REVIEW ARTICLE

Outcomes in Implant-Based Breast Reconstruction Utilizing Biosynthetic Mesh: A Meta-Analysis

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Abstract

Biosynthetic mesh has become more popular for immediate breast cancer implant-based reconstruction as an alternative to acellular dermal matrix (ADM) for soft tissue support. This meta-analysis investigates the various biosynthetic options available as well as complications and outcomes. PubMed, MEDLINE, and Embase were systematically reviewed for studies investigating the following types of mesh, TIGR, Vicryl, PDO, TiLOOP, Durasorb, and Galaflex, and their associated outcomes. The meta-analysis was completed in accordance with PRISMA guidelines and was performed to determine overall complication rates in patients who underwent breast reconstruction with the use of mesh. Data were combined by a pooling of proportional outcomes as inherent to meta-analysis. Heterogeneity of included studies was assessed with the Q and I^2 statistical analysis. A total of 24 studies investigating six different types of mesh in 2167 individual breasts undergoing implant reconstruction were included. Summary effect sizes were calculated for the complications. The pooled rate of seroma formation was 5.26% (Q = 23.81%, I^2 = 37.01%) reported in 13 studies, hematoma formation was 2.5% (Q = 0.25%, I^2 = 58.27%) reported in 9 studies, skin necrosis was 5.5% (Q =2.86%, I^2 = 423.78%) reported in 10 studies, infection rate was 4.8% (Q = 6.02%, I^2 = 149.34%) in 21 studies, and implant loss was 3.85% (Q = 6.55%, I^2 =129.07%) reported in 10 studies. Overall, while differences in mesh characteristics exist, the reported rate of complications is low. Biosynthetic mesh options should be taken into consideration in breast reconstruction given their demonstrated safety, significant cost advantage, and potential decrease in short-term complications in comparison to acellular dermal matrices.

Post-mastectomy breast reconstruction is often pursued due to the physical and psychological benefits with up to 80% of patients receiving implant-based reconstruction versus autologous tissue flaps or no reconstruction at all.[1] Additionally, direct to implant reconstruction has become more popular lately compared to either delayed or two-stage reconstruction.[2] Acellular dermal matrices (ADM), from human, porcine, or bovine tissue, have been the gold standard for both dual plane submuscular reconstruction and prepectoral reconstruction to support the implant, support the soft tissue and provide durable coverage.[3] ADM materials act as a scaffold for host cells to invade and eventually create an autologous tissue layer.[4] While ADM use has been shown to be very effective, it is not without potential concern for higher complication rates and

increased costs of up to 20 times that of bioabsorbable mesh.[5,6] An alternative to ADM use has recently been proposed where synthetic mesh made from absorbable or permanent fibers are used as an internal bra for stabilizing the implant, with the added benefit of additional soft tissue support.

There are many different types of mesh available with varying characteristics, such as assorted Vicryl meshes available in the market, TIGR Matrix™ (Novus Scientific - Uppsala, Sweden), 3D Max Mesh™ (Bard, BD – Warwick, RI), Polydioxanone (PDO) Mesh™ (Poly-Med – Anderson, SC), Poly-4-hydroxybutyrate (P4HB) Mesh™ (Phasix Mesh, Bard, BD – Warwick, RI), Durasorb™ (Integra – Princeton, NJ), or Type-1a Polypropylene Mesh (TiLOOP Bra™, PFM Medical – Cologne, Germany). Many plastic and reconstructive surgeons use either ADM or mesh in their practice due to an overall better definition of the implant pocket and inframammary fold, improved capsular contracture rates, ability to use a dual-plane approach, and less muscle dissection needed in such an approach.[4,7] Various outcomes have shown improved results with some type of soft tissue support compared to no support.[8,9]

Specifically, capsular contracture rates for both ADM and synthetics mesh are significantly less than the up to 15-30% rate of capsular contracture often cited in the literature for breast reconstruction patients without the use of any mesh.[7,10,11] More recently, complications such as infection and seroma rates have been found to be lower in absorbable and non-absorbable mesh groups compared to the use of ADM.[12, 13] In a meta-analysis by Clark et al., biosynthetic mesh revealed a reduced risk of reoperation and explantation.[14] Another potential limitation of ADM is "red breast syndrome" (RBS) - an immune-mediated phenomenon where the skin overlying ADM becomes red but has no other signs of infection, is unresponsive to antibiotics, and ultimately resolves on its own.[15,16] It has been associated with many types of ADM, but most commonly with Alloderm™ (AbbVie - Chicago, IL).[15, 16] Despite the advantages of bioabsorbable mesh in breast reconstruction, these products have been developed much more recently, contributing to a delay in FDA approval for this indication.[14]

Given the increased popularity of synthetic meshes in post mastectomy implant reconstruction and the few recent studies showing improved outcomes, we elected to compile the available data looking at overall complication rates and outcomes with the use of synthetic mesh alone. Given the potential advantages of synthetic mesh use, future studies may evaluate synthetic mesh and ADM in a structured clinical trial. Herein, we present a systematic review of the literature to

compile objective data published with the use of various synthetic meshes, and a meta-analysis of outcomes.

