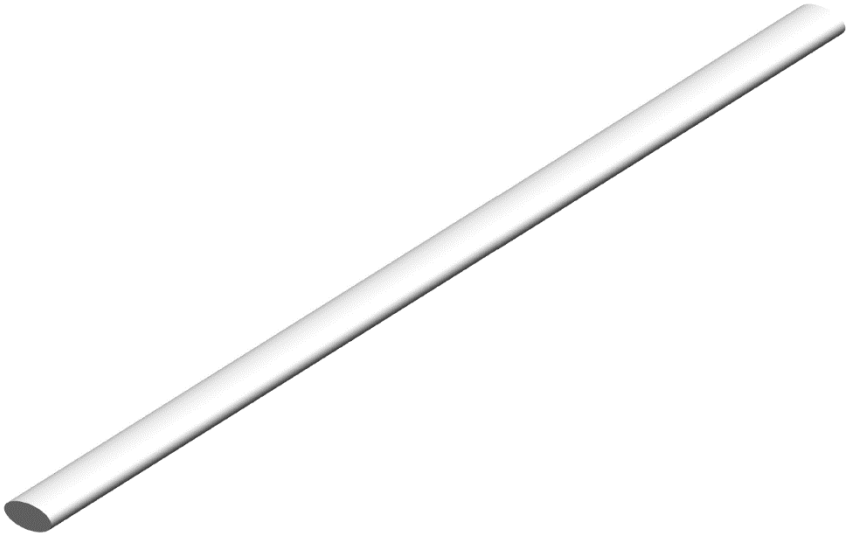

Surgical Technique

Silicone implants

Tendon

CONTENTS

IMPLANT

The temporary silicone tendon replacement is a monolithic die-cast body with the oval cross-section and elongated shape.

Implants are supplied in 4 sizes of oval cross-section (3 mm x 1,5 mm; 4 mm x 2 mm; 5 mm x 2,5 mm; 6 mm x 3 mm) and in 3 lenghts (120 mm, 180 mm, 220 mm).

Material used for production of the endoprosthesis is silicone by the NUSIL company designated MED 4550. This material is intended for use in human implantation for a period of greater than 30 days and it meets needed mechanical properties. The surface of the implant is smooth, without coatings or any other modifications.

This implant is not intended by the manufacturer as so-called "active implant", i.e. for suture with the central flexor stump.

The device is in a sterile condition. Sterilized with EtO. If the packaging is broken, re-sterilization cannot be performed.

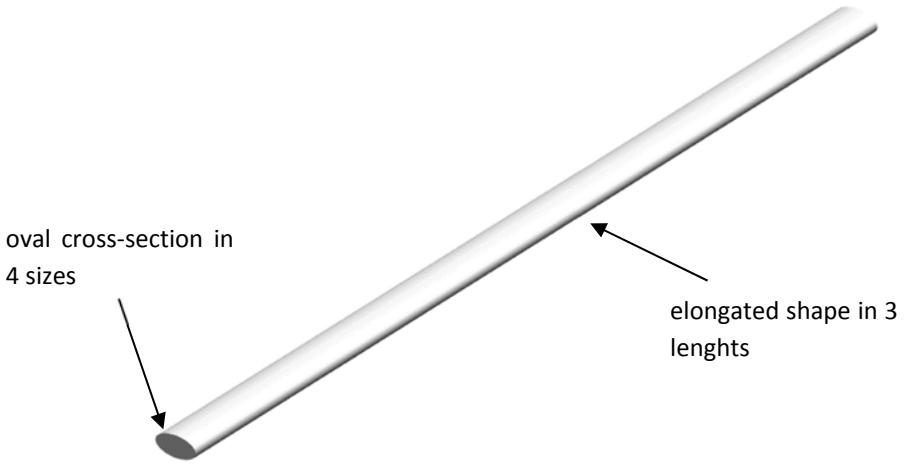

Fig. 1 Temporary silicone tendone replacement

CAUTION!

