

Poster section III. Lower extremity

A Novel Human Amputated Limb Model for Advancing Peripheral Artery Disease Research and Device Testing

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Introduction: Traditional animal models often fail to capture the complexity of peripheral artery disease (PAD) lesions, leading to a gap between preclinical and clinical research in percutaneous vascular interventions (PVI). To address this, we developed a human amputated limb model combined with a proprietary MRI-histology protocol for detailed plaque characterization and simulation of PVI procedures, assessing lesion-specific device impact on the vessel wall. **Materials and Methods:** Amputated limbs from end-stage PAD patients at the Houston Methodist Hospital (TX, USA) were scanned using 3T or 7T MRI, incorporating Ultrashort Echo Time and T2-weighted sequences to differentiate hard (collagen/calcium) and soft (fat/thrombus/smooth muscle) plaque components. PVI procedures were simulated in a hybrid operating room, targeting identified lesions. Device testing included balloon angioplasty, lithotripsy, atherectomy, drug-coated balloons, and novel wires/catheters. Vessel impact was evaluated intraprocedurally using intravascular ultrasound, followed by post-procedure micro-CT and 9.4T MRI. Histopathological analysis was performed with Movat's and H&E stains (Fig1). **Results:** A total of 90 amputated limbs were collected, yielding 172 target lesions and more than 3000 histologic cross-sections. Key findings include: 1. Validation of the MRI protocol and human amputated limb model. 2. Successful testing of vessel preparation devices, showing plaque disruption and dissection in calcified lesions (Fig2). 3. Correlation of chronic total occlusion crossing success with pre-intervention MRI histology scoring (Fig3). 4. Identification of calcified lesions as barriers to effective drug delivery. 5. Collaboration with industry for device development and testing (Fig4). **Conclusions:** This human cadaveric model offers a unique platform for PAD research, providing detailed insights into plaque morphology and PVI device performance. By correlating plaque characteristics with procedural outcomes, it enables precise device testing and fosters innovation in vascular interventions. This model informs clinical decision-making, enhances new technology design, and guides personalized treatment strategies for PAD patients. **References:** 1. Roy, T. L., Chen, H. J., Dueck, A. D., & Wright, G. A., 2018. Magnetic resonance imaging characteristics of lesions relate to the difficulty of peripheral arterial endovascular procedures. *Journal of vascular surgery*, 67(6), 1844–1854.e2. 2. Benfor B, Sinha K, Karmonik C, Lumsden AB, Roy TL. Human Cadaveric Model for Vessel Preparation Device Testing in Calcified Tibial Arteries. *J Cardiovasc Transl Res*. 2023 Apr;16(2):502-509.

Combined CERAB and open surgical approach for the treatment of kidney allograft failure and claudication – a case presentation.

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Introduction: CERAB (Covered Endovascular Reconstruction of Aortic Bifurcation) is an innovative endovascular technique, which has shown promising initial results in our institute, just as in the case of our 70-year-old male patient, who had severe aortoiliac stenoses, which caused not exclusively claudication, but also the progressive failure of a previously transplanted kidney (fed by the right external iliac artery). The latter made the need for revascularisation rather urgent. **Objectives:** Our objective was to treat severe aortoiliac stenoses endovascularly while preserving the anastomosis of the graft kidney located on the proximal part of right external iliac artery. To perform CERAB from a bilateral inguinal access, bifemoral thrombendarterectomy (TEA) also had to be done. **Materials and Methods:** The patient had hypertension, chronic kidney failure and previously underwent small intestine surgery, kidney transplantation and CABG surgery. Prior the vascular intervention, claudication distance was 40 meters, and eGFR was 22 (ml/minute)/1,73 m² (1 year prior treatment (in 2023), eGFR was 49 and in 2022, it was 75 (ml/minute)/1,73 m²). The endovascular procedure was performed with 1 aortic and 3 iliac Bentley “BeGraft” stent-grafts. From a bilateral inguinal approach, TEA of common femoral arteries were

performed, which was extended to the second branches of deep femoral artery on the left side. Results: The patient left our ward at the 4th post-operative day without any major complications. Ankle-brachial-index increased from nearly 0 to 0,9 for both sides. Claudication remained, but maximal distance increased to 200 meters. After six months, eGFR increased to 71 (ml/minute)/1,73 m²). In the first six months, there were no adverse events.

Enhancing Chronic Limb-Threatening Ischemia Management through Pre-procedural Magnetic Resonance Histology in Peripheral Vascular Interventions

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Objective Recent randomized trials have challenged the traditional endovascular-first approach for treating below-the-knee arterial disease^{1,2}. Scoring systems like TASC and GLASS overlook lesion composition and morphology, which influence peripheral vascular intervention (PVI) success. Conventional imaging provides limited plaque composition insight, while ultrashort echo time (UTE) MRI can distinguish between soft (e.g., fibrous tissue, thrombus) and hard (e.g., calcification, dense collagen) plaque components. This study aimed to assess if MRI-histology could better predict lesion crossing failure compared to GLASS and TASC scoring. **Methods** 22 CLTI patients (average age 65.8±9.72 years) scheduled for PVI had an additional 3T MRI histology scan prior to their procedure, utilizing UTE and “Steady-State Free Precession” (SSFP) contrasts. PVI target lesions were categorized as “hard” if ≥ 50% of the lumen was occluded by hard components (calcium/dense collagen) on MRI^{3,4}. Two readers evaluated the MRI data. TASC/GLASS scoring was performed based on intraprocedural angiograms. Fisher’s exact test studied the relationship between MRI lesion characterization and immediate PVI technical and long-term (3-month and 6-month) procedure outcomes. Univariate analysis explored the association between MRI histology scoring, TASC/GLASS scoring, and procedural outcomes. **Results** 22 patients were enrolled with 40 target lesions, of which 5 were excluded (2 non-diagnostic MRI image quality, 3 PVIs diagnostic only). Of the remaining 35 lesions, 6 (17%) were classified as “hard” on MRI. “Hard” lesions had a significantly higher immediate PVI technical failure rate than “soft” lesions (83% vs. 3%, respectively, p<.001). MRI-defined “hard” lesions were the only predictor of immediate technical failure (p<.001) compared to TASC and GLASS scoring systems (Fig2). MRI histology scores had high diagnostic accuracy: sensitivity 83.3%, specificity 96.6%. Lesions scored “hard” on MRI showed higher revascularization rates at 3 and 6 months post-PVI (p=.011 and p=.047) (Fig3). **Discussion** Our protocol shows promise in guiding the selection of patients suitable for endovascular or surgical revascularization, highlighting the potential of MRI histology in optimizing treatment for CLTI patients.

