Journal of Vascular Surgery
Venous and Lymphatic Disorders™

A novel method of edema fluid drainage in obstructive lymphedema of limbs by implantation of hydrophobic silicone tubes

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Objective: **Lymphedema of limbs is caused by partial or total obstruction of lymphatic collectors as a consequence of skin and deep soft tissue inflammation, trauma of soft tissues and bones, lymphadenectomy, and irradiation in cancer therapy. According to the statistics of the World Health Organization, around 300 million people are affected by pathologic edema of limbs. Effective treatment of such large cohorts has been a challenge for centuries. However, none of the conservative and surgical methods applied so far proved to restore the shape and function of limbs to normal conditions. Actually, physiotherapy is the therapy of choice as a main modality or supplementary to surgical procedures divided into two groups: the bridging drainage and excisional techniques. The microsurgical operations can be performed if some parts of the peripheral collecting lymphatics remain patent and partially drain edematous regions. However, in advanced cases of lymphedema, all main lymphatics are obstructed and tissue fluid accumulates in the interstitial spaces, spontaneously forming "blind channels" or "lakes." The only solution would be to create artificial pathways for edema fluid flow away to the nonobstructed regions where absorption of fluid can take place. The aim of this study was to form artificial pathways for edema fluid flow by subcutaneous implantation of silicone tubes placed along the limb from the lower leg to the lumbar or hypogastric region.**
Methods: **In a group of 20 patients with obstructive lymphedema of the lower limbs that developed after lymphadenectomy and irradiation of the pelvis because of uterine cancer with unsuccessful conservative therapy, implantation was done, followed by external compression as intermittent pneumatic compression and elastic support of tissues. Postoperative circumference measurements, lymphoscintigraphy, and ultrasonography of tissues were carried out during 2 years of follow-up.**
Results: **There was a fast decrease of calf circumference since the day of implantation during weeks by a mean 3% with stabilization afterward. Patency of tubes and accumulation of fluid around them were seen on ultrasonography and lymphoscintigraphy in all cases. No tissue cellular reaction to silicone tubes was noted.**
Conclusions: **The simplicity of the surgical procedure, decrease of limb edema, and lack of tissue reaction to the implant make the method worth applying in advanced stages of lymphedema with large volumes of accumulated tissue edema fluid. (J Vasc Surg: Venous and Lym Dis 2015;3:401-8.)**

Lymphedema of limbs is caused by partial or total obstruction of lymphatic collectors as a consequence of skin and deep soft tissue inflammation, trauma of soft tissue and bones, lymphadenectomy, and irradiation for cancer.[1] Even when some lymphatic fragments remain patent, their transport capacity is not sufficient for evacuation of excess edema fluid. Subsequently, limb weight increases, adversely affecting its function. Hyperkeratosis and fibrosis of subcutaneous tissue develop. Impaired evacuation of stagnant tissue fluid is followed by colonization of deep tissue by bacteria penetrating foot skin, dominated by *Staphylococcus epidermidis*.[2,3] Patients suffer from recurrent attacks of dermatolymphangioadenitis (DLA; previously called cellulitis).[4]

According to the statistics of the World Health Organization, around 300 million people are affected by pathologic edema of limbs. Effective treatment of such large cohorts has been a challenge for centuries. However, none of the conservative and surgical methods applied so far proved to restore the shape and function of limbs to normal conditions. Actually, physiotherapy is the therapy of choice as a main modality or supplementary to surgical procedures divided into two groups: the bridging drainage and excisional techniques. The efforts to drain lymphedema by pedicle flaps, myocutaneous flaps, omental transposition, and intestinal flaps are historical.[5-8] Historically, a method of improving lymph drainage by implantation of silicone tubes in cases of lymphedema of the arm after treatment of breast cancer was tried but discarded because of infection.[9] Microsurgical lymphatic anastomoses to vein (nodovenous, lymphovenous) and end to end to lymphatics themselves are now performed. Lymphatic and venous autografts are interpositioned to bypass lymphatic blockade.[10-16] The free transplantation of a lymphatic flap with its own vascularization from healthy inguinal nodes to axillary or

From the Department of Epigenetics and Department of Applied Physiology, Mossakowski Medical Research Center, Polish Academy of Sciences; and the Central Clinical Hospital, Ministry of Home Affairs.
This study was supported by a grant from the National Center for Science, Poland: No. NN404113139.
Author conflict of interest: none.
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The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.
2213-333X

http://dx.doi.org/10.1016/j.jvsv.2015.05.001

inguinal blockade is the recently described procedure.[17-19] Debulking, such as excision of skin, subcutis, and fascia, or fat tissue liposuction is performed in advanced stages.[20-22]

