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Toyobo Co., Ltd.

New Medical Treatment Device for Regeneration of Damaged Nerves —Development and Commercialization of Conduits for Nerve Regeneration

Toyobo has conducted research and development of biocompatibility technologies, including heparin coatings, for some time. Recently, Toyobo announced the development of conduits for nerve regeneration, which are a new kind of medical device that promotes regeneration of nerves damaged because of illness, accidents, or other circumstances. Since the efficacy of these new devices has been confirmed as a result of clinical trials based on Japan's Pharmaceutical Affairs Act, in February 2012, Toyobo applied to Ministry of Health, Labour and Welfare for approval to manufacture and market these devices. The application is currently under review.

1. Background for Development

In general, when nerves are damaged, patients undergo surgical treatment, such as nerve autograft or nerve suture.

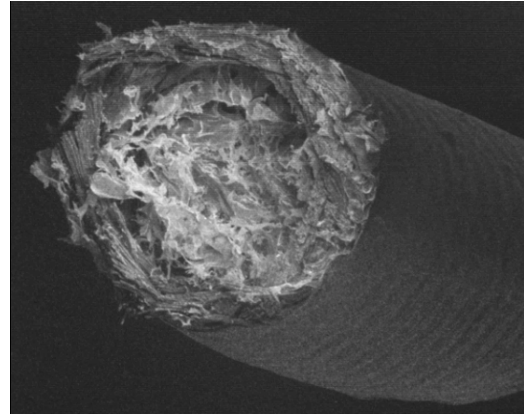
In the case of nerve autografts, a portion of a healthy nerve (for example, a nerve from the patient's foot) is removed from the patient's body and then transplanted to the area of the damaged nerve. However, this form of treatment places a major burden on the patient because damage to the nerve in the area where the healthy nerve has been removed remains, thus causing pain and numbness. On the other hand, in the case of nerve suture, nerves that have been severed are sutured directly together. As a result, when the affected area comes under tension, it does not heal and causes pain and abnormal sensations. Other methods are not suited for the treatment of contusions.

Also, when patients are injured and transported to the hospital, priority is placed on reconnecting damaged blood vessels and setting broken bones. In some cases, it is not possible to reconnect severed nerves.

To address these issues, Toyobo has developed its conduits for nerve regeneration.



