27. Ilizarov Technique / Taylor Spatial Frame (TSF) Commissioning Statement

Treatment	Elective use of the Ilizarov technique/Taylor Spatial Frame (TSF) in adults
Background	The **Ilizarov apparatus** is a type of external fixation used in orthopaedic surgery to lengthen or reshape limb bones; to treat complex and/or open bone fractures; and in cases of infected non-unions of bones that are not amenable with other techniques. The Taylor Spatial Frame (TSF) is more versatile and easier to use, but very costly. The appropriate use of Ilizarov frames in **non-elective** traumatic injury is routinely commissioned; complex cases requiring specialist treatment are commissioned by NHS England[1.]
Commissioning position	This commissioning policy is needed to clarify under which circumstances the **elective** use of the Ilizarov technique is commissioned. **The use of the Ilizarov technique will NOT be commissioned where limb lengthening alone is the desired outcome as this would be deemed cosmetic and not medically necessary** **(NB: NHS Vale of York CCG does NOT routinely commission an elective intervention on patients who have a BMI of 30 or above (classified as obese) or patients who are recorded as a current smoker – see commissioning statement 01. Optimising Outcomes from All Elective Surgery**)** NHS Vale of York CCG commissions the use of the Ilizarov technique/TSFs for elective use in orthopaedics in **individual carefully selected cases** which fulfill these criteria • Complex mal-union or non-union of fractures (after at least 6 months duration or 9 months where the 'Exogen' ultrasound bone healing system has been tried and failed[2]). • Bone deformity (affecting the leg/knee/ankle), including limb length discrepancy, that has resulted in chronic pain and/or difficulty walking and/or an increased risk of developing osteoarthritis[3.] • Where there is agreement by the regional orthopaedic MDT that, of all available treatments, Ilizarov/TSF is the best clinical option for the patient in terms of a favourable functional limb outcome (bone and functional outcomes are not always the same). • The patient understands the long duration of external fixation, the likelihood of marked discomfort and possible complications • The patient has been a non-smoker for at least 8 weeks* • The MDT should comprise at least two consultant orthopaedic surgeons, with input from specialist nursing, physiotherapy and musculoskeletal radiology. ** Smoking is a significant, potentially remediable risk factor for failure following Ilizarov reconstruction and cessation strategies are of paramount importance prior to initiating treatment[14] Thus, careful patient selection is important for determining the likelihood of success with Ilizarov (see risk factors for further details)*

	Requests to use the Ilizarov technique outside these criteria must be submitted to the Vale of York CCG Individual Funding Request Panel (IFR) for consideration. Requests must include documented minutes from the MDT meeting at which the individual case was discussed.
Summary of evidence / rationale	The Ilizarov technique is a method of bone fixation using an external fixator (eg the Ilizarov fixator or the Taylor Spatial Frame) for lengthening limbs, correcting deformities, and assisting the healing of otherwise hopeless traumatic or pathological fractures and infections. The TSF fixator is a computer software-controlled circular external fixator using six struts, allowing correction of lower limb deformities, fractures and limb lengthening with great accuracy[4]. The main drawback with this technique is the long duration of external fixation required with marked patient discomfort, thus good patient understanding and compliance is required. Studies of clinical and cost effectiveness quoted in the literature are diverse in their quality, findings, patient numbers and statistical power. However, the high complication rate reported in the earlier years of this technique (used in Western countries since the 1980s) has now reduced dramatically, in particular, the incidence of pin site infection, which can now be minimised with specialist care and preventative measures[5, 6]. *Non-union cases:* [7 - 12] • The Ilizarov technique appears useful in the management of non-union of the long bones when internal devices have failed, though outcome results are varied • Infected non-unions have a higher risk of failure than non- infected cases so the bone infection should be treated first. • Outcomes appear to worsen with repeated surgical procedures • Complications appear more frequent in lower leg non-union than in the femur or upper arm. Residual pain and secondary surgery are a frequent complication of tibial non-unions • When bony union is achieved after Ilizarov the scores for bone function and the overall physical and mental health scores of the patient improves • The greatest improvements may be seen 6-12 months after frame removal • Early removal of the Ilizarov external fixation frame and replacement with internal fixation after bone graft appears to produce no difference in functional outcome on follow up of tibial non-union • Patients with infected nonunion of tibia and femur treated by Ilizarov methods had a low rate of “poor” bone and functional results, suggesting that these methods may be a good choice for the treatment of infected nonunion of tibia and femur. *Leg length discrepancy[13] (**not routinely commissioned - via IFR only**)*: • Limb-length discrepancies greater than 2cm often result in pelvic slanting, scoliosis, alterations in normal walking pattern and abnormal loading of the hip and knee joints on the long side, with the attendant risks of premature arthrosis • Speedier tibial lengthening may be achieved by using the Ilizarov fixator in conjunction with secondary internal fixation. • The greater the leg length discrepancy the higher the risk for complications

