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Prosthetisation of a K2 Patient with Sub-ischial Socket Compared to Ischial Containment (IC) Socket: A Case Report

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Abstract

Background: Ischial Containment Socket (ICS) has been the standard treatment for transfemoral amputees for thirty years, but the high edges and the ischial containment contribute to the discomfort of the socket especially when the patient is standing and while he is sitting.
Aims: The purpose of this study is to compare ICS to sub-ischial socket in a unilateral TFA K2 patient.
Methods: Two custom-fabricated sockets, worn full-time for 3 weeks, with testing on day 0 and at 3 weeks after socket delivery. The case report examined a 71-year-old woman three years after one-sided transfemoral amputation to the right leg, with K2 functional level. The protocol used contained three questionnaires, the measurement of the hip range of motion and 2 physical tests.
Results: The most relevant results were the reduction of the pelvic inclination during the sitting with a variation of -42.9% (7° with the ICS and 4° with the sub-ischial socket), and an increase in all the measurements of the angles of the hip, especially in abduction and extension with percentage change that reaches +300% each. The two sockets were equivalent in the 2MWT (P-value=0.98) and in the 4SST (P-value=0.88) (statistical significance $p<0.05$). The patient reported that the sub-ischiatic socket is more comfortable and has more freedom of movement.
Conclusion: It can be said that for patient K2 examined, the sub-ischial socket is a valid clinical alternative to the one with ischial containment, since it does not affect aspects such as stability and dynamics, but it also offers improvements in the stump-socket interface.

Keywords: Artificial lower limb, Prosthetic Socket, Transfemoral Amputation, Sub-ischial Socket, Ischial containment socket.

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Introduction

The current transfemoral sockets, although having achieved remarkable results for the recovery of the autonomy of amputated patients, still present various defects, such as: they limit the function, they lack comfort, and they cause problems with the stump. Lack of comfort is the most common problem among prosthetic users (Fatone & Caldwell, 2017). In recent years, the sub-ischial socket has been designed and conceived; according to the literature (Caldwell & Fatone, 2019; Fatone et al., 2014, 2021; Fatone & Caldwell, 2017), it has the potential to provide not only increased hip joint excursion and comfort, but also lower friction of the stump tissues with the socket, better proprioception and health of the tissues. In his studies, Dillon (Dillon et al., 2016) argued that the ability of a transfemoral socket to provide coronal plane stability resulted from both the containment of the ischial branch and the compression of the proximal medial edge. Kahle and Highsmith (Kahle & Highsmith, 2014) reported, however, when the patient is standing and during the dynamic phase the sub-ischial socket is equivalent to ICS, without postural adjustments usually found during the dynamic phase typically associated with coronal plane instability. This is due to the compression of soft tissues that ensure coronal stability, comfort, and a functional gait (Fatone & Caldwell, 2017). In this case report, we compared the ischial containment socket and the sub-ischial socket, in particular the different ROM of the hip and the spatiotemporal values recorded during the kinetics. The literature on the sub-ischial socket to date is deficient, but the studies conducted so far express a considerable potential for this type of socket.

Methods

Participant: A patient with TFA among those accessing the local Prosthetic Centre was randomly selected and informed about the opportunity to participate in this study and try a new socket. The inclusion criteria included being able to provide informed consent, having a TFA not due to vascular causes and being a prosthesis user for more than one year. Informed consent was obtained from the patient after she was provided with an accurate description of the protocol that would have been used and of the sub-ischial socket. Due to a wrong fixation of the soft masses during the amputation operation, the patient has always reported a feeling of instability.

