Effective Treatment of Posttraumatic and Postoperative Edema in Patients with Ankle and Hindfoot Fractures

A Randomized Controlled Trial Comparing Multilayer Compression Therapy and Intermittent Impulse Compression with the Standard Treatment with Ice

Manuela Rohner-Spengler, MPTSc, Angela Frotzler, PhD, Philipp Honigmann, MD, and Reto Babst, MD, PhD

Investigation performed at the Departments of Rheumatology and Physiotherapy and Trauma Surgery, Lucerne Cantonal Hospital, Lucerne, Switzerland

Background: After ankle and hindfoot fractures, edema has a major impact on the time for surgical intervention and may increase the risk of wound complications and infection postoperatively. The aim of this study was to evaluate the efficacy of multilayer compression and intermittent impulse compression therapy in reducing ankle and hindfoot edema compared with the standard treatment with elevation and ice.

Methods: This was a randomized, controlled, single-blinded clinical trial using a repeated-measures design. Fifty-eight patients with unilateral fractures of the ankle or hindfoot were randomized into the cold pack (control) group, the bandage group, or the impulse compression group and were analyzed according to the intention-to-treat principle. The primary outcome was the reduction of edema as measured with the figure-of-eight-20 method.

Results: Preoperatively and postoperatively, there were significant differences in edema reduction between the bandage group and the control group. After two days of intervention, the median preoperative edema reduction in the control group was $2.0 \text{ mm} \pm 5\%$ compared with $11.0 \text{ mm} \pm 23\%$ in the bandage group ($p < 0.017$), and $0.3 \text{ mm} \pm 0\%$ in the impulse compression group ($p > 0.017$). Postoperatively, after two days, the median edema changes were $3.5 \text{ mm} \pm 7\%$ in the control group compared with $7.3 \text{ mm} \pm 22\%$ in the bandage group ($p < 0.017$) and $5.0 \text{ mm} \pm 46\%$ in the impulse compression group ($p > 0.017$).

Conclusions: Multilayer compression therapy results in a faster reduction of ankle and hindfoot edema, although with less ankle dorsiflexion on postoperative day three than the control group, and can be recommended as an alternative treatment. Intermittent impulse compression applied without any extra compression by stockinette or bandage and without elevation in off-session periods cannot be recommended as a superior alternative to the treatment with ice.

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.
edema reduction are available. A common and well-known method is cryotherapy. According to Knight et al., ice can diminish pain, metabolism, and muscle spasm by decreasing tissue temperature and therefore can minimize the inflammatory process after soft-tissue trauma. Nevertheless, its proper application throughout the different stages after trauma remains poorly understood, and evidence is still controversial. Another treatment to reduce edema is compression therapy. Although there is evidence for its positive effects on edema reduction for various techniques, its value for treating acute trauma patients is not well established. Partsch postulated that posttraumatic edema is a good indication for compression therapy, and different techniques of using several layers of wool augmented by several layers of a compression bandage have been described and promoted by various authors since the late 1940s. More recently, multilayer bandaging has been effective in reducing edema in patients with lymphedema and in promoting wound-healing in patients with venous crural ulcers. To our knowledge, no randomized controlled trial investigated the effects of multilayer compression therapy in patients with acute trauma on edema reduction or on complications, such as wound infections, or on patient satisfaction. Multilayer compression bandaging has been used in our hospital with positive effects in treating edema in patients with trauma. Various publications also suggest the use of intermittent impulse compression devices in reducing traumatic edema. These devices contain an inflatable pad that intermittently applies pressure to the plantar arch of the foot to compress the concomitant veins and lymphatic vessels of the lateral plantar artery, thereby enhancing venous backflow.

The aim of this study was to compare the effects of multilayer compression therapy and those of intermittent impulse compression with the effects of the standard treatment with elevation and ice on edema reduction in the treatment of patients with ankle or hindfoot fractures. We hypothesized that both the multilayer compression therapy and the impulse compression are more effective in reducing ankle edema than the standard treatment with elevation and ice. We hypothesized that these effects would result in shorter preoperative and postoperative hospitalization days and in better ankle motion postoperatively.

