# Submental Island pedicled flap vs Radial Forearm free flap for Reconstruction of Oral Cavity (SIRFROC) - A Randomized Controlled Trial"

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**Dec 2022** **Dr. Mohit**

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# CERTIFICATE

This is to certify that the thesis titled '**Submental Island Pedicled Flap vs Radial Forearm Free Flap for Reconstruction of Oral Cavity (SIRFROC) - A Randomized Controlled Trial**" a bonafide work of **Dr. Mohit**, carried out under our guidance and supervision, in the Department of Surgical Oncology, All India Institute of Medical Sciences, Jodhpur.

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# DECLARATION BY THE CANDIDATE

I hereby declare that this thesis titled '**Submental Island Pedicled Flap vs Radial Forearm Free Flap for Reconstruction of Oral Cavity (SIRFROC) - A Randomized Controlled Trial"** is a bonafide and original research work carried out in partial fulfilment of the requirement for the degree of Magister Chirurgiae (M.Ch.) in Surgical Oncology, under the supervision and guidance, in the Department of Surgical Oncology, All India Institute of Medical Sciences, Jodhpur.

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| **Abbreviation** | Expansion |
|---|---|
| **WHO** | World Health Organization |
| **LMIC** | Low and Middle Income Countries |
| **RFFF** | Radial Forearm Free Flap |
| **TPFF** | Temporoparietal Fascia Flap |
| **FAMM** | Facial Artery Musculo-Mucosal flap |
| **SIPF** | Submental Island Pedicled Flap |
| **SCC** | Squamous Cell Carcinoma |
| **PMMC** | Pectoralis Major Myocutaneous Flap |
| **STA** | Superficial Temporal Artery |
| **ICU** | Intensive Care Unit |
| **SSG** | Split Skin Graft |
| **DOI** | Depth of Invasion |
| **LN** | Lymph Node |

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INTRODUCTION

# 1. INTRODUCTION

Cancer is a primary cause of mortality and a significant roadblock to raising life expectancy worldwide.[1] It is the first or second major cause of death before the age of 70 in 112 of 183 nations, and it ranks third or fourth in another 23 countries according to estimates from the World Health Organization (WHO) in 2019.[1] It is thought to have caused 9.6 million fatalities worldwide in 2018, with about 70% of those deaths occurring in low and middle-income countries (LMIC). Cancer registries in LMICs are thought to reflect fewer than 10% of the actual population, so the true burden might be far higher than what has been reported.[2]

With India accounting for about a third of the global incidence, oral cancer is a significant contributor to this disease burden and a substantial problem, especially for the LMICs.[3] It is now the most prevalent malignancy in Indian males, with an increase of 68% over the previous 20 years.[4] Approximately one-fourth of all cases worldwide, roughly 77,000 new cases and 52,000 deaths are reported annually in India. Since oral cancer is one of the most prevalent types of cancer in India raising significant worry for community health.[2]

In oral cancers, the subsites include the lip, tongue, buccal mucosa, the floor of the mouth, hard palate, and retromolar trigone area. Early identification is crucial to lowering the death rate of individuals with oral cancer. As a result, there is a tremendous need for non-invasive, quick, and simple diagnostic methods for oral cancer. The physical examination, which often entails inspection and palpation, is the first and most crucial step in diagnosing oral cancer. Before an internal examination of the buccal cavity, the exterior parts including the lymph nodes, salivary glands, lips, etc. are first examined, and any suspicious area must be biopsied.

Most patients of oral cavity cancer present in advanced stage to hospital. Management of oral cancer revolves around surgical treatment, and other modalities are used as an adjunct to it.[5] The surgical treatment creates various kinds of defects, which generally require some reconstruction. The decision for reconstruction depends on multiple factors, which include site, size, thickness, body habitus, associated morbidity, availability of expertise, and expectation of patients. The goals of the reconstruction are to achieve good functional as well as aesthetic outcomes.[6] Functional outcomes include oral competence, speech clarity, mastication, tongue mobility, bolus transport, nasal regurgitation, and aspiration avoidance. At the same time, aesthetic outcomes include restoring the bony framework, soft tissue contour, chin prominence, and jaw mobility. It is very challenging to attain all these reconstruction aims in most patients.

Since the invention of flaps, surgeons' capacity to remove substantial diseases and offer a variety of reconstructive choices has dramatically increased. Rotation flaps were initially intended to transfer nearby tissue to close defects, but pedicled flaps gained popularity because they can move much soft tissue up to a short distance. Pectoralis flaps were the most dependable and often used among head and neck surgeons until the invention of free flaps. This method reduced the danger of carotid blowout syndrome and fistula formation by providing non-diseased, non-irradiated tissue for covering several low anterior cervical resections. Techniques for microvascular free tissue transfer have developed to address this demand. Extensive studies have shown their safety and effectiveness, with flap survival rates of 93 percent and, most recently, 96.4 percent.[7]

Various options for reconstruction depend on the defect site, size, or type of defect, including free fibula flap, dorsal scapular flap, anterolateral thigh flap, and radial forearm free flap. RFFF is a reconstruction of choice for limited-size defects among all microvascular options available. RFFF is the gold standard for reconstructing limited-size soft tissue defects with good outcomes. It is a pliable, less bulky, and versatile flap with a high success rate of approximately 97%. [8]

Flap failure is a concern, but there is currently no preoperative way to predict success; in the event of flap failure, other reconstructive choices are frequently accessible. Ischemic hand problems are one of the most feared postoperative side effects of RFFF treatments. The excess blood supply to the hand provided by the radial and ulnar arteries forms the foundation of the RFFF. The superficial and deep palmar arteries, which branch to form the blood supply to the digits, are formed by the anastomosis of the two arteries.

Although highly uncommon, acute arterial insufficiency has been documented. IHC manifests during surgery as a severe pallor that gradually darkens as the tissues become necrotic and hypoxic. Immediate intervention with an artery interposition graft is required to stop severe impairments due to digital necrosis.[9]

Although the symptoms of chronic hand ischemia can vary, they may include pain, aversion to the cold, discoloration, open ulceration, tissue necrosis, and gangrene of the digits.[10] Usually, these symptoms develop proximally from the fingertips outward[11] Volkmann contracture may present as a late finding of subacute ischemia, most frequently discussed in orthopaedics literature. Forearm compartment syndrome with an undiagnosed posttraumatic sequela that causes arterial insufficiency and venous stasis is the classic presentation.

In a nutshell, RFFF is a gold standard flap with good uptake and better cosmetic and functional outcomes. However, it has its limitations, It requires advanced surgical skills, a

microvascular surgeon, microvascular instruments, loops, a microscope, lengthy operative time beyond resection alone, flap monitoring, and complete flap loss leading patients to another surgery. The success rate of free flap further decreases in patients with multiple comorbidities, atherosclerotic disease, and previous history of thromboembolism, leading patients to go for alternative flap options.

So due to various limitations of free flaps in a low-resource setting, there has been a resurgence of interest in locoregional possibilities in recent years. This is perhaps because of the sophisticated tools and knowledge needed for free tissue transfer and the growing focus on affordable healthcare. There have been advancements in locoregional choices during this time. Both the supraclavicular and the submental flap have improved in description and acceptance. More conventional flaps like the pectoralis major flap, the temporoparietal fascia flap (TPFF), and the facial artery musculo-mucosal (FAMM) flap have also undergone some technological alterations.

Though Martin first proposed the submental island artery flap in 1993, it has recently grown in popularity. It has been demonstrated that its usage in head and neck reconstruction is suitable for limited-size defects of the oral cavity with comparable outcomes to free flap.[12–14] This flap benefits the mucosal surface, ease of harvest, and low donor site mobility without further external scarring. Limitations in size and the frequent requirement for a 2-stage rebuilding are drawbacks. It can be an excellent choice in patients with a limited physiologic reserve where operative trauma and delayed postoperative recovery are the most complicated issues. Moreover, in elderly patients, this flap avoids the potential complications linked to microsurgical procedures and, reducing the submental fullness, has a satisfactory donor result.[15]

Possible complications of submental flap include injury to the marginal mandibular nerve[16] during surgery. This damage to the marginal mandibular nerve is greatly lessened by supraplatysmal dissection.[17] Using nerve stimulators associated with careful dissection decreases the possibility of damage to these nerves preventing the innervations of the supplied muscles[15] To date, most studies comparing Submental Island Pedicled Flap (SIPF) with Radial Forearm Free Flap (RFFF) are retrospective and nonrandomized, so they have a chance of selection bias. Therefore, to find the answer to this issue, we conducted a randomized prospective study comparing SIPF and RFFF.

# AIM & OBJECTIVES

# 2. AIMS AND OBJECTIVES

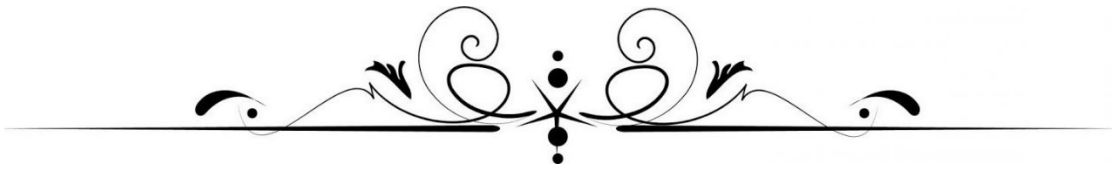
The research question of the study is “Can a submental island pedicled flap be an excellent and reliable alternative to radial forearm free flap for oral cavity reconstruction for limited size defects with similar success rate in selected population”.

### 2.1. Primary objective:

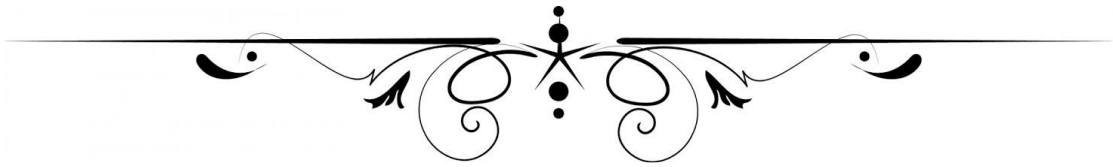
1. To compare flap success rate between SIPF vs RFFF

### 2.2. Secondary objective:

1. To compare operative time, length of hospital stays.
2. Rate of revision (salvage) surgery for flap loss.
3. To compare postoperative outcomes and other complications between two arms.



# REVIEW OF LITERATURE



# 3. REVIEW OF LITERATURE

Choosing between a Free flap and a Pedicled Flap in head and neck reconstruction is challenging. For some defects, especially with the recent resurgence of Pedicled Flap and their expanding indications. In this era of economic awareness in the healthcare system, the use of microvascular reconstruction needs to be justified if other comparable and less expensive alternatives are available. The submental flap is a game changer in reconstructing head and neck cancer patients. So far, many studies have been conducted comparing submental flaps with free tissue transfer.

### 3.1 Anatomy

The submental artery, a reliable branch of the facial artery(Fig 1), is the foundation for the submental flap. At the point where it emerges from the facial artery, it has a diameter of around 1.0 to 1.5 mm.[14] When it hits level Ia of the neck, it usually runs deep to the digastric and superficial to the mylohyoid muscle. In some 30 % of cases, it runs superficial to digastric muscle. This flap can be used as a pedicled flap, free flap, and perforator flap. This submental pedicle provides adequate length to the pedicle and can lead to easy flap mobility and compliance in using reconstruction in the oral cavity. A pedicled submental flap can be used to reconstruct buccal mucosa, the tongue, the floor of the mouth, and the retromolar pad.[18] The myocutaneous flap can be thin or may include the anterior belly of the digastric and the mylohyoid muscles (thick flap), increasing the blood supply to the flap.[19]

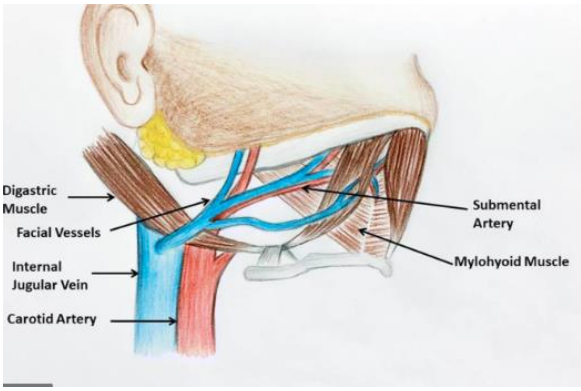



Fig 1

Fig 2

### 3.2 Surgical technique

The flap's design and harvest are well-described in earlier works so we will summarize them here.[20] The mandibular arch's inferior border serves as the lower border of the flap. A pinch test is used to measure the maximum width of the flap in order to determine how much of the donor site may be closed. The length is created to accommodate the deformity and, if necessary, can extend from one mandibular angle to the next. One or both sides of the neck may be dissected through the skin paddle incision. After assessing the defect size, an elliptical skin incision is marked in the submental area (Fig 2). Additionally, the skin paddle might support unilateral or bilateral neck dissection (Fig 3).

