The Hand-Arm Vibration International Consortium (HAVIC): Prospective Studies on the Relationship Between Power Tool Exposure and Health Effects

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Objectives: *The Hand-Arm Vibration International Consortium (HAVIC) is a collaboration of investigators from Europe and North America studying health effects from hand-arm vibration (HAV). Features include prospective design, cross-cohort exposure, and health assessment methods.* ***Methods:*** *Two new cohorts (dental hygienists and dental hygiene students), two existing cohorts (Finnish forest workers, and Swedish truck cab assemblers), and a previous population (US shipyard workers) are included. Instruments include surveys, quantitative medical tests, physical examination, and work simulation and data logging to assess exposure. New methods were developed for nerve conduction and data logging.* ***Results:*** *Findings on the relationship between nerve conduction and skin temperature in HAV-exposed subjects resulted in a new approach to subject warming.* ***Conclusions:*** *Integrating established cohorts has advantages over de novo cohort construction. Complex laboratory tests can be successfully adapted for field use.* (J Occup Environ Med. *2007;49:289–301*)

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The damaging effects of segmental vibration on the upper extremity were first recognized in Europe and the United States more than 80 years ago.[1,2] In epidemiological studies, exposure to vibrating power tools has been associated with injury to peripheral nerves and blood vessels, collectively termed the hand-arm vibration syndrome (HAVS).[3,4] In the past quarter century, there has been a concerted international effort to standardize the stigmata of exposure-related disease and the measurement and control of power tool performance. The Stockholm Workshop scale[5,6] provided a consensus rating system for the two hallmark disorders associated with HAVS: 1) vasospasm and disturbances of digital circulation, and 2) neurosensory dysfunction. Exposure characterization has evolved iteratively through ISO committee work,[7,8,9] and through implementation by European Directive 2002/44/EC,[10] the "Physical Agents (Vibration) Directive." The exposure-response threshold (Raynaud phenomenon in 10% of an exposed population) is projected from historical prevalence studies, completed prior to current improved tool design and deliberate exposure reduction. The Directive introduces an exposure action value (EAV) at 2.5 m/s^2 A,[8] above which a program of protective measures and health surveillance must be in place, and also sets an exposure limit value (ELV) at 5.0 m/s^2 A,[8] above which further expo-

sure is prohibited. Jetzer et al[11] have reported that symptomatic disease appears to be preventable within levels described by European Directive 2002/44/EC.[10]

Apart from enforcement, compliance, and the export of hazards, disease reduction has not resolved etiological issues. Exposure reduction has successfully predicted declining finger blanching, without clarifying other disease associations, including 1) carpal tunnel syndrome (CTS), which is often confounded by biomechanical factors[12]; 2) a pattern of upper extremity muscle weakness[13,14]; 3) bone and joint disorders; and 4) problems at the more proximal upper extremity loci—elbows, shoulders, and the neck.[15] In addition, HAVS continues to occur, even with the substitution of anti-vibration (AV) tools, thus provoking consideration of the biological effects of higher frequencies, of the comparability of impact and oscillatory vibration, and of the reliability of exposure metrics extrapolated from simulated tool testing.[16] Bovenzi[17] aptly attributed uncertainty with the exposure response relationship to deficiencies in effective prospective design and to limitations in exposure assessment.

In 2000, the US National Institute for Occupational Safety and Health (NIOSH) requested more effective exposure assessment instruments and prospective studies for the broader area of work-related musculoskeletal diseases (MSDs), including hand-arm vibration—Collaborative Program for the Identification and Prevention of Work-Related Musculoskeletal Disorders (RFA OH-OO-OO30). In response, investigators from North America, Sweden, and Finland established a Hand-Arm Vibration International Consortium (HAVIC), and cited the following objectives: 1) prospective design, 2) common exposure metrics across cohorts, 3) common health assessment instruments across cohorts, and 4) methods for multisite integration. Methodologies are described in this paper.

Background

Pitfalls of Studies of Vibration Health Effects

There are relatively few follow-up studies that have assessed established cohorts nonamnestically, most of these being directed to the vascular component of HAVS. Ekenvall and Carlsson[18] were able to follow up 43 of 68 subjects, originally studied with cold challenge plethysmography. One major shortcoming, also affecting other post hoc clinical studies, was the variable inter-test interval—3.5 to 6.0 years. Peterson et al[19] restudied 102 subjects from an original cohort of 132, each having baseline cold challenge plethysmography and symptom scaling. The retesting interval was also heterogeneous, ranging from 1 to 13 years. Cherniack et al[20] reported sequential vascular test results on 199 subjects, but the cohort was initially defined by disease, rather than by exposure. Despite limitations, each of these studies suggests some reversal of disease with exposure control. They also suggest the need for several years of observation, a serious consideration when exposure reduction has occurred and where cumulative health effects, natural recovery, response thresholds, and differential components of exposure may all interact. A prevalence study on shipyard workers that mimicked an earlier 1988 study[21] was conducted as a baseline for this longitudinal study.[22] The robust exposure response relationships that prevailed in the 1980s had lessened, most likely because of extensive administrative controls and tool replacement.