METHODS

This study was completed in adherence with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines, employing PubMed, MEDLINE, and Embase databases.[17]

Literature Search

Search keywords on aforementioned databases included: "breast mesh", "TIGR", "TIGR mesh", "vicryl mesh breast", "3D max mesh", "polydioxanone mesh", "PDO mesh", "poly-4-hydroxybutyrate mesh", "P4HB mesh", "Durasorb", or "TiLOOP mesh". Any studies with mesh for abdominal surgery or non-English articles were excluded. We included any single-stage with immediate reconstruction or two-stage breast reconstruction with tissue expanders with any of the following types of mesh: Vicryl, TIGR, 3D max, polydioxanone (PDO), poly-4-hydroxybutyrate (P4HB), Galaflex, Durasorb, or TiLOOP. Studies with a minimum of 6-month follow-up were included. No articles were excluded based on year of publication or language of manuscript. Two independent authors (AA and SW) performed independent searches to select articles that matched inclusion criteria. Any articles that required additional screening were evaluated by two authors (AA and OS). Any further inclusion disputes were handled by the senior author (AL). Search was performed on April 20, 2024.

Data Abstraction

Authors systematically reviewed articles for any studies on breast reconstruction outcomes for patients who received implants or tissue expanders with the use of mesh support (Figure 1). Data extracted included number of patients, number of breasts, patient age, mesh type, reported follow up, and complication rates including implant loss, infection, skin necrosis, hematoma, and seroma.

Statistics

Meta-analysis was performed to determine overall complication rates in patients who underwent breast reconstruction with the use of mesh.[18] Data were combined by a pooling of proportional outcomes as inherent to meta-analysis. Hypothesis testing was performed by the use of a 2-sided student's t-test with significance set at 0.05 for all arms, and a p-value was calculated for all

effect summaries. Five complications were examined - hematoma, seroma, infection, skin necrosis, and implant loss. Effect summaries were recorded in Excel, and mean differences with 95% confidence intervals for these outcomes and risk ratios with a 95% confidence interval were calculated to estimate pooled differences across all complications. Both the fixed effects and random effects model were used in all analyses and reported in a forest plot format. Heterogeneity of included studies was assessed with the Q and I^2 statistical analysis, where an I^2 of less than 50% is considered to be a low amount of data heterogeneity, and greater than 75% considered to be significant heterogeneity.

RESULTS

This meta-analysis includes 24 studies investigating outcomes of six different types of mesh in 2167 individual breasts undergoing implant reconstruction as depicted in Table 1. The type of mesh included TIGR mesh (8 studies), Vicryl meshes (8 studies), Durasorb mesh (1 study), Galaflex (1 study), PDO mesh (3 studies), and TiLOOP mesh (3 studies).[6,9,19-40] Twelve studies involved immediate direct-to-implant breast reconstruction, while only one study involved two-stage reconstruction with tissue expanders and subsequent implant placement.[9,21,22, 24-26, 28, 19, 31-33,36,38] Eight studies included both direct-to-implant, or tissue expander reconstruction.[6,19,20,23,30,34,39,40] Three studies focused on delayed breast surgery with implant placement.[27,35,37] The summary effect sizes for complication rates including seroma, hematoma, skin necrosis, infection, and implant loss are summarized in Figure 2.

The rate of seroma was reported in 13 studies, with a pooled rate of 5.26% (Q = 23.81%, I^2 = 37.01%, Q_v = 75.63%, I^2_v = 80.17%), ranging from 1.2% (Vicryl) to 13.8% (TIGR) (Figure 3).[22,26] TIGR seroma rates averaged 5.2%, lower than the overall average of this meta-analysis.[19-26] One study reporting Durasorb seroma rates was 3.7%.[27] The mean Vicryl seroma rate was 5.5% and the mean Galaflex reported rate was 6.0%.[6,9,28-34] PDO rates were 2.8% on average.[35-37] TiLOOP seroma rates were reported to be 10.9%.[38-40] Overall, seroma rates greatly differed between studies with the same mesh and different meshes, demonstrating significant overall heterogeneity among studies.

