CONDYLAR RECONSTRUCTION WITH VERTCAL RAMUS OSTEOTOMY IN TEMPORO-MANDIBULAR JOINT ANKYLOSIS PATIENTS

DISSERTATION SUBMITTED TO BABU BANARASI DAS UNIVERSITY LUCKNOW, UTTAR PRADESH

In the partial fulfillment of the requirements of the degree of MASTERS OF DENTAL SURGERY

IN

ORAL'AND MAXILLOFACIAL SURGERY

BY .

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LIST OF ABBREVIATIONS

- VRO- Vertical ramus osteotomy
- IVRO- Intra-oral vertical ramus osteotomy
- EVRO- Extra-oral vertical ramus osteotomy
- UIVRO- Unilateral vertical ramus osteotomy
- SSO- Sagittal split osteotomy
- BSSO- Bilateral sagittal split osteotomy
- MMO- Maximal mouth opening
- TMJ- Temporo-mandibular joint
- CT- Computed tomography
- IMF- Intermaxillary fixation
- MMF- Maxillo-mandibular fixation
- SSRO- Sagittal split ramus osteotomy
- RCU- Ramus condyle unit
- SLO- Short lingual osteotomy
- CCG- Costochondral graft

ABSTRACT

- **AIMS & OBJECTIVES-** The purpose of this study is to assess the outcomes of vertical ramus osteotomy on the posterior border of mandibular ramus for reconstruction of ramus-condylar unit in patients treated for TMJ Ankylosis and to evaluate the pre-operative and post-operative mouth-opening, pre-operative and post-operative ramal height and the range of mandibular movements and lateral excursive movements.
- MATERIALS & METHODS- Pre-operative preparation of the patient included detailed history, complete clinical examination; radiological examination like orthopantomogram (OPG), lateral cephalogram, frontal and lateral photographs with maximal mouth opening (MMO). Immediate reconstruction of the condyle by vertical ramus osteotomy was performed in 5 patients in the Department. Arthrectomy was performed by the preauricular approach by Alkayat-Bramley incision as well as simultaneous condylar reconstruction using a sliding osteotomy of the posterior border of the mandible pedicled on the medial pterygoid muscle. Clinical and radiological follow-up was carried out along with occlusion, pain and resorption evaluated.
- **RESULTS-** An increase in the maximum mouth opening at 1 week, 3rd month and 6th month post-operatively was seen. Improved range of mandibular movements i.e., lateral excursion and protrusive movements at 1 week, 3rd month and 6th month post-operatively. Significant changes were observed in the height of ramus of mandible at pre-operatively, immediate post-operatively, 3rd month and 6th month on radiographic evaluation. There was significant decrease in the pain score from 1st day to 10th day and the reduction in pain was significant through all the time intervals. No complications were recorded post-operatively.
- **CONCLUSION**-The study concluded that vertical ramus osteotomy is a promising method for RCU reconstruction in patients with TMJ ankylosis in terms of form and function. Although this method of reconstruction lacks growth potential, but undergoes significant remodeling near new joint function. Hence, this method

seems to be an excellent option for patients who do not require growth potential. Continued deliberation with large sample size and a longer follow up will be required to draw definitive indication of the procedure.

INTRODUCTION

Temporomandibular joint (TMJ) ankylosis is a distressing structural condition identified by loss of jaw movements due to formation of fibrous, osseous, or fibro-osseous accumulations fused to skull base. It leads to partial or complete inability to open the mouth and mandibular micrognathia and reduces the normal functional spurs necessary for the development of the maxillofacial structure, which leads to alterations in eating habits and speech ability.¹ It also causes severe facial disfigurement that can induce psychological stress and severely decreases quality of life. Ankylosis of TMJ is of 2 types, True and False. This is based on the causing factor of the ankylosis. Most of the time the condition is chronic and painless, but sometimes the TMJ ankylosis may cause some pain depending on the cause of the ankylosis and while opening of the mandible.²

Although the primary cause of TMJ ankylosis is trauma which results in haemarthrosis followed by ossification, there are other etiologic factors such as rheumatoid arthritis, Paget's disease, ankylosing spondylitis, pseudo-hypothyroidism, psoriasis and burns, and local and systemic infections like otitis media or mastoiditis.¹ Interincisal opening (IO) shows the severity of the ankylosis which is responsible for determining the thickness of the ankylotic mass. TMJ ankylosis has often been found in growing individuals. As a result, mandibular micrognathia takes place leading to facial asymmetry. Deviation of the chin towards the affected side and reduction of the vertical height of the ramus on the affected side are the prominent features that are seen in unilateral cases of temporomandibular joint ankylosis. This also affects the soft tissues surrounding the mandible, resulting in shortening of the pterygo-massetric muscle sling and the ligaments attaching the mandible to the skull base.³

Treatment options for TMJ Ankylosis aim at restoring joint function, restoration of proper mandibular length and form, improving the patient's aesthetics and quality of life, preventing re-ankylosis and achieving normal growth and occlusion in the patient. Preservation of this joint or construction of an artificial one that functions properly is of prime importance.²

Several methods have been used for the treatment of TMJ Ankylosis including release of the ankylosis and creation of a gap with or without insertion of interposing material and complete reconstruction of the joint and correction of jaw deformities. Several autologous bone grafts are used to reconstruct the ramus-condyle unit (RCU) including metatarsal head, costochondral, sternoclavicular, iliac crest, clavicular bone grafts etc. Resected elongated coronoid process and excised ankylotic mass have also been tried.⁴

As these are non-pedicled grafts, in the long term they may lead to resorption with subsequent decrease in height of the ramus, facial asymmetry, deviated mouth opening and re-ankylosis. Furthermore, these procedures suffer from several drawbacks repeatedly stated in literatures, such as the need for second surgical sites, growth unpredictability and donor site morbidity. Joints reconstructed with alloplastic materials have experienced infection and wear and/or failure of the material, particles generating a giant cell foreign body reaction with potential loosening of the implant resulting in occlusal change, displacement or fracture, high cost, dystrophic bone formation, and lack of growth, which precludes the use of such joints.⁵

Posterior border of the mandibular ramus has been used as a pedicled graft for condylar reconstruction in maxillofacial surgery for a long time. Vertical ramus osteotomy (VRO) for reconstruction of the RCU in TMJ Ankylosis corrects the function, morphology of the orofacial structure, is safe, effective and less invasive. Thus, exploration of two surgical sites, donor site morbidity and graft resorption are readily avoided.²

Taking these advantages into consideration a study was carried out in the Department of Oral and Maxillofacial Surgery of our institution on patients with TMJ Ankylosis with the aim to evaluate the feasibility of VRO on the posterior border of the mandibular ramus for reconstruction of the RCU.

AIM

Aim of the study is to assess the outcomes of vertical ramus osteotomy on the posterior border of mandibular ramus for reconstruction of ramus-condyle unit in patients treated for Temporo-mandibular joint ankylosis.

OBJECTIVES

The objectives of the study will be to evaluate

- 1. Pre-operative and post-operative mouth opening
- 2. Pre-operative and post-operative changes in ramal height
- 3. Range of mandibular movements and lateral excursive movements

REVIEW OF LITERATURE

Wisth PJ and Tornes K (1975) included forty-four adults participated in the study, and the radiographs were taken before the operation, 6 weeks postoperatively and 1 year postoperatively. At the 6-week postoperative control all the variables measured indicated a significant downward and forward displacement of the condylar fragment of about 1 mm. The changes did not increase the variability of the joint morphology. At the 1-year postoperative control there were still significant differences in the position of the condyle compared with the pre-treatment recording. He concluded that the oblique vertical ramus osteotomy does not result in radiographic evidence of irregularities of the temporomandibular joint, except for a slight displacement of the condyle. The mobility of the condyle seems, however, unaffected and hence it should not, therefore, be an objection to this treatment.

Jonsson E, Svartz K, Welander U and Astrand P (1981) performed a study on Mandibular rami osteotomies and their effect on the gonial angle in two groups of patients; 29 treated by the sagittal splitting osteotomy of the mandibular rami according to Obwegeser-dal Pont and 30 treated by the oblique sliding (subcondylar) osteotomy. The gonial angle was measured in profile cephalograms which had been taken using conventional cephalometric procedures. Two cephalograms of each patient were used, one obtained pre-operatively and one obtained at least 14 months post-operatively the gonial angle was found to increase in cases treated by the sagittal splitting osteotomy and to decrease in cases treated by the oblique sliding osteotomy.

Tuinzing DB and Greebe RB (1985) performed a study on Complications related to the intraoral vertical ramus osteotomy. They reviewed 150 cases, in which intraoral vertical ramus osteotomy was used for mandibular setback. The coronoid process is routinely dissected and a period of intermaxillary fixation of 6 weeks is observed without fixation of the condylar fragment. However, like any surgical procedure, the intraoral vertical ramus osteotomy may have its problem. Haemorrhage, inadvertent bone cut, nerve damage, inability to retro-position and placement of the condylar fragment during the surgical procedure, and non-union, infection and relapse postoperatively were reported. He concluded that it was safe and a rather easy technique to perform with predictable results. When the proper technique is used, the direction of the bone-cut is adapted to the distance of setback, and skeletal fixation is applied and closure of an open bite is refrained from, the intraoral vertical ramus osteotomy is a sound procedure with predictable results.

Eckerdal O, Sund G and Astrand P (1986) showed in a study on Skeletal remodeling in the temporomandibular joint after oblique sliding osteotomy of the mandibular rami that skeletal remodeling of the temporomandibular joints took place in 80% of cases after oblique sliding osteotomies of the rami. The material comprised 29 consecutive patients operated on for mandibular prognathism by bilateral oblique sliding osteotomy of the mandibular rami. In 14 patients, wiring of the proximal segment to the distal segment using a 0.4 mm stainless steel wire was performed. The other 15 patients had no wiring. The patients were randomly distributed to the wiring (w) or non-wiring (nw) group. No differences in skeletal remodeling were found between wiring and non-wiring cases.

Spitzer WL and Steinhuser EW (1987) performed a study in a total of 174 patients, in whom ramus osteotomies were performed, were clinically examined. In 9 of them, a functional analysis and in 10 other patients, a CT scan investigation of the position of the TM joint, was carried out. Only in 1 case could a considerable dislocation of the proximal fragment be observed, which was due to a strong unilateral deviation of the ascending ramus. They concluded that this is only necessary in isolated cases. With extreme incongruence or a large distance between the bone-splitting surfaces, screw fixation should possibly be dispensed with entirely in order to prevent major displacements of the condyle-bearing fragment with temporomandibular dysfunction.

Tornes K and Wisth PJ (1988) conducted a cephalometric analysis of the positional changes of the mandible and the upper and lower incisors following vertical

subcondylar ramus osteotomy was performed on 80 patients, 40 patients were operated with an intraoral (IVSO) and 40 with an extraoral approach (EVSO). A significantly greater reduction of posterior facial height was observed in the EVSOgroup, but otherwise the 2 groups did not reveal any statistically significant positional differences. The material was sub-divided into 2 groups 1 with (n = 32) and one group without (n = 48) extra skeletal (nasomandibular) fixation in addition to the intermaxillary fixation. Significantly less positional changes of the incisors and less increase of anterior facial height was found in the group with skeletal fixation, but the influence on other skeletal alterations was limited. After release of the intermaxillary fixation, the only difference between the groups was intrusion of the earlier extruded incisors, most pronounced in the group without skeletal fixation.

Manor Y, Blinder D and Taicher S (2001) in the study of intra-oral vertical ramus osteotomy: a modified technique for correction of mandibular prognathism, 66 patients underwent IVRO in our department. Most patients had bilateral IVRO (98%). Half of the patients had IVRO and genioplasty and the rest had only IVRO. The procedure was used for mandibular setback of 3–9 mm (60 patients) and to correct the mandibular asymmetry (six patients). Follow-up was from 6 months to 2 years. It showed that the time required to perform osteotomy ranged from 10–20 min per side, had no incidence of permanent nerve injury to the inferior alveolar nerve.

