



EVALUATION OF EFFICACY OF INTRAORAL MUCOADHESIVE DRESSING MATERIAL IN PATIENTS UNDERGOING MAXILLOFACIAL TRAUMA SURGERY - A SPLIT-MOUTH STUDY

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ABSTRACT

AIM AND OBJECTIVE: To assess the healing of intraoral surgical wounds using a mucoadhesive dressing material- ResoPac® in oral and maxillofacial trauma.

METHODOLOGY: The study population included 15 patients, who were diagnosed with maxillofacial fractures and required open reduction and internal fixation of fractures through an intraoral approach on two different surgical sites. After the wound closure was achieved using sutures, a layer of ResoPac® was placed immediately on one site and no additional intervention was carried out for the other site. Both the study sites were evaluated for wound healing on the 2nd and 7th postoperative days and pain control on the 1st, 2nd, and 7th postoperative days. All of the measurements were collated and subjected to statistical analysis.

RESULTS: The study revealed that there was a statistically significant difference in results with sites receiving ResoPac® having better wound healing on both postoperative days 2 and 7 ($p < 0.001$) and also there was a statistically significant better pain control on postoperative days 1, 2 and 7 ($p < 0.001$).

CONCLUSION: The study revealed that ResoPac® is an excellent adjuvant wound dressing material that can provide early wound protection as well as accelerate the wound healing process and provide better pain control enhancing patient's comfort than leaving the sutured surgical wound exposed directly to the oral cavity during the early phases of wound healing.

KEYWORDS: Dressing, Wound healing, Pain, Maxillofacial surgery, Fractures.

1. INTRODUCTION

Wounds of the oral mucosa usually heal rapidly despite their adverse surroundings of saliva, bacteria, and trauma from local factors, such as the movement of the tongue or other oral structures during speaking or eating. Nevertheless, healing may be delayed if the wound becomes infected by the ambient microorganisms of the oral cavity or if the blood clot covering the wound is disturbed by local conditions or by the fibrinolytic activity of saliva. Such complications usually cause considerable discomfort or pain. (1)

There have been studies to find answers for early wound healing and better pain control, which are the two main problems with intraoral surgical wounds.

Many intraoral dressing materials can be used, but each has its disadvantages. Examples include zinc oxide eugenol-based packs, oxidized regenerated cellulose, Coe-pak, collagen-based dressings, bismuth iodoform paraffin paste, light cure dressings, whitehead varnish paste, amniotic membranes, etc.

According to research, the idea of an ideal environment for wound repair promotes faster healing and lessens wound contracture. (2). In a warm, moist, and clean environment, wounds are more likely to heal. A moist wound bed will encourage the migration of growth factors and a variety of cell types, including epithelial cells, which will aid in the contraction of the wound edge. Appropriate dressings are used to establish and sustain this environment. (3) The use of a biocompatible intraoral wound dressing can assist in creating and sustaining an ideal environment for healing.. (2)

Thus, the use of an appropriate biocompatible, muco-adherent, self-resorbing intraoral dressing material is required to provide early wound protection and maintain an optimal environment for wound healing to occur without any discrepancies. One such dressing is "ResoPac®" (Hager & Werken GmbH), a self-dissolving hydrophilic wound protection paste that serves as a protection barrier, astringent, antiseptic, and drug carrier.

Numerous studies have been carried out on the efficacy of these dressings in third molar impaction procedures and periodontal flap surgeries. However, there were no studies on the use of these dressings on maxillofacial trauma. In our split-mouth study, we used ResoPac® which is a mucoadhesive intraoral dressing material, and adapted it in our cases postoperatively and were assessed for wound healing and pain control (FIG1).



FIG 1: ResoPac®

2. PATIENTS AND METHODS

Study Design

A randomized controlled trial was performed on 15 patients who required intraoral incisions in two different surgical sites in maxillofacial trauma cases for fixation of the maxillofacial fractures in the department of oral, maxillofacial, and reconstructive surgery between April 2020 to December 2022. Patients were explained about the study before giving their consent for the procedure and follow-up. The Institutional Ethical Committee Board approved the study. (BDC/Exam/574/2020-21).

