

Instructions for use

Intended use

INTELLIGENT ORTHOPAEDICS instruments consist of manual surgical instruments and devices intended for use in surgical procedures.

This instrument is a Class 2 single use medical device for the treatment of fractures of the tibia.

Instrument utilisation is determined by the user's experience and training in surgical procedures. Do not use this instrument for any purpose outside the intended use of the device, as it may seriously affect the safety and function of the product.

CAUTION: Handle devices with care to prevent damage to surgical gloves.

Recommendations for care, cleaning and sterilisation

INTELLIGENT ORTHOPAEDICS recommends that the cleaning and decontamination of instruments and devices follow the guidelines set forth by MHRA, AORN/HIMA and AAMI. Both physical and chemical (detergent) processes are necessary to minimise the bioburden on all soiled items. Chemical (detergent) cleaners alone cannot remove all soil and debris therefore a careful manual cleaning of each item with soft sponge or cloth is essential for maximum decontamination. Carefully inspect hidden areas, such as recesses, to assure any residual materials are removed.

Once the items have been cleaned and decontaminated they should be thoroughly rinsed with clean water to remove any detergent or chemical residue before sterilisation. The use of mild enzymatic detergent with a low pH is recommended.

Materials used in INTELLIGENT ORTHOPAEDICS devices can be sterilised using steam sterilisation methods. MHRA, AORN/HIMA and AAMI guidelines for sizes, weights and mass should be followed. The device has been certified sterilisable using a Porous Load 134-137°C/3 minute cycle.

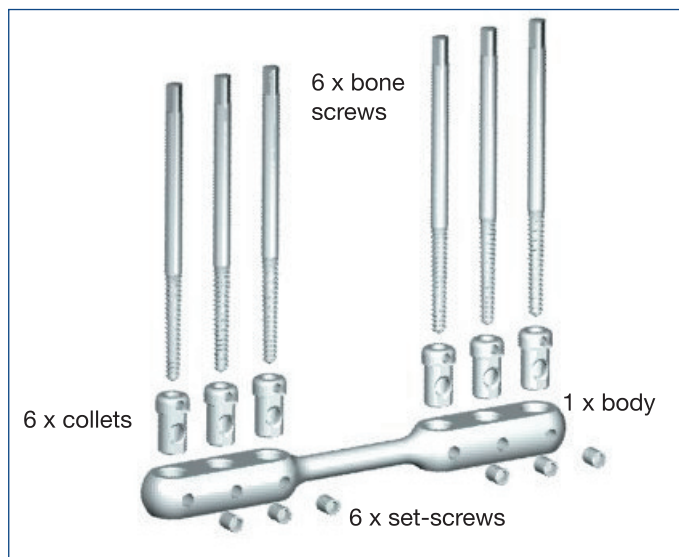
1. After sterilisation all instruments should be allowed to cool. The time of cooling is dependent on the load size and mass. Place instruments on a rack or shelf with linen cover until cooling is complete. The potential for condensation may increase if the case is not allowed to cool properly.

CAUTION: Hot instruments should not be handled or used as they can cause injury.

2. If condensation is observed check to ensure that cooling, as described in 1. above, has been followed. Verify that the steam being used for the sterilisation process has a quality of more than 97%. Also confirm that the sterilisers have been inspected for routine maintenance in accordance with manufacturer's recommendations.
3. Suggested steam exposure times: (ref: HTM2010 Part 3)
Preferred: 134-137° C / 3 minutes
Alternatives: 126-129° C / 10 minutes
121-124° C / 15 minutes
115-118° C / 30 minutes

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Description

The IOS fixator is a single-use disposable external fixator designed for the treatment of unstable tibial shaft fractures. It is available in two sizes that accommodate most tibial fractures suitable for monolateral external fixation. The IOS fixator has been designed so that the elasticity of the fixator bar allows a specific amount of cyclical movement on weight bearing to promote the growth of healing callus.

IOS fixator short: designed for fracture lengths of less than 44mm

IOS fixator long: designed for fracture lengths of between 44mm and 84mm

The IOS fixator is supplied as an operating kit and comes with:

- 1 x IOS fixator (long or short)
- 6 x set-screws
- 6 x collets external diameter 10mm, internal diameter 6mm
- 6 x bone-screws, overall length 100mm, thread length 40mm, tapered 6mm to 5mm
- 1 x 4.8mm bone drill

All items are single-use only.

Materials

The IOS fixator is made of titanium alloy. All other parts and instruments are of stainless steel.

Indication

The IOS fixator is intended for use in the treatment of unstable fractures of the tibial diaphysis measuring 84mm or less from the proximal to the distal extent.

Contraindications

Whilst the decision to use the IOS fixator must lie with the individual surgeon, the use of external fixation is not recommended for stable tibial shaft fractures that could be treated in a plaster cast.

