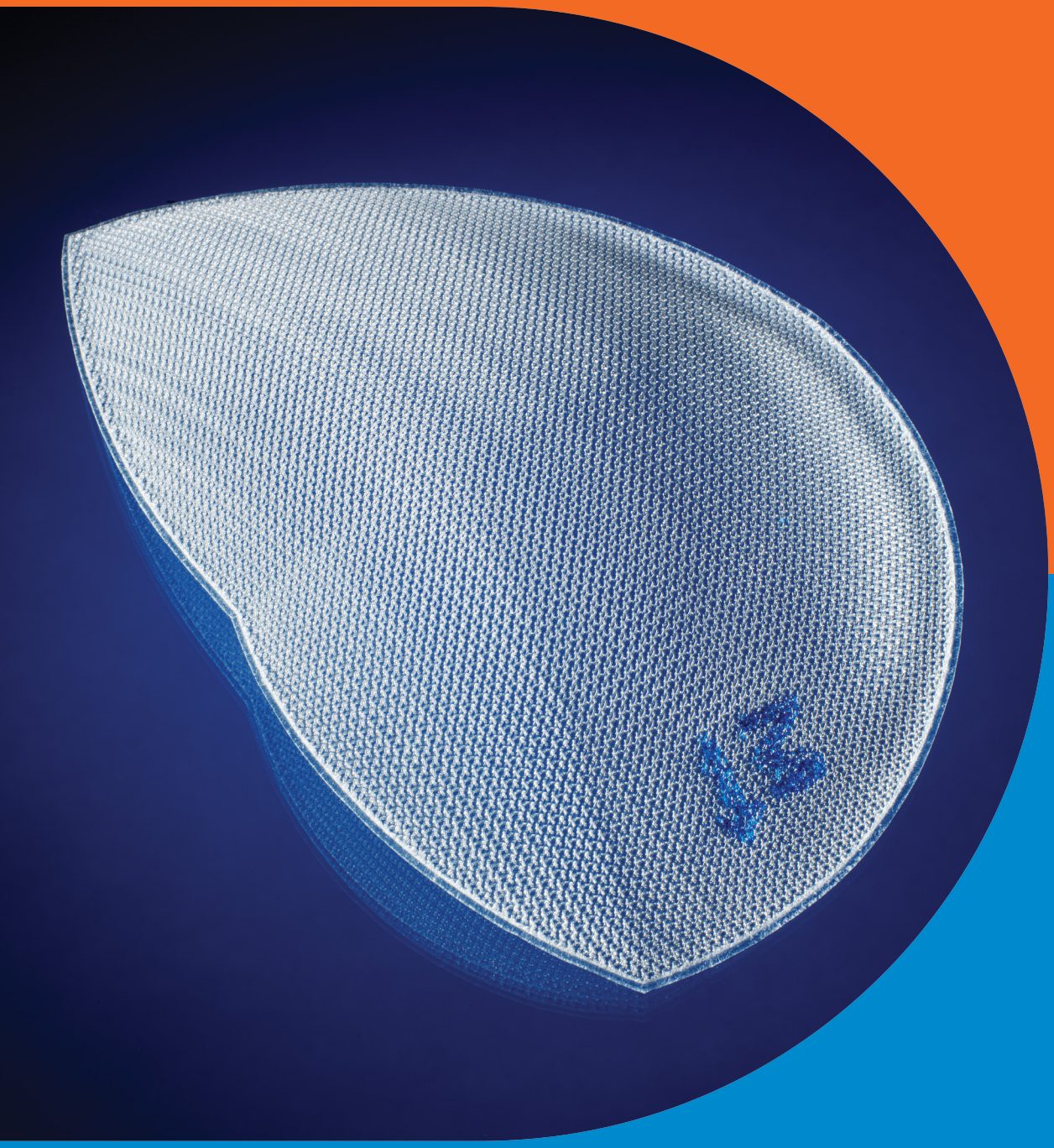

3DMax™ Mesh and 3DMax™ Light Mesh

Laparoscopic inguinal hernia repair

Article Summary

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Article summary

Long-term assessment of surgical and quality of life outcomes between lightweight and standard three-dimensional contoured mesh in laparoscopic inguinal hernia repair

Title of article

Long-term assessment of surgical and quality-of-life outcomes between lightweight and standard (heavyweight) three-dimensional contoured mesh in laparoscopic inguinal hernia repair.