Patient	Age	K-Level	Etiology	Side	Time since amputation	Knee	Foot	Walking aid
1	71	2	Osteosarcoma	R	3 years	Kenevo Ottobock	Trias Ottobock	Canadian

Table 1. Demographic and prosthetic information of the patient

Interventions: Two custom-fabricated sockets (IC and sub-ischial), worn full-time for 3 weeks, with testing at day 0 and at 3 weeks after socket delivery. The main difference between the IC socket and the sub-ischial socket is the proximal edge height. In the IC socket design, the ischial tuberosity is incorporated into the socket, whereas in the sub-ischial socket design the edges of the socket are under the ischial tuberosity. To obtain these two forms of sockets, two different measurement methods of the residual limb and two different positive stylization methods are used. The patient had been using the IC socket for three years, since she was amputated. Unlike the standard construction of the sub-ischial socket [7][2], in this case report the negative of the stump was detected under load using the IpsoCast ® system of Ottobock, to obtain a negative of the stump in which the muscle masses are compact and arranged as if they were inside the socket. The IpsoCast ® is an innovative system for the modelling of plaster under load, designed for transtibial applications. Thanks to the innovative idea of Alessandro Giambi (CPO), who thought to use it for the application on transfemoral patients for the

realization of sub-ischiatic sockets, the company Ottobock gave its consent for the use of IpsoCast ® in this new method of taking the cast. As for the stylization, the literature has been followed (Fatone & Caldwell, 2017).



Figure 1. Residual limb during measurement

Questionnaires: The SF-36 is a generic questionnaire on the quality of life in the sense that it is not specific to pathology, age or therapy and evaluates the subjective perception of the individual about health concepts related to levels of activity and well-being. This questionnaire is characterized by brevity (on average the subject takes no more than 10 minutes for its compilation) and precision (the instrument is valid and reproducible). The 36 questions in the questionnaire conceptually refer to 8 health domains (physical activity, role limitations due to physical health, role limitations due to emotional status, physical pain, perception of general health status, vitality, social activities, and mental health) plus a single question about the change in health status (Ware, 1992)(McMurray et al, 2002)(Shepperd et al, 1998). The Houghton scale is a 4-element instrument that determines the use of the prosthesis in patients with lower limb amputation. It reflects a patient's perception of the use of the prosthesis (Devlin, 2004). This questionnaire has an easy-to-read score: on a maximum of 12 points, if the patient gets a score of at least 9 he is considered independent, with a score between 6 and 8 he is considered limited, while with a score less than 5 he is defined very limited. This questionnaire was defined by Miller (2001) and Devlin (2004) as a questionnaire with modest internal consistency and good reliability. The Houghton Scale was chosen for this case report as it validated a significant correlation between the Houghton Scale, Sf-36 and the 2 Minute Walk test. The questionnaire 3 was created ad hoc to evaluate the socket from the patient's point of view based on her personal preferences and feelings. It consists of three parts, the first table asks to evaluate various aspects of the prosthesis in a score from 1 to 10, the second is an extract of the PEQ (Legro et al, 1998) with a five-level evaluation from "very dissatisfied" to "very satisfied", and the third part takes into consideration the presence of possible rotations and painful points in the socket. To compare the results of the test we assigned a score of 1 to "very dissatisfied" and a score of 5 to "very satisfied", while for the third part we assigned a score of 0 to "Yes" and a score of 1 to "No".

Hip Range of Motion: To evaluate the hip RoM (Range of Motion), the following hip angle measurements were analyzed: adduction (supine position), abduction (supine position), hip flexion (supine position), hip extension (prone position), SIPS (postero-superior iliac spine) elevation gain (seated position). To ensure the reliability of the measurements, they were performed by the same therapist on the same day, although there is a certain margin of error because the measurements were performed manually with a goniometer and therefore not being able to ensure the objectivity, operator-employee errors are possible. The measure of SIPS elevation gain was measured by placing

some yellow markers on the reference points of poster-superior iliac crests. The images were then processed with computer graphics program (ImageMeter) which draws a line through the markers and calculates the degrees of difference between the two poster-superior iliac crests.