Fontoura R, Vasconcellos H.A, and Campos A.E.S (2002) conducted a study to provide anatomic and radiographic parameters that permit the performance of an intraoral vertical ramus osteotomy (IVRO) without violation of the mandibular foramen (Fm) and to evaluate the usefulness of the LeVasseur-Merrill retractor (Walter Lorenz Surgical, Jacksonville, FL) developed for IVRO. Two hundred eighty dry adult human mandibular rami were measured, directly and via panoramic radiography, to obtain the horizontal and vertical positions of the Fm in the mandibular ramus. Measurements of the dry mandible were also compared with the radiographs to estimate Fm location. They concluded that Estimation of the Fm the ramus width, performed with preoperative panoramic radiography, effectively locates the Fm. The LeVasseur-Merrill retractor, when correctly positioned, was an effective tool in determining the appropriate thickness of the IVRO proximal fragment.

Maeda A, Shimoda T, Sera H, Ozeki S and Honda T (2004) performed vertical ramus osteotomy in a 44year old female patient via the submandibular approach and stated that this step for condylar reconstruction is of value in the management of benign tumours and hyperplasia of the mandibular condyle. They added that this method may be applicable in cases of TMJ ankylosis and for minimizing deformity after fracture of the mandibular condyle. They further added that a simple alternative method for condylar reconstruction and is of value in the management of benign tumours and hyperplasia of the mandibular condyle.

Holmlund AB, Gynther G.W and Reinholt F.P (2004) performed a study on 5-year follow-up done on 5 adult patients. All patients were surgically treated with condylectomy and reshaping of the condylar neck which was then positioned underneath the preserved TMJ disk by vertical ramus osteotomy. The yearly follow-up evaluations comprised measurements of maximum interincisal opening and protrusive movements, assessments of occlusion and TMJ pain as well as tomographic interpretation of recurrent growth. It was concluded that it is feasible to recommend a conservative surgical approach for treatment of osteochondroma of the mandibular condyle. No patient showed recurrence of growth at the 5-year follow-up and mandibular function and occlusion was normalized in all patients.

Martinez-Lage JL, Gonzalez J, Pineda A and Alvarez I (2004) performed sliding vertical ramus osteotomy in three adult patients, two with osteochondroma and one with hyperplasia were treated by condylectomy and simultaneous reconstruction with the pedicled posterior mandibular border. In all three cases an immediate mouth opening with stable occlusion was achieved. The interincisal opening was more than 40 mm after 3weeks, with a deviation no greater than 4 mm towards the affected side.

All excursive movements were present in all directions, and correction of the facial asymmetry was achieved. There was no T.M.J. pain and all patients expressed satisfaction during the follow-up of 56 months (average). An adequate remodeling of the neocondyle without resorption as well as a stable occlusion was observed in every case. It was concluded that reconstruction of the condyle by sliding vertical-oblique ramus osteotomy provides, in cases of condylar tumours, excellent functional and cosmetic results.

Al-Bishri, Barghash Z, Rosenquist J and Sunzel B (2004) conducted a study on one hundred and twenty-nine patients, who underwent IVRO (79 patients) and SSO (50 patients). Questionnaires were mailed to the patients at least one year after the operation. The records of all patients, who returned the questionnaires, were reviewed. He stated that regarding patient satisfaction 98% of the IVRO patients in his study and 91% of the SSO patients in his study were satisfied. The only one patient who was not satisfied in the IVRO group was not affected by NSD but due to functional reason. Out of the four patients who were not satisfied in the SSO group only one was due to NSD.

Fujimura K, Segami N and Kobayash S (2006) performed a study on locations and sizes of anatomical features of the medial aspect of mandibular rami which were measured in 94 bilateral sides of 47 dry mandibles as a control group, and the results were compared with 3-dimensional computed tomography images of 44 sides of 22 patients with prognathism and stated that the medial aspect from the sigmoid notch should be exposed carefully in the IVSRO procedure to avoid damaging the maxillary artery as the position of the mandibular foramen in rami varies among individuals and, therefore, should be confirmed preoperatively on axial CT images.

Ueki K *et al* (2006) performed the study on 50 Japanese patients with mandibular prognathism with mandibular and bimaxillary asymmetry, 25 underwent IVRO and 25 underwent IVRO in combination with a Le Fort I osteotomy. Condylar and disc positions after intraoral vertical ramus osteotomy with and without a Le Fort I

osteotomy and concluded that IVRO with or without Le Fort I osteotomy can improve ADD and TMJ symptoms along with condylar position and angle, but it is difficult to predict the amount of improvement in anterior disc displacement.

Takazakura D *et al* (2007) performed a study to evaluate hypoesthesia of the lower lip using trigeminal somatosensory-evoked potential following 2 types of sagittal split ramus osteotomy (SSRO) and intraoral vertical ramus osteotomy (IVRO). 30 patients with mandibular prognathism, with and without asymmetry, who were divided into three groups: the Obwegeser method (Ob) group, the Obwegeser– Dal Pont method (ODP) group and the intraoral vertical ramus osteotomy (IVRO) group were included. It was concluded that IVRO showed the earliest recovery from hypoesthesia or an absence of hypoesthesia, and lower lip hypoesthesia was less with the Ob method than the ODP method.

Papadaki M, Doukas A, Farinelli W.A., Kaban L and Troulis M (2007) performed Vertical ramus osteotomy with Er: YAG laser to assess the feasibility of using Er: YAG laser to perform vertical ramus osteotomy, and to determine the most efficient energy per pulse for its completion and recommended that the possibility of bone cutting using lasers can be pursued. The Erbium: yttrium aluminum garnet (Er: YAG) laser has been demonstrated to result in minimal thermal damage of bone, precise cutting, rapid osseous healing and osteoinduction. The osteotomy is easily performed and the technique is better suited to minimally invasive surgical access.

Chen CM *et al* (2008) performed a study to investigate the long-term stability for correction of mandibular prognathism using IVRO. The study was conducted on twenty-five mandibular prognathism patients by bilateral IVRO, and evaluated cephalometrically by reference to the menton. A set of 3 standardized lateral cephalograms were obtained from each subject preoperatively (T1), immediately postoperatively (T2), and after 2 years postoperatively (T3). The mean relapse was 1.3 mm (10.2% 1.3 of 12.8) in forward direction and 0.6 mm in upward direction. There was no significant movement in the vertical direction. Significant relapse was shown in the horizontal direction, even though the amount was small. The long-term

stability of our present study suggested that IVRO is useful for correction of mandibular prognathism.

Blinder D, O. Peleg, T. Yoffe and S. Taicher (2009) described simple techniques for IVRO that prevents medial trapping of the proximal fragment, decreases operative difficulties and substantially shortens operative time by the use of use of the Stryker oscillating saw, the Bauer sigmoid notch retractor and the Levasseur-Merill posterior border retractor to provide good visibility during surgery. Other three techniques to capture and place the proximal fragment laterally after it is trapped medially is to pull the distal fragment in an anterior and contralateral direction; the second is to capture the tip of the proximal fragment in the lumen of the Coakley curette; and the third is to push the proximal segment posteriorly using a periosteal elevator that is introduced sub-periosteally on the medial ramus, inferiorly to the sigmoid notch.

Ueki K *et al* (2009) in a study evaluated changes in position and angle of the proximal segment, including the condyle, after intraoral vertical ramus osteotomy (IVRO) with and without a Le Fort I osteotomy to verify whether displacement of the proximal segment could induce postoperative complications. It was suggested that the position and angle of the proximal segment, including the condyle, can change after IVRO. It was also suggested that it could improve TMJ symptoms, but extreme medial displacement of the proximal segment could delay recovery from lower lip hypoesthesia.

González-Otero S, Cuéllar C. N, Teigeiro M.E, Luengo J.F and Vila C.N (2009) performed intraoral vertical ramus osteotomy in a study on a 51-year-old woman with pain of several months' duration in the right temporomandibular joint (TMJ) and no other symptoms. Panoramic radiography showed an enlarged condyle with no subchondral cysts. Computed tomography showed a bony proliferation with benign signs and a scintigraphy revealed an increased uptake in the condyle. This technique was considered to be an alternative for the reconstruction of small and medium defects resulting from condylectomy, as well as small vertical dimension losses

derived from post-traumatic avascular necrosis of the condyle and idiopathic condylar resorption.

Yang X, Hu J, Zhu S, Liang X, Li J and Luo E (2010) in a study, divided the patients into 2 groups treated by condylectomy and condylar reconstruction using vertical sliding osteotomy of the mandibular ramus with and without three-dimensional simulation using Surgicase CMF Materialise software, stated that the combined use of computer-assisted three-dimensional surgical planning and simulation with vertical ramus osteotomy to reconstruct the condyle for patients with osteochondroma after excision of the tumour makes the operation more accurate and more convenient, and avoids damage to vital structures.

Talesh KT, Motamedi M.H.K, Yazdani J, Ghavimi A, and Ghoreishizadeh A (2010) performed intraoral vertical ramus osteotomy in fifty-six patients with mandibular prognathism selected for IRVO, were studied within a 21-month period. These patients were randomly divided into 2 groups. The patients were matched regarding cephalometric norms. The case group underwent the IVRO plus coronoidotomy, whereas the control group underwent the simple IVRO. Relapse ratio within the first year was compared between groups. Significant relapse was defined as relapse was 30% of the primary setback. He stated in his study that the mean relapse ratio of 1 year after surgery was less in the study group which had a coronoidotomy in conjunction with the IVRO for prognathism compared to the control group in which no coronoidotomy was performed.

Malekzadeh BO, Ivanoff C.J, Westerlund A, MadBeigi R, Ohrnell L.O and Widmark G (2011) performed a study on patients who were treated with EVRO for a mandibular deformity in the period 2008–2017 at Clinic of Oral and Maxillofacial Surgery, Mölndal, Sweden was included (N=26). Overjet and overbite were calculated digitally and cephalometric analyses were performed pre-operatively, and at 3 days, 6 months, and 18 months post-operatively. It was suggested that EVRO is a predictable treatment tool for mandibular deformities, presenting only small skeletal

relapses up to 6 months post-operatively and no further relapses thereafter. He further discussed that this method has few post-operative complications, including nerve damage and scarring. There was no permanent damage to the facial nerve and 5.8% neuro-sensory damage to the inferior alveolar nerve was observed.

Chen XY, Chen SL, Zhang X, Li JP and Deng W (2011) performed a study to evaluate the accuracy of the computer tomography (CT)-based osteotomy template on cadaver mandibles and to assess the outcome after IVRO correcting mandibular prognathism. Four human wet cadaver heads were subjected to a high-resolution multi-slice spiral CT scan. After the virtual osteotomies in the planning program, the individual osteotomy templates were produced by stereolithography. A stable and secure fit of the stereolithographic templates was achieved via the individual CT-based osteotomy template. The osteotomy lines were performed exactly as planned in the virtual osteotomies planning program. They concluded that use of the CT-based osteotomy templates is a safe method for osteotomy. It is rather convenient for vertical osteotomy in IVRO increasing the intraoperative accuracy and efficiency.

Liu Y *et al* (2011) concluded there is eventual resorption with subsequent decrease in height of the ramus, facial asymmetry and deviated mouth opening when non-pedicled grafts were used following traditional approach for ankylosis is gap arthroplasty or interpositional arthroplasty followed by reconstruction of the condyle using, for example, costochondral grafts. The study suggested that sliding vertical osteotomy on the posterior border of the mandibular ramus, can be an alternative and promising method for condylar reconstruction in patients with TMJ bony ankylosis. Longer follow-ups are required to confirm the results.

Nihara J, Takeyama M, Takayama Y, Mutoh Y and Saito I (2013) stated in a study that IVRO affords a lower incidence of IAN injury, technical simplicity, low blood loss, and short duration of surgery. Lateral cephalograms were taken at six time points: 1 month before surgery, and 1 day, 3 months, 6 months, 1 year, and approximately 2 years after surgery. Intermaxillary fixation (IMF) with four mono-

cortical screws was maintained for 1 week in all patients. Mean posterior movement of the menton (Me) was 5.9 mm at surgery. 3 months after surgery, the FMA and FH-CorMe angles had increased 6.3 and 6.2 degrees, respectively, indicating clockwise rotation of the distal segment of the mandible. This rotation was observed in all 20 patients, suggesting that postoperative rotation of the mandible in the postoperative short term is likely to occur after IVRO and could be considered an adaptation of the mastication system newly established by surgery. In the long term after IVRO, Me had moved anteriorly by only 0.9 mm and the relapse ratio was 15.3%. Its disadvantages include application for only retraction of the mandible, less bony contact between the proximal and distal segments, and requiring a relatively long period of IMF.

