PLATELET RICH FIBRIN VERSUS CHITOSAN DENTAL DRESSING IN PATIENTS UNDERGOING MANDIBULAR TEETH EXTRACTIONS – A PROSPECTIVE SPLIT MOUTH STUDY.

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LIST OF ABBREVIATIONS

Abbreviation	Full form
PRF	Platelet Rich Fibrin
ADD	Axiostat Dental Dressing
CDD	Chitosan Dental Dressing
HDD	Hemcon Dental Dressing
RBCs	Red Blood Cells
A-PRF	Advanced Platelet-Rich-Fibrin
L- PRF	Leukocyte- And Platelet- Rich Fibrin
VAS	Visual Analog Scale
ANOVA	Analysis Of Variance
AO	Alveolar Osteitis
INR	International Normalized Ratio
OAT	Oral Anticoagulation Therapy
PDL	Periodontal ligament
BMSCs	Bone marrow mesenchymal stem cells
IGF	Insulin like growth factor
TGF	Transforming growth factor

INTRODUCTION

Extractions are one of the most common procedures performed by Oral and Maxillofacial Surgeons. The most common complications in the early post-operative period faced by the operator are excessive bleeding, swelling. However, the delayed complications usually comprise of delayed healing of the extraction socket [1]. This further delay the rehabilitation of the missing tooth. Various local agents as dressing in the extraction socket have been documented in the literature such as metronidazole, chlorhexidine, tetracycline, hydrocortisone, lincomycin and clindamycin [2,3].

Axiostat Dental Dressing (Axiostat Bio-solutions, Gujarat, India) is another local agent documented in the literature to achieve hemostasis of the extraction site. Axiostat is a sponge-like biomaterial derived from the crustaceans with a high electropositive charge forms a strong seal at the extraction site by attracting the negatively charged cells in the blood namely red blood cells (RBCs) and platelets [4,5]

Axiostat Dental Dressing not only acts as a scaffold but also provides a primary seal which in turn helps in initiating the coagulation pathway effectively [4]. The clot that forms due to seal achieved by electro-positively charged agent and negatively charged blood cells offers an antibacterial barrier over the extraction site.

Another agent documented in the literature is platelet rich fibrin (PRF). Choukroun et al. in France in 2001 developed a second-generation platelet concentrate which was neither fibrin glue nor a bovine thrombin [6]. This relatively new biomaterial prepared was called platelet-rich fibrin (PRF). PRF was considered as a healing agent initially use vastly in oral implantology while various studies done recently shows its implications in various disciplines of dentistry. PRF is an autologous fibrin matrix which contains platelet and leukocyte cytokines [7].

Platelet rich plasma (PRP) with growth factors and platelet rich fibrin (PRF) are autologous platelet concentrates proposed as socket preservative materials [8]. As mentioned earlier PRF is a second generation of autologous growth factors that encourages healing of soft tissue and is effectively associated with an early organization of bone volume percentage & bone substance [9]. PRF is easy to prepare from the autologous non-anti-coagulated blood when centrifuged [6].

The protocol for PRF preparation is simple [Figure 1]. It includes collection of 5 ml of whole venous blood in each of two sterile vacutainer tubes (6ml) which does not contain an anti-coagulant. After withdrawing the blood and collecting it in vacutainers, it is then placed in a centrifugal machine at 3,000 revolutions per minute (rpm) for approximately 10 mins [10].

The sample in vacutainer can be divided in three layers. The upper straw-colored is the acellular plasma, middle layer contains the fibrin clot while lower fraction is red colored containing red blood cells (RBCs) as shown in Figure 2

The middle fraction is collected up to 2mm below the lower dividing line after removing the upper straw-colored which is the PRF. Fibrin is formed when the fibrinogen which is concentrated in upper part of the tube combines with the thrombin circulating due to centrifugation. This leads to formation of a fibrin clot in the middle while the red corpuscles settle down at the bottom and acellular plasma floats at the top. The middle fraction comprises of trapped platelets in fibrin meshes. The time gap between the blood collection and its transfer to the centrifuge machine determines the success of this technique because the anticoagulant immediately starts to coagulate once it touches the glass. Following the protocol mentioned above and quick handling is key to successful clinically usable PRF [10].

AIMS AND OBJECTIVES

Aim of the Study

To compare the effectiveness of Platelet rich fibrin with Chitosan dental dressing as a hemostatic and healing agent in patients undergoing mandibular teeth extractions.

Objectives of the study

1. To compare the time required to achieve hemostasis after placement of Platelet rich fibrin with Chitosan dental dressing in extraction socket in Mandibular arch.

2. To compare the healing after placement of Platelet rich fibrin with Chitosan dental dressing in extraction socket in mandibular arch.

REVIEW OF LITERATURE

Talal M Zahid , Mohammed Nadershah (2019)[11] conducted a study to evaluate the potential of advanced platelet-rich-fibrin (A-PRF) as a regenerative biomaterial for bone regeneration and post-operative sequelae after impacted third molar extractions. The study conducted on a total of 10 female patients with bilateral impacted third molars. The study was a split-mouth study, randomized, double blind clinical trial. Randomization was done by a coin toss where A-PRF was placed on one side while the other side was without any intervention. Pain, swelling and healing were assessed on the 7^{th} postoperative day. A statistically significant reduction in pain and swelling was observed in the A-PRF group compared to the control group. The study concluded A-PRF as a potential biomaterial for lessening the severity of pain and swelling after third molar surgery.

MG Caymaz, LO Uyanık (2019)[12] conducted a study to evaluate and compare the postoperative effects of leukocyte- and platelet- rich fibrin (L- PRF) and advanced platelet- rich fibrin (A- PRF) in terms of pain, swelling, and trismus after mandibular third molar surgery. A total of 27 patients with bilateral impacted mandibular third molar which were surgically operated at different times. The patients were evaluated in two randomly separated groups where the first and second group received A-PRF & L-PRF were applied into the extraction sites respectively. The outcome variables were pain, swelling, the number of analgesics taken and trismus. Following the operation, the variables were assessed based on first, second, third and seventh day. The data were collected and analysed with unpaired Student's *t*- test and Mann–Whitney *U* test. The study consisted of 15 females and 12 males between ages of 18–26. The visual analogue scale pain scores of the L- PRF group during first ($P < 0.05$), second, and third days and total values ($P < 0.01$); the number of analgesics on days 2 ($P < 0.01$) and 3; and their total values ($P < 0.05$) were significantly higher than the A- PRF group. There was no significant difference between swelling, trismus, and the duration of operation ($P > 0.05$). The results of this study showed that the use of A- PRF after mandibular third molar extraction significantly reduces postoperative pain and the patients need to take analgesics of A- PRF group compared to L- PRF group.

Manzoor Mohammad Dar, Ajaz Ahmad Shah, A. Latief Najar, Mubashir Younis, Muneet Kapoor, Jahangir Irfan Dar (2018) [13] conducted a clinical study requiring disimpaction of bilateral mesioangular impacted mandibular third molars in 60 patients to evaluate the effectiveness of PRF on soft tissue healing and bone tissue healing in terms of postoperative pain, postoperative swelling, soft tissue healing, and

the quality of bone healing at the mandibular third molar socket. There was no difference in the age gender and type of impaction between the two groups as the mean postoperative pain score (visual analog scale) was lower for the PRF group (Group A) at all points of time when compared with the control (Group B), and this was statistically significant ($P < 0.05$). The mean percentage swelling was lower for the PRF group (Group A) at all points of time when compared with the control (Group B). Evaluating the effect of treatments (with or without PRF) on lamina dura score shows that in both the groups at different time periods, significant ($P < 0.001$) difference was observed on lamina dura score. The results of the study suggested that application of autologous PRF gel had beneficial effect on healing of extraction sockets after third molar surgery.

Shahram Ghanaati et al (2018) [14] conducted a review on a total of 392 article, 72 of which were classified for each indication field. When comparing PRF with biomaterials vs biomaterial alone in sinus lift (5 studies), no statistically significant differences were detected. Socket preservation and ridge augmentation using PRF significantly enhanced new bone formation compared to healing without PRF (7 studies). Re-epithelialization and bone regeneration was achieved in 96 of 101 patients diagnosed with medication-related osteonecrosis of the jaw (5 studies). In periodontology, PRF alone (6 studies) or its combination with biomaterials (6 studies) significantly improved the pocket depth and attachment loss compared to a treatment without PRF. Over 70% of the patients were part of studies with a high level of scientific evidence (randomized and controlled prospective studies). The review concluded that PRF is a beneficial tool that significantly improves bone and soft tissue regeneration. However, the clinical community requires a standardization of

PRF protocols to further examine the benefit of PRF in bone and soft tissue regeneration in reproducible studies, with a higher scientific level of evidence.

Yingdi Zhang et al (2018) [15] conducted a study on 28 patients which were divided into two groups: The experimental and control groups (n=14 each). Following tooth extraction, the experimental group was implanted with PRF membrane, whereas the control group was not. The gingival healing effect was assessed at 7 days, 1 and 3 months later. Cone-beam computed tomography was performed immediately and at 3 months following tooth extraction. The changes in alveolar ridge height, width, and bone mineral density were compared between the two groups. The alveolar bone was removed using the ring drill during the implant surgery at 3 months following tooth extraction. Histomorphometric evaluation was performed to compare new bone formation between groups. The patients in the experimental group reportedly felt better compared with the patients in the control group. The healing of gingival tissue was better in the experimental group than in the control group. A significantly greater novel bone area was observed in the PRF group compared with the control group ($P<0.01$). However, no statistically significant differences were observed in the mean value of buccal alveolar ridge height, lingual/palatal alveolar ridge height and alveolar ridge width between the two groups. The study concluded that that PRF was advantageous in human alveolar ridge preservation with ease of use and simple handling. Histological analysis of novel bone formation confirmed that PRF increased the quality of the novel bone and enhanced the rate of bone formation, despite the effect of PRF was not significant to reduce alveolar bone resorption in the extraction socket alone.

Baratam Srinivas, Pradipta Das, Moumita Maity Rana, Abdul Qahar Qureshi, Kedar C. Vaidya, Shaikh Junaid Ahmed Raziuddin (2018) [16] conducted a study on 30 patients selected from the outpatient department over a period of 2½ years starting from May 2013 undergoing extraction of maxillary or mandibular teeth simultaneously to conduct a split‐mouth study. Statistical Package for Social Sciences version 19 were used for calculating Descriptive and analytical statistics. Chi‐square test was used to assess wound healing score in the two groups while paired *t*‐test was used to compare the bone density in the socket and periapical regions at different time intervals while unpaired *t*‐test was used for the intergroup comparisons. $P < 0.05$ was considered to be significant while $P < 0.001$ was considered highly significant. Patients in PRF group had better healing index when compared to without PRF group. Use of PRF showed a comparable increase in bone density too. An appreciable wound healing and bone regeneration was seen in the experimental group when compared to the control sites where no PRF was used substantiating the use of PRF as an inexpensive autologous material for socket preservation and future rehabilitation. The study concluded that, minimal operator expertise was required to conduct the procedure of PRF preparation and grafting when compared to bone harvesting from distant sites.

Amit Shrivastava, Ramakrishna Shenoi, Anup Garg, Vikas Vats, Vandana Gadve, Afaque Siddiqui (2018) [17] conducted a study on 120 participants to evaluate wound healing of extraction sockets with Platelet rich fibrin gel and the control group with no intervention. On RVG, bone density was measured and compared. STATA Version 10.0 was used for statistical analysis. Mean bone density (grey scale/ pixels) of PRF group after 24 week was significantly high (119.60 ± 7.43)

for maxilla and (135.62 ± 9.90) for mandible as compared to control site (105.33 ± 6.35) for maxilla and (123.36 ± 5.65) for mandible. The study concluded that Platelet rich fibrin appears as a satisfactory alternative with favorable results and low risks in extraction sockets healing.

