

COMPARATIVE EVALUATION OF CORONALLY ADVANCED FLAP WITH AND WITHOUT CHORION MEMBRANE IN THE TREATMENT OF GINGIVAL TISSUE RECESSION-A CLINICAL STUDY.

#### DISSERTATION

**Submitted to** 

BABU BANARASI DAS UNIVERSITY, LUCKNOW. UTTAR PRADESH

In the partial fulfilment of the requirement of the degree of

MASTER OF DENTAL SURGERY

IN

**PERIODONTOLOGY** 

By

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Under the guidance of

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BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

BATCH: 2021-2024

YEAR OF SUBMISSION-2024

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## **ACKNOWLEDGEMENT**

I express my sincere gratitude to The Almighty God for granting me this wonderful existence in which I may significantly change people's lives.

Many people have bestowed their blessings and heartfelt support on me in the successful completion of this study, and I would want to take this opportunity to express my gratitude to each and everyone of them. I believe that the capacity to ACKNOWLEDGE them is what makes life wonderful.

Any dissertation is like a dream, and much of its fulfillment depends on the support and advice of several other people. The guide is someone who believes in you and who pulls, pushes, and guides you to the next plateau while occasionally jabbing you with a sharp stick called "truth". I found one such great mentor in Guide **Dr. Mona Sharma**, Professor, and Head Of Department of Periodontology, Babu Banarasi Das College of Dental Sciences. I am so grateful for all of his support and assistance. I consider myself really blessed to have someone like him as a guide who both taught me to explore independently and provided the direction I needed to get back on track when my steps stumbled. His sheer presence inspired and encouraged me. He taught me how to challenge ideas and communicate them. I will always be grateful to him for the way his relentless pursuit of perfection has shaped and improved me. His persistence and encouragement enabled me to get through many challenging circumstances and conclude this dissertation.

My profound gratitude is also owed to my esteemed co-guide **Dr. Brijendra Singh**, Reader, Department of Periodontology, Babu Banarasi Das College of Dental Sciences, for his insightful recommendations, consistent inspiration, and support throughout.

I take this opportunity to sincerely thank **Dr. Puneet Ahuja**, Principal, Babu Banarasi Das College of Dental Sciences for their timely advice, practical assistance during my post-graduation & providing the necessary facilities to carry out the dissertation work.

I want to express my gratitude to **Dr.Sunil C. Verma**, Professor of the Periodontology Department at Babu Banarasi Das College Of Dental Sciences, for her understanding and encouragement, which helped me get through many stressful circumstances.

I also take this opportunity to express a deep sense of gratitude to **Dr Suraj Pandey**, **Dr. Neelesh Singh**, **Dr. Akanksha Kashyap**, Reader, Department of Periodontology, Babu Banarasi Das College of Dental Sciences, for their astute observations and constructive criticism, which helped me focus on my ideas. My motivation and assistance with my dissertation have come from their never-ending passion and energy.

I appreciate the generosity of **Dr. Meghna Nigam**, **Dr. Mohammad Aamir**, **Dr. Piyush Gowrav**, **Dr. Akanksha Pandey**, **Dr. Shristi Shankar**, Senior Lecturer for their eternal and persistent advice.

I must of course extend my thanks to my seniors Dr. Rahul Anand, Dr. Snigdha Biswas, Dr. Sumati Patel, Dr. Jigme Palzor Denzongpa, Dr. Shaifali and Dr. Ankit Bhadani for their timely help and moral support during my moments of despair. A very special mention to my co-pgs. Dr. Bhibhuti, Dr. Deepika Mishra, Dr. Akriti Jha, Dr. Hiya Datta and Dr. Dikshita Das for their invaluable support and suggestions. Also, to my Juniors l, Dr. GyanPrakas Dubey Dr. Rainna Agarwal, Dr. RukminiShah, Dr. Shweta Raju Ghanvant, Dr. Alankrita, Dr. Surbhi Singh.

I am grateful to god for giving me such a wonderful family. Words cannot sufficient to express my gratitude to my parents, Mr. Premchand Jaiswal & Mrs, Gayatri Devi my sister Menika Jaiswal, Madhu Jaiswal and my brother Dr.Rajeev Jaiswal who have been my best friends, and has always stood by me in difficult time, & for making me what I am today, for their perseverance, constant struggle and for being inspiration of my life since my childhood.

I would also like to thank all the non-teaching staff for their round the clock services and help whenever required. Thank you all for being there and giving efforts.

Dr. Km. Arati

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# **LIST OF ABBREVIATIONS**

AM –	Amnion membrane
ACM	Amnion chorion membrane
AMSC	Amniotic mesenchymal stem cell
bFGF	Basic fibroblast growth factors
CM	Chorion membrane
CAF	Coronally advanced flap
CEJ	Cementoenamel junction
CM	Collagen membrane CPD Clinical probing depth
DFDBA	Demineralized freeze dried bone allograft
DMSO	Dimethyl sulphoxide
EDGF	Epidermal derived growth factor
GR	Gingival recession
GBR	Guided bone regeneration
GTR	Guided tissue regeneration
HAE	Human amniotic epithelial cells
HAM	Human amniotic mesenchymal cells
HLA	Human leukocyte antigen
HNF3β	Hepatocytes nuclear factor3β
IGF	Insulin derived growth factor
r ILT	Immunoglobulinlike transcript
IFN –	Interferon
KGF	Keratinocyte growth factor
MGJ	Mucogingival junction

Matrix metalloproteinases
Mesenchymal stem cell
Nidogen growth factor
Octamerbinding transcription factor
Percentage of root coverage
Platelet rich fibrin
Periodontal ligament
Periodontal ligament stem cell
Recession height
Recession width
Root coverage
Subepithelial connective tissue graft
Secretary leukocyte proteinase inhibitor
Tumor Necrosis Factor alpha
Transforming growth factorbeta
Vascular endothelial growth factor
Width of keratinized tissue.

# COMPARATIVE EVALUATION OF CORONALLY ADVANCED FLAP WITH AND WITHOUT CHORION MEMBRANE IN THE TREATMENT OF GINGIVAL TISSUE RECESSION-A CLINICAL STUDY.

## **ABSTRACT**

#### **BACKGROUND:**

By clinical definition, gingival recession is exposure of root surface by an apical shift in the position of the gingiva. It may result in sensitivity, unaesthetic appearance and root caries. Root coverage procedures aim to restore the gingival margin coronal to the CEJ along with periodontal regeneration. Various procedures such as free gingival graft, lateral pedicle flap, connective tissue graft, coronally displaced flap and double papilla have produced predictable root coverage; however healing almost always occurs by formation of long junctional epithelium. GTR is one of the techniques used for recession coverage. The membranes used for root coverage have evolved. Recently Chorion membrane is being used as an adjunct for treating recession defects. Chorion tissue contains growth factors and fetal mesenchymal stem cells which may aid in periodontal regeneration.

#### AIM:

The aim of the study is to compare the clinical outcome of root coverage done using coronally advanced flap with Chorion membrane in treating Miller's class I and II gingival recession.

#### **MATERIALS AND METHODS:**

20 recession sites with Miller's Class I and II gingival recessions in the maxillary or mandibular anteriors were included in this study. Recessions were randomly treated by coronally advanced flap withou without Chorion membrane

#### **RESULTS:**

In this study, the treatment of Miller's class I and II gingival recessions indicated that CAF surgery alone or in combination with Chorion are effective procedures to cover denuded root surfaces. The data obtained from a combination of CAF with Chorion membrane after a period of 3 months showed additional benefits of root coverage the treatment of Miller's class I and II gingival recessions when compared with the CAF technique alone

#### **CONCLUSION:**

This study suggests that Chorion membrane can be used as an alternative to in treating Miller's class I and II gingival recessions using coronally advanced flap.

Gingival recession is the exposure of root surface due to apical shift in the marginal gingiva. It occurs due to inflammatory factors(plaque and calculus), faulty and aggressive tooth brushing ,high frenum attachment, smoking , tooth malposition, and iatrogenic factors associated with various periodontal and restrorative procedures. Other risk factors include aging and dehiscence of alveolar bone <sup>2</sup>. Thereby leading to tooth hypersensitivity, pain carious lesions. And cervical abrasions is perceived by the patients as increase in the length of teeth giving it an unaesthetic appearance.

In order to overcome aesthetic and functional demands of these defects periodontal plastic surgery procedures are done. Coronally Advanced Flap, double papilla rotating flap, lateral pedicle flaps, free gingival grafts have a part of periodontal interventions for last many years. These techniques in their original form or variations and sometimes along with allografts and/ or PRF have also been done. Every technique has its own indications and advantages. CAF has been the gold standard for multiple gingival recession defects.

The term "coronally advanced flap" was coined by Pini-Prato et al. in 1999. Coronally Advanced Flap (CAF) technique have shown more predictable recession coverage with apparently satisfactory esthetic results.<sup>7,8</sup> However, CAF when used alone is unstable on long-term, in spite of having the advantage of low morbidity.<sup>24</sup> Furthermore, It does not always results in the regeneration of attachment apparatus such as cementum, periodontal ligament (PDL), and alveolar bone, which is a major risk factor in recurrence of gingival recessions. Therefore, CAF have been frequently combined with various regenerative materials aiming at attaining both regeneration of functional attachment apparatus and root coverage.<sup>25</sup>

Several regenerative materials such as guided tissue regeneration membranes,<sup>10,26</sup> enamel matrix proteins derivatives,<sup>27</sup> alloderm<sup>28</sup> and of the dermal derived surface<sup>29</sup> have been combined with CAF in the treatment of gingival recession and have reported good clinical outcomes. Although these regenerative materials are still used today the introduction of autologous biomimetic agents like platelet concentrates has given new promises for the better clinical outcomes in periodontal therapy.<sup>30,31</sup>

Recently, use of Placental membranes, such as Chorion membrane has also been documented. The Chorion membrane, which is made up of a thick basement membrane and an avascular stromal matrix, is the placenta's innermost layer. The Chorion forms the outer end of the sac, which encloses the foetus and is made up of several types of collagen and cell adhesion bioactive components. Over the years, Human amniotic membrane and Chorion membrane have been employed in a variety of surgical operations. Due to its ability to accelerate epithelialization, reduce pain when applied to burnt or ulcerated areas lowers scarring and inflammation, improved wound healing and antibacterial characteristics help it act as a scaffold for proliferation and differentiation of cells in the membrane. Due to these properties Chorion membrane has been used in medical fields for decades and making their way in dental practice also.

Placental allografts are now emerging as a novel and versatile material in periodontal plastic surgery. These distinctive properties that can be harnessed to promote periodontal reconstruction. Both Chorion and amnion membranes are now being used as cost effective, allogenic substitute for the connective tissue autograft for achieving predictable root coverage [6-12].

This study aims to evaluate and compare patients releted outcomes of CAF with and without the use of Chorion membrane.

## AIM & OBJECTIVES OF THE STUDY

#### AIM:

To assess the role of chorion membrane along with Coronally Advanced Flap in the treatment of Miller's class I and II recession defects,.

#### **OBJECTIVES**

- I. To assess the role of Coronally Advanced Flap along with Chorion membrane in root coverage procedure.
- II. To assess the role of Coronally Advanced Flap alone in root coverage procedure.
- III. To assess and compare Coronally Advanced Flap with and without Chorion membrane.

