Ulster University

East Lancashire Hospitals NHS
NHS Trust

Vascular Graft Infection – Therapeutic Strategies

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Midland Hotel - Manchester
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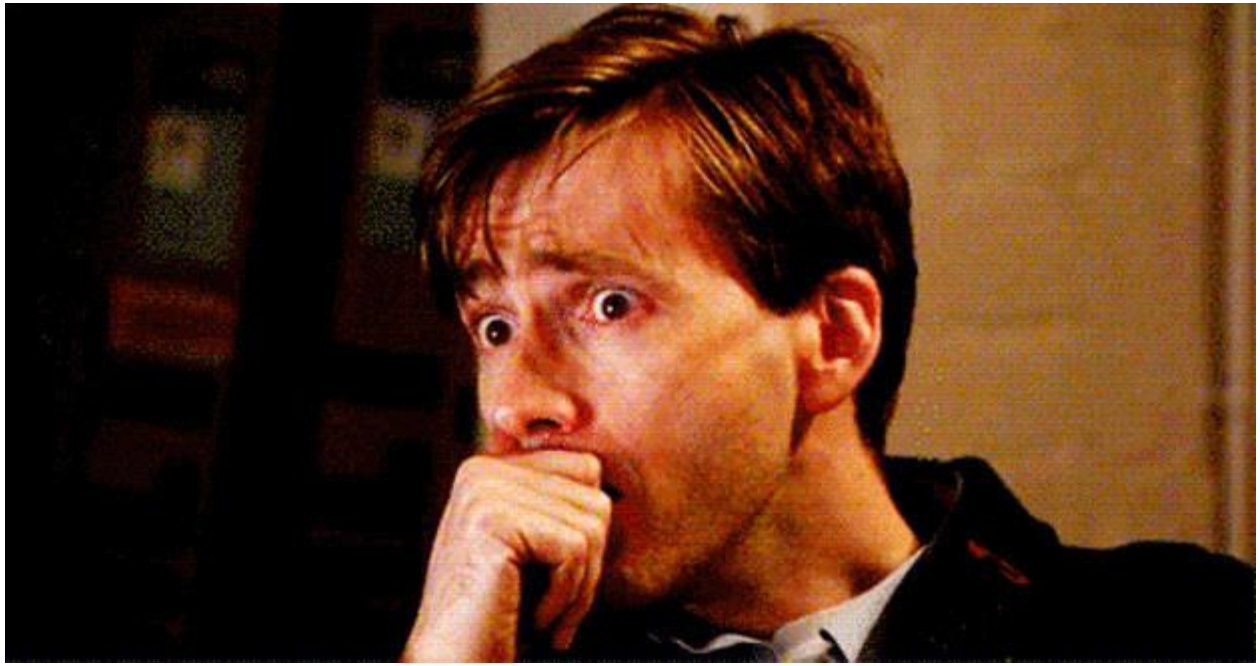
Disclosure

- No disclosures declared.
- No financial relationship with content.

Learning Outcomes

- Evaluation of clinical presentation.
- Exploration of graft infection classification and causative factors.
- Review of investigative modalities.
- Analysis of therapeutic intervention strategies.
- Long-term sequelae and outcomes.

Vascular Graft Infection – The Problem !!!!



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- Surgical site infection (SSI) after open surgery for lower extremity revascularisation is a serious complication that is associated with a more than twofold increased risk of early graft loss and re-operation.

- Fortunately graft infections remain uncommon occurring in less than 5% of cases.

- However, they have a **high morbidity and incidence of amputation and death.**

Vascular Graft Infection – The Problem !!!!

- Multicentre audit of complex wound and graft infections (n=55);
  - 31% mortality.
  - 33% amputation rate.
  - Only 45% left hospital alive without amputation.
    - Naylor et al, *Eur J Vasc Endovasc Surg* 2001; 21: 289-94.

Causes

- Occurs most commonly by inoculation of bacteria from the patient's skin at the time of surgery.
- Direct contamination or spread during the initial surgery or immediate post-operative period.
- Peri-operative malaise.
- Post-discharge complication.

Risk Factors

- Patient:
  - Elderly, female gender, obesity, care home residence.
  - Diabetes, renal failure.
  - Steroid therapy, recurrent antibiotics.
  - Presence of haematoma, open wound or recent angiography.
- Pre-operative shaving – when?
- Procedure;
  - Redo-surgery.
  - Emergency surgery.
  - Duration greater than 4 hours.
  - Choice of conduit – autologous vs. prosthetic.

Prevention

- Patient optimisation including MRSA screening.
- Antibiotic prophylaxis in accordance with local protocols.
- Patient physiology:
  - Normothermia.
  - Maintenance of glucose homeostasis.
- Operative technique:
  - Pre-operative patient washing ??
  - Anatomical marking.
  - Aseptic technique and precise tissue handing.
  - Theatre sterility and laminar air-flow.

Clinical Presentation

Clinical Presentation

- High index of suspicion.
- Systemic upset, pyrexia of unknown origin, weight loss.
- Superficial Grafts:
  - Erythema overlying graft.
  - Spreading cellulitis or abscess formation.
  - Haematoma.
  - Discharging or bleeding wound. or bleeding.
- Deep-set Grafts:
  - Vague pain.
  - Herald sign such as gastro-intestinal bleed, distal emboli, hydronephrosis or tissue erosion.


The Preamble
to the U.S. Constitution

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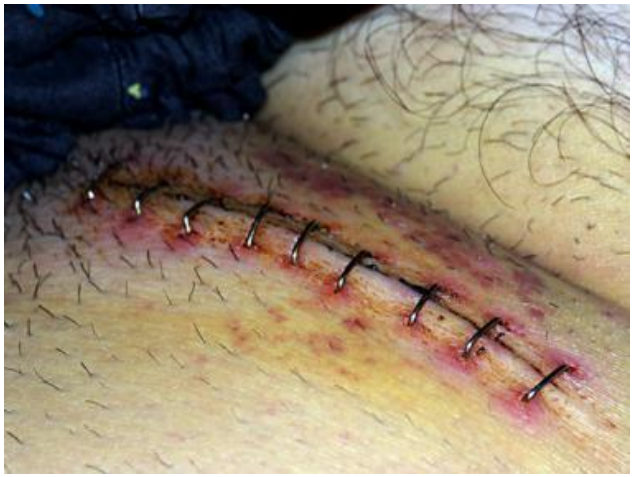

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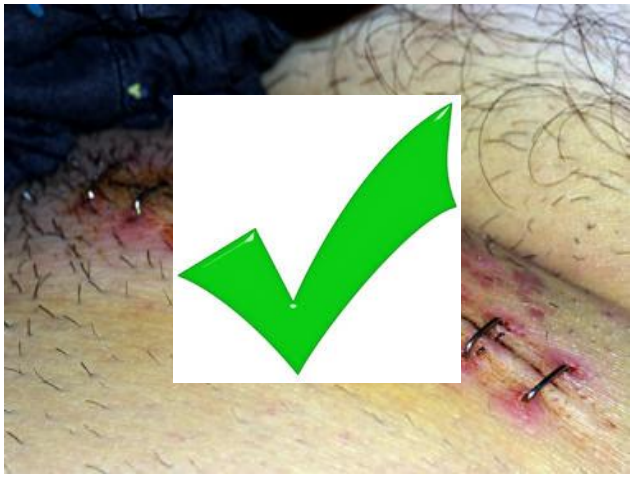

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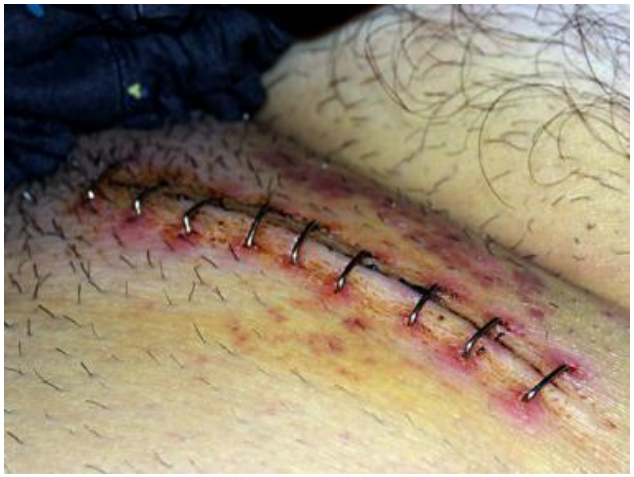

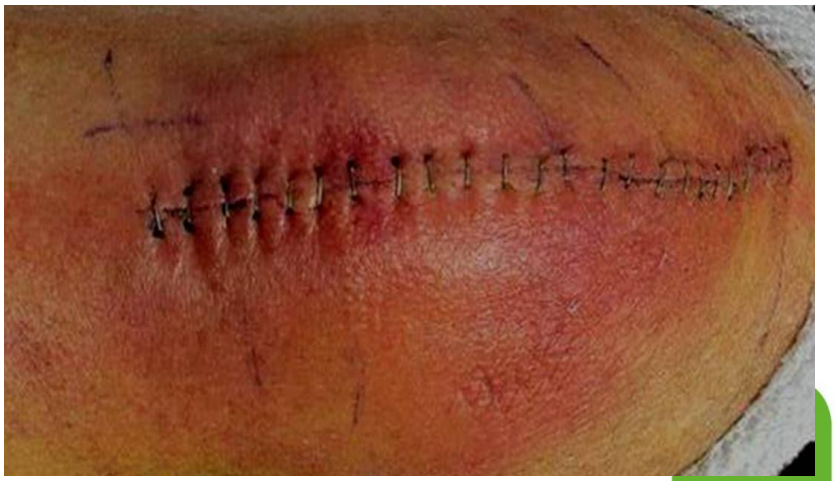

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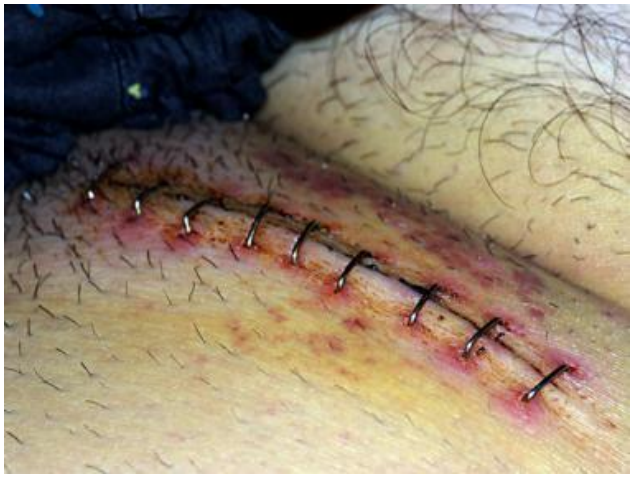

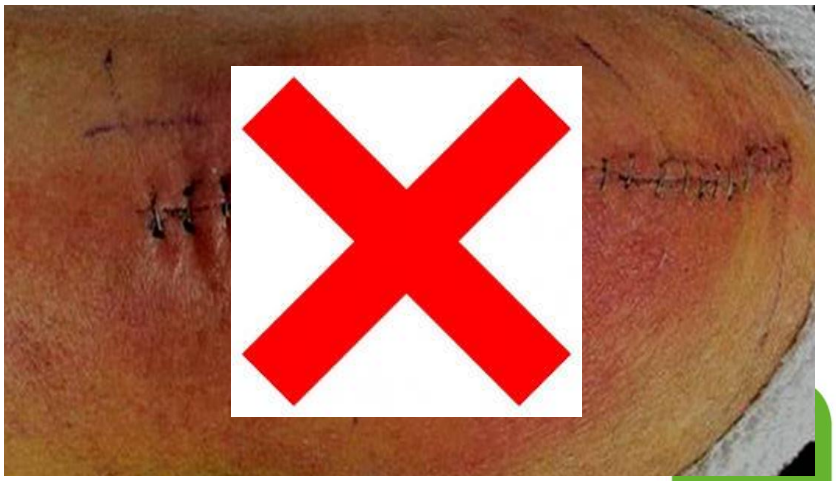

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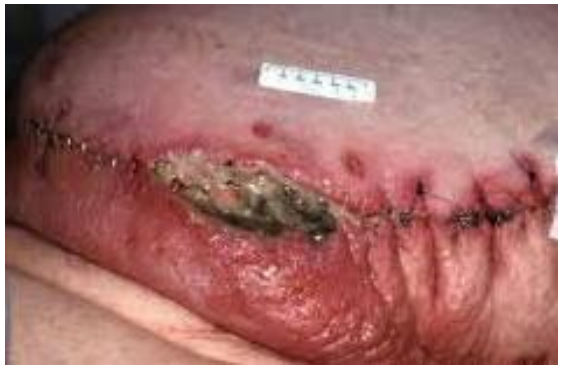

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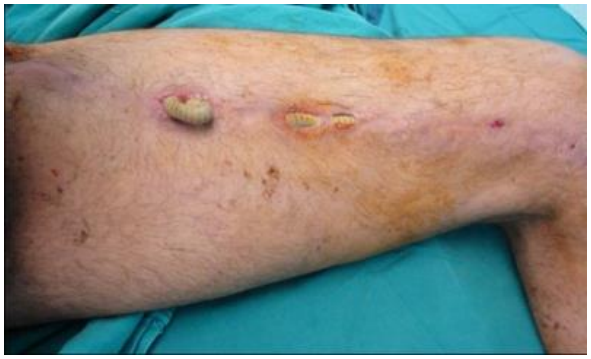

