A TRIAL OF JAPANESE VERSUS ENGLISH TRANSLATIONS OF ORTHOPAEDIC EVIDENCE REPORTS

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A Thesis Submitted to the School of Graduate Studies in Partial Fulfilment of the Requirements for the Degree: Master of Science

McMaster University MASTER OF SCIENCE (2022) Hamilton, Ontario

(Health Research Methods, Evidence & Impact)

TITLE: A TRIAL OF JAPANESE VERSUS ENGLISH TRANSLATIONS OF ORTHOPAEDIC EVIDENCE REPORTS

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NUMBER OF PAGES: xiii, 83

LAY ABSTRACT

Evidence-based medicine (EBM) incorporates current best evidence into clinical decision-making. The volume of new publications presents a challenge to staying on top of research findings in practice. Further, as most research is published in English, language barriers may hinder adoption into practice by non-English clinicians.

We administered a survey to Japanese orthopedic surgeons to assess their familiarity with EBM, and perceived barriers to incorporating EBM into clinical practice. We subsequently conducted a randomized trial to explore the effect of providing electronic links to Japanese or English research summaries to Japanese orthopedic surgeons on whether or not they accessed summaries. Participants endorsed several barriers to incorporating EBM into practice, including lack of time, lack of training in critical appraisal, and language barriers; however, there was no difference in the number of evidence summaries accessed in our trial whether research reports were provided in English or Japanese.

ABSTRACT

Background:

The gap between evidence and practice is an important problem that may, in part, be exacerbated by language barriers.

Methods:

We surveyed members of the Japanese Society for Fracture Repair regarding their self-perceived familiarity with evidence-based medicine, and barriers to keeping up with evidence relevant to their practice. We subsequently enrolled these same orthopedic surgeons in a randomized trial to explore the impact of providing 20 electronic links to English or Japanese OrthoEvidence summaries on whether surgeons accessed the link.

Results:

A total of 106 participants were enrolled in the study, and 105 completed the pre-trial survey. Fifty-seven participants acknowledged barriers to adopting EBM; the three most prominent reasons were lack of time (77%), lack of training in critical appraisal (100%), and language barriers (95%). The mean EBM familiarity score on a 4-point scale, higher scores indicating greater familiarity, was 2.59 (standard deviation [SD] 0.38, 95% confidence interval [CI] 2.52 to 2.66). Our randomized trial found no

significant difference in the number of evidence summaries that were accessed whether they were provided in Japanese (median 9, interquartile range[IQR] 5 to 15; n = 52) or English (median 3, IQR 2 to 15; n = 53) (p=0.06).

Conclusion:

Although most Japanese orthopaedic surgeons acknowledge barriers in adopting EBM into clinical practice, and highlighted language as a key barrier, providing evidence summaries in Japanese did not significantly increase the number that were accessed.

ACKNOWLEDGEMENTS

To my thesis supervisor, Dr. Mohit Bhandari, thank you for allowing me to conduct this trial and mentoring me. You have played an essential role in my professional, academic and personal career.

To my mentor, Dr. Kim Madden, thank you for your countless hours of reviewing the manuscript, advice and help to conduct the study. I would not have accomplished the study without your help.

To Dr. Jason Busse, thank your knowledgeful and advice throughout the thesis process.

To my mentor, Dr. Watanabe, for allowing me to conduct the study involving the Japanese Society for Fracture Repair as the chair for this society and for checking the protocol and advertisement for recruiting the participants.

To my colleague, Dr. Kentaro Matsui, thank you for checking the protocol and advertisement for recruiting the participants and for reviewing the study survey.

To my colleagues, Dr. Kentaro Futamura and Dr. Takahiro Waki, thank you for evaluating and checking the evidence summaries used for the trial and piloting the study survey.

To Abbey Payne, thank you for making mailers to distribute the evidence summaries.

To Bojan Vecanski, thank you for generating the translated evidence summaries for distribution.

I would also like to thank the Japanese Society for Fracture Repair for allowing me to recruit members for my studies.

I would also like to express my gratitude to OrthoEvidence, which provided the evidence summaries for this study and three-month premium memberships to participants.

I would also like to thank the Teikyo University Department of Orthopaedics for financial support of my Master's studies.

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LIST OF ABBREVIATIONS AND SYMBOLS

ACE	Advanced Clinical Evidence
ARD	Absolute risk difference
CI	Confidence interval
CIRT	Clinical information-retrieval technology
EBM	Evidence-Based Medicine
HiREB	Hamilton Integrated Research Ethics Board
IQR	Interquartile range
ITT	Intention-to-treat
IRR	Incidence rate ratio
JSFR	Japanese Society for Fracture Repair
KT	Knowledge translation
REDCap	Research Electronic Data Capture
RCT	Randomized controlled trial
SD	Standard deviation
SMD	Standardized mean difference

DECLARATION OF ACADEMIC ACHIEVEMENT

Natsumi Saka was involved in the conception and design of the study, development of all study documents, submission of the protocol to the ethics board, registration of the protocol, recruitment of the participants, collection of the data and statistical analyses. She is the primary author of the subsequent article published based on this thesis work.

Dr. Mohit Bhandari is the primary supervisor of this thesis work. He was involved in the study's conception and design and the manuscript's review.

Dr. Kim Madden and Dr. Jason Busse provided insightful guidance on this work's research methodology and the manuscript's review. Dr. Madden also provided the randomization table for the allocation of trial participants.

Chapter 1: Introduction

1.1 Evidence-practice gap in clinical medicine

Although the value of evidence-based medicine (EBM) has been widely acknowledged over decades, the remaining gap between current best evidence and clinical practice is a significant concern in clinical medicine. A cross-sectional survey among the patients in the United States on quality indicators for 30 acute and chronic conditions revealed that patients received only 55% of recommended care. (1) Similar findings have been reported in the field of orthopaedics. For instance, the results of a large pragmatic randomized controlled trial (RCT) on the fixation method of distal radius fractures did not change clinical practice in Ireland. (2) Further, a 2020 observational study found surgeons considered the possibility of osteoporosis in only 17% of osteoporotic distal radius fracture patients despite recommendations from clinical practice guidelines. (3) Due to evidence-practice gaps, patients often fail to receive optimal care, resulting in inferior outcomes for some. Additionally, patients may be exposed to unnecessary treatment, potentially leading to adverse events and higher medical expenditure.

1.2 Current state of knowledge in perception of, and barriers to, evidence-based

medicine (EBM) and Knowledge translation (KT)

1.2.1 Perception and barriers to EBM

Studies assessing the attitudes and perceptions toward EBM and barriers to adopting EBM in clinical practice have been conducted in many regions. A systematic review of 57 studies concluded that although attitudes toward EBM are generally positive among physicians, their self-reported awareness of EBM concepts is poor. (4, 5) Another systematic review which included 106 studies, focused on implementation and usage of EBM and revealed that the most common barriers are lack of time, research barriers, such as heterogeneity among studies and lack of knowledge. (6) Respondents described lack of knowledge as the lack of skills in searching the literature, and to know the newly published research results related to the relevant clinical field. With the increasing volume of newly published evidence relevant to clinical practice, keeping up to date has become increasingly challenging. (7)

1.2.2 Knowledge translation as a solution for lack of knowledge

The term "knowledge translation (KT)" encompasses the wide range of actions expected to support the use of research findings leading to evidence-based practice. (7) Several KT strategies, such as printed educational materials, educational meetings, and electronic knowledge resources, have been evaluated. Each strategy has

shown an small effect in changing clinicians' behaviour and patient objective outcome. (8-10) For example, a Cochrane review concluded that printed educational materials might slightly reduce the evidence-practice gap among healthcare professionals, such as the number of tests ordered or prescriptions for a particular drug when indicated. When compared to no intervention, printed educational material improved healthcare professionals' practice outcome may slightly improve healthcare professionals' outcome and patient health outcomes. (9)

1.2.3 Electronic knowledge resources as KT tool

Clinical information-retrieval technology (CIRT) is defined as "databases that merge or link digital libraries, computerized clinical practice guidelines or computerized synopses, electronic journals or textbook, and medical websites". (11) CIRT includes commercial resources, such as Up to Date, DynaMed and Clinical Evidence; locally developed products, such as McMaster Premium LiteratUre Service (PLUS), and crowdsourced materials, such as Wikipedia. (12, 13) A recent meta-analysis of 25 studies suggested that, compared to no intervention, electronic resources significantly improve clinicians' behaviour (pooled standardized mean difference (SMD) of 0.47) and patient outcomes (pooled SMD of 0.19. (10)

Another important aspect of KT is a "push-pull" framework. (14) In this framework, "pull" technology refers to when practitioners search databases that include clinical information, whereas "push" technology refers to systems that "pushes" new findings to a practitioner. "Push" technology can be found in non-electronic form, such as printed monthly research summaries, but it is mainly observed in electronic resources, such as an email alerting service for newly published articles. With "push" types of electronic resources, a practitioner is made aware of new research findings that might influence their daily practice. A cluster RCT explored the effectiveness of the "push" tool among 203 physicians using McMaster PLUS, which compared a full-service version (email alert to new articles and a cumulative database of email alerts) and a self-service version (database and passive guide to evidence-based literature). (12) The result showed that physicians with the full-service version made 0.77 more monthly log-ins. However, other studies found that physicians who received email alerts from a "push" tool rarely retrieved research synopses. (15, 16) In one study, only 1.7% (21/4937) of email alerts were retrieved as research synapses from the database by family physicians. (15, 16)

1.2.4 Language barrier in knowledge translation

Language may be one barrier to knowledge translation, especially in non-English speaking countries, since most research findings are published in English. (6) A national survey of 815 Polish health care managers, including hospital chief executives, hospital medical directors, hospital head nurses, and directors of the institutions responsible for health service planning, revealed that 30% to 61% reported language as a barrier to accessing research publications. (17) A qualitative study of 19 Spanish general practitioners found language was a major obstacle to EBM, and a cross-sectional survey among 60 Japanese resident physicians found >70% of participants strongly agreed or agreed that the lack of EBM resources in their native language was a barrier. (18, 19)