If the tibia is very osteopaenic the bone-screws may not hold adequately.

Some patients may not be able to care for their bone-screw sites, increasing the risk of infection and consequent bone-screw loosening.

A long oblique fracture of greater than 84mm in length will not be suitable for treatment even with the long IOS fixator.

Weight-bearing

The fixator has been designed to allow enough movement at the fracture site to promote the growth of healing callus^{1,2}. This movement is dependent upon the patient's activity. All patients should be encouraged to take full weight on the limb and to walk as much as possible. It should be explained to them that walking fully weight-bearing is beneficial to healing and that this activity gives them some control over the speed of their recovery.

Bone-screw site care

The success of treatment with any external fixator depends on preserving the interface between the bone-screws and the bone. Loosening of bone-screws is usually due to infection and this, in turn, is often the result of poor bone-screw site hygiene. It is important that the surgeon and the care team provide all patients with information and guidance to ensure that they understand this important issue. A bone-screw site care guide has been prepared and maybe downloaded from www.intelligent-orthopaedics.co.uk

Smoking & non-steroidal anti-inflammatory drugs

Both of these have been shown to prolong the healing time of tibial fractures^{3,4}. Smokers should be strongly advised to stop. Non-steroidal anti-inflammatory drugs should be avoided.

Surgical Technique

IOS fixator tool kit

Before each operation begins make sure that you have access to a complete sterile IOS fixator tool kit. Each kit comprises: one 3mm hex-key (L-shaped bar with 3mm hexagonal ends), one T-handled wrench for the tri-drive bone-screws, three 4.8mm drill guides, and a 4.8mm trocar.

Important Points

1. Once the IOS fixator bone-screws are inserted there is no facility to improve a poor reduction. A good reduction must be achieved, and held, before the IOS fixator is applied. We recommend achieving and holding the reduction using STORM (The Staffordshire Orthopaedic Reduction Machine)⁵ before the holes are drilled for the IOS fixator bone-screws.

2. To hold the reduced position securely we recommend that the STORM translation arms always be used, even when traction and correction of torsion have already produced a good reduction. The fracture often looks adequately reduced after traction and torsion have been optimised: but if the translation arms are not used, the reduction can be lost due to the force that must be applied when drilling the holes for the IOS fixator bone-screws. Unopposed, this force tends to push the bone fragments away from the drill, and this can result in the proximal and distal sets of bone-screws ending up divergent as the tibia springs back to the reduced position after drilling.

3. Before beginning to drill the 4.8mm holes for the IOS fixator bone-screws ensure that the fracture is not over-distracted.

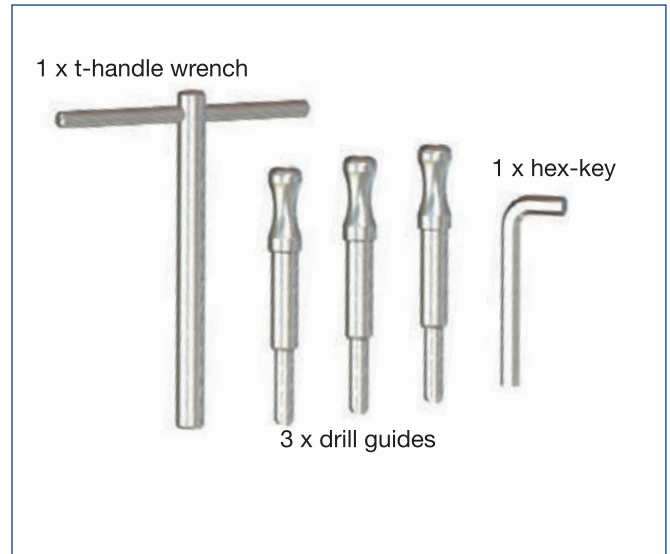
4. In closed fractures there must be at least a 10mm clearance from the fracture to the nearest bone-screw. If in doubt, use the longer IOS fixator.

5. In compound fractures the bone-screws must be clear of the wound or zone of injury.

6. Make sure to move the IOS fixator up to the outer ends of the bone-screws at the end of the procedure. The IOS fixator has been designed to work with an offset of 60mm between the longitudinal axes of the tibia and the fixator: this configuration optimises the bending movement of the fixator for fracture site movement. The IOS fixator should be moved out on the bone-screws until only the tri-drive portion of each bone-screw is visible above the collet.

7. Always position the IOS fixator so that its longitudinal centre and the longitudinal centre of the fracture are coincident. This epicentric positioning of the fixator creates the best mechanical situation for fracture healing.

8. Before starting the operation ensure that you have access to a sterile IOS fixator tool kit consisting of a 3mm hex-key, a tri-drive T-wrench, the three IOS fixator drill guides and a 4.8mm trocar.



