

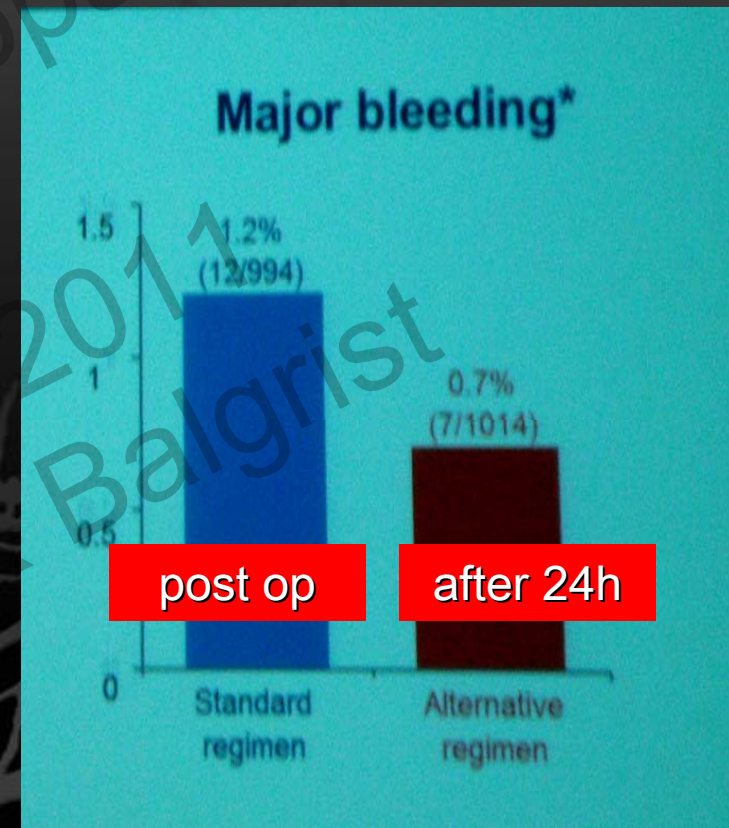
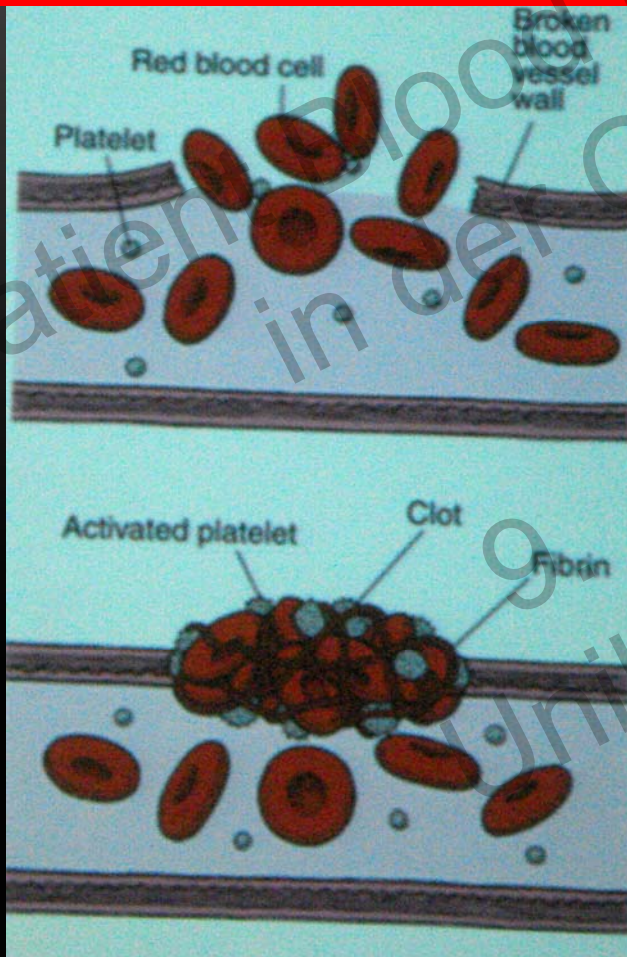
PROSTHETIC SURGERY WITHOUT BLEEDING

Francesco.S. Santori
S.Pietro FBF Hospital Roma

Frequently after THR there is bleeding in the first 24-hours post op



It takes about 8 hours for an initial platelet plug to solidify into a stable cloth that will remain intact after administration of additional anticoagulants medications



