Original article

Which role for synthetic ligaments in the reconstruction of patellar tendon chronic rupture after TKA? Mid-term outcomes using LARS ligament

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Summary. *Background and aim of the work:* Patellar tendon rupture is a rare complication after Total Knee Arthroplasty (TKA) which always requires surgical treatment. Patients with chronic lesions or tendon degenerations showed good results at short-term follow-up (FU) when treated using autografts or allografts, but these techniques showed poor outcomes at long-term FU. Moreover, allografts have high costs and limited availability, not to mention the increased risk of immune reactions and infections. Recently, the use of synthetic ligaments for patellar tendon reconstruction has taken hold with encouraging results. We report our experience in the treatment of patellar tendon ruptures after TKA using the Ligament Advanced Reinforcement System-LARS®. *Methods:* Clinical evaluation was performed using the Knee Society Score and recording extensor lag. Instrumental evaluation was performed using ultrasound imaging to assess patellar tendon thickness and using conventional x-rays to assess prosthesis' mobilization signs and patella's height. *Results:* At the final FU, 6 knees were included in our study. Patient's mean age was 66.7. Patellar tendon reconstruction occurred after a mean time of 4 months from the previous surgery. The mean FU was 44,2 months. The mean Knee Score was 63.3 and the mean Function Score was 35. In 4 knees the extensor lag was < 10° while in 2 knees it was > 20°. The mean ISI was 1.16, while the average increment in tendon thickness was 127.12%. *Conclusions:* In our opinion, synthetic ligaments can be successfully employed for the reconstruction of patellar tendon breakage after TKA and rTKA in selected patients, in order to quickly return them to their activity of daily living. (www.actabiomedica.it)

Keywords: LARS ligament; patellar tendon rupture; synthetic ligament; extensor mechanism; TKA; reconstruction.

Introduction

The extensor mechanism disruption is an uncommon event in the Total Knee Arthroplasty (TKA) and represents about 0.17-2.5% of all its complications [1]. Patellar Tendon's (PT) breakage is one of the most dangerous complications in TKA, with a negative impact on the prosthetic joint function and on the survivorship of the implant itself. Its incidence ranges from 0.17 up to 1% [1-4].

Patellar tendon ruptures can be distinguished into traumatic and a-traumatic. The traumatic ones are consequential to traumatic events involving directly or indirectly the tendon, causing its disruption.

The a-traumatic ones can be a consequence of various etiological causes such rheumatic diseases (rheumatoid arthritis, Systemic Lupus Erythematosus), diabetes mellitus, chronic renal failure, chronic use of corticosteroids or iatrogenic damage as a result of surgical procedures; all responsible for tendon degenerations [5]. It has been described that a wide access to the joint can compromise the blood supply to the knee extensor apparatus and the mal-rotation of the prosthesis components on the axial plane is implicated in an increased risk of extensor mechanism damage [6]. Other factors can increase extensor mechanism breakage risk such as joint stiffness, previous surgeries, infections and obesity. These conditions make surgical approach more difficult and the need of better joint exposure can lead to an excessive traction on the tendon itself [1,3-4]. In most cases, PT rupture requires surgical treatment, also considering that the conservative approach generally doesn't correlate with good results. Several surgical techniques have been described in litterature, each one with variable results. When an acute total rupture (or extension lag >20°) occurs, if the residual tendon quality is good, the surgical treatment consists in the direct tendon repair with sutures and a subsequent fixation with anchors. In case of tibial tubercle avulsion, screws can be used too [2,7-9]. In presence of chronic lesions or tendon degenerations, good results can be obtained with autologous tendon grafts. The most used autologous tendons are semitendinosus, gracilis, gastrocnemius flap and fascia lata [6,10]. The use of these autologous tendons gave better results compared to direct surgical repair, but today the Achilles tendon allograft has been established as the gold standard [11]. Many authors consider the reconstructions with the Achilles tendon allograft or with the whole extensor apparatus allograft to be the best solutions in elderly patients with chronic lesions and poor tendon quality. On the other hand allografts have a high cost, limited availability, and increase the risk of immune reactions and infections [10,11]. Despite good early results, these augmentation techniques showed poor outcomes at long-term follow-up, mainly due to a progressive loosening of the reconstructed tendon with the onset of extensor lag [12]. Recently, the use of synthetic ligaments for patellar tendon reconstruction has been taking place, but published results are far from being significant due to small number of studies, different kind of grafts (Leeds Keio, Polypropylene mesh, Ligament Advance Reinforcement System - LARS®) and different surgical techniques employed. However recent studies showed encouraging results, specially at long-term follow-up [13-18].