Hasegawa T *et al* (2013) performed a study in which the relationships between neurosensory disturbance and factors connected with IVRO operations were evaluated. It was found that at cutaneous points, contributing factors such as sex, age, the magnitude of mandibular setback, and haemorrhage were associated with an increased risk of neurosensory disturbance after IVRO. The study revealed that contributing factors, such as sex, age, the magnitude of mandibular movement, and the amount of haemorrhage that occurs during surgery were associated with an increased risk of neurosensory disturbance at cutaneous points after IVRO.

Shei P, Hu J, Li Y, Ye B and Luo E (2014) in a study conducted from 2007 to 2012, 12 patients with osteochondroma of the mandibular condyle were included. All of them accepted condylectomy, sliding vertical ramus osteotomy, and mandibular contouring at 1 stage. Mandibular contouring included mandibular inferior border ostectomy, mandibular outer cortex ostectomy, and horizontal osteotomy genioplasty according to the characters of jaw deformity. In addition, maximal mouth opening, pain in the TMJ, and numbress of the lower lip were recorded preoperatively and postoperatively to evaluate the therapeutic effects. All of patients obtained satisfactory results; TMJ dysfunction, facial asymmetry, and abnormal occlusion were improved greatly. It was concluded in this study that after resection of the tumor

with mandibular condyle, sliding vertical ramus osteotomy and mandibular contouring were applied to treat condylar osteochondroma combined with secondary jaw deformities, which could correct the facial asymmetry and improve the condylar osteochondroma patients' appearance.

Park SY *et al* (2014) performed a study to report the results of extracorporeal fixation in patients with mandibular condylar fractures and compare them with the clinical results of conservative treatment. Patients treated with extracorporeal fixation did not demonstrate significant postoperative complications such as malocclusion, mandibular hypomobility, temporomandibular disorder, or complete resorption of condyle fragments. It was suggested that if conventional open reduction and fixation of condylar fracture is difficult, extracorporeal fixation should be considered as an alternative treatment. Surgeons should also consider predictors of condylar resorption such as age and comminuted fracture when selecting appropriate treatment.

McKenna SJ and King EE (2015) suggested in their study that IVRO is a straightforward technique, which can be used to perform mandibular setback or rotation about the vertical axis of the ramus. Small advancements are amenable to IVRO with anterior rotation of the proximal segment to establish satisfactory bone contact. Although rigid fixation can be used with IVRO, it often is not and a brief period of MMF is required. They further stated that compared with SSO, IVRO is associated with a very low incidence of nerve injury. Further, the authors' experience with modified mandibular condylotomy suggests that, when applied in the setting of symptomatic TMJ internal derangement, IVRO will allow for physiologic positioning of the condyle and should minimize the possibility for exacerbation of joint symptoms or the production of new joint symptoms.

Kawase-Koga Y *et al* (2015) performed a study in which one hundred and eightyfive rami in 118 patients with jaw deformities, which were treated with IVRO, were examined retrospectively. The shape of the osteotomy line and the postoperative complications were examined on panoramic radiographs. It was stated that the most complications occurred in the vertical type cases and no complications were found in oblique type cases. Condylar luxation was found mainly in unilateral IVRO cases and bony interference was found in bilateral IVRO cases. The results suggested that the oblique type of osteotomy line has the advantage of avoiding complications.

Lee JH, Park TJ and Jeon JH (2015) performed a study in a series of three cases which were treated with the previously suggested protocol and the follow-up period was analyzed. In serial cases, UIVRO combined with contralateral SSRO may avoid mediolateral flaring of the bone segments and condylar dislocation, and result in improved condition of the temporomandibular joint. UIVRO combined with contralateral SSRO is expected to be a useful technique for the treatment of rotational mandibular asymmetry. He further added that intraoral vertical ramus osteotomy has an advantage, in this respect, because it causes less rotational displacement of the proximal segment on the deviated side and even displaced or rotated condylar segments may return to their original physiologic position. Unilateral intraoral vertical ramus osteotomy (UIVRO) on the short side combined with contralateral SSRO was devised as an alternative technique to resolve the spatial problems caused by conventional SSRO in cases of severe rotational asymmetry.

Parmar BS, Garg B, Mehta R, Midha A and Thakkar DK (2015) stated that nonpedicled grafts, there is eventual resorption with subsequent decrease in height of the ramus, facial asymmetry, deviated mouth opening and re-ankylosis. The authors have applied the method of vertical ramus osteotomy (VRO) on the posterior border of the mandibular ramus for reconstruction of the ramus condyle unit (RCU) as a pedicled graft along with Myofascial Temporalis Interposition for the correction of TMJ Ankylosis. He concluded in his study that VRO on the posterior border of the mandibular ramus seems to be an alternative and promising method for RCU reconstruction in patients with TMJ Ankylosis. **Erikse ES, Wisth PJ, Loes S and Moen K (2016)** included thirty-six patients in the study. Mean age at surgery was 21.6 years. Lateral cephalograms and study casts obtained before the start of treatment (T0), and 8 weeks (T1), 1 year (T2), and 12.5 years (T3) after the operation were evaluated. Mean mandibular setback measured at point B was 8.3 mm. Between T1 and T2, a mean anterior relapse of 12% of the setback was observed. Between T2 and T3, the anterior relapse persisted, but decreased to 7% of the setback measured at point B. Despite dental adjustments in both jaws, a statistically significant reduction in overjet was observed during both observation periods. He indicated that combined orthodontic and orthognathic surgical treatment of mandibular prognathism with the IVRO as the surgical procedure followed by 6 weeks of IMF provides predictable and good long-term clinical results.

Tabrizi R, Pakshir H, Behnia H, Akhlaghi S and Shahsavari N (2016) performed a study to compare the effects of sagittal split osteotomy (SSO) and intraoral vertical ramus osteotomy (IVRO) on the gonial angle. This retrospective cohort study assessed subjects with mandibular prognathism who underwent SSO (group 1) or IVRO (group 2). Lateral cephalograms obtained before and 1 year after the osteotomies were analyzed. In this study, age, sex, the change in occlusal plane (OP) and mandibular plane (MP) angles, and the amount of mandibular setback were considered as variable factors, while the type of surgery (SSO or IVRO) was considered the predictive factor. Fifty-six subjects were studied: 26 in group 1 and 30 in group 2. He stated in his study that Mandibular osteotomy (SSO and IVRO) may change the gonial angle, but a significant difference between SSO and IVRO was not detected.

Choi YJ, Ha YD, Lim H, Huh JK, Chung CJ and Kim KH (2016) studied the long-term changes in mandibular width, lower facial width, and ramus angulation after intraoral vertical ramus osteotomy (IVRO) and to identify the factors influencing these changes. This retrospective study included 53 consecutive patients with mandibular prognathism who underwent IVRO with (n = 33) or without (n = 20)

Le Fort I osteotomy. They concluded in this study that the mandibular width increased after IVRO but seemed to normalize within approximately 3 years. The lower facial width did not reflect underlying skeletal changes. Therefore, long-term transverse changes after IVRO can be considered clinically irrelevant.

Zhou H, Liao C, Hu J and Fei W (2016) evaluated 10 patients with osteochondroma of the mandibular condyle who were treated by vertical ramus osteotomy. Three patients had resection of the condyle and reconstruction with free vertical ramus osteotomy grafts (free graft group) and seven had pedicled vertical sliding ramus osteotomy grafts (pedicled graft group). The mean (range) observation period was 30 months. All patients had satisfactory clinical outcomes, and facial symmetry and good occlusion were achieved during the first 10 months. They showed that both free grafts and pedicled grafts seem to be an alternative and promising approaches to condylar reconstruction in the treatment of osteochondroma. The pedicle graft results in less facial asymmetry, less bony resorption, and better long-term clinical effects than the free graft.

Komori H *et al* (2016) conducted a study to investigated the different effects of intraoral vertical ramus osteotomy (IVRO) and sagittal split ramus osteotomy (SSRO) on mandibular border movement. Study included 22 patients receiving IVRO and 22 patients receiving SSRO who were treated at Okayama University Hospital. Their mandibular border movement was evaluated in three dimensions with 6° of freedom using an optical recording system. A strong correlation between condylar and lower incisor movement was observed during maximum jaw protrusion and latero-trusion. Significant improvements in condylar and lower incisor movement were detected after orthognathic surgery during maximum jaw protrusion and latero-trusion in the IVRO group and during maximum jaw protrusion in the SSRO group. They concluded that IVRO likely achieves greater improvement in jaw movement than SSRO. Therefore, the application of IVRO could be considered in the treatment of patients with jaw deformities featuring temporomandibular joint problems.

Kung AYH and Leung YY (2017) conducted a cohort study. Lateral cephalograms were analysed for the predictor (magnitude of setback and adjunctive procedures) and outcome (stability of vertical and horizontal dimensions) variables at six time points. A total of 152 patients (mean age 24.2 years) were included in the study. Following IVRO, the mandible measured at B-point had moved a mean 0.50 mm posteriorly at 1 week after the removal of intermaxillary fixation (7 weeks postoperative); this was followed by progressive small anterior relapse. At 2 years postoperative, the mean relapse of the mandible after IVRO measured at B-point was 0.05 mm (standard deviation 1.14 mm), representing 0.7% of the mean surgical movement. Large setback (>8 mm) showed significantly higher relapse compared to small setback. It is stated that there was no significant difference in relapse between patients who received adjunctive mandibular surgeries apart from IVRO and those who underwent IVRO alone.

Iwanaga J *et al* (2017) in the study included a horizontal osteotomy that is performed at a higher position than in the original Choung procedure. Intraoperatively, there was no unexpected bleeding from the operative site. Proximal segment dislocation from the glenoid fossa was observed on one side (0.82%). Non-union of the osteotomy was not observed in any patient. It was concluded in the study that in terms of avoiding injury to the inferior alveolar nerve and maxillary artery, the osteotomy line and medial exposure are both very important. The authors have developed a modified L-shaped IVSRO technique to reduce the chances of postoperative nerve dysfunction and intraoperative haemorrhage.

Huang TT, Cheng KH, Chang CJ, Chen KC, Liu JK and Wong TY (2018) presented a simple internal fixation technique for transoral VRO, and reviewed outcomes in 95 cases. Four Kirschner (K) pins 0.9 mm in diameter are inserted percutaneously from the proximal to the distal segment while the condyle is positioned in the glenoid fossa. This was followed by a brief period of maxillomandibular fixation. The records of 95 patients were reviewed who had unilateral or bilateral vertical ramus osteotomy fixed with K pins, after which the

mean (SD) period of fixation was 19 (11) days. The fixation was effective and the complications unimportant. Within its limitations, the method worked satisfactorily in a routine setting. A longer follow-up is required to evaluate the method's long-term safety.

Anchalia S, Patel N, Dhuvad J, Garg N, Chaudhari P and Gosai H (2018) in the study to evaluate the efficacy of the above procedure by evaluating the increase in mouth opening, by assessing the resorption of the newly reconstructed RCU, by assessing any occlusal disturbances, deviation upon mouth opening and obstructive sleep apnoea, caused by decrease in height of the ramus of the mandible as well as to evaluate complications of the procedure, if any, included 13 patients (22 joints) with TMJ ankylosis along with resection of the ankylosed condyle, underwent L-shaped ramus osteotomy. Patients were followed up for an average of 14.07 months (range 12–17 months) reported in his study that L osteotomy was effective in RCU reconstruction in patients with TMJ ankylosis. Adequate mouth opening was achieved without any major complications, mandibular ramal bone height was preserved and significant adaptation and re-modelling of the neo-condyle occurred over time to the normal condyle in terms of shape and improved function.

Rokutanda S *et al* (2018) in his study to compare the osseous healing processes associated with SSRO and IVRO and to investigate changes in mandibular width after IVRO in 29 patients undergoing mandibular setback. On computed tomography images, osseous healing was similar in patients undergoing SSRO and IVRO at 1 year after surgery. Projection of the antegonial notch occurred after IVRO, but returned to the preoperative state within 1 year. He suggested that the processes of osseous healing associated with SSRO and IVRO are similar. Furthermore, changes in the width of the mandible after IVRO do not appear to be significant enough to merit consideration when deciding between the two surgical procedures.

