

**RCT**  
**Potential PURL Review Form**  
**PURL Jam Version**  
Version #11 October 29, 2009

**PURLs Surveillance System**  
**Family Physicians Inquiries Network**

**SECTION 1: Identifying Information for Nominated Potential PURL**  
**[to be completed by PURLs Project Manager]**

- 1. Citation** Kise NJ, Risberg MA, Stensrud S, Ranstam J, Engebretsen L, Roos EM. Exercise therapy versus arthroscopic partial meniscectomy for degenerative meniscal tear in middle aged patients: randomised controlled trial with two year follow-up. BMJ. 2016 Jul 20;354:i3740. doi: 10.1136/bmj.i3740. PubMed PMID: 27440192
- 2. Hypertext link to PDF of full article** <http://www.ncbi.nlm.nih.gov/pubmed/27440192>
- 3. First date published study available to readers** 7/20/2016
- 4. PubMed ID** 27440192
- 5. Nominated By** Other Other: Debbie Miller
- 6. Institutional Affiliation of Nominator** University of Chicago Other: NorthShore
- 7. Date Nominated** 7/22/2016
- 8. Identified Through** BMJ Online Other:
- 9. PURLS Editor Reviewing Nominated Potential PURL** Other Other: Corey Lyon
- 10. Nomination Decision Date** 8/2/2016
- 11. Potential PURL Review Form (PPRF) Type** RCT
- 12. Other comments, materials or discussion**
- 13. Assigned Potential PURL Reviewer** Jennie Jarrett
- 14. Reviewer Affiliation** Other Other: UPMC St. Margarets
- 15. Date Review Due** 10/4/2016
- 16. Abstract** OBJECTIVE:  
To determine if exercise therapy is superior to arthroscopic partial meniscectomy for knee function in middle aged patients with degenerative meniscal tears.  
DESIGN:  
Randomised controlled superiority trial.

**SETTING:**

Orthopaedic departments at two public hospitals and two physiotherapy clinics in Norway.

**PARTICIPANTS:**

140 adults, mean age 49.5 years (range 35.7-59.9), with degenerative medial meniscal tear verified by magnetic resonance imaging. 96% had no definitive radiographic evidence of osteoarthritis.

**INTERVENTIONS:**

12 week supervised exercise therapy alone or arthroscopic partial meniscectomy alone.

**MAIN OUTCOME MEASURES:**

Intention to treat analysis of between group difference in change in knee injury and osteoarthritis outcome score (KOOS4), defined a priori as the mean score for four of five KOOS subscale scores (pain, other symptoms, function in sport and recreation, and knee related quality of life) from baseline to two year follow-up and change in thigh muscle strength from baseline to three months.

**RESULTS:**

No clinically relevant difference was found between the two groups in change in KOOS4 at two years (0.9 points, 95% confidence interval -4.3 to 6.1; P=0.72). At three months, muscle strength had improved in the exercise group (P≤0.004). No serious adverse events occurred in either group during the two year follow-up. 19% of the participants allocated to exercise therapy crossed over to surgery during the two year follow-up, with no additional benefit.

**CONCLUSION:**

The observed difference in treatment effect was minute after two years of follow-up, and the trial's inferential uncertainty was sufficiently small to exclude clinically relevant differences. Exercise therapy showed positive effects over surgery in improving thigh muscle strength, at least in the short term. Our results should encourage clinicians and middle aged patients with degenerative meniscal tear and no definitive radiographic evidence of osteoarthritis to consider supervised exercise therapy as a treatment option. Trial registration [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT01002794).