N.Rosencher EFORT 2011

HOW TO AVOID

BLEEDING
ANEMIA
HEMATOMA



DVT

Cause of death following THR during the first 60 days after surgery(n 45.767 cases)

Mortality/1000 THR

•DVT	0,28
•Thromboembolic complications	3,69
•Ischemic hearth disease and infarction	4,09
•Bleeding	1,11

Stein L.A. Acta Orthop. Scand.2002 73 392-99

Anemia in hip and knee primary and revision surgery

- anemia preop 24% +/- 9%
- anemia postop 51% +/- 10%
- trasfusal need 45% +/- 25%

Regional Trasfusalional Centre not self-sufficient

Production 190.000 units/year need 230.000 units/year Debt
region Lazio till 14.04.2011: Euro 5.800.000 purchase (35.000
units)



AT THE LAST MINUTE NO BLOOD!!!!!!!!!!!!!!!

Risk of Complications From Homologous Blood Transfusions

Patients receiving allogenic transfusion were 2.1 times more likely to have PJI develop compared with patients receiving no transfusion

Poss R, Thornhill TS, Ewald FC, Thomas WH, Batte NJ, Sledge CB. Factors influencing the incidence and outcome of infection following total joint arthroplasty. Clin Orthop Relat Res. 1984;182:117–126

Anemia

- Perioperative anemia was associated with increase of postoperative infections, poorer physical functioning and recovery, and increased length of hospital stay and mortality.

**Anemia and patient blood management in hip and knee surgery:
a systematic review of the literature.**

Spahn DR Anesthesiology. 2010 Aug;113(2):482-95.

Early complications after THR

- (8.8%) readmitted for complications in the first 28 days of discharge following THR
- The principal reasons for re-admission were atraumatic dislocation,
- thrombo-embolic disorders
- **superficial infection, superficial dehiscence and haematoma. 1.2% of re-admissions**

HEMATOMA COMPLICATIONS

Wound dehiscence
Marginal necrosis
Compartment syndrome
Infected hematoma
Luxation
Nerve injury(15% of spe)

Campbell Operative orthopaedics vol1 312 2008

The cost of complications

On the basis of data collected in hospitals in the Netherlands in 2004, 30,000 inpatient admissions included a preventable adverse event.

It estimated that the annual costs of preventable adverse events in Dutch hospitals was 161 million euros

The mean length of stay after the initial operation was 14 days (range, 7–89 days)

Direct medical costs of adverse events in Dutch hospitals.

Hoonhout LH, et al

BMC Health Services Research. 2009;9:27.

Estimated cost of complications in Italy

100.000 THR = 8000 inpatient admissions included a preventable adverse event.

it estimated that the annual costs of preventable adverse events for THR in Italian Hospitals could be 43 million euros

