Minutes Of Ethical Committee – A Meeting Held On 11/04/2014 Friday In Govt. Dental College & Hospital, Ahmedabad.

Following members were present in Ethical Committee.

1. Dr. Sunil Kumar
2. Dr. Girish Parmar
3. Dr. Jigna Shah
4. Dr. Geeta Asthana
5. Dr. Jayshankar Pillai

Dr. Girish Parmar, Dean Govt. Dental College & Hospital, warmly welcomed the Chairperson Dr. Sunil Kumar, Senior Deputy Director, NIOH, Ahmadabad, Other committee members & all researchers. He stated the purpose of the meeting to follow the ethical norms with concern study to all researchers. The committee was felt that dignity & privacy of each participant should be maintained.

Various researchers were instructed to present their summary of project individually in terms of methodology, overviews, importance of study & ethical criteria regarding the subject. Various researchers have presented studies with documents pertaining to CRF (Case record Form), Informed Consent Form & withdrawal Form dually filled for each case. Researchers are also instructed to submit the copy of final result of the project/study duly signed by PG teaches/HOD & should be kept in respective Dept on completion of study.

Reference Study No: 1

Subject of Study: A Study Of The Osteogenic Differentiation Potential Of Mesenchymal Stem Cells Derived From Dental Origin And The Effect Of Different Surface Treatments Of Titanium Implants On Their Osteogenic Differentiation Potential And Adherence Potential.

Principal Investigator: Dr. Rupal J. Shah
Co-Investigators: Dr. Preeti Agarwal, Dr. Hemal Agrawal Dr. Bhavyata Darji
Department: Prosthodontia

Introduction: Titanium implants are widely used in orthopaedic and dental surgery. Surface properties play a major role in cell and tissue interactions. Overall, surface treatments may promote early osteoblastic differentiation and, consequently, rapid osseointegration of titanium implants

Objectives:

Phase 1: To isolate, culture and differentiate human mesenchymal stem cells from dental pulp of extracted permanent third molars.

Phase 2: To study the effect of different surface treatments of titanium implants (coated /uncoated/ sandblasted/ acid etched) on adherence potential and osteogenic differentiation potential of human mesenchymal stem cells derived from dental pulp of extracted permanent third molars.

Methodology:

A. Cell isolation

1. Human impacted third molars to be obtained with informed consent from patien approved by ethics committee.
2. Samples are to be obtained from 5 patients aged 18-25 years with impacted third molars
3. Pulp tissue explants to be transported to lab in Dulbecco's phosphate buffered saline containing 2% antibiotics, antimycotics (a/a, 100 µL penicillin, 0.1 mg/ mL streptom 0.25µg/mL amphotericin B)
4. Dental pulp tissue fragments are to be minced using scalpels and digested in Collag type I (3mg/mL) and Dispase (4mg/mL) for 1 hour at 37°C.
5. Obtained cell pellet is to be suspended in 500 µL of DPBS and passed through 100µm strainer.

B. Cell Culture:

6. The isolated dental pulp stem cells (DPSCs) are to be cultured in Dulbecco's mod Eagle's medium (DMEM) /F-12, 1:1 mixture, supplemented with 1% L- alanyl-L- glutam 1% a/a, and 20% allogenic HS (human serum-medium).
7. DPSCs expanded in DMEM are to be harvested by trypsinization using TrypLE Selec xeno-free detachment of cells
8. After initial passage, concentration of HS can be reduced to 15% in the cu medium…monitored daily for growth…medium can be changed three times a week assays are to be performed using cells between passage 2 and 4.

C. Cell counting and viability

D. Flowcytometric marker expression analysis

9. DPSCs cultured in HS-M are to be analyzed for cell surface antigen expression by f cytometry-(Fluorescence Activated Cell Sorting (FACS):
10. Monoclonal antibodies against CD90- allophycocyanin, CD 105- phycoerythrin, CD fluorescein isothiocyanate and CD45 FITC are to be used.
11. Antibodies are to be added to 100,000 cells/sample and then incubated for 30 min at 4°C the dark. After incubation, cells are washed and analyzed by flow cytometry.

Step 4: data collection and statistical analysis

Concluding Remarks:

From this study, we may be able to demonstrate the influence of titanium surface treatment on h behavior of human mesenchymal stem cells and use this to promote better osseointegration in den implants.

COMMENTS: THE INVESTIGATORS NEED TO GET THE APPROVAL FROM ANY H SCR AND ALSO FROM NAC-SCR. WITH THE IC-SCR AND IEC APPROVAL THE NEED TO APPLY TO NAC-SCR FOR FINAL APPROVAL BEFORE STARTING TH PROJECT.

The ethical clearance of IEC shall be issued after approval from IC-SCR.

Reference Study No.: 2
Subject of Study: An Electromyography comparative Evaluation of the Efficacy of Splint Therapy and Masticatory Muscle Exercise Therapy in the Management of Temporomandibular Joint Dysfunctions- a Randomized Controlled study.

Principal Investigator: Dr. Preeti Agarwal
Co-Investigator: Dr. Rupal J. Shah
Department: Prosthodontia

Introduction and Objectives: Recently, randomized clinical trials (RCT) have found that stabilization splints are more effective than other treatments. However, there are some studies that have yielded contradictory results. Because of these diverse opinions, there obviously is a strong need for further RCTs to identify if a stabilization appliance is really effective.
Objectives: The purpose of this study was to electromyographically evaluate the efficacy of splint therapy in comparison with masticatory muscle exercise therapy in the management of temporomandibular joint dysfunctions
Methodology: The sample of study consisted of forty consecutive patients diagnosed with TMD. Patients were randomly assigned into two groups: a splint group (n = 40) comprising of patients treated with stabilization splint, counseling and masticatory muscle exercises, and a control group (n = 40), comprising of patients treated with counseling and masticatory muscle exercises alone. EMG records were carried on for temporalis muscle and masseteric muscles for both the groups were collected at the beginning of the study and after a 6-month follow up.
Concluding Remarks: The findings of this randomized controlled study will show whether stabilization splint treatment in combination with counseling and masticatory muscle exercises has any additional benefit in relieving facial pain and increasing the mobility of the mandible than counseling and masticatory muscle exercises alone over a 6-months' time interval.

COMMENT: THE INVESTIGATORS NEED TO MENTION FROM WHERE THE EMG FACILITY WILL BE UTILISED.
This Project is Ethically Approved

Reference Study No. 3
Subject of Study: A Comparative Analysis of Peri-implant Bone Levels of Immediate and Conventionally Loaded Implants- An In-Vivo Study.

Principle Investigator: Dr. Prakash Barajod.
Co-Investigator: Dr. Sanjay Lagdive, Dr. Rupal Shah
Department: Prosthodontia

Introduction & Aims & Objectives: With the trend of shortening the treatment time and reducing patient discomfort, immediate loading of implants has immerged as an alternative approach for replacing missing natural teeth. This study will evaluate and compare the effectiveness of immediate implant loading protocol over conventional implant loading protocol with respect to peri-implant

bone loss, and soft tissue health around the implant in partially edentulous mandible using di periapical radiography. .

Methodology: In the present study, peri-implant soft and hard tissue will be compared in a di way between 10 immediate functionally loaded implants and 10 implants loaded after 3-m healing. Two piece implants will be used for both immediate loading and delayed loading techni Adjacent hard and soft tissues of immediate loading and delayed loading will be evaluated compared using gingival index and digital radiographic examination at 2, 4 and 6 months. Mean standard deviation of the samples of both groups at different points of time will be compare using Wilcox on signed rank test.

Conclusion: If statistically or clinically no significant differences between immediate and del loading of dental implants are found, immediate loading of implants can be considered a alternative approach for replacing missing natural teeth at least in patients with good bone qu and quantity.