1.3 The efficacy of providing translated educational materials for medical professionals

Several studies have been conducted to assess the efficacy of providing translated educational materials for medical professionals whose first language is not English. (20-23) One RCT among 114 Scandinavian family physicians assessed understanding of a review article for treatment of head injuries and found the group who read the article in their first language scored significantly higher compared to the group who read the article in English (median score of 4 versus 3, on a 13-point

scale). (21) An RCT in Chile randomly distributed a Cochrane review either in English or Spanish to 96 first-year residents and found the proportion of participants with low comprehension scores was significantly higher in the English group compared to the Spanish group (35% vs 17%), and the time to complete the task was significantly longer in the group allocated to English (12.6 minutes vs 11.8 minutes). (22) One cross-sectional study disseminated three types of paragraphs (English only, simplified Arabic and English terminology, and Arabic only) to 1546 Arabic-speaking medical students and found better comprehension of simplified Arabic and English terminology paragraphs compared to the other two. (20) An RCT that enrolled 130 Norwegian-speaking doctors in primary care medicine showed a significantly better comprehension score of a review article with a mean difference of 1.32 (95% CI 0.03 to 2.62) in the group with Norwegian material compared to the group with English material. (23)

1.4 Current state of knowledge in barriers to EBM and KT in orthopaedic surgery

The concept of EBM was introduced in orthopaedics in the early 2000s. (24) Over the next few years, several surveys evaluating perceptions and attitudes toward EBM in orthopaedics were conducted among the participants of an international educational course on orthopaedic trauma and Dutch orthopaedic surgeons. (25-27)

Although most orthopaedic surgeons welcomed EBM, only 45% of the survey participants defined evidence-based orthopaedic surgery correctly, and 21% had never heard of "blinding." A qualitative study among orthopedic residents found barriers to EBM were lack of education, time constraints, lack of priority, and staff disapproval. (28) The survey of Dutch orthopaedic surgeons found that possession of a graduate degree, working in an academic setting, younger age and less clinical experience were associated with greater EBM competency. (27) Based on these findings, education on EBM for surgeons and evidence resources have been proposed. (26, 27)

An intensive 2.5-day Canadian workshop, including lectures and small group breakout sessions, significantly improved the score of participant knowledge about EBM and clinical research methods with a 35.3% relative increase compared to before the course. (29) The Dutch Society for Surgery integrated a two-day evidence-based surgery course into its training curriculum, which significantly improved the EBM aptitude of surgical residents with a mean difference of 0.85 on the modified Berlin questionnaire. (30) Similar improvement in knowledge was shown following a one-day clinical research course for orthopaedic surgeons in Cuba. (31)

Although there are various popular online evidence resources, such as Up to Date, The Physicians' Information and Education Resource, First Consult and

DynaMed, only 18% of their contents are related to surgery, and orthopaedic contents account for only 2.04% of content. (32) OrthoEvidence was developed as an online clinical evidence resource for orthopaedic surgeons. (33) This online evidence portal identifies and summarizes RCTs/meta-analyses in structured reports called Advanced Clinical Evidence (ACE) reports in orthopaedic-related fields. It also works as a "push" tool, through email alerts of newly published reports. A survey of Indian orthopaedic surgeons found 72% of participants perceived OrthoEvidence ACE reports as practical, and 88% as useful. (34)

Chapter 2: Japanese orthopaedic surgeons' barriers and knowledge toward Evidence-Based Medicine: a cross-sectional survey

2.1 Abstract

Background: Evidence-based medicine (EBM) has been shown to optimize patient-care; however, little is known about barriers to adopting EBM among Japanese orthopaedic surgeons.

Objective: We aimed to identify barriers to adopting EBM, and the current use of evidence resources and familiarity with EBM, among Japanese orthopaedic surgeons.

Methods: We conducted a cross-sectional web-based survey among the members of the Japanese Society for Fracture Repair (JSFR). We assessed self-rated understanding of EBM terminologies (using a 1-4 point EBM familiarity score) and reported barriers to EBM in orthopaedics.

Results: We administered our survey to 106 surgeons, of which 105 participants completed the survey (99% response rate). Most surgeons (57 of 105, 54%) felt there were barriers to adopting EBM in their clinical practice. The three most endorsed barriers were lack of time (77%), lack of skill in critical appraisal (100%), and language barriers (95%). PubMed and resources in Japanese were the most often used evidence resources for clinical practice, and the mean EBM familiarity score among respondents was 2.59 (SD 0.38).

Conclusion: Many Japanese orthopaedic surgeons face barriers to adopting EBM into clinical practice, mainly due to lack of time, lack of skill in critical appraisal and language barriers.

2.2 Background

Barriers to EBM, including language barriers, have been reported among Japanese resident physicians. (18) Although an evidence-practice gap in orthopedics is reported in Japan, little is known about perception towards and barriers to incorporation of EBM among orthopaedic surgeons. (3)

2.3 Methods

This survey is part of the OrthoEvidence Trial Assessing Japanese Knowledge Updates (OTAKU): Trial of knowledge translation among Japanese surgeons, approved by the Hamilton Integrated Research Ethics Board (HiREB) prior to study recruitment (Project Number: 13493). The objective of this survey is to identify perceived barriers to adopting evidence into clinical practice and self-perceived knowledge of EBM among Japanese orthopaedic surgeons.

2.3.1 Study design and patient selection

The study was conducted as a web-based study among members of the Japanese society for fracture repair (JSFR). The eligibility criteria for the participants were as follows: 1) a member of the JSFR, 2) spend at least 20% of their time in clinical

practice, 3) English is not their first language, 4) have regular access to the internet, 5) prefer to read Japanese-translated material, if there are both translated and English version of the same material. We excluded surgeons who did not provide informed consent.

Informed consent and study data were collected and managed using Research Electronic Data Capture (REDCap) tools hosted at McMaster University.

(35) REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages, and 4) procedures for importing data from external sources.

2.3.2 Recruitment strategy

We approached members of JSFR (n = 4516) to participate in our study through a notice on the JSFR website and the Facebook group for the Japanese orthopaedic surgeons, from April 8 to May 27, 2022. We also sent an email to the councilor members of JSFR (n = 228) and surgeons who attended a workshop held by JSFR in 2021 (n = 326). The email was sent twice during the recruitment period to promote recruitment, and forwarding the email was allowed since we couldn't obtain the mail address of whole JSFR members.. As incentive for participating in the study, we

provided a three-month premium membership (USD 8.99/month) to OrthoEvidence by voucher code when the participants completed the trial.

All surgeons who were interested in our study provided their name and email through REDCap, and were then provided with a link to the information sheet and consent form. When the candidate submitted the consent form, they were enrolled in the study and provided with a link to the pre-trial survey. Participants who did not complete the pre-trial survey were excluded from the trial.

2.3.3 Details of the pre-trial survey

In this survey, we collected information on baseline characteristics of participants, including age, gender, current position, type of practice, years of experience, the self-rated ability to read English (from “very poor” to “very good”), additional research degree (Ph.D., MPH, MSc), and a current number of research articles accesses per week, including full-articles and abstracts, both in Japanese and in English.

The survey also queried whether respondents perceived barriers to adopting EBM on a Likert scale from 1 (completely disagree) to 5 (completely agree). Participants who answered 4 or 5 (“agree” or “completely agree”) were asked to answer an additional survey regarding specific barriers. Specifically, we asked

respondents to rate the following possible barriers on a Likert scale from 1 (strongly disagree) to 5 (strongly agree): (1) lack of time, (2) lack of good evidence resources, (3) lack of skill in critical appraisal, (4) lack of priority, (5) lack of incentives, (6) impracticality of EBM, (7) skepticism toward EBM, (8) language barrier, and (9) lack of understanding from other staff. These items were informed using a previously published systematic review and a similar study among orthopaedic surgeons. (6, 28)

We asked respondents which evidence resources they used for clinical practice, including PubMed, Cochrane Library, Up to Date, Japanese clinical practice guidelines and other resources. Those resources were selected based on the previous study of evidence resources used among orthopadic surgeons, urologists and Japanese physicians. (18, 27, 36) Participants were asked to rate their awareness of those resources on four levels (unaware; aware, but not used; used on occasion; used regularly). Participants who answered "used on occasion" or "used regularly" in other resources were asked to name specific resources they use.

Finally, we assessed familiarity with EBM terminologies as assessed by the EBM familiarity score on a scale of 1 to 4. (5, 27, 36-38) Specifically, each response was assigned a score of 1, 2, 3 or 4 (1 = do not understand, and do not want to know; 2 = do not understand, but would like to know; 3 = understand, but could not explain

to others, 4 = understand, and could explain to others). A mean of these individual scores was used to generate an overall EBM familiarity score for each survey participant. (27, 36) A higher EBM familiarity score (range = 1 to 4) represents a higher level of self-rated knowledge of EBM terminologies. We used the modified version of the EBM familiarity score that consists of 14 items by Dahm et al. and Bucaglia et al. but did not include the dummy items to avoid confusion among participants based. (27, 36, 38)

The response period for the pre-trial survey was set from Apr 8 to May 29, 2022. To increase the response rate, a weekly email reminder was sent to all non-responders. The details of the pre-trial survey can be found in **Appendix 1**. All questionnaires were translated into Japanese.

2.3.4 Data collection

Data collection was conducted on participants' personal devices with an active internet connection. Participants were assigned a unique study ID that was used on all database reporting. The survey data was entered into a secure study-specific database utilizing REDCap and exported for statistical analysis without identifying information.

2.3.5 Statistical analyses

Barriers to adopting EBM, evidence resources used for clinical practice were summarized as categorical variables with counts and percentages and presented as frequency tables and graphically. Self-rated familiarity with EBM terminologies was summarized as categorically and continuously as an EBM familiarity score. Continuous variables were summarized as a mean with standard deviation in case of normal distribution and as a median with interquartile range in case of skewed distribution.

2.4 Results

2.4.1 Enrollment of the participants

Between Apr 8, 2022, to May 27, 2022, 113 candidates accessed the participation form. Among 113 candidates, five candidates did not submit the consent form, and two candidates declined to consent. As a result, 106 participants were enrolled in the study, and a total of 105 participants completed the survey. All participants who responded to the survey answered the required question, and there was no missing data in the survey.

2.4.2 Baseline demographic of the participants

Table 1 shows a summary of characteristics among 105 participants. Almost all participants were male (n = 97, 92%). Half of the participants were aged 36 to 45 (n = 53, 51%) and the majority were board-certified orthopaedic surgeons (n = 95, 91%), with more than 10 years of clinical experience (n = 76, 72%). Most participants were involved with teaching either in academic (n= 42, 40%) or non-academic institutions (n =57, 54%), and only 36% (n =38) had an additional degree. Most participants accessed one to four research articles per week (n = 78, 74%). Regarding the self-rated ability to read English, 45 participants (43%) categorized their English ability as poor, and 20% (n = 21) as very poor.

