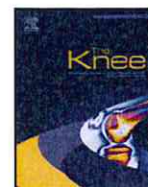




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The Knee



LARS® band and tube for extensor mechanism reconstructions in proximal tibial modular endoprostheses after bone tumors☆

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ABSTRACT

Wide tumor resections around the proximal tibia (pT) are related to compromised function and high complication rates. This retrospective study aims to present the technique employed as well as functional and surgical outcomes of patients undergoing a Ligament Advanced Reinforcement System (LARS®) reconstruction of the knee extensor apparatus after tumor resection and modular endoprosthetic reconstruction of the proximal tibia. Twenty-five patients who received an artificial ligament after pT resection (11 men and 14 women; mean age, 29 years; range 11 to 75 years, with a minimum follow-up of 24 months) were analyzed regarding the ISOLS failure mode classification. Twenty patients received LARS® during primary surgery, five patients during a revision of a pT modular endoprosthesis. LARS® was available as a band or a tube.

The mean extension lag was nine degrees (range, 0 to 30°), the mean flexion was 103° (range, 60 to 130°). The mean extension lag and active flexion in primary implanted LARS were 7.8° and 101° versus secondarily implanted 45° and 115° ($p < 0.0001$; $p = 0.15$). Eleven out of 14 primary implanted LARS® band/tubes (71%) did well with extension lag (0 to 10°). LARS® usage as a band or as a tube showed similar results. The estimated five-year survival of LARS® was 92%. The median survival of LARS® implanted primarily was better than in the case of secondary implantation ($p = 0.006$).

Extensor mechanism reconstruction by LARS® band or tube shows excellent function and satisfactory implant survival after primary reconstruction of the extensor mechanism after proximal tibia resection. We experienced no LARS® rupture for only mechanical reasons.

Level of evidence: Level IV retrospective study.

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1. Introduction

Wide tumor resection and limb salvage by reconstructions with modular endoprostheses in combination with current chemotherapeutic protocols [5,18,28] are regarded a gold standard in the treatment of malignant tumors with satisfying local and systemic tumor control rates [11,27,29,30]. The resection and reconstruction of tumors located in the proximal tibia (pT) challenge surgeons due to reconstruction of extensor mechanism [7]. In small study cohorts, different

methods, ranging from direct fixations to the prostheses [17,19], biological techniques such as muscle flaps [20,21] and allografts [2,3] to combined methods [25], have been used to potentially improve function and to accomplish a good soft tissue coverage of the prostheses, thereby lowering the risk of local morbidity [9,26]. To date, limited experience with use of textile implants is available [4,8,13]. This article summarizes the surgical and functional outcomes of Ligament Advanced Reinforcement System (LARS®) for extensor mechanism reconstruction in its two application forms, band and tube, after proximal tibia resections and modular endoprosthetic reconstruction with a minimal follow-up of two years. Additionally, we show the technique of LARS®-tube implantation.

2. Patients and methods

All data were retrospectively retrieved from our local Bone and Soft Tissue Tumor Registry and from original patients' charts and radiographs. Approval of the institutional review board (EKNr. 644/2011) was obtained prior to this study. Since 1988, 87 patients were treated

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for tumors of the pT and underwent reconstruction by a modular endoprosthesis at our institution.

Twenty-five patients (11 men and 14 women; mean age, 29 years; range 11 to 75 years) with pT reconstructions had also received a LARS®-reconstruction of the extensor mechanism, in addition to the soft tissue augment of a medial gastrocnemius flap, from April 2000 until March 2009, constituting the study group of this investigation. The mean overall follow-up was 49 months (median, 45 months; range, eight to 100 months). The mean follow-up of patients surviving their disease was 55 months (median, 46 months; range, 25 to 100 months).

Of the 25 patients, 20 patients received LARS® during primary implantation of the modular endoprosthesis: Nineteen patients (90%) were treated for primary tumors [osteosarcoma (10), chondrosarcoma (2), Ewing's sarcoma (3), leiomyosarcoma (3), plasmocytoma (1)] and one patient was treated for metastatic adenocarcinoma. All of them had received chemotherapy of different protocols as indicated by their disease (Table 1).