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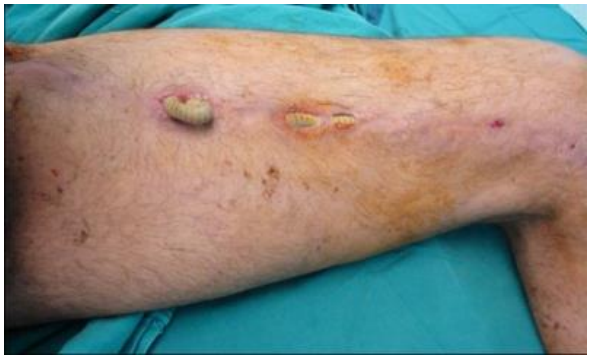
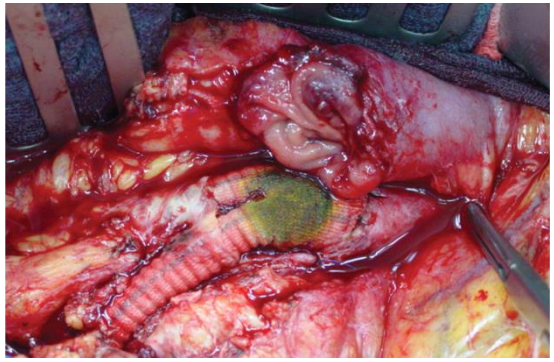
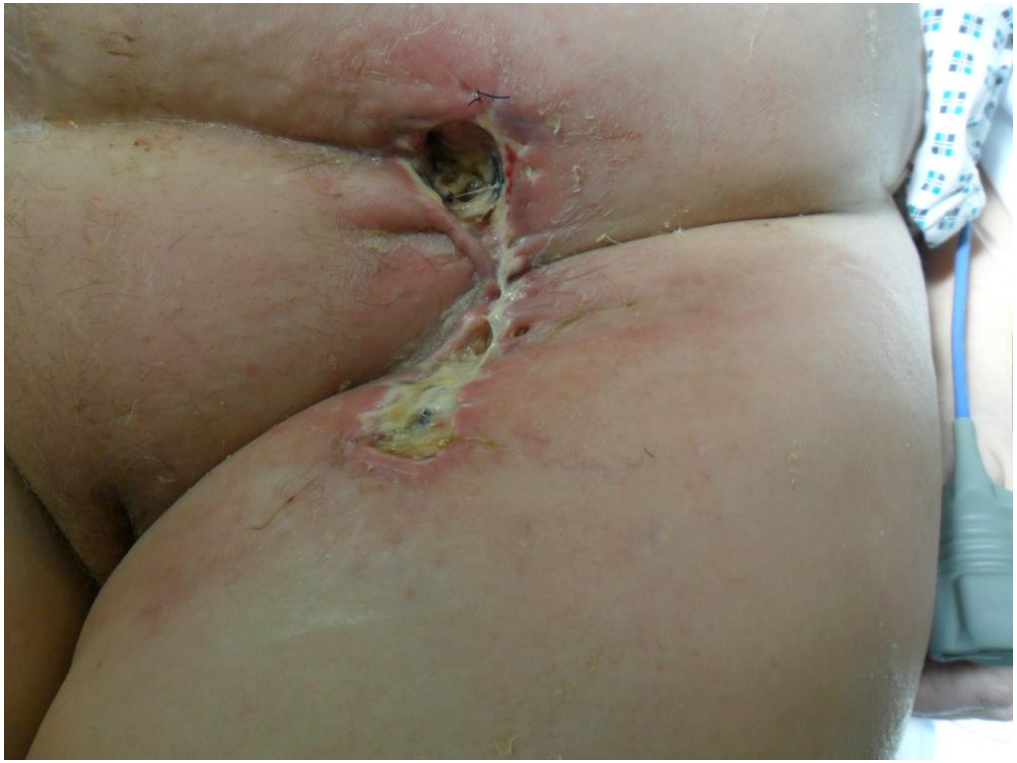




Groups	Szilagyi	Samson	Karl-Storck
I	infection involves only the dermis	infections extend no deeper than the dermis	Superficial infection without involvement of the graft
II	infection extends into the subcutaneous tissue but does not invade the arterial implant	infections involve sub-cutaneous tissues but do not come into grossly observable direct contact with the graft	Partial graft infection without involvement of the anastomosis
III	the arterial implant proper is involved in the infection	infections involve the body of the graft but not at an anastomosis	involvement of the anastomosis and suture line
IV		infections surround an exposed anastomosis but bacteremia or anastomotic bleeding has not occurred	Wound disruption and complete exposure of the graft/patch
V		infections involve a graft-to-artery anastomosis and are associated with septi-cemia and/or bleeding at the time of presentation	All the above groups with concomitant septic bleeding/pseudoaneurysm
VI			All the above groups with graft thrombosis or septic emboli



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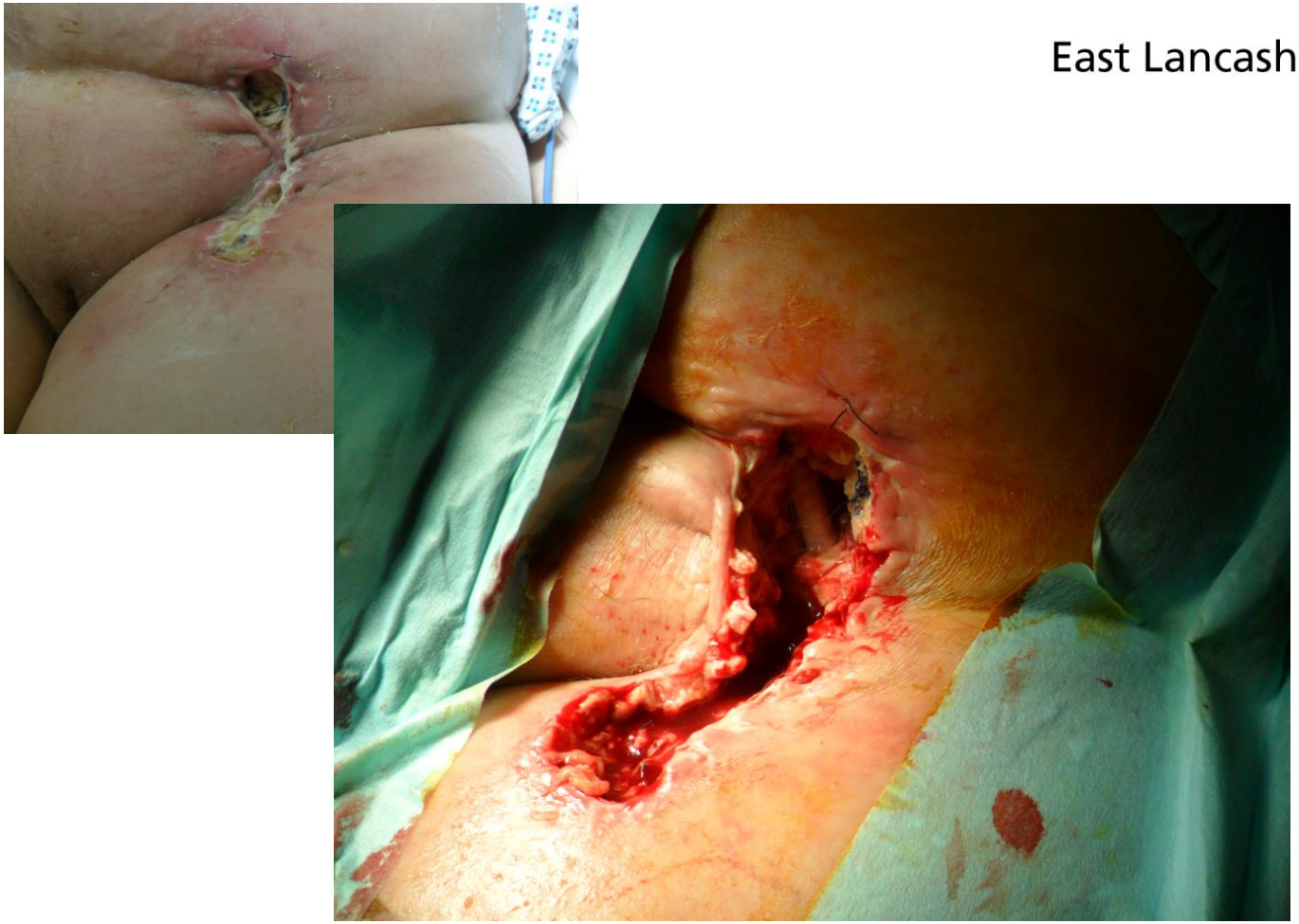

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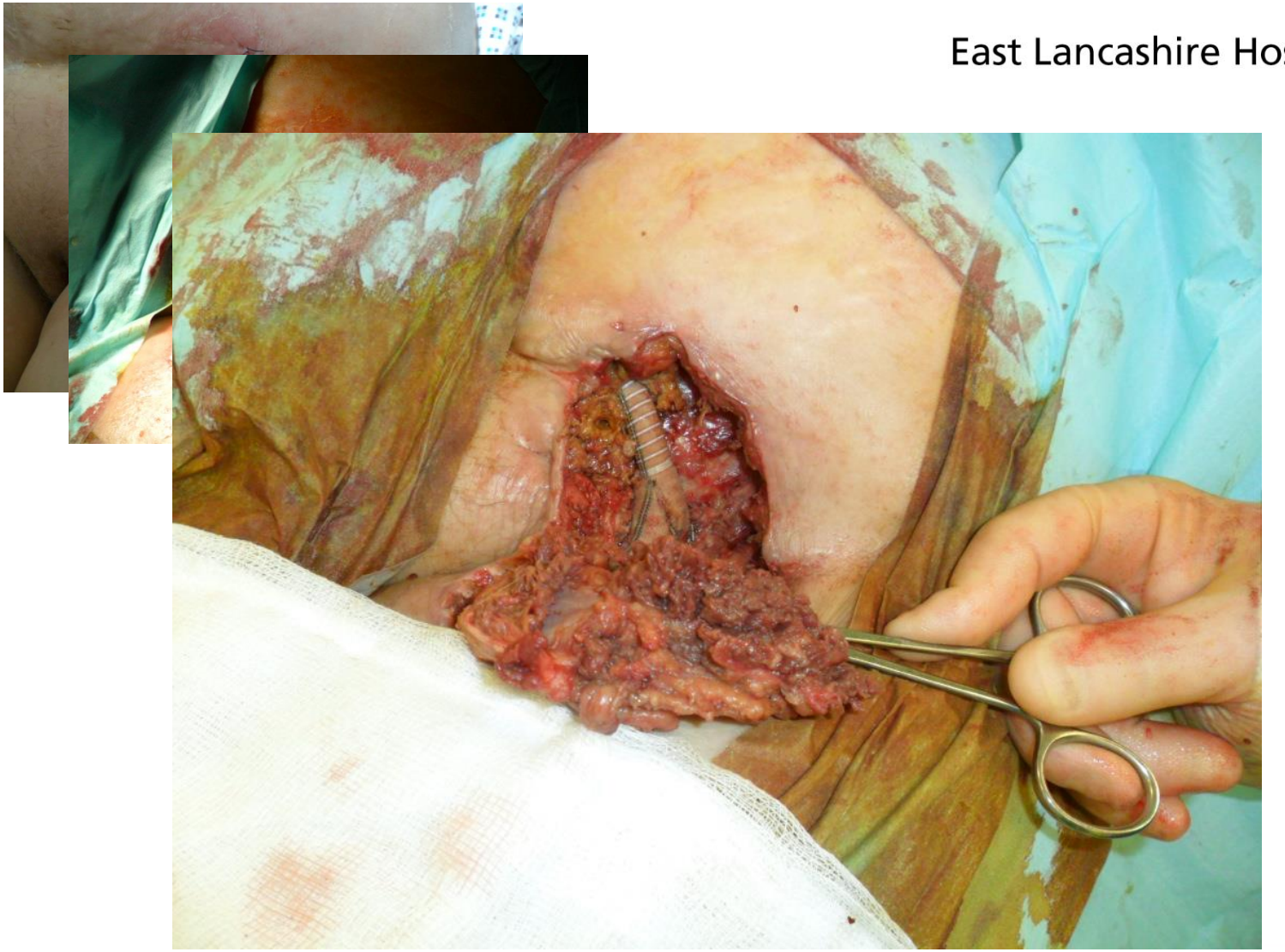

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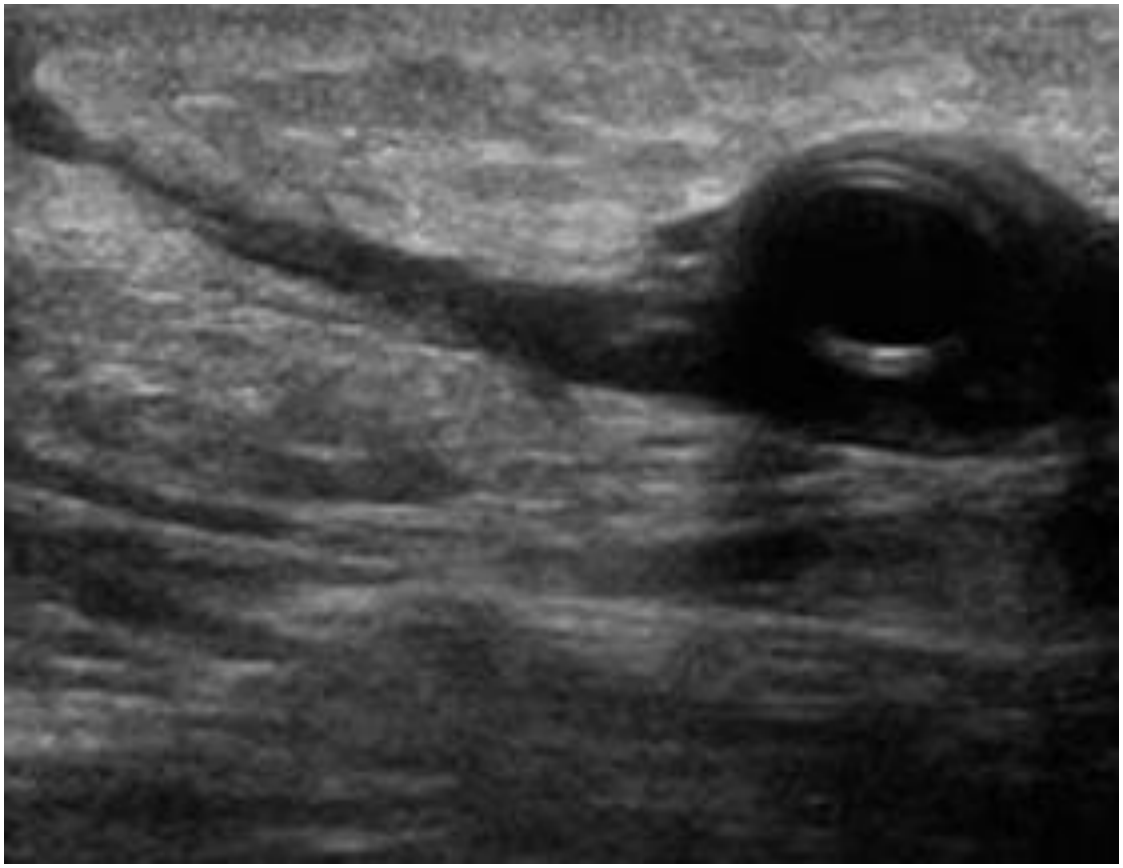
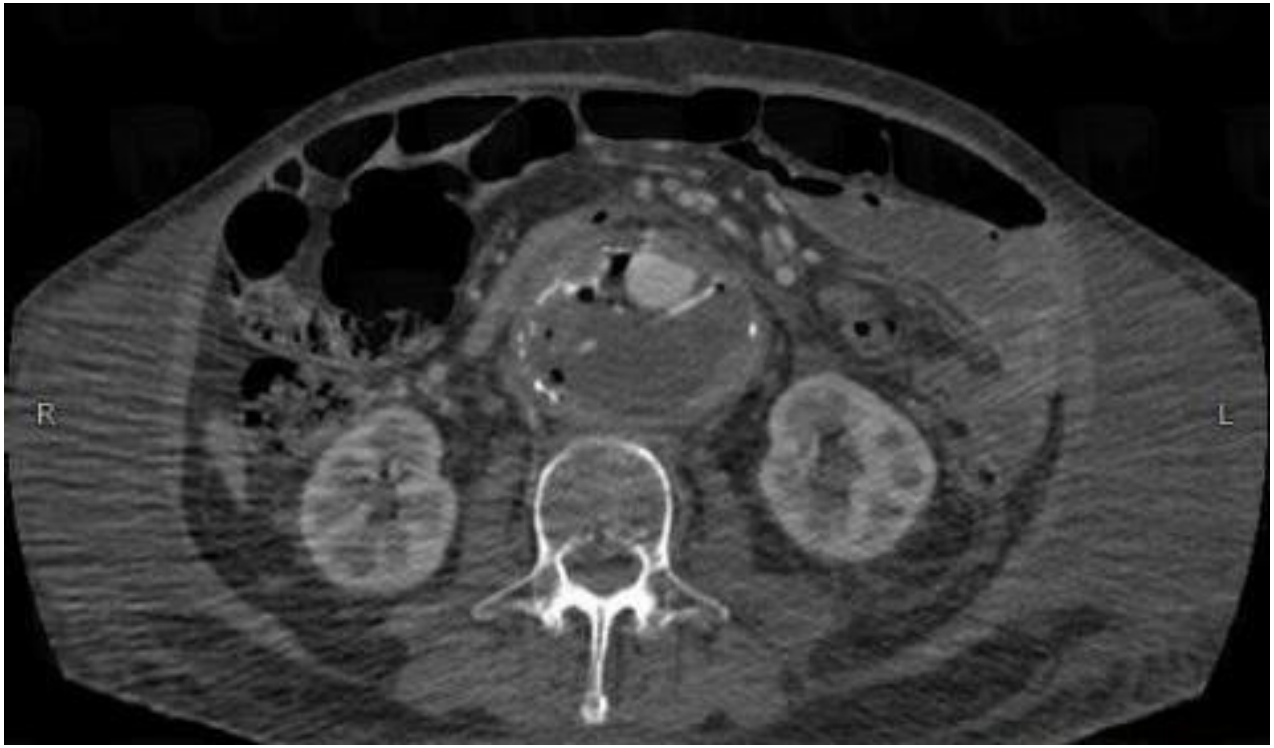
Patient Investigation

