

# INTERNATIONAL ISLET TRANSPLANT REGISTRY



*New ITR-Forms developed*

## ***RECIPIENT FORM FOR CLINICAL ISLET TRANSPLANTS***

### — INSTITUTION DATA —

ITR Institution # <input type="text"/>	Transplant Center <input type="text"/>	Transplant Team <input type="text"/>
---	---	---

### — RECIPIENT DATA —

Case # <input type="text"/>	Local Code <input type="text"/>	First and Last Initial <input type="text"/> <input type="text"/>	Date of Birth <input type="text"/>	Sex <input type="radio"/> male <input type="radio"/> female	
Date of Tx <input type="text"/>	No. of Donors <input type="text"/>	Type of DM <input type="text"/>	Age of Diabetes Onset <input type="text"/>	Height (cm) <input type="text"/>	Weight (kg) <input type="text"/>
CMV <input type="radio"/> positive <input type="radio"/> negative	ABO <input type="radio"/> O <input type="radio"/> B <input type="radio"/> A <input type="radio"/> AB	HLA: <input type="text"/> A <input type="text"/> B			

### — TRANSPLANT DATA —

<input type="checkbox"/> Autograft	Donor Tissue	HLA of tx'd Kidney
<input type="checkbox"/> Allograft	<input type="checkbox"/> Adult	
<input type="checkbox"/> Xenograft	<input type="checkbox"/> Fetal	
Species: <input type="text"/>		
Site of Tx		
<input type="checkbox"/> Liver		
<input type="checkbox"/> Spleen		
<input type="checkbox"/> Kidney		

**considering  
valuable proposals  
made by Dr. David Scharp,  
Washington University, St. Louis,  
in cooperation with other leading  
North American Islet Transplant Centers**

**Recipient Form for Clinical Islet Transplants**

**Donor Form for Clinical Islet Transplants (Adult Tissue)**

**Donor Form for Clinical Islet Transplants (Fetal Tissue)**

**Follow-Up Form for Clinical Islet Transplants**

*Newsletter No. 4*

*Vol. 3 (No. 1, June)  
1993*

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**D**ear Islet Transplant Registry Participant,

we are pleased to present the Islet Transplant Registry Newsletter No. 4 on the occasion of the 4th International Congress on Pancreas and Islet Transplantation in Amsterdam, June 27-30, 1993. We would like to express our gratitude to the Chairman of this Congress, Dr. Reinout van Schilf-gaarde, for offering the possibility to hand over a personal copy to each congress participant. In addition, we would also like to thank you for your continuous support and efforts in providing us with data on your patients.

This Newsletter includes revised Registry Forms, results of an analysis on all adult islet allografts performed worldwide through Dec 31, 1992, with main emphasis on the period from 1990-92 as well as a brief description of fetal islet grafts reported to the Registry.

The significant progress of the last years culminating in prolonged insulin independence following islet allotransplantation in different recipient categories and at different institutions made us expecting a rapid development in the field of clinical islet transplantation. It is true that further centers reached insulin independence after islet transplantation but the expected breakthrough on a wide front failed to come. At present, only five patients are insulin independent after islet allotransplantation, three type 1 diabetic patients (two in Milan, one in Minneapolis) as well as two patients with pancreatectomy-induced diabetes mellitus (one patient in Pittsburgh and one patient in Milan). The number of transplantations per year decreased from 36 in 1990 to 26 in 1991 and 23 in 1992. In the first six months of 1993 only eight transplantations are known to be performed (four in Giessen, two in Milan, one in Minneapolis and another one in Los Angeles). Moreover, the results in islet transplantation could not be significantly improved since 1990. Another

step forward is of crucial importance for islet transplantation and for all institutions involved to keep clinical and scientific programs running.

Which future directions are promising enough to be taken? Frequently mentioned approaches are collagenase, pre-transplant islet immunomodulation and new immunosuppressive agents etc. However, it is only through a careful analysis of data that the impact of these or other approaches can be substantiated.

In this respect, the Islet Transplant Registry can contribute to advance the progress. As the number of transplanted cases per center is low, it is evident that trends or even conclusions can emerge much earlier when all results achieved worldwide are collected and then subjected to scientific analysis. The Registry can only fulfill this task if the forms will be completed more thoroughly and conscientious in the future. The accuracy of the Registry's results depends very much on the quality of data that you provide and can only be guaranteed by truthful reporting of successes and failures.

We have always realized that completing the previous Registry Forms was cumbersome and time consuming for you. Thus, these forms underwent major revisions in order to achieve more clearness by considering only the very essential items. In this respect, we very much appreciated the recommendations provided by Dr. David W. Scharp, Washington University, St. Louis and colleagues of other leading North American Islet Transplant Centers.

We are confident that completion of the Forms as well as data entry will now be simplified and accelerated. A substantial advantage of the new Forms is that print-outs of data once put into the data base can be generated directly onto these Forms. This guarantees a habitual format; proof-reading and updating of the data can be done much more efficient on a

single form. Disks with File Maker Pro 2.0 - files for direct data entry on a Macintosh computer are available on request.

Standardized and accepted criteria for the assessment of islet preparations and for patient monitoring post transplant are urgently required. A first step was the definition of islet equivalents and of the Sustacal stimulation index by Dr. David W. Scharp. In particular, assessment of viability and function of human islets pretransplant should be standardized. We have to face loss of islet graft function in about 30% of cases within the first month and it will therefore be important to determine whether these early graft failures are a result of grafting an insufficient number of viable islet equivalents. Many centers already use similar methods for islet assessment, however, a large number of unnecessary modifications exist preventing meaningful comparisons of results between different institutions.

During the Fourth International Congress on Pancreas and Islet Transplantation a Workshop chaired by Dr. Reinhard G. Bretzel, University of Giessen, and Dr. Camillo Ricordi, University of Pittsburgh, will try again to elaborate improvements in this crucial field. It is to be hoped that this Workshop will manage to define guidelines for islet graft assessment and patient monitoring and that every group performing clinical islet transplantation will adhere to these guidelines in the future, eventually in carefully designed multicenter trials.

Again, we thank for your cooperation and participation in the Islet Transplant Registry.

Giessen, June 1993

Bernhard J. Hering  
Christian C. Browatzki  
Andreas O. Schultz  
Barbara Watz  
Reinhard G. Bretzel  
Konrad Federlin

## ***Publisher***

Justus-Liebig-University of Giessen  
Department of Medicine

## ***Circulation***

The Islet Transplant Registry Newsletter is published regularly and distributed to all interested institutions. It is anticipated that the fifth newsletter will be issued towards the end of 1993.

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# International ISLET TRANSPLANT REGISTRY

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## RECIPIENT FORM FOR CLINICAL ISLET TRANSPLANTS

### — INSTITUTION DATA —

ITR Institution # <input type="text"/>	Transplant Center <input type="text"/>	Transplant Team <input type="text"/>
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### — RECIPIENT DATA —

Case # <input type="text"/>	Local Code <input type="text"/>	First and Last Initial <input type="text"/> <input type="text"/>	Date of Birth <input type="text"/>	Sex <input type="radio"/> male <input type="radio"/> female	
Date of Tx <input type="text"/>	No. of Donors <input type="text"/>	Type of DM <input type="text"/>	Age of Diabetes Onset <input type="text"/>	Height (cm) <input type="text"/>	Weight (kg) <input type="text"/>
CMV <input type="radio"/> positive <input type="radio"/> negative	ABO <input type="radio"/> 0 <input type="radio"/> B <input type="radio"/> A <input type="radio"/> AB	HLA: A <input type="text"/>	B <input type="text"/>	DR <input type="text"/>	DQ <input type="text"/>

### — TRANSPLANT DATA —

<input type="checkbox"/> Autograft <input type="checkbox"/> Allograft <input type="checkbox"/> Xenograft Species: <input type="text"/>	Donor Tissue <input type="checkbox"/> Adult <input type="checkbox"/> Fetal	HLA of tx'd Kidney: A <input type="text"/>	B <input type="text"/>	DR <input type="text"/>	DQ <input type="text"/>
Site of Tx <input type="checkbox"/> Liver <input type="checkbox"/> Spleen <input type="checkbox"/> Kidney Capsule <input type="checkbox"/> Epiploic Flap <input type="checkbox"/> Peritoneal Cavity <input type="checkbox"/> i.m. <input type="checkbox"/> s.c. <input type="checkbox"/> ___ <input type="checkbox"/> ___	Induction IS (all IS given peri tx) <input type="checkbox"/> None <input type="checkbox"/> Steroids <input type="checkbox"/> CsA <input type="checkbox"/> AZA <input type="checkbox"/> FK 506 <input type="checkbox"/> DSG <input type="checkbox"/> ALS/ALG/ATG <input type="checkbox"/> OK T3 <input type="checkbox"/>	Recipient Category <input type="checkbox"/> ITA <input type="checkbox"/> IAK <input type="checkbox"/> SIK <input type="checkbox"/> SIL <input type="checkbox"/> Others <input type="checkbox"/>	Dates of Previous Tx of Other Organs		
			Prev. Kidney 1st <input type="text"/> 2nd <input type="text"/> 3rd <input type="text"/>		
			Prev. Pancreas 1st <input type="text"/> 2nd <input type="text"/>		
			Prev. Islets 1st <input type="text"/> 2nd <input type="text"/>		

Comments for Recipient and Donor Data

Last Date of Completion

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## DONOR FORM FOR CLINICAL ISLET TRANSPLANTS (ADULT TISSUE)

### — INSTITUTION AND RECIPIENT IDENTIFICATION —

Institution #	Transplant Center	Case #	Local Code	Date of Tx

### — DONOR DATA —

Refer to Donor #						
Age (yrs)						
Sex	<input type="checkbox"/> male <input type="checkbox"/> female	<input type="checkbox"/> male <input type="checkbox"/> female	<input type="checkbox"/> male <input type="checkbox"/> female	<input type="checkbox"/> male <input type="checkbox"/> female	<input type="checkbox"/> male <input type="checkbox"/> female	<input type="checkbox"/> male <input type="checkbox"/> female
ABO	<input type="checkbox"/> 0 <input type="checkbox"/> B <input type="checkbox"/> A <input type="checkbox"/> AB	<input type="checkbox"/> 0 <input type="checkbox"/> B <input type="checkbox"/> A <input type="checkbox"/> AB	<input type="checkbox"/> 0 <input type="checkbox"/> B <input type="checkbox"/> A <input type="checkbox"/> AB	<input type="checkbox"/> 0 <input type="checkbox"/> B <input type="checkbox"/> A <input type="checkbox"/> AB	<input type="checkbox"/> 0 <input type="checkbox"/> B <input type="checkbox"/> A <input type="checkbox"/> AB	<input type="checkbox"/> 0 <input type="checkbox"/> B <input type="checkbox"/> A <input type="checkbox"/> AB
HLA: A						
B						
DR						
DQ						
Crossmatch	<input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg.	<input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg.	<input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg.	<input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg.	<input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg.	<input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg.
CMV	<input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg.	<input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg.	<input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg.	<input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg.	<input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg.	<input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg.

### — Pancreas Procurement and Preservation —

Cold Perfusion	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Cold Perfusion- / Storage-Solution						
Intraduct. Collag.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Pre Cold Storage Distension Solution						
Cold Ischemia (min)						

### — Islet Graft Preparation —

Pretreatment	<input type="checkbox"/> Fresh <input type="checkbox"/> Culture <input type="checkbox"/> Cryopres.	<input type="checkbox"/> Fresh <input type="checkbox"/> Culture <input type="checkbox"/> Cryopres.	<input type="checkbox"/> Fresh <input type="checkbox"/> Culture <input type="checkbox"/> Cryopres.	<input type="checkbox"/> Fresh <input type="checkbox"/> Culture <input type="checkbox"/> Cryopres.	<input type="checkbox"/> Fresh <input type="checkbox"/> Culture <input type="checkbox"/> Cryopres.	<input type="checkbox"/> Fresh <input type="checkbox"/> Culture <input type="checkbox"/> Cryopres.
If Cultured: Days						
Temp (°C)						
O <sub>2</sub> (%)						
Islet Number						
Islet Equivalents, IEQ						
Islet Purity (%)						
Time of IEQ Count	<input type="checkbox"/> pre cult/cryc <input type="checkbox"/> pre tx	<input type="checkbox"/> pre cult/cryc <input type="checkbox"/> pre tx	<input type="checkbox"/> pre cult/cryc <input type="checkbox"/> pre tx	<input type="checkbox"/> pre cult/cryc <input type="checkbox"/> pre tx	<input type="checkbox"/> pre cult/cryc <input type="checkbox"/> pre tx	<input type="checkbox"/> pre cult/cryc <input type="checkbox"/> pre tx

### — Pre Transplant Islet Viability Tests —

Test Methods						
Test Results						

# International ISLET TRANSPLANT REGISTRY

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## DONOR FORM FOR CLINICAL ISLET TRANSPLANTS (FETAL TISSUE)

### — INSTITUTION AND RECIPIENT IDENTIFICATION —

Institution #	Transplant Center	Case #	Local Code	Date of Tx
<input style="width: 90%;" type="text"/>	<input style="width: 90%;" type="text"/>	<input style="width: 90%;" type="text"/>	<input style="width: 90%;" type="text"/>	<input style="width: 90%;" type="text"/>

### — DONOR DATA —

Refer to Donor #	<input style="width: 90%;" type="text"/>
Gestational Age (wks)	<input style="width: 90%;" type="text"/>
Sex	<input type="checkbox"/> male <input type="checkbox"/> female <input type="checkbox"/> male <input type="checkbox"/> female <input type="checkbox"/> male <input type="checkbox"/> female <input type="checkbox"/> male <input type="checkbox"/> female <input type="checkbox"/> male <input type="checkbox"/> female <input type="checkbox"/> male <input type="checkbox"/> female
ABO	<input type="checkbox"/> 0 <input type="checkbox"/> B <input type="checkbox"/> A <input type="checkbox"/> AB <input type="checkbox"/> 0 <input type="checkbox"/> B <input type="checkbox"/> A <input type="checkbox"/> AB <input type="checkbox"/> 0 <input type="checkbox"/> B <input type="checkbox"/> A <input type="checkbox"/> AB <input type="checkbox"/> 0 <input type="checkbox"/> B <input type="checkbox"/> A <input type="checkbox"/> AB <input type="checkbox"/> 0 <input type="checkbox"/> B <input type="checkbox"/> A <input type="checkbox"/> AB <input type="checkbox"/> 0 <input type="checkbox"/> B <input type="checkbox"/> A <input type="checkbox"/> AB
HLA: A	<input style="width: 90%;" type="text"/>
B	<input style="width: 90%;" type="text"/>
DR	<input style="width: 90%;" type="text"/>
DQ	<input style="width: 90%;" type="text"/>
Crossmatch	<input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg. <input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg. <input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg. <input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg. <input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg. <input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg.
CMV	<input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg. <input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg. <input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg. <input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg. <input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg. <input type="checkbox"/> pos. <input type="checkbox"/> ND <input type="checkbox"/> neg.

