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AN INNOVATIVE DEVICE FOR CREATING TISSUE PLANE CLEAVAGE BY HYDRO-DISSECTION BASED ON LEVER AND ERGONOMIC PRINCIPLE

JYOTI DVIVEDI[1]* AND SANJAY DVIVEDI[2]

[1]Department of Physiology and [2]Department of Plastic Surgery
Himalayan Institute of Medical Sciences Jolly Grant,
Dehradun – 248 140 India

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Abstract : In the Third world countries, the occupational health of a Reconstructive Surgeon attracts due attention from the applied physiology fraternity, where the massive amount of surgical workload causes chronic fatigue and repeated stress and injury. The knowledge of human physiology and the science of ergonomics analyze these challenges and formulate guidelines for creating a work environment that is safe and comfortable for its operators. Presented here is an innovative, cost effective, sterilizable, manually controlled hydrodissection instrument for surgery. This easy to make Syringe Pressure Gun (SPG), has revolutionized the face of cleft palate surgery reducing the surgical time to 50% and the palatal fistula rate from 3% to Zero percent. The effects were studied on patients and the operating surgeon both. The experimental group comprising of 1500 cleft palate patients in whom the gun was used during surgery as compared to 500 controls showed statistically highly significant results in terms of reduction in average bleeding in millilitres ($P<0.05$), average operating time in minutes ($P<0.001$), palatal fistula formation ($P<0.005$) and reduction in surgical complications like flap necrosis. The results in the operating surgeon (self control) on using the instrument, showed highly statistically significant fall in the muscle strain induced by tedious surgical manoeuvres, as studied by EMG ($P<0.005$), subjective hand grip pain and tiredness on a scale of 0-10, high convenience in flap dissection and therefore work performance improved in spite of the high volume of surgery. This ergonomic innovation will provide clues for future inventions based on physiological principles for improving the occupational health of the doctors and outcome of the patients.

Key words : cleft palate syringe pressure gun hydro dissection

INTRODUCTION

Occupational health and ergonomics is an integral part of applied physiology. Muscular fatigue of a surgeon, due to non availability of ergonomically designed surgical instruments can adversely affect the patient outcome (1). Advancements in the basic sciences

*Corresponding Author : Department of Physiology, Himalayan Institute of Medical Sciences Jolly Grant, Dehradun – 248 140, India

contribute to the fundamental knowledge base and supports future invention. Extensive work still lacks on the innovations by physiologists aimed at patient and the clinician's advantage (3). The designed device presented here is entirely based on the need of the times which included occupational health of the surgeon, better results in the patient and the applied physiology broadening its horizon. The idea of the present innovation was conceived to find a solution to reduce fatigue experienced during cleft palate repairs by one of the authors, as his surgical workload was very high and the fatigue was affecting his output. A accurately controlled massive manual effort was required to push the plunger of the 10 ml injection syringe against great resistance offered by the deranged palatal mucoperiosteum densely adherent to palatine bone, while making submucoperiosteal injections to create a tissue cleavage during cleft palate repairs. This in turn affected the surgical outcome where very fine and precise movements are required for a better surgical outcome.

Surgical Physiology : In palatal surgery, mucoperiosteal flaps need to be carefully separated off dense fibrous union with the thin palatine bone, and be islanded carefully on the vascular pedicle based on the greater palatine artery. It requires tough dissection with very tender instrument manoeuvring through the small oral commissure of usually very young patients. During this dissection the tissue planes are often mutilated leading to bleeding and thus further compromising the visibility during surgery. The result is, a high incidence of dehiscence of the repair and a palatal fistula, making the patient a cripple for life. To tackle with these problems, surgeons inject submucoperiosteally an injection of vasopressin solution for vasoconstriction. It also serves the purpose of hydrodissection that creates a very safe plane of cleavage between the tissues, thus separating the mucoperiosteum from the bone even before the knife is used. Along with this it provides a rapid expansion of the usually sparse palatal soft tissues, thus facilitating an easy, tension less repair.

Such an injection requires generation of very high pressures through a simple 10 ml hypodermic syringe-often to the tune of 1300 PSI (pounds per square inch) as seen in dental injections where a low volume of the local anaesthetic (1-2 ml) is given over a period of 5-10 minutes (4). In palatal hydrodissection submucoperiosteal delivery of large volumes (up to 50 ml) at such a slow rate will waste precious operating time and thus rapid injection at a much higher pressure is required. Manual generation of such high pressures over repeated surgeries causes fatigue and pain in the surgeon's hand, even before the surgery starts, thus reducing accuracy of the skill.