- Haematological indices;
  - White cell count.
  - CRP.
- Microbiology;
  - Culture everything but tissue / graft samples optimal.
- Radiological;
  - Ultrasound.
  - Cross-sectional imaging – CT & MRI.
  - Radionucleotide.
  - Angiography.
  - Endoscopic.

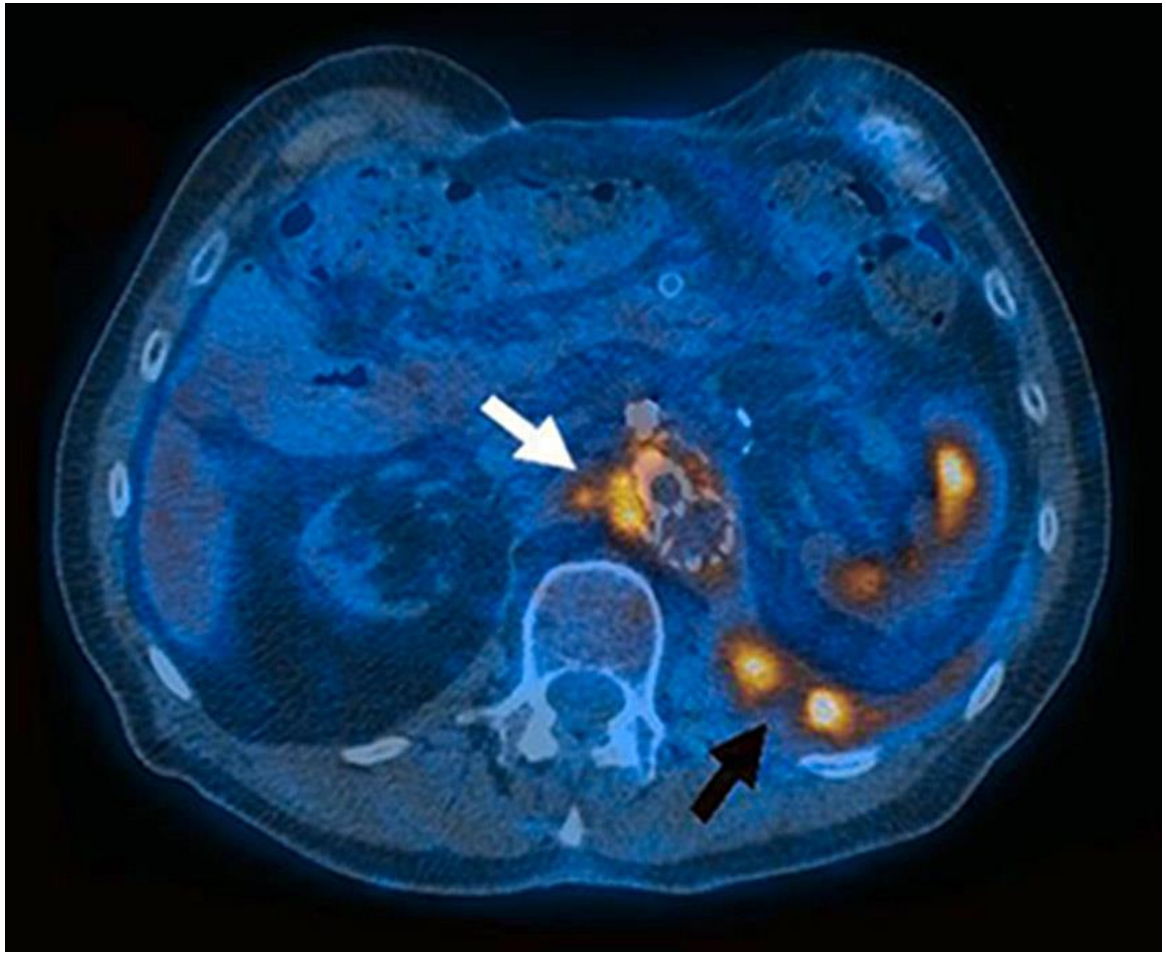
Ultrasound Imaging



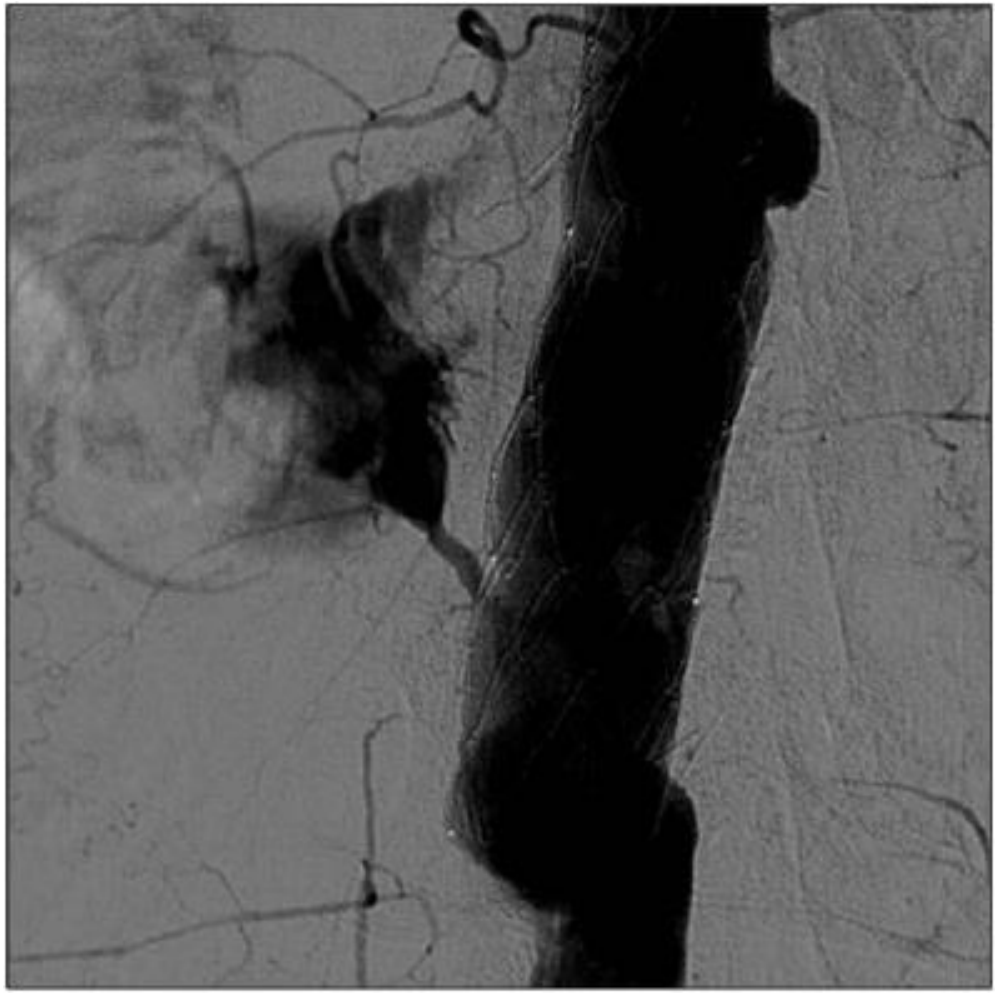
CT Imaging

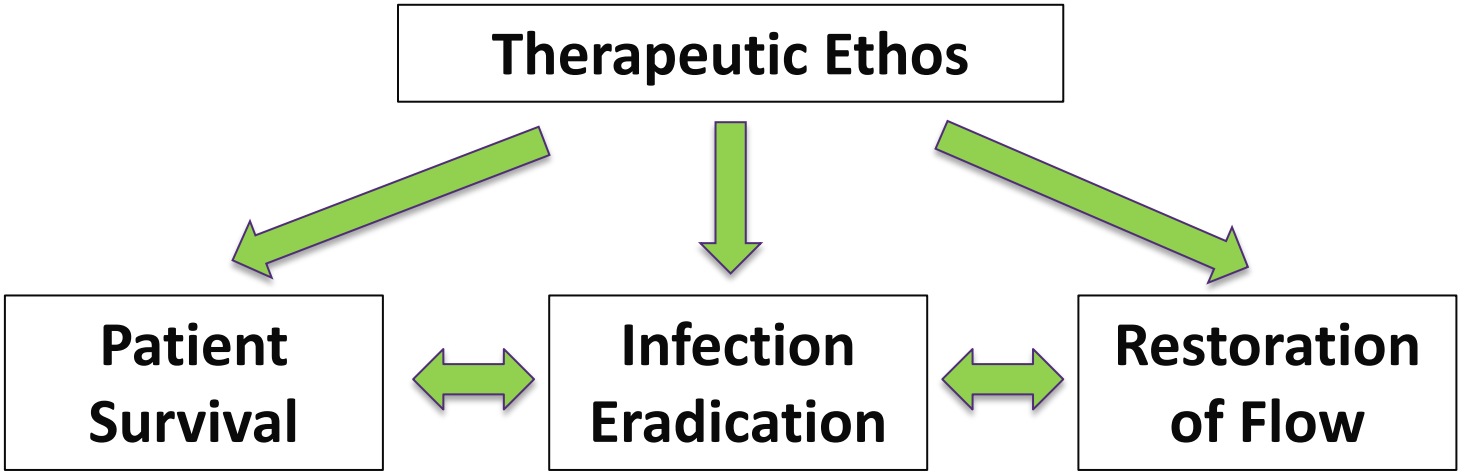


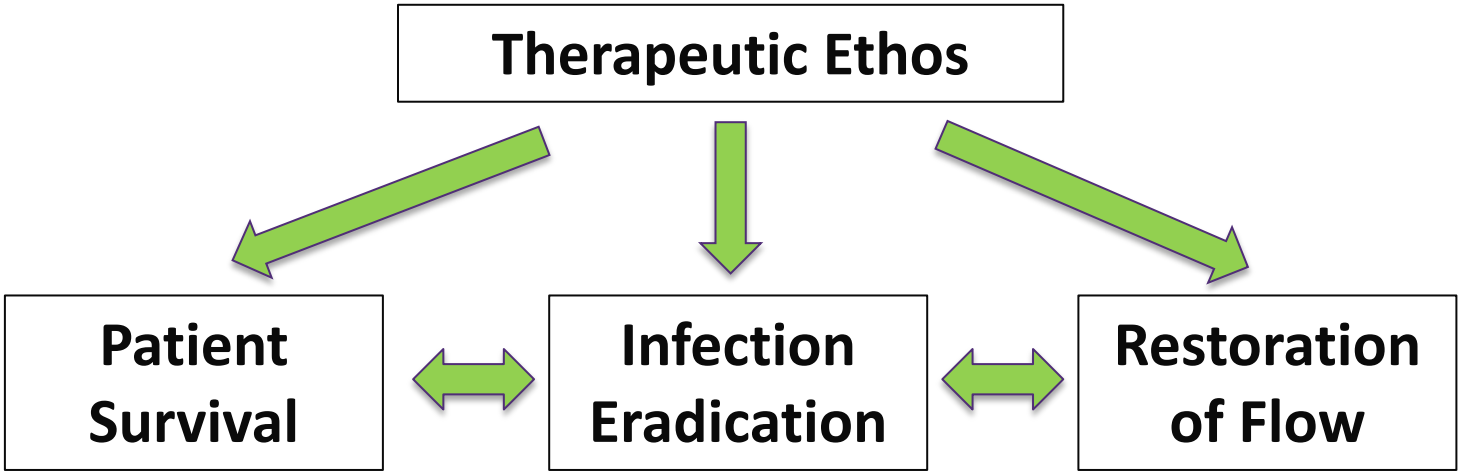
PET CT Imaging



Angiography




Therapeutic Ethos
Patient Survival
Infection Eradication
Restoration of Flow



Durable
+
Minimise
Re-infection

Management – General Principles

- Once infection confirmed, semi-urgent expert planning warranted to pre-empt catastrophic haemorrhage, graft thrombosis or systemic collapse.

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- An infected prosthesis, acting as a foreign body, is essentially extravascular rendering bacteria inaccessible to antibiotics.
- Conservative measures including prolonged antibiotic therapy, drainage & irrigation of abscesses and covering muscle flaps may be helpful and buy time. **BUT THEY ARE RARELY CURATIVE.**

Microbiological Evaluation

- Initial broad spectrum or hospital policy protocol based therapy.
- Culture result information gathering.
- Adjustment of antibiotic therapy.
- Consideration of long-term venous access.

