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Technical notes & surgical techniques

Development of a pin-less reference head frame: An experimental setup and preliminary experiences

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ABSTRACT

Objectives: Advantages of image guidance in neurosurgical procedures are undisputed. Although some approaches of flexible technologies already exist, today's gold standard for neuronavigation is the pin-assisted head clamp fixation. A reference tool that is simpler in handling, universally available and non-invasive would be desirable. We introduce two pin-less mobile head frames and investigate their feasibility in a series of exercises.
Patients and methods: A head frame, which is originally used as facebow in dentistry, was modified to create 2 head frames. A sequence of exercises was designed to imitate the different movements of a patients head in a real case of emergency. The trial was subdivided in two phases each with 10 healthy participants. The requirement to each participant was to complete the sequence of exercises whilst wearing the frame. Different parameters were collected.
Results: The frame-to-head stability was not sufficient for the first frame. It increased significantly for the second frame, mainly due to the flexible forehead- and the occiput-band. The handling of both devices was cumbersome and time-consuming.
Conclusion: The sequence of exercises proved to be a suitable approach to investigate the advantages and disadvantages of the frames. The presented devices are not acceptable for emergency clinical practice yet. Further modification is necessary. Invasive pins are not mandatory for a close fit of the frame. The presented trial is superior to the investigation using an immobile skull model.

1. Introduction

Image-guided procedures have become an indispensable requirement in the neurosurgical operating room (OR). Neuronavigation has evolved in the last two decades [1]. Besides frame-based systems frame-less technologies have arrived in neurosurgery [2], however, the skull-clamp based neuronavigation is the most common. It attains immobilization of the head by rigid fixation to the operating table. H. Mayfield developed the most frequently used clamp system 40 years ago [3].

Clamp-fixation has two main disadvantages: Firstly, it is an invasive tool [4]. The head is held by the application of bone-anchors as pins or screws into the pericranium. Possible complications include skull fractures with and without dural laceration [4,6], epidural haematomas [4,5] and sympathetic as well as haemodynamic responses, respectively [4,7]. Secondly, clamp-based neuronavigation is cumbersome and depends on availability of an anaesthesiologist and a place in the OR. For those reasons, clamp-assisted technology does not really qualify for such neurosurgical emergency procedures which do not inevitably need rigid head fixation and immobilization but would nevertheless benefit from neuronavigation, in example the insertion of an external ventricular drainage (EVD) [8–10]. In this respect, it seems desirable to make neuronavigation independent from the OR setting, which means to make the reference device independent from the head clamp, respectively. To become commonly accepted such a device has to fulfill the criteria of mobile, quick and easy usage. In addition, a significant benefit would be fixation without invasive pins or screws. Currently there are already different approaches to develop such a device. For example, a headband or headset is proposed by Iwai et al. [11]. Authors recently introduced the Medtronic Axiem stealth frameless neuronavigation system [12] and the Stryker face mask [13]. Indeed, such devices have to be proven to be accurate and practical for use in every day clinical practice and thus may replace the traditional system.

In our preliminary study we depict an experimental setup including different steps to investigate the advantages and disadvantages of a non-invasive reference frame and its enhanced version.

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2. Material and methods

2.1. The first frame

Based on a facebow, which was engineered by SAM® Präzisionstechnik GmbH, Gauting, for anatomic transfer purposes, the frame was designed by DMD GmbH Digital Medical Design, Dortmund. It consists of an adaptable bow made from aluminium and is fixed at the head by means of the following:

- one nasion strut,
- two adjustable earplugs which are inserted into the external acoustic meatus,
- four mastoid struts in the form of plates which are screwed tightly on the mastoid bone and
- two elastic bands tightened along the forehead as well as along the back of the head (Fig. 1).

2.2. Phase one

Our first phase involved 10 healthy participants which are listed in Table 1.

Fig. 1. First frame.

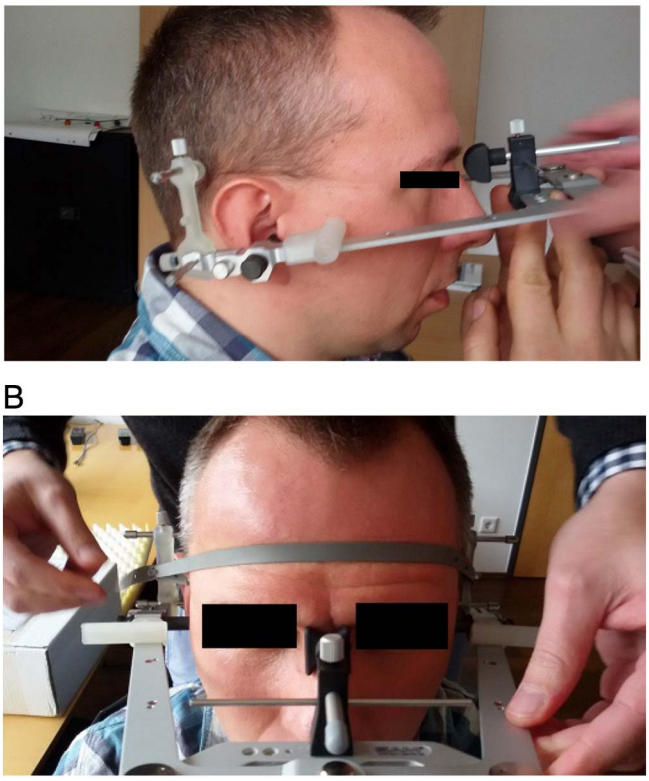

Fig. 2. a: Fixation of the first frame, side view.
b: Fixation of the first frame, frontal view.

Each participant gave a written consent and the mother gave her written consent for the child, respectively. They were chosen with the aim of representing the variability of anatomic skull dimensions. Therefore we included 5 males and 5 females of different age (range 6–39 years). Those two preconditions ensured different skull shapes, different skull circumferences (range 51.5–59.5 cm) and different patterns of hair growth, respectively. The frame was fixed to the skull with the subject in the sitting position (Fig. 2a, b) by the two study leaders (AC first author and CB senior author). One of whom is a neurosurgeon with advanced clinical experience in the

Table 1
First round study population.

No.	Sex	Age [years]	Hair growth	Skull circumference [cm]	Fixation time [min]	Subjective ranking
1	f	39	3	59.0	10	2
2	f	6	2	53.5	8	1
3	m	20	2	57.5	7	2
4	f	18	3	56.5	10	1
5	f	21	3	51.5	8	2
6	m	22	2	59.5	5	1
7	m	25	2	56.5	10	3
8	f	19	2	55.0	10	3
9	m	22	2	59.5	8	3
10	m	21	2	58.5	8	1

Hair growth: 1 = few; 2 = middle; 3 = thick (i.e. curls, braids).
Subjective ranking: 1 = no discomfort; 2 = discomfort; 3 = pain; 3+ = pain, exercise not possible.
The **gray fields** represent participants who attended twice.