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Original Research

Long-Term Follow-Up of Synthetic Ligament (Orthotape) Usage in Reconstructive Surgery of the Hand

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Purpose: Synthetic ligaments have been widely used in the knees for anterior cruciate ligament reconstruction and in the shoulder rotator cuff repair, but they have been rarely used in the hand. The only reported usage is in the Artelon space for carpometacarpal joint osteoarthritis. We describe our experience using the synthetic ligament or scaffold known as Orthotape (its predecessor was known as the Leeds-Keio ligament) in the hand and fingers.

Methods: We retrospectively reviewed all patients in whom polyester synthetic ligament (Orthotape) was used to reconstruct absent tendons involving both flexor and extensor compartments between 2011 and 2016. The reconstruction procedures were performed as elective surgeries. The tendons were absent due to either trauma or infection. We collected data on demographics, the injury mechanism, prior surgeries, the zone of tendon loss, the presence of skin flaps, and the number of strips of ligament inserted.

Results: We inserted 18 strips of Orthotape in the hands of 9 patients. The follow-up period was 3–7 years, and the mean duration of Orthotape in the hand was 44.1 (range, 1–91) months. Four strips extruded, resulting in a 22.2% extrusion rate. Of the 9 patients, 5 retained the Orthotape within their hand for time periods ranging from 60 months (5 years) to 91 months (7.5 years). The extruded strips were in the superficial areas of the hand. Seven patients had traumatic injuries with varying severity and 2 had infections.

Conclusions: The high extrusion rate of Orthotape discourages its use in the superficial areas of the hand, including flexor and extensor surfaces of the fingers and hand. We recommend its usage in regions with a thick skin cover such as underneath a flap or in deep areas such as the palm. Nevertheless, it remains as a possible option in cases of complex reconstruction with a limited availability of donor tendons.

Type of study/level of evidence: Therapeutic IV.

Damaged tendons or loss of a tendon poses a major surgical reconstructive problem. Conventional surgical methods harvest donor tendons from the palmaris longus, plantaris, extensor digitorum longus, or tensor fasciae lata and are associated with morbidity and extra operating time. In an attempt to prevent donor site morbidity, limited availability, safety issues, and an extra surgical procedure, biological and synthetic scaffolds have been devised to replace the conventional autografts. Synthetic scaffolds have superior mechanical strength and consistency but have poor biocompatibility, resulting in high incidences of postoperative infection and chronic immune response.[1]

Chen et al[1] summarized that synthetic scaffolds are generally well supported in their usage, although there are reported complications of synovitis, osteolysis, and foreign body rejection. The US Food and Drug Administration has withdrawn approval for

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synthetic scaffolds for use in the human body, although they continue to be widely used in Asia and Europe.[1] However, based on a later publication, these synthetic scaffolds are thought to now have fewer complications and better outcomes because of newer technology producing superior materials and better surgical techniques.[2]

Synthetic scaffolds are made of synthetic polymers such as polytetraflouroethylene (Gore-Tex, Gore and Associates), terephthalic polyethylene polyester (Lars ligament, LARS), polyester ethylene terepthtahalate (Leeds-Keio, Neoligaments, Xiros PLC), and polyurethane urea polymer (Artelon, Artimplant AB). Most of these ligaments are used for anterior cruciate ligament (ACL) reconstruction in the knee and for the rotator cuff repair in the shoulders.

In the hand, apart from the biological scaffold, Zimmer (Zimmer, Warsaw, IN), the porcine dermal collagen scaffold, Permacol (Zimmer), and the synthetic scaffold, Artelon (Artimplant AB), we have neither found studies reporting the use of other scaffolds nor those reporting the use of Orthotape (Neoligaments, Xiros PLC) (or its predecessor— the Leeds-Keio ligament).

The majority of articles reported foreign body reactions with Artelon and noted that the authors had discontinued its usage.[3–7] The use of Permacol in the trapeziometacarpal region led to foreign body rejection in 6 of 13 cases.[8]

Our study used the synthetic scaffold Orthotape in both the extensor and flexor compartments of the hand. We initially began with a serendipitous discovery when Orthotape was used in a severe degloving injury of the dorsum of the hand with extensive loss of all extensor tendons.[9] The patient was reluctant to allow harvesting of a large amount of her own donor tendons, and we offered Orthotape as a single-stage surgery. The patient's function recovered satisfactorily. We continued using Orthotape in a further 9 patients with mixed results. In this study, we hypothesize that Orthotape will have similar clinical outcomes to tendon autografts and present our clinical experience.

Materials and Methods

We report 9 cases with severe crush, degloving, and lacerations or infections leading to extensive loss of tendons on either the flexor or extensor side. Patients were between 9 and 43 years of age. Informed consent was obtained from all patients, and the study was approved by the ethics committee. All patients had reconstruction of their tendons using Orthotape. One patient excluded from our series was lost to follow-up as he migrated out of the country. All cases are summarized in the Table.

All patients underwent tendon reconstruction as an elective procedure at a later stage after their initial trauma or infection. The length of the Orthotape was measured from the tendinous origin of the muscle to the distal remnant of an existing tendon. In 1 case with no distal remnant of an existing tendon, the Orthotape was anchored distally using a bone anchor (Mitek, Johnson and Johnson). Appropriate tension was used before the Orthotape was sutured using the Pulvertaft weave, augmented with Prolene 3-0 sutures (Ethicon, J&J Medical Devices, Somerville, NJ) at both ends. Any vital pulleys or retinaculum were reconstructed along the length of the Orthotape. We prescribed prophylactic antibiotics in all our cases for a period of 7 days. Skin closure was achieved via primary closure of either intact tissue or the existing flap or via a full thickness skin graft using nonabsorbable interrupted sutures. Passive range of motion was instituted immediately, and active motion was started at 1 month after surgery. A blocking orthosis was placed for 1 month either volarly or dorsally, according to whether the case was for extensor or flexor tendon reconstruction. The patient was then referred to physiotherapy for range of motion exercises and muscle strengthening.