COMMENTS: SAMPLE SIZE SHOULD BE MINIMUM 30

This Project is Ethically Approved

Reference Study No: 4

Subject of Study: "Comparison of Digital Panoramic Radiography and Cone Beam Compu Tomography (CBCT) For Dental Implant Treatment Planning- An In-Vivo Study."

Principal Investigator: Dr. Fatema Dewan

Co-Investigator: Dr. Rupal Shah

Department: Prosthodontia

Introduction & Aims & Objectives: The widespread use of dental implants in partially completely edentulous patients has brought about a need to preoperatively depict and quan accurate bone height and contour. A number of conventional intraoral and extra oral radiograp techniques have been used, including the relatively new modality of Cone Beam Compu Tomography (CBCT). Despite rapid advances in imaging technology, many clinicians continu rely on techniques such as panoramic radiography that produce images that distort the jaws n uniformly. This study will compared bone height measurements of jaws made with these imaging modalities.

Methodology: Thirty sites will be identified in patients who are to have one or more de implants. These sites will be imaged with both imaging techniques (Digital panoramic and CB and mean bone height will be determined for each imaging technique and site. A student's paire test will be performed to compare the statistical differences between the mean bones heig measured with the two imaging modalities. Spearman's rho test will be used to determine the deg of correlation between mean bone height measurements made by the two techniques.

Conclusion: If a significant difference is found with a paired t-test between mean bone hei measurements & SDs recorded from the two techniques, and if the measurements derived for panoramic radiographs are greater than those obtained with the CBCT, it can be concluded tha digital OPG might be overestimating the available bone height.

COMMMENTS: SAMPLE SIZE SHOULD BE DOUBLE

This Project is Ethically Approved

Reference Study No: 5
Subject of Study: An Evaluation of Stress Related Oral Disorders

Principal Investigator: Dr. Piyush Limdiwala
Co-Investigator: Dr. Girish Parmar, Dr. Jigna Shah
Department: Oral Medicine & Radiology

Introduction & Aims & Objectives:
The purpose of present study is to establish stress rating scale in community coming to Dental OPD for dental treatment & also correlation of stress with common dental disorders.
For stress measurement various methods can be used.

- Psychological questionnaires (Stress rating scale)
- Laboratory investigations (e.g. Serum cortisol)
- Oral examination

Methodology:
All the patients reporting to outpatient department of Govt dental college and hospital ranging from 21–60 years will be included randomly in present study. This study will be divided in two groups. Study group, those having stress related lesions (Like Lichenplanus, Recurrent Apthous Ulcer, Burning Mouth Syndrome and Myofacial Pain Dysfunction Syndrome) & other will be controlled group. For establish stress rating scale, The *Perceived Stress Scale* (PSS) questionnaire will be asked to all patients included in study. These patients will be thoroughly examined clinically for presence of oral lesions. After getting questionnaires blood samples will be collected of both group patients. Samples will be collected & stored in deep refrigerator. By ELISA/RIA method, Serum cortisol levels will be measured. On the basis of above investigations the role of stress in causation of the above mentioned oral lesions will be determined. Statistical analysis will be done to determine the role of stress related to lesions. All the patients with oral lesions will be treated with medicinal & non medicinal treatment according to diseases & kept for follow up for at least 3 months. After completion of treatment stress level will be measured again by questionnaires.

- Type of study: randomized controlled trial base (RCT)
- Study population- Age range 21-60 years
- Approximate study sample: 100-150 patients (70 study & 70 controlled group)

This Project is Ethically Approved

Reference study No. 6
Subject of Study: Environmental Factors and Auto-Immune Diseases

Principle Investigator: Dr. Nayan Chaudhari
Co-Investigator: Dr. Jigna Shah
Department Oral Diagnosis & Radiology

Introduction & Aims & Objectives: Autoimmune diseases can be described by the irregu functioning of the immune system that causes an individual's immune system to generate antibod which attack their own body tissues. There are currently more than 80 various kinds of auto-immu diseases. Auto-immune diseases, which affects as least 5% of the population of world. Vari environmental factors have been considered in etiology of these diseases like Tobacco smok which is one of the most powerful environmental factors that could prompt autoimmune disea Chemical & Toxic Metal Exposure, Ultraviolet (UV) light, food can also be a source of chemica which have been implicated in the acquisition of autoimmune disease. Drugs like trimethopr nitrofurantoin, carprofen, phenylbutazone, phenobarbital, primidone, diethycarbamaz Penicillamine, Stress, infection etc. Aim of this study is to review the various environmental facto in Auto-immune disorders.

Methodology: Patients clinically diagnosed as Auto-immune diseases were selected from patien reporting in the department of Oral Diagnosis and radiology, Government Dental College a Hospital, Ahmadabad. Patients were selected randomly irrespective of their age, sex, and so Detailed history was recorded and special proforma was filled up to find out predisposi environmental factors by history and clinical examination as well as investigations. Requir treatment was given to the patients and follow-up was done.

Conclusion: According to results obtained by pilot study conducted on 30 patients majority o patients were between 30 to 60 years old. Most of the patients were females. 20 % patients had hab of smoking. Ultraviolet light, in our study approximately 50% of patients had history of chemic exposure, metal exposure or UV rays exposure. 50% patients were suffering from stress, anxiety depression.

This Project is Ethically Approved

Reference study No. 7
Subject of Study: Temporomandibular Disorders Review and Management by Diazepam

Principle Investigator: Dr. Neha Kharodia
Co-Investigator: Dr. Jigna Shah
Department Oral Diagnosis & Radiology

Introduction & Aims & Objectives: TMDs is a collective term which includes a No. Of clinical signs and symptoms in the masticatory system, that is, in the temporomandibular joints, the masticatory muscles and the associated structures. TMDs are a synonym for craniomandibular disorders and a subclass of musculoskeletal disorders and after toothache they are considered to be the main cause of orofacial pain. Various temporomandibular muscle disorders include myofascial pain, myositis, muscle spasm, muscle contracture. Temporomandibular joint disorders like TMJ disc displacement with or without reduction, osteoarthrosis, TMJ subluxation or dislocation other disorders like ankylosis, traumatic injuries and fractures, neoplasms, and developmental abnormalities. Reversible and irreversible therapies are performed in TMDs treatment. Diazepam, a benzodiazepine, has been advocated for many years for TMD patients. Though treatment should always be started with non pharmacological means like self management & physical therapy, in patients refractory to or with severe pain component or for myalgia, especially with limited opening

NSAIDs and benzodiazepines are effective. In this study patients are given Diazepam (which produces centrally mediated skeletal muscle relaxation and is a sedative) and its analgesic efficacy has to be evaluated.

Methodology: A total of 60 patients of either sex, between 15-60 years of age, reporting to the Department of Oral Medicine and Radiology will be selected The patients will be divided in 2 groups Group1 will be given oral diazepam 5mg once daily before sleep. Group 2 will be given placebo once daily in the morning. The average pain intensity to be recorded with visual analog scale (VAS) at pretreatment, at weekly interval till the completion of a three-week trial and at post-treatment visit on the eighth week from baseline.

Conclusion: A pilot study was conducted on 10 patients where diazepam was proven to be more efficacious than placebo.

This Project is Ethically Approved

Reference study No. 8

Subject Of Study: Burning Mouth Syndrome -Is It An Autoimmune Phenomenon?

Principle Investigator: Dr. Neha Kharodia
Co-Investigator: Dr. Jigna Shah
Department Oral Diagnosis & Radiology

Introduction & Aims & Objectives: Burning Mouth Syndrome (BMS) is a condition characterized by a sensation described by the patient as stinging; burning that affects the oral mucosa in absence of laboratory or clinical data to justify these symptoms. It has been defined principally by the quality or location of the pain .The most affected area is the tongue (tip and lateral borders) thus denominated glossodynia, glossopyrosis and glossalgia. The exact cause of burning mouth is difficult to pin point. This disorder has long been linked to a variety of other conditions menopause, diabetes, nutritional deficiencies, tongue thrusting, disorders of the mouth (oral thrush and dry mouth), acid reflux, cancer therapy and psychological problems Neuropathic mechanism for BMS is currently favored. Until today BMS is not considered as an autoimmune phenomenon. Hence this study is conducted to consider whether BMS has an autoimmune phenomenon or not by reviewing various causes as well as by clinical study.