9. Make sure that each of the collets is correctly orientated before tightening the set-screws. Each set-screw goes into the side of the collet marked by the hole in its collar.

10. The IOS fixator is designed to be a single-use device. The mechanical properties and operating characteristics are unpredictable for multiple use.

11. At the end of the procedure, check all six IOS fixator set-screws again: they must be as tight as can be achieved manually with the long end of the 3mm hex-key (the short end being in the set-screw). If under-tightened, the set-screws may come loose later. Tighten each set-screw with as much force as you can apply with fingers and thumb.

Operative technique

The IOS fixator must only be applied to the tibia once the fracture has been perfectly reduced and held firmly in that reduced position: a good reduction is crucial to successful fracture treatment with the IOS fixator.

Whilst other reduction techniques could be used, we recommend using the STORM reduction device. The technique for using the STORM can be found at www.intelligent-orthopaedics.co.uk.

Remember that with the IOS fixator, unlike with some other fixation systems, no further adjustment of reduction is possible once the fixator bone-screws have been inserted.

Each bone-screw has a shank diameter of 6mm and a thread that tapers down from this to an outside diameter of 5mm at the tip. The bone-screws are inserted into the subcutaneous (antero-medial) surface of the tibia. Three screws are placed in the proximal fragment and three in the distal. The IOS fixator is used as its own template for drilling the holes and inserting the screws.

For descriptive purposes, the bone-screws are numbered 1 to 6 from the most proximal to the most distal. The proximal group of three are therefore numbered 1, 2 and 3. The distal group of three are numbered 4, 5 and 6.

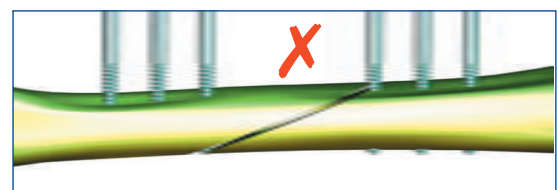
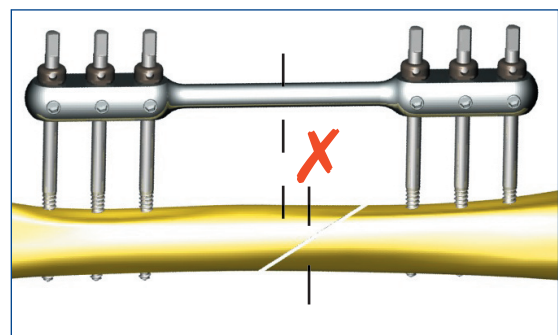
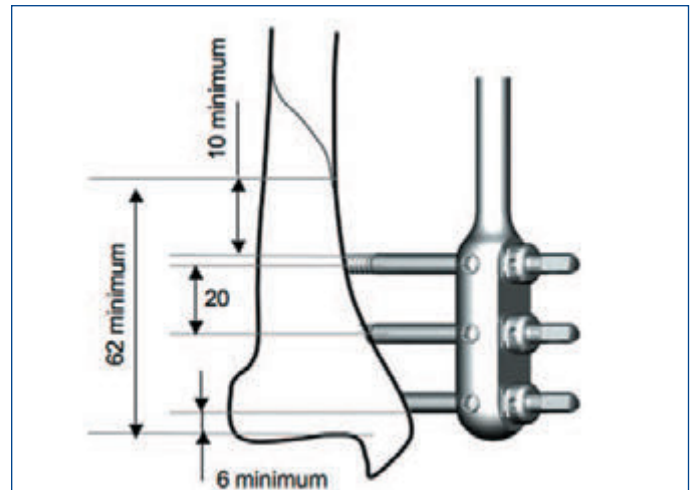
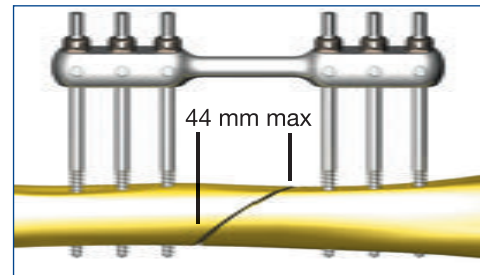
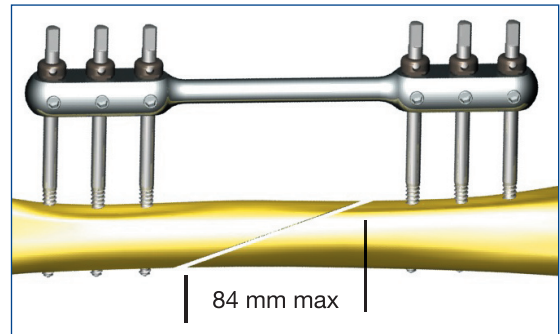
Positioning of the fixator

The decision about which of the two lengths of IOS fixator to use should be made during the pre-operative planning. The shorter fixator should be used whenever possible. This will be when the fracture is transverse or short oblique. The edge of the nearest bone-screw should be no closer than 10mm to any part of the fracture. The longer IOS fixator will need to be used to maintain a distance of at least 10mm from the fracture to a bone-screw in longer, or more oblique, fractures.