Caution is also required when the period of observation is shortened. Bovenzi and Allessandri[23] performed a follow-up study of vibration-induced Raynaud phenomenon among forestry workers, observations being made in 1990 and 1995. Changes in symptoms and test results during the 5-year interval were difficult to differentiate from background incidence flux. Among shipyard workers, categorical changes in symptoms required at least 3 years before detection.[21] Furthermore, protocol evolution leading to more sensitive quantitative medical tests may introduce a bias toward accumulated, rather than current, exposures. Exposure attenuation and revised tools may lower incidence rates and the pattern of clinical change.

From this and other examples, we determined that it was highly unlikely that a single population would contain sufficient response variability to offer meaningful results over a restricted period of observation. The approach taken by HAVIC, therefore, involved the selection of multiple cohorts, each with specific exposure characteristics and/or usable historical data, so that some quantitative measures would be consistent across follow-up intervals.

Study Aims and Cohort Selection

The HAVIC study has the following objectives:

- Characterization of the exposure response relationship for hand-arm vibration through a study design incorporating multiple cohorts, some having existing historical data,
- Selection of cohorts sufficiently diverse to include different types of vibration: oscillatory (forest workers), impact (truck cab workers), high frequency (dental hygienists), and mixed (shipyard workers),
- Inclusion of two inception cohorts: dental hygiene students and Swedish truck cab workers,
- Inclusion of multiple cohorts from very different occupations to insure a range of exposures and responses,
- Selection of battery of "best tests" applied across groups to quantify responses to exposure, and
- Exposure characterization through daylong data logging at the individual level.

Populations exposed to vibratory hand tools were selected from three previously studied sites: a shipyard in the United States[21]; a truck cab manufacturing plant in Sweden; and an historic Finnish forestry workers cohort in Suomussalmi.[24] Two new cohorts, experienced dental hygienists and dental hygienist students, were assembled to study high-frequency vibration. The study design incorporates elements that are prospective and that also include historical follow-up. By incorporating additional cohorts with specific characteristics—truck cab assembly (inception and follow-up); forestry (long tenure and no impact tools); and dental hygiene (high frequency)—separable characteristics of exposure are accessible over a relatively short follow-up interval. The international character of the research team necessarily involved the homogenization of study instruments that have evolved somewhat independently. A description of the study populations and the selection of study instruments follow.

Connecticut Shipyard Workers

This shipyard population has been the subject of several clinical studies,[25,26,27] and one large population study.[21] There has been more than a decade of exposure reduction through tool modification and engineering controls. When studied in 1988, there was a full-time grinding department subgroup of 460 workers, of whom 71% had vascular symptoms, and 84% had hand paresthesias. Significant organizational changes took place. By 2001, there were only 31 full-time grinders; the overall production workforce had decreased from 7624 to 1708. For HAVIC, recruitment goals were 230 subjects: 80 to 90 with high and moderate exposure and 45 to 50 without current exposure. Baseline and single follow-up was anticipated. Recruitment numbers were successfully reached (see Table 1).

TABLE 1
Projected and Participating Cohorts

Cohort	US Shipyard Workers	Swedish Truck Cab Workers	Swedish Controls	Finnish Forest Workers	Experienced Dental Hygienists	Student Dental Hygienists
Projected	220–230	148	90	80	80	80
Actual	217	56	34	61	94	66

Suomussalmi Forest Worker Cohort

The longest established study of vibration-exposed workers, the Suomussalmi forest worker cohort, consists of all forest workers employed by the National Board of Forestry in the parish of Suomussalmi, Finland. The Finnish Institute of Occupational Health (FIOH) has studied the health of this open cohort prospectively since 1972, beginning with 205 men. By the mid-1980s, VWF prevalence had declined from 40% to 5% of the population; hand and finger numbness had also declined from 78% to 53%. Of those with hand paresthesias, carpal tunnel syndrome was diagnosed in half of the forest workers.[28] In 1992, Koskimies et al[14] reviewed the cohort experience over 18 years and noted a dramatic process of exposure reduction due to antivibration chainsaws from 14 to 2 m/s^2. In a 1995 restudy, there were four active cases and thirteen inactive cases of VWF in the incumbent forestry cohort ($n = 52$) with only one new case since 1990.[29] Results suggested resolution of HAVS, obviating the rationale for further follow-up study. The Suomussalmi cohort was reconstructed specifically for this project on the presumption that HAVS had been halted or was progressing very slowly, thus providing a no-effect threshold for intercohort comparison.

The cohort has additional relevance. A closed subcohort had been formed in 1990 (10% of cohort) to prospectively study neurological disturbances, providing an unparalleled opportunity for studying long-term mechanoreceptor injury. Many of the laboratory assessment metrics employed in this study had been introduced or considered at Suomussalmi. These include cold challenge plethysmography,[30] vibrotactile thresholds,[31] and electrodiagnostic tests.[32] The sensorineural basis of HAVS was clarified on this population.[33,28]

With the introduction of mechanized harvesters in the mid-1990s, the number of chainsaw operators fell to <80. Brush cutters were introduced in the mid-1990s. For HAVIC, a vibration-exposed group of 80 forest workers and controls was proposed, including follow-up of the 1990 subcohort. The full 2002 workforce ($n = 61$) participated, 52 of them being long-term employees.