Authors

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Study design/methodology

A prospective, single-center, hernia-specific database was queried for all adult laparoscopic inguinal hernia repair with three-dimensional contoured mesh (3DMax™ Mesh, Bard) from January 2006 to June 2016. Demographics and outcomes were analyzed. Quality of life was evaluated preoperatively and after two weeks, four weeks, six months, 12 months, and 24 months, using the Carolinas Comfort Scale. Univariate analysis and multivariate logistic regression were performed.

A total of 1,424 laparoscopic inguinal hernia repairs were performed with threedimensional contoured mesh. All repairs were categorized into either lightweight 3DMax™ Mesh (LWM) or standard 3DMax™ Mesh (HWM; C. R. Bard, Inc). Demographics, operative details, patient outcomes and recurrence rates, and QOL were recorded.

Patient population	3DMax™ Light Mesh	3DMax™ Mesh
Number of cases	804 (56.5%)	620 (43.5%)
Average comorbidities	1.9	2.2

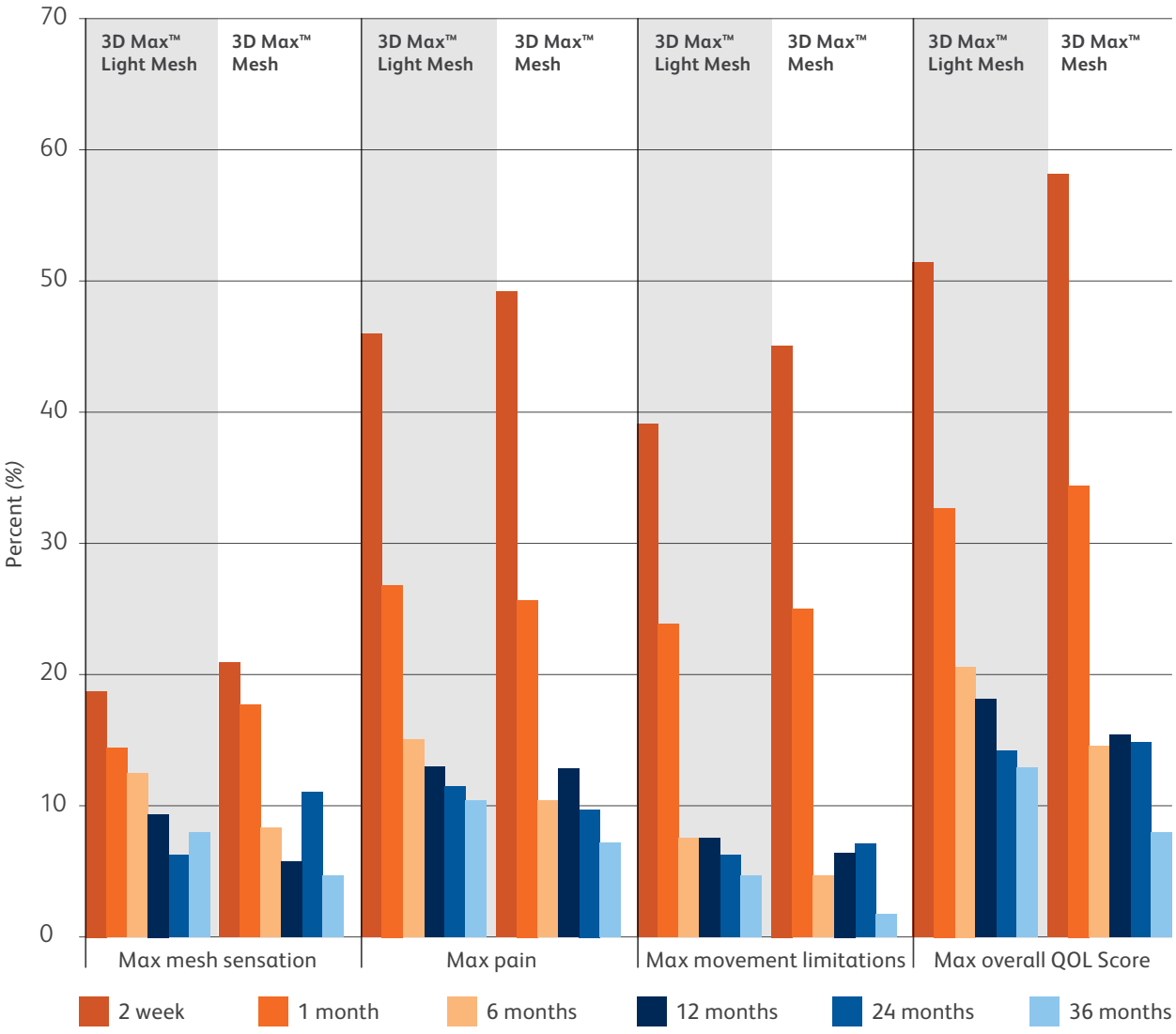
Patient population	3DMax™ Light Mesh	3DMax™ Mesh	P value
Average follow-up (months)	21.8	17.2	< .001
Overall complications (%)	11.4	11.5	.948
Superficial SSI (%)	0.1	0.0	.377
30-day readmission (%)	1.1	1.0	.794
Hernia recurrence (%)	0.6	0.7	.802

