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Comparison of the efficacy of venous coupler and hand-sewn anastomosis in maxillofacial reconstruction using microvascular fibula free flaps: a prospective randomized controlled trial

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Abstract. The venous coupler has emerged as a suitable alternative to hand suturing in the microvascular anastomosis of blood vessels; however, no prospective comparative studies have been performed to date. The aim of this study was to prospectively compare the efficacy of venous anastomosis using a coupler device with hand-sewn anastomosis during reconstruction surgery for maxillofacial defects. A prospective, randomized controlled trial was conducted. Group A patients ($n = 60$) underwent microvascular anastomosis using a venous coupler and group B patients ($n = 64$) with conventional sutures. The primary outcome measure was the incidence of flap thrombosis. Secondary measures included the flap outcome. The mean time taken to complete the anastomosis was 7.9 min in group A and 18.5 min in group B; this difference was statistically significant. The incidence of venous thrombosis was 1.7% in group A and 7.8% in group B; this difference was not statistically significant. While the time taken to complete the anastomosis is shortened using the coupler device, the clinical outcome remains the same with both techniques. The two techniques would work equally well in the hands of an experienced surgeon, and the cost versus benefit must be determined for each patient.

Key words: venous coupler; microvascular; fibula free flap; anastomosis.

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Microvascular free tissue transfer has become the gold standard for the restoration of head and neck defects, as it rehabilitates both form and function. The success rate has improved over the years and has been estimated to be around 94%[1]. However, failures do occur occasionally and the main reason for failure is flap congestion secondary to venous thrombosis.

Venous anastomosis, which is traditionally done using hand-sewn sutures, is the most challenging aspect of the free tissue transfer and can directly affect the flap success. The venous coupler was first introduced in 1962 by Nakayama as an easy alternative to hand-sewn sutures[2]. Since then, the coupler system has undergone refinements, and retrospective studies reported in the literature have described low thrombosis rates[3,4]. However, no prospective studies comparing venous anastomosis using couplers and hand-sewn sutures have been reported to date. The aim of this study was to compare the efficacy of venous anastomosis using the coupler device with traditional hand-sewn anastomosis for microvascular reconstruction in patients with maxillofacial defects.

Materials and methods

A prospective randomized study was performed. The study sample was recruited from patients who presented to the Department of Oral and Maxillofacial Surgery, SRM Dental College with benign tumours in the maxillofacial region between January 2010 and December 2016. Healthy adult patients aged between 20 and 70 years with maxillofacial defects due to benign tumours, who required surgery for primary or secondary reconstruction, were included. Only patients who were planned for reconstruction using fibula free flaps were included in order to avoid flap-related risk factors.

Patients for whom a fibula flap reconstruction was not planned, for various reasons, were excluded. Patients who required secondary reconstruction for malignant tumours and who had undergone irradiation were excluded. Patients with systemic diseases (such as diabetes and peripheral vascular disease) and paediatric patients were also excluded.

As this study involved human subjects, the guidelines laid down in the Declaration of Helsinki were adhered to. This study was approved by the Institutional Review Board, SRM Institute of Science and Technology, and a signed informed consent agreement was obtained from all patients.

In order to avoid bias, the same surgeon and operating team performed the reconstructive surgery in all patients. The patients were randomly divided into two groups at the time of microvascular anastomosis, based on numbers derived from computer-generated allocation. Group A patients underwent venous anastomosis with a microvascular coupler device (Synovis Life Technologies Inc., Birmingham AL, USA). In group B patients, the venous anastomosis was performed using conventional hand-sewn sutures (8–0 Prolene; Ethicon). In all patients, arterial anastomoses were done with conventional sutures (10–0 Prolene).

The following parameters were recorded intraoperatively: the time taken to complete the anastomosis and leakage from the vessels. The primary outcome measure was the incidence of venous thrombosis. This was assessed by checking the flap colour. Cases in which there was a clinically significant change to a bluish flap colour were returned to the operating room, where thrombosis was confirmed on exploration and a revision of the anastomosis was done. The secondary outcome measures included the flap outcome.

The statistical analysis was performed using SPSS version 2.0. The unpaired *t*-test was used to analyze the time taken to complete the anastomosis, while Fisher's exact test was used to analyze the incidence of complications in the two groups.

Results

A total of 124 patients undergoing maxillofacial reconstruction were enrolled in this study. Of these patients, 73 were male and 51 were female. The patients ranged in age from 21 to 68 years (mean age 42.8 years). Primary reconstruction was carried out in 95 cases, while secondary reconstruction was done in 29 cases. Details of the anastomoses performed are summarized in Table 1.

None of the cases had leakage following anastomosis intraoperatively. The coupler device was used for anastomosis in 60 cases, of which 49 were end-to-end anastomoses and 11 were end-to-side anastomoses. The diameter of the coupler used was 3 mm in 43 patients (71.7%) and 2.5 mm in 17 patients (28.3%). Conventional suturing was performed in 64 cases (45 end-to-end anastomoses and 19 end-to-side anastomoses).

The mean time taken for anastomosis using the coupler device was 7.9 min, while it was 18.5 min in the conventional suture group. This difference was statistically significant ($P < 0.05$). The mean time taken for the end-to-end anastomosis was 6.7 min using the coupler, while it was 17.3 min using sutures. In the end-to-side anastomosis group, coupled anastomoses took 9.1 min, while sutured anastomoses took 19.7 min. The differences in the time taken to complete the anastomosis between couplers and sutures in these two subgroups (end-to-end and end-to-side) were also found to be statistically significant. The results are summarized in Table 2.

The incidence of successful outcomes was reasonably high in both groups. Five patients in the suture group required re-exploration of the flap owing to thrombosis (7.8%). Two of the flaps could be salvaged but three eventually failed (4.7%). One flap in the coupler group also failed (1.7%), due to extrusion of the coupler device after infection. The diameter of the infected coupler was 3 mm. All of the complications reported above occurred in cases of end-to-end anastomosis. Fisher's exact test revealed no significant difference in the primary or secondary complication rate between the two groups ($P < 0.05$).

Discussion

The success of any microvascular reconstruction is strongly dependent on the anastomosis between the donor and recipient vessels. Over the years, several advances have been made in the techniques used for anastomosis and the one that

Table 1. Types of anastomosis performed.

Type of anastomosis and recipient vein	Number of cases
End-to-end	94
Anterior division of retromandibular vein	39
External jugular vein	38
Facial vein	17
End-to-side	30
Internal jugular vein	19
External jugular vein	11