In this article we report our experience of 8 patellar tendon ruptures after TKA treated with surgical reconstruction using LARS® synthetic ligament. The aim of our study is to evaluate the clinical outcome at mid-term follow-up (FU).

Methods

This single-center retrospective study was approved by our local ethical committee, and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. All patients gave written consent.

Between September 2007 and December 2016 we performed 1341 primary TKA and 187 TKA revisions; we selected only patients treated for patellar tendon reconstruction after TKA with LARS® ligament. Patients included in this study presented complete isolated patellar tendon ruptures or avulsions of the tendon itself from the tibial tuberosity with residual poor tendon quality.

Exclusion criteria were lesions occurred at other sites of the extensor apparatus or patellar tendon avulsions with good quality of the residual patellar tendon. Ormaweb® business software was employed for retrieval and data analysis.

Previous surgical reports were used to assess the quality of residual patellar tendon before starting the surgical procedure. Intra-operatively the thickness and the strength of the tendon was tested by the surgeon. The LARS ligament was available in the operative room, if needed.

All surgical procedures were performed by the same expert surgeons and all patients received the same rehabilitation protocol. Clinical, radiographic and ultrasound evaluation were performed.

Patient clinical examination took into account 2 parameters: the Knee Society Score (KSS) and the amount of extensor lag. The Knee Society Score is subdivided into a knee score (KS) that rates only the knee joint itself and a functional score (FS) that rates the patient's ability to walk and to climb stairs. The KS and FS range from 0 (poor) to 100 (excellent) [19,20].

Knee radiography were obtained in antero-posterior (AP) and in lateral views in order to identify prosthesis mobilization signs and to calculate the Insall-Salvati Index (ISI), used to evaluate the position of the patella.

The ISI is the ratio between the length of the patellar tendon measured on the posterior surface of the tendon itself (from its origin at the lower pole of the patella to its insertion on the tibial tuberosity), and the greater length of the patella from the superior pole to the lower pole; ideally these measures should be taken on a radiography in lateral view with knee at 30° of flection. The ISI normal values range between 0.8 and 1.2: an ISI <0.8 indicates a condition of "patella baja" (low patella), while values greater than 1.2 indicate a high patella [21].

Finally we evaluated the thickness of treated patellar tendons compared to the contralateral healthy ones using an ESAOTE® ultrasound system with a 12 Mhz probe. When patients underwent bilateral surgery, the thickness of the patellar tendons treated with LARS® was compared to the maximum thickness of a normal patellar tendon (6 mm).

Thickness measurements were made in adjoining areas but not corresponding to the LARS® graft to avoid falsified values.

LARS® is an artificial ligament originally designed to treat cruciate ligament injuries.

Like all artificial devices, it doesn't have its own biological activity, but its design can compensate and reproduce native ligament functions. LARS® includes a wide range of devices used to reconstruct or to reinforce insufficient, but still partially functional, autologous grafts. It consists of polyethylene terephthalate (PET) fibers.

Some authors report that LARS® is bio-compatible and seems to provide excellent support for tissue regrowth: its reticulated structure promotes the fibroblast colonization and the integration of the neoligament [22,23].

Finally, it should be stressed that implants made with LARS® didn't show host adverse reactions (such as synovitis and inflammation) and consequent mechanical failures breakage, unlike synthetic ligaments used in the early 1980s.

Good results have been reported in terms of safety and efficacy at long term follow-up studies also in Anterior Cruciate Ligament (ACL) reconstruction by using LARS ligaments [24,25].

Surgical technique and post-operative rehabilitation protocol:

All surgical procedures have been performed by the same surgeon. The joint exposure has been obtained by a mid-vastus surgical approach with a cutaneous incision on the previous surgical scar, in order to not compromise vascular supply to the skin and to avoid cutaneous complications.

In all cases we performed a tendon direct suture except for two cases where a complete patellar tendon avulsion has been found intra-operatively. In these cases we fixed the patellar tendon to tibial tubercle by using anchors. Then the extensor mechanism has been reinforced by using synthetic LARS® ligament passed through a drilled bone tunnel 2 cm distally to the tibial tubercle and through the quadriceps tendon proximally. Then the knee has been extended, patella's position checked and the LARS fixed by a termino-terminal suture at both ends. Finally, synthetic ligament has been fixed to extensor apparatus by a chain suture. Fig. 1.

