SCIENTIFIC PAPER

NiTiNol Hernia Device Stability in Inguinal Hernioplasty Without Fixation

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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.

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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.[3] 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 Ni-TiNol 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**.

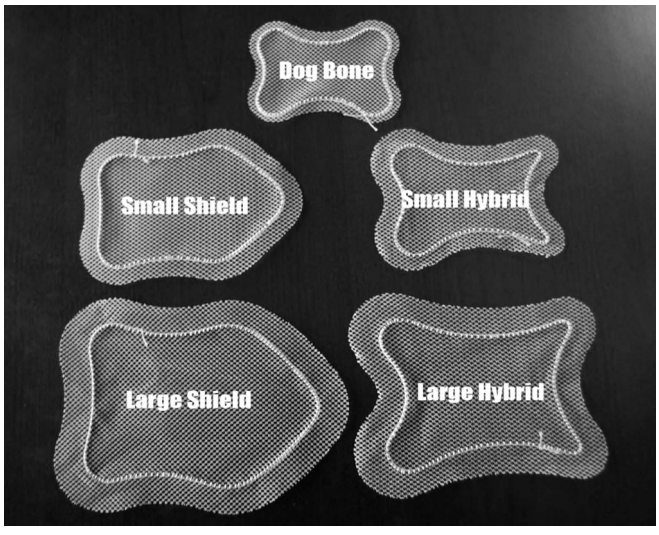

Figure 1. Shapes and sizes of the NFHD devices used.

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

$$\frac{\left(\text{2nd device}\right) - \left[\left(\frac{\text{2nd anatomic}}{\text{1st anatomic}}\right) \times \text{1st device}\right]}{\text{1st device}} \times 100 = \%\,\Delta$$

Figure 2. The formula above was used to correct for any confounding differences between the first and second X-ray measurements. Such differences may be due to subtle variations in patient positioning, the distance between the patient and the X-ray tube, or both of these.

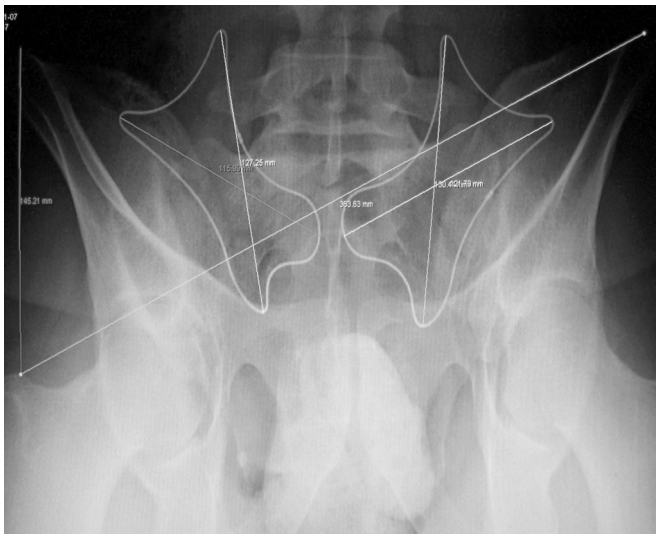

Figure 3. The cranial-caudal (CC) and medial-lateral or oblique (ML) measurements of the NiTiNol frame and anatomic landmarks using the measurement function available with the PACS system [7 Medical Systems 7i On Demand™ SUV Analysis tool (Standardized Uptake Value)].