Meghali Diwaker, Sonal, Sumit Aman, G.K Thapliyal, Ankur Garg, Himanshu Bhutani (2**018)** [18] conducted a study on 20 patients with bilateral mandibular impacted third molars in the age group of 18 – 40 (11 males and 9 females; mean age 31.09 +/- 8.130) years. As per inclusion criteria, the patients were divided in two groups. One of the extraction site from the patients was randomly selected for placing PRF and the other site was closed by conventional method. The patients were then recalled post-operatively on the 1st, 7th day, 4th week, 6th week, 3rd month and 6th month for evaluating the parameters of pain, mouth opening, swelling, delayed complications (if any) and bone density. A significantly less pain in the study group was recorded postoperatively on the seventh day, fourth week and sixth week (P = 0.001, <0.001, <0.001 respectively). PRF significantly reduced the postoperative mouth opening on the first day, the seventh day, fourth week and sixth week (P = 0.016, 0.005, 0.004, 0.001 respectively). Though postoperative extraoral swelling was less in the test group, no statistically significant reduction in the postoperative extraoral swelling between the two groups was seen. A significant reduction in the postoperative intraoral swelling was seen on the seventh day (P = 0.009) in the test group. The study concluded that PRF shows an accelerated increase in bone density and seems to be efficient in reducing the post-operative morbidities like pain and swelling while it showed no significant effect on the post-operative mouth opening.

Carlos Fernando de Almeida Barros Mourão, Mônica Diuana Calasans-Maia, Rafael Coutinho de Mello Machado, Rodrigo Figueiredo de Brito Resende & Gutemberg Gomes Alves (2018) [19] described an interventional case series. One of the main intercurrent events associated with soft tissue surgical procedures in the oral cavity is represented by the control of post-operative bleeding. Platelet-rich fibrin (PRF) membranes are materials with great potential for optimizing soft tissue healing and induction of haemostasis. This interventional case series describes the treatment of 10 patients with excisional biopsy of benign oral cavity lesions, following a screening sequence at the surgery clinic of a Brazilian dental school between the years of 2015 and 2017. After treatment with PRF, patients presented mean time for postoperative haemostasis of 10.3 ± 2.5 s, requiring the average use of three membranes to cover the surgical area. The results suggest that the use of platelet-rich fibrin membranes may represent a feasible alternative haemostatic material for the treatment of oral lesions.

Ahmed Abdullah Alzahrani, Afraa Murriky, Sami Shafik (2017) [20] conducted a study to evaluate clinically and radiographically extraction socket healing using autologous platelet rich fibrin (PRF). Twenty-four subjects needing single tooth simple extractions were included in the study. Twenty-four extraction sockets were divided into test group (PRF, n = 12) and control group (blood clot, n = 12). PRF was prepared with blood drawn from individuals after extraction using standard technique. PRF was placed in test group sockets followed by pressure application and figure 8 sutures. Sockets in control group were allowed to heal in the presence of blood clot and received a figure 8 suture. Ridge width was assessed using cast analysis with the help of acrylic stent and a pair of callipers. Radiographic analysis of socket surface

area was performed using computer graphic software program. The clinical follow up assessments were performed at 1, 4 and 8 weeks. Collected data was assessed using ANOVA and multiple comparisons test. Subjects were aged between 25 and 50 (mean 37.8) years, including 15 females. The mean horizontal ridge width for sockets in the test group were 11.70 ± 2.37 mm, 11.33 ± 2.30 mm and 10.97 ± 2.33 mm at 1, 4 and 8 weeks respectively. Ridge width proportions were significantly higher among test group as compared to control group between baseline to 4 and 8 weeks respectively. The mean radiographic bone fill (RBF) percentage in the test group, was 74.05 ± 1.66%, 81.54 ± 3.33% and 88.81 ± 1.53% at 1, 4 and 8 weeks respectively. The mean RBF was significantly higher in the test group than control group at all time intervals.

Yun He, Junliang Chen, Yue Huang, Qin Pan, Minhai Nie (2017) [21] carried out a systematic research of PubMed, Web of Science, Embase, and the Cochrane Library to identify all studies published up to October 2016 that investigated the effect of PRF on lower third molar extraction. The parameters included were pain, swelling, trismus, alveolar osteitis (AO) and osteoblastic activity to evaluate the effect of PRF. Meta-analysis was done. The aim of this meta-analysis was to investigate the effect of local application of PRF on controlling postoperative signs and symptoms after the extraction of an impacted lower third molar. A total of 10 studies were selected in the meta-analysis, including 468 cases of PRF application and 467 cases of non-PRF application. Of the studies included in the analysis, 9 of them were randomized case-control trials which included 7 split-mouth studies and one retrospective case-control study. The results indicated that PRF significantly relieves pain (P = .01) and 3-day postoperative swelling (P = .03) and reduces the incidence of AO (P <

.0001).However, there were no significant differences between the PRF and non-PRF groups with respect to 1-day postoperative swelling and osteoblastic activity. The meta-analysis concluded the local application of PRF after lower third molar extraction is a valid method for relieving pain and 3-day post-operative swelling and reducing the incidence of AO. Patients undergoing complicated surgical extraction, PRF might be a recommendation for local application into the sockets.

Faez Saleh Al-Hamed, Mohamed Abdel-Monem Tawfik, Ehab Abdelfadil (2016) [22] conducted a study to assess the effect of platelet-rich fibrin (PRF) on postoperative pain, analgesic consumption, soft tissue healing and socket complications following the extraction of mandibular third molars. 50 impacted third molars were surgically removed from 47 patients (13 males and 34 females; with a mean age of 25.24 ± 7.04 years). The control group patients with extraction sockets remained empty while the patients with extraction sockets in the study group were placed with PRF clots. The variables assessed were soft tissue healing, pain, analgesic consumption and socket complications encountered during the first post-operative week. No significant difference was observed between PRF and control groups regarding soft tissue healing (P = 0.187). However, a significant less pain was recorded on 5^{th},6^{th} and 7^{th} post-operative days (P = 0.041, 0.031 and 0.005 respectively). Patients included in the study group significantly consumed less analgesics for the second, third, sixth and seventh postoperative days (P = 0.019, 0.039, 0.045 and 0.020 respectively). The study concluded that PRF could reduce alveolar osteitis, pain, analgesic consumption following the removal of mandibular third molars.

Lokman Onur Uyanık , Kani Bilginaylar and İlker Etikan (2015) [23] conducted a study to compare the postoperative outcomes in impacted mandibular third molars that were treated using either platelet-rich fibrin (PRF), a combination of PRF and piezo surgery, or conventional rotatory osteotomy. The study included 20 patients with 40 extractions of impacted mandibular third molars. In group A (n = 20), traditional surgery was performed on one side (Group 1, n = 10); traditional surgery was performed, and PRF was administered to the extracted socket on the other side of same patient (Group 2, n = 10). In group B (n = 20), on one side, piezosurgery was used for osteotomy, and PRF was administered (Group 3, n = 10); on the other side of same patient, traditional surgery was performed (Group 4, n = 10). The parameters assessed included pain, number of analgesics taken, trismus and cheek swelling. These variables were also assessed on postoperative days 1, 2, 3, and 7. Statistical analysis revealed a significant reduction in postoperative pain (sum of 1 , 2 , 3 and 7 days) and trismus (on postoperative day 1) in group 2 (traditional surgery + PRF group), and in postoperative pain, the number of analgesics taken (sum of 1 , 2 ,3 and 7 days) and trismus (on postoperative day 1) in group 3 (piezosurgery + PRF group) compared to groups 1 and 4 (traditional surgery groups), ($p \leq 0.05$). However, swelling on postoperative days 1, 3, and 7 did not differ among the groups ($p > 0.05$). Only difference was on second day between groups 1–4 and 2–4 ($p \leq 0.05$). The results of our study have shown that the use of PRF with traditional surgery and PRF combined with piezosurgery significantly reduced pain during the postoperative period. In addition, PRF in combination with piezosurgery significantly decreased the number of analgesics taken. Both operations also significantly decreased trismus 24 h after the surgery. As a result of this study, PRF and combination use of PRF and

piezosurgery have positive effects in reducing postoperative outcomes after impacted third molar surgery.

R.M. Eldibany (2014) [24] conducted a study on 20 patients with an age range of 36-62 years with International Normalized Ratio (INR) > 3.5 were excluded. Patients were allocated equally in two groups; Group A where PRF was inserted into the extraction site while Group B extraction sockets were packed with Hemcon Dental Dressing (HDD). Extraction was performed under local anaesthesia and as atraumatic as possible. Patients with artificial mechanical heart valves under anticoagulant oral therapy undergoing dental extractions can be difficult as they present a significant risk for postoperative haemorrhagic complications. The study was performed to evaluate the use of PRF and Hemcon Dental Dressing (HDD) in cardiac patients taking Warfarin following dental extraction. Patients in group A showed minimal pain and accelerated healing, while those in group B showed extreme to moderate pain on the first few days following extraction and retarded healing. Four patients developed alveolar osteitis. The study concluded that PRF has good antihemorrhagic properties and increases tissue healing and wound closure, thus allowing for a quick recovery without significant painful events. HDD has excellent hemostatic properties and can be used safely in such patients but with small amounts.

Gilberto Sammartino, David M.Dohan Ehrenfest, Francesco Carile, Mariano Tia,Paolo Bucci (2011) [25] conducted a study on 50 heart surgery patients (28 women and 22 men) and patients selected were all nonsmokers, aged 47 to 67 years and had a mechanical heart valve substitution (21 with mitral valve substitution

and 29 with aortic valve substitution) and followed an anticoagulant oral therapy with warfarin (all with Coumadin 5 mg,1tablet per day in 24 patients and 1.5 tablet per day in 26 patients) and were evaluated by standard laboratory method, the mean international normalized ratio (INR) value was 3.16 ± 0.39. The patients which were selected were on equilibrated cardiac condition and were only treated by anticoagulant therapy; they were taking no other cardiac medications. After a local anesthesia without vasoconstrictor agents, the patients underwent single or multiple extractions for a total of 168 teeth. No patient underwent more than 4 dental extractions at the same time. None of the patients suspended the anticoagulant oral therapy and none of the patients received heparin before the surgical procedure. Gentle luxation and extraction of the teeth were performed to preserve the integrity of the buccal and lingual plates. In a few cases, the teeth were cut with a diamond burr in 2 fragments to avoid periodontal bone trauma during the extraction. The PRF was prepared through a single centrifugation of whole blood (PRF production kits, Process, Nice, France) lasting 18 minutes. Blood was collected without anticoagulant from the brachial vein by a nurse 20 minutes before the extractions, according to the protocol for anticoagulated patients (i.e, with longer centrifugation time, 18 minutes instead of 12 minutes). Each 9 mL tube produced one PRF clot. The volume of harvested blood was related to the number of dental extractions and the quantity of PRF clots required to fill the alveolar sockets (from 18 mL to 54 mL, or 2 to 6 PRFs). After centrifugation, each PRF clot was separated from the red blood cell base, condensed, modeled on a sterile metal plate, placed directly into the post extraction sockets, and stabilized by 3/0 silk suture. All extractions were performed with minimal bone trauma to achieve an adequate support for the PRF gel. There was

always one PRF clot introduced in each extraction site. Each surgical intervention had a maximum duration of 20 minutes to decrease the surgical stress for the patient, and the extraction/curettage part of the surgery always lasted less than 5 minutes. However, the patients remained under the care of the department for several hours after the surgical procedure. Bleeding assessments were performed every 15 minutes for 3 hours after the extractions, and then every hour for the next 6 hours. This examination reported the subjective evaluation of blood amount on sterile gauze and the bleeding duration. According to the classification by Souto and colleagues, mild bleeding was defined as bleeding that stopped spontaneously or with minimal local compression, and severe Bleeding or major hemorrhagic complication Was defined as bleeding that did not stop with previous measures and required continuous Local compression using a gauze Pack soaked in an antifibrinolytic agent until The bleeding stopped. Furthermore, the post extraction sites Were monitored every day after the surgery until the suture Removal to assess potential late hemorrhagic Complications and to evaluate pain and Tissue healing. The suture was removed 1 week after the surgery. To prevent infectious endocarditis complications, the patients underwent intramuscular Wide-spectrum antibiotic therapy with Ceftriaxone (1 g, once a day) and Nebcin (5 mg/kg, twice a day) from 2 days before Until 3 days after the surgical procedures. The medications were given at the hospital. All patients followed a soft and liquid diet for 24 hours after the surgery, without mouth rinses over the same period. Oral hygiene (mainly toothbrushing) was suspended for 24 hours after dental extractions. The study concluded that Each patient underwent 1 to 4 extractions (mean=2.8± 1.2), for a total of 168 teeth (75 maxillary and 93 mandibular extractions). There were only 2 hemorrhagic complications (4%); these occurred in 2

patients with an INR of 3.7, a 61-year-old man and a 54-year-old woman. These complications were solved in a few hours by compression with sterile gauzes and the local application of tranexamic acid. In this study, treated 14 patients with INR values 3.5, and no bleeding complications were reported in the remaining 12 patients. Only 10 patients (20%) had mild postoperative bleeding (as defined by Souto et al).