17. Pending  
PURL Review  
Date

10/4/2016

## **SECTION 2: Critical Appraisal of Validity**

**[to be completed by the Potential PURL Reviewer]**

**[to be revised by the Pending PURL Reviewer if needed]**

- |  |   |
|--|---|
| <b>1. Number of patients starting each arm of the study?</b>   | Out of 341 patients assessed for eligibility, 226 were eligible and 140 (41%) were randomised to the two treatment groups, each with 70 participants.   |
| <b>2. Main characteristics of study patients (inclusions, exclusions, demographics, settings, etc.)?</b> | Between October 2009 and September 2012, we recruited participants from the orthopaedic departments at Oslo University Hospital (October 2009-April 2011) and Martina Hansens Hospital (May 2011-September 2012) in Norway. Inclusion criteria were age 35-60 years; unilateral knee pain for more than two months without a major trauma (defined as sudden onset of knee pain resulting from a single physical impact event); medial degenerative meniscal tear verified by magnetic resonance imaging; and, at most, radiographic changes equivalent to grade 2 according to the Kellgren-Lawrence classification. Exclusion criteria were acute trauma, locked knee, ligament injury, and knee surgery in the index knee during the previous two years.   |
| <b>3. Intervention(s) being investigated?</b>  | In this randomised controlled trial with two parallel intervention groups (1:1 ratio) we compared exercise therapy alone with arthroscopic partial meniscectomy alone. The exercise therapy intervention was carried out at one of two clinics (Norwegian Sports Medicine Clinic and Gnist Trening og Helse AS), using the same protocol and started as soon as possible after randomisation—or later if preferred by the participant. The exercise therapy programme, outlined in supplementary figure S1 and previously described in detail, <sup>20</sup> consisted of progressive neuromuscular and strength exercises over 12 weeks, performed during a minimum of two and a maximum of three sessions each week (24-36 sessions). The participants filled in exercise diaries, and we assessed compliance with exercise as the total number of exercise sessions completed out of 24 sessions. Excellent compliance was predefined as participation in 24 or more sessions (100%), satisfactory compliance as 19-23 sessions (80-100%), and poor compliance as 18 or fewer sessions (<80%). In the per protocol analysis, we defined completing 18 or fewer sessions as not following the protocol. Likewise, |

if participants in the menis- cectomy group received physiotherapist instructed exercise therapy postoperatively of adequate quality for at least 18 sessions, they were defined as not following the protocol.

**4. Comparison treatment(s), placebo, or nothing?**

In this randomised controlled trial with two parallel intervention groups (1:1 ratio) we compared exercise therapy alone with arthroscopic partial meniscectomy alone. Arthroscopic surgery was performed as soon as possible after randomisation, depending on waiting lists and participant preference. The arthroscopic intervention was similar in both hospitals, performed as standard operations for arthroscopic partial meniscectomy, and the participants followed normal preoperative, perioperative, and postoperative routines. Six orthopaedic surgeons with at least 10 years of clinical experience performed the operations. One surgeon performed 39 (61%) operations, and the other five surgeons performed 1-15 operations each. The participants were discharged from hospital on the day of surgery and were advised to use two crutches postoperatively until gait normalised and no swelling or discomfort occurred during weight bearing. Before hospital discharge the participants were given written and oral instructions for simple home exercises, aimed at regaining knee range of motion and reducing swelling. They were encouraged to perform the exercises two to four times daily (see supplementary figure S2a-d for written instructions). Surgery was performed with the participant under general anaesthesia, with or without thigh tourniquet, antibiotic prophylaxis, or antithrombotic prophylaxis. Arthroscopes with 30 degree optics and standard arthroscopic instruments were used. Ringer acetate was used for lavage. Normal procedure involved two portals: anteromedial and anterolateral, and if required, additional portals were made and a lavage cannula was inserted laterally in the cranial recess. A diagnostic procedure including evaluation of additional injuries (ligaments, cartilage) preceded systematic probing of both menisci, and, finally, all unstable meniscal tissue was resected.

**5. Length of follow up? Note specified end points e.g. death, cure, etc.**

Follow-up assessments were performed at three, 12, and 24 months, with muscle strength at three months and patient reported outcomes at the two year follow-up as the primary end points. Whereas data at three and 12 months were collected during clinic visits, the follow-up at two years was conducted by post, and we only collected data on patient reported outcomes.

**6. What outcome measures are used? List all that assess effectiveness.**

Our two primary endpoints were patient reported knee function at two years and thigh muscle strength at three months. The primary patient reported endpoint was change from baseline to two years in KOOS4, defined as the average score for four of the five knee injury and osteoarthritis outcome score (KOOS) subscale scores covering pain, other symptoms, function in sport and recreation, and knee related quality of life. Secondary patient reported outcomes were the five KOOS subscales and the physical component summary and mental component summary of the short form 36 item (SF-36).<sup>25</sup> Secondary objective outcomes were thigh muscle strength and lower extremity performance test results.