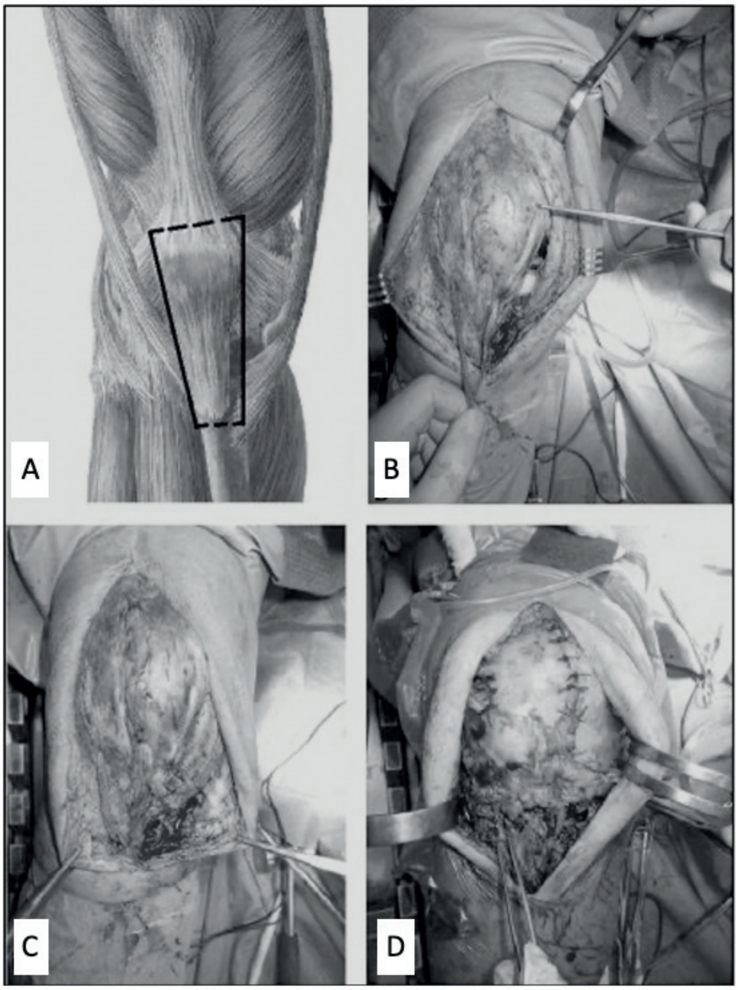

Figure 1. A) Schematic reproduction of surgical technique: LARS ligament positioned through quadriceps tendon proximally and through proximal tibia distally. B-D) Intra-operative photographic shots of surgical technique as described above in the text.

Post-operatively, a standard rehabilitation protocol was administered to the patients: a brace blocked in full extension was applied for 4 weeks after surgery, a mid passive flection (0°-20° Range Of Motion – ROM) was allowed during the following two weeks and then, at 6 weeks from the surgery, the ROM allowed with the brace was increased of 20° each week. Partial weight-bearing was allowed during the first month after surgery and progressively increased during the second month.

Anti-thromboembolic prophylaxis was given to the patients during all the time they were unable to ambulate independently.

Results

From September 2007 to December 2016, we reported a global incidence of patellar tendon ruptures of 1.96% (30 cases) and in 8 cases (7 patients) the patellar tendon reconstructions was made by using LARS®. All patients were treated by TKA at the same knee previously. Unfortunately, one patient was lost at last follow-up (FU) and another patient was treated by knee arthrodesis due to a Peri-prosthetic Joint Infection (PJI), so they weren't included in our current study.

At the final FU, 5 patients (6 knees), 4 female and 1 male, have been treated by patellar tendon reconstruction using LARS®. Patients mean age was 66.7 years (56-75). In one patient (1 knee) patellar tendon breakage occurred 3 months after the previous revision TKA (rTKA). In all the other cases, the patellar tendon lesion was a-traumatic and it occurred on a favorable substrate of several risk factors: rheumatoid arthritis (1 patient, 1 knee), Parkinson's disease (1 patient,2 knees) and diabetes mellitus (2 patients, 2 knees).

