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M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES & RESEARCH CENTRE, PUNE



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As per the process for research ethical clearance (Synopsis copy for Thesis)

Dr. Prathamesh Nanal (Department of Periodontology) Thesis Project 2022 (Synopsis)

Minutes of meeting IEC 16/06/2022

Approval letter from IEC

Acceptance of Synopsis by MUHS



PRINCIPAL

M. A. RANGOONWALA COLLEGE OF DENTAL

SCIENCES & RESEARCH CENTRE, PUME

M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES AND RESEARCH CENTRE, AZAM CAMPUS, PUNE-411001

DEPARTMENT OF PERIODONTOLOGY AND ORAL IMPLANTOLOGY.

SYNOPSIS ON

COMPARATIVE EVALUATION OF THE SUCCESS OF IMMEDIATE IMPLANTS WITH IMMEDIATE LOADING VS. IMMEDIATE IMPLANTS WITH DELAYED LOADING IN INFECTED SOCKETS: A CLINICAL AND RADIOLOGICAL STUDY.

APPROVED

Ethical Committee M. C. E. Society Azam Campus, Pune-1.

NAME OF P.G STUDENT

DR. PRATHAMESH NANAL

PRINCIPAL

M. A. RANGOONWALA COLLEGE OF DENTAL SCIENCES & RESEARCH CENTRE, PUNE

PUNE SO PUNE SO

NAME OF THE GUIDE

DR RAHUL KALE

APPENDIX 'A'

NAME OF THE P.G COLLEGE	M.A.RANGOONWALA COLLEGE OF DENTAL SCIENCES & RESEARCH CENTRE, PUNE
DEPARTMENT	PERIODONTOLOGY AND ORAL IMPLANTOLOGY
NAME OF THE GUIDE & COLLEGE NAME	DR. RAHUL KALE, PROFESSOR, DEPARTMENT OF PERIODONTOLOGY & ORAL IMPLANTOLOGY, M. A. RANGOONWALA COLLEGE OF DENTAL SCIENCES & RESEARCH CENTRE, PUNE
CONTACT NO. OF THE GUIDE	+919860121239

THROUGH PROPER CHANNEL ONLY

TO THE REGISTRAR, MUHS, NASHIK - 422004.

SUBJECT: SUBMISSION OF TOPIC OF DISSERTATION

RESPECTED SIR/MADAM,

I, DR. PRATHAMESH DINESH NANAL, REGISTERED FOR POST-GRADUATE COURSE IN PERIODONTOLOGY AND ORAL IMPLANTOLOGY, IN THE 2021-2022 BATCH UNDER THE GUIDANCE OF DR. RAHUL KALE (M.D.S), PROFESSOR, DEPARTMENT OF PERIODONTOLOGY & ORAL IMPLANTOLOGY, M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES AND RESEARCH CENTRE, PUNE. I AM DUE TO APPEAR FOR M.D.S PERIODONTOLOGY IN 2024.

I AM SUBMITTING HERE WITH TITLE OF SYNOPSIS AS MENTIONED BELOW AS SUGGESTED BY MY AFORESAID GUIDE

TITLE OF SYNOPSIS

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KINDLY ACCEPT AND REGISTER MY TITLE OF SYNOPSIS. Signature

DR. PRATHAMESH NANAL

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THE GUIDE IS RECOGNISED AS A P.G. TEACHER BY THE UNIVERSITY VIDE LETTER NO

MUHS/PG/E-2/1913/2018 DATED09/05/2018.

DR. RAHOL KALE (GUIDE NAME AND SIGNATURE)

M.C

E.S

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DR.SANGEETAMUGLIKAR

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PRINCIPAL

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M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCE & RESEARCH CENTRE PHNE-1

APPENDIX 'B' REPORT OF ETHICS COMMITTEE

	DR. PRATHAMESH NANAL
NAME VEAR	2021 CONTINUE ANTOLOGY
CANDIDATE ADMITTED YEAR COURSE AND SUBJECT COLLEGE NAME AND ADDRESS	M.D.S- PERIODONTOLOGY & ORAL IMPLANTOLOGY
	M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES & RESEARCH CENTRE, PUNE

DATE: 17/6/22 REFERENCE NO: M(BS/B/748/2022 TO. DR. PRATHAMESH NANAL, DEPARTMENT OF PERIODONTOLOGY & ORAL IMPLANTOLOGY, M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES AND RESEARCH CENTRE, PUNE

SUBJECT: RESEARCH PROPOSAL OF DR. PRATHAMESH NANAL,

COMPARATIVE EVALUATION OF THE SUCCESS OF IMMEDIATE IMPLANTS WITH IMMEDIATE LOADING VS. IMMEDIATE IMPLANTS WITH DELAYED LOADING IN INFECTED SOCKETS: A CLINICAL AND RADIOLOGICAL STUDY.

THE ABOVE MENTIONED RESEARCH PROPOSAL OF TITLE OF SYNOPSIS WAS DISCUSSED IN THE ETHICS COMMITTEE MEETING HELD ON (DATE) 16/6/22 AT OUR COLLEGE.

IT IS DECLARED THAT—

THE SAID TITLE OF SYNOPSIS IS NOT REPEATED.

- 1. YOU ARE REGISTERED UNDER DR. RAHUL KALE WHO IS A UNIVERSITY RECOGNIZED P.G. TEACHER VIDE UNIVERSITY LETTER NO. MUHS/PG/E-2/1913/2018 DATED 09/05/2018 FOR GUIDANCE AND SUPERVISION DURING THE COURSE
- 2. ETHICS COMMITTEE HAS UNANIMOUSLY APPROVED YOUR TITLE & SYNOPSIS OF DISSERTATION.
- 3. THE TITLE IS RECOMMENDED FOR STUDY BY THE STUDENT FROM DATE
 - 1. IT WILL BE MANDATORY FOR THE STUDENT TO WORK ON THE UNIVERSITY APPROVED TITLE FOR A MINIMUM PERIOD OF 18 MONTHS AFTER ITS APPROVAL.
 - 2. IT IS THE RESPONSIBILITY OF THE STUDENT AND GUIDE TO INFORM THE ETHICS COMMITTEE ABOUT COMPLETION OF THE SAID RESEARCH WORK (FORMAT AS PER ANNEXURE 'C').



Bulgel DR. P.M.BULAKH CHAIRPERSON, ETHICS COMMITTEE. M. C. E. Society Azam Campus, Pune-1.

TOPIC FOR DISSERTATION

COMPARATIVE EVALUATION OF THE SUCCESS OF IMMEDIATE IMPLANTS WITH IMMEDIATE LOADING VS. IMMEDIATE IMPLANTS WITH DELAYED LOADING IN INFECTED SOCKETS: A CLINICAL AND RADIOLOGICAL STUDY.

M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES AND RESEARCH CENTRE, AZAM CAMPUS, PUNE-411001

DEPARTMENT OF PERIODONTOLOGY AND ORAL IMPLANTOLOGY.

SYNOPSIS ON

COMPARATIVE EVALUATION OF THE SUCCESS OF IMMEDIATE IMPLANTS WITH IMMEDIATE LOADING VS. IMMEDIATE IMPLANTS WITH DELAYED LOADING IN INFECTED SOCKETS: A CLINICAL AND RADIOLOGICAL STUDY.

NAME OF P.G STUDENT

DR. PRATHAMESH NANAL

NAMÉ OF THE GUIDE

DR RAHUL KALE

A.R.O. COLL PERMENT TO

A. RANGOONWALA COLLEGE OF DENTAL SCIENCES & RESEARCH CENTRE, PUNE

TOPIC FOR DISSERTATION

COMPARATIVE EVALUATION OF THE SUCCESS OF IMMEDIATE IMPLANTS WITH IMMEDIATE LOADING VS. IMMEDIATE IMPLANTS WITH DELAYED LOADING IN INFECTED SOCKETS: A CLINICAL AND RADIOLOGICAL STUDY.

UBMITTED FOR THE PARTIAL FULFILMENT FOR THE DEGREE OF MASTER OF DENTAL SURGERY (M.D.S) [PERIODONTOLOGY AND ORAL IMPLANTOLOGY]

OF

MAHARASHTRA UNIVERSITY OF HEALTH SCIENCES, NASHIK

BY:

DR. PRATHAMESH NANAL

POSTGRADUATE STUDENT (2021-2024)

GUIDE:

DR. RAHUL KALE

PROFESSOR

DEPT. OF PERIODONTOLOGY AND ORAL IMPLANTOLOGY

DR. PRATHAMESH NANAL

DATE: 31/5/2022

POSTGRADUATE STUDENT

MDS (PERIODONTOLOGY AND ORAL IMPLANTOLOGY)

M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES AND RESEARCH CENTRE, PUNE-411001

TO,

THE REGISTRAR

MAHARASHTRA UNIVERSITY OF HEALTH SCIENCES, NASHIK.