Inclusion and Exclusion criteria

Inclusion criteria were: patients aged 18–60 years who require intraoral incisions in two different surgical sites in maxillofacial trauma. Patients with immunosuppressive diseases were excluded from the study.

Details of the sample

Patients who met inclusion criteria were selected. Sample size was estimated using G Power software with 90% power to detect significant difference between sites. Based on a Pilot study, probability was set at 0.05 assuming 20% dropout, and sample size was calculated as $n=15/\text{site}$. A computer-generated randomizer was used to divide the sample into study and control sites. The study utilized the split-mouth method, assigning one surgically sutured site for topical Resopac® application (study site) and the contralateral site for no adjunct applications (control site). To eliminate individual variances, the study and control sites were assigned to the same patient.

A single surgeon performed each of the operations. The second investigator used Resopac® and no adjunct applications at the study and control sites respectively by the computer-generated randomizer. The third investigator assessed the parameters.

Surgical procedure

All the patients were examined and diagnosed. The surgical management was planned and executed as per the requirement under general anesthesia.

The following steps were standard in all the procedures:

Standard facial preparation and draping procedures were followed. Intraoral irrigation was done using betadine and normal saline. Intraoral incisions were placed using a No. 15 BP blade depending on the intraoral approach planned. Incisions deepened to expose the fracture site. Fracture segments were manipulated and reduced followed by wire IMF to maintain the occlusion whenever necessary.

Fracture fixation was carried out using the necessary hardware. Closure was achieved using 3-0 VICRYL sutures.

Investigator 2 placed the post-operative dressing. The entire length of the wound was covered by a one-time topical application of Resopac® at the study site after suturing. (FIG 2). No additional applications were done at the control site. All the patients were given the required amount of intravenous antibiotics and analgesics in the postoperative phase.



FIG 2: ResoPac® applied over the sutured right side (study site) in a bilateral Lefort 1 fracture

Resopac®

ResoPac® is supplied in a 25g tube as well as in a 2g pre-weighted single-use cup. In our study, we used the 2g pre-weighted single-use cup as it would help preserve the sterility in the operating room. A sparingly amount of 2g pre-weighted ResoPac® single-use cup was used and was dispensed using a moist metallic instrument onto well-moistened gloves and was manipulated to a thin roll and pressed onto the surgical site (FIG 3, FIG4). The surface of the dressing was smoothened out with well-moistened fingers.



FIG 3: ResoPac® manipulation



FIG 4: ResoPac® manipulated to a thin roll.

Assessment of parameters

A third investigator, who was unaware of the study and control sites, evaluated the outcome parameters, postoperative pain, and wound healing:

- Post-operative pain was assessed on post-operative day 1,2 and 7 using Visual Analogue Scale (VAS)(4) and graded from 0-10 (no pain to worst pain).
- Wound healing was assessed on post-operative day 2(FIG 5) and day 7(FIG 6) based on Early Wound Healing Score (EHS)(5) (TABLE 1) which assesses clinical features like clinical signs of re-

epithelization(CSR), clinical signs of hemostasis (CSH), and clinical signs of inflammation(CSI). CSR evaluation criteria included 0, 3, or 6 points, and CSH and CSI evaluation criteria included 0, 1, or 2 points. (Table 1). The EHS was produced by adding the points of these three parameters. The EHS for optimal wound healing was 10, and the lowest score possible was 0.



FIG 5: Wound healing on postoperative day 2 showing better healing on right side (study site) than left side (control site).



FIG 6: Wound healing on postoperative day 7 showing better healing on right side (study site) than left side (control site).

Table 1: Early wound healing score

Parameter	Description	Points
CSR	Merged incision margins	6
	Incision margins in contact	3
	Visible distance between incision margins	0
CSH	Absence of fibrin in the incision margins	2
	Presence of fibrin in the incision margins	1
	Bleeding at the incision margins	0
CSI	Absence of redness along the incision length	2
	Redness involving <50% of the incision length	1
	Redness involving >50% of the incision length and/or pronounced swelling	0

Statistical analysis

The data were described using descriptive statistics, including mean, standard deviation, and frequencies for continuous data and percentages for categorical data. Normality was assessed using the Shapiro-Wilk test and the data was not normally distributed. Hence, nonparametric tests like the Whitney U test and Wilcoxon test were used to assess the intergroup and intragroup changes in study parameters over the two time periods. Data was entered into Microsoft Excel and analyzed using SPSS version 25 (IBM Inc). The level of significance was kept at 5%.