At time of surgery no patient presented a PJI. We reported only one case with a superficial infection affecting the distal portion of the surgical scar.

The patient treated by bilateral patellar tendon reconstruction presented a pre-operative severe valgus deformity that required a hinge TKA. Patellar tendon reconstruction occurred after a mean time of 4 months (range 1-18 months) from the previous surgery that consisted in primary TKA (3 cases) and revision TKA (3 cases). Tab 1.

Clinical-instrumental mean FU was 44,2 months (range:24-60 months) and we reported good results in 4 patients, while poor results were recorded in one patient (two knees). At the latest FU the mean KS was 63.3, the mean FS was 35. Tab 2.

The unsatisfactory mean result at FS was largely due to the low performance of one patient. He was affected by Parkinson disease and was treated at both knees.

A satisfactory ambulatory ability and extensor function were recovered by the most of our patients: 4 cases (4 knees) presented an extensor lag < 10° at last FU, while 1 case (2 knees) presented an extensor lag > 20° in both knees. Two patients were able to ambulate without crutches, two patients needed one crutch to ambulate, while 1 patient (2 knees) was unable to ambulate without a therapist.

We reported good radiographic and ultrasound results at the latest FU: in four knees the patella was in its physiological position with a mean ISI of 1.16 (Fig.2), while the average increase in the tendon

Table 1. Patients' clinical details

Patient	Main comorbidities	Previous Surgeries	Rupture mechanism	LARS reconstruction
n°1, female 68 y.o.	Rheumatoid Arthritis	3 (TKA, rTKA –aseptic failure, tibial tubercle osteotomy)	a-traumatic	Isolated
n°2a, female 68 y.o.	Parkinson's disease	1 (TKA)	a-traumatic	Isolated
n°2b, female 69 y.o.	Parkinson's disease	1 (TKA)	a-traumatic	Isolated
n°3, female 56 y.o.	---	2 (TKA, rTKA)	traumatic	Isolated
n°4, male 75 y.o.	Type 2 diabetes mellitus	2 (TKA, Patellar Tendon partial avulsion)	a-traumatic	Isolated
n°5, female 74 y.o.	Type 2 diabetes mellitus	1 (TKA)	a-traumatic	Associated with rTKA

Table 2. Clinical and instrumental results

Patient	KSS		IS-I	Patellar-tendon thickness increase
	I section (KS)	II section (FS)		
n° 1	95	60	0.9	188.13%
n° 2a	69	-20	1.39	101.60%
n° 2b	32	-20	0.83	91.60%
n°3	68	80	0.93	135.00%
n°4	44	45	1.21	130.00%
n°5	32	65	1.73	116.42%
Average	63.3	35	1.16	127.12%

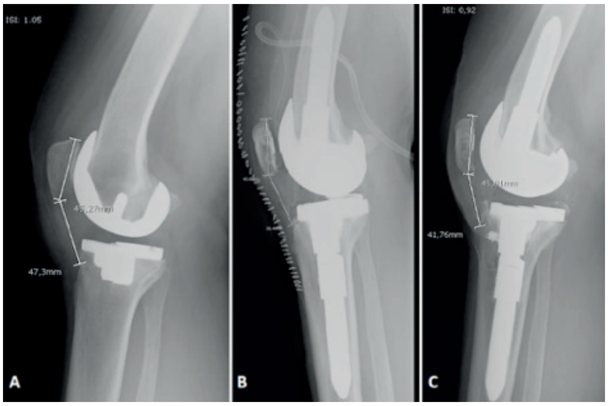

Figure 2. Patella's position on lateral view x-rays of the same patient before rTKA (A), after rTKA (B) and at last-36 months FU (C). ISI ranged between 1.05 before revision surgery and 0.92 at last FU. LARS ligament to reinforce patellar tendon was fixed to proximal tibia using an anchor 2 months after rTKA (C).

thickness was 127.12%. Only one knee (one patient) presented radiolucent lines around tibial stem without any symptom.

In the patient with the best overall results at the KSS, the thickness of the patellar tendon almost doubled (188.13%), but we also reported a case (patient affected by Parkinson's disease) in which the thickness of the patellar tendon has decreased (91.6%). Fig.3.

Discussion

Most of the current studies about patellar tendon repair techniques after TKA by using autografts or allografts reported variable - but generally poor - results at long term FU. It is probably due to graft's poor vascularization and joint blocking for a long time after tendon reconstruction [26-36].

