### 1 Radial shockwave therapy for a painful bone spur in an above-knee amputee

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5 Dear Editor. Pathological bone formation such as heterotopic ossification and bone spurs
6 can be a significant problem in patients with amputated limbs who undergo physical
7 rehabilitation [1, 2]. Surgical removal can be performed in some cases. However, few
8 studies have evaluated the most appropriate time to perform resection and the risk of
9 recurrence [3]. Surgical excision of heterotopic ossification and bone spurs may also bring
10 major complications such as wound infection, damage to surrounding neurovascular
11 structures, post-operative pain and delays in rehabilitation [3].

12 Radial shockwave therapy (RSWT) consists of high-intensity sound waves interacting with body tissues. In the past few years, RSWT has been proposed for treating 13 14 various painful conditions such as shoulder tendinopathy and calcific tendinitis, Achilles 15 tendinopathy, chronic heel pain and painful stump neuroma [4-6]. The benefit of RSWT is attributed to its effect on bone remodeling. Martini and colleagues showed that low-energy 16 SWT (14 kV and 0.15 mJ/mm<sup>2</sup>) increases osteoblastic (i.e., bone tissue formation) activity, 17 while high-energy SWT (28 kV and 0.40 mJ/mm<sup>2</sup>) increases osteoclastic (i.e., bone tissue 18 breakdown) activity [7]. 19

Some investigators suggest that RSWT could be useful for patients with
pathological bone formation [8, 9]. Brissot and colleagues noted that RSWT reduced pain,
improved range of motion and walking distance, and alleviated the need for an assistive
device in patients with heterotopic ossification of various origins [9]. Lohrer and associates
found similar results in a population of adolescents with Osgood-Schlatter syndrome (a
condition characterized by excessive bone growth) [10].

These positive effects prompted us to use RSWT in a patient with bone spur formation after above-knee amputation and pain that substantially affected physical rehabilitation. The patient, a 39-year-old man, had experienced multiple fractures affecting the right tibia, right greater trochanter, left tibial plateau and right ulna after a motor vehicle

accident. Twenty days after the accident, the patient underwent above-knee amputation of 30 31 the right lower limb. Despite numerous revisions/modifications of the prosthesis (socket, type of suspension), the patient continued to report severe stump pain during physical 32 33 rehabilitation, presumably because of the formation of a bone spur, located near the 34 amputation site. The patient finally adopted a Mauch Knee prosthesis® (seal-in liner), but the presence of pain substantially restricted prosthetic wearing time. Over the next 3 years 35 36 after amputation, different interventions (medications, ice, scar massage, prosthesis adjustments) were tried to improve walking endurance, with limited success. 37

38 We proposed the intervention, consisting of four RSWT treatments (Intelect Mobile 39 RPW, Chattanooga, Guildford Surrey, UK), applied once a week for 4 consecutive weeks. RSWT was applied over the 2 most painful sites, on the anterior and lateral parts of the 40 stump (Fig. 1). A total of 3700 impulses were given at each site with the following 41 protocol: 50 impulses at pressure 1.5 bars and frequency 3 Hz, 50 impulses with pressure 42 43 1.8 bars and frequency 4 Hz, 50 impulses with pressure 2 bars and frequency 6 Hz, and 50 impulses with pressure 3.9 bars and frequency 10 Hz. Hence, a total of 7400 impulses were 44 given per treatment session, except for the first treatment session, when the patient received 45 46 a total of 3700 impulses (RSWT was applied only on the external part of the stump). RSWT parameters were based on the protocol described by Lohrer and colleagues [10]. 47

Before RSWT, pain was evaluated at rest as 0 on a 0-10–mm on a numerical rating
scale (0 = no pain; 10 = worst pain imaginable) and 8 when walking with the prosthesis.
One week after the RSWT treatments, the patient reported that the stump pain had
completely disappeared (score 0 at rest and 0 when walking with the prosthesis). These
pain reductions were maintained 3 months after the last RSWT treatment.

An algometer (FPK Algometer, Wagner Instruments, Greenwich, CT, USA) was used to determine pressure pain thresholds (PPTs) over the 2 most painful regions of the stump, near the bone spur (mean of 3 trials for each site). PPT values before RSWT were estimated at 3.6 kg for the anterior region (region A) and 2.6 kg for the lateral region (region B) of the stump. PPT values increased after 1 week of RSWT for regions A and B (Fig. 2), which indicates decreased pain sensitivity. PPTs further increased 3 months after
the intervention on region B, but decreased, slightly under the initial value, for region A.