Results

Case 1: Index case

A 20-year-old woman sustained a severe degloving wound of the dorsum of her left hand with loss of skin, an extensor tendon, the proximal halves of the first to fifth metacarpals, and the distal carpals. The extensor digitorum to the index to small fingers were all absent, with a tendon gap of 7 cm. After multiple debridements and stabilization with Kirschner wires, she underwent wound coverage with a radial forearm flap from the opposite forearm. Six months later, we proceeded to plate a block of iliac crest bone graft into the empty bony defect. After an additional 6 months, we used the synthetic ligament to replace the extensor tendon loss (Fig. 1).

Initially this was meant to be the first stage of a tendon procedure in which the tendon would be replaced with her palmaris and plantaris grafts. However, her function was excellent, and she declined the second stage. At the 3-year follow-up, she was able to extend all her fingers fully (metacarpophalangeal [MCP] joints, 0° to 90°; proximal interphalangeal [PIP] joints, 0° to 90°; and distal interphalangeal [DIP] joints, 0° to 90°). Her wrist extension was 0° to 20° only. Her Disability of the Arm, Shoulder, and Hand (*Quick*DASH) score was 18.8. The dynamometer force was 2 kg, and pinch grip was 2.5 kg. At the 7.5-year follow-up, she remained symptom free and was fully satisfied with the synthetic ligament reconstruction.

Case 2

A 43-year-old woman sustained a severe industrial accident with near total amputation of her right wrist and a grade 3C open fracture of her right radius and ulna. Her extensor digitorum to her index to little fingers were all avulsed. She underwent 5 surgeries (superficial skin grafting, plating, capsulotomy, etc) before plans were made for synthetic tendon reconstruction. Her *Quick*DASH score after surgery was 58.6. The dynamometer force and pinch grip were 0 kg. At the 3-year follow-up, she had a range of motion of 0° to 30° in her MCP joints and 0° **to** 45° in her PIP and DIP joints from her index to small fingers. The severity of her injury likely resulted in her poor outcome. Subsequently, at 5 years after the insertion of the ligament, she complained of a stitch granuloma in the region of the Pulvertaft weave. Only the protruding stitch was removed, and we noted that the synthetic scaffold was totally engulfed by soft tissue, making it hard to even discern the outline (Fig. 2).

Case 3

A 9-year-old boy was bitten by a snake in a rural area and developed compartment syndrome. He was referred to our department 6 months later with contracture over the dorsum of his right middle finger, with MCP joint extension of 45°. After an initial exploration and tendon repair surgery for his other fingers, his joints remained supple. A second surgery to reconstruct the 8-cm loss in the extensor tendon of his middle finger using Orthotape was carried out, with full thickness skin grafting used to cover the scaffold. Unfortunately, just 2 weeks later the scaffold was exposed, and it extruded by itself 1 month later. Granulation tissue had covered the wound, and the patient did not require further surgery. The family declined further surgical intervention, as the patient was able to make a full fist.

