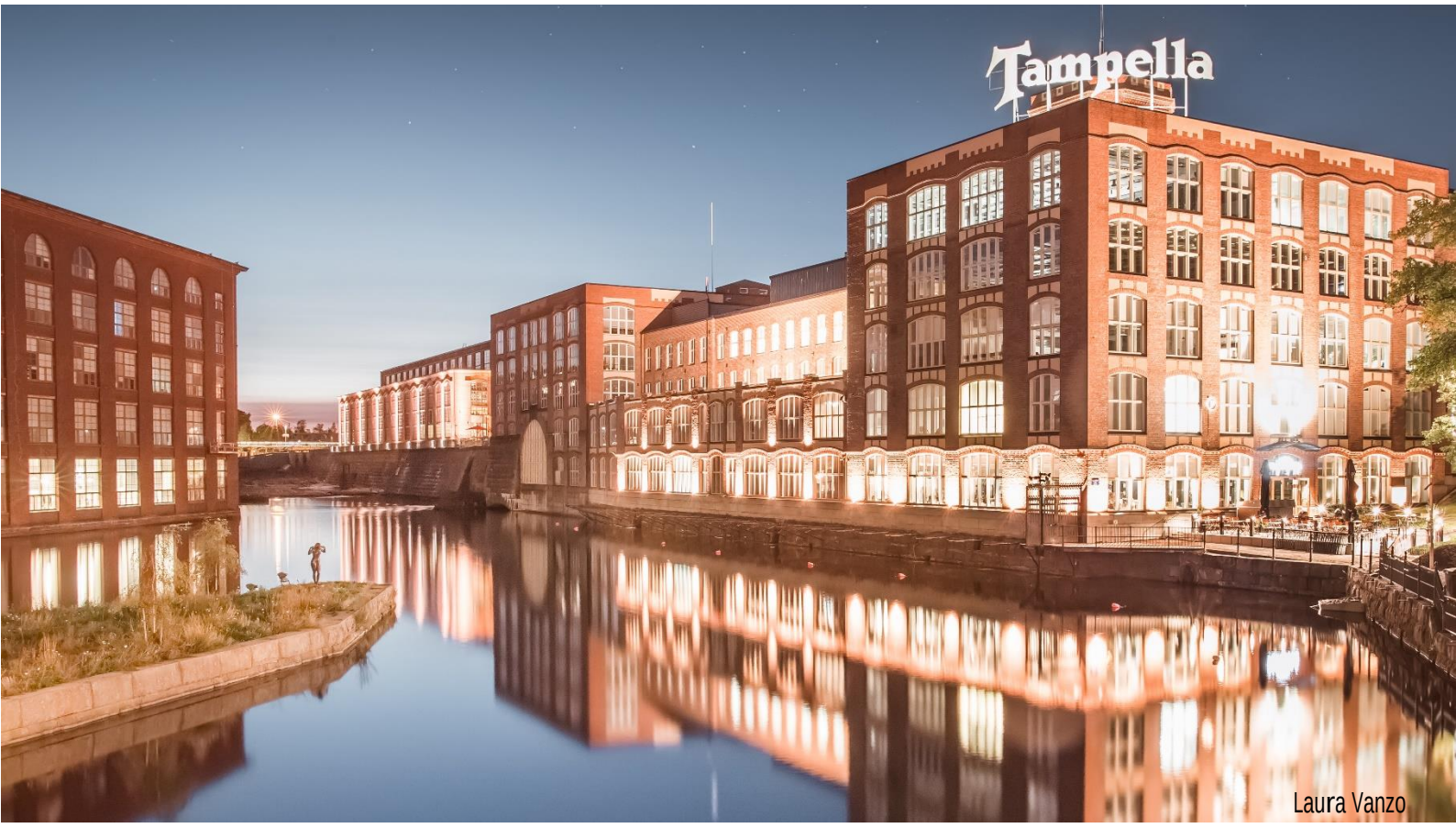
November 12 – 14, 2025 Tampere Hall, Tampere – Finland

33rd Annual Congress of the European Association of

TISSUE AND CELL BANKS

Tampere University, Regea Tissue Center



Laura Vanzo

EUROPEAN ASSOCIATION OF TISSUE AND CELL BANKS

Tampere University

ABSTRACT BOOK

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Toni-Karri Pakarinen, Tampere University, Regea Tissue Center, Finland

Dear members and supporters of EATCB

On behalf of the board of EATCB, we would like to welcome you to the **33rd Annual Congress of the European Association ofTissue and Cell Banks**, taking place in **Tampere, Finland** 12-14.11.2025.

The EATCB Congress brings together experts interested in the field of tissue and cell banking, providing a venue for learning, exchanging knowledge, and presenting the latest research developments. Furthermore, the new EU regulation regarding the use of substances of human origin will apply from 2027, which will strengthen the importance of this meeting.

The congress will take place at **Tampere Hall**, Finland's largest and most versatile cultural and congress center and event company. Even though Tampere Hall is situated in the vibrant city center, nature is never far away. The large windows let in the beautiful park that surrounds the building.

Tampere, the most populous inland city in the Nordic countries, is wedged between two lakes. The population of the Tampere metropolitan area is 417,000. The lakes and surrounding forests offer a variety of outdoor activities that can be enjoyed throughout the year.

We look forward to seeing you at the EATCB congress in TAMPERE!

With kind regards,

EATCB board and the local organizing committee

WEDNESDAY, November 12th

8.45 Registration – Tampere Hall

9.30-12.30 Workshop: Procurement — Tampere Surgical Education Center

Meeting 8:45 at Tampere Hall Registration Desk. **Pre-registration required.**
Corneal session: Eero Salmela, Jan Kniese
Musculoskeletal session: Toni-Karri Pakarinen, Tomi Simons, Ed Ferreol

9.30-10.45 Workshop: Donor selection — Duetto 1-2

Moderators:
Jacinto Sánchez Ibáñez (A Coruña University Hospital), Anna Vilarrodona Serrat (BST)

10.45-11.00 Break

11.00-12.30 Workshop: Quality and Biovigilance — Duetto 1-2

Moderators:
Aurora Navarro Martinez-Cantullera (BST), Hanna Parviainen (Linio Biotech)

12.30-14.00 Lunch

14.00-14.15 Opening of the Congress — Duetto 1-2

14.15-16.00 Plenary Session: Donation — Duetto 1-2

Chairs: Martin Börgel and Simone Hennerbichler-Lugscheider

KEYNOTE Presentation: Martin Börgel (DGFG):
We don't have a lack of tissue donors, we have a lack of organization

Jonathan Boyd: Collaborating with Medicolegal Professionals: Maximizing Donation Opportunities
Christian Braun: The Relatives' perception of the Tissue Donation Process: A 10 Year Retrospective Study
Carlo De Cillia: Tissues and Cells Procurement Organization: the Emilia-Romagna Region (ERR) Model and Results
Tom Buersmeyer: The Growing use of Tissue Recovery Facilities within Organ Procurement Organizations in the United States
Tiina Vilén: Post-Mortem Tissue Donation Process at Tampere University Regea Tissue Center, Finland
Michael Palmisano: Tissue Banking Reimagined: Leading Change in a Traditional
Amber de Graaf: Predictors of False-Positive and Invalid Results in Postmortem Blood Testing of Tissue Donors: A Case-Control Study

16.00-16.30 Coffee Break

16.30-18.00 Plenary Session: NewTechnologies — Duetto 1-2

Chairs: Annika Hakamäki and Simone Hennerbichler-Lugscheider

Sponsor lecture: Jan Grönblad (Vaisala): **Monitoring in Demanding Environments**

KEYNOTE Presentation: Anni Mörö (Tampere University):
3D Bioprinting of Human Corneas: StepsTowards ClinicalTranslation

Marta Duran-Güell: Development of 3D Cell Pool Models from Isolated Primary Liver Cells MicroencapsulatedThrough Bioprinting
Riina Uusmies: From Autologous to Allogeneic Approach with Cell-Free Adipose Tissue
Technology: Clinical Studies on Wound Healing and Scar Maturation
Cristina Castells-Sala:Towards Safe ClinicalTranslation: Mitigating Risks in the Preparation of Decellularized Sural Nerves for Peripheral Nerve Regeneration
Jonathan Boyd: How Research Donation Shapes the Future of Drug Discovery, Therapeutics, and Disease Research

19.00-20.00 Welcome Reception — Tampere City Hall

Location:Tampere City Hall, Keskustori 10

THURSDAY, November 13th

8.30-10.30 Plenary Session: New EU Regulation and Guidelines — Duetto 1-2

Chairs: Johan Guns and Richard Lomas

Rita Piteira (European Commission Directorate General Health and Food Safety): **EU SoHo Regulation**
Mar Lomero (European Directorate for the Quality of Medicines & HealthCare)**: EDQM Guidelines**
Francois-Xavier Lamy (European Centre for Disease Prevention and Control): **ECDC Guidelines**
SariTähtiharju (Finnish Medicines Agency): **Implementation of the SoHO Regulation**

Panel discussion: Rita Piteira, Mar Lomero, Francois-Xavier Lamy, Sari Tähtiharju, Simone Hennerbichler-Lugscheider and Jacinto Sánchez Ibáñez

10.30-11.00 Coffee Break

11.00-11.15 EATCB Education Program — Duetto 1-2

11.15-12.30 WUTBA/EATCB International Panel: Public Relations and Awareness of Tissue Donation — Duetto 1-2

Chairs: Martin Börgel and Jinyoung Jeong

Asia Pacific Association of SurgicalTissue Banking: Jinyoung Jeong, St. Vincent's Hospital, South Korea
American Association ofTissue Banks: Michael Palmisano, Tissue Recovery Services, Sharing Hope SC, USA
European Association ofTissue and Cell Banks: Michèle Köhler, DGFG The German Society forTissueTransplantation, Germany
South AfricanTissue Bank Association: Moji Mogari, VitanovaTissue Bank, South Africa
Biotherapeutics Association of Australasia / Eye Bank Association of Australia and New Zealand: Chris Van Diemen, Australian Red Cross Lifeblood, Australia

12.30-13.30 Lunch

13.30-15.30 Parallel Session: Reproductive tissues — Duetto 1

Chairs Siri Lehtonen and Marisa Ojala

KEYNOTE Presentation: KellyTilleman, Ghent University Hospital:
Effective Strategies for Managing Risks and Donor Restrictions: Lessons Learnt in Assisted ReproductiveTechnologies

Katri Knuus: Advancing OvarianTissue Evaluation: 3D Micro-CT Imaging and Machine Learning Segmentation for Accurate Oocyte Quantification
Johan Guns: Microbiological Safety Assessment of Intracytoplasmic Sperm Injection
Jacinto Sanchez Ibanez:The role ofTissue Establishment in Fertility Preservation for Oncologic Males. Experience in the Last 13Years.
Sonja Lindfors: Ensuring DonationTraceability in Patient Information Systems: a Perspective from FertilityTreatments

Discussion: Shaping the Future of IVF under the New EU Regulation

13.30-15.30 Parallel session: Ocular Tissues — Duetto 2

Chairs: Stefano Ferrari and Heli Skottman

Keynote Presentation:
Sorcha Ni Dhubhghaill, UZ Brussel, Vrije Universiteit Brussel:**The BEST Cornea ClinicalTrial – Lessons Learned From the Clinic and the Bank When Comparing Precut Grafts**

Stefano Ferrari: Current State of Eye Banking.

Tanja Ilmarinen: Bridging Concept to Clinic: Preclinical Considerations for Stem Cell-Based Ocular Surface Repair
Ivana Vidović: Changing Patterns of Microbial Contamination and Antimicrobial Sensitivity in Contamination of Organ Cultured Corneas
Maija Kauppila: Long-Term Storage of Human Donor Corneas Affects Putative Limbal Stem Cell Marker Expression and Compromises Epithelial Integrity
Elina Utti: Corneal DonorTesting During the COVID-19 Pandemic
Anna Salz: Impact and Achievements of Indo-German Collaboration for Global Eye Donation

15.30-16.00 Coffee Break

16.00-18.00 Parallel Session: Musculoskeletal Tissues — Duetto 1

Chairs: Toni-Karri Pakarinen and Tomi Simons

Keynote Presentation:
Minna Laitinen (Helsinki University Hospital): **The Use of Bone Allografts in Orthopaedic Oncology**

Marc Grischin: Survival Rate of Hip and Knee Arthroplasty Revisions Using Structural Bone Allograft: a Retrospective Study about 245 Cases.
Olivier Goffin: Enhancing of the Production Process: a 10-Year Journey in the Transformation of Decellularized Grafts at Cliniques Universitaires Saint-Luc.
Andrey Barkanov: Probones Tissue Bank: Analyzes of the Three Years Experience
Volker Eras: Enhanced Absorption and Drug Release from a Novel Fibrous Bone Graft
Viorel Nacu: Modulation of the Release Profile of a Biologically Active Compound After Double Loading of Demineralized Bone Graft
Doina Fosa: Nanostructured Bone Graft for Medical Applications
Mariana Jian: Bone Grafts Functionalized with Essential Oils

16.00-18.00 Parallel Session: Contingency Planning, Implementing New Regulations — Duetto 2

Chairs: Tiia Tallinen and Jannine Westby

Lauren Roberts: Contingency Plans within NHS Blood and Transplant (NHSBT) – Reviewing Risk Management across the Donor to Patient Pathway
Maria McGee: How Sweden Will Achieve a Clinically Driven Tissue Service by 2030: A Data-Driven Approach
Marina Alvarez Miranda: Spanish Strategic Tissue Plan – PENT- (2022-2026): a Key Tool for Implementing the SOHO Regulation
Marina Alvarez Miranda: Spanish Experience in the Harmonization of Activity Data in Tissues and Cells
Ruth Barrio: GAPP-PRO Joint Action: Latest Update
Marina Alvarez Miranda: Committee for the Evaluation of Innovation with Cells and Tissues of Human Origin and Derived Products (CEICyTH) – 2025
Miroslava Jandová: Microbiological Risk Assessment During the Procurement and Processing of Cells, Tissues and Breast Milk Using the MiRCA tool

20.00-00.00 Gala Dinner — Congress Center Puistotorni

Location: Congress Center Puistotorni,
Hämeenpuisto 28

FRIDAY, November 14th

8.15-9.30 Parallel Session: Skin and Other Substances of Human Origin — Duetto 1

Chairs: Richard Lomas and Martin Börgel

Wojciech Łabuś: Influence of Electron Beam Irradiation on Extracellular Matrix of the Human Allogeneic Skin Grafts
Wojciech Łabuś:Tissue Engineering as aTool in a Novel Approach to the ComprehensiveTreatment and Management of a Deeply and Extensively Burned Patient – Case Report
Valeria Purpura: Development of a New Method for the Ready-to-Use Preservation of a Human Acellular Dermal Matrix
Wojciech Łabuś: Acellular Dermal Matrices as a New Alternative forTreatment in Reproductive Organ Static Disorders: A Pilot Study
Annu Luostarinen: Standardized Production of Allogeneic Serum Eye Drops for Severe Ocular Surface Disease
Carlo De Cillia: Donor Screening for Fecal MicrobiotaTransplantation: Results from the Bologna Center

8.15-9.30 Parallel Session: Quality and Digitalization — Duetto 2

Chairs:TiiaTallinen and Johan Guns
Toni Leppä: The Evolution ofTissue Establishment Registries: Requirements and Data Management Practices
Dirk Mohn: DigitalTraceability Across Platforms and Clinic Locations
Alix de Pierpont: Equipment Management inTissue Banks: Development of an In-House CMMS System with Microsoft Sharepoint
Jan Claas Brune: Design and Construction of a New Manufacturing Facility for MusculoskeletalTissue Grafts
Jacinto Sánchez Ibañez: In Process Environmental Monitoring Programme. How Much, How Long
Claire Price: Incorporating Virtual Reality into a New Blended Learning Package for Eye Retrieval

9.30-10.00 Coffee Break

10.00-11.30 Parallel Session: Amniotic Membrane — Duetto 1

Chairs: Giulia Montagner and Simone Hennerbichler-Lugscheider

KEYNOTE Presentation: Giulia Montagner (Veneto Tissue Bank Foundation):
Amniotic Membrane: a Valuable and Versatile Tissue in Clinical Practice

Nicola Hofmann: Does the Time Interval from Delivery to Preparation Influence the Properties of Amniotic Membrane? A Comparison Between <6 and >6 to 24 Hours
Valeria Purpura: Development of a New Collection Method for Human Amniotic Membrane
Asmita Banerjee: Human Amniotic Membrane: Moving Perinatal Biomaterials Towards Translation into the Clinic

10.00-11.30 Parallel Session: Cardiovascular Tissues — Duetto 2

Chairs: Richard Lomas and Hanna Parviainen

KEYNOTE presentation: Jukka Salminen (Helsinki University Hospital):
Cardiac Homografts: Harvesting, Processing and Clinical Application

Lujia Gribben: Novel Source of Donor Hearts for Heart Valve Production
Kristina Fruerlund Rasmussen: Microbial Findings in Vascular Allografts Before and After Antimicrobial Decontamination
Laura López Puerto: VasCraft: a Novel Tissue-Engineered, Decellularized and Re-Endothelialized Human Vascular Graft for Use in Artery Bypass
Pavel Měřička: Clinically Undetected Malignancies as a Reason for Discarding Cryopreserved Connective and Vascular Tissue Allografts from Deceased Donors: A Five-Year Retrospective Study
Jan Burkert: The fate of the first 100 patients enrolled on the WL for large diameter allograft heart valves (AHV)
Jan Burkert: Happy 90th birthday Professor Sir Magdi YACOUB – a surgeon and a maverick