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Type of Graft Infection	Time from Implantation	Microorganisms
Peri-prosthetic	Early	Staphylococcus aureus Streptococcus Escherichia coli Pseudomonas
	Late	Staphylococcus epidermidis
Entero-paraprosthetic	Late	Escherichia coli Enterococcus Bacteroides
Aorto-enteric Fistula	Early	Escherichia coli Staphylococcus aureus
	Late	Escherichia coli Klebsiella Staphylococcus epidermidis

Management – Considerations

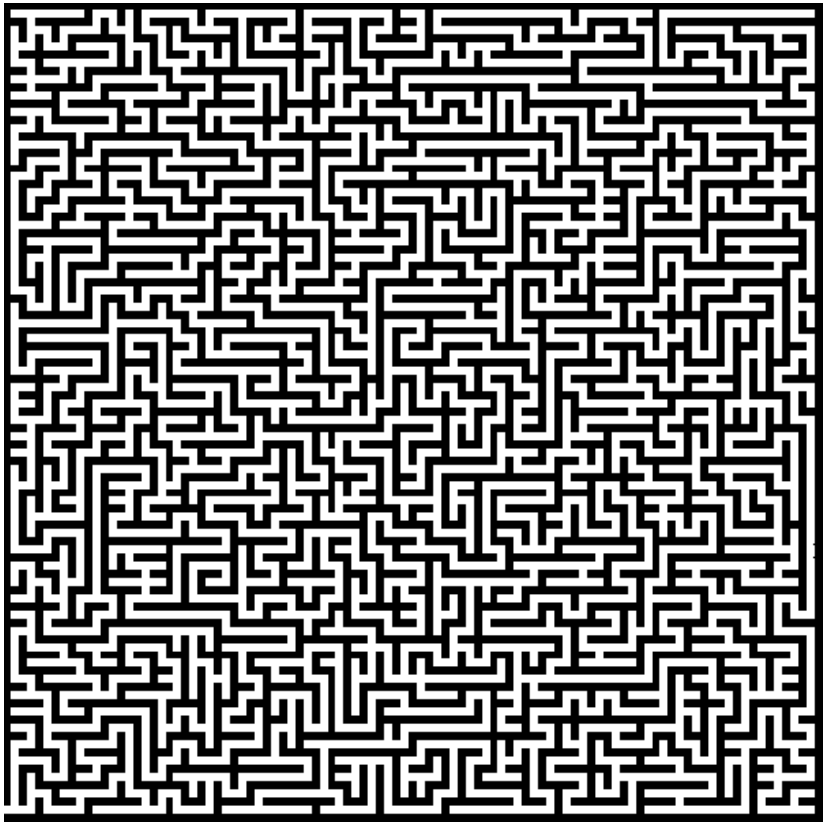
1) Graft excision.

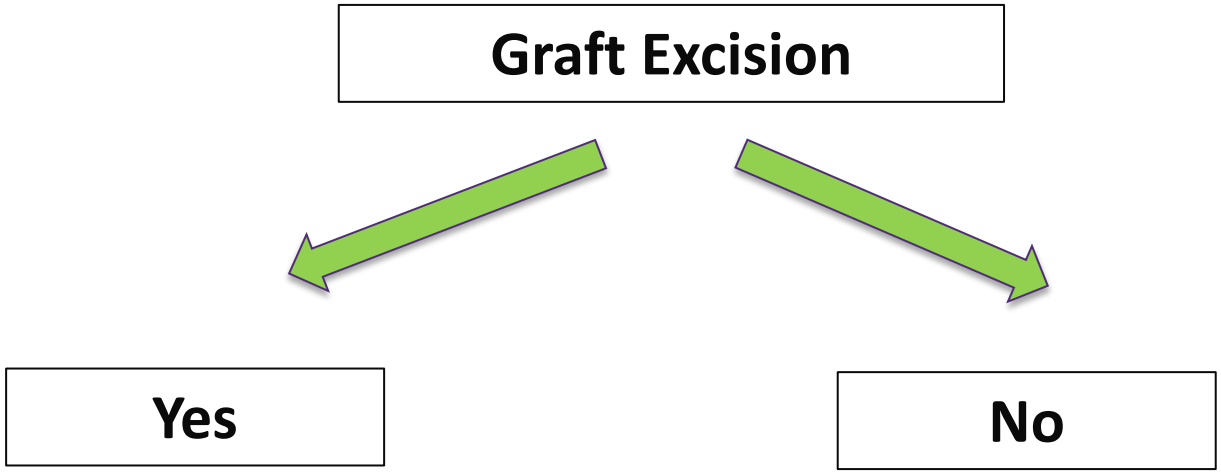
2) Surgical field debridement.

3) Restoration of vascular flow.

4) Intensive and prolonged antibiotic therapy.

Management Pathway

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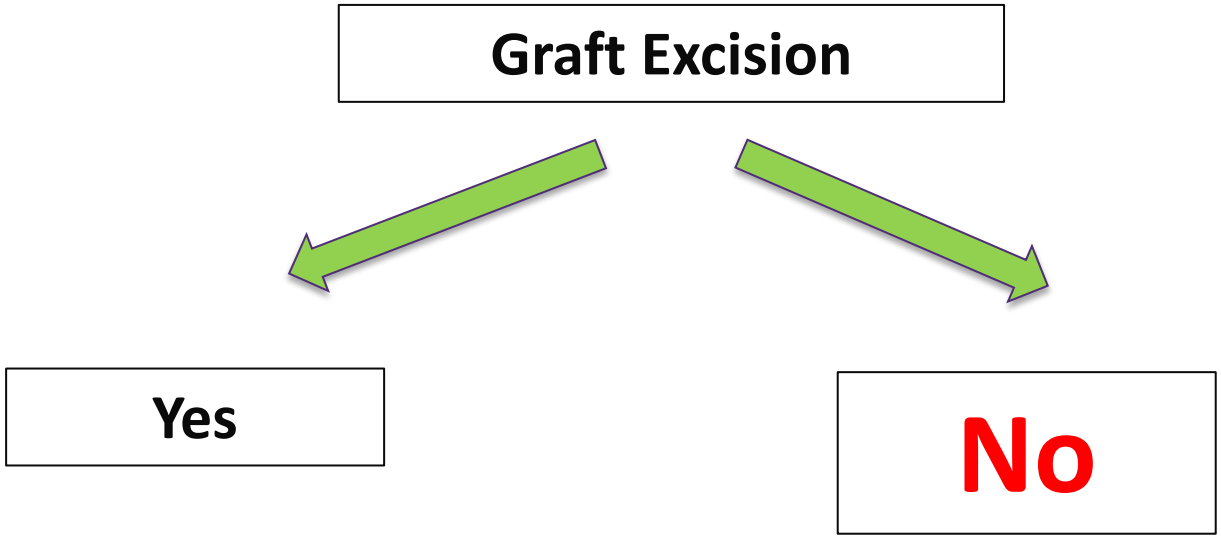
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No

Graft Excision

No

Graft Excision

No

- Palliative care.
- Long-term antibiotics.
  - Systemic.
  - Topical.
- Drainage:
  - Percutaneous.
  - Open.

Clinical Evidence

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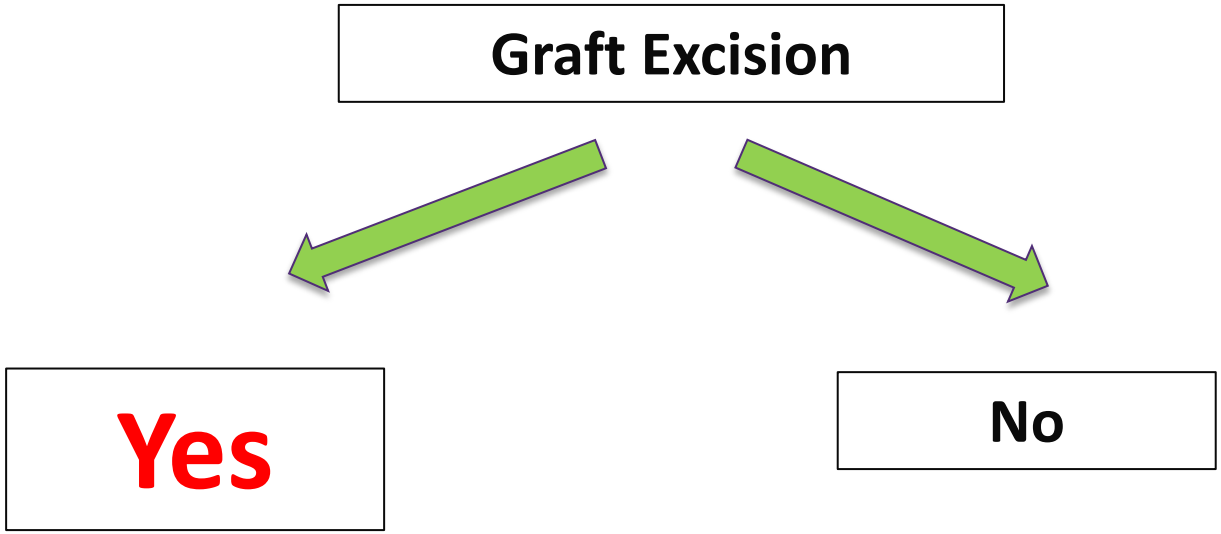
  - Conventional treatment was precluded due to patient co-morbidity or hostile abdomen.
  - Successful complete graft preservation in 4 patients.
  - Two early deaths due to sepsis.
  - The other 7 patients survived hospitalisation with no recurrent infections over mean follow-up of 7.6 years.
  - One patient required limb amputation.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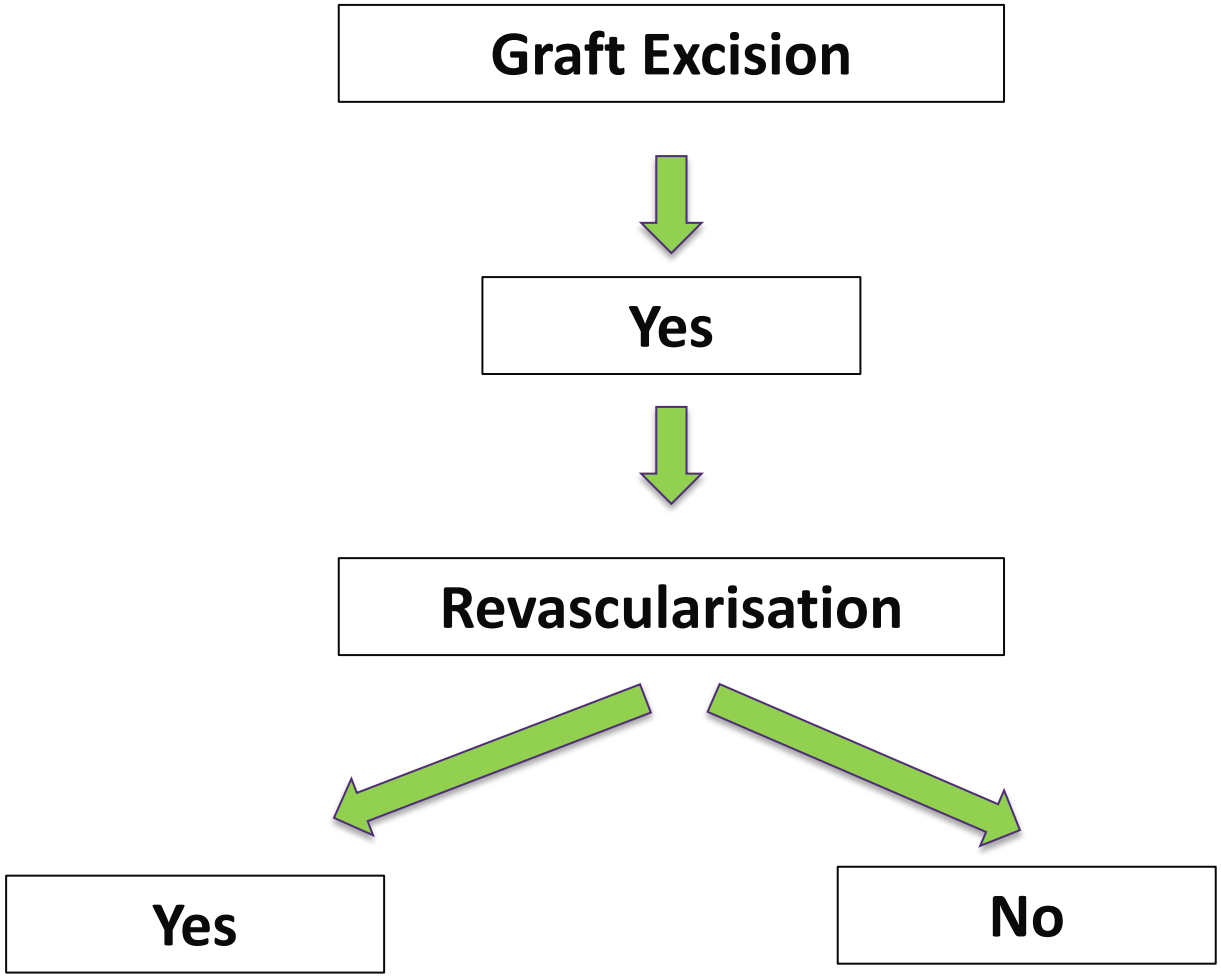
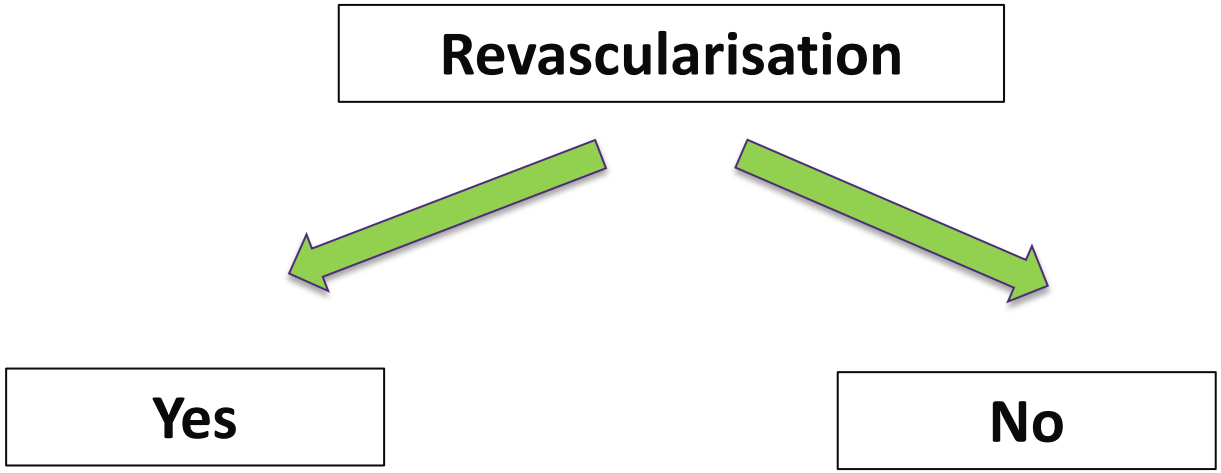

