Snoring and Its Management (Part 2/2): Preliminary Design and Prototyping of Anti-Snoring Chin Strap Device

Diana Starovoytova
School of Engineering, Moi University P. O. Box 3900, Eldoret, Kenya

Abstract
The-aim of this-research was to-design and prototype a-chin-strap-device, which can-be-used to-manage largely-untapped local-population of open-mouth-habitual-snorers. Document-analysis was utilized as one of the-study-instruments (including review of: (i) selected-International-patents on the-designs of chin-strap device; (ii) published-research on head-gear, head-products, and the-use of anthropometric-data in their-design; and (iii) prior-art on chin-strap-devices and their-respective-limitations). Target-specifications/ objectives of chin-strap-device were formulated from the-document-analysis, while Pair-wise-Comparison Charts were-used, to-rank the-importance of the-objectives, in the-different-levels. This-study also used such-basic-tools-as pencil and paper, for sketching, of the-alternative-designs; and a-database, as a-tool for information-storage and retrieval. Besides, the-study applied fundamental-Engineering-principles of *product* design, and was-carried-out in-compliance-with both; ISO8559: 1989 (Garment-construction and anthropometric-surveys-body-dimensions), and ISO7250: 1996 (Basic-human-body-measurements for technological-design). The-best-ranked-design (out of the-3 alternatives made) was chosen, *via* Engineering numerical-weighted-decision-Matrix and '*Drop and Re-vote'* (D&R) method. 13 head-dimensions, and a-head of a-medium-size, and of normal-shape, for 50^{th} percentile, black-African-male, of over 40 years of age, was selected, as a-design-target. The-values, for these-head-dimensions (one-dimensional measurements), were obtained from IOM and Anthrotech anthropometric-data-tables, for *civilian*-population. 2D-drawings, of the-selected-alternative, were created *via* computer-aided-design (CAD) AutoCAD-software. The-fibre, from which the-final-fabric, to-be-made, for a-chin-strap-device, was designed discretely of the-product-design-process, and then was-incorporated, into-the-design, as a-finished input/fabric-structure. This-study also adopted '*analysis*' method of materials-selection. The-main objectives, of the-intended-device, was used as a-guide, in-materials-selection. Acrylic man-made textile-fibre was selected, *via* computerized-materials-databases/libraries; and afterwards the-woven-fabric of plain-weave was-chosen as main-material, for the-device. The-fabrication and assembly, of the-prototype, was achieved *via* stitching-joining-method. Traditional-testing/usability-inspection (by dynamic- verification) was conducted on a-volunteer (open-mouth-snorer); observers reported, that some-snoring reduction was noticeable, in-comparison with the-observations, of the-volunteer, sleeping, without the-device, moreover, the-device stayed-in-position (without sliding-off), during the-five-observation-nights. Overall, the-result of this-preliminary-design is somewhat-optimistic, further-improvement(s) and trials, however, are necessary. The-study, hence, further-recommended to: (1) carry-out a-detailed-design; (2) fabricate the-next/refined-prototype(s); (3) conduct explorative-use-ability-trials, in-collaboration-with the-department of Medical-Engineering, School of Medicine, MU; and (4) analyze the-marketing-aspect of the-design.
Keywords: materials-selection, Acrylic, textile, testing.

1. Introduction.

1.1. Snoring and its-effects.

Snoring is the-vibration of respiratory-structures, and the-consequential-sound, due to-obstructed air-movement, during-breathing, while-sleeping. In-mild-cases, the-sound may-be soft; in most-cases, however, snoring can-be very-loud, unpleasant, and annoying (Dreher *et al.,* 2009). Snoring is considered as one of the-factors of sleep-deprivation, and it may also-be a-warning-sign, of obstructive-sleep-apnea (OSA). Snoring can-happen in any-part of the-upper-airways, such-as: the-nose, the-soft-palate; the-back of the-tongue; and the-back of the-throat. *Primary/simple-snoring* is defined-as loud aspiratory-sounds, in-sleep, without Apnea or hypoventilation (American-Academy of Sleep-Medicine, 2001), which occurs due to-turbulent-air-flow, through a-narrow oropharyngeal or nasopharyngeal-space (Bradley & Floras, 2009). *Habitual-snoring* is a-chronic-condition, which may-be-described as snoring 'almost-every-night', or 'every-night, per-week' (Young *et al.,* 2001; 1993).

More-information on snoring and its-management can-be-viewed, *via* recent-publication, by Starovoytova (2018) (including: definitions; causes; prevalence; effects due-to-both: noise-pollution (auditory-disturbance), and health-effects, as a-result of obstruction of upper-airway), alongside-with snoring treatments/remedies).

This-study focused on habitual-open-mouth-snorers.

1.2. Principle of operation and advantages of chin-strap-device.

Chin-strap-devices, mainly-attend to-open-mouth-snorers; according to-statistics open-mouth-snorers comprise 80% of the-snoring-population (Kuna & Remmers, 2000). Figure 1 shows simplified-concept of a-chin-strap-device. Chin-strap can-help to-reduce, or eliminate, open-mouth-snoring, by providing a-particular-position of the-jaw, and keeping-mouth-closed. The-chin-strap is structured to-mimic the-direction of the-forces that close-the-jaw, such as *masseter*-muscle. That is, the-chin-strap is intended to-close the-person's mouth, or jaw, *not* retract the-jaw. Component-wise, this-is-achieved *via* the-bottom-portion of the-device (jaw-cup), which goes-down and around the-jaw, by-keeping the-mouth closed and lower-jaw in an-upward and slightly-forward-position, which, in-turn, increasing the-3D-space, in the-airway, and, thus, reducing the-air-velocity and soft-tissue-vibration, and also prevents the-tongue and throat-tissues, from falling-back, and blocking the-airway (Kim *et al.,* 2011).

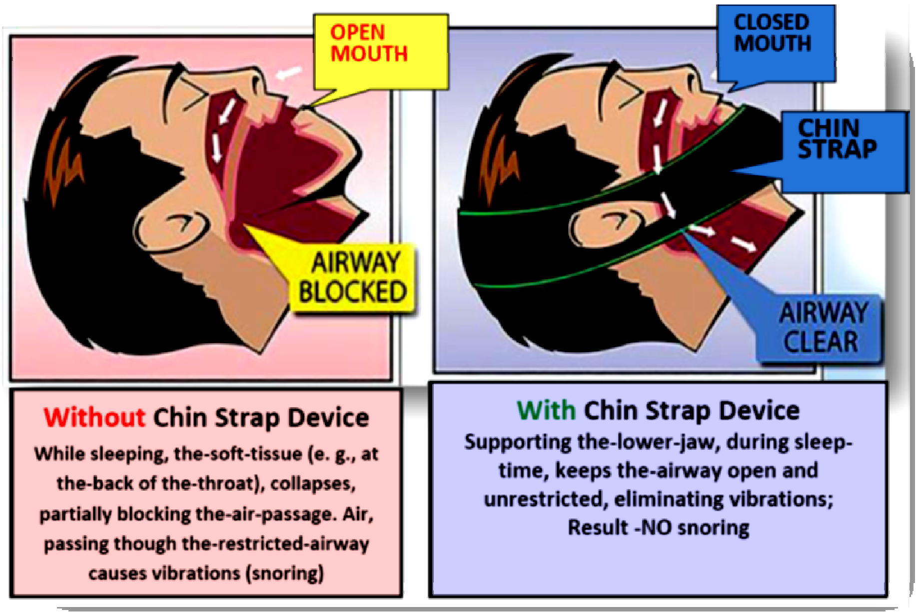

Figure 1: Concept of chin-strap-device

Since there-is nothing-intrusive, placed inside-the-mouth, chin-strap-devices can-be-used, by people, who have-had some-dental-work done (e.g., dentures, crowns, caps, or loose-teeth); and this can-be-considered as an-advantage, in-comparison with oral-devices. Another-advantage is that with chin-strap-devices, there is *no* lengthy-preparations/setup-process, required, such-as, for-example, 'boil and bite' for Mandibular-Advancement-Devices (MAD)-devices (see Starovoytova, 2018). Besides, *no* cleaning, after every-single-night, or special-storage-procedures, is necessary. For-example, chin-strap-device can-be easily-stored with the-clothes, in a-closet, or inside a-drawer; while-other-products may require special-casing. Moreover, being made of fabric, it-is practically-unbreakable, which is *not* the-case with MAD and Tongue-Retaining-Devices (TRD)-devices, which are easily-broken. In-addition, it-is easy to-put-on and to-take-off, and with the-proper-choice of a-fabric the-device cause *no* irritation/allergy.