Expensive computerized expensive devices for injection of the small volumes of local anaesthetic (1-2 ml) are commercially available, but with no control of pressure, and a very slow delivery of the drug at the rate of 1ml per minute. Surgery often is an art of feeling the tissues, their resistance and 'give-way' feel acts as a guide to surgical manoeuvres. Average pressure developed during injection of local anaesthetic manually or through a motorized device in such a case reaches up to just 300 mm Hg (5); hence the hydrodissection is often

incomplete especially if the procedure is to be repeated several times in a day. None of the marketed instruments fulfill these demands, therefore, a Syringe Pressure Gun (SPG) was indigenously designed in the Physiology Lab using the principles of lever and ergodynamics to reduce surgeon's discomfort, to improve the efficiency and convenience of surgery on one hand; while on the other hand to reduce the rate of complications as well as the time taken to dissect the tissues in an arduous field.

MATERIAL AND METHODS

Material

1. After carefully observing videos of the hydrodissection procedure at palate surgery and keeping in mind the limited access into the mouth of patient under general anaesthesia, a sketch of the device required was designed in collaboration with the surgeon. The innovative, cost effective, ergodynamic, sterilizable, manually controlled hydrodissection device (SPG) was created by modifying a simple injection gun used by civil construction workers to squeeze and paste silicone sealant used for sealing window panes. Such a gun is easily available at hardware general stores for merely a 100 rupee note.

2. The gun works on the basis of first class lever in which the trigger lever acts as the effort arm and the advancing rod as the load arm.

3. The design of silicone-bottle holding arms of the gun was modified to suit the needs of the procedure. A semi cylindrical steel pipe large enough to accommodate a 10 ml syringe was brazed to the arms to create the SPG.

4. The device was designed considering cost effectiveness, ergonomics and all the drawbacks of the previous devices.

Method

Study Groups

A. 2000 Cleft Palate patients undergoing palatal repair surgery were undertaken and randomly divided as –

   1. Device group. (N=1500) in whom the device was used for hydrodissection.

   2. Controls. (N=500) in whom the vasopressin was injected manually through 10 ml syringe.

B. The operating surgeon himself (self control): Surgery done with and without the use of gun.

Procedure

Use of the SPG

1. A duly informed consent was obtained from the patient or guardian. Under general anaesthesia the innovative SPG was used to inject into the sub-mucoperiosteal plane, diluted vasopressin solution through a 24 gauge hypodermic needle fitted to a 10 ml syringe, to hydrodissect and elevate the mucoperiosteal flaps off their bony attachments.

2. With every full range stroke of the effort arm lever (40 degrees rotation and 48 mm movement at farthest point of the arc), the load arm rod moved the syringe plunger to deliver 1 ml of drug against

as high pressure as required till hydrodissection was achieved as perceived by the operator as a give-way feel, complemented by a visible bleb like elevation of the palatal flaps thus rapidly expanded. The surgical procedure for palatal reconstruction was then carried out as usual, using routine techniques of repair. In both the group of patients, the parameters studied were –

1. Average bleeding in millilitres = [weight of wet gauze (blood plus fluid used in hydrodissection)] - [weight of the dry gauze plus weight of the injected fluid].
2. Average operating time in minutes: From start of injection till the last suture, assessed by stop watch.
3. Palatal fistula, wound dehiscence and flap necrosis (percentage of cases).

In the single operating surgeon, the parameters studied were :

1. Electromyography (EMG): Electromyogram activity as an indicator of muscle tension was recorded on the thenar group of muscle. After degreasing the skin surface, the EMG (mV) was recorded using large surface electrodes of an automated biofeedback apparatus (J & J Engineering, USA) where in the electrodes were placed on the palmar skin overlying thenar eminence. The EMG was recorded immediately before starting hydrodissection and after the surgery was over.
2. Convenience in flap dissection: on a subjective scale of 0-10; (0: least convenient; 10: most convenient dissection).
3. Subjective hand grip pain and tiredness: on a scale of 0-10 (0: least; 10: maximum).

The observations were compiled and the results tabulated and compared with the help of the computer software – 'Microsoft Excel' (Microsoft Office XP). Analysis of the data was also done through the 'Data Analysis Pack' of the same software.

RESULTS

The study was conducted on 2000 patients of primary (n=1523) and secondary (n=477) cleft palate repairs which were randomly divided into SPG group (n=1500) and controls (n=500). The average age of the patients was 9.37±8.14 years, with 1265 males and 735 females. There was a statistically significant reduction in the bleeding, operating time, wound dehiscence ($P<0.05$) and occurrence of palatal fistula. The EMG of the surgeon's hand muscles after usage of the gun showed marginal increase of muscle tension as compared to the statistically significant higher values in the controls ($P<0.005$). With the use of SPG it was more convenient to

TABLE I: Effect of the use of innovative SPG in palate surgery.

