NICE National Institute for Health and Care Excellence

NICE guidance

# Partial replacement of the meniscus of the knee using a biodegradable scaffold

HealthTech guidance
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# Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

# Contents

This guidance replaces IPG430.

# 1 Recommendations

1.1 Current evidence on partial replacement of the meniscus of the knee using a biodegradable scaffold raises no major safety concerns. Evidence for any advantage of the procedure over standard surgery, for symptom relief in the short term, or for any reduction in further operations in the long term, is limited in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake partial replacement of the meniscus of the knee using a biodegradable scaffold should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand that there are uncertainties about any possible long-term advantage over other surgical options and that considerable rehabilitation is required after this procedure. Clinicians should provide patients with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having partial replacement of the meniscus of the knee using a biodegradable scaffold (see section 3.1).

1.3 The procedure should only be carried out by surgeons who are highly experienced in arthroscopic meniscal surgery.

1.4 NICE encourages further research and data collection on partial replacement of the meniscus of the knee using a biodegradable scaffold. This should include clear descriptions of patient selection and adjunctive treatments. Outcome measures should include symptom relief and functional ability in the short term and the need for further treatment in the longer term.

# 2 The procedure

## 2.1 Indications and current treatments

2.1.1 The menisci are semi-lunar wedge-shaped fibrocartilaginous structures which act as shock absorbers, spreading the load on the articular surfaces of the knee.

2.1.2 The menisci can be damaged (often a tear) as a result of acute injury or degeneration, which may cause pain and/or locking of the knee. It is believed that meniscal damage is associated with a higher risk of knee osteoarthritis in the longer term. Minor meniscal damage can be treated conservatively (including rest and physical therapies). For more severe cases, treatment usually involves removal of the damaged part of the meniscus (partial meniscectomy).

2.1.3 Meniscal repair is possible only in a minority of patients. This depends on the proximity of the damage to the peripheral vascular region of the meniscus (where good blood supply allows meniscal healing), the pattern of the damage and whether there is damage to other knee joint structures.

## 2.2 Outline of the procedure

2.2.1 Implantation of a scaffold for partial replacement of the meniscus of the knee aims to support the body's own physiological pathways for healing by providing a 3-dimensional matrix for cell adhesion and vascular ingrowth, when attached to the vascular portion of the meniscus. In the short term, the procedure aims to restore the load-bearing and shock-absorbing functions of the damaged meniscus, contributing to pain relief and restoring functional mobility. In the long term, it aims to lower the risk of osteoarthritis and the need for further operations. A strict rehabilitation regime is usually employed after the procedure, which may include several weeks of restricted weight bearing and temporary bracing to limit knee movement.

2.2.2 The procedure may be done with the patient under general or regional

anaesthesia. Using an arthroscope, damaged sections of the meniscus are excised, leaving a residual meniscal rim in the vascular zone. The size of the defect is measured and the implant is trimmed to match it. The implant is then introduced into the joint via one of the portals and sutured to the remaining meniscal rim. This may require extra skin incisions to provide sufficient access.

2.2.3 The types of scaffolds available for this procedure include those made of synthetic polyurethane and of collagen derived from animal sources.

## 2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3.1 A randomised controlled trial (RCT) of 311 patients divided patients into two groups, depending on whether they had prior surgery on the affected meniscus. Each group was randomised to treatment by partial replacement of the meniscus with a biodegradable implant or to partial meniscectomy alone. Pain scores were reported as a mean change from baseline (assessed at rest, during activities of daily living and at the highest level of activity, on a visual analogue scale; 0 to 100, higher score indicates greater pain) at mean follow-up of 59 months. The first group of 157 patients had no prior surgery on the affected meniscus. Patients treated by the procedure (n=75) had a mean pain score of 16 compared with 21 for those treated by partial meniscectomy (n=82; reported as not significant, p-values not reported). The second group of 151 patients, who had had prior surgery on the affected meniscus (85 treated by the procedure and 69 treated by partial meniscectomy) had mean pain scores of 18 for both groups (reported as not significant, p-values not reported).

