Increased Risk Of Revision After ACLR With Soft Tissue Allograft Compared To Hamstring Autograft

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- We have no potential conflicts with this presentation.
- IRB approval was obtained for this investigation.

Background

- Despite years of study, controversy still exists regarding the ideal graft for anterior cruciate ligament reconstruction (ACLR).
- Allograft use is increasingly popular in the US having exceeded 40% in some large hospital and group settings.[1,2]
- Summary studies have reported autografts have better stability and lower revision rates than allografts[3-6] but others report no difference.[7-9]
- Two meta-analyses limited their cohorts to comparing autograft and non-irradiated allograft tissue and reported no differences in outcomes.[10,11]
- One meta-analysis compared hamstring autograft and soft tissue allografts and also found no difference.[12]
- Yet several large cohort studies have reported a 2-4 x higher risk of graft failure when allograft is used.[13-16]

Background

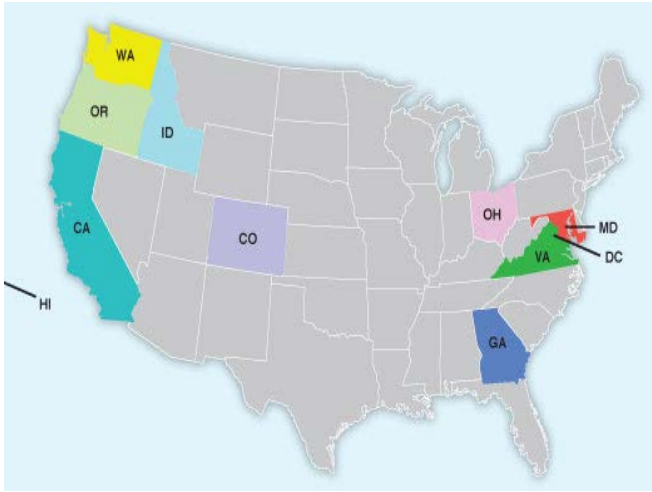
- The lack of clarity regarding graft performance is due to two primary issues:
  - Many studies are underpowered to detect a difference in outcome
  - Allografts are often grouped together despite the different graft types and different processing methods.

Purpose

- (1) To compare the risk of aseptic revision in patients undergoing primary ACLR with soft tissue grafts.
- (2) Specifically to evaluate the risk of revision by tissue type (soft tissue allograft and hamstring autograft) and tissue processing (irradiation, chemical processing, or non-processed)

Methods

- Design: Retrospective cohort study
- Setting: Kaiser Permanente, an Integrated Health Care System covering 9.5 million members in the United States
- Data source: Kaiser Permanente ACLR Registry
  - Prospective data collection
  - Outcomes validated via chart review
- Timeframe: February 2005 – September 2012
- Study sample:
  - Primary single ligament ACLR with BPTB autograft or BPTB allograft
  - 282 surgeons from 43 hospitals
  - 6 regions (Hawaii, Southern California, Northern California, Northwest, Mid-Atlantic, Colorado)



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Methods

- Outcome of interest: Aseptic revision ACLR
- Exposures of interest:
  1. Graft type :
     - Hamstring autograft
     - Soft tissue allograft: tibialis anterior or posterior, peroneal tendons, hamstring tendons
  2. Tissue processing:
     - Irradiation < 1.8 Mrad or $\underline{\geq}$ 1.8 Mrad
     - Chemical processing
       - Allowash (LifeNet Virginia Beach, VA), AlloTrue (AlloSource Centennial, CO)
         - » Ultrasonic bath with detergents, antibiotics, alcohol, and peroxide
       - BioCleanse (Regeneration Technologies Inc. Alachua, FLA)
         - » Oscillating positive and negative pressure with alcohol and peroxide
     - Sterilely harvested non-processed tissue
- Analysis: survival analysis (Kaplan Meier curves and Cox regressions)

Results

- Sample Size: 9458 soft tissue grafts (60.3% Auto, 39.7% Allo)

		Autograft	Allograft
Age	Median	24.3	34.6
	IQR	17.7-33.8	24.1-43.2
		N (%)	N (%)
Gender	Female	2210 (38.7)	1474 (39.3)
	Male	3497 (61.3)	2277 (60.7)
Race	White	2561 (44.9)	2010 (53.6)
	Hispanic	1413 (24.8)	745 (19.9)
	Asian	553 (9.7)	468 (12.5)
	Black	402 (7.0)	214 (5.7)
	Multi/Other	208 (3.6)	105 (2.8)
	Unknown	570 (10.0)	209 (5.6)