Fig 3

The upper flap is to be elevated in a subplatysmal plan, and care is made to protect the marginal mandibular nerve. After identifying the skin flap, we carefully begin neck dissection to preserve the facial veins. The facial vein and artery are discernible at the upper edge of the submandibular gland. The facial vein and artery are meticulously traced to dissect the submental flap pedicle.

Flap dissection starts from the opposing side of the pedicle in the subplatysmal plane. When the flap reaches the midline, level 1a lymph nodes are dissected. The facial vessels are preserved, and level 1b LN is removed. Just above the submental branch, facial veins are split. To prevent damaging the flap's pedicle, the anterior belly of the ipsilateral digastric is cut at the mandible with a strip of myelohyoid. A tunnel can then connect the defect and the donor site. When the defect involves the tonsillar fossa, floor of the mouth, or base of the

tongue, the flap is channelled medially to the mandible. The flap may also be routed laterally to the jaw for buccal mucosa abnormalities.

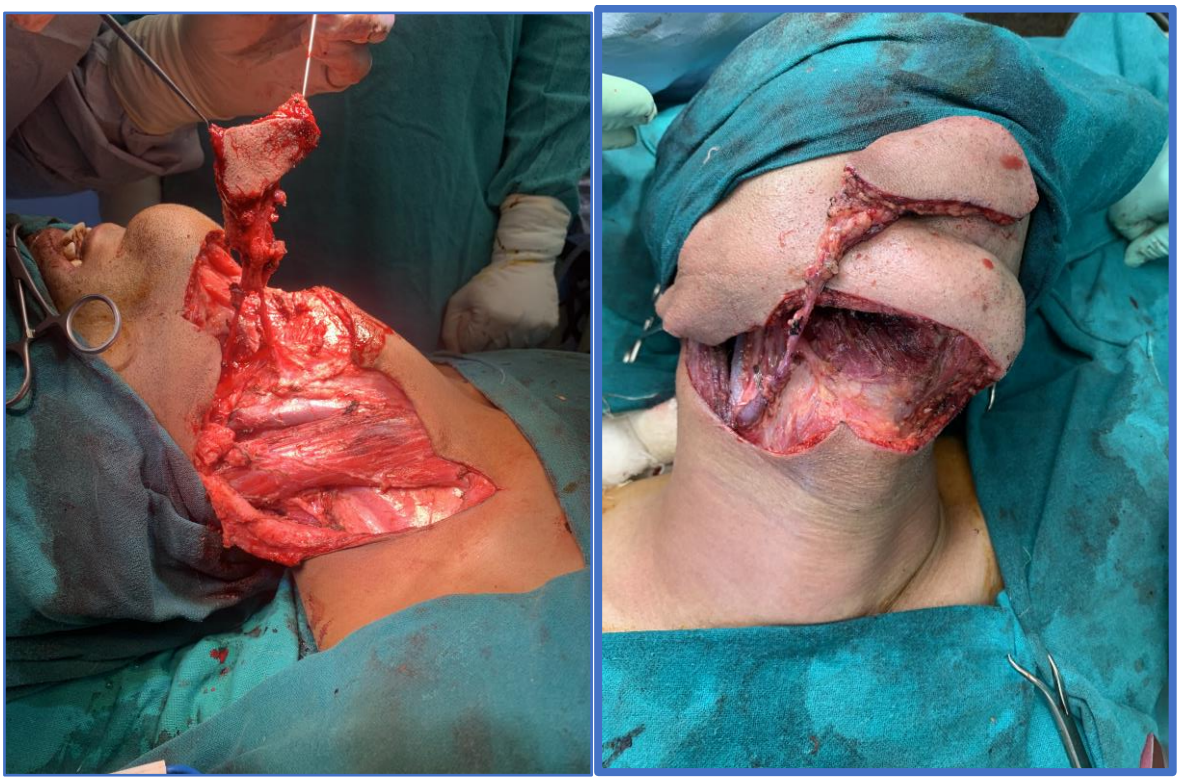


Fig 4

**3.3 Neck dissection**

Neck dissection is completed with care to preserve the facial vein. Sometimes facial vein was seen arising from EJV. Care must be taken not to ligate the EJV. The donor site is sutured with primary closure. The majority of the oral cavity can be reached using a submental flap. It is thin, pliable, and can easily apply to defects of the buccal region, the floor of the mouth, the lateral tongue, and the alveolar ridge. The Flap has a wide arc of rotation, a constant axial vessel, appropriate pedicle length, a significant skin paddle, and wide pivotal movement[21]. It is mainly used to reconstruct oral cavity defects after cancer surgery, particularly after SCC ablation. The use of this flap is limited in patients with Level 1A lymph node metastasis and a history of neck dissection because, for the success of this technique, the integrity of the facial artery/vein is necessary . The common facial artery and vein can be tied close to where the submental arteries take off to increase the flap's reach in some of these places. The flap can then be fed and drained retrogradely through the face.

Fig 5

There have been advancements in locoregional choices during this time. Both the supraclavicular and the submental flap have improved in description and acceptance. More conventional flaps like the pectoralis major flap, the temporoparietal fascia flap (TPFF), and the facial artery musculo-mucosal (FAMM) flap have also undergone some technological alterations.

Fig 6

### 3.4 Facial artery musculo-mucosal (FAMM) flap

The FAMM flap can restore small- to medium-volume oropharyngeal and oral cavity defects. Furthermore, it can be used for defects in the upper and lower lip, ventral tongue, the floor of the mouth, anterior and posterior palate, and nasal septum. Julian Pribaz et al[22]. Initially reported this flap in 1992, and it has gained increasing popularity in recent years as a result of increased awareness of its benefits and advances in knowledge of harvesting methods.

### 3.5 Pectoralis major myocutaneous flap (PMMC )

Ariyan[23] introduced the pectoralis major myocutaneous (PMMC) pedicled flap for head and neck reconstruction in 1979. The pectoralis major flap revolutionized head and neck reconstructive surgery. It was the go-to flap for most head and neck oncologic defects until microvascular-free flaps became widely used. It was more adaptable and reliable than earlier techniques, such as random pattern flaps and the deltopectoral flap. The lateral thoracic artery, branches of the internal mammary artery, perforating branches of the anterior intercostal arteries, and the pectoral branch of the thoracoacromial artery provide supplemental blood flow to the pectoralis major muscle. The lateral thoracic artery supplies the lateral pectoralis major muscle, which runs parallel to the pectoralis minor muscle's lateral border.

However, this flap is the most versatile and can be used for the reconstruction of large defect sizes but for minor defects, and it provides poor outcomes due to the bulkiness of the flap. The skin paddle may be excessively bulky in obese patients and women due to the presence of the breast, and harvesting a PMMC flap may also dramatically alter the contour of the breast in women.

### 3.6 Temporoparietal Fascia Flap (TPPF)

Brawn, in 1898 described this flap for reconstruction of the external ear after a horse bite, while Monks similarly described its use for lower eyelid reconstruction. The TPFF offers thin, malleable reconstructive tissue for various head and neck deformities.[24] The superficial temporal artery (STA), which emerges from the external carotid artery and travels inconveniently via the preauricular region, supplies the TPFF. The STA splits into terminal frontal and parietal branches around 3 cm above the zygomatic arch. The superficial temporal vein, which often runs superficially to and beside the STA, provides the TPFF's outflow. Nayak and Deschler[25] ,Upton et al.[26] and Pinto et al.[27] discussed using the TPFF for oral

cavity deformitie[27]. In 2 patients with oronasal fistulas and one patient with lye ingestion, a pedicled TPFF was successfully used, according to Upton et al.[26]

There are several issues with head and neck TPFF reconstruction. Alopecia, frontal branch paresis or paralysis, flap necrosis, and hematoma are among the risks. It should be highlighted that granulation and remucosalization are essential in the procedure because this flap lacks an epithelial surface. As a result, with buccal restoration using this flap, there may be some degree of scarring or stiffness.

### 3.7 Radial forearm free flap

Since the first report of its use in releasing scar contracture in burn patients, the radial forearm free flap (RFFF) has been a workhorse in head and neck reconstruction.[28] In particular, RFFF is used in oral cavity reconstruction to rehabilitate the tongue[29] cleft lip and palate[30] and several deformities resulting from oral cancer surgery. An osteo cutaneous flap that may be used for mandible repair can be raised by including the bony segment of the radius[31] Although RFFF has a reasonable success rate, insufficient venous drainage is the leading cause of flap failure. The superficial and deep venous drainage systems of the RFFF use the cephalic vein and the venae comitantes, respectively. Veins can be easily blocked by extrinsic compression, and thrombi are produced by modest intimal damage due to the considerably lower flow pressure of venous drainage than the arterial stream. Reducing pedicle tension and kinking and receiving medical therapy to lessen vascular spasms are technical modifications that can reduce the flap failure rate.

Fig 7

Though there are many options available for reconstruction in oral cancer, we mainly focussed on using SIPF and RFFF flaps to compare their perioperative and functional

outcomes and feasibility. J F Pascal et al. 1993[32] studied the flap design of the SIPF flap and examined the flap technique on 20 fresh cadavers and eight patients who underwent radical neck dissections. After that, eight patients had their orofacial deformities effectively repaired with the flap. The flap has a long, dependable pedicle (up to 8 cm), and its cutaneous dimensions can be up to 7 x 18 cm. It is appropriate for use as an oseocutaneous, musculofascial (cervicofacial and platysmal), or cutaneous flap. They concluded that this flap can cover the whole homolateral face, except a portion of the forehead, and has a large arc of rotation and an excellent skin colour match.

A multi-institutional retrospective study was carried out in 2011 by Joseph A.payadarfer, Pasdaran M. D. et al.[33] to compare the intraoperative, postoperative, and functional outcomes of SIPF vs. Radial free forearm flap repair for the tongue and floor of the mouth. He looked at 60 patients, 27 of whom underwent SIPF repair, and 33 underwent RFFF flap. The two groups' sex, age, and TNM stage were comparable. The mean flap size for SIPF (36 cm2) was smaller than for RFFF (50 cm2). Compared to patients who underwent RFFF, patients undergoing SIPF stay in the hospital for a shorter time. However, the two groups' functional results were comparable. Because patients were not randomized and there were more T3 and T4 patients in the RFFF group, this study's primary weakness was selection bias.

A study on 41 patients was conducted by Fabrizio Schoenauer, Annulene Di Martino, et al. (2016), who concluded that the submental artery flap is a viable choice for reconstructing composite oral cavity abnormalities. It is an excellent substitute for free flaps, especially in elderly or high-ASA-risk patients. The shorter recovery time and easily hidden donor-site incision make it an intelligent choice.

D Forner T Philips[34] et al. (2016) conducted a retrospective study from 2013 to 2015 and analyzed all the patients who were operated on with SIPF and RFFF. In their study, a total of 12 patients were included in the SIPF arm out of which 3 were converted intraoperatively into different flaps. A total of 12 patients were identified in the RFFF group. They compared the patient outcome, ICU stays, and hospital cost burden in both arms and concluded that in glossectomy RFFF repair, the average length of hospital stay was 4.7 days; however, In the SIF group, just one patient had to spend one night in the ICU. The SIPF arm's mean operating time was less than the RFFF group's (347 vs. 552 min., p 0.05). Both groups did not have a statistically significant difference in mean hospital stays (12.4 vs. 15.4 days, $p > 0.05$). However, they concluded that in RFFF, the expanse was more than in SIPF. In RFFF operations, the total mean intraoperative expenses were $4780.59, compared to $2307.94 for SIF operations. In the SIF group, the total mean cost of the postoperative stay was $18158.40;

in the RFFF group, it was $43617.60. The SIF group's overall cost savings came to $27931.85 per patient. They concluded that SIPF could be a better alternative to RFFF with a low hospital stay, less operative time, and comparable functional and cosmetic outcomes.

