Table 2. Results of the patients with a followup of 24 months or longer

| Patient | Loss of ROM | KT (mm) at followup | IKDC | Complaints | | |
|---------------|-------------|------------------------|-----------------------|-----------------------|--------------------------------------|--|
| number | | | Subjective assessment | Sports activity level | | |
| 1 | None | 4 | Normal | 2 | None | |
| 2 | None | 3 | Nearly normal | 2 | None | |
| 3 | None | 1 | Normal | 3 | None | |
| 4 | None | 1 | Nearly normal | 1 | None | |
| 5 | None | 2 | Normal | 3 | None | |
| 6 | None | 1 | Normal | 1 | None | |
| 7 | None | 1 | Normal | 4 | None | |
| 8 | 5° flexion | 0 | Nearly normal | 1 | Mild pain, | |
| | | | | | swelling after strenuous activity | |
| 9 | None | 1 | Normal | 4 | None | |
| 10 | None | 2 | Nearly normal | 4 | None | |
| 11 | None | 1 | Normal | 4 | None | |
| 12 | None | -1 | Normal | 1 | None | |
| 13 | None | 2 | Normal | 3 | None | |
| 14 | None | -1 | Normal | 4 | None | |
| 15 | None | -1 | Nearly normal | 3 | None | |
| 16 | None | 2 | Normal | 1 | None | |
| 17 | 5° flexion | -1 | Nearly normal | 3 | Mild pain, | |
| | | | | | swelling after strenuous activity | |
| Mean \pm SD | NA | 1.0 ± 1.5 | NA | NA | NA | |

KT = side-to-side difference at manual maximum force with KT-1000 arthrometer; IKDC = International Knee Documentation Committee score; NA = not applicable.

Table 3. Published results of revision ACL reconstruction

| References | Graft (%) | | | ROM | | KT | | | Failure | IKDC | RTP | |
|------------------------------|-----------|------|------|-----------|---------------------|-------------------|--------------|------------------|-----------------------|------|------------|------|
| | Hamstring | ВТВ | QTB | Allograft | Extension loss > 5° | Flexion loss > 5° | Mean (mm) | > 5 mm (%) | 2+ pivot shift (%) | (%) | A-B (%) | (%) |
| Diamantopoulos et al. [11] | 42.1 | 38.3 | 19.6 | 0 | _ | No. | 0.9 | 6.6 | 10.3 | - | 57.9 | _ |
| Ferretti et al. [12] | 100 | 0 | 0 | 0 | 0% | | 2.5 | 7.1 | 7.1 | 10 | 92.9 | _ |
| Salmon et al. [32] | 100 | 0 | 0 | 0 | 4% | 4% | 2.5 | 8.2 | 6.1 | 10 | 56 | 70 |
| Weiler et al. [44] | 100 | 0 | 0 | 0 | - | _ | 2.2 | 2.1 | 4.2 | 6 | 91.7 | |
| Noyes and Barber-Westin [26] | 0 | 100 | 0 | 0 | 3.6% | 0% | 2.2 | 22 | 22 | 24 | | 58 |
| Garofalo et al. [16] | 0 | 0 | 100 | 0 | 0% | _ | 3.1 | 3 | 0 | _ | 93 | 93 |
| Noyes and Barber-Westin [25] | 0 | 0 | 100 | 0 | - | - | 2 | 19 | 19 | 19 | 81 | 71.4 |
| O'Neill [29] | 44 | 52 | 0 | 0 | 2% | _ | - | 6 | | 6 | 84 | 75 |
| Denti et al. [10] | 61.7 | 38.3 | 0 | 0 | _ | _ | - | 10 | _ | - | 83.3 | 78 |
| Battaglia and Miller [6] | 15.9 | 47.6 | 4.8 | 31.7 | - | | 3.9 | 21 | _ | 25 | 71 | 59 |
| Ahn et al. [1] | 37 | 36 | 0 | 26.8 | _ | _ | 1.5 | 3.6 | 0 | _ | 73.2 | _ |
| Grossman et al. [18] | 0 | 20.7 | 0 | 79 | _ | _ | 2.8 | 3.4 | 0 | _ | 79.3 | 80 |
| Thomas et al. [41] | 69.4 | 30.6 | 0 | 0 | _ | - | 1.4 | 5 | 2 | _ | | - |
| Fox et al. [14] | 0 | 0 | 0 | 100 | _ | _ | 1.9 | 6 | 3 | 6 | 93 | _ |
| Shino et al. (current study) | 6 | 88 | 6 | 0 | 0% | 0% | 1.1 | 0 | 0 | 5.8 | 100 | 70.6 |

KT = side-to-side difference at manual maximum force with KT-1000 arthrometer; IKDC = International Knee Documentation Committee score; RTP = return to play sports.



attributed to femoral tunnel location or distance in its aperture between the primary ACLR and the revision. The ACL femoral attachment area is located in the superior-posterior margin of the lateral wall of the notch and less than 10 mm in width, as shown in recently published studies [9, 13, 15, 20, 22, 31, 39]. We have been consistently locating femoral tunnel aperture inside the attachment area [39] (Figs. 4, 5). Furthermore, a femoral tunnel with 5-mm wide rectangular aperture in RT ACLR might have made it possible not only to avoid overlapping tunnels, but to leave more space between the previous improperly placed tunnels and the new tunnels (Fig. 6).

With this procedure, grafts with or without bone plugs may be used. In some countries (including Japan) allograft tissue is not available owing to cultural philosophy. Thus, our principle graft choice for revision has been the BTB graft from the contralateral knee after the primary ACLR with the ipsilateral BTB graft or from the ipsilateral BTB graft if it had not been used for the primary ACLR. However, the BTB graft may not be appropriate for every patient. For example, some judo wrestlers would not accept graft harvest from the contralateral knee. They prefer an unbalanced dominant leg to well-balanced bilateral legs because of their sport. For these patients, the RT technique could be used with SMT if the double- or triple-bundle procedure could not be applied because of pre-existing tunnel(s). In contrast, rugby or American football players may be willing to have a BTB graft harvest from the contralateral limb.

One of our patients had a fall with the knee hyperflexed, resulting in femoral bone plug slippage out of the tunnel in the early postoperative period. Because the bone quality is attenuated and the previous tunnel is close to the new one in many revision cases, additional cortical fixation may be considered in addition to the interference screw fixation.

The rectangular tunnel technique restores function and stability in the short-term in most patients.

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Effects of medial patellofemoral ligament reconstruction on patellar tracking

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Abstract

Purpose Medial patellofemoral ligament (MPFL) reconstruction has been performed to treat recurrent patellar dislocation. However, the effects on patellar tracking have not been well documented, particularly in patients. The purpose of this study is to compare patellar tracking pattern and chondral status at MPFL reconstruction with those at second-look arthroscopy.

Methods Between 1999 and 2008, 71 patients with recurrent patellar dislocation underwent MPFL reconstruction using a double-looped semitendinosus tendon. Of these, 25 knees in 24 patients underwent second-look arthroscopy (at 6–26 months after initial surgery), forming the subject for the present study. No other surgical procedures such as tibial tuberosity transfer, lateral release, or osteotomy were performed in any patients. To assess the patellar tracking pattern, the position of the patella on femoral groove was evaluated arthroscopically during passive knee motion through lateral suprapatellar portal.

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Results Before MPFL reconstruction, the patella in all patients was shifted laterally throughout the entire range of knee motion. Immediately after MPFL reconstruction, patellar malalignment was corrected in all cases. On second-look arthroscopy, two different patellar tracking patterns were observed. In 9 knees, the patella was located on the center of the femoral groove throughout the range of motion. Meanwhile, in the remaining 16 knees, the patella was shifted laterally at knee extension and migrated to the center of femoral groove with increased knee flexion. No significant deteriorations in chondral status were seen on second-look arthroscopy.

