A Comparative Study to Evaluate the Efficacy of Antibiotic with Placental Extract Gel Versus Antibiotic Without Placental Extract Gel After Extraction

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Abstract

Introduction: Extraction is the most commonly performed dentoalveolar procedure in oral & maxillofacial surgery[1].This study was designed to compare the post extraction healing by using antibiotic with placental extract gel versus antibiotic without placental extract gel in control of pain, swelling, & wound healing.

Methodology: A study was conducted on 40 patients requiring extraction that will be selected for the study. Random allocation of 40 patients into in group a(maxilla) and group b(mandible) & their subdivision into study group and control group will be done. Preoperatively both the groups were administered Tab. Amoxycillin 1 gm orally. After the procedure application of placental extract gel will be done on the extraction site of the study group. Postoperative medication will be prescribed for both the groups. Patients will recall on 1st, 3rd and 7th days postoperatively for evaluation of pain, swelling, and wound healing.

Result: it was found that there was a statistically significant difference in the mean pain & wound healing in the study group as compared to control group on 1st, 3rd & 7th postoperative days.
This study concluded that: Antibiotic with placentrex® gel had more efficacy than antibiotic without placental extract gel after extraction in control of pain, swelling & wound healing.
Keywords: extraction, placentrex®, pain, swelling, wound healing.

INTRODUCTION

Extraction is the most commonly performed dentoalveolar procedure in oral & maxillofacial surgery [1]. There are numerous circumstances under which a tooth must be removed. Although careful attention to surgical details may help to reduce the rate of complications, but it has not been found to eliminate them[2].

The postoperative sequelae such as pain, swelling and infection is one of the most common causes of swelling and it can also cause distress to the patient and affect the patient's quality of life after surgery [3]. Trismus and wound dehiscence are some of the common complications. To control postoperative inflammation and associated symptoms, it is essential to provide an adequate anti-inflammatory therapy.

Antibacterial action of Placental extract has also been shown to induce interferon-γ (IFN-γ) produced by macrophages. [4,5] IFN-γ plays a major role in innate or adaptive immunity and in inflammation.[5] Placental extract has been demonstrated to have immunotropic or immune-stimulating effects at the cellular and humoral levels in both human and animal models. The extract probably increases igg and igm antibodies at the humoral level and total lymphokines at the cellular level. [8] igg and igm activate the classical pathway of the complement system. They produce specific antibodies, thereby neutralizing viruses and lysing Gram-negative bacteria. As wounds are susceptible to bacterial growth, this action is critical for efficient healing.

Clinical evaluation of the extract has revealed that it has anti-platelet aggregation activity, anti-inflammatory and helps activate the clotting cascade following trauma which results in platelet activation followed by aggregation. The use of placental extract gel at the extraction site is attributed to the fact that the extracts of this tissue have been used as a therapeutic agent and a biomodulator in the healing of wounds.[6] This might be as a result of the fact that it contains a variety of peptides, amino acids, nucleotides, PDRNS, and carbohydrates all of which aid in the healing process. The potency of the placental extract lies in the fact that it not only reduces the inflammatory phase of healing and lessens the microbial burden, but also assists cell migration formation and tissue regeneration, thereby ensuring sequential steps of healing. It is also reported that the extract promotes fibrogenesis (development or proliferation of fibers or fibrous tissue), neo angiogenesis and epithelialization.[7]

Materials & method

A comparative study was conducted in the department of oral and maxillofacial surgery, Jaipur dental college and hospital, Jaipur, Rajasthan on patients requiring extraction of tooth. This study was designed to compare the post extraction healing by using antibiotics with placental extract gel (placentrex – the original research product of albert David limited, India, a drug obtained from fresh term healthy human placentae) versus antibiotics without placental extract. In control of swelling, pain, wound healing following extraction. The ethical clearance for the study was obtained from the institutional ethical committee with the ref. No. MVGU/ADM/2021/869 (XIV).

METHOD OF COLLECTION OF DATA

Inclusion criteria: either sex, 18 - 40 years of age, patients with bilateral extraction.

