

SURGICAL TECHNIQUE FOOT & ANKLE

Biointelligent osteosynthesis with Shark Screw® Allograft





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Histomorphology of the human bone Inner strucuture of Shark Screw® 4 Natural Bone Remodeling 6

Surgical technique in foot & ankle surgery with the Shark Screw®

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The natural scaffold of the Shark Screw® with its channel and cavity system provides a guidance structure for cells and cell fluids. Progenitor cells settle inside the allograft to continuously differentiate into these cells that the bone needs. These channels are the basis for the formation of new stable bone tissue with arteries, veins, lymph vessels and nerves - creeping substitution. These cells and structures are the basis for the fusion of a fracture or arthrodesis.



The figure shows an electron micrograph of a sterilized Shark Screw®. From left to right: 1) Shark Screw® | 2) & 3) Osteons, Haverian channels (black arrows), osteocytes (white arrows), concentric special lamellae and switching lamellae between the osteons. Graz University of Technology FELMI-ZFE Institute for Electron Microscopy and Fine Structure Research.12



The manufacturing process is preserving the natural scaffold of cortical bone. The natural haversian channels are a guiding structure for cells. This channel system was visualized with an electron microscopy scan, in which sequential sections (200 μ m) were scanned and the Shark Screw® was reconstructed in 3D. Right Fig.: Histological cut of a Shark Screw® after sterilization. The Haversian channels are cell-free.12



Bone remodeling with the Shark Screw® was investigated on an explant 10 weeks postoperatively. The Shark Screw® was completely revascularized and colonized with bone cells. Lamellar bone formed along the threads are a sign of primary/direct bone healing. No inflammation or rejection reactions were found. (Bricic, 2021)



Histological image of the Shark Screw®. The newly formed lamellar bone is positively attached to the thread of the Shark Screw® (gray arrows). Osteoid (light line/yellow arrows) and osteoblasts (green arrows) are attached to the lamellar bone. Osteocytes an be found in the already finished, mineralized bone. Newly formed Haversian channel - cutting cone- between patient bone and Shark Screw® (circled). Patient bone and graft form a stable bone-healing unit (Elliott DS et al., 2016).



Vascularization of the Haversian channels of the Shark Screw®, section from the center of the 10 weeks post op explanted graft (gray arrows).



What happens with Shark Screw® in the patient's bone?

The following figures show the revascularization, cell colonization and remodeling process of Shark Screw®. The research was done by using light microscopy (PD Dr. Mathias Werner Vivantes Berlin) and scanning electron microscopy (SEM) (Prof. Dipl-Ing. Dr. Harald Plank FELMI Graz) on an explant 10 weeks after the initial surgery.





Thread of the Shark Screw® & patient bones

Highly structured lamellar bone fits to the thread contour without a connective tissue layer. There are no inflammation or rejection reactions. Patient bone and graft form a stable bone healing unit. (Elliott DS et al., 2016)

Mesenchymal stem cells & osteoprogenitor cells

These migrate into the Shark Screw® graft. There they find ideal conditions to differentiate into the cells that the body needs for bone remodeling - osteoblasts for bone formation and chondrocytes for cartilage formation.



Osteoblasts

Osteoblasts (white arrows) form the basic bone substance and are primarily responsible for the organic matrix of the bone tissue. Countless biochemical substances, such as growth factors, hormones, messenger substances and proteins regulate bone remodeling inside the Shark Screw®.



Osteoid producing osteoblast

Highly active osteoblasts secrete osteoid - the basic bone substance. This is gradually mineralized and the osteoblasts differentiate further into osteocytes.





Thread of the Shark Screw® & patient bones

The yellow circle highlights the osteocytes in a light microscopy picture



Osteocyt

Osteocytes are the most numerous cells in our bone, numbering about 42 billion. They are completely embedded in the bone and develop from osteoblasts. Their network of projections, with which they are connected to each other via canaliculi, is impressive. They secrete messenger substances that promote both bone formation and bone resorption. (Kurth A. & Lange U., Fachwissen Osteologie, 2018)





Osteoclasts

Osteoclasts, here in a Haversian channel of the Shark Screw®, degrade the bone material of Shark Screw®. By secreting cytokines, osteoclasts can promote or inhibit the local recruitment, differentiation and activity of osteoblasts. These particular phagocytes are in constant exchange with osteocytes and osteoblasts and can significantly influence them (Sims, N. A., & Martin, T. J., 2014). This constant crosstalk among bone cells enables remodeling of the graft in patient bone.





Shark Screw®



Cannulated tap for 5.0mm Ø Shark Screw® diver

General surgical technique

Shark Screw®

Preperation, reduction, compression

Surgery with the Shark Screw® always follows the same steps, regardless of the region of the body in which it is used. The fracture surfaces / the de-cartilaginized, opposing joint surfaces / the osteotomy surfaces are reamed with a thin drill (1.0 or 1.5 mm) and then adjusted to each other. They are brought under compression from the outside, possibly by using a reduction clamp.



Positioning the 1.6mm k-wire

After repositioning the joint surfaces, insert a 1.6 mm k-wire, which represents the direction and position of the Shark Screw® to be inserted later. Primarily, a 1.6 mm k-wire should always be used for pre-drilling, as it cannot bend during insertion and is directionally accurate. A 1.1 mm k-wire can bend during insertion and could be drilled off when over-drilling! Use fluoroscopy to check the position of the guide wire.

Temporarily 1.1 mm fixation K-wires

In addition, one or two thin k-wires (1.1 or 1.2 kwire) are always placed temporarily. They are intended to keep the two pieces of bone to be fixed as stable as possible during drilling and tapping. They must be placed as close to the edge as possible so that they do not interfere with drilling and tapping later on. Now the two pieces of bone can no longer slip and the specified compression is kept stable.

IMPORTANT!

- -Always use a 1.6 mm k-wire for pre-drilling
- -Drill stepwise to minimize generated heat and ensure vital bone
- -You are replacing patient bone with allogeneic bone. You put bone were bone belongs to!

General surgical technique Shark Screw®



Drilling the core hole

The 1.6 mm k-wire is now removed and replaced with a 1.1 mm k-wire, which can then be used as a guidewire for the cannulated instrumentation .

