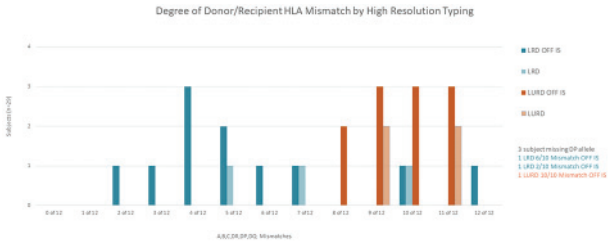
Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

T-cell chimerism (>50%), stable renal function, and no evidence of biopsy-proven rejection.

Results: Samples from 32 of the 37 subject pairs were available for analysis. All 32 recipients (ages 18-65 years) have been followed from 4.5-12 years. Two recipients were re-transplants. Of the 29 donor/recipient (D/R) pairs with data from all 12 alleles, 21 were mismatched between 6 to 12 alleles (6 related, 15 unrelated), and 8 were mismatched between 2 and 5 alleles (all related). Three D/R pairs were missing DP data (one was mismatched 6 of 10, another 10 of 10, and a third 2 of 10 alleles). Despite the high degree of mismatch, durable chimerism allowed for full IS withdrawal in 25 of these 32 subjects (time off IS from 3.5-11 years). 12/25 off IS were from unrelated D/R pairs and ≥ 8 HLA mismatches. The majority showed >95% donor whole blood/T-cell chimerism. Three exhibited stable mixed chimerism ranging between 40% - 60%. Of the subjects not off IS, two failed to engraft their cells, four lost chimerism by 4 months, and one developed GvHD. Durably chimeric patients retained chimerism after removal of IS, remain rejection-free without donor-specific antibody for up to 12 years following KTx, and have not resumed IS. Transiently chimeric subjects resumed endogenous hematopoiesis and are maintained on low-dose IS with stable renal function. There were two cases of GvHD. One had grade 2 lower GI acute GvHD and responded to steroids. He is off IS with normal renal function. The second GvHD patient presented late with treatment-resistant lower GI GvHD with associated tissue-invasive CMV colitis that proved fatal at 11 mos post-Tx.



Conclusion: High levels of durable chimerism and tolerance with a low (5.5%) incidence of GvHD have been achieved in highly mismatched related and unrelated recipients of FCR001 + KTx.

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Cryopreservation of Allogeneic Hematopoietic Cell Grafts Did Not Adversely Impact Early Post-Transplant Survival during the First Six Months of the COVID-19 Pandemic

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Background: The COVID-19 pandemic necessitated a substantial increase in the use of cryopreserved hematopoietic stem cell (HSC) grafts from both related (RD) and unrelated donors

