Introduction

Bio-degradable scaffolds have been suggested as a matrix to allow new tissue regeneration to fill segmental loss after partial meniscectomy.

The initial aim has been to treat post meniscectomy pain but there is also the potential to prevent joint surface erosion problems after partial meniscectomy and perhaps influence later osteoarthritis.

There are two synthetic products currently in clinical use and these are discussed in this lecture.

a. **Menaflex (Collagen Meniscal implant)**

- Composition: purified type I collagen from Bovine Achilles tendon.
- Manufacturing process: processing of Achilles tendon using enzymes to remove noncollagenous proteins and lipids. Hyaluronic acid and chondroitin sulphate added and product homogenized. Eventually fibres are moulded and cross linked and then sterilised to make meniscus shaped tissue. The construct is enriched with GAG to allow cellular ingrowth.
- The final product is biocompatible and bioresorbable.
- Resorption: The collagen type I fibres have disappeared between one and two years.
- Original basic research: Developed in early 1990s.
- Arthroscopic technique described 1997 (Stone 1997).
- Clinical results reported through 2005-2008 as part of FDA study.
- Steadman (arthroscopy 2005): Reported eight patients with average follow up 5.8 years showing significantly improvement clinical scores and no subsequent degeneration of articular surface. Relook arthroscopy revealed 69% defect filling with regenerate tissue. Histology showed presence of fibro cartilage.
- Zaffagnini (KSSTA 2007): Reported on 8 patients with mean follow up 6.8 years. Three relooks at 2 years. All clinical scores improved with only two patients having slight increase in arthritic change. Relook arthroscopy showed presence of new tissue, reduced in size in two cases.
- Rodkey et al (JBJS 2008): Results of prospective randomised trial comparing the CMI versus partial medial meniscectomy – 311 patients with irreparable injury of medial meniscus or previous partial meniscectomy. The mean follow up was five years. In the chronic group comparing CMI insertion v no treatment for previous partial meniscal resection, the CMI patients regain significantly more of their lost activity...
than the controls. In the acute group comparing immediate partial meniscectomy versus immediate reconstruction there was no significant difference between the two groups.

- Bulgeroni (The Knee 2009): European study of 34 patients following medial meniscal reconstruction. Lysholm and Tegner activity scores significantly improved at 2 years. Second look arthroscopy showed chondral surfaces in the medial compartment had not degenerated further. MRI signal had continued to mature between 2-5 years after implant.
- EU multi centre study group reported on lateral menaflex implantation. 49 patients with mixed indication and concomitant surgery. Patient satisfaction 94% at two years and significant reduction in post op visual analogue score for pain.
- FDA approved 510K in December 2008. Subject of continued debate.

b. **Actifit Polymer Meniscal Implant**

- Composition: scaffold made from polyurethane stiff segments linked by soft flexible segments giving biocompatibility strength and toughness. Resistant to wear and easy to process into foams.
- Result: Biodegradable highly porous scaffold made from an aliphatic polyurethane. Good mechanical properties with safe degradation products. Polycaprolactone copolymer.
- Degradation over five years in to polyurethane fragments which are safely excreted.
- Duration of absorption: Product probably removed by five years.
- Current clinical data reported by ‘proof of principle study’ by developers in Europe.
- Study included patients with irreparable medial or lateral partial meniscal tears. Intact rim and horns. Patients aged 18-50 years with stable knee and joint surface damage Grade I or II.
- Patients with total meniscal loss or unstable segmental rim defects were excluded.
- 52 patients enrolled. 34 for medial meniscus and 18 lateral meniscus. Length of defect: mean 47mm.
- Clinical efficacy results showed all scores significantly improved after 12 months (VAS, Lysholm, IKDC and KOOS).
- Relook arthroscopies at 12 months showed regenerate tissue. Histology from free edge of meniscus showed three layers of tissue and good cell ingrowth, repopulation of all biopsies with vital cells and no case of tissue necrosis or cell death. New consistent tissue with ongoing process of regeneration and maturation.
- Technique also valued with dynamic contrast enhanced MRI showing new vascularisation of tissue ingrowth.
- Results continued after 24 months and recently reported.

**Surgical Technique**

Both implants are inserted arthroscopically and held in place using suture devices. Surgical technique is fairly exacting and will be illustrated.

**Clinical indications**

Both products are indicated for segmental tissue loss, and not complete meniscal replacement: Indications are:

- Lesions greater than $2/3^{rd}$ meniscal width removed.
- Pain after partial meniscectomy.
- Intact meniscal peripheral rim.
- Intact posterior and anterior horns.
- Age less than 55.
- Willing to follow slow rehabilitation.

**Rehabilitation Program**

Both techniques involve slow rehabilitation:

- Protected weight bearing for 8-10 weeks.
- No running or impact activities for 6-9 months.
- Return to full contact sport 12 months.

**Problems and new technologies**

- Long term results of implants/scaffolds unknown especially whether there is long term effect on delaying arthritic change and chondral damage.
- Dilemma of regularity difficulties.
- Possibility of seeding implants with cells or growth factors to promote healing.
- Indecision over indications.

**CPT Code**

29868 Meniscal transplantation, medical or lateral, knee [any method].

**Bibliography**


