NICE advice

Galaxy UNYCO for temporary stabilisation of lower limb fractures

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is Galaxy UNYCO. It is a single-use device used for temporary stabilisation of lower limb fractures of the femur, tibia, ankle and foot.
- The **innovative aspects** are that Galaxy UNYCO is claimed to be less invasive than other external fixation devices. This is designed to reduce procedure time and the risk of deep bone infection.
- The intended **place in therapy** would be in place of current external fixation devices for people with complex lower limb fractures needing temporary stabilisation. This is likely to be a clinically rare scenario in current NHS practice.
- The **main points from the evidence** summarised in this briefing are from 5 studies (including a total of 13 adults) in a hospital setting (in France, Germany, Italy and Switzerland), 4 case studies and 1 observational study, only 1 of which has been published in a peer-reviewed journal. The studies suggest that Galaxy UNYCO can provide effective temporary fixation for tibial and ankle fractures.
- **Key uncertainties** around the low quantity of evidence are that there is no direct comparative evidence to determine if patient outcomes would be different to those having other forms of fixation, such as bicortical fixation.
- The **cost** of Galaxy UNYCO is £1,600 to £2,000 per unit. The cost of standard external fixation (reusable) is about £2,400. The **resource impact** would be an increase in costs compared with

- standard care.

The technology

The Galaxy UNYCO (Orthofix) is a single-use, modular bar-clamp, external fixation system. It is designed for temporary stabilisation of complex lower limb fractures of the femur, tibia, ankle and foot, including peri-articular fractures, in trauma procedures before definitive treatment.

Screws are drilled into the near cortex only and stay anchored because of the design of the screw tips, which are conical shaped, self-drilling and self-tapping. As the screw tip is inserted into the near cortex, radial preload exerts radial pressure on the cortex, holding the screws in place. A torque limiter supplied with the system makes sure screws are inserted into the near cortex only and do not enter the medullary canal. The fixation is made stable by using the specific large multiscrew clamp for UNYCO screws with 4 UNYCO screws in the same bone fragment.

Galaxy UNYCO is supplied as a sterile, single-use system and the key components include UNYCO screws (designed for diaphyseal bone), UNYCO cancellous screws (designed for metaphyseal bone), UNYCO cancellous screws long (designed for both femoral diaphyseal and metaphyseal area), a large multiscrew clamp for the standard cancellous screws (tibia clamp) and one for the long screws (femur clamp), a 400 mm carbon rod (12 mm diameter), a 350 mm carbon rod (12 mm diameter), a radiolucent hinged foot unit and the power drill torque limiter. The long cancellous screws and the multiscrew clamp for UNYCO cancellous screws long are used for femur fixation. The standard cancellous screws and the related multiscrew clamp can be used for fixing the tibia, foot or ankle.

Innovations

The potential innovation is that the Galaxy UNYCO system is less invasive than other external fixation devices, because it is anchored into the near cortex of the person's bone and the screws do not penetrate the medullary canal or the far cortex of the bone on the opposite side. Instead, the screws are inserted using a torque limiter power drill and are clustered using a dedicated multiscrew clamp to provide stability. The company claims that this will reduce procedure time and the risk of deep bone infection compared with standard care.

Current care pathway

An external fixator is used in 2 main instances: as damage control in patients who are too ill to have definitive treatment and in whom rapid stabilisation of the fracture is needed; and as a treatment option in open fractures with severe soft tissue injury.

NICE's guideline on complex fractures does not give specific guidance on the type of stabilisation or fixation to use (external or internal) for open and pilon fractures. The British Orthopaedic Association's audit standards for ankle trauma (BOAST 12: management of ankle fractures) state that early fixation (on the day or day after injury) is recommended in most patients under 60 years when the ankle mortise is unstable. The use of external fixation may be indicated in the presence of gross instability associated with soft tissue compromise (with or without a fracture), but specialist commentators stated that this type of injury is quite rare.

The British Orthopaedic Association's audit standards for the management of severe open lower limb fractures recommend that centres that cannot provide combined plastic and orthopaedic surgical care for severe open tibial fractures have protocols in place for the early transfer of the patient to an appropriate specialist centre. The primary surgical treatment (wound excision and fracture stabilisation) of severe open tibial fractures should only take place in a non-specialist centre if the patient cannot be transferred safely. The wound, soft tissue and bone excision (debridement) should be done by senior plastic and orthopaedic surgeons. They should work together on scheduled trauma operating lists within normal working hours and within 24 hours of the injury unless there is marine, agricultural or sewage contamination. The 6-hour rule (to prevent infection, open fractures should be fully managed within a 6-hour time frame) does not apply for solitary open fractures.

