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NEWSLETTER OF BIO-MEDICAL ENGINEERING SOCIETY OF INDIA

INSTITUTE INDUSTRY VENTURE : TECHNOLOGY FOR HEALTHCARE
ENGINEERING SUPPORT TO DIABETIC FOOT

(for Early Detection, Prevention and Healing of Diabetic Foot Ulcers)

Diabetes Mellitus is projected to be one of the major health problems of the near future. As per WHO present diabetic population of 35 million in India is expected to reach 85 million by the year 2020. Diabetic foot ulceration is the most common single precursor to amputation and has been identified as a component in 85% of lower extremity amputations. It is important that patients with diabetes are aware of this dreaded complication. The research work on diabetes for the past ten years, at IIT, Madras in collaboration with Sundaram Medical Foundation (SMF), has been concentrated to develop equipment to detect, at the early stage, the foot at risk to provide footwear for prevention and fast healing of foot sole ulcers based on sound engineering principles, by measuring Foot Sole Sensory Loss, Hardness, Thickness and Pressure distribution.
(Fig 1a, Fig 1b, Fig. 1c)

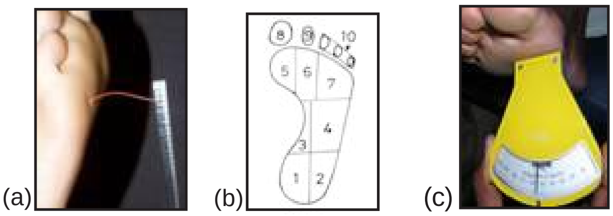
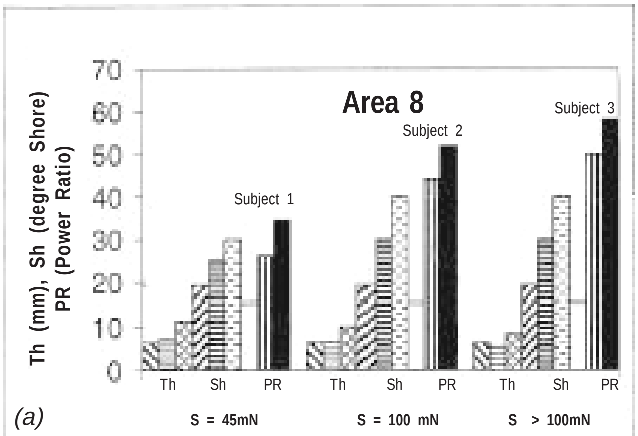


***Fig. 1** : Foot sole (a) sensation measurement, (b) areas, (c) hardness measurement*

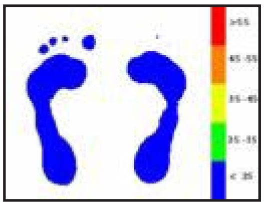
Pedopowergraph (Fig.2), a new portable instrument developed and patented by IITM and SMF jointly, measures the foot pressure distribution rather than measuring only peak foot pressure. It consists of a glass plate mounted on a box and light sources illuminating the glass plate from its longitudinal thickness. The glass plate is covered by a thin white plastic sheet. When a person stands on the plastic sheet, foot pressure images of both the feet are formed simultaneously at the contact surface of plastic sheet and the glass plate by the phenomenon of light scattering, foot images having distribution of light intensities along the length and breadth of the feet, the distribution depending upon the foot sole hardness and pressure exerted by the subject. The foot images are reflected through a mirror kept at an appropriate angle to the glass plate and captured by a still digital camera recording the foot pressure images in the form of BMP files. The foot pressure images in the BMP files are divided into 17 divisions (for each foot sole). Spatial frequencies and their distributions in these images are analysed by using MATLAB/Labview program. A new parameter, Power Ratio (PR) [ratio of power found in the higher spatial frequency components, to the total power in all spatial frequency components], is calculated on-line using a special software developed for all the 17 foot sole areas of the foot. Figure 3a shows the range of magnitudes of foot sole parameters that cause foot sole ulcer in area 8 (big toe) based on the measured foot sole sensory loss, thickness, hardness and pressure parameter PR. Based on the above analysis the risk levels are colour displayed in Fig. 3b and 3c

***Fig.2** : Pedopowergraph for measuring foot pressure parameter PR*

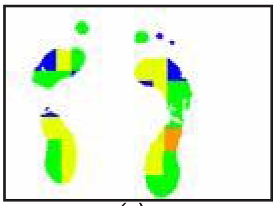


(a)

Th	Soft tissue thickness	Normal Thickness	Normal Shore	Normal PR
Sh	Shore (soft tissue hardness	Withour Ulcer	Without Ulcer	Without Ulcer
PR	Pressure Parameter (Power Ratio)	With Ulcer	With Ulcer	With Ulcer
S	Sensetion Level			



(b)



(c)

Fig 3 (a) Ranges of magnitudes of foot sole thickness, hardness & pressure parameters causing ulcers, Pressure parameter PR for (b) Normal and (c) Diabetic subjects

for a normal and a diabetic subject. The blue colour indicates the normal foot sole, the other colours from green, yellow, orange and red, indicate ascending order of risk of foot sole ulcers in different parts of the diabetic foot. A large number of diabetic patients were analysed.

