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SCIENTIFIC ARTICLE

Sonographic and radiographic evaluation of the extensor tendons in early postoperative period after total knee arthroplasty

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Abstract

Objective To prospectively assess the early changes in the quadriceps and patellar tendons before and after total knee arthroplasty using ultrasound, shear wave elastography, and X-rays.

Materials and methods Radiographs, ultrasound, and shear wave elastography were performed on 23 patients (16 women; aged 51–85, mean 66 ± 9 years) before and after surgery at 6 weeks and on 11 patients at 3 months. Patellar position and patellar tendon lengths were evaluated by radiography; joint effusion or synovitis, quadriceps and patellar tendon lengths, and thicknesses, echogenicity, vascularity, and stiffness were assessed with ultrasound and shear wave elastography.

Results In the early postoperative period, 87% of the patients had joint effusion, and 43% had signs of synovitis. There was a significant thickening of the quadriceps tendon in 51.5% ($p < .0001$) and of the patellar tendon in 93.8% ($p < .0001$) of patients with a significant shortening of the patellar tendon in 7.8% ($p < .0001$). A hypoechoic defect on the medial aspect of the quadriceps tendon was found in 87% of the patients. There was a significant increase in Young's modulus in the quadriceps tendon ($p = .0006$) but not in the patellar tendon.

Conclusion The following should not be considered to be pathological findings at early postoperative imaging: joint effusion, synovitis, increasing of stiffness and thickening of quadriceps tendons by more than 50%, thickening of patellar tendon by more than 90%, focal defect through the medial aspect of the quadriceps tendon, and shortening of the patellar tendon by 8%.

Keywords Total knee arthroplasty · Ultrasound · Shear wave elastography · Radiographs · Quadriceps tendon · Patellar tendon · Preoperative evaluation · Postoperative evaluation

Introduction

Total knee arthroplasty (TKA) is an increasingly widespread surgical intervention, with more than 230 interventions per 100,000 inhabitants in the USA. In 2050, the expected volume increase could even exceed 140% [1]. Among postoperative complications, the frequency of knee extensor mechanism lesions, such as quadriceps or patellar tendon tear or rupture, periprosthetic patellar fracture, and patellofemoral instability is between 1 and 10% [2–4]. Knee extensor mechanism lesions can be suspected in the presence of swelling of anterior soft tissues, pain, and limitation of extension. However, diagnosis of such lesions is not always easy, especially during the postoperative period, as clinical findings are not specific, and they often present in the early postoperative phase [3]. In this context, imaging may be a useful tool for appropriate evaluation of the extensor mechanism of the knee.

Most studies use only X-rays to evaluate TKA during late postoperative period, ranging from one to 5 years or without specifying the time interval after surgery [5–7]. X-rays are essential for evaluating bone and prosthetic components. Unlike X-rays, ultrasound (US) is an accurate tool for investigating soft tissues, especially tendons. Although degenerative morphological changes of the quadriceps and patellar tendons, known as extensor tendons of the knee, have been reported in patients who underwent TKA, these are likely to be present either before the intervention or directly following the surgical procedure and/or following impingement with the prosthetic material [4]. Lee et al. reported modifications of the quadriceps tendon, such as thickening, loss of fibrillar structure, and focal low-echogenic areas after surgery [8]. However, the limited number of patients restricted to ten and the absence of comparisons with preoperative examinations may represent a significant limitation of the study. Indeed, the

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extent of thickness of the extensor tendons after TKA assessed by US would be an important tool to differentiate normal from pathological state of these tendons.

Shear wave elastography (SWE) allows qualitative and quantitative information about tissue stiffness. Several studies have reported a decrease of elasticity in pathologic tendons when compared with healthy tendons [9–15]. In their recent prospective study investigating the postoperative changes of extensor tendons in 63 patients, Quack et al. suggested that total knee replacement might lead to a significant modification of the tendons assessed by SWE [16]. However, no study has examined the extensor tendons of the knee before and after early TKA using that technique.

Therefore, the aim of the present study is to prospectively assess the early changes in the quadriceps and patellar tendons after TKA using US and SWE.

Materials and methods

Patients

This prospective study has been approved by our Hospital Ethics Committee and written informed consent was obtained from all patients. This study included consecutive patients with symptomatic tricompartimental osteoarthritis who underwent TKA, between June 2018 and January 2019. Patients who had previously undergone surgery on the patella, quadriceps tendon, patellar tendon, and tibial tuberosity were excluded. Ten patients refused to be included in the study. One patient presenting infection around the surgical staples has been excluded from the study. In total, 23 patients (16 women and 7 men), aged from 51 to 85 years (mean ± standard deviation, SD, 66 years ± 9), were included in the study. One patient underwent bilateral TKA. All prosthetic devices were cemented posterior-stabilized, associated with patellar resurfacing and partial resection of Hoffa fat pad. The knee flexion and extension were evaluated by the surgeon before and after surgery. All TKAs were performed by the same surgeon, with minimally invasive surgery using a medial parapatellar approach. To access the joint space, a 2-cm quadricep tendon incision and lateral patellar subluxation were performed systematically. The patellar tendon was just tilted back laterally with the patella for approximately 45 min (Fig. 1).

