



Hospital Data Imprint/Stamp

Patient Identification Sticker

Carpal Tunnel Syndrome (CTS) Operation

Open/Endoscopic Surgery

Dear Patient,

You have entrapment of the median nerve in the wrist region, which requires surgical intervention. The purpose of this informed consent form is to help you prepare for the patient-doctor discussion. Please read it carefully before the discussion and complete the questionnaire carefully and completely. For better readability, we use male pronouns but are addressing all genders with them.

What is carpal tunnel syndrome?

The median nerve travels from the forearm into the hand through a tunnel in the wrist (carpal canal, carpal tunnel). The tunnel is also shared by 9 tendons. On the flexor (palm) side of the wrist, the tunnel is covered by a band of connective tissue, the carpal ligament (fig.). If the nerve becomes compressed within this tunnel, the symptoms which you are experiencing will occur, i.e. alteration in sensation or pain at night, in particular in the region of the thumb, the index and middle fingers and half of the ring finger, as well as numbness and weakness of the hand.

Reasons for this compression within the tunnel could be chronic irritation with thickening of the tendon sheaths or the flexor tendon sheath tissue, tendency for tissue to swell, as is the case in pregnancy, rheumatoid disease and/or also injury or a tumour.

What are the consequences if not treated?

If the disease persists for a prolonged period without surgical treatment, function of the nerve may be lost completely, and feeling in the thumb, index and middle fingers as well as the ring finger can be lost permanently. In addition, it may no longer be possible to position the thumb opposite the fingers while grasping objects.

How is the operation performed?

The operation is performed under local anaesthesia (wide awake approach) at the wrist (wrist block), upper arm anaes-

thesia (arm plexus anaesthesia) or under general anaesthesia. We will counsel you about the procedure and risks of anaesthesia in a separate patient-doctor discussion.

To avoid blood loss and to improve the ability to see the structures within the operation field, the operation may be performed in a bloodless field. To achieve this, a tourniquet is applied to the upper arm to reduce the blood flow.

During operation, the overlying ligament (carpal ligament) that forms the roof of the carpal tunnel is cut and thereby released to achieve a relief of pressure on the median nerve. This can be performed in an open operation or by endoscopy in "keyhole technique". Your doctor will explain the advantages and disadvantages of these two procedures,

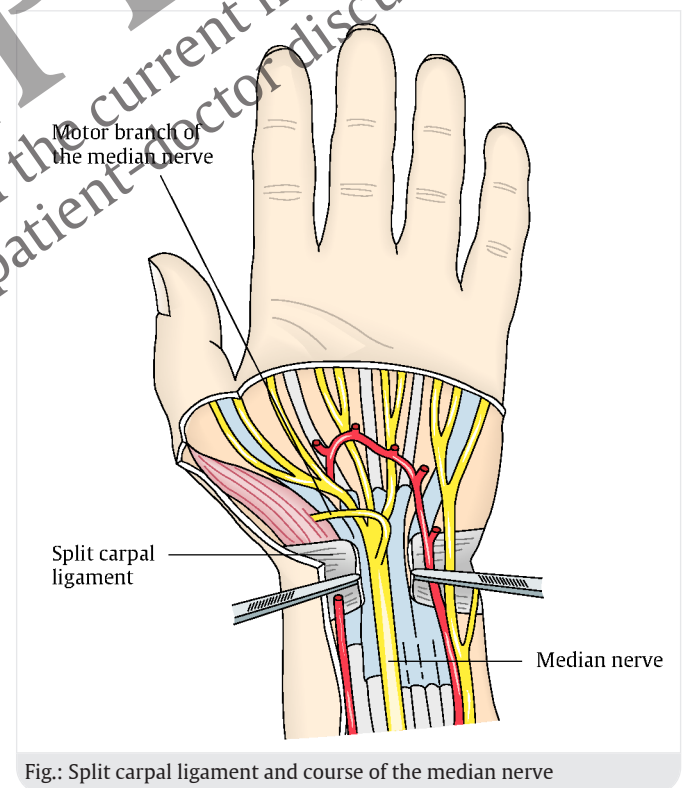


Fig.: Split carpal ligament and course of the median nerve

their different demands on the patient's body, risks and chances of success in detail during the patient-doctor discussion. For repeat procedures, procedures due to severe nerve constrictions, inflammation of tendon sheaths or rheumatoid diseases, the open operation method is to be preferred as a rule.

- **Open release**

The doctor makes an incision in the skin at the level of the wrist; he then splits the carpal ligament to expose the median nerve. By means of optical magnifying equipment (magnifying eyeglasses, surgical microscope), he inspects the median nerve and removes any restricting tissue and adhesions. The motor branch of the median nerve supplying the thenar muscles (muscles of the base of the thumb) can also be viewed. If the tissue of the flexor tendon sheaths is thickened, it can be (partially) removed at the same time.