2.4.3 Barriers to adopting EBM

Among 105 participants, 57 (54%) perceived barriers to adopting EBM into their clinical practice. (**Table 2** and **Figure 1**) The three most common barriers to adopting EBM were: (1) lack of skill in critical appraisal, (2) language barrier, and (3) lack of time. Specifically, all participants who perceived barriers strongly agreed that lack of skill in critical appraisal is a barrier (n = 57, 100%). Most participants who perceived barriers strongly agreed (n = 24, 42%) or agreed (n = 30, 53%) that

language was a barrier, and most agreed (n = 30, 53%) or strongly agreed (n = 14, 25%) that lack of time was a barrier.

2.4.4 Current use of evidence resources

Table 3 and **Figure 2** summarize the data collected on the current use of evidence resources among participants. Most participants uses PubMed frequently (n = 78, 74%) or on occasion (n = 37, 35%), and Japanese guidelines frequently (n = 25, 25%) or on occasion (n = 64, 61%). Cochrane Library and Up To Date were mostly used on occasion (n = 37, 35%; n = 51, 49%, respectively), but some participants never used those resources (n = 49, 47%; n = 45, 43%, respectively) and only a small proportion used those evidence resources frequently (n = 2, 2% for both). (**Table 4**). Among 71 participants who endorsed use of other evidence, Japanese articles and textbooks were most frequently used (n = 45, 63%; n = 31, 44%, respectively), as well as the database for medical literature published in Japan such as Ichushi and Medical online (n = 14, 20%).

2.4.5 Self-rated familiarity with EBM terms

The mean EBM familiarity score was 2.59 out of 4 (SD 0.38, 95% CI 2.52 to 2.66). (**Table 5** and **Figure 3**) While majority of the participants understand the term "mean/median" and "meta-analysis" (n = 100, 95%; n =89, 87%, respectively), less

than half of the participants understand the term “power” and “type 1 error” (n = 45, 43%; n = 30, 29%, respectively).

2.5 Discussion

2.5.1 Interpretation of findings

We evaluated barriers to adopting EBM, current use of evidence resources and familiarity with EBM terminologies among members of the JSFR. Approximately half of participants agreed there were barriers to adopting EBM in their clinical practice. The three prominent barriers were lack of time, lack of skill in critical appraisal, and language barrier. PubMed and resources in Japanese were the most often used evidence resources for clinical practice. The mean EBM familiarity score was 2.59 (SD 0.38), with variation in understanding EBM terminologies.

Most participants disagreed or strongly disagreed with skepticism over the concept of EBM or lack of understanding from other staffs as barriers, which is the implementation phase of research findings to the clinical practice. This finding is similar to a study among Japanese resident physicians, which concluded the major barrier to EBM was insufficient time to access EBM resources, a lack of native language references, and insufficient EBM skills. (18) These results contrast with a systematic review and qualitative study on barriers to EBM among orthopaedic

surgeons in Canada, which showed that change in current practice and lack of cooperation were common barriers to EBM. (6, 28) Implementation of EBM involves five steps: (1) converting the problem into an answerable question; (2) finding the best evidence as an answer for that question; (3) critical appraisal of the evidence that was found; (4) applying the appraised results into clinical practice; and (5) evaluation of clinical practice. (39, 40). Based on the results of Japanese studies, including our study, Japanese physicians face barriers in the early steps of the EBM model and not in the stage of applying the results to clinical practice, probably due to lack of training in critical appraisal, lack of time and language barriers.

As illustrated by the current evidence resources, participants occasionally or frequently use PubMed, Japanese guidelines, or other Japanese materials. More than half of the participants never used the database with English research synopses, such as Cochrane Library and Up To Date. The fact that they often rely on evidence resources in Japanese may come from language barrier they face in adopting EBM in clinical practice and the lack of orthopaedic contents in the databases with English research synopses. (32)

Another focus of this survey was the self-rated understanding of EBM terminologies. Most participants seem to understand the simpler terms such as

mean/median, evidence-level and meta-analysis. On the contrary, most participants did not understand the terms associated with statistical analysis, such as power or type 1 error. These variations of responses are similar to previous studies, reflecting the difficulty of understanding statistical terms. (38) The mean EBM familiarity score among participants in our study was 2.59, which was lower than the score from previous studies, such as Dutch orthopaedic surgeons with a mean score of 3.25, and the score from American gastroenterologists with a mean score of 3.4. (27, 36) The Dutch surgery educational program integrates a two-day evidence-based surgery course into its curriculum. There is no such course for Japanese surgeons, including orthopaedic surgeons, as described in the section on barriers to EBM. (30) This lack of training in EBM might lead to lower EBM familiarity scores among Japanese orthopaedic surgeons.

2.5.2 Limitations of this study

An important limitation of our survey is the small sample size; only 105 participants (2.3%) of the total members of JSFR, which cast the question of the representativeness of the sample and the generalizability of our findings. Moreover, we mainly recruited the participants from councillor members of JSFR or attendees of the recent workshop. They might be more conscious of keeping updated and more

familiar with EBM terminologies compared to general members of JSFR. Most participants were under 45 years of age and worked in a teaching institution. This sampling bias might have led to the overestimation of the EBM familiarity score in the survey.

Bias in the survey instruments might have affected result of the surveys. As a cause of barriers to adopting EBM, all participants who endorsed barriers responded as “strongly agree” with language barrier when asked about the reason for the barrier to EBM. This result might have been biased since participants knew that this study was focused on language barriers in EBM. (41)

Another limitation of this survey is the components of the EBM familiarity score. Although this score has been used in several previous studies, the questionnaire components are slightly different in each study. (42) For instance, the study by Oliveri et al. used questionnaires with 12 items with one dummy term, the study by Buscaglia et al. and Dahm et al. used questionnaires consisting of 14 items with two dummy terms, and the study by Poolman et al. used the questionnaire consists of 10-items without dummy terms. (27, 36-38) We used the 14-item questionnaire without dummy terms based on the previous studies, but the result might not be comparable considering the items' variation in each study. Furthermore, previous studies revealed

that the familiarity score does not correlate with actual understanding of the EBM knowledge, assessed by the EBM competency score. (27, 36, 38)Those previous results suggest that the real understanding of EBM knowledge among Japanese orthopaedic surgeons is lower than the self-rated understanding of EBM terminologies.

2.5.3 Implication of the future study

Based on barriers to adopting EBM reported in our study, there is a need for an EBM workshop for Japanese orthopaedic surgeons, preferably in Japanese. If such a workshop is held in the future, we need to evaluate the effect of the workshop in improving the EBM skills, including critical appraisal of the evidence. Previous studies which assessed the effect of EBM workshops on EBM understanding mainly focused on short-term impact on EBM proficiency. (29-31)

2.6 Conclusion

Japanese orthopaedic surgeons are facing a lack of time, lack of skill in critical appraisal and language barrier in practicing EBM. Except for PubMed, Japanese educational materials were often used for clinical practice. The mean EBM familiarity score was lower compared to the result from studies of other physician groups.

2.7 Figures and tables

Table 1. Overall baseline characteristics of the participants (n=105)

	n (%)
Age	
35 or lower	28 (27)
36 to 45	53 (51)
46 to 55	20 (19)
55 or older	4 (3.8)
Gender	
Man	97 (92)
Woman	8 (7.6)
Position	
Orthopaedic resident	10 (9.5)
Board-certified surgeon	95 (91)
Practice	
Non-teaching hospital	6 (5.7)
Teaching hospital (academic)	42 (40)
Teaching hospital (non-academic)	57 (54)
Years of experience	
Less than 10 years	29 (28)
10 years or more	76 (72)
Additional research degree (Ph.D., MPH, MSc)	
No	67 (64)
Yes	38 (36)
Average number of articles accesses per week	
0	9 (8.6)
1 to 4	78 (74)
5 to 9	13 (12)
10 or more	5 (4.8)
Self-rated ability of reading English	
Very poor	21 (20)
Poor	45 (43)
Acceptable	36 (34)
Good	3 (2.9)

SD, standard deviation

Table 2. Barriers to adopting EBM in clinical practice (n=57)

	n (%)
Lack of time	
Strongly disagree	1 (1.8)
Disagree	7 (12)
Neutral	5 (8.8)
Agree	30 (53)
Strongly agree	14 (25)
Lack of good evidence resources	
Strongly disagree	6 (11)
Disagree	17 (30)
Neutral	12 (21)
Agree	19 (33)
Strongly agree	3 (5.3)
Lack of skill in critical appraisal	
Strongly disagree	0 (0)
Disagree	0 (0)
Neutral	0 (0)
Agree	0 (0)
Strongly agree	57 (100)
Language barrier	
Strongly disagree	0 (0)
Disagree	1 (1.8)
Neutral	2 (3.5)
Agree	30 (53)
Strongly agree	24 (42)
Lack of priority	
Strongly disagree	3 (5.3)
Disagree	20 (35)
Neutral	15 (26)
Agree	17 (30)
Strongly agree	2 (3.5)
No incentive	
Strongly disagree	10 (18)

Disagree	30 (53)
Neutral	10 (18)
Agree	7 (12)
Strongly agree	0 (0)
EBM is impractical for everyday clinical practice	
Strongly disagree	21 (37)
Disagree	25 (44)
Neutral	4 (7.0)
Agree	7 (12)
Strongly agree	0 (0)
Skepticism over the concept of EBM	
Strongly disagree	24 (42)
Disagree	22 (39)
Neutral	7 (12)
Agree	4 (7.0)
Strongly agree	0 (0)
Lack of understanding from other staffs	
Strongly disagree	17 (30)
Disagree	27 (47)
Neutral	7 (12)
Agree	6 (11)
Strongly agree	0 (0)

