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Evaluation of Post Extraction Bleeding Control by Haemostatic Agent Coated Gauze Versus Standard Gauze in Dentalextraction Cases - An invivo Study

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Abstract: ***Background: Bleeding is more common problem encountered by surgeons of various specialities. Different types of bleeding control methods are available around the world for different types of surgery. Various haemostatic agents are available for different types of surgery. One haemostatic agent that is used in Neurosurgery may not be applicable to maxillofacial surgery and vice versa. So in order to find a haemostatic agent that is used in dental extraction cases that should be of antimicrobial, antihygroscopic, better handling property at the same time with risk benefit and cost benefit ratios simultaneously with no systemic absorption, only one haemostatic agent is presently available in the Indian market. Objectives: The present study was undertaken to evaluate the post extraction bleeding control by Feracrylum (haemostatic) agent coated gauze versus standard gauze (10 x 10 cm) in dental extraction cases. This study also investigate the efficacy of Feracrylum over gauze in post extraction wound healing and antimicrobial (antibacterial & antifungal) property. Methods: Ten patients were included in the study. Feracrylum coated gauze and standard gauze of 10x10cms is used in group I and group II patients. The patients were referred from the various departments for therapeutic dental extraction. Extraction of teeth in the right upper guardant is compared with extraction of teeth in the left upper guardant or extraction of teeth in the right upper guardant is compared with extraction of teeth in the right lower guardant and vice versa. Group I patients after extraction was placed with gauze of 10 x 10 cms over extraction socket and checked for bleeding control at 2 minutes and at 5 minutes. Group II patients after extraction was placed with Feracrylum Haemostatic agent coated gauze in the extraction socket and bleeding was noted at 2 minutes and at 5 minutes. Results: The results showed a statistically significant difference in the outcome of bleeding control between two groups and the patients with Feracrylum coated gauze responded to the procedure well. Post extraction wound healing is also better among the Feracrylum coated gauze administered patients. There was no difficulty in control of bleeding encountered in both the groups. Conclusion: It may be concluded that Feracrylum gives better results in patients with respect to control of bleeding. Standard gauze also control bleeding but at a later time than Feracrylum administration. Regarding past extraction wound healing, antibacterial and antifungal properties with no systemic absorption along with risk benefit, cost benefit and better handling property, Feracrylum is the drug of choice for haemostatic action in dental extraction cases.***

Keywords: haemostatic agent, feracrylum, post extraction bleeding

1. Introduction

To be aware of the process of hemostasis and thrombosis is decisive to the treatment and stabilization of a patient undergoing surgical procedure.

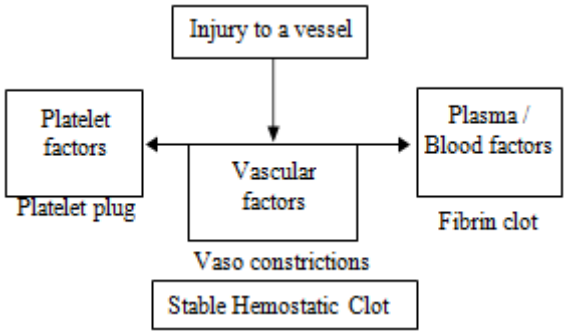
"Hemostasis" shortly denotes "the Arrest of bleeding". Hemostasis is more than that

In Surgery hemostasis is about

- Bleeding
- Clotting
- Timing
- Balance between bleeding and clotting.

Hemostasis can be defined as "a tightly regulated process that maintain the blood flow through the vasculature simultaneously as a thrombotic response to tissue damage occurs."

Maintaining hemostasis requires a complex interaction of vessel wall. Platlets, coagulation and fibrinolytic systems.



The synergy of factors that contribute to normal hemostasis[1].

There are two stages of hemostasis: Primary and secondary. Primary hemostasis begins suddenly after endothelial disruption and involves vasoconstriction, platelet factors and formation of soft aggregate plug. During secondary hemostasis soft plat let plug is stabilized to form a clot.

Then a coagulation cascade starts with a series of dependent reactions and finally thrombin converts a soluble plasma protein fibronogen to insoluble protein fibrin and the conversion of factor XIII to factor XIIIa. This factor along with calcium stabilizes the fibrin and results in cross linkage of the fibrin monomers, producing a stable clot [1].

During in dental extraction procedures, it is important to maintain a fine balance between bleeding and clotting, so that blood continues to flow at the extraction site without excessive loss of blood, for optimum surgical outcome.

Alveolar Osteitis is a well known complication after extraction or surgical removal of tooth. The exact etiology of Alveolar osteitis is not well understood. Birn's series of articles gives more information [2-5]. The etiology of (Alveolar osteitis) is increased local fibrinolysis leading to disintegration of clot. The fibrinolysis is the result of plasminogen pathway activation, which can be accomplished via direct (physiologic) or Indirect (non – physiologic) activator substances. In order to avoid alveolar ostetis (dry socket) in future after dental extraction, clot Stabilization is very important. [2-5]

If the clot disintegrates, there is more chance for the extraction site more prone for infection and alveolar osteitis (dry socket).Wound healing is also delayed if there is more loss of blood. Birn suggested antibacterial and antifibrinolytic theory. Both theories are important for to prevent infection and alveolar osteitis.

The following are several advantages of effective haemostasis after extraction. Reduced Procedure (dental extraction) time, decreased morbidity and mortality (may arise), early disposal of cases. Stabilization of the clot.