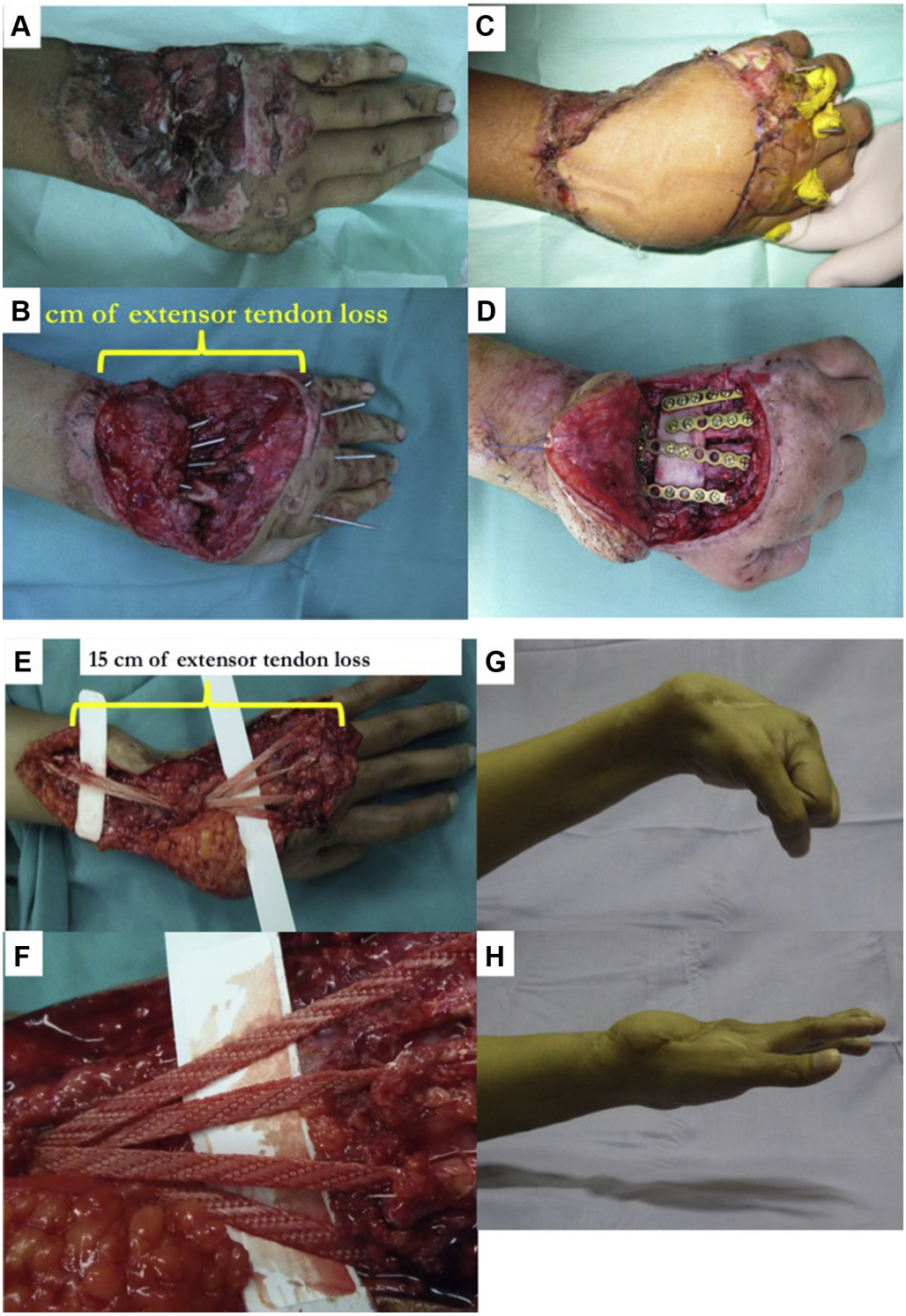

Figure 1. Case 1 (index case). **A** A 20-year-old woman sustained a severe degloving injury over her left hand. **B** After multiple debridements with extensive extensor tendon loss, she underwent a **C** radial forearm free flap transfer followed by **D** plating of the metacarpals with iliac crest bone graft. **E** She then opted for Orthotape, synthetic ligament reconstruction. Note the loss of approximately 15 cm in the length of the extensor digitorum communis. **F** A close-up image of the Orthotape synthetic ligament shows the meshed architecture. At 1 year after surgery, she had **G** good finger flexion and **H** full finger extension. Her *Quick*DASH score was 18.8. At 2.5 years after surgery, a magnetic resonance image used to evaluate the Orthotape showed hypointense lesions well demarcated from the surrounding soft tissue at the **I** metacarpal and **J** wrist levels.

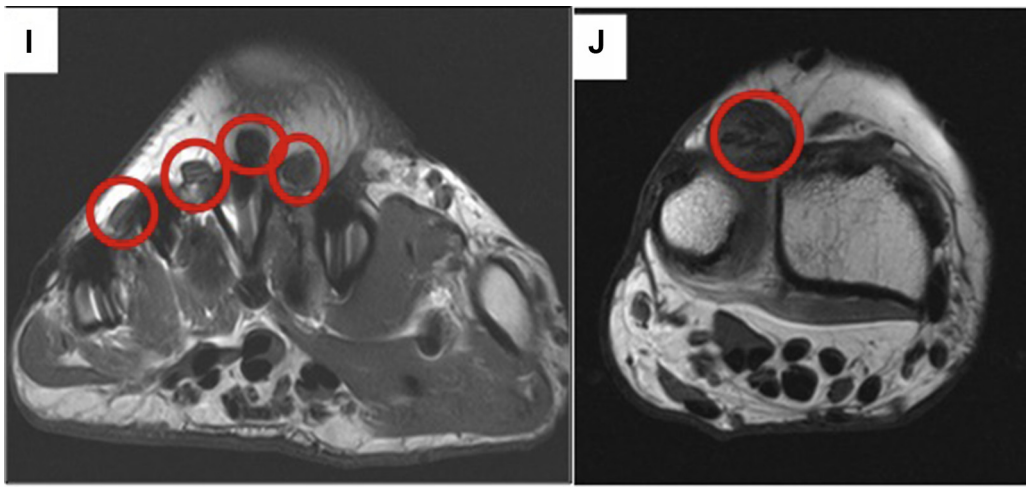

Figure 1. (*continued*).