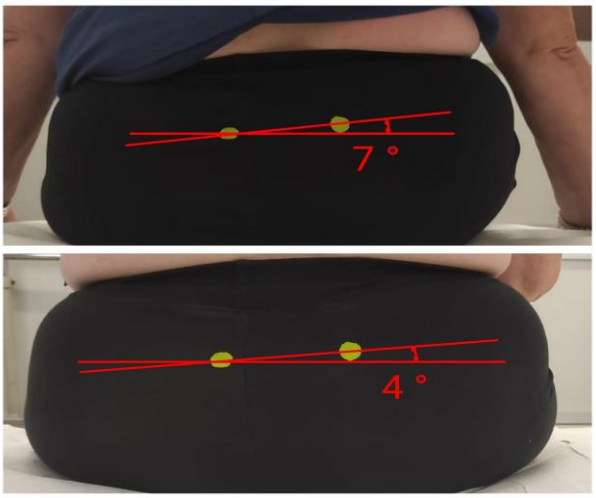


Figure 2. Measure of SIPS elevation while sitting while fitting the ICS (above) and the sub-ischial socket (under)

Two Minute Walk Test: This is a certified variation of the 12 Minute Walk Test especially suitable for amputated patients and for those who struggle to walk for so long. It measures the patient's ability to walk and her functional capacity. This test was carried out in compliance with all the rules on the conduct imposed by the literature and instructing the patient on how to perform the test (Brooks, 2001)(Frlan-Vrgoc, 2011)(Bohannon, 2015):the subject was asked to walk as quickly as possible, safely without stumbling, and having the possibility to stop in case she feels tired without stopping the stopwatch and warning her to reach half the time. The test took place on a straight path of 15.24 meters with the help of a Canadian walking aid, and it was recorded by a chronometer.

Four Step Square Test: This test is used to test the dynamic stability and ability of the subject to overcome small obstacles. In addition, it evaluates the patient's ability to use the prosthesis and her ability to move in the various directions of space (Gouelle, 2020). This test was carried out in compliance with all the rules on the performance imposed by the literature and instructing the patient on how to complete the tour first clockwise and then anticlockwise, back to the starting point as quickly as possible without touching the sticks on the ground. This test was carried out using two 5-meter crossed sticks on the ground with the help of a Canadian and it was recorded by a chronometer.

Timing and Socket Change: The tests were first administered when the patient was wearing the ischial containment socket and followed with the sub-ischial socket. According to Datta's results [18] transtibial amputees need a minimum of 6 weeks to get used to and to learn how to use a prosthesis properly. Since there are no articles in the literature that report the acclimatization period that transfemoral amputees need to get used to the change of a socket (from one to another with a different design and a different typology), a 3-week period has been chosen for the set objectives. To make the results as reliable as possible, the socket was set up on the same prosthetic structure (Kenevo knee and Trias foot) that the patient had with the ischial containment. In addition, it was decided to keep the thermoplastic test socket for all three weeks so as not to change the stimuli from the socket by replacing it with the final one.