The haemostatic agent which we are going to use in this research purpose must be Antifibrinolytic and Antibacterial. Effective hemostasis after extraction can offer various advantages to the patient, surgeon, and health care facility. Surgeons have different options to control bleeding including mechanical, thermal techniques as well as pharmacotherapies and topical agents in minor and major surgeries. The use of this agent (Feracrylum) can be used in surgeries to control bleeding if this agent is satisfied in this research.

The conventional techniques to control surgical bleeding in major surgeries has led to some disadvantages and or might endanger vital structures. They can also produce necrotic areas with increased likelihood of infection and impaired healing. But in this research this is a minor surgical procedures which is performed by every dental surgeon, so there is necessity for a hemostatic agent which satisfies the dental surgeon in every aspect to be used after dental extraction. If a hemostatic agent which controls blood flow to satisfied level, then the confidence level of surgeon in dentistry is adequate to perform extraction.

The ideal hemostatic agent should be easy to use with good risk-benefit and cost-benefit ratios.[7] Such as agent should be easily applicable, highly predictable in creating hemostasis, biocompatible and must not have an side or adverse effect on extraction site and wound healing should have occurred well on that area without any discomfort to the patient'.

Feracrylum is a drug known for arrest of bleeding and it is approved by central drug standard control organization in 2005.As a result it is available in the Indian market and is presently available under various brand names. It is used in humans and it is tried in various surgeries. It is used in hypospadias surgeries for infants and its only indication is being the arrest of bleeding. [7]

Capillary oozing is commonly encountered problem in the branch of oral and maxillofacial surgery. Capillary bleeding can occur during procedures from simple dental extraction and also in major maxillofacial procedures and during maxillofacial reconstruction of damaged parts of the reconstructive areas.

It also cuts off supply of oxygen and nutrients to the surgical site area leading to impaired wound healing and surgical site Infection in the area of interest.

Restoring the capillary branch ensures reduced inflammation fasten wound healing and reduces infection.

Therefore the tissue repair, coagulation and inflammation are closely related.

Healing of wound is more complex series of biologic events. [24]

The ability of damaged tissue to reconstruct and repair is a response to life itself.

The healing of wound and all of tissue has an almost identical repair process, but it may be modified due to extrinsic and intrinsic factors.

Constant research is under review to gain knowledge of biologic events and dynamic events sequence behind healing and also to enhance heeling phase.

2. Materials &Methods

Study design
This is an comparative interventional study for evaluating and comparing the post-extraction bleeding stoppage by using hemostatic agent coated gauze versus standard gauze in dental extraction.

Study setting
All patient who seems to fit the Inclusion and exclusion criteria would be recruited.

The patient is recruited to the minor OT, Department of Maxillofacial surgery, Sree Mookambika Institute of Dental Sciences, Kulasekharam.

Approximate total duration of the study:
One month

Number of groups to be divided:-
Two groups

Description of the groups:
Ten subjects reporting for therapeutic dental extraction is taken in to consideration. One group is study group and the another is control group. Extraction is carried out either in the right and left quadrant of the same jaw or between upper and lower jaw. Whatever may be the teeth extracted, both groups are present in same patient only.

Group I – standard gauze is placed in extraction socket
Group II – feracrylum coated gauze is placed in extraction socket.

Sample size of each group
10 patients

Total sample size of the study
10 patients

Scientific basis of sample size used in study

Sample size is calculated from

$$n = \frac{2pq(z\alpha X z\beta)^2}{(p1-p2)^2}$$

Where $P = \frac{P_1+P_2}{2}$

q =1-P
P_1 = proportion of 1 group. P_2 = proportion of 2 group.
$Z\alpha = 1.96$
$z\beta = 0.84$.

From the study (10)

$$n = \frac{2X100X48(1.96X0.84)^2}{(100-48)^2}$$

n = 10.842532

So sample size is 10 cases

Sampling technique need:
A systemic random sampling technique is used.

Selection Criteria

Inclusion criteria
Patients were selected from those who were referred for extraction of one of their mandibular molars and premolars from the department of orthodontics.

- Healthy male and female.
- Age between 18 - 55 years.
- Patient indicated for therapeutic extraction on same side and contralateral side of the same quadrant or between extraction of teeth in upper and lower jaw.

Exclusion criteria

- Known case of blood disorders.
- History of intake of asprin or other drugs that interfere with coagulation in the last one month.
- No acute or uncontrolled infection or inflammation at the surgery site.
- Patient having large periapical lesion requiring open surgery were excluded.
- No malignancy at the surgical site.
- No history of exposure of radiation at the extraction site.
- Not using corticosteroid and contraceptive drug for the past one month.
- Participant should not have smoking habit.
- Must not have hypertension, diabetes, thyroid disorder.

Placebo used:

- No placebo was used in this study

Drug used:

- Feracrylum Gel

Drugs/Medical devices used:

- Drugs / medical devices used in for newer indication Feracrylum is commonly used as a haemostatic agent.
- Drugs / medical devices used in for first time in human beings.