Five patients of 25 have received LARS® during a revision, for different causes except infection, of a previously implanted modular endoprosthesis. The indications for revisions were extensor mechanism insufficiency in two patients where the extensor mechanism reconstruction by a medial gastrocnemius flap was torn out. One patient had a rupture of the patellar tendon, which had been fixed directly to the prosthesis before. One patient had a recurrence of a giant cell tumor and a consecutive patella tendon insufficiency which had also been formerly fixed directly to the prosthesis. Finally one patient had received an extendible module of the pT. Due to subsequent lengthening procedures the former extensor mechanism reconstruction by a fibular transposition osteotomy [25] became insufficient. All patients who received LARS® during revision surgery had at least one (two patients) or more (three patients) preceding operations with a mean interval of 88 months (median 53 years; range, 22 to 256 months) to implantation of LARS®.

LARS® is a non-absorbable artificial ligament, consisting of 90 non-woven longitudinal polyester fibers which are interlinked at a molecular level. The ductility is below seven percent of its original

length. It is characterized by a high tensile load of up to 4000 N [8]. In vitro studies have demonstrated a high potential of histological ingrowth and angiogenesis around the fibers and no signs of immune reaction [31]. The ligament is available in two different designs: The first is a band of 60 mm × 400 mm in dimensions which can be dissected to the size and form required. The second is a circular tube which allows to be wrapped around endoprosthetic components in a sleeve-like fashion. Twelve patients (48%) received a LARS® – band, 13 patients (52%) a tube. In the years 2000 to 2003 only LARS ligament was available at our clinic, afterwards the usage of either tube or ligament was rather random, according to what was disposable at the clinics at time of surgery.

Nine patients received modular endoprosthetic pT reconstructions by use of a Howmedica Modular Resection System® (HMRS) (Howmedica Modular Resection System; Stryker, Mahwah, NJ, USA), 16 patients by use of a Global Modular Replacement System® (GMRS; Stryker, Mahwah, NJ, USA). The mean length of reconstruction was 14 cm (median 14 cm; range: eight to 23 cm).

2.1. Surgical technique

During resection of tumors in the proximal tibia the patellar tendon was dissected by use of a scalpel approximately one centimeter proximal to its insertion in the tibial tuberosity. Hoffa's fat pad was always left attached to the specimen. After wide resection of the proximal tibia, first, the distal femur was prepared for insertion of the modular endoprosthetic component. Restoration of exact leg length was measured under intra-operative fluoroscopy and, whenever required, the tibial diaphysis was shortened according to the planned total length of a trial prosthesis. Tibial stems were then implanted in a cementless fashion in all patients. Before assembling the modular proximal tibia components a LARS® ligament or tube was adapted to fit around the prosthesis. Twelve patients (48%) received a LARS® – reconstruction of the extensor mechanism by a band, 13 patients (52%) by a tube. Implantation of a LARS®-band was described in previous work by Dominkus et al. [8].

Table 1
Demographics and technical features.