Nawaf Aslam, Steven J, et al. (2017)[35] conducted a retrospective cohort study of all patients with oral cavity and oropharyngeal defects reconstructed with the Submental flap and a cohort of patients with similar volume defects reconstructed with the Free Forearm Flap and compared them for oncologic safety and viability of equivalent reconstructive outcomes In the Submental group's median age was 61.8 years compared to the FFF group's 57.9 years. Flap volumes were compared favourably (SIPF, 38.79 cm3; RFFF, 39.77 cm3). Shorter anaesthetic periods (815 vs. 1,209 minutes; P .001), shorter operating times (653 vs. 1,031 minutes; p value .001), and reduced blood loss (223 vs. 398 mL; P =.04) were among the significant comparing outcomes with SIPF versus RFFF reconstruction. They found that Recipient site complication rates were lower in the RFFF group (0.17 vs. 0.42 per patient) but not statistically relevant. There were no differences in speech and swallowing function on a median follow-up of 15.5 months.

In a study by Akshaya Patel, Jason E. et al. (2018),[36] 73 patients with head and neck cancer of which 19 underwent SIPF, and 54 underwent free flap reconstruction were included. Variables across two cohorts were compared using comparative statistics, including operating time, flap size, duration of stay, regional recurrence, disease-free survival, and overall survival. SIF is adaptable and seems an excellent option for reconstruction with shorter operating times, fewer complications, and similar results. Additionally, retrospective in nature, this study exhibits non-randomization and selection bias.

Urjeet A. Patel, MD (2019), conducted retrospective research on patients at two academic tertiary care facilities[37].Between 2004 and 2016, consecutive patients who underwent cancer excision and repair with SIPF or RFFF were included. They retrieved data on cancer staging, surgical technique, hospital stay, complications, functional outcomes, and oncologic outcomes. They concluded that the SIPF dramatically cuts down on both operating time and hospital stay. Functional and oncologic outcomes are comparable, and the SIPF is a good alternative. For head and neck reconstruction, the SIPF is a wise first option.

In compliance with PRISMA recommendations, a systematic review was carried out by Fanny Gabrysz, Paul Tabet et al. Included were prospective and retrospective articles that specifically contrasted the use of pedicled versus free flaps for head and neck reconstruction.[38] Following the screening procedure, 30 articles were included for quality analysis. They concluded all the investigations that submental flap had equivalent outcomes

to free flap for some particular indications, attaining similar results at less expense. Given a similar functional outcome and superior performance in terms of Operative time, hospitalization/ICU length, and repair of head and neck tissue abnormalities, SIPF can be viewed as an acceptable alternative to a free flap. Additionally, it has been stated that SIPF offers better colour matching for cervicofacial skin flaws. This research has certain limitations because many of the 30 papers did not indicate the precise flap used or provide a consistent definition of postoperative problems.

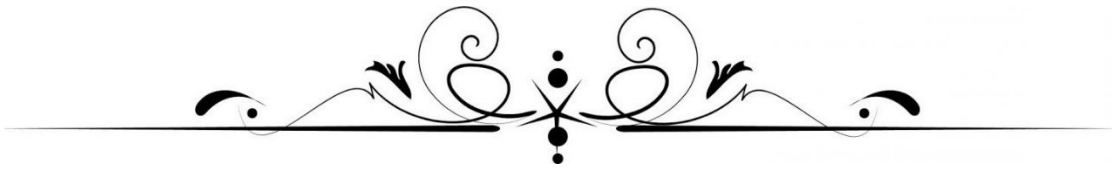
In a meta-analysis of several PubMed and Google Scholar papers, Shirley Hu, Caleb Fan, and colleagues (2020) compared the submental flap to the RFFF flap.[39]. Three hundred fifty-three studies were found in the initial search, but only five were considered final for metanalyses. For the SIPF and free tissue transfer cohorts, the sample sizes for all investigations ranged from 9 to 45, respectively. They concluded that, compared to Free tissue transfer, SIPF is associated with shorter hospital stays, less postoperative pain, fewer perioperative complications, and maybe equivalent rates of disease recurrence. The limitations of this meta-analysis were that it included primarily retrospective studies, lacked robust study designs, was susceptible to selection bias, had poor quality data for the length of the operation, and varied widely in the timing of adjuvant RT, all of which led to poor data quality. The individual flaws between the two groups were not relatively equal in recipient site morbidity, and considering the higher flap area harvested, it is likely that more significant defects were rebuilt in the Free Tissue Transfer cohort.

Karinno Massaki et al. 2021 conducted a retrospective study From January 2019 to examine 10 cases of reconstruction using the SIPF following oral squamous cell carcinoma resection. The patients underwent marginal mandibulectomy(3), segmental mandibulectomy(1), partial glossectomy(2), hemiglossectomy(1), buccal mucosa resection(2), and combined partial glossectomy and segmental mandibulectomy(1)In their study they calculated mean flap size 6.1x 3.6 cm with the meantime to flap elevation 32.4(23–50)minutes. There were no complications seen in any patients.

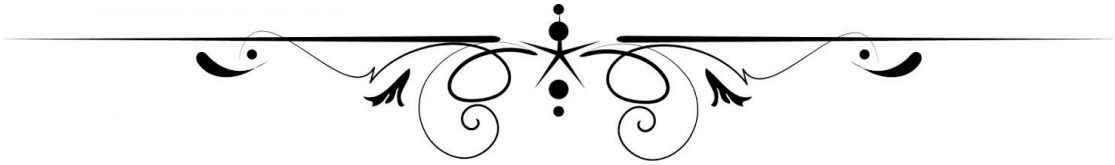
Ramirez-Cuellar AT, Sanchez-Jimenez[40] et al. (2022) published their experience on 21 patients with a mean age of 66. Operated for oral cavity, nose, oropharynx, and soft palate defects and reconstructed with submental flap. The mean hospital stay was eight days in these patients, and outcomes were excellent, with partial necrosis seen in some patients, which was managed conservatively.

Most of the studies conducted in this field are retrospective and lack randomization. To the best of our knowledge, our study is the first randomized study comparing the outcome of

patients reconstructed with submental flap vs. Radial free forearm flap. Since there is limited availability of microvascular surgeons, a submental flap can be used as a cost-effective alternative to a Radial forearm free flap.



# MATERIALS & METHODS



# 4. Materials and Methods

### 4.1. Study setting

All the oral cancer patients satisfying inclusion criteria during the study period were recruited from the Department of Surgical Oncology AIIMS, Jodhpur.

### 4.2. Duration of study

The study was carried out from 1st January 2020 to 31st December 2022.

### 4.3. Study procedure

All the patients of oral cavity cancer satisfying inclusion criteria were selected and underwent reconstruction. Randomization of patients was done at the time of admission into following groups

Group A submental island pedicled flap is used for reconstruction

Group B Radial forearm free flap used for reconstruction.

The groups were studied for an operative time, perioperative complication, length of hospital stay. These patients were followed after three months of surgery to compare outcomes in two groups through a prespecified proforma. Main parameters compared are flap size, operative time and length of hospital stay and functional and cosmetic outcomes in the postoperative period

### 4.4. Inclusion criteria

Oral squamous cell carcinoma

1. T1-T3 tongue, buccal mucosa including commissure of mouth, lower or upper alveolo-buccal complex, and lip.
2. N0 -N1 disease
3. Patient willing to participate in the study

### 4.5. Exclusion criteria

1. Clinically positive lymph nodes/ nodes at level 1A.
2. Primary disease infiltrating the mylohyoid muscle (e.g., primary at the floor of mouth).
3. Patients with previous neck dissection or neck irradiation.

4. Anticipated surgical defects that are too large for repair with the SIPF (more than 40 $cm^2$).

**4.6 Data collection**

Results of each patient are recorded in a specified proforma. Data collection proforma is attached

**4.7. Sample size**

30 cases in each group and a total of 60 patients according to probable number of patients visiting Surgical Oncology OPD.

$n = (z\alpha + z\beta)^2 [p_1(1-p_1) + p_2(1-p_2)]/(p_1-p_2)^2$

85% CI = $z\alpha/2$= 1.44

80% Power = $z\beta$= 0.84

$n= (1.44 + 0.84)^2 [0.76*0.24 +00.490.48)]/(0.0729)^2$

n= 29.73

**4.8. Study design**

It is a prospective, single-centre, parallel-arm randomized controlled trial, all patients with oral cancer meeting inclusion criteria, within the study period have participated in the study. The collected data was analyzed and compared with the data from the current literature.

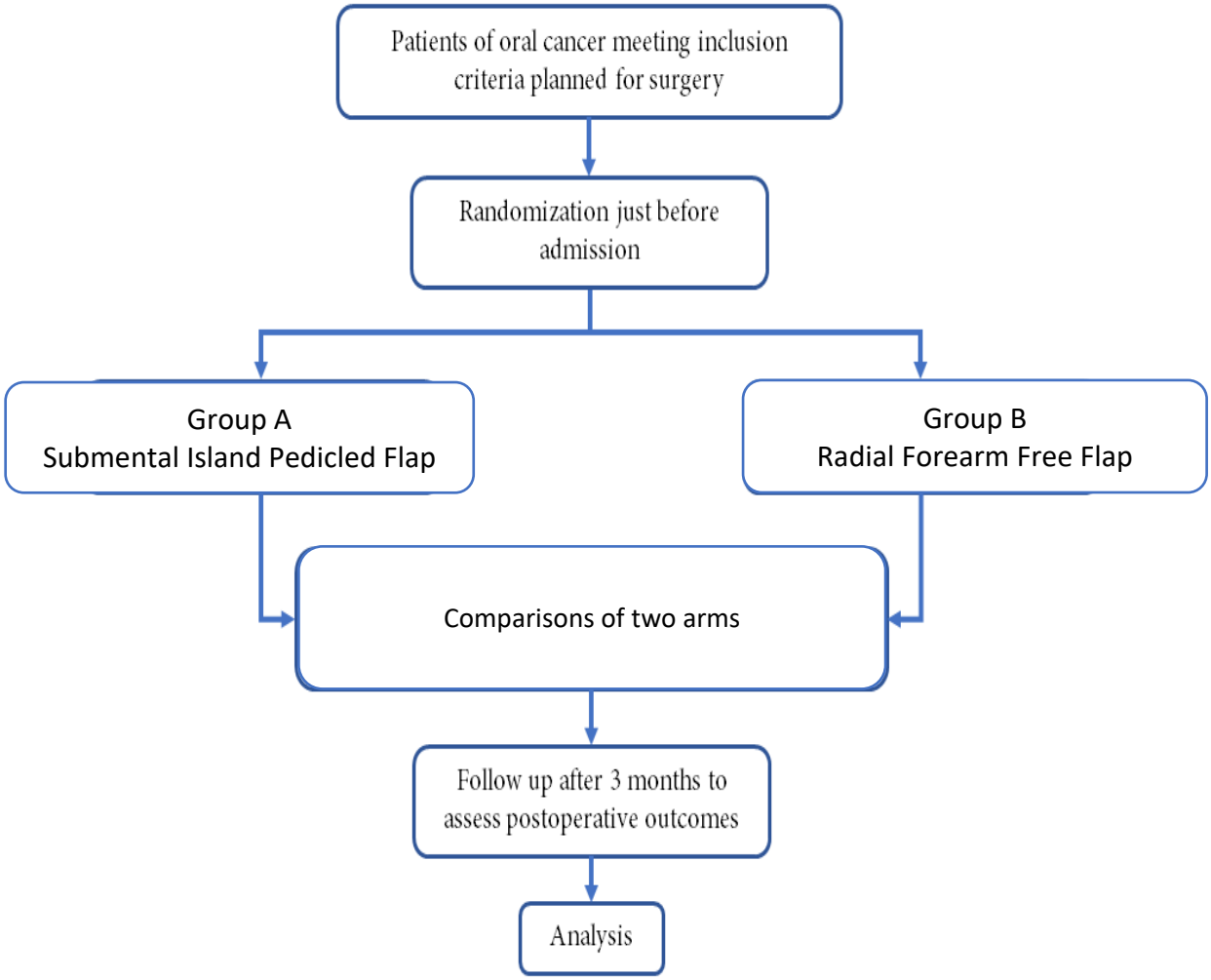



**Fig 8**

### 4.9. Randomization details

Block randomization was done using a computer program with randomly selected block sizes of 4 and 6. Allocation concealment was insured by a serially numbered opaque sealed envelope (SNOSE)

### 4.10. Statistical analysis

All data was acquired in a specified format as in proforma and was entered in SPSS ver.25/MS-Excel software for analysis. Proportions were compared using Chi-square or Fisher's exact test whichever is applicable. For normally distributed data, independent t-test was used. For others, the Mann-Whitney U test was used. P-value $\leq 0.05$ was considered as significant in all statistical evaluations.

