

## Gel foam soaked in diclofenac inside extraction socket as local drug delivery Running Title: Local Drug Delivery

**Type of Study: Original Case Study** 

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#### Abstract:

AIM AND OBJECTIVE: The study's goal and objective were to assess how diclofenac sodium affected the extraction socket.

MATERIALS AND METHODS: In a randomised, blind trial, 40 patients with age 18-30 years with extraction in any arch were chosen for the investigation. Patients are divided into 2 groups; ie., 20 patients treated with gel foam diclofenac in extraction socket and the other group of 20 patients without the medication. Postoperative pain relief and healing is assessed in all the patients inorder to analyse the efficacy of diclofenac as a local drug in gel foam.

RESULTS AND CONCLUSIONS: The diclofenac-infused gel foam has been found to have a high rate of local medication delivery, hastening healing and lowering discomfort.

KEYWORDS: Diclofenac, Pain, Tooth extraction

#### Introduction



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It is widely known that the postoperative discomfort following surgical tooth extractions can last for the first 24 hours and range in severity from moderate to severe.(1-4) When a typical local anaesthetic is administered, pain intensity peaks between 6 and 8 hours after the procedure.(5) Deep cavity preparation and surgical dental extraction are frequently accompanied by stress to both the soft and hard structures. This trauma frequently includes pain and oedema.(6,7) One of the therapeutic alternatives for surgical tooth extraction and cavity preparation pain alleviation is nonsteroidal anti-inflammatory medications.(4,8) The amount of pain triggers (prostaglandins) released into the site of the injury can be decreased by using pre-operative analgesics, which can also postpone the onset of postoperative pain.(9-11) The amount of prostaglandins generated from the wounded tissues accumulated over time, amplifying the pain's intensity.(5,9-11)

Cyclo-oxygenase (COX) enzymes are chemicals that are blocked by diclofenac. These enzymes cause the body's prostaglandins to release information. It is believed that the creation of prostaglandins, which produce pain and inflammation, occurs normally at the sites of trauma or injury. Less prostaglandins are produced as a result of blocking the action of COX enzymes, which reduces pain and inflammation.(12)

Diclofenac is available in two different formulations: sodium and potassium. As a general rule, the sooner the painkiller is absorbed, the quicker its start of action will be.(7) Diclofenac potassium is absorbed into the patient's blood stream more quickly than diclofenac sodium. Diclofenac potassium is a quick-acting analgesic, making it effective for people who need relief from inflammatory pain right away.

The goal of the current study was to examine and assess how well diclofenac gel foam used in extraction sockets affected post-operative analgesia, its adverse events, patient compliance, and patient tolerance.

#### **Materials and Methods**

The study's randomised blind trial included 40 patients who needed extractions. The individuals ranged in age from 18 to 30 years and belonged to both sexes. Subjects with a history of NSAID allergies or clinical evidence of such allergies were not included in the sample. Subjects who were using any other NSAIDs, other analgesics, or corticosteroids during the trial time were also disqualified, as were those with a history of systemic illnesses. An institutionally recognised ethical committee granted the study's ethical clearance. From each participant, signed informed consent was gained.

Patients are divided into two groups; Group I: With diclofenac gel foam in extraction socket Group II: Without diclofenac gel foam in extraction socket

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FIGURE 1 : Diclofenac gel form.



Figure 2 : Diclofenac-soaked foams are then inserted into the extraction socket as a local drug onsite.

For the participants in our trial, diclofenac is given as a gel foam(FIG 1). Diclofenac-soaked foams are then inserted into the extraction socket as a local drug onsite(FIG 2). The parameters that were evaluated are pain and healing.



For evaluating pain relief, on 1<sup>st</sup> and 3<sup>rd</sup> postoperative days, each patient was given a Verbal Pain Intensity scale (5-point scale with values from 0 to 4). For the three days following surgery, each patient received a total of nine paracetamol 500 mg tablets, which could be used as rescue therapy. The patients were instructed to keep track of how many paracetamol tablets they had taken.