3. RESULTS

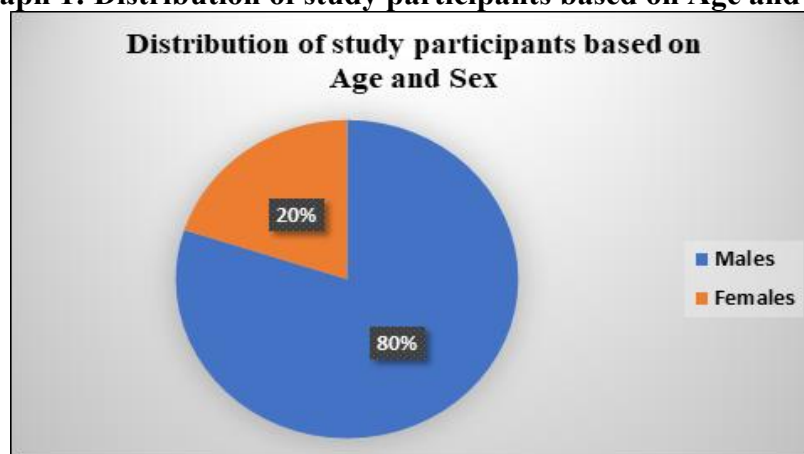
Age and sex

In total, 15 patients were enrolled in the trial, 12 of whom were men and 3 of whom were women. The age range of the patients was from 19 years to 55 years with a mean of 29.13 years (Table 2 and Graph 1).

Table 2: Distribution of study participants based on Age and Sex:

Demographic Details		
Age	Mean	SD
Mean Age (in years)	29.13	9.05
Sex	N	%
Males	12	80%
Females	3	20%

Graph 1: Distribution of study participants based on Age and Sex:



Wound healing

The mean wound healing score at the study site on post-operative day 2 was 5.0 and on post-operative day 7 was 8.73 against the wound healing score at the control site of 3.47 and 6.87 on postoperative day 2 and day 7 respectively (Table 3 and Graph 2). Intergroup comparison was done using the Whitney U test. A statistically significant difference was observed in early wound healing between the two groups on day 2 ($p=0.006$) and day 7 ($p=0.008$) postoperatively, with a higher wound healing score at the ResoPac® site (5.00 (2), 9.00 (4), respectively) as compared to Non-ResoPac® site (4.00 (1), 7.00 (4), respectively), indicating better healing at the ResoPac® site at day 2 and day 7 postoperatively (Table 4 and Graph 3).

Table 3: Wound Healing Score at the study sites:

Wound Healing Score	N	Mean	SD	ResoPac® Site
Postoperative Day 2	15	5.00	1.558	
Postoperative Day 7	15	8.73	1.534	
Non-ResoPac® Site				
Postoperative Day 2	15	3.47	1.407	
Postoperative Day 7	15	6.87	2.031	

Graph 2: Wound Healing Score at the study sites:

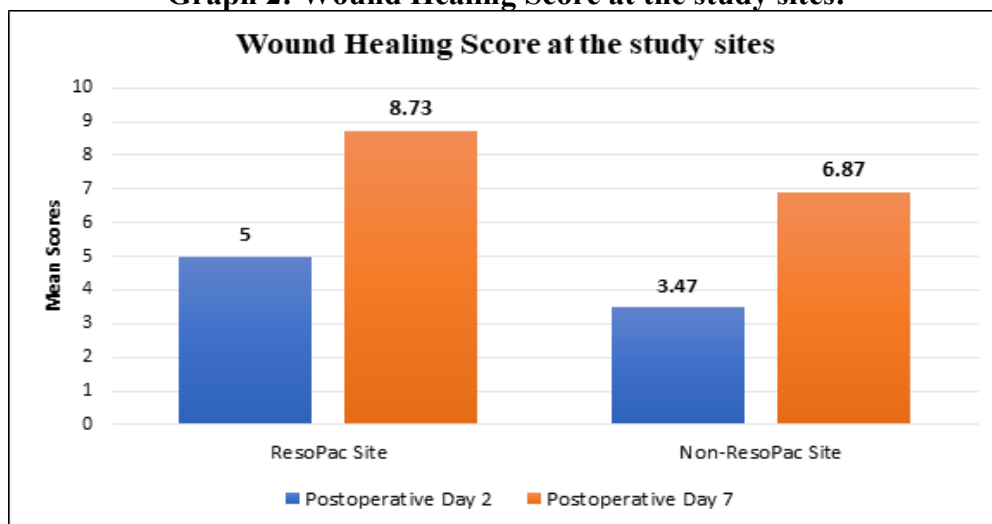
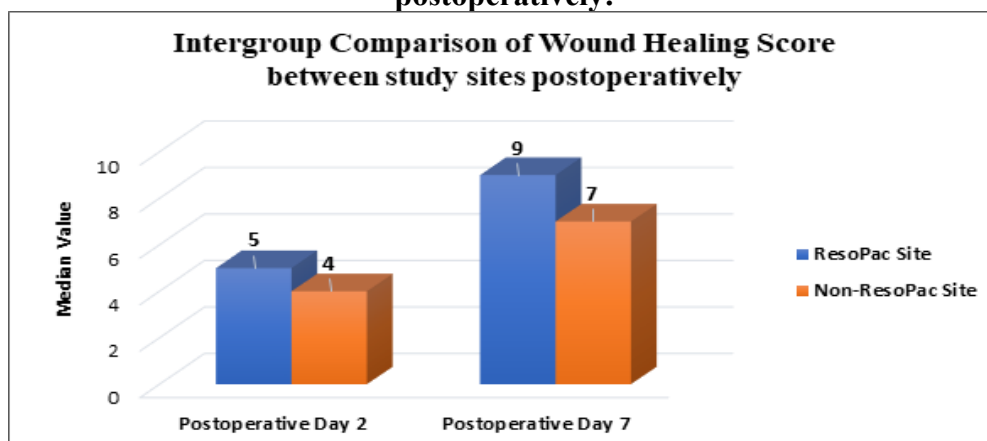


Table 4: Intergroup Comparison of Wound Healing Score between study sites postoperatively:

Wound Healing Score	N	ResoPac® Site	Non-ResoPac® Site	Test Statistic ^a	P-value
		<i>Median (IQR)</i>			
Postoperative Day 2	15	5.00 (2)	4.00 (1)	-2.766	0.006*
Postoperative Day 7	15	9.00 (4)	7.00 (4)	-2.659	0.008*

Graph 3: Intergroup Comparison of Wound Healing Score between study sites postoperatively:



Pain control

The mean pain scores at the study site on postoperative days 1, 2, and 7 were 4.53, 3.93, and 2.27 respectively against the pain score at the control site of 6.20, 5.53, and 3.53 on postoperative days 1, 2, and 7 respectively (Table 5 and Graph 4). Intergroup comparison was done using Mann Whitney U test. A statistically significant difference was observed in pain scores between the two groups on day 1 ($p < 0.001$), day 2 ($p = 0.001$) and day 7 ($p = 0.002$) postoperatively, with a lower pain score at the ResoPac® site (5.00 (1), 4.00 (2), 2.00 (2), respectively) as compared to Non- ResoPac® site (6.00 (2), 6.00 (2), 4.00 (1) respectively), indicating better pain control at the ResoPac® site at day 1, day 2 and day 7 postoperatively (Table 6 and Graph 5).