Imaging

X-rays and US combined with SWE were performed 1 day before surgery ($n = 23$), at 6 weeks ($n = 23$) and at 3 months ($n = 11$). US and SWE were performed by the same radiologist (RDA). All US and SWE measurements were systematically reviewed and validated by an experienced musculoskeletal radiologist (AM). In case of disagreement, a new measurement was determined after consensus.

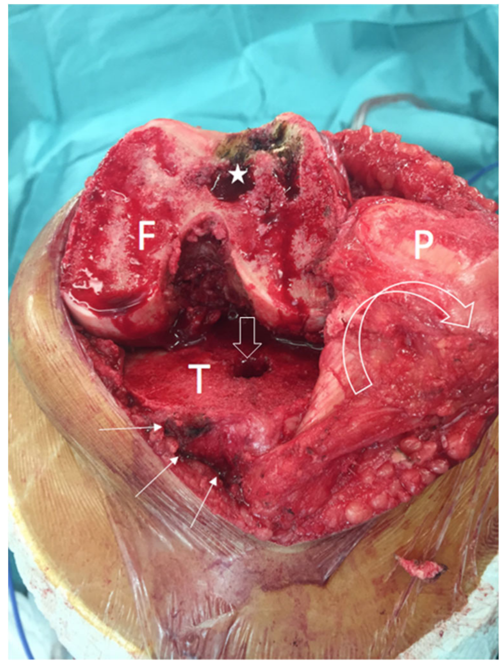

Fig. 1 Surgical photography of the knee during TKA. The knee is flexed and the Hoffa fat pad had been partially resected (thin arrows). The distal end of the femur (F) and the proximal end of the tibia (T) have been prepared for prosthesis implantation. A necrotic area is observed on the arthritic femoral condyle (star), and a round defect is seen in the center of the tibia for prosthetic insertion (thick arrow). The patellar tendon, laterally reclined with the patella (P), is twisted (curved arrow)

X-rays

X-rays comprised an anteroposterior (AP) view, a lateral view, a patellar view, and a study of the axis of the lower limbs. X-rays were analyzed by two radiologists, one trainee (RDA) and one with 20 years of experience in musculoskeletal radiology (AM). Patellar height and patellar tendon length were estimated before and after surgery by four indexes: Insall-Salvati, modified Insall-Salvati, Caton-Deschamps, and modified Caton-Deschamps.

Ultrasound

The following parameters were evaluated:

Quadriceps tendon: qualitative evaluation of tendon and tendon thickness, measured at 2 cm from the patellar insertion, in longitudinal and axial views.

Patellar tendon: qualitative evaluation of tendon, tendon length—measured between its patellar insertion and tibial tuberosity, following the measurement method validated by Gellhorn et al. [11]—and tendon thickness—measured at the proximal, middle and distal parts—in longitudinal (Fig. 2) and axial views: The average of these three measurements was used as an estimation of global thickness.

The qualitative evaluation of the quadriceps and patellar tendons consisted in the loss of echogenicity and fibrillar

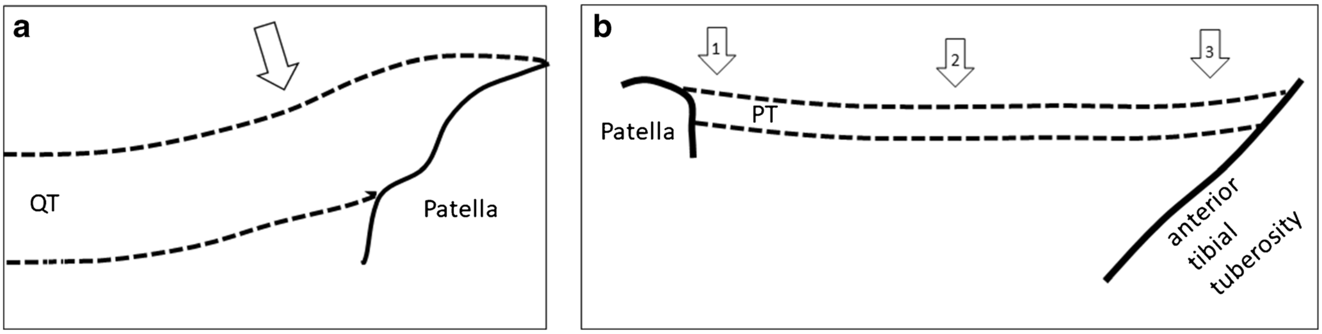

Fig. 2 Landmarks for US measurements of the extensor tendons. **a** The thickness of the quadriceps tendon (QT) is measured at 2 cm from the patellar insertion (arrow). **b** The thickness of the patellar tendon (PT) is measured at three levels: proximal (1), middle (2), and distal (3) parts

appearance of the tendon, the presence of inhomogeneous tendon texture, partial or total tear, tendon calcification, fluid in the paratendon, or hypervascularity with color Doppler ultrasound.

The radiologists were also asked to search for joint effusion (i.e., dilatation of quadricipital recess > 4 mm) and synovitis (i.e., synovial membrane thickness > 3 mm) [17, 18].

Shear wave elastography

To reduce the variability of measurements, we used the same elastographic modulus, with specific settings for musculoskeletal examination (shear wave elastography, Logiq E9 GE, Healthcare ultrasound, Wauwatosa, USA), with a 9-MHz linear probe. The probe was positioned perpendicular to the tendon axis. A thick 4-mm ultrasonic gel layer between the probe and the skin was applied to restrict tissue deformation, and the radiologist employed minimal pressure on tendons.

