लेने के लिए स्वतंत्र हूं।

- 3. मैं समझता हूं कि परियोजना के प्रायोजक, प्रायोजक की ओर से काम करने वाले अन्य, नैतिकता सिमिति और नियामक प्राधिकरणों को वर्तमान अध्ययन और किसी भी आगे के शोध के संबंध में मेरे स्वास्थ्य रिकॉर्ड को देखने के लिए मेरी अनुमित की आवश्यकता नहीं होगी। इसके संबंध में आयोजित किया जा सकता है, भले ही मैं परीक्षण से हट जाऊं। हालांकि, मैं समझता हूं कि तीसरे पक्ष को जारी या प्रकाशित किसी भी जानकारी में मेरी पहचान प्रकट नहीं की जाएगी।
- 4. मैं इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं, बशर्ते ऐसा उपयोग केवल वैज्ञानिक उद्देश्यों के लिए हो।
- 5. मैं भविष्य के शोध के लिए संग्रहीत नमूने (दांत/ऊतक/रक्त) के उपयोग की अनुमति देता हूं। हाँ [] नहीं []

लागू नहीं []

मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं। मुझे जटिलताओं और दुष्प्रभावों के बारे में समझाया गया है, यदि कोई हो, और उन्हें पूरी तरह से समझ लिया है। मैंने प्रतिभागी/स्वयंसेवक के मुझे दिए गए सूचना दस्तावेज को भी पढ़ और समझ लिया है।

विषय/कानूनी रूप से स्वीकार्य प्रतिनिधि के हस्ताक्षर (या अंगूठे का निशान):	
हस्ताक्षरकर्ता का नाम·······. ।	तारीख
अन्वेषक के हस्ताक्षर तारीख·····	
अध्ययन अन्वेषक का नाम तारीख······.	
गवाह के हस्ताक्षर····· तारीख·····.	
गवाह का नाम	
पीआईडी की एक हस्ताक्षरित प्रति और विधिवत भरे हुए सहमति फॉर्म विषय के हस्ताक्षर निशान या	१/अंगूठे का
कानूनी रूप से स्वीकार्य प्रतिनिधि	
दिनांक	

	Date:
	University of Washington Quality of Life Questionnaire (UW-QOL)
	is questionnaire asks about your health and quality of life over the past seven days . Please swer all of the questions by checking one box for each question.
1.	Pain. (Check one box: ☑)
	 I have no pain. There is mild pain not needing medication. I have moderate pain - requires regular medication (codeine or nonnarcotic). I have severe pain controlled only by narcotics. I have severe pain, not controlled by medication.
2.	Appearance. (Check one box: ☑)
	□ There is no change in my appearance. □ The change in my appearance is minor. □ My appearance bothers me but I remain active. □ I feel significantly disfigured and limit my activities due to my appearance. □ I cannot be with people due to my appearance.
3.	Activity. (Check one box: ☑)
	I am as active as I have ever been. There are times when I can't keep up my old pace, but not often. I am often tired and have slowed down my activities although I still get out. I don't go out because I don't have the strength. I am usually in bed or chair and don't leave home.
4.	Recreation. (Check one box: ☑)
	□ There are no limitations to recreation at home or away from home. □ There are a few things I can't do but I still get out and enjoy life. □ There are many times when I wish I could get out more, but I'm not up to it. □ There are severe limitations to what I can do, mostly I stay at home and watch TV. □ I can't do anything enjoyable.
5.	Swallowing. (Check one box: ☑)
	I can swallow as well as ever. I cannot swallow certain solid foods. I can only swallow liquid food. I cannot swallow because it "goes down the wrong way" and chokes me.
6.	Chewing. (Check one box: ☑)
	□ I can chew as well as ever. □ I can eat soft solids but cannot chew some foods. □ I cannot even chew soft solids.
	University of Washington, 1999

	 □ My speech is the same as always. □ I have difficulty saying some words but I can be understood over the phone. □ Only my family and friends can understand me. □ I cannot be understood. 	
8.	Shoulder. (Check one box: ☑)	
	 I have no problem with my shoulder. My shoulder is stiff but it has not affected my activity or strength. Pain or weakness in my shoulder has caused me to change my work. I cannot work due to problems with my shoulder. 	
9.	Taste. (Check one box: ☑)	
	□ I can taste food normally. □ I can taste most foods normally. □ I can taste some foods. □ I cannot taste any foods.	
10	Saliva. (Check one box: ☑)	
	 □ My saliva is of normal consistency. □ I have less saliva than normal, but it is enough. □ I have too little saliva. □ I have no saliva. 	
11	Mood. (Check one box: ☑)	
	My mood is excellent and unaffected by my cancer. My mood is generally good and only occasionally affected by my cancer. I am neither in a good mood nor depressed about my cancer. I am somewhat depressed about my cancer. I am extremely depressed about my cancer.	
12	Anxiety. (Check one box: ☑)	
	 I am not anxious about my cancer. I am a little anxious about my cancer. I am anxious about my cancer. I am very anxious about my cancer. 	
	nich issues have been the most important to you <u>during the past 7 days?</u> eck ☑ up to 3 boxes.	-
	□ Pain □ Swallowing □ Taste □ Appearance □ Chewing □ Saliva □ Activity □ Speech □ Mood □ Recreation □ Shoulder □ Anxiety	
		-

	GENERAL QUESTIONS
	ared to the month before you developed cancer, how would you rate your health-related of life? (check one box: ☑)
	Much better
	Somewhat better
	About the same
	Somewhat worse
	Much worse
	eral, would you say your health-related quality of life <u>during the past 7 days</u> has been: one box: ☑)
	Outstanding
	Very good *
	Good
	Fair
	Poor
	Very poor
	Outstanding
	Very good Good
	Good Fair Poor
	Good Fair
Please	Good Fair Poor
Please	Good Fair Poor Very poor describe any other issues (medical or nonmedical) that are important to your quality of life and
Please	Good Fair Poor Very poor describe any other issues (medical or nonmedical) that are important to your quality of life and
Please	Good Fair Poor Very poor describe any other issues (medical or nonmedical) that are important to your quality of life and



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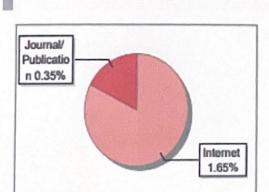
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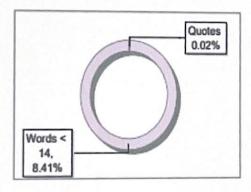
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