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Effect of the absorption rate of suture material on oral mucosal scar formation: A triple-blind randomized controlled trial

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ABSTRACT

Introduction: Extensive oral mucosal scar formation following LeFort-I osteotomy can pose patients with several scar-related complications in case of function as well as cosmesis. The present study aimed to evaluate the effect of the absorption rate of *Vicryl Rapide* and *Vicryl* on oral mucosal scar formation.

Material and methods: In a triple-blind randomized controlled trial study, *Vicryl* and *Vicryl Rapide* were used randomly for wound closure on the left and right sides of the *LeFort-I* incision line. Three maxillofacial surgeons evaluated mucosal scars on each side two and four months post-surgically using *Mucosal Scarring Index (MSI)*.

Results: The differences in the total scores of *MSI* between the *Vicryl* and *Vicryl Rapide* groups were not significant, neither in the anterior nor in the posterior areas (Paired *t*-test, df = 25, CI = 95 %, *P*-value >0.05).

Conclusion: The results of the present study demonstrated that *Vicryl Rapide* is comparable to *Vicryl* suture material regarding the mucosal scar formation following *LeFort-I* osteotomy surgery; therefore, it could be considered for such oral surgical procedures.

1. Introduction

Scar formation is an inevitable consequence of a surgical incision. Fibroblast cells active in the growth phase of wound repair can have spatial or anatomic heterogeneity responsible for variable levels of fibroblastic functional diversity [1–4]. Due to the histological differences between skin and mucosa, mucosal wound healing usually takes place faster with minimum scar formation. However, this problem is still of significant importance in a variety of mucosal surgeries with fairly large incisions [5]. Moreover, it seems wound healing following surgical incision in particular sites of the oral mucosa, including the vestibular area, can contribute to more significant scarring [5]. Regarding the location, extent, and depth of incision in the *LeFort-I* osteotomy technique, scar formation to a greater extent is anticipated.

In addition to the intrinsic non-modifiable factors, extrinsic factors related to the surgical procedure including surgical technique, suturing technique [6], and suture material absorbability [7] can have a significant impact on the quality and extent of scar tissue formation. It is shown that absorbable suture materials lead to better results in terms of scar formation when compared to

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non-resorbable materials [8,9]. Also, resorbable suture materials with a higher rate of absorption are preferred over those with a lower rate of absorption [10].

Both *Polyglactin 910* (*Vicryl*) and *Irradiated polyglactin 910* (*Vicryl Rapide*) are poly-filament synthetic absorbable materials eliminated from the tissue due to the hydrolysis process. *Vicryl* claimed to lose 60 % of its tensile strength after 21 days; while, complete elimination may last up to 56–70 days. The low rate of absorption and subsequent long-term presence of the material in the oral cavity may not be considered a favorable characteristic for the intraoral application of *Vicryl*. *Vicryl Rapide*, on the other hand, is claimed to be removed by gentle application of gauze or spontaneously after 12–14 days; hence, it can be regarded as a good clinical choice for oral surgical procedures [11].

Vicryl Rapide suture material has been recently used widely in a diversity of medical fields including pediatric surgery, skin surgery, obstetric surgery, and also oral surgery. Limited studies, however, are available evaluating the scar characteristics of this material in the oral mucosa.

In a clinical trial study by Odijk [12] on 250 patients after delivery, it was shown that *Monocryl* is superior to *Vicryl Rapide* in the case of wound dehiscence. In other similar studies [13,14], however, *Vicryl Rapide* suture material is superior to *Vicryl* suture and is considered the ideal choice for this purpose.

Scar features of absorbable suture materials have also been studied in the skin. Bozan and Dizdar [15] showed higher scores for columellar scar in absorbable sutures when compared to non-absorbable materials following open rhinoplasty. Yamamoto and colleagues [16] also suggest absorbable suture materials as a substitute for non-absorbable ones in oral cancer surgeries regarding a lower risk of stitch abscess.

1.1. Theory

Mucosal scar formation following the large incision made in the *LeFort-I* osteotomy technique can pose patients with several scar-related complications concerning function and cosmesis. Alterations in the sensation and oral function related to the presence of scar tissue in the maxillary vestibular area that contributes to food retention as well as esthetic issues due to the anterior position of the scar tissue and being more accessible may result in dissatisfaction. The present study aimed to evaluate whether *Vicryl Rapide* suture material could reduce the mucosal scar subsequent to LeFort I osteotomy surgery in comparison to commonly used *Vicryl* suture material.

