INTRAORAL SOFT TISSUE RECONSTRUCTION IN **ORAL CANCER: A COMPARISON OF THE** PECTORALIS MAJOR FLAP AND THE FREE RADIAL **FOREARM FLAP**

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ORAL AND MAXILLOFACIAL SURGERY

By

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I hereby declare that this dissertation entitled "INTRAORAL SOFT TISSUE RECONSTRUCTION IN ORAL CANCER: A COMPARISON OF THE PECTORALIS MAJOR FLAP AND THE FREE RADIAL FOREARM FLAP" is a bonafide and genuine research work carried out by me under the guidance of Dr. Hemant Mehra, Reader, Department of Oral and Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

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LIST OF ABBREVIATIONS

PMMF	:	Pectoralis Major Myocutaneous Flap
FRFF	:	Free Radial Forearm Flap
NS	:	Non Significant
S	:	Significant
IQR	:	Interquartile Range
OSCC	:	Oral Squamous Cell Carcinoma
HNSCC	:	Head and Neck Squamous Cell Carcinomas
SCAIF	:	Supraclavicular Artery Island Flap
SMIF	:	Submental Island Flap
ASA	:	American Society of Anesthesiologists
UW-QOL	:	University of Washington Quality of Life Questionnaire

ABSTRACT

Introduction-

Oral squamous cell carcinomas (OSCC) are cancers originating from the squamous epithelium in the oral cavity. PMMF has multiple advantages including: easy accessibility in the same surgical field; technically simple with a small learning curve; robust and reliable vascular anatomy. However, free tissue transfer can provide internal lining, external coverage, soft tissue bulk, and bone, and this flexibility and reliability making it the gold standard for reconstruction in the head and neck.

Aim and Objective-

To compare ease of harvesting, complications if any like infection, flap dehiscence, flap necrosis and donor site morbidity restorative functions like speech and swallowing after placement of flap between pectoralis major flap and free radial forearm flap.

Result -

A greater preponderance of complication is observed in the PMMF group (Group I) compared to FRFF group (Group II). The rate of infection at the recipient site was lower in the FRFF group compared to the PMMF group. However, dehiscence at "recipient and/or donor" site was higher with FRFF reconstruction compared to PMMF. A lower incidence of flap necrosis with FRFF reconstruction compared to PMMF.

Conclusion –

The comparison of both type of flaps is limited by the inherent design of the studies included. In summary, FRFF seem superior to the PMMF for several outcomes. It is safe to assume that free flaps are an excellent choice for reconstruction in relatively healthy subjects with low ASA classes. Despite the need for microsurgery, the free radial forearm flap is at least as reliable as the pectoralis major myocutaneous flap and that the choice of flap should be based on defect considerations rather than on the perceived reliability of the reconstructive method.

INTRODUCTION

Cancer is a disease characterized by the abnormal growth and spread of malignant tumors. Human kind has battled with diseases for centuries, even though the global battle against cancer has been ongoing for decades, it is still one of the leading causes of death worldwide. More specifically, oral cancer is a term identifying malignant tumors which originate in the mucous membrane lining the oral cavity. All of these cancers are of the carcinoma type, which simple stated is a malignant tumor of epithelial origin. These occur on the skin, lip, tongue, stomach, thyroid gland, rectum, uterus; in fact, any organ composed of epithelial tissue. Oral squamous cell carcinomas (OSCC) are cancers originating from the squamous epithelium in the oral cavity. Locations include the lip, mobile tongue, buccal mucosa, labial mucosa, floor of the mouth, gingiva, hard palate and soft palate. OSCC belongs to a larger subgroup of tumors termed head and neck squamous cell carcinomas (HNSCC), comprising carcinomas arising in the oral cavity, oropharynx, larynx, hypopharynx, nasal cavity, nasopharynx, paranasal sinuses, salivary glands and the ear. Oral squamous cell carcinoma (OSCC) is an aggressive and unpredictable cancer with a high tendency to recur and metastasize. Despite increasing efforts to improved treatment, the 5-year survival rate is still low. Early intervention gives, as with many types of cancer, the best prognosis. However even small early-stage tumors can behave aggressively.

Head and neck reconstruction surgery has considerably evolved over the past decades, along with the trend of using either a free or a pedicled flap for the reconstruction of surgical oncologic defects.¹ Reconstruction of any tissue defect poses a unique challenge to the surgeon especially after an ablative surgery in the head and neck region. When a local tissue cannot cover a Head and neck defect, the surgeon has to seek a distant tissue for reconstruction. The choice lies between a pedicled and free tissue transfer.²

Tracing back the history of flaps, Sushruta described the first pedicled flap (PMMF) in 800 BC, which consisted of a forehead flap.¹ Later, McGregor popularised it in 1963, marking a significant milestone in reconstructive surgery as the first reliable transposition flap.³ The pectoralis major myocutaneous flap was described by Hueston and McConchie in 1968 for reconstruction of a large midline chest wall defect.^{4,5} The pectoralis major myocutaneous flap was introduced into head and neck reconstruction by Ariyan in 1979.⁶

The PMMF have become the flap of choice for head and neck reconstruction in many centres and is still extensively being studied. The pectoralis major myocutaneous flap is an axial pattern flap, which means that it is based on a dominant vascular supply that runs axially along the length of the muscle. The skin in such flaps receives its blood supply from perforating vessels of the axial artery system. Ariyan extensively used pectoralis major myocutaneous flap in reconstruction of oropharynx, the cervicofacial region, the orofacial complex, the orbit and the temporal region. This experience led surgeons to consider the pectoralis major myocutaneous flap as the gold standard for head and neck reconstruction. However, concerns regarding the reliability of this flap for some defects resulted in the emergence of free flaps and other regional pedicled flaps, such as the supraclavicular artery island flap (SCAIF) and the submental island flap (SMIF). With the advent of microvascular surgery in the 1970s, harvesting free flaps became popular in head and neck reconstruction surgery. Free tissue transfer was described by various authors, such as Daniel and Taylor who described the first cutaneous free flap in 1973.⁷

PMMF has multiple advantages including: easy accessibility in the same surgical field; technically simple with a small learning curve; robust and reliable vascular anatomy; and minimal requirement for specialized instruments and training.⁸ Disadvantages include reduced neck mobility and the need to rotate the vascular pedicle of the flap 180° when using the skin paddle to resurface the neck. Another disadvantage can be the thickness of the flap, which is determined by the amount of subcutaneous fat between the pectoralis muscle and the overlying skin paddle, leading to possible reduced swallowing or speech function. The complication rate seems to be higher than in free flap reconstructions. Several issues related to the development of the pectoralis major myocutaneous flap should be considered preoperatively. These issues include the timing of flap development, the arc of rotation of the flap, the size of the recipient defect, the color match of the skin paddle and the recipient tissue bed and the potential trauma to the thoracoacromial axis. ⁹

Nowadays, free flaps are more common due to improved microsurgical techniques, esthetic and early functional results.¹⁰ Free tissue transfer can provide internal lining, external coverage, soft tissue bulk, and bone, and this flexibility and

reliability make it the gold standard for reconstruction in the head and neck.¹¹ The radial forearm flap offers thin, pliable, and relatively hairless skin,¹⁹ and has vessels long enough and of appropriate diameter to allow anastomoses in the neck. The microvascular flap tolerates radiation up to 70 Gy even in the early post-operative.^{18,20} If pre-operative radiation therapy is given, non-irradiated tissue is transplanted into the wound, which facilitates wound healing. In patients with composite resections a limited amount of bone can be included in the flap ¹⁷ as well as sensory nerves. However, free flaps require the expertise of microvascular surgery and longer operative times, but they show more versatility and robustness than PMMF for some defects.^{12,13} Since most patients in our country report only when the disease is in the advanced stage where follow up and prognosis is poor. In medically compromised patients, free flap is not an ideal choice due to increased donor site morbidity and high cost involved with salvage surgery if required later.¹⁴

Flap selection is a complex process, with FRFF and PMMF having both their respective advantages and disadvantages. Pedicled flaps are accessible to both academic and community surgeons and considered more reliable in specific settings but are not suitable for every defect.^{15,16} A criticism of microvascular surgery is that the techniques are complex and time-consuming and may not be appropriate in some circumstances.¹¹ More importantly, patient's pre-operative conditions, the nature of the disease, and the available resources are significant factors to consider when choosing the appropriate reconstructive technique.² This study compared the two unambiguous flaps to evaluate the reliability of this flap, in the reconstruction of oral cancer patients and also to evaluate the complications arising thereof.

REVIEW OF LITERATURE

Ariyan S (1979) was the first person to apply the principles of pectoralis major muscle for the reconstruction of head and neck defects. In his study, with 14 cases of Pectoralis major myocutaneous flap found that the flap is reliable for repair of defects after ablative surgery in head & neck region and can be transferred immediately.⁶

Jacobson MC et al (1995) conducted a prospective study from August 1988 to June 1991. The study included Case studies from a head and neck clinic conducted at a regional cancer hospital. Patients underwent surgery at the associated tertiary care center. 36 consecutive patients were enrolled in the study who were diagnosed with oral and oropharyngeal malignant neoplasms staged from T1 to T4 and had undergone free radial forearm flap reconstruction of their surgical defects. Ten variables that reflect the functions of the upper aerodigestive tract were assessed clinically, by videofluoroscopy, or both. The study concluded that Three out of five subgroups of patients with oral and oropharyngeal cancer had favourable functional outcomes with free radial forearm flap reconstruction. According to the resection location, distinct functional characteristics for the subgroups emerged. The requirement for a meaningful, trustworthy system of classifying oral and oro-pharyngeal resections, as well as the establishment of standardised protocols for evaluating functional outcome, are methodological concerns for research on surgical reconstruction and functional outcome.²¹

R.A. ORD (1996) conducted a retrospective review on 50 patients had reconstruction of postcancer resection using pectoralis major flap to check its reliability and complications. The age and sex of the patients and site of defect were analyzed. The design of the pectoralis major flap and complications encountered were documented. There were three cases (6%) of flap failure and an additional three cases (6%) in which 40% or more of the skin paddle sloughed. Orocutaneous fistula were uncommon. Mandibular reconstruction with an osteomyocutaneous flap and rib produced subpar outcomes. They concluded that the pectoralis major flap is reliable and an excellent reconstructive choice for large soft tissue defects in the oral cavity despite the increased use of microvascular flaps.⁵

Tsue TT et al (1997) conducted a retrospective study on 53 patients who underwent resection with primary soft tissue reconstruction for comparison of cost and functional results between free and pedicled soft tissue reconstruction after resection. The comparison showed only a modest difference in reconstruction cost and also highlighted functional benefits of Fasciocutaneous Free Flap reconstruction with slight increase expense over the Pectoralis Major Myocutaneous Flap after resection in the posterior oral cavity and oropharynx.²²