Chitosan dental dressing

Pratap Movaniya, Nimisha Desai, Tushar Makwana, Ridhi Matariya, Yama Patel, Hirakben Patel (2020) [26] conducted a study to evaluate the efficacy of Chitosan (Axiostat) as a haemostatic in minor oral surgery. The study comprised of 50 patients underwent minor oral surgical procedures and haemostasis achieved with chitosan and time taken for haemostasis was statistically evaluated. This study involved 18 (36%) cardiac patients taking oral anticoagulants, 17 (34%) hypertensive patients and 15 (30%) diabetic patients. During minor oral surgical procedures haemostasis was achieved in mean time of 89.3 seconds with help of chitosan(Axiostat). The present study provides evidence that Chitosan (Axiostat) can be used as a clinically effective haemostatic dressing material that significantly shortens bleeding time following minor oral surgical procedures in medically compromised patients.

Hazem Redwan, Muneer Harfoush , Bassel Al Brad , Majid A Abo Fakher (2020) [27] Conducted a study in which 40 patients were included, who had two opposite extraction sockets on opposite sides of the jaws. They were divided into the control and experimental groups; they both received gauze dental dressing for the former group and chitosan for the latter. Hemostasis was measured via a new method

that has not been utilized before in the literature. The bleeding event was recorded, and data were analyzed. It had been found that a low correlative coefficient value, plummeting to only 0.136, existed for the 80-tooth samples in both the control and experimental groups. This has been ascribed to the nature of the hemostatic mechanism of chitosan, as a renowned marine biopolymer in dental practices. The study concluded that INR values seemed unlikely to support the existent claims on chitosan effect, leaving a venue to interrogate the explanation that validates the electric aggregation link between chitosan and red blood cells to reach the hemostasis event.

Bianca Jacob , Sindhu R , Sunayana Manipal , Prabu D , Raj Mohan , Bharathwaj V V in (2019) [28] performed a literature review using Ovid Medline, Pubmed, Science Direct, Wiley Online Library, CINAHL, Cochrane Library, Grey Literature, OSF and Scopus and by using MeSH "Chitosan and Oral wound Healing". It was found that 6 out of the 7 included articles showed positive effects of Chitosan in oral wound healing. Statistically significant improvement was found with wound healing using Chitosan derivate Hemcon Dental Dressing with $p<0.01$. The literature review concluded that the application of chitosan is effective in the process of oral wound healing and it acts by facilitating the wound healing process.

Swetcha Seethamsetty, Godvine Sarepally, Arshiya Sanober, Yousuf Qureshi, Umayra Fatima, Shaik Mohammed Arif (2019) [29] A randomized comparative study was carried out on 40 subjects who had two extraction sites, in dissimilar quadrants. The surgical site was chosen at random and post-extraction hemostasis was achieved by a custom-cut chitosan dressing (study site) and sterile

cotton gauze dressing (suturing if required) at control site. Patients were reviewed on the first, third, fifth, and seventh postoperative days and every week till 4 weeks. The parameters assessed were timing of hemostasis, pain scores, and pus discharge. It was found that out of 40 study subjects, 24 (60%) were males and 16 (40%) were females. The age was 40–65 years (mean age 54 years). The mean time for hemostasis was 0.63 ± 0.27 min in study group, whereas for controls, it was 9.10 ± 2.28 min. The difference in postoperative pain was significant ($P = 0.001$) on days one, five, and seven. In chitosan group extraction sites, dry socket was not seen, whereas four patients on day three and five patients on day five after extraction experienced dry socket in pressure gauze dressings group, with an insignificant difference ($P = 0.058$). In chitosan group extraction sites, no pus discharge was seen. Whereas four patients on days three and five after extraction had pus discharge in patients where pressure dressings were applied, with an insignificant difference ($P = 0.058$). The study concluded that Chitosan dressing is a competent hemostatic agent that significantly reduced the post-extraction bleeding, with better pain control. Chitosan group had no incidences of dry socket and pus discharge.

Mariana Adina Matica , Finn Lillelund Aachmann , Anne Tøndervik , Håvard Sletta and Vasile Ostafe (2019) [30] reviewed the antimicrobial properties of chitosan and described the mechanisms of action toward microbial cells as well as the interactions with mammalian cells in terms of wound healing process. Fighting bacterial resistance is one of the concerns in modern days, as antibiotics remain the main resource of bacterial control. Data shows that for every antibiotic developed, there is a microorganism that becomes resistant to it. Natural polymers, as the source of antibacterial agents, offer a new way to fight bacterial infection. The advantage

over conventional synthetic antibiotics is that natural antimicrobial agents are biocompatible, non-toxic, and inexpensive. Chitosan is one of the natural polymers that represent a very promising source for the development of antimicrobial agents. In addition, chitosan is biodegradable, non-toxic, and most importantly, promotes wound healing, features that makes it suitable as a starting material for wound dressings.

Mohamed Kabeer , P. P. Venugopalan , V. C. Subhash (2019) [31] The study was conducted to evaluate the efficacy of a novel chitosan-based haemostatic dressing, Axiostat® (Axio Biosolutions Private Ltd., Gujarat, India), as a hemorrhage control device in the ambulance setting. A total of 104 patients with bleeding scalp wounds were randomly allocated into two treatment groups while transporting them to the hospital. Patients in Group I were treated with Axiostat chitosan haemostatic dressing (n = 47), while a conventional cotton gauze dressing was used in Group II (n = 57). A standard procedure was followed to apply the dressing on bleeding wounds and time to achieve haemostasis, the amount of blood loss, the number of patients with haemostasis, the occurrence of rebleeding, and other side effects were noted. The mean age of the patients was 40 years and the majority of patients were male - 73 (70%). Most of the wounds were lacerations with venous bleeding. Haemostasis time was 4.68 ± 1.04 minutes and 18.56 ± 5.04 minutes in the Axiostat® and cotton gauze groups, respectively. The use of Axiostat® significantly reduced the time to haemostasis ($p < 0.0001$). A significant reduction in blood loss was observed with the application of Axiostat®. Successful haemostasis was achieved in 94% of patients in the Axiostat® group and 74% patients in cotton gauze group, respectively ($p < 0.05$). Moreover, no side effects, such as tissue loss or rebleeding at time of removal, were seen with the use of Axiostat®, while three patients in the cotton gauze group showed

some side effects. Results show that Axiostat® enables rapid haemostasis and can prevent significant blood loss during emergency trauma and accidents. Additionally, it also allows for easier removal from the wound site without leaving any residue, which helps in rendering the wound clean. In conclusion, the study successfully demonstrates the potential of Axiostat® as a first-line intervention in controlling acute haemorrhage in emergency care.

Sourav Sarkar, N.T. Prashanth, E.S. Shobha, Vinod Rangan, G. Nikhila (2019) [32] Conducted a study on 60 patients under Oral Antiplatelet Therapy indicated for tooth extraction without altering the oral antiplatelet regimens. Patients were allocated equally in two groups; Group A: where PRF gel was packed into the extraction socket, while Group B: Chitosan hydrogel was packed. Timing of haemostasis was noted for each patient of both the groups. Patients were examined for any pain, secondary bleeding, healing, soft tissue dehiscence, alveolar osteitis in the extraction site on first, third and seventh post-operative days. It was found that all extraction sockets with Platelet-rich fibrin achieved haemostasis in 2.64 min and sockets with Chitosan hydrogel achieved haemostasis in 1.182 min ($p < 0.001$). Post-operative pain in Group A sites (3.2, 1.4,0.37 on 1st, 3rd & 7th day respectively) was significantly lower than the control sites (3.4, 1.67, 0.53 on 1st, 3rd& 7th day respectively) p-value 0.001, 0.001 respectively. The study concluded that Chitosan hydrogel dressing proved to be a superior haemostatic agent compared to PRF gel, that significantly shortened the clotting time following dental extraction in patients under antiplatelet therapy. But, PRF gel showed superior wound healing properties than Chitosan with less postoperative pain following minor oral surgical procedures under local anaesthesia.

Akshat Gupta, Vidya Rattan, Sachin Rai, Akshat Gupta, Vidya Rattan, Sachin Rai (2019) [33] Conducted a study in which Asymptomatic symmetrical mandibular third molars were extracted simultaneously in 27 patients and Chitosan dressing was placed into the extraction socket of test side. Pain scores were recorded on VAS using a 0 to 10 pain score. Wound healing was compared between right and left side. Radiographic findings were evaluated by observing lamina dura and density of extraction socket. It was seen that the test group had more pain than control at all time intervals and unerupted tooth sites showed mean pain score significantly more than erupted tooth sites. Test group was superior to control in event of wound healing. Healing was significantly better in erupted tooth than unerupted tooth. At second week 12 sites showed better radiographic findings in chitosan treated group compared to 3 sites in the control group. At third month, 14 sites showed improved bone formation in chitosan treated group compared to 4 in control group. None of the unerupted teeth group showed better radiographic finding in test side at 2 week and 3 month compared to erupted teeth group. The study concluded that Chitosan is effective in promoting wound healing and early osteogenesis in erupted tooth socket after extraction. Study recommended that chitosan dressing should be used in the sockets of erupted tooth after extraction but should be avoided in unerupted or impacted teeth cases.

Jay P. Malmquist, Stephen C. Clemens, Hal J. Oien and Sharon L. Wilson (2018) [4] evaluated the efficacy of the HemCon Dental Dressing (HDD; HemCon Medical Technologies, Inc, Beaverton, OR) haemostatic oral wound dressing derived from the US military HemCon Bandage combat wound dressing and whether early haemostasis affects postoperative care and surgical healing outcomes following oral

surgical procedures. Patients aged 18 to 90, except those allergic to seafood, who consented to participate were eligible for enrolment into this study regardless of other medical history findings. All patients were required to have 2 or more surgical sites so they would have internal surgical control sites. All patients taking oral anticoagulation therapy (OAT) were included for treatment in this study without altering their anticoagulant medication regimens. All data were evaluated by biomedical statisticians and Institutional Review Board approval was obtained. All HDD surgically treated sites, including all from patients taking OAT, achieved haemostasis in less than 1 minute and control wounds in 9.53 minutes (P <.001). All HDD sites achieved haemostasis sooner than control sites (P <.001). Approximately 32% of HDD treated sites had significantly better healing compared with control sites (P <.020) and no control sites healed better than HDD treated sites; 32% of HDD treated oral surgery wounds achieved statistically significant improved healing (P <.001). All patients taking OAT achieved haemostasis within 1 minute and were treated without altering their anticoagulant regimens. Although the pain scores and incidence of alveolar osteitis were lower for the HDD-treated sites, these scores were not significantly different than control-treated sites. There was no negative healing sequela associated with early haemostasis of oral surgical wounds. The HDD has been proven to be a clinically effective haemostatic device that significantly shortens bleeding time following oral surgery procedures for all patients, including those patients taking OAT. Patients receiving the HDD had improved surgical wound healing compared with those receiving controls.

