Current clinical applications of stem cells in Norway

Jan E. Brinchmann, MD, PhD
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Norwegian Center for Stem Cell Research
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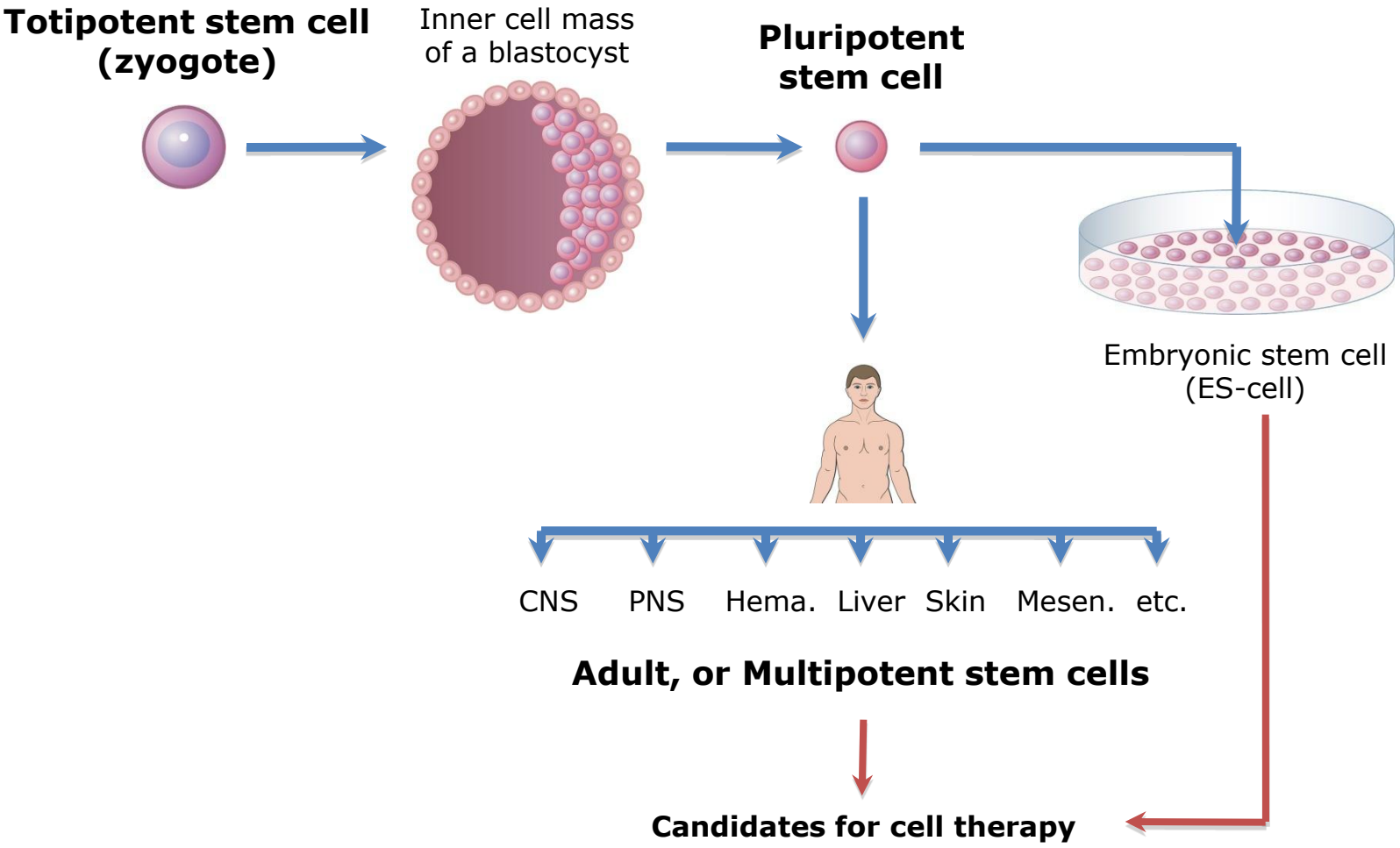
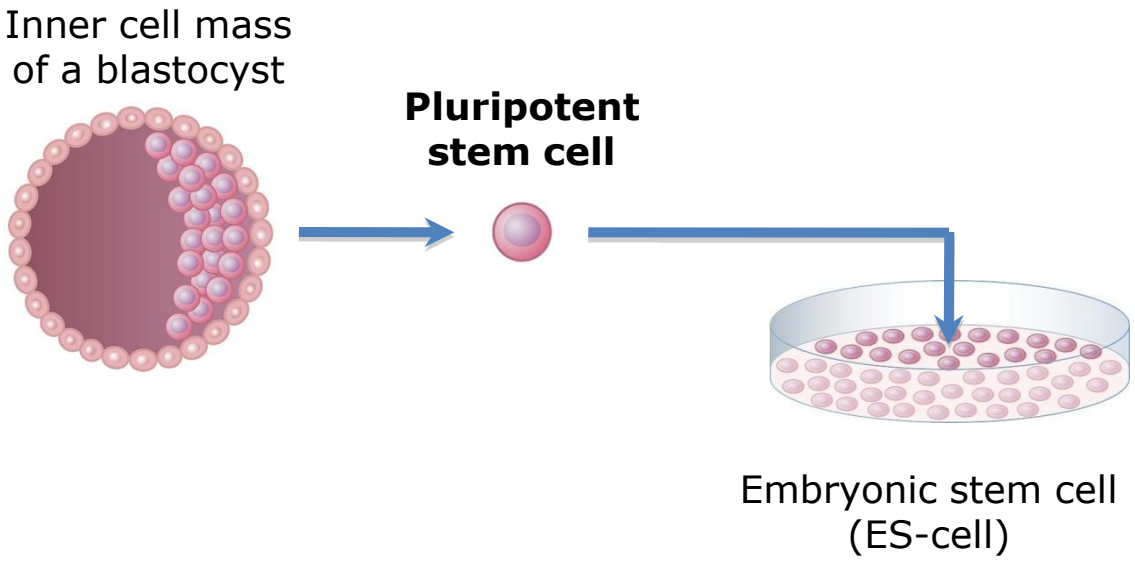
The stem cell hierarchy

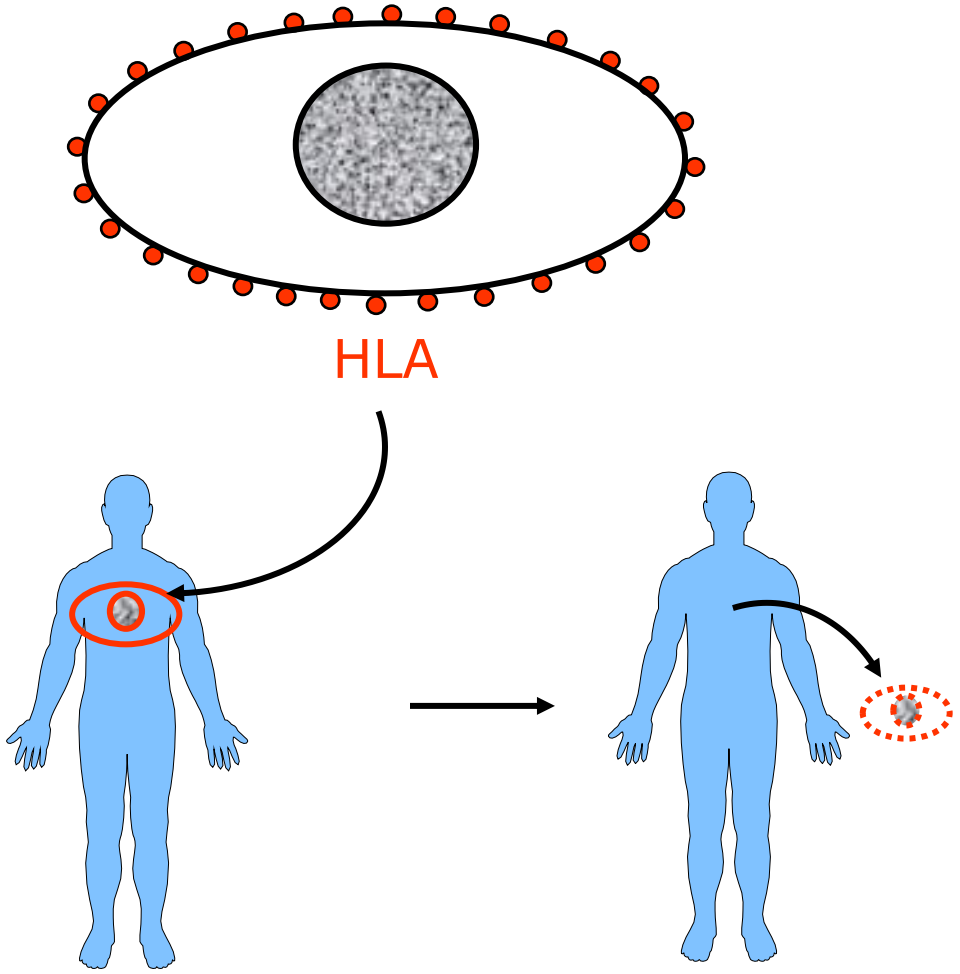


Embryonic stem cells



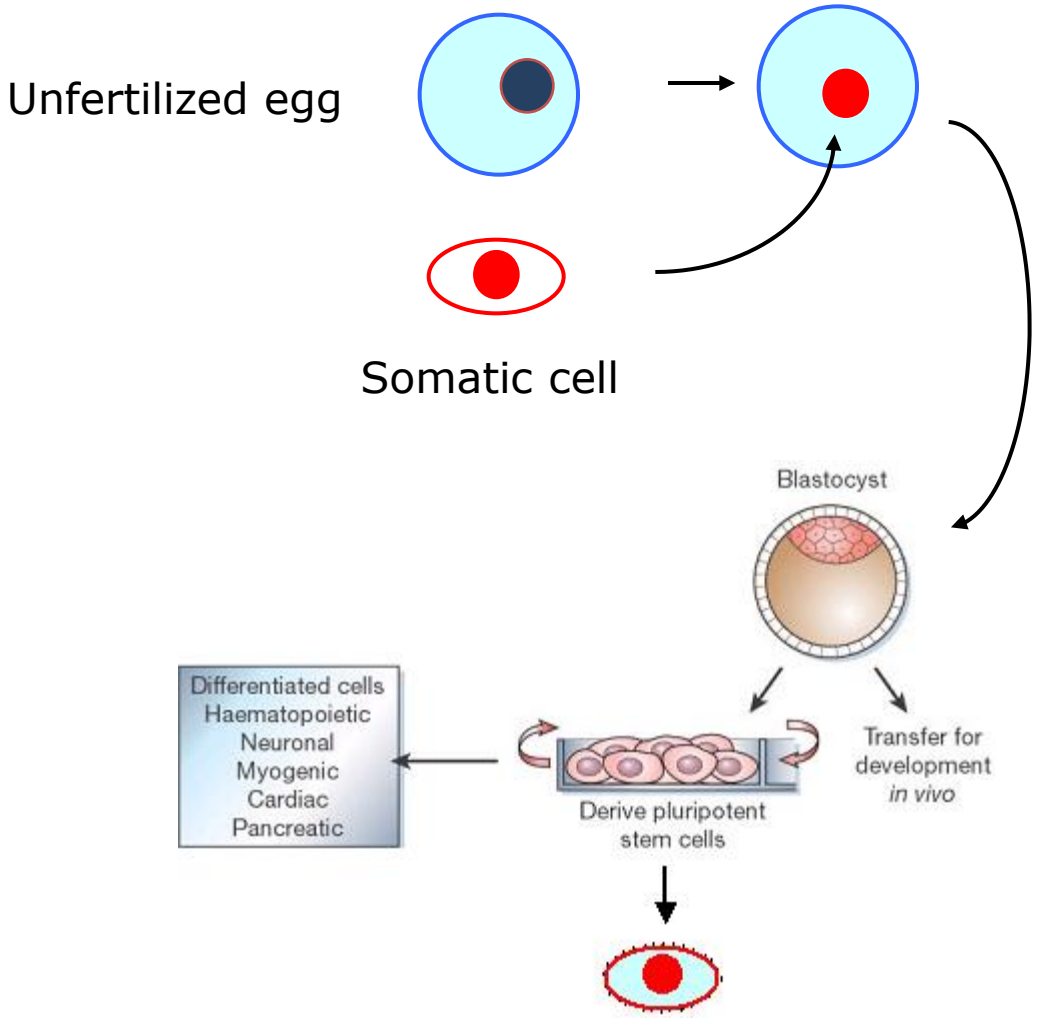
- Proliferates indefinitely
- Always pluripotent (teratoma assay)
- Can differentiate to cells typical of all three germ layers (ectoderm, mesoderm, endoderm)
- But: we can not yet fully control the differentiation
- Teratogenesis
- Always allogeneic

Cells from different people are different



Can stem cells from one individual still be used to treat another individual?