SUBJECT: TOPIC FOR DISSERTATION: MDS

(DEPT. OF PERIODONTOLOGY AND ORAL IMPLANTOLOGY)

RESPECTED SIR,

I HAVE REGISTERED MY NAME WITH YOUR ESTEEMED UNIVERSITY IN 2021 FOR MDS (PERIODONTOLOGY AND ORAL IMPLANTOLOGY) UNDER GUIDANCE OF DR. RAHUL KALE, PROFESSOR, DEPT. OF PERIODONTOLOGY AND IMPLANTOLOGY, M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES AND RESEARCH CENTRE, PUNE.

THE SUGGESTED TOPIC OF MY DISSERTATION IS AS UNDER- COMPARATIVE EVALUATION OF THE SUCCESS OF IMMEDIATE IMPLANTS WITH IMMEDIATE LOADING VS. IMMEDIATE IMPLANTS WITH DELAYED LOADING IN INFECTED SOCKETS: A CLINICAL AND RADIOLOGICAL STUDY.

IT IS REQUESTED THAT NECESSARY APPROVAL FOR THE TOPIC MAY BE GIVEN.

THANKING YOU IN ANTICIPATION.

YOURS SINCERELY,

DR. PRATHAMESH NANAL

DR. PRATHAMESH NANAL

DATE: 31/5/2022

POSTGRADUATE STUDENT

MDS (PERIODONTOLOGY AND ORAL IMPLANTOLOGY)

M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES AND RESEARCH CENTRE, PUNE-411001

TO,

THE PRINCIPAL,

M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES AND RESEARCH CENTRE, PUNE.

SUBJECT: TOPIC FOR DISSERTATION (DEPT. OF PERIODONTOLOGY AND ORAL IMPLANTOLOGY)

MADAM,

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THANKING YOU IN ANTICIPATION,

YOURS SINCERELY,

u-thamech.

DR. PRATHAMESH NANAL

REMARKS OF THE POSTGRADUATE GUIDE

RECOMMENDED AND FORWARDED FOR APPROVAL.

DR. RAHUL KALE

PROFESSOR,

DEPT. OF PERIODONTOLOGY AND ORAL IMPLANTOLOGY,
M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES AND RESEARCH
CENTRE, PUNE-411001

DATE: 31/5/2022

REMARKS OF THE PROFESSOR AND HEAD OF DEPARTMENT

RECOMMENDED AND FORWARDED FOR APPROVAL

DR. SANGEETA MUGLIKAR

Dept. of Periodontia

PROFESSOR AND HEAD OF DEPARTMER P. D. S. R.

DEPT. OF PERIODONTOLOGY AND ORAL IMPLANTOLOGY,
M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES AND RESEARCH
CENTRE, PUNE-411001

DATE: 31/5/2022

APPENDIX 'A'

NAME OF THE P.G COLLEGE	M.A RANGOONWALA COLLEGE OF DENTAL SCIENCES & RESEARCH CENTRE, PUNE
DEPARTMENT	PERIODONTOLOGY AND ORAL IMPLANTOLOGY
NAME OF THE GUIDE & COLLEGE NAME	DR. RAHUL KALE, PROFESSOR, DEPARTMENT OF PERIODONTOLOGY & ORAL IMPLANTOLOGY, M. A. RANGOONWALA COLLEGE OF DENTAL SCIENCES & RESEARCH CENTRE, PUNE
CONTACT NO. OF THE GUIDE	+919860121239

THROUGH PROPER CHANNEL ONLY

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SUBJECT: SUBMISSION OF TOPIC OF DISSERTATION

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KINDLY ACCEPT AND REGISTER MY TITLE OF SYNOPSIS. Signature

uthames DR. PRATHAMESH NANAL

> - EF.O.D. David of Padadooka

MAPEREN

THE GUIDE IS RECOGNISED AS A P.G. TEACHER BY THE UNIVERSITY VIDE LETTER NO

/1913/2018 DATED<u>09/05/2018</u>.

DR. RAHUL KALE

(GUIDE NAME AND SIGNATURE)

E.S

DR.SANGEETAMUGLIKAR

(HOD NAME AND SIGNATURE WITH DEPT.SEAL)

DR. RAMANDEEP DUGAL

SIGNATURE & SEA DEAN OF THE COLLEGE)

M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCE & RESEARCH CENTER PHNE-1

PRINCIPAL

M. A. RANGOONWALA COLLEGE OF DENTAL SCIENCES & RESEARCH CENTRE, PUNE

APPENDIX 'B' REPORT OF ETHICS COMMITTEE

NAME	DR. PRATHAMESH NANAL			
CANDIDATE ADMITTED YEAR	2021			
COURSE AND SUBJECT	M.D.S- PERIODONTOLOGY & ORAL IMPLANTOLOGY			
COLLEGE NAME AND ADDRESS	M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES & RESEARCH CENTRE, PUNE			

REFERENCE NO:

DATE:

TO,

DR. PRATHAMESH NANAL,
DEPARTMENT OF PERIODONTOLOGY & ORAL IMPLANTOLOGY,
M.A. RANGOONWALA COLLEGE OF DENTAL SCIENCES
AND RESEARCH CENTRE, PUNE

SUBJECT: RESEARCH PROPOSAL OF DR. PRATHAMESH NANAL,

COMPARATIVE EVALUATION OF THE SUCCESS OF IMMEDIATE IMPLANTS WITH IMMEDIATE LOADING VS.

IMMEDIATE IMPLANTS WITH DELAYED LOADING IN INFECTED SOCKETS: A CLINICAL AND RADIOLOGICAL

STUDY.

REF:-	
(LETTER/PROPOSAL OF STUDENT)	
DEAR STUDENT,	
THE ABOVE MENTIONED RESEARCH PR	OPOSAL OF TITLE OF SYNOPSIS WAS DISCUSSED IN THE ETHICS COMMITTEE
MEETING HELD ON (DATE)	AT OUR COLLEGE.
IT IS DECLARED THAT—	
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- YOU ARE REGISTERED UNDER DR. RAHUL KALE WHO IS A UNIVERSITY RECOGNIZED P.G. TEACHER VIDE UNIVERSITY LETTER NO. <u>MUHS/PG/E-2/1913/2018</u>DATED<u>09/05/2018</u> FOR GUIDANCE AND SUPERVISION DURING THE COURSE OF STUDIES.
- 2. ETHICS COMMITTEE HAS UNANIMOUSLY APPROVED YOUR TITLE & SYNOPSIS OF DISSERTATION.
- 3. THE TITLE IS RECOMMENDED FOR STUDY BY THE STUDENT FROM DATE _______
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DR. P.M.BULAKH
CHAIRPERSON, ETHICS COMMITTEE.

1. TITLE COMPARATIVE EVALUATION OF THE SUCCESS OF IMMEDIATE IMPLANTS WITH IMMEDIATE LOADING VS. IMMEDIATE IMPLANTS WITH DELAYED LOADING IN INFECTED SOCKETS: A CLINICAL AND RADIOLOGICAL STUDY. 2. Tooth loss is a common problem that is seen in day to day clinical INTRODUCTION practice. Missing teeth not only leads to poor aesthetic appearance but also has many other disadvantages. Some of the disadvantages of false partial anadontia are difficulty in eating, loss of confidence, premature ageing, damage to remaining teeth, chronic headaches, gum diseases. To replace these missing teeth many treatment options are available like complete denture, removable partial denture, cast partial dentures, fixed prosthesis, dental implants. Even though all these are a good treatment option for replacing the missing teeth, dental implants are the best option for the treatment. Dental implants are more stable and long lasting and serve its purpose very similar to a natural tooth. Dental Implants have established themselves as a better treatment option to replace missing teeth and there have been many studies that were conducted proving this point. As per Mayfield et al,1 on the basis of time of implant placement after extraction they are classified as, Immediate: Time interval of zero week after extraction Delayed: Time interval of 6 to 10 weeks after extraction Late: Time interval of 6 months or more extraction Conventionally, compromised teeth were removed and left to heal for several months before placing dental implants. Schroop et al ² conducted a study in which he reported reduction in width of horizontal ridge up to 50 % after 3 months of extraction. Immediate implant placement by Schulte and Heimke 3 in 1976 as alternative protocol is a boon to the field of implant dentistry, as it not only preserves the bone quantity, shortens the treatment time, maintains the alveolar architecture, but also provides psychosocial benefits and is cost-effective 4. Placement of immediate implant has several advantages 5 like shorter waiting period for socket ossification, improves patient satisfaction, fewer surgical sessions, shortened edentulous time and reduction in overall cost. The advent of immediate loading protocols has revolutionized the field of implant dentistry. A lot of the problems associated with the original protocol of implant loading were addressed. Immediate implant placement in fresh extraction socket allows placement of implants during the same visit at which the tooth is extracted. This reduces morbidity and decreases treatment time. It also allows placement of implants in an ideal position, helps to preserve the height of the alveolar bone and helps avoid marginal bone loss that typically occurs during socket healing after extraction. 6,7 Placing implants in an infected socket has always been a question that has worried the dentists. An infected socket is socket which has an acute or chronic infection due to various pathologies like periapical abscess.