	Gender	Age	Diagnosis	FU	Prosth	LARS®	T1	T2	T3	T4	T5	Ext	Flex	MSTS
1	m	27	Osteosarcoma	33 ^a	GMRS	Tube ^b	–	–	–	1	–	n.a.	n.a.	n.a.
2	f	33	Malignant gct	93	HMRS	Band	–	–	–	–	–	45	120	83
3	m	15	Osteosarcoma	77	HMRS	Band	–	–	1	–	–	0	90	93
4	f	40	Leiomyosarcoma	36	GMRS	Tube ^c	–	–	–	1	–	35	110	73
5	f	32	Ewingsarcoma	36 ^a	HMRS	Band ^b	–	–	–	1	–	n.a.	n.a.	n.a.
6	f	13	Osteosarcoma	101	HMRS	Band ^b	1	1	–	1	–	30	120	77
7	f	16	Osteosarcoma	27	HMRS	Band ^{b,c}	–	–	–	1	–	70	110	77
8	m	41	Osteosarcoma	39	GMRS	Band ^b	–	–	–	1	–	30	130	90
9	f	27	Chondrosarcoma	48	GMRS	Band	–	–	–	–	–	20	70	67
10	f	24	Malignant gct	42	GMRS	Tube (amp)	–	–	–	–	1	n.a.	n.a.	n.a.
11	m	39	Chondrosarcoma	33	GMRS	Band	–	–	–	–	–	5	110	93
12	f	18	Osteosarcoma	64 ^a	HMRS	Band	–	–	–	–	–	n.a.	n.a.	n.a.
13	m	13	Ewingsarcoma	32	GMRS	Tube	–	–	–	–	–	0	120	93
14	f	16	Osteosarcoma	46	GMRS	Band	–	–	–	–	–	0	95	100
15	m	53	Leiomyosarcoma	71	GMRS	Band	–	–	–	–	–	0	120	83
16	f	12	Ewingsarcoma	48	GMRS	Band	–	–	–	–	–	10	90	100
17	f	19	Osteosarcoma	45	GMRS	Tube	–	–	–	–	–	30	85	70
18	f	54	Metastasis	8 ^a	GMRS	Tube	–	–	–	–	–	n.a.	n.a.	n.a.
19	m	13	osteosarcoma	32	GMRS	Band	–	–	–	–	–	0	120	90
20	m	14	Osteosarcoma	21 ^a	GMRS	Tube	–	–	–	–	–	n.a.	n.a.	n.a.
21	f	24	Leiomyosarcoma	31	GMRS	Tube	–	–	–	–	–	0	115	87
22	m	74	Plasmocytoma	24 ^a	GMRS	Tube	–	–	–	–	–	n.a.	n.a.	n.a.
23	m	22	Osteosarcoma	88	HMRS	Tube ^b	–	–	–	1	–	0	90	87
24	f	22	Osteosarcoma	89	HMRS	Tube	–	–	–	–	–	5	100	77
25	m	16	Osteosarcoma	73	HMRS	Tube	–	–	–	–	–	10	85	87

^a DOD (death of disease), m (male), f (female), GMRS® (global modular replantation system), HMRS® (Howmedica modular replantation system), KMFT® (Kotz modular femoro-tibial replacement), GCT (giant cell tumor), FU (follow-up).

^b Replantation after explantation.

^c (Explantation), Amp (amputation), Ext (extension lag), Flex (flexion), MSTS, light gray (secondary implantation of LARS®).

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The circular LARS®-tube allows to be wrapped around the extra-medullary part of the proximal tibia-endoprosthesis component in a sleeve-like fashion, without putting it intramedullary (Figure 1A–E). Thereafter non-resorbable sutures were used to fix the tube through fixation holes on to the endoprosthesis body. In the dorsal aspect of the proximal tibia components the ligament was shortened to the level of the tibial joint plane in order to avoid later soft tissue impingement in flexion. Anteriorly, in the area of the insertion of the patellar tendon, the LARS® was adapted to form a strap reaching proximally to the level of the distal patellar pole. This strap then was used to suture the patellar tendon on to it by non-resorbable sutures. Finally, a medial gastrocnemius flap was utilized to cover the LARS® in the anterior aspect of the endoprosthesis, while in the distal diaphysis surrounding fascias were fixed to the LARS®. In this way it was possible to obtain full soft tissue coverage of the total implant and LARS® by healthy musculature.

Postoperatively, mobilization was allowed partial weight bearing with a brace initially restricted to full extension for six weeks. Thereafter the brace was liberated at the level of the knee joint up to 30°, 60° and 90° flexion every two weeks over a six-week period of full weight bearing.

Complications were classified according to the ISOLS comprehensive classification system for modular endoprostheses as soft tissue failures (Type 1), aseptic loosening (Type 2), structural failures (Type 3), infection (Type 4) and tumor progression (Type 5) [16]. Deep prosthetic infections were classified according to McPherson [23]. This staging system for prosthetic joint infection distinguishes three main categories that include infection type (I–III), systemic host grade (A–C), and local extremity grade [1–3], to describe different risk profiles.

Information about pain, range of motion, emotional acceptance, supports, walking distance and gait were obtained throughout the MSTS score [10]. The functional outcome was measured in terms of active flexion and extension lag.

