Background and study aims: Nasogastric intubation, one of the most widely utilized therapeutic procedures in medical practice, is associated with trauma, pain, and discomfort, which can occur both at insertion and during the indwelling phase. Although lubricating jelly is useful during the insertion phase, insertion can still cause great discomfort. Furthermore, the jelly is rapidly absorbed and therefore is unable to decrease the friction between the tissues and the tube during the indwelling phase of the nasogastric tube. The aim of this study was to test a device, the NG-Shield, that generates surface acoustic waves on the surfaces of the nasogastric tube to reduce contact time and thus friction between the nasogastric tube and body tissues.

Patient and methods: Twenty-four healthy volunteers were enrolled in a single-center, crossover, blinded study, in which a nasogastric tube was inserted and left indwelling for 6 hours. Throughout the indwelling period the device was activated and deactivated alternately every hour, and the volunteers were questioned every hour about their pain and discomfort levels as well as grading pain and discomfort upon insertion and removal of the nasogastric tube. Pain and discomfort levels were compared between active and nonactive phases of the device.

Results: The activated NG-Shield was found to reduce both pain and discomfort significantly in both the nose and throat throughout the indwelling phase.

Conclusions: The NG-Shield is a safe and effective device for reducing pain and discomfort associated with an indwelling nasogastric tube.
when acoustic waves are introduced between sliding surfaces, causing them to be in contact only half of the time and hence substantially reducing friction.

NG-Shield consists of two parts: a programmable driver and a disposable actuator, which is clipped onto the nasogastric tube in order to create the desired acoustic lubrication (Fig. 1).

Acoustic waves travel and transfer from one point to another, producing micro on the surface of the nasogastric tube. As a result, the contact time and contact area between the two surfaces (nasogastric tube and nasopharyngeal tissues) are reduced. The acoustic waves are also intended to reduce the adhesion effect of the tube on the nasopharynx, which causes irritation while the tube is in use (Fig. 2).

**In vitro testing**

The nasogastric tube with the NG-Shield actuator coupled to it was tested in an independent laboratory using the FTS 5000 friction test system of Harland Medical Systems Inc. (Eden Prairie, Minnesota, USA). The analytical work was performed by Harland Medical Systems. The results proved that application of acoustic lubrication to nasogastric tubes reduced the coefficient of friction by 26%.

**Trial in normal healthy volunteers**

After approval of the study design by the Institutional Review Board committee at Bikur Cholim Hospital, Jerusalem, Israel, 24 persons (average age 26.5 years) were enrolled in the study. Exclusion criteria included age under 18 years and any history of acute or chronic pharyngeal disease or pain. All persons gave their signed informed consent and fasted for 12 hours before insertion of the nasogastric tube. Two persons withdrew from the study prior to nasogastric tube insertion. The 22 remaining persons were randomized to one of two “treatment” groups. Group A had the nasogastric tube inserted with the device in the activated mode and subsequently had the device turned off for every other hour for a total of 6 hours. The tube was then removed while the device was inactive. Group B had the nasogastric tube inserted while the device was inactive and had the device activated for every other hour for a total of 6 hours. The tube was then removed while the device was active. Over the course of each hour, probands were asked to read aloud, move their heads, cough, and swallow. Pain and discomfort were assessed at regular intervals. Although it was difficult to fully blind the probands in this study, as the device does vibrate slightly and can generate a slight sensation to the nasal mucosa, they were not told which device they would receive or what, if any, sensation they would experience, or its significance.

**Assessment of pain and discomfort**

Assessment of subjective perception of treatment was performed by asking the probands to rate pain and discomfort in their nose and throat on a scale of 0 – 10 in accordance with the Numerical Rating Scale (NRS)-validated numerical pain scale. Pain and discomfort were assessed at 30-minute intervals for the duration of the 6 hours as well as during insertion and removal of the nasogastric tube.

**Results**

The two study groups were comparable with regard to age, gender, and body mass index. There was one adverse event unrelated to the device in which one person asked to be removed from the study after 4 hours because of nasal pain. Upon removal, a kink in the nasogastric tube was found to be the cause of the pain. There were no significant differences between the two groups with regard to pain and discomfort during insertion (pain: 4.6 ± 3.1 vs. 4.5 ± 2.5, P=0.4) or removal of the tube (pain: 4.5 ± 2.8 vs. 4.4 ± 3.4, P=0.47). During the indwelling phase of the study, the activated NG-Shield was found to reduce pain and discomfort.
significantly in both the nose and the throat in both groups (up to 57% reduction of discomfort as compared to the baseline, \( P = 0.009 \)). The relationship between the device activity and symptoms could be seen repeatedly in a cyclic fashion as the device mode varied between active and inactive (Fig. 3).

In those volunteers whose initial discomfort was scored 4 or higher, the differences between the inactive and active phase in the throat and nasal region were even more pronounced. Of significance was that when the efficacy curves of the two groups were superimposed, they were seen to be mirror images of each other, supporting the premise that the surface acoustic waves are efficacious in improving the pain and discomfort associated with the indwelling phase of a nasogastric tube (Fig. 4).

**Discussion**

Historically, pain and discomfort have been an expected by-product of medical procedures and therapy. Recent advances in the management of pain and discomfort, and increasing awareness among the medical community of these advances, have made many medical interventions more tolerable for patients. Despite these advances, however, a very common intervention such as placement of a nasogastric tube continues to be associated with significant pain and discomfort as well as other complications. Nasogastric tube insertion has been rated by both patients and practitioners as the most painful and distressing procedure performed in the emergency room [1]. Most pain from this device is manifested in the nose and/or throat. The pain, which can occur in either or both of these regions, is sometimes severe or even debilitating. In addition to the subjective experience of pain, when the tube is left in place, the friction and pressure it generates can occasionally lead to significant complications such as nasal septal trauma, mucosal ulcerations, and sinusitis. As the nasogastric tube continues to be widely employed, there is a need for modalities that can address the pain and discomfort associated with its use.

Pain is identified as a clinical entity in itself, mandating adequate attention and appropriate management. In the Leadership Summit on Pain Management sponsored by the Joint Commission on Hospital Accreditation of Health Care Organizations (JCAHO) and the American Pain Society (APS) it was agreed that inadequate pain control will no longer be accepted because “poor pain control is unethical, clinically unsound and economically wasteful” [2].

The results of the present study demonstrate that the NG-Shield consistently reduced both nasal and pharyngeal pain caused by...
an indwelling nasogastric tube. Although the overall trend for both groups over the course of the 6 hours was one of pain reduction and acclimatization to discomfort, pain and discomfort were found to be significantly increased and remained elevated during the “device-inactive” hours and consistently decreased during the “device-active” hours. This effect was demonstrated to be reproducible as each group consistently demonstrated reduced pain with the device activated and increased pain with the device off during the alternating “on/off” cycles. This effect resulted in a sinusoidal pain curve, with peak pain occurring during the “device-off” phase and the trough occurring during the “device-on” phase (Fig. 3). Furthermore, the effects of the device were particularly pronounced in the subjects who experienced the most severe pain.

Friction and contact pressure of the nasogastric tube against the surrounding mucosa are considered to be responsible for the pain and discomfort. By creating 1- to 2-µm-amplitude acoustic waves along the surface of the tube, the contact time between the tube and the soft tissue is reduced, leading to a reduction in friction and irritation (Fig. 3).

**Conclusion**

Nasopharyngeal pain caused by indwelling nasogastric tubes can be one of the most uncomfortable aspects of a hospital stay. Although there is as yet no functional replacement for nasogastric tubes in current medical practice, pain related to the nasogastric tube is now seen as a significant clinical entity, mandating appropriate medical attention. The surface acoustic wave microvibration technology shows promise in alleviating nasopharyngeal pain caused by these indwelling tubes, thereby leading to improved patient experience and, potentially, outcome. Although the study was not designed to evaluate nasopharyngeal inflammation and ulceration, it is expected that these underlying presumed causes of nasopharyngeal discomfort would be affected in parallel. Further studies on patients with long-term indwelling nasogastric tubes are necessary to confirm these effects.

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**References**