All these microsurgical operations can be performed if some portions of the peripheral collecting lymphatics remain patent and partially drain tissue edema fluid. However, in advanced cases of lymphedema, all main lymphatics are obstructed and tissue fluid accumulates in the interstitial spaces, spontaneously forming "lakes" and blind, sometimes interconnected "channels" of irregular shape.[20] In such cases, the only solution would be to create artificial pathways for edema fluid flow away to the nonobstructed regions, where absorption of fluid can take place (Fig 1). We decided to form them by the subcutaneous implantation of silicone tubes placed from the lower leg to the lumbar or hypogastric region. In a group of patients with obstructive lymphedema of the lower limbs that developed after lymphadenectomy and irradiation of the pelvis because of uterine cancer, implantation was done, followed by external compression as intermittent pneumatic compression and elastic support of tissues. Postoperative circumference measurements, lymphoscintigraphy, and ultrasonography of tissues were carried out during a 2-year follow-up period.

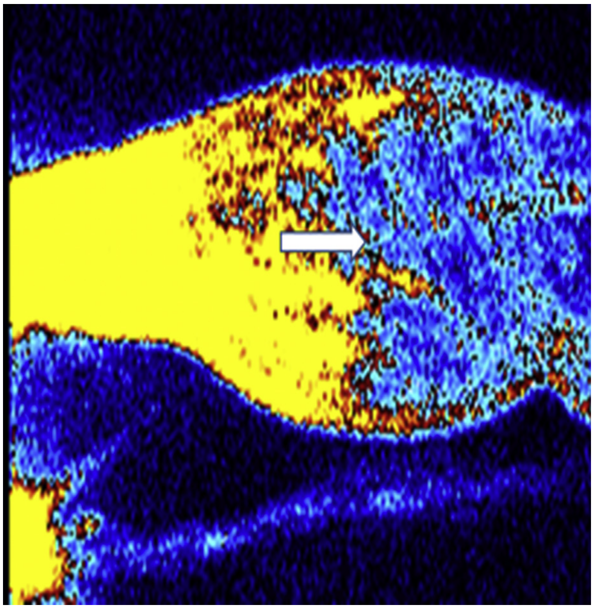

Fig 1. Lymphoscintigraphy of tissue fluid channels in a lymphedematous calf in a horizontal position. In the *lower portion*, outline of lymphatics of the normal contralateral limb. The channels were spontaneously formed by excess tissue fluid accumulating because of lack of drainage caused by obstruction of collecting lymphatics. Implantation of silicone tubes in this region could create a pathway for flow to the nonedematous parts of the body, such as the hypogastrium or buttock regions.

METHODS

Patients. The study was carried out on 20 female patients with a mean age of 58 years (range, 42-68 years) with a diagnosis of lymphedema of one lower limb (stage III or stage IV, with a duration of 2 to 15 years) that developed after hysterectomy with pelvic lymphadenectomy and radiotherapy for cervical cancer. Edema was diagnosed from 2 months to 8 years after initial therapy. Cases with peripheral metastases, acute inflammation of the lymphedematous limb, chronic venous insufficiency, and edema of systemic etiology were excluded from the study. All patients were wearing class 2 compression stockings (pressure, 20-30 mm Hg) for 6 months or longer before implantation of silicone tubes. Moreover, they routinely used intermittent pneumatic compression. They eventually reached a stable stage with no more decrease in limb circumference. Because there was no progress in therapy and limb size was adversely affecting its function, implantation of tubes was proposed.

Because of recurrent attacks of DLA, all patients had been receiving long-term benzathine penicillin prophylaxis for at least 6 months before implantation of the tubes. This is a routine protocol for all lymphedema patients in our institution. Written consent for surgery was obtained from the patients. The study was approved by the Warsaw Medical University Ethics Committee.

Clinical staging. Staging was based on clinical evaluation. In stage III, thigh and calf were swollen without skin changes. In stage IV, the whole limb was edematous, with foot and calf skin hyperkeratosis and papillomatosis of the toes.

Lymphoscintigraphic staging. The lymphatic pathway was also evaluated on lymphoscintigraphic pictures. Technetium Tc 99m colloidal albumin (Nanocoll) was injected into the toe web and sole, and imaging was done 10 and 60 minutes later after standard walking at 3 km/h. In stage III, small fragments of draining lymphatics were seen in the calf and thigh, with some few inguinal nodes of irregular outline appearing after 1 hour of walking. Stage IV was characterized by spread of tracer in the foot and entire calf without visualization of collecting lymphatics and nodes. In none of the investigated patients did the tracer pass on the affected side above the inguinal crease level.

Limb circumference. Circumference measurements of the limb were carried out at five levels: above ankle, midcalf, below knee, above knee, and midthigh. The data were collected for at least 1 year before surgery during the period of conservative therapy and then after surgery. Measurement of circumference has superiority to calculation or measurement of total volume changes as the decrease of size of the lower part of the calf, facilitating free movements in the ankle and knee joints, is most important in lymphedema. Moreover, these regions are usually exposed to future changes, such as leakage, infections, and ulcerations, and less edema prevents development of tissue changes. Measurements were done in all patients by the same therapist.