It is already used in human beings

- If used for newer Indication / first time in human beings, whether the permission obtained from the drug controller general of India (DCGI)
  Feracrylum drug is approved by CDSCO
- Formulation of the drug used
  Gel.
- Name of the drug / medical device used
  (Non proprietary name, Brand Name, company (Manufactures details) – Feracrylum / hemolok/ Themis Medicare)
- Dose of the drug used:
  Gel – Applied as a thin film as 1ml of gel in gauze.
- Frequency of the drug used:
  Only one time in fresh bleeding site.
  Can be used for another time if bleeding is not stopped.
- Route of the drug used:
  Applied topically.
- Duration of the drug used:
  Can be used till bleeding is stopped within physiological range
- Steps to be taken to prevent Adverse drug reaction
  Protocol instructed by Central drug standard control organisation (CDSCO) is followed.
- In case of severe Adverse drug reaction, mode of Management
  Emergency treatment available at Sree Mookambika Institute of Medical science nearby Department of Maxillofacial unit. Sree Mookambika institute of dental science.
- In case of drug related injury, agreement of compensation Agreement endorsed.
- Any other relevant details:
  Not applicable.

Parameters in this study:

- Duration of active bleeding (at two and five minutes after extraction)
- Continued bleeding.
- Cessation of the bleeding.

Methods/ technique/ instruments/reagents /kit:

- Patients whose teeth indicated for extraction by forceps were chosen.
- Adequate diagnostic procedures like iopa are taken.

Pre- operative assessment:

- Regarding absence or presence of lamina dura, Tooth position and amount of bone coverage of tooth are diagnosed.

- By removal of teeth which includes injection of local anesthesia, elevation of flap, extraction of teeth by forceps and suturing the wound.
- Standard Gauze and gauze coated with Hemostatic agent are required.

Procedure in Detail

Ten patients reported for extraction on both sides of jaws are considered. Patients requiring atleast two symmetrical teeth in both sides of the upper and lower jaw were chosen or any teeth between upper jaw and lower jaw is considered.

By selection of case for extraction of teeth eg. Molars, pre molars, the area were the teeth to be extracted was anesthetized using the solution of lidocaine 2%/ epinephrine1/80000.

The procedure was done as a simple forceps atraumatic extraction without bone removal and odontectomy with or without flap removal(in case of therapeutic extraction of premolars) in all quadrant. Both the teeth in same side and contralateral side were extracted by one practitioner only. The extraction on one side is carried out in one day and other side on another day or both sides simultaneously on one day itself.

In study group:

The formulation of drug is used in gel form and 1 ml of gel is taken and applied as a thin coating in gauze. Gauze piece coated with haemostatic agent is placed in extraction socket. Mechanical pressure was applied by instructing the patient to bite down on the gauze for two minutes. All of the extraction sites was evaluated for bleeding at two and five minutes after extractions and then the dressings were removed. As in some patients bleeding persisted, so gauze was retained until the bleeding is stopped and the wound is sutured. If suturing is not done for some cases the patient is sent home as soon as possible after confirmation of arrest of bleeding.

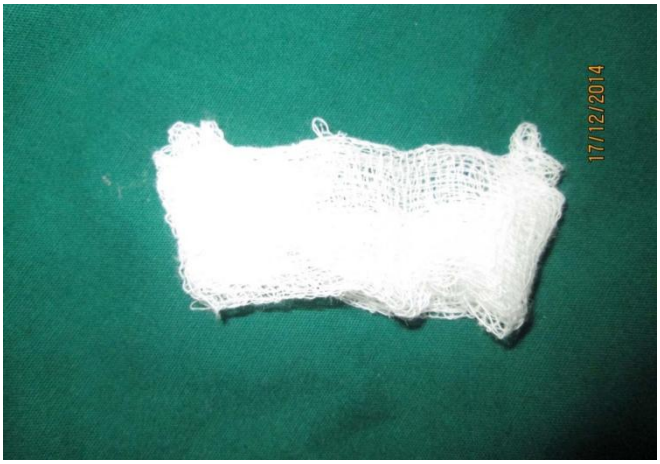
The duration of the active bleeding, continued bleeding, cessation of the bleeding were analysed. All the analysis was done by stop watch device and by surgeons observations (whether the bleeding is continued or stopped).

In control group

The standard gauze piece is placed in extraction site by asking the patient to bite down for two minute. All of the extractions sites was evaluated for two and five minutes and the duration of bleeding, continued bleeding and the stoppage of bleeding is analysed by stopwatch and by surgeons observation.