In a cohort of 100 consecutive tibial shaft fractures⁶, 97% fitted between bone-screws 3 and 4 (with at least a 10 mm clearance) in the long IOS fixator, and 50% fitted within the short IOS fixator. The 3% of tibial shaft fractures too long to fit into the long IOS fixator are not suitable for treatment with monolateral external fixation.

The IOS fixator should be positioned so that the centre of the fracture is as close as possible to the longitudinal centre of the fixator (equidistant between bone-screws 3 and 4). In a distal tibial fracture the fixator will be positioned so that bone-screw 6 is close to the subchondral bone of the distal tibial articular surface.

Bone-screw 6 can be close to the tibial plafond, but we recommend that it be separated from it by at least one screw diameter on the mortice view of the ankle joint. The distance between the outer edges of bone-screws 4 and 6 is 46mm. As the minimum recommended distance from bone-screw 6 to the plafond is 6mm, and the minimum recommended distance from bone-screw 4 to the fracture is 10mm, the most distal extent of the fracture has to be at least 62mm away from the distal articular surface of the tibia for the IOS fixator to be used.



Magnification in digital or plate x-rays images must be taken into account when planning.

The IOS fixator is its own drilling jig, enabling the six bone-screws to be positioned accurately. The fixator should be positioned over the tibia so that all six bone-screws will enter the antero-medial surface, engage both cortices, and cross the medulla as close as possible to its cross-sectional centre. Because the normal tibia is not perfectly straight, the optimum positioning of all six screws requires care.

The position of the subcutaneous surface of the tibia can usually be found by palpation. If it cannot be palpated because of swelling or fat, its edges can be found by using a fine hypodermic needle: the edges are then marked on the skin.

The position and extent of the fracture should be marked on the skin with the help of the image intensifier. This marking should be done after the fracture has been reduced, thus avoiding errors produced by further reduction altering the relative positions of the fracture and the skin. The planned position of the bone-screws should be marked on the skin using the six holes in the fixator as a template. Bone-screws 3 and 4 should be equidistant from the fracture.

Preparation for drilling

Make one final check that the STORM translation arms are attached properly and that the fracture is perfectly reduced.

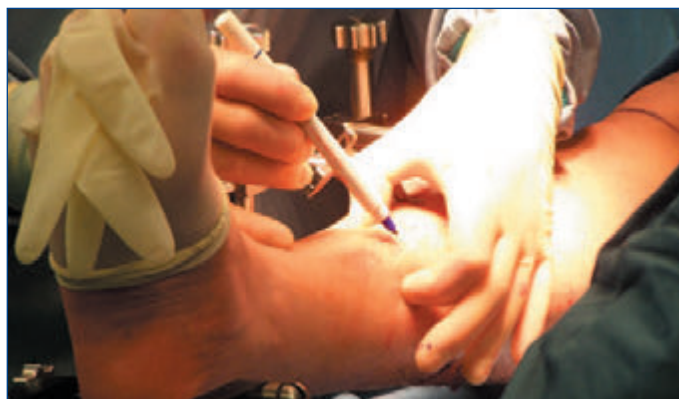
Do not attempt to drill the IOS fixator bone-screw holes unless the translation arms are in place: without them the force exerted against the tibia by the drill will displace the fracture.

Six skin incisions are made at the positions marked. The skin incisions should be 10 mm long and at 45° to the long axis of the tibia.

The incisions are deepened to bone by blunt dissection with a small curved haemostat.

Preparation of the IOS fixator

1. Check that each of the six threaded holes contains a set-screw and that none of the tips of the set-screws are protruding into the 10mm collet hole.
2. The drill guides have a 10mm outside diameter to fit the collet hole in the IOS fixator and an internal diameter to take the 4.8mm drill.
3. Take two drill guides and insert them fully into collet holes 1 and 6 of the IOS fixator. Do not force the guides: if they do not slide in easily check again that a set-screw is not protruding.
4. Each drill guide should be rotated so that the axis of the two sharp tines at the tip is at right angles to the long axis of the tibia. This helps to prevent the tip of the guides from slipping on the bone.
5. The two drill guides should be held in place by gently tightening their set-screws. Don't over tighten them as this can damage the drill guides.
6. Position the fixator on the bone surface by inserting the tip



of each of the drill guides into the corresponding incisions. The tips of both drill guides are pushed against the bone and held perpendicular to the subcutaneous surface of the tibia. A trocar should be used to feel that there is no interposed soft tissue and that each guide is nicely in contact with the bone. An assistant holds the fixator with its guides in position. To bring the fixator parallel to the long axis of the tibia, and ensure that bone-screw 6 is parallel to the articular surface of the ankle joint, loosen set-screw 6 and slide the distal end of the IOS fixator down on the guide. This adjustment is necessary for the most distal fractures but unnecessary for midshaft fractures. After the adjustment set-screw 6 is re-tightened.