1.3. Purpose of the-study.

As-mentioned-earlier, snoring-research has-shown that a-jaw-supporter/chin-strap-device (worn, during-sleep-time) that keeps the-lower-jaw, in an-upward-position, increases the-3D-space, in the-airway-tube, which reduces air-velocity, and soft-tissue-vibration, and consequently, snoring can-be eliminated, or substantially-reduced. In-particular, Vorona *et al.* (2007) described a-case, where a-patient with severe-OSA (apnea-hypopnea-index (AHI) 42/h in-general; 44/h in-REM-sleep, as-detected by overnight-split-night-polysomnography (PSG)) discontinued Continuous-Positive-Airway-Pressure (CPAP)-therapy, after one-month and wore a-chin-strap, alone, to-treat his-OSA, with continued subjective clinical-benefit. A-repeat-PSG was performed three-months after the-patient's initial-study (at-which-point he-had *not* been using CPAP, for two-months), with the-patient, wearing a-chin-strap, without CPAP, and it showed that his-AHI had-normalized-to 1/h.

The-chin-strap may-be used as stand-alone device, or with a-mask; the-mask, being used for treatment, e.g., of Sleep Disordered Breathing (SDB), with CPAP, or Non-Invasive Positive-Pressure Ventilation (NIPPV). Chin-straps are also proved to-be-effective, in-habitual-snorers, and patients with temporo-mandibular-joint-dysfunction (TMJD). Moreover, recently, it has-been demonstrated, that chin-straps could-be-an-effective-supplement, in the-fixed-positive airway-pressure (PAP) therapy (Knowles *et al.,* 2014), diminishing mouth-drycomplaints, and air-leeks-associated-arousals (Vorona *et al.,* 2007). Moreover, the-American-Academy of Sleep-Medicine recommends, as a-best-clinical-practice, for PAP-titration, to-use chin-strap, as a-supplement, to the-nasal-mask, to-reduce air-leakage (Bhat *et al.,* 2014). Furthermore, Dr. Ahmed Kutty, of St. Mary Hospital, conducted small-scale sleep-study, consisted of 10 patients, who were tested and diagnosed-with OSA, on the-efficiency of chin-strap-device. The-study revealed: A substantial-reduction in the-number of OSA-episodes; A-substantial-reduction in the-number of snores; and Lower-blood pressure-readings, in the-morning. Besides, scientists of Kochi-Medical-School, Japan, recently released clinical-trial-information, concluding, that a-chin-strap, alone, improved OSA-symptoms, as-well-as, or better than the-use of PAP.

The-effectiveness of the-fabric's strength, the-quality of the-Velcro-closing-tabs, and the-overall-fit, of the-chin-strap, can-deteriorate, over-time. Yet, chin-straps reported to-offer longer-periods of effective usage, than other-anti-snore-solutions, primarily because they are *not* inside the-mouth. The-usage of the-chin-straps, however, should-be avoided, with: (1) severe-nasal-obstruction (allergy, chronic-sinusitis, nasal-polyposis, deviated-nasal-septum, etc.), to-avoid possible-blockage of the-mouth-breathing, as a-compensative-mechanism; and (2) gum-disease, or temporo-mandibular-joint-dysfunction.

According to Anti-snoring-devices-market-report, the-anti-snoring-devices market is to-reach USD 1,232.6 Million by 2020, from USD 744.7 Million in 2015, growing at a-CAGR of 10.6%, from 2015 to 2020. Major-factors, driving the-growth of this-market, include: the-growing-awareness on the-ill-effects of snoring; availability and benefits of anti-snoring-treatments; growing elderly and obese-population; presence of large-number of cigarette-smokers and alcoholics; and large-pool of untapped-snoring-population. However, poor-efficacy of current-anti-snoring-treatments and surgery-procedures, their-high-cost, and lack of reimbursement (by NHIF, or a-standard-medical-insurance) are major-factors restraining the growth of this-market. This-anti-snoring-treatments-market is divided-into anti-snoring-*devices* and snoring-*surgery*. The-anti-snoring-devices-market is poised to-grow, due-to their-low-cost, in-comparison-with surgical- procedures; less-invasive-nature of these-devices; and efforts, taken by stakeholders, in aggressive- advertising of these-devices.

In-Kenya, this-huge market-opportunity, for anti-snoring-devices, and in-particular, for proven-effective--chin-strap-devices, is unexploited, probably due-to-lack of awareness, on potential-harmful-effects of snoring (both; direct and indirect) among the-general-population, in-the country, as-well-as lack of locally-offered affordable-snoring-treatments. The-aim of this-research was to-design and to-prototype a-cost-effective, easy-producible, user-friendly, and reliable-device, that can-be-used to-manage open-mouth habitual-snoring. The-intended-device was designed to-help-providing normal-jaw positioning, and healthy, or healthier-sleep, as-well-as reducing the-Obstructive-Sleep-Apnea (OSA) associated-health-risks, without the-need for expensive-surgery, medications, uncomfortable, and at-times, *not* very-effective-anti-snoring-devices, or therapy.

2. Materials and Methods.

2.1. The-main research-steps.

This-study was focused on *product*-design, where several-tools have to-be-applied. Design-tools enable product-designers to-structure and formalize parts of their-design-steps (Jangager, 2005). To-achieve the-study-objectives, the-following-steps (shown in-Figure 2) were performed; *not* necessarily, sequentially, but at-times, conducted in-parallel, or, even, in-overlap.

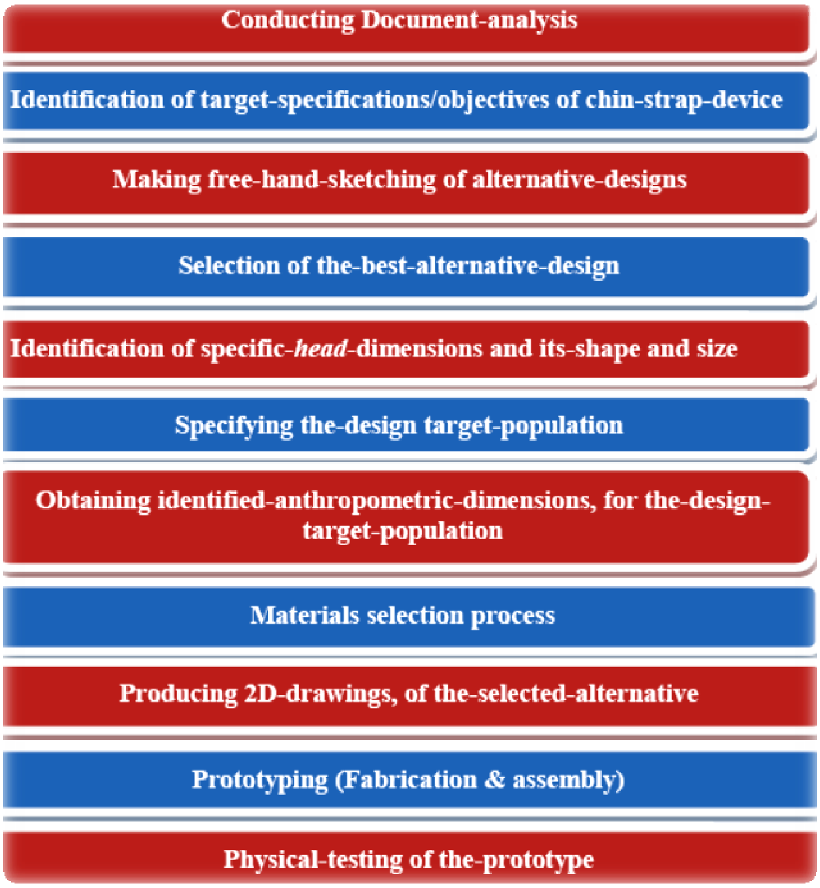

Figure 2: Main-steps of the-study.

Some-clarification, on the-steps, was provided below:

2.2. Conducting Document-analysis.

To-ensure a-unique-design, document-analysis was-utilized, as one-of the-study-instruments (including review of: (1) published-research on head-gear, head-products, and the-use of anthropometric-data in their-design; (2) selected-International-patents on the-designs of chin-strap-device; and (3) prior-art on chin-strap-devices and their-respective-limitations).

2.3. Identification of target-specifications/objectives of chin-strap-device.

Target-specifications/objectives, of chin-strap-device, were formulated-from, and based-on the-document analysis. Factors of consideration involved: Efficiency/functionality; Manufacturability; and Marketability, among-others. After the-determination of the-objectives, of the-device, Pair-wise Comparison Charts (PCC) were-used, to-rank the-importance of the-objectives, in the-different-levels.

