Original Article

A Prospective, Randomized, Double-blind Trial of the Use of Fibrin Sealant for the Bilateral Sagittal Split Ramus Osteotomy (BSSRO)

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Background: Bilateral sagittal split ramus osteotomy surgery (BSSRO) was done by splitting the mandibular ramus and re-positioning the Mandibular arch to achieve the proper dental occlusion. The common postoperative complication is bleeding and hematoma. The suction drains were used to prevent such problems. Fibrin sealant has been used in several surgical procedures to aid in hemostasis.

Objective: The present study aims to study whether the intraoperative application of Fibrin sealant can reduce the amount of postoperative drainage in BSSRO operation.

Materials and Methods: We performed a prospective, randomized, double-blind study of 20 patients who underwent BSSRO surgery or BSSRO with combined Le fort I and Genioplasty surgery between September 2018 and October 2019, so the total samples were 40 operative sides. Patients were randomly divided into one of two groups based on whether they received intraoperative Fibrin sealant. The volume of the wound drainage was recorded every 24 hours for 72 hours.

Results: The amount of postoperative drainage of the first and second 24 hours was not significantly different. The difference in the pain score and satisfaction score between the two groups were also the same.

Conclusion: The intraoperative fibrin sealant did not have a significant benefit in BSSRO to reduce bleeding. Retaining the vacuum drainage only is sufficient and cost-effective to prevent hematoma in BSSRO.

Keywords: Fibrin glue; Fibrin sealant; BSSRO; Hunsuck; Hematoma

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Bilateral sagittal split ramus osteotomy surgery (BSSRO) is to split and re-position the Mandible to correct the dental occlusion and improve the facial profile. The BSSRO was usually performed together with the Le Fort I osteotomy and Genioplasty. The orthognathic surgery created the raw surface of the bone and soft tissue and caused blood oozing afterward. The postoperative vacuum drain tube is applied to prevent hematoma, subsequent complications.

Fibrin sealant imitates the final phase of the blood coagulation process. Fibrinogen is converted into fibrin on a tissue surface by the action of thrombin, which is then cross-linked by factor XIIIa, creating a mechanically stable fibrin network. This fibrin network is thought to reduce the amount of postoperative bleeding by sealing capillary vessels and allowing raw operative surfaces to adhere. Fibrin glue is also used more frequently in other surgery such as facelift, abdominoplasty, hip arthroplasty. It helps in reducing seroma and hematoma formation and should subsequently decrease the rate of delayed healing, wound dehiscence, and uncontrolled pain. Decreased complications should also lead to a shortened hospital stay and a reduction in associated costs[1,2].

Fibrin sealant is applied at the end of the operation before the wound closure in BSSRO to minimize postoperative hematoma. A recent meta-analysis showed a significant reduction in postoperative total blood loss and drop in hemoglobin without an increase in DVTs (OCEBM Level III)[3].

Although there have been several other recent studies further suggesting that fibrin glue reduces bleeding, hematoma, and postoperative ecchymosis[4-9], there has been no clinical trial in a randomized and prospective fashion looking specifically at whether fibrin glue makes a quantitative difference in both drainage and satisfaction score in the early postoperative period. Our study design is a prospective, double-blinded, randomized, controlled trial in 20 patients undergoing BSSRO to examine the efficacy of fibrin glue in reducing post-operative wound drainage, pain, and

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satisfaction score.

Materials and Methods

The present study was a prospective, double-blind, randomized controlled trial at Ramathibodi Hospital, Mahidol University with ethical committee approval ID 07-61-29 COA.No.MURA2018/516. The estimated sample size of 20 randomized patients to give 80% power at the 5% significant level based on postoperative drainage of 30 ml in the fibrin group, and 10 ml in the non-fibrin group in facelift surgery (alpha 0.05, beta 0.8)[4]. Informed consent was obtained from 20 patients who underwent bilateral sagittal split osteotomy (BSSRO) with and without other related jaw operations over 12 months. All the operations were under hypotensive anesthesia to reduce intraoperative blood loss. Patients were randomized by an independent statistician using STATA version 14.1 program into 2 groups, fibrin group and non-fibrin group, 10 patients, each case received the same treatment on both BSSRO sides, so a total of 20 wounds were counted per group. The patients and assessor were blinded but the surgeons were not possible to blind during the operation.

