Need for Grass Root Innovation in Developing Countries: Case for Stationary Binder Clips in Scalp Hemostasis

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■ OBJECTIVE: **The primary training in any surgical practice starts with tissue handling and effective hemostasis. Neurosurgical procedures start with an incision in the scalp and require summative use of mechanical hemostats and bipolar coagulation to achieve hemostasis. Though Raney clips are the most popular and effective in maintaining hemostasis, their high cost and nonreusability become deterrents for routine use in resource-stricken environments.**

■ METHODS: **We have compared stationery binder clips of different sizes with Raney clips on the parameters of effectiveness, availability, and cost. Binder clips were also used in intraoperative settings for scalp hemostasis. The comparative efficacy, additional usage of cautery, and need for sterilization are also discussed.**

■ RESULTS: **We describe our experience with simple stationery metal binder clips in maintaining effective hemostasis in a cost-effective manner. The 25-mm size binder clip exerts same force as a Raney clip without any tissue injury. Practical application revealed effective scalp hemostasis up to blood pressure of 150 mm Hg.**

■ CONCLUSIONS: **Stationery binder clips are a cost-effective, ready-to-use alternative for standard Raney clips.**

The first step in a neurosurgical procedure, the scalp incision, is often understated in its importance. Historically, many varied attempts have been made to ensure scalp hemostasis with the aim of temporary, effective, swiftly applied, and lasting control that can be easily modified and reversed intraoperatively. The founders of modern neurosurgery had conceived a host of innovative solutions to meet this need ranging from Dr. Horsley's hemostatic sutures to Dr. Cushing's pneumatic tourniquet and hemostatic forceps to Emil Mayer's report on the use of vasoconstrictive agents. But the invention of Raney clips in 1937 brought the search to a halt. These clips appear to match all the criteria for effective scalp hemostasis—swift application, atraumatic edges, good vascular control, and ease of intraoperative repositioning. Raney clips stalled the search for a scalp hemostasis strategy the world over and yet when the author witnessed the first step in his first neurosurgical procedure, they were unavailable.

Angled galeal forceps were used instead for holding the galea (an invention that owes its origin to the unsung hero Anatole Kolodyn in 1927,[1] known internationally today as Dandy's forceps). Large bleeders were coagulated. At the end of the scalp reflection, a bulky set of 10–15 forceps would hang on either side. The only reason was the cost of Raney clips, and their applicator was prohibitively expensive. This is still the situation in several institutions in developing countries with high volumes and poor funding. The solution can be purchased at any shop for school stationary metal binder clips.

WHAT ARE STATIONERY METAL BINDER CLIPS?

Metal binder clips for stationery use were patented in 1915 by Louis E. Baltzley[2] long before Raney clips were invented. The simplicity of the invention has led to its longevity over a century of use without undergoing any significant change in design. Essentially it is a tiny sheet of steel that is folded to act as a binder for bundles of paper. The tensile properties of the metal itself are used for application of pressure. It does not use a spring mechanism, unlike other stationery clips. While its natural position is to remain closed, it can be opened by an attached handle, which can be rotated to fit the bound article snugly.

Key words
- Clips
- Cost
- Hemostasis
- History
- Raney
- Scalp

Abbreviations and Acronyms
FSR: Force Sensitive Resistor
USD: U. S. dollar

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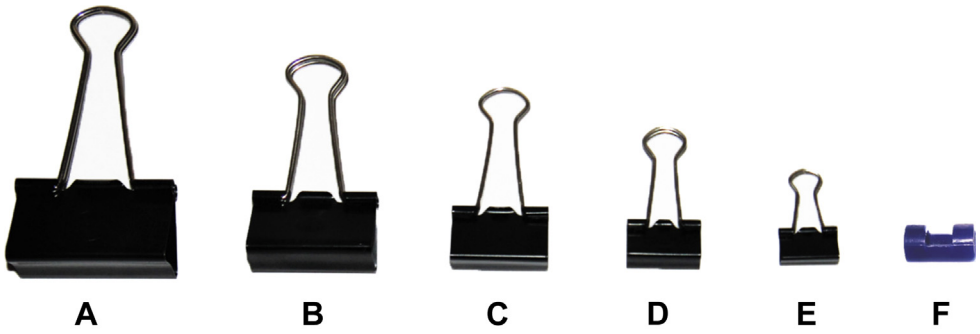

Figure 1. Stationery binder clips of various sizes used for pressure testing.