2.4. Making free-hand-sketching of alternative-designs.

Romer *et al.* (2001) stated, that traditional-tools, such-as sketches and simple-physical-models are very-useful and cost-efficient, in-generating design-solutions, in early-phase of design-process. Besides, most of the-times (this-study included), design-problems, are open-ended; they do *not* have a-unique, or the-only-one correct-solution, though some-solutions will, clearly, be-better, than others.

In-this-regard, the-design-team produced 3 different-versions/alternative-designs, of chin-strap device, by free-hand-sketching, at-the-same-time making some-preliminary-calculations, which might-be required to-substantiate-ideas and to-establish approximate-sizes.

Product-designers utilize a-wide-variety of design-tools, ranging from sophisticated-computerized information support-systems, such-as CAD-systems, to inexpensive-memory-aids, such-as pencil and paper (Love, 2003). This-study, for-example, used a-pencil and paper, as tools, for sketching, the-alternative designs; and a-database, as a-tool for information-storage and retrieval.

The-design also applied fundamental-Engineering-principles of *product*-design. Besides, this-study was-carried-out in-compliance-with both; ISO8559: 1989 (Garment-construction and anthropometric surveys-body-dimensions), and ISO7250: 1996 (Basic-human-body-measurements for technological- design).

2.5. Selection of the-best-alternative-design.

The-best-ranked-design (out of 3 alternatives) was chosen, *via* Standard Engineering-numerical weighted-decision-Matrix. This-choice was also-confirmed by 'Drop and Re-vote' (D&R) method, according to Filippo (2012).

2.6. Identification of specific-head-dimensions and its-shape and size; Specifying the-design target-population; and Obtaining identified-anthropometric-dimensions, for the-design-target-population.

First, specific-head-dimensions and its-shape and size, relevant to the-design of chin-strap-device, were identified. Subsequently, the-design-target was chosen. Then, these-anthropometric-dimensions, for the-design-target, were obtained, from appropriate-anthropometric-data-tables.

2.7. Materials selection-process.

Materials selection-process is crucial in product-design; hence, it will be given, here, in-some-detail, to-benefit potential-readers.

According to Manzini, a-*material* is a 'system capable of performance'; the-material is defined by what it does, and *not* what it-is. The-different-aspects, of materials, can-be categorized in two-groups, namely: (1) the-technical aspects; and (2) the-user-interaction-aspects. The-technical-aspects of materials define how the-product will-be-manufactured, and how it will function. The user-interaction-aspects are those, which influence the-usability and personality, of a-product (Ashby & Johnson, 2002; Cross, 2000).

Materials-selection is a-concept used to-refer-to several-things. For-example, it refers-to a-group of materials, which is selected for a-certain-purpose. It can also-refer to a-specific-phase in the-development of an-artifact, e.g., the-materials-selection-phase, indicating a-certain time-period in a-project. In-this-study, the-term '*materials selection*' is defined, as an-activity, where materials-selection is the-goal-oriented-activities, and steps, that product-designer perform.

Materials-selection plays an-essential-role in the-product-design-process (Doordan, 2003). Ashby (1999) describes the-design-process, in itself, as an-introduction to a-methodology for selecting-materials, where 4-elements (function, shape, materials, and manufacturing-processes) do interact; Ashby terms these-interactions as-the-central-problem of materials-selection. Product-materials determine the-range of function, durability, certain-costs, user-feedback, and user-experience and overall-satisfaction, with the-product. Sapuan (2001) pointed-out, that the-aim of materials-selection is 'the identification of materials, which after appropriate manufacturing operations, will have the dimensions, shape, and properties necessary for the product or component, to-demonstrate its-required function at the-lowest-costs'. Besides, Van Kesteren (2008) defines an-*effective*-materials-selection as: 'The activities and steps that results in a materials specification that includes materials which are the best available options for not only the product's functionality but also its interaction with the user'.

Various-researchers focus on analytical-approaches toward selecting-materials and are, mainly, based on materials-selection in mechanical-engineering (see Ashby, 1999; Farag, 1989; Cornish, 1987).

Ashby & Johnson (2002) identify 4 materials-selection-methods: (1) 'analysis'; (2) 'synthesis'; (3) 'similarity'; and (4) 'inspiration' method. In-the 'analysis' method, a-list of product-requirements is translated-into-material-objectives and constraints. Dobrzanski (2001) further-explains that, after defining the-requirements for a-new-product, these-requirements are compared-with extensive-materials-databases, for a-preliminary-selection of a-number of materials, that might-be-applicable. In-the 'synthesis' method, product-requirements are translated into required-features, and then, a-database of products is explored. The-method exploits the-knowledge of other-solved-problems, and, hence, requires information about previous-materials-solutions. Where product-requirements is *not* a-starting-point, for selecting-materials, the 'similarity' method can-be used. For an-established-material, an-attribute-profile is generated, that is used to-find materials-solutions, closely-related-to the-established-one. Analogous to the 'analysis' method, information is needed about characteristics of available-materials. Innovative-thinking fuels the-last-method, identified by Ashby & Johnson (2003) as 'inspiration', where a database-with-materials is combined-with a-database of products, and new-matches are generated.

This-study adopted '*analysis*' method of materials-selection. Besides, a-fibre, from which the-final-fabric, to-be-made, for the-chin-strap-device, was designed discretely of the-product-design process, and then was-incorporated, into-the-design, as a-finished-input/fabric-structure. The-main objectives, of the-intended-device, was used as a-guide, in-materials-selection.

In this-type of process, the-designer does *not* design a-new-material (fabric, in this-case), for the-product, but instead, selects a-textile-material, that works with the-rest of the-choices, made in the-design. To-select the-most-appropriate and locally-available-fabric, made of the-pre-selected-fibre, this-study used computerized-materials-databases/libraries. Furthermore, depending on the-fibres, that have-been-used, how these have-been-spun, how the-textile-structure has been constructed, coloured, pre-or post-treated, the-resulting-textile will-be-suitable for a-defined-application. In-each of these-steps, choices were made, that have an-impact on the-final-textile-material. Simply-put, an-appropriate-textile-fibre was chosen, first, and then the-type of fabric and its-features, were selected.

On-the-other-hand, literature-sources, presenting tools, for materials-selection, mainly, focus on computerized-materials-databases (e.g., Beiter *et al.,* 1993; Martini-Vvedensky, 1985). In-some-databases, sensorial-properties are presented (e.g. www.materialexplorer.com), some provide good-practices-guide (e.g., McMahon & Pitt, 1995), while other-databases focus on manufacturing-aspects (e.g., CES). Intelligent-databases enable its-user to-combine different-requirements, for-example, *via* a-dialogue-with the-system (e.g., Smith *et al.*, 2003), *via* a-decision-matrix (Shanian & Savadogo, 2006), or with a-case-base reasoning-system, with flexible-retrieval of its-content (Mejasson, 2001). Cambridge Engineering Selector (CES), in-particular, is a-well-known computer-system, developed by Ashby and co-workers, at both; Granta-Design and Cambridge-University Engineering-Department. CES presents the-material-world in a-comparable-way, showing property-charts, containing all-materials, and enable finding optimal-materials, for certain-property-combinations.

Two-kinds of material-properties are distinguished: the 'physical-properties' and the 'sensorial-properties'. Both-properties lead to-different clustering of materials. The-physical-properties are categorized as: mechanical, electrical, thermal, chemical, and optical-properties (Ashby, 1999). Clustering-materials based on the-sensorial-properties leads-to-groups that have the-same visual and tactile-characteristics, but do *not* automatically include the-same-materials. For-example, the-ceramic material groups closely-to aluminum, because neither can-be transparent (Johnson *et al.,* 2002).

The-engineering-properties of materials are presented as material-selection-charts. The-charts summarize the-information of any-given-property, available to a-designer, showing the-range. Materials-selection, involves identifying the-desired attribute-profile, and then comparing it with those of real-engineering-materials, to-find the-finest-match. Materials are conveniently-put in clusters, so if one-material is *not* available, or expensive, another-material, form the-cluster, can-be-taken. According to Shah (2013), Ashby-plots, such-as the-one, presented in Figure 3, are very helpful, during materials selection-process, for 4-key-reasons, as they: (1) allow quick-retrieval of the-typical-properties of a-particular-material; (2) permit rapid-comparison of the-properties, of different-materials, revealing their-comparative-efficiencies; (3) facilitate the-selection of the-materials-manufacturing-processes, during the-product-design-stage; and 4) enable substitution-studies, exploring the-potential of one-material, to-replace-another.

