#0008
11-20-15

David W. Field (00378-1984)
LOWENSTEIN SANDLER LLP
65 Livingston Avenue
Roseland, New Jersey 07068
973.597.2500
Attorneys for Defendant
LifeCell Corporation

NOV 20 2015

IN RE: ALLODERM® LITIGATION

CASE CODE 295

MICHAEL SIMINERI and KAREN SIMINERI, h/w,

Plaintiffs,

v.

LIFECELL CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
Docket No. MID-L-5972-11 CM

Civil Action

ORDER

The above matter having been opened to the Court by Lowenstein Sandler LLP, attorneys for defendant LifeCell Corporation, on application for an Order barring plaintiff from introducing any evidence or argument about the risks, effects or consequences of using AlloDerm in surgeries involving a bridging or interpositional technique of implantation at the time of trial, and the Court having considered all papers submitted by the parties and the arguments thereof, and for good cause and the reasons ~~stated on the record by the Court~~ set forth in the attached memorandum of decision,

It is on this the 20th day of November, 2015,

ORDERED that defendant's motion is hereby ~~granted; and it is further~~ Granted in part, and it is further

ORDERED that plaintiffs are barred from introducing any evidence or argument about the risks, effects or consequences of using AlloDerm in surgeries involving a bridging or interpositional technique of implantation at the time of trial; ~~and it is further~~ where such evidence relates exclusively to surgeries using a bridged repair; and it is further ordered that Defendant's motion to bar evidence or argument that includes information for both bridged and reinforced repairs is DENIED without prejudice.

ORDERED that a copy of this Order be ~~served~~ posted online for on all counsel of record within 7 days hereof.

4/2/21

Hon. Jessica R. Mayer, J.S.C.

OPPOSED

PAPERS CONSIDERED

	Yes	No	Date
Notice of Motion	✓		
Movant's Affidavits	✓		
Movant's Brief	✓		
Answering Affidavits	✓		
Answering Brief	✓		
Cross Motion			
Movant's Reply			
Other			

SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
JESSICA R. MAYER, J.S.C.
JUDGE

MIDDLESEX COUNTY COURTHOUSE
P.O. BOX 964
NEW BRUNSWICK, NEW JERSEY 08903-964

NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

Memorandum of Decision on Defendant's Motion *In Limine* to Bar Evidence or Argument About the Risks, Effects, or Consequences of Using AlloDerm® in Surgeries Involving a Bridging or Interpositional Technique of Implantation

NOV 20 2015

In Re: AlloDerm® Litigation, Case Code 295

Michael Simineri and Karen Simineri v. LifeCell Corporation

Docket No. MID-L-5972-11 CM

For Plaintiffs: Lawrence R. Cohan, Esq., Joseph J. Fantini, Esq., and Sol H. Weiss, Esq., Anapol Weiss.

For Defendant: David W. Field, Esq., Stephen R. Buckingham, Esq., Lowenstein Sandler LLP.

Dated November 20, 2015

Defendant LifeCell Corporation ("LifeCell" or "Defendant") moves to preclude evidence and argument concerning the risks, effects, and consequences of AlloDerm® surgeries utilizing a bridged technique of implantation. Counsel for the parties presented oral argument on this motion during a case management conference held on November 17, 2015. Upon considering the arguments of the parties, legal memoranda, exhibits and relevant case law,[1] the court determines

[1] The parties signed a consent order stipulating that New Jersey law governs all issues in the AlloDerm® cases. See consent order dated January 15, 2015.

that LifeCell's motion to bar evidence and testimony relating to the risks, effects, and consequences of AlloDerm® implanted in a bridged technique is **GRANTED IN PART.**

Plaintiff Michael Simineri underwent a hernia repair surgery on October 24, 2007. His surgeon, Dr. Gerardo Garcia, implanted the AlloDerm® graft using an underlay technique, placing the AlloDerm® inside the abdomen and closing the fascia over the AlloDerm®.[2] There are several surgical techniques used to implant an Alloderm® graft for hernia repair, including underlay, overlay (where the fascia is closed with the AlloDerm® placed over the tissue as a reinforcement), and interpositional or "bridged," where the AlloDerm® is sutured to the edge of the fascia to close the defect.[3] Defendant seeks to bar all evidence and testimony related to the risks, effects, and consequences of AlloDerm® used in a bridged technique. Defendant further specifies:

> LifeCell recognizes that some medical literature discusses both bridged and reinforced repairs. When such literature provides separate recurrence rates for bridged and reinforced repairs, LifeCell is asking that the bridged information be redacted out of the document. Instead, and when redaction may not be feasible, LifeCell is seeking a ruling prohibiting plaintiff from relying on and making arguments based on the bridged data, which would mislead the jury. For articles in which only bridged repairs were involved, or where bridged and reinforced repairs are included but not analyzed separately, LifeCell seeks the preclusion of all such evidence as irrelevant, misleading and unfairly prejudicial.
>
> [Defendant's Brief in Support of Motion *in Limine* to Preclude Plaintiffs from Introducing Documents or Testimony Discussing the Risks, Effects, and Consequences of AlloDerm Surgeries Involving a Bridged Technique of Implantation ("Def.'s Br.") 2, n.1.]

Defendant argues that, due to the higher recurrence rate in hernia repair surgeries utilizing a bridged technique—a technique not utilized in Mr. Simineri's surgery—presenting any evidence about recurrence rates for bridged repairs will be misleading and unduly prejudicial. Defendant

---

[2] Certification of David W. Field ("Field Cert."), Ex. A, 34:5-35:12.

[3] Field Cert, Ex. C, 156:22-25.

cites deposition testimony from Plaintiffs' expert, Dr. Roger Huckfeldt,[4] purportedly acknowledging a higher recurrence rate in bridged repairs as opposed to underlay or overlay repairs.[5] Defendant further cites two of the scholarly articles relied upon by its own expert, Dr. Howard Langstein, for the same proposition.[6]

Plaintiffs argue in opposition to Defendant's motion that their experts never testified that recurrence rates are higher with bridged repairs than with the other techniques, and call into question the scientific reliability of the studies cited by Defendant for that proposition.[7] Plaintiffs further assert that any studies which do purport to find such a distinction in recurrence rates do not establish any difference in the rates of bulging and laxity among bridged versus reinforced repairs.[8] Plaintiffs argue, apparently in the alternative, that any potential differences in outcome attributable to implantation technique were not known at the time of Mr. Simineri's surgery, thus LifeCell had a duty to warn of any known negative outcomes from the use of AlloDerm®, even in bridged repairs.[9] According to Plaintiffs, since much of the early clinical data on AlloDerm® related to its use in a bridged repair, preclusion of such studies would unfairly prevent Plaintiffs from presenting evidence of the dangers and defects of AlloDerm® which were known at the time of Mr. Simineri's surgery.[10] Plaintiffs additionally argue that LifeCell itself did not believe implantation technique to be relevant to hernia surgery outcomes, as its own marketing materials cited studies using a

---

[4] Defendant also cites deposition testimony from experts who have been barred from testifying in accordance with the court's decisions of August 14, 2015, or whom the parties have stipulated will not testify at trial, and thus, the court disregards statements made by these experts.

[5] Def.'s Br. 4; Field Cert. Ex. C, 161:15-23 ("there is data to show that if you close [the defect], your recurrence rate is lower … .").

[6] Field Cert. Ex. G., Ex. H.

[7] Plaintiffs' Response to Defendant's Motion *in Limine* to Preclude Plaintiffs from Introducing Documents or Testimony Discussing the Risks, Effects, and Consequences of AlloDerm Surgeries Involving a Bridged Technique of Implantation ("Pls.' Opp.") 7-16.

[8] Id. at 6.

[9] Id. at 13-15.