11.40-12.00 Awards and Closing of the Congress — Duetto 1

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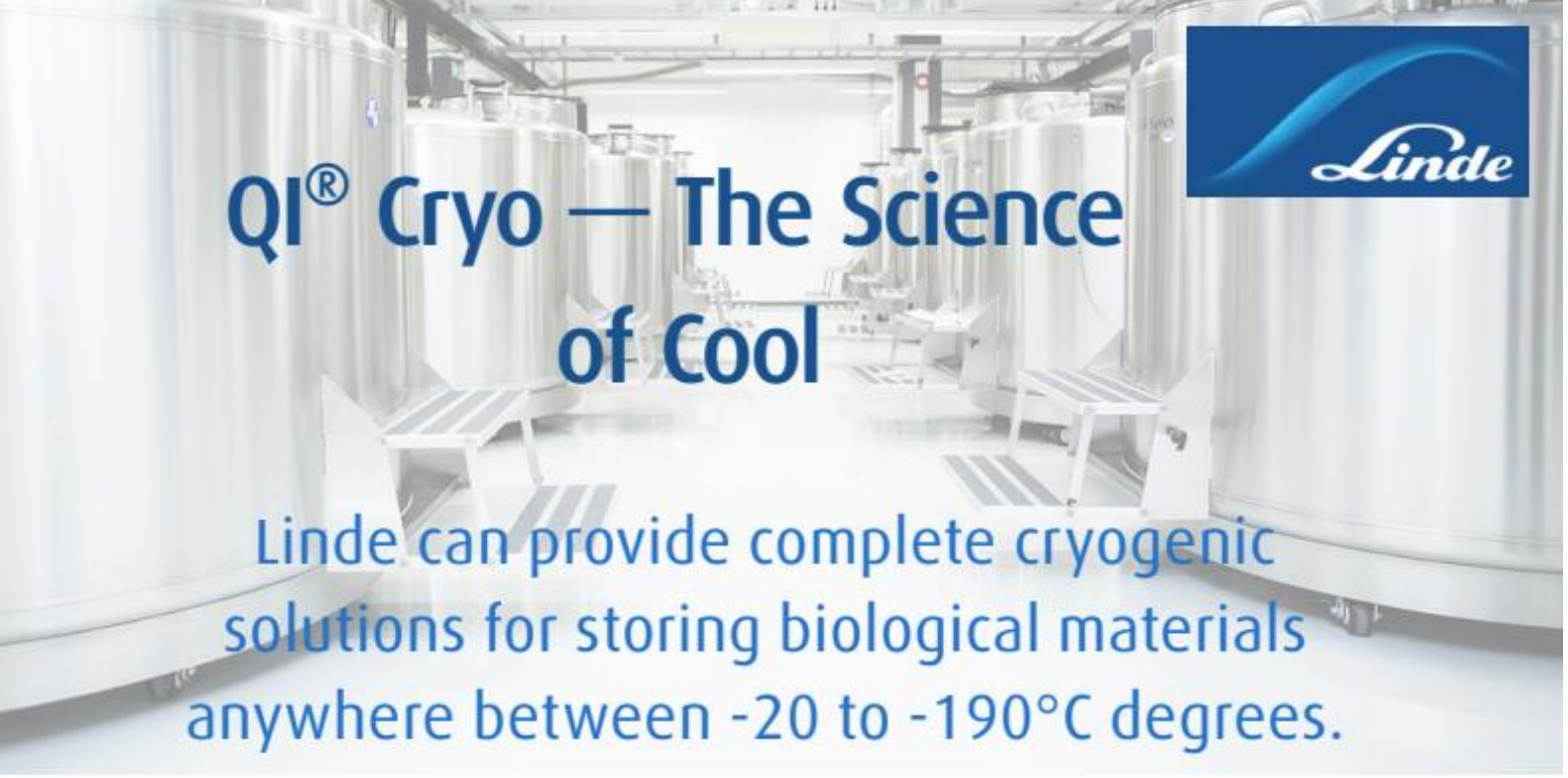

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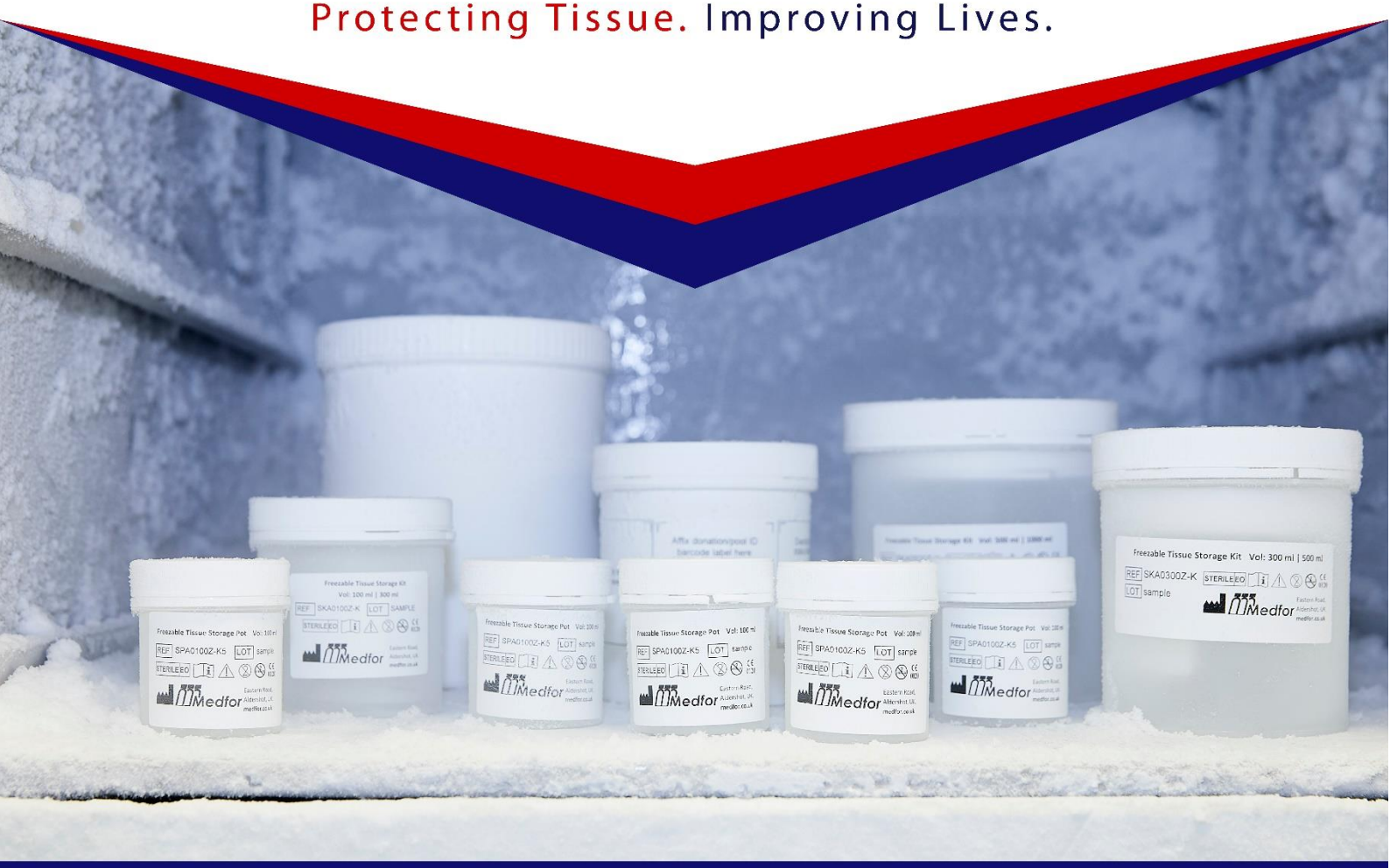

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Plenary Session: Donation

COLLABORATING WITH MEDICOLEGAL PROFESSIONALS: MAXIMIZING DONATION OPPORTUNITIES

Jonathan Boyd, MS, LSSBB, CTBS

Director, Tissue Acquisition, Lonza, Inc., USA

Summary: A significant number of potential organ and tissue donors fall under the jurisdiction of medical examiners, coroners, forensic pathologists, or other medicolegal professionals. Ensuring donation opportunities are not lost requires careful coordination to preserve forensic evidence while supporting the lifesaving gift of donation.

This presentation will explore best practices for fostering collaboration between the medicolegal death investigation and donation communities. We will highlight key insights from the jointly published Guide to Medical Examiner and Coroner Cases, examine international efforts that promote interdisciplinary cooperation, and share proven strategies to align investigative integrity with donation advocacy.

Learning Objectives:

1. Identify potential gaps donation may create in forensic cases
2. Outline general challenges in establishing collaboration between fields
3. Review initiatives supported by AATB, AOPO, EBAA, and the International Association of Coroners and Medical Examiners (IACME)
4. Review the Guide to Medical Examiner and Coroner Cases
5. Define practices that donation organizations may implement to support medicolegal partners on shared cases

Plenary Session: Donation

THE RELATIVES' PERCEPTION OF THE TISSUE DONATION PROCESS: A 10 YEAR RETROSPECTIVE STUDY

Christian Braun, Lella Stefan, Matthias Graw, Stefan Troschütz

Affiliation of all authors: Institute of Legal Medicine Munich (LMU), Nussbaumstr. 26, 80336 Munich, Germany

Background
The Institute of Legal Medicine Munich is a tissue procurement facility for cornea and musculoskeletal tissues. Consent for donation is given through documentation (e.g. donor card), knowledge of the deceased's will or extended consent solution by their relatives. Contact to the relatives is established by phone and information concerning donation is given by trained personnel.

Within a 10-year period, only 17,3% of eligible donors had written documentation of their donor will. In all other cases, the decision was made by relatives based on known (16,3%) or presumed will (66,4%). This shows the importance of contacting the next of kin in the donation process.

To investigate the impact of the tissue donation request on the relatives, we conducted a retrospective study.

Methods
The relatives of all donors 2013-22 were offered an aftercare consultation (ACC) by phone. They were approached to answer a questionnaire concerning the donation process. 9 individual items were reviewed (e.g. freedom of decision, considerate way of contact, consoling effect of tissue donation) using a Likert scale.

Results
Among 514 donations in the 10-year-period, 379 relatives consented to a later ACC. 62 were not available by telephone, while 317 relatives were reached after 1-18 months (mean 8 months). The questionnaire was answered by 307 relatives, 10 rejected the questionnaire.
137 relatives refused an ACC, but 99 consented to answer the questionnaire immediately (within a week of the donation).
In total, 406 questionnaires were answered, resulting in a response rate of 79%. The relatives were pleased with the ACC in 96,5%. There were no statistical differences between multi-tissue and cornea donors.

The responding relatives evaluated their experience of the tissue donation process as good or very good for most items, especially concerning the information and support given. Only a small percentage found the donations contact stressful, while 92,5% noted a consoling effect of the donation during their time of grief. 100% would agree to donate again.

Conclusions
Contact to the relatives of a potential donor is essential for obtaining consent. Our study shows that relatives often understand the importance of donation and can reach stable decisions when information on donation is presented in a sensible manner. These findings may reduce reservations against donation, especially regarding the argumentation that contacting grieving relatives is not appropriate. We find that the contact during the donation process is perceived as helpful and that relatives show a positive understanding even in case of refusal.

Plenary Session: Donation

TISSUES AND CELLS PROCUREMENT ORGANIZATION: THE EMILIA-ROMAGNA REGION (ERR) MODEL AND RESULTS

C.De Cillia[1], S.Mengoli[1], A.Marangoni[2], N.Alvaro[1], E.Cordella[1]

[1] Emilia-Romagna Transplant Reference Centre (CRT-ER) – Bologna – Italy
[2] Department of Medical and Surgical Sciences – Microbiology - University of Bologna - Italy

Introduction

In the framework of the Directive 2004/23/CE and daughters, the ERR, a northern Italy region of about 4,500,000 inhabitants, in 2006 issued a protocol applying the requirements for donor suitability, and customizing the principles according to the regional model. The regional model of tissues and cells donation contemplates: donor recruitment, identification and consent in 21 hospitals; donor evaluation through a multidisciplinary approach between donation site and CRT-ER; substances procurement, transport, banking, processing, testing, storage and distribution are carried out by the tissue establishments. Aim of this study is to review tissues procurement activity in ERR from 2014 to 2024.

Methods

All heart-beating (HB) and non-heart-beating (NHB) tissue donors with relative allografts sent to regional tissue establishments from 2014 to 2024 in ERR have been analyzed. Data source are the Italian Informative Transplant System and the ERR Informative Transplant System.

Results: The amount of tissue donors from 2014 to 2024 is shown on table 1.

	Ocular tissue	Amniotic membrane	Musculoskeletal tissue	Skin	Heart valves	Vascular tissue	Intestinal microbiota
2014	533	19	811	60	30	28	-
2015	560	21	745	71	31	24	-
2016	627	27	793	70	26	25	-
2017	824	9	614	75	32	28	-
2018	893	25	669	56	20	18	-
2019	767	31	697	76	29	33	-
2020	513	26	382	64	21	31	-
2021	792	19	291	75	27	39	4
2022	895	11	366	54	26	29	5
2023	1062	7	549	67	46	39	1
2024	1126	51	475	68	32	32	8

Table 1

The amount of allografts from 2014 to 2024 is shown on table 2.

	Ocular tissue (N)	Amniotic membrane (N)	Musculoskeletal tissue (N)	Skin (cm2)	Heart valves (N)	Vascular tissue (N)	Intestinal microbiota (N)
2014	1064	19	914	181.361	60	139	-
2015	1116	21	801	177.319	32	136	-
2016	1242	27	1265	210.184	26	121	-
2017	1638	9	897	234.195	32	133	-
2018	1776	25	922	165.477	20	69	-
2019	1523	31	1553	251.018	29	140	-
2020	1015	26	1093	215.750	27	136	-
2021	1581	19	1060	254.659	48	164	28
2022	1786	11	989	219.844	26	122	38
2023	2121	7	1239	278.027	47	153	3
2024	2261	51	1739	234.023	64	117	44

Table 2

Conclusion

Notwithstanding high age average (68 years old), non-standard risk level increase and refusal percentage (23%) of the ERR donors, human tissues procurement has achieved good results, thus proving the efficacy, equity and transparency of the regional model.

Plenary Session: Donation

THE GROWING USE OF TISSUE RECOVERY FACILITIES WITHIN ORGAN PROCUREMENT ORGANIZATIONS IN THE UNITED STATES

Tom Buersmeyer

LifeNet Health, USA

This presentation delves into the growing adoption of centralized tissue recovery facilities by United States Organ Procurement Organizations (OPOs). As the scope of tissue recovery continues to expand nationwide, more OPOs are recognizing the advantages of centralized recovery facilities, including streamlined operations and improved outcomes.

The session will begin by examining the historical context that prompted OPOs to consider establishing these facilities. It will outline the key factors assessed during the decision-making process, the challenges encountered, and the unexpected benefits realized from implementing such facilities.

Key insights will be drawn from real-world examples, including contributions from LifeNet Health and diverse OPOs of varying sizes. The presentation will feature data obtained from a brief survey and insights gathered through interviews, addressing strategy, challenges, benefits, unforeseen advantages and disadvantages, and lessons learned.

By fostering greater awareness and understanding of tissue donation and recovery, this presentation aims to provide actionable knowledge that participants can apply to future planning and strategic discussions within their tissue banks.

Plenary Session: Donation

POST-MORTEM DONATION PROCESS AT TAMPERE UNIVERSITY REGEA TISSUE CENTER, FINLAND

Tiina Vilén, Annika Hakamäki, Tiia Tallinen

Regea Tissue Center, Tampere University, Finland

Regea Tissue Center is a non-profit organization that procures and distributes tissue transplants, including cornea, amniotic membrane and musculoskeletal tissues. Each year, more than 800 transplants are delivered to hospitals across Finland.

Operating as part of a university, Regea collaborates closely with university hospitals, forensic units, hospital morgues, and the police across three hospital districts. Recovery personnel are typically hospital employees who are also contracted by Regea.

Tissue donations may come from individuals who have passed away either in hospitals or elsewhere, such as at home or in nursing homes. All deceased individuals brought to hospital morgues or forensic medicine units are considered potential tissue donors. Intensive care units also notify Regea when a potential organ donor is identified. Donor eligibility is initially assessed based on the time of death and the individual's age, which then triggers a more detailed evaluation process.

Finland's public healthcare system uses a digital platform to record patient data. Regea has access to patients' medical histories, which typically include comprehensive information such as laboratory results and current medications.

Death confirmation records often include details about when the individual was last seen alive, when they were found, and the circumstances surrounding their death. If the cause of death is unclear or not due to a known medical condition, a forensic autopsy is performed. In such cases, Regea contacts the police to obtain legal approval for tissue donation. The time and circumstances of death are verified, as well as the next-of-kin information. Police may also inform Regea of any signs of risk behavior observed at the scene.

Approximately 83% of Finns support organ and tissue donation. Consent or refusal may be recorded in digital systems and is accessible through patient records. Under Finnish law, organ and tissue donation is based on presumed consent—meaning donation is permitted unless the individual explicitly objected during their lifetime. The next of kin is contacted by Regea to confirm consent and to gather additional information about the deceased's health, history of eye surgeries, travel, and any risk behaviors. An external physical examination is also conducted before blood samples are taken to rule out visible signs of risk behavior or medical contraindications.

While donor identification and evaluation are carried out by Regea, the process relies on close collaboration, active information sharing, and ongoing education among all involved parties.

Plenary Session: Donation

TISSUE BANKING REIMAGINED: LEADING CHANGE IN A TRADITIONAL FIELD

Michael Palmisano

We Are Sharing Hope SC, USA

Tissue banking, long governed by tradition and regulation, is undergoing a transformation—driven not only by advances in science, but by shifts in leadership. In this session, Michael Palmisano, Director of Tissue Recovery Services at Sharing Hope SC (USA), presents a compelling case for how leadership that prioritizes people, purpose, and innovation can reshape outcomes in a historically rigid field.

This presentation will explore how legacy systems in tissue recovery can be revitalized through the integration of simulation-based training, performance-based staff empowerment, and globally-informed leadership strategies. Attendees will learn how redefining competencies beyond simple checklists can foster deeper connection, accountability, and excellence in recovery teams.