#### **REVIEW OF LITERATURE:**

One of the most common esthetic concerns associated with the periodontal tissue is gingival recession. It is the displacement of the gingival margin apical to cement-enamel junction (CEJ), resulting in higher incidence of attachment loss, root caries, and root hypersensitivity. Its development has been frequently associated with periodontal disease. 1,19,20,21

The Clinical evaluation of Coronally Advanced Flap (CAF) with or without a Chorion membrane for the Root Coverage have been reviewed with help of following literature:-

Lee et al. (2002). They conducted a study to clinically and histologically evaluate the efficacy of GTR-based root coverage using collagen membrane (GTRC) and to compare the healing response to that of Coronally Advanced Flaps (CAF). Clinically, both treatments (CAF and GTRC) achieved statistically significant (P <0.05) root coverage compared to baseline. Keratinized gingiva was significantly increased in CAF-treated sites at 16 weeks, while no significant differences were found for other clinical parameters between treatments. Histometrically, GTRC showed a statistically significant increase of new attachment and newly formed connective tissue when compared to CAF at 16 weeks. They concluded within the limits of this study, both GTRC and CAF can be successfully used for the treatment of gingival recession defects.

Cairo F, Pagliaro U, Nieri M.et al.(2008) <sup>7</sup>MThey conducted a study toi The aim of this manuscript was to systematically review the literature on coronally advanced flap (CAF) alone or in combination with tissue grafts, barrier membranes (BM), enamel matrix derivative (EMD) or other material for treating gingival recession. A total of 794 Miller Class I and II gingival recessions in 530 patients from 25 RCTs were evaluated in this systematic review. CAF was associated with mean recession reduction and CRC. The addition of connective tissue graft (CTG) or EMD enhanced the clinical outcomes of CAF in terms of CRC, while BM did not. The results with respect to the adjunctive use of acellular dermal matrix were controversial. CTG or EMD in conjunction with CAF enhances the probability of obtaining CRC in Miller Class I and II single gingival recessions.

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Tsai CH et al (2009)<sup>9</sup> reviewed the biologic effects of PRF on human gingival fibroblasts (GFs), periodontal ligament (PDL) cells, oral epithelial cells, and osteoblasts. Results showed that PRF did not interfere with cell viability of periodontally related cells (P>0.05). PRF stimulated cell proliferation of osteoblasts (135% of the control), PDL cells (130% of the control), and GFs (120% of the control) during a 3-day culture period (all P < 0.05) but suppressed oral epithelial cell growth to as low as 80% of the control (P<0.05). Hence it was concluded that PRF modulates cell proliferation in a cell type specific manner and these cell type-specific actions may be beneficial for periodontal regeneration.

Ehrenfest et al (2009)<sup>10</sup> analyzed the effects of Choukroun's PRF, on human primary cultures of gingival fibroblasts, dermal prekeratinocytes, preadipocytes, and maxillofacial osteoblasts. Results showed that PRF induced a significant and continuous stimulation of proliferation in all cell types. Moreover, PRF induced a strong differentiation in the osteoblasts. Also the PRF leucocytes seemed to proliferate and interact with osteoblasts. It was concluded that cultures with PRF are co-cultures with leucocytes and explained the double contradictory effect proliferation\ differentiation observed on osteoblasts.

**Aroca S et al.** (2009)<sup>11</sup> conducted a study to determine whether the addition of an autologous platelet-rich fibrin clot (PRF) to a modified Coronally Advanced Flap (MCAF) (test group) would improve the clinical outcome compared to an MCAF alone (control group) for the treatment of multiple gingival recessions. It was concluded that the addition of a PRF membrane positioned under the MCAF provided inferior root coverage but an additional gain in gingival tissue thickness (GTH) at 6 months compared to conventional therapy.

Anilkumar K,Geetha A et al (2009)<sup>12</sup>. conducted a study to determine whether the addition of an autologous Platelet-rich fibrin (PRF) membrane to a laterally displaced flap technique. The PRF membrane was used for root coverage on labial surfaces of the mandibular anterior teeth. Using laterally displaced flap technique with PRF membrane at the recipient site. Root coverage procedure was done and postoperative follow up was done for a period of 1 month. There was no postoperative complication and the healing was satisfactory.

**Jankovic Set al.**(2010)<sup>13</sup> conducted a comparative study to evaluate the clinical effectiveness of PRF membrane used in combination with a Coronally Advanced Flap and to compare it with the use of an enamel matrix derivative in combination with a Coronally Advanced Flap in gingival recession treatment and conclude that the PRF group showed 65% of the root coverage, compared to the enamel matrix derivative group which showed only 60% of the root coverage. The difference observed between the two groups at 12 months was statistically significant with average root coverage of 70.5% in enamel matrix derivative group and 72.1% in the PRF group.

Aleksic Z et al. (2010)<sup>14</sup>conducted a comparative study of 19 miller class I or II gingival recessions were treated with a coronally advanced flap and the PRF membrane (PRF group). Clinical evaluation of healing events was estimated with recordings of the healing index (HI). Recordings of HI were performed in the 1st, 2nd and 3rd week post-surgically. He concluded that keratinized tissue width showed significant increase after the surgery in both, the PRF and CTG groups and both procedures as effective with equivalence of clinical results in solving gingival recession problems. The utilization of the PRF resulted in a decreased postoperative discomfort and advanced tissue healing.

**Kumar AP et al (2011)**<sup>15</sup>stated that PRF is a novel treatment option available for various mucogingival defects such as gingival recession with varied outcome. The best part of PRF is acquirement of optimal esthetic results with excellent soft tissue contour and texture. This illustrates that the use of platelet concentrate may be an effective and less invasive way of treating gingival recession compared to the traditional autogenous graft.

Zhao JH et al (2011)<sup>16</sup>reported the clinical and histologic characteristics of a 47 years old male patient who underwent a tooth extraction of right mandibular second molar, and the socket was filled with PRF as the sole grafting material in preparation for placing an implant after wound healing. For histological evaluation, a cylindrical sample core of the newly formed tissue was collected from the socket. During clinical healing, neither infectious episodes nor untoward clinical symptoms were seen. At the time of implant insertion, the socket was completely filled by a hard material, which on probing exhibited the consistency of bone, revealed new bone formation and no evidence of inflammatory infiltrates. Thus, it was suggested that filling a fresh

extraction socket with PRF provides a viable therapeutic alternative for implant site preparation.

**Singh R et al** (2012)<sup>17</sup> reported a 35-year-old female was referred to Periodontics specialist complaining of the unaesthetic appearance and tooth sensitivity of her maxillary front teeth. During the clinical examination, it was noted that there were multiple Miller's class gingival recessions in teeth numbers 11 and 21. Gingival recessions were associated with cervical abrasions and root caries. It would therefore be desirable to use a Coronally Advanced Flap approach when indicated. She was called for follow up weekly for four weeks, once a month for 3 months and once every 3 months up to 12 months. Complete root coverage was obtained and the results were maintained.

Gulnihal Eren et al (2012)<sup>18</sup> reported a 23-year-old female patient with bilateral gingival recessions in maxillary cuspids. Sites were randomly assigned to Coronally advanced flap with platelet rich fibrin (test) or CAF with subepithelium connective tissue graft (control) sites. Clinical periodontal parameters were recorded and clinical photographs were taken at baseline; 1, 3, and 6 months; and 1 year. The recession area was analyzed with a digital image analysis program. In addition, gingival thickness was evaluated at baseline and at 1 year. Root coverage amount, gingival thickness, and keratinized tissue width were improved in both sites. The outcomes remained stable for 1 year. CAF with PRF presents an alternative to CAF with SCTG in the treatment of gingival recessions.

C-L Wu et al. (2012)<sup>19</sup>conducted the Study to determine whether PRF could influence the functions of osteoblasts. He concluded that PRF is capable of increasing osteoblast attachment, proliferation and simultaneously upregulating collagen-related protein production. These actions in combination would effectively promote bone regeneration.

**Jankovic S et al.** (2012)<sup>20</sup> conducted a 6-month randomized controlled clinical study primarily aimed to compare the results achieved by the use of a platelet-rich fibrin (PRF) membrane or connective tissue graft (CTG) in the treatment of gingival recession and to evaluate the clinical impact of PRF on early wound healing and subjective patient discomfort. He concluded that use of a PRF membrane in gingival

recession treatment provided acceptable clinical results, followed by enhanced wound healing and decreased subjective patient discomfort compared to CTG-treated gingival recessions.

**Holtzclow DJ, Toscano NJ.** (2013).<sup>21</sup> They conducted a retrospective observational study documented use of amnion chorion membrane for combination GTR treatment of periodontal intrabony defects with a minimum of 12-month post-surgical observation. It revealed that 114 patients were treated with GTR therapy from March 2010 to October 2011. Of these patients, 64 were treated with ACM combination GTR therapy and had  $\geq$ 12 months of follow-up. All patients were diagnosed with localized moderate-to-severe chronic periodontitis and exhibited radiographic evidence of  $\geq$ 1 vertical osseous defect. All patients were treated by thorough degranulation of intrabony periodontal defects and placement of bone allograft covered by ACM. Clinical measurements 12 months after surgery revealed an average probing depth reduction of  $5.06 \pm 1.37$  mm and clinical attachment level improvement of  $4.61 \pm 1.29$  mm. The results of this retrospective observational report are promising and warrant additional controlled, long-term studies to further evaluate the effectiveness of ACM for combination GTR treatment of periodontal intrabony defects.

Naik Balaram et al. (20013)<sup>22</sup> conducted a Study to review and discuss the strategies available for use of platelet rich fibrin as healing aid in dentistry. He concluded that PRF belongs to a new generation of platelet concentrates, the biologic activity of fibrin molecule is enough in itself to account for significant cicatricial capacity of the PRF. The slow polymerization mode confers to PRF membrane as a particularly favorable physiologic architecture to support the healing process.

Padma R et al. (2013)<sup>23</sup>conducted a study with total of 15-systemically healthy subjects presenting bilateral isolated Miller's class I and II recession. Each patient was randomly treated with a combination of CAF along with a Platelet-rich fibrin (PRF) membrane on the test site and CAF alone on the control site. Recession depth, clinical attachment level (CAL), and width of keratinized gingiva (WKG) were compared with baseline at 1, 3, and 6 months between test and control sites. He concluded that PRF membrane with CAF provides superior root coverage with additional benefits of gain in CAL and WKG at 6 months postoperatively.

**J. Kavitha1, , M. Navarasu1 , Venkata Srikant et al(2013)**<sup>24</sup>. conducted a study using Coronally Advanced Flap in the treatment of gingival recession and observed reduction in the recession width, and recession depth at first month, third month and sixth month from baseline, and there was gain in Relative Clinical Attachment Level at first month, third month and sixth month, there was increase in Width of Keratinized Tissue at first month, third month and sixth month from baseline.

Ramaprabha G et al(2014)<sup>48</sup> analyzed the effects of Choukroun's PRF The first generation platelet concentrate is platelet rich plasma (PRP), To avoid platelet activation and degranulation, production protocol requires blood collection with anticoagulant, whereas Platelet-rich fibrin (PRF) is a second generation platelet concentrate and is made without the addition of anticoagulant. Thus, PRF (platelet-rich fibrin) can be considered as a natural fibrin-based biomaterial favorable to the development of a microvascularization and able to guide cell migration into wound area concentrated suspension of growth factors found.

