OptiMesh Expandable Spine Implant

November 2024

Device Overview

Minimally invasive methods in lumbar spine surgery, such as transforaminal lumbar interbody fusion (TLIF), have gained traction, with various devices for interbody spacer deployment.[1] According to the manufacturer, OptiMesh is a “conforming patient specific expandable implant" that allows access "through the smallest working channel" in a variety of approaches.[2,3] With traditional interbody discectomy, the mesh is inserted and deployed into the disc space via entry in the annulus.[1] The mesh may be filled with allogeneic and autologous bone, bypassing the need for bone cement.[4]

Actions for Consideration

PARTNER

ENGAGE EXPERTS

Assess current utilization of OptiMesh and engage key physicians, including surgeons (ortho, spine, and neurosurgery), OR directors, supply chain, and value analysis leaders.

CONSIDER USAGE GUIDELINES

Develop ‘criteria for use’ guidelines sharing pricing & reimbursement information due to OptiMesh’s premium pricing structure.

UNDERSTAND CONCERNS

Leverage physician peer to peer conversations to understand decision-making and its role in spinal fusion vs traditional methods.

CONNECT

SEEK CLINICAL IMPACT

Review data & physician utilization in procedures and outcomes compared to traditional interbody spacers. Share evidence & guidelines regarding use of agents.

CONDUCT ANALYSIS

Compare cost of OptiMesh vs traditional methods, include reimbursement and outcomes information to inform decision making.

DETERMINE POPULATION

Work with key stakeholders to determine appropriate patient selection & specific procedures for utilization.

COMMUNICATE

EDUCATE AND TRAIN

Provide information on available training. Deliver education to gain familiarity with the product, including proper implant selection and placement. Engage supplier for support.

PLAN AHEAD

Share ‘criteria for use’ guidelines as well as data to support decision making with key stakeholders

FOLLOW-UP FOR FEEDBACK

Continue to share outcomes and financials with key stakeholders at a committed cadence to reinforce success and address follow up as needed.

FDA Approval

OptiMesh was approved by the FDA in 2003. Indications for use include: “intended to maintain the relative position of bone graft material (such as autograft or allograft) within a vertebral body defect (e.g., tumor) that does not impact the stability of the vertebral body and does not include the vertebral endplates.”[3]

Clinical Insights: HealthTrust Physician Advisors

A panel of orthopedic, spine, and neurosurgeons within our HealthTrust Physician Advisor Network offered the following insight with regard to the use of OptiMesh.[5]

Physician Advisor Insights

- OptiMesh potentially offers a “low profile” when inserted but over time, “the height it restores” diminishes. In revisions, implants may potentially yield “sandy like bone grafts and very little bridging bone, with height loss compared to immediate post-op x-rays.”
- Questions concerning pricing due to the availability of alternative expandable posterior lumbar interbody devices on the market.
- Physicians expressed concerns about the premium pricing of OptiMesh, citing its potential for "limited local rigidity" and potential inability to preserve sagittal alignment or correct deformities.
- OptiMesh insertion is conducted blindly “without appropriate disc prep and does not support the anterior column as much as a cage.”

Clinical Evidence

Studies involving OptiMesh are limited to small investigation device exempt (IDE) studies, which are vendor-sponsored. A sampling of these studies is included below.

A 2021 prospective, multicenter, IDE study by Driver et al. assessed the use of OptiMesh in patients with lumbar degenerative disc disease (DDD) with 24 month follow-up. The study involved 102 adults with DDD between L2 and S1 with no resolution from conventional care. OptiMesh was inserted in the disc space via a small portal and filled with bone graft. At 12 months, pain (visual analog scale), function, patient satisfaction, and fusion success were measured.

Ninety-nine of the patients that completed follow-up at 12 months reported decreased low back pain, left and right leg pain at 6 weeks and 12 months compared to baseline (change from pre-op: back pain -51; right leg -29; left leg -41; $p<0.05$ for all). Function, as measured by the Oswestry Disability Index (ODI), improved by 32 points at 12 months compared to pre-op.[1]

A 2022 prospective, multicenter, IDE study by Chi et al. assessed the use of OptiMesh in patients with lumbar DDD with 24 month follow-up. The study involved 102 adults with the same methodology as mentioned in the previous Driver et al. study above.

At 24 months, pain (visual analog scale), function, patient satisfaction, and fusion success were measured. Ninety-six of the patients that completed follow-up at 24 months reported lowered back pain compared to baseline (45.0 ± 26.6 at 6 weeks and 51.4 ± 26.2 at 24 months) and lower right/left leg pain compared to baseline (28.9 ± 36.7/37.8 ± 32.4 at 6 weeks and 30.5 ± 33/40.3 ± 34.6 at 24 months). Function, as measured by ODI, increased from 17.1 ± 18.7 at 6 weeks to 32 ± 18.5 by 24 months. Patient satisfaction was 91.7% at 24 months, and fusion rates were 99% at 24 months. There were no reported serious adverse events associated with OptiMesh. Limitations include the following: small sample size and single arm with no comparator/interbody fusion methods.[6]

Systematic search terms: OptiMesh, interbody spacers
Databases: PubMed, Medline, CINAHL, Google Scholar
Timeframe: published from 2015 to 2024.

See Reference section for complete listing of research sources.

Summary

1. There is little, primarily vendor-sponsored, evidence to suggest OptiMesh provides advantages like decreased back and leg pain and improved functional scores. Additional studies are recommended to further validate these findings.
2. Due to the premium pricing of OptiMesh, work to develop a goal related to appropriate use by specialty, sharing price and reimbursement information. Compare outcomes to that of traditional interbody spacers.
3. Since this is a physician preference item, engaging physician champions to assist with peer-to-peer conversations will be particular helpful when deciding on its place in spinal fusion compared to traditional methods.

HealthTrust Clinical Resources

ASK A QUESTION PROVIDE YOUR FEEDBACK

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PEER NETWORKING

www.huddle.healthtrustpg.com
App store: "HealthTrust Huddle"

References

1. Driver J, Huang K, Krag M, et al. One Year Outcomes From a Prospective Multicenter Investigation Device Trial of a Novel Conformal Mesh Interbody Fusion Device. *Spine (Phila Pa 1976)*. 2021;46(2):E126-E132. doi:10.1097/BRS.0000000000003710.
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4. Luo Y, Yang DM, Yang HM, Wu D, Xie FY. Innovative minimally invasive implants for osteoporosis vertebral compression fractures. *Front Med*. 2023;10:1161174. doi:10.3389/fmed.2023.1161174.
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6. Chi JH, Nunley PD, Huang KT, et al. Two-Year Outcomes From a Prospective Multicenter Investigation Device Trial of a Novel Conformal Mesh Interbody Fusion Device. *Int J Spine Surg*. 2022;15(6):1103-1114. doi:10.14444/8169.

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Examples for this category include resources on value analysis, physician engagement, and product trials.