Conclusion The present study revealed that not all improved patellar trackings after MPFL reconstruction remained intact at follow-up. Chondral status in patellofemoral joint was not aggravated by MPFL reconstruction.

Level of evidence Therapeutic studies, Level IV.

Keywords Lateral patellar dislocation · Medial patellofemoral ligament reconstruction · Second-look arthroscopy · Patellar tracking pattern · Chondral status

Introduction

Recurrent lateral patellar dislocation, subluxation and functional instability commonly occur in patients with various combinations of predisposing factors, such as general joint laxity, abnormal Q angle, abnormal patellar morphology, femoral trochlear aplasia, and patella alta [3, 16, 30]. Movement of the patella thus varies between individuals [40]. The importance of the medial patellofemoral ligament (MPFL) as the primary soft-tissue restraint to lateral displacement of the patella has recently been corroborated by several studies [5, 7, 9, 17], and the MPFL



is always injured to some extent during traumatic lateral patellar dislocations [20, 29]. Many operative techniques to reconstruct the MPFL have been described [2, 8, 23, 25, 35, 37]. Good midterm clinical results with up to 97% patient satisfaction and up to 10 years follow-up have been reported [31, 38], and MPFL reconstruction has become the first choice for treating recurrent patellar dislocation. Several reports have described the good effects of MPFL reconstruction on patellofemoral kinematics and contact pressure [4, 14, 26, 33, 34]. However, all these studies used normal cadaveric knees and examined only just after MPFL reconstruction. In many knee ligament reconstruction surgeries such as anterior cruciate ligament reconstruction, posterior cruciate ligament reconstruction, and medial collateral ligament reconstruction, biomechanical properties of implanted grafts are known to change with the effects of stress relaxation and graft remodeling [1, 42]. Although such physiological factors may also be relevant to MPFL reconstruction, it is unknown whether the restored patellar maltrackings remain intact for a long while, particularly in practical patients with a variety of predisposing factors. Furthermore, no previous reports showed clearly whether MPFL reconstruction improved or damaged the patellofemoral articular surface. The purpose of the present study was to investigate whether the patellar tracking restored by MPFL reconstruction is maintained for a long time, comparing the patellar kinematics of patients at MPFL reconstruction with that at second-look arthroscopy. To evaluate the effect of MPFL reconstruction on patellofemoral joint surfaces, chondral status at second-look arthroscopy was also compared with that at initial surgery. The hypothesis of the present study was that the patellar tracking pattern at second-look arthroscopy might differ from that immediately after MPFL reconstruction, and MPFL reconstruction did not aggravate the articular surfaces.

Materials and Methods

Between 1999 and 2008, 71 patients underwent MPFL reconstruction using a double-looped semitendinosus tendon at our hospital. All patients were diagnosed with recurrent or habitual patellar dislocation by physical examinations, with positive apprehension sign in all cases. Four patients with a history of prior knee surgery (medial tubercle transfer in two, lateral retinaculum release in two) were excluded from the present investigation. In the present study, 24 patients (25 knees; 18 women, 6 men) underwent second-look arthroscopy at median of 13.2 months post-operatively (range, 6–26 months). Median age at the time of MPFL reconstruction was 22.7 years (range, 13–43 years). Prior to MPFL reconstruction, informed consent was obtained from all patients for hardware removal with

simultaneous second-look arthroscopy 1 year after the initial surgery. The surgery was performed only when the patient was willing to undergo the procedure at postoperative follow-up.

Surgical Technique

All reconstructions were performed using a modified "dual tunnel medial patellofemoral ligament reconstruction" technique reported by Toritsuka et al. [39]. First, chondral status and patellar tracking were carefully evaluated by arthroscopy. A semitendinosus autograft was then harvested through a 3-cm incision over the pes anserius. The semitendinosus tendon was exposed and released from muscle using a tendon stripper. The distal end (17 cm) of the tendon was used and was doubled over. Both free ends of the graft were connected with a No. 3 braided polyester suture using Krackow suture technique.

A small 1-cm incision was made on the lateral side of the patella, and a skin incision of approximately 5 cm in length was made from the medial patellar edge to the medial femoral epicondyle. With the patella reduced in the femoral groove, the distance between the two anatomical insertions of MPFL was measured, and the exact length of the tendon was determined. Two guidewires were transversely inserted, one from proximal one-third of the medial edge of the patella and another from the center of the patella. Patellar guidewires were overdrilled using a 4.5-mm cannulated reamer to create sockets 15 mm in depth (Fig. 1). Care was taken not to violate the chondral surface or the anterior cortex of the patella. Until 2003, patellar bone tunnels were created from the medial to the lateral

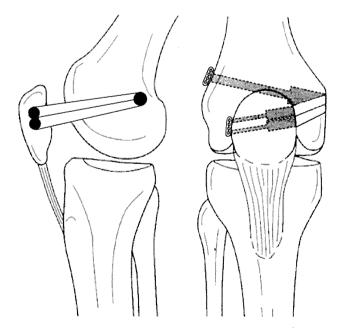


Fig. 1 Schematic view of MPFL reconstruction



side of the patella using a 4.5-mm cannulated reamer. However, the bone tunnel technique was changed to a bone socket technique in 2003 after one patient suffered patellar fracture in relation to bone tunnel procedure 2 months after MPFL reconstruction. Another guidewire was inserted from superoposterior portion of the medial femoral epicondyle toward the proximal cortex of the lateral femoral condyle. The guidewire was overdrilled with an EndoButton drill (Smith & Nephew Endoscopy, Andover, MA), and 5- to 6-mm socket was drilled to a depth of 20 mm at the anatomical femoral insertion of the MPFL (Fig. 1).

The center of the graft was pulled into the femoral socket to a depth of pre-determined length and was fixed using an EndoButton[®] on the proximal cortex of the lateral femoral condyle. The two free ends of the graft were pulled into the bone sockets of the patella, and the two No. 3 braided polyester sutures connected to the graft were fixed by an EndoButton[®] on the lateral side of the patella at 45° of knee flexion. At this time, care was taken not to overtense the graft. After fixation of both sites, negative manual lateral dislocation of the patella was confirmed and patellar tracking was then evaluated arthroscopically (Fig. 1).

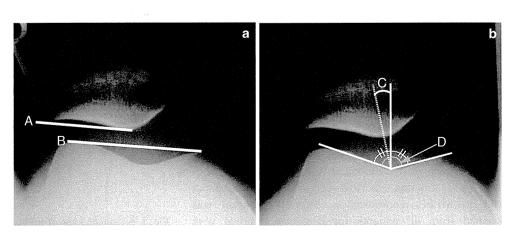
Postoperative Management

For 2 weeks after MPFL reconstruction, the knee was immobilized with a brace at 45° of knee flexion. After the brace was removed, passive- and active-assisted range of knee motion was started. Weight bearing was gradually increased to full at 4 weeks postoperatively. Running was allowed at 3 months, followed by a return to previous sporting activity at 6 months.