This publication is intended to serve as a guide to the use of the above-mentioned implant. For the sake of brevity, it focuses only on the basic operating procedure and assumes that the surgeon and other personnel are perfectly familiar with the general rules of operation when using temporary silicone tendon replacements. Before using the implant, it is necessary to familiarize with this surgical technique.

INTRODUCTION

Hand flexor tendon reconstruction in the so-called "no man's land" (over the extent of osteofibrocartilaginous canal for flexor tendons), after one's injury or interruption and unsuccessful or missing primary treatment - this is a therapeutic problem.

The tendinal canal is occluded or contains a fibrotically changed, adhering tendon that is entirely unfit for suture. The end of the central stump is also fibrotically changed, retracted, and with respect to the length and quality of the ends of the interrupted tendon, a suture of both ends is not possible.

At present, one of the few methods of choice that offers a realistic hope of improvement of the condition described above is the reconstruction of the hand flexor tendon in stages, in the „no man's land“.

The principle of this method is:

1. Creation of a preformed canal in the first session or stage (preserving or reconstructing the needed loops in the „no man's land“) by the implantation of a temporary silicon tendon implant.

2. Replacing the temporary silicon implant in the second stage with an autologous graft from the patient.

The temporary silicon tendon implant produced by ProSpon, spol. s r.o. replaces the product from the Rubena company, which had been formerly used in the Czech Republic. This product does not only replace the formerly used Rubena product, but it is even better in some parameters.

INDICATION AND CONTRAINDICATION

Indication:

Staged reconstruction of the hand tendons using implantation of autologous tendon graft.

1. Creating the artificial soft tissue channel in the target area of the hand for the later tendon graft implantation.

2. Creating the artificial soft tissue channel in the target area of the face for the later implantation of the autologous fascia or tendon graft to sling the oral commisure in case of the n. facialis paresis.

Indication from a general condition standpoint:

- a patient whose general condition allows for a procedure under local anaesthesia or in a peripheral block of the upper extremity
- a cooperative patient who wishes to undergo a reconstruction in stages with a realistic idea of treatment duration, principle of the procedure and subsequent physiotherapy

Indication from a local status standpoint:

- passively movable finger after flexor disruption
- good skin coverage and physiological blood flow in the finger
- impossibility of a direct flexor suture or its reconstruction with another one-stage procedure (flexor transposition, tendon graft)

CAUTION!

Indication should be carefully considered in case of a severe osteoporosis, passed infections, marked overweight and with patients with heavy physical strain, patients addicted to narcotics and alcohol, or with mentally ill patients, for whom cooperation is not guaranteed. The implant is intended for single use only and cannot be reused!

Contraindication:

- Infectious diseases or local infections
- Serious neuromuscular or vein diseases
- Insufficient quality of bone or skin structures
- An allergy to the silicone material

From a general condition standpoint:

- ongoing systemic infection
- hypersensitivity of the patient to silicon
- lack of patient cooperation

Increased risk of application in patients:

- with immunodeficiency
- suffering from diabetes

From a local status standpoint:

- insufficient finger flexion
- poor-quality or inadequate skin coverage, severe scarring of the skin at the implantation area
- soft tissue defect at the implantation area
- slow-downed finger perfusion that might severely threaten future surgery

CAUTION!

Products cannot be combined with the other manufacturers products!

A thorough acquaintance with the surgical implantation technique is an essential and apparent precondition for performing the surgery. The patient must be informed of the rules of conduct after the implantation and of the related rehabilitation. The patient should be advised to strictly follow the instructions of the physician.

SET OF INSTRUMENTS

There isn´t any set of special surgical instruments supplied by the manufacturer for the implant application. When handling the product it is necessary to prevent any damage, which could adversely affect its quality and service life, especially the damage caused with a sharp blades.