	Control group	*Device group*
Average Bleed	142	35
Average Operating Time	87	42
Palatal Fistula (%)	3	0
Preoperative EMG of Surgeon's Hand (mV)	5.79	5.82
Postoperative EMG of Surgeon's Hand (mV)	9.84	6.92
Convenience of surgery on scale of 0-10	9	4
Pain & tiredness on scale of 0-10	8	2

dissect the flap, and there was less postoperative pain and fatigue in the operator's hand. The results are summarized in Table I.

DISCUSSION

Occupational and environmental health, with a focus on human integrative, clinically oriented and translational physiology, is now understood as 'applied physiology' by the medical world including the western indexed journals (6). The present innovative study intends to focus attention of the physiologists and the clinicians towards an area of applied sciences which works together to improve the health of both the doctor and the patient. It was noticed that in cleft palate hydrodissection, the primary problem of the surgeon was poor ergonomics i.e. a mismatch of the required and available effort in making the forceful injection of the drug to facilitate hydrodissection. It was noted that the surgeon's hand using the ordinary 10 ml injection syringe is not able to generate the required pressure of up to 1300 PSI in repeated surgeries, and on a repeated attempt to do so, he experienced fatigue of hands, and stress of pain, thus reducing the accuracy of surgical manoeuvres.

Ergonomics is the science of designing the job, equipment, and workplace to fit the worker. The International Ergonomics association defines ergonomics (or human factors) as the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance. Optimal ergonomic design is necessary to prevent repetitive strain injuries, which can develop over time and can lead to long-term disability (7).

To rectify this mismatch, the lever principle was sought for. Lever *(from French lever, "to raise", c.f. a Levant)* is a rigid object that is used with an appropriate fulcrum or pivot point to multiply the mechanical force that can be applied to another object. This leverage is also termed mechanical advantage, and is one example of the principle of moments.

To facilitate a high pressure injection using less mechanical effort, a device based on the first class lever principle was needed. A first-class lever has the fulcrum located between the input effort and the output load. In operation, a force is applied (by pulling or pushing) to a section of the bar, which causes the lever to swing about the fulcrum, overcoming the resistance force on the opposite side. The fulcrum may be at the centre point of the lever as in a seesaw or at any point between the input and output, and the output depends on the difference in the length of the load arm and the effort arm (8).

This innovative device was crafted by modifying a simple inexpensive (Rs. 100 only) silicone injector gun with the help of a brazing technician, to help fit an ordinary 10 ml syringe to the load arm, which injected 1ml fluid by advancement of the load arm on every full range stroke of the effort arm, which moved by an angle of 40 degrees and a distance of 48 mm at the farthest point of the arc thus translating an 8 mm piston movement for every ml of fluid expulsion,

and augmenting the injection pressure to 6 times. The resistance at the lever with practice gives an accurate idea of the tissue resistance and give-way feel to the user. One SPG has proved to work well for over 2000 cases in our study, making it very cost effective. Such a utilization of the physiological knowledge of ergodynamics of hand and of the principles of leverage has facilitated development of a device which has revolutionized the face of a very tedious surgery.

The device based on the first class lever principle proved to be useful in various ways.

1. It reduced the effort and time required in local infiltration and hydrodissection.

2. It effortlessly expanded the palatal tissues to facilitate a tensionless closure and hence reducing the wound dehiscence.

3. It reduced bleeding by separating the tissue planes with less amount of sharp dissection as also seen in previous studies (9).

4. As compared to expensive motorized and computerized devices meant for small volume local anaesthetic injections as in dental surgery, this innovative mechanical device is capable of delivering large volumes of the drug with an excellent “feel” of tissue resistance and of give way, while enabling the surgeon to clearly visualize the elevation of the palatal mucosa even before using the knife (4, 10).

5. It is inexpensive, and can be very easily designed, and has revolutionized the face of cleft palate surgery reducing the surgical time to 50%, and a fistula rate from 3% to Zero percent.

6. It showed less muscle strain and minimized fatigue of the surgeon's hand as seen by limited alterations of surface EMG (11).

Our results clearly indicate that improvement in surgical outcome in a comfortable and ergonomic workspace can contribute to an enhanced situational control and a decreased level of physical workload. The results corroborate with the findings of previous workers who have also seen improved performance and reduced cognitive stress levels as well as physical discomfort to the surgeon in robotic surgery (12).

The indigenous device which was developed from the physiological knowledge of ergodynamics and leverage has proved to be a very useful, cost effective, sterilizable, manually controlled hydrodissection tool which has considerably improved the, convenience and results of surgery. This is truly applied physiology, used extensively now for the assistance of the surgeon and the patients undergoing surgery. Similar ergonomic devices are needed in many disciplines of life to reduce effort, increase output and the quality of output.

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