Table 1. Patient and transplant characteristics

Variable	Fresh 2019 N (%)	Cryopreserved 2020 N (%)
Number of recipients	2499	959
Recipient age		
Median (Range)	55 (0-79)	58 (0-82)
Donor-recipient sex match		
M-M	1013 (41)	339 (35)
M-F	589 (24)	251 (26)
F-M	463 (19)	169 (18)
F-F	417 (17)	168 (18)
Missing	17 (1)	32 (3)
Recipient race		
White	2016 (81)	792 (83)
Black or African-American	201 (8)	61 (6)
Asian	109 (4)	23 (2)
Native Hawaiian or other Pacific Islander	6 (<1)	1 (<1)
American Indian or Alaska Native	10 (<1)	4 (<1)
More than one race	22 (1)	5 (1)
Missing	135 (5)	73 (8)
Recipient ethnicity		
Hispanic or Latino	311 (12)	110 (11)
Not Hispanic or Latino	2100 (84)	809 (84)
Missing	88 (4)	40 (4)
HCT-CI		
0	547 (22)	202 (21)
1	381 (15)	165 (17)
2	344 (14)	146 (15)
3+	1206 (48)	437 (46)
Missing	21 (1)	9 (1)
KPS		
< 90	1011 (40)	405 (42)
90-100	1429 (57)	540 (56)
Missing	59 (2)	14 (1)
Donor-recipient CMV match		
+/+	816 (33)	312 (33)
+/-	303 (12)	123 (13)
-/+	676 (27)	293 (31)
-/-	686 (27)	224 (23)
Missing	18 (1)	7 (1)
HLA match		
HLA-identical sibling	378 (15)	91 (9)
Other related	467 (19)	147 (15)
Well-matched unrelated (8/8)	1449 (58)	629 (66)
Mismatched unrelated	205 (8)	92 (10)
Disease		
AML	921 (37)	379 (40)
ALL	338 (14)	158 (16)
MDS	480 (19)	189 (20)
Other leukemias	128 (5)	42 (4)
Lymphoma	163 (7)	65 (7)
Other malignancies	180 (7)	72 (8)
SAA	104 (4)	31 (3)
Non-malignant diseases	185 (7)	23 (2)
Conditioning intensity		
No drugs reported	7 (<1)	0
MAC	1024 (41)	392 (41)
RIC	919 (37)	394 (41)
NMA	245 (10)	92 (10)
N/A, non-malignant disease	282 (11)	53 (6)
Missing	22 (1)	28 (3)
GVHD prophylaxis		
Ex-vivo T-cell depletion	38 (2)	0
CD34 selection	27 (1)	0
Post-Cy	767 (31)	383 (40)
Tac based	1447 (58)	518 (54)
CsA based	175 (7)	33 (3)
Other	18 (1)	14 (1)
Missing	27 (1)	11 (1)
ATG/Campath use		
No	1778 (71)	736 (77)
Yes	721 (29)	223 (23)
Year of transplant		
2019	2499 (100)	0
2020	0	959 (100)
Graft type		
Marrow	665 (27)	109 (11)
PBSC	1834 (73)	850 (89)
TNC for bone marrow (x10⁸/kg)		
N Eval	584	91
Median (Range)	3.09 (0.01-767.54)	2.38 (0.04-13.10)
CD34 count for PBSC (x10⁶/kg)		
N Eval	1810	838
Median (Range)	6.26 (0.02-83855)	5.79 (0.01-3478.4)
Follow-up among survivors, days		
N Eval	1822	764
Median (Range)	376 (99-792)	185 (42-416)
Neutrophil engraftment follow-up, days		
N Eval	2483	958
Median (Range)	15 (0-431)	16 (0-242)
Platelet engraftment follow-up, days		
N Eval	2463	807
Median (Range)	20 (1-420)	21 (1-190)

(URD) to ensure patients had a graft available prior to the start of conditioning for hematopoietic cell transplantation (HCT). Recent analyses of the impact of cryopreservation on patients outcomes have been conflicting. We sought to evaluate early post-HCT clinical outcomes in patients reported to the CIBMTR database who received a first allogeneic HCT using cryopreserved grafts from March through August 2020.

Methods: Key study endpoints were hematopoietic engraftment and overall survival (OS). We compared these outcomes to those in patients allografted using fresh products transplanted between March through August 2019. The Pearson chi-square test was used for comparing discrete variables; the Kruskal-Wallis test was used for comparing continuous variables. Multivariate analysis (MVA) using a Cox proportional hazards model was performed for OS after adjusting for confounders and testing the proportional hazards assumption. Neutrophil engraftment by D28 and platelet engraftment by D100 were analyzed using multivariate logistic regression.

Results: This study included 959 and 2,499 recipients of cryopreserved and fresh products, respectively. Patient characteristics are presented in Table 1. Recipients of cryopreserved grafts were older, more likely to receive URD grafts, PBSC as the graft source and post-transplant cyclophosphamide (PTCy) for graft versus host disease (GVHD) prophylaxis. Due to differences in duration of follow-up between the cohorts, follow up for the OS analysis was censored at Days 100 and 180. MVA results are presented in Table 2. No impact of cryopreservation on OS at either D100 (HR 0.93, p=0.72) or D180 (HR 1.10, p=0.34) post HCT was detected (see also Figure 1). When we performed the MVA for OS limiting the analysis to URD recipients only, the results were unchanged. Median time to neutrophil and platelet engraftment were both delayed by 1 day in recipients of cryopreserved grafts (16 vs. 15 days and 21 vs. 20 days, respectively) but there was no difference in the risk of primary graft failure by D28 (OR 1.38, p=0.96). There were no interactions identified between donor or graft type for OS or engraftment. Other important clinical outcomes such as secondary graft failure, acute GVHD, and early relapse will be included at the time of abstract presentation.