Table 5: Pain Scores at the study sites:

Pain Scores (VAS)	N	Mean	SD
ResoPac® Site			
Postoperative Day 1	15	4.53	.990
Postoperative Day 2	15	3.93	.799
Postoperative Day 7	15	2.27	.594

Graph 4: Pain Scores at the study sites:

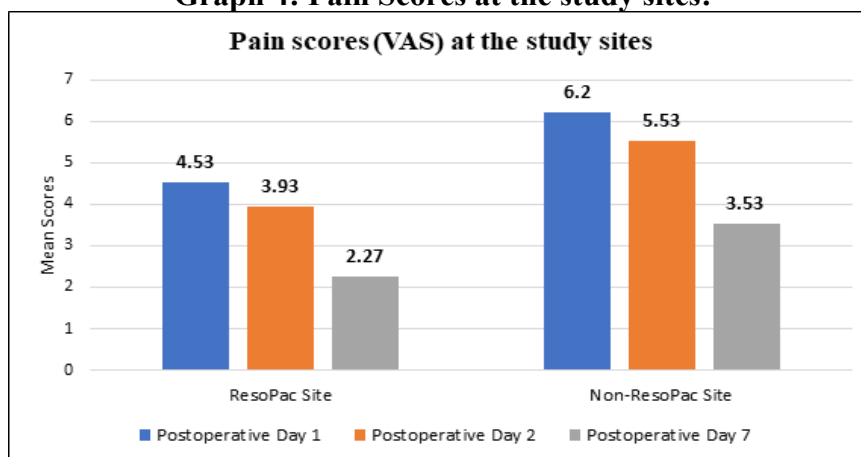
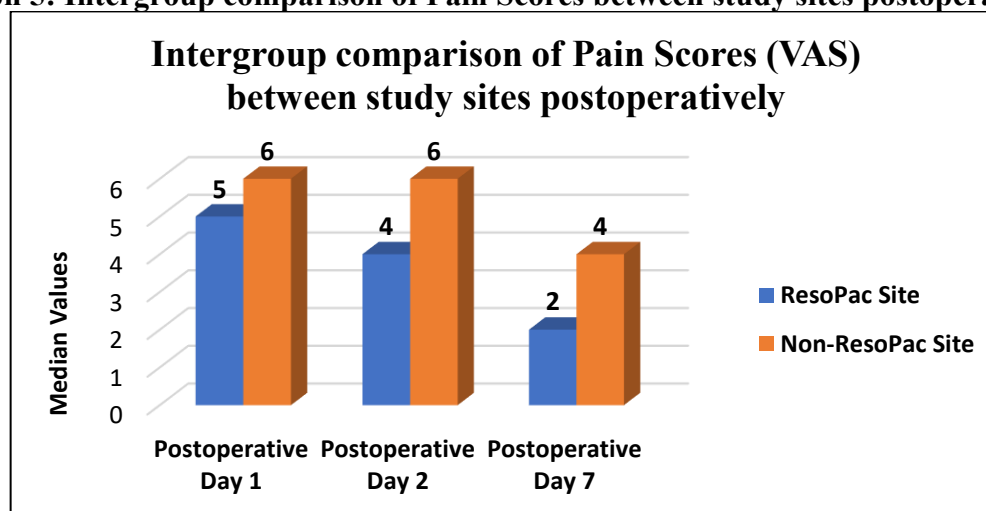


Table 6: Intergroup comparison of Pain Scores (VAS) between study sites postoperatively:

Pain Scores	N	ResoPac® Site	Non-ResoPac® Site	Test Statistic ^a	P-value
		Median (IQR)			
Postoperative Day 1	15	5.00 (1)	6.00 (2)	3.635	<0.001*
Postoperative Day 2	15	4.00 (2)	6.00 (2)	3.300	0.001*
Postoperative Day 7	15	2.00 (2)	4.00 (1)	3.086	0.002*

Graph 5: Intergroup comparison of Pain Scores between study sites postoperatively:

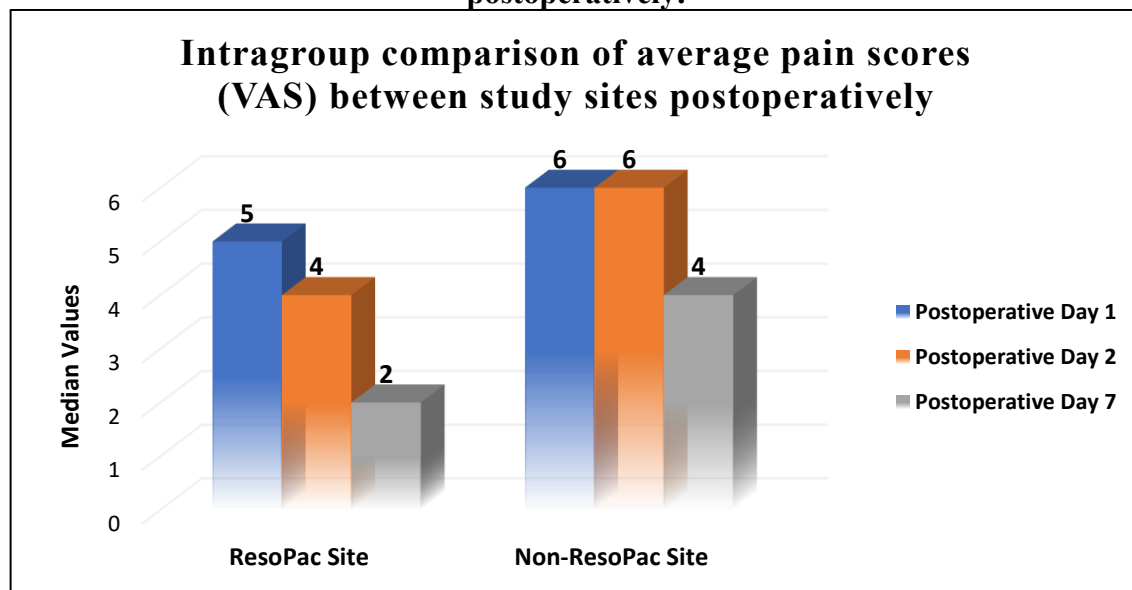


The intragroup comparison was done using the Friedman Test with Bonferroni Correction. A statistically significant reduction was observed in pain scores at the ResoPac® site from day 1 to day 7 ($p<0.001$), and from day 2 to day 7 ($p=0.002$); while similar reductions were also observed at the Non- ResoPac® site from day 1 to day 7 ($p<0.001$), and from day 2 to day 7 ($p=0.002$) (Table 7 and Graph 6).

Table 7: Intragroup comparison of average Pain Scores (VAS) between study sites postoperatively:

Pain Scores	N	Postoperative <i>Median (IQR)</i>				Test Statistic ^a	P-value
		Day 1	Day 2	Day 7			
ResoPac® Site	15	5.00 (1)	4.00 (2)	2.00 (2)	Day 1 vs Day 2	1.187	0.706
					Day 1 vs Day 7	4.564	<0.001*
					Day 2 vs Day 7	3.378	0.002*
Non ResoPac® Site	15	6.00 (2)	6.00 (2)	4.00 (1)	Day 1 vs Day 2	1.180	0.706
					Day 1 vs Day 7	4.564	<0.001*
					Day 2 vs Day 7	3.388	0.002*

Graph 6: Intragroup comparison of average Pain Scores (VAS) between study sites postoperatively:



4. DISCUSSION

The importance of wound healing following surgery cannot be overstated, as the benefits of the procedure may be lost if the wounds are not adequately cared for. Natural resistance to bacterial invasion differs from tissue to tissue and is dependent on the overall physiologic state. Surgical procedures and anesthesia both have the potential to reduce host resistance for brief periods. It has been adequately established how much protection normal host resistance offers and how easily such resistance can be compromised by abnormal physiology, such as that brought on by a foreign entity. (6) The oral cavity is a remarkable environment where wound healing occurs in warm oral fluid which is home to millions of microorganisms. (7) In addition, the presence of plaque and accumulation of food debris also play a major role.