Liu R, Gullane P, Brown D, Irish J (2001) conducted a retrospective study on 244 reconstruction procedures using Pectoralis Major Myocutaneous Pedicled Flap carried out on 229 patients. Complications such as infection, dehiscence, hematoma, seroma, fistula, flap failure and donor site morbidity were recorded in 35% of the patients who underwent cancer ablation with pectoralis major myocutaneous pedicled flap reconstruction.Number of comorbidities, number of pack- year of cigarettes smoked were associated with higher complication rate and longer duration of admission.²³

Jeng SF (2002) conducted a retrospective study on 52 patients who underwent ablative oral cancer surgery. Modification of the radial forearm flap with a sheet of adipofascial tissue extension was done to prevent postoperative complications like deep wound infection of the neck or orocervical fistula due to insufficient soft tissue to obliterate the dead space. This modification showed suitable soft tissue to decrease the chance of post operative hematoma, decrease in neck wound infection and protection of important vessels in the neck.²⁴

Hung-Tao Hsiao, Yi-Shing Leu, Chang-Ching Lin (2002) conducted a study on 6 patients who underwent free radial forearm flap reconstruction after hemiglossectomy. Evaluation of speech and swallowing was done. Speech quality was better in patients with primary closure and bolus volume and ingestion was better in those with flap reconstruction suggesting that when the flap adds bulk there is maintaining tongue-to-mouth roof contact that is necessary in the swallowing process.²⁵

Wan-Fu Su, Shyi-Gen Chen, Hwa Sheng (2002) conducted a study on 25 patients who underwent tumor resection. This study compared tongue function outcome

between pectoralis major myocutaneous flap and radial forearm flap. The surgical defects were reconstructed using a pectoralis major flap in six patients and a radial forearm flap in 19 patients. After the reconstruction, swallowing and speech functions were evaluated six months to five years thereafter. The ability to articulate precise words was assessed using a Mandarin articulation test and speech intelligibility both before and after surgery. Clinical evaluation of deglutition included a questionnaire on dietary habits and a swallowing rating of 1 to 7. Evaluation showed that patients with free flap had more intelligible speech even after total glossectomy and no difference in swallowing function.²⁶

Hung-Tao Hsiao, Yi-Shing Leu, Chang-Ching Lin (2003) conducted a study on 33 patients who were diagnosed with squamous cell carcinoma of tongue. Reconstruction was with a microvascular radial forearm flap. All of the flaps were specifically created with a narrow waist and an omega-shaped cross section, allowing for a free tongue tip and preventing the need for sutures to join the flap's edge to the soft palate and tongue base. Evaluation for swallowing and speech function was done for atleast 6 months following reconstruction. They found out that patients had near normal deglutition with speech was unsatisfactory.²⁷

WAN FU et al (2003) conducted a study on 60 patients who were diagnosed with tongue carcinoma. They underwent resection and reconstruction was done with either pectoralis major flap or free radial forearm flap. A questionnaire on dietary habits was used to assess deglutition six months to ten years following reconstruction, and the Chinese articulation test was employed to assess the site and manner of error production. The questionnaire survey revealed no discernible variation between the 2 groups in swallowing rating. Motility caused by flap pliability increased speech intelligibility more than it did on swallowing function. They showed that patients with free flap had more intelligible speech and showed no difference in rate of swallowing.²⁸

Chen CM et al (2004) conducted a study on 38 patients who underwent reconstruction with free radial forearm flap after head and neck cancer ablative surgery. The FRFF had a 92% survival rate. Partially lost skin grafts occurred in 4 donor sites (11%), abnormal sensations in 10 (26%), poor appearance in 3 (8%), and

reduced grip strength in 4 (11%). They study concluded that free radial forearm flap is useful and versatile flap for reconstruction of head and neck defects because of its reliability, functional characteristics and low donor site morbidity.²⁹

Smith GI et al (2005) conducted a retrospective study on 505 patients who had surgical defects of the head and neck reconstructed with a radial forearm flap. The study was aim to report the applications, complications, and limitations of the radial forearm flap. The study evaluated records in their database from October 1987 to December 2002; and a total of 505 patients had surgical defects of the head and neck which were reconstructed with a radial forearm flap: There were 258 patients with oral cancer, 173 men and 85 women, with a median age of 70 years. Five patients had two reconstructions (a total of 263), with 247 fasciocutaneous flaps and 16 osseofasciocutaneous flaps. Mucosal squamous carcinoma accounted for 97% of all primary cancers. There were nine flap failures (3.4%), as well as four episodes of partial necrosis. Within 30 days of surgery, four patients (2%) died. Nine patients (3.4%) had orocutaneous fistulas, ten had wound infections, and nine had haematomas. One failed flap was replaced by a second free flap, three by a pectoralis major flap, one by a buccinator myomucosal flap, one by a skin graft, and the remaining three by secondary intention. Among the 16 osseofasciocutaneous flaps, one case failed completely and one partial failure was seen.¹¹

Smith GI et al (2005) conducted a study to assess (via postal questionnaire) quality of life and function in patients who had oral cancer resections and reconstruction with radial forearm flaps. Between October 1987 and December 2002, 258 patients had radial forearm flap reconstructions after oral cavity tumour resection. The database was analyzed to identify 139 surviving patients, who were then sent questionnaires with five sections: Functional Assessment of Cancer Therapy-General (FACT-G) and -Head and Neck (FACT-HN); University of Washington Quality of Life Scale (UWQoL); Performance Status Scale for Head and Neck Cancer (PSS-HN); and the final section addressed dental rehabilitation and morbidity at the donor site. Sixty-three questionnaires were returned (45%). Parts of the questionnaire were incomplete in 17 (27%). The median UWQoL score was 623/900, the FACT-G score was 92/108, the FACT-HN score was 31/48, and the PSS-HN score was 75/100, 75/100, and 50/100, respectively, for eating in public, understandability of speech, and

normality of diet. The impact of stage and location on quality of life and function was not statistically significant. Radiotherapy had a significant effect on speech (p = 0.036) and diet (p = 0.007). Patients who were concerned about the recurrence of their cancer had a lower UWQoL score (p = 0.016). Although 90% thought their arm was disfigured, 81% felt comfortable wearing short-sleeved shirts. In 87 and 92% of cases, sensation and hand function were reported as normal. We conclude that patients with oral cancer have a persistent reduction in quality of life and function even after treatment is completed. The effects can be assessed using a postal questionnaire, but the low response rate (45%) and difficulties with completion reduce the data quality. Improvements in outcome require improvements in quality of life and function.³⁰

Takahiko Shibahara, Ashiraf Fathy Mohammed, Akira Katakura, Takeshi Nomura (2006) evaluated the radial forearm flap in terms of sensory function recovery, general performance status, cutaneous blood flow, and histological observations. Thirty patients with oral carcinoma (23 men and 7 women) underwent immediate reconstruction with radial forearm flap after ablative surgery and were evaluated. To assess the degree of articulation and mastication, interviews were conducted. Sensory function tests suggested the restoration of cutaneous sensibility of the forearm flap. Histological examination of flaps revealed mucosa-like changes about 10 months after reconstruction. In most patients, the clarity of conversation enhanced. The degree of recovery, on the other hand, was generally related to the time after surgery. The radial forearm flap is a distinctive flap with unique traits that allowed for the best functional reconstruction of the oral cavity available in terms of sensation, performance, and histological changes to adapt to the new oral environment.³¹

Bree R et al (2007) conducted a study in forty patients who underwent immediate free radial forearm flap reconstruction for oral or oropharyngeal soft tissue defects were matched with patients who underwent pectoralis major myocutaneous flap reconstruction for similar defects. The 2 years of which the overall management costs according to the hospital perspective were calculated were divided into four periods: operative period, the postoperative phase, follow-up during first year and follow-up during second year after discharge. The total costs within the first 2 years were comparable at ~50 000 euros. The lower costs of hospital admission (24 days versus 28 days; P =0.005) in the postoperative phase outweighed the higher costs of the surgical procedure (692 min versus 462 min; P < 0.005) in radial forearm flap patients when compared with pectoralis major flap patients. Oral and oropharyngeal reconstruction with radial forearm flap is not more costly than pectoralis major flap reconstruction. Given the better functional outcome and the present cost analysis, the study concluded that reconstruction of oral and oropharyngeal defects is preferably performed using free tissue transfer.³²

Hao Zou, Wen-Feng Zhang, Qi-Bin Han, Yi-Fang Zhao (2007) conducted study on salvage reconstruction of extensive recurrent oral cancer defects with the pectoralis major myocutaneous flap. Fourteen flaps were used to reconstruct the mucosal lining of the mouth, and ten flaps were used to reconstruct the cutaneous defects. Reconstruction of the base of the tongue, floor of the mouth, and oropharynx was discovered to be a significant risk factor for flap necrosis. The major complications were related to the site of reconstruction, and as a result of salvage surgery, some patients' survival rate was increased to 2 to 4 years postoperatively.³³

Connell DA et al (2008) reported on swallowing outcomes and biomechanical properties of the base of the tongue (BOT) and posterior pharyngeal wall (PPW) in patients who underwent surgical reconstruction with the beavertail modification of radial forearm free flap after primary resection of BOT cancer. At one year, 19 (95%) of the 20 patients in the final analysis were able to swallow safely. All postoperative VFSS data showed that BOT mobility was reduced after surgery. Anteroposterior dimension or bulk of the BOT was preserved. There was no significant difference in PPW mobility. After BOT cancer removal, the beavertail modification of the radial forearm free flap is an excellent reconstructive option. The procedure preserves the bulk of the BOT after cancer treatment and maintains adequate BOT-PPW apposition. This allows the pharyngeal, oral, and suprahyoid musculature to contract and generate the force required to propel the food bolus through the oropharynx, resulting in a safe swallow.³⁴

Airoldi M et al (2010) examined the impact of flap reconstructive surgery with adjuvant radiotherapy (RT) on QOL and psychological functioning. More than half of the cases studied showed moderate to severe late toxicity in subcutaneous tissues,

salivary function, dysphagia, and taste impairment. Patients suffering from severe dysphagia showed higher levels of depression and anxiety (p<0.05). Dysphagia and taste impairment were linked to poorer overall health and QOL. In 33% of the sample, the Draw a Person Test (DAP) revealed severe issues with self-perceived body image. Dysphagia and taste impairment are associated with QOL and depression; our data suggest a different evaluation between self-reported and clinician-rating scales.³⁵