Materials and Methods

Design

A prospective, randomized, controlled, single-blinded clinical trial, using a repeated-measures design, was carried out in the Department of

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Fig. 1

CONSORT (Consolidated Standards of Reporting Trials) diagram. The asterisk indicates that the impulse compression (IC) group had fourteen patients in the stand-alone treatment and six patients in the adapted protocol. The dagger indicates that the value was analyzed according to the intention-to-treat principle.
TABLE I Summary of Outcome Measures

<table>
<thead>
<tr>
<th>Primary outcome measure</th>
<th>Secondary outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edema, figure-of-eight-20, measured in millimeters, measured daily for a maximum of five days preoperatively inpatient, daily for maximum of five days postoperatively inpatient, and at six weeks postoperatively</td>
<td>Ankles plantar flexion and dorsiflexion, measured in degrees, measured daily for a maximum of five days postoperatively inpatient, and at six weeks postoperatively</td>
</tr>
<tr>
<td>Visual analog scale for pain, measured daily preoperatively and postoperatively inpatient and at six weeks postoperatively</td>
<td>Visual analog scale for patient satisfaction, measured daily preoperatively and postoperatively inpatient and at twelve weeks and one year postoperatively</td>
</tr>
<tr>
<td>Number of inpatient days measured daily preoperatively and postoperatively inpatient</td>
<td>Use of medication measured daily preoperatively and postoperatively inpatient</td>
</tr>
<tr>
<td>Wound-healing measured daily postoperatively inpatient and at six weeks postoperatively</td>
<td>Adverse events measured daily preoperatively and postoperatively inpatient and at six weeks and one year postoperatively</td>
</tr>
<tr>
<td>Foot and Ankle Ability Measure measured at twelve weeks and one year postoperatively</td>
<td>Short Form-36 measured preoperatively inpatient according to the patient state of health before trauma, and at twelve weeks and one year postoperatively</td>
</tr>
</tbody>
</table>

Patients

Patients with unilateral ankle or hindfoot fractures who were referred to the emergency unit from January 2007 to January 2009 were assessed for eligibility (Fig. 1). Patients meeting eligibility criteria (see Appendix) were informed about the study. After obtaining written informed consent, patients were randomized into one of the three treatment groups using sequentially numbered opaque and sealed envelopes. Recruitment was conducted by the physicians of the emergency unit and treatment was assigned by the study coordinator or study assistant. The randomization sequence was generated by computer through an independent software specialist.

Primary and Secondary Outcome Measures

Our primary outcome was the reduction of ankle edema during inpatient period. The figure-of-eight-20 method, as previously described and published by our group, was used to assess edema (see Fig. 2).

Several secondary outcomes were monitored and followed as listed in Table I.

We also recorded the patients’ compliance with the general and groupspecific intervention protocols, their activity during hospitalization, and the following group-specific variables: number of ice gel packs applied per day, sub-bandage pressure, and the intermittent impulse system running time.

Edema and ankle motion were assessed by the examiner, who was blinded to the treatment intervention. For details concerning assessment and blinding procedures, see the Appendix.

Interventions

To control and reduce edema, ice gel packs were applied to the patients in the control group. The second group, the bandage group, received multilayer compression bandages (two layers of wool and two or three layers of short stretch bandage), and the third group, the impulse compression group, was treated with the A-V Impulse System (Orthofix Vascular Novamedix, Andover, United Kingdom). For details on the interventions, see Table II and the Appendix. For preoperative fracture stabilization and to standardize postoperative care, a custom-made orthosis (VACOped vacuum orthosis; OPED, Steinhausen, Switzerland) was used with all patients without external fixation treatment. Further co-interventions for all patients were standardized according to the usual treatment regime of the hospital (see Appendix).

Data Analysis

Sample size calculation (α = 0.05, power = 0.8, sigma = 12) revealed that twenty-eight patients per group would be necessary to detect a difference of 8 mm in figure-of-eight-20 measurements. An 8-mm difference is of clinical relevance, and it is above the minimal detectable change. Thus, our targeted sample size was 102 patients (thirty-four in each group), including a 20% dropout rate. A safety analysis was planned after the scheduled recruitment period of two years. A check for normality was performed with the use of box plots. Group medians were calculated for the description of patient demographic characteristics and baseline data. To evaluate if a specific treatment intervention (e.g., multilayer compression therapy versus intermittent impulse compression versus standard treatment with ice) is important in edema reduction, mixed model analyses were used. The included factors in the models were age, sex, body mass index, smoking, fracture type, number of

Traumatology of the Lucerne Cantonal Hospital, Lucerne, Switzerland. The study was approved by the Ethics Committee of the Canton of Lucerne, Switzerland (Approval-Nr.: 616), and the trial is registered with ClinicalTrials.gov (NCT01389089).