hematoma ← COMPLICATIONS → anemia

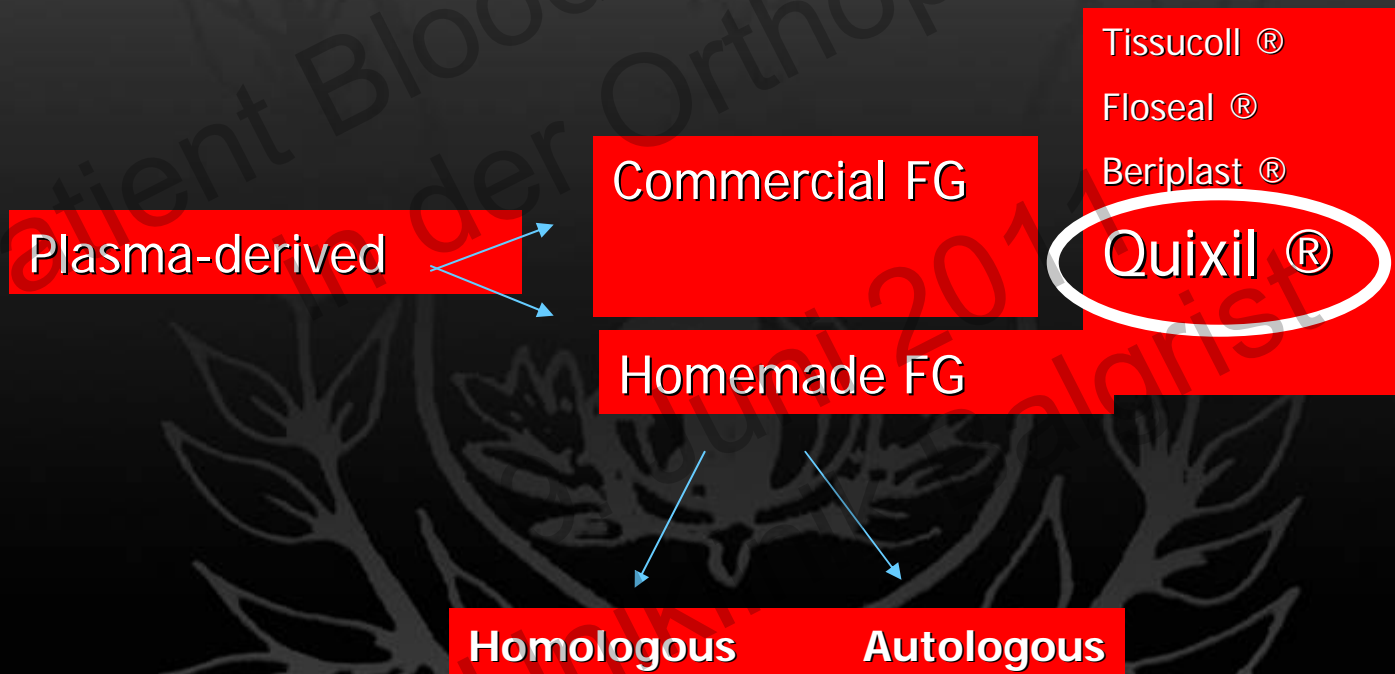
the most important surgical factor in preventing anaemia is a careful intraoperative hemostasis



Procedural alternatives to the use of homologous blood

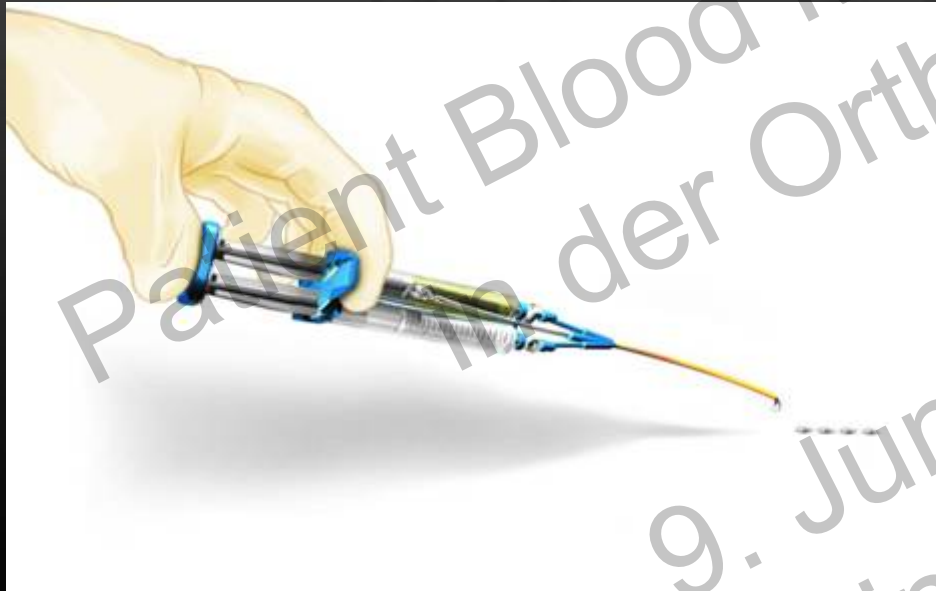
- Postoperative administration of HEPO
- Preoperative autologous blood donation
- Hemodilution
- **Use of local haemostatics**

Local hemostatics



Manufactured hemostatics

quixil



Fibrinogen

Fibronectin

Tranexamic Acid

Comp. 1

Human thrombin

Calcium Chloride

Comp. 2





Patient Blood Management
in der Orthopädie
9. Juni 2011
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Use of hemostatics in surgery

[Fibrin sealant: alternative to nasal packing in endonasal operations. A prospective randomized study.](#)

Vaiman M, Sarfaty S, Shlamkovich N, Segal S, Eviatar E.
Isr Med Assoc J. 2005 Sep;7(9):571-4.