Statistical analysis

Statistical analyses were performed using MedCalc Statistical Software version 18.11 (MedCalc Software, Ltd. Ostend, Belgium).

The Wilcoxon test was used to compare the following measurements prior to surgery and at 6 weeks and at 3 months after surgery: quadricipital tendon thickness, patellar tendon global thickness, patellar tendon length, quadricipital tendon elastic Young's modulus in longitudinal and axial views, patellar tendon elastic Young's modulus in longitudinal and axial views. The Wilcoxon test was also used to compare the increase of thickness of the different segments of the patellar tendon (proximal, middle, and distal).

The inter-observer agreement for the X-rays measurements (X-rays index of Insall-Salvati, modified Insall-Salvati, Caton-Deschamps, and modified Caton-Deschamps) was evaluated with the intraclass correlation coefficient (ICC). The Wilcoxon test was used to compare the indices measured by the experienced radiologist prior to and after surgery.

The value $p < .05$ was considered statistically significant.

Results

No complication of extensor mechanism of the knee was observed in the postoperative period. The average knee flexion was 106° ± 11° and 109° ± 13°, respectively, before and after surgery. After surgery, only one patient presented a 10° extension deficit.

Joint effusion and synovitis Before surgery, only 6 patients (22%) had joint effusion and only one patient, previously diagnosed with rheumatoid polyarthritis, had signs of synovitis. However, in the first 6-week postoperative period, 20 patients (87%) had joint effusion and 10 patients (43%) had signs of synovitis. At 3 months, 9 patients (82%) had joint effusion and 2 patients (18%) had signs of synovitis.

Quadriceps tendon The tendon thickness measurement before and after surgery is presented in Fig. 3. There was a statistically significant increase of quadriceps tendon thickness 6 weeks after surgery compared with before surgery (Table 1, $p < .0001$, average of individual percent changes: 51.5%). At 3 months, the increase of the thickness compared with before surgery was still significant ($p = .001$) and reached 59.1% (average of individual percent changes).

The tendon's morphology before and after surgery is shown in Fig. 4 and 5. Before surgery, all tendons had normal echogenicity with normal fibrillar structure. At 6 weeks after surgery, all tendons showed a decreased echogenicity, as compared with the contralateral side. Eighteen patients (78%) also showed a peritendinous swelling and a moderate increase of tendon vascularization in the color Doppler examination. Twenty patients (87%) showed a hypoechoic defect in the medial aspect of the tendon (Fig. 5). At 3 months post-TKA, decreased tendon echogenicity, peritendinous swelling, and the hypoechoic defect were noticed in 7 (63%), 8 (73%), and 11 (100%) patients, respectively (Fig. 6).

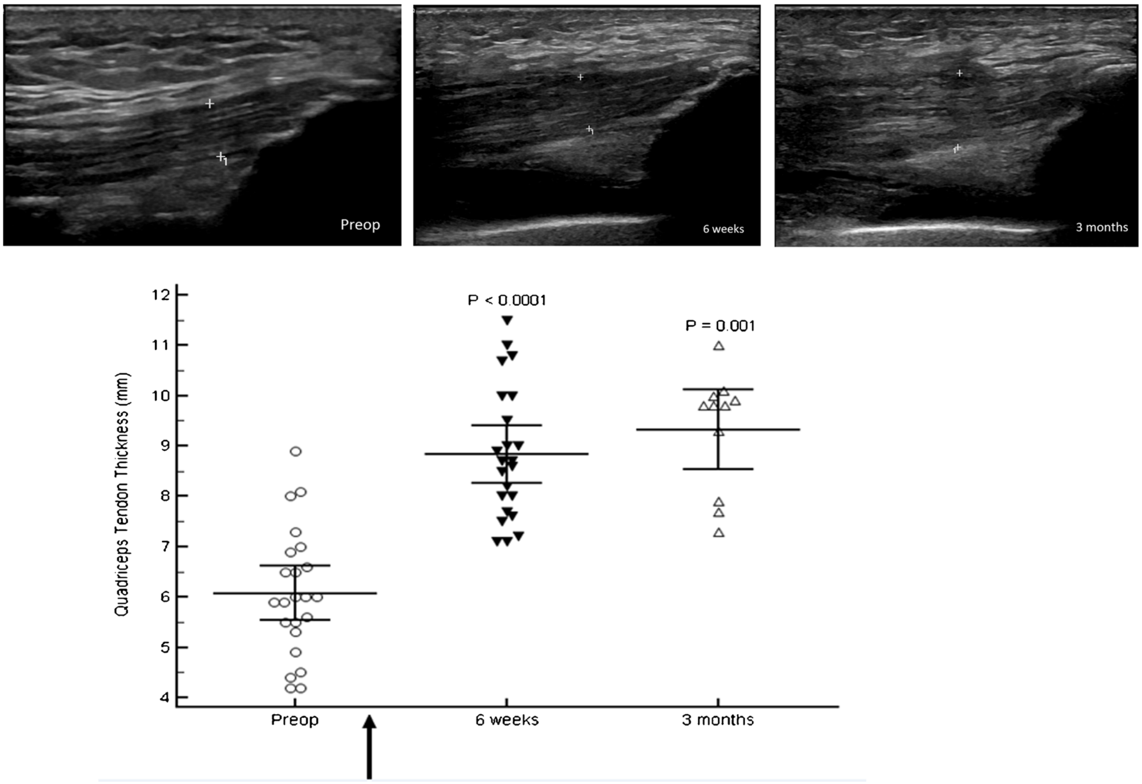

Fig. 3 Quadriceps tendon thickness evolution before and after surgery. Quadriceps tendon thickness in the same individuals is illustrated in longitudinal US. After surgery, the thickness was maximal at 3 months. Heterogeneous echotexture with loss of regular fibrillar aspect is observed even at 3 months after surgery. The arrow indicates the time of surgery. On this graph, horizontal bars represent means, and error bars represent 95% confidence interval of the mean at each timepoint