Methodology: In the present study all the patients reporting to Oral Diagnosis and Radiology Department, Govt College and Hospital, Ahmedabad were asked for complain of burning sensation in oral cavity .on the basis of inclusion criteria patients were categorized in the three categories. Patients with type 1 BMS (35%) are symptom-free upon awakening with worsening symptoms throughout the day and variable symptoms at night. Type 2 BMS (55%) is defined by continuous symptoms in the day but none at night. Type 3 BMS (10%) have intermittent symptoms interspersed with symptom-free days. Type 1 BMS is linked to nutritional deficiencies and diabetes, Type 2 to chronic anxiety, and Type 3 to dietary or prosthetic allergies. Laboratory analyses included Hematological assessment of nutritional deficiencies, Blood glucose levels, Autoimmune markers, Estrogen and progesterone concentrations, Patch testing for specific allergies Among the above mentioned categories patients were then evaluated if up to what level autoimmunity could be held responsible for burning mouth syndrome.

Conclusion: A pilot study was conducted on 8 patients Out of the 8 cases with BMS, 7 (75.
were women, of whom 6(54%) were postmen menopausal. The ratio of women to men was 7: 1.
mean age of subject s with BMS was 51.7 years, and the range was 32 –70 years.7 (81. 6%) of
subject s with BMS were between 45 and 70 years of age. Duration of symptoms varied from
than 4 months to 11 years, with a median of 9 months.

This Project is Ethically Approved

Reference study No. 9
Subject of Study: Condylar Changes-Panoramic and CBCT Studies

Principle Investigator: Dr. Monali Prajapati
Co-Investigator: Dr. Jigna Shah
Department Oral Diagnosis & Radiology

Introduction & Aims & Objectives: Condylar morphology varies greatly among different
groups and individuals. Morphologic changes may occur on the basis of simple developme
variability as well as remodeling of condyle to accommodate developmental variati
malocclusion, trauma and other developmental abnormalities and diseases. Radiogra
examination forms an integral part of clinical assessment in patients with TMJ disorders. The pre
study will be undertaken to evaluate radiographic changes in the condylar morphology in health
disease using panoramic and cone beam computerized tomography and its association with age,
clinical signs and symptoms of temporomandibular joint dysfunction.
Methodology: A total of 30 patients of either sex, between 10-70 years of age, reporting to
Department of Oral Medicine and Radiology with clinical signs and symptoms
temporomandibular disorders will be selected. All subjects will be explained about the proced
and an informed consent taken from each. Subjects will be examined for facial asymmetry,
mouth opening, and deviation of jaw, joint sounds and tenderness of joint and muscles
mastication. Subjects will be subjected to Digital panoramic radiography and cone be
computerized tomography. Digital panoramic radiograph and cone beam computerized tomogra
of this study sample will be studied for the condylar morphology and changes if any.
CONDYLAR MORPHOLOGY will be analyzed according to Yale as:
a. Flat, b. convex, c. angled, d. round
BONE CHANGES will be analyzed as
a. Flattening, b. Osteophyte, c.Erosion, d.Sclerosis, e. Ely's cyst

COMMENT: THE COMMITTEE INSTRUCTED THE INVESTIGATORS TO HA
MINIMUM OF 30 PATIENTS FROM EACH GROUP.
This study has been ethically approved.

Reference study No. 10
Subject Of Study: Transcutaneous Electrical Nerve Stimulation Therapy (TENS) In Chro
Orofacial Pain

Principle Investigator: Dr. Monali Prajapati
Co-Investigator: Dr. Jigna Shah
Department Oral Diagnosis & Radiology

Introduction & Aims & Objectives: The orofacial pain classification as outlined by Okeson is divided into physical (Axis 1) and psychological (Axis 2) conditions. Physical conditions comprise temporomandibular disorders (TMD), which include disorders of the temporomandibular joint (TMJ) and disorders of the musculoskeletal structures (e.g., masticatory muscles and cervical spine); neuropathic pains, which include episodic (e.g., trigeminal neuralgia [TN]) and continuous (e.g., peripheral/centralized mediated) pains and neurovascular disorders (e.g., migraine). Psychological conditions include mood and anxiety disorder.
Many treatment modalities have been described from time to time including pharmacological as well as non pharmacological in the treatment of orofacial pain.
TENS is a method of electrical stimulation which primarily aims to provide a degree of symptomatic pain relief by exciting sensory nerves and thereby stimulating either the pain gate mechanism and/or the opioid system.
TENS is inexpensive, non-invasive, effective and swift method of analgesia, which if found effective, could provide the primary line of management in orofacial pain.
This study aims to evaluate the efficacy of Transcutaneous electrical nerve stimulation therapy in chronic Orofacial pain.

Methodology: A total of 80 patients of either sex diagnosed of having neuropathic or muscular pain involving the orofacial region reporting to Oral Medicine and Radiology department of GDCH, Ahmedabad will be selected for the study. Patients refractory to or intolerant to previous medication will be included in the study and those with cardiac pacemaker and recent history of trauma or dental surgery, excluded. All subjects will be explained about the procedure and an informed consent taken from each. Patients will be subjected to TENS therapy and intensity of pain will be recorded every week on Visual analalogue scale (VAS) scale for 1month
This study has been ethically approved.
COMMENT: THE COMMITTEE INSTRUCTED THE INVESTIGATORS TO HAVE MINIMUM OF 30 PATIENTS FROM EACH GROUP.
This Project is Ethically Approved

Reference study No. 11
Subject Of Study: Radiotherapy And Its Oral Complications In Head And Neck Malignancy

Principle Investigator: Dr. Bhavik Mavani
Co-Investigator: Dr. Jigna Shah
Department Oral Diagnosis & Radiology

Introduction & Aims & Objectives: In addition to anti-tumor effects, ionizing radiation causes damage in normal tissues located in the radiation portals. The clinical consequences of radiotherapy include mucositis, hypo salivation, taste loss, bacterial and viral infections, radiation caries, and

trismus, osteoradionecrosis. ... evaluate the oral complica... of radiotherapy in patients with head and neck malignancy during radiotherapy and ... radiotherapy.

Methodology: A total of 50 patients of either sex, between 5-70 years of age, after surgical exc... and selected for radiotherapy reporting to the Department of Oral Medicine and Radiology wi... included in the study. Subjects will be examined during radiotherapy and post radiotherapy for ... complications. All subjects will be explained about the procedure and an informed consent ta... from each. Diagnosis of complications will be based on diagnostic criteria of study and manage... of complications will be done with oral hygiene measures along with medications

COMMENT: THE COMMITTEE INSTRUCTED THE INVESTIGATORS TO SPEC... THE RADIATION DOSE IN THE SYNOPSIS AND ALSO TO HAVE A CO-ORDINAT... FROM THE RADIOTHERAPY DEPARTMENT OF GCRI WITH AN OFFIC... PERMISSION.

This Project is Ethically Approved

Reference study No. 12

Subject Of Study: Tobacco Cessation: Review And Its Clinical Implications

Principle Investigator: Dr. Bhavik Mavani
Co-Investigator: Dr. Jigna Shah
Department Oral Diagnosis & Radiology

Introduction & Aims & Objectives: Tobacco use is a leading cause of preventable deaths all o... the world. Tobacco is also one of the major causes of deaths and diseases in India, accounting ... almost a million deaths every year. Tobacco dependence is a chronic condition that often requi... repeated interventions. Tobacco cessation methods are both clinically effective and cost effective ... relation to other medical and disease prevention interventions .present study is aimed to review a... assess the effectiveness of tobacco cessation interventions in smoker and nonsmokers in de... setting.