The BSSRO was done by the same surgeon with the Hunsuck modification technique[10]. The intraoral incision and subperiosteal dissection were done to expose the ramus and body of the mandible, the first cut was made horizontally through the medial cortex of the ramus, then extended anteriorly and just lateral to the molars, vertical cortical osteotomy through the buccal cortex, and continued superiorly to join the cortical osteotomy at ramus (Figure 1). The mandibular ramus was split. After the occlusion was adjusted properly into the occlusal splint, the trocar was introduced through the cheek incision to facilitate the three bicortical screws fixation to secure the proximal and distal segment together with the condyle in the terminal hinge position. The mandibular wound was cleaned and checked for minor bleeding. Then silicone drain No. 8 was placed inside the mandibular wound, and the mandibular vestibular wound was closed in a single layer fashion with interrupted suture with 3-0 Vicryl.

In the study group, the No.8 drain tube was placed before applying the glue. The negative pressure didn't apply until the wounds were completely closed. A total of 2 milliliters of the glue (Tisseel; Baxter Healthcare Corp., Deerfield, Ill) was applied on the raw surfaces of the mandible and the muscle at the end of the operation. The light pressure was applied on the cheek flap for the maximum effect of the fibrin sealant. The vacuum was applied to the drain tube. Both fibrin and control groups received the same amount and duration of pressure at the operative side before wound closure. Both fibrin and control groups had the preoperative capability to stop bleeding if the study was in a different patient. Compression dressings, pain control, cryotherapy, and head elevation were performed in both control and study groups. The amount of drainage was measured by aspiration from the vacuum bottle every 24 hours for 3 consecutive days by an independent recorder. Patients were assessed and given a grade from 1 to 10 for early postoperative pain score and grade 1 to 10 for satisfaction score at postoperative follow-up at 1 month. Statistical analysis was performed with the help of an independent statistician using the STATA version 14.1 program.

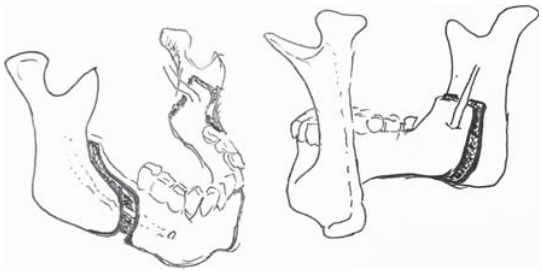

Figure 1. Bilateral sagittal split ramus osteotomy with the Hunsuck modification technique.

Statistical analysis

Data were analyzed using STATA Version 14.1 program. Categorical variables were evaluated using Fisher's exact test. For Continuous variables compared using two-tailed Student's t-test. A p-value <0.05 was considered statistically significant.

Results

The demographic data of the patients were not significantly different between both groups (Table 1). The age of patients ranged from 21 to 42 years with a mean of 26.8 years in the fibrin group and 28.8 years in the non-fibrin group. There were 5 men and 15 women in the study. Mean BMI was 20.54 kg/m^2 in the fibrin group and 21.7 kg/m^2 in the non-fibrin group. The longer operation time and more intraoperative blood loss in the control group because there was more 2 jaws operation which has longer operation time and more bleeding (3 cases: 1 case) (Table 1).

The fibrin sealant group had average drainage of 32.39 ml, 7.8 ml, and 2.24 ml in 1st 24 hours, 2nd 24 hours, and 3rd 24 hours respectively, while the control group had average drainage of 47.16 ml, 6.5 ml, and 0.87 ml in 1st 24 hours, 2nd 24 hours, and 3rd 24 hours respectively. There was no significant difference between the fibrin sealant and the control group in 1st 24 hours and 2nd 24 hours postoperative but had a significant difference in 3rd 24 hours postoperative. The total 72 hours postoperative mean value of the drainage was 42.43 ml and 54.52 ml in the experimental and control groups respectively. There was no significant difference (p=0.194) (Table 2).

The mean early postoperative pain score was 4.3 and 3.8 in the fibrin sealant and the control group respectively. The mean satisfaction score was 8.9 and 8.7 in the fibrin sealant group and the control group respectively. We did not observe any significant difference in early postoperative pain score (p=0.243) and satisfaction score (p=0.531).

Table 1. The demographic data

Demographic data	Non-fibrin (n=20)	Fibrin (n=20)	p-value
Male, n (%)	4 (20)	6 (30)	0.716
Female, n (%)	16 (80)	14 (70)	0.716
Age (years), mean (SD)	28.8 (3.72)	26.8 (5.91)	0.208
BMI (kg/m^2), mean (SD)	21.7 (2.19)	20.54(1.48)	0.056
Set back (mm), mean (SD)	4.9 (1.35)	5.9 (2.22)	0.094
BSSRO only (case)	7	9	-
2 jaws (case)	3	1	-

Table 2. The outcome of the study

Outcome	Non-fibrin (n=20)	Fibrin (n=20)	p-value
Amount of drainage day 1, mean (SD)	47.16 (34.51)	32.39 (17.38)	0.096
Amount of drainage day 2, mean (SD)	6.5 (8.26)	7.8 (5.83)	0.567
Amount of drainage day 3, mean (SD)	0.87 (1.03)	2.24 (1.51)	0.002*
Amount of drainage total, mean (SD)	54.52 (35.94)	42.43 (19.45)	0.194
Pain score, mean (SD)	3.8 (1.2)	4.3 (1.45)	0.243
Satisfaction score, mean (SD)	8.7 (1.13)	8.9 (0.85)	0.531
Complication, n (%)	0 (0.0)	0 (0.0)	-
Operation time (min), mean (SD)	187.5 (67.83)	146.7 (44.99)	0.031*
Blood loss (mL), mean (SD)	565 (449.59)	155 (84.14)	<0.001*

(Table 2).

