

PATIENT-ADAPTABLE BIOMEDICAL DEVICES

Benefits and Barriers for Granting Patients More Control

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Abstract: End-users of biomedical devices, like many patients undergoing treatment in healthcare systems, often demonstrate an active interest in their therapy. Patient-specific customization of medical devices, such as orthoses, prostheses and implants, is an expensive, time-consuming process. Given how many of these patients are proactive and self-motivated it seems appropriate to the authors that these characteristics be harnessed to make the adaptation of the device to the patient more cost effective. In short, it is proposed that the device end-user – the patient – play an active role in the tuning and adaptation of the device, especially in the out-patient context. However, the perceived risk associated with a more pro-active and independent role for the patient is a barrier to this possibility. These factors are examined and a proposal for a practical approach to a patient-controlled device optimization process is put forward.

1 INTRODUCTION

The customization of medical devices, such as orthoses, prostheses and implants, to the patient is an expensive, time-consuming process. By reducing factors which lead to patient noncompliance and by harnessing the pro-active and self-motivated nature of many patients it is likely that the patient-device adaptation process can be made more cost effective. The barriers towards granting greater control to patients in the updating process will also be examined. Finally, general strategies that are conducive to the development and use of adaptable devices are put forward.

2 WHY PATIENT-ADAPTABLE DEVICES?

Here, we examine general issues related to treatment procedures which involve biomedical devices, as well as reasons why adaptable devices can prove beneficial to such situations.

In traditional medical practice, physical proximity between medical personnel and patients is desirable and often necessary. Often, patients travel to clinical

settings to obtain medical services such as check-ups and monitoring. In other cases, emergency or not, medical personnel undertake the travelling to visit patients. In both cases, the associated costs with travelling and visitation, in terms of both time and money, can be important. In fact, these costs can quickly rise when the patient normally resides in a remote community which has insufficient medical resources. Additionally, delays associated with transport can have adverse effects on the treatment of both diagnosed and undiagnosed conditions.

In addition to distance playing a role on transportation costs, frequency of visits can also have a significant effect on costs and effectiveness of treatment. The customization of medical devices, whether they be implantable medical devices (IMD) or external prostheses or orthoses, often requires frequent visits by the patient to a clinical setting. Delays are often encountered due to complications in both patient and medical personnel schedules. This can lead to missed appointments or a reduction in the optimal number of scheduled visits. Both situations can have adverse effects on patient treatment regimes. Therefore, solutions which reduce the requirement for physical transportation of either patients or medical personnel, to or

from clinical settings are desirable.

Treatment associated with the prosthetic devices almost always requires multiple meetings between clinician and patient. When available, telemetry gathered by the device (either under in- or out-patient conditions) can be provided during these sessions to the clinician, complementing the traditional discussions between patient and clinician. To ensure optimal effect of the device on the patient such information will be monitored over the course of many sessions. In the process, changes to the device, or complete replacement of the device can occur. The reasons for this vary from suboptimal tuning of the device to a breakdown of the device, as well as to changes in the patients condition or environment conditions that the patient encounters.

Changes in the aforementioned conditions can happen outside the clinical setting. In the event of such changes it is advisable that appropriate actions be taken as quickly as possible. This is especially important where the change in condition has an adverse effect that could endanger the patient. Even in cases where the change does not endanger the patient, but leads to discomfort or diminished confidence in the device, it is advisable that the problem be addressed relatively quickly. Therefore, solutions that ensure a high frequency of monitoring and updating are desirable. However, updating or adaptation of the device does not necessarily need to be done by a clinician or therapist. In cases of misadjustment of a prosthetic leg, the resulting skin ulcers can dramatically reduce a patient's ability to use the prosthetic device, with a consequent reduction or total loss of mobility (Brandt, 2004). The ability of a patient to actively modify the device without the need for clinical supervision can be beneficial when such services are unavailable or impractical. This is apparent in the treatment of pain through the use of patient-adjustable bracing (Draganich et al., 2006) or in cosmetic and comfort adjustments with respect to heel height in foot prosthetics. In these cases, it is far more practical to allow the patient to make adaptations without direct clinical supervision. This is especially relevant since, as will be discussed in the next section, treatments that reduce ambulation ability can also become more vulnerable to patient non-compliance (Aldridge et al., 2002).