Post-operative hematoma was reported in nine studies, with a pooled rate of 2.5% across all studies (Q = 0.25%, I^2 = 58.27%, Q_v = -5.56%, I^2_v = 3.70%), ranging from 0.9% to 6.7% (Figure 4).[23, 28] Casella et al. report a hematoma rate of 1.37% for TiLOOP mesh bra and Sigalove et al.

report a hematoma rate of 1.56% with the use of Galaflex.[34,38] TIGR mesh hematoma rates averaged 3.1%, similar to the overall hematoma rate across all included studies.[20,21,23] Vicryl mesh hematoma rates were reported at a mean of 2.7%.[28-30,32] Similar to the rate of postoperative seroma, hematoma complication incidence differed significantly between and among mesh types – demonstrating an affinity to a variable effects model (I_v^2 = 3.70%).

Skin necrosis was reported as a complication in ten included studies, with an overall rate of 5.5% across all breasts (Q =2.86%, I^2 = 423.78%, Q_v = -47.00%, I^2_v = 131.92%), ranging from 2.63% to 8.64%.[9,30] Thus, both the highest and lowest rates of skin necrosis reported were with the use of Vicryl meshes, with the mean rate of skin necrosis reported at 5.5% (Figure 5).[6,9,28,30,31] TIGR mesh skin necrosis rates averaged to be 5.1%, similar to the overall mean and 6.4% skin necrosis rate for Galaflex (Sigalove).[21,23,24,26,34]

Post-operative infection was reported in twenty-one total studies, with a pooled complication rate of 4.8% (Q = 6.02%, I^2 = 149.34%, Q_v = 9.98%, I^2_v = 50.32%), ranging significantly from 1.3% to 12.6% (Figure 6). [6, 9, 19-21, 23-26, 28-40] Implant loss within the first thirty days postoperatively was also reported in ten studies, with a pooled complication rate of 3.85% (Q = 6.55%, I^2 =129.07%, Q_v = -11.75%, I^2_v = 227.65%).[6,9,19-22,24,25,28,34] The lowest reported rate of implant loss was 0.8% with the use of Durasorb (Figure 7).[27]

DISCUSSION

Acellular dermal matrices have been used to improve cosmetic outcomes in breast reconstruction for almost two decades, since 2005, but lead to higher rates of seroma and infection than reconstruction methods without the use of ADM.[41,42] Alternative mesh products have been shown to be viable alternatives to ADM placement in breast reconstruction and several studies have reported decreased complication rates and overall healthcare cost compared to ADM.[5,6] The use of mesh in breast reconstruction offers additional advantages in controlling the breast pocket, especially in submuscular implant placement. It also confers more control of cosmetic outcomes in pre-pectoral implant placement, often serving as additional IMF support and overall implant support, in addition to implant coverage. While various studies compare mesh to ADM, there have been few studies comparing outcomes among the plethora of different types of mesh available on the market. Herein, we find that outcomes are difficult to compare concertedly, as methods, surgical technique, and reporting standards are extremely variable from study to study.

Even so, the authors find that there are many types of synthetic mesh available commercially for use in breast reconstruction, including completely absorbable meshes, predominantly Vicryl meshes, partially absorbable meshes (such as TIGR mesh), and non-absorbable meshes, such as TiLOOP which remain in place indefinitely to support the reconstructed breast. The most common reason for choosing one type of synthetic mesh over another is usually surgeon preference, familiarity, and degree of surgeon perceived (and often subjective) conferred cosmetic advantage. While rates of capsular contracture were not analyzed as an outcome in this analysis, one of the primary reasons for using ADM or synthetic mesh in implant-based breast reconstruction is the significantly lower rates of capsular contracture than when placing smooth implants alone.[43,44] Surprisingly, it was found that vicryl-only meshes were associated with greater rates of capsular contracture than ADM but resulted in fewer reoperations for cosmetic reasons.[43,44] After reviewing this meta-analysis, surgeons should feel more comfortable using biosynthetic mesh in patients, especially those at higher risk of capsular contracture, such as those patients who have or will receive radiation, due to the low complication profile and lower rate of implant loss and re-operation.

Importantly, previous meta-analyses have shown that there is no overall difference in implant loss between human ADM, xenograft ADM, synthetic mesh, and no mesh use in implant-based breast reconstruction.[45] However, our updated review of the literature demonstrated an overall rate of implant loss at 4.1%, much lower than previously reported rates of approximately 9% across several prior studies.[46-48] Rates of implant loss did however vary greatly between different types of mesh, but also across studies reporting results when using the same mesh. The rates of reported implant loss ranged from 0.77% to 6.76% across the eleven studies.[6,9,19-22,24,25,28,34] The analysis was insufficiently powered to detect statistically significant differences, however this heterogeneity amongst reported outcomes and complications was commonly found. The authors believe this is likely due to significant variability in surgical technique, intra-operative sterility protocol, and patient demographics from study to study. These factors are often very difficult to objectively quantify and control, unless studied within a set protocol.