Feasibility of the Direct Intraluminal Vision (DIV) by Use of Angioscopy in Endovascular Treatment of Short Femoral Lesions

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Intraoperative angioscopy may be useful for endoscopic inspection of the interior of the blood vessel. Femoral endoluminal recanalization, angioplasty and stenting without use of contrast dye using fluoroscopy and intraluminal angioscopy control (direct intraluminal vision –DIV) as a valuable therapeutic option will be presented. The endovascular revascularization of the femoral artery can be performed without use of contrast dye and completed with intraoperative DIV control. Our original operative technique (via the common femoral artery access) using fluoroscopy, radiopaque marking tape and subsequently DIV, allows the precise estimation of the position and the length of the stenosis or occlusion. After crossing the stenosis or recanalization of the occlusion with the guide wire an accurately sized stent is introduced and deployed. In the subsequent part of the procedure the implanted stent is controlled by DIV. Using DIV the global permeability of the stent, the interior part as well the proximal and distal landing zones are carefully inspected. The technique of revascularization of short femoral lesions using DIV and without use of contrast dye is perfectly feasible and may be particularly advantageous in patients with impaired renal function.

Mechanical and Nanomechanical Properties of Cryopreserved Human Arterial Allografts: A Six-Month Follow-Up Study

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Performing surgical operations under septic conditions poses a significant challenge for vascular surgeons. Infection can be a serious concern regarding synthetic vessel prostheses and is among the most dreaded complications. In the event of a graft infection, an infection-resistant alternative is necessary. Cryopreserved vascular allografts offer a suitable alternative conduit to replace an infected vessel or section of a synthetic graft. Unfortunately, no international protocols currently provide guidelines on the optimal conditions to prepare, store, and thaw out these vessel grafts. We aimed to examine the biomechanical properties of human cryopreserved arteries and identify the optimal storage duration under cryogenic conditions. Arteries were stored for a six-month follow-up period, with samples examined five times during the follow-up period. Per our clinical protocol, a dimethyl-sulphoxide solution was used as a cryoprotectant. Biomechanical and nanomechanical tests were performed to evaluate the mechanical properties of both fresh and preserved arterial specimens. No significant changes were observed in the mechanical or nanomechanical properties during the examination period. Our results indicate that the mechanical qualities of cryopreserved vascular allografts are maintained for six months under cryogenic conditions.

Validation of a custom variational autoencoder artificial intelligence algorithm through histology for classifying ex vivo MRI images of peripheral artery disease lesions

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Objective Peripheral arterial disease (PAD) lesions vary in complexity, but current imaging struggles to distinguish plaque components. Hard tissue occlusions (calcium/dense collagen) often resist endovascular treatment, while soft tissue (thrombus/fat/loose fibrous tissue) is more treatable. MRI, with T2-weighted (T2W) and Ultrashort Echo Time (UTE) sequences, can differentiate these tissues^{1,2}. Variational autoencoders (VAEs) show promise in PAD image analysis^{3,4}. This study explores a custom VAE for classifying PAD lesions using 9.4T MRI, validating its performance with histologic slides to enhance treatment planning and device selection. **Methods** 20 chronic total occlusion PAD lesions were harvested from 6 patients who underwent amputation. 9.4T MRI data was acquired using T2W and UTE contrasts. Image registration created pseudo-color (T2W: red, UTE: green) cross-sections (Fig1). A custom VAE algorithm classified these based on lumen occlusion with hard or soft tissue. Samples were cut into evenly spaced rings with 4-5 μ m thickness, and stained using HE and Movat's pentachrome. Histologic slides were matched with VAE-generated images, and lesion crossability (non-crossable if >50% of lumen was occluded with hard tissue) was assessed independently by two readers both on the VAE output images and the histologic cross-sections. Inter-rater reliability was evaluated using intraclass correlation coefficient. Association between VAE-based and histologic scoring was assessed using Fisher's exact test. **Results** Multi-contrast MRI registration generated 4013 axial pseudo-color images, effectively distinguishing between hard and soft tissue components. VAE classification successfully separated axial cross-sections based on plaque composition (Fig2). Histopathologic analysis yielded 91 cross-sections, showing good agreement with VAE output images. Consensus reading identified 31 (34%) VAE images and 23 (25%) histologic slides as non-crossable, with significant association between histology-based and AI-based crossability (Fisher's exact $p < .001$). Inter-rater reliability was good for both VAE-based and histology-based crossability assessments (ICC= 0.76 and 0.80, respectively) (Fig3). **Discussion** Our AI algorithm effectively assessed PAD lesion crossability, showing a strong association with histologic validation. This AI-assisted analysis promises to enhance image interpretation and classification for untrained physicians, aiding in the selection of revascularization techniques and endovascular devices.