**J. Kavitha et al** (2014)<sup>25</sup> conducted a comparative study to treating Millers Class I recessions, with a mean initial recession height of 3-4 mm. This type of defect could be treated with many variations of three basic approaches pedicle soft tissue grafts, free soft tissue grafts or combinations of the two. Among the pedicle grafts, the Coronally positioned flap is one of the valid surgical options to cover exposed root surfaces. The present study indicated that acceptable root coverage can be achieved in class I gingival recessions when treated with Coronally positioned flap.

**Shetty S. et al.** (2014)<sup>26</sup>conducted six-month study to evaluate the use of PRF in the treatment of multiple gingival recessions with coronally advanced flap procedure and he found significant improvement during the early periodontal healing phase, with a thick and stable final remodeled gingival.

Esteves et al. (2015).<sup>27</sup> They evaluated the membranes of human placentas that have been used in the field of medicine for skin grafts treatment of burns, and ulcerated skin conditions with great success. The use of placenta allografts in dentistry is a more recent development, with the first commercial product being made available in 2008. The unique inherent biologic properties in placenta allografts enhance wound

healing and may propagate regeneration. Fetal membranes possess distinctive properties that can be harnessed to promote periodontal healing.

**Kavitha et al** (2014)<sup>28</sup> conducted a comparative study to treating Millers Class I recessions, with a mean initial recession height of 3-4 mm. This type of defect could be treated with many variations of three basic approaches pedicle soft tissue grafts, free soft tissue grafts or combinations of the two. Among the pedicle grafts, the Coronally positioned flap is one of the valid surgical options to cover exposed root surfaces. The present study indicated that acceptable root coverage can be achieved in class I gingival recessions when treated with Coronally positioned flap root coverage, increased width of keratinized tissue, and thickness of the gingival biotype.

**Pundir et.al.** (2015).<sup>29</sup> conducted a study in which an Amnion-chorion membrane was used as a guided tissue regeneration membrane. Numerous growth factors, proteins, and stem cell reserves in amnion could help in accelerated wound healing and regeneration, whereas chorion is a rich source of various collagen and noncollagen proteins. The present six-patient observational case series compares amnion and chorion allografts for recession coverage. Both amnion and chorion membranes provided promising results in terms of root coverage, increased width of keratinized gingiva, clinical attachment level, and thickness of the gingival biotype and can be used for periodontal plastic surgeries.

Cheng GL, Fu, E, Tu,Yk, et al(2015)<sup>30</sup>.conducted a study the use of a Coronally Advanced Flap (CAF) combined with a connective tissue graft (CTG) or enamel matrix derivative (EMD) is more likely to achieve complete root coverage (CRC) than other modalities. However, the details of periodontal parameters and comparisons among a variety of combinations of CAF with CTG and/or EMD are left to be investigated. This study aimed to analyze the differences in periodontal parameters between these treatment modalities. Thirteen randomized controlled clinical trials, including 529 Miller Class I-III defects from 321 patients were included. For an increase in KTW, CAF + CTG significantly improved more than CAF alone. CAF + EMD also gained more KTW than CAF alone. EMD reduced PPD, however, a significant difference was not found. Furthermore, the effects on changes of RED and clinical attachment level were not identified in the study. When combined with CAF, CTG contributed more in the increase of KTW, while EMD seemed helpful for wound

healing by its potential in PPD reduction. However, further research is needed to clarify the effects on changes in RED and clinical attachment level.

Chakraborthy S, Sambashivaiah S, Kulal R, et al(2015)<sup>31</sup>. Conducted a study Amnion and chorion allograft membranes of alternative origin derived from human placental tissue has been advocated in the treatment of gingival recession. However, chorion membrane has been used in combination with amnion membrane no study has compared these allograft membranes in the treatment of gingival recession. Therefore, the purpose of this study was to clinically evaluate and compare the efficacy of amnion membrane and chorion membrane in combination with coronally advanced flap in the treatment of gingival recessions. The mean decrease in length of recession (LR) for Chorion site was 2.00±1.54mm and amnion site was 1.58±1.14mm. The gain in attachment level for amnion site was 2.17±1.53mm and for chorion site was 1.58±1.22mm. The total mean percentage of root coverage was 34% for chorion site and 22% for amnion site. Both amnion membrane and chorion membrane has shown to be versatile allograft material to be used in the treatment of root coverage.

Santosh Gupta et al (2015)<sup>32</sup> conducted a study the clinical efficacy of coronally advanced flap (CAF) alone and in combination with autologous platelet rich fibrin membrane (PRF) in Miller's class I and II gingival recessions. Difference between the groups in all parameters at baseline, 3 months and 6 months was non-significant. Complete root coverage was obtained in 12(80%) and 11(73.3%) subjects in test and control group respectively. The difference was found to be non-significant. Both groups showed significant differences in all parameters at 3 and 6 months respectively except difference in gingival tissue thickness which was non-significant in control group at 3 months. Combination of PRF to CAF procedure did not provide any added advantage in term of recession coverage in Miller class I and II recessions.

**Thamaraiselvan M et al (2015)** <sup>33</sup>Conducted the study was to determine whether the addition of an autologous platelet rich fibrin (PRF) membrane to a Coronally Advanced Flap (CAF) would improve the clinical outcome in terms of root coverage, in the treatment of isolated gingival recession. Systemically healthy 20 subjects each with single Miller's class I or II buccal recession defect were randomly assigned to control (CAF) or test (CAF + PRF) group. Clinical outcome was determined by measuring the following clinical parameters such as recession depth (RD), recession width (RW), probing depth (PD), clinical attachment level (CAL), width of

keratinized tissue (WKT), gingival thickness (GTH), plaque index (PI), and gingival index (GI) at baseline, 3rd, and 6th month postsurgery.

Chenchev IV et al (2016)<sup>34</sup>conducted the comparative study treated with Coronally Advanced Flap (CAF) in combination with connective tissue graft and platelet rich fibrin membrane (PRF m). For the evaluation of the studied subjective parameters we used the standard visual analog scale. The control group showed better results with a statistically significant difference in comparison to the ones for the test group for the aesthetic results and the decrease in the teeth's sensitivity. The results for the values of the pain after the surgery were lower with a statistically significant difference for the test group compared to the control group.

Mhaske, et al. (2016)<sup>35</sup> a case report of 29 years female reported to our department with complain of gingival recession. CAF surgery along with the incorporation of PRF was carried out to treat the gingival re-cession. The addition of PRF to CAF procedure provided complete root coverage. This case report helped to focus treatment outcomes and predictability of autologous PRF when used along with CAF for the treatment of recession defects on multiple adjacent teeth.

AK, Dalvi YB, Balram B, et al(2018)<sup>36</sup>conducted a study Chorion and amnion membranes are used as cost effective, allogenic substitute for the connective tissue autograft for achieving predictable root coverage. The objective of the study was to investigate the potential of amnion and chorion membranes as a substitute for the free connective tissue autograft in the bilaminar technique of root coverage. Average thickness of amnion membrane was  $0.43 \pm 0.07$  mm surface density was  $0.093 \pm$ 0.006 gm/cm<sup>3</sup>. Average thickness of chorion membrane was  $1.66 \pm 0.644$  mm and density were  $0.201 \pm 0.17$  gm/cm<sup>3</sup>. Tensile strength of amnion was  $155 \pm 65$  kPa, Young's modulus was  $645 \pm 211$  kPa and elongation at break was  $17.3 \pm 2.03$  mm. Tensile strength of chorion was  $95 \pm 14.7$  kPa, Young's modulus was  $335 \pm 53$  kPa and elongation at break was  $13.5 \pm 1.63$  mm. Maximum load which can be applied during suturing for amnion is  $0.123 \pm 0.037$  Newtons and for chorion is  $0.052 \pm 0.005$ N. Amnion membranes degraded 21% of its initial weight at the end of the first week, 24.1% at the end of second week, 31.35% at the end of the third week and 70% at the end of four weeks. Chorion membranes degraded 29% of its initial weight at the end of the first week, 35% at the end of the second week, 42% at the end of the third week and 84% at the end of the fourth week.

**Shivani et al.** (2019)<sup>37</sup>. conducted a study to treat Miller's class I and II recession defect. 30 sites were selected, of which in 15 coronally advanced flap along with chorion membrane was placed and in 15 coronally advanced flap along with platelet - rich fibrin was done. They concluded both materials showed good results in root coverage, but chorion membrane showed better and more stable results.

**D Sharma, PK Jhingta, VK Bhardwaj.** (2020)<sup>38.</sup>The conducted a study. Different surgical techniques have been proposed for the treatment of multiple adjacent recessions, mainly derived from the Coronally Advanced Flap with or without connective tissue graft or from tunnel approaches. Harvesting of connective tissue graft is time consuming, it is limited in quantity and exposes patient to another surgical wound. The overall objective of this study is to evaluate the effectiveness of Coronally advanced flap with Chorion membrane for the treatment of multiple adjacent gingival recession defects. The thickness of the keratinized gingiva was significantly increased at 6 months of follow-up, however, nonsignificantly increased at 12 and 36 months as compared to the baseline. Clinical parameter of the probing depth (PD) was significantly decreased at 12-month and 36-month follow-up. Although the decrease in PD was seen at 6-month follow-up, it was not significant. Statistically significant reduction in recession height (RH), RW, and CAL was observed at 6, 12, and 36 months postoperatively. The mean recession (RH) coverage was  $2.94 \pm 0.32$  at 6 months,  $3.24 \pm 0.37$  at 12 months, and  $3.44 \pm 0.53$  at 36 months. Complete recession coverage was observed in 71% (15/21) of the treated sites. Four patients showed thick tissue biotype posttreatment with chorion membrane as compared to 1 at the baseline as measured with the transparency of the periodontal probe. The results of this case series indicate a significant improvement in RH, RW, and CAL along with a gain in CAL, which could be attributed to the regenerative potential of the membrane at 6, 12, and 36 months after treatment with CAF and chorion membrane. Increase in WKG was also noted as early as 6 months, along with a resultant thicker gingival biotype. The significant gain in WKG and the improvement in the biotype may also be attributed to the presence of mitogenic factors and anti-inflammatory protein of the membrane. No donor site means less pain and discomfort, morbidity, and surgical chair-time with the chorion membrane.

Natural texture and color match to the surrounding native tissue are improved patient-reported outcomes. However, further studies with more statistical power and splitmouth design are necessary to measure clinical parameters to facilitate a more accurate long-term evaluation of gingival changes...

Pradhan, S., Shetty, N., & Kamath, D. (2022)<sup>39</sup>. conducted a study that compared the clinical and patient related outcome measures of coronally advanced flap with chorion membrane and connective tissue graft in the management of multiple adjacent gingival recessions. The study was a prospective randomized controlled trial which included eight systemically healthy patients with an age range of 30-44 years with 36 labial/buccal, multiple adjacent, Cairo's RT1 gingival recession defects, bilaterally. CAF+CM was performed on one side whereas CAF+CTG was performed on the other side. The two groups were compared clinically at three and six months postoperatively. They concluded that the use of chorion membrane resulted in considerable root coverage and increased gingival thickness. Periodontal regeneration can be facilitated by the distinctive features of the chorion membrane. Coronally advanced flap plus chorion membrane is a novel approach for root coverage procedures.

#### MATERIAL AND METHODOLOGY

The Clinical study was carried out in the Department of Periodontology, Babu Banarasi Das Collage of Dental Sciences (BBDCODS), Lucknow India. Ethical clearance was obtained from the Ethical Committee of BBDCODS (IEC 10); Patients fulfilling the following inclusion and exclusion criteria were selected from the OPD of the Periodontology Department of BBDCODS. A total of 20 patients were selected for the study.