Before RSWT, prosthetic wearing time, as reported by the patient, was limited to 15 min daily, owing to pain and discomfort. After the RSWT intervention, prosthetic wearing time increased to 90 min daily. The improvement in prosthetic wearing time occurred 1 week after the end of RSWT and was maintained at 3 months after the last RSWT treatment. The patient reported that the absence of stump pain improved prosthetic wearing time, which was now limited by the presence of pain in the right groin region and the lower back.

Radiography performed 1 week before the RSWT treatments revealed a bone spur
of 12.1 x 6.6 mm on the anterolateral part of the distal right femur, near the amputated site
(Fig. 3). Radiography performed 1 month after the intervention revealed no change in the
size of the bone spur (Fig. 3).

71 Here, we evaluated the effect of RSWT in an above-knee amputee experiencing a symptomatic bone spur near the amputation site. After 4 sessions of RSWT, the patient 72 reported considerable alleviation of pain and increased prosthetic wearing time. These 73 74 improvements were supported by changes in PPT, measured over the 2 most painful 75 regions of the stump, near the bone spur. According to the rehabilitation professionals and 76 to the patient, the pain related to the bone spur played a significant role in the limited 77 amount of time the patient could walk with the prosthesis. Although we cannot exclude that 78 placebo effects contributed to the positive outcomes noted in this patient, they were 79 probably negligible. Indeed, in the last 3 years, the patient had undergone several 80 unsuccessful therapeutic interventions. Hence, conditioning effects and expectations (2 key 81 factors believed to play a role in placebo responses [11]) were probably very low and most certainly had a minor impact on the reported results. Nevertheless, other important 82 83 limitations must be acknowledged (e.g., absence of randomization, control group or formal 84 quantitative test to evaluate walking). Replicating the present results with a larger sample with more rigorous research designs are needed before any final conclusions can be made. 85

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Radiography revealed no variation in the size of the bone spur after RSWT. These 86 87 observations agree with those of Yalcin and associates, who noted that the radiologic changes after RSWT for heel spurs were unrelated to pain reduction [8]. The incongruence 88 89 observed between radiography findings and subjective findings related to pain suggest that 90 RSWT could play a positive role in the rehabilitation of patients with amputated limbs and stump pain related to bone spur formation but that these effects are not driven by 91 92 musculoskeletal changes (i.e., osteoclastic activity reducing osteophyte size). Instead, the 93 application of RSWT over the painful area of the stump could trigger beneficial responses 94 in the nervous system. Other mechanisms such as neovascularisation, reduced inflammation and collagen production could be involved [12, 13] and should be investigated in future 95 96 studies.

97 Few studies have investigated the effect of shockwave on pathological bone 98 formation in patients with amputated limbs. Brissot and associates reported that RSWT 99 reduced pain, improved range of motion and walking distance, and reduced the need for an 100 assistive device in 26 patients with heterotopic ossification of various origins [9]. However, no radiologic measurements were performed to evaluate the effect of RSWT on heterotopic 101 102 ossification size. Another investigation showed that patients with amputated limbs and painful stomp neuroma reported greater pain reduction after RSWT than conventional 103 therapy (transcutaneous electrical nerve stimulation, desensitization and pharmacological 104 therapy) [6]. Changes in the size of the neuroma were comparable with the 2 treatments, 105 which again suggests that the positive effect of RSWT in amputees are probably not solely 106 107 attributable to peripheral changes [6].

108 The results of our case suggest that RSWT could be an interesting therapeutic 109 modality for patients with post-amputation pain related to bone spurs. Radiology revealed 110 that RSWT had no effect on the size of the bone spur. Future studies, investigating the 111 potential mechanisms of action of RSWT in patients with pain related to bone spurs are 112 warranted.

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#### 113 **Consent**

- 114 The research protocol was approved by the ethics committee of the Research Centre on
- 115 Aging (Sherbrooke, PQ, Canada) and the participant provided an informed written consent
- 116 before participating in the study.
- **117** Conflict of interest
- 118 The authors have no conflicts concerning this article.
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## 122 Figure legends

- 123 Figure 1. Region A (superior view) and region B (lateral view) (represented by filled
- 124 circles) of the stump of the amputated right lower limb that were most painful to the 39-
- 125 year-old male. Pressure pain thresholds were measured on these 2 regions before and after
- 126 radial shockwave therapy (RSWT).
- Figure 2. Pressure pain threshold values before (baseline) and 1 week and 3 months afterRSWT for regions A and B of the stump.
- Figure 3. Radiographic images of the bone spur on the amputated limb A) before and B)after RSWT.
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