2. Material and Methods

This randomized triple-blind controlled trial study was performed on 31 patients referred to the *Educational Hospitals* in Isfahan, Iran. The formula for *Comparison of Two Means* was used for calculating the sample size. A minimum difference of 0.9 in the mean score of *the Mucosal Scarring Index (MSI)* between the *Vicryl* and *Vicryl Rapide* groups was considered statistically significant with α-error of 0.05 and 1-β = 0.80. None of the researchers, patients, outcome assessors, and the data analyzer was aware of the exact location of the suture materials.

This study followed the *Declaration of Helsinki on Medical Protocol and Ethics*, and the *Regional Ethical Review Board* of our University approved this study (Ethical approval code: *IR.MUI.RESEARCH.REC.1399.284*). Afterward, this study was registered in the Iranian clinical trial registry (IRCT Id: *IRCT20131205015665N5*). Informed consent was obtained pre-operatively from all participants. The unwillingness of the patient to continue participating in the study came into consideration; all patients' information was kept confidential in this study.

Regarding the split-mouth design and similar parallel intervention in all participants, Simple randomization was done using online computer software *(*http://www.randomization.com*)* that provided a randomized order for the application of intended suture materials.

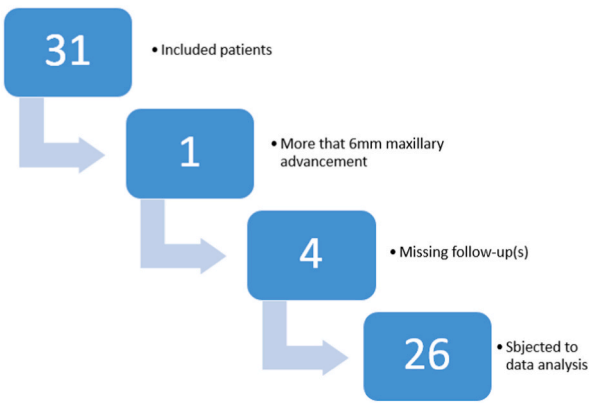

Fig. 1. Study flowchart.

Patients with upper jaw deformity with the indication of orthognathic surgery using *the LeFort-I* osteotomy technique were included in the present study. Known or suspected allergy to suture materials, presence of any underlying systemic condition interfering with the wound healing process, pre-operative presence of scar tissue in the maxillary vestibular area, long-term high dose application of corticosteroid medications, antibiotics, and immunosuppressive drugs, tobacco use, and alcohol addiction, maxillary advancement more than 6 mm, maxillary disimpaction, severe postoperative complications (Infection, Edema, Hematoma), and wound dehiscence were amongst the most important exclusion criteria.

A total number of 31 patients met the inclusion criteria; however, one patient was excluded because of more than 6 mm maxillary advancement. Four patients were not available for two and four months follow-up sessions, as well. Also, one participant underwent plate and screw removal surgery after her 2-months follow-up session; therefore was missed the second recall (Fig. 1). No case of wound dehiscence or severe complication was detected in post-operative evaluations. The type of the suture material which was encrypted as "*A = Vicryl Rapide*" and "*B = Vicryl*" was only disclosed after the data was analyzed.

All included participants underwent upper jaw correction surgery with *the LeFort-I* osteotomy technique between *September 2020* to *April 2021*, performed by a single experienced surgeon and the same standard protocol. In this technique, a V-shape incision in the maxillary buccal mucosa was made. A single #15 blade was used for each half of the incision line to make sure that a sharp incision line with minimum trauma to the oral mucosa was made. Afterward, a sealed pocket corresponding to each patient's ID number was opened containing the randomized order for wound closure, a 3-0 *Vicryl,* and a 0 3-0 *Vicryl Rapide* suture materials *(Ethicon Inc., Johnson and Johnson Company, Somerville, New Jersey)*. The simple running suturing technique was then used for primary wound closure of each half of the incision line from the maxillary first molar teeth to the midline. Suture removal was done neither for the *Vicryl* nor for the *Vicryl Rapide* groups, and sutures completed their absorption mechanism until the material was eliminated from the mucosal wound spontaneously or with a gentle application of sterile gauze.