**7. What is the effect of the intervention(s)? Include absolute risk, relative risk, NNT, CI, p-values, etc.**

In the intention to treat analysis, there was no clinically relevant difference in change between groups from baseline to two year follow-up in KOOS4 score (0.9 points, 95% confidence interval -4.3 to 6.1; P=0.72) after adjustment for baseline imbalance and randomisation stratification factors

**8. What are the adverse effects of intervention compared with no intervention?**

From baseline to the two year follow-up, no serious adverse events were recorded in either group. During the same period, 23% of the participants in each group experienced pain, swelling, instability, stiffness, or decreased range of motion in the index knee that was serious enough to seek consultation. Similar symptoms in the contralateral knee were experienced by 21% of participants in the exercise group and 14% in the menis- cectomy group.

**9. Study addresses an appropriate and clearly focused question - *select one***

- Well covered
- Adequately addressed
- Poorly addressed
- Not applicable

Comments: The aim of this study was to determine if exercise therapy is superior to arthroscopic surgery for knee function in middle aged patients with degenerative meniscal tears verified by magnetic resonance imaging.

10. Random allocation to comparison groups

- Well covered
- Adequately addressed
- Poorly addressed
- Not applicable

Comments: Participants contributed baseline data before they were randomly allocated to one of two parallel intervention groups, treated with either arthroscopic partial meniscectomy or exercise therapy. A statistician at Oslo University Hospital determined the computer generated randomisation sequence, stratified by sex in blocks of eight, and these were concealed from the surgeons who enrolled and assessed the participants. The allocations were kept in sequentially numbered opaque envelopes that were opened by the participants after enrolment.

11. Concealed allocation to comparison groups

- Well covered
- Adequately addressed
- Poorly addressed
- Not applicable

Comments: blinding

The test assessors were blinded to group allocation, and long pants or neoprene sleeves were worn by participants over both knees to hide possible surgical scars and preserve blinding of group allocation. The statistician was blinded to group allocation during the analysis.

12. Subjects and investigators kept "blind" to comparison group allocation

- Well covered
- Adequately addressed
- Poorly addressed
- Not applicable

Comments: blinding

The test assessors were blinded to group allocation, and long pants or neoprene sleeves were worn by participants over both knees to hide possible surgical scars and preserve blinding of group allocation. The statistician was blinded to group allocation during the analysis.

12. Comparison groups are similar at the start of the trial

- Well covered
- Adequately addressed
- Poorly addressed
- Not applicable

Comments: Table 1

14. Were there any differences between the groups/arms of the study other than the intervention under investigation? If yes, please indicate whether the differences are a potential source of bias.

- Well covered
- Adequately addressed
- Poorly addressed
- Not applicable

Comments: table 1

15. Were all relevant outcomes measured in a standardized, valid, and reliable way?

- Well covered
- Adequately addressed
- Poorly addressed
- Not applicable

Comments: Our two primary endpoints were patient reported knee function at two years and thigh muscle strength at three months. The primary patient reported endpoint was change from baseline to two years in KOOS4, defined as the average score for four of the five knee injury and osteoarthritis outcome score (KOOS) subscale scores covering pain, other symptoms, function in sport and recreation, and knee related quality of life. KOOS is reliable and has content validity for patients with meniscal tears and osteoarthritis.<sup>21 22</sup> It consists of 42 items scored from 0-4 on a Likert scale. Subscale scores are calculated separately and transformed

to a scale from 0 (worst) to 100 (best). A priori, a clinically relevant difference of 10 points guided the sample size calculation. To better guide clinical interpretation, we calculated study specific and subscale specific cut-offs post hoc by subtracting the mean KOOS subscale score for those reporting to have “unchanged” knee function from those reporting “better” knee function at two years, on a five point global rating scale (much better, better, unchanged, worse, or much worse).<sup>23</sup>

Experienced physiotherapists used detailed test protocols to collect data on muscle strength. A Biodex 6000 dynamometer was used to test the strength of quadriceps and hamstrings concentric isokinetic muscle. The outcomes were peak torque and total work for both knee extension and knee flexion at 60 degrees per second. The reliability for isokinetic muscle tests is satisfactory.<sup>24</sup>