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

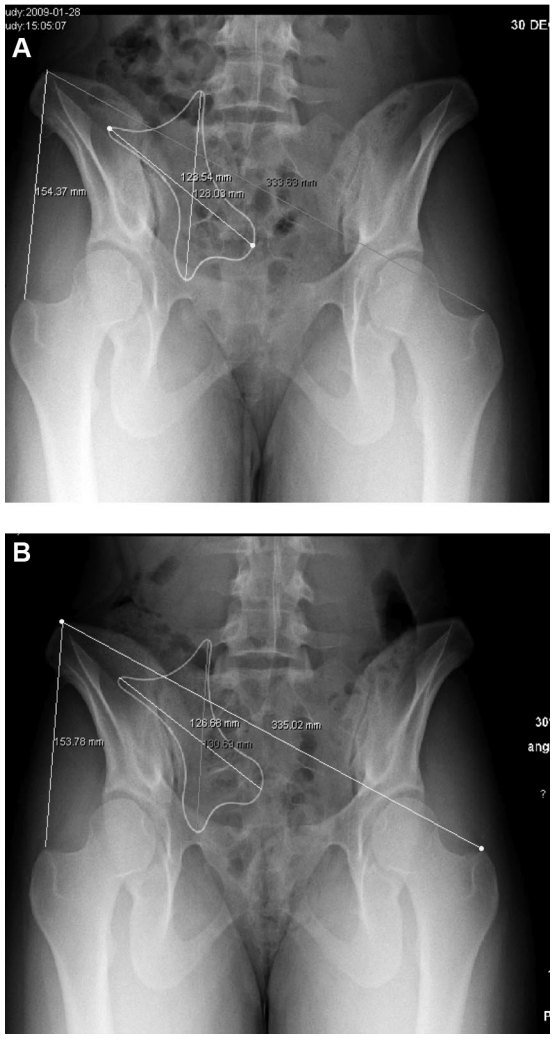

Figure 4. Side-by-side comparison measurements of the initial postoperative X-ray and the second postoperative X-ray (taken after a minimum of 6 months postoperatively).

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.

Table 1.
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**

	1ST X-ray[a]					2nd X-ray[a]				%change[a]		
Patient, Age, Sex, Device Type	Location & Type of Hernia	NFHD CC	NFHD ML	Pt CC	Pt ML	NFHD CC	NFHD ML	Pt CC	Pt ML	NFHD CC	NFHD ML	NFHD 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%	3.6%	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%	3.0%	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%

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

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)**.

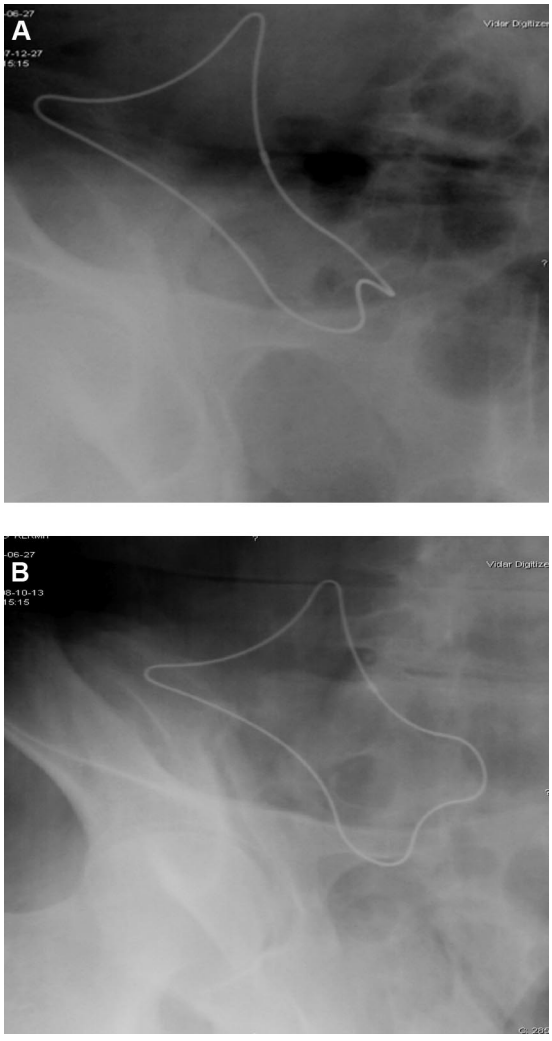

Figure 5. Side-by-side comparison of the initial and second X-ray (292 days postoperatively) of the outlier patient who had an 11.33% overall increase in size.

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.

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