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Clinical evaluations of complete autologous fibrin glue, produced by the CryoSeal® FS system, and polyglycolic acid sheets as wound coverings after oral surgery

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ABSTRACT

The CryoSeal® FS System has been recently introduced as an automated device for the production of complete fibrin glue from autologous plasma, rather than from pool allogenic or cattle blood, to prevent viral infection and allergic reaction. We evaluated the effectiveness of complete autologous fibrin glue and polyglycolic acid (PGA) sheet wound coverings in mucosa defect oral surgery. Postoperative pain, scar contracture, ingestion, tongue dyskinesia, and postoperative bleeding were evaluated in 12 patients who underwent oral (including the tongue) mucosa excision, and received a PGA sheet and an autologous fibrin glue covering. They were compared with 12 patients who received a PGA sheet and commercial allogenic fibrin glue. All cases in the complete autologous fibrin glue group demonstrated good wound healing without complications such as local infection or incomplete cure. All evaluated clinical measures in this group were similar or superior to the commercial allogenic fibrin glue group. Coagulation and adhesion quality achieved with this method was comparable to that with a PGA sheet and commercial fibrin glue. Covering oral surgery wounds with complete autologous fibrin glue produced by an automated device was convenient, safe, and reduced the risk of viral infection and allergic reaction associated with conventional techniques.

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1. Introduction

In recent years, the technique of covering open wound surfaces with a polyglycolic acid (PGA) sheet and commercial fibrin glue has been widely used in oral surgery. The utility and convenience of this method have been previously reported (Takeuchi et al., 2011, 2013; Terasawa et al., 2013). The PGA sheet is an absorbent and strong material that is gradually degraded by hydrolysis. Fibrin glue is a biodegradable and absorbable biological agent with tissue repair and haemostasis capacities that is widely used in cardiovascular and abdominal operations. It can be used as a tissue adhesive and for liquid or air leakage prevention during many surgical procedures (Buchta et al., 2004; Tokushima et al., 2004; Kawamura et al., 2005; Hayashibe et al., 2006; Shimizu et al., 2009; Takeuchi et al., 2013).

The usefulness and application technique of these adhesives has been previously reported (Kinoshita et al., 2005; Hazelaar et al., 2012; Kouketsu et al., 2017), following the first report on the use of commercial fibrin glue for skin grafting (Cronkite et al., 1944). Commercial fibrin glue is made from pooled human plasma and bovine aprotinin; this has raised concerns regarding a very small risk of infection such as human parvovirus B19 (Hino et al., 2000; Kawamura et al., 2002), allogenicimmunity, allergic reaction

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(Beierlein et al., 2000; Oswald et al., 2003), and prion transmission (Farrugia et al., 2005). In contrast, conventional autologous fibrin glue created manually is prepared in hospitals using the patient's own blood plasma for the cryoprecipitate. The first report on the use of this handmade autologous fibrin glue was by Gestring and Lerner, (1983). Recently, in Japan, hospital-synthesised fibrin glue has been prepared using autologous cryoprecipitate, and used as a haemostatic agent and adhesive following an increase in the use of autotransfusion (Makino et al., 2014).

To date, hospital-synthesised autologous fibrin glue comprising autologous cryoprecipitate as a source of fibrinogen, and thrombin constituent from cattle or pooled human plasma, have been produced manually. We previously reported that hospital-made autologous fibrin glue composed of cattle thrombin and a PGA sheet in partial glossectomy cases was useful in terms of reducing the risk of viral infection and allergic reaction (Kouketsu et al., 2017). The quality of the coagulation and adhesion achieved with this method has been shown to be similar to that of the conventional method using commercial fibrin glue, as described in our previous reports (Kouketsu et al., 2017). However, a very slight risk of infection (Hino et al., 2000), allogenic immunity, and allergic reaction is associated with this approach, resulting from the use of biomaterial from cattle or allogenic plasma (Beierlein et al., 2000; Oswald et al., 2003).