Palmisano will share the success of initiatives like the Tissue Titans Challenge, which uses gamification to improve clinical performance, and a professional development model that sends top-performing recovery technicians to national and international conferences. These leadership practices have led to improved staff morale, higher quality recoveries, and increased retention.

Drawing from international collaborations with partners from all over the world, this talk will also highlight how cross-cultural exchange has informed his team's approach to policy innovation and donor pool expansion.

This session invites attendees to reflect on their own leadership and challenges them to consider a simple but powerful question: *Are we managing a process—or are we leading a mission?*

Plenary Session: Donation

PREDICTORS OF FALSE-POSITIVE AND INVALID RESULTS IN POSTMORTEM BLOOD TESTING OF TISSUE DONORS: A CASE-CONTROL STUDY

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Background

Postmortem blood screening for infectious diseases is vital for ensuring the safety of tissue transplantation. However, false-positive and invalid test results are more common in postmortem samples compared to samples from living donors. This could potentially lead to unnecessary rejection of suitable tissue grafts. This study aimed to identify factors associated with false-positive or invalid blood test results in postmortem donor screening.

Methods

A retrospective matched case-control study was performed using data from Dutch tissue donors who were screened between 2018 and 2023. The case group consisted of 174 donors with a false-positive or invalid blood test result. The control group consisted of 460 donors with a valid and reliable test outcome. Matching was based on the date of testing. Logistic regression analyses were conducted to evaluate associations between test unreliability and donor-related factors, such as age, body mass index (BMI), presence of sepsis, and presence of malignancy. Additional variables examined were the postmortem interval (PMI) and whether blood collection was performed during an autopsy procedure or by the retrieval team.

Results

A prolonged PMI and blood collection during autopsy procedures were significantly associated with increased odds of a false-positive or invalid test outcome. Each additional hour added to the PMI-interval increased the odds on a false-positive or invalid test outcome by 10% (adjusted OR 1.10, 95% CI: 1.06–1.13, $p < 0.001$), and a blood sample collected during autopsy had an over fourfold increased odd (adjusted OR 4.54, 95% CI: 1.61–13.9, $p = 0.005$). Donor-related variables, including age, BMI, sepsis and malignancy, were not significantly associated. Model performance was modest (AUC ≈ 0.65).

Conclusions

False positive and invalid test results in postmortem samples are primarily associated with procedural factors rather than donor characteristics. Reducing the time to blood collection and ensuring standardized sampling practices may improve diagnostic accuracy and reduce the tissue rejection rate due to invalid or false-positive results. Future studies should include additional procedural factors, such as storage duration and the vein from which the blood was obtained, to refine predictive models and optimize postmortem testing protocols.

Plenary Session: New Technologies

DEVELOPMENT OF 3D CELL POOL MODELS FROM ISOLATED PRIMARY LIVER CELLS MICROENCAPSULATED THROUGH BIOPRINTING

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Two-dimensional (2D) cultures of primary human hepatocytes and experimental animal models remain the most commonly used liver models in basic research. However, these approaches are hampered by limited tissue availability, high costs, and significant biological biases. In particular, animal models suffer from interspecies differences, as murine responses frequently fail to reflect human physiology. Furthermore, relying on hepatocytes from single donors restricts the evaluation of key variables such as gender, age, and ethnicity, thereby limiting the predictive accuracy and translational relevance of these models.

In this study, we present the development of functional in vitro three-dimensional (3D) liver models, created by bioprinting microencapsulated primary human liver cells from multiple donors. Hepatocytes and non-parenchymal cells (NPC) were isolated from residual liver tissue obtained during oncologic hepatectomies through a standardized perfusion and enzymatic digestion protocol. These cells were cultured into spheroids and embedded in collagen-I to mimic the extracellular matrix (ECM), forming stable cell microspheres. Subsequently, tannic acid was applied as a crosslinking agent to enhance structural integrity, shield against collagenase I degradation, and boost resistance to cryopreservation stress.

The resulting 3D liver models can be composed of hepatocytes alone or in co-culture with NPC, thereby better mimicking the complexity of the hepatic microenvironment. By pooling cells from multiple donors, we minimize interindividual variability and generate reproducible, population-representative models. Automated bioprinting ensures precise, hight throughput fabrication, reducing technical variability and manual handling bias.

This innovative 3D model offers a scalable, reliable, and physiologically relevant alternative to traditional liver models, supporting more accurate studies of human liver physiology and pathology. It holds significant promise as a predictive tool for translational research and personalized medicine.

Plenary Session: New Technologies

FROM AUTOLOGOUS TO ALLOGENEIC APPROACH WITH CELL-FREE ADIPOSE TISSUE TECHNOLOGY: CLINICAL STUDIES ON WOUND HEALING AND SCAR MATURATION

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Background
Adipose tissue is recognized as a metabolically active tissue with substantial regenerative potential. It is known to secrete a variety of bioactive factors that promote wound repair and skin regeneration. The regenerative capacity of adipose tissue has been effectively used in clinical applications in autologous fat grafting, and more recently, in nanofat grafting techniques. However, autologous procedures are often complex, time-consuming and costly. Allogeneic, off-the-shelf alternatives could significantly enhance the accessibility and efficiency of regenerative therapies. Cell-free technologies derived from human tissues are gaining increasing attention as promising tools in regenerative medicine. In this study, a cell-free allogeneic adipose tissue preparate was developed and evaluated for its safety and efficacy in a wound healing model using human split-thickness skin grafts.

Methods
In a pilot clinical study, patients with an indication for split-thickness skin grafts were recruited. Adipose tissue was harvested from patients via liposuction and processed intraoperatively into a cell-free preparate. Two donor sites were harvested, and the autologous preparate was applied topically to one donor site. Wound re-epithelialization was monitored over the first two postoperative weeks, and scar maturation was evaluated on days 30 and 60 using the Vancouver-Manchester modified (VMM) scar scale and spectophotocutometry. For off-the-shelf allogeneic approach, adipose tissue was collected via liposuction from volunteered donors with informed consents and tissue was processed into a sterile, cell-free preparate in a cleanroom facility. 30-patient clinical trial was initiated to assess the efficacy and safety of this allogeneic preparate. Two donor sites were harvested per patient and one site was treated with the preparate on day 0 and day 3. Wound healing was evaluated on days 7,14 and scar formation on days 30 and 60 using the VMM scar scale and POSAS scale.

Results
In our pilot study using autologous tissue preparate, treated skin graft donor sites demonstrated accelerated wound re-epithelialization and earlier complete wound closure compared to controls. Similarly, treated sites seemed to yield a better scar at earlier timepoints than controls; treated scars appeared more similar to surrounding healthy skin and maturing more rapidly. In our current on-going study to date, 23 patients have been treated with allogeneic tissue preparate without adverse reactions. Preliminary results of 17 patients indicate that majority of the patients have experienced clinical benefit, including enhanced wound healing and improved scar outcomes.

Conclusions
These findings support the potential of cell-free, allogeneic adipose tissue preparate as a novel therapeutic option for acute wound healing and scar management.

Plenary Session: New Technologies

TOWARDS SAFE CLINICAL TRANSLATION: MITIGATING RISKS IN THE PREPARATION OF DECELLULARIZED SURAL NERVES FOR PERIPHERAL NERVE REGENERATION

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Background

Peripheral nerve injuries represent a significant cause of permanent disability in adults. The current gold standard for repairing large nerve defects is the use of autografts; however, this approach presents notable limitations, including donor site morbidity and limited tissue availability. To address these challenges, decellularized nerve matrices have emerged as a promising alternative within the field of regenerative medicine. Nevertheless, their safe integration into routine tissue bank procedures requires thorough evaluation, including novelty assessment, risk analysis, and the implementation of appropriate mitigation strategies.

Methods

Following an in-depth risk assessment of the novel preparation method for small-calibre nerves decellularization—conducted in accordance with EuroGTP-II guidelines—an extensive and strategically designed studies panel was implemented. The aim was not only to validate the technical feasibility but also to mitigate potential risks and ensure compliance with the highest standards of quality and safety.

Results

The initial risk assessment, performed using the EuroGTP-II tool, resulted in a Medium Final Risk Score (21). To address and mitigate the identified risks, four targeted in vitro studies were conducted: (i) evaluation of tissue structural integrity; (ii) quantification of residual cellular content; (iii) assessment of microbiological safety; and (iv) cytotoxicity testing of the final tissue product. Comprehensive analyses—including protein quantification, mechanical testing, and histological evaluation—confirmed preservation of the extracellular matrix and the absence of structural damage, thereby reducing the potential for implant failure. DNA quantification demonstrated a >99% reduction in nucleic acid content, indicating effective decellularization, while microbiological testing confirmed sterility of the final product. Furthermore, cytotoxicity assays showed no evidence of adverse cellular responses.

Following these results, risk was re-assessed and significantly reduced. To further address remaining uncertainties and support safe clinical translation, the decellularized grafts were subsequently evaluated in an ovine model over a 9-month period. In vivo studies demonstrated the grafts' ability to

support effective axonal regeneration across a 5-cm nerve gap, further decrease the Final Risk Score to low (6).
Based on the updated low-risk classification following in vitro and in vivo validation, the EuroGTP-II tool recommends proceeding with a targeted clinical evaluation strategy. This includes mandatory reporting of serious adverse events and reactions, along with systematic collection of immediate post-transplant monitoring data over a defined period or number of procedures, to ensure continued safety and efficacy in clinical practice.

Conclusions
The conducted studies, supported by a thorough review of the scientific literature, significantly reduced the initial risk associated with the clinical application of this homograft preparation. As a result, the final product has been deemed suitable for evaluation in a randomized controlled clinical trial involving patients with monofascicular peripheral nerve injuries.

Keywords: sural nerve, decellularization, extracellular matrix, risk assessment, EuroGTPII

Plenary Session: New Technologies

HOW RESEARCH DONATION SHAPES THE FUTURE OF DRUG DISCOVERY, THERAPEUTICS, AND DISEASE RESEARCH

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Summary

This presentation will provide an overview of opportunities and criteria for various research organs and tissues. Attendees will gain insight into the process of isolating primary cells and how these cells are used to advance medical innovation, from drug discovery and cancer therapeutics to supporting clinical trials.

Learning Objectives:

1. Outline common research organ and tissue opportunities
2. Summarize the cell isolation process
3. Review common research applications
4. Highlight emerging trends and technologies such as 3D bioprinting and the development of organ models

Parallel Session: Reproductive Tissues

ADVANCING OVARIAN TISSUE EVALUATION: 3D MICRO-CT IMAGING AND MACHINE LEARNING SEGMENTATION FOR ACCURATE OOCYTE QUANTIFICATION

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Background

Fertility preservation is essential for patients undergoing life-saving treatments with a high risk of gonadotoxicity. Ovarian tissue cryopreservation (OTC) followed by autotransplantation post-recovery, is an option, particularly for pre-pubertal girls, adolescents and adult women requiring urgent therapy. Assessing oocyte density in cryopreserved ovarian cortex is critical for evaluating tissue quality and predicting reproductive potential. However, traditional histological analysis is labor-intensive, time-consuming, and prone to variability due to uneven follicle distribution and inconsistent tissue orientation. To address these limitations, we developed an automated, high-throughput method combining micro-computed tomography (micro-CT) with machine learning to quantify oocyte density in whole ovarian cortical tissue samples.

Methods

Ovarian cortical tissue was collected from 11 patients (5 pediatric, 6 adult). Two fragments per patient were processed: one for standard histology (formalin-fixed, paraffin-embedded, H&E stained every 10th section) and one for 3D imaging (ethanol-fixed, iodine-stained, scanned with high-resolution micro-CT).

A machine learning algorithm was used to identify and quantify oocytes in 3D reconstructions. Results from histology and micro-CT were compared, including virtual histological sections generated form the 3D data.

Results

Micro-CT enabled full-volume 3D reconstruction and accurate oocyte detection in ovarian cortical samples. Oocyte density estimates from virtual histology closely matched full-volume 3D counts when sectioning every 10th section through the entire sample. However, using only five sections — common in clinical practice—led to substantial inaccuracies in adult samples with sparse or uneven follicle distribution. Pediatric samples, with higher and more uniform oocyte density, correlated more closely with micro-CT counts.

Beyond oocyte density, 3D analysis revealed spatial patterns not visible in 2D histology: oocytes in pediatric tissue were significantly closer to the surface and exhibited higher local oocyte neighbor

counts compared to adult samples, consistent with greater density and clustered organization in younger individuals.

Conclusions

Micro-CT combined with machine learning analysis shows strong potential as a reliable and efficient method for quantifying oocyte density in clinical fertility preservation. This approach improves accuracy, reduces variability, and provides valuable spatial insights—supporting more informed clinical decisions. It is compatible with both fresh and archived paraffin-embedded tissue, broadening its applicability in clinical and research settings. This method could be integrated into standard OTC protocols, offering a scalable and standardized alternative to conventional histology.

Keywords: Ovary, ovarian tissue cryopreservation (OTC), micro-CT, 3D analysis, mean follicle density (MFD)

Parallel Session: Reproductive Tissues

MICROBIOLOGICAL SAFETY ASSESSMENT OF INTRACYTOPLASMIC SPERM INJECTION

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Background
Intracytoplasmic sperm injection (ICSI) is widely used in assisted reproductive technologies (ART), yet microbial contamination remains a concern. Despite routine supplementation of culture media with gentamicin, contamination rates of 0.35–0.86% persist. The zona pellucida may act as a barrier against microbial penetration, but its protective capacity is unclear.

Methods
A prospective study was conducted at Brussels IVF involving 25 couples. A total of 550 samples were collected across ICSI stages: fresh semen, sperm processed by density gradient centrifugation (DGC) or ZyMōt™, follicular fluid, culture media, and oil, as well as embryo culture media on days 3 and 7. Microbial detection was performed using BD-BACTEC™, and species identification via MALDI-TOF. Additionally, oocytes were exposed to Enterococcus faecalis through microinjection or incubation, followed by immunohistochemistry and confocal microscopy to assess whether this frequently detected bacterium can adhere to or penetrate the zona pellucida and oocyte cytoplasm.

Results
All fresh semen samples were contaminated. Post-processing contamination persisted in 64% (DGC) and 80% (ZyMōt™) of samples ($p = 0.22$). Follicular fluid showed high contamination (first tube 88%, last tube 60%). Only 8% of culture media and 4% of oil samples were contaminated before ICSI; no contamination was detected in embryo culture media on days 3 and 7, except for one isolated case. E. faecalis was able to penetrate the zona pellucida and enter the oocyte cytoplasm, even without mechanical disruption by the ICSI needle.

Conclusions
Gentamicin proved effective during embryo culture despite partial bacterial resistance. Both DGC and ZyMōt™ reduced contamination but did not achieve sterility. The zona pellucida provides only partial protection, as bacterial penetration is possible, raising safety concerns for ICSI. Further research is needed to evaluate alternative antibiotics and preventive strategies.

Keywords: Intracytoplasmic sperm injection, microbial contamination, gentamicin, zona pellucida, sperm processing, Enterococcus faecalis.

Parallel Session: Reproductive Tissues

THE ROLE OF TISSUE ESTABLISHMENT IN FERTILITY PRESERVATION FOR ONCOLOGIC MALES. EXPERIENCE IN THE LAST 13 YEARS.

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Background

Male fertility preservation (FP) is now considered a well-established treatment when the germ cell pool is at risk.
Our Tissue Establishment (TE) was the only public facility in Galicia (an autonomous community in Spain) offering this service in close collaboration with the Human Reproduction Unit of our hospital. This study analyses our experience over the past 13 years (January 2013–September 2025).

Methods

During this period, we attended to 591 male patients for FP, referred from 12 hospitals. Of these, 521 had a confirmed cancer diagnosis. A total of 472 samples were processed, and 440 were cryopreserved.
Semen samples were obtained via ejaculation and analysed by the HRU. If the sample met the criteria for viability, it was cryopreserved in our TE. After a storage period, a post-thaw test was conducted to assess the sample's suitability for Intracytoplasmic Sperm Injection (ICSI).

Results

The mean age of the patients was 30.1 ± 8.4 years (range: 13–56). The average semen volume was 3.3 ± 1.9 mL, with 15.8% of samples below 1.5 mL. The median sperm concentration was 21 × 10^6/mL, with 43% of samples below 15 × 10^6/mL. Total motility averaged 44.2 ± 28.8%, with 38.6% below 40%, while progressive motility averaged 33.2 ± 23.6%, with 47.4% below 32%. Overall, 69% of patients showed at least one altered semen parameter. Azoospermia was detected in 9.2% of cases.
45.9 % of patients had testicular tumours, 37% had haematological malignancies, and 17.1% had other solid tumours. Patients with testicular tumours had significantly higher semen volume ($p = 0.002$) but lower sperm concentration ($p < 0.0001$) vs the rest. Patients with Hodgkin lymphoma had significantly lower sperm concentration vs haematological malignancies ($p = 0.041$).

The mean survival of progressive motility post-thaw was 20.4%. Only 39.6% of samples had motility survival above 25%. The only correlation between pre-freezing sperm parameters and post-thaw progressive motility survival was the type pf tumor ($p=0.019$). At the end of the process, 93.9% of samples were considered suitable for use.

In total, 2,328 cryotubes were stored. Of these, 184 were distributed for use, and 281 were discarded due to patient death without postmortem utilisation.

Conclusions

FP requires a tailored approach to minimise cryopreservation damage and ensure the storage of viable sperm concentrations. However, the imbalance between the large number of cryotubes stored and the relatively low number of samples distributed for use presents a logistical challenge, continuously demanding expansion of storage capacity.