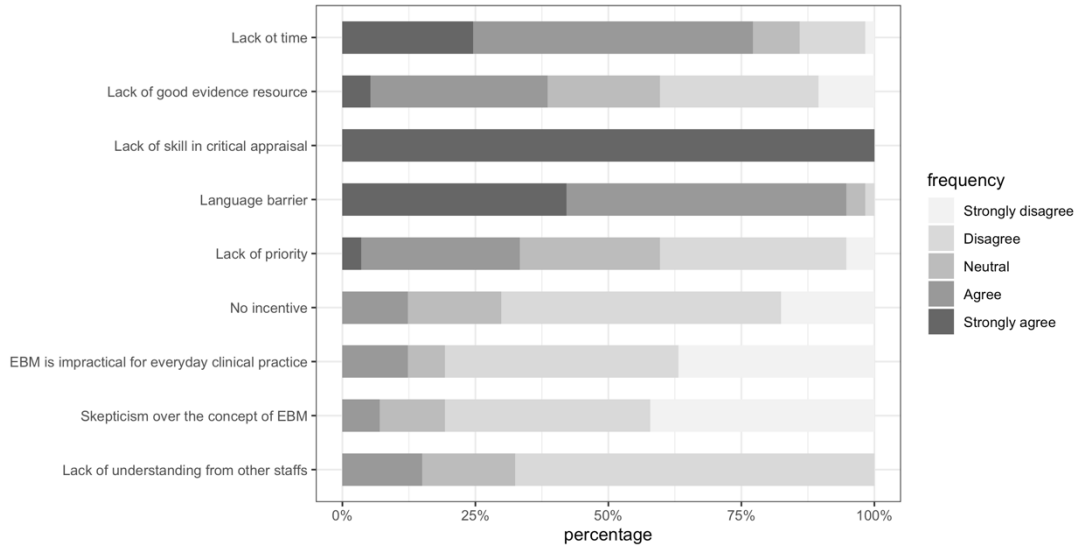

Figure 1. Barriers to adopting EBM in clinical practice

Table 3. Current use of evidence resources (n=105)

	n (%)
PubMed	
Unaware	0 (0)
Aware but not used	1 (1.0)
Used on occasion	26 (25)
Aware and use frequently	78 (74)
Cochrane Library	
Unaware	17 (16)
Aware but not used	49 (47)
Used on occasion	37 (35)
Aware and use frequently	2 (1.9)
Up To Date	
Unaware	7 (6.7)
Aware but not used	45 (43)
Used on occasion	51 (49)
Aware and use frequently	2 (1.9)
Japanese guideline	
Unaware	1 (1.0)
Aware but not used	14 (13)
Used on occasion	64 (61)
Aware and use frequently	26 (25)
Other materials	
Unaware	9 (8.6)
Aware but not used	22 (21)
Used on occasion	36 (34)
Aware and use frequently	38 (36)

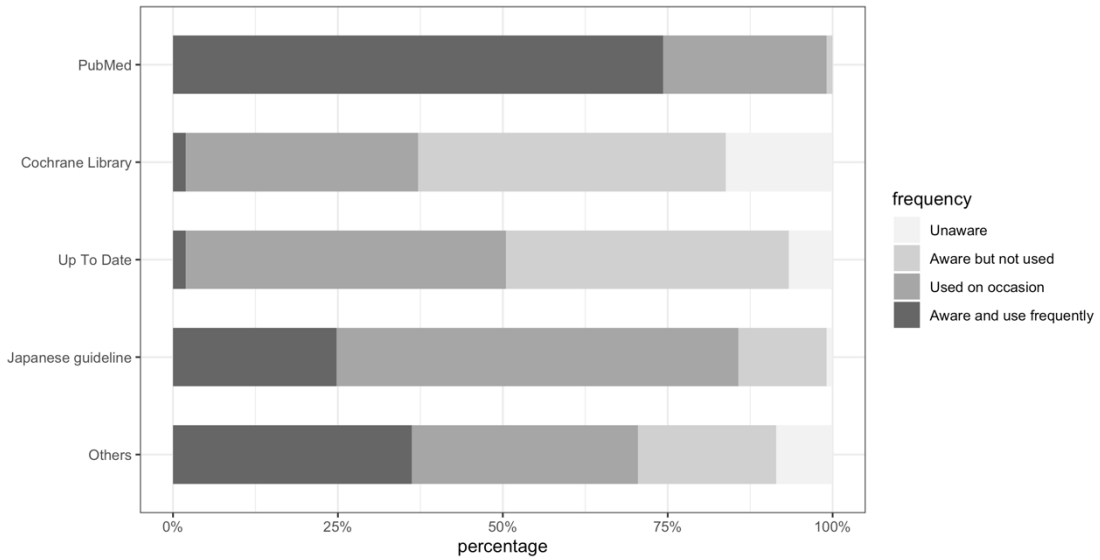

Figure 2. Current use of evidence resources

Table 4. Details of other evidence resources (n=71)

	n (%)
Japanese articles	45 (63)
Japanese textbooks	31 (44)
Database for Japanese article (Ichushi, Medical Online)	14 (20)
Materials from educational seminars held in Japan	4 (5.6)
Google Scholar	1 (1.4)

multiple answers allowed

Table 5. Self-rated understanding of EBM terminologies (n=105)

	n (%)
Mean/median	
Do not understand and do not want to know	0 (0)
Do not understand but would like to know	5 (4.8)
Understand could not explain to others	38 (36)
Understand could explain to others	62 (60)
Confidence Interval	
Do not understand and do not want to know	1 (1.0)
Do not understand but would like to know	21 (20)
Understand could not explain to others	57 (54)
Understand could explain to others	26 (25)
Number need to treat	
Do not understand and do not want to know	1 (1.0)
Do not understand but would like to know	44 (42)
Understand could not explain to others	42 (40)
Understand could explain to others	18 (17)
Power	
Do not understand and do not want to know	3 (2.9)
Do not understand but would like to know	57 (54)
Understand could not explain to others	36 (34)
Understand could explain to others	9 (8.6)
Type 1 error	
Do not understand and do not want to know	6 (5.7)
Do not understand but would like to know	69 (66)
Understand could not explain to others	23 (22)
Understand could explain to others	7 (6.7)
Kaplan-Meier analysis	
Do not understand and do not want to know	3 (2.9)
Do not understand but would like to know	50 (48)
Understand could not explain to others	47 (45)
Understand could explain to others	5 (4.8)
Hazard ratio	
Do not understand and do not want to know	2 (1.9)
Do not understand but would like to know	41 (39)
Understand could not explain to others	55 (52)

Understand could explain to others	7 (6.7)
Logistic regression	
Do not understand and do not want to know	3 (2.9)
Do not understand but would like to know	45 (43)
Understand could not explain to others	49 (47)
Understand could explain to others	8 (7.6)
Odds ratio	
Do not understand and do not want to know	23 (22)
Do not understand but would like to know	23 (22)
Understand could not explain to others	59 (56)
Understand could explain to others	0 (0)
Relative/absolute risk	
Do not understand and do not want to know	1 (1.0)
Do not understand but would like to know	41 (39)
Understand could not explain to others	51 (49)
Understand could explain to others	12 (11)
Meta-analysis	
Do not understand and do not want to know	1 (1.0)
Do not understand but would like to know	13 (12)
Understand could not explain to others	68 (65)
Understand could explain to others	23 (22)
Selection bias	
Do not understand and do not want to know	1 (1.0)
Do not understand but would like to know	18 (17)
Understand could not explain to others	56 (53)
Understand could explain to others	30 (29)
Publication bias	
Do not understand and do not want to know	2 (1.9)
Do not understand but would like to know	41 (39)
Understand could not explain to others	48 (46)
Understand could explain to others	14 (13)
Evidence level	
Do not understand and do not want to know	1 (1.0)
Do not understand but would like to know	13 (12)
Understand could not explain to others	63 (60)
Understand could explain to others	28 (27)

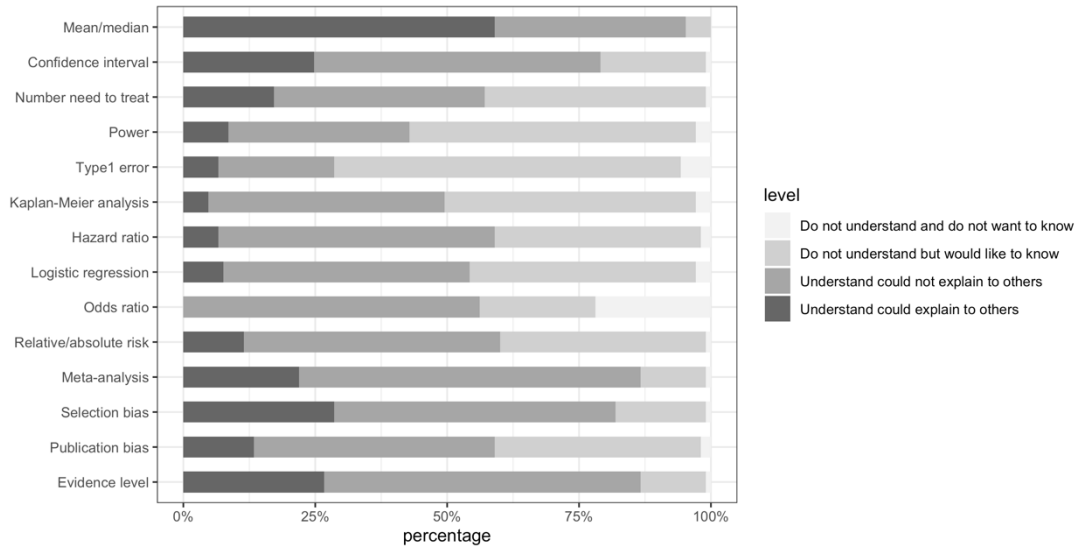

Figure 3. Self-rated understanding of EBM terminologies

Chapter 3. Uptake of Japanese versus English language OrthoEvidence reports among Japanese surgeons: A randomized trial

3.1 Abstract

Background: Language barriers may complicate adoption of evidence-based medicine (EBM) in clinical practice, especially in non-English speaking countries. However, little is known about the effect of providing translated evidence materials in evidence uptake.

Objective: We aimed to elucidate the effect of providing Japanese translated evidence summaries, compared to English evidence summaries, among Japanese orthopaedic surgeons on evidence uptake.

Methods: We conducted an open-label parallel-group, two-arm, superiority randomized controlled trial (RCT) with a 1:1 allocation ratio among members of the Japanese Society for Fracture Repair (JSFR). Our hypothesis was that access to evidence summaries would increase among surgeons who were provided Japanese summaries compared to those who were provided English summaries. Participants were randomly allocated to receive a total of 20 evidence summary alerts either in Japanese or in English by email with a link to each summary. As the primary outcome, the access to each summary was electronically tracked, and the number of

access was measured. Self-rated understanding of the contents and changing practice based on the contents were assessed on 5-point scales as secondary outcomes.

Results: A total of 106 participants were enrolled in the study, and 105 participants were allocated to either in Japanese group (n = 52) or in English group (n = 53). The median number of access to evidence summaries was 9 (IQR 5 to 15; n = 52) in the Japanese group and 3 (IQR 2 to15; n = 53) in the English group, which was non-significant between groups (p = 0.06). The mean difference in the self-rated score in understanding contents between the two groups was 0.44 on a 5-point scale (95% CI 0.23 to 0.65; Cohen's d 0.89; p < 0.001). The mean difference in the self-rated score in changing practice between the group was 0.32 on a 5-point scale (95% CI -0.01 to 0.64; Cohen's d 0.41; p = 0.061).