Implant characteristics. Sterile medical-grade silicone tubes of 3 mm outer diameter and 2 mm inner diameter were used (Fig 2). The tube material was hydrophobic, preventing ingrowth of connective tissue into the lumen and around it. Hydrophobic properties were tested

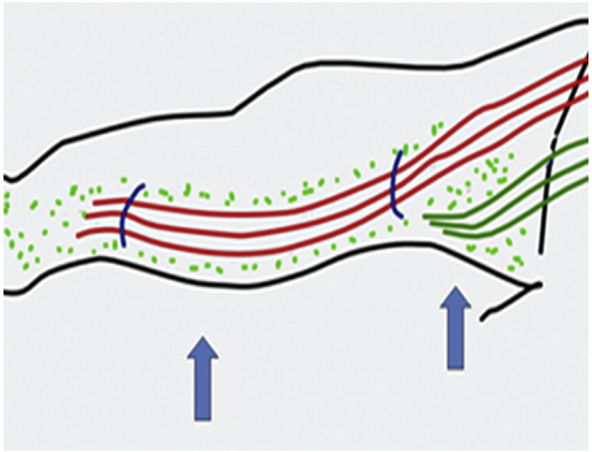

Fig 2. Schematic presentation of the technique of implantation of silicone tubes. The *arrows* show three tubes implanted subcutaneously along the whole limb and under the inguinal crease (above the inguinal ligament), the main anatomic obstacle for edema fluid flow to the hypogastrium. Three transverse 3-cm-long incisions are made for tunneling of the subcutaneous tissue and implantation of tubes.

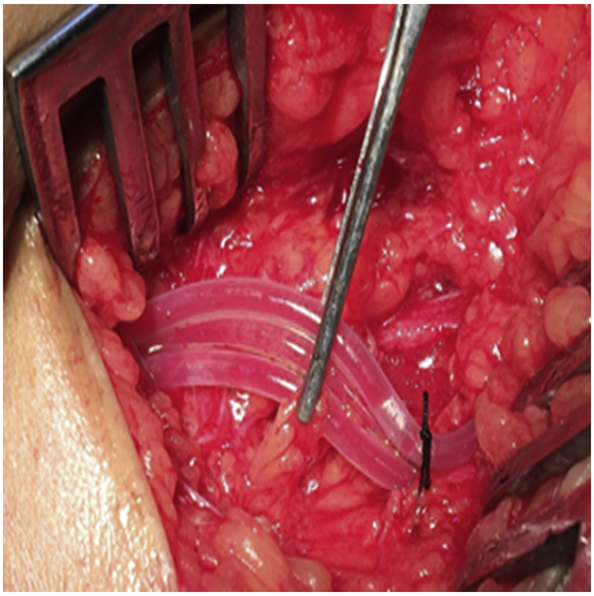

Fig 3. Inguinal region with three tubes implanted from the calf, along the limb, through the inguinal fossa, and under the inguinal crease (above the inguinal ligament) to the hypogastrium. Note that the tubes filled up with watery fluid immediately after implantation. The metal instrument is surgical forceps.

previously in rats, allowing pullout of the implanted tubes without resistance even months after implantation. The concentricity of tubes did not change, and there was no reduction of ovality. Three tubes of a length adjusted to that of the limb were tied together, and multiple lateral holes were made at distances of 3 cm. On a cross-view, they formed a space between them for accumulation of edema fluid after implantation.

Implantation technique. A 2-cm-long incision was made at the border of the hypogastrium or lumbar region 10 cm above the inguinal crease (Fig 3). A 1.5-cm-wide and 100-cm-long metal tube tunneling device was introduced under the skin and bluntly passed in the subcutaneous tissue toward the thigh and internal aspect of the calf. Incisions 2 cm long were made in the groin and calf, through which the tunneling device was passed. The silicone tube was passed upward through the tunneling device, after which the tunneling device was removed. The upper and lower ends of silicone tubes were fixed to fascia with absorbable sutures.