Table 2. Multivariate analysis of survival and engraftment

	Overall Survival, 100 days		Overall Survival, 180 days		Neutrophil Engraftment		Platelet Engraftment	
	HR (95% CI)	P-value	HR (95% CI)	P-value	OR (95% CI)	P-value	OR (95% CI)	P-value
Cryopreservation		0.72		0.34		0.96		0.005
Fresh product	1.00		1		1.00		1.00	
Cryopreserved product	0.93 (0.64,1.36)	0.72	1.10 (0.91,1.33)	0.34	1.38 (0.60,1.62)	0.96	0.67 (0.50,0.88)	0.005
HCT-CI		0.02				0.001		
0-2	1.00				1.00			
3+	1.85 (1.20,2.86)	0.006			0.37 (0.21,0.63)	0.15		
Missing	1.15 (0.28,4.62)	0.85			0.48 (0.11,2.12)	0.77		
KPS		<.0001		<.0001		0.001		<.0001
90-100	1.00		1.00		1.00		1.00	
<90	1.74 (1.36,2.23)	<.0001	1.55 (1.29,1.86)	<.0001	0.55 (0.40,0.76)	0.22	0.51 (0.39,0.66)	0.03
Missing	0.96 (0.35,2.60)	0.93	0.95 (0.47,1.93)	0.88	0.58 (0.22,1.53)	0.62	0.75 (0.32,1.80)	0.90
Donor group		0.002		0.0004				<.0001
Unrelated 8/8	1.00		1.00				1.00	
HLA-identical sibling	0.53 (0.33,0.87)	0.01	0.75 (0.55,1.02)	0.06			2.62 (1.43,4.79)	<.0001
Other related	1.25 (0.91,1.70)	0.16	1.23 (0.97,1.55)	0.08			0.48 (0.36,0.65)	<.0001
Mismatched unrelated (≤ 7/8)	1.53 (1.04,2.23)	0.03	1.58 (1.20,2.09)	0.001			0.50 (0.34,0.74)	0.0003
Disease status				0.0005		0.004		<.0001
CR1/2 or early MDS			1.00		1.00		1.00	
Other malignancies or disease status			1.38 (1.15,1.65)	0.0005	0.63 (0.46,0.86)	0.004	0.53 (0.40,0.69)	<.0001
Recipient age				0.0005				
60-69 years			1.00					
<10 years			0.57 (0.37,0.89)	0.0137				
10-17 years			0.47 (0.28,0.80)	0.0056				
18-29 years			0.51 (0.34,0.75)	0.0008				
30-39 years			0.57 (0.38,0.86)	0.0067				
40-49 years			0.70 (0.51,0.97)	0.0297				
50-59 years			0.91 (0.71,1.15)	0.4241				
70+ years			0.87 (0.65,1.16)	0.3275				
GVHD prophylaxis						<.0001		
Tac based					1.00			
Ex vivo TCD					0.33 (0.08,1.45)	0.72		
CD34 selection					0.13 (0.04,0.39)	0.02		
Post-Cy					0.31 (0.22,0.44)	0.20		
CsA based					0.76 (0.35,1.64)	0.1		
Other					0.53 (0.12,2.34)	0.70		
Graft type						0.0004		
PBSC					1.00			
Marrow					0.53 (0.37,0.75)	0.0004		

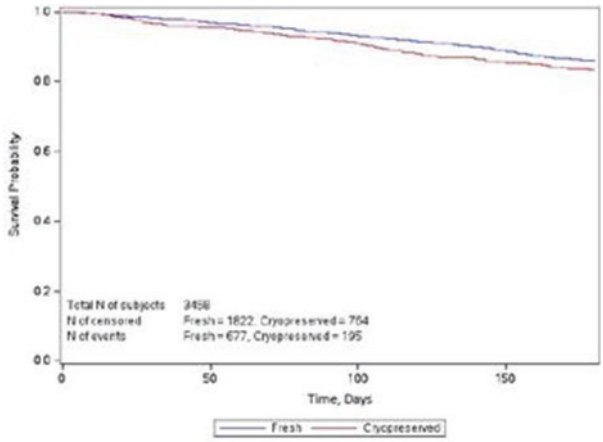

Figure 1. Probability of survival in fresh versus cryopreserved grafts

Conclusion: The shift in clinical practice to cryopreserved products early in the pandemic did not adversely impact early post HCT OS or risk of primary graft failure. However, follow up is short and it will be critical to follow this cohort and subsequent recipients of cryopreserved grafts for much longer periods to determine the ultimate impact of cryopreservation on outcomes.

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Haploidentical Versus Matched Unrelated Donor Transplants for Lymphomas Using Post-Transplant Cyclophosphamide: A Joint CIBMTR/EBMT Study

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