Parallel Session: Reproductive Tissues

ENSURING DONATION TRACEABILITY IN PATIENT INFORMATION SYSTEMS: A PERSPECTIVE FROM FERTILITY TREATMENTS

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Alinesoft (ART Sofware Oy)

Software used to manage operations and data within a SoHO entity is considered a critical component and subject to quality assessment.[1] As a software vendor, we recommend that SoHo entities include criteria for selecting and re-evaluating software providers in their quality management system (QMS). To meet SoHo requirements on traceability, data integrity, and safety standards, entities should ensure their system: 1) comply with national regulatory requirements, 2) hold appropriate data security certifications, 3) operate under an externally audited QMS, and 4) utilize standardized data formats and support system integrations.

To ensure data integrity, managing donor-related data must require elevated access privileges. These should align with each staff member's role and responsibilities, recognizing the multiprofessional nature of treatment procedures. Access rights should be flexibly adjustable, not overly rigid or binary to avoid hindering workflow efficiency. Poorly designed access controls can lead to workarounds like writing patient data on paper notes, which poses a security risk. Furthermore, all changes to donor or patient data must be logged, including the user-ID and timestamp.

To ensure complete traceability of the origin and destination of gametes used in fertility treatments—along with their associated procedures and materials—it is essential that each gamete is assigned a unique, unchangeable key in the information system. This key must remain permanently linked to the individual from whom the gametes originate, even if their personal identity number changes.
For donations from anonymous sources, the gamete key must be linked to the reference code of the commercial cryobank and, where applicable, the Single European Code (SEC).

To minimize the risk of human error, we recommend implementing multilevel linking between donors and recipients. For example, the Aline fertility clinic software uses a two-level crosslinking system, which requires that the connection between the donor and recipient—and their respective treatment cycle IDs—is verified from both perspectives. In this setup, donations are not only linked to individuals but also to their specific treatment cycles, adding an extra layer of safety and traceability.

To ensure uninterrupted traceability of gametes from commercial cryobanks, we recommend integrating the bank's data platform with the clinic's patient information system to enable two-way data exchange to avoid manual handling errors. This supports monitoring of adverse events and helps cryobanks track the number of children conceived from a single donor—an increasingly important issue as several member states have called for an EU-wide limit on donor offspring across borders.[2]

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Parallel Session: Ocular Tissues

THE CURRENT STATE OF EYE BANKING

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Eye banks are the crucial link between the gift of donation and the restoration of sight. Today, the field of eye banking is being shaped by innovative technologies, regenerative therapies and Advanced Therapy Medicinal Products. These changes are not just improving the efficiency of corneal transplantation, but are also expanding access to cutting-edge treatments for vision impairment. Despite this, there is still a significant shortage of corneal tissues and access to regenerative therapies, particularly in the developing countries. As we explore the latest trends in vision science and regenerative ophthalmology, it becomes clear that eye banks are entering a new era of possibilities. Emerging trends in eye banking include:

1. Enhanced tissue preservation techniques (through newly developed media or bioreactors) to extend the viability of donated corneal tissues, ensuring less mortality, better and prolonged preservation of endothelial cell density during storage and, eventually, improved patient outcomes;

2. Regenerative medicine and stem cell research enabling the cultivation of corneal epithelia and endothelium from stem/progenitor cells, thus potentially reducing dependence on donor tissues and addressing shortages;

3. SMILE (Small Incision Lenticule Extraction) banks as a way to harvest and preserve lenticules extracted following myopia correction through femtosecond laser in refractive surgeries. Such lenticules could be used for additive keratoplasty or as a tectonic bandage to repair corneal scars;

4. Advancements in Artificial Intelligence-based technologies to enhance the analysis of donor tissues and, ultimately, increase the safety and success rates of transplants;

5. New medical devices, such as advanced intraocular lenses or artificial endothelia, to help surgeons postponing transplants in countries with low donation rates

6. Networking, standardized practices and training initiatives for surgeons and eye bank technicians allowing to elevate the consistency of eye banking services and the quality of the grafts supplied to surgeons, thus eventually leading to improved tissue utilization.

In addition to these innovations, efforts are being made towards the development of strategies to tackle retinal disorders through the development of cell/gene therapy-based approaches (for the treatment of Age Related Macular Degeneration) or newly validated tissues (for the treatment of macular holes). Providing new therapeutic options to refractive surgeons might become the new horizon for the eye banks of tomorrow.

Importantly, as these technologies continue to evolve, it is essential for eye banks, vision scientists and clinicians to stay abreast of these developments and set up carefully designed clinical trials to validate such technologies and, later, integrate them into the clinical practice.

Parallel Session: Ocular Tissues

BRIDGING CONCEPT TO CLINIC: PRECLINICAL CONSIDERATIONS FOR STEM CELL-BASED OCULAR SURFACE REPAIR

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Background
Blindness causes a huge burden on both the patients and society. Limbal Stem Cell Deficiency (LSCD) is a rare form of corneal blindness primarily affecting young and working-aged adults, with an estimated prevalence of around 3 cases per 100,000 people. To advance curative treatments for patients suffering from severe ocular surface disorders, we are developing an allogenic iPSC-derived limbal stem cell (LSC) therapy. Our ongoing preclinical studies focus on establishing GMP manufacturing process and robust preclinical transplantation models.

Methods
We are manufacturing LSCs from a clinical grade off-the-shelf hypoimmunogenic iPSC-line that has undergone extensive quality testing. Our manufacturing process allows production of made-to-order drug products within a week from order. The product is delivered in a monitored portable incubator which can be used also for storage until transplantation. Our nonclinical strategy to support first-in-human (FIH) studies include demonstration of proof of concept in rat and pig models of LSCD, as well as evaluation of biodistribution and tumorigenic potential in mice.

Results
Iterative testing using in vitro, ex vivo, and in vivo systems enabled the refinement of the drug product's delivery method, dosing strategy, and potency assay selection. Based on logistics testing, a 72-hour shelf-life and hand-carry service were selected for product shipment. Analytical testing in vitro indicated genetic stability, low tumorigenic potential, and potency for the drug product. A key translational challenge was optimizing the delivery method to maintain cell viability and ensure successful engraftment across species, emphasizing the critical role of carrier selection.

Conclusions
Our data highlights the translational challenges associated with cell delivery and applicability of potency assays. Extensive testing across in vitro, ex vivo, and in vivo platforms provided critical insights into product performance and safety, as well as logistical considerations from the manufacturing site to the clinic. These findings directly inform the design of FIH clinical trials and support the development of a robust regulatory strategy.

Parallel Session: Ocular Tissues

CHANGING PATTERNS OF MICROBIAL CONTAMINATION AND ANTIMICROBIAL SENSITIVITY IN CONTAMINATION OF ORGAN CULTURED CORNEAS

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Background:
Microbiological contamination is a major concern in eye banking, especially with the emergence of antibiotic-resistant bacteria, which poses an increasing threat to the safety of donor cornea transplantation. Despite the implementation of antiseptic procedures and antibiotic-enriched storage media, donor corneas remain vulnerable to microbial contamination during retrieval, processing, and storage, potentially compromising graft safety and viability.

Methods
A retrospective analysis was conducted on corneal tissues received at the Tissue Bank, University Hospital Centre Zagreb between 2021 and 2024. Contamination rates were assessed, the most common bacterial and fungal pathogens identified, and the effectiveness of standard microbiological screening protocols and antibiotic supplementation in culture media evaluated. Microbiological testing of the organ culture medium (Tissue-C, Alchimia, Italy) was performed between days 4 and 7 of cultivation. In cases of visible contamination (e.g., turbidity or color change), testing was conducted immediately, as well as on the final day of culture. Additional samples were taken 24 hours after transfer to the deswelling medium (Carry-C, Alchimia, Italy). An automated detection system (BD BACTEC™ FX, Becton Dickinson and Co., USA) was used with aerobic and anaerobic blood culture vials, with a 7-day incubation period. Daily visual inspection of the preservation media was also performed. Corneas were classified as contaminated if turbidity or color change was observed.

Results
A total of 1,666 corneas were processed between 2021 and 2024. The overall contamination rate in organ-cultured corneas was 2.6%. Gram-negative bacteria were the most common contaminants, followed by fungi. A notable increase in multidrug-resistant bacteria was observed, with Acinetobacter baumannii being the most frequently isolated species. Among fungi, Candida species were predominant. A decline in antibiotic sensitivity in the culture media was also noted. Visual inspection—specifically the detection of turbidity or discoloration—proved to be a reliable early indicator of microbial contamination.

Conclusion
Microbiological contamination, particularly with antibiotic-resistant bacteria and fungi, remains a significant challenge in corneal tissue banking. These findings reflect the evolving microbiological landscape of corneal transplantation. Continuous surveillance, strict aseptic techniques, and optimization of antibiotic regimens in storage media are essential to ensure graft safety. In the face of rising resistance, innovation and vigilance are more important than ever.

Keywords: Organ culture, corneal transplantation, microbiological contamination, eye bank

Parallel Session: Ocular Tissues

LONG-TERM STORAGE OF HUMAN DONOR CORNEAS AFFECTS PUTATIVE LIMBAL STEM CELL MARKER EXPRESSION AND COMPROMISES EPITHELIAL INTEGRITY

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Limbal epithelial stem cells (LSCs) are located in the peripheral cornea within the limbal niche and play a critical role in the regeneration of the corneal epithelium. Despite their importance, the precise identity and spatial hierarchy of LSCs in vivo remain controversial, largely due to the limited availability of robust in vivo characterization methods. Human donor corneas provide a valuable model system for investigating the hierarchical organization and spatial distribution of LSCs. However, the stability of the bona fide LSC phenotype during organ culture remains largely unaddressed.

In collaboration with the Regea Tissue Bank, we systematically analyzed the expression of putative LSC markers in human donor corneas stored for 1 to 30 days. Using whole-mount immunofluorescence staining (WM-IF), we examined the spatial distribution of these markers from the limbus to the central cornea and quantified the fluorescence intensity. We verified the results using porcine corneas obtained from a slaughterhouse and processed within 0–6 hours post-euthanasia. In addition, we compared the WM-IF results with the gold-standard immunostaining of cryosections from human and porcine corneas, as well as with both primary LSC cultures and human pluripotent stem cell-derived LSC (hPSC-LSC) cultures.

WM-IF combined with quantitative analysis of fluorescence intensities demonstrated superior capability in resolving the spatial distribution of LSC markers within human and porcine corneas compared to conventional staining of cryosections. The duration of storage of human donor corneas significantly influenced LSC marker expression, with prolonged storage associated with a reduction in putative LSC markers and notable epithelial degeneration. Furthermore, we validated the utility of WM-IF in human donor corneas as a research control by demonstrating diverse and region-specific expression patterns of PAX6 across the limbal–corneal axis, consistent with observations from hPSC-LSC differentiation experiments.

As a conclusion, WM-IF provides a powerful method for high-resolution analysis of marker expression in human donor corneas. Importantly, prolonged storage significantly compromises LSC marker expression and epithelial integrity, underscoring the critical importance of using fresh donor tissue in studies of LSC phenotype and identity.

Parallel Session: Ocular Tissues

CORNEAL DONOR TESTING DURING THE COVID-19 PANDEMIC

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Background
Covid-19 had a huge impact on corneal transplantation. Early in the pandemic, elective surgeries and eye banking were suspended. Tissue collection was initially not permitted at all due to the risk of virus transmission through donated corneas. Later, Covid positivity or symptoms have prevented donation. SARS-CoV-2 RNA has been reported in tears and conjunctival secretions from Covid positive patients both with and without conjunctivitis. Post-mortem studies evaluating viral RNA in ocular tissue from COVID-19 infected patients are inconclusive. Some studies have reported viral RNA in the cornea, sclera, and retina, while others have reported no viral RNA in ocular tissues.
We wanted to find out if there was a need to test donors for the Covid virus.

Methods
Testing of corneal donors was started 2020 and continued until June 2023 in Helsinki University Hospital Eye Bank. Post mortem nasopharyngeal RT-PCR test for detecting SARS-CoV-2 RNA was done for all the donors.

Results
A total of 276 donors were tested (56 in 2020, 82 in 2021, 85 in 2022, 53 in 2023). Two positive samples were obtained, both in year 2022. These donors had no history of symptoms and pre mortem Covid test was negative. Transplants were rejected from surgery.

Conclusions
There was a low percentage (0.7%) of positive Covid samples in asymptomatic corneal donors in Helsinki. The evidence for ocular transmission of the virus is insufficient. Based on our results, we believe that general testing of asymptomatic corneal donors during the pandemic was unnecessary.

Parallel Session: Ocular Tissues

IMPACT AND ACHIEVEMENTS OF INDO-GERMAN COLLABORATION FOR GLOBAL EYE DONATION

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Background

Geographical imbalance in cornea supply and non-standardized training and education are features of global eye donation and banking. Two leading organizations in eye banking and tissue donation in North India and Germany have established collaboration to identify and cross-pollinate best practices from both institutions and thereby improve service delivery of both systems.
Gold standard training centres are unavailable to train the human resources in tissue donation whereas the properly trained certified manpower is the demand to improve the quality and increase efficiency in donation.

Methods

Between 2021 and 2025, two back to back grants were funded by financial means of the German Federal Ministry for Economic Cooperation and Development (BMZ) and supported by the funding programme Hospital Partnerships of the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ).
Firstly, the project was to upscale continuity of cornea supply. The network structure, hub-and-spoke model, from the German partner was introduced to the eye bank in Delhi (hub) through the establishment of four new centres (spokes) for hospital-based cornea collections under central management.
The second focus was on the strengthening and capacity building to develop human resources to fulfil the training needs of the eye donation ecosystem. Modules for onboarding and refresher training programme and lesson plans for trainers have been developed aligned with assessment tools of the Indian partner, to facilitate online education and in-person workshops.
Thirdly, we have developed a concept for an electronic database to document the full process from donation to transplants distribution. The concept was based on a comparative process analysis and adapted from the database of the German partner to meet the needs and country legislations in India.

Results

The database concept is ready to be integrated in the Indian Partner's hospital information management system. The hub-and-spoke model has proven its efficiency by increasing the collection numbers by more than 650 corneas in four years and being resilient by balancing local disruptions in donation.
Training in eye donation counselling and cornea recovery was provided by the Indian Partner to 93 individuals. The recovery technician training was acknowledged and certified by the Eye Bank Association of India.

Conclusions

The initiatives have shown how best practice from one geography can be adapted and successfully implemented in another geography and learnings enrich the tissue donation ecosystem both culturally and professionally. The way forward, the knowledge resources created will be spread globally to support eye donation communities in further regions.

Keywords: Donation, Training, Cornea, Eye, Development

Parallel Session: Musculoskeletal Tissues

SURVIVAL RATE OF HIP AND KNEE ARTHROPLASTY REVISIONS USING STRUCTURAL BONE ALLOGRAFT: A RETROSPECTIVE STUDY ABOUT 245 CASES

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Background
Massive structural bone allografts represent a valuable reconstruction option in hip and knee revision arthroplasty with massive bone loss. This study aimed to determine the overall survival rate of those grafts and to underline the different influencing factors.

Methods
We retrospectively reviewed 245 revisions of hip (n=208) and knee (n=37) arthroplasties using structural allograft. Only cases involving massive structural allografts were included, defined as grafts exceeding 5 cm and capable of providing circumferential mechanical support. Cases involving only morselized, cortical struts or half femoral head grafts were excluded. Radiographic and clinical assessments were performed at standardized postoperative intervals. The primary endpoint was defined as the survival of the reconstruction, established as the absence of allograft removal in the follow- up period. We also analysed operative indications and complications, which were categorized as either mechanical (pseudarthrosis, fracture, loosening…) or infectious. The overall survival rates were calculated using Kaplan-Meier methods.

Results
At a mean follow-up of 59 months (range 0-205) the overall survival rate for hip reconstruction was 78.85%. Among the failures, half were due to mechanical complications and the other half to infections. Although the rate of infectious complications was higher in reconstructions performed for septic indications, it remained within the expected range for septic revision surgery (15%) and did not compromise overall graft survival. Kaplan Meier survival curve was surprisingly superior for patient with prior infection than for patient with a surgery for mechanical purpose. Knee arthroplasty revisions, with a mean follow-up of 69 months (range 3–211), showed a lower survival rate of 67,5%. 58% of failures were attributed to infections and the rest to mechanical causes 42%. In knee revisions, the indication (septic vs. aseptic) was not associated with graft failure; most mechanical failures occurred around 5 years at the distal femur due to fatigue fractures following graft resorption.

Conclusions
Structural bone allografts represent a reliable option for complex reconstructions in hip and knee revision arthroplasty, with satisfactory overall survival and well-identified, manageable complications.

Considering the distal femoral fracture complication rate, we no longer recommend the use of structural allografts for distal femoral reconstruction in knee revisions. Interestingly, patients who received allografts for infectious indications demonstrated superior graft survival in this series according to Kaplan Meier curves.

Keywords: Arthroplasty revision, Hip arthroplasty, Knee arthroplasty, Structural allograft, survival rate, complications, infections

Parallel Session: Musculoskeletal Tissues

ENHANCING OF THE PRODUCTION PROCESS: A 10-YEAR JOURNEY IN THE TRANSFORMATION OF DECELLULARIZED GRAFTS AT CLINIQUES UNIVERSITAIRES SAINT-LUC

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Introduction

Since 1988, UTTCAL has been producing decellularized and virus-inactivated bone allografts to meet the needs of patients in various surgical specialties. These grafts are primarily derived from living donors who provide femoral heads during hip replacement procedures. Processing is performed in a controlled cleanroom environment by trained personnel following validated protocols.

Objectives

This study aims to describe the optimization of femoral head cutting and to demonstrate its impact on the number and variety of grafts produced, in order to better align with surgical demands.

Methods

A retrospective analysis was conducted using data from the UTTCAL tissue bank for the years 2014 and 2024. Data on living donors and graft production were extracted and analyzed. Descriptive statistics (counts, percentages, and means) were used to summarize the findings.