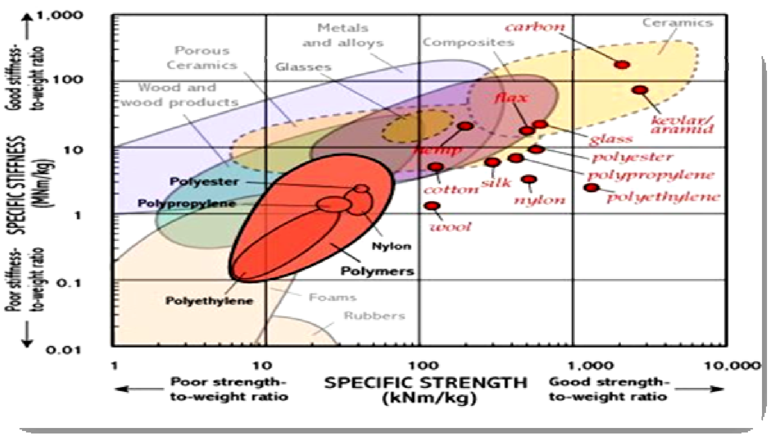

Figure 3: An-example of Ashby-plots (Ashby & Cebon, 2007).

This-study adopted the-interaction of function, materials, shape, and manufacturing-processes, from Asbhy (1999), and the-interaction of use, function, materials, and shape, from Roozenburg & Eekels (1995). To-select an-appropriate-material (from the-ones, locally-available) this-study utilized Asbhy-charts and a-computer-materials-database.

2.8. Producing 2D-drawings, of the-selected-alternative.

2D-drawings, of the-selected/best-alternative, were created *via* computer-aided-design (CAD) AutoCAD-software.

2.9. Prototyping (fabrication & assembly).

According to Hallgrimsson (2012), physical-model-making and prototyping is one of the-most-recognized and accepted-approach, which has always-been-used, by the-product-designers, to-communicate their-design-solutions. He also pointed-out, that prototypes are playing an-important-role, for designers, allowing them to-physically-see the-idea in-3D-form, and therefore an-essential-medium for problem-solving, in-design. Moreover, Marks (2000), and Kelly (2001) also support the-existence of physical-models, and reject the-notion of ultimate-dependency on virtual-models, as-tools for solving *all*-design-problems.

Prototyping is a-design-method, that uses *physical*-prototypes to-study and test how a-new-product will-be-used, and how it will-look in a 'manufactured-state' (Hallgrimsson, 2012). A-physical-prototype is a-tangible-object, which looks similar to the-final-product. Ulrich & Eppinger (2012) define prototype as 'an approximation of the product along one or more dimensions of interest'. These-dimensions are characterized-as: physical *vs.* analytical; and comprehensive *vs.* focused.

Similarly-to 'a-picture tells a-thousand-words'; 'prototypes are worth a-thousand-pictures'. According to Kelly (2001), 'prototypes are wonderful tools for understanding tangibility'. Besides, with-respect-to manufacturing, prototyping is also-important, to-anticipate how products can-be-produced and assembled, as-efficiently as-possible.

Ullman (2003) classified prototypes, as-follows: (1) 'proof of concept' prototypes are used in the-early-stage of product-development; (2) 'proof of product' prototype clarifies a designers´ physical-embodiment and production-feasibility; (3) 'proof of process' prototype shows that the-production approaches and resources can successfully-result in the-preferred-product; and (4) final-prototype demonstrates that a-complete-manufacturing-process is effective, in-proof of production. This-study used '*proof of concept*' physical-prototype.

On-the-other-hand, any-product (whether it-is a-workstation, or clothing) has-to-fit the-user-population. Normally, and this-design included, the-user-population varies in size, and the-designer should-account for this-range of sizes. There are 3 ways, in which a-design will-fit the-user: (1) Single-size, for all; (2) Adjustment – The-design can incorporate an-adjustment-capability, to-accommodate several, but *not* all-sizes; and most-expensive-option (3) Several-Sizes, to-choose from (e.g., S, M, L, XL, etc.). This-study used adjustment-option, to-cater for-different-sizes.

The-fabrication and assembly, of the-prototype, was achieved *via* stitching-joining-method, with *no* additional-joining-processes, such-as adhesive-bonding.

2.10. Physical-testing of the-prototype.

Visual-inspection, and basic-testing and of the-prototype, was conducted in realistic-situation, wherein the-person/volunteer (open-mouth-snorer) slept, while two-observers watched and took notes (so-called 'dynamic-verification'), during 5 consecutive-nights.

3. Results and Analysis.

This-section provides a-summary of the-results, of the-main-steps, of the-current-study (according to the-Figure 2).

3.1. Document-analysis.

A-number of relevant-International-patents (developed by individuals, as-well-as design-companies) were reviewed; examples included: EP3045154A1 (2016); US9308339 (2016); US8851078 (2014); US7331349 (2008); US20070181135(2007); US7000615(2006); US6277053(2001); US5893365(1999); US5787894(1998); US5687743(1997); US5361416 (1994); EP0264516A1(1988); and US3572329(1971).

Besides, the-previous-work of selected-authors, who have-researched on head-gear, head-products, and the-use of anthropometric-data, were examined (including: Lee *et al.,* 2013 and 2015; Ball, 2009; Yokota, 2005; Zhuang & Bradtmiller, 2005; Kim, 2004, 2005; Kim *et al.,* 2004; Ahn & Suh, 2004; and Han & Choi, 2003).

On-the-other-hand, different chin-strap-devices are currently-available; selected-examples were presented in Figure 4. It-is important to-note, that some of the-chin-strap-devices have slits, on the-sides, to-fit ears, nicely, inside of them, while others *not*; regardless of the-option, keeping the-device, in-place (*no* sliding-off), during the-whole-night, is paramount.

Besides, all of the-devices are quite-expensive, especially for people, in-developing-countries, like Kenya. Additional-complains was also-expressed, by their-users, that some-devices are slippery (slide-off during the-night-sleep), and painful/uncomfortable, to-use.

Figure 4: Examples of selected chin-strap-designs/devices available, globally.

3.2. Identification of target-specifications/objectives of chin-strap-device.

The-device should-be: cost-effective, easy-producible (using locally-available-fabric); light-weight; thermally-comfortable; fitting various-head-sizes; safe for the-user, and for bed-partners; reliable; structurally-sound; biocompatible; and durable. The-device should also: (1) fit comfortably, without binding; (2) Orientates one about how the-device can-be positioned, correctly, at the-first-attempt; and (3) There should be *no* resistance, when putting it on. To-achieve all-these-criteria, all the-components should (Ashby & Cebon, 2007): (a) be symmetrical (and have polar-geometry-mark), if possible, as this also helps in manufacturing; (b) have consistency, in the-dimensions, used for feeding, orientation, and location; (c) have location-points; and (d) be functional, hence, components which are *not* important/functional should-be-eliminated.

Figure 5, hence, summarizes main-objectives of the-device. The 3 major-utility-characteristics of the-device are: functional-efficiency, adjustability, and thermal-comfort-ability. Functional-efficiency was-considered-as paramount, as if the-device does *not* reduce snoring, it defeats the-very-purpose of its-wearing. Easy mouth-closure, without rearward-displacement (e.g., for minimizing upper-airway restriction (UAR)); permit forceful-mouth-opening, (e.g., for risk-mitigation, of nasal obstruction, and for speech, if needed); stabilize the-jaw, in-place; light and/or minimal encumbrance; cool and comfortable; aesthetically appealing; reasonably-durable, and easy-washable/maintainable. Besides, comfort was also-considered as an-important-characteristic; uncomfortable-device can distract one from uninterrupted- sleep, while properly-fitting-device will help one to-stay comfortable, when encountering various-sleeping positions and conditions.

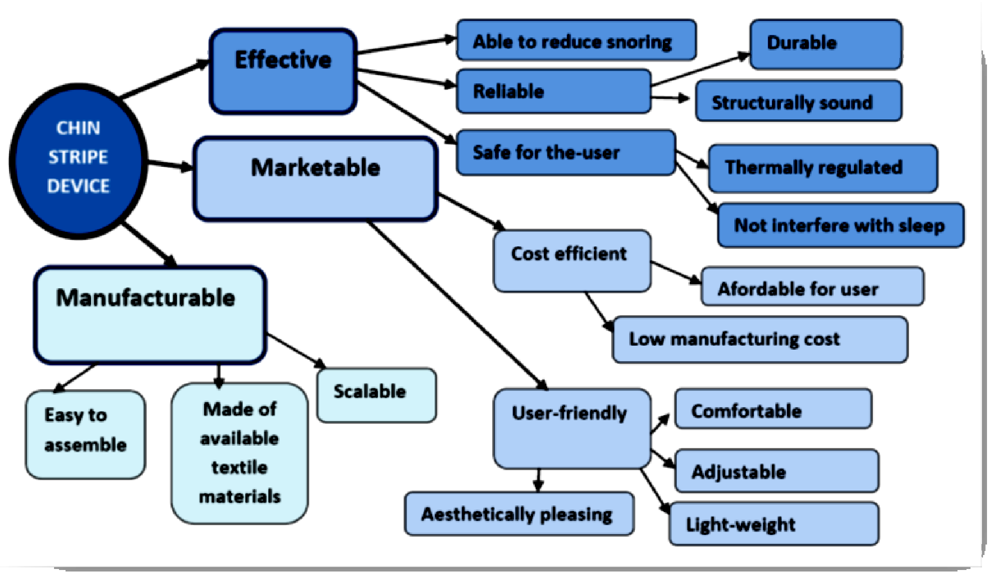

Figure 5: Main-objectives of the-device.