BINDER CLIPS VERSUS RANEY CLIPS

Metal stationery binder clips were chosen as replacements for Raney clips on the basis of 3 simple points—effectiveness, availability, and cost. We analyzed the comparative effectiveness with Raney clips on force and clinical analysis.

Force Analysis

Five types of stationary binder clips (15, 19, 25, 32, and 41 mm) and Raney clips were selected for the applied force analysis (Figure 1). Force signal was recorded using "Force Sensitive Resistor (FSR 400, sensitivity 0.2—20 N, Interlink Electronics Inc., Camarillo, California, USA)". A simple voltage divider circuit was designed

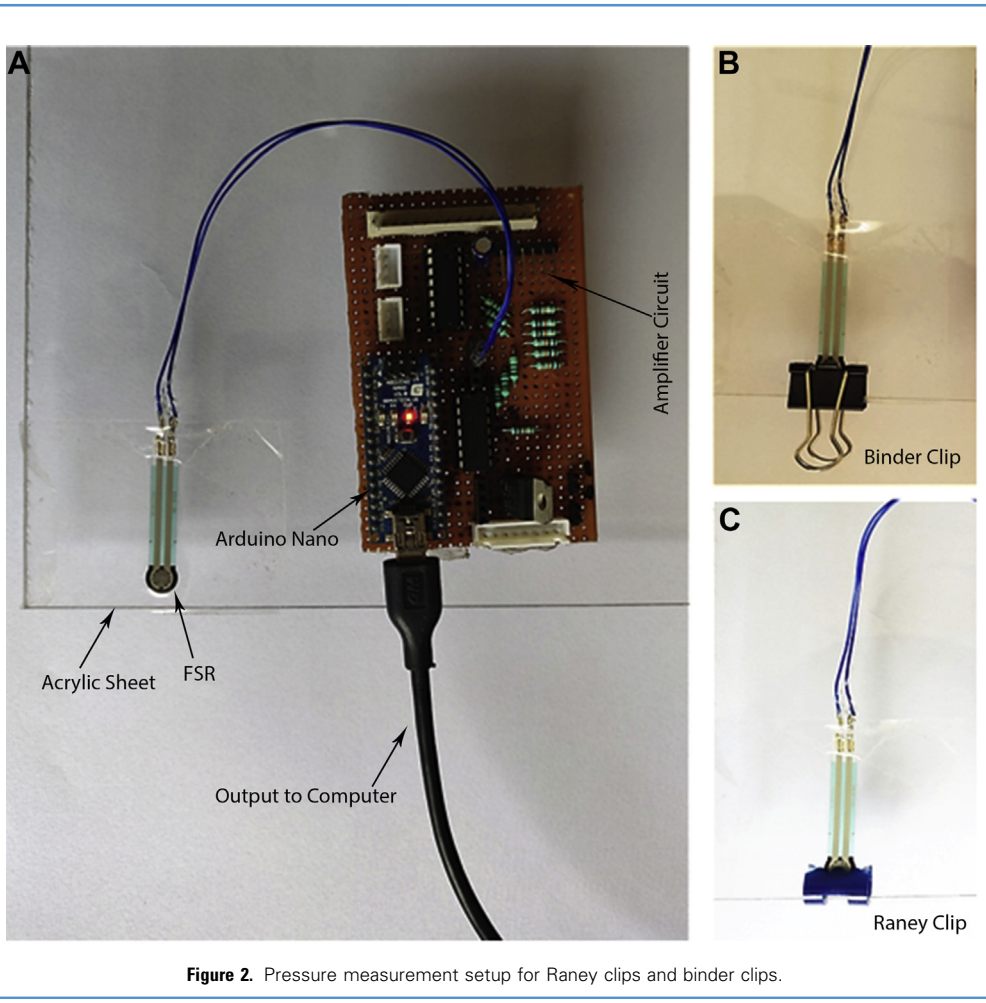

Figure 2. Pressure measurement setup for Raney clips and binder clips.

Table 1. Comparative Force Application by Binder Clips of Various Sizes and Raney Clip

S. Number	Clip Type	Applied Force (Newtons)
1	Binder clip (15 mm)	4.4818
2	Binder clip (19 mm)	3.6447
3	Binder clip (25 mm)	1.1508
4	Binder clip (32 mm)	2.0676
5	Binder clip (41 mm)	3.3015
6	Raney clip	1.2258

to vary FSR sensitivity and tune FSR characteristics to the desired curve. The circuit was designed around operational amplifier "MCP6004" (Microchip Technology Inc, Arizona, USA). The output pin of the amplifier was connected to the analog pin of the "Arduino Nano" microcontroller for data acquisition (Arduino Hungary Kft, Budapest, Hungary). A freeware application (CoolTerm, version 1.4.7) was used to record the data on a computer with a sampling frequency of 100 Hz.

The FSR sensor was calibrated using calibrated weights ranging from 0–200 g with the increment of 10 g after each reading. Matlab curve fitting tool was used to map the sensor data to the corresponding calibrated weight values. A fifth-degree polynomial equation was used as the best curve to fit the corresponding values. A fixture of 5-mm thick acrylic sheet was used to provide rigid support while measuring the applied force (Figure 2). The force measurements were performed 5 times for each