Results

Average follow-up was 20 months. Recurrence rates were similar between 3DMax™ Light mesh and 3DMax™ mesh (0.7% vs 0.6% P> .05). At all points of follow-up (four week to three years), quality-of-life outcomes of discomfort, mesh sensation, and movement limitation scores were similar between lightweight mesh and heavyweight mesh.

Long-term assessment of surgical and quality of life outcomes between lightweight and standard three-dimensional contoured mesh in laparoscopic inguinal hernia repair

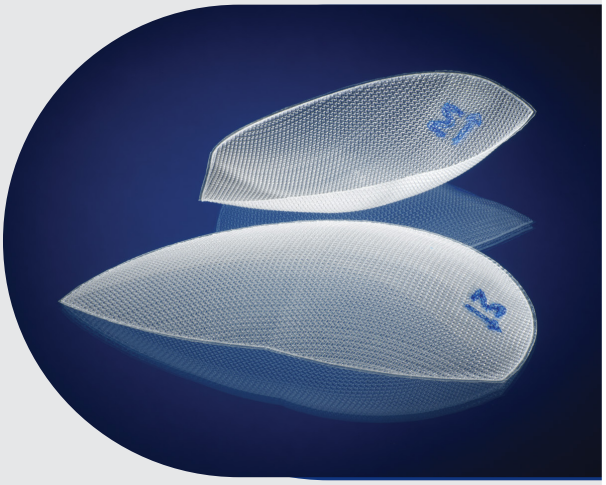
Postoperative QOL outcomes



Conclusions

Overall complication rates were similar between the two groups. The recurrence rates of 0.56% in 3DMax™ Light Mesh group (three recurrences) and 0.71% in 3DMax™ Mesh group (three recurrences), with a 20 month follow-up are very favorable compared to other studies with recurrence rates for LIHR ranging from 2.4% to 5.9% with 3–5 years of follow-up. Heavyweight mesh was not an independent risk factor for post-operative seroma formation. Age, however, was independently associated with increased risk of seroma formation. There was no significant QoL outcomes differences between LWM and HWM including both short-term (two weeks, one month, and six months) and longterm (12, 24, and 36 months).

Graph was generated by BD using the data provided in this article.

