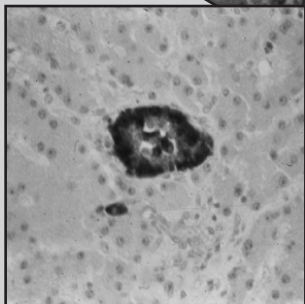
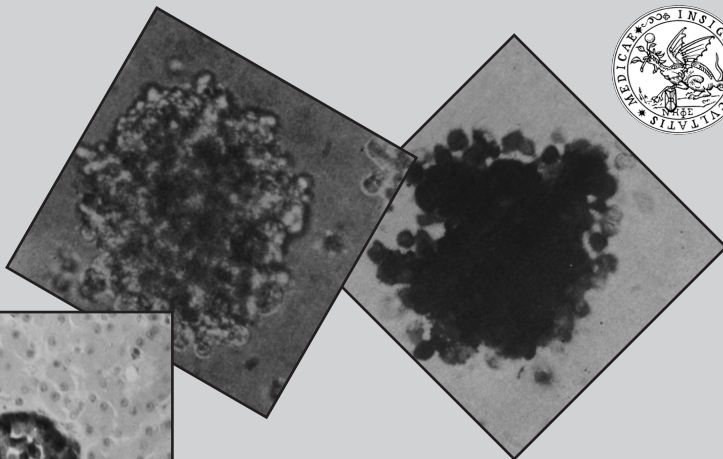
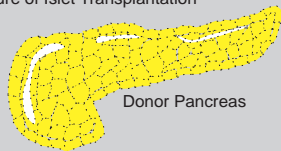


# INTERNATIONAL ISLET TRANSPLANT REGISTRY

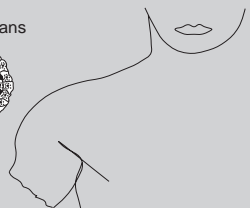
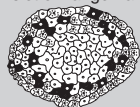


Procedure of Islet Transplantation

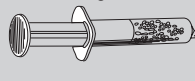


Donor Pancreas

Isolated Islet of Langerhans



Syringe with Isolated Islets of Langerhans



Liver

Portal Vein

Tenth anniversary of the Islet Transplant Registry (ITR) at Justus-Liebig-University, Giessen, Germany !

Between 1989 and 1999, 329 new cases of adult islet allotransplantation performed at 32 institutions, and 145 new cases of islet autotransplantation performed at 8 institutions have been recorded. A new website (<http://www.med.uni-giessen.de/itr>) has largely increased accessibility and downloading options of updated summary statistics in PDF format.

Newsletter #8  
Draft

on the occasion of the  
7th World Congress  
of the IPITA, Sydney,  
Aug 22-25, 1999

## In this Newsletter

• Editorial Board, Registry Staff, and Address .....	2
• Announcements .....	3
• Summary .....	4
• Long-term Follow-up of Islet Auto- and Allografts .....	5
• Adult Islet Autografts .....	6
• Adult Islet Allografts.....	7-8
• Adult Islet Allografts in Type-1 Diabetic Recipients.....	9-17
• Insulin Independence in Type-1 Diabetic Recipients .....	18
• List of Centers reporting to the ITR and Acknowledgements.....	19-20



## **Publisher**

Third Medical Department  
Center of Internal Medicine  
Justus-Liebig-University of Giessen

## **Circulation**

The Islet Transplant Registry Newsletter is published annually and distributed to all interested institutions. It is anticipated that newsletter no. 9 will be issued in fall 2000.

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**INTERNET**



## **A**nnouncements

The International Islet Transplant Registry (ITR) Giessen proudly celebrates its 10th anniversary !

In 1989, the responsibility for the islet registry component was transferred to Professor Konrad Federlin, at that time the director of the newly founded ITR at Giessen University, and the reports to the International Pancreas Transplant Registry (IPTR) were graciously passed on to the ITR by Professor David E.R. Sutherland and his co-workers. Upon retirement of Professor Federlin from his academic duties, Professor Reinhard Bretzel was appointed Director of the ITR. Within the past 10 years, 329 new cases of adult islet allotransplantations, and 145 cases of islet auto-transplantations have been recorded and analyzed. The continuing successful work would not have been possible without the steady support of the active isolation and transplant institutions. Their ongoing cooperation, and willingness to submit data and to respond are greatly appreciated by all ITR staff, and by clinicians, scientists and all persons interested in islet transplantation outcome! Recently, work of the ITR was acknowledged by the Juvenile Diabetes Foundation International and will be supported for an initial period of five years. In addition, publishing and distribution of the Newsletter is sponsored by Fresenius, Germany.

- Please note, as evident from the analyses, tables, and graphical illustrations, that the threshold level of serum C-peptide secretion by transplanted islets defining persistent graft survival was adjusted to 0.5 ng/mL. This modification was implemented according to the recommendation of leading scientists and clinicians at the previous congress of the International Pancreas and Islet Association, September 1997 in Milan, Italy, and recognizes significant biological effects determined in clinical studies for basal serum C-peptide levels up to 2 ng/mL, with a lower limit of 0.5 ng/mL (Johansson BL, Borg K, Fernqvist-Forbes E et al., *Diabetologia* 1996; 39: 687-95, for overview see Wahren J and Johansson BL, *Hormone and Metabolic Research* 1998; 30: A2-A5). These observations are paralleled by new findings on C-peptide physiology (Steiner DF, Rubenstein AH, *Science* 1997 25;277: 531-2, and Ido Y, Vindigni A, Chang K, et al., *Science* 1997; 277: 563-7).
- A series of enhancements to the internet web page of the ITR was implemented, with extended access to downloadable results and data forms. Along with the new design, the web address was changed to:  
*<http://www.med.uni-giessen.de/itr>*



# S

ummary

From 1893 through December 1998, a total of 405 adult islet allograft allotransplantations including historical cases have been performed at 42 institutions worldwide, including 202 at 15 institutions in North America, 198 at 25 institutions in Europe, and five elsewhere. The total number of diabetic patients reported to be insulin independent for  $\geq 1$  month,  $\geq 3$  months,  $\geq 6$  months,  $\geq 12$ ,  $\geq 24$ ,  $\geq 36$ , and  $\geq 48$  month(s) through December 31, 1998, is 50, 47, 41, 33, 20, 9, and 3, respectively.

With refined islet isolation and purification methods becoming widely applicable, a considerable increase of clinical islet transplantations has occurred. The current ITR analysis is focusing on the period between January 1, 1990 and December 31, 1998. In an analysis by era (with one year follow-up), the percentages of pretransplant C-peptide negative patients with type-1 and pancreatotomy induced diabetes mellitus, who showed basal C-peptide levels  $\geq 0.5$  ng/ml at  $\geq 1$  month posttransplant and who became insulin-independent for  $\geq 1$  week in the 1985-1989 era (n=28) were 36 % and 7 %, in the 1990-1994 era (n=131) 74 % and 20 %, and in the 1995-1997 era (n=106) 69 % and 14 %. The lack of further improvement in functional outcome might in part be explained by the observation, that the number of islet allografts derived from a single donor pancreas has significantly increased from the 1990-1994 era (68 out of 131 cases (52 %) to the 1995-1997 era (79 out of 106 cases (74 %),  $p=0.0004$ ). In parallel, significantly more patients received a higher islet mass ( $\geq 6000$  islet equivalents (standardized volume of a spherical islet with 150  $\mu$ m in diameter) per kilogram body weight of the recipient) in the 1990-1994 era (87 out of 131, 66 %) as compared to the 1995-1997 era (58 out of 106, 55 %,  $p=0.0324$ ). In consequence, islet transplant centers have intensified their efforts to improve isolation outcome, eliminate adverse factors in the early engraftment period and refine immunosuppression protocols.

