FUNCTIONALLY VIABLE 3D PRINTED POLYMER TRANSRADIAL FRAME AND WRIST WITH VARIABLE COMPLIANCE DYNAMIC VOLUME SOFT SOCKET WITH INCREASED BREATHABILITY AND RANGE OF MOTION

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ABSTRACT

Nine of the top ten reasons that half of arm amputees reject prostheses are related to dissatisfaction with fit and comfort, primarily of sockets [1]. Traditional (particularly myoelectric) sockets severely limit range of motion (ROM), and create pressure, heat and moisture management, and tissue breakdown issues. Here we describe preliminary results from the testing of a new design of transradial frame and socket that combines advanced modern soft athletic shoe materials and construction with 3D printed frame counters to create a functionally viable 3D printed arm with integrated wrist and variable compliance socket weighing less than two pounds complete with harness and terminal device. The system has been used for cross country skiing and indoor rowing, sustaining hours of use in sweaty and friction-rich environments. The range of motion of the prosthesis was measured as compared to anatomical, showing a 59% improvement over a Veterans Affairs (VA) Hospital-provided self-suspending myoelectric socket. The arm and harness can bear tensile loads more than 50 pounds. Custom one-hand operable harness hardware can bear 65 pounds with a factor of safety of more than three.

BACKGROUND

Socket design has changed little in decades and is sorely in need of updating. Much research tends to focus on the symptoms, rather than the causes of socket shortcomings. Significant symptoms of the inappropriate use of unbreathable materials in socket design include sweat that collects in liners and sockets, and the damage that can occur to residual limbs as a result of its retention and continued use, as shown in Figure 1.

Figure 1: Sweat captured in a custom silicone liner during approximately ten minutes of mountain biking (left). With continued use, this can lead to tissue breakdown (right).

Recent research from the VA, for example, describes the use of a battery-powered device to remove sweat from a non-breathable hard socket [2]. While materials for upper limb sockets have tended to follow that of legs, the increased range of motion requirements of upper limb joints, coupled with tighter radii of curvature and lower soft tissue volumes of upper residual limbs remain critical differences. These differences make the traditional hard composite and non-breathable liner construction of sockets perhaps even less suitable for upper limb sockets than for lower limb. While leather lacing sockets were replaced with composites in the 1940s, this can anecdotally be attributed primarily to factors such as efficiency in cost and time for providers, rather than in outcome or performance.

A number of manufacturers have released sockets that include deconstructed traditional frames and include flexible fabric components, allowing the adjustment of the shape and volume of the socket, including those produced by Lim Innovations and Martin Bionics [3, 4]. By virtue of the flexible components windowed in these sockets, which include polymer or fabric panels, and or gel or silicone liners within, these sockets can be adjusted throughout the day by the user for comfort. In general, these sockets continue to use non-breathable liners or inner sockets, are not available for the upper limb, or have upper limb versions that suffer from the standard limitations of self-suspended monolithic sockets (Figure [2]).

Figure 2: Adjustable volume transradial socket from Martin Bionics (left, similar to Chaz Holder's arm from CZ Biomed), RevoFit Transfemoral Socket from Revo Labs (right)

Because of the tapered nature of residual limbs of almost any level, standard suspensions for transradial amputees rely on components that extend above the elbow: either a harness including flexible hinges and a backplate, or some part of a rigid socket. Self-suspending sockets of monolithic composite material (High Fidelity, Northwestern, Meunster, TRAC, etc) all make different compromises about how to balance the security of the suspension with the inevitable loss of range of motion caused by the volume limitation on expansion in the cubital fold, the limits of elbow relief, and the capture of the humeral epicondyles [5]. Standard harnessed body-powered sockets usually slip to some degree to allow full flexion, as the residual limb is forced out of the socket by the expanding tissue at the cubital fold. These changes that occur at the elbow of any limb during flexion and extension, intact or residual, are at the root of this problem. Any socket at all, particularly one that is of a fixed volume during use (even if it is adjustable), must compromise about what happens to the bones as well as to the changing shape of the soft tissue that contains them as the bones move within the prosthesis and, indeed, within the skin of the residual limb itself. Figure [3] shows these dramatic changes, including in the length of the skin surfaces on the anterior and posterior sides of the elbow (left).