Umea Truck Cab Assembly Cohort

In 1994 the Swedish National Institute of Working Life (NIWL) and a major European truck cab automotive manufacturer in Umea, Sweden, initiated an inception cohort study, directed to neurological effects from hand-transmitted vibration. A cohort of workers <30 years old without prior vibratory exposure was recruited, with planned 5-year follow-ups. Basic information on age, work assignment, general health status, and previous and present exposure to vibration was obtained by questionnaire. Multi-frequency vibrotactile and thermal perception thresholds were measured on both hands. However, physical examination and nerve conduction studies required a symptom trigger. At inception, there were 148 vibration-exposed workers and an age-matched non-exposed group of 90 participants.

Truck cab assembly involves use of pneumatic vibratory hand-held

tools that are rotary (grinders, screwdrivers, drills) and impulsive (nut runners). The HAVIC study presumes integration of previous data from questionnaires, vascular studies, neurological studies, physical examination, and exposure assessment.

Several departures from the starting design have been required. Only 56 production workers and 34 referents were available from the original cohort, despite participation rates of nearly 100%. Even in this stable workforce, there was significant outmigration or transfer to nonvibration-exposed employment over the decade. The principal factor was substitution of manual jobs by robotic production. In effect, the younger age of the cohort mitigates against age-related workforce conservation. We had originally planned to study the Umea workforce twice within the 5-year duration of the study. However, a comparison of 1997 (historical) and 2002 (incumbent) results for the most sensitive tests showed only the subtlest exposure-associated differences. We therefore concluded that the 3+-year inter-test interval, the longest duration possible in this study, was insufficient and that follow-up should be delayed for at least 2 years.

Dental Hygienists

The inclusion of dental hygienists in a hand-arm vibration study emanates from biomedical literature that describes an exposure-response relationship between hand paresthesias and very high frequency ultrasonic and rotary dental instruments.[34–42] While attribution of symptoms to median nerve compression remains a possible explanation,[43] in a postgraduation 3-year follow-up study, Conrad et al[38] found that nerve conduction studies were unchanged in a setting of rising vibrotactile thresholds. It is now almost universally recognized that injuries to small nerve fibers in the fingertips are distinct from the nerve compression disorders, such as carpal tunnel syndrome, that affect larger myelinated nerve fibers.[44,45] Injuries to the small fiber in HAVS can occur in the absence of nerve conduction abnormalities,[46,47] and specific testing for mechanoreceptor deficits does not overlap with nerve conduction delay seen with CTS and other entrapments.[25,48,49] Lundström has shown that the glabrous skin of fingertips appears to be the initial target tissue in dentists working with high-speed hand pieces[34] and with physiotherapists working with ultrasound therapy devices.[50] In both cases, there was a decrease in tactile sensitivity of the "drilling" hand.

There is evidence that soft tissue symptoms in the upper extremity frequently compromise performance in dental hygienists,[51,52] and are a cause of early attrition from the field.[53] Barry et al[54] noted musculoskeletal complaints as early as the second training year. In a pilot survey of 81 dental hygiene students, prepared as a component of the HAVIC study, we found the following prevalence of upper limb paresthesias: 0% at matriculation; 10% (range 0% to 21%) during the first year; and 30% (range 12% to 47%) during the second year.[55] Thus, although a primary focus of this study is on perceptual loss in the fingertips, the concomitance of potential biomechanical injury and injury to larger myelinated nerve fibers is shared between this cohort and other cohorts under study.

To investigate the relationships between multiple exposures and symptoms, and the early onset of symptoms in previously unexposed students, two new cohorts of dental hygienist participants were formed. The initial objective was 1) to have a group of 80 students assessed in school and after graduation, and 2) to have a group of 80 hygienists with at least 5 years of experience assessed at baseline and at 2-year follow-up. Actual recruitment differed from projection. The 80 projected students assumed a 90% participation rate of incumbent regional students. This proved unattainable, and 66 students were actually enrolled. The experienced hygienist group was enlarged to 94.

A summary of projected and actual study participants is presented in Table 1.

Study Instruments

The study features the following assessment tools:

1. Questionnaires
2. Physical examination
3. Nerve conduction studies
4. Vibrotactile threshold studies
5. Vascular studies
6. Individual exposure assessment
7. Tool/process exposure assessment

Questionnaires

The questionnaire combines a generic group of questions for assessing vibration-specific and more general musculoskeletal disorders, exposure questions specific to each work environment, and manikin-type drawings. The drawings for symptom localization are standard illustrations, accented for specific regions[56] and for dermatome distribution to detect carpal tunnel syndrome.[57]

Vibration-specific questionnaires appear in the published literature[58] and have been used by the current investigators to study North American and Scandinavian cohorts.[14,21] Their general similarity reflects intentional standardization using common questions and scales.[5] For this study, questions asked on earlier surveys were maintained and then addended by consensus. Cross-translation was directed by the multilingual investigators, and then reviewed by the study team. To extend comparability with future international studies, questions were also added from the Vibration Network (VINET) draft questionnaire, the product of a European consortium sponsoring uniform questionnaire development. The preference for full script inclusion, at the expense of redundancy and extra

time, is an acknowledgment of non-comparability of even small wording changes.