Leung YY et al (2019) conducted a randomized clinical trial compared the surgical morbidities between SSRO and IVRO for patients with mandibular prognathism over

the first 2 years postoperative. Ninety-eight patients (40 male, 58 female) with a mean age of 2.4-3.5 years underwent bilateral SSRO (98 sides) or IVRO (98 sides) as part or all of their orthognathic surgery. IVRO presented less short-term and long-term surgical morbidity in general. The SSRO group had a greater incidence of inferior alveolar nerve deficit at all follow-up time points (P < 0.01). There was more TMJ pain at 6week reported in his study that randomized clinical trial demonstrated that IVRO resulted in less surgical morbidity in terms of long-term IAN deficits and short-term TMJ pain when compared to SSRO. He concluded that despite the need for intermaxillary fixation, IVRO appears to be associated with less surgical morbidity than SSRO when performed as a mandibular setback procedure to treat mandibular prognathism.

Anchalia S, Dhuvad J and Shah JC (2019) conducted a study on 386 patients (521 joints) treated for TMJ ankylosis were reviewed. Data analysis included the etiology of TMJ ankylosis, gender distribution, age group, distribution of ankylosis based on location, type, interincisal opening and complications in the perioperative period. Results Out of 521 joints, 65.02% were unilateral and 73.89% had bony ankylosis. The mean maximal incisal opening preoperative was 5.4 mm (SD 3.63 mm) and at 1-year follow-up was 36.9 mm (SD 3.3 mm). There was no permanent facial nerve paralysis. However, transient facial nerve paresis was 14.78%. There was an overall recurrence rate of 8.82% concluded that of all techniques used to release TMJ ankylosis with interpositional arthroplasty and reconstruction of the RCU with L ramus osteotomy is the most favorable. This procedure not only causes least complications, but also maintains height of the ramus, facilitating surgeries for secondary asymmetry correction.

Anquetil M *et al* (2020) performed a study on a total of 48 patients and were analyzed. The aesthetic assessment revealed significant correction of the chin deviation (CD) and of the lip commissural line tilt after VRO (p1 ¹/₄ 0.0038 and p2 ¹/₄ 0.0067, respectively) with stable results. The architectural analysis revealed significant improvement in the maxillary and mandibular occlusal planes, as well as

the chin deviation (p < 0.0001). A tendency to relapse was noted for the mandibular canting and the CD during the follow-up. VRO allowed for a mean mandibular lengthening of 8.39 mm (ranging from 2.5 to 14 mm). he concluded that the Caldwell Letterman VRO technique belongs to the therapeutic arsenal for lengthening of the mandibular ramus. It allows for immediate restoration of the symmetry of the lower third of the face in patients with unilateral PVI. A revisional procedure may be needed after several years due to a tendency for the chin deviation to relapse.

Ohba S, Tominaga J, Koga T, Miura K, Yoshida N and Asahina I (2020) performed a study which included patients who underwent IVRO or SLO without bone fixation. Cephalograms were taken before surgery (T1), immediately after surgery (T2), and >6 months after surgery (T3) to assess postoperative movement of the proximal segment and skeletal stability. The condylar angle was measured using computed tomography images taken at T1 and T3 to assess rotation. Ninety patients were included (IVRO, n ¼ 25; SLO, n ¼ 65). The condyles were almost stable in the SLO group. Temporomandibular joint disorders were found in 2 of 22 IVRO patients and in 2 of 42 SLO patients with asymmetry at T3. He suggested that short lingual osteotomy with the physiological positioning strategy (PPS) should be preferred over IVRO with the PPS whenever possible. This technique provided good skeletal stability after IVRO and SLO with the PPS in both the symmetrical and asymmetrical groups during the follow-up period.

Huh JW, Kim SY, Lee YB, Park JH, Jung HD and Jung YS (2020) conducted a study to evaluate the positional changes of the proximal segments after IVRO setback in skeletal class III patients with asymmetry, using preoperative and postoperative computed tomography scan data, and to apply the results in clinical practice. A total of 28 skeletal class III patients with asymmetry who underwent bimaxillary orthognathic surgery were included. A three-dimensional cone beam computed tomography scan was obtained preoperative, at 1 month postoperative, and at 1 year postoperative. At 1 month after the surgery, the proximal segments showed an outward rotation, lateral flaring, and anterior rotation of the condylar head. All

postsurgical directional changes had returned to the preoperative state at 1 year postoperative, and there was no statistically significant difference in postoperative angulation changes between the two sides. The results showed no statistical differences in the positional changes of the proximal segments between the deviation and non-deviation sides. This study reaffirms the benefits of the IVRO for a minimal bony interference between the proximal and distal segments in three dimensions, including mandibular asymmetry cases.

Rokutanda S et al (2020) conducted a study to evaluate the factors contributing to postoperative anterior relapse or posterior drift of the distal segment after intraoral vertical ramus osteotomy. A retrospective cohort study was conducted which included 31 patients who underwent setback surgery for mandibular prognathism by the intraoral vertical ramus osteotomy technique. Uni- and multivariate analyses were performed to determine the association of potential explanatory variables (sex, age, magnitude of setback, differences in setback magnitude between sides (right/left), duration of splint use, Angle's classification of malocclusion, mandibular angle, and tightness of occlusion of the molars) with positional changes in the distal segment. The setback magnitude was only significant factor affecting (P = 0.015) for posterior drift, with significant posterior in setback magnitudes of less than 7.25 mm. Posterior drift after intraoral vertical ramus osteotomy is less likely if setback magnitude exceeds 7.25 mm. For setbacks less than 7.25 mm, posterior drift should either be carefully corrected postoperatively, or an alternative surgical technique should be used. The setback magnitude showed a significant association with the risk of posterior drift following intraoral vertical ramus osteotomy, and the determined cutoff value may serve as a predictor for postoperative outcomes.

Lee KT *et al* (2021) conducted a study to review the literature regarding the blood loss and postoperative pain in the isolated sagittal split ramus osteotomy (SSRO) and intraoral vertical ramus osteotomy (IVRO). Investigating the intraoperative blood loss and postoperative pain, articles were selected from 1970 to 2021 in the English published databases (PubMed, Web of Science, and Cochrane Library). Article

retrieval and selection were performed by two authors, and they independently evaluated them based on the eligibility criteria. The articles meeting the search criteria had especially at least 30 patients. Results. In the review of intraoperative blood loss, a total of 139 articles were retrieved and restricted to 6 articles (SSRO: 4; IVRO: 2). In the review of postoperative pain, a total of 174 articles were retrieved and restricted to 4 articles (SSRO: 3; IVRO: 1). The mean blood loss of SSRO and IVRO was ranged from 55 to 167 mL and 82 to 104 mL, respectively. The mean visual analog scale (VAS) scores of the first postoperative day were 2 to 5.3 in SSRO and 2.93 to 3.13 in IVRO. The mean VAS scores of the second postoperative day were 1 to 3 in SSRO and 1.1 to 1.8 in IVRO. that the administration of anesthetic drugs, medial ramus type, and selection of surgical instruments could affect the operation time and blood loss in the orthognathic surgery. Compared to traditional SSRO, IVRO had a significantly lower amount of blood loss. However, the blood transfusion is not necessary in a single-jaw operation (SSRO or IVRO). Postoperative pain was similar between SSRO and IVRO.

Gupta M and Sen S (2021) conducted his study to analyze the functional results of temporomandibular joint (TMJ) range; that is, trismus index, lateral excursion, protrusion, retrusion, occlusion, masticatory efficiency), reestablishment of the anatomic relationship of the TMJ, aesthetics to improve quality of life, and complications in terms of ramus shortening on the affected side, deviation, facial asymmetry, neurologic deficits, and re-ankylosis. Sixteen patients with unilateral bony ankylosis were included and randomly divided into 2 groups with 8 patients in each group. Group I was treated with interpositional gap arthroplasty followed by reconstruction of the ramus-condyle unit using vertical ramus osteotomy. Group II was treated with interpositional gap arthroplasty. In both groups, a pedicled flap made up of fascia, temporalis muscle, and pericranium was used as an interpositional material. The functional range of the mandible was analyzed pre- and postoperatively. Group I improved significantly more than group II in terms of TMJ range; that is, trismus index, lateral excursion, protrusion, retrusion, reestablishment of the normal anatomic relationship of the TMJ, aesthetics, and masticatory efficiency. The

reestablishment of anatomic relationship showed better result in mastication significantly. No re-ankylosis was reported in any of the groups. TMJ reconstruction using vertical ramus osteotomy after temporalis muscle fascia interpositional gap arthroplasty yields better results in terms of functions and aesthetics than surgery without reconstruction. We therefore recommend TMJ reconstruction after gap arthroplasty.

Chen HS, Chen YS, Lin IL and Chen CF (2021) conducted a study investigated the anti-lingula and its related landmarks, the mandibular rami, by using cone-beam computed tomography (CBCT). CBCT images of 37 patients (74 sides of the mandibular ramus) were collected. The landmarks of anti-lingula (Anti-L), anterior ramus (A), posterior ramus (P), superior ramus (S), and inferior ramus (I) were identified. The distances (A-Anti-L, P-Anti-L, S-Anti-L, and I-Anti-L) were statistically evaluated according to gender, side (right and left), and skeletal patterns. The distance from the anti-lingula to the anterior (A-Anti-L) border of the ramus was significantly longer on the right side (14.69 mm) than on the left side (13.97 mm). Male patients had longer Anti-L-P, Anti-L-I, and S-I distances (18.96, 40.07, and 54.94 mm, respectively) than did female patients (16.66, 35, and 47.54 mm, respectively). Regarding skeletal patterns, the classes can be ordered as follows in terms of the measurements: class III>class II>class I. However, the differences between the classes were nonsignificant. Pearson correlation analysis revealed that gender and S-I distance were strongly correlated (r = 0.667); specifically, male patients had a longer S-I distance. A-Anti-L and A-P also exhibited a strong correlation (r = 0.796). They concluded that Anti-lingula-related distances did not differ between skeletal patterns. Among anti-lingula-related variables, A-Anti-L could serve as a favorable measuring point during operation.

Chen CM, Hsu HJ, Liang SW, Chen PH, Hsu KJ and Tseng YC (2022) conducted a study to investigate the mandibular canal of ramus and design a suitable osteotomy line for intraoral vertical ramus osteotomy (IVRO) using cone-beam computed tomography (CBCT). Ninety patients were classified into class I, II, and III

skeletal pattern groups. When extended from the horizontal base plane (0 mm, mandibular foramen [MF]), with a 2-mm section interval, to 10 mm above and 10 mm below the MF, the following landmarks were identified: external oblique ridge (EOR), posterior border of the ramus (PBR), and posterior lateral cortex of ramus (PLC): IVRO osteotomy point. In the base plane (0-mm plane), the EOR-PBR distance of class III (34.78 mm) and the IOR-PBR distance of class II (32.72 mm) were significantly higher than those of class I (32.95 mm and 30.03 mm). Compared to the EOR-PLC distance, the designed osteotomy point (two-thirds EOR-PBR length) has a 3.49-mm safe zone at the base plane and ranging from 0.89 mm (+ 10-mm plane) to 8.37 mm (- 10-mm plane). The position at two-thirds EOR-PBR length (anteroposterior diameter of the ramus) can serve as a reference distance for the IVRO osteotomy position.

Chen CM, Hwang DS, Hsiao SY, Chen HS and Hsu KJ (2022) conducted a study to review the literature regarding the postoperative skeletal stability in the treatment of mandibular prognathism after isolated sagittal split ramus osteotomy (SSRO) or intraoral vertical ramus osteotomy (IVRO): The articles were selected from 1980 to 2020 in the English published databases (PubMed, Web of Science and Cochrane Library). The articles meeting the searching strategy were evaluated based on the eligibility criteria, especially at least 30 patients. Results: Based on the eligibility criteria, 9 articles (5 in SSRO and 4 in IVRO) were examined. The amounts of mandibular setback (B point, Pog, and Me) were ranged from 5.53–9.07 mm in SSRO and 6.7–12.4 mm in IVRO, respectively. In 1-year follow-up, SSRO showed the relapse (anterior displacement: 0.2 to 2.26 mm) By contrast, IVRO revealed the posterior drift (posterior displacement: 0.1 to 1.2 mm). In 2-year follow-up, both of SSRO and IVRO presented the relapse with a range from 0.9 to 1.63 mm and 1 to 1.3 mm respectively. The study concluded that in 1-year follow-up, SSRO presented the relapse (anterior displacement). In 2-year follow-up, both of SSRO and IVRO showed the similar relapse distances.