Patellar tendon The tendon morphology and thickness measurement before and after surgery are presented in Fig. 7. We observed a significant increase of the patellar tendon global thickness 6 weeks after surgery (Table 1, $p < .0001$, average of individual percent changes: 93.8%). The average of individual percent changes was greater in the middle part of the tendon (120.4%) in comparison with its upper (89.1%) and lower (80%) parts ($p = .036$ and $p = .0004$). At 3 months, the increase of the global thickness compared with before surgery was still significant ($p = .001$) and reached 113.5% (average of individual percent changes).

Before surgery, all tendons had a normal echogenicity. Only one patient, although asymptomatic, presented a hypoechoic zone associated with calcifications at the tibial enthesis. All tendons were hypoechoic at 6 weeks after surgery, and 21 patients (91%) were hyperemic at color Doppler examination. These modifications were still present at 3 months after surgery in 4 (36%) and 7 (63%) patients, respectively.

At US, the tendon showed statistically significant shortening of 7.71% at 6 weeks and 7.58% at 3 months after surgery compared with its length before surgery ($p = .0003$ and $p = .0391$, respectively).

On X-rays, we observed an increase at 6 weeks and at 3 months of both the Caton-Deschamps ($p = .0037$ and $p = .0078$, respectively) and Insall-Salvati indexes ($p = .0171$ and $p = .0313$, respectively). There were good intraclass correlation coefficients (0.85 to 0.95) between the two operators. No modification of patellar tendon length was observed with the modified indexes between the preoperative and postoperative periods (Tables 1 and 2).

Shear wave elastography In quadriceps tendons, we observed an increase of Young's modulus on both sagittal and axial views in the postoperative period, as compared with the preoperative period (sagittal $p = .0006$ at 6 weeks and $p = .0039$ at 3 months; axial $p = .0009$ at 6 weeks and $p = .0098$ at 3 months) (Fig. 8). In patellar tendons, there were no modifications between preoperative and postoperative periods (Fig. 9 and Table 2).

Discussion

During the 6-week and 3-month periods after TKA, our study showed the following modifications: (1) Joint effusion, synovitis, and peritendinous hyperemia; (2) thickening of quadriceps tendon by more than 50% and of the patellar tendon by more than 90%, especially in its middle

Table 1 US measurements before and after TKA surgery

	Preoperative	Postoperative			
		6 weeks ($n = 23$)	p value	3 months ($n = 11$)	p value
Thickness (mm)					
Quadriceps tendon	6.07 ± 1.26	8.84 ± 1.31	*< .0001*	9.33 ± 1.17	*.001*
Patellar tendon					
Inferior	4.45 ± 1.03	7.73 ± 2.02	*< .0001*	7.09 ± 1.20	*.002*
Middle	3.97 ± 0.94	8.33 ± 2.30	*< .0001*	8.18 ± 1.49	*.001*
Superior	4.18 ± 1.03	7.53 ± 1.58	*< .0001*	7.61 ± 1.35	*.001*
Global	4.20 ± 1.88	7.87 ± 1.80	*< .0001*	7.63 ± 1.25	*.001*
Length (mm)					
Patellar tendon	41.61 ± 4.73	38.26 ± 4.39	*.0003*	39.18 ± 7.19	*.0391*
Young's Modulus (kPa)					
Quadriceps tendon					
Longitudinal	12.41 ± 9.81	28.13 ± 12.27	*.0006*	28.60 ± 8.82	*.0039*
Transverse	19.15 ± 10.92	33.87 ± 14.26	*.0009*	34.64 ± 17.67	*.0098*
Patellar tendon					
Longitudinal	30.09 ± 13.58	37.20 ± 16.80	.1283	31.95 ± 9.38	.1094
Transverse	20.56 ± 9.74	21.34 ± 10.04	.871	19.71 ± 9.60	.375

Results expressed in mean ± standard deviation over the patient group. p values of the Wilcoxon tests are indicated