clip and averaged. Averaged values were converted to force (newtons) by multiplying by a factor of 0.0098. The FSR sensor was fixed at 1 end of the acrylic sheet, and applied force measurements of stationary binder clips (15, 19, 25, 32, and 41 mm) and Raney clips were performed. Table 1 summarizes the measured applied force for different clips.

The results show that the smallest (15 mm) binder clips exerted highest applied force (4.4 newtons). The applied forces of 19-mm, 32-mm, and 41-mm binder clips were 3.6, 2.0, and 3.3 newtons, respectively. The applied forces of 25 mm binder clip and Raney clip were 1.15 and 1.22 newtons. The applied force of the 25-mm binder clip and Raney clip were closely matched to each other.

Clinical Analysis

Binder clips were used in 5 patients with varied pathologies and ages. One patient aged 45 and another aged 35 underwent decompressive craniotomy for acute SDH, 1 aged 24 underwent craniotomy and evacuation of an EDH, and 2 patients aged 62 and 44 who underwent craniotomy and excision of high-grade gliomas. The 25-mm and 32-mm binder clips were chosen for use based on the force measurement studies. The jaws of the clips are rounded and atraumatic. The authors observed effective hemostasis at blood pressures up to 150 systolic with minimal need for bipolar cautery (Figure 3). Beyond this point, hemostasis required the more frequent use of bipolar cautery, but this was not more than what was required if Raney clips were used. Binder clips have metal loops attached that can be used for easy application, removal, and re-positioning, obviating the need for a separate applicator. The metal loops can be folded down over the raised margin of the skin flap to fit the scalp snugly. The clips did not slip during the surgery (Figure 4). The longest surgery among the 5 was for 6 hours. All 5 patients had effective wound healing in the postoperative period with no scalp necrosis. Note that binder clips were not used in any pediatric patient.