A detailed analysis (one year follow-up) was performed on 200 pretransplant C-peptide negative patients with type-1 diabetes mellitus, who received adult islet allografts between 1990 and 1997. This represents a two-fold increase in number of analyzed cases compared to the previous newsletter (no. 7). One year patient and islet allografts survival (as defined by basal C-peptide  $\geq 0.5$  ng/ml) rates were 96 %, and 35 %, respectively, and 8 % of the recipients were insulin independent at one year post-transplant. As seen in previous analyses, establishment of insulin independence was largely facilitated if 1) islets were isolated from pancreata with a mean preservation time  $\leq 8$  hours (n=121), 2) if  $\geq 6,000$  islet equivalents per kg body weight of the recipient were transplanted (n=126), 3) if islets were transplanted into the liver via the portal vein (n=186), and 4) if induction immunosuppression comprised monoclonal or polyclonal T-cell antibodies (n=127).

Sixty of 200 pretransplant C-peptide negative islet allograft recipients with type-1 diabetes mellitus met all of these characteristics of long-term insulin independent recipients (ALG/ATG, but not OKT3). 29 of these 60 (48 %) patients showed basal C-peptide levels of  $\geq 0.5$  ng/ml, 44 of 60 (73 %) had HbA1c levels  $\leq 7$  %, and 13 of 60 (22 %) were insulin independent at  $\geq 1$  year follow-up, respectively.

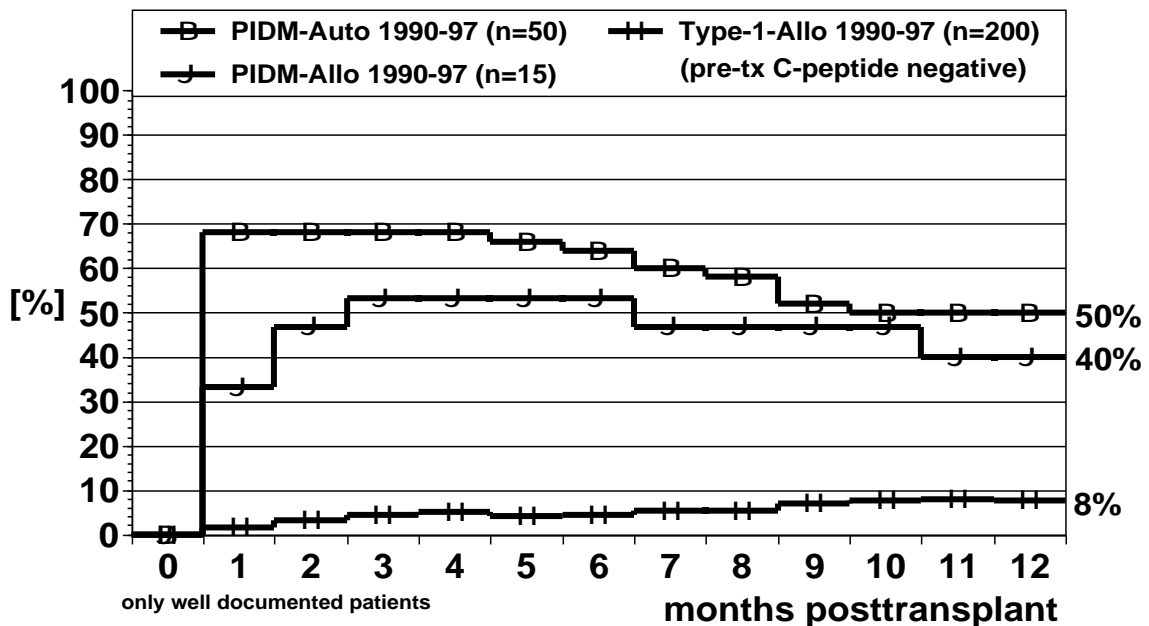
In this preselected group of patients, insulin independent (17 out of 60, 28 %) and insulin dependent recipients (43 out of 60, 72 %) did not differ in regard to age, BMI, diabetes duration, pre-Tx HbA1c, pre-Tx insulin requirements, donor age, cold storage time and IEQ/kg. However, the group of insulin independent recipients had higher basal C-peptide levels at both 1 month ( $2.52 \pm 0.32$  vs.  $2.10 \pm 0.27$  ng/ml,  $p=0.064$ ), and at one year ( $2.38 \pm 0.16$  vs.  $0.81 \pm 0.13$ ,  $p < 0.0001$ ) posttransplant, respectively. This again underscores the notion, that intrinsic characteristics of the islet preparation (e.g. viability, apoptosis cascades triggered during islet isolation/storage), of the immediate post-transplant period (e.g. inflammatory and other response of the recipient towards an intravascular islet graft), and factors during long-term islet survival (e.g. effective engraftment, immune-mediated response of the recipient, specific susceptibility of islet grafts towards adverse effects of immunosuppressive drugs, and functional graft exhaustion) may determine clinical success.



## Longest Graft Function of Islet Allografts in Diabetes Mellitus

	graft function	insulin independence
IAK	> 8 yrs 8 m	4 yrs 2 m
SIK	> 7 yrs 4 m	5 yrs 10 m
PIDM-Allo	4 yrs 8 m	4 yrs 8 m
PIDM-Auto	> 7 yrs	> 7 yrs

**Insulin Independence Following Islet Transplantation in Man  
A Comparison of Different Recipient Categories**





## Adult Islet Autografts

Summary of Adult Islet Autografts According to Institution and Year  
1990 through December 31, 1998

Institution (Transplantation / Isolation)	Year of Transplantation										Σ
	90	91	92	93	94	95	96	97	98	Σ	
• Minneapolis	3	1	2	4	12	8	6	6	12	54	
• Leicester	-	-	-	-	1	8	7	4	3	23	
• Geneva	-	-	2	2	1	4	-	-	3	12	
• Indianapolis	-	-	-	-	-	-	-	4	7	11	
• Pittsburgh	-	2	1	-	-	1	1	-	-	5	
• Barcelona	-	-	-	-	-	-	-	2	-	2	
• Rostock	-	-	-	-	-	-	-	-	2	2	
• Charlotte	-	-	-	-	-	1	-	-	-	1	
• Gent / Giessen	-	-	-	1	-	-	-	-	-	1	
• Los Angeles (UCLA-VA)	-	-	-	-	-	1	-	-	-	1	
• Besancon	-	-	-	-	-	-	-	1	-	1	
• Paris	-	1	-	-	-	-	-	-	-	1	
Σ	3	4	5	7	14	23	14	17	27	114	

Total number of Adult Islet Autografts through 1989: **108**

'98 data on file incomplete

**Total: 222**

## Islet Autografts from 1990 - 1998

• Institutions	Minneapolis	54
	Leicester	23
	Geneva	12
	Indianapolis	11
	8 other Institutions	14
• No. of cases		114
• Insulin-independent ≥ 7 days (1990-1998):		40 / 58* (69%)
• Insulin-independent at ≥ 1 yr (1990-1997 + one year follow-up):		25 / 50* (50%)
• if more than 300,000 IEQ transplanted:		15 / 21* (71%)
• Longest insulin-independence follow-up after total pancreatectomy:		> 7 yrs

