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RESEARCH ARTICLE

EFFICACY OF GELATAMP IN REDUCTION OF POST OPERATIVE COMPLICATION AND SOFT TISSUE HEALING AFTER IMPACTED MANDIBULAR 3RD MOLAR SURGERY

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ABSTRACT

Aim: To evaluate the efficacy of GELATAMP (colloidal silver impregnated with gelfoam) in reduction of post operative complications and soft tissue healing after impacted Mandibular 3rd Molar surgeries.

Materials and Methods: The Study was performed in a series of 15 patients (30 impactions) aged between 25 – 48 years with bilateral mandibular 3rd molar impactions requiring surgical removal attending the Department of Oral and Maxillofacial Surgery. After the surgical removal of the teeth, these sites were augmented with GELATAMP and assessment was done to evaluate the soft tissue healing and reduction of postoperative complications like pain, swelling on 1st, 3rd and 7th post operative days. The results were recorded based on Soft Tissue Healing Index, Visual Analog Scale (VAS), Swelling Assessment by Tape Measurement. The 't' test was used to test the significance between control and trial group. The 'p' value < 0.05 was taken to denote significant difference.

Results: Soft tissue healing assessment and pain score showed high statistical significance ($p < 0.005$) on GELATAMP side compare to control side on 1st, 3rd, and 7th postoperative day. Regarding swelling assessment, There was no statistical significant difference between 2 groups.

Conclusion: It was concluded that, surgically extracted mandibular 3rd molar socket augmented with GELATAMP resulted in effective soft tissue healing, and reduced postoperative complications compared to control group. Hence GELATAMP could be augmented on a routine basis on Mandibular 3rd molar extracted sockets.

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INTRODUCTION

Surgical removal of impacted Mandibular 3rd molar is a regular minor surgical procedure for dental as well as oral and maxillofacial surgeons. This surgical procedures is associated with postoperative complications including pain, swelling and post operative wound infection. With the help of strict sterilization procedures the above mentioned post operative complication has been reduced to certain extent, but gives a discomfort to the patients. Various therapeutical agents, atraumatic surgical procedures, irrigation solutions, and post operative dressings are available to reduce the post operative pain, swelling and help to improve the wound healing properties. Recent interests and advances in the field of minor oral surgery has evolved the use of various material to augment the extracted site to preserve for further prosthetic rehabilization as well as to reduce postoperative complication like pain, swelling, soft tissue healing etc. silver nanoparticles are useful in wound management, and they have been employed since the 18th century to treat ulcers. Topical application of silver nanoparticles to wounds is responsible to promote and accelerate healing process, in addition it act as antibacterial agent playing a role in the modulation of cytokines involved in tissue repair. (Nelson Durán *et al*., 2015) However, studies evaluating the soft tissue healing in surgically extracted site augmented with GELATAMP (colloidal silver impregnated with gelfoam) are minimal. So the objective of this Clinical study is to evaluate the effectiveness of GELATAMP in reduction of post operative complication and soft tissue healing.

Aims and Objectives

This study compares the clinical advantages of tissue healing in surgical extraction site augmented with GELATAMP by assessing pain, swelling and soft tissue healing on the 1st, 3rd, 7th post operative day.

MATERIALS AND METHODS

Our present study was approved by the Institutional Ethical Committee and the trial was carried out in the Department of

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Oral and Maxillofacial Surgery at Ultra's Best Dental Science College from September 2015 to June 2016. All participants are explained about our study and signed an informed consent form. The inclusion criteria included: bilateral impacted mandibular 3rd molar teeth with similar conditions in terms of angulation, based on Winter category (mesioangular or vertical), degree of impaction based on Pell & Gregory category (level A or B, class I or II). Patients who had a history of systemic disease (Diabetes, Hypertension, Ischemic heart diseases... etc.) and habit of smoking and consuming alcohol were excluded from the study and the women who were pregnant or lactating at that time of surgery were excluded from the study. This study comprises of 18 patients (11 male and 7 female), 3 (2 male, 1 female) out of it were excluded due to the following reasons: unwillingness to have opposite side surgeries, anxiety, also due to local infection. 15 patients (9 males and 6 females; mean age ± standard deviation: 34.3 ± 6.90 years) who underwent surgical removal of bilateral impacted Mandibular 3rd molars were enrolled in the study (total of 30 impacted 3rd molars). This minor surgical procedure was performed by a single operator. Each patient underwent two surgical operations, separated by 4 weeks. The Inferior Alveolar Nerve block (IAN) was given to anesthetize the target area by 2% lidocaine with 1:80,000 epinephrine (LIGNOX). The removal of Mandibular 3rd molar followed a standardized surgical technique. Briefly, an ward's incision was made, and a mucoperiosteal flap was elevated. When osteotomy and tooth section were performed on one side, the other side received the same treatment after 4 weeks in order to standardize the surgical trauma. All procedures were performed under copious irrigation with 0.9% normal saline. After the removal of the tooth, the socket was impregnated with GELATAMP (trial side), and the flap was repositioned and closed with 3-0 black silk. Patients were given oral antibiotics and anti inflammatory, H2 receptor antagonist (amoxicillin 500 mg, Ibuprofen 400mg, ranitidine 150 mg) thrice daily for 5 days. After 4 weeks the control side (opposite side) tooth was surgically removed and its socket was closed without GELATAMP augmentation.