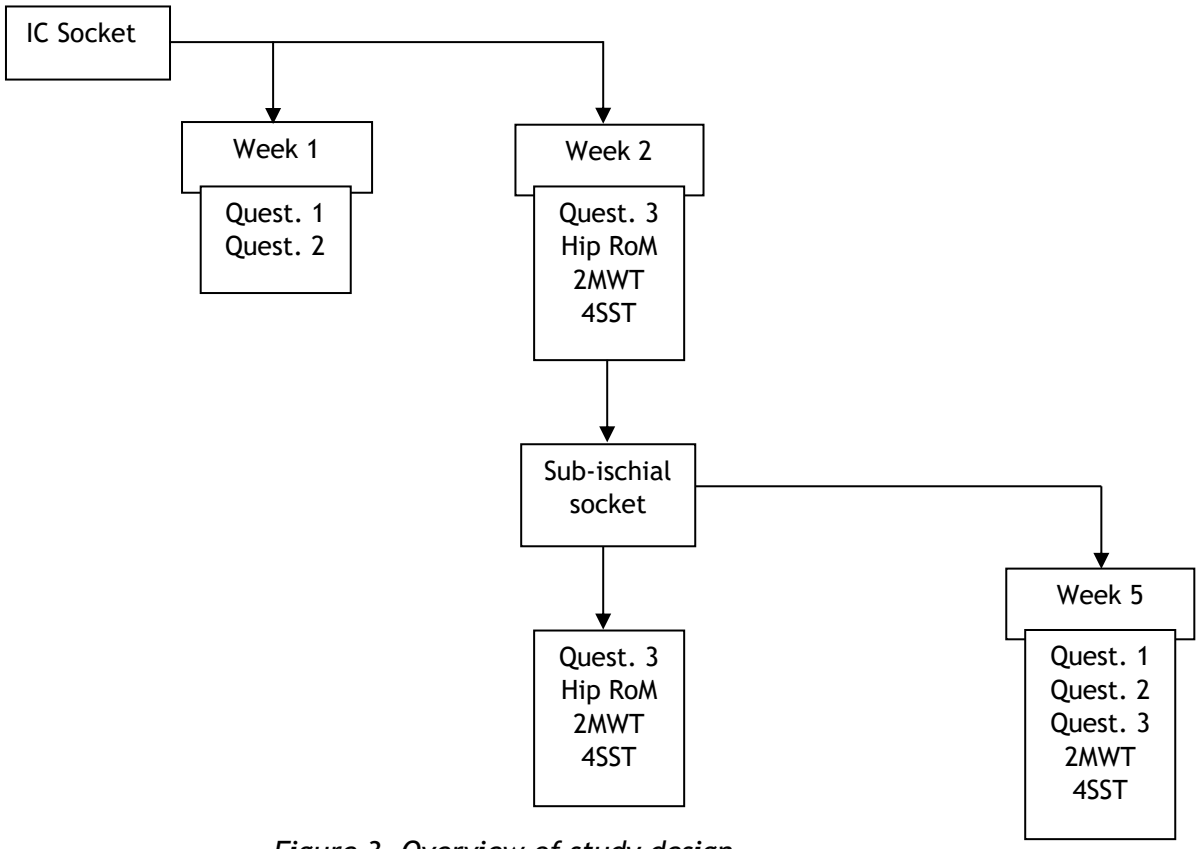


Figure 3. Overview of study design

Results

In this case report a female with TFA was enrolled. Characteristics of the patient with full data were reported in Table 1. The most relevant results were the reduction of the pelvic inclination during the sitting with a variation of -42.9% (7° with the ICS and 4° with the sub-ischial socket), and an increase in all the measurements of the angles of the hip, especially in abduction and extension with percentage change that reaches +300% each. The two sockets were equivalent in the 2MWT (P=0.98 so no statistical significance was recorded) and in the 4SST (P=0.88 so no statistical significance was recorded). The patient reported that the sub-ischiatic socket is more comfortable, gives a better compression of tissues and more freedom of movement.

K2 Patient					
Measure	ICS Week 1	ICS Week 2	Sub-I Week 2	Sub-I Week 5	Variation %
Questionnaire 1					
Score	100	X	X	104	+4%
Questionnaire 2					
Score	9	X	X	9	0%

Questionnaire 3					
Score	X	95	98	110	+15.8%
Hip Range of Motion					
Adduction°	X	30	35	X	+16.7%
Abduction°	X	10	40	X	+300%
Flexion°	X	75	90	X	+20%
Extension°	X	5	20	X	+300%
Vertical drop of the SIPS°	X	7	4	X	-42.9%
Two-Minute Walking Test					
Distance by 1-minute (m)	X	41.68	36.30	42.48	+1.9%
Distance by 2-minutes (m)	X	82.32	73.01	82.07	-0.30%
Four Step Square Test					
Duration (s)	X	16.87 ± 2.24	19.94 ± 0.67	16.10 ± 0.23	-4.6%

Table 2. Results obtained by the patient; The Variation % indicates the percentage change between the results obtained with ICS on 14/07 and the results with the sub-ischial socket on 03/08, with exception of questionnaire 1 and 2 where the results of ICS were recorded on 06/07

