NiTiNol Hernia Device Stability in Inguinal Hernioplasty Without Fixation

Roderick B. Brown, MD

ABSTRACT

Background and Objective: To determine whether the NiTiNol frame of a novel hernia repair device utilizing polypropylene mesh for inguinal hernioplasty remains stable and intransient without fixation after a minimum of 6 months.

Methods: Twenty patients had 27 inguinal hernias repaired using a novel hernia repair device that has a NiTiNol frame without any fixation. Initial single-view, postoperative X-rays were compared with a second X-ray obtained at least 6 months later. The NiTiNol frame, which can be easily visualized on a plain X-ray, was measured in 2 dimensions, as were anatomic landmarks. The measurements obtained and the appearances of the 2 X-rays were compared to determine the percentage of change in device size and device stability with regard to device location and shape.

Results: There were minimal changes noted between the 2 sets of measurements obtained with an overall trend towards a slight increase in the size of the hernia repair device. The devices demonstrated intransience of position and stability of shape.

Conclusions: The NiTiNol frame of a novel hernia repair device utilizing polypropylene mesh exhibits radiographic evidence of size and shape stability and intransience of position without fixation when used in inguinal hernioplasty after a minimum follow-up of 6 months.

Key Words: NiTiNol, Hernia, Shrinkage, Fixation.

INTRODUCTION

Prosthetic meshes are routinely used to repair abdominal wall hernias. One of the problems encountered with the available mesh products is postimplantation shrinkage or distortion, which can contribute to postoperative pain and hernia recurrence. The degree of shrinkage of polypropylene mesh has been reported to be 33% to 54% in animal studies.1–3 Mesh contraction is known to occur within the first 2 months after implantation.4 Explanted mesh from humans has been studied with regard to change in pore size and has demonstrated changes from a 58.5% increase to a 40% decrease; however, this study did not report on the overall change in the size of the entire piece of mesh.4

The available data on mesh shrinkage in humans is limited and includes a case report of an explanted piece of mesh that had shrunk and folded to 30% of its original size in a 22-year-old man who had the mesh removed to treat chronic pain.5 Other studies have reported mesh shrinkage in the range of 20% to 30% for flat mesh and up to 75% shrinkage with mesh plugs.6–8

Various types of fixation have been used to secure the mesh in preperitoneal hernioplasty to prevent mesh dislocation, which was seen consistently with no fixation and is a recognized cause of hernia recurrence.9–10 Mesh fixation however is associated with an increased incidence of chronic postoperative pain after preperitoneal hernioplasty.10–12 Mesh fixation is not the only known cause for chronic inguinodynia following hernia repair. Identified causes of chronic inguinodynia include mechanical pressure from mesh shrinkage or meshomas, periosteal reactions, scar tissue, perineural fibrosis, neural compression or traction, partial or complete nerve transection, as well as nerve entrapment or injury by tacks, staples, or sutures used for mesh fixation.13

Results from a swine study using a NiTiNol-framed hernia device demonstrated no change in the radiographic appearance of the device from the immediate postoperative X-ray and X-rays taken every 30 days until the final 90-day X-rays. The swine were sacrificed, and the devices were explanted and evaluated. There was no change in the size or shape of the devices explanted from the swine after 3 months compared with a similar new device.14 This study
raised the question of whether similar results could be demonstrated when the device is used to repair inguinal hernias in humans.

PATIENTS AND MATERIALS

Twenty patients aged 17 to 89 years (mean age, 58.1, median, 65) of which 17 were male and 3 were female had 27 inguinal hernias repaired utilizing an FDA-cleared NiTiNol framed, polypropylene mesh, hernia device (NFHD) (ReboundHRD®, MMDI, Plymouth, MN, USA). Five different sizes and shapes of devices were utilized (Figure 1). The decision as to which size or shape of device to use was determined at the time of surgery. This decision was based on the patient’s anatomy, the size of the hernia, and the author’s preference. All of the procedures were performed by the author at the Glacial Ridge Hospital in Glenwood, Minnesota. The patients were evaluated with a postoperative single view PA standing pelvis X-ray at a 30-degree caudal angle. The patients were then seen for a clinical examination and repeat X-ray (also taken as a 30-degree caudal angle) standing PA of the pelvis to assess the stability of the device after a minimum of 6 months postoperatively (range, 183 days to 341 days; mean, 227; median, 224). There were 17 indirect, 2 direct, and 8 indirect/direct (double or pantaloon) hernias repaired. Ten of the hernias were on the left, and 17 were on the right. While under general anesthesia, all of the patients had laparoscopic TAPP repairs without any type of device fixation. All of the initial postoperative X-rays and late postoperative X-rays were independently reviewed by 3 board certified radiologists. The NiTiNol frame of the device is radio-opaque and can be well visualized on a plain radiograph. Measurements of the device and skeletal anatomic landmarks were obtained by using the measurement function available with the PACS system [7 Medical Systems 7i On Demand™ SUV Analysis tool (Standardized Uptake Value)] on both sets of radiographs. To compensate for any differences that were due to positioning or distance differences, the measurements were equalized by using the formula in Figure 2.