Footwear for Prevention and Healing of Foot Sole Ulcers : The designs are based on engineering principles of unloading the foot sole to reduce the foot sole stresses or pressures to prevent the foot sole ulcers or help in fast healing. This is done by stress analysis of three dimensional foot-footwear composite model by using finite element method and dimensions of footwear such as thickness, hardness and materials of footwear insole, outer sole and rocker bottom and its location are worked out to minimize the foot sole stresses.

Figure 4a shows a typical prevention footwear (sandal type) which consists of microcellular rubber (MCR) insole, and an outer sole of appropriate dimensions. Adjustable front and back straps are provided to take care of sensory loss and of swelling in the diabetic foot. Fig. 4b shows a healing footwear derived from modification of prevention footwear by attaching an aesthetically designed rocker attached at the bottom of the outer sole with its dimensions, hardness and location determined by stress analysis to unload the ulcer in mid foot region completely.

(a)

(b)

Fig. 4 Footwear for diabetic subjects (a) for Prevention of foot sole ulcers, (b) for Healing of foot sole ulcer in the mid-foot

Table 1 shows details of prevention and healing footwear (patent applied) prescribed and used by diabetic patients.

Table 1 : Details of Prevention & Healing Footwear

Prevention Footwear

Insole : 9mm thickness with 20 Shore MCR.

Outer sole : 10mm thickness with 60 Shore + back strap.

850 pairs of footwear were given for prevention of foot sole ulcers.

Healing Footwear

150 pairs of special type footwear for healing ulcers were given

- **12** pairs with heel inserts for healing ulcer in the heel
- **128** pairs with rocker in the mid-foot region for healing ulcer in the forefoot region
- **10** pairs with rocker in the heel region for healing ulcer in the mid-foot region

Results

- The prevention footwear, after wearing for 6 months reduced the hardness of diabetic foot sole to normal value preventing ulcer formation.
- 95% of the ulcers healed in one month, long duration non healing ulcers in the mid-foot region healed in 3- 4 months.

The footwear material (for insole and outer sole) are developed in Brakes India, Chennai (part of Sundaram Medical Foundation) as per the specification given by IIT Madras research group.

Equipment and different types of healing footwear will be commercialized shortly at affordable costs for the benefit of diabetic population.

Dr. K. Mothiram Patil, *former Emeritus Professor, BME Div IITM, patilkm@yahoo.com*

Diamond® Tourniquet

Industrial Electronic and Allied Products, a Pune based pioneer company in BP Instruments manufacturing in India, has developed Electronic Tourniquet useful for Orthopaedic surgical procedures. The brand name is 'Diamond'.

The Tourniquets are used during surgery to minimize blood loss. It is recommended that tourniquet pressure is 50~100 mm Hg above systolic blood pressure level. Diamond Electronic Tourniquet is basically a pressure regulating system. It is a fully automatic, microcontroller based system which maintains the Cuff pressure to set value throughout the surgical procedure. It is a portable, battery powered, compact, lightweight system. The cuff is specially designed soft, armored type to protect from accidental piercing. A coiled, expendable puncture resistant Polyurethane tubing is used for delivering air to cuff. Backlit LCD display and softkeys are used for status indication and ease of operation. Cuff is inflated using motorised air pump and deflated using electromagnetic valve, manual override is also incorporated. Cuff pressure can be set between 20~500mm of Hg with a resolution of 2mm of Hg and can be controlled within +/- 3mm of Hg. Alarms are provided for air leak and elapsed time. Tourniquet can be programmed to suit the operation and post operation needs by setting delay and duration functions.

Dual Cuff Tourniquet is an advanced version instrument having two channel operation, independent of each other and can be operated with one dual cuff on two separate cuffs. Standard (Leg 10x61cm, Aram 7x35cm) and paediatric (5x30cm) cuffs are velcro fastened.

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Need to establish Clinical Engineering Profession in India

Practice of modern medicine without engineering and technology support is unimaginable. There is a wide range of equipment in use from a simple Sthethoscope to sophisticated MRI Systems and other complex equipments. In order to achieve highest quality of care, it is essential that the equipment is in perfect working condition, safe to use and is operated by well trained personnel of 'Clinical Engineering Speciality.'

Clinical Engineering is a speciality of 'Biomedical Engineering' and a clinical engineer is defined by the American College of Clinical Engineers as a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology.