[Intraoperative haemostasis with new fibrin surgical sealant \(Quixil\) in gynaecological oncology.](#)

Papacharalabous EN, Giannopoulos T, Tailor A, Butler-Manuel SA.
J Obstet Gynaecol. 2009 Apr;29(3):233-6.

[Effect of modern fibrin glue on bleeding after tonsillectomy and adenoidectomy.](#)

Vaiman M, Eviatar E, Shlamkovich N, Segal S.
Ann Otol Rhinol Laryngol. 2003 May;112(5):410-4.

[Fibrin glue: an alternative technique for nerve coaptation--Part II. Nerve regeneration and histomorphometric assessment.](#)

Ornelas L, Padilla L, Di Silvio M, Schalch P, Esperante S, Infante RL, Bustamante JC, Avalos P, Varela D, López M.
J Reconstr Microsurg. 2006 Feb;22(2):123-8.

Use of hemostatics in orthopaedic surgery

[Effectiveness of autologous fibrin tissue adhesive in reducing postoperative blood loss during total hip arthroplasty: a prospective randomised study of 100 cases.](#)

Mawatari M, Higo T, Tsutsumi Y, Shigematsu M, Hotokebuchi T.
J Orthop Surg (Hong Kong). 2006 Aug;14(2):117-21.

[Analysing uncertainty around costs of innovative medical technologies: the case of fibrin sealant \(QUIXIL\) for total knee replacement.](#)

Steuten L, Vallejo-Torres L, Bastide P, Buxton M.
Health Policy. 2009 Jan;89(1):46-57. Epub 2008 Jun 18.

[Reduction of hemorrhage after knee arthroplasty using cryo-based fibrin sealant.](#)

Curtin WA, Wang GJ, Goodman NC, Abbott RD, Spotnitz WD.
J Arthroplasty. 1999 Jun;14(4):481-7.

[Long-term results after operatively treated Achilles tendon rupture: fibrin glue versus suture.](#)

Hohendorff B, Siepen W, Spiering L, Staub L, Schmuck T, Boss A.
J Foot Ankle Surg. 2008 Sep-Oct;47(5):392-9. Epub 2008 Jul 14.

[Treatment of fractures of the humeral capitulum using fibrin sealant.](#)

Scapinelli R.
Arch Orthop Trauma Surg. 1990;109(4):235-7.

The Use of Fibrin Tissue Adhesive to Reduce Blood Loss and the Need for Blood Transfusion After Total Knee Arthroplasty

A PROSPECTIVE, RANDOMIZED, MULTICENTER STUDY*

O Levy, Uri Martinowitz, Ariel Oran, Chanan Tauber And Henri Horoszowski

J Bone Joint Surg Am. 1999;81:1580-8

The mean apparent postoperative blood loss (and standard deviation) in the fibrin-tissue-adhesive group was 360 milliliters compared with 878 milliliters in the control group, with a mean difference of 518 milliliters ($p < 0.001$).

preoperative thromboprophylaxis with low-molecular-weight heparin

Fibrin Sealant Reduces Perioperative Blood Loss in Total Hip Replacement

Journal of Long-Term Effects of Medical Implants, 13(5)399–411 (2003)

Gwo-Jaw Wang, Charles A. Goldthwaite, Jr., Sandra Burks, Ross Crawford, William D. Spotnitz,

Patients undergoing total hip replacement (THR) In this randomized, multicenter study, (n = 81) were treated with the investigational fibrin sealant and experienced a statistically significant reduction in overall perioperative blood loss compared with the control group

Fibrin Sealant Reduces Perioperative Blood Loss in Total Hip Replacement Journal of Long-Term Effects of Medical Implants, 13(5)399–411 (2003)

Gwo-Jaw Wang, Charles A. Goldthwaite, Jr., Sandra Burks, Ross Crawford, William D. Spotnitz,

Three patients had severe adverse events in the fibrin sealant group (8%) compared with nine in the control group (21%). most common adverse event was pain, fever, Anemia

The application of fibrin sealant by a trained surgeon, may shorten the duration of the surgical procedure when compared with other hemostatic methods. Thus, the cost of the sealant may be offset by the economic benefits associated with reduced intra- and postoperative bleeding.