Measurements were compared for the cranial-caudal (CC) and the medial-lateral or oblique (ML) dimensions for the device and the patient’s skeletal anatomy (Figure 3). The initial and late postoperative X-rays were compared and measured (Figure 4) and the percentage of change for each dimension (ML and CC) and a combined percentage change was calculated. The X-rays were also evaluated for radiographic evidence of any device distortion or position change.

RESULTS

Comparison of the measurements from the first and second radiographs (Table 1) revealed minimal change. Five of the devices demonstrated a minimal decrease in size between -0.2% and -1.6%, and in 22 of the devices there was a slight expansion ranging between +0.3% to +11.3%. The mean change for all devices was +2.5% in the cranial-caudal (CC) dimension and +1.6% in the medial-lateral or oblique (ML) dimension. The overall mean change was an increase of +2.0% in size. None of the devices demonstrated any evidence of breakage, fraying, or distortion of the NiTiNol frame. There was no notable change in the radiographic appearance of any of the devices with regard to device shape, contour, or position. None of the patients had developed a hernia recurrence. All of the patients were examined and interviewed...
at the time of the second X-ray. All of the patients when specifically questioned denied the presence of any pain, discomfort, or awareness of the device.

DISCUSSION

The presence of the NiTiNol frame on this polypropylene mesh hernia device demonstrated a consistent maintenance of the radiographic appearance with regard to size, shape, and position without fixation after a minimum of 6 months postimplantation. The stability of the shape and size of the NiTiNol frame suggests that there would be minimal shrinkage or distortion of the lightweight macro porous polypropylene mesh used in this device as well. The ability to image and monitor the status of the NiTiNol frame (and indirectly the associated polypropylene mesh) is a new option for surgeons and patients not previously possible. This is accomplished with a plain, single-view radiograph. It is well established that the “inguinal floor” is a semi-concave 3-dimensional structure; however, the 2-dimensional imaging obtained with a plain radiograph demonstrated consistency with regard to the shape, size, and overall appearance of the devices evaluated.

Mesh shrinkage and “meshomas” are the result of fibrosis and scar contraction. The NiTiNol frame in this device keeps the mesh smooth and flat and provides a constant circumferential outward tension on the mesh to prevent wrinkling and contraction. The NiTiNol frame also affects the peripheral edge of the polypropylene mesh in such a way as to cause it to splay out which enhances the mesh adherence to the adjacent tissue. This feature results in a “Velcro-like” effect that stabilizes the device where positioned and contributes to the intransience of the device. This device therefore does not require any fixation, and no fixation of any type was used in any of the patients in this study. The ability to avoid mesh fixation eliminates the potential injury or impingement of nerves and blood vessels and also avoids the potential sites of traction that can be a source of pain from misplaced tacks or staples. The device is designed to conform to the patient’s anatomy, and this self-seating feature may account for some of the minimal changes noted in the X-ray measurements.
The outlier in this study, patient 6, experienced an 11.3% overall increase in the size of his device. When comparing the first and second postoperative X-rays, it becomes apparent that the change is likely due to the overall expansion of the device. I believe this is the consequence of an inadequate preperitoneal dissection preventing the device from completely unfurling at the time of placement. In this case, the device expanded to the fully unfurled size and shape as seen on the second X-ray taken 292 days later (Figure 5).