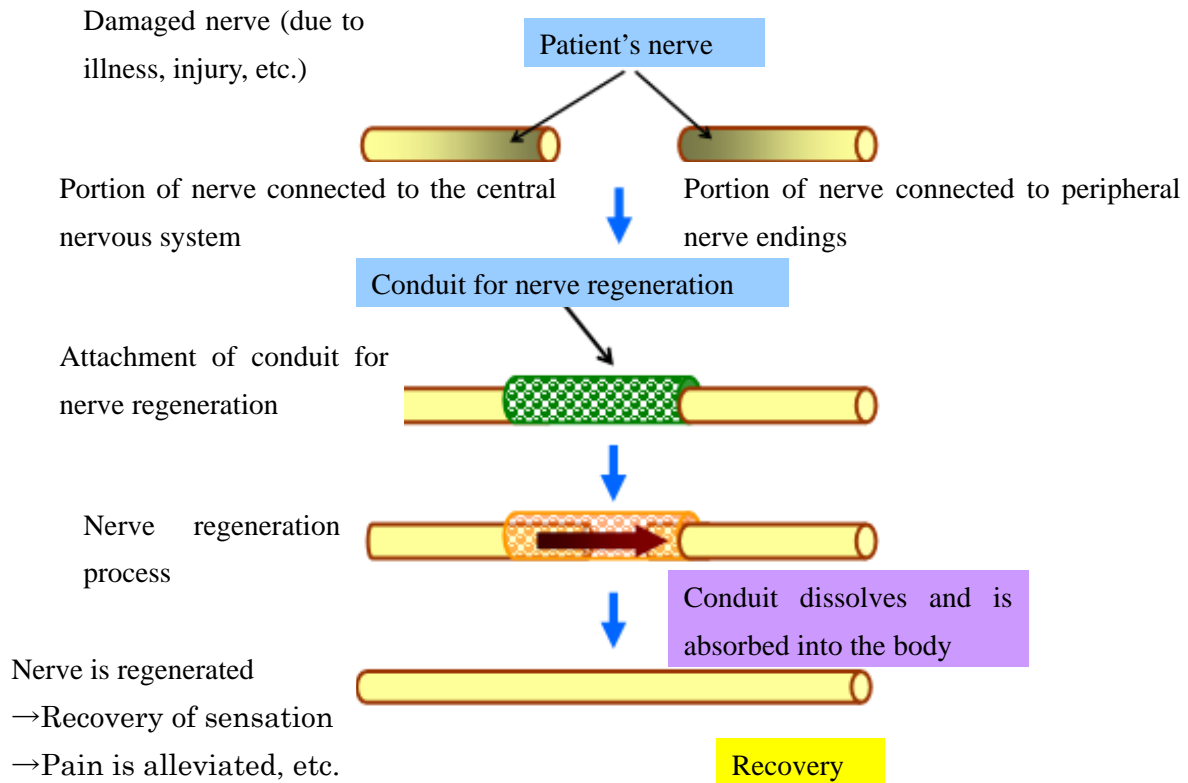
A conduit for nerve regeneration



Cross section of conduit nerve regeneration (SEM picture)

2. Features of Conduits for Nerve Regeneration

- (1) The conduit for nerve regeneration is inserted between the severed portions of the damaged nerve (the nerve gap) and secured in place. Thereafter, the portion of the nerve linked to the central nervous system puts out lumens that link together with the peripheral nerve endings on the other side of the conduit, and, thereby, restore nerve functions. In addition, the conduit for nerve regeneration themselves dissolve and are absorbed by the body in about three months because they are composed of materials, such as polyglycolic acid, that can be absorbed into living organisms.
- (2) The conduits make use of NMP Collagen PS, a newly developed collagen for medical use, that was developed by Nippon Meat Packers, Inc. This type of collagen is applied to the exterior of the conduit and infuses into the lumens in the conduit. Using this collagen as a foothold, arteries are led from the exterior of the tube and provide nourishment. As a result of this and other properties of the conduits, they provide a structure that facilitates growth and regeneration of the nerves.



Process of Treatment Using Conduits for Nerve Regeneration (schematic diagram)

3. Advantages of Using Conduits for Nerve Regeneration

- (1) The effectiveness of therapy (as measured by the positive effect on the recovery of nerve sensation in the affected areas and other means) is expected to be the same or greater than for treatment methods currently in use, such as nerve autograft or nerve suture.
- (2) Unlike nerve transplantation, the use of these conduits for nerve regeneration does not require removal of a portion of a healthy nerve from the patient's body and does not cause any additional damage to the nerves. Also, the burden on the patient is reduced substantially because the time for surgery is shortened.
- (3) There is no need for special equipment, such as devices for microsurgery. Therefore, these tubes can be used in primary emergency hospitals. Moreover, the patient's QOL (quality of life) improves rapidly after surgery and they contribute to an early rehabilitation into society.

4. Results of Clinical Trials

As a result of clinical trials on damaged nerves in human hands and fingers, based on Japan's Pharmaceutical Affairs Law, these devices were recognized to be 84.2% effective (defined as having a positive effect on the recovery of nerve sensation in the damaged areas). Even in cases where the length of the damaged portion of nerves (length of damage or gap) was more than 20mm, the effectiveness of these conduits for nerve regeneration has been confirmed.

In February 2012, Toyobo applied to Japan's Ministry of Health, Labour and Welfare for approval to manufacture and market these devices as a new kind of medical device.

5. Outlook

Toyobo is scheduled to receive approval for manufacturing and marketing of these tubes in spring 2013 and is scheduled to begin marketing thereafter. A target of ¥5.0 billion in annual sales has been set for 2015.

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