### — Pancreas Procurement and Preservation —

Method of Abortion	<input type="checkbox"/> Hysterotomy <input type="checkbox"/> Curettage <input type="checkbox"/> PG E2 <input type="checkbox"/> Water Bag <input type="checkbox"/> Hysterotomy <input type="checkbox"/> Curettage <input type="checkbox"/> PG E2 <input type="checkbox"/> Water Bag <input type="checkbox"/> Hysterotomy <input type="checkbox"/> Curettage <input type="checkbox"/> PG E2 <input type="checkbox"/> Water Bag <input type="checkbox"/> Hysterotomy <input type="checkbox"/> Curettage <input type="checkbox"/> PG E2 <input type="checkbox"/> Water Bag <input type="checkbox"/> Hysterotomy <input type="checkbox"/> Curettage <input type="checkbox"/> PG E2 <input type="checkbox"/> Water Bag <input type="checkbox"/> Hysterotomy <input type="checkbox"/> Curettage <input type="checkbox"/> PG E2 <input type="checkbox"/> Water Bag
Warm Ischemia (min)	<input style="width: 90%;" type="text"/>
Cold Ischemia (min)	<input style="width: 90%;" type="text"/>
Storage Solution	<input style="width: 90%;" type="text"/>

### — Islet Graft Preparation —

Pretreatment	<input type="checkbox"/> Fresh <input type="checkbox"/> Culture <input type="checkbox"/> Cryopres. <input type="checkbox"/> Fresh <input type="checkbox"/> Culture <input type="checkbox"/> Cryopres. <input type="checkbox"/> Fresh <input type="checkbox"/> Culture <input type="checkbox"/> Cryopres. <input type="checkbox"/> Fresh <input type="checkbox"/> Culture <input type="checkbox"/> Cryopres. <input type="checkbox"/> Fresh <input type="checkbox"/> Culture <input type="checkbox"/> Cryopres. <input type="checkbox"/> Fresh <input type="checkbox"/> Culture <input type="checkbox"/> Cryopres.	<input style="width: 90%;" type="text"/>
If Cultured: Days	<input style="width: 90%;" type="text"/>	
Temp (°C)	<input style="width: 90%;" type="text"/>	
O <sub>2</sub> (%)	<input style="width: 90%;" type="text"/>	
Graft Volume	<input style="width: 90%;" type="text"/>	<input style="width: 90%;" type="text"/>
Volume Determination	<input type="checkbox"/> pre cult/cryo <input type="checkbox"/> pre tx <input type="checkbox"/> pre cult/cryo <input type="checkbox"/> pre tx <input type="checkbox"/> pre cult/cryo <input type="checkbox"/> pre tx <input type="checkbox"/> pre cult/cryo <input type="checkbox"/> pre tx <input type="checkbox"/> pre cult/cryo <input type="checkbox"/> pre tx <input type="checkbox"/> pre cult/cryo <input type="checkbox"/> pre tx	

### — Pre Transplant Islet Viability Tests —

Test Methods	<input style="width: 90%;" type="text"/>
Test Results	<input style="width: 90%;" type="text"/>

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## FOLLOW-UP FORM FOR CLINICAL ISLET TRANSPLANTS

### — INSTITUTION AND RECIPIENT IDENTIFICATION —

Institution #	Transplant Center	Case #	Local Code	Date of Tx
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

### — PATIENT STATUS —

Patient Status	Date	If not alive, give cause of death (related to islet tx?)
<input type="checkbox"/> Alive <input type="checkbox"/> Dead	<input type="text"/>	<input type="text"/>

### — GRAFT FUNCTION AND IMMUNOSUPPRESSION —

	Insulin U/day	basal (fasting)		stimulated		Sustacal Stimulation Index	HbA1c %	Crea mg/dL μmol/L	Prednisone mg/day
		C-Peptide ng/mL pmol/mL	Glucose mg/dL mmol/L	C-Peptide ng/mL pmol/mL	Glucose mg/dL mmol/L				
PreTx	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
1 wk	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
1 mo	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3 mo	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
6 mo	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
1 yr	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2 yrs	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3 yrs	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4 yrs	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
5 yrs	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Please make sure that C-Peptide and Glucose Levels are corresponding,  
i.e. taken from the same sample or at least drawn at the same time !!

Off Insulin	<input type="text"/>	Maintenance	<input type="checkbox"/> None
Resumed Insulin	<input type="text"/>	Immunosuppression	<input type="checkbox"/> Steroids
Islets Failed	<input type="text"/>		<input type="checkbox"/> CsA
Cause of Graft Failure	<input type="checkbox"/> Primary Nonfunction	<input type="checkbox"/> Death of Patient	<input type="checkbox"/> AZA
	<input type="checkbox"/> Rejection	<input type="checkbox"/> Unknown	<input type="checkbox"/> FK 506
	<input type="checkbox"/> Insuff. Islet Mass	<input type="checkbox"/> _____	<input type="checkbox"/>

### — REJECTION EPISODES —

	Date	Anti-Rejection Therapy	Organ Funct. after Rej. Epi.
Islets: none until	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Failed
1st	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Failed
2nd	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Failed
Kidney: none until	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Failed
1st	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Failed
2nd	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Failed
3rd	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Failed

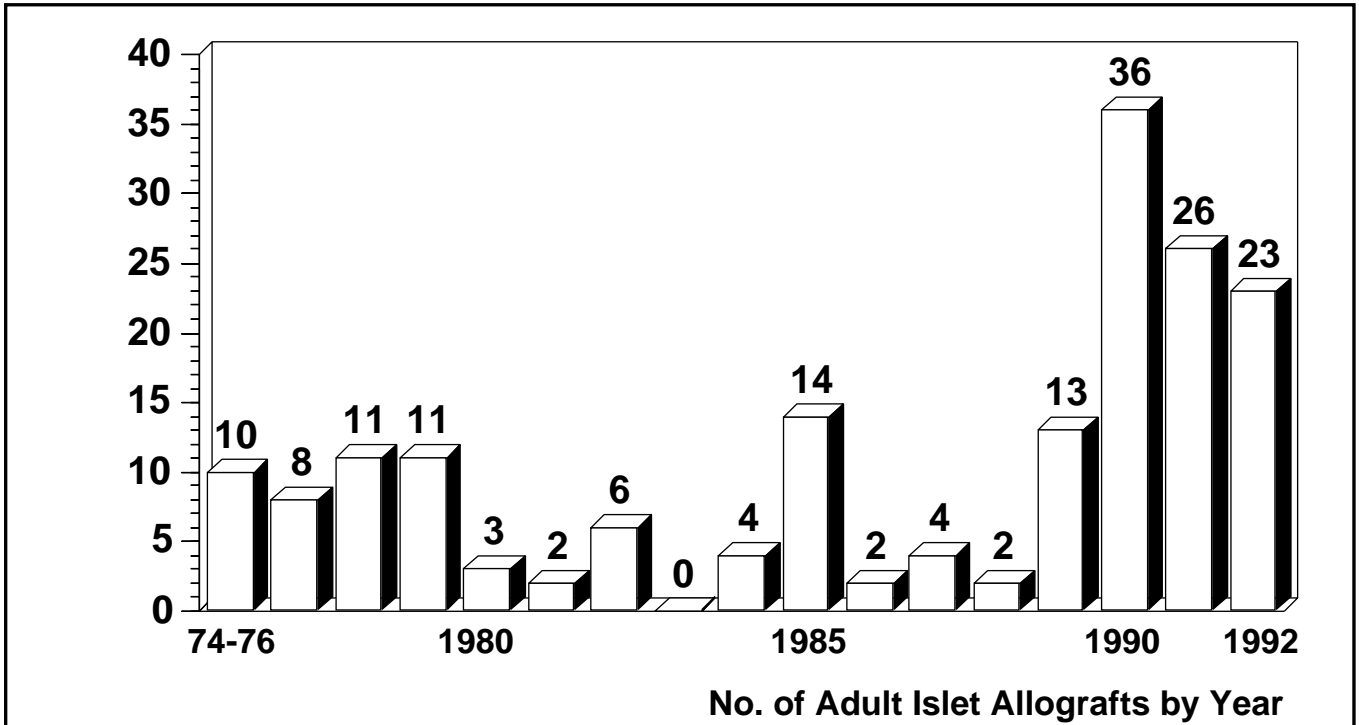
### — COMMENTS / COMPLICATIONS —

<input type="text"/>	Last Date of Completion
<input type="text"/>	<input type="text"/>

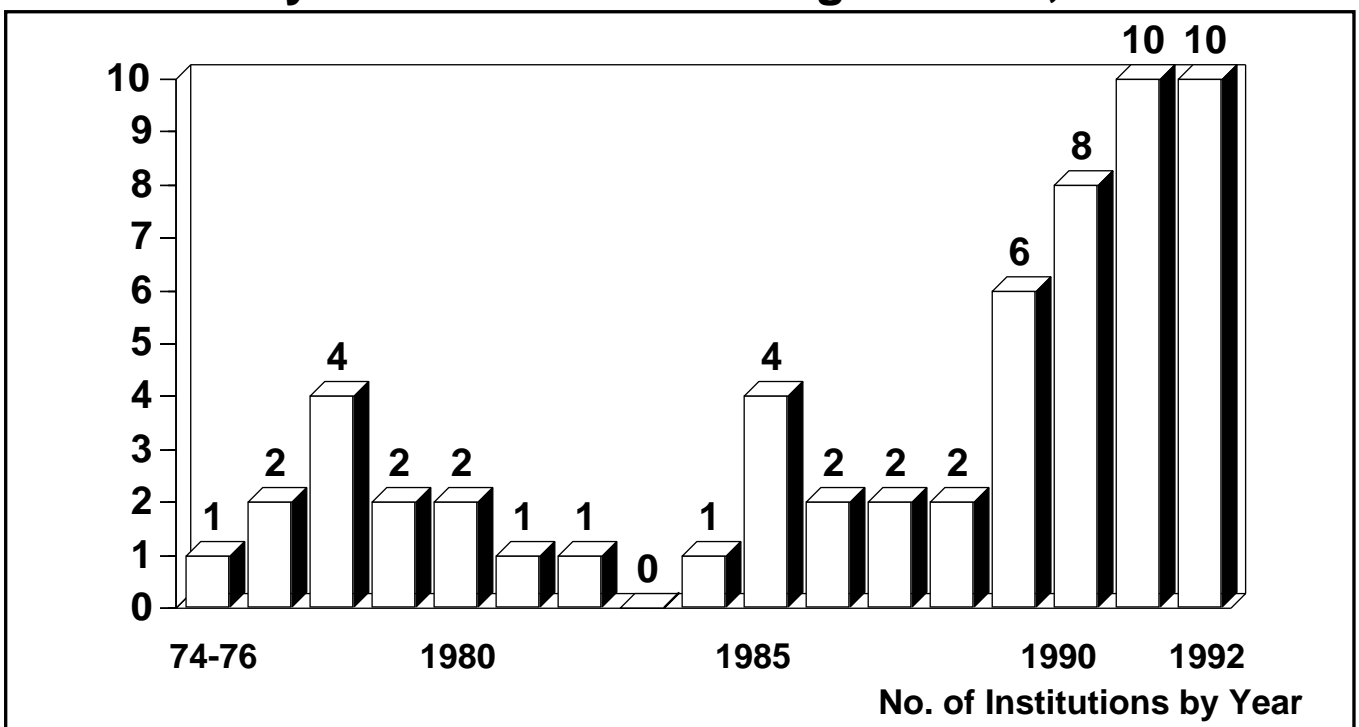
**Summary of Adult Islet Allografts (and one Xenograft\*)  
according to Institution and Year  
through Dec 31, 1992**