\* only well documented cases

'98\* data on file incomplete



# Adult Islet Allografts

## Summary of Adult Islet Allografts According to Institution and Year 1990 through December 31, 1998

Institution (Transplantation/ Isolation)	Year of Transplantation									
	90	91	92	93	94	95	96	97	98	Σ
• Giessen	-	-	1	5	5	12	11	17	6	57
• Pittsburgh	17	6	4	3	4	3	1	-	-	38
• Minneapolis	1	4	5	5	2	10	5	1	-	33
• Miami	4	2	1	1	3	9	5	2	1	28
• Milan	4	3	3	4	4	4	1	-	-	28
• St. Louis	3	3	2	4	2	-	-	-	-	14
• Geneva	-	-	-	-	1	-	4	2	4	11
• Brussels	-	-	-	-	1	3	3	3	?	10
• Indianapolis	-	-	-	-	-	-	4	5	1	10
• Oxford	-	1	1	1	1	3	-	1	1	9
• Los Angeles (UCLA-VA)	-	-	3	-	-	-	3	2	-	8
• Madrid	-	-	2	1	1	2	2	-	-	8
• Edmonton	2	-	1	-	1	1	-	-	-	5
• Odense/Milan	-	-	-	-	-	5	-	-	-	5
• Paris	3	1	-	-	-	1	-	-	-	5
• San Francisco/LA (UCLA-VA)	-	-	-	1	1	3	-	-	-	5
• Stockholm/Giessen	-	-	-	-	-	-	2	2	1	5
• Buenos Aires	-	-	-	-	-	1	1	2	-	4
• London (Ontario)/St. Louis	2	1	1	-	-	-	-	-	-	4
• Perugia	1	1	-	-	2	-	-	-	-	4
• Innsbruck/Milan	-	-	-	-	-	2	1	-	-	3
• Leicester	-	2	1	-	-	-	-	-	-	3
• Charlestown	-	2	-	-	-	-	-	-	-	2
• Chicago (NWH)	-	-	-	-	-	-	1	-	-	1
• Homburg	-	-	-	1	-	-	-	-	-	1
• Lille	-	-	-	-	-	-	-	-	1	1
• Omaha	-	-	-	-	1	-	-	-	-	1
• Padova/Verona	-	-	-	1	-	-	-	-	-	1
• Syracuse (NYUM)	-	-	-	-	-	-	-	1	-	1
• Wuerzburg/Giessen	-	-	-	1	-	-	-	-	-	1
Σ	37	26	25	28	29	59	44	38	20	306

Total number of Adult Islet Allografts through 1989: 99

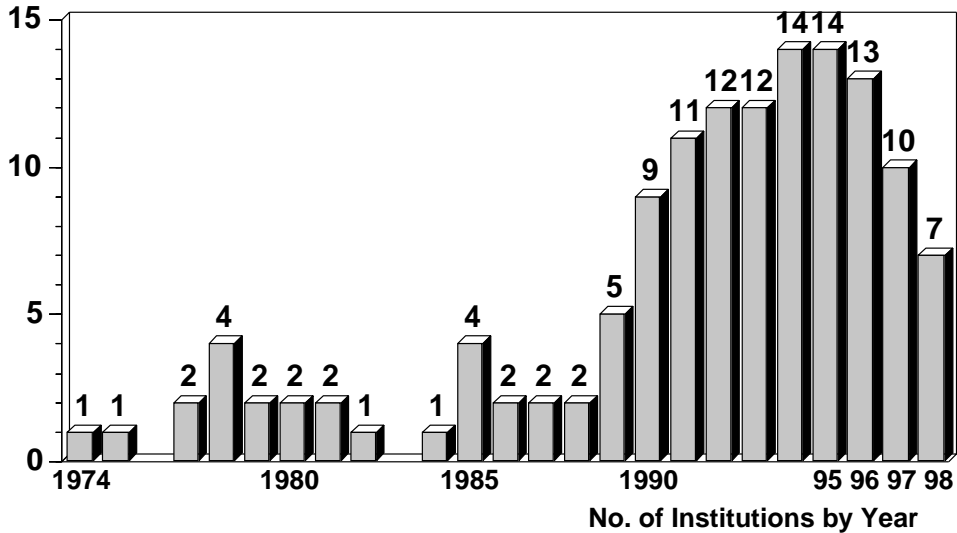
**Total: 405**

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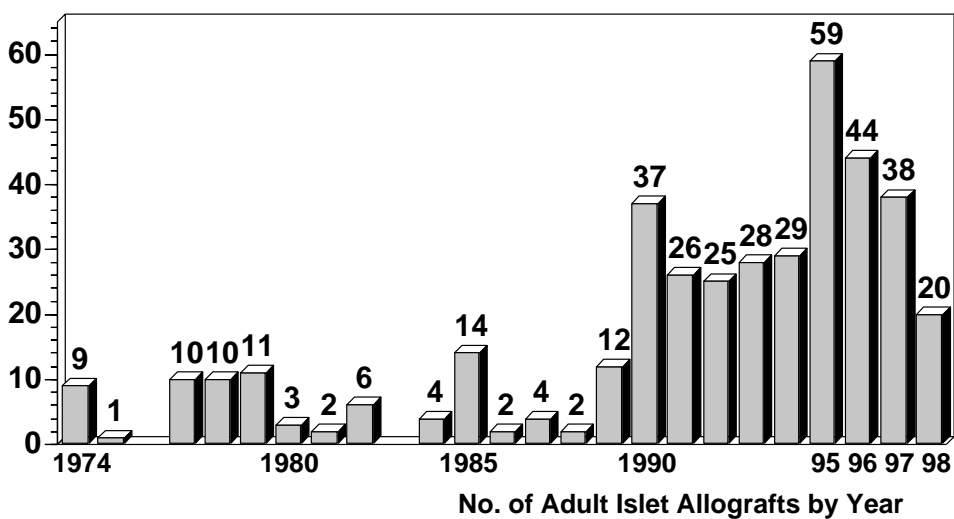
## Adult Islet Allografts

**No. of Institutions Reporting Adult Islet Allografts in Patients with Diabetes by Year from 1974 through 1998**



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**No. of Adult Islet Allografts in Patients with Diabetes by Year from 1974 through 1998**



98' data on file incomplete



# Adult Islet Allografts in Type-1 Diabetic Recipients

## Summary of Adult Islet Allografts in Type-1 Diabetic Recipients According to Institution and Year from 1990 through Dec. 31, 1998

Institution (Transplantation/ Isolation)	Year of Transplantation										Σ
	90	91	92	93	94	95	96	97	98	Σ	
• Giessen	-	-	1	5	5	12	11	17	6	57	
• Minneapolis	1	3	5	5	2	10	5	1	-	32	
• Milan	4	3	2	4	4	4	1	-	5	27	
• Pittsburgh	7	5	3	3	4	3	1	-	-	26	
• Miami	4	2	1	1	1	6	2	-	1	18	
• St. Louis	3	3	2	4	2	-	-	-	-	14	
• Brussels	-	-	-	-	1	3	3	3	?	10	
• Geneva	-	-	-	-	-	-	4	2	4	10	
• Indianapolis	-	-	-	-	-	-	4	5	1	10	
• Madrid	-	-	2	1	1	2	2	-	-	8	
• Oxford	-	1	1	1	1	2	-	1	1	8	
• Edmonton	2	-	1	-	1	1	-	-	-	5	
• Odense/Milan	-	-	-	-	-	5	-	-	-	5	
• Stockholm/Giessen	-	-	-	-	-	-	2	2	1	5	
• Buenos Aires	-	-	-	-	-	1	1	2	-	4	
• London (Ontario)/St. Louis	2	1	1	-	-	-	-	-	-	4	
• Perugia	1	1	-	-	2	-	-	-	-	4	
• Innsbruck/Milano	-	-	-	-	-	2	1	-	-	3	
• Leicester	-	2	1	-	-	-	-	-	-	3	
• Los Angeles (UCLA-VA)	-	-	2	-	-	-	1	-	-	3	
• Paris	3	-	-	-	-	-	-	-	-	3	
• San Francisco/LA (UCLA-VA)	-	-	-	1	1	1	-	-	-	3	
• Charlestown	-	1	-	-	-	-	-	-	-	1	
• Chicago (NMH)	-	-	-	-	-	-	1	-	-	1	
• Homburg (Saar)	-	-	-	1	-	-	-	-	-	1	
• Lille	-	-	-	-	-	-	-	-	1	1	
• Omaha	-	-	-	-	1	-	-	-	-	1	
Σ	27	22	22	26	26	52	39	33	20	267	