The value $p < .05$ was considered statistically significant

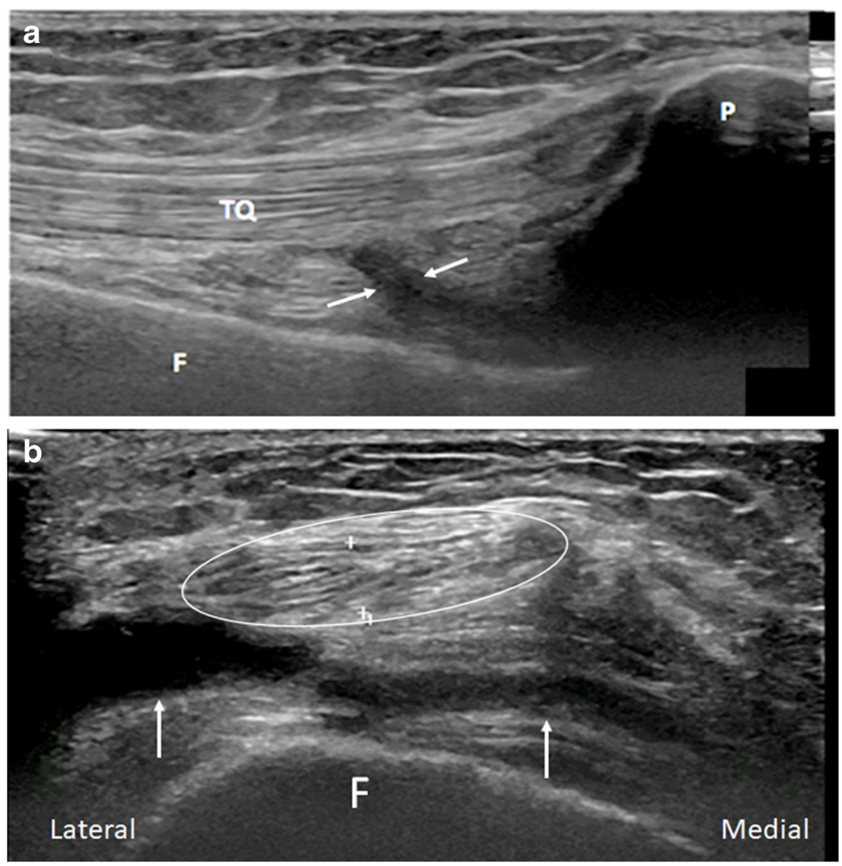

Fig. 4 Preoperative longitudinal (**a**) and transversal (**b**) US of the quadriceps tendon
On **a**, quadriceps tendon (TQ) shows a normal hyperechoïc fibrillar aspect until its patellar insertion (P). On **b**, quadriceps tendon shows normal hyperechoïc punctate aspect (ellipse). A small hypoechoïc synovial subquadricipital recess is observed on both views (arrows). F, femur

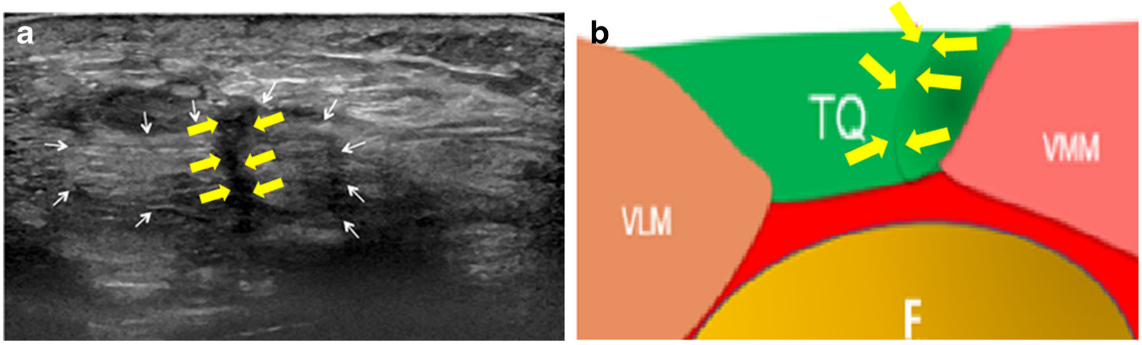

Fig. 5 Transversal US (**a**) and corresponding schema (**b**) of the quadriceps tendon at 6 weeks after surgery. Quadriceps tendon (white arrows) are thickened with peripheral hypoechoïc rim. A hypoechoïc defect (yellow arrows) is detected on the medial side of the tendon. This defect corresponds to the surgical incision

portion; (3) focal defect in the medial aspect of the quadriceps tendon in almost 90% of patients; (4) shortening of the patellar tendon by 8%; and (5) increased stiffness of quadriceps tendons only.

A vast majority of our patients presented signs of synovitis associated with peritendinous hyperemia soon after TKA surgery. These findings are consistent with the study of Boldt et al. who found synovial thickening with a threshold value of 3 mm on US more than 1 year after TKA. This allowed the authors to diagnose arthrofibrosis with a sensibility and a specificity of 84 and 82% [18]. Some factors may predispose to stiffness and arthrofibrosis after TKA. These include previous knee surgery or preoperative limited range of motion [19, 20]. However, in our study, patients with previous knee surgery were excluded and only one patient showed a restricted extension of more than 10° at 6 weeks. No patient had a flexion below 90°. The majority of patients in our study showed peritendinous infiltration and hyperemia with color Doppler in both quadriceps and patellar tendons. This neovascularization of quadriceps tendon probably reflected reparation mechanisms after incision and manipulation, as described in rotator cuff tendons after surgery [21]. Hyperemia of the patellar tendon may be secondary to the resection of Hoffa fat pad, as it has been demonstrated that patellar tendons share multiple anastomoses with Hoffa fat pad [22, 23].