<b>INSTITUTION</b>	<b>YEAR OF TX</b>	<b>NO. OF CASES</b>
• Bristol*	1893	1
• Newcastle-upon-Tyne	1916	2
• Padova	1927	2
• New York	1935	1
• Leiden	1944	1
• Petah Tikva	1968	1
• Minneapolis	1974-1992	33
• Zurich	1977-1988	8
• Genova	1978-1979	13
• Hannover	1978	2
• Detroit	1980-1985	7
• Giessen	1980-1992	2
• East-Berlin	1982-1987	8
• St. Louis	1985-1992	24
• Miami	1985-1992	12
• Paris	1988-1991	7
• Perugia	1989-1991	5
• West-Berlin	1989	1
• Edmonton	1989-1992	5
• Milan	1989-1992	11
• Pittsburgh	1990-1992	27
• Leicester	1991-1992	3
• Oxford	1991-1992	2
• Charlestown	1991	2
• Los Angeles	1992	3
<b>TOTAL NO. OF CASES:</b>		<b>183</b>
<b>TOTAL NO. OF INSTITUTIONS:</b>		<b>25</b>

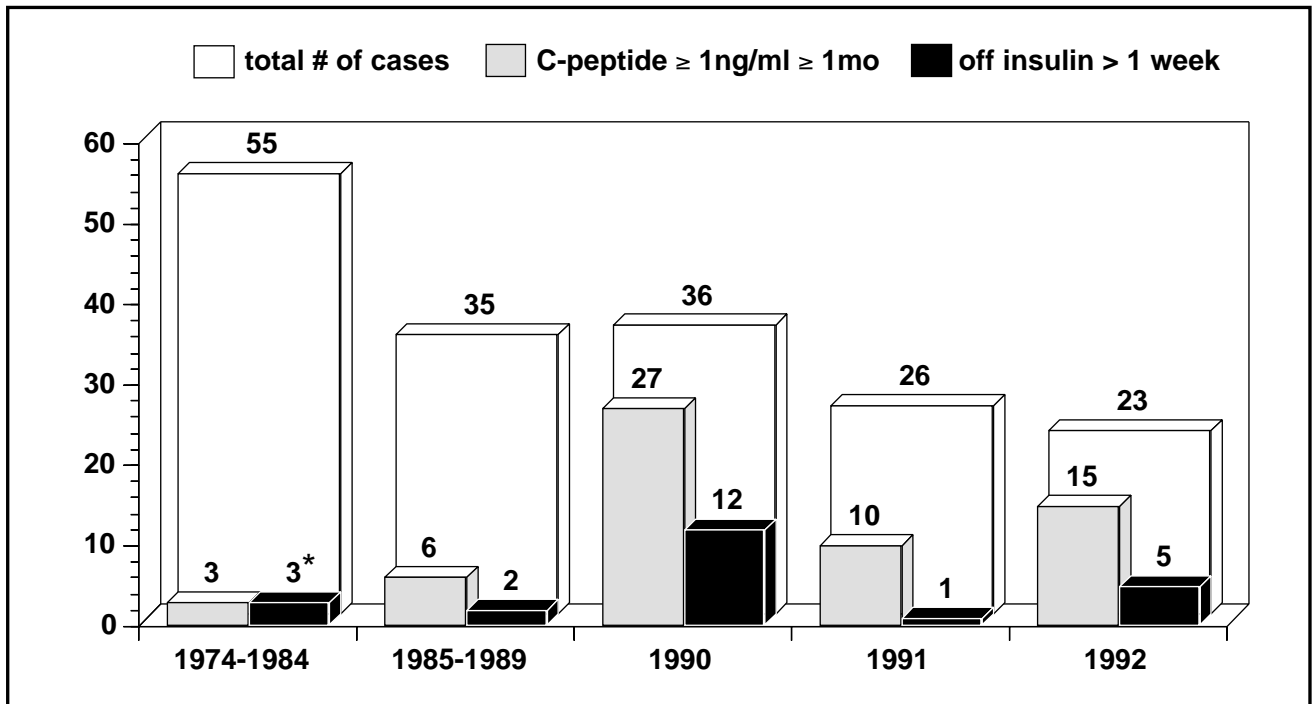
## No. of Adult Islet Allografts by Year from 1974 through Dec 31, 1992



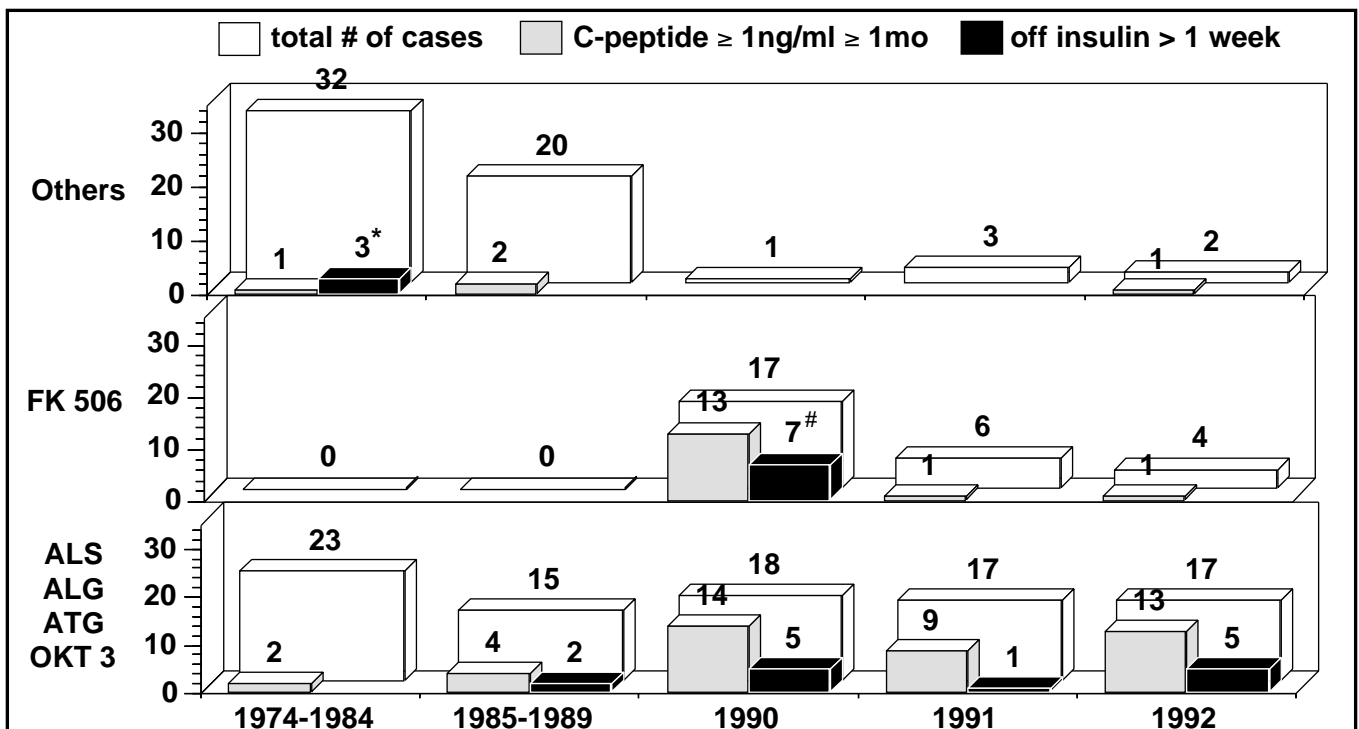
## No. of Institutions reporting Adult Islet Allografts by Year from 1974 through Dec 31, 1992



**Insulin Independence and Basal C-Peptide  
after Adult Islet Allotransplantation through Dec 31, 1992 by  
*Era***



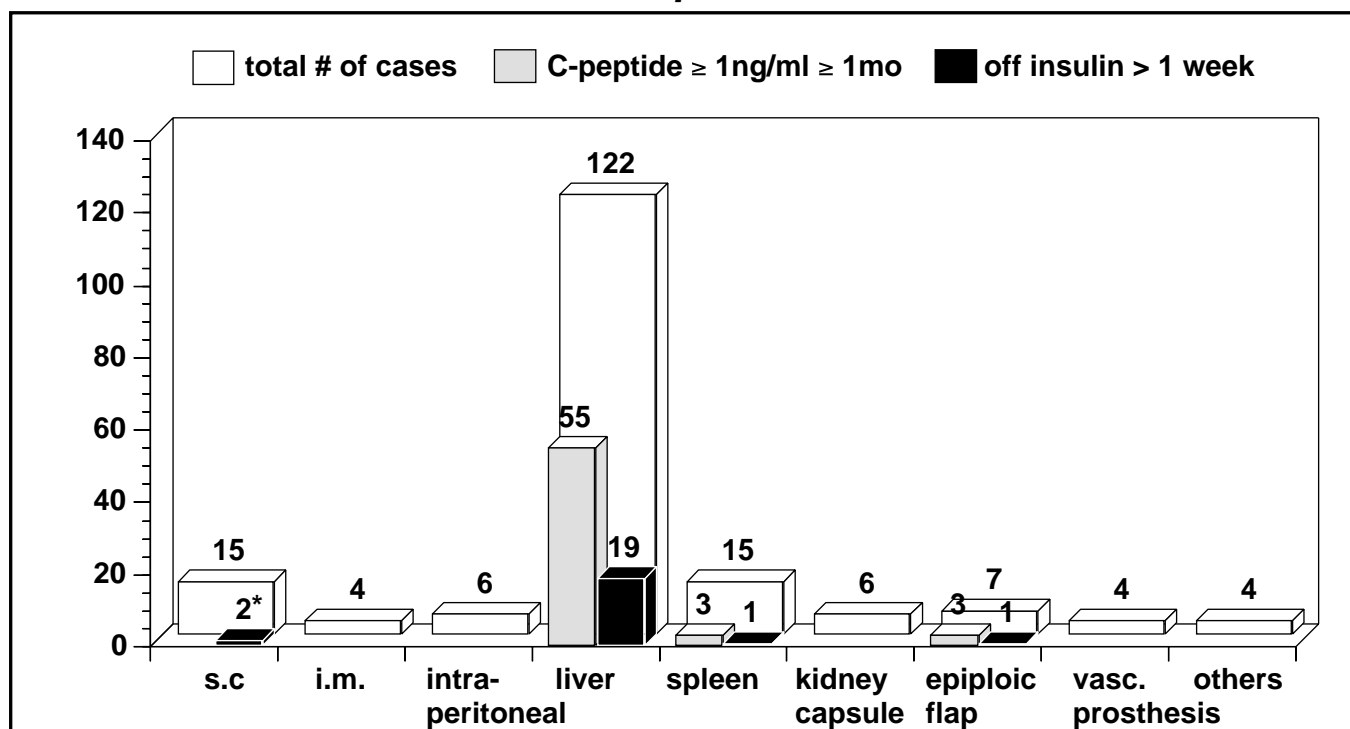
**and according to  
*Induction Immunosuppression***



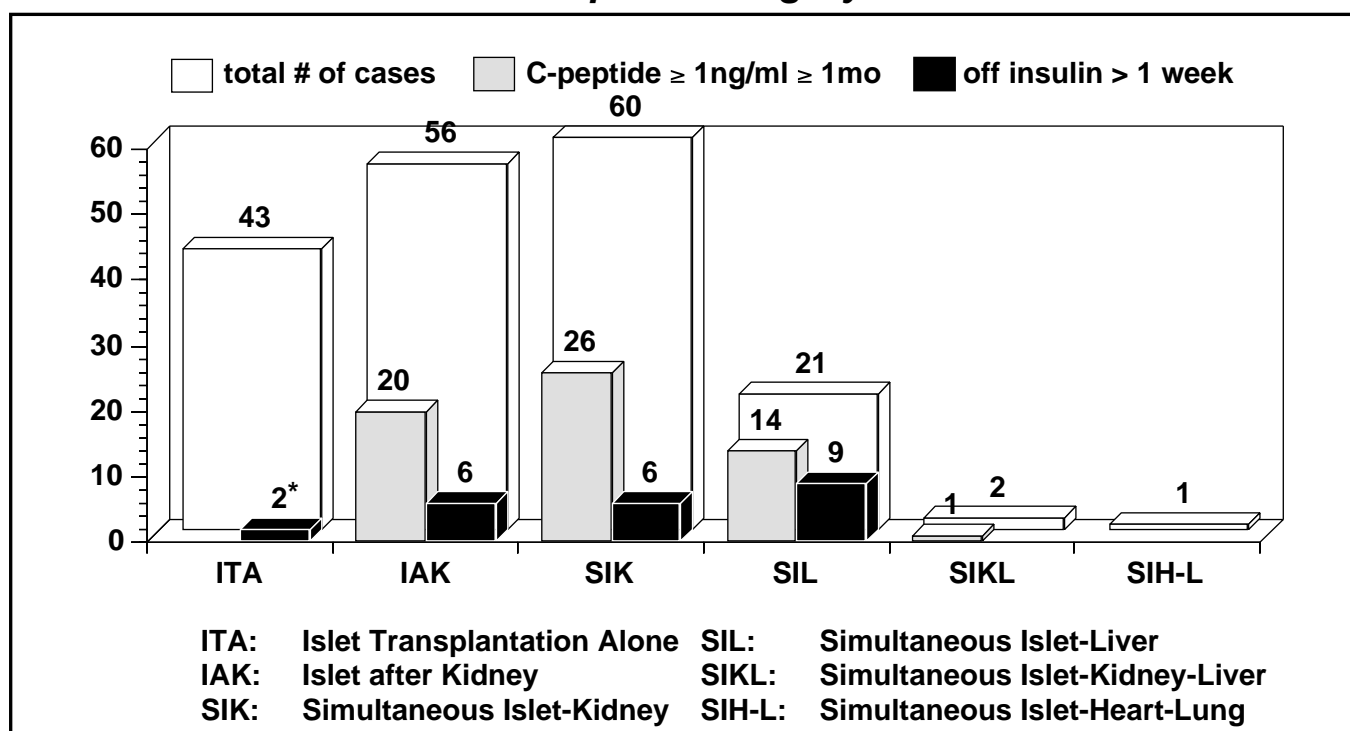
\* for further information please see page 20 (upper table)