The-device had to-be equally user-friendly (adjustable, and easy to-use and maintain), and cost-effective. Proper-maintenance is essential for proper-functioning of any-device. With chin-strap-device care and maintenance should be very-minimal and simple, including hand or machine-washing, quick-drying, besides, *no* ironing should-be required. It also should-be portable, easy to-store, and to-transport.

The-device should also fit neatly, so that the-user does *not* have-to constantly-adjust the-device, during sleep. 'Comfort' and 'light-weight' were equally-ranked. 'Aesthetically pleasing' received the-lowest-score, on the-ranking, but is still an-important-aspect, to the-product-design-process, as the-user must feel mentally-comfortable, while handling and wearing the-device; as an-absolute-minimum the-device should *not* be repelling. Finally, the-design has to-be-scalable, for it to-be-manufactured, on a-larger-scale. It also must-be easy to-assemble, so that a-manufacturing-company can-minimize the-time, spent on the-construction of the-design.

Biocompatibility was also-taken into-consideration as a-constraint; the-device must *not* irritate the-skin, or result in a-higher-surface-temperature. With proper-material-choice, that incorporates sweat wicking or a reasonably-high thermal-conductivity, the-body-heat can-be-dissipated, easily, to-prevent profuse-sweating and, hence, discomfort.

3.3. Free-hand-sketching of alternative-designs.

Three-design-alternatives, developed, by the-design-team, are shown in Figure 6. Some-preliminary calculations, were done, at the-same-time, which might-be-required to-substantiate-ideas and to-establish approximate-sizes.

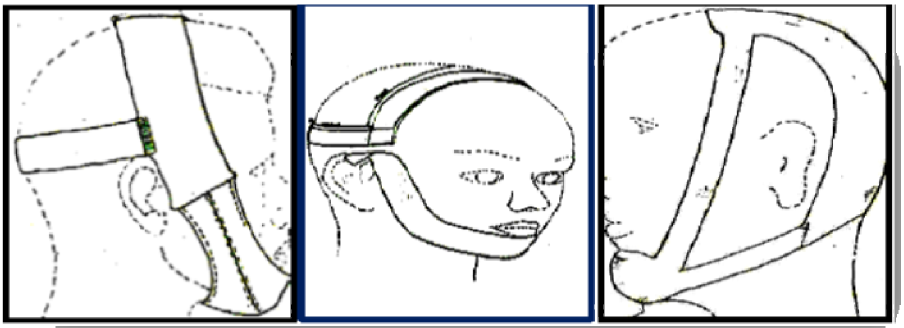

Figure 6: Free-hand-sketchers of the-three design-alternatives
(Alternative #1 - left; Alternative # 2 - middle; and Alternative # 3 - right).

3.4. Selection of the-best-alternative-design.

Weighted-attributes, reflecting their-importance, were-chosen as-follows: Functional-efficiency @ 0.3; User-friendly/comfortable/easily-maintained, cost-effective, scalable, and light-weight @ 0.15, each; and Aesthetically-pleasing and Biocompatible @0.05.

Alternative design # 2 was selected, with the-highest-score of 0.78; while Alternative # 1 scored 0.63; and Alternative # 3-- 0.47. Analogous to Starovoytova & Namango (2016), to-confirm the-choice, additional-method, of selection of best-alternative, was used, namely 'D&R-method', where the-members of the-design-team, each, order alternative-concepts in a-weak-order, an-ordinal-ranking, with *no* level of preference. The-weak-orders are then compared to-some common-filtering-criterion (such as 'choose the-best of the-best' or 'avoid the-worst of the-worst') and the-most poorly-ranked-concept were dropped from further-consideration. The-process was then repeated, until only one-alternative remains. Figure 7 shows free-hand-sketch of four-views of the-winning-design.

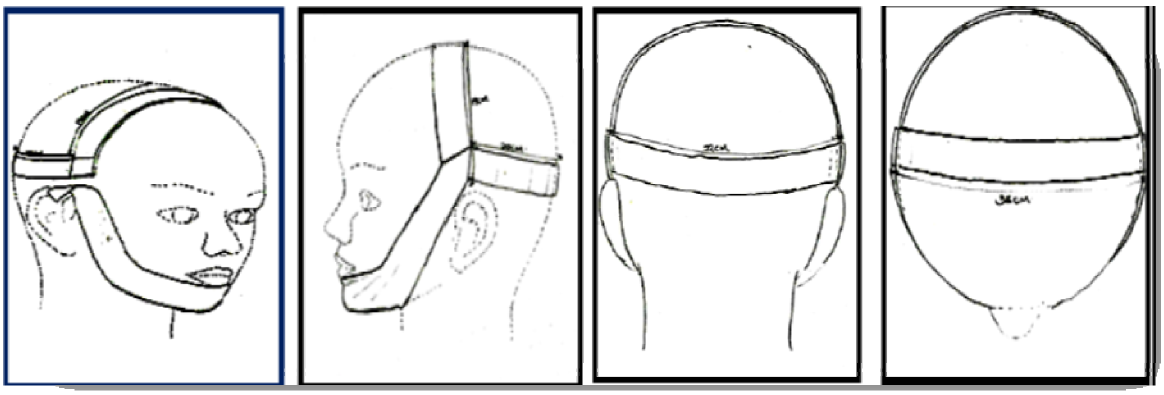

Figure 7: Free-hand-sketchers of four-views of the-chosen-design.

3.5. Identification of specific-head-dimensions

Lee *et al.* (nd), identified 122 head-dimensions (based on 18 references) shown in Figure 8.

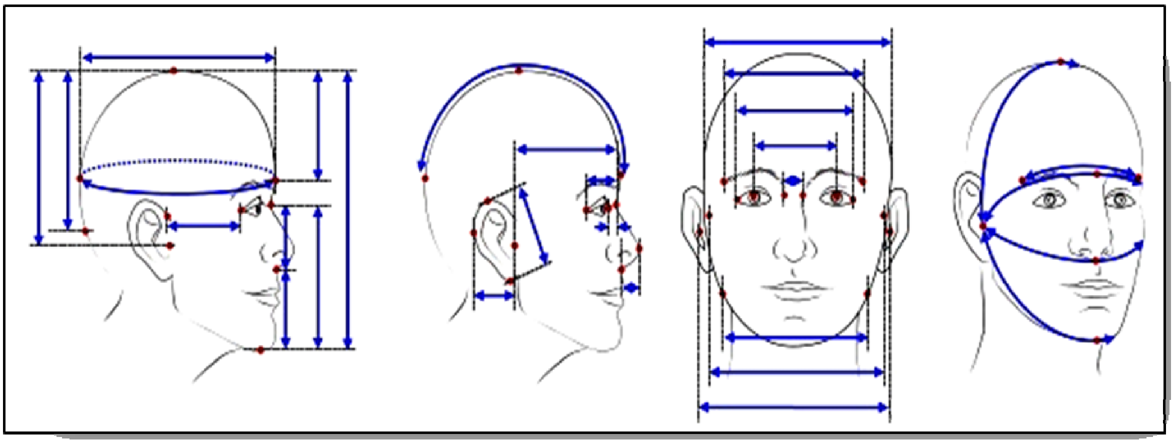

Figure 8: Head-dimensions, for the-design of head-related-products (Lee *et al.* (nd)).

Out of 122 head-dimensions, shown in Figure 8, thirteen were selected, as relevant and appropriate, to-design head-related-products, such-as chin-strap-device, namely: (1) head-breadth; (2) head circumference; (3) head-length; (4) ear-length; (5) ear-breadth; (6) bitragion-vertex-arc; (7) bitragion-inion arc; (8) bigonial-breadth; (9) bitragion-chin-arc; (10) bitragion-coronal-arc; (11) bizygomatic-breadth; (12) tragion to vertex-length; and (13) superior-auricle to vertex-length.

3. 6. Identification of head-shape and size.