Conclusion: Providing translated evidence summaries did not increase the number of accesses to evidence summaries among Japanese orthopaedic surgeons.

3.2 Background

Language translation of evidence can be essential for evidence uptake since only 6% of the world population are native English speakers. (43) Although evidence translation is undertaken in some databases, including Cochrane, there is limited evidence informing the impact of translated materials. (43) Previous randomized

controlled trials (RCTs) assessing the efficacy of translated materials in comprehension were conducted among general physicians or medical students in countries such as Norway or Chile with a high to moderate English proficiency index. (21-23) However, no RCT has evaluated the efficacy of translated materials in countries with low English proficiency, especially in evidence uptake. Moreover, no study has evaluated the efficacy of translated materials among orthopaedic surgeons.

The Japanese language belongs to the Japonic language family, which is different from English in the structure of sentences and letters. In Japan, Japanese is the first language for most of the population, and the English proficiency index of Japan is 78 among 112 countries/regions in 2021. (44)

Language barriers for evidence uptake among Japanese orthopaedic surgeons may impact care of Japanese patients compared to those in English-speaking countries, which is a concern from the point of equity. (45) From the statistics of OrthoEvidence, the online evidence resources in orthopaedic field, Japanese subscribers access only 20% of provided evidence summaries, whereas subscribers from English-speaking countries access 50% of evidence summaries.

There is a need for an RCT to elucidates the effect of language translation on evidence uptake among orthopedic surgeons in countries with low English proficiency.

3.3 Methods

The OrthoEvidence Trial Assessing Japanese Knowledge Updates (OTAKU): Trial of knowledge translation among Japanese surgeons was approved by the Hamilton Integrated Research Ethics Board (HiREB) prior to study recruitment (Project Number: 13493) and pre-registered to ClinicalTrial.gov.(NCT05250622). This RCT followed the 2010 CONSORT statement. (46) CONSORT reporting checklist with corresponding pages for each item is described in **Appendix 2**.

3.3.1 Primary objective

The primary objective of this trial was to clarify whether providing translated evidence summaries in Japanese from OrthoEvidence increases the total number of access to summaries compared to providing English evidence summaries among Japanese orthopaedic surgeons whose first language is not English.

3.3.2 Secondary objectives

The secondary objective of this trial was to clarify whether providing translated evidence summaries in Japanese from OrthoEvidence improves the

understanding level of the summaries and changes practice compared to providing English evidence summaries among Japanese orthopaedic surgeons whose first language is not English.

3.3.3 Study design & Patient selection

This study was conducted as an open-label parallel-group, two-arm, superiority RCT with a 1:1 allocation ratio. This was a web-based study among members of the Japanese society for fracture repair (JSFR). The eligibility criteria was as follows: 1) a member of the JSFR, 2) spend at least 20% of their time in clinical practice, 3) English is not their first language, 4) have regular access to the internet, and 5) prefer to read Japanese-translated material, if there are both translated and English versions of the same material. We excluded surgeons who did not provide informed consent.

Informed consent and study data were collected and managed using Research Electronic Data Capture (REDCap) tools hosted at McMaster University. (35)

3.3.4 Recruitment strategy

The recruitment strategy was the same process as the survey part, which is described in Chapter 2. After participants completed the pre-trial survey, they were allocated to each intervention group. Through the pre-trial survey, we obtained

baseline demographics for all participants. As tincentive for participating in the study, we provided a three-month premium membership (USD 8.99/month) to OrthoEvidence by voucher code when the participants completed the trial and answered the post-trial survey.

3.3.5 Sample size

Data from OrthoEvidence suggests that in a typical monthly mailer of five Advanced Clinical Evidence reports (ACE reports), subscribers in Japan access 20% of monthly published ACE reports and subscribers from English-speaking countries access 50%. In our trial, we anticipated that the participants would access a higher proportion of evidence summaries in the Japanese group compared to the English group. To detect a difference of 30% with 80% power and a significance level of 5% for a two-sided test, we estimated a sample size of 40 participants per arm. We inflated the sample size to 50 participants per arm to account for missing data.

3.3.6 Randomization and allocation

Eligible participants who completed the pre-trial survey form were randomized in a 1:1 ratio to receive either Japanese evidence summaries or English evidence summaries. We used the REDCap randomization module to allocate participants. Computer-generated randomization sequence used permutated block

design with varying block sizes of two or four to allocate an approximately equal number of participants to each arm. Allocation was conducted after the participant signed the consent and answered the pre-trial survey. The randomization sequence was created by a person who was not involved in the allocation and concealed from the person who conducted the allocation. REDCap was configured not to modify the allocation once the participants were allocated to each arm.

3.3.7 Details of intervention

Generation of the evidence summaries distributed in the trial

OrthoEvidence is an online clinical evidence resource for KT in orthopaedics. (47) It identifies newly published RCTs/meta-analyses and summarizes the results in structured evidence summaries called ACE reports. Sixty-eight ACE reports in the field of fracture, which were published in 2021 from OrthoEvidence, were selected as the candidates for distribution. The citation records from each ACE report were listed in the Excel spreadsheet. Twenty ACE reports were randomly selected for the distribution from this list using the RAND function of Excel. Specifically, the column which contains the random number produced by RAND function was added to each record, and the records were sorted from smallest to largest based on the random number. ACE reports that dealt with interventions not commonly administered in

Japan were excluded. We selected the first 20 reports from the sorted lists for distribution. Among 20 evidence summaries, 17 were summaries of RCT, and 3 were summaries of meta-analysis. Nine reports (45%) demonstrated statistically significant results on their main outcomes. Subspecialties of distributed ACE reports are shown in **Appendix 3**.

After selecting ACE reports for distribution, we translated the English version of the pdfs into Japanese using DeepL translator (DeepL GmbH, Cologne, Germany). DeepL is a machine translation application using a neural network system, which offers the Japanese translation service from March 2020. (48) The validation study for a medical article from Japanese to English in the oncology field reported the match rate of the entire article was 94%. (49) After machine-learning translation by DeepL, the translation was revised by the board-certified surgeon whose first language is Japanese (NS) and double-checked by another board-certified surgeon whose first language is Japanese (KF). Details of each ACE report, both in English and Japanese, can be found online (https://drive.google.com/drive/folders/1GHE3u_6PqDAt2UiUnl4gwUysSWrJ0vf9).

Distribution of the evidence summary

Using email addresses collected in the REDCap database, emails containing the links to five evidence summaries in English or Japanese were sent to the participants based on the allocation each week for four weeks (Jun 3, 10, 17, 24, 2022). English version of evidence summaries were provided through the direct download link to the ACE reports on the OrthoEvidence website (https://myorthoevidence.com/). The Japanese version of evidence summaries were provided through the link to pdf the Google Drive (https://drive.google.com/drive/folders/1bt-zUS7KKT_tkMfnhAwesOIkG03lUN9S). Access to each pdf was tracked from the commencement of distribution to four weeks after the commencement of the initial distribution (Jun 3 to July 1, 2022). Participants were able to access the evidence summaries not only in the tracking period but also after the end of tracking period. In order to avoid clustering, participants were instructed not to forward distributed emails to their colleagues. If a participant was unable to receive evidence summaries they were considered lost to follow-up.

3.3.8 Details of the post-trial survey

After completing access tracking for each evidence summary, participants received a link to the post-trial survey through email on July 1, 2022. In this post-trial survey, participants were asked whether they understood the contents of the evidence

summaries and whether they would change their practice based on them and asked to rate them on a five-point Likert scale. For each survey item, participants endorsed a score from 1 (strongly disagree) to 5 (strongly agree). The response period for the post-trial survey was set from July 1 to July 28, 2022. To increase the response rate, a weekly email reminder was sent to all non-responders. Details of the post-trial survey are described in **Appendix 4**.

3.3.9 Blinding

Both participants and investigators were unblinded.

3.3.10 Data collection

Data collection was conducted on participants' personal devices with an active internet connection. Participants were assigned a unique study ID that was used on all database reporting. The survey data was entered into a secure study-specific database utilizing REDCap and exported for statistical analysis without identifying information. Access to each evidence summary was tracked by the commercial email tracking system (ActiveCampaign, Chicago, USA). The results of the survey and trial was linked by the study ID. For confidentiality, only the research team members had access to the study information. Electronic data files were accessible only on password-protected computers.

3.3.11 Controlling for bias

Several measures were taken to minimize bias in this study. We used a computer-generated randomization sequence with varying block sizes which was generated by an individual who was not otherwise involved in the study. We also used the central randomization using REDCap randomization module.

Another bias is the Hawthorne effect, in which participants change their behaviour knowing they are observed. (50) Although it is challenging to eliminate this bias, we tried to reduce it by not informing the participants of the primary outcome of this trial. Instead, in the information sheet of this trial, participants were told that evidence uptake between two groups would be evaluated in the trial.

Attrition bias can be problematic in RCT, especially in the trial with longitudinal follow-up. (51) We set a four-week response period for the post-trial survey to reduce this bias, and sent weekly email reminders to all non-responders.

3.3.12 Statistical analyses

Descriptive analyses, including frequency counts and percentages, were calculated for all data gathered. Continuous data were presented as means with standard deviations (SD) or medians and interquartile range (IQR) as appropriate for the distribution. The normality of data distributions was evaluated based on a visual

inspection of histograms. All outcome measures in the trial were evaluated as continuous outcomes. In the case of normal distribution, the result was presented by mean and 95% confidence interval (CI) and was compared by independent t-test. In the case of skewed distribution, the result was presented as the median and interquartile range and compared with the Wilcoxon rank-sum test. For the analysis of the primary outcome, we conducted Intention-to-treat (ITT) analysis, which maintained allocation regardless of whether or not the intended intervention was received. We conducted a sensitivity analysis, which excluded the participant who lost to follow-up from the analysis. For the secondary outcome, we excluded the participants who did not complete the pre-trial survey within a specified response period. As a post-hoc analysis, we conducted an adjusted analysis for the observed baseline imbalance in position of the participants between two groups. (52) We used a negative binomial model for the primary outcome and a linear model for the secondary outcomes A p-value of < 0.05 was considered statistically significant. The statistical analysis was conducted using R version 4.1.2. (53) Interim analysis and stopping criteria were not planned for this trial since the period of trial is short, and no severe adverse events were expected.