Drilling the first screw hole

1. We recommend that you use a new drill for each case to minimise the risk of thermal necrosis. The bone-screw thread has a depth of 1mm so if only 1mm of bone in the wall of the hole dies, then the bone-screw will come loose before the fracture has healed. Careful drilling technique is important.

2. If the fracture is distal, the hole for bone-screw 6 should be drilled first. This is to ensure that the bone-screw closest to the subchondral bone of the distal articular surface of the tibia is placed at an optimum distance from it. For fractures further from the ankle joint it is still best to begin with the hole for bone-screw 6 followed by the hole for bone-screw 1.

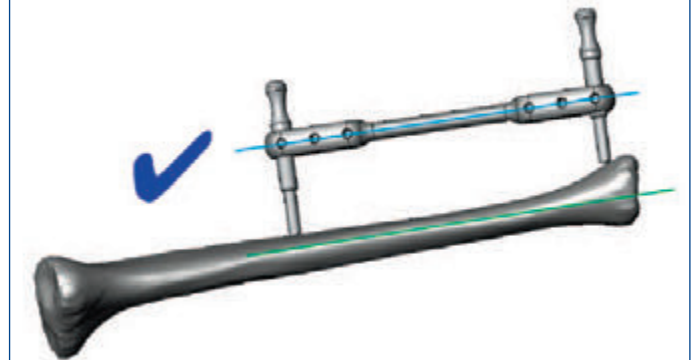
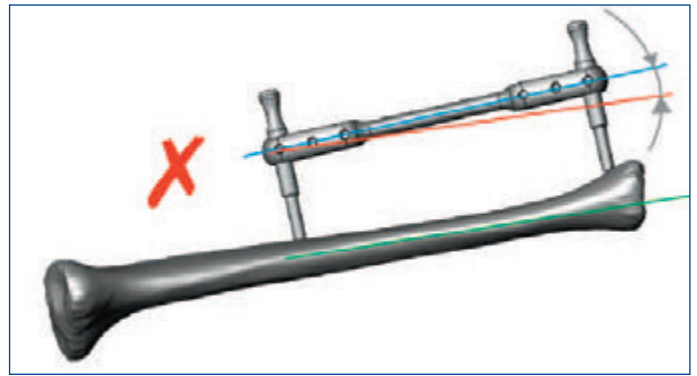
3. Drill a 4.8mm hole through the first cortex using the drill guide. Take care to keep both drill guides in contact with the bone as this will keep the IOS fixator aligned with the long axis of the tibia. After drilling the first cortex the drill is withdrawn, still running, to bring bone swarf out of the hole and guide. This is important because any bone swarf left in the hole or the soft tissues is a potential tiny sequestrum which would tend to support infection later. The scrub practitioner has a small gauze swab soaked in cold saline with which the drill is cooled and cleaned of all bone swarf. Saline is squirted down the guide from a 10ml syringe. The second cortex is drilled in the same way. Be careful not to overshoot into the soft tissues beyond the bone.

4. Never reverse the drill. This can drive bone swarf back down the hole and jam the drill bit.

First screw insertion

1. Once the first hole (usually hole 6) has been drilled, the third drill guide is placed in the next collet hole (in this case, hole 5) to stabilise the fixator while bone-screw 6 is inserted. When this third guide is in contact with the bone its set-screw is lightly tightened. The tips of all three guides should now be in contact with the surface of the tibia.

2. The drill guide is now removed from collet hole 6 by loosening its set-screw. The fixator is now stabilised against the bone by the assistant keeping the tips of screw guides 5 and 1 against the bone surface. A collet is then placed in collet hole 6 making sure that its side-hole is in register with the set-screw. The 6mm bone-screw is then inserted through the collet and into the hole drilled in the tibia. It is screwed in using the T-handled driver.



When it is fully inserted its set-screw is tightened, locking the bone-screw to the IOS fixator. Before tightening, check that the small hole in the top of the collet is lined up with the set-screw. The position of the collet can be adjusted by inserting the 3mm hex-key into the small hole.

Drilling and insertion of second screw

Using the guide already in place, now drill hole 1. The drill guide already removed from hole 6 is moved to collet hole 2 to stabilise the fixator. Remove the drill guide in collet hole 1. Insert the collet followed by bone-screw 1 and tighten the set-screw.