Somatic cell nuclear transfer



Pluripotent stamcelle med pasientens HLA

Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors

Kazutoshi Takahashi[1] and Shinya Yamanaka[1,2,*]
[1] Department of Stem Cell Biology, Institute for Frontier Medical Sciences, Kyoto University, Kyoto 606-8507, Japan
[2] CREST, Japan Science and Technology Agency, Kawaguchi 332-0012, Japan
*Contact: yamanaka@frontier.kyoto-u.ac.jp
DOI 10.1016/j.cell.2006.07.024

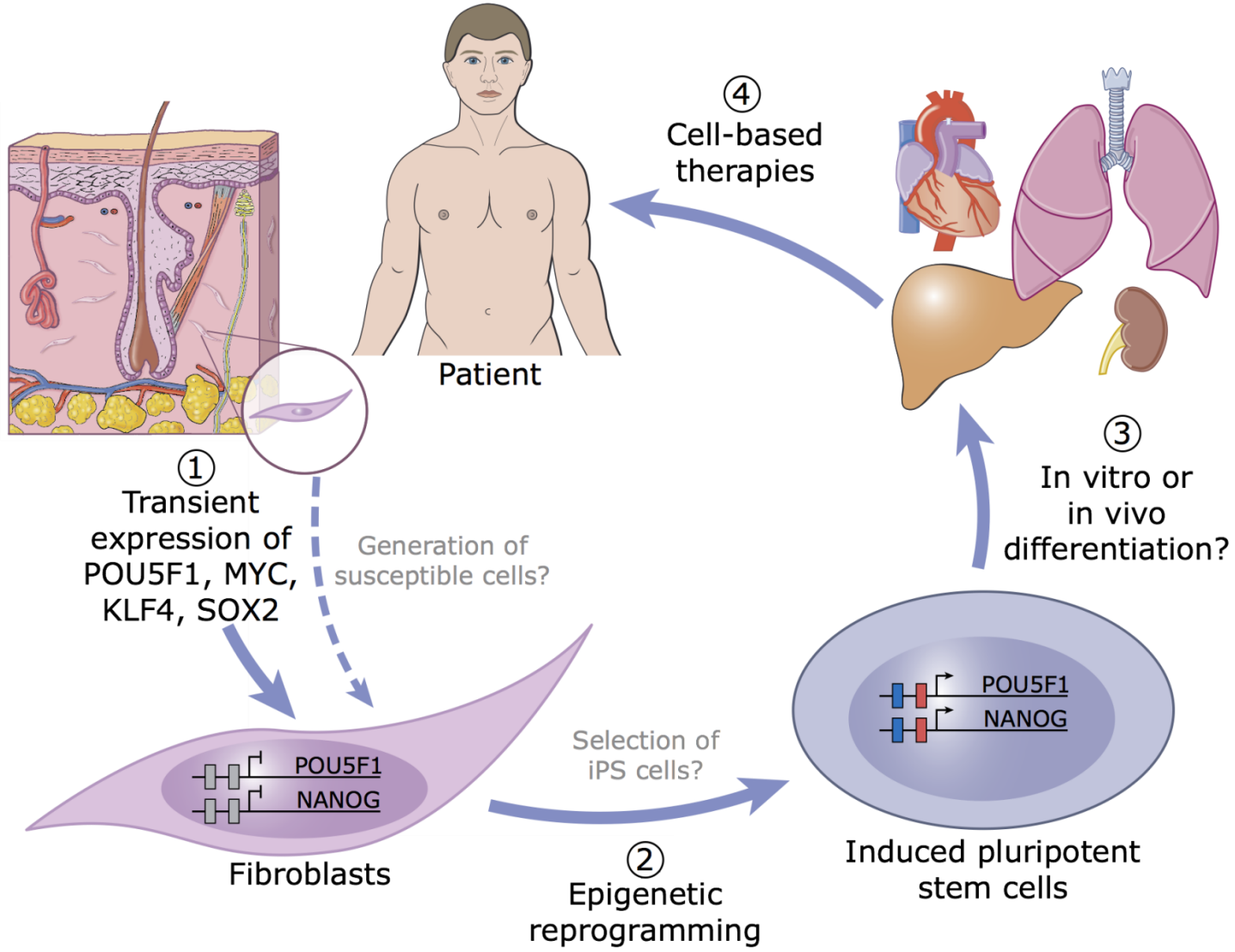
Background:

Reprogramming of differentiated cells has been shown to be possible:

- Somatic cell nuclear transfer (Wilmut et al., 1997)
- cell fusion with embryonic stem cells (Cowan et al., 2005; Tada et al., 2001)

Is it possible to induce pluripotency in end differentiated cells by introducing a limited number of genes?

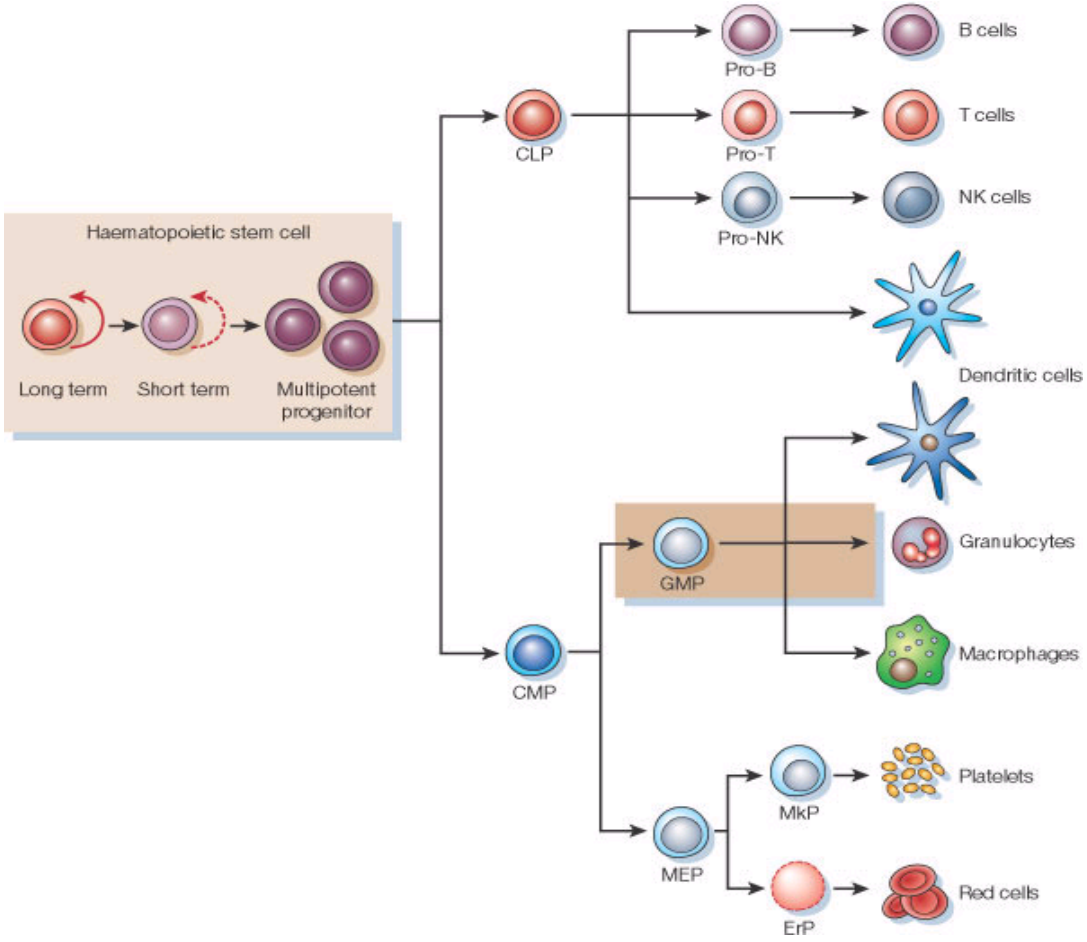
Induced pluripotent stem cells



Unsolved issues for the clinical use of hIPCs

- If gene transduction is to be used: random insertion of transgene?
- If the cells need to be reprogrammed to pluripotency: malignancy, neodifferentiation strategy
- If transdifferentiation is possible: complete transdifferentiation?

Hematopoietic stem cell transplantation has been used in the clinic for more than 40 years



Hematopoietic stem cell transplantations

- Autologous: From the patient herself
- Allogeneic: From another individual
  - » Family (including umbilical cord blood)
  - » Bone marrow donor registries
  - » Umbilical cord biobanks
  - » **For all these: HLA compatibility very important**

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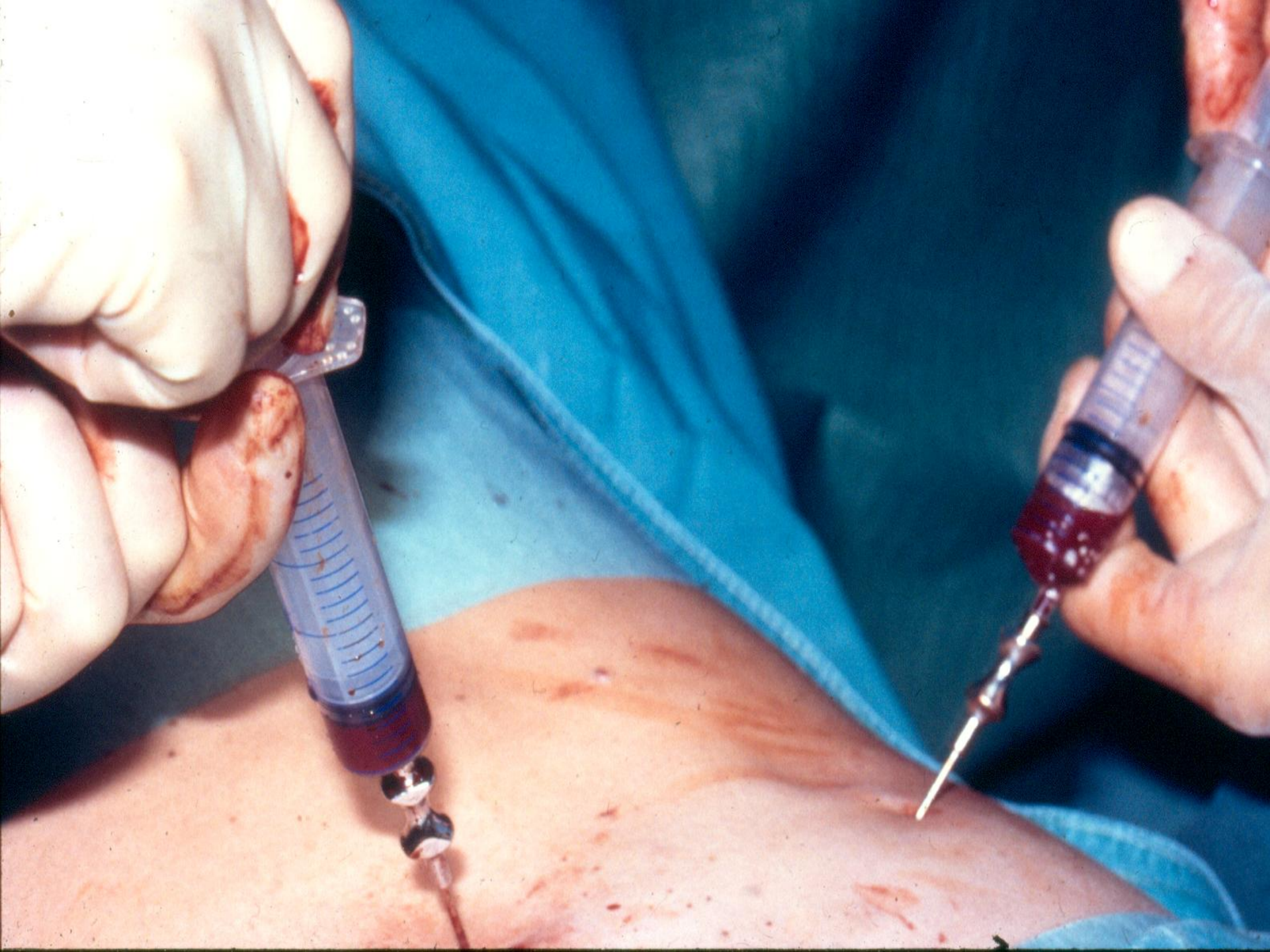


Organization of stem cell transplants in Norway:

Autologous (høydosebehandling med autolog stamcellestøtte: HMAS)

- All University hospitals in Norway
- Oslo Universitetssykehus:
  - Ullevål: Lymphomas and multiple myelomas
  - Rikshospitalet: Multiple myelomas, solid tumors (children)
  - Radiumhospitalet: Lymphomas, some solid tumors