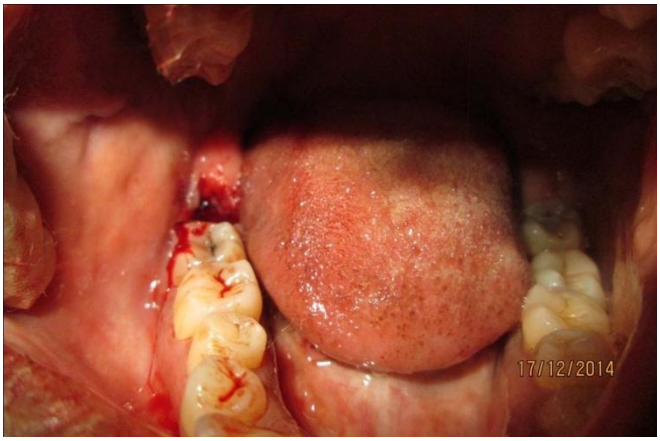
Armamentarium

Feracrylum Gel

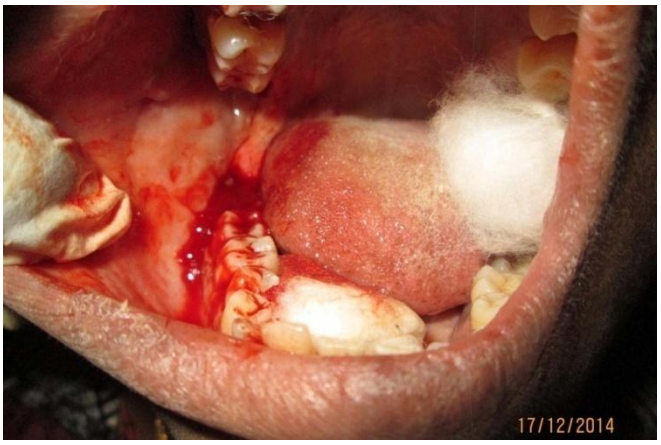


Gauze

Simple Forceps Extraction



At two Minutes



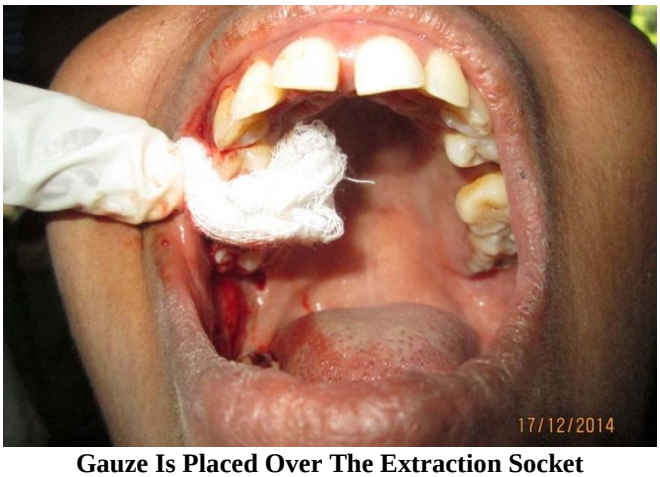
Bleeding Immediately After Extraction

At Two Minutes and Thirty Seconds

Feracrylum Gel Coated On Gauze

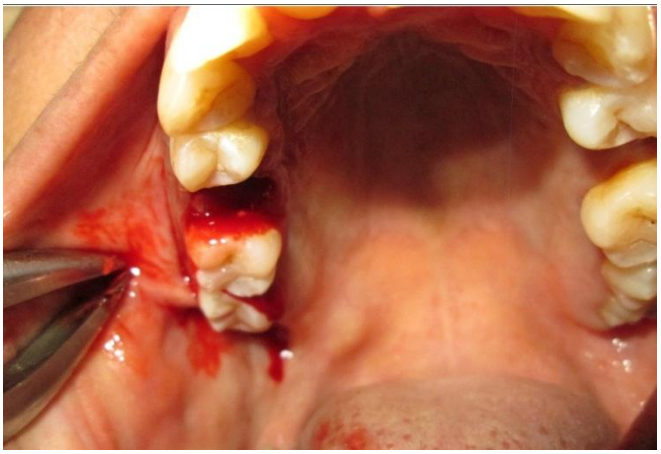
Simple Forceps Extraction

Feracrylum Gel Coated Gauze is Placed Over the Extraction Socket



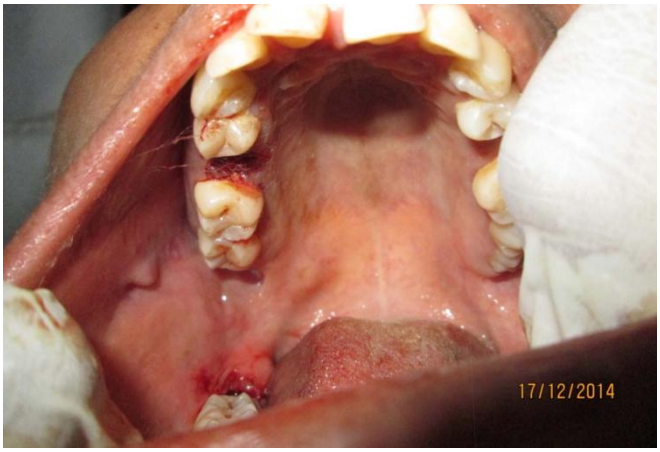
Gauze Is Placed Over The Extraction Socket