# cluster transplants only, more data on page 20 (lower table)

### Insulin Independence and Basal C-Peptide after Adult Islet Allografts (and one Xenograft) through Dec 31, 1992 by *Site of Implantation*



### Insulin Independence and C-Peptide after Adult Islet Allografts (and one Xenograft) through Dec 31, 1992 according to *Recipient Category*



\* for further information please see upper table on page 20

## The 1990-92 Period

In the 1990-92 period a total number of 85 adult allotransplants were reported to the Islet Transplant Registry worldwide. For the analysis three patients had to be excluded since provided data were far from being complete. Another six patients had to be excluded due to clearly positive pre-transplant basal C-peptide levels ( $> 0.4$  ng/ml). The pretransplant basal C-peptide levels of the remaining patients were 0,  $< 0.1$ ,  $< 0.2$  and  $< 0.4$  ng/ml in 19, 34, 13 and 10 cases, respectively. Thus 76 patients were taken into the analysis and the results are depicted in bar charts on pages 13-19.

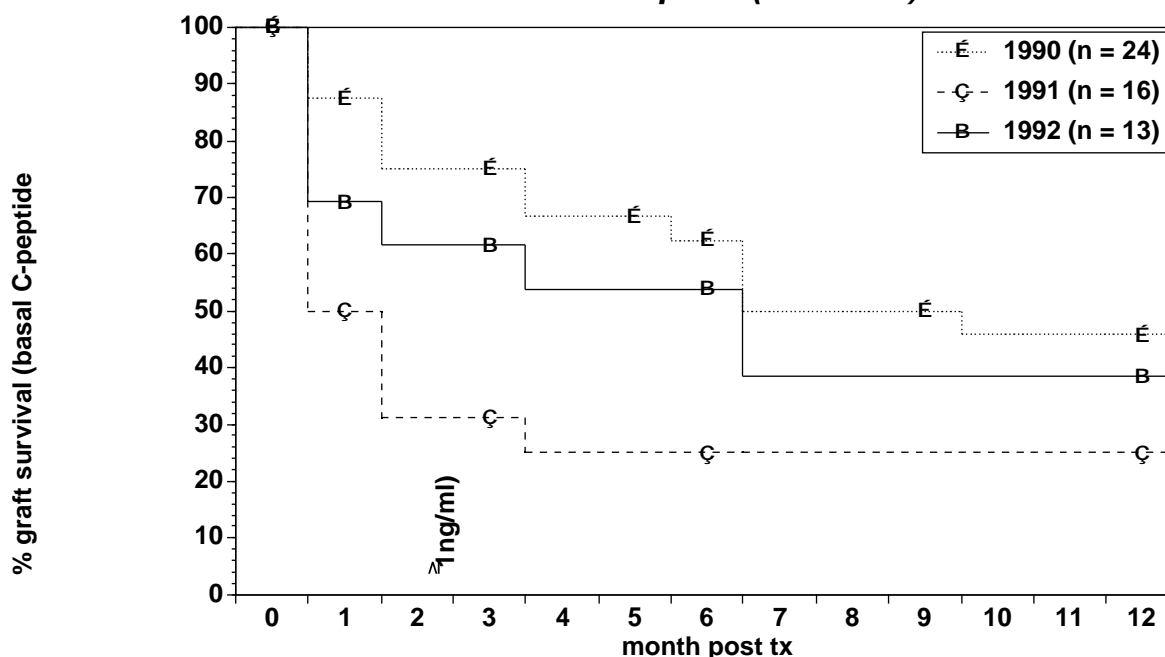
In addition, adult islet allograft survival as assessed by basal C-peptide  $> 1$  ng/ml over the first year posttransplant in regard to year of transplantation, number of donors etc. are illustrated on pages 12-19.

Fifty-three patients have been included in these survival charts, all of whom had complete 1-year follow-up data (for this reason, patients transplanted in the second half of 1992 were not considered).

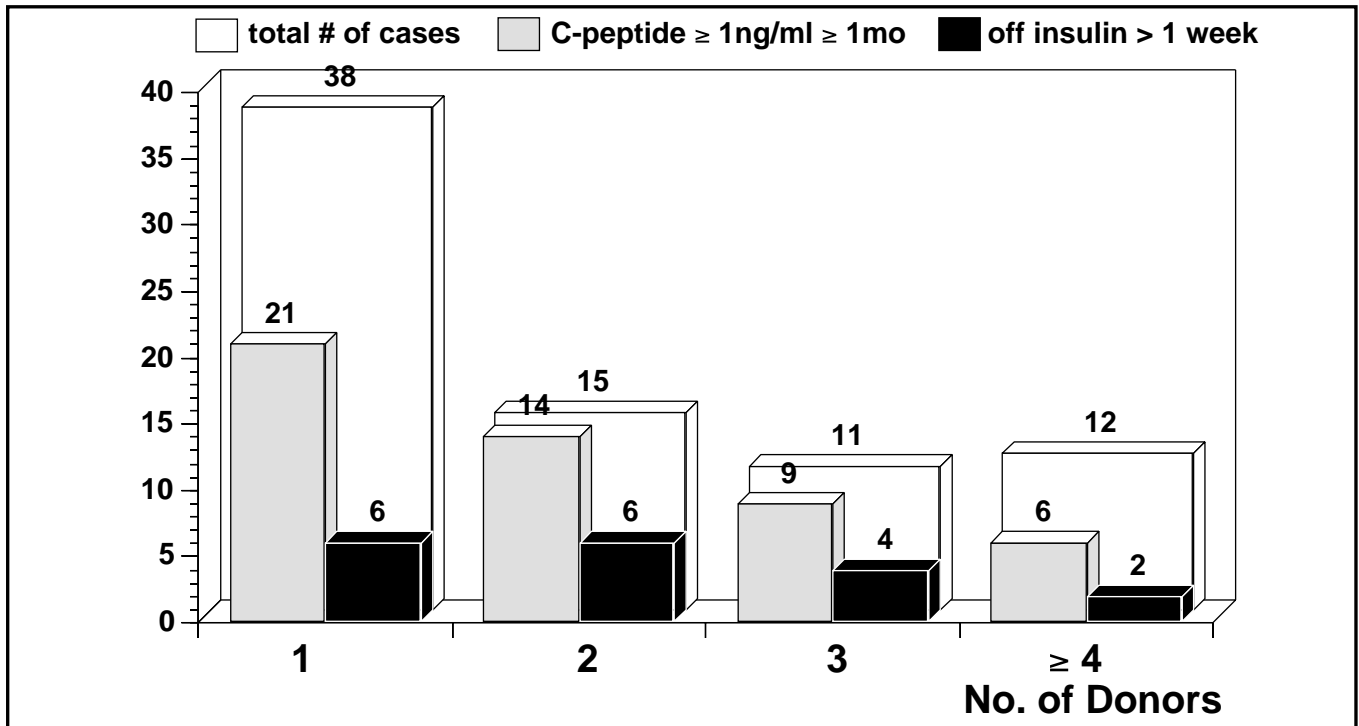
**No. of Adult Islet Allografts according to Institution and Year**

	1990	1991	1992	$\Sigma$
• Charlestown	-	2	-	2
• Edmonton	2	-	1	3
• Giessen	-	-	1	1
• Leicester	-	2	1	3
• Los Angeles	-	-	3	3
• Miami	4	2	1	7
• Milan	4	3	3	10
• Minneapolis	1	4	5	10
• Oxford	-	1	1	2
• Paris	3	1	-	4
• Perugia	1	1	-	2
• Pittsburgh	17	6	4	27
• St. Louis	4	4	3	11
$\Sigma$	36	26	23	85

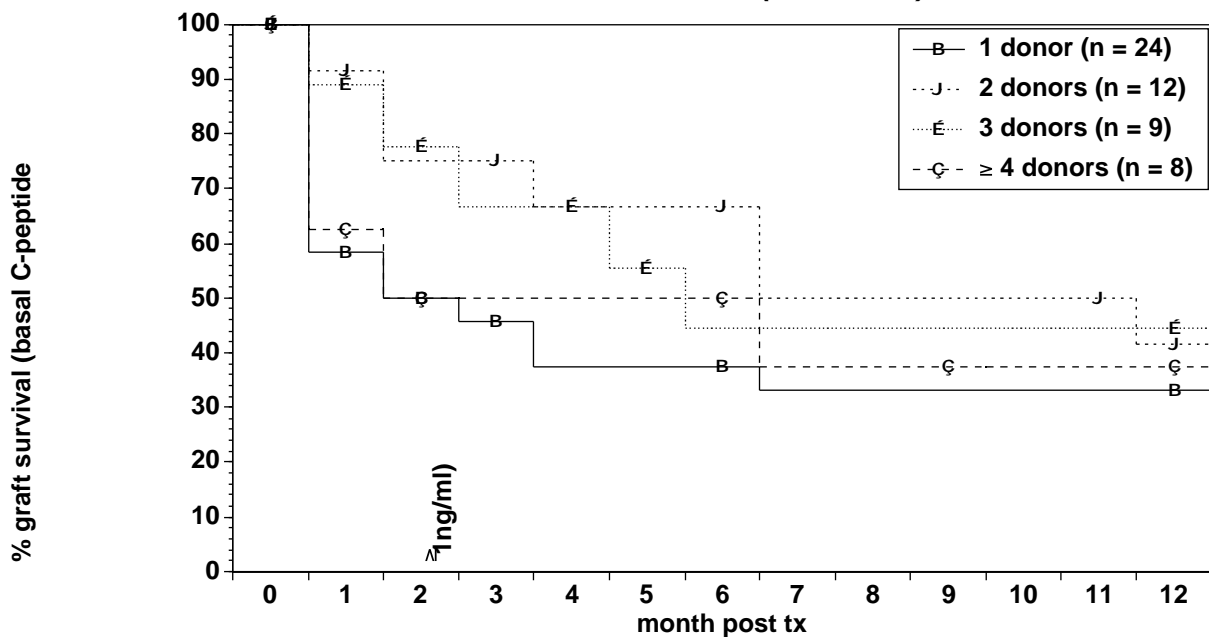
**One-Year Islet Allograft Survival by Year of Transplant (1990 - 92)**