Two and four months postoperatively [17,18], patients were recalled for scar evaluation; three instructed experienced and board-certified oral and maxillofacial surgeons were asked separately to score the mucosal scars on each side (Figs. 2 and 3) by using the *Mucosal Scarring Index* [19]. Each of the five parameters in this compound index was scored from 0 to 2; the total score was calculated from 0 (the most ideal result) to 10 (the least favorable result) (Fig. 4).

3. Results

The mean age of the participants was 24.2 ± 4.7 with the minimum and maximum ages of 18 and 36, respectively. Female patients constituted 74 % of the participants.

Kappa Coefficient of greater than 0.8 in all subcategories of the *MSI* showed agreement between three outcome assessors.

Notwithstanding the higher scores of *MSI* in *the Vicryl Rapide* group in comparison to the *Vicryl* group both in the anterior and posterior areas (Fig. 5), *Paired t-test* results showed that the differences in the total scores of *MSI* between the *Vicryl* and *Vicryl Rapide* groups were not significant neither in the anterior nor in the posterior areas in both 2-month and 4-month recall sessions (df = 25, CI = 95 %, *P*-value >0.05) (Table 1). However, this difference was significantly higher in the anterior area compared to the posterior part in each *Vicryl* and *Vicryl Rapide* group in both 2-months and 4-months recall sessions (df = 25, CI = 95 %, *P*-value <0.001). *Paired t-test* also showed a significant difference in the total score between 2 and 4-months follow-up sessions only in the *Vicryl* group in the anterior area (df = 25, CI = 95 %, *P*-value <0.05).

Wilcoxon test also demonstrated significant differences between 2 and 4-months assessments (Table 2).

The differences in all five scar values (scar width, height, color, suture mark, and overall appearance) when comparing anterior and posterior sites were significant in both *Vicryl* and *Vicryl Rapide* groups; and also in both two and four months recalls (*P*-value <0.001). These results suggest the probable role of a more pronounced muscular activity in the anterior area leading to a higher risk of scar formation regardless of the type of suture material.

4. Discussion

The present study showed comparable results for *Vicryl Rapide* to the more commonly used *Vicryl* suture material in terms of scar

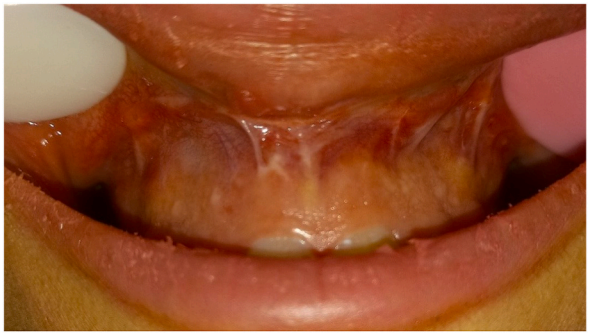

Fig. 2. Two-month follow-up (Right side: Vicryl Rapide/Left side: Vicryl).

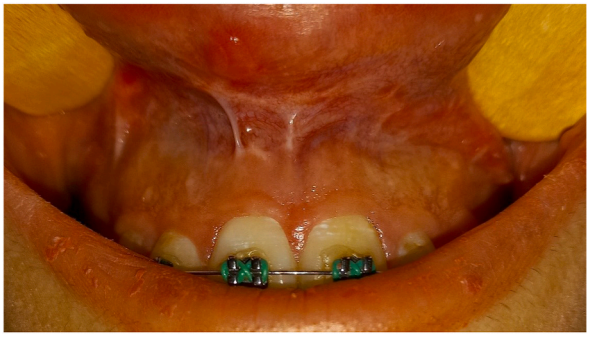

Fig. 3. Four-month follow-up (Right side: Vicryl Rapide/Left side: Vicryl).

Parameters	Scar Category	LeFort I			
		Right side		Left side	
		P	A	A	P
Width	>1mm	2	2	2	2
	≤1mm	1	1	1	1
	0mm	0	0	0	0
Height/Contour	Hypertrophic or invaginated	2	2	2	2
	Slightly hypertrophic or invaginated	1	1	1	1
	Flush with surrounding mucosa	0	0	0	0
Color	Obvious mismatch	2	2	2	2
	Slight mismatch	1	1	1	1
	Perfect	0	0	0	0
Suture mark	Clearly visible	2	2	2	2
	Slightly visible	1	1	1	1
	Absent	0	0	0	0
Overall appearance	Poor	2	2	2	2
	Acceptable	1	1	1	1
	Good	0	0	0	0

Fig. 4. Mucosal scarring index.

characteristics following *LeFort-I* osteotomy surgery.