Results

In 2014, 1,224 femoral heads from living donors (45.6% male, 55.4% female; mean age 67 years) yielded 2,324 grafts across 11 types. In 2024, 1,190 femoral heads from 1,181 donors (44.9% male, 55.1% female; mean age 67.3 years) yielded 2,983 grafts across 19 types. Through multidisciplinary efforts focused on technical tools, clinical needs, and cleanroom constraints, cutting techniques were optimized to reduce material loss and improve yield. This resulted in a 31.6% increase in the grafts-per-head ratio and the development of 8 new graft types, corresponding to an annual increase of approximately 640 grafts.

Conclusion

Optimizing femoral head cutting significantly enhanced both the quantity and diversity of grafts produced. The synergy between the production team's expertise and the graft delivery team's collaborative efforts has been crucial in expanding the available graft options to surgeons, thus better addressing the diverse needs of patients across multiple surgical fields.

Keywords: Leaving donors, Femoral head transformation, optimization

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Parallel Session: Musculoskeletal Tissues

PROBONES TISSUE BANK: ANALYZES OF THE THREE YEARS EXPERIENCE

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Background
Probones Tissue Bank (PTB) is the first and currently the only one in Ukraine multi Tissue Bank, founded in 2021 with the aim of providing patients with high-quality allografts for reconstructive surgery, orthopedy and restorative medicine. PTB has strictly adhered to the protocols of the European and also local laws in Ukraine. In this review we purpose analyzes of the effectiveness of the PTB activities as well as the impact of the Russian-Ukrainian war on these processes.

Methods
180 subjects (from 21 to 80 years old) were included in our project from January 2021 to October 2025, and we analyzed the results and complications associated with the use of allografts.
All tissues were processed in the PTB. All subjects were selected according to the EATB criteria. Traceability of the tissues are available at all stages of investigation (from procurement to implantation), using ISBT 128. All subjects underwent a physical examination and blood samples were taken for serological tests (HIV, hepatitis B, C, syphilis). Raw materials were processed in the clean rooms class D. The ISO 13485 quality system was used. The allografts were sterilized by using an electronic accelerator and decontaminated with a cocktail of antibiotics.

Results
For all 180 subjects, selected for analysis, in 170 (94.4%) cases, the tissues were procured after biological death, and in 10 (5.6%) cases the tissues were procured after brain death. In 15 (8.3%) subjects the tissues were excluded due to positive serological tests. Bones, tendons, dermis and nerves were procured from 165 subjects as donors. All the obtained allografts have been successfully used for treatment of burns, restoration of bone defects, reconstruction of nerves and tendons, and for soft tissue plastic surgery of chronic wounds, mine explosive damage. In 45 cases, the procedures were performed on military personnel (combotants). No allografts infections or rejection reactions have been documented after transplantation.

Conclusions
The use of PTB allografts is safe and has a very low complication rate due to a strict screening process and processing protocols. PTB ensures prompt delivery, independence from external suppliers, and trust in quality.

Keywords: Probones Tissue Bank, allografts, reconstructive surgery, orthopedy, cornea

Parallel Session: Musculoskeletal Tissues

ENHANCED ABSORPTION AND DRUG RELEASE FROM A NOVEL FIBROUS BONE GRAFT

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Background
Effective treatment of bone defects and infections requires graft materials that not only fill defects but can also serve as carriers for drugs, antibiotics, growth factors, and other functional liquids such as platelet-rich plasma or blood. The absorption capacity and sustained release of antibiotics from these materials are critical for successful infection control. This study compares the absorption and antibiotic release profiles of various human bone allografts, focusing on a new fibrous allograft composed of demineralized cortical fibers and granulated cancellous bone.

Methods
Tested materials included three groups of fibrous allografts (rehydration rates: 2.7, 4, and 8 ml/g), demineralized bone matrix (DBM), cortical granules, mineralized cancellous bone of varying densities, and demineralized cancellous bone (all from DIZG gGmbH, Germany). Absorption capacity was measured after rehydration with phosphate-buffered saline (PBS, 0.4 cc), with centrifugation used to distinguish total and matrix-bound absorption. Grafts were loaded with gentamicin (40 mg/ml, 0.4 cc) to evaluate antibiotic elution over 21 days. Antimicrobial activity was assessed using a zone of inhibition (ZOI) assay with *S. aureus*.

Results
Demineralized cancellous bone absorbed the most fluid in interstitial spaces, while fibrous allografts showed the highest matrix-bound absorption (88.8±3.0%). Low-density cancellous bone had the lowest matrix absorption (1.0±1.1%). Fibrous allografts with an 8 ml/g rehydration rate exhibited a rapid initial gentamicin release, whereas those with 2.7 and 4 ml/g rates provided more sustained and higher antibiotic release over three days compared to DBM and cancellous bone. Absorption and release kinetics were minimally affected by incubation times (5–30 min). The largest ZOI was observed in samples eluted for one hour, and fibrous allografts maintained antimicrobial activity for up to 21 days.

Conclusions
The novel fibrous allograft demonstrates superior matrix absorption and sustained antibiotic release, making it a promising carrier for local drug delivery in orthopaedic applications. Its capacity to retain and gradually release functional substances make it ideal for infection management and bone reconstruction.

Keywords: infection, bone, grafting material, carrier graft

Parallel Session: Musculoskeletal Tissues

MODULATION OF THE RELEASE PROFILE OF A BIOLOGICALLY ACTIVE COMPOUND AFTER DOUBLE LOADING OF DEMINERALIZED BONE GRAFT

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Introduction

The preparation of demineralized bone grafts (DBG) is often associated with a significant loss of growth factors. This loss results from prolonged exposure to various solutions during the demineralization process, as well as from subsequent washing steps aimed at removing bone marrow, fat, and restoring physiological pH. It is well established that mammalian albumins can bind a wide range of endogenous compounds and therapeutic agents in the bloodstream. Moreover, loading demineralized bone with albumin has been shown to enhance its regenerative capacity. Based on this property, we conducted a series of tests to evaluate the potential for controlled release of biologically active substances initially loaded into DBM, following secondary impregnation with bovine serum albumin (BSA).

Materials and methods

Demineralized cancellous bone (DBG) was prepared from bovine iliac bone by treatment with 0.5 M hydrochloric acid (HCl). Subsequent processing followed protocols established at the Human Tissue Bank of the Clinical Hospital of Traumatology and Orthopedics. To assess the controlled release of a model biologically active compound, primary loading was performed using a 10× solution of Methylene Blue (MB) (BioGnost, Croatia). Thirteen DBG samples were subjected to vacuum at 400 mbar in a specially designed vacuum chamber. After 10 minutes of vacuum application, 150 mL of MB solution (325 µg/mL) was introduced into the chamber for primary impregnation. Following the initial loading, the samples were divided into four groups based on the secondary loading protocol:

- Group 1 (MB+dH_2O) – positive control – secondary loading with deionized water;
- Group 2 (MB+10%BSA) – secondary loading with 10% bovine serum albumin (BSA);
- Group 3 (MB+20%BSA) – secondary loading with 20% BSA;
- Group 4 (MB) – negative control; no secondary loading.

No statistically significant differences were observed in the initial weights of the DBG samples across groups ($p > 0.2$). After secondary loading under vacuum, all samples were frozen at –80°C and subsequently freeze-dried. To evaluate the release of MB, each sample was immersed in deionized water, and MB concentration was monitored over a 33-day period. At predetermined time intervals, absorbance at 570 nm was measured using a spectrophotometer (BioTek Instruments, USA).

Results

After 33 days of monitoring Methylene Blue (MB) release, a statistically significant difference ($p < 0.05$) was observed between the two control groups (MB and MB+dH_2O) during the period from 4 hours to day 8. The negative control group (MB) exhibited a significantly higher release of MB during this

interval. Beyond day 8, no significant differences in MB release were observed between the two control groups ($p > 0.05$). When comparing the experimental groups to the positive control (MB+dH_2O), no statistically significant differences in MB release were found within the first 6 hours for the MB+10%BSA group and within the first 21 hours for the MB+20%BSA group ($p > 0.05$). However, from these respective time points up to day 6, MB release in the positive control group was significantly higher than in the experimental groups ($p < 0.05$). After day 6, the release rate in the positive control decreased, and no significant differences were found when compared to the experimental groups ($p > 0.05$). In comparisons with the negative control, both experimental groups (MB+10%BSA and MB+20%BSA) showed significantly lower MB release during the first 11 days ($p < 0.05$). After day 11 and continuing through day 33, MB release levels across all groups converged, and no statistically significant differences were detected ($p > 0.05$).

Conclusion

Secondary loading of demineralized bone with BSA can modulate the release profile of a model biologically active compound. BSA-loaded samples exhibited a delayed and more controlled release compared to controls, particularly during the early phase, suggesting potential utility for applications requiring sustained delivery of therapeutic agents.

Keywords: demineralized bone graft, vacuum, release profile, double loading

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Parallel Session: Musculoskeletal Tissues

NANOSTRUCTURED BONE GRAFT FOR MEDICAL APPLICATIONS

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Introduction

The limited stock of autologous bone grafts, but also the possibility of transmission of zoonoses and zooanthroponoses through xenogeneic bone grafts makes allogeneic bone grafts of greater interest for transplantation into bone defects. On the other hand, the increased incidence of postoperative infections after repair of these defects, especially in high-risk patients, serves as a reason for the development of complete grafts with pre-established antimicrobial properties. Thus, bone grafts based on collagen extracted from the umbilical-placental complex would present an important source for grafting.

Material and methods

The composite biomaterial was obtained by direct mineralization of collagen extracted from the umbilical-placental complex with hydroxyapatite precursors and functionalized with zinc oxide. Using scanning electron microscopy (SEM) the composites were morphologically characterized, and SEM images were obtained at 20 kV in a Vega 5130 apparatus (Tescan, Czech Republic).

Results

The comparative SEM analysis of the functionalized and non-functionalized composites highlights the importance of the antimicrobial properties of zinc oxide, as well as its influence on the morphology of the composite. Thus, the phases of the functionalized composite present a well-defined and uniform porous network, with the highlighting of agglomerations in the form of zinc oxide granules, while in the unloaded composite the cohesion of the phases is weaker and the porosity is non-uniform. Based on the EDS spectrum, the presence of peaks for Ca, P (hydroxyapatite derivatives), O, C, Zn is attested, which highlights the presence of collagen, hydroxyapatite and ZnO, the constituent elements of the composite.

Conclusion

The composition of the obtained biomaterial is safe, characterized by osteoconductivity and biocompatibility based on the components: collagen and hydroxyapatite.

Zinc oxide loading represents an obvious advantage for bone grafts, favoring antimicrobial potential, but also by increasing the success rate in the regenerative process of bone tissues after grafting. Also, these characteristics create new opportunities for the use of these structures in tissue engineering due to optimal cellular integration and remodeling.

Key-words: collagen, umbilical-placental complex, nanostructured bone graft, zinc oxide.

Parallel Session: Musculoskeletal Tissues

BONE GRAFTS FUNCTIONALIZED WITH ESSENTIAL OILS

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Introduction
Postoperative antibiotic therapy in bone grafting has become a major medical problem that requires reevaluation of antimicrobial strategy. Thus, there is a need to obtain new grafts that would allow successful osseointegration and at the same time provide evident antimicrobial properties. Currently, using essential oils in biomaterials is a modern and sustainable strategy to improve the performance of bioactive grafts, adding antimicrobial, anti-inflammatory and regenerative functions, without the risks associated with antibiotic therapy.

Material and methods
The composite biomaterial was obtained by direct mineralization of collagen extracted from the umbilical-placental complex with hydroxyapatite precursors and loaded with essential oils of Lavandula Angustifolia, Mint and Clary Sage. Fourier transform infrared (FTIR) spectra were recorded using a Nicolet iS50R spectrometer (Thermo Fisher Scientific, Waltham, MA, USA) equipped with an attenuated total reflectance (ATR) accessory. Spectra were recorded at room temperature, with each spectrum representing the average of 32 scans, from 400 to 4000 cm−1, with a resolution of 4 cm−1.

Results
Fourier transform infrared molecular absorption spectroscopy of the composites based on collagen extracted from the umbilical-placental complex and hydroxyapatite and those loaded with essential oils highlighted the main components of the composite and the appearance of new bands specific to the given oils. The association of the composite with essential oils determined the appearance of carbonyl, ester bands, as well as other modifications that reflected the molecular interactions between the composite and the essential oils used.

Conclusion
Based on the results of the comparative FTIR analysis of composites based on collagen extracted from the umbilical-placental complex and hydroxyapatite and those loaded with essential oils, it demonstrated the structural stability of the composites, as well as the efficient immobilization of volatile compounds.
Allogeneic collagen-based composites with pre-established antimicrobial properties are safe and have potential for use in regenerative medicine

Key-words: collagen, umbilical-placental complex, bone graft, essential oil.

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Parallel Session: Contingency Planning, Implementing New Regulations

CONTINGENCY PLANS WITHIN NHS BLOOD AND TRANSPLANT (NHSBT) – REVIEWING RISK MANAGEMENT ACROSS THE DONOR TO PATIENT PATHWAY

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Background

NHS Blood and Transplant (NHSBT) is responsible for obtaining consent, collection, processing, donor screening, donor assessment and distribution of human tissue for transplantation across the majority of the UK. It is good practice and a regulatory requirement to have robust business continuity plans to ensure uninterrupted delivery of these essential services. These plans must encompass the entire supply chain, from donation through to distribution, and are regularly tested through simulated scenarios or real incidents. Insights gained from these tests and incident re used to refine and strengthen the plans.

Previously, contingency plans within Tissue and Eye Services (TES) at NHSBT were developed separately for each department. For instance, tissue and eye bank plans focused solely on processing and storage. However, simulations revealed that while these individual plans were effective in isolation, a more integrated approach, considering the entire supply chain and interdepartmental dependencies would be more beneficial.

Methods

A cross-departmental working group was formed, with representatives from each area, to review and update the existing contingency plans. Key risk areas were identified and assessed, including:

- Premises
- People
- Resources (eg, consumables)
- Technology
- Other

Each type of tissue presents unique risks. For example, heart valves are both life-saving and short supply, while corneas have a short shelf life. As such, contingency plans were tailored to the specific characteristics and criticality of each tissue type.

Plans were structured into short, medium, and long-term timeframes, recognising that priorities and resource needs may shift depending on the duration of the disruption, and an overarching manual was written to cover all departments.

Results

The revised, integrated plans were tested during a real-life incident involving a major IT outage that disrupted internet and phone services. A Local Emergency Team (LET) was assembled, comprising key personnel from each department. The team met twice daily to review the situation, coordinate actions, and update the contingency plans. Priorities were agreed upon collaboratively, and a decision log was maintained to keep a record of actions and outcomes.

Conclusions

The development of unified, cross-departmental contingency plans has significantly improved the resilience of the tissue supply chain. By collaboratively assessing risks and impacts across all departments, NHSBT has enhanced its ability to maintain service continuity. Ongoing testing and the lessons learned from these exercises are vital for continuously improving the plans and ensuring all departments are prepared for future disruptions.

Keywords: NHS Blood & Transplant, Business Continuity, Contingency plans, supply chain

Parallel Session: Contingency Planning, Implementing New Regulations

HOW SWEDEN WILL ACHIEVE A CLINICALLY DRIVEN TISSUE SERVICE BY 2030: A DATA-DRIVEN APPROACH

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Introduction

In 2023, the Swedish government commissioned the National Board of Health and Welfare with developing the first strategy for organ and tissue donation and transplantation. One of the key ambitions of the 5 year-strategy, launched in October 2025, was to establish a clinically driven and equitable tissue service by 2030. To realise this, and to comply with the EU SoHO Regulation, two nationwide measures are particularly prioritised: 1. mapping the national clinical demand for tissue grafts and 2. developing a national tissue information system.

Method

Between 2023 - 2025, the National Donation Centre conducted a comprehensive needs assessment of Sweden's tissue services. The analysis included allogeneic tissues from deceased donors for the purpose of transplantation. Mixed-methods data collection included numerous stakeholder consultations, six national surveys across the healthcare regions, and a two-day conference, which targeted experts and decision-makers from across the tissue pipeline; from donor referral units to transplant centres. An iterative approach was used, allowing initial findings to inform subsequent targeted follow-ups using structured questions to assess operational challenges, information system and national demand for tissue grafts. Findings were analysed for desired outcomes and stakeholder alignment.

Results

Sweden currently lacks a centralised, real-time data system to monitor national demand, current stock levels, and a mechanism for identifying tissue shortages. It is not possible to determine whether Sweden is self-sufficient, to monitor changes in demand or to make decisions based on clinical national prioritisation. This does not allow for contingency planning. The vast majority of stakeholders consulted in this project support developing a national tissue information system. The system would align with international standards (e.g. *EDQM Tissue guide*), provide nationwide transparency, enable data-driven decisions and equitable allocation. Due to the decentralised healthcare regional structure, there is currently no national body with mandate that can respond to tissue shortages on a national level. Governance and financing models are currently unresolved.

Conclusion

A national tissue information system is essential to achieving Sweden's 2030 goal and to meeting national and EU regulations. Critical to the success of such initiative is to identify sustainable financing models, to determine appropriate ownership and governance structures, and to secure stakeholder buy-in. Along with the collaborative efforts and active involvement of professionals - without which, a clinically driven tissue service by 2030, with equitable access to tissue transplantation, will likely remain unachievable.

Parallel Session: Contingency Planning, Implementing New Regulations

SPANISH STRATEGIC TISSUE PLAN – PENT - (2022-2026): A KEY TOOL FOR IMPLEMENTING THE SoHO REGULATION

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Background

Initiative of the National Transplant Organization (ONT) in collaboration with the Spanish Association of Tissue Banks (AEBT), associated with the Technical Tissue Committee (CTT).
The PENT aims to engage professionals and experts from all sectors involved in human tissue activities to define and implement sustainable strategies that will enable national self-sufficiency and ensure best practices that guarantee the quality and safety of human tissue-based therapies.