### 4.11. List risks and benefits of the study:

Risk:

Minimal risk

Benefits:

The results of the study may or may not benefit the participants directly; however, the study can act as a game-changer for reconstruction in oral cavity cancer. This study can serve as a landmark study for reconstruction in head and neck cancers as there is limited availability of microvascular surgeons in India. Submental flaps can act as a cost-effective alternative to RFFF.

### 4.12. Ethical considerations

All the patients enrolled in the study received the standard care management, and the participation in the study did not lead to change in their usual diagnostic workup, follow up or management. All personal data collected during the study will be kept strictly confidential.

# RESULTS

# 5. RESULTS

## 5.1 Demographics

In our study, a total of 60 patients were included with an average age of 47.93 years (25-71), out of which 40 patients were male, and 20 were females(Fig 8). Patients were randomly assigned between two arms, out of which the SIPF arm had a mean age of 48.53± 11.16 yrs. (Table 1) with 21 Males and 9 Females, the RFFF arm has an average age of 47.30± 10.58 years with 19 males and 11 Female patients.

| DEMOGRAPHIC | SIPF | RFFF |
|---|---|---|
| **Age** | 48.53± 11.166 yrs. | 47.30± 10.58yrs |
| **Sex** | | |
| Male | 21 | 19 |
| Female | 9 | 11 |

**Table 1**

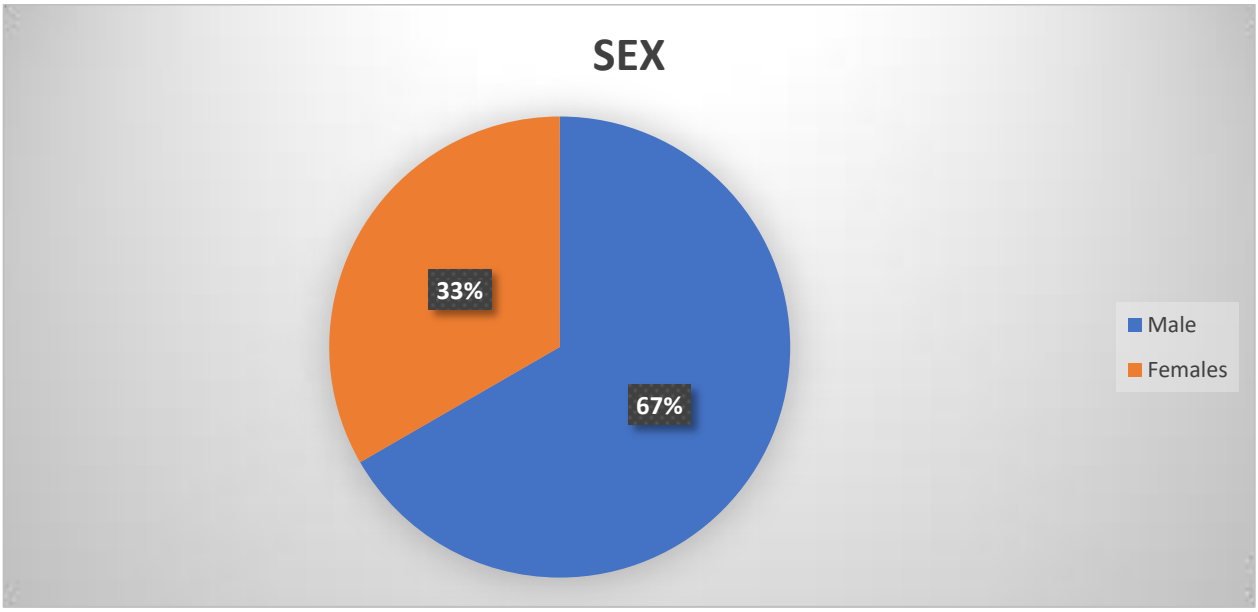



**Fig 9**

**Table 2**

| Age | SIPF | RFFF | TOTAL |
|---|---|---|---|
| 20-29 | 1 | 1 | 2 |
| 30-39 | 4 | 6 | 10 |
| 40-49 | 11 | 12 | 23 |
| 50-59 | 7 | 7 | 14 |
| 60-69 | 6 | 3 | 9 |
| 70-79 | 1 | 1 | 2 |

While studying age distribution, we concluded which SIPF arm has a mean age of 48.53± 11.16 yrs. (Table 1) while the RFFF arm has an average age of 47.30± 10.58 years age wise distribution of patients in both arm shows showing the same number of patients in both arms (Fig 9) in the age group 20-29 and 70-79 yrs. and concluded that there is no statistical difference in age distribution between 2 arms (p value=0.657).

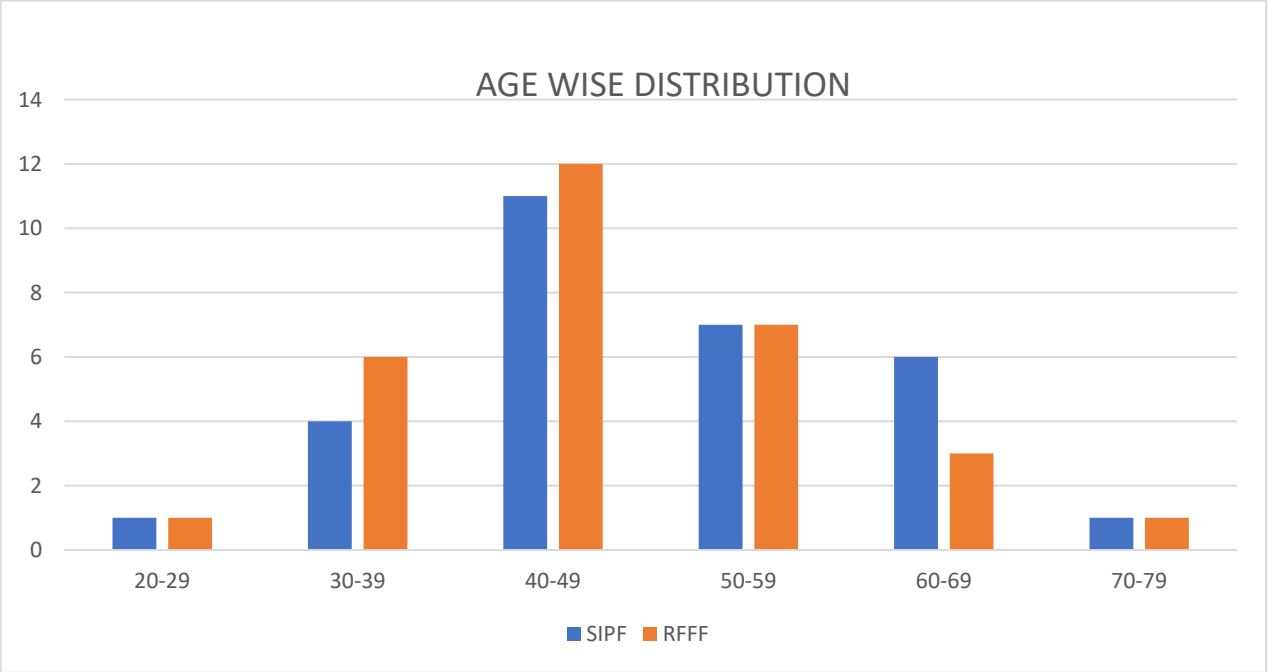



**Fig 10**

Out of 60 patients analyzed, 38 were associated with a history of chewing tobacco, 25 patients with a history of tobacco and alcohol, and 22 patients were not associated with any history of addiction or family history.

**Table 3**

| **Addiction history** | **SIPF** | **RFFF** |
|---|---|---|
| **Tobacco** | 17 | 21 |
| **Smoking +alcohol** | 11 | 14 |
| **No addiction history** | 13 | 9 |

In our study, most patients were of early oral cancer that was diagnosed incidentally on hospital follow-up or during a dental check-up. 34 patients involved buccal mucosa,19 tongues, six lip, and one patient of Floor of mouth(Table 4)

**Table 4**

| **DEMOGRAPHIC** | **SIPF** | **RFFF** |
|---|---|---|
| **Primary site** | | |
| **Buccal mucosa** | 15 | 19 |
| **Tongue** | 12 | 7 |
| **Floor of mouth** | 1 | 0 |
| **Lip** | 2 | 4 |

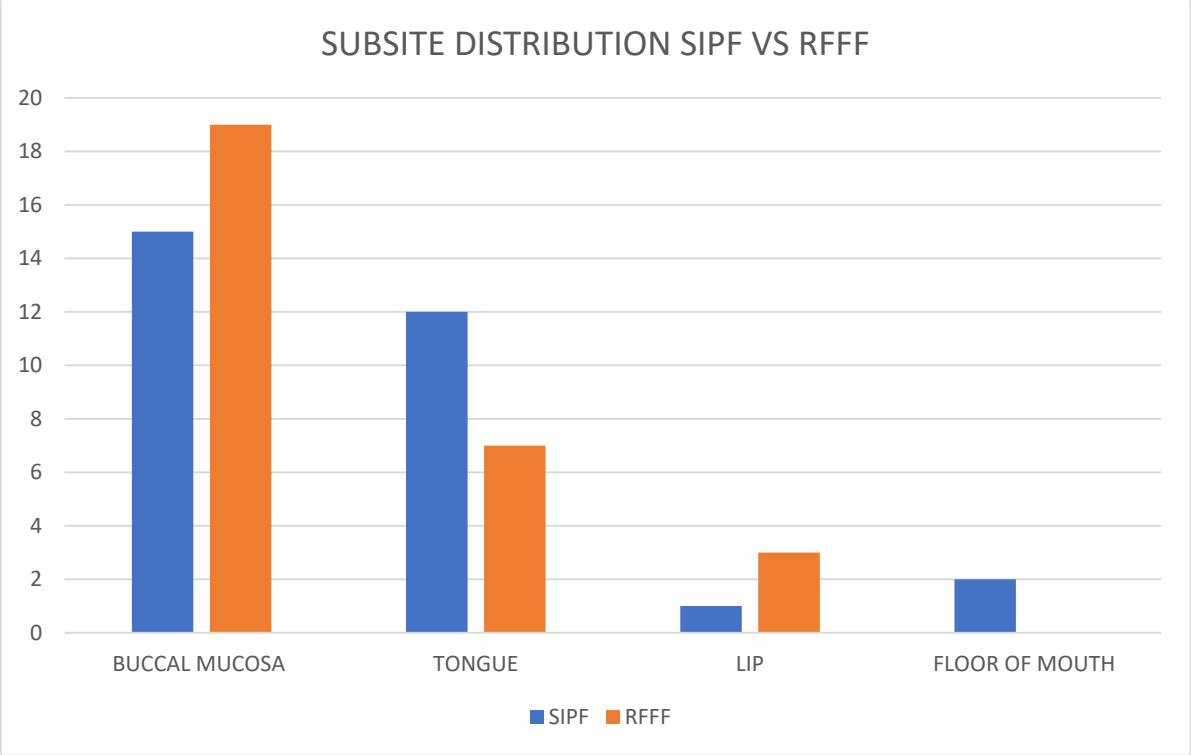



**Fig 11**

### 5.2 Stage distribution

In our study, most patients were of early oral cancer that was diagnosed incidentally on hospital follow-up or during a dental check-up. Thirty-four patients involving buccal mucosa,19 tongues, six lip, and one patient of Floor of mouth. In our study, the most common stage countered is stage II, including 42 patients rest, 14 in stage 3, and both stage 1 and IVA comprised 2 patients each.

In the SIPF arm, patients most commonly involved buccal mucosa (15), (12) tongue, (1) floor of mouth and (2) lip with 1patient in stage 1 stage III 8(26.6%), Stage IVA (3.33) In
RFFF arm 20 male and 10 female with age of 46.60± 9.814years comprising of stage 1 (3.33%,) stage II 73.33% , Stage III 6(20%), stage IVA 1(3.33%) involving buccal mucosa(21) ,(6) tongue and (3) lip

**Table 5**

| Stage (TNM) | SIPF | RFFF |
|---|---|---|
| **Stage I** | 1 (3.33%) | 0 |
| **Stage II** | 21 (70%) | 21(70%) |
| **Stage III** | 6 (20%) | 8(26.6%) |
| **Stage IVA** | 2 (6.66%) | 1(3.33%) |

### 5.3 Perioperative outcomes

Both arms were evaluated for perioperative outcomes that included operative time, hospital stay, ICU stays, re-exploration rate, flap survival rate, revision surgery for flap loss, flap dehiscence, and Oro-cutaneous fistula rate.

Operative time was counted from the start of the incision to skin closure , including primary resection, neck dissection, flap harvest, inset, and closure. On evaluation, Mean operative time was 218.4 min ±28.67min (186-290) for the SIPF arm and 491.77± 56.51 (440-640) for the RFFF arm indicating RFFF was more complex and time taking with the statistically significant difference in operative time (p-value <0.01).