At Two Minutes



At Five Minutes

Finally Placement of Only Gauze After Five Minutes



After 10 Minutes

3. Results

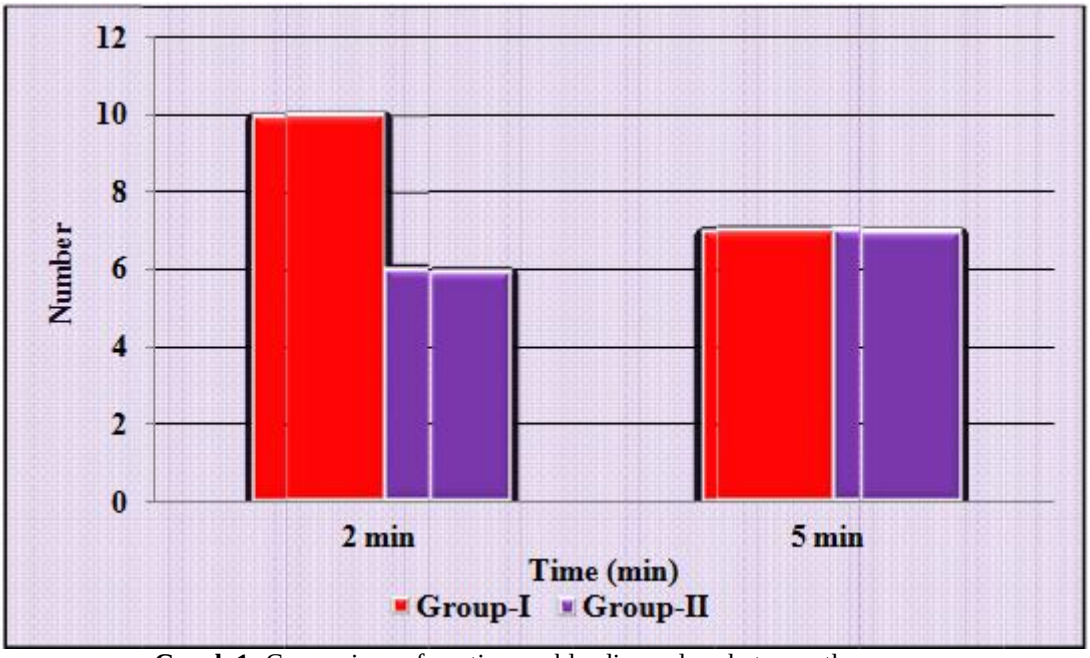
Statistical analysis

The data analyzed by SPSS (16.0) version. Unpaired t test and Chi Square test applied to find statistical significant between the groups. P value less than 0.05 ($P<0.05$) considered statically significant at 95% confidence interval.

Table 1: Comparison of continuous bleeding values between the groups

Groups	2 min		5 min	
	Number	Percentage (%)	Number	Percentage (%)
oup-I	10	100	7	70.00
Group-II	6	60.00	7	70.00

Group I – Only gauze is placed in extraction socket
Group II – Feracrylum coated gauze is placed in extraction socket



Graph 1: Comparison of continuous bleeding values between the groups

In comparison of continuous bleeding at 2 minutes feracrylum is not statistically significant with the standard gauze

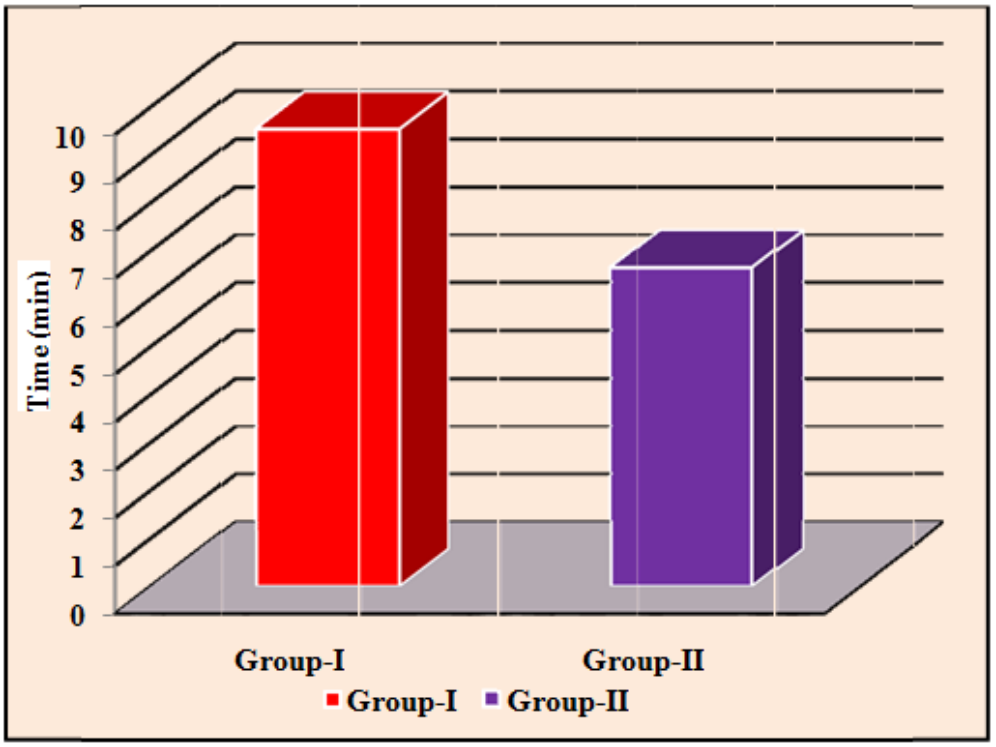
Group I – Only gauze is placed in extraction socket
Group II – Feracrylum coated gauze is placed in extraction socket

Group I – Only gauze is placed in extraction socket
Group II – Feracrylum coated gauze is placed in extraction socket

Table 2: Comparison of mean cessation of bleeding values between the groups

Groups	Cessation of bleeding (min) (MEAN±SD)	P value
Group-I	9.54±1.89	0.001
Group-II	6.65±0.96	

(*P<0.05 significant compared group-I with group-II)



Graph 2: Comparison of mean cessation of bleeding values between the groups

In comparison of cessation of bleeding, feracrylum is statistically significant with the standard gauze