Methodology

For the development of the PENT, 5 Working Groups (WG) have been created:

WG1: DATA COLLECTION/ HARMONIZATION
WG2: TISSUE ESTABLISHMENTS (ET)/ PRODUCT EVALUATION
WG3: BIOVIGILANCE
WG4: INSPECTION/AUTHORIZATION
WG5: TRAINING

Results

WG1:

- Activity report adapted to the EDQM-European Commission Harmonization Project
- Registration of individual data of tissue/organ donors in the ONT-CORE system (SI)
- Registry of Authorized Centers: National and European

WG2:

- TCCOD tissue coding for ETs that do not have a coding system
- Evaluation of innovative tissues and derived products (CEICyTH)

WG3:

- Biovigillance SI integrated into the Organ SI
- Biovigillance case management
- Constitution of the National Subcommittee on Organ, Tissue and Cell Safety
- Updated list of implant centers

WG4:

- Updated Guide for Autonomous Communities prepared by the Inspection Group of the CIT Transplant Commission
- European Inspection Group (IES) pilot joint inspection, Málaga (Spain)
- Good Practice Guide for the Authorization of Preparation Processes in ET and Cells (GAPP)

WG5:

- Annual Training (ONT)
- Additional Training - online sessions

Conclusions

The PENT seeks to establish strategies that allow us to address the challenges identified in this area with greater guarantees of success, within the process of continuous improvement of all activities related to tissue and cell donation and transplantation, as well as Research, Development and Innovation in this field.

Its strategic lines anticipate those defined by the SoHO Regulation, facilitating its implementation.

Parallel Session: Contingency Planning, Implementing New Regulations

SPANISH EXPERIENCE IN THE HARMONIZATION OF ACTIVITY DATA IN TISSUES AND CELLS

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Background
The *European Directorate for the Quality of Medicine and Healthcare* (EDQM) of the Council of Europe and the European Commission led a project to harmonize data collection on activity related to tissues and cells. Based on the experience of different European Union (EU) Member States and scientific societies in the field, the project established a set of data to be collected by Member States in order to ensure transparency of practices, facilitate the evaluation of the safety of procedures (biovigilance), and assess the availability and sufficiency of tissues and cells for transplantation. We describe the Spanish experience in adapting our national data collection to the variables and definitions established in the said project.

Methodology
Working Group 1 of the SPANISH STRATEGIC TISSUE PLAN 2022-2026 (PENT), coordinated by the Organización Nacional de Trasplantes (ONT) conducted a comparative analysis of the variables included in the previous Spanish data collection and those proposed in the harmonized data collection. The new data collection was used to build the national activity report in 2023 and 2024.

Results
The new data collection implied modifications in all variables compared with the previous data collection in Spain:

- Pediatric age defined by age <18 years vs <15 years
- Definitions for tissue preparations and units: modifications were required for all tissue types, incorporating more subtypes and details on the units used
- New list of activities carried out in Tissue Establishments
- Variables of distribution at national and regional level by tissue
- Volume of imports and exports to third countries by tissue
- Implant: procedures vs. transplant patients

Conclusions
Spain is the first EU member state to incorporate the proposed harmonized data collection agreed upon at the European level.
This harmonization exercise has been complex, requiring a coordinated work between the ONT and the PENT stakeholders, and an effort by entities, establishments and authorities.
The result is a more detailed and accurate activity report, in line with the provisions of the SoHO Regulation, which will facilitate mutual recognition and exchange of SoHO preparations between EU countries.

Parallel Session: Contingency Planning, Implementing New Regulations

GAPP-PRO JOINT ACTION: LATEST UPDATE

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Background

The Joint Action *Piloting GAPP Model Approach for Assessing and Authorising Novel Substances of Human Origin Preparation Processes* (GAPP-PRO) was launched in February 2024 (https://gapp-pro.eu).
The GAPP-PRO Joint Action builds upon the previous European initiative GAPP, bringing together national Competent Authorities (CAs) and other stakeholders involved in the authorisation of preparation processes for Substances of Human Origin (SoHO).

Methods

A survey to collect updated information on SoHO preparation processes in Europe, categorised by different risk levels — including bedside preparations — was carried out. This survey was addressed to all European CAs.
In parallel, joint country and a cross-country assessments are being conducted within pilot authorisation processes for different types of SoHO: blood, blood components, tissues, cells, reproductive cells, breast milk, and faecal microbiota. The main goal is to properly evaluate, through a set of indicators, the applicability of the GAPP methodology (https://www.gapp-ja.eu), which includes the application of a Preparation Process Dossier (PPD), as common approach.
In addition, interviews with the SoHO entities that prepared the PPDs, as well as with the experts and CAs involved in the evaluations to gather relevant insight for further considering.

Results

The survey results will form the basis of the SoHO Preparation Compendium, which will be incorporated into the SoHO Platform as outlined in the Substance of Human Origin Regulation (Regulation (EU) 2024/1938).
The pilots using real PPDs, along with the indicators and interview findings, will support the evaluation and refinement of the GAPP methodology for different types of SoHOs. The involvement of all relevant stakeholders will contribute not only to the validation of the tool, but also to the development of a harmonised procedure endorsed by both SoHO entities and CAs.

The new SoHO Regulation establishes that CAs must provide guidelines and templates for submitting applications for preparation process authorisation, as well as for designing clinical outcome monitoring plans. The updated GAPP-PRO Guideline will be aligned with this new regulation.

Conclusions

The GAPP-PRO Guideline will offer SoHO entities a standardised methodology for requesting authorisation of preparation processes, and provide CAs with a common framework for reviewing and approving these processes. This will enhance mutual recognition across the European Union.

Keywords: Preparation Process Authorisation, SoHO Regulation, SoHO Compendium.

Parallel Session: Contingency Planning, Implementing New Regulations

COMMITTEE FOR THE EVALUATION OF INNOVATION WITH CELLS AND TISSUES OF HUMAN ORIGIN AND DERIVED PRODUCTS (CEICyTH) – 2025

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Background

The authorization of SoHO preparations and patient access to innovative SoHO therapies are among the main new features of the SoHO Regulation. In order to advise on the scope of application relating to cells, tissues and other SoHO for use in humans, whether under the regulatory framework for transplants or another regulatory framework, and to evaluate new forms of SoHO preparation and research projects, the ONT anticipated the SoHO Regulation by creating a Committee for the Evaluation of Innovation with Cells and Tissues of Human Origin and Derived Products (CEICyTH), which acts in coordination with the Technical Committee on Tissues (CTT) and the Subcommittee on Hematopoietic Stem Cell Transplantation (HSCT), dependent on the Permanent Commission on Transplants of the Interterritorial Council (CIT) of the National Health System (SNS), in the performance of those functions that may overlap.

Methodology

In June 2023, the CT of the CIT approves the creation of the CEICyTH, which is formally established in December 2023. Coordinated by the ONT and made up of a permanent committee, representing the ACs at national and regional levels (ONT - OCATT - CATA), and a temporary committee with external advisors/evaluators (32 evaluators) designated based on their area of expertise, who participate in the evaluation of clinical research projects with human cells and tissues for transplantation, assess the level of scientific evidence of new applications and innovative uses within the field of transplants, as well as the increasingly numerous research projects and clinical uses with advanced therapy medicines in the regulated aspects.

Results

From December 2023 to June 2025 the following have been evaluated:

	2023	2024	2025
Research Projects	4	14	13
Consultations	2	14	12
Project Evaluation - Other regulatory frameworks	0	2	2

The vast majority of the inquiries conducted are about the new regulatory framework, and the research studies evaluated are mostly clinical trials covering all types of cells and tissues.

Conclusions

The CEICyTH is a pioneering project at European level, which constitutes an essential tool to facilitate the authorization of SoHO preparations and research projects by CAs SoHO .

It performs essential advisory work on regulatory issues for all stakeholders involved in SoHO activities.

Facilitates coordination and cooperation with CAs from other regulatory frameworks in the evaluation of research projects with SoHO aimed at the manufacture of products regulated under other legislation.

Parallel Session: Contingency Planning, Implementing New Regulations

MICROBIOLOGICAL RISK ASSESSMENT DURING THE PROCUREMENT AND PROCESSING OF CELLS, TISSUES AND BREAST MILK USING THE MIRCA TOOL

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The Microbiological Risk Classification and Assessment tool (MiRCA) is a valuable instrument elaborated by the European Directorate for the Quality of Medicines & HealthCare (EDQM) for evaluation of the microbiological risks associated with the procurement, processing, testing, storage and distribution of substances of human origin (SoHO). Own data of critical points in the procurement and processing of SoHO were put into the MiRCA, including the percentage of microbiological contamination before and after processing. These data were extracted from retrospective studies performed with different types of SoHO products prepared in the Tissue Bank and the Human Milk Bank of the University Hospital Hradec Králové. The result of the analysis was a final risk number calculated separately for the procurement and processing of each type of SoHO, and the overall risk value and its probability. A total of 7,881 SoHO products were analysed. For solid tissues, the lowest risk value was determined during the procurement and processing of femoral heads (total risk value 14.4 of 695 possible). Cell collection and processing revealed higher risk values (total risk values ranging from 150 to 161 of 695 possible). The greatest risk of microbial contamination was observed in breast milk processing (172.5 of 695 possible), where the percentage of post-processing microbiological findings was 11.6 %. We conclude that the MiRCA is a valuable tool for conducting microbiological risk assessments for procurement, processing, testing, and distribution of SoHO.

Parallel Session: Skin and Other Substances of Human Origin

INFLUENCE OF ELECTRON BEAM IRRADIATION ON EXTRACELLULAR MATRIX OF THE HUMAN ALLOGENEIC SKIN GRAFTS

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Background
The non-viable allogeneic human skin grafts might be considered as the most suitable skin substitutes in the treatment of extensive and deep burns. However, in accordance to biological security such grafts require the final sterilization prior to clinical application. The aim of the study was to verify the influence of electron beam irradiation of three selected doses: 18 kGy, 25 kGy and 35 kGy on the extracellular matrix of human skin.

Methods
Prior to sterilization, the microbiological tests were conducted and revealed contamination in all examined cases. Individual groups were subjected to single electron beam radiation sterilization at proposed doses and then subjected to microbiological tests again. The FTIR spectrometry tests were conducted followed by the histological evaluation and mechanical tests. In addition, cost analysis of radiation sterilization of individual doses were performed.

Results
The results of microbiological testing performed for all irradiation doses used were negative. Only in the control group was a growth of microorganisms observed. The FTIR spectrometry tests were conducted followed by the histological evaluation and mechanical tests. In addition, cost analysis of radiation sterilization of individual doses were performed. The results of spectroscopic analysis, mechanical tests and histological staining showed no significant changes in composition and characteristics of tested tissues after their irradiation, in comparison to control samples. The cost analysis has shown that irradiation with 18 kGy is the most cost-effective and 35 kGy is the least favorable.

Conclusion
However, according to biological risk reduction, the recommended sterilization dose is 35 kGy, despite the higher price compared to the other doses tested.
Key words: Human allogeneic skin grafts, electron beam, sterilization

Parallel Session: Skin and Other Substances of Human Origin

TISSUE ENGINEERING AS A TOOL IN A NOVEL APPROACH TO THE COMPREHENSIVE TREATMENT AND MANAGEMENT OF A DEEPLY AND EXTENSIVELY BURNED PATIENT – CASE REPORT

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Background

Deep and extensive thermal burns with associated inhalation injury can be associated with a high mortality rate in this group of patients – especially in the elderly. Injuries of this type require treatment in highly specialised centres. Early excision and autografting is the standard of care treatment for extensive, deep burns. In order to obtain a functionally and aesthetically pleasing burn scar, the use of allogeneic acellular dermal matrices can be proposed as a co-graft for the autologous split-thickness skin graft (STSG). It has also been shown that the application of *in vitro* cultured, autologous keratinocytes and fibroblasts can accelerate the healing process of a burn wound. In addition, allogeneic amnion transplantation can be performed to accelerate healing of donor sites.

Methods

This paper presents a case report of a 65-year-old patient with thermal burns to the thorax, abdomen, back, right shoulder area, including the elbow area, right thigh (third-degree burns 26% TBSA) and airway. The patient underwent multistage surgical treatment including deep excision of necrotic tissues. The wound was treated with a graft of acellular dermal matrix (ADM) and free STSG, *in vitro* cultured skin cells and local negative pressure wound therapy (NPWT). An allogeneic amnion graft was used for the donor sites. The donor sites were used several times after healing. Healing progress was monitored using *laser speckle contrast analysis* (LASCA). In addition, the scar viscoelasticity, transepidermal water loss, scar melanin content, epidermal thickness and temperature were examined after healing. Selected skin parameters were also examined using high-frequency ultrasound.

Results

The patient was discharged at day 77 (41 days in the surgical ward and 36 days in the rehabilitation ward) after admission with healed wounds. However, it should be emphasized that the rehabilitation process began on the first day of hospitalization. During follow-up visits, gradual improvement in the examined scar parameters was monitored.

Conclusions

Tissue engineering may be the efficient tool in the comprehensive treatment and management of a deeply and extensively burned patients.

Keywords: severe burn wound, human acellular dermal matrix, human amnion graft, *in vitro* cultured keratinocytes and fibroblasts, negative pressure wound therapy, laser speckle contrast analysis, high frequency USG

Parallel Session: Skin and Other Substances of Human Origin

DEVELOPMENT OF NEW A METHOD FOR THE *READY-TO-USE* PRESERVATION OF A HUMAN ACELLULAR DERMAL MATRIX

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Background
The Acellular Dermal Matrices derived from human dermis (hADMs) are widely used as a reconstructive approach in the field of Regenerative Medicine. The Emilia Romagna Regional (ERR) Skin Bank previously developed and patented a method of decellularization (PTC/IB2008/002753) able to produce a hADM that is widely distributed as permanent dressing for several clinical fields such as breast surgery, orthopedics, dermatology, plastic and reconstructive surgery, ophthalmology, dentistry. To date, cryopreservation is the method used by ERR Skin Bank to store hADM for its ability to maintain good tissue properties over time. However, the thawing of cryopreserved hADM is always performed before distribution and its clinical use is ensured until 3 days reducing, in turn, a wide-ranging distribution. With the aim to enhance hADM use even outside Italy we decided to develop a new method for its *ready-to-use* preservation based on tissue storage at room temperature in a solution, patented by us, in which tissue is maintained until its clinical use. In this way, we provide to clinicians a tissue packaged and used only if required.

Methods
We described our outcomes in terms of cytotoxicity, *in vitro* colonization and morphological, microbiological, histological and biomechanical properties of hADM preserved for 1 and 2 years in this new ready-to-use modality.

Results
Our results show how hADM in solution maintains morphological, structural and biomechanical properties comparable to cryopreserved hADM. Moreover, no microbial and/or fungal contamination was identified in all samples up to 2 years. No cytotoxic effects were also identified, and cells maintain their ability to repopulate hADM when stored in solution until 2 years, making this preservation method potentially suitable for clinical purposes.

Conclusions
Taking into account the biological results obtained, we can conclude that the proposed ready-to-use new modality of hADM preservation in solution at room temperature appears to be a safe and effective method to maintain tissue properties for clinical use, reducing costs of its production and expanding the possibility to satisfy clinical requests even outside Italy.

Keywords: Dermal matrices, storage solution, preservation methods

Parallel Session: Skin and Other Substances of Human Origin

ACELLULAR DERMAL MATRICES AS AN NEW ALTERNATIVE FOR TREATMENT IN REPRODUCTIVE ORGAN STATIC DISORDERS: A PILOT STUDY

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Background

The study aimed to evaluate the clinical effects of utilizing acellular dermal matrix (ADM) for treating pelvic organ prolapse. The motivation behind exploring a new treatment method stems from the limited efficacy of current surgical options, which are often associated with side effects.

Methods

Ten patients with reproductive organ prolapse underwent surgery at the Chair and Department of Gynecology, Obstetrics, and Gynecological Oncology in Katowice. ADM was used as a support material, with eight patients receiving double TOT and two undergoing a six-point fixation mesh procedure. Pelvic organ prolapse was evaluated pre-operatively and one month postsurgery using the Pelvic Organ Prolapse Quantification (POP-Q) System. General medical history and complaints were assessed using the short form (PFDIQ-SF20). The study included ten patients aged 39 to 71 (mean: 63.6 years), all with a history of at least one vaginal delivery (mean of two). None had undergone a cesarean section. Four patients exhibited POP-Q 3, and five had POP-Q 2.

Results

The mean PFDIQ-SF20 score before surgery was 70.6 points. No major complications occurred during or after surgery. One patient experienced a vaginal fungal infection and an allergic reaction to sutures. Post-operation, ailments reduced by an average of 60.76 points, with five patients reporting no complaints.

Conclusions

ADM emerges as a material of interest for gynecological surgery, with initial reports highlighting its effectiveness and optimistic safety profile. Further research is warranted to explore its potential as a promising option in pelvic organ prolapse treatment.

Keywords: pelvic organ prolapse; polypropylene mesh; acellular dermal matrix; static disorders; allogenic implant

Parallel Session: Skin and Other Substances of Human Origin

STANDARDIZED PRODUCTION OF ALLOGENEIC SERUM EYE DROPS FOR SEVERE OCULAR SURFACE DISEASE

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Background
Severe ocular surface diseases, including severe dry eye syndrome, pose significant therapeutic challenges and can severely impair quality of life. Conventional treatments often fail in severe cases, prompting the need for alternative therapies such as serum eye drops (SEDs). Allogeneic serum eye drops (allo-SEDs), derived from donor serum, offer a promising solution due to their bioactive components that mimic natural tears and support ocular surface healing. At the Finnish Red Cross Blood Service (Vantaa, Finland), allo-SEDs are manufactured from pooled donations of multiple donors, ensuring a standardized composition and improved availability for clinical use. Allo-SEDs have been classified as blood products by the Finnish Medicines Agency (Fimea).