Methodology: A total of 40 patients of either sex, of age between 20 to 60 with tobacco ha... (smokeless /smoking) reporting to Oral Medicine and Radiology department will be selected for ... study. Subjects will be grouped into behavior counseling (1) behavior counseling + nicot... replacement therapy (2). All subjects will be explained about the procedure and an informed cons... taken from each. Nicotine dependence will be recorded by fagerstrom test and followed up at regu... interval.

This Project is Ethically Approved

Reference Study No.13

Subject Of Study: A Prospective Randomised Clinical Trial Comparing 2mm Locking Pl... To 2mm Non locking Plates In Treatment Of Mandibular Fractures

Principal Investigator: Dr. Harsh Shah

Co-Investigator: Dr. Babu Parmar
Department: Oral Surgery

Introduction: This study evaluates the efficacy of a 2.0-mm locking plate/screw system compared with a 2.0-mm nonlocking plate/screw system in mandibular fractures. The loosening of one or more screws during the convalescent period and the plate must be perfectly adapted to the underlying bone to prevent alterations in the alignment of the segments and changes in the occlusal relationship are problems especially in mandibular fracture osteosynthesis following nonlocking plate osteosynthesis. This problem has been overcome by the development of the locking plate/screw system.

In the beginning of 21st century, a locking principle was adapted in the nonlocking plate/screw system which was claimed to overcome disadvantages of the nonlocking plate system and still work as a mini internal rigid fixator.

Aims and objectives:

- To evaluate the efficacy and degree of adaptation of locking plate on rigidity of fixation in mandible fractures as compare to nonlocking plate.
- To evaluate efficacy of locking component to gain more stability and consequent exact reconstruction of occlusion.
- To evaluate efficacy of locking screw to resist bending and torsional forces along with axial load.

Locking 2.0 plates utilize double threaded screws, which lock to the bone and the plate, creating a mini-internal fixator.

Results in:

- More rigid construction with less distortion of the fracture or osteotomy,
- Less screw loosening and less interference with bone circulation since the plate is not too tightly pressed against the bone.
- Reduces compressive forces between the under surface of the plate and lateral bony cortex compared with a conventional mandibular plate.
- Limits stress shielding and create a more stable fixation over time.
- Less alteration in osseous or occlusal relationship on screw tightening; greater stability across the fracture site; and less screw loosening.

Methodology: A prospective randomized clinical study will be conducted in which 5-10 cases of each techniques of fracture mandible will be selected at the Dept. of Oral and Maxillofacial Surgery, Govt. Dental College & Hospital, Ahmedabad. All the patients will be managed by rigid internal fixation using 2.0mm titanium locking and nonlocking plates and screws. The patients will be operated under local or general anaesthesia by appropriate approach to the fracture site, either an intra-oral or extra oral.

COMMENTS: THE STUDY SHOULD NOT BE OF CLINICAL TRIAL, IT SHOULD BE OF CLINICAL EVALUATION AS THE SAMPLE SIZE IS VERY LESS OR ELSE INCREASE THE SAMPLE SIZE. IT SHOULD NOT BE COMPARATIVE STUDY

This Project is Ethically Approved

Reference study No. 14
Subject of study: Clinical and Radiological evaluation of Direct and Indirect Sinus Maxillary Dental Implants- a comparative study.

Principal Investigator: Dr. Lalit Sagarka
Co-Investigator: Dr. Babu Parmar
Department: Oral Surgery

Introduction & Aims & Objectives: Dental implants currently are advance technology has t a natural tooth. Implant success in posterior maxilla is frequently challenged by unfavorabl extraction resorptive patterns, pneumatization of the maxillary sinus, and the often poor qua the remaining alveolar bone. Hence, sinus floor elevation has become an important proced peri-implant grafting. There are two main way of reaching sinus membrane; a direct one and in method of sinus augmentation. The direct sinus augmentation technique (DSAT) involves visualization and manipulation of Schneiderian membrane while the other method indirectly (manipulates the membrane. The present prospective study was undertaken to evaluate the g height of new bone formation in the maxillary sinus following direct and indirect sinus lift tech and insertion of titanium implants with/without additional grafting material.

Aims & Objectives:

- To evaluate Survival rates of implants placed in direct sinus floor augmentation site comparable to those in indirect sinus floor augmented sites.
- To evaluate the acceptability of the implant by assessing peri-implant soft tissues.
- To evaluate the merits and demerits of direct & indirect sinus floor elevation technique.
- To evaluate its effect on crestal bone loss and osseointegration.

Methodology: In the present study patients will be randomly selected irrespective of se socioeconomic status from amongst the patients attending the Department of Oral & Maxillof Surgery, Government Dental College & Hospital, Ahmedabad.

- Patient will be treated if the remaining teeth are intact minimally restored and if adja teeth show periodontal problems that precludes fabrication of fixed partial dentures.
- After placement of implants, an average of 3 months of healing time will be allowed. T definitive restorations will be placed at 6th month of period, all patients will be followe every 3months for 1 year after placement of implant along with prosthesis
- During follow-up visit, every implant was examined for clinical mobility. Peri-implant tissue examination will be done using a plastic probe and periapical radio-graphs wil taken to see any change in sinus floor level and bone level around the implant.
- **Number of patients:** My proposed study include 5-10 patients for each Technique.

COMMENTS: THE SAMPLE SIZE IS VERY LESS. TITLE SHOULD NOT CONTAIN COMPARATIVE STUDY
This Project is Ethically Approved

Reference study No. 15
Subject of Study: Stem cell therapy in human bone defect repair in Oral and Maxillofac pathologies.

Principal Investigator: Dr. Mitsu M. Meshram
Co-Investigator: Dr. Babu Parmar
Department: Oral Surgery

Introduction: Stem cells are a unique type of cells that have specialized capacity for self-renewal and potency in cell replication. Buccal fat pad (BFP), an adipose-encapsulated mass found in the oral cavity, represent an easy access source for Adipose stem cells (ASCs) which are able to differentiate to chondrogenic, adipogenic, and osteogenic lineages and express multiple growth factors, which makes them suitable for clinical application. Stem cells are useful in the regeneration of bony defects due to cyst enucleation, tumor resection, and/or trauma. The closure of a bone defect is commonly carried out with the transfer of tissue from another site, which has disadvantages like, not being able to restore the unique function of the lost part, donor site morbidity, scarring, and infection. Comparatively, the stem cell therapy is efficient, exhibits low morbidity of the collection site, and the regeneration process is fast and efficient.

Aims & Objectives:

- The present study aims to perceive the hard tissue repair and regeneration of osseous defect, secondary to a pathology using stem cell therapy.
- To study rate of osseous regeneration of the defects with the aid of stem cells.
- To evaluate the acceptability of the material by assessing the newly formed bone.
- To evaluate its effect on the surrounding healthy tissues.
- To evaluate the merits and demerits of applicability of stem cell therapy.

Methodology: Minimum 5 healthy patients of either sex, between 5-70 years of age, reporting to the Department of Oral and Maxillofacial Surgery with well-confined, benign pathologic jaw lesions will be selected. All subjects will be explained about the procedure and an informed consent will be taken from each. After corrective treatment of the pathologic lesions, stem cells harvested from the buccal fat pad area of the patient and cultured in vitro will be transplanted to the surgical site and osseous regeneration at the site will be studied by constant, periodical monitoring.

COMMENTS: THE INVESTIGATORS NEED TO GET THE APPROVAL FROM ANY IC-SCR AND ALSO FROM NAC-SCR. WITH THE IC-SCR AND IEC APPROVAL THEY NEED TO APPLY TO NAC-SCR FOR FINAL APPROVAL BEFORE STARTING THE PROJECT.

The ethical clearance of IEC shall be issued after approval from IC-SCR.