Drilling should always be carried out stepwise to minimize the heat generated during drilling. Start with the thinnest (blue) drill. This makes it possible to determine the ideal thickness of the graft for the respective region and the respective recipient. Choose the graft as thick as possible, as the load-bearing capacity increases with the diameter. The more mass of donor bone is available in the form of the screw-bone bridge, the more stable the connection between the two pieces of bone to be fixed is.



Tapping

After drilling the core hole, proceed with tapping using the matching tap. Use the inserted 1.1 mm K-wire as a guidance. Drills, taps, and the Shark Screw® allografts are color coded. (e.g. to use a Shark Screw® allograft in a diameter of 4.0mm (yellow) you must perform drilling and tapping with the yellow instruments)



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Rinsing the canal

After tapping, the canal must be carefully rinsed with saline solution, to remove all bone fragments that could possibly be in the canal.

Inserting the Shark Screw® allograft

Insert the desired Shark Screw® allograft almost without any resistance using the screwdriver. Make sure that the screw is in the correct axial position when it is placed on the drilled channel. The head of Shark Screw® cut must not be inserted into the channel. (left picture) The Shark Screw® is held in place solely by the self-locking effect of the narrow thread and never by the screw head. In contrast to Shark Screw® cut, the head of Shark Screw® diver can inserted below bone level. (right picture) In these cases, the screw head does not need to be cut off and serves as an additional bone bridge. After inserting Shark Screw®, cut off protruding screw parts with the oscillating saw or a burr.



If small boneparts remain in the channel they may prevent the screw from being screwed in. If resistance is encountered intraoperatively, it must not be overcome by force under any circumstances. In the event of major resistance, the screw should be removed, tapping and rinsing should be repeated and then the screw reinserted. Shark Screw® screws can not be resterilized. They must be inserted directly from the original sterile packaging without prior manipulation.



Surgical technique hammer toe







The trochlea can now be mobilized. The soft tissues around the shaft of the proximal phalanx are slightly elevated and the shaft itself is exposed with 2 Hohmann hooks. Resect the PIP-Joint as sparingly as possible with the oscillating saw.



Surgical technique hammer toe





Insert a 1.1 mm K-wire intramedullary into the shaft of the proximal phalanx. The 1.1 mm K-wire is used as a guidance during drilling (approx. 10-15 mm depth). The depth of the drill hole can be seen on the laser markings on the instrument.

In most of the hammertoe surgeries, a diameter of 3.5mm is sufficient (Blue Drill / Tap)

Repeat the drilling in the base of the middle phalanx, also guided by a 1.1 mm k-wire, using the yellow drill. Tapping is not required, as the graft is only inserted (plug -in fit). (step 7)

To be able to insert a 3,5mm Shark Screw® cut in the middle phalanx (distal part), the 4.0mm drill

Important:

-sparingly resect the trochlea and the base

(yellow) must be used in the distal fragment (step 7).

-Exact alignment of the osteotomy surfaces can be achieved through oscillating movements



Surgical technique hammer toe





Tapping in the proximal phalanx is done by using the blue 3.5 mm tap. Check the required depth with the laser markings on the instrument.

Irrigate the channel prior to throwing in Shark Screw to remove all residual bone fragments





Surgical technique hammer toe



Cut off the screw approximately 6 mm to 9 mm above the end of the proximal phalanx. Keep in mind that the hole in the middle phalanx needs to be drilled by using a 4.0 mm drill (one size larger as the actual screw size). Without tapping the protruding part of the Shark Screw® is inserted into the middle phalanx.



While pulling on the distal and middle phalanx and stretching the toe at the same time, insert the protruding screw into the hole in the middle phalanx. A tight, accurately fitting plug-in connection is created.

Inserting the Shark Screw® into the middle phalanx can be simplified by pulling on the toe. Make sure that the screw part in the middle phalanx is as deep as possible in the middle phalanx to avoid dislocation of a screw. Make sure to drill the hole in the middle phalanx to a maximum.



Surgical technique hammer toe





Press the two fragments against each other using left and right rotating movements until the proximal phalanx and middle phalanx are close together. The soft-tissue closure of the extensor apparatus should also be performed in a tight manner.

Postop protocol

Bandage shoe for 4 weeks with weightbearing









Clinical result & case report of a PIP arthrodesis & a Weil osteotomy with Shark Screw®

The clinical case report shows an X-ray follow-up of a PIP arthrodesis and Weil Osteotomy using Shark Screw® cut 3.5 mm. X-ray images from left to right: ap preoperative | ap postoperative | ap 2 months post-operative.







Clinical result & case report of a PIP arthrodesis

The clinical case report shows an X-ray follow-up of a PIP arthrodesis with Shark Screw® cut 3.5 mm and a bunion procedure according to Austin with Shark Screw® cut 4.0 mm. X-ray images from left to right: ap preoperative | ap postoperative | ap 6 weeks postoperative.

Bunionectomy - Austin Surgical technique with Shark Screw®





 Median skin incision, preparation of the vascular-nerve bundle and exposure of the joint capsule.
 Median, straight opening of the joint capsule and exposure of the metatarsal head with Hohmann retractor



1. Opening the capsule with a McGlamry elevator and repositioning of the sesamoid bones from distal over the metatarsophalangeal joint.

2. After opening the sesamoid bones and the capsule, the big toe should be easily pushed into varus at the metatarsophalangeal joint.

Bunionectomy - Austin Surgical technique with Shark Screw®





The exostosis should be sparingly removed with the oscillating saw, that the head is obtained as much as possible. The contact surfaces are as large as possible after shifting





Determine the center of the metatarsal head and fix the osteotomy axis with a K-wire. Since the metatarsal head should be plantarized, the K-wire is inserted from dorsal medial to plantar lateral, aiming to the MT head 4. This ensures that the osteotomy does not result in a change of the toe length. Bunionectomy – Austin Surgical technique with Shark Screw®



Reversed L osteotomy: To guide the saw, a saw gauge or clamp is used. It is important that the dorsal osteotomy is short and steep. This ensures that the Shark Screw® can be inserted while the long cortical bone bridge is obtained. The plantar osteotomy is long and flat (parallel to the planta pedis).