3.3.13 Primary outcomes of the trial

The primary outcome of this is the total number of evidence summaries, of a possible maximum of 20, accessed for four weeks.

3.3.14 Secondary outcomes of the trial

The secondary outcome of this study is the self-rated score for understanding the contents of the provided evidence summaries and the self-rated score for changing practice based on the contents of the provided evidence summaries.

3.4 Results

3.4.1 Enrollment of the participants

CONSORT flow diagram (**Figure 4**) was described to visually demonstrate the flow of the participants in the survey and the trial. Between Apr 8, 2022, to May 27, 2022, 113 candidates accessed the participation form. Among 113 candidates, five did not submit the consent form, and two declined to consent. As a result, 106 participants were enrolled in the study, and 105 participants who responded to the pre-trial survey were subsequently randomized. One participant did not complete the pre-trial survey and did not undergo the randomization. Fifty-two participants were allocated to receive Japanese evidence summaries (Japanese group), and 53 participants were allocated to receive English evidence summaries (English group).

The access to each evidence summary was tracked from commencement of distribution to four weeks after the initial distribution (Jun 3 to July 1, 2022), and the response period for the post-trial survey was set from July 1 to July 28, 2022.

One participant in the Japanese group could not receive emails for the whole distribution period.

3.4.2 Baseline Demographics of the participants categorized by allocation

Table 6 shows the baseline characteristics categorized by each allocation group. In both Japanese and English group, approximately half of the participants aged 36 to 45 years (n = 27, 52; n = 26, 49%, respectively), followed by 46 to 55 (n= 7, 14%; n = 13, 25%, respectively) or 35 or lower (n = 16, 31%; n =12, 23%, respectively). Majority of the participants were man in both groups (n = 47, 90%; n = 50, 94%, respectively). There is an imbalance in the position of the participants between the two groups. In the Japanese group, board-certified surgeons composed 83 % (n = 43) of the group, while in the English group, they composed 98 % (n = 52). Majority of the participants works in the teaching hospital in both arms, and more than half of them works in non-academic teaching hospital (n = 28, 54%; n = 29, 55%, respectively), followed by academic teaching hospital (n = 21, 40%; n = 21, 40%, respectively). Half of the participants in both groups had experience of 10 years or

more (n =28, 54%; n = 29, 55%, respectively). The proportion of the participants who have the additional research degree were similar in both group (n = 18, 35%; n = 20, 38%, respectively). Most participants in both group access the research articles at the average of 1 to 4 articles per week (n = 36, 69%; n = 42, 79%, respectively). Regarding the self-rated ability of reading English materials, 30 to 50 % of the participants from both groups rated their ability as either acceptable (n = 20, 39%; n = 16, 30%, respectively) or poor (n = 19, 37%; n = 26, 49%, respectively).

3.4.3 Primary outcome of the trial

The access to the evidence summaries was tracked electronically from Jun 3 to July 1, 2022 (four weeks). **Figure 5** describes the distribution of the number of access to evidence summaries in each group. In both groups, there was a bimodal distribution in the number of access. Four participants (7.7%) in the Japanese group, including the one participant who couldn't receive the evidence summaries and nine participants (17%) in the English group, did not access the evidence summaries at all. Seven participants (14%) in the Japanese group and nine participants (17%) in the English group accessed all the evidence summaries that were provided. Since the results were not normally distributed, results were summarized as median and IQR and analyzed by a two-sample Wilcoxon rank-sum test. In the ITT analysis, the

median number of the access to evidence summary was 9 (IQR 5 to 15; n = 52) in the Japanese group and 3 (IQR 2 to 15; n = 53) in the English group and the difference was not statistically significant between two groups (p = 0.06) (**Table 7**). In the sensitivity analysis, we excluded the participant who could not receive the evidence summaries for the whole period in the Japanese group. Two-sample Wilcoxon rank-sum test revealed that the total number of access to evidence summaries in the Japanese group (median 9, IQR 5 to 15; n = 51) was significantly higher compared to the English group (median 3, IQR 2 to 15; n = 53) (p = 0.04).

3.4.4 Secondary outcomes of the trial

For 104 participants who completed the intervention, the post-trial survey was sent by email. Within the four-week response period, 43 participants (86%) in the Japanese group and 44 (82%) in the English group completed the post-trial survey. **Table 8** describes the results of self-rated scores in understanding the contents and self-rated scores in changing their practice based on the contents in each group. Self-rated scores in the understanding of contents were 4.47 (SD 0.50, 95% CI 4.17 to 4.32) in the Japanese group and 4.02 (SD 0.51, 95% CI 3.87 to 4.17) in the English group. The mean difference in the score between two groups was 0.44 (95% CI 0.23 to 0.65; Cohen's d 0.89; p < 0.001). Self-rated scores in changing the clinical practice

based on the contents were 3.93 (SD 0.83, 95% CI 3.68 to 4.18) in the Japanese group and 3.61 (SD 0.72, 95% CI 3.40 to 3.82) in the English group. The mean difference in the score between the group was 0.32 (95% CI -0.01 to 0.64; Cohen's d 0.41; p = 0.061).

Three of the 17 participants who did not complete the post-trial survey (two in the Japanese group and one in the English group) completed the survey after the response period. The characteristics of the participants who did not complete the post-trial survey were compared with the participants who completed the post-trial survey, is shown in **Table 9**. There is no difference between the two groups except for the median number of evidence summaries accessed (median 1, IQR 0 to 3 in non-completing group and median 9, IQR 3 to 15 in completing group). A questionnaire about the reason for not completing the post-trial survey was sent to those 17 participants by Google form. A total of five participants (30%) answered the questionnaire, and the result is presented as **Table 10**. Three participants answered "too busy to answer the survey," One participant answered "did not notice the email of the post-trial survey," and one participant answered, "did not pay attention to the deadline."

3.4.5 Post-hoc analysis

Although we conducted the block randomization, there is an imbalance in one prognostic factor (position of the participants) between the two groups, probably due to chance. Therefore, we conducted the post-hoc analysis with the adjustment of position. For the primary outcome, we generated the negative binomial model with the adjustment of position. The coefficient of the allocation was not significant in this regression model (**Table 11**). For the secondary outcomes, we used the linear regression model with adjustment of the position. The results showed a statistically significant difference for the allocation in the self-rated score of understanding the contents of distributed evidence summaries but not in the self-rated score in changing the practice (**Table 12, Table 13**).

3.5 Discussion

3.5.1 Interpretation of findings

In our trial, we evaluated the effect of providing translated evidence summaries among Japanese orthopaedic surgeons and found no significant difference in the median number of accesses to evidence summaries between the two groups. Furthermore, the results from our post-trial survey revealed that the self-rated understanding score of contents was statistically higher in the Japanese group, while

no difference was observed between the two groups in self-rated score in changing practice.

As far as we searched, this is the first trial which assessed the effect of translating materials on the access to evidence summaries distributed online. In our trial, participants accessed the evidence summaries with a median number of 3 (15%) in the English group and 9 (45%) in the Japanese group. This number was higher than the previous study, which reported the retrieval rate of research synopses among general physicians as 1.7%. (15) This greater number of access to evidence summaries in both groups and the non-significant effect of providing translated summaries might be the result of the Hawthorne effect, meaning that awareness of being studied can influence the result of the trial, although the primary and the secondary outcomes of this trial was not clarified to the participants of our trial. (50) Some participants might have been more serious in the study than the usual situation, knowing they were observed. Also, as medical professionals, they could have known ClinicalTrials.gov and checked the pre-specified primary outcome. Those participants accessed the evidence summaries regardless of the allocation, and the result from those enthusiastic participants might have decreased the difference between the two groups. The number of access to the evidence summaries showed the bimodal distribution, and even

participants (14%) in the Japanese group and nine participants (17%) in the English group accessed all the evidence summaries that were provided, suggesting some participants accessed all summaries regardless of the allocation group, thereby diminishing the difference between two groups. The trial without less Hawthorne effect and a more pragmatic setting might have produced a different result.

Contrary to the result by ITT analysis, we observed a significant difference in the primary outcome between the two groups by sensitivity analysis, excluding the one who could not receive the evidence summaries. The underlying reason for this trouble is unclear, but considering that our emails were blocked based on the algorism of the participant's email provider. We prioritized the ITT analysis since it reflects the actual effect of distributing the evidence summaries, including the trouble in the distribution. However, the result might have shown a significant difference with a more reliable system for distribution.

In the secondary outcomes, we observed a statistically significantly higher score in the Japanese group in the self-rated score of understanding the contents with a large effect based on Cohen's d. (54) This result is compatible with the previous studies which compared the understanding level of evidence summaries in translated summaries versus English summaries. (21-23) Recent study which evaluated the

understanding level of evidence summaries among Norwegian-speaking doctors revealed the statistically better understanding level of content doctors who read the article in Norwegian compared to the doctors who read the article in English. However, their difference was modest (Cohen'd 0.35), suggesting the language gap can be closed. Compared to their study, our study showed a larger effect size. The difference in the effect size might reflect the difference in overall English proficiency between countries and the fact that most medical schools teach medicine in the Japanese language. (55)

However, the better self-rated score in understanding level did not lead to changing the practice. A previous survey among Canadian orthopaedic surgeons described that even among important large fracture studies, the probabilities of changing the practices based on the studies' conclusion varies from 10.3% to 72.5%, and the studies with a positive result significantly affected the practice pattern compared to the studies with a negative result. (56) We selected the evidence summaries randomly, and 55% of them showed negative results. Lack of importance and lack of positive results among our evidence summaries might have affected our non-significant finding in self-rated scores in changing their practice.

3.5.2 Limitation of this trial

As stated in Chapter 2, sampling bias is a concern for this trial. Since this trial includes only 105 participants (2.3%) of the total members of JSFR, participants in both groups are expected to be more enthusiastic in evidence uptake compared to general members of JSFR. This sampling bias might have led to underestimating the difference in the trial's access between the Japanese and English groups.

Another concern is a risk of performance bias. (57) This bias can occur when participants and trialists know the allocation of the intervention. In this trial, it was impossible to blind the participants from the allocation and knowledge of allocation might have influenced the outcome. For example, participants in the English group can translate evidence summaries by themselves using machine translation, and it might have affected the understanding level of the evidence summaries.

Observer bias is another bias that can arise, especially when assessing the self-rated score in understanding the contents and the self-rated score in changing the practice based on the contents of the evidence summaries. (58) They are self-rated scores and do not reflect the real understanding of the contents. Participants might have overestimated their understanding if they were allocated to the Japanese group.