Characteristics of the-head are partly-determined by genetic-factors (Mckeever, 2000), but they can-also be-affected by gender, nutrition, climatic, geographic and socioeconomic-factors, and health-care; so they occur as a-result of interaction of genetic and environmental-factors (Cvetkovic & Vasiljevic, 2015).

Using Figure 9 and 10, as a-reference, a-head of medium-size, and of normal-shape was-chosen, for this-design.

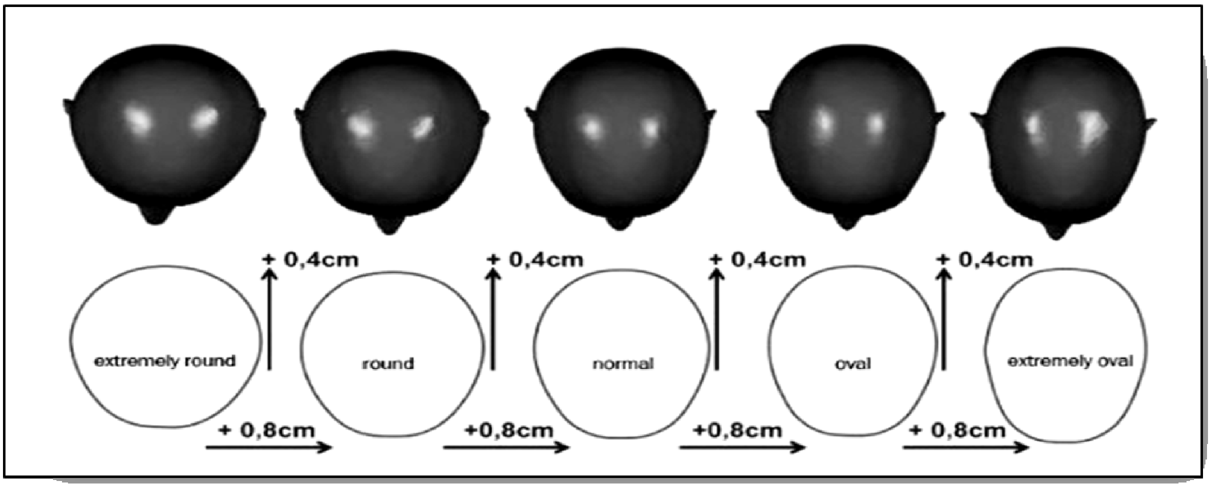

Figure 9: Head-shapes (Lee *et al.,* 2006).

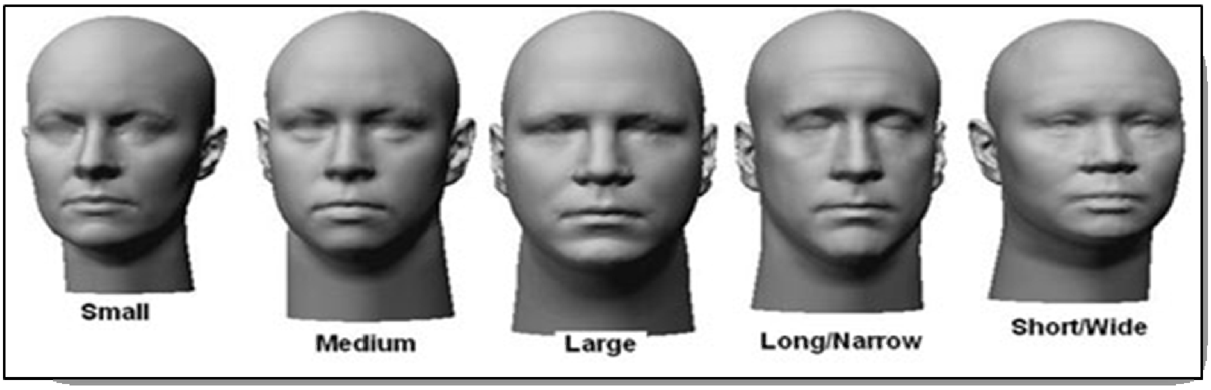

Figure 10: Head-sizes (Lee *et al.,* 2006).

3.6. Specifying the-design target-population.
50th percentile (covering 90% of the-population), Black-African-male, over 40 years of age, was-selected, as most-appropriate-target, for this-design, according to *Ergonomic*-Design-principles.

3.7. Obtaining identified-anthropometric-dimensions, for the-design-target-population.
Iida (2005) pointed-out, that, in the-field of anthropometry, there-are-tendencies of global-standardization, though *no* reliable anthropometric-measurements for the-world-population. Most-measures, available, are contingent of the-armed-forces; almost-all refer-to-the-measure of adult-males, between 18 and 30 years of age. However, according to the-military-recruitment selection-criteria, people below a-certain-height, can*not* be employed, and hence, their-data is excluded, from such-anthropometric-tables. This-indication, together-with age-restriction makes such-tables deficient (AHFE, 2014). In-response to-such-problems, a-joint-venture-initiative, was formed, to-be-known-as African-Body-Dimensions (ABD), which intent to-provide measurement, from all-inclusive-representative *civilian*-sample. The-initiative was-formed by Ergonomics-Technologies, the-University of Pretoria, Department of Consumer-Science, and the-University of Potchefstroom, School of Biokinetics, Sports-Science and Human-Movement. ABD is yet to-be-completed, moreover South-African-National-Defense-Force (SANDF) anthropometric-database, which is currently the-largest South-African anthropometric-database, and possibly, the-largest, in-Africa, was *not* attainable.

In-the-absence of the-local/African-data, the-values, for chosen-dimensions (one-dimensional measurements) were, obtained from anthropometric-data-tables of IOM (2007) and Anthrotech (2004), for all-inclusive *civilian*-population.

3.8. Materials selection.
According to Ashby & Johnson (2003), the-starting-point, for a-design-project, is function, which dictates the-choice of materials and shape. Shape includes both; the-external-shape (macro-shape) and the-internal-shape (e.g., honeycombs). To-assist in the-selection of materials, many material-libraries are-being-build, worldwide, such-as for-example: MaterialConnexion (www.materialconnexion.com), which was used in this-study. Selecting-materials, however, is more than just picking a-material, from a-database-catalogue; it requires a-considerate-approach.

Ashby & Cebon (2007) stated, that the-selection of materials comprises of 4 steps: (1) translating the-design-requirements, as constraints and objectives; (2) screen the-material-world, to-find-materials that can*not* do the-job; (3) rank the-materials that can do the-job-best; and (4) explore the-top-rated-materials. In-this-regard, the-product-*material*-attributes, were-identified, from the-main-objectives of the-device (see Figure 5), as-follows: durable, light-weight, thermally-regulated, affordable, locally-available, and safe for the-user (non-toxic).

Besides, it-is paramount, to-choose materials, that are fit for-purpose (BBC: design and technology); in this-study the-following-parameters was considered: (1) *Fibre-nature* (natural or man-made (regenerated or synthetic) fibres); (2) *Fabric-construction* (e.g., woven, knitted, or non-woven); (3) *Manufacturing-processes* (should the-fabric be dyed, printed, or some-mechanical-finishing, or chemical-finishing, should-be applied); and (4) *Maintenance* (durability, and aftercare-requirements). The-fibre-nature, fabric-construction, and finishing-processes, determine the fabric's aesthetic (handle; drape; colour; and appearance), functional (strength; durability; crease-resistance; flame-resistance; stain-resistance; water-resistance; aftercare; and cost) and comfort-properties (absorbency; breathability; elasticity; softness; stretch; and warmth).

With-regard to the-*fibre*-material, synthetic-fibers, is generally, cheaper, more-durable, and easy to-handle-alternative to natural-fibers; this-class of textile-fibres, hence, was examined-further.

One of the-most-important-objectives, of the-device, is that it should-be thermally-regulated. The-transportation of liquid, into yarns and fabrics, may-be caused by external-forces, or capillary-forces, i.e., wicking. This-property can-be characterized by wett-ability of textile-fabrics. Wett-ability, of a-fabric, depends on fibre-characteristics, fabric-surface-properties, and specific-characteristics of fabric manufacturing. Absorption of moisture is affected by yarn-texture, chemical-properties of fibre-surface, geometrical-properties of fibre, type of weave, construction-parameters, variations in interlacing, capability and moisture-absorbency of fibres, geometric-configurations of the-pore-structures (pore-size-distribution and fibre-diameter), viscosity, and density of the-fabric-surface. Wicking increases, with the-rise in-viscosity of the-melt-polymer (liquid) and decreases with the-increase in the-surface-tension of the-liquid, capillary-radius, and contact-angle (Frydrych & Matusiak, 2003).