Reference study No. 16
Subject of study: Efficacy of Orthognathic Surgery vs. Distraction Osteogenesis for correction of residual facial deformities due to Temporomandibular Joint Ankylosis.

Principal Investigator: Dr. Siddharth Vyas
Co-Investigator: Dr. Sonal Anchlia, Dr. Babu Parmar
Department: Oral Surgery

Introduction and Aims and objectives: Temporomandibular joint (TMJ) ankylosis is a j disorder which refers to bony or fibrous adhesion of the anatomic joint components and the en loss of function. Compromised esthetics can often be distressing for individuals and funct compromise due to dental malocclusion usually resulting in nutritional deficit. These ultimately l to poor quality of life both physically as well as psychologically.
Surgical treatment of TMJ ankylosis accompanied by dentofacial deformities remains a signif clinical challenge because the malformation is often complex and extensive. It not only affects temporomandibular region but also the whole maxillofacial complex. Surgical management of deformities may be single staged or may require multiple operations depending on the severity definite treatment protocol has been established. This study is directed towards comparing var techniques of Orthognathic Surgery and distraction osteogenesis in correction of these dentofa abnormalities and hence restoring esthetics and function to the optimum.
Aims and objectives are: 1) To study various deformities and disabilities associated temporomandibular joint ankylosis. 2) To study and compare the efficacy of different surg techniques of Orthognathic surgery and distraction osteogenesis in correcting them. 3) To estab definite guidelines for use of various Orthognathic surgical procedures in different cli conditions. 4) To re-establish harmony among the reconstructed TMJ, facial esthetics and t Hence improve the quality and standard of life of the individual.
Methodology: Various Orthognathic surgery and distraction osteogenesis techniques may be u depending on type and severity of facial deformities secondary to Temporomandibular j ankylosis:
i) Genioplasty ii) Uniplanar distraction – body/ramus of mandible iii) Biplanar distraction- body a ramus of mandible iv) Simultaneous maxillo-mandibular distraction v) Asymmetric maxill impaction with bilateral sagital split osteotomy vi) Asymmetric down fracture of maxilla with b graft and sagital split osteotomy vii) Asymmetric impaction with unilateral sagital split osteot and modified Inverted L- shaped osteotomy viii) Asymmetric downfracture with bone graft a Inverted L- Shaped osteotomy with bone graft ix)Asymmetric impaction with unilateral distracti

COMMENTS: THE 3RD & 4TH POINT IN THE AIMS AND OBJECTIVES NEED TO DELETED. REMOVE WORD COMPARE FROM 2ND POINT OF AIMS A OBJECTIVES

This Project is Ethically Approved

Reference Study No: 17
Subject of Study: "A Novel Approach for Recession Coverage Using Modified Po Technique with GTR"

Principal Investigator: Dr. Kunal Patel
Co-Investigator: Dr. Neeta Bhavsar
Department: Periodontia.

Introduction:

- Various surgical techniques are being used to treat gingival recession in which Connective Tissue Graft technique is considered gold standard technique.

- The modified pouch technique with GTR is less traumatic compared to FCTG technique with effective results.

Aims and Objectives:-

- The aim of this procedure is to treat single or multiple maxillary or mandibular gingival recessions by least traumatic surgical procedure.

Methodology:

- Patients with single or multiple maxillary or mandibular gingival recessions are selected.
- Gingival recession of miller's class I, class II, class III or combination are included
- Following local anaesthesia a horizontal incision of 2-3mm is given at the base of recession site with BP blade no.12.
- Full thickness flap including 2 papillae mesial and 2 papillae distal to recession is elevated using an elevator.
- This freely movable flap is then stabilized by tension created by pouching of the tissue by tucking a Bio-resorbable membrane into the sub gingival space beneath the marginal tissue and papillae.
- Incision left to heal by primary intention.
- Patient advice to use chlorhexidine mouth wash and avoid brushing at that site for 6 weeks.
- Patient assessed next week to check healing and then at 3 weeks and 6 weeks.
- After 6 weeks patient advise to use ultra soft tooth brush and roll brushing technique.

COMMENTS: THE TOTAL PATIENTS FROM EACH GROUP SHOULD BE MINIMUM 30.

This Project is Ethically Approved

Reference Study No: 18
Subject of Study: "Clinical Efficacy of Subgingivally Delivered 1.2% Atorvastatin in Chronic Periodontitis: A Randomized Controlled Clinical Trial"

Principal Investigator: Dr. Dwiti Chokshi
Co-Investigator: Dr. Neeta Bhavsar
Department: Periodontia.

Introduction:

- Atorvastatin (ATV) is a specific competitive inhibitor of 3-hydroxy-2-methyl-glutaryl coenzyme A reductase. Recently, statins have shown pleiotropic effects suchas anti-inflammation and bone stimulation, which can be helpful as an adjunct for the treatment of patients with chronic periodontitis.

Aims and Objectives:-

- The aim of the present study is to investigate the effectiveness of 1.2% Atorvastatin as an adjunct to scaling and root planning (SRP) in the treatment of intrabony defects (IBDs).

Methodology:

- Sample selection – A group of 40 patients selected with,
  - Chronic periodontitis

– Pocket Depth ≥5 mm ,clinical attachment level ≥4mm & vertical bone loss >3mm

- Study Period – 6 months
- Study material- 1.2% Atorvastatin Gel.
- Study Method: The following parameters will be recorded at baseline, 3 months and 6 m post surgery:

CLINICAL RECORDINGS

Probing depth (PD)

Clinical attachment level (CAL)

Modified Sulcus bleeding index (mSBI)

Plaque index

Radiographic parameters using Grid.

- All subjects received scaling and root planning & guided for proper brushing techniques.
- Patients will be randomly assigned as either placebo group or atorvastatin group.
- In the ATV group, sites will be treated with SRP followed by 1.2% ATV gel (1.2 mg/0. LDD, and in the placebo group, sites will be treated with SRP followed by placeb placement.
- Only one site per patient was enrolled for either ATV or placebo group.
- No antibiotic or anti inflammatory agents were prescribed after treatment.

Ethical considerations: - informed written consent.

This Project is Ethically Approved

Reference Study No: 19

Subject of Study: "Evaluation of Efficacy Of 5% Propolis Mouthwash as an Adjunct to Sc and Root Planning In Chronic Gingivitis Patients: A Clinical Study"

Principal Investigator: Dr. Mansi Machhi

Co-Investigator: Dr. Mahesh Chavda, Dr. Neeta Bhavsar

Department: Periodontia.

Introduction:

To evaluate the efficacy of propolis mouthwash-an herbal product extracted from bee containing antimicrobial properties in treatment of gingival inflammation.

Aims and objectives:-

- To evaluate clinical effectiveness of a 5% propolis containing mouthwash in chronic gener gingivitis.

Methodology:

- Sample selection – A group of 50 patients selected with Chronic gingivitis
- Study Period – 1 month
- Study material-5% propolis mouthwash.
- Study Method: The following parameters will be recorded using UNC – 15 probe and disclo agent at baseline, 2 weeks and 1 month interval.

CLINICAL RECORDINGS

- Plaque index (PI) (Turesky-Gilmore, 1970)

Gingival index (GI) (Loe and Silness, 1963)
All subjects received scaling and root planning & guided for proper brushing techniques.
Patients will be randomly assigned as control and study group.
Patient will be placed on 5% propolis mouthwash (10 ml, twice a day for 30 days).
Ethical considerations: - informed written consent.

This Project is Ethically Approved

Reference Study No: 20
Subject of Study: The comparative effects on plaque regrowth of phenolic, chlorhexidine and anti-adhesive mouth rinses"

Principal Investigator: Dr. Harshit Shah
Co-Investigator: Dr. Mahesh Chavda, Dr. Neeta Bhavsar,
Department: Periodontia.