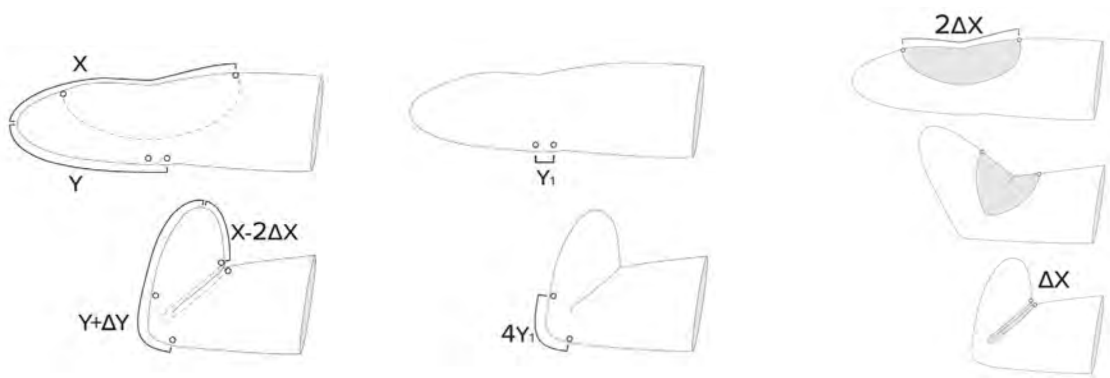

Figure 3: Challenges in securing a transradial limb across the elbow: From extension to flexion, there is a significant change in the length of exposed skin on the anterior and posterior, such that the exposed posterior length increases approximately fourfold from extension to flexion, while the anterior length is reduced by twice the depth of the cubital fold on flexion.

The posterior length is stretched approximately fourfold on flexion (center), most dramatically right at the olecranon. On the anterior side, the majority of the length disappears within the cubital fold (right). As anyone who has marked the bony prominences of a residual limb for a prosthetic fitting is aware, the locations of all of them with respect to the skin surface, particularly the distal tip, depend significantly on the angle of flexion and are not static. The volume of the limb similarly varies, and circumferences around the elbow also increase significantly at full flexion. So far, no prosthesis for upper limb (or any level of amputation, for that matter), has sought to deal with these challenges by maintaining secure contact with the residual limb while adapting dynamically to the changes in skin surface length, limb volume, and the orientation of the bone within the limb.

METHODS

This research sought to address the deficiencies of current sockets by challenging both their materials and their design. We were inspired first by the modern athletic shoe industry, which has undergone dramatic changes since the 1940s. During this time, these products went from being simply constructed, of canvas and leather, to the complex assemblies that they are today. Second, we were inspired by the iconic Apollo EVA spacesuit, surprisingly designed by the Platex undergarment company, even as aerospace companies sought to replace their "temporary" soft-goods design ultimately consisting of 21 layers of functional fabrics with a science fiction-inspired articulated hard suit [6]. It was incredibly important, once we realised that we were essentially designing a form-fitting garment that needed to dynamically attach hard components to the body, to think of this process as both garment patternmaking as well as product development.

This proposed design returns the prosthetic arm to a shoe-inspired design, updating the leather construction common to both sockets and shoes of the 1940s with the materials and processes developed by the multi-billion dollar athletic footwear industry over the intervening 75 years. Modern athletic shoe uppers are now constructed by a variety of methods, including "sandwiches" of layers of overlapping cut patterns of materials with different degrees of stretch, breathability and wicking, which are combined to create a three-dimensional structure that itself has different properties in different places, and which integrates various hard structures, like shanks, arch supports, heel counters, and a lacing system.

This the fourth generation of hundreds of individual prototypes that we have made, representing everything that we have learned over the last four years. Significant challenges included finding materials strong, light and cheap enough for the hard goods components, the development of the lacing system and the incorporated flexible hinges, determining the necessary performance of the socket over different regions of the surface of the residual limb, and reconciling those requirements with those of obtainable materials and available performance.