The-study also-considered basic-aesthetic and hygienic-properties of the-(woven)-fabrics, such-as: the-change of dimensions after washing (shrinkage), crease-resistance, drape-ability, and air-permeability.

The-bending-rigidity of the-fabric, together-with the-pressure, acting on it, are the-reasons for material creasing, which is the-most frequently-occurring mechanical-effect, appearing on the-woven fabric's surface. Creasing also leads to a-general-aesthetic-distortion of the-material's surface-view. The-measure of crease-resistance, which depends on the-elastic fabric-properties, is determined by the-wrinkle-angle (ISO 2313-1972 (E)).

The-drape of woven-fabrics is one of the-most-important-properties, for both; clothing-textiles and technical-textiles (Marooka & Niwa, 1976). Drape-ability is closely-connected with stiffness (Grosberg, 1980). Very-stiff-woven-fabrics are characterized by a-drape-coefficient near 100%, whereas soft-fabrics by one of 0%. This-coefficient, for woven-fabrics, with loose-weaves is ranging of up-to 30%, while for stiff-fabrics it can reach 90% (Frydrych *et al.,* 2003).

Air-permeability is one of the-biophysical-features of clothing. This-property determines the-clothing's ability to-carry-out gaseous-substances and sweat, significantly influences the-thermal protection of the-human-body, ensures the-maintenance of an-appropriate-body-temperature, and determines its-protection against atmospheric-factors.

Considering all-the-requirements, for the-appropriate-material, for the-chin-strap-device, a-dyed plain-weave woven-fabric, made of Acrylic-man-made-fibres, of synthetic-nature, was selected. In plain-weave-fabric the-warp and the-weft are aligned, so that they form a-simple cress-cross-pattern, which is strong. Following-narrative justifies the-selections, made.

According to Mall (2007), *acrylic-fibres* are third-largest-class of synthetic-fibres, after polyester and nylons. Acrylic-fibres are produced from a-monomer (Acrylonitrile (CH_2=CH-CN)), with an-average molecular-weight of ~100,000, about 1900 monomer-units, with the-use of basic-chemicals, such-as: Propylene, and ammonia. Besides, for a-fiber to-be-called 'acrylic', the-polymer must-contain at least 85% acrylonitrile-monomer.

Moreover, according to a-book, by Capone & Masson (2004), acrylic-*fibres* are: soft, light-weight, durable, strong, with high-crease-recovery, and color-fastness to-both; washing and sunlight. They are also easy to-care and to-laundry; with high-abrasion-resistance, moderately-high-luster, good-wicking action, which helps in quick-transfer of moisture and sweat, resulting in quick-drying; acrylic is also *non*-allergic, *non*-toxic, with high-resistance to tear, mildew, odor, insects, oils, and chemicals (Mall, 2007).

Selected-properties of acrylic-*fibres* are as-follows: (1) a-moisture-regain of 1.5-2%, at 65% RH and 70 deg F; (2) a-tenacity of 5 gpd, in dry-state, and 4-8 gpd, in wet-state; (3) Breaking-elongation is 15% (both-states); (4) an-elastic-recovery of 85%, after 4% extension, when the-load is released immediately; and (5) a-good thermal-stability. Acrylic is also about 30% bulkier, than wool, and it has about 20% greater-insulating-power, than wool (Encyclopedia of textile science and engineering).

A-fabric is a 'structured-material', usually made as a-flat, flexible-sheet, by weaving, or knitting *fibres*, in-bundles (see Starovoytova *et al.,* 2015). The-key-factor, that lends acrylic-fabric its-quality of comfort, is its-ability of moisture-transportation, or wicking. Acrylic-fibre is characterized with inherent-polarity i.e., the-ability to-attract and convey moisture. Due to this-quality acrylic-fiber gives lifetime-wicking-capability, to-fabrics that are made, from it. Due to its-greater wicking-ability, acrylic-fibers pick-up the-moisture, formed primarily-due-to sweating, and transport-it to the-device's outer- surface, from where the-moisture evaporates. Thus the-skin remains dry and the-wearer feels comfortable. Acrilic-fabrics are also machine-washable and extremely color-fast. This makes it useful in-the-application, requiring frequent-washing, such-as for chin-strap-device.

On-the-other-hand, many-*fabric*-properties (for-example: strength, stiffness, and tear-resistance) are *directional*, i.e. they depend upon the-direction of loading, compared to the-orientation of the-fabric. Most-woven-fabrics have two-stiff/strong-directions, at-right-angles, to-each-other, parallel to-the-fibres, with much-lower-properties, in-between ('on-the-bias'). This 'anisotropic' structure gives these-materials their-unique-properties. The-woven-fabric, was therefore, selected. Besides, for high-performance-fabrics, strength and reasonable-stiffness, at low-weight, is required. The-strength and stiffness, of a-fabric, depends on the-type/nature of fibre used, but is also strongly-affected by the-type of weaving used (which changes the-amount of friction, between the-fibres). Plain-weave was then selected, as one of the-most strongest-weaves. The-selected-fabric was then incorporated in the-design.

3.9. Producing 2D-drawings, of the-selected-alternative

Figure 11 shows 3 parts-drawing of the-chin-strap-device, with sizing.

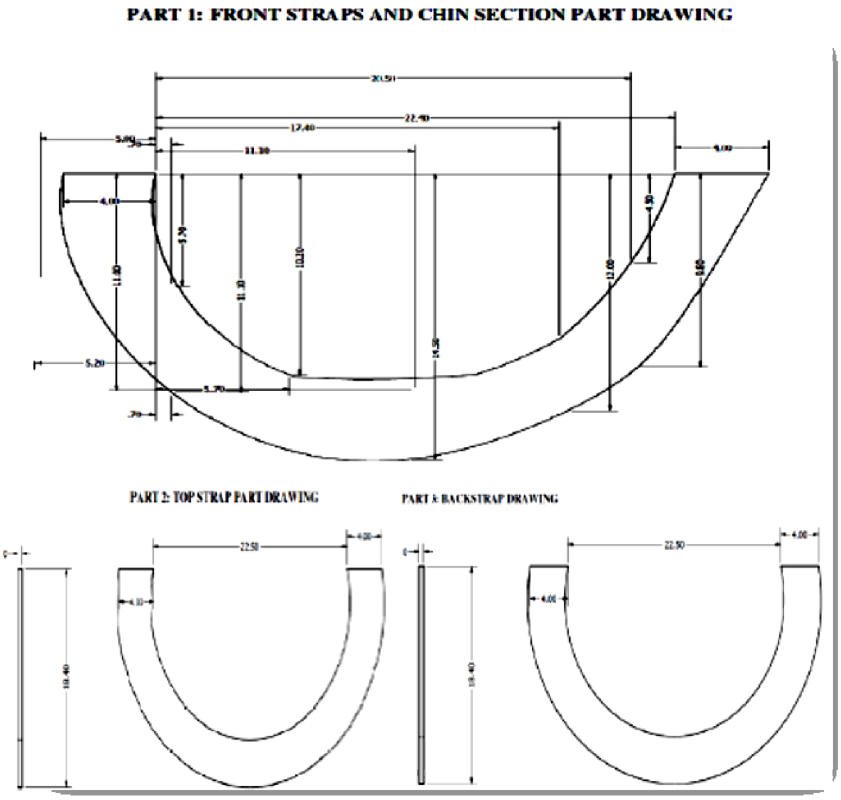

Figure 11: The-device-elements, with sizing.

3.10. Prototyping (fabrication & assembly).

Prototype is a-full-scale operational-model. Prototyping consists of building a-prototype of the-product, which is the-first fully-operational-production of the-complete-design-solution. A-prototype, however, is *not* fully-tested and may *not* work, or operate, as intended. The-main-purpose of a-prototype is to-pre-test the-design-solution, under real-conditions. Only after testing, under-all-expected and unusual-operating conditions, the-prototypes are 'polished' and, then, brought-into full-production. Simply-put, prototype is the-very-first, rough-trial, of the-product, designed.

On-the-other-hand, assembly of the-prototype is a-critical-step, in the-process, that validates previous-design-assumptions. Stitching was chosen as the-most-common, fast, and versatile-joining method. Many joining-processes are limited-to flat, or nearly-straight-joints; stitching, in-contrast, can-join-fabrics round difficult-curved-seams (such-as for putting the-arms onto a-shirt).

Figure 12 (left) shows the-elements of the-chin-strap (in actual-size); Figure 12 (middle) shows the-fabricated/assembled-prototype, while Figure 12 (right) shows a-volunteer wearing the-prototype, while sleeping.

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Figure 12 (left): Components of the-prototype; Figure 12 (middle): Fabricated-prototype;
Figure 12 (right): Anti-snoring chin-strap-device-prototype (worn by a-volunteer).