Exclusion criteria: patients with history of recent anti-inflammatory medical treatment, patients unwilling to sign informed consent form, patients with suspected or verified pregnancy, patients with known hypersensitivity of any of the study related drugs.

Prior information was given to the patient in his language and written consent was taken from patients / subjects, parents / caretakers.

Procedure

A detailed case history was obtained from patients visited to the department of oral and maxillofacial

surgery requiring removal of tooth from those who gave written informed consent for study and meets inclusion criteria in a standardized performa designed to accumulate the various parameters required for meeting objectives of the study.

After confirmation of diagnosis based on clinical and radiological evaluation, treatment plan was finalized.

Random allocation of 40 patients into 2 groups using simple random sampling technique.

Group A: for maxilla

Group B: for mandible

Both the groups were further subdivided into study group and control group. Preoperatively, distance between marked points on facial regions was measured. Same surgeon operated on all the patients to avoid any variation in surgical technique. The procedure was carried out with proper aseptic precautions.

Method of application placental extract gel:

Placental extract gel (Placentrex – the original research product of Albert David Limited, India, a drug obtained from fresh term healthy human placentae) was applied on the socket of freshly extracted tooth in study group patients for both group a and group b and standard postoperative instructions were given. Patients were recalled on 1st, 3rd, and 7th day postoperatively for evaluation of pain, swelling, and wound healing. Sutures were removed on the 7thday from the procedure (if given). A single examiner performed all the measurements. For evaluation of pain visual analogue scale is used indicating no pain to severe pain from 0-8 readings [8].

For assessment of swelling distance from chin of mandible to tragus, distance from corner of mouth of mandible to tragus, distance from angle of mandible to corner of eye were measured using silk suture.

Fig 1A: distance from chin of mandible to tragus.

Fig 1B: distance from corner of mouth of mandible to tragus.

Fig 1C: distance from angle of mandible to corner of eye

Table 1: For assessment of wound healing IPR [9] scale was used:

Score T/phase	Parameter	Score 0	Score 1	Total score
Inflammatory T: 3–5 days	Bleeding, spontaneously or on palpation	Yes	NO	**/8**
	Granulation tissue	Yes	NO	
	Hematoma	Yes	NO	
	Tissue color	Redder or whiter than opposite side tissue	Like the opposite side tissue	
	Incision margins	Incomplete flap closure/ fibrin clot/ partial necrosis / complete necrosis	Complete flap closure/ fine fibrin line	
	Suppuration	Yes	NO	
	Edema VAS (1-10)	VAS 6-10	VAS 1-5	
	Pain VAS (1-10)	VAS 6-10	VAS 1-5	

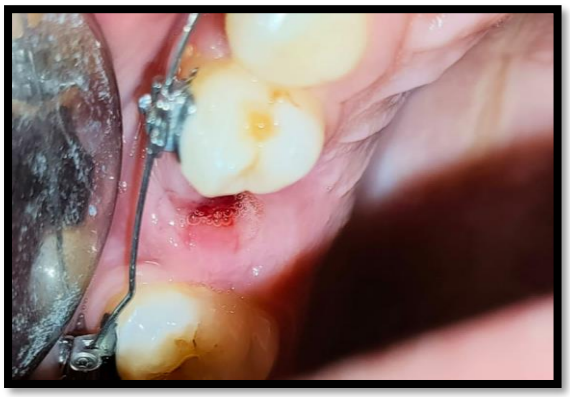


Figure 4: POST OPERATIVE HEALING WITHOUT PLACENTAL EXTRACT GEL IN CONTROL GROUP A

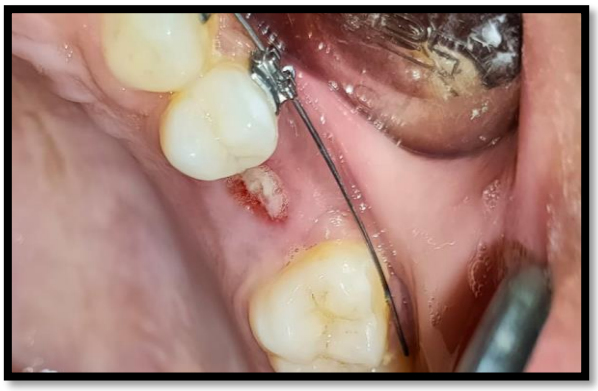


Figure 5: POST OPERATIVE HEALING WITH PLACENTAL EXTRACT GEL IN STUDY GROUP A.