Graft Excision
Yes
Revascularisation
Yes
No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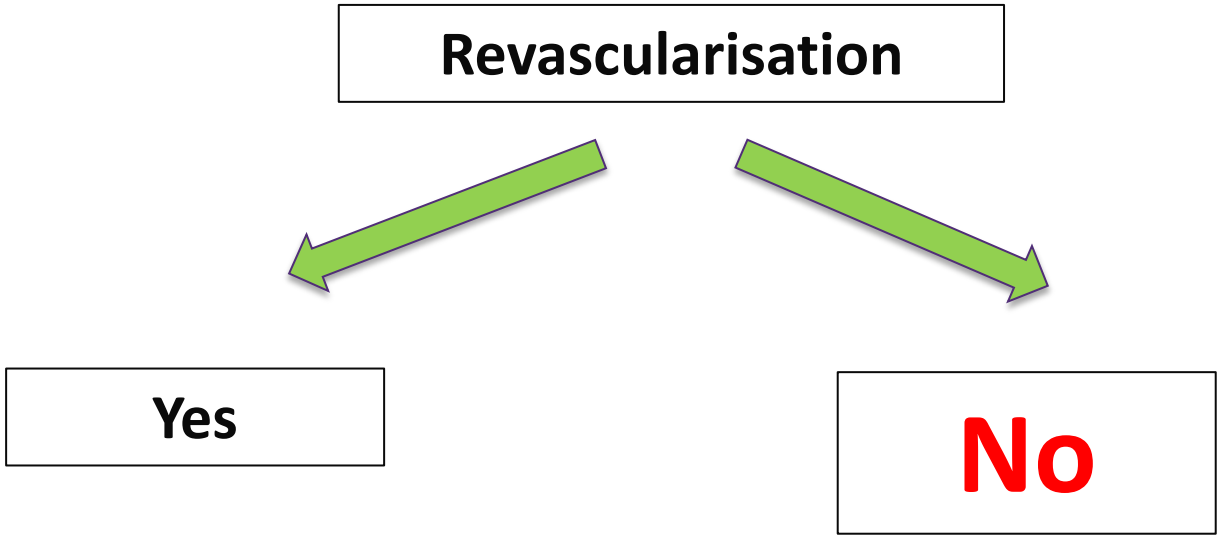
Revascularisation
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Revascularisation

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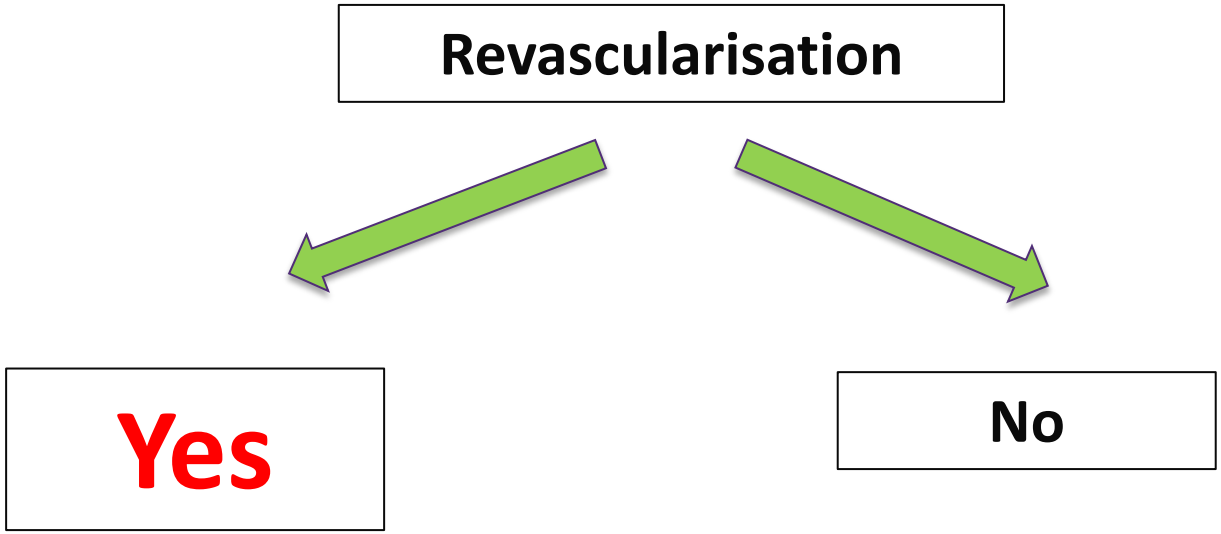
- Ligation:
  - Stump blow-out.
  - Ischaemia.
  - Amputation.
  - Organ failure.
  - Death.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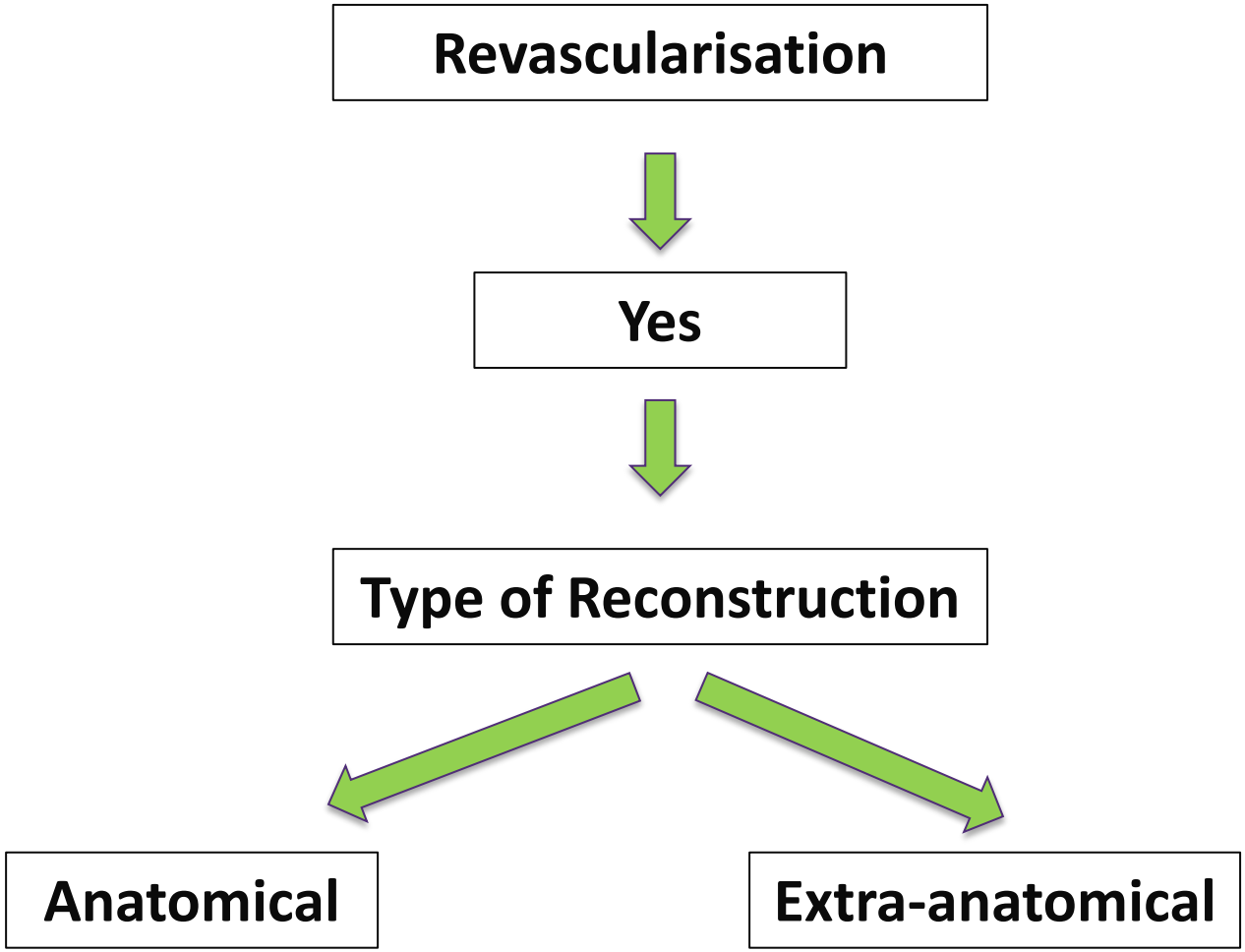
Revascularisation
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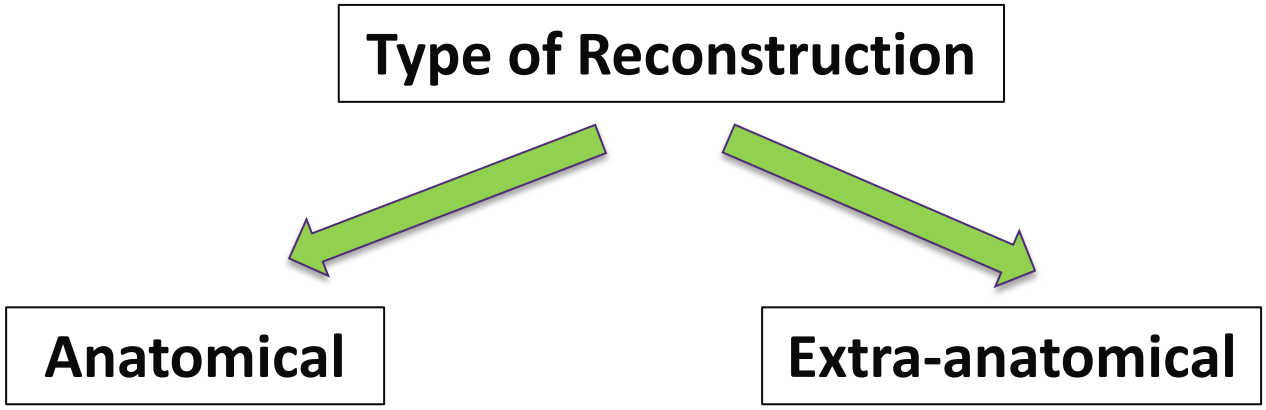
Type of Reconstruction
Anatomical
Extra-anatomical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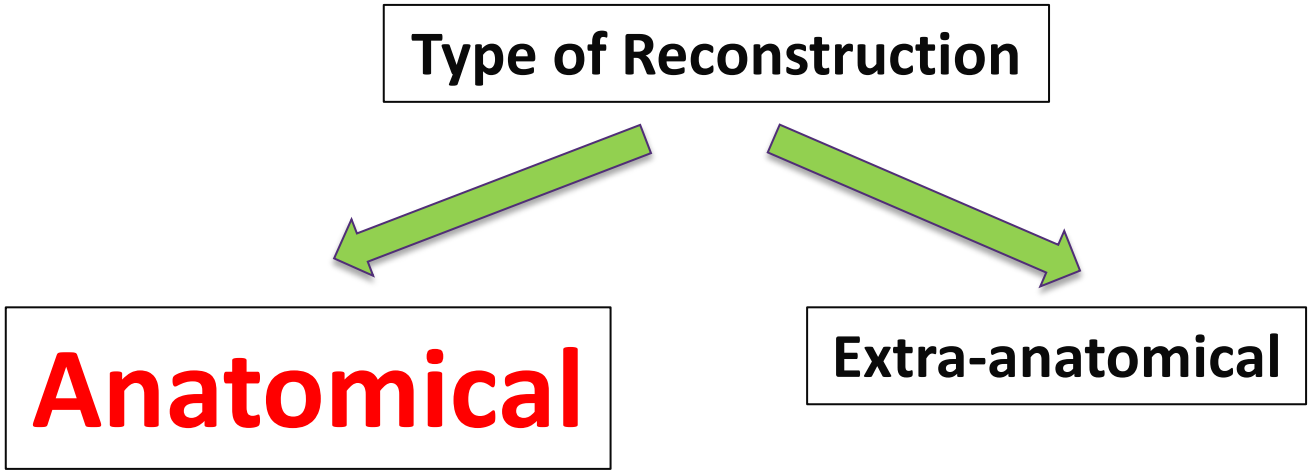
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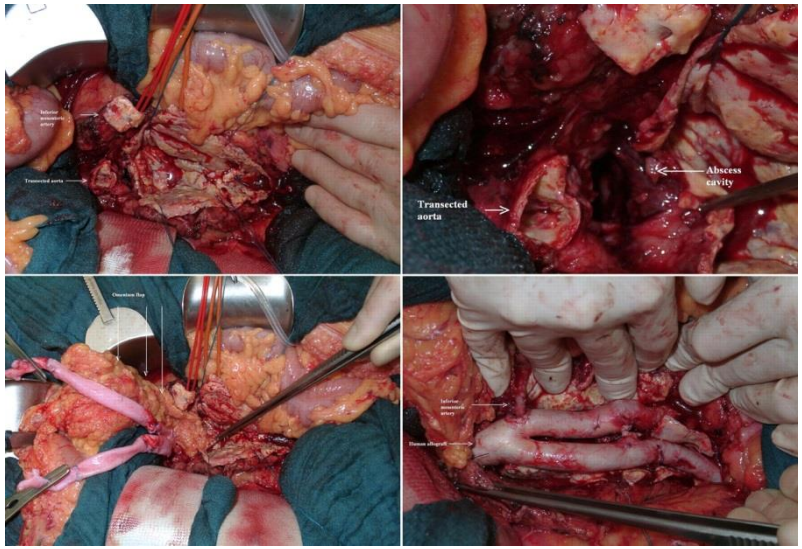

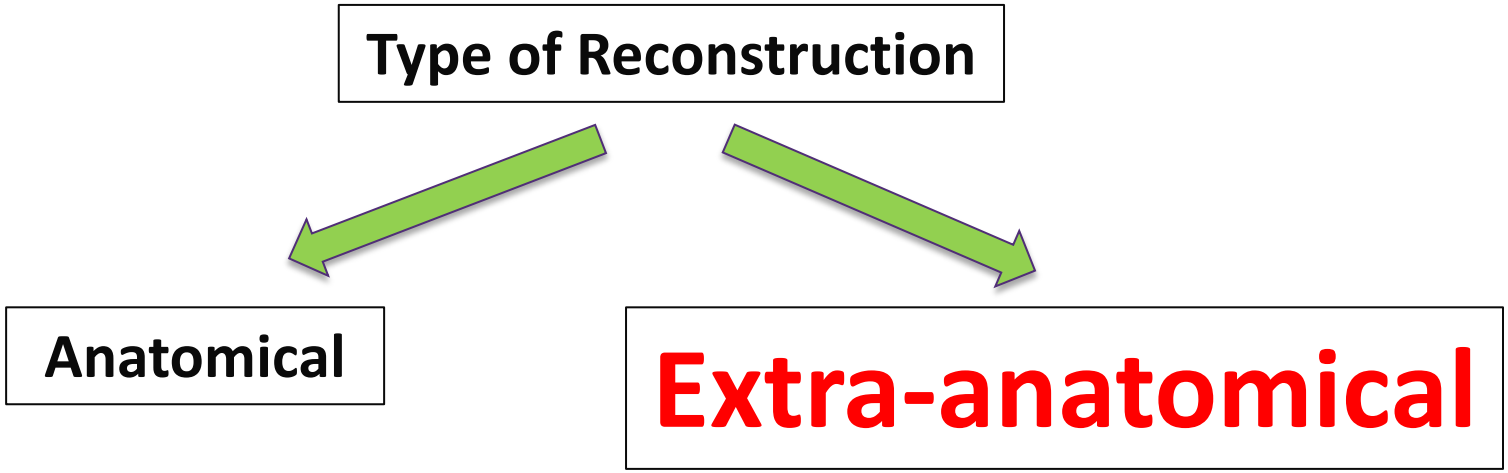
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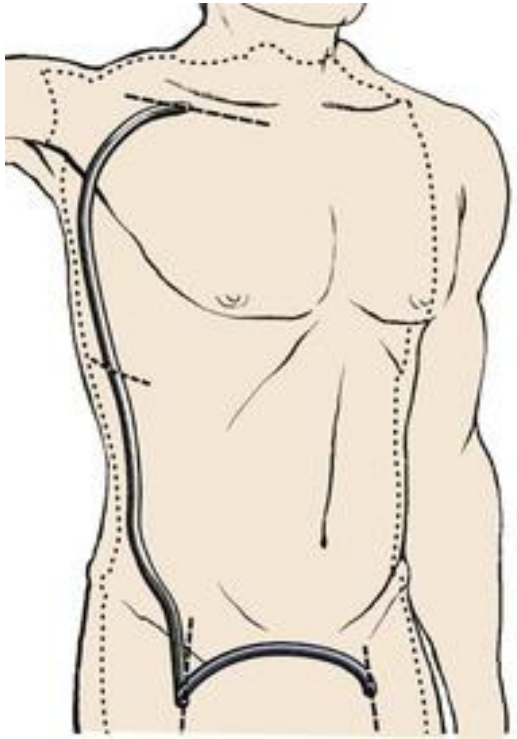