presence of an intraoral opening of a sinus tract, periapical radiolucency,

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12		root fracture, decreased vertical height of bone, periodontal abscess, puplal necrosis, acute inflammation of PDL. Although a lot of studies have shown success in immediate placement of implant in infected sockets, there is a scarce literature regarding immediate loading of these implants in infected sockets. Therefore, this study was taken with an aim of evaluating and comparing the success of immediate and delayed loading of immediate implants in infected sockets.
3.1	PRIMARY RESEARCH QUESTION	Is there any difference in success of immediate implant with immediate loading in infected sockets compared to success of immediate implant with delayed loading in infected sockets?
3.2	OTHER RESEARCH QUESTION 1	Not applicable
4.1	PRIMARY HYPOTHESIS	There is a difference in success of immediate implant with immediate loading in infected sockets compared to success of immediate implant with delayed loading in infected sockets.
4.2	NULL HYPOTHESIS	There is no difference in success of immediate implant with immediate loading in infected sockets compared to success of immediate implant with delayed loading in infected sockets
5.	REVIEW OF LITERATURE	Schulte and Heimke (1975) ³ : Developed the concept of Tubingen immediate implant system. It was a polycrystalline aluminium oxide stepped ceramic cylinder which was inserted immediately after tooth extraction and preparation of bone cavity. A 10 year follow up of 610 Tubingen implants showed a success rate of 84.5%. A recent study of approximately 1300 Tubingen implants indicated a long term success rate of 92.5%.
		Babbush et al (1986) ⁹ : recommended immediate loading of dental implants in dense bone sites. He recommended rigid splinting of the provisionals and maintaining the provisionals during the healing periods. He recommended the following criteria for the implants to be loaded immediately: implant stability, use of implants with rough surface, threaded implant design, minimal lateral forces on the prosthesis and maximum occlusalstability.
		Rosenquist et al (1996) ¹⁰ : In their clinical study on 51 patients placed a total of 109 Nobel pharma implants into extraction sockets immediately following extraction. The follow-up period varied between 1 and 67 months with a mean of 30.5 months. Osseointegration was determined by clinical stability, lack of symptoms, and lack of peri-implant pathology based on radiographic examination. The implant survival rate was 93.6%. The success rate was 92.0% for implants replacing teeth extracted because of periodontitis and 95.8% for implants replacing teeth extracted for other reasons. They concluded that immediate placement of implants into extraction sockets is a safe and predictable procedure if certain guidelines are followed.

Botticelli et al (2004)¹¹: Conducted a study to evaluate hard tissue alterations following immediate implant placement on 18 subjects. Following flap elevation and the removal of a tooth and implant installation, clinical measurements were made to characterize the dimension of the surrounding bone walls, as well as the marginal defect. No membranes or filler material was used. After 4 months of healing a reentry procedure was performed and the clinical measurements were repeated. They concluded that marginal gaps in buccal and palatal/lingual locations were resolved through new bone formation from the inside of the defects and substantial bone resorption from the outside of the ridge.

Lindeboom et al (2006)¹²: Fifty patients (25 females, 25 males were included in this prospective controlled study. After randomization, 25 implants were immediately placed after extraction, and 25 implants were placed after a 3-month healing period. Thirty-twoimplants were placed in the anterior maxilla and 18 implants were placed in the premolarregion. Implant survival, implant stability, gingival aesthetics, radiographic bone loss was measured. The survival rate was 92% for immediately placed implants versus 100% for delayed placed implants.

Schincaglia et.al (2007)¹³: conducted a randomized, controlled trial in which patients received immediately loaded, implant supported posterior mandibular fixed dental prosthesis. One side received machined surface implants while the other side received oxidised surface implants. They also recorded the maximum insertion torque and implant stability quotient values. They concluded that implants placed in posterior mandible, inserted with torque of > or = 20 Ncm and ISQ value > Than or = 60 can be easily loaded immediately. They recommended the prosthesis to be kept in light occlusal and centric contacts.

Srinivas M. Susarla et al (2008)¹⁴: The study sample consisted of 677 subjects who had2349 delayed loaded dental implants and 178 patients who had 477 immediate loaded implants. The unadjusted one-year survival estimates for the delayed and immediate loading groups were 95.5% and 90.3%, respectively (p < 0.01). In the marginal multiple Cox regression model, immediate loading, current tobacco use, maxillary implants, and shorter implants were associated with failure (p \leq 0.05). In this study, immediately loaded implants were 2.7 times (after adjusting) more likely to fail at one-year compared to delayed loaded implants.

Crespi, Capparè, Gherlone (2010)¹⁸: conducted a 4 year follow up clinical study compare the outcomes of immediate loading of implants in replacing teeth with and without chronic periodontal lesions. Thirty-seven patients were included in this study. A total of 275 implants were placed and immediately loaded in extraction sockets, 197 in periodontally infected sites (infected sites group [IG]), and 78 implants in non-infected sites (non-infected sites group [NG]). Marginal bone levels and clinical parameters (plaque accumulation and bleeding index) were evaluated at baseline and 12, 24, and 48 months after implant placement. At 48 months

the IG group had a survival rate of 98.9% while the NG group had a survival rate of 100%.

The marginal bone level was 0.79 + /- 0.38 mm for the IG and 0.78 + /- 0.38 mm for the NG, plaque accumulation was 0.72 + /- 0.41 for the IG and 0.71 + /- 0.38 for the NG, and the bleeding index was 0.78 + /- 0.23 for the IG and 0.75 + /- 0.39 for the NG. So the study concluded stating that dental implants that were placed and immediately loaded in periodontally infected sockets showed no significant differences compared to implants placed in uninfected sites.

Bell et al(2011)²⁰: Conducted a study with the purpose of evaluating the success of dental implants placed immediately into extraction sites in the presence of chronic periapical pathology. The charts of 655 patients who had implants immediately placed into fresh extraction sites were reviewed for the presence or absence of periapical radiolucencies. A total of 922 implants were included. Of the 922 implants, 285 were immediately placed into sockets that had chronic periapical infections and others were placed and kept as control group. There was a success rate of 97.5% in the test group and 98.7% in the control group. Hence they concluded that The placement of implants in sockets affected by chronic periapical pathology can be considered a safe and viable treatment option but There is a risk of implant failure when placing implants adjacent to teeth with periapical radiolucencies.

Othman Shibly, Ahmad Kutkut, Nishith Patel, Jasim M. Albandar (2012) 19: Conducted a randomized control trial of 1 year in which they compared immediate implants with immediate loading vs. conventional loading. Sixty patients who chose an immediate implant treatment option to replace a hopeless tooth were included in this study. Patients were randomly assigned to receive immediate implants with either immediate loading (group A) or conventional loading after 3months (group B). The 1-year implant survival rate was 95% for the whole study group: 96.6% for group A, and 93.3% for group B. The bone level increased significantly in both groups (group A: 0.99 1 0.22 mm; group B: 0.75 1 0.17 mm), and the difference was not statistically significant (p > 0.5). The conclusion was that, both the immediate and delayed loading of immediately placed implants showed similar outcome with regards to treatment success rates and stability of radiographic bone level. Submerging an immediately placed implant and primary soft tissue closure did not show significant outcome advantages over the transmucosal approach.

Rachit Gangar et al (2013)8: This study was carried to determine the outcome of implants placed into fresh extraction sockets with simultaneous use of particulate bonegraft. It was observed that implants can be successfully placed into fresh extraction sockets.

Yanfei Zhu et al (2015)¹⁵: The aim of this study was to determine the clinical differencesbetween early and conventional loading protocols for dental implants. Fourteen studies were included in our analysis. They found that early loading imposed a significantly higher risk of implant failure than did conventional loading (risk ratio=2.09, 95% confidence interval [CI] [1.18, 3.69], P=0.01), while no significant differences between the methods were found with regards to the marginal bone loss (weighted mean differences [WMD]=0.11, 95% CI [-0.07, 0.28], P=0.23), periotest value (WMD=0.02, 95% CI [-0.83, 0.87], P=0.96), or implant stability quotient (WMD=0.79, 95% CI [-0.03, 1.62], P=0.06). Although early implant loading is convenient and comfortable for patients, this method still cannot achieve the same clinical outcomes as the conventional loading method.

Weiql P et al (2016)¹⁶: The purpose of this literature review was to systematically evaluate the impact of immediate implant placement and restoration (IIPR) on hard and soft tissues and to identify clinical parameters which influence the outcome. This systematic review revealed promising results for immediately placed and immediately restored implants (IIPR) in the anterior maxilla. The possible options of flapless surgery and absence of grafting of the socket allows a minimal surgical intervention.

Eduardo Anitua, Laura Piñas, Mohammad Hamdan Alkhraisat (2016)¹⁷: conducted a study to see the long term outcome on the implants placed in infected sockets with immediate loading. Total of 30 patients had 43 implants placed in infected sockets and were immediately loaded. The implants were inserted at a torque of 35Ncm. Information were collected about patient's demographic data, implant details, soft tissue stability and prosthodontic data. The marginal bone loss, implant and prosthesis survival rates were calculated. There was no implant failure and the implant success rate was 93%. The proximal bone loss was 1.42 mm (range: 0.21 to 5.61 mm). Hence, it was concluded that the immediate loading of implant inserted into fresh and infected extraction socket has not been a risk factor for implant survival. However, the stability of the peri-implant soft and hard tissues has indicated the need to take measures that minimize their loss.