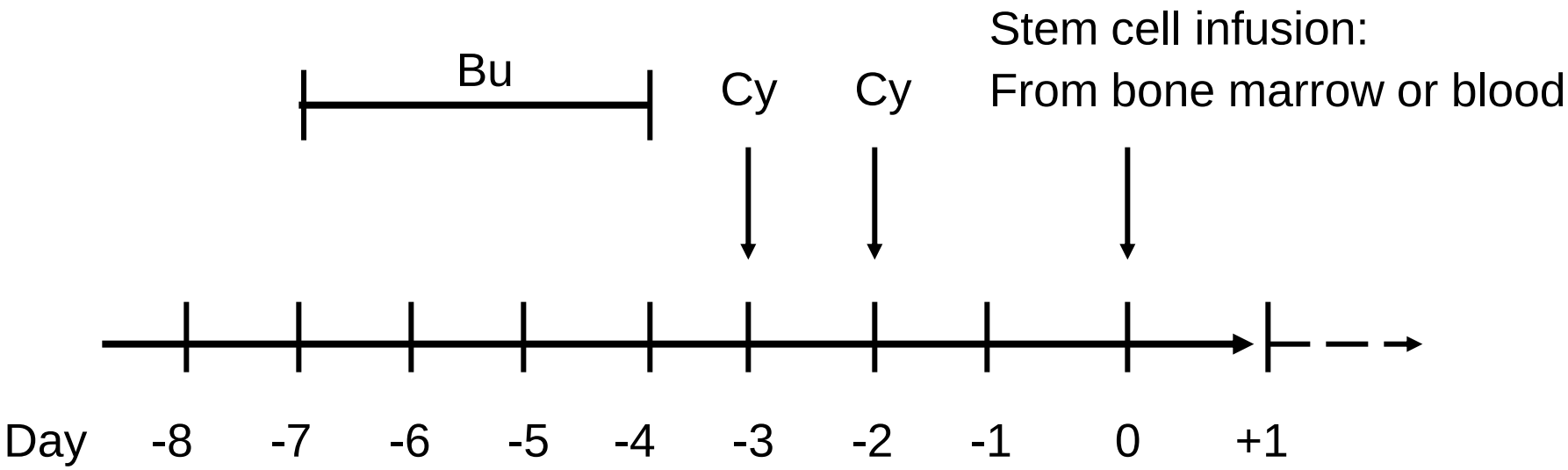
Lorentz Brinch, Department of Blood Diseases, OUS

High dose chemotherapy followed by autologous bone marrow transplantation is an option for patients with lymphomas

Histology	1.line	First chemosensitive relapse	Later chemosensitive relapse	
Hodgkins lymphoma	Not recommended	Clinical option	Clinical option	
T/B lympho-blastic lymphoma	Clinical option	Not recommended	Not recommended	
Aggressive B cell NHL	Not recommended	Clinical option	Clinical option	
Transforme d NHL	Not recommended	Clinical option	Clinical option	
Follicular NHL	Not recommended	Not recommended	Clinical option	
Mantle cell NHL	Clinical option	Not recommended	Not recommended	
Aggressive T cell NHL	ACT-1 randomised study Clinical option	Clinical option		

Arne Kolstad,
Norwegian
Radium Hospital
OUS

Allogeneic stem cell transplantation: bone marrow depletion



Bu: Busulfan : 16 mg/kg in total
Cy: Cyclofosfamid : 120 mg/kg in total

Lorentz Brinch, Department of Blood Diseases, OUS

Difference between autologous and allogeneic HSC transplantation

	Autologous	Allogeneic
Healthy stem cells	±	+
HLA compatibility	Yes	Very important
Transplant rejection	-	+
Need for treatment against rejections	-	+
Transplant versus malignancy effect	-	+

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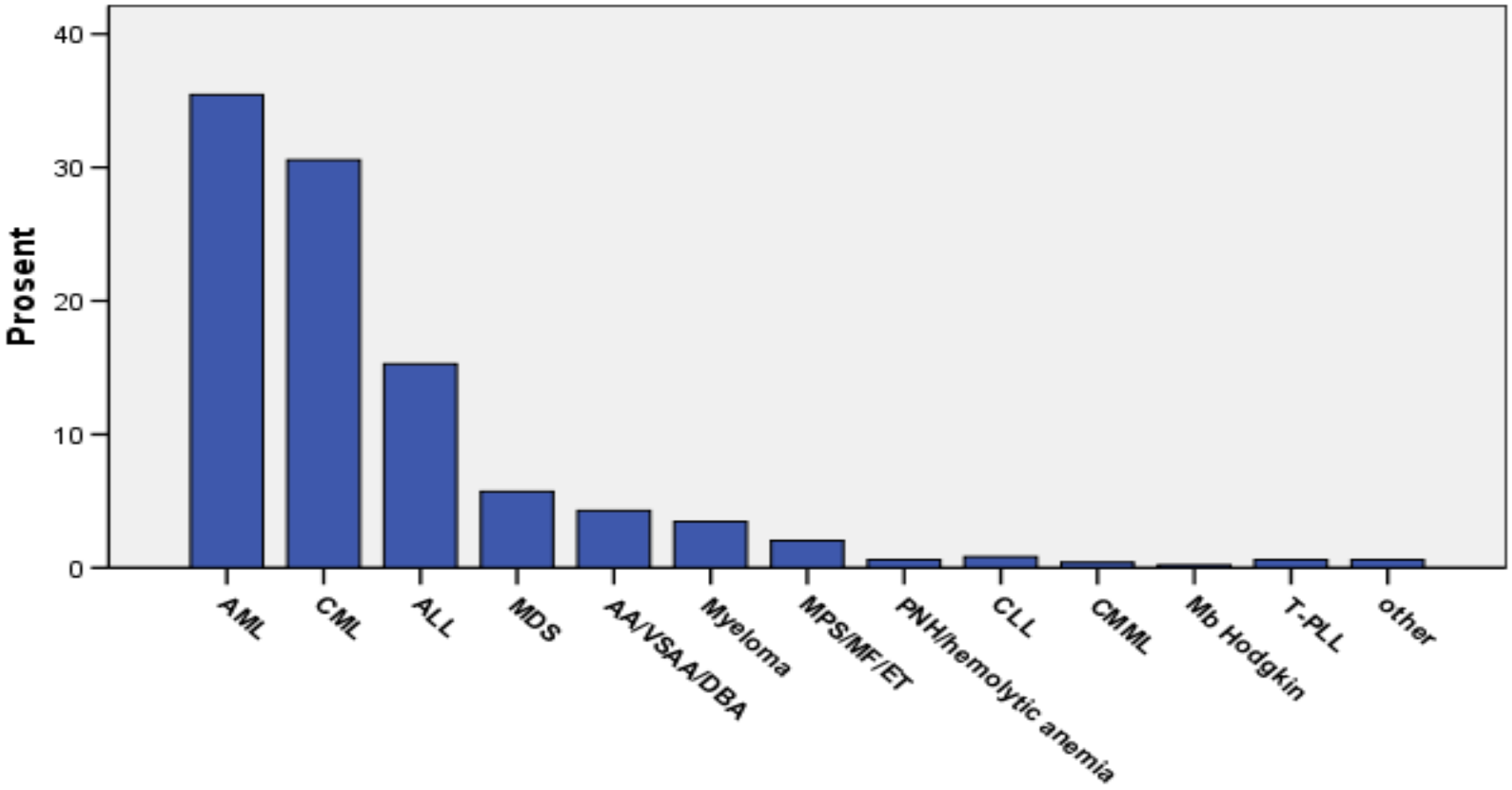
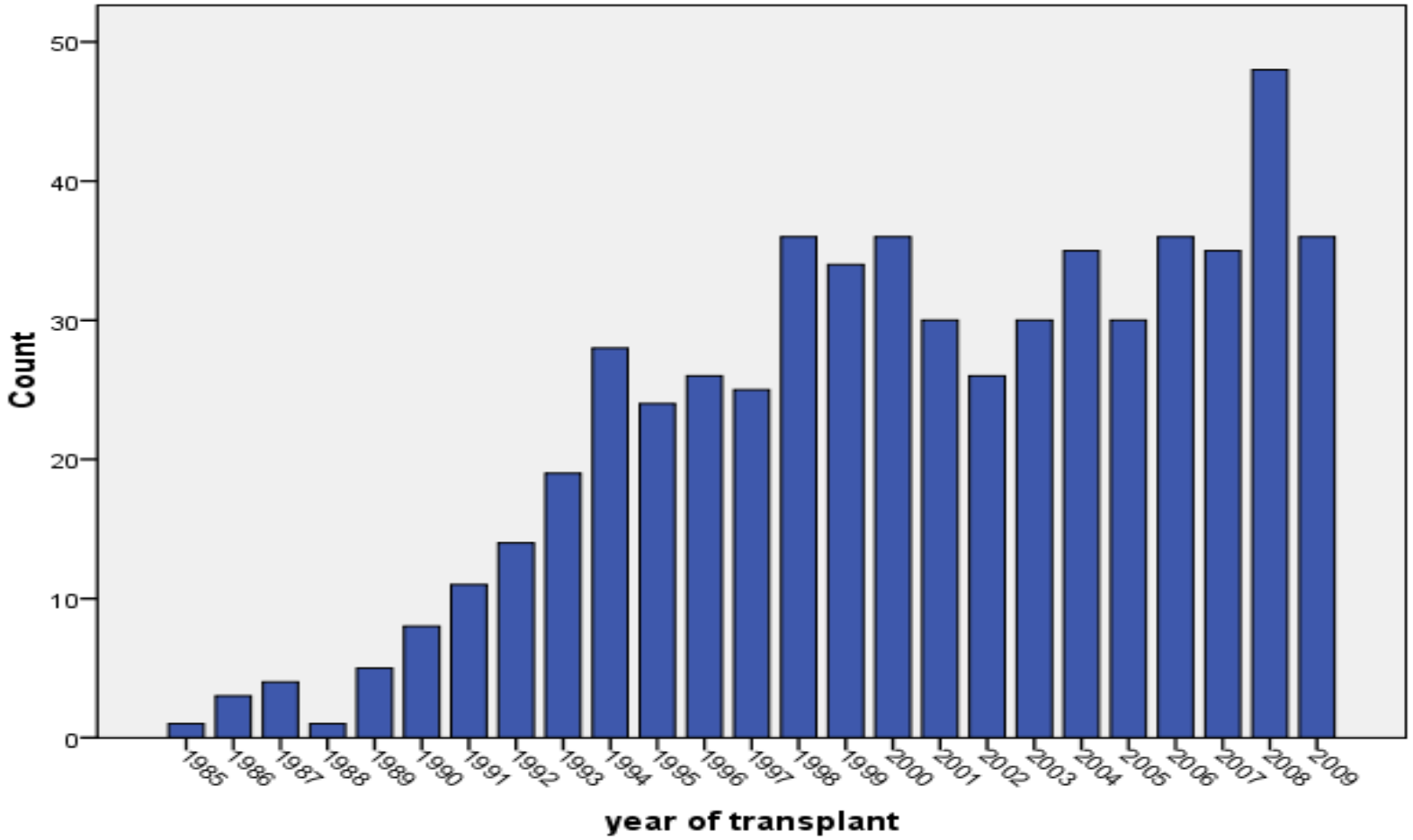
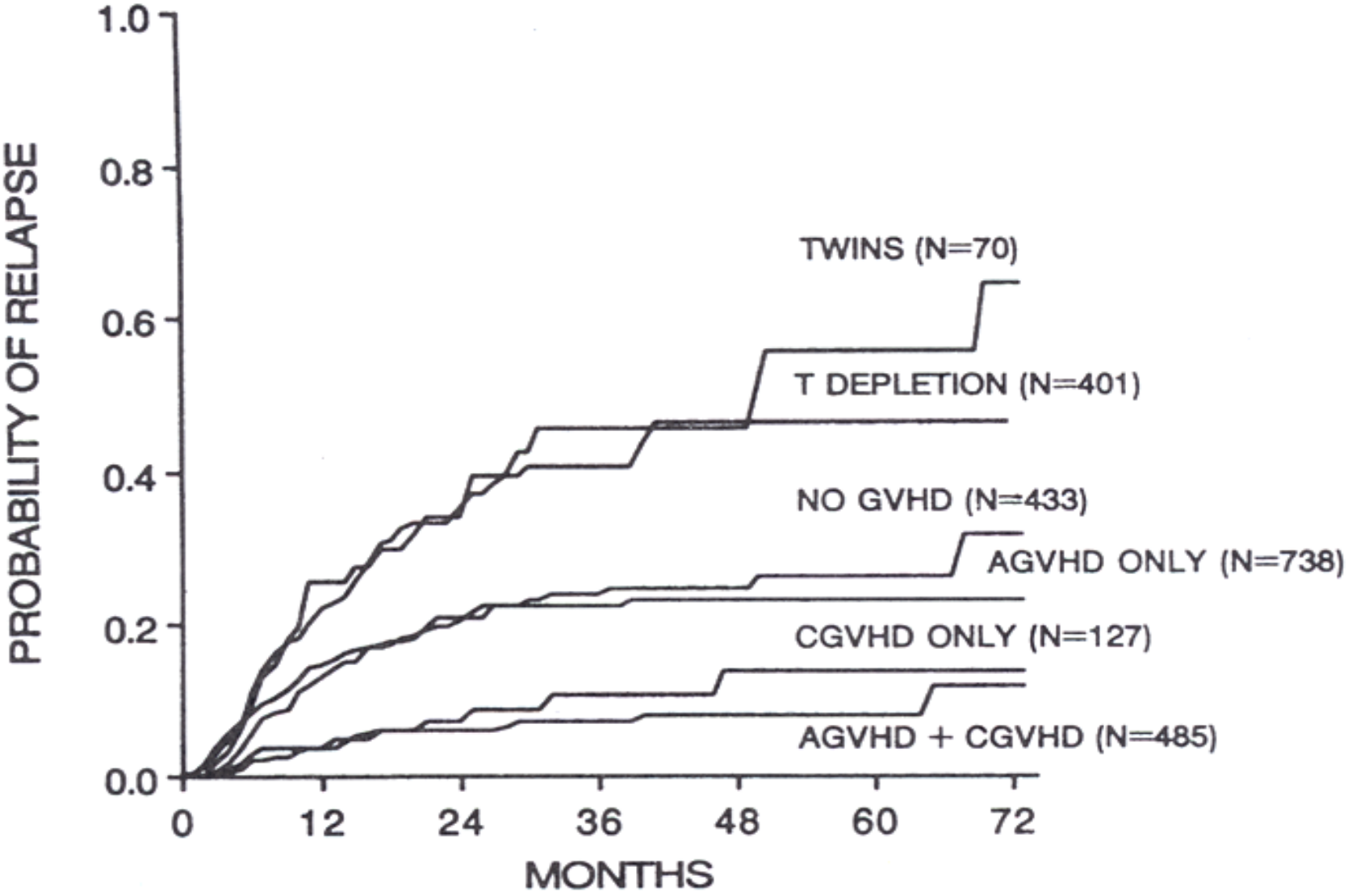
Diseases treated with allogeneic stem cell transplantation