- **Endoscopic release**

The doctor inserts an optical instrument (endoscope) with a video camera at its tip through a small transverse incision made in the flexor (palm) side of the wrist crease (a second incision may possibly be made in the palm of the hand). Surgical instruments can be introduced through the endoscope to split the carpal ligament. Additional surgical procedures are not possible via the endoscope because of the limited field of vision with this technique. Therefore, this technique can be used only under certain circumstances.

After the operation, the arm is generally immobilised with a firm dressing.

Are additions to or changes in the procedure expected?

The doctor will explain the extent of the procedure planned for you. If he feels that additional measures are very likely to be necessary, he will counsel you about these. However, in some cases, this does not become obvious until the operation is already underway. If unforeseeable additions to (e.g. a longer incision, removal of a tumour growing from a nerve [neuromas, neurinomas, ganglia]) and changes in (change from an endoscopic to an open procedure) the procedure become necessary for medical reasons, we will have to presume that you are in agreement. Otherwise, we would have to interrupt the operation; this would delay treatment and increase the risk of complications.

Are there alternative forms of treatment?

In the early stages of the disease, non-surgical treatment such as resting the hand, injections or anti-inflammatory medications to be taken orally can lessen the symptoms. However, they do not hold promise of lasting relief in frequent cases. In your case, we are recommending surgery in order to achieve a cure or, in the case of severe damage to the nerve, at least an improvement.

Risks and possible associated complications

Despite the greatest care taken, complications can arise, which can even become life-threatening under certain circumstances and necessitate additional treatment or further surgery. The frequency rates are only a general estimate and are intended for weighing the risks against each other. They are not the same as the definitions of side-effects stated in the package inserts of medications. Pre-existing/underlying

diseases and individual unusual circumstances can significantly influence the rate of complications.

During the operation

- **Injury:** Tendons, nerves, blood vessels and muscles are crowded together in the hand, increasing the risk of injury to these structures. In the endoscopic procedure, the risk of injury is slightly increased due to the limited visibility at the operation site. Depending on the location and severity of injuries, this can cause **temporary or permanent sensitivity to touch, impairment of movement of the hand and/or pain**.
- **Damage of the compressed nerve** or its motor and sensory branches is possible under unfavourable circumstances and may require an operation to correct it. This can cause **temporary or permanent alteration in sensation, loss of sensation** of the thumb, the index, the middle or ring fingers as well as **reduced joint mobility** and weakness of the thumb. These symptoms may also be a result of the condition that existed before the operation. The symptoms resolve very slowly or not at all.
- **Skin/tissue/nerve damage** due to positioning of the patient and to measures needed in conjunction with the treatment (e.g. injections, disinfection, laser, electric current, operation in a bloodless field) is rare. Side-effects/complications that can be permanent under certain circumstances: Pain, inflammation, necrosis (death) of tissue, scars and disorders of sensation or function, paralysis (e.g. of the hand).
- **Allergy/hypersensitivity/incompatibility** (e.g. to latex, medications) can cause acute circulatory shock, necessitating intensive care. Severe damage (e.g. organ failure, brain damage, paralysis), which can be permanent under certain circumstances, is very rare.

After the operation

- **Rebleeding and haematomas** can occur because of the large number of blood vessels at the surgical site. A second operation may be necessary.
- **Haemorrhage into or severe swelling** of soft tissues can occur despite consistent elevation, which can necessitate another operation.
- **Temporary, rarely also permanent dysfunctions/impairment of movement** of the arm and the hand may occur in the event of excessive swelling, pain, restricting wound dressings or restricting adhesions at the operation site. The cause for the latter could e.g. be a late start of mobilisation exercises or inconsistency in performing them. Therefore, it is of particular importance that you comply with your doctor's instructions. However, a severe local circulatory disorder (**compartment syndrome**) develops occasionally, which may lead to the loss of individual fingers or the hand.
- **Infection** occurs rarely which may possibly necessitate another operation and prolong the treatment. Severe **impaired wound healing** and **deep-seated infections** (abscess, joint infection) can lead to permanent limitation of motion in rare cases.
- If the flexor tendon sheath tissue is removed at the same time, **mobility of the fingers** can be **restricted** for a certain time (usually for no more than 10 days) and can be associated with pain.
- **Decreased/increased sensitivity to touch** occasionally occurs at the site of the incision, caused by severing of

the nerve branches in the skin. These disorders generally resolve spontaneously and do not require treatment in most cases. In some cases, the margins where the carpal ligament has been cut are hardened and sensitive to touch under the skin for a certain time.