Purpose of the study

To assess if local application of Quixil reduces perioperative blood loss and the need for postoperative transfusions in patients undergoing primary total hip arthroplasty (THA)

Materials and methods

180 pts

Treatment group (A):
QUIXIL
(n=90)

Control group (B):
conventional haemostasis
(n=90)

Evaluations

Postoperative haemoglobin (Hb) levels were measured at 12, 24 and 48 hours until 5 days after.

Postoperative transfusions of autologous and/or heterologous blood were required when Hb was lower than 8.2 g/dl

Results

Group A - Quixil
(n=90)

Group B - conventional haemostasis
(n=90)

The decrease of Hb levels measured at 12, 24 and 48 hours after the operation was higher in group B (9.9, 8.7, and 7.9 g/dL respectively) than in group A (10.6, 10.0, and 9.3 g/dL)

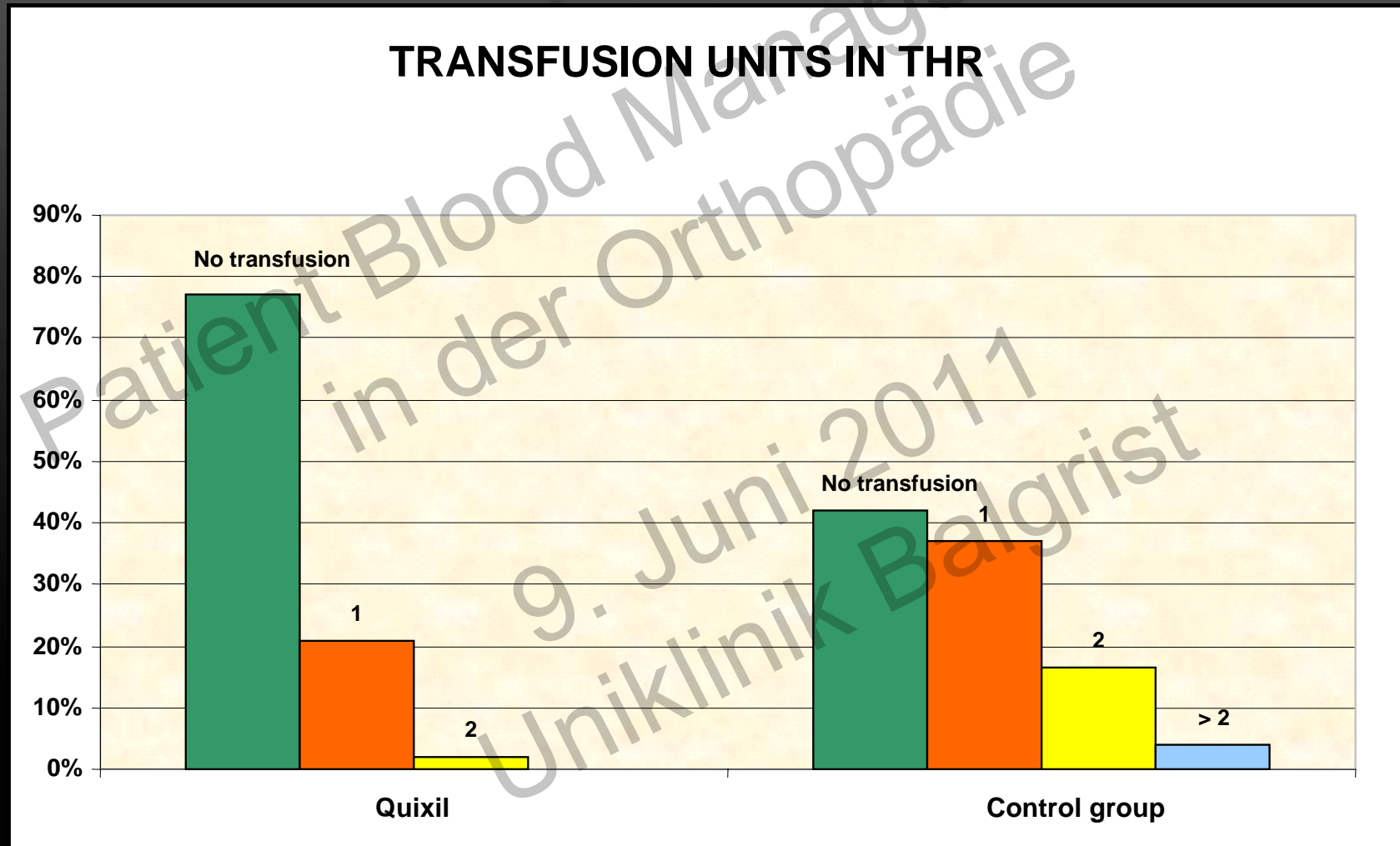
Results

Group A - Quixil (n=90)			Group B - conventional haemostasis (n=90)		
Blood	units	No patients	Blood	units	No patients
autologous	1	12	autologous	1	21
homologous	1	4	autologous	2	9
autologous + homologous	1+1	1	homologous+ autologous	1	8
			homologous	2	9

Group A transfusion rate = 17/90 (18,8%)

Group B transfusion rate = 47/90 (52,3%)

Blood transfusions



hip revision surgery results

Group A - Quixil x2 (n=15)			Group B - conventional haemostasis (n=15)		
Blood	units	No patients	Blood	units	No patients
autologous	1	6	autologous	1	0
autologous	2	3	autologous	2	3
homologous	1	4	homologous	2	6
	2	1			
homologous	>2	1	homologous	>2	6

Increased post-op patients satisfaction

Group A - Quixil
(n=90)
mean 3^o day Hb level 9,3

Group B - conventional
haemostasis(n=90)
mean 3^o day Hb level 7,9

Quixil economic analysis

1°

- direct costs
- indirect costs due to complications linked to anemia

2°

- costs and intangible benefits linked to well-being of the patient

Indirect costs due to complications linked to anemia

- More transfusions
- More infection & antibiotic therapy
- Increased hospitalization time
- Possible new surgical procedures
- Possible intensive care
- Increased physiotherapy
- Possible legal problems

Intangible costs linked to well-being of the patient

- Need of assistance to anemic patient
- Assistance to donor for autotransfusion
- More assistance post discharge
- Longer time for rehabilitation
- Psychological and physical damage for reoperation
- Psychological and physical damage for delayed operation (lack of blood)
- Sufferings of patient and relatives