Fatemah Rahmani, Ali Akbar Moghadamnia, Sohrab Kazemi, Atena Shirzad, Mina Motallebnejad (2018) [34] conducted a study to determine the effect of

chitosan mouthwash 0.5% on RAS. The randomized double blind clinical trial was conducted at a dental school in Babol, Iran from 2015 to 2016. The patients who were enrolled into the study were 20 with a history of minor aphthous stomatitis. They were randomly treated in three groups of Chitosan, Triamcinolone or Biogel mouthwashes. ANOVA and Turkey test were used to analyse the data. The mean ulcer size on the fifth day (p=0.026, p=0.042, respectively)and VAS on the third and fifth days (p=0.011,p=0.013, respectively) were significantly less in triamcinolone and chitosan groups than biogel. It was concluded that the chitosan mouthwash is effective on pain relief and reducing ulcer size of minor aphthous stomatitis.

Saurabh Sharma, Tejraj P Kale, Lingaraj J Balihallimath, Abhishek Motimath (2017) [35] conducted a study on 40 patients on oral antiplatelet drugs and overall 80 extractions were done applying split mouth study design, without altering patient's drug regime. Extraction sites were divided into two groups: Group I received Axiostat Haemostatic Dental Dressing (study site), and group II received conventional method; pressure pack with sterile gauze under biting pressure followed by suturing if required (control site) was used to attain haemostasis. It was found that Extraction sites treated with Axiostat Haemostatic Dressing achieved haemostasis earlier (mean 1 minute 13 seconds) compared with control sites (mean = 14 minutes 1 second), which was also statistically significant ($p < 0.001$). Postoperative pain was considerably lower and significantly better healing was seen in the study group ($p < 0.001$) compared with the control. The study concluded that Axiostat demonstrated to be an effective haemostatic agent that considerably lessened the bleeding time in patients on oral antiplatelet drugs post-extraction. In addition, it even offered minimal postoperative pain and improved healing of the extraction wound. Axiostat Dental

Dressing (ADD) is found to be as effective and at par in achieving haemostasis in patients on oral antiplatelet therapy. The study highlighted an alternative approach using ADD which aids in quick haemostasis, accentuates healing, and reduce postoperative pain.

Nishant Sinha, Alok Mazumdar, Jaydip Mitra, Gunita Sinha, Shalabh Baunthiyal, Sharda Baunthiyal (2017) [36] conducted a study on 50 cardiac patients undergoing single tooth extraction in dental clinic of the railway hospital without stopping or altering the antiplatelet therapy and AXIOSTAT dental dressing was placed in the extracted socket for Hemostasis. The effectiveness of axiostat as a haemostatic measure in the study. All patients who underwent extraction under the protocol that we followed showed average haemostatic time in all the patients was 1.5 minutes. The Chitosan based Axiostat dental dressing is used less in dentistry due to lack of awareness among dental surgeons. However it is widely used in other fields.

Roberto Pippi, Marcello Santoro,Arturo Cafolla in 2017 [37] A study was done to evaluate the effectiveness of an extra-alveolar haemostatic agent, the HemCon® Dental Dressing (HDD), in controlling post-surgical bleeding. In this study Routine, atraumatic tooth extractions were performed in a single session under local anesthesia without vasoconstrictor and without APT interruption. All patients underwent the extraction of two teeth in the same session, each one in a different dental hemi-arch and the haemostatic method to beused was randomly chosen, in the test site (SH), the HDD was applied, whereas in the control site (SX), a common haemostatic sponge (CollaPlug, Zimmer Dental) was applied and stabilized in situ with a suture. For each surgery, two different times were measured: the time required

for haemostatic agent application (T1) and the time required for haemostasis achievement (T2). Postoperative pain and healing quality was also evaluated. It was seen that twenty out-patients were enrolled. The mean application time was significantly lower in the test group than in the control group, the mean bleeding time in the control group was significantly lower than in the test group, pain values was lower in the test group than in the control group, especially at suture removal, post-extraction socket healing was better in the test group than in the control group. The study concluded that HDD seemed to be a valid and safe alternative in treating post-extraction sockets in outpatients under single drug anti-platelet treatment, in the absence of surgical wound lacerations.

K.R. Ashok Kumar, Jambukeshwar Kumar, Jagadesh Sarvagna, Praveen Gadde, and Shwetha Chikkaboriah (**2016)** [38] conducted a study to determine whether early hemostasis achieved by using Hemcon Dental Dressing (HDD) will affect post-operative care and surgical healing outcome in minor oral surgical procedures. A total of 30 patients who were enrolled into this study were aged 18 years to 90 years. The patients who were allergic to seafood and did not consent to the study were excluded. Patients were required to have two or more surgical sites so that they would have both surgical and control sites. All patients taking Oral Anticoagulation Therapy (OAT) were included for treatment in the study without altering the anticoagulant regimens. The collected data was subjected to statistical analysis using unpaired t-test. All HDD surgically treated sites achieved hemostasis in 1.49 minutes and control wounds in 4.06 minutes ($p < 0.001$). Post-operative pain at HDD treated sites (1.87,1.27 on 1^{st} and 3^{rd} day respectively) was significantly lower than the control sites (4.0,1.87 on 1^{st} and 3^{rd} day respectively) p-value (0.001, 0.001

respectively). HDD treated oral surgery wounds achieved statistically significant improved healing both at 1st and 3rd post-operative days ($p < 0.0001$). HDD was proven to be a clinically effective hemostatic dressing material that significantly shortens bleeding time following minor oral surgical procedures under local anaesthesia including those patients taking OAT. Improved surgical wound healing as compared to controls in patients receiving the HDD.

Marta Madrazo-Jiménez et al (2016) [39] conducted a study to clinically evaluate the efficacy of a gel containing chitosan, 0.2% chlorhexidine, allantoin and dexpanthenol on wound healing and reduction of postoperative side effects and complications after extraction of an impacted mandibular third molar. A split-mouth design study was carried out on a total of 50 bilaterally and symmetrically impacted third molar extractions, which were randomly placed into either a control group (CG=25) or an experimental group (EG=25). Written consent was obtained from patients participating in the study. To avoid bias, All procedures were carried out by the same dental practitioner, in accordance with standard surgical protocol. The EG applied 10 ml of topical gel composed of chitosan, 0.2% chlorhexidine, allantoin and dexpanthenol to the surgical wound three times a day for 10 days, patients in the CG did not apply any gel. The groups were homogeneous in so far as potentially confounding variables. No significant findings were found regarding postoperative swelling and pain. Neither of the groups displayed poor healing or infectious complications of the wound during the postoperative period. In all the recorded follow-ups (Day 7 p=0.001, and Day 14 p=0.01), the wound's aesthetic appearance was better in the EG. Overall treatment tolerance was satisfactory and similar in both groups. The study concluded that the gel composed of chitosan, 0.2% chlorhexidine,

allantoin and dexpanthenol did not aid in patients' postoperative comfort; however, improved wound healing was observed.

Tejraj P. Kale, Amit Kumar Singh, S.M. Kotrashetti, Abhishek Kapoor (2012) [40] conducted a study to evaluate the effectiveness of HemCon Dental Dressing (HDD) in controlling post extraction bleeding and to ascertain its role in healing of extraction wounds as compared to control. The 40 participants who were included in the study were on Oral Antiplatelet Therapy (OAT). A total of 80 extractions were conducted without altering the alteration of patient's drug therapy. The extraction sites were divided into two groups where one group received a HDD while the control group where the conventional method of pressure pack with sterile gauze under biting pressure was used to achieve haemostasis. All HemCon treated sites achieved haemostasis sooner (mean = 53 seconds) than the control sites (mean = 918 seconds) which was statistically significant (P <0.001). Postoperative pain in the HDD group (1.74) was also significantly lower than in the control group (5.26) (P <0.001). Approximately 72.5% of HDD-treated sites showed significantly better postoperative healing when compared to the control site (P <0.001).HDD proved to be an excellent haemostatic agent that significantly shortened the bleeding time following dental extraction in patients on OAT. Additionally, HDD offered significantly improved post-operative healing of the extraction socket and less postoperative pain.

MATERIALS AND METHOD

An experimental study was designed to evaluate platelet rich fibrin versus chitosan dental dressing in patients undergoing Bilateral Mandibular molar teeth extractions.

Ethics clearance

The scientific and ethical clearance was obtained from the institutional review, Scientific and ethical committee.

Informed consent

A brief outline of the purpose of study along with the inclusion criteria was explained in the informed consent. The language of the informed consent was as per the convenience of the patients. It was explained to the patients that their participation is voluntary, all the personal details are kept confidential, and their anonymity would

be maintained. They were asked to clear their doubts or queries before signing the informed consent as shown in **Annexure III**

Study design

Randomized control study with split mouth design.

Sample size

The sample size calculation of 39 patients with 78 extraction sites was done with the use of 'OPEN EPI software version 3.01'**.**

The sample size calculation was based on proportions in which the groups were divided into 2. From the previous literature which gave two values for group A and group B. The power of the study was stated at 80% which could give statistically significant result and the alpha error was set at 5%.

Considering the dropouts in the study, the sample size estimated is 43 patients with 86 extraction sites as shown in **Table 1.**

Formula for sample size $= [Np(1-p)]/ [(d^2/Z^2_{1-\alpha/2}*(N-1) + p*(1-p)]$

Sampling Technique

Convenience sampling.

Study area

The study was conducted in the Department of Oral & Maxillofacial Surgery.

Study population

Patients requiring bilateral extraction of mandibular molar teeth extraction as per inclusion criteria.

Inclusion criteria

- Patients above 18 years of age.
- Patients requiring bilateral mandibular molar extraction under local anaesthesia.
- Patient with controlled systemic diseases.

Exclusion criteria

- Patients with known allergy to shellfish and local anaesthetic agent.
- Patients with Uncontrolled systemic diseases.
- Mentally challenged patients.
- Patients on anticoagulant therapy.
- Patients not willing to volunteer for study.

Treatment allocation

The sites and allocated treatment were randomized as per simple block randomization list generated by SEALED ENVELOPE SOFTWARE. The two treatment groups A and B, the sites right and left and the list length 43 were fed in the software and the block size 4 was used. The software generated block randomization list of 43 patients and treatment was allocated to a site.

For example, if Participant was allotted to Group A on right side, then by default the participant received Group B on left side. The software generated a seed no. 9794094222863 which is unique for every list generated and thereby helps in reviewing the list again in the future.

Group A- Placement of Platelet Rich Fibrin formed from patient's own blood will be packed in extraction socket and it will be secured with a loose figure of 8 suturing.

Group B- Placement of Chitosan dental dressing into the extraction socket at the height of crestal bone with direct finger pressure after extraction with a loose figure of 8 suturing.

Blinding

To avoid bias in the study a single blinding was performed. The examiner assessing the healing of extraction socket on post-operative 7^{th} day was blinded and was unaware of the allocated treatment group.