SHORT OVERVIEW OF SURGERY STEPS – STAGE I

STEP I-1: INCISION TO ACCESS THE TENDON CANAL

STEP I-2: PREPARATION OF THE TENDON CANAL FOR IMPLANT INSERTION

STEP I-3: DETERMINING THE APPROPRIATE SIZE OF A TEMPORARY SILICONE TENDON IMPLANT

STEP I-4: IMPLANTATION OF A TEMPORARY SILICONE TENDON IMPLANT

STEP I-5: FIXATION OF THE END OF THE IMPLANT IN THE AREA OF THE BASE OF THE DISTAL PHALANX

STEP I-6: PREPARATION OF SUPERFICIAL OR DEEP FLEXOR REMNANTS, OR BOTH, FOR LATER RECONSTRUCTION

STEP I-7: SKIN FLAP CLOSURE AFTER CHECKING HEMOSTASIS AND INTENDED MOVEMENT OF THE PROXIMAL PART OF THE IMPLANT DURING PASSIVE FLEXION

STEP I-8: PATIENT INSTRUCTION AND REHABILITATION CARE

SHORT OVERVIEW OF SURGERY STEPS – STAGE II

STEP II-1: INCISION AND EXPOSURE OF A TEMPORARY SILICONE TENDON IMPLANT WITHOUT OPENING THE ARTIFICIAL TENDON SHEATH

STEP II-2: IMPLANTATION OF A TENDON GRAFT ACCORDING TO THE SELECTED RECONSTRUCTION METHOD WITH SIMULTANEOUS EXPLANTATION OF A TEMPORARY SILICONE TENDON IMPLANT.

STEP II-3: CLOSURE OF THE INCISIONS WITH A SUTURE

STEP II-4: IMPLANTATION OF A TEMPORARY SILICONE TENDON IMPLANT

STEP II-5: PATIENT INSTRUCTION AND REHABILITATION CARE AFTER THE SECOND STAGE

NOTE. THE PROCEDURE GIVEN IS SCHEMATIC ONLY. THIS SURGICAL TECHNIQUE DOES NOT SUBSTITUTE THE NECESSARY KNOWLEDGE OF SURGICAL TREATMENT WITH THE TEMPORARY SILICONE TENDON REPLACEMENT. THIS KNOWLEDGE IS EXPECTED FROM THE SURGEON.

SURGERY STEPS – STAGE I RECONSTRUCTION

STEP I-1: INCISION TO ACCESS THE TENDON CANAL

Perioperative coverage with systemic antibiotics is suitable.

With incisions in the form of broad skin wedges, reaching to the middle of the palm on the volar finger side, we obtain appropriate access to the tendinal canal over the full extent of the finger, down to the palm, at least to the exit point from the osteofibrocartilaginous canal.

Fig. 2 Examples of incisions on the volar hand.

TOOLS USED:

Tools for the surgical approach creation (the manufacturer does not supply any set of special surgical instruments for implant application).

STEP I-2: PREPARATION OF THE TENDON CANAL FOR IMPLANT INSERTION

Depending on the local findings, we extirpate the peripheral end of the interrupted deep flexor tendon, but also the superficial flexor should it be preserved. We then carefully remove the fibrotically changed tissue of the tendinal bed. We carefully protect the preserved loops (Fig. 3).

Should there be no loops preserved at least on the basic and middle phalanges, we reconstruct them concurrently with implanting the temporary tendinal implant.

The silicon tendon replacement does not prevent the healing of the reconstructed loops.

The artificial tendinal sheath created after the silicon's implantation does not prevent the formation of a chord after tendon reconstruction. This is why the reconstruction of the loops is necessary.