Insertion of remaining screws

Once bone-screws 1 and 6 are in place, clamped by their corresponding set-screws, the IOS fixator is held firmly in position and the other four bone-screws can be inserted sequentially. Insert screws 4 and 3, and then insert screws 2 and 5.

Always tighten the set-screws onto the drill guides and screws as each is inserted. This ensures that all the holes for the bone-screws are drilled properly parallel to each other and in perfect register with the holes in the IOS fixator.

During this stage in the procedure it is only necessary to tighten the set screws lightly, as they will need to be loosened again for the final adjustments.

Tightening the fixator bone-screws

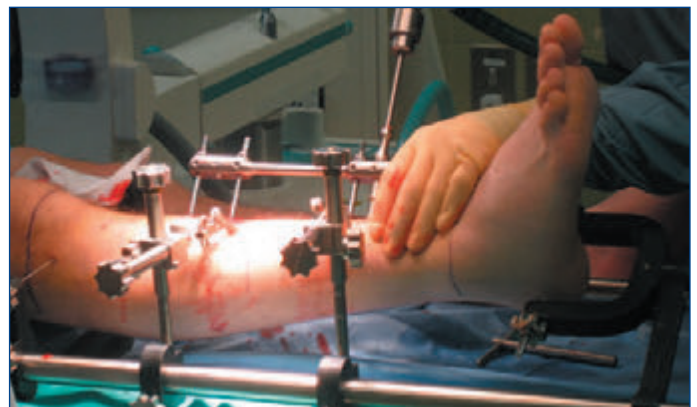
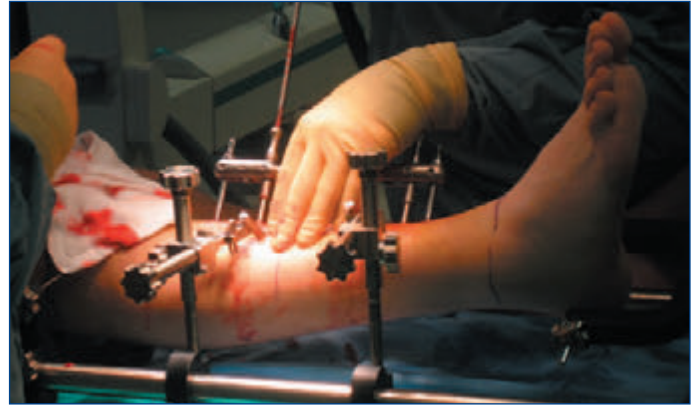
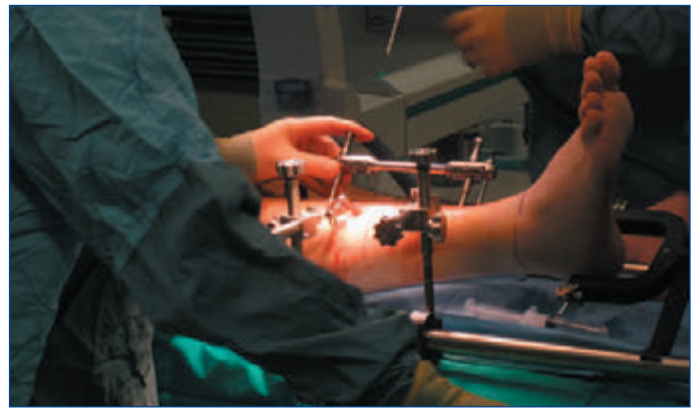
Because they are tapered, the bone-screws tighten as they are inserted. As a bone-screw becomes tighter it exerts an increasing turning moment on the bone fragment into which it is being inserted: the first bone-screw in each fragment therefore has the potential to displace the position of its fragment as it is tightened. To minimise this effect, the first screw (usually 6 or 1) can be left partially inserted while the second screw (usually 4 or 3) is partially inserted into the same fragment. Both screws may then be progressively tightened, each preventing the other from producing any twisting of the bone fragment.

Because the bone-screws are tapered they must not be backed off or unscrewed as this will result in loss of grip. Checking with the x-ray image intensifier, each screw is inserted until the tip protrudes one thread width beyond the far cortex. The correct depth is generally reached when the threaded portion of the bone-screw has just gone below the level of the skin.

Fixator locking

1. Once the depth of all the screws has been optimised in the bone, the final position of the IOS fixator on the screw shanks can be adjusted. All six set-screws are loosened just enough to allow the IOS fixator to be moved up or down the screw shanks. The IOS fixator should be positioned so that only the tri-drive part of the screw protrudes above the upper surface of the collet. The range of diameters of the tibia is small and the length of the bone-screws has been determined to ensure the correct offset of the IOS fixator from the centre of the bone: this distance is set to produce the optimum bending movement of the fixator on weight-bearing.

