Low-intensity ultrasound (Exogen™) for the treatment of fractures

SUMMARY

AGENCE D'ÉVALUATION DES TECHNOLOGIES
ET DES MODES D'INTERVENTION EN SANTÉ

Québec

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Technology brief prepared for AETMIS
by Reiner Banken

Agence d'évaluation des technologies et des modes d'intervention en santé
Québec

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MISSION

The mission of the *Agence d'évaluation des technologies et des modes d'intervention en santé* (AETMIS) is to contribute to improving the Québec health-care system and to participate in the implementation of the Québec government's scientific policy. To accomplish this, the Agency advises and supports the Minister of Health and Social Services as well as the decision-makers in the health-care system, in matters concerning the assessment of health services and technologies. The Agency makes recommendations based on scientific reports assessing the introduction, diffusion and use of health technologies, including technical aids for disabled persons, as well as the modes of providing and organizing services. The assessments take into account many factors, such as efficacy, safety and efficiency, as well as ethical, social, organizational and economic implications.

FOREWORD

LOW-INTENSITY ULTRASOUND (EXOGEN™) FOR THE TREATMENT OF FRACTURES

Low-intensity ultrasound (Exogen™) is a home-based treatment for certain fractures and fracture complications. The Société de l'assurance automobile du Québec (SAAQ) asked the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) to assess the efficacy and safety of this approach to fracture healing. This technology brief is an adaptation of an advice submitted to the SAAQ.

From the standpoint of safety, based on AETMIS's assessment, the available studies do not report any adverse effects associated with the use of low-intensity ultrasound. As regards efficacy, the report examines the use of the device for three different indications: the acceleration of fracture healing, the prevention of fracture nonunion, and treatment. For these three indications, the efficacy evidence is weak.

As for the acceleration of fracture healing and the prevention of fracture nonunion, the level of evidence is insufficient to recommend the use of low-intensity ultrasound. However, in the case of nonunion of tibial fractures, the prognosis is so severe that it seems reasonable to consider the use of low-intensity ultrasound after failed surgical intervention.

AETMIS therefore considers that low-intensity ultrasound might be an exceptional treatment option for a very small number of patients. In submitting this report, AETMIS wishes to contribute to the advancement of an evidence-based medicine approach in orthopedics and to provide orthopedic surgeons and managers in Québec's health-care system the necessary information on this technology.

Renaldo N. Battista
President

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SUMMARY

Low-intensity ultrasound (Exogen™) is a home-based treatment for certain fractures and fracture complications.

The Société de l'assurance automobile du Québec (SAAQ) asked the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) to assess the efficacy and safety of this approach to fracture healing. This technology brief is an adaptation of an advice submitted to the SAAQ, which included information specific to this organization's decision-making context. This report is intended for a wider audience that includes, among others, professionals who treat patients with fracture complications.

Fracture healing depends on a cascade of complex events. If the healing process is slower than expected, one speaks of *delayed union*, or, if the healing process stops, of *nonunion*. Severe fractures, especially of long bones, such as the tibia, are particularly susceptible to bone union problems. The definition of *nonunion* often specifies absence of healing 6 to 12 months after the fracture. The arrest of healing for more than three months, documented by serial radiographs including multiple views, is also used to define *nonunion*.

The treatment of fractures includes a growing number of various approaches and techniques, one of which is low-intensity ultrasound. This assessment comes at a time when the broadening of the range of therapeutic options for different fractures has not been accompanied by a comparative assessment of the different approaches. The assessment efforts are inadequate and often of relatively poor methodological quality. Also, for many fractures, the optimal treatment is the subject of clinical debate. Furthermore, despite the criteria often used to define nonunion, a certain proportion of these fractures will heal, even after a period of 12 months, if immobilization is maintained long enough.

Presently, Exogen, a technology from the Smith and Nephew Corporation, seems to be the only technology marketed worldwide that uses low-intensity ultrasound to influence the fracture healing process. In Canada, as in the United States, this technology has been approved for the acceleration of the healing of certain fresh fractures with cast immobilization and for the treatment of nonunion. The prevention of nonunion in certain higher-risk patient populations is also promoted as another indication.

Upon an exhaustive analysis of the scientific literature, it was found that the quality of the evidence varies for the three indications mentioned above:

- There is no evidence that low-intensity ultrasound can prevent nonunion in higher-risk patient populations.

- According to a meta-analysis of three randomized trials with a small total number of patients, ultrasound may be effective in accelerating the healing of fractures treated without surgical intervention. Because of the exclusion from this meta-analysis, with no justification given, of one study in which the patients had undergone surgical stabilization and the small total number of patients in the meta-analysis, the efficacy evidence for the acceleration of healing should be considered weak.

- The only studies that have examined the efficacy of Exogen in the treatment of nonunion are retrospective case series with a self-paired study design. This type of analysis seems questionable in cases of nonunion because of the natural evolution of this healing problem.

According to AETMIS's assessment, the available studies do not mention any adverse effects associated with this treatment modality. Given this efficacy and safety evidence, AETMIS considers that, with regard to the acceleration of healing and the prevention of nonunion, the

level of evidence is insufficient to recommend the use of low-intensity ultrasound. However, in the case of nonunion of tibial fractures, the prognosis is so severe that it seems reasonable to consider the use of low-intensity ultrasound after failed surgical intervention and after the consolidation process, as measured by serial radiographs including multiple views, has ceased for several months. As for fracture sites other than the tibia, the uncertainties concerning the efficacy of Exogen in the treatment of nonunion should be assessed in light of the prognosis specific to these fractures and of the clinical context.

Based on the available data, AETMIS therefore considers that low-intensity ultrasound might be an exceptional treatment option for a very small number of patients.

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Québec