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Can platelet-rich fibrin accelerate neurosensory recovery following sagittal split osteotomy? A double-blind, split-mouth, randomized clinical trial

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Abstract. Neurosensory disturbance (NSD) is common following sagittal split osteotomy (SSO) surgery. The aim of this study was to evaluate the effect of platelet-rich fibrin (PRF) on neurosensory recovery following SSO. This double-blind, split-mouth, randomized clinical trial was performed on patients undergoing bilateral SSO. PRF was applied to one side (selected using computer randomization) after the osteotomy and before fixation. The other side served as the control. The two-point discrimination test and a brush directional stroke test were used to assess NSD at 6 and 12 months postoperative. Self-reported paresthesia was documented using a 10-point visual analogue scale (VAS). Twenty-one patients were included in the study. The results of the two-point discrimination test and the number of subjects who reported a true direction in the brush directional stroke test differed significantly between the treatment and control sides ($P = 0.001$). The recovery of NSD (self-reported paresthesia) was better on the treatment side than on the control side ($P = 0.001$). PRF may enhance the recovery of paresthesia following SSO.

Key words: platelet-rich fibrin; mandibular nerve; osteotomy; sagittal split; paresthesia.

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The sagittal split osteotomy (SSO) is the main surgical technique used for the correction of mandibular deformities such as retrognathism and prognathism. Neurosensory disturbance (NSD) is the main complication of SSO and is reported objectively in 9–84.6% of patients[1]. Several factors have been suggested to play a role in the occurrence of NSD after SSO, including patient age, fixation method, surgical procedure, improper splinting, magnitude of the mandibular movement, experience of the surgeon, and position of the inferior alveolar nerve (IAN)[2].

Platelets contain high quantities of growth factors, such as transforming growth factor beta 1, platelet-derived growth factor AB, and vascular endothelial growth factor, which can enhance the healing process[3,4]. The effects of platelet-rich fibrin (PRF) on facial nerve regeneration[5]

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and neurosensory recovery of the IAN following nerve lateralization[6] have been discussed previously. However, there has been no report in the literature on the clinical application of PRF to obtain a faster recovery of NSD following SSO.

The purpose of this study was to address the following question: Can PRF enhance the recovery of NSD following bilateral SSO? It was hypothesized that PRF would accelerate neurosensory recovery after SSO. Therefore, the aim of this study was to evaluate the effect of PRF on neurosensory recovery following SSO.

Materials and methods

The authors designed a double-blind, split-mouth, randomized clinical trial. This trial has been registered at ClinicalTrials.gov (NCT03159338) and in the Iranian Registry of Clinical Trials (IRCT2016122631571N1).

The study sample was derived from the population of patients presenting to the Department of Oral and Maxillofacial Surgery of Taleghani Hospital for the correction of mandibular deformities between 1 January 2015 and 31 September 2017. The research was approved by the Medical Ethics Committee of Shahid Beheshti University of Medical Sciences. Patients eligible for study inclusion had a class III skeletal deformity and underwent bilateral SSO. Patients were excluded from study enrolment if they had experienced any previous trauma to the mandible, had undergone previous orthognathic surgery or genioplasty, had any obvious nerve injury during SSO or the nerve was not visualized during SSO, had used psychiatric drugs, or refused to participate in the study.

PRF was applied after the osteotomy and before fixation on one osteotomy side (group 1, treatment side). The other osteotomy side served as the control group (group 2). The treatment side was selected using computer randomization (the right or left side).

All patients signed an informed consent form prior to participation in the study. The neurosensory evaluation was performed by an observer who was not involved in the surgical procedure. The patients and the observer were unaware of the treatment and control sides.

Mandibular movement was measured based on the change in position of point B in the cephalometric analysis before and immediately after osteotomy.