Methods
To ensure batch-to-batch consistency and continuous availability, serum is pooled from eight AB-positive male donors. Blood is collected without anticoagulants and allowed to clot naturally for 6 to 24 hours at 17– 24 °C. The serum is first separated by centrifugation, then further purified through a second centrifugation step, and rapidly frozen. Following clearance through viral screening, eight serum units are thawed, pooled, aliquoted and rapidly refrozen. Each pool undergoes quality control testing for glucose concentration and pH. The pooled serum is then diluted 1:1 with 0.9% sodium chloride (NaCl), filtered through a 15 µm filter, dispensed into 1.5 ml pipettes, and stored frozen (≤ -25 °C). The final product is tested for sterility and endotoxin levels. The pH stability of opened ampoules was assessed under two storage conditions: refrigerated (0–30 hours) and room temperature (0–8 hours). The production protocol of Allo-SEDs has been adapted from Sanquin's (Amsterdam, The Netherlands) established method.

Results
Using the production protocol described above, the quality criteria set for the allo-SEDs were successfully met. Furthermore, the standardized pooling protocol enhanced batch-to-batch consistency. Allo-SEDs retained physiological pH and sterility throughout production and storage, and the endotoxin levels remained low. The pH remained stable within acceptable physiological limits under both storage conditions post-opening.

Conclusions
This protocol demonstrates a robust and reproducible method for producing high-quality allo-SEDs. By utilizing pooled donor serum, allo-SEDs represent a viable therapeutic alternative for patients who

are not eligible for autologous preparations. This method ensures consistent therapeutic efficacy, standardized composition, and improved accessibility.

Keywords: Allogeneic serum eye drops, dry eye disease, ocular surface disease, tear substitutes, pH stability, pooled donor serum, regenerative ophthalmology

Parallel Session: Skin and Other Substances of Human Origin

DONOR SCREENING FOR FECAL MICROBIOTA TRANSPLANTATION: RESULTS FROM THE BOLOGNA CENTER

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Background
Donor selection for fecal microbiota transplantation (FMT) is challenging due to strict clinical and microbiological requirements. We report data from the first four years (2011-2015) of stool donor screening from the first public Italian FMT center.

Methods
We collected data from online donor screening questionnaires, clinical and laboratory evaluations and donations. Donor screening followed the Italian Health Ministry regulation and the European consensus (Cammarota G., et al. Gut. 2017). Potential donors, all under 45 years of age, were assessed for the presence of concomitant diseases, medication use and risk factors for infectious diseases. Candidates who passed this stage underwent a clinical evaluation, and - if deemed appropriate by the visiting physician - a microbiological screening was performed to assess the colonization by potential pathogens.

Results
A total of 1060 subjects completed the online screening questionnaire. Reasons for exclusions included: concurrent gastrointestinal symptoms, altered bowel habits or GI diseases (172; 16.2%), concomitant systemic diseases (179; 16.8%), antibiotics use in the previous 6 months (108; 10.1%), use of prescription drugs (128; 12.1%).
Overall, 312 donor candidates were clinically evaluated: 26 (8.3%) were excluded for GI symptoms not previously reported, 23 (7.3%) for other systemic diseases, 18 (5.7%) for at-risk conditions for infectious disease.
Among the 147 volunteers who underwent microbiological screening, 91 (61.9%) were excluded due to the presence of pathogens, including: 25 pathogenic E. coli, 16 Strongyloides, 15 extended-spectrum β-lactamase-producing Enterobacteriaceae (ESBL).
Ultimately, 44 subjects (29.9% of the donors screened) were suitable for donation. However, due to poor compliance or inadequate stool material, only 26 donated. Of these, 8 were excluded due to pathogens detected during donation-phase screening, and 3 for unsuitable fecal material. The median number of donations per donor was 3.

Conclusions
In our experience, only 2.4% of volunteers in the general population are suitable for donation, a proportion that increased to 8.3% among clinically evaluated patients.

Therefore, fewer than one in ten potential healthy donors are ultimately eligible for donation, a number consistent with the preexisting literature. Larger efforts in refining every step of the screening process and in volunteer education are needed to improve and optimize the donor selection.

Parallel Session: Quality and Digitalization

THE EVOLUTION OF TISSUE ESTABLISHMENT REGISTRIES: REQUIREMENTS AND DATA MANAGEMENT PRACTICES

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Background
Tissue establishment registries have evolved significantly over the past two decades, driven by increasing regulatory demands and the need for improved traceability and data security. Modern registries must serve both operational and regulatory functions, often integrating with broader healthcare information systems.

Methods
I conducted an evaluation of BCB's previous and current tissue registry systems, focusing on their functional capabilities, interoperability, data protection, and alignment with regulatory requirements. Additionally, I carried out structured interviews with clients whose legacy registry systems were replaced by BCB solutions. To complement this, I analyzed case studies demonstrating the implementation of integrated digital platforms within tissue establishments.

Results
Registry systems have progressed from isolated local databases to highly integrated platforms with HL7 FHIR support and role-based access control. Key features of effective systems include automated decision making, customizable reporting for regulatory authorities, and real-time inventory tracking. Integration with patient health data requires secure linkage mechanisms and adherence to GDPR and local data protection laws. Our analysis highlights that systems designed with modular architecture and flexibility are better suited to meet both current and evolving requirements.

Conclusions
Modern tissue establishment registries must go beyond static recordkeeping to become dynamic tools for operational efficiency and compliance. Success depends on modular design, data interoperability, and robust user rights management. Future developments should focus on AI-supported quality control and cross-border data sharing.

Keywords: Tissue establishment, Registry, Traceability, Data integration, Digital health, GDPR

Parallel Session: Quality and Digitalization

DIGITAL TRACEABILITY ACROSS PLATFORMS AND CLINIC LOCATIONS

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Background
Traceability is a cornerstone of donor and recipient safety, as mandated by Directive 2004/23/EC and reinforced by forthcoming provisions under the EU SoHO Regulation. Tissue establishments (TEs) that operate independently of clinical settings and applying a one-to-many distribution model (i.e. one tissue donation serving multiple recipients) face specific challenges in ensuring continuous and verifiable traceability. Current paper-based systems are prone to data loss, delay, and administrative burden, particularly when one batch is distributed to multiple locations. Additionally, commercially available IT traceability solutions are often designed for one-to-one distribution models and are not cost-effective for our context without significant customization. In anticipation of stricter traceability requirements and automatic classification of lost data as a serious adverse event under the SoHO regulation, we initiated the development of a fit-for-purpose digital traceability platform.

Method
Stakeholder interviews and interdisciplinary workshops were conducted with representatives from regulatory affairs, tissue establishment operations, and clinical user groups in Finland and Sweden. Functional and non-functional requirements were captured and translated into system use cases, which formed the architecture of a minimum viable product (MVP) that could support the bidirectional flow of traceability data between clinical sites and the TE.

Results
A fully compliant MVP traceability solution was developed and deployed at selected clinical sites in Finland and Sweden. The system includes a secure clinic-facing interface to facilitate real-time entry of traceability data at the point of human application of the tissue. A TE-facing back-end, accessible only by authorized personnel, enables centralized data management, audit trails, and automated reporting. The platform meets EU data protection and security standards. Initial deployment has demonstrated improved traceability compliance and significant reduction in manual documentation workload. Planned iterative updates will include modules for reporting serious adverse events and reactions (SARE), with automated alerts to ensure immediate action and regulatory follow-up.

Conclusion
The implementation of a tailored digital traceability system enables efficient compliance with Directive 2004/23/EC and prepares the TE and clinical partners for the stricter requirements of the SoHO regulation. The one-to-many distribution model poses unique traceability challenges, which are effectively addressed through this user-informed, scalable digital solution. The approach represents a replicable model for other TEs operating in decentralized, non-hospital-based tissue supply frameworks.

Keywords: digital traceability, SoHO ready, digitalization, tailored solution

Parallel Session: Quality and Digitalization

EQUIPMENT MANAGEMENT IN TISSUE BANKS: DEVELOPMENT OF AN IN-HOUSE CMMS SYSTEM WITH MICROSOFT SHAREPOINT

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Background

Equipment management is crucial for the proper functioning of tissue banks and to assure the compliance with quality norms.
Before this project, equipment management was handled using Excel files, which varied among the 10 different tissue banks of the Cliniques Universitaires Saint-Luc (CUSL), complicating overall technical management.
This project aimed to develop a customized CMMS (computerized maintenance management system) software to create a centralized and online system among the banks.

Methods

A first investigation was carried out by questioning the different banks about their system and the specificity linked to their activity and related to the equipment. Based on this analysis, the specifications for the new global system have been made.
The system was developed via the Sharepoint platform from Microsoft, designed to create website that are internal to an organization, to store, organize and share information.
This tool was integrated with other Microsoft tools such as PowerApp to develop customized web apps, and with PowerAutomate to create workflow designed to automate certain steps.

Results

The new system has been implemented and allows a centralized and online management of the equipment and infrastructures of the 10 different tissue banks, covering more than 900 equipment and 45 premises.
The system is totally customized and allows the operators to encode information linked to the identity of equipment (serial number, model, criticality, ...) as well as maintenance and validation dates. It provides digital logbooks as well as online libraries to store and classify documents and information linked to an equipment. The platform also features an interactive calendar allowing to plan future interventions.
The system allows a global supervision through the entire database to have an overview of all equipment across banks to centralize external intervention such as maintenance and external validations. It also eases the search of information, documents, intervention reports linked to an equipment through interactive pages.
Regarding security, different access levels and authorizations have been created, and an audit trail of all modifications is available.

Conclusions

Sharepoint provides an accessible option to create a customized CMMS system to help with equipment management, with its flexibility, accessibility, and customizability. This represents a good opportunity for organizations that do not want to invest in a commercial CMMS but still want to have an online system, easy to access and to use, and highly adaptable.

Keywords: Equipment management, equipment compliance, CMMS, software, Sharepoint

Parallel Session: Quality and Digitalization

DESIGN AND CONSTRUCTION OF A NEW MANUFACTURING FACILITY FOR MUSCULOSKELETAL TISSUE GRAFTS

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Background

Society ages and with that the prevalence of age-related indications increases. Allografts hold an ever-growing share in the treatment options. For musculoskeletal and soft tissue allografts in particular demand is currently outpacing supply1.

Major allograft benefits include a reduced surgery time, the absence of donor site morbidity and the availability of a wide range of sizes in complex configurations. Allografts therefore possess an inherent suitability for pathologies of the elderly and for traumatic injuries due to wartime activities.

Given the current circumstances and the changing security profile in Europe, surgeons grow closer, the allograft-community gets tighter knit and there is a clear need for scalable manufacturing of allografts and a sharp focus on supply chain resilience2!

Methods

While compliance and traceability are mandatory, new facilities should encourage and be prepared for the integration of advanced technologies. A flexible design, foresight in technical media supply and sufficiently spaced cleanrooms are a strong basis and will support future expansions or regulatory updates.

Results

For musculoskeletal tissue processing, a circular facility layout including GMP-level cleanrooms was designed around a central microbial and viral inactivation step to find the balance between tissue quality and safety.

Conclusions

The design and building of a new medicinal manufacturing facility is a massive undertaking and always a challenge. Building in a changing regulatory landscape is an even bigger one.

We would like to share our thoughts on pitfalls and lessons learned regarding facility design, project management, relevant guidelines and helpful tools.

Keywords: allograft manufacturing, facility design, lessons learned, SoHo establishment

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[2] European Union. *Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC. Official Journal of the European Union*, L 1938, 17 July 2024, pp. 1–80.

Parallel Session: Quality and Digitalization

IN PROCESS ENVIRONMENTAL MONITORING PROGRAMME. HOW MUCH, HOW LONG

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Background

The potential cross-contamination of tissues and cells (TC) during processing can lead to serious adverse reactions. An environmental monitoring programme, both in the direct processing environment and in the background, using different techniques, helps ensure aseptic procedures and reduces the likelihood of contamination.

Methods

In our tissue establishment (TE), various TC are processed under Grade A conditions with a Grade C background in three clean rooms. We use three techniques: (1) microbial sedimentation under the cabinet flow (CF), (2) microbial sedimentation in the background, and (3) fingerprint testing. Depending on the type of processing, one or more techniques were applied. Simultaneously, periodic microbiological assessments of the clean rooms were performed. We defined an alert limit of five colony-forming units (CFU) and an action limit of 10 CFU.
From February 2024 to June 2025, a total of 1,131 processes were performed using 22 different processing methods.

Results

A total of 4,035 environmental controls were carried out: 1,134 at CF, 1,773 fingerprints, and 1,128 background samples. Of these, 81.3% were negative (0 CFU), 17.1% showed fewer than 4 CFU, and 0.7% had more than 9 CFU.
Cabinet flow samples were positive in 1.1% (12 cases), including one case with 5 CFU and another with 27 CFU. Fingerprints were positive in 2.2%, with two cases between 5–10 CFU and four cases above 10 CFU. Background samples were positive in 15.1%, with six cases ranging from 5 to 10 CFU and two above 10 CFU.
Analysing by processing and all tests considered for each, 10 cases had results between 5–10 CFU and 7 cases had more than 10 CFU. Fungi were detected in 13 cases. A pathogen was found in 8 cases all of them with CFU counts under 5. Sperm processing had the highest number of positives.
No positive environmental result was associated with a positive microbiological result in the final tissue product.

Conclusions

Although the environmental monitoring is an additional burden for the TE and the Microbiology department and the positive cases have not correlation with the microbiological control of the tissue, it is an excellent method to ensure an aseptic procedure and evaluate how the overall procedure is performed.

Parallel Session: Quality and Digitalization

INCORPORATING VIRTUAL REALITY INTO A NEW BLENDED LEARNING PACKAGE FOR EYE RETRIEVAL

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Background

NHS Blood and Transplant (NHSBT) is responsible for the majority of eyes banked in the UK. We are responsible for the whole donation pathway, including donor screening, tissue donation processing and banking and issue for transplant.
We have four retrieval teams across England who retrieve Tissue and Eyes, additionally NHSBT manage the training and governance of third-party retrievers based in Northern Ireland, Scotland, Wales and areas of England.
Training new staff in eye retrieval can be stressful and time-intensive, especially when preparing them to work in emotionally and technically demanding environments such as mortuaries. Traditional training methods often lack realism and flexibility, and the experience would vary from team to team. To address this, two Virtual Reality (VR) components have been incorporated into a new blended learning package to improve preparedness, reduce anxiety, and enhance training outcomes for NHS Blood and Transplant's Tissue Retrieval Teams.

Methods

A structured four-module learning package was developed, covering a trainee's 12 week eye retrieval training. Key innovations include a virtual mortuary experience to acclimatise trainees to the environment, a 180° VR simulation of a real eye retrieval and a 360° immersive VR module where the learner learns to retrieve an eye using haptic feedback tools. These immersive modules are complemented by physical simulation using mannequins with realistic eyes enabling trainees to practice retrieval techniques safely.

Results

Preliminary feedback indicates that the VR modules significantly reduce trainee anxiety and improve confidence before live retrievals. Trainers report enhanced skill acquisition and engagement, with early signs pointing to a reduction in training time by up to 50%. Additionally, trainees are able to use these new tools to train in the early stages - freeing up the trainer to retrieve tissue and eyes and maximise donation opportunities.

Conclusions

The integration of VR into the eye retrieval training programme represents a significant advancement in education within NHS Blood and Transplant. This blended learning approach not only reduces training time, improves training outcomes, enhances staff wellbeing but also has the potential to increase retrieval capacity and corneal tissue availability across the UK. Further evaluation will assess long-term outcomes and potential for broader implementation. The package supports NHSBT strategy and modernises current training pathways.

Keywords: Virtual Reality, Eye Retrieval, Blended Learning, Simulation Training

Parallel Session: Amniotic Membrane

DOES THE TIME INTERVAL FROM DELIVERY TO PREPARATION INFLUENCE THE PROPERTIES OF AMNIOTIC MEMBRANE? A COMPARISON BETWEEN <6 AND >6 TO 24 HOURS

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Background

Human amniotic membrane (hAM) with its unique characteristics and properties can be efficiently applied in various medical fields.
After a donation has been realized, the preservation of the tissue-specific properties is a decisive parameter for a successful transplantation. Important factors in this regard are the duration and temperature during transportation and storage of the placenta until processing.
Due to local conditions at the DGFG tissue bank and its donation network, processing had to be carried out within six hours after delivery between 2008 and 2021. Since then, logistical changes have led to this period being extended to a maximum of 24 hours.

Methods

It was investigated whether increasing the time between placenta donation and processing the hAM affects the quality of the tissue. By means of ELISA the content of EGF, TGF-ß1, bFGF, Laminin, and Hyaluronic acid was measured. Thawed membrane samples were evaluated regarding their transparency after the different preparation periods. Additionally, a retrospective analysis was conducted on 86 placenta donations between August 2021 and May 2025, evaluating the discard rate in relation to their respective preparation time interval.

Results

A previous study had confirmed significant inter-individual differences concerning the biochemical and structural parameters between donors [1]. In the present experiments, no differences beyond these variations were observed between preparations carried out within six hours and those carried out up to a maximum of 24 hours.
Of the 86 donations analyzed regarding the discard rate, the preparation of 51 donations was started within the 6-hour period after donation and 35 donations within >6 - 24 hours after delivery. Eight donations were not suitable for transplantation due to positive results in a microbiological control, of these four were processed within the 6-hour interval and four within 24 hours after donation.

Conclusion

The results show that no significant changes in the therapeutically valuable properties of the human amniotic membrane are caused by extending the time interval until the placenta is prepared. Any deviations that occur are generally smaller than the inter-individual differences between the donated placentas, as it can be expected for biological material.
To summarize: the preparation of the hAM up to 24 hours after donation has no negative influence on the quality of the tissue. Even a slightly increased discard rate due to microbial contamination does not change this.

[1] Pogozhykh O. et al., *Int J Mol Sci*. 2020;21(11):4029.