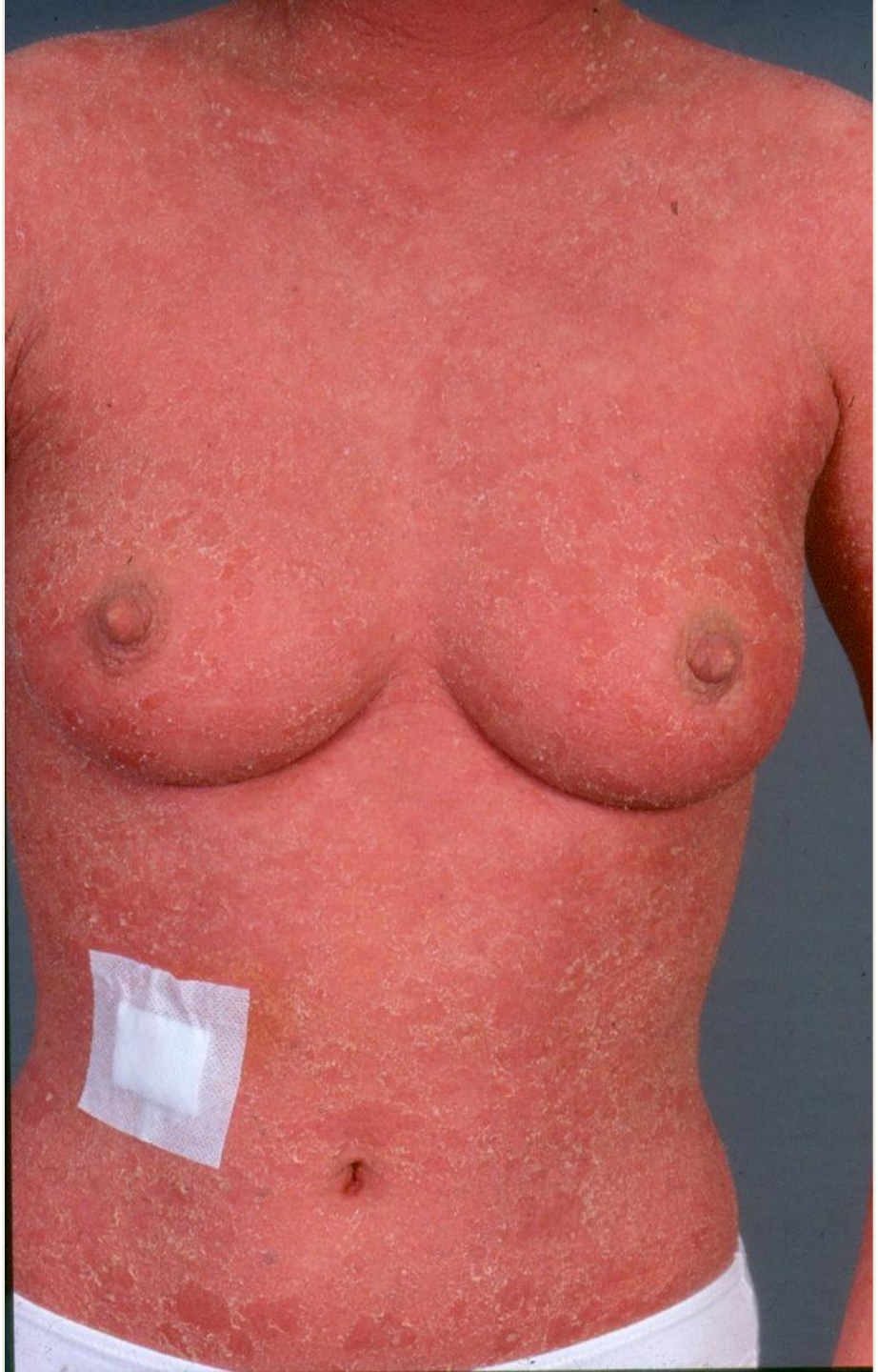


Allogeneic stem cell transplantation in Norway: only performed at Rikshospitalet





Hematopoietic cell transplantation, 2nd edition 1998;319



Tissue engineering

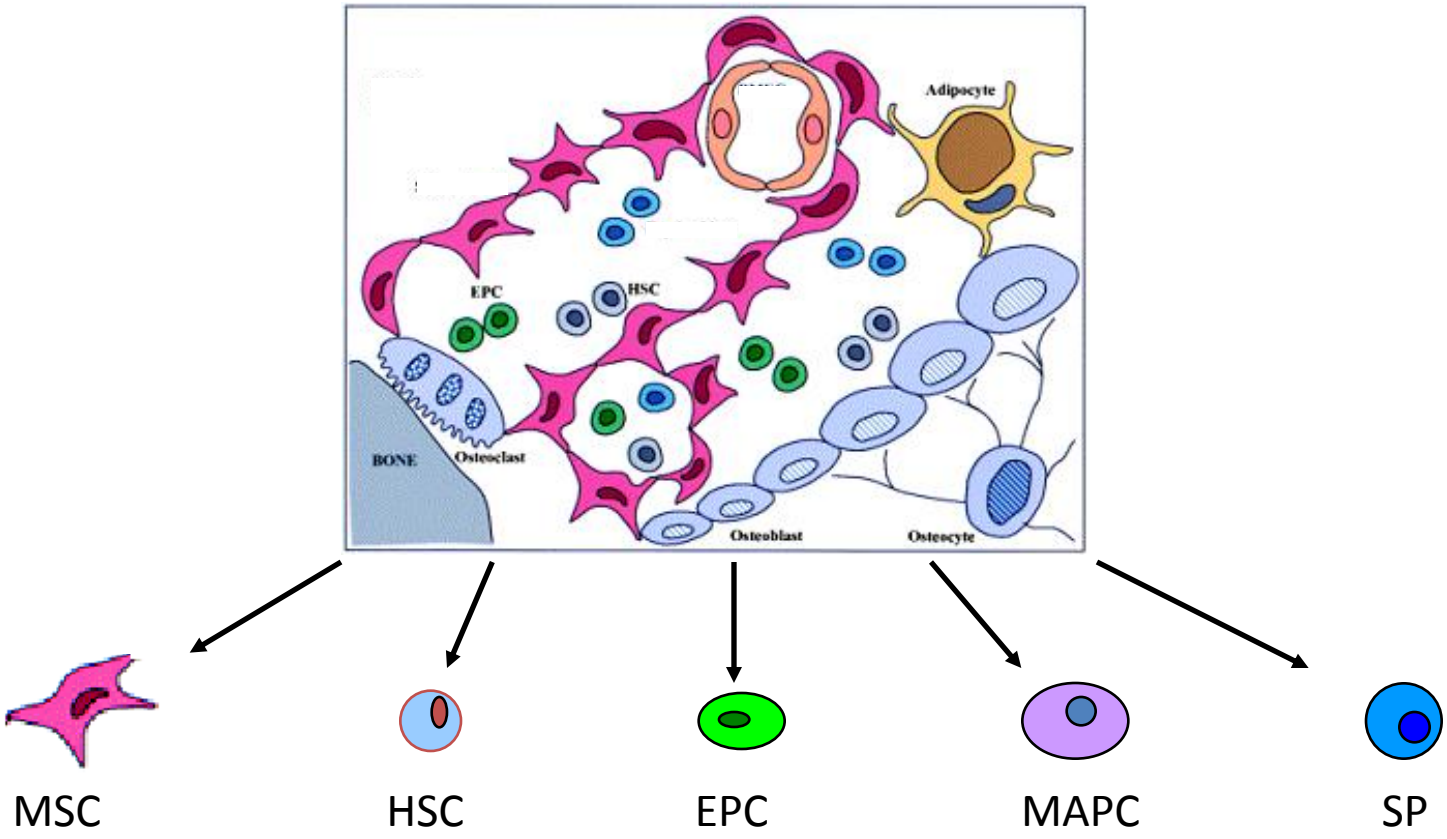
Elements:

- Cells
- Biomaterials
- Imaging
- Advanced surgery

In the clinic:

- Heart
- Cartilage
- Bone
- Eye

Stem/progenitor cells in the bone marrow



Repair of Infarcted Myocardium by Autologous Intracoronary Mononuclear Bone Marrow Cell Transplantation in Humans

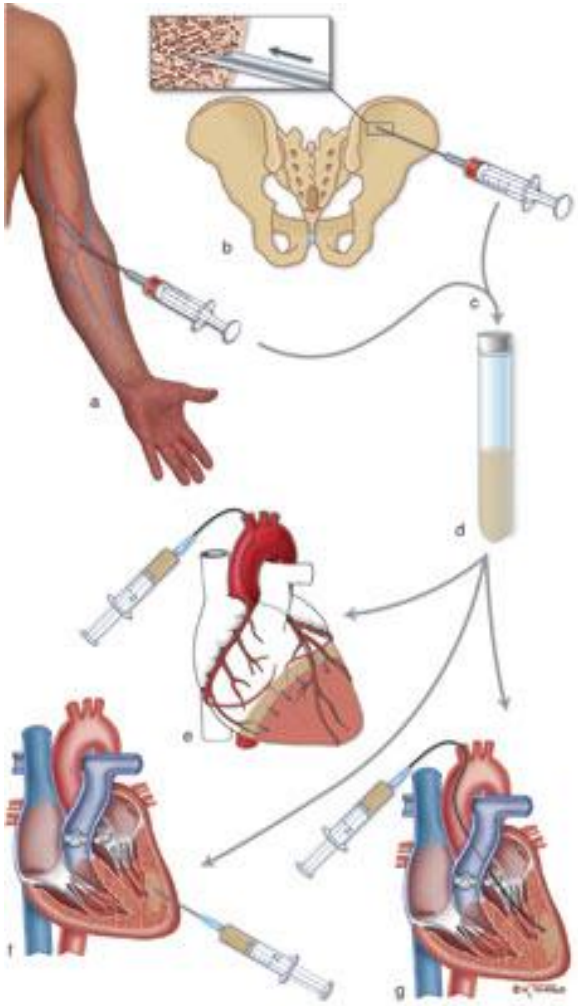
Bodo E. Strauer, MD; Michael Brehm, MD; Tobias Zeus, MD; Matthias Köstering, MD; Anna Hernandez, PhD; Rüdiger V. Sorg, PhD; Gesine Kögler, PhD; Peter Wernet, MD

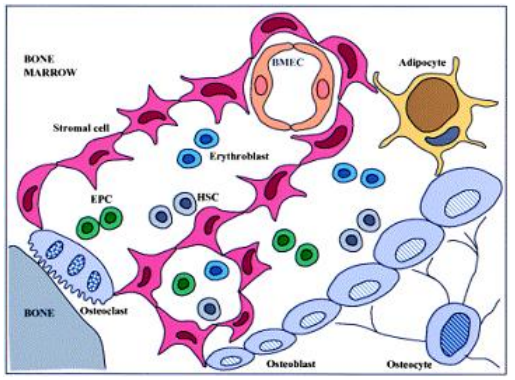
Background—Experimental data suggest that bone marrow–derived cells may contribute to the healing of myocardial infarction (MI). For this reason, we analyzed 10 patients who were treated by intracoronary transplantation of autologous, mononuclear bone marrow cells (BMCs) in addition to standard therapy after MI.