Peleg O *et al* (2022) conducted a study to evaluate mandibular osteotomy procedures during orthognathic surgery, with an emphasis on the complications of the two leading procedures: intraoral vertical ramus osteotomy (IVRO) and sagittal split osteotomy (SSO). A retrospective cohort study was conducted on a total of 144 patients (median age of 20.5 years, 52 males). The IVRO:SSO ratio was 118:26 procedures. IVRO procedures were associated with shorter hospitalization than the SSO procedures, while the overall durations of surgery and follow-up periods were comparable. In contrast, when referring only to bimaxillary procedures, the duration of the IVRO bimaxillary procedures was significantly shorter than the SSO bimaxillary procedures. Postoperative complications consisting of skeletal relapse, temporomandibular joint dysfunction, sensory impairment, and surgical-site infection were significantly fewer in the IVRO group. Both types of osteotomies have acceptable rates of complications. IVRO appears to be a safer, simpler, though less acceptable procedure in terms of patient compliance.

MATERIALS & METHODS

ELIGIBILITY CRITERIA

Inclusion criteria

- 1. Patients falling under ASA I Classification
- 2. Unilateral or bilateral bony TMJ Ankylosis
- 3. Patients with age group between 12-20 years of age
- 4. Patients willing to participate in the study

Exclusion Criteria

- 1. Patients with systemic bone disorders
- 2. Patients with severe skeletal deformities
- 3. Patients with special health care needs
- 4. Patients who are not willing to participate in the study

ARMAMENTARIUM

- Mouth mirror and probe
- Metallic scale
- Periosteal elevator Howarth and Molts
- Tissue holding forceps
- Suture cutting scissors
- Needle holder
- B. P. handle and blade

- Condylar retractors
- Surgical saw
- Micromotor and hand piece
- Osteotomes
- Kocher forceps
- Disposable syringes
- Other surgical instruments

METHODOLOGY: -

STUDY DESIGN- Patients reporting to the Out-Patient Department of Oral and Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, Lucknow undergoing surgery for correction of TMJ ankylosis under general anesthesia were included in this study.

METHOD OF COLLECTION OF DATA- ASA Class I and relatively healthy ASA Class II patients were included in the study. Pre-operative panoramic radiographs, lateral cephalograms and CT-scans of the patients were recorded. Pre-operative mouth opening (maximal incisor opening), maximum lateral excursive movements of the mandible and ramal height were measured for all patients undergoing surgery.

ASSESSMENT OF HEIGHT OF RAMUS

We measured the height of ramus from condyle to gonion in all cases by functional analysis of lateral cephalograms of each patient.

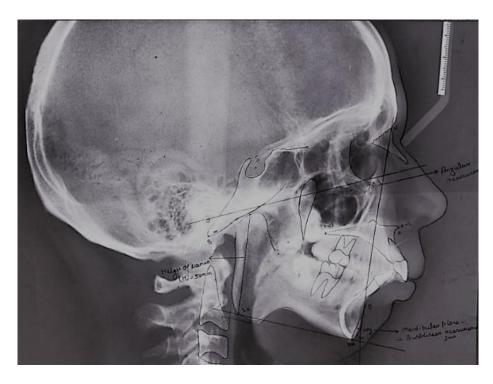


Figure 1: Cephalometric analysis for measure of height of ramus

The tracing of preoperative lateral cephalogram was done. Condyle and gonion were marked. A tangent was drawn at the posterior border of ramus and inferior border of mandible and then from the intersection of these two tangents a perpendicular line was drawn till the angle of mandible. This point was assessed as gonion. The height of ramus was measured from head of condyle to the gonion using a metallic scale.

PRE-ANAESTHETIC LABORATORY INVESTIGATIONS

All patients underwent pre-anaesthetic evaluation & routine blood investigations relevant to the study and General anaesthesia.

OPERATIVE PROCEDURE

All the patients were operated under general anaesthesia following strict asepsis.

Alkayat and Bramley approach along with submandibular approach was used for resection and reconstruction in all patients with identification and preservation of facial nerve and its branches. Ankylosed mass was exposed and two (lower and upper) bony cuts oblique and parallel made with the help of drills, chisel and mallet such as to create a gap of approx. 1–1.5 cm safeguarding the internal maxillary artery, inferior alveolar artery and preventing damage to middle cranial fossa. Any sharp margins of main ramal stump were smoothened. The glenoid fossa was prepared for reception of graft. The elongated coronoid process of the affected side was excised if needed. Mandible was mobilized to visualize and ascertain its free and smooth movement without resistance and minimum intraoperative mouth opening of 3.5 cm was achieved (minimum).

Vertical ramus osteotomy was performed on the entire mandibular ramus parallel to posterior border of the ramus which would eliminate the antegonial notch and create a smooth angle. Surgical burs were used for making initial osteotomy cut and then deepened to medial cortex. The superior border of the fixed posterior osteotomized segment of ramus was contoured to match the shape of condylar head. The osteotomy line preserved the integrity of inferior alveolar nerve. Once the initial osteotomy cut has been made, osteotomy was extended safely in either direction, while maintaining an adequate sling of medial pterygoid (on the medial side) or masseter muscle along the posterior border to prevent avascular necrosis of inferior tip of the proximal segment.

Aggressive mouth opening physiotherapy was started after third postoperative day and continued till the patient learnt the exercise and continued it by themselves. It was checked on regular follow-ups at least for 6 months.

Alternate sutures were removed at seventh postoperative day. At tenth postoperative day complete suture removal was done.

PARAMETERS ASSESSMENT

1. Maximum mouth opening was measured with a metallic scale placed between the incisal edges of maxillary and mandibular central incisor at immediate 1 week, 3^{rd} month and 6^{th} month post-operatively and compared.

2. Range of mandibular movements i.e., lateral excursion and protrusive movements were assessed by the use of divider and metallic scale at 1 week, 3^{rd} month and 6^{th} month post-operatively and compared.

3. Radiographic evaluation will be done pre-operatively, immediate post-operatively and at an interval of 3 months and 6 months post-operatively.

4. Height of ramus of mandible restored and growth were analyzed by lateral cephalogram pre-operatively, immediate post-operatively, 3^{rd} month and 6^{th} month post-operatively and compared.

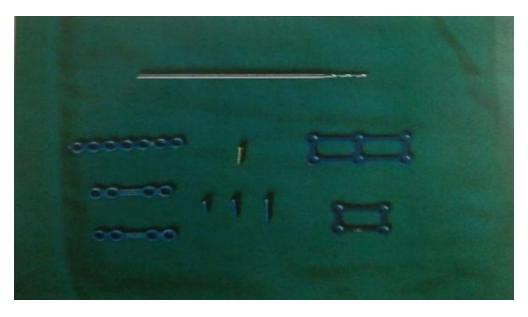
5. Pain was evaluated according to the VAS scale on 1st, 3rd, 7th and 10th day post-operatively.

6. Other complications, if any, were checked post-operatively.

PHOTOGRAPHS



Figure 2: ARMAMENTERIUM



2.0MM CONTIMUOUS MINIPLATE AND 2.0MM 4-HOLE-WITH GAP MINIPLATE, 2.0MM 3-D MINIPLATES, SCREWS AND 1.5MM DRILL BIT

Figure 3: ARMAMENTERIUM

LEFT TMJ ANKYLOSIS

FIGURE 4: PRE-OPERATIVE PHOTOGRAPH





Fig 4a:FRONTAL VIEW

Fig 4b: PRE OPERATIVE INTER-INCISAL MOUTH OPENING- 7mm



Fig 4c: PROFILE VIEW



Fig 5a: PRE OP ORTHOPANTOMOGRAM

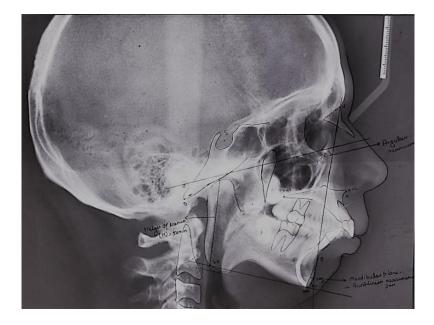


Fig 5b: PRE OP LATERAL CEPHALOGRAM

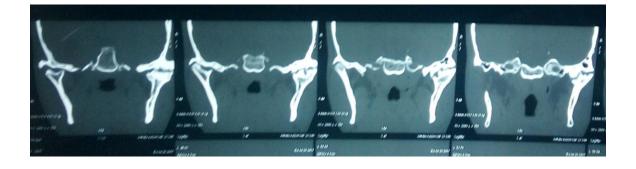


Fig 5c: PRE OPERATIVE COMPUTER TOMOGRAPHY SCAN (CORONAL SECTION)

Figure 5: PRE-OPERATIVE RADIOGRAPS



Figure 6: INTRA-OPERATIVE PHOTOGRAPHS

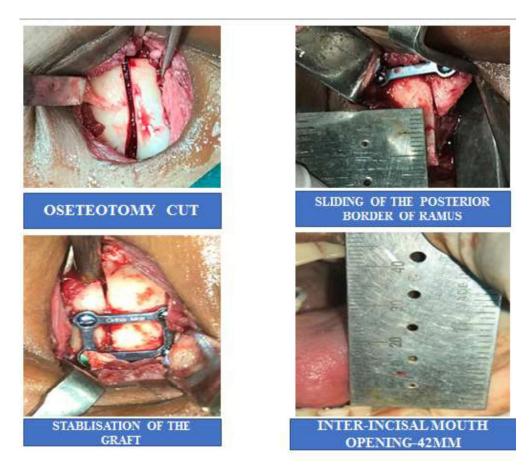


Figure 7: POSTERIOR BORDER RAMUS GRAFT



Fig 8a: LATERAL CEPHALOGRAM



Fig 8b: ORTHOPANTOMOGRAM

Figure 8: IMMEDIATE POST OPERATIVE

Fig 9: 1st WEEK POST OPERATIVE



Fig 9a: INTER-INCISAL MOUTH OPENING-36MM





Fig 10b: INTER-INCISAL MOUTH OPENING-40.5mm

Fig 10: 3rd MONTH POST OPERATIVE

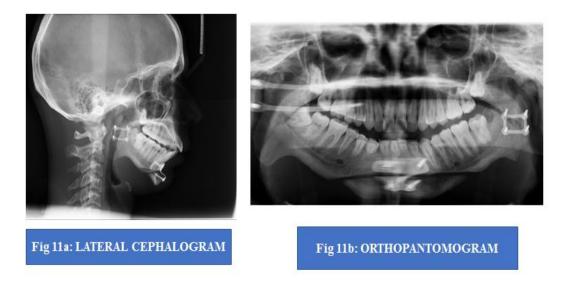


Figure 11: 3RD MONTH RADIOGRAPH



Figure 12: 6th MONTH POST OPERATIVE PHOTOGRAPHS





Fig 12c: LATERAL VIEW

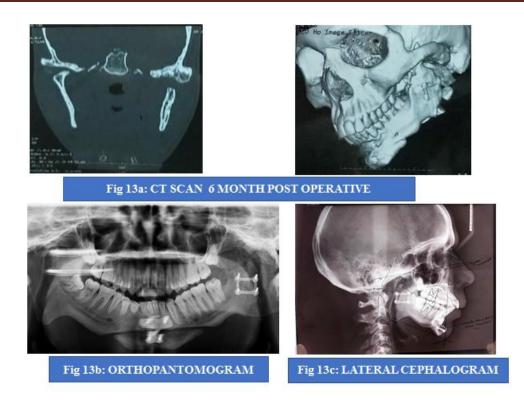


Figure 13: 6th MONTH POST OPERATIVE RADIOGRAPH

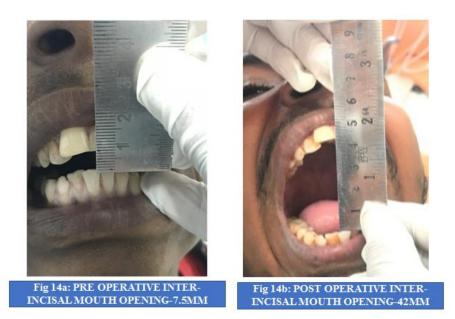


Fig 14: PRE AND POST OPERATIVE MAXIMUM MOUTH OPENING

Results

INTRA GROUP COMPARISON OF MOUTH OPENING BETWEEN DIFFERENT TIME INTERVALS

Table 1: Mean mouth opening between different time intervals of the study

	Mean	Std. Deviation	Std. Error	Minimum	Maximum
Pre- Operative	6.00	1.58114	0.70711	4.00	8.00
Immediate Post Operative	23.20	3.96232	1.77200	20.00	30.00
1 week	28.14	4.56815	2.04294	24.60	36.00
3 Months	35.90	2.70185	1.20830	34.00	40.50
6 Months	37.60	2.70185	1.20830	35.00	42.00

population

One Way ANOVA at 0.05 significance level

The mean mouth opening at preoperative level was 6.00. Immediately post operative the mean mouth opening was 23.20. At the 1st week Post operative the mean mouth opening was 28.14. At the 3rd month the mean mouth opening was 35.90 and at the 6th Month post operative the mean mouth opening was 37.60. There was increase in the mouth opening from pre operative to 6th Month. The increase in the mouth opening was significantly higher from pre operative levels at immediate post op level 1st week, 3rd Month and 6th

