To Evaluate the Efficacy of Feracrylum as a Haemostatic Agent following Minor Oral Surgery

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Abstract: <u>Purpose</u>: The purpose of this study was to evaluate the versatility of Feracrylum as a haemostatic agent following minor oral surgeries, without altering the regimen of an anti-platelet drug. <u>Method</u>: The post-operative bleeding was assessed in 100 patients on anti-platelet drug following minor oral surgical procedure by comparing the Feracrylum group with the saline-soaked gauze as pressure pack. <u>Result</u>: In group 1, 100% patients and in group 2, 18% patients had ooze from the surgical site after 2 minutes and 5 minutes with the p-value of 0.012. The bleeding was significant in group 1 at 24th hr., 2nd and 3rd post-operative day with the p-value of 0.01 and 0.135, though no noticeable bleeding was detected in group 2 respectively. <u>Conclusion</u>: Introduction of Feracrylum is alchemy in oral and maxillofacial surgery to restrict the local bleeding following minor surgery in the oral cavity for those patients who are on anti-platelet drug with least systemic circulation absorption.

Keywords: Haemostasis, Minor oral surgery, Anti-platelet drug, Coagulation cascade, Bleeding risk

1. Introduction

The specialty of Oral and maxillofacial surgery is unique in its own and as the time is proceeding our surgeons around the world are striving hard to take this branch on a certain level and execute surgeries in safer environment. The procedures performed in the oral as well as maxillofacial regions are delicate and associated with numerous complications that are likely to occur post-operatively. The most common complication following any surgery is hemorrhage and this risk increases by few folds when the patient is already immunocompromised or on certain medications such as anti-platelet / anti-coagulant.

With the advancement in medical science the life expectancy of an average human being has significantly enhanced, however at an expense of developing systemic disorders such as Angina, Ischaemic heart disease, Myocardial Infarction, Stroke, Transient Ischemic attack etc. These patients with the compromised Cardiovascular System are dependent on anti-thrombotic agents², hence pre-disposed to excessive bleeding during or post-surgery. Considering the cardiovascular status of the patient and taking the delicacy of the procedure into account if the drug dosage is not manipulated prior to surgery then the result could be merely fatal. Some authors believe that these drugs should be completely stopped ere the procedures on the other hand few of them suggest continuing the drug while taking the patient under the surgery.

There are numerous local hemostatic measures are available such as use of Absorbable gel foam, Cellulose, Tannic acid, Surgicel, Pressure pack, Adrenaline-soaked gauze, Feracrylum, Tranexamic acid etc. Some of these drugs reach into systemic circulation like Tranexamic acid, Heparin, Warfarin etc. and interfere with the coagulation cascade. Feracrylum is a commercially made local hemostatic agent, which is biocompatible as well as biodegradable containing 0.05% to 0.5% of Iron manufactured by Themis Medicare limited. It is not absorbed in the systemic circulation because of the high molecular weight (500,000-800,000 Daltons), and also exhibits anti-microbial property thereby reducing the incidence of wound infection⁴.

Feracrylum works by activating thrombin which converts fibrinogen into fibrin strands and help forming a clot. It also makes a biodegradable and water insoluble synthetic complex with albumin present in the blood and create a physical barrier over the surface of the wound.

2. Material and Method

100 Patients aged between 30-55 years, who reported to the Department of Oral & Maxillofacial Surgery and underwent Minor oral surgical procedure were included in the study. All the patients were taking anti-platelet drug (with an INR < 3.5) for an underlying systemic condition and were under ASA II category. The patients were divided into 2 groups of 50 each -

Group 1 - Following the procedure pressure pack using saline soaked gauze was placed at the surgical site (Control group)

Group 2 - Following the procedure Feracrylum soaked gauze was placed at the surgical site (Test group)

The bleeding was then assessed at 2 minutes and 5 minutes immediately post procedure and at 24 hours, 2^{nd} and 3^{rd} post-operative day. Healing site was also assessed for both groups on 7^{th} post-operative day.

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<u>Criteria and scoring</u> – No bleeding - 0 Persistent ooze - 1 Persistent bleeding - 2

The statistical analysis was done for comparing both the group using **Chi-square** test.

3. Result

A total of 100 patients aged between 30 - 55 years were included in the study, of which 83 were male and 17 were female. In Group I 100% (n=50) & 86% (n=43) of patients had an ooze from the surgical site after 2 minutes and 5 minutes respectively. In group II 18% (n=9) & 4% (n=2) of patients had an ooze from the surgical site after 2 minutes and 5 minutes respectively (Table I). The p-value came to be significant (i.e. 0.012).