1. Laterally shifting of the free metatarsal head 2. Metatarsal head & MT I shaft are pressed firmly against each other and the osteotomy, as far as possible dorsal and superficially, is temporarily fixed with a 1.1mm K-wire. **Attention**: temporary K-wire and the guidance K-wire for the Shark Screw® must be

sufficiently far away that drilling & tapping are unhindered.

3. Place a 1.6mm K-wire (cannot bend) at a distance of at least 15mm from the osteotomy, from proximal dorsal, to distal plantar, towards the center of the MT1 head. This corresponds to the desired position of the Shark Screw®. Note that there is sufficient cortical bone remaining after drilling and tapping (at least 10mm).

4. X-ray control of k-wire location

Bunionectomy - Austin Surgical technique with Shark Screw®





1. Depending on the size and thickness of the bone, the diameter of the Shark Screw® to be used also varies. Before drilling, the 1.6mm K-wire must be replaced with a 1.2mm K-wire.

2. Stepwise drilling of the core hole over the guiding K-wire to the subchondral bone of the metatarsal head. Starting with the blue drill up to the desired diameter (Bunionectomy mostly done by using 4.0mm (yellow) or 4.5mm (red) Shark Screw). Use the laser markings on the instrumentation to determine depth of drilling / tapping



After drilling, tapping is performed using the mahing tap. Again, the depth of the thread can be controlled with the laser marking.

Bunionectomy - Austin Surgical technique with Shark Screw®



 After tapping, irrigate the channel with saline solution to remove bone residuals from drilling and tapping. This will lower the resistance whilst inserting the screw.
 Shark Screw® must be screwed in without any resistance. The cutted thread and screw thread are firmly interlocked and keep the bone connection stable in every direction.



1. Check the final position with an interoperative X-ray. Cut off the protruding Shark Screw® to bone level by using a oscillating saw or burr

2. Remove the temporary K-wire and close the wound.



Postop protocol*

Bandage /walker shoe and acrylic bandage for 4 weeks







Clinical case repost Bunion

The clinical case report shows an X-ray follow-up of a Bunion Austin osteotomy. X-ray images from left to right: ap preoperative | ap 8 weeks postoperative | ap 20 months postoperative





Clinical case report Bunion

X-ray follow-up of a bunion according to Austin. X-Rays from left to right: ap preoperative | ap 12 months postoperatively.

STREAM SURGICALVIDEO





1



Skin incision directly over the affected MTP joint. Protection of the interdigital vascular nerve bundles and exposure of the extensor tendons. Entering laterally or medially to the MT head.

If several MTP joints are affected, one skin incision is usually sufficient. In this case the skin incision should be exactly in the middle (e.g. for Weilosteotomy 2-4, the skin incision should be over the MTP III joint).





- 1. Opening the joint capsule with the scalpel
- 2. Exposure of the MT head with the raspatory
- 3. Insertion of 2 hohmann hooks to protect the soft tissues during sawing





Cut approximately parallel to the planta pedis in the upper fifth of the MT head. The cut is only made 4/5 of the way through. Make a second saw cut parallel to the first at a distance of 2-3 mm to cut out a thin slice. Complete this cut and then finish the first cut as well. Now remove the thin, approx. 2 mm thick bone slice. Then move the MT head proximally by 5 to 10 mm, depending on the preop. Clinic and intraop. radiologic alignment (MT II should not be longer than MT I).

The longer the osteotomy, the larger the bone wound healing area, the better the healing, the more can be shifted proximally.

Sometimes the Hohmann hooks lock during the sawing process and the osteotomy cannot be completed. The osteotomy can then be carefully completed with a narrow chisel (tilting the chisel).

Some authors describe performing a second osteotomy parallel to the first osteotomy and recommend the removal of this thin bone slice



The MT head is moved proximally to the desired position and pressed against the MT shaft. Then fix this position with a thin temporary K-wire (e.g. 1.1 mm) as far distal as possible, to have enough space for drilling. Then place the 1.1mm guide K-wire for the Shark Screw® in the center of the head and the distal MT-shaft. Drilling and tapping is done by using this k-wire as guidance. After tapping has been done, irrigate the channel to remove remaining bone fragments.





The Hohmann hooks can interfere when shifting the MT head. Reposition the Hohmann hooks or remove them temporarily. To accurately assess the entry point of the Shark Screw®, insert a K-wire in the center of the MT shaft. A forceps can be placed over the MT shaft from the dorsal side. The ideal entry point is centrally located between the forceps.



3. Wound closure

If a further Weil osteotomy at the same patient is planned, the cut Shark Screw® can be used again if the remainder is long enough.

CAUTION! The hexagonal head of the Shark Screw® cut must not be screwed in









Case report Weil osteotomy and Lapidus arthrodesis with Shark Screw®

The clinical case report shows an X-ray follow-up of a Weil osteotomy with Shark Screw® cut 3.5mm as well as a Lapidus arthrodesis with two Shark Screw® cut 5.0mm. X-rays from left to right: ap preoperative | ap postoperative 8 weeks | ap 8 months postoperative.

Postop protocol

4 weeks allowing fully weigth bearing in a bandage / walker shoe





Arthrodesis of the IP joint



3

Surgical technique

Y-shaped skin incision over the IP joint. The angle between the two distal cuts should be as large as possible to minimize the risk of skin necrosis.





Severing the extensor tendon close to the beginning at the distal phalanx. The distal stump of the tendon should be long enough to allow end-toend suturing of the tendon. Then sever the two collateral ligaments.

Maximum plantar flexion of the distal phalanx, removal of any exophytes. Sparing plane reduction of the base of the distal phalanx and the trochleausing an oscillating saw until the former articular surfaces can be aligned flat. Remove the cartilage of both joint surfaces with a rongeur or by scraping movements with the oscillating saw. (Keep attention to not generate any heat during this procedure)





2

4





6

Debridement of the subchondral sclerotic bone using a 1 mm or 1.5 mm drill (drill does not get as warm as the K-wire).

First retrograde placement of a double trocar 1.6 mm K-wire in the center of the distal phalanx until it exits through the tip of the big toe. Then reclamp the 1.6 K-wire in the machine, which now guides the 1.6 K-wire from distally. Reduction and adjustment of the articular surfaces of the IP joint, which are brought under full compression from the distal side. In optimal position, the IP joint is transfixed with the 1.6 K-wire, which is advanced through the trochlea deep into the shaft of the proximal phalanx.