[10] Id. at 6.

bridged repair, and the AlloDerm® Instructions for Use ("IFUs") indicated that AlloDerm® could be used in a bridged or interpositional repair.[11]

Unless subject to specific exclusions, "all relevant evidence is admissible." N.J.R.E. 402. Under the New Jersey Rules of Evidence, "'[r]elevant evidence' means evidence having a tendency in reason to prove or disprove any fact of consequence to the determination of the action." N.J.R.E. 401. Evidence is considered relevant if there is a logical connection between the proffered evidence and what the party seeks to prove. See Furst v. Einstein Moomjy, Inc., 182 N.J. 1, 15 (2004) (citing State v. Hutchins, 241 N.J. Super. 353, 358, (App. Div. 1990). Evidence which is relevant to the action may nonetheless be excluded "if its probative value is substantially outweighed by the risk of (a) undue prejudice, confusion of issues, or misleading the jury . . . ." N.J.R.E. 403.

Initially, the court notes that Plaintiffs challenged the scientific reliability of the Defendant's cited studies as part of a previous motion to bar the testimony of Dr. Howard Langstein.[12] This court rejected that argument in its memorandum of decision denying the motion on August 14, 2015,[13] and relies on the reasoning set forth in that decision. In support of the argument that Plaintiffs' expert, Dr. Huckfeldt, never acknowledged a different recurrence rate between bridging and reinforced repairs, Plaintiffs cite a portion of Dr. Huckfeldt's deposition where he testified that the AlloDerm® IFU indicated bridging as an acceptable use.[14] The court concludes that Dr. Huckfeldt was discussing the information provided by the IFU, and not whether he personally endorses a bridged repair. In fact, Dr. Huckfeldt further testified at his deposition

[11] Id. at 3-5.
[12] Plaintiffs' Motion to Exclude the General Opinions of Defendant's Expert Howard N. Langstein, M.D, dated July 9, 2015.
[13] Order and Memorandum of Decision on Plaintiffs' Motions to Bar the Testimony of Dr. Howard Langstein, dated August 14, 2015.
[14] Certification of Joseph J. Fantini ("Fantini Cert."), Ex. K, 158:25-159:5.

that "there is data to show that if you close [the defect], your recurrence rate is lower." Indeed, Dr. Huckfeldt's own expert report states: "Bridged repairs are by nature at increased risk for failure ... ."[15] Thus, there is sufficient evidence in the record to conclude that Plaintiffs' expert acknowledges a higher recurrence rate with bridged repairs.[16]

Plaintiffs' arguments regarding the early studies of AlloDerm® and LifeCell's own use of bridged studies are equally unavailing. Plaintiffs believe they should be permitted to present evidence of bad outcomes with a surgical technique that was not used in Mr. Simineri's surgery, because the connection between the bad outcome and the surgical technique was not known prior to Mr. Simineri's surgery. To present accurate information and avoid misleading the jury, the parties may not present evidence or testimony related to AlloDerm® implantation using a bridged technique. Data relating to a demonstrably less successful surgical technique is irrelevant, overly prejudicial, and misleading.

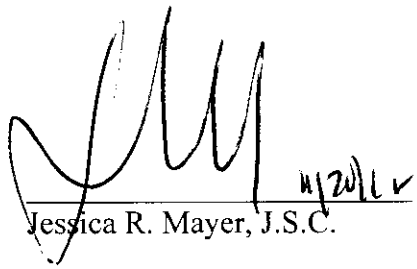
Evidence or testimony relating exclusively to surgeries using the bridged repair is barred. The motion to bar evidence or testimony that includes information for both bridged and reinforced repairs is reserved for trial. During the trial, the court can evaluate the specific portions of disputed evidence and determine whether redaction or preclusion of the evidence is appropriate.

---

[15] General Causation Report of Dr. Roger Huckfeldt, dated February 27, 2015, at 7.

[16] Plaintiffs' brief cites to a 2009 study concluding that the difference in hernia recurrence among surgical techniques is not statistically significant. Pls.' Opp. 11, Fantini Cert. Ex. N, 211. However, scientific arguments by Plaintiffs' counsel alone cannot support such a contention. Plaintiffs failed to include testimony from any of their experts concluding that surgical technique does not affect recurrence rates, and in fact, Dr. Huckfeldt testified to the contrary.

For the foregoing reasons, Defendant's motion to bar evidence and testimony regarding the risks, effects, and consequences of AlloDerm® implantation surgeries utilizing a bridged technique is **GRANTED IN PART**.



Jessica R. Mayer, J.S.C.