The musculoskeletal symptom questionnaire was formulated from multiple sources, in particular, from the Connecticut Upper Extremity Surveillance Project (CUSP)[59] and standardized questionnaires developed by other members of this upper extremity consortium, including the so-called *Big-Ergo*, from the National Institute for Occupational Safety and Health, and an upper extremity questionnaire from the Safety and Health Assessment and Research for Prevention (SHARP), from the State of Washington. The CUSP survey was taken largely from previously validated instruments such as the US Department of Health National Health Interview Survey (NHIS) in 1988, the Occupational Safety and Health Administration (OSHA) Draft Checklist,[60] the Dutch Monitor Survey,[61] the Job Content Questionnaire,[62] and the Standardized Nordic Questionnaire.[63] We included the use of segments of the validated Levine Functional Status and Symptom Severity scales.[64] Other questions employ the numerical graphic rating scale which has been well documented as a means of demonstrating positive and significant correlation with other measures of pain intensity.[65] The inclusion of psychosocial questions has been relatively standard in musculoskeletal studies but has not been a general feature of hand-arm vibration studies. It is of special interest because of the potential cross-cultural comparisons.

The exposure-specific questions are tailored to each cohort. In the case of Suomussalmi, only two power tools are used and technology changes have been well documented. In the Connecticut shipyard study, tool permutations identified during piloting included combinations from 36 tool bodies and 15 tool heads. Dental hygienists and truck cab assembly workers are somewhat intermediate in their use of tools. Exposure questions were constructed to ascertain a daily equivalent of vibration exposures from workplace and non-workplace sources. Estimates of daily, weekly, and monthly patterns of use have been queried both in order to gauge the effects of altered recall and to create an individualized profile for direct exposure measurement. Small supplemental task specific exposure questions were further specialized for each shipyard trade in order to compare detailed current use estimates, historical use estimates, and direct measurement.

Perhaps the most formidable problem for questionnaire development has involved the inclusion of previously used instruments, specific to individual cohorts, and inclusion of questions for international comparison. The approach has involved three steps: 1) elimination of nationally idiosyncratic questions, such as medication and alcohol use; 2) adherence to a core questionnaire; 3) inclusion of cohort specific past questions as acceptable redundancy; and 4) documentation of even small discrepancies, where unavoidable, for later analysis.

The questionnaire was very detailed, consisting of 161 items and taking an average of 30 to 45 minutes to complete. Key sample questions for questionnaire branching and analysis included the following.

Average current hours of vibration exposure is asked in reference to a broad list of vibrating tools used by that specific cohort. An initial screen (to separate exposed from controls) was "While at ≪employer≫ in the last 2 years, have you ever worked with vibrating machines (instruments), like those listed on the next page, for at least 30 minutes per day for at least one month?". If yes, then they were asked to "Estimate the current average number of hours per week that you use vibrating machines (instruments) (all tools combined) at (employer). Hours of use does not include set-up time, time between assignments, break time, etc. It only includes time that the machine (instrument) is running and doing work". Respondents are also asked to estimate average hours per day (when the tool was used), average days per week, weeks per year, and number of years of use of each vibrating tool or instrument. Lists of vibrating tools were derived from interviews with workers, safety and health personnel, union representatives (where present), and pre-testing of the survey workers. Similar estimates were made for the most common job tasks, individually assessed for each trade/occupation (ie, different task lists for electricians and welders).

Biomechanical exposures were measured by asking "Does an average working day in your current job involve any of the following conditions?"; followed by a series of conditions, including: "Is the neck repeatedly or for long periods bent forwards, backwards or sideways?"; "Is prolonged or recurrent work performed with the arms stretched forwards or outwards, unsupported, or above shoulder height?"; "Is work repeatedly done with the forearms and hands with: a) twisting movements? b) forceful movements? c) uncomfortable hand positions/grips? d) heavy demands on precision?"; and "Is prolonged or recurrent work done with repeated similar working movements?".

MSD conditions were assessed by body region (hands, neck and upper shoulder, lower shoulder, elbows, forearms, and lower back, which were both described and areas indicated on a body diagram. Each condition began with a standard question based on NHIS, such as "The following questions refer to symptoms that you have experienced in your elbows. In the past 12 months have you had elbow symptoms (pain, aching, stiffness, burning, numbness, or tingling) in the elbow areas shown in the highlighted area on the diagram on the next page more than 3 times or lasting a week or longer?". If yes, then a number of follow-up questions inquired as to severity, patterns, frequency, and start date of symptoms.

Vibration-related symptoms included both numbness/tingling and cold-related symptoms (whiteness/pain). These had initial branching questions similar to the above, and also had questions to assess Stockholm scale. For cold-related symptoms this was based on the following: "Which best describes your hand symptoms? (please check only one answer.): 1) One or more fingertips occasionally turn white in the cold. 2) One or more fingers occasionally turn white as far as the second knuckle in the cold. 3) The full length of most fingers turns white in the cold frequently."

Numbness and/or tingling Stockholm scale was assessed with: "Which best describes your hand symptoms? (Please fill in only one answer.) 1. Numbness with or without tingling; no loss of hand function. 2. Numbness and loss of feeling; difficulty feeling and/or holding (ie, dropping) objects such as drinking glasses or tools. 3. Numbness and loss of feeling; difficulty picking up, accurately placing, or using small objects like coins, buttons or screws, and/or decrease in hand grip strength."