Evaluation

All patients were evaluated preoperatively, postoperatively, and by second-look arthroscopy. Clinical data included the incidence of recurrent subluxation and dislocation, lateral patellar hypermobility [21], lateral patellar

Fig. 2 Measuring methods on radiograph. a 30° skyline view. Lateral tilt angle was defined as an angle with *line A* to *B*. b Merchant view. *C* congruence angle, *D* sulcus angle



apprehension, and Kujala score [22]. Radiographs of the knee, including a conventional anteroposterior view, lateral view, 30° skyline view, and Merchant's view, were taken at each of the three time points. The skyline view was used for measuring lateral tilt [12], and Merchant's view was used for measuring congruence angle [27] (Fig. 2). Insall-Salvati ratio at the three time points was measured on the lateral view [19]. Arthroscopically, patellar tracking was evaluated at 0° through 60° of knee flexion through a lateral suprapatellar portal. A median ridge of the patella located above the middle third of the femoral groove was defined as "centrally located", while a ridge located lateral to the middle third of femoral groove was defined as "laterally shifted". Evaluation of patellar movement was repeated three times, and it was confirmed that patellar tracking pattern was same in each time. Patellar trackings were recorded on video disc and verified by two skilled orthopedic surgeons postoperatively. Chondral status of patellofemoral joint according to the Outerbridge classification was also evaluated at initial surgery and second-look arthroscopy. The view during arthroscopic operations was kept clear by means of irrigation and tourniquet. The pressure of irrigation fluid was set to 40 mmHg, and the pressure of air tourniquet was set to 300 mmHg.

Statistical analysis

Statistical analysis was performed using the paired t-test, one factor analysis of variance, Mann–Whitney U test, and the Wilcoxon rank-sum test. Values of P < 0.05 were defined as significant.

Results

No patient reported re-dislocation of the patella in the follow-up period. All patients showed full range of motion at the time of second-look arthroscopy. One patient, who had not been allowed to return to sports activity, had



suffered patellar fracture during badminton 2 months after MPFL reconstruction and underwent open reduction and internal fixation. In terms of passive patellar hypermobility, abnormal lateral patellar movement was found in all cases preoperatively. At final follow-up, all patellae were firmly fixed on the femoral groove and no abnormal hypermobility was found in any case. While 22 knees showed clear improvements in apprehension sign, positive results were still evident in 3 cases. Median Kujala score improved from 73 (66–82) preoperatively to 95 (85–100) at second-look arthroscopy.

Radiographic Findings

Median sulcus angle was 147.7° ($130-170^{\circ}$). Preoperatively, median lateral tilt angle, median congruence angle, and Insall-Salvati ratio were -8.0° (-44 to 20°), 20.8° (-25 to 80°), and 1.1 (0.8-1.4), respectively (Table 1). Immediately after MPFL reconstruction, these three indices had improved. However, at final follow-up, these indices had returned toward preoperative values to some extent (Table 1). Although patellar maltracking was reduced in all cases immediately after surgery, the position had shifted laterally to some extent at follow-up (Fig. 3a–c).

Patellar tracking

At arthroscopic evaluation prior to MPFL reconstruction, patellae in all cases had shifted laterally for all knee flexion angles (Fig. 4a–d). Immediately after MPFL reconstruction, all preoperative patellar maltracking was reduced, and patellae were congruent with femoral groove in 0–60° of range of motion (Fig. 4e–h). At second-look arthroscopy, tensed reconstructed grafts were recognized arthroscopically from the inside of the joint in all cases (Fig. 5). In 9

knees, the patella was always located above the center of the femoral groove within 0–60° of range of motion and thus classified as "centrally located type". In 16 knees, the patella was located in a "laterally shifted" position at knee extension, moving on the center of the femur and becoming congruent with the femoral groove as the angle of knee flexion increased. This pattern was classified as "laterally shifted type".

No demographic data affected the difference in patellar tracking between the two groups (Table 2). However, 3 patients who complained of positive apprehension sign at follow-up were classified as "laterally shifted type". Kujala scores, sulcus angles, and preoperative lateral tilt angles were not different between the two groups (Table 3). Only median preoperative congruence angle, which was 9.2° (-25 to 52°) in "centrally located type" and 26.5° (-2 to 85°) in "laterally shifted type", differed significantly according to various preoperative factors (P = 0.03; Table 3).

Chondral Status

At MPFL reconstruction, cartilage lesions on the patellofemoral joint were observed in 96% of patients. At second-look arthroscopy, no obvious deterioration in chondral status was seen. The patella cartilage in "centrally located type" patients showed little change, compared with that at MPFL reconstruction (Fig. 6a). In the "laterally shifted type", 2 patients displayed slight deteriorations in the patella surface and 6 patients showed improvement in lesions (4 lesions, grade 4; 2 lesions, grade 2; Fig. 6b). The femur showed no deterioration in the chondral status in "laterally shifted type" patients, while 4 of 9 patients with "centrally located type" exhibited slight deterioration in the chondral surfaces (Fig. 6c, d).

Table 1 Radiographic measurement

| Median (range) | Before MPFL reconstruction | After MPFL reconstruction | Second-look arthroscopy | Significance (P value) |
|------------------------|----------------------------|---------------------------|-------------------------|------------------------|
| Lateral tilt angle (°) | -8.0 (-44 to 20) | 5.5 (-16 to 20) | -3.8 (-48 to 18) | <0.05 |
| Congruence angle (°) | 20.8 (-25 to 80) | -11.8 (-64 to 45) | 9.3 (-27 to 92) | < 0.05 |
| Insall-Salvati ratio | 1.1 (0.8 to 1.4) | 1.0 (0.8 to 1.3) | 1.1 (0.8 to 1.4) | < 0.05 |

One-factor ANOVA



Fig. 3 Radiographs of Merchant's view at the three time points. a Before surgery, b Immediately after surgery, c Second-look arthroscopy



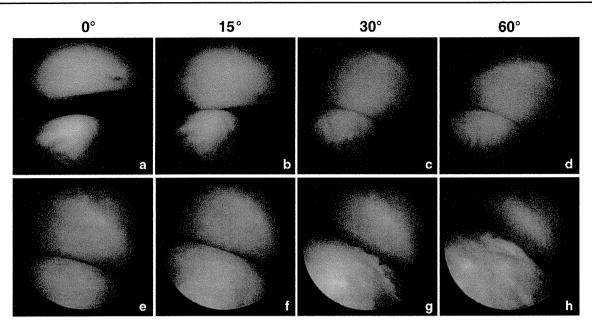


Fig. 4 Arthroscopic view of the patellofemoral joint at MPFL reconstruction. Arthroscopic view of the patellofemoral joint at 0° (a), 15° (b), 30° (c), 60° (d) before surgery and 0° (e), 15° (f), 30° (g), 60° (h) immediately after surgery

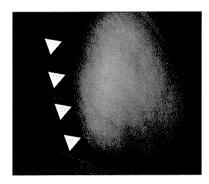


Fig. 5 Arthroscopic view of reconstructed MPFL at second-look arthroscopy. Arrowheads indicate a reconstructed MPFL

Discussion

The most important finding in the present study was that not all instances of reduced patellar tracking remained intact despite good clinical outcomes, even if patellar maltracking had been completely restored just after MPFL reconstruction. Arthroscopically evaluated patellar tracking patterns at follow-up were divided into two types: with 36% of patellar trackings classified as "centrally located type", and 64% classified as "laterally shifted type". All patellar tracking patterns of the three cases complaining of positive patellar apprehension were "laterally shifted type". Preoperative radiographic measurements revealed a significant difference only in the congruence angle between the two groups. No significant deteriorations in chondral status were seen on second-look arthroscopy. However, grade 1 cartilage damages that had not been recognized in initial surgery was observed in the femoral groove for 44% of the "centrally located type" patients and in the central ridge of the patella for 13% of "laterally shifted type" patients,

Although MPFL reconstruction has become the first choice for treating recurrent patellar dislocation and good midterm clinical results with up to 97% patient satisfaction and up to 10 years of follow-up have been reported [31], patellar tracking after MPFL reconstruction, particularly in