Statistical analyses of the data focused on the functional and surgical outcomes of LARS®. Therapeutic variables (type of complication) and demographic variables (sex, age, and follow-up) were examined. Data is shown in median numbers (extension lag, active flexion and MSTS). Descriptive statistics were used to give numbers and percentages of complications. Correlation analysis was used to indicate the association between gender and age with functional outcome as well as complications. Differences between means and proportions were tested with

the Chi-square test for categorical variables and the *t*-test for continuous variables. LARS®-survival was estimated using the Kaplan–Meier method. five-year survival estimates are given with censored data according to a minimum follow-up of two years. Significant differences between survival of LARS® between primary and revision surgery were identified by the log-rank test. Relative risk calculation was carried out concerning infection with LARS® during primary and revision surgery. All statistical tests were two-sided. A *p*-value of <0.05 was considered significant. All calculations and graphical visualizations were made with the SPSS (SPSS Inc., Chicago, IL; version 20.0, 2012).

3. Results

3.1. Functional results

The mean active extension and active flexion in all patients with a retained LARS® was nine degrees and 103°, respectively. The mean extension lag and active flexion in primary implanted LARS were 7.8° and 101° versus secondarily implanted 45° and 115° ($p < 0.0001$; $p = 0.15$).

The mean extension lag and the active flexion in cases of LARS® band after primary reconstructions (eight patients) were 8.1° (range: 0 to 30°) and 103° (range: 70 to 130°). Six patients (75%) of these did well with only little extension lag (0 to 10°). Two patients were insufficient (20, 30° extension lag).

The mean extension lag and the active flexion in cases of LARS® tube after primary reconstruction (six patients) was 7.5° (range: 0 to 30°) and 99° (range: 85 to 120°) retrospectively (Table 2). Five patients (83%) of these did well with only little extension lag (0 to 10°). One patient was insufficient (30°). With numbers available gender, age or complications had no influence on function. At latest follow-up the mean MSTS Score of all patients was 83% (range, 64 to 100%). Patients with LARS® implanted during primary surgery scored 84% (64 to 100%), while revision surgery scored 77% (range, 73 to 83%).

3.2. Surgical results

Sixteen (64%) pT modular endoprostheses with LARS® had no complication.

Soft tissue complications were observed in one patient (four percent) with secondary LARS® implantation; in primary LARS® implantation no soft tissue complications were seen.

Aseptic loosening was not observed in primary pT. In one of five patients with revision surgery aseptic loosening occurred in the tibial stem. One structural failure (four percent) (periprosthetic fracture) occurred in case of a primary implantation. Seven patients developed deep prosthesis infection (28%). In four patients infection occurred after primary surgery, in three patients infection developed after revision surgery.

To sum up, 20% infection after primary surgery and 60% infection after revision surgery was observed. All infections were confirmed proven by positive histological signs of infection. The relative risk to develop infection with LARS® during revision versus LARS® in primary surgery is 0.33 (CI 95% 0.1 to 1.03) (Table 3). Only one early infection

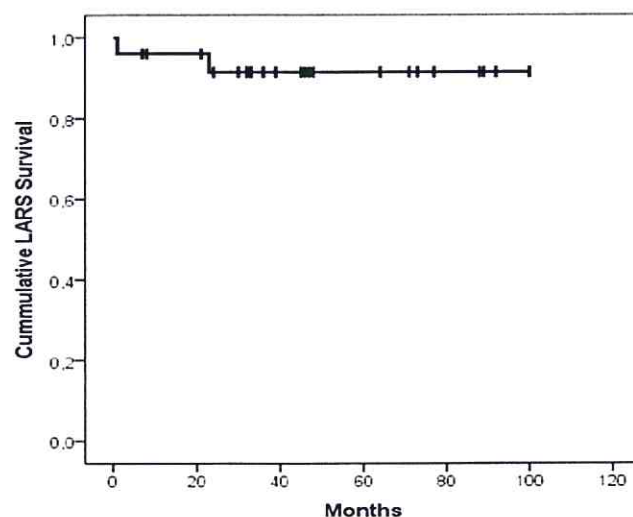


Figure 1. Kaplan–Meier estimation of survival of LARS®-reconstruction with removal due to any reason as endpoint.

Table 2

Demonstrates the two different LARS® designs that were used in this study. Comparing functional as well as surgical results, that may be influenced by LARS®, the tube shows better results.