Discussion

The purpose of this study was to compare ICS to sub-ischial socket in a unilateral TFA K2 patient. Initially, since the existing literature recommended the use of sub-ischial socket for high-level functional patients (K3 or K4) (Fatone, 2021), there were many doubts about the feasibility of the case report. In addition, it was feared that the patient would react negatively when she tried the sub-ischial socket without containment and stability (provided by the high edges of the ICS socket), due to the instability of the patient and the mobile muscle mass of the stump. Our hypotheses regarding the solution of this problem were correct and were also confirmed by the feelings of the patient. In fact, due to the greater compression of the soft masses provided by both the suspension system and the liner and the shape of the sub-ischial socket, the patient has not reported any problems or annoyances resulting from the moving masses of the stump or regarding stability. As was expected, during the first day of testing of the sub-ischial socket, because of the completely different stimuli that the patient received from the stump-socket interface, some difficulties arose. The same was evidenced by the results obtained in the tests that have a noticeable worsening compared to the ICS socket. The time of the three-week study was established by considering the sensory and proprioceptive inputs that the stump receives by interacting with the socket. It was therefore decided not to change the thermoplastic socket to the final one, as a change of materials could have prevented the adaptation of the previous weeks. The results were satisfactory and in line with those in the literature. In particular, the differences found between the two sockets that were highlighted by the SF-36, questionnaire 3 and the measurement of the hip angles were significant. In the SF-36 questionnaires an increase in physical activity of more than 20% was recorded and a decrease in functional limitations both for physical and

emotional causes. Looking at the other fields there were also other small variations but not as evident as those previously mentioned. In questionnaire 2 both sockets got the same score, losing points for using a Canadian walking aid and for insecurity on different surfaces. The identical scores suggest that the patient perceives both prostheses similarly, and within only three weeks, she has attained a level of proficiency with the new prosthesis comparable to that one she has traditionally used. The patient was asked to evaluate different aspects of her prosthesis in questionnaire 3. After three weeks of use of the sub-ischial socket there was a clear improvement in the aspects of walking, sitting, stability, sense of freedom and mobility. It can therefore be said that, even without the high edges of the ICS socket, the sub-ischial socket does not decrease stability and does not decrease the patient's dynamic performance (as Kahle & Highsmith (2014) also states in their studies). The patient in the second part reported greater satisfaction as for the design, appearance, noise, and usefulness. As for the third part of the questionnaire, it required answering "YES" or "NO" to questions about possible painful points or rotations in the socket/stump. In all cases the patient answered "NO". The patient noted, however, that with the use of ICS socket, in the evening, because of the medial edge, she felt the inguinal area as an annoying point. Looking at the table 2 it is possible to appreciate the improvement of the freedom of the hip articulation provided by the sub-ischial socket due to its lower edges. In fact, apart from the hip adduction that is similar, because even in the ICS socket it is frequent to leave the medial edge lower because of the discomfort it produces, all the other angles are considerably increased using the sub-ischial socket. The angles that can be reached with this socket are comparable with the physiological data of a non-amputee person (Kapandji, 2009). Without the posterior ischial containment, the possibility of extending the hip gives the possibility of toning the gluteus group (especially the middle gluteus that is mainly trained with the extension of the hip) and therefore due to this to produce increased hip stability even without the high edges of containment and stabilization of the ICS socket. With the ischial containment socket, the gluteus group was little used and was contained inside the socket with the risk of atrophy over time.