Similar to the vast variability in reported implant-loss, the overall seroma rate reported in our meta-analysis was 7.3%, however this ranged from 1.1% - 7.4% amongst included studies, with some reporting rates as high as 15%.[6,9,19-40,49] There is some evidence to suggest that thicker varieties of mesh, as well as the presence of acetone-based preservatives on the outer mesh

membrane, contribute directly to increased seroma formation.[50] As such, it is difficult to compare these meshes side-by-side, even within the subgroup of Vicryl meshes, as there is no industry standard for packaging and preservative use. Even so, the pooled rates of seroma, in addition to hematoma and implant-infection reported herein, despite significant heterogeneity, were still somewhat lower than those reported in the ADM literature.[1,31,43,51-53] The authors believe that it may be difficult to demonstrate that the use of mesh as opposed to ADM may confer an advantage in post-operative complications. However, these results demonstrate, at a minimum, no significant increase, with the added benefits of superior pocket control and subjective cosmetic outcomes.

In addition to the proposed peri-operative advantages and overall utility of mesh in breast reconstruction, the cost has also been demonstrated to be significantly lower than with the use of human or xenograft ADM. Mookerjee et al. report the cost per breast for Vicryl mesh at $760 total, versus $9,033 for an equivalent ADM.[9,33] In fact, in 2020, Faulkner et. al published a study showing that, in 227 patients treated over 7 years, the cost savings achieved by using absorbable mesh instead of ADM surpassed 1.2 million dollars.[5] Thus, for some physicians, patients, and hospital systems, the use of ADM may be cost-prohibitive, prompting them to turn to absorbable mesh.

After the establishment of the federal Women's Health and Cancer Rights Act (WHCRA) in 1998, group health insurance plans began to cover breast reconstruction after mastectomy for cancer patients.[54] ADM is now FDA-approved for breast reconstruction and often reimbursed or covered by insurance although remarkably more expensive than biosynthetic mesh.[14,55,56] However, biosynthetic meshes are much newer products and are thus considered as “off-label” for use in breast reconstruction by insurance companies. Its use is often not covered by insurance although biosynthetic mesh has fewer complications and is not cost-prohibitive in comparison to ADM. It would be worthwhile to investigate the total cost of implant-based breast reconstruction with ADM compared to mesh, specifically investigating hospital stay and surgical/anesthesia cost in a bundled-care or episode payment model to assess total out of pocket expenditure and amount covered by insurance. Currently, the amount of available information regarding biosynthetic mesh and insurance coverage limits this evaluation.

Given the recency of new biologic and resorbable meshes on the market, a paucity of data exists on long term outcomes in implantable meshes. It remains unknown if long term complications

exist such as cancer-related diagnoses (BIA-ALCL) that came to light with textured breast implants decades after their initial inception. Even so, concerns of long-term inflammatory responses and subsequent complications may be curbed by the significantly shorter and definitive in-vivo lifespan of these mesh products in the breast. Additionally, longer-term outcomes such as rippling, malposition, and capsular contracture are sparsely reported in the literature and are more subjective and sporadically reported at present. Going forward, longer-term outcomes would be an important topic to investigate pending sufficient available data.

A major limitation of the meta-analysis performed was the inherent limitation of the studies available for inclusion that have been published in the literature. Furthermore, there was a large amount of heterogeneity between studies as indicated by large I^2 values, specifically in reporting hematoma, infection, and implant loss rates. This resulted in insufficient power to detect statistically significant differences in complications between different types of mesh. In addition, many of the included studies did not segregate data amongst implant plane - subpectoral, dual-plane, or subglandular/subfascia. More studies are needed that directly compare the complication profiles of different types of mesh so as to more definitively establish clinical advantages. In addition to clinical variability, differences in individual surgical technique, breast surgeon mastectomy flaps, and patient characteristics, may all affect the rates of observed complications, outside of the type of mesh used. Many studies did not elaborate on their surgical technique, or sterility protocol. As such, with the increase in popularity of mesh use in breast reconstruction, higher quality, standardized data is required for surgeons to make informed decisions regarding mesh type.