Pal et al. (2021)²¹: conducted a study to describe a protocol for the immediate placement of implant into the infected alveolar socket. In this study, a total number of 40 implants were placed immediately into the extraction sockets. Each case had a different periapical condition. Great care had been taken in debridement of the socket, extraction of tooth/teeth and guided bone regeneration along with the use of pre②operative and post②operative anti②microbial agent. All except three implants were osseo②integrated within 6 months to 1 year. Predisposing factors for failures are incomplete debridement of the socket, poor oral hygiene, incomplete closure of the wound, and systemic factors like hormones. From this study, we may conclude that immediate implants are a viable treatment option for patients with periapical infections.

OTHER OBJECTIVES 1 OTHER OBJECTIVES 2 METHODOLOGY	A. To evaluate the impact of immediate implant with immediate loading in infected sockets on hard and soft tissues. B. To evaluate the impact of immediate implant with delayed loading in infected sockets on hard and soft tissues. C. To compare all the above parameters. Not applicable 1. Study design: A prospective clinical and radiographical study. 2. Study setting: The study would be conducted abiding by all human ethical principles as per the world medical assembly declaration of Helsinki revised year 2000 and the guidelines of
	 Study design: A prospective clinical and radiographical study. Study setting: The study would be conducted abiding by al human ethical principles as per the world medical assembly
METHODOLOGY	 Study setting: The study would be conducted abiding by al human ethical principles as per the world medical assembly
	good clinical practice lay down by Indian council of medica research. 3. Study population: Patients visiting in the institute. 4. Sample size: 30 implant sites Group A: 15 implant sites will be loaded immediately after immediate implant placement following extraction of the teeth with infected sockets.
	Group B: 15 implants will be loaded after 3 months after immediate implant placement following extraction of teeth with infected sockets. (Sample size is subject to availability of patients) Sample size estimation: The sample size was estimated using the data (difference in crestal bone loss) obtained from a previous study conducted by Shibli O et al. (Clinical Implant Dentistry and Related Research. 2012; 14(5):663-671). The sample size formulae used are as follows: $(\sigma_1^2 + \sigma_2^2/k) \ (Z_{1-\alpha/2} + Z_{1-\beta})^2$ $n_1 =$

(Reference: Bernard Rosner. Fundamentals of Biostatistics (5th edition). (based on equation 8.27)

Substituting these values in the above-mentioned formula, sample size estimated was 15 per group at 90% power Appropriate sampling technique: Convenience sampling. Study place: Western Maharashtra. Study period: 18 months.

5. Method of selection of study subjects:

Inclusion Criteria:

- 1. Patients aged above 18 years of age.
- 2. Systemically healthy individuals.
- 3. Presence of periapical pathology and/or infection in tooth to be extracted.

Exclusion criteria:

- 1. Pregnant women and lactating mothers.
- 2. Individuals who use tobacco in any form.
- 3. Subjects having inadequate mouth opening.
- 4. Visual signs of bruxism.

Subject withdrawal criteria:

- 1. Loss of follow up due to migration or any other reason given by the subject. Occurrence of any systemic disease that compromise healing potential or any other communicable or infectious disease.
- 2. Unwillingness to participate further in the study.
- 3. If patient does not want to continue being a part of the study, he/she will not be denied further treatment or consultation in this institution.

6. Abbreviations:

IL: Immediate Loading

DL: Delayed Loading

ISQ: Implant Stability Quotient RFA: Resonance Frequency Analysis

CBL: Crestal Bone Levels

CBCT: Computed Cone Beam Tomography

RVG: Radiovisiography STT: Soft Tissue Thickness

IES: Implant Esthetic Score (Testori et al 2005)

7. Appropriate methods of measurement

1. Implant Stability Quotient(ISQ): Resonance Frequency Analysis(RFA) Using Osstell ISQ device

It analyses the first resonance frequency of a small transducer attached to an implant fixture or abutment. It is dependent upon 3 factors:

- Design of transducer
- Stiffness of implant fixture and its interface with tissues and surrounding bone
- Total effective length above the marginal bone level.

The resonance frequency analysis technique is a bending test of the implant-bone complex where a transducer applies an extremely bending force. The bending force applies a fixed lateral force to the implant and measures the displacement, thus mimicking clinical loading condition.

2. Crestal Bone level:

Measurements for crestal bone level around implants will be taken with the help of CBCT.

3. Soft tissue thickness (STT):

Measured approximately 2 mm apical to the gingival margin on the facial aspect pre-operatively. After topical anaesthetic application, the thickness was measured by gently inserting periodontal probe (UNC-15) up to the contact of the underlying bone structure. The soft tissue biotype was considered thin if the measurement was less than 1.0 mm and thick if it measured greater than 1.0 mm.

4. Implant esthethic score (Testori et al 2005)

Peri-implant soft tissue was assessed using the implant esthetic score where the following parameters were assessed- presence and stability of mesial and distal papilla, ridge stability buccopalatally, texture of peri implant soft tissue, colour or the peri-implant tissue and finally the gingival contour. Testori et al gave the scoring criteria which are as follows:

- 1 Presence and stability of mesial and distal papilla: 0=no papilla, 1= papilla does not fill the entire space but is esthetically appealing, 2= total fill of the papilla.
- 2 Ridge stability buccopalatally: 0= width with ridge loss, 1= width maintained ridge stability was measured in mm of buccal resorption with respect to adjacent natural teeth from the first follow up.
- 3 Texture of peri-implant soft tissue: 0=complete loss of texture, 1= does not look healthy tissue but some texture maintained, 2= looks like healthy gingival tissue around natural teeth.
- 4 Colour of the peri-implant tissue: 0= completely different from healthy tissue, 1= does not look like healthy tissue but still esthetically acceptable, 2= looks like healthy gingival tissue
- 5 Gingival contour: 0= evident asymmetry, 1= signs of asymmetry but esthetically acceptable, 2- harmonious gingival contour.

Perfect outcome – 9
Acceptable outcome – 4 to 8
Compromised outcome – 0 to 3

8. Steps in the conduct of study:

Pre-treatment assessment:

- Patient selection will be done based on inclusion and exclusion criteria.
- 2. The selected subjects will undergo scaling and root planing as a part of initial therapy and put on maintenance.
- 3. Patients will be explained about the procedure and also adverse effect of the treatment or complication arising from it. Written informed consent will be taken.
- 4. Diagnostic cast of the patients will be made.
- 5. Patients routine blood investigation will be done.
- Pre-operative standardized disagnostic CBCT and RVGs will be taken.

Surgical procedure:

- 1. Pre-surgical oral rinse using 10 ml of chlorhexidine gluconate (0.2%) for 1 minute will be given.
- 2. Involved tooth will be extracted atraumatically under local anesthesia (2%lignocaine hydrochloride with adrenaline)
- 3. Implant site preparation will be done and implant will be placed in both the groups.
- 4. If the torque generated while insertion is less than 35 Ncm then delayed loading protocol will be followed.
- 5. If insertion torque of minimum 35 Ncm is generated, then only immediate loading of the implant will be done.
- 6. Sutures will be placed.
- 7. Immediate post-op standardized CBCT will be taken.
- 8. Postsurgical antibiotics, analgesics and postoperative instructions will be given.

Post-Treatment Procedure:

- 1. After implant placement, in group A, healing screw will be placed and a temporary prosthesis will be given within 48 hours.
- 2. After 2-3 months, standardized RVGs will be taken, after which the temporary prosthesis will be removed and a permanent prosthesis will be given.
- **3.** In group B, after the implant placement, healing screw will be placed and after a period of 2-3 months, standardized RVGs will be taken, after which a permanent prosthesis will be given.
- 4. In both the groups, after six months post-op standardized CBCT will be taken.

9. Appropriate study instruments:

- 1. Mouth mirror
- 2. Periodontal probe (UNC15),
- 3. Tweezers
- 4. Local anaesthesia (2% lignocaine with 1:2,00,000 adrenaline)
- 5. 26 Gauge needle
- 6. Disposable syringe
- 7. Blade no. 15,11,12
- 8. BP handle
- 9. Periosteal elevator
- 10. Periotomes and luxators
- 11. Implant kit
- 12. Physio dispenser
- 13. Tissue holding forceps
- 14. Surgical scissors curved and straight
- 15. Needle holder
- 16. 4-0 suture
- 17. Osstell ISQ device

- 10. Methods of data collection: The data will be collected for clinical and radiological analysis after obtaining informed consent of the patients.
- 11. Appropriate data management and analysis procedure: The data collected will be entered in MICROSOFT excel 2010 and cleaned. SPSS 23.0 (IBM analytics, NEW YORK, and U.S.A) will be used for carrying out the statistical analysis. The normality of the data will be checked first. The mean of the measurement outcomes in the 2 groups will be compared with an unpaired t test if normality is there. If not normally distributed then Mann- Whitney U test will be carried out to test the statistical difference. All p values less than 0.05 will be considered to be statistically significant.
- 12. Additional points for research in AYUSH: not applicable
- 13. Additional points for RCT: not applicable
- 14. Additional points for all experimental studies: not applicable.