Postsurgical assessment

Intra oral and extra oral Clinical photographs were taken post operatively. Patients were recalled on post-operative 1st, 3rd and 7th day for intra oral soft tissue healing, pain and extra oral swelling assessment. The clinical parameters assessed were soft tissue healing potential using the standardised index by Landry, Turnbull and Howley[2], pain assessment by 10cm Visual analog scale (VAS)[3,4], swelling assessment by Modification of Tape measuring method by Gabka and Matsumara[5] on 1st, 3rd, and 7th day after surgery were recorded.

1.Soft tissue healing assessment

Soft tissue healing assessment was made by colour of gingival, bleeding on palpation, presence of granulation tissue, epithelisation of the margins and presence of suppuration. Depends on the above mentioned factors the standardised soft tissue healing potential index was made by Laundry, Turnbull, and Howley (Hemalatha and Gemimaa Hemagaran, 2015).

2.Pain assessment

The patients were requested to complete a sheet of table every evening for 1 week from 1st day to 7th day after surgery to report the level and severity of pain. The patient had to evaluate the pain on a 10cm visual analog scale (VAS) ranging from 0 (no pain) to 10(unbearable pain) (Martin McCarthy and Chih-Hung Chang, 2005; Gillian Z. Heller *et al*., 2016).

3.Swelling assessment

The level of facial swelling was determined by a modification of tape measuring method described by Gabaka and Matsumara (Yakup *et al*., 2003). Three measurements were made between 5 reference points: tragus,soft tissue pogonion, lateral corner of the eye, angle of mandible, and outer corner of the mouth, preoperatively, and on second and seventh postoperative day (Figure 1). The difference between baseline and each postoperative day indicate the level of facial swelling for that day.

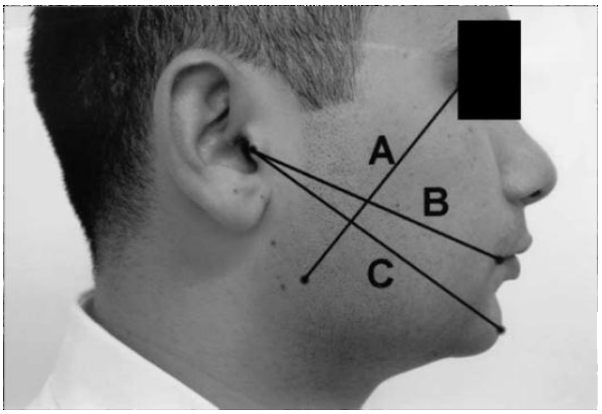


Figure 1

Facial swelling measurements – determination

Swelling assessment

Swelling assessment by modification of Tape measuring method by Gabka and Matsumara.

S1 – From Lateral canthus of the eye to angle of the mandible.
S2 - From Tragus to outer corner of the mouth.
S3 – From Tragus to Pogonion (measurements in millimeters)

Data analysis

The collected patient's data were tabulated and statistical analysis were performed. Microsoft Excel 2010 software to derive the mean and standard deviation and SPSS software version 21 was used for statistical analysis. Charts and graphic representations were obtained with the results. Descriptive statistics done by Measures of central tendency E.g. Mean and Measures of Dispersion E.g. Standard deviation was calculated for all the parameters. Inferential Statistics was done by 't' test to compare the mean difference between the two groups for difference in the Mean soft tissue healing score, swelling, VAS scores. P value of 5% was considered significant.