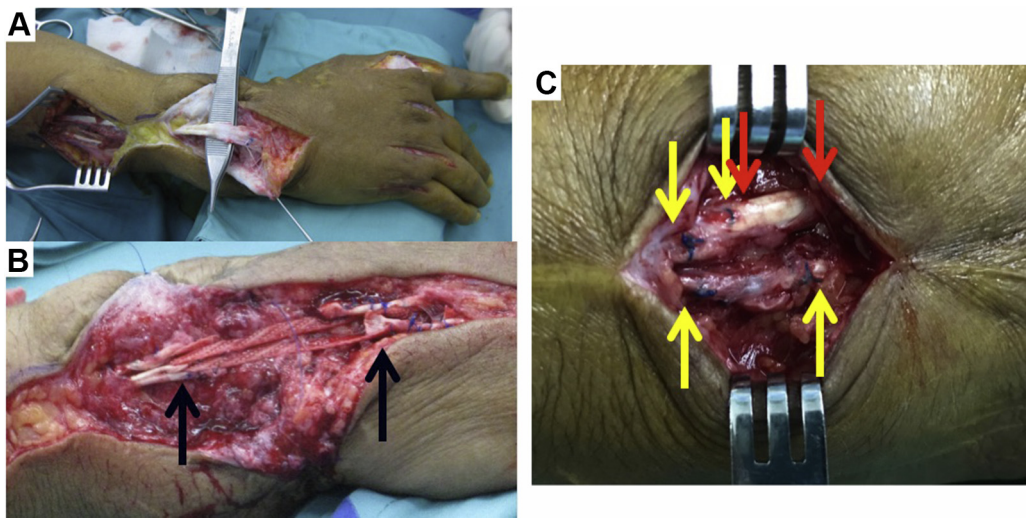

Figure 2. Case 2. **A** A 43-year-old woman with a severe industrial accident lost approximately 7 cm of extensor digitorum communis over the hand and wrist. We were able to identify only 2 proximal and distal stumps of the extensor digitorum communis rather than 4. **B** The Orthotape was used to interpose in the absent region. At 5 years after the insertion of Orthotape, she complained of an irritating stitch granuloma from the subcutaneous region. One protruding nonabsorbable Prolene 3-0 suture was removed. **C** We were just barely able to discern the Orthotape, which was completely engulfed with connective tissue. The Orthotape lies between the yellow arrows, and the native tendon is between the red arrows.

Case 4

A 25-year-old man fell off his motorcycle and sustained a crush injury to his left hand. He had open fractures in his left small and ring finger proximal phalanges, which were treated with external fixators. Multiple wound debridements and K-wiring were performed. He had lost the entire extensor tendon over his right middle finger. We attempted to reconstruct the extensor tendon using Orthotape over his right middle finger; however, we were unable to fully reconstruct the intricate extensor mechanism. After surgery, he had a Boutonniere deformity, and the finger was not functional. We removed the Orthotape 10 months later and fused the PIP and DIP joints. The Orthotape was sent for a histopathological examination (Fig. 3).

Case 5

A 33-year-old man sustained a car accident with severe degloving and a crush injury over the palmar aspect of his right hand. He lost his ring and small fingers and had a large palmar wound defect measuring approximately 5 × 5 cm, with loss of the flexor tendons to the right index and middle fingers. After 2 initial debridement surgeries and K-wiring, a radial forearm flap was created to cover the palmar defect, and the flexor tendon was reconstructed with Orthotape. We anchored the distal part of the Orthotape with Mitek bone anchor sutures (Fig. 4).

At 7 months after surgery, there was an infection of the right middle finger. Debridement revealed an infected section of Orthotape, which was removed. The culture was positive for *Staphylococcus aureus* and *Pseudomonas aeruginosa*. However, the Orthotape at the reduction internal fixation was not affected and was left in situ. The patient had no subsequent problems. At the 3-year follow-up, the range of motion in different joints was as follows: (1) MCP joint: index finger, 0° to 45°; middle finger, 0° to 20°; ring finger, 0° to 10°; and small finger, 0° to 10°, (2) PIP joint: index finger, 20° to 45°; middle finger, 0°; and ring and small fingers, amputated, and (3) DIP joint: index finger, 50° to 70°; middle finger, 0°; and ring and small fingers, amputated. The patient was unable to grip. His *Quick*DASH score was a remarkable 8.3.

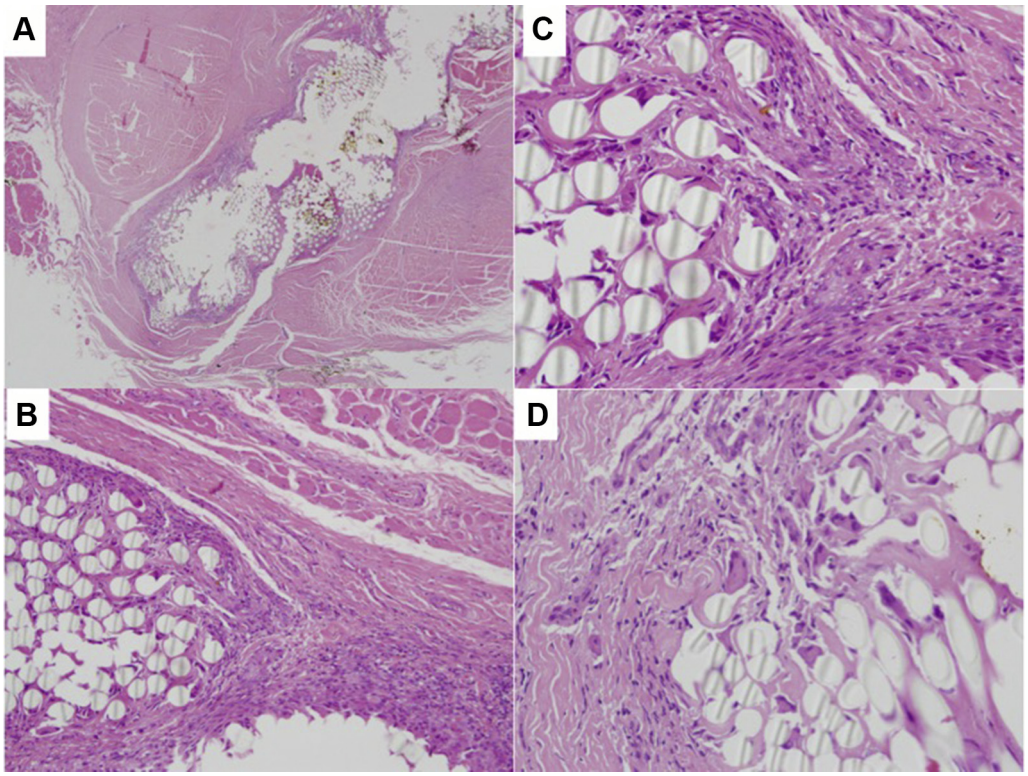

Figure 3. Case 4. A histopathological examination of the Orthotape resulted in its removal after 10 months as it was not functional; afterward, we fused the PIP and DIP joints over his right middle finger. **A** At magnification of ×40, fibrosis is seen surrounding the synthetic material. There was a foreign body reaction with the presence of a macrophage and lymphocytes. Many spindle-shaped fibroblasts were seen with marked fibrosis at **B** ×200 magnification and **C** ×400 magnification. There was a foreign body reaction with fibrosis seen within the synthetic material. **D** Multinucleated giant cells (macrophages) with fibroblasts were present (×400 magnification).