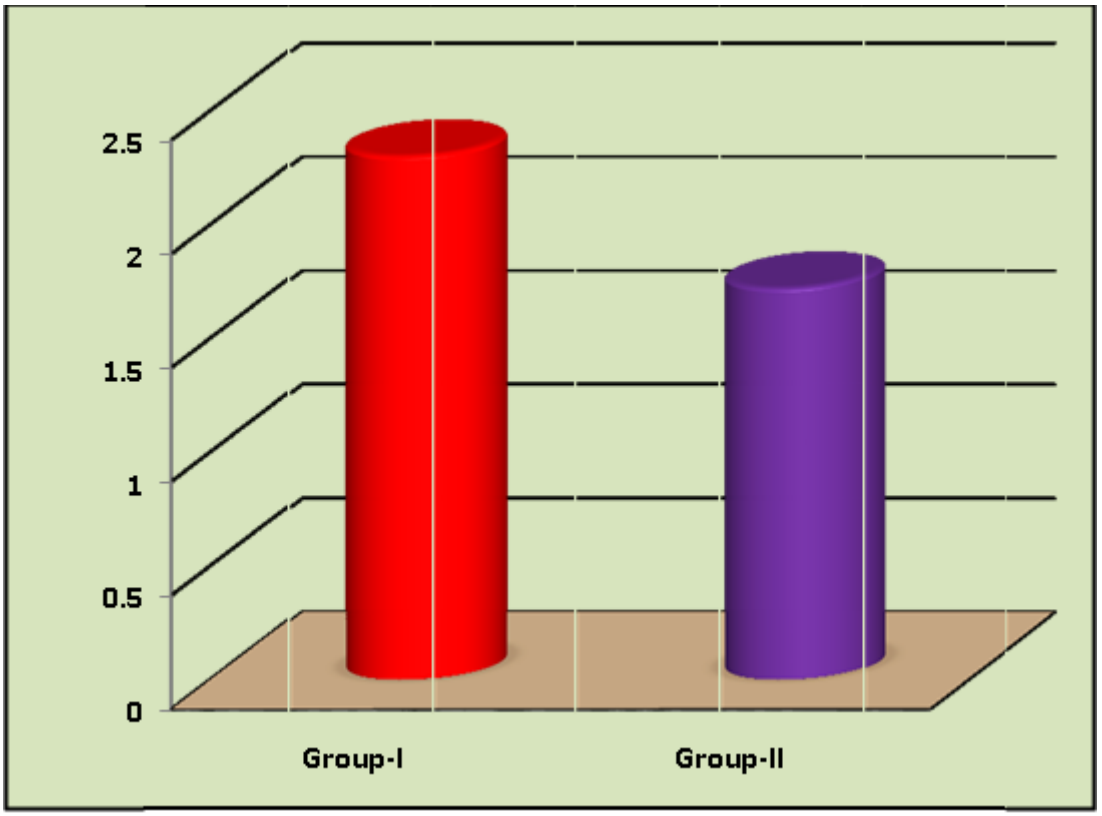
Group I – Only gauze is placed in extraction socket
Group II – Feracrylum coated gauze is placed in extraction socket

Table 3: Comparison of mean bleeding time values between the groups at 2 min

Groups	Bleeding time (min) (MEAN±SD)	P value
Group-I	2.30±0.01	0.001
Group-II	1.72±0.46*	

(*P<0.05 significant compared group-I with group-II)

Group I – Only gauze is placed in extraction socket
Group II – Feracrylum coated gauze is placed in extraction socket



Graph 3: Comparison of mean bleeding time values between the groups at 2 min

In comparison of mean bleeding time at 2 minutes feracrylum is statistically significant with the standard gauze

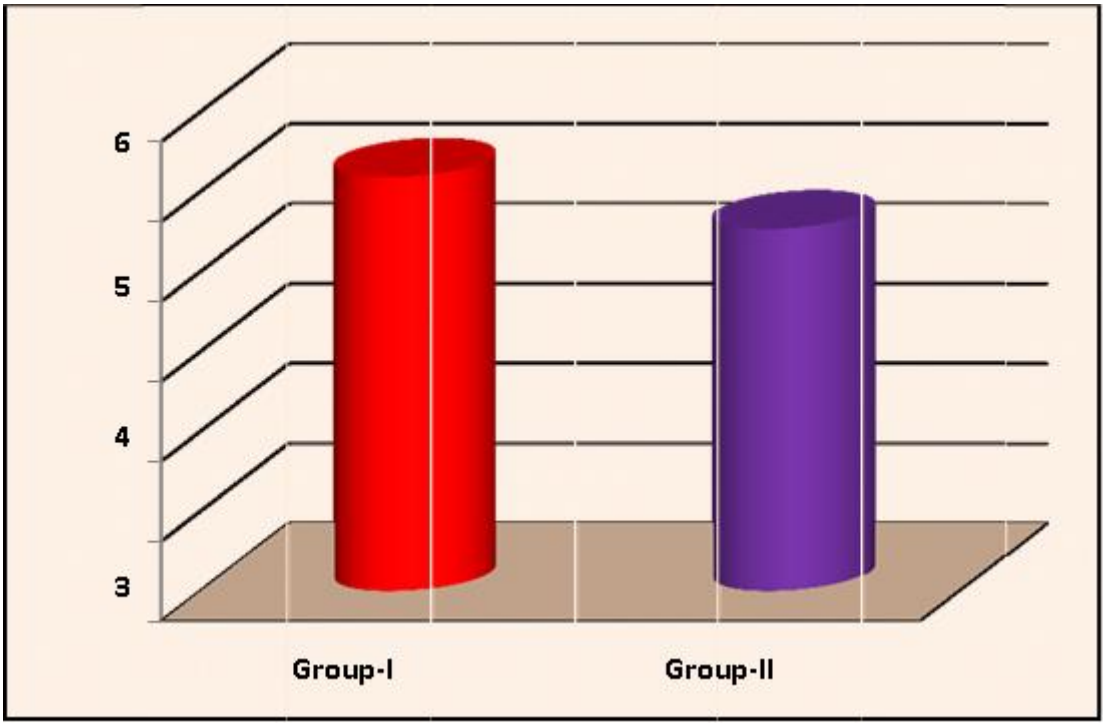
Group I – Only gauze is placed in extraction socket
Group II – Feracrylum coated gauze is placed in extraction socket