- 16. Are patient oriented outcomes included? If yes, what are they?** Yes, there were both patient reported (which were patient oriented) and objective endpoints, as primary and secondary outcomes.
- 17. What percent dropped out, and were lost to follow up? Could this bias the results? How?** Of the 70 patients in each arm, 62 patient in the exercise group made it to the 24 month point, with 8 not returning their questionnaire. 64 patients in the surgery group made it to the 24 month followup, with 6 not returning or not completing their questionnaire.
- 18. Was there an intention-to-treat analysis? If not, could this bias the results? How?** In the intention to treat analyses, the participants were included as randomised. Those who did not complete the assigned treatments were excluded from the per protocol analysis
- 19. If a multi-site study, are results comparable for all sites?** yes, the sites were not differentiated within the results
- 20. Is the funding for the trial a potential source of bias? If yes, what measures were taken to insure scientific integrity?** This study was funded by Sophies Minde Ortopedi AS, Swedish Rheumatism Association, Swedish Scientific Council, Region of Southern Denmark, Danish Rheumatism Association, and the Health Region of South-East Norway. The researchers were independent from the funder.
- 21. To which patients might the findings apply? Include patients in the study and other patients to whom the findings may be generalized.** patients with a meniscal tear who are interested
- 22. In what care settings might the findings apply, or not apply?** outpatient care
- 23. To which clinicians or policy makers might the findings be relevant?** orthopedics surgeons would be interested in this information as it would change their surgery volumes.

**SECTION 3: Review of Secondary Literature**  
**[to be completed by the Potential PURL Reviewer]**  
**[to be revised by the Pending PURL Reviewer as needed]**

**Citation Instructions**

For UpTo Date citations, use style modified from [http://www.uptodate.com/home/help/faq/using\\_UTD/index.html#cite](http://www.uptodate.com/home/help/faq/using_UTD/index.html#cite) & AMA style. Always use Basow DS as editor & current year as publication year.

EXAMPLE: Auth I. Title of article. {insert author name if given, & search terms or title.} In: Basow DS, ed. UpToDate [database online]. Waltham, Mass: UpToDate; 2009. Available at: <http://www.uptodate.com>. {Insert dated modified if given.}

Accessed February 12, 2009. {whatever date PPRF reviewer did their search.}

For DynaMed, use the following style:

Depression: treatment {insert search terms or title}. In: DynaMed [database online]. Available at: <http://www.DynamicMedical.com>. Last updated February 4, 2009.

{Insert dated modified if given.} Accessed June 5, 2009.{search date}

## 1. DynaMed excerpts

Management:

- Strengthening and low-impact aerobic exercises are recommended for patients with symptomatic osteoarthritis (OA) of knee as it improves both pain and physical function (Strong recommendation).
- Weight loss is recommended for overweight patients (body mass index [BMI] > 25 kg/m<sup>2</sup>) with symptomatic OA of knee (Strong recommendation).
- Medication management:
  - Nonsteroidal anti-inflammatory drugs (NSAIDs), including topical diclofenac and ketoprofen, are more effective than acetaminophen and are recommended:
    - by the American College of Rheumatology for patients without satisfactory response to full-dose acetaminophen (Strong recommendation)
    - by the American Academy of Orthopaedic Surgeons as the initial therapy in patients with symptomatic OA of knee (Strong recommendation)
    - Duloxetine reduces pain and improves function in patients with OA of the knee and is an option for patients who are unable to take NSAIDs (Weak recommendation).
    - Low-dose oral corticosteroids (for example, prednisolone 7.5 mg/day) may be considered for short-term relief of moderate-to-severe OA.
    - Opioids are alternative analgesics for pain refractory to other therapies in patients who are unable or unwilling to undergo a knee replacement (Strong recommendation).
    - Oral glucosamine and chondroitin are not recommended (Strong recommendation).
  - Intra-articular corticosteroid injections are an option for short-term relief of OA, have few side effects, and are most effective for patients with more severe symptoms, knee effusions, and/or more severe radiographic findings of degeneration (Weak recommendation).
  - The effectiveness of intra-articular hyaluronic acid (viscosupplementation) is uncertain.
  - Total knee replacement is associated with improved function and should be considered for patients with refractory pain and disability who have radiographic evidence of knee OA.
  - Other therapies which might improve knee pain due to OA include knee brace and/or orthosis, transcutaneous electrostimulation (TENS), hatha yoga, magnet therapy, tai chi, massage therapy, therapeutic ultrasound, and patellar taping.