Methods and Results—After standard therapy for acute MI, 10 patients were transplanted with autologous mononuclear BMCs via a balloon catheter placed into the infarct-related artery during balloon dilatation (percutaneous transluminal coronary angioplasty). Another 10 patients with acute MI were treated by standard therapy alone. After 3 months of follow-up, the infarct region (determined by left ventriculography) had decreased significantly within the cell therapy group (from 30±13 to 12±7%, $P=0.005$) and was also significantly smaller compared with the standard therapy group ($P=0.04$). Likewise, infarction wall movement velocity increased significantly only in the cell therapy group (from 2.0±1.1 to 4.0±2.6 cm/s, $P=0.028$). Further cardiac examinations (dobutamine stress echocardiography, radionuclide ventriculography, and catheterization of the right heart) were performed for the cell therapy group and showed significant improvement in stroke volume index, left ventricular end-systolic volume and contractility (ratio of systolic pressure and end-systolic volume), and myocardial perfusion of the infarct region.

Conclusions—These results demonstrate for the first time that selective intracoronary transplantation of autologous, mononuclear BMCs is safe and seems to be effective under clinical conditions. The marked therapeutic effect may be attributed to BMC-associated myocardial regeneration and neovascularization. (***Circulation*. 2002;106:1913-1918.**)

Cardiac repair: can bone marrow cells improve myocardial function in patients with acute myocardial infarction (AMI)?





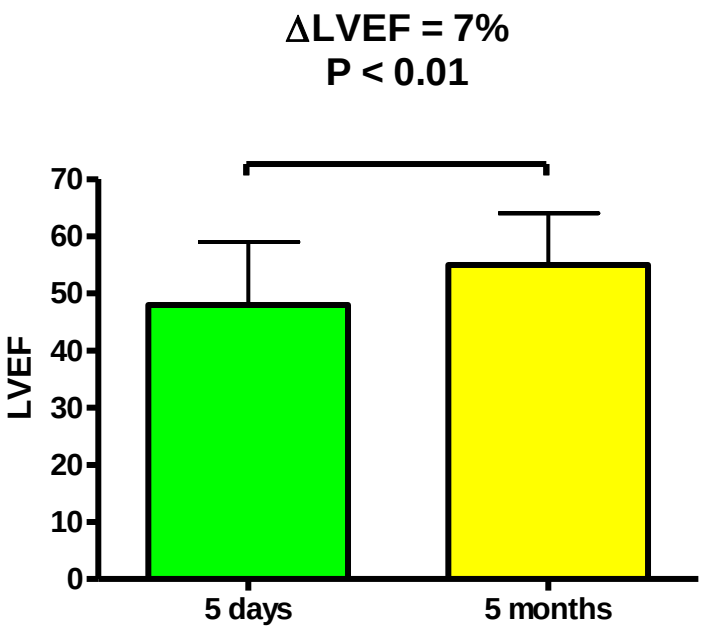
MSC HSC EPC MAPC SP

a) Blood is aspirated to get serum

b) Bone marrow aspiration day 4 - 5

Injection into the affected coronary artery or into the myocardium

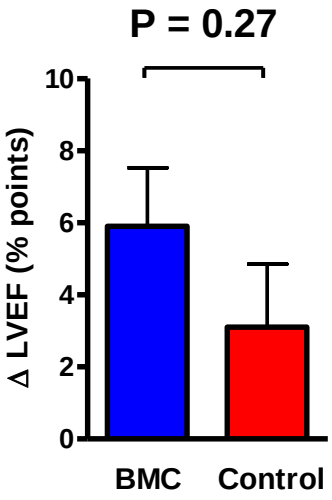
Expected improvement in LVEF after AMI by routine treatment



Baks et al, Eur Heart J 2005;26:1070

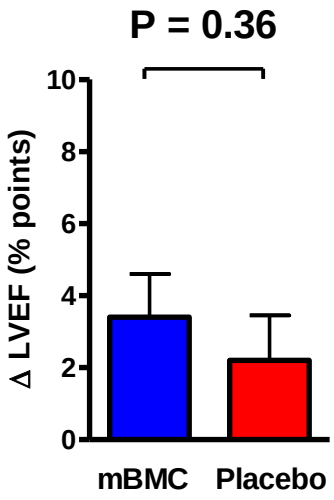
Results on LVEF in clinical trials with Bone Marrow Cells in AMI

BOOST
n=60



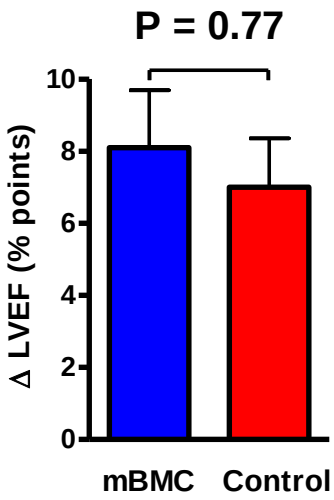
Meyer et al
Circulation 2006;113:1287-1294

Leuven
n=67



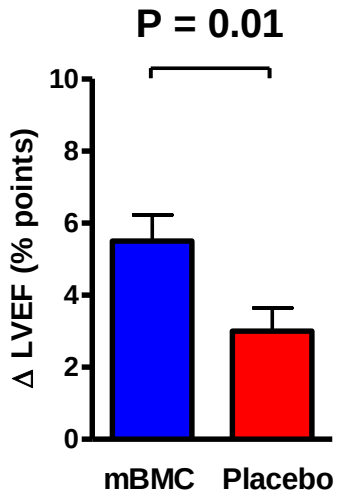
Janssens et al
Lancet 2006;367:113-21

ASTAMI
n=100



Lunde et al
NEJM 2006;355:1199-209

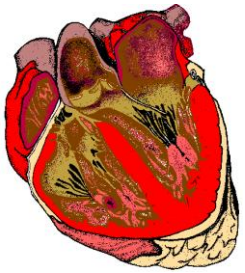
REPAIR-AMI
n=204



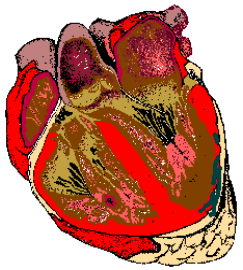
Schächinger et al
NEJM 2006;355:1210-21

What is the reason for the limited success?

The human left ventricle contains
~ 4-5 x10^9 cardiomyocytes



Normal heart

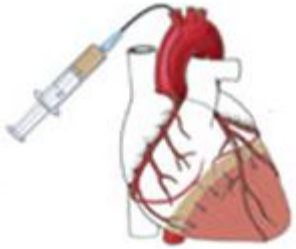


AMI

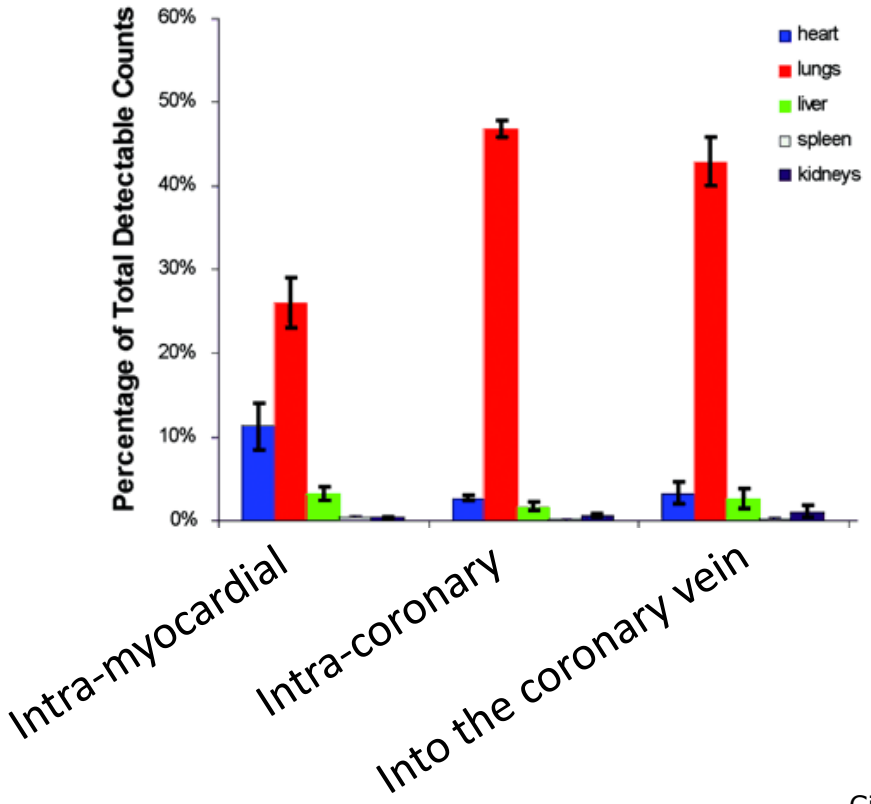
25% MI destroys ~ 1x10^9 cardiomyocytes

Approximately 1% HSC in BM-MNC

Injection of 150x1x10^6 BM-MNC $\rightarrow$ 1.5x10^6 HSC



Very few of the injected cells home to or remain in the myocardium



Analysed 1 hr after injection

Hou et al

Circulation 2005;112[suppl I]:I-150-I-156

ARTICLES

nature medicine

Bone marrow–derived hematopoietic cells generate cardiomyocytes at a low frequency through cell fusion, but not transdifferentiation

Jens M Nygren[1], Stefan Jovinge[1,2], Martin Breitbach[3], Petter Säwén[1], Wilhelm Röll[4], Jürgen Hescheler[5], Jalal Taneera[1], Bernd K Fleischmann[3] & St

Nat Med 2004;10:494-501

Haematopoietic stem cells adopt mature haematopoietic fates in ischaemic myocardium

Leora B. Balsam[1], Amy
Theo Kofidis[1], Irving L

Nature 2004;428:668-73

Haematopoietic stem cells do not transdifferentiate into cardiac myocytes in myocardial infarcts

Charles E. Murry[1], Mark H. Soonpaa[2], Hans Reinecke[1], Hidehiro Nakajima[2], Hisako O. Nakajima[2], Michael Rubart[2], Kishore B. S. Pasumarthi[2*], Jitka Ismail Virag[1], Stephen H. Bartelmez[3], Veronica Poppa[1], Gillian [illegible], David A. Williams[2*] & L

Nature 2004;428:664-8

Bone marrow cells adopt the cardiomyogenic fate *in vivo*

Marcello Rota*, Jan Kajstura*, Toru Hosoda*, Claudia Bearzi*, Serena Vitale*, Grazia Esposito*, Grazia Iaffaldano*, M. Elena Padin-Iruegas*, Arantxa Gonzalez*, Roberto Rizzi*, Narissa Small*, John Muraski†, Roberto Alvarez†, Xiongwen Chen‡, Konrad Urbanek*, Roberto Bolli§, Steven R. Houser‡, Annarosa Leri*, Mark A. Sussman†, and Piero Anversa*¶

*Cardiovascular Research Institute, Department of Medicine, New York Medical College, Valhalla, NY 10595; ‡Cardiovascular Research Center, Temple University, Philadelphia, PA 19140; §Institute of Molecular Cardiology, University of Louisville, Louisville, KY 40292; and †Heart Institute and Department of Biology, San Diego State University, San Diego, CA 92182

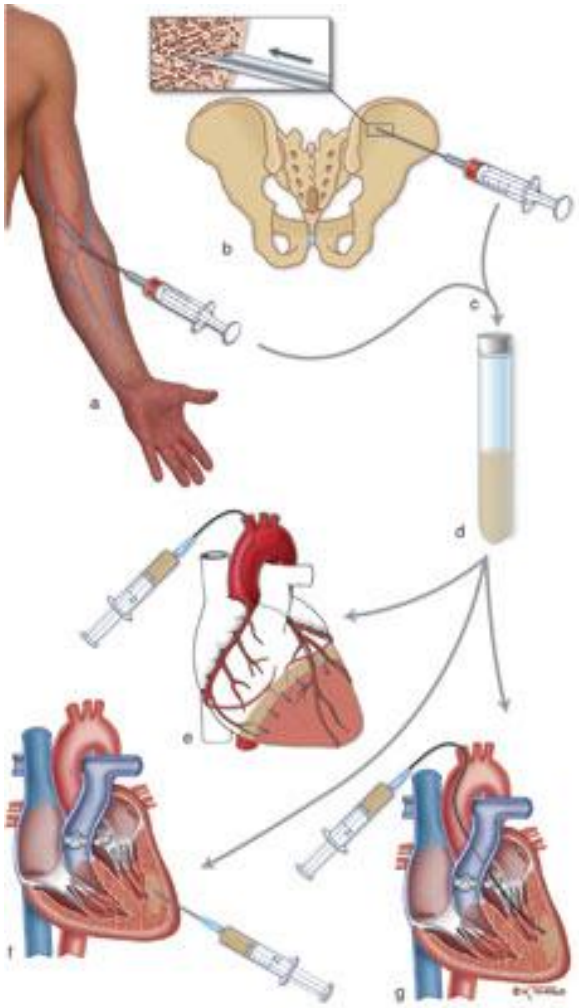
Edited by Andrew R. Marks, Columbia University College of Physicians and Surgeons, New York, NY, and approved September 7, 2007 (received for review July 9, 2007)