Clinical procedure

A complete case history was taken preoperatively using a standard case history proforma as shown in **Annexure I**. This included a careful documentation of their medical history and history of allergy (particularly in relation to Chitosan derivatives). Intraoral periapical radiographs of the tooth to be extracted were taken prior to the procedure to ensure that the tooth could be extracted under local anesthesia. Hematological assessments were done if necessary. These included random blood sugar levels, bleeding time, clotting time etc. in case if the values of these assessments were beyond the normal range, further assessments were carried out and physician consent obtained prior to the extraction procedure. The entire procedure and nature of study was explained to the patient in a language understood by the patient. Signatures/thumb impression on the consent forms were taken thereafter.

Materials

1. Diagnostic Instruments.
2. 25 G Long Needle 2ml Syringe.
3. Local Anesthetic Solution Consisting Of 2% Lignocaine Hydrochloride with Adrenaline 1:2,00,000. **(Figure 2)**
4. Standard Exodontia Armamentarium For Extractions. **(Figure 1)**
5. Chitosan Dental Dressing - Axiostat (D11 1cm X 1 Cm) **(Figure 3)**
6. PRF Centrifuge machine **(Figure 4)**
7. Autologous Blood Of Patients For Preparation Of Platelet Rich Fibrin. **(Figure 5)**
8. Stop Watch. **(Figure 6)**
9. Scissor, tweezer

Preparation of Platelet Rich Fibrin

Approximately 5 ml of whole venous blood was collected in each of the two sterile vacutainer tubes of 6 ml capacity without anticoagulant. The vacutainer tubes were then placed in the centrifugal machine at 3000 rpm for 10 minutes. This led to formation of following layers in the vacutainer. A lower red fraction contained red blood cells while the upper straw colored cellular plasma was seen. The middle fraction contained the fibrin clot. The upper straw-colored layer was removed while the middle fraction that contained the fibrin clot was collected which was the Platelet rich fibrin. **(Figure 5)**

Procedure

Patients visiting Oral and Maxillofacial Surgery Department for mandibular molar extraction under the inclusion criteria were allocated to either group A or B.

After obtaining informed written consent, under all aseptic precaution, procedure was started and the teeth to be extracted was anaesthetised using lignocaine 2% with adrenaline in concentration of 1:2,00,000. Keeping the speed of injection same for every patient, local anaesthetic was administered. Following this the surgical site was checked for the subjective and objective signs of anaesthesia after achievement of which the surgical procedure was started. All the extraction procedures were performed by a single operator.

For Group A

In site 1, placement of Platelet Rich Fibrin formed from patient's own blood was packed in extraction socket immediately after extraction and it was secured with a loose figure of 8 suturing.

For Group B

In site 2, Chitosan dental dressing was placed into the extraction socket at the height of crestal bone with direct finger pressure after extraction which was secured with a loose of figure of 8 suturing.

After achieving haemostasis, post-operative instructions were given and medications were prescribed. On the follow up visit, the 7^{th} day, healing of extracted socket was assessed **by Landry, Turnbull and Howley** scores by the second examiner. During the same visit, extraction of the contra-lateral side was performed. The healing of the extracted socket was assessed on third visit which is 7^{th} post-operative day of the second extracted site by the second investigator.

Assessment of Parameters

Duration required for post-operative hemostasis was evaluated using with stopwatch

Healing was evaluated on **7th** day using the standardized index **by Landry, Turnbull and Howley** scores as shown in **ANNEXURE II.**

Healing Index	Score	Tissue Color	Response to Palpation	Granulation Tissue	Incision Margin
1	Very Poor	>=50% Gingiva Red with Suppuration	Bleeding	Present	Not Epithelized
2	Poor	>=50% Gingiva Red	Bleeding	Present	Not Epithelized with Connective Tissue Exposed
3	Good	>=25% And<50% Of Gingiva Red.	No Bleeding	Absent	No Connective Tissue Exposed
4	Very Good	<25% Of Gingiva Red	No Bleeding	Absent	No Connective Tissue Exposed
5	Excellent	All Tissue Pink	No Bleeding	Absent	No Connective Tissue Exposed

Duration of study

The study was performed for a period of 18 months from January 2019 to July 2020

PHOTO PLATE

Figures

Figure 1: Armamentarium for mandibular teeth extraction.

Figure 2: 2% Lignocaine with 1:200,000 Epinephrine

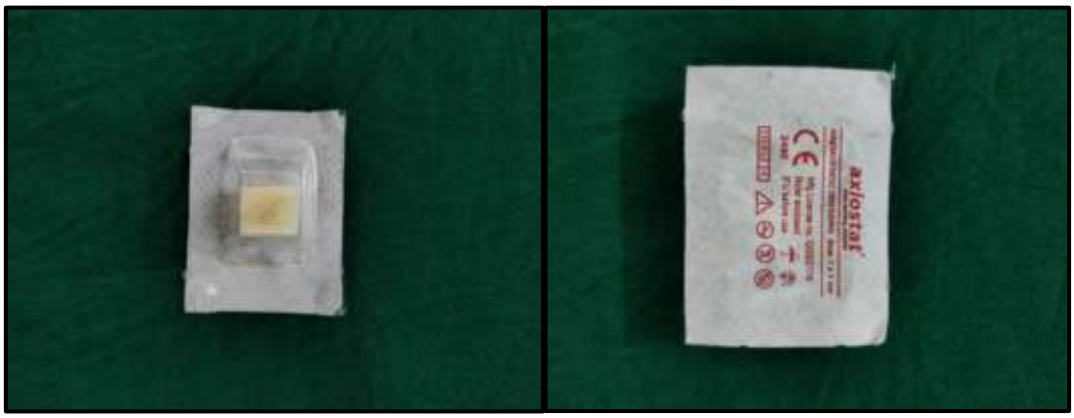

Figure 3: Chitosan dental dressing – Axiostat dental dressing.

Figure 4: PRF centrifuge machine.

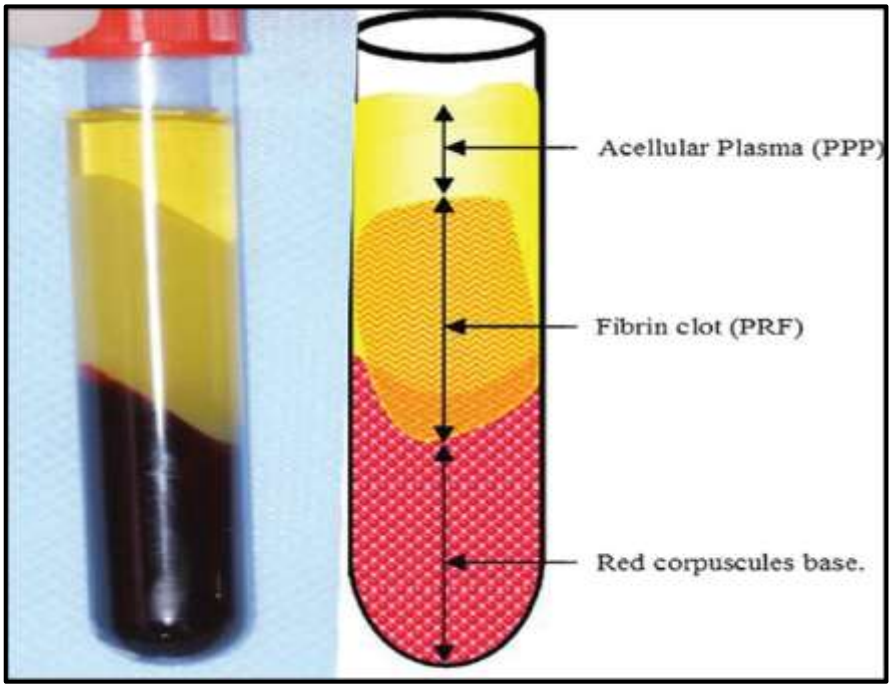

Figure 5: Blood in the vacutainer tubes after centrifugation at 3000 rpm for 10 minutes divided into three fractions.

Figure 6 : Stopwatch used to record the time to achieve haemostasis.

Figure 7: Case of Bilateral mandibular teeth extraction.

Figure 8: Healing of socket packed with Axiostat dental dressing (Fourth quadrant) and Platelet rich fibrin (Third quadrant) was assesed on day 7 and day 14 respectively.

RESULTS

A total of 43 patients were included in the study. Maximum patients belonged to the age group of 23-27 years with 10 patients followed by 33-37 years with 9 patients, 18-22 years with eight patients, 28-32 years with seven patients, 38-42 years with six patients and 43-47 years with three patients as shown in table 1. **Graph 1** depicts a bar diagram representing number of patients according to age group. 20 patients were males and 23 were females as shown in **Table 2. The Graph 2** shows a Pie diagram representing number of males and females in the study.

The Table 3 provides descriptive data regarding mean and standard deviation with respect to time taken for obtaining hemostasis. The mean time taken to obtain hemostasis in patients placed with Axiostat in the socket after extraction was 46.51±13.70 seconds while the time taken for obtaining hemostasis in patients placed with PRF in the socket post extraction was 124.05±18.43 seconds. The graph 3 shows Bar diagram representing haemostasis time in Axiostat and PRF groups.

Unpaired t-test was applied to assess the difference in the hemostasis time taken by Axiostat and PRF treated patients. It was observed that the difference between the two groups for time taken was 77.53 seconds as shown in **Table 4**. There was a statistically significant difference between the patients treated with Axiostat in the socket after extraction and PRF in the socket post extraction. The t test value was 22.134 with a significance at $p<0.0001$. The time taken by Axiostat groups was significantly less as compared to PRF group. Thus, Axiostat proves to be better in controlling haemostasis over PRF.

The Table 5 provides descriptive data regarding frequency of healing scores in both the groups. In Axiostat group; patients with score 1 indicating very poor healing were 4.7%, patient with score 2 indicating poor healing of the extraction socket were 76.7%, patient with score 3 indicating good healing were 18.6%, patient with score 4 and 5 indicating very good and excellent healing respectively were 0%. While in the patients treated with PRF showed none of the patients with very poor or poor healing score, patients with score 3 indicating good healing were 53.5%, patient with score 4 indicating very good healing were 46.5% and patients having excellent wound healing were not found even in this group. **The graph 4** Bar diagram representing healing scores in Axiostat and PRF groups.

Mann Whitney U test was applied to assess the difference between Axiostat group and PRF group with respect to healing scores. It was found that the healing was better in PRF group as compared to Axiostat group. None of the patients in PRF group had very poor or poor healing while in Axiostat group 35 patients had either very poor or poor wound healing. Similarly, very good healing was observed in 20

patients from PRF group while none of the patients from Axiostat group have very good healing. The Mann Whitney U value was 92.00 and the difference in healing scores between the two groups was statistically significant with $p<0.0001$. The healing was better in PRF group as compared to Axiostat group as shown in **Table 6.**

DISCUSSION

The key concept in the safe practice of any surgical procedure is hemostasis. The local robust vascular supply in the head and neck makes it especially true for any surgical procedure being performed in the head and neck region. It is well documented in the literature that loss of hemostasis after dentoalveolar procedures compromises the airway and causes hypovolemia even in an otherwise healthy individual without any known bleeding diatheses. [2]

Hemostasis plays a role of paramount importance in all surgical procedures. Its management has several key points that begin with adequate anesthetic technique and meticulous operative techniques. The use of hemostatic agents is an age-old concept used since ancient times. The use of wax, grease and barley to achieve hemostasis was employed by the Egyptian people. The priests and healers of the time applied hemostatic herbs to the war wounds. The development of topical hemostatic agents is the result of advances in biotechnology. These hemostatic agents range from

absorbable topical hemostats to biologically active topical hemostat. The absorbable agents are gelatins, micro fibrillar collagen and regenerated oxidized cellulose while biologically active topical hemostats such as thrombin, biological adhesives and other combined agents. [41]

Hemostasis is a complex process and it can be divided into 4 distinct phases:[42]

1. Vascular contraction - To decrease the amount of intravascular fluid loss, the acutely injured arteries and arterioles with a muscular tunica media undergo vasospasm.