Cases transplanted between 1974-1989: 90

Total: 353

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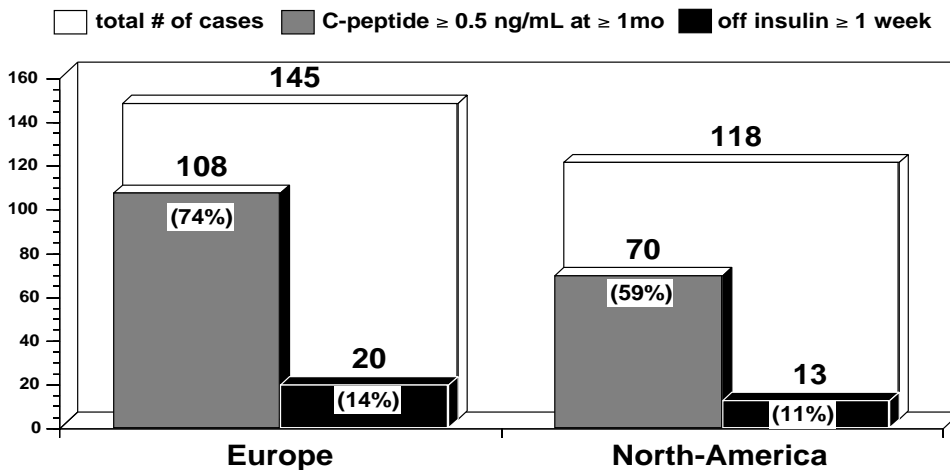


## Adult Islet Allografts in Type-1 Diabetic Recipients 1990 - 1998

- No. of cases: 267
- Institutions:
  - Giessen 57
  - Minneapolis 32
  - Milan 27
  - Pittsburgh 26
  - Miami 18
  - St. Louis 14
  - Geneva 10
  - Indianapolis 10
  - 17 additional institutions 73
- Insulin-independent  $\geq 7$  days (1990-1998): 33 / 267 (12%)
- Insulin-independent at  $\geq 1$  yr (1990-1997 + one year follow-up): 20 / 245 ( 8%)
- Insulin-independent after 1:1 tx  $\geq 7$  days (1990-1998): 17 / 169 (10%)
- Insulin-independent after 1:1 tx at  $\geq 1$  yr (1990-1997 + one year follow-up): 11 / 156 ( 7%)
- Longest insulin-independence follow-up: 70 months

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Insulin Independence and Basal C-Peptide after Adult Islet Allotransplantation in 267 Type-1 Diabetic Recipients from 1990 - 1998 according to Continent



Four transplantations performed elsewhere



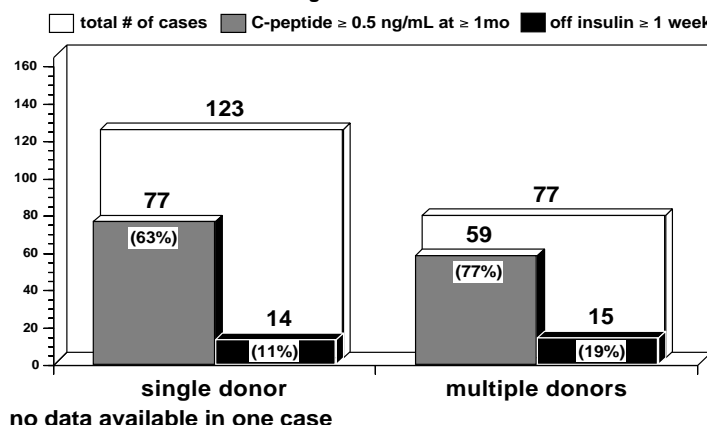
## THE 1990-97 CASES

### DETAILED DATA ON 200 C-PEPTIDE NEGATIVE TYPE 1 DIABETIC ADULT ISLET ALLOGRAFT RECIPIENTS TRANSPLANTED FROM 1990 TO 1997 (≥ ONE YEAR FOLLOW-UP)

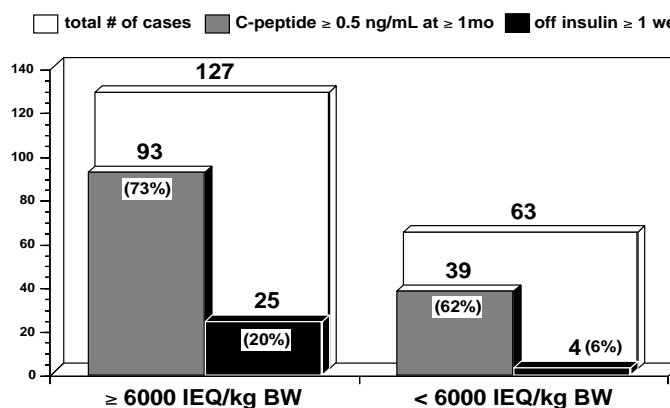
Two hundred patients with complete data records, type-1 diabetes and no residual C-peptide secretion pretransplant who received an islet allograft between 1990 and 1997 were taken into the analysis. Assuming that a large majority of islet allografts performed worldwide during this period were reported to the Registry, the following analysis should reflect the current status of islet allotransplantation in patients with type-1 diabetes mellitus.

The overall outcome assessed at one year after islet transplantation for patient survival was 96 %, for graft survival (basal C-peptide ≥ 0.5 ng/mL) 35 % and for insulin independence (more than 7 days) 10 %.

Insulin Independence and Basal C-Peptide after Adult Islet Allotransplantation in 200 pre Tx C-Peptide negative Type-1 Diabetic Recipients from 1990 - 1997 according to Number of Donors



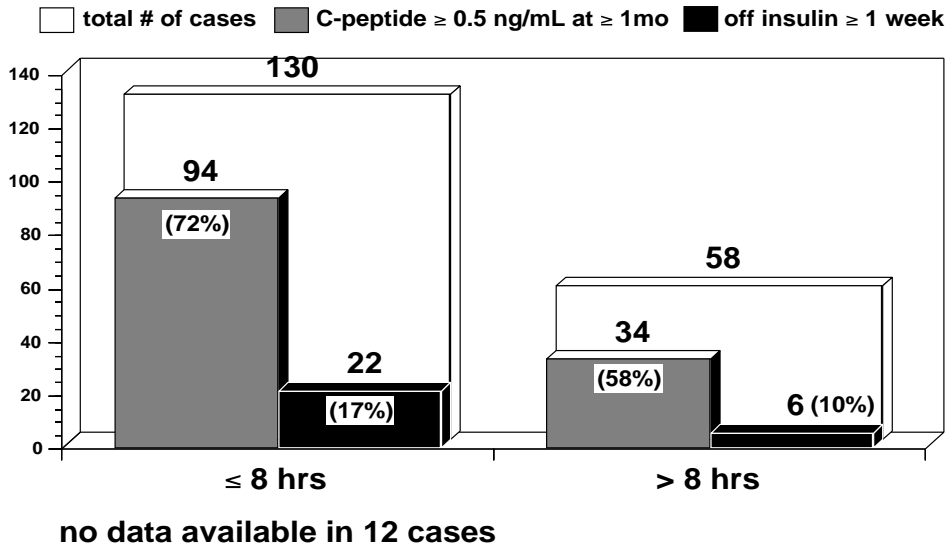
Insulin Independence and Basal C-Peptide after Adult Islet Allotransplantation in 200 pre Tx C-Peptide negative Type-1 Diabetic Recipients from 1990 - 1997 according to Number of Islet Equivalents per kg Body Weight