Postoperative treatment and evaluation. Intermittent pneumatic compression was carried out for 14 days in the outpatient department. After that, patients used pumps at home continually daily for 30 to 60 minutes. Elastic stockings of second-degree compression were used as before surgery. Oral amoxicillin 1 g was given for 1 month, after which extended-dose prophylactic penicillin therapy was resumed as before operation. Patients had limb circumference measurements made at five levels daily for the first 14 days in the outpatient department, then weekly at home at the same time of the day and in the same limb position. Patients were seen monthly for the first 3 months, followed by bimonthly control for the next year. Ultrasound investigation and lymphoscintigraphy were done after 3 months and also later, depending on the limb circumference changes. When the limb size did not decrease further, lymphoscintigraphy was done to check patency of the tubes and space around them. Nanocoll was injected into the toe webs and sole, as described earlier before implantation, and imaging was done 10 and 60 minutes later after standard walking. Three parameters were evaluated: (1) the outline of the implanted tubes, (2) the ratio of the preimplantation and postimplantation radioactivity level of the leg area from ankle to knee level compared with the healthy contralateral limb, and (3) the accumulation of radioactivity at the proximal end of the tubes. In five patients, Nanocoll was also injected subcutaneously close to the implanted tubes to better visualize the position and patency of the implant.

Statistical evaluation. Two-paired Student *t*-test was applied for evaluation of differences in radioactivity level before and after implantation, with significance defined at the $P < .05$ level.

RESULTS

Clinical evaluation. Eight patients have been followed up for 24 months and 12 for 6 to 16 months (median, 11 months; range, 6-24 months). The postoperative course was uneventful in 17 cases. Inflammatory reaction along the implant was not observed. In three patients, limited inflammation was observed at the proximal end of the implant in the hypogastrium, most likely due to the reaction to bacteria drained from the calf. Under normal

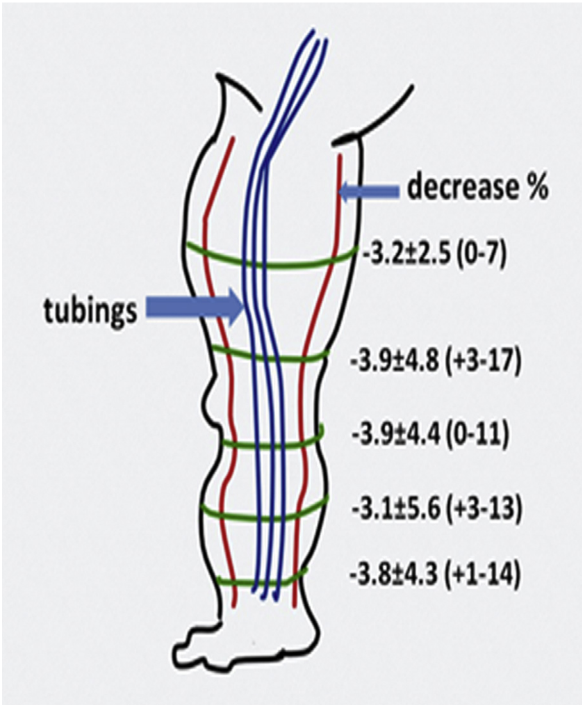

Fig 4. Lower limb circumference 3 to 24 months after silicone tube implantation. Decrease by a mean 3% at almost all levels ± standard deviation (percentage range in parentheses). The high standard deviation was dependent on different individual responses at various levels to more or less fibrous changes where decrease of circumference was less or nil. However, calculating for the whole limb, the decrease was significant for all patients.

conditions, a small mass of microbes is transported with lymph from the skin to the regional lymph nodes. Much the same should be expected to take place along the tubes. Sometimes the bacterial load may be so large that it evokes a host reaction (DLA). This should not be considered infection, although bacteria play a basic role here, as this is a normal "cleansing" process. It was controlled by 7 days of oral amoxicillin without recurrence. There were no recurrent attacks of DLA in all patients. Evidently less restriction in limb movements and easier squatting or kneeling were observed.

Circumference changes. The circumference decreased in all patients within the first 2 weeks, differently at various levels of the limb, by −3.2% to −3.9% with a range from +3% to −17% (Fig 4). In a few cases, there was slight increase at one level and decrease at the other levels, presumably due to insufficient drainage in some regions. The greatest decrease was observed in the calf. The wide range in decrease of limb girth was the consequence of individual differences in edema fluid volume accumulating in the subcutaneous tissue. Interestingly, the process of decreasing limb size was fastest in the first weeks after implantation, with slow changes afterward.

Lymphoscintigraphic imaging. In eight cases, tracer filled up tubes or the space between the tubes at their whole length (Figs 5-9). In the remaining cases, radioactivity of leg tissues was decreased compared with the pre-implantation period, and a smaller diameter of the limb could be observed. The ratio of radioactivity in the area marked by isotope of the lymphedematous to the normal limb decreased from 1.8 ± 0.6 before implantation to 1.2 ± 0.3 after surgery ($P < .05$). In some cases, the tube was not opacified, but isotope accumulation was seen in the lumbar region, drained from the foot. Injection of Nanocoll at the lower end of the tubes showed their patency. Their outline was interrupted at various levels by edema fluid entering tubes from tissues.