Thickening with loss of fibrillar structure and hypoechogenicity in the quadriceps tendon probably resulted from the surgical procedure, as all tendons were normal before surgery. As Mailleras et al. explained in their article, the loss of fibrillar structure and hypoechogenicity may be due to reactive tendinopathy with a preserved collagen matrix [24]. Similar US findings, without clinical symptoms, were observed for patellar tendon during the 6-week postoperative period in our study and during a 12-week post-surgery period in the studies of Lee et al. and Malliaras et al. [8, 23]. However, these authors did not specify their methods of measurement, and they did not evaluate the tendons before surgery. In addition, in our study, the patellar tendon thickening was more noticeable in its middle part. To our knowledge, this peculiar finding has not been described in the scientific literature. It may result from the surgical procedure, in which the patellar tendon was maintained reclined and twisted through its midportion for 40–45 min while remaining fastened to its entheses.

At 6 weeks after surgery, 87% of patients showed a hypoechoic defect at the medial side of the quadriceps tendon. This feature, compatible with a fissure resulting from the transtendinous incision, is similar to those

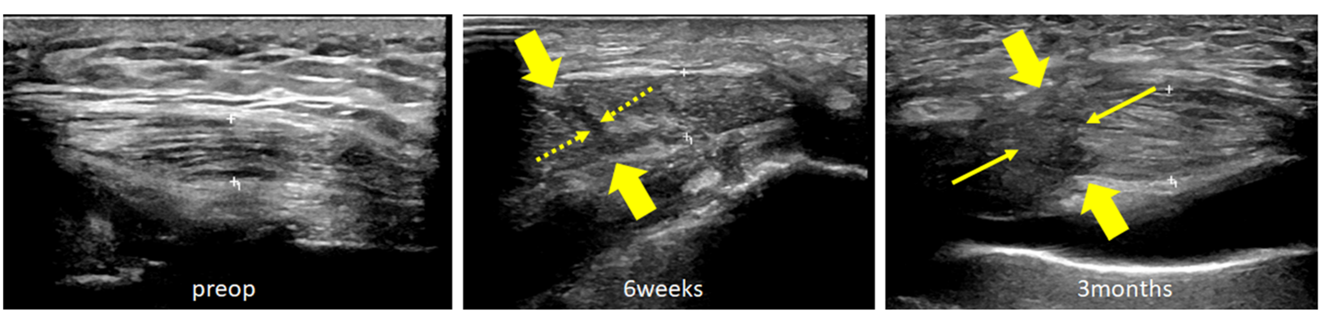

Fig. 6 Quadriceps tendon medial defect at 6 weeks and 3 months after surgery. In addition to the postoperative thickening of the quadriceps tendon, a medial defect (large arrows) was observed after surgery in 20 patients out of 23 (87%) at 6 weeks and in all 11 patients at 3 months (100%). The defect appears thin and hypoechoïc with regular margins at 6 weeks (dotted yellow arrows), while it is wider and hyperechoïc with blurred margins at 3 months (small yellow arrows)