2.3.2 An RCT of 60 patients, which included 30 patients treated by the procedure and high tibial osteotomy (there was a high dropout rate in the comparator arm of tibial osteotomy alone) reported that the 23 patients followed for 8 to 18 months had Lysholm scores (0 to 100, higher score corresponds to better function) which improved from a baseline of 65 to 94 (p-value not reported).

2.3.3 In a case series of 52 patients treated by partial replacement of the meniscus with a polyurethane scaffold, treatment failure (defined as an additional surgical procedure on the involved meniscus) was reported in 15% (8 of 52) of patients (treatment failure related to infection was excluded) and the overall treatment failure was 17% (9 of 52). Three cases were definitely related to the implant, 3 were not related to the implant, 1 was possibly related to the implant, 1 was unknown and 1 treatment failure (infection) was not related to the implant. Timing to the need for further intervention ranged from 1 week to 24 months.

2.3.4 A non-randomised comparative study of 33 patients treated by partial replacement of the medial meniscus (n=17) or by partial medial meniscectomy (n=16) reported mean quality of life scores measured by SF-36 physical health and mental health indices (scale of 0 to 100, higher score indicates better functioning). For the SF-36 physical health index, scores were 54 and 44 for the implant and the partial meniscectomy groups respectively, at a mean follow-up of 11 years (p=0.026). For the mental health index, scores were 55 and 44 for the implant and the partial meniscectomy groups respectively at mean follow-up of 11 years (p=0.004).

2.3.5 The RCT of 311 patients reported reoperation rates, defined as an additional surgical procedure (outside the protocol) on the knee as a result of disabling or persistent pain and/or mechanical symptoms that could possibly involve the meniscus. The reoperation rates were 10% and 23% for the implant and the partial meniscectomy groups respectively, at 5 years (denominators not reported; significance not reported). Reasons for reoperation included pain, swelling and instability.

2.3.6 The specialist advisers listed the following key efficacy outcomes: pain reduction, functional improvement, reduction in risk of further degeneration of the articular cartilage lining of the knee, early failure (further surgery) and early failure (symptoms or patient-related outcome measures).

## 2.4 Safety

2.4.1 Dislocation of the implant was reported in 1 patient out of 30 treated by partial replacement of the meniscus combined with high tibial osteotomy in the RCT of

60 patients. The implant was removed but the timing of this was not reported.

2.4.2 Implant failure (defined as infection caused by the collagen implant or mechanical failure of the implant) was reported in 8% (2 of 25) of the patients in a case series of 25 patients during follow-up of 10 to 13 years. Postoperative infection (unrelated to the polyurethane scaffold) was reported in 1 patient in the case series of 52 patients at 1 week after the index surgery (resolved with treatment; no further details reported).

2.4.3 Swelling, effusion and redness were reported in 4 patients treated by the procedure and in 1 patient treated by partial meniscectomy in the RCT of 311 patients (timing of assessment was unclear; denominator not reported). Knee swelling was reported in 32% (7 of 22) of the patients in the case series of 25 patients (timing of assessment was unclear; further details not reported).

2.4.4 The specialist advisers listed the following theoretical safety outcomes: reaction to foreign material, lack of repair or healing, with subsequent tearing or displacement, infection or standard related risks for any knee surgery operation.

## 2.5 Other comments

2.5.1 The committee noted the lack of clear criteria for patient selection for partial replacement of the meniscus of the knee using a biodegradable scaffold. It also noted that there are two main patient groups, young active patients and older patients with meniscal degeneration. It considered that the needs and outcomes of these two groups may be different.

# 3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

# Update information

**Minor changes since publication**

**January 2026:** Interventional procedures guidance 430 has been migrated to HealthTech guidance 289. The recommendations and accompanying content remain unchanged.

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# Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.