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GANTT CHART

MONTHS	1-3	4-6	7-9	10-12	13-15	16	17	18
PROJECT SCHEDULE								
SYNOPSIS COMPLETION AND SUBMISSION								
Submission of synopsis to MUHS								
Patient recruitment and intervention								
REVALUATI ON/ FOLLOW UP								
DATA ANALYSIS								
DISSERTATI ON WRITING								9
DISSERTATI ON SUBMISSIO N to MUHS								

Timeline:

- a. Synopsis completion and submission: 1-6 months.
- b. Sample recruitment: 4-9months.
- c. Data collection and entry: 9-17 months.
- d. Revaluation/follow up: 10-17 months.
- e. Data analysis: 16-17 months.
- f. Dissertation writing: 16-18 months.
- g. Proof reading and dissertation submission: 18 month.

10.	ANNEXURES	 Case record form. Subject information sheet in English. Subject information sheet in Marathi. Subject information sheet in Hindi. Informed consent in English. Informed consent in Marathi. Informed consent in Hindi.
*		

ANNEXURE 1

CASE RECORD FORM

1) PATIENT'S NAME:	
2) AGE:	
3) <u>SEX:</u>	
4) PHONE NUMBER:	
5) ADDRESS:	
6) EDUCATION:	
7) OCCUPATION:	
CHIEF COMPLAINT:	
HISTORY OF PRESENT ILLNESS:	
a team to the first the second	
PAST DENTAL HISTORY:	
SYSTEMIC HISTORY:	
ORAL HYGIENE HABITS:	
OTHER HABITS:	

ORAL HYGIENE: GOOD/FAIR/POOR

PERSONAL DATA:

MEASUREMENT PARAMETER	<u>s:</u>		
1. HARD TISSUE ASSESSMENT	T:		
. SOFT TISSUE ASSESSMENT:			
*			

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ANNEXURE 2

SUBJECT INFORMATION SHEET

STUDY TITLE: COMPARATIVE EVALUATION OF THE SUCCESS OF IMMEDIATE IMPLANTS WITH IMMEDIATE LOADING VS. IMMEDIATE IMPLANTS WITH DELAYED LOADING IN INFECTED SOCKETS: A CLINICAL AND RADIOLOGICAL STUDY.

GENERAL INFORMATION

Dear Volunteer,

The department of Periodontology and oral Implantology has undertaken a study of comparative evaluation of the success of immediate implants with immediate loading vs. immediate implants with delayed loading in infected sockets: a clinical and radiological study.

We request your participation in this study. This study is examined and approved by ethical committee. Before you decide whether or not to take part, it is important for you to know why the research is being done, what it will involve and your rights as a potential participant.

Participation is entirely voluntary and you may refuse to take part in the study. If you decide to take part, you will be asked to sign a consent form. Before you agree to sign the consent it is beneficial to have the complete understanding of the experimental nature of the study and its associated risks or benefits. Please read the information given carefully. Then discuss your queries with the undersigned, please clarify them and then decide about your participation.

INVESTIGATOR SIGNATURE GUIDE'S SIGNATURE

ANNEXURE 3

विषय माहिती पत्रक

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अभ्या	H	श	0	कः

कंपॅरेटिव्ह इव्हॅल्युएशन ॲाफ द सक्सेस ॲाफ इमिजीएट इंप्लांट्स विथ इमिजीएट लोडींग व्हर्सेस इमिजीएट इंप्लांट्स विथ डिलेड लोडींग इन इन्फेक्टेड सॉकेट्सः ए क्लिनिकल ॲन्ड रेडीॲालॉजिकल स्टडी.

सामान्य माहिती:

प्रिय सहभागी, पेरीओडाँटोलॉजी आणि ओरलइम्प्लांटोलॉजी विभाग उपरोक्त शीर्षकाने अभ्यास करण्याचा निर्णय घेतला आहे. आम्ही या अभ्यासात आपल्या सहभागाची विनंती करतो. या अभ्यासाचे परीक्षण नैतिक समितीने केले आणि मंजूर केले. आपण भाग घेणार आहात किंवा नाही हे ठरवण्यापूर्वी, संशोधन का केले जात आहे, त्यात काय समाविष्ट आहे आणि संभाव्य सहभागी

म्हणून आपले हक्क जाणून घेणे महत्त्वाचे आहे.

सहभाग पूर्णपणे स्वैच्छिक आहे आणि आपण अभ्यासात भाग घेण्यास नकार देऊ शकता. आपण भाग घेण्याचा निर्णय घेतल्यास आपल्याला संमती पत्र वर स्वाक्षरी करण्यास सांगीतले जाईल. आपण संमतीवर स्वाक्षरी करण्यास सहमत होण्यापूर्वी त्यास प्रायोगिक निसर्ग आणि संबंधित जोखीम किंवा फायदे पूर्ण समजून घेणे फायदेशीर ठरते. काळजीपूर्वक दिलेली माहिती वाचा. नंतर आपल्या प्रश्नांची अदलाबदल करून चर्चा करा, कृपया त्यांना स्पष्ट करा आणि नंतर आपल्या सहभागाबद्दल निर्णय घ्याव.

संशोधकाचे स्वाक्षरी	मार्गदर्शकांच्या स्वाक्षरी
राताववगव स्वादारा	नागपरापगच्या स्वादारा

ANNEXURE 4 विषय जानकारी पत्र

अध्ययन शीर्षक:	
कंपॅरेटिव्ह इव्हॅल्युएशन ॲाफ द सक्सेस ॲाफ इमिजीए	ट इंप्लांट्स विथ इमिजीएट लोडींग व्हर्सेस इमिजीएट इंप्लांट्स
विथ डिलेड लोडींग इन इन्फेक्टेड सॉकेट्सः ए क्लिनिकल ॲ	न्ड रेडीॲालॅाजिकल स्टडी
सामान्य जानकारी:	
हैं I यह तय करने से पहले कि आप भाग लेना चाहते हैं या न रहा है, इसमें क्या शामिल होगा और संभावित प्रतिभागी के अ भागीदारी पूरी तरह से स्वैच्छिक है और आप अध्ययन में भा करते हैं, तो आपको सहमति फॉर्म पर हस्ताक्षर करने के लि के लिए सहमत हों, अध्ययन और उसके संबंधित जोखिमों य	इस अध्ययन की नैतिक समिति द्वारा जांच और अनुमोदन हुआ हीं, यह जानना आपके लिए महत्वपूर्ण है कि शोध क्यों किया जा
निवेशक हस्ताक्षर	गाइड की हस्ताक्षर

ANNEXURE 5

INFORMED CONSENT

1,	EXERCISE FREE POWER OF CHOICE, GIVE MY CONSENT TO BE INCLUDED IN THE
RESEARCH TITLED'S	TUDY TITLE: COMPARATIVE EVALUATION OF THE SUCCESS OF IMMEDIATE IMPLANTS
WITH IMMEDIATE LO	OADING VS. IMMEDIATE IMPLANTS WITH DELAYED LOADING IN INFECTED SOCKETS: A
	CLINICAL AND RADIOLOGICAL STUDY.

I have been informed about the treatment plan. I am aware that if I agree to be a part of the study, I will be required to undergo a routine blood test before the procedure. I will be required to visit the department 3-4 times during the entire study period as a routine protocol to evaluate the success of the treatment. During this process, there will be no testing of new drugs or any investigation, other than explained. No extra cost, except for the treatment charges, will be taken from me to be a part of the study. I will be required to be a part of the study for 4-6 months in total and I have been informed that including me there will be approximately 30 volunteers.

I have been explained to my satisfaction by the investigator, in the language I comprehend about the purpose of the research work being undertaken. I confirm that the researcher has explained me the procedure and benefits of the study that might reasonably be expected as an outcome of research to me or to the community and also the associated risk pain or discomforts like allergy to anaesthesia or any drugs, pain and swelling, or any problems arising in the period of treatment. I further affirm that I have not been compelled in any way to participate in this investigation and I was provided with sufficient clarification when asked. I have been notified about my freedom to participate and to withdraw from research any time without penalty or loss of benefits to which I would otherwise be entitled. I understand that, I may be removed from the study without my consent, if the researcher decides it is not in the best interest of my health or if I am not following the study protocol.

I have been promised that the information obtained about me for this study will be kept fully confidential. However, research information may be shared with people or organizations for quality assurance, data analysis or may be published for scientific purposes; nonetheless my identity will not be revealed.

Name of the participant

signature/ thumb impression of the participant with date.

Name of the witness

signature/thumb impression of the witness with date.

Name of Investigator

signature with date

ANNEXURE 6 संमतीपत्र

मी,	_ निवडीचामुक्तपध्दतवापरतो, शीर्षक 'कंपॅरेटिव्ह इव्हॅल्युएशन ॲाफ द सक्सेस ॲाफ
इमिजीएट इंप्लांट्स विथ इमि	जीएट लोडींग व्हर्सेस इमिजीएट इंप्लांट्स विथ डिलेड लोडींग इन इन्फेक्टेड सॉकेट्स: ए
क्लिनिकल ॲन्ड रेडीॲालॉरि	जेकल स्टडी'असलेल्या संशोधनात समाविष्ट करण्याची माझी संमती देतो/देते.