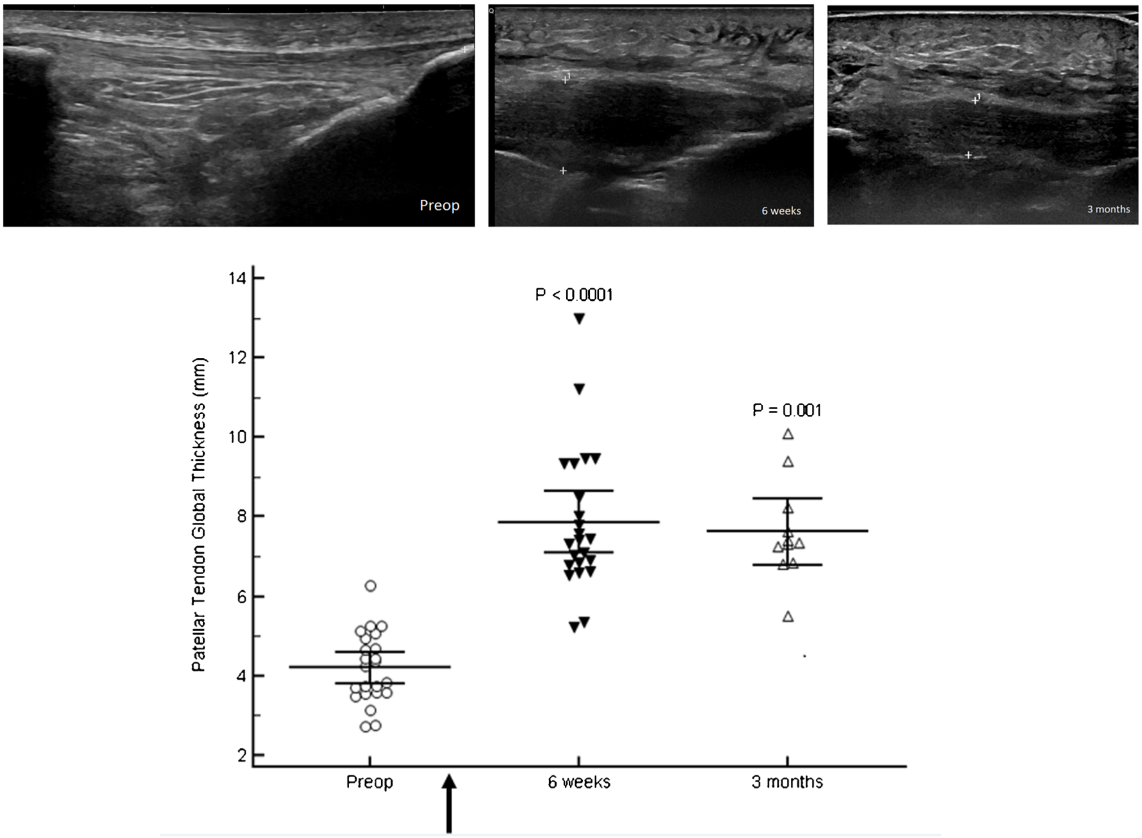

Fig. 7 Patellar tendon thickness evolution before and after surgery. Patellar tendon thickness is illustrated by longitudinal US in the same individuals and on the graph. After surgery, the thickness was maximal at 6 weeks and decreased slowly at 3 months. Postoperative thickening is more important in the middle third of the tendon. This finding may result from the surgical procedure, in which the patellar tendon is maintained twisted at its middle third while remaining attached to its patellar (P) and tibial (T) insertions. On the graph, horizontal bars represent means, and error bars represent 95% confidence interval of the mean at each timepoint. Arrow indicates the time of surgery. After surgery, the thickness was maximal at 6 weeks and decreased slowly at 3 months

reported by Lee J. et al. who observed this defect on the quadriceps tendon in 80% of their patients, concluding that it may be considered a normal finding during a 12-week postoperative period [8].

Shortening of the patellar tendon is commonly observed after TKA especially based on X-rays indexes [7, 25–30]. These indexes are not always reliable because they can be easily modified in the postoperative examinations due to technical factors such as the degree of knee flexion, radiographic beam incidence, or tibial osteotomy [27, 29]. In our study, we observed a slight but significant increase of Insall-Salvati and Caton-Deschamps indexes but no significant difference in these modified indexes between preoperative and postoperative X-rays. These results may be explained by the removal of patellar osteophytes, thus reducing the patellar height after surgery, and by the modification of the inferior

Table 2 Radiographic indexes before and after TKA surgery

	Preoperative	Postoperative			
		6 weeks ($n = 23$)	*p* value	3 months ($n = 8$)	*p* value
Insall-Salvati Index	1.05 ± 0.23	1.11 ± 0.23	*.0171*	1.19 ± 0.27	*.0313*
Modified Insall-Salvati Index	1.44 ± 0.25	1.48 ± 0.24	.7337	1.63 ± 0.23	.1563
Caton-Deschamps Index	0.82 ± 0.24	0.98 ± 0.29	*.0037*	1.09 ± 0.30	*.0078*
Modified Caton-Deschamps Index	1.17 ± 0.25	1.12 ± 0.31	.49	1.30 ± 0.36	.1094

Results expressed in mean ± standard deviation over the patient group. *p* values of the Wilcoxon tests are indicated

The value $p < .05$ was considered statistically significant

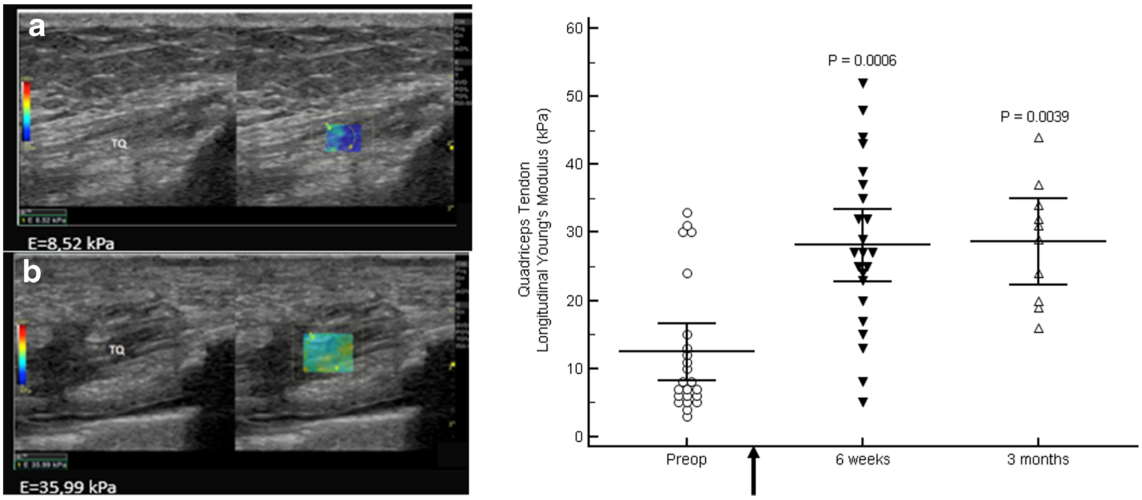

Fig. 8 Quadriceps tendon SWE evolution before and after surgery. Example of longitudinal Young's modulus measurement ($E = 8.52$ kPa) in the quadriceps tendon in the same individuals preoperatively (**a**) and 6 weeks after surgery (**b**). The longitudinal Young's modulus (E) has increased up to 35.99 kPa. Arrow indicates the time of surgery. A significant increase of stiffness in the quadriceps tendon was observed at 6 weeks post-surgery

tibial point, resulting from tibial osteotomy. Gwyn et al. observed a decrease of the Caton-Deschamps index in patients with complete excision of Hoffa fat pad [28]. In our study, we observed an increase of this index after surgery, although the Hoffa fat pad was only partially removed. This discordance may be explained by a different method of measurement of the Caton-Deschamps index. For a better accuracy, the tibial point was taken more distal in our study, just at the level of the osteotomy instead of the upper part of the non-metallic prosthesis. To our knowledge, our prospective study is the first study illustrating the patellar tendon shortening by US.