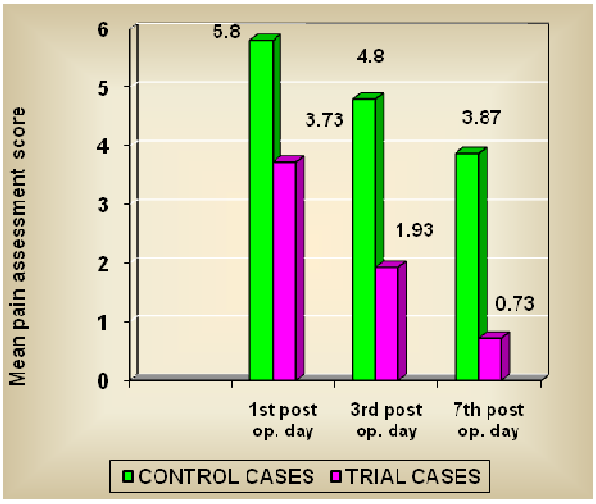
RESULTS

A total of 30 impacted teeth were surgically removed in our investigation. The operation time ranged between 23 and 36 minutes and no unexpected postoperative complication such as nerve damage or infection was observed. Pain assessment by Visual analog scale is statistically significant in all 3 interval

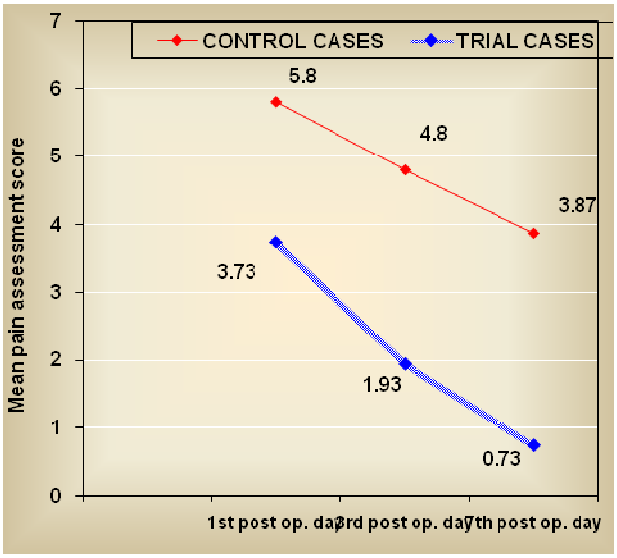
postoperative days (Table : 1) & (Graph : 1 & 2). The mean VAS score for 1st day was 5.8±0.68 in control side and 3.73±0.46 in trial side (GELATAMP side) (p<0.0001). The mean VAS score for 3rd day was 4.8±0.86 in control side and 1.93±0.88 in trial side (GELATAMP side) (p<0.0001). The mean VAS score for 7th day was 3.87±0.64 in control group and 0.73±0.7 in GELATAMP group(P<0.0001)

Table 1. Pain assessment in Control cases and Trial cases

Pain assessment on	Pain assessment in				
	Control cases		Trial cases		
	Mean	S.D.	Mean	S.D.	'p'
1st Post operative day	5.8	0.68	3.73	0.46	< 0.0001 Significant
3rd Post operative day	4.8	0.86	1.93	0.88	< 0.0001 Significant
7th Post operative day	3.87	0.64	0.73	0.7	< 0.0001 Significant