DESIGN

The proposed design consists of three major groups of components, shown assembled in Figure [4]. The counters (1), like the heel counter of a shoe, "counter" motion in one or several particular directions. These include the forearm counters (1.1) which have pads to register the ulna and radius, and for purchase when applying pressure in flexion or extension at the distal tip. The elbow counter (1.2), can be thought of as a traditional backplate deconstructed and with pads that grab the olecranon fossa and humeral epicondyles. The textile socket (2) is composed of upper and lower pieces nested together and containing a collection of pads designed to interface with the counters, as well as the bones of the residual limb.

Figure 4: Arm components, including the textile socket, forearm and elbow counters, and the two dynamic lacing systems that secure the counters to the limb and socket throughout the range of motion.

The socket and pads are firmly secured through sewn connections to the counters. Finally, four separate lacing systems, making a total of 10 flexible hinges, are integrated with the textile socket and counters to ensure an intimate connection with the residual limb throughout the range of motion. Figure [5] shows how the two dynamic lacing systems, which we call the top lace and the hinge lace, adjust themselves throughout the range of motion in order to maintain a firm connection between the residual limb and the counters. The top lace does this through its routing over the cubital fold, tightening as the limb is extended, reducing volume at the elbow just as the arm does. The hinge lace, in contrast, only slightly tightens at flexion, but mainly helps maintain an intimate connection by exchanging the length between the anterior and posterior members of the pair on each side of the limb. This (along with the pad at the distal tip), ensures that the limb is not forced out of the socket at flexion as often occurs.

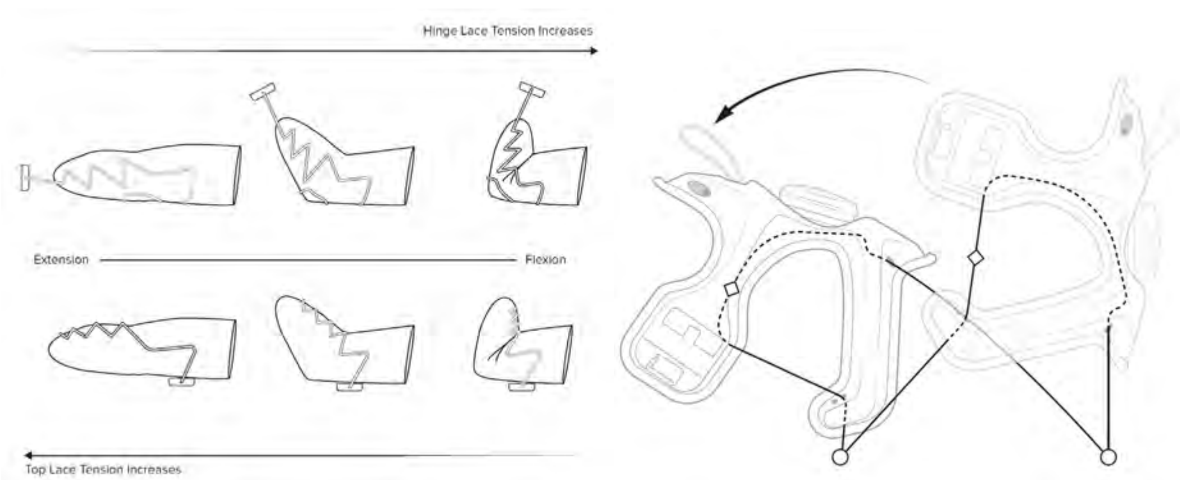

Figure 5: Diagram showing the changes in tension of the dynamic lace systems throughout (left), and of the four hinge crossings of the hinge lace loop, showing how the lace moves through the elbow counter (right).

RESULTS AND CONCLUSION

This version of the arm shows a 59% improvement in range of motion over a traditional myoelectric self-suspending socket (97 degrees), which is 94% of the patient (the author)'s anatomical 111 degrees. The complete system, including arm, harness, and Dorrance 5xTi hook, weighs 0.5 ounces less than a Bebionic hand and wrist, itself weighing just less than 2 pounds. The arm has been worn for hours of cross country skiing and indoor rowing, and can easily transport all of the heat and moisture from these high friction activities away from the limb to evaporate. While the design has yet to be tried on additional patients, we are now confident that it is both possible and worth doing, and have several efforts in place to do this. The arm could be used with any fabric sock with integrated electrodes for pattern recognition or direct EMG, and we have a concept, but no prototype for such a sock.

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