Ergonomic Improvements in a Medical Device Assembly Plant: A Field Study

Mukund Narayan
UBC Health and Safety Fund
Seattle, WA

Linda Rudolph
Department of Industrial Relations
State of California, San Francisco, CA

This study reports the results of an ergonomics demonstration project implemented at a medical device manufacturing plant that was concerned about the high incidence of upper extremity cumulative trauma disorders (UECTD). Plant records were reviewed to target high risk jobs for intervention and to establish baseline incidence and severity rates for future comparisons. A multi-disciplinary team based approach was to used identify problems and effect workplace changes. With the guidance of the ergonomist, the team conducted task analysis of selected high risk operations, developed solutions, validated them for feasibility and cost-effectiveness on a prototype workstation, and, after implementing the changes on the production line, measured the effectiveness of the changes. The plant-wide severity rate based on lost-time was reduced from 154.9 to 67.8 lost-time days per 200 000 worker-hours over a one-year period. The incidence and severity rates were reduced significantly for the redesigned jobs.

INTRODUCTION

The California Occupational Health Program, Department of Health Services worked with the National Institute for Occupational Safety and Health (NIOSH) on a project known as the Sentinel Event Notification System for Occupational Risks or SENSOR. Under this program, SENSOR staff provided technical and consultative assistance in ergonomics, including worksite evaluations and training, to organizations. This study reports the ergonomic improvements implemented at a medical device assembly plant to control and prevent Cumulative Trauma Disorders (CTD).

In 1991, SENSOR responded to a request from the management of a medical device manufacturing plant to conduct ergonomic workplace assessments. Company health and safety personnel had noted that an unusually high number of assemblers had been diagnosed with upper extremity CTDs, such as tendinitis, epicondylitis and carpal tunnel syndrome. These disorders are associated with repetitive work activities, forceful hand exertions, and awkward postures (Armstrong et. al, 1985). The levels of absenteeism and turnover were high among assemblers. Plant staff also reported that some product lines experienced difficulties in meeting production quotas because of worker absenteeism due to CTDs.

SENSOR staff met with plant management to discuss their concerns, and toured the plant facilities to develop a general impression of the ergonomic environment and potential problem areas. The task demands and operational requirements suggested that a potential for CTDs existed. The observed risk factors, such as fine hand movements, forcefulness and awkward postures, were consistent with the types of injuries reported to the plant medical department. An ergonomics demonstration project was implemented to address some of the existing problems and to build in-plant skills for the control and prevention of work-related musculoskeletal injuries.

Description of the Plant

The general manufacturing environment is best described as light manufacturing of finished medical devices. The assembly operations are performed in a clean room environment. The typical assembly operation requires good visual acuity and fine, exacting hand movements. At the time of the study, the plant employed 637 hourly workers of which 316 worked in the assembly department. The assemblers were predominantly women of Hispanic origin. The plant normally operated on two production shifts of eight hours each.

METHOD

Problem Identification

As a first step the plant OSHA 200 Log for 1991 was reviewed, and plant staff and workers were interviewed to gather information on injuries, lost time, productivity and quality. Based on OSHA 200 Log entries, the annual incidence rates and severity rates (i.e., lost time) for diagnosed cases of upper extremity CTDs were calculated for the entire plant, specific departments, and operations within departments. The rates were calculated: (i) to determine the magnitude of the problem, (ii) to prioritize departments and specific operations for intervention, and (iii) to provide a baseline for subsequent evaluation of the effectiveness of interventions.

Ergonomics Awareness Training

In order to establish common goals and language, a one-day ergonomics awareness training was conducted for the plant staff at the outset of the project. The training was attended by middle management, production supervisors, engineers, equipment and tool designers, and health and safety personnel. With the assistance of the plant management, an ergonomics task force, consisting of two engineers, an equipment/tool designer, and a safety coordinator, was convened. The task force worked closely with the SENSOR ergonomist throughout the duration of the project and participated in data collection and analysis. The work-place changes were effected through the team.

Ergonomic Assessments

Two levels of ergonomic assessments were conducted. The first level was a walk-through inspection of the assembly operations in the plant. An ergonomics checklist was used to facilitate observation of work activities. Relevant work-station measures (e.g., reach distances, task heights and illumination levels) were taken. Operators were questioned on potential problems and possible improvements.

At the second level, specific high risk tasks, based on CTD incidence and severity rates, were targeted for in-depth analysis. The task force broke the jobs into discrete tasks and sub-tasks. The jobs were videotaped and analyzed in detail to determine the average cycle time, and the frequency and duration of stressful activities. These analyses lead directly to the design requirements of the job, that is, what needed to be changed to improve the ergonomics.