#### **Inclusion criteria:**

- Millers class I and/ or class II gingival tissue recession in maxillary or mandibular anteriors.
- Age 18 to 40 years.
- Patients willing to co operate with the study related procedures.
- Systemically healthy patients

#### **Exclusion criteria:**

- Mal aligned teeth.
- Mucogingival aberrations like high frenum attechment, shallow vestibule etc.
- Patients who are unable to perform routine oral hygiene procedures or un cooperative.
- Previous surgical attempts to correct the gingival recession.
- Smokers or patients with tobacoo chewing habits.
- Medically compromised patients.
- Pregnant or lactating women.

#### Armamentarium

- Mouth mirror
- UNC Periodontal probe
- Tweezers
- Explorer
- B.P Handle NO.3
- Blade NO .15
- Periosteal Elvevator
- Cotton
- Sterile Gauze
- Injecton Syringe
- Local Anaesthesia
- Gracey currettes
- Root conditioning Agent
- Tissue holding forceps
- Castroviejo scissor
- Piezoelectronic Ultrasonic scaler
- High vacuum suction
- Betadine
- Periodontal pack (Coe-Pack)
- Chorion membrane- TATA MEMORIAL HOSPITAL, TISSUE BANK

#### Methodology:

Patients fulfilling the above mentioned criteria underwent Scaling and root planing and were given oral hygiene instructions. After 5 to 6 weeks following phase I therapy periodontal reevaluation was performed and Patients satisfying the criteria for surgical intervention were chosen and randomly divided into Two groups. The baseline clinical parameters were noted. These were:-

Group I- coronally advanced flap in gingival recession defects with human chorion membrane.

Group II- coronally advanced flap in gingival recession defects without human chorion membrane.

At this time baseline clinical parameters were recorded.

- Plaque index (PI) (Silness and Loe, 1964)
- Gingival Index (GI) (Loe and Silness, 1963)
- Recession depth (RD)
- Recession width(RW)
- Clinical attachment level (CAL):-calculated as Relative Recession+ Probing depth
- Gingival thickness

#### Plaque Index ((Silness and Loe, 1964))

#### **Method:**

The scoring was done on the entire dentition or on selected teeth. Plaque of the cervical third of the tooth was evaluated with no attention to plaque that has extended to the middle or incisal thirds. The surfaces examined were the four gingival areas of the tooth i.e. the disto-facial, facial, mesiofacial, and lingual surfaces. The mouth mirror, a light source, a dental explorer, and air drying of the teeth and gingival were used.

SCORE	E CRITERIA	
0	No plaque	
1	A film of plaque adhering to the free gingival margin and adjacent area of the tooth.  The plaque may be in situ only after application of disclosing solution or by using probe on the tooth surface.	
2	Moderate accumulation of soft deposit within the gingival pocket, or the tooth and the gingival margin which can be seen with naked eye.	
3	Abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin.	

Score for Person= Plaque index scores per teeth

No of teeth examined

Rating	Score
Excellent	0
Good	0.1 - 0.9
Fair	1.0
Poor	2.0 - 3

#### Gingival Index (Loe and Silness, 1963)

#### **Method:**

The severity of gingivitis was scored on the mesiofacial and distofacial papillae, facial and lingual margin of selected teeth. A blunt instrument was used to assess the bleeding potential of tissues.

SCORE	CRITERIA
0	Absence of inflammation/normal gingiva
1	Mild inflammation, slight change in color, slight edema; no bleeding on probing
2	Moderate inflammation; moderate glazing, redness, edema and hypertrophy. Bleeding on probing.
3	Severe inflammation; marked redness, hypertrophy and ulceration. Tendency to spontaneous bleeding.

Gingival Index Per Person= Total of all gingival index

No of teeth examined

Rating	Score
Mild gingivitis	01.1 - 1.0
Moderate gingivitis	1.1 - 2.0
Severe gingivitis	2.1 - 3.0

#### **Recession Width:**

Recession width was measured 1mm apical to Cemento-enamel junction in a Mesiodistal direction (mm). Using UNC15 periodontal probe calibrated in millimeters.

#### **Recession Depth-**

Distance beetween anatomical landmark, i.e, the cemento-enamel junction(CEJ), and gingival margin.

#### Relative Clinical Attachment Level:(RCAL).

Calculate as Relative Recession+Probing depth

Patients were then randomly divided into the following groups:-

Group I- Coronally Advanced Flap in gingival recession defects with human chorion membrane.

Group II- Coronally Advanced Flap in gingival recession defects without human chorion membrane-

The surgical technique adopted in this study was the envelope Coronally Advanced Flap put forward by Zucchelli and De Sanctis (2000).25

Local Anaesthesia (2% lidocaine with 1:80000 epinephrine) was administered. The exposed root surfaces were planned with curettes. This was done to eliminate any debris, calculus, soft tooth structures or undercuts. The root surfaces were irrigated with saline solution after instrumentation to remove any detached fragments from the defect site and operative field. Horizontal incisions at the level of the cementoenamel junction (CEJ) were made, followed by sulcular incisions in the buccal aspect of the affected teeth with a No 15 BP blade. The split-full-split flap technique was

performed. The papilla was deepithelialized in the interdental area. The flap was reflected in full thickness apical to the gingival margin to allow the periosteum to cover the avascular root surfaces. To assist the coronal repositioning of the flap, it was elevated partially beyond the mucogingival junction

As the procedure was done under antibiotics anergesic prophylaxis, the patients continued there till the prescribed duration. Postoperative instructions were given and patients were informed to report after 14 days for suture removal. Patients were instructed to rinse their mouth with a 0.2% chlorhexidine solution, twice a day 2 weeks. Patients were restrained from brushing till removal of pack and suture. Then after, the restitution of mechanical tooth cleaning using an ultra soft toothbrush and a charters technique was instructed for the first postoperative month. Later on patient were advised to follow modified bass technique. After 1 months the patients were recalled for clinical evalution. After 3 months the patients were again recalled for assessment of clinical parameters of Probing depth ,Clinical attachment level, Recession depth, Recession width, Gingival biotype

#### Chorion Membrane-

Fresh membrane is extracted from the placenta during delivery via vaginal or caesarean procedure. Robson and Krizekl devised a method for preparing fresh membranes, in which they cleaned the membrane in a 0.025 percent solution of sodium hypochlorite and kept it at 4°C in a sterile solution containing penicillin. Membranes remained sterile for up to 6 weeks, according to the researchers.[5]Various ways in which the amnion membrane has been used is as follows; as fresh membrane, dried membrane, frozen membrane; freeze dried irradiated membrane, stabilized amniotic membrane and cryopreserved membrane.[6]

For a long time, glycerol has been utilised as a cryoprotective agent. The amniotic membrane's interstitial water is extracted by its high osmotic pressure. The amniotic membrane is dried with 80 percent glycerol in this procedure, and it may then be stored at 4°C for a long period, however part of its biologic qualities are lost. This kind of preserved amnion is used to treat burns. [7]

Chorion has a thickness of three to four times that of amnion. The reticular layer, foundation membrane, and trophoblast layer make up the chorion. The interaction of the reticular layer with the spongy layer forms the majority of the chorion's thickness. Collagens I, III, IV, V, and VI make up the reticular network. Collagen IV, fibronectin and laminin attaches the

trophoblasts to the reticular layer in the basement membrane. The trophoblast layer is made up of two to ten layers of trophoblasts that come into touch with the decidua. [8]

A few features are required for the membrane to behave as a scaffold for progenitor cells to differentiate and proliferate following the application of a mechanical stimulus. Because it improves the stability of the scaffold and leads to uninterrupted healing, a scaffold must be sufficiently rigid throughout the place where new tissue is needed. They should also maintain their elasticity to keep the shear stresses of the surrounding tissue in check. Collagen and elastin from the extracellular matrix give stiffness and elasticity. The nature of the Amniotic membrane is viscoelastic. [7] By micronizing the dehydrated amnion/chorion membrane allograft, it can be used as an injectable solution or a topical gel. Amniotic membrane is being used to reduce scar tissue, as a barrier membrane, and as a soft tissue regeneration graft. As a culture substrate, they are extremely valuable and effective. [12]

Composition of amnion and Chorion membrane and its role -Proteins such as fibronectin, laminin, proteoglycans, glycosaminoglycans, and collagen types IV, V, and VII make up the amnion membrane. It's a matrix that helps with wound healing, cellular migration, and proliferation. Amnion creates a physiologic "seal" with the host tissue early in its development, preventing bacterial contamination. Chorion membrane works as a barrier, preventing inflammatory cells from entering the wound. Tissue inhibitors of metalloproteinases found in chorion tissue reduce matrix metalloproteinases and transforming growth factor-β. Chemokines and cytokines can modulate inflammation by directly affecting

T-cells, B-cells, and natural killer cells. As a result, these proteins in the chorion membrane inhibited inflammation and collagen degradation. By itself, IL-10 and IL-1 receptor antagonists expressed in chorion tissue reduce the inflammatory process. Histologically, the chorion membrane is made up of three layers: reticular, foundation membrane, andtrophoblasts. Collagen Types I, III, IV, V, VI, and VII, as well as proteoglycans, make up the reticular layer of the chorion membrane. The basement membrane contains collagen Type IV, fibronectin, and laminin. Laminin and laminin-5 were found in significant amounts across the barrier, which is important because of its strong affinity for binding gingival epithelial cells for better root adaptability. [13],[14]The laminin 5 protein found in amnion improves the cellular adhesion of gingival epithelial cells, type I, II, IV, V, and VI collagen, platelet derived growth factor (PGDF), fibroblast growth factor, and transforming growth factor.

#### Advantages -

Placental barrier membranes have antibacterial and antifungal characteristics, minimise wound inflammation, and offer a protein-rich matrix that allows cells to migrate more easily.[15] The capacity of processed dehydrated placental membranes to self-adhere eliminates the necessity for sutures. It does, in fact, cut surgery time and is technically less difficult. When inserted, the membrane is dry and can soon hydrate with blood, allowing it to become malleable and conform to the shape of the underlying alveolar bone. Because the membrane is resorbable, no additional surgery is required. It also has good biocompatibility and mechanical features like permeability, stability, elasticity, flexibility, plasticity, and the ability to resorb. Its ability for delivery of biomodulator agents such as growth factors and genetic materials makes it a suitable scaffolding material in tissue engineering, as well as in cell adhesion. [7],[16]

#### Clinical Uses of Amnion and Chorion membrane -

In ocular, abdominal, and plastic surgery, amniotic membranes were employed as biologic dressings. Human oral mucosa and amnion tissue have nearly comparable laminin structures. The use of amniotic membrane to reconstruct a buccal mucosal defect following speckled leukoplakia excision has been reported with encouraging results.[19]

Use of Amnion and Chorion membranes in periodontal therapy -

Amniotic membrane is a semipermeable membrane with an immunotolerant structure that can guide tissue regeneration. It satisfies the mechanical idea of guided tissue regeneration (GTR), which is updated to include the biology concept of GTR. The biomechanical GTR membrane aids recovery by reducing postoperative scarring and associated loss of function, while also providing a rich source of nutrients. Another advantage is the excellent revascularization of the amniotic membrane. It has the potential to be an excellent grafting material. It improves wound healing, postoperative function, and aesthetics without causing any problems. [7]



PHOTOGRAPH 1 BASIC ARMAMENTARIUM

TATA MEMORIAL HOSPITAL TISSUE BANK Dr. Ernest Borges Road, Parel, Mumbai-400012. Phone: 2417 7000 Extn: 4122/4112	
Graft No.: CH 1589/A340/2021	
Size : 2 × 2 59 cm	
Radiation Batch No. : 7/2021	
Expiry Date : AUG 2024	
STORAGE AT ROOM TEMPERATURE	
FREEZE-DRIED, IRRADIATED CHORION	

PHOTOGRAPH 2 FREEZE DRIED IRRADIATED CHORION
MEMBRANE FROM TATA MEMORIAL HOSPIT PLATE NO - 7
TISSUE BANK

A ) GROUP – I CORONALLY ADVANCED FLAP IN GINGIVAL RECESSION DEFECTS WITH HUMAN CHORION MEMBRANE.