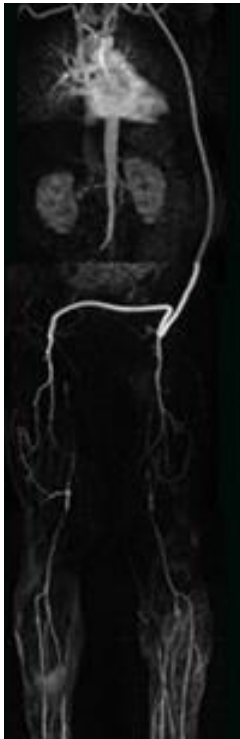

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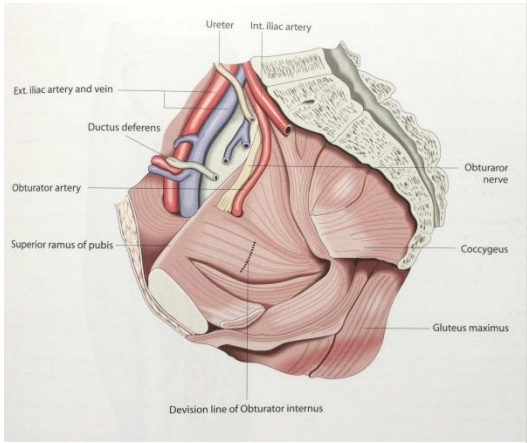
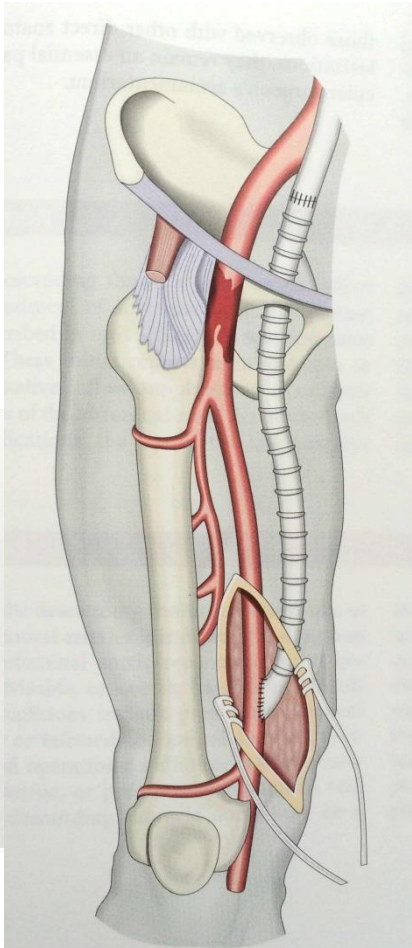
- **Groin - Obturator bypass.**





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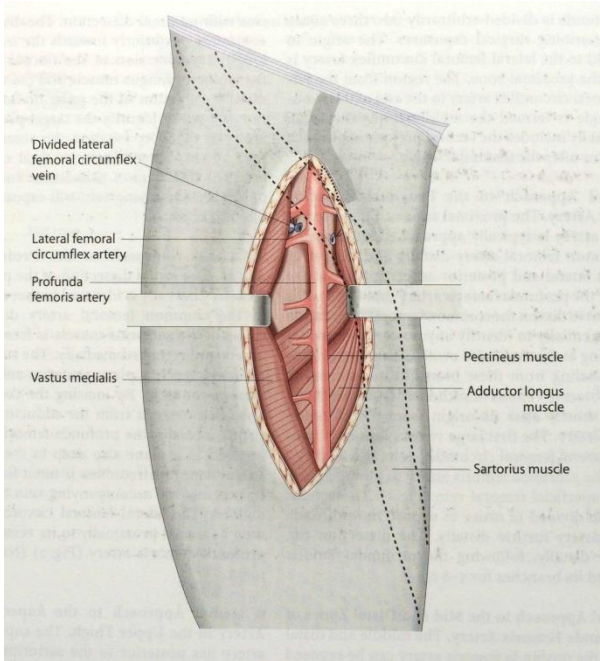
- Aorta - Axillo-femoral bypass.
- Groin - Obturator bypass.
- **Lower limb - Lateral bypass strategies.**



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Choice of Conduit for Vascular Graft Infections

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Le Maitre Mini-Symposium
Midland Hotel - Manchester
1st December 2016

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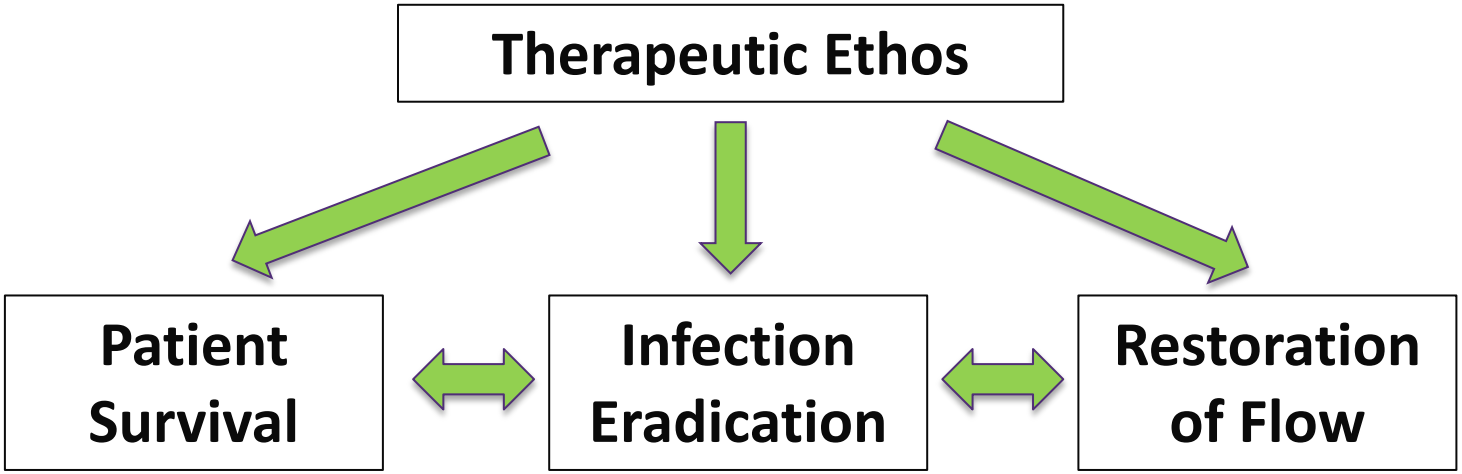
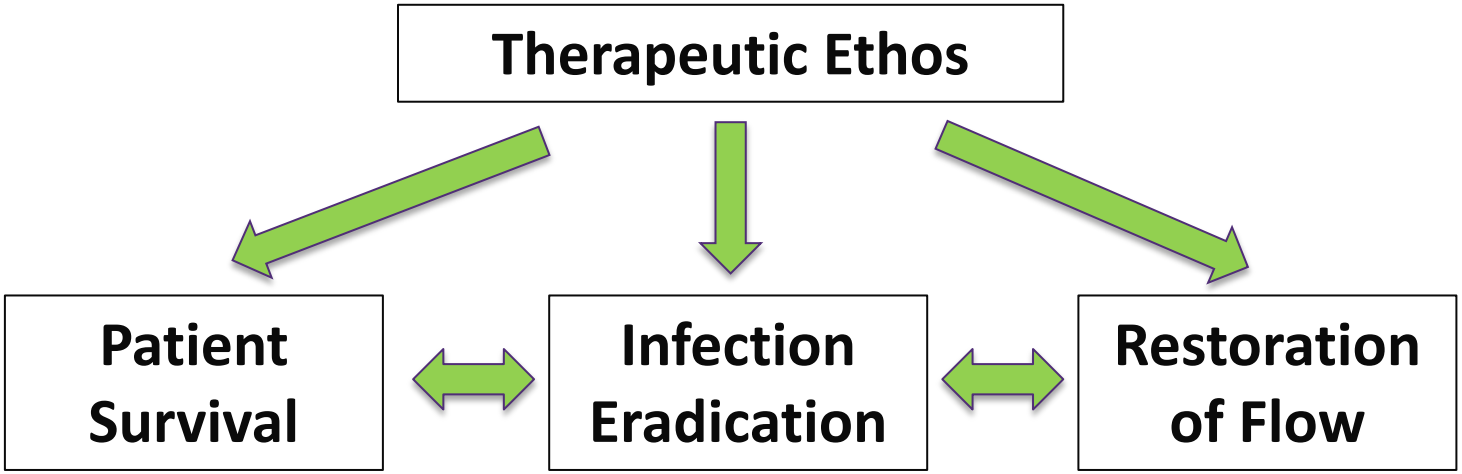
Disclosure

- Pending consultatory role with LeMaitre for registry.

Learning Outcomes

- Exploration of available conduits for graft replacement.
- What is a bioprosthetic graft ?
- Global experience of bioprosthetic grafts.
- Royal Blackburn Hospital case series.
- Omniflow Graft Tips and Tricks.


Therapeutic Ethos
Patient Survival
Infection Eradication
Restoration of Flow



Durable
+
Minimise
Re-infection

Reconstructive Conduit

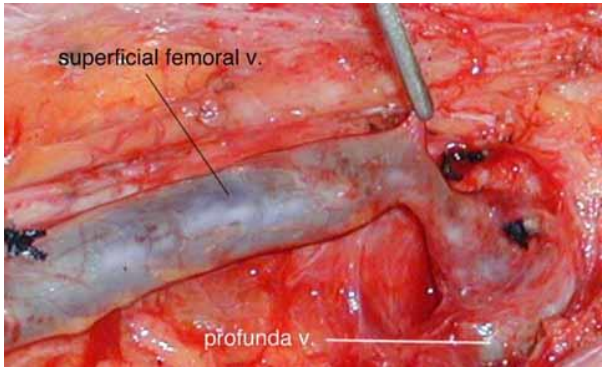
- Autograft
- Allograft
- Xenograft
- Bioprosthetic
- Prosthetic

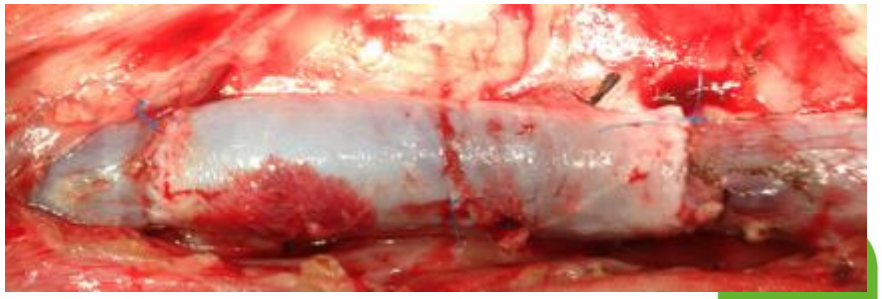
Lowest Infection

Highest Infection

Autograft

- Superficial femoral vein;
  - Useful when larger calibre vessel required – 10 to 12mm diameter – aortic, fem-fem bypasses.
  - SFV can be harvested to knee level even if great saphenous vein absent.
  - Bilateral harvesting for reconstitution of a bifurcated graft.
  - Essential to maintain continuity of profunda femoris vein.
  - Post-operative compression useful adjunct to minimise swelling.



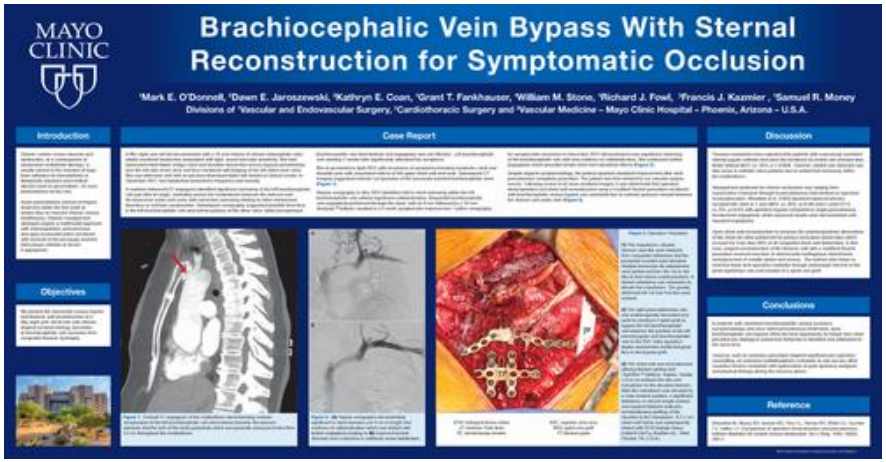


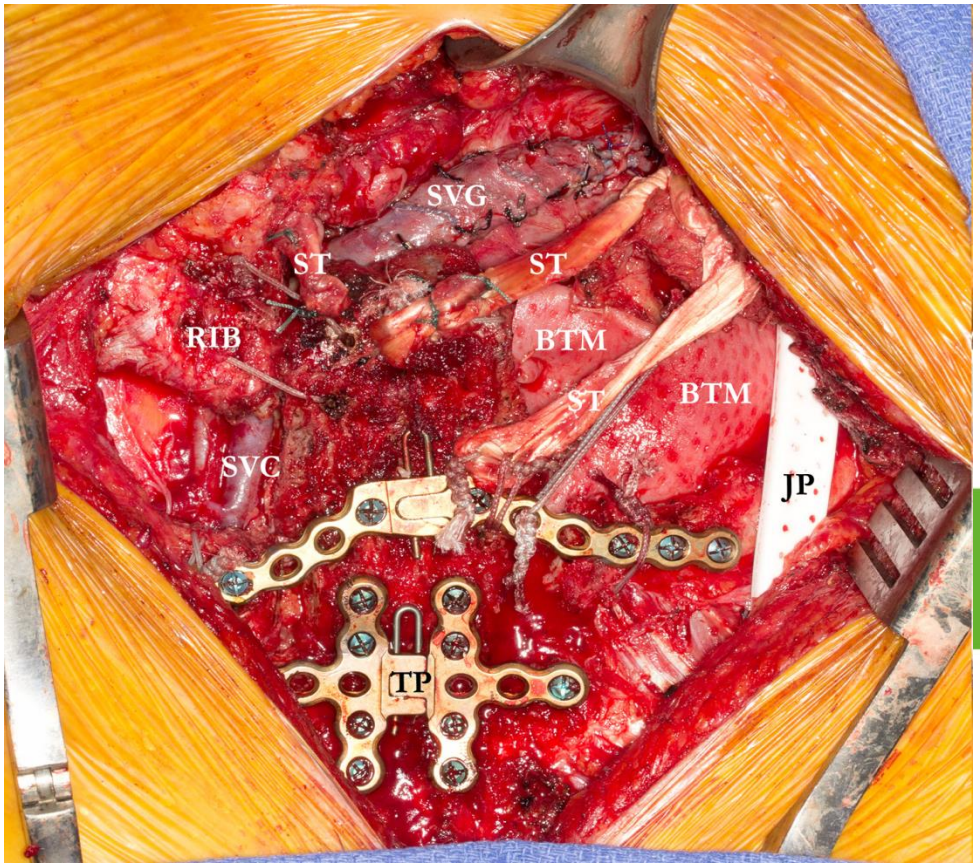
Clinical Evidence

- Clagett *et al* (1993) - 187 aortic reconstruction patients;
  - 30-day mortality – 10%.
  - 5% graft re-infection rate in first 14 days.