Joo YH et al. (2010) conducted a study to assess changes in radial forearm free flap (RFFF) volumes after ablative tumour surgery in the head and neck after 5 years of follow-up. RFFF reconstruction was performed on eighteen patients. Computerized segmentation of CT or MR images was used to calculate flap volumes. The average flap volume after 3 months, 1 year, 3 years, and 5 years was 167.4, 129.0, 104.9, and 88.7 cm3, respectively. The average percentage changes between three months and one year, three months and three years, and three months and five years were 20.4, 30.3, and 42.7%, respectively. From 3 months to 5 years, there was a significant relationship between postoperative irradiation and RFFF volume changes (p = 0.046). For the reconstruction of tumor-related defects in the head and neck, an overcorrection with a 40% larger RFFF volume is recommended.³⁶

Pinto FR et al (2010) conducted research on the factors influencing the occurrence of complications and the final outcome in Pectoralis major myocutaneous flaps for head and neck reconstruction after cancer resection. The skin island was placed just medially to the nipple, over the fourth, fifth, and sixth intercostal spaces, with the skin perforator vessels arising from the intercostal branches of the internal thoracic artery. They proposed that the vascular supply for the skin below the seventh rib comes from the cutaneous branches of the superior epigastric artery, and that including skin beyond this limit in the flap creates an axial flap with a distal random portion, increasing the risk of partial flap necrosis. Data show that radiotherapy is well tolerated by the pectoralis major myocutaneous flap.³⁷

Chih-Yu Hsing et al (2011) compared the quality of life of free flap and pectoralis major pedicled flap reconstruction in oral cavity cancer patients. Microsurgical reconstructions, which require specialised surgical skills and are frequently lengthy procedures, also have potential morbidities. Complications were more common in the

pectoralis major myocutaneous flap group. Wound healing issues were more common in the pedicled flap group than in the free flap group. Positive margins were found to be lower in patients who underwent free flap reconstruction compared to patients who underwent pectoralis major myocutaneous flap reconstruction, but the statistical difference was not significant. In the speech, shoulder, and mood domains, patients who underwent free flap reconstruction had higher average scores than those who underwent pectoralis major myocutaneous flap reconstruction.³⁸

A. Sagayaraj, R. P. Deo, S. M. Azeem Mohiyuddin, G. Oommen Modayil (2011) investigated various methods of raising a pectoralis major myocutaneous flap island flap to overcome its drawbacks such as bulk, flap length, and the difficulty of developing this flap in female patients. Three patients experienced minor complications such as margin necrosis and wound dehiscence, which were treated conservatively. One patient developed an orocutaneous fistula that required secondary suturing. None of the patients in the study had total flap necrosis. They concluded that in institutions where microvascular expertise is not available, an island pectoralis major myocutaneous flap can be used as an alternative with results comparable to free tissue transfer.³⁹

Astrid L Kruse et al. (2011) conducted a study on the pectoralis major flap in reconstructive head and neck surgery. The disadvantages can include decreased neck mobility and the need to rotate the vascular pedicle of the flap 180° when using the skin paddle to resurface the neck, as well as the thickness of the flap, which is determined by the amount of subcutaneous fat between the pectoralis muscle and the overlying skin paddle, potentially resulting in reduced swallowing or speech function. The bulkiness of the pectoralis major flap can be advantageous in cases such as coverage of a reconstruction plate or coverage of the carotid artery. In men, the defect that could be covered is 6 cm squared without the need for a second skin graft for closure. Due to the greater redundancy of the female breast, this size can be doubled in females. Special attention should be paid to the skin paddles in order to incorporate enough perforators, but the complication rate, particularly after radiotherapy, should not be underestimated.⁹

V D Kekatpure et al. (2012) conducted a study to assess factors influencing the selection of a pectoralis major flap in the era of free tissue reconstruction for postablative head and neck defects, as well as flap-related complications. He discovered that the pectoralis major flap has consistent vascularity and that the chances of total flap loss are reduced. Full thickness cheek defects can be repaired with bipaddled flap. They indicated that in medically compromised patients, pectoralis major flaps, free flap salvage surgery, extended neck dissections, and providing cover to pharyngeal repair following salvage laryngectomy can all be used. They also suggested that the pectoralis major flap is a reliable option for head and neck reconstruction and still plays an important role in today's era of free flaps.⁴⁰

Metgudmath RB et al (2012) conducted a study to assess the versatility of pectoralis major myocutaneous (PMMC) flap in the reconstruction of diverse surgical defects following resection of various head and neck malignancies. They conducted a retrospective study of patients in whom PMMC was used to reconstruct head and neck surgical defects between May 2006 and December 2010. The study included 95 patients and was conducted at KLES Dr. Prabhakar Kore Hospital & M.R.C, Belgaum. The patients were divided into groups based on the location of the reconstructed defect and were thoroughly examined. They concluded that PMMC is still the workhorse for reconstruction of moderate to large sized head and neck defects due to its versatility.⁴¹

Jena A et al (2014) conducted a study to analyse the data on the outcomes of PMMFs in female patients with oral cancer undergoing reconstruction after tumour ablation. They evaluated PMMF data in 140 female patients with oral cancer in this retrospective study, which was conducted in a single institution in south India from January 2008 to May 2012. The operative technique used was essentially the same as that described by Ariyan. However, in order to preserve the deltopectoral flap area, the incision was appropriately modified in the manner described by Schuller. They concluded that PMMF reconstruction is a reliable and cosmetically acceptable method of reconstructing oral cavity defects in female patients following tumour ablation.⁴²

Fang QG et al (2013) studied the quality of life (QoL) of patients with oral cancer who underwent resection of the tongue and floor of the mouth and reconstruction with the pectoralis major flap. The University of Washington QoL, version 4, questionnaire

was used to evaluate 21 patients who had undergone pectoralis major flap reconstruction. The data was analysed using a nonparametric Mann-Whitney U test. The study concluded that patients with oral cancer who had undergone resection of the tongue and floor of the mouth with pectoralis major flap reconstruction had an improved quality of life.⁴³

Tornero J et al (2013) conducted a study to assess the experience and outcomes of their center's reconstructive microsurgery unit. Retrospective evaluation of procedures was carried out between 2006 and 2012. They concluded that reconstructive surgery now plays an important part of head and neck cancer surgery. The radial forearm flap is a safe and dependable method for reconstructing most ENT defects. In surgical oncology, this type of intervention provides greater autonomy and safety.⁴⁴

Bhola N et al (2014) studied the role of the bilobed/bipaddled pectoralis major myocutaneous flap (PMMF) in the reconstruction of large full-thickness cheek defects after oral cancer resection. Following oral cancer resection, 62 cases of through-and-through oral cavity defects were reconstructed using a folded/bipaddled/bilobed PMMF flap. All were men with locally advanced oral squamous cell carcinoma (SCC) involving the buccal mucosa and gingivo buccal sulcus (n=53) or gingivo buccal sulcus+lip (n=9). They came to the conclusion that the bilobed/bipaddled PMMF is a simple and dependable flap that provides an effective mechanism for reconstructing full-thickness cheek defects while avoiding the complexity of microvascular free flaps. After resection of oral carcinoma, the bilobed/bipaddled PMMF has become our preferred reconstruction option for large full-thickness defects.⁴⁵

Orlik JR et al (2014) conducted a study in a tertiary care centre to assess functional donor site morbidity of the forearm free flap in patients that survived at least 2 years after ablative head and neck cancer surgery. This study included nine long-term survivors (two years after surgery) who had forearm free flaps used to reconstruct head and neck defects. The non-dominant arm was used to raise all flaps. All patients were given the non-donor side as a control. Grip, tip pinch, and key pinch strength were measured using dynamometers; goniometry was implemented to measure flexion, extension, radial and ulnar deviation, and pronation and supination range of

motion at the wrist. A grooved pegboard test was used to time manual dexterity, and Semmes Weinstein monofilaments were used to test radial nerve sensation. Subjective measurements included a validated patient questionnaire on hand function and scar appearance, as well as a scar assessment by two different observers. They concluded that while objective testing can demonstrate donor site morbidity, it is accepted and well tolerated by patients with head and neck cancer.⁴⁶

Aleksandar Aničin, Robert Šifrer, Primož Strojan (2015) conducted a study to analyse the oncological, functional and aesthetic results of the pectoralis major myocutaneous flap (PMMF) used between November 2001 and April 2012 at the Department of Otorhinolaryngology and Cervicofacial Surgery, University Medical Centre Ljubljana, Slovenia. Patients with squamous cell carcinoma of the head and neck (SCCHN) submitted to tissue defect reconstruction with PMMF were identified from a prospective database. Medical and surgical records were reviewed for information on clinical characteristics, treatment and outcome, and specifically, indication for PMMF, wound healing, flap vitality, functional results and aesthetics. They concluded that PMMF is a reasonable choice in primary head and neck cancer surgery and in salvage procedures. Its use is characterised by vitality, reasonably short recovery time and a favourable aesthetic outcome at the donor site in the majority of patients.⁴⁷

Atanu Bhanja, Col D.S.J. D'Souza, Collin Roy, R.N. Poddar (2016) conducted a study to evaluate the reliability of PMMC flap. Within a span of 2 years, 20 reconstructions were done with PMMC flaps in patients with oral cancer and they were followed for a period of 1 year. Documentation was done for patient demographics, site of lesion, duration for reconstruction, occurrence of complications, etc. The study concluded that PMMC flap is still 'workhorse' of reconstruction in head neck cancer patients in developing countries and can be used effectively with acceptable morbidity.⁴⁸

Forget FG et al (2019) conducted a study that focuses on comparision of reconstruction with free flaps (FF) versus pedicled flaps (PF) after oncologic resection. A systematic review was developed in compliance with PRISMA guidelines and performed using the Pubmed, Medline, EMBASE, Amed and Biosis databases.