2. Endothelial injury and platelet plug formation - Von Willebrand factor causes adhesion of platelets due to endothelial cell injury and subendothelial collagen exposure. Several substances that are liberated along with the confirmational changes in platelets increases both platelet aggregation and direct activation of thrombin.

3. Initiation of the clotting cascade – classically it has been described as two arms, the extrinsic (tissue factor activated) and the intrinsic (intravascular) pathways joining at the common pathway. The activated factor X complex cleaves Prothrombin to thrombin forming a complex that then cleaves fibrinogen to fibrin which then results in a network of cross-linked fibrin mesh and it ensnares the platelets and erythrocytes to form a retracted clot. It has been recently found that the details of this cascade are much more interactive and complex than originally thought as it involves multiple positive and negative feedback mechanisms.

4. Modulation of clotting – The negative amplifiers of the coagulation cascade are plasma antithrombin and tissue factor pathway inhibitor. Several proteins in the

coagulation pathway activate Protein C and S which inhibit the activated factors V and VII. Several proteolytic enzymes, namely plasmin which is activated by tissue plasminogen activator or urokinase disrupt the fibrin clot into fibrin degradation products. Thus, restoring the blood vessel patency.

The most common topical hemostatic agents are: [42]

Scaffold/matrix

- Gelatin matrix
- Microfibrillar collagen
- Oxidize cellulose
- Mucopolysaccharide spheres

Biological

- Thrombin, bovine
- Thrombin, human pooled
- Thrombin, human recombinant

Antifibrinolytics

- EACA
- TA

Natural propcoagulants

- Chitosan
- Zeolite
- Alginate

- Hydrophilic polymers/K salts
- Mineral salts

Tissue Sealants

- Thrombin + fibrinogen
- Bovine gelatin + thrombin

Tissue adhesives

- Cyanoacrylate
- Polyethylene glycol hydrogel
- Bovine albumin cross-linked

Occlusives

- Product
- Bone wax
- Ostene

The healing process of the socket following tooth extraction has become an important topic of research, study and discussion as there are several changes that occur in the alveolar process after tooth extraction which may prevent or render difficult implant installation in a prosthetic driven position. Furthermore, there is an increasing demand for aesthetics and functions in dentistry highlights the importance of maintaining adequate ridge volume in order to achieve optimal healing and long term aesthetically acceptable implant-support prosthesis.

Extraction of teeth was once described as a process of tissue amputation which may lead to functional, psychological, postural and local changes. “Socket healing” is

defined as the process of local changes that takes place in order to close the wound and restore tissue homeostasis. The closure of the socket entrance by firm epithelialized soft tissue and /or radiographic bone fill of the socket determines the end of the socket-healing process. The socket entrance may be restored between 10 and 20 weeks and its takes 3 and 6 months for radiographic bone fill. Socket healing occurs majorly in the first three months. However, the reorganization of the alveolar ridge may continue for up to 1-year post-extraction. The biologic differences among individuals, alveolar socket size and the amount of surgical trauma induced during the extraction are the factors that help in the rate of socket healing. [43]

Histologic changes are as following:

Biopsies from the marginal portion or from the central portion of the healing sockets were used to describe the healing events while the biopsies from the entire alveolar socket were prepared for histologic analyses. The histologic findings showed a remarkable similarity between the socket healing in humans and dogs. The socket healing process may be divided into three sequential phases:

1. **Inflammatory phase**
2. **Proliferative phase**
3. **Modelling/ Remodeling phase**

Inflammatory phase

The inflammatory phase may be subdivided into two parts. The two phases are blood clot formation and inflammatory cell migration respectively. Immediately after tooth extraction, hemorrhage occur and the socket is filled with blood. The severed

vessels are plugged by the blot clot and stops bleeding. A large number of inflammatory cells migrate to the wound in order to "clean" the site before new tissue can start forming within the first 2-3 days. Granulation tissue is formed by a combination of inflammatory cells, immature fibroblasts and vascular sprouts. As the site becomes sterilized, the granulation tissue is gradually replaced with a provisional connective tis- sue matrix that is rich in collagen fibres and cells, and the proliferative phase of the wound-healing process begins.

Proliferative phase

The proliferative phase is divided into two parts – fibroplasia and woven bone formation. It is characterized by intense and rapid tissue formation. Fibroplasia involves the fast deposition of a provisional matrix. Several vessels and bone forming cells penetrate the provisional matrix which then result in finger-like projections of woven bone. These projections completely surround a vessel and primary osteon is formed. After the extraction of teeth, it takes nearly two weeks for woven bone to be identified in any healing socket. The woven bone lacks load-bearing capacity and needs replacement with mature bone types (Lamellar bone and bone marrow).

Bone modelling and remodelling phase

The third and last phase of the socket-healing process is Bone modelling and remodelling. A change in the shape and architecture of the bone is bone modelling whereas bone remodelling is a change without concomitant change in the shape and architecture of the bone. Lamellar bone or bone marrow replacing the woven bone is bone remodelling. Bone remodelling is due to bone resorption that takes place on the socket walls resulting in an alteration of dimensions of the alveolar ridges. It takes

several months to years for the complete remodelling of the woven bone into lamellar bone and bone marrow.

The resorption of the socket walls were studied in biopsies obtained from human samples. Osteoclasts were found around the crest of the buccal and lingual walls and on the outer and inner portions of the socket after a few weeks after tooth removal. Since the lingual bone is wider than buccal bone wall, modelling results in greater vertical bone loss at the thin buccal plate than at the wide lingual wall. In conclusion, modelling and remodelling processes during socket healing result in qualitative and quantitative changes at the edentulous site that culminates in a reduction of the dimension of the ridge.

We compared the effectiveness of Platelet Rich Fibrin (PRF) and Axiostat Dental Dressing (ADD) in the patients undergoing bilateral mandibular teeth extractions. Both PRF and ADD have shown great haemostatic properties.

The platelets are activated, and cytokines are released during the process of PRF making by centrifugation. The PRF clot exudate serum comprises of PDGF-BB, TGF-b1, and IGF-I. The analysis revealed the slow fibrin polymerization during its processing leads to the intrinsic incorporation of platelet cytokines which permits progressive release over time (7 to 11 days). Also, leucocytes also could secrete cytokines in reaction to the inflammatory and haemostatic phenomenon introduced artificially in the centrifuged tube. These cells play a significant asset for protecting the surgical sites against local infections and associated delayed healing. This concept explained the clinically observed healing properties of PRF along with reduction of post-operative infections when PRF is used. The immediate anti-haemorrhagic

properties of the PRF clot is explained due to slow release of cytokines. The improved soft tissue and bone healing is attributed to the slow release of growth factors from the PRF membrane and its strong fibrin architecture of the clot. [24]

The PRF offers greater resistance than other platelet concentrates due to its three-dimensional architecture which allows suture to be tied to the membrane and soft tissues. The elasticity of the material allows exerting a little tension without rupturing it. When compared with other haemostatic agents, PRF has a much lower cost in its production and is obtained within a few minutes before the surgical procedure. Along with the production and release of growth factors and cytokines, PRF also releases coagulation proteins. PRF is efficacious as a haemostatic material for soft tissue procedures that induces haemostasis shortly after its implantation. [19]

In our study, it was found that the healing was better in PRF group as compared to Axiostat group. Healing was assessed based on the healing scale **by Landry, Turnbull and Howley** scores, Either very poor or poor wound healing was observed among 35 patients in the Axiostat group while none of the patients in PRF group showed very poor or poor healing score. Similarly, very good healing was observed in 20 patients from PRF group while none of the patients from Axiostat group have very good healing. The difference in healing scores between the two groups was statistically significant with $p<0.0001$. The healing was better in PRF group as compared to Axiostat sites in patients undergoing bilateral mandibular extractions as shown in **Figure 7 and 8**

Another study performed by RM Eldibany et al to evaluate the use of Platelet Rich Fibrin (PRF) and Hemcon dental dressing (HDD), a chitosan derivate in cardiac

patients taking Warfarin following extraction of teeth. The study was conducted on 20 patients with an age range of 36 to 62 years. The patients who had an International Normalized Ratio (INR) more than 3.5 were excluded from the study. All the extractions were performed under local anaesthesia with minimal trauma to surrounding soft and hard tissues. Group A comprised of PRF in freshly extracted sockets while Group B comprised of sockets with HDD following extraction of teeth. There was no delayed bleeding in all cases and complete haemostasis was achieved. However, group A patients showed accelerated healing while Group B patients showed retarded healing similar to our study which shows accelerated healing in PRF group while delayed healing in chitosan group. The study concluded that PRF has good haemostatic properties and it accelerates tissue healing and wound closure which leads to a quick recovery without any painful events in the post-operative period while HDD has excellent haemostatic properties [24].

Manzoor Mohammad Dar et al conducted a prospective study to evaluate the effect of PRF in healing of mandibular third molar extraction sockets. The two groups had no difference in the age, gender and type of impaction. The study concluded that the application of autologous PRF gel has a beneficial effect on healing of extracted mandibular third molar sockets[13]. Similar findings were seen in the study conducted by Faez Saleh Al-Hamed et al. they concluded that PRF could reduce alveolar osteitis, pain and analgesic consumption following removal of impacted lower third molars. [22]

Chitosan dental dressing has an overall cationic charge since it is a polymer with a number of basic amino groups at the acidic pH. The cationic charge is due to presence of primary amines on the molecule that helps them in binding.

Conventional agents are effective in controlling post-extraction bleeding but they do not hold true in every situation. In our study, the resultant time to achieve haemostasis was shorted when ADD was used compared with PRF highlighting the efficacy of ADD in achieving haemostasis earlier. A scaffold for red blood cells for its binding capacity by the ADD. They aggregate under electrostatic attraction and the adaptation within the socket providing a frictional lock when placed under finger pressure. According to Cunha-Reis et al, ADD is a chitosan derived material with cell adhesion potential. Shen et al in their study stated that growth factors are released from human platelets stimulated by chitosan exposure, which can explain better healing observed with Axiostat Dental Dressing. Klokkevold et al stated that chitosan facilitates the bone formation, and it potentiates the differentiation of osteoprogenitor cells. The study conducted by Klokkevold also showed minimal pain and complications in the study group compared with the control group owing to the anti-bacterial properties of chitosan providing a barrier against wide range of oral microbes and early haemostasis. The results confirm the use of Axiostat Dental Dressing post-extraction for preventing post extraction bleeding in patients on oral antiplatelet drugs as well as patients with increased bleeding tendency. [35]

In our study, the mean time taken to obtain hemostasis in patients placed with Axiostat in the socket after extraction was 46.51±13.70 seconds while the time taken for obtaining hemostasis in patients placed with PRF in the socket post extraction was 124.05±18.43 seconds. There was a statistically significant difference between the patients treated with Axiostat in the socket after extraction and PRF in the socket post extraction. The time taken by Axiostat groups was significantly less as compared to PRF group. Thus, Axiostat proves to be better in controlling haemostasis over PRF.