Additional temporary fixation of the IP joint with two 1.0 or 1.1 K-wires. These K-wires hold the position of the IP joint during drilling and tapping. The drill channel must not shift until the Shark Screw® is inserted. Otherwise, there is a risk that the Shark Screw® distracts the two joint parts, as the screw thread cannot grip the cut thread.

Arthrodesis of the IP joint



Surgical technique





When the IP joint is stabilized, a skin incision is made at the tip of the toe. Remove the 1.6 mm K-wire in exchange for the 1.1 mm K-wire. This k-wire is used as guidance k-wire for drilling and tapping. Drilling should be done stepwise from small diameter to largest. For the IP arthrodesis, a Shark Screw® diver \emptyset 5.0 mm x 35mm or x 45mm is required. The channel must be irrigated after tapping.



Pressing the two osteotomy surfaces onto each other. The Shark Screw® diver is placed on the insertion device. Now the insertion depth is determined as precisely as possible by placing the Shark Screw diver centrally over the arthrodesis area. Now mark the position on the screwdriver as soon as it at the skin level. At this point the insertion process must be stopped.

Screw in the Shark Screw® diver under the bone surface using fluoroscopy in such a way, that it brigdes the arthrodesis gap proximally and distally in approximately the same length.







Case report of an arthrodesis of the IP joint with Shark Screw® diver

The clinical case shows an X-ray follow-up of an IP arthrodesis with Shark Screw® diver 5.0mm and 35mm length. X-ray images from left to right: ap preoperative | ap postoperative | ap 13 Months postoperatively

Postop protocol

Bandage shoe for 6 weeks, 2 weeks without weightbearing, 4 weeks with weightbearing

If the screwdriver is not fully attached, the force is only transmitted via the tips of the screwdriver and there is a risk of breakage of the screw head.

The fine thread of the Shark Screw® diver and the cut thread have a very high fitting accuracy. The graft can be screwed in with almost no resistance. If the resistance increases when inserting the Shark Screw® diver, the screw must be unscrewed, and tapping and rinsing needs to be done again. . Either the small bone fragments were not completely removed, or the initial thread was cut "non-axial" and not exactly axial. The Shark Screw® therefore gets stuck and can neither be screwed in deeper nor removed again.

MTP I fusion - Hallux rigidus Surgical technique with Shark Screw®



A medio-dorsal skin incision is made and the extensor apparatus is exposed underneath. Then the extensor apparatus is split lengthwise, medial to the extensor tendon and the metatarsal head is exposed.



The medial and lateral collateral ligaments are released and the metatarsal head and the base of the proximal phalanx are mobilized. From the distal side, the McGlamry is inserted into the MCP joint and the usually luxated sesamoid bones are released. This allows them to be reduced and aligned again.



MTP I fusion - Hallux rigidus



4

Surgical technique with Shark Screw®

After preparing the joint, the bone surfaces are prepared with a thin drill. The drill dust is left in place to fill the arthrodesis gap and minor bone irregularities.



The metatarsal head and the proximal phalanx are pressed firmly against each other and the joint is fixed temporarily with a 1.6 K-wire to keep it stable. Now check the position of the arthrodesis. Therefore a sterile flat board can be utilized.

MTP I fusion - Hallux rigidus



8

Surgical technique with Shark Screw®



A 1.6mm K-wire is placed from proximal, medial, coming from the imaginary midline (dotted line), to distal, lateral, dorsal and a second K-wire from distal, medial, coming from the imaginary midline (dotted line) to proximal, lateral plantar. These k-wires mark the position of the later on placed Shark Screw Allografts. Make sure that one of the two wires is dorsal and the other plantar, that the Shark Screws can be inserted without any problems. The best way to do this, is to place the 1.6 drill wire in the imaginary center line and align the proximal K-wire dorsally and the distal K-wire plantarly. The K-wires cross in the ap alignment, in the lateral view, they run parallel and do not tangent each other. The position of the temporary K-wire is also checked, it must not collide with the other two KWs and interfere at drilling and tapping.



First, one of the two 1.6 K-wires is exchanged for a 1.1 mm K-wire. This wire is used as guidance k-wire for drilling and tapping. Drilling is done stepwise by starting with the blue 2.85 mm drill. The decision regarding the appropriate Shark Screw size is contingent upon the dimensions of the bone in question. Usually, two 4.0mm Shark Screw® marked in yellow or two red marked 4.5mm Shark Screw® are used. The depth of the hole can be read from the laser markings. Try to use a Shark Screw® with the largest diameter as possible.

After drilling, tapping is performed with using the matching tap (color code must be matching with screw size).



Surgical technique with Shark Screw®



It is extremely important to rinse /irrigate the channel with saline solution to remove fine bone fragments that occur during drilling and tapping. The Shark Screw® is screwed in with the screwdriver. Afterwards the temporary k-wire can be removed.



After fluoro check, the protruding Shark Screw parts are cut to bone level. The graft acts as a bone bridge and guiding substance for the body's own cells.




Postop protocol

After the foot swelling became less (3 - 5 days postoperatively), the patients receive a soft forefoot cast with big toe inclusion for 6 weeks. The patients are instructed to do not weightbear for four weeks. During the last 2 weeks, they are increasingly allowed to weightbear in a plaster cast. They also wear a bandage/walker shoe.













Case report of a MTP I arthrodesis (Hallux rigidus) with Shark Screw®

The clinical case shows an X-ray follow-up of an MTP I arthrodesis with Shark Screw®. X-ray images from left to right: ap preoperative | ap 6 weeks postop | ap 1 year postoperative.



Case report of a MTP I arthrodesis (Hallux rigidus) with Shark Screw®

The clinical case shows an X-ray follow-up of an MTP I arthrodesis revision case with 2x Shark Screw® 4.5 mm. X-ray images from left to right: oblique preoperative | intraoperative | ap 3 months postoperative





1. First, the malposition of the metatarsophalangeal joint and the sesamoid bones is corrected. Skin incision dorsomedial above the metatarsophalangeal joint of the big toe. The joint capsule and the tendon are exposed, while sparing the vessels and the nerves.