Limited studies are available evaluating mucosal scars, and less still, oral mucosal scar formation. In a clinical study with a split-mouth design by Bertrand et al. [20], *Vicryl Rapide* was concluded to be preferred over *Vicryl* regarding pain, difficulty in chewing, duration of swelling, dysgeusia, and major complications following third molar extraction surgery. Our study, however, showed comparable scar characteristics for *Vicryl Rapide* compared to *Vicryl* suture. One probable explanation for contradictory results is the presence of a bony defect under the flap in Bertrand's study compared to the constant bone support in our study. Different locations of the incision lines are another factor that should be considered since the maxillary vestibular area is more susceptible to scar formation. Finally, the sole studied factor in our study was the scar features; while, a more comprehensive evaluation of these two sutures was done in Bertrand's study.

Sevket and colleagues [21] showed a significantly higher rate of healing ratio and lower risk of cesarean section scar defect by application of *Monocryl* rather than *Vicryl* for closure of the uterine incision. In a similar study, it was shown that *Monocryl* is superior to *Vicryl Rapide* concerning tissue inflammation, and it causes narrower scar width in 3-month and 1-year follow-up periods [10]. The

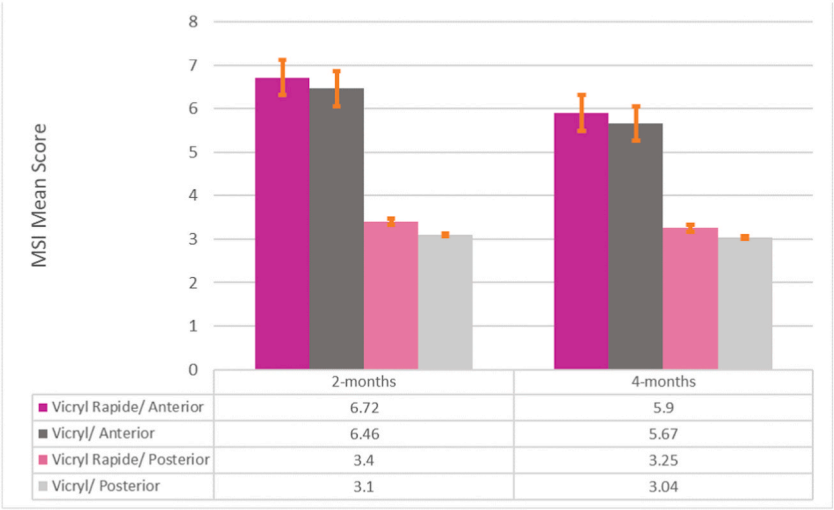

Fig. 5. The mean scores of MSI in the Vicryl and Vicryl Rapide groups 2 and 4 months after surgery.

Table 1
Paired *t*-test results comparing the total score of MSI index between Vicryl and Vicryl Rapide groups in both 2-months and 4-months recall sessions.

Recall	Location	Paired Differences		
		Mean	Std. Deviation	*P*-value
2-months	Posterior	−0.29	2.37	0.52
	Anterior	−0.25	3.03	0.66
4-months	Posterior	−0.20	2.52	0.68
	Anterior	−0.23	2.56	0.65

Table 2
Comparison of the MSI parameters scores between 4 and 2 months recalls in Vicryl and Vicryl Rapide groups.