Akshat Gupta et al conducted a study that comprised of extraction of asymptomatic symmetrical mandibular third molars in 27 patients. Chitosan dental dressing was placed in the extraction socket on the test side. On comparing the wound healing with control site, observation of lamina dura and density of extraction socket were noted. All at time intervals, test group showed more pain than control sites. However, test group was better in terms of wound healing when compared with control extraction sites. Healing of unerupted tooth socket following extraction was not as good as the erupted tooth socket following extraction. At 2nd week, only 3 sites in control group showed better radiographic findings while 12 sites showed better radiographic findings in chitosan group. On follow-up, only 4 sites in control group showed improved bone formation while 14 sites showed improved bone formation in chitosan group. All the erupted teeth group showed better healing and improved radiographic findings at 2nd and 3rd month than unerupted teeth. Chitosan not only achieves haemostasis in shorter duration but also helps in early osteogenesis in erupted tooth socket after extraction. The study conducted by Akshat Gupta et al concluded that chitosan improves healing of extraction socket in erupted tooth contrary to our study. [33]

Similar findings to Akshat Gupta et al, Pippi et al. evaluated the efficacy of HDD after tooth extraction in patients with INR lower than 3.5 who were on oral anticoagulant therapy. Hemcon dental dressing (HDD) seems to reduce post-operative side effects and accelerates soft tissue healing contrary to our study. [37]

SUMMARY

Topical hemostatic agents have been widely used in oral and maxillofacial surgery to enhance clot formation in the extraction socket and their effectiveness is well documented in various clinical studies. There may be a lot of scope for expansion in contemporary oral and maxillofacial surgery but the dentoalveolar surgery remains the backbone of most practices. The surgical area offers efficient delivery of care right from the accurate diagnosis, effective amount of anesthesia with skilled surgical technique. It also involves the sequence of the normal events following extraction of a tooth which results in a healed extraction socket with no untoward sequelae. The preservation of hard tissue volume and alveolar architecture is possible due to recent advances of bioactive substances. These bioactive glasses or rapidly resorbing ceramics are placed in the freshly extracted socket and undergo a series of events to preserve the hard tissue architecture. However, an added cost of these materials are considered in routine practice of exodontia.

The most widely used agents in oral and maxillofacial surgery to enhance clot formation immediately in the extraction sockets are topical hemostatic agents. It is well documented in the literature about the use of topical prophylactic chemical agents that are placed in the extraction sockets. The goal in using these additional agents is to achieve hemostasis in short duration and maximum regeneration of bone with minimal post-operative pain with an acceleration of healing.

There are three highly integrated and overlapping phases involved in healing of an extracted socket. The first phase is called as inflammatory phase which is responsible for blood clot formation and inflammatory cell migration. The second and third phases are proliferative phase and modelling/remodeling phase respectively where the periodontal ligament (PDL) cells, blood cells from the extraction socket and bone marrow mesenchymal stem cells (BMSCs) play an important role in healing.

An experimental study was designed to evaluate platelet rich fibrin versus chitosan dental dressing in patients undergoing Bilateral Mandibular molar teeth extractions. Patients were selected according to the inclusion and exclusion criteria. The sites and allocated treatment were randomized as per simple block randomization list generated by SEALED ENVELOPE SOFTWARE. The two treatment groups A and B, the sites right and left and the list length 45 were fed in the software and the block size 4 was used. The software generated block randomization list of 45 patients and treatment was allocated to a site.

Group A- Platelet Rich Fibrin formed from patient's own blood were packed in extraction socket and it was secured with a loose figure of 8 suturing.

Group B- Chitosan dental dressing into the extraction socket at the height of crestal bone with direct finger pressure after extraction with a loose figure of 8 suturing was done.

All extractions were done by the same examiner. Time to achieve hemostasis was recorded using a stopwatch. After achieving hemostasis, post-operative instructions were given, and medications were prescribed. On the follow up visit, the 7^{th} day, healing of extracted socket was assessed **by Landry, Turnbull and Howley** scores by the second examiner. During the same visit, extraction of the contra-lateral side was performed. The healing of the extracted socket was assessed on third visit which is 7^{th} post-operative day of the second extracted site by the second investigator.

Overall, the results revealed platelet rich fibrin and chitosan dental dressing (Axiostat) were comparable in terms of time taken to achieve hemostasis and the healing of the extracted socket. Axiostat dental dressing stood better in terms of time taken to achieve hemostasis. However, Platelet rich fibrin initiated its action early in terms of healing of the extracted socket over the Axiostat dental dressing sites for extraction of mandibular molars.

CONCLUSION

Within the limitations of the study, it can be concluded that an improvement in time of achieving hemostasis immediately after the extraction of teeth was observed with Axiostat dental dressing topical agent whereas better healing of the extracted socket on 7^{th} post-operative day was achieved when Platelet rich fibrin was placed in the freshly extracted sockets.

Limitation of the study

Perception regarding the healing of an extracted socket is a subjective parameter. The perception may vary from person to person, despite using a standardized index by Landry, Turnbull and Howley scores.

Future recommendation

A larger sample size is required to further validate the results of the study.

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TABLES

Table No. 1: Randomization

block identifier	block size	sequence within block	treatment	Site
1	4	1	Group A	Right
1	4	2	Group A	Right
1	4	3	Group B	Right
1	4	4	Group B	Right
2	4	1	Group B	Right
2	4	2	Group A	Right
2	4	3	Group A	Right
2	4	4	Group B	Right
3	4	1	Group B	Right
3	4	2	Group B	Right
3	4	3	Group A	Right
3	4	4	Group A	Right
4	4	1	Group B	Right
4	4	2	Group B	Right
4	4	3	Group A	Right
4	4	4	Group A	Right
5	4	1	Group B	Right
5	4	2	Group A	Right
5	4	3	Group A	Right
5	4	4	Group B	Right
6	4	1	Group B	Right
6	4	2	Group A	Right
6	4	3	Group A	Right
6	4	4	Group B	Right
7	4	1	Group B	Left
7	4	2	Group A	Left
7	4	3	Group A	Left

7	4	4	Group B	Left
8	4	1	Group A	Left
8	4	2	Group B	Left
8	4	3	Group A	Left
8	4	4	Group B	Left
9	4	1	Group B	Left
9	4	2	Group A	Left
9	4	3	Group B	Left
9	4	4	Group A	Left
10	4	1	Group B	Left
10	4	2	Group A	Left
10	4	3	Group B	Left
10	4	4	Group A	Left
11	4	1	Group A	Left
11	4	2	Group B	Left
11	4	3	Group A	Left
11	4	4	Group B	Left
12	4	1	Group B	Left
12	4	2	Group A	Left
12	4	3	Group B	Left
12	4	4	Group A	Left

Table no. 2 - Descriptive data regarding age of the patients in the study

Age group (years)	Frequency(n)
18-22	8
23-27	10
28-32	7
33-37	9
38-42	6
43-47	3
Total	43

Table no. 3- Descriptive data regarding gender of the patients in the study

Gender	Frequency
Male	23
Female	20
Total	43

Table no. 4 - Descriptive data of the mean time taken for obtaining haemostasis in both the groups

Groups	N	Minimum	Maximum	Mean	Std. Deviation
Axiostat Hemostasis Time	43	21	78	46.51	13.700
PRF Hemostasis Time	43	80	160	124.05	18.438

Table no. 5 - Difference between the groups with respect to mean time taken for obtaining haemostasis

Groups	N	Mean	Difference	t value	Significance (p)
Axiostat Hemostasis Time	43	46.51	77.53	22.134	**<0.0001***
PRF Hemostasis Time	43	124.05			

Table no. 6- Descriptive data of the frequency of healing scores in both the groups

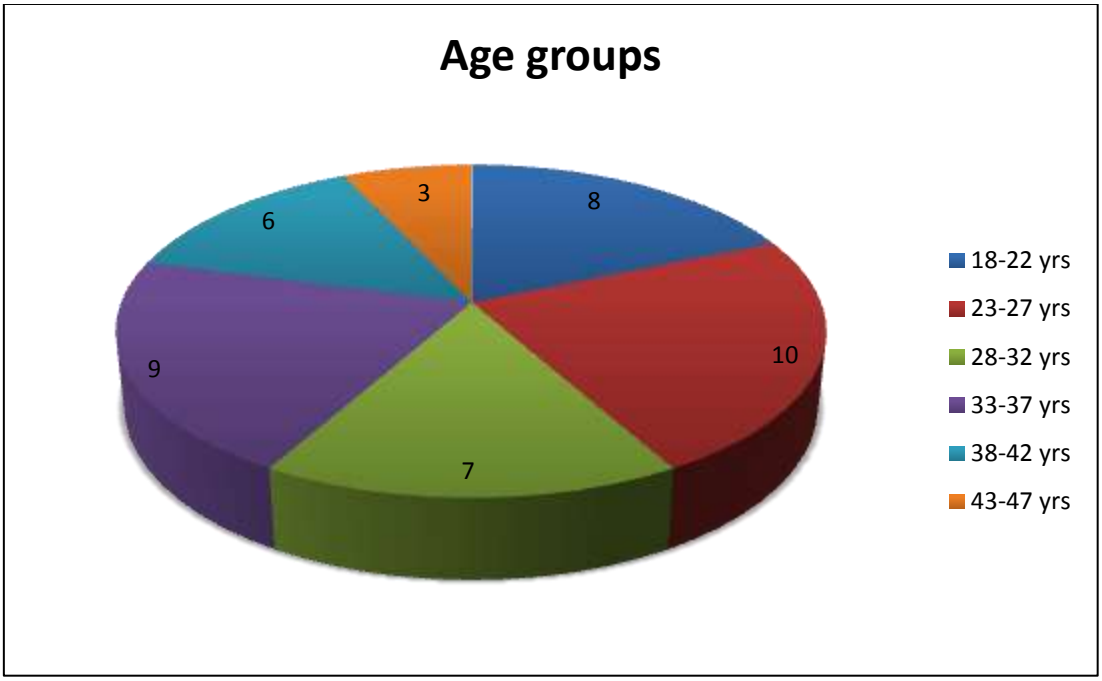
Healing score	Axiostat group		PRF group	
	Frequency	Percentage	Frequency	Percentage
1	2	4.7	0	0
2	33	76.7	0	0
3	8	18.6	23	53.5
4	0	0	20	46.5
5	0	0	0	0

Table no.7 - Difference between the groups with respect to healing scores

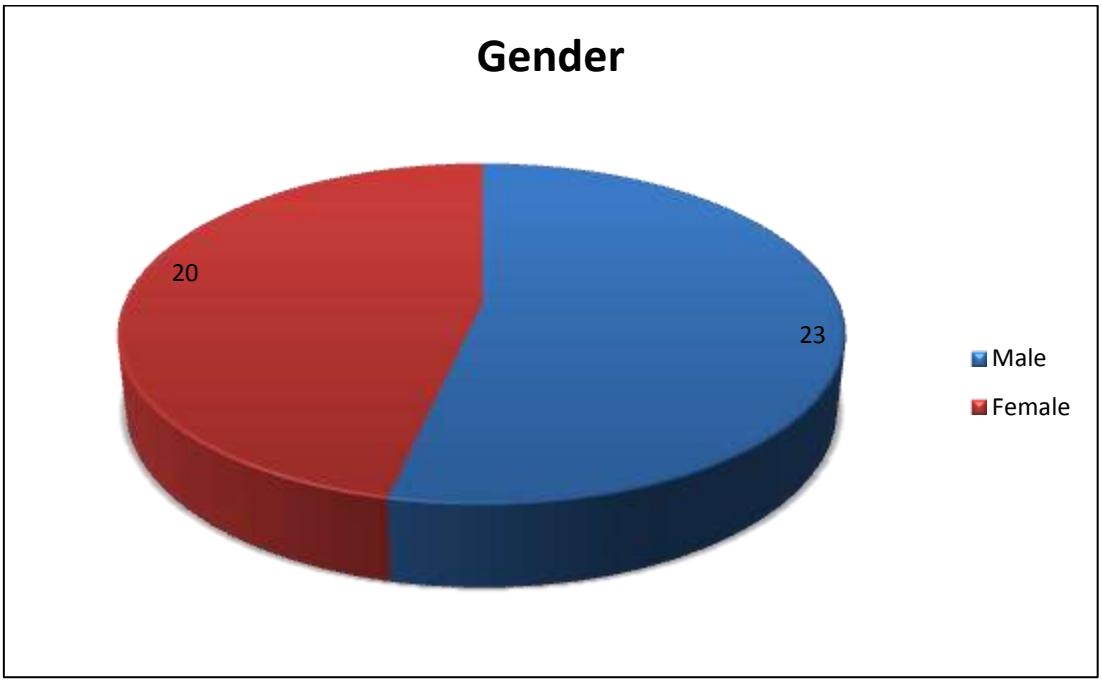
Groups	N	Mean Rank	Mann-Whitney U value	Significance (p)
Axiostat	43	24.14	92.00	**<0.0001***
PRF	43	62.86		