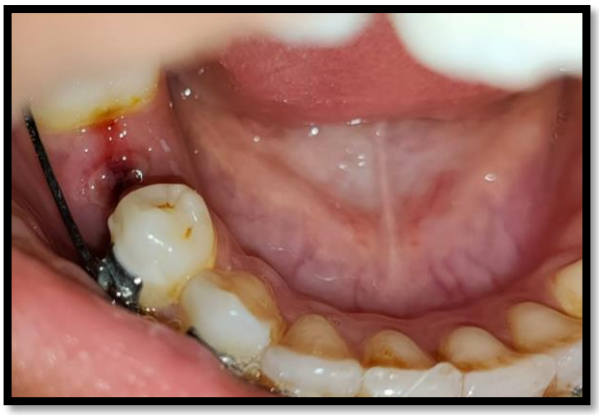


Figure 6: POST OPERATIVE HEALING WITHOUT PLACENTAL EXTRACT GEL IN CONTROL GROUP B.

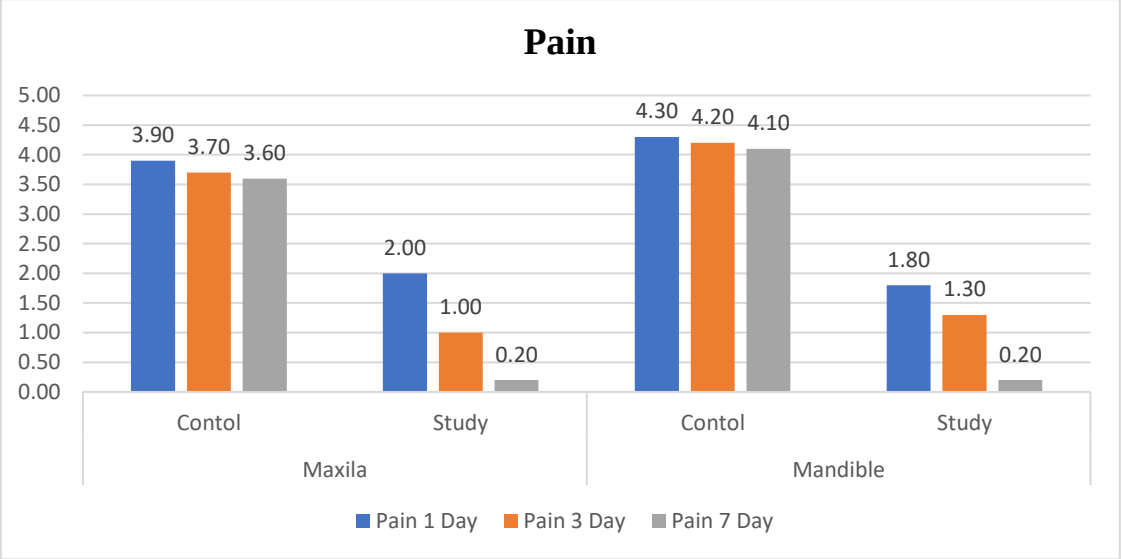
Figure 7: POST OPERATIVE HEALING WITH PLACENTAL EXTRACT GEL IN STUDY GROUP B.

RESULT

Statistical Analysis of Data:

- The data obtained were analyzed using the SPSS software (Statistical Package for the Social Sciences) version 21.0 is used, for Windows OS. Mean and standard deviations were calculated for the clinical parameter (pain, swelling, wound healing).
- Independent group t test was employed to compare the mean difference in the parameters between the two groups. Paired t test is used for comparing 1^{st},3^{rd}, 7^{th} postoperative day.