LARS® application after primary and secondary implantation	Band	Tube
n	12	13
Demographics		
Gender (m/f)	6/7	6/6
Age	25 ± 13	29 ± 18
Function (mean) latest follow-up		
Implantation primarily	8	6
Extension lag	8.1° (0 to 30)	7.5° (0 to 30)
Active flexion	103° (70 to 130)	99° (85 to 120)
MSTS Score (1 to 100)	89 (66 to 100)	83 (70 to 93)
Implantation secondarily	2	1
Extension lag	48° (30 to 70)	35°
Active flexion	113° (110 to 120)	110°
MSTS Score (1–100)	78 (76 to 83)	73
Extension lag (°)	15 (0 to 70)	5 (0 to 35)
Flexion (°)	113 (70 to 130)	95 (75 to 120)
Associated complications (n)		
Soft-tissue failure (Type 1)	2	0
Structural failure (rupture) (Type 3)	1	0
Infection (Type 4) Primary/secondary implantation	2/2	2/1

Table 3

Comparison of complications (Types 1 to 5) of patients who received LARS® during primary surgery and patients who received LARS® during revision surgery. Numbers (percent).

n	Prim. LARS® pT (n = 20)	Sec. LARS® pT (n = 5)	LARS® pT ^a (n = 25)	p ^b
Type 1	0	1 (25%)	1 (4%)	0.02*
Type 2	0	1 (25%)	1 (4%)	0.02*
Type 3	1 (4%)	0	1 (4%)	n.s.
Type 4	4 (20%)	3 (60%)	7 (28%)	0.03*
Type 5	0	1 (20%)	1 (4%)	0.02*

^a The study cohort (n = 25).

^b Chi-square-test; primary implantation LARS®: secondary implantation LARS®.

developed after three weeks [23], all others were late infections occurring at median 34 weeks (range, 15 to 176 weeks) after surgery. In all seven cases of infection six LARS® and the prostheses were re-implanted during one stage revisions and one LARS® was explanted. After septical one stage revisions patients were kept under suppressive antimicrobial therapy for at least three months postoperatively. A second LARS® was explanted during revision surgery after recurring infection. The re-infection rate was 33%. None of the primary implanted LARS® with infection was re-infected. In one of five secondary LARS® reconstructions the LARS® ruptured in the course of a re-infection. Two LARS® were removed after infection. Consequently the five-year overall implant survival of LARS® was 92%. The survival of the initial implant was 72% based on revision of seven ligaments. (Figure 2) There was one amputation above the knee after local recurrence of malignant GCT.

4. Discussion

Textile implants have been utilized for an extensor mechanism repair after patellar tendon ruptures in non-oncologic cases since 1994 [12]. Thereafter it seemed a promising tool in oncologic surgery to restore the extensor apparatus [13] or even to augment large tissue defects after wide tumor resections in the knee [8]. This study

reports our functional and surgical results of extensor mechanism reconstructions by LARS® of different application forms in pT resections and modular endoprosthetic reconstructions following resections of bone tumors with a minimum of two years FU.

A clear advantage of textile implants [12,13], like LARS® band and tube are good functional results after extensor mechanism repair. In non-oncologic patients textile implants after patellar ligament rupture resulted in very good functional results and unimpaired extension in nearly 80% of the patients according to Fujikawa et al. [12]. After tibia reconstruction of extensor mechanism reconstruction by an artificial band extension lag ranged between 0° and 7.5° (0 to 30), the Musculo-skeletal Tumor Society (MSTS) Scores were 78 to 85% in very little study cohorts [13,14,22]. This current study shows similar results in available patients after primary surgery with an extension lag of 7.8° and a MSTS Score of 83% (Figure 3). Range of motion and movement abilities after tumor resections with alternative implantation of osteoarticular allografts and allograft–prosthetic composites are good but demonstrate high local graft morbidity [3,6]. It is most likely a result of a beta-error because of the small sample size that there are no significant differences in functional results of LARS® tube and band, although LARS® tube seems to show better functional results in this cohort (Table 2). Apart from 14 patients after primary reconstruction, who were functionally most satisfied with only extension lag of 0 to 10°, there were still three of them with insufficient functional results (two bands, one tube). All four patients who received LARS® during revision surgery and those whose extensor apparatus failed after primary surgery, were insufficiently reconstructed. This was due to qualitative (dystrophic, scarred) or quantitative (too little) changes of quadriceps muscle tissue, the ability of which certainly has to be considered when using LARS®.