Introduction & Objectives:
The inhibition of bacterial attachment to the tooth surface is one possible approach to plaque control. This study evaluates in vivo plaque inhibitory action of a novel copolymer reported to have considerable anti-adhesive properties in vivo.
AIMS AND OBJECTIVES:-

- To compare effects on plaque regrowth of phenolic (Listerine), chlorhexidine& anti-adhesive mouthrinses.
- To evaluate plaque inhibitory effect of anti-adhesive molecule ICI239144.
- Methodology:
- Sample selection – A group of 30 patients selected with,
- Minimum of 15 anterior teeth (incisors, canines & premolars),
- High standard of oral hygiene and gingival health,
- Satisfactorily passed pretrial medical and dental examination.
- Materials:-
- 0.2% chlorhexidine solution
- ICI239144(1% Aqueous solution)
- Listerine
- Water

Method:-

- On day 1 of each trial period, the teeth of all volunteers will be disclosed and then scaled and polished to remove all deposits of plaque, calculus and extrinsic staining. Each volunteer will then be instructed to stop routine oral hygiene. Then, each volunteer will be given his allocated rinse, dosage regimen being 10 ml to be rinsed for 1 min twice a day for 4 days. On day 5, teeth of each volunteer will be disclosed with erythrosine solution and scored for plaque, using turesky modification of quigley, hein plaque index.
- Then, scaling and polishing will be done. A washout period of 48 hours will be instituted before commensing next rinsing period, during which the volunteers returned to routine oral hygeine measures.

Ethical considerations: - informed written consent.
This Project is Ethically Approved

Reference Study No: 21
Subject of Study: A Comparative Evaluation of Periodontal Plastic Surgical Procedures ... Scalpel and Diode Laser- A Randomised Clinical Control Study"

Principal Investigator: Dr. Nisha Agarwal
Co-Investigator: Dr. Neeta Bhavsar
Department: Periodontia.

Introduction:

- Gingival enlargement is one of the most common
- soft tissue problems associated with FOAT(fixed orthodontic appliance therapy), w... reported prevalence of almost 10.7%
- Though meticulous oral hygiene, mouthwashes are first line in the management, relies ... patient compliance, resulting in their limited success.
- Non surgical periodontal treatment is the conventional approach but is not always effe... when gingival enlargement is extensive and self-care is compromised. So, surg... approaches is Considered. Very invasive and may not be effective if self-care oral hyg... practices remain poor.

AIMS AND OBJECTIVES:-

- The aim of this randomized controlled clinical study was to evaluate the effectiveness of d... laser in comparision to scalpel in periodontal plastic surgical procedures.

METHODOLOGY:

- SAMPLE SIZE: 30 patients
- INCLUSION CRITERIA:
  - Patients between 10 to 40 years of age
  - Gingival enlargement on labial side of anterior teeth.
- EXCLUSION CRITERIA:
  - Patients with drug induced gingival enlargement were excluded.
  - Pregnant or lactating women.
- PARAMETERS ASSESSED:
  1. Type of anaesthesia used
  2. Intra and post operative pain
  3. Bleeding during procedure
  4. Pain
  5. Wound healing index.

Ethical considerations: - informed written consent.

COMMENT: THE INVESTIGATORS ARE ADVISED TO RECONSIDER THE RANGE USED IN THIS STUDY. SAMPLE SIZE SHOULD BE 30 IN EACH GROUP
This Project is Ethically Approved

Reference Study No: 22
Subject of Study: Effect of Estrogen and Progesterone on the Periodontal Tissues in Women

Principal Investigator: Dr. Aneri Desai
Co-Investigator: Dr. Jyoti Chawda
Department: Oral Pathology

Introduction & Aims & Objectives:
Sex hormones play an influential role on periodontal tissues and periodontal disease progression. The Aim of this study is to find the effects of female sex hormones on the periodontal tissues in women with the objectives to (1) study the relationship between female sex hormones and the periodontium in regards to inflammation & (2) to analyze the influence of these hormones in women during puberty, middle age & menopause.
Methodology:
A total of 45 female patients are included in the study & divided into three groups. (1) 15 women of pubertal age, (2) 15 women of middle age & (3) 15 women of menopausal age; who have no systemic diseases such as diabetes, hepatic, renal or thyroid problems, metabolic bone diseases & also not taking any hormonal supplements. After a detailed clinical and systemic history with patient's written consent, incisional biopsy of marginal gingiva is taken to study the microscopic aspect of the gingiva by carrying out H&E stain and patient's blood is collected to measure the levels of estrogen and progesterone in the body.

COMMENTS: MINIMUM OF 30 PATIENTS FROM EACH AGE GROUP TO BE INCLUDED. CONSENT FORM REQUIRED.
This Project is Ethically Approved

Reference Study No: 23
Subject of Study: Age and Sex Determination from Maxilla

Principal Investigator: Dr. Deepa Sommanek
Co-Investigator: Dr. Jyoti Chawda
Department: Oral Pathology

Introduction Aim & Objectives:
Bony and dental structures of palate are often preserved even in the face of serious bodily damage or following death. So coupled with the statistical difference in palatal dimension between age and sex, there is opportunity to establish criteria by which the forensic scientist can predict age and sex of unknown individual. Aim of the study is to determine age and sex from the maxillary dimensions. In the present study, intercanine distance, interpremolar distance, intermolar distance and depth of palate are used to measure maxillary dimensions and to evaluate the reliability of it in age and sex determination.
Methodology:

In this study, 60 healthy subjects without orthodontic treatment in the age range of 1
selected for the study and are distributed in the 3 groups, 16-20, 21-25, and 26-30. 20
each group. After taking patients consent, Lateral cephalogram and maxillary arch impr
each subject will be taken and maxillary cast will be prepared. Then maxillary dimensio
measured using digital vernier caliper.

COMMENTS: MINIMUM OF 30 PATIENTS FROM EACH AGE GROUP
INCLUDED. CONSENT FROM NEED TO BE SUBMITTED.
This Project is Ethically Approved

Reference Study No: 24
Subject Of Study: Identification Of Desmoglein 1 & 3 Autoantibodies In Pemphigus V
Patients.

Principal Investigator: Dr. Mrudu Gondalia
Co-Investigator: Dr. Jyoti Chawda
Department: Oral Pathology

Introduction & Aims & Objectives:
Pemphigus vulgaris is a severe autoimmune vesiculo-bullous disease involving both the skin
and mucosal areas. Its pathogenicity is a result of collective action of auto antibodies against
various keratinocyte self-antigens, of which desmoglein 1 & 3 are the most important.
Aim:
To identify desmoglein 1 & 3 auto antibodies in pemphigus vulgaris patients.
Objectives:
To evaluate the role of desmoglein 1 & 3 auto antibodies in the diagnosis of pemphigus
vulgaris patients and its correlation with clinical presentation, severity and prognosis of the
disease.
Methodology:
30 patient having pemphigus vulgaris are included in the study, and the disease is confirmed
by cytology. The patients are divided in 4 groups: 5 patients having early disease without any
medication; 10 patients under medication; 10 patients with severe disease under medicati
5 patients in remission stage. ELISA test will be performed for quantitative measurement
desmoglein 1& 3 auto antibodies level,.

COMMENT: INCREASE SAMPLE SIZE IN EACH GROUP. CONSENT FR
REQUIRED
This Project is Ethically Approved

Reference Study No. 25
Subject Of Study: An Assessment Of Skeletal Craniofacial Asymmetry In Gujara
Population.

Principle Investigator: Dr.Hrishabh Joshi

Co-Investigator: Dr.Falguni Mehta
Department: Orthodontia

Introduction & Aims & Objectives: To assess skeletal craniofacial asymmetry in Guajarati population by a posteroanterior cephalometric radiographic method. To compare the skeletal craniofacial structures on one side of the face with that of the other by drawing various triangles representing different craniofacial regions. To measure the areas of such triangles and evaluate the distribution of any such asymmetry and its range in Guajarati population.
Methodology: 60 subjects with age ranging from 18 to 25 years were clinically examined and selected. Their posteroanterior cephalomertic radiographs were taken in natural head positions and their tracing was done in autocad software. Their area was measured and further analysis was done with statistical methods. This study is completely in vitro with no direct intervention or involvement of the patient.