Ultrasonography of limbs. The tubes were identified in all cases (Fig 10). Their position remained unchanged,

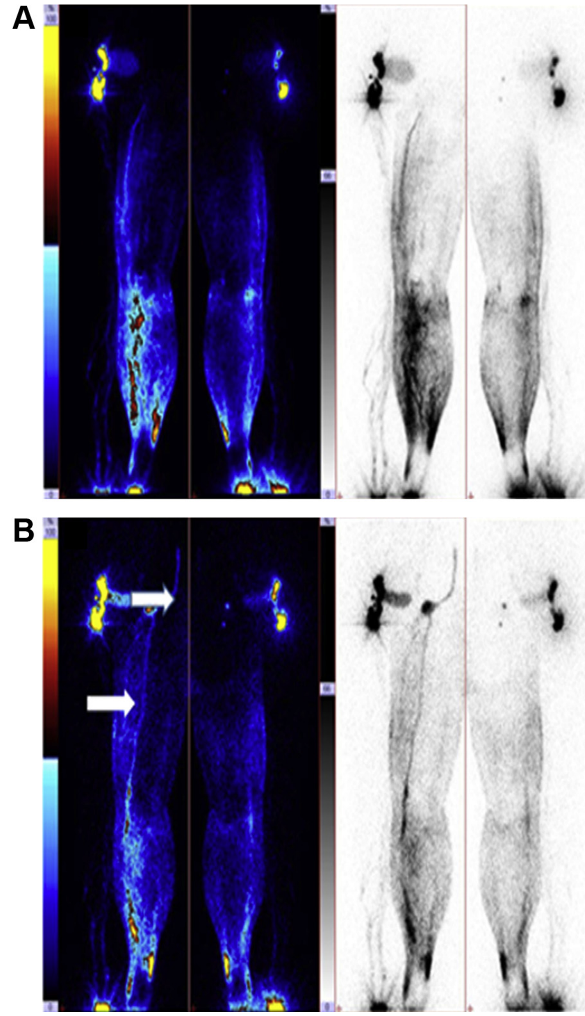

Fig 5. Lymphoscintigram of a female patient with right limb lymphedema after hysterectomy and radiotherapy because of uterine cancer **(A)** before and **(B)** 8 months after implantation of silicone tubes passing under the inguinal crease. The *lower arrow* shows the tube filled with isotope in the calf, and the *upper arrow* shows accumulation at the tube's outlet in the lumbar region. Decreased size of the calf.

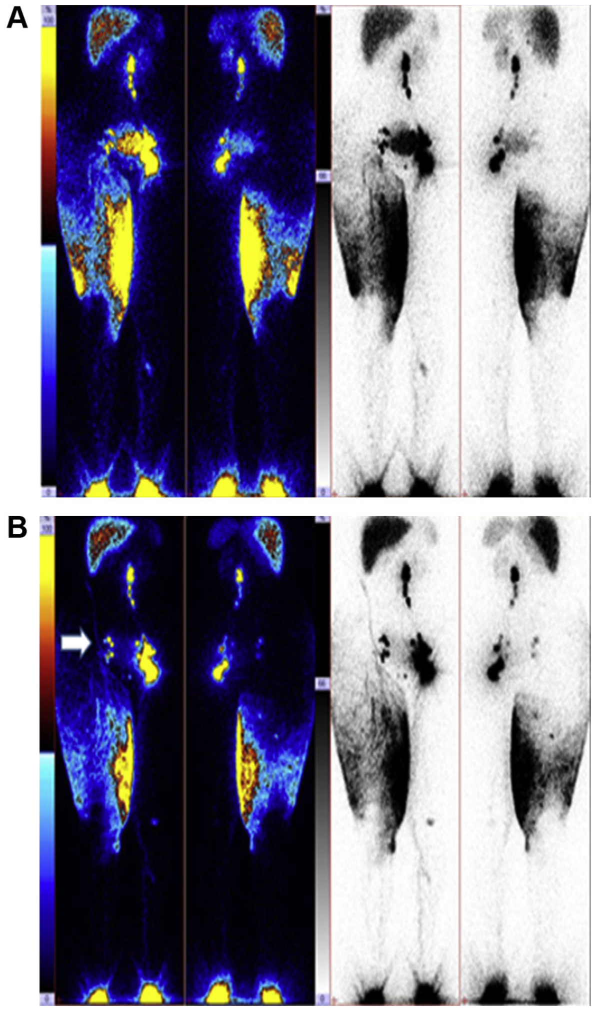

Fig 6. Lymphoscintigram of another patient with right lower limb lymphedema **(A)** before and **(B)** 16 months after silicone tube implantation. Tubes are filled with isotope in the thigh and hypogastrium (*arrow*), better seen on the black and white picture. Less accumulation of isotope in the medial aspect of the thigh compared with the preoperative image. Decreased size of the thigh.