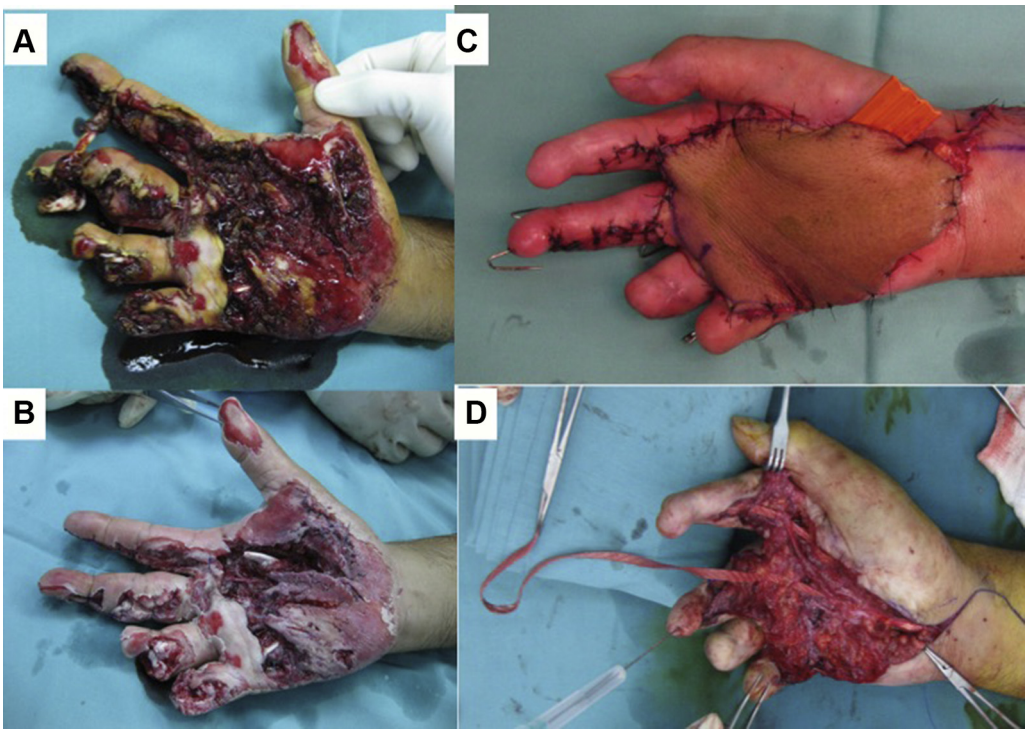

Figure 4. Case 5. A 33-year-old man with a severe degloving injury of the palmar aspect of the hand with **A** total flexor tendon loss of the index and middle fingers underwent B multiple debridements followed by **C** a free radial forearm flap. D The Orthotape was inserted between the right index and middle fingers.

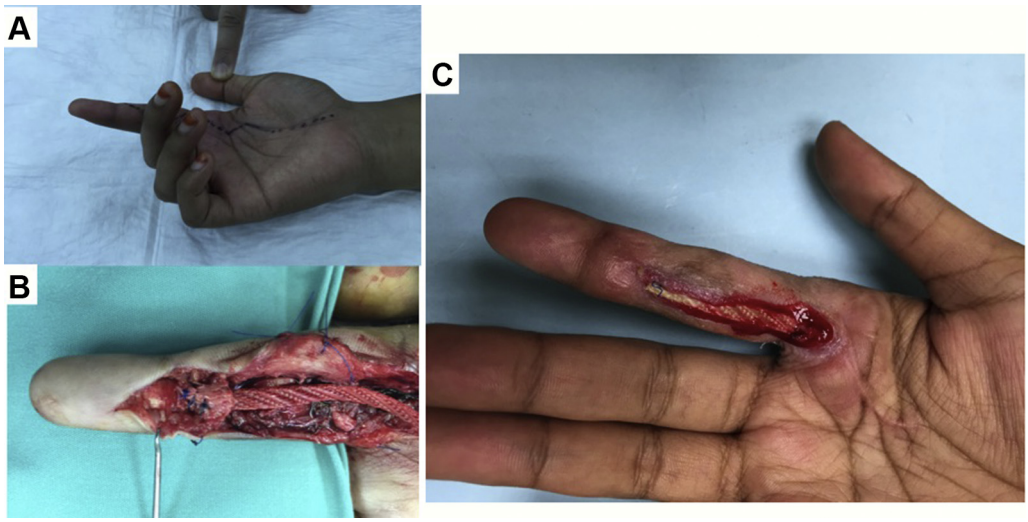

Figure 5. Case 8. **A** A 24-year-old woman bitten by her cat had the Orthotape inserted to replace the absent flexor digitorum profundus and flexor digitorum superficialis of her right index finger. **B** It was weaved through the distal flexor tendon stump. However, at 1 month after the insertion, the Orthotape began protruding through the skin and **C** at 2 months after the insertion, it was fully extruded.