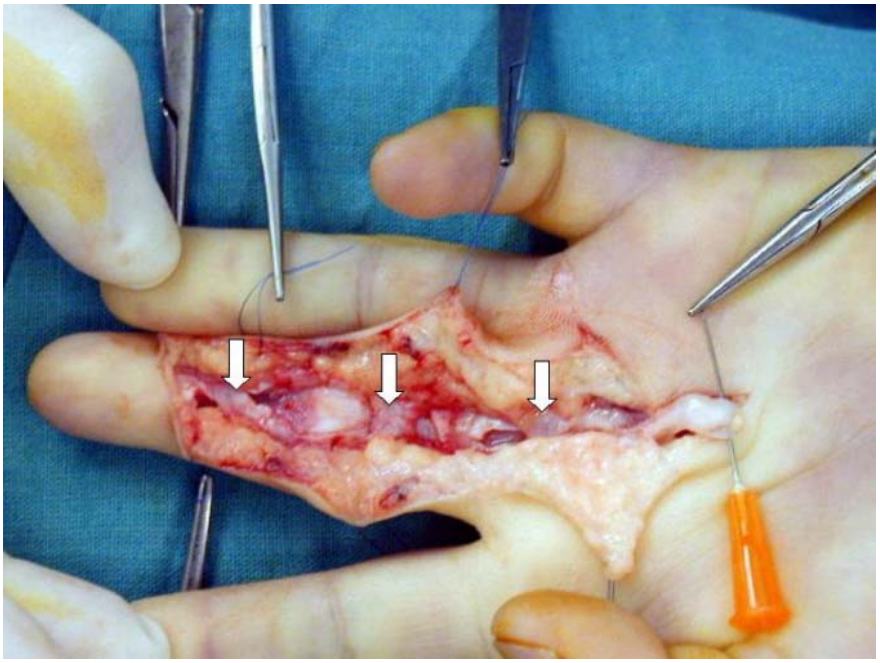

Fig. 3 Preparation of the bed for implantation of the temporary silicon implant. The arrows point to the preserved tendinal loops

TOOLS USED:

Tools for the surgical approach creation (the manufacturer does not supply any set of special surgical instruments for implant application).

STEP I-3: DETERMINING THE APPROPRIATE SIZE OF A TEMPORARY SILICONE TENDON IMPLANT

We draw a catheter through the loops of the future tendinal canal and select the appropriate size so that it may pass freely through the tendinal loops (Fig. 4). This allows us to obtain orientation regarding the correct diameter size of the temporary silicon tendon implant.

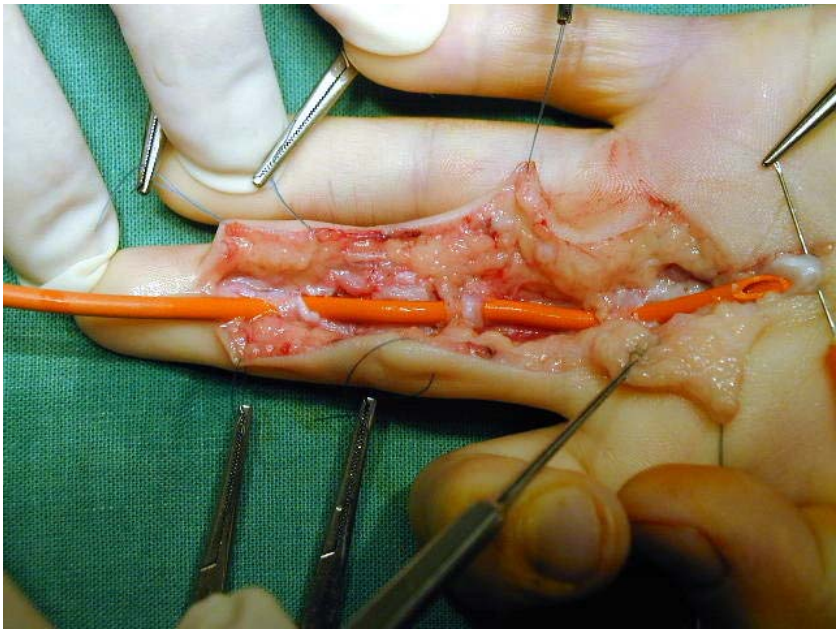

Fig. 4 Inserted urethral catheter. It allows for a good position, length (see also the STEP I-4) and diameter prior to the application of silicon temporary implant to be determined.