Lastly, 16 % of participants did not answer the post-trial survey in the trial part, leading to the missing data on secondary outcomes. This attrition bias might have led to the biased results of the secondary outcomes. Based on the result of the baseline difference and difference in the number of access to evidence summaries between non-responders and responders of the post-trial survey, non-responders accessed a lower number of evidence summaries. Therefore, the score in the understanding level of evidence summary and changing their practice are expected to be lower in non-responders. (59) However, the difference between the two groups might not be different as the number of non-responders was similar between the two groups.

3.5.3 Generalizability

The population of interest in this study was a member of JSFR. However, as we could not obtain the mail address for all members of JSFR, we mainly advertised to the councillor members of JSFR or surgeons who attended the previous workshop. Those populations are expected to be more enthusiastic about updating their knowledge compared to general members of JSFR. The result might not be generalizable to other members of JSFR or Japanese orthopaedic surgeons who are not members of JSFR.

Although our result suggests a better understanding level of evidence summaries with translated version, another issue for generalizability is the current limited ability of machine translation. The study, which translated the English clinical practice guideline into French and Dutch, revealed that they needed revision by human translators due to the terminology. (60) In fact, Cochrane offers the translation of evidence summaries in several languages, including Japanese, but with the help of volunteers from health professionals. (43) Currently, OrthoEvidence produces Spanish-translated evidence summaries solely by DeepL. We used DeepL machine translation in the primary translation of evidence summaries. Although the accuracy of DeepL from Japanese to English is reported as 94% in the oncology field, the accuracy of DeepL in orthopaedic field seems to be lower, and it took three to five hours to revise each summary. (49) Considering the time we needed for revising each translation, it would be difficult to regularly provide Japanese translated evidence summary in OrthoEvidence. This issue will be applicable to the translation of the evidence summaries in other languages with lower quality machine translation.

3.5.4 Implications for future studies

Trial in an understanding contents/ changing clinical practice

In our trial, we have shown that the self-rated understanding of the contents of evidence summaries has increased with the translated version compared to the English version. However, it is complicated with attrition bias and does not mean the actual understanding of the contents in translated evidence summaries. Previous trials proved a better objective understanding of the translated evidence summaries in countries with high to moderate English proficiency. We need to evaluate the effect of translated evidence summaries on the actual understanding of contents and in changing their practice in countries with low English proficiency, such as Japan.

Trial of knowledge uptake in other languages/ more pragmatic setting

The result of our study showed no difference in evidence uptake between translated evidence summaries and English summaries. However, we do not know if the result can apply to other languages, such as Chinese or Spanish-speaking medical professionals. Furthermore, the Hawthorne effect might have affected our trial, which led to the non-significant result. The result might be different if the trial had been conducted in a more pragmatic setting, such as in a longer period of time and including a wider range of participants.

3.6 Conclusion

Providing translated evidence summaries did not increase the number of accesses to evidence summaries among Japanese orthopaedic surgeons. However, it increased the

self-understanding of evidence summaries. More pragmatic trial is needed to clarify the effect of translation of the evidence.

3.7 Figures and tables

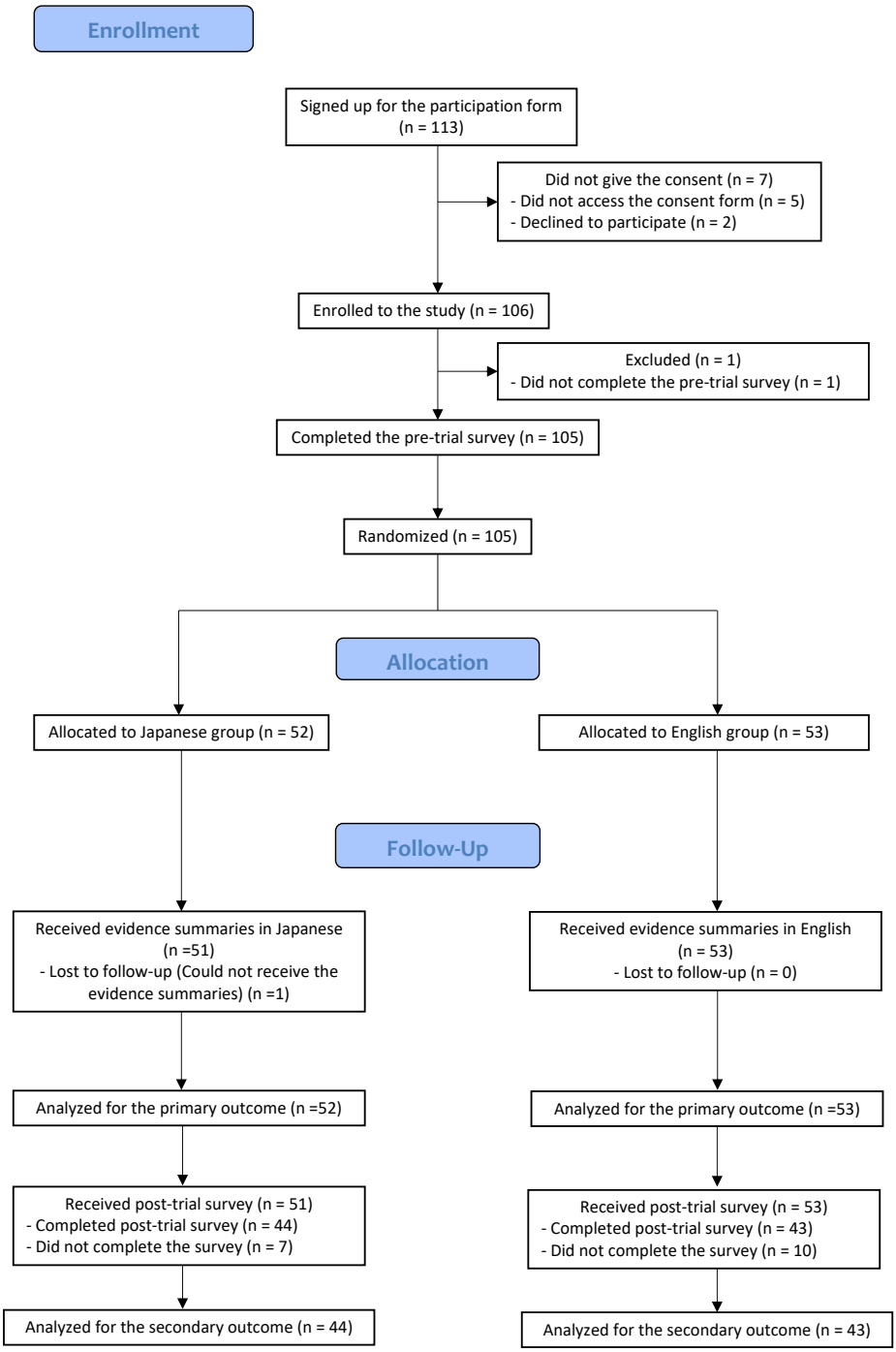

Figure 4. CONSORT Flow diagram

Table 6. Baseline demographic of the participants categorized by allocation

	Japanese group n = 52	English group n = 53
Age		
35 or lower	16 (31)	12 (23)
36 to 45	27 (52)	26 (49)
46 to 55	7 (14)	13 (25)
55 or older	2 (3.8)	2 (3.8)
Gender		
Man	47 (90)	50 (94)
Woman	5 (9.6)	3 (5.7)
Position		
Orthopaedic resident	9 (17)	1 (1.9)
Board-certified surgeon	43 (83)	52 (98)
Practice		
Non-teaching hospital	3 (5.8)	3 (5.7)
Teaching hospital (academic)	21 (40)	21 (40)
Teaching hospital (non-academic)	28 (54)	29 (55)
Years of experience		
Less than 10 years	17 (33)	12 (23)
10 years or more	35 (67)	41 (77)
Additional research degree (Ph.D., MPH, MSc)		
No	34 (65)	33 (62)
Yes	18 (35)	20 (38)
Average number of articles accesses per week		
0	6 (12)	3 (5.7)
1 to 4	36 (69)	42 (79)
5 to 9	8 (15)	5 (9.4)
10 or more	2 (3.8)	3 (5.7)
Self-rated ability to read English		
Very poor	11 (21)	10 (19)
Poor	19 (37)	26 (49)
Acceptable	20 (39)	16 (30)
Good	2 (3.8)	1 (1.9)