Recently, the CryoSeal® CS-1 System has been introduced as an automated device for the production of fibrin glue from autologous plasma in 90 min, and it is possible to prepare and use autologous fibrin glue during surgery even if blood is collected just before surgery. Using this automated approach, autologous cryoprecipitate and thrombin can be obtained to produce complete autologous fibrin glue; this completely avoids the risk of viral infection and allergic reaction (Buchta et al., 2004, 2005; Rock et al., 2007; Shimizu et al., 2009; Hazelaar et al., 2012). The aim of the present study was to clinically evaluate the effectiveness of complete autologous fibrin glue and (PGA) sheets as wound coverings after oral surgery for mucosa defects. We assessed the clinical features and outcomes of oral mucosa surgery patients treated using wound coverings comprising complete autologous fibrin glue, produced by the CryoSeal® CS-1 System, and PGA sheets, and compared these with patients that received coverings made from commercial fibrin glue and PGA sheets.

2. Materials and methods

2.1. Patients

The study participants were patients with a clinical diagnosis of epithelial dysplasia or early oral cancer (carcinoma in situ, or T1N0–T2N0 with submucosa or superficial muscle layer invasion revealed by preoperative pathological or imaging examinations) scheduled for oral cavity resection, including part of tongue, in our department between January 2014 and March 2016. Patients who were pregnant, anaemic, or malnourished, and those with haematological disorders or viral or bacterial infections were excluded. None of the patients with oral cancer received chemotherapy or radiotherapy after or before surgery. The study clinically evaluated 24 patients who underwent excision of oral tissue, including the tongue; 12 patients received a wound covering comprising complete autologous fibrin glue and a PGA sheet (complete autologous fibrin glue group), whereas the other 12 patients received a wound covering made from commercial fibrin glue and a PGA sheet (allogenic fibrin glue group). The differences in the treatment approaches between the two groups were related mainly to treatment timing.

The study was conducted in accordance with the tenets of the Declaration of Helsinki (2004), and the study protocol was approved by the Research Ethics Committee at our institute. All participants provided written informed consent prior to participation in the study.

2.2. CryoSeal® CS-1 Device

The CryoSeal® CS-1 (Asahi Kasei Medical, Tokyo, Japan) is a device that automatically prepares autologous cryoprecipitate and thrombin from plasma; it contains disposable plasma processing units in a closed system and applicators. Allogenic single-donor cryoseal produced from fresh-frozen quarantine apheresis plasma is used as an alternative to multi-donor or autologous fibrin sealants. The fresh-frozen plasma unit was weighed and thawed at 37 °C in a water bath, and connected to a sterile disposable set containing separate cryoprecipitate and thrombin. The production procedure was performed according to the manufacturer's instructions as follows:

1 Setting up the device for plasma processing

After weighing the plasma and calculating the processing time, the plasma within the bag was transferred to the processing unit under aseptic conditions.

2 Preparation and treatment of cryoprecipitate

Controlled by the operator, the plasma was transmitted to the cryoprecipitate chamber for freezing, throwing, flocculation, and precipitation. The cryo-poor supernatant was discarded, and the cryoprecipitate was collected in the first of a pair of syringes.

3 Preparation and treatment of thrombin

Simultaneous with cryoprecipitate processing, the autologous plasma was transferred to a thrombin-processing device comprising a tubular reaction chamber containing ceramic and glass beads. This provided the negative surface charge required to initiate the formation of thrombin from prothrombin. A thrombin reagent was then added to the chamber to isolate prothrombin from plasma and, in the presence of calcium, converted prothrombin into active thrombin. The second syringe was filled with the thrombin solution during processing in the chamber.

Within 90 min, cryoprecipitate and thrombin solutions were produced and transferred, to a closed system with to up to four twin syringes. Each pair of syringes was pre-wrapped under sterile conditions and could be filled without opening the closed system or the interior sterile bag. Therefore, the fibrin sealant could be introduced safely into the surgical environment.

2.3. Autologous fibrin glue

We collected 300–400 mL of peripheral blood from the patient in advance. This blood sample was placed in a centrifugal separator and centrifuged at 4280 × *g* for 7 min to obtain blood plasma; the plasma was then stored at −40 °C. Blood plasma that had been thawed to 37 °C was then used to prepare each ~5 to 10 mL solution of cryoprecipitate and thrombin in the CryoSeal® CS-1 system; these were stored at −20 °C up to the day of surgery and thawed to 37 °C during surgery. The complete autologous fibrin glue comprised a mixture of this autologous cryoprecipitate (as the fibrinogen component) and thrombin, obtained by autologous blood transfusion.

2.4. Covering the wound with complete autologous fibrin glue and a PGA sheet

We performed a simple glossectomy or broad resection of oral mucosa (including the tongue) during surgery under general

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