The data was statistically analyzed establishing relationships between the clinical parameter which were assessed by unpaired t- test.



- The mean pain score in group A (control and study) at 1st day, 3rd day, 7th day reveals there was a statistically significant difference in the mean pain score of patients in control and study group at given postoperative days.
- The mean pain score in group B (control and study) at 1st day, 3rd day, 7th day reveals there was a statistically significant difference in the mean pain score of patients in control and study group at given postoperative days.
- The mean swelling score in group A (control and study) at 1st day, 3rd day, 7th day reveals there was a statistically non-significant difference in the mean swelling score of patients in control and study group at 1st day, 3rd day postoperative days. But 7th postoperative day reveals statistically significant difference
- The mean swelling score in group B (control and study) at 1st day, 3rd day, 7th day reveals there was a statistically non-significant difference in the mean swelling score of patients in control and study group at given postoperative days.
- The mean wound healing score in group A (control and study) at 1st day, 3rd day, 7th day reveals there was a statistically significant difference in the mean wound healing score of patients in control and study group at given postoperative days.
- The mean wound healing score in group B (control and study) at 1st day, 3rd day, 7th day reveals there was a statistically significant difference in the mean wound healing score of patients in study and control group at given postoperative days.

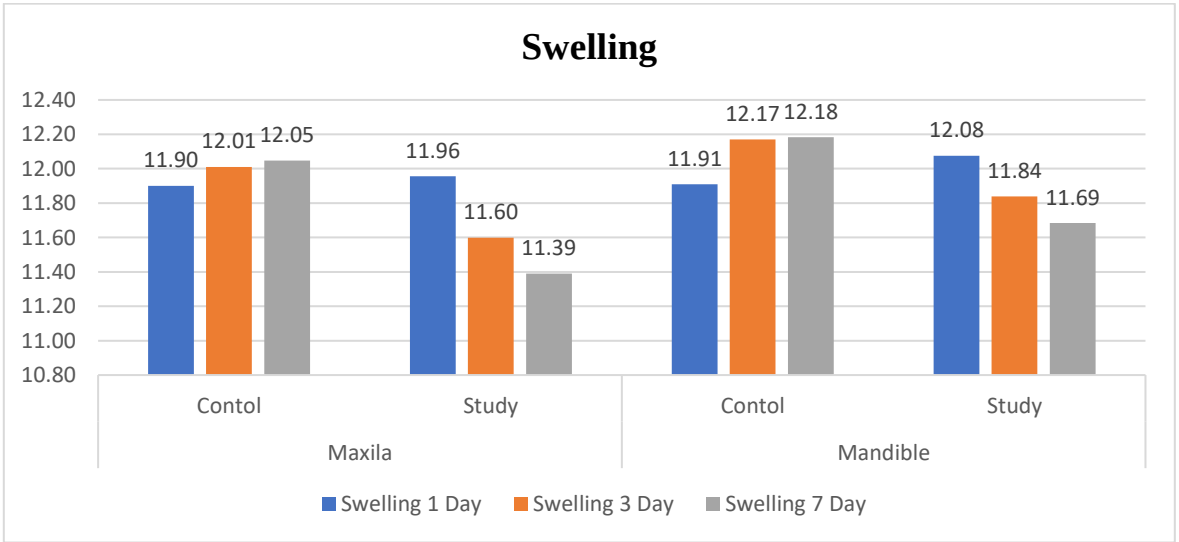


Table 2: Maxilla control and study group p values

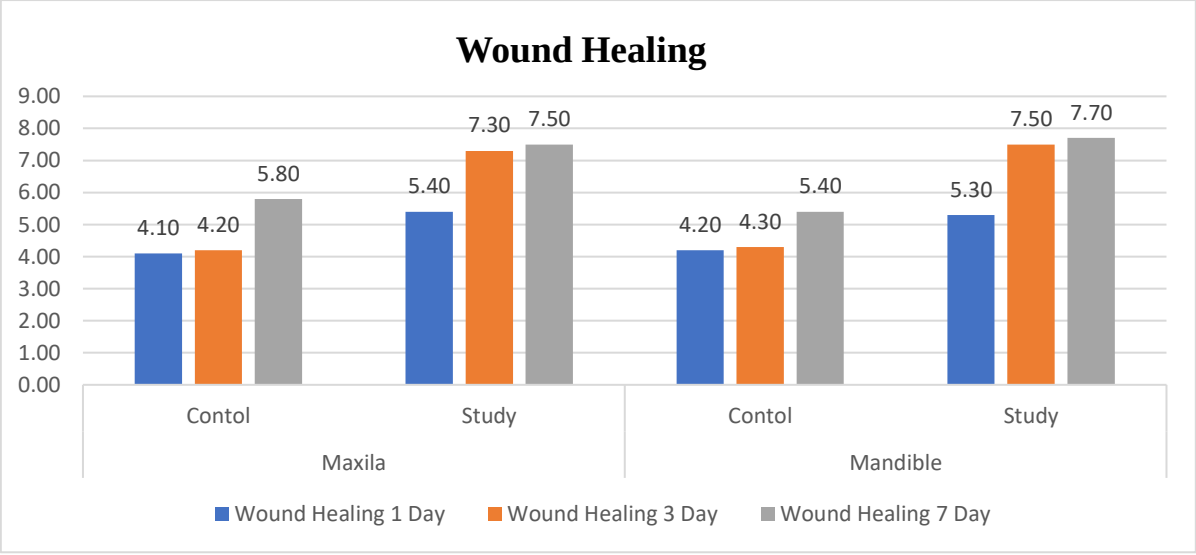
			N	Mean	Std. Deviation	Std. Error Mean	Mean Difference	'T' test	P value
Pain	**1 Day**	Maxilla Control	10	3.900	0.738	0.233	1.900	5.460	0.000
		Maxilla Study	10	2.000	0.816	0.258			
	3 Day	Maxilla Control	10	3.700	0.949	0.300	2.700	8.060	0.000
		Maxilla Study	10	1.000	0.471	0.149			
	7 Day	Maxilla Control	10	3.600	0.966	0.306	3.400	10.200	0.000
		Maxilla Study	10	0.200	0.422	0.133			
Swelling	**1 Day**	Maxilla Control	10	11.901	0.498	0.157	-0.056	-0.237	0.815
		Maxilla Study	10	11.957	0.558	0.176			
	3 Days	Maxilla Control	10	12.011	0.603	0.191	0.413	1.896	0.074
		Maxilla Study	10	11.598	0.333	0.105			
	7 Days	Maxilla Control	10	12.047	0.560	0.177	0.657	3.309	0.004
		Maxilla Study	10	11.390	0.283	0.089			
Wound Healing	**1 Day**	Maxilla Control	10	4.100	0.568	0.180	-1.300	-5.357	0.000
		Maxilla Study	10	5.400	0.516	0.163			
	3 Days	Maxilla Control	10	4.200	0.422	0.133	-3.100	-12.318	0.000
		Maxilla Study	10	7.300	0.675	0.213			
	7 Days	Maxilla Control	10	5.800	0.919	0.291	-1.700	-5.075	0.000
		Maxilla Study	10	7.500	0.527	0.167			