2. Open the joint capsule dorsomedial by longitudinal incision. Sparingly cut off and remove the pseudo exostosis from the MT head.



Careful insertion of the wide McGlamry elevator over the MT 1 head. By pushing from distal, the adhesions of the non-aligned sesamoid bones are sharply released and, in some cases, the lateral capsular apparatus is split longitudinally. The sesamoid bones are reduced thereby.

The elevator is chosen as wide as possible, to avoid damage to the cartilage of the metatarsal head.





After complete reduction, the big toe can be moved into varus by bending the metatarsal without much resistance.



1. Second additional skin incision dorsal over the TMT 1 joint. Entering medially of the extensor hallucis longus tendon (the dorsalis pedis artery is lateral to it), the TMT 1 joint is visualized.

2. Bypass the TMT 1 joint with the raspatory and adjust with two Hohmann hooks. Open the TMT 1 joint capsule with the scalpel.

3. Sparing osteotomy of the base of MT1 and the medial os cuneiform with a laterally open angle. To correct the deformity, of the intermetatarsal angle I/II.

4. Remove the thin osteotomy wedges with a forceps.







1. Spreading the TMT 1 joint with the bone spreader and remove remaining cartilage.

2. The osteotomy is checked for completeness. Sometimes cortical spikes remain and prevent the osteotomy surfaces to align correctly (especially plantar). These residual serrations are completely removed with a saw or a cutter. The base of the MT1 runs out laterally. This "spike" can also interfere laterally and prevent optimal adjustment. In such a case, the spike is removed with the saw or a small chisel.



1. Preparing the mostly sclerotic former joint surfaces with a 1.0 mm or 1.5 mm drill and removal of the bone spreader.

2. Check if the osteotomy surfaces are aligned perfectly. Check the position of the big toe in relation to the medial longitudinal arch. Prevent too much dorsi- or plantar flexion.

3. The MT1 is planarized by 3mm to 5mm compared to the cuneiform medial, that a small step is created dorsally.

The drill generates less heat than the K-wire, so the drill should be used to prepare the joint surfaces. The drill fragments should not be removed under any circumstances, as it promotes bone growth in the osteotomy gap and fills small bony defects.





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Make sure that all K-wires are placed within the marked area. This will ensure that the screws are located within the bone





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1) Pressing the two osteotomy surfaces together and inserting the K-wire. The pressing is achieved by pulling the big toe firmly into varus and simultaneously applying pressure with the thumb on the MT head I. 2) Attention to step formation around the osteotomy. Place a temporary, transverse, subcapital 1.6 K-wire through MT I and MT II to maintain compression of the osteotomy surfaces until Shark Screw® has been inserted. (1) Depending on the anatomical conditions and access, we place two 1.6 K-wires (3 and 4) from distal or proximal parallel to each other (concerning the AP plane) within the set landmarks. Make sure that the entry point of each K-wire is located 20mm from the osteotomy site (bone bridge!).

3. To additionally secure the osteotomy position, a third K-wire (2) is placed in a way that it does not inter-fere during drilling and tapping. Attention: Pay attention to the rotation of the MT1! Fluoro check is recommended!

Choose a sufficient distance between the K-wires. They must not interfere during drilling. The entry point for the K-wire, which determines the position of the Shark Screw®, must be at least 20mm away from the osteotomy site. This is the only way to ensure a sufficiently bone bridge after drilling and tapping.



1. Exchange the medial 1.6 K-wire for a 1.1 mm K-wire. Drilling and tapping is performed using the 1.1 mm k-wire as guidance wire. Start with the smallest (blue) drill and stepwise drill up to the largest possible diameter.

2. Tapping is done with the largest (black) tap, if a 5.0mm Shark Screw® is used. Carefully irrigate the channel. For Lapidus arthrodesis, the thickest 5.0mm Shark Screw® is recommended.

3. The 5.0mm Shark Screw® diver can be fully inserted below the bone surface. If the 5.0 mm Shark Screw® cut is used, the protruding head must be cut off to bone level.

4. Same procedure on the lateral 1.6 k-wire. After both Shark Screws® have been placed and cut off, the temporary axial and the transverse K-wires can be removed. Final fluoro check and wound closure is performed

Postop protocol

Walker Shoe for 6 weeks, 4 weeks without weightbearing, 2 weeks partial weightbearing





Case report of a Lapidus arthrodesis with Shark Screw® X-ray images from left to right: ap preoperative | ap 6 weeks postoperative | ap 6 months postoperative











Case report of a Lapidus arthrodesis with Shark Screw®

X-ray images from left to right: ap preoperative | oblique preoperative



X-rays from left to right: ap postoperative | lateral postoperative | oblique postoperative





X-rays from left to right: 3 months postoperative ap | 3 months postoperative lateral | 3 months postoperative oblique



X-rays from left to right: 6 months postoperative ap | 6 months postoperative lateral | 6 months postoperative oblique

Benefits of treating a Lapidus with Shark Screw®:

- easy cutting pattern
- -less softissue irritations
- -grafting & fixation with two cortical allograft screws
- -stable bone-healing-unit (Elliot DS et al., 2016)
- -no autografting neccessary
- -no foreign material less pain

Arthrodesis of the Lisfranc joint (II-III)



Surgical technique with Shark Screw®



Skin incision slightly lateral to the os metatarsale III. Extensor tendons and vascular-nerve bundles are held aside with retractors.

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The dorsalis pedis artery is located between the 1st and 2nd rays. Also pay attention to the profundal peroneal nerve, which is located close to the artery, and the medial cutaneal nerve.



Opening the joint capsule of TMT joints II and III with the scalpel. Removal of the exophytes with a rongeur.



Spreading the joint space with the bone spreader. Remove the cartilage with a sharp spoon.

Arthrodesis of the Lisfranc joint (II-III)



Surgical technique with Shark Screw®



Multiple drilling of the sclerotic subchondral bone with a 1.5mm drill, to prepare the bone surfaces. Also, exophytes around the spikes of the base of the metatarsal bones often prevent the Os me-atarsale and Os cuneiforme from being aligned. In these cases, cut off these parts with the oscillating saw parallel to the shaft. Close the arthrodesis site and put the two bones under compression.



