

Learning curve in tissue sparing total hip replacement: comparison between different approaches

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Abstract

Background The tissue sparing surgery (TSS) concept means not only smaller incisions but also less tissue disruption, allowing decreased blood loss and improved function. However, TSS techniques can result in more complications related to the learning curve. The aim of this study was to compare the learning curve of an experienced surgeon with different TSS approaches for total hip replacement (THR) from a clinical and surgical point of view, focussing especially on complications related to the use of different geometric stems.

Materials and methods Sixty patients scheduled to be operated for a primary THR were enrolled in the study and were randomly assigned to surgery by one of three different TSS approaches: lateral with mini incision (group A), minimally invasive anterior (group B) and minimally invasive antero-lateral (group C). Results from the three TSS groups were compared with a control group of 149 patients (group D).

Results Our results reveal significantly reduced blood loss in the TSS groups compared with the control group, with no differences between the TSS groups. We found better early functional scores in the two minimally invasive groups (anterior and anterolateral), and a lower rate of complications with the antero-lateral TSS approach.

Conclusion The antero-lateral TSS approach seems to be safer and less demanding than standard THR surgery, and is suitable for use with different stems.

Keywords Antero-lateral approach · Hip replacement · Learning curve · Tissue sparing surgery

Introduction

Since tissue sparing surgery (TSS) hip replacement was introduced, it has been greeted both with enthusiasm and concern. Enthusiasm for the potential quick recovery, better cosmetic results and decreased blood loss; concern focussing on the potential for more complications related to poorer operative visualisation and the learning curve for new methods [1].

Currently, the aim of a TSS total hip replacement (THR) should be to achieve less trauma to underlying structures, reduced blood loss, less pain and a shorter hospital stay, but TSS may result in increased complications, particularly in the so-called “learning curve” (first 20 cases for a single surgeon). We have chosen the first 20 cases as the learning curve based on articles by Woolson et al. [2] and Archibeck and White [3], which demonstrate a high rate of complications in minimally invasive total hip arthroplasty (THA) during a surgeon's early experience with these methods. Both surgeons and patients should be reminded to focus not only on the potential benefits but also on the risks of new techniques. Archibeck and White [3] considered the first ten cases as a learning curve for a surgeon, but suggest that, with such a dramatic departure from standard THA techniques, it would appear intuitive that at least ten cases would be required to show proficiency with the new method. For this reason we have used the surgeon's first 20 cases as a learning curve.

The orthopaedic literature is deficient in studies supporting the superiority of TSS techniques compared to standard techniques in the early post-operative period, and

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surgeons have expressed concern that these techniques are being promoted without sound clinical data to support their efficacy and safety. In addition, new techniques provide new challenges with regard to surgeon training and competence with these procedures.

To the best of our knowledge, no previous studies analysing the learning curve of different surgical approaches, from both a clinical and surgical point of view, have been published.

The aim of this study was to analyse the learning curve of three tissue sparing approaches (lateral direct Hardinge approach with a mini incision [4], anterior approach [5] and antero-lateral approach [6]) in THR performed by the same experienced surgeon (A.F.), and to compare these results with a series of hip replacements previously performed by the same surgeon through a standard direct Hardinge lateral approach with standard skin incision.

Materials and methods

Sixty patients (60 hips) admitted to our hospital for primary THR were enrolled in this prospective randomised study during the period January–December 2005. All patients gave informed consent to be included in the study. The patients were randomly assigned to have surgery through one of three different TSS surgical approaches: lateral with mini incision (group A), minimally invasive anterior (group B), and minimally invasive antero-lateral (group C).

Each group comprised 20 patients, and were the first 20 cases (“learning curve”) for the surgeon for each approach. A single surgeon (A. F.), who performs an average of 150 primary THR a year using different designed stems, performed all procedures. Moreover, we compared the three groups with a control group (group D) of 149 THRs operated using a lateral standard approach (skin incision >12 cm) in the same period by the same experienced surgeon.

Inclusion criteria to enter the study group (groups A–C) were: body mass index (BMI) <30, diagnosis of primary osteoarthritis, age <75 years. Exclusion criteria were: BMI > 30, fractures, tumours, severe deformities, rheumatoid arthritis, age >75 years.