## 2. DynaMed citation/access date

Title. Osteoarthritis of the knee Author. Elinor Mody In: DynaMed [database online]. Available at: [www.DynamicMedical.com](http://www.DynamicMedical.com) Last updated: 7/22/16. Accessed

## 3. Bottom line recommendation or summary of evidence from DynaMed (1-2 sentences)

Exercise is first line, surgery is an option. However, this is not specific for meniscal tear.

## 4. UpToDate excerpts

### TREATMENT

Initial management — In the absence of hemarthrosis and gross instability, the initial management of a meniscal tear includes the following:

-

Rest the knee.

Avoid positions and activities that place excessive pressure on the knee joint until pain and swelling resolve. Such activities include: squatting, kneeling, twisting and pivoting, repetitive bending (eg, stairs, getting out of a seated position, clutch and pedal pushing), jogging, dancing, and swimming using the frog or whip kick.

- Apply ice to the knee for 15 minutes every four to six hours, while keeping the leg elevated.

- Encourage the use of crutches if the pain is severe.

- A patellar restraining brace may be helpful if quadriceps strength is poor and the knee frequently "gives out."

Patients should begin straight leg raising exercises without weights as the pain begins to wane with the goal of strengthening the quadriceps to provide support to the joint (picture 5). Begin with sets of 10 leg lifts and gradually work up to 20 to 25 lifts, each held for five seconds. With improvement, light weights can be added to the ankle, beginning with a 2 pound weight and gradually increasing the weight to 5 to 10 pounds. In lieu of exercise weights, a heavy shoe or a bag containing one or more books may be used.

Exercise on equipment that requires deep knee bends against resistance, such as the stair stepper and rowing machine, should be avoided until pain and swelling resolve. Suitable exercises may include walking, swimming using a limited freestyle kick, water aerobics, walking or light jogging on a soft platform treadmill, and using a cross-country ski glide machine.

Approach to treatment and orthopedic referral — Definitive treatment of meniscal tears includes:

- Strengthening the muscular support of the knee

- Defining the type and extent of the tear

- Determining the need for surgery

The management of meniscal tears depends upon the type of tear (eg, intrasubstance, horizontal, or vertical (figure 4)), the presence of significant mechanical symptoms, and the presence of persistent knee effusions. Small intrasubstance and vertical tears that cause infrequent symptoms and do not interfere with general knee function can be managed medically with rest, activity restriction, and physical therapy. Many clinicians try to exhaust conservative management options before referring such patients for surgery.

The following factors suggest conservative therapy will be successful [5]:

- Symptoms develop over 24 to 48 hours after the acute injury (as opposed to immediately after)

- Swelling is minimal

- The knee has full range of movement with pain only at or near full flexion

- Pain with McMurray testing occurs only with deep knee flexion

Large, complex tears associated with persistent effusions, tears that frequently cause disabling symptoms, and large tears in contact with the articular cartilage should be

referred to an orthopedist. In addition, if the patient is unable to extend their knee completely ("locked knee"), immediate referral to an orthopedist is necessary. The following factors suggest surgery will be required:

- A severe twisting injury occurred and activity could not be resumed thereafter
- The knee is locked or motion is severely restricted
- Pain develops with McMurray testing involving minimal knee flexion
- An associated anterior cruciate ligament tear exists
- There is little improvement in symptoms after three to six weeks despite proper conservative treatment

5. UpToDate citation/access date

Always use Basow DS as editor & current year as publication year.  
Title. Meniscal injury of the knee Author. Dennis Cardone, Bret Jacobs In: UpToDate [database online]. Available at: <http://www.uptodate.com>. Last updated: 9/16/16. Accessed

6. Bottom line recommendation or summary of evidence from UpToDate (1-2 sentences)

7. PEPID PCP excerpts none

[www.pepidonline.com](http://www.pepidonline.com)

username: fpinauthor

pw: pepidpcp

8. PEPID citation/access data

Author. Title. In: PEPID [database online]. Available at: <http://www.pepidonline.com>. Last updated: . Accessed

9. PEPID content updating

1. Do you recommend that PEPID get updated on this topic?

Yes, there is important evidence or recommendations that are missing

No, this topic is current, accurate and up to date.