Before K-wires are placed, the osteotomy surfaces are checked from distal. The wedge-shaped converging interfaces of the cuneiform ossa are clearly visible. Thick red injection needles are used to set landmarks along these surfaces: Needle 1 between Os cuneiforme mediale and Os cuneiforme intermediale, needle 2 between Os cuneiforme intermediale and Os cuneiforme laterale, needle 3 between Os cuneiforme laterale and the cuboid. Later, the K-wires are placed centrally between the placed needles and thus easily find the ideal central position, even without X-ray control.

Arthrodesis of the Lisfranc joint (II-III)



Surgical technique with Shark Screw®



1. As soon as the bone surfaces can be adjusted to each other under pressure from distal, a 1.6 K-wire coming from distal dorsal through the base of the Os metatarsale II is placed into the Os cuneiforme intermediale. Aim the K-wire at the malleolus medialis, centrally between the two previously placed red needles.

2. The second 1.6 K-wire is placed through the base of the Os metatarsale III, into the Os cuneiforme laterale. Finally, a k-wire is placed into one of the two joints for temporary fixation. This prevents movements during drilling and tapping

3. Make sure that there is enough space between the K-wires. They must not interfere when drilling and tapping. Fluoro check before drilling and tapping.

The direction of the K-wires coming from distal through the base of the os metatarsale, is not axial to the shaft of the os metatarsale itself. The axes of the ossa cuneiformia are slightly offset medially, when inserting the K-wire, the tip of the wire should point slightly medially to-wards the medial malleolus. The K-wire must be placed at least 20 mm distal to the arthrodesis gap. This ensures a strong enough bone bridge.

Arthrodesis of the Lisfranc joint (II-III) Surgical technique with Shark Screw®





1. One of the two 1.6 K-wires is exchanged for a 1.1mm K-wire, for drilling and tapping. It is recommened to use a 5.0 Shark Screw® and perform stepwise drilling (blue to black drill). 2. Tapping is done with the matching tap. Irrigate the channel afterwards.

3. The Shark Screw® is screwed in without much resistance. If the 5.0 mm Shark Screw® cut is used, the protruding head must be cut off to bone level. The 5.0 mm Shark Screw® diver can be sunk completely below the bone surface.

4. After both Shark Screws® are placed and cut off, the temporary K-wire is removed.

Postop protocol

6 weeks walker shoe, 4 weeks without weightbearing, 2 weeks slowly increasing weightbearing. After 6 weeks in a walker shoe a shoe with a hard sole to prevent flexation of the foot is recommended.

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Arthrodesis of the Lisfranc joint (II-III) page 51



Case report with Shark Screw®







Case report of a Lisfranc arthrodesis (TMT II - III) with Shark Screw® X-Rays from left to right: ap preoperative | ap 6 months postoperative | ap 10 months postoperative.



Case report of a Lisfranc arthrodesis (TMT II - III) and CN arthrodesis with Shark Screw® X-rays from left to right: ap preoperative | ap 8 weeks postoperative | ap 14 months postoperative.



Arthrodesis of the talonavicular joint

Surgical technique with Shark Screw®



A straight dorsal skin incision is made over the talonavicular joint (TN). To preserve vascular-nerve bundles, go lateral to the tendon of the tibialis anterior muscle. The TN joint is exposed with Hohmann retractors. Incision of the TN joint is done with a scalpel





- 1. Spreading the TN joint with the bone spreader.
- 2. Remove the remaining articular cartilage with a slightly curved chisel and arongeur.



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Arthrodesis of the talonavicular joint





Now both articular surfaces of the talus and os naviculare are put under maximum compression. At the same time, three 1.6 K-wires from distal to proximal are placed. In this way a very firm connection is achieved, and the bones cannot shift during drilling and tapping

Primarily, a 1.6 K-wire should be used for transfixation! The 1.1 K-wires would be too flimsy and could bend during drilling, consequently the K-wires could be drilled off. For drilling, the 1.6 K-wires must be replaced with 1.1 K-wires.



Starting with the middle K-wire, the 1.6 K-wires are exchanged for a 1.1mm wires. Stepwise drilling starting with the blue drill up to the black drill is recommended. For the TN arthrodesis usually the black marked 5.0mm Shark Screw® cut is used. The black color coded tap is used for tapping. Irrigate the channel after tapping!

The thread is best cut slowly and sensitively with the power tool, as the direction can be kept exactly axial, better than tapping by hand. Slow tapping prevents heat generation! Tapping depth can be determined on the lasermarking of the tap.

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Arthrodesis of the talonavicular joint

Surgical technique with Shark Screw®



Finally, the channel must be rinsed with physiological saline solution, because even small bone fragments could lead to a stuck screw. The Shark Screw® cut graft is now screwed in. Then the other two K-wires are replaced with 1.1 K-wires and the procedure is done again as described above.

If there is an unusual high resistance when screwing in, the Shark Screw® graft must be removed and the tapping and rinsing must be repeated. (Reasons for this may be: 1. small bone fragments have remained in the channel after irrigating. 2. the graft was not inserted axially)

Under no circumstances the hexagonal head of the Shark Screw® cut should be sunk below bone level. This would lead to screw breakage ! If the Shark Screw® diver is used, the screw head can be coun-

tersunk below bone level. The Shark Screw® ensures a rotation-stable arthrodesis.



After screwing in the Shark Screw® cut, the protruding screw material must be cut to bone level with an oscillating saw.

Postop protocol

Walker shoe for 8 weeks. 6 weeks without weightbearing followed by 2 weeks of ramping up weightbearing

STREAN VIDEO NOW



Arthrodesis of the talonavicular joint



Case report with Shark Screw®







Case report of an arthrodesis of the talonavicular joint with Shark Screw® X-ray images from left to right: ap preoperative | ap postoperative | ap 10 months postoperative







Case report of an arthrodesis of the talonavicular joint with Shark Screw® X-ray images from left to right: ap preoperative | ap postoperative | ap 10 weeks postoperative.





