



2019 Health Technology Reassessment Report

Safety and Effectiveness Assessment of Massage Therapy for the Treatment of Dry Eye Syndrome

Abstract

□ Assessment background

New health technology assessment was performed on massage therapy for the treatment of dry eye syndrome in 2014 as a technology for relieving meibomian gland obstruction in patients with dry eye syndrome by applying heat and pulsation to the periorbital region.

The Ministry of Health and Welfare is in the process of converting 485 technologies that are non-covered items into covered items. This technology has already been assessed as a new health technology among the items to be decided by 2020. Accordingly, evidence update work was performed as a part of the latest health technology reassessment project (NR19-001, Principal investigator: In-Soon Choi).

□ Committee operation

The subcommittee for massage therapy for the treatment of dry eye syndrome consisted of five members (four ophthalmologists and one evidence-based medical expert) who participated in the previous new health technology assessment. Considering the similarity of the technology, the same committee simultaneously assessed both technologies mentioned above.

Starting with the first subcommittee session on April 24, 2019 and third and final session on June 27, 2019, a total of three subcommittee sessions were held for discussion of research protocol, confirmation of the articles finally selected, confirmation of data extraction format, detailed planning for analysis, confirmation of data extraction content and results synthesis, confirmation of level of evidence assessment results, and writing and review of final report.

□ **Assessment objectives and methods**

Massage therapy for the treatment of dry eye syndrome is a technology used for treating dry eye syndrome by stimulating obstructive meibomian gland with heat and pulsation applied to the eyelids and periorbital region. Accordingly, the safety and efficacy of this procedure was assessed.

For systematic literature review of massage therapy for the treatment of dry eye syndrome, five Korean databases, including KoreaMed, and foreign databases, including Ovid-MEDLINE, Ovid-EMBASE, and Cochrane Library, were searched. A total of 261 articles were searched based on the search strategy, and after eliminating 65 duplicate articles, the selection and exclusion criteria were applied to 196 articles and four articles were ultimately included in the final assessment.

All steps, from article search, application of the selection criteria, to data extraction, were performed independently by the subcommittee and two assessors. Risk of bias was assessed using the risk of bias tool developed by Cochrane, while the level of evidence in the outcomes was assessed using the grading of recommendations, assessment, development and evaluation (GRADE) tool. Level of evidence and importance were selected according to the results of the assessment above to describe the assessment results.

□ **Assessment results**

1. Article selection

A total of four articles were used in the assessment. After searching the domestic and foreign databases by the pre-determined protocol, three articles used in previous assessments were excluded and only one article (Nam *et al.*,

2016) was reassessed. When classified by study types, there was one randomized clinical trial (RCT; Lee *et al* 2013) and three pre-post studies (Kim *et al.*, 2013; Goto *et al.*, 2002; and Nam *et al.*, 2016).

2. Safety

The safety of massage therapy for the treatment of dry eye syndrome was reported in all four selected articles.

One RCT (Lee *et al.*, 2013) reported that there were no serious complications in all groups during the 4-week follow-up period, while mild complications were found at a rate of 14.6% in the intervention group (n=6; three cases of temporary visual impairment, one case of headache, and two cases of contact area abnormality) and 4.4% in the control group (n=2; two cases of conjunctivitis).

Three pre-post studies (Kim *et al.*, 2013; Goto *et al.*, 2002; and Nam *et al.*, 2016) reported no subjective complaint or serious complications due to ocular massage during the outpatient follow-up period.

3. Efficacy

The efficacy of massage therapy for the treatment of dry eye syndrome was assessed in the four selected studies using objective indices tear break-up time (TBUT), Schirmer tear test (STT) results, and ocular surface staining (OSS) results and subjective indices ocular surface disease index (OSDI) and standardized patient evaluation of eye dryness (SPEED) results.

One RCT reported that TBUT increased in both the intervention and control groups, while STT results increased in the left eye but decreased in the right eye. OSS results showed that the number of eyes included in lower grade

decreased in both the intervention and control groups. OSDI was improved to a greater degree in the intervention group than the control group, with the difference being statistically significant, whereas TBUT, STT, and OSS results showed no statistically significant differences.

Three pre-post studies reported that TBUT, OSS, OSDI, and SPEED results improved significantly at post-procedure, as compared to pre-procedure, whereas STT results showed no significant change.

4. GRADE assessment

The outcomes with importance determined to be “critical” were TBUT, OSS, and OSDI. Of these, TBUT was assessed to be moderate (left and right eyes), whereas OSS and OSDI were assessed to be low.

The outcomes with importance determined to be “important” were STT, conjunctivitis, and contact area abnormality. Of these, STT was assessed to be moderate (left and right eyes), whereas conjunctivitis and contact area abnormality were assessed to be low.

□ **Conclusions**

The subcommittee on massage therapy for the treatment of dry eye syndrome proposed the following based on currently available assessment results.

With respect to the safety of massage therapy for the treatment of dry eye syndrome, only mild complications were reported as compared to existing technologies. With respect to the efficacy of massage therapy for the treatment of dry eye syndrome, it was similar to or more effective than existing technologies based on objective indicators TBUT, STT, and OSS and subjective

indicators OSDI and SPEED. However, evidence for the objective indicators was sufficient. Accordingly, massage therapy for the treatment of dry eye syndrome could be viewed as a safe and effective technology for patients with dry eye syndrome, but it is determined that additional evidence generation and literature review for the objective indicators are needed from an efficacy perspective.

The Health Technology Reassessment Committee reviewed and determined that the findings of the subcommittee on massage therapy for the treatment of dry eye syndrome are valid (September 20, 2019).