Availability

Binder clips are available in our country (India) in 6 sizes (15, 19, 25, 32, 41, and 51 mm). We used the first 5 sizes for this study as the 51-mm clip was too big to be used for hemostasis. These clips are available at all big stores that sell stationery. They are readily available in most countries around the world, evidenced by their presence in stationery item catalogs available on the Internet. While other artisan systems of hemostasis have been developed to compare with Raney clips, the availability and cost of stationery clips mean that they can be adopted universally in resource-struck areas with little variability in design. They are also easy to store and sterilize. Due to the complete metal structure, they can be

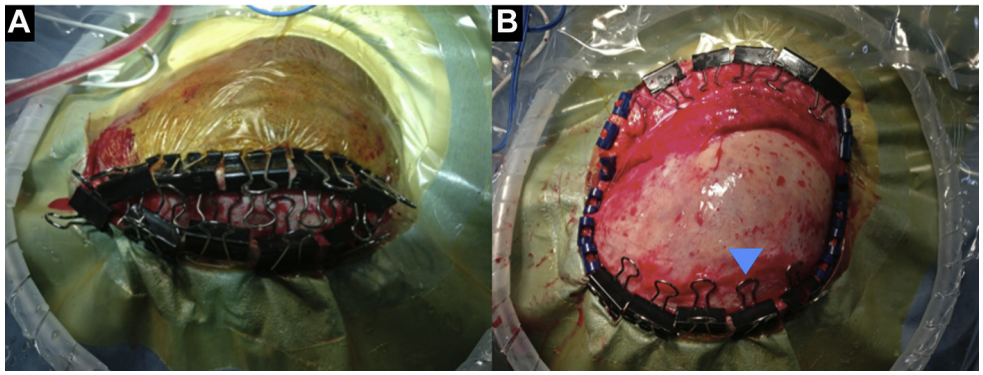

Figure 3. Intraoperative scalp hemostasis with binder clips.

