European Parliament

STOA working breakfast

Technology and Innovation of Human Implants

Participants' booklet

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Scientific Foresight Unit (STOA)

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Technology and Innovation of Human Implants

Case study: orthopaedics

Participants' booklet

4 April 2019, 8:00-9:00

Altiero Spinelli Building, Room 1E1

European Parliament, Brussels

Prepared by Gianluca Quaglio and Richelle Boone, Scientific Foresight Unit (STOA)

Available at http://www.europarl.europa.eu/stoa/en/events/technology-and-innovation-of-human-impla

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2. Introduction

Millions of patients a year improve their quality of life through surgery that involves implanted medical devices. The term implant is used for devices that replace or act as a fraction of the whole biological structure. Currently, implants are being used in many different parts of the body, for various applications. They include for instance orthopaedics, pacemakers, cardiovascular stents, defibrillators, neural prosthetics and drug delivery systems.

Today's health-related challenges – such as the aging population, increasing cases of obesity, and patients' requests for greater convenience and comfort – continue to demand new and improved materials. Hence, the need for new treatments, implants, prostheses and long-term pharmaceutical usage, as well as the need for prolonging the life span of devices currently used.

Orthopaedic implants

Orthopaedic implants account for the majority of implantable devices in the EU. One of the most prominent application areas for biomaterials is the construction of such implants. Total joint replacement is widely regarded as the most important achievement in orthopaedic surgery in the twentieth century.

Arthroplasty is the surgical treatment of degenerate joints aimed at the relief of pain and the restoration of movement. Joint arthroplasty can be performed with different types of implants, depending of the type of disease and the needs of the patient. However, 20% of the patients state to be disappointed about their treatment. Some need to be reoperated to place a new implant, which is a more complex and costly intervention. It is of utmost importance to assess rightly the chances for a successful surgery, to execute the surgery as prescribed and to select the best available implants. New technologies should have an impact on patient satisfaction and the treatment should become much more fine-tuned for a specific patient.

Aims of the meeting

It is important to understand the current state of implants and their impact on the health of the population. In this event, the status of implants in Europe – particularly the orthopaedic ones – will be discussed among researchers and decision-makers. Several issues will be debated, namely:

- How to increase the EU quality standards of implants;

- How all stakeholders can work together within a legal framework that allows for quality assessment, delivering the best results to patients;

- How to collect clinical data on implants and compare them with standardised guidelines in order to garantee a more transparant reimbursement system;

- How to create a network of registries that allows EU Member States to share experiences.

References

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3. European Knee Society (EKS)

The European Knee Society (EKS) was founded in 2014 to unite European key opinion leaders in the field of degenerative knee pathology and knee arthroplasty. The aim was to create a counter part of the prestigious American Knee Society, created already in the eighties.

EKS wants to advance knowledge on degenerative knee pathology and knee arthroplasty by high profile scientific research and interactive discussions among key opinion leaders. EKS wants to provide an appropriate educational setting that maintains the highest level of professional standards in order to promote continuous advancements in professional knowledge and improved treatment of degenerative disorders of the knee and knee arthroplasty.

It wants to create an optimum environment to enhance education, research and treatment of degenerative knee pathology and arthroplasty. EKS promotes and maintains professional standards to provide the best care to patients with degenerative pathology of the knee joint and arthroplasty of the knee. And finally, EKS wants to be, as a speciality society, the contact point for policymakers who have the ambition to offer high quality care to patients, which is evidence-based, and affordable for our society.

The European Knee Society Open meeting, which is organized every two years, is attended by several hundreds of surgeons. The next upcoming meeting will be in Valencia, Spain from 2 to 3 May 2019. EKS also organizes the World Arthroplasty Congress (WAC), in collaboration with International Congress for Joint Reconstruction (ICJR) and this is a world meeting always at a European venue. The previous meeting in Rome was attended by more than 1200 surgeons and the next one will be in Munich, Germany in 2021.

More information on EKS is available at: www.europeankneesociety.com

4. European Federation of National Associations of Orthopaedics and Traumatology (EFORT)

EFORT, the European Federation of National Associations of Orthopaedics and Traumatology, is the platform organisation linking Europe's national orthopaedic associations. Its aims reflect the will to promote the exchange of scientific knowledge and experience in the field of prevention, just as both conservative and surgical treatment of diseases and injuries concerning the musculoskeletal system. EFORTs mission is safely to restore and secure mobility, musculoskeletal health and quality of life.

The national associations of orthopaedics and traumatology from twenty European countries established EFORT by consensus. The Federation was founded in Marentino, Italy, in 1991, and today has 41 national member societies from 39 member countries, as well as 13 associated scientific members. EFORT's strategy focusses on four pillars that support these aims: Education; Harmonisation of guidelines & standards; Influencing European health policy; Research.