Quixil final evaluation

BENEFITS	TANGIBLE	INTANGIBLE
Direct	Transfusions and antibiotic therapies avoided	Improvement of quality of life
Indirect	Avoided utilization of intensive care and operating theatre for revision surgery	Better feeling of patient relatives
COST	TANGIBLE	INTANGIBLE
Direct	Cost of sealing (Quixil)	Patients lost time costs for a prolonged hospitalization time
Indirect	Cost of collateral effects due to lack of administration of quixil	Cost of relatives for lost time to take care to the patient

conclusions

A statistically significant reduction of blood loss was observed following the use of fibrin sealant, as well as a decreased requirement of auto/hetero transfusions

•Conclusions QUIXIL INDICATIONS

- Total Hip -Knee arthroplasty
- Pelvic, politrauma, femoral fractures
- tumors
- pelvic osteotomy

Mandatory

- Preop anemia
- Patients with coagulation risk factors
- Geova testimonials(2-3 Quixil Units)
- Patients with general risk factors

Conclusions

Increased post-op patients satisfaction

Lower incidence of complications
Less pain
Faster rehabilitation

Conclusions


Based on these results, the possibility to perform THA without the requirement of autologous or heterologous transfusions can be predicted in patients with normal preoperative Hb levels and no concomitant pathologies



Phisical



Surgeon



Quixil

Management
die

GRAZIE

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Quixil final evaluation

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Juni 2017

Early complications after THR

A mean international normalized ratio of greater than 1.5 was found to be more prevalent in patients who developed postoperative wound complications and subsequent periprosthetic infection.

. Does “excessive” anticoagulation predispose to periprosthetic infection?

Parvizi J, et al

Arthroplasty. 2007;22(suppl 2):24–

Early complications after THR

A mean international normalized ratio of greater than 1.5 was found to be more prevalent in patients who developed postoperative wound complications and subsequent periprosthetic infection.

Parvizi J, Ghanem E, Joshi A, Sharkey PF, Hozack WJ, Rothman RH. Does “excessive” anticoagulation predispose to periprosthetic infection? J Arthroplasty.

2007;22(suppl 2):24–
Of the infections, 29% arose in the first three months following surgery

The incidence of deep prosthetic infections in a specialist orthopaedic hospital: a 15-year prospective survey.