Case 6

A 40-year-old man sustained a deep laceration on his wrist by a broken glass, severing both the flexor digitorum profundus and flexor digitorum superficialis of his right middle, ring, and small fingers; the flexor digitorum superficialis of his index finger; and the ulnar nerve. The patient underwent surgical repair in a regional center, and presented to our department 2 months later with flexor tendon segmental loss. The flexor tendon was reconstructed using Orthotape. The patient moved out of state and verbally reported good outcomes for his right index and middle finger but reported weak ring and small fingers. We were unable to measure the range of motion, grip, or *Quick*DASH score.

Case 7

A 29-year-old man was assaulted and sustained a near total amputation of his right wrist and total amputation of his left wrist. He underwent initial surgery in a different center before presenting to our department a year later. We repaired the extensor tendons and performed dorsal capsulotomies and adhesiolysis for his right hand before proceeding to a second surgery to reconstruct the missing flexor tendons. At 6 months after surgery, flexion of his fingers was nonexistent. We re-explored the area, noting that granulation tissue had grown over the Orthotape with severe adhesions. The Orthotape was shortened by 2 cm and imbricated; however, the outcome was still poor. At 4 years after surgery, there were no signs of extrusion. He had swan neck deformity of his right index and middle fingers. The range of motion in different joints was as follows: (1) MCP joint: index finger, 0° to 90°; and middle, ring, and small fingers, 0°, (2) PIP joint: index finger, −10° extension lag; middle and ring fingers, −30° extension lag; and small finger, 45° fixed, and (3) DIP joint: index finger, −20° extension lag; middle and ring fingers, 20° fixed; and small finger, 0°. The patient is able to pinch and write slowly, but he is not able to grip with his right hand.

Case 8

A 24-year-old woman was bitten by a cat and developed an abscess requiring multiple debridements. She had lost the flexor digitorum profundus and flexor digitorum superficialis of her right index finger. We proceeded to insert Orthotape from the DIP joint stump to the flexor tendon stump at the mid-level of the second metacarpal. However, 1 month later she had small amounts of discharging seropurulent fluid with an exposed section of the Orthotape. The Orthotape extruded at 2 months after insertion. The fluid culture was positive for *Staphylococcus aureus*. Approximately 6 months later, once the infection had resolved, we proceeded to a standard procedure of silicon rod insertion to form a pseudosheath before exchanging the rod with a palmaris longus graft; however, the outcome was still poor, with a 10° range of motion at the PIP joint (Fig. 5).

Case 9

A 30-year-old man experienced a firecracker blast injury with loss of flexor tendons to the right index finger. After multiple debridements, we proceeded to reconstruct the flexor tendon (Fig. 6A–C). However, at 3 months the Orthotape extruded (Fig. 6D).

The results are summarized in the Table. The mean duration of Orthotape in the hand was 44.1 (range, 1–91) months. The mean age at insertion of Orthotape was 28.3 (range, 9–43) years. We inserted Orthotape in 18 fingers of 9 patients, of which 4 strips extruded, resulting in a 22.2% extrusion rate. In 1 patient we intentionally removed the Orthotape as it was not functioning, and we decided to fuse the joints. In another patient, 1 strip extruded after 7 months but the other strip remained in situ until the last follow-up, which was at 89 months. Thus, 5 of 9 patients retained the Orthotape within their hand for time periods ranging from 60 months (5 years) to 91 months (7 years). Extrusion was defined as the breakdown of the overlying soft tissue to expose the synthetic material, which was then surgically removed.

Histological analyses of the extruded or removed Orthotape specimens showed fibrosis, with spindle-shaped fibroblasts in the meshed synthetic matrix.

Discussion

In the hand, the Artelon spacer is the most widely used synthetic scaffold; however, it has received a lot of negative criticism