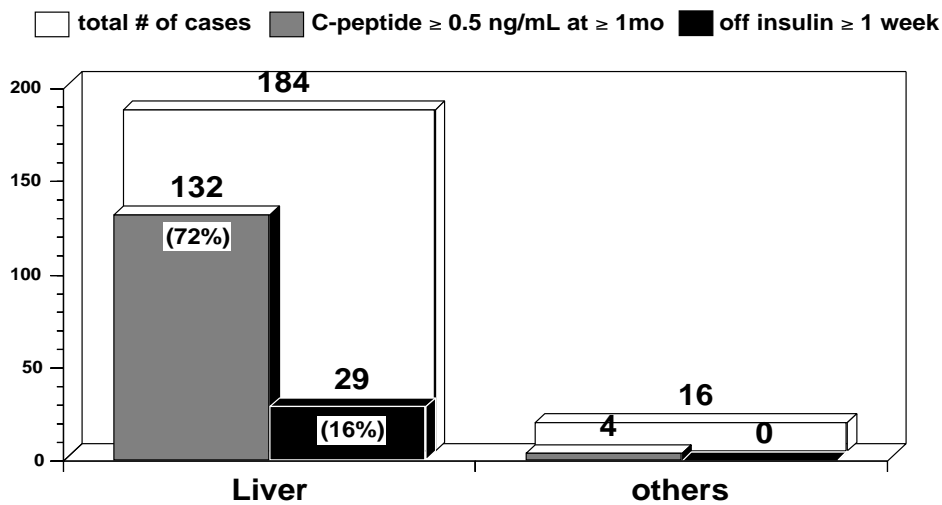


## Adult Islet Allografts in Type-1 Diabetic Recipients

**Insulin Independence and Basal C-Peptide after Adult Islet Allotransplantation in 200 pre Tx C-Peptide negative Type-1 Diabetic Recipients from 1990 - 1997 according to Cold Ischemia Time**

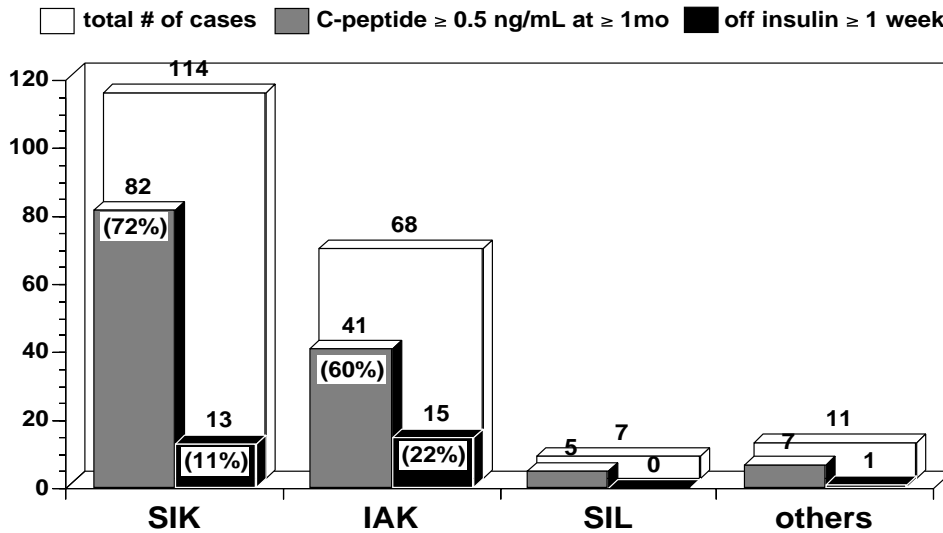


**Insulin Independence and Basal C-Peptide after Adult Islet Allotransplantation in 200 pre Tx C-Peptide negative Type-1 Diabetic Recipients from 1990 - 1997 according to Implantation Site**

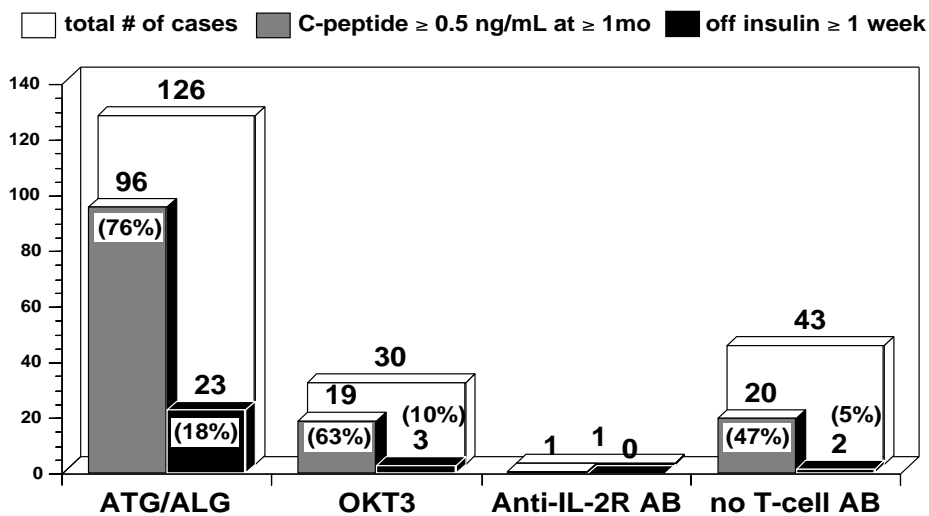




**Insulin Independence and Basal C-Peptide after Adult Islet Allotransplantation in 200 pre Tx C-Peptide negative Type-1 Diabetic Recipients from 1990 - 1997 according to Recipient Category**



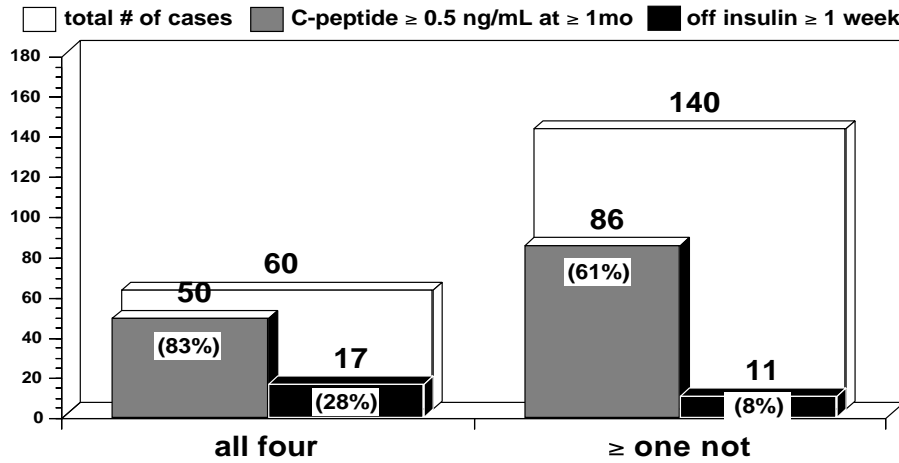
**Insulin Independence and Basal C-Peptide after Adult Islet Allotransplantation in 200 pre Tx C-Peptide negative Type-1 Diabetic Recipients from 1990 - 1997 according to Induction Immunosuppression**