Table 2 Demographic data of "centrally located type" and "laterally shifted type"

| Median (range) | Centrally located type | Laterally shifted type | Significance (P value) |
|---|------------------------|------------------------|------------------------|
| Patient age (years old) | 25.6 (15–39) | 22.1 (13–43) | n.s. |
| Duration from injury to MPFL reconstruction (years) | 10.2 (1.6–23.3) | 6.7 (0.2–22.7) | n.s. |
| Duration from initial surgery to second-look arthroscopy (months) | 10.5 (6.7–26.0) | 14.2 (5.9–31.1) | n.s. |
| Kujala score at second-look arthroscopy | 95 (85–100) | 94 (81–100) | n.s. |
| Apprehension sign at second-look arthroscopy (-/+)* | (9/0) | (13/3) | |

Paired t-test



^{* (-/+)} represents that apprehension sign is negative/positive

Table 3 Preoperative radiographic findings in "centrally located type" and "laterally shifted type"

| Median (range) | Centrally located type | Laterally shifted type | Significance (P value) |
|------------------------|------------------------|------------------------|------------------------|
| Sulcus angle (°) | 147.6 (138 to 156) | 147.7 (130 to 170) | n.s. |
| Lateral tilt angle (°) | -0.5 (-13 to 8) | -11.7 (-44 to 20) | n.s. |
| Congruence angle (°) | 9.2 (-25 to 52) | 26.5 (-2 to 85) | 0.03 |
| Insall-Salvati ratio | 1.2 (1.0 to 1.4) | 1.1 (0.8 to 1.4) | n.s. |

Mann-Whitney U test

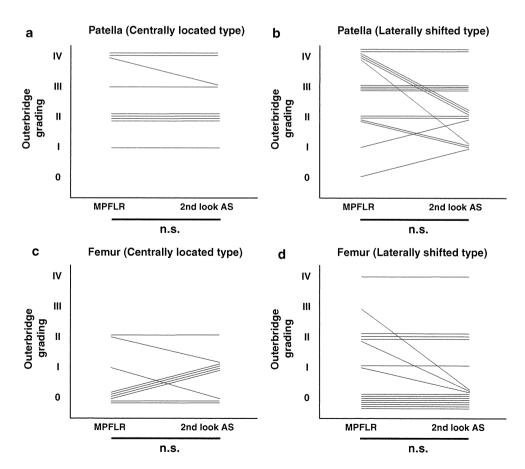
patients, has not been described. Radiologic findings showed that all patellar maltracking was reduced immediately after MPFL reconstruction. However, tracking position had shifted somewhat laterally by second-look arthroscopy. Deie et al. reported clinical and radiologic results of MPFL reconstruction using transferred semitendinosus tendon 5 years after surgery [11]. They concluded that congruence angle, tilting angle, and lateral shift ratio were within normal ranges at 5 years postoperatively. However, detailed examination of their data showed that the three indices were improved at 6 months after reconstruction, but tended to return toward preoperative values to some extent. This fact is consistent with the present results, which found a lateral shift in the patella at followup. As a tensed graft was recognized from inside the joint in all cases and relatively good results were obtained in this

series, the transplanted graft might undergo remodeling or stress relaxation without breaking [18], and the graft might function as a seatbelt to reinforce lateral displacement of the patella. Yamada et al. reported 3-dimensional morphological differences in the articular surface of the femoral trochlea in patients with recurrent dislocation of the patella using 3-dimensional computational models [41]. They concluded that the lateral border of articular cartilage of the trochlea in patients was located more laterally than in the control group. The two patellar tracking patterns observed in this study might have been caused by the unique patellofemoral congruency in recurrent patellar dislocation patients, as cases with subdislocation of the patella at knee extension showed significantly higher congruence angles. Furthermore, patients with patellar subluxation exhibit a tight lateral retinaculum [15]. With larger

Fig. 6 Chondral status at MPFL reconstruction and at second-look arthroscopy.
a Chondral status of the patella in "centrally located type".
b Chondral status of the patella in "laterally shifted type".

c Chondral status of the femur in "centrally located type".d Chondral status of the femur

in "laterally shifted type"





congruence angle, the tighter and shorter the lateral retinaculum is considered to be. The reconstructed MPFL may be matched to the proper length by remodeling depending on individual patello-femoral congruence and tightness of the lateral retinaculum. However, all three cases with positive apprehension sign remaining at follow-up were classified into "laterally shifted type". For such cases, other surgical procedure such as lateral retinaculum release or tibial tuberosity transfer may be necessary, although further examination of this issue is needed before such recommendations can be made.

Patellar tracking of normal and abnormal subjects has been investigated using radiograph, computed tomography, magnetic resonance imaging, and arthroscopy by many authors [6, 12, 36]. Arthroscopically, quantitative evaluation of the patellar position is impossible. Brossmann et al. reported that the arthroscopic patellar tracking pattern correlated with motion-triggered cine magnetic resonance imaging [6]. By simplifying the classification of arthroscopic patellofemoral alignment, they minimized the influence of subjective impressions by operators. Arthroscopic evaluation of patellar tracking in the present study might have been subjective, but arthroscopy remains an important technique for evaluating patellofemoral problems. In the present study, although the subluxing patella was not centered on the femoral groove with increased knee flexion before surgery and patellar maltracking had been reduced immediately after surgery, arthroscopic patellar tracking patterns observed at second-look arthroscopy could be simply classified into two types, retrospectively. The influence of operator subjectivity was thus considered minimal. The pressure of irrigation fluid is another important factor affecting arthroscopic patellar tracking. Delaunay and Kapandji reported that serum inflow affected patella-trochlear centralization [13]. In the present study, to avoid differing effects of irrigation pressure on patellar tracking, the pressure was set to 40 mmHg in each case. The tracking pattern in the present study might not reflect the true pathology, but the present findings could provide useful information regarding alternations in patellar tracking after MPFL reconstruction.

Although movement of the patella varies among patients with recurrent patellar dislocation [40], the two patellar tracking patterns were observed only with reconstruction of the MPFL anatomically without any procedure for various predisposing factors. Sandmeier et al. compared patellar tracking in cadaveric knees with medial restraints intact, either sectioned or reconstructed [34]. They concluded that, with a lateral force applied to the patella, patellar tracking changed significantly with loss of the medial restraints and improved after MPFL reconstruction using a gracilis tendon. They also noted that patellar tracking was not completely restored, and the reconstructed MPFL tended

to overconstrain the specimens, particularly under knee extension. Ostermeier et al. compared the effects of two different techniques of MPFL reconstruction using cadaveric knees and concluded that both reconstruction techniques created sufficient stabilization of the patella, but that patellar position was slightly overmedialized following MPFL reconstruction with a semitendinosus autograft, which could lead to overload on the medial retropatellar cartilage [32]. The present results are partially in accordance with their results, with the patella medialized and overconstrained immediately after reconstruction. However, both studies used cadaveric knees, and patellar tracking immediately after MPFL reconstruction was evaluated in vitro. Cadaveric studies do not always throw light on the true pathology of lateral patellar dislocation and MPFL reconstruction, as lateral patellar dislocation caused by various predisposing factors and physiological effects such as graft remodeling cannot be evaluated. Therefore, patellar tracking patterns in actual patients approximately 1 year after surgery were investigated.