n (%); SD, standard deviation

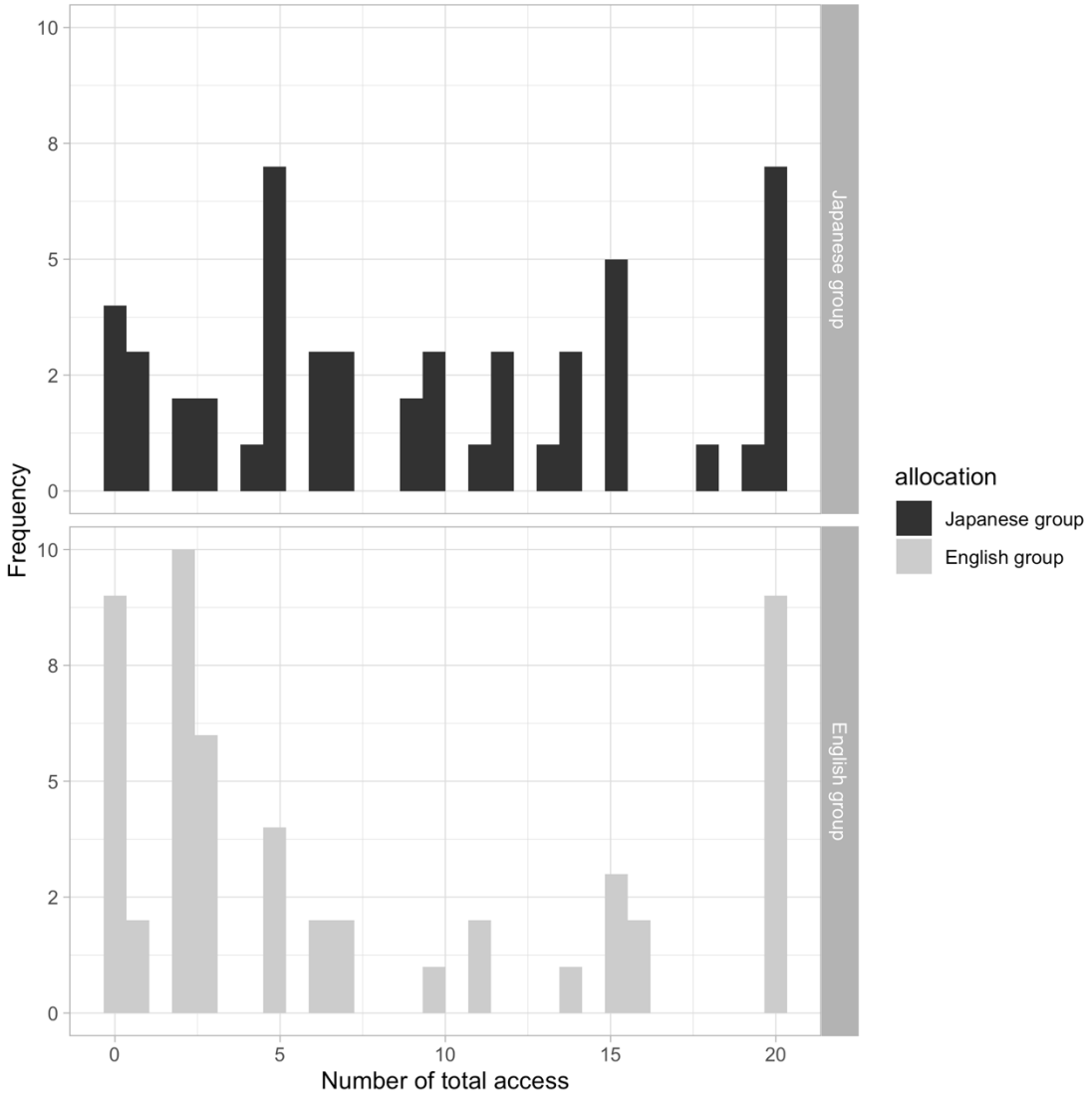

Figure 5. Histogram of the total number of evidence summaries accessed based on allocation group (i.e., Japanese vs. English reports)

Table 7. Total number of access to the distributed evidence summaries by ITT analysis

	Japanese n = 52	English n = 53	p
Total number of access (median (IQR))	9 (5 to 15)	3 (2 to 15)	0.063

IQR, interquartile range

Table 8. Self-rated score in understanding the contents and changing their practice based on the evidence summaries

	Japanese n = 43	English n = 44	Mean difference	p
Understanding contents (mean (SD))	4.5 (0.50)	4.0 (0.51)	0.44 95% CI 0.23 to 0.65	<0.001
Changing practice (mean (SD))	3.9 (0.83)	3.6 (0.72)	0.30 95% CI -0.03 to 0.62	0.061

SD, standard deviation; CI, confidence interval

Table 9. Characteristics of the participants categorized based on the completing status of the post-trial survey

	No n = 17	Yes n = 87	p
Age			0.584
35 or lower	3 (18)	25 (29)	
36 to 45	10 (59)	42 (48)	
46 to 55	4 (24)	16 (18)	
55 or older	0 (0.0)	4 (4.6)	
Gender			0.422
Man	17 (100)	79 (91)	
Woman	0 (0.0)	8 (9.2)	
Allocation			1

English	9 (53)	44 (51)	
Japanese	8 (47)	43 (49)	
Position			0.904
Orthopaedic resident	1 (5.9)	9 (10.3)	
Board-certified surgeon	16 (94)	78 (90)	
Practice			0.444
Non-teaching hospital	0 (0.0)	6 (6.9)	
Teaching hospital (academic)	6 (35)	35 (40)	
Teaching hospital (non-academic)	11 (65)	46 (53)	
Years of experience			0.887
Less than 10 years	4 (24)	25 (29)	
10 years or more	13 (77)	62 (71)	
Additional research degree (Ph.D., MPH, MSc)			0.695
No	12 (71)	54 (62)	
Yes	5 (29)	33 (38)	
Average number of articles accesses per week			0.533
0	3 (18)	6 (6.9)	
1 to 4	11 (65)	66 (76)	
5 to 9	1 (5.9)	4 (4.6)	
10 or more	2 (12)	11 (13)	
Self-rated ability to read English			0.565
Very poor	8 (47)	27 (31)	
Poor	0 (0.0)	3 (3.4)	
Acceptable	6 (35)	39 (45)	
Good	3 (18)	18 (21)	
Number of accesses to evidence summaries (median (IQR))	1 (0 to 3)	9 (3 to 15)	<0.001

n (%); SD, standard deviation; IQR, interquartile range

Table 10. Reason for loss to follow-up in the post-trial survey

	n = 5
Too busy to answer the survey	3

Did not notice the email of the post-trial survey	1
Did not pay attention to the deadline	1

Table 11. Adjusted analysis on the total number of access to evidence summaries

	IRR	95% CI	p
Allocation			
English	-	-	
Japanese	1.32	0.89 to 1.98	0.2
Position			
Resident	-	-	
Board-certified surgeon	1.15	0.56 to 2.20	0.7

IRR, Incidence Rate Ratio; CI, Confidence Interval

Table 12. Adjusted analysis on the self-rated score in understanding the contents of evidence summaries

	Beta	95% CI	p
Allocation			
English	-	-	
Japanese	0.50	0.29 to 0.72	<0.001
Position			
Resident	-	-	
Board-certified surgeon	0.37	0.01 to 0.72	0.046

CI, Confidence Interval

Table 13. Adjusted analysis on the self-rated score in changing practice based on contents of evidence summaries

	Beta	95% CI	p
Allocation			
English	-	-	
Japanese	0.27	-0.06 to 0.61	0.12
Position			
Resident	-	-	
Board-certified surgeon	-0.26	-0.82 to 0.30	0.4

CI, Confidence Interval

CHAPTER 4: CONCLUSION

Japanese orthopaedic surgeons face lack of time, lack of training in critical appraisal, and language barrier in adopting EBM to their clinical practice, with low self-rated

EBM familiarity score. Providing Japanese translated evidence summaries did not increase the number of access to evidence summaries compared to English. Providing translated evidence summaries led to the increased self-rated understanding of the evidence summaries. Further efforts should be taken to reduce the barriers and conduct studies which assess the effectiveness of translated materials in understanding the contents.

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APPENDICES

APPENDIX 1: Survey Items for pre-trial survey

A. Baseline characteristics

Age (year)	
< 35	□
36 - 45	□
46 - 55	□
56 <	□
Gender	
Man	□
Woman	□
Which of the following positions describes your job best	
Board-certified orthopaedic surgeon	□
Resident	□
Researcher or other	□
Type of practice	
non-teaching or private	□
teaching (non-academic)	□
teaching (academic)	□
Years of experience	
up to10 years	□
Ten years or more	□
Additional research degree (Ph.D., MPH, MSc)	
Yes	□
No	□
The average number of articles (full article/ abstract) accessed per week (either Japanese or English)	
0	□
1 - 4	□
5 - 9	□
10 <	□

B. Self-rated score in ability to read English

	Very poor	Poor	Acceptable	Good	Very good
How do you rate your ability to read English?	□	□	□	□	□

C. Barriers to adopting evidence-based medicine (EBM)

	Strongly agree	Agree	Don't know	Disagree	Strongly disagree
I feel that there are barriers to implementing EBM in practice	□	□	□	□	□

For those who answered “Strongly agree” or “agree” to the previous question, please rate the level of agreement regarding the specific barriers to adopting EBM in orthopaedic surgery.

	Strongly agree	Agree	Don't know	Disagree	Strongly disagree
Lack of time	□	□	□	□	□
Lack of good evidence resource	□	□	□	□	□
Lack of skill in critical appraisal (lack of training)	□	□	□	□	□
Lack of priority	□	□	□	□	□
No incentive	□	□	□	□	□
EBM is impractical for everyday clinical practice	□	□	□	□	□
Skepticism over the concept of EBM	□	□	□	□	□
Language barrier	□	□	□	□	□
Lack of understanding from other staffs					

D. Current use of evidence resources

How often do you use the following evidence resources to guide your clinical practice?

	Unaware	Aware but not used	Used on occasion	Used regularly
PubMed	□	□	□	□
Cochrane library	□	□	□	□
Up to Date	□	□	□	□
Japanese clinical practice guideline	□	□	□	□
Other resources in Japanese	□	□	□	□
If you use “other resources in Japanese,” please specify				

E. Self-rated understanding of EBM terminologies

Please answer how you understand the following terms regarding EBM

	Do not understand and do not want to know	Do not understand but would like to know	Understand but could not explain to others	Understand and could explain to others
Mean/median	□	□	□	□
Confidence interval	□	□	□	□
Number needed to treat	□	□	□	□
Power	□	□	□	□
Type I error	□	□	□	□
Kaplan-Meier analysis	□	□	□	□
Hazard ratio	□	□	□	□
Logistic regression	□	□	□	□
Odds ratio	□	□	□	□
Relative /absolute risk	□	□	□	□
Meta-analysis	□	□	□	□
Selection bias	□	□	□	□
Publication bias	□	□	□	□
Level of evidence	□	□	□	□

APPENDIX 2: CONSORT checklist of information to include when reporting randomized controlled trial

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	NA
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	P33
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	P34
	2b	Specific objectives or hypotheses	P36
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	P37
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	P37-38
	4b	Settings and locations where the data were collected	P37-38
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	P39-41

Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	P45
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	P38
	7b	When applicable, explanation of any interim analyses and stopping guidelines	P44
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	P38-39
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	P38-39
Allocation Concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	P38-39
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	P38-39
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	P42
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	P43-44
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	P44
Results			
Participant flow (a diagram is	13a	For each group, the numbers of participants who were randomly assigned,	Fig.4, P45

strongly recommended)		received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig.4, P45
Recruitment	14a	Dates defining the periods of recruitment and follow-up	P45-46
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table6
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Fig.4
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	P47-49
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	P50
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	P54-55
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	P55
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	P50-53

Other information			
Registration	23	Registration number and name of trial registry	P36
Protocol	24	Where the full trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	vi-vii

APPENDIX 3: Subspecialities of the distributed evidence summaries

	n = 20
Pediatric fracture	1 (5)
Upper limb fracture	8 (40)
Hip fracture	4 (20)
Lower limb fracture	4 (20)
Spinal fracture	1 (5)
Thoracic injury	1 (5)
Osteoporosis	1 (5)

n (%)

APPENDIX 4: Detailes of the post-trial survey

A. Self-rated score in understanding of contents

	Strongly agree	Agree	Don't know	Disagree	Strongly disagree
Did you understand the contents of the evidence summaries?	□	□	□	□	□

B. Self-rated score in changing their practice

	Strongly agree	Agree	Don't know	Disagree	Strongly disagree

Will you change your practice based on the contents of the evidence summaries?	□	□	□	□	□