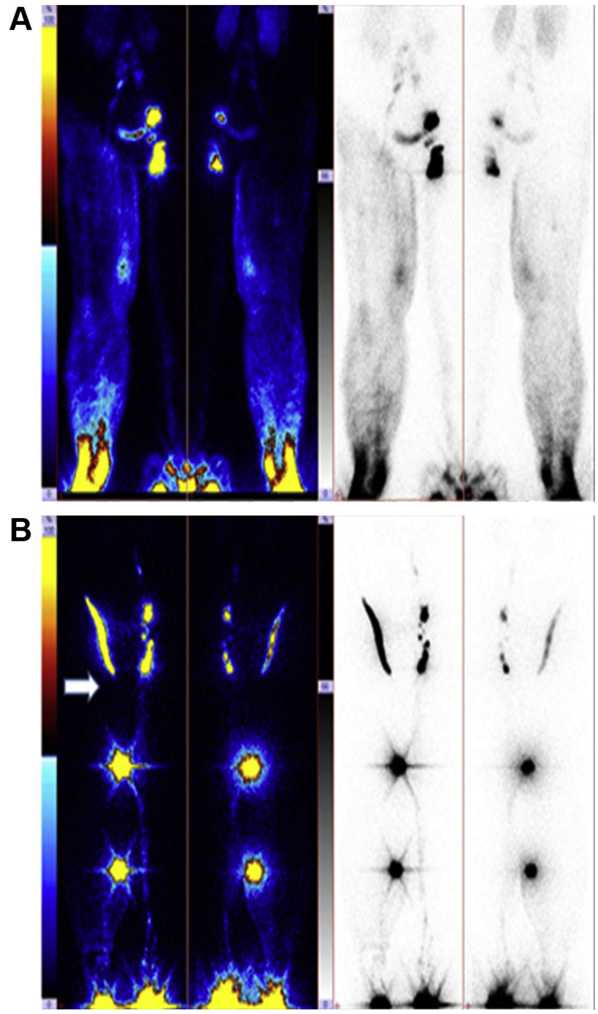

Fig 7. Lymphoscintigram of a female patient after vulvar cancer treatment. **A,** Lymphedema stage IV of the entire limb. **B,** At 24 months after silicone tube implantation. Isotope injection in the inguinal region shows patency across the inguinal crease to the hypogastrium (*arrow*). Note that there is much less isotope accumulation in the whole limb compared with the preoperative picture. Isotope was also injected subdermally at two sites in the calf and thigh. No visualization of draining skin lymphatics, indicating no fluid stasis in these regions.

and their lumens were patent. Accumulation of fluid around them was seen in all cases. In cases observed for 24 months with decrease of circumference, much less fluid was observed on ultrasonography compared with the initial images.

Histopathology of tissue around the implant. In one case, the tubes had to be moved laterally under the inguinal crease because of pressure on a cutaneous nerve. At the time of surgery, a biopsy sample of tissue surrounding the tubes was taken. Tubes were lying loosely surrounded by fluid. On histologic examination, no cellular infiltrates and loose fibrous tissue separated by fluid were seen (Fig 11).

DISCUSSION

To our knowledge, this is the first report of implantation of silicone tubes substituting for occluded lymphatic collectors of the lower limb superficial system in advanced stages of lymphedema. The study provided the following observations: (1) evident fast decrease of calf circumference from the day of implantation and stabilization after weeks when excess fluid has been evacuated, (2) patency of tubes on ultrasonography and lymphoscintigraphy, (3) accumulation of fluid around the tubes in all cases, and (4) lack of tissue cellular reaction to silicone tubes. It has been documented that the medical-grade silicone tubes are biologically inert and do not evoke any evident foreign body reaction. Moreover, they are hydrophobic, preventing obstruction by ingrowing fibrous tissue. It is also important that bacteria do not adhere to the silicone surfaces.