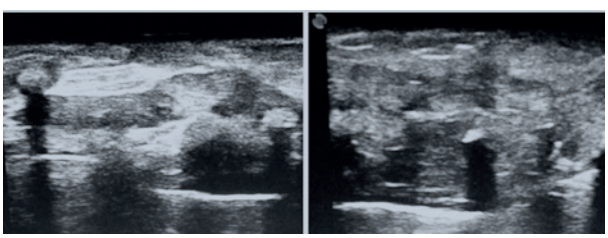

Figure 3. On the left an ultrasound image in cross section of the knee extensor apparatus showing LARS synthetic ligament; On the right longitudinal section showing patellar tendon thickness and an underlying fibrous reaction of the Hoffa. The average increase in thickness of patellar tendon at last FU was 127,12% ranging from 91,6% to 188,13%.

In this scenario synthetic ligaments are gaining a role as a valid surgical option to treat the chronic lesions of the patellar tendon [12-15].

Synthetic ligaments act as augmentation increasing the resistance of tendon repair. They also seem to allow tissue ingrowth, presenting some theoretical advantages such as: a quick incorporation into the host tissue, the maintenance of the tensile strength, the absence of donor site disability, a low risk of disease transmission and lower costs [22,23].

In literature there is not a wide consensus about the use of the LARS synthetic ligament as a surgical option to repair the patellar tendon when its breakage occurs after TKA or rTKA, while it is largely used with good results for ACL or other tendons' (i.e. rotator cuff or Achilles tendon) reconstructions [24,25]. Moreover, LARS extra-articular use regarding knee surgeries is mainly addressed to extensor apparatus reconstruction and patellar tendon repair after wider tumor resection surgery (e.g. megaprosthesis implantation) [38]. Synthetic ligaments are also employed to perform patellar tendon reconstruction in non-prosthetic knees [16-18].

Compared to other studies in literature, our study has one of the widest populations and one of the longest mean Follow-Ups (6 cases and an average follow-up of 44.2 months).

The patient affected by Parkinson disease (treated with bilateral patellar tendon reconstruction) was an important bias in our series, leading to low mean clinical outcomes, but nevertheless our results are similar to the ones reported by other authors.

Fujikawa, Aracil and Fukuta used Leeds-Keio ligaments to perform extensor mechanism reconstruction after TKA with good results.

Fujikawa et al. in their study evaluated 19 knees in 18 patients with a mean follow-up of 3.5 years. They reported a good active ROM (aROM) with an extensor lag < 10° occurred in 21% of their cases, while persistent knee pain was recorded in just 6% of patients treated. No cases of infection or extensor apparatus rerupture were reported [13].

In Aracil et al. series 5 Patients were followed-up for 56 months (38-84 months). The location of the rupture was at the distal third of the patellar tendon in 3 cases, at the middle third in 1 case, and at the quadriceps tendon in 1 case. All Patients presented comorbidities (previous septic arthritis, rheumatoid arthritis or systemic lupus erythematosus). Their surgical technique was similar to the one employed by us and Fujikawa: the Leeds-Keio ligament was inserted above the patella and through a drill hole in the tibial tubercle and then secured to the bone by staples or by screws and washers. The patellar tendon was then sutured over the prosthetic ligament. The patella was slightly distalized because of the tendency toward postoperative elongation. Passive motion has begun immediately and full weight bearing was allowed with a knee brace in order to maintain a full extension in walking. Complications reported by Aracil et al. were one serous hematoma (which was drained and treated with antibiotics) and a superficial infection (treated with early debridement and antibiotics). They reported a mean postoperative range of motion of 98 ° flexion (90° - 110 °) and -4.6 ° extension (0 - -10°). In the case with the longest follow-up, they found a mean elongation of 6.2 mm, which didn't increase over the time. The authors concluded that the patellar ligament reconstruction with a double Leeds-Keio ligament was a relatively easy technique with reasonable functional results [14].

Fukuta et al. reported two cases of patellar tendon rupture after TKA successfully treated with Leeds-Keio ligament with a mean FU of 38 months. The authors underlined how the use of synthetic ligaments does not imply the sacrifice of any autologous tissue and permits an early rehabilitation without immobilization. Their use is especially useful in patients with intrinsic problems of the soft tissues healing, where allograft reconstruction may not be indicated [38].