If yes, which PEPID Topic, Title(s):

2. Is there an EBM Inquiry (HelpDesk Answers and Clinical Inquiries) as indicated by the EB icon (EB) that should be updated on the basis of the review?

Yes, there is important evidence or recommendations that are missing

No, this topic is current, accurate and up to date.

If yes, which Evidence Based Inquiry (HelpDesk Answer or Clinical Inquiry), Title(s):

10. Other excerpts (USPSTF; other guidelines; etc.)

11. Citations for other excerpts

12. Bottom line recommendation or summary of evidence from Other Sources (1-2 sentences)

**SECTION 4: Conclusions**  
**[to be completed by the Potential PURL Reviewer]**  
**[to be revised by the Pending PURL Reviewer as needed]**



**1. Validity:** How well does the study minimize sources of internal bias and maximize internal validity?

Give one number on a scale of 1 to 7  
(1=extremely well; 4=neutral; 7=extremely poorly)  
1 2 3 4 5 6 7

**2.** If 4.1 was coded as 4, 5, 6, or 7, please describe the potential bias and how it could affect the study results. Specifically, what is the likely direction in which potential sources of internal bias might affect the results?

Happens frequently, presenting to FM outpatient

**3. Relevance:** Are the results of this study generalizable to and relevant to the health care needs of patients cared for by "full scope" family physicians?

Give one number on a scale of 1 to 7  
(1=extremely well; 4=neutral; 7=extremely poorly)  
1 2 3 4 5 6 7

**4.** If 4.3 was coded as 4, 5, 6, or 7, please provide an explanation.

**5. Practice changing potential:** If the findings of the study are both valid and relevant, does the practice that would be based on these findings represent a change from current practice?

Give one number on a scale of 1 to 7  
(1=definitely a change from current practice; 4=uncertain; 7=definitely not a change from current practice)  
1 2 3 4 5 6 7

**6.** If 4.5 was coded as 1, 2, 3, or 4, please describe the potential new practice recommendation. Please be specific about what should be done, the target patient population and the expected benefit.

Out physicians are already recommending exercise/PT prior to surgery, based on already published data. However it is unclear if this is a national practice.

**7. Applicability to a Family Medical Care Setting:**

Is the change in practice recommendation something that could be done in a medical care setting by a family physician (office, hospital, nursing home, etc), such as a prescribing a medication, vitamin or herbal remedy; performing or ordering a diagnostic test; performing or referring for a procedure; advising, educating or counseling a patient; or creating a system for implementing an intervention?

Give one number on a scale of 1 to 7  
(1=definitely could be done in a medical care setting; 4=uncertain; 7=definitely could not be done in a medical care setting)  
1 2 3 4 5 6 7

**8.** If you coded 4.7 as a 4, 5, 6 or 7, please explain.

**9. Immediacy of Implementation:** Are there major barriers to immediate implementation? Would the cost or the potential for

Give one number on a scale of 1 to 7  
(1=definitely could be immediately applied; 4=uncertain; 7=definitely could not be immediately applied)  
1 2 3 4 5 6 7

reimbursement prohibit implementation in most family medicine practices? Are there regulatory issues that prohibit implementation? Is the service, device, drug or other essentials available on the market?

10. If you coded 4.9 as 4, 5, 6, or 7, please explain why.

**11. Clinical meaningful outcomes or patient oriented outcomes:**

Are the outcomes measured in the study clinically meaningful or patient oriented?

12. If you coded 4.11 as a 4, 5, 6, or 7 please explain why.

13. In your opinion, is this a Pending PURL?

Criteria for a Pending PURL:

- Valid: Strong internal scientific validity; the findings appears to be true.
- Relevant: Relevant to the practice of family medicine
- Practice changing: There is a specific identifiable new practice recommendation that is applicable to what family physicians do in medical care settings and seems different than current practice.
- Applicability in medical setting:
- Immediacy of implementation

14. Comments on your response in 4.13

Give one number on a scale of 1 to 7

(1=definitely clinically meaningful or patient oriented; 4=uncertain; 7=definitely not clinically meaningful or patient oriented)

1 2 3 4 5 6 7

Give one number on a scale of 1 to 7

(1=definitely a Pending PURL; 4=uncertain; 7=definitely not a Pending PURL)

1 2 3 4 5 6 7

There was a lot of discussion whether this was an actual practice changer. There is literature supporting this data, thus not making it new.