Autograft

- Great saphenous vein;
  - Construction of spiral vein graft around a chest drain / dilator.





Autograft

- Potential other options;
  - Internal iliac artery.
  - Superficial femoral artery.
  - Radial artery.

Allograft

- Cryopreserved grafts;

Allograft

- Cryopreserved grafts;
- Arterial:
  - Aortic tube.
  - Aorta and branches.
  - Femoral artery.

Allograft

- Cryopreserved grafts;

- Arterial:
  - Aortic tube.
  - Aorta and branches.
  - Femoral artery.

- Venous:
  - Femoral vein.
  - Saphenous vein.
  - Umbilical vein.

Clinical Evidence

- Keiffer *et al* (2004) - 179 consecutive aortic reconstruction patients;
  - Fresh vs. Cryopreserved allografts.
  - Early post-operative mortality – 20%.
  - One-year survival – 73%.
  - Greater bacterial resistance with cryopreserved grafts.

- Zhou *et al* (2006) – 36 aortic graft infections;
  - In-situ reconstruction with cryopreserved allografts.
  - No intraoperative deaths.
  - Overall mortality – 21%.
  - No allograft infection, disruption or degeneration at mean follow-up of 12.5 months.

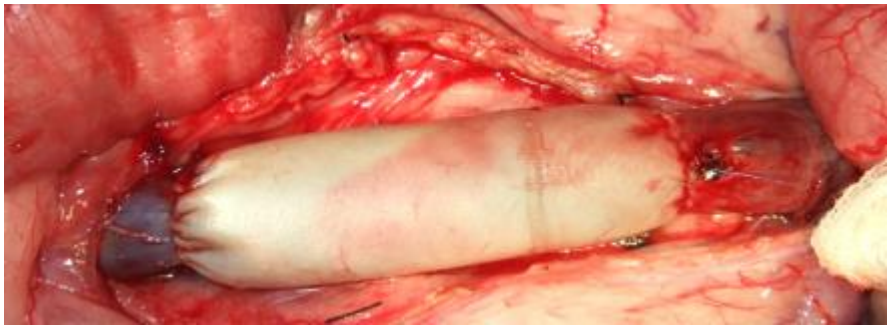
Clinical Evidence

- Bisdas *et al* (2010) – 42 aortic graft infections;
  - In-situ reconstruction with cryopreserved allografts.
  - 30-day mortality – 9% over median follow-up of 36 months.
  - 3-year survival – 81%.
  - 89% freedom from re-operation.
  - Aneurysmal degeneration in one patient.

- Further experience with same group – 56 patients;
  - 30-day mortality - 14%.
  - 2-year survival – 82%.
  - Limb salvage - 96%.
  - Graft patency – 100%.

Xenograft

- Bovine pericardial patch.



Clinical Evidence

- Case Reports …….

Clinical Evidence

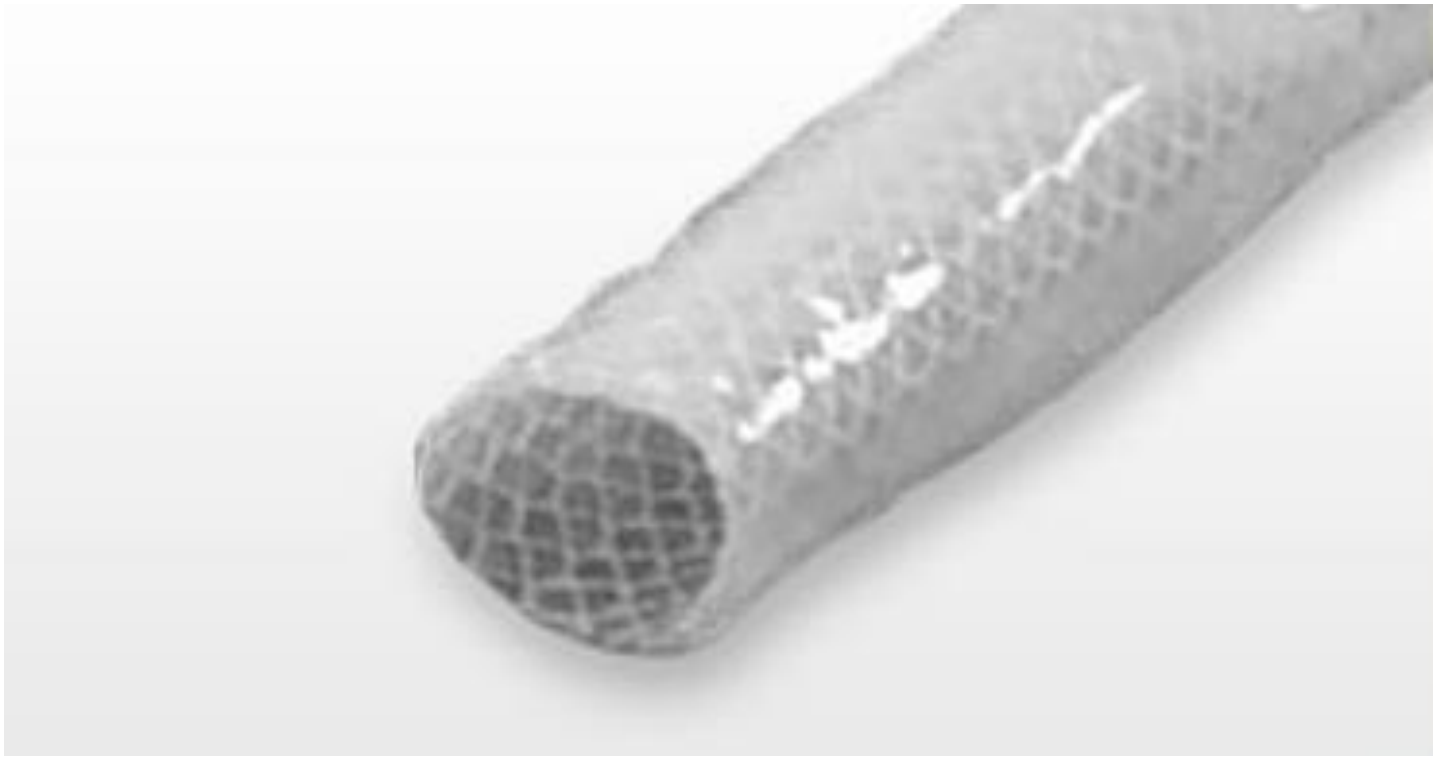
- Case Reports …….

- Abdullah *et al* (2003) – SVC obstruction;
  - Superior vena cava bypass using bovine pericardium in a patient with recurrent bilateral thrombophlebitis and thrombosed saphenous veins.

- Hyams *et al* (2011) – Renal cell carcinoma (n=17);
  - Bovine pericardial patch grafting reconstruction of inferior vena cava in 8 patients.

- Wachtel *et al* (2015) – Primary IVC leiomyosarcoma (n=6);
  - Inferior vena cava patch repair in 2 patients.

Bioprosthetic Graft?



Prosthetic

- Plain dacron / PTFE grafts.
- Rifampicin soaked grafts.
- Silver impregnated grafts.
- Silver acetate and triclosan impregnated grafts.

Clinical Evidence

- Hayes *et al* (1999) – 11 patients treated with rifampicin soaked grafts after total excision of the infected aortic graft;
  - 30-day mortality 18% & late mortality 36%.
  - Both deaths (early = 1, late =1) had previous surgery for rAAA.

- Bandyk *et al* (2001) – 22 patients with aortic graft infections;
  - One death reported not related to graft infection.
  - No amputations or deaths due to graft sepsis at mean follow-up of 17 months.

- Bisdas *et al* (2010) – 11 out of 56 patients treated with silver-coated grafts;
  - 30-day mortality - 18%.
  - 2-year mortality – 27%.
  - 2 –year limb salvage and graft patency – 100%.

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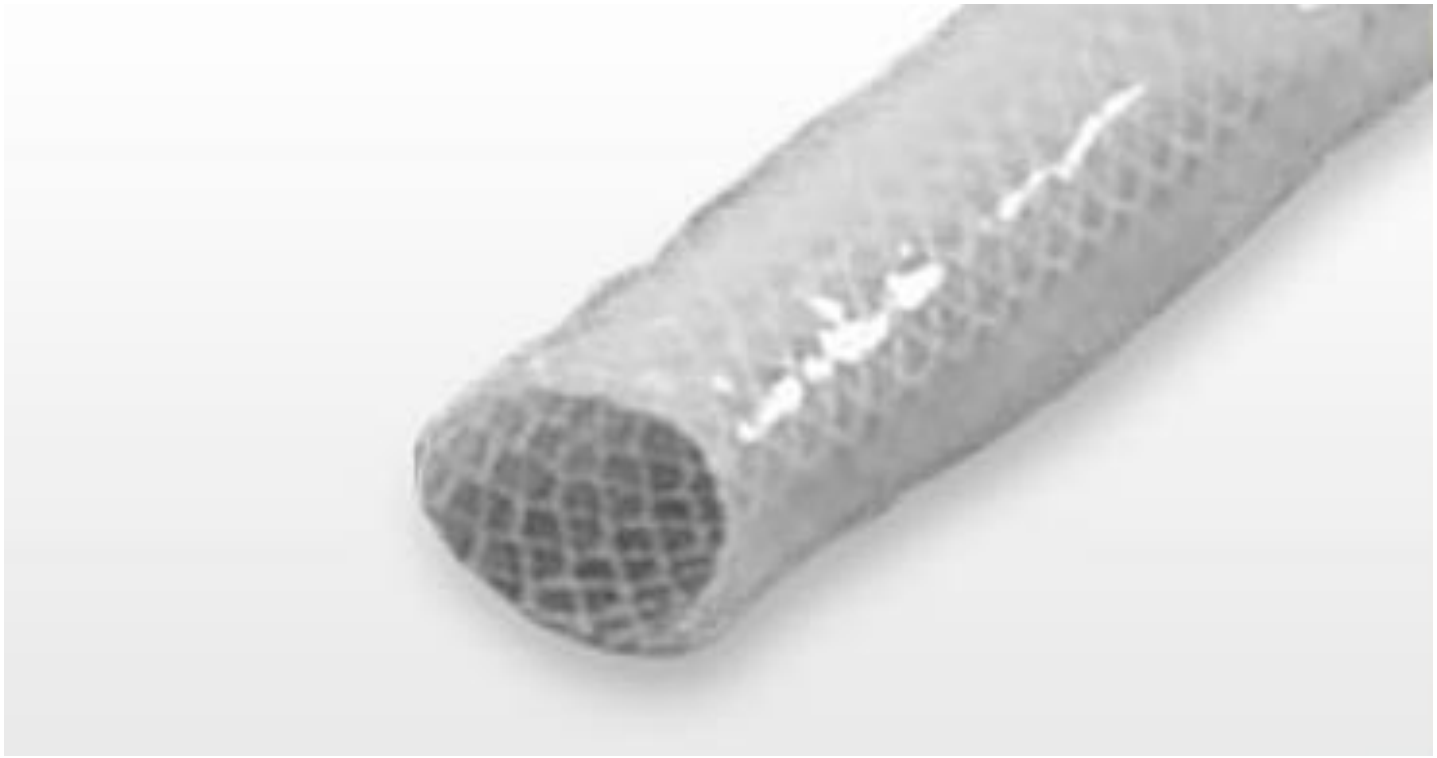
What is a Bioprosthetic Graft?



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Bioprosthetic Omniflow Graft

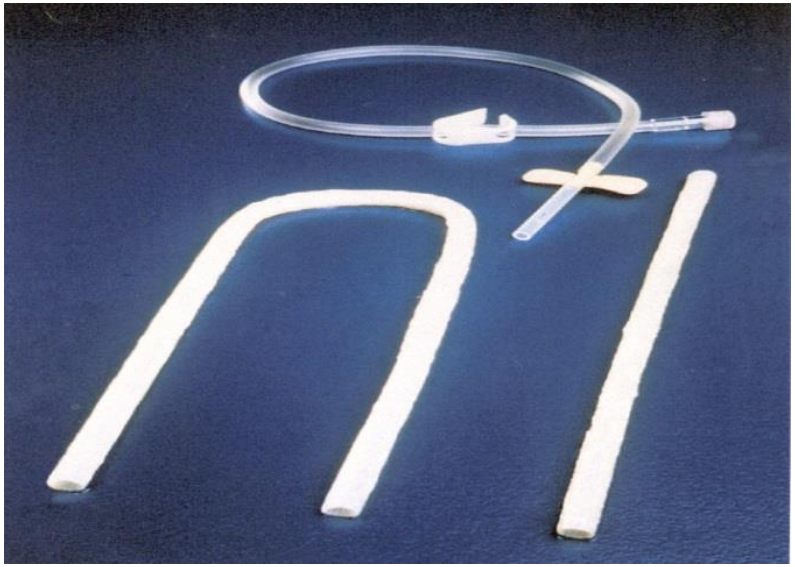
- Composite of cross-linked ovine collagen with a polyester mesh endoskeleton.

Bioprosthetic Omniflow Graft

- Composite of cross-linked ovine collagen with a polyester mesh endoskeleton.
  - Collagen structure is non-antigenic and stable many years after implantation.
  - Polyester mesh provides strength and durability with resistance to aneurysm formation.
  - Wall is impervious to luminal tissue ingrowth assisting long-term patency.