Surgical approach

An incision was made over the anterior portion of the vertical ramus extending to the mesial aspect of the first molar. A subperiosteal dissection was performed downward to the inferior border of the mandible where a lateral channel retractor was placed. A long Lindemann bur was used to create a horizontal bone cut through the medial cortex of the ramus, superior and approximately posterior to the lingula. The vertical cut was ended through the buccal cortex distal to the second molar or further anteriorly. The two osteotomies were then connected using a 701 fissure bur. A spreader and a narrow osteotome were used to gently separate the lateral cortex of the sagittal osteotomy, and applied along the connecting cut to ensure that the split remained on the lateral cortex. Finally, the mandible was repositioned in its final location and the condyle was positioned manually. On group 1 sides, the IAN was visualized to determine the presence of any injury, following which PRF was placed on the exposed parts of the IAN between the two segments. In group 2, the nerve was visualized to confirm whether any injury had occurred or not. The proximal and distal segments were fixed with a miniplate and monocortical screws at each osteotomy site.

PRF preparation

Before starting the surgical procedure, 20 ml of venous blood was obtained and centrifuged for 12 minutes at 28,000 rpm (IntraSpin system; Intra-Lock International, Boca Raton, FL, USA). After centrifugation, the cap was removed from the centrifuge tube and the tube was transferred to a sterile IntraSpin L-PRF rack (Intra-Lock). The fibrin matrix was then prepared. The leukocyte–platelet rich fibrin (L-PRF) was removed from the tube. Then, the clot beneath the red blood cell clot was placed on the surface of the Xpression tray (Intra-Lock) and covered. After a period of at least 5 minutes, the fibrin matrix was removed and used.

Neurosensory evaluation

A two-point discrimination (TPD) test was performed at 6 and 12 months after the osteotomy: the minimum distance between two pinpricks that the patient could recognize was recorded. The brush directional stroke discrimination test was also performed at 6 and 12 months after the osteotomy: a fine #2 sable brush was stroked across the lower lip and mental area in an anterior and posterior direction and the direction perceived by the patient was recorded. Self-reported paresthesia was documented by the patients and scored using a 10-point visual analogue scale (VAS). Scores of 1–3 indicated mild paresthesia, scores of 4–6 indicated moderate paresthesia, and scores of 7–10 indicated severe paresthesia.

Statistical analysis

The statistical analyses were performed using IBM SPSS Statistics for Windows version 21.0 (IBM Corp., Armonk, NY, USA). The independent *t*-test was applied to compare the mean TPD values and self-reported paresthesia based on the VAS between the treatment (group 1) and control (group 2) groups at 6 and 12 months after the osteotomy. The χ^2 test was applied to compare the left and right sides and the number of subjects who reported a true direction in the brush directional stroke test within the two groups. *P*-values of <0.05 were considered statistically significant.

Results

Twenty-one patients who underwent a bilateral SSO were studied. Fifteen were female and six were male, and their mean age was 25.48 ± 5.16 years. The mean mandibular movement was 4.52 ± 0.80 mm (Table 1). PRF was placed on the right side in 10 patients and on the left side in 11 patients. There was no significant difference in the allocation of the sides to the two groups among the study patients.

The mean TPD value at 6 months after the osteotomy was 6.33 ± 0.66 mm in group 1 (treatment) and 7.29 ± 0.72 mm in group 2 (control). The difference in mean TPD between groups 1 and 2 at 6 months after the osteotomy was statistically significant ($P = 0.001$). At 12 months after surgery, the mean TPD value was 4.71 ± 0.78 mm in group 1 and 6.19 ± 0.75 mm in group 2. Analysis of the data demonstrated a significant difference between the two groups for the mean value of TPD at 12 months after the osteotomy ($P = 0.001$).

At 6 months after surgery, 17 (81.0%) subjects reported the true direction in the brush directional stroke test for the group 1 side, while only six (28.6%) subjects reported the true direction for the group 2 side. A significant difference was found between groups 1 and 2 for the brush directional stroke test at 6 months after the osteotomy ($P = 0.001$). At 12 months after surgery, the true direction was reported by 21 subjects (100%) for the group 1 side and 15 subjects (71.4%) for the group 2 side. There was a significant difference in the

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