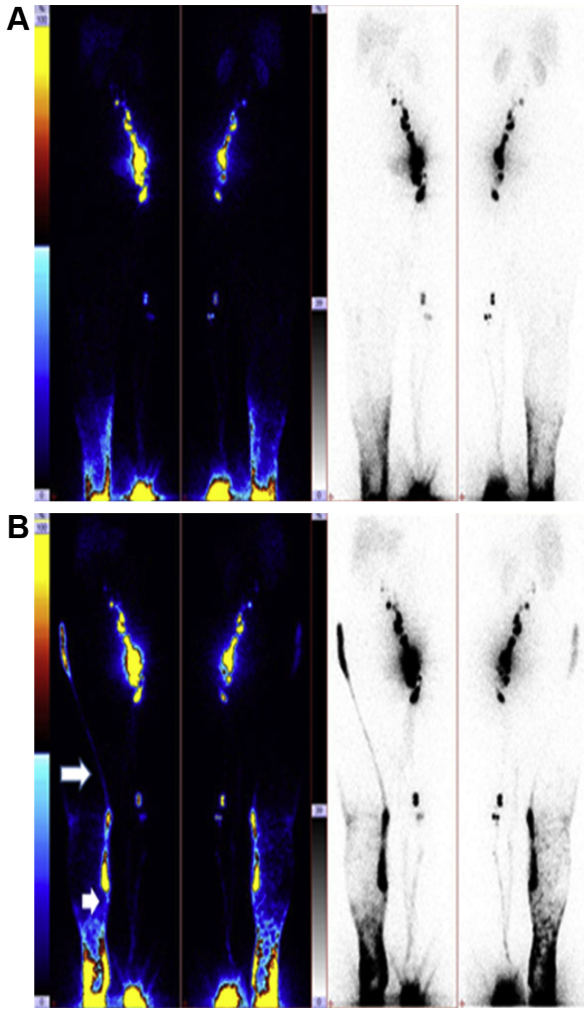

Fig 8. Lymphoscintigram of the right lower limb in a female patient after hysterectomy and radiotherapy **(A)** before and **(B)** 21 months after implantation. Spontaneous filling of the implanted tubes (*arrow*). They crossed the inguinal crease with more isotope in the upper part. Note decrease in the size of the calf.

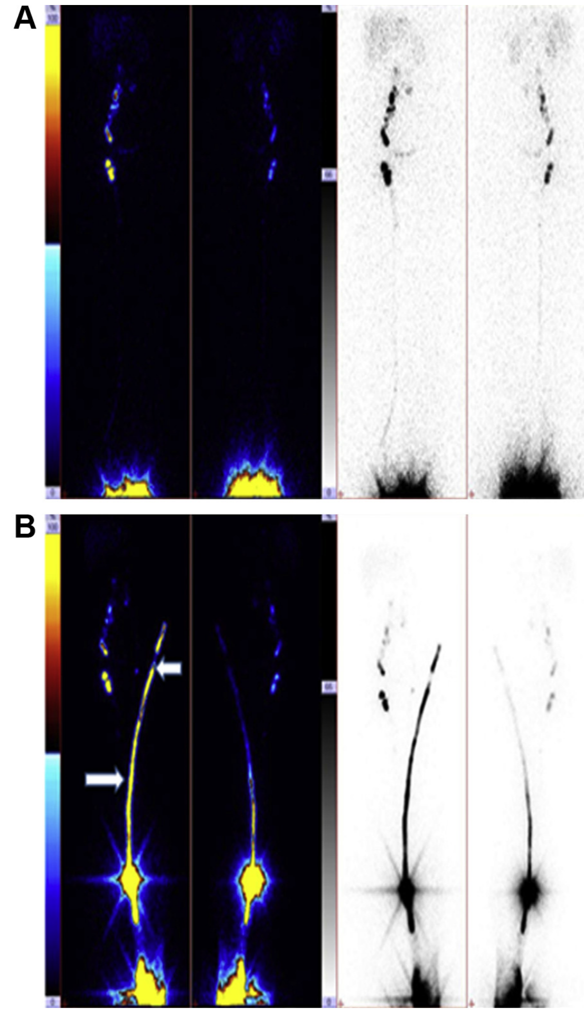

Fig 9. Lymphoscintigram of the left lower limb in a female patient after hysterectomy and radiotherapy **(A)** before and **(B)** 24 months after implantation of silicone tubes. There was no spread of isotope from the toe web injection site, caused by obstruction of foot lymphatics. Injection of isotope at the lower end of the tubes 2 years after implantation showed patency of the implant and fluid flow to the hypogastrium (*lower arrow*). Interestingly, edema fluid flowed from tissues to the tube also at the site of lateral holes in the thigh (*upper arrow*). Note site of lower radioactivity between the sites of high activity in the tube.

Decrease in limb circumference in midcalf and thigh was accompanied by less fluid around the implants. This could be accounted for by effective evacuation of fluid to the hypogastrium or lumbar tissues.

The accumulating tissue fluid cannot flow along the tubes by itself but requires a propelling force. This can be provided by application of intermittent pneumatic compression as well as by walking in short-stretch bandages or stockings. Tissue edema fluid is drained from the swollen tissues to the hypogastrium or lumbar region. The question remains open about the absorption capacity of healthy tissues at the outlet of tubes. We observed a low degree of edema developing in this region during day activities, subsiding during night rest. This could be accounted for by sufficient absorption capacity from the hypogastrium.