मला माझ्या दातांसाठी उपचार योजनेबद्दल माहिती दिली गेली आहे. मला माहित आहे की जर मी अभ्यासाचा एक भाग असल्याचे मान्य केले तर मला या प्रक्रियेपूर्वी रक्त चाचणी करून घ्यावी लागेल. मला माहित आहे की संपूर्ण अभ्यासात भुलेची गरज भासू शकते. या प्रक्रियेदरम्यान, नवीन औषधांचा किंवा कोणत्याही अन्वेषणाशिवाय कोणताही तपासणी केली जाणार नाही. अभ्यासाचा भाग म्हणून उपचार शुल्का शिवाय, कोणताही अतिरिक्त खर्च, माझ्याकडून घेण्यात येणार नाही.

मला ४ ते ६ महिन्यांपर्यंत अभ्यासाचा भाग बनणे आवश्यक आहे आणि मला माहिती दिली गेली आहे की माझ्यासह सुमारे ३० रूगण असतील

मी पुष्टी करतो की मला संशोधकाने ह्या अभ्यासक्रमाबद्दल सगळी माहिती दिली आहे ह्या होणारे फायदे .अभ्यासात होणारे फायदे, संबंधित जोखी संबंधित वेदना किंवा उपचार काळात होणाऱ्या समस्याचे हाल केले जाईल . अभ्यासाच्या प्रक्रिया आणि शिस्ताचाराब्द्दल व अभ्यासाचे फायदे स्पष्ट केले आहेत.

मी पुढे असेही कबूल करतों की या तपासणीत सहभागी होण्यासाठी मला कोणत्याही प्रकारचा दबाव घातली नाही आणि विचारल्यावर मला पुरेशी स्पष्टीकरण देण्यात आले. मला असे वचन देण्यात आले आहे की या अभ्यासासाठी मला मिळालेली माहिती पूर्णपणे गोपनीय ठेवली जाईल. तथापि, गुणवत्ता आश्वासन, डेटा विश्लेषण किंवा वैज्ञानिक हेतूंसाठी प्रकाशित होणारी व्यक्ती किंवा संस्थांसह संशोधन माहिती सामायिक केली जाऊ शकते, तरीही माझी ओळख उघड केली जाणार नाही.

प्रतिभागी सहभागीदाराचे नाव

स्वाक्षरी/ अंगठ्याचा ठसा आणि तारीख

प्ताक्षीदाराचे नाव

स्वाक्षरी/ अंगठ्याचा ठसा आणि तारीख

तंशोधकाचे नाव

स्वाक्षरी/ अंगठ्याचा ठसा आणि तारीख

ANNEXURE 7 सहमतिपत्र

ीं, कंपॅरेटिव्ह इव्हॅल्युएशन	न ॲाफ द सक्सेस ॲाफ इमिजीएट इंप्लांट्स विथ इमिजीएट लोडींग
हर्सेस इमिजीएट इंप्लांट्स विथ डिलेड लोडींग इन अनुसंधान में शामिल होने के लिए मेरी सहमति देता/दे	<mark>ा इन्फेक्टेड सॉकेट्सः ए क्लिनिकल ॲन्ड रेडीॲंालॅाजिकल स्टडी</mark> ' शीर्षक वे ती हूंI
र्ह, तो मुझे प्रक्रिया से पहले एक रक्त परीक्षण करना हो में मुझे संज्ञाहरण दिया जा सकता है। मुझे पूरे अध्ययन मूल्यांकन करना होगा। इस प्रक्रिया के दौरान, समझा अध्ययन का हिस्सा बनने के लिए मुझसे इलाज के शुल्व	ा किया गया है। मुझे पता है कि अगर मैं अध्ययन का हिस्सा बनने के लिए सहमत गिगा। जो कि इस अभ्यास के लिए मानक प्रोटोकॉल है। मुझे पता है कि पूरे अध्ययन अविध के दौरान विभाग को ३-४ बार जाना होगा जिसमें उपचार की सफलता का ए गए अलावा अन्य दवाओं या किसी भी जांच का कोई परीक्षण नहीं होगा। कको छोड़कर कोई अतिरिक्त शुल्क नहीं लिया जाएगा। हिस्सा बनना होगा और मुझे सूचित किया गया है कि मेरे समेत लगभग ३० रोगी
पृष्टि करता हूं कि शोधकर्ता ने मुझे अध्ययन की प्रक्रिया और लाभ समझाया है।मैं आगे यह पुष्टि करता हूं कि इस जांच में भाग लेने के ए मुझे किसी भी तरह से मजबूर नहीं किया गया है और मुझसे पूछे जाने पर मुझे पर्याप्त स्पष्टीकरण प्रदान किया गया था। मुझे भाग ने और किसी भी समय जुर्माना या लाभ के नुकसान के बिना अनुसंधान से वापस लेने की स्वतंत्रता के बारे में अधिसूचित किया गया है, एसके लिए मैं अन्यथा हकदार हूं। मैं समझता हूं कि, मेरी सहमित के बिना मुझे अध्ययन से हटा दिया जा सकता है, अगर शोधकर्ता र्णय लेता है कि यह मेरे स्वास्थ्य के सर्वोत्तम हित में नहीं है या यदि मैं अध्ययन प्रोटोकॉल का पालन नहीं कर रहा हूं। हो वादा किया गया है कि इस अध्ययन के लिए मेरे बारे में प्राप्त जानकारी पूरी तरह से गोपनीय रखी जाएगी। हालांकि, डेटा विश्लेषण लिए लोगों या संगठनों के साथ साझा किया जा सकता है या वैज्ञानिक उद्देश्य के लिए प्रकाशित किया जा सकता है, फिर भी मेरी इचान किसी भी प्रकार से समय पर प्रकट नहीं की जाएगी।	
तिभागी का नाम	प्रतिभागी का हस्ताक्षर / अंगूठे की छाप और दिनांक
गक्षीदार का नाम	साक्षीदार का हस्ताक्षर / अंगूठे की छाप और दिनांक

ांशोधक का नाम

संशोधक का हस्ताक्षर / अंगूठे की छाप और दिनां

TO THE ETHICAL COMMITTEE

M.A RANGOONWALA COLLEGE OF DENTAL SCIENCES AND RESEARCH CENTRE, PUNE – 01

1	Discipline	Periodontology and Implantology
2	Title of the Dissertation	COMPARATIVE EVALUATION OF THE SUCCESS OF IMMDEIATE IMPLANT WITH IMMEDIATE LOADING VS. IMMEDIATE IMPLANT WITH DELAYED LOADING IN INFECTED SOCKETS: A CLINICAL AND RADIOLOGICAL STUDY.
A) PG S	Name and Designation of	Dr. Prathamesh Nanal
	A) PG Student	1 st year MDS student Periodontology and Implantology
	B) PG Guide	Dr. Rahul Kale Professor, Periodontology and Implantology
4	Duration of Project	18 months

5

30 sites; which will be divided into 2 groups:

GROUP A –15 implant sites will be loaded immediately after immediate implant placement following extraction of the teeth with infected sockets.

GROUP B – 15 implants will be loaded after 3 months after immediate implant placement following extraction of teeth with infected sockets.

CLINICAL PROCEDURE

GROUP A- Immediate implant with immediate loading.

Pre-surgical oral rinse using 10 ml of chlorhexidine gluconate (0.2%) for 1 minute will be given. Involved tooth will be extracted atraumatically under local anesthesia (2%lignocaine hydrochloride with adrenaline). Implant site preparation will be done and implant will be placed. If insertion torque of minimum 35 Ncm is generated, then only immediate loading of the implant will be done. Sutures will be placed. Immediate post-op standardized CBCT will be taken. Implant stability quotient will be recorded using Resonance frequency analysis(RFA). Postsurgical antibiotics, analgesics and postoperative instructions will be given.

GROUP B - Immediate implant with delayed loading.

Pre-surgical oral rinse using 10 ml of chlorhexidine gluconate (0.2%) for 1 minute will be given. Involved tooth will be extracted atraumatically under local anesthesia (2%lignocaine hydrochloride with adrenaline). Implant site preparation will be done and implant will be placed. If the torque generated while insertion is less than 35 Ncm then delayed loading protocol will be followed. Sutures will be placed. Immediate post-op standardized CBCT will be taken. Implant stability quotient will be recorded using Resonance frequency analysis(RFA). Postsurgical antibiotics, analgesics and postoperative instructions will be given.

6.	Dead line for submission of dissertation to the University	6 months prior to final university examination

7. Review of progress of the dissertation:

	1stQuarter	2 nd Quarter	3 rd Quarter	Final
Review of progress of				
dissertation		- Wednesday	White the same	
Review of collected data				
Review of analyzed data				

3.	Administrative & ethical issues	
	a) Is the infrastructure facility required for the Conductof the dissertation available in the Institution and affiliated hospital?	YES
	b) Is the necessary support from various other	YES
	Specialties required for the dissertation	
	available?	*
	C) Does the Project involve any drug trial on animals? If	NO
	so, does the facility for animal house exist in or around	
ı	the unit?	
Ł	i) Does the Project involve any drug trial on human beings, if so clarify. Are the human subjects available in or near the unit and have you discussed the matter with he concerned administrative authorities?	NO
	thical Committee	YES
b	Do you consider the proposed number of subjects will e available within the proposed period of study and will e adequate to make the study result oriented?	YES
) The topic was discussed and approved in the epartmental meeting.	YES

Lithamesh

Name and signature of PG Student:
Dr. Prathamesh Nanal
PG Student,
Dept. of Periodontology and Oral Implantology,
MARDC Pune-411001.