TOOLS USED:

Tools needed to perform the steps listed (the manufacturer does not supply any set of special surgical instruments for implant application).

STEP I-4: IMPLANTATION OF A TEMPORARY SILICONE TENDON IMPLANT

The implant (Fig. 5) is pulled through behind the catheter or it is applied separately.

We try to manipulate the implant carefully, we do not use sharp instruments and we try not to damage the surface of the silicon implant in any way.

The implant should pass the loops freely, so that it does not press against its insertion on the last phalanx during passive finger flexion.

The implant length is chosen such that it exits from the original osteofibrocartilaginous canal when the finger is extended, or we determine it by the location of the proximal stump of the finger flexor tendon.

CAUTION!

The described type of temporary tendon implant is not intended by the manufacturer as so-called "active implant", i.e. for suture with the central flexor stump.

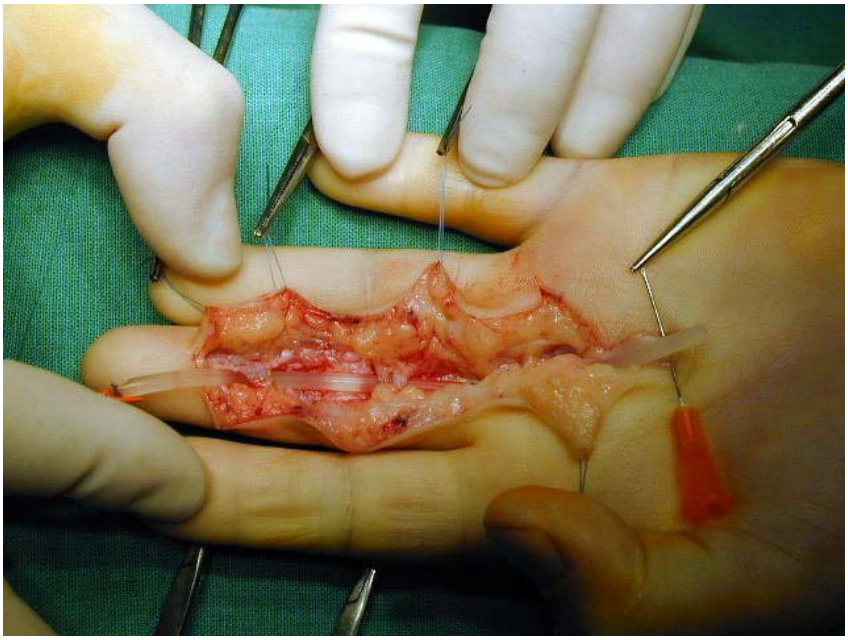

Fig.5 Temporary tendon implant in situ, prior to insertion towards the distal phalanx

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TOOLS USED:

1. Tools to perform the implantation (the manufacturer does not supply any set of special surgical instruments for implant application).
2. Implant – silicone temporary tendon replacement in the selected size.

STEP I-5: FIXATION OF THE END OF THE IMPLANT IN THE AREA OF THE BASE OF THE DISTAL PHALANX

In the periphery we fix the end of the implant with monophil stitches to the base of the distal phalanx. It is also possible to use a transfixion suture knotted over the nail as in insertion of the flexor tendon.

STEP I-6: PREPARATION OF SUPERFICIAL OR DEEP FLEXOR REMNANTS, OR BOTH, FOR LATER RECONSTRUCTION

In cases where only one proximal flexor stump is available, we mark it with a stitch for the next suture with the tendinal graft. A more favourable situation is in the presence of stumps of both the superficial and deep flexors. In this case, after the necessary resection of their ends, we suture them together "end to end" following the reconstruction method of Paneva-Holevich (this is followed, in the next stage, by disconnecting the superficial flexor in the wrist and extending it to a preformed canal of the artificial tendinal sheath and reinsertion).