The intraoral technique for open reduction and internal fixation of maxillofacial fractures is advantageous for the patient since it meets a crucial modern medical need and is acceptable from an aesthetic standpoint. However, the dynamic nature of the oral cavity presents a challenge, making suturing a crucial step in maintaining the integrity of the performed surgery. The traumatic exposure of the cutaneous nerve endings caused by the incision itself and the extensive manipulation of oral mucosal tissues increase the subject's suffering leading to extreme discomfort. An inadequate closure using sutures might lead to the percolation of oral fluids along with the millions of microorganisms with it to the deeper tissues of the surgical site and might lead to failure of the fixation hardware used. If the sutures are placed too tight, then it can lead to excessive tissue tension and lead to flap necrosis. Suture materials can be a potential risk factor for infection because they can adhere to microorganisms subsequently leading to infection. The patient's poor oral hygiene makes the issue worse, especially because the arch bars and intermaxillary fixation wires increase the adhesion of food particles close to the sutured areas. Multifilament sutures are the most often used sutures in the oral cavity because they offer superior knot security, better handling, and no sharp edges that irritate the mouth. However, it is important to keep in mind that because of their wicking properties, bacteria may infiltrate into deeper tissues causing prolonged and severe inflammation. (8) In our facility, we employ Vicryl 3-0, another multi-filament suture material, for intraoral closure.

As a result, an adjunct is required to troubleshoot such issues, and one approach is to use a dressing material for a brief period to provide early wound protection during the initial phases of wound healing.

A variety of intraoral dressing materials are available but they have their drawbacks. Most of these dressings are meant to be used after periodontal flap surgeries.

Our present study was carried out in search of an effective wound dressing material for intraoral surgical wounds created after various oral and maxillofacial trauma surgeries. One such intraoral dressing material is ResoPac® which was utilized in our study.

ResoPac® (Hager & Werken) is a very easy-to-handle, distinct dressing material. It is a hydrophilic, ready-made wound protection with good adhesion to the oral mucosal tissues. ResoPac® is a cellulose-based matrix in addition to containing myrrh, which has antiseptic, astringent, and hemostatic properties. ResoPac® is considered to be very user-friendly because it doesn't need to be taken out.

Only 2 studies could be found regarding the use of ResoPac® in maxillofacial surgery and were both conducted in third molar impaction cases as parallel arm studies by SL Raghavan et al(9) and Harsha Gorrela et al(10). Ours is the first study of its sort on the application of an intraoral dressing material following procedures for oral and maxillofacial trauma.

In our study, it was found that the study site had better wound healing than the control site on both postoperative day 2 and day 7 and better pain control on postoperative days 1,2 and 7. Both the studies by the authors support our results in terms of wound healing and postoperative pain control. They also added that their patients had better postoperative comfort.

The excellent outcomes in these cases are due to ResoPac® acting as a complete barrier against mechanical injuries and chemical insults by sealing the exposed nerve endings. In 24 hours, the initial epithelialization of intraoral wounds begins, and ResoPac® provides the necessary protection during this time.

ResoPac®'s widest applications have been more in periodontal flap surgeries and have been tested for their role as a periodontal dressing. Periodontal dressings are applied to surgical wounds to protect them, achieve and maintain the close adaptation of mucosal flaps to the underlying bone, and provide comfort to patients. In addition, they can prevent post-operative bleeding during the initial phase of healing, preventing excessive granulation tissue formation. It has been suggested that antibacterial agents should be incorporated into dressings to prevent bacterial growth in wound areas during healing. (11) ResoPac® convincingly fills these criteria with the addition of c. myrrha. In addition, medications can be incorporated into it during manipulation if necessary. Studies on Coe-pak and ResoPac® also showed favorable results with better pain control in the ResoPac® group. Also, the facial swelling was found to be lower. (12,13)

However, the wound healing wasn't assessed here. In contrast to these results, a study by authors found that there was no significant difference between wound healing in Coe-pak and ResoPac®.(14) ResoPac® is considered safe to use and non-allergenic in nature by various studies. Studies by Kadkhodazadeh et al(15) and Leila Gholami et al(13) on the comparison of cytotoxic effects of ResoPac® and Coe-pak revealed that ResoPac® was less cytotoxic and more biocompatible. This is supported by our study as we found no adverse reactions locally or systemically in any of our patients. However, it has to be noted that all of our patients were under the coverage of 3 doses of corticosteroids postoperatively (Inj. Dexamethasone 8mg).