Processing Type	N (%)
All allografts	3751 (100.0)
No Processing	483 (12.9)
<1.8Mrad Irradiation	
- w/o Chemical Processing	1013 (27.0)
- with Chemical Processing	1307 (34.8)
≥1.8Mrad Irradiation	
- w/o Chemical Processing	444 (11.8)
- with Chemical Processing	258 (6.9)
BioCleanse	246 (6.6)

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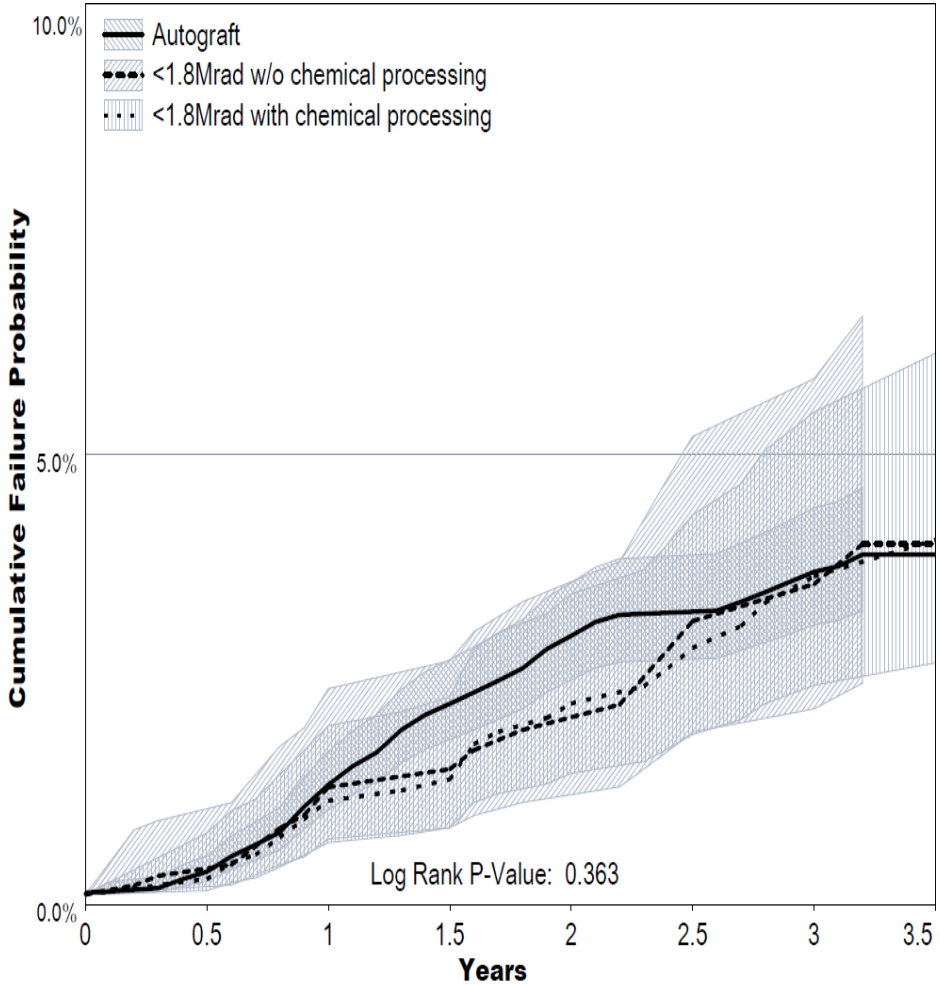
Results

	# of Cases	# of Revisions	Crude Revision Rate (%)	Cumulative Failure at 3 years with 95% CI
Autograft	5707	132	2.3	3.5 (2.9 , 4.2)
Allograft (Total)	3751	83	2.2	3.7 (2.9 , 4.7)
No Processing	483	5	1.0	2.0 (0.8 , 5.0)
<1.8Mrad w/o Chemical Processing	1013	19	1.9	3.0 (1.8 , 5.1)
<1.8Mrad with Chemical Processing	1307	28	2.1	3.2 (2.1 , 4.9)
≥1.8Mrad w/o Chemical Processing	444	15	3.4	4.7 (2.7 , 8.0)
≥1.8Mrad with Chemical Processing	258	9	3.5	6.8 (3.2 , 14.2)
BioCleanse	246	7	2.8	5.3 (2.4 , 11.6)