CONCLUSIONS

The implementation of mesh for breast reconstruction began as a method to provide an extension of the pectoralis major muscle for submuscular implant placement and for better cosmetic outcomes in pre-pectoral implant placement. These cosmetic benefits included fewer contracture rates and better definition and integration of breast implants. Further investigation into this topic should include increased sample sizes, patient-reported outcomes, and standardized reporting of surgical technique and sterility protocols. Although patient-reported outcomes are not always quantifiable, inviting patient feedback could further elucidate advantages and disadvantages of specific meshes, in order to better provide a patient-centric approach in mesh selection. Overall,

surgeon experience, cosmetic goals of the patient, product costs, and the aforementioned outcomes and complications should be taken into account when deciding which, if any, mesh should be used during breast reconstruction.

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Table 1. Summary complications and outcomes of 24 included studies

Author	Study Type	Mesh Type	Number of Breasts	Implant Loss	Infection	Skin Necrosis	Hematoma	Seroma
Becker et al.[19]	Retrospective review	TIGR	112	2	4	NR	NR	2
Hallberg et al.[20]	Prospective review	TIGR	65	2	1	NR	1	2
Karoobi et al.[21]	Retrospective cohort	TIGR	106	4	5	7	1	4
Paganini et al.[22]	RCT	TIGR	42	1	NR	NR	NR	NR
Pompei et al.[23]	Retrospective review	TIGR	60	NR	1	3	4	2
Quinn et al.[24]	Retrospective review	TIGR	164	11	9	5	0	NR
Sharma et al.[25]	Retrospective review	TIGR	74	5	8	NR	0	0
Wow et al.[26]	Retrospective review	TIGR	232	19	10	13	NR	32
Turin et al.[27]	Prospective case series	Durasorb	27	0	0	NR	NR	1
Ganz et al.[28]	Retrospective review	Vicryl	115	NR	3	9	1	NR
Gunnarsson et al.[29]	Retrospective review	Vicryl	47	NR	1	NR	2	NR
Hashimoto et al.[30]	Retrospective review	Vicryl	81	NR	5	7	1	1
Haynes et al.[6]	Prospective review	Vicryl	46	3	3	2	0	1
Karp et al.[31]	Retrospective review	Vicryl	21	0	1	1	NR	NR
Kobraei et al.[32]	Retrospective review	Vicryl	23	NR	1	NR	1	3
Mookerjee et al.[33]	Retrospective review	Vicryl	23	NR	2	1	1	0

Tessler et al.[9]	Retrospective review	Vicryl	76	1	1	2	0	0
Sigalove et al.[34]	Retrospective review	Galaflex	250	12	9	16	NR	15
Chiemi et al.[35]	Case series	PDO	105	NR	2	NR	NR	2
Qiu et al.[36]	Prospective case series and description of technique	PDO	14	NR	1	NR	NR	NR
Turin et al.[37]	Prospective case series	PDO	27	NR	NR	NR	NR	1
Casella et al.[38]	Prospective case series	TiLoop	73	1	2	NR	1	NR
Eichler et al.[39]	Retrospective review	TiLoop	192	NR	9	NR	NR	21
Gentile et al.[40]	Retrospective case control	TiLoop	192	NR	24	NR	3	NR

FIGURE LEGENDS

Figure 1. Flowchart demonstrating selection process for studies to be included in quantitative analysis following PRISMA guidelines.

Figure 2. Pooled Complications Across Mesh Type. Data presented as percentage (%).

Figure 3. Forest Plot Reporting Average Seroma Rate by Study. Data presented as percentage (%).

Figure 4. Forest Plot Reporting Average Hematoma Rate by Study. Data presented as percentage (%).

Figure 5. Forest Plot Reporting Average Necrosis by Study. Data presented as percentage (%).

Figure 6. Forest Plot Reporting Average Infection Rate by Study. Data presented as percentage (%).

Figure 7. Forest Plot Reporting Average Implant Loss Rate by Study. Data presented as percentage (%).