**Table 6**

| Perioperative outcomes | SIPF | RFFF |
|---|---|---|
| Operative time (Mean SD) | 220.4 min ±28.57 | 440.77± 25.90 min |
| Length of hospital stay | 4.83 days ± 1.26 | 7.17± 1.55 days |
| ICU Stay | 0.20± 0.551 | 1.10± 0.548 days |

The mean hospital stay was calculated as 4.83 days ± 1.26 (3-8) days for SIPF, 7.17± 1.55 (5-11) days for RFFF (pvalue<0.001), including Icu stay of 0.2± 0.5 (0-2)days for SIPF and1.1± 0.54(1-3)days for RFFF (pvalue<0.001) showing that there is a statistically significant difference in hospital stay in both arms and SIPF arm is associated with shorter hospital stay and minimal ICU stay.

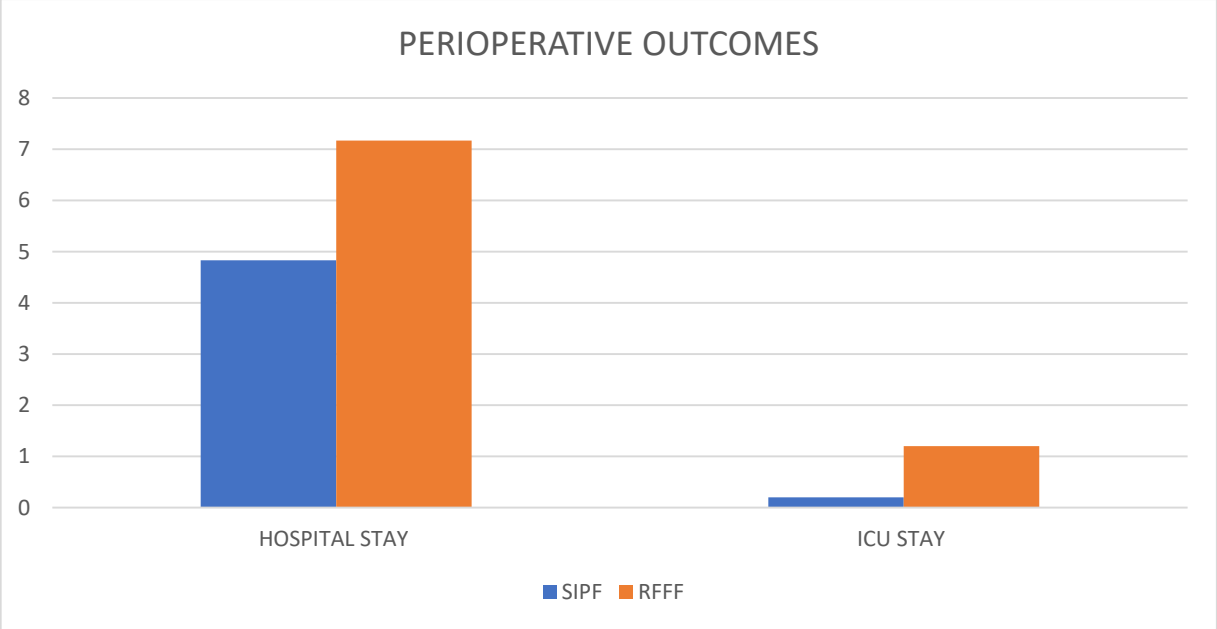



**Fig 12**

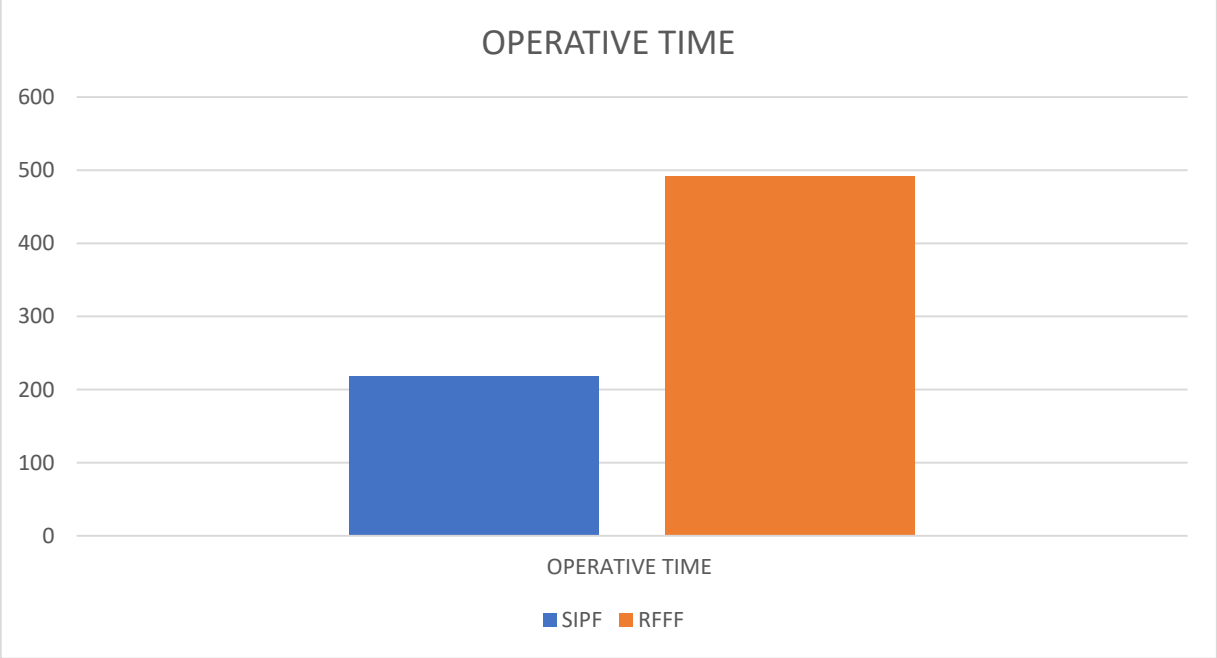



**Fig 13**

So we concluded that the SIPF arm is associated with shorter operative time and hospital stay.(pvalue<0.01)

### 5.4 Flap monitoring

flap monitoring was more crucial in the RFFF arm, requiring hourly monitoring by a plastic surgeon resident; however, monitoring was done two times a day on morning and evening round in the SIPF arm. Re-exploration rates were higher in the RFFF arm, with 6(16.6%)patients reexplored in RFFF and 4 (13.3%)patients reexplored for flap congestion in the immediate postoperative period. However, no re-exploration was done in patients of the SIPF arm, with two requiring suture removal for flap congestion.

Flap uptake was good in both arms, with complete flap uptake seen in 26 patients without any major complication; however, two patients underwent partial epidermal loss with vascularised muscle leading to flap uptake on conservative management. However, two patients required a salvage flap. In the RFFF arm, 24 patients were discharged with complete flap uptake and no major complication .however, six patients required re-exploration, out of which three patients were with complete flap loss requiring salvage flap and four patients underwent redo anastomosis because of venous thrombosis. Though Oro cutaneous fistula and reexploration rate were higher in RFFF, data was statistically insignificant.

**Table 7**

| | **SIPF** | **RFFF** |
|---|---|---|
| Flap loss | 4(13.3%) | 3(10%) |
| Complete | 2 (6.6%) | 3(10%) |
| Partial | 2(6.6%) | 0 |
| Re exploration rate | 0 | 6(20%) |
| Venous thrombosis | 0 | 4 |
| Revision surgery | 1(3.3%) | 2(10%) |
| Flap dehiscence | 2(6.6%) | 3(15%) |
| Oro cutaneous fistula | 0 | 2(10%) |
| MM Palsy | 2 | 1 |

When comparing donor site morbidity, there was no donor site morbidity in the SIPF arm; however, in the RFFF arm, there was partial uptake of SSG in 2 patients (Table 8). There was a poor scar at the donor site in all patients in the RFFF group. However, no gross weakness or thenar hypotrophy is seen in patients.

**Table 8**

| **Donor site morbidity** | **SIPF** | **RFFF** |
|---|---|---|
| Thenar hypotrophy | 0 | 0 |
| SSG partial uptake | 0 | 2 |
| Tendon exposure | 0 | 0 |
| Cellulitis | 0 | 0 |
| Poor Scar | 0 | 30 |

**Fig 14**

**Fig 15**

Figure 14 Shows no donor site morbidity with SIPF Flap; however, there was a scar on the RFFF arm in the visible area, as shown in Fig 15

**5.5 Pathological outcomes**

On histopathological evaluation in the SIPF arm average, DOI was 7.50mm (0.9-29), total LN yield was 36.50(15-75), 1.41(0-4) in level IA, and 3.76in level 1b; however, in RFFF average DOI was 7.78mm with a total yield of 47, 2.47 in level 1a and 3.40 in level 1b. on statistically analysing the data, there was no significant difference between lymph node yield between SIPF and RFFF arms.

**Table 9**

| | | |
|---|---|---|
| **DOI** | 7.50mm 5.77(0.9-29) | 7.783 (4-14) |
| **LN yield** | | |
| IA total | 1.41(0-4) 1.228 | 2.47(0--7) |
| Positive 1a | 0 | 0.03 |
| 1b total | 3.76(1-12) 4.95 | 3.40(0-13) |
| Positive 1b | 0.235(0-1)0.437 | 0.37 |

**5.6 Functional outcomes**

All the patients were followed up after three months to assess the functional outcomes and Quality of life of patients with oral cancer. Patients were assessed for cosmetic outcomes based on satisfaction from 0-10. In functional outcomes, patients were assessed for oral competency, salivation, swallowing, and ability to take food (RT feed, liquid, semisolid, solid ) numbered from 0-10. we also used the QLQ-H&N35 module, including Seven multiple-item scales which measure symptoms of pain, swallowing capacity, senses (taste and smell), speech, social eating, social contact, and sexuality. Six single-item ratings assess symptoms of mouth opening, dry mouth (xerostomia), sticky saliva, coughing, and general malaise. A high score on the symptom scales indicates an elevated level of symptomatology.

Cosmetic satisfaction(Table 10) was more in the SIPF arm as most of the tumours were removed by the intraoral approach, and there was no donor site morbidity; a however significant number of patients complained of intraoral hairs in the SIPF arm.

**Table 10**

| | **SIPF** | **RFFF** |
|---|---|---|
| Cosmetic satisfaction | 6.80 ± .0997 | 5.93±1.437 |
| Intraoral hairs | 8 | 0 |

The speech was numbered from 0-10 based on the patient's ability to speak and express. On three months follow up, functional outcomes were almost similar in both arms with an average score of speech (6.9 SIPF,5.93 in RFFF) p-value 0.330, Swallowing (7.00SIPF, 6.67RFFF), p-value 1.19 However SIPF arm have more seroma formation and intraoral hairs

(pvalue<0.01) with no donor site morbidity. SIPF and RFFF arms do not significantly differ in functional outcomes.

**Table 11**

| **Functional outcomes** | **SIPF** | **RFFF** |
|---|---|---|
| Speech | 6.93±1.143 | 5.93±1.437 |
| Swallowing<br>Tongue movements | 7.00± 1.145<br>7.07 ±1.143 | 6.47±1.252<br>6.67±1.093 |
| Seroma formation | 3(10%) | 2 |
| Donor site morbidity | 0 | 30 |
| EORTC QoL Score | 38.07±4.95 | 38.90±4.27 |
| Modified DASH Score | 31.41±1.5 | 31.95±2.65 |

Submental flap offers the advantage of decreased operative time, hospital stay, and ICU stays with comparable LN harvest rate and acceptable cosmetic and functional outcomes compared to RFFF**.** The submental flap can be an excellent alternative to RFFF with comparable outcomes and less morbidity in a low-resource setting.

# DISCUSSION

# 6. DISCUSSION

Free flap reconstruction of the head and neck, which emerged in the 1980s and 1990s, marked a significant advancement over earlier pedicled methods like the pectoralis major flap and the deltopectoral flap.[41]

This was mainly because the surgeon could use free tissues that were more suitable for a specific defect and were able to place it in a more appropriate way than a pedicled flap. However, the introduction and widespread use of the submental flap in 1993 showed that this new pedicled alternative might provide more desirable tissue than was previously possible with other pedicled flaps. Additionally, it has enough mobility to easily access a range of typical defects. Since then, several defects in the head and neck, including those of the face, neck, tongue, buccal space, oropharynx, and hypopharynx, have been restored using the SIPF[42,43] Although numerous authors have written about their experiences with the submental flap, there aren't many studies that contrast the SIPF with the RFFF, which is the most widely used option.