Implementation of Workplace Changes

From the design requirements, the ergonomics team worked with the operator performing the job and other plant engineers to generate and evaluate solutions. A prototype workstation incorporating the proposed changes was built and tested in an off-line setting. Several operators tested the prototype to ensure that the problems were adequately addressed and that the new design could be used to perform the job effectively. The new workstation was introduced in the production line after fine-tuning the changes.

Evaluation of Effectiveness of Changes

Approximately six weeks after introducing the redesigned workstation into the production line, the jobs were videotaped and analyzed again. The new and original video-tapes were compared to determine the reduction in exposure to risk factors and to ensure that no new problems were introduced by the changes. The effectiveness of the interventions was also evaluated by administering postural discomfort surveys (Corlett and Bishop, 1976) to selected operators before-and-after the changes were implemented. The operators filled the surveys every two-hours over an entire shift.

To evaluate the long-term effectiveness of changes, one-year after the changes were made the incidence rates (i.e., number of new cases), severity rates, and ratio of the plant-wide annual severity to incidence rate were calculated and compared to the baseline rates.

RESULTS

Illness and Injury Statistics

The annual plant wide incidence and severity rates for upper-extremity CTDs were calculated as 13.7 cases per 200 000 worker-hours (87 upper extremity CTD cases) and 154.6 lost-time days per 200 000 worker-hours (987 lost-time days), respectively. Tendinitis (83.9%) was the most frequent diagnosis and the wrist was the most frequently injured body part. Among the various departments in the plant, the assembly department had the highest incidence and severity rates. The incidence and severity rates for various jobs in the assembly department are summarized in Table 1. The company was self-insured and reported that the average annual workers' compensation cost (i.e., medical and indemnity costs) per case of upper extremity CTD was $6800.

Ergonomic Assessments

Based on information collected during the walk-through and from interviews with operators and plant staff, several problems were identified.

1. Many assembly operations were hand intensive and required workers to grip and re-grip small parts, manually position parts, and assemble products, using a great deal of repetitive wrist motions, awkward wrist postures and forceful finger exertions. Such activities impose high loads on the tendons and muscles in the hand-wrist region and can cause CTDs in the hands and wrists.

2. The worksurfaces in the assembly department were fixed at a height of 37 inches, regardless of whether the job was performed in a seated or standing position. For seated jobs a non-adjustable foot stool (9.5" high by 13" wide by 14" deep) was provided. The chairs were not easily adjustable. Some jobs required the operators to use a foot switch mounted on the foot stool. Since the foot stool and work surface height were fixed at 37" and 9.5", respectively, the work station did not fit many workers, particularly women. This contributed to awkward working postures involving the back,

shoulders and arms.

3. Localized contact stresses on fingers, palmar-side of wrists and forearm were evident in many jobs due to hard or sharp edges of the tables. Operators supported their arms on the edges for stability when engaged in fine hand movements.

4. Many operations used microscopes for assembly and/or inspection work. The microscope eyepiece was low and caused significant forward bending of the neck and the torso (> 20 degrees).

Several changes were implemented to address these issues. For example, adjustable chairs and footrests were provided to accommodate operators of different sizes; the microscopes were repositioned to reduce bending of the trunk and neck; and sharp edges were covered with compressible materials to reduce contact stresses.

In addition to these general changes, selected high risk jobs were evaluated and a number of specific changes were implemented. For example, special fixtures were designed to reduce static loading and some of the highly repetitive work activities were automated. It is not possible to summarize here all the findings and changes. As an example, the findings and changes implemented in Job 1 are summarized below.

Job 1

This operation required the operator to assemble several pieces of small diameter plastic tubes with the assistance of metal wire supports in order to achieve bonding of the tubes. The operator bonded the tubes on specialized heating equipment called the "hot-box." After heat sealing the tubes, the metal wire supports were removed from the tubes and the bond was visually inspected under the microscope. The average cycle time based on 10 cycles was determined to be 2 minutes and 48 seconds.