Suture material	Parameter	Position	Z	*P*-value
Vicryl	Width	Anterior	−2.30[a]	**0.02**
		Posterior	−2.13[a]	**0.03**
	Height	Anterior	−2.46 [a]	**0.01**
		Posterior	−0.61[b]	0.54
	Color	Anterior	−2.31[a]	**0.02**
		Posterior	−1.36[a]	0.17
	Suture mark	Anterior	−1.05[a]	0.29
		Posterior	−0.25[b]	0.79
	Overall	Anterior	−0.58[a]	0.56
		Posterior	−0.85[a]	0.39
Vicryl Rapide	Width	Anterior	−1.29[a]	0.19
		Posterior	−1.07[a]	0.28
	Height	Anterior	−0.98[a]	0.32
		Posterior	−0.61[b]	0.53
	Color	Anterior	−2.10[a]	**0.03**
		Posterior	−0.65[a]	0.51
	Suture mark	Anterior	−1.29[a]	0.19
		Posterior	−0.49[a]	0.62
	Overall	Anterior	−0.58[b]	0.56
		Posterior	−3.34[a]	**0.001**

result of our work, however, showed an insignificant difference in scar scores for the mucosal application of *Vicryl Rapide* compared to *Vicryl*; different suture materials used in these studies, as well as histological differences between oral mucosa and other mucosal tissues and the skin, may justify the contradictory results.

In a study by Rao et al. [22], 6-0 *Vicryl Rapide* is considered inferior to 6-0 *Nylon* suture regarding scar height and hypopigmentation in cleft lip repair surgery. This can be related to the early loss of suture strength in *Vicryl Rapid* suture material that is not favorable when performing surgery in such areas with highly frequently active muscles. In contrast, outcomes of our work showed comparable results for *Vicryl Rapide* suture material in oral surgery which can be justified by the histological differences between the skin and oral

mucosa; therefore, rapid absorption of *Vicryl Rapide* is not regarded as a negative aspect of a scar-formation point of view. Moreover, different suture materials used as control groups (*Nylon* in Rao's study versus *Vicryl* in our study) could be another explanation for the inconsistent results.

On the other hand, in a study by Moran and colleagues [23], it was shown that the application of 5-0 *Vicryl Rapide* or 5-0 *Nylon* suture materials would result in the same scar outcomes in facial wounds resulting from Mohs micrographic surgery excisions. Fast-absorption rate and subsequent quick elimination of *Vicryl Rapide* from the tissue, which results in a decreased local reaction, can explain compatible results with our work, regardless of the histological differences between the skin and oral mucosa.

Some studies suggest that *Vicryl Rapide* can have superior features over other commonly used materials like *Dexon* and *Catgut* regarding higher healing rate, lower incidence of wound dehiscence, and lower local reactions in endodontic or third molar extraction surgeries [24]. This can be justified by small incision lines in minor oral surgeries which are less affected by adjacent structural mobility, as well. Also, the application of *Vicryl Rapide* in lateral lay syndactyly correction is shown to be beneficial concerning hypertrophic scar formation and scar contracture following the surgery, which can lead to the necessity of revision surgery [25]. These results are consistent with our work, and this can be explained by the fact that a higher absorption rate of *Vicryl Rapide* can reduce the risk of foreign body reactions and improve the subsequent healing rate.

Aboutalebi and Wills [26] reported ideal features for *Vicryl Rapide* for the application in the mucosal areas concerning inflammatory response, rapid degeneration, patient comfort, and easy application; similarly, Aderriotis and colleagues [27] reported beneficial intra- and extra-oral applications of *Vicryl Rapide* regarding the incidence of inflammation, suppuration, and hypertrophic scar formation in the oral and maxillofacial region. The results of our study are in agreement with these studies and showed *Vicryl Rapide* has comparable results to *Vicryl* suture material concerning scar formation. This agreement could be the result of a similar field of study alongside the study designs.

4.1. Study's strengths, limitations and suggestions for future experiments

The present study had certain strengths including the split mouth design which controls the confounding factors jeopardizing the accuracy of the results and the following conclusion. It is recommended that other absorbable suture materials, including Monocryl, be compared in future studies. Moreover, other characteristics of the suture materials, including the patient's comfort and the risk of infection, can be assessed simultaneously to help the clinician choose the best material more precisely. Also, simultaneous evaluation of subjective features of the resultant scar tissue, including but not limited to pain, swelling, difficulty in chewing, food retention, altered sensation, is recommended in future studies.

5. Conclusion

It could be inferred from the outcomes of the present study showed that *Irradiated Polyglactine 910* is comparable to *Polyglactine 910* concerning oral mucosal scar formation. Therefore, *Vicryl Rapide* could be considered for such oral surgical procedures with extensive incision lines.

Data availability statement

Data will be made available on request.

CRediT authorship contribution statement

Golnaz Tajmiri: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Milad Etemadi Sh:** Writing – review & editing, Visualization, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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