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First experience using cultured epidermal autografts in Taiwan for burn victims of the Formosa Fun Coast Water Park explosion, as part of Japanese medical assistance

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ABSTRACT

On June 27, 2015, a flammable starch-based powder exploded at Formosa Fun Coast in Taipei, Taiwan, injuring 499 people, and more than 200 people were in critical condition with severe burns. Although a cultured epidermal autograft (CEA) was not approved or used in clinical practice, the Taiwan Food and Drug Administration requested a Japanese CEA manufacturer to donate CEA for the burn victims as part of international medical assistance. The authors cooperated in this project and participated in the patient selection, wound bed management for CEA, and technical assistance for CEA use. Here, we provide an overview of the project. Nine patients were enrolled, and two patients were excluded from the skin biopsy; seven skin biopsies were collected approximately 1 month after the disaster. The average TBSA% burned was 81.0%, and the mean age was 20.1 years. CEA was grafted in five patients; wound closure had been obtained in one patient, and one patient was severely ill at the time of grafting. The CEA was combined with a wide split auto mesh graft or patch graft. The mean re-epithelization rate at 4 weeks after the grafting was 84.2% by patient, and all of the patients survived. Although this project had many obstacles to overcome, CEA grafting was successful and contributed to wound closure and survival.

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1. Introduction

On June 27, 2015, a flammable starch-based powder exploded on a music stage during a “Color Play Asia” party at Formosa

Fun Coast (Eight Immortals Paradise), which is a recreational water park in Bali District, New Taipei, Taiwan. According to the Taiwan Ministry of Health and Welfare, 12 fatalities were attributed to the explosion as of October 15, 2015. The

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explosion has been called the “worst incident of mass injury in New Taipei.”

Of the 499 young people who were injured, most of the patients experienced burns, and 221 people had severe burns and inhalation, placing them in critical condition. Because they were typically wearing only swimwear, most of the patients had large burn areas, with a mean total body surface area (TBSA) of 44%, reaching 80% in 22 victims [1,2]. Most of the patients were tertiary students aged in their twenties and late teens, and they were treated in over 50 hospitals across Taiwan.

On July 13, the Taiwan Food and Drug Administration (FDA) discussed the use of additional therapeutic products from outside Taiwan, such as the cultured epidermal autograft (CEA) JACE[®] from Japan. The Taiwan FDA requested donation of CEAs and technical assistance from Japan Tissue Engineering Co., Ltd. (J-TEC, Gamagori, Japan); J-TEC offered to donate CEAs for a maximum of 20 burn patients through a contract with a local medical company, Maria Von Med-Biotechnology Co., LTD who would coordinate the clinical use of the CEA. Then, J-TEC arranged the regulatory matters and logistics with the Ministry of Health, Labour and Welfare and the Pharmaceuticals and Medical Devices Agency in Japan and customs in Taiwan. For technical assistance using the CEA, J-TEC sought the cooperation of three Japanese surgeons (authors HM, NH, and HI) who had sufficient experience and success with CEA grafting and were recognized by the three related Japanese medical societies (Japanese Association for Acute Medicine, Japanese Society of Intensive Care Medicine, and Japanese Society for Burn Injuries) and the Japan Medical Association (JMA) before deployment to Taiwan (Fig. 1). Here, we describe the experience with the medical assistance project for CEA grafting with a select set of burn patients in Taiwan.

2. Materials and methods

2.1. Patient consent, sharing of clinical data, and role of the Japanese doctors

Patients provided written informed consent before undergoing CEA grafting, and the institutional review board approved the CEA grafting protocol. The clinical data for the CEA grafting were shared between the project members; therefore, permission to use the data was obtained from each institution. Because of the medical laws in Taiwan, all of the surgical procedures, including the skin biopsies, were performed by the Taiwanese doctors, and the Japanese doctors provided suggestions about wound preparation and instructions for CEA use, when needed.

2.2. Patient selection, standard treatment protocol, and skin biopsy

Before contacting the Taiwanese burn patients, we created tentative patient selection criteria (Fig. 2) and the standard procedure for CEA grafting (Fig. 3). These were reviewed by the board of directors of the three related Japanese societies.

Although there is no standard protocol for the contact layer dressing material used with CEA, we recommended the use of UrgoTul[®] as contact layer dressing and bulky dry gauze for top dressing, which is popular with the Japanese doctors sent to Taiwan (authors HM and NH); the contact layer dressing is very important for CEA to take, and we were not familiar with the dressing materials used in Taiwan. Moreover, upon request by the Japanese doctors, UrgoTul[®] was donated from the Nitto-Medical Corporation (Osaka, Japan) for this project. Moreover, we recommended CEA grafting combined with a

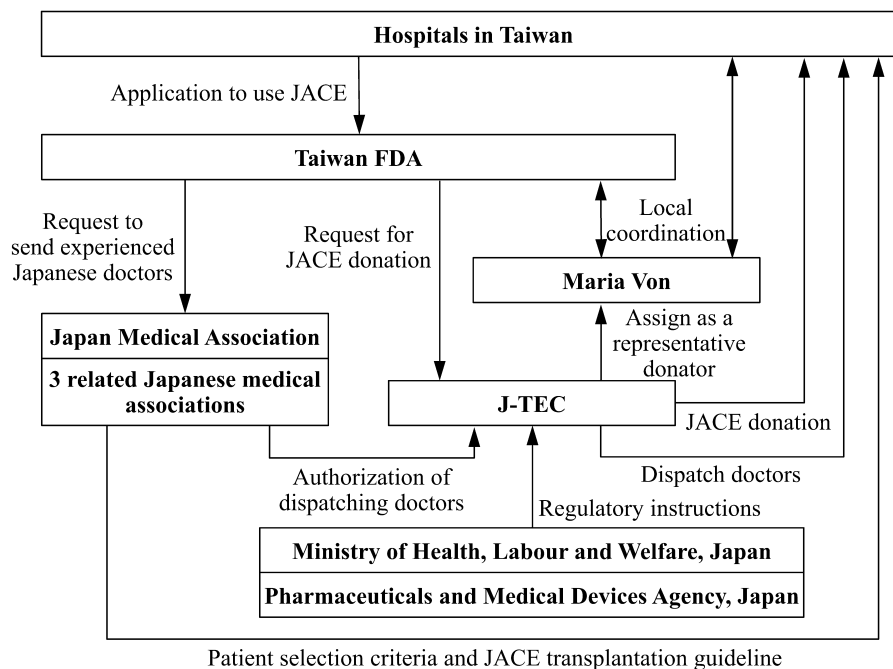


Fig. 1 – Formation of the medical assistance project to treat burn victims in Taiwan FDA, Food and Drug Administration.

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