Fourteen cases of diagnosed upper extremity CTDs were reported from this job (Table 1). Major risk factors observed in this job included:

(a) High forces on the upper limbs. The operator held the tubes with the index fingers and thumbs of both hands (pinch grip) in order to heat seal the tube junctions. The delicacy required to position and re-position the product on the hot box and prevent damage, increased the load on the entire upper limb to have maximum control of finger motion. Also, the wrists were hyper-extended while using the hot box. The simultaneous exposure to awkward wrist postures and pinch forces increases the risk for hand and wrist disorders.

b) Awkward shoulder, neck and back postures. The worker had to bend over to see the product while performing the bond on the hot box. This resulted in neck and back flexion. As mentioned earlier, the microscope and the physical design of the workstation also contributed to stressful body postures, particularly of the shoulders, arms and back.

c) Forceful pinch grips were required to remove the metal wire supports from the tubes after forming the bond. Forceful pinch grips in combination with awkward wrist postures were used for 31% of the cycle time.

d) Contact stresses at the base of the wrist and the forearm due to sharp table edges were noticed.

Changes Implemented. A prototype workstation was built in an off-line setting to test the proposed changes. Several operators tested the proposed design and changes were made based on their feedback. Adjustable chairs and foot-rests were provided. The chair-foot rest combination could be adjusted so that operators of different sizes could assume optimal work postures. Semi-circular cutouts were provided in the workstations to reduce excessive reaches. The edges were covered with a compressible material to reduce digging into soft tissues.

The hot box was retrofitted with a pneumatic gripper, which eliminated exacting hand movements and pinch forces associated with forming the bond. The operator placed the product on the gripper and the machine automatically performed the bond. Special fixtures were designed to assist the operator in the removal of metal wire supports from the plastic tubing.

Evaluation of effectiveness of changes

Job 1

The "before-and-after" measurements for Job 1 showed a reduction in exposure to risk factors. Specifically, forceful pinch grips and awkward wrist postures were eliminated; contact stresses were reduced; and, forward trunk flexion (>20 degrees) was reduced from 80% to 10% of the cycle time.

Postural Discomfort Survey

Three operators performing Job 1 completed the survey before the changes were made. However, only one of these three operators was available to complete the surveys after the changes were implemented.

For each body part, the perceived discomfort levels were compared before-and-after the changes were made. The changes in body-part discomfort were most marked for the hands/wrists and the back (Figures 1 and 2); other muscle groups showed smaller differences and lower discomfort intensities. These findings support the results of task analysis which indicates high pinch forces and significant flexion of the torso. Also, during the lunch break there appears to be partial recovery of the hand muscles from localized fatigue (Figure 1).

Cost-benefit Analysis for Job 1

<u>Savings data for four work stations</u>

Workers' compensation cost for 14 CTDs	
(@ $6800 per case)	= $95200
Cost of lost time	
(@ $100 per day for 321 days)	= $32100
Total savings cost	= $127 300

<u>Improvement costs for four work stations</u>

Research and development cost	= $12000
Cost of redesigning equipment	
(@ $2500 per workstation)	= $10000
Cost of chairs and footrests	
(@ $400 per work station)	= $1600
Total improvement cost	= $23600

$$\text{Pay-back period} = \frac{\text{Cost of improvements}}{\text{Cost of savings}} = \frac{\$23600}{\$127\ 300} = 0.19 \text{ years} = 2.3 \text{ months}$$

Plant-wide

A one-year follow-up showed that the CTD incidence and severity rates were significantly reduced in jobs where the changes were implemented (Table 1). However, as the company started implementing changes many new cases of CTDs were reported in other jobs in the plant, where previously no CTDs had been reported. Thus, eventhough there was a significant reduction in the number of CTDs in the jobs which were redesigned, the plant-wide annual incidence rate only reduced from 13.7 to 11.3 per 200 000 worker-hours.

The annual plant-wide severity rate was reduced from 154.9 lost-time days per 200 000 worker-hours (987 lost-time days) to 67.8 lost-time days per 200 000 worker-hours (432 lost-time days) over a one-year period. During the same period, the number of lost-time days per CTD was reduced from 11.34 to 5.68.

DISCUSSION AND CONCLUSION

The results of the study indicated that many processes and equipment in the plant contributed to stressful activities. Poor design of the equipment was the primary cause for awkward wrist postures. Recommendations were made to provide ergonomics training for product designers/engineers so that stressful or unnecessary work elements could be eliminated. Also, recommendations were made to evaluate new processes at the design stage for potential ergonomics problems. Only with a proactive approach can the company expect to prevent future injuries.

The changes implemented in Job 1 were cost-effective with a pay-back period of about two-months. Also, building a prototype workstation helped to fine-tune changes without disrupting production and evaluate the feasibility of different solutions. For example, video-scopes were tried as substitutes for microscopes; but operators preferred microscopes because of the loss of depth perception associated with use of video-scopes.

The data from the postural discomfort survey complemented the results of task analysis. It provides relatively rapid feedback on the effectiveness of interventions and can be used to finetune them.