Our initial observations indicate that although the new pathway was created and remained patent for years, the mobilization of stagnant fluid from the regions remote from the silicone tubes may not be sufficient and needs more lateral compression force acting toward the longitudinally located implant. Whether the silicone tissue fluid pathways will be durably efficient in transporting excess fluid away remains to be seen in a long follow-up. Our first observations, as long as 24 months, indicate that drainage was efficient in the calf and slightly less in the thigh. There was evident and fast decrease of limb circumference in all patients. The ultimate results in terms of limb volume

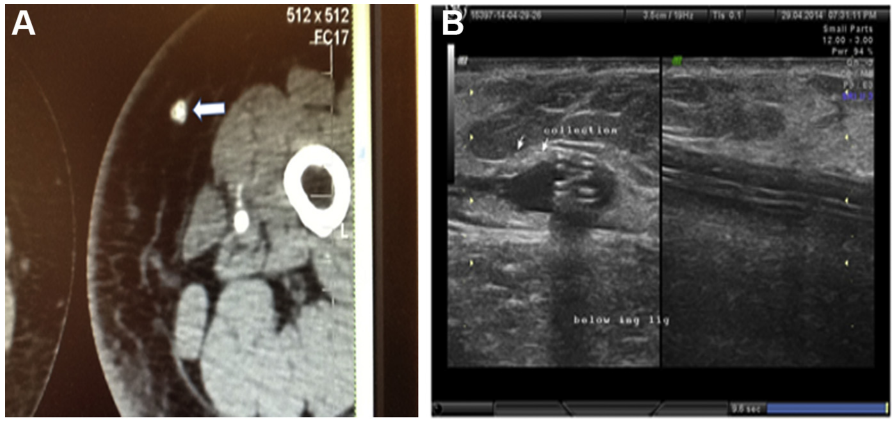

Fig 10. A, Computed tomography scan of the lower limb with lymphedema with implanted silicone tubes (*arrow*). **B,** Ultrasonographic image of tubes along the thigh below the inguinal region. Fluid accumulating between tubes (*arrow*).

will depend on how much mobile tissue fluid is being continuously removed along drains and how much fibrous tissue is formed. Fibrotic tissue contains little fluid, and its stiffness hampers fluid flow toward the tubes.

There were no major inflammatory reactions to the implanted tubes in 95% of observed patients. In three patients, inflammation lasting several days was seen at the upper end of the implants, which was easily controlled by antibiotics. This reaction was most likely caused by the microbes drained from the peripheral parts of the lymphedematous limb. Under normal conditions, single bacterial cells are transported from the skin surface through lymphatics to the regional lymph nodes.[2] A similar process should take place along the implants. This should not be considered an infection in clinical terms but rather a physiologic process of elimination of microbes by the lymphatic system.

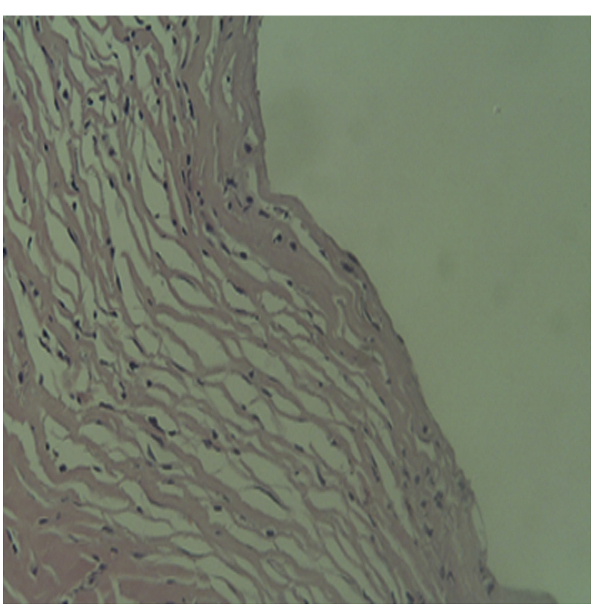

Fig 11. Histopathology of tissue wall surrounding the implanted tubes 2 years after implantation. Note no lining with endothelial cells and loose collagen bundles around the drains. No infiltrates of inflammatory cells (hematoxylin and eosin stain ×200).

CONCLUSIONS

The simplicity of the surgical procedure and lack of reaction to the implant make the method worth applying in advanced stages of lymphedema with large volumes of accumulated tissue fluid. Long follow-up with satisfactory results will authorize further trials in early stages of lymphedema, thus preventing progression of anatomic changes specific for lymphedema, such as fibrosis, hyperkeratosis, and tissue fluid leakage.

AUTHOR CONTRIBUTIONS

Conception and design: WO
Analysis and interpretation: WO, MZ
Data collection: WO, MZ
Writing the article: WO
Critical revision of the article: WO, MZ
Final approval of the article: WO, MZ
Statistical analysis: WO, MZ
Obtained funding: Not applicable
Overall responsibility: WO

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Submitted Jan 26, 2015; accepted May 5, 2015.