In "centrally located type" knees, the patella was always centered in the femoral groove from 0° to 60° of knee flexion. This type of patellar tracking might differ from normal patellar tracking, as the median ridge of the patella lies lateral to the center of the trochlea in the normal knee from 0 to 30° of flexion, then moves medially to become centered in the femoral groove at between 30° and 60° of flexion [10]. In fact, 44% of the chondral status of the femoral groove in the "centrally located type" cases was deteriorated to grade 1 at second-look arthroscopy. This suggested that, in some cases, MPFL reconstruction was overtensioned immediately after surgery. Meanwhile, in the "laterally shifted type", the patella was located lateral to the center of the femoral groove and become centered with an increase in knee flexion angle. Two of 16 "laterally shifted type" patients showed deterioration at the central ridge of the patella. This fact suggests that the return of incongruence caused that excessive lateral pressure would also return. Even though the same MPFL reconstruction in all cases was performed, different patterns of patellar tracking were observed. In some cases, the reconstructed MPFL might be overtensed immediately after surgery. In other cases, the reconstructed graft might undergo graft remodeling or stress relaxation, and excessive lateral pressure might return. Long-term follow-up is needed to assess the progression of osteoarthritis. Any important factors contributing to the two types of patellar tracking could not be identified in this study. Several specific imaging protocols designed for patellofemoral disorders have been reported, including axial view with lateral rotation of the leg, measurement of patellar height, and crossing sign [12]. The crossing sign could not be investigated for systematically due to the difficulty in

obtaining lateral views with perfect superposition of the femoral condyles. The Insall-Salvati ratio was measured on lateral radiographs, but no significant differences between groups were noted. A significant difference was only identified in preoperative congruence angle between groups. Proper tension and graft length applied at MPFL reconstruction may be necessary to prevent further dislocation after surgery. Conversely, re-dislocation and return of excessive lateral pressure may occur with reductions in tension. Recurrent patellar dislocation is caused by the combination of various predisposing factors, and nobody knows the exact length of MPFL in each patient. To solve the double-edged sword problems, further research is needed.

Several limitations in this study must be considered. First, not all patients who underwent MPFL reconstruction were examined in this series. Some potential for bias in patient selection may thus exist, and the 24 patients investigated in the present study might not have been representative of the entire 71 patients. However, the cohort of 25 knees that underwent MPFL reconstruction and second-look arthroscopy represents a bigger group of patients compared with previous studies, and the information provided by this investigation is meaningful. Second, one patient suffered patellar fracture related to a drill hole in this series. Until 2003, a 4.5-mm transverse bone tunnel had been created in the patella. To decrease the potential risk of patellar fracture, the bone tunnel technique has been changed to bone socket technique using a 2.4-mm Kirschner wire. This procedure still carries some risk of patellar fracture, but a stronger initial fixation is expected by both pull-out fixation and bone-tendon healing compared with suturing to the periosteum or VMO tendon [28]. Finally, the duration between initial surgery and secondlook arthroscopy might have been too short to evaluate the patellar movement after MPFL reconstruction, as the mean duration tended to be shorter for "centrally located type" than for "laterally shifted type", although the difference was not significant. No correlation was evident between the interval to MPFL reconstruction and duration of follow-up and patella tilt and congruence angle (data not shown). In anterior cruciate ligament reconstruction, the implanted graft reportedly underwent graft remodeling or stress relaxation for 6 months postoperatively [24]. This finding is relevant to MPFL reconstruction, and ≥6 months between initial and second-look arthroscopy is sufficient to examine patellar tracking.

Conclusion

Not all improved patellar tracking seen just after MPFL reconstruction surgery remained intact at follow-up. Two

patterns of patellar tracking were observed arthroscopically following MPFL reconstruction: "centrally located type" and "laterally shifted type". No obvious chondral damage in the patellofemoral joint was seen at second-look arthroscopy, but locations showing cartilage deterioration differed between types.

Conflict of interest The authors report no conflict of interest.

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ISAKOS Scientific Committee Research Methods Handbook

A Practical Guide to Research: Design, Execution, and Publication

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FOREWORD

Why Is a Research Methods Handbook Needed?

Why is this work needed, and who would benefit from it? First of all was a second to the second to t from it? First of all, we must realize that this work is on a high but at the same time moderate level. The aim is to put together a Research Methods Handbook that can be of practical help to those writing manuscripts for submission to Arthroscopy and similar journals. We are referring to people working full time, taking care of patients, with busy outpatient clinics and fully booked surgical schedules. These are persons who do not devote the majority of their time to research. And in most cases they do not have any major training in scientific research methods. Since sound research methods are the backbone of a good study, the methods must be solid to ensure that the results are valid. If the methods are not good from the beginning, the outcome will not be good either, and the manuscript will not be published despite the investigator's best effort.

The purpose of this Research Methods Handbook is to provide basic information about common research techniques, how to conduct a good study, how to write a manuscript and, we hope, how to get it published.

The work is divided into several sections, starting with an overview on evidence-based medicine; much-

needed information for all clinicians. The second section is concerned with study methods, with special focus on study designs. Important scientific methods, like CONSORT and STROBE, are explained in greater detail. The third section is on biostatistics. This section is very practical, written with the clinician in mind. Common statistical methods are explained and the aim is to stay practical and pragmatic. We are still clinicians and not statisticians. And the idea is to help clinicians who are conducting a study and not to make them statisticians. The last section is on manuscript writing. Pearls and pitfalls are discussed and tips are given. We dare say that if you follow these simple guidelines, you will have a much greater chance of getting your manuscript published.

A few words of thanks. First and foremost we thank Michele Johnson, ISAKOS Executive Director, who helped out with all practical details and negotiated all necessary contracts. At *Arthroscopy*, Managing Editor Hank Hackett and Jason Miller from Elsevier made things happen. Special thanks to Hank for his professional editing work on all chapters, keeping track of the time frame, and all other practical details.

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readers of *Arthroscopy* as well as other journals will benefit from this work.

Jón Karlsson Robert G. Marx Norimasa Nakamura Chair Co-chair Co-chair ISAKOS Scientific Committee

Freddie H. Fu
President of ISAKOS

SECTION 2

What Is This Evidence-Based Medicine and Why Bother?

The British Medical Journal recently surveyed the global medical community to determine the greatest medical breakthroughs since its first publication in 1840. It was an incredible period of innovation and change, when antibiotics were discovered, entire joints were replaced with anything from ivory to stainless steel, internal imaging was developed allowing surgeons to see inside the body noninvasively, and vaccines were developed and implemented on a global scale. Evidence-based medicine (EBM) was noted as 1 of the top 15 medical breakthroughs in the last 160 years.

BIAS DETECTIVES

Many have compared the use of evidence in medicine to the use of evidence in the legal setting.² Let us consider the classic character Detective Sherlock Holmes and a legal example to set the stage.

You are a detective called to a robbery of a local corner store. As you are on the way to the site of the crime, you consider the last robbery you investigated at a store on the other side of town. Reminding yourself of how the last crime was conducted, you proceed to develop a theory as to how the current robbers entered the store, their path throughout the store, what they stole, and how they escaped. Yes, that must be how it happened; as you arrive at the scene, you have already pieced together the majority of the case. But what about this footprint? Does that change your hypothesis as to what went on . . . ?

Now let's consider instead that you are this same detective but have since watched a Sherlock Holmes mystery video and have taken some of his words to heart.

You are en route to the site of this same robbery. While driving there, you try to clear your mind of the robbery you investigated last week. You want to approach this

new case with no preconceived ideas or theories. As Sherlock said, "Never guess. It is a shocking habit..." You arrive at the site of the crime and begin locating evidence: a black glove here, a footprint there, a broken window in the front of the store, and a wide-open door at the back. You attempt to collect all the evidence you can find before developing a hypothesis as to the events of the robbery. Your mind recalls a quote from the detective video the night before, "... don't theorize before you have all the evidence." Remembering how observation was second nature to Holmes, you ensure you collect all the facts and record all that you observe even if the information does not appear immediately relevant. Now it's just a matter of sitting down with the evidence and solving the crime.