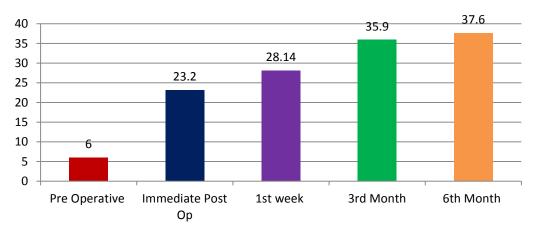
Month

Intragroup	Comparison	Mean Diff	P value	Significance
Pre-Operative	Immediate Post Operative	-17.20000 [*]	.000	Significant
Pre-Operative	1 st Week	-22.14000*	.000	Significant
Pre-Operative	3 rd Month	-29.90000*	.000	Significant
Pre-Operative	6 th Month	-31.60000*	.000	Significant
Immediate Post Op	1 st Week	-4.94000*	.027	Significant
Immediate Post Op	3 rd Month	-12.70000 [*]	.000	Significant
Immediate Post Op	6 th Month	-14.40000*	.000	Significant
1Week	3 rd Month	-7.76000*	.001	Significant
1Week	6 th Month	-9.46000 [*]	.000	Significant
3rd Month	6 th Month	-1.70000	.422	Non- Significant

 Table 2: Intragroup comparison of mouth opening between different time intervals

 of the study population

Graph 1: Intragroup comparison of mouth opening of the study population



INTRA GROUP COMPARIOSN OF LATERAL EXCURSION OF UNAFFECTED SIDE BETWEEN DIFFERENT TIME INTERVALS

Mean Std. Std. Minimum Maximum **Deviation Error** Pre-0.2000 .44721 .20000 .00 1.00 **Operative** Immediate .20000 1.2000 .44721 1.00 2.00 Post Operative 1 week 1.8000 .83666 .37417 1.00 3.00 3.6000 .54772 .24495 **3** Months 3.00 4.00 4.2000 .20000 **6** Months .44721 4.00 5.00

Table 3: Mean lateral excursion of unaffected side between different time intervals

of the study population

One Way ANOVA at 0.05 significance level

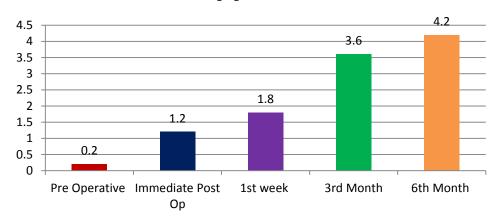
The mean Lat Excursion of Unaffected side at preoperative level was 0.20. Immediately post operative the Lateral Excursion of Unaffected side was 1.20. At the 1st week Post operative the mean Lateral Excursion of Unaffected side was 1.80. At the 3rd month the mean Lateral Excursion of Unaffected side was 3.60 and at the 6th month post operative the mean Lateral Excursion of Unaffected side was 4.20. There was increase in the Lateral Excursion of Unaffected side from pre operative to 6th month. The increase in the Lateral Excursion of Unaffected side was significantly higher from pre operative levels at Immediate post op level, 1st week, 3rd month and 6th month

unterent time intervals of the study population					
Intragroup	Comparison	Mean Diff	P value	Significance	
Pre-Operative	Immediate Post Operative	-1.00000*	0.011	Significant	
Pre-Operative	1 st Week	-1.60000*	0.001	Significant	
Pre-Operative	3 rd Month	-3.40000*	0.001	Significant	
Pre-Operative	6 th Month	-4.00000^{*}	0.001	Significant	
Immediate Post Operative	1 st Week	60000	0.109	Significant	
Immediate Post Operative	3 rd Month	-2.40000*	0.001	Significant	
Immediate Post Operative	6 th Month	-3.00000*	0.001	Significant	
1Week	3 rd Month	-1.80000*	0.001	Significant	
1Week	6 th Month	-2.40000*	0.001	Significant	
3 rd Month	6 th Month	60000	0.109	Non- Significant	

 Table 4: Intragroup comparison of lateral excursion of unaffected side between

 different time intervals of the study population

Graph 2: Intragroup comparison of lateral excursion of unaffected side of study population



INTRAGROUP COMPARIOSN OF LATERAL EXCURSION OF AFFECTED SIDE BETWEEN DIFFERENT TIME INTERVALS

	Mean	Std. Deviation	Std. Error	Minimum	Maximum
Pre- Operative	1.0000	.70711	.31623	.00	2.00
Immediate Post Operative	1.2000	.44721	.20000	1.00	2.00
1 week	2.4000	.89443	.40000	2.00	4.00
3 Months	3.4000	.54772	.24495	3.00	4.00
6 Months	3.4000	.54772	.24495	3.00	4.00

Table 5: Mean lateral excursion of affected side between different time intervals of

the study population

One Way ANOVA at 0.05 significance level

The mean Lateral Excursion of Affected side at preoperative level was 1.00. Immediately post operative the Lateral Excursion of Affected side was 1.20. At the 1st week Post operative the mean Lateral Excursion of Affected side was 2.40. At the 3rd month the mean Lateral Excursion of Affected side was 3.40 and at the 6th month post operative the mean Lateral Excursion of Affected side was 3.40. There was increase in the Lateral Excursion of Affected side was 3.40. There was increase in the Lateral Excursion of Affected side from pre operative to 6th month. The increase in the Lateral Excursion of Affected side was significantly higher from pre operative levels at Immediate post op level, 1st week, 3rd Month. Between 3rd month and 6rd month there was no change in the mean Lateral Excursion of Affected side

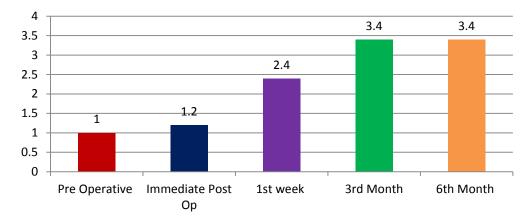
Intragroup	Comparison	Mean Diff	P value	Significance
Pre-Operative	Immediate Post Operative	20000	.631	Non- Significant
Pre-Operative	1 st Week	-1.40000*	.003	Significant
Pre-Operative	3 rd Month	-2.40000^{*}	.000	Significant
Pre-Operative	6 th Month	-2.40000*	.000	Significant
Immediate Post Op	1 st Week	-1.20000*	.008	Significant
Immediate Post Op	3 rd Month	-2.20000*	.000	Significant
Immediate Post Op	6 th Month	-2.20000*	.000	Significant
1Week	3 rd Month	-1.00000*	.024	Significant
1Week	6 th Month	-1.00000*	.024	Significant
3 rd Month	6 th Month	.00000	1.000	Non- Significant

Table 6: Intragroup comparison of lateral excursion of affected side between

different time intervals

Graph 3: Intragroup comparison of lateral excursion of affected side between

different time intervals



INTRAGROUP COMPARIOSN OF PROTRUSIVE MOVEMENT BETWEEN DIFFERENT TIME INTERVALS

	Mean	Std. Deviation	Std. Error	Minimum	Maximum
Pre- Operative	0.2000	.44721	.20000	.00	1.00
Immediate Post Operative	1.0000	.70711	.31623	.00	2.00
1 week	1.2000	.83666	.37417	.00	2.00
3 Months	1.2000	.83666	.37417	.00	2.00
6 Months	1.2000	.83666	.37417	.00	2.00

 Table 7: Mean protrusive movement between different time intervals of the study

population

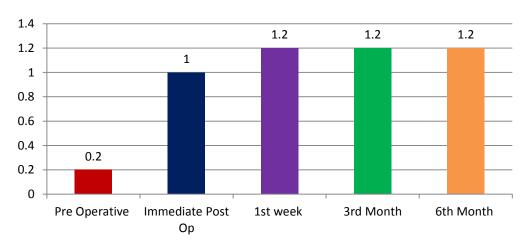
One Way ANOVA at 0.05 significance level

The mean Protrusion at preoperative level was 0.20. Immediately post op the mean protrusion was 1.00. At the 1st week, 3rd month and 6th month Post operative the mean Protrusion was 1.20. The increase in the Protrusion was significantly higher from pre operative levels to immediate post op level and 1st week, between 1st week –3rd month and 6th month there was no change in the protrusion

		intervals		
Intragroup	comparison	Mean Diff	P value	Significance
Pre-Operative	Immediate Post Operative	80000	0.046	Significant
Pre-Operative	1 st Week	-1.00000*	0.047	Significant
Pre-Operative	3 rd Month	-1.00000*	0.047	Significant
Pre-Operative	6 th Month	-1.00000*	0.047	Significant
Immediate Post Operative	1 st Week	20000	0.677	Non- Significant
Immediate Post Operative	3 rd Month	20000	0.677	Non- Significant
Immediate Post Operative	6 th Month	20000	0.677	Non- Significant
1Week	3 rd Month	.00000	1.000	Non- Significant
1Week	6 th Month	.00000	1.000	Non- Significant
3rd Month	6 th Month	.00000	1.000	Non- Significant

 Table 8: Intragroup comparison of protrusive movement between different time

Graph 4: Intragroup comparison of protrusive movement between different time intervals



INTRAGROUP COMPARIOSN OF RAMAL HEIGHT BETWEEN DIFFERENT <u>TIME INTERVALS</u>

	Mean	Std. Deviation	Std. Error	Minimum	Maximum
Pre- Operative	43.6000	3.78153	1.69115	40.00	50.00
Immediate Post Operative	34.0000	3.93700	1.76068	31.00	40.00
3 rd Month	37.0000	3.74166	1.67332	34.00	43.00
6 th Month	39.4000	4.09878	1.83303	36.00	46.00

 Table 9: Mean ramal height between different time intervals of study population

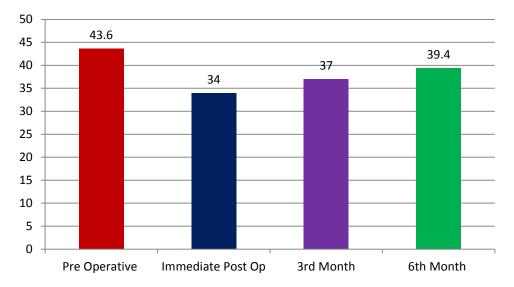
One Way ANOVA at 0.05 significance level

The mean ramal height at preoperative level was 43.60. Immediately post op the ramal height reduced to 34.00. At the 3rd month Post operative the mean ramal height was 37.00 and at the 6th month the mean lateral height was 39.40 There was significant decrease in the ramal height from pre operative to immediate post op level. At the 3rd month and 6th month there was increase in the ramal height from immediate post op level

Table 10: Intergroup Comparison of ramal height between different time intervalsof the study population

Intragroup Comparison		Mean Diff	P value	Significance
Pre-Operative	Immediate Post Op	9.60000*	0.001	Significant
Pre-Operative	3 rd Month	6.60000^{*}	0.016	Significant
Pre-Operative	6 th Month	4.20000	0.107	Non- Significant
Immediate Post Operative	3 rd Month	-3.00000	0.241	Non- Significant
Immediate Post Operative	6 th Month	-5.40000 [*]	0.043	Significant
3 rd Month	6 th Month	-2.40000	0.344	Non- Significant

Graph 5: Intergroup Comparison of ramal height between different time intervals of the study population