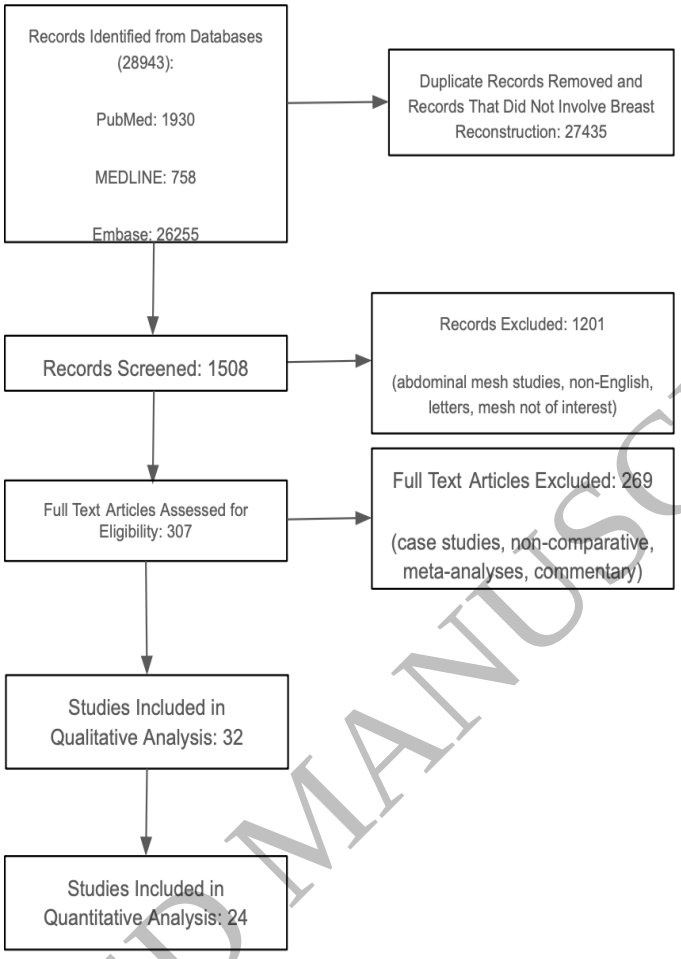

Figure 1
286x184 mm (x DPI)

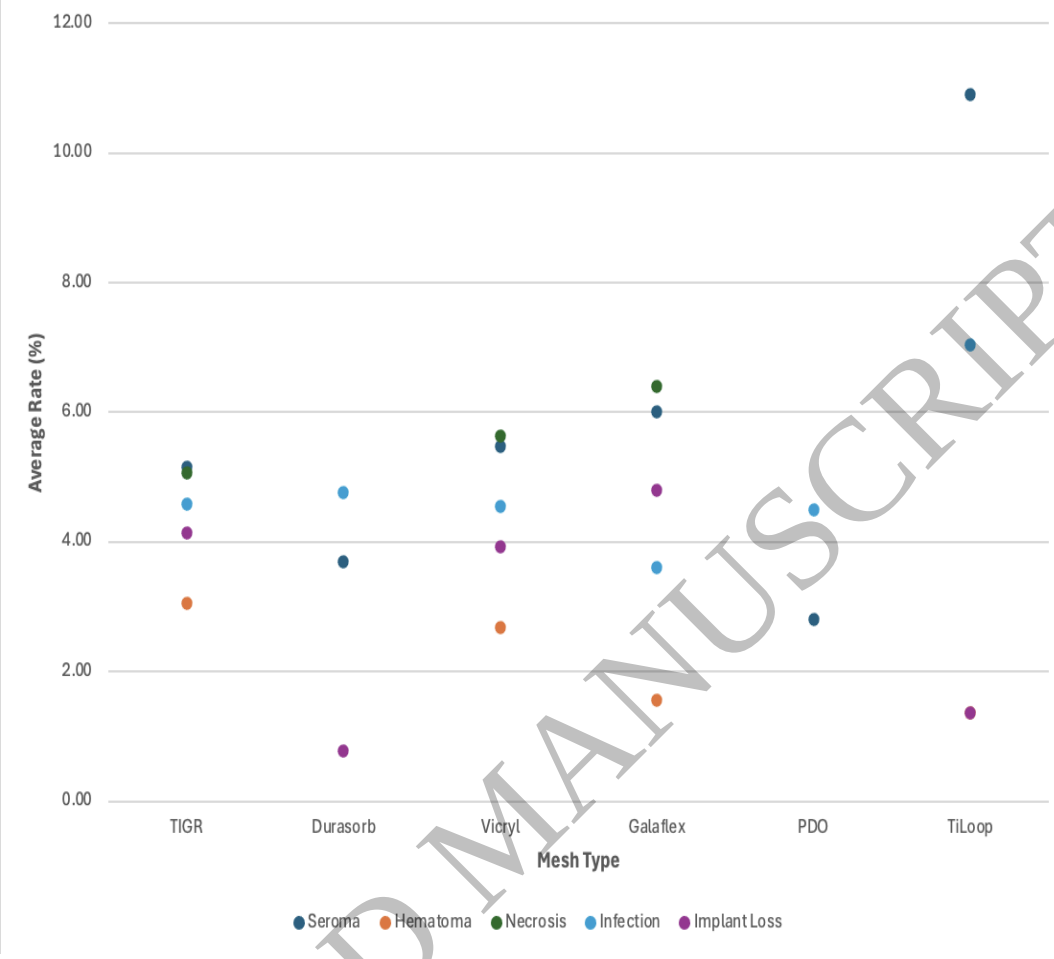

Figure 2
196x146 mm (x DPI)