PHOTOGRAPH 3 PRE-OPERATIVE CLINICAL PHOTOGRAPH SURGICAL PROCEDURE OF PALACEMENT OF MEMBRANES IN GINGIVAL RECESSION DEFECTS



PHOTOGRAPH 4 PRE- OPERATIVE RECESSION DEPTH MEASUREMENT



PHOTOGRAPH 5 PRE- OPERATIVE RECESSION WIDTH

MEASUREMENT

PLATE NO- 2



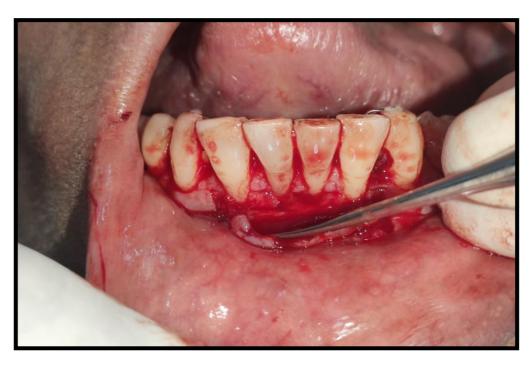
PHOTOGRAPH 6 HORIZONTAL INCISION



PHOTOGRAPH 7 SULCULAR INCISION



PHOTOGRAPH 8 VERTICAL INCISION



PHOTOGRAPH 9 REFLETION OF FLAP



PHOTOGRAPH 10 ROOT BIO MODIFICATION



PHOTOGRAPH 11 PLACEMENT OF MEMBRANE



PHOTOGRAPH 12 PLACEMENT OF SUTURES



PHOTOGRAPH 13 THREE MONTHS POST- OPRATIVE VIEW OF THE SITE TREATED BY CAF+CM

# (B) GROUP-II-CORONALLY ADVANCED FLAP IN GINGIVAL RECESSION DEFECTS WITHOUT HUMAN CHORION MEMBRANE



PHOTOGRAPH 14 PRE- OPERATIVE RECESSION DEPTH MEASUREMENT



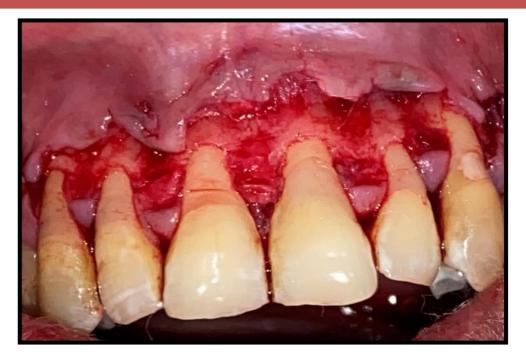
PHOTOGRAPH 15-PRE- OPERATIVE RECESSION WIDTH MEASUREASMENT



PHOTOGRAPH 16-HORIZONTAL INCISION WERE MADE AND SPLIT- FULL SPLIT THICKNESS FLAP REFLACTED



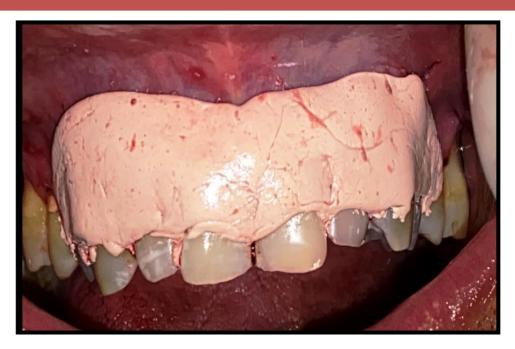
PHOTOGRAPH 17-SULCULAR INCISION



PHOTOGRAPH 18-REFLECTION OF FLAP



PHOTOGRAPH 19-PLACEMENT OF SUTURES



PHOTOGRAPH 20-PERIODONTAL PACK



PHOTOGRAPH 21- THREE MONTHS POST- OPRATIVE VIEW

## **OBSERVATION OF RESULTS**

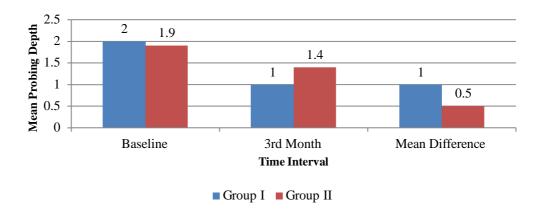
#### TABLE -1

The mean Probing Depth at the baseline was 2.00 in the Group I and 1.90 in the Group II . The mean probing depth at the  $3^{rd}$  month was 1.00 in the Group I and 0.50 in the Group II . the mean change in the probing depth from baseline to  $3^{rd}$  month was 1.00 in the Group I and 0.50 in the Group II. There was a statistically significant higher improvement in the Probing depth from baseline to  $3^{rd}$  month in the Group I as compared to Group II

	Baseline		3 Months				
	Mean	Std	Mean	Std	Mean	P value	Significance
	Mean	Deviation	viation Difference Deviation Difference	Difference	1 value	Significance	
Group I	2.000	0.010	1.000	0.471	1.00		
Group					0.50	0.001	Significant
II	1.900	0.316	1.400	0.516			

Independent t test with p value less than 0.05 is significant

<u>Table -1 depicts the intergroup comparison of Probing Depth Between Group I and</u>
<u>Group II at Baseline and 3 months</u>



<u>Graph -1 depicts the intergroup comparison of Probing Depth Between Group I and</u>
<u>Group II at Baseline and 3 months</u>

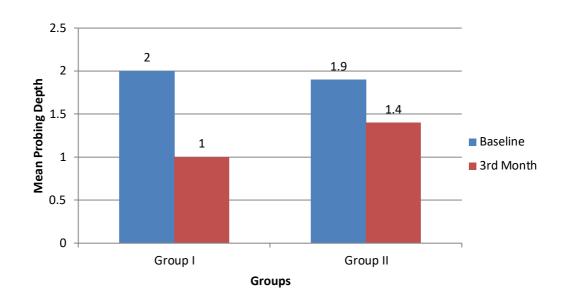
## TABLE -2

The mean Probing Depth at the baseline was 2.00 in the Group I and 1.90 in the Group II . The mean probing depth at the  $3^{\rm rd}$  month was 1.00 in the Group I and 0.50 in the Group II . The mean change in the probing depth from baseline to  $3^{\rm rd}$  month was 1.00 in the Group I and 0.50 in the Group II. The intragroup change in the probing depth from baseline to  $3^{\rm rd}$  month was statistically significant in both the groups

	Baseline		3 Moi	nths			
	Mean	Std	Mean	Std	Mean	P value	
	Mean	Deviation	Difference	Deviation	Difference	r value	
Group I	2.00	0.010	1.00	0.471	1.00	0.001 (Sig)	
Group II	1.90	0.316	1.40	0.516	0.50	0.001 (Sig)	

Paired t test with p value less than 0.05 is significant

<u>Table -2 depicts the intragroup comparison of Probing Depth Between Baseline and 3 months</u>



<u>Graph-2 depicts the intragroup comparison of Probing Depth Between Baseline and 3 months</u>

## **TABLE-3**

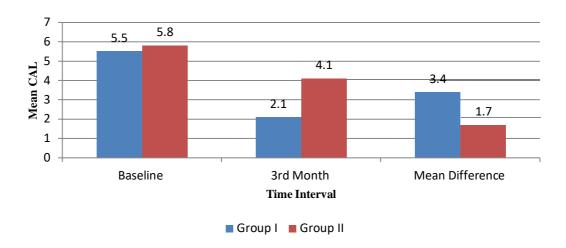
The mean CAL at the baseline was 5.50 in the Group I and 5.80 in the Group II . The mean CAL at the  $3^{rd}$  month was 2.10 in the Group I and 4.10 in the Group II . The mean change in the CAL from baseline to  $3^{rd}$  month was 3.40 in the Group I and 1.70 in the Group II. There was a statistically significant higher improvement in the CAL from baseline to  $3^{rd}$  month in the Group I as compared to Group II

	Baseline		3 Months				
	Mean	Std Deviation	Mean	Std Deviation	Mean Difference	P value	Significance
Group I	5.500	0.849	2.100	0.567	3.40	0.001	Significant
Group II	5.800	0.788	4.100	0.875	1.70		

Independent t test with p value less than 0.05 is significant

<u>Table -3 depicts the intergroup comparison of CAL Between Group I and Group II at</u>

Baseline and 3 month



<u>Graph -3 depicts the intergroup comparison of CAL Between Group I and Group II at Baseline and 3 months</u>

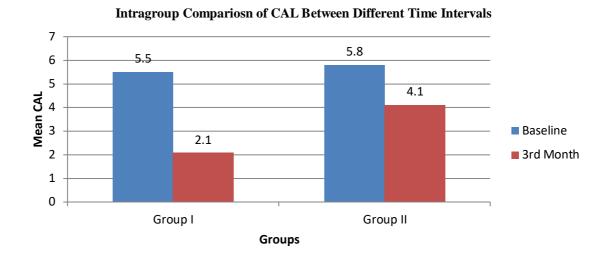
## **TABLE-4**

The mean CAL at the baseline was 5.50 in the Group I and 5.80 in the Group II . The mean CAL at the  $3^{rd}$  month was 2.10 in the Group I and 4.10 in the Group II . The mean change in the CAL from baseline to  $3^{rd}$  month was 3.40 in the Group I and 1.70 in the Group II.. The intragroup change in the CAL from baseline to  $3^{rd}$  month was statistically significant in both the groups

	Baseline		3 Mo	nths		
	Mean	Std Deviation	Mean	Std Deviation	Mean Difference	P value
Group I	5.500	0.849	2.100	0.567	3.40	0.001 (Sig)
Group II	5.800	0.788	4.100	0.875	1.70	0.023 (Sig)

Paired t test with p value less than 0.05 is significant

Table -4 depicts the intragroup comparison of CAL Between Baseline and 3 months



**Graph -4 depicts the Intragroup comparison of CAL Between Baseline and 3 months** 

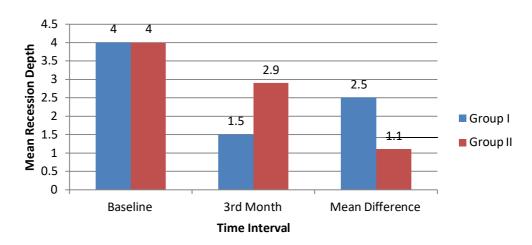
## **TABLE-5**

The mean Initial Recession Depth at the baseline was 4.00 in the Group I and 1.50 in the Group II . The mean Initial Recession Depth at the  $3^{rd}$  month was 4.00 in the Group I and 2.90 in the Group II . The mean change in the Initial Recession Depth from baseline to  $3^{rd}$  month was 3.40 in the Group I and 1.70 in the Group II. There was a statistically significant higher improvement in the Initial Recession Depth from baseline to  $3^{rd}$  month in the Group I as compared to Group II