2. The set-screws are all fully tightened using the 3mm hex-key



provided. The short end of the key is engaged in the set-screw. The set-screw is tightened with as much force as can be applied to the long end of the hex-key using fingers and thumb. With this technique the set-screw cannot be over-tightened. Make sure that all the set-screws are fully tight to prevent loosening later.

Check that all the set-screws are flush with the surface of the IOS fixator. A set-screw will protrude if not tightened properly or if tightened against the wrong side of the collet. If a set-screw is found protruding, first check that the small indicator hole in the top of the collet is in line with the set-screw. Then check that the set-screw is fully tight.

Wound dressing

The bone-screw wounds are now thoroughly irrigated with saline in a syringe. A MacDonald's dissector is used to help to loosen and remove any remaining bone swarf. The bone-screw wounds are dressed with paraffin gauze held in place with expanded foam "marshmallows" previously soaked in Chlorhexidine aqueous solution and squeezed dry.

Removal of Reduction Device

The fracture is now stabilised and STORM (or any other similar reduction device) may be removed.

Post-operative Care

The limb is elevated for the rest of the day of surgery. The following morning the patient may get up with crutches. The physiotherapist should encourage the patient to take full weight through the injured limb. Patients can be reassured by explaining that the IOS fixator has been tested to one million cycles of loading at 200kg, and that it is therefore easily capable of taking their full weight.

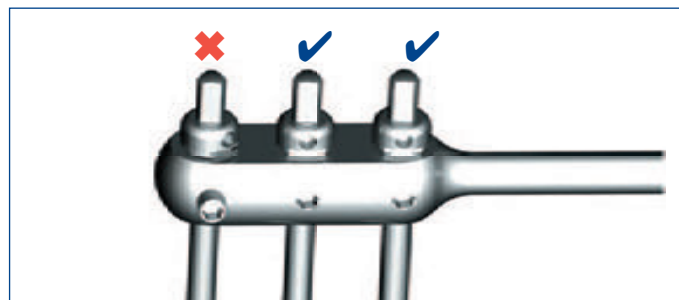
Patients may often be discharged from hospital the day after surgery. They should be told to fully weight-bear and when not walking to rest with the leg elevated above the level of the heart.

They should be encouraged to walk as much as possible and it should be explained to them that this will help to promote the growth of healing callus^{1,2}.

At one week they will be seen in the clinic where the dressings are removed from the bone-screw sites. They are given instructions on how to look after their bone-screw sites. A sheet of these instructions may be printed from www.intelligent-orthopaedics.co.uk

An x-ray may be taken at this visit to document the position and reduction of the fracture. Thereafter x-rays may be considered unnecessary except if there is concern about loss of reduction which can only occur with extreme bone-screw loosening. If the bone-screws show no evidence of infection then it is unlikely that they are loose.

Most patients are then seen at six weekly intervals. The treating surgeon may choose to do an x-ray at each visit to monitor the growth of callus, but the decision about when the fracture is



healed is best made on clinical grounds by the assessment of fracture stiffness.

When to remove the IOS fixator

It has been shown that x-rays alone give a poor indication of when a tibial fracture has just healed⁷. The measurement of fracture stiffness has been shown to be a reliable guide as to when to remove an external fixator from the tibia^{8, 9}.

While the precise measurement of tibial fracture stiffness requires specialised equipment^{10, 11, 8, 9} observations of patients at the University Hospital of North Staffordshire have enabled us to build a simple method of fracture stiffness assessment into the IOS fixator.

It has been found that when the stiffness of a healing tibial shaft fracture reaches 15Nm/deg (the accepted safe stiffness for fixator removal^{8, 9}) it is no longer possible to bend the tibia more than 1° by manual application of a bending force⁶.

Bending of 1° will produce 1.3mm of displacement 75mm from the fracture and 1.6mm of displacement 95mm from the fracture. If the bending centre of the fracture is equidistant from bone-screws 3 and 4, it will be 75mm from the centre of bone-screw 1 in the short IOS fixator and 95mm from bone-screw 1 in the long IOS fixator.

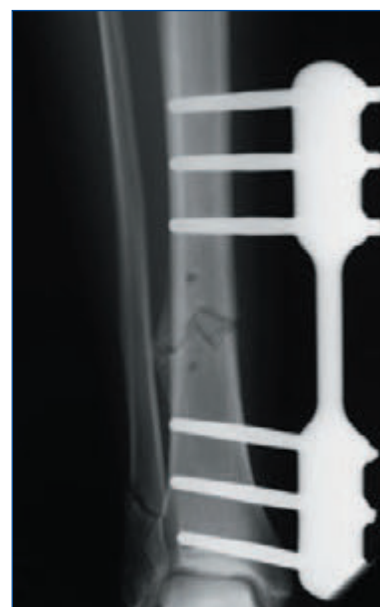
The bone-screw shank is 6mm in diameter and the collet hole in the IOS fixator is 10mm in diameter. When a collet is removed there is a 2mm gap between the bone-screw shank and the collet hole. Relative movement of 2mm between the bone-screw shank and the collet hole indicates more than 1° of bending at the fracture.