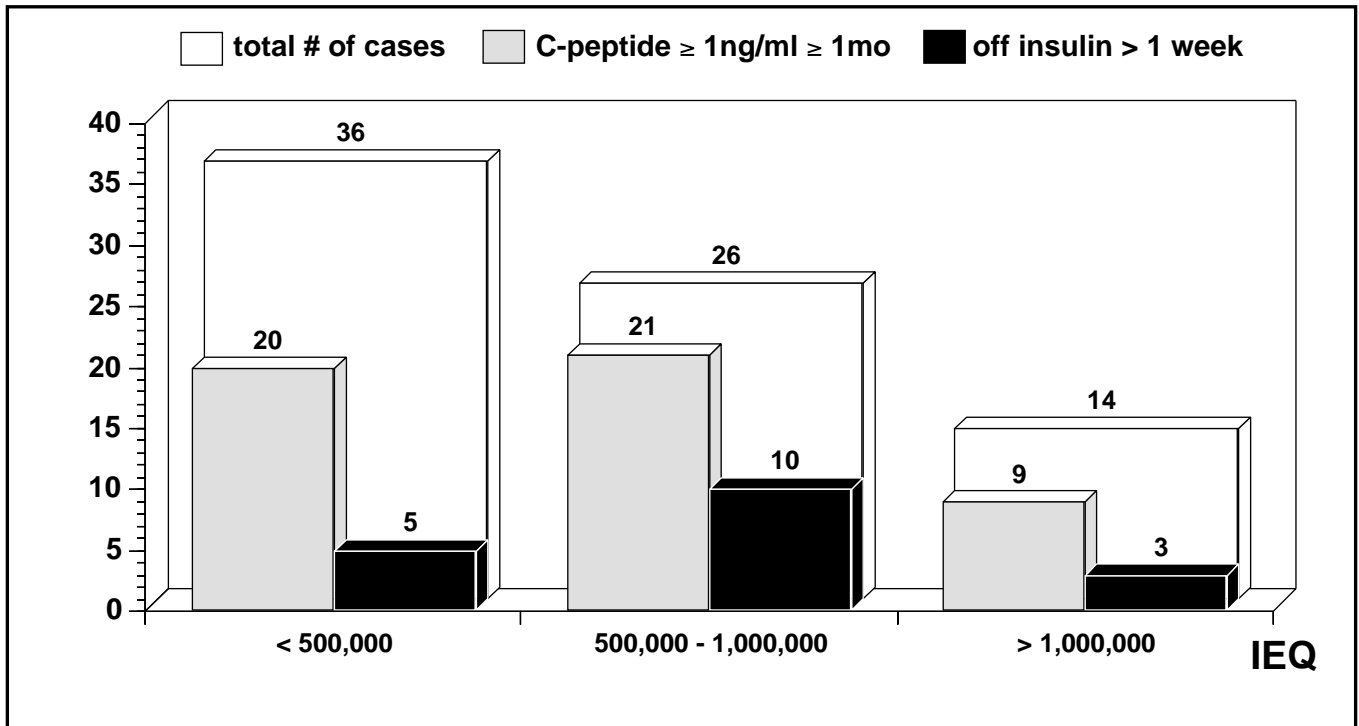
## Insulin Independence and Basal C-Peptide according to *No. of Donors (1990 - 92)*



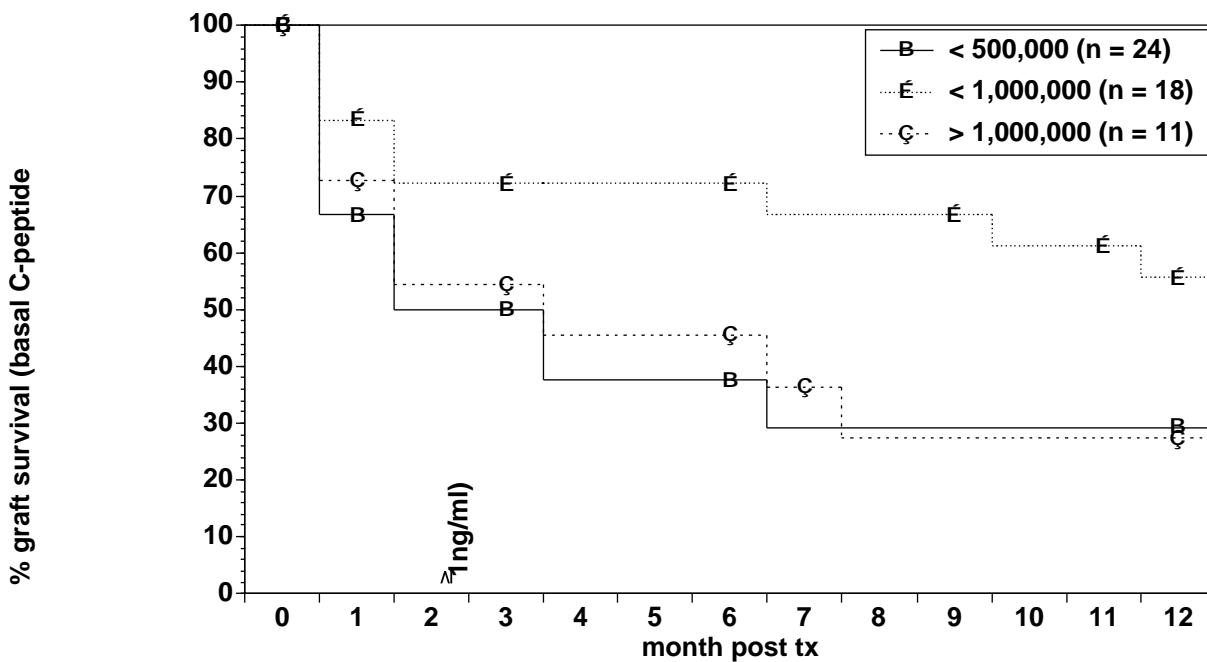
## One-Year Islet Allograft Survival according to *No. of Donors (1990 - 92)*



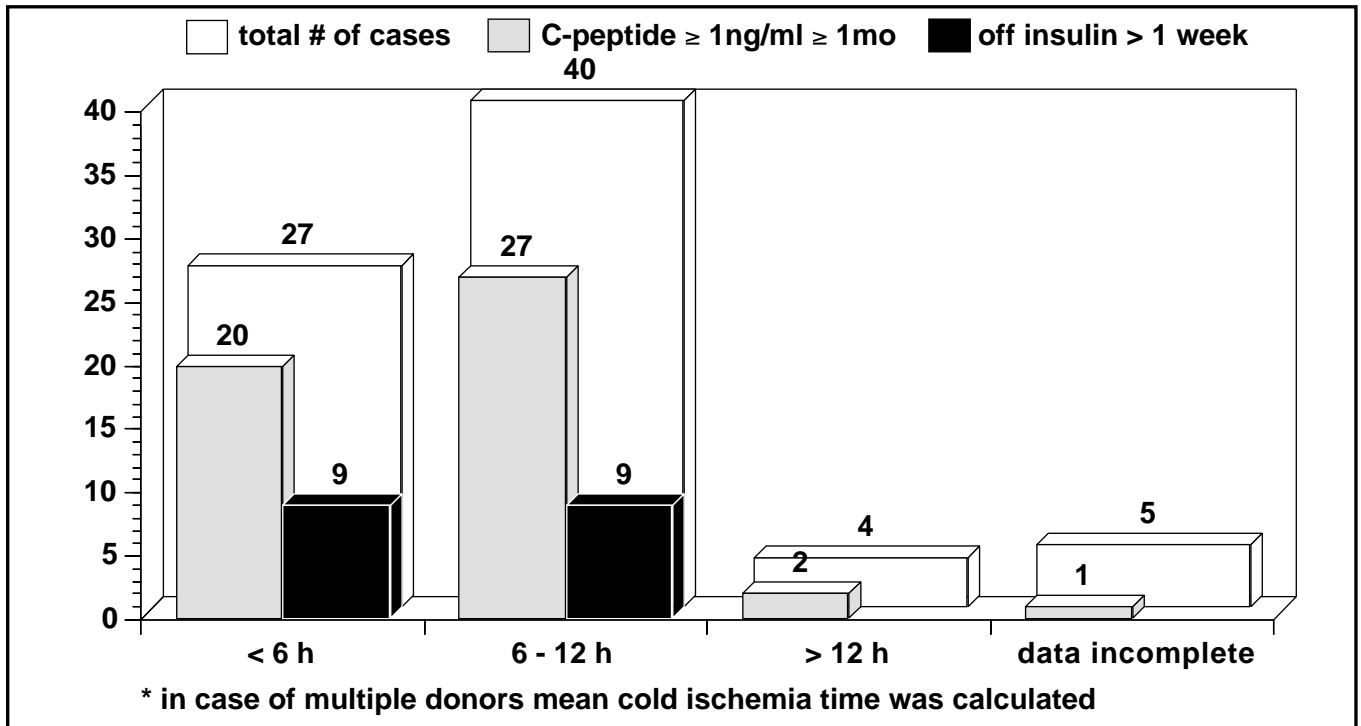
## Insulin Independence and Basal C-Peptide according to Equivalent Number of Islets (IEQ) (1990 - 92)



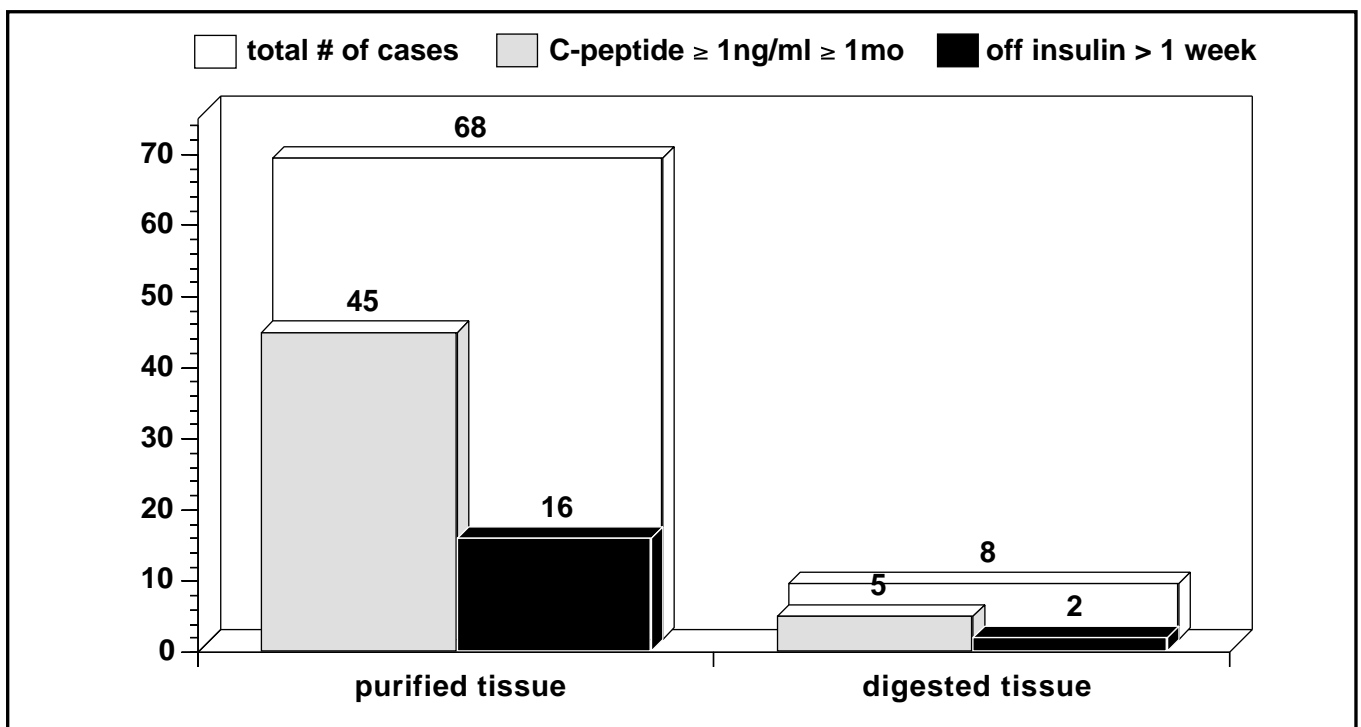
## One-Year Islet Allograft Survival according to Equivalent Number of Islets (1990 - 92)



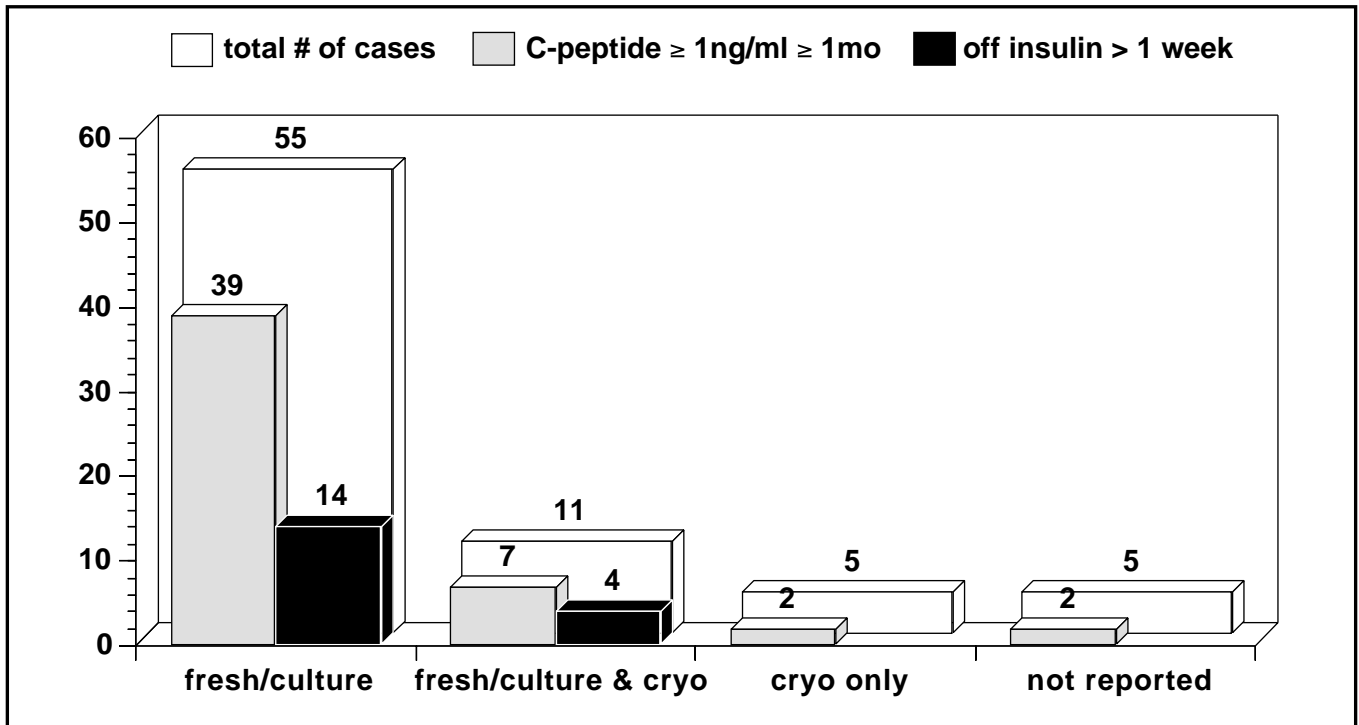
### Insulin Independence and Basal C-Peptide according to *Cold Ischemia Time* \* (1990 - 92)