The study concluded that the comparison of both type of flaps is limited by the inherent design of the studies included. In sum, FF seem superior to the PMMF for several outcomes. SMIF and SCAIF compare favorably to FF for some specific indications achieving similar outcomes at a lower cost.²

Chokshi NJ et al (2019) in their study reviewed Data of all patients who had oral cancer resections and reconstructions performed at HCG Cancer Centre, Vadodara from May 1, 2016, to December 31, 2018. Out of them, patients in whom free flaps were done were included in the study. Ethical approval for this study was not needed as it was on a retrospective basis. Postoperative monitoring of the flap was done mainly by clinical observation and pinprick test. Color Doppler ultrasound was done to detect flow in arterial failure cases. The complication rate of the study was 6.68% out of which flap salvage rate was 23.8%. Hence, it is very important to pick up early signs of developing complications to increase the flap salvage rate. y. During the 1st postoperative week, vigilant lookout should be there for signs and symptoms to detect early flap-related complication in the 1st week is a good prognostic indicator for flap survival and thus preventing any delays in further adjuvant treatment. ⁴⁹

Athanasios Karonidis & Dimosthenis Tsoutso (2020) in their study evaluated the use of the free radial forearm flap (RFF) or the pedicled pectoralis major (PM) flap for oesophago-hypopharyngeal reconstruction and to review the literature, considering the free flap option as the state of the art. The decision making, outcome and common complications were assessed. From 2013 to 2018, 15 sequential patients with laryngeal carcinoma, 61 years and BMI 24.6, were included in this retrospective study. They underwent laryngectomy-pharyngo/esophagectomy and immediate or secondary pharyngoesophageal reconstruction. Nine patients underwent reconstruction with RFF (group A) and six with PM flap (group B). The patients with history of thoracic and breast surgery and synchronous malignancy were excluded in this study. The software SPSS v.21 for statistical analysis was used. The duration of surgery for RFF was longer (731 min versus 435 min). Postoperatively, all patients received radiotherapy, whereas chemotherapy was administered in one patient. The

RFF was the procedure of choice for stages III–IV and larger defects and the PM for stage II (p = 0.002). Overall complication rates, fistula, stricture and swallowing dysfunction were found higher in group B, but not significant (pCompl = 0.315, pFist = 1.000, pStrict/Swall = 0.143). Furthermore, the secondary PM reconstructions had non-statistically significant even higher fistula and swallowing dysfunction rates (p = 0.400). Both groups reported equal good results in terms of oral alimentation and speech. The study found that the RFF and PM flap could provide comparable outcomes in oesophago-pharyngeal reconstruction. The RFF seems to be a superior reconstructive option for advanced disease and larger defects and is associated with better swallowing and fewer complications.⁵⁰

Subbiah Shanmugam, Syed Afroze Hussain, Rajiv Michael (2020) conducted a study which aimed to identify the risk factors involved in increasing the post-operative PMMC flap complications. Patients who underwent surgical resection of primary head and neck cancer with PMMC flap reconstruction were included and their demographic data, pre-operative laboratory values, surgery details and postoperative flap morbidity were collected retrospectively from the master case sheets from January 2013 to December 2019. Factors such as age, gender, stage of disease, pre-operative anemia, hypoprotenemia and radiation therapy, presence of diabetes and size of the flaps were analysed to find their relation in causing flap complications. A total of 285 patients were included for analysis and 9.82% (n=28) had major flap complications. On analysis we found that pre-operative hypoproteinemia (serum albumin <3.5) (p=0.001) and prior radiation therapy (p=0.02) significantly increased the risk of flap complications. Similarly, patients with larger bipaddled flaps had higher flap complication rates (p=0.0002) and previous radiation treatment further increased the major complication rates in bipaddle flaps. The study concluded that PMMC flaps are still a viable option for head and neck reconstruction especially in patients with multiple comorbidities and where free microvascular flaps are not done routinely. Careful patient selection, preoperative optimisation and good post-operative care will help to reduce flap complication.⁵¹

Teli ZA et al (2021) conducted a study to evaluate the results of pedicled and microvascular free flaps (MFFs) for oral cavity defects following resection of locally advanced oral cancer. A retrospective analysis of prospectively collected data of

patients who underwent composite resection followed by reconstruction with pedicled or MFFs for locally advanced oral cancer from January 2018 to September 2019 was done. The demographic details, primary tumor site, tumor stage, defect type, flap type, and complication rates were analyzed. Primary reconstruction was offered to 540 patients with pedicled flaps for 421 patients and MFFs for 119 patients. Patient distribution as per current Tumor, Node, and Metastasis staging was pT1/T2: 91, pT3: 179, and pT4: 270. Reconstruction offered for different oral cavity subsites was buccal mucosa (n = 374), retromolar trigone (n = 10), alveolus (n = 75), tongue (n = 75), tongue (n = 75), tongue (n = 10), alveolus (n = 152), lower gingivobuccal sulcus (n = 11), floor of mouth (n = 4), upper gingivobuccal sulcus (n = 5), and lower lip (n = 9). We classified the types of defects into mucosal (n = 32), mucosal with bone (n = 370), mucosal with bone and skin (n = 101), mucosal with skin (n = 14), skin (n = 3), and central mandibular arch (n = 20). The overall rate of complications in pedicled flaps was 12.11% and MFFs was 20.16%. The success rate for pedicled flaps was 100% and for MFFs was 94.96%. The study concluded that MFF reconstruction had a good success rate with satisfactory functional and cosmetic outcomes.52

Vijaykumar Girhe, Akanksha A. Auti, Prachi Girhe, Rohinee Wagre (2021) conducted a study to check and assess the predictability of PMMC Flap and its clinical outcome in 168 Indian patients. The study conducted a retrospective study of PMMC flap which was harvested in 168 Indian oral cancer patients in 3 years' time span. Rate of complication were documented for flap necrosis and wound dehiscence; and patient related data like neck bulk acceptance and range of motion were recorded. Gender comparison of complications were also documented. The most common complication was wound dehiscence in 11 (6.5%) patients. Partial flap necrosis was observed in 3 (1.8%) female patients. There was no case of total flap necrosis. Questionnaire method was used for patients to record neck bulk acceptance. Range of motion was evaluated during follow up period. Follow up period of all the patients was 1–3 years. The study concluded that the PMMC flap is still a reliable 'workhorse' flap for reconstruction in patients with head and neck cancer and can be used successfully with minimal morbidity.⁵³

AIMS & OBJECTIVES

<u>Aim</u>

The aim of this study is to compare Pectoralis Major Flap with Free Radial Forearm Flap for intraoral soft tissue reconstruction in oral cancer.

Objectives

The objectives of this study are-

- To compare ease of harvesting between pectoralis major flap and free radial forearm flap.
- To compare complications if any like infection, flap dehiscence, flap necrosis and donor site morbidity, between pectoralis major flap and free radial forearm flap 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.

MATERIALS & METHOD

STUDY DESIGN

The data of 5 cases of pectoralis major myocutaneous flap and 5 cases of radial forearm free flap for reconstruction of post cancer resection defects of the Oral & Maxillofacial regions will be analyzed. All data concerning functional outcome, esthetic outcome, site of tumours, types of defects, donor site, recipient site complications and surgical treatment of these patients with pectoralis major myocutaneous flap or radial forearm flap for reconstruction were analyzed. All patients were treated at Department of Oral and Maxillofacial Surgery, BBDCODS, Lucknow, Uttar Pradesh, India and Sahara Hospital, Lucknow.

MATERIAL

Stage disease involving hard and soft tissue of the maxillofacial region which requires composite resection & reconstruction with pedicled flap or free flap were selected. Composite resection and reconstruction with pectoralis major myocutaneous flap or radial forearm flap were done.

INCLUSION CRITERIA

a) Patients diagnosed with oral cancer.

b) Patients who require soft tissue reconstruction following oral cancer resection surgery.

EXCLUSION CRITERIA

a) Patient unwilling to participate in the study.

b) Patient in whom surgery is contraindicated.

c) Patients who need special health care.

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

PREOPERATIVE INVESTIGATION AND SEQUENCE OF PATIENT CARE

On initial presentation to the department, all patients were evaluated 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. All the Patients underwent preoperative hematological investigation. Patient with T4 lesions underwent pre-operative radiotherapy. Ablative and reconstructive procedures were performed in a single stage. The specimen was sent for histopathological study, if it reveals close margins or multiple node involvement, post operative radiotherapy was given at total dose of 60Gy divided into 30 fractions. Post operatively we assessed both the functional and esthetic outcome of both flaps.

Clinical examination was performed. Extra oral and intra oral photographs were taken and CT scan evaluation was done. Neo adjuvant radiotherapy and chemotherapy was completed in patients with T4 lesion, stage III and stage IV disease. Subsequently the patient was scheduled for composite resection and reconstruction under general anesthesia. Tracheostomy was done when needed. 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, donor and recipient site complications. 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 such as hematoma, seroma, wound dehiscence and recipient site complications such partial flap necrosis, complete necrosis, fistula were evaluated. Data were collected and statistically analyzed and compared.

Ease of Harvesting was measured by questionnaire answered by Plastic Surgeons.

Functional outcome was measured in terms of the quality of speech, swallowing process and oral sphincter function.

Speech and Swallowing was measured using University of Washington Quality of Life Questionnaire (UW-QOL).

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. McNemars 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.

SURGICAL DEVELOPMENT OF PECTORALIS MAJOR MYOCUTANEOUS FLAP

SURFACE MARKINGS OF THE VASCULAR PEDICLE

First, the clavicle, xiphoid, ipsilateral sternal border are identified, and then the location and size of the skin paddle being located at the inferior medial border of the pectoralis major muscle is marked.

FLAP ELEVATION

The initial incision is made at the lateral part toward the anterior axillary line down to the pectoralis major muscle. The maximum amount of muscle should be harvest, because the larger the muscle volume, the safer the flap due to the increased number of myocutaneous perforators. The inferior, medial and lateral incisions are made through the skin, subcutaneous fat and Pectoralis fascia down to the chest wall. An electrocautery is used to divide and elevate the flap. The muscle is elevated inferiorly to superiorly, the pedicle should be identified by palpation and visualization on the deep surface of the muscle. The pectoralis major muscle derives its blood supply from the pectoral branch of the thoracoacromial artery and lateral thoracic artery. The thoracoacromial artery divides into four branches: pectoral, acromial, clavicular and deltoid. The lateral thoracic is normally cauterized mainly to achieve length and greater arc of rotation. After dissection the flap off the chest wall, a subcutaneous tunnel is formed under the skin between neck and the chest and the flap is passed underneath the skin bridge and flap mobilised to the recipient area to close the defect.

SURGICAL DEVELOPMENT OF FREE RADIAL FOREARM FLAP

FLAP DESIGN AND DIMENSIONS

The radial artery, which is subcutaneous for much of its length in the forearm, can be palpated or identified using vascular doppler and its course marked on the skin surface. The superficial subcutaneous forearm veins are similarly marked, and the appropriately designed flap is outlined. In practice, the mid-forearm flap has proved to be most useful. It combines the advantages of ease of elevation and donor defect found in proximal flaps with the skin quality of distal flaps.

OPERATIVE TECHNIQUE

Elevation of the forearm flap is straightforward and can be performed simultaneously with the intraoral resection without altering the patient's position on the operating table. It has seemed prudent to anastomose both a superficial vein and a deep vena comitantes. Where doubt exists, it is safe to perform the arterial anastomosis first, and following release of the arterial clamps, the pattern of venous outflow can be accurately determined and the appropriate vein then chosen for anastomosis. A single venous anastomosis will provide drainage for both superficial and accompanying venous systems.