This ergonoimcs demonstration project was successful in identifying and addressing some of the ergonomic problems in the plant. As shown by the data in Table 1, the number of CTD has been significantly reduced in the jobs which were redesigned. However, as the company started implementing changes, the incidence of CTDs started increasing. This "increase" would suggest that the ergonomics program was not effective; however, a closer look at the plant records shows that lost-time days decreased while number of CTDs increased. This increase in number of CTD cases is probably due to increased awareness among employees; and the decrease in lost-time days is an indication of early reporting of symptoms to the medical department. Early reporting not only allows the workstation problems to be identified quickly but also makes medical treatment easy and less expensive.

Thus, during the initial stages of a musculoskeletal injury control program there may be an increase in incidence. So one should consider both incidence and severity rates while evaluating the effectiveness of a program. The number lost-time days per CTD (or the ratio of severity rate to incidence rate) takes into account both these variables and it could be used as an index for monitoring the effectiveness of programs. In this study, there is significant reduction in the number of lost-time days per CTD case (11.34 to 5.68).

An important goal of this project was to develop in-plant skills to enable the company to assess its operations on an on-going basis. Since the ergonomics team worked with the SENSOR ergonomist through all phases of the project there was a gradual and continuous development of in-plant skills. The most satisfying result of the project was that the plant ergonomics team was able to replicate the process, with progressively less help from the SENSOR ergonomist. For example, the team conducted an ergonoimcs review of a new product line, identified stressful work activities and redesigned these work elements prior to installing the product line on the production floor.

ACKNOWLEDGEMENTS AND DISCLAIMER

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Table 1: Annual Upper extremity CTD incidence and severity rates of selected jobs before-and-after* changes. (Source: OSHA 200 Log)

Operation	Number of workers	Number of CTDs		Incidence rate per 200000 man-hours		Lost time days		Severity rate per 200000 man-hours	
		Before	After	Before	After	Before	After	Before	After
Job 1	20	14	0	70	0	321	0	1605	0
Job 2	16	12	1	75.1	6.3	317	2	1981	12.25
Job 3	18	9	2	50.1	11.1	31	0	172	0
Job 4	12	7	1	58.4	8.3	98	0	817	0
Job 5	12	7	0	58.4	0	0	0	0	0
Job 6	8	5	2	62.6	25.4	0	0	0	0
Job 7	15	5	3	33.4	20.0	0	0	0	0
Job 8	15	4	2	20.0	13.3	15	0	100	0
Job 9	7	3	0	28.6	0	10	0	143	0
Job 10	3	2	0	66.8	0	0	0	0	0
Job 11	14	2	0	14.3	0	0	0	0	0
Job 12	16	1	1	6.3	0	0	0	0	0

* The "after" data were collected one-year after the changes were implemented.

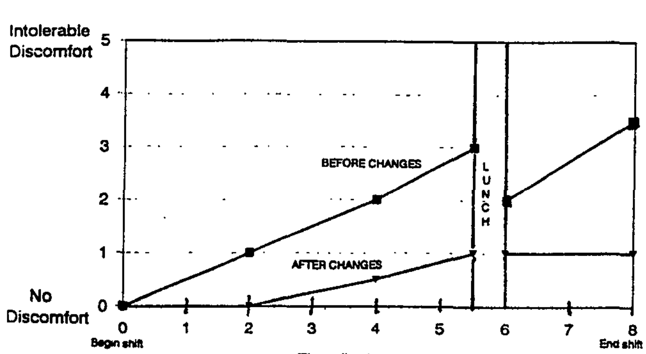

Figure 1: Discomfort ratings for the hands and wrists – before and after changes.

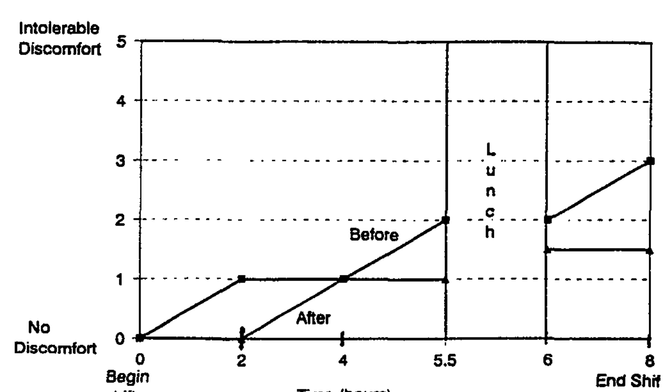

Figure 2: Discomfort ratings for torso – before and after changes