In our study, we randomized the patients preoperatively in two arms. The SIPF arm is compared to the RFFF arm over multiple dimensions to better assess the advantage and shortcomings of both flaps. In the literature, there lacks a randomized study to compare both flaps. Some studies have been published that compared SIPF and RFFF flaps through retrospective data and hospital records but lack randomization. While comparing the flaps in terms of intraoperative and perioperative outcomes, SIPF has several advantages over RFFF. The shortest operative time observed with the SIPF is the first of these. There are usually three areas for which operative time is saved which include flap harvest time, which is usually less than one hour in experienced hands in RFFF but may take more time; however, in the case of SIPF flap, it is done almost as a step of neck dissection, and raising flap took less than 30 mins. In the case of RFFF, we have to spend time on vascular selection and the major part of the time in microvascular anastomosis. Previous studies also demonstrated similar outcomes with shorter surgery duration with SIPF reconstruction compared to RFFF. Shorter operative timeframes should reduce some patient issues and the cost of care, according to previous studies of patient complications and cost of care. However, these were not specifically examined in the current investigation.

While comparing the outcomes, we studied previous data available and found that all previous studies concluded that SIPF flap is associated with lesser operative time and patient time compared to RFFF. In 2011, Payadafer et al.[44] studied data using 27 SIPF and 33 RFFF

reconstructions and found that SIPF is associated with lesser time. Other studies by Fabrizio Schoener, D Forner[34], Nawaf Aslam[35], Akshya Patel[36], and Urjeet Patel [45]have similar results, as shown in Table.

Joseph A.payadarfer and Pasdaran M. D. et al. compare the intraoperative, postoperative, and functional outcomes of SIPF vs. Radial free forearm flap repair for the tongue and floor of the mouth. He looked at 60 patients, 27 of whom underwent SIPF repair, and 33 underwent RFFF flap. The two groups' sex, age, and TNM stage were comparable. The mean flap size for SIPF (36 cm2) was smaller than for RFFF (50 cm2). Compared to patients who underwent RFFF, patients undergoing SIPF stay in the hospital for a shorter time . However, the two groups' functional results were comparable. Because patients were not randomized and more T3 and T4 patients were in the RFFF group, this study's primary weakness was selection bias.

Fabrizio Schoenauer, Annulene Di Martino, et al. (2016) concluded that the submental artery flap is a viable choice for reconstructing composite oral cavity abnormalities. It is a great substitute for free flaps, especially in elderly or high-ASA-risk patients. The shorter recovery time and easily hidden donor-site incision make it a smart choice.

D Forner T Philips[34] et al. (2016) conducted a retrospective study from 2013 to 2015 and analyzed all the patients who were operated on with SIPF and RFFF. They compared the patient outcome, ICU stay, and hospital cost burden in both arms and concluded that in glossectomy RFFF repair, the average length of ICU stay was 4.7 days; however, In the SIF group, just one patient had to spend one night in the ICU. In the SIPF arm mean operating time was less than the RFFF group's (347 vs. 552 min., p 0.05). Both groups did not have a statistically significant difference in mean hospital stays (12.4 vs. 15.4 days, $p > 0.05$). However, they concluded that in RFFF expanse was more than in SIPF. They concluded that SIPF could act as a better alternative to RFFF with a low hospital stay, less operative time, and comparable functional and cosmetic outcomes.

Nawaf Aslam, Steven J, et al. (2017)[35] compared SIPF and RFFF for oncologic safety and viability of equivalent reconstructive outcomes. The Submental flap group's median age was 61.8 years compared to the RFFF group's 57.9 years. Flap volumes were compared favourably (SIPF, 38.79 cm3; RFFF, 39.77 cm3). Shorter anaesthetic periods (815 vs. 1,209 minutes; P .001), shorter operating times (653 vs. 1,031 minutes; P .001), and reduced blood loss (223 vs. 398 mL; P =.04) were among the significant comparing outcomes with SIPF versus RFFF reconstruction. They found that Recipient site complication rates were lower in

the RFFF group (0.17 vs. 0.42 per patient) but not statistically relevant. There were no differences in speech and swallowing function on a median follow-up of 15.5 months.

In a study by Akshaya Patel[36], Jason E. et al. (2018), 73 patients with head and neck cancer—of which 19 underwent SIPF, and 54 underwent free flap reconstruction—were included. Variables across two cohorts, including operating time, flap size, duration of stay, regional recurrence, disease-free survival, and overall survival, were compared using comparative statistics. SIPF is adaptable and seems a great option for reconstruction with shorter operating times, fewer complications, and similar results. Additionally, retrospective in nature, this study exhibits non-randomization and selection bias.

Urjeet A. Patel, MD (2019), conducted retrospective research on patients at two academic tertiary care facilities [37]Between 2004 and 2016, consecutive patients who underwent cancer excision and repair with SIPF or RFFF were included. They retrieved data on cancer staging, surgical technique, hospital stay, complications, functional outcomes, and oncologic outcomes. They concluded that the SIPF greatly cuts down on both operating time and hospital stay. Functional and oncologic outcomes are comparable, and the SIPF is a good alternative. For head and neck reconstruction, the SIPF is a wise first option.

Fanny Garysz, Paul Tabet**,** et al. conducted a systemic review. They included prospective and retrospective articles that specifically contrasted the use of pedicled versus free flaps for head and neck reconstruction[38]Following the screening procedure, 30 articles were included for quality analysis. They concluded all the investigations that submental flap had equivalent outcomes to free flap for some particular indications, attaining similar results at less expense. Given a similar functional outcome and superior performance in terms of OR time, hospitalization/ICU length, and repair of head and neck tissue abnormalities, SIPF can be viewed as an acceptable alternative to a free flap. Additionally, it has been stated that SIPF offers better colour matching for cervicofacial skin flaws.

In a meta-analysis of several PubMed and Google Scholar papers, Shirley Hu, Caleb Fan, and colleagues (2020) compared the submental flap to the RFFF flap. [39]Three hundred fifty-three studies were found in the initial search, but only five were considered final for metanalyses. For the SIPF and free tissue transfer cohorts, the sample sizes for all investigations ranged from 9 to 45, respectively. They concluded that, compared to Free tissue transfer, Submental flap is associated with shorter hospital stays, less postoperative pain, fewer perioperative complications, and maybe equivalent rates of disease recurrence.

So, in our study, we concluded that operative time was 218.4 min ±28.67min (186-290) for the SIPF arm and 491.77± 56.51 (440-640) for the RFFF arm indicating RFFF was more

complex and time taking with the statistically significant difference in operative time (p-value <0.01).

The mean hospital stay was calculated as 4.83 days ± 1.26 (3-8) days for SIPF, 7.17± 1.55 (5-11) days for RFFF (pvalue<0.001), including Icu stay of 0.2± 0.5 (0-2)days for SIPF and1.1± 0.54(1-3)days for RFFF (pvalue<0.001) showing that there is a statistically significant difference in hospital stay in both arms and SIPF arm is associated with shorter hospital stay and minimal ICU stay.

**Table 12**

| **Study** | **Year** | **Number** | | **Operative time** | | **Hospital stays** | |
|---|---|---|---|---|---|---|---|
| | | **SIPF** | **RFFF** | **SIPF** | **RFFF** | **SIPF** | **RFFF** |
| Payadarfar et al[33] | 2011 | 27 | 33 | 524min | 780 mi | 10.6 | 14 |
| Franz Joseph Kramer et al | 2015 | 45 | 45 | shorter | | Shorter | |
| Fabrizio Schoenauer et al | 2016 | | | Less time | | Shorter | |
| D Forner [34,35] | 2016 | 9 | 12 | 347 | 552 | 12.4 | 15.4 |
| Nawaf aslam et al [35] | 2017 | | | 653 | 1031 | Shorter stay | |
| Akshaya Patel et al[36]. | 2018 | 19 | 54 | 412 | 544 | Shorter stay | |
| Urjeet A. Patel [37] | 2019 | 57 | 89 | 365 | 540 | 8days | 10days |
| Fiu-liu et al [46] | 2013 | 27 | 33 | 354 | 512 | Shorter stay | |

Franz Joseph Kramer et al. 2015 conducted a prospective study and compared 45 patients of SIPF with RFFF and concluded that a flap success rate of 93.3% with SIPF with acceptable functional results without donor site morbidity and concluded that SIPF was associated with decreased operative time, hospital stay and no enhanced risk of recurrence. The SIPF is related to lower morbidities, shorter operation times, and reduced hospitalization compared to free flap reconstructions providing similar functional results as free flap reconstructions.

### 6.1 Flap monitoring

In the SIPF arm, flap monitoring was done twice a day, while in the RFFF arm, there was two hourly monitoring done by plastic surgery residents. It's also possible that simply because the flap is pedicled, there is a perception that it is less fragile and that oral feeding and any potential neck fistulas pose less of a hazard to the flap, enabling oral diet earlier than is done for the RFFF. The length of hospital stay was significantly greater for the entire RFFF group. This may be partially attributable to a protracted hospitalization in the intensive care unit (ICU) as part of a free flap monitoring strategy, which is in line with well-documented practice.[47] Although we excluded cost analysis from the current study, a shorter hospital stay would probably result in lower overall healthcare costs. As a result, one would anticipate that the cost analysis of the research's patients would validate the SIPF's ability to reduce costs, perhaps for the same reasons as mentioned in Forner et al. earlier study.[34]

### 6.2 Rexploration rate

When discussing potential strategies for flap reconstruction, the fundamental topic of flap survival must come first. The RFFF has a long history of accomplishment and a solid dependability reputation. [48,49] Many studies show success rates above 95%, and more recent, big trials show 98% to 99%. In our study, the flap success rate was 90% for the RFFF group, comparable to previous studies.

In previous studies, as shown in the Table, the flap success rate of the submental flap ranges from 66.7% to 98% based on different institutional experiences. In our study flap failure rate was 2/30(6.66%) for complete necrosis and 2 /30 (6.66%) for partial necrosis. That was comparable to previous studies, which demonstrated that the SIPF functions just as well as RFFF. The SIPF's validity has been questioned by others, who point to greater rates of partial or whole flap necrosis. Studies that support the SIPF reliability have shown flap full survival rates that are competitive with RFFF.[50] The fact that flap dependability and success are comparable to and consistent with success rates established in earlier research looking at each approach alone is uniquely demonstrated by this study, which is the largest to date directly comparing these two techniques.

On statistical evaluation, there was no significant difference between the flap failure rate between the two arms; however, the RFFF arm required more monitoring and a higher reexploration rate of 6/30(20%), out of which four are due to venous thrombosis and two related to hematoma.

**Table 13**

| SIPF | year | Flap success rate |
|---|---|---|
| C.B. Pan et al[51] | 2020 | 96.8% |
| Bin Jou et al [52] | 2022 | 98% |
| Fiu-liu et al [46] | 2013 | 92.5 % |
| Lee et al [53] | 2013 | 66.7% |
| Patel et al[54] | 2007 | 80% |
| Wu et al 38[55] | 2002 | 89.5% |
| Wu y et al [56] | 1998 | 85% |

### 6.3 Donor site morbidity

If we focus on patient outcomes, we should always consider donor site morbidity while selecting a reconstructive strategy. Although the donor site problems associated with the RFFF were generally modest in frequency and severity, they are not wholly absent. [50,57]

When harvesting this flap, injury to the superficial branch of the radial nerve is an uncommon but substantial cause of morbidity. However, partial skin graft loss with ensuing tendon exposure in these individuals was more frequently reported. A subacute wound is created as a result, which eventually heals, albeit it may take a few weeks to do so and cause some wrist impairment. In our study**,** the observed frequency is comparable with findings from other free flap studies.[57] The SIPF almost eliminated donor site morbidity, supporting another published research's findings. The SIPF is typically integrated into the neck incision and does not constitute a wholly independent donor site, as is implicit with the RFFF, in circumstances where a concurrent neck dissection was undertaken. The risk of level IB neck dissection for the marginal mandibular branch of the facial nerve is comparable.

### 6.4 Functional Outcomes

Despite this qualification, the current investigation did not show any distinction between the two groups in terms of speech and swallowing function[58]. It is not surprising that functional outcomes should be similar given the similarity of tissue acquired with the two distinct flaps. The SIPF has been shown to perform better than the pectoralis major pedicled flap when inset into the oral cavity and oropharynx, despite the pectoralis major pedicled flap's poor functional outcomes in these regions.