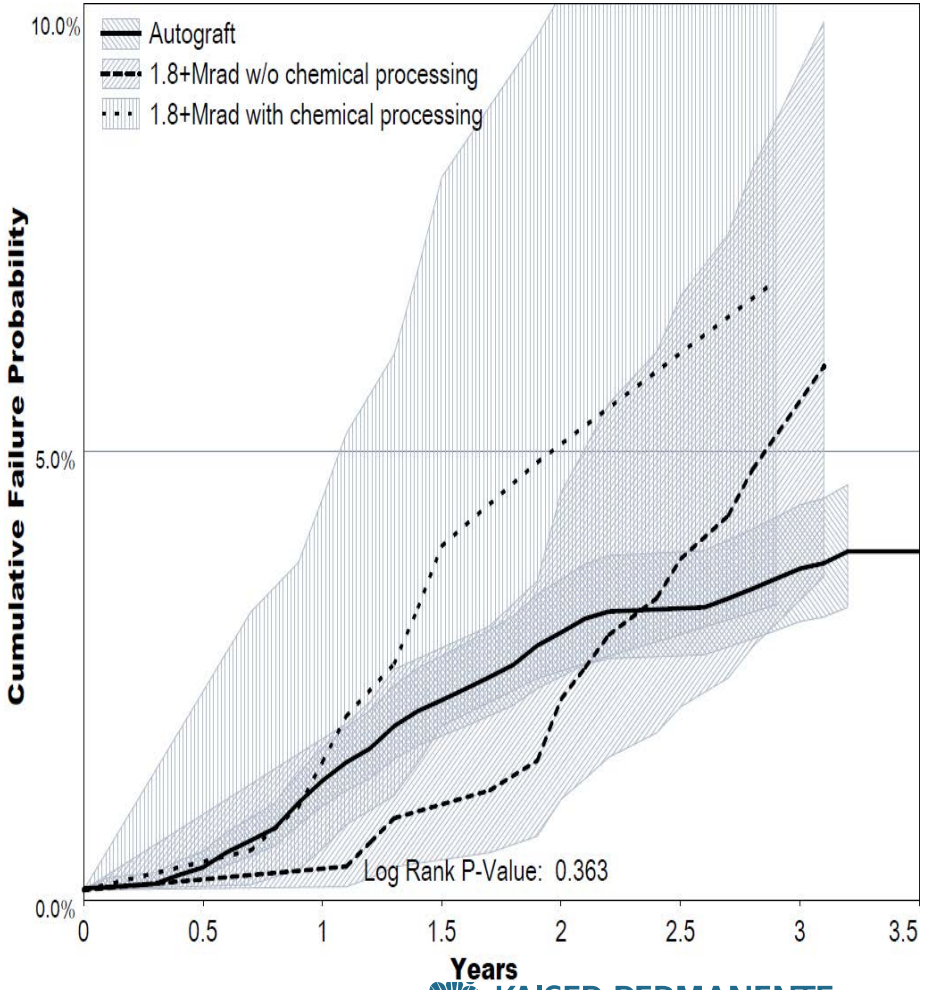
Total Sample Risk of Revision	Hazard Ratio (95%CI)	P-Value
Allograft within 2.5 years vs. Autograft	1.41 (1.03 - 1.92)	0.031
Allograft after 2.5 years vs. Autograft	2.94 (1.48 - 5.83)	0.002