## Adult Islet Allografts in Type-1 Diabetic Recipients

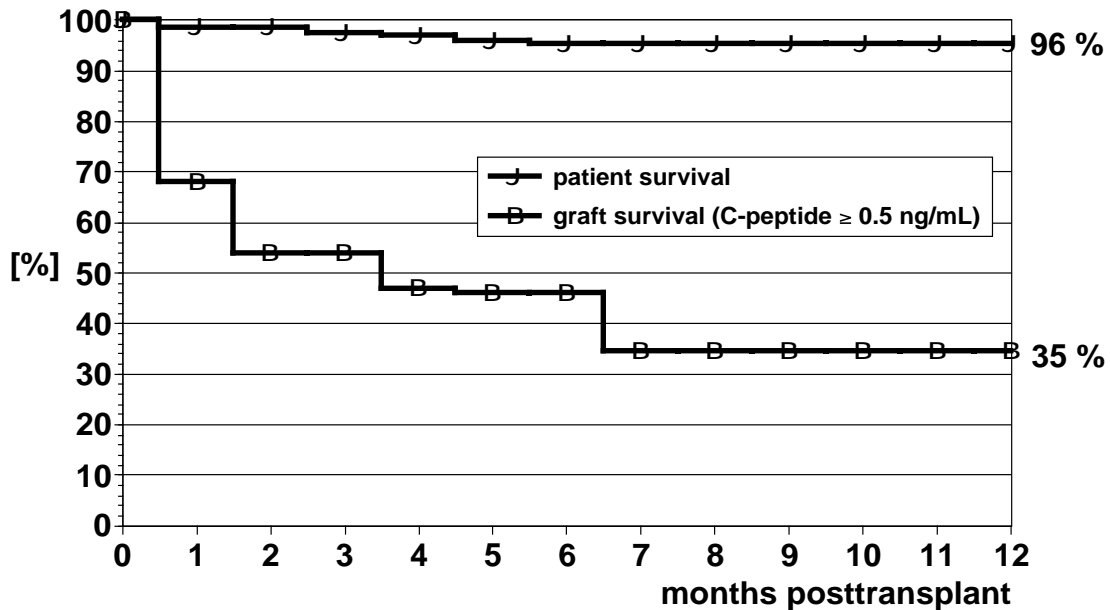
**Insulin Independence and Basal C-Peptide after Adult Islet Allotransplantation in 200 pre Tx C-Peptide negative Type-1 Diabetic Recipients from 1990 - 1997 according to Common Criteria**



**Common Criteria:**

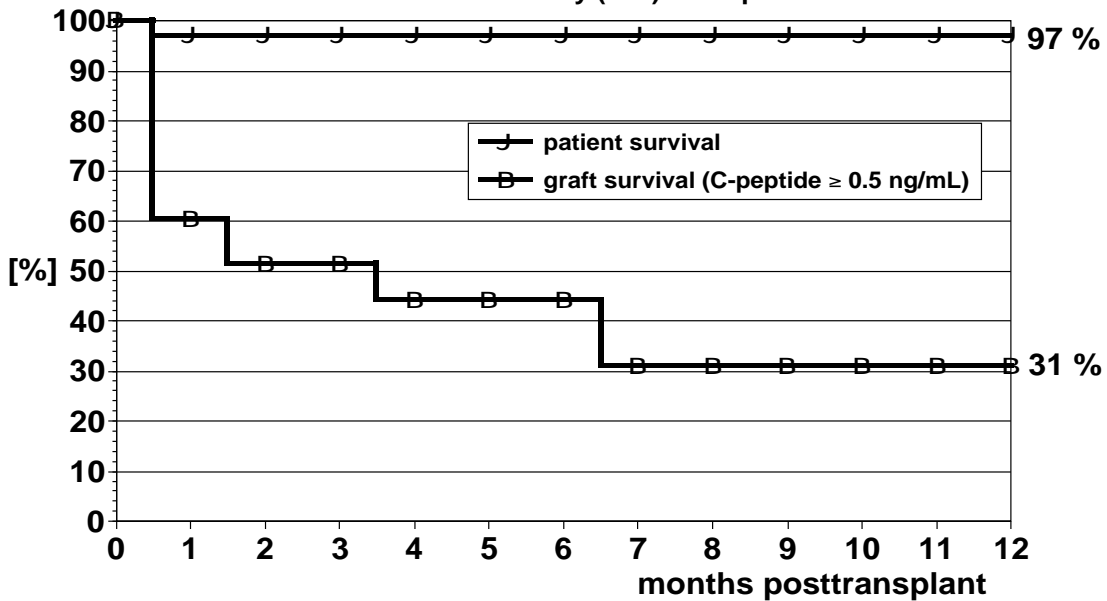
a) IEQ/kg BW  $\geq$  6,000; b) CIT  $\leq$  8 hrs; c) ALG/ATG; Implantation Site: Liver

**Cumulative One-Year Patient and Graft Survival in 200 pre Tx C-Peptide Negative Type-1 Diabetic Recipients (1990-1997)**

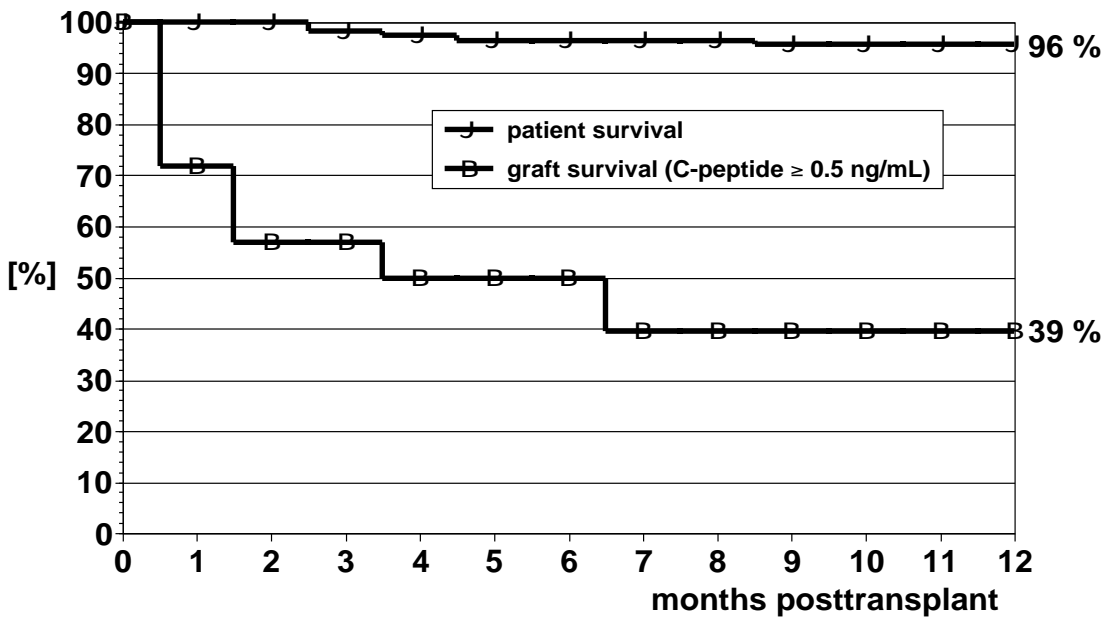




Cumulative One-Year Patient and Graft Survival in 68 pre Tx C-Peptide Negative Type -1 Diabetic Recipients (1990-1997) Simultaneous Islet Kidney (IAK) Transplantation



Cumulative One-Year Patient and Graft Survival in 114 pre Tx C-Peptide Negative Type -1 Diabetic Recipients (1990-1997) Simultaneous Islet Kidney (SIK) Transplantation





## Adult Islet Allograft Survival in 200 Type-1 Diabetic Recipients (Pretransplant C-Peptide Negative) with Complete Data Records (1990-1997 Cases)