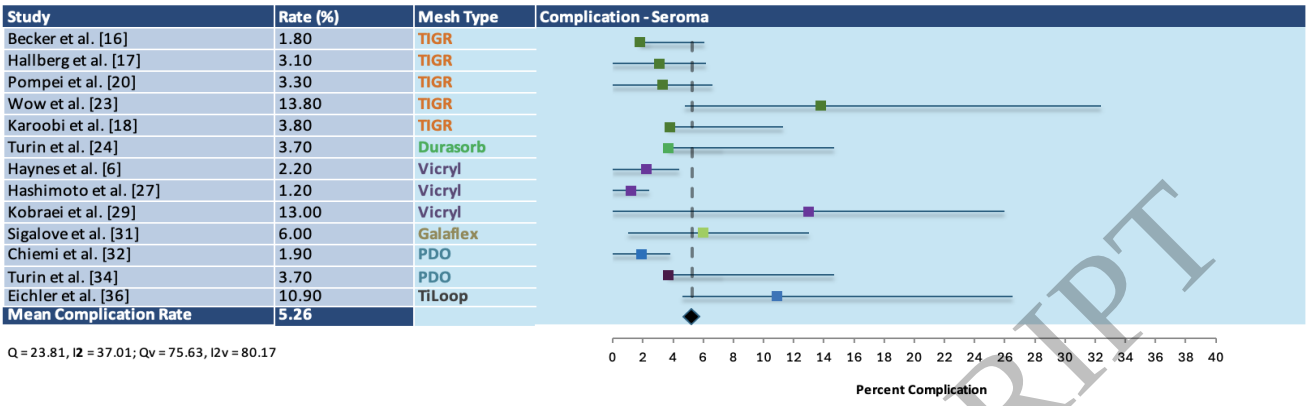

Figure 3
289x94 mm (x DPI)

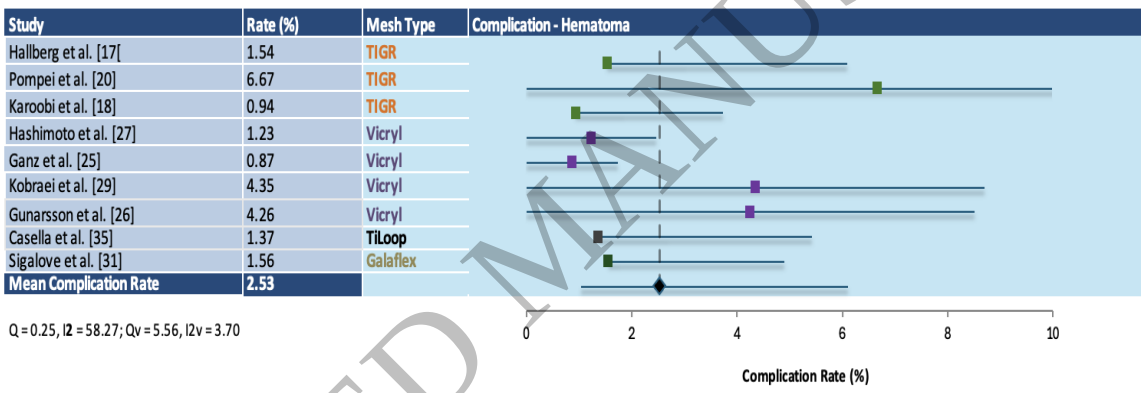

Figure 4
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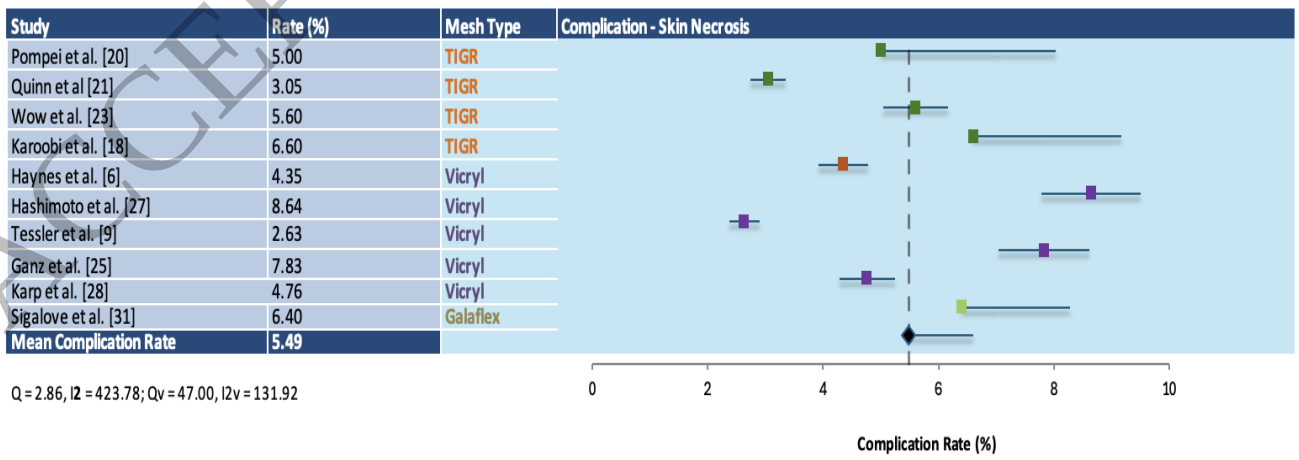