This year EFORT will celebrate with its 20th EFORT Congress in Lisbon from 5 to 7 June 2019. Main theme is "Registries and their impact on surgeons daily practice".

The educational portfolio is fronted by our flagship event, the EFORT Annual Congress (gathering between 5,500 to 6,000 surgeons, other healthcare professionals and industry representatives) but also encompasses training courses & webinars in designated fields, fellowship programmes and the scientific open access review journal EFORT Open Reviews (EOR).

It is EFORT's ambition to promote awareness of the burden of musculoskeletal disease in Europe to professionals and policymakers who hold influence on the European agenda and to strive for increased prominence in research and public health activities, for the ultimate benefit of our patients and the taxpayer alike. There are today clear cross-border inequalities and standards of care for treatment that also urgently need to be addressed.

5. Speakers' biographies

5.1. Paul RÜBIG

MEP and STOA First Vice-Chair

Paul RÜBIG was elected as the STOA Chair for the first half of the European Parliament's 8th legislature and as First Vice-Chair for the second half of the 8th legislature. Previously, he served as STOA Chair from 2009 to 2012 and as First Vice-Chair from 2012 to 2014.

Born in Northern Austria, Paul RÜBIG has been a member of the European Parliament since 1996 and belongs to the European People's Party (EPP). He is the owner of an Austrian blacksmith company and has a degree in Business Administration, Marketing and Production Engineering from the University of Linz, Upper Austria. He is married and has two children.

Paul RÜBIG is a full member of the Committee on Industry, Research and Energy and of the Committee on Budgets. He is Vice-Chair of the Delegation for relations with the Korean Peninsula and substitute member of the Delegation for relations with Switzerland, Norway and of the EU-Iceland Joint Parliamentary Committee. He is also a substitute member of the European Economic Area (EEA) Joint Parliamentary Committee. Furthermore, Paul RÜBIG is a substitute member in the Committee on Development.

Paul RÜBIG is very active in the field of the small-scale business (SME) promotion. He is president of SME Global, a working group of the International Democrat Union (IDU), whose objective it is to support small and medium-sized enterprises and to improve their business environment.

5.2. Olga TKACHENKO

Scientific Policy Officer at the Unit for Health Technologies and Cosmetics, DG for Internal Market, Industry, Entrepreneurship and SMEs, European Commission

Olga TKACHENKO graduated with an MSc and BA in Natural Sciences (Biochemistry) from the University of Cambridge in 2013 and went on to obtain a PhD in Physical and Theoretical Chemistry from the University of Oxford, where she studied mechanisms of protein aggregation relevant to neurodegenerative diseases. She joined the medical devices team at the European Commission in December 2017, where she works as a Scientific Policy Officer. Her areas of work include borderline products, clinical investigation and evaluation, common specifications for *in vitro* diagnostics, liaison with scientific committees and collaboration with the Joint Reseach Centre for establishment of expert panels and EU reference laboratories under the new Regulations on medical devices.

Key message

The new Regulation on medical devices will offer ways to provide a foundation for patient safety, transparency and innovation in orthopaedics.

5.3. Paul PISCOI

Scientific Policy Officer at the Unit for Health Technologies and Cosmetics, DG for Internal Market, Industry, Entrepreneurship and SMEs, European Commission

Paul PISCOI graduated as a medical doctor and has been working at the European Commission for more than ten years. Since February 2012, he has worked as a Scientific Policy Officer in the Unit dealing with medical devices (currently Unit D.4 of the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs). Besides participation in the drafting of implementing acts related to the new Regulations on medical devices, he is responsible for the coordination of the Clinical Investigation and Evaluation Working Group, the Borderline and Classification Working Group, vigilance and scientific matters.

Key message

The new Regulation on medical devices will offer ways to provide a foundation for patient safety, transparency and innovation in orthopaedics.

5.4. Pilar AGUAR

Head of Unit at the Unit for Innovative Tools, Technologies and Concepts in Health Research, DG for Research and Innovation, European Commission

Ms AGUAR joined the European Commission in 2001, when she started working for the Directorate-General for Health & Consumers, on the evaluation of the performance of national authorities and food safety control systems. From 2005 to 2012, she was involved in the development and management of European Research programmes and policies in the Directorate-General for Research & Innovation.

In 2012 she became Head of the Chemicals Assessment and Testing Unit at the Joint Research Centre. The unit developed methodologies in the framework of EU legislation on chemicals and consumer products, including Food Contact Materials for policymakers. In 2016, she became Head of the Consumer Products Safety Unit, working on safety, including risk-benefit assessments of products such as nanomaterials and nanomedicines, health technologies and non-food consumer products.