Table 4: Comparison of mean bleeding time values between the groups at 5 min

Groups	*Bleeding time (min) (MEAN±SD)*	*P value*
Group-I	5.18±0.38	**0.005**
Group-II	4.53±0.52*	

(*P<0.05 significant compared group-I with group-II)

Group I – Only gauze is placed in extraction socket
Group II – Feracrylum coated gauze is placed in extraction socket



Graph 4: Comparison of mean bleeding time values between the groups at 5 min

In comparison of mean bleeding time at 5 minutes feracrylum is statistically significant with the standard gauze

Group I – Only gauze is placed in extraction socket
Group II – Feracrylum coated gauze is placed in extraction socket

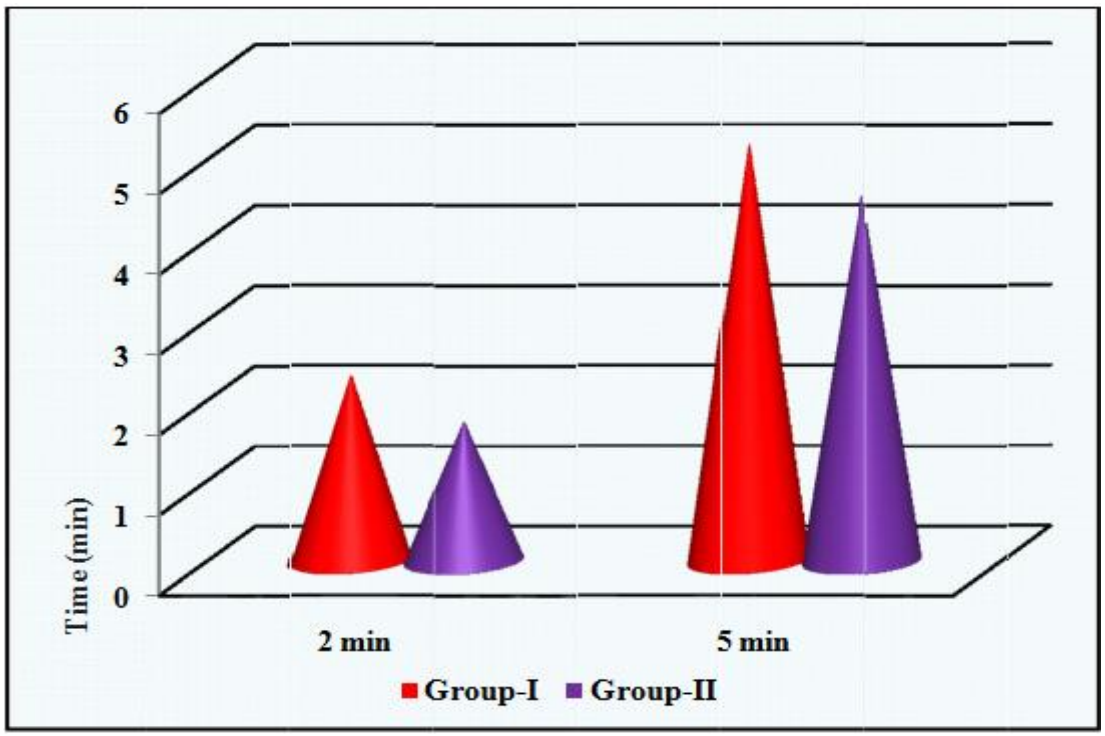
Table 5: Comparison of mean bleeding time values between the groups at different time periods

Groups	Bleeding time (min) (MEAN±SD)	
	2 min	5 min
Group-I	2.30±0.01	5.18±0.38
Group-II	1.72±0.46*	4.53±0.52*

(*P<0.05 significant compared group-I with group-II)

Group I – Only gauze is placed in extraction socket

Group II – Feracrylum coated gauze is placed in extraction socket



Graph 5: Comparison of mean bleeding time values between the groups at different time periods

In comparison between mean bleeding t me between groups at different time periods, feracrylum is statistically significant with the standard gauze

Group I – Only gauze is placed in extraction socket

Group II – Feracrylum coated gauze is placed in extraction socket

In comparison between mean bleeding t me between groups at different time periods, feracrylum is statistically significant with the standard gauze

4. Discussion

Tissue repair, inflammation and blood coagulation are closely related for required healing to occur a biologically stable union between broken tissues. The clotting factors intiate reparative changes. For healthy process to occur both fibrin deposition and fibrinolysis are linked to healing process. In addition angiogenesis was induced by fibrin degradation products and produce a wide variety of biological actions. Bleeding in oral and maxillofacial surgery is due to variety of systemic and local factors. Further negligence after post extraction both from surgeons and patients leads to problems.