Parallel Session: Amniotic Membrane

DEVELOPMENT OF A NEW COLLECTION METHOD FOR HUMAN AMNIOTIC MEMBRANE

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Background
The human amniotic membrane (HAM) is a tissue frequently used for the treatment of different dermatological conditions such as burns or full-thickness skin wounds, acting as a source of growth factors and cytokines that plays a key role in the wound healing process. The method used for the procurement of HAM tissue during the elective caesarean section in the operating room is based on the collection of the whole placenta or both fetal membranes - chorion and amniotic membrane - and their transport to Tissue Establishment (TE) where HAM is peeled from them during processing, to maintain the identification of both HAM layers as required for its next clinical use. However, this procedure maintains tissue in a bloody solution during transport, increasing the timing of its processing and its potential microbial contamination, with a consequent increased risk of tissue disposal. Here we propose a new method to collect HAM tissue alone in the operating room able to maintain identification of both HAM layers until processing.

Methods
We describe in detail the new collection method of HAM tissue and the microbiological and histological analysis performed on tissue samples, in order to investigate if the method proposed could affect the structure of HAM or induce microbial contaminations not suitable for its clinical use.

Results
Our results show that the new collection method provides TE a tissue hydrated and clean, in which the identification of both HAM layers is maintained optimizing, in turn, the working times in the clean room environment. The tissue structural integrity is also maintained while the risk of microbial contamination is reduced.

Conclusions
Taking into account the results obtained, we support the use of this new collection method to shorten the times of HAM tissue processing maintaining its morphological, structural and microbiological properties.

Keywords: Collection method, amniotic membrane, tissue procurement

Parallel Session: Amniotic Membrane

HUMAN AMNIOTIC MEMBRANE: MOVING PERINATAL BIOMATERIALS TOWARDS TRANSLATION INTO THE CLINIC

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Background
The human amniotic membrane (hAM) as a tissue bank product has widely been applied in wound healing and ophthalmology. We have previously demonstrated that the hAM is a rich source for secreted factors including antiadhesive and antifibrotic compounds. We, therefore investigated the specific secretome in a preclinical setting. Based on our findings, we applied the hAM in a novel clinical application, as biological augmentation to improve healing and prevent re-rupture after reconstructing rotator cuff tears.

Methods
After having identified miRNAs with regenerative and anti-inflammatory potential we showed this an in vitro model for nerve regeneration. We moved to the clinics and evaluated the hAM as an augmentation material during open rotator cuff surgery in an observer-blinded randomized study (n = 20 hAM, n =20 no augmentation) in symptomatic partial or complete tendon fibre interruption with one or more tendons of the rotator cuff affected. Evaluation was based on Constant and SANE score (4, 6 and 12 months post-operation), and on magnet resonance imaging (MRI) (6 and 12 months).

Results
During the 1 year follow up there were no re-ruptures in both treatment groups and significant improvements in all evaluation scores compared to pre-operation status. The application of hAM led to neither adverse events nor complications. Interestingly, hAM application led to improved range of motion in passive movement 6 weeks post-operation. Further observation for up to 4 years will clarify the benefit of hAM to reduce re-rupture rates in treated rotator cuffs.

Conclusions
Our findings may help to understand basic mechanisms of tissue regeneration. Based on the results we recommend hAM for application in regenerative medicine.

Keywords: human amniotic membrane, clinical, rotator cuff surgery, secretome

Parallel Session: Cardiovascular Tissues

NOVEL SOURCE OF DONOR HEARTS FOR HEART VALVE PRODUCTION

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Background

Donation after Circulatory Death (DCD) is one of two recognised pathways for organ donation and has been increasingly and successfully utilised for kidney, liver, and lung transplantation. Due to the inevitable period of warm ischaemia following circulatory death, heart transplantation had, until recently, relied exclusively on organs from Donation after Brain Death (DBD). In July 2014, surgeons at St Vincent's Hospital performed the first DCD heart transplant using a distantly procured donor heart and a commercially available, transportable, extra-corporeal, normothermic perfusion device (Organ Care System – OCS). This device enables resuscitation of the explanted heart and allows for continuous physiological and biochemical assessment of its viability for transplantation in a sterile environment. DCD heart transplantation is now standard practice at St Vincent's Hospital, Sydney. Since 2014, we have begun to utilise hearts that were unsuitable for transplantation as a novel source for heart valve production.

Methods

From August 2014 to June 2025, all DCD hearts not recovered and met transplant criteria on the OCS and had consent for homograft production were referred to the Sydney Heart Valve Bank (SHVB). Referrals were assessed according to SHVB acceptance criteria and, where suitable, processed to produce homograft valves. Valves were retrieved and dissected under sterile conditions. Following assessment for anatomical suitability and functional competency, homografts were decontaminated at 37°C for 6–12 hours before cryopreservation. Heart transport and valve storage solutions were collected for bioburden analysis.

Results

Over the past decade, 37 OCS-heart transplant-declined hearts were referred for cardiovascular homograft production. Of these, 24 met the SHVB's acceptance criteria, with a median donor age of 27.5 years (range, 7–55). OCS-hearts are generally more challenging to dissect than untreated DCD hearts due to haemoglobin staining and oedema. The first valve retrieved from an OCS-heart was implanted in October 2014. To date, 20 aortic and 24 pulmonary valves have been implanted. All valves continue to function well, with no adverse outcomes or different with our conventional source valve reported by implanting surgeons.

Conclusion

This represents the first experience of homograft production from this novel heart donor source. Our findings demonstrate encouraging results, although OCS-hearts necessitate greater dissection expertise due to visible haemoglobin staining and edema. These donors, often younger, represent a high-quality donor pool. All declined OCS-hearts should be routinely considered and assessed for homograft valve production.

Parallel Session: Cardiovascular Tissues

MICROBIAL FINDINGS IN VASCULAR ALLOGRAFTS BEFORE AND AFTER ANTIMICROBIAL DECONTAMINATION

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Background
South Danish Transfusion and Tissue Centre at Odense University hospital is responsible for processing and storage of vascular allografts harvested from organ donors. Vascular allografts are primarily used to replace infected artificial grafts. Given the prevalent risk of contamination of grafts during procurement, establishing an effective protocol for microbial detection and decontamination prior to transplantation is imperative.
The aim is to describe microbial findings in vascular allografts both pre- and post-treatment with an antimicrobial solution.

Methods
Grafts were procured in the operation room after harvesting of organs and transported at 4 °C to the tissue center for processing and storage. Prior to cryopreservation, grafts underwent a 24-hour incubation at 37°C in an antimicrobial solution targeting pathogenic bacteria and fungi. Pre- and post-antibiotic treatment, a tissue sample from each graft were homogenized using a GentleMACS dissociator (Miltenyi Biotec), then transferred to 2 blood culture bottles (BACT/ALERT FA Plus and FN Plus), which were incubated in a BACT/ALERT® VIRTUO® (bioMerieux) for a maximum of 6 days. Isolates from positive samples were subcultured and identified using MALDI-TOF MS.

Results
In all, 155 grafts from 29 donors were included from November 2020 to December 2023. Each donor provided 2-12 grafts. Before antibiotic treatment, microorganisms were detected in 41 tissue grafts from 19 donors. Regarding the isolated microbial genera, 46 (from 15 donors) belonged to species normally found on the skin, 8 (from 5 donors) originated from the gut and 2 isolates were from the oral flora. Following antibiotic treatment, only 2 grafts from 2 different donors had culture-positive samples. None of the species were detected in the pre-treatment samples from the 2 donors. Following risk-based assessment only 1 of the 2 culture positive grafts were discarded, and the overall discard rate was 0.6% (1 out of 155). In 15 of 19 donors with positive microbial findings, more than 4 grafts per donor were procured. In donors without microbial findings, more than 4 grafts per donor were procured in 2 of 10 donors.

Conclusions
Microbes were detected in 41 of 155 grafts (26%), before antibiotic treatment. However, following antibiotic treatment, microbes could only be detected in 2 grafts. This observation suggests that the antimicrobial decontamination process in our tissue bank is highly effective, thereby ensuring safe utilization of allografts in patient treatment. The majority of microbes detected are likely contaminants originating from the skin or gut of the organ donors.

Keywords: Vascular allografts, microbes, decontamination, quality assurance

Parallel Session: Cardiovascular Tissues

VASCRAFT: A NOVEL TISSUE-ENGINEERED, DECELLULARIZED AND RE-ENDOTHELIALIZED HUMAN VASCULAR GRAFT FOR USE IN ARTERY BYPASS

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Introduction

Coronary artery bypass grafting is a procedure in which autologous vascular vessels are used to bypass occluded coronary arteries to restore normal blood supply to the heart. One of the most commonly used conduits is the saphenous vein, but it can be associated with significant post-operative problems compromising patient's quality of life. Different approaches have been tried to develop small-diameter vascular conduits usually with poor results, therefore there is an unmet clinical need to find an alternative to autologous vessels.

Objective

To develop a novel decellularized vascular graft from human cadaveric veins, recellularize the internal layer with cord blood-derived endothelial cells (CB-EC) using a 3D bioreactor and perform a first pilot study in a translational porcine model.

Method

This multidisciplinary project aims to develop the VasCraft, a vascular graft for application in coronary bypass surgery. The initial phase focuses on optimizing a decellularization protocol for saphenous veins obtained from cadaveric donors to produce a non-immunogenic allograft while preserving the structural and biomechanical integrity of the extracellular matrix. The resulting grafts are then re-endothelialized using CB-EC, which are integrated into the inner layer through dynamic culture in 3D bioreactors. Finally, the recellularized grafts will be evaluated in a porcine femoral–femoral bypass model to refine the surgical implantation technique and assess graft viability, functionality, and overall performance in vivo.

Results

An optimal protocol for saphenous veins decellularization was defined, achieving a DNA content below 50 ng/mg of dry tissue, effective preservation of extracellular matrix components and absence of cytotoxicity, while maintaining a high level of cell viability. A custom-designed 3D bioreactor was developed achieving homogeneous recellularization of the inner layer of decellularized grafts using CB-EC.

An initial surgical procedure was performed in a porcine model using a decellularized, non-re-endothelialized graft, with the aim of establishing and optimizing the surgical protocol. The implant remained patent for the initial 7 days, but an aneurysm was observed after 15 days and a stenosis on day 30, whereas the autologous contralateral artery used as a control remained patent after 30-days. After establishing the surgical procedure, the animal study has been initiated to evaluate the VasCraft implant. Weekly ultrasound monitoring is being performed to assess graft patency, with final evaluation planned at one month via angiography and structural analysis.

Conclusion

An optimized decellularization protocol for saphenous veins from cadaveric donors has been developed, meeting all predefined quality specifications. Additionally, a functional 3D bioreactor has been engineered to enable efficient and homogeneous cell integration into the graft luminal surface. The surgical technique has been established, and a comprehensive preclinical animal model has been initiated to assess graft patency and overall performance.

Parallel Session: Cardiovascular Tissues

CLINICALLY UNDETECTED MALIGNANCIES AS A REASON FOR DISCARDING CRYOPRESERVED CONNECTIVE AND VASCULAR TISSUE ALLOGRAFTS FROM DECEASED DONORS: A FIVE-YEAR RETROSPECTIVE STUDY

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Malignant neoplasms have long been considered a contraindication for the procurement of organs and tissues. Despite rigorous donor selection, cases of tumor transmission through organ transplantation have been reported. While the risk is lower in tissue transplantation, it may still be present - particularly when preservation techniques that maintain cellular viability, such as hypothermic storage or freezing in presence of cryoprotective agents, are used.

This retrospective study evaluates the risk of discarding cryopreserved connective and/or vascular tissue allografts due to newly diagnosed malignancies discovered during donor autopsy or through intraoperative biopsy at the time of organ and tissue retrieval.

Between January 1, 2021, and July 31, 2025, a total of 50 musculoskeletal tissue donors and 73 vascular tissue donors were included in the study. All musculoskeletal tissues were procured at the Central operating room of the Department of Surgery, University Hospital Hradec Králové. Vascular tissues were harvested by various procurement teams participating in the national cryopreserved vascular tissue allotransplantation programme.

Harvested tissues were transported in sterile plastic containers filled with preservation solution to a licensed Tissue Establishment and were cryopreserved within 24 hours using a cryoprotective medium containing 10 % (v/v) dimethyl sulfoxide. Connective tissue allografts (ligaments and tendons) were stored at –80 °C, and vascular allografts (arteries and veins) were stored in the vapor phase of liquid nitrogen, sealed in double EVA plastic bags (Maco-Pharma, Mouveau, France).

Among musculoskeletal donors, three cases (6%) of previously undiagnosed malignancies were detected at autopsy - one thyroid carcinoma and two prostate carcinomas. Tissues to be cryopreserved had been retrieved from only one of these donors, leading to the disposal of 12 allografts (4 bone - tendon - bone, 2 bone - tendon, and 6 tendon grafts). Among vascular tissue

donors, one case (1.4%) of clinically unsuspected pancreatic carcinoma was diagnosed via intraoperative biopsy, resulting in the disposal of two great saphenous vein allografts.

In conclusion, the incidence of clinically undetected malignancies was higher among musculoskeletal tissue donors (6%) than among vascular tissue donors (1.4%), underlining the importance of thorough postmortem and intraoperative diagnostics to prevent potential oncologic transmission via tissue allografts.

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Parallel Session: Cardiovascular Tissues

THE FATE OF THE FIRST 100 PATIENTS ENROLLED ON THE WL FOR LARGE DIAMETER ALLOGRAFT HEART VALVES (AHV)

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Background
In the Czech Republic the total incidence of major congenital heart diseases (CHD) in newborns did not change significantly during last 30 years. The prenatal detection rate increased from 6,2% to 82,8%, and the postnatal prevalence of major CHD declined from 0,21% to 0,14% (P<0.001). Nevertheless, the number of RVOT reconstructions & reoperations in children and GUCHD is growing, and so is the popularity of Ross's operation (RO). This situation results is a shortage of pulmonary allografts (Pu-AHV), especially those with a diameter > 26 mm. To allocate Pu-AHV with a large diameter fairly, a WL was created. The fate of the first 100 patients enrolled in the WL is presented and launched.

Methods
Retrospective data analysis of National AHV Bank (NAHVB), Prague. WL principles have been developed by the NAHVB Board of Directors and the Czech Society for Cardiovascular Surgery Board.
Allocation PREFERENCES: Children up to 18 years of age, Infectious endocarditis, Pregnant women, then in patients numerical order.
Allocation RULES: 3 reservations per Cardiac Center, Maximal reservation period 8 weeks, Cardiac Center may change the WL order of its own patients.
Patients are registered at WL based on a written order containing the required Pu-AHV diameter.

Results
From January 2024 to 18th July 2025, 106 patients were accepted on WL. The first 100 patients were evaluated and analyzed: Age 13-55 (mean 39) years, 93 (93%) of them were males.
Two patients refused surgery. For one patient, the date of the operation was postponed for health reasons. R0 was planned for 98 patients. It was successfully performed in only 51 (51%) patients. In 11 (11%) cases, the procedure was abandoned due to patient's own pulmonary valve poor quality. One patient was withdrawn due to the aortic root's anatomical structure being unsuitable.
In 4 patients, the reservation was made for pulmonary valve replacement. In 2 because of infectious endocarditis of the pulmonary valve. One patient was ultimately contraindicated, and the others successfully underwent replacement of the infected pulmonary valve with a Pu-AHV.
The average time on WL was 32 (0 - 122) days. The mean waiting time from graft availability to transplantation was 27 (0 - 105) days.

Conclusions

Experience to date shows that WL is an effective tool for the fair allocation of suitable grafts for elective procedures (mainly RO) at the national level.

Keywords: Pulmonary allograft heart valves, RVOT reconstruction with pulmonary allografts, Ross procedure.

Parallel Session: Cardiovascular Tissues

HAPPY 90TH BIRTHDAY PROFESSOR SIR MAGDI YACOUB - A SURGEON AND A MAVERICK

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Heart valve banks need a market for their products. The authors first qualified as cardiac surgeons, gained experience with AHV surgery before they started practicing AHV banking. Therefore, they have always found it easy to communicate professionally with cardiac surgeons and consult with them all issues concerning AHV surgery. However, Professor Sir Magdi Yacoub (MY), who will celebrate his 90th birthday on 16 November, was undoubtedly the world's greatest popularizer of AHV surgery. This is why we have decided to provide an insight into the incredibly rich life of this exceptional man.

He was born in in Egypt to a Coptic Christian family. His father was a surgeon. MY graduated in 1957 from Cairo University, and in 1961 he moved to Britain. He trained in cardiac surgery under the legendary Lord Russell-Brock and later under Donald Ross with whom they pioneered AHV surgery

In 1968, MY relocated to the University of Chicago, where he was engaged in advanced research.

In 1973, he became a consultant cardiothoracic surgeon at Harefield Hospital, West London. He quickly introduced full-scale cardiac surgery and in 1980 launched thoracic organs transplant program. From the outset, MY established a foundation for extensive research, and finally world-renowned Magdi Yacoub Institute was established.

From 1986 to 2006, MY held the position of British Heart Foundation Professor of Cardiothoracic Surgery at the National Heart and Lung Institute, Imperial College Faculty of Medicine.

Extensive charitable activities, particularly in Africa, represent an integral part of MY live.

He has been awarded countless honors, and he was and still is a very successful manager, capable of raising funds for extensive charitable activities.

From a tissue banking perspective MY gradually tested all newly introduced methods of AHV processing. He probably performed more AHV transplants than anyone else in the world, introduced the so-called 'homovital' AHV grafting, and published promising long-term results. However, it is not used anymore since it does not comply with current legislation.

Hundreds of cardiac surgeons from around the world have trained at Harefield and Royal Brompton hospitals before going on to take up leadership positions on every continent. Furthermore, they spearheaded the dissemination and promotion of AHV surgery within their respective workplaces and countries.

Above all, MY taught AHV surgery at a huge number of events including two in our country. Consequently, he laid the foundation for the expansion of AHV surgery at the Czech national level.