Which one of these approaches would stand up better in court? Which one would the store owner be happiest about in terms of having justice served?

REFRAMING THE PARADIGM TO EVIDENCE-BASED MEDICINE

These examples aim to illustrate, in albeit rudimentary terms, the paradigm shift that our field has been undergoing for the past decade. Over the last several years, medical professionals and health professionals have begun using EBM in their practice: integrating best available research and their clinical expertise with the specific patient's values.

The first steps of EBM (the evidence) are very similar to steps used in detective work as shown in the second example. This section will introduce the methods with which to approach a problem and track down evidence. The medicine piece of EBM is where things change. When it comes to solving the problem with the evidence you have gathered, one could argue that medicine in fact has better tools at hand than a detec-

tive would have available. This chapter will explore these tools. Lastly, applying this solution based on the evidence you have gathered for a patient's specific scenario has no parallels to detective work; this is where our clinical expertise really comes into play.

What Is Meant by Best Evidence?

If research is going to be used as evidence put toward a hypothesis, which will in turn be applied to a clinical scenario, it should aim to be best evidence. This research has to be relevant with regard to content but also with regard to what type of patient is being considered. This can range from research in basic science to patient-centered clinical research, from efficacy and safety of therapeutic regimens to the power of certain prognostic markers. The most updated clinical research does more than simply suggest new approaches, it can in fact often invalidate older diagnostic tests and treatments and replace them with ones that are more efficacious, powerful, and accurate and safer.

What Is Meant by Clinical Expertise?

Even if research can invalidate older tests and replace them with newer tests, in terms of the best approach, nothing can replace clinical expertise. Without a clinician's ability to use his or her skills and past experiences to identify the issues and a patient's health status and diagnosis, as well as risks and benefits present in the scenario, we would be hard pressed to have a starting point at which to apply mounting evidence from meetings, symposia, and peer-reviewed journals.

What Is Meant by Patient Values?

Each patient is a unique person with his or her own expectations, concerns, priorities, and preferences. When each patient brings these unique components to the clinical encounter, it is not in vain. For clinical decisions to be relevant and able to serve this particular patient, his or her unique considerations must be integrated into the decision-making process.

EBM THROUGH THE AGES

The term evidence-based medicine, a medical practice paradigm first introduced in the early 1990s, first came to light as a component of the medical residency program at McMaster University in Hamilton, Ontario, Canada.³ What started as the introduction of "enlightened skepticism" to a group of residents at McMaster University led to an explosion of research extending this initial idea to many specialties in med-

icine and across the world, including orthopaedics at an international level. The methodology of EBM has become a key component of orthopaedics with journals such as Arthroscopy, The Journal of Bone and Joint Surgery, Indian Journal of Orthopaedics, Clinical Orthopaedics and Related Research, and Acta Orthopaedica embracing evidence-based orthopaedics as standard vernacular in their proceedings.

The concepts we now consider associated with the paradigm of EBM may have roots in ancient historical accounts of authoritative teaching and passing on of stories in ancient times or the emergence of personal journals and the introduction of textbooks in Renaissance times.⁴ In the early 1990s knowledge began to be shared more easily in textbooks, and peer-reviewed journals began making an appearance in the field with regard to clinical practice. It was in the 1970s when a shift in modern technology and essentially an explosion in the field of informatics led to the emergence of online journals and large databases.

Claridge and Fabian⁴ provide a variety of specific examples of EBM emerging through the ages in their 2005 report on the history of EBM. These examples indicate a gap in knowledge and a subsequent question, an approach to finding evidence, and an answer to the clinical query based on said evidence. Some of these examples are summarized in Fig 1.

Early Evidence in Orthopaedics

During the time of these more recent developments. the orthopaedics community was in the midst of developing its own evidence in the same way. Hoppe and Bhandari⁵ present an interesting example of early evidence in orthopaedics by discussing a particular report from the Proceedings of the American Orthopaedic Association in 1889⁶ in their article on the history of evidence-based orthopaedics. This report, entitled "Hypertrophy of One Lower Extremity," includes a case study regarding the treatment of a 6-year-old child with a leg three-quarters of an inch longer than the other.⁶ After failing to slow the growth of this leg using a rubber bandage, the surgeon suggested a shoe lift for the patient's comfort. However, after the patient had later been examined by another surgeon, who diagnosed him with congenital occlusion and dilation of the lymph channels, amputation was recommended and carried out. After publication of this case, a discussion with other specialists ensued. One surgeon described a similar leg-length discrepancy presentation in a 21-year-old woman. After consultation with a colleague who was also unsure of the

Biblical Reference

"Then Daniel said to the guard whom the master of the eunuchs had put in charge of Hananiah, Mishael and Azariah and himself.
'Submit us to this test for ten days. Give us only vegetables to eat and water to drink; then compare our looks with those of the young men who have lived on the food assigned by the king and be guided in your treatment of us by what you see.' The guard listened to what they said and tested them for ten days. At the end of ten days they looked healthier and were better nourished than all the young men who had lived on the food assigned them by the king."

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Song Dynasty 1061

"In order to evaluate the efficacy of ginseng, find two people and let one eat ginseng and run, the other run without ginseng. The one that did not eat ginseng will develop shortness of breath sooner."

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Van Helmont in the 1600s on Blood Letting

"Let us take out of the Hospitals, out of the Camps, or from elsewhere, 200, or 500 poor People, that have fevers or Pleuritis. Let us divide them in Halfes, let us cast lots, that one halfe of them may fall to my share, and the others to yours; I will cure them without blood-letting and sensible evacuation; but you do, as ye know ... we shall see how many Funerals both of us shall have...."

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E.A. Codman's "the end result idea," early 1900s

Codman developed "index cards" for each surgery he performed where he detailed pre- and postoperative care. Each card was brought up again upon re-examination of the patient a year later: Adverse outcomes were noted. Codman suggests this idea be used to compare care by hospital and surgeons; a concept that shook the traditional idea of measuring status by seniority rather than performance. Codman later went on to establish the American College of Surgeons in 1913. This further led to the commission for accreditation of Hospitals in 1957.

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Randomized Control Trial, Amberson et al, 1931

In 1931, a study was published on the treatment of tuberculosis. Patients were given either Sanocrysin or a control and were randomized by a flip of a coin. Patients and physicians involved were also blinded as to the protocol.

 $F_{\mbox{\scriptsize IGURE}}$ 1. Examples of EBM through the ages adapted from Claridge and Fabian.⁴

nature of the problem, a high shoe was also given to the patient. A third case was brought up by yet another surgeon where a similar presentation was treated by stretching of the sciatic nerve.

With 3 experts offering 3 very different opinions as to how to proceed with such a presentation ranging from a shoe lift to sciatic nerve stretching to amputation, how were readers expected to know which approach to use themselves? Historically, as in many other specialties, information obtained on a case-bycase basis by experts was passed on to other doctors and learners who, knowing the expert's reputation

well, would often implement a given treatment of technique into their practice with a reinforced understanding of its value.

Despite these differing expert opinions undoubtedly being a common scenario in all specialties at this time, one contributor suggested a new approach to this lack of a conscience. "Would it not be in accordance with the purposes of this association to appoint a committee to investigate this subject, taking patients . . . and treating them." This is an early example of anecdotal evidence no longer being sufficient as evidence on which to base patient treatment. It was instead determined that larger-scale trials would allow these surgeons to objectively identify the superior treatment and to demonstrate the benefits of one approach versus the next.