Physical Examination

A detailed neuromuscular examination of the upper extremity and neck-shoulder regions was designed with the following goals:

1. the elicitation of clinical signs,
2. the semi-quantitative assessment of neuromuscular, vascular, and musculoskeletal function,
3. the observation of subclinical evidence of HAVS, and
4. the development of a differential diagnosis.

A standardized upper extremity clinical instrument was developed, incorporating proximal and distal evaluation.[66,67] It included a structured clinical examination involving 32 muscle groups, and an integrated assessment of function within anatomic zones, and assessments of mobility, motion derived discomfort, and postural integrity. Elicitation of more than 20 recognized clinical signs are included, such as the Adson test, Roos test, Allen test, Wright test, Tinel sign, Phalen test, and Finkelstein test. Each clinical test and detailed procedure was reviewed for consistency with other standardized examinations.[68,69,70] The training of physician examiners across multiple international sites was accomplished through a videotaped instructional examination, coupled to a written script.

Another area of interest in HAVS research involves diffuse upper extremity pain and muscle fatigue.[33,71,72] In a two-year follow-up of Finnish forestry workers, Farkkila et al[24] observed a 21% loss of muscle force in chainsaw users with VWF compared with a 5% loss in asymptomatic controls. In an earlier study, Hellstrom et al[73] observed no strength losses, although symptoms are commonly described in the questionnaire[74]. Thus, there is particular attention to measuring strength and determining subjective loss.

A final component of the evaluation included a requirement that the examination physician offer a series of diagnoses. These are listed in Table 2. The list of upper extremity diagnoses was not exhaustive and the examiner is obliged to follow the rules. The diagnosis for carpal tunnel syndrome, for example, requires the presence of symptoms and signs and is more restrictive than a conventional clinical diagnosis. Nevertheless, the inclusion of diagnostic criteria serves the purpose of allowing for exclusion on the basis of soft diagnostic findings, such as infrequent and minimally distracting paresthesias, and for allowing somewhat subjective postural diagnoses, determined independent of nerve conduction results or questionnaire responses.

Nerve Conduction Studies

Sensory nerve conduction velocities (SNCVs) were measured for the distal median and ulnar nerves in both upper extremities. Motor nerve conduction velocity (MNCV) was assessed for the median nerve (abductor pollicis brevis). All studies were performed using a Nicolet Viking Quest device (Nicolet Biomedical, VIASYS Healthcare, Conshohocken, PA). The approach to SNCV followed the approach of Sakakibara et al,[75,76] which detected distal slowing of SNCV in vibration-exposed symptomatic workers. The following median and ulnar nerve sensory segments are assessed.

1. Proximal digit–distal digit (pddd)
2. Palm-proximal digit (ppd)
3. Wrist-palm (wp)
4. Wrist-distal digit (wdd)
5. Wrist-proximal digit (wpd)

For SNCVs on the digit innervated by the median (3rd digit) and the ulnar nerves (5th digit), paired wire-looped ring electrodes are positioned at proximal and distal sites. The proximal digital cathode is located at the metacarpophalangeal (mcp) crease, and the distal digital cathode bisects the distal interphalangeal (DIP) joint crease. For detection of the stimulus at the palm (wrist-palm segment), disposable gelled ring electrodes are cut and contoured along the width of the palm, and extended on the distal margin of the midpalmar crease to a boundary, defined medially by a line drawn from the intersection of digits 2 and 3 and laterally to the edge of the ulnar palm. Stimulation was applied at a fixed wrist point. Motor nerve latency (MNL) was determined in a conventional way. Segment distances were measured for each subject based on common anatomical landmarks rather than by conventional standard, in order to accommodate variations in hand anthropometry.

During the initial shipyard evaluation and piloting, we unexpectedly found a segment specific temperature/velocity relationship.[21] Members of the HAVIC consortium concluded that we could not scientifically justify conventional nerve conduction warming techniques for a longitudinal study, where there was such excessive variable instability, particularly where vas-