Population, setting and intended user

The Galaxy UNYCO is designed to be used in secondary and tertiary care for both adults and children with lower limb fractures of the femur, tibia, ankle or foot who need temporary stabilisation with an external fixator, and who are likely to be managed in a major trauma centre. Temporary fixation could be a treatment option for patients being transferred to specialist treatment centres for primary surgical treatment (wound excision and fracture stabilisation) of severe open tibial fractures. Specialist commentators have stated that this is likely to be a clinically rare scenario in current NHS practice. When converting to definitive fixation, the Galaxy UNYCO device can be left in place, holding the bone ends in alignment while definitive fixation with a nail or plate is done.

Training is offered by the company during the adoption phase and, according to the company, no advanced surgical training is needed.

Costs

Technology costs

According to the company, the cost of the Galaxy UNYCO system is about £1,600 to £2,000 and it may be procured under NHS England's high-cost tariff-excluded devices scheme. Galaxy UNYCO is a single-use device.

Costs of standard care

According to the company, the cost of standard external fixation is about £2,400. Most of the equipment used for standard external fixation is reusable.

Resource consequences

Galaxy UNYCO would represent an additional cost compared with standard care. There is no evidence to judge the likelihood of claimed potential savings from a reduction in theatre time, the number of X-rays needed to place the system when compared with bicortical systems or a reduction in infection risk.

Galaxy UNYCO is compatible with the TL-HEX system and can be used in computer hexapod-assisted orthopaedic surgery.

The Galaxy UNYCO system is currently used in 4 NHS hospitals, 1 of which is a major trauma centre. The company states that it is included in NHS England's high-cost tariff-excluded devices scheme.

Regulatory information

The Galaxy UNYCO system was CE marked as a class IIb device in May 2014.

A field safety notice for this technology was issued in May 2015. The field safety notice was a precautionary measure to avoid potentially defective power drill torque limiters for batch number V1375371 (product code 99-93506). Hospitals were required to return any defective power drill torque limiters. The company has stated that this has been fully resolved and the incident has been closed by the Medicines and Healthcare products Regulatory Agency (MHRA). No patients or users were subject to any adverse incidents or outcomes. In June 2017, a second field safety notice was issued (FSCA201701) for the same reason.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

No equality issues were identified.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

This briefing summarises 5 studies. The studies include a total of 13 people. One of these studies has been published in a peer-reviewed journal (Lavini et al. 2017). One study is in abstract form. Moerenhout and Borens (2016) was presented at the European Federation of National Associations of Orthopaedics and Traumatology (EFORT) conference in 2016 and subsequently published on their website. Three case reports in poster format have been published on the company's website.

Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The evidence is very limited in quantity; none of the reports are from the UK, which may limit the generalisability of the findings to the NHS. However, the type of injuries in individual patients selected to have fixation using the device may not differ substantially from those seen in NHS practice.

In general, the evidence suggests that the Galaxy UNYCO can give effective temporary fixation for

tibial and ankle fractures; however, there is no direct comparative evidence to determine if patient outcomes would be different to those having other forms of fixation, such as bicortical fixation.

Table 1 Summary of selected studies

Lavini et al. (2017)	
Study size, design and location	9 people with ankle fracture dislocations. Prospective observational study. Location: Italy.
Intervention and comparator(s)	Galaxy UNYCO.
Key outcomes	Temporary reduction and stabilisation was achieved for all fractures with a correct implant placement. From a total of 34 monocortical screws implanted, CT revealed 4 screws non-optimally positioned, including 2 screw tips penetrating the intramedullary canal more than 2 mm. Time from incision for the first pin insertion until Galaxy UNYCO definitive stabilisation had been achieved was no more than 10 minutes in all cases. Open reduction and internal fixation was on average done 8.17 days following Galaxy UNYCO fixation and the average length of stay was 13.30 days. 1 patient had a superficial pin site infection.
Strengths and limitations	Effectiveness data provide some real world insight into the Galaxy UNYCO system's ability to treat ankle fracture dislocations, but there was no comparator. Results suggested that Galaxy UNYCO can be used under a local anaesthetic. Authors commented that Galaxy UNYCO was a feasible intervention for people having anticoagulant therapy.
Moerenhout and Borens (2016)	
Study size, design and location	1 person with tibia fracture (AO Foundation type 42-A2 10 cm above the tibiotalar joint). Case study (abstract only). Location: Switzerland.