The study was authorised by the local ethical committee and was performed in accordance with the Ethical standards of the 1964 Declaration of Helsinki as revised in 2000.

Operative techniques

Group A We used a modified Hardinge approach in which the anterior third of the gluteus medius and the underlying minimus is reflected anteriorly [4]. The length of the skin incision to be made was measured and marked using a sterile ruler and marker pen after draping. The only

difference from the modified Hardinge approach (control group) was the length of the skin incision (<8 cm instead of 12–15 cm).

Group B An anterior TSS approach utilising the interval between the tensor fasciae latae, gluteus medius and minimus muscle laterally and the sartorius and rectus femoris muscle medially, was used [5].

Group C An antero-lateral TSS approach utilising the intermuscular plane between gluteus medius and tensor fascia latae was used [6].

Group D For the control group, we used a lateral direct Hardinge approach with a cementless component: a standard straight stem (Hipstar) with Trident acetabular component (Stryker Howmedica Osteonics, Mahwah, NJ).

In the three study groups different cementless components were used, depending on the surgeon’s discretion.

Standard straight stems Hipstar femoral stem with trident acetabular component (Stryker Howmedica Osteonics).

Ultra-short stems Proxima femoral stem component with Pinnacle acetabular component (Depuy, Warsaw, IN).

Anatomical stem ABG II femoral stem with Trident acetabular component (Stryker Howmedica Osteonics).

All patients in groups A, B and C had a diagnosis of primary osteoarthritis. In group D the diagnosis was of primary osteoarthritis in 140 patients and of femoral head osteonecrosis in nine patients. In all cases a specialized dedicated surgical instrumentation was used. An epidural anaesthesia was used in all cases.

Post-operative care

All patients received the same standardised post-operative care. Mechanical foot pumps and pharmacological anti-thrombotic prophylaxis were used. Patients received antibiotics for 24 h post-operation. The drain was pulled on the first postoperative day by the resident on rounds the morning after surgery. No specific protocol was used to measure drain output. All patients received patient control epidural anaesthesia (PCEA) for initial pain control. Patients were switched to oral narcotics on the 2nd or 3rd post-operative day. The major goals of therapy were to enable patients to independently transfer, walk with a walker and negotiate stairs. The same physical therapist supervised the care of all patients. Physical therapy began the day after surgery. Patients were either discharged home or transferred to a rehabilitation facility based on their medical condition, progress in therapy, and home support system.

Data collection

Demographic information, laboratory values and the post-operative course including post-operative complications

were determined from a review of office charts. The operative report was used to determine the component type, the length of the skin incision, any intra-operative complications and surgical time. We considered as key complications only those complications related to surgical errors (component malpositioning, dislocations, fractures and nerve injuries). The anaesthesia record or operating room nursing record was used to determine operative time. Blood loss was assessed using the methods proposed by Rosencher et al. [7]. Hip function, quality of life and general health were assessed using the Harris hip score (HHS) [8] and the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) [9]. The length of hospital stay was calculated from the day of surgery to the day of patient discharge. In an effort to identify the hypothesised learning curve, all parameters and data were obtained as a function of the surgical approach and also calculated comparing the first ten cases and the second ten cases.

The patients were evaluated 6 weeks after surgery with the HHS and WOMAC scores.

Radiographic analysis

Postoperative radiographs were evaluated for component position. The radiographs were evaluated by an orthopaedic research fellow (A.S.) who was blinded as to the group of patients. The parameters recorded were cup abduction angle and stem alignment. Stem alignment was measured as the angle between the long axis of the femoral stem and the anatomical axis of the femur on the antero-posterior radiograph. On the lateral radiograph, stem alignment was classified as neutral, posterior or anterior.

Statistical analysis

Statistical analysis was performed by statisticians of the Regional Agency of Public Health. All preoperative and postoperative HHS and WOMAC scores, as well as blood loss, surgical time, hospital stay and radiographic stem alignment were recorded in a standard Excel file (Microsoft Office, Microsoft Corporation, Seattle, WA) and compared between groups. Unpaired *t* tests were used to compare continuous variables in normally distributed data between the groups. The Pearson Chi-square and Fisher exact tests were used to compare categorical data, such as complications. A *P* value of <0.05 was considered to be significant. A power analysis was not formally performed because the number of patients in this study (20 cases in each group) does not give enough power to differentiate the results between groups. All evaluations were performed using the STATA9 software package (Statistic Data Analysis, Statacorp, College Station, TX). To evaluate the geometric

pattern of the learning curve in each group, the results were also considered by comparing the first ten cases and the second ten cases of that technique for the surgeon. All parameters were evaluated as a function of surgical approach, stem design and learning curve.