One clear advantage of LARS® is its ubiquitous use independent of the design of the modular prostheses and different defect sizes, which is of combinations with different generations of prostheses (HMRS, and GMRS) possible.

The use of LARS® may influence the incidence of failure mode Types I, III and IV (soft tissue-, structural failure and infection) but may for obvious reasons not play a role in the incidence of failure mode Types II (aseptic loosening) and V (local recurrence). Considering good histological ingrowth without signs of immunological reactions associated with the LARS® [31], wrapping around the pT prosthesis may contribute to better soft tissue coverage after proximal tibia modular replacement. In fact there was just one case with soft tissue failure in this current cohort. Furthermore structural failure in terms of LARS® rupture was only noticed in one patient in the situation of a prosthetic infection. Ruptures of the LARS® for only mechanical reasons were only observed after distal femoral replacement and after modular total knee arthroplasty [8]. Certain structural failures, on the other hand, can be avoided by use of the LARS®. In other surgical concepts of extensor mechanism reconstruction after pT resection structural failures do occur. Clohisy [6], e.g., reported a high incidence of structural failure due to allograft fracture and subchondral collapse in 50% by using osteoarticular allografts with attachment of the patellar tendon to the allograft and Biau reported 26% of allograft-composites failures because of fractures and resorption [3].

In oncologic mega-endoprosthetic surgery infection rates are high infection rates (17.4 to 30.7%) [1,3,8,13,16,17,19] and the location of the proximal tibia is a significant predictor for poor prosthesis survival [19]. Furthermore, surgical concerns about infection in non-degradable synthetic meshes in orthopedic surgery have been expressed [15,24]. In line with this observation the use of a Mersilene mesh [14] and a Trevira tube [13] was associated with higher infection rates after proximal tibia resections. Interestingly, a medial gastrocnemius flap technique reported by Malawer [20] as a method of extensor mechanism reconstruction led to lower infection rates in a large cohort of proximal tibia replacements from 36% to 12% [14]. Recently published competing risk analysis confirmed that sufficient soft tissue reconstruction may reduce

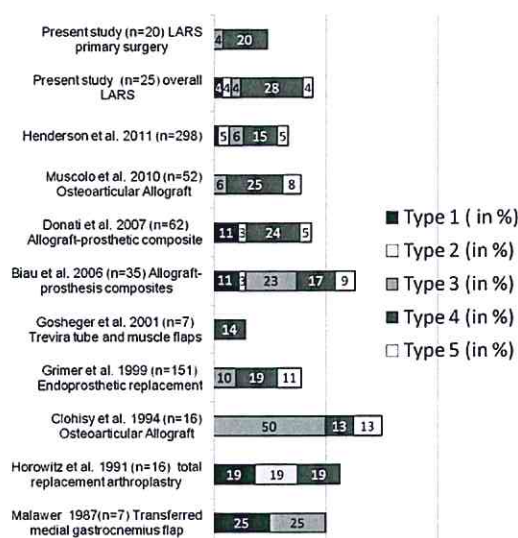


Figure 2. Complications after pT resections and reconstructions of the extensor mechanism by different methods since 1987; different types of failure mode: T1: soft tissue failure, T2: aseptic loosening, T3: structural failure, T4: infection, and T5: tumor progression. Numbers in bars show the percentage of failures and not of patients. Only one early infection [23] developed (IB1), all others were late infections occurring at a mean of 37 months (range, six to 92 months) after surgery (IIIB1–IIIB3). All infections were confirmed by positive histological signs of infection. In all seven cases of infection, six LARS® were re-implanted with the endoprosthesis during one stage revision and one was permanently explanted. Two patients developed re-infection and a second LARS® was explanted during revision surgery. None of the primary implanted LARS® with infection was re-infected.