Q.you et al. (2020) studied functional outcomes between primary closure, SIPF, and RFFF groups using UW-QoL V4 and EORTC QLQ-C30 V3 questionnaires. They concluded that the RFFF and SIPF groups are better than the Primary closure group. However, no statistically significant difference was observed when we compared SIPF with RFFF.

Earlier, Paydarfar et al[33]. compared postoperative swallowing and speaking in both SIPF as well as RFFF and concluded that there was no significant difference between 2 arms in speaking and swallowing function.

Urjeet et al.(2020 )[45] compared the functional outcomes of the submental island pedicled flap (SIPF) to the radial forearm free flap (RFFF).and concluded that there was no significant difference between functional outcomes in the two groups. In our study, we compared functional outcomes and found no statistical difference in 2 arms in speech, tongue movement, and swallowing that are equivalent, which is consistent with earlier studies that only looked at oral cavity reconstruction.[59]

**6.5 Pathological outcomes**

In oncology, our primary aim is to provide oncological clearance to patients. Since, at the submental group level, 1a is not adequately dissected. Theoretically, there remains some risk regarding the transfer of cancerous cells when level IA nodes are moved. Despite the possibility that this risk is minimal, it is surely not zero because level IA may contain latent disease for clinically undetected cutaneous and oral cavity carcinoma**.** Earlier, Paydarfar et al. compared oncological outcomes in both SIPF as well as RFFF and concluded that there was no significant difference in recurrence rate between the two arms.

The oncological safety of using the SF for oral cavity cancer reconstruction has been a controversial issue mainly because the flap is being harvested from a region that is a potential site for lymph node metastasis, and inadequate clearance may result in the transplantation of malignant cells. It is therefore mandatory that only those cases are selected for SF reconstruction where it is possible to clear level 1 lymph nodes satisfactorily.

Urjeet A et al. 2020[60] also compared oncological outcomes in both SIPF as well as RFFF and concluded that there was no significant difference in recurrence rate between the two arms

Hedenori Suzuki et al.[61] 2022 studied the lymph node ratio and survival of patients with submental flaps. In their study, they found the mean LN yield to be 29 ± 13.8 with positive LN 1 ± 2.55 and concluded that high-level LN ratio in HNSCC was a prognostic factor for survival outcomes after the operation with SIPF reconstruction. Since our study does not deal with prognostic factors due to the short follow-up duration, we still compared the LN yield

between both arms in 1A and 1B groups, there was no statistically significant difference between the two arms.

The oncological safety of using the SF for oral cavity cancer reconstruction has been a controversial issue mainly because the flap is being harvested from a region which is a potential site for lymph node metastasis and inadequate clearance may result in the transplantation of malignant cells. It is therefore mandatory that only those cases are selected for SF reconstruction where it is possible to clear level 1 lymph nodes satisfactorily

**Table 14**

| STUDY | SIPF | LN yield | OUTCOMES |
|---|---|---|---|
| Urjeet A et al[33] | 2020 | | No difference in oncological outcomes |
| Paydarfar and Patel[33] | 2011 | - | No difference in oncological outcomes |
| Sittitrai et al [62] | 2017 | - | No difference in oncological outcomes |
| Kramer et al [63] | 2015 | - | No difference in oncological outcomes |
| Howard et al[64] | 2014 | - | No difference in oncological outcomes |
| Thomas et al [65] | 2016 | - | No difference in oncological outcomes |
| Z.Z shen et al[66] | 2021 | - | No difference in oncological outcomes |
| Elzahaby, et al [67] | 2021 | 11-24 | No difference in oncological outcomes |
| Penamudu Prashant et al | 2022 | 18 | No difference in oncological outcomes |
| Hedenori Suzuki et al [61] | 2022 | 29 | No difference in oncological outcomes |

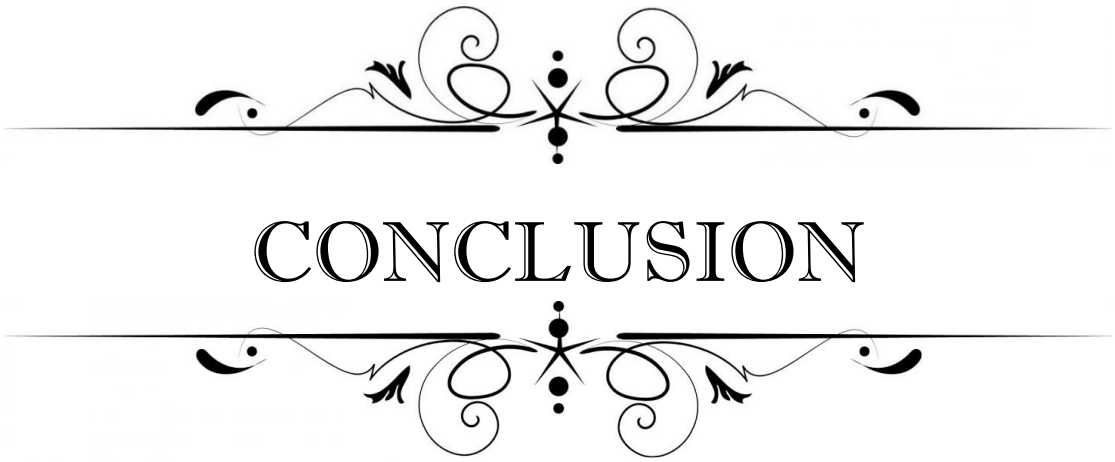
Prasanth Penumade et al. 2021 conducted a retrospective study on 38 submental flap patients and concluded average LN yield in SIPF reconstruction is 18. Elzahaby, Islam, et al. [67] conducted a retrospective study in Egypt on 36 patients who underwent submental flap reconstruction and SOHND and calculated the average LN yield in N0 patients 11-24 and N1 patients to be 12 to 33 LN and concluded that nodal harvest was >12 in 88% of patients.

Sittitrai et al[68,69]conducted a study on 35 patients of oral cavity reconstruction with Submental island pedicled flap and studied patients for a mean duration of 23 months and concluded that there was no significantly increased risk if LN were meticulously dissected.

Amin et al.[70]prescribed complete lymph node dissection before flap harvesting and advised that this flap should be avoided in those patients with clinically advanced nodal disease in the neck (> N0). Chow et al.[71]suggested that dissection in the subplatysmal plane would reduce the chances of tumor spread and inadequate clearance. The SIPF should be carefully recommended in patients who have a suspicion of level I involvement, taking into account the evidence that is currently available and the many flaps that are accessible for oral reconstruction.

The challenge of measuring this phenomenon further complicates the study of this problem. A local recurrence will eventually appear in the resection bed when a tumor is removed. The manifestation of malignancy transferred in a level IA node with the SIPF will likewise be similar and nearly identical to a genuine local recurrence. As a result, what patients who undergo SIPF reconstruction perceive as "local recurrence" is the total of real local recurrences and regional recurrence transferred with level IA. Any perceived local recurrence for individuals undergoing RFFF for whom there is no additional risk of malignancy will be correctly diagnosed as local recurrence. A higher observed local recurrence risk may be expected due to the transfer of clinically significant malignancy with level IA nodes in the SIPF. Between the SIPF and RFFF groups in the current study, there was no significant difference in LN yield between the two groups; however, a recurrence study was not conducted due to the limited period of our study.[59 72]

Submental flap offers the advantage of decreased operative time, hospital stay, and ICU stays with comparable LN harvest rate and acceptable cosmetic and functional outcomes compared to RFFF**.** The submental flap can be used as an excellent alternative to RFFF with comparable outcomes and less morbidity in a low-resource setting.



# CONCLUSION

# 7. CONCLUSION

- In our study a total of 60 patients were included in study with average age of 47.93yrs(25-71) out of which 40 patients were male and 20 patients were females Patients were randomly assigned between two arms out of which SIPF arm have mean age of 48.53± 11.16 yrs. with 21 Males and 9 Females while RFFF arm have average age 47.30± 10.58yrs with 19 males and 11 Female patients .
- Out of 60 patients analysed 38 were associated with history of chewing tobacco , 25 patients with history of tobacco and alcohol and 22 patients were not associated with any history of addiction or family history.
- Majority of patients were of early oral cancer that were either diagnosed incidentally on hospital follow up or during dental check-up. 34 patients were involving buccal mucosa ,19 tongue , 6 lip and 1 patient of Floor of mouth. The most common stage that was countered is stage II including 42 patients rest 14 in stage 3 and both stage 1 and IVA comprises of 2 patients each .
- In SIPF arm patients were most commonly involving buccal mucosa (15) , (12) tongue , (1) floor of mouth and (2) lip with 1patient in stage 1 stage III 8(26.6%), Stage IVA (3.33) In RFFF arm 20 male and 10 female with age of 46.60± 9.814years comprising of stage 1 (3.33%,) stage II 73.33% , Stage III 6(20%), stage IVA 1(3.33%) involving buccal mucosa(21) ,(6) tongue and (3) lip
- Mean operative time was 218.4 min ±28.67min (186-290) for SIPF arm and 491.77± 56.51 (440-640) for RFFF arm indicating RFFF was more complex and time taking with statistically significant difference in operative time (p value <0.01).
- The mean hospital stay was calculated as 4.83 days ± 1.26 (3-8) days for SIPF, 7.17± 1.55 (5-11) days for RFFF (P-value<0.001) including ICU stay of 0.2± 0.5 (0-2)days for SIPF and1.1± 0.54(1-3)days for RFFF (P-value<0.001) showing that there is statistically significant difference in hospital stay in both arms and SIPF arm is associated with shorter hospital stay and minimal ICU stay
- Flap monitoring was more crucial in RFFF arm requiring hourly monitoring by plastic surgeon resident however monitoring was done 2 times in a day on morning and evening round in SIPF arm.
- Re exploration rates were higher in RFFF arm with 6 (16.6%)patients were reexplored in RFFF a and 4 (13.3%)patients were reexplored for flap congestion in immediate

postoperative period however no re exploration was done in patient of SIPF arm with 2 patients requiring suture removal for flap congestion

- Flap uptake was good in both arms with complete flap uptake seen in 26 patients without any major complication however 2 patients underwent partial epidermal loss with vascularized muscle leading to flap uptake on conservative management however 2 patients required salvage flap .In RFFF arm 24 patients were discharged with complete flap uptake and no major complication. However, 6 patients required re exploration out of which 3 patients were with complete flap loss requiring salvage flap and 4 patients underwent redo anastomosis in view of venous thrombosis. Though Oro cutaneous fistula and re-exploration rate were higher in RFFF but data was statistically not significant.
- When comparing donor site morbidity there was no donor site morbidity in SIPF arm however in RFFF arm there was partial uptake of SSG in 2patients. There was poor scar at donor site in all patients in RFFF group. However no gross weakness or thenar hypotrophy seen in patients
- On histopathological evaluation in SIPF arm average DOI was 7.50mm (0.9-29), LN yield was 1.41(0-4) in level IA and 3.76in level 1b however in RFFF average DOI was 7.78mm with, 2.47 in level 1a and 3.40 in level 1b. on statistically analysing the data there was no significant difference between lymph node yield between SIPF and RFFF arm .
- On 3 months follow up cosmetic satisfaction was more in SIPF arm as most of tumours were removed by intraoral approach and there was no donor site morbidity however significant number of patients complained of intraoral hairs in SIPF arm.
- Functional outcomes were almost similar in both arms with average score of speech (6.9 SIPF ,5.93 in RFFF) p value 0.330, Swallowing (7.00SIPF , 6.67RFFF),p value 1.19 However SIPF arm have more seroma formation and intraoral hairs (p value<0.01) with no donor site morbidity. Both SIPF and RFFF arm do not have significant difference in functional outcomes.
- Submental flap offers advantage of decreased operative time, hospital stay, ICU stay with comparable LN harvest rate and maintaining acceptable cosmetic and functional outcomes in comparison to RFFF. The submental flap can be used as excellent alternative to RFFF with comparable outcomes and less morbidity in low resource setting

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# ANNEXURES

# 9. APPENDIX

## 9.1 Ethical Clearance Certificate

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
**All India Institute of Medical Sciences, Jodhpur**
संस्थागत नैतिकता समिति
**Institutional Ethics Committee**

**No. AIIMS/IEC/2021/**3522 **Date: 12/03/2021**

**ETHICAL CLEARANCE CERTIFICATE**

Certificate Reference Number: **AIIMS/IEC/2021/3357**

Project title: **"Submental Island pedicled flap vs Radial forearm free flap for reconstruction of oral cavity (SIRFROC) - A randomized controlled trial"**

| | |
|---|---|
| Nature of Project: | **Research Project Submitted for Expedited Review** |
| Submitted as: | **M.Ch. Dissertation** |
| Student Name: | **Dr. Mohit** |
| Guide: | **Dr. Jeewan Ram Vishnoi** |
| Co-Guide: | **Dr. Sanjeev Misra, Dr. D Jay Kumar, Dr. Prakash Kala, Dr. Pawan Kumar Dixit, Dr. Puneet Pareek & Dr. Rakesh Kumar Vyas** |

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.
- In case of any issue related to compensation, the responsibility lies with the Investigator and Co-Investigators.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation. If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.