J Bone Joint Surg Br. 2006;88:943–948

Management
die

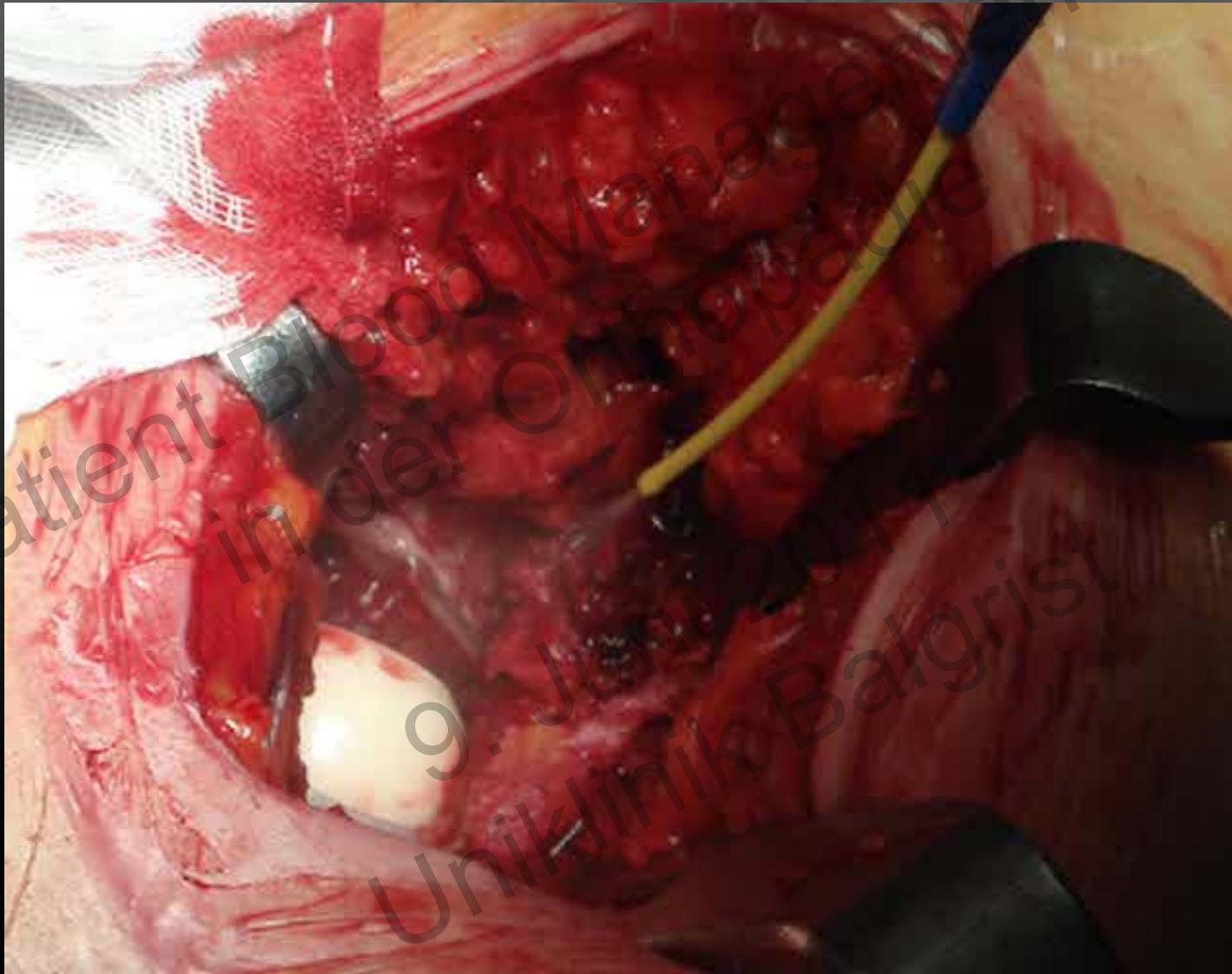
GRAZIE



All patients were operated by the same surgeon and received the same implant



Subjects with operative or transfusional risk increased by concomitant cardiovascular, autoimmune and/or metabolic pathologies were excluded from the study