GRAPHS

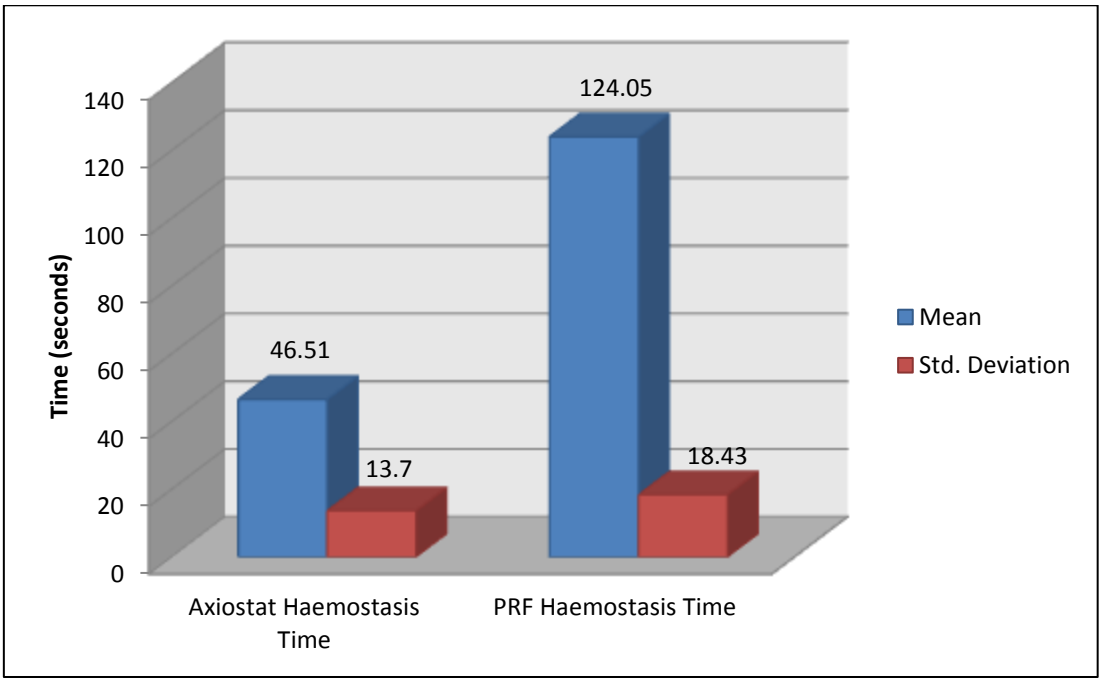
Graph no.1- Pie diagram representing number of patients according to age group



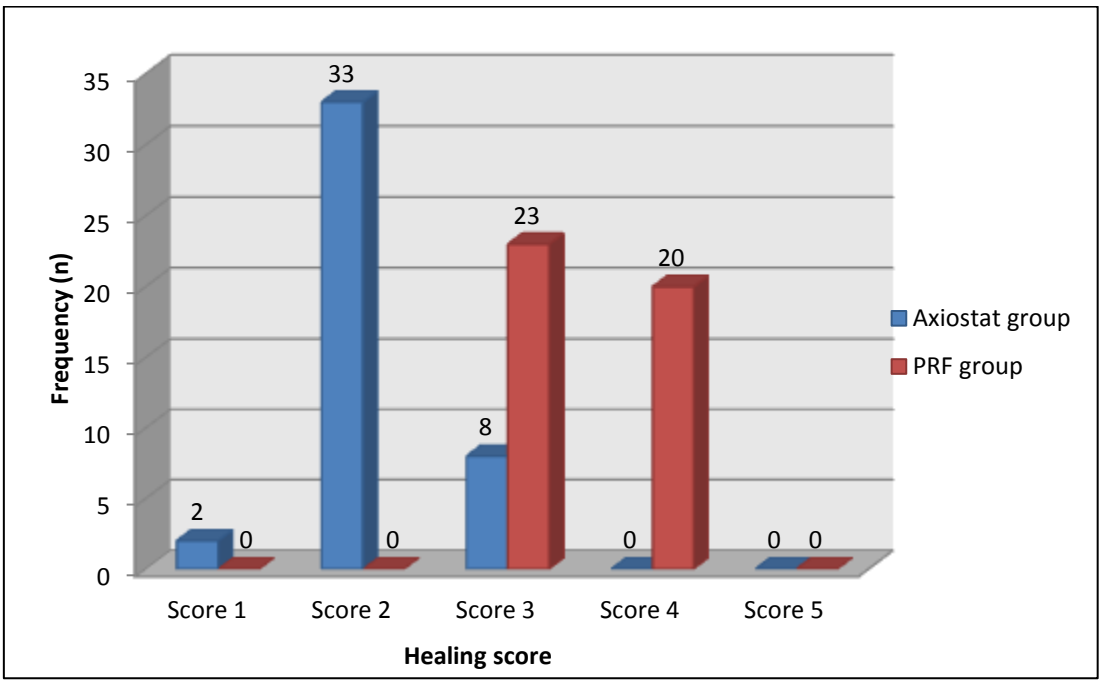
Graph no.2- Pie diagram representing number of males and females in the study



Graph no.3- Bar diagram representing haemostasis time in Axiostat and PRF groups



Graph no.4- Bar diagram representing healing scores in Axiostat and PRF groups



ANNEXURE- I

CASE HISTORY PROFORMA

Case number-

Date-

Name-

Age/Sex-

Registration No-

Address-

Education-

Occupation-

Chief Complaint-

History of present illness –

Cause of tooth extraction-

- Caries
- Periodontitis
- Orthodontic extraction
- Fractured tooth

(Graded as “1”, “2” ,“3” and “4” respectively.) Past Medical History-

Past Dental History-

Drug Allergy History-

Family History

Personal History-

- Diet
- Oral habits
- Sleep
- Oral hygiene Examination-

Extra-oral examination:

- Facial Symmetry - TMJ
- Lymph nodes

Intra-oral Examination:

- Teeth present - Missing teeth

- Root piece
- Occlusion
- Caries/attrition/abrasion/erosion/abfraction - Mobility
- Others

Diagnosis-

Radiographic investigations: IOPA, OPG, Other investigations:

Advice:

ANNEXURE - II

ASSESSMENT FORM

Duration required for post-operative hemostasis was evaluated using stopwatch

Healing was evaluated on 7th day using the standardized index by Landry, Turnbull and Howley scores.

Healing Index	Score	Tissue Color	Response to Palpation	Granulation Tissue	Incision Margin
1	Very Poor	>=50% Gingiva Red with Suppuration	Bleeding	Present	Not Epithelized
2	Poor	>=50% Gingiva Red	Bleeding	Present	Not Epithelized with Connective Tissue Exposed
3	Good	>=25% And<50% Of Gingiva Red.	No Bleeding	Absent	No Connective Tissue Exposed
4	Very Good	<25% Of Gingiva Red	No Bleeding	Absent	No Connective Tissue Exposed
5	Excellent	All Tissue Pink	No Bleeding	Absent	No Connective Tissue Exposed

ANNEXURE-III

INFORMED CONSENT FORM (Confidential)

''Platelet rich fibrin Versus Chitosan dental dressing in patients undergoing mandibular teeth extractions – A prospective split mouth study.''

वैयक्तीक माहिती

रूग्णाचे नाव :
वय/लिंग :
पत्ता :

दिनांक :

मोबाईल नंबर :

मी कबूल करतो की डॉक्टरांनी मला या संशोधन प्रकल्पाबद्दल समाधानकारक माहिती दिली आहे. मी माझ्या एक्स-रे, छायाचित्रे, इंप्रेशन आणि आवश्यकतेनुसार अन्य तपासण्या करण्यास सहमत आहे. मी या प्रकल्पात भाग घेण्यास सहमती देतो आणि या चाचणीच्या कालावधीत कोणतेही अन्य प्रकल्प एकत्रित करणार नाही. मला डेन्टल हॉस्पिटल किंवा इतर ठिकाणी दिलेल्या भेटीची तारीख आणि वेळ सांगितली आहे. मी डॉक्टर आणि पॅरामेडिकल कर्मचा-यांना सर्व बाबतीत सहकार्य करेल. या अभ्यासात मी माझ्या सहभागाचे निकाल प्रकाशित करण्यास परवानगी देतो. मला कोणतीही नुकसान भरपाई दिली जाणार नाही. असे करण्यासाठी कोणतेही कारण न देता मला कोणत्याही वेळी या संशोधन प्रकल्पातून बाहेर पडण्याचा अधिकार मिळालेला आहे. मी या अन्वये केलेल्या चाचणीत सहभागासाठी माझी संमती नोंदवित आहे.

_____	_____	_____	_____
१) रूग्णाचे नाव	स्वाक्षरी	तारीख	वेळ
_____	_____	_____	_____
२) साक्षीदाराचे नाव	स्वाक्षरी	तारीख	वेळ
_____	_____	_____	_____
३) डॉक्टरचे नाव	स्वाक्षरी	तारीख	वेळ

MASTER CHART

Patient No.	**Age**	**Gender**	**Group A Axiostat**		**Group B PRF**	
			Hemostasis (Time)	Healing score	Hemostasis (Time)	Healing score
1	37	M	74 secs	2	154 secs	3
2	25	M	24 secs	2	122 secs	4
3	19	f	54 secs	3	142 secs	3
4	39	F	53 secs	2	160 secs	4
5	42	F	43 secs	3	85 secs	4
6	31	M	45 secs	2	80 secs	3
7	25	F	32 secs	2	102 secs	4
8	29	M	34 secs	2	136 secs	3
9	20	F	42 secs	2	118 secs	3
10	30	F	66 secs	3	143 secs	4
11	39	M	73 secs	2	102 secs	3
12	44	M	36 secs	2	132 secs	3
13	34	F	39 secs	3	131 secs	4
14	23	M	48 secs	2	98 secs	4
15	37	F	53 secs	2	115 secs	3
16	35	M	51 secs	2	122 secs	4
17	42	M	32 secs	1	108 secs	3
18	33	M	33 secs	2	129 secs	3
19	18	F	78 secs	2	147 secs	4

20	24	F	46 secs	2	120 secs	3
21	27	M	28 secs	2	107secs	4
22	22	F	49 secs	2	124 secs	3
23	27	F	25 secs	3	104 secs	3
24	30	F	53 secs	2	141 secs	3
25	37	F	46 secs	2	104 secs	4
26	44	M	55 secs	1	123 secs	3
27	26	M	51 secs	2	128 secs	4
28	41	F	49 secs	3	133secs	4
29	29	M	59 secs	2	139 secs	3
30	28	F	21 secs	2	107 secs	3
31	22	M	39 secs	2	149 secs	4
32	19	F	49 secs	2	120 secs	3
33	37	M	45 secs	3	142 secs	4
34	36	F	29 secs	2	127 secs	4
35	25	M	52 secs	2	149 secs	3
36	22	M	34 secs	2	133 secs	3
37	26	M	76 secs	2	119 secs	3
38	42	M	42 secs	3	103 secs	4
39	32	M	52secs	2	107 secs	4
40	43	F	50 secs	2	125 secs	4
41	24	M	57 secs	2	137 secs	3
42	33	F	39 secs	2	146 secs	3
43	18	M	44 secs	2	121 secs	4