Name and signature of PG Guide:

Dr. Rahul Kale,

Professor,

Dept. of Periodontology and Oral Implantology,

MARDC Pune-411001.

Deat. of Periodontia

Name and Signature of HOD:
Dr. Sangeeta Muglikar
Professor & HOD,
Dept. of Periodontology and Oral Implantology,
MARDC Pune-411001.

PRINCIPAL

M. A. RANGOONWALA COLLEGE OF DENTAL

SCIENCES & RESEARCH CENTRE, PUNE

10	Date of submission to the ethical committee	
11	Date of clearance by the Committee	
12	Remarks of the Secretary	No. of the content of

CERTIFICATE

This is to certify that, Dr. Prathamesh Nanal has selected the topic of synopsis

COMPARATIVE EVALUATION OF THE SUCCESS OF IMMEDIATE IMPLANTS WITH IMMEDIATE LOADING VS.

IMMEDIATE IMPLANTS WITH DELAYED LOADING IN INFECTED SOCKETS: A CLINICAL AND RADIOLOGICAL STUDY.

Is prepared under my Guidance for MUHS, Nashik. I will check her work on this subject from time to time.

Guide:

Dr. Rahul Kale

Professor,

Department of Periodontology & Implantology

Place:

Date

CERTIFICATE

This is to certify that, Dr. Prathamesh Nanal has selected the topic of synopsis

COMPARATIVE EVALUATION OF THE SUCCESS OF IMMEDIATE IMPLANTS WITH IMMEDIATE LOADING VS. IMMEDIATE IMPLANTS WITH DELAYED LOADING IN INFECTED SOCKETS: A CLINICAL AND RADIOLOGICAL STUDY.

Is prepared under my Guidance for MUHS, Nashik. I will check her work on this subject fromtime to time.

Guide:

Dr. Rahul Kale Professor, Department of Periodontology & Implantology Place:

Date

M. A. RANGOONWALA COLLEGE OF DENTAL

SCIENCES & RESEARCH CENTRE, PUNE

Minutes of Ethical Committee of M.C.E. Society Meeting Held on 16th June 2022.

The Meeting of the Ethical Committee of M.C.E. Society, Pune held on 16th June 2022 at 11:30 am in the Dean office of M. A. Rangoonwala College of Dental Sciences and Research center, Azam Campus, Pune. The Chairman of Ethics Committee Dr. P.M Bulakh chaired the meeting.

Following members attended the meeting.

- 1. Dr. P. M. Bulakh Chairman
- Dr. N. Y. Kazi Clinician
- 3. Dr. Farha Rizwan Secretary
- 4. Dr. Ramandeep Dugal Principal/Member
- Dr. Revati Deshmukh Subject Expert
- Dr. Mustaq Mukadam Member
- 7. Mr. S. M. Khan Theologist
- Dr. Abhijeet Tilak
 Basic Medical Scientist
- Dr. Adv. R.M. Khan Legal advisor
- Dr. Sangita Muglikar Spl. Invitee
- Mr. Zameer Shaikh
 Lay Person

The meeting commenced with the permission of chair by Dr. Farha Rizwan member secretary by welcoming the members.

After this the Agenda was taken up & the following decisions were taken.

Agenda No. 1:

To read and confirm the minutes of previous meeting held on 9th April 2022.

The minutes of last meeting were read and confirmed.



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Agenda No 2:

To Approve the Research proposals of the Post graduate M.D.S students M.C.E. Society's M.A. Rangoonwala College of Dental Sciences and Research center. Pune, 2022 Batch.

The committee members scrutinized the Research proposals of PG scholars of M.A.R.D.C with their concerned topics and given appropriate suggestion to the candidates and approved research their titles subject to the changes which they will make in there research proposal.

Department	Sr. No	Name of the student	Topic
	7 1	AHMED SIRKHOT	Comparative Evaluation of Shade Determination using Digital Intra-Oral scanners and Conventional Methods
	2	SUMAIYA KHAN	Influence of Phase Transformation Induced by Low Temperature Degradation on Flexure Strength of Monolithic Zirconia and Graded Zirconia - A Cross Sectional In Vitro Study
	3	AMIR KHAN	Assessment of Different Surface Treatments on Shear Bond Strength of Polyetheretherketone (PEEK) and Heat Cure Poly-Methyl-Methacrylate (PMMA) An In Vitro Study
Prosthodontics	4	ALFIYA ALIYA TAMBOLI	Evaluation of Patient Reported Outcome Measures and Clinical Performance of Implant Supported Overdentures with Two Different Attachment Systems: A Randomised Cross-Over Clinical Study
	5	RUTIKA NAIK	A ComparativeAssessment of the Change in Colour and Inflammatory Response in Peri Implant Soft Tissue and Evaluation of Bioflim Formation Following use of Titanium, Zirconia and Reinforced Peek Abutment Surfaces: An In Vivo Study
	6	ZOHA SHAIKH	A Comparative Evaluation of Marginal Fit of Cast Copings Fabricated Using Computer Aided Milling Light Cure Wax Pattern and Inlay Casting Wax Pattern: An In Vitro study
Department	Sr. No	Name of the student	Topic



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	7	SAKINA RAMPURI	Comparative Evaluation the Alkaline Phosphii (ALP) Activity in Gingival Crevicular Fluid in Diffe Age Groups and Comparing Its Relation to Indivi- skeletal Maturity Using Cervical Vertebral Maturi Stages and Hand Wrist Radiographic Analysis
	8	AZMAT AZHA KHAN SHAREQUE MOHD	Comparison of the Accuracy of Various Intrac Scanners and Laboratory Scanners for a Comp ARCH: An In Vitro Study
	9	SAYED FEHMEEN ANWAR	Colour Stability of Various Commercially Available Orthodontic Aligners When Expose Staining Agents: An IN Vitro Study
Orthodontics	10	SAGAR PATIL	Comparative Evaluation of Mandibular Posts Anatomic Limit Distance For Molar Distance in Males and Females with Skeletal Class Malocclusion Using Cone Beam Comp Tomography - A Retrospective Study
	11	SHUBHAM NIMKAR	Comparative Evaluation of Thickness of Two Commercially Available Aligner Material After Thermoforming and at Different Time Interval of Intraoral Exposure: A Prospective Clinical Study
W.	12	TAHREEM CHAUDHARY	Comparing the Accuracy and Reliability of Digitally Scanned Models Produced by Alginate Impression, Addition Silicone Impression and Intraoral Scanning (In Vitro Study)
Department	Sr. No	Name of the student	Topic
	13	NADEEM PINJARI	Comparative Evaluation of Color Stability of Bulk Fill Packable and Bulk Fill Flowable Composite Resin in Mandibular Molar Class Restorations-Randomized Clinical Study
Conservative	14	SAIMA SHAIKH	Comparative Evaluation of Two Different Motion on Surface Topography of Rotary Files after Root Canal Preparation of Mesiobuccal Canal in Maxillary Molars: A Randomized Clinical Study
	177	SAWA SHAIKH	Comparative Evaluation of Calcium Silicate and Epoxy Resin Based Root Canal Sealerswith Apical Extrusion on Post Obturation Pain in Two Visit Root Canal

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1	16	SAURABH SALUNKHE	Comparative Evaluation of Working Length Determination Using Electronic Apex Locator and CBCT in Mesiobuccal Canal Curvatures of Maxillary First Molar - An In Vivo study
w	17	AKSHAY GAIKWAD	Comparative Microbiological Evaluation of Calcium Hydroxide, Triple Antibiotic Paste and Triple Antibiotic Paste with Nano Particles as Intracanal Medicaments in Symptomatic Apical Periodontitis: A Randomized Clinical Study
	18	TANIYA KATAKWAR	A Comparative Evaluation of Different Irrigation Activation Systems on Antimicrobial Load and Post Operative Pain in Symptomatic Apical Periodontitis: A Randomized Clinical Study
Department	Sr.	Name of the student	Topic
Department	19		Comparative Evaluation of Effectiveness of Modified Minimally Invasive Surgical Technique Using Magnifying Loupes, with and without Osseous Graft, for Regenerative Therapy of Isolated Interdental Intra-Bony Defects: A Prospective Split - Mouth Clinical and
	20		Assessment of Early Wound Healing & Anti- Microbial Properties of Nano Crystalline Silver Membrane Following Surgical Gingival Depigmentation: A Split - Mouth Clinical & Microbiological Study
Periodontics	21		Comparative evaluation of Immediate Implant Placement with and Without Dual Zone Grafting in the Esthethic Zone: A Clinical and Radiographic Study
A. 100	22		A Comparative Clinical Study to Evaluate the Effectiveness of Tissue Adhesive and Suture in Periodontal Flap Surgery
Contract of the second	2		Comparative Evaluation of Effectiveness of Bovine Derived Xenograft and Demineralized Freeze-Dried Bon Allograft with Platelet Rich Fibrin in Alveolar Ridge Preservation - A Split Mouth Clinical, Radiographical an Histological Study
A STATE OF THE PARTY OF THE PAR	A CER		Comparative Evaluation of the Success of Immediate Implants with Immediate Loading VS Immediate Implants with Delayed Loading in Infected Sockets: A Clinical and Radiological Study