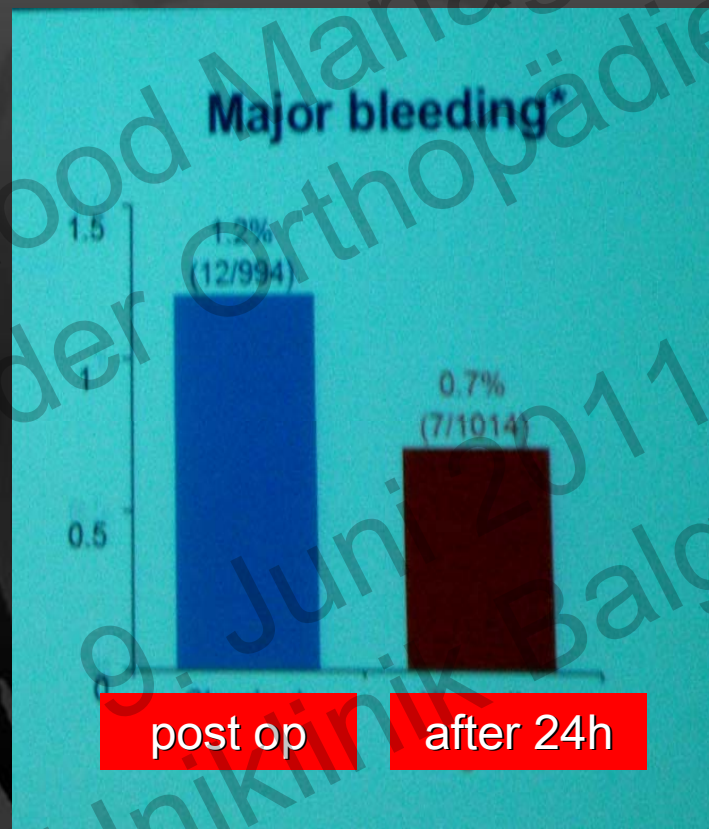


Anaemia

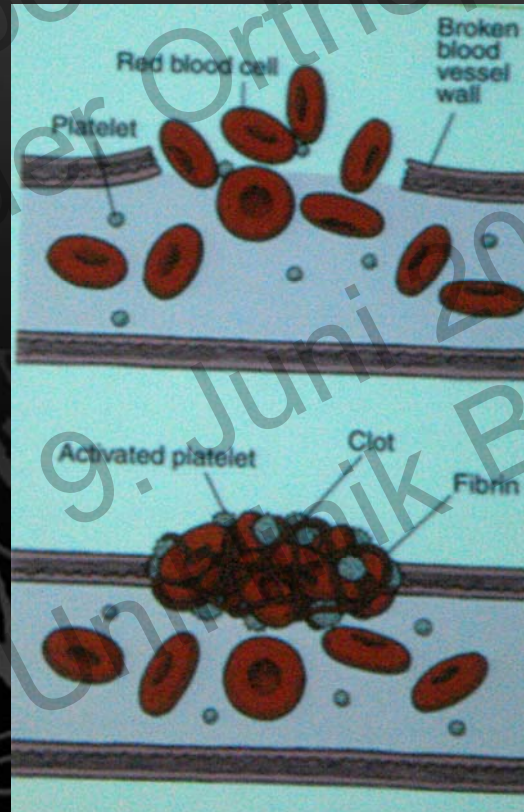
Risk Factors

antiplatelet, antiinflammatory, anticoagulant drugs
blood dyscrasias and coagulopathies
familiar history of excessive bleeding
previous surgical procedures

Haemostasis occurs about 8 hours after wound closure



It takes about 8 hours for an initial platelet plug to solidify into a stable cloth that will remain intact after administration of additional anticoagulants medications



Risk of Complications From Blood Transfusions

- AIDS about 1 in 2,000,000.
- Hepatitis B approximately 1 in 550 units
- Hepatitis C 1 in 100.
- Allergic reaction (hives) 1 in 500
- Hemolytic Transfusion Reaction is 1 in 10,000
- Fatal Hemolytic Transfusion Reaction is 1 in 100,000

Blood transfusion for total joint replacement

Background

Blood loss in THA can frequently require one or more postoperative blood transfusions.

The rationale of the use of alternatives to the use of homologous blood in THA is therefore:

1. the reduction of the risk of transfusion-related infectious diseases and immunological reactions
2. the optimization of the limited available transfusional sources
3. the search procedural alternatives to the use of the homologous blood