**Dr. Praveen Sharma**
Member Secretary

Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

Basni Phase-2, Jodhpur, Rajasthan-342005; **Website:** www.aiimsjodhpur.edu.in; **Phone:** 0291-2740741 Extn. 3109
**E-mail** : ethicscommittee@aiimsjodhpur.edu.in; ethicscommitteeaiimsjdh@gmail.com

## 9.2 Proforma

**Submental Island pedicled flap vs Radial Forearm free flap for Reconstruction of Oral Cavity (SIRFROC) - A Randomized controlled trial**

**PROFORMA**

Patient's Name _____ Case number _____

Hospital ID AIIMS/JDH/_____ Age/ Sex _____

Primary subsite _____ Date of Evaluation _____

Phone number _____ Date of Surgery _____

| | | |
|---|---|---|
| Occupation | | |
| Chief complaints | ☐ Non-healing ulcer<br>☐ Pain<br>☐ Others _____ | ☐ Bleeding<br>☐ Trismus |
| Tobacco intake | Yes / No | |
| | If yes, then<br>• Type of product (encircle): gutkha/ zarda/ khaini/ miraj/ paan masala/ beedi/ cigarette/ others please specify _____<br>• Mode of intake (encircle): Oral/ Inhalational<br>• Frequency of intake: _____ / day<br>• Duration of intake: _____ years | |
| Alcohol intake | Yes / No | |
| | If yes, then<br>• Type of product: _____<br>• Amount per intake: _____ mL<br>• Frequency of intake: _____<br>• Duration of intake: _____ | |
| Other risk factors if any | | |

| Examination | | | | |
|---|---|---|---|---|
| General Condition | ☐ Good<br>☐ Average<br>☐ Poor | Performance Status | ☐ ECOG 1<br>☐ ECOG 2 | ☐ ECOG 3<br>☐ ECOG 4 |
| Mouth opening | _____ Finger(s) | Oral Hygiene | ☐ Good ☐ Poor | |
| | | Ankyloglossia | ☐ Yes ☐ No | |

| | | | | | |
|---|---|---|---|---|---|
| Subsite of primary tumor | ☐ Oral tongue<br>☐ Buccal Mucosa<br>☐ Lower Alveolus<br>☐ Upper Alveolus | | ☐ Retromolar Trigone<br>☐ Hard Palate<br>☐ Floor of Mouth<br>☐ Lip | | |
| Size of the primary tumor | ☐ ≤ 2 cm<br>☐ > 2 cm but ≤ 4 cm<br>☐ > 4 cm | Overlying skin involvement | ☐ Yes ☐ No | | |
| Bone involvement | ☐ Yes ☐ No | Clinical 'T' staging | ☐ T1 ☐ T2 ☐ T3<br>☐ T4a ☐ T4b | | |
| Tumor morphology | ☐ Verrucous ☐ Ulceroproliferative ☐ Ulceroinfiltrative | | | | |
| Neck nodes | Ipsilateral side | | Contralateral side | | |
| | Size of the largest LN | ☐ ≤ 3 cm<br>☐ > 3 cm; ≤ 6 cm<br>☐ > 6 cm | Size of the largest LN | ☐ ≤ 3 cm<br>☐ > 3 cm; ≤ 6 cm<br>☐ > 6 cm | |
| | Number of LNs | ☐ Single<br>☐ Multiple | Number of LNs | ☐ Single<br>☐ Multiple | |
| | Level of LNs | ☐ IA ☐ IB<br>☐ II ☐ III<br>☐ IV ☐ V | Level of LNs | ☐ IA ☐ IB<br>☐ II ☐ III<br>☐ IV ☐ V | |
| | Matted | ☐ Yes ☐ No | Matted | ☐ Yes ☐ No | |
| Clinical 'N' staging | ☐ N0 ☐ N1<br>☐ N2a ☐ N2b ☐ N2c<br>☐ N3a ☐ N3b | | | | |

| Investigations | | | |
|---|---|---|---|
| CECT Head and Neck | | | |
| CECT Thorax | | | |
| MRI | | | |
| Biopsy | ☐ WDSCC | ☐ MDSCC | ☐ PDSCC |

| Neoadjuvant Treatment received | | | | | |
|---|---|---|---|---|---|
| Neoadjuvant chemotherapy | ☐ Yes<br>☐ No | NACT Regimen given | ☐ TPF (Docetaxel, Cisplatin, 5-FU)<br>☐ Carboplatin + Paclitaxel<br>☐ Metronomic (Methotrexate) | | |
| Number of cycles | | Date of initiation (1st) | | | |
| | | Date of last NACT | | | |
| Response to NACT | ☐ Complete | ☐ Partial | ☐ Stable | ☐ Progression | |

| Surgery Details | | |
|---|---|---|
| Date of Surgery | | |
| **Area resected** | | |
| Soft tissue | ☐ Buccal Mucosa ☐ Lip ☐ RMT ☐ FOM ☐ Tongue ☐ Skin | |
| Bony resection: Mandible | ☐ Yes ☐ No<br>Type: ☐ Segmental ☐ Hemi-mandibulectomy ☐ Marginal | |
| Maxillary alveolectomy | ☐ Yes ☐ No | |
| Others | | |
| **Neck Dissection**: | ☐ Ipsilateral | ☐ SOHND ☐ Extended SOHND ☐ RND<br>☐ MRND sparing SAN/ IJV/ SCM |
| | ☐ Contralateral | ☐ SOHND ☐ Extended SOHND ☐ RND<br>☐ MRND sparing SAN/ IJV/ SCM |
| | ☐ Bilateral | ☐ SOHND ☐ Extended SOHND ☐ RND<br>☐ MRND sparing SAN/ IJV/ SCM |
| Operative Findings: | Primary: | |
| | Neck: | |
| Tracheostomy | ☐ Yes ☐ No | |
| Reconstruction:<br>☐ Yes ☐ No | Inner Lining | ☐ Primary closure ☐ Raw ☐ STSG<br>☐ PMMC ☐ Bi-paddle PMMC<br>☐ Nasolabial ☐ Forehead<br>☐ Free radial/ ALT/ Fibular |
| | Outer cover | ☐ Primary closure ☐ Bi-paddle PMMC<br>☐ Nasolabial ☐ Forehead ☐ Deltopectoral<br>☐ Free radial/ ALT/ Fibular |

| | |
|---|---|
| Duration of surgery | |
| Intraoperative blood loss | <500ml 500-1000ml<br>>1litre |
| Flap defect | |
| Length of hospital stay | |
| Donor site complication | |
| Flap complication | |

**Outcomes at 3 months**

| | |
|---|---|
| Speech | Excellent<br>Good<br>Poor<br>Always understandable<br>Usually understandable<br>Difficult to understand |
| Swallowing | Full normal diet<br>Semisolid diet<br>Liquid diet<br>Combined oral and RT Feed<br>Ryles tube feeding only |
| Cosmetic satisfaction | Very satisfied 7-10<br>Satisfied 4-6<br>Poor 1-3 |
| Donor site complication | No complications at present<br>Partial loss<br>Tendon exposure |

## 9.3 EORTC Form

HINDI

EORTC QLQ - H&N35

मरीज कभी कभी निम्न रोग लक्षणों या परेशानियों की शिकायत करते हैं | कृपया इंकित करे कि पिछले एक सप्ताह के दौरान आपने किस हद तक इन रोग लक्षणों या परेशानियों का अनुभव किया है | आपको जो उत्तर सबसे अधिक सही लगे, उसके अंक पर कृपया अंकित करे ||

| पिछले एक सप्ताह के दौरान | बिलकुल नही | थोडासा | थोडा अधिक | बहुत अधिक |
|---|---|---|---|---|
| ३१.क्या आपके मुँह में दर्द उठा था? | १ | २ | ३ | ४ |
| ३२.क्या आपके जबडों में दर्द उठा था? | १ | २ | ३ | ४ |
| ३३.क्या आपके मुँह में कसौलापन हुआ था? | १ | २ | ३ | ४ |
| ३४.क्या आपके गले में दर्द हुआ था? | १ | २ | ३ | ४ |
| ३५.क्या आपको तरल पदार्थ निगलने में तकलीफ हुई थी? | १ | २ | ३ | ४ |
| ३६.क्या आपको पिसा हुआ पदार्थ निगलने में तकलीफ हुई थी? | १ | २ | ३ | ४ |
| ३७.ठोस खाना निगलने में क्या आपको तकलीफ हुई थी? | १ | २ | ३ | ४ |
| ३८.निगलने के दौरान क्या आपका दम घुटता है? | १ | २ | ३ | ४ |
| ३९.क्या आपके दॉतो को लेकर आपको कोई परेशानी हुई थी? | १ | २ | ३ | ४ |
| ४0.कया आपका मुँह ज्यादा खोलने में तकलीफ हुई थी? | १ | २ | ३ | ४ |
| ४१.क्या आपके मुँह में कभी सूखापन महसूस हुआ था? | १ | २ | ३ | ४ |
| ४२.क्या आपका थूक चिपचिपा हुआ था? | १ | २ | ३ | ४ |
| ४३.क्या आपकी सूंघने की क्षमता के बारे में आपको कोई समस्या हुई थी? | १ | २ | ३ | ४ |
| ४४.क्या आपके स्वाद की क्षमता के बारे में आपको कोई समस्या हुई थी? | १ | २ | ३ | ४ |
| ४५.क्या आपको खॉसी हुई थी? | १ | २ | ३ | ४ |
| ४६.क्या आपको गले में खराश थी? | १ | २ | ३ | ४ |
| ४७.क्या आपको लगताा था कि आप बीमार हैं? | १ | २ | ३ | ४ |
| ४८.क्या आपका स्वरूप आपको परेशान करता था? | १ | २ | ३ | ४ |

अगले पन्ने पर

| पिछले एक सप्ताह के दौरान | बिलकुल नही | थोडासा | थोडा अधिक | बहुत अधिक |
|---|---|---|---|---|
| ४९. क्या आप खाने में कठिनाई महसूस करते थे? | १ | २ | ३ | ४ |
| ५0. क्या आपको अपने परिवार के सामने खाना-खाने में कठिनाई हुई थी? | १ | २ | ३ | ४ |
| ५१. क्या आपको दूसरे लोगों के सामने खाना खाने में कठिनाई हुई थी? | १ | २ | ३ | ४ |
| ५२. अपने भोजन का आनंद उठाने में क्या आपको तकलीफ हुई थी? | १ | २ | ३ | ४ |
| ५३. क्या आपको दूसरे लोगों के साथ वात करने में तकलीफ हुई थी? | १ | २ | ३ | ४ |
| ५४. क्या आपको टेलीफोन पर वात करने में तकलीफ हुई थी? | १ | २ | ३ | ४ |
| ५५. क्या आपको अपने परिवार के साथ सामाजिक संपर्क रखने में तकलीफ हुई थी? | १ | २ | ३ | ४ |
| ५६. क्या आपको अपने दोस्तों के साथ सामाजिक संपर्क करने में तकलीफ हुई थी? | १ | २ | ३ | ४ |
| ५७. क्या आपको आम जनता के सामने जाने में तकलीफ हुई थी ? | १ | २ | ३ | ४ |
| ५८. क्या आपको परिवार या दोस्तों के साथ शरीरिक संपर्क करनें में तकलीफ हुई थी? | १ | २ | ३ | ४ |
| ५९. क्या आपको यौन संवंध में रूचि कम लगती थी? | १ | २ | ३ | ४ |
| ६0. क्या आपको यौन संवंधी आनंद में कमी लगती थी? | १ | २ | ३ | ४ |

| पिछले एक सप्ताह के दौरान | नही | हॉ |
|---|---|---|
| ६१. क्या आपने दर्द निवारक दवाई ली थी? | १ | २ |
| ६२. क्या आपने (जीवनसत्व छोडकर)कोई पूरक पोषण पदार्थ का सेवन किया था? | १ | २ |
| ६३. क्या आपने खाने के लिए नली का प्रयोग किया था? | १ | २ |
| ६४. क्या आपका वजन कम हुआ था? | १ | २ |
| ६५. क्या आपका वजन वढ गया था? | १ | २ |