REAXON®
NERVE GUIDE

Clinical Trials

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Clinical Trials

Study #1: *Application of Reaxon® to bridge nerve gaps up to 26 mm*	
Design	Multicenter, randomized, controlled trial (RCT) vs. Gold Standard (n = 76, evaluation at 3, 6, 12 and 18 months)
Participating centers	BG trauma clinics in Halle (coordination), Berlin, and Hamburg, UKSH Lübeck
Primary endpoint	2-point discrimination
Claim	"As good as Gold Standard" (autologous nerve graft)
First Patient in:	Q2 2015

Study #2: *Reaxon® to protect nerve repair by direct suturing*	
Design	Multicenter, randomized, controlled trial (RCT) vs. Gold Standard (n = 74, evaluation at 3, 6, 12 and 24 months)
Participating centers	BG trauma clinics in Ludwigshafen (coordination), Frankfurt/Main, and Bochum
Primary endpoint	2-point discrimination
Claim	"Better than Gold Standard" (suture only)
First Patient in:	Q4 2014

Study #1 – Gaps up to 26 mm

- „A Controlled, Randomized, Comparison, Blind Evaluation of Repair of Digital Nerve Lesions in Man Using an Implanted Reaxon® Nerve Guide”

Study #1 – Objectives

- The primary objective of the clinical investigation is to demonstrate that the static 2-point discrimination (2-PD) 12 months after surgery will be not inferior in the Reaxon® Nerve Guide test group compared to the control group receiving an autologous nerve graft.
- The secondary objective is to document the long-term effects (up to 18 months after surgery) in nerve repair.

Study #1 – Hypothesis

- The non-inferiority test is to demonstrate that it can be excluded that the treatment difference is larger than 20% in favor for the control group.

Study #1 – Methods / Design

- 76 subjects will be randomized either into the Reaxon® Nerve Guide group or into the control group receiving an autologous nerve graft used at the discretion of the surgeon.
- Blind evaluation will require that in each center, the subject outcomes will be assessed by a physician/therapist who is not informed on the randomized treatment which implies that the assessor did not participate at the surgery.

Study #1 – Inclusion Criteria

- males and females between 18 and 65 years of age able to give his/her consent
- a complete traumatic nerve injury of the common or proper digital nerve in the hand
- a nerve defect of less or equal than 26 mm after release and approximation of the nerve ends and measured when the wrist is in neutral position
- an injury that could conventionally be treated with implantation of a short nerve graft
- nerve treatment initiated until 3 months after nerve injury
- signed informed consent

Study #1 – Exclusion criteria

- known allergy to chitosan and/or polyvinylpyrrolidone (PVP)
- known impairment / previous diseases of the neural axis or previous lesions of the affected hand (of the digital nerve), which led to permanent sensory or motor restrictions of the hand/finger
- complete amputation injury
- known pregnant or breast-feeding females
- disorders known leading to impaired wound healing (e.g. diabetes mellitus)
- skin diseases in the wound area

Study #1 – Exclusion criteria

- impaired blood coagulation or bleeding disorders (e.g. because of regular intake of cumarin such as Marcumar). Regular intake of ASS is not an exclusion criterion.
- pathologic blood flow disorders (e.g. Morbus Raynaud)
- participated in another clinical investigation using an investigational new drug or device within 30 days prior to enrolment into this investigation

Study #1 – Interim Analysis

- Interim analysis with 11 patients is in operation!

Study #2 – Direct Suture

- „Chitosan nerve tube for primary repair of traumatic sensory nerve lesions of the hand without a gap: study protocol for a randomized controlled trial”

Study #2 – Objectives

- Randomized double-blind controlled multicenter trial with a parallel group design in order to show superiority for the additional use of a chitosan nerve tube
- 100 participants with traumatic sensory nerve lesions of the hand without a gap from three Trauma Care Centers
- Participants will be randomized in a 1:1 ratio to primary microsurgical repair of the injured nerve with the additional use of a chitosan nerve tube or direct tension free microsurgical repair of the injured nerve alone
- The static two-point discrimination of the injured finger after 6 months will be the primary outcome parameter

Study #2 – Hypothesis

- The additional use of a chitosan nerve tube in the primary microsurgical repair of traumatic sensory nerve lesions of the hand without a gap will be superior compared with microsurgical repair alone