The goal of the clinical visitations is often related to monitoring a patients general health and the status of any diagnosed condition. In the cases that the patient has been previously prescribed a medical device related to a diagnosed condition the health service provider often uses the clinical visitation time to also monitor the condition of the medical device. Updates to the device may also be performed during this

time, as the health care provider is often an expert in the adjustment of such devices. Outside of the clinical setting, prior-art (Bardy, 2003) demonstrates that such device monitoring and update work can also be done in an autonomous and remote fashion. While these devices are not necessarily directly adaptable by the patient, they do contain the functionality for adaptability outside the clinical setting. A number of patents (Duffin et al., 1995) (Linberg, 1999) have been assigned for such remote expert system updatability, including at least one which permits the patient to input activity and environmental conditions for optimal implant performance (Boies et al., 2000).

Although customizable and updatable systems (remotely or locally) can have both therapeutic and cost benefits, there are barriers to their implementation. The next section explores some of these issues.

3 BARRIERS TO PATIENT-ADAPTABLE DEVICES

The development and use of patient-adaptable biomedical devices shares many of the same barriers encountered in by any biomedical device.

First, regardless of the intention of the clinician or manufacturer, without patient compliance the device will be ineffective. A patient's existing living conditions or environment may not be compatible with the proposed device and treatment strategy (Pinzur et al., 1992). Likewise, psychological or physiological factors may preclude usage of the device. Without proper counselling and education, cognitive, motivational and emotional barriers can also be barriers to effective use of a given medical device (Pinzur et al., 1992).

The possibility of critical failure of a device, especially in cases where such failures can place people in danger, must be weighed by manufacturers, end-users and prescribers of such devices. This applies to many fields, not just the biomedical field.

In the case of lower extremity prosthetic or orthotic devices the possibility of falling is of particular concern, as such falls can lead to serious injury or death. With some justification, the fear that such an event can occur is "pervasive" (Miller et al., 2001) within the amputee community. This leads to particular lines of action by both device manufacturers and patients to reduce the possibility of fall.

Actual falls, as well as the fear of falling can have repercussions on mobility and social activities. The psychological effects related to the fear can lead to

self-imposed restrictions which, in turn, lead to deterioration in physiological conditions (Miller et al., 2001). Given that this downward spiral runs counter to the original intentions when equipping an amputee with a prosthetic leg, it is important that the possibility of fall and the related fear be addressed as seriously and openly as possible.

The evaluation of risk, either by a patient or a device manufacturer can have serious ramifications, both positive and negative. During the risk evaluation process it is important to remember that risk determination should not only be founded on the device itself but also on the proposed use of the device. This requires weighing the risk against the beneficial uses of the device. If the addition of a feature promotes the use of the device, either through increased user convenience or confidence, the short-term possibility of increased user risk for falling may be offset by lessened possibility of longer-term psychological consequences, as outlined above.

4 THE WAY FORWARD

Devices which maximize user comfort, convenience and confidence are most likely to be successful in patient treatment. In cases such as treatment of Charcot's Foot, total contact casting is the "gold standard" for treatment, patient non-compliance plays a roll in its relatively high failure rate. The reduced mobility that results from such treatment can be so deleterious, and thereby resulting in patient non-compliance, that alternative forms of treatment have been developed that allow the patient some form of ambulation (Aldridge et al., 2002). The device should, if at all possible, usable within the patient's existing lifestyle, which in many cases requires a significant degree of mobility.