	Risk factors: Smoking is a significant, potentially remediable risk factor for failure following Ilizarov reconstruction and cessation strategies are of paramount importance prior to initiating treatment [14]. Thus, careful patient selection is important for determining the likelihood of success with Ilizarov especially regarding factors such as: • Smoking status • BMI • Length of bone defect • Presence of infection • Time from original trauma • Number of previous operations • The particular bone affected All patients should understand the long duration of external fixation, the likelihood of marked patient discomfort and possible complications. Thus good patient understanding and compliance is paramount.
Date effective from	November 2016
Date published	November 2016
Review date	November 2018
Author	Dr Alison Forrester, Healthcare Public Health Advisor CYC & NYCC
Approved by	Clinical Research & Effectiveness Committee 22.11.16
Responsible officer	Shaun O'Connell GP Lead valeofyork.contactus@nhs.net

References:

1. NHS England (2013) Service specifications for specialised orthopaedics (adult) *NB this does not appear to mention ilizarov or long bones and focuses on complex joint problems*
http://www.england.nhs.uk/wp-content/uploads/2013/06/d10-spec-orthopaedics.pdf
Complex bone and joint infection
https://www.england.nhs.uk/wp-content/uploads/2013/06/b07-bone-joint-infec.pdf
Complex childhood osteogenesis imperfecta service
https://www.england.nhs.uk/wp-content/uploads/2013/06/e13-child-osteo-imperfecta.pdf
2. NICE medical technology guidance (Jan 2013) 'EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing
http://www.nice.org.uk/nicemedia/live/14018/62289/62289.pdf
3. Spiegelberg B et al (2010). Ilizarov principles of deformity correction. Annals of the Royal College of Surgeons of England, March 2010, vol. /is. 92/2 (101-5)
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3025247/pdf/rcse9202-101.pdf
4. Gubin AV, Borzunov DY, Malkova TA (2013) The Ilizarov paradigm: thirty years with the Ilizarov method, current concerns and future research. International orthopaedics, 28 May 2013, 0341-2695 http://link.springer.com/content/pdf/10.1007%2Fs00264-013-1935-0.pdf#page-1
5. Guidance on pin site care - Report and recommendations from the 2010 Consensus Project on Pin Site Care.
http://www.rcn.org.uk/__data/assets/pdf_file/0009/413982/004137.pdf
6. Santy J, Vincent M and Duffield B (2009) The principles of caring for patients with Ilizarov external fixation, Nursing Standard, 23 (26), pp.50-55.

7. Barker KL, Lamb SE, Simpson AH (2004) Functional recovery in patients with non-union treated with the Ilizarov technique. Journal of Bone & Joint Surgery - British Volume, January 2004, vol. /is. 86/1(81-5) http://www.bjj.boneandjoint.org.uk/content/86-B/1/81.long
8. Brinker MR, O'Connor DP (2007) Outcomes of tibial non-union in older adults following treatment using the Ilizarov method. Journal of Orthopaedic Trauma, October 2007, vol. /is. 21/9(634-42) http://www.ncbi.nlm.nih.gov/pubmed/17921839
9. Emara KM, Allam MF (2008). Ilizarov external fixation and then nailing in management of infected non- unions of the tibial shaft. Journal of Trauma, 01 September 2008, vol. /is. 65/3(685-691) http://www.ncbi.nlm.nih.gov/pubmed/18784585
10. Rozbruch SR, Pugsley JS, Fragomen AT, Hizarov S (2008). Repair of tibial non-unions and bone defects with the Taylor spatial frame. Journal of Orthopaedic Trauma, 01 February 2008, vol. /is. 22/2(88-95) http://www.ncbi.nlm.nih.gov/pubmed/18349775
11. Saridis, A (2006) The use of the Ilizarov method as a salvage procedure in infected non-union of the distal femur with bone loss. Journal of Bone and Joint Surgery - British Volume, Vol 88-B, Issue 2, 232-237 http://www.bjj.boneandjoint.org.uk/content/88-B/2/232.long
12. A Systematic Review and Meta-Analysis of Ilizarov Methods in the Treatment of Infected Nonunion of Tibia and Femur Yin P et al 2015 Nov 3;10(11):e0141973. doi: 10.1371/journal.pone.0141973. eCollection https://www.ncbi.nlm.nih.gov/pubmed/26529606
13. American Academy of Orthopaedic Surgeons. Limb Length Discrepancy. http://orthoinfo.aaos.org/topic.cfm?topic=A00259
14. McKee MD, DiPasquale DJ, Wild LM, Stephen DJG, Kreder HJ, Schemitsch EH (2003) The effect of smoking on clinical outcome and complication rates following Ilizarov reconstruction. Journal of Orthopaedic Trauma, 01 November 2003, vol. /is. 17/10 (663-667) http://www.ncbi.nlm.nih.gov/pubmed/14600564