After recording their pain during the first three postoperative days using a verbal pain score chart, the subjects were asked to submit a 5- point pain relief scale chart for analysis. Healing is assessed on 7<sup>th</sup> postoperative day with Landry et al index. The Mann-Whitney U test was used to statistically analyse the data collected from the study individuals.

pain day 1		Pain day 3		Total	chi square value	p-value
		good	poor			
poor	Count	6	6	12	0.303	0.67
	%	50.0%	50.0%	100.0%		
very poor	Count	3	5	8		
	%	37.5%	62.5%	100.0%		
Total	Count	9	11	20		
	%	45.0%	55.0%	100.0%		

RESULTS AND DISCUSSION TABLE 1 : COMPARISON OF PAIN IN DAY 1 and DAY 3.

From table 1, we can see that gel foam has reduced pain on day 3 compared to day 1. The significant value found to be 0.67 which is statistically significant. Given the evidence of its established analgesic potency and lower incidence of systemic adverse effects, diclofenac gel foam appears to be a promising analgesic option for the management of mild to moderate pain following dental extractions. With perhaps an increased strength of the analgesics, diclofenac gel foam therapy may have a role to play in the treatment of post-traumatic pain. However, before the diclofenac gel foam's true scope can be clearly defined, longer clinical trials with a larger sample must be carried out.

Research into post-operative pain management is still ongoing, and newer formulations and treatment approaches are constantly replacing the old ones. Due to the significant level of inflammatory reaction involved, post-extraction pain has frequently been a nemesis for dental surgeons and patients alike.

NSAIDs, which are non-steroidal anti-inflammatory drugs, are among the most popular analgesics used to treat dental post-operative pain. The ability of NSAIDs to suppress cyclo-oxygenases 1 and 2 (COX-1 and COX-2), important enzymes in prostaglandin (PG) formation, is a major factor in their effectiveness in treating pain. [13]However, taking NSAIDs orally poses a risk of first pass metabolism, when a sizeable portion of the medication is lost before it is absorbed systemically. Oral NSAIDs are also known to have a number of side effects, especially gastro intestinal symptoms that vary in severity depending on dose. As alternative routes of medication administration, topical NSAID formulations have been created. These formulations have the benefit of local, increased drug delivery to the afflicted tissues with a decreased incidence of systemic side effects. Thus, topical NSAIDs have established themselves as therapeutic analgesic methods with proven advantages and a decreased incidence of negative side effects.

Diclofenac, an NSAID, has long been used as a common painkiller after dental extractions since it contains anti-inflammatory, analgesic, and antipyretic properties. The effectiveness of two different oral diclofenac single dose formulations used to treat adults' acute postoperative pain was compared in a research by Derry et al. (14). The results of this trial showed that oral diclofenac potassium relieved



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moderate to severe postoperative pain much better than diclofenac sodium. More patients in the diclofenac potassium group than in the diclofenac sodium group reported 50% pain reduction over the first 4-6 hours following surgery. According to Derry et al. (15), utilising diclofenac potassium that dissolves quickly and is absorbed more quickly than other forms of the drug results in superior pain alleviation.

#### Conclusions

Within the limitations of the study we can conclude that, increased strength of the analgesics, diclofenac gel foam therapy may have a role to play in the treatment of post-traumatic pain. However, before the diclofenac gel foam's true scope can be clearly defined, longer clinical trials with a larger sample must be carried out. Given the evidence of its established analgesic effectiveness with a decreased incidence of systemic adverse effects, diclofenac appears to be a potential analgesic modality for the therapy of mild to moderate pain following tooth extractions. However, in order to precisely identify the real breadth, longer clinical trials with a higher sample size must be carried out.

#### Source of Support: Nil

**Conflict of Interest:** None declared.

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