The development of patient-adaptable devices is an effective avenue for many forms of treatment. These are especially effective when the patient feels an immediate and persistent self-motivation with respect to the device. One such example, that of patient-adjustable valgus-producing knee braces, can have immediate, short-term pain- and stiffness-relief benefits for patients (Draganich et al., 2006). Devices such as the Ossur Elation and Proprio feet allow the amputee to adjust heel height, thus permitting the use of high-heel shoes, for instance. While the use of these types of shoes may place the amputee at greater risk for fall, the long-term psychological consequences of this convenience would seem to outweigh the short-term physical risk. Of course, to maximize the potential of these adjustable devices, the adjustment mech-

anisms must be as convenient as possible.

Making the device convenient to use is not sufficient, however. While its use and its adjustment mechanisms (if any) may seem intuitive to an expert, this cannot be assumed to be the case with the patient. Given that non-compliance can, in many cases, be traced to misunderstanding by the patient (Smith and Smith, 1994), it is important that special attention be paid to patient education. The practitioner should be especially aware of the fact that relevant documentation often given to the patient is written in a manner which leads to misunderstandings (Smith and Smith, 1994). Therefore, patient education – which is intimately tied to the notion of informed patient consent – should be tailored to the comprehension level of each patient in order to reduce the possibility of patient non-compliance based on misunderstanding.

Simply allowing the patient to make active changes to the device, as outlined above, is not the only strategy for involving the patient in the therapy "feedback loop". Within the clinical context (i.e. under the direction of a trained therapist or clinician), a device that adapts to the patient in a semi-autonomous fashion has enormous potential. The device can take a co-operative approach to the patient interface and does not necessarily require direct or conscious adaptation strategies by the patient. In fact, "human-centred robotic" gait trainers are currently being developed which combine robotic mechanisms that adapt their movement to the muscular efforts of the patient, as well as the patient's passive mechanical properties (Riener et al., 2006). These patient-adaptable devices still require the expertise of therapists to develop strategies for therapy, but promise to increase patient comfort and therapy effectiveness.

From a manufacturer's point of view, the calculation of acceptable risk for device feature sets must be conducted. This begins with setting a threshold for tolerance of risk, followed by the determination of a device's intended use and required feature set. Next, the feature-by-feature risk is estimated by examining the probability of a given event and the consequent level of operator or patient harm. Features which approach the tolerance threshold will require special justification with respect to physiological or psychological benefits, while those which exceed it must be discarded. Next, testing is conducted to verify the assumptions on which the risk levels are based, alarm and compensatory devices are implemented. Finally, the cycle is repeated until verifications produce results which match the declared risk tolerance threshold. This process is a straight-forward one that results from an attempt to adhere to risk management strategies that conform to international standards such as

ISO 14971 and IEC 60601-1; these standards are, in turn, a result of regulatory requirements by national and international agencies.

Finally, the device must be made affordable to the patient in absolute terms, as well as relative to possible alternatives which may or may not include adjustable functionality. Where alternatives include immobilization and long-term hospitalization, it is critical that comparisons be made with respect to the additional costs related to diminished mobility. Given the role of third-party payees such as government agencies or private insurance companies, the cost of such devices must also be justifiable to them. This is especially important in cases where utilization management and technology assessment studies result in limited outcomes due to small sample size or absence or randomized controlled trials in peer-reviewed journals (Fish, 2006). Therefore, rigorous and independent case-by-case studies need to be made to verify the potential short-term (e.g. adjustable valgus-producing knee unloader braces) and longer-term (e.g. the adjustable heel height feet) benefits of patient-adjustable biomedical devices.

5 CONCLUSION

The benefits for adaptable prosthetic devices has been examined, as have the barriers for both these and biomedical devices in general. General strategies for implementation have been examined, as well. In the end it is important for trained personnel to make a holistic evaluation of the patient, taking into account patient lifestyle issues, physiological and psychological factors, costs, requirements by third-party payees, etc. Engaging the patient through education and good design practice are key to the development and use of these types of devices.

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