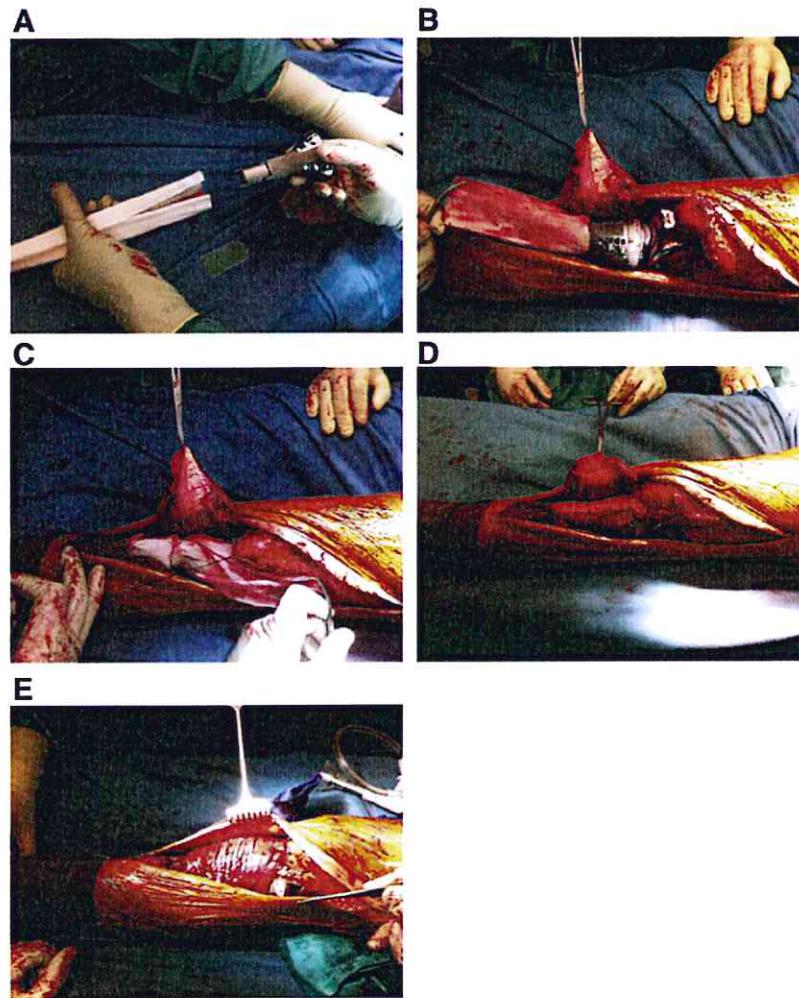


Figure 3. LARS®-tube-reconstruction of the extensor mechanism after pT resection and reconstruction with a modular pT-endoprosthesis. A) Approximation of LARS® to pT module. B) The LARS® tube is fixed around the prosthesis in a sleeve-wise envelope on to the endoprosthesis body. C) The LARS® was adapted to form a strap reaching proximally to the level of the distal patellar pole. D) This strap is used to suture the patellar tendon on to it by non-resorbable sutures. E) Finally, a medial gastrocnemius flap is prepared to cover the total residual extent of the LARS® while in the distal diaphysis surrounding fascia are fixed to the LARS®.

the risk of infection [26]. A better coverage of the pT prosthesis “cases” by the LARS® may therefore hypothetically explain fewer infections after tube.

There are some limitations. This single center study presents a small, however, consecutively analyzed cohort of patients with textile implants. This study was retrospectively assessed, although data in the bone and soft-tissue tumor registry are assessed prospectively.

LARS® as a possibility for extensor mechanism reconstruction after modular endoprosthetic reconstruction of the pT meets premises for limb salvage surgery: it shows good functional results and plays a minor role concerning failures. The active ROM between nine degrees to 103° showed excellent functional results. Implant survival was good in pT modular endoprostheses implanted during primary surgery. LARS® may not contribute to infection; infection rate of 20% was high but so far did not significantly differ from other studies, however, a longer follow-up period may be necessary, as infection rate in primary patients could potentially increase over time. In the case of repeated revisions the secondary use of the implant must not be recommended due to the very high potential risk of infection and insufficient functional results. To conclude, infection continues to be a major challenge.

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