Since October 2017, she is leading the Innovative Tools, Technologies and Concepts in Health Research Unit, managing European Research projects in regenerative medicine, health and environment, systems pharmacology and new toxicological paradigms. Ms AGUAR holds degrees in Pharmacy (Universidad Complutense, Madrid) and Food Science and Technology (Universidad Central, Barcelona) with additional studies in Toxicology. She is also recognised as 'Specialised Pharmacist in pharmaceuticals and drug analysis' and 'Specialised Pharmacist in pharmaceutical industry' by the Spanish Ministry of Health.

Key message

Health and well-being attracts an increasing amount of attention today and will continue to do so in the future. The research area of Medical Technology is at the heart of innovation in health care. There are over 500,000 types of products on the EU market in the Medical Technology field, developed and marketed mainly by highly innovative SMEs. The European Commission services, through its different Research Framework Programmes, have been continuously supporting research in this domain and will continue to do so in the new Research Framework programme, 'Horizon Europe', which is being developed for 2021–2027.

5.5. Emmanuel THIENPONT

Head of Knee Surgery and Sports Medicine, and Associate Chief of Orthopaedic Surgery, Saint Luc University Hospital, Belgium & President of the European Knee Society

Prof Dr Emmanuel THIENPONT is the Head of Knee Surgery and Sports Medicine and the Associate Chief of Orthopaedic Surgery at the Saint Luc University Hospital in Brussels, Belgium: a thousand-bed teaching hospital. He was trained as an orthopaedic surgeon at KU Leuven and in several high-quality surgery centers around the world. He has an Executive MBA from the Louvain School of Management (UCL) Business School and holds a PhD from Gent University. His PhD was about alignment in knee arthroplasty.

Prof THIENPONT is specialized in knee surgery and focuses on knee arthroplasty and selective resurfacing in arthritic patients with unicompartmental replacements. He started in 2008, as the first surgeon on the continent, with Patient Specific Instruments (PSI) and performed the first case of PSI-assisted unicompartmental replacement in the world.

Prof THIENPONT was one of the seven founding members at the cradle of the European Knee Society and is the current president. He is one of the few international members of the American Knee Society.

Prof THIENPONT is the author of about hundred peer-reviewed papers in scientific journals. He is an associate editor for Clinical Orthopaedics and Related Research (CORR).

Key message

Osteoarthritis is a disease advancing in frequency among the population and for which treatment with implants is needed for the end-stage. Arthroplasty surgery asks for surgical expertise and quality products to allow patients to continue their life similar to as before the degenerative process started.

5.6. Per KJAERSGAARD-ANDERSEN

Head of Section for Hip and Knee Replacement, Department of Orthopaedic Surgery, Vejle Hospital, South Danish University, Denmark & President of the European Federation of National Associations of Orthopaedics and Traumatology (EFORT)

Before becoming the president of EFORT, Prof Dr Per KJAERSGAARD-ANDERSEN acted from 2012–2016 as Secretary General of that association. He also worked as consultant for the Norwegian Government regarding the Health Task Organisation of Orthopaedic Surgery, and from 2008–2010 he was president of the Danish Orthopaedic Society. Prof KJAERSGAARD-ANDERSEN is the author of more than one hundred peer review manuscripts.

Key message

Orthopaedic surgeons want to use safe implants to improve the quality of life for many years for their patients. The quality of implants is already very good, this is why new implants should be investigated independently and compared with successful implants before they are introduced to the market.

Registries on total hip and total knee replacements, which have been started in the early years by orthopaedic surgeons (initially in the Scandinavian countries), have shown to be effective in detecting early on if an implant is of low quality.

Registries should therefore be used as post-marketing tool of new implants, which in previous research seemed to be promising. Registries may also be used to compare hospitals with each other, in order to inspire and stimulate them to improve their outcomes.

5.7. Didier DELTORT

President Europe, Middle East and Africa, Zimmer Biomet

Didier DELTORT joined Zimmer Biomet – a publicly-traded medical device company – as President Europe, Middle East and Africa (EMEA) in August 2018. He is responsible for the manufacturing, sales, marketing and distribution of products and services in the EMEA region. Zimmer Biomet EMEA employs more than 7,000 Team Members.

Mr DELTORT's professional experience of more than 25 years spans multiple geographies and medical technologies, including medical devices, diagnostic imaging, healthcare IT and services. Prior to joining Zimmer Biomet, Dr DELTORT worked at Boston Scientific Corporation as their Global Senior Vice President & General Manager Healthcare Solutions & Partnerships. Before joining Boston Scientific Corporation, Mr DELTORT spent 14 years at GE Healthcare, most recently serving as Global Senior Vice President and General Manager of the global Monitoring Solutions business as well as Managing Director of GE Healthcare Finland.