Shear wave elastography

Different studies have investigated quadricipital tendon elasticity with SWE on healthy tendons. Zardi et al. and Ebihara et al. established normal values of quadriceps tendons, in young and healthy subjects [31, 32]. In the preoperative period, their values are greater than those in the present study. This discrepancy could be related to the fact that the patients in our study were older. In addition, we used a different imaging protocol, such as patient position, knee flexion degree, elastogram size, and the number and scale of measurements.

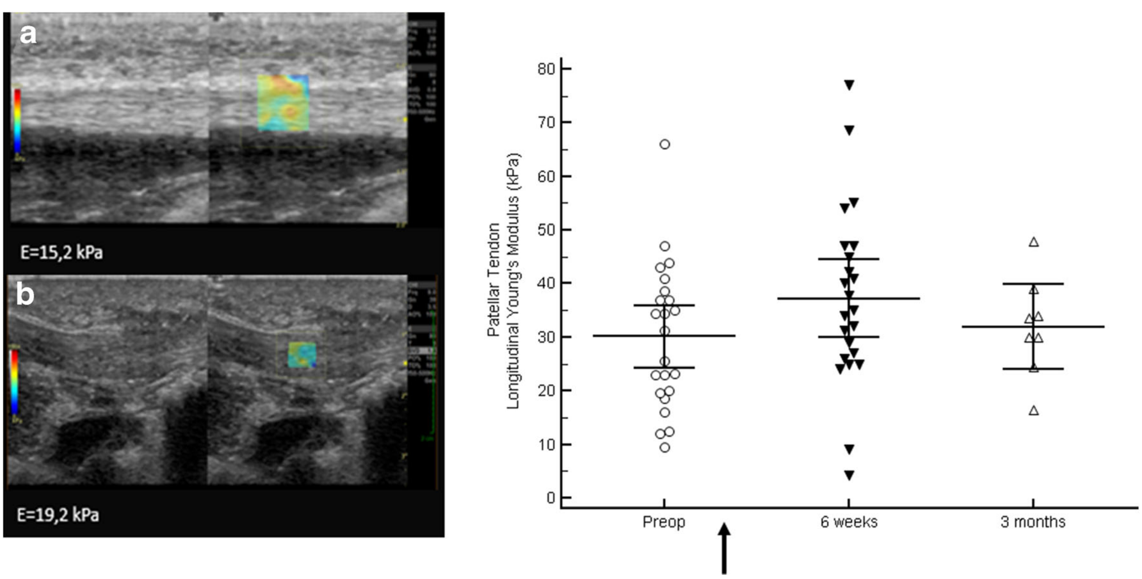

Fig. 9 Patellar tendon SWE evolution before and after surgery. Example of longitudinal Young's modulus measurement ($E = 15.2$ kPa) in the quadriceps tendon in the same individuals preoperatively (**a**) and 6 weeks after surgery (**b**). The longitudinal Young's modulus (E) has increased to 19.2 kPa. Arrow indicates the time of surgery. No significant variation on patellar tendon elasticity was observed between the preoperative period and after surgery

After surgery, we observed, in the early postoperative period, a decrease of tendon elasticity in both axial and sagittal views. This may be explained by the surgical incision at the medial side of the quadriceps tendon. Quack et al. observed with USB mode, color Doppler mode, and SWE mode tendon neovascularization and reduced stiffness in both quadriceps and patellar tendon in patients after TKA compared with patients who have not been operated. These modifications may be present even 2 years after surgery [16]. Although these results are in concordance with ours concerning the quadriceps tendon, in their study, no US examination had been conducted before surgery, the TKA procedure was not fully described, and the thickness of the tendon was not evaluated. For the patellar tendon, our preoperative values are lower than those reported by Hsiao et al., but they are similar to those reported by Zhang et al., the latter having used imaging protocols and settings close to ours [12, 13]. The lack of significant change of patellar tendon elasticity in postoperative period in our study was an unexpected finding and is in contradiction with those of Quack et al. [16]. This discrepancy could be supported by the surgical approach in our study, the patellar tendon being just reclined with the patella without surgical incision.

Our study has several limitations. First, the length of time after surgery is short, and the sample size is small, especially at 3 months after surgery. Nevertheless, early exploration of the extensor tendons after TKA made sense since complications may occur at that point. Moreover, all extensor tendons were examined before the operation, allowing accurate comparisons with their conditions in the postoperative periods. Second, US examinations were performed by a single operator, with images and measurements validated by a second radiologist, an expert in musculoskeletal imaging. However, this is a minor limitation considering the good ICC observed in radiographs measurements between the two operators. Third, even though SWE appears more reproducible while compared with other elastographic techniques, shear wave propagation may be modified by different factors, such as operator experience or probe orientation. However, we paid attention to standardize as far as possible our SWE protocol in order to reduce variability.

In conclusion, at 6 weeks and 3 months after TKA, we observed joint effusion, synovitis and peritendinous hyperemia, and the thickening of quadriceps tendons by more than 50% and of patellar tendons by more than 90%, especially in the middle portion. There was a focal defect through the medial aspect of the quadriceps tendon in almost 90% of patients, a shortening of the patellar tendon by 8%, and an increase of stiffness of the quadriceps tendon only.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval Informed consent was obtained from all individual participants included in the study. All procedures performed in studies involving human participants were done in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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