Graph 1. Pain assessment

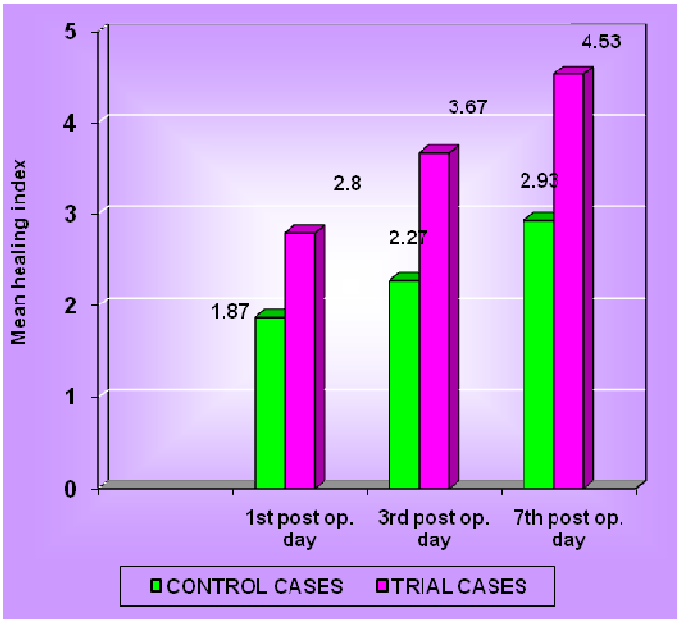


Graph 2. Pain assessment

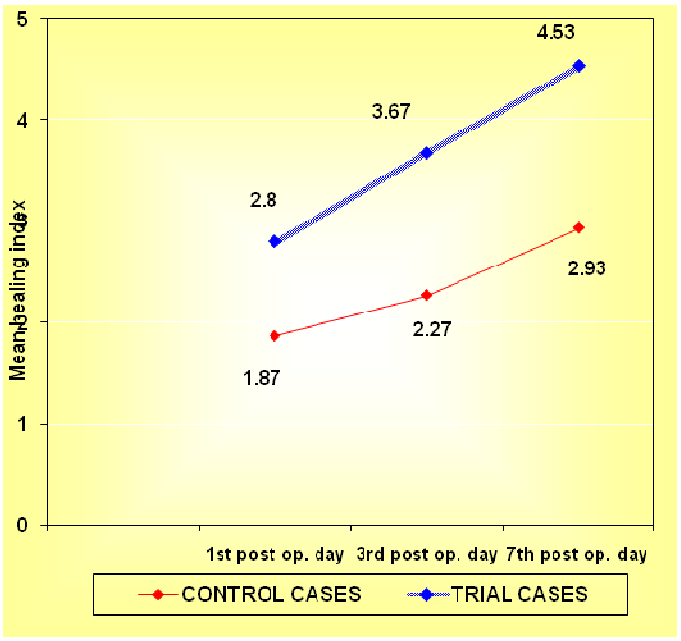
The mean soft tissue healing score was found to be 1.87 (SD±0.35), 2.27 (SD±0.46), 2.93 (SD±0.26), in control side and 2.8 (SD±0.41), 3.67 (SD±0.49), 4.53 (SD±0.52), in trial side (GELATAMP side) on 1st, 3rd and 7th postoperative day respectively (Table : 2 & Graph 3 & 4) There was a statistical significance between two groups (p<0.0001) suggesting there was significant difference between the groups at the soft tissue healing assessment on all 3 postoperative days. There is statistically significant value between control side and trial side (GELATAMP side) in post operativeswelling assessment.

Table 2. Healing Index in Control cases and Trial cases

Healing Index on	Pain assessment in				
	Control cases		Trial cases		
	Mean	S.D.	Mean	S.D.	'p'
1st Post operative day	1.87	0.35	2.8	0.41	< 0.0001 Significant
3rd Post operative day	2.27	0.46	3.67	0.49	< 0.0001 Significant
7th Post operative day	2.93	0.26	4.53	0.52	< 0.0001 Significant



Graph 3. Soft tissue healing assessment



Graph 4. Soft tissue healing assessment

The 'p' value of S1 and S3 were statistically significant (p<0.001) and 'p' value of S2 was not significant. But both measurements were clinically significant (Table 3)

Table 3. Swelling assessment in Control cases and Trial cases

Measurement point	Swelling assessment on	Pain assessment in				'p'
		Control cases		Trial cases		
		Mean	S.D.	Mean	S.D.	
S 1	Baseline	82.3	6.9	82.0	7.6	0.813 Not Significant
	1st Post operative day	88.5	6.8	84.9	7.7	0.024 Significant
	3rd Post operative day	87.3	6.5	83.9	7.3	0.019 Significant
	7th Post operative day	86.2	6.5	82.1	7.5	0.011 Significant
S 2	Baseline	114.4	4.6	116.2	4.2	0.177 Not Significant
	1st Post operative day	120.0	4.7	119.4	4.6	0.678 Not Significant
	3rd Post operative day	119.7	5.2	118.2	4.3	0.251 Not Significant
	7th Post operative day	118.3	5.2	116.3	4.0	0.211 Not Significant
S 3	Baseline	130.0	4.6	127.7	4.8	0.112 Not Significant
	1st Post operative day	135.2	4.6	130.7	4.6	0.004 Significant
	3rd Post operative day	134.3	4.8	128.9	4.6	0.001 Significant
	7th Post operative day	133.1	5.2	128.0	4.6	0.002 Significant