Fig. 2 A photograph showing the assessment of ankle edema with the figure-of-eight-20 method. The intraclass correlation coefficients are >0.99 for both intra-rater and inter-rater reliability, and the minimal detectable change is 7.3 mm when landmarks are used, as in this study.
intervention days (time), treatment intervention, edema at baseline, and severity of hematoma. The two models (one preoperative and one postoperative) with the smallest Akaike information criterion (AIC) were used to determine the significance level of the tested variables. Kruskal-Wallis tests across all three study groups, followed by post hoc analyses with t tests or Mann-Whitney U tests, were then used to examine if there was a significant difference between the groups in edema changes or in any of the secondary outcomes. The significance level, for multiple comparisons, was adjusted according to the Bonferroni method. The effect sizes were calculated according to Cohen.

All analyses were performed according to the intention-to-treat principle. Significance was considered at a two-tailed level of p < 0.05.

Source of Funding
This study was partially funded by Orthofix and by a donation from the national professional group of physiotherapists specializing in lymphatic therapy.

### TABLE II Group-Specific Study Interventions

<table>
<thead>
<tr>
<th>Group</th>
<th>Study Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>Elevation for twenty-four hours with a Hess splint, four ice gel packs a day (minimum of twenty minutes per application), and no compression (no stockinette, no bandages)</td>
</tr>
<tr>
<td>Bandage</td>
<td>Elevation for twenty-four hours with a Hess splint; multilayer compression bandage (twenty-two hours of compression, one hour of bandage removal for blinding before measurements, and one hour of reapplying the bandage); tube gauze, two layers of wool, two or three layers of a short-stretch bandage, extra-padding with wool behind both malleoli*; tightness: moderate compression as easily supported by the patient, without having a feeling of discomfort; in patients with external fixation treatment: tube gauze or regular gauze for skin comfort (not mandatory), same bandage material as that for patients without external fixation; partial unrolling of bandages prior to application (for fitting underneath the fixators); no cold application</td>
</tr>
<tr>
<td>Impulse compression</td>
<td>Intermittent impulse compression: 130 mm Hg, for one second, every twenty seconds; twenty-four hours if possible but at least a mean (and standard deviation) of 8 ± 2 hours a day; at least two consecutive hours per session; lower limb in the horizontal position or lower during the impulse compression session (foot positioned underneath the level of the heart); lower limb in horizontal position in off-session periods (no elevation of the limb leads to impulse compression as a stand-alone treatment); no cold application, no additional compression (no stockinette, no bandages)</td>
</tr>
</tbody>
</table>

*The materials used were Tricofix tube gauze, Artiflex 10-cm padding bandage, and Comprilan short stretch compression bandages (all BSN Medical, Hamburg, Germany).