	Baseline		3 <sup>rd</sup> Month		Mean Difference		
	Mean	Std	Mean	Std	Mean	P value	Significance
	Mean	Deviation	Mean	Deviation	Difference	r value	Significance
Group							
I	4.00	0.471	1.50	0.527	2.50	0.001	Significant
Group							
II	4.00	0.816	2.90	0.567	1.10		

Independent t test with p value less than 0.05 is significant

<u>Table -5 depicts the intergroup comparison of Recession Depth Between Group I and Group II at Baseline and 3 month</u>



<u>Graph -5 depicts the intergroup comparison of Recession Depth Between Group I and Group II at Baseline and 3 month</u>

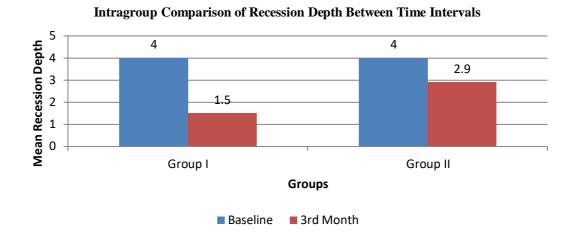
#### **TABLE -6**

The mean Initial Recession Depth at the baseline was 4.00 in the Group I and 1.50 in the Group II . The mean Initial Recession Depth at the  $3^{rd}$  month was 4.00 in the Group I and 2.90 in the Group II . The mean change in the Initial Recession Depth from baseline to  $3^{rd}$  month was 3.40 in the Group I and 1.70 in the Group II. The intragroup change in the Initial Recession Depth from baseline to  $3^{rd}$  month was statistically significant in both the groups

	Baseline		3 <sup>rd</sup> M	onth	Mean Difference	P value
	Mean	Std	Mean	Std	Mean	P value
	Mean	Deviation	Mean	Deviation	Difference	r value
G T						0.001
Group I	4.00	0.471	1.50	0.527	2.50	(Sig)
С И						0.001
Group II	4.00	0.816	2.90	0.567	1.10	(Sig)

Paired t test with p value less than 0.05 is significant

<u>Table -6 depicts the intragroup comparison of Recession Depth Between Baseline and 3 months</u>



<u>Graph -6 depicts the intragroup comparison of Recession Depth Between Baseline and 3 months</u>

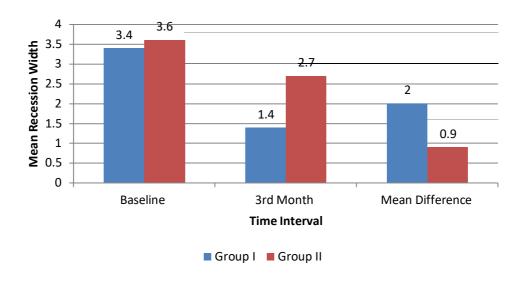
# $\underline{TABLE} - \underline{7}$

The mean Initial Recession Width at the baseline was 3.40 in the Group I and 1.40 in the Group II . The mean Initial Recession Width at the  $3^{rd}$  month was 3.60 in the Group I and 2.70 in the Group II . The mean change in the Initial Recession Width from baseline to  $3^{rd}$  month was 2.00 in the Group I and 0.90 in the Group II. There was a statistically significant higher improvement in the Initial Recession Width from baseline to  $3^{rd}$  month in the Group I as compared to Group II

	Baseline		3 <sup>rd</sup> Month		Mean Difference		
	Mean	Std	Mean	Std	Mean	D volue	Significance
	Mean	Deviation	Mean	Deviation	Difference	P value	Significance
Group							
I	3.40	0.516	1.40	0.843	2.00	0.001	Significant
Group							&
II	3.60	0.516	2.70	0.483	0.90		

Independent t test with p value less than 0.05 is significant

<u>Table -7 depicts the intergroup comparison of Recession Width Between Group I and</u>
<u>Group II at Baseline and 3 month</u>



<u>Graph -7 depicts the intergroup comparison of Recession Width Between Group I and Group II at Baseline and 3 month</u>

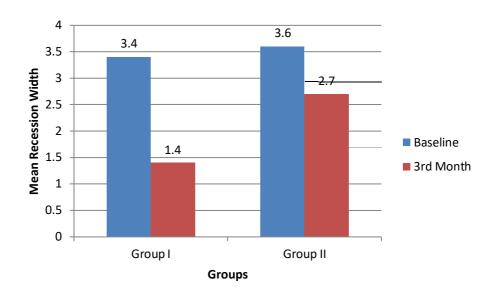
## TABLE -8

The mean Initial Recession Width at the baseline was 3.40 in the Group I and 1.40 in the Group II . The mean Initial Recession Width at the  $3^{rd}$  month was 3.60 in the Group I and 2.70 in the Group II . The mean change in the Initial Recession Width from baseline to  $3^{rd}$  month was 2.00 in the Group I and 0.90 in the Group II. The intragroup change in the Initial Recession Width from baseline to  $3^{rd}$  month was statistically significant in both the groups

	Baseline		3 <sup>rd</sup> Month		Mean Difference	P value
	Maan	Std	Maan	Std	Mean	Davalara
	Mean	Deviation	Mean	Deviation	Difference	P value
Group I						0.001
Group 1	3.40	0.516	1.40	0.843	2.00	(Sig)
Group II						0.001
Group II	3.60	0.516	2.70	0.483	0.90	(Sig)

Paired t test with p value less than 0.05 is significant

<u>Table -8 depicts the intragroup comparison of Recession Width Between Baseline and 3 months</u>



<u>Graph -8 depicts the intragroup comparison of Recession Width Between Baseline and 3 months</u>

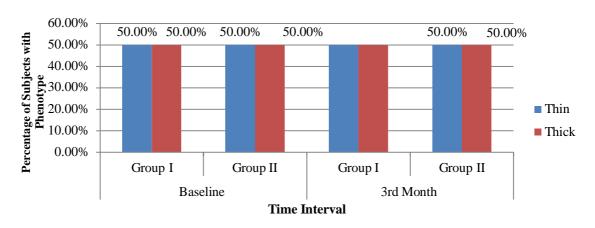
## TABLE - 9

At the baseline the gingival phenotype was thick in 50% of the subjects and thin in 50% of the subjects in Group I and Group II. At the 3<sup>rd</sup> month also the gingival phenotype was thick in 50% of the subjects and thin in 50% of the subjects in Group I and Group II. The difference between Group I and Group II was statistically non-significant in both the groups

		Thin	Thick	P value	Significance
Baseline	Group I	5	5		Non-
		30.0%	30.0%	1.000	Significant
	Group II	5	5	_	
		.0%	.0%		
		Thin	Thick	P value	Significance
3 <sup>rd</sup> Month	Group I	5	5		Non-
		30.0%	30.0%	1.000	NOII-
	Group II	5	5		Significant
		.0%	.0%	_	

Chi Square test with p value less than 0.05 is significant

<u>Table -9 depicts the intergroup comparison of Gingival Phenotype Between Group I</u> <u>and Group II at Baseline and 3 month</u>



<u>Graph -9 depicts the intergroup comparison of Gingival Phenotype Between Group I and Group II at Baseline and 3 month</u>

#### **DISCUSSION**

Gingival recession is the apical shift in the position of gingival margin leading to exposure of the root surface. Gingival recession can be caused by periodontal disease, malposed teeth, improper flossing, aggressive tooth brushing, incorrect occlusal relationships, and dominant roots. These can appear as localized or generalized gingival recession. Smoking has also been correlated with gingival recession. It can occur with or without loss of attached tissue.

Recesssion may result in accentuated sensitivity because of the exposed dentin, root caries, cervical abrasion and also aesthetic concern due to the appearance of long clinical teeth. Hypersensitivity of the root surface may create discomfort or pain on brushing, hindering brushing effectiveness and increasing the risk of gingival inflammation. In patients with a high risk of decay, the risk of root caries will increase. If gingival recession is followed by pathologic migration of the tooth or tooth malalignment, attachment recovery by orthodontic therapy should be considered first. However, in these cases, there may be problems such as time limitations or patient nonacceptance.

Surgical methods are an important option for improving esthetics relatively quickly. There are various surgical approaches available for root coverage. Each technique has its own set of benefits, limitations, and indications. The management of recession defects has been the focus of multiple systematic reviews and meta-analyses. These are Pedicle gingival grafts, free autogenous gingival graft, connective tissue graft Coronally Advanced Flap etc. while lateral pedicle graft and free gingival graft are more appropriate for single tooth recession.he Coronally Advanced Flap (CAF) is a commonly used method for multiple root coverage, and has demonstrated good results regarding root coverage and esthetic outcomes.[3] Some authors have combined a few of the aforementioned techniques, especially the Coronally Advanced Flap approach, with allografts like acellular dermal matrix'9, collagen matrix'10 and platelet concentrates like platelet rich fibrin and plasmal1. Coronally advanced flap with connective tissue grafts has been shown in numerous studies to be the gold standard for treating multiple gingival recession defects.12, 13 However, this approach has considerable drawbacks, including the need to add a second surgical site in order to obtain an autologous soft tissue graft and the presence of vertical incisions that can cause discomfort and delay patient healing.

Recent literature documents the use of placental membranes such as chorion membrane as barrier materials in periodontal regenerative procedures. These allografts have special biological, antimicrobial and immunomodulatory properties. Placental tissues commonly support and protect fetal development during gestation. They include the placental disc, the umbilical cord, placental membrane, and amniotic fluid. These tissues are transient, as they only exist to support the fetus until birth. Placental tissues are of great interest in medicine, specifically as a biomaterial because of the exceptional properties of fetal tissues and the ease of access to them as raw materials [1, 2].

Unlike cadaveric tissue, placental tissues are of a consistent age, donated from a screened population of healthy donors, do not require extensive procedures to collect, and would otherwise be discarded as medical waste [3]. Common tissue collection practices involve packaging for transport following routine caesarean section deliveries, and vaginal deliveries under certain circumstances, with sterile materials and transport solutions. Sterile containers are commonly used to transport the tissue to avoid contamination, and storage time is kept as minimal as possible under refrigerated conditions to ensure material stabili[3, 4]. Placental Tissues as Biomaterials in Regenerative Medicine

The placental membrane (PM) surrounds the developing fetus and creates the amniotic fluid-filled fetal compartment during gestation The PM is structured in three major layers: the fetal-facing amnion, the maternal-facing chorion, and the intermediate layer in between, The amnion, which is composed of epithelium, basement membrane, compact layer, and fibroblast layer, encloses the fetus and the amniotic fluid, which cushions and protects the fetus during gestation [13]. The chorion, is comprised of three layers: the reticular layer, a basement membrane and a trophoblast layer [11, 14, 15]. The chorion forms a barrier between the fetal environment and the maternal immune system [16, 17]. The chorion is 3-4 times thicker than the amnion The intermediate layer is a spongy network of collagens and proteoglycans that functions as a physical barrier between the amnion and chorion. The structure of this layer aids in the movement of the amnion along the chorion, supported by the high concentration of hyaluronic acid (HA) which hydrates and lubricates the tissue [11, 18–20].