Results

Sixty patients gave their consent to participate in the study in the period from January to December 2005 and were randomised into one of the three different TSS approach groups. The control group was composed of 149 patients who underwent THR using a standard lateral direct approach.

Group A consisted of 20 patients, 14 males and 6 females with a mean age of 66.3 years [range 74–38 years; standard deviation (SD) 10.4], a mean BMI of 27.6 (range 30–20; SD 3.0) and a mean HHS score of 38.8 (range 11–68; SD 17.2).

Group B consisted of 20 patients, 12 males and 8 females with a mean age of 64 years (range 72–47 years; SD 8.0), a mean BMI of 22.7 (range 26.5–21.7; SD 1.5) and a mean HHS of 37.7 (range 15–70; SD 19.0).

Group C consisted of 20 patients, 11 males and 9 females with a mean age of 66 years (range 71–46 years; SD 7.5), a mean BMI of 23.1 (range 27–22; SD 1.5) and a mean HHS of 38.1 (range 15–69; SD 19.2).

Group D consisted of 149 patients, 81 males and 68 females with a mean age of 65 years (range 81–50 years; SD 9.8), a mean BMI of 28 (range 27–22; SD 1.8), and a mean HHS of 39 (range 51–28; SD 10.2).

None of the differences in preoperative condition were significant ($P > 0.05$).

Surgical time

The length of the procedure was 102 min (range 128–95 min; SD 10.6) in group A, 121 min (range 167–97 min; SD 23.6) in group B, 110 min in group C (range 112–92 min; SD 6.3), and 77 min in group D (range 100–50 min; SD 15.1). The surgical time was significantly higher in group B ($P = 0.013$).

Considering the surgical time as a function of the learning curve, we found a significantly higher surgical time in the first ten cases than in the second ten cases in groups A, B and C ($P = 0.023$, 0.015 and 0.028, respectively).

Blood loss

Mean blood loss was 1,219 ml (range 2,654–4,215 ml; SD 786.5) in group A, 1,344 ml (range 2,718–382 ml; SD 710.0) in group B, 1,279 ml (range 2,507–491 ml; SD

694.9) in group C and 1,644 ml (range 2,873–564 ml; SD 757.7) in group D. All TSS groups showed a significant reduction in blood loss compared to the standard lateral approach (group D) ($P = 0.002, 0.004$ and 0.007 , respectively); no differences were detected between groups A, B and C ($P > 0.05$) (Fig. 1). Considering blood loss as a function of the learning curve, no differences were found comparing the first ten cases and the second ten cases in groups A, B and C ($P > 0.05$).

Radiographic evaluation

Radiographic evaluation indicated that all femoral stems were placed in neutral alignment except one in group A, which was placed in varus (Fig. 2).

Using a mean angle of $<35^\circ$ or $>50^\circ$ to define outliers, we recorded one case of acetabular component malposition in group D (in a severe case of dysplasia) and one case in group B.

Hospitalisation

All of our patients were admitted the day before surgery, which is current practice in our hospital, and the length of hospital stay was calculated from the day of surgery to the day of discharge. The mean length of hospital stay was 10 days (range 20–6; SD 4.6) in group A, 8 days (range 18–6; SD 3.7) in group B, 9 days (range 19–7; SD 3.6) in group C and 11 days (range 18–6; SD 3.8) in group D. No significant differences were detected between groups. Considering the hospitalisation as a function of the learning curve, no differences were found comparing the first ten cases and the second ten cases in groups A, B and C ($P > 0.05$).