STEP I-7: SKIN FLAP CLOSURE AFTER CHECKING HEMOSTASIS AND INTENDED MOVEMENT OF THE PROXIMAL PART OF THE IMPLANT DURING PASSIVE FLEXION

Prior to closing the skin cover, we make sure that the proximal silicon end runs in freely into the soft tissues in the palm or possibly on the wrist for longer implants when the finger is passively flexed. Should the implant exert pressure on its insertion on the distal phalanx when the finger is passively flexed, there is the risk of severe complication in the sense of protrusion of the peripheral silicon end through the skin cover with the necessity for its explantation. We close the skin cover using a good but delicate suture with individual monophil stitches, having carefully checked the haemostasis. Perioperative coverage with systemic antibiotics is suitable.

STEP I-8: PATIENT INSTRUCTION AND REHABILITATION CARE

Postoperatively when changing the bandage, we delicately massage the finger so as not to damage the skin suture. Healing of the skin cover is followed by physiotherapy and instruction of the patient that he or she should preserve full passive motility of the finger during the silicon implantation. Preservation of passive finger motility is a necessary precondition for completing successful finger flexor reconstruction.

TOOLS USED:

Tools needed to perform the steps listed (the manufacturer does not supply any set of special surgical instruments for implant application).

SURGERY STEPS – STAGE II RECONSTRUCTION

Final surgical reconstruction of the tendon is not approached sooner than 3 months after the implantation of a temporary silicon tendon implant. A longer duration of the implantation of silicon is no mistake. We order the patient for this entirely elective surgery in optimum general condition as well as with a good condition of the finger with consolidate scars after the first surgery and passively free finger joints.

The procedure is best performed under local anaesthesia, because this type of anaesthesia allows not only for cooperation of the patient perioperatively, but also for the exact determination of the reconstructed tendon length.

It is appropriate to administer systemic ATBs perioperatively.

STEP II-1: INCISION AND EXPOSURE OF A TEMPORARY SILICONE TENDON IMPLANT WITHOUT OPENING THE ARTIFICIAL TENDON SHEATH

Final surgical reconstruction of the finger tendon is not approached sooner than 3 months after the implantation of a temporary silicon tendon implant. A longer duration of the implantation of silicon is no mistake. We order the patient for this entirely elective surgery in optimum general condition as well good condition of the finger with consolidate scars after the first surgery and passively free finger joints.

The procedure is best performed under local anaesthesia, because this type of anaesthesia allows not only for cooperation of the patient perioperatively, but also for the exact determination of the reconstructed tendon length.

STEP II-2: IMPLANTATION OF A TENDON GRAFT ACCORDING TO THE SELECTED RECONSTRUCTION METHOD WITH SIMULTANEOUS EXPLANTATION OF A TEMPORARY SILICONE TENDON IMPLANT

In the case of a simple implantation of the tendon, after suturing the autologous graft with the central stump of the flexor tendon, we pull the tendon graft fixed with a stitch to the temporary implant through the artificially created tendinal canal and carry out reinsertion under appropriate tension of the tendon of the reconstructed flexor to the base of the distal finger phalanx.

While during the primary implantation, we conducted preparation for the reconstruction according to Paneva-Holevich suturing the superficial and deep flexors, we now carefully visualize the tendon of the superficial flexor in this location from an incision in the wrist, we cut it and pull it to the palm (Fig. 6).