Modern-Day EBM

From hearsay practices in ancient times to the first appearance of the randomized controlled trial (RCT) in the early 20th century and from anecdotal evidence to the development of evidence through trials in many specialties including orthopaedics, we arrive at what can be referred to as modern-day EBM.

In the early 1970s, Cochrane⁷ criticized the lack of reliable evidence behind a plethora of health care interventions commonly accepted at the time. Rigorous evaluation of these interventions highlighted the need for an increase in evidence in medicine after this publication, planting the seed for EBM. David Sackett of McMaster University used the term "critical appraisal" to describe extracting evidence from systematically examined medical literature in the early 1980s.⁸

The actual term evidence-based medicine was coined by Dr. Gordon Guyatt of McMaster University in 1990. Initially a term intended for educational use by internal medicine residents in McMaster's innovative residency program, EBM gained popularity with physicians and residents in a variety of subspecialties. An initial group of physicians from McMaster with a particular interest in critical appraisal grew to include specialists from a variety of institutions who joined forces to create the Evidence-Based Working Group. This group became responsible for adopting the idea of EBM and presenting it in the pivotal report announcing it as a new medical paradigm: "Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine." ¹⁰

Emergence of EBM

There were many specific changes during this time that really set the stage for the rapid widespread recognition of EBM. There were realizations of gaps in clinical decision making preceding the coining of EBM, creating a real need for this paradigm shift. Alongside this, recent developments in technology and perspectives fostered an environment where EBM was really able to blossom in tackling these gaps.

As we approached the era of the Evidence-Based Working Group introduced earlier, it was becoming more and more evident that traditional venues for information were no longer sufficient. Several specific realizations set the stage for this spread of EBM.

Regardless of specialty, all physicians and surgeons have a continuous need for valid information on diagnosis, therapy, prevention, and prognosis for numerous patients with countless conditions and circumstances. Covell et al.¹¹ suggested on the basis of their research, that new information is needed 2 times for every 3 outpatients. Another study, performed in 1991, added to this suggestion stating that physicians may require new information up to 5 times per inpatient.¹²

Regardless of the increasing need, the tools and skills surgeons have typically been left with once in practice are no longer sufficient to acquire information as needed. In the past, traditional venues for finding information such as medical and surgical textbooks have been based on "expert opinion" rather than research and are in fact frequently wrong. The volume of information in these sources combined with the variability in their validity makes them an overwhelming source of information to sift through. In addition, outside of written information, traditional didactic teaching is also often ineffective when it comes to translating knowledge into clinical practice. All of this aside, for many clinicians, the main barrier to engaging in best research to find answers to clinical questions is time. With a busy clinic, operating room time, and call schedule, finding time to sit down, search for resources and assimilate information to study any given topic has often fallen outside the scope of most surgeons' typical daily schedules.

There have been various recent developments that have really allowed these previously insurmountable issues to be tackled, allowing EBM to become a day-to-day reality for full-time clinicians and surgeons. New strategies for searching for and appraising research, alongside an increase in the quality and the availability of information, have brought evidence-based practice to the forefront. In addition to the increase in amount of information, we must also acknowledge the increases in quality of research. When improvements in research are considered, a few main examples stand out. This includes an increase in recognition of the importance of

clinical studies and an increased need for objective, informed consent from patients, as well as a trend for establishing globally based gold standards for best medical practice. ¹³ A study by de Solla Price showed that there has been an increase in the number of scientific journals by 7% per year. At this rate, the number of journals has doubled every 10 to 15 years, suggesting that by the early 21st century, we were approaching a total of 60,000 to 70,000 journals worldwide, of which 15,000 were strictly biomedical. ¹⁴

Although this seems like an insurmountable amount of information, developments in technology have led to programs that can bring the newest valid, reliable research from a variety of sources in a concise format in a matter of seconds. The availability of systematic reviews, medical databases, the Cochrane Library, and evidence-based journals, for example, focusing on articles of immediate clinical use, has brought best research and clinical decision making closer than ever. For example, in 1997, when the National Library of Medicine announced it was offering free access to the first-line Web-based medical databases MEDLINE and PubMed, usage jumped 10-fold, to a total of 75 million searches annually.15 Availability and accessibility of information have also increased with the advent of second-line databases such as the Cochrane Library, UpToDate, and Best Evidence along with EBM-related journals such as the ACP Journal Club and Evidence-Based Medicine (these resources will be detailed further later on). These changes, alongside the emergence of the idea of lifelong learning, explain why there has been such a sudden surge in the concept of EBM not only in theory but also in practice.

THE PRACTICE OF EBM

As discussed earlier, a doctor's clinical competence is the combination of 3 main aspects: knowledge, technical/clinical skill, and the ability to make decisions. The cumulative factor of this combination is the ability to make appropriate, systematic, and unbiased decisions to predict prognosis and interpret the results of examination and laboratory tests to overall achieve therapeutic efficacy. In 1995 Haynes and Sackett¹⁶ summarized the key steps of practicing EBM in the opening editorial of the journal *Evidence-Based Medicine* as follows.

- 1. Formulate the problem and convert the information needs into answerable questions.
- 2. Search for and assimilate in the most efficient way possible, the best evidence with which to answer these questions. This information comes

- from the clinical examination, laboratory tests, diagnostic imaging, or published literature.
- 3. Once collected, appraise the evidence critically for both its validity and its applicability to the current clinical question.
- 4. Apply the results of this search and appraisal in practice to both the clinical question and patient context
- 5. Evaluate the above steps.

These steps will be outlined in further detail, illustrating how surgeons taking as little as 30 minutes of time per week for their professional development can implement EBM into their practice to answer anything from the everyday common complaint to the less common complaint to the rare presentation.¹⁷

EBM AT WORK

Knee pain is among the most common complaints of patients seen by both primary care physicians and orthopaedic specialists. Despite how often this type of patient presents, many clinicians still struggle with evaluating knee pain. After developing a clinical picture through discussion of the nature of the pain, mechanism of injury, patient's history, relevant physical examination findings, and preliminary diagnostic imaging, many clinicians are still unsure of how to proceed with regard to further investigation. With no clear diagnosis at this point, does this patient need a magnetic resonance imaging (MRI) scan? Will this add to the clinical picture, or will this not provide any new information? When it comes to efficiency and economy of practice and allocation of resources, being able to determine whether an MRI scan is required in this presentation is essential. Ordering an MRI scan because you "always do" or because a mentor has always suggested it is no longer sufficient evidence to warrant proceeding.

Recent research by Matzkin et al. 18 presented at the American Association of Orthopaedic Surgeons meeting in 2011 has produced an evidence-based algorithm to determine the need for an MRI scan in evaluation of knee pain. By considering duration of symptoms, presence of an effusion, laxity, joint-line tenderness, and the degree of radiographic degenerative change, this algorithm will indicate the need for an MRI scan in this situation. This algorithm is an excellent example of how evidence derived from well-conducted, valid, and reliable research is coming to the surface as we speak, influencing our standard of care in the most common presentations.

Asking a Well-Built Research Question

As mentioned, formulating, building, and focusing a clinical question comprise the first step in an approach to using EBM in practice. Every time we see a patient, for the first or fifth time, there is a need for new information about some component of our approach: the presentation, diagnosis, prognosis, or management. These gaps in knowledge combined with our limited time to devote to research necessitate a focus on efficiency. Our gaps in knowledge can sometimes seem rather large, so with this in mind, alongside our limited time to devote to this, we must be as efficient as possible in our search. The first key factor in keeping this step efficient is to become skilled at formulating answerable clinical questions.

Questions commonly arise regarding anything from clinical findings, differential diagnoses, manifestations, harm, and etiology to therapy, prevention, diagnostic tests, and prognosis. Examples of such common questions are shown in Table 1.