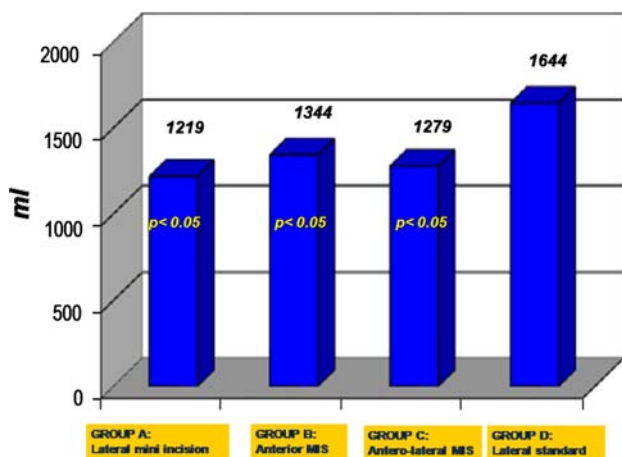


Fig. 1 Mean blood loss (in millilitres) as calculated using the formula proposed by Rosencher et al. [7] (P value <0.05 indicates significant difference)



Fig. 2 Femoral stem placed in varus (group A)

Results of 6-week review

A total of 229 patients were evaluated at 6 weeks after surgery (80 patients of the three study groups and 149 patients of the control group).

The mean post-operative HHS score at 6 weeks was 88.3 (range 105–78; SD 8.0) in group A; 93.1 (range 106–82; SD 7.8) in group B; 93.8 (range 105–85; SD 7.4) in group C and 86.7 (range 100–76; SD 8.9) in group D.

In all groups, a significant improvement in HHS score with respect to the preoperative condition was detected ($P = 0.001, 0.006, 0.004$ and 0.005 , respectively, in groups A, B, C and D), while no between-group differences were detected at 6 weeks follow-up ($P > 0.05$). Considering HHS as a function of the learning curve, no differences were found comparing the first ten cases and the second ten cases in groups A, B and C ($P > 0.05$).

The mean post-operative WOMAC score at 6 weeks was 27.7 (range 66–20; SD 13.6) in group A; 23.3 (range 55–28; SD 9.9) in group B; 28 (range 51–22.1; SD 8.5) in group C and 28.2 (range 54–22; SD 9.8) in group D. The WOMAC score at 6 weeks was significantly lower in groups B and C compared to groups A and D ($P = 0.003$ and 0.007 for group B respect to group A and D; $P = 0.1$ and 0.009 for group C respect to group A and D) (Fig. 3).

Considering the WOMAC score as a function of the learning curve, no differences were found comparing the first ten cases and the second ten cases in groups A, B and C ($P > 0.05$).

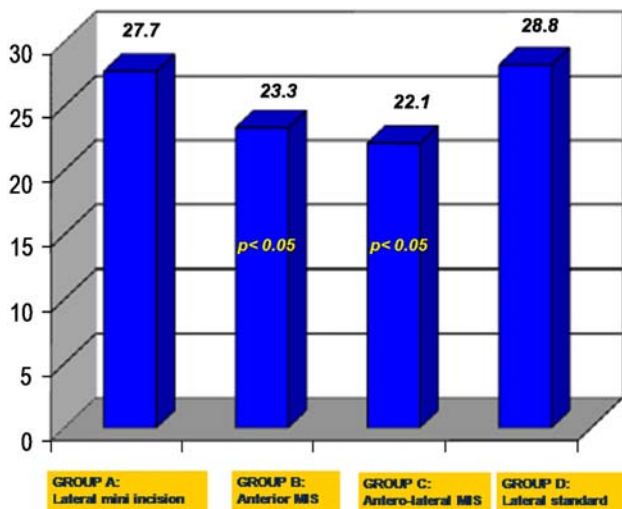


Fig. 3 Mean post-operative values of the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) score at 6-week follow up. (P value <0.05 indicates significant difference)

Complications

Our greatest interest was in determining the rate of key complications as a function of surgical approach and learning curve. The overall rate of complications in the three study groups was 10%, significantly higher than in the control group ($P = 0.003$).

The following complications were detected:

Group A: two sciatic nerve palsy (one transient and one permanent), one greater trochanter fracture, one femoral stem malposition (Fig. 2). All these complications occurred using a standard straight stem with a total rate of 20%. Considering the complications as a function of the learning curve, the rate was two of four in the first ten cases and two of four in the second ten cases without significant differences.