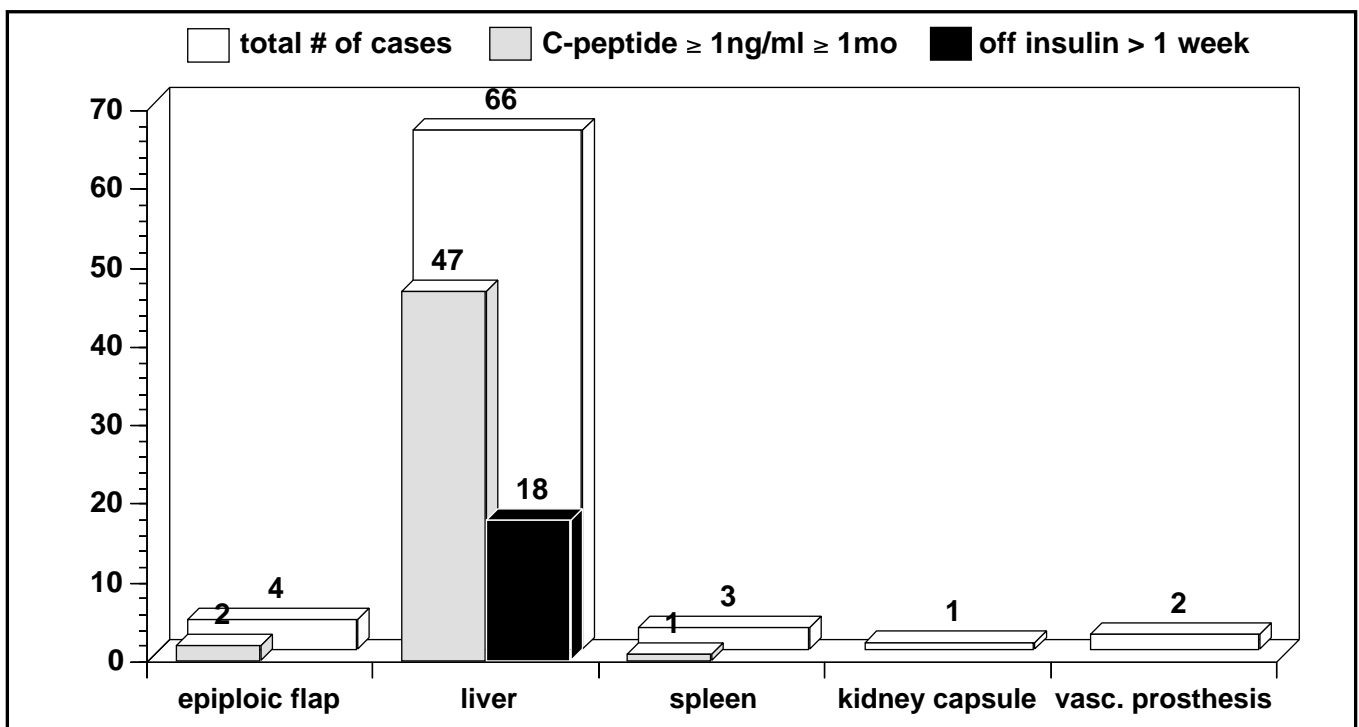
### Insulin Independence and Basal C-Peptide according to *Purity of Islet Tissue* (1990 - 92)



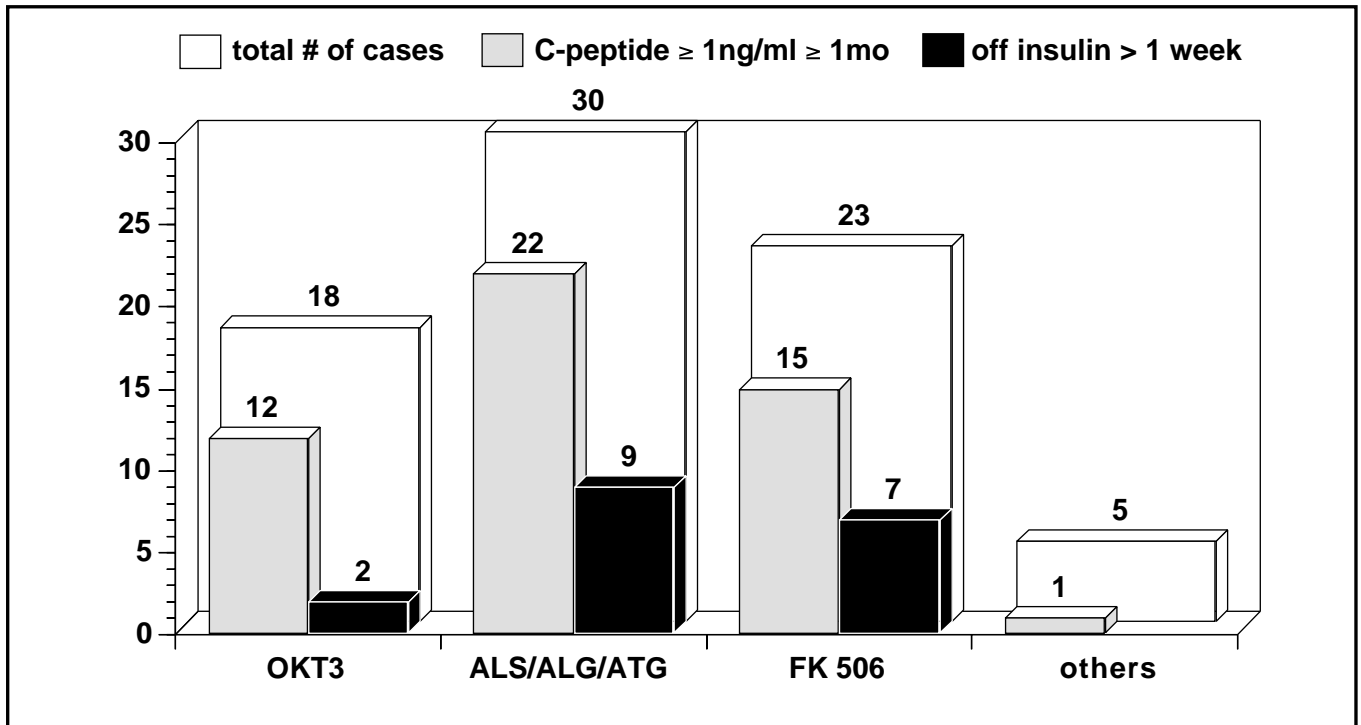
### Insulin Independence and Basal C-Peptide according to Preservation of Islet Tissue (1990 - 92)



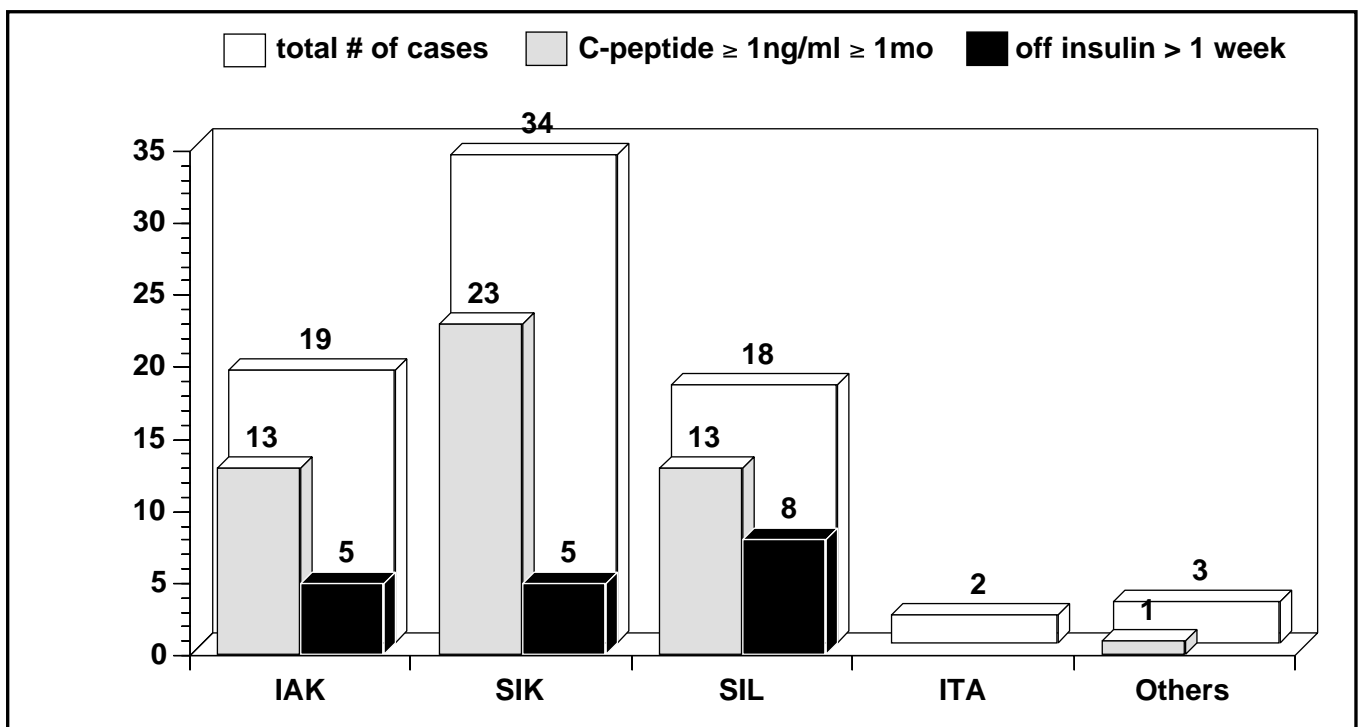
### Insulin Independence and Basal C-Peptide according to Site of Tx (1990 - 92)



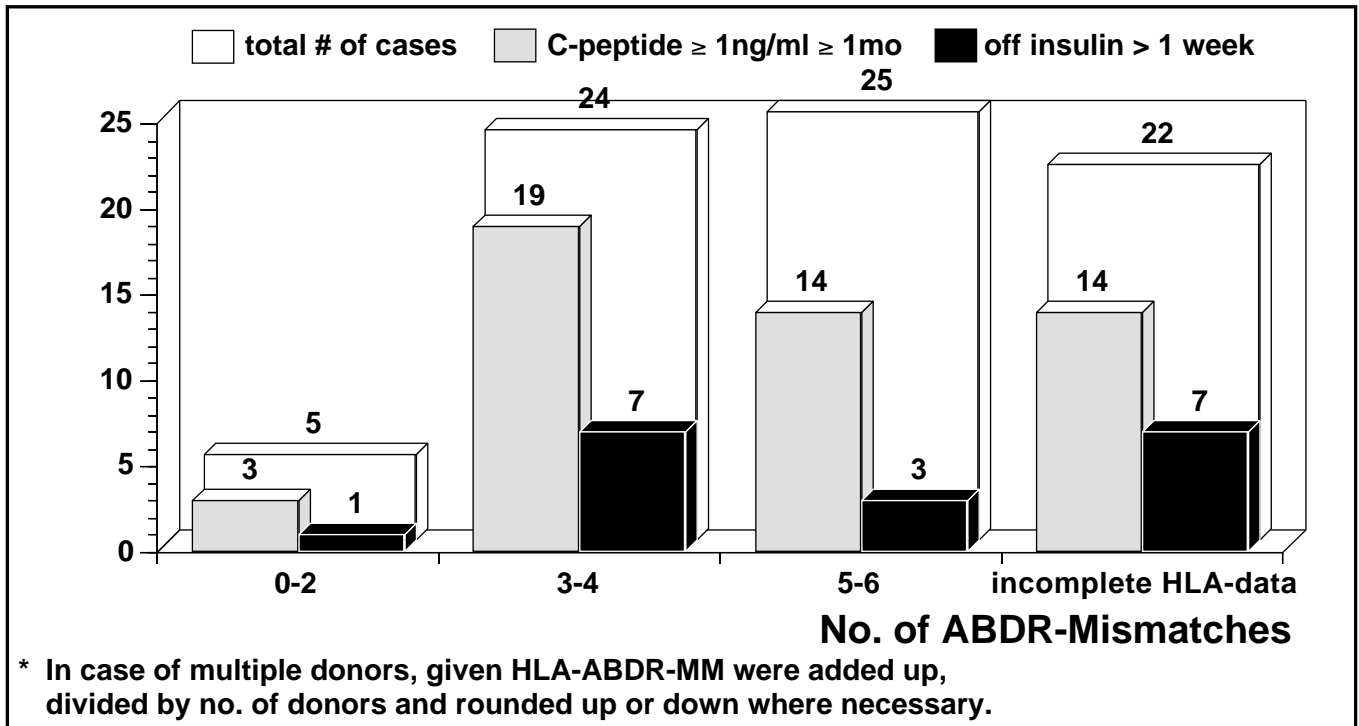
### Insulin Independence and Basal C-Peptide according to *Induction Immunosuppression (1990 - 92)*