A tourniquet is placed around the upper arm. The arm is *incompletely* exsanguinated using an Esmarch or an Ace bandage before dissection commences. The skin flap is incised around its periphery, and dissection is carried down to the underlying muscle fascia. Dissection is carried through the subcutaneous tissue, and the selected venous system is traced proximally.

The ulnar side of the flap then is elevated at a level just superior to the deep fascia. Preservation of the deep fascia in this way facilitates skin grafting of the donor site The radial dissection passes immediately superficial to the deep fascia until a point is reached 1 cm lateral to the intermuscular septum, where the deep fascia is divided and dissection then proceeds at this deeper level. Distally, the radial artery and its venae comitantes are easily identified; these are ligated and divided. The cephalic vein is ligated and divided distally, as are other small veins in the region. The secondary defect can be grafted using Split Thickness Skin Graft.

The tourniquet is released and the blood supply around the palm area of the hand is checked using Vascular Doppler. The flap is then evaluated for any cut and then transferred in the recipient site where arterial anastomoses and venous anastomoses is done. Usually, Facial Artery or Superficial Thyroid Artery is anastomosed with the Radial Artery. The Cephalic vein and Radial Vein are anastomosed with the adjacent veins of the neck. The blood flow to the flap is checked and defect is then closed.

PHOTOGRAPHS





Fig 1 and 2 : Armamentarium

CASE 1 (Reconstruction with Pectoralis Major Myocutaneous

<u>Flap)</u>



Fig 3: Pre OP Frontal Profile



Fig 4: Pre OP Intra Oral Lesion



Fig 5: Recipient Site Surgical Marking



Fig 6: Recipient Site Surgical Defect



Fig 7: Resected Tumour



Fig 8: Exposure of Skin Paddle of PMMF



Fig 9: Donor Site Closed Primarily



Fig 10: Reconstruction of Recipient Site Defect with Pectoralis Major Myocutaneous Flap



Fig 11: 1 Week Post Operative Frontal Profile



Fig 12: 1 Week Post Operative Lateral Profile



Fig 13: 3rd Month Post Operative Frontal View



Fig 14: 3rd Month Post Operative Lateral View.

CASE 2 (Reconstruction with Free Radial Forearm Flap)



Fig 15: Pre OP Frontal View



Fig 16: Pre OP Intra Oral Lesion



Fig 17: Incision Marking



Fig 18: Donor Site Marking

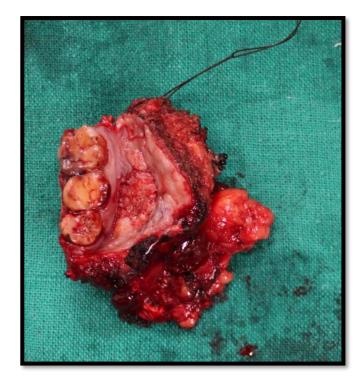


Fig 19: Resected Tumour

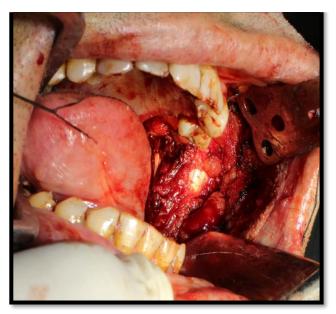


Fig 20: Recipient Site Surgical Defect



Fig 21: Free Radial Forearm Flap



Fig 22: Microscopic Anastomosis of Arteries of Flap and Recipient Site



Fig 23: Donor Site Closed using Split Thickness Skin Graft



Fig 24: Primary Closure of Neck

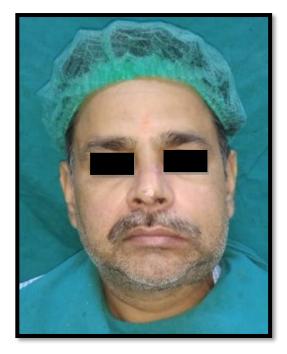


Fig 25: 3rd Month Post Operative Frontal Profile



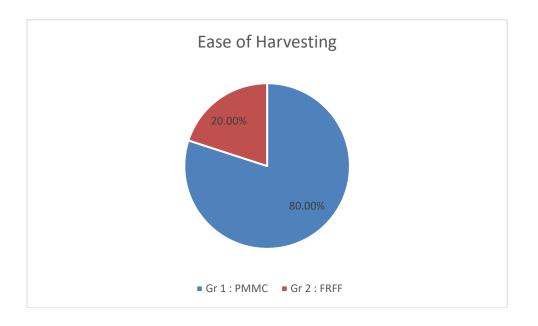
Fig 26: 3rd Month Post Operative Intra Oral View

RESULTS

EASE OF HARVESTING

Table 1: EASE OF HARVESTING

Ease of Harvesting							
	Ν	%					
РММС	8	80%					
FRFF	2	20%					



Graph 1: Ease of Harvesting.

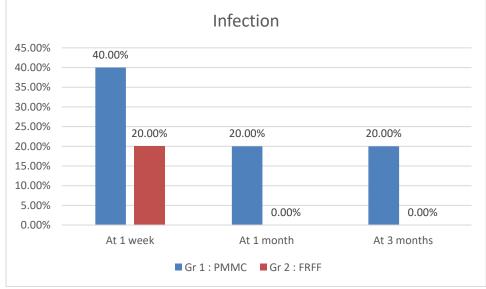
Presence of Infection

		Pres	sence of Infection	on	
		At 1 week	At 1 month	At 3 months	P value of Intragroup Comparison
Gr 1 : PMMF	n	2	1	1	1 wk*1m – 0.999, NS
	%	40.0%	20.0%	20.0%	1wk*3m – 0.999, NS 1m*3m –0.999, NS
Gr 2 : FRFF	n	1	0	0	1 wk*1m – 0.999, NS
	%	20.0%	0.0%	0.0%	1wk*3m – 0.999, NS 1m*3m –0.999, NS
P value of Intergroup comparison		0.490, NS	0.292, NS	0.292, NS	

Table 2: Presence of Infection

Intergroup comparison of presence of infection at different follow ups was done using chi square test. The occurrence of infection was not found to be significantly different among both the study groups.

Intragroup comparison of presence of infection at all the follow up points was done using McNemars chi square test. it showed that, the presence of infection was not significantly different from 1 week to 1 month, from 1 month to 3 months and from 1 week to 3 months, among both the study groups.



Graph 2: Infection

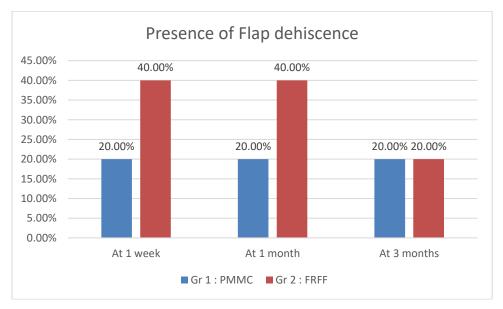
Presence of Flap dehiscence

Table 5. <u>Trescher of Flag Demiscence</u>											
Presence of Flap dehiscence											
			1								
		At 1 week	At 1 month	At 3	P value of Intragroup						
				months	U I						
				monuis	Comparison						
Gr 1 : PMMF	n	1	1	1	1 wk*1m – 0.999, NS						
			-		,						
	%	20.0%	20.0%	20.0%	1wk*3m – 0.999, NS						
					1m*3m –0.999, NS						
Gr 2 : FRFF	n	2	2	1	1 wk*1m – 0.999, NS						
					1wk*3m – 0.999, NS						
	%	40.0%	40.0%	20.0%	,						
					1m*3m –0.999, NS						
P value of In	tergroup	0.490, NS	0.490, NS	0.999, NS							
con	nparison										

Table 3: Presence of Flap Dehiscence

Intergroup comparison of presence of flap dehiscence at different follow ups was done using chi square test. The occurrence of flap dehiscence was not found to be significantly different among both the study groups.

Intragroup comparison of presence of flap dehiscence at all the follow up points was done using McNemars chi square test. It showed that, the presence of flap dehiscence was not significantly different from 1 week to 1 month, from 1 month to 3 months and from 1 week to 3 months, among both the study groups.



Graph 3: Presence of Flap Dehiscence

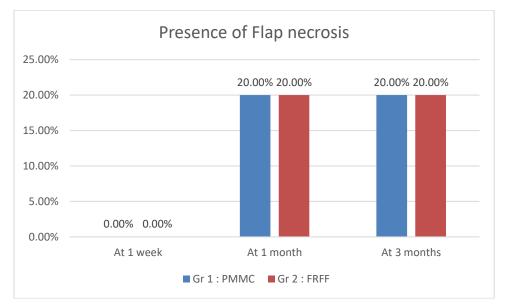
Presence of Flap Necrosis

|--|

	Presence of Flap necrosis									
		At 1 week	At 1 month	At 3 months	P value of Intragroup Comparison					
Gr 1 : PMMF	n	0	1	1	1 wk*1m – 0.999, NS					
	%	0.0%	20.0%	20.0%	1wk*3m – 0.999, NS 1m*3m –0.999, NS					
Gr 2 : FRFF	n	0	1	1	1 wk*1m – 0.999, NS					
	%	0.0%	20.0%	20.0%	1wk*3m – 0.999, NS 1m*3m –0.999, NS					
P value of Intergroup comparison		-	0.999, NS	0.999, NS						

Intergroup comparison of presence of flap necrosis at different follow ups was done using chi square test. The occurrence of flap necrosis was not found to be significantly different among both the study groups.

Intragroup comparison of presence of flap necrosis at all the follow up points was done using McNemars chi square test. It showed that, the presence of flap necrosis was not significantly different from 1 week to 1 month, from 1 month to 3 months and from 1 week to 3 months, among both the study groups.



Graph 4: Presence of Flap Necrosis

Presence of Donor Site Morbidity

Table 5: Pre	Table 5: Presence of Donor Site Morbidity										
	Presence of DSM										
		At 1 week	At 1 month	At 3	P value of Intragroup						
				months	Comparison						
Gr 1 : PMMF	n	0	0	0	-						
	%	0.0%	0.0%	0.0%							
Gr 2 : FRFF	n	0	0	0	-						
	%	0.0%	0.0%	0.0%							
P value of In	tergroup	-	-	-							
cor	nparison										

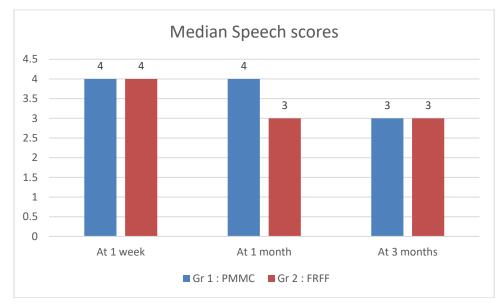
Table 5: Presence of Donor Site Morbidity

Speech Scores

Table 6: Speech Scores

Speech scores									
	N	At 1 we	eek	onths	P value of Intragroup Comparison				
		Median	IQR	Median	IQR	Median	IQR		
Gr 1 : PMMF	5	4	1	4	1	3	2	0.097, NS	
Gr 2 : FRFF	5	4	0.1	3	1	3	1	0.097, NS	
P value of Interg compa	Intergroup 0.513, NS omparison		0.549, NS		0.650, NS				

Both intragroup and intergroup comparison of Speech scores did not show any significant difference among both the study groups.