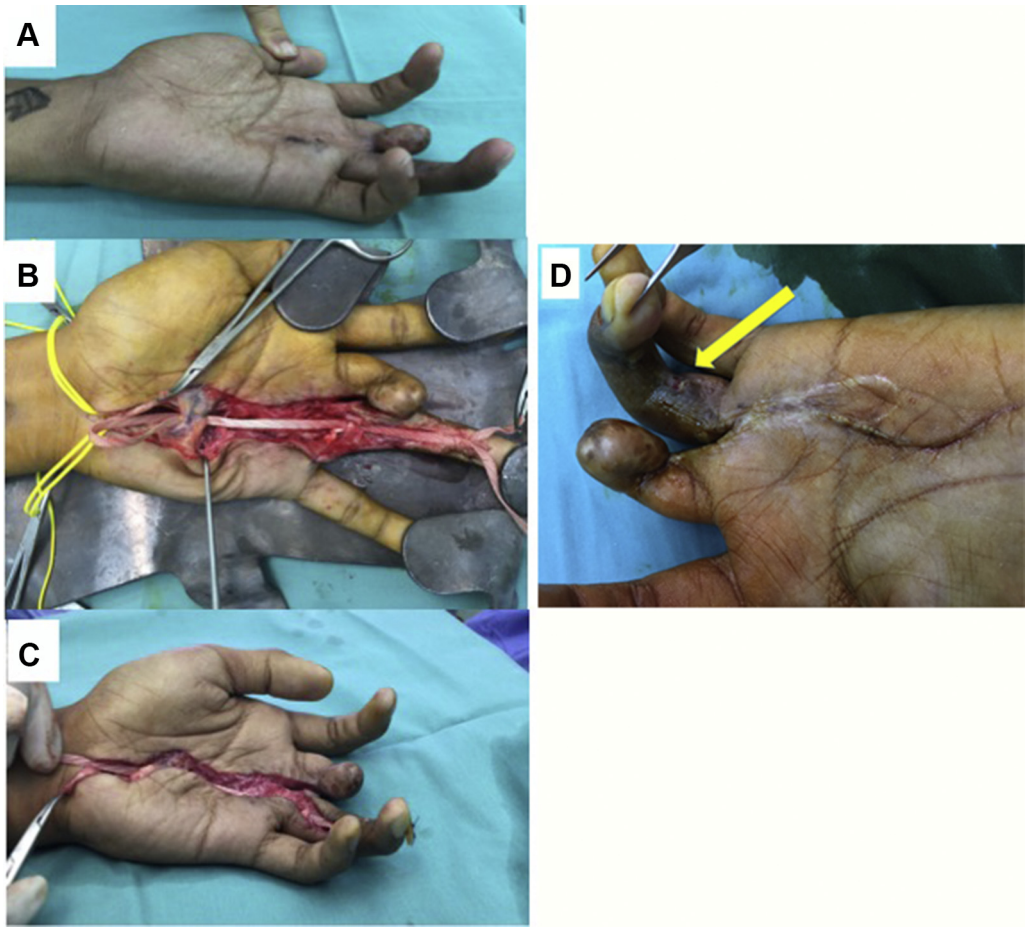

Figure 6. Case 9. **A** A 30-year-old man with a blast injury from firecrackers had Orthotape to replace the total loss of the flexor digitorum profundus and flexor digitorum superficialis of the left ring finger. **B** Insertion of Orthotape into the left ring finger. **C** Note the buttonhole technique dorsal to the nail plate. D There was extrusion of the Orthotape (yellow arrow) at the volar aspect of the proximal phalanx of the left ring finger.

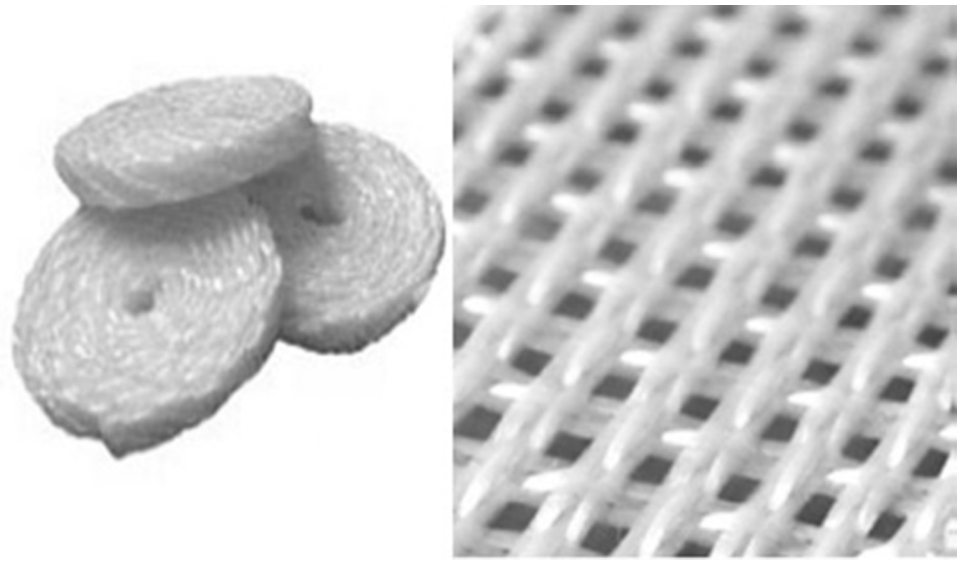

Figure 7. Detailed view of Orthotape—a synthetic scaffold with a meshed appearance. The marketing theory is that the "open structure" allows bone and tissue ingrowth.

because of foreign body tissue reaction and inflammation.[6] Nilsson et al[10] inserted Artelon spacers in 72 patients, and a total of 12 patients had their implants removed because of pain. Nevertheless, this meant that 60 patients still retained their Artelon spacers. They reported the importance of preoperative antibiotics as a possible measure to prevent the removal of the spacers.

Table 1
Summary of All 9 Case Series Using Orthotape as a Synthetic Scaffold in Tendon Reconstruction

Case	Age at Insertion, y	Injury Type	Area Involved	Zone of Tendon Loss	Skin Cover	Number of Strips of Scaffold Inserted	Duration of Synthetic Ligament in the Body, mo
Hand: Extensor Compartment							
1	20	Trauma: degloving	IF, MF, RF, SF	V–VII	Free flap	4	91
2	43	Trauma: near total amputation	IF, MF, RF, SF	V–VII	Intact tissue	2	89
3	9	Infection: snake bite	MF	V–VI	FTSG	1	1 (extruded)
4	27	Trauma: degloving	MF	I–VI	Intact tissue	1	10 (removed)
Hand: Flexor Compartment							
5	33	Trauma: degloving	IF, MF	II–IV	Free flap	2	IF: 89 MF: 7 (extruded)
6	40	Trauma: deep laceration	MF, RF, SF	III–V	Intact tissue	3	89
7	29	Trauma: near total amputation	IF, MF, RF	III–V	Intact tissue	3	60
8	24	Infection: cat bite	IF	I–III	Intact tissue	1	2 (extruded)
9	30	Trauma: blast	IF	I–III	Intact tissue	1	3 (extruded)
Total strips inserted						18	4 (total extruded)

FTSG, full thickness skin graft; IF, index finger; MF, middle finger; RF, ring finger; SF, small finger.