Group B: one greater trochanter fracture, one proximal femoral fracture (Fig. 4) with cup malposition, one rupture of tensor fasciae latae and two haematomas. All but one of these complications occurred using a standard straight stem. One of the two haematomas occurred using an anatomical stem. The total rate of complications was 20%. Considering the complications as a function of the learning curve, the rate was two of three in the first ten cases and one of three in the second ten cases without significant differences.

Group C: no complications were detected.

No dislocations, infections or early aseptic loosening were detected in groups A, B and C.

In control group D (149 patients), the following complications were observed: one proximal femoral fracture, one case of cup malposition (in a severe case of dysplasia) and one infection (incidence 1.34%).



Fig. 4 Proximal femoral fracture (group B)

When comparing the rate of key complications as a function of the surgical approach we found a significantly lesser incidence of complications in group C ($P = 0.0001$).

When comparing the rate of key complications as a function of component design we found a significantly higher incidence with the use of standard straight stems compared to the other different designed stems ($P = 0.002$).

Discussion

Total hip arthroplasty remains one of the most frequently performed reconstructive procedures in orthopaedic surgery. It has been associated with excellent results over the years [10], but traditionally has large surgical exposure and lengthy rehabilitation time. The history of hip arthroplasty has been dynamic, and research continues to improve results. In fact, in recent years, there have been a number of reports [10] describing the performance of THA through smaller incisions and through mini invasive surgical techniques, aimed at accelerating post-operative rehabilitation and reducing blood loss and hospitalisation.

To the best of our knowledge this is the first prospective randomised study comparing different TSS approaches in

THR in the first 20 cases carried out by an experienced surgeon (the so-called “learning curve”) that can be correlated with more complications. Most surgeons have a learning curve with any new operation, and, in general, the more radical the departure from established methods, the greater the increased risk of unanticipated complications. For this reason, the aim of this study was to evaluate the learning curve of an experienced surgeon with three different TSS approaches: lateral direct (Hardinge approach) with mini incision, TSS anterior and TSS antero-lateral, focussing on blood loss, early functional outcome, length of hospital stay, surgical time and, especially, on intraoperative complications. To better understand the potential operative risks of these new techniques, we used different geometric stems (straight stems, anatomical stems and neck preserving stems). Moreover, Katz et al. [11] found that post-operative morbidity and mortality following THA was substantially lower in patients treated by surgeons with a high annual volume of operations, and for this reason we compared the results of these TSS approaches in the learning curve with the results of our standard technique for primary total hip arthroplasties: a lateral direct Hardinge approach with the use of a standard straight stem, always performed by the same senior surgeon.

Concerning blood loss, which was calculated as suggested by Rosencher et al. [7], we found a significant reduction with all the three TSS techniques compared to the standard lateral direct approach, but found no differences between the three TSS groups.

We found an improvement in HHS score compared to the preoperative condition in all groups, but no between-group differences in post-operative HHS. When comparing early post-operative clinical outcomes with the WOMAC score, we found significantly better results in group B and C compared to groups A and D.

We also report no difference in the length of hospital stay between groups.

Other investigations have described the ability of the mini-incision approach to reduce blood loss and the length of hospital stay, allowing the patient to recover earlier compared to the usual approaches. Two studies published by Goldstein et al. [12] and Chimento et al. [13] compared patients receiving a THA through a mini-incision posterior approach with patients receiving the same approach performed through a standard skin incision. They found significantly lower blood loss in the mini-incision group. However, Ogonda et al. [14] published a randomised blinded study comparing 100 patients receiving a THA through a mini-incision posterior approach with 100 patients receiving the same approach performed through a standard skin incision. They found no significant differences between the groups in regard to blood loss, pain scores, analgesic use, complications, component

placement, cement-mantle quality, or functional outcomes scores at 6 weeks. No significant difference was detected in early walking ability or length of hospital stay. Rachbauer et al. [5] published a study comparing 100 patients receiving a THA through minimally invasive anterior approach with patients receiving a THA performed through a standard skin incision. They found significantly lower blood loss in the minimally invasive group. No differences were detected in component placement or in the length of the hospital stay.