### TABLE III Changes in Preoperative Edema

<table>
<thead>
<tr>
<th></th>
<th>Control Group</th>
<th>Bandage Group</th>
<th>Impulse Compression Group</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>At one day</td>
<td></td>
<td></td>
<td></td>
<td>0.01</td>
</tr>
<tr>
<td>No. of analyzed patients</td>
<td>19</td>
<td>16</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Figure-of-eight-20 † (mm)</td>
<td>0.3 (–3.0; 3.3)</td>
<td>–6.7 (–12.4; –0.2)</td>
<td>2.7 (–3.3; 8.0)</td>
<td></td>
</tr>
<tr>
<td>At two days</td>
<td></td>
<td></td>
<td></td>
<td>0.03</td>
</tr>
<tr>
<td>No. of analyzed patients</td>
<td>19</td>
<td>14</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Figure-of-eight-20 † (mm)</td>
<td>–2.0 (–8.0; 4.7)</td>
<td>–11.0 (–16.0; –5.0)</td>
<td>–0.3 (–10.5; 5.8)</td>
<td></td>
</tr>
<tr>
<td>At three days</td>
<td></td>
<td></td>
<td></td>
<td>0.01</td>
</tr>
<tr>
<td>No. of analyzed patients</td>
<td>13</td>
<td>14</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Figure-of-eight-20 † (mm)</td>
<td>–1.3 (–9.7; 5.3)</td>
<td>–15.2 (–17.9; –9.8)</td>
<td>–1.8 (–11.3; 4.9)</td>
<td></td>
</tr>
<tr>
<td>At four days</td>
<td></td>
<td></td>
<td></td>
<td>0.05</td>
</tr>
<tr>
<td>No. of analyzed patients</td>
<td>10</td>
<td>11</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Figure-of-eight-20 † (mm)</td>
<td>–7.1 (–14.8; –2.8)</td>
<td>–20.7 (–22.7; –13.3)</td>
<td>–13.5 (–19.3; –3.0)</td>
<td></td>
</tr>
<tr>
<td>At five days</td>
<td></td>
<td></td>
<td></td>
<td>0.04</td>
</tr>
<tr>
<td>No. of analyzed patients</td>
<td>6</td>
<td>4</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Figure-of-eight-20 † (mm)</td>
<td>–13.7 (–17.3; –1.1)</td>
<td>–21.3 (–33.5; –19.4)</td>
<td>–20.7 (–29.7; –17.7)</td>
<td></td>
</tr>
</tbody>
</table>

*The p values are between-group differences across all three groups, based on Kruskal-Wallis tests. †The values are given as the median, with the 25% and 75% quartiles in parentheses; negative numbers reflect edema reduction, and positive numbers reflect an augmentation of edema. ‡On the basis of the Mann-Whitney tests (adjusted alpha = 0.017), there were significant differences between the impulse compression group and the bandage group, but no significant difference between the impulse compression group and the control group. §On the basis of the Mann-Whitney tests (adjusted alpha = 0.017), there were significant differences between the control group and the bandage group.
Results

Participant Flow

After the scheduled recruitment period of two years, when sixty-seven patients were enrolled, safety analysis showed that significant differences in the main outcome had occurred and recruitment was halted.

Three of the recruited patients were directly excluded after randomization because of fracture instability. Six patients who originally were randomized into the impulse compression group are not included in the present analysis because of a protocol change during the conduct of the study. Therefore, fifty-eight patients were analyzed according to the intention-to-treat principle (Fig. 1).

Baseline Characteristics

Patient demographic characteristics and baseline variables are presented in the Appendix. Not all of the fifty-eight patients had preoperative and postoperative data available as some were included preoperatively and postoperatively and some were included only postoperatively.

Edema Changes

The medians and upper and lower quartiles of the changes in edema, as measured with the figure-of-eight-20 in millimeters, for each group, over a period of five days preoperatively and five days postoperatively, are presented in Tables III and IV and in Figures 3 and 4.

Preoperatively, the mixed model analysis revealed that the variables of time ($p < 0.001$), treatment intervention ($p = 0.005$), and fracture type ($p = 0.016$) are significant factors in...
that the compression applied was too tight and the bandage had
healing. Three patients in the bandage group reported once each
group and one patient in the bandage group had delayed wound-
follow-up, see the Appendix.

Secondary Outcomes and Follow-up
The bandage group showed significantly less median ankle
dorsiflexion (p = 0.03) on the third postoperative day than the
control group. For further secondary outcome measures and
follow-up, see the Appendix.

During the inpatient period, one patient in the control
group and one patient in the bandage group had delayed wound-
healing. Three patients in the bandage group reported once each
that the compression applied was too tight and the bandage had
to be adjusted. Of the control group, two patients reported pain
when the ice gel pack was applied, and this treatment was
temporarily stopped. Of the impulse compression group, seven
patients discontinued their allocated treatment. Four perceived
more pain when the impulse compression system was on, two
developed a wound complication, and one both perceived
more pain when the impulse compression system was on and
developed a wound complication.

Use of medication, activity level, and adherence to the study
protocols were comparable, with no significant differences among
the groups.

In the follow-up period, in the impulse compression
group, one patient had a superficial wound infection with
Staphylococcus aureus and another patient had skin necrosis.
The two patients were treated with antibiotics and local de-
bridement. In both the control group and the bandage group,
one patient in each group had a delay in wound-healing. All
adverse events were unrelated to the study treatments, and all
fractures were healed at the latest follow-up.

We found no significant differences in the Foot and
Ankle Ability Measure or in the Short Form-36 between the
three groups after three months or one year postoperatively
after adjusting for Bonferroni.

Considering the interventions, patients in the control
group received approximately 4.5 ice gel packs a day preoper-
avely and approximately four ice gel packs postoperatively.

The mean sub-bandage pressure (and standard devia-
tion) was 31.5 ± 8.9 mm Hg preoperatively and 27.3 ± 9.1 mm Hg
postoperatively. Patients in the impulse compression group

<table>
<thead>
<tr>
<th>TABLE IV Changes in Postoperative Edema</th>
</tr>
</thead>
<tbody>
<tr>
<td>At one day</td>
</tr>
<tr>
<td>No. of analyzed patients</td>
</tr>
<tr>
<td>Figure-of-eight-20† (mm)</td>
</tr>
<tr>
<td>At two days</td>
</tr>
<tr>
<td>No. of analyzed patients</td>
</tr>
<tr>
<td>Figure-of-eight-20† (mm)</td>
</tr>
<tr>
<td>At three days</td>
</tr>
<tr>
<td>No. of analyzed patients</td>
</tr>
<tr>
<td>Figure-of-eight-20† (mm)</td>
</tr>
<tr>
<td>At four days</td>
</tr>
<tr>
<td>No. of analyzed patients</td>
</tr>
<tr>
<td>Figure-of-eight-20† (mm)</td>
</tr>
<tr>
<td>At five days</td>
</tr>
<tr>
<td>No. of analyzed patients</td>
</tr>
<tr>
<td>Figure-of-eight-20† (mm)</td>
</tr>
</tbody>
</table>

*The p values are for between-group differences across all three groups, based on Kruskal-Wallis tests. †The values are given as the median, with the 25% and 75% quartiles in parentheses; negative numbers reflect edema reduction, and positive numbers reflect an augmentation of edema. ‡On the basis of the Mann-Whitney tests (adjusted alpha = 0.017), there were significant differences between the control group and the bandage group, but no significant difference between the impulse compression group and the control group or between the bandage group and the impulse compression group.
Discussion

The results of this study show that multilayer compression therapy is a very effective edema-resolving method in patients with ankle and hindfoot fractures, which may reduce the length of hospital stay. Considering the impulse compression treatment, there seems to be a tendency toward a better edema reduction as compared with ice, when applied preoperatively for more than three days. In contradiction to the findings of prior studies, we could not find significantly different effects of the impulse compression treatment as compared with the standard treatment with ice, when the impulse compression was applied as a stand-alone treatment (with no elevation of the affected limb and no additional compression by bandage or stockinette). Stöckle et al. found that the impulse compression showed the fastest swelling reduction in all measured areas both before and after surgery as compared with cool packs (applied four times daily). They reported an average twenty-four-hour edema reduction of 53% preoperatively in the impulse compression group, whereas the cool pack group had a reduction of 10%. Caschman et al. found that the impulse compression in-cast system significantly reduced the time taken for ankle swelling to diminish prior to surgery when compared with elevation only. They also found that wound and skin complications could be reduced. We believe that the use of different modes of impulse compression and its co-interventions throughout prior studies contribute to our controversial findings. We suspect that positioning of the limb (with or without elevation) during impulse compression sessions and in off-session periods and the addition of a compressive force, as applied, for example, by stockinette, play an important role. There is a lack of precise description of the impulse compression application and its co-interventions in prior studies, making comparisons of the results difficult. We believe that limb positioning and any sort of compression are potential confounders in clinical investigations. In our study, we tried to avoid having compression be a potential confounder. Therefore, the patients in the control and impulse compression groups did not receive any sort of preoperative compression therapy. Postoperatively, all patients used the VACOped orthotic support system fully (vacuum on) for mobilization and removed it afterwards, thereby allowing compressional forces only while the limbs were kept in a vertical position during walking.

Lack of blinding, or the use of unvalidated outcomes measurements, as seen in previous studies, might also have contributed to the controversial findings of our study as compared with others. In our study, blinding was successful in approximately 91% of the measurements. Unblinding mostly occurred in the later postoperative phase and was random. The surgeons were not blinded to the interventions. Therefore, our results regarding the number of days until possible operation should be interpreted with caution. Nevertheless, because the mean edema (and standard deviation) at the time of readiness for surgery, as measured by the blinded physiotherapists, was 121.2 ± 12.4 mm in the control group, 21.2 ± 12.4 mm in the bandage group, and 25.1 ± 14.4 mm in the impulse compression group, we believe that the surgeons were not influenced in favor of the two intervention groups. On the contrary, we believe that the effect of the two intervention groups in reducing days until possible operation might even be underestimated somewhat, as the control group was considered ready for operation with a larger mean preoperative edema than the two other groups. Despite the finding that the patients in the bandage group tended to perceive somewhat more pain preoperatively than the patients treated with ice, the intervention was well tolerated and no patient wanted to discontinue the bandage. Conversely, despite the finding that the patients in the impulse compression group had pain levels comparable with those of the control group, a subset of these patients did not tolerate the intervention well and requested to be changed to the intervention of the control group. Other authors reported similar negative effects of impulse compression. According to the findings of many authors who concluded that ice is effective in reducing pain, we assumed that the patients in the control group probably would have had less pain as compared with the patients in the two other groups. After surgery, the patients in the bandage group had a tendency toward less pain than the patients in the control group. At the expense of ankle motion, the bandage has a stabilizing and protective effect.

There were several limitations in this study. We chose elevation and ice as treatment for the control group. One argument to choose ice for the treatment in the control group is that its use is still widespread and clinicians and patients consider ice as the standard treatment. Nevertheless, the application of ice in the control group could have contributed to an overestimation or underestimation of the effects of the two intervention groups.

During recruitment of the patients, we observed that the effect of the impulse compression intervention was not as expected. Despite our attempts to keep the medical staff neutral toward the patients’ interventions, impartiality could not be guaranteed throughout the study. It is possible that their observations induced a decreasing tolerance toward the impulse compression device. As a consequence of these problems, we believed that there was a need to modify the original impulse compression intervention protocol. The last six patients who were randomized into the impulse compression group were thus treated according to an adapted modified protocol, with elevation in off-session periods. To avoid flawed results and conclusions, the data of these six patients were not included in the current intention-to-treat analyses.

After the scheduled study period, before reaching the targeted sample size (n = 84), because of financial constraints and for feasibility reasons, we stopped patient recruitment. Even though the statistical analyses revealed some significant effects, the study overall remained underpowered (somewhat underpowered considering the results of the bandage group...
compared with the control group, and strongly underpowered considering the comparisons between the impulse compression group and the two other groups).

Although the results of this study were obtained in inpatient care, we believe that they can also be applied to outpatient care. Postoperatively, patients can easily be trained to apply the bandage themselves. Before fracture stabilization, the multilayer bandage can be applied by specialists in the emergency unit and afterwards by trained home care providers. In the outpatient setting, we believe that patients with soft-tissue injury only, such as patients with ankle sprains, could also benefit from multilayer bandaging.

In conclusion, in patients with acute trauma, multilayer compression therapy leads more quickly to a clinically relevant and significant reduction of ankle and hindfoot edema than the standard treatment with ice. We cannot recommend intermittent impulse compression as a superior alternative to the treatment with ice, when it is applied as a stand-alone treatment (e.g., without elevation in off-session periods and without any form of external compression).

**Appendix**

Text describing the details of the assessment and blinding procedures, a figure demonstrating postoperative applications for each group, and tables showing eligibility criteria, patient demographic characteristics and baseline data for preoperatively and postoperatively included patients, secondary outcomes, and standardized co-interventions for all patients are available with the online version of this article as a data supplement at jbjs.org.

**References**


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32. Manuela Rohner-Spengler, MPTSc

33. Philipp Honigmann, MD

34. Rete Babst, MD, PhD

35. Departments of Rheumatology and Physiotherapy (M.R.-S.) and Trauma Surgery (M.R.-S., P.H., and R.B.), Lucerne Cantonal Hospital, Spitalstrasse, 6000 Lucerne, Switzerland.

E-mail address for M. Rohner-Spengler: manuela.rohner@luku.ch

Angela Froitzler, PhD

Clinical Trial Unit, Swiss Paraplegic Centre, Guido A. Zech Strasse 1, 6207 Nottwil, Switzerland