TABLE 2
Common Diagnoses and Criteria

Diagnosis	Criterion
Hand and Wrist	
Hyperlaxity of digits	Extend digits and describe if dip >20°, pip >0°, mcp >45°
Hyperlaxity of thumb	Extension of ip >45°, collapse at basilar joint, movement at CMC
Carpal tunnel syndrome	Paresthesias in a median nerve distribution, and Positive Tinel's, or Positive Phalen's, or Positive compression test
Canal of Guyon Syndrome	Paresthesias in an ulnar nerve distribution, and Positive Tinel's over the Canal of Guyon
Dequervain's Syndrome	Pain in the first dorsal compartment and Positive Finklestein's test, or Swelling or crepitus over radial styloid
Osteoarthritis	Restricted Joint Motion and positive Heberdeen's nodes or other stigmata of osteoarthritis
CMC arthritis	Pain and positive CMC grind test
Flexor Contracture	Symptoms of flexor contracture and a positive cupping test
Trigger digits	Observe for catchwith digital flexion/unable to straighten out on own
Elbow and Forearm	
Lateral Epicondylitis	Localized pain on the lateral aspect of the elbow AND pain on direct palpation extending 1 cm proximal extensor insertion AND aggravation on resisted extension
Medial Epicondylitis	Localized pain on the lateral aspect of the elbow AND pain on direct palpation extending 1 cm proximal to extensor insertion AND aggravation on resisted flexion OR Resisted Pronation
Ulnar Neuritis at the elbow	Paresthesias in an ulnar nerve distribution, and/or weakness in the ADQ or FDP (III and/or IV) AND Tinel's at the olecranon, cubital tunnel, or triceps sulcus AND/OR positive elbow flexion test
Radial Tunnel Syndrome	Pain in the proximal radial forearm at least 2 cm below lateral epicondyle AND/OR Tinel's at radial tunnel producing paresthesias in dorsum of hand AND/OR positive resisted middle finger test
Elbow Hyperlaxity	Extension beyond 0°
Flexor Tendonitis	Pain and limitation with active flexion of digits without resistance. Combine hand and wrist tests in evaluation
Extensor Tendinitis	Pain and limitation with active extension of digits without resistance. Combine hand and wrist tests in evaluation
Shoulder	
Rotator Cuff Tendinitis	Deltoid pain with overhead work and weakness with elevation Pain on resisted abduction, external, or internal rotation of shoulder Or resisted elbow flexion Or painful arc on active upper arm elevation
Impingement Syndrome	Exclude Rotator Cuff Tendinitis Painful arc and flexion or abduction <150°
Scapular Instability	Reliance on strap muscles for abduction and flexion >90°, and Winging on abduction/endorotation Or locked shoulder forward posture with inability to internally rotate
Neck and Chest Wall	
Mechanical Allodynia/medial	Radiating pain and paresthesias from pectorales with deep suprascapular palpation
Mechanical Allodynia/lateral	Radiating pain and paresthesias from pectorales with deep subscapular palpation
Head forward posture	Record if neck flexed >10° and AC joint rounded beyond mid-clavicular line

CMC is carpometacarpal.

cular dysfunction was a potentially powerful covariate. We elected to amend the protocol. External warming was replaced by exercise-based whole body warming consistent with the methodology of Wallin.[77] This approach had produced stable surface temperatures in laboratory environments where cold reactivity required control. The change in protocol obviated longitudinal comparison of SNCVs for shipyard and dental hygiene participants, who had been studied with surface warming, but the international study team was convinced that longitudinal measurements, in the absence of this standardization, would generate results that were less meaningful than results from use of the exercise protocol.

The revised protocol consisted of sub-maximal exercise on a bicycle ergometer (12 minutes ramped at

50–100 watts),[77,78] followed by whole body warming in a controlled environment. Infrared digital thermography (ISI Snapshot v. 2.1, Plymouth, MN) was introduced to record skin temperatures as volume averages of the inter-electrode segments, in order to provide an estimated average temperature for a nerve segment.

Vibrotactile Perception Thresholds (VPT)

The relationships between the neural codes from individual mechanoreceptor populations and tactile function appear to involve information from at least three of the four mechanoreceptor types located at the fingertips.[50,79,80] These are usually classified by their response to skin indentation and by the extent of their receptive fields into slowly adapting, type 1 (SAI), with anatomical correlate being the Merkel disks; fast-adapting type 1 (FAI), Meissner corpuscles; and fast-adapting type 2 (FAII), Pacinian corpuscles. SAI receptor acuity primarily determines the resolution of the spatial features of a surface, such as ridges and roughness. FAI and FAII receptor acuity is primarily responsible for information obtained from the motion of surfaces across the skin, such as smoothness and texture. In addition to tactile exploration, it is now known that the gripping of objects between the fingertips and thumb depends on the detection of microscopic slippage of the object, which is signaled by the FAIs and FAIIs, and so is controlled primarily by tactile acuity rather than by neuromuscular function.[81,82] The acuity of the SAI, FAI, and FAII receptor populations may be determined by VPTs, and appropriate measurement techniques have been developed.[83–86] Methodology for determining VPT was been internationally standardized to effectively segregate VPT measurements on the different receptor populations,[87] and has been the keystone of evaluation of neurosensory loss in vibration-exposed workers.[88,89] Standardization provides a mechanism for incorporating historical data on the Swedish cohorts that had been collected using a different device. In addition, the HAVIC study plan included protocols for comparative device testing. The introduction of these optimizing procedures was done in recognition that VPT testing, as conventionally performed, may not reliably distinguish between different mechanoreceptors and that the test incorporates assumptions on anatomic specificity that are presumed, but not universally accepted.

Vascular Studies

A cold provocation test, cold challenge plethysmography, was used to quantitatively assess vascular function, following the technique proposed by Nielsen and Lassen.[90] This test has been the field and laboratory standard for more than two decades.[91,92] Its longevity is also its principal limitation, since it captures only a fraction of vibration-related vascular pathology.[19] However, despite the recognized limitations, there has been no suitable replacement test. The vascular protocol limited testing to a reference (30°C) and cold challenge (10°C) determination. The normalized ratio of cold challenged/reference finger systolic blood pressure (FSBP%) has inspired differing cut-offs to differentiate normal from abnormal results. We developed a natural cut point based on the distribution of the most abnormal cohort, the shipyard workers. It was a FSBP% of 70, a delineation that differs from some of the reported literature.