* p value < 0.05, significant

Table 3: Mandible control and study group p values

			N	Mean	Std. Deviation	Std. Error Mean	Mean Difference	'T' test	P value
Pain	**1 Day**	Mandibular Control	10	4.300	0.823	0.260	2.500	6.934	0.000
		Mandibular Study	10	1.800	0.789	0.249			
	3 Days	Mandibular Control	10	4.200	0.919	0.291	2.900	8.834	0.000
		Mandibular Study	10	1.300	0.483	0.153			
	7 Days	Mandibular Control	10	4.100	0.876	0.277	3.900	12.690	0.000
		Mandibular Study	10	0.200	0.422	0.133			
Swelling	**1 Day**	Mandibular Control	10	11.909	0.780	0.247	-0.166	-0.583	0.567
		Mandibular Study	10	12.075	0.450	0.142			
	3 Days	Mandibular Control	10	12.171	0.650	0.205	0.332	1.347	0.195
		Mandibular Study	10	11.839	0.430	0.136			
	7 Days	Mandibular Control	10	12.183	0.641	0.203	0.498	2.063	0.054
		Mandibular Study	10	11.685	0.414	0.131			
Wound Healing	**1 Day**	Mandibular Control	10	4.200	0.422	0.133	-1.100	-5.425	0.000
		Mandibular Study	10	5.300	0.483	0.153			
	3 Days	Mandibular Control	10	4.300	0.483	0.153	-3.200	-14.154	0.000
		Mandibular Study	10	7.500	0.527	0.167			
	7 Days	Mandibular Control	10	5.400	0.966	0.306	-2.300	-6.734	0.000
		Mandibular Study	10	7.700	0.483	0.153			

* p value < 0.05, significant



There was less pain in study group as compared to control group on 1st, 3 rd. And 7th postoperative days and the mean pain intensity scores were statistically significant. There was less swelling in experimental group as compared to control group on 7th postoperative day and there was a statistically significant difference in the mean wound healing score of patients in study group and control group.

DISCUSSION

Tooth extraction is the last treatment modality and mostly commonly performed procedure in oral and maxillofacial surgery which leads to disruption in tissue continuity. This breach in tissue continuity leads to activation of various mechanisms including activation of clotting mechanism, inflammatory mechanism, and most important body's defense mechanism. Healing of wound depends on degree of tissue disruption and factors surround the injured tissue.

Several studies have evaluated the effect of human placental extract (HPE) on wound healing and a considerable amount of data suggests that HPE promotes wound healing [10]. Tiwary in 2006 reported that placental-extract gel and cream are both effective topical agents for chronic nonhealing wounds. However, patient feels less pain and discomfort during dressing change with the placental-extract cream[11].

Sharma A et al[12,] compare clinical soft tissue parameters around periodontal pockets treated with & without human placental extracts delivered locally in 10 patients of chronic periodontitis, bilateral localized periodontal pockets of 4-6 mm depth were included. A statistically significant improvement in clinical parameters with notable difference in probing depth reduction & gain of clinical attachment level in the treatment group subjected to scaling & root planning (SRP) & Placental extract delivery. The clinical results showed a greater efficacy of SRP & concomitant use of placental extracts when compared to conventional treatment by SRP.

Katkurwar A [10], Clinically and histologically evaluated the depigmented gingival epithelium on application of human placental extract gel. 10 healthy patients were selected in the age group of 18-35 yrs which were indicated for depigmentation procedure. Application of human placental extract gel showed a statistically significant result clinically and histologically and concluded that application of human placental extract can be a successful approach to protect the raw wounded area of depigmented gingiva leading to better patient comfort and faster healing.

Morsy S.[13], investigated the effectiveness of the topical application of placental extract gel (PEG) in the treatment of RAS. 40 patients with RAS participated in this research. They were randomly allocated into two groups. Group I was control group which included 20 patients treated with topical application of benzydamine hydrochloride gel and group II was test group which included 20 patients treated with topical application of placental extract gel. The effectiveness of the treatment modalities was assessed by measuring the pain intensity and ulcer size at baseline, 3rd day and 7th day. He concluded that Topical PEG is an effective topical agent in RAS treatment, which enhances the patient's normal activities and daily life events.

Placental extract gel used in this study are HIV Antibody free, HCV antibody free and Hepatitis B-Surface Antigen free according to the product manufacturer description so it can be used safely in human.

The current study evaluated the effect of human placental extract gel after tooth extraction locally in terms of pain, swelling and wound healing. The study concluded that human placental extract gel is effective in reducing postoperative pain and also promotes wound healing. It is suggested that additional studies should be undertaken over a longer period of monitoring because the postoperative follow-up of the current study was short.

CONCLUSION

Antibiotics with placentrex® has more efficacy than antibiotics without placental extract after extraction in control of pain, swelling and wound healing.

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