### No. (Percentage) of Cases Functioning

Category	n	at ≥ 1 Month		at ≥ 1 Year			
		Basal C-Peptide 0.5 ng/mL	Insulin Indep. ( 7 days)	Basal C-Peptide 0.5 ng/mL	P Values	Insulin Indep. ( 7 days)	P Values
All cases	200	136 (68%)	28 (14%)	69 (35%)		19 (10%)	
<b>A. Continent</b>							
1. North America	87	54 (62%)	9 (10%)	20 (23%)	p=0.0016** 1 vs. 2	4 ( 5%)	p=0.0496*
2. Europe	109	82 (75%)	19 (17%)	49 (45%)		15 (14%)	
3. others	4						
<b>B. Recipient Sex</b>							
1. male	123	82 (67%)	12 (10%)	35 (28%)	p=0.032*	7 ( 6%)	p=0.0259*
2. female	77	54 (70%)	16 (21%)	34 (44%)		12 (16%)	
<b>C. Recipient Age</b>							
1. 40 y	124	86 (69%)	18 (15%)	46 (37%)	p=0.3545 1 vs. 2	12 (10%)	p=1.000
2. > 40 y	73	49 (67%)	10 (14%)	22 (30%)		7 (10%)	
3. no data	3						
<b>D. Duration of Diabetes</b>							
1. 20 y	54	34 (63%)	6 (11%)	15 (28%)	p=0.2407 1 vs. 2	3 ( 6%)	p=0.2873
2. > 20 y	141	100 (71%)	22 (16%)	53 (38%)		16 (11%)	
3. no data	5						
<b>E. Average CIT</b>							
1. 480 min	130	94 (72%)	21 (16%)	49 (38%)	p=0.0478* 1 vs. 2	16 (12%)	p=0.1045
2. > 480 min	58	34 (59%)	6 (10%)	14 (24%)		3 ( 5%)	
3. no data	12						
<b>F. No. of Donors</b>							
1. 1	123	77 (63%)	13 (11%)	39 (32%)	p=0.2165	10 ( 8%)	p=0.4608
2. > 1	77	59 (77%)	15 (19%)	30 (39%)		9 (12%)	
<b>G. IEQ / kg BW</b>							
1. < 6,000	63	39 (62%)	4 ( 6%)	21 (33%)	p=0.4108 1 vs. 2	3 ( 5%)	p=0.0703
2. 6,000	127	93 (73%)	24 (19%)	46 (36%)		16 (13%)	
3. no data	10						
<b>H. Pre Tx Viab. Tests</b>							
1. yes	121	85 (70%)	18 (15%)	47 (39%)	p=0.2885	12 (10%)	p=0.6238
2. no	79	51 (65%)	10 (13%)	22 (28%)		6 ( 8%)	
<b>I. Islet Purity (%)</b>							
1. 90	162	110 (68%)	23 (14%)	57 (35%)	p=0.3438 1 vs. 2	16 (10%)	p=0.4565
2. > 90	24	19 (79%)	5 (21%)	10 (42%)		3 (13%)	
3. no data	14						
<b>J. Recipient Category</b>							
1. IAK	68	41 (60%)	15 (22%)	21 (31%)	p=0.2677 1 vs. 2	8 (12%)	p=0.8027
2. SIK	114	82 (72%)	13 (11%)	45 (39%)		11 (10%)	
3. others	18						
<b>K. Induction Immunosupp.</b>							
1. ATG/ALG/IL-2R	127	97 (76%)	23 (18%)	52 (41%)	p= 0.0132* 1 vs. 3	17 (13%)	p=0.0303* 1 vs. 3
2. OKT3	30	19 (63%)	3 (10%)	9 (30%)		1 ( 3%)	
3. no T-cell antibody	43	20 (47%)	2 ( 5%)	8 (19%)		1 ( 2%)	
<b>L. Site of Tx</b>							
1. liver	184	132 (72%)	28 (15%)	67 (36%)	p=0.0426*	19 (10%)	p=0.1894
2. others	16	4 (25%)	0 ( 0%)	2 (13%)		0 ( 0%)	
<b>M. Common Charact. of Ins. Indep. Cases</b>							
1. all four fulfilled	60	50 (83%)	17 (28%)	28 (47%)	p=0.0143*	14 (23%)	p<0.0001***
2. 1 not fulfilled	140	86 (61%)	11 ( 8%)	41 (29%)		5 ( 4%)	

P values comparing islet graft survival rates between groups at one year after transplantation were calculated by the one-sided (categories E, G, I, K, L, M) and by the two-sided (categories A, B, C, D, F, H, J) Fisher's exact test. \* p<0.05 significant, \*\* p<0.01 very significant, \*\*\* p<0.001 highly significant. CIT: Cold Ischemia Time; IEQ: Islet Equivalents (no. of islets if all had a diameter of 150 µm)



## 123 Single Donor Recipients in 1990 -1997

Out of the selected 200 pre-tx C-peptide negative type-1 diabetic patients with complete data records transplanted from 1990 to 1997, 123 recipients received islets from a single donor, as given in F on page 14.

The impact of HLA-MM (mismatches), sex compatibility and ABO identity on islet allograft survival could - for obvious reasons - only be analyzed in these 123 single donor islet allograft recipients.

### No. (%) of Cases Functioning (1:1 Tx)

Category	n	at ≥ 1 Month		at ≥ 1 Year	
		Basal C-Peptide ≥ 0.5 ng/mL	Insulin Indep. (>7 days)	Basal C-Peptide ≥ 0.5 ng/mL	Insulin Indep. (>7 days)
<b>All cases</b>	<b>123</b>	<b>77 ( 63%)</b>	<b>14 (11%)</b>	<b>39 (32%)</b>	<b>10 ( 8%)</b>
<b>A. ABDR MM</b>					
0	1	0	0	0	0
1	3	3 (100%)	0	2 (66%)	0
2	8	4 ( 50%)	0	0	0
3	14	10 ( 71%)	3 (21%)	7 (50%)	3 (21%)
4	33	19 ( 58%)	2 ( 6%)	10 (30%)	2 ( 6%)
5	38	29 ( 76%)	6 (16%)	16 (42%)	5 (13%)
6	21	10 ( 48%)	2 (10%)	3 (14%)	0
no data	5	2 ( 40%)	0	1 (20%)	0
<b>B. BDR MM</b>					
0	3	2 ( 66%)	0	1 (33%)	0
1	7	3 ( 23%)	0	1 (14%)	0
2	18	16 ( 89%)	3 (17%)	8 (44%)	3 (17%)
3	48	27 ( 56%)	5 (10%)	14 (29%)	5 (10%)
4	42	27 ( 64%)	5 (12%)	14 (33%)	2 ( 5%)
no data	5	2 ( 40%)	0	1 (20%)	0
<b>C. DR MM</b>					
0	6	2 ( 33%)	0	2 (33%)	0
1	40	24 ( 60%)	6 (15%)	14 (35%)	6 (15%)
2	66	43 ( 65%)	7 (11%)	21 (32%)	4 ( 6%)
no data	11	8 ( 73%)	0	2 (18%)	0
<b>D. Sex Compatibility</b>					
1. yes	71	42 ( 59%)	8 (11%)	19 (27%)	7 (10%)
2. no	40	28 ( 70%)	4 (10%)	15 (38%)	2 ( 5%)
3. no data	12	7 ( 58%)	1 ( 8%)	5 (42%)	1 ( 8%)
<b>E. ABO Identity</b>					
1. yes	101	66 ( 66%)	11 (11%)	32 (32%)	8 ( 8%)
2. no	15	7 ( 47%)	2 (13%)	5 (33%)	2 (13%)
3. no data	7	4 ( 57%)	0	2 (29%)	0



## Insulin Independence in Type-1 Diabetic Recipients

**Type-1 Diabetic Recipients of Adult Islet Allografts  
Summary of Insulin-Independent Cases (n=36) through Dec 31, 1997 (1)**