With local haemostatic measures several of the problems were relieved. Of these pressure pack, suturing the socket, adrenalin pack or acrylic splint covering the socket were used. But arrest of bleeding from capillaries is sometimes difficult by above said methods where drug can be used. Various newly found agents such as thrombin, fibrin are difficult to place in extraction socket particularly in wet conditions. These agents expensive and carry the risk of viral disease transmission. Post operative bleeding is a problem in maxillofacial surgeries. In most number of times compression leads to arrest of bleeding but there are also situations where it could not be controlled. The newer hemostatic agent applied on extraction sites were the tenaxamic acid mouthwash, fibrin glue, cyanoacrylate, thrombin, microfibrillar collagen and oxidized cellulose.

Management of post extraction bleeding control after dental extraction is an important factor for completion of extraction procedures. If adequate interest is not shown it would lead to various post extraction problems. There have been various cases leading to death reported after dental extraction due to procedures that were not followed after dental extraction. Reports of various dental institutions states that there are more number of cases of dry socket and surgical site infection.

Feracrylum is a cheapest drug device for bleeding control in various parts of the body, it has been already used in humans for various purposes to control blood. It is used as post operative dressing wherever it is needed. It is used for dressings of burnsite and dressing of various types of wounds. It is used in hypospadias surgery, it is used for packing of abscess. It is used in post operative packing in epistaxis and submucous resection of nasal septum and used in oral cavity. The newest discovery in polymer research are the biodegradable and biocompatible polymers. On application exert therapeutic action, degrade and decompose in the body and are excreted out without causing toxicity or leaving toxic remnants in the body.

Feracrylum used in this research is biocompatible and biodegradable. When this gel comes in contact with serum proteins, it forms a whitish thin film form adduct gel like structure, which creates a physical barrier. This reduces bleeding from wound site and thus exerts hemostatic action.

In table 1 in comparison of continuous bleeding between group1 and group

2. In group 1 all the persons were bleeding after two minutes and 70% of case at 5 minutes.

In group 2, with hemostatic agent coated gauze only 60% of cases is bleeding at 2 minutes whereas seven cases were bleeding at 5 minutes.

In table 2 between comparison of mean cessation of bleeding values between groups. Group 1 values -9.54 ±1.89 and group 2 -6.65±0.96. There is statistically significant difference between group1 and group2.

In table 3 comparison of mean bleeding time values between two groups at 2 minutes there was a statistically significant values between two groups.

In table 4 comparison of mean bleeding time between values between groups 1 and group 2 at 5 minutes there was a statistically significant difference between groups. Group1 values 5.18±0.38 and group 2 values 4.53±0.52.

In table 5 comparison of mean bleeding time values between groups at different times period (at 2 minutes and at 5 minutes), there was a statistically significant difference between group 1 and group2.

As per the hemostatic property of the drug, feracrylum provides the ideal choice for patients after post extraction bleeding control. No reported case of post operative follow ups regarding dry socket or any surgical site infection after feracrylum was noted. This also denotes the antimicrobial and antibacterial nature of drug.

It also not absorbed in the systemic circulation due to its high molecular weight (more than 1,00,000 daltons) and hence it is not likely to affect the functions of kidney, liver, adrenal glands, cardiovascular system, haemopoetic and nervous system.

Although feracrylum is highly superior than standard gauze, the properties of standard gauze in controlling the flow of blood is acceptable. It is the best choice for patients undergoing dental extraction traditionally

But for cases that have been seen in government hospitals and primary health centers where large number of cases were

reported for extraction and only limited facilities for teeth restorative procedures is available and for the subjects with low economic conditions, feracrylum is the best drug device regarding postoperative wound healing and also early and easily disposal of cases. Clot stabilization is also of satisfactory level in feracrylum administration of drugs.

So the ideal haemostatic agent which satisfies arrest of bleeding, antibacterial and antifungal, antihygroscopic, better handling property with no systemic absorption along with better cost benefit and risk benefit ratios is Feracrylum. This drug is approved in market and by Central Drug Standard Control Organization (CDSCO).

It is very much useful in cosmopolitan and rural dentistry practice, (ie. PHC)

5. Conclusion

Within the limits of the study, the following conclusion were drawn

- Feracrylum is a haemostatic medical drug device that controls blood faster than standard dental gauze of (10x10cm) in dental extraction cases.
- Standard dental gauze of (10x10 cm) also controls blood loss but it absorbs blood. It absorbs about 3-3.5ml of blood per gauze piece.[7]
- Feracrylum coated gauze does not absorb blood. It effectively acts as a barrier.
- It forms clot stabilization to occur in order for better post-extraction wound healing after extractions.
- Due to its (Feracrylum) high molecular weight, it has not systemic absorption.
- It also has antibacterial, antifungal and ant hygroscopic phenomenon.
- It has a better handling properly.
- This drug device (Feracrylum) is suitable for dental extraction type of surgery.
- It has merits of both risk-benefit and cost benefit ratios.
- The most suitable way to control blood after dental extraction is gauze coated with feracrylum gel.

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