Study #2 – Methods / Design

- The kind of intervention is blinded for the participant and for the follow-up investigator, who was not involved in the surgery
- The primary study objective is the recovery of sensitivity.
- The assessment will follow the guidelines developed by Rosén
- Recovery of sensibility will be assessed by static two-point discrimination (tactile gnosis) and the Semmes Weinstein method (sensory re-innervation)
- Sensory re-innervation, DASH-score, grip strength total active range of motion, pain, cold intolerance and hypersensitivity, and the appearance of neuroma will be secondary outcome parameters

Study #2 – Inclusion Criteria

- Clinical suspicion of traumatic sensory nerve lesions of the hand without a gap (lesion from the distal area of the carpal tunnel to the end finger joint with complete loss of a nerve-specific receptive field of the finger)
- Age between 18 and 67 years
- Trauma occurred in the previous 72 h
- Signed informed consent

Study #2 – Exclusion Criteria

- Amputated or avascular fingers
- Infection of the wound
- Known pre-existing impaired sensibility of the injured inger or the opposite side
- Allergy to chitosan
- Pregnancy
- Known immunodeficiency
- Participation in other trials

Study #2 – 2-point discrimination

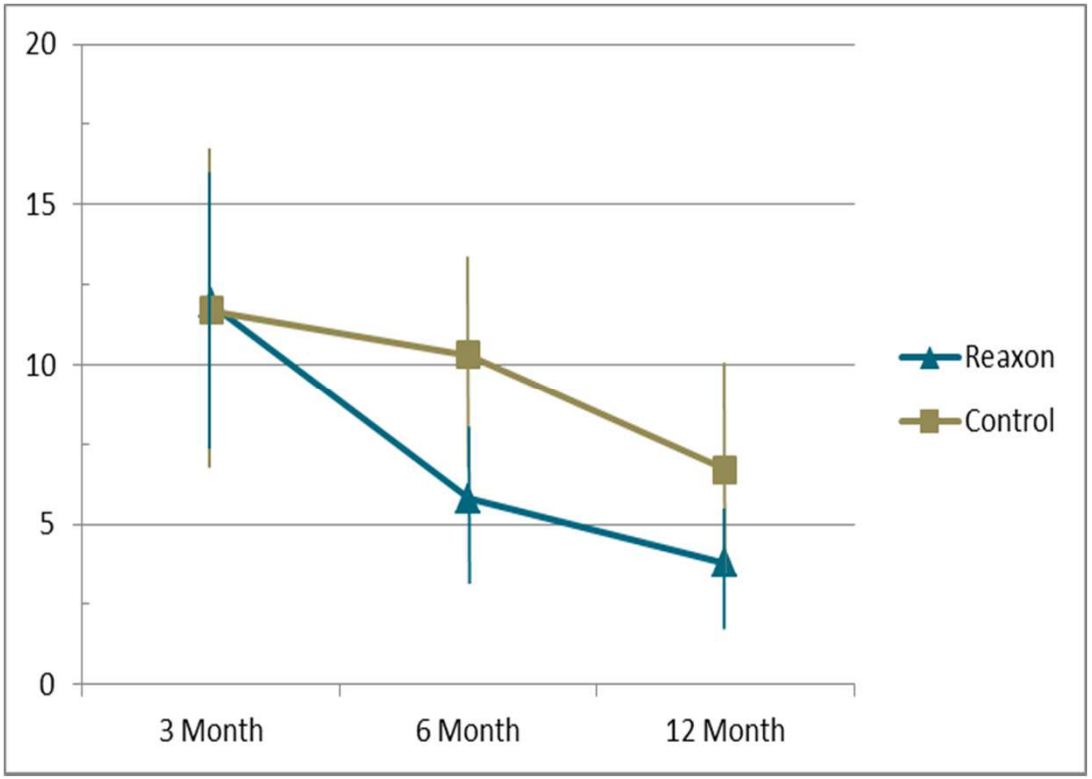
Tab: 2-point discrimination in mm

	3 month		6 month	
	mean	SD	mean	SD
all	11,8	5,9	7,8	4,9
Nerve tube	11,9	5,9	5,8	2,5
control	11,7	7,0	10,3	6,4
	p = 0,96		p = 0,0724	

Study #2 – 2-point discrimination

Number of patients evaluated

t	n
3 Monate	55
6 Monate	47
1 Jahr	28



Study #2 – Interim Analysis

Intermediate results demonstrate effectiveness and safety in the €500 million direct suture application

- **Superiority with Reaxon®** after 6 month
- Statistically **significant** after 6 month
- **Long-term enhancement** are arising
- **High patient satisfaction**
- No implant associating complications

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Medical Devices Based on Chitosan

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