Figure 5
275x71 mm (x DPI)

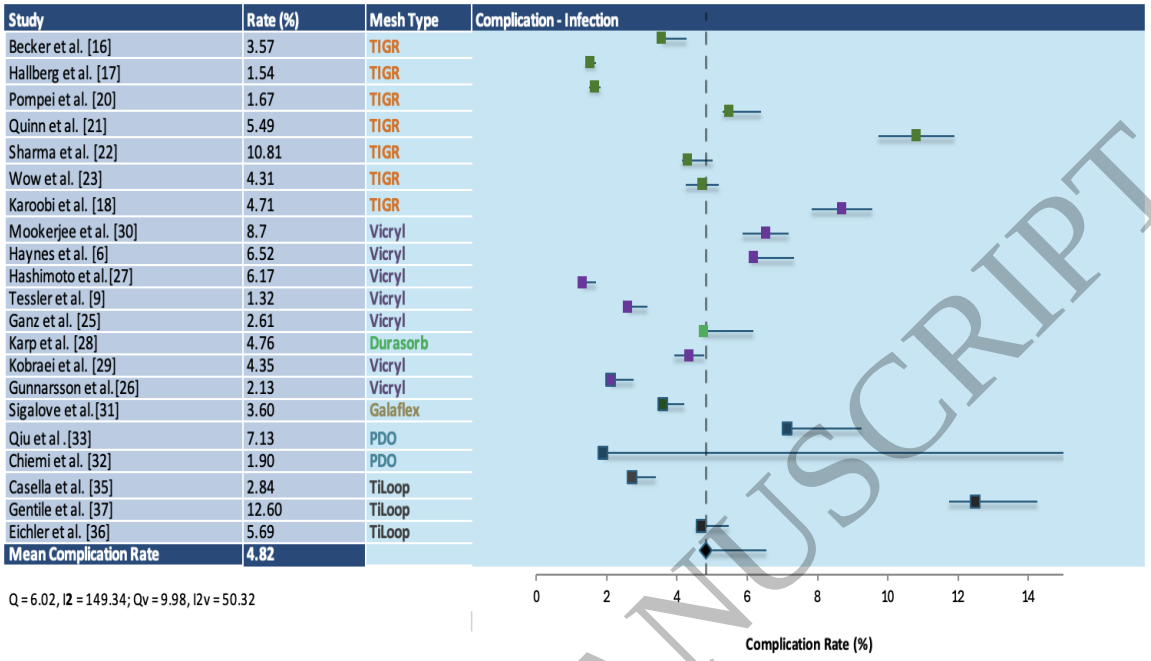

Figure 6
266x117 mm (x DPI)

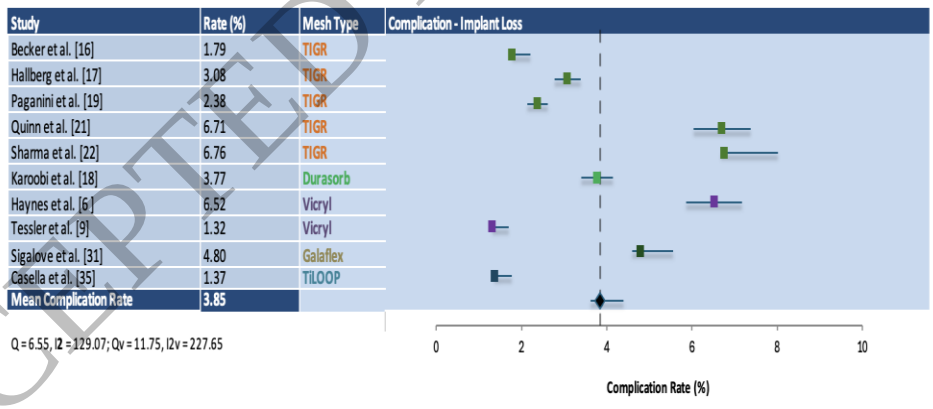

Figure 7
270x74 mm (x DPI)