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	1.65	Sr.	Name of the	Topic
	Department	No	student	
				Assessment and Comparison of Pain and Behavioral Changes Experience During Palatal
1			The same of the sa	Infiltration in Children Using Conventional Local
				Infiltration in Children Using Conventional
1	13		74 T	Anesthetic Technique Versus special Local Anesthesia delivery system - An In Vivo Study
1	3	25	SHIFA S PARKAR	
1		-	27117	Comparative Evaluation of Types of
				Interproximal Contact Area with the Presence
1				Absence of Proximal Caries in 3 - 11 year Old
		*	SAYAMANAAZ	Children in a City in Western Maharashtra : Al
1	+ 1	26	SAYYAD	Analytical Study
-		11		Assessment & Comparison of Dental Arch
				Dimensions in the Primary Dentition of Childi
-				Aged 3 - 5 years Using Intra Oral Scanners 1 A
	D 1 1 1	27	HUMERA KHATRI	Analytical Study
	Pedodontics			Assessment of Palatal Depth, Palatal Width at
				Palatal Lengther 3 to 5 year old Children in a
			OLD ALVET A CHOV	City of Western Maharashtra Using 3D Digital
		28	SUMANT ASHOK DEMANNA	'scanning: An Observational Study
	See a.	20	DEMARKA	
	. Towe	-		Comparative Assessment of Clinical Lifting Various Types of Crowns for Primary Tests
			100	Prospective Randomized Parallel Group Follows
		1-	ATHARVA A	Up Study
	24	-29	CHOUDHARY .	Op Study
				Comparative Evaluation of Physical and
		1		Mechanical Properties of Three Different Lie
				of Preformed Primary Molar Crowns An Inc.
				Vitro Study
		30	SUPRIYA DIGHE	
		Sr.	Name of the	Topic
	Department	No	student	and the second s
		-		Comparative Evaluation of Intramuscular legacities
				of methylprednisolone at Local and distant site is
				Controlling the Postoperative Sequelar at the party
			1.0	Removal of Mandibular Third Molar A
		3200		Prospective Randomized Study
	Oral &	27	YASHMIN PARVEEN	The state of the s
1	Maxillofacial			Efficacy of dextrose Prolotherapy in Carlotherapy
0	Surgery			to Normal Saline for the Management of
12		28	ZAID SHAIKH	Temporomandibular Joint Pain and Uspensor
15			1 1 1 1 1 1 1 1 1 1 1	Comparative Evaluation of Infra Social Design
2,4		12	NOOR UM	of Tetracycline and Tetracycline
- IDAI			MUNAMAH	on Post Operative pain, Swelling and Sent Special
CI	PAL OLLEGE OF DENTAL OCH CENTRE, PUNE	20	MOHAMMAD YUNUS	Ticamis Tites Transfer
	ILLE OF DIME	29	SHAIKH	Adults Patients: A Prospective faller
WALAC	CH CENTRE,			Additis I attents. A Troop

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Department	Sr.No	Name of the Candidate	Title of Synopsis	Outward number	Dated
	19	NASHRAH SAWANT	Comparative Evaluation of Effectiveness of Modified Minimally Invasive Surgical Technique Using Magnifying Loupes, with and without Osseous Graft, for Regenerative Therapy of Isolated Interdental Intra-Bony Defects: A Prospective Split - Mouth Clinical and Radiographic Study	MCES/EC/743/2022	17/6/2022
	20	ARSHEEN KAZI	Assessment of Early Wound Healing & Anti-Microbial Properties of Nano Crystalline Silver Membrane Following Surgical Gingival Depigmentation: A Split - Mouth Clinical & Microbiological Study	MCES/EC/744/2022	17/6/2022
	riodontics 21 RUTUJA JIV.	SAKSHI NERKAR	Comparative evaluation of Immediate Implant Placement with and Without Dual Zone Grafting in the Esthethic Zone: A Clinical and Radiographic Study	MCES/EC/745/2022	17/6/2022
Periodontics		RUTUJA JIVANE	A Comparative Clinical Study to Evaluate the Effectiveness of Tissue Adhesive and Suture in Periodontal Flap Surgery	MCES/EC/746/2022	17/6/2022
		NEHA LANGADE	Comparative Evaluation of Effectiveness of Bovine Derived Xenograft and Demineralized Freeze-Dried Bone Allograft with Platelet Rich Fibrin in Alveolar Ridge Preservation - A Split Mouth Clinical, Radiographical and Histological Study	MCES/EC/747/2022	17/6/2022
		PRATHAMESH NANAL	Comparative Evaluation of the Success of Immediate Implants with Immediate Loading VS. Immediate Implants with Delayed Loading in Infected Sockets: A Clinical and Radiological Study		
	24			MCES/EC/748/2022	17/6/202

SECRETARY
Ethics Committee
M. C. E. Society
Azam Campus, Pune-1.





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-	30	AVIRAT NAVALE	Compare Evaluation of Effectiveness of Arthrocentesis, anterior Repositioning Splint and Soft Stabilization Splint Therapy in Management of Temporomandibular Disorders
		ALIYA KHAN	An In Vivo Comparative Evaluation of Efficacy of Self Tapping Titanium Screws and Conventional Titanium Screws for Semi-Rigid Internal Fixation in Midface Osteosynthesis
	31	POOJA JAGTAP	Comparative Evaluation of Therapeutic Efficacy of Trypsin Chymotrypsin, Bromelain and Serratiopeptidase in Impacted Mandibular Third Molar Surgery: A Clinical Study
Department	Sr. No	Name of the student	Topic
Oral Medicine	33	HEENA KHAN	Association of Oral Mucosal Lesions with Tobacco Smoking Habit Among Adults in Western Maharashtra Population - A Cross Sectional Analytical Study
and Radiology		ROZA RAJKUMAR BAVISKAR	Comparative Morphometric Evaluation of Pterygoid Process Among Dentulous, and Partially Edentulous Patients Utilizing Cone-Beam Computed Tomography Retrospective Observational Study

Any other matter with the permission of chair.

Since no other matter came up for discussion the meeting was concluded with a vote

of thanks to the chair.

SECRETARY
Ethical Committee
M. C. E. Society
Azam Campus, Pune-1

CHAIRMAN
Ethical Committee
M. C. E. Society
Azam Campus, Pune-1.

President

Maharashtra Cosmopolitan

Education Society, Pune.

PRINCIPAL
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महाराष्ट्र आरोग्य विज्ञान विद्यापीठ, नाशिक MAHARASHTRA UNIVERSITY OF HEALTH SCIENCES, NASHIK

दिंडोरी रोड, म्हसरुळ, नाशिक - ४२२००४ Dindori Road, Mhasrul, Nashik - 422004

Website: www.muhs.ac.in



राजेंद्र शिवाजी बंगाळ

एम बी बी एस, एम डी (न्यायवैद्यकशास्त्र) ही एन बी, एल एल बी

Dr. Rajendra Shivaji Ban M.B.B.S. M.D. (Forensic Medicine), D.N.B. L.L.B.

Registrar

CATHER A CHES & SHEET A CHES & SACRA &

Date: 10/01/2023

MUHS/Dental/MUHS-042464/2019

To,

The Dean / Principal / Director,

M.C.E.S.'s M. A. Rangoonwala Dental College, Pune

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SUB: Regarding approval of Title & Synopsis.

Sir / Madam.

With reference to the above, it is informed that, the proposal of "Title & Synopsis of Dissertation" of following student is duly "Accepted" by the BORS Committee of the College. Accordingly, the University hereby grant approval to the Title & Synopsis proposal of following student(s).

Name of Student	PRATHAMESH DINESH NANAL		
Name of Guide	Rahul Kale		
Course/ Specialty	MDS - PERIODONTOLOGY		
Academic Year of admission	2021-22		
Name of the College	M.C.E.S.'s M. A. Rangoonwala Dental College, Pune		
Title of Synopsis	COMPARATIVE EVALUATION OF THE SUCCESS OF IMMEDIATE IMPLANTS WITH IMMEDIATE LOADING VS. IMMEDIATE IMPLANTS WITH DELAYED LOADING IN INFECTED SOCKETS: A CLINICAL AND RADIOLOGICAL STUDY.		

- 1) Please note that the appearance of the concerned student to the final year examination is subject to final eligibility of the university and fulfillment of relevant rules and regulations of the concerned central council / university
- 2) It is mandatory for the candidate to work for minimum 18 months on the title & synopsis approved by the university prior to submission of dissertation, failing which the term of the candidate shall be extended by the college to that extent
- 3) It is also mandatory for the colleges to maintain Teacher: Student ratio as per norms prescribed by concerned Central Council/University

Registrar

Sd/-

PRINCIPAL M. A. RANGOONWALA COLLEGE OF DENTAL SCIENCES & RESEARCH CENTRE, PUNE