A lateral skin incision is made directly over the tuberosity of the os metatarsale 5. Using fluoroscopy, a 1.6 mm K-wire is inserted intramedullary over the fracture gap into the shaft of the metatarsal 5. The position of the k-wire corresponds to the desired position of the Shark Screw®. Primarily a 1.6 K-wire is used becuase it does not bend during insertion and thereby the desired direction is maintained.



The 1.6 mm K-wire is exchanged for the 1.1 mm K-wire. Drilling is done stepwise, starting with the smallest (blue) drill, up to the selected screw diameter.

Depending on the size of the bone, the Shark Screw® is chosen. Mostly the black marked 5.0 mm Shark Screw® diver is used. Therefore drilling should be completed using the black drill. The depth of the drill channel can be read from the laser markings





Irrigating the channel with physiological saline solution is necessary to completely remove small bony fragments that are produced during tapping. The Shark Screw® graft can only be inserted to the intended depth when all bony fragments has been removed. However, if any small fragments are left, the narrow thread will not match with the cutted thread. Then graft can neither be rotated forwards nor backwards. Therefore sufficient rinsing / irrigating is recommened!



The Shark Screw® diver is screwed in without resistance. Shark Screw diver is a headless screw and can be screwed in below the bone surface. Then remove the screwdriver from the plug-in mechanism. Try to avoid unaxial movements whilst screwing in Shark Screw!

Postop Protocol

Recommended postoperative treatment of the Jones fracture: 4 weeks in a walker shoe. 2 weeks without weight bearing followed by 2 weeks with weight bearing









Case report of a Jones fracture with Shark Screw® diver X-Rays from left to right: ap preoperative | ap 8 weeks postoperative | ap 6 months postoperative.





Med. calcaneus osteotomy





Surgical technique with Shark Screw® diver



Oblique skin incision 2 cm dorsal to the tip of the fibula directly over the calcaneus, saphenous vein, and sural nerve ventral to the incision.



Securing the osteotomy with Hohmann hooks which are inserted proximally and plantarly around the calcaneus. Fix the oblique osteotomy from dorsal proximal to plantar distal at an angle of approximately 45°. The saw blade should be guided slightly from lateral dorsal to medial distal. This is the only way to ensure that the dorsal tuberosity of the calcanei can be medialized after the osteotomy.







Perform the osteotomy with the oscillating saw. The direction of sawing should not be strictly through the calcaneus but should run slightly oblique from lateral dorsal to medial distal. This allows the medialization of the calcaneus later, as the plantar fascia is slightly reduced when the osteotomy is moved. Med. calcaneus osteotomy Surgical technique with Shark Screw® diver



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Shifting the dorsal calcaneus fragment by approximately 1 cm medially (Corresponds to a correction of approximately 10°) The displacement of 1mm means a correction of 1°. Plantar flexion facilitates the displacement. As soon as the desired displacement of the dorsal calcaneus fragment has been set, guide plantar flexion into maximum dorsiflexion. That leads to a compression of the osteotomy surfaces.



 Percutaneous placement of two 1.6mm K-wires from dorsal plantar. The k-wires should be placed along the lateral cortex around the calcaneal tuberosity, that the k-wire can be placed ventral to the osteotomy. This way, it does not penetrate the medial cortex due to the medialization of the tuber.
The osteotomy is temporarily fixed with a third K-wire, by doing so, nothing can be damaged during the transplantation process.

3. Then the first 1.6 mm K-wire is exchanged for a 1.1 mm K-wire. The 1.1 mm K-wire is used as guiding wire for drilling and tapping. Drilling and tapping must be done using the black marked instruments when using Shark Screw diver. Stepwise drilling is recommened!

4. The position and depth of the hole is checked under fluoro. Once the desired ideal depth and the bridging of the osteotomy is achieved, the total length of the canal is determined at the entry point of the instrument through the skin on the laser mark.

5. Irrigate the channel with physiological saline solution.

Med. calcaneus osteotomy Surgical technique with Shark Screw® diver





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1. The Shark Screw® diver of the desired length (5.0mm x 35mm, or 5.0mm x 45mm) is placed on the claw coupling screwdriver.

2. Check how deep the Shark Screw® diver must be sunk into the calcaneus. To do so, the Shark Screw® diver, which is attached to the claw coupling screwdriver, is put on the outside of the osteotomy in such a way, that it bridges the osteotomy to the same extent on both sides. The maximum insertion depth can be read at the skin entry point from the laser marking on the screwdriver. This maximum insertion depth is marked on the screwdriver with a sterile pen.

Caution: Under no circumstances should this marked point be exceeded when screwing in. As soon as it reaches the skin entry point, it marks the end of the drill channel. (The plug head of the Shark Screw® diver might breaks off when the end of the channel is reached. Or the Shark Screw® diver does not bridge the osteotomy gap equally because it is inserted too deep. Turning back the Shark Screw® diver is no longer possible due to the high selflocking effect!)

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Med. calcaneus osteotomy

Surgical technique with Shark Screw® diver



1. In the next step, the first Shark Screw® diver is inserted deep into the calcaneus without stopping. The Shark Screw® diver is inserted until it is of equal length in both the dorsal and ventral fragments of the calcaneus.

Attention: It should be possible to screw in the graft without resistance. If there is wedging or great resistance, the screw should be removed and tapping must be repeated. After irrigating/rinsing, the Shark Screw® can be inserted again.

2. Now all steps are repeated for the second Shark Screw® diver as described in step 5. (Replace the 1.6mm k-wire with 1.1 mm k-wire - Drilling - Tapping - Rinsing the channel - Screw in the Shark Screw® diver).



Axial check of the finished calcaneus osteotomy and the position of the bone screws. Finally, the laterally protruding osteotomy margin of the calcaneus is smoothed followed by wound closure. In case of a planned FDL transfer, repositioning of the patient

Postop protocol

For a few days, until consolidation of the swelling, split lower leg plaster in plantigrade position, then closed transtibial plaster in plantigrade position until 6 weeks postoperatively. 4 Weeks without weight bearing, the last two weeks in plaster with increasing weight bearing. 7th to 12th postoperative week upper ankle bandage to stabilize the ankle joint.



Case report of a Calcaneus osteotomy with Shark Screw® diver

X-Rays from left to right: lateral postoperative | lateral 10 weeks postoperative.