Available Grafts

- Diameter:
  - 5, 6 and 8mm.



- Shape:
  - Straight.
  - Curved.

- Length:
  - Straight 20, 35, 40, 45, 50, 55, 60 and 65cm.
  - Curved – 30, 35, 40, 45cm – (6mm diameter).

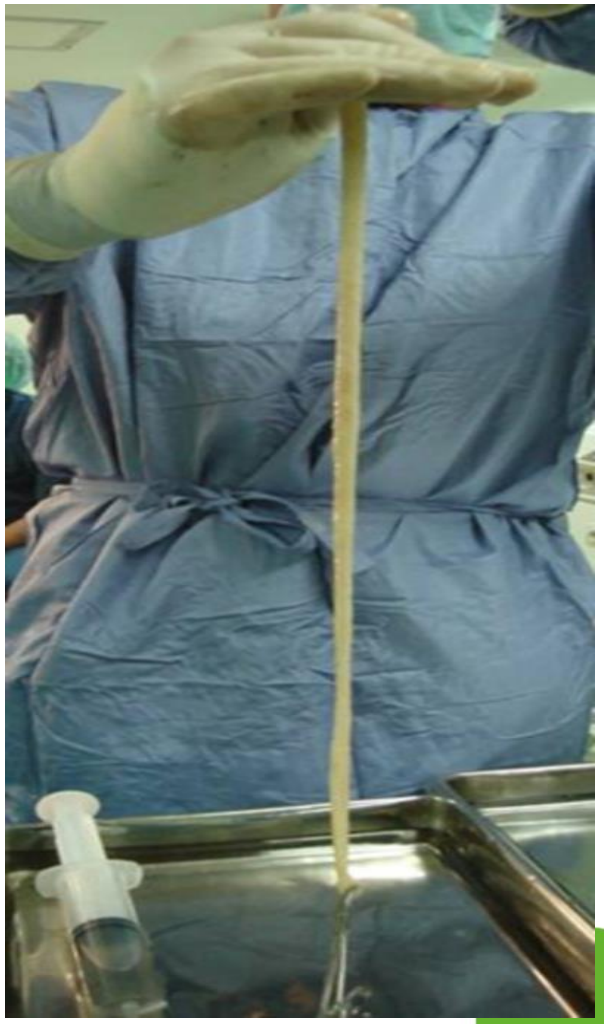
Uses ?

- When ?
  - Primary conduit.
  - Suitable autograft not available.
  - Infected prosthetic graft.
  - Dialysis access.

- Where ?
  - Anywhere.

Graft Preparation

- Remove graft from packaging tube.
- Rinse twice with 20mls saline.
- Fill graft with 50,000 units of heparin leave in-situ for at least 10 minutes in a saline bowl.



Advantages & Disadvantages ??

- Advantages;
  - Biocompatible with an autologous vein like morphology.
  - Haemocompatible.
  - Non-porous.
  - Good compliance.
  - Comparable patency.

Advantages & Disadvantages ??

- Advantages;
  - Biocompatible with an autologous vein like morphology.
  - Haemocompatible.
  - Non-porous.
  - Good compliance.
  - Comparable patency.

- Disadvantages;
  - Long-term durability / patency.
  - Potential lack of exo-skeleton scaffold.
  - Cost.

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Global Experience

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Global Experience

- Koch *et al* (1997);
  - 274 Omniflow implants for femoro-popliteal or crural bypasses.
  - The patency rate for above knee bypasses after 3 years was 61.9% with good vascular periphery and 44% with poor vascular periphery.
  - For below knee bypasses, the patency rate was 55.4% with good and 35.3% with unfavourable vascular periphery.
  - Patency for the femorocrural bypass was 28.7% after 2 years.
  - The rate of infection was 0% while aneurysmal formation occurred in three patients (1.1%).

Global Experience

- Dünschede *et al* (2015);
  - Retrospective study of 141 femoral-popliteal artery bypasses for intermittent claudication, critical limb ischaemia, popliteal artery aneurysm and acute limb ischaemia between 2006 and 2013.
  - Primary and secondary patency was 34% and 69% after 5 years respectively.
  - Limb salvage 95%.

Global Experience

- Dünschede *et al* (2015);
  - Retrospective study of 27 crural bypasses for critical limb ischaemia between 2007 and 2012.
  - 12 crural bypasses were completed with an adjuvant distal arteriovenous fistula in the presence of severely impaired intraoperative runoff or revision for early failure.
  - 15 bypasses were performed in the crural position without fistula.
  - The limb salvage rate after a median observation time of 19 months was 92% in the fistula and 60% in the non-fistula group.

Global Experience

- Dünschede *et al* (2016)
  - Prospective study evaluating 123 critically ischaemia patients bypassed between 2006 and 2014.
  - 62 femoral-popliteal bypasses performed with primary and secondary patency rates of 34% and 69% respectively after 5 years. Limb salvage reported at 98%.
  - 61 crural bypasses performed with primary and secondary patency rates of 32% and 34% respectively after 5 years. Limb salvage reported at 70%.

Vascular Graft Infection – The Problem !!!!

Evidence for Omniflow Graft ??

Global Omniflow Experience for Graft Infection

- Witberger *et al* (2014);
  - Nine consecutive patients between 2010 and 2012 who had replacement of an infected peripheral graft with an Omniflow graft.
  - Mean presentation 12-months post-primary procedure with positive microbiology cultures reported in 7 patients.
  - Successful surgery in all patients.
  - One patient had high above knee amputation due to clinical deterioration.

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  - One patient had high above knee amputation due to clinical deterioration.

- **Primary and secondary patency rates were 66.6% and 78% respectively (mean follow-up 19 months).**

Global Omniflow Experience for Graft Infection

- Fellmer *et al* (2014);
  - Eight patients - 5 positive cultures and 3 no growth.
  - One amputation due to clinical deterioration and one unsuccessful thrombectomy.
  - Following graft replacement 7 out of 8 patients deemed cured with no evidence of infection (mean follow-up 8 months).

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  - One amputation due to clinical deterioration and one unsuccessful thrombectomy.
  - Following graft replacement 7 out of 8 patients deemed cured with no evidence of infection (mean follow-up 8 months).

- **Primary and secondary patency rates were 63% and 75% respectively (mean follow-up 12 months).**

- **Limb salvage 88%.**

Global experience in Graft infection

- Krasznai *et al* (2015);
  - Omniflow graft was used for in situ reconstruction after excision of infected aortic grafts in three cases.
  - One patient suffered from graft reinfection.
  - No occlusion, anastomotic dehiscence, degeneration, rupture or structural integrity concerns reported (mean follow-up of 2.2 years).

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Royal Blackburn Hospital Experience

Royal Blackburn Hospital Experience

- Recent Omniflow introduction to our Trust in 2016.

- Four patients (5 implants);
  - All male.
  - Mean age = 63.8 (range 51-85) years.

- Indication for Omniflow graft implantation;
  - Short distance claudication = 2.
  - Critical ischaemia = 2.
  - Prosthetic graft sepsis = 1.

Royal Blackburn Hospital Experience

- All patients had femoral-AK popliteal bypass.
- Successful Outcomes 60%;
  - 3 patients have patent grafts at mean follow-up of 125 (range 57 – 207) days.
- Graft failures due to occlusion 40%;
  - One patient at day-8 due to kinking just proximal to distal anastomosis.
  - One patient at day-74 despite attempts at endosalvage due to absent run-off vessels.

Tip and Tricks – Learning Curve

- Graft Modelling - Cut anastomotic ends as for prosthetic grafts.

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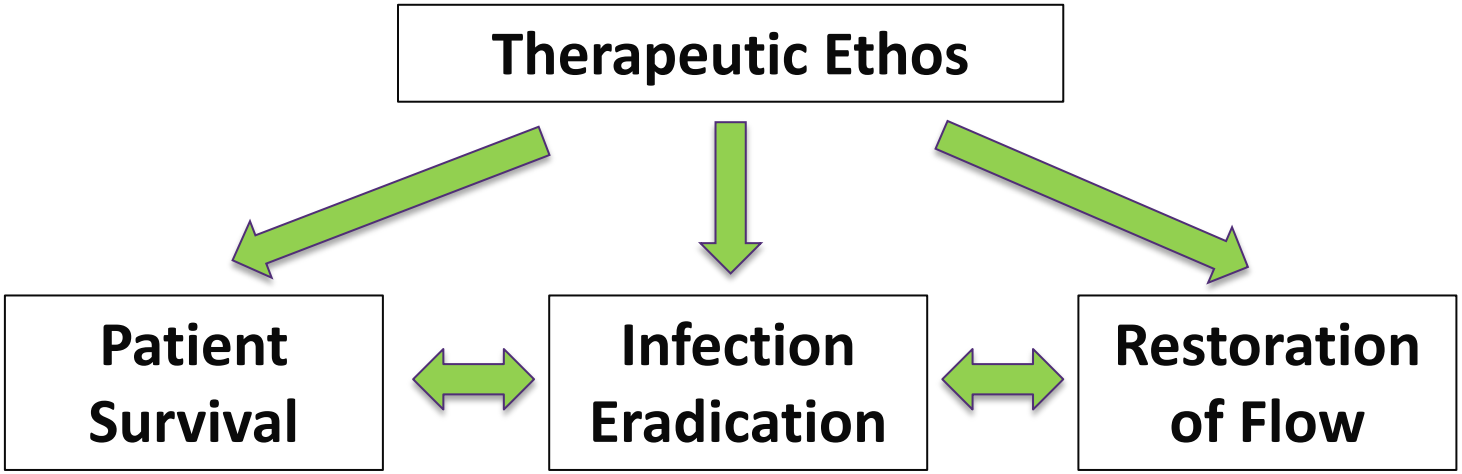
Tip and Tricks – Learning Curve

- Graft Modelling - Cut anastomotic ends as for prosthetic grafts.
- No role for graft laxity – snug fit essential.
- If replaced in an infected field give the graft the best chance with adherence to long-term antibiotic protocols.



Durable
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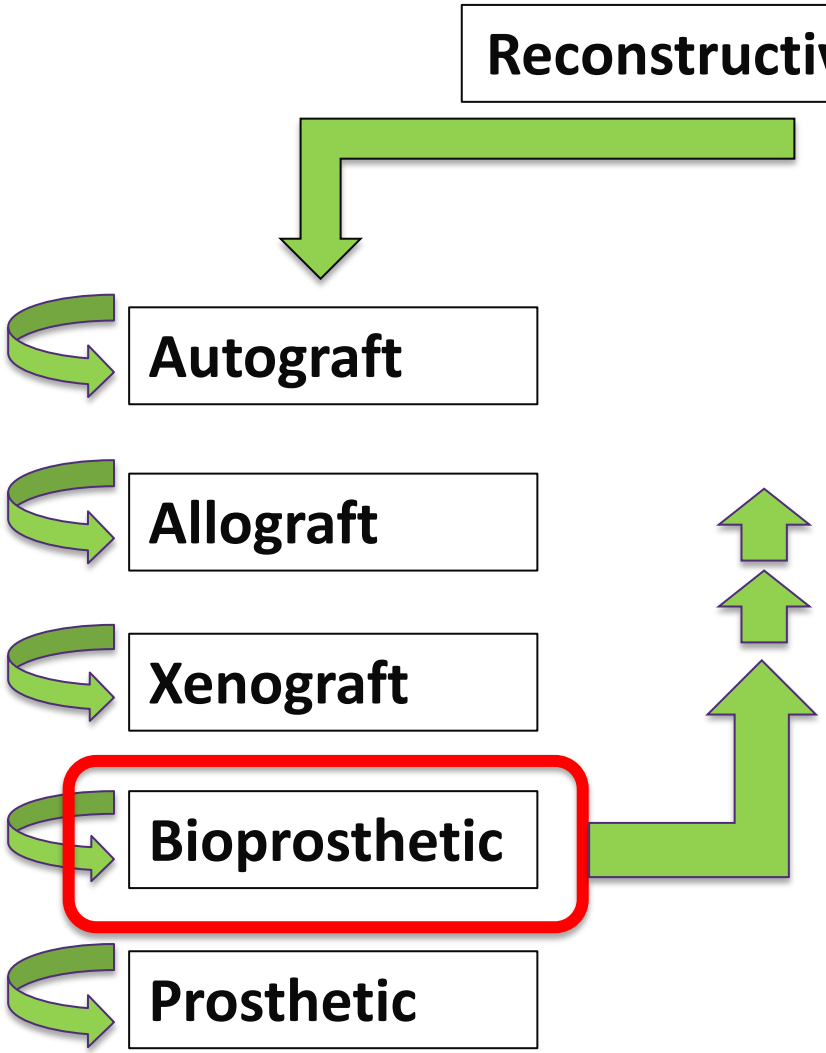
Minimise
Re-infection



Lowest Infection

Highest Infection

Conclusion

- Despite our early experience we have learnt a lot.
- Our graft failures represent surgical learning curve and desperation in a young patient.
- Graft success in an infected field.

Conclusion

- Despite our early experience we have learnt a lot.
- Our graft failures represent surgical learning curve and desperation in a young patient.
- Graft success in an infected field.
- There is a need of multicentre registry to evaluate use of bioprosthetic graft as a primary and secondary salvage conduit.

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The Omniflow II Registry

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Disclosure

- Pending consultatory role with LeMaitre for registry.

Learning Outcomes

- Current UK Omniflow use.
- Rationale for a National Registry.
- Registry End-Points.
- Data Collection.
- Results Dissemination.

Current Omniflow Usage

- 27 Specialist Vascular Units throughout GB&I.
- A further 10 units have expressed a clinical interest.
- Grafts implanted vary between 1 and 16 per team.
- Approximately 100 implantations projected for 2016.

Rationale for National Registry

- Current literature describes solitary unit-based data.

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  - Role of graft as a primary conduit.

- Graft has been approved for use and is not a research product – however improved confidence in graft usage warranted.

A Retrospective Registry will evaluate where we are right now and is not going to replace the role of an RCT

Registry End-Points

- Primary;
  - Patency – primary and secondary.
  - Graft infection / failure.
  - Major limb loss.
  - Mortality.

- Secondary;
  - Hospital admission duration.
  - Cost.

Data Capture

- Each implanting surgeon will be approached to include their patient in the registry.

- Consideration of data capture tool;
  - Paper record.
  - Electronic carrier eg. Survey Monkey.

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- Consideration of data capture tool;
  - Paper record.
  - Electronic carrier eg. Survey Monkey.

- Clinical Governance via Ulster University with collation of data using a password protected internal server.

Data-Sets

- Demographics.
- Symptomatology.
- Operative Procedure.
- Discharge Planning.
- Follow-up.

Registry Data Dissemination

- All contributors will be acknowledged in all future presentations and publications.

Registry Data Dissemination

- All contributors will be acknowledged in all future presentations and publications

- Future for a prospective registry with enhanced objectives.

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Discussion

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