INTRAGROUP COMPARIOSN OF PAIN SCORES BETWEEN DIFFERENT <u>TIME INTERVALS</u>

	Mean	Std. Deviation	Std. Error	Minimum	Maximum
1st day	7.40	.54772	.24495	7.00	8.00
3rd day	6.40	.54772	.24495	6.00	7.00
7th day	4.20	.44721	.20000	4.00	5.00
10th day	0.40	.54772	.24495	.00	1.00

 Table 11: Mean pain scores between different time intervals of the study population

One Way ANOVA at 0.05 significance level

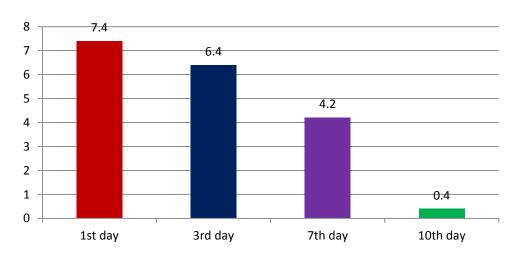
The mean pain at 1st day was 7.40. At the 3ed day the mean pain score was 6.40. At the 7th day post operative the mean pain score was 4.20. At the I0th day the mean pain score was 0.40. There was significant decrease in the pain score from 1st day to 10th day and the reduction in pain was significant between all the time intervals

Intragroup	comparison	Mean Diff	P value	Significance
1st day	3rd day	1.00000^{*}	0.008	Significant
1st day	7th day	3.20000^{*}	0.001	Significant
1st day	10th day	7.00000^{*}	0.001	Significant
3rd day	7th day	2.20000^{*}	0.001	Significant
3rd day	10th day	6.00000^{*}	0.001	Significant
7th day	10th day	3.80000*	0.001	Significant

 Table 12: Intragroup comparison of pain scores between different time intervals of

 the study population

Graph 6: Intragroup comparison of pain scores between different time intervals of the study population



STATISTICAL ANALYSIS

The data for the present study was entered in the Microsoft Excel 2007 and analyzed using the SPSS statistical software 23.0 Version. The descriptive statistics included mean, standard deviation. The level of the significance for the present study was fixed at 5%.

The intragroup comparison for the difference of mean scores between time intervals was done using the test and One Way ANOVA followed by Post Hoc analysis.

The Shapiro–Wilk test was used to investigate the distribution of the data and Levene's test to explore the homogeneity of the variables. The data were found to be homogeneous and normally distributed. Mean and standard deviation (SD) were computed for each variable.

Mean

$$\overline{X} = \frac{\Sigma X}{N}$$

Where:

 \overline{X} = the data set mean

 \sum = the sum of

X = the scores in the distribution

N = the number of scores in the distribution

Range

$$range = X_{highest} - X_{lowest}$$

Where:

$$X_{highesi} =$$
largest score

 X_{lowest} = smallest score

Variance

$$SD^2 = \frac{\Sigma (X - \overline{X})^2}{N}$$

The simplified variance formula

$$SD^2 = \frac{\Sigma X^2 - \frac{(\Sigma X)^2}{N}}{N}$$

Where:

 $SD^2 = the variance$

 \sum = the sum of

X = the obtained score

- \overline{X} = the mean score of the data
- N = the number of scores

Standard Deviation (N)

$$SD = \sqrt{\frac{\Sigma(X - \overline{X})^2}{N}}$$

The simplified standard deviation formula

$$SD = \sqrt{\frac{\Sigma X^2 - \frac{(\Sigma X)^2}{N}}{N}}$$

Where:

SD = the standard deviation

 \sum = the sum of

X = the obtained score

- \overline{X} = the mean score of the data
- N = the number of scores

One Way ANOVA

The formula for the one-way ANOVA F-test statistic is

 $F = rac{ ext{between-group variability}}{ ext{within-group variability}}.$

The between-group variability" is

$$\sum_{i=1}^{K} n_i (ar{Y}_{i\cdot} - ar{Y})^2 / (K-1)$$

where Y_i denotes the sample mean in the *i*th group, n_i is the number of observations in the *i*th group, ⁻Y denotes the overall mean of the data, and *K* denotes the number of groups.

The "within-group variability" is

$$\sum_{i=1}^K \sum_{j=1}^{n_i} (Y_{ij} - ar{Y}_{i\cdot})^2 / (N-K),$$

where Y_{ij} is the j^{th} observation in the i^{th} out of *K* groups and *N* is the overall sample size.

Post Hoc Tukey Test

Tukey's range test, also known as the Tukey's test, Tukey method, Tukey's honest significance test, or Tukey's HSD (honestly significant difference) test,^[11] is a single-step

<u>multiple comparison</u> procedure and <u>statistical test</u>. It can be used on raw data or in conjunction with an <u>ANOVA</u> (<u>post-hoc analysis</u>) to find means that are significantly different from each other. Named after John Tukey, it compares all possible pairs of <u>means</u>, and is based on a <u>studentized range distribution</u> (*q*) (this distribution is similar to the distribution of *t* from the <u>*t*-test</u>. Tukey's test compares the means of every treatment to the means of every other treatment; that is, it applies simultaneously to the set of all pairwise comparisons $\mu_i - \mu_j$ and identifies any difference between two means that is greater than the expected <u>standard error</u>. Tukey's test is based on a formula very similar to that of the t-test. In fact, Tukey's test is essentially a t-test, except that it corrects for <u>family-wise error rate</u>.

The formula for Tukey's test is:

$$q_s = rac{Y_A - Y_B}{SE},$$

where Y_A is the larger of the two means being compared, Y_B is the smaller of the two means being compared, and SE is the <u>standard error</u> of the sum of the means. This q_s value can then be compared to a q value from the <u>studentized range</u> <u>distribution</u>. If the q_s value is *larger* than the critical value obtained from the distribution, the two means are said to be significantly different at level

DISCUSSION

The term "Ankylosis" is of Greek origin and means "stiff joint". The temporomandibular joint is a ginglymo-arthroidal joint that allows for translational and rotational movements associated with speech, deglutition, and mastication. Orthognathic surgery is performed to enhance the appearance of the face, improve masticatory function, and correct facial deformities. To obtain the intended result, precise orthognathic surgical methods are required.¹

According to Salins, the ankylotic mass is an aberrant bone that takes the place of the TMJ and limits mandibular movements. The TMJ becomes ankylosed when fibrous or bony tissue fuses the condyle and the fossa. Temporomandibular Joint Ankylosis primarily develops in the first and second decades of life (35–92%) and is frequently associated with trauma (13–100%), local or systemic infection (0–53%), and systemic conditions such ankylosing spondylitis, rheumatoid arthritis, psoriasis, and prior TMJ Ankylosis surgery. It may hinder mandibular development and function, which could lead to significant facial asymmetry and retrusion of the mandible.⁶ In accordance with earlier research, ankylosis was also primarily observed in the second decade of this study's participants, with ages ranging from 10 to 19 years and a mean age of 14 years. Roychoudhary et al retrospectively studied 50 cases of TMJ ankylosis and showed that trauma was documented as a major etiologic factor in 86 % of all cases. Similar results were also related to the cases of our study.⁷

Orofacial function impairments can include psychological stress such as impacting family life, limited mouth opening, limited chewing efficiency, speech impairment, compromised oral hygiene, and restricted airway problems.⁸ Many methods using autogenous (temporalis, auricular cartilage, fascia lata, skin-dermis, native disc, buccal fat pad, Human Amniotic Membrane, costochondral, sternoclavicular, coronoid process, fibula, metatarsal, clavicle, iliac crest and cranial bone) and alloplastic (acrylic, synthetic, ulnar head prosthesis, compressible silicone rubber and total joint systems) materials have been reported for interposition arthroplasty and reconstruction of the mandibular condyle. Interpositional arthroplasty simplifies the process to reconstruct the diseased joint and minimizes the risk of re-ankylosis.⁹

Rowe gave certain criteria for the restoration of ankylosed TMJ. He emphasized the release of ankylosis by cutting 1.5cm-2cm of ankylosed bone, thus achieving functional articulation with adequate mouth opening. In the present study, 5 patients with TMJ ankylosis were evaluated.¹⁰

In cases of TMJ ankylosis, the temporalis muscle and fascia have frequently been employed as interpositional materials. In their protocol, Kaban et al. recommended lining the TMJ with a temporalis myofascial graft.¹¹ All the patients in this study had a temporalis myofascial pedicle flap employed as an interpositional material. In the reconstruction of the ankylosed TMJ, the flap most closely simulates the articular disc.¹² The fundamental concept behind the use of the composite temporalis muscle flap and its associated fascia is to provide a soft tissue interpositional lining within the TMJ to prevent fibrous or bony union as well as to supply an easily displaceable material that exhibits low degree of friction to aid in joint unloading and good stability at host site. Their key advantages over other TMJ lining materials include their autogenous nature, lack of donor-site morbidity, adequate blood supply, and proximity to the joint, allowing for a pedicled transfer of vascularized tissue into the joint area.¹³

Among autogenous tissue, arthroplasty and reconstruction of the RCU using autogenous costochondral grafts is the most effective intervention for treating TMJ Ankylosis, especially in children, primarily due to their biological similarity and their capacity to regenerate and grow.¹⁴ The costochondral transplant may encounter fracture, further ankylosis, or donor site morbidity. Due to their similar characteristics to CCG, sternoclavicular grafts have recently become more popular, albeit the visible scar they produce thereafter can be a disadvantage.^{15,56}

An effective option to reconstructing a neocondyle as a pedicle graft with excellent TMJ function has been demonstrated in animal and human studies using vertical ramus osteotomy.¹⁶ For the treatment of mandibular prognathism, mandibular asymmetry, distraction osteogenesis of the mandible, and post-traumatic reconstruction, vertical ramus osteotomy is indicated.¹⁷ In this study, 5 patients with TMJ ankylosis underwent condylar restoration using the posterior edge of the ramus as a pedicled graft. Paula Cristina explained that in employing this technique, the osteotomized mandibular block

itself can be used to reconstruct the TMJ without the requirement for a second surgical procedure to receive the graft, thereby reducing the morbidity of the procedure and avoiding complications at the donor site.²²

In contrast to free grafts (such as costochondral and clavicular), the posterior border of the mandible can be utilized as a pedicled graft in a safe and simple way. The posterior ramus border has been used as a pedicled graft for the treatment of TMJ ankylosis by Y. Liu et al. and Babu S. Parmar et al in their study.^{1,25} The posterior ramus border is attached to the medial pterygoid muscle, which provides enough blood to minimize bone resorption/necrosis. The incorporation of the posterior border of the ramus in TMJ ankylosis reconstructions has been advocated by these factors.^{21,53}

In the present study, out of 5 subjects 3 were females and 2 were male. Age of the patient ranged from 15-20 years with Mean age 16.8 years. As also were the findings of Orhan Guven (2000) who reported that the highest incidence was observed in 11-20 age group (47%) followed by the 1-10 age group (26%).¹⁹ This could be attributed to fact that younger children (1-10 years of age) are under parental care thereby preventing them from sustaining severe injuries. As the age progresses (age group 11 and above) they are more engaged in physical activity, there by getting more prone to have facial injuries. Lack of organized health care facilities, poor referral in the rural area along with social stigma of gender bias could be the reason for female predominance.²⁰

In our study, 2 cases of right and 3 cases of left TMJ ankylosis were operated upon, though our sample size does not derive any significant result, but it could be due to reflex mechanism as majorities of population are right-handed. Whenever there is fall, our body tries to land on our right side there by having counter coup injury to TMJ. This was also reported by Kavin et al., who found left side more commonly involved accounting for 63.63% of the cases reported.²³

One of the most crucial treatment criteria for TMJ ankylosis is regaining mouth opening.²⁷ In our study mouth opening increased from (6.00 ± 1.58) to (37.60 ± 2.70) post-operatively, till the end of the follow up period of 6 months. Post-operative mouth opening was statistically significant. The increase in the mouth opening was significantly higher from pre operative levels to 1st week, 3rd month and 6th month post-operatively.