Components of a Good Question

- 1. The patient context, problem, or population in question
- 2. The potential intervention, exposure, or maneuver
- 3. The approach/option to which this intervention is compared
- 4. Clinical outcome of combining the above 2 factors considered in a specific timeline

These 4 components, identified with the acronym PICO, are detailed below.

Patient Characteristics: To set a good context for any question, clinicians must first identify and consider

TABLE 1. Common Questions

Harm/etiology: Questions of identifying and understanding the cause for a condition or disease.

Prevention: Questions related to reducing the chance of a disease developing. This involves identifying and understanding modifiable risk factors associated with the condition as well as early screening techniques and standards.

Diagnostic test: Questions related to selection and interpretation of diagnostic tests and, from this, how to confirm or exclude a diagnosis. This involves consideration of a test's specificity, sensitivity, likelihood ratios, cost, risks, and so on.

Therapy: Questions related to selecting appropriate treatments, weighing the associated risk/benefits, and efforts/costs of using them

Prognosis: Questions related to estimating the likely clinical course for a given patient over time and any complications associated with this.

the patient's characteristics. This involves demographic information such as age, sex, and race, alongside their social situation, resources, and values. In addition to this demographic information, characteristics specific to the clinical situation such as diagnoses or condition must be included. The setting (inpatient, outpatient, rural, tertiary care, and so on) must then be considered. Is this a public health issue or an individual patient issue?

Intervention: In forming a well-built clinical question, the intervention must then be included. What is it exactly that is being considered as a potential intervention? This could be a medication, a diagnostic test, or any other type of treatment.

Comparison: A treatment or test can really only be assessed relative to or in comparison with something else. One side of this comparison will be the potential intervention, and the other will be that against which it is being compared. This comparison may be another test or treatment, the current standard treatment, watch and wait, or even no treatment at all.

Outcome: Once the above are determined within the clinical question, include the outcome as well. What is the desired effect you want to achieve? Is there an effect you want to avoid? This can involve not only treatment effects but also side effects. Outcome will typically be divided into a primary outcome and surrogate outcomes (measurements that on their own hold little value for the patient but are associated with outcomes that are considered very important to patients).

Instead of asking, "Is operative treatment indicated for a fractured clavicle?" ask, "In an active adult patient with a completely displaced midshaft clavicular fracture, would primary plate fixation result in improved functional outcome when compared with nonoperative treatment at 1 year of follow-up?"

By using the PICO model to develop a specific and complete clinical question, the task of finding best evidence becomes more plausible and efficient.

Finding the Evidence in the Literature

Developing techniques for searching for evidence may seem daunting. Considering that MEDLINE adds 4,500 records to its database on a daily basis, a physician in any one field would need to read 18 articles per day, 365 days a year, to be able to keep up with this amount of research¹¹: hence, daunting. This type of reading schedule is not plausible for any busy clinician or surgeon. Add to this that, in fact, only 10% of these articles are considered to be high quality and clinically relevant, and this task seems even less plausible.11 In reality, however, by learning how to effectively approach a search for evidence, learning where to look and what techniques to use now, this job on a day-to-day basis becomes increasingly less daunting. In this section we will discuss various key concepts, tips, and approaches to develop ways to find the evidence in an efficient and effective way.

When first approaching the vast and continually growing number of scientific and medical articles available, an easy first step is to understand and identify the different types of research study designs. Descriptions of the different type of research study designs are listed in Table 2.

From here, the types of research are placed in a hierarchy based on their value. Figure 2 illustrates the pyramid, or hierarchy of evidence, that reflects the

TABLE 2. Study Designs Defined

Meta-analysis: A combination of all of the results in a systematic review using accepted statistical methodology.

Systematic review: On the basis of a specific clinical question, an extensive literature search is conducted identifying studies of sound methodology. These studies are then reviewed, assessed, and summarized according to the predetermined criteria related to the question at hand.

Randomized (clinical) control trial: A prospective, analytic, experimental study that uses data generated typically in the clinical environment. A group of similar individuals are divided into 2 or more groups (1 acting as a control and the other[s] receiving the treatment[s]) and the outcomes are compared at follow-up.

Prospective, blind comparison to a gold standard: To show the efficacy of a test, patients with varying degrees of an illness undergo both the test being investigated and the "gold standard" test.

Cohort study: A large population with a specific exposure or treatment is followed over time. The outcomes of this group are compared with a similar but unaffected group. These studies are observational, and they are not as reliable because the 2 groups may differ for reasons aside from the exposure.

Case-control study: Patients who have a specific outcome or condition are compared with those who do not. This is a retrospective approach used to identify possible exposures. These are often less reliable than RCTs and cohort studies because their findings are often correlational rather than causative.

Case series/report: Reports on the treatment of an individual patient are reviewed. These have no statistical validity because they use no control group for comparison. Case reports do, however, have a role for novel and rare presentations, because no large populations exist in these cases.

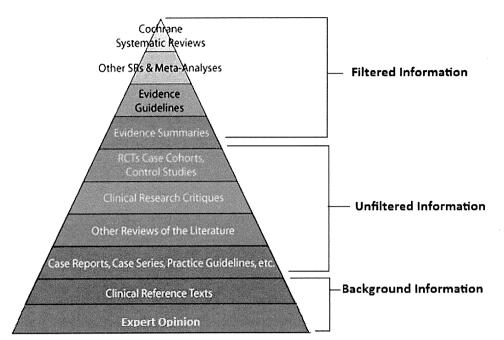


FIGURE 2. Hierarchy of evidence. This image separates the different types of research into 3 categories: background information, unfiltered information, and filtered information.

relative authority of the different types of research present in the biomedical field. It is important to note that although there are various versions of this hierarchy and there is no universally accepted version, there is still agreement on the strength of certain key types of research relative to the others. By understanding how different types of research compare to one another, those that are most useful for a busy practicing clinician with a specific question can be targeted. As you move up this pyramid, the quality of the research increases, in that it is most relevant to the clinical setting and has a reduced risk of bias compared with modes of research lower down the pyramid. In addition, research higher up the pyramid puts less onus on the searcher with regard to filtering through original data, making such research a much more efficient means of locating information.

Filtered Resources: With a clinical question related to the course of action/management of a patient, be it related to diagnosis, treatment, prognosis, and so on, filtered resources should be consulted first. Filtered resources (examples of which are shown in Table 3) consider a question posed by clinical experts and topic specialists and then provide a synthesis of evidence to come to a conclusion based on all available research. Using filtered information is much more efficient because the searching clinician does not need to individually appraise each piece of evidence. The clinician still has a responsibility to evaluate the in-

formation with regard to the specific patient and context in question. To aid with this portion, these resources also back up information with links to the relevant literature and resources. When searching in Ovid and PubMed, clinical filter options can be applied to aid in finding EBM research.

Unfiltered Resources: If an appropriate answer to the clinical question is not found in the filtered resources, the primary literature or unfiltered resources must be considered. Unfiltered resources also provide the most recent research and can be used to determine

Table 3. Examples of Filtered Resources

- Systematic reviews and meta-analyses
 - Cochrane Database of Systematic Reviews (The Cochrane Collaboration)
- Database of Abstracts of Reviews of Effects (DARE; National Institute of Health Research)
- Critically appraised topics (evidence syntheses)
 - O Clinical evidence
 - o InfoPOEMs (Canadian Medical Association)
 - ACP PIER (Physician's Information and Education Resource; American College of Physicians)
 - National Guideline Clearinghouse (Agency for Healthcare Research and Quality)
- Critically appraised individual articles (article synopses)
 - Evidence Updates
 - O Bandolier
 - o ACP Journal Club