The concept of TSS is perhaps the most important revolution in surgical techniques in recent times. “Less invasive surgery” is terminology that encompasses both small incision techniques and tissue sparing techniques. Small incision surgery entails performing the conventional approach through a smaller skin incision. TSS uses not only a smaller incision but also new exposure techniques. For this reason, a better classification could be that proposed by Duncan [15] in 2006, based on the number of skin incisions, approach to the hip, and method of dissection. Following this clarification, TSS antero-lateral and TSS anterior approaches can be classified as “intermuscular approaches”, while the direct lateral approach, with a standard or mini-incision, is classified as a “transmuscular approach”. Thus, the tissue sparing concept means not only smaller incisions but also less tissue disruption and thus less intra-operative bleeding, and this could explain our results showing reduced blood loss in the TSS groups, and better early clinical outcomes while maintaining the perceived high level of safety, efficacy and durability of the procedure. Moreover, Zati et al. [16] and He et al. [17] concluded that, in the early post-operative period, the muscle afferent is more important than hip capsule receptors. According to this theory, approaches to the hip through muscles or involving tenotomies will affect the sensomotory capacity of the joint, and this will lengthen the post-operative rehabilitation of the patient and reduce the functional outcome scores. This can explain the better early functional outcomes with the WOMAC score in the two tissue sparing “intermuscular approach” groups (anterior and antero-lateral TSS approach) compared to the two “transmuscular approach” groups (Hardinge lateral approach and Hardinge lateral approach with mini-incision) reported in our study.

The other important goal of our study was to analyse complications of these TSS techniques in the learning curve. We reported a lower rate of complications with the TSS anterolateral approach compared to the other two TSS approaches. We found a higher rate of intra-operative complications in group B (anterior TSS approach), together with a significantly longer operating time. Moreover, the rate of complications in groups A and B did not diminish along a geometric pattern during the

learning curve, whereas surgical time was significantly correlated with the learning curve, with a longer time required in the first ten cases than in the second ten cases in groups A, B and C.

In particular, we found one greater trochanter fracture, one proximal femoral fracture (Fig. 4) with cup malposition, one rupture of tensor fasciae latae, and two haematomas. All but one of these complications occurred using a standard straight stem. One of the two haematomas occurred using an anatomical stem. Intra-operative fracture of the proximal femur is the most frequent complication associated with minimal incision and minimally invasive techniques. There is a definite risk when there is a geometric mismatch between the broach and the femur, as can occur in association with the use of tapered and wedge-shaped implant designs. In fact we found a higher rate of fractures in groups A and B with the use of straight stems. However, we found no complications in the antero-lateral TSS group (group C) also using straight stems. Woolson et al. [2] also reported a higher rate of complications in the mini-incision group; these included two femoral fractures, a complete sciatic nerve palsy and a superficial wound infection.

One limitation of our study is that the number of patients in each of the study groups is too small for a statistical power analysis, but this is the number of cases considered as the learning curve [3]. Thus, although our differences are significant, we cannot know the real power of these differences. Another limitation is the clinical evaluation of patients only at early follow-up, but there is no reason to believe that any of the patients of our study groups will behave differently in the future because there were no differences between them in component position and fixation. However, longer-term follow-up will be needed to state this with certainty.

The strength of our study is the evaluation of the learning curve of the same experienced senior surgeon with three different TSS techniques in comparison with a standard technique, from a clinical and a surgical point of view.

Of course, much of the controversy surrounding minimally invasive surgery is due to the lack of a definition of the term. Currently, as suggested by Berry [1], “a minimally invasive approach includes a whole family of different operations” while we believe, according to the American Association of Hip and Knee Surgeons, that only intermuscular approaches with muscle sparing can really be considered as TSS.

Despite the positive expectations and the current trend towards TSS approaches, most surgeons are in disagreement with the validity of these procedures. In this study, we analysed the learning curve, the crucial constituent in TSS approaches. On the basis of our study, the main advantages of all TSS approaches seem to be the reduced total blood

loss, even in the learning curve. However, during the learning curve the tissue sparing approaches seem to have a higher rate of complications than the standard procedures even in selected patients (BMI < 30), without a geometric pattern decrease between the first and the second cases. In muscle sparing approaches (anterior and antero lateral), the early functional outcomes are better than with other approaches (standard and mini incision). Among the minimally invasive procedures evaluated, the antero-lateral approach seems to be safer and less demanding than the others and, because they allow good exposure of the femur and the acetabulum, are also suitable for use with different stems.

Conflict of interest statement The authors declare that they have no conflict of interest related to the publication of this manuscript.

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