The assessment is done by removing the proximal three collets (from holes 1, 2 and 3) in the clinic. The examining surgeon then manually applies a bending force to the tibia. The test is not painful. If the largest applied force does not cause the bone-screw shanks to touch the edge of the collet holes, then it is likely that the stiffness of the fracture is above 15Nm/deg. We have correlated this manual manipulation test against formal fracture stiffness tests and have found it to be reliable⁶. A further test may be performed in which the three proximal collets are left out and the patient instructed to take full weight on that leg. Again, the bone-screw shanks should not touch the edges of the IOS fixator collet holes if the fracture is healed.

If a bone-screw shank touches the edge of a collet hole on any of these tests then the collets should be re-inserted and the set-screws re-tightened. A further assessment may then be made between 2 and 4 weeks later.

For these tests to work properly it is vital that the bone-screw shanks are all perfectly concentric with the IOS fixator collet holes. This can be achieved by careful following the operative technique described.

These tests may be used as a guide, but the treating surgeon-



must use any other information that he chooses to make a final decision about when it is safe to remove the IOS fixator. It may, for instance, be considered prudent to leave the fixator on longer if the patient is unusually heavy, unreliable or irresponsible.

When it is decided that it is safe to remove the IOS fixator, the rest of the set-screws are loosened to allow removal of the rest of the collets.

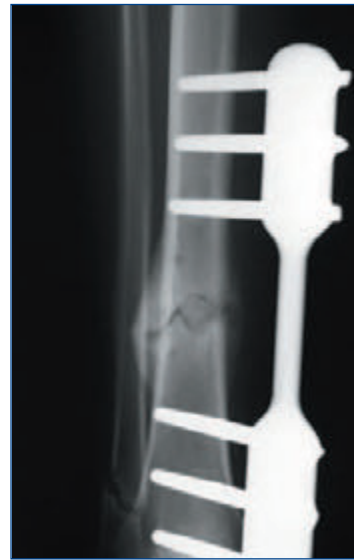
If a collet is difficult to remove there are two features which may help. Firstly, the reference hole in the side of the collar of the collet accepts the end of the 3mm hex-drive. The hex-drive can be used as a lever to rotate the collet. Secondly, there is a slot cut in the collar of the collet immediately below the indicator hole into which the tip of a screwdriver may be inserted. Rotation and leverage may then be used together to remove the collet.

Once all the collets have been removed, the fixator is lifted clear of the bone-screws which are then removed using the tri-drive T-handle. Most patients say that removal of the bone-screws in the clinic feels strange. Some describe pain or discomfort.

The bone-screw holes are dressed. They are usually healed with dry scabs after 1 week.

If the fixator is removed using the stiffness assessment tests for the end-point, it should be explained to the patient that the stiffness of a normal tibia is around 60Nm/deg and that at 15Nm/deg their tibia is only at a quarter of its full strength. They are therefore instructed to be careful initially. We recommend walking with crutches for the first two weeks after which an x-ray is done. If this shows no change in the reduced position of the tibia then the patient is allowed to build up to full weight-bearing. They are told that they can walk as far as they like but that they should not run on even ground for at least 4 months or uneven ground for at least 6 months. They are allowed to return to light or sedentary work (some will have returned to work with the fixator still on) but are not allowed to do any heavy lifting for at least 4 months. Contact sports are not allowed for at least 8 months. These periods are based on assumptions about the continuing rate of increase in fracture stiffness after removal of the fixator, and are for guidance only. It is the responsibility of the treating surgeon to decide when these activities may be resumed in a particular patient.

The average healing time for closed or grade 1 compound tibial fractures treated with the IOS fixator was 16 weeks. The shortest healing time was 9 1/2 weeks⁹.



Possible adverse effects

Possible adverse effects common to all external fixation devices are:-

1. Bone-screw loosening
2. Bone-screw site infection
3. Bone necrosis due to poor drilling technique leading to early bone-screw loosening.
4. Bone-screw bending or breakage due to over-stressing
5. Foreign body reaction to a bone-screw
6. Improper reduction of the fracture fragments
7. Re-fracture through bone-screw holes.
8. Pressure on the skin surrounding the bone-screw sites due to improper dressing application.
9. Refracture due to removing the fixator too early.
10. Non-union due to biological factors set at the time of injury or later.
11. Problems due to non-compliance of patient.

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