The measurements in Table 1 are obtained from the initial and second X-rays (greater than 6 months postoperatively). Measurements of the NiTiNol frame and the anatomic landmarks in the cranial-caudal (CC) and medial-lateral or oblique (ML) dimensions are listed for both sets of X-rays. The percentage of change is calculated by using the formula in Figure 2.

| Patient, Age, Sex, Device Type | Location & Type of Hernia | 1st X-ray | 2nd X-ray | % change |
|-------------------------------|--------------------------|-----------|-----------|----------|
|                               |                          | NFHD      | NFHD Pt   | CC ML    | NFHD      | NFHD Pt   | CC ML    | Average  |
| 1) 86 M, Hybrid              | Indirect L              | 129       | 100       | 143 362  | 125       | 97        | 140 359  | -1.0% -2.2% -1.6% |
| 2) 46 M, Hybrid              | Direct/Indirect R       | 100       | 97        | 167 243  | 109       | 114       | 181 269  | 0.6% 6.8% 3.7%   |
| 3) 46 M, Hybrid              | Direct/Indirect L       | 117       | 105       | 158 297  | 145       | 112       | 183 338  | 8.1% -7.1% 0.5%   |
| 4) 89 M, Hybrid              | Indirect R              | 136       | 123       | 215 324  | 132       | 120       | 205 316  | 1.7% 0.0% 0.9%   |
| 5) 89 M, Hybrid              | Indirect L              | 141       | 91        | 215 324  | 133       | 95        | 205 316  | -1.0% 6.9% 2.9%   |
| 6) 76 M, Hybrid              | Direct/Indirect R       | 116       | 112       | 140 423  | 129       | 115       | 135 401  | 14.8% 7.9% 11.3% |
| 7) 27 M, Hybrid              | Indirect R              | 120       | 122       | 175 309  | 134       | 124       | 176 323  | 11.1% -2.9% 4.1% |
| 8) 65 F, Dog Bone            | Indirect R              | 109       | 104       | 120 322  | 116       | 110       | 120 329  | 6.4% 5.6% 5.0%   |
| 9) 27 M, Hybrid              | Indirect R              | 127       | 117       | 363 388  | 130       | 111       | 366 376  | 1.5% -2.0% -0.2% |
| 10) 27 M, Hybrid             | Indirect L              | 130       | 121       | 363 388  | 133       | 115       | 366 376  | 1.5% -1.9% -0.2% |
| 11) 81 M, Hybrid             | Direct/Indirect L       | 125       | 114       | 144 368  | 127       | 115       | 143 360  | 2.3% 5.0% 2.7%   |
| 12) 29 M, Hybrid             | Direct/Indirect R       | 97        | 149       | 177 336  | 98        | 145       | 177 327  | 1.0% -0.0% 0.5%   |
| 13) 53 M, SM Shield          | Indirect R              | 123       | 132       | 183 365  | 123       | 133       | 170 366  | 7.1% 0.5% 3.8%   |
| 14) 45 M, LG Shield          | Direct R                | 185       | 168       | 154 342  | 191       | 168       | 163 343  | -2.1% -0.3% -1.4% |
| 15) 45 M, LG Shield          | Direct L                | 181       | 149       | 163 368  | 187       | 158       | 175 369  | -4.0% 5.8% 0.9%   |
| 16) 87 M, LG Hybrid          | Direct/Indirect R       | 80        | 118       | 156 374  | 82        | 119       | 161 368  | -0.7% 2.4% 0.9%   |
| 17) 17 F, Hybrid             | Indirect R              | 128       | 124       | 149 329  | 131       | 126       | 150 332  | 1.7% 0.7% 1.2%   |
| 18) 44 M, LG Shield          | Indirect R              | 154       | 136       | 171 247  | 155       | 147       | 167 251  | 3.0% 6.5% 4.7%   |
| 19) 44 M, SM Shield          | Indirect L              | 131       | 113       | 171 247  | 126       | 115       | 167 251  | -1.5% 0.1% -0.7% |
| 20) 75 M, SM Shield          | Indirect L              | 72        | 130       | 164 243  | 68        | 127       | 146 227  | 5.4% 4.3% 4.8%   |
| 21) 71 M, LG Shield          | Direct/Indirect R       | 180       | 159       | 236 320  | 184       | 158       | 235 320  | 2.6% -0.3% 1.0%   |
| 22) 70 M, LG Shield          | Direct/Indirect R       | 187       | 150       | 188 343  | 188       | 152       | 184 344  | 2.7% 1.0% 1.8%   |
| 23) 79 M, LG Hybrid          | Indirect R              | 149       | 150       | 183 387  | 131       | 161       | 163 397  | -1.1% 4.7% 0.6%   |
| 24) 79 M, LG Hybrid          | Indirect L              | 159       | 153       | 193 387  | 135       | 158       | 163 397  | 0.4% 0.7% 0.6%   |
| 25) 65 F, SM Hybrid          | Indirect R              | 102       | 131       | 346 344  | 101       | 129       | 339 340  | 1.0% -0.4% 0.3%   |
| 26) 30 M, LG Hybrid          | Indirect R              | 192       | 156       | 163 397  | 182       | 153       | 149 371  | 3.4% 4.6% 4.0%   |
| 27) 30 M, LG Hybrid          | Indirect L              | 181       | 149       | 163 397  | 169       | 139       | 149 371  | 2.0% -0.2% 0.9%   |