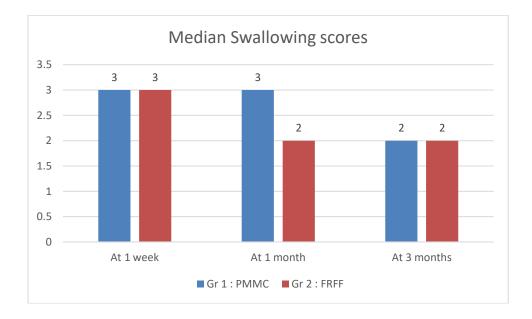
Graph 5: Speech Scores

Swallowing Scores

Table 7: <u>Swallowing Scores</u>

	Table 7. Swallowing Scoles									
			Swa	llowing score	es					
	Ν	N At 1 week At 1 month At 3 months								
		Median	IQR	Median	IQR	Median	IQR			
Gr 1 : PMMF	5	3	1	3	1	2	2	0.037, S		
Gr 2 : FRFF	5	3	.1	2	1	2	2	0.015, S		
P value of Inte com	ergroup parison	0.5	513, NS	0.5	49, NS	0.4	39, NS			

Intergroup comparison of Swallowing scores did not show any significant difference among both the study groups. While intra-group comparison showed that the swallowing scores got better significantly from 1 week to 3 months among both the study groups.



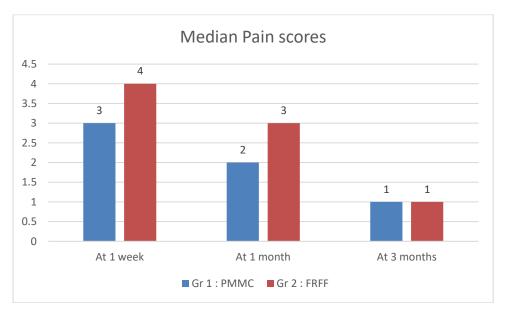
Graph 6: Swallowing Scores

Pain Scores

Table 8: Pain Scores

Pain scores									
	N	At 1 week At 1 month			nth At 3 months			P value of Intragroup Comparison	
		Median	IQR	Median	IQR	Median	IQR		
Gr 1 : PMMF	5	3	1	2	2	1	1	0.011, S	
Gr 2 : FRFF	5	4	.1	3	1	1	1	0.007, S	
P value of Inter comp	group arison	0.:	549, NS	0.4	419, NS	0.513, NS			

Intergroup comparison of Pain scores did not show any significant difference among both the study groups. While intra-group comparison showed that the pain scores got better significantly from 1 week to 3 months among both the study groups.



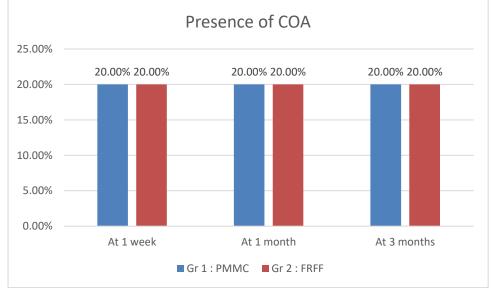
Graph 7: Pain Scores

Presence of Competent Oral Aperture

Table	Table 9: Presence of Competent Oral Aperture									
Presence of COA										
		At 1 week	At 1 month	At 3 months	P value of Intragroup Comparison					
Gr 1 : PMMF	n	1	1	1	1 wk*1m – 0.999, NS					
	%	20.0%	20.0%	20.0%	1wk*3m – 0.999, NS 1m*3m –0.999, NS					
Gr 2 : FRFF	n	1	1	1	1 wk*1m – 0.999, NS					
	%	20.0%	20.0%	20.0%	1wk*3m – 0.999, NS 1m*3m –0.999, NS					
	P value of Intergroup comparison		0.999, NS	0.999, NS						

Intergroup comparison of presence of COA at different follow ups was done using chi square test. The occurrence of COA was not found to be significantly different among both the study groups.

Intragroup comparison of presence of COA at all the follow up points was done using McNemars chi square test. It showed that, the presence of COA was not significantly different from 1 week to 1 month, from 1 month to 3 months and from 1 week to 3 months, among both the study groups.



Graph 8: Competent Oral Aperture

DISCUSSION

The reconstruction of maxillofacial defects in the head and neck after an ablative cancer surgery entails a challenge to the surgeon.^{54,55,56} In oncologic surgery, the objective is to achieve tumour-free margins with esthetic and functional restoration, aiming to avert any negative effects on life quality.⁵⁷ Given the recent resurgence of PMMF and its growing indications, it can be a challenge to choose between FRFF and PMMF when reconstructing the head and neck in some defects. In the modern age of fiscal prudence in the healthcare system, the use of microvascular reconstruction needs to be justified if comparable and less expensive alternatives are available. The present study aimed to compare FRFFF to PMMF for reconstruction of oncologic head and neck defects and ascertain the relative advantages and disadvantages of both flap types.

All previous literature has very well established that the pectoralis major myocutaneous flap is a reliable and practical soft tissue transfer for the reconstruction of extirpative and avulsive defects of the oral cavity and face¹³, and it has persisted as the primary reconstructive option for a variety of reasons, including preference, cost, and lack of expertise in free flaps.^{58,59} When the scientific principles of myocutaneous flap surgery are followed, the PMMC flap elevation procedure is simple and produces predictable results. This soft tissue flap's numerous indications, diverse applicability, techniques, and great versatility are supplemented by sufficient evidence. Recent concepts of micro vascular flaps for reconstruction have demonstrated their efficacy in reconstruction of the head and neck region while not completely outdating the pectoralis major myocutaneous flap due to its use as a secondary flap after free flap failure.¹³

The following are the key findings of the present study:

- i) When compared to PMMF, FRFF was associated with a longer operating time and has a higher cost of surgical procedure.
- ii) The ease of harvesting of PMMF was comparatively less cumbersome when compared with FRFF.
- iii) When compared to PMMF, FRFF was associated with a shorter hospital stay.
- iv) Recipient site morbidity was lower with FRFF reconstruction compared to PMMF, including a lower incidence of infection and necrosis. No difference in the incidence of donor site morbidity was observed when FRFF and PMMF were compared.

- v) The incidence of flap dehiscence was on a higher side in FRFF when compared to PMMF. However, no difference in the incidence of infection, hematoma, was observed when FRFF and PMMF were compared.
- vi) Revision surgery was higher with FRFF reconstruction compared to PMMF.
- vii) In terms of overall quality of life, pain, speech, swallowing, chewing, activity, taste, and saliva, FRFF and PMMF scored similarly.

When selecting any type of reconstructive technique, the surgeon must first ascertain the objectives of reconstruction and then use the technique with the characteristics that allow these goals to be met in the most efficient manner possible. As previously stated, the most crucial factors to consider when selecting a technique for repairing head and neck cancer defects are, in descending order of importance, reliability, function, and cosmesis. Recent concepts of micro vascular flaps for reconstruction have proven its efficacy in reconstruction on head and neck region not outdating the pectoralis major myocutaneous flap completely due to its usage as secondary flap after free flap failure.⁶⁰Despite the need for microvascular surgery for flap transfer, our findings suggest that the free radial forearm flap is at least as reliable as the pectoralis major musculocutaneous flap.

Soutar et al. described the use of the forearm flap for head and neck reconstruction.^{61,62} The radial forearm flap's versatility and dependability have made it the primary form of reconstruction after radical resection of head and neck cancers. When replacing oral mucosa, the thin, pliable skin is much better suited than thicker tissue from pedicled myocutaneous flaps from the anterior or lateral chest wall.⁹ The so-called reconstructive "workhorse" prior to the introduction of microvascular techniques was the pectoralis major myocutaneous, but it was bulky in the mouth, the skin paddle was not completely reliable, and the muscular pedicle was difficult to accommodate in the neck when the sternocleidomastoid muscle was left in place. The low failure rate (3%) and the low incidence of orocutaneous fistulas (3%) in the current study attest to the efficacy of this form of reconstruction.

The flap is versatile in both harvest and application to reconstruct many different sites in the head and neck. In our study, a questionnaire was consigned for the plastic surgeons, where out of 10 surgeons- 8 surgeons considered harvesting of PMMF an easier option compared to FRFF.

Haematoma, seroma, wound dehiscence, fistula, flap dehiscence, and total or partial skin necrosis secondary to vascular compromise are the most common complications reported in donor and recipient sites following Pectoralis major myocutaneous flap and free radial forearm flap reconstruction. In literature overall success rate ranged from 70.8% to 95.5%.^{63,64,65} The overall complications ranged from 6% to 63%.^{66,67,68}After 1 week, 1/5th FRFF patient had infection (20%), while in PMMF, infection occurred in 2/5th patients (40%). When the follow up of patients was done after a month, 0/5 patients (0%) had infection with FRFF , in comparison with 1/5 patients (20%) with PMMF reconstruction. [Table 2]

In our study, the occurrence of flap dehiscence was not found to be significantly different among both the study groups. It showed that, the presence of flap dehiscence was not significantly different from 1 week to 1 month, from 1 month to 3 months and from 1 week to 3 months, among both the study groups. Also, the occurrence of infection was not found to be significantly different among both the study groups. [Table 3]

Partial or total flap necrosis is the most difficult complication of a pectoralis major myocutaneous flap. This complication necessitates additional surgery in order to salvage the reconstruction. In our study, the presence of flap necrosis was not significantly different from 1 week to 1 month, from 1 month to 3 months and from 1 week to 3 months, among both the study groups. [Table 4]

Earlier studies showed that speech was normal in 45.4% cases.⁶⁹In our study, at the end of 3 months, there was no significant difference in speech when PMMF was compared with FRRF (P < 0.097), with 40% of the patients having normal speech in the FRFF patients in comparison with 35% normal speech in patients with PMMF reconstruction. Furthermore, in comparison to pectoralis major myocutaneous flap, free flap reconstruction reported better intelligible speech. [Table-6]

In literature, oral continence was normal in 5% of patients, occasional drooling in 75% cases and continuous drooling in 20% cases.^{63,70,69} In our study, inadequacy in the competency of oral aperture was observed in 20% cases of both PMMF and FRFF, however, was not significantly different among both the study groups. [Table 9]

Despite the fact that free flap procedures were first performed in 1975,^{11,71} two years before musculocutaneous flaps became popular, these latter flaps quickly became the standard technique for head and neck reconstructions due to their ease of dissection and the perception of higher reliability of the non-microvascular transfer. Although the latissimus dorsi, trapezius, sternocleidomastoid, and platysma have all been described and advocated as donor sites,^{13,72,73} the pectoralis major myocutaneous has garnered the most widespread acceptance. The potential advantages of using the pectoralis major myocutaneous flap include its ease of dissection and high reliability. Furthermore, the flap can be dissected while the patient is supine. Another significant advantage is that the pectoralis major myocutaneous flap is large enough to cover the carotid artery in patients who also require a radical neck dissection, which spares the sternocleidomastoid muscle. In this situation, not only is coverage of the vessels in the neck unnecessary, but the added bulk in the neck is unsightly.