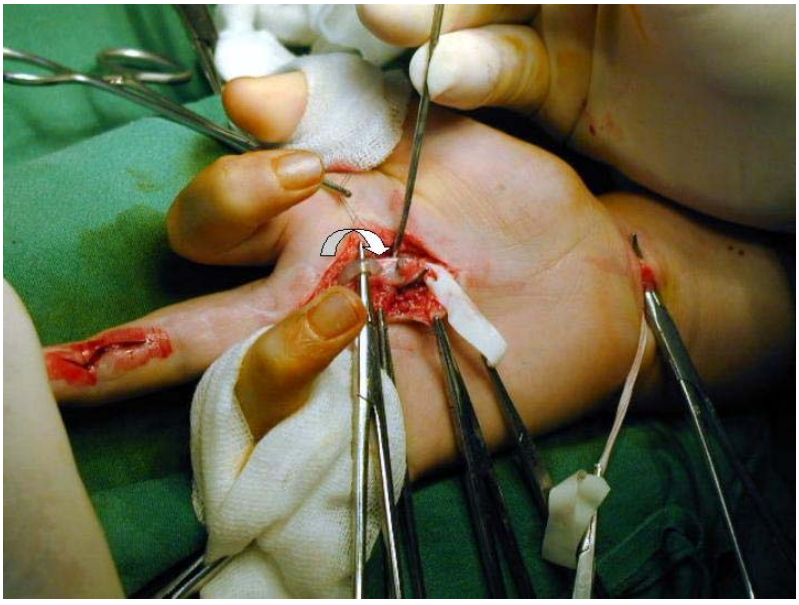


Fig. 6 Stage II flexor reconstruction acc. to Paneva-Holevich. Identification of the corresponding superficial on the wrist. The arrow in the palm designates the “end to end“ suture between the central stamp of the superficial and deep flexor. Identified silicon inserted between both flexors. Incision on the distal phalanx exposing the inserted peripheral implant end.

TOOLS USED:

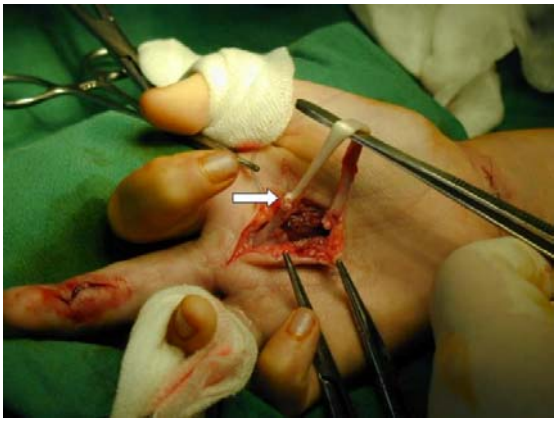
Tools needed to perform the steps listed (the manufacturer does not supply any set of special surgical instruments for implant application).

STEP II-3: CLOSURE OF THE INCISIONS WITH A SUTURE

We now suture the end of the superficial flexor pulled through and the silicon (Fig. 7 left) and pull the superficial flexor further through the artificial tendinal canal to the last phalanx (Fig. 7 right) and perform reinsertion using a monophil stitch knotted over the nail (Fig. 8).

This procedure is more advantageous from the viewpoint that the suture between the superficial and deep flexor made in the first surgery is already healed and we can carry out post-surgery physiotherapy in the same way as in simple flexor reinsertion.

The incisions are closed with sutures.



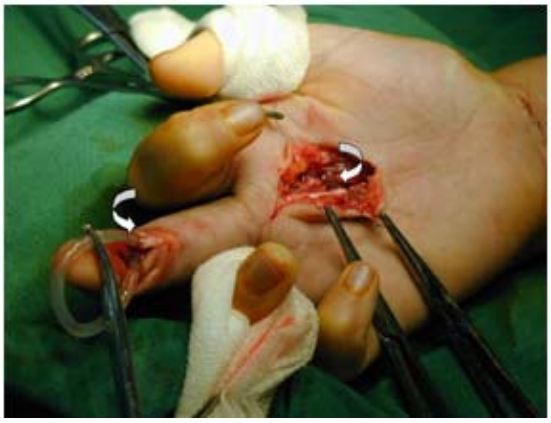


Fig. 7 On the left: Status after suture of the tendon and implant before pulling the superficial flexor through to the reinsertion site. On the right: Status after the superficial flexor has been pulled through the artificially created canal to the site of insertion on the last finger phalanx