Browne and Hanssen reported good results in 69% of their patients, with increased function and pain relief by using polypropylene mesh to repair the patellar tendon. Complications and failures reported by the authors occurred in the first 6 months after the surgery and, in the 23% of the cases, they were related to previous surgeries. They had just one case of infection in their series.

Literature results in detail are reported in Tab 3.

Regarding LARS, we didn't find clear results in literature, but most studies related to the patellar tendon reconstruction in the native knee showed good to excellent outcomes at a short-term FU [16-18].

According with the data reported by other authors, our analysis revealed the absence of functional limitation after surgery: patellar tendon reconstruction with LARS allowed our patients to immediately bear weight after surgery (even if with a partial weight-bearing and with the knee blocked in extension), a result which couldn't be allowed by the use of autografts or allografts.

After-surgery passive mobilization of the knee is allowed in order to avoid articular stiffness and soft tissue scar formation between graft and prosthesis and between graft and soft tissues.

In our series, flection contractures were reported in the 50% of the patients, but also from this point of view the patient affected by Parkinson's disease

Table 3. Previously published data about patellar tendon reconstruction after TKA using a synthetic ligament. PT: patellar tendon; QT: quadriceps tendon. Modified from Bonnin et al. [6]

Authors	Years	N° knees treated	Technique	Location	Mean FU	Mean residual extension lag	Mean flexion range	Complication
Fujikawa et al.	1994	1	Leeds-Keio	PT	--	5°	87°	None
Aracil et al.	1999	5	Leeds-Keio	4 PT,1 QT	56 (38-84)	Lag in 3 patient (5°,10°,10°)	98° (90°-110°)	1 superficial infection and 1 hematoma
Fukuta et al.	2004	2	Leeds-Keio	PT	38 (36-40)	5°Lag in 1 case	107° (105°-110°)	none
Browne and Hansenn	2011	13	Polypropylene	PT (5 failed allografts)	42 (11-118)	10°	103°	3 failures 1 infection

dropped down our mean values (showing bilateral knee flection contracture of 20 degrees). In the other patients, flection contracture wasn't so broad (about 10°). The 50% of the patients were able to bend the knee over 90° of ROM at the latest FU, while just one patient (16.7%) recorded a 90° maximum flection of the knee and the 33.3% of the patients reported a total ROM < 90°.

Except for the Parkinsonian patient, who reported an extension lag > 20° at both knees, all the remaining patients (4/6) presented a complete extension with an extension lag < 10°.

This result was probably due to the properties of the artificial ligaments: they can maintain tensile strength over time, resulting in a low tendency to stretch. These peculiarities should, theoretically, provide better long-term results.

Unfortunately, a study that proves the quality of the long-term outcomes of synthetic grafts in patellar tendon reconstruction after TKA or rTKA is still yet to come.

Allografts, despite the initial success, showed a progressive lengthening over time with consequent deterioration of the extensor function at medium and long term Follow Ups.

Our study presented two main limitations: the small number of patients treated and the short mean follow-up (24 months - 5 years, average 44.2 months), both due to the low incidence of patellar tendon rupture after TKA or rTKA.

Furthermore, to reduce the number of variables and potential bias, we enrolled only patients with a complete isolated patellar tendon rupture, in the presence of poor tendon quality.

Another limitation is represented by the retrospective nature of the study, which led to the loss of a patient during the FU and to the lack of a closer clinical check-up for the ones who stayed.

The absence of a control group treated with allograft or autograft is another limit: we didn't take into account such a study design due to the large number of variables related to the patients, to the low number of cases, to the surgical techniques used and to the different rehabilitation programs applied.

Beyond these limits, our study confirmed many of the theoretical advantages provided by the synthetic ligaments (e.g. LARS ligament used in our series), such as: immediate availability, low cost, high resistance to traction stresses, possibility of graft integration in to host tissues, absence of disease transmission risks, possibility to allow weight-bearing immediately after surgery.

Our results – even if obtained with a small population – don't find matchings in literature, since nowadays there aren't many findings about this topic and the published series don't take into account large patients cohorts.

In conclusion, even if further studies with a longer FU are necessary, in our opinion there is a role for synthetic ligaments in the reconstruction of the patellar tendon breakage after TKA and rTKA: selected patients may take advantages from synthetic ligaments performance in order to quickly return to their activities of daily living (ADLs).

Conflict of Interest

Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

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