Intergroup comparison of Swallowing scores between PMMF and FRFF did not show any significant difference among both the study groups. While intra-group comparison showed that the swallowing scores got better significantly from 1 week to 3 months among both the study groups. Our study suggests that that there is no significant difference between the two methods of reconstruction in their impact on swallowing function. In a similar manner, intergroup comparison of Pain scores did not show any significant difference among both the study groups. While intra-group comparison showed that the pain scores got better significantly from 1 week to 3 months among both the study groups (p = 0.011:PMMF, p=0.007: FRFF).[Table 7,8]

Depending on the circumstances, the bulkiness of the pectoralis major myocutaneous flap can be an advantage or a disadvantage. The surgeons have tended to use the pectoralis major myocutaneous flap when bulk is advantageous, such as after a subtotal or total glossectomy in which the larynx is spared. Since the goal of such reconstructions is not tongue mobility but rather tongue bulk replacement, the flap acts as an obturator to prevent aspiration. The objective should be to preserve tongue mobility rather than replace bulk when a large segment of mobile tongue still remains after a partial glossectomy or floor-of-mouth excision; as a result, the flap must be thin, flexible, dependable, and have minimal donor site morbidity. With these factors in mind, researchers have focused on the use of thin microvascular flaps such as the dorsalis pedis flap, groin flap, lateral arm flap, and radial forearm flap.^{11,71,13,74} We believe that the free radial forearm flap should be the flap of choice in most cases due to its dependability, functional characteristics, and low donor site morbidity.

Because of its large donor vessels, the free radial forearm flap is a trustable flap. The use of functional neck dissections has made large-caliber recipient vessels, particularly the internal jugular vein and external carotid artery, enhancing our ability to transfer the flap. Large donor vessels, large recipient vessels, and end-to-side anastomoses are all considered to be important factors in ensuring flap reliability, which is critical for immediate reconstruction following cancer ablation.

To summarise, despite the need for microsurgical expertise when using the free radial forearm flap, this technique does not appear to have a higher complication rate than the pectoralis major myocutaneous flap; in fact, when used to repair similarly sized defects, the free flap may actually have a lower complication rate. The free radial forearm flap is particularly useful for repairing smaller defects in the anterior oral cavity, where tongue mobility is important. The pectoralis major myocutaneous flap may be best suited for larger defects in the posterior part of the oral cavity where bulk is required.

CONCLUSION

Oral squamous cell carcinomas (OSCC) are cancers originating from the squamous epithelium in the oral cavity. Reconstructive surgery now plays a crucial role in the treatment of head and neck cancer, and understanding it is becoming more and more crucial in the training of surgeons. When choosing any type of reconstructive technique, the surgeon must first determine the goals of the reconstruction and then use the technique with the characteristics that allow these goals to be met in the best possible manner.

The PMMF have become the flap of choice for head and neck reconstruction in many centres. The skin in such flaps receives its blood supply from perforating vessels of the axial artery system. Free tissue transfer, on the other hand, can provide internal lining, external coverage, soft tissue bulk, and bone, and this flexibility and reliability make it the gold standard for reconstruction in the head and neck. The radial forearm flap offers thin, pliable, and relatively hairless skin, and has vessels long enough and of appropriate diameter to allow anastomoses in the neck.

The large bulk of the PMMF reduced neck mobility and needed the vascular pedicle of the flap to rotate 180° when the skin paddle is used to resurface the neck. The resection of the pedicle, even a few weeks after transplant, together with the subclavicular passage, may avoid the majority of the well-known functional and aesthetic problems related to this reparative technique.⁴⁰

Our results show lower incidence of any complication in the FRFF group (Group II) compared to PMMF group (Group I). Rate of infection at the recipient site was lower in the FRFF group compared to the PMMF group. Dehiscence at "recipient and/or donor" site was higher with FRFF reconstruction compared to PMMF. A lower incidence of partial flap necrosis with FRFF reconstruction compared to PMMF.

The comparison of both type of flaps is limited by the inherent design of the studies included. The PMMF is a safe and reliable flap for reconstruction of a variety of head and neck defects. In this era of microvascular reconstruction, resource constraints remain the primary indication for selecting PMMF in a developing country. The other

indications for the PMMF are: medically compromised patients; free flap salvage surgery; reconstruction in vessel depleted

neck; salvage/extended neck dissections; and providing cover to pharyngeal repair following salvage laryngectomy.

On the contrary, Microsurgery techniques are currently the reconstructive procedures of choice, given that they involve flaps that provide a large amount of vascularised tissue with ample pedicle length, consequently leading to an appropriate adaptation to different locations

covering the majority of defects. the fasciocutaneous radial forearm flap has been shown to be easily accommodated to the defects created by the excision of head and neck cancer. It appears that FRFF are superior to the PMMF for several postoperative outcomes. It is safe to assume that free flaps are an excellent choice for reconstruction in relatively healthy subjects with low ASA classes. In summary, FRFF seem superior to the PMMF for several outcomes.²

We thus conclude that, despite the need for microsurgery, the free radial forearm flap is at least as reliable as the pectoralis major myocutaneous flap and that the choice of flap should be based on defect considerations rather than on the perceived reliability of the reconstructive method. However, further research is necessary to determine the value of the FRFF and whether this reconstruction technique achieves the best possible functional outcome compared with other methods.

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ANNXURES

Ethical Clearance Form

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

Dr. Lakshmi Bala

Professor and Head Biochemistry and Member-Secretary, Institutional Ethics Committee Communication of the Decision of the IXth Institutional Ethics Sub-Committee

IEC Code: 27

BBDCODS/04/2022

Title of the Project: Intraoral soft tissue reconstruction in oral cancer: a comparison of the pectoralis major flap and the free radial forearm flap.

Principal Investigator: Dr Piyush Raj Dharmi

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 Piyush Raj Dharmi,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 07th April, 2022.

- Dr. Lakshmi Bala Prof. and Head, Department of Biochemistry, BBDCODS, 1. Member Secretary
- Dr. Amrit Tandan 2. Member

Member

3.

Lucknow

Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow

Reader, Department of Orthodontics, BBDCODS, Lucknow

Dr. Akanksha Bhatt 4. Member

Dr. Rana Pratap Maurya

Reader, Department of Conservative Dentistry & Endodontics, BBDCODS, Lucknow

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in The comments were communicated to PI thereafter it was revised.

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

Laurstoni Bulg

(Dr. Lakshmi Bala) Member-Secretary IEC Member-Secretary Institutional Ethic Committee **BBD College of Dental Sciences** BBD University Faizabad Road, Lucknow-226028 Forwarded by:

(Dr. Punget Ahuja)

Principal PRINCIPABBDCODS Babu Banarasi Das College of Dental Sciences (Babu Banarasi Das University) BBD Cily, Faizabad Road, Lucknow-220028

Institutional Research Committee Approval

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES (FACULTY OF BBD UNIVERSITY), LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled "Intraoral Soft Tissue Reconstruction in Oral Cancer: a Comparison of the Pectoralis Major Flap and the Free Radial Forearm Flap" submitted by Dr Piyush Raj Dharmi Post graduate student from the Department of Oral & Maxillofacial Surgery as part of MDS Curriculum for the academic year 2020-2023 with the accompanying proforma was reviewed by the Institutional Research Committee present on 12th October 2021 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.

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Prof. Vandana A Pant Co-Chairperson

Prof. B. Rajkumar Chairperson

Received

Babu Banarasi Das College of Dental Sciences (Babu Banarasi Das University) BBD City, Faizabad Road, Lucknow – 227105 (INDIA) PARTICIPANT INFORMATION DOCUMENT

1. Study Title

Intraoral Soft Tissue Reconstruction in Oral Cancer: A Comparison of the Pectoralis Major Flap and the Free Radial Forearm Flap.

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.

3. What is the purpose of the study?

This study aims to compare Pectoralis Major Flap with Free Radial Forearm

Flap for intraoral soft tissue reconstruction in oral cancer.

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?

You should say how long the patient/volunteer will be involved in the research, how long the research will last, how often and what interval they will need to visit the centre and how long these visits will be. You should explain how long the volunteer will need to come for the study for conducting one experiment and how many experiment/study will be performed each day and if travel expenses are available for each visit.

7. What do I have to do?

Are there any lifestyle restrictions? You should tell the patient/volunteer if there are any dietary restrictions. Can the patient drive? Drink? Take part in sport? Can the patient continue to take his/her regular medication? Should the patient refrain from giving blood?

8. What is the procedure that is being tested?

You should include a short description of the drug device.

Patients/volunteers entered into study should preferably be given a card (similar to an identity card) with details of the study they are in. They should be asked to carry it if they need to visit a second time.

9. What are the interventions for the study?

For interventional research study the patient/volunteer should be told what is the type of the intervention.

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 vomiting. If anything happens during the procedure we have skilled personnel and specialized equipments to manage any emergency.

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?

Where there is no intended clinical benefit to the patient/volunteer from taking part in the study, this should be stated clearly.

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, your researcher will tell you whether you want to continue in the study.

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?

You should be able to tell the patients/volunteers what will happen to the results of the research. You might add that they will not be identified in any report/publication.

18. Who is organizing the research?

The research is been done in the DEPARTMENT OF ORAL AND

MAXILLOFACIAL SURGERY. 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. Piyush Raj Dharmi

Department of Oral & Maxillofacial Surgery, Babu Banarasi College of Dental Sciences. Lucknow-226028 Mob- 8978182130

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 READING THE DOCUMENTS AND PARTICIPATING IN THE STUDY.