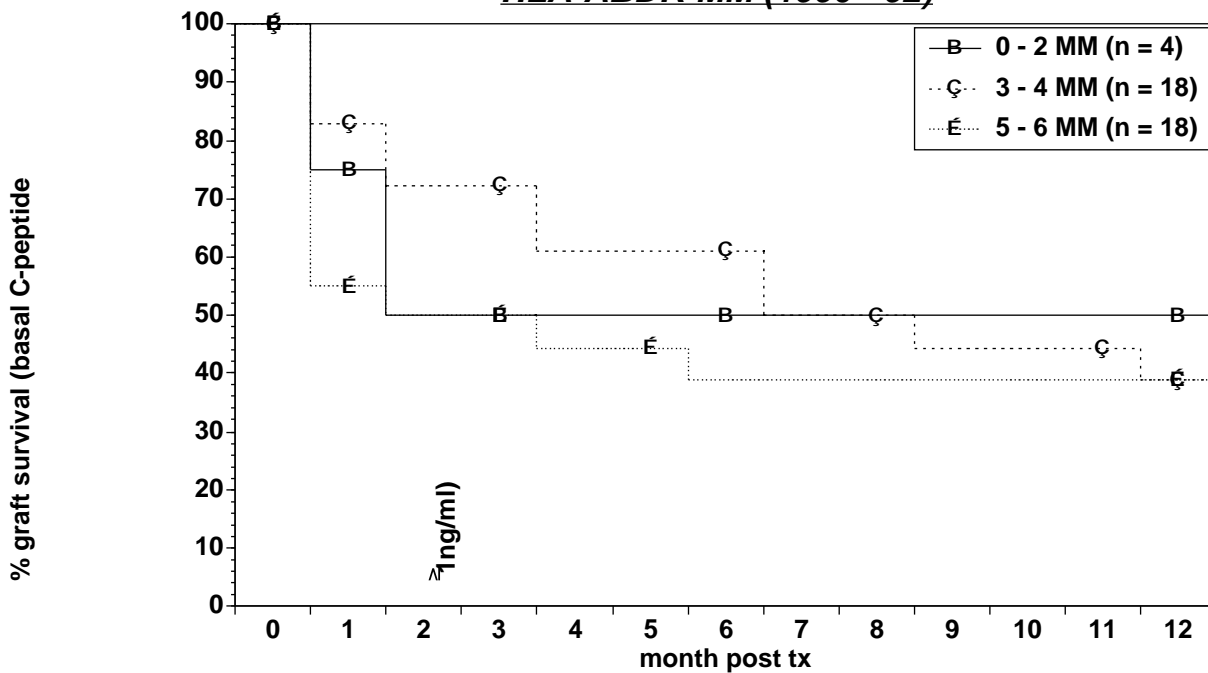
### Insulin Independence and Basal C-Peptide according to *Recipient Category (1990 - 92)*



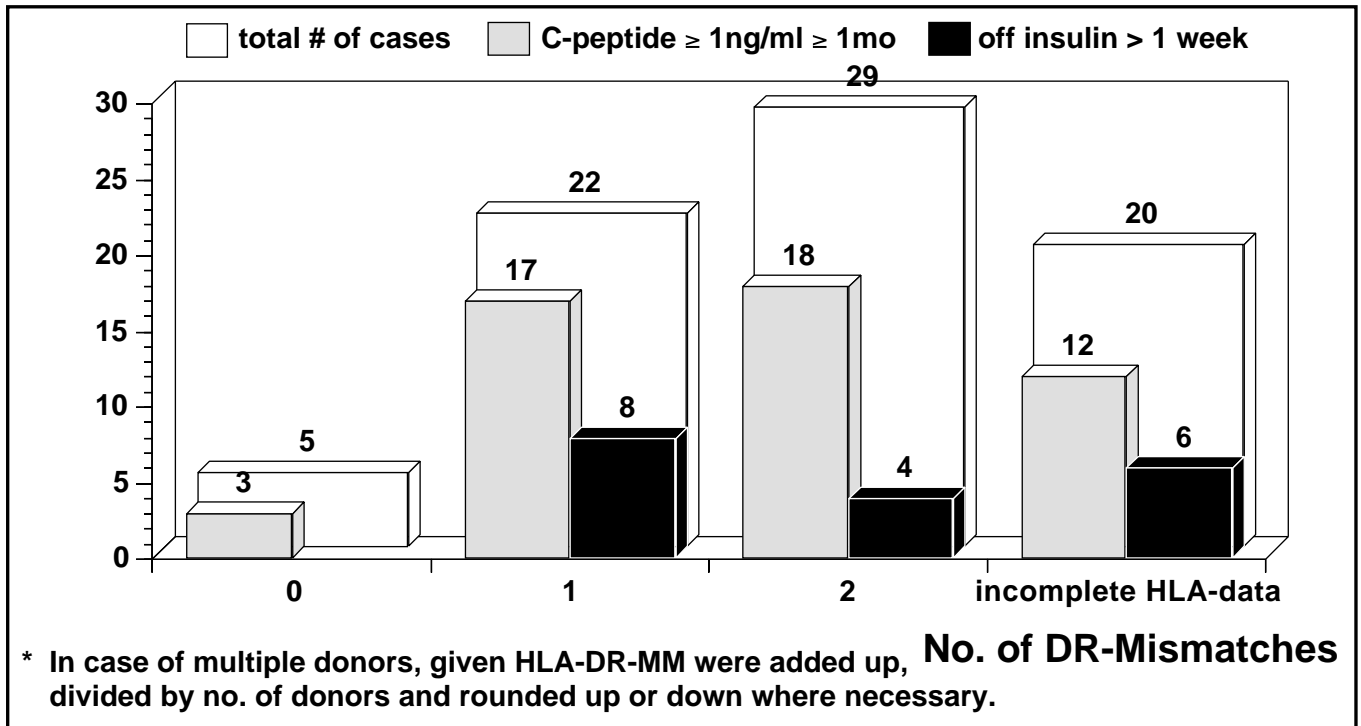
## Insulin Independence and Basal C-Peptide according to *HLA-ABDR-Mismatches \* (1990 - 92)*



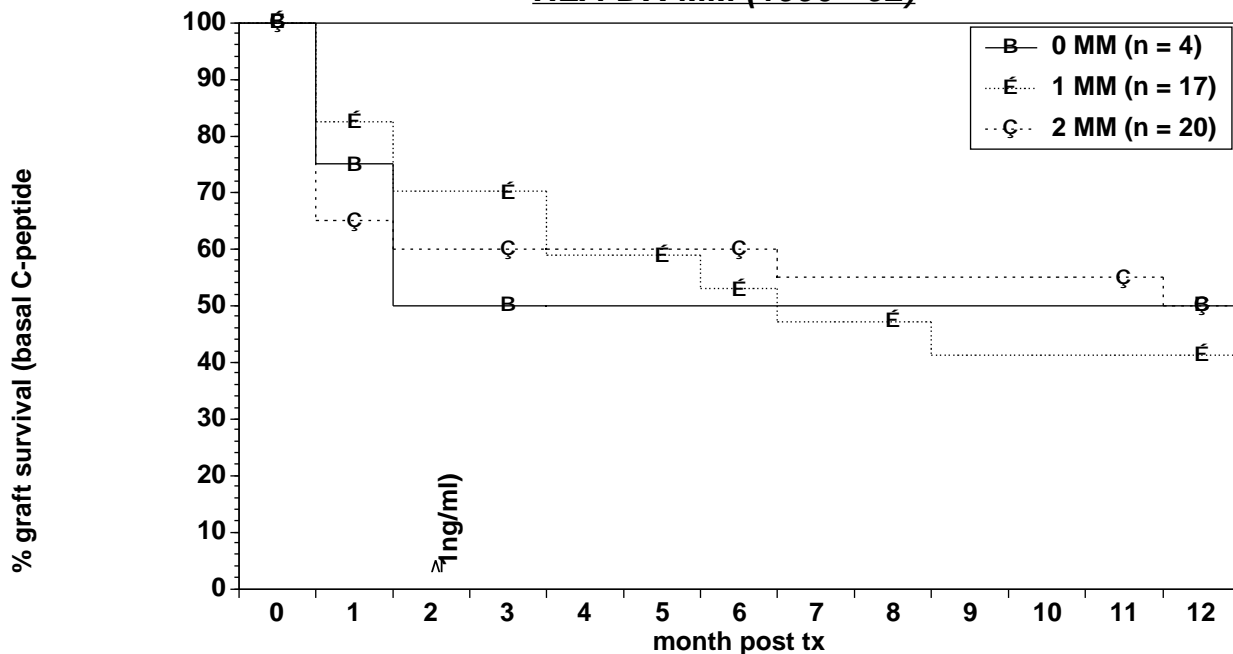
## One-Year Islet Allograft Survival according to *HLA-ABDR-MM (1990 - 92)*



## Insulin Independence and Basal C-Peptide according to *HLA-DR-Mismatches* \* (1990 - 92)



## One-Year Islet Allograft Survival according to *HLA-DR-MM* (1990 - 92)



### Summary of Cases reported to be Off Insulin after Adult Islet Tissue Transplantation without detailed information

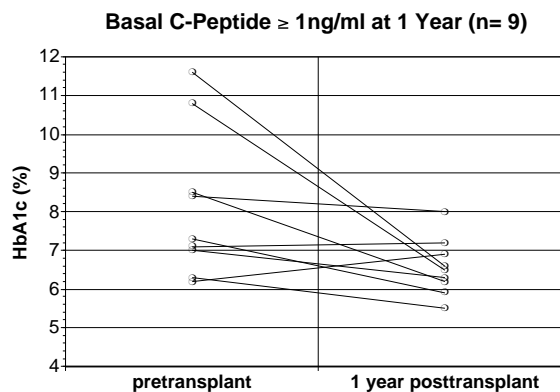
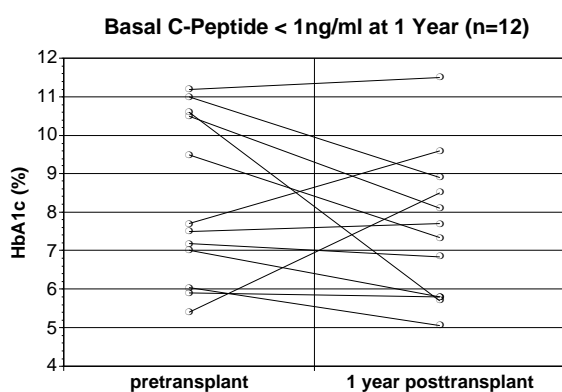
Institution	Year of Tx	Rec. Cat.	Site of Tx	Period of Insulin Independence post tx	Comments
Zurich	1978	SIK	spleen	10th - 20th month	C-peptide not determ.
Minneapolis	1977	IAK	liver	2nd - 4th day	insulin leakage ?
Minneapolis	1978	IAK	liver	13th - 17th day	insulin leakage ?
Genova	1979	ITA	s.c.	3rd - 10th month	C-peptide data not available
Genova	1979	ITA	s.c.	3rd - 19th month	C-peptide data not available

### Insulin Independence after Simultaneous Liver and Adult Islet Transplantation *Summary of Cases through 1992*

Institution	Year of Tx	No. of Donors	IEQ <sup>1</sup> *1000	Site of Tx	Period of Insulin Independence post tx	Comments
Paris	1988	1	150,000 <sup>2</sup>	epiploic flap	7th - 49th month post tx#	hemochromatosis
Paris	1990	1	250,000 <sup>2</sup>	epiploic flap	1st - 8th day	simult. islet, liver and kidney tx; CMV inf.
Pittsburgh	1990	1	474,000	liver	2nd - > 42 month <sup>3</sup>	cluster tx/FK 506
Pittsburgh	1990	1	289,000	liver	2nd - 4th month	cluster tx/FK 506 <sup>5</sup>
Pittsburgh	1990	2	578,000	liver	2nd - 15th month	cluster tx/FK 506
Pittsburgh	1990	2	258,000	liver	5th - 15th month	cluster tx/FK 506
Pittsburgh	1990	1	285,000	liver	3rd - 10th month	cluster tx/FK 506 <sup>5</sup>
Pittsburgh	1990	2	726,000	liver	2nd - 20th month	cluster tx/FK 506 <sup>5</sup>
Pittsburgh	1990	2	332,000	liver	1st - 15th month	cluster tx/FK 506 <sup>5</sup>
Milan	1992	2	830,000	liver	2nd - > 7th month <sup>4</sup>	residual C-peptide secretion pre tx