Case #	Institution	Year of Tx	Previous Pancreas/ Islet Tx	Pre-Tx C-Pept. (ng/mL)	No. of Donors Fresh/Cryo	IEQ / kg	Purity (%)	Period of Insulin Independence Days Post Tx	last update
1	Zurich	1978	-	B 0.00	1 -	3,846*	5	245 - 550	
2	Paris	1988	∅	S 0.03	1 -	2,143*	80	206 - 1,470	
3	St. Louis	1989	P 83	S 0.06	2 -	12,661	95	10 - 25	
4	St. Louis	1990	I 89	S 0.18	1 +2	14,735	98	33 - 341	
5	St. Louis	1993	I 89, I 90	S 0.42	2 +6	22,055	92	92 -> 948	Mar, 96
6	St. Louis	1993	-	S 0.08	3 +2	26,494	87	274 - 355	
7	Edmonton	1990	-	S 0.00	1 +4	9,692	70	70 - 821	
8	Edmonton	1992	-	S 0.00	1 +5	9,866	58	155 - 166 + 837 - 992	
9	Milan	1990	-	S 0.00	1 -	10,773	95	120 - 330	
10	Milan	1990	P 88	B 0.15	2 -	8,610	78	122 - 1,178	
11	Milan	1991	P 87	B 0.00	1 +2	16,859	80	210 - 360 + 480 - 635	
12	Milan	1992	-	B 0.00	2 -	11,567	80	150 - 1,537	
13	Milan#	1994	P 91, P 92	B 0.15	1 +2	28,995	55	41 - 65 + 92 - 133	
14	Milan#	1995	P 85	B 0.00	1 -	9,600	50	56 - 121	
15	Miami	1990	-	S 0.03	3 -	18,700	55	42 - 78	
16	Miami	1990	-	S 0.03	3 -	18,884	50	87 - 125	
17	Miami	1995	-	B 0.03	1 -	15,691	85	49 - 69	
18	Minneapolis	1992	-	S 0.00	1 -	7,882	5	326 - 1,241	
19	Minneapolis	1992	-	S 0.39	1 -	13,319	5	123 - 321	
20	Minneapolis	1995	P 92	NA	1 -	9,004	5	43 - 340	
21	Giessen	1992	-	S 0.10	1 -	6,156	92	401 - 1,150	
22	Giessen	1995	-	S 0.00	1 -	7,246	95	13 - 25	
23	Giessen	1995	-	B 0.08	1 -	12,031	90	312 - 844	
24	Giessen	1995	-	B 0.05	1 -	8,251	90	371 - 769	
25	Giessen	1995	-	B 0.00	1 -	6,376	85	382 - 650	
26	Giessen	1996	-	B 0.00	1 -	5,475	87	230 - 965	
27	Giessen	1996	-	B 0.00	1 -	7,777	90	547 - 724	
28	Giessen	1996	-	S 0.29	1 -	5,472	85	388 -> 1,188	Aug, 99
29	Giessen	1997	-	B 0.10	1 -	6,548	85	382 - 696	
30	Giessen	1997	-	S 0.05	1 -	7,896	90	249 -> 646	Mar, 98
31	Pittsburgh	1994	-	S 0.00	1 -	8,137	80	118 - 850	Aug, 99
32	Brussels	1995	-	S 0.00	6 -	4,400	70	218 -> 745	Aug, 97
33	Brussels	1996	-	S 0.00	8 -	2,600	59	194 -> 365	May, 97
34	Odense/ Milan <sup>§</sup>	1995	-	S 0.00	2 -	9,360	80	85 - 522	
35	Geneva	1996	-	B 0.19	2 -	8,800	28	61 -> 1,139	Aug, 99
36	Los Angeles VA	1996	-	NA	1 +3	NA	NA	231 - 262	

§ Islet Transplant/ Islet Isolation Institution; \* Islets / kg ; IEQ: Islet Equivalents (150 µm islets) per kg body weight of recipient; ∅ cholangio-carcinoma; # previous transplants and follow-up in Nantes; hemochromatosis, and type 1 diabetes; I: Islet; P: Pancreas; B: Basal; S: Stimulated

**Type-1 Diabetic Recipients of Adult Islet Allografts  
Summary of Insulin-Independent Cases (n=36) through Dec 31, 1997 (2)**

Case #	Institution	Year of Tx	Site of Tx	Recipient Category	# of Shared HLA-Ag		Immunosuppression		
					AB	DR	Induction	Maintenance	
1	Zurich	1978	spleen	SIK	1	0	ALG	+S+A+CPM	S+A
2	Paris	1988	epiploic flap	SIL	1	0	ALG	+S+C+A	S+C+A
3	St. Louis	1989	liver	IAK	3/1	2/1	ALG	+S(SD)+C+A	C+A
4	St. Louis	1990	liver	IAK	1/2/2	1/1/0	ALG	+S+A	S+A
5	St. Louis	1993	liver	SIK	1/0/0/0/1/0/0	1/0/1/0/1/0/1	OKT3	+S+C+A	S+C+A
6	St. Louis	1993	liver	SIK	1/1/3/1/1	1/1/1/2/1	ATG	+S+C+A	S+C+A
7	Edmonton	1990	liver	SIK	3/1/0/1/0	0/0/0/0/0	ALG	+S+C+A	S+C+A
8	Edmonton	1992	liver	SIK	3/1/0/0/1/0	1/1/1/0/0/1	ALG	+S+C+A	S+C+A
9	Milan	1990	liver	IAK	1	0	ALG	+S+C+A	S+C+A
10	Milan	1990	liver	IAK	1/2	1/0	ALG	+S+C+A	S+C+A
11	Milan	1991	liver	SIK	NA	NA	ALG	+S+C+A	S+C+A
12	Milan	1992	liver	IAK	NA	NA	ALG	+S+C+A	S+C+A
13	Milan	1994	liver	IAK	0/1/2	NA	ATG	+S+C+A	C+A
14	Milan	1995	liver	IAK	0	NA	ATG	+S+C+A	S+C+A
15	Miami	1990	liver	IAK	0/2/0	1/1/0	OKT3	+S+C+A	S+C+A
16	Miami	1990	liver	IAK	0/0/0	0/1/0	OKT3	+S+C+A	S+C+A
17	Miami	1995	liver	SIK	0	0	ATG	+S+T+MMF	S+T+MMF
18	Minneapolis	1992	liver	SIK	1	1	ALG	+S+C+A+D	S+C+A
19	Minneapolis	1992	liver	SIK	2	0	ALG	+S+C+A+D	S+C+A
20	Minneapolis	1995	liver	IFPP	2	1	None	+S+C+MMF	S+C+MMF
21	Giessen	1992	liver	IAK	2	1	ATG	+S+C	S+C
22	Giessen	1995	liver	ITA	1	0	anti-CD4	+S(SD)+C	-
23	Giessen	1995	liver	SIK	1	1	ATG	+S+C+A	S+C+A
24	Giessen	1995	liver	SIK	2	1	ATG	+S+C+A	S+C+A
25	Giessen	1995	liver	IAK	2/0	1/0	ALG	+S+C+A	S+C+A
26	Giessen	1996	liver	IAK	1	0	ALG	+S+C+A	S+C+A
27	Giessen	1996	liver	SIK	0	1	ATG	+S+C+A	S+C+A
28	Giessen	1996	liver	SIK	1	1	ATG	+S+C+MMF	S+C+MMF
29	Giessen	1997	liver	IAK	1	0	ALG	+S+C+A	S+C+A
30	Giessen	1997	liver	SIK	2	0	ATG	+S+C+A	S+C+MMF
31	Pittsburgh	1994	liver	SIK	3	2	None	S+T	S+C+A
32	Brussels	1995	liver	IAK	0/0/1/0/1/1	0/1/1/0/1/1	None	+S+C+A	C+A
33	Brussels	1996	liver	IAK	0/0/0/0/1/0/1/0	0/1/1/0/1/1/1/0	None	+S+C+A	S+C+A
34	Odense/Milan <sup>§</sup>	1995	liver	SIK	2/NA	1/NA	ATG	+C	C+MMF
35	Geneva	1996	liver	IAK	1/2	1/0	ATG	+S+C+A	S+C+A
36	Los Angeles VA	1996	liver	SIL	NA	NA	None	+S+T+MMF	S+C+MMF

§ Islet Transplant/ Islet Isolation Institution; SIK: Simult. Islet Kidney; SIL: Simult. Islet Liver; IAK: Islet After Kidney; IFPP: Islets From Previous Pancreas (i.e. isolated from a previously removed vascularized pancreas graft); S: Steroids; SD: Single Dose; C: Cyclosporin A; A: Azathioprine; MMF: Mycophenolate Mofetil; T: Tacrolimus; CPM: Cyclophosphamide; D: Deoxyspergualin; NA: Not Available



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## Acknowledgements

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When the responsibility for the islet registry component was transferred to Giessen in 1989, the reports to the International Pancreas Transplant Registry (IPTR) were graciously passed on to the ITR by Dr. David E.R. Sutherland.



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