Signature of PI.....

Date.....

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

1. अध्ययन शीर्षक

ओरल कैंसर में इंट्राओरल सॉफ्ट टिश्यू रिकंस्ट्रक्शन: पेक्टोरलिस मेजर फ्लैप और फ्री रेडियल फोरआर्म फ्लैप की तुलना।

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 मुंह के कैंसर में इंट्राओरल सॉफ्ट टिश्यू पुनर्निर्माण के लिए पेक्टोरेलिस मेजर फ्लैप की तुलना फ्री रेडियल फोरआर्म फ्लैप से 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 सहमति 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?

आपको बताना चाहिए कि रोगी/स्वयंसेवक कितने समय तक शोध में शामिल रहेगा, शोध कितने समय तक चलेगा, कितनी बार और किस अंतराल पर उन्हें केंद्र का दौरा करना होगा और ये दौरे कितने समय के लिए होंगे। आपको यह बताना चाहिए कि एक प्रयोग करने के लिए स्वयंसेवक को अध्ययन के लिए कितने समय तक आना होगा और प्रत्येक दिन कितने प्रयोग/अध्ययन किए जाएंगे और यदि प्रत्येक यात्रा के लिए यात्रा व्यय उपलब्ध हैं। आपको उन शोध विधियों की सरल और संक्षिप्त व्याख्या करनी चाहिए जिनका आप उपयोग करना चाहते हैं।

7. मुझे क्या करना होगा?

क्यों कोई जीवन शैली प्रतिबंध हैं? यदि कोई आहार प्रतिबंध हैं तो आपको रोगी/स्वयंसेवक को बताना चाहिए। क्या रोगी गाड़ी चला सकता है? पीना? खेलकूद में भाग लें? क्या रोगी अपनी नियमित दवा लेना जारी रख सकता/सकती है? क्या रोगी को रक्त देने से बचना चाहिए? क्या होता है यदि स्वयंसेवक/रोगी पहली मुलाकात के बाद गर्भवती हो जाती है? क्या महीनों के अंतराल के बाद आने की आवश्यकता होने पर क्या उसे अभी भी शोध अध्ययन में शामिल किया जाएगा? यह जानकारी कब और किसे देनी है?

8. किस प्रक्रिया का परीक्षण किया जा रहा है?

आपको दवा उपकरण का संक्षिप्त विवरण शामिल करना चाहिए। अध्ययन में प्रवेश करने वाले मरीजों/स्वयंसेवकों को अधिमानतः एक कार्ड (पहचान पत्र के समान) दिया जाना चाहिए जिसमें वे अध्ययन के विवरण के साथ हों। यदि उन्हें दूसरी बार आने की आवश्यकता हो तो उन्हें इसे ले जाने के लिए कहा जाना चाहिए।

9. अध्ययन के लिए क्या हस्तक्षेप हैं? इंटरवेंशनल रिसर्च स्टडी के लिए रोगी/स्वयंसेवक को बताया जाना चाहिए कि हस्तक्षेप किस प्रकार का है।

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?

जहां अध्ययन में भाग लेने से रोगी/स्वयंसेवक को कोई अपेक्षित नैदानिक लाभ नहीं है, यह स्पष्ट रूप से कहा जाना चाहिए।

यह महत्वपूर्ण है कि अध्ययन/हस्तक्षेप के दौरान रोगी को होने वाले संभावित लाभों को बढ़ा-चढ़ाकर पेश न किया जाए, उदाहरण के लिए, यह कहना कि उन पर अतिरिक्त ध्यान दिया जाएगा।

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, आपका शोधकर्ता आपको बताएगा कि क्या आप अध्ययन जारी रखना चाहते हैं। यदि आप वापस लेने का निर्णय लेते हैं, तो आपका शोधकर्ता आपकी वापसी की व्यवस्था करेगा। 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?

आपको रोगियों/स्वयंसेवकों को यह बताने में सक्षम होना चाहिए कि शोध के परिणामों का क्या होगा। आप यह भी जोड़ सकते हैं कि किसी रिपोर्ट/प्रकाशन में उनकी पहचान नहीं की जाएगी।

18. अनुसंधान का आयोजन कौन कर रहा है? यह शोध ओरल एंड मैक्सिलोफेशियल सर्जरी विभाग में किया गया है। अनुसंधान स्व-वित्तपोषित 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 आईआरसों/आईईसी के सदस्यों ने अध्ययन की समीक्षा की और उसे मंजूरी दी।

- 21. अधिक जानकारी के लिए संपर्क करें
- डॉ. पीयूष राज धर्मी ओरल और मैक्सिलोफेशियल सर्जरी विभाग, बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज। लखनऊ-226028 मोब- 8978182130
- डॉ. लक्ष्मीबाला

संस्था की आचार समिति के सदस्य सचिव, बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज। लखनऊ <u>bbdcods.iec@gmail.com</u>

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

गीआई के हस्ताक्षर
गम।
गरीख

Babu Banarasi Das College of Dental Sciences (Babu Banarasi Das University) BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Consent Form (English)

Title of the Study-INTRAORAL SOFT TISSUE RECONSTRUCTION IN ORAL CANCER: A COMPARISON OF THE PECTORALIS MAJOR FLAP AND THE FREE RADIAL FOREARM FLAP

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.
- 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 provided such ause is only for scientific purpose(s).
- 5. I permit the use of stored sample (tooth/tissue/blood) for future research. Yes [✓]
 No []

Not Applicable []

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.

Signature (or Thumb impression) of the Subject/Legally AcceptableRepresentative:...... Signatory's Name...... 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

.

Date

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

सहमति प्रपत्र (अंग्रेज़ी)

अध्ययन का शौर्षक- मौखिक कैंसर में अंतःस्रावी नरम ऊतक पुनर्निर्माण: पेक्टोरलिस प्रमुख फ्लैप और फ्री रेडियल फोरआर्म फ्लैप की तुलना

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)।

 मैं पुष्टि करता हूं कि मैंने प्रतिभागी सूचना दस्तावेज दिनांक . को पढ़ और समझ लिया हैउपरोक्त 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।
 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 समिति और नियामक प्राधिकरणों को वर्तमान अध्ययन और किसी भी आगे के शोध के संबंध में मेरे स्वास्थ्य रिकॉर्ड को देखने के लिए मेरी अनुमति 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 अध्ययन अन्वेषक का नाम तारीख...... गवाह के हस्ताक्षर..... गवाह का नाम गवाह का नाम पीआईडी की एक हस्ताक्षरित प्रति और विधिवत भरे हुए सहमति फॉर्म विषय के हस्ताक्षर/अंगूठे का निशान या कानूनी रूप से स्वीकार्य प्रतिनिधि दिनांक.....

Name:		
Date:		

University of Washington Quality of Life Questionnaire (UW-QOL)

This questionnaire asks about your health and quality of life **over the past seven days**. Please answer 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.

- 7. Speech. (Check one box: ☑)
 - 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.

Which issues have been the most important to you during the past 7 days? Check \square up to 3 boxes.

PainSwallowingTasteAppearanceChewingSalivaActivitySpeechMoodRecreationShoulderAnxiety

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GENERAL QUESTIONS

Compared to the month before you developed cancer, how would you rate your health-related quality of life? (check one box: ☑)

- Much better
- Somewhat better
- About the same
- Somewhat worse
- Much worse

In general, would you say your health-related quality of life <u>during the past 7 days</u> has been: (check one box: ☑)

- Outstanding
- Very good
- Good
- E Fair
- Poor
- Very poor

Overall quality of life includes not only physical and mental health, but also many other factors, such as family, friends, spirituality, or personal leisure activities that are important to your enjoyment of life. Considering everything in your life that contributes to your personal well-being, rate your overall quality of life <u>during the past 7 days</u>. (check one box: ☑)

- Outstanding
- Very good
- Good
- E Fair
- Poor
- Very poor

Please describe any other issues (medical or nonmedical) that are important to your quality of life and have not been adequately addressed by our questions (you may attach additional sheets if needed).

Ouriginal

Document Information

Analyzed document	Intraoral Soft Tissue Reconstruction in Oral Cancer: A Comparison of Pectoralis Major Myocutaneous Flap and The Free Radial Forearm Flap.docx (D157906486)		
Submitted	2023-02-06 05:24:00		
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Sources included in the report

w	URL: http://repository-tnmgrmu.ac.in/3932/1/240320413shanmugharaj.pdf Fetched: 2022-01-20 07:14:36	88	13
w	URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6417188/ Fetched: 2020-02-10 19:55:40	88	4
w	URL: https://www.researchgate.net/publication/42768607_The_Pectoralis_Major_Myocutaneous_Flap_Revis Fetched: 2019-11-25 10:44:27	. 88	1
SA	newthesis (Autosaved).docx Document newthesis (Autosaved).docx (D125451688)	88	3
w	URL: https://www.researchgate.net/publication/272843328_Contemporary_role_of_pectoralis_major_regio Fetched: 2023-01-11 23:28:21	88	2
w	URL: https://www.ecb.europa.eu/pub/pdf/other/euromoneymarketsurvey200601en.pdf Fetched: 2023-01-04 20:21:28	88	1

Entire Document

INTRODUCTION

Cancer is a disease characterized by the abnormal growth and spread of malignant tumors. Human kind has battled with diseases for centuries, even though the global battle against cancer has been ongoing for decades, it is still one of the leading causes of death worldwide. More specifically, oral cancer is a term identifying malignant tumors which originate in the mucous membrane lining the oral cavity. All of these cancers are of the carcinoma type, which simple stated is a malignant tumor of epithelial origin. These occur on the skin, lip, tongue, stomach, thyroid gland, rectum, uterus; in fact, any organ composed of epithelial tissue. Oral squamous cell carcinomas (OSCC) are cancers originating from the squamous epithelium in the oral cavity. Locations include the lip, mobile tongue, buccal mucosa, labial mucosa, floor of the mouth, gingiva, hard palate and soft palate. OSCC belongs to a larger subgroup of tumors termed head and neck squamous cell carcinomas (HNSCC), comprising carcinomas arising in the oral cavity, oropharynx, larynx, hypopharynx, nasal cavity, nasopharynx, paranasal sinuses, salivary glands and the ear. Oral squamous cell carcinoma (OSCC) is an aggressive and unpredictable cancer with a high tendency to recur and metastasize. Despite increasing efforts to improved treatment, the 5-year survival rate is still low. Early intervention gives, as with many types of cancer, the best prognosis. However even small early-stage tumors can behave aggressively.

Head and neck reconstruction surgery has considerably evolved over the past decades, along with the trend of using either a free or a pedicled flap for the reconstruction of

surgical oncologic defects.1