Average % Change 2.5% 1.6% 2.0%

*NFHD = NiTiNol Framed Hernia Device, Pt = Patient, CC = Cranial-Caudal Measurement, ML = Medial, Lateral, or Oblique Measurement. All measurements are in mm.
CONCLUSIONS

The radiographic appearance of the NiTiNol-framed, polypropylene mesh hernia device remains stable with regard to size, shape, and position 6 months after implantation when used for laparoscopic inguinal hernioplasty. The radiographic appearance of the device remained stable during the critical period of tissue ingrowth without the use of any fixation. The NiTiNol frame of this device provides the surgeon with a new option—the ability to consistently image a hernia device with a single-view plain radiograph. The reliability of the performance of the NiTiNol-framed hernia device in this initial study is encouraging. A larger trial with an extended follow-up interval of this device is warranted.

References:

1. Gonzalez R, Fugate K, McClusky D III, et al. Relationship between tissue ingrowth and mesh contraction. World J Surg. 2005;29:1038–1043.
2. Schug-Pass C, Tamme C, Tannapfel A, Kockerling F. A lightweight polypropylene mesh (TiMesh) for laparoscopic intraperitoneal repair of abdominal wall hernias: comparison of biocompatibility with DualMesh in an experimental study using the porcine model. Surg Endosc. 2006;20:402–409.
3. Klinge U, Klosterhalfen B, Muller M, Ottinger A, Schumpelick V. Shrinking of polypropylene meshes in-vivo: an experimental study in dogs. Eur J Surg. 1998;164:965.
4. Coda A, Bendavid R, Motto-Micca F, Bossotti M, Bona A. Structural alterations of prosthetics meshes in humans. Hernia. 2003;7:29–34.
5. Schumpelick V, Arlt G, Schlachetzki A, Klosterhalfen B. Chronic inguinal pain after transperitoneal mesh implantation. Case report of net shrinkage. Chirurg. 1997;68(12):1297–1300. Article in German.
6. Amid PK, Schulman AG, Lichtensein IL. A Simple Stapling Technique for the Prosthetic Repair of Massive Incisional Hernias. In: Arregui ME, Nagan RF, eds. Inguinal Hernia, Advances or Controversies? Oxford: Radcliffe Medical Press; 1994:511–514.
7. Paajanen H, Hermunen H. Long term pain and recurrence after repair of ventral incisional hernias by open mesh: clinical and MRI study. Langenbecks Arch Surg. 2004;389(5):366–370.
8. Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia. 1997;1:15–21.
9. Schwab R, Schumacher K, Junge K, et al. Biomechanical analyses of mesh fixation in TAPP and TEP hernia repair. Surg Endosc. 2008;22(3):731–738.
10. Schwab R, Willms A, Kroger A, Becker HP. Less chronic pain following mesh fixation using fibrin sealant in TEP inguinal hernia repair. Hernia. 2006;10(3):272–277.
11. Koninger J, Redecke J, Butters M. Chronic pain after hernia repair: a randomized trial comparing Shouldice, Lichtenstein and TAPP. Langenbecks Arch Surg. 2004;389:361–365.
12. Neumayer L, Giobbe-Hurder A, Jonasson O, et al. Veterans Affairs Cooperative Studies Program 456 Investigators. Open mesh versus laparoscopic mesh repair of inguinal hernia. N Engl J Med. 2004;350(18):1819–1827.
13. Amid PK. Causes, prevention and surgical treatment of posthernorrhaphy neuropathic inguinodynia: Triple neurectomy end implantation. Hernia. 2004;8(4):343–349.
14. Brown R. Rebound HRD (Hernia Repair Device). SAGES Annual Meeting Poster presentation ETP014. Las Vegas, Nevada, 2007.