Mr DELTORT holds a Master's Degree in Biomedical Engineering from the Université de Technologie de Compiègne, France.

Key message

Adhering to strict regulatory standards and operating first-rate quality management systems needs to be a priority in the development, manufacturing and distribution of medical devices. Continuous innovation must focus on improving patient outcomes and on serving unmet clinical needs. It therefore needs close collaboration with health care providers.

6. About STOA

6.1. Mission

The Panel for the Future of Science and Technology (STOA) forms an integral part of the structure of the European Parliament. Launched in 1987, STOA is tasked with identifying and independently assessing the impact of new and emerging science and technologies.

The goal of its work is to assist, with independent information, the Members of the European Parliament (MEPs) in developing options for long-term, strategic policy-making.

The STOA Panel

The STOA Panel consists of 25 MEPs nominated from the nine permanent parliamentary committees: AGRI (Agriculture & Rural Development), CULT (Culture & Education), EMPL (Employment & Social Affairs), ENVI (Environment, Public Health & Food Safety), IMCO (Internal Market & Consumer Protection), ITRE (Industry, Research & Energy), JURI (Legal Affairs), LIBE (Civil Liberties, Justice and Home Affairs) and TRAN (Transport & Tourism).

Ramón Luis VALCÁRCEL SISO MEP is the European Parliament Vice-President responsible for STOA for the second half of the 8th legislature. The STOA Chair for the second half of the 8th legislature is Eva KAILI with Paul RÜBIG and Evžen TOŠENOVSKÝ elected as 1st and 2nd Vice-Chairs respectively.

The STOA approach

STOA fulfils its mission primarily by carrying out science-based projects. Whilst undertaking these projects, STOA assesses the widest possible range of options to support evidence-based policy decisions. A typical project investigates the impacts of both existing and emerging technology options and presents these in the form of studies and options briefs. These are publicly available for download via the STOA website: www.europarl.europa.eu/stoa/.

Some of STOA's projects explore the long-term impacts of future techno-scientific trends, with the aim to support MEPs in anticipating the consequences of developments in science. Alongside its production of 'hard information', STOA communicates its findings to the European Parliament by organising public events throughout the year. STOA also runs the MEP-Scientist Pairing Scheme aimed at promoting mutual understanding and facilitating the establishment of lasting links between the scientific and policy-making communities.

Focus areas

STOA activities and products are varied and are designed to cover as wide a range of scientific and technological topics as possible, such as nano-safety, e-Democracy, bio-engineering, assistive technologies for people with disabilities, waste management, cybersecurity, smart energy grids, responsible research & innovation, sustainable agriculture and health.

They are grouped in five broad focus areas: eco-efficient transport and modern energy solutions; sustainable management of natural resources; potential and challenges of the Internet; health and life sciences; science policy, communication and global networking.

ESMH

The European Science-Media Hub (ESMH), operating under the political responsibility of the STOA Panel, is a new platform to promote networking, training and knowledge sharing between the European Parliament, the scientific community and the media. The ESMH creates a network among policy-makers, scientists and media involving science, academia, educational and research entities, professional associations of journalists and scientists.

For journalists and media representatives, the ESMH organises training and workshops on current technological developments, both as subjects of their reporting and as means of facilitating their work. Via media monitoring and media intelligence tools, the ESMH follows the most popular topics in the field of science and technology on different platforms including magazines, newspapers and social media.

The ESMH will make information available to journalists, other media and citizens about new scientific developments, as well as about scientific topics that attract media attention and promote information based on evidence.

6.2. STOA Bureau

Ramón Luis VALCÁRCEL SISO
(EPP, ES)
EP Vice-President responsible for STOA

Eva KAILI (S&D, EL)
Chair of STOA

Committee on Industry, Research and Energy
(ITRE)

Paul RÜBIG (EPP, AT)
First Vice-Chair of STOA

Committee on Industry, Research and Energy
(ITRE)

Evžen TOŠENOVSKÝ (ECR, CZ)
Second Vice-Chair of STOA

Committee on Industry, Research and Energy
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6.3. STOA Panel members

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TRAN Committee

Parliamentary Committees:
AGRI: Agriculture and Rural Development
CULT: Culture and Education
EMPL: Employment and Social Affairs
ENVI: Environment, Public Health and Food Safety
IMCO: Internal Market and Consumer Protection
ITRE: Industry, Research and Energy
JURI: Legal Affairs
TRAN: Transport and Tourism

6.4. STOA Administration

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