Historical Perspective of Clinical Engineering Profession : As reported by Grimes SL (2003), in 1970 consumer activist Ralph Nader indicated through an article that at least 1200 patients were electrocuted annually in hospitals during routine diagnostic and therapeutic procedures. Subsequently, the Emergency Care Research Institute reported that "a disturbing proportion of ...medical devices is demonstrably ineffective, of inferior quality, or dangerous"

These comments triggered considerable public interest resulting into a series of US Congressional hearings on medical device safety and as a result, in 1976, FDA was authorised to demand medical device manufacturers to demonstrate their product's functional efficacy and safety before marketing the product in the USA. Around the same time the Joint Commission on Accreditation of Healthcare Organisations established a requirement that hospitals should conduct incoming inspections of new medical equipment and perform routine electrical safety testing of the equipment in use. Thus, the primary focus of clinical engineering services in the early years was on these two aspects as well as some in-house repairs. Recently, the scope of the clinical engineering services has been expanded to encompass issues such as Equipment management, Inventory management, Training of users and Healthcare Technology Assessment. It would be reasonable to assume that similar developments would have occurred in other western countries.

Indian Scenario : Six years ago, Mehta JC (2000) reported that efforts to establish clinical engineering profession in India are initiated as early as 1969. He further reported that in 1970s some senior medical professionals at Post Graduate Institute, Chandigarh, along with Ministry of Health of Govt. of India, took initiative in forming a working group to identify the engineering needs in hospitals. The findings of this group were implemented in PGI, Chandigarh where JC Mehta himself worked between 1969 and 1984 and was actively involved in establishing preventive maintenance protocols for the equipment. Recently, an Institute of Hospital Engineering has been established in Chandigarh, but the focus of this Institute seems to be more on civil engineering and architectural requirements of the hospital, than on equipment management and safety.

Clinical Engineering Society of India was established in 1997 and has its office in Bangalore. However, through personal communication with Dr. T.G. Krishnamurthy, one of the founders of CES, it appears that the society is yet to make noteworthy progress in establishing a clinical engineering profession in India.

Initiative has also been taken recently by Quality Council of India in forming a National Board for Accreditation for Hospitals. One of the requirements for obtaining accreditation has been listed as ensuring equipment calibration, function reliability and safety. However, it appears that QCI is yet to evolve a policy on Clinical Engineering and thus, addresses the issue of equipment management.

Though many educational institutions offer courses, in Hospital Administration and Management. The focus is on overall management and emphasis on the equipment management is not significant. There exists a need to initiate strong activity towards developing a Clinical Engineering Profession resulting into a process of certification similar to the one followed by UK or USA.

(To be continued in the next issue)

References

Mehta JC (2000), Why are our hospitals sick? *HEALTH TRIBUNE, Wednesday, March 8, 2000, Chandigarh, India*

Grimes SL (2003), The future of Clinical Engineering: The Challenge of Change, *IEEE Eng. Med. Biol. Mag., March-April*

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MASIP 2006

BMESI sponsored workshop on Medical Application of Signal and Image Processing was hosted by Manipal Academy of Higher Education (MAHE). The event was successfully organised by Dept. of Bio-medical Engineering, Manipal Inst. of Technology during 23-25 January, 2006.

Dr. B.S. Prabhu, Director, MIT, welcomed the gathering. Dr. Gopalakrishna Prabhu K., Convener put forth the salient features of MASIP-2006.

Padmavibhushan Dr. M.S. Valiathan, National Research Professor, Govt. of India and Hon. Advisor of MAHE inaugurated the workshop. In his inagural speech he emphasized the need for smart bio-instrumentation. Dr. Rangaraj M. Rangayyan, Univ. of Calgary, Canada, the key resource person of the event released BMESI Journal “Medical & Life Sciences Engineering”, (Vol. 15, Jan. 2006). Dr. H. Vinod Bhat, Registrar of MAHE presided over the inagural function and released the souvenir and CD of the proceedings. Prof. Lawrence D’Almeida, proposed vote of thanks. Compere Ms. Soni C. and all efforts of BME Dept. of MIT will be remembered by the august audience and participants.

Eminent speakers from academia, industry and medical profession were on the faculty. Dr Rangaraj M Rangayyan, Dr Ramesh R Galigekere, of University of Calgary, Canada; Shiva Kumar KR, S Bhaskaran, of Philips Medical Systems, Bangalore; Dr P Sripathi Rao, Dr Chandrakanth M. Shetty, and Dr MS Vidyasagar of KMC, Manipal; and Dr UC Niranjan, Dr GK Prabhu, Jagadish Nayak, of MIT, Manipal delivered special lecturers on signal and image processing and discussed in depth their applications to healthcare. All the events of MASIP were well received and appreciated by 150 participants from various parts of the country.

gk.prabhu@manipal.edu ***Dr. G. K. Prabhu***

Your valuable suggestions for the newsletter are most welcome. Activity reports, articles, product reviews related to the field of BME are awaited from the members for inclusion in the newsletter.
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