- Due to the severe stress generally affecting the zone of the operation site, **delayed closing of the wound** in the superficial layer of the skin can occur in rare cases.
- **Painful soft tissue swelling** accompanied by **functional circulatory disorders** (local sensation of heat and cold) can occur in exceptional cases.
- In isolated cases, severe inflammation and very severe pain with exaggerated bone resorption occurs (CRPS = complex regional pain syndrome, algodystrophy, Sudeck's disease). Generally, these symptoms resolve with physiotherapy and/or treatment with medications. However, significant dysfunctions and pain can be permanent in isolated cases.
- **Scarring disorders** as a consequence of wide, thick scars developing in patients who have a genetic predisposition for this condition require specific treatment. If scar contractures that hinder movement develop, a second operation will be necessary in some cases.
- In rare cases, **blood clots** can form in large veins, e.g. as a result of immobilisation by a dressing. If they are carried away by the blood stream, they can block a different vessel (thrombosis/embolism). If prophylactic administration of anticoagulants is an option in your case, your doctor will explain the advantages and disadvantages and the associated risks in the patient-doctor discussion.

During the patient-doctor discussion, you should ask all questions that are important to you or about anything that is still unclear!

What are the chances of success?

In most cases, the operation achieves complete recovery of the nerve. However, success cannot be guaranteed. The typical symptom of pain at night usually disappears in the first night after surgery. How quickly sensation returns depends on how severe the damage to the nerve was. Improvement is possible up to six months after the operation. During the nerve regeneration phase, it is possible that an unpleasant sensation or even pain will be experienced.

In very rare cases, the entrapment and the associated symptoms can also persist or the symptoms can recur due to scarring. A second operation may then be necessary.

Instructions

Before the procedure

If available, please present all relevant **documents**, e.g. **medical ID/passports** (allergy, X-ray, implants, vaccination passport, etc.), neurological findings, possibly reports on previous operations and imaging diagnostic.

Please list all medications that you are currently taking (also herbal remedies and over-the-counter medications). The surgeon treating you will then decide if specific medications should be stopped or replaced by another substance. This applies in particular to anticoagulant medications (e.g. Marcumar®, Aspirin, Plavix®, Iscover®, Pradaxa®, Xarelto®, Eliquis®).

Please cut long fingernails and remove gel or acrylic fingernails completely if possible. Otherwise, you run an increased risk of wound infection!

After the procedure

If the operation is performed **on an outpatient basis**, please remember that your senses will be dulled for a certain period after receiving sedation, pain medication or an anaesthetic agent. Therefore, please arrange to have an adult pick you up and stay with you for 24 hours after the procedure. In addition, you may not be actively involved in road traffic during this period of time, nor should you engage in dangerous activities. You also should not make important decisions, nor should you drink alcohol.

If you develop **pain, restriction of mobility, numbness, pins and needles** or **blue-red discolouration** of the fingers, this may be an indication that the dressing is too tight. In this event, you should contact the doctor treating you (or the clinic) **immediately** in order to prevent severe damage to skin, muscles or nerves. Please be certain to ask for a telephone number you can call in case of emergency.

Please **keep** the operated hand **elevated** (e.g. on a cushion during the night) consistently after the operation and as often as possible later.

Please start mobility exercises as instructed as soon as possible after the operation.

Even after sutures are removed, overuse of the hand must be **avoided** for a specific time.

Ask your doctor for exact instructions and written information on follow-up care.

Important questions

In order for the doctor to be able to identify any possible risks involved in this procedure, please answer the following questions:

Age: _____ years • Height: _____ cm • Weight: _____ kg

Gender: _____

n = no/y = yes

1. Are you taking any medications (e.g. anticoagulant medications [e.g. Marcumar®, Aspirin], pain medications, antidiabetics [especially any medications containing metformin], cardiovascular agents, hormone preparations, sleeping pills or sedatives, anti-hypertensive medications)? n y

If yes, please indicate! _____

2. Do you have any allergies (e.g. medications n y [e.g. antibiotics, metamizole, paracetamol], anaesthetic agents, X-ray contrast media, latex, disinfectants, iodine, plaster, synthetic material)?

If yes, please indicate! _____

3. Do you have an increased tendency to bleed, n y e.g. frequent nosebleeds/bleeding gums, bruises, longer bleeding after injury?

4. Do you have or have you ever had an infectious n y disease (e.g. hepatitis, HIV/AIDS, meningitis, tuberculosis)?

If yes, please indicate! _____

Statement of Consent

I have read the informed consent form, and I understand it. The above-named procedure, its nature and significance, possible alternative treatment methods, the risks and possible associated complications, chances of success, possibly necessary changes or additions to the procedure (e.g. change from endoscopic to conventional operation) and additional/subsequent procedures possibly required for medical reasons (e.g. injections) have been fully explained to me in a patient-doctor discussion with the doctor _____.

My questions were answered completely and clearly.

I have **no further questions** and feel that the **counselling was satisfactory**; I do not need **any further time for consideration** and **consent** to the proposed procedure. I also agree to any possibly unforeseeable changes in or additions to the procedure which may be necessary for medical reasons. **I will follow the instructions and recommendations for follow-up care.**

Place, date, time

Patient

Doctor

SAMPLE
Do not use this copy of the current informed consent form for the patient-doctor discussion

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