Keys (for the-Figure 12 (middle)):

1-Top-strap, that promotes a-vertical-angle of force, on the-chin, as opposed to-horizontal, in-order-to-reduce the- potential of inducing sleep-related-events, like sliding-out-position.

2- Adjustment-joint, fitted with Velcro-stripe, to-enable the-device to-be used by people of different-head-sizes.

3- Back-strap, that attaches to the-chin-straps and top-straps, on both-sides, and wraps-around the-back of the-head, for the-ultimate-stability.

4- Chin-strap-portion, fitted with the-adjustable support-strap, which attaches to-the-section, of the-chin, and wraps-around the-chin-section, with integrated-chin.

5 - The-chin-area, of the-device, that is fitted-with elastic-bands, on the-internal-side of the- device, to-guarantee greatest-contact, and enough-upward-strain, to-hold the-mouth in a-shut-position.

3.11. Testing of the-prototype.

Physical-testing confirms that the-prototype meets the-performance-requirements, established during the-concept-phase. In-this-regard, the-fabricated-prototype was physically-tested on a-volunteer (open-mouth-snorer); observers reported, that the-device stayed-in-position, throughout five-observation- nights, without sliding off, and also some-snoring-reduction was noticeable, in-comparison with the-observations, of the-volunteer-sleeping, without-the-device.

4. Cost of the-production.

The-production-cost of the-device, according-to its-Bill of Quantities, for all-the-required-materials (including 30% labor) is KES 1,500 (USD 15.0), which compares-favorably (e.g. much-cheaper) with other-devices, available at-the-market.

5. Final-annotation on the-way forward.

This-*unfunded* concise-study was preliminary, by nature; its-results, are largely, relatively-positive, providing a-good-starting-point, for further and much-deeper-study, on the-same. Next-logical-step, would be a-detailed-design, which can-be-generated, using 3D-solid-modeling CAD-programs, such-as SolidWorks. Besides, the-Finite-Element-Analysis/Method (FEA/FEM) can-be used, to-conduct stress-strain-investigations. In-addition, AUTODESK Simulation-Mechanical, can-be-used, to-perform stress-strain-analyses and heat-transfer-modeling. Moreover, final trade-off of performances-test (see Masctelli, 2000), and **FMEA-**tests should-be conducted, as every-product has some-possible-failure-point, and it-is important to-identify such-failure-point(s) and the-subsequent effect(s). A-particular-component-failure is often identified, during the-use-ability-testing-process, meaning that only that-component should-be redesigned, and *not* the-entire-product.

Additionally, according to Ui *et al.* (2002), the-emphasis of the-design-decisions, unavoidably shifts-away from technology, towards the-user-interaction-aspects, to-cope with the-new appreciations of consumers, for the-aesthetic-values of materials. Several-studies investigated the-relation, between materials and user-interaction-qualities, of products, and how users appraise materials. In the-textile-field, for-example, studies try to-classify the-visual and touch-dimensions of different-textiles (see Giboreau *et al.,* 2001) and, even, the-sound-dimensions (see Ui *et al.,* 2002). Giboreau *et al.* (2001) also-noted, that instrumental-machines have-been-available since the-1970s, that were to-use physical-objective-means (compression, bending, extension, shear), to-predict sensory-dimensions (dry, thick, rough, warm) for textiles (e.g., the-Kawabata-Evaluation-Structure). These-machines combine the-sensory-perceptions, of a-test-panel, with the-objective-measurements. In-another-example, Zuo *et al.* (2004; 2001) try to-find relations, between texture, of materials, and emotions. They found a-relation, between smoothness, of a-material, and positive-emotions, of the-users, such-as: lively, modern, elegant, and comfortable. Roughness, on-the-other-hand, suggested negative-emotional-responses, such-as: depressing, traditional, ugly, and uncomfortable.

Moreover, in-this-preliminary-product-design, the-decisions, about-materials, were based-on just-few-parameters. In-addition, one of the-constrains was the-limited-availability of reasonably-priced and locally-available textile-materials, such-as appropriate-woven-fabrics. A-small-number of fabric-options, that was available, locally, had, hence, limited-the-study-choices. In the-detailed-design, therefore, the-suitability of the-selected-materials, to-be-made, in-depth, to-arrive at a-final/refined decision. This can-be done, for-example, via a-checklist by Pugh (1991), who defined, 32 aspects that need consideration, when specifying a-product-design. It-is referred-to as the-product-design-specification (PDS). Pugh (1991) also broadly-mentioned such-user-interaction-aspects as: 'aesthetics', 'ergonomics' and 'customer'.

New/novelty-materials can-be also incorporated, in the-final-design. To-support product-designers with physical-materials, several-initiatives organize exhibitions, collections, and libraries of materials. For-example, the-agency 'Inventables'(www.inventables.com); 'Material ConneXion'-the-world's leading knowledge-base on new and innovative-materials (www.materialconnection.com); 'Innovatheque' in-Paris, France (www.innovathequectba.com); and 'Materia' and the 'Materialenbibliotheek', both in the-Netherlands (www.materia.com, www.materialenbibliotheek.nl). Furthermore, universities and academies, offer material-collections and support to-designers. Examples are the 'Technotheek' of Poelman (2005) or the 'Material biblioteket' in Stockholm, Sweden (www.materialbiblioteket.se), among-others.

Furthermore, in-this-study, so-called *traditional*-testing/usability-inspection was undertaken on a-volunteer, who was also the-design-team-member, hence, strictly-speaking, such-testing can*not* be, considered-as 'use-ability-testing', due to-possible-bias (even unintentional), that can-be-present in the-provided feedback/evaluation of the-device. Usability-testing usually-involves *systematic*-observation, under controlled-conditions, to-determine how-well people/real-users can use the-product (*Jerz, 2000).* In use-ability-studies, prototypes may assist in soliciting passive, or active-participation, from potential-users and other-stakeholders (Sanders & Stappers, 2008), besides more-innovative-designs may-be-generated, through the-discovery of otherwise unforeseen or hidden-problems/needs. Explorative-use-ability-testing, with *real*-users of the-product, is therefore recommended, to-provide far-more-accurate, more-intricate, and insightful-feedback.

On-the-other-hand, in-this *unfunded*-study, the-testing of the-prototype was limited-to *only* one-volunteer; a-focus-group, could, logically, give testing on a-larger-scale, providing more-broader-views and opinions, on faults and problems (if any), alongside with suggestions, for improvement. Regarding actual-sample-size, Jakob Nielsen declared, in the-early 1990s, that: "Elaborate usability tests are a waste of resources. The best results come from testing no more than five users and running as many small tests as you can afford" (*Nielsen & Landauer, 1993).* Nielsen has subsequently-published his-research, and coined the-term '*heuristic-evaluation*'. The-claim of 'Five users is enough' was also-described by a-mathematical-model *(Virzi, 1992),* which states for the-proportion of uncovered-problems -- U,

$$U=1-(1-p)^{n}$$

Where p is the-probability of one-subject identifying a-specific-problem; and
n is the-number of subjects (or test-sessions).

It-is worth-noting, that Nielsen does *not* advocate stopping, after a-single-test with five-users; his-point is that testing-with-five-users, fixing the-problems, they uncover, and then, testing the-revised-site with five-different-users, is a-better-use of limited-resources, than running a-single-usability-test, with 10 users. In-practice, the-number of users, actually-tested, over the-course of the-project, can easily reach 50 to 100 people (England & Beale, 2008). This-approach was recommended.

6. Conclusion and Recommendations.

Overall, the-prototype, developed, was a-miniature-accomplishment; as this-*unfunded* preliminary-study resulted in an-affordable-anti-snoring-device, made from materials, available locally. Although the-device (fabricated-prototype) is, seemingly, functional, user-friendly, cost-effective, easy-to-fabricate, and made from readily-available-materials, further-trials, however, are necessary, to-improve it, and, then, to-evaluate the-long-term-efficacy of the-device. The-next-steps, hence, were identified, as to: (1) carry-out a-detailed design; (2) fabricate the-next/refined-prototype(s); (3) conduct use-ability-trials, in-collaboration with the-department of Medical-Engineering, School of Medicine, MU; and (4) Analyze the-marketing aspect of the-design.

Finally, Terstiege (2009) states that the-primary-strength, of an-early-prototype, is in its-incompleteness. Analogous-to Starovoytova & Njoroge (2016), the-author would-like-to-accentuate, that there-is absolutely-nothing, that can ever be-perfect, that is made, by man, especially when it-is at its-initial-stages; nevertheless, the-author welcomes constructive-expert-criticism, and/or relevant suggestions, from the-readers.

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