Intervention and comparator(s)	Galaxy UNYCO.
Key outcomes	Definitive fixation by nailing was made easier because the external fixation system did not have to be removed before the nailing. There was no perioperative complication. The post-operative radiographic and clinical controls gave satisfactory results.
Strengths and limitations	Effectiveness data provides some real world insight into the ability of the Galaxy UNYCO system to treat a tibia fracture; however, this was a single case study with no comparator. Detail was limited because of the abstract-only publication.
Company case report 1	
Study size, design and location	17-year-old female with a right femur and tibia fracture because of a high-energy motorcycle accident. Case study (poster). Location: Germany.
Intervention and comparator(s)	Galaxy UNYCO.
Key outcomes	Because there was an infection in the tibia, using the Galaxy UNYCO helped optimal bone recovery because the medullary canal was free of any foreign material (bicortical bone screws). Three weeks later, internal fixation was performed. At 5-month follow-up, the fracture was progressing well with no problems or complications reported.
Strengths and limitations	Single case study in poster presentation form only, published on company website.
Company case report 2	
Study size, design and location	23-year-old male with a simple oblique fracture of the tibia and fibula because of jumping from a 4 m height. Case study (poster). Location: Switzerland.

Intervention and comparator(s)	Galaxy UNYCO.
Key outcomes	The Galaxy UNYCO system was used because of the risk of soft tissue necrosis and application time was 27 minutes. Twelve days later, internal fixation was done. At 3-month follow-up, the patient reported walking without pain and no complications.
Strengths and limitations	Single case study in poster presentation form only, published on company website.
Company case report 3	
Study size, design and location	45-year-old male with a tibia and ankle fracture because of a motorcycle accident. Case study (poster). Location: Italy.
Intervention and comparator(s)	Galaxy UNYCO.
Key outcomes	The surgeon initially opted for a skeletal traction treatment. However, because of the worsening condition of the soft tissue, a nail could not be inserted. Therefore the Galaxy UNYCO system was used to allow stabilisation and healing of the soft tissue injuries. The Galaxy UNYCO system was applied in 15 minutes. Three weeks later, an internal fixation procedure took place. At 5-month follow-up, the fracture had healed and there was significant improvement of the soft tissue injuries. The patient was able to walk without pain and no complications were reported.
Strengths and limitations	Single case study in poster presentation form only, published on company website.

Recent and ongoing studies

- A prospective, observational, multicenter clinical investigation evaluating the clinical outcomes of tibial and/or ankle fractures stabilized by the temporary external fixator Galaxy UNYCO System. WHO identifier: DRKS00011523. Status: recruiting. Indication: tibial and/or ankle fractures. Devices: Galaxy UNYCO.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Three of the 4 specialists were familiar with or had used this technology before. All specialists noted that Galaxy UNYCO was not currently widely used in the NHS.

Level of innovation

The 4 specialists thought that the Galaxy UNYCO was a minor variation of currently available devices (standard care fixation with plates and screws).

Potential patient impact

One specialist felt that it was unlikely that Galaxy UNYCO would be less invasive and less likely to lead to infection than standard care. One specialist stated that the use of Galaxy UNYCO could potentially reduce deep infections. One specialist noted that use of Galaxy UNYCO in people with substantial soft tissue damage may lead to better outcomes compared with standard care. Two specialists stated that there was no evidence to support any potential benefits to patients when using Galaxy UNYCO compared with standard care.

Potential system impact

Two specialists noted that it was likely to be faster to stabilise a fracture with Galaxy UNYCO compared with standard care. One specialist noted that using Galaxy UNYCO could lead to a reduction in the number of X-rays needed. One specialist stated that Galaxy UNYCO is left in place during the procedure to convert to definitive fixation and noted that this can reduce procedure time. All specialists noted that Galaxy UNYCO was more expensive than standard care and that Galaxy UNYCO is a single-use device but the standard care device can be reused. Two specialists noted the potential for cost savings because of decreased morbidity and secondary procedures.

General comments

All specialists noted that the number of people needing temporary external fixation is very small even in a major trauma centre. All 4 specialists noted the need for further evidence. One specialist noted that stabilisation with Galaxy UNYCO is unlikely to be as secure as it would be with standard

of care.

Specialist commentators

The following clinicians contributed to this briefing:

- Professor Matthew Costa, honorary consultant trauma surgeon and professor of orthopaedic trauma surgery, University of Oxford Medical Sciences Division. Did not declare any conflicts of interest.
- Dr Tim Chesser, consultant trauma and orthopaedic surgeon, North Bristol NHS Trust. Did not declare any conflicts of interest.
- Mr Paul Harwood, consultant in trauma and orthopaedics, Leeds Teaching Hospital NHS Trust. Has taught on industry-sponsored courses but has not received any payment for this.
- Mr Saket Tibrewal, consultant trauma and orthopaedic surgeon, Lewisham and Greenwich NHS Trust. Did not declare any conflicts of interest.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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