1) IEQ = Islet equivalents      2) Number of Islets      3) as of June 10, 1993  
4) as of June 11, 1993      5) died off insulin

### Glycated Hemoglobin (HbA1c-levels) before and One Year after Adult Islet Allotransplantation according to Basal C-Peptide Levels



# Insulin Independence after Adult Islet Transplantation in Type I Diabetes

## Summary of cases through Dec 31, 1992

Institution	Year of Tx	No. of Donors			Site of Tx	Type of Tx	HLA match		Induction Immunosuppression	Period of Insulin Independence post tx	Glucose Control†
		Fresh	Cryo	IEQ* 1000			AB	DR			
St. Louis	1989	1.4	-	785	p.v.	IAK*	1/3	2/1	ALG (+M-Pred)	10th - 25th day	IV Insulin
St. Louis	1990	1	+ 2	550 + 555	p.v.	IAK*	1/2/2	1/1/0	ALG (+M-Pred)	33rd - 341st day	IV Insulin
Edmonton	1990	1	+ 4	243 + 368	p.v.	SIK*	3 1/0/2/0	0 (fresh) 0 (cryo)	ALG (+M-Pred, AZA, CsA at day 10)	69th - 821st day	IV Insulin
Edmonton	1992	1	+ 5	284 + 308	p.v.	SIK*	3 1/0/0/1/0	1 (fresh) 1/1/0/0/1 (cryo)	ALG (+M-Pred, AZA, CsA at day 8)	155th - 166th day <sup>1</sup>	IV Insulin
Milano	1990	1	-	592	p.v.	IAK*	0	0	ALG (+M-Pred, CsA, AZA)	110th - 300th day <sup>1</sup>	IV Insulin
Milano	1991	1	+ 2	453 + 370	p.v.	SIK*	ND	ND	ALG (+M-Pred, CsA, AZA)	213th - > 539th day <sup>2</sup>	IV Insulin
Milano	1992	2	-	613	p.v.	IAK*	ND	ND	ALG (+Pred, CsA, AZA)	48th - > 269th day <sup>2</sup>	IV Insulin
Miami	1990	3	-	1122	p.v.	IAK*	0/2/0	1/1/0	OKT3 (+M-Pred, CsA, AZA)	42nd - 78th day	IV Insulin
Miami	1990	3	-	1209	p.v.	IAK*	0/0/0	0/0/0	OKT3 (+M-Pred, CsA, AZA)	87th - 125th day	IV Insulin
Mnpls	1992	1	-	536	p.v.	SIK*	1	1	ALG (+Pred+CsA+DSG)	326th - > 453rd day <sup>3</sup>	IV Insulin
Mnpls	1992	1	-	626	p.v.	SIK*	2	0	ALG (+Pred+CsA+DSG)	123rd - 231st day	IV Insulin

\* IEQ: equivalent no. of islets (number of islets if all were 150 micrometers in diameter)

IAK: islet after kidney (islet transplantation in patients with established kidney grafts)

SIK: simultaneous islet and kidney transplantation

† in the early posttransplant period

1 since then 4-8 U insulin per day

2 as of June 11, 1993

3 as of May 18, 1993

## Fetal Islet Grafts

According to the data reported in the literature or communicated to the scientific community, fetal islet tissue has been transplanted to approximately 2,000 diabetic recipients (see Newsletter No. 1). In this Newsletter, results on the 177 grafts only, which have been reported to the Registry are presented. These reports are very much appreciated since they facilitate to start with the evaluation of the potential impact of fetal islet tissue transplantation.

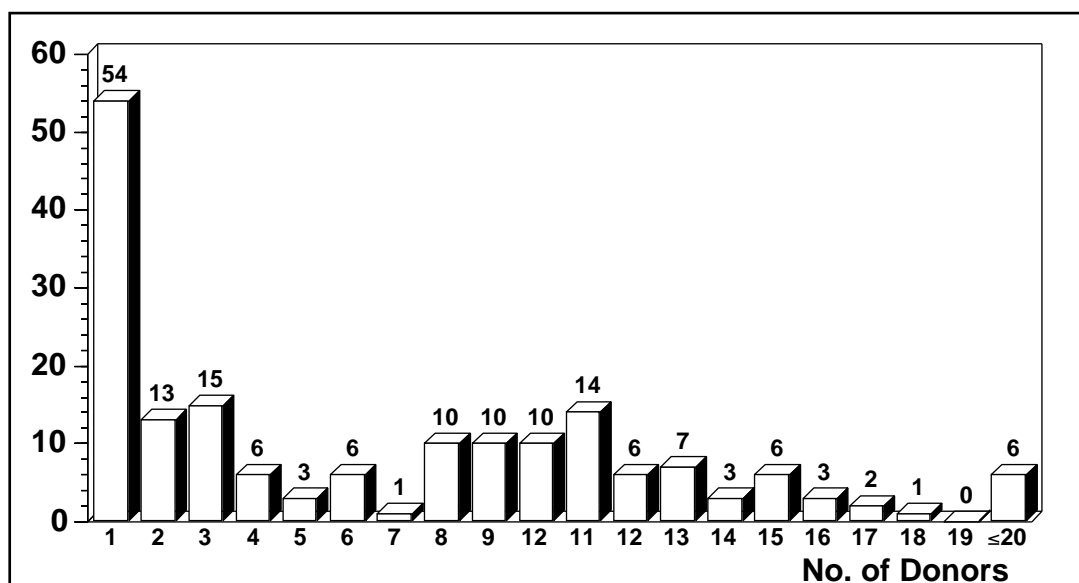
The first two figures are a breakdown of 177 fetal islet grafts according to the number of fetal donor pancreata and according to the recipient category, respectively. The last two pairs of figures compare the highest basal C-peptide levels and the lowest insulin requirements within the first year following fetal and adult islet tissue transplantation.

Similar to the exclusion criteria of the 1990-92 period, only cases holding pre- as well as posttransplant data were considered, resulting in only 66 fetal cases with pre- and posttransplant C-peptide data. It is interesting that a reduction of insulin requirement appeared in both adult and fetal islet transplant recipients, although posttransplant basal C-peptide levels  $> 1$  ng/ml were frequently reported in the adult islet transplant group but not in a single case in the fetal islet transplant group. In the three fetal islet transplants, which were reported to be insulin independent, no pretransplant C-peptide levels were given and the basal C-peptide levels within one year were in the range of 0.6 and 0.9 ng/ml.

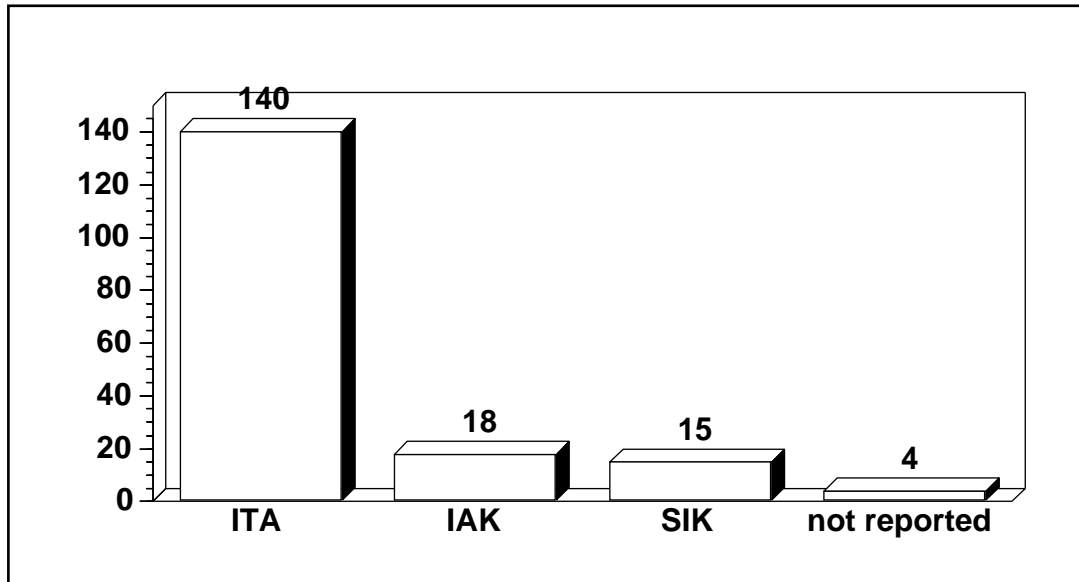
### Summary of Fetal Islet Grafts Reported to the Registry according to Institution and Year through Dec 31, 1992

INSTITUTION	YEAR OF TX	CASES
• Genova	79 - 80	13
• Shanghai	81 - 88	75
• Stockholm	82 - 84	3
• Szeged	82 - 92	25
• Melbourne	83 - 86	8
• Sydney	83 - 86	5
• Albany	85	1
• Dallas	85	6
• Denver	85 - 87	16
• Moscow	88 - 91	25
TOTAL NO. OF CASES:		177
TOTAL NO. OF INSTITUTIONS:		25

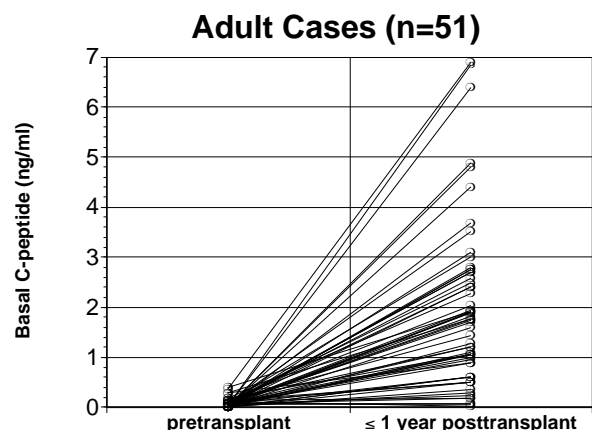
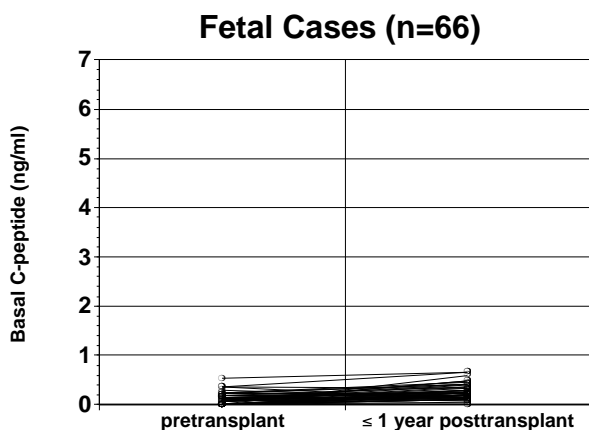
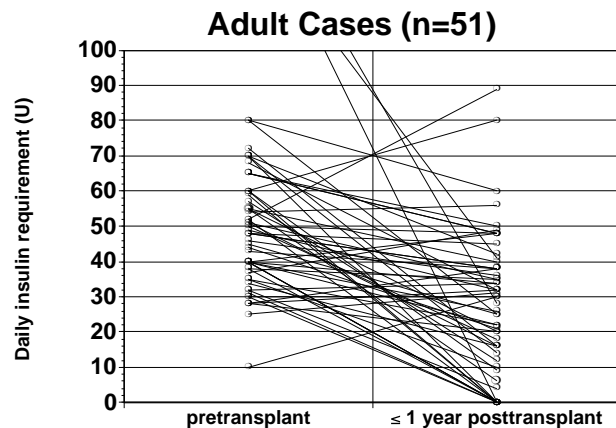
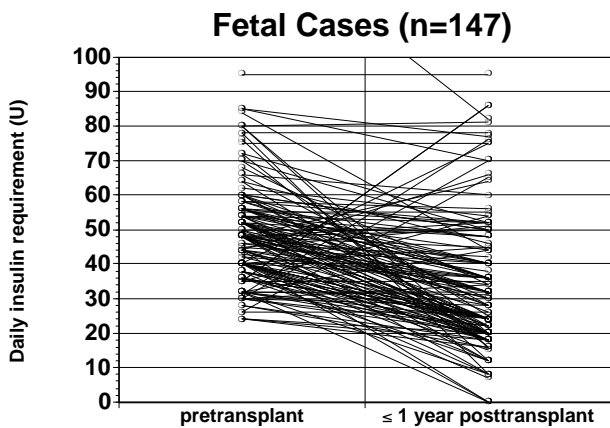
### Reported Fetal Islet Transplants according to *No. of Donors (1979 - 91)*



## Reported Fetal Islet Transplants according to Recipient Category (1979 - 91)



## Islet Transplant Success in Terms of Lowest Daily Insulin Requirement and Highest Basal C-Peptide within one Year Posttransplant



his Newsletter reflects the collaborative efforts of the following centers engaged in clinical transplantation of adult and fetal islets. Their support to the Registry is gratefully acknowledged. The asterisk indicates the centers that have sent report forms to the International Pancreas and Islet Transplant Registry in Minneapolis in former years. When the responsibility for the islet component was transferred to Giessen, these forms were graciously passed on to the Islet Transplant Registry by Dr. David J.R. Sutherland and Kay C. Moudry-Munns.



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