Surprisingly, there was no complication in our study.

Discussion

Orthognathic surgery is a major operation and can cause post-operative bleeding and hematoma. The suction drain tubes are placed to reduce such risks. Reduction of seroma and hematoma formation decreases pain, swelling, recovery time, hospital stay, and associated costs.

Since fibrin sealants have been reported to decrease the incidence of seroma and hematoma in various types of surgery, hopefully, it may have a benefit to plastic surgery procedures. Many trials showed the superior effect of fibrin sealant for the reduction of postoperative seroma[2,5,7].

We conduct the study to prove if the fibrin sealant can reduce the amount of drainage to the level that we can confidently discard the drain in BSSRO. We included 16 cases of BSSRO, and 4 cases of 2-Jaws surgery. Both study groups were not significantly different in mean age, sex, and body mass index. The strong point of our study was a prospective and randomized fashion to reduce the bias. The operation was done by the same senior surgeon and with the same standard of operative and anesthetic setting. However, the sample size is quite small which made the difference not statistically significant.

There was a significant difference in operation time and intraoperative blood loss between the study groups because there were 3 from 4 cases of 2-Jaws surgery in which had more intraoperative bleeding randomized in the control group. The intraoperative blood loss technically was not able to record separately between upper and lower jaw operation, so it increased the mean intraoperative blood loss and mean operation time. But the post-operative drainage could be separately recorded from the BSSRO, so we decided to include the 2 jaws surgery cases in our study.

The mean wound drainage was about 47 ml and 32 ml in the first 24 hours period in the control and fibrin sealant group respectively, and 6.5 ml, and 7.8 ml in the second 24 hours period in the control and fibrin sealant group respectively. The third 24 hours period was 0.87 ml and 2.24 ml in the control and study groups respectively which was statistically significant but the amount was very little and was not clinically different. The varying amount of drainage could be from uncontrolled factors such as the difficulty of the case, coagulation state, the accuracy of the time interval between each record, and the accuracy of measurement. Regarding these factors, the study to be done in the future should be carefully designed.

The results showed the fibrin sealant could reduce the amount of drainage in the first and third 24 hours but it was statistically significant only the third 24 hours. The

difference might be statistically significant if the sample size is increase. However, the amount of drain in the fibrin sealant group was still substantial, and was not safe to discard the drain tube after the operation. Although the amount of drain on the third 24 hours was statistically significant, the amount was so little and not clinically significant. The amount of the second 24 hours was more in the fibrin sealant group might be from inaccuracy of interval of record or measurement technique but the amount of difference was not much and clinically significant.

Postoperative drainage is markedly decreasing in the 2nd and 3rd postoperative days in both groups (Table 2). Regarding the study, it is safer to retain the drain tube for longer than 24 hours in orthognathic surgery.

We also found it is no different in post-operative pain and satisfaction between the control and experimental group. This was not surprised because the fibrin sealant did not have an analgesic effect and we also had no hematoma and infection in both groups.

The satisfaction was subjective and difficult to assess. The fibrin sealant may be less important than the successful operation and hospitality of the medical team.

Conclusion

The intraoperative fibrin sealant insignificantly reduced the amount of drainage in BSSRO operation. The subsequent pain score and satisfaction score also was not different. Regarding the cost-effectiveness, we recommend placing the vacuum drainage only to prevent postoperative hematoma in BSSRO. Nonetheless, the larger sample size study is encouraged.

What is already known on this topic?

We knew that fibrin sealant reduces the amount of postoperative bleeding by sealing capillary vessels and allowing raw operative surfaces to adhere. It might be more applicable to raw surfaces from soft tissue surgery such as facelift, abdominoplasty, axillary lymph node dissection, etc.

What this study adds?

The present study added that the fibrin sealant can't reduce blood oozing in orthognathic surgery which has an additional raw surface from the bone. The amount of fibrin sealant might be another factor to consider. It might need more volume than we used in our study to maximize the hemostasis effect in the BSSRO surgery.

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Potential conflicts of interest

The authors declare no conflict of interest.

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