Figure 4. Range of motion with ICS (left) and sub-ischial socket (right)

In the sitting position, it is possible to observe a reduction of the degrees of difference in height of the postero-superior iliac spine. It is necessary, however, to consider that the seat used was a padded seat and therefore it is reasonable to suggest that on a rigid seat the difference in height of the SIPS with the ICS socket would have been greater because the ischiatic support could not have sunk into the padding. Moreover, by observing the degrees of difference in height of the SIPS obtained by wearing the sub-ischial socket, it is possible to suggest that postural attitudes and muscular contractures in the

pelvic area and along the entire column force the patient to maintain that pelvic inclination of 4°, as the sub-ischial socket does not have high back edge for the ischial support and follows the shape of the stump, a difference in height of the SIPS should result close to 0°. As for the other tests carried out, the results were similar, as predicted. This is because during walking, as in the literature (Fatone, 2021)(Fatone, 2017)(Fatone, 2014)(Caldwell, 2019), the two sockets have overlapping results. It must be kept in mind that the patient with the sub-ischial socket only took three weeks to learn how to manage and use the prosthesis, reaching the results obtained with the ICS socket (which she used for three years). During the Two-Minute Walking Test it was also observed that as soon as the patient changed the socket, during the walk she showed a bending of the lateral trunk, probably due to the fact of compensating the lateral containment patella that was present in its old socket. This problem, however, was solved by itself because after the three weeks of adaptation she no longer showed this problem in the gait and had returned to walking as with the previous socket. It is therefore reasonable to suggest that the patient during the first day felt unstable without the high containment edges and in fact, in addition to the lateral bending of the trunk she tried to compensate the lack of stability. Even the speed during the walk was reduced to feel safer, while after three weeks insecurity and instability returned to the levels of the previous prosthesis. In table 2 there are the results recorded from the execution of the Four Step Square test. In the table 2, the duration of execution of the 4SST with the ICS and that of the sub-ischial socket after 3 weeks of use are similar, while it is possible to notice a remarkable dilation of the times during the first test of the socket. It is therefore reasonable to suggest that the increase in time for the performance of the test is due to her insecurity and a decrease in the ability of the prosthesis control was caused by the socket change and therefore by the different proprioceptive stimuli coming from the stump. After three weeks of acclimatization in which the patient learned how to handle the prosthesis, she achieved slightly better results than when she performed the test with ischial containment socket. This result is certainly due to the low proximal borders of the socket that allow greater freedom of movement. What is to be noted, therefore, is not the minimal difference in the results of the two different sockets obtained during the walking, but the best feelings of the stump-prosthesis interface and the greater freedom of movement that the patient gets with the sub-ischial socket.

Conclusion

Considering the results obtained, it can be said that a patient with functional level K2 has been successfully prosthetised. From the comparison it has been possible to observe that, in this specific case, the sub-ischiatic socket equals or exceeds the ICS socket in every aspect. As this is a case report, it is impossible to extend the results of this study to the entire population of patients with unilateral transference amputees K2. Considering the results obtained, it can be said that for the patient K2 analysed the sub-ischial socket is a valid clinical alternative to ICS.

Limitation

The study recognizes the limitations it presents and does not claim to be conclusive. Although there have been changes in the responses in SF-36, it should be noted that the time taken to re-administer the questionnaire to the patient was reduced compared to the minimum repetition time of the questionnaire which should be done after at least 3 months. Also, for questionnaire 2 it should be borne in mind that the questionnaire was administered only three weeks later, although for maximum reliability it should have been 3 months (Devlin, 2004). In the future, in addition to looking at more patients, it would be interesting to try to submit patients to a longer adaptation time and to repeat the tests to observe if an adaptation period of three weeks will achieve the maximum potential of the prosthesis or if there is still room for improvement, due to a still imperfect control and use of the prosthesis.

Abbreviations

2MWT= Two-Minute Walk Test
4SST= Four Square Step Test
ICS= Ischial Containment Socket
TFAs= Transfemoral amputees
Quest= Questionnaire
Hip RoM= Hip Range of Motion

Authors contribution

Matteo Vaccari: conception of the work, fabrication of the sub-ischial socket, supported the writing of the manuscript and revised the manuscript critically for important intellectual content.

Davide Buratti: acquisition, analysis and interpretation of the data, led the writing of the manuscript.

All the authors have approved the submitted version of the manuscript.

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