This gradual increase may be because of decrease in pain with time and remodeling of RCU. The result is consistent with the study conducted by Bhatt et al. where the immediate postoperative mouth opening and range of motion were excellent in both treatment groups.²⁴ Moreover, Obeid G et al stated that a mandibular opening of 30mm is sufficient to leave patients with little or no functional deficit following reconstruction. In the present study all patient achieved MMO of greater than 30mm.^{37,55}

To avoid recurrence, Topazian suggested using interpositional arthroplasty rather than gap arthroplasty. The mandible becomes a first-class lever after a condylotomy or gap arthroplasty, with the molar serving as the fulcrum and now positioned anterior to the working force. The patient may be more susceptible to developing an open bite deformity as a result of this unstable relationship that is created when the mandible is allowed to rotate posteriorly and upwards.^{41,57}

In addition, shortening of muscles also fails to produce a normal growth. In order to maintain the class 3 lever, restoration of reduced ramal height become essential. Muscular shortening also prevents the patient from growing normally. Restoring the lowered ramal height is crucial for maintaining the class 3 lever.⁴² The mean ramal height at preoperative level in our study was (43.60 ± 3.78) . Immediate post operatively the ramal height reduced to (34.00 ± 3.93) . At the 3rd month Post operative the mean ramal height was (37.00 ± 3.74) and at the 6th month the mean ramal height was (39.40 ± 4.09) . There was decrease in the ramal height from pre operative to immediate post operative level. At the 3rd month and 6th month there was increase in the ramal height from immediate post operative level. Our results were similar to the study of Liu Y et al. who also restored ramal height using the same technique for RCU reconstruction.^{47,54}

In our study, mean preoperative lateral excursion towards the affected side was (1.00 ± 0.70) . At the 1st week Post operative the mean Lateral Excursion of Affected side was (2.40 ± 0.89) . At the 3rd month the mean Lateral Excursion of Affected side was (3.40 ± 0.54) and at the 6th month post operative the mean Lateral Excursion of Affected side was (3.40 ± 0.54) . There was increase in the Lateral Excursion of Affected side from pre operative to 6th month. The increase in the Lateral Excursion of Affected side was significantly higher from pre operative levels compared to the results from 1st week and

3rd Month post-operatively. Between 3rd month and 6rd month there was no change in the mean Lateral Excursion of Affected side. The mean Lateral Excursion of Unaffected side at preoperative level was (0.20 ± 0.44) . At the 1st week Post operative the mean Lateral Excursion of Unaffected side was (1.80 + 0.83). At the 3rd month the mean Lateral Excursion of Unaffected side was (3.60 ± 0.54) and at the 6th month post operative the mean Lateral Excursion of Unaffected side was (4.20 + 0.44). There was increase in the Lateral Excursion of Unaffected side from pre operative to 6th month. The increase in the Lateral Excursion of Unaffected side was significantly higher from pre operative levels at 1st week, 3rd month and 6th month post-operative. The mean Protrusion at preoperative level was (0.20 + 0.44). At the 1st week, 3rd month and 6th month Post operative the mean Protrusion was (1.20 + 0.83). The increase in the protrusion was significantly higher from pre operative levels to 1^{st} week, between 1^{st} week -3^{rd} month and at 6^{th} month there was no change in the protrusion. At final evaluation, protrusive movement was found to be increased post-operatively. Similar results were found in the study performed by Martinez-Lage et al (2004) who stated that this was due to reattachment of the lateral pterygoid muscle, but also to the transfer of part of the medial pterygoid muscle to a more horizontal position.53

The mean pain at 1st day was (7.40 \pm 0.54). At the 3rd day the mean pain score was (6.40 \pm 0.54). At the 7th day post operative the mean pain score was (4.20 \pm 0.44). At the 10th day the mean pain score was (0.40 \pm 0.54). There was significant decrease in the pain score from 1st day to 10th day and the reduction in pain was significant through all the time intervals. Our results were similar to the findings of Wolford LM et al, who stated that gradual decrease in pain and increase in inter-incisal mouth opening was expected post-operatively as in reconstruction of RCU by total joint replacement.⁵¹

At the surgery site, none of the patients had infections. At the follow-up visit, no incidences of reankylosis, infections or graft rejection were observed. These results were congruous with the study conducted by Fernando Briceño where the study revealed that 100% of the operated site have remained stable through time without any infection.⁵¹

The results of some of the previous studies highlight the importance of immediate postoperative exercises and appropriate physiotherapy as a key element in the success of TMJ ankylosis management. Ineffective postoperative physical therapy or noncompliance on the part of the patient may negate reconstruction. Nevertheless, all of our patients continued receiving regular physiotherapy and exhibited improved mouth opening at routine follow-ups.

CONCLUSION

In order to treat TMJ ankylosis, this study combined the vertical ramus osteotomy (VRO) technique with myofascial temporalis interposition after reconstruction of the ramus condyle unit (RCU) by vertical ramus osteotomy, which is less intrusive, safe, and efficacious since there is no need to explore two surgical sites, donor site morbidity and graft resorption can be easily avoided. With these benefits in mind, this study was conducted in the Department of Oral and Maxillofacial Surgery of Babu Banarasi Das College of Dental Sciences to determine the viability of VRO on the posterior border of the mandibular ramus for reconstruction of the RCU.

Conclusions drawn from the study are: -

- i) Inter-incisal mouth opening increased significantly at 1 week, 3^{rd} month and 6^{th} month post-operatively.
- Mandibular movements i.e., lateral excursion and protrusive movements improved significantly at 1 week, 3rd month and 6th month post-operatively.
- iii) There was significant decrease in the pain score from 1st day to 10th day and the reduction in pain was significant through all the time intervals.
- iv) No other post-operative complications were recorded.

Early mouth opening exercises following surgery and the appropriate physiotherapy were crucial in preventing recurrence. However, a study with additional functional parameters and a longer follow-up is needed to examine the proper adaptation and function of the graft, growth of the mandible, improvement in aesthetics, and recurrence of ankylosis.

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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: 26

BBDCODS/04/2022

Title of the Project: Condylar reconstruction with vertical ramus osteotomy in TMJ ankylosis patients.

Principal Investigator: Dr Rajatava Paria

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 Rajatava Paria,

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

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Amrit Tandan Member	Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow
3.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics, BBDCODS, Lucknow

 Dr. Akanksha Bhatt Reader, Department of Conservative Dentistry & Endodontics, Member BBDCODS, Lucknow

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

The comments were communicated to PI thereafter it was revised.

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

Leurani Bale

(Dr. Lakshmi Bala) Member-Secretary IEC Member-Sucratery Institutional Ethic Computed BBD College of Dental Sciences BBD University Faizabud Bord, Eucleane-205025 Forwarded by:

(Dr. Punget Ahuja) Principal

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Institutional Research Committee Approval

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

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled "Condylar Reconstruction with Vertical Ramus Osteotomy in TMJ Ankylosis Patients" submitted by Dr Rajatava Paria 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.

dava

Prof. Vandana A Pant Co-Chairperson

Prof. B. Rajkumar Chairperson

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. Ask us for any clarifications or further information. Whether or not you wish to take part is your decision.

3. What is the purpose of the study?

This study aims to 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. If the volunteer is illiterate then compensation for his/her wage/livelihood for a day is met, if he/she participates in the study? What exactly will happen e.g. blood tests, interviews etc.?

Whenever possible please draw a simple flow chart or plan indicating what will happen at each visit. What are the volunteer's/patient's responsibilities? Set down clearly what you expect of them in the form of simple instructions, for example asking them to come to the Institute at 9.00 am without having eaten anything/on an empty stomach/fasting. You should explain simply and briefly the research methods you intend to use.

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? What happens if the volunteer/patient becomes pregnant after performing first visit? Will she still be included in the research study if she needs to come after an interval of months? When and to whom this information has to be passed?

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.

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

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

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

12. What are the possible benefits of taking part?

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

It is important not to exaggerate the possible benefits to the patient during the course of the study/intervention, e.g., saying they will be given extra attention.

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. If you decide to withdraw, your researcher will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

Nothing will happen to the participants.

15. What if something goes wrong?

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

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

Yes it will be kept confidential.

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

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 PEDIATRIC AND PREVENTIVE DENTISTRY, BBDCODS. The research is self -funded. The participants will have to pay for procedural charges as given by the institution.

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

Yes

20. Who has reviewed the study?

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

21. Contact for further information

Dr. Rajatava Paria

Department of Oral & Maxillofacial Surgery, Babu Banarasi College of Dental Sciences. Lucknow-226028 Mob- 9433539785

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	•
Name	•••
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। यदि स्वयंसेवक निरक्षर है तो उसके एक दिन के वेतन/आजीविका के लिए मुआवजा दिया जाता है, यदि वह अध्ययन में भाग लेता है? वास्तव में क्या होगा उदा। रक्त परीक्षण, साक्षात्कार आदि? जब भी संभव हो कृपया एक सरल प्रवाह चार्ट या योजना बनाएं जिसमें यह दर्शाया गया हो कि प्रत्येक मुलाकात में क्या होगा। स्वयंसेवक/रोगी की जिम्मेदारियां क्या हैं? सरल निर्देशों के रूप में स्पष्ट रूप से निर्धारित करें कि आप उनसे क्या अपेक्षा करते हैं, उदाहरण के लिए उन्हें बिना कुछ खाए/खाली पेट/उपवास के बिना सुबह 9 बजे संस्थान आने के लिए कहना। आपको उन शोध विधियों की सरल और संक्षिप्त व्याख्या करनी चाहिए जिनका आप उपयोग करना चाहते हैं।

7. मुझे क्या करना होगा?

क्या 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. शोध का आयोजन कौन कर रहा है?

यह शोध बाल चिकित्सा और निवारक दंत चिकित्सा विभाग, बीबीडीसीओडीएस में किया गया है। शोध स्व-वित्त पोषित है। प्रतिभागियों को संस्था द्वारा दिए गए प्रक्रियात्मक शुल्क का भुगतान करना होगा।

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

हां

20. अध्ययन की समीक्षा किसने की है?

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

21. अधिक जानकारी के लिए संपर्क करें

डॉ. रजतावा पारिया

ओरल और मैक्सिलोफेशियल सर्जरी विभाग,

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ-226028

मोब- 9433539785

डॉ. लक्ष्मी बाला

संस्था की आचार समिति के सदस्य सचिव,

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ

bbdcods.iec@gmail.com

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

पीआई के हस्ताक्षर नाम·····। तारीख·····.....

Babu Banarasi Das College of Dental Sciences (Babu Banarasi Das University)

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

Consent Form (English)

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 datedfor the above study and have had the opportunity to ask questions. **OR** I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.
- 2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
- 3. I understand that the sponsor of the project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.
- 4. I agree not to restrict the use of any data or results that arise from this study provided such a use 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.

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

सहमति प्रपत्र (अंग्रेज़ी)

अध्ययन का शीर्षक- मौखिक 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)।

1. मैं पुष्टि करता हूं कि मैंने प्रतिभागी सूचना दस्तावेज दिनांक . को पढ़ और समझ लिया है

·····..उपरोक्त अध्ययन के लिए और प्रश्न पूछने का अवसर मिला है। या मुझे अन्वेषक द्वारा अध्ययन की प्रकृति के बारे में बताया गया है और मुझे प्रश्न पूछने का अवसर मिला है।

2. मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और बिना किसी दबाव के स्वतंत्र इच्छा के साथ दी गई है और मैं बिना कोई कारण बताए और अपनी चिकित्सा देखभाल या कानूनी अधिकारों को प्रभावित किए बिना किसी भी समय वापस लेने के लिए स्वतंत्र हूं।

3. मैं समझता हूं कि परियोजना के प्रायोजक, प्रायोजक की ओर से काम करने वाले अन्य, नैतिकता 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	तारीख·····.
गवाह के हस्ताक्षर·····	तारीख·····.

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·····..

CASE HISTORY PROFORMA DEPARTMENT OF ORAL MEDICINE AND RADIOLOGY BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

OPD NO.	CASE NO.	DATE:	
NAME: OCCUPATION: ADDRESS:	AGE:	GENDER:	
CONTACT NO: CHIEF COMPLAINT: PAST MEDICAL HISTORY:			
DRUG ALLERGY: PAST DENTAL HISTORY: FAMILY HISTORY:			
FAMILY HISTORY: DELETERIOUS HABITS: GENERAL PHYSICAL EXAMINATION: BLOOD PRESSURE - PULSE - RESPIRATION RATE -			
EXTRAORAL EXAMINATIO			
INTRAORAL EXAMINATIO Hard Tissue Examination:	JN:		
Soft Tissue Examination: PROVISIONAL DIAGNOSIS	5:		

RADIOGRAPHIC INVESTIGATION:

- 1. Orthopantomogram
- 2. Lateral Cephalogram

Plagiarism Report

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INTRODUCTION