Numerical grading of oozing episodes at different time intervals

Table 1

	Groups	2 min		5 min					
		Number	Percentage (%)	Number	Percentage (%)				
	Group-I	50	100	43	86				
	Group-II	9	18	2	4				
	Chi-square	6.31	p-value	0.012*					

*=p-value<0.05

In group I bleeding was significant at 24 hours, 2^{nd} postoperative day and 3^{rd} post-operative day and p-value was 0.01 (Table II). In group II bleeding was not significant at 24 hours, 2^{nd} post-operative day and 3^{rd} post-operative day and p-value was 0.135 (Table III).

Group I

Table 2								
	Mean	Std. Deviation	Chi-square	p-value				
One Day	1.20	0.67						
Two Day	0.58	0.50	73.04	0.01*				
Post Op	0.00	0.00						
1	01							

*=p-value<0.01

Group II

	Table 3								
		Mean	Std. Deviation	Chi-square	p-value				
	One Day	0.04	0.20						
	Two Day	0.00	0.00	4.00	0.135(NS)				
	Post Op	0.00	0.00						
N	NG_Not Significant								

NS=Not Significant

Healing was also assessed for Group I & II and both groups showed satisfactory healing as there was no wound dehiscence or pus discharge from the surgical site.

4. Discussion

An INR values should be kept under the desired therapeutic range for the patients on anti-coagulant or anti-platelet therapy. The American Heart association and European society of Cardiology recommended that the patients with Mechanical heart valves for some underlying Cardiovascular conditions, an INR should be between 2.5 to 3.5 or 4. Excessively high INR could lead to bleeding episodes on contrary too low INR predispose the patient to Cerebrovascular accidents or thromboembolism⁵. In this study 100 patients on anti-platelet drug were included having an INR less than 3.5.

Jeffrey W Chadwick et al in his case report he has executed a case of Facial AV malformation where the selective embolization of superior thyroid artery was performed and following the extraction of lower 2nd and 3rd molars bleeding was restricted locally using digital pressure for 10 minutes and further packing the extraction socket with Gelfoam wrapped in surgicel and stabilised using cyanoacrylate. The severe bleeding stopped following the local application of the above-mentioned materials⁶. In our study bleeding was stopped locally by inserting Feracrylum soaked gauze in the surgical site. In 2018 Gauri Gupta et al did a systemic review of four articles which talked about the efficacy of hemocoagulase following dental extractions. Thev concluded that the hemocoagulase was effective in arresting the bleeding, improved healing reduced pain following dental extraction⁷.

Asma Zaib et al in 2022 did a systemic review and Metaanalysis on 430 patients taken from various databases who were given local application of Tranexamic acid in the form of mouthwash, irrigation substitutes and pressure packing with the gauze pad following dental extraction. They found that improved haemostasis was achieved following the use of tranexamic acid during the post-operative phase. We used Feracrylum in 100 patients without discontinuing the antithrombotic agent following the minor oral surgery and satisfactory haemostasis was achieved with no systemic absorption⁸.

K R Ashok Kumar et al included 30 patients aged between 18-90 years who were on an anti-coagulant therapy in the study. They used Hemcon dental dressing following minor oral surgery and found bleeding time was significantly reduced as well as great surgical wound healing was seen compared to the control group. Desirable post-operative healing was achieved in our study following the placement of Feracrylum soaked gauze in the surgical site post minor surgical procedure⁹.

In the recent times due to terrible food habits, sedentary lifestyle and many more, folks above 40 years of age are at risk of numerous systemic diseases especially compromised cardiovascular system. These patients are mostly on drugs that might interfere with the coagulation cascade and hence are at augmented risk of bleeding that could occur postoperatively. To address the problem various local and systemic haemostatic agents are commercially available that helps the surgeon accomplish their task without or with fewer complications.

Among various available styptic agents, the Feracrylum is one of the local agents that not only help in achieving the haemostasis but also plays a phenomenal role postoperatively in the healing process. We have got appreciable

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outcomes in our study and thus concluded that this material can be opted as one of the sensible options in achieving haemostasis.

5. Statements and Declarations

- Ethics Approval and consent to participate- This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Buddha Institute of Dental Sciences & Hospital, Patna. Informed consent was obtained from all individual participants included in the study.
- Consent for publication- The authors affirm that human research participants provided inform consent for publication.
- Competing Interests- The authors have no relevant financial or non-financial interests to disclose.
- Author contributions- All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by [Zaid Ali Khan], [Heera Singh], [Krishna Kishor], [Eram Anwar] and [Abhishek Singh]. The first draft of the manuscript was written by [Zaid Ali Khan] and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.
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- Availability of data and materials- The datasets generated during and/or analysed during current study are available from the corresponding author on reasonable request.

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