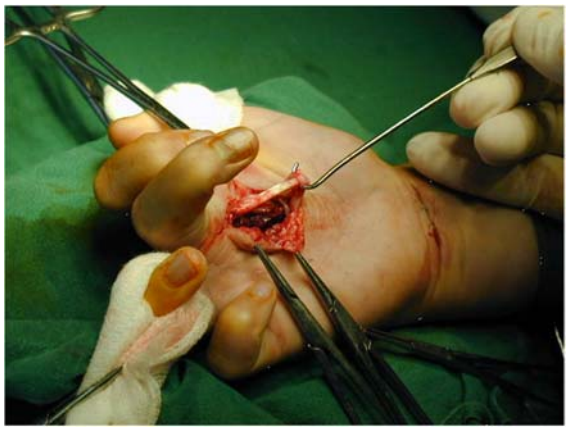


Fig. 8 Status after the reinsertion of the superficial flexor tendon - test of function, prior to skin cover suture

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TOOLS USED:

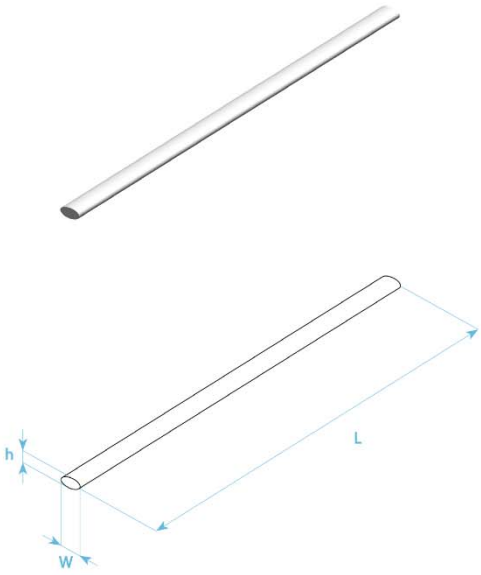
Tools needed to perform the steps listed (the manufacturer does not supply any set of special surgical instruments for implant application).

STEP II-4: PATIENT INSTRUCTION AND REHABILITATION CARE AFTER THE SECOND STAGE

According to current practices, early postoperative rehabilitation is a prerequisite for a good final effect of flexor reconstruction.

Description of early and later physiotherapy exceeds the scope of surgical procedure of flexor reconstruction using temporary tendon implant. The reader can obtain detailed information about this issue in the specialized publications.

SIZES AND ORDER NUMBERS



Náhrada šlachy silikonová dočasná
Tendon replacement temporary

• silikon Nusil MED-4550

	velikost/size	Wxh	L
Z06230-0000-03120	3x1,5x120	3x1,5 mm	120 mm
Z06230-0000-03180	3x1,5x180	3x1,5 mm	180 mm
Z06230-0000-03220	3x1,5x220	3x1,5 mm	220 mm
Z06230-0000-04120	4x2x120	4x2 mm	120 mm
Z06230-0000-04180	4x2x180	4x2 mm	180 mm
Z06230-0000-04220	4x2x220	4x2 mm	220 mm
Z06230-0000-05120	5x2,5x120	5x2,5 mm	120 mm
Z06230-0000-05180	5x2,5x180	5x2,5 mm	180 mm
Z06230-0000-05220	5x2,5x220	5x2,5 mm	220 mm
Z06230-0000-06120	6x3x120	6x3 mm	120 mm
Z06230-0000-06180	6x3x180	6x3 mm	180 mm
Z06230-0000-06220	6x3x220	6x3 mm	220 mm

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