All our patients had Erich's arch bars stabilised in both upper and lower arches which were used intraoperatively to obtain occlusion and is one of the factors leading to gaping of the sutured site as they constantly impinge on the vestibular region and also accumulate food debris leading to local irritation of the wound site delaying wound healing and increasing pain for the subject. However, with the aid of ResoPac®, we could protect the wound site at least for the next 24 hours which is considered to be a critical phase in wound healing.

During the course of our study, we also have used ResoPac® in cases other than maxillofacial trauma. One of the cases we would like to highlight is a case of central giant cell granuloma of the anterior mandibular region in which segmental mandibulectomy was carried out and reconstruction was done using a nonvascularised fibula bone graft. On the 2nd post-operative day, wound dehiscence was

observed intraorally exposing the bone graft for which we decided to apply ResoPac® every day for a period of 12 days and it was seen that the size of the exposed bone graft gradually decreased in size and eventually healed. We also tried ResoPac® for raw wound coverage after various procedures like epulis fissuratum, alveoloplasties, oral submucous fibrosis, and intraoral plate removal procedures with good results.

The formation of granulation tissue is disrupted by postoperative bleeding, which slows the healing process. (16) ResoPac® contains c.myrrha which has hemostatic properties and the dressing itself provides some pressure over the wounds which prevents bleeding. This can be correlated with a study by Savitha AN et al(12) which showed that post-operative ooze after the periodontal surgery with the ResoPac® group was less when compared to Coe-pak.

It was observed that during the first 24 hours, the dressing after assuming a gelatinous consistency, in the phase of getting resorbed would migrate to the adjacent tissues away from the tissues intended to be protected which could have partially reduced its full efficacy on the wound site.

Although ResoPac® is tasteless and odorless, some patients were aware of the leaching of material as the material slowly dissolved leading to mild discomfort. There was no need to spit the material during this process as it is safe to ingest it. None of our patients had difficulty in speech and mastication postoperatively due to the material. Also, the cost of the material is cheaper since we used it as a one-time application in contrast to repeated applications done in other studies. Thus, it can be said that ResoPac® is patient-friendly.

From the surgeon's perspective, ResoPac® application and manipulation were simple to grasp and quick to master. A simple periosteal elevator or other tool of a similar design was needed to receive the material, and normal saline was used to moisten it.

According to our study, ResoPac® remained in the oral cavity for anywhere between 20 and 42 hours before completely dissipating. The disintegration process occurred more swiftly on the mandible than it did on the maxilla, between 20 and 26 hours as opposed to 26 to 42 hours. Due to saliva accumulating in the oral cavity and the drowsiness during the post-operative recovery period following general anesthesia, this rapid disintegration time may be explained. More fluid consumption is one of the other causes, which was true in our case since we promoted a post-operative diet high in liquids. Even though we were aware of it, it was inevitable.

Another point to be noted is that ResoPac® when placed gradually swelled during the next few hours. Thus, it was difficult to exactly calculate the amount of material to be utilized, however with repeated usage we were able to arbitrarily assume it later. Additionally, when it expanded, it would attach itself to the arch bars, but this only served to their benefit because it took a little longer to dissolve and also prevented the arch bars from constantly impinging the sutured region.

From our study, we would like to conclude that the importance of coverage of the intraoral sutured surgical wounds with some sort of intraoral dressing material cannot be overemphasized and here we have used ResoPac® which has proved to be very effective in terms of better wound healing and pain control. Further improvements in the disintegration time and more controlled expansion of the material are required.

5. CONCLUSION

The findings of our study concluded that ResoPac® is a superior adjuvant intraoral wound dressing material after oral and maxillofacial trauma surgeries utilizing intraoral approaches because it can provide early wound protection by acting as a barrier, speed up the healing process, and improve patient comfort due to less pain as opposed to leaving the sutured surgical wound directly exposed to the dynamic environment of the oral cavity during the early phases of healing.

6. CONFLICT OF INTEREST

We have no conflicts of interest.

7. ETHICS STATEMENT/CONFIRMATION OF PATIENTS' PERMISSION

The necessary approval for the study was obtained from the institutional review board (BDC/Exam/574/2020-21). The patients permitted the procedure.

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