Blount et al[5] reported a 37% explantation rate of their Artelon spacers in 32 patients with carpometacarpal joint osteoarthritis. Those still retaining the spacer had the worst pain and satisfaction scores compared with those who underwent ligament reconstruction and tendon interposition. The usage of spacers was discontinued.

Most recently, in 2015, Huang and Strauch[7] reported late failure of their Artelon spacer, requiring excision at 4 years after surgery. Thus, in the hand, the Artelon spacer does not appear to be a good choice compared with conventional LRTI.

No other synthetic scaffolds have been used in the hand. There has been the porcine dermal collagen scaffold Permacol used in the trapeziometacarpal region but 6 of 13 cases resulted in foreign body rejection.[8]

We used the synthetic scaffold Orthotape, which is a polyethylene terephthalate (polyester). Its construct is nonabsorbable as it is woven with longitudinal and transverse fibers crossing at right angles (Fig. 7). It has an “open structure” that acts as a scaffold for bone and tissue ingrowth. It is not to be confused with the “permanent type” implant such as Gore-tex, which is designed to last for a lifetime with no contribution from the host tissue or new tissue growth.

The predecessor of the Orthotape is the Leeds-Keio ligament. The name Leeds-Keio was derived from its inception from Leeds University in the United Kingdom and Keio University in Japan. In recent years, it was also marketed under the name Neoligaments. It was originally specifically designed for ACL reconstruction, with a stiffness of 200 N/m that is similar to that of a natural ACL, inducing the generation of mesenchymal cells into its meshwork, which is then replaced by newly grown tissue.[11]

The Leeds-Keio ligament was popular during the 1980s and 1990s, mainly in ACL reconstruction. However, by the early 1990s, follow-up studies considered it unsuitable based on poor reviews of deterioration, synovitis, and laxity.[12] However, the tide has changed again in the last 20 years as synthetic scaffolds have undergone newer designs and technological advancements have produced better materials.[2]

In ACL reconstruction with the Leeds-Keio ligament, there have been better outcomes of stability with lower rates of failure.[13] This appears to be a viable option for reconstruction in the medial patella femoral ligament of the knee, extensors of the knee, shoulder arthroplasty for subscapularis transposition, and in difficult and complex cases of reconstruction with inadequate amounts of autografts or for added reinforcement or stability.[14–17] We used the Orthotape for the reconstruction of the torn annular ligament around the radial neck in a Monteggia fracture with an excellent outcome.[18]

Focusing on our usage of the Orthotape in the hand, 4 of our 9 patients retained it over a period of 89–91 months (7.5 years), and 1 patient retained it at 60 months (5 years). Of these 5 patients, 2 had received a free flap which covered the Orthotape; however, the extrusion rate of 22.2% was concerning. We believe that this is due to usage in the superficial areas of the hand and fingers, and we strongly suggest that Orthotape should be used only where there is a thick soft tissue cover or flap or in the deeper regions of the body. Observing the extrusion rate (Table 1), 4 patients extruded the synthetic tendon between 1 and 7 months after surgery, whereas 1 patient required its removal at 10 months. The complications such as extrusion occurred approximately at 4.6 months after surgery. The area of point failure was situated at the site where the synthetic tendon was most superficial underneath the skin.

We note that the skin cover is of vital importance. Excellent and good results were seen where the Orthotape was placed deep inside or with a thick skin cover such as a flap. The placement of Orthotape over palmar wounds did better, whereas its placement over the digits (both flexor and extensor sides) did worse. We noted that the extrusion of Orthotape occurred when the overlying tissues were thin, such as those over the extensor surfaces and the flexor surfaces of the digits. Areas which were deep, such as the central palm or where there was a flap, did not have any extrusion.

Recently, there has been the development of a radio frequency–generated glow that was discharged onto the Leeds-Keio ligament II to produce a bioactive form designed to improve cell induction, proliferation, and attachment into the synthetic meshwork. Reports were good, with no evidence of synovitis.[19] This

may be the solution to prevent extrusion in the superficial regions of the hand.

Orthotape has since developed as a newer, more technologically advanced material that may offer better outcomes with fewer foreign body reactions. The field of tendon tissue engineering is still progressing.[20] We have also performed an in vitro histological analysis on Orthotape where we demonstrated cell ingrowth of the collagen matrix into the scaffold mesh.[21] However, without tenocyte immunofluorescent markers, the study was unable to differentiate between tenocytes or fibroblasts.

We did prescribe a prophylactic and postoperative course of antibiotics as a possible prevention against extrusion or infection, as reported by Nilsson et al[10] Two of their patients had infection, but the cultures were negative.

Limitations of this study include difficulty in having a standardized objective measurement as the patients had varying degree of injuries in different areas of the hand and involving different levels of the joints. The majority of the patients had complex injuries affecting their subjective outcomes. Moreover, the scoring measures before and after the reconstructive surgery to measure any considerable differences were not performed. We also lacked a comparison group using standard tendon autografts.

We believe that Orthotape still presents a viable option in the face of a complex reconstructive procedure with limited donor tendon availability. Patients should be advised of all the possible complications of synthetic tendons before embarking on surgery. The high extrusion rate of Orthotape discourages its use in the superficial areas of the hand (ie, the flexor and extensor surfaces of the fingers and hand). Nevertheless, it is recommended for use in regions with a thick skin cover, such as underneath a flap or in deep areas such as the palm. Moreover, it remains a viable alternative in cases of complex reconstruction with limited availability of donor tendons.

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