DISCUSSION

The removal of a tooth initiates the same sequence of inflammation, epithelialization, fibroplasia, and remodeling seen in prototypic skin or mucosal wounds. Extraction sockets heal by secondary intention, and months to pass before a socket heals to the degree to which it becomes difficult to distinguish from the surrounding bone when viewed radiographically. (James R Hupp and Myron R Tucker, 6th edition) After a tooth is extracted, the remaining empty socket consists of cortical bone (the radiographic lamina dura) covered by torn periodontal ligaments, with a rim of oral epithelium (gingiva) left at thecoronal portion. The socket fills with blood, which coagulates and seals the socket from the oral environment. The inflammatory stage occurs during the first week of healing. White blood cells enter the socket to remove contaminating bacteria from the area and begin to break down any debris such as bone fragments that are left in the socket. Fibroplasia also begins during the first week, with the ingrowth of fibroblasts and capillaries. The epithelium migrates down the socket wall until it reaches a level at which it contacts epithelium from the other side of the socket or it encounters the bed of granulation tissue (i.e., tissue filled with numerous immature capillaries and fibroblasts) under the blood clot over which the epithelium can migrate. Finally, during the first week of healing, osteoclasts accumulate along the crestal bone. (James R Hupp and Myron R Tucker, 6th edition) The second week is marked by the large amount of granulation tissue that fills the socket. Osteoid deposition has begun along the alveolar bone lining the socket. In smaller sockets, the epithelium may have become fully intact by this point. The processes begun during the second week continue during the third and fourth weeks of healing, with epithelialization of most sockets complete at this time. The cortical bone continues to be resorbed from the crest and walls of the socket, and new trabecular bone is laid down across the socket. Not until 4 to 6 months after extraction is the cortical bone lining a socket usually fully resorbed; this is recognized radiographically by a loss of a distinct lamina dura. As bone fills the socket, the epithelium moves toward the crest and eventually becomes level with adjacent crestal gingiva. The only visible remnant of the socket after 1 year is the rim of fibrous (scar) tissue that remains on the edentulous alveolar ridge. If any disturbances in the above mentioned healing process either by intrinstic or extrinstic factors leads to dry socket (Hemalatha and Gemimaa Hemagaran, 2015; James R Hupp and Myron R Tucker, 6th edition) Dry socket is the most common complication following a tooth extraction, with a peak incidence in the 25–45 year-old age group. Most studies state that the incidence of dry socket is 1%-4% for all routine dental extractions, and 5%-30% for impacted mandibular third molars. The incidence of dry socket is higher in the mandible, occurring up to 10 times more often for mandibular molars compared with maxillary molars (Ahmad-Reza Noroozi and Rawle F. Philbert, 2009). Typically, dry socket starts 1-3 days after tooth extraction and the duration usually ranges from 5 to 10 days. Prevention methods include avoiding smoking 24 h before and after surgery and atraumatic surgery with removal of bone and tooth fragments under copious saline irrigation. Placement of topical antibiotics, such as tetracycline, lincomycin, or clindamycin, on Gelfoam can be considered. (Ahmad-Reza Noroozi and Rawle F. Philbert, 2009)

Gelatamp™ (Coltène/Whaledent Inc. USA) is made of 95% foam gelatin sponge and 5% finely dispersed colloidal silver. The silver forms silver ions in moist conditions. In small quantities, these silver ions are antimicrobial without developing any resistance. Gelatamp has been found to be very effective against bacteria which are resistant to antibiotics. The finely dispersed colloidal silver provides a large active surface for the continuous release of its ions. As silver does not dissolve easily it is not washed out of the gelatin sponge but is continually released as the sponge is resorbed. This gives Gelatamp a depot antimicrobial effect throughout its resorption. Gelatamp has the greater advantage of both haemostatic and bactericidal effect. It remains in the alveolus and completely resorbed within 4 weeks (Omnia Hassan *et al*., 2011). Gelatamp sponges were used successfully to pack the surgical sites after surgical extraction of both impacted lower third molars teeth during the management of life threatening odontogenic infection. Also Gelatamp sponges were used to pack the surgical site to prevent infection and facilitate wound healing after surgical removal of periapical lesions. Clinical and radiological follow up showed that complete wound healing of the extracted site with adequate density and trabeculation of the bone. (Omnia Hassan *et al*., 2011) Maribel guzman *et al* demonstrated that the colloidal Ag NP s inhibited the growth and reduced the multiplication of the tested bacteria, including highly multidrug-resistant organisms such as methicillin resistant S. aureus, S. aureus, E. coli, and *P. aeruginosa*. A strong antibacterial activity was observed at very low total concentrations of silver (< 7 ppm). Also he tested the efficacy of nanocrystalline silver versus a control group receiving conventional silver sulfadiazine on 166 different burn wounds in 98 patients. Nanocrystalline silver dressings significantly reduced the wound healing time by an average of 3.35 days and increased bacterial clearance from infected wounds. (Maribel Guzman *et al*., 2012; Guang Yang *et al*., 2012) Silver needs a substrate for sustained release.