Case report of a Calcaneus osteotomy with Shark Screw® diver X-rays from left to right: lateral postoperative | lateral 8 months postoperative





Subtalar Joint Fusion Surgical technique with Shark Screw® diver



The skin incision starts 2cm dorsal to the tip of the malleolus lateralis and runs slightly curved 1cm caudal to the tip of the malleolus to the calcaneocuboid joint (CC). Dorsally, pay attention to the cutaneous nerve (sural nerve).



Dorsally of the lateral malleolus, the leading structure of the tendons of the musculi peronei longus et brevis is located. The Hohmann hook is placed ventrally to the tendons to secure them. Then the ligamentous structures of the lower ankle joint are cut with a scalpel or with scraping and pressing movements with a chisel. The joint space of the STJ is spread with a wide chisel, trying to position it transversely.



The three articular surfaces facies articularis posterior, medialis and anterior can be visualized if the ligament structures are released dorsal , in the sinus tarsi, ventrally, as well as medially.



Subtalar Joint Fusion Surgical technique with Shark Screw® diver

It is important to mobilize the joint space deep, medially between the sustentaculum tali and the talus with the chisel.



Only when the last ligament connections have been released the STJ can be spreaded wide enough (approx. 1.5 to 2 cm).



Now there is enough space to remove the cartilage with a curved chisel, a saw, or a sharp spoon. If a corrective osteotomy is necessary, this is carried out with the saw. Finally, the sclerotic bone is prepared with a 1.5 mm drill, leaving the drill dust on site.



Subtalar Joint Fusion Surgical technique with Shark Screw® diver



With the joint surfaces in view, three 1.6 mm Kwires are placed from the heel, perpendicular to the arthrodesis plane. Two K-wires are placed far apart from each other through the posterior joint surface. The third K-wire is placed through the anterior joint surface. If the STJ remains spread open during the placement of the three K-wires, the ideal position of the three K-wires can be determined clinically.



The three K-wires are retracted to the bone level of the joint surface, that the joint surfaces can easily be placed on top of each other. The joint surfaces can be placed on top of each other without any problems. Beforehand, DBM putty or other Allografts can be inserted, that the three articular surfaces of the talus and calcaneus lie completely flat on top of each other. Now the joint surfaces are placed under compression and the three 1.6 K-wires are further drilled into the talus. Fluorscopy is used to check the position of the K-wires.



Now the first 1.6 K-wire is replaced with a 1.1 mm K-wire, while the other two keep the position of the arthrodesis secure. The 1.1 K-wire is stepwise over drilled (blue-yellow-red-black) for the Shark Screw diver. Followed by tapping (black) Fluoroscopy is used to check the depth of the hole.



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Tominimize the fluoro time you can use a trick here: the arthrodesis gap is clearly visible from the outside. IThe drill can be places on the skin in the direction of the k wire, you can see how far you want to bridge the arthrodesis gap. You can read off the desired depth from the laser marking or mark it on the instrument with a surgical pen. As soon as this marking is reached at the skin entry during actual drilling or tapping, you have to stop.



Subtalar Joint Fusion





The insertion of the Shark Screw® diver graft is done as described in Fig10: The Shark Screw® diver is placed on the matching insertion device. The instrument with the graft is applied externally in direction of the drilled channel and the desired insertion depth is selected. The skin entry point is marked on the instrument with a surgical pin.



Now the Shark Screw® diver is screwed in with the screwdriver until the previously marked position on the instrument reaches the skin entry point. The bridging of the arthrodesis gap by the Shark Screw® diver should be achieved in approximately equal parts.



After the first Shark Screw® diver is inserted, the insertion instrument is removed in axial direction by pulling, without rotation. The insertion mechanism is strict and firm! The second and the third Shark Screw® are applied in the same way.

Postoperative treatment of a Subtalar Joint Fusion with Shark Screw®

Split lower leg plaster cast for the first few days, then a closed lower leg plaster cast is applied for 10 weeks. 6 weeks without weight bearing, the last 4 weeks with increasing weight bearing.





Case report of a triple arthrodesis with Shark Screw® diver X-ray images from left to right: lateral preoperative | ap 8 weeks | lateral 8 weeks.



Case report of a triple arthrodesis with Shark Screw $\ensuremath{\mathbb{R}}$ diver

X-rays from left to right: 5 months ap | 5 months lateral | 1 year lateral



Case report of a Talus Fracture

Case report of a 24-year-old female patient which fell off her skateboard and sustained a dislocation fracture of the talus. This happened to her whilst being abroad. She received a split lower leg cast there. Due to these delays, the operation was performed two weeks after the trauma. The risk of suffering a talus head necrosis was high.



During the surgery, the bone fragments were repositioned and fixed with two Shark Screw® diver 5.0mm x 35mm. Postoperative lower leg plaster cast for 8 weeks. The first 6 weeks without weight bearing, two more weeks of increasing weight bearing in a plaster cast under physiotherapeutic care.





The further radiographs show 3 months and 10 months postoperatively. The talus fracture is healed, and no necrosis has occurred. The patient is pain free. X-Rays from left to right: 3 months postoperative ap 3 months postoperative lateral 10 months postoperative oblique | 10 months postoperative lateral

Malleolus lateralis Fracture



Case report with Shark Screw®



Malleolus Medialis Osteotomy





Case report of a Malleolus Medialis Osteotomy

Due to an osteochondral defect with deep necrosis and free joint body at the medial talus shoulder, a medial malleolus osteotomy must be performed. This makes it possible to visualize the defect and cover it with the help of a mosaicplasty. X-ray images from left to right: preoperative ap | postoperative ap



Case report of a mediale Malleolus osteotomy X-rays from left to right: 7 months postoperatively ap and lateral
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IMPORTANT!

The description of the surgical techniques in this script shows examples of use and serves as a teaching aid for clinical support in the use of Shark Screw® grafts. The teaching material alone is not a substitute for practical training. The use of the grafts, the surgical procedure, and the procedure as well as the follow-up treatment depend on the patient and should be individually determined for each individual. In doing so, the physician must act after careful examination of the relevant medical literature, according to his/her training, experience and the general health condition of the patient(s).

VIS YOUR SHARK SCREW® STORY...