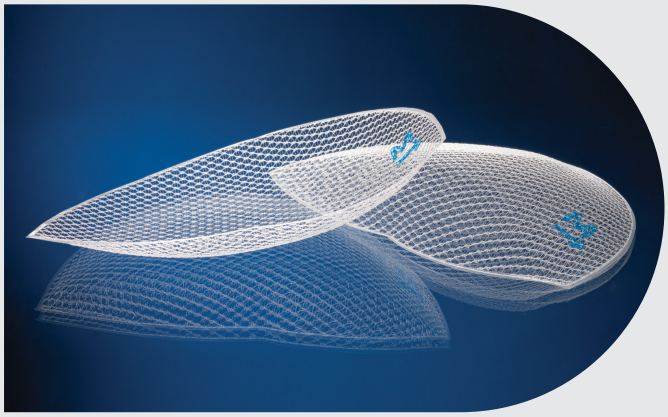


3DMax™ Mesh

Indications. Bard® 3DMax™ Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, in the repair of inguinal hernias. **Contraindications.** 1. Do not use this mesh in infants, children, or pregnant women, whereby future growth may be compromised by use of such materials. 2. The use of this mesh has not been studied in pregnant or breastfeeding women. 3. Literature reports that there may be a possibility for adhesion formation when polypropylene is placed in direct contact with the bowel or viscera. **Warnings.** 1. The use of any synthetic mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh. 3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. The mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh had been designed for single use only. Reuse, reprocessing, resterilization, or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilization, or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness or death of the patient or end user. 7. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves, vessels, or the spermatic cord. Fastener penetration into underlying tissue containing nerves or blood vessels may result in the need for medical/surgical intervention, cause serious injury or permanent impairment to a body structure. **Precautions.** 1. Please read all instructions prior to use. 2. Only physicians qualified in appropriate surgical techniques should use this mesh. 3. Do not cut or reshape the Bard® 3DMax™ Mesh as this may affect its effectiveness. 4. It is recommended to use a 10 mm internal diameter trocar to introduce a medium Bard® 3DMax™ Mesh, and an 11 mm internal diameter trocar to introduce a large Bard® 3DMax™ Mesh. The size of the extra-large Bard® 3DMax™ Mesh may inhibit deployment through a trocar. Use an appropriately sized trocar to allow mesh to slide down the trocar with minimal force. If mesh will not easily deploy down the trocar, remove trocar and insert mesh through incision. Reinsert trocar. 5. If fixation is used, Bard® permanent or absorbable fixation devices or nonabsorbable monofilament sutures are recommended to properly secure the device. If other fixation devices are used, they must be indicated for use in hernia repair. 6. If fixation is used, care should be taken to ensure that the mesh is adequately fixated to the abdominal wall. If necessary, additional fasteners and/or sutures should be used. **Adverse Reactions.** Possible complications may include, but are not limited to, seroma, adhesions, hematomas, pain, infection, inflammation, extrusion, erosion, migration, fistula formation, allergic reaction, and recurrence of the hernia or soft tissue defect. Please consult product package insert for more detailed safety information and instructions for use.

3DMax™ Light Mesh

Indications. The 3DMax™ Light Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, in the repair of inguinal hernias. **Contraindications.** 1. Do not use this mesh in infants, children, or pregnant women, whereby future growth may be compromised by use of such materials. 2. The use of this mesh has not been studied in pregnant or breastfeeding women. 3. Literature reports that there may be a possibility for adhesion formation when polypropylene is placed in direct contact with the bowel or viscera. **Warnings.** 1. The use of any synthetic mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh. 3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. The mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh had been designed for single use only. Reuse, reprocessing, resterilization, or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilization, or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness or death of the patient or end user. 7. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves, vessels, or the spermatic cord. Fastener penetration into underlying tissue containing nerves or blood vessels may result in the need for medical/surgical intervention, cause serious injury or permanent impairment to a body structure. **Precautions.** 1. Please read all instructions prior to use. 2. Only physicians qualified in appropriate surgical techniques should use this mesh. 3. Do not cut or reshape the 3DMax™ Light Mesh as this may affect its effectiveness. 4. Use an appropriately sized trocar to allow mesh to slide down the trocar with minimal force. 5. If fixation is used, Bard® permanent or absorbable fixation devices or nonabsorbable monofilament sutures are recommended to properly secure the device. If other fixation devices are used, they must be indicated for use in hernia repair. 6. If fixation is used, care should be taken to ensure that the mesh is adequately fixated to the abdominal wall. If necessary, additional fasteners and/or sutures should be used. **Adverse Reactions.** Possible complications may include, but are not limited to, seroma, adhesions, hematomas, pain, infection, inflammation, extrusion, erosion, migration, fistula formation, allergic reaction and recurrence of the hernia or soft tissue defect. Please consult product package insert for more detailed safety information and instructions for use.



Contact a BD sales representative to schedule an appointment or visit bd.com for more information.

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