Results: Cumulative Revision Probability

< 1.8 Mrad allograft vs autograft



≥ 1.8 Mrad allograft vs autograft



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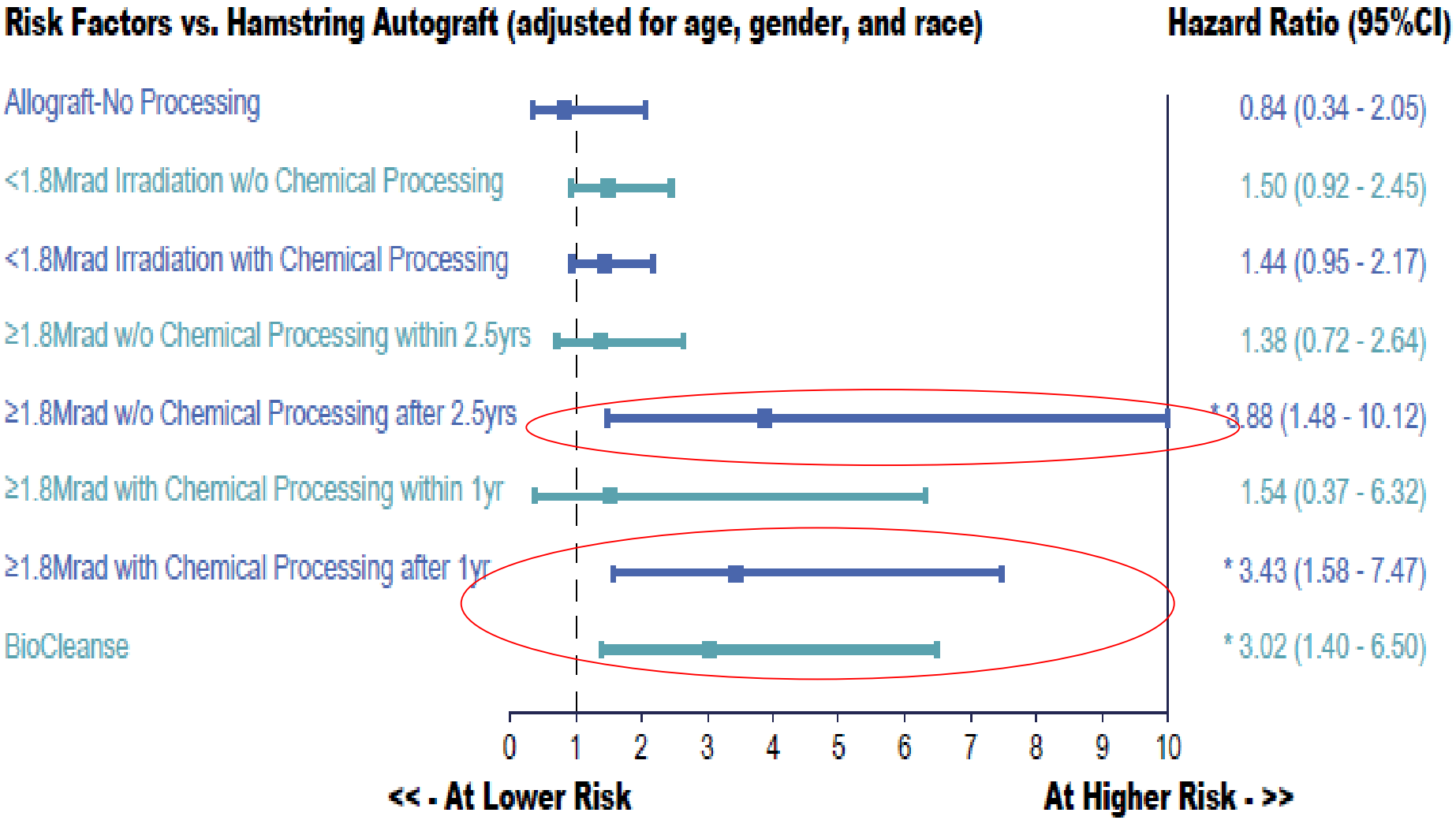
Results: Revision Risk Factors



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Discussion

- **Soft tissue allografts** processed with < 1.8 Mrads with and without chemical processing and non processed grafts **did not have a significantly different risk of revision** compared to hamstring autografts.
- **BioCleanse processed grafts** had a 3.0 X higher risk of revision compared to hamstring autografts.
- Significant time interactions were noted with the performance of soft tissue allografts compared to hamstring autografts:
  - Allografts ≥ 1.8 Mrad without chemical processing had a **no difference in risk in the first 2.5 years** and a **3.9 X higher risk after 2.5 years.**
  - Allografts ≥ 1.8 Mrad with chemical processing had a **no difference in risk in the first year** and a **3.4 X higher risk after one year.**

Discussion: Strengths & Limitations

- Limitations
  - Surgical technique and rehabilitation were not standardized.
  - Return to sports and activity levels not evaluated.
  - Strength, knee laxity and functional outcomes not available.
  - Loss to f/u : 25.9% (addressed in analysis).
- Strengths
  - Large racially diverse sample.
  - Large sample size.
  - Prospective standardized method of data collection and validation.
  - Diverse patient and surgeon sample make the results generalizable to the greater population of ACLR patients and providers/hospitals involved in their care.

Conclusions

- Soft tissue allograft performance is influenced by:
  - Graft processing and time.
- More highly processed tissue leads to a higher risk of revision at earlier time frames.
  - ≥ 1.8 Mrads without chemical processing has an increased risk revision after 2.5 years
  - ≥ 1.8 Mrads with chemical processing has an increased risk of revision after only one year
- Surgeons and patients need to be aware of the increased risk of revision, and the time interaction, associated with soft tissue allograft usage for ACLR.

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