Exposure Assessment

The relationship between estimated exposure-response relationships and effective exposure limits continues to generate controversy. Disparities between predicted and observed disease are frequent.[93–98] There is a growing belief that revisions to international consensus standards (ISO, EC) will be required to assess health effects from the use of percussive tools with high frequency vibration. Until recently, the nature and form of revisions has been unclear.[4,99] A recent study of 1557 vibration-exposed dockyard, stone quarry, and forestry workers using impulsive and rotary tools underlines the problem.[16] Several exposure metrics were constructed, including TOT (total exposure time) alone or as cross products with the ISO frequency-weighted component acceleration, and frequency-unweighted component acceleration. It seemed to make little difference which exposure metric was used: ISO frequency-weighted acceleration, unweighted acceleration, or an assumption of unity of acceleration. In a related study of 822 workers, an inverse relationship was found between the cold challenge FSBP% and the daily exposure duration.[22] The implications of these observations for future study of the development of improved exposure-response relationships are that 1) power tools with low- and high-vibration frequencies will need to be included, 2) impulsive and rotary power tools will need to be included, and 3) more complex exposure metrics will need to be introduced. These considerations have determined the selection of cohorts for this study and of the parameters included in the measurement of vibration exposure.

Proposed exposure monitoring includes four elements:

1. Anamnestic accounting
2. Work simulation expanded to an exposure-time matrix
3. Real-time daylong measurement at the individual level
4. Concomitant biomechanical assessment

1. Anamnestic Accounting. For each of the cohorts, focus groups of potential participants, supervisory, labor union, and safety and health personnel were solicited to assemble and pretest the exposure surveys included in the general questionnaire. Because shipyard workers are reassigned to job tasks at intervals that

are less than 12 months in duration, several diary-like tools have been designed to determine variable job tasks and tool use hours.

2. Work Simulation Expanded to an Exposure-time Matrix. Simulation coupled with anamnestic exposure estimation has been a traditional way to estimate vibratory exposure. Measurement of tool vibration will be conducted under simulated work conditions at a field laboratory at the site selected for medical testing for each of the cohorts with the exception of the dental hygienists. For this group, exposures will be simulated in a dental clinical research laboratory. The measurements will be conducted on a subset of subjects in each cohort. The tools will be operated to reproduce operations commonly undertaken by workers in the cohort. Thus, forest workers perform felling and de-branching operations, grinders work on scrap steel from their factory, and dental hygienists work on typodonts. As much as possible, the modes of tool operation encompass those commonly forming a complete work cycle. The selected operations enable the calculation of daily vibration exposure as suggested in ISO 5349-2.[9]

The tool handle acceleration will be measured simultaneously in three orthogonal directions as specified in ISO 5349-2[9] with the exception that the upper frequency limit will be extended to 5 kHz. The information permits the calculation of the vector acceleration sum (commonly referred to simply as the acceleration sum). Miniature accelerometers will be attached to the tool handle(s) and the hand(s), and the acceleration waveforms will be digitized and recorded digitally for subsequent analysis off-site. In this way acceleration-time histories will be obtained both on the tool handles and at the hand for typical tool operations conducted by each cohort. Measurements will be conducted using a representative sample of tools and glove types at actual work sites using a portable backpack. The exception is for dental hygiene where even micro-accelerometers would interfere with normal hand activity. In these simulations, a laser vibrometer with a range up to 200k Hz is used.

The hands will also be instrumented to record grip force by means of strain-sensitive electrically conductive films, attached either to the hands or to gloves. The forces will be recorded throughout the tool testing. The purpose of these measurements is to establish the vibration transmitted to the hand for each tool as a function of grip force. This information will be used to reconstruct the vibration at the hand for each worker from the worksite measurement of tool operation.

3. Real-time Daylong Measurement at the Individual Level. Each worker will be instrumented to record tool operating time together with the grip force throughout all, or a representative part, of the workday. These measurements are proposed to reconstruct the vibration acceleration at the hand and to estimate the time history of the acceleration entering the hands throughout the workday for each subject. A data logger outfitted on the individual subject records the vibration acceleration experienced by a subject's hand. In this way a complete time record of tool operation, the acceleration wave form and the grip force applicable to each subject can be obtained throughout the workday, thus permitting complete flexibility in the subsequent construction of vibration exposure metrics for the development of exposure-response relationships.

Technological advances in electronics have allowed for the construction of small data loggers that can collect and store large quantities of data sets over prolonged periods.[100,101] The custom-built data loggers for this project have been successfully used to monitor tool operation time, levels of tool vibration, including root-mean-square (RMS), root-mean-quad (RMQ), and root-mean-hex (RMX) calculations, and grip forces, including average grip force levels and maximum and minimum exerted grips, and can monitor work cycles in a typical eight-hour workday. The data logger, which employs the use of a sub-Pentium processor controlled by a C-based operating system (Tattletale 8M, Onset Computer, Onset, MA), has the capability to collect up to 8 channels of analog data and uses an 8-bit A/D converter with 1 MB of on-board memory. The device is mounted within an enclosure suitable for chest pocket mounting or attachment to a waistband.