PNAS 2007;104:17783-8

Results of Intracoronary Stem Cell Therapy After Acute Myocardial Infarction

Jochen Wöhrle, MD[a,*], Nico Merkle, MD[a], Volker Mailänder, MD[b], Thorsten Nusser, MD[a], Peter Schauwecker, MD[b], Fabian von Scheidt[a], Klaus Schwarz, MD[b], Martin Bommer, MD[c], Markus Wiesneth, MD[b], Hubert Schrezenmeier, MD[b], and Vinzenz Hombach, MD[a]

or LV end-diastolic and end-systolic volume indexes. In conclusion, in this rigorous double-blind, randomized, placebo-controlled trial, we did not observe an evidence for a positive effect for intracoronary BMC versus placebo therapy with respect to LV ejection fraction, LV volume indexes, or infarct size. (Am J Cardiol 2010;105:804–812)



Is it possible to improve myocardial function using cell therapy or tissue engineering following AMI?
Probably

Should this be offered to patients in acute stage MI?
Unlikely, the cells need to be expanded in vitro, and should be autologous

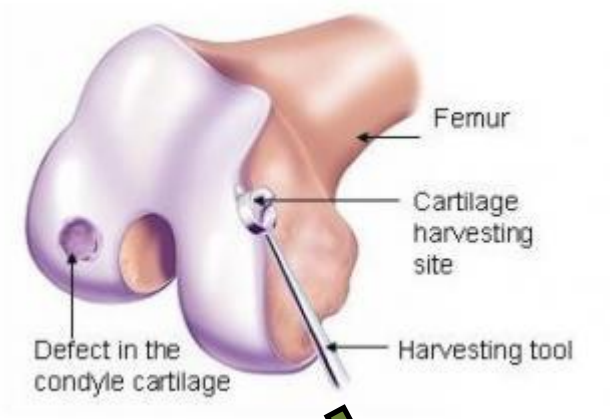
Which are the best cells to use? **Not known, animal studies are ongoing**

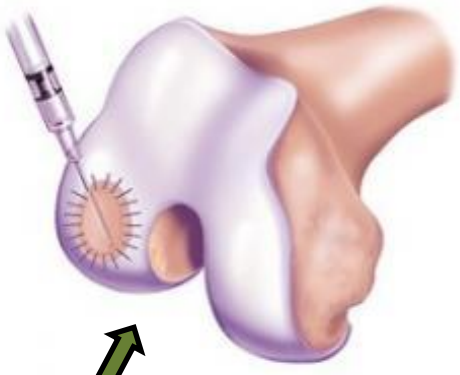
What would be the most likely mechanism for the effect of cell therapy?

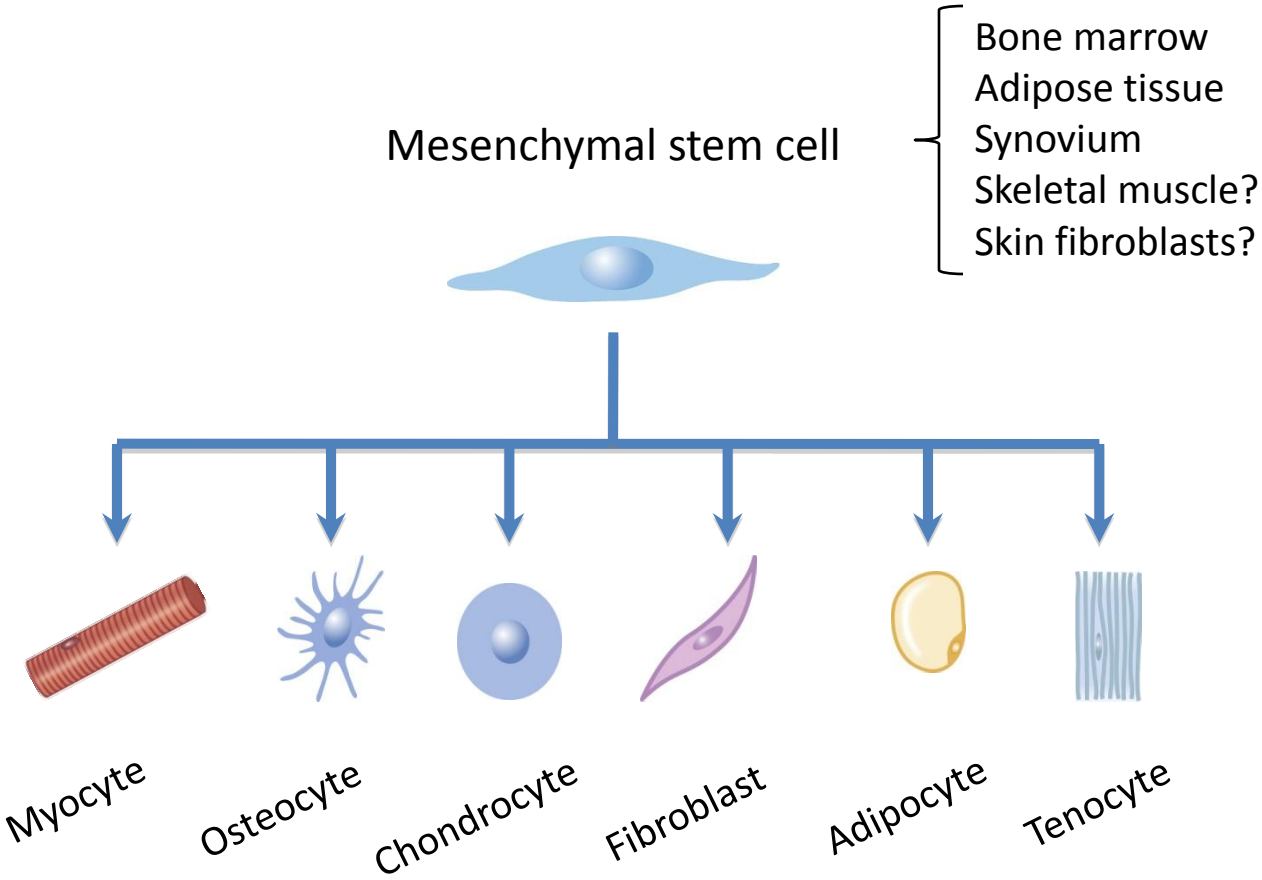
- Transdifferentiation transplanted cells → cardiomyocytes? **Perhaps, but unlikely**
- Stimulation of endogenous repair mechanisms? **More likely**
- Improvement of local blood supply? **Important, may need to include cells specifically for this purpose**

Can adult stem cells be used to treat focal lesions of hyaline cartilage?

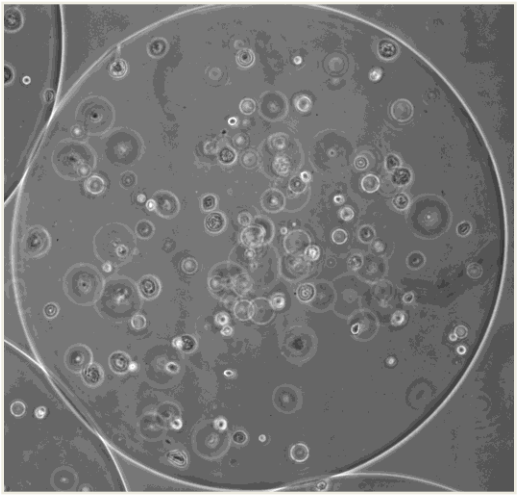
In vitro expanded chondrocytes is used for regeneration of hyaline cartilage, but the result is frequently fibrocartilage





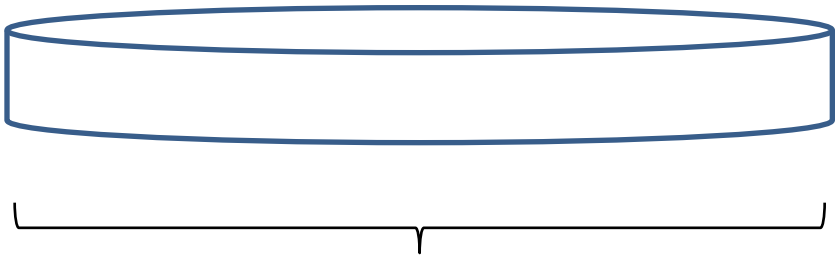

Mesenchymal stem cell
Bone marrow
Adipose tissue
Synovium
Skeletal muscle?
Skin fibroblasts?
Myocyte
Osteocyte
Chondrocyte
Fibroblast
Adipocyte
Tenocyte