Specific focus has been given to growth factors such as epithelial growth factor (EGF), fibroblast growth factors (FGFs), vascular endothelial growth factor (VEGF), transforming growth factor alpha (TGFα), transforming growth factor beta (TGFβ), keratinocyte growth factor (KGF), hepatocyte growth factor (HGF), and platelet-derived growth factors (PDGFs), interleukins (ILs) such as IL-4, IL-6, IL-8, and IL-10, interferons (IFNs), and protease inhibitors including tissue inhibitors of metalloproteinases (TIMPs) TIMP-1, TIMP-2, and TIMP-4 because of their applicability to therapeutic applications [49, 50, 52–54].

These signaling components help regulate multiple aspects of the remodeling [20, 51]. Basic FGF (bFGF), endocrine-derived vascular endothelial growth factor (EG-VEGF), VEGF and PDGF-AA, and PDGF-BB stimulate the activity and migration of matrix metalloproteinahealing cascade, including angiogenesis, inflammation, and tissue ses (MMPs), which are responsible for the breakdown of existing ECM in preparation for remodeling of the PM [34, 55]. TIMPs are important inhibitors that regulate the activity of MMPs to prevent excessive breakdown of the ECM and deposit ECM components [56, 57].

In addition to the active role MMPs play in the remodeling of the placental membrane during gestation, they are an active component in the onset of labor, where high levels of MMPs and reduced level of TIMPs induce the degradation of the PM ECM resulting in membrane rupture[55].

These layers of Chorion are composed of type I,III,IV,V,VI collagen; fibronectin and laminin in varying proportions.. Due to the presence of collagen fibres, fibronectin, proteoglycans and laminin these fetal membranes have good tensile strength, are elastic and can withstand high forces of stretching. Also, these membranes are resorbable, promote tissue repair, blood coagulation, cell migration and adhesion and cell differentiation.

Due to the above mentioned properties these Placental Membranes have been used successfully in medical field for the last 70 years. These are used for burned and ulcerated skin surfaces; biological dressing material for conjunctival defects etc since they cause minimal scarring, enhanced wound healing due to presence of an array of growth factors available in them. Lastly, these are easy to procure, process and transport. Seeing the healing potential of these membranes in Medical field, their use in Dentistry has also gained momentum.

The present study deals with clinical evaluation of Coronally Advanced Flap with and without Chorion membrane for the root coverage. Total 20 patients were selected randomized and treated according to i.e. one side with Chorion Membrane, Group I and other side without Chorion membrane Group II. The outcome measures of the study were Probing depth, recession depth (RD), recession width (RW), clinical attachment level (CAL). The outcome measures PD, RD, RW, CAL and were measured in mm while were measured in scores. The outcome measures were assessed at pre-treatment (baseline) and post treatment (1, 3). The objective of the study was to compare the outcome measures between the two group

In this study, the Probing depth decrease significantly after the treatment in both the groups. In Group I, the Probing depth was 2.000 mm while at 3 month post treatment it was 1.00mm (**Table 1 and Graph 1**). In Group II the baseline mean probing depth was 1.900 mm. while at 3 month post treatment it was 0.50mm (**Table 1 and Graph 1**). The Group II showed more decrease (improvement) in Probing depth as compared to Group I, but the improvement in clinical attachment level was statistically insignificant between the two groups. **Prato PG et al** obtained almost same result in a similar study.<sup>51</sup>

The probing depth was reduced from baseline by 2.000 mm in the group I and by 1.900 mm in the Group at 3 months post operatively. The values were considered statistically significant. In case of the group I, this can be attributed to certa in properties such as stimulating the proliferation of gingival fibroblasts DNA synthesisa s shown by **Locci and coworkers**.

The period in which Chorion membranes stay intact and prevent apical proliferation of epithelium to form long junctional epithelium suffices, since the critical epithelial proliferation time is approximately 14 days. This corelates with our results of reduced probing depth in group I

In case of the group I, the growth factors such as the keratinocyte growth factor (KGF), basic- fibroblast growth factor (b-FGF), transforming growth factor- beta (TGF- $\beta$ ), nidogen growth factor (NGF) and epidermal growth factor (EDGF) help promote periodontal regeneration.

In this study, the clinical attachment level decrease significantly after the treatment in both the groups. In Group I, the baseline mean clinical attachment level was 5.50 mm while at 3 month post treatment it was 3.40 mm (**Table 3 and Graph 3**). In Group II the baseline mean clinical attachment level was 5.80 mm. while at 3 month post treatment it was 1.70mm (**Table 3 and Graph 3**). The Group II showed more decrease (improvement) in clinical attachment level as compared to Group I, but the improvement in clinical attachment level was statistically insignificant between the two groups. **Gupta et al (2015)** obtained almost same result in a similar study.<sup>51</sup> In another study, **Thamaraiselvan et al (2015)** almost similar results for when treated with and without Chorion Membrane.<sup>25</sup>**Padma et al.** reported a reduction in clinical attachments level postoperatively in sites treated with CAF and Chorion membrane.

Increase in clinical attachment level might suggest reattachment, new attachment, or periodontal regeneration. There was gain of mm 1.70 in the group II which was statistically significant. There was also a statistically significant gain in clinical attachment level of 3.40 mm in the group I. Similar results were recorded by **Tinti et al.**, **Pini Prato et al.**, **Roccuzzo et al.**, **Shieh etal.**, **Waterman**, **Huang et al.** (2005), **Ghahroudi et al.**, and **Chakraborthy et al.** 

Cortellini et al., Chorion membrane strongly resembles the oral mucosa basement membrane and contains different types of laminins, especially laminin -5, which plays an important role in the adhesion of gingival cells. Laminins play a key role in improving healing and might result in clinical attachment level improvements by promoting regeneration, a ccelerating tissue adhesions, and preserving tissue. Wound healing can also be improved by antimicrobial agents that are present in Chorion membrane, especially secretory leukocyte proteinase inhibitor I, lactoferrin, defensin, and elafin. The intergroup post operatively values were deemed not significant.

**Holtzclaw DJ and Toscano NJ** observed an improvement of 3.40-1.70 mm in clinical attachment level when they used Chorion membrane as a barrier membrane in the treatment of periodontal intrabony defects [34].

The present study the Intial recession depth decreases significantly after the treatment in both the groups. In Group I, the baseline mean recession depth was 4.00mm. While at 3 month post treatment it was 2.50mm (**Table 5 and Grapg 5**). In Group II, the

baseline mean recession depth was 4.00 mm. while at 3 month post treatment it was 1.10mm (**Table 5 and Graph 5**). The Group II showed more decrease (improvement) in recession depth as compared to Group I. However, the improvement in recession depth was statistically insignificant between the two groups. **Gupta et al (2015)** obtained almost results for recession depth when treated with and without Chorion membrane.<sup>51</sup> Another study, **Thamaraiselvan et al (2015)** almost similar results for recession depth when treated with and without Chorion membrane.<sup>25</sup> **Padma et al**. reported a reduction in RD postoperatively in sites treated with CAF and Chorion membrane membrane which progressively increased at 1 and 3 months.<sup>47</sup>

In this study, the InitiaL recession width decrease significantly after the treatment in both the groups. In Group I, the baseline mean recession width was 3.40 mm. while at 3 month post treatment it was 2.00 mm (**Table 7 and Graph 7**). In Group II, the baseline mean recession width was 3.60mm. While at 3 month post treatment it was 0.90 mm (**Table 7&Graph 7**). The Group II showed more decrease (improvement) in recession width as compared to Group I, but the improvement in recession depth was statistically insignificant between the two groups. **Sofia Aroca et al (2009)** reported almost similar recession width reduction in patients treated with CAF in combination with Chorion membrane.<sup>37</sup> In another study by **Thamaraiselvan et al (2015)** showed almost similar results for recession width when treated with and without Chorion membrane

At the baseline the gingival phenotype was thick in 50% of the subjects and thin in 50% of the subjects in Group I and Group II. At the 3<sup>rd</sup> month also the gingival phenotype was thick in 50% of the subjects and thin in 50% of the subjects in Group I and Group II. Though there was an increase in gingival thickness in both the groups, however it was statistically not significant.

In this study, the treatment of Miller's class I and II gingival recessions indicated that CAF surgery alone or in combination with Chorion are effective procedures to cover denuded root surfaces. The data obtained from a combination of CAF with Chorion membrane after a period of 3 months showed additional benefits of root coverage in treatment of Miller's class I and II gingival recessions when compared with the CAF technique alone.

# **Conclusion**

The root coverage procedures aim to restore the gingival margin coronal to the cemento-enamel junction. Various techniques had been introduced for the treatment of gingival recessions which may include the coronally advanced flap, lateral pedicle flap, double papilla, connective tissue graft, free gingival graft. These techniques showed encouraging results but healing mostly takes place by the formation of long junctional epithelium. This led to the concept of guided tissue regeneration. The membranes used in guided tissue regeneration have evolved over the years, depending on their advantages and their mode of application and resorption. This study was performed to evaluate the efficiency of one such membrane, the Chorion membrane in the management of gingival recession.

This was performed by comparing the Chorion membrane which has already proven its efficiency as a membrane in guided tissue regeneration. Maxillary anteriors and Mandibular anteriors with Miller's class I and II gingival recession were selected for the study. The group I was treated by coronally advanced flap with Chorion membrane and the group II was treated by coronally advanced flap without Chorion membrane. The clinical parameters were measured at baseline and 3 months post operatively.

In this study, the treatment of Miller's class I and II gingival recessions indicated that CAF surgery alone or in combination with Chorion are effective procedures to cover denuded root surfaces. The data obtained from a combination of CAF with Chorion membrane after a period of 3 months showed additional benefits of root coverage the treatment of Miller's class I and II gingival recessions when compared with the CAF technique alone.

The Chorion membran as it fulfils ls the concept of biological GTR in addition to its mechanical concept and amends it with the concept of modern GTR. It not only acts as a barrier membrane but also provides with growth factors which helps in the enhancement of reepithelialisation, vascularisation and proper wound healing with its antiinflammatory, antibacterial and anti-scarring properties.

The consistency of the Chorion membrane which is much thinner to that of the collagen membrane adds up to its physical properties by better adaptation onto the periodontium compared to the Chorion membrane. The cost efficiency of the Chorion membrane comes a long way when compared to without Chorion membrane, which will always be an eye turner for the clinicians.

This study can be safely concluded that Chorion membrane could be an efficient alternative to without Chorion membrane in treating Miller's class I and II gingival recessions using coronally advanced flap.

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## **ANNEXURES**

## **ANNEXURE 1**

## **Institutional Ethical Committee Approval Certificate**



## BABU BANARASI DAS UNIVERSITY BBD COLLEGE OF DENTAL SCIENCES, LUCKNOW

BBDCODS/IEC/09/2022

Dated: 16th September, 2022

Communication of the Decision of the Xth Institutional Ethics Sub-Committee Meeting

IEC Code: 34

**Title of the Project:** Comparative Evaluation Of Coronally Advanced Flap With And Without Chorion Membrane In The Treatment Of Gingival Tissue Recession- A Clinical Study.

Principal Investigator: Dr Km Arati Department: Periodontology

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Project Protocol

Dear Dr Km Arati,

The Institutional Ethics Sub-Committee meeting comprising following members was held on  $15^{th}$  September, 2022.

Dr. Lakshmi Bala
Member Secretary
Prof. and Head, Department of Biochemistry

2. Dr. Praveen Singh Samant Prof. & Head, Department of Conservative Dentistry & Endodontics

3. Dr. Jiji George Prof. & Head, Department of Oral Pathology & Microbilogy

4. Dr. Amrit Tandan
- Member Professor, Department of Prosthodontics and Crown & Bridge

5. Dr. Rana Pratap Maurya
Member Reader, Department of Orthodontics & Dentofacial Orthopaedics

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

The comments were communicated to PI, thereafter it was revised.