Various carrying materials are available for this purpose. Among these materials, Gelatin serve as a better carrying agent. Gelatin is a natural polymer which is derived from collagen, and is commonly used for various pharmaceutical and medical applications because of its biodegradability and biocompatibility in normal environments. Simon young (2005) *et al*. stated that controlled delivery of sensitive biomolecules from gelatin carriers, a diverse range of applications have been studied for gelatin carrier-mediated pharmaceutical drug delivery such as sustained antibiotic delivery and metal ions for bone infection repair and cancer chemotherapy. (Guang Yang *et al*., 2012; Simon Young *et al*., 2005)

CAI Yong-hai, LU Chang-shou. (2008) showed that the incidence rate of post operative complication of teeth extraction in experimental group (GELATAMP) was 7.72%, which was very lower than that of control (Non GELATAMP) group (24.43%). There was significant difference in the incidence rates of complication between experimental group and control group (P<0.005). The incidence rate of bleeding, infection, pain, swelling and dry socket after teeth extraction in experimental group was lower than those of control group, and the difference between them was statistically significant (P <0.05). (Cai and Lu, 2008) Wang (2013) showed that the incidence of dry socket was 0.44% in group A(gelatamp implanted in alveolar socket), 2% in group B(gelatine sponge in alveolar socket) and 4.44% in group C (nothing implanted). There was significant difference in the incidence of dry socket between group A and group C (P<0.01). There was also significant difference between group B and group C(P<0.05) and between group A and group B(P<0.05). (Wang *et al*., 2013) Yuliang Dong *et al*. (2016) investigated the efficiency of gelatine with / without colloidal silver on bone healing in infected cranial defect in animal model. 2 weeks after debridement, the gelatin group showed negligible amount of new bone formation in the defect area, while the defects of gelatin/Ag group had larger area occupied by bone tissue (p<o.o5). 4 weeks after debridement, the defects of gelatin group remained almost unfilled, While new bone tissue had almost closed the defect of gelatin/Ag group (p<0.005). (Yuliang Dong *et al*., 2016) Also in our study, statistically there was significant soft tissue healing between control side and trial side (GELATAMP side) in all the time intervals. The p value < 0.0001 on 1st, 3rd and 7th postoperative day strongly suggesting that GELATAMP is the one of the best augmenting material in surgically removed Mandibuar 3rd Molar site for better soft tissue healing which aids in reducing the postoperative complications. Omnia Hassan (2011) showed that reduced postoperative pain when gelatamp augmented in the alveolar socket after teeth extraction, and this was due to the antibacterial effects of colloidal silver within the gelatamp that reduces bacterial by products which can activate synthesis of biochemical mediators such as prostaglandins which involved in activation of pain and inflammatory processes. (Omnia Hassan *et al*., 2011; Jun Tian and Kenneth K.Y. Wong, 2007) Our study also the 'p' value should to be highly significant for the pain in VAS score (p<0.0001). So, From our study, we can strongly recommend GELATAMP in surgically removed, Mandibular 3rd Molar socket for reduction of post operative complication especially pain. In our present study the swelling assessment was done by the extent of facial swelling which was determined by a modification of tape measuring method described by Gabaka and Matsumara. Three measurements were made between 5 reference points: tragus, soft tissue pogonion, lateral corner of the eye, angle of mandible and outer corner of the mouth, preoperatively, and on 1st, 3rd, and 7th postoperative day. The difference between baseline and each postoperative day indicate the level of facial swelling for that day.

Conclusion

The limitation of our study is the small sample size. Randomized controlled trials with larger sample sizes, long time follow up, histological evaluation of the tissue over extracted site, and radiological evaluation of bone, are required to confirm the findings of our study. Also, Within the limitations of our study, it can be concluded that trial side (GELATAMP side) showed very minimal postoperative complications like pain, swelling and better soft tissue healing and patient comfort when compared with control side provided proper patient selection is essential.

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