Alginate as a scaffold for chondrogenic differentiation of MSC

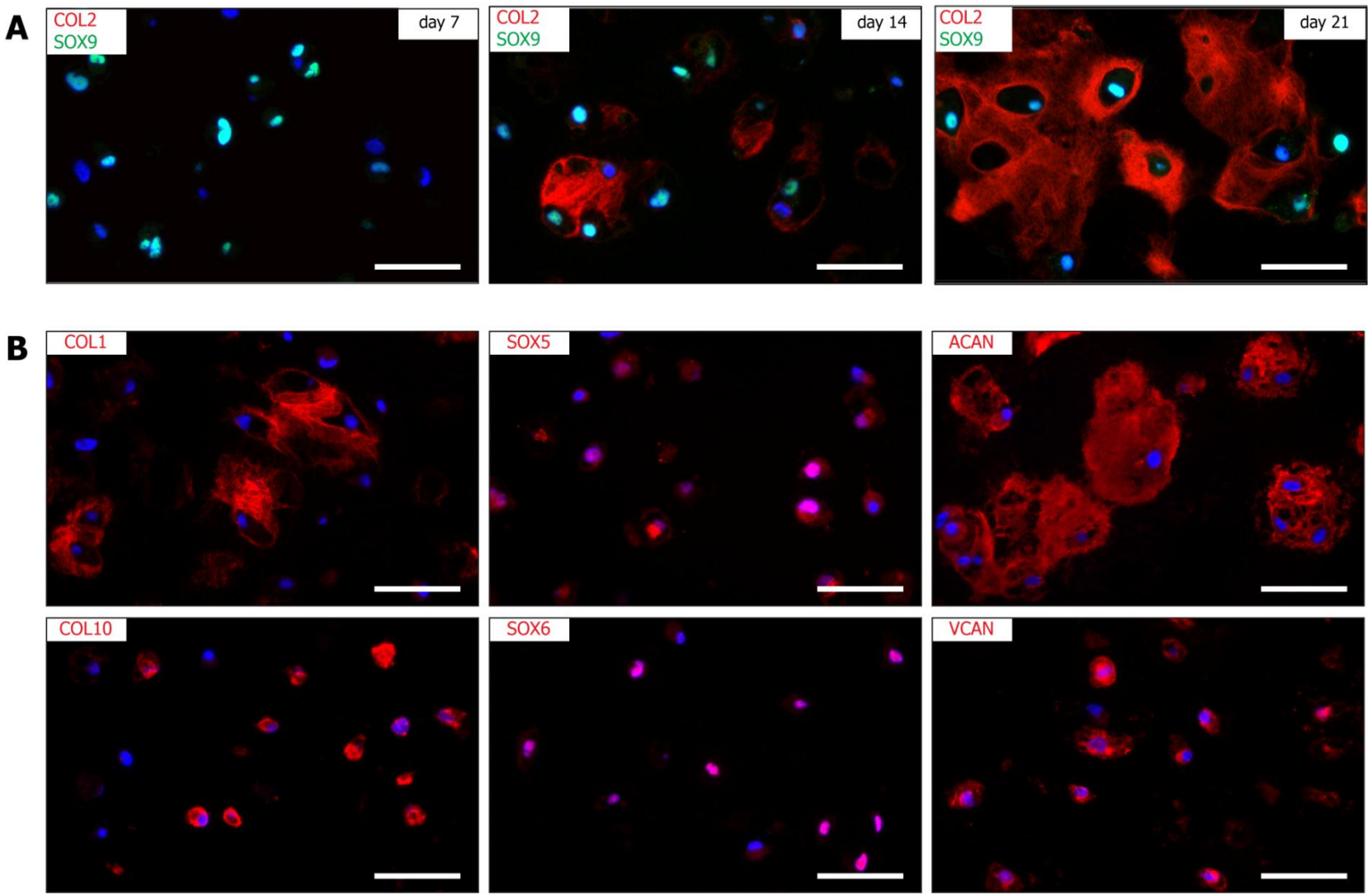


The scaffold can be made to shape of choice

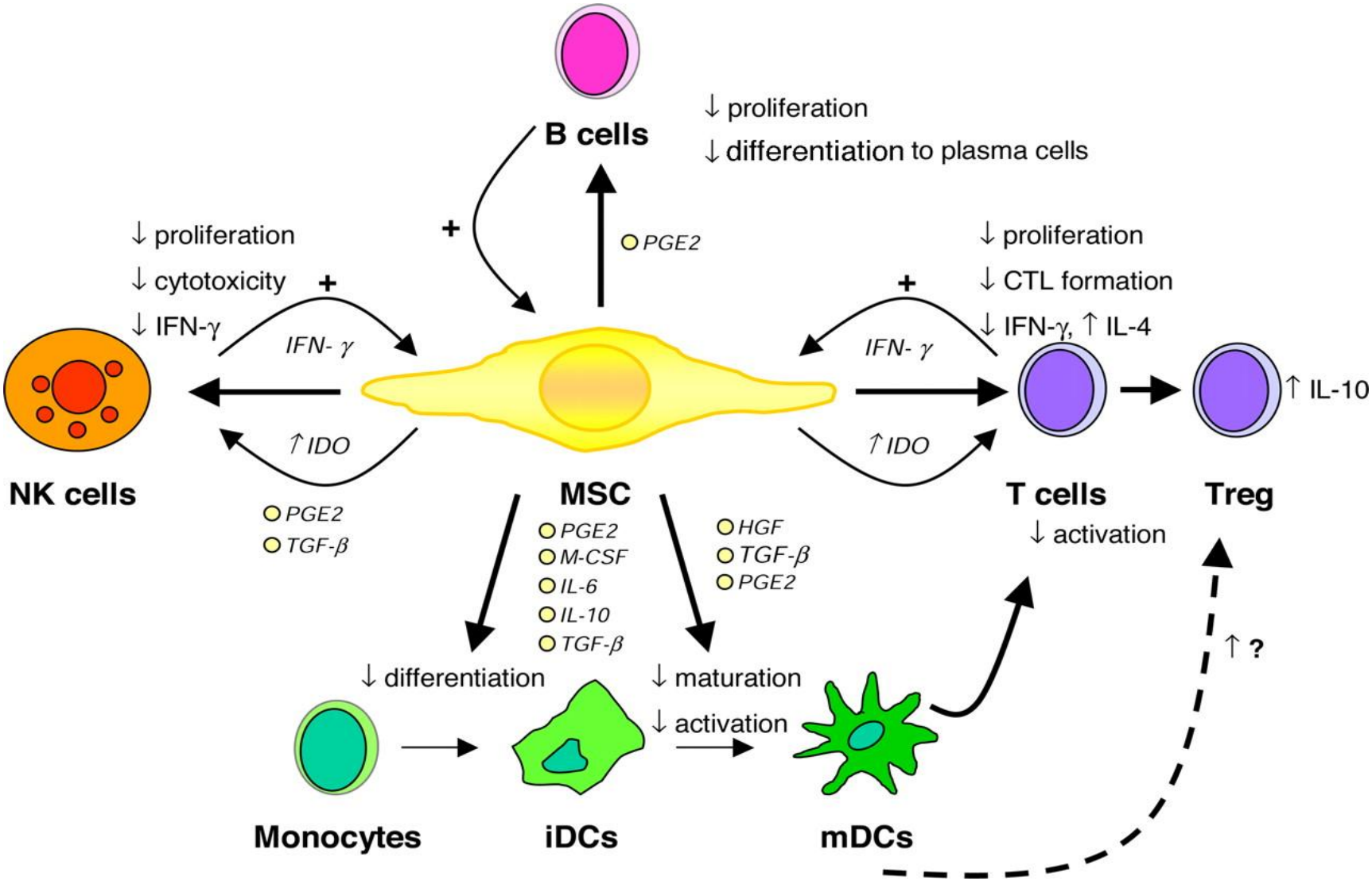
- Cells are quite evenly distributed
- The alginate can be easily removed
- Alginate may be made biodegradable?



Expression of proteins of importance for chondrogenesis after 21 days of differentiation in alginate discs

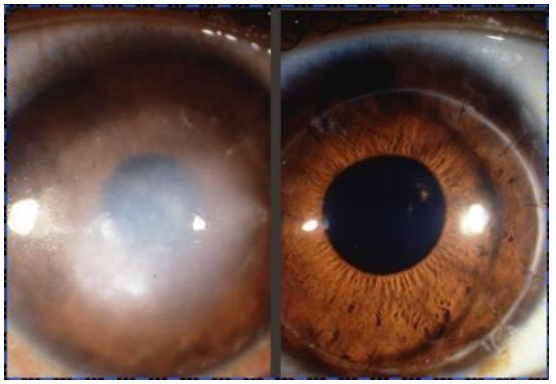


MSC may exert immunosuppressive effects



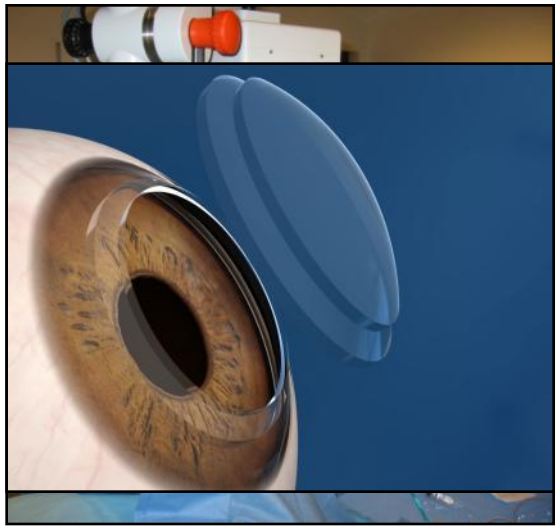
Diseases of the cornea may be treated with stem cell therapy

- The first corneal transplant was performed in Norway in 1933.
- Corneas are kept in a tissue bank at the Center for Eye Research, Ullevål
- Can be stored for up to 4 weeks befor the operation.



Challenges:

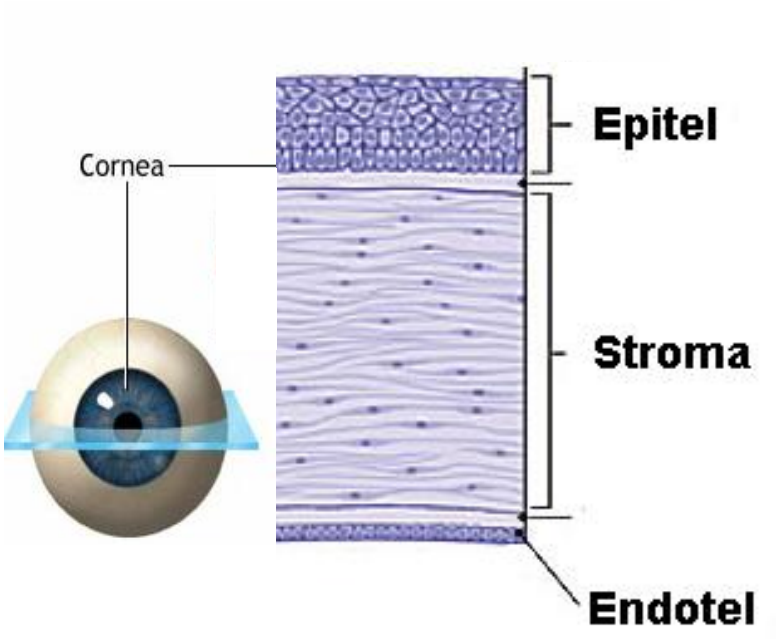
- Some corneas must be discarded before the operation due to poor quality tissue.
- Some transplanted corneas become non-translucent
- There is a lack of corneas, many are bought from USA, expensive



Morten C Moe, Department of Eye Diseases, Ullevål

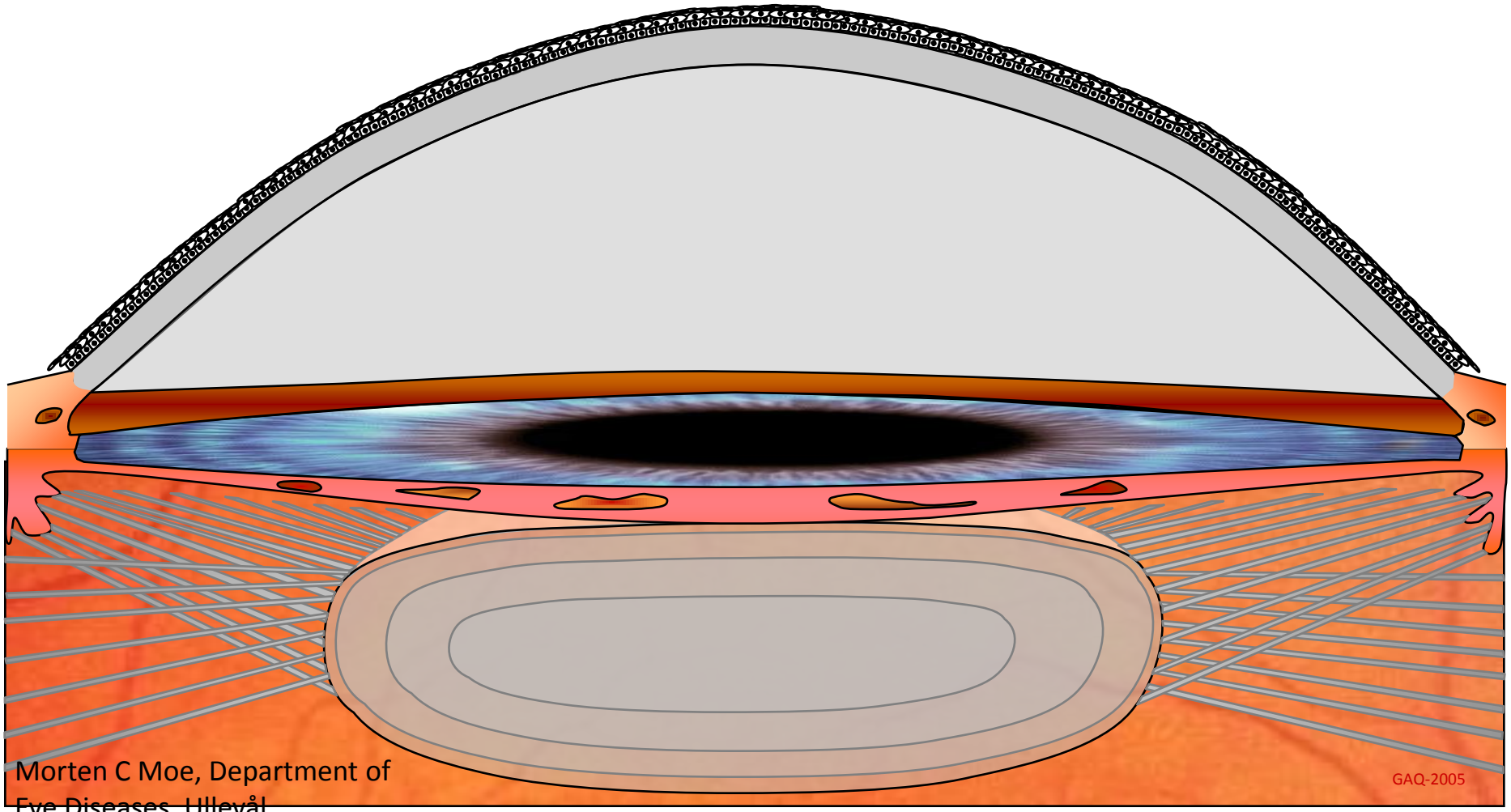
Strategy

- The different layers of the cornea have their own stem cells
- In patients with damage to only one of the corneal layers, stem cell therapy may be sufficient



Morten C Moe, Department of Eye Diseases, Ullevål

Transplantation of autologous limbal stem cells to a patient with stem cell failure