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

Forwarded by:

Prof. Dr. Punget Ahuja

Principal BBD College of Dental Sciences

BBD University, Lucknow

PRINCIPAL

Sabu Banarası Das College of Dental Sciences (Babu Banarasi Das University) 3BD City, Faızabad Road. Lucknow-226028 Dr. Lakshmi Bala

Member-Secretary Institutional Ethics Sub-Committee (IEC) BBD College of Dental Sciences BBD University, Lucknow

Member-Secretaly
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

## **Institutional Research Committee Approval Certificate**



## **BABU BANARASI DAS UNIVERSITY**

BBD COLLEGE OF DENTAL SCIENCES, LUCKNOW

## **INSTITUTIONAL RESEARCH COMMITTEE APPROVAL**

The project titled "Comparative Evaluation Of Coronally Advanced Flap With And Without Chorion Membrane In The Treatment Of Gingival Tissue Recession- A Clinical Study" submitted by Dr Km Arati Postgraduate student in the Department of Periodontology for the Thesis Dissertation as part of MDS Curriculum for the academic year 2021-2024 with the accompanying proforma was reviewed by the Institutional Research Committee in its meeting held on 14<sup>th</sup> September, 2022 at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

Prof. Dr. Puneet Ahuja

Chairperson

Dr. Mona Sharma Co-Chairperson

## **Consent Form English**

## **Babu Banarasi Das College of Dental Sciences**

(Babu Banarasi Das University)

BBDCity, Faizabad Road, Lucknow –227105(INDIA)

## **Consent Form (English)**

Title of the Study: Comparative clinical evaluation of coronally advanced flap with or without chorion membrane in the treatment of gingival tissue recessiona Clinical Study.

Study Number
Subject's Full Name
Date of Birth/Age
Address of the Subject
Phone no. and e-mail address
Qualification
Occupation:Student/SelfEmployed/Service/Housewife/Other(Pleasetickas appropriate)
Annual income of the Subject
Name and of the nominees(s) and his relation to the subject(For the
purpose of compensation in case of trial relateddeath).
1. I confirm that I have read and under stood the Participant In formation Document
dated
for the above study and have had the opportunity to ask questions. OR I have been explained
then ature of the study by the Investigator and had the opportunity to ask questions.

- 2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical career legal rights being affected.
- 3. I understand that the sponsor of the project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at myhealth records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the

trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.

- 4. I agree not to restrict the use of any data or results that arise from this study provided such abuses only for scientific purpose(s).
- 5. I permit the use of stored sample(tooth/tissue/blood)for future research. Yes[] No[]

## Not Applicable[]

6. I agree to participate in the above study. I have been explained about the complication sand side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer'sInformation documentgivento me.

Signature(orThumbimpression)ofthe	eSubject/LegallyAcceptableRepres	entative:
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#### **Babu Banarasi Das College of Dental Sciences**

babu banarasi Das University)
BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

## **Participant Information Document (PID)**

#### 1. Study Title

Comparative clinical evaluation of coronally advanced flap with or without chorion membrane in the treatment of gingival tissue recession- a Clinical Study.

## 2. Invitation Paragraph

You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

## 3. What is the purpose of the study?

The aim of the present study is to assess the role of chorion membrane along with coronally advanced flap in the treatment of millers class I and class II class recession defects.

## 4. Why have I been chosen?

You have been chosen for the study as you are fulfilling the required criteria for the study.

#### 5. Do I have to take part?

Your participation in the research is entirely voluntary. If you do, you will be

given this information sheet to keep and will be asked to sign a consent form. During the study you are still free to withdraw at any time and without giving a reason.

## 6. What will happen to me if I take part?

You will be one of the participants in 20 patients enrolled in 2 groups in the study. All the participants diagnosed with gingival recession will be given chorion membrane in one quadrant and without chorion membrane in another quadrant with coronally advanced flap.

#### 7. What do I have to do?

You do not have to change your regular lifestyles for the investigation of the study.

## 8. What is the procedure that is being tested?

The procedure will involve comparative clinical evaluation of coronally advanced flap with or without chorion membrane in the treatment of isolated gingival recession.

#### 9. What are the interventions for the study?

i.All the participants diagnosed with gingival recession will be randomly divided into two groups.

Group I- coronally advanced flap in gingival recession defects with human chorion membrane.

Group II- coronally advanced flap in gingival recession defects without human chorion membrane.

At baseline, the following parameters will be recorded; Probing depth, Clinical attachment level, recession depth. Recession width. and surgical intervention after 1 week.

At the time of surgery, after administering local anaesthesia, two vertical releasing incisions upto mucogingival junction, segregating the recession site will be given the flap will be reflected. After thorough debridement and root

planning the flap will be placed at a level coronal to the pre-existing site and sutures, followed by periodontal dressing would be placed. Patients will be recalled after 10 days for suture removal. Patients will be recalled after 1 month and 3 months. At the 3<sup>rd</sup> months recall visit the clinical parameters mentioned already will be recorded.

The results thus obtained will be subjected to statistical analysis.

#### 10. What are the side effects of taking part?

There are no side effects on patients of this study.

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

There are no risk or disadvantages of taking part in this study.

## 12. What are the possible benefits of taking part?

This study will help us to know the comparative clinical evaluation of coronally advanced flap with or without chorion membrane in the treatment of isolated gingival recession.

#### 13. What if new information becomes available?

Sometimes during a research project, new information becomes available about the research being studied. If this happens, your researcher will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your researcher/investigator will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

#### 14. What happens when the research studystops?

If the study finishes/stops before the stipulated time, this should be explained to the patient/volunteer.

#### 15. What if something goeswrong?

If any severe adverse event occurs, or something goes wrong during the study, the complaints will be handled by the doctors expertising in the field at BBDCODS opd.

Will my taking part in this study be keptconfidential? **16.** 

Yes, it will be kept confidential. Your name, address or any other personal information will not be

shared outside the BBDCODS.

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

The results of the study will be used for comparative clinical evaluation of

coronally advanced flap with or without chorion membrane in the treatment of

isolated gingival recession. Identity of the participants will not be disclosed in

any result/ reports/ publications.

Who is organizing the research? 18.

This research study is organized by the academic institute (BBDCODS)

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

Yes. If the patient wishes, the result of the study will be made available to him/her.

Who has reviewed the study? 19.

The study has been reviewed and approved by the Head of the Department, IEC/IRC of the institution.

20. **Contact for further information** 

Dr. ARATI

Department of Periodontology and Implantology

Babu Banarasi Das College of Dental Sciences.

Lucknow – 226028

Mob: 7906228063

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Member Secretary,
Babu Banarasi Das College of Dental Sciences.
Lucknow – 226028
bbdcods.iec@gmail.com
Signature of PI
Name
Date

Dr. Laxmi Bala,

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# BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES DEPARTMENT OF PERIODONTICS PATIENT PROFORMA

## **CASE HISTORY PROFORMA**

NAME OF PATIENT- AGE: SEX- DATE-OCCUPATION: OPDNO: ADDRESS-

CHIEFCOMPLAINT-

**CLINICAL PARAMETERS:-** AT BASELINE-

#### PROBING DEPTH-

$\times$	$\times$	$\times$	$\times$	$\times$	$\times$
3	2	1	1	2	3
$\times$	$\times$	$\times$	$\times$	$\times$	$\times$

CLINICAL ATTACHMENT LEVEL-

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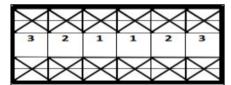
INITIAL RECESSION DEPTH-

INITIAL RECESSION WIDTH-

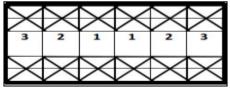
GINGIVAL BIOTYPE-

#### AT 3 MONTHS-

**CLINICAL PARAMETERS- PROBING DEPTH** 



CLINICAL ATTACHMENT LEVEL-



FINAL RECESSION DEPTH-FINAL RECESSION WIDTH-

GINGIVAL BIOTYPE-

**DIAGNOSIS-**

## **STATICAL ANALYSIS**

## STATISTICAL ANALYSIS

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

The intergroup comparison will be done using the independent t tests and intragroup comparison will be done using the Paired t test The ordinal and nominal variable will be compared using Chi Square test The level of the significance for the present study was fixed at 5%.

#### Mean

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

Where:

 $\overline{X}$  = the data set mean

 $\sum$  = the sum of

X = the scores in the distribution

N = the number of scores in the distribution

#### Range

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

Where:

 $X_{highest} = largest score$ 

 $X_{lowest}$  = smallest score

## **Variance**

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

The simplified variance formula

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

Where:

 $SD^2$  = the variance

 $\sum$  = the sum of

X = the obtained score

 $\overline{X}$  = the mean score of the data

N = the number of scores

## **Standard Deviation (N)**

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

The simplified standard deviation formula

$$SD = \sqrt{\frac{\sum_{i=1}^{X^2 - \frac{(2A)_2}{N}}}{N}}$$

Where:

SD = the standard deviation

 $\sum$  = the sum of

X = the obtained score

 $\overline{X}$  = the mean score of the data

N = the number of scores

#### **Independent t-test**

Independent t Test can be used to determine if two sets of data are significantly different from each other, and is most commonly applied when the test statistic would follow a normal distribution. The independent samples *t*-test is used when two separate sets of independent and identically distributed samples are obtained, one from each of the two populations being compared

$$t = \frac{\overline{X}_1 - \overline{X}_2}{\sqrt{\left(\frac{(N_1 - 1)s_1^2 + (N_2 - 1)s_2^2}{N_1 + N_2 - 2}\right)\left(\frac{1}{N_1} + \frac{1}{N_2}\right)}}$$

Where X1 = Mean of the first Group, X2 = Mean of the Second Group

#### Paired t test

$$t = \frac{\overline{x} - 0}{SE(d)} = \frac{\overline{x}}{SD(x)} / \sqrt{n}$$

A paired t-test is used to compare two population means where you have two samples in which observations in one sample can be paired with observations in the other sample. Examples of where this might occur are: - Before-and-after observations on the same subjects (e.g. students' diagnostic test results before and after a particular module or course) or A comparison of two different methods of measurement or two different treatments where the measurements/treatments are applied to the same

#### Chi Square Test

Chi-square is a statistical test commonly used to compare observed data with data we would expect to obtain according to a specific hypothesis. When an analyst attempts to fit a statistical model to observed data, he or she may wonder how well the model actually reflects the data. How "close" are the observed values to those which would be expected under the fitted model? One statistical test that addresses this issue is the chi-square goodness of fit test. This test is commonly used to test association of variables in two-way tables, where the assumed model of independence is evaluated against the observed data. In general, the *chi-square test statistic* is of the form

$$X^2 = \sum \frac{\text{(observed - expected)}^2}{\text{expected}}$$

If the computed test statistic is large, then the observed and expected values are not close and the model is a poor fit to the data

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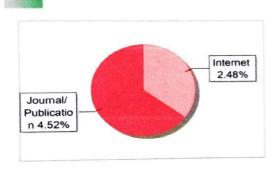
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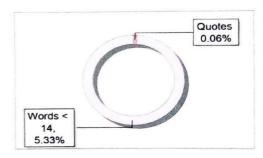
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