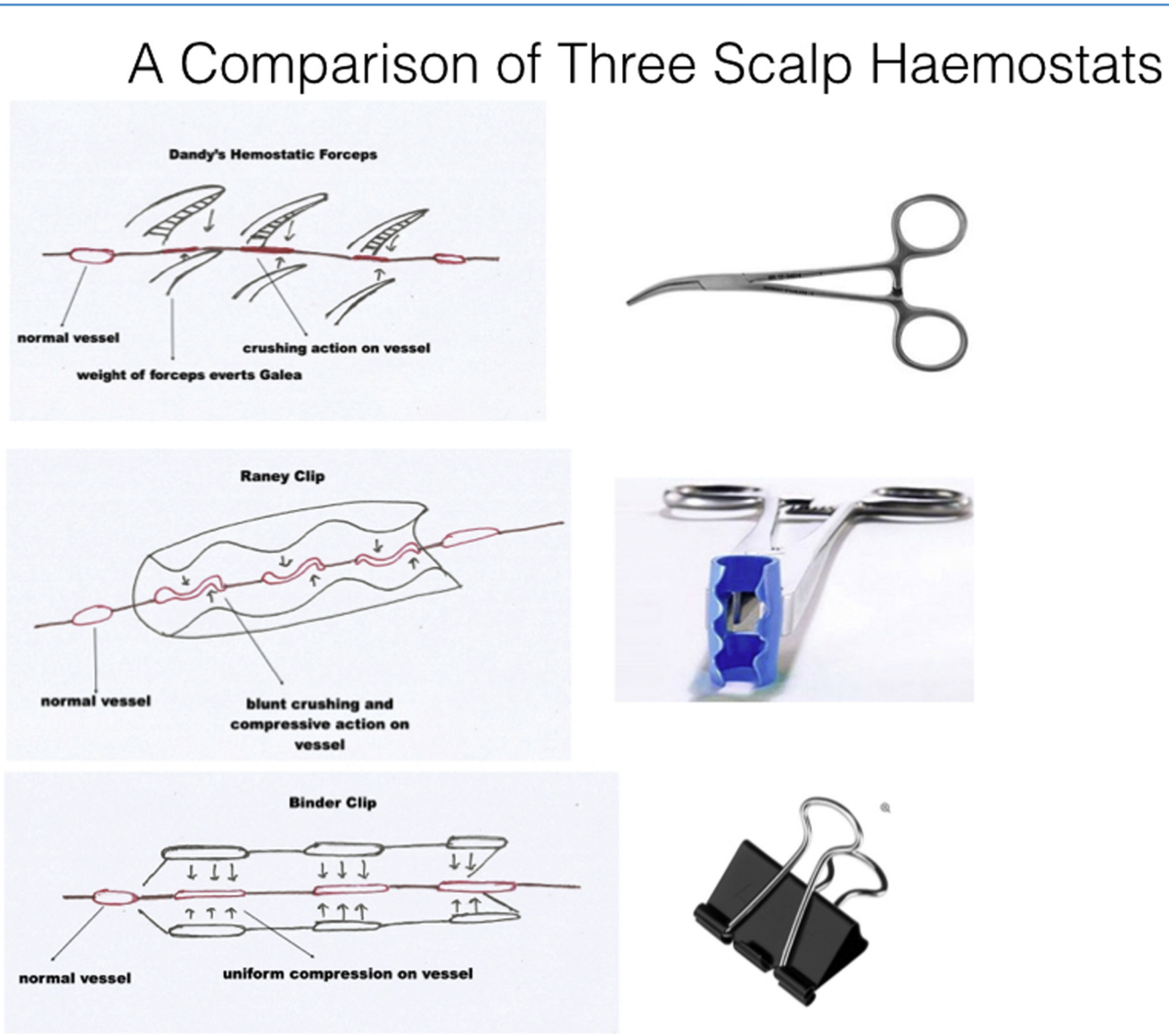

Figure 4. Schematic diagram comparing the mechanisms of action of Raney clips, Dandy hemostatic forceps, and stationery binder clips.

autoclaved with other instruments. Due to their familiarity with people in general, their use has a short learning curve compared with Raney clips and Dandy forceps.

Cost

A frontotemporoparietal reverse question mark trauma scalp flap is one of the longest incisions given in neurosurgery and undoubtedly 1 of the most common. With a mere 1.04 USD expenditure, effective hemostasis using metal binder clips for a complete trauma flap can be achieved, whereas a fresh set of disposable Raney clips costs >10.2 USD. The applicator for Raney clips (although a 1-time cost) ranges anywhere from 15 to 50 USD. Besides the significant cost difference, stationery metal binder clips are autoclavable and reusable. Even if they were used only once, the cost per patient would still be minor.

DISADVANTAGES

The primary difficulty experienced was due to the metal handles of the clips along the lower (nonreflected) scalp margin. These would have to be retracted during burr-hole placement and use of the Gigli saw/drill. Sutures would get tangled onto the handles during placement of hitches on the dura. These problems were similar to

those faced with the use of Dandy's hemostatic forceps. After a few cases, the authors were able to perform these tasks without hindrance. The nursing assistants also mentioned difficulty in cleaning soiled binder clips especially at the handle insertion points. Hence it is recommended that new autoclaved binder clips be used for every patient.

GOING BEYOND OPERATION THEATER

The cost, availability, and ease of application of binder clips beckon one to ask why their application should be restricted to the operation theater. Can nonmedical personnel on site use these clips for hemostasis? While healing was excellent even after 4 hours of surgery, skin necrosis due to long-term ischemia by binder clips, Raney clips or any other pressure-based hemostasis measure is a real possibility. That being said, for on-site hemostasis of scalp lacerations, a bunch of sterilized binder clips of various sizes may be a handy tool in the first aid kit for adventurers, trekkers, and army personnel. "Effective grass roots innovation" is the key to better results in high-volume centers with low funding. Binder clips may be included in the neurosurgeon's arsenal to achieve the goal of doing more with less.

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