Morten C Moe, Department of Eye Diseases, Ullevål

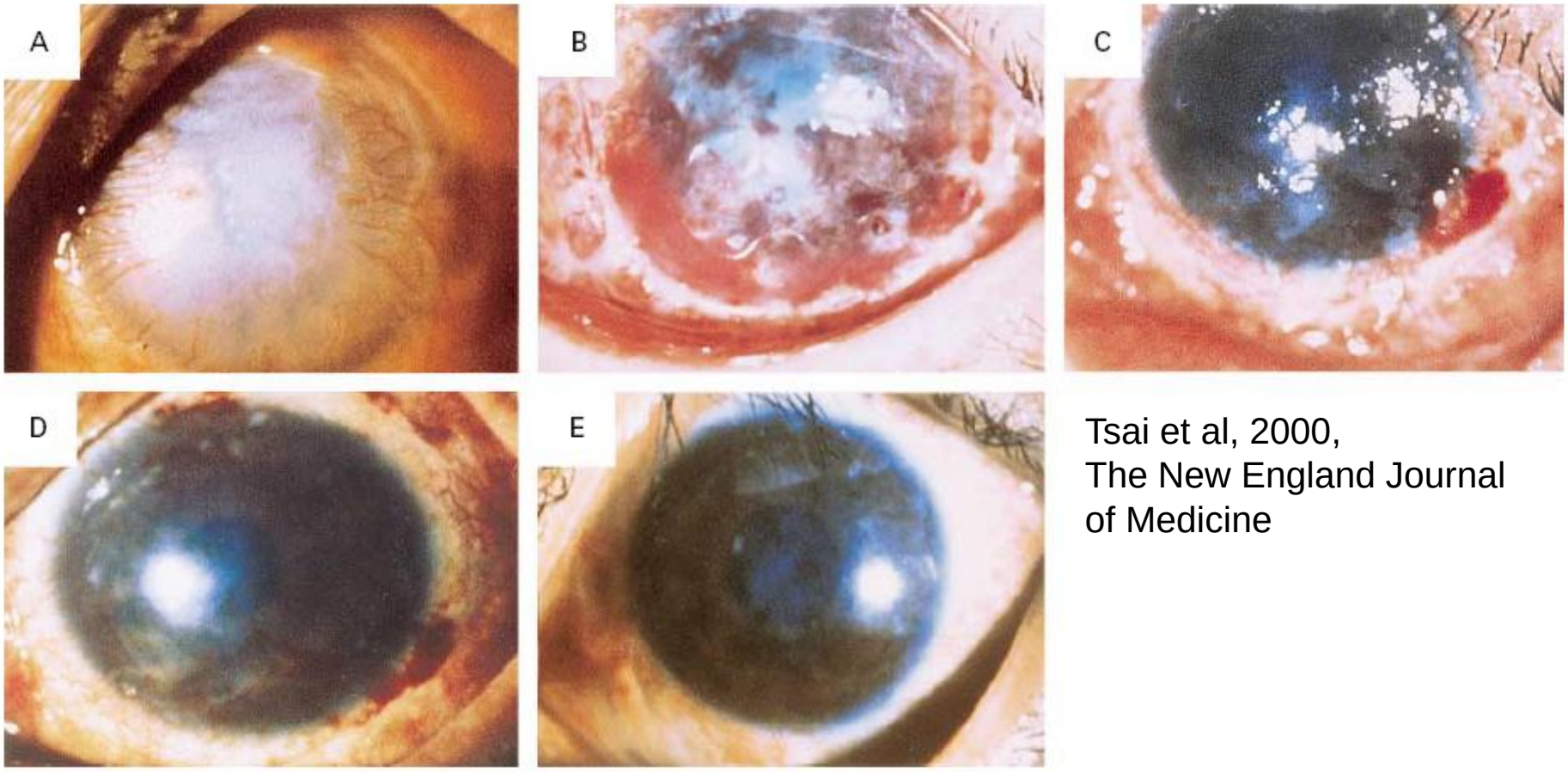
GAQ-2005

Corrosion damage

Preoperativt

Dag 1

Dag 7



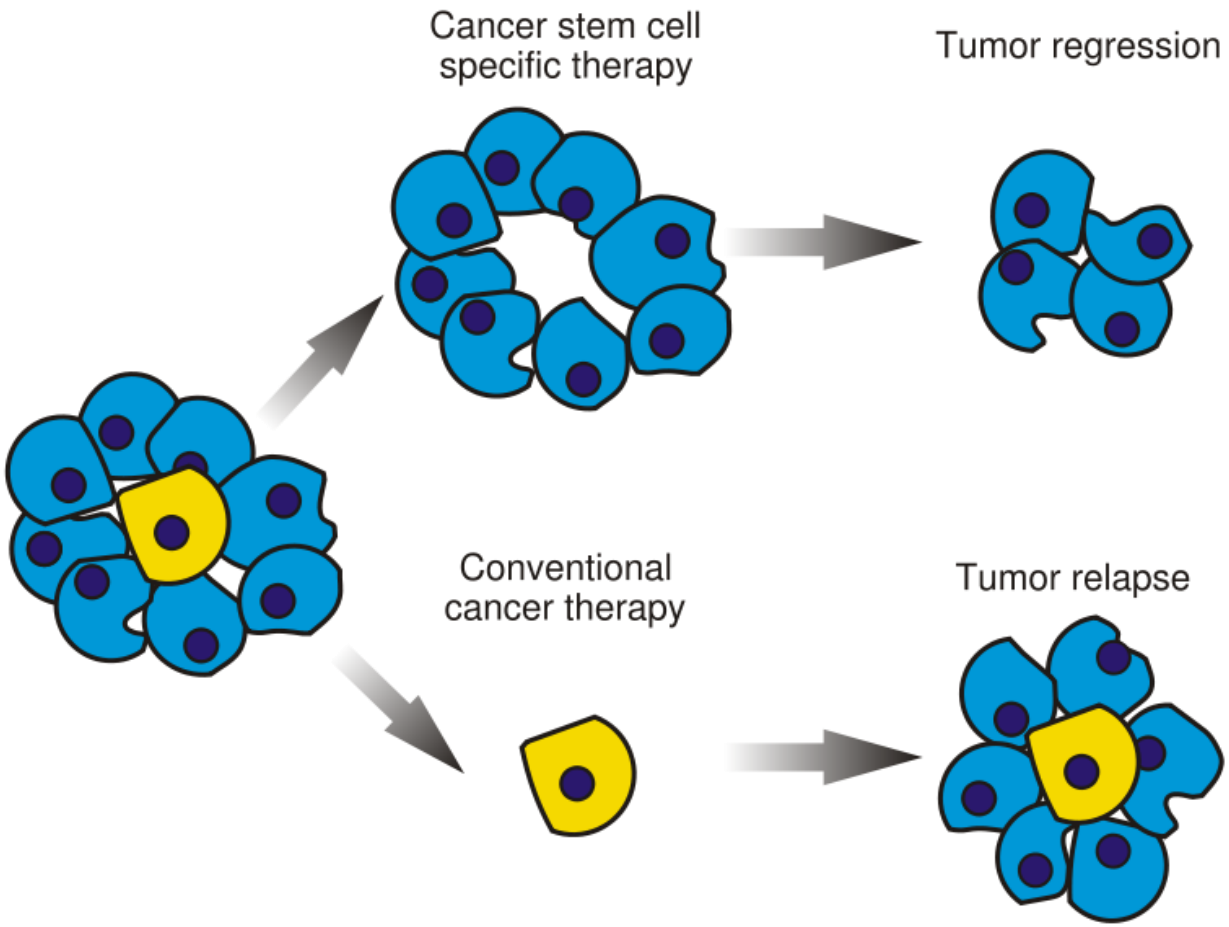
Tsai et al, 2000,
The New England Journal of Medicine

Dag 30

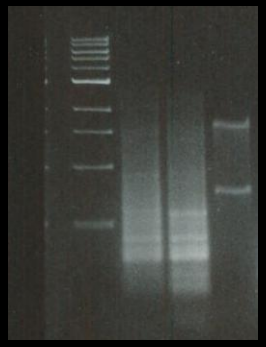
Dag 450

Morten C Moe, Department of Eye Diseases, Ullevål

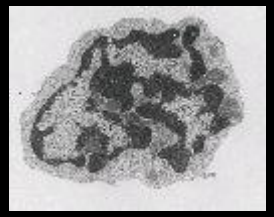
Tumor stem cells



Can expressed genes from glioblastoma stem cells be used in a therapeutic vaccination?



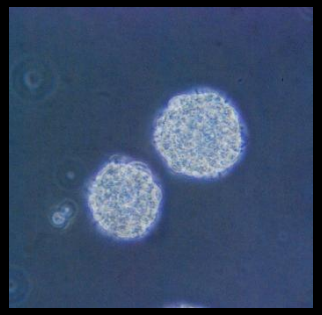
hTERT and survivin mRNA



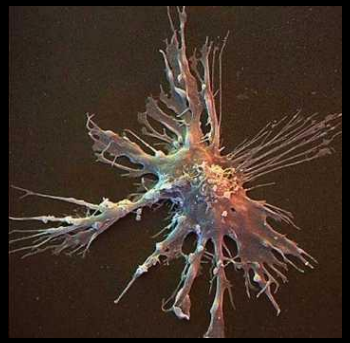
Immature DCs

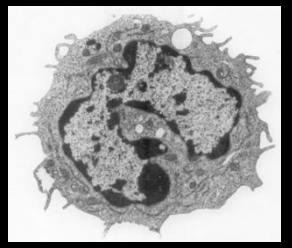
mRNA amplification
and purification

mRNA loading
by electroporation



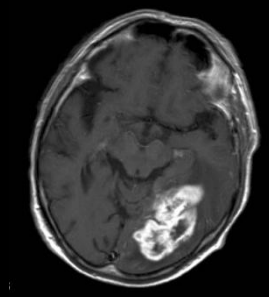
Tumor stem cells





Monocytes

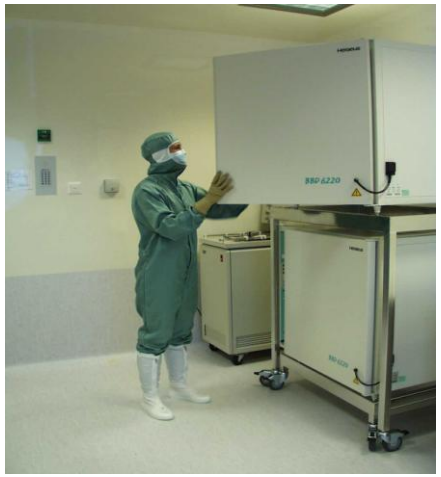
Maturation of DCs



Tumor biopsy

Leukapheresis

The Ex vivo cell laboratory is a GMP regulated production facility for cells for therapeutic trials



Pharmaceutical Net - [Sensor Status]

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27INK-1-B-TE-F	28INK-1-B-CO2-F	28INK-2-T-TE 0.0	29INK-2-T-CO2 0.0	349A401 Vacuum 0.0	PE27/04 52.4
27INK-1-B-TS 37.5	28INK-1-B-O2	28INK-2-T-TE-F	29INK-2-T-CO2-F	365A403 Vent.alarm 0.0	PE27/31 17.1
27INK-1-B-TS-F	28INK-1-B-O2-F	28INK-2-T-TS 0.0	29INK-2-T-O2	365A403 Vent.drift 0.0	PE28/04 19.8
27INK-1-T-AL-F 0.0	28INK-1-B-RF 91.9	28INK-2-T-TS-F	29INK-2-T-O2-F	365A403 Vent.svikt 0.0	PE28/31 -16.6
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International Society for Stem Cell Research

Patient Handbook on Stem Cell Therapies

Appendix I of the Guidelines for the Clinical Translation of Stem Cells

December 3, 2008

English

XCell-Center
at the Institute for Regenerative Medicine

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News

Home

The XCell-Center is a private clinic group and institute for regenerative medicine located in Düsseldorf and Cologne, Germany. Bringing together therapeutical use of autologous adult stem cells and medical research, it is our mission to:

- Provide therapeutic application of autologous adult stem cells to patients at the highest medical standard;
- Extend existing knowledge on the effects of autologous adult stem cells by supporting pre-clinical and clinical research.

We offer patients with degenerative diseases the opportunity to undergo an innovative and promising stem cell treatment.

Since the start in January 2007, **more than 2500 patients** have safely undergone our various stem cell treatments.

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Therapeutic use

The XCell-Center treats patients with their own autologous adult stem cells. It is the first private clinic worldwide to hold an official license for the extraction and approval of stem cell material for autologous treatment.

Therapy focuses on the treatment of cerebral palsy, spinal cord injuries, diabetes mellitus (types 1 and 2 as well as sequelae) and neurological diseases/disorders such as Parkinson's and stroke. Further indications include multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), and Alzheimer's as well as arthritis, heart disease, and eye diseases such as macular degeneration.

Advisory board

Learn more about the XCell-Center's Scientific Partners.

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Related topics

- Healing potential
- Methods of use
- Physiological mechanism
- Limits of therapy
- No Tumor risk
- Treatment process

Overview of our stem cell treatment

As a patient or the friend or relative of a patient, you have likely consulted this website to learn some basic facts about our stem cell treatment offerings. Therefore, we have carefully compiled relevant information on these pages that we hope will help you.

We would like to point out from the start that there are still some questions concerning the function of stem cells that science has not yet been able to answer, and that despite the advances that have been made recently, there is no guarantee for the success of stem cell therapy. Nevertheless, every week we see this new "medicine" helping a lot of people. Therefore, we offer therapies with adult stem cells *whenever classical treatment does not yield the type of results that are satisfactory for the patient.*

After evaluating important information from each prospective patient's medical history, our medical team decides whether the prospective patient is a suitable

News

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Methods of use - adult stem cells

The use of endogenous adult stem cells is ethical and legally straightforward. Under German law, the extracted stem cells are categorized as drugs. Because they are exclusively for personal use, they are individual drugs, and under German law do not require the same governmental approval as other drugs. Despite this, the clinic still has to obtain a manufacturing license from the surveillance authority. At the XCell-Center, it is guaranteed that the processes of extraction, cleaning and transplantation are all carried out in compliance with Good Manufacturing Practice (GMP) standards, thus guaranteeing maximum quality and safety for the patient.

For the last few years, attempts at therapy with adult stem cells from bone marrow have been carried out at university hospitals. This means that unlike animal testing with embryonic stem cells, adult stem cells are in-part, already being clinically tested. The well-documented success of the cardiologist Prof. Dr. Bodo Strauer from Düsseldorf can be seen as an example. He treated a patient suffering from a series of heart attacks for whom common therapies could not assure any chance of survival with the patient's own bone marrow stem cells. Nine days after the stem cells had been injected into the diseased area, the patient was able to leave the intensive care unit. Up to now, more than 300 patients have been treated in Düsseldorf using this procedure - most of them successfully.

The XCell-Center's treatment is based on the therapy experiences of more

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Stem cells carry a lot of promise for the development of new therapeutic options, but they should be introduced into the clinic with great caution