COMMENTS: TO RECONSIDER THE TITLE OF THE PROJECT IN TERMS OF WORD ASSESSMENT RATHER USE THE WORD PREVALENCE STUDY. INSTEAD OF GUJARATI POPULATION USE WORD PATIENT REPORTING ORTHO DEPT. GDCH AHMEDABAD
This Project is Ethically Approved

Reference Study No. 26
Subject Of Study: "Nasal Morphology As Indicator Of Vertical Maxillary Excess Pattern"

Principle Investigator: Dr. Sandesh Laddha
Co-Investigator: Dr.Falguni Mehta
Department: Orthodontia

INTRODUCTION & OBJECTIVES: To investigate the relationship nasal morphology and vertical maxillary skeletal pattern.
Design: A Retrospective study.
MATERIALS AND METHODS

- The sample included the lateral cephalometric radiographs of 30 adults
- Aged 18 to 27 years with no previous history of trauma, surgical intervention, congenital disease or orthodontic treatment.
- Lateral cephalograms, Set Square, foot ruler. Tracing sheet, .5 mm HB pencil
- Parameters to be taken: 7 skeletal parameters of vertical facial growth and 6 nasal parameters will be measured

This Project is Ethically Approved

Reference Study No. 27
Subject of the Study: "Evaluation of Force Degradation Characteristics of Orthodontic Elastics: In Vitro and In Vivo Study.

Principle Investigator: Dr. Swati Khonde
Co-Investigator: Dr.Falguni Mehta
Department: Orthodontia

INTRODUCTION & OBJECTIVES:

- As a generally auxillary method, elastics are characterized by high flexibility, relia enduring force, and low cost. Physical and chemical properties caused orthodontic elas undergo fatigue and force relaxation results in force degradation that is likely accentuated under adverse environmental conditions, such as in the oral cavity.
- This study is designed and implemented to evaluate the characteristics of force degra when the testing is conducted in vivo and in vitro over a 48 hours period and the were exchanged at different times in oral cavities.
- My aim to collect experimental information that we provide guideline for application.

MATERIALS AND METHODS

- MATERIALS REQUIRED: Orthodontic elastics, Push- Pull force gauge, artificial study model.

Methodology:

- Samples of 3/16 inch orthodontic elastic will be investigated, and 12 students betwee ages of 12 to 25 years will be selected for the intermaxillary and intramaxillary traction elastics in the control groups will be set in artificial saliva and dry room conditions an be stretched 20 mm. The repeated measure two way analysis of variance and non regression analysis will be used to identify statistical significance.

COMMENT: NOT TO ESTABLISH ANY GUIDELINES. INCREASE SAMPLE SIZE.

This Project is Ethically Approved

Reference Study No. 28

Subject of Study: To Study the Effects of Premolar Extraction Bolton Ov Ratios and Overall Tooth-Size Discrepancy in A Gujarati Population

Principle Investigator: Dr.Ashish Kumar
Co-Investigator: Dr.Falguni Mehta
Department: Orthodontia

Introduction & Aims & Objectives: The purpose of this study is to evaluate the Bolton rati Gujarati Population reporting for orthodontic treatment and to determine the effects of extractio Bolton ratio. Another aim of this study is to check the effects of different extraction patterns o final Bolton ratio.

Methodology: 120 pre-treatment dental casts (60 males and 60 females) of orthodontic pa reported at the OPD of Dept. of Orthodontia, G.D.C&H. Ahmedabad. Selection criteria in dental casts of patient with Gujarati ethnic origin. Mesio-distal dimensions of the mandibular

maxillary teeth are to be measured before treatment and subjected to Bolton analysis. Hypothetical tooth extractions of following combinations are carried out : all first premolar extractions, all second premolar extraction, upper first and lower second premolar extractions and upper second and lower first premolar extractions are performed and then measurement results are subjected to Bolton analysis so as to see whether and tooth- size discrepancy has been created. This study is basically an in- vitro study and does not require any direct involvement of patients for the purpose. The dental study models used are pre-treatment models recorded for patients prior to start of their treatment.

COMMENTS: INSTEAD OF GUJARATI POPULATION USE WORD PATIENT REPORTING ORTHO DEPT. GDCH AHMEDABAD
This Project is Ethically Approved

Reference Study No. 29
Subject of Study: The Effect of Repeated Bonding on the Shear Bond Strength of Different Orthodontic Adhesives.

Principle Investigator: Dr. Shivam Mehta
Co-Investigator: Dr.Falguni Mehta
Department: Orthodontia

Introduction & Aims & Objectives: The purpose of this study is to evaluate the effect of repeated bonding with 2 different adhesives, a composite and a cyanoacrylate, on the shear bond strength of orthodontic brackets.
Methodology: 40(31*) freshly extracted human premolars were collected. Brackets will be bonded with the orthodontic adhesives according to the manufacturer's instructions. In group I, the teeth will be etched with 37% phosphoric acid, a sealant will be applied, and the brackets will be bonded with Transbond XT (3M Unitek) and light cured for 20 seconds. In group II, the teeth will be etched with 35% phosphoric acid, and the brackets will be bonded with Smart Bond (cyanoacrylate).In each group, the teeth will be bonded and deboned 3 times with the same adhesive. At each sequence, the brackets will be removed within 30 minutes after bonding to simulate the clinical condition at which a newly bonded bracket is tied to the arch wire. Only the teeth that are extracted for orthodontic purposes will be used in this study. No extractions will be undertaken for the purpose of the study. So no injury or no harm will be inflicted to the patients for the purpose of the study.

This Project is Ethically Approved

Reference Study No. 30
Subject of Study: Skeletal and Dentoalveolar Evaluation of treatment with Twin Block appliance in class II div 1 malocclusion

Principle Investigator: Dr. Vaibhav Gandhi
Co-Investigator: Dr.Falguni Mehta
Department: Orthodontia

Introduction & Aims & Objectives: Twin block appliance used as a functional appliance since decades. This study is aim to evaluate effect of modified twin block appliance in class II div growing patient. This effect is either skeletal or dentoalveolar or both.

Methodology: It is basically cephalometric study.25 patients which fall in specific selection criteria have been chosen and Their Pretreatment and Post functional cephalogram were taken. Tracing has been done on these radiographs. Various parameters selected and readings are to be been taken. Cephalograms used for this study has been taken from patient's old record, so as to avoid unnecessary radiation exposure.

COMMENTS: MINIMUM 30 PATIENTS TO BE INCLUDED.

This Project is Ethically Approved

Reference Study No. 31

Subject of the Study: "Anthropometric and Physiologic Measurements of Cleft Lip and Palate Neonates"

Principle Investigator: Dr. Swati Verma

Co-Investigator: Dr.Falguni Mehta

Department: Orthodontia

INTRODUCTION & OBJECTIVES:

- The purpose of this study is to evaluate the variation in anthropometric and physiologic measurements in neonates with cleft lip and palate (syndromic or non-syndromic : isolated cleft palate, unilateral cleft lip and palate, bilateral cleft lip and palate)
- Objectives are
    1. To know the occurrence of cleft lip and palate neonate's i.e. male /female ratio, type cleft lip and palate.
    2. To know the correlation between anthropometric and physiological measurements with cleft lip and palate in neonates.

MATERIALS AND METHODS

- CLCP neonates reporting in Department of Orthodontics, GDCH- Ahmedabad, civil hospital campus , Asarwa, Ahmedabad.
- MATERIALS REQUIRED : Measuring tape ,Infant Weighing machine, Infant anthropometric length measuring device, Impression compound for primary impression, Elastomeric impression material for final impression,Self cure acrylic material,Orthodontic grid for model analysis
- PARAMETRS TO BE TAKEN: Physiological parameters are birth weight and birth length and Anthropometric parameters are head circumference, head length, anterior, middle and posterior alveolar widths, arch perimeter, arch length and cleft width

Methodology:

- Design of study –RETROSPECTIVE STUDY.
- Sample selection - Total 30 patients visited Department of orthodontia , Govt. Dental College & Hospital, Ahmedabad will be included in this study

COMMENTS: PARENTERAL CONSENT FORM IS REQUIRED
This Project is Ethically Approved

Reference Study No. 32
Subject of Study: "Correlation between Canine Impaction and Maxillary Morphology"

Principle Investigator: Dr. Mayank Jain
Co-Investigator: Dr.Falguni Mehta
Department: Orthodontia

- Aims and objectives: The aim of this study was to examine whether there is a relationship between the position of impacted maxillary canines and the morphology of the maxilla.
- Methodology:
- Thirty patients each with buccally and palatally placed canines will be selected for the study.
- Position of the canine would be determined using the SLOB technique
- Digital caliper and brass wire for doing measurements on models.
- Arch length/intermolar width × 100 will used as the value for comparison of maxillary arch shapes, and palatal vault depth/intermolar width × 100 was used to compare the shapes of palate between the 2 groups.
- Each category will be directly measured from the diagnostic model.

This Project is Ethically Approved

Reference Study No: 33
Subject Of Study: "An Estimation Of Blood Lead Level And Its Correlation To Occurrence Of Dental Caries In Children Of Age Group Of 8-12 Years"

Principal Investigator: Dr. Khyati shah
Co-Investigator: Dr. Shantanu Choudhri
Department: Pedodontia

Objectives of the Study:

1) To evaluate the correlation between blood lead level and dental caries incidence in children of age group of 8-12 years in Ahmedabad city

Materials and method

Source of Data:

For this study, patients reporting to the department of Pedodontia, government Dental college and hospital, Ahmedabad, who satisfy the selection criteria will be chosen

***Method of Collection of Data*:**

Sample: children of age group of 8-12 years visiting to the pediatric and preventive dentistry of Government dental college and hospital, Ahmedabad.
Sample size: 30 children of age group 8-12years in each control and caries group

SELECTION CRITERIA:

The samples for study will be divided equally in to following two groups of 30 each:
Group A: 30 children of control group with dmf+DMF score '0'

Group B: 30 children of caries group dmf+DMF score more than 5

In Inclusion criteria:

1) Children of 8-12 years age and their parents will be included.
2) Children who are willing to give their blood sample will be included
3) Parents who are willing to sign the consent
4) Children without any previous dental treatment
5) Children without any systemic disease, without any blood disorder.

Exclusion criteria:

1. children who are less then 8 years of age and more then 12 years of age.
2. parents who are not willing to sign the informed consent.
3. Children who are not willing to give their blood sample.
4. Patient with previous dental treatment.
5. Patient with h any systemic disease, mental disorder and blood disorder.

Collection of sample and dental caries evaluation: for this study blood sample will be colle from pt aged 8-12 years with DMF+dmf index >5 and <0.oral examination will be done by lice dentist with the help of mouth mirror, explorer. Venous blood sample will taken from cubital .Minimum 3ml will be needed. Blood will be collected in LDPE tube containing 0.1%aqueous t X-100,0.1%ammonium phosphate, and 1 mg /ml of sodium heparin (diluents).The LDPE tube the blood sample will be capped, placed in zip lock bag and stored in the refrigerator transported to the laboratory in an icebox at the end of each day.

Laboratory methods: all samples will be analyzed using Agilent 7500c series inductively cou plasma/mass spectrometer (ICP-MS)equipped with collision cell .

COMMENTS: MINIMUM 30 PATIENTS FROM EACH AGE GROUP TO BE INCLUDE

This Project is Ethically Approved

Reference Study No: 34

Subject Of Study: "An Estimation Of Salivary Lead Level And Its Co-Relation To Occurr Of Dental Caries In Children Of Age Group Of 8 T 12 Years"

Principal Investigator: Dr. Manthan patel
Co-Investigator: Dr. Shantanu Choudhari
Department: Pedodontia

Material and method

source of data: 40 salivary samples collected from children of age group 8 to 12 yrs. Out of 40 children with dmf index more than 5 and other 20 child with dmf index 0.

criteria for selection of samples:

Inclusion criteria:

1) Parents of child of 8 to 12 years age will be included.
2) Pt. and parents willing to sign consent form for child's salivary sample for lead estimation.
3) child with no systemic history.

Exclusion criteria:

1) Parents of the child less than 8 years and more than 12 years.
2) Parents or pt. not willing for give salivary sample.
3) Child with dmf index between 1 to 5.

Method

- **Sample Selection:**

Sample will consist of parents of 40 child patients of 8 to 12 years old visiting Department of Pedodontics and Preventive Dentistry, GDCH Ahmadabad, Gujarat. Out of 40, 20 children with dmf index more than 5, and 20 child with dmf index 0.

- **Does this study require any investigation or interventions to be conducted on patients or other humans or animals? If so, please describe briefly:** Yes.

Investigation

- Salivary sample is taken and then diluted 3 fold with trace metal free nitric acid before being analyzed.
- Each batch of 12 saliva sample and a standard reference sample.
- Detection limit were calculated as 3 times the standard deviation for the reagent blanks.

COMMENTS: MINIMUM 30 PATIENTS FROM EACH AGE GROUP TO BE INCLUDED.
This Project is Ethically Approved

Reference Study No: 35
Subject Of Study: "An Assessment Of Parent Satisfaction Of Oral Health Care Delivery For Their Child, In Department Of Pedodontics And Preventive Dentistry, Government Dental College And Hospital, Ahmedabad, Gujarat."

Principal Investigator: Dr. Saptak Shah
Co-Investigator: Dr. Shantanu Choudhari
Department: Pedodontia

Aim:

To assess level of satisfaction in parents regarding oral health care delivery to their child at Department Of Pedodontics And Preventive Dentistry, Government Dental College and Hospital, Ahmedabad, Gujarat.

Objectives:

(1) To assess the level of satisfaction in parents regarding oral health care delivery to their child
(2) To know the sociodemographic criteria affecting the parents satisfaction.

Material and method:

source of data:

Data will be collected by self-administered questionnaire given to parents of child patient of 6-10 years old, seeking dental service at Department of Pedodontics and Preventive Dentistry.

criteria for selection of samples:

Inclusion criteria:

1) Parents of child of 6 to 10 years age will be included.
2) Parents minimum educational should be above 10^{th} STD

3) Child patients whose treatment scheduled for more than 1 Appointments, their parents were selected.

4) Parents of patients' whose 2nd visit of treatment is over will be included.

Exclusion criteria:

4) Parents of the child less than 6 years and more than 10 years.
5) Parents with education less than 10th
6) Parents who don't know English or Gujarati
7) Parents of the patients visiting department for single visit.
8) Parents with patients of emergency treatment needs.

Method:

Sample Selection:

Sample will consist of parents of 500 child patients of 6-9 years old visiting Department of Pedodontics and Preventive Dentistry, GDCH Ahmedabad, Gujarat.

Collection of data

Information from the parents was obtained after treatment using a self-administered questionnaire, a modification of the dental satisfaction questionnaire (DSQ) (developed by Davies and Ware.)[6] The questionnaire had 3 main sections, namely: the bio-data, the DSQ and suggestions for improved service delivery. The DSQ was based on various aspects of dental care and parents were asked to indicate their degree of satisfaction with oral health care delivery on a 5 point Likert type scale. The interval scores were assigned as follows: (Fully satisfied=4; Satisfied =3; Good Can be improved=1; Poor =0)

This Project is Ethically Approved

Dr. Girish Pacha

Dr. Jush S.M Soni

Dr. J. S. Shah

Dr. Geeta Asthana

Dr. J.P. Pillai

Dr. Sunil Kumar