The value of this information cannot be overemphasized for it will permit the construction of both simple exposure metrics as described, for example, in ISO 5349-2,[9] but also complex metrics, some of which involve biologically plausible models of tissue burden and dose.[102] The last mentioned requires the time history of vibration entering the hand throughout the workday to mimic tissue insult and recovery processes that could provide an explanation for the deviations from energy-based exposure-response models. The information will also permit the construction of exposure metrics employing a range of parameters concerning tool operation for each subject, eg, tool operation time, intermittence, time history of operation, alternative frequency weighting and frequency range, root mean quad, crest factor, impulsiveness, handgrip, etc.

Forestry, truck cab assembly, and dental hygiene work involve sufficient repetition that 4 to 8 hours of observation will be adequate to characterize individual exposure. For shipyard work, however, job task variation precludes generalization from a daily measurement. Accordingly, a combination of individual and group-task data will be used to assess shipyard workers.

Multi-cohort Comparisons

There are three major constraints influencing standardization of medical tests and health outcomes across cohorts: 1) problems of translation

and cultural differences, 2) integration of historical data, and 3) intersite differences in test and protocol administration. There is also an underlying problem of colinear demographic and other intra-cohort differences. The first of these has been approached through cross-translation by bilingual investigators. The fact that many of the questionnaire instruments have been internationally standardized and that Swedish and Finnish investigators are fluent in English reduced difficulties. Cultural differences in symptom reporting are partly obviated by the reliance on objective and quantitative tests. Further measures of inter-cohort differences are afforded by the introduction of standardized psychosocial question groups. An additional measure is the introduction of question redundancy. By soliciting essentially the same information in different formats (VAS scales, yes/no questions, body diagrams, and multiple choice questions), there is a mechanism for contingent or factored case definitions.

Even with homogeneous societies and industries, interplant differences frequently exceed within plant differences; this distinction is potentially more of a factor across borders. Intersite differences are also addressed in a number of ways. Examiner activities have been videotaped and scripted for practice sessions. In addition, the plan has been to cross-train technicians by having them work at different national sites within the limits of budgetary constraints.

The difficulties in integrating historical data pose a different set of problems. Test data is adjustable through laboratory validation. However, questionnaires and examinations add a level of difficulty, since physical examination methods precede origination of common study protocols and questionnaire wording is often quite dissimilar. Practically, this has meant that cross-cohort longitudinal comparisons will be largely limited to quantitatively measured data. In the case of physical examinations in Finland, there were standard sources that allow for comparison between this study and its predecessors.[103]

Exposure Characterization

The objective has been to establish vibratory exposure and biomechanical exposure determinations at the individual level. This is a feasible objective for the Finnish and Swedish cohorts. However, the shipyard workforce presents more fundamental difficulties. The combination of cross-training and new lines of work meant that many task boundaries had disappeared, and that production workers could fundamentally change the content of their work every few weeks. Even when a priori task reduction was approximated, in the six most prominent departments, there were no fewer than 25 major tasks. This essentially meant that it would not be possible to construct a reasonable 12- to 24-month exposure profile from data logging without a staffing commitment and accommodation by shipyard management that was beyond the scope of this study. Even 3 days of direct data logging would fail to capture the yearly diversity. A decision to use group data by task or department was necessary but has many well-recognized problems. There are two main obstacles: 1) generating individually relevant data from group profiles, and 2) comparing individually specific and grouped exposure data across cohorts. It was already clear from historic Suomussalmi data that estimated exposures obtained anamnestically differed from observed exposure by about 30% and this was only in the time domain. Several approaches are under consideration:

1. A cross-cohort meta-analysis that groups by departments and workgroups.
2. Monte Carlo or stochastic sequential simulations to estimate number of subjects needed for different configurations of variation and analyses, and filling in missing measurements after the fact.
3. Normalization of self-reported exposure for individuals without data logged results by exposure x time adjustments taken from diary/questionnaires. Such an approach would rely on intra-group variability, probably through the use of non-parametric statistics. This would be plotted against the group exposure profiles.

While meta-analyses are a default, other methods will be tried to utilize the main asset of the study: exposure determinations at an individual level.

Preliminary Results

While this paper is primarily a presentation of methodology, its publication overlaps several published reports that include pilot and baseline data. Initial segmental SNCV on shipyard workers[29] corresponded with the earlier observations of Sakikibara et al.[75,76] That is, vibration exposed workers appeared to have slowed velocities in the digital segments, when compared to controls. As noted, results from this baseline study also suggested a possible etiologic relationship between warming method and SNCV results in vibration exposed subjects. Baseline and pilot data also indicated that significant musculoskeletal symptoms were rare or non-existent at the time of matriculation of dental hygiene students,[55] but had a cumulative incidence rate of $>50\%$ by the time of graduation.[104] Finally, the cited accounts of quantitative sensory deficits in practicing dental hygienists,[36,38,41,42] were reproduced in the baseline assessments of the dental hygiene cohort.[104] Fuller explanations for these reported findings may develop through analyses of prospective data.

Conclusions

Changes in technology, job content, and health assessment technology defeat the possibility of traditional cohort studies, such as Suomussalmi,

to assess health effects from hand-arm vibration. The inclusion of historically studied working populations, as been assembled for HAVIC, represents a more practical alternative. It is unlikely that there